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RE: PMA P020014, BAY 1454032
Bayer's Final Executive Summary for FDA Panel Meeting
Essure System for Permanent Birth Control

Dear Ms. Craig:

Reference is made to PMA P020014, Essure System for Permanent Birth Control and to the email dated July 15, 2015 from the Designated Federal Officer (DFO) regarding the upcoming meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee scheduled for September 24, 2015.

The purpose of this submission is to provide FDA with Bayer's Final Executive Summary which provides data to support the positive benefit-risk profile of Essure.

This Executive Summary is being submitted via UPS as 5 paper binders and 30 CD packs in electronic form. The eCopy is an exact duplicate of the paper copy except for the literature references, which are included as PDF files on the eCopy.

Please let me know if you have any questions or need additional information. I can be reached by phone at (908) 200-9718 or by email at manal.morcos@bayer.com.

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Bayer HealthCare

Respectfully,
Bayer HealthCare LLC.

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ESSURE System for Permanent Birth Control

Executive Summary

For the FDA Advisory Committee Meeting

24 September 2015

Available for public disclosure without redaction

This document is an Executive Summary of the contraceptive device "Essure®", prepared for the Food and Drug Administration Meeting of the Obstetrics and Gynecology Devices Panel on September 24, 2015 to Discuss the Benefits and Risks of Essure®

Executive Summary
For the FDA Advisory Committee meeting for Essure

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Abbreviations

AEs	Adverse events
ANSM	French National Agency for Medicine and Health Products Safety
ART	Assisted Reproductive Technology
BTL	Bilateral tubal ligation
CDC	Centers for Disease Control
CDRH	Center for Devices and Radiological Health
CI	Credible Interval for the ESS305 TVU study or Confidence Interval for other studies
CO_2	Carbon dioxide
CREOG	Council on Resident Education for Obstetrics and Gynecology
CREST	Collaborative Review of Sterilization
CRF	Case Report Form
CSS	Clinical Sales Specialist
DESH	Dutch Essure® versus Salpingectomy for Hydrosalpinx Trial
FDA	Food and Drug Administration
HSG	Hysterosalpingogram
HCP	Health Care Physician
IDE	Investigational Device Exemption
IFU	Instructions for Use
ISO	International Organization for Standardization
ITT	Intent-to-treat
IVF	In-vitro fertilization
MC	Medically confirmed
MedDRA	Medical Dictionary for Regulatory Activities
Non-MC	Not medically confirmed
NSAIDs	Non-steroidal anti-inflammatory drugs
OB/Gyn	Obstetrics and Gynecology
PAC	Post alternative contraception
PAS	Post approval study
PDP	Post-device placement
PET	Polyethylene terephthalate
PIB	Patient Information Brochure

PIRs	Physician Inquiry Requests
PMA	Premarket Approval
PT	Preferred Term
SD	Standard deviation
STOP	Selective Tubal Occlusion Product
TVU	Transvaginal ultrasound
UK	United Kingdom
US	United States

This document is an Executive Summary of the contraceptive device "Essure®", prepared for the Food and Drug Administration Meeting of the Obstetrics and Gynecology Devices Panel on 24 SEP 2015 to Discuss the Risks and Benefits of Essure®

1. Introduction

Permanent birth control is the second most common method of contraception in the United States and the most common among women 21 to 45 who have completed their families. Approximately 5.6 million women in the United States (US) rely on this method of contraception (1), which offers high efficacy without the need for ongoing patient compliance. Individual contraceptive needs and desires are variable and it is essential for women to have options.

In 2002, the US Food and Drug Administration (FDA) approved Essure® as a novel method of permanent birth control for women. Prior to this, if a woman desired a permanent method of fertility control, her only option was to undergo a laparoscopic tubal ligation or laparotomy/mini-laparotomy. With the approval of Essure, women were given an option that took advantage of the natural pathway to the fallopian tubes through the vagina, the cervix, and the uterine cavity using a hysteroscope. This procedure avoids surgical incisions, entry into the peritoneal cavity, and the need for general anesthesia.

The FDA announced that an advisory committee meeting for Essure will be held on 24 SEP 2015 to seek expert scientific and clinical opinion on the benefits and risks of the Essure System. In this Executive Summary, Bayer will provide data from clinical studies, literature, and post market monitoring to support the safety and efficacy and the positive benefit/risk profile of Essure. The Committee Panel Review offers all sides the opportunity to examine the data, to listen to the concerns, and to reach appropriate recommendations moving forward.

In 2002, data on safety and efficacy were reviewed by the FDA as part of the Premarket Approval (PMA) process where it was determined that all criteria for approval were met and the clinical benefits outweighed the risks. Since that time, additional company sponsored postmarketing studies and clinical trials have continued to support the positive benefit/risk profile. Dozens of external studies, both prospective and retrospective, have generated data consistent with clinical trial data both in terms of efficacy and safety. This device has been studied with a total of > 10,000 women since Essure was first developed. In addition, review of spontaneously reported safety data on over one million Essure systems distributed worldwide support a product that has for the past 13 years, offered women a safe, viable alternative to laparoscopic tubal ligation.

While Essure is highly efficacious, the data show that Essure is not without risks, including those associated with the device itself or with the placement procedure. Since approval, the Instructions for Use (IFU, Section 10.6, Appendix 6) have clearly outlined the adverse events

(AEs) experienced by some women in the clinical trials as well as other potential risks associated with the device or the procedure. Both the IFU as well as the Patient Information Brochure (PIB, Section 10.7, Appendix 7) contain comprehensive information about patient selection and counseling, directions for use, contraindications, warnings, and precautions. They also contain detailed information on the procedure itself, the need for alternative contraception for 3 months, and the importance of obtaining the Essure Confirmation Test before a woman can rely on Essure for contraception.

In addition to clear, consistent messages on the benefits and risks related to the use of Essure in the IFU and PIB, a comprehensive and mandatory physician training program, including didactics, an extensive training manual, hands-on simulation training, and proctoring of the initial cases has existed since approval. Prior to the submission of the PMA, the company performed a validation study of their proposed training program and found that physicians trained with this program achieved placement rates comparable to the clinical investigators in the clinical trials (data on file). Additional support services and enhancements were made to physician training as device modifications were introduced (see Section 10.1, Appendix 1) and as new technology became available (eg, simulation software). Training enhancements will continue to be made as appropriate.

Recently, a citizen petition regarding Essure was submitted to the FDA by a law firm that has filed several Essure product liability lawsuits naming Bayer as a defendant. Several allegations regarding the clinical trials, safety, efficacy, and training were made. The FDA closed the petition and forwarded it to the Office of Compliance within the Center for Devices and Radiological Health (CDRH) as a trade complaint. The Office of Compliance is investigating the complaint and will pursue actions as deemed necessary. As stated in its response to the former petition (submitted to CDRH on 18 AUG 2015), Bayer strongly disagrees with the allegations made in the petition.

It is vital that women continue to be offered a variety of permanent contraceptive methods in order to achieve individual reproductive objectives and avoid unintended pregnancies. While Essure is not the right method for all women, Essure is an appropriate choice for those who desire a non-hormonal, non-incisional method of permanent birth control. Ultimately, the benefit/risk analysis derived from data from the clinical development program, post approval studies, external literature and extensive postmarketing safety analysis points to a product that offers women an important option.

1.1 Scientific Background

Approximately half of the 650,000 tubal ligations that occur each year in the US are performed at a time remote from pregnancy. These "interval" tubal ligation procedures are usually performed by laparoscopy. Laparoscopic bilateral tubal ligation (BTL) is regarded as a safe and effective procedure; (2) however, it requires entry into the peritoneal cavity and general anesthesia. Many of the risks of BTL are related to these factors. The risks are increased in obese women and in those who have had previous pelvic or abdominal surgery.

The first major study to evaluate the efficacy and risks associated with BTL was the US Collaborative Review of Sterilization (CREST), a large, prospective, multicenter observational study of 10,685 women conducted by the Center for Disease Control (CDC) and Prevention that reported results on long-term failure rates for several types of sterilization procedures.(3) Overall, CREST found that the failure rate for BTL was higher than previously believed (overall failure rate of 1.3%), varied by type of sterilization procedure performed, and by age at time of procedure. Of the 9475 women in the study who underwent interval laparoscopic tubal ligation, the overall standard complication rate was 1.6 %.(4) This included an unintended major surgery rate of 0.9 %.

In 1979, the CDC began surveillance of deaths attributable to tubal ligation. From 1977 through 1981, they identified 29 deaths.(5) Utilizing medical records of women reported to the Commission on Professional and Hospital Activities in 1979 and 1980, Escobedo et al (6) projected that the most reasonable case-fatality rate for tubal sterilization is ~9 per 100,000 sterilizations if all deaths associated with the procedure are considered, and between 1 and 2 per 100,000 sterilizations when only deaths that can be attributed to sterilization per se are considered.

In 2001, Huber et al (7) performed a retrospective analysis on the database of the Swiss obstetric study group and identified 20,325 cases of laparoscopic tubal ligation performed between JAN 1993 and DEC 2001. They found that the rate of major complications was 0.1%, half of which were unintended major surgery.

Approximately half of the serious injuries that occur in conjunction with laparoscopy happen while accessing the abdominal cavity using a Veress needle and/or a trocar. In a recent review of access-related bowel injury, Jansen et al (8) found an injury rate of 0.44 per 1000 gynecological laparoscopic procedures overall. Most recently, Llarena et al (9) performed a systematic review of bowel injury in all types of gynecologic laparoscopy. Over 474,000 gynecologic laparoscopies in 90 studies published between 1972 and 2014 met eligibility criteria. The rate of bowel injury varied by procedure; the rate specific to laparoscopic sterilization was 1 in 3,333 (0.03%, 95% confidential interval 0.01-0.03%). In 2006, approximately 643,000 sterilizations were performed in the US, half of which were interval procedures.(10) This would translate to approximately 95 bowel injuries annually due to laparoscopic tubal ligation.

The use of general anesthesia, insufflation of the abdomen with carbon dioxide (CO_2) gas, and the use of steep Trendelenburg position sometimes needed to access pelvic structures also increase the risk of all laparoscopic surgeries. There may be increased risks of aspiration, respiratory dysfunction, and cardiovascular dysfunction during laparoscopy.(11)

Cottin et al (1996) reported seven cases of gas embolism during laparoscopy, 2 of which were fatal. (12) All cases occurred in women with a history of previous abdominal surgery. Their review of the literature indicated that this event is rare, with an incidence of 15/113,253 (Wadhwa et al, 1978 [13]) to 7/1194 (Hynes et al, 1992 [14]) gynecological laparoscopies.

The prevalence of permanent birth control procedures in the US and the known risks associated with laparoscopic tubal ligation described above highlight the need for additional options for women. With the approval of Essure in 2002, women gained access to a method that not only avoids entry into the abdominal cavity, but also the need for general anesthesia and its associated complications.

2. Regulatory History

The Essure System for Permanent Birth Control is a Class III medical device. Essure consists of an insert and a disposable delivery system and has undergone clinical investigations since 1996. The Essure System was initially *Conformité Européene* (CE) Mark approved on 09 FEB 2001 and received US FDA approval on 04 NOV 2002 following the FDA PMA review pathway, the most stringent regulatory review process for devices prior to marketing. Essure was the first of its kind device and as such, the FDA referred the PMA to an outside panel of experts (advisory committee) on 22 JULY2002, for review. The panel was asked to vote on questions that discussed: safety, efficacy, labeling, training and post approval requirements. The majority of the experts (8 of 9) on the panel agreed that the Essure System should be approved; one member abstained due to personal reasons.

Essure is commercially available in the US, Canada, several European countries, Australia and several Latin/South American and Asia Pacific countries. Initially, Essure was manufactured and marketed by Conceptus, Inc., which was acquired by Bayer on 05 JUNE 2013.

Since the PMA review and approval of Essure, the FDA has conducted 8 inspections including reviews of manufacturing, quality system processes and procedures, as well as clinical data integrity. All findings observed during the inspections were appropriately addressed by the company and subsequently closed out by the FDA.

Post approval requirements

Based on the expert opinion from the PMA Advisory Committee Panel meeting in 2002, the FDA required a post approval study (PAS) as a condition of the original Essure PMA approval. In addition to the PAS (to evaluate bilateral placement rate for newly trained physicians), the FDA required Conceptus to continue to follow all women in the phase II and

the pivotal trial through five years (see Section 4.1.4) in order to obtain longer term safety and effectiveness outcomes data.

PMA annual reports and adverse device reporting is a condition of PMA approval which has allowed for continuous interactions with the FDA throughout the life cycle of the device.

Since 2002, the FDA has reviewed and approved many post approval reports and 39 supplements to the PMA; including 15 approved PMA supplements to update the IFU (Section 10.6 [Appendix 6]) and the PIB (Section 10.7 [Appendix 7]).

3. Device and its characteristics

Device description: The Essure system is comprised of a disposable delivery system and a wound-down insert. The insert consists of a super-elastic nitinol (nickel titanium alloy) outer coil and a medical grade 316L stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers.

The inner coil is attached to the outer coil by a tin-silver alloy solder at the distal end of the insert. The wound-down (unexpanded) insert is approximately 4 cm in length and 0.8 mm in diameter. When released, the outer coil expands up to 2.0 mm in diameter, conforming itself to the varied diameters and shapes of the fallopian tube (Figure 3–1).

Figure 3–1: Essure insert

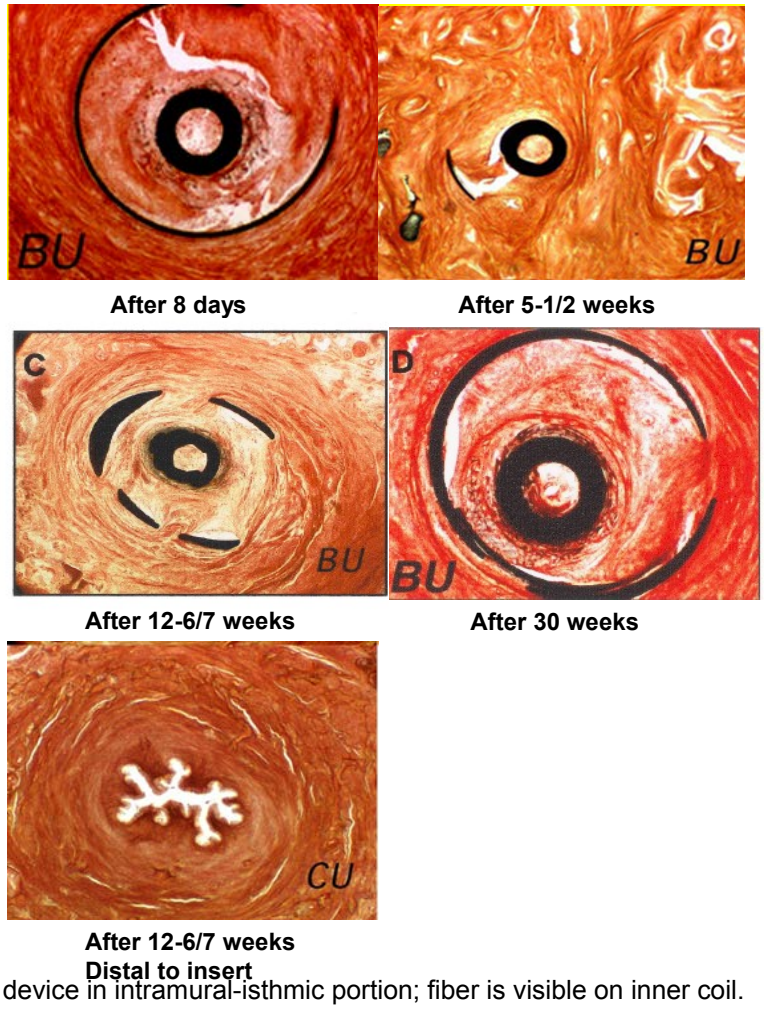
Mechanism of action: Once Essure is placed in the fallopian tube, the dynamic outer coil expands and secures the insert in place in the uterotubal junction region. Tubal occlusion is attributed to the space filling design of the device and the predictive, progressive and occlusive tissue response. The PET fibers cause tissue in-growth into and around the insert, facilitating insert retention and pregnancy prevention. During this three month period of in-growth, a woman must use an alternative form of contraception.

Histological data gathered in prehysterectomy clinical trials have shown that the tissue response to the Essure device is occlusive in nature, providing long term anchoring of the device.(15) These studies demonstrated that the tissue in-growth response was predictable, occurred in all fibered specimens collected, and was localized to the inner portion of the

fallopian tube wall, with normal tubal architecture present within 5 mm of the distal end of the device. There was no evidence that fibrosis induced by the device extended into the wall of the fallopian tube or caused peritubal adhesions or serositis. The tissue response varied according to the elapsed time after placement (Figure 3–2). Acute inflammation was predominant in early specimens whereas chronic inflammation and fibrosis was more extensive in the fallopian tubes of women who had worn the device for longer than 8 weeks. The acute inflammatory and low-level chronic inflammatory responses were consistent with other devices that have used PET fibers. At 12-13 weeks post device placement, the Essure insert became completely incorporated into the fallopian tube with a proliferation of fibrotic tissue.(15) By 30 weeks, dense fibrosis replaced the tubal lumen; only scant acute inflammatory cells were present.

Figure 3–2 provides the histology of human fallopian tube.

Figure 3–2: Human histology specimens after device wearing



After 8 days

After 5-1/2 weeks

After 12-6/7 weeks

After 30 weeks

After 12-6/7 weeks
Distal to insert

BU = device in intramural-isthmic portion; fiber is visible on inner coil.
CU = cross-section of fallopian tube 5 mm distal to device location.
Source: Valle RF et al, 2001 (15)

Device Biocompatibility

The Essure system (insert and delivery catheter) passed extensive biocompatibility testing in accordance with ISO 10993 (International Organization for Standardization). The following testing has been performed: cytotoxicity, sensitization, genotoxicity, muscle implantation, vaginal irritation, mutagenicity, subchronic toxicity, and acute systemic toxicity. Based upon biocompatibility testing and human clinical studies, the Essure device is well tolerated by the human body. In addition, all materials used in Essure are well characterized with a long history of clinical use in, and similar in form to, approved and marketed long-term implantable medical devices.

The PET fiber was chosen for this application due to its success in causing tissue in-growth in other medical applications, such as prosthetic arterial grafts, aneurysm coils, and other long-term implants since the 1940's.(16, 17, 18, 19, 20) Polyethylene terephthalate has been demonstrated to produce an immediate local tissue response characterized by macrophages, fibroblasts and collagen.(21) When used for stent-grafts in humans, the tissue reaction observed tends to be composed predominantly of macrophages and monocytes. A moderate foreign-body tissue reaction is also elicited by the PET fibers.(22) This tissue response has been noted to peak between two and three weeks, after which the tissue response slowly resolves during a 10-week period, resulting in extensive fibrosis which occludes and anchors the PET material and any associated medical device.

The unique combination of shape, memory and superelasticity properties, coupled with its proven biocompatibility and corrosion resistance, has made nitinol a suitable material for medical and dental applications since the mid 1980's. Products such as orthodontic arch wire, vena cava filters, guide wires, stents, distal protection devices, heart valves, support membranes in a catheter wall, and bone anchors are all common nitinol applications.

The nickel ions in nitinol are tightly bonded to titanium, and the nitinol used is processed so that the entire alloy surface is covered with a protective layer of titanium oxide; both of these characteristics act to minimize nickel ion release. An in vitro study was performed to determine the amount of nickel leached after the Essure insert was placed in saline solution for various lengths of time up to 6 months. The maximum nickel leaching rate was 0.14 µg/day.(23) This is far less than that for other approved nitinol implants which range from 0.42 – 8.40 µg/day.(24) In addition, it is over 2000 times less than the amount of nickel that is ingested from water and food each day (~300 µg/day).

Based on the literature research, testing data, and widespread human use of the device materials, the Essure device testing met the requirements of ISO 10993 for a surface device with permanent contact with mucosal membrane tissue and the FDA determined that the safety profile was acceptable for permanent birth control.

Design changes

Since the PMA was originally approved by the FDA in 2002, Essure has undergone several design changes to improve performance and these changes were approved by the FDA prior to marketing (Section 10.1, Appendix 1). The original approved model was the STOP device. The first US launched device was the ESS205 model which employed the same insert as the STOP device and incorporated delivery system changes. Subsequent changes to the Essure system were mainly made to the delivery catheter based on feedback gathered through direct customer input and/or post-market monitoring. For the ESS305 model, minor changes were also made to the insert to accommodate changes to the delivery system. These changes did not affect the critical design aspects of Essure and the safety and efficacy of the device. The current ESS305 model has been commercialized since 2007.

4. Clinical Development Program

Data for the phase II and pivotal studies in this document is based on the final study report with 5 years of follow-up.

The "Essure® Permanent Birth Control System" or "Essure® System" was previously known as a "Selective Tubal Occlusion Procedure" or "STOP" device or the ESS005 Model. The device is indicated for permanent birth control (female sterilization) by occlusion of the fallopian tubes.

All studies in the clinical development program of Essure are summarized in this section as follows:

- Premarket studies supporting the initial PMA are presented in Section 4.1 (Table 4–1).
- Completed post approval studies in the US are presented in Section 4.2.1 (Table 4–6).
- Ongoing post approval studies in the US are presented in Section 4.2.2 (Table 4–7).
- Post approval observational studies are presented in Section 4.3.

4.1 Studies supporting the initial Premarket Approval

For the initial PMA submission, 4 studies were included with a total of 903 women undergoing the Essure procedure (not including the 4 women without case report forms (CRFs) from Germany in STOP 01 study). Of these, 643 women (194 in the phase II study and 449 in the pivotal study) with bilateral placement who were told to rely on Essure were followed for safety and effectiveness.

Studies that supported the initial PMA approval of Essure® are presented in Table 4–1.

Table 4–1: Overview of studies demonstrating safety and efficacy of Essure

Study number	IDE number	Study title	Study dates / countries	Women enrolled / Women underwent placement procedure
Studies supporting the initial Premarket Approval				
Phase IA / STOP 01	IDE G960052	STOP Device Placement Feasibility Study Using Hysteroscopic Visualization.	July 1998 – Nov 2000 / Australia, Europe, Mexico, US	99 / 95
Phase IB / STOP 06	IDE G960206	Evaluation of the Safety and Principles of Operation of the Selective Tubal Occlusion Procedure (STOP) Device in Women who are scheduled to undergo a hysterectomy.	Oct 1998 – Dec 2001 / Mexico and US	63 / 63
Phase II (STOP 10)	IDE G980152	Phase II Study – A Multi-Center Clinical Trial to Evaluate the Safety and Effectiveness of the STOP Device to Prevent Pregnancy in Women Who are Seeking Permanent Contraception.	Nov 1998 – June 2000 / Australia, Belgium, Spain, USA	269 / 227
Pivotal (STOP 2000)	IDE G000055	A Multi-Center Clinical Trial to Demonstrate the Safety and Effectiveness of the STOP Device in Providing Permanent Contraception.	May 2000 – 05 Dec 2007 / Australia, Belgium, Spain, UK, US	657 / 518

IDE = Investigational Device Exemption; STOP = Selective Tubal Occlusion Procedure; UK = United Kingdom; US = United States (of America).

4.1.1 Pre- and peri-hysterectomy studies

Two studies (STOP 01 and STOP 06) were conducted in women who were scheduled to undergo hysterectomy for benign reasons in order to demonstrate the feasibility and acute safety of Essure placement and to provide support for the postulated mechanism of action and the ability of the inserts to occlude the fallopian tubes. In addition, the STOP 06 study evaluated detachment of the insert from the delivery wire, woman's tolerance of and recovery from placement procedure, stability of the insert within the tube until hysterectomy, tubal occlusion within 24 hrs to 12 weeks, local tissue response and the effect of fiber on the ability to create a local tissue response.

In STOP 01 study, 99 women were enrolled, however, 95 women were evaluated (4 women were excluded from data analysis due to the Investigator's death at a site in Germany and the CRFs from this site could not be obtained).

In STOP 06 study, 63 women underwent placement attempt with a Gamma design and 54 women had at least one device placed.

In these two studies, device handling and placement were found to be acceptable and the short-term wearing of the insert (1 to 30 weeks) was found to be acceptable with no reported side effects. The placement procedure was found to be safe with minimal post-procedure discomfort and minimal AEs and was able to be accomplished with local or regional anesthesia.

In addition, tubal occlusion based on hysterosalpingogram (HSG) occurred in 92/93 (99%) of tubes containing inserts at the time of hysterectomy, supporting the postulated mechanism of action, and the tissue in-growth reaction was predictable, localized to the insert, and did not result in adverse clinical sequelae.

4.1.2 Phase II study (STOP 10)

This was a prospective, multi-center, international phase II study of women seeking permanent contraception**.** Four design concepts (Beta 1, Beta 2, Beta 3 and Gamma) were clinically evaluated during the development of the Essure insert and were tested in this study. The Gamma design was ultimately selected for PMA approval.

The objectives of the study were to evaluate the woman's tolerance of and recovery from the insert placement procedure, the woman's tolerance of the placed inserts, the safety of the placement procedure, the long-term safety and stability of the placed inserts, and the effectiveness of the inserts in preventing pregnancy.

The study with the Gamma design enrolled 269 women, 227 of whom underwent an insert placement procedure. None of the women in this study became pregnant while relying on the Gamma design for contraception. One woman relying on an earlier (Beta) design did become pregnant. This was reported to FDA at the time. Specific data on device placement, confirmation testing and subject satisfaction are presented in Section 7.

Safety data: Based on the final 5-year study report (dated 06 JAN 2006), a total of 21/227 (9.3%) women reported AEs, 12/227 (5.3%) related to episodes of period pain (dysmenorrhea), ovulatory pain or changes in menstrual function. The remaining 9 reported AEs: perforation (7 [3.1%]), expulsion 1 [<1%]), and other (1 [<1%]) were due to unsatisfactory device location. Further information on perforations, expulsions, pain and device removals is provided in Section 7. (Note: The data described in this paragraph uses the total number of women with device placement attempt (227) as the denominator. In this study, 206 women had at least one device placed).

4.1.3 Pivotal study (STOP 2000)

The objectives of this pivotal study were to determine the bilateral placement, reliance, pregnancy, and AE rates in women undergoing Essure placement procedure. Women in this study were followed one week post-device placement (PDP); 3 months PDP; 3, 6, and 12

months post-alternative contraception (PAC); and 18 months to 5 years PAC as a part of FDA's required post approval commitment.

In total, 657 women enrolled in the study. Ninety-nine women subsequently changed their mind about participating and 40 were considered screen failures. Therefore, 518 women underwent hysteroscopy and 507 underwent attempted Essure placement. At the conclusion of this study, 364 women with bilateral devices and 2 women with unilateral devices (with unicornuate uterus or with contralateral proximal tubal occlusion on HSG) that were relying on Essure for contraception had completed their required 5-year follow-up. In addition, 20 women who were followed for safety only (ie, were not relying on Essure for contraception) completed the 5-year follow up period (Table 4–2).

Table 4–2: Follow-up of women up to five years (pivotal study)

Follow-up visit post-alternative contraception	Number completing visits to 05 DEC 2007 data cut-off date
12-month	461
24-month	435
36-month	423
48-month	403
60-month	386

Adverse events on the day of insert placement procedure occurred in 16 (3.0%) women. With the exception of one woman who had an adverse reaction to pain medication and required overnight observation, all events resolved prior to discharge. No event occurred in more than 1% of women.

Post-operative recovery was reported as "uneventful" in 313 (60%) women. The most common post-operative events were cramping and pain occurring in 31.0% and 13.5% of women respectively, followed by nausea in 9.7% of women.

Four luteal phase pregnancies were reported (pregnancies occurring prior to insert placement but not detected on the day of placement). However, none of these 4 women became pregnant while relying on Essure and all conception dates were before the insert placement procedure. No other pregnancies were reported in this study (see Section 7.6).

Overall comfort with long-term wearing of the inserts was high (see Section 7.3, Patient Satisfaction). Adverse events rated by the investigator as at least possibly related to Essure during the first year of reliance are presented in Table 4–5.

4.1.4 Safety and efficacy data in IFU from phase II and pivotal studies

Phase II (STOP 10) and pivotal (STOP 2000) studies form the basis for safety and efficacy data in the FDA approved IFU (Section 10.6, Appendix 6). The objective of these studies was

to demonstrate safety and effectiveness of Essure system in providing permanent contraception.

In the two studies combined, the effectiveness of Essure inserts was assessed in 635 women who relied on Essure for contraception. There were no reported pregnancies (Table 4–3).

Table 4–3: Cumulative failure rates (phase II and pivotal trials combined)

One-year [c] N=635	Two-year c N=605	Three-year [c] N=586	Four-year [c] N=567	Five-year [c] N=567
0% 95% CI, (0 - 0.10%) [a, b]	**0%** 95% CI, 0 - 0.20%) [a, b]	**0%** 95% CI, (0 - 0.30%) [a, b]	**0%** 95% CI, (0 - 0.40%) [a, b]	**0%** 95% CI , (0 - 0.50%) [a,b]

N = number of women; CI = confidential interval
[a] 95% confidence intervals are based on a "constant-hazard" exponential failure-time model, whose parameter is determined by the total number of woman-months accumulated during the trial.
[b] Combined effectiveness data obtained using Bayesian statistics.
[c] The number of women "N" were considered to have completed follow-up at 1 year if patient contact occurred at ≥ 11 months, 2 years if contact occurred at ≥ 23 months, 3 years if contact occurred at ≥ 35 months, 4 years if contact occurred ≥ 47 months and 5 years if contact occurred at ≥ 59 months.

Adverse events occurring during the hysteroscopic placement procedure in these studies are summarized in the IFU (Section 10.6, Appendix 6) presented in Table 4–4. Data presented below are taken from the IFU and reflect percentage of events as a function of the number of procedures recorded.

Table 4–4: Adverse events reported on day of placement procedure

Adverse event / side effect	Phase II trial	Pivotal trial
	Number of procedures	
	N=233 (100%)	N=544 (100%)
Cramping	NA [a]	161 (29.6%)
Pain	2 (0.9%)	70 (12.9%)
Nausea/vomiting	NA [a]	59 (10.8%)
Dizziness / light headed	NA [a]	48 (8.8%)
Bleeding / spotting	NA [a]	37 (6.8%)
Other [b]	NA [a]	16 (2.9%) [b]
Vaso-vagal response	2 (0.9%)	7 (1.3%)
Hypervolemia	NA [a]	2 (0.4%)
Band detachment	3 (1.3%)	2 (0.4%)

[a] Data not collected
[b] Other for the pivotal trial includes: ache (3), hot/hot flashes (2), shakiness (2), uncomfortable (1), weak (1), profuse perspiration (1), bowel pain (1), sleepiness (1), skin itching (1), loss of appetite (1), bloating (1), allergic reaction to saline used for distension (1).

Table 4–5 summarizes AEs with >0.5% incidence rated as at least "possibly" related to the insert or procedure during the first year of reliance in the pivotal trial (approximately 15 months post-device placement). The most frequently reported AEs in the first year were back pain, abdominal pain/cramps and dyspareunia. Data below are taken from the IFU and are presented as the number of events as divided by the total number of subjects with at least one insert in place.

Table 4–5: Adverse events by body systems, first year of reliance (≥ 0.5%), (pivotal trial)

Adverse events by body system	Number (%) [a]
Total number of women placed with at least one insert	**476 (100%)**
Abdominal	
Abdominal pain/abdominal cramps	18 (3.8%)
Gas/bloating	6 (1.3%)
Musculo-skeletal	
Back pain/low back pain	43 (9.0%)
Arm/leg pain	4 (0.8%)
Nervous/Psychiatric	
Headache	12 (2.5%)
Premenstrual Syndrome	4 (0.8%)
Genitourinary	
Dysmenorrhea/menstrual cramps (severe)	14 (2.9%)
Pelvic/lower abdominal pain (severe)	12 (2.5%)
Persistent increase in menstrual flow [b]	9 (1.9%) [b]
Vaginal discharge/vaginal infection	7 (1.5%)
Abnormal bleeding – timing not specified (severe)	9 (1.9%)
Menorrhagia/prolonged menses (severe)	5 (1.1%)
Dyspareunia	17 (3.6%)
Pain/discomfort - uncharacterized:	14 (2.9%)

[a] Percentages reflect the number of events divided by the number of women in the trial. When numerous episodes of the same event were reported by one woman, each report was counted as a separate event. Therefore, percentages may over-represent the percentage of women who have experienced that event.
[b] Eight women reported persistent decrease in menstrual flow

4.2 Post approval studies in the United States

4.2.1 Completed post approval studies in the United States

Two studies were conducted and completed after approval of Essure (Table 4–6).

Table 4–6: Completed post approval studies

Study	PMAS	Objective	Date/country	Enrolled / underwent procedure
ESS205	P020014	Post approval study for newly trained physicians	May 2003 – Oct 2005 / US	585 / 564
ESS305	P020014	ESS305 post approval study	Aug 2007 – May 2009 / US	619 / 593

PMAS = postmarketing approval study;

4.2.1.1 ESS205 post approval study

This study was intended to document the bilateral placement rate for newly trained physicians using the ESS205 system. The data were to be used to evaluate bilateral placement rate to newly trained physicians. Data collected included the following:

- Rates of successful bilateral placement of the Essure System at first attempt; and
- Identification of factors predictive of failure to achieve bilateral placement.

A total of 585 women were enrolled and 564 underwent placement attempt. Of these women, 194 placement attempts were made with the Gamma (ESS005) catheter and 370 placement attempts with the coil catheter (ESS205).

Adverse events (during and after the placement procedure) were reported in 15/585 (2.6%) women, inclusive of one woman in whom one insert perforated the left uterine fundus and embedded in the omentum, causing pain. The peritoneal portion of the insert was laparoscopically removed and each tube was banded with Falope rings. The woman reported increased pain of unknown etiology and was to be scheduled for diagnostic studies and was lost to follow-up. No unanticipated adverse device effects were reported.

4.2.1.2 ESS305 post approval study

The Essure (ESS205) system was modified to the ESS305 model based on feedback gathered through direct customer input and postmarket monitoring (see Section 10.1, Appendix 1 for design changes).

The objective of this study was to validate the ESS305 device changes in both the newly trained and experienced physicians and it is the basis for the placement rate in the approved IFU (Section 10.6, Appendix 6) from 2010 through JUNE 2015 when the IFU was modified to include the TVU/HSG confirmation test algorithm. This study initially planned to enroll 800 women but was terminated early, after enrollment of 619 women. Upon agreement from the FDA, this smaller sample size was deemed to be sufficient to demonstrate statistically significant results for the study endpoints.

A total of 625 women were enrolled and 6 women were excluded from the placement rate calculation: 5 women withdrew consent prior to placement attempt and one woman underwent placement procedure with the incorrect device (ESS205). Therefore, 619 women are included in the ITT population with the placement rate of 95.8%. Essure inserts were placed through the operating port of the hysteroscope in 612 women. Of these 612 women, 593 (96.9%) had successful bilateral placement. Data on potential differences in placement rates between newly trained and experienced physicians is presented in Section 7.4.

Device issues and malfunctions: Essure device issues were reported in 14 of the placement procedures (one procedure may have had multiple events reported). In five of these cases, the distal tip of the insert was bent. This is not a device malfunction per se since tip bending is a feature of the device (rather than cause damage when it comes into forceful contact with the uterus or the fallopian tubes). Bent tips can occur in the commercial use of Essure and may be caused by rough handling when placed into the introducer, advanced through the hysteroscope, and when manipulating the device inside the uterus.

Ten of the reported device issues represent device malfunctions. These include six insert deployment or detachment issues, one thumbweel retraction difficulty, and three unspecified device issues. Each of these issues have been captured in Conceptus' product surveillance system and investigated under standard quality system procedures.

Safety data: Six of 619 women were reported to have AEs during and after the Essure placement procedure. One woman was hospitalized after hysteroscopy due to a uterine perforation by the hysteroscope (and not the Essure device). None of these AEs represent unanticipated adverse device effects.

4.2.2 Ongoing post approval studies in the United Studies

Two studies are currently ongoing (Table 4–7): the transvaginal ultrasound (TVU) study and the NovaSure PAS.

Table 4–7: Ongoing post approval studies

Study number	PMA number	Objective	Dates and countries	Women enrolled / undergoing procedure
ESS305 TVU Study (Study 16974)	P020014	Use of Transvaginal Ultrasound to Confirm Essure® Insert Placement in Women: Demonstration of Effectiveness (Essure® TVU study).	May 2011 Canada, Netherlands, Spain, US, 10 year study	620 / 597
NovaSure PAS (Study 16975)	P020014	To Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test	Nov 2012 US	Currently enrolling (220 planned)

PMA = Premarketing approval; TVU = transvaginal ultrasound; PAS = post approval study; US = United States

4.2.2.1 Transvaginal ultrasound study (ESS305, Study 16974)

The TVU study is a currently ongoing phase IV study being conducted in order to support the use of TVU as a first line confirmation test in the US. Enrollment was completed on 11 OCT 2012. Women in this study are to be followed for 10 years following discontinuation of alternative contraception after being instructed to rely on Essure for contraception. The TVU/ HSG confirmation test algorithm was approved on 29 JUNE 2015 based on the 1-year effectiveness data from this study.

The objectives of the study are to:

- Evaluate the effectiveness of the Essure procedure when the TVU/HSG algorithm is used for confirmation testing (co-primary endpoint)
- Evaluate the intent-to-treat reliance rate 3 months following TVU/HSG confirmation test algorithm (co-primary endpoint)
- Evaluate subject satisfaction with the TVU confirmation test

A total of 620 women were enrolled into the study; of these, 23 women withdrew prior to undergoing the Essure placement and 597 women underwent the Essure procedure and constitute "the intent-to-treat" (ITT) population.

All women in the ITT population (n = 597) underwent insert placement procedure. Details on placement status are provided in the topics of interest section (Section 7.1). Bilateral placement was achieved in 582 of 597 (97.5%) of women.

Overall, 547 women were told to rely on Essure based on the TVU/HSG confirmation test algorithm (Table 4–8). The reliance rate in the ITT population was 91.6% (547/597) with the posterior credible interval of 89.2% - 93.6%. The posterior probability that the reliance rate is > 86.7% is 99.99%, which exceeds the preset probability threshold of 97.5% for the study.

Table 4–8: Confirmation test for reliance with Essure in women with bilateral placement

	Told to rely, number (%)		
Test	**Yes**	**No**	**All**
Total	**547 (100)**	**35 (100)**	**582 (100)**
Transvaginal ultrasound alone	470 (85.9)	4 (11.4)	474 (81.4)
Transvaginal ultrasound followed by Hysterosalpingogram	47 (8.6)	6 (17.1)	53 (9.1)
Hysterosalpingogram alone	30 (5.5)	2 (5.7)	32 (5.5)
No test performed [a]	0	23 (65.7)	23 (4.0)

[a] women withdrew prior to Transvaginal ultrasound or Hysterosalpingogram

One year effectiveness: As of 12 AUG 2014 (data cutoff for 1-yr effectiveness report), 4 pregnancies were reported, 3 pregnancies during the first year and 1 pregnancy during the second year of wearing of Essure insert (no additional pregnancies have been reported through JULY 2015). The total 1-year reliance follow-up time at data cutoff was 6217 women-months. The estimate of the monthly pregnancy rate is 3/6217 or 0.048% (95% CI: 0.01%, 0.13%) and the 1-year pregnancy rate is 0.67% (95% CI: 0.16%, 1.53%). The probability that the upper credible limit of the 1-year pregnancy rate is <2.1% is >99.99%. This is greater than the study's predefined probability cutoff of 97.5%, so this co-primary endpoint was met.

An annual report was submitted to the FDA with a cut-off date of 19 JUN 2015. As of this cut-off date, 473 subjects had a 2-year follow-up visit and 90 subjects had a 3-year follow-up visit. As of this date, no additional pregnancies have been reported and the follow-up is 16,897 women-months. Based on the life table analysis, the 2-year pregnancy rate is 0.754%.

The 4 pregnancies (none ectopic) mentioned above were reported from 4 different sites, 3 in the US, and one in the Netherlands. All 4 women were compliant with the 3 month study visit, underwent confirmation testing within the protocol designated time window, and were told to rely on Essure based upon TVU alone. A review of the root cause for Essure insert efficacy failure in these 4 cases appears to be perforation in 2 women and unsatisfactory insert location in the other 2 women. These root causes are consistent with those described with the commercial use of Essure.

The secondary efficacy objective of this interim report is to evaluate subject satisfaction with the TVU confirmation test. The analysis of subject satisfaction was reported as very satisfied or somewhat satisfied by a total of 520/528 (98.5%) women; neither satisfied or dissatisfied by 3 (0.6%) women; and somewhat dissatisfied by 3 (0.6%) women.

Safety data: As of a data cutoff date of 19 JUNE 2015 (for the recent PAS Annual Report), a total of 493 AEs were reported in this study. The severity of most (n=280) AEs was considered mild. Moderate and severe AEs were reported for 113 and 44 events, respectively. Thirteen AEs were reported as 'definitely' related to the Essure system. Hospitalization was required for 11 AEs that occurred in 8 women: pelvic inflammatory disease (PID), pleomorphic adenoma, adnexa uteri pain, intervertebral disc protrusion, abdominal pain, nausea, chest pain, pelvic pain, anxiety, cerebrovascular accident and myocardial infarction.

The most common AEs by Medical Dictionary for Regulatory Activities (MedDRA) preferred term (PT) were: pelvic pain (n=28), menorrhagia (n=23), abdominal pain (n=16), dysmenorrhea (n=15), vaginal hemorrhage (n=14), uterine hemorrhage (n=9), and ovarian cyst (n=9).

As of the data cutoff date (19 JUNE 2015), there were 28 SAEs in 20 women. Three of these events (PID, adnexa uteri pain, and pelvic pain) were categorized as "possibly related" and one event (pregnancy) as "probably related" to treatment with Essure.

4.2.2.2 Novasure post approval study (Study 16975)

The purpose of the study is to evaluate the effectiveness and safety of the Essure System when a NovaSure endometrial ablation procedure is performed following a successful Essure Confirmation Test. The primary variable is the occurrence of confirmed pregnancy at 1 year and 3 years among women relying on Essure inserts for permanent birth control when NovaSure EA is performed following a successful Essure Confirmation Test. The study began enrollment on 12 NOV 2012 and enrollment is currently ongoing. To date, no pregnancies and no new or unexpected safety findings have been reported.

4.3 Post approval studies (observational)

Several post approval *observational* studies have been conducted by Conceptus, one of which is currently ongoing (SUCCES II).(25) Three published observational studies: ESTHYME study (26), SUCCES I (27) and CONFORM study (28) were conducted between 2002 and 2006.

In addition, two ongoing studies compare the rates of hysterectomy following hysteroscopic sterilization with that of laparoscopic sterilization (Intermountain Healthcare and MarketScan).

4.3.1 SUCCES II

The SUCCES II study is an ongoing multicenter, observational study being conducted in France that was initiated in 2008 by Conceptus France and which will be concluded in 2016. A total of 2,600 women were enrolled in the study. A total of 2,281 women reached the 3-months follow-up, and continued follow-up is planned for 5 years following placement through 2016.

As outlined in the study protocol, the study's primary objective is "to assess patient's satisfaction of the Essure procedure at 5 years."

The secondary objectives aim to assess:

- Pain experienced when placement is performed without anesthesia and the potential risk factors of pain,
- Methods used and the interpretation of the 3-month control test and
- Effectiveness, complications and satisfaction of the Essure procedure at short-, mid- and long-term (3, 12, 24 months and 5 years).

Selected aspects of the interim results of SUCCES II, namely, the results of the placement phase conducted between 2008-2011, were published as an abstract in the Journal of Minimally Invasive Gynecology in 2012. (25) In 2,366 (93.3%) cases, the first placement attempt was successful and 97% women reported being satisfied or very satisfied.

Subsequent to assuming responsibility for AE reporting from Conceptus France, Bayer extracted all paper-based case report forms (CRFs) and transferred all data on AEs and potential AEs into its safety database, consistent with its standard reporting processes. Of the 1,059 AE cases identified, 42 were classified as reportable and disclosed to the FDA, among other regulatory authorities, including the French National Agency for Medicine and Health Products Safety (ANSM).

To date, 5 pregnancies have been reported resulting in a calculated pregnancy rate of 0.19% and a contraceptive efficacy rate of 99.8%. None of the pregnancies were ectopic.

The study data as available to date confirm the high safety and efficacy of Essure and of the Essure placement procedure. The SUCCES II study provides further confirmatory evidence of a favorable benefit-risk profile, including considerations of the alternatives in this indication (ie, laparoscopic tubal sterilization).

4.3.2 Intermountain Healthcare

This is a retrospective analysis using electronic medical record database in the US. A 10-year observational period from 01 APR 2005 – 31 MAR 2015 is planned. This is a descriptive study with the primary objective of describing hysterectomy rates in women having undergone hysteroscopic permanent birth control and women having undergone tubal ligation.

4.3.3 MarketScan

This is a retrospective cohort study using a US claims database of women undergoing hysteroscopic or laparoscopic tubal ligation procedures. The observational period is from JAN 2010 – DEC 2012. The analysis will be performed separately for individuals with and without a pre-existing diagnosis of pain prior to the procedure. The rates of post-procedural pain and surgical procedures across all groups will be examined.

5. Training

Training of physicians on the use of Essure is important to ensure its safe and appropriate use. The IFU (Section 10.6 [Appendix 6]) for Essure clearly states: “Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure Training Program, including preceptoring in placement until competency is established, typically 5 cases.” Hysteroscopy has been a part of obstetrics/gynecology (OB/Gyn) residency training for decades. As with any procedure learned in residency, each physician must critically self-

assess their level of comfort and experience with hysteroscopy before undergoing training on Essure.

As part of the initial PMA, detailed materials were provided to the FDA describing the training program. In addition, a validation of the training program was performed in 2002, demonstrating that newly trained physicians achieved placement rates comparable to those in the clinical trials (data on file). Continuous re-evaluation, as well as new data and technological advances in simulation training, have led to updates to the program.

Specific training to use Essure, or the "Clinical Pathway," consists of multiple steps. The first step consists of didactic review on appropriate patient selection, indications, contraindications, warning and precautions. The device itself, the clinical trials leading to approval, as well as insert placement steps and the confirmation test are also reviewed in detail. In order to assist in this stage, a Clinical Resource ("Training Manual") is available in both printed and electronic format. Bayer last updated and revised the Clinical Resource in 2014. At the current time, didactic training involves a one-on-one discussion between the physician and a Clinical Sales Specialist (CSS). All CSS's undergo comprehensive training that lasts for approximately three months. Bayer is in the process of also creating an interactive online training program for physicians.

After completion of didactics, physicians then move onto simulation. The EssureSim™ is a validated computer-based system that takes a physician through several Essure-based scenarios.(29, 30) Feedback is immediately available and simulated cases become progressively more difficult. A uterine model and hysteroscope may also be used to practice placing Essure. Both deployable and nondeployable demonstration devices are available. A physician completes a minimum of 5 proctored cases before being eligible to have their final case proctored and receive their Certificate of Completion. These cases must be completed with either the CSS or an Essure trained Physician Proctor in attendance. Data on the learning curve for Essure supports this approach (see Section 7.4 on Learning Curve). A physician may continue to have a CSS or a Physician Proctor present for cases beyond completion of the Clinical Pathway if so desired. Additionally, office staff of a physician who will perform the placement procedure in their office may receive training that is specific to their responsibilities.

All physicians have access to a wide variety of materials on the Essure MD website (www.EssureMD.com) and this site is updated regularly as new information becomes available. These materials include sample informed consent documents and procedure notes, checklists, patient education materials, and additional training on the Essure Confirmation Test.

Several other resources and training opportunities are available to physicians. These are summarized below:

- *Physician Inquiry Requests*: Physicians are encouraged to contact Bayer with Essure related questions or to report AEs. A dedicated Bayer Medical Information employee is available during business hours. Questions may also be escalated to the Medical Director (a board-certified OB/Gyn) as necessary or required.
- *National Consultancy Network*: Questions that are out of the scope of Bayer's ability to answer are forwarded to small group of physicians with extensive experience with Essure by the Essure Medical Director. All AEs of the case are captured and forwarded to the pharmacovigilance department; patient management decisions remain the responsibility of the querying physician.
- *Advanced Training Summits*: In conjunction with a global manufacturer and distributor of endoscopes, Bayer currently offers a 1½ day didactic, simulator and uterine model program for physicians who have completed the Clinical Pathway. These programs emphasize troubleshooting, interpretation of the HSG confirmation test, patient identification and counseling, and techniques for ensuring patient safety in the office.
- *Radiologist Training Program*: A program tailored for radiologists was developed in order to provide information and guidance on performance of the modified-HSG and appropriate interpretation of confirmation test films.
- *Residency Training*: As of January, 2013, the Council on Resident Education for OB/Gyn (CREOG) changed their guidelines to now state that all OB/Gyn residents must know how to perform hysteroscopic sterilization. In order to assist resident programs with this task and ensure that residents receive a thorough education on the procedure, a six-module resident education program was developed. This program relies on faculty input and participation and is designed to complement existing hysteroscopy training that residency programs are mandated to deliver. Access to the EssureSim™ is provided to residents as part of these programs.
- *Proctors*: Essure proctors are physicians with extensive experience with the Essure procedure. Proctors are fully trained on compliance and AE reporting as well as what their roles and responsibilities will be. Proctors may observe other physicians during or after completion of the Clinical Pathway. Physicians and appropriate staff may also go to the proctor's office to observe cases and safe placement techniques in an office setting.

6. Postmarketing Safety Reporting Overview

The safety profile of Essure is well known from clinical trials, observational research and postmarketing reporting. The amount of postmarketing reporting has increased over time which is reflective of the increasing postmarketing exposure to Essure as it can be estimated based on sold Essure kits (each containing two inserts).

Besides this, an increase of case reports since Q3 2013 has been observed. The increase coincides with Bayer´s acquisition of Conceptus in JULY 2013 and with Bayer assuming responsibility for AE case handling and case reporting in OCT 2013.

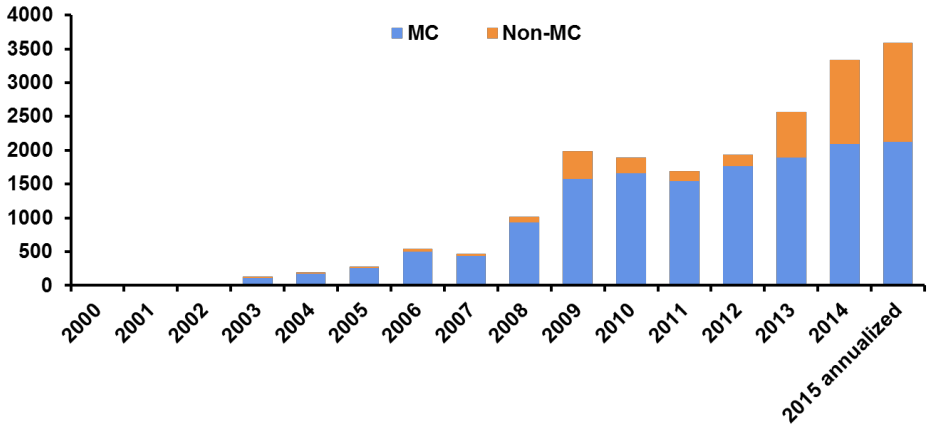
Over this period, the number of medically confirmed case reports has increased only slightly, whereas the number of non-medically confirmed case reports has increased disproportionally. The difference in case numbers before and after Q3 2013 is predominantly explained by an increase in non-medically confirmed reports, mostly from the US.

Figure 6–1 presents the annualized number of individual safety (case) reports of AEs as included in the sponsor's global safety database through 15 June 2015, regardless of their relationship with Essure. Cases are presented by the year of initial receipt, date for medically confirmed events and non-medically confirmed reports separately. The latter represent cases received from patients/consumers without further confirmation by a Health Care Physician.

Several elements are likely to have influenced the observed trends globally and in particular from the US. Bayer closely monitors and continuously evaluates the safety profile of Essure. This includes monitoring of spontaneous reports of AE and associated reporting rates as well as publications from medical journals and information from general and social media. There are secular trends of increased reporting observed in postmarketing AE reporting at Bayer across the portfolio, that impacts on reporting with Essure. Besides this, the acquisition of Conceptus by Bayer led to increased public attention to Essure and an increase in interest in the product's safety profile by attorneys and their affiliates at least in part focused on potential avenues for liability, which was noticeable in social and other media, but also in reporting to Bayer call centers and websites. Bayer responded to these trends with activities that aimed at facilitating reporting from non-medically confirmed sources; for example, active online listening and outreach programs.

Also, as a matter of general policy and in the attempt to facilitate comprehensive assessment by receiving Health Authorities and regulatory bodies, Bayer favors an assessment of reportability, which may be more comprehensive than with other companies. It is, however, Bayer's understanding that Conceptus has always fulfilled regulatory reporting requirements for Essure. In parallel, reporting from social media has increased for Essure, facilitated through the availability of public mobile AE reporting applications, including the FDA released MedWatcher app, which are assisting consumers in submitting AE reports to the FDA (31). Limitations of postmarket AE reporting are well known, accepted and described in the FDA regulation.(32) Consistently, the review of the information available from postmarketing indicates that the types and rates of AEs that were received are within the expected range for the Essure inserts and the procedure associated with their placement. No new safety information has been identified to date that would indicate a change in the positive benefit/risk ratio.

Figure 6–1: Adverse event reporting over time (data through 15 JUNE 2015)



MC = medically confirmed; Non-MC = not medically confirmed.

Detailed evaluations of cumulative information available to date were conducted in support of the preparations for the advisory panel meeting. It should be noted that in parallel to taking over the AE reporting obligation, Bayer transferred all postmarketing legacy AE reports from Conceptus into the Bayer global pharmacovigilance database. While no individual follow-up reports were filed for this transfer step, all data compiled by Conceptus are now included in aggregate analyses.

The information derived from these postmarketing evaluations are consistent with the known safety profile of Essure and the information as labeled in the IFU (Section 10.6, Appendix 6). Although increases in reporting rates were observed in recent years since Conceptus was acquired by Bayer, the numerical increase can be explained by factors influencing postmarketing safety reporting. Reporting rates remain compatible in line with the data generated in clinical studies.

7. Topics of Interest

Several topics of interest were identified in preparation for this meeting. The following sections identify these topics and present data from the clinical trials, the published literature, and postmarketing monitoring. Within the literature, very few studies include a comparison group which makes it difficult to put incidence rates and relatedness into context. In addition, many studies were retrospective reviews; this needs to be considered when interpreting results. However, the data is important to consider when assessing the benefit/risk profile. In order to help minimize potential biases, we chose to focus primarily on US-based studies that were not company sponsored or funded.

7.1 Placement rate

In order to be effective, the Essure inserts must be properly placed across the uterotubal junction. There are a small number of cases where individual pelvic anatomy (eg, cervical stenosis, intracavitary lesions) precluded even attempting placement of Essure inserts. An alternate form of contraception (eg, tubal ligation) is needed in these women. In other cases, other anatomic or physiologic circumstances (eg, laterally placed tubes, tubal spasm) make a particular placement more challenging. In some of these instances, a second attempt at placement may be successful. In the small number of cases where successful bilateral placement is not achieved, a woman must be counseled about her contraception needs moving forward.

7.1.1 Sponsor's clinical data

The phase II and pivotal clinical trials for Essure were conducted with the ESS005 (STOP) device. This was replaced by the ESS205 device in 2003. Both of these devices required the physician to physically unscrew the delivery catheter from the insert at the completion of the procedure. In 2007, the ESS205 device was replaced with the ESS305, the currently marketed device. With this device, the detachment procedure is carried out by using a button and wheel on the delivery handle, both of which are activated with the thumb. In the ESS305 post approval study, the Essure bilateral placement rate improved. In addition, the time to place the device decreased. A summary of the placement data from the clinical trials is presented in Table 7–1.

Table 7–1: Essure placement rate in clinical trials

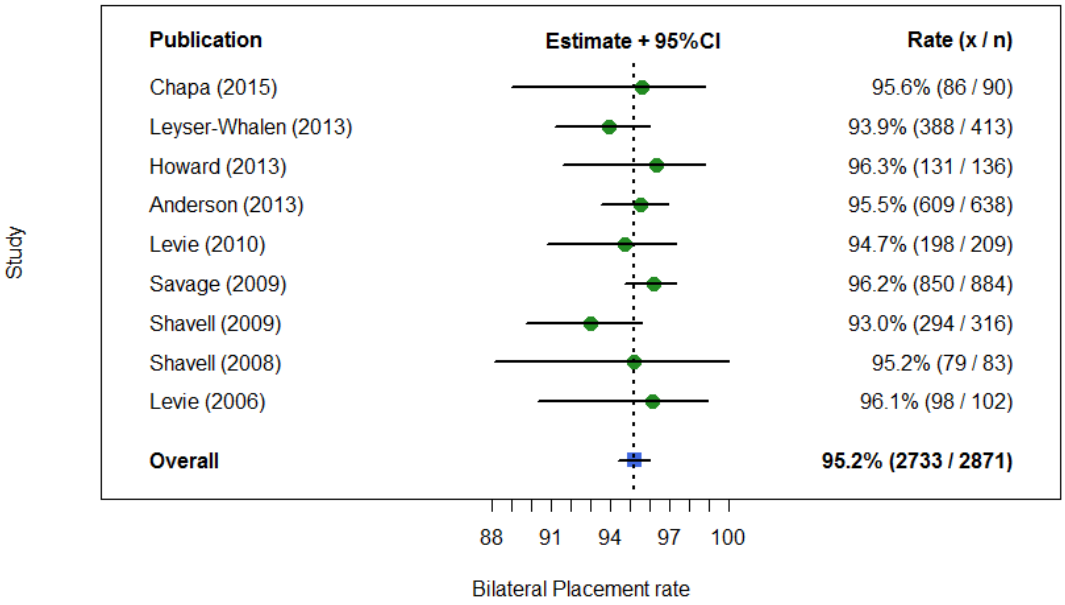
Study	Women enrolled	Women undergoing hysteroscopy (ITT)	Women undergoing Essure placement attempt	Bilateral placement rate (ITT)	Device group bilateral placement rate	Number of unilateral placements
Phase II (STOP 10)	269	227	227	200/227 (88.0%)	200/227 (88%)	6
Pivotal (STOP 2000)	657	518	507	464/518 (89.6%)	464/507 (91.5%)	12
ESS205 PAS	585	585	564	525/585 (89.7%)	525/564 (93.1%)	27
ESS305 PAS	619	619	612	593/619 (95.8%)	593/612 (96.9%)	12
ESS305 TVU (Study 16974)	620	597	594	582/597 (97.5%)	582/594 (98.0%)	5

ITT = intent to treat; PAS = post approval study; TVU = transvaginal ultrasound

7.1.2 Literature

Several published studies have also investigated placement rates, with data collected prior to 2007 looking at the ESS205, and later studies looking at the ESS305 (see Figure 7–1). Additional details about these studies (eg, study design, year of data collection, number of placement attempts, comments) can be found in Section 10.2, [Appendix 2]. Overall, the results from these studies are consistent with those found in the clinical trials. Literature has also found that placement rates appear to be independent of the level of training,(33, 34) location of service (operating room verses office), anesthesia verses no anesthesia, and degree of patient obesity.(34)

Figure 7–1: Studies based in the United States



CI = confidence interval; x = number of bilateral placements; n = toal number of women.
Chapa, 2015 (35); Leyser-Whalen, 2015 (40); Howard, 2013 (42); Anderson, 2013 (34); Levie, 2010 (48); Savage, 2009 (41); Shavell, 2009 (36); Shavell, 2 008 (39); Levie, 2006 (33).

7.1.3 Conclusion

Placement rate is very important when physicians counsel women prior to the attempted procedure, as women need to be aware of the possibility placement may not occur. Still, with the currently available ESS305 device, both the clinical trial data as well as several external studies show a placement rate of at least 95%.

7.2 Confirmation test

Once the Essure procedure is complete, a woman must use alternate contraception and undergo a confirmation test after three months. Only after a satisfactory result on the confirmation test can a woman rely on Essure for permanent birth control. Need for a post-procedure confirmation test is also part of the algorithm for male sterilization procedures (ie, vasectomy).

The IFU summarizes the data obtained from the MAUDE database on pregnancies in the commercial setting (see Section 10.6, Appendix 6). From worldwide commercial launch in 2001 through the end of 2010, 660 pregnancies in the US were reported. In 32% of cases (n=213), patient non-compliance (eg, failure to use alternate contraception or return for Essure Confirmation Test) was identified. This points to the absolute importance of patient compliance with the confirmation test.

7.2.1 Sponsor's clinical data

In the phase 2 study, HSG was performed in the 200 women who initially had bilateral placement (and in 2 women with unilateral placement) to assess tubal occlusion at the 3-month visit. Insert location was assessed using either HSG or ultrasound and 194/200 women had satisfactory insert location and 187 women had successful bilateral occlusion at 3 months and were able to rely on Essure for contraception. Additionally, the 7 subjects with patency noted at 3 months were found to have bilateral tubal occlusion at repeat 6 month HSGs and were therefore told to rely.

In the pivotal study, of the 507 women undergoing attempted device placement, 464 had bilateral device placement; 456 underwent 3 month follow-up (HSG) to assess location of insert and occlusion and 453 were told to rely on Essure for contraception. Of the 49 remaining subjects, 31 had no devices placed, 3 were lost to follow-up prior to the 3 month visit, 3 did not have an HSG but relied (protocol violations), 2 had unsatisfactory placement detected before 3 months and 12 had unilateral placement.

In the TVU study (Study 16974), of the 597 women who underwent Essure placement attempt, 559 (93.6%) underwent confirmation testing and 547 were told to rely. Of the 38 women not undergoing confirmation testing, 23 were lost to follow up or withdrew and 15 had non-bilateral placement.

7.2.2 Literature review

In European studies, where several methods for assessing the ability to rely on Essure are available, compliance with the post-procedure confirmation test is very high (Povedano et al 2012, 96.8% [4108/4306] [37]; Ubeda et al, 2004 93% [75/81] [38]). In the US, compliance with HSG is variable. In a retrospective review of medical records in an inner city clinic population, Shavell et al (39) reported a compliance rate of 12.7% (10/79). In contrast, in a

primarily Hispanic population,(33) 92 out of 98 women (94%) completed their HSG. Additional studies found rates of 85% (243/286) in a publicly funded clinic,(40) 87% (739/850) at Kaiser Permanente Northern California,(41) and 53% (70/132) in a publicly insured population.

Several factors are associated with increased compliance with HSG. Anderson et al (34) found that women were 1.51 times more likely to undergo HSG if the Essure procedure was performed in the office setting versus the operating room. Women were 2.05 times more likely to undergo HSG if they had private insurance compared with Medicaid. Howard et al (42) found that women 35 years and older had an almost 4-fold higher odds of HSG compliance. Women who had their Essure procedure performed at a campus with a dedicated protocol to improve compliance had almost a 4-fold higher rate of compliance (odds ratio=3.67). This finding points to the fact that programs can be put into place to increase compliance.

Guiahi et al (43) reported that when a staff nurse was dedicated to tracking women's HSG results, compliance went from 78% pre-intervention to 90.9% post-intervention. Finally, Mahmud et al (44) reported that the implementation of an electronic reminder increases post-Essure HSG adherence, particularly in a resident clinic patient population. Pre-reminder compliance with HSG in a faculty practice was 90% (62/69) while compliance in the resident clinic was 47% (32/68). Post-reminder, compliance for the faculty practice remained high (19/20, 95%) while compliance in the resident clinic increased to 72% (39/54).

7.2.3 Conclusion

The Essure Confirmation Test is a vital part of the Essure procedure and must be completed in order to assess a woman's ability to rely on the Essure inserts for contraception. Some studies indicate poor compliance with the confirmation test. It appears that measures can be put into place, such as patient reminders, in order to increase women's compliance with this aspect of the procedure.

7.3 Patient satisfaction

While patient satisfaction is subjective and the tools used to assess this endpoint vary from study to study, collection of this data adds to the understanding of how women perceive a particular procedure or experience, and therefore, this is an important aspect of clinical research.

7.3.1 Sponsor's clinical data

Pivotal study (STOP 2000)

In the pivotal study, a woman's comfort with wearing STOP insert and her overall satisfaction with the STOP device were queried by the investigator at the 3-month post-device placement

visit and at 3, 6, 12, 18, 24, 36, 48 and 60 months post-alternative contraception follow-up visits. Comfort was rated as "good" to "excellent" by at least 95% women at all visits. Satisfaction was "somewhat satisfied" to "very satisfied" in at least 97% women at all visits through 5 years.

ESS305 TVU study (Study 16974)

In the ongoing ESS305 TVU study (Study 16974), both comfort and satisfaction with wearing the inserts were high at each of the 3 follow-up visits for which data is currently available: 3-months, 6-months, and 12-months.

Comfort level with the wearing of inserts was described as "excellent", "very good" and "good" by 495 (98.4%) women at 12-month visit (Table 7–2).

Table 7–2: Overall comfort level with wearing the inserts during the 1st year of follow up

Overall comfort level [a]	3-month visit N=558 n (%)	6-month visit N=536 n (%)	12-month visit N=503 n (%)
Excellent, very good, good	552 (98.9)	518 (96.6)	495 (98.4)
Excellent	351 (62.9)	374 (69.8)	366 (72.8)
Very good	151 (27.1)	114 (21.3)	108 (21.5)
Good	50 (9.0)	30 (5.6)	21 (4.2)
Fair	4 (0.7)	8 (1.5)	4 (0.8)
Poor	0	1 (0.2)	1 (0.2)
Not reported	2 (0.4)	9 (1.7)	3 (0.6)

N, n = number of women
[a] Question was asked "How does the woman rate her comfort with the wearing of inserts"?

Satisfaction with the wearing of inserts was described as very satisfied and somewhat satisfied by 495 (98.4%) women at the 12-month visit (Table 7–3).

Table 7–3: Overall satisfaction level with wearing the inserts during the 1st year of follow up

Overall satisfaction level [a]	3-month visit N=558 n (%)	6-month visit N=536 n (%)	12-month visit N=503 n (%)
Very satisfied and somewhat satisfied	547 (98.0)	513 (95.7)	495 (98.4)
Very satisfied	484 (86.7)	479 (89.4)	462 (91.8)
Somewhat satisfied	63 (11.3)	34 (6.3)	33 (6.6)
Neither dissatisfied nor satisfied	9 (1.6)	12 (2.2)	4 (0.8)
Somewhat dissatisfied	0	2 (0.4)	1 (0.2)
Not reported	2 (0.4)	9 (1.7)	3 (0.6)

[a] Question was asked "How does the woman rate her overall satisfaction with the wearing of inserts"?

Similar levels of comfort and satisfaction were recorded throughout the duration of the 5 year follow-up with no trend of an increase or decrease in comfort or satisfaction over time.

7.3.2 Literature

A number of published studies also include a measure of patient satisfaction. Some studies have assessed patient satisfaction with the procedure itself. In a prospective case series of 1630 women who underwent Essure placement in Spain from JAN 2003 to JUNE 2006, 91% of women rated the procedure as a "10" (highly satisfied) on a visual analog scale, and no woman rated it below an "8." In addition, 97% of women said they would recommend the procedure to a friend.

Additional studies included the confirmation test in the overall patient satisfaction rating as they considered this part of the overall procedure. Sinha et al (45) sent a questionnaire to 84 women post-confirmation test, which was returned by 76 (90%) women. The majority of women (70/76; 92%) were satisfied with the overall experience. Of the 6 women reporting that they were not satisfied, one stated that this was due to "extreme" pain during the procedure, three stated that this was related to their experience of the HSG, and the other two gave no reason. Most of the women (69/76; 91%) reported that they would recommend the procedure to a friend or relative. Miño et al (46) also assessed satisfaction at 3 months in 857 women. Overall patient satisfaction was rated as "very high" by 806 women (94%) and "high" by 51 (6%). None of the women reported being dissatisfied. Ubeda et al (38) performed a prospective, observational study at a private university hospital in Spain. Eighty-five cases were performed between JULY 2002 and JULY 2003. Satisfaction was characterized by good or excellent in all but 3 women (96%) in the immediate post-operative period and, at 3 months, all women said they would advise a friend or a sister to undergo the procedure.

Few studies offer long-term follow up on patient satisfaction. Anderson et al (47) performed a retrospective review of 61 women who underwent Essure placement between 2002 and 2007.

A questionnaire was sent to these women one to five years post-procedure and was returned by 50 women (81.9%). Average follow up period was 23 months (7 to 67 months). All women who returned the questionnaire expressed overall satisfaction with the procedure and all said they would recommend the procedure to others. Levie et al (48) contacted women who received Essure in the outpatient setting 13 weeks to 1 year post procedure to assess satisfaction. They were able to reach 176/209 women (84%). Within this group, the mean satisfaction score was 4.7 (standard deviation [SD] 0.71) on a scale of 1 to 5 (5 being most satisfied). In addition, 164 women (93%) reported they would have the procedure again and 173 (98%) stated that they would recommend the procedure to a friend.

In the only comparative study, Duffy et al (49) performed a cohort controlled comparative study of Essure versus laparoscopic tubal ligation in the United Kingdom (UK) and assessed satisfaction 90 days post procedure (N=89 total). Overall, satisfaction was high with both groups: 94% of the women in the Essure group and 80% of the women in the laparoscopic group were either “very” or “somewhat” satisfied at 90 days post-procedure. With regard to speed of recovery, 100% women in the Essure group were “very satisfied” verses 80% in the laparoscopic group.

7.3.3 Conclusion

Both the clinical trials and external studies demonstrate overall satisfaction (>92%) with the Essure placement procedure as well as ongoing use of the inserts. When compared to laparoscopic tubal ligation at 90 days post procedure (in one study), Essure compared very favorably with regard to overall satisfaction, speed of recovery, and choice of chosen procedure.

7.4 Learning curve

7.4.1 Sponsor’s clinical data

Data on this topic (learning curve with Essure placement) is available from two large prospective studies conducted by the sponsor, the original pivotal study and the ESS305 PAS.

Pivotal study (STOP 2000)

A learning curve analysis based on procedure time and a second analysis based on placement rates were conducted as part of this study.

Procedure time decreased significantly after the first 5 cases, and slowly thereafter for both experienced and non-experienced healthcare providers. However, there was a smaller decrease in hysteroscopy times with increased experience.

Bilateral placement rates did not improve substantially with increased experience with the device (Table 7–4).

Table 7–4: Placement rate in first attempt by order of procedure

	All	Procedure number for center			
		1 to 5	6 to 10	11 to 20	More than 20
Placement after first procedure	N	N (%)	N (%)	N (%)	N (%)
Not bilateral	43	11 (12.8%)	5 (6.8%)	11 (10.0%)	16 (7.6%)
Bilateral	438	75 (87.2%)	69 (93.2%)	99 (90.0%)	195 (92.4%)
All	481	86 (100.0%)	74 (100.0%)	110 (100.0%)	211 (100.0%)

ESS305 Post approval study

The ESS305 post approval study was designed to compare successful bilateral placement rates during the first placement attempt of newly trained verses experienced physicians. The bilateral placement rate in the experienced physician group was 342/349 (98.0%) and the bilateral placement rate in the newly trained physician group was 223/232 (96.1%). The difference in placement rate (1.9%) was not statistically significant (Fisher's exact test p = 0.2009). A random effects model showed similar results (p = 0.1855). The conclusion of this study was that there was no significant difference in placement rates between newly trained and experienced physicians when using the ESS305 system.

Levie and Chudnoff published the results of this study in 2011.(50) They describe that, an average of 7.7 procedures (±3.3 SD) were performed per physician. Of the physicians, 39 were experienced Essure users and 37 were newly trained. As noted above, there was no statistically significant difference in placement rates when comparing novices and experienced physicians. Experienced physicians, however, were approximately 3 minutes faster in performing placement procedures. The authors concluded that this study confirmed that the learning curve for the Essure procedure is steep and that once a physician performs 3 to 5 proctored cases, they can be relatively reassured that they will have high placement rates.

7.4.2 Literature

Review of the literature has provided one additional external study that specifically looked at the learning curve for placement of Essure. Janse et al (29) examined learning curves for 15 gynecologists over the period of JAN 2005 to DEC 2009 in 10 different community and teaching hospitals in the Netherlands. A total of 631 women underwent Essure placement during this time; the median number of women per gynecologist was 29 (range: 9 to 116). All procedures were performed with oral diclofenac for analgesia. The study examined procedure time, pain score during the procedure, successful bilateral placement rate, and number of complications. Only procedure time showed a statistically significant difference with experience and thus a learning curve. The authors suggested that for the other parameters, "The Essure procedure is not difficult for a gynecologist experienced in performing hysteroscopies, so immediate high success percentages can be achieved."

7.4.3 Conclusion

Data from the clinical trials as well as external studies demonstrate that novice and experienced physicians achieve similar rates of successful placement when appropriately trained. The amount of time needed for placement does appear to decrease with experience using the product. Given this data, the training requirement for at least 5 proctored cases prior to sign off appears to be appropriate.

7.5 Contraceptive efficacy

While no method of contraception can offer 100% efficacy, Essure offers women a highly effective method of permanent birth control. Once a woman has Essure inserts successfully placed and her confirmation test confirms appropriate placement and tubal occlusion, data from both the clinical trials (see Table 7–5) and external published literature both show that Essure is highly effective.

7.5.1 Sponsor's clinical data

Table 7–5 displays pregnancy data (failure rates) in the phase II study, pivotal study, and the TVU study. One additional pregnancy was reported in the ESS305 TVU study during the second year of follow-up and no pregnancies were reported during the additional 5 years of follow up in the phase II and pivotal studies.

Table 7–5: One-year cumulative failure rates

	Phase II	Pivotal	Combined (original data)	ESS305 TVU
	N = 193	**N = 439**	**N = 632**	**N = 547**
1 year	0% (95% CI: 0-1.53%) [a]	0% (95% CI: 0-0.68%) [a]	0% (95% CI: 0-0.47%) [a]	0.67% (95% CI: 0.16-1.53%) [b]

[a] CI = Confidence interval; [b] CI = Credible interval
TVU = transvaginal ultrasound

7.5.2 Literature

Clinical trial conditions may not be reproducible in real world settings, so it is important to assess the efficacy in a variety of clinical situations. The largest US-based published study took place at Kaiser Permanente, Northern California.(41) This was a retrospective review of 884 women, 118 physicians at 30 different facilities, with placements from JAN 2004 to DEC 2006 and follow up through DEC 2008. Initial placement attempt was successful in 850 women (96.2%). The loss to follow up prior to HSG was 13% (115 women). Bilateral occlusion was found in 687/739 women who underwent HSG. Pregnancy was identified in 8 women: one never returned for HSG, four had an HSG showing at least one patent tube, and

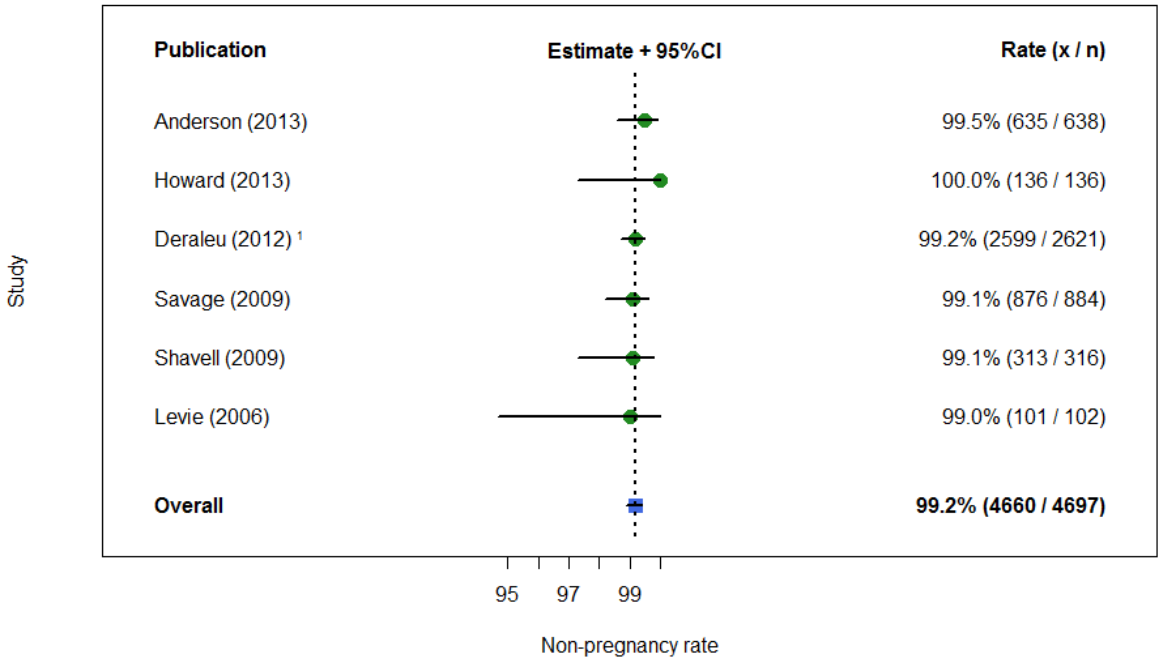
three had HSG interpreted as bilaterally occluded. Among the three women who conceived after the HSG was read as occluded, subsequent review suggested that none of the inserts were properly placed.

A more recent study by Anderson et al (34) was a retrospective cohort analysis of 638 women who underwent hysteroscopic sterilization between 01 JULY 2005 and 30 JUNE 2011. Approximately two-thirds of the procedures performed in the operating room and slightly less than half of the procedures performed in the office setting were performed by resident physicians in training. There was no statistical difference (p=.10) in the placement rate between experienced surgeons and resident physicians. In an analysis looking at all pregnancies, 3 pregnancies were reported prior to HSG confirmation, which were judged to be unrelated to the device effectiveness. There were no pregnancies reported in women after HSG confirmation of bilateral tubal occlusion, with follow-up of at least one year. In addition, there were no known pregnancies among women who did not complete the HSG.

The largest retrospective cohort study to date took place in France.(51) The purpose of this study was to compare the rates of pregnancy among women who underwent Essure hysteroscopic sterilization versus tubal ligation in France between 2006 and 2010. During the study period, French hospitals performed 109,277 tubal sterilization procedures: this included 39,169 Essure procedures and 70,108 laparoscopic tubal ligation procedures. A Cox model was performed and after adjusting for age, women with Essure became pregnant at a significantly lower rate than women with laparoscopic tubal ligation (0.36% versus 0.46%, respectively, hazard ration = 0.62 [0.40-0.96]).

Figure 7–2 summarizes five published papers and one published abstract in the US. Additional information on these studies as well as studies performed elsewhere in the world are available in Section 10.3, Appendix 3.

Figure 7–2: Efficacy rates in five studies based in the United States



CI = confidence interval
Anderson, 2013 (34); Howard, 2013 (42); Deraleu, 2012[1] (Published abstract) (52); Savage, 2009 (41); Shavell, 2009 (39); Levie, 2006 (33).

A single published paper (53) describes a potential efficacy rate of Essure of approximately 90%. Essure <90%. Rather than a prospective or retrospective study, this paper is a theoretical Markov model comparing the efficacy of Essure to tubal ligation. While the model is data based, it does not take into account all of the data supporting the efficacy of Essure, including the single largest study to date by Povedano et al (37) (N=4306) showing an efficacy of >99%. In addition, the model contains several assumptions (eg, women who receive Essure, who have an average age in their mid-thirties, are assumed to have an annual fecundity rate of 85% for 10 years if they are unable to rely on the device) that can be disputed.

7.5.3 Postmarketing monitoring

A search of the global safety database through 15 JUNE 2015 revealed 2207 reports describing pregnancy after Essure procedure. Assuming a cumulative total exposure of approximately one million devices sold, the reporting frequency of pregnancy overall is approximately 0.21%. Most reports were spontaneous reports, followed by literature as described above.

A small number of cases on intended pregnancy could be identified from the literature (n=57) describing off-label use of Essure as a treatment for hydrosalpinx prior to Assisted Reproductive Technology (ART) typically with intended fresh or frozen embryo transfers, resulting in a reporting rate of 0.006%. No increased risk for the developing fetus secondary to the presence of Essure is described for these intended pregnancies.

7.5.4 Conclusion

No method of contraception is 100% effective. Clinical trials, extensive published literature, and postmarketing monitoring of Essure all point to a product with very high efficacy. Essure is a multi-step procedure: not only must the device be placed, the woman must comply with a confirmation test 3 months later. Data from several external studies demonstrate that even when including pregnancies in women who were told not to rely on Essure for contraception and pregnancies occurring in the first 3 months, contraceptive efficacy is still high. The pregnancy rate with Essure continues to compare favorably with that of surgical sterilization and is lower than that seen with some forms of temporary contraception.

7.6 Pregnancy outcome

Pregnancy, whether planned or occurring as a consequence of contraceptive failure, may be accompanied by a number of adverse outcomes. Sporadic miscarriage is the most common complication of pregnancy, and approximately 25% of all women who become pregnant will experience a pregnancy loss.(54) The vast majority (approximately 80%) (55) are early, occurring well before 12 weeks of gestation. Sporadic miscarriage after this time complicates no more than 1 to 2% of pregnancies. Maconochie et al (56) found that the risk of miscarriage rises sharply after age 35, with a 75% increase for mothers aged 35 to 39 years and a 5-fold increase where the mother is aged 40 and above (relative to mothers aged 25 to 29 years).

Preterm labor, preterm premature rupture of membranes, and premature delivery are later complications of pregnancy. Preterm birth rates have been reported to range from 5% to 10% of live births in some developed countries and have shown a dramatic rise over the past 20 years. A Canadian study found a prevalence of preterm premature rupture of membranes in tertiary university healthcare centers of 2.3% and an incidence of 2.8% of all pregnancies.(57)

The background incidence of ectopic pregnancy in the US is estimated at 1.3 – 2.1%.(58, 59) Damage to the fallopian tubes, including prior tubal ligation, greatly increases the risk of ectopic pregnancy. The CREST study found that with some methods of tubal ligation (eg, bipolar cautery), ectopic pregnancy rates may be as high as 65% of all pregnancies that occur after these procedures.(60) Finally, in an overview of US background incidences (58) which used data from the CDC and Prevention looking at more than 67 million pregnancies, the overall rate of pregnancies resulting in fetal death was 0.5%. For pregnancies conceived with ART, the 2012 CDC national report found a stillbirth rate (death after 20 weeks gestation) of 0.6% (CDC 2012, http://www.cdc.gov/reproductivehealth/data_stats/).

When a pregnancy occurs with the Essure device in place, there are two ways to investigate the pregnancy outcome: first, by looking at unintended pregnancies in women who had Essure inserts placed for contraception, and second, by examining desired pregnancies conceived via in-vitro fertilization (IVF) or related ART procedures.

7.6.1 Sponsor's clinical data

Pivotal study (STOP 2000)

Outcome of luteal phase (pre-placement) pregnancies: Four women had insert placement in the second half of the menstrual cycle and despite negative urine pregnancy tests on the day of the procedure, these women conceived during this cycle. None continued the pregnancy: one aborted spontaneously, and the other three terminated the pregnancies (one medically and 2 surgically). All four of these women continued to use alternative contraception for the remaining 3-month time period, underwent the 3-month HSG, and were found to have bilateral occlusion and inserts in satisfactory location. All were ultimately able to rely on the Essure inserts for contraception, and are included in the "Reliant Population" for the STOP 2000 study. None conceived while relying on Essure.

One woman with successful bilateral placement underwent IVF with the inserts in situ, became pregnant and subsequently delivered a healthy baby. After her pregnancy, she continued to rely on her inserts for permanent birth control.

ESS305 TVU study (Study 16974)

Four pregnancies were reported in this study, 3 during the first year and 1 during the second year of wearing of Essure insert. Two were electively terminated and two ended in spontaneous first trimester abortions.

7.6.2 Literature

Veersema et al (61) performed a retrospective analysis of pregnancies reported with Essure in the Netherlands (2002-2010). They found 26 cases of unintended pregnancies. Of these, 17 women chose to terminate the pregnancy, 8 women had term, healthy deliveries, and the results for one are unknown.

Several additional case reports of unintended pregnancy with Essure exist. Ory et al (62) reported a conception 6 months post-HSG which resulted in a term delivery in a 30-year old. Moses et al (63) reported two cases. In the first, a 38 year old woman had 8 coils present on the right and 13 on the left. She conceived approximately 6 months after placement (she did not complete the Confirmation Test) and delivered a term pregnancy. In the second case, a 35 year old woman had documentation of devices extending from each tubal ostium into the uterine cavity on HSG. She became pregnant approximately one year later. She carried the pregnancy to 19 weeks, and chose to terminate. Hastings-Tolsma et al (64) reported a

placement with 9 coils on the right and 3 on the left. Her pregnancy occurred almost two years later and was carried to term. Finally, Arjona et al (65) reported a complicated placement which resulted in pregnancy over two years later. The pregnancy was uncomplicated.

A large proportion of pregnancies following a failed Essure procedure are terminated, making it difficult to assess pregnancy outcomes. For this reason, studies that followed pregnancies conceived with ART methods after Essure placement are useful in studying pregnancy outcomes. It must be kept in mind that women undergoing IVF may represent a very different population than women with unintended pregnancies. They may be of a different age, and they often have other concomitant issues that may adversely affect pregnancy. These are also clearly desired pregnancies. Overall, only a small fraction of pregnancy relate to intended pregnancies.

The publications describing off-label use of Essure for treatment of hydrosalpinx in the context of ART do not report an increased risk for the developing fetus secondary to the presence of Essure. No pregnancy reports from sources other than literature have been received in this context.

Pregnancy rates in a normal fertile population average approximately 20 to 25% per month and should be considered when interpreting pregnancy rates from ART. Rosenfield et al (66) published the first report of a successful IVF pregnancy and live birth in a morbidly obese woman with extensive pelvic adhesions following the placement of Essure for hydrosalpinx. Since that time, several additional studies have been published.

Arora et al (67) published a systematic review and pooled analysis on Essure for management of hydrosalpinx prior to in vitro fertilization. They included 11 studies for a total of 115 women, highlighting the fact that off-label use of Essure for the purpose of hydrosalpinx treatment is very rare. Overall, Essure was successfully placed in 96.5% of women and tubal occlusion was confirmed in 98.1% of cases. In vitro fertilization subsequent to Essure resulted in 54 pregnancies for a pregnancy rate of 39% per embryo transfer. Of the 54 pregnancies, 14 resulted in miscarriages and the remainder resulted in live births (25.9%) giving a live birth rate per embryo transfer of 29%. Legendre et al (68) conducted a national survey of 45 French hospitals and performed a retrospective analysis of 41 women with unilateral or bilateral hydrosalpinges and successful Essure placement. Mean number of visible coils at the end of the procedure was 1.61 (±1.6); 27 women (65.9%) had fewer than 3 coils. Overall, the clinical pregnancy rate was 40.7% (22/54). Among clinical pregnancies, there were 7 early spontaneous miscarriages (31.8%) and one intrauterine death due to fetomaternal platelet alloimmunization. There were 14 live births (including 4 sets of twins) for a live birth rate per transfer of 25.9% (14/54).

Mijatovic et al (2009) reported on a case of IVF pregnancy that resulted in pre-term premature rupture of membranes, chorioamnionitis, pre-term delivery at 24 weeks, and subsequent death of the child. Hysteroscopic evaluation of the uterus post-delivery showed total tissue

encapsulation of the left device and only the tip of the right device was visible. Her delivery was attributed to an incompetent cervix and in their follow-up report, Mijatovic et al (2012) reported a subsequent near-term delivery after placement of a primary cervical cerclage.

Most recently, Ozgur et al (71) performed a retrospective study of 26 women who had Essure placed due to laparoscopic contraindications verses 76 women who had laparoscopic tubal ligation. In the Essure group, no more than 4 coils were left protruding into the uterus. Live birth rate per assisted reproductive procedure was 23.8% in the hysteroscopy group and 32.1% for the laparoscopy group. These results were deemed to be "highly comparable." The results of the currently ongoing Dutch Essure® versus Salpingectomy for Hydrosalpinx (DESH) Trial will add to the ongoing body of literature.

7.6.3 Postmarketing monitoring

In order to address what impact Essure may have on pregnancy outcomes in individuals who decide to continue their pregnancy, all reported pregnancies and outcomes were reviewed for any pattern or type of abnormality which could indicate any influence of Essure on the developing pregnancy. This evaluation includes 57 intended pregnancies reported with ART and 2150 pregnancies not associated with ART. Information regarding pregnancy outcome is available for 671 of these cases while 422 cases are reported as ongoing pregnancies. Since some cases can have more than one outcome such as preterm labor and live birth, the total number of individual events will be greater than the number of cases with a pregnancy outcome. Elective termination of pregnancy was reported in 175 cases. Spontaneous miscarriage was reported in 198 cases and ectopic pregnancy in 75 cases. Considering that the average age of Essure users is towards the higher end of reproductive age at which the incidence of these events increase significantly and that the more serious adverse outcomes tend to be preferentially reported, the rates are within the expected range.

Preterm events: There were a total of 31 preterm events reported, including premature rupture of membranes, preterm labor and preterm delivery. Twelve of these are from ART procedures and 19 from unintended pregnancies.

Premature rupture of membranes: Three cases of premature rupture of membranes were reported in the medical literature from ART. In all cases the authors stated that they did not see the premature rupture of membranes as related to Essure. One case reports a healthy term delivery while no outcomes are reported for the other two.

Preterm labor: Seven cases of preterm labor were reported of which 5 reported term deliveries of healthy infants. The two other cases were due to polyhydramnios and cervical insufficiency which are well established causes of preterm labor. The outcome was not reported. Six cases are from unintended pregnancies and one is from ART.

Preterm delivery: Of the eight cases associated with ART there were 5 healthy infants, 2 neonatal deaths (at 19 and 24 weeks of gestation), and one without outcome information.

Thirteen non-ART cases included 4 births with healthy infants some of whom required transient respiratory support, 2 neonatal deaths (at 25 and 26 weeks gestation) and no outcome information for the remaining 7 cases.

*Fetal demise and stillbirth***:** Five of the seven reported cases are derived from ART related publications. One case which was also reported as premature delivery at 19 weeks, had Essure removed and suffered another stillbirth leading to the author's conclusion that these events were independent of Essure. Two of the cases of fetal demise were reported as secondary to alloimmunization. Two additional ART cases report delivery at 21 and 27 weeks without further information. The 2 non-ART cases include delivery at 22 weeks gestation and at an undetermined gestational age respectively.

*Live births***:** There were 217 reports of live births of which 107 were reported without further information; 82 were reported as healthy. There were 16 cases reporting transient neonatal abnormalities. Most of these were related to respiratory assistance and one fractured clavicle during delivery. Congenital anomalies were reported in 4 cases. Two cases reported genetic deletion without further specification and one case reported developmental delay. In addition to the fatalities discussed above associated with prematurity, there was one case of anencephaly.

There are very limited data on pregnancy outcomes with Essure as would be expected with a highly effective contraceptive. The ART pregnancies are very closely monitored. Published reports show the outcomes of these pregnancies to be consistent with that of the overall ART population. In summary, the reported data regarding pregnancy outcomes with Essure does not demonstrate any increase in the rate of adverse pregnancy outcomes.

7.6.4 Conclusion

The body of evidence from the literature, which is primarily reporting on closely monitored ART pregnancies, is reassuring due to the lack of reports of premature rupture of membranes and preterm labor and delivery. Similarly, all of the Essure data from postmarketing monitoring show AEs (eg, miscarriage, stillbirth, preterm delivery, fetal anomalies) to be well within the background rate for a similarly aged population.

7.7 Unsatisfactory device location (perforation, migration or expulsion)

The ideal location of the Essure insert is symmetrically spanning the interstitial segment of the fallopian tube. The location is primarily determined by the position of the Essure device at the time of deployment during the placement procedure. Unsatisfactory locations can be divided into two groups.

- Locations where the insert is not sufficiently far into the fallopian tube to cause occlusion, but rather too much of the insert is within the uterine cavity.

- Locations where the insert has advanced too far and is distal to the desired location.

The first group is detected by the presence of too many coils of the insert in the uterine cavity by either HSG or an ultrasound. Some of these inserts will spontaneously be expelled into the vagina. Those requiring intervention may be removed hysteroscopically. When women do present with symptoms they usually involve bleeding and/or dysmenorrhea which is characteristic of the uterus expelling a foreign body.

The second group represents inserts that are in the distal fallopian tube, or are perforating the fallopian tube or uterus. These cases may require a laparoscopic or laparotomy approach when insert removal is required. Embedment represents an insert that is fixed in location. This most commonly describes a device that has been deployed into the myometrium and may be extending either into the uterine cavity or into the peritoneal cavity.

7.7.1 Sponsor's clinical data

Data from the pre and peri-hysterectomy studies are presented separately as these studies were with individuals requiring hysterectomy for gynecological abnormalities rather than individuals meeting the criteria for use of Essure for permanent birth control.

STOP 01: Three subjects experienced a perforation during the procedure. One of the perforations occurred with the use of the support catheter that was associated with high number of perforations in other studies and was discontinued in 1999. Another occurred in a woman who had a prior tubal ligation (an exclusion criterion for the study). No etiology was identified for the third.

STOP 06: Three perforations were noted at the time of hysterectomy, 2 occurred in women in whom the since discontinued support catheter was used. Women who experienced the perforations reported no discomfort or difference in tolerance to the inserts than women without perforation.

Table 7–6 presents the number of subjects with unsatisfactory device location in clinical trials for contraception.

Table 7–6: Women with unsatisfactory device location with at least one insert placed (perforation, migration or expulsion)

Study	Women with placement attempt, (n)	Women with perforation, n (%)	Women with expulsion, n (%)	Unsatisfactory device location, other [c], n (%)	Total unsatis-factory location, n
Phase II (STOP 10)	227	7 [a]	1/206 (0.5%)	1/206 (0.5%)	9
Pivotal (STOP 2000)	507	5/476 (1.1%)	14/476 (2.9%)	12/476 (2.5%)	31
ESS305 TVU (Study 16974)	597	2/587 (0.3%)	3/587 (0.5%)	7/587 (1.2%)	12 [b]

TVU = transvaginal ultrasound; n = number of women
[a] support catheter that has since been discontinued was used in 5 of 7 cases
[b] does not include 23 subjects lost to follow up and did not undergo confirmation testing. May include patency seen on HSG.
[c] includes proximal placement, distal placement and not classified.

Phase II study (STOP 10)

Expulsion: The 3-month HSG indicated a unilateral insert expulsion in one woman. In this case, at the time of placement, the Investigator suspected the insert was not placed far enough into the tube and had anticipated that the insert would be expelled.

Perforations: There were 7 women who were diagnosed with a perforation. The 3-month HSG indicated perforation in 4 women and a repeat HSG at 18 months diagnosed a perforation in a fifth woman. A sixth woman was found to have a peritubal perforation noted on gross examination following device removal for pain. During laparoscopy on a seventh woman, it was discovered that the right device had perforated the tube, although HSG demonstrated tubal occlusion.

Five of these women went on to laparoscopic sterilization and the sixth woman had a cornual resection for persistent pain. Histological evaluation in the sixth woman confirmed the device had perforated the tube just past the uterotubal junction. The seventh received a Filshie clip sterilization of the left tube after failure to place the Essure insert and began to rely on the clip and the insert in the occluded, perforated right tube for contraception.

Intraperitoneal devices: Intraperitoneal devices were successfully retrieved in 4/6 women. There were no adverse tissue reactions noted at the insert retrieval site in the peritoneal cavity in any of these women. One woman had a device left in the peritoneal cavity. She reported some pain on follow-up visits that did not seem related to the perforated device, as the reports were of rare twinges on the side with both a well-placed Essure insert and a Filshie clip. The other woman whose perforated device was not retrieved had an insert placed into the

myometrium (embedment/partial perforation). The device has remained in place with no sequelae.

Of these 7 perforations, 5 occurred with the support catheter that was discontinued due to its high rate of perforations.

Pivotal study (STOP 2000)

In the pivotal study, x-ray noted a perforation in one woman that was diagnosed on the day of the placement. Therefore this subject was followed for safety only. This woman did not undergo HSG and had a tubal ligation after Day 0. Another woman found an expelled insert ex-vivo prior to the 3-month visit.

Table 7–7 summaries AEs that initially impacted the woman's ability to rely on the Essure insert for contraception.

Table 7–7: Adverse events preventing reliance in women with bilateral placement

Event	Number initially diagnosed	Suspected cause	Management	Ultimately affected reliance
Total	**21 (4.5%)**			**12 (2.6%)**
Expulsion	14 (3.0%)	Proximal placement (13); placement into endometrial tissue (1).	9 successfully underwent second insert placement procedure; 4 underwent laparoscopic sterilization; One woman with Crohns disease required laparotomy for management	5 (1.1%)
Perforation	4 (0.9%)	Pre-existing tubal occlusion (2); poorly identified ostium (2);	3 underwent laparoscopic sterilization; one requesting repeat insert placement procedure	4 (0.9%)
Unsatisfactory device location and perforation	1 (0.2%)	Unsatisfactory placement on one side (0 mm trailing) and difficulty placing on the perforated side.	Proximal insert removed hysteroscopically during lap sterilization, perforated side was suspicious on x-ray and confirmed during lap sterilization	1 (0.2%)
Unsatisfactory placement	2 (0.4%)	Unsatisfactory placement (1); hydro-salpinx (1)	Awaiting women's decision to undergo lap sterilization (2)	2 (0.4%)

ESS305 TVU study (Study 16974)

Unsatisfactory device location was reported in 45/519 (8.67%) women's TVU examination. Forty of these women underwent HSG of which 36 were told to rely (Table 7–8).

Table 7–8: Transvaginal ultrasound findings

Insert location	N	Location (if not optimal)	Right (N)	Left (N)	Both (N)
Transvaginal ultrasound was performed on Total = 528 subjects [a]					
Inserts were identified on both sides with Transvaginal ultrasound = 519 subjects					
Optimal or satisfactory	474				
Unsatisfactory	45	Distal placement	12	12	2
		Proximal placement	0	2	0
		Perforation	2	1	0
		Expulsion	0	1	0
		Unclassified	4	4	2
		Other	6	7	0

[a] 527 subjects with bilateral placement and 1 subject with unilateral placement

7.7.2 Literature

In cases reporting perforation, some women were asymptomatic. When symptoms were reported (most commonly abdominal pain), the onset ranged from days to months following the placement procedure.(72, 73, 74, 75, 76, 77, 78, 79, 80, 81) A 7-year retrospective study evaluated complications of tubal sterilization with Essure in 4,306 women.(37) Within this study, one woman (0.02%) had a tubal perforation discovered after pregnancy. Three women (0.06%) had the device inadvertently placed in the myometrium, and 2 women (0.04%) had asymptomatic migration of the device into the abdominal cavity. In both of these cases, a second device was placed and the migrated device left in situ. The women remained asymptomatic. A small number of case reports discuss small bowel obstruction and perforation with Essure. (82, 83, 84, 85, 86)

7.7.3 Postmarketing monitoring

A query of the global safety database on Essure through 15 JUNE 2015 revealed 4,308 reports of unsatisfactory device location. The majority of these cases (83.9%) were medically confirmed. It is acknowledged that some Essure devices when placed under hysteroscopic visualization will not be appropriately located to achieve tubal occlusion. This is the basis for conducting the Essure Confirmation Test. The reporting frequency for all unsatisfactory device locations is 0.4%.

Of the 4,308 reports, 777 were expulsions, 346 reported a missing insert during imaging or surgery and 3237 reported either a perforation/migration/embedment/dislocation or more than 1 event. The majority of events (95.6%) were from the US where the highest number of placements have occurred. Among the medically confirmed cases, most unsatisfactory device locations were diagnosed at the confirmation test (48.3%) with 17.2% detected at the placement procedure, 4.8% prior to the scheduled confirmation test, 8.2% beyond the

scheduled confirmation test at 3 months and 21.6% in which the time of diagnosis was not provided.

Devices primarily located in the uterus were removed hysteroscopically when indicated, while those located distal to the optimal location were most commonly managed with laparoscopy alone or laparoscopy in combination with additional procedures.

7.7.4 Conclusion

Unsatisfactory device placement, including perforations, are known complications of Essure and their recognition during the confirmation test with appropriate management continues to be a focus of the ongoing training and patient management programs for Essure. In the clinical trials, the incidence of all unsatisfactory device locations ranged from approximately 3.5% to 4.5%. The postmarketing data is consistent with that in the clinical trials, all of which is reflected in Sections IX, X, and XVII of the IFU (Section 10.6, Appendix 6).

7.8 Pain (persistent/chronic)

Chronic pelvic pain is a common gynecological problem with an estimated prevalence of 38 per 1000 in women aged 15 to 73 years, a rate comparable with that of asthma (37/1000) and chronic back pain (41/1000).(87) There is wide variation in clinical evaluation of women with chronic pelvic pain. Diagnostic laparoscopy is often carried out after referral to a gynecologist as an initial investigation to uncover pathological causes, for example, endometriosis or adhesions, but has negative results in over half the cases.

Chronic pelvic pain in association with sterilization has been described in the literature.(88, 89) Hiemstra et al (89) recommend a bio-psychosocial approach to the issue of post-sterilization pain, though this is not always possible.

7.8.1 Sponsor's clinical data

Phase II study (STOP 10)

In the phase II study, 205 women completed patient questionnaires about their procedure. The remaining 22 women who underwent procedues did not complete the questionnaire because they were bilateral failures (20 women) or had unilateral placement only (2 women). Post-procedure pain was reported in 156/205 (76%) women. The pain resolved within one day in 58% women, within 3 days in 87% and within one week in 99% of these women. Pain was resolved within 2 weeks of the procedure for the remaining 2 women (information from the 3-month follow-up visit). Thirteen of 199 (6.5%) women who completed the 6-month follow-up visit reported recurrent pain (reported on two or more visits that may or may not be consecutive) while persistent pain (reported at every visit) was not reported by any woman.

Table 7–9 summarizes the pain noted at each of the follow-up visits. Types of pelvic pain reported most commonly included dysmenorrhea, dyspareunia, and other pelvic pain (mostly ovulation pain). Of the women reporting dysmenorrhea in the first 3 months following the procedure, 11/29 (38%) reported pain in the first week following the procedure and 23/29 (79%) reported pain in the first month following the procedure. Women also reported symptoms of pain that were not related to the insert.

Table 7–9: Pain reported at follow-up visits in phase II study

Follow-up visit	Dysmenorrhea	Pelvic pain, Dyspareunia	Other pelvic pain	Other pain
3-month	29/203 (14%)	17/203 (8%)	5/203 (2%)	2/203 (<1%)
6-month	11/199 (6%)	3/199 (2%)	3/199 (2%)	1/199 (<1%)
12-month	5/196 (3%)	0	5/196 (3%)	0
18-month	2/193 (1%)	0	10/193 (5%)	2/193 (1%)
24-month [a]	8/194 (1%)	0	6/194 (3%)	6/194 (3%)
36-month [a]	7/182 (4%)	1/182 (<1%)	2/182 (1%)	1/182 (<1%)
48-month [a]	9/176 (5%)	2/176 (1%)	2/176 (1%)	2/176 (1%)
60-month [a]	4/171 (2%)	1/171 (<1%)	3/171 (2%)	2/171 (1%)

[a] No data reported for some women that indicated other types of pain (N = 2 at 24 months; N = 1 at 36, 48 and 60 months).

Pivotal study (STOP 2000)

Table 7–10 summarizes various types of pelvic pain reported by women during follow-up visits.

Of the women who reported pain, one woman reported “persistent” pelvic pain at two years of follow-up. None of the women reporting at 3, 4 and 5 year follow-up indicated persistent pelvic pain of any kind. Twenty-nine women (6.1%) had at least two (recurrent) episodes of dysmenorrhea, 18 women (3.8%) reported “recurrent” dyspareunia, 14 women (3.0%) reported “recurrent” ovulatory pain, and 25 (5.3%) reported “recurrent” other pelvic pain that could not clearly be classified into a different category.

Table 7–10: Pelvic pain reported at follow-up visits (pivotal study)

Follow-up visit	Pelvic pain			
	Dysmenorrhea	**Dyspareunia**	**Ovulatory**	**Other [c]**
Baseline (N=518)	183 (35%)	22 (4.2%)	N/a	N/a
3-month post-device placement (N=467)	29 (6.2%)	29 (6.2%)	5 (1.1%)	32 (6.9%)
Post-alternative contraception				
3-month (N=440)	20 (4.5%)	10 (2.3%)	6 (1.4%)	26 (5.9%)
6-month (N=436)	15 (3.4%)	8 (1.8%)	3 (0.7%)	16 (3.7%)
12-month (N=460)	17 (3.7%)	15 (3.3%)	5 (1.1%)	27 (5.9%)
18-month (N=410)	14 (3.4%)	9 (2.2%)	10 (2.4%)	11 (2.7%)
24-month (N=435)	22 (5.1%)	9 (2.1%)	22 (5.1%)	13 (3.0%)
36-month (N=422) (data missing on 1 patient)	14 (3.3%)	7 (1.7%)	12 (2.8%)	6 (1.4%)
48-month (N=402)	3 (0.7%)	5 (1.2%)	6 (1.5%)	11 (2.7%)
60-month (N=386)	14 (3.6%)	8 (2.1%)	10 (2.6%)	9 (2.3%)
Recurrent (N=473) [a]	29 (6.1%)	18 (3.8%)	14 (3.0%)	25 (5.3%)
Persistent (year 1), (N=460) [b]	0	0	0	1 (0.2%)
Persistent (year 2), (N=435) [b]	0	0	0	1 (0.2%)
Persistent (year 3), (N=422) [b]	0	0	0	0
Persistent (year 4), (N=402) [b]	0	0	0	0
Persistent (year 5), (N=386) [b]	0	0	0	0

[a] *Recurrent:* symptom reported at more than one visit.
[b] *Persistent:* symptom reported at all prior visits.
[c] *Other:* defined as pelvic pain that was not reported to be dysmenorrhea, dyspareunia or ovulatory pain.

ESS305 TVU study (Study 16974)

Table 7–11 presents AEs with abdominal, back or pelvic pain.

Table 7–11: Adverse events of abdominal or pelvic pain and related terms

MedDRA System Organ Class	**MedDRA Preferred Term**	**Total = 597 (100%) N (%) events**
Gastrointestinal disorders	Abdominal pain	16 (2.7)
	Abdominal pain, lower	1 (0.2)
Musculoskeletal and connective tissue disorders	Back pain	3 (0.5)
Reproductive system and breast disorders	Adnexa uteri pain	2 (0.3)
	Dysmenorrhea	15 (2.5)
	Dyspareunia	4 (0.7)
	Metrorrhagia	5 (0.8)
	Ovulation pain	4 (0.7)
	Pelvic pain	28 (4.7)

MedDRA = Medical Dictionary for Regulatory Activities; N = number

7.8.2 Literature

Pain associated with the Essure procedure may occur at three general time points: pain during the actual placement and immediately post-procedure, pain that occurs acutely following the procedure and pain that is persistent or "chronic pain." Exact definitions for these time periods vary by study, however, literature exists for each of these broad categories.

Studies examining pain at time of the procedure (90, 45, 48) show that while the majority of women rate pain associated with the procedure as tolerable, a small number of women (3.1 to 17%, depending on study) rated the procedure as painful.

There are two studies comparing hysteroscopic versus laparoscopic sterilization with regard to post-procedural pain. Duffy et al (49) performed a cohort controlled comparative study in the UK. Self-assessment diaries were completed on days 7 and 90 post-procedure. Post procedure, 31% of the Essure group reported moderate or severe pain compared with 63% of the laparoscopic group (P=0.08). Syed et al (91) examined 20 cases each of laparoscopic and hysteroscopic sterilization (Staten Island, NY). Women were asked about pain one week and four weeks post-procedure on a scale of 0 ("no pain") to 10 ("worst pain ever experienced"). Immediately post-procedure, mean pain score in the hysteroscopic group was 0.6 (median=0) and in the laparoscopic group it was 5.05 (median=6) ($t = -8.17$, $p<.0001$). One week post-procedure, none of the women with Essure reported pain, while the mean score in the laparoscopic group was 2.65 (median=3). Four weeks post procedure, 35% of the laparoscopic group continued to experience pain (mean=0.60, median=0).

With regard to acute pain, in Sinha et al,(45) women were surveyed three months post-Essure placement. At this time, 5/76 (6%) women reported new pain or discomfort since the procedure and 2/76 (3%) described new pain or discomfort with sexual intercourse. No further information is available on these women. Yunker et al (92) performed a retrospective cohort, single center study (Vanderbilt University, TN) of 458 women who underwent Essure placement between JAN 2005 and JUNE 2012. A pre-procedural diagnosis of chronic pain (chronic pelvic pain, chronic low back pain, chronic headache, fibromyalgia) was noted in 8.7% of women. They found the incidence of acute post-Essure pelvic pain (within 3 months) was 8.1%. Women with previous diagnoses of any chronic pain were significantly more likely to complain of acute pelvic pain (odds ratio 6.81; 95% confidential interval, 2.98 to 15.73) following the placement of Essure.

A similar study found that pre-existing pain may also affect laparoscopic procedures. Rudin et al (93) assessed potential predictive factors of post-operative pain in 59 women undergoing BTL with bipolar cautery. They found that in their multiple regression model, report of preoperative pain (eg, back, neck, shoulder, hip, leg, arm, hand, abdomen, headache) and preoperative heat perception were predictive variables for post-operative pain.

A recent analysis of the MarketScan commercial claims database revealed that women undergoing both hysteroscopic and laparoscopic sterilization frequently reported pain in the 6 months prior to their procedure (interim data on file). Claims data from JAN 2010 through DEC 2012 were analyzed. Six months of pre-index data were required for inclusion. Claims for post-partum tubal ligation or claims associated with a pregnancy in the preceding 6 weeks were excluded. Women undergoing any additional surgical procedure on the day of the sterilization procedure were also excluded. This resulted in 12,031 cases of hysteroscopic sterilization (which included both Essure and Adiana, a hysteroscopic device now off the market) and 7,286 cases of laparoscopic sterilization. Pre-procedure diagnoses are summarized in Table 7–12.

Table 7–12: Women with diagnoses of pain, 6 months preceding sterilization procedure

	Hysteroscopic procedure (N = 12,031)	Laparoscopic procedure (N = 7,286)
Mean age	37 years	35.8 years
Any pain	2827 (23.5%)	1971 (27.1%)
Pelvic pain/lower abdominal pain	1515 (12.6%)	1129 (15.5%)
Low back pain	1097 (9.1%)	3724 (9.9%)
Chronic headache	529 (4.4%)	397 (5.4%)
Fibromyalgia	248 (2.1%)	150 (2.1%)

Chronic Pain: Yunker et al (92) continued to follow women in their study beyond the 3 month time period and found that at 6 months, the incidence of pain decreased from 8.1% (at 3 months) to 4.2%. As with acute pain at 3 months, women with a previous diagnosis of any chronic pain (pelvic, low back, headache, and fibromyalgia) were significantly more likely to report chronic pelvic pain at 6 months, odds ratio, 6.15 (Confidence Interval: 2.09-18.05).

Reports of pain post-procedure appear to be lower in studies outside of the US. In a large case series of 4,274 women who underwent Essure at a Spanish teaching hospital,(94) a total of seven women (0.16%) presented with chronic pain requiring insert removal. Mean time between placement and removal was 29.4 months. In all cases, the symptoms disappeared after Essure removal.

Comparative studies help place rates of pain in context. Conover et al (95) performed a retrospective review of the MarketScan claims database and compared incidence of opioid-managed pelvic pain within 12 months after hysteroscopic versus laparoscopic sterilization. They found the rates of opioid-managed pelvic pain were low overall (0.88% in the hysteroscopic group and 0.93% in the laparoscopic group) and that there was no statistical difference between the two groups.

Several studies have attempted to identify factors related to the development of pain following placement of Essure. Case reports show that perforation of the tube or uterus may

cause pain in some women (96) and removal may provide relief. In a systematic review of PubMed, Scopus, Embase, and the Cochrane library, Adelman et al (97) identified seven cases of persistent pain without evidence of perforation. All women underwent bilateral insert removal via hysteroscopy or laparoscopy. Four of the 7 women experienced complete resolution of pain, one noted some improvement in daily pain but still experienced intermittent abdominal pain, and outcome on one was unknown. In the seventh woman, chronic pelvic pain continued despite laparoscopic salpingectomy and appendectomy.

7.8.3 Postmarketing monitoring

A search of the global safety database revealed 3,539 cases containing at least one event of abdominal, pelvic and back pain (data lock point: 08 JULY 2015). Based on the total estimated exposure of 1 million devices sold, the reporting rate for abdominal, pelvic and back pain was 0.3%. A search for cases specifically reporting “chronic”, “persistent”, “consistent”, “constant” or “continuous” pain indicated that these encompassed about 10% of all cases (0.03%).

All reports were considered regardless of causality, severity, duration, temporal relationship to the insert placement process and any co-reported conditions. Each case may contain more than one reported term. Of all events, 58 were reported from interventional studies with the different models of Essure, 2,804 were spontaneous reports, 637 were from observational studies, 40 from literature and 58 from interventional studies.

About half of all cases of abdominal, pelvic and back pain were medically confirmed reports, and half were from consumers. Pain was often reported in the context of other AEs. Heavy menstrual bleeding was a common complaint in addition to pain. Medically confirmed cases more frequently reported additional events of unsatisfactory device location, including perforation, expulsion, improper placement or device malfunction. Consumer reports at times included up to 20 or 30 events describing changes ranging from menstrual cycle disturbances, to cognition, skin appearance, sexuality, mood and general well being.

Onset latency information indicated that the onset of pain may range from as early as immediately after placement to several years after placement. Most reports, report an onset within the first year after insert placement. The onset of events five years or later is very rare.

7.8.4 Conclusion

Abdominal and pelvic pain are common in women of reproductive age. Pain after Essure sterilization is an anticipated event reflected in the IFU (Section 10.6, Appendix 6) and PIB (Section 10.7, Appendix 7). Clinical trial data indicate that the highest frequency of abdominal, genital and back pain can be expected at the time of the insert placement and shortly thereafter, but women may also experience pain immediately after the insert placement period. Chronic pelvic pain in association with female sterilization has been described in the literature. The etiology often remains unclear, although improper placement

of involved devices and a history of a previous pain diagnosis have been identified as potential contributory factors.

7.9 Menstrual changes

Abnormal uterine bleeding is a broad spectrum term that includes irregular, heavy or prolonged menstrual bleeding or an altered bleeding pattern. The condition has a high prevalence in all countries; it is estimated that the worldwide prevalence of abnormal uterine bleeding is between 4% and 52% depending on the study techniques used.(98, 99)

In 1951, Williams et al (100) first hypothesized that sterilization may affect a woman's risk of abnormal bleeding (defined as increased intermenstrual bleeding and increased flow). The phrase "post tubal sterilization syndrome" was coined to describe a variety of symptoms occurring after female sterilization.(101) This may include: abnormal bleeding and/or pain, changes in sexual behavior and emotional health, exacerbation of premenstrual symptoms, significant menstrual disturbances leading to further surgery (eg, hysterectomy, tubal reanastomosis). The existence and potential mechanism of a post-tubal ligation syndrome has been debated.(101, 102) According to the ACOG Practice Bulletin (2) on the Benefits and Risks of Sterilization: "prospective studies that account for confounding factors, such as presterilization use of hormonal contraception, have found that tubal occlusion has little or no effect on menstrual patterns". The studies cited by ACOG regarding menstrual patterns/changes during various procedures of sterilization are provided in Section 10.5 (Appendix 5).

7.9.1 Sponsor's clinical data

Phase II study (STOP 10)

Post-procedure bleeding of any kind was reported in 83% of respondents. Bleeding resolved within 3 days for most women and within one week for 96% of women. When asked to compare this bleeding with bleeding during normal menses, 71% women reported it was less than their previous period, 17% reported it was the same, 8% a little more and 4% as a lot more than their previous period.

Table 7–13 provides a summary of bleeding reports at the follow-up visits.

Persistent bleeding was not reported in this study. Fifteen women (15/199 [7.5%]) reported recurrent menstrual changes, one woman (1/199 [0.5%]) reported recurrent post-coital bleeding and no women reported persistent menstrual changes.

Table 7–13: Bleeding reported at follow-up visits in phase II study

Follow-up visit	Irregular menses	Spotting	Changes in flow	Other and unspecified
3-months	not asked	not asked	not asked	not asked
6-months	3/199 (2%)	6/199 (3%)	3/199 (2%)	0
12-months	6/196 (3%)	5/196 (3%)	4/196 (2%)	0
18-months	9/193 (5%)	4/193 (2%)	5/193 (3%)	0
24-months [a]	4/194 (2%)	4/194 (2%)	10/194 (5%)	3/194 (1.5%)
36-months [a]	4/182 (2%)	3/182 (2%)	4 (182 (2%)	3/182 (1.6%)
48-months [a]	4/176 (2%)	3/176 (2%)	9/176 (5%)	3/176 (1.7%)
60-months [a]	16/171 (9%)	3/171 (2%)	11/171 (6%)	3/171 (1.8%)

[a]No data reported for some women that indicated other/unspecified bleeding (N=2 at 24 months; N=1 at 36, 48 and 60 months)

Pivotal study (STOP 2000)

Table 7–14 presents changes in menstrual function reported at follow-up visits.

Table 7–14: Changes in menstrual function reported at follow-up visits (pivotal study)

Follow-up visit	Irregular menses	Bleeding between menses	Heavier than usual menstrual flow	Less than usual menstrual flow
Baseline, N=518	**9 (1.7%)**	**12 (2.3%)**	**N/A**	**N/A**
3-months post-device placement	48 (10.3%) N=467	110 (23.6%) N=466	89 (19.2%) N=463	56 (12.1%) N=463
Post-alternative contraception				
3-months	36 (8.2%) N=440	40 (9.1%) N=440	96 (21.9%) N=439	55 (12.5%) N=439
6-months	36 (8.2%) N=437	29 (6.6%) N=437	94 (21.6%) N=435	57 (13.1%) N=435
12-months	35 (7.7%) N=455	31 (6.7%) N=460	77 (16.8%) N=458	67 (14.6%) N=458
18-months	19 (4.6%) N=410	42 (10.2%) N=411	70 (17.0%) N=411	63 (15.3%) N=411
24-months	20 (4.6%) N=435	32 (7.4%) N=435	89 (20.6%) N=432	53 (12.3%) N=432
36-months	31 (7.4%) N=420	25 (6.0%) N=420	83 (20.2%) N=411	47 (11.4%) N=411
48-months	33 (8.4%) N=393	33 (8.3%) N=396	69 (17.9%) N=386	52 (13.5%) N=386
60-months	45 (11.7%) N=386	29 (7.5%) N=386	74 (19.6%) N=377	40 (10.6%) N=377
Recurrent[a]	70 (14.8%) N=473	89 (18.8%) N=473	177 (37.5%) N=472	110 (23.3%) N=472
Persistent (year 1)[b]	3 (0.7%) N=455	2 (0.4%) N=460	7 (1.5%) N=458	12 (2.6%) N=458
Persistent (year 2)[b]	0 (0.0%) N=435	1 (0.2%) N=435	4 (0.9%) N=432	3 (0.7%) N=432
Persistent (year 3)[b]	0 (0.0%) N=420	1 (0.2%) N=420	4 (1.0%) N=411	2 (0.5%) N=411
Persistent (year 4)[b]	0 (0.0%) N=393	0 (0.0%) N=396	3 (0.8%) N=386	1 (0.3%) N=386
Persistent (year 5)[b]	0 (0.0%) N=380	0 (0.0%) N=386	2 (0.5%) N=377	0 (0.0%) N=377

[a] *Recurrent*: symptom reported at more than one visit during the follow-up period (ie, symptoms do not have to be reported on consecutive visits). The denominator ("N") is the sum of all unique women who responded over the course of their follow-up period. Not all women responded at all follow-up visits.
[b] *Persistent*: symptom reported at all visits during the follow-up period. The denominator ("N") is the total number of unique women responding at the latest follow-up visit.

ESS305 TVU study (Study 16974)

In this ongoing study, no data is collected asking women to compare the bleeding that they experienced during the study to their typical menstrual periods and no specific data is collected on the recurrence or persistence of such events.

A listing of all events related to uterine or vaginal bleeding is in Table 7–15. Please note: women may have reported more than one such event.

Table 7–15: Adverse events related to uterine or vaginal bleeding

Adverse events	n (%)
Amenorrhea	3 (0.5%)
Dysfunctional uterine bleeding	2 (0.3%)
Hypomenorrhea	1 (0.2%)
Menorrhagia	23 (3.9%)
Menstruation delayed	1 (0.2%)
Menstruation irregular	3 (0.5%)
Polymenorrhea	1 (0.2%)
Uterine hemorrhage	9 (1.5%)
Vaginal hemorrhage	14 (2.3%)

7.9.2 Literature

Menstrual changes post-Essure have been reported in several small studies. A summary of these studies is shown in Section 10.5 (Appendix 5). The only study to compare bleeding patterns between Essure and laparoscopic sterilization looked only at short-term bleeding.(91) The study group was a convenience sample of 40 women: 20 underwent Essure placement and 20 underwent laparoscopic tubal ligation. Bleeding was assessed during the week following the procedure. In the Essure group, 40% reported minimal spotting and 60% reported no bleeding. In the laparoscopic tubal ligation group, 25% reported minimal spotting and 75% reported light bleeding. There are no long term comparisons between the two procedures in the literature.

7.9.3 Postmarketing monitoring

A search of the global safety database through 15 JUNE 2015 revealed 2,232 cases containing at least one event of menstrual bleeding disturbances resulting in a reporting rate of 0.22%, with 0.12% from consumers/women and 0.10% were classified confirmed by Health Care Provider (HCP).

Clustering into subtypes of menstrual bleeding disturbances showed that increased or irregular menstrual bleeding (or unspecific changes in bleeding pattern) was reported at a

frequency of 0.2%, painful menstrual bleeding at 0.03%, and decreased or infrequent menstrual bleeding at 0.02%.

The pathophysiology of heavy or prolonged menstrual bleeding in Essure users outside of unsatisfactory device location is not clear. Review of the literature shows that changes in bleeding pattern were examined also in conjunction with laparoscopic tubal sterilization. Studies that considered confounding factors such as pre-sterilization bleeding pattern during hormonal contraceptive use found no link between the sterilization procedure and changes in bleeding. It can be assumed that similar confounding factors may also apply for menstrual bleeding disturbances in conjunction with Essure.

7.9.4 Conclusion

Abnormal, heavy or prolonged menstrual bleeding is a condition with a high prevalence in the fertile female age group. Other than the possibility of endometrial irritation in very proximally placed inserts, the pathophysiology behind heavy or prolonged menstrual bleeding in Essure users is not clear. Review of the literature shows that when changes in bleeding pattern were examined in conjunction with laparoscopic tubal sterilization, studies which considered confounding factors, such as pre-sterilization, bleeding pattern, or hormonal contraceptive use did not substantiate any causal relationship between sterilization and altered bleeding patterns. These confounding factors may also apply for menstrual bleeding changes with Essure as well.

7.10 Headache

Headache is a very common symptom that is reported in almost all individuals at some time in their life. The lifetime prevalence of any form of headache, migraine, and tension headache in women were 99%, 25%, and 88%, respectively. The prevalence of migraine and tension-type headache over 1-year in women were 15% and 86% respectively.(103) Chronic daily headache is reported in 5% of females.(104)

7.10.1 Sponsor's clinical data

Phase II study (STOP 10): In the phase II study 8/206 (3.9%) of women reported headache (not including migraine). An additional 2 women (1.0%) reported events of migraine.

Pivotal study (STOP 2000): Headache and related events during the 5 year follow up period have been analyzed based on data provided in the final 5-year pivotal study report. Out of 518 women with hysteroscopy performed, a total of 98 (18.9%) women reported 226 such events. Of these events, headache only was reported in 76 (14.7%) women (167 events); headache with other symptoms in 25 (4.8%) women (32 events), migraine only in 14 (2.7%) women (24 events) and migraine with other symptoms in 3 (0.6%) women (3 events). The range of events per woman was 1 – 17 (one woman reported 17 events of headache only). A minority of these

events (12 events total in 9 women, 0.7%) were considered to be at least possibly related to Essure.

ESS305 TVU study (Study 16974): In the Essure TVU study, headache was reported in 0.7% women and migraine in 0.2%.

7.10.2 Literature

Duffy et al 2005 (49) reported one woman with headache at the post-operative visit following Essure placement. No other publications were found on Essure and headache.

7.10.3 Postmarketing monitoring

A search of the global safety database through 15 JUNE 2015 revealed 773 reports describing headache in association with Essure yielding a reporting rate of 0.08%, of which 0.07% of reports were from consumers/women, while 0.01% were classified as medically confirmed.

The overwhelming majority of cases describe either “headache” or “migraine”. Over 90% of headache/migraine-related events were classified as non-serious. The reporting rate for cases containing terms suggestive of chronic or recurrent headaches was 0.008%.

Most cases in the headache/migraine case cluster are non-medically confirmed consumer cases. Many of these cases are reported in conjunction with a large range of different symptoms or events. The reporting of headache in conjunction with many other symptoms or events increases the probability of the headache being secondary to these other conditions.

In only a very small number of headache/migraine cases a targeted diagnostic intervention (head/neck imaging or neurological examination) is reported. In a few of these cases, the diagnostic intervention revealed a cause for the headache/migraine. These causes are all assessed to be unrelated to Essure (eg, brain infarction, pituitary tumor, lymphoma).

7.10.4 Conclusion

Headache and migraine are conditions with a very high prevalence, especially in the female population between the ages of 25 and 50 years of age. Thus headache is a commonly reported symptom. External triggers, as well as hormonal changes have been described as potential causal factors in these conditions. The analysis of the available postmarketing case reports of headache or migraine reported in conjunction with Essure shows a small number of serious cases and very few diagnostic investigations, suggesting that the headache symptoms in the majority of cases were not determined to be of high clinical significance. When a medical evaluation of the headache was performed, the resulting diagnoses were unrelated to Essure.

A change of contraceptive method to Essure can often entail stopping previous hormonal contraceptives which could be postulated to exert a certain influence on the occurrence rates

of headache or migraine. Apart from this change, no plausible pathophysiological link is currently known between Essure´s localized mode of action and the development of headache or migraine.

7.11 Infectious complications

Any time a body cavity is entered, there is a risk of infection. This is no different with hysteroscopy. Infectious morbidity following hysteroscopy, however, is extremely low.(105) As with all hysteroscopic procedures, Essure should not be placed in women with any evidence of active or recent upper/lower genital tract infection as stated in the IFU (Section 10.6, Appendix 6).

7.11.1 Sponsor's clinical data

The incidence of infectious complications in the phase II, pivotal and the TVU study is summarized in Table 7–16.

Table 7–16: Infectious complications in Essure studies

Study	Number of women undergoing placement attempt	Number of infectious complications (upper genital tract)[a]	Incidence of infectious complications
Phase II (STOP 10)	227	0	0%
Pivotal (STOP 2000)	507	5 2 cases of PID, 2 of endometritis, 1 pelvic infection	0.99%
ESS305 TVU (Study 16974)	597	4 [b] 2 cases of PID 2 cases of endometritis	0.34%

TVU = transvaginal ultrasound; PID = pelvic inflammatory disease
[a] may have been reported remote from the time of insert placement and therefore may have been unrelated to placement or devices.
[b] Does not include one case of sepsis after surgery for uterine prolapse 2+ years after Essure placement.

7.11.2 Literature review

Adelman et al (97) performed a systemic review of complications encountered with Essure. They reviewed 594 sources, including clinical trials, previous systemic reviews, case series, and case reports. They found a single case report of a ruptured tubo-ovarian abscess 3 years after placement of Essure. Group A β-hemolytic streptococci were isolated and the woman ultimately had a total abdominal hysterectomy. Adelman et al (97) state: "While it was not clear that the Essure inserts contributed to the ascending infection, it did not prevent it as is

observed with other forms of tubal sterilization." A second case of bilateral cornual abscesses followed endometrial ablation after Essure placement one year previously. Povedano et al (37) did a retrospective review of medical records of the 4,306 women who underwent Essure placement at their own site and found two cases of PID, both of which resolved with IV antibiotics.

7.11.3 Postmarketing monitoring

A total of 240 cases of potential pelvic infection were found, of which 214 were spontaneous reports. All but 18 cases were classified serious, and less than half of the cases (n=100) were medically confirmed. Age ranged from 20 to 47 years, with a median of 33 years in cases in which it was provided. One case was fatal secondary to toxic shock syndrome. The reported rate of infectious complications is 0.02%.

There are a total of 16 cases where documented serious infections related to Essure have been reported. Eleven of these cases had onset of symptoms within one month of the procedure. Two of these involved concomitant endometrial ablation with Essure placement one of which involved a bowel injury secondary to thermal necrosis and one Group B streptococcal infection. Of the 9 cases with Essure placement alone, two required a hysterectomy due to necrotic uterine tissue. One case involved unrecognized ongoing PID with infected tissue noted during the procedure and a second case diagnosed as severe PID had necrotic endometrium and myometrium noted on pathological examination. There was one case of tubal abscess following a difficult placement associated with perforation which required a hysterectomy. Two cases of tubal abscess were successfully managed with drainage and antibiotics. One case of PID was managed with IV antibiotics without surgery. One case of toxic shock syndrome secondary to Group A strep had a fatal outcome. The final case was a pyosalpinx in a woman with known salpingitis who had Essure placed in preparation for in-vitro fertilization. This case was managed with radiological drainage and antibiotics.

Five cases were reported one month or more following the Essure procedure. One report of PID was treated with IV antibiotics. There was one tubal abscess treated with laparoscopic drainage and IV antibiotics 4 months post placement. Two cornual abscesses diagnosed one and a half years post placement were managed by hysterectomy and a case of tubovarian abscess was managed by salpingo-oophorectomy. Following a hysterectomy performed for pain, menorrhagia and dysmenorrhea, the surgeon dissected the fallopian tubes and diagnosed an infection.

In summary, when infections associated with Essure placement do occur, they are relatively infrequent, and generally manageable with favorable outcomes. Placement of Essure in a woman with an active genital tract infection can exacerbate the infection which may result in surgical removal of the uterus and fallopian tubes. Antibiotic treatment alone may be sufficient in women diagnosed with PID following Essure placement, although the presence of an abscess should be investigated and if found may require drainage. The number of

reports of PID following Essure is low and may indicate that when bilateral tubal occlusion is achieved, this creates a barrier to ascending genital tract infections. The cases reported with endometrial ablation performed sequentially with Essure placement indicate a higher risk of serious infectious complications. Section VI ("Warnings") of the IFU (Section 10.6, Appendix 6) in the US has an extensive discussion regarding the risk of performing these procedures concomitantly in the warnings section.

7.11.4 Conclusion

Data indicate that the rate of serious infection following placement of Essure is low. It is important that physicians follow guidance outlined in the IFU to help prevent such occurrences.

7.12 Allergy reactions/hypersensitivity (to nickel)

Nickel allergy was a contraindication for Essure when the product was first marketed. Based on biocompatibity data (see Section 3) and lack of correlation between history of nickel allergy and clinical outcome,(23) in agreement with the FDA, this was changed to a warning in 2009. The IFU continues to state: "women who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies." Typical allergy symptoms include rash, pruritis, and hives.

7.12.1 Sponsor's clinical data

One subject in the ESS305 TVU study (Study 16974) had an increased sensitivity to metals, reported as an AE by MedDRA PT "allergy to metal". One case of allergic reaction to distention medium was reported in the Pivotal Study. No further information is available on this case. All other allergic reactions and similar events reported were related to medication or environmental exposure of some type.

7.12.2 Literature

Systemic allergic reactions to nitinol in Essure are also rare. To date, there have been three published case reports describing reactions necessitating surgical removal of the devices.(106)

Peter et al (107) conducted a prospective study to determine if the nitinol in Essure inserts can cause nickel sensitivity. The study included 200 women. All women received two skin patches consisting of a nickel and a control. All women underwent Essure sterilization regardless of the skin test results. Results showed that 25% of the women had a positive skin test prior to placement of Essure. No clinical symptoms of allergy were reported in any woman, regardless of skin patch results.

Such lack of concordance has been demonstrated with other nitinol-containing devices. For example, nitinol is commonly used in heart and endovascular prostheses. Despite the nickel

content, there are few reports of nickel allergy associated with these devices, with a risk estimate of 1/17,000 devices.(108)

Zurawin et al (23) reported on a case series regarding AEs of suspected nickel hypersensitivity associated with Essure, the subsequent clinical outcomes in women with these insert placements, and the correlation of nickel allergy-related AEs with positive results of nickel patch testing. Through multiple sources, 63 reports of suspected nickel hypersensitivity were identified. Twenty women had patch testing: 13 had positive and 7 had negative test results. In 9 of the 13 women who tested positive on the patch test, Essure was removed. Symptoms resolved in 4 of the 9 women, 2 did not resolve, and 2 were unknown.

7.12.3 Postmarketing monitoring

A broad query of the global safety database revealed 641 reports as per 15 JUNE 2015 where a suspicion of allergic reactions to Essure was raised by the reporting healthcare professional or consumer/women (reporting frequency, 0.06% of all placements). Most reports were spontaneous reports from the US. Ninety one women were identified, who had reported testing positive for allergy to nickel prior to or after Essure placement (reporting frequency, 0.01% of all placements). The clinical events reported in this group of 91 testing positive for nickel allergy were similar to those reported in all 641 cases.

To date, there have been no credible reports of true, immediate-type anaphylactic or fatal allergic reactions to Essure.

7.12.4 Conclusion

While nickel allergy assessed by skin patch test is a common occurrence, positive skin patch test is not a reliable predictor of clinically significant reactions to implanted nickel-containing devices. Data from the clinical trials and literature indicate these reactions are relatively rare. Postmarketing monitoring indicates that the term ‘allergy’ appears to be often used in an unspecific manner.

7.13 Device removal

Essure inserts are intended to be left in place permanently. There are no well-controlled trials that have studied removal of inserts remote from placement. Clinical judgment as to the appropriate procedure for removal must be used. Additional information on device removal was recently added to the IFU.

7.13.1 Sponsor’s clinical data

Compiled data on device removals based on data from the phase II and pivotal study reports and from the ongoing TVU (16974) study are provided in Table 7–17. In addition, there are 5 subjects (1 in the phase II study and 4 in the pivotal study) who underwent device removal

at the time of salpingectomy for sterilization but for whom this information is not documented in the above mentioned study reports, although it is documented in other legacy Conceptus files.

This table does not include hysteroscopic device removals that occurred immediately at the time of placement.

Table 7–17: Essure device removal in clinical trials

	Phase II study (STOP 10)	Pivotal study (STOP 2000)	ESS305 TVU (Study 16974)
Total device removals	11	20	11
Number attempted placement	227	507	597
Laparoscopic removal	4	5 [a]	7
Other removal	2 [c]	-	-
Removal with hysterectomy	5	15 [b]	4
	3 bleeding and/or pain 2 prolapse	9 bleeding and/or pain 6 other (1 Asherman's syndrome, 1 fibroids, and 4 missing)	1 pain 1 fibroids 1 endometriosis 1 bleeding

TVU = transvaginal ultrasound
[a] inserts removed laparoscopically prior to IVF in 1 woman desiring pregnancy, 4 others at time of sterilization
[b] 6 women with device fragments remaining in situ after hysterectomy
[c] includes one woman with devices removed via cornual resection and one woman with devices removed via laparotomy due to pain.

7.13.2 Literature

A limited number of case reports indicate that the device may be removed hysteroscopically up to 7 weeks following placement if the proximal coils are easily visible and gentle traction is applied.(109, 81, 110) Case reports show that linear salpingostomy or salpingectomy via laparoscopy or laparotomy can be used to remove the insert. In post approval published literature, salpingostomy has been described from 35 days to 8 months post-placement. Laparoscopic salpingectomy has been described from10 weeks post-placement and up to 4 years post-placement.(110) In some cases, a cornual resection of the proximal fallopian tube may be required for removal. In these cases, women should be counseled about the risk of hysterectomy in order to achieve hemostasis.(110)

Removal technique for perforated devices or those within the peritoneal cavity will depend on the location of the device. Localization should be confirmed prior to the surgical procedure. Use of intra-operative fluoroscopy or plain film is recommended to identify the location of the

insert(s) or pieces of the insert prior to and during surgery as this may prevent future operative interventions.(97)

7.13.3 Postmarketing monitoring

A search of the global safety database through 15 JUNE 2015 revealed 1,127 reports describing removal of Essure in association with, but not exclusively due to, complaints considered to be causally related to the device. This corresponds to a reporting rate of 0.11%. Most reports were spontaneous reports from US HCPs or consumers/ women.

Forty-five percent of device removals were associated with an unsatisfactory device location such as a perforation, embedment, dislocation or expulsion. Pain and bleeding disturbances were reported in 72.6% and 29.4% of these cases, respectively, indicating that the presence of these symptoms influenced the decision for removal. Pain and heavy bleeding were the most common symptoms associated with removal. Device breakage which can occur during the placement procedure was reported in 11.7% of removals which is the appropriate management of a broken device, deployment difficulty or any device suspected of malfunction. Allergy to metals was reported in 10% of removal cases.

Complications associated with device removal were reported in less than 5% of these cases, or 0.006% of the total population. Among medically confirmed cases, device breakage with removal of all fragments was reported in 2.0% of these cases. Suspected incomplete removal was reported in 1.1% and inability to remove the device as planned in 0.6% of cases. In 0.6% of cases the device could not be located. In order to minimize this occurrence, the IFU (Section 10.6, Appendix 6) recommends the availability of intra-operative imaging procedures.

7.13.4 Conclusion

The need for removal of Essure is overall infrequent. Device removals during the placement procedure represent appropriate recognition and management of unsatisfactory device physical properties or location. Device removal is commonly associated with symptoms of pain and bleeding. The least invasive method of removal that can be safely conducted should be performed. In situations where other existing gynecological diagnoses are present, concomitant removal of the uterus with the device may be warranted.

7.14 Death

Death represents the most serious outcome of any AE. It is important to distinguish between fatal outcomes secondary to the product under evaluation, specifically Essure, from fatal outcomes due to other medical conditions in women who have decided to use Essure for contraception. We have examined all reports that could potentially reflect fatal outcomes as discussed in this section.

7.14.1 Sponsor's clinical data

Two deaths occurred in clinical trials with Essure. One woman in the pivotal study (STOP 2000) secondary to leukemia and one woman in ESS305 TVU study (Study 16974) secondary to a myocardial infarction ten days following coronary artery bypass graft surgery. None of these events occurred around the time of the Essure placement or confirmation test. Both events were considered not to be related to Essure.

7.14.2 Literature

There were no reports from the literature on death in association with Essure placement.

7.14.3 Postmarketing monitoring

The sponsor's global safety database was searched through 15 JUNE 2015 for events with a fatal outcome. This process identified 22 cases containing non-fatal events including terms such as "bleeding to death" or "I felt like dying". These were excluded as they did not report fatal outcomes. Three reports were considered as invalid cases because they did not meet the criteria for case creation. Sixteen cases were excluded from this analysis as they referred to reports on loss of pregnancies (miscarriage, stillbirth, neonatal death). These reports are included in the analysis on pregnancy outcomes.

There are 12 postmarketing reports with fatal outcomes, all from the US. In 7 of these cases a cause of death is identified whereas in 5 no cause is reported. Of the cases with no reported cause of death, 3 were from social media, one from a television website, and one from an individual who heard it from another individual who saw it on television. In all of these cases, no specifics regarding the date or cause of death or the relation to a procedure was reported.

There are 7 cases in which the cause of death is reported. Three of these involve deaths related to anesthetic complications (2 local and one general anesthesia). A woman with severe pulmonary hypertension had a cardiac arrest during removal of a carotid catheter which was fatal. She had Essure inserted in general anesthesia. A woman with sleep apnea experienced a fatal outcome in her sleep. She had taken phenergan to facilitate sleep. One case of toxic shock syndrome secondary to the transfer of Group A streptococcus into the upper genital tract during hysteroscopy was reported.

Six of these seven cases were reported by a HCP. The seventh case reported from social media describes death due to an embolism during a hysterectomy. No further information was provided.

7.14.4 Conclusion

A comparison to the deaths with tubal sterilization performed laparoscopically is helpful in putting the fatal cases reported with Essure users into perspective. As discussed in the introductory section of this document, the leading causes of death with laparoscopic

sterilization were anesthesia and infection related. In Essure users there were 3 anesthesia related fatalities and 1 infection related fatality. The projected case fatality rate for tubal sterilization (6) was projected at ~9 per 100,000 with a rate of 1-2 per 100,000 that are directly procedure related. Given the approximately 1 million procedures performed, the rates reported for Essure are within these estimates.

8. Benefit/Risk Summary

Benefit

All female permanent birth control methods are highly effective. The following table presents comparative pregnancy rates by sterilization method, as recently compiled by the American College of Obstetricians and Gynecologists.(2)

Table 8–1: Pregnancy rates by sterilization method

Method	5-year / 1,000 procedures	10-year / 1,000 procedures	Ectopic / 1,000 procedures
Postpartum partial salpingectomy	6.3	7.5	1.5
Bipolar coagulation [a]	16.5	24.8	17.1
Silicone band methods	10.0	17.7	7.3
Spring clip	31.7	36.5	8.5
Hysteroscopy (Essure) [b]	1.64	-	-
Vasectomy	11.3	-	No association

[a] Secondary analysis of 5-year failure rates with bipolar coagulation performed in different decades found that failure was significantly lower in later periods, reflecting improved technique with the method: 19.5 per 1,000 procedures for 1978 – 1982 vs 6.3 per 1,000 procedures for 1985 – 1987.

[b] US FDA recommended projections based on Bayesian statistical analysis.(111)

In a review of the literature, Grunert found that the tubal patency rate following incisional tubal ligation was 3.2% with a subsequent pregnancy rate of 0.8%. Grunert concluded that "although there may be a failure of absolute physical occlusion of the tubes, this cannot be directly equated with failure of the sterilization".(112)

Clinical trials including a 5-year follow-up study did not show any pregnancies after Essure placement. Later clinical trials demonstrated low rates of unintended pregnancy.

Clinical studies in the literature confirm that hysteroscopic sterilization with the Essure device is a very effective method of contraception with reported efficacy in the literature and clinical trials of >99%.

Based on postmarketing monitoring and considering its inherent limitations, pregnancy rates with the marketed product have been consistent with rates determined in clinical trials and as found in the literature.

No contraceptive method is 100% effective and contraceptive failures with Essure have been reported in clinical studies and post-marketing. Data suggest that compliance with the requirement to undergo a confirmation test three month after the Essure placement is critical to achieve the benefits inherent to the Essure method. This is addressed in the IFU (Section 10.6, Appendix 6) and physician training.

Placement rate is very important when physicians counsel patients prior to the attempted procedure, as patients need to be aware of the possibility placement may not occur. Still, with the currently available ESS305 device, both the clinical trial data as well as several external studies show a placement rate of at least 95%.

Both the clinical trials and external studies demonstrate overall satisfaction (>92%) with both the Essure placement procedure as well as ongoing use of the inserts. When compared to laparoscopic tubal ligation at 90 days post procedure, Essure compared very favorably with regard to overall satisfaction, speed of recovery, and choice of chosen procedure.(49)

Risk

Prior to Essure, the primary option for women desiring permanent birth control at a time remote from pregnancy was laparoscopic BTL. While BTL is regarded as safe and effective,(2) it is an invasive procedure requiring entry into the peritoneal cavity and general anesthesia. Many of the risks of the procedure are related to the required surgical entry into the abdominal cavity, including trochar or Verres needle injuries to intra-abdominal structures, bleeding, sepsis, and bowel injury. The use of general anesthesia, insufflation of the abdomen with CO_2 gas, and the use of steep Trendelenburg position sometimes needed to access pelvic structures also increase the risk of all laparoscopic surgeries. There may be increased risks of aspiration, respiratory dysfunction, and cardiovascular dysfunction during laparoscopy. The ability to perform the Essure procedure without general anesthesia is therefore a clinically relevant consideration.

The main risks with Essure as described in the IFU (Section 10.6, Appendix 6) and PIB (Section 10.7, Appendix 7) include: uterine, or tubal perforation, pregnancy (including ectopic pregnancy), infection, menstrual changes, pain, allergy/hypersensitivity reactions and lack of contraceptive effect due to improper placement or expulsion/migration of the inserts.

Benefit/Risk assessment

The Essure system provides permanent birth control without invasive surgery or the need for general anesthesia, and their attendant risks. It is a highly effective form of permanent birth

control, even when taking into account the follow-up protocol required. The risk profile is well characterized and compares favorably with the risk profile of BTL.

Risks related to Essure and the placement procedure are mitigated through the detailed information presented in the IFU and PIB, a robust multi-step physician training program, and restricted distribution of Essure to only those physicians who have completed this training. In addition, there are numerous physician support programs in place. We continue to conduct postmarketing surveillance and to work closely with Health Authorities, such as the FDA, to identify and address any changes to the benefit/risk profile.

The safety profile of Essure is consistent with other methods of female permanent birth control and may present advantages for a number of women.

Data from the sponsor's extensive clinical program, comprehensive review of peer-reviewed literature, and continuous postmarketing activities support the safety and efficacy of Essure.

Overall, this assessment concludes that the benefit/risk profile of Essure remains positive.

9. References

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10. Appendices

10.1 Appendix 1: Essure design changes

Key design changes since original US FDA Premarket Approval

Device	Insert	Catheter	Clinical data	Key reason for change
STOP	Original approved design	Braided delivery catheter	Phase II (STOP10) and pivotal studies (STOP2000)	Original PMA approval
ESS205	No change	Coil Catheter	Post approval study (ESS205 PAS) conducted to validate delivery system changes	Original launched design Improved bilateral placement rate
ESS305 Currently marketed model	Similar to ESS205, removal of taper “pigtail” at proximal end of outer coil	Modified detachment and deployment mechanism; replaced “unscrew” step with second roll-back	Post approval study (ESS305 PAS) conducted to validate delivery system changes	(a) Improved bilateral placement rate (b) Improved ease of use by simplifying placement procedure (reduced the total number of operational steps required for insert release by eliminating counter-clockwise turns). (c) Improve reliability (reduce detachment / disengagement difficulties between insert and delivery system)

STOP = Selective Tubal Occlusion Product; PMA = Pre-market approval; PAS = post approval study.

10.2 Appendix 2: Literature on Essure placement rates

Essure placement rate in real-world setting

Study	Location	Design	Findings
Satisfaction and tolerance with office hysteroscopic tubal sterilization. Fertil Steril. 2008 Oct;90(4):1182-6. doi: 10.1016/j.fertnstert.2007.08.007. Epub 2008 Jan 16. Arjona JE, Miño M, Cordón J, Povedano B, Pelegrin B, Castelo-Branco C. http://www.ncbi.nlm.nih.gov/pubmed/18201703	Spain	Prospective analysis of case series; Gynecology department in a teaching hospital; A total of 1,630 women, January 2003 to June 2006.	Out of a total of 1,630, fifteen women (<1%) dropped out because of a failure in the procedure (insertion success rate >99%).
Hysteroscopic sterilization success in outpatient vs office setting is not affected by patient or procedural characteristics. J Minim Invasive Gynecol. 2013 Nov-Dec;20(6):858-63. doi: 10.1016/j.jmig.2013.05.020. Epub 2013 Jul 23. Anderson TL, Yunker AC, Scheib SA, Callahan TL. http://www.ncbi.nlm.nih.gov/pubmed/23891205	USA (Vanderbilt, Nashville, TN)	Retrospective cohort analysis 638 women who underwent hysteroscopic sterilization between July 1, 2005 and June 30, 2011.	The overall success in bilateral placement of inserts was 95.5%, with no significant difference in so far as the setting in which the procedure was performed (office vs OR), anesthesia verses no anesthesia, surgeon experience level, obesity.
Hysteroscopic female sterilization with Essure in an outpatient setting. Andersson S, Eriksson S, Mints M. Acta Obstet Gynecol Scand. 2009 88(6):743--6 http://www.ncbi.nlm.nih.gov/pubmed/19412802	Sweden	61 women underwent outpatient hysteroscopic sterilization between 2002 and 2007.	Fifty-eight (95%) women were sterilized according to this method. Successful bilateral device placement was achieved in 52 women (85%) during the first attempt and in six (9.8%) during the second, overall 58/61 (95.1%). Three women declined a second attempt and underwent laparoscopic sterilization.
Vaginoscopy compared to traditional hysteroscopy for hysteroscopic sterilization. A randomized trial. Chapa HO. J Reprod Med. 2015 Jan-Feb;60(1-2):43-7. **http://www.ncbi.nlm.nih.gov/pubmed/25745750**	USA (TX)	Single center, randomized, prospective, n=90.	Successful bilateral placement at first attempt in 86/90 (95.4%) overall (including 3 subjects in whom vaginoscopy was unsuccessful and traditional hysteroscopy utilized).
Initial Asian experience in hysteroscopic sterilisation using the Essure permanent birth control device. BJOG. 2005 Sep;112(9):1322-7.	Singapore.	A retrospective study. 80 women seeking permanent birth control. Analysis of initial experience with the Essure permanent birth control over a	Bilateral placement at first attempt: 72 (90%); bilateral placement at second attempt 5(6.2%); overall bilateral placement (1st and 2nd attempts) 77/80 (96.2%).

Study	Location	Design	Findings
Chern B, Siow A. http://www.ncbi.nlm.nih.gov/pubmed/16101615		period of 18 months from 22 June 2001 to 22 December 2002.	
Placement of a permanent birth control device at a university medical center. J Reprod Med. 2009 Apr;54(4):218-22. Shavell VI[1], Abdallah ME, Diamond MP, Berman JM. http://www.ncbi.nlm.nih.gov/pubmed/19438163	USA (Detroit Medical Center, Detroit, MI)	Single center, retrospective study, 316 women, January 1, 2003, to June 30, 2007.	The rate of successful placement of the Essure was 92.1% (294/316). Of the 22 placement failures, 11 were attributed to difficulty visualizing the tubal ostia
Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. BJOG. 2005 Nov;112(11):1522-8. Duffy S, Marsh F, Rogerson L, Hudson H, Cooper K, Jack S, Hunter D, Philips G. http://www.ncbi.nlm.nih.gov/pubmed/16225573	Multicenter, UK	Cohort controlled comparative study. The day surgery and outpatient unit of three large UK hospitals. 59 women underwent Essure placement.	Bilateral placement first attempt 76% (45/59); The overall bilateral placement rate for the ESSURE device was 81% (48/59). For 3 patients the investigators were unable to enter the uterine cavity with the hysteroscope
What are the factors predictive of hysterosalpingogram compliance after female sterilization by the Essure procedure in a publicly insured population? Matern Child Health J. 2013 Dec:17(10):1760-7 Howard DL, Wall J, Strickland JL http://www.ncbi.nlm.nih.gov/pubmed/23212398	USA (2 campuses of Truman Medical Center, Kansas City, Missouri)	Multi-site, 136 patients presenting for Essure placement between January 1 2005 and December 31 2010	Placement of the Essure permanent birth control device was attempted in 136 patients, 131 of whom had successful placement (96.3 %) [includes one unilateral placment in patient with salpingectomy].
Analysis of pain and satisfaction with office-based hysteroscopic sterilization. Fert Steril. 2010 Sep4(4):1189-94 Levie M, Weiss G, Kaiser B, Daif J, Chudnoff SG. http://www.ncbi.nlm.nih.gov/pubmed/19683232	USA (NY)	From June 2003 to June 2006, 209 patients were recruited, at a faculty practice office at an inner-city urban medical center.	Successful placement occurred in 198/209 (95%)
Prospective analysis of office-based hysteroscopic sterilization. Levie MD, Chudnoff SG J Minim Invasive Gynecol. 2006;13(2):98–101. http://www.ncbi.nlm.nih.gov/pubmed/16527710	USA, NY	Prospective, longitudinal analysis, of 102 women at university out-patient office.	Bilateral placement of the device was successful in 98 (96%) of 102 patients; 92 had f/u HSG, 1 pregnancy (luteal phase pregnancy-pregnant at procedure or shortly after)
A comparison of novice and experienced physicians performing hysteroscopic sterilization: an analysis of an FDA-mandated trial. Levie M; Chudnoff SG Fertility and Sterility. 2011 Sep; 96(3):643-648.e1. http://www.ncbi.nlm.nih.gov/pubmed/?term=21782168	Multicenter USA (Subanalysis of ESS305 PAS)	Multicenter prospective cohort study. Seventy-six sites throughout the U.S. comprising community hospitals, teaching institutions, surgery centers, and office-based practices. A total of 578 women seeking	N=578, A total of 625 patients were recruited with 578 eligible cases performed by 37 newly trained and 39 experienced physicians: 562/578 (97.2%) overall had successful placement, with 98% successful placement rate versus 96.1% for experienced versus novice physicians,

Study	Location	Design	Findings
		hysteroscopic sterilization.	respectively.
Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. Miño M, Arjona JE, Cordón J, Pelegrin B, Povedano B, Chacon E. BJOG 2007 Jun;114(6):763-6 http://www.ncbi.nlm.nih.gov/pubmed/?term=17516970	Spain	Single center, retrospective, 857 women with Essure system. inserted in an outpatient setting, January 2003 to January 2005.	At the first attempt, 96.5% of insertions (827 women) were successful, which included 812 bilateral insertions and 15 unilateral (14 of whom had previous salpingectomy and one had a unicornuate uterus). Bilateral success was achieved at the second attempt in 18 women (2.1%). In the 12 women in whom insertion was not achieved, five were bilateral and seven were unilateral failures. Overall bilateral placement rate 845/857=98.6%.
Complications of hysteroscopic Essure(®) sterilisation: report on 4306 procedures performed in a single centre. Povedano B, Arjona JE, Velasco E, Monserrat JA, Lorente J, Castelo-Branco C. BJOG 2012. Jun;119(7):795-9 http://www.ncbi.nlm.nih.gov/pubmed/22360159	Spain	Retrospective 7-year study, Office hysteroscopic unit in a teaching hospital, 4306 women sterilized from March 2003 and June 2010.	Of the 4306 women undergoing hysteroscopic Essure® sterilisation, 4242 (98.5%) were successfully completed, of which 4075 were successfully sited at one attempt (96%), without the need for a second-stage procedure at a later date.
The feasibility, success and patient satisfaction associated with outpatient hysteroscopic sterilisation. D. Sinha, V. Kalathy, J.K. Gupta BJOG. 2007 Jun;114(6):676-83. http://www.ncbi.nlm.nih.gov/pubmed/17516957	UK	Prospective cohort study, large teaching hospital, 112 women enrolled August 2002 and June 2006.	Successful bilateral tubal placement of the Essure microinserts was achieved in 103/112 (92%, 95% confidence interval 85-96%) women.
Post-Essure hysterosalpingography compliance in a clinic population. Shavell VI, Abdallah ME, Diamond MP, Kmak DC, Berman JM. J Minim Invasive Gynecol. 2008 Jul-Aug;15(4):431-4. doi: 10.1016/j.jmig.2008.03.004. Epub 2008 Apr 28. http://www.ncbi.nlm.nih.gov/pubmed/18588851	US (Wayne State, Detroit)	83 women, Retrospective chart review, University teaching hospital, placement attempted during January 2003 through June 2007.	Placement of the Essure permanent birth control device was attempted in 83 patients, of which 79 were successfully completed (95.2%).
Hysteroscopic sterilization in a large group practice: experience and effectiveness. Savage UK, Masters SJ, Smid MC, Hung YY, Jacobson GF Obstet Gynecol. 2009 Dec;114(6):1227-31. doi: 10.1097/AOG.0b013e3181c2a10d.	North California, Kaiser Permanente (USA)	Retrospective review, 884 women, 118 physicians at 30 different facilities, from January 2004 to December 2006, f/u through December 31, 2008	The initial placement attempt was successful in 850 (96.2%), failed in 31 (3.5%), and could not be determined in three (0.3%). 13 ptatients underwent two attempts *(eventual bilateral placement rate not given, just initial)*.

Study	Location	Design	Findings
http://www.ncbi.nlm.nih.gov/pubmed/19935023			
Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting A. Ubeda, R. Labastida, S. Dexeus Fertility & Sterility, Volume 82, Issue 1, July 2004, Pages 196–199 http://www.sciencedirect.com/science/article/pii/S0015028204006843	Barcelona, Spain	Prospective, observational study, Private university hospital, 85 women, enrolled July 2002 - July 2003.	Successful placement was achieved in 81 (95%) patients, including one case of two-step procedure (placement of devices in two consecutive menstrual cycles because of unilateral tubal spasm), one unicornuate uterus, and a woman in whom only one device could be placed and whose hysterosalpingogram revealed contralateral tubal obstruction.
Hysteroscopic permanent tubal sterilization using a nitinol-dacron intratubal device without anaesthesia in the outpatient setting: procedure feasibility and effectiveness. Litta P1, Hum Reprod. 2005 Dec;20(12):3419-22. Epub 2005 Aug 5. http://www.ncbi.nlm.nih.gov/pubmed/?term=16085664	Italy	Prospective study of 36 consecutive cases of outpatient hysteroscopic tubal sterilization using a nitinol-dacron intratubal device without anaesthesia. Successful device placement was assessed after 3 months by hysterosalpingography and diagnostic hysteroscopy.	Successful bilateral placement was obtained in 32 patients (88.9%); in one (2.8%) the placement was monolateral; and in three (8.3%) the procedure failed.
Confirmation of Essure placement using transvaginal ultrasound. Veersema S1, J Minim Invasive Gynecol. 2011 Mar-Apr;18(2):164-8. doi: 10.1016/j.jmig.2010.10.010. Epub 2011 Feb 1. http://www.ncbi.nlm.nih.gov/pubmed/21282075	Netherlands	Prospective multicenter cohort study Outpatient departments of 4 teaching hospitals in the Netherlands. 1145 who underwent hysteroscopic sterilization using the Essure device between March 2005 and December 2007.	Of 1145 hysteroscopic sterilization procedures, bilateral placement was successful in 1034 (90.3%), unilateral placement was successful in 13 patients (1.1%), and bilateral placement was successful after the second attempt in 25 patients (2.2%). The overall successful placement rate was 93.6% (1072 of 1145 intentions to treat).
3D ultrasound to assess the position of tubal sterilization microinserts. Legendre G1, Hum Reprod. 2011 Oct;26(10):2683-9. doi: 10.1093/humrep/der242. Epub 2011 Aug 16. http://www.ncbi.nlm.nih.gov/pubmed/21846730	France	Retrospective observational study examined the case records of 311 women who underwent hysteroscopic sterilization from October 2002 through October 2008.	The insertion procedure was completed in 94.2% patients.
Learning curve of hysteroscopic placement of tubal sterilization microinserts in 15 gynecologists in the Netherlands.	Netherlands	Prospective multicenter study, Ten community (teaching) hospitals in the Netherlands. A	Excluding the patients lost to follow-up evaluation, a success rate of 80.0% for bilateral placement at first attempt was

Study	Location	Design	Findings
Janse JA1, Fertil Steril. 2013 Sep;100(3):755-60. doi: 10.1016/j.fertnstert.2013.05.019. Epub 2013 Jun 12. http://www.ncbi.nlm.nih.gov/pubmed/?term=23768989		total of 631 women who underwent permanent sterilization by tubal microinserts.	observed. If successful unilateral placement at first attempt is included (ptx w prior tubectomy), a success rate of 82.2% was achieved. Including the successes at second attempt, an overall success rate of 89.5% was achieved
Oral analgesia vs intravenous conscious sedation during Essure Micro-Insert sterilization procedure: randomized, double-blind, controlled trial. Thiel JA1J Minim Invasive Gynecol. 2011 Jan-Feb;18(1):108-11. doi:10.1016/j.jmig.2010.10.006 http://www.ncbi.nlm.nih.gov/pubmed/21195962	Canada	Randomized, double-blind, placebo-controlled trial. Tertiary care ambulatory women's clinic. 87 women of reproductive age women requesting permanent sterilization.	Bilateral placement of the Essure device was successful in 84 patients (97%).
Incorrect position of Essure microinserts 3 months after successful bilateral placement. Gerritse MB, Fertil Steril. 2009 Mar;91(3):930.e1-5. doi: 10.1016/j.fertnstert.2008.08.013. Epub 2008 Oct 21. http://www.ncbi.nlm.nih.gov/pubmed/?term=18945426	Netherlands	100 patients who underwent hysteroscopic sterilization using Essure between December 2003 and June 2004.	Bilateral placement of Essure microinserts in one session was successful in 93 women (93%).
Hysteroscopic tubal sterilization with Essure intratubal devices: a case-control prospective with inert local anesthesia or without anesthesia P. Lopes, E. Gibon, T. Linet, et al. Eur J Obstet Gynecol Reprod Biol, 138 (2008), pp. 199–203 http://www.ncbi.nlm.nih.gov/pubmed/?term=17822834	France	Between February 2002 and May 2005, one operator performed 140 sterilization procedures in this prospective study: the first 70 were performed using local anesthesia and the following 70 began without administration of anesthesia.	N=140, successful bilateral micro-insert placement in the first 70 cases,utilizing paracervical block, was 82.8% and did not differ significantly from the next 70 cases, without anesthesia (91.4%). The first 70 patients had hysteroscopic sterilization under anesthesia: the success rate for placement was 58/70 (82.8%). Hysteroscopies for the next 70 patients, planned without anesthesia, had a placement success rate of 91.4% (64/70). Overall: 87.1% (122/140).
Efficacy of Essure hysteroscopic sterilization--5 years follow up of 1200 women Ríos-Castillo JE Gynecol Endocrinol. 2013 Jun;29(6):580-2. doi: 10.3109/09513590.2013.777419. Epub 2013 Apr 5 http://www.ncbi.nlm.nih.gov/pubmed/?term=23557170	Spain	Outpatient hysteroscopy facility in a large teaching hospital. One-thousand three-hundred and twenty-one women who underwent hysteroscopic sterilization with Essure device, between January 2003 and May 2005.	Satisfactory insertion was accomplished in the first attempt in 1166 women (97.16%). After the second attempt, successful insertion rate rise to 98.6%. (n = 31, 2.6%).

10.3 Appendix 3: Literature on pregnancy

Studies reporting the efficacy of Essure

Study	Location	Design	Findings
Complications of hysteroscopic Essure(®) sterilisation: report on 4306 procedures performed in a single centre. Povedano B, Arjona JE, Velasco E, Monserrat JA, Lorente J, Castelo-Branco C. BJOG. 2012 Jun;119(7):795-9. http://www.ncbi.nlm.nih.gov/pubmed/22360159	Spain	Retrospective 7-year study, Office hysteroscopic unit in a teaching hospital, 4306 women sterilized from March 2003 and June 2010.	A total of seven women (0.16%), three before and four after the 3-month follow-up, became pregnant. The pregnancy rate after assessment for satisfactory placement was 0.09%.
Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. Miño M, Arjona JE, Cordón J, Pelegrin B, Povedano B, Chacon E. BJOG. 2007 Jun;114(6):763-6. http://www.ncbi.nlm.nih.gov/pubmed/?term=17516970	Spain	Single center, retrospective, 857 women with Essure system inserted in an outpatient setting, January 2003 to January 2005.	1 luteal phase pregnancy (elective termination) [1/857 = 0.1%].
Prospective analysis of office-based hysteroscopic sterilization. J Minim Invasive Gynecol. 2006;13(2):98–101. Levie MD, Chudnoff SG. http://www.ncbi.nlm.nih.gov/pubmed/16527710	USA, NY	Prospective, longitudinal analysis, university out-patient office.	Bilateral placement of the device was successful in 98 (96%) of 102 patients; 92 had f/u HSG, 1 pregnancy (luteal phase pregnancy-pregnant at procedure or shortly after – SAB at 8w).
Hysteroscopic sterilization in a large group practice: experience and effectiveness. Savage UK, Masters SJ, Smid MC, Hung YY, Jacobson GF Obstet Gynecol. 2009 Dec; 114(6):1227-31. http://www.ncbi.nlm.nih.gov/pubmed/?term=19935023	Kaiser Permanente, Northern California	Retrospective review, 884 women, 118 physicians at 30 different facilities, from January 2004 to December 2006, f/u through December 31, 2008.	8 pregnancies identified: one never returned for hysterosalpingography, four had a hysterosalpingogram with at least one patent tube, and three had the hysterosalpingogram interpreted as bilaterally occluded.
What are the factors predictive of hysterosalpingogram compliance after female sterilization by the Essure procedure in a publicly insured population? Howard DL, Wall J, Strickland JL Matern Child Health J. 2013 Dec;17(10):1760-7. http://www.ncbi.nlm.nih.gov/pubmed/23212398	2 campuses of Truman Medical Center, Kansas City, Missouri	Multi-site, 136 patients presenting for Essure placement between January 1 2005 and December 31 2010.	No documented pregnancies after the Essure procedure.

Study	Location	Design	Findings
Hysteroscopic sterilization success in outpatient vs office setting is not affected by patient or procedural characteristics. Anderson TL, Yunker AC, Scheib SA, Callahan TL. J Minim Invasive Gynecol. 2013 Nov-Dec;20(6):858-63 http://www.ncbi.nlm.nih.gov/pubmed/23891205	Vanderbilt (Nashville, TN)	Retrospective cohort analysis 638 women who underwent hysteroscopic sterilization between July 1, 2005 and June 30, 2011	3 Pregnancies were reported prior to HSG confirmation (ITT=3/638=0.5%); these were unrelated to device effectiveness. No pregnancies were reported in patients after HSG confirmation of bilateral tubal occlusion, with follow-up of at least 1 year. In addition, there were no known pregnancies among patients who did not complete HSG assessment.
Placement of a permanent birth control device at a university medical center. J Reprod Med. 2009 Apr;54(4):218-22. Shavell VI[1], Abdallah ME, Diamond MP, Berman JM. http://www.ncbi.nlm.nih.gov/pubmed/19438163	Detroit Medical Center (Detroit, MI)	Single center, retrospective study, 316 women, January 1, 2003 to June 30, 2007	3 pregnancies, giving a post-Essure pregnancy rate of 0.95%
Hysteroscopic female sterilization with Essure in an outpatient setting. Anderson S, Eriksson S, Mints M. Acta Obstet Gynecol Scand. 2009;88(6):743-6 http://www.ncbi.nlm.nih.gov/pubmed/19412802	Sweden	61 women underwent outpatient hysteroscopic sterilization between 2002 and 2007	No pregnancies reported
Initial Asian experience in hysteroscopic sterilisation using the Essure permanent birth control device. BJOG. 2005 Sep;112(9):1322-7. Chern B, Siow A. http://www.ncbi.nlm.nih.gov/pubmed/16101615	Singapore	A retrospective study. 80 women seeking permanent birth control. Analysis of initial experience with the Essure permanent birth control over a period of 18 months from 22 June 2001 to 22 December 2002. *[probably ESS205]*	As of 22 June 2003, 77 women had accumulated 1218 months of wearing the Essure device. All 67 women on regular follow up and with radiological evidence of tubal occlusion did not report any pregnancy. The remaining 10 women who have defaulted follow up were contacted through telephone and there were no pregnancies reported as well in this group.
Pregnancies after hysteroscopic sterilization: a systematic review. Contraception. 2013 May;87(5):539-48. doi: 10.1016/j.contraception.2012.08.006. Epub 2012 Oct 4. Cleary TP, Tepper NK, Cwiak C, Whiteman MK, Jamieson DJ, Marchbanks PA, Curtis KM. http://www.ncbi.nlm.nih.gov/pubmed/23040124	Review	22 studies of women who underwent Essure® placement	Eleven articles that documented bilateral tubal occlusion with hysterosalpingogram (HSG) or placement with X-ray or ultrasound following Essure® placement did not report any pregnancies with follow-up ranging from 7 months to 7 years. The remaining 11 articles identified 102 reported pregnancies. Eighteen of these pregnancies occurred prior to the 3-month period required before imaging for contraceptive reliability. Two articles did not report what follow-up imaging was performed among women after Essure® placement; one of

Study	Location	Design	Findings
			these articles reported three pregnancies.
Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. Duffy S, Marsh F, Rogerson L, Hudson H, Cooper K, Jack S, Hunter D, Philips G. BJOG. 2005 Nov;112(11):1522-8. http://www.ncbi.nlm.nih.gov/pubmed/16225573	UK	Cohort controlled comparative study. The day surgery and outpatient unit of three large UK hospitals. 59 women underwent Essure placement	The overall bilateral placement rate for the ESSURE device was 81% (48/59). One ESSURE patient became pregnant during the study (1/48 = 2.1%). (Author comments "X-ray showed that the left device was suspiciously sited. Patient failed to attend on two occasions for HSG. It is likely that she had an immediate expulsion post-placement of the left-sided device").
Satisfaction and tolerance with office hysteroscopic tubal sterilization. Arjona JE, Fertil Steril. 2008 Oct;90(4):1182-6. doi: 10.1016/j.fertnstert.2007.08.007. Epub 2008 Jan 16. http://www.ncbi.nlm.nih.gov/pubmed/?term=18201703	Spain	Prospective analysis of case series 1615 patients Up to 3.5years follow-up/analysis	3 pregnancies (0.2%) [all occurred within 90d]
Unintended pregnancies after Essure sterilization in the Netherlands. Veersema S, Fertil Steril. 2010 Jan;93(1):35-8. doi: 10.1016/j.fertnstert.2008.10.005. Epub 2008 Nov 21. http://www.ncbi.nlm.nih.gov/pubmed/19027109	Netherlands	Retrospective, national, multicenter ~ 6000 sterilizations (estimated from distributor) Up to 5 ~ follow-up	Ten cases of unintended pregnancies after Essure sterilization out of an estimated 6000 hysteroscopic sterilizations were performed in 45 hospitals in the Netherlands from August 2002 to May 2008 as estimated from the data from the Dutch distributor *(Author comments "Most pregnancies occurred in patients with only one device placement and bilateral occlusion on HSG. Other cases included misinterpretation of HSG, undetected abnormal device position by ultrasound, one undetected preprocedure pregnancy, and two patient failures to follow up with the physician advice").*
Essure® permanent birth control effectiveness: a seven-year survey. Jost S1, Eur J Obstet Gynecol Reprod Biol. 2013 Jun;168(2):134-7. doi: 10.1016/j.ejogrb.2012.12.042. Epub 2013 Jan 30. http://www.ncbi.nlm.nih.gov/pubmed/?term=23375900	France	Retrospective National Survey 53,003 kits sold. Up to 7.5 follow-up/analysis	58 pregnancies (0.1%).
Contraceptive Failures Associated with Hysteroscopic Sterilization. Deraleu & Heinlein, Journal of Minimally Invasive Gynecology S19 (2012) S1–S35 http://www.jmig.org/article/S1553-4650(12)00398-	USA, CA	Retrospective study, Kaiser Permanente Northern California database 2,621 women, 1-8 year follow-up/analysis	22 pregnancies (0.8%)

Study	Location	Design	Findings
6/abstract			
Tubal sterilization: pregnancy rates after hysteroscopic versus laparoscopic sterilization in France, 2006-2010. Fernandez H, Eur J Obstet Gynecol Reprod Biol. 2014 Sep;180:133-7. doi: 10.1016/j.ejogrb.2014.04.043. Epub 2014 May 14. http://www.ncbi.nlm.nih.gov/pubmed/?term=24993770	France	Retrospective cohort study To compare the rates of pregnancy among women who underwent Essure hysteroscopic sterilization versus tubal ligation in France between 2006 and 2010	During the study period, French hospitals performed 109,277 tubal sterilization procedures: 39,169 Essure sterilizations and 70,108 laparoscopic tubal ligations A Cox model has been performed. Following sterilization, after adjustment on age Essure patients became pregnant at a significantly lower rate than laparoscopic ligation patients 0.36% versus 0.46%, respectively (HR=0.62 (040-096).
Efficacy of Essure hysteroscopic sterilization--5 years follow up of 1200 women Ríos-Castillo JE Gynecol Endocrinol. 2013 Jun;29(6):580-2. doi: 10.3109/09513590.2013.777419. Epub 2013 Apr 5 http://www.ncbi.nlm.nih.gov/pubmed/?term=rios-castillo+essure	Spain	Retrospective analysis of case series	Three pregnancies had been reported after 5 years follow up, which implies an overall absolute rate of 0.25%. This represents a Pearl index of 0.05 after 72,000 months of surveillance. All of them occurred in the first year of use of the microinsert. There has been no unintended pregnancy in the next 4 years
Definitive contraception with Essure device: Single institutional experience on 517 procedures Aparicio-Rodríguez-Miñón P Ginecol Obstet Mex. 2015 Jan;83(1):16-22 http://www.ncbi.nlm.nih.gov/pubmed/26016312	Spain	Retrospective descriptive study, 517 procedures	7 (1.35%) unintended pregnancies were observed.
Hysteroscopic tubal sterilization with Essure intratubal devices: a case-control prospective with inert local anesthesia or without anesthesia P. Lopes, E. Gibon, T. Linet, et al. Eur J Obstet Gynecol Reprod Biol, 138 (2008), pp. 199–203 http://www.scopus.com/record/display.url?eid=2-s2.0-44249108785&origin=inward&txGid=A2B0BAFB03F13FF7328FB6DC3CE46984.I0QkgbIjGqqLQ4Nw7dqZ4A%3a8	France	Prospective case-controlled cohort study, 140 women	No pregnancy was reported in our study. The meanfollow-up for the first group of patients (with local anesthesia) was 48 months (39–58 months). The mean follow-up for the second group was shorter: 30 months (19–39 months) because it was a before-and-after study.
Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting A. Ubeda, R. Labastida, S. Dexeus Fertility & Sterility, Volume 82, Issue 1, July 2004, Pages 196–199 http://www.sciencedirect.com/science/article/pii/S0015028204006843	Spain	Prospective, observational study, Private university hospital, 85 women, enrolled July 2002 - July 2003	None of the patients has become pregnant after device placement.

Study	Location	Design	Findings
3D ultrasound to assess the position of tubal sterilization microinserts. Legendre G1, Hum Reprod. 2011 Oct;26(10):2683-9. doi: 10.1093/humrep/der242. Epub 2011 Aug 16. http://www.ncbi.nlm.nih.gov/pubmed/21846730	France	Retrospective observational study examined the case records of 311 women who underwent hysteroscopic sterilization from October 2002 through October 2008. Imaging with 3D-US or pelvic X-radiography or both was performed 3 months after the procedure to verify device position. Hysterosalpingography (HSG) was performed when a bilateral procedure was not completed because of a history of salpingectomy or blocked tube, when doubt persisted after 3D-US or pelvic radiography, or for comparative purposes in a prospective study. The positions seen on 3D-US were classified in four categories according to a specific scale we devised.	2 pregnancies (live birth, elective termination). Neither pregnancy nor early expulsion occurred when 3D-US found that the devices were correctly placed.
Confirmation of Essure placement using transvaginal ultrasound. Veersema S1, J Minim Invasive Gynecol. 2011 Mar-Apr;18(2):164-8. doi: 10.1016/j.jmig.2010.10.010. Epub 2011 Feb 1. http://www.ncbi.nlm.nih.gov/pubmed/21282075	Netherlands	Prospective multicenter cohort study. Outpatient departments of 4 teaching hospitals in the Netherlands. 1145 women who underwent hysteroscopic sterilization using the Essure device between March 2005 and December 2007	The cumulative pregnancy rate after 18 months was 3.85 per thousand women.

10.4 Appendix 4: Literature on post-tubal syndrome

Studies cited in ACOG "*Practice Bulletin on the Benefits and Risks of Sterilization*" regarding menstrual patterns/changes during various procedures of sterilization:

- Bhiwandiwala PP et al. (Level II-3): Menstrual pattern changes following laparoscopic sterilization with different occlusion techniques: a review of 10,004 cases. Am J Obstet Gynecol 1983; 145:684-94. http://www.ncbi.nlm.nih.gov/pubmed /6219585.

- DeStefano F et al. (Level II-2): Long-term risk of menstrual disturbances after tubal sterilization. Am J Obstet Gynecol 1985; 152:835-41. http://www.ncbi.nlm.nih.gov/pubmed/4040707.

- Foulkes J, Chamberlain G. (Level II-3): Effects of sterilization on menstruation. South Med J 1985;78:544-7. http://www.ncbi.nlm.nih.gov/pubmed/3992301.

- Rivera R et al. (Level I): Menstrual patterns and progesterone circulating levels following different procedures of tubal occlusion. Contraception 1989;40:157-69. http://www.ncbi.nlm.nih.gov/pubmed/2758840.

- Sahwi S et al. (level I): Changes in menstrual blood loss after four methods of female tubal sterilization. Contraception 1989;40:387-98. http://www.ncbi.nlm.nih.gov/pubmed/2582767.

- Thranov I et al. (Level I): Hormonal and menstrual changes after laparoscopic sterilization by Falope-rings or Filshie-clips. Fertil Steril 1992;57:751-5. http://www.ncbi.nlm.nih.gov/pubmed/1532561.

- Rulin MC et al. (Level II-2): Long Term effect of tubal sterilization on menstrual indices and pelvic pain. Obstet Gynecol 1993;82:118-21. http://www.ncbi.nlm.nih.gov/pubmed/8515910.

10.5 Appendix 5: Menstrual changes post-Essure placement

Studies with data on menstrual changes post-Essure placement

Study	Location / Design	Findings
Kerin JF, Munday D, Ritossa M, Rosen D. Tissue encapsulatin of the proximal Essure micro-insert from the uterine cavity following hysteroscopic sterilization. J Minimally Inv Gynecol. Mar-Apr 2007;14(2):202-204. http://www.sciencedirect.com/science/article/pii/S1553465006005474#	US, multicenter / Retrospective observational study of 545 women who underwent Essure placement, 1997-2005	Of the 545 placements, 20 (3.7%) required a subsequent diagnostic second look hysteroscopy for abnormal and/or heavy bleeding. Mean interval to second look, 19.73 months (SD 11.74). Findings included 2 endocervical polyps, 3 endometrial polyps, 1 submucosal myoma, 1 case benign hyperplasia. No evidence of visual epithelial abnormalities, tissue inflammation or abnormal vascular patterns.
Sinha D, Kalathy V, Gupta JK, Clark TJ. The feasibility, success and patient satisfaction associated with outpatient hysteroscopic sterilization. BJOG 2007 Jun:114(6):676-683. http://www.ncbi.nlm.nih.gov/pubmed/17516957	UK / Prospective cohort study, 112 consecutive Essure placements	Successful placement 103/112 (92%); HSG in 84/112 (75%); 100% tests satisfactory. 76/84 (90%) returned questionnaire. At 3 months: 20/76 (26%) reported persistent change in menstrual pattern, 14/76 (18%) reported heavier, 2/76 (3%) reported irregular, 1/76 (1%) reported intermenstrual spotting, 3/76 reported amenorrhea.
Miño M, Arjona JE, Cordón J, Pelegrin B, Povedano B, Chacon E. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. BJOG. 2007 Jun;114(6):763-6. http://www.ncbi.nlm.nih.gov/pubmed/?term=17516970.	Spain / Single center, prospective study of 857 women undergoing Essure	Successful placement 857/863(99%); 3 month follow up 100%. On survey, no woman reported any change to volume or pattern of menstruation.
Chern B and Siow A. Initial Asian experience inhysteroscopic sterilization using the Essure permanent birth control device. BJOG: an International J Obstet Gynecol. 2005;Sep(112):1322-1327. http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2005.00436.x/full).	Singapore / Retrospective study, June 2001-December 2002, 80 women undergoing Essure placement	Successful placement: 77/80 (96.2%); 3 month confirmation test 67/77 (87%), 100% satisfactory; at 3 month follow up, no patient complained of menstrual disturbance.
Ubeda A, Labastida R, Dexeus S. Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting. Fertility & Sterility, Volume 82, Issue 1, July 2004, Pages 196–199. http://www.ncbi.nlm.nih.gov/pubmed/15237011.	Spain / Prospective, observational study 85 women, July 2002 – July 2003	Successful placement: 81/85 (95%); 3 month confirmation test 75/81 (93%), 100% satisfactory. No patients reported change to menstrual pattern.
Anderson S, Eriksson S, Mints M. Acta Obstet Gynecol Scand. 2009;88(6):743-6. Hysteroscopic female sterilization with Essure in an outpatient setting. http://www.ncbi.nlm.nih.gov/pubmed/19412802.	Sweden / Retrospective review of 61 women who had Essure placed 2002-2007. Questionnaires sent 1-5 years post-procedure	Successful placement: 58/61 (95%); 3 month confirmation test 100%; 57/58 (98%) confirmation tests satisfactory. Questionnaire sent to all women; 50/61 (82%) returned. 9/50 (18%) reported heavier periods (none sought treatment) and 8/50 (16%) reported lighter periods.

US = United States; UK = United Kingdom; SD = standard deviation; HSG = hysterosalpingogram.

10.6 Appendix 6: Instructions for Use

ESSURE®

permanent birth control

INSTRUCTIONS FOR USE

essure®
permanent birth control

BAYER

Instructions for use	**English**	**USA only ⚠**	**1 - 6**
Instrucciones de uso	**Español**		**7 - 10**
Mode d'emploi	**Français**		**11 - 14**
Gebruiksaanwijzing	**Nederlands**		**15 - 18**
Gebrauchsanweisung	**Deutsch**		**19 - 22**
Brugsanvisning	**Dansk**		**23 - 26**
Instructions for use	**English**	**Outside the USA only ⚠**	**27 - 30**
Istruzioni per l'uso	**Italiano**		**31 - 34**
Bruksanvisning	**Norsk**		**35 - 38**
Instruções de utilização	**Português**		**39 - 42**
Bruksanvisning	**Svenska**		**43 - 46**
Käyttöohjeet	**Suomi**		**47 - 50**
Οδηγίες Χρήσης	**Ελληνικά**		**51 - 54**

English USA only

essure®
Permanent Birth Control

BAYER

INSTRUCTIONS FOR USE

IMPORTANT

- Caution: Federal law restricts this device to sale by or on the order of a physician. Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the **Essure**® training program, including preceptoring in placement until competency is established, typically 5 cases.

IMPORTANT

- Patient should not rely on **Essure** inserts for contraception until an **Essure** Confirmation Test [modified hysterosalpingogram (HSG)] demonstrates bilateral tubal occlusion **and** satisfactory location of inserts.
- If **Essure** inserts cannot be placed bilaterally, then the patient should not rely on **Essure** inserts for contraception. The effectiveness of the **Essure** procedure when unilateral insert placement occurs has not been evaluated.
- This product does not protect against HIV infection or other sexually transmitted infections.

I. OVERVIEW OF ESSURE PROCEDURE AND PRINCIPLES OF OPERATION

Step 1: **Essure** insert placement procedure ("procedure").

Step 2: Patient must remain on alternative contraception until **Essure** Confirmation Test (modified HSG).

Step 3: **Essure** Confirmation Test (modified HSG) must show fallopian tube satisfactory insert location and occlusion before the patient can rely on **Essure** for contraception.

Using a transvaginal approach, one flexible **Essure** insert ("insert") is placed in the proximal portion of each fallopian tube lumen. The insert expands upon release to conform to and acutely anchor in the tubal lumen. Subsequently, the insert elicits a benign tissue in-growth that permanently occludes the fallopian tube, resulting in contraception.

II. DEVICE DESCRIPTION

The **Essure** system ("system") is comprised of a disposable delivery system and a wound-down insert. A disposable introducer is also provided to facilitate delivery system entry into the hysteroscope operating channel. The insert consists of a super-elastic Nitinol outer coil and a stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers. The wound-down insert is approximately 4 cm in length and 0.8 mm in diameter (**Figure 1a**). When released, the outer coil expands up to 2.0 mm in diameter, conforming itself to the varied diameters and shapes of the fallopian tube (**Figure 1b**).

Figure 1a
Essure Insert
Wound-down configuration, attached to the delivery system
(NOT TO SCALE)

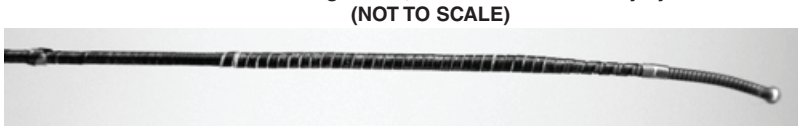
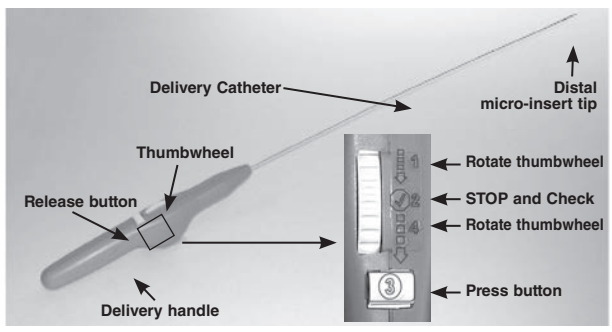


Figure 1b
Essure Insert
Expanded configuration, detached from the delivery system
(NOT TO SCALE)

The disposable delivery system, (shown in **Figure 2**), consists of a delivery wire, a release catheter, a delivery catheter and a delivery handle.

NOTE: The delivery wire and the release catheter are not visible in Figure 2.

Figure 2
Essure System
Showing detail of placement procedure symbols.
(NOT TO SCALE)



The wound-down insert is attached to a Nitinol delivery wire and sheathed by a flexible delivery catheter. A black positioning marker on the delivery catheter aids in proper insert placement.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts the delivery catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to deploying the outer coils. The delivery wire is detached from the insert by continuing to rotate the thumbwheel. To remind the physician of these placement procedure steps, symbols are located on the delivery handle (refer to **Figure 2**).

The **DryFlow**® introducer ("introducer") (**Figure 3**) helps facilitate entry and advancement of the insert during insertion into the hysteroscope, also minimizing fluid back splash. (Additional introducers are available.)

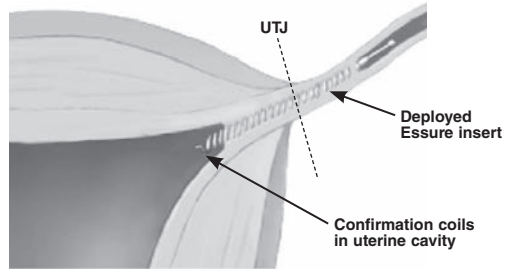
Figure 3
DryFlow Introducer
(NOT TO SCALE)

III. MECHANISM OF ACTION

A. Placement at Utero-Tubal Junction

Proper placement occurs when the insert spans the utero-tubal junction (UTJ) (**Figure 5**). This location is distal enough to avoid expulsion, yet proximal enough to visualize trailing coils to show placement.

Figure 4:
Ideal Essure Insert Placement



B. Dynamic Anchoring

The insert is a dynamic and flexible spring-like device. The outer coil expands upon deployment, conforms to and pushes against the fallopian tube wall, acutely anchoring the insert in the UTJ.

C. Tubal Occlusion and Tissue In-Growth

Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention and pregnancy prevention.

IV. INDICATIONS FOR USE

Essure is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

V. CONTRAINDICATIONS

Contraindicated for patients who:

- Are uncertain about ending fertility.
- Can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus).
- Have previously undergone a tubal ligation.
- Are pregnant or suspect pregnancy.
- Have delivered or terminated a pregnancy less than 6 weeks prior to the **Essure** procedure.
- Have an active or recent upper or lower pelvic infection.
- Have a known allergy to contrast media.

VI. WARNINGS

- Pregnancies (including ectopic pregnancies) have been reported among women with inserts in place. Some of these pregnancies were due to patient non-compliance, which included failure to:
  - o use alternate contraception during the 3-month "waiting period" prior to **Essure** Confirmation Test (modified HSG);
  - o return for the **Essure** Confirmation Test (modified HSG) to determine if the inserts are in the correct location and tubal occlusion is present; and
  - o use alternate contraception or undergo sterilization by another method if the **Essure** Confirmation Test (modified HSG) reveals tubal patency. In this case, the clinician should inform the patient of the **Essure** Confirmation Test (modified HSG) finding and counsel her not to rely on the **Essure** System for contraception.

  Therefore, it is critical that clinicians properly counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all stages of the **Essure** procedure.
- Physicians performing the **Essure** procedure must adhere to the **Essure** Confirmation Test (modified HSG) protocol in these Instructions for Use. The protocol for interpretation of the **Essure** Confirmation Test (modified HSG) is different from a standard HSG for infertility. In addition to patient noncompliance, incorrect interpretation of the **Essure** Confirmation Test (modified HSG) has led to pregnancy.
- The **Essure** procedure should be considered irreversible. Safety or effectiveness of reversal surgery is unknown.
- Effectiveness rates for the **Essure** procedure are based on patients who had bilateral placement. Little effectiveness data exist for unilateral insert placement in patients with unicornuate uteri or contralateral proximal tubal occlusion (PTO).
- Do not attempt hysteroscopic **Essure** insert removal once placed unless 18 or more trailing coils are seen inside the uterine cavity. Attempted removal with less than 18 trailing coils may result in fractured insert, fallopian tube perforation or other injury.
- To reduce risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- The **Essure** insert may conduct energy and cause patient injury if contacted by an active electrosurgical device. Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts. During Laparoscopically Assisted Vaginal Hysterectomy, do not place instruments more proximal than the ampullary portion of the tube.
- Avoid direct contact between inserts and monopolar radio frequency (RF) energy instruments as bench studies suggest damage to surrounding tissue should monopolar RF instruments contact inserts.
- Patients undergoing immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) are discouraged from undergoing the **Essure** procedure because the immunosuppressant may lead to decreased tissue in-growth.
- To reduce risk of uterine perforation, terminate procedure if excessive force is required to achieve cervical dilation.
- Never attempt to advance **Essure** insert(s) against excessive resistance. If tubal or uterine perforation occurs or is suspected, discontinue procedure and work-up patient for possible complications related to perforation, including hypervolemia. A false positive HSG and pregnancy have been associated with tubal perforation by insert in the literature; evaluate **Essure** Confirmation Test for perforation if excessive resistance is experienced during procedure. Only 1.8% (12/682) of clinical trial patients had device related perforations. If necessary, retrieval of perforating inserts requires surgery.
- Some **Essure** patients have reported pelvic pain that may be device related. If device removal is indicated, this will require surgery. (refer to section XVIII. INSERT REMOVAL)
- Effects, including risks, of **Essure** inserts on in vitro fertilization (IVF) have not been evaluated. Risks to the patient, fetus and continuation of pregnancy are unknown.
- The Essure micro-insert includes nickel-titanium alloy, which is generally considered safe. However, *in vitro* testing has demonstrated that nickel is released from this device. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. In addition, some patients may develop an allergy to nickel if this device is implanted. Typical allergy symptoms reported for this device include rash, pruritus, and hives.

Essure and Global Endometrial Ablation

- DO NOT perform the **Essure** procedure concomitantly with endometrial ablation. Ablation causes intrauterine synechiae which can compromise (i.e. prevent) the **Essure** Confirmation Test (modified HSG). Women with inadequate confirmation tests cannot rely on **Essure** for contraception.

  Bench and clinical studies demonstrate balloon thermal (THERMACHOICE® Uterine Balloon System) and hydro-thermal (HTA® System) endometrial ablation can be safely and effectively performed with **Essure** inserts in place. However, balloon thermal and hydro-thermal endometrial ablation should only be performed after the **Essure** Confirmation Test (modified HSG).

  Bench and clinical studies have been conducted which demonstrate that bipolar radio frequency (RF) NovaSure® Impedence Controlled Endometrial Ablation System endometrial ablation of the uterus can be safely performed with **Essure** inserts in place. However, thermal injury to the proximal portion of the fibrotic in-growth that causes tubal occlusion may occur. It is unknown whether partial thermal injury will interfere with tubal occlusion. Contraception rates following NovaSure with **Essure** inserts in place are under investigation.

  Bipolar RF ablation device may contact inserts. As a result of contact, heat from a bipolar RF device may be propagated along the insert. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa. Therefore, do not perform bipolar RF ablation in patients who may have undiagnosed perforation e.g., patients whose **Essure** procedure was difficult or atypical.

  Performing intrauterine procedures without direct visualization may result in trailing coils of insert being ensnared in another device. When device is withdrawn, the insert may be removed and tubal patency be restored. In one study, the risk of insert being ensnared by a bipolar RF endometrial ablation array was approximately 3%.

  Note: All trademarks are property of their respective companies.

- Safety of cryo-ablation, laser-ablation, or microwave ablation with **Essure** inserts in place is unknown and little data exist. Microwave energy near metallic implants may pose risk of serious patient injury; therefore avoid use of microwave endometrial ablation devices near inserts.

VII. PRECAUTIONS

- Women undergoing sterilization at a younger age are at greater risk of regretting their decision.
- Perform the **Essure** procedure during early proliferative phase of the menstrual cycle to increase ostia visualization and prevent placement in a patient with an undiagnosed (luteal phase) pregnancy. Women with menstrual cycles shorter than 28 days should undergo careful ovulation day calculations.
- As with any tubal sterilization procedure, performing endometrial ablation following **Essure** insert placement may increase the risk of post-ablation tubal sterilization syndrome.
- Safety and effectiveness of **Essure** is not established in patients under 21 or over 45 years old, nor in patients who delivered or terminated a pregnancy less than 8-12 weeks before procedure.
- Do not advance the **Essure** delivery system once the end of the black positioning marker has reached the tubal ostium as unsatisfactory insert placement could result.
- Use caution and avoid the **Essure** inserts when undertaking blind intrauterine procedures as disturbing the inserts could interrupt their ability to prevent pregnancy. Direct visualization of inserts during intrauterine procedures is optimal. Insert retention and location should be verified by hysteroscopy, X-ray, or ultrasound following intrauterine procedures. There could be risks associated with intrauterine procedures and the presence of inserts not currently identified.
- Have appropriate equipment, medication, staff, and training in place to handle emergency situations such as vaso-vagal response.
- Uterine or fallopian tube anomalies may make it difficult to place **Essure** inserts. Identify and assess both tubal ostia prior to insert placement. Do not attempt to place an insert in one tubal ostium unless there is a reasonable expectation that the contralateral tube is accessible and patent.
- Do not advance the **Essure** system if the patient is experiencing extraordinary pain or discomfort. Terminate the procedure and work-up patient for possible perforation.
- Never attempt to re-sterilize the **Essure** system as it is single use only. Resterilization may adversely affect device function or cause patient injury.
- Utilize eye protection as back splash of hysteroscopic distention fluid (saline) into face can occur.
- Use an introducer to avoid insert tip damage.
- Keep the operating channel of the hysteroscope open to avoid damage to insert or introducer.
- Do not place more than one **Essure** insert in a single fallopian tube.
- Do not use **Essure** if sterile package is open or damaged, or if insert is damaged.
- ***MRI Information.*** The **Essure** insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

  Non-clinical testing demonstrated that the **Essure** insert is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

  -Static magnetic field of 3-Tesla or less

  -Maximum spatial gradient magnetic field of 720-Gauss/cm or less

  MRI-Related Heating

  In non-clinical testing, the **Essure** insert produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.7°C

  Therefore, the MRI-related heating experiments for the **Essure** insert at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 3.0-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.8-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C.

  Artifact Information

  MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **Essure** insert. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

  Dimensions: Wound-down and expanded length: 4-cm
  Expanded diameter: 1.5 to 2.0-mm

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	173-mm^2	53-mm^2	621-mm^2	277-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

VIII. ADVERSE EVENTS

A. Patient Population

From November 1998 - June 2001, a total of 745 women underwent the **Essure** procedure in two clinical trials that evaluated safety and effectiveness (227 Phase II; 518 Pivotal[1]). Placement of at least one insert was achieved in 682 women (206 Phase II study; 476 Pivotal). If bilateral placement was not initially achieved, some women underwent additional procedure(s).

B. Observed Adverse Events

Adverse events resulting from the placement procedure are detailed in Table 1.

Table 1
Adverse events reported day of placement procedure in Phase II & Pivotal Trials

Adverse Event/ Side Effect	Phase II Trial		Pivotal Trial	
	Number (N=233 procedures)	Percent	Number (N=544 procedures)	Percent
Cramping	**	**	161	29.6%
Pain	2	0.9%	70	12.9%
Nausea/vomiting	**	**	59	10.8%
Dizziness/light headed	**	**	48	8.8%
Bleeding/spotting	**	**	37	6.8%
Other	**	**	16*	2.9%
Vaso-vagal response	2	0.9%	7	1.3%
Hypervolemia	**	**	2	0.4%
Band Detachment	3	1.3%	2	0.4%

*Includes: ache (3), hot/hot flashes (2), shakiness (2), uncomfortable (1), weak (1), profuse perspiration (1), bowel pain (1), sleepiness (1), skin itching (1), loss of appetite (1), bloating (1), allergic reaction to saline used for distension (1).

**Data not collected

During and immediately following the procedure, the majority of participants experienced mild to moderate pain. The majority of participants experienced spotting for an average of 3 days after the procedure. Pain was managed with oral non-steroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

Table 2 summarizes adverse events rated as "possibly" related to the insert or procedure during the first year of reliance in the Pivotal trial (approximately 15 months post-device placement). Percentages reflect the number of *events* divided by the number of *participants* in the trial. When numerous episodes of the same event were reported by one participant, each report was counted as a separate event. Therefore, percentages may over-represent the percentage of *women* who have experienced that event.

Table 2
Pivotal Trial
Adverse Events by Body Systems, First Year of Reliance*
(N=476 patients implanted with at least one insert)

Adverse Events by Body System	Number	Percent
Abdominal:		
Abdominal pain/abdominal cramps	18	3.8%
Gas/bloating	6	1.3%
Musculo-skeletal:		
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
Nervous/Psychiatric:		
Headache	12	2.5%
Premenstrual Syndrome	4	0.8%
Genitourinary:		
Dysmenorrhea/menstrual cramps (severe)	14	2.9%
Pelvic/lower abdominal pain (severe)	12	2.5%
Persistent increase in menstrual flow	9**	1.9%
Vaginal discharge/vaginal infection	7	1.5%
Abnormal bleeding - timing not specified (severe)	9	1.9%
Menorrhagia/prolonged menses (severe)	5	1.1%
Dyspareunia	17	3.6%
Pain/discomfort - uncharacterized:	14	2.9%

* Only events occurring in ≥ 0.5% are reported

** Eight women reported persistent decrease in menstrual flow

In the Phase II trial, 12/206 (5.8%) women with at least one insert reported episodes of period pain, ovulatory pain, or changes in menstrual function.

C. Potential Adverse Events Not Observed in Clinical Studies

The following adverse events were not experienced by Phase II/Pivotal clinical trial participants prior to marketing but are still possible and/or have occurred in the commercial setting:

- Pregnancy and ectopic pregnancy in women relying on **Essure**[2] inserts.
- Perforation of internal bodily structures other than the uterus and fallopian tube.
- Adnexal infection/salpingitis.
- Adverse events associated with the **Essure** Confirmation Test (modified HSG).
- Pregnancy due to uterine or fallopian tube procedures causing failure of insert.
- Adverse events associated with surgery attempting to reverse the procedure, pregnancy following a reversal, or an IVF procedure.
- Adverse events associated with gynecologic surgical procedures (e.g. endometrial ablation).

D. Adverse Event Reporting

Report any adverse event involving the Essure system to *Bayer HealthCare LLC* immediately by calling 888-84 BAYER (888-842-2937).

IX. CLINICAL STUDIES

A. Purpose of the Study, Study Design, Primary Endpoints

Two clinical trials were conducted (Phase II Trial; Pivotal Trial) prior to marketing to demonstrate safety and effectiveness of the **Essure** system in providing permanent contraception. Additionally, two studies were performed after pre-marketing approval to evaluate rates of bilateral **Essure** placement, however, the study using the ESS305 is the only post approval study presented in this label.

1. Phase II Trial

Phase II was a prospective, multi-center, single-arm, non-randomized, international study which evaluated:

- Participant's tolerance of, and recovery from, procedure
- Safety of the procedure
- Participant's tolerance of implanted inserts
- Long-term safety and stability of implanted inserts
- Effectiveness of the inserts in preventing pregnancy

2. Pivotal Trial

The Pivotal trial was a prospective, multi-center, single-arm, non-randomized, international study which used the U.S. Collaborative Review of Sterilization (CREST study) as a qualitative benchmark. The study included the following primary endpoints:

- Prevention of pregnancy
- Safety of insert procedure
- Safety of insert wearing

Secondary endpoints included:

- Participant satisfaction with procedure
- Participant satisfaction with insert wearing
- Bilateral device placement rate
- Profile development for appropriate procedure candidates

[1] Pivotal trial: 657 women initially enrolled; 518 underwent the procedure; 99 changed their minds about participating; 23 did not meet the inclusion criteria and were terminated from study; 17 failed screening tests.

[2] One Phase II trial participant received a prior device design that was discontinued in 1998 (the Beta design of the STOP device) and became pregnant after nearly two years of reliance. That pregnancy is not included in the effectiveness rate calculations, since that design was not subject of the Premarket Approval Application (PMA) supporting **Essure** approval.

3. **ESS305 Post Approval Study**

The ESS305 Post Approval Study was a prospective, multi-center, single-arm, non-randomized United States study intended to document the bilateral placement rate using the ESS305 delivery system. The main primary endpoint for the study was successful bilateral placement rate at first attempt.

B. Patients Studied

Table 3
Age Distribution (Combined Data from Pivotal Study and Phase II Study); Average age: 33

<28 years old	28-33 years old	≥34 years old
14%	40%	46%

Table 4
Patient Demographics

	Phase II and Pivotal Studies Combined N=745
Race*	
White/Caucasian	**428**
Latin	**31**
Black	**24**
Other	**9**
Gravidity	**Mean=2.91 (0 – 11)**
Parity	**Mean=2.23 (0 – 6)**
Body Mass Index (BMI) (kg/m^2)	**Mean=27 (16 – 57)**

* Data from Pivotal study only; race not collected in Phase II study.

1. The Phase II and Pivotal trials combined consisted of 664 participants in whom bilateral insert placement was achieved after one or more attempts (200 Phase II study; 464 Pivotal). Tables 6 and 7 present patient demographic information. Participants were between 21 and 45 years of age and seeking permanent contraception. All participants had at least one live birth, regular menstrual cycles and were willing to use alternative contraception for the three months following the procedure.

2. The study population of the ESS305 Post Approval Study consisted of 581 women in whom insert placement was attempted using the ESS305 delivery system. A total of 70 investigators performed the procedures at 70 US sites. All study participants were between 21 and 51 years of age and were seeking permanent contraception prior to enrollment.

C. Methods

All Phase II and Pivotal Trial participants were screened for eligibility. Medical history, physical examination and required laboratory tests were performed.

Insert placement was attempted in each fallopian tube. In the Pivotal trial, pelvic X-rays were performed within 24 hours of placement to serve as a baseline evaluation of insert location. Participants used alternative contraception for three months following the procedure.

An **Essure** Confirmation Test (modified HSG) was performed three months post procedure to evaluate insert location and fallopian tube occlusion. If bilateral placement and occlusion were satisfactory, participants discontinued alternative contraception and relied on the inserts for contraception.

D. Results

As of the final 5-year follow-up data extracts (Phase II-January 6, 2006; Pivotal-December 5, 2007), 643 trial participants with bilateral placement (194 Phase II; 449 Pivotal) contributed 35,633 months of follow-up time with zero pregnancies reported. Adverse events reported in Pivotal and Phase II clinical studies conducted prior to marketing are provided in Section VIII B above, and events by study are below. Tables 5A, 5B and 6 present principal safety and effectiveness results.

Table 5A
Insert Reliance Rates
in the Phase II and Pivotal Clinical Studies

Outcome	**Phase II and Pivotal Trials N=745**	
	Number	**Percent**
Reliance Rate*: *Among women with bilateral placement*	643/664	97%

*The reliance rate is the number of women who relied on **Essure** for contraception divided by the number of women with bilateral insert placement. In the Phase II trial, the following adverse events prevented reliance: Perforation (7/206; 3.4%, including one patient that that relied for 31 months before laparotomy and cornual resection due to pain, the other six never relied); Expulsion (1/206; 0.5%); Unsatisfactory insert location (1/206; 0.5%); Initial tubal patency (7/200; 3.5%) was found at the 3-month Essure Confirmation Test (modified HSG), however, all had tubal occlusion at a 6-month repeat **Essure** Confirmation Test (modified HSG). In the Pivotal trial, the following adverse events prevented reliance: Perforation (5/476; 1.1%); Expulsion (14/476; 2.9%, nine out of the fourteen underwent a successful second placement procedure; Unsatisfactory insert location (3/476; 0.6%); Initial tubal patency (16/456; 3.5%) was found at the 3-month **Essure** Confirmation Test (modified HSG), however, all had tubal occlusion at a 6 or 7-month repeat **Essure** Confirmation Test (modified HSG).

Table 5B
Insert Placement Rate at first attempt in the Commercial Setting
Using the Essure System ESS305

Placement Status	**ESS305 Post Approval Study**	
	Number	**Percent**
Bilateral Placement*:	593/612	96.9%
Intent-to-Treat Bilateral Placement**:	593/619	95.8%
Unilateral Placement or No devices placed***:	26/619	4.2%

*Bilateral placement rate excludes seven patients in whom insert placement was not attempted.

** Intent-to-treat bilateral placement rate includes all participants who underwent hysteroscopy regardless of whether insert placement was attempted.

*** Unilateral placement occurred in 10 participants; 6 participants had no placement in either fallopian tube; insert placement was not attempted in 7 participants. Tubal obstruction and visualization problems due to uterine anatomy were the most common reasons for placement failure.

Table 6
Effectiveness Results as of December 2007

CUMULATIVE FAILURE RATES Phase II and Pivotal Trials Combined				
One-Year[C]	**Two-Year[C]**	**Three-Year[C]**	**Four-Year[C]**	**Five-Year[C]**
0% **N=635** (95% CI 0 – 0.10%)[A, B]	**0%** **N=605** (95% CI 0 – 0.20%)[A, B]	**0%** **N=586** (95% CI 0 – 0.30%)[A, B]	**0%** **N=567** (95% CI 0 – 0.40%)[A, B]	**0%** **N=567** (95% CI 0 – 0.50%)[A, B]

[A] 95% confidence intervals are based on a "constant-hazard" exponential failure-time model, whose parameter is determined by the total number of woman-months accumulated during the trial.

[B] Combined effectiveness data obtained using Bayesian statistics.

[C] The number of women "N" were considered to have completed follow-up at 1 year if patient contact occurred at ≥ 11 months, 2 years if contact occurred at ≥ 23 months, 3 years if contact occurred at ≥ 35 months, 4 years if contact occurred ≥ 47 months and 5 years if contact occurred at ≥ 59 months.

No pregnancies were reported in the clinical trials. However, no method of contraception is 100% effective and pregnancies have occurred in the commercial setting.

Effectiveness rates for the **Essure** procedure compare quite favorably to the effectiveness rates for other methods of tubal sterilization at these time points.

X. ESSURE EFFECTIVENESS IN THE COMMERCIAL SETTING

In the commercial setting, unintended pregnancies have been reported in women who have worn the inserts.

Table 7 summarizes the reasons for pregnancy from reports received by Bayer HealthCare LLC and additional reports from the published scientific literature.

Table 7: Summary of Pregnancies Reported in Commercial Use of Essure*

Potential Contributing Factor	**United States**		**Outside the United States****		**Total**	
	n	**% of US causes**	**n**	**% of OUS causes**	**n**	**%**
Patient Non-compliance (e.g., failure to use alternate contraception or return for **Essure** Confirmation Test)	213	32%	16	18%	229	31%
Perforation*** / #	91	14%	4	5%	95	13%
Unsatisfactory Placement***	32	5%	13	15%	45	6%
Physician Non-compliance	22	3%	13	15%	35	5%
Pregnant at time of Placement (Luteal)	26	4%	6	7%	32	4%
Inadequate Confirmation Test***	28	4%	0	0%	28	4%
Expulsion***	20	3%	4	5%	24	3%
Tubal Patency***	19	3%	1	1%	20	3%
Insufficient Information to determine	209	32%	31	35%	240	32%
Total	660		88		748****	

*Table includes pregnancy reports received directly by Bayer HealthCare LLC, recorded in the FDA MAUDE database and reported in the scientific literature; data reported to FDA in PMA Annual Reports. Pregnancies in **Essure** patients may be underreported.

Outside of the United States, the **Essure Confirmation Test may be an x-ray or transvaginal ultrasound; device location alone, not occlusion, is primarily used to determine whether the patient may rely on **Essure**.

*** Most of these pregnancies are due to misinterpreted **Essure** Confirmation Tests. Please note that many misinterpretations are due to the fact that occlusion is seen on the HSG films even though the insert is not properly located.

****Number of pregnancies reported from worldwide commercial launch in 2001 through end of 2010. 497,306 **Essure** kits sold during this time. Note that an accurate pregnancy rate is difficult to obtain as the number of devices actually implanted is not known.

#The causal association cannot be established between the perforation and the pregnancy. However, perforations have been identified in pregnant women who were relying on **Essure** for contraception.

The majority of unintended pregnancies are preventable. Most unintended pregnancies are related to patient non-compliance and physician misinterpretation of the **Essure** Confirmation Test. In order to ensure maximum contraceptive effectiveness by **Essure**, the physician should ensure that the patient is properly counseled in accordance with Section XI. It is also important to evaluate both insert location and occlusion carefully before telling the patient that she may rely on **Essure** for contraception.

References

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Table 8 provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

Table 8
Pregnancy Rates for Birth Control Methods
(For One Year of Use)

Method	**Typical Use Rate of Pregnancy**
Sterilization:	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods:	
Implant *(Norplant ™ and Norplant ™ 2)*	0.05%
Hormone Shot *(Depo-Provera™)*	3%
Combined Pill *(Estrogen/Progestin*) and Progestin-only Pill	8%
NuvaRing	8%
Ortho Evra	8%
Intrauterine Devices (IUDs):	
Copper T *(ParaGard*)	0.8%
LNG-IUS *(Mirena)*	0.2%
Barrier Methods:	
Male Latex Condom[1]	15%
Diaphragm[2]	16%
Female Condom	21%
Spermicide: *(gel, foam, suppository, film)*	29%
Natural Methods:	
Withdrawal	27%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%
No Method:	85%

[1] Used Without Spermicide [2] Used With Spermicide

Data adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive Technology: Nineteenth Revised Edition. New York NY: Ardent Media, 2007.

XI. PATIENT SELECTION AND COUNSELING

Consider risks and benefits as described in Sections VIII and IX.

A. Patient selection factors should include:

- Certainty about desire to end fertility
- Evaluation for pelvic infection, cervicitis, undiagnosed vaginal bleeding, anatomical variants and/or uterine pathology that may make patient unsuitable for procedure

The decision to undergo treatment is at patient discretion, following physician counseling and informed consent.

IMPORTANT: Counsel patients that this product does not protect against either HIV infection or other sexually transmitted infections.

B. Patient counseling should include the following:

- Patient must use alternative contraception (except an IUD or IUS) for three months post-procedure until insert placement and fallopian tube occlusion is confirmed by the **Essure** Confirmation Test (modified HSG). Notify patient that alternative contraception is critical due to a theoretical increased risk of ectopic pregnancy. Ensure patient is supplied with the most effective means of contraception for which she is a candidate during this time frame.
- The Patient Information Booklet details risks associated with placement and wearing of the inserts.
- The procedure is permanent, and irreversible.
- Like all birth control methods, there is a risk of pregnancy.
- Bilateral insert placement may not be successful. Discuss a management plan with the patient in the event that bilateral placement is not achieved.

XII. HOW SUPPLIED

Each **Essure** kit contains:

- Two (2) **Essure** systems
- Two (2) **DryFlow** Introducers
- One (1) Instructions for Use (IFU)
- One (1) Patient Identification Card

The **Essure** system is available in one size only.

STERILE: Each **Essure** system is supplied sterile. Do not reuse or resterilize. Inspect each package and do not use if damaged.

STORAGE: Store in a cool, dry place.

XIII. PHYSICIAN TRAINING MANUAL

Refer to the **Essure** Physician Training Manual for detailed information not included in this IFU.

XIV. DIRECTIONS FOR USE

A. Prior to Insert Placement Procedure

1. Perform procedure during early proliferative phase of the menstrual cycle to increase ostia visualization and prevent placement in a patient with an undiagnosed (luteal phase) pregnancy. Women with menstrual cycles shorter than 28 days should undergo careful ovulation day calculations. Insert placement should not be performed during menstruation.
2. Administer a pregnancy test within 24 hours prior to the procedure.
3. Administration of nonsteroidal anti-inflammatory drugs (NSAIDs) is strongly recommended 1-2 hours pre-procedure as this was shown to increase likelihood of placement success in clinical trials. To reduce anxiety, an anxiolytic agent may be given 30 minutes before the procedure.

B. Essure Insert Placement Procedure

1. Use universal precautions and sterile technique.
2. Check all equipment for damage; ensure there are no missing parts.
3. Place patient in the lithotomy position. Use under buttocks drape with fluid control pouch for fluid management.
4. Introduce speculum to allow cervical access. Prep cervix with betadine or other antibacterial solution according to standard practice.
5. Administer anesthesia, preferably local block with or without IV sedation.
6. Insert sterile hysteroscope, with camera and operating channel (≥ 5 French), through cervix into uterine cavity, and remove speculum. Do not perform cervical dilation unless necessary; if necessary, dilate only enough for hysteroscope insertion.
7. Distend uterus with a pre-warmed physiologic saline solution. Maintain uterine distension throughout procedure for optimal visualization. Use gravity feed to minimize tubal spasm and over-distension. Monitor fluids to reduce the risk of hypervolemia; terminate procedure if fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes.
8. Identify and assess both tubal ostia prior to insert placement. Do not attempt placement in one tubal ostium unless expectation of contralateral tubal patency exists.
9. Insert introducer through sealing cap on the operating channel of the hysteroscope. Keep the channel open to avoid damage to the device and introducer.
10. Insert delivery catheter through the introducer; avoid bending the insert tip. Under direct visualization, advance catheter through the operating channel into the proximal fallopian tube with gentle, constant forward movement to prevent tubal spasm. If excessive resistance occurs (i.e. catheter does not advance toward tubal ostium and/or catheter bends or flexes excessively), terminate procedure to avoid uterine perforation or placement into a false passage.

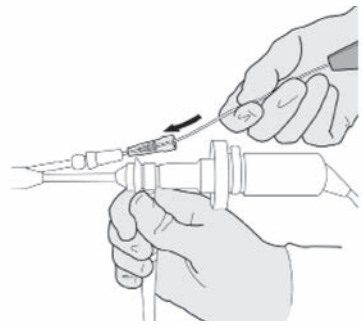


Figure 5: Insert the introducer through sealing cap on the hysteroscope operating channel, then place delivery catheter through the introducer.

11. Align the proximal end of the black positioning marker with the ostium. Proper alignment leads to ideal placement for the insert, with the outer coil spanning the uterotubal junction. Do not rotate the thumbwheel until the marker is properly aligned.

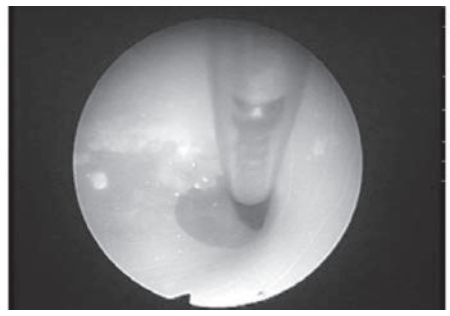


Figure 6: Advance until black positioning marker at tubal ostium, indicating proper position.

12. Stabilize the delivery system handle against the hysteroscope to prevent inadvertent forward movement. Refer to the Physician Training Manual for techniques for stabilizing the handle.

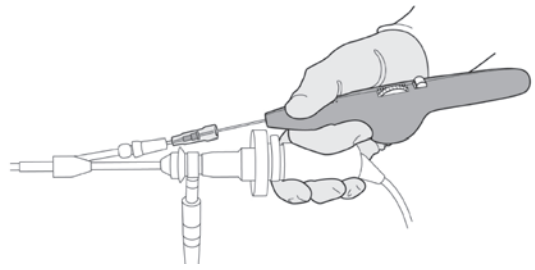


*Figure 7: Stabilize handle against camera head or some other fixed object to prevent inadvertent forward movement of the **Essure** system*

Before proceeding with the **Essure** procedure, recall that two distinct operations will take place. The first is retraction of the delivery catheter away from the insert, prior to actual detachment of the insert. Full retraction is accomplished by rotating the thumbwheel to the point where you cannot rotate the thumbwheel any further. Actual detachment is accomplished after retraction by pressing the handle button and then continuing to rotate the thumbwheel. Only after detachment of the insert has occurred can you remove the delivery system.

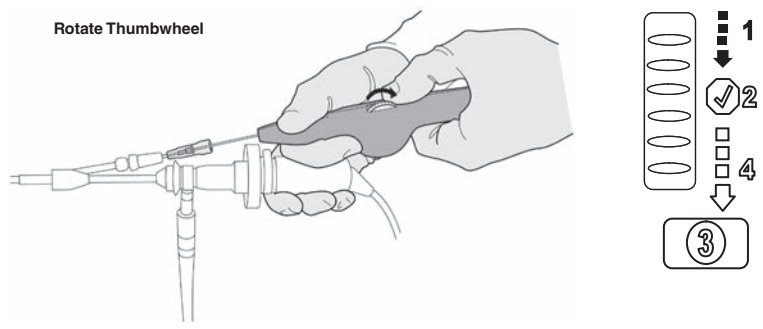


Figure 8: Rotate thumbwheel to retract delivery catheter, exposing wound down insert

13. Rotate the thumbwheel on the handle toward you until the wheel no longer rotates (corresponds to the symbol ⇩1 on the delivery system handle). The delivery catheter and black positioning marker will move away from the tubal ostium and disappear into the operating channel, exposing approximately 1 cm of the wound-down insert.

    NOTE: The thumbwheel cannot be reversed, therefore, ensure that the proximal edge of the black positioning marker is aligned at the ostium before rotating thumbwheel.

14. Stop and check proper positioning, which corresponds to the symbol ✓2 on the delivery system handle. Confirm placement of the gold marker band just outside the ostium, and confirm visualization of the distal tip of the green release catheter. If more than 1 cm of the insert is visible in the uterus, then the insert should be repositioned by moving the entire system further into the tube, if possible.

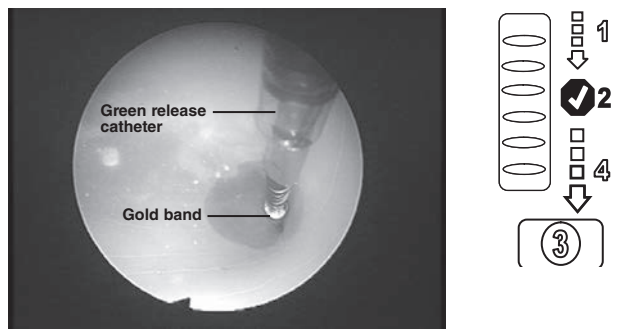


Figure 9: Visualize gold band at ostium and green release catheter.

15. Press the button on the delivery handle which corresponds to the symbol ③ on the handle button. This enables the thumbwheel to be rotated further for insert deployment.

    NOTE: DO NOT PUSH THE BUTTON until delivery system is in correct position for insert placement.

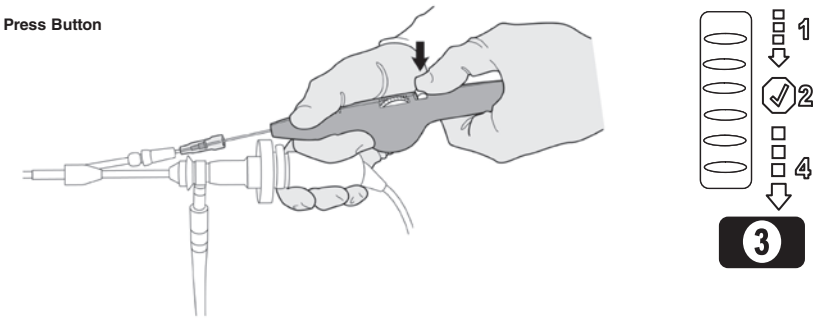


Figure 10: Press button to enable the thumbwheel to rotate again.

16. Rotate the thumbwheel once more (symbol 4) until the thumbwheel cannot turn any further. When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, remove the delivery system.

    Note: Hold the valved introducer in place during removal of the delivery system as it may also be inadvertently withdrawn. If the introducer is removed, replace with a new introducer provided in the **Essure** system packaging.

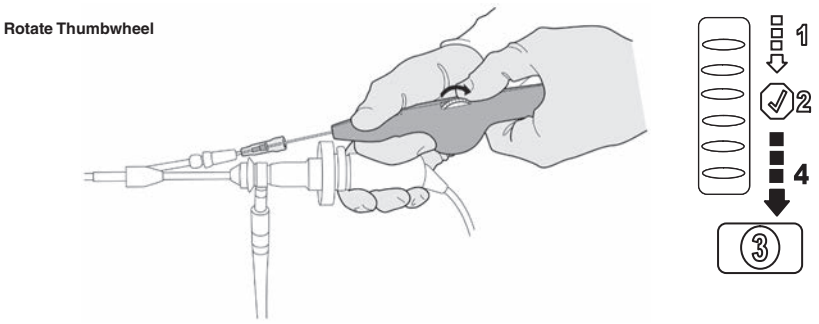


Figure 11: Rotate thumbwheel to allow outer coils to expand and release the insert from the delivery system

17. Repeat procedure in contralateral fallopian tube.

C. Assessment of Insert After Deployment

1. Assess insert position immediately after deployment. Inserts showing 0-17 trailing coils should be left in place and evaluated via **Essure** Confirmation Test (modified HSG). Ideally, 3 to 8 expanded outer coils should be trailing into the uterus.

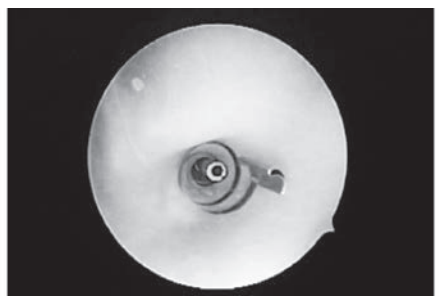


Figure 12: Ideal placement of insert

2. If no trailing coils are visible, examine delivery system upon removal from the hysteroscope. Refer to images below to determine if the insert has been deployed from the delivery system. **IMPORTANT**: If insert was inadvertently deployed in the uterine cavity and not in the tube, remove from uterus and attempt another placement.

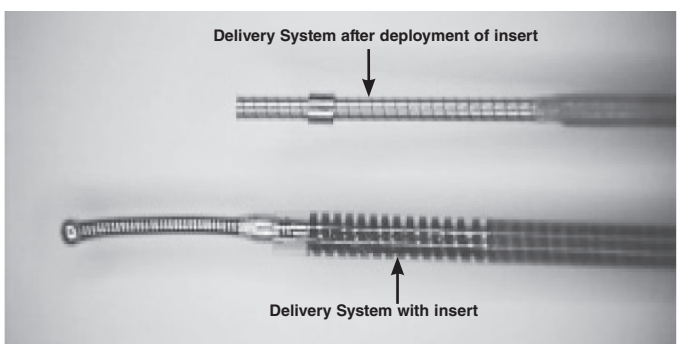


Figure 13: Delivery systems showing absence of insert after deployment (top) and with insert attached (bottom)

WARNING: Do not attempt insert removal hysteroscopically unless 18 or more coils of the Essure insert are trailing into the uterine cavity. Removal of insert may not be possible; attempted removal of inserts having fewer than 18 trailing coils may cause insert to fracture or patient injury.

3. If insert removal is indicated, perform removal immediately after failed placement as follows:
   a – As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.
   b – Introduce a grasping instrument through hysteroscope operating channel.
   c – Grasp both the outer and inner coils of the insert together.
   d – Withdraw the grasping instrument and hysteroscope simultaneously; the insert may stretch or elongate. Do not pull insert through the operating channel.
4. If insert removal is successful, repeat the **Essure** insert placement procedure. If removal is not accomplished, leave insert in place. If insert is not completely removed, do not place additional inserts. Take a diagnostic X-ray to determine if insert fragment remains *in vivo*. If fragment remains, refer to section XVIII Insert Removal.
5. Document procedural concerns. Review during **Essure** Confirmation Test (modified HSG). Note possible perforations due to:
   a. excessive or sudden loss of resistance;
   b. inability to visualize coils;
   c. problems with identification of tubal ostium;
   d. poor distension;
   e. poor illumination;
   f. or poor visualization secondary to endometrial debris.

D. Post Procedure Instructions and Patient Follow-up Requirements

1. Ensure patient uses alternative contraception until the **Essure** Confirmation Test (modified HSG). Counsel patient on theoretical increased risk of ectopic pregnancy.
2. Schedule patient for an **Essure** Confirmation Test (modified HSG) three months following the procedure to evaluate insert location and fallopian tube occlusion.
3. Provide patient with the Patient Identification Card and instruct her to show it to her physicians.

XV. MANAGEMENT OF CASES WITH UNSUCCESSFUL INSERT PLACEMENT

In the event of placement failure, inform patient permanent contraception is not complete.

Counsel patient on undergoing a second procedure, especially if unilateral placement was achieved. In the Pivotal trial, 83% of those who underwent a second procedure achieved bilateral placement. Before a second placement attempt, determine tubal patency by an **Essure** Confirmation Test (modified HSG). Schedule after patient's next menses. If second attempt fails, success with subsequent attempts is unlikely.

If one insert is left *in vivo*, counsel patient to not rely on the insert for contraception. Do not remove a unilaterally placed insert unless the patient experiences an adverse event(s) due to its presence. Three months after bilateral placement, follow-up patient with a second **Essure** Confirmation Test (modified HSG) to verify location and tubal occlusion.

If the patient chooses laparoscopic sterilization, clip or coagulate both fallopian tubes distal or proximal to the insert. Do not perform clipping or coagulation adjacent to or over the insert.

XVI. PERFORMING AND EVALUATING ESSURE CONFIRMATION TEST (MODIFIED HSG) THREE MONTHS POST- INSERT PLACEMENT

The **Essure** Confirmation Test (modified HSG) is performed three months post-placement to evaluate insert location and fallopian tube occlusion. Follow the summary instructions below for performing and evaluating the **Essure** Confirmation Test (modified HSG). For the full protocol, please visit **Essure**MD.com or refer to the Physician Training Manual.

A. Performing the Essure Confirmation Test (modified HSG)

Guidelines:

1. Obtain good cornual filling so that uterine cavity silhouette is clearly seen.
2. Place fluoroscopy beam as close to A/P projection as possible.
3. Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
4. Downward traction on cervical tenaculum may be required for midpositional uteri. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
5. Take a minimum of 6 radiographs to assess insert location and tubal occlusion.

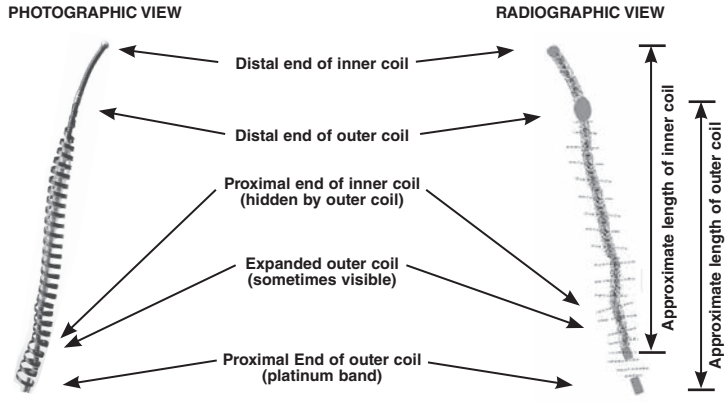


*Figure 14: Corresponding radiographic view of the **Essure** insert*

Radiograph 1 – "Scout Film" - Uterus and inserts without contrast

Radiograph 2 – Minimal Fill of Cavity - uterus and inserts with small amount of contrast

Radiograph 3 – Partial Fill of Cavity - uterus and inserts when nearly full of contrast

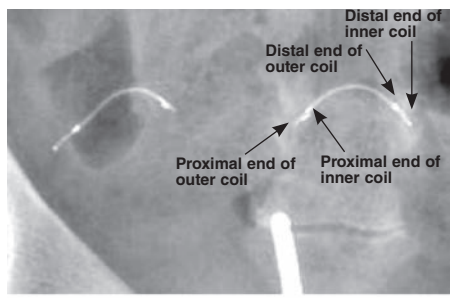
Radiograph 4 – Total Fill of Cavity - uterus and inserts when the cornua is distended by contrast

Radiographs 5 & 6 - Magnifications of uterine cornua - insert within the fallopian tube with right (5) and left (6) cornua

CAUTION: Avoid excessive intrauterine pressure beyond Radiograph 4 to avoid undue patient discomfort and vaso-vagal reaction.

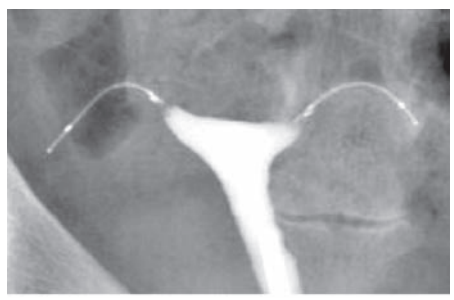
NOTE: Immediately repeat **Essure** Confirmation Test (modified HSG) if insert cannot be located or position is unclear.

Figure 15



Radiograph 1: Scout Film

Figure 16



Radiograph 4: Total Fill of Cavity

B. Assessing Insert Location

During evaluation, note four "markers" at each end of the inner and outer coils. Note that the distal markers are fixed in relation to one another, but the proximal markers may move or seem stretched because of the flexibility of the outer coil. Ideal insert location is when the inner coil crosses the utero-tubal junction.

Assess insert location:

1 – Expulsion or proximal placement: Insert is not present, or ≥ 50% of inner coil trailing into uterine cavity.

2 – Satisfactory placement: Distal end of inner coil is within the tube, with < 50% of inner coil trailing into the uterine cavity, or proximal end of inner coil ≤ 30 mm into tube from where contrast fills cornua.

3 – Distal placement or perforation: Insert is in tube but proximal end of the inner coil > 30mm distal from where contrast fills cornua or the insert is completely or partially perforated.

C. Assessing Tubal Occlusion

Determine whether the contrast is visible beyond the insert and note any degree of proximal tubal filling even if tube is occluded.

Assess tubal occlusion:

1 – Satisfactory occlusion: Tube is occluded at the cornua.

2 – Satisfactory occlusion: Contrast seen within tube but not past distal end of outer coil.

3 – Unsatisfactory occlusion: Contrast seen past the distal end of the insert or in the peritoneal cavity.

D. Assessing Ability to Rely

If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue alternative contraception.

If location is unsatisfactory, instruct patient to not rely on the inserts for contraception.

If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain on alternative contraception. Repeat the **Essure** Confirmation Test (modified HSG) in three months. If occlusion is still unsatisfactory, instruct patient to not rely on the inserts for contraception.

XVII. MANAGEMENT OF INSERT EXPULSION OR UNSATISFACTORY INSERT LOCATION

1. Insert is too proximal (≥50% of the inner coil trails into the uterine cavity): Do not advise patient to rely on insert, continue alternative contraception or consider incisional sterilization.
2. Insert is too distal (proximal end of the inner coil is > 30mm from cornua): If tube is patent counsel patient on repeat placement procedure. If tube is occluded, advise patient on potential for false positive diagnosis of occlusion. Also counsel patient on incisional sterilization or remaining on alternative contraception.
3. Unilateral or bilateral insert expulsion: If tube is patent, counsel patient on repeat placement procedure. If tube(s) where insert was expelled is occluded, advise patient on potential for false positive diagnosis of occlusion. Also counsel patient on incisional sterilization or remaining on alternative contraception.
4. Unilateral or bilateral insert perforation: If tube is patent, counsel patient on repeat placement procedure. If tube is occluded, advise patient on potential for false positive diagnosis of occlusion. Also counsel patient on incisional sterilization or remaining on alternative contraception.
5. If a patient opts for incisional sterilization, clip or coagulate both fallopian tubes distal or proximal to the insert even if any remaining insert is in a satisfactory location. Do not perform clipping or coagulation adjacent to or over the insert. An attempt should be made to retrieve a perforated insert if the physician believes it can be done safely, however insert retrieval may not be possible. Refer to section XVIII. INSERT REMOVAL.

XVIII. INSERT REMOVAL

WARNING: **Essure** inserts are intended to be left in place permanently. Do not remove insert(s) unless patient is experiencing an adverse event(s) associated with its presence, or if removal is demanded. If insert removal is indicated, patient should be counseled on unknown risks as techniques for insert removal post-placement have not been evaluated in clinical studies.

For all surgical device removal procedures, care should be taken to avoid transecting the insert during removal. Avoid use of any instrument that is likely to result in fragmentation of the insert. Application of electrocautery to the outer coil should be avoided. During removal, grasping both the inner and outer coils together may help prevent excessive stretching of the outer coil, which could result in fragmentation.

Location of **Essure** inserts should be confirmed through imaging prior to any attempted surgical removal.

Limited case reports describe hysteroscopic insert removal up to seven weeks following placement. In these cases the proximal coils were visible within the uterine cavity and were easily removed with gentle traction. When hysteroscopic removal is not feasible, linear salpingotomy or salpingectomy via laparoscopy or laparotomy can be used to remove an insert within the tube. In some cases, a cornual resection of the proximal fallopian tube may be required for removal. In these cases patients should be counseled about the risk of hysterectomy in order to achieve hemostasis.

1. To perform a linear salpingotomy, make a small incision (approximately 2 cm in length) along the antimesenteric border of the fallopian tube overlying the insert. Use of vasoconstrictive agents is at the discretion of the operating surgeon. The insert needs to be exposed and may need to be freed from the surrounding tissue prior to grasping the coils. Once the insert is exposed, a grasping instrument may be used to extract the insert using gentle traction. Removal may be along with, or independent of, an incisional sterilization procedure.
2. When removing insert via salpingectomy, the location of the proximal and distal portions of the insert within the fallopian tube should be reconfirmed intraoperatively by palpation and/or imaging prior to transecting the tube. The insert may be exposed and visualized via salpingotomy prior to transection or removal of the fallopian tube.
3. The technique for removal of an insert that has perforated the uterus or tube or is within the peritoneal cavity will depend on the location of the insert. Localization should be assessed with imaging prior to the surgical procedure and confirmed intraoperatively. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during surgery.

XIX. SYMBOL LEGEND

STERILE EO	Sterilized using ethylene oxide		Use by	EC REP	Authorized European Representative
LOT	Batch code		Keep away from heat	CE 0050	Device complies with European Directive
	Do not reuse	MR	MR Conditional		Keep dry
REF	Catalog number		Do not use if package is open or damaged	CONT	Content
	Attention, See Instructions for Use				

Manufactured by:
Bayer HealthCare LLC
1011 McCarthy Blvd.
Milpitas, CA 95035
USA
essure.com

Recyclable

PN-84731145, ART Rev. B

Español

essure®

Anticonceptivo permanente

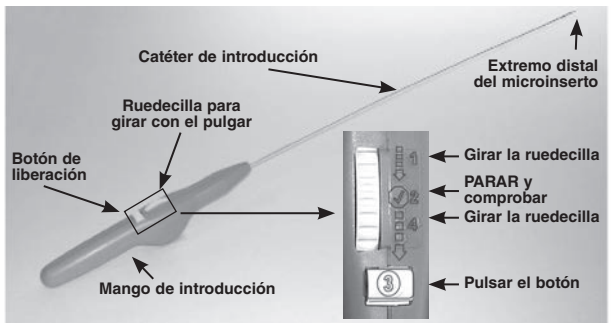
BAYER

INSTRUCCIONES DE USO

I. Descripción del microinserto

El sistema anticonceptivo permanente **Essure**® consta de varios componentes. El microinserto **Essure**, un microinserto que se expande dinámicamente, está acoplado a un alambre de introducción y a un catéter de liberación. La totalidad del conjunto está enfundada dentro de un catéter de introducción. Este sistema (que aparece ilustrado en la Figura 1) está acoplado a un mango que facilita la introducción y despliegue del microinserto. Junto con el sistema **Essure** se suministra un introductor con valvas, a saber, el **DryFlow**® Introducer, diseñado para ayudar a proteger el microinserto **Essure** cuando se hace pasar este último a través del orificio de goma del canal de trabajo del histeroscopio.

Figura 1
Sistema de introducción Essure
Detalle de los símbolos del procedimiento de colocación.
(NO A ESCALA)



II. Mecanismo de acción

En condiciones de visualización histeroscópica, mediante el sistema **Essure** se introduce un microinserto **Essure** en la sección proximal de la luz de la trompa de Falopio. Cuando el microinserto **Essure** se expande al liberarse, queda fijado firmemente a la trompa de Falopio. A continuación, el microinserto provoca una respuesta tisular benigna esperada, que causa un encarnamiento del tejido en el interior del microinserto, lo que fija firmemente el microinserto en el interior de la trompa de Falopio. Esta respuesta tisular benigna es de naturaleza local, fibrótica y oclusiva.

El sistema **Essure** se esteriliza con óxido de etileno y se suministra estéril para un solo uso. No lo reutilice ni lo esterilice. La reesterilización puede afectar negativamente al correcto funcionamiento mecánico y podría causar lesiones a la paciente.

III. Indicaciones de uso

El sistema **Essure** ha sido diseñado para utilizarse como microinserto de oclusión de las trompas de Falopio, y constituye así un método anticonceptivo permanente.

IV. Contraindicaciones

- La paciente no está segura de querer esterilizarse definitivamente.
- Embarazo o sospecha de embarazo.
- Parto o finalización de un embarazo en su segundo trimestre menos de 6 semanas antes de la colocación del microinserto **Essure**.
- Infección pélvica activa o reciente.
- Cervicitis aguda no tratada.
- Hemorragia vaginal grave o idiopática.
- Tumores ginecológicos malignos (diagnosticados o sospechados).
- Constancia de anomalías, en la cavidad uterina o en las trompas de Falopio, que dificulten o imposibiliten la visualización de los ostium tubáricos o la canulación de la parte proximal de las trompas.
- Alergia a los medios de contraste (puede que sea necesario realizar una histerosalpingografía tres meses después de la colocación del microinserto).
- La paciente está tomando corticosteroides.

V. Advertencias

- El procedimiento **Essure** sólo deben llevarlo a cabo histeroscopistas experimentados que hayan recibido el programa de formación de *Bayer HealthCare LLC* sobre este procedimiento.
- Las personas alérgicas al níquel-titanio pueden presentar reacciones alérgicas al microinserto.
- No utilice el sistema **Essure** si el envase está abierto o dañado. No utilice tampoco el sistema si el microinserto está dañado.
- Al introducir el microinserto **Essure** en la trompa de Falopio, no haga avanzar nunca el microinserto si advierte demasiada resistencia.
- No continúe haciendo avanzar el sistema **Essure** una vez que el marcador de posición que hay en el catéter haya alcanzado el ostium tubárico. Si se hace avanzar el sistema más allá de este punto, el microinserto podría quedar en una posición no satisfactoria o perforar la trompa de Falopio o el útero.
- En caso de constancia o sospecha de perforación de la trompa, no continúe con el intento de introducción del microinserto **Essure**. Un porcentaje muy reducido de las mujeres que participaron en los ensayos clínicos del sistema **Essure** (1,8%: 12 de 682 pacientes) presentaron perforaciones de la trompa relacionadas con el dispositivo. La recuperación del microinserto, en caso de que éste perfore la trompa, requiere laparoscopia u otros métodos quirúrgicos.
- Si los intentos de colocación del microinserto **Essure** no tienen éxito 10 minutos después del intento de canulación por trompa, el procedimiento deberá suspenderse y, si se considera oportuno, volverse a programar.
- Una vez colocado el microinserto (es decir, cuando se haya desprendido del alambre de introducción), no debe intentarse su extracción histeroscópicamente a menos que haya 18 o más espirales del microinserto **Essure** en el interior de la cavidad uterina. Si se desea extraer un microinserto, deberá hacerse inmediatamente después de su colocación. Sin embargo, puede ocurrir que la extracción no sea posible.
- La paciente deberá utilizar un método anticonceptivo alternativo hasta que una radiografía realizada tres meses después de la colocación del microinserto demuestre que la colocación del microinserto es la adecuada.
- Las pacientes que se someten a la colocación del microinserto **Essure** pueden someterse en años venideros a terapias intrauterinas que utilicen energía eléctrica. Se recomienda evitar el empleo de la electrocauterización en los procedimientos quirúrgicos realizados en los cuernos uterinos o en las trompas de Falopio. En cualquier otro tipo de procedimientos en la pelvis, deberá evitarse usar electrocauterización en un radio de 4 cm en torno al microinserto. La presencia de microinsertos **Essure** podría conllevar riesgos asociados con tales procedimientos (riesgos que, actualmente, no han sido identificados).
- Cualquier procedimiento intrauterino que incluya ablación endometrial, por ejemplo, procedimientos intrauterinos tales como la biopsia endometrial, la dilatación y el legrado, o la histeroscopía diagnóstica u operatoria, podría alterar la capacidad de los microinsertos para evitar el embarazo. Asimismo, la presencia de los microinsertos **Essure** podría conllevar riesgos asociados con tales procedimientos (riesgos que, actualmente, no han sido identificados).
- Las pruebas de rendimiento y los estudios clínicos han mostrado que la ablación endometrial del útero puede realizarse de manera segura y eficaz con el sistema de balón uterino GYNECARE THERMACHOICE*, el sistema de ablación endometrial NovaSure de Hologic** y el dispositivo de termoablación Hydro ThermAblator de Boston Scientific*** inmediatamente después de la colocación de microinsertos **Essure**. No se han realizado estudios específicos para evaluar la expulsión de los microinsertos **Essure** ni los índices de anticoncepción después del uso de procedimientos combinados **Essure**-ablación endometrial
- Las pacientes pueden decidir en años venideros someterse a fertilización in vitro (FIV) para quedarse embarazadas. Se desconocen los efectos de los microinsertos **Essure** sobre el éxito de la FIV. Si se produce un embarazo, los riesgos del microinserto para la paciente, para el feto y para la continuación del embarazo son también desconocidos.

* Marca comercial de ETHICON, INC.
** Marca comercial de Hologic, Inc.
*** Marca comercial de Boston Scientific Corporation

VI. Precauciones

- Siempre que sea posible, la colocación del microinserto deberá realizarse entre los días 7 y 14 del ciclo menstrual (el día 1 es el primer día de hemorragia), con el fin de mejorar la visualización de los ostium de las trompas de Falopio y de reducir la posibilidad de colocación de un microinserto en una paciente con un embarazo no diagnosticado.
- Una anatomía uterina atípica podría dificultar la colocación de los microinsertos **Essure**.
- Para reducir el riesgo de perforación uterina, el procedimiento deberá suspenderse si se requiere demasiada fuerza para conseguir la dilatación del cuello uterino.
- Los ostium de las dos trompas de Falopio deberán identificarse y evaluarse mediante histeroscopía antes de proceder a la colocación del microinserto **Essure**. No se deberá intentar la colocación de un microinserto en el ostium de una trompa a menos que haya una expectativa razonable de que la trompa opuesta sea accesible y permeable.
- Si se realiza una ablación endometrial inmediatamente después de la colocación de microinsertos **Essure**, es posible que aumente el riesgo de síndrome de esterilización tubárica postablación, una afección infrecuente que se ha observado en mujeres con antecedentes de ligadura de trompas que se someten a ablación endometrial.
- No haga avanzar el sistema **Essure** si la paciente está teniendo dolores o molestias anormales.
- Almacene el sistema **Essure** en un lugar fresco y seco.

VII. Posibles efectos adversos

A. Embarazo

Existe el riesgo de embarazo y de embarazo ectópico, así como riesgos asociados con el tratamiento de ambos estados. Si la paciente se queda embarazada y opta por continuar con un embarazo intrauterino, deberá ser informada de que se desconocen los riesgos que puede acarrear el microinserto para la paciente, para el feto y para la continuación del embarazo.

B. Riesgos asociados al procedimiento de colocación del microinserto

- Para evitar o reducir las molestias, puede administrarse a la paciente anestesia local, analgesia o sedación por vía oral, anestesia regional (es decir, anestesia intradural o epidural), sedación oral o consciente (intravenosa), o anestesia general. Cualquiera que sea el tipo de anestesia, es posible que las pacientes no puedan reanudar sus actividades normales hasta transcurridas entre 12 y 24 horas tras el procedimiento.
- La paciente puede experimentar dolores, espasmos o hemorragias vaginales durante y después del procedimiento de colocación del microinserto. Generalmente, estos incidentes son tolerables, pasajeros y se tratan eficazmente con medicación.
- Durante e inmediatamente después del procedimiento de colocación del microinserto, existe el riesgo de que la paciente experimente náuseas o vómitos. Es de esperar que sea un efecto pasajero, y puede tratarse con medicación según sea necesario.
- El día del procedimiento, las pacientes pueden sufrir desmayos o respuestas vasovagales.
- Existe el riesgo de perforación o disección de la trompa de Falopio o de los cuernos uterinos. Dicha perforación o disección puede provocar hemorragias y cicatrices; sin embargo, generalmente no será necesario ningún tratamiento.
- Existe el riesgo de causar perforación uterina con el histeroscopio, con el sistema **Essure** o con otros instrumentos utilizados durante el procedimiento, con posibles lesiones en el intestino, la vejiga urinaria o vasos sanguíneos importantes. Si se produjera una lesión de ese tipo, aunque es improbable que se requiera una intervención quirúrgica, ésta podría ser necesaria. Para reducir el riesgo de perforación uterina, el procedimiento deberá suspenderse si se requiere demasiada fuerza para conseguir la dilatación del cuello uterino.
- Existe el riesgo de que el microinserto **Essure** pueda colocarse involuntariamente en el interior del miometrio del útero y no en la luz de la trompa de Falopio. Si ya se ha implantado correctamente uno de los microinsertos en una trompa de Falopio, además de la colocación involuntaria en el miometrio, el médico puede intentar implantar un tercer microinserto para completar el procedimiento. En caso de no conseguirse la colocación bilateral en las trompas de Falopio, esto puede ocasionar que la paciente tenga un microinserto en la trompa de Falopio y uno en el miometrio; este último microinserto no será eficaz como método anticonceptivo. Si se coloca un microinserto en el miometrio, puede aparecer dolor posoperatorio u otras reacciones adversas. Si fuera necesaria la extracción quirúrgica del microinserto o los microinsertos, podría requerirse una salpingectomía o una histerectomía.
- Existe el riesgo de que el microinserto **Essure** pueda colocarse en una posición demasiado distal en la trompa de Falopio. Si fuera necesaria la extracción del microinserto, se requeriría cirugía (laparoscopia o laparotomía).
- Existe el riesgo de que el microinserto **Essure** pueda colocarse en una posición demasiado proximal en la trompa de Falopio. Si en el momento de la colocación son visibles 18 o más espirales del microinserto **Essure**, deberá intentarse inmediatamente la extracción del microinserto (consulte el apartado XIII, Extracción del microinserto **Essure**). Si se intenta extraer el microinserto **Essure**, es posible que no se consiga o que el microinserto se rompa y quede un fragmento de él dentro del cuerpo de la paciente. Si se intenta extraer el microinserto (se consiga extraerlo o no), también existe la posibilidad de que la paciente pueda experimentar más dolores, espasmos y hemorragias durante y después del procedimiento de colocación del microinserto **Essure**.
- Existe el riesgo de que el microinserto **Essure** pueda perforar la pared tubárica o los cuernos uterinos, lo que podría llevar a la liberación del microinserto en la cavidad peritoneal. Como consecuencia, después de la operación la paciente podría experimentar dolor, trastornos menstruales u otras reacciones adversas. Si la paciente decide someterse a una esterilización quirúrgica o a otra intervención quirúrgica, se podrá intentar extraer el microinserto de la cavidad peritoneal, siempre que el médico crea que es seguro hacerlo. Sin embargo, la extracción del microinserto podría no ser posible si el médico no puede visualizarlo o acceder a él.
- Existe el riesgo de que la colocación del microinserto **Essure** sólo se consiga en una trompa de Falopio. En ese caso, podría ocurrir que las pacientes quedasen con un solo microinserto implantado, que no será suficiente para lograr una anticoncepción permanente.
- Existe el riesgo de que la colocación del microinserto **Essure** no sea posible en ninguna de las trompas de Falopio.
- Existe un riesgo mínimo de absorción excesiva del líquido de la solución salina fisiológica utilizada para dilatar el útero y realizar el procedimiento histeroscópico.
- Como ocurre con todos los procedimientos invasivos, el procedimiento de colocación del microinserto puede ocasionar infecciones, que pueden causar lesiones en el útero, en las trompas de Falopio o en la cavidad pélvica. En caso de infección, puede ser necesario administrar antibióticos o, en casos poco frecuentes, efectuar una hospitalización o cirugía, incluida una histerectomía.

C. Riesgos asociados al hecho de llevar microinsertos Essure

- Existe el riesgo de que el microinserto **Essure** pueda desplazarse fuera de las trompas de Falopio. Este desplazamiento podría deberse a una expulsión (salida del microinserto de las trompas de Falopio y hacia el interior de la cavidad uterina, el cuello uterino o la vagina, o bien fuera del cuerpo) o a un desplazamiento (movimiento del microinserto hacia la porción distal de la trompa de Falopio o fuera de la misma y hacia el interior de la cavidad peritoneal). Para la identificación de la ubicación de los microinsertos podrían necesitarse radiografías adicionales; la extracción de los microinsertos podría requerir cirugía. El desplazamiento del dispositivo podría provocar embarazo intrauterino, embarazo ectópico, dolores y trastornos menstruales, u otras reacciones adversas.
- Como sucede con los métodos anticonceptivos mecánicos permanentes actuales (es decir, grapas y anillos), si el microinserto **Essure** ha de extraerse, será necesaria una intervención quirúrgica. Además, es posible que se requiera la extirpación quirúrgica de las trompas de Falopio (salpingectomía) y del útero (histerectomía).
- La paciente podría sufrir dolores y espasmos abdominales o pélvicos. Éstos pueden ser más probables durante la menstruación, durante y después del coito o mientras se realizan otras actividades físicas.
- También pueden presentarse hemorragias intermenstruales o menstruales más intensas de lo normal.
- Ocasionalmente, alguna paciente podría arrepentirse de su decisión de haber optado por un método anticonceptivo permanente y sufrir una ligera depresión u otros trastornos emocionales por esta razón.

D. Riesgos asociados a los procedimientos de seguimiento

- Existe el riesgo de radiación asociada a la radiografía pélvica que hay que hacer tres meses después de la colocación del microinserto para determinar la ubicación de éste. También puede ser necesaria una Prueba de Confirmación **Essure** (HSG). Se producen aproximadamente 0,033 cGy en la fase fluoroscópica (< 30 segundos) del procedimiento de histerosalpingografía. Como referencia, la exposición a radiación producida por un enema opaco es de 0,85 cGy, cantidad superior a la requerida en la Prueba de Confirmación **Essure** (HSG). La cantidad de exposición a radiación producida por una radiografía pélvica es aproximadamente la misma que la cantidad que recibiría un individuo en un año por radiación de origen natural.
- De ser necesaria la Prueba de Confirmación **Essure** (HSG), dicha prueba conlleva los siguientes riesgos adicionales: respuesta vasovagal; infección, que puede requerir tratamiento con antibióticos y, en casos excepcionales, hospitalización; intravasación; perforación del útero; espasmos uterinos o hemorragias; dolores y molestias; y reacción alérgica al látex. Se ha documentado que, en casos excepcionales, la exposición al látex puede causar reacciones anafilácticas que pueden ocasionar la muerte.

- El uso de medios de contraste, empleados en la realización de la Prueba de Confirmación **Essure** (HSG), se ha asociado a reacciones alérgicas en algunas pacientes. La reacción alérgica puede provocar urticaria o dificultad para respirar. En algunos casos podría producirse una respuesta anafiláctica que podría ocasionar la muerte.

E. Riesgos asociados a los posibles procedimientos futuros

- Las pacientes que se someten a la colocación del microinserto **Essure** podrán someterse en años venideros a terapias intrauterinas que utilicen energía eléctrica. Se recomienda evitar el empleo de la electrocauterización en los procedimientos quirúrgicos realizados en los cuernos uterinos o en las trompas de Falopio. En el resto de procedimientos efectuados en la pelvis deberá evitarse el uso de electrocauterización en un radio de 4 cm en torno al microinserto. La presencia de microinsertos **Essure** podría conllevar riesgos asociados con tales procedimientos (riesgos que, actualmente, no han sido identificados).
- Cualquier procedimiento intrauterino que incluya ablación endometrial, por ejemplo, procedimientos tales como la biopsia endometrial, la dilatación y el legrado, o la histeroscopía diagnóstica u operatoria, podría alterar la capacidad de los microinsertos para evitar el embarazo. Asimismo, la presencia de los microinsertos **Essure** podría conllevar riesgos asociados con tales procedimientos (riesgos que, actualmente, no han sido identificados).
- Las pacientes pueden decidir en años venideros someterse a fertilización in vitro (FIV) para quedarse embarazadas. Se desconocen los efectos de los microinsertos **Essure** sobre el éxito de la FIV. Si se produce un embarazo, los riesgos del microinserto para la paciente, para el feto y para la continuación del embarazo son también desconocidos.
- Los microinsertos **Essure** son radiopacos, y seguros en caso de realización de resonancias magnéticas. Los microinsertos **Essure** son compatibles con las resonancias magnéticas, excepto en el caso de la adquisición de imágenes pélvicas, en la que pueden causar algunos artefactos.
- **Es posible que existan riesgos aún desconocidos.**

VIII. Instrucciones de uso

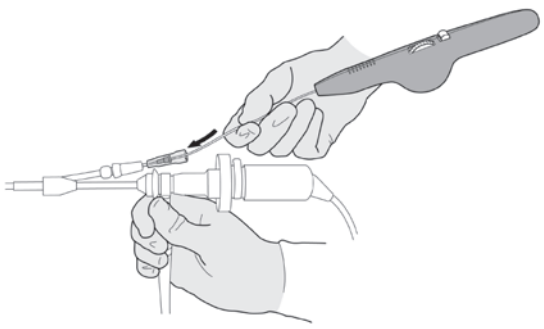
A. Antes del procedimiento de colocación del microinserto

1. La colocación del microinserto deberá realizarse durante los días 7-14 del ciclo menstrual (el día 1 es el primer día de hemorragia), con el fin de mejorar la visualización de los ostium de las trompas de Falopio y de reducir la posibilidad de colocación de un microinserto en una paciente con un embarazo no diagnosticado.
2. El médico o una persona encargada deberán realizar una prueba de embarazo durante las 24 horas anteriores al procedimiento de colocación del microinserto o inmediatamente antes de dicho procedimiento.
3. Se recomienda encarecidamente la administración de un antinflamatorio no esteroideo, como la indometacina (por vía oral o en supositorio), una o dos horas antes del procedimiento de colocación del microinserto, ya que los datos de los estudios clínicos demuestran que el uso de antinflamatorios no esteroideos aumenta considerablemente la probabilidad de éxito de la colocación. Si solamente se usa un bloqueo paracervical, también puede ofrecerse a la paciente la posibilidad de administrarle diazepam (por vía oral) o un medicamento similar 30 minutos antes del procedimiento, con el fin de reducir su ansiedad.

B. Procedimiento de colocación del microinserto Essure

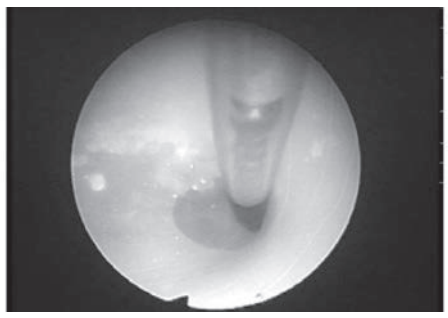
El procedimiento de colocación del microinserto **Essure** puede realizarse en un ambulatorio o en un centro de cirugía ambulatoria. Durante el procedimiento de colocación del microinserto deberá utilizarse una técnica estéril. La cantidad de tiempo requerida para completar el procedimiento de colocación del microinserto no deberá exceder de 30 minutos.

1. Sitúe a la paciente en posición de litotomía.
2. Introduzca un espéculo en la vagina para facilitar el acceso al cuello uterino. Prepare el cuello uterino con Betadine® u otra solución antibacteriana apropiada, conforme a las prácticas habituales.
3. La anestesia local es el método recomendado para la implantación de los microinsertos. Se puede administrar un bloqueo paracervical. Si fuera necesario, también puede administrarse midazolam (por vía intravenosa) o un medicamento similar para prevenir o reducir las molestias.
4. Introduzca un histeroscopio estéril con una cámara acoplada, y con un canal operatorio (≥ 5 Fr), en la cavidad del útero a través del cuello de éste. Si fuera necesario, dilate el cuello uterino para facilitar la introducción. Para evitar perforaciones uterinas, el procedimiento deberá suspenderse si se requiere demasiada fuerza para conseguir la dilatación del cuello uterino.
5. La distensión de la cavidad uterina deberá conseguirse con una infusión salina fisiológica administrada a través del canal de trabajo del histeroscopio. Se recomienda encarecidamente calentar previamente la solución salina hasta que alcance la temperatura corporal, e introducirla mediante perfusión por gravedad para reducir al mínimo los espasmos de las trompas de Falopio. Durante todo del procedimiento deberá conseguirse y mantenerse una distensión uterina óptima, y seguirse los procedimientos habituales de vigilancia de los líquidos. Los ostium de las trompas de Falopio deberán identificarse mediante visualización histeroscópica.
6. Ambos ostium tubáricos deberán ser identificados y evaluados mediante histeroscopía antes de proceder a la colocación del microinserto **Essure**. No se deberá intentar la colocación de un microinserto en un ostium tubárico a menos que haya una expectativa razonable de que la trompa opuesta sea permeable.
7. Una vez identificados los ostium de las trompas de Falopio, inserte el introductor con valvas a través del tapón de sellado del canal de trabajo del histeroscopio. La llave de paso del canal operatorio deberá permanecer abierta (el dispositivo, el introductor o ambos podrían resultar dañados si se cierra la llave de paso de alguno de ellos). Haga pasar el sistema de introducción **Essure** a través del introductor y haga avanzar aquél a través del canal de trabajo del histeroscopio. Si no se ha deteriorado con la primera colocación del microinserto, el introductor con valvas puede permanecer en el canal operatorio durante todo el procedimiento **Essure**.



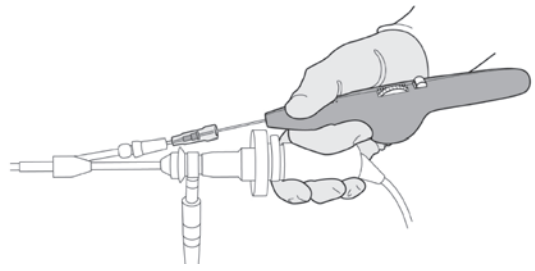
Inserte el introductor a través del tapón de sellado del canal de trabajo del histeroscopio y a continuación inserte y haga avanzar el sistema de introducción **Essure** *a través del introductor.*

8. Haga avanzar el sistema de introducción **Essure** hasta la parte proximal de la trompa de Falopio con un movimiento lento y sostenido para evitar espasmos tubáricos. Haga avanzar el sistema de introducción hasta que el marcador de posición del catéter de introducción alcance el ostium de la trompa de Falopio. Este marcador visual indica que el microinserto **Essure** se extiende desde el segmento intramural distal hasta los segmentos ístmicos proximales de la trompa de Falopio, con la espiral exterior extendida a lo largo de la unión útero-tubárica. Ésta es la colocación ideal para el microinserto **Essure**.



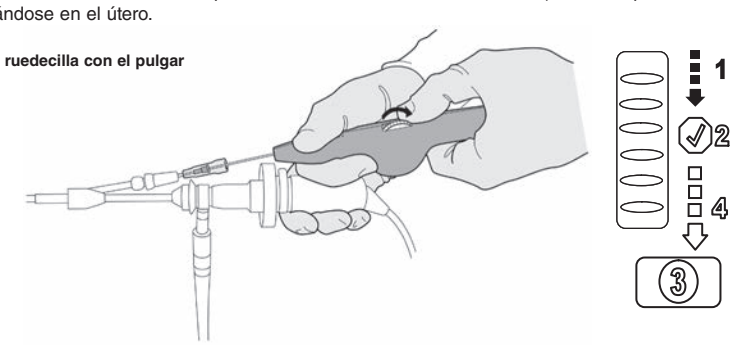
Haga avanzar el sistema de introducción **Essure** *hasta que el marcador de posición negro se encuentre en el ostium tubárico. Este marcador es un indicador visual de la posición correcta para el despliegue.*

9. Si es posible hacer avanzar el catéter bajo visualización directa sin demasiada resistencia, es señal de que se ha conseguido una alineación concéntrica adecuada del catéter de introducción con la apertura de la trompa. La resistencia al avance se nota generalmente de dos formas: 1) el marcador negro que hay en la superficie exterior del catéter no avanza hacia el ostium tubárico, o 2) el catéter de introducción se dobla o flexiona demasiado, impidiendo al médico aplicar presión sobre el conjunto del catéter para hacerlo avanzar. Si se observa resistencia al avance del catéter, no debe volverse a intentar la colocación del microinserto, ya que hay que evitar la posibilidad de perforación uterina o de colocación involuntaria del microinserto en la musculatura uterina en lugar de en el interior de la luz de la trompa. Se deberá realizar una Prueba de Confirmación **Essure** (HSG) de seguimiento para determinar si la trompa es permeable.
10. Si no es posible hacer avanzar el catéter hasta el marcador de posición una vez transcurridos varios minutos, se puede hacer una prueba de perfusión con un catéter para desobstrucción (si no se ha utilizado ya), con el fin de determinar si la trompa es permeable. Si la trompa está bloqueada o si no se consigue hacer avanzar el catéter hasta el marcador de posición, el procedimiento deberá suspenderse. Si la colocación del microinserto **Essure** no ha tenido éxito transcurridos 10 minutos de intento de canulación por trompa, el procedimiento deberá suspenderse.
11. Cuando haya hecho avanzar el catéter de introducción hasta el marcador de posición, proceda a desplegar el microinserto. Para hacerlo, primero estabilice el mango del microinserto **Essure** contra la cámara del histeroscopio o contra algún otro objeto fijo, con el fin de evitar el avance involuntario del sistema **Essure** durante la retracción del catéter de introducción.



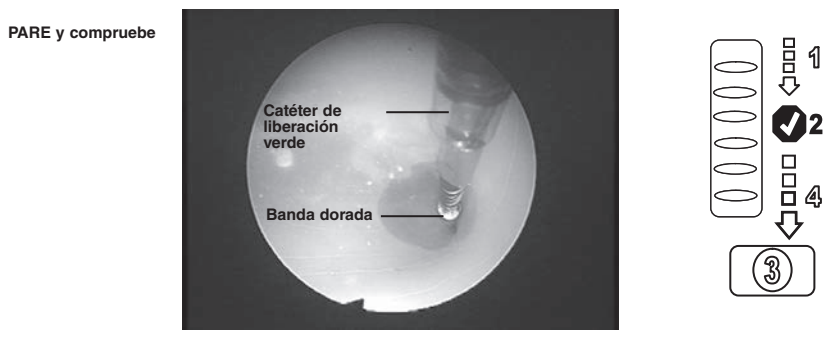
Estabilice el mango contra el cabezal de la cámara o contra algún otro objeto fijo, con el fin de evitar el avance involuntario del sistema **Essure**

12. Asegurándose de que el marcador de posición de color negro se encuentra en el ostium de la trompa de Falopio, gire la ruedecilla del mango con el pulgar hasta que no se pueda girar más. Esta operación se corresponde con el símbolo ⇩1 que hay en el mango del sistema de introducción. Esto facilita la extracción del catéter de introducción; verá que el marcador de posición negro se aleja del ostium tubárico (hacia el histeroscopio) y desaparece en el interior del canal operatorio. La extracción del catéter de introducción deja al descubierto el microinserto **Essure** arrollado. Al extraer el catéter de introducción, debería verse aproximadamente 1 cm del microinserto (con las espirales arolladas) internándose en el útero.



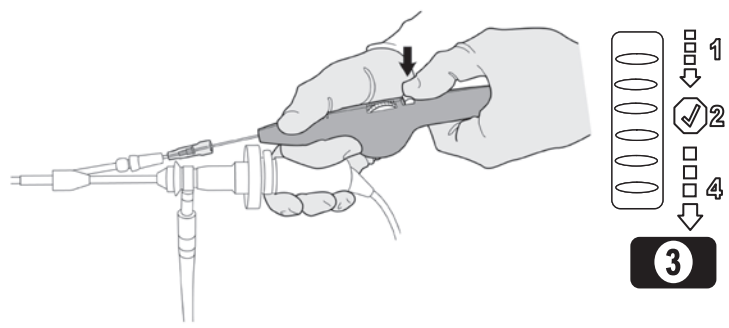
Gire la ruedecilla con el pulgar para retraer el catéter

13. Para confirmar que la posición es la correcta, sitúe la banda marcadora dorada justo en el exterior del ostium, operación que se corresponde con el símbolo ✓2 que hay en el mango del sistema de introducción. La visualización de la banda dorada justo en el exterior del ostium, así como la visualización del extremo distal del catéter de liberación verde, confirmará que la posición es correcta. Si se ve en el útero más de 1 cm del microinserto, éste deberá cambiarse de posición, si es posible, antes de pasar al siguiente paso, haciendo avanzar más todo el sistema hacia el interior de la trompa.



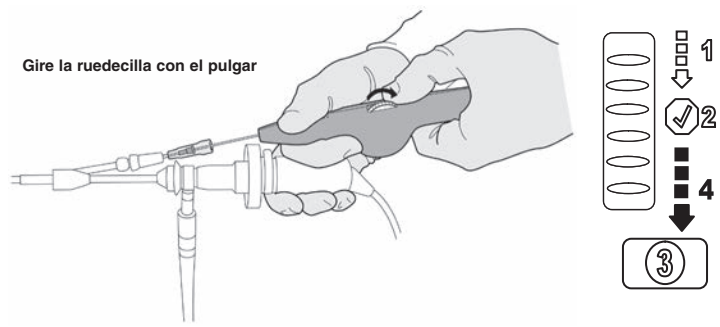
Visualice la banda dorada en el ostium

14. Pulse el botón que hay en el mango de introducción para conseguir que la ruedecilla se pueda seguir girando, operación que se corresponde con el símbolo ③ que hay en el botón del mango.



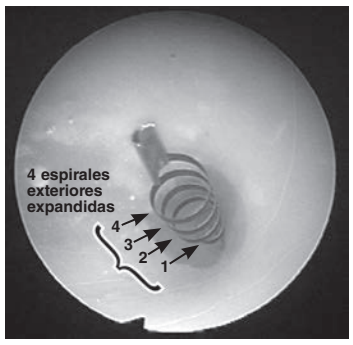
Pulse el botón para conseguir que la ruedecilla se pueda volver a girar

15. Gire la ruedecilla hacia usted para desplegar la espiral exterior del microinserto, operación que se corresponde con el símbolo ⇩4 que hay en el mango del sistema de introducción. Siga girando la ruedecilla hasta que deje de girar. Cuando no sea posible girar más la ruedecilla y las espirales exteriores expandidas sean visibles, retire el sistema.



Gire la ruedecilla con el pulgar para desplegar la espiral exterior del microinserto

16. La posición del microinserto **Essure** desplegado se evaluará mediante visualización histeroscópica. Idealmente, debería haber de 3 a 8 espirales exteriores expandidas del microinserto **Essure** internándose en el útero.



Las espirales exteriores expandidas del microinserto **Essure** *internándose en el útero indican una colocación ideal*

17. Si el médico no está satisfecho con la colocación del microinserto que puede ver mediante la histeroscopía, o si sospecha que ha habido perforación tubárica o del útero, deberá dejar el microinserto o microinsertos en su lugar y realizar una evaluación de los mismos, mediante radiografía pélvica o HSG, tres meses después del procedimiento.

    ADVERTENCIA: UNA VEZ QUE HAYA COLOCADO EL MICROINSERTO Y QUE LO HAYA LIBERADO EN LA TROMPA DE FALOPIO, NO INTENTE EXTRAERLO HISTEROSCÓPICAMENTE A MENOS QUE HAYA 18 O MÁS ESPIRALES DEL MICROINSERTO ESSURE INTERNÁNDOSE EN LA CAVIDAD UTERINA. La extracción de un microinserto que esté en esas condiciones debe intentarse de inmediato durante el intento de colocación. Sin embargo, la extracción puede no ser posible (consulte el apartado XIII, Extracción del microinserto **Essure**). Si el microinserto fue desplegado involuntariamente en la cavidad uterina y no en la trompa de Falopio, deberá extraerlo del útero y volver a intentar colocar un microinserto en la trompa de Falopio.
18. Repita el procedimiento de colocación del microinserto **Essure** en la trompa de Falopio contralateral.
19. Registre la longitud del microinserto que se interna en la cavidad uterina, y registre también cualquier incidencia con la que se encuentre durante la identificación o durante la confirmación del ostium de cada trompa, así como cualquier sospecha de perforación. Dichas incidencias deben anotarse en los historiales de las pacientes para que sirvan de referencia al revisar la Prueba de Confirmación **Essure** *(consulte el apartado IX, Prueba de Confirmación* ***Essure****)*.
20. **Recuerde a la paciente que deberá utilizar un método anticonceptivo alternativo (que no sea un DIU) durante los 3 primeros meses posteriores al procedimiento de colocación del microinserto.**
21. Concierte una cita con la paciente para realizarle una Prueba de Confirmación **Essure** tres meses después de la colocación del microinserto **Essure** y evaluar si el microinserto ha sido retenido y su ubicación.

IX. Prueba de Confirmación Essure

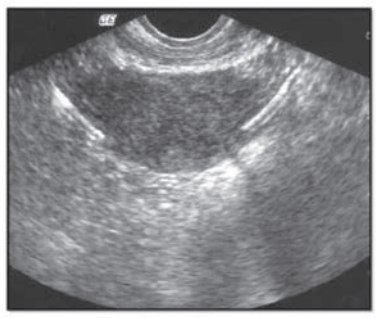
A. Tres meses después de la colocación del microinserto deberá hacerse una Prueba de confirmación **Essure** para evaluar si el microinserto ha sido retenido y su ubicación. Las Pruebas de Confirmación **Essure** (ecografía transvaginal, radiografía pélvica o histerosalpingografía) deben ser realizadas exclusivamente por un ginecólogo, ecografista o radiólogo con experiencia y que haya recibido la formación debida para efectuar el protocolo de la prueba de confirmación **Essure** correspondiente. Con la formación se proporciona un protocolo detallado con imágenes y consejos de realización de las pruebas; se pueden obtener copias adicionales descargando una copia en essure.com.

B. Como prueba de confirmación de primera línea, deberá realizarse una radiografía pélvica o una ecografía transvaginal tres meses después de un procedimiento de colocación de microinserto bilateral no complicado.

1. La radiografía y la ecografía no deberán usarse como Prueba de Confirmación **Essure** en las siguientes circunstancias:
    a) Procedimiento de colocación con una o más de las siguientes dificultades:
        (1) Sospecha de perforación durante la colocación debido a que se requirió una fuerza excesiva para la introducción del microinserto y/o a una ausencia repentina de resistencia.
        (2) La identificación del ostium tubárico fue difícil durante la colocación debido a una variación anatómica o a factores técnicos como distensión inadecuada, iluminación insuficiente o residuos endometriales.
        (3) El cirujano tiene dudas sobre la colocación.
    b) Duración del procedimiento superior a 15 minutos (desde la inserción hasta la retirada del endoscopio).
    c) Colocación con cero o más de 8 espirales internándose en la cavidad uterina.
    d) Dolor postoperatorio inusual —que puede ser transitorio o persistente, o aparecer tiempo después del procedimiento— sin que exista otra causa identificable.
2. En caso de que la radiografía y la ecografía no estén indicadas, se debe realizar una histerosalpingografía para evaluar la ubicación del microinserto y la oclusión tubárica. La ecografía transabdominal no se puede usar como sustituto de una ecografía transvaginal. Si la radiografía o ecografía es dudosa o insatisfactoria, la paciente deberá someterse a una histerosalpingografía para evaluar la ubicación del microinserto y la oclusión tubárica.

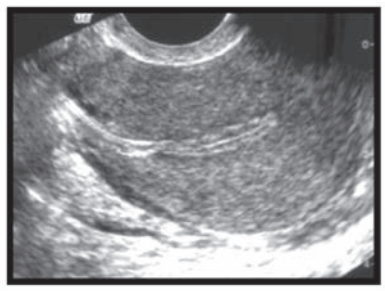
C. Ecografía transvaginal

1. Deberán obtenerse y conservarse para documentación un mínimo de tres imágenes:
    a) Una imagen frontal o frontal oblicua en la que se muestre una porción de cada microinserto en el cuerno, que se etiquetará como “imagen simple”.



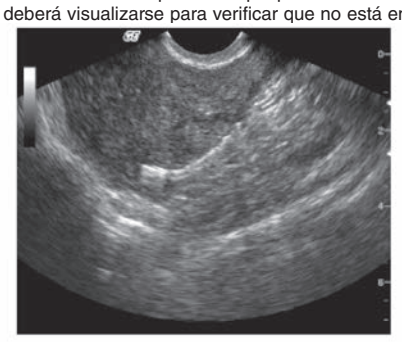
En esta imagen transversal (frontal / frontal oblicua) se identifican microinsertos bilaterales.

    b) Una imagen frontal o frontal oblicua del eje lineal del microinserto izquierdo que incluya el extremo proximal cruzando el miometrio en el cuerno (porción intersticial de la trompa de Falopio) o en contacto con la serosa de la unión uterotubárica, que se etiquetará como “izquierda”.
    c) Una imagen frontal o frontal oblicua del eje lineal del microinserto derecho cruzando el miometrio en el cuerno (porción intersticial de la trompa de Falopio) o en contacto con la serosa de la unión uterotubárica, que se etiquetará como “derecha”.
    d) Las tres imágenes deberán capturarse en película e incluirse en la historia clínica de la paciente para documentar la ubicación y retención satisfactorias de los microinsertos.
2. Clasificación de la ubicación de los microinsertos
    a) Identificación de los microinsertos: en una única imagen sin contraste deberá visualizarse una porción de cada microinserto en el cuerno en la proyección frontal o frontal oblicua para garantizar la ubicación bilateral y reducir el riesgo de imagen duplicada del mismo microinserto. El eje lineal de los microinsertos deberá verse relativamente simétrico.
    b) Ubicación óptima
    La ubicación del microinserto es óptima cuando su extremo proximal está en contacto con la cavidad uterina o el endometrio y el eje lineal está dentro del miometrio del cuerno (porción intersticial de la trompa de Falopio) y se puede visualizar en la serosa de la unión uterotubárica (SUUT) o cruzándola. La porción del microinserto situada en la trompa de Falopio puede visualizarse o no. El eje lineal del microinserto deberá visualizarse para verificar que no está enroscado ni estirado.



Ubicación óptima

    c) Ubicación satisfactoria
    La ubicación del microinserto es satisfactoria cuando su extremo proximal está en posición distal al endometrio, el eje lineal está dentro del miometrio del cuerno (porción intersticial de la trompa de Falopio) y se puede visualizar en la SUUT o cruzándola. La porción del microinserto ubicada en la trompa de Falopio puede visualizarse o no. El eje lineal del microinserto deberá visualizarse para verificar que no está enroscado ni estirado.

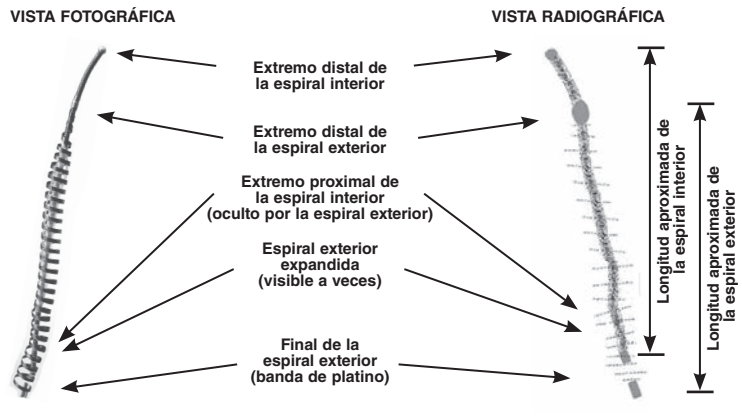


Ubicación satisfactoria

    d) Ubicación insatisfactoria
        (1) La ubicación del microinserto es insatisfactoria si no se puede visualizar en los cuernos una porción de cada microinserto en la proyección frontal o frontal oblicua en una imagen simple.
        (2) Existe sospecha de expulsión si no se puede identificar en los cuernos uno de los microinsertos o ambos en una proyección frontal en una única imagen simple.
        (3) Existe sospecha de colocación distal si el extremo proximal del microinserto no está ubicado en el miometrio del cuerno (porción intersticial de la trompa de Falopio) y no cruza la SUUT ni está en contacto con ella.
        (4) Existe sospecha de colocación proximal si se visualiza más del 50% o la mayoría del microinserto en la cavidad uterina o si el eje lineal del microinserto (o los microinsertos) se visualiza en la proyección sagital media.
        (5) Existe sospecha de perforación si el eje lineal de uno o ambos microinsertos es paralelo al epitelio endometrial en la proyección sagital o si el eje lineal de un microinserto se visualiza atravesando el miometrio en la proyección sagital media.
        (6) Posición sin clasificar: si no se puede identificar el eje lineal de un microinserto, lo cual indica que puede estar enroscado, doblado o estirado, la ubicación del microinserto se considera insatisfactoria. Si las partes blandas circundantes no están claramente definidas, la posición se considera insatisfactoria.
3. Si la evaluación ecográfica es dudosa o insatisfactoria, la paciente deberá someterse a una histerosalpingografía para evaluar la ubicación del microinserto y la oclusión tubárica.

D. Radiografía pélvica

1. Obtenga una imagen del útero en la que se vean con claridad los dos microinsertos **Essure**. Deberá anotarse la posición y la curvatura de los microinsertos.



Vista radiográfica correspondiente del microinserto ***Essure***

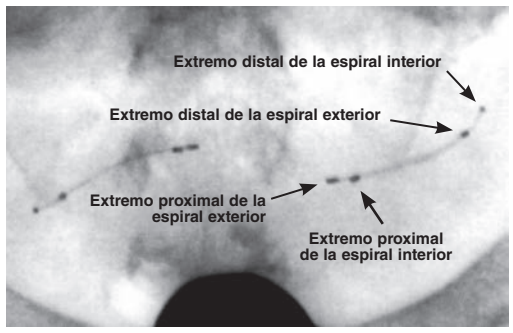
2. Evalúe la radiografía pélvica como sigue:
    a) Satisfactoria: los microinsertos parecen estar en la luz de la trompa, parecen extenderse a lo largo de la unión uterotubárica y parecen relativamente simétricos. Las pacientes cuyas radiografías se consideren “satisfactorias” pueden empezar a utilizar el microinserto **Essure** como método anticonceptivo.
    b) Sospechosa: uno o ambos microinsertos parecen estar en posición distal o proximal respecto a la ubicación óptima, pueden haber perforado parcial o totalmente la trompa y/o parecen relativamente asimétricos. Las pacientes cuyas radiografías se consideren “sospechosas” deberán ser informadas de que tendrán que seguir utilizando un método anticonceptivo alternativo y hacerse una histerosalpingografía.
    c) Insatisfactoria: ubicación intraperitoneal obvia o expulsión del microinserto.
3. Si una evaluación radiográfica es dudosa o insatisfactoria, o si la ubicación del microinserto es sospechosa, la paciente deberá someterse a una HSG para evaluar la ubicación del microinserto y la oclusión tubárica.

E. Realización y evaluación de histerosalpingografías modificadas

1. La histerosalpingografía se hace para evaluar más detalladamente la ubicación del microinserto **Essure** y la oclusión de la trompa de Falopio, si se considera necesario por los resultados de la radiografía. Para realizar y evaluar la histerosalpingografía, siga las instrucciones que figuran a continuación.
2. Pautas para la realización de la histerosalpingografía:
    a) Obtenga un buen llenado de los cuernos para que la silueta de la cavidad uterina se vea con claridad.
    b) Sitúe el haz fluoroscópico lo más próximo posible a la proyección anteroposterior.
    c) No dilate el cuello si no es necesario; en caso de que se produzca dilatación, mantenga un buen sellado cervical.
    d) En las pacientes que tengan el útero en posición medial puede ser necesario aplicar una tracción descendente sobre el tenáculo del cuello del útero. Retire el espéculo antes de la radiografía para visualizar mejor la anatomía uterina.
    e) Haga un mínimo de seis radiografías para evaluar la ubicación del microinserto y la oclusión tubárica.
        (1) Radiografía 1, radiografía simple: útero y microinsertos sin contraste.
        (2) Radiografía 2, llenado mínimo de la cavidad: útero y microinsertos con una pequeña cantidad de contraste.
        (3) Radiografía 3, llenado parcial de la cavidad: útero y microinsertos cuando están casi llenos de contraste.
        (4) Radiografía 4, llenado total de la cavidad: útero y microinsertos cuando los cuernos están distendidos por el contraste.

(5) Radiografías 5 y 6, ampliaciones de los cuernos uterinos: el microinserto dentro de la trompa de Falopio del cuerno derecho (5) e izquierdo (6).

PRECAUCIÓN: evite una presión intrauterina excesiva después de la radiografía 4 para evitar molestias innecesarias a la paciente y una reacción vasovagal.



3. Evaluación de la ubicación del microinserto
   a) Durante la evaluación, observe los cuatro "marcadores" situados en los extremos de las espirales interior y exterior. Tenga en cuenta que la relación de los marcadores distales entre ellos en cuanto a la posición es fija, mientras que los marcadores proximales pueden moverse o parecer que se han ensanchado debido a la flexibilidad de la espiral exterior. La ubicación ideal del microinserto es aquella en la que la espiral interior cruza la unión uterotubárica.
   b) Evalúe la ubicación del microinserto:
      (1) Expulsión o colocación proximal: microinserto ausente o ≥ 50% de la espiral interior sale a la cavidad uterina.
      (2) Colocación satisfactoria: el extremo distal de la espiral interior está dentro de la trompa, con < 50% de la espiral interior saliendo a la cavidad uterina o ≤ 30 mm del extremo proximal de la espiral interior dentro de la trompa desde donde el contraste llena el cuerno.
      (3) Colocación distal o perforación: el microinserto está en la trompa pero el extremo proximal de la espiral interior está a > 30 mm en posición distal con respecto a donde el contraste llena el cuerno o el microinserto está completa o parcialmente perforado.
4. Evaluación de la oclusión tubárica
   a) Determine si el contraste es visible más allá del microinserto y anote cualquier grado de llenado tubárico proximal, incluso si la trompa está ocluida.
   b) Evalúe la oclusión tubárica:
      (1) Oclusión satisfactoria: la trompa está ocluida en el cuerno.
      (2) Oclusión satisfactoria: se ve el contraste dentro de la trompa, pero no pasado el extremo distal de la espiral exterior.
      (3) Oclusión insatisfactoria: se ve el contraste pasado el extremo distal del microinserto o en la cavidad peritoneal.
5. Evaluación de la fiabilidad
   a) Si tanto la ubicación como la oclusión tubárica se consideran satisfactorias, informe a la paciente de que puede dejar el método anticonceptivo alternativo.
   b) Si la ubicación es insatisfactoria, informe a la paciente de que no debe confiar en los microinsertos para la anticoncepción.
   c) Si la ubicación es satisfactoria pero la oclusión es insatisfactoria, informe a la paciente de que debe seguir con el método anticonceptivo alternativo. Repita la histerosalpingografía a los tres meses. Si la oclusión sigue siendo insatisfactoria, informe a la paciente de que no debe confiar en los microinsertos para la anticoncepción.

X. Tratamiento de la ubicación insatisfactoria del microinserto

A. Ubicación insatisfactoria del microinserto diagnosticada mediante histerosalpingografía

1. Ubicación proximal: se ve más del 50 % de la longitud de la espiral interior del microinserto internándose en el útero.
2. Ubicación distal: el microinserto está en la trompa de Falopio, pero el extremo proximal de la espiral interior está a más de 30 mm del medio de contraste que llena los cuernos uterinos.
3. Expulsión completa del microinserto; el microinserto no está en el cuerpo.
4. Perforación: el microinserto perfora total o parcialmente la trompa de Falopio.
5. Ubicación intraperitoneal del microinserto; es obvio que el microinserto se encuentra fuera de la trompa de Falopio.

B. Tratamiento de la expulsión del microinserto o de la ubicación insatisfactoria de éste

1. Expulsión bilateral de los microinsertos con oclusión bilateral: la paciente debe ser informada de que tiene la opción de someterse a esterilización quirúrgica o de confiar en la oclusión proximal bilateral de sus trompas de Falopio como método anticonceptivo, dada la posibilidad de que la Prueba de Confirmación **Essure** (HSG) indique un diagnóstico positivo falso de oclusión tubárica.
2. Expulsión bilateral de los microinsertos con oclusión en una trompa y permeabilidad en la trompa contralateral: puede considerarse la posibilidad de volver a intentar un procedimiento adicional en la paciente para reponer el microinserto en la trompa permeable, de forma que pueda utilizar un microinserto **Essure** y la oclusión tubárica proximal (OTP) de la trompa contralateral como método anticonceptivo. La paciente debe ser informada de esta opción, dada la posibilidad de que la Prueba de Confirmación **Essure** (HSG) indique un diagnóstico positivo falso de oclusión tubárica. También se le deberá asesorar sobre la opción de someterse a esterilización quirúrgica.
3. Expulsión unilateral de un microinserto o ubicación insatisfactoria unilateral del mismo (en el miometrio o en la cavidad intraperitoneal), con el microinserto contralateral en una ubicación satisfactoria: si la Prueba de Confirmación **Essure** (HSG) muestra que hay un bloqueo tubárico en la trompa de Falopio que expulsó el microinserto o donde debería estar colocado el microinserto, la paciente puede fiarse del microinserto colocado satisfactoriamente y de la OTP contralateral, dada la posibilidad de que la Prueba de Confirmación **Essure** (HSG) indique un diagnóstico positivo falso de oclusión tubárica. También se le deberá asesorar sobre la opción de someterse a esterilización quirúrgica.
4. Ubicación unilateral insatisfactoria de un microinserto (en el miometrio o en la cavidad intraperitoneal) con el microinserto contralateral en una ubicación satisfactoria: si la Prueba de Confirmación **Essure** (HSG) muestra que hay permeabilidad en la trompa de Falopio en la que debería estar colocado un microinserto, se le puede ofrecer a la paciente la oportunidad de volver para un nuevo intento de colocación del microinserto. También se le deberá asesorar sobre la opción de someterse a esterilización quirúrgica.
5. Expulsión unilateral de un microinserto; ubicación unilateral insatisfactoria de un microinserto (en el miometrio o en la cavidad intraperitoneal); ubicación unilateral insatisfactoria de un microinserto en "ubicación proximal" (>50 % de la longitud de la espiral interior aparece como internándose en el útero) o en "ubicación distal" (el microinserto está en la trompa de Falopio, pero el extremo proximal de la espiral interior está a más de 30 mm del medio de contraste que llena los cuernos uterinos), con el microinserto contralateral en una ubicación insatisfactoria: la paciente debe ser informada de que tiene la opción de someterse a esterilización quirúrgica. En todos los casos, si se considera necesario extraer el microinserto y no es posible la extracción histeroscópica, puede que sea necesario realizar una intervención quirúrgica.
6. Si una paciente ha optado por la esterilización quirúrgica después de alguna de las situaciones citadas anteriormente, deberán ocluirse ambas trompas, haya o no algún microinserto colocado en una ubicación satisfactoria. La recuperación de los microinsertos deberá intentarse siempre que el médico considere que puede hacerse de manera segura; no obstante, puede que no sea posible dicha recuperación. Se recomienda el uso de fluoroscopía intraoperatoria para determinar la ubicación de los microinsertos antes de la intervención quirúrgica y durante ésta. El intento de recuperación no deberá durar más de 30 minutos.

XI. Tratamiento de casos de colocación insatisfactoria del microinserto Essure

Si fracasa la implantación unilateral o bilateral de un microinserto o microinsertos, la paciente deberá ser informada de que el procedimiento de anticoncepción permanente no se ha completado. Si la paciente decide someterse a esterilización laparoscópica (es decir, aplicación de grapas o electrocauterización), deberán pinzarse o cauterizarse ambas trompas de Falopio, incluso si una de ellas tiene implantado un microinserto **Essure**. El pinzamiento o la cauterización de las trompas de Falopio deberá realizarse en posición distal respecto al microinserto **Essure**.

Si la paciente no opta por la esterilización laparoscópica, se le puede ofrecer la realización de una Prueba de Confirmación **Essure** (HSG) después de sus siguientes menstruaciones (antes de la ovulación: entre los días 7 y 14, teniendo en cuenta que el día 1 es el primer día de hemorragia) para determinar si hay permeabilidad tubárica. Si se observa permeabilidad tubárica, el médico puede ofrecer a la paciente un segundo intento de colocación de microinsertos. Si el segundo intento de colocación de microinsertos fracasa, es improbable que se pueda tener éxito en intentos posteriores de colocación de microinsertos en esa paciente. Si a la paciente le quedase un microinserto *in vivo*, se le deberá recomendar que no utilice ese microinserto unilateral como método anticonceptivo.

Si solamente se consiguió una colocación unilateral y la Prueba de Confirmación **Essure** (HSG) confirma la existencia de oclusión tubárica proximal (OTP) de la trompa contralateral, deberá informarse a la paciente de que tiene la opción de confiar en el único microinserto, dada la posibilidad de que la Prueba de Confirmación **Essure** (HSG) indique un diagnóstico positivo falso de OTP. La oclusión tubárica se define como la incapacidad del medio de contraste para pasar de la cavidad uterina al interior de la cavidad peritoneal en el momento de la Prueba de Confirmación **Essure** (HSG). También se le deberá asesorar sobre la opción de someterse a esterilización quirúrgica. No se recomienda intentar la extracción de un microinserto implantado unilateralmente, a menos que la paciente esté experimentando reacciones adversas al microinserto.

XII. Extracción del microinserto Essure

ADVERTENCIA: UNA VEZ IMPLANTADO, NO DEBE INTENTARSE EXTRAER HISTEROSCÓPICAMENTE EL MICROINSERTO ESSURE, A MENOS QUE HAYA 18 O MÁS ESPIRALES INTERNÁNDOSE EN LA CAVIDAD UTERINA. En ese caso, la extracción del microinserto deberá intentarse inmediatamente después de la colocación. Sin embargo, la extracción podría no ser posible. Si se intenta la extracción, deberán seguirse los pasos siguientes:

1. Introduzca un instrumento prensor a través del canal de trabajo del histeroscopio.
2. Sujete la espiral exterior del microinserto **Essure**. Intente sujetar conjuntamente las espirales exterior e interior del microinserto.
3. Tire hacia atrás del instrumento prensor y del histeroscopio al mismo tiempo, de manera que todo el sistema se extraiga del útero a la vez.
4. Las espirales exterior e interior del microinserto **Essure** podrían estirarse o alargarse en el momento de la extracción.
5. Si fuera necesario, administre analgesia o anestesia para reducir o evitar molestias a la paciente.
6. Si se consigue extraer completamente el microinserto **Essure**, deberá intentarse colocar otro.
7. Si el médico no quedase completamente convencido de que se ha extraído la totalidad del microinserto **Essure** de la trompa de Falopio, **NO** deberá colocarse otro microinserto en esa trompa y deberá hacerse una radiografía posterior al procedimiento para determinar si algún fragmento del microinserto permanece *in vivo*.

Aparte de lo descrito anteriormente, la extracción del microinserto deberá intentarse únicamente si la paciente está experimentando alguna reacción adversa, o si ella solicita la extracción del mismo.

Si se considera necesaria la extracción del microinserto, se requerirá un abordaje transabdominal (es decir, laparotomía o laparoscopia).

Si el microinserto está ubicado apropiadamente en la unión útero-tubárica, será necesaria una resección de cuernos de la parte proximal de la trompa de Falopio.

Un microinserto **Essure** que haya sido colocado incorrectamente o que se haya desplazado más allá de la unión útero-tubárica deberá extraerse con una salpingotomía lineal tradicional o con una salpingectomía mediante laparoscopia o laparotomía.

1. Para realizar una salpingotomía lineal, se hará una pequeña incisión (de aproximadamente 2 cm de longitud) a lo largo del borde antimesentérico de la trompa de Falopio, directamente por encima del microinserto.
2. Para recuperar el microinserto puede practicarse una salpingectomía total o parcial junto con un procedimiento tradicional de esterilización tubárica, o independientemente de dicho procedimiento.

XIII. Tarjeta de identificación de la paciente

Cada paciente que tenga implantados microinsertos **Essure** deberá recibir una tarjeta laminada de tamaño apropiado para carteras (billeteras) que indique que tiene implantados microinsertos **Essure**. **La tarjeta viene incluida en este paquete.** La tarjeta indicará también que puede haber riesgos asociados con la realización futura de procedimientos intrauterinos o cirugía en los órganos reproductores de la paciente.

XIV. Explicación de los símbolos

STERILE EO	Esterilizado con óxido de etileno
LOT	Código de lote
	No reutilizar
REF	Número de catálogo
	Consulte las instrucciones de uso
	Fecha de caducidad
	Mantener alejado de fuentes del calor
	No utilizar si el envase está abierto o dañado
MR	RM condicionada
EC REP	Representante europeo autorizado
CE 0050	Este dispositivo cumple los requisitos de la Directiva Europea 93/42/CE
	Mantener seco
CONT	Contenido

Fabricante:
Bayer HealthCare LLC
1011 McCarthy Blvd.
Milpitas, California 95035
USA
essure.com

Representante autorizado para Europa:
Bayer Pharma AG
Müllerstr. 178
13353 Berlín
Alemania

Para solicitar el producto o notificar reacciones adversas, póngase en contacto con el representante local de Bayer HealthCare LLC.

Français

essure®
Contraception permanente

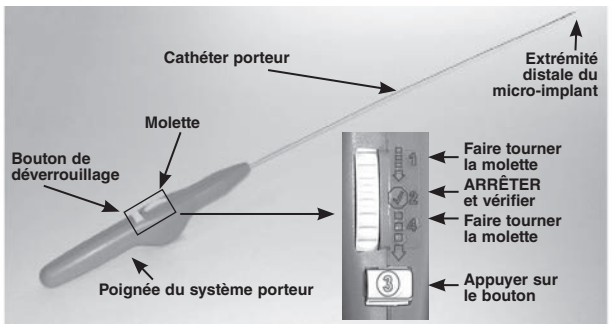
BAYER

MODE D'EMPLOI

I. Description des micro-implants

Le système de contraception permanente **Essure**® comprend plusieurs composants. Le micro-implant **Essure**, un dispositif à expansion dynamique, est fixé à un guide porteur et à un cathéter de largage. L'ensemble est protégé sous gaine dans un cathéter porteur. Ce système (représenté à la figure 1) est fixé à une poignée qui facilite la mise en place et le déploiement des micro-implants. Un introducteur **DryFlow**® à valve est également fourni avec le système **Essure**. Cet introducteur est destiné à protéger le micro-implant **Essure** lors de son passage à travers l'orifice en caoutchouc du canal d'insertion de l'hystéroscope.

Figure 1
Système porteur Essure
Avec détail des symboles utilisés pour la procédure de mise en place
(NON À L'ÉCHELLE)



II. Mécanisme d'action

Sous hystéroscopie, le système **Essure** délivre un micro-implant **Essure** dans la section proximale de la lumière d'une trompe de Fallope. Lorsque le micro-implant **Essure** se déploie après son largage, il s'ancre profondément dans la trompe de Fallope. Le micro-implant induit ultérieurement une réaction tissulaire bénigne, aboutissant à une encapsulation du micro-implant, ancrant fermement celui-ci dans la trompe de Fallope. Cette réaction tissulaire bénigne est locale, fibreuse et de nature occlusive.

Chaque système **Essure** est stérilisé avec de l'oxyde d'éthylène et fourni stérile pour un usage unique. Ne pas réutiliser, ni re-stériliser. La re-stérilisation peut avoir des répercussions sur le fonctionnement mécanique correct du dispositif, ce qui entraînerait un risque de blessure pour le patient.

III. Indications

Le système **Essure** est destiné à être utilisé comme micro-implant d'occlusion tubaire implanté à des fins de contraception permanente.

IV. Contre-indications

- Incertitude de la patiente quant à son désir de mettre un terme à sa fertilité.
- Grossesse réelle ou soupçonnée.
- Accouchement ou interruption d'une grossesse de second trimestre, moins de 6 semaines avant la pose des micro-implants **Essure**.
- Infection pelvienne évolutive ou récente.
- Cervicite aiguë non traitée.
- Saignements vaginaux inexpliqués ou graves.
- Malignité gynécologique (soupçonnée ou documentée).
- Anomalie reconnue de la cavité utérine ou des trompes de Fallope rendant difficile voire impossible la visualisation des ostiums tubaires et/ou la canulation de la trompe proximale.
- Allergie aux produits de contraste (une hystérosalpingographie peut s'avérer nécessaire trois mois après la pose des micro-implants).
- La patiente est actuellement sous corticostéroïdes.

V. Avertissements

- La procédure **Essure** ne doit être réalisée que par des hystéroscopistes expérimentés qui ont participé à terme au programme de formation *Bayer HealthCare LLC* concernant cette intervention.
- Les personnes allergiques au nickel-titane peuvent présenter une réaction allergique au micro-implant.
- Ne pas utiliser le système **Essure** si l'emballage est ouvert ou endommagé. Ne pas utiliser si l'un des micro-implants est endommagé.
- Lors de l'introduction d'un micro-implant **Essure** dans la trompe de Fallope, ne jamais le pousser contre une résistance excessive.
- Interrompre la progression du système **Essure** lorsque le marqueur de positionnement du cathéter a atteint l'ostium tubaire. Une progression au-delà de ce point pourrait aboutir à une mise en place inadéquate du micro-implant ou à une perforation tubaire ou utérine.
- Si on constate ou on soupçonne une perforation tubaire, ne pas continuer la mise en place d'un micro-implant **Essure**. Un très faible pourcentage des femmes incluses dans les essais cliniques du micro-implant **Essure** (1,8% ou 12/682 patientes) ont été identifiées comme présentant des perforations tubaires liées à l'utilisation du micro-implant. S'il s'avère nécessaire, le retrait du micro-implant perforateur devra être effectué par laparoscopie ou une autre technique chirurgicale.
- Si les tentatives de mise en place d'un micro-implant **Essure** échouent après 10 minutes de canulation par trompe, mettre fin à l'intervention et, le cas échéant, la remettre à une date ultérieure.
- Une fois qu'un micro-implant est en place (c'est-à-dire détaché du guide porteur), ne pas tenter son retrait sous hystéroscopie avant de s'être assuré qu'au moins 18 spirales du micro-implant **Essure** se trouvent dans la cavité utérine. Dans un tel cas, le retrait du micro-implant doit être tenté immédiatement après la mise en place. Il se peut toutefois, que son retrait s'avère impossible.
- La patiente doit recourir à une autre méthode contraceptive jusqu'à ce que la radiographie réalisée trois mois après la pose des micro-implants démontre que leur site d'implantation est adéquat.
- Il se peut que dans l'avenir, des patientes porteuses de micro-implants **Essure** puissent nécessiter des traitements intra-utérins reposant sur l'énergie électrique. Il est recommandé d'éviter l'utilisation d'un électrocautère lors d'une intervention chirurgicale impliquant les cornes utérines ou les trompes de Fallope. Pour toutes autres interventions pelviennes, éviter le recours à un électrocautère à une distance inférieure à 4 cm du micro-implant. La présence des micro-implants **Essure** peut engendrer des risques associés à de telles interventions, et non identifiés à ce jour.
- Toute intervention intra-utérine telle qu'une biopsie endométriale, un curettage, une hystéroscopie (diagnostique ou opératoire) dont l'ablation de l'endomètre, risque de compromettre la capacité contraceptive des micro-implants. En outre, la présence des micro-implants **Essure** peut entraîner des risques associés à de telles interventions qui n'ont pas encore été identifiés.
- Des études cliniques et sur banc d'essai ont montré que l'ablation de l'endomètre pouvait s'effectuer efficacement et sans danger avec le système à ballonet intra-utérin GYNECARE THERMACHOICE*, le système d'ablation de l'endomètre Hologic NovaSure**, et l'Hydro Thermablator*** de Boston Scientific, **immédiatement** après la mise en place du micro-implant **Essure**. Aucune étude spécifique n'a été menée afin d'évaluer les taux d'expulsion ou de contraception avec le micro-implant **Essure** à la suite des procédures combinées **Essure** et ablation de l'endomètre.
- Les patientes peuvent ultérieurement décider de recourir à une fécondation in vitro (FIV) pour devenir enceintes. Les effets des micro-implants **Essure** sur la réussite d'une FIV ne sont pas connus. En cas de grossesse, les risques présentés par les micro-implants pour la patiente, le fœtus et la continuation de la grossesse ne sont pas connus.

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** Marque de commerce propriété de Hologic, Inc.
*** Marque de commerce propriété de Boston Scientific Corporation

VI. Mises en garde

- La mise en place des micro-implants doit avoir lieu si possible entre les jours 7 et 14 du cycle menstruel (où le jour 1 représente le premier jour des règles) afin d'améliorer la visualisation des ostiums tubaires et de réduire les risques de pose des micro-implants chez une patiente présentant une grossesse non diagnostiquée.
- Une anomalie anatomique de l'utérus risque de compliquer la mise en place des micro-implants **Essure**.
- Afin de réduire les risques de perforation utérine, mettre fin à l'intervention si la dilatation du col utérin demande une force excessive.
- Repérer et évaluer les deux ostiums tubaires sous hystéroscopie avant de procéder à la mise en place des micro-implants **Essure**. Ne jamais tenter la pose d'un micro-implant dans un ostium tubaire sans une anticipation raisonnable que l'autre trompe est accessible et non occluse.
- La réalisation de l'ablation de l'endomètre immédiatement après la mise en place de micro-implants **Essure** peut augmenter le risque de syndrome de la stérilisation tubaire post-ablation, une affection rare qui a été rapportée chez des femmes avec des antécédents de stérilisation tubaire qui subissent une ablation de l'endomètre.
- Ne pas avancer le système **Essure** si la patiente éprouve des douleurs ou un malaise inattendus.
- Conserver le système **Essure** dans un endroit frais et sec.

VII. Effets indésirables possibles

A. Grossesse

Il existe des risques de grossesse normale ou extra-utérine, ainsi que des risques associés au traitement dans les deux cas. Si la patiente conçoit et choisit de continuer une grossesse intra-utérine, il convient de l'informer que les risques présentés par les micro-implants pour elle, le fœtus et la continuation de la grossesse ne sont pas connus.

B. Risques associés à la procédure de mise en place des micro-implants

- On peut administrer une anesthésie locale, une analgésie ou sédation par voie orale, une anesthésie régionale (c.-à-d., rachidienne ou épidurale), une sédation par voie orale ou intraveineuse (patiente éveillée), ou une anesthésie générale à la patiente afin d'éviter ou de réduire les douleurs. Indépendamment du type d'anesthésie, il est possible que certaines patientes ne puissent pas reprendre leurs activités normales pendant 12 à 24 heures après l'intervention.
- Des douleurs, des crampes et des saignements vaginaux sont possibles pendant et après la pose des micro-implants. Ces réactions sont généralement tolérables, passagères et facilement traitées par médicaments.
- Pendant et/ou immédiatement après la pose des micro-implants, la patiente peut éprouver des nausées ou des vomissements. Ces réactions sont généralement passagères et peuvent être traitées par médicaments selon les besoins.
- Certaines patientes peuvent éprouver un évanouissement ou une réaction vaso-vagale le jour de l'intervention.
- Il existe des risques de perforation ou de dissection des trompes de Fallope ou des cornes utérines. Une telle perforation ou dissection peut entraîner des saignements et des cicatrices, mais ne nécessite généralement pas de traitement.
- L'hystéroscope, le système **Essure** ou d'autres instruments utilisés pendant l'intervention engendrent des risques de perforation utérine et de lésions de l'intestin, de la vessie et des principaux vaisseaux sanguins. Dans de tels cas, une intervention chirurgicale peut s'avérer nécessaire, bien qu'improbable. Afin de diminuer les risques de perforation utérine, mettre fin à l'intervention si la dilatation du col utérin demande une force excessive.
- Un micro-implant **Essure** peut être accidentellement placé dans le myomètre de l'utérus et non dans la lumière d'une trompe de Fallope. Si un micro-implant a déjà été correctement mis en place dans une trompe de Fallope, et que le second se trouve accidentellement placé dans le myomètre, on peut tenter la pose d'un troisième micro-implant pour terminer la procédure. Si la mise en place dans les deux trompes de Fallope s'avère impossible, la patiente peut avoir un micro-implant dans une trompe et/ou un autre dans le myomètre, sur lequel on ne peut pas compter pour la contraception. La mise en place d'un micro-implant dans le myomètre peut entraîner des douleurs postopératoires ou d'autres effets indésirables. Dans un tel cas, si le retrait chirurgical de l'un ou des deux micro-implants s'avère obligatoire, il pourra nécessiter une salpingectomie ou une hystérectomie.
- Un micro-implant **Essure** peut être mis en place trop en aval dans la trompe de Fallope. Dans un tel cas, si le retrait du micro-implant s'avère nécessaire, une intervention chirurgicale (laparoscopie ou laparotomie) sera requise.
- Un micro-implant **Essure** peut être mis en place trop en amont dans la trompe de Fallope. Si 18 spirales ou plus du micro-implant **Essure** sont visibles au moment de la mise en place, tenter immédiatement le retrait du micro-implant (voir la section XIII, Retrait d'un micro-implant **Essure**). Dans un tel cas, il se peut que la tentative de retrait échoue ou que le micro-implant **Essure** se brise en laissant un fragment *in vivo*. Si le retrait du micro-implant est essayé et/ou réussi, la patiente peut ressentir des douleurs, des crampes et des saignements plus importants pendant et après la mise en place du micro-implant **Essure**.
- Le micro-implant **Essure** peut perforer la paroi tubaire ou l'une des cornes utérines, ce qui risque d'aboutir au largage du micro-implant dans la cavité péritonéale. Des douleurs postopératoires et/ou des troubles menstruels ou d'autres effets indésirables peuvent s'ensuivre. Si la patiente choisit de se soumettre à une stérilisation par incision ou une autre intervention chirurgicale, on peut tenter de retirer le micro-implant de la cavité péritonéale si le médecin estime cette tentative sans danger. Toutefois, ce retrait peut s'avérer impossible si le micro-implant ne peut être visualisé ou s'il n'est pas accessible.
- La mise en place du micro-implant **Essure** peut n'être obtenue que dans une seule trompe. Dans ce cas, le micro-implant laissé *in vivo* n'est pas fiable pour une contraception permanente.
- La mise en place d'un micro-implant **Essure** peut s'avérer impossible dans les deux trompes.
- Il existe un risque minime d'absorption excessive du sérum physiologique utilisé pour la dilatation de l'utérus nécessaire à la procédure hystéroscopique.
- Comme lors de toute intervention invasive, la mise en place des micro-implants peut entraîner une infection. Une infection peut aboutir à des lésions de l'utérus, des trompes de Fallope ou de la cavité pelvienne nécessitant un traitement par antibiotiques ou, plus rarement, une hospitalisation ou une intervention chirurgicale, dont une hystérectomie.

C. Risques associés au port des micro-implants Essure

- Un micro-implant **Essure** peut migrer hors d'une trompe de Fallope. Ce déplacement peut être une expulsion (déplacement hors d'une trompe de Fallope et dans la cavité utérine, le col utérin, le vagin ou hors du corps) ou une migration (déplacement vers la trompe distale ou hors de la trompe et dans la cavité péritonéale). Il peut falloir recourir à des radiographies supplémentaires afin de repérer le ou les micro-implants, ainsi qu'à une intervention chirurgicale visant à leur retrait. Le déplacement d'un micro-implant peut entraîner une grossesse normale ou extra-utérine, des douleurs, des troubles menstruels et d'autres effets indésirables.
- Comme avec les autres méthodes actuellement disponibles de contraception mécanique permanente (telles que ligatures et anneaux), le retrait d'un micro-implant **Essure** nécessite une intervention chirurgicale. Il peut de plus nécessiter l'ablation chirurgicale des trompes de Fallope (salpingectomie) et de l'utérus (hystérectomie).
- Des douleurs et des crampes abdominales ou pelviennes peuvent se manifester. Ces douleurs et ces crampes peuvent survenir plus fréquemment lors des règles, pendant et après des rapports sexuels ou au cours d'autres activités physiques.
- Des saignements intermenstruels ou plus importants qu'à l'ordinaire lors des règles peuvent être constatés.
- Une femme regrette parfois sa décision d'avoir été l'objet d'une contraception permanente et en éprouve une légère dépression ou d'autres troubles émotionnels.

D. Risques associés aux procédures de suivi

- Il existe un risque associé à l'exposition aux rayonnements produits par la radiographie pelvienne obligatoire trois mois après la pose des micro-implants pour évaluer leur position. Un test de confirmation **Essure** (HSG) peut être également nécessaire. La partie fluoroscopie de l'hystérosalpingographie expose la patiente à environ 0,033 rad (pendant < 30 secondes). À titre de comparaison, l'exposition aux rayonnements associée à un lavement baryté est de 0,85 rad, soit une valeur supérieure à celle du test de confirmation **Essure** (HSG) requis. La quantité d'exposition aux rayons provenant d'une radiographie pelvienne est approximativement la même que celle reçue par une personne en un an de radioactivité naturelle.
- Les autres risques suivants sont associés à la procédure du test de confirmation **Essure** (HSG), si elle s'avère nécessaire: réaction vaso-vagale ; infection pouvant nécessiter un traitement par antibiotiques et dans de rares cas une hospitalisation ; pénétration intravasculaire ; perforation de l'utérus ; crampes et/ou saignements utérins ; douleurs et malaise et réaction allergique au latex. Dans de rares cas, l'exposition au latex a été associée à des réactions anaphylactiques susceptibles d'aboutir au décès.
- Chez certaines patientes, l'utilisation des produits de contraste utilisés pour réaliser le test de confirmation **Essure** (HSG) a été associée à des réactions allergiques. Les réactions allergiques peuvent se manifester par de l'urticaire ou des troubles respiratoires. Dans certains cas, des réactions anaphylactiques peuvent se produire et aboutir au décès.

E. Risques associés à des interventions ultérieures possibles

- Il se peut que dans l'avenir, des patientes porteuses de micro-implants **Essure** puissent nécessiter des traitements intra-utérins reposant sur l'énergie électrique. Il est recommandé d'éviter l'utilisation d'un électrocautère lors d'une intervention chirurgicale impliquant les cornes utérines ou les trompes de Fallope. Pour toutes autres interventions pelviennes, éviter le recours à un électrocautère à une distance inférieure à 4 cm du micro-implant. La présence des micro-implants **Essure** peut engendrer des risques associés à de telles interventions, et non identifiés à ce jour.
- Toute intervention intra-utérine telle qu'une biopsie endométriale, un curettage, une hystéroscopie (diagnostique ou opératoire) dont l'ablation de l'endomètre, risque de compromettre la capacité contraceptive des micro-implants. En outre, la présence des micro-implants **Essure** peut entraîner des risques associés à de telles interventions qui n'ont pas encore été identifiés.
- Les patientes peuvent ultérieurement décider de recourir à une fécondation in vitro (FIV) pour devenir enceintes. Les effets des micro-implants **Essure** sur la réussite d'une FIV ne sont pas connus. En cas de grossesse, les risques présentés par les micro-implants pour la patiente, le fœtus et la continuation de la grossesse ne sont pas connus.
- Les micro-implants **Essure** sont radio-opaques et ne présentent aucun risque sous IRM. Ils sont compatibles avec l'IRM, sauf pour l'imagerie pelvienne au cours de laquelle ils peuvent provoquer des artefacts.
- **Il est possible que des risques inconnus existent.**

VIII. Mode d'emploi

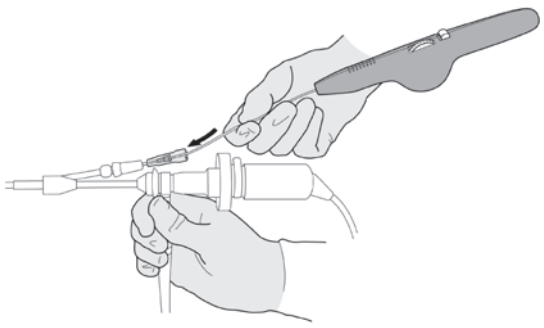
A. Avant la procédure de mise en place des micro-implants

1. La mise en place des micro-implants doit avoir lieu entre les jours 7 et 14 du cycle menstruel (où le jour 1 représente le premier jour des règles) afin d'améliorer la visualisation des ostiums tubaires et de réduire les risques de pose des micro-implants chez une patiente présentant une grossesse non diagnostiquée.
2. Un test de grossesse réalisé par le médecin ou une personne désignée doit être effectué dans les 24 heures précédentes ou immédiatement avant la procédure de mise en place des micro-implants.
3. L'administration d'un anti-inflammatoire non stéroïdien (AINS) tel que l'Indocide (par voie orale ou en suppositoire), une à deux heures avant la mise en place des micro-implants, est fortement recommandée car les données des essais cliniques démontrent que son utilisation augmente de manière significative la probabilité de réussite de la mise en place. Si l'on recourt seulement à une anesthésie paracervicale, du diazépam (par voie orale) ou un produit similaire, peut également être donné 30 minutes avant l'intervention pour diminuer l'anxiété.

B. Mise en place des micro-implants Essure

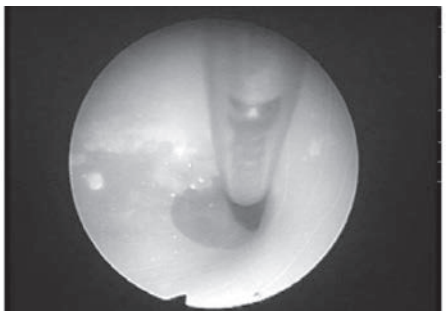
La mise en place des micro-implants **Essure** peut être réalisée en service de chirurgie d'un jour ou en ambulatoire. Employer une technique stérile pendant la mise en place des micro-implants. La durée d'intervention pour la mise en place d'un micro-implant ne doit pas dépasser 30 minutes.

1. Placer la patiente en position gynécologique.
2. Introduire un spéculum dans le vagin pour permettre l'accès au col utérin. Badigeonner le col avec de la bétadine ou une autre solution antibactérienne adéquate conformément aux méthodes habituelles.
3. Une anesthésie locale est la méthode préférentielle pour la mise en place des micro-implants. Une anesthésie paracervicale peut être administrée. Du midazolam (par voie intraveineuse) ou un produit similaire peut également être administré afin d'éviter ou de réduire la douleur, le cas échéant.
4. Introduire un hystéroscope stérile, auquel sont fixés une caméra et un canal d'insertion (d'un diamètre ≥ 5 Fr) par le col dans la cavité utérine. S'il y a lieu, réaliser une dilatation cervicale pour permettre l'insertion. Afin d'éviter une perforation utérine, mettre fin à l'intervention si une force excessive s'avère nécessaire pour obtenir la dilatation cervicale.
5. Dilater la cavité utérine au moyen d'une injection de sérum physiologique par le canal d'insertion de l'hystéroscope. Il est vivement recommandé de préchauffer le sérum physiologique à la température du corps et de l'introduire par gravité afin de minimiser les spasmes des trompes de Fallope. On doit obtenir et maintenir une excellente distension utérine pendant toute l'intervention. Suivre les méthodes standard de monitorage d'absorption du liquide pendant toute l'intervention. Repérer les ostiums tubaires sous hystéroscopie.
6. Identifier et évaluer les deux ostiums tubaires par hystéroscopie avant de procéder à la mise en place du micro-implant **Essure**. Ne jamais tenter la pose d'un micro-implant dans un ostium tubaire sans une anticipation raisonnable que l'autre trompe n'est pas occluse.
7. Une fois les ostiums tubaires repérés, insérer l'introducteur dans le bouchon d'étanchéité du canal d'insertion de l'hystéroscope. Garder le robinet du canal d'insertion en position ouverte (le micro-implant et/ou l'introducteur pourraient être endommagés par la fermeture du robinet). Placer le système porteur du micro-implant **Essure** dans l'introducteur et le faire avancer par le canal d'insertion de l'hystéroscope. S'il n'a pas été endommagé suite à la première mise en place du micro-implant, l'introducteur à valve peut demeurer dans le canal d'insertion tout au long de l'intervention **Essure**.



Insérer l'introducteur dans le bouchon d'étanchéité du canal d'insertion de l'hystéroscope, puis placer le système porteur **Essure** *dans l'introducteur.*

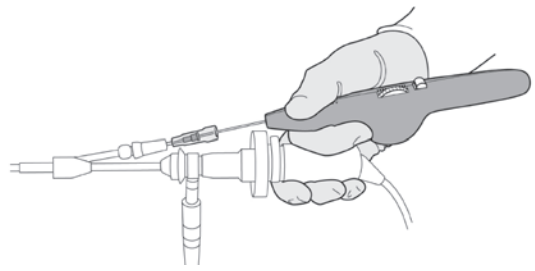
8. Faire avancer le système porteur **Essure** dans la trompe proximale d'un lent mouvement continu afin d'éviter des spasmes tubaires. Avancer le système porteur jusqu'à ce que le marqueur de positionnement du cathéter porteur atteigne l'ostium tubaire. Ce repère visuel indique que le micro-implant **Essure** enjambe du segment intramural distal à l'isthme proximal de la trompe de Fallope, la spirale externe enjambant la jonction utéro-tubaire. Ceci décrit la mise en place idéale du micro-implant **Essure**.



Faire progresser jusqu'à ce que le marqueur de positionnement noir atteigne l'ostium tubaire. Ceci est un indicateur visuel de la bonne position pour le déploiement.

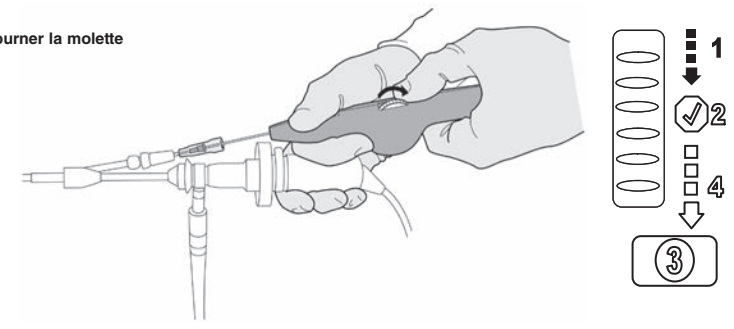
9. La capacité de faire avancer le cathéter sous visualisation directe sans résistance excessive indique l'alignement concentrique correct du cathéter porteur avec la lumière tubaire. Une résistance à la progression se manifeste généralement de deux façons : 1) le repère noir situé sur la surface externe du cathéter ne progresse visiblement pas vers l'ostium tubaire et/ou 2) le cathéter porteur se courbe ou se fléchit excessivement, ce qui empêche d'exercer une pression vers l'avant sur l'assemblage du cathéter. Si l'on constate que le cathéter présente une telle résistance de progression vers l'avant, ne pas forcer la mise en place du micro-implant afin d'éviter des risques de perforation utérine ou une mise en place accidentelle du micro-implant dans la musculature utérine au lieu de la lumière tubaire. Un test de confirmation **Essure** (HSG) devra être effectué pour évaluer la perméabilité tubaire.
10. S'il n'est pas possible de faire avancer le cathéter jusqu'au marqueur de positionnement, on peut effectuer un test de perfusion avec une sonde de perméabilité, si cela n'a pas déjà été fait pour évaluer la perméabilité tubaire. Si la trompe est bloquée ou si le cathéter ne peut pas être avancé jusqu'au marqueur de positionnement, mettre fin à l'intervention. Si la pose du micro-implant n'a pas été effectuée après 10 minutes de tentative de canulation par trompe, mettre fin à l'intervention.

11. Lorsque le cathéter porteur a été avancé jusqu'au marqueur de positionnement, déployer le micro-implant. Pour ce faire, stabiliser d'abord la poignée du micro-implant **Essure** contre la caméra de l'hystéroscope ou un autre objet fixe afin d'éviter la progression accidentelle du système **Essure** pendant la rétractation du cathéter porteur.



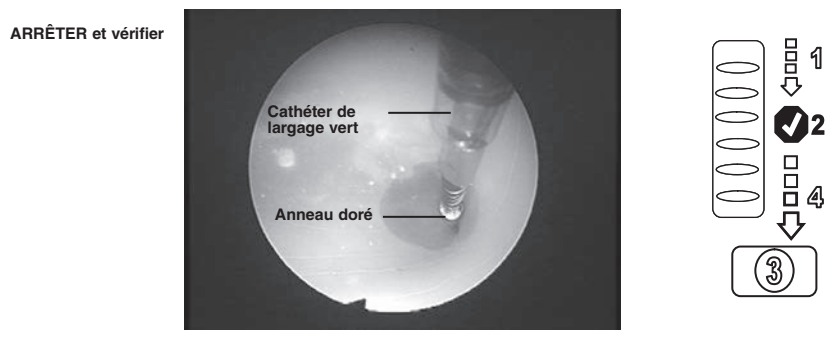
Stabiliser la poignée contre la tête de la caméra ou un autre objet fixe afin d'éviter la progression accidentelle du système **Essure**

12. Après s'être assuré que le marqueur de positionnement noir se trouve au niveau de l'ostium tubaire, tourner la molette de la poignée vers soi jusqu'à ce que la molette ne tourne plus. Cette opération correspond au symbole ⇩1 sur la poignée du système porteur. Ceci facilite le retrait du cathéter porteur. On observera que le marqueur de positionnement noir s'éloigne de l'ostium tubaire (en direction de l'hystéroscope) et disparaît dans le canal d'insertion. Le retrait du cathéter porteur expose le micro-implant **Essure** enroulé. Environ 1 cm du micro-implant (spirales enroulées) doit apparaître dans l'utérus lorsque le cathéter porteur est retiré.



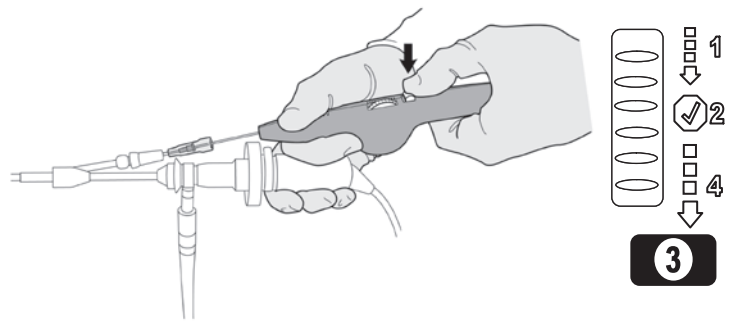
Faire tourner la molette pour rétracter le cathéter

13. Pour vérifier le bon positionnement du système, placer l'anneau marqueur doré à l'extérieur de l'ostium, ce qui correspond au symbole ✓2 sur la poignée du système de livraison. Le repérage visuel de l'anneau doré juste à l'extérieur de l'ostium, ainsi que de l'extrémité distale du cathéter de largage vert, confirme que le système est correctement positionné. Si plus d'1 cm du micro-implant est visible dans l'utérus, il conviendra de repositionner le micro-implant en faisant, si possible, avancer l'ensemble du système dans la trompe avant de passer à l'étape suivante.



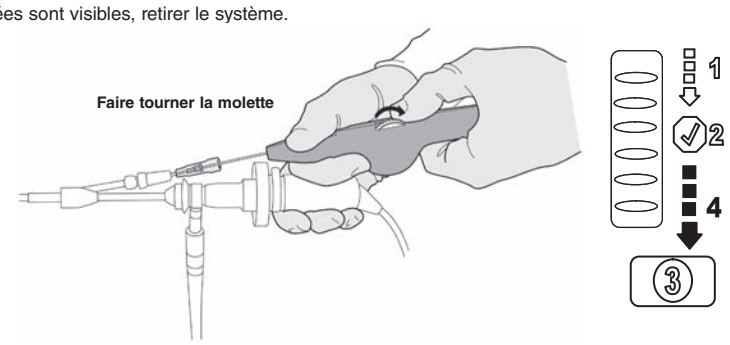
Repérage visuel de l'anneau doré au niveau de l'ostium

14. Appuyer sur le bouton de la poignée du système porteur pour permettre à nouveau la rotation de la molette, ce qui correspond au symbole ③ sur le bouton de la poignée.



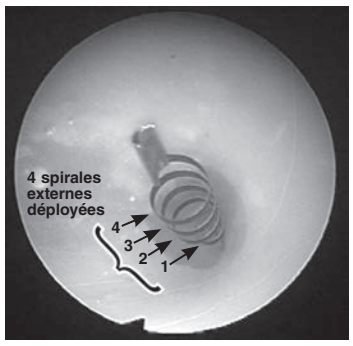
Appuyer sur le bouton pour permettre à nouveau la rotation de la molette

15. Faire tourner la molette vers soi pour déployer la spirale externe du micro-implant, ce qui correspond au symbole ⇩4 sur la poignée du système porteur. Continuer à faire tourner la molette jusqu'à ce qu'elle ne puisse plus tourner. Lorsque la molette ne peut plus tourner et que les spirales externes déployées sont visibles, retirer le système.



Faire tourner la molette pour déployer la spirale externe du micro-implant

16. Évaluer la position du micro-implant **Essure** déployé sous hystéroscopie. Idéalement, on doit observer 3 à 8 spirales externes du micro-implant **Essure** déployées dans l'utérus.



La présence de spirales externes du micro-implant **Essure** *déployées dans l'utérus indique la mise en place idéale*

17. Si le médecin n'est pas satisfait de la mise en place du micro-implant sous observation hystéroscopique ou soupçonne une perforation tubaire ou utérine, il conviendra de laisser le(s) micro-implants en place et de les évaluer via radiographie pelvienne ou HSG à trois mois suivant leur mise en place.

    AVERTISSEMENT : UNE FOIS QUE LE MICRO-IMPLANT A ÉTÉ LARGUÉ ET MIS EN PLACE DANS LA TROMPE DE FALLOPE, NE PAS TENTER SON RETRAIT SOUS HYSTÉROSCOPIE AVANT DE S'ÊTRE ASSURÉ QU'AU MOINS 18 SPIRALES DU MICRO-IMPLANT ESSURE SE TROUVENT DANS LA CAVITÉ UTÉRINE. Dans un tel cas, le retrait du micro-implant doit être tenté immédiatement pendant la mise en place. Toutefois, son retrait peut s'avérer impossible (voir la section XIII, Retrait d'un micro-implant **Essure**). Si le micro-implant a été accidentellement déployé dans la cavité utérine et non dans la trompe, on doit le retirer de l'utérus et tenter de nouveau sa mise en place dans la trompe.

18. Répéter la procédure de mise en place du micro-implant **Essure** dans la trompe controlatérale.

19. Noter la longueur du micro-implant présente dans la cavité utérine en incluant tout problème de repérage ou de vérification de l'un ou de l'autre des ostiums tubaires ainsi que tous problèmes de perforation possibles. Ces faits doivent être inscrits dans le dossier de la patiente afin de pouvoir s'y reporter ultérieurement lors du Test de confirmation Essure *(voir la section IX ci-dessous – Test de confirmation* **Essure***).*

20. **On devra avertir la patiente d'utiliser une autre forme de contraception (autre qu'un stérilet) pendant les 3 premiers mois suivant la mise en place des micro-implants.**

21. Prendre un rendez-vous pour un Test de confirmation **Essure** trois mois après la mise en place des micro-implants pour évaluer leur emplacement et rétention.

IX. Test de confirmation Essure

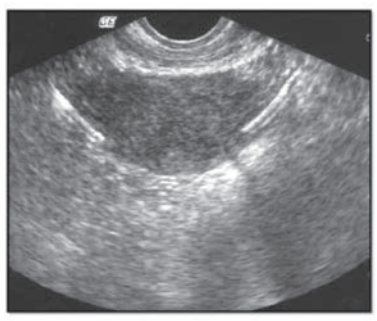
A. Il conviendra de passer un test de confirmation **Essure** après la mise en place des micro-implants afin d'évaluer leur rétention et emplacement. Le Test de confirmation **Essure** (échographie trans-vaginale – ETC, radiographie pelvienne ou hystérosalpingographie – HSG) devra être exécuté uniquement par un gynécologue expérimenté, un spécialiste de l'échographie et/ou un(e) radiologue formé(e) au protocole du Test de confirmation **Essure** correspondant. Un protocole détaillé avec des images et des conseils sur la réalisation du test est fourni avec la formation ; des exemplaires supplémentaires peuvent être obtenus en téléchargeant une copie à l'adresse : essure.com.

B. Pour un test de confirmation en première ligne, soit une radiographie pelvienne, soit une ETV peut se pratiquer trois mois après la mise en place, bilatérale et sans complications, des micro-implants.

1. La radiographie pelvienne et l'ETC ne devront pas être utilisées comme test de confirmation **Essure** sous conditions suivantes :
    a) Mise en place difficile, y compris selon un ou plusieurs des cas suivants :
        (1) Craintes de perforation lors de la mise en place en raison de l'application d'une force excessive pour l'introduction du micro-implant, et/ou d'une perte de résistance soudaine.
        (2) Repérage de l'ostium tubaire compromis lors de la mise en place en raison d'une dilatation insuffisante, d'un mauvais éclairage ou de la présence de débris d'endomètre.
        (3) Le chirurgien est incertain concernant l'emplacement du micro-implant.
    b) Durée de l'intervention > 15 minutes (entre l'introduction et le retrait de la sonde).
    c) Mise en place avec zéro ou > 8 spirales déployées dans l'utérus
    d) Post-intervention, présence de douleur inhabituelle, transitoire ou persistante, ou déclenchée ultérieurement sans autres causes identifiables.
2. Si la radiographie pelvienne ou l'échographie ne sont pas indiquées, la patiente devra se soumettre à une HSG permettant d'évaluer la position du micro-implant et l'occlusion tubaire. Une échographie trans-abdominale ne peut pas remplacer l'ETV. Lorsque les résultats de la radiographie pelvienne ou de l'échographie sont équivoques ou insatisfaisants, la patiente devra effectuer une HSG, ce qui permettra d'évaluer la position du micro-implant ainsi que l'occlusion tubaire.

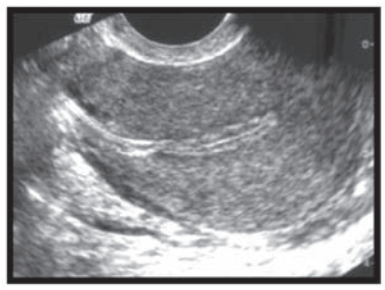
C. Échographie trans-vaginale

1. Trois clichés au minimum doivent être obtenus et conservés à titre de documentation :
    a) Un cliché en coupe coronale ou coronale oblique pour mettre en relief une partie de chaque micro-implant dans les cornes utérines, classé « Cliché de repérage ».



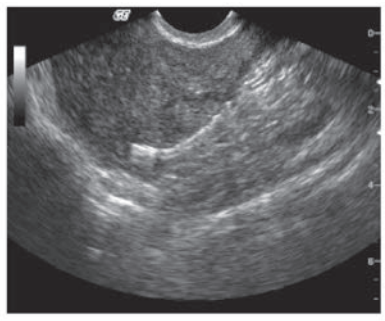
Les micro-implants sont repérés dans ce cliché transversal (coupe coronale /coronale oblique).

    b) Cliché en coupe coronale ou coronale oblique de l'axe linéaire gauche du micro-implant, y compris l'extrémité proximale qui traverse le myomètre des cornes utérines (partie interstitielle des trompes de Fallope) ou en contact avec la jonction utéro-tubaire séreuse, marqué « gauche ».
    c) Cliché en coupe coronale ou coronale oblique de l'axe linéaire droit du micro-implant, y compris l'extrémité proximale qui traverse le myomètre des cornes utérines (partie interstitielle des trompes de Fallope) ou en contact avec la jonction utéro-tubaire séreuse, marqué « droit ».
    d) L'ensemble des trois clichés devra être conservé sur pellicule et déposé dans le dossier médical de la patiente afin de documenter la rétention et la position satisfaisantes du micro-implant.
2. Classement des positions de micro-implants
    a) Repérage : Dans un cliché unique, une portion de chacun des micro-implants doit être visible dans les cornes utérines sous coupe coronale ou coronale oblique afin d'assurer leur position bilatérale et d'éviter le risque de duplicata des clichés d'un seul implant. L'axe linéaire des micro-implants devrait se présenter de façon relativement symétrique.
    b) Position optimale
    La position des micro-implants est optimale lorsque l'extrémité proximale du micro-implant se trouve en contact avec la cavité utérine ou l'endomètre, et l'axe linéaire s'inscrit dans le myomètre des cornes utérines (partie interstitielle des trompes de Fallope) et que ceci peut se visualiser à la jonction utéro-tubaire séreuse (JUTS) ou à son travers. La partie du micro-implant qui se trouve à l'intérieur de la trompe de Fallope sera visualisée ou non. L'axe linéaire du micro-implant devra être visible afin de confirmer que l'implant ne s'est pas allongé, ni enroulé.



Position optimale

    c) Position satisfaisante
    La position du micro-implant est satisfaisante lorsque l'extrémité du micro implant se trouve en position distale par rapport à l'endomètre, toutefois l'axe linéaire se trouve dans le myomètre des cornes utérines (partie interstitielle des trompes de Fallope) et est visible à la jonction utéro-tubaire séreuse (JUTS) ou à son travers. La partie du micro-implant à l'intérieur de la trompe de Fallope sera visible ou non. L'axe linéaire du micro-implant doit être visualisé pour confirmer que l'implant n'est pas enroulé ni allongé.

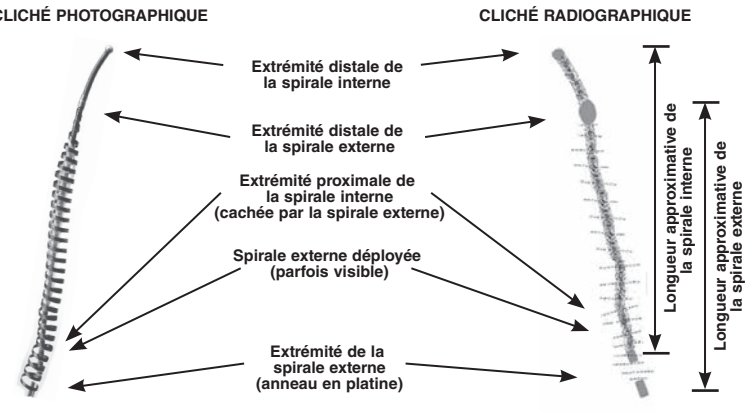


Position satisfaisante

    d) Position insatisfaisante
        (1) La position du micro-implant est insatisfaisante lorsqu'une partie de chaque micro-implant n'est pas visible dans les cornes utérines sous coupe coronale ou coronale oblique d'un des clichés de repérage.
        (2) L'expulsion sera soupçonnée si un ou les deux micro-implants ne sont pas repérés dans les cornes utérines sous coupe coronale d'un des clichés de repérage.
        (3) Une position distale sera soupçonnée lorsque l'extrémité proximale du micro-implant ne se trouve pas au niveau du myomètre des cornes utérines (partie interstitielle des trompes de Fallope), et ne traverse pas, ni entre en contact avec la JUTS.
        (4) Une position proximale sera soupçonnée lorsque plus de 50% ou la totalité du micro-implant est visible à l'intérieur de la cavité utérine ou si l'axe linéaire du/des micro-implant(s) est visible en ligne médiane d'une coupe sagittale.
        (5) Une perforation sera soupçonnée lorsque l'axe linéaire d'un ou des deux micro-implants se trouve parallèle à la partie endomètre d'une coupe sagittale ou si l'axe linéaire du micro-implant traverse le myomètre en ligne médiane d'une coupe sagittale.
        (6) Position incertaine : Lorsque l'axe linéaire du micro-implant n'est pas repéré et laisse supposer que l'implant est enroulé, tordu ou allongé, sa position est jugée insatisfaisante. Lorsque les tissus mous à proximité ne peuvent pas être clairement définis, sa position est jugée insatisfaisante.
3. Lorsque l'évaluation échographique est équivoque ou insatisfaisante, la patiente devra subir un examen HSG, ce qui permettra d'évaluer la position et l'occlusion tubaire de l'implant.

D. Radiographie pelvienne

1. Prendre un cliché de l'utérus permettant de visualiser clairement les micro-implants **Essure**. La position et la courbe des micro-implants devront être notées.



Perspectives radiographiques correspondant aux micro-implants **Essure**

2. Évaluer la radiographie pelvienne de la manière suivante :
    a) Satisfaisante : Les micro-implants semblent se trouver dans la lumière tubaire, enjamber la jonction utéro-tubaire, et être relativement symétriques. Les patientes dont les radiographies sont jugées « satisfaisantes » peuvent commencer à se fier aux micro-implants **Essure** comme méthode de contraception.
    b) Suspecte : L'un ou les deux micro-implants se trouvent en aval ou en amont par rapport à la position optimale, ou ont partiellement ou complètement perforé la trompe, et/ou semblent relativement asymétriques. On devra avertir les patientes dont les radiographies sont jugées « suspectes » de continuer à utiliser une autre méthode contraceptive et de se soumettre à une HSG.
    c) Insatisfaisante : Implantation visible du micro-implant dans la cavité péritonéale ou expulsion.
3. Lorsque les résultats de l'évaluation radiographique sont équivoques ou insatisfaisants ; ou la position du micro-implant est suspecte, la patiente doit passer une HSG permettant d'évaluer la position du micro-implant et l'occlusion tubaire.

E. Réalisation et évaluation des (hystérosalpingographies) HSG

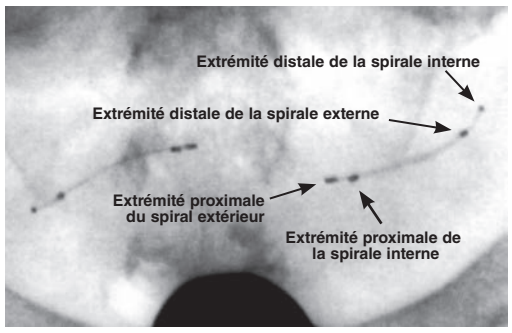
1. L'HSG a pour but d'évaluer plus précisément le site d'implantation des micro-implants **Essure** et l'occlusion des trompes de Fallope, le cas échéant, selon les résultats de la radiographie. Il conviendra de suivre les directives ci-dessous pour le déroulement et l'évaluation de l'HSG.
2. Directives pour l'HSG
    a) La silhouette de la cavité utérine doit être nettement visible et présenter un bon remplissage des cornes.
    b) Le faisceau fluoroscopique dirigé vers l'utérus doit être aussi proche que possible d'une projection A/P.
    c) Sauf nécessaire, ne pas dilater le col de l'utérus. En cas de dilatation, maintenir une étanchéité cervicale adéquate.
    d) Une traction descendante sur le tenaculum cervical sera peut-être nécessaire lorsque l'utérus est en position médiane. Retirer le speculum avant la fluoroscopie pour obtenir une visualisation optimale de l'anatomie utérine.
    e) Prendre au moins six clichés pour évaluer le site d'implantation du micro-implant et l'occlusion tubaire.
        (1) Radiographie 1 – « Cliché de repérage » - Utérus et micro-implants sans produit de contraste.
        (2) Radiographie 2 – Remplissage minimum de la cavité -– Utérus et micro-implants avec une petite quantité de produit de contraste

(3) Radiographie 3 – Remplissage partiel de la cavité - Utérus et micro-implants - lorsque presque rempli de produit de contraste.

(4) Radiographie 4 – Remplissage total de la cavité - Utérus et micro-implants, lorsque les cornes sont distendues par le produit de contraste.

(5) Radiographies 5 & 6- Agrandissements des cornes utérines – Micro-implants à l'intérieur de la trompe de Fallope avec cornes à droite (5) et à gauche (6)

ATTENTION : Éviter une pression utérine excessive au-delà de la Radiographie 4 afin d'éviter de provoquer un inconfort démesuré et la survenue d'un malaise vaso-vagal.



3. Évaluation du site d'emplacement du micro-implant
   a) Lors de l'évaluation de la position des micro-implants, remarquer les quatre « marqueurs » à chaque extrémité du spiral intérieur et extérieur. Remarquer que les marqueurs distaux sont fixes les uns par rapport aux autres, alors que les marqueurs proximaux peuvent se déplacer ou paraître s'étirer en raison de la flexibilité du spiral extérieur. Un micro-implant est en position idéale lorsque le spiral intérieur enjambe la jonction utéro-tubaire.
   b) Évaluer l'emplacement du micro-implant
      (1) Expulsion ou position proximale : Le micro-implant n'est pas présent ou ≥ 50% du spiral intérieur se trouve déployé à l'intérieur de la cavité utérine.
      (2) Position satisfaisante : L'extrémité distale du spiral intérieur se trouve à l'intérieur du tube, avec <50% du spiral intérieur déployé à l'intérieur de la cavité utérine ; ou l'extrémité proximale du spiral intérieur se trouve à ≤ 30 mm du site de remplissage des cornes avec le produit de contraste.
      (3) Position distale ou perforation : Le micro-implant se trouve à l'intérieur du tube mais l'extrémité proximale du spiral intérieur se trouve en position distale à > 30 mm du site de remplissage des cornes avec le produit de contraste ; ou le micro-implant se trouve complètement ou partiellement perforé.
4. Évaluation de l'occlusion tubaire
   a) Déterminer dans quelle mesure le produit de contraste se trouve visible au-delà du micro-implant et noter tout remplissage tubaire proximal quel qu'il soit, même lorsqu'il existe une occlusion tubaire.
   b) Évaluer l'occlusion tubaire
      (1) Occlusion satisfaisante : Il y a occlusion des tubes au niveau des cornes utérines.
      (2) Occlusion satisfaisante : Le produit de contraste est visible à l'intérieur du tube, mais pas au-delà de l'extrémité distale du spiral extérieur.
      (3) Occlusion insatisfaisante : Le produit de contraste est visible au- delà de l'extrémité distale du micro-implant ou dans la cavité péritonéale.
5. Évaluation de la fiabilité du dispositif
   a) Lorsque l'emplacement et l'occlusion tubaires sont jugés satisfaisants, conseiller aux patientes d'interrompre toute autre méthode de contraception alternative
   b) Lorsque la position est insatisfaisante, informer la patiente qu'elle ne doit pas se fier aux micro-implants comme moyen de contraception.
   c) Lorsque la position est satisfaisante alors que l'occlusion est insatisfaisante, conseiller aux patientes de conserver leur moyen de contraception alternatif et de repasser une HSG sous trois mois. Si l'occlusion demeure insatisfaisante, conseiller aux patientes de conserver leur moyen de contraception alternatif et de repasser une HSF sous trois mois. Si l'occlusion est toujours insatisfaisante, conseiller aux patientes de ne pas se fier aux micro-implants comme moyen de contraception.

X. Traitement d'un site d'implantation insatisfaisant d'un micro-implant

A. Site d'implantation insatisfaisant d'un micro-implant diagnostiqué par hystérosalpingographie

1. Emplacement proximal : plus de 50% de la longueur de la spirale interne du ou des micro-implants se trouve dans l'utérus.
2. Emplacement distal : le ou les micro-implants se trouvent dans les trompes mais l'extrémité proximale de la spirale interne se situe à plus de 30 mm du produit de contraste remplissant les cornes utérines.
3. Expulsion complète du ou des micro-implants ; le ou les micro-implants ne se trouvent pas dans le corps de la patiente.
4. Perforation : le ou les micro-implants ont engendré une perforation partielle ou totale.
5. Le ou les micro-implants se trouvent dans la cavité péritonéale ; ils sont manifestement implantés hors des trompes.

B. Traitement d'une expulsion ou d'un site d'implantation insatisfaisant d'un micro-implant

1. Expulsion bilatérale des micro-implants avec occlusion bilatérale : Conseiller la patiente sur l'option d'une stérilisation par incision ou sur la possibilité de se fier à l'occlusion tubaire proximale bilatérale pour la contraception, en raison du risque de diagnostic faussement positif d'occlusion tubaire par Test de confirmation **Essure** (HSG).
2. Expulsion bilatérale des micro-implants avec occlusion d'une trompe et perméabilité de l'autre : Envisager la pose d'un autre micro-implant pour remplacer celui situé dans la trompe perméable afin que la patiente puisse se fier à un micro-implant **Essure**, et à l'occlusion tubaire proximale controlatérale pour la contraception. Présenter cette option à la patiente, en raison du risque d'un diagnostic faussement positif d'occlusion tubaire par Test de confirmation **Essure** (HSG). Lui présenter également l'option d'une stérilisation par incision.
3. Expulsion unilatérale du micro-implant ou site d'implantation unilatéral insatisfaisant du micro-implant (dans le myomètre ou la cavité péritonéale) avec implantation insatisfaisante du micro-implant controlatéral : Si le Test de confirmation **Essure** (HSG) indique un blocage tubulaire au niveau du site d'expulsion du micro-implant ou au site où il aurait dû être mis en place, la patiente peut se fier au micro-implant dont le site d'implantation est satisfaisant et à l'occlusion tubulaire proximale controlatérale, en raison du risque d'un diagnostic faussement positif d'occlusion tubulaire par le Test de confirmation **Essure** (HSG) . Présenter également à la patiente l'option d'une stérilisation par incision.
4. Site d'implantation unilatéral insatisfaisant du micro-implant (dans le myomètre ou la cavité péritonéale) avec implantation insatisfaisante du micro-implant controlatéral : Si le Test de confirmation **Essure** (HSG) indique la perméabilité de la trompe qui aurait dû recevoir le micro-implant, on pourra offrir à la patiente la possibilité d'une seconde intervention visant à une nouvelle tentative de mise en place d'un autre micro-implant. Conseiller également la patiente sur l'opportunité d'une stérilisation par incision.
5. Expulsion unilatérale d'un micro-implant ; site d'implantation unilatéral insatisfaisant du micro-implant (dans le myomètre ou la cavité péritonéale) ; site d'implantation unilatéral insatisfaisant du micro-implant dans un « site proximal » (> 50% de la longueur de la spirale interne se trouve dans l'utérus) ou dans un « site distal » (le micro-implant se trouve dans la trompe mais l'extrémité proximale de la spirale interne est située à > 30 mm du produit de contraste remplissant les cornes utérines) avec implantation insatisfaisante du micro-implant controlatéral : Présenter à la patiente l'option d'une stérilisation par incision. Dans tous les cas, si le retrait du micro-implant s'avère nécessaire mais n'est pas possible par hystéroscopie, une intervention incisionnelle peut être requise.
6. Si une patiente a choisi une stérilisation par incision à la suite de l'un des scénarios mentionnés ci-dessus, les deux trompes doivent être occluses même en présence d'un micro-implant implanté dans un site satisfaisant. Le médecin doit tenter le retrait d'un micro-implant s'il pense que cette intervention peut être réalisée sans danger, mais ce retrait peut s'avérer impossible. Le repérage du site du ou des micro-implants en pré- et peropératoire doit se faire sous observation radioscopique. La tentative de retrait ne doit pas dépasser 30 minutes.

XI. Traitement des cas d'échec de mise en place des micro-implants Essure

Si la mise en place des micro-implants a échoué unilatéralement ou bilatéralement, informer la patiente que sa contraception permanente n'a pas été possible. Si la patiente choisit une stérilisation laparoscopique (c.-à-d., par ligature ou électrocautère), ligaturer ou cautériser les deux trompes de Fallope, même si l'une des trompes porte un micro-implant **Essure** implanté. Réaliser la ligature ou la cautérisation de la trompe ou des trompes en aval du micro-implant **Essure**.

Si la patiente n'a pas choisi une stérilisation laparoscopique, on peut lui suggérer un test de confirmation **Essure** (HSG) après ses prochaines règles (avant l'ovulation : entre les jours 7 et 14 du cycle menstruel, où le jour 1 représente le premier jour des règles) pour déterminer la perméabilité tubaire. Si celle-ci est constatée, on peut proposer à la patiente une seconde tentative de mise en place des micro-implants. Si cette seconde tentative échoue, il est peu probable que les tentatives ultérieures réussissent. Si la patiente n'a qu'un micro-implant *in vivo*, on doit l'avertir de ne pas s'y fier pour la contraception.

Si l'on n'a pu accomplir qu'une mise en place unilatérale et que le Test de confirmation **Essure** (HSG) confirme l'occlusion tubulaire proximale controlatérale, conseiller la patiente sur l'option de se fier à un seul micro-implant, en raison du risque d'un diagnostic faussement positif d'occlusion tubulaire proximale par Test de confirmation **Essure** (HSG). L'occlusion tubulaire est définie comme l'incapacité du colorant à passer de la cavité utérine à la cavité péritonéale lors d'un Test de confirmation **Essure** (HSG). Conseiller également la patiente sur l'opportunité d'une stérilisation par incision. Il n'est pas recommandé de tenter le retrait d'un micro-implant unilatéral, à moins que la patiente en éprouve des effets indésirables.

XII. Retrait d'un micro-implant Essure

AVERTISSEMENT : UNE FOIS QU'UN MICRO-IMPLANT ESSURE A ÉTÉ MIS EN PLACE, NE PAS TENTER DE LE RETIRER SOUS HYSTÉROSCOPIE AVANT DE S'ÊTRE ASSURÉ QU'AU MOINS 18 SPIRALES SE TROUVENT DANS LA CAVITÉ UTÉRINE. Dans un tel cas, le retrait doit être tenté immédiatement après la mise en place. Toutefois, il se peut que le retrait s'avère impossible. Si un retrait est tenté, observer les étapes suivantes :

1. Introduire un instrument de préhension par le canal d'insertion de l'hystéroscope.
2. Saisir la spirale externe du micro-implant **Essure**. Essayer de saisir ensemble les spirales interne et externe du micro-implant.
3. Rétracter simultanément l'instrument de préhension et l'hystéroscope, afin de pouvoir retirer de concert tout le système hors de l'utérus.
4. La spirale externe et/ou la spirale interne du micro-implant **Essure** peut s'étirer ou s'allonger lors de la tentative de retrait du micro-implant.
5. Au besoin, administrer un analgésique et/ou un anesthésique afin de réduire ou d'éviter des douleurs à la patiente.
6. Si le retrait complet du micro-implant est accompli, on doit essayer de mettre un autre micro-implant **Essure** en place.
7. Si le médecin n'est pas absolument certain que le micro-implant **Essure** a été entièrement retiré de la trompe de Fallope, **NE PAS** mettre en place un autre micro-implant dans cette trompe, et prendre une radiographie pour déterminer si un fragment du micro-implant est resté *in vivo*.

Outre le scénario décrit ci-dessus, le retrait du micro-implant ne doit être tenté que si la patiente éprouve des effets indésirables ou exige son retrait.

Si le retrait du micro-implant s'avère nécessaire, on doit y procéder par voie transabdominale (c'est-à-dire par laparotomie ou laparoscopie).

Une résection de la corne de la trompe de Fallope proximale est alors nécessaire si le micro-implant est correctement implanté sur la jonction utéro-tubaire.

Si un micro-implant **Essure** a été incorrectement placé ou a migré au-delà de la jonction utéro-tubaire, il doit être retiré au moyen d'une salpingotomie linéaire classique ou d'une salpingectomie accomplie par laparoscopie ou laparotomie.

1. Pour réaliser une salpingotomie linéaire, pratiquer une petite incision (sur environ 2 cm) le long du bord antimésentérique de la trompe de Fallope, directement au-dessus du micro-implant.
2. On peut réaliser une salpingectomie totale ou partielle pour retirer le micro-implant en même temps, ou indépendamment d'une procédure de stérilisation tubaire classique.

XIII. Carte d'identification de patiente

Chaque patiente ayant subi l'implantation de micro-implants **Essure** doit recevoir une carte laminée de taille portefeuille indiquant qu'elle porte ce ou ces micro-implants. **La carte est ci-jointe dans cet emballage.** La carte indique également que des risques peuvent être associés à des procédures intra-utérines ultérieures ou à des interventions chirurgicales sur les organes reproductifs de la participante.

XIV. Légende des symboles

STERILE EO	Stérilisé à l'oxyde d'éthylène	MR	IRM conditionnel (ASTM F2503)
LOT	Numéro de lot	EC REP	Représentant européen agréé
	Ne pas réutiliser	CE 0050	Le micro-implant est conforme à la Directive européenne 93/42/CEE
REF	Numéro de catalogue		Conserver à l'abri de l'humidité
	Attention, consulter le mode d'emploi	CONT	Contient :
	Utiliser avant le		
	Conserver à l'abri de la chaleur		
	Ne pas utiliser le produit si l'emballage est ouvert ou détérioré		

Fabriqué par :
Bayer HealthCaer LLC
1011 McCarthy Blvd.
Milpitas, CA 95035
USA
essure.com

Représentant européen agréé :
Bayer Pharma AG
Müllerstr. 178
D-13353 Berlin
Allemagne

Pour toute commande de produits ou pour signaler un événement indésirable, veuillez contacter votre représentant Bayer HealthCare LLC local.

PN-84731145, ART Rev. B

Netherlands

essure®
Permanente anticonceptie

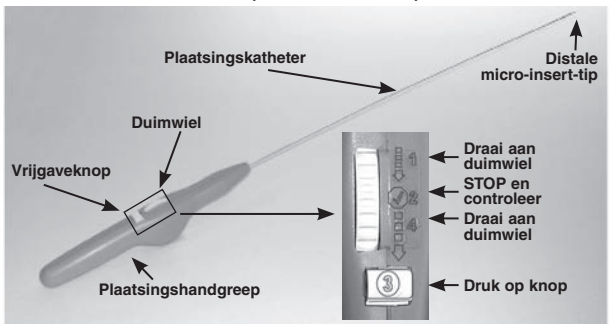
BAYER

GEBRUIKSAANWIJZING

I. Beschrijving van de micro-insert

Het **Essure**® permanent anticonceptiesysteem bestaat uit diverse onderdelen. De **Essure**-micro-insert, een zich dynamisch uitzettende micro-insert, is aangebracht op een plaatsingsdraad en een vrijgavekatheter. Het geheel bevindt zich in een plaatsingskatheter. Dit systeem, (zoals getoond in afbeelding 1), is op een handgreep aangebracht waarmee de micro-insert geplaatst en geëxpandeerd wordt. Bij het **Essure**-systeem wordt tevens een introducer met klep, de **DryFlow**®-introducer, geleverd. Dit onderdeel dient ter bescherming van de **Essure**-micro-insert op het moment dat deze door de rubber poort van het werkkanaal van de hysteroscoop wordt gevoerd.

Afbeelding 1
Essure-plaatsingssysteem
Toont details van symbolen van plaatsingsprocedure
(NIET OP SCHAAL)



II. Werkingsmechanisme

Met behulp van hysteroscopische visualisering wordt met het **Essure**-systeem een **Essure**-micro-insert in het proximale gedeelte van het lumen van de eileider geplaatst. Wanneer de **Essure**-micro-insert wordt losgelaten en zich uitzet, verankert hij zich direct in de eileider. Vervolgens veroorzaakt de micro-insert een geplande goedaardige reactie van het weefsel, hetgeen resulteert in weefselgroei in de micro-insert, waarmee deze stevig in de eileider wordt verankerd. Deze goedaardige weefselgroei is plaatselijk en fibrotisch van aard en dient voor occlusie.

Elk **Essure**-systeem is gesteriliseerd met ethyleenoxide en wordt steriel, uitsluitend voor eenmalig gebruik bestemd geleverd. Het mag niet opnieuw gebruikt of opnieuw gesteriliseerd worden. Hersterilisatie kan een negatieve uitwerking hebben op een goede mechanische werking en kan leiden tot letsel aan de patiënt.

III. Indicaties voor gebruik

Het **Essure**-systeem dient te worden gebruikt voor occlusie van de eileiders teneinde permanente anticonceptie te bewerkstelligen.

IV. Contra-indicaties

- Onzekerheid van de patiënte omtrent haar wens haar vruchtbaarheid te beëindigen.
- Zwangerschap of vermoede zwangerschap.
- Bevalling of beëindiging van een zwangerschap in het tweede trimester minder dan zes weken vóór de plaatsing van de **Essure**-micro-insert.
- Actieve of recente infectie in het bekken.
- Niet-behandelde acute cervicitis.
- Onverklaarde of ernstige vaginale bloeding.
- Gynaecologische kwaadaardigheid (vermoed of bekend).
- Bekende abnormale baarmoederholte of tubae die visualisering van de uitmondingen van de tubae en/of canulatie van de proximale tuba moeilijk of onmogelijk maken.
- Allergie voor contrastmiddelen (er kan een hysterosalpingogram nodig zijn drie maanden na plaatsing van de micro-insert).
- De patiënte gebruikt op dit moment corticosteroïden.

V. Waarschuwingen

- De **Essure**-behandeling mag uitsluitend worden verricht door vakbekwame hysteroscopisten die het opleidingsprogramma van *Bayer Healthcare LLC* voor deze behandeling met succes hebben beëindigd.
- Personen die allergisch zijn voor nikkeltitaan kunnen een allergische reactie op de micro-insert krijgen.
- Gebruik het **Essure**-systeem niet indien de verpakking geopend of beschadigd is. Gebruik het systeem niet indien de micro-insert beschadigd is.
- Bij het inbrengen van de **Essure**-micro-insert in de eileider mogen de micro-insert(s) bij duidelijke weerstand nooit worden opgevoerd.
- Voer het **Essure**-systeem niet verder op dan tot het punt waarop de merkring op de katheter de uitmonding van de eileider heeft bereikt. Wanneer de micro-insert verder wordt opgevoerd, kan dit leiden tot onjuiste plaatsing van de micro-insert of perforatie van de eileider of de baarmoeder.
- Ga niet verder met het plaatsen van de **Essure**-micro-insert indien perforatie van de eileider plaatsvindt of wordt vermoed. Bij een klein percentage vrouwen (1,8% of 12/682 patiënten) in de klinische proeven met **Essure** zijn instrument-gerelateerde perforaties van de eileider gevonden. Perforerende micro-inserts moeten zo nodig worden verwijderd met laparoscopie of andere chirurgische methoden.
- Indien het plaatsen van de **Essure**-micro-insert niet lukt na 10 minuten pogingen tot canulatie per eileider, dient de poging te worden gestaakt en kan de plaatsing eventueel later opnieuw worden uitgevoerd.
- Nadat de micro-insert is geplaatst (d.w.z. is losgemaakt van de plaatsingsdraad), mag niet worden geprobeerd de micro-insert hysteroscopisch te verwijderen, tenzij er ten minste 18 coils van de **Essure** micro-insert in de baarmoederholte uitsteken. In dat geval moet worden geprobeerd om de micro-insert onmiddellijk na plaatsing te verwijderen. Verwijderen kan echter onmogelijk blijken.
- De patiënte moet een alternatieve vorm van anticonceptie toepassen totdat een röntgenfoto die drie maanden na het plaatsen van de micro-insert is gemaakt, aantoont dat de plaats van de micro-insert bevredigend is.
- Patiënten bij wie een **Essure**-micro-insert wordt geplaatst, kunnen in de jaren daarna intra-uteriene behandelingen ondergaan waarbij gebruik wordt gemaakt van elektrische energie. Aanbevolen wordt elektrocauterisatie te vermijden bij chirurgische behandelingen van de cornua uteri en de eileiders. Bij alle andere behandelingen in het bekken dient elektrocauterisatie binnen 4 cm van de micro-insert te worden vermeden. Door de aanwezigheid van de **Essure**-micro-inserts kunnen er bij deze behandelingen risico's bestaan die op dit moment nog niet bekend zijn.
- Intra-uteriene ingrepen zoals endometriële biopsie, dilatatie en curettage, hysteroscopie (diagnostisch of operatief) met inbegrip van endometriële ablatie kunnen een onderbrekende werking uitoefenen op het vermogen van de micro-inserts om zwangerschap te voorkomen. Bovendien kunnen door de aanwezigheid van **Essure**-micro-inserts risico's bestaan bij deze behandelingen die op dit moment nog niet bekend zijn.
- Benchmark-onderzoeken en klinische proeven hebben aangetoond dat endometriële ablatie van de baarmoeder veilig en effectief kan worden verricht met het GYNECARE THERMACHOICE* baarmoederballonsysteem, het Hologic NovaSure** endometrieel ablatiesysteem en de Boston Scientific Hydro ThermAblator*** onmiddellijk **na** plaatsing van de **Essure**-micro-insert. Er is geen specifiek onderzoek verricht om de expulsie van de **Essure**-micro-insert of de mate van anticonceptionele werkzaamheid te evalueren na gecombineerde **Essure**- en endometriële ablatieprocedures.
- Patiënten kunnen in de toekomst besluiten een behandeling voor in-vitrofertilisatie (IVF) te ondergaan om zwanger te worden. De effecten van de **Essure**-micro-inserts op het succes van in-vitrofertilisatie zijn niet bekend. Bij zwangerschap zijn de risico's van de micro-insert voor de patiënte, de foetus en het verloop van de zwangerschap onbekend.

*Handelsmerk van ETHICON, INC.
** Handelsmerk van Hologic, Inc.
*** Handelsmerk van Boston Scientific Corporation

VI. Voorzorgsmaatregelen

- Indien mogelijk moet de plaatsing van de micro-insert worden verricht gedurende dag 7-14 van de menstruatiecyclus (waarbij dag 1 de eerste dag van de bloeding is) teneinde de uitmondingen van de eileiders beter zichtbaar te kunnen maken en de kans te verkleinen dat de micro-insert bij een patiënte met een niet-gediagnosticeerde zwangerschap wordt geplaatst.
- Een afwijkende anatomie van de baarmoeder kan de plaatsing van de **Essure**-micro-inserts bemoeilijken.
- Om het risico op perforatie van de baarmoeder te verkleinen, dient de behandeling te worden gestaakt indien er overmatige kracht nodig is om de baarmoederhals te verwijden.
- Beide uitmondingen van de eileiders moeten vóór plaatsing van de **Essure**-micro-insert hysteroscopisch zichtbaar worden gemaakt en worden gecontroleerd. Er mag geen poging worden ondernomen om de micro-insert te plaatsen in de uitmonding van één eileider, tenzij redelijkerwijs te verwachten is dat de andere eileider toegankelijk en doorgankelijk is.
- Endometriële ablatie onmiddellijk na de plaatsing van **Essure**-micro-inserts verhoogt mogelijk het risico van post-ablation tubal sterilization syndrome, een zeldzame conditie waarvan bekend is dat ze voorkomt bij vrouwen met een geschiedenis van eileidersterilisatie die endometriële ablatie ondergaan.
- Voer het **Essure**-systeem niet op indien de patiënte buitengewone pijn of ongemak ervaart.
- Bewaar het **Essure**-systeem op een koele, droge plaats.

VII. Mogelijke bijwerkingen

A. Zwangerschap

Er bestaat een risico van zwangerschap en buitenbaarmoederlijke zwangerschap; er bestaan tevens risico's met betrekking tot de behandeling van beide vormen van zwangerschap. Indien de patiënte zwanger wordt en ervoor kiest een baarmoederlijke zwangerschap voort te zetten, dient zij geïnformeerd te worden dat de risico's van de micro-insert voor de patiënte, voor de foetus en voor de voortgang van de zwangerschap onbekend zijn.

B. Risico's die gepaard gaan met de plaatsingsprocedure van de micro-insert

- Plaatselijke verdoving, orale pijnstilling/sedatie, regionale verdoving (d.w.z. spinaal of epiduraal), orale of bewuste (intraveneuze) sedatie of algehele verdoving kan worden gebruikt om ongemak van de patiënte te verminderen of te voorkomen. Ongeacht het type verdoving is het mogelijk dat de patiënte gedurende 12-24 uur na de behandeling niet in staat is haar normale activiteiten te hervatten.
- Pijn, krampen en vaginale bloeding kunnen optreden tijdens en na de plaatsingsprocedure van de micro-insert. Normaal gesproken zijn deze incidenten verdraagbaar en van korte duur en kunnen met medicatie goed worden behandeld.
- Tijdens en/of onmiddellijk na de plaatsingsprocedure van de micro-insert bestaat het risico dat de patiënte misselijk wordt of moet overgeven. Deze toestand is waarschijnlijk van korte duur en kan zo nodig met medicatie worden behandeld.
- Het is mogelijk dat de patiënte op de dag van de procedure flauwvalt of te maken krijgt met een vasovagale respons.
- Er bestaat een kans op perforatie of dissectie van de eileider of de cornua uteri. Een dergelijke perforatie of dissectie kan bloeding en littekenvorming tot gevolg hebben; over het algemeen is er echter geen behandeling nodig.
- Er bestaat een risico op perforatie van de baarmoeder door de hysteroscoop, het **Essure**-systeem of andere instrumenten die tijdens de behandeling worden gebruikt. Letsel aan de ingewanden, blaas en grote bloedvaten kan hiervan het gevolg zijn. Hierbij kan chirurgisch ingrijpen noodzakelijk zijn, hoewel dit bij dergelijk letsel onwaarschijnlijk is. Om het risico van perforatie van de baarmoeder te verkleinen, dient de behandeling te worden gestaakt indien er overmatige kracht nodig is voor verwijding van de baarmoederhals.
- Er bestaat een risico dat de **Essure**-micro-insert onverhoopt in het myometrium van de baarmoeder en niet in het lumen van de eileider wordt geplaatst. Indien één micro-insert reeds op correcte wijze in één eileider is geplaatst, kan de arts proberen naast de onverhoopte plaatsing in het myometrium een derde micro-insert te plaatsen om de behandeling te voltooien. Indien er geen bilaterale plaatsing in de eileiders tot stand wordt gebracht, kan dit resulteren in een situatie waarin bij de patiënte één micro-insert in de eileider is geplaatst en/of één micro-insert in het myometrium is geplaatst waarop niet kan worden vertrouwd als anticonceptie. Plaatsing van de micro-insert in het myometrium kan resulteren in postoperatieve pijn of een andere bijwerking. Indien chirurgische verwijdering van de micro-insert(s) noodzakelijk is, is het mogelijk dat een salpingectomie of hysterectomie moet worden verricht.
- Er bestaat een risico dat de **Essure**-micro-insert te distaal in de eileider wordt geplaatst. Indien verwijdering van de micro-insert is vereist, dan is chirurgie (laparoscopie of laparotomie) noodzakelijk.
- Er bestaat een risico dat de **Essure**-micro-insert te proximaal in de eileider wordt geplaatst. Indien er ten minste 18 coils van de **Essure**-micro-insert zichtbaar zijn tijdens de plaatsing, dient onmiddellijk te worden geprobeerd de micro-insert te verwijderen (zie deel XIII, verwijdering van een **Essure**-micro-insert). Indien wordt geprobeerd de micro-insert te verwijderen, bestaat de kans dat de verwijdering zonder goed gevolg verloopt of dat de **Essure**-micro-insert breekt, waardoor er een gedeelte van de micro-insert *in vivo* achterblijft. Indien wordt geprobeerd de micro-insert te verwijderen en/of dit is gelukt, bestaat tevens de mogelijkheid dat de patiënte tijdens en na de plaatsingsprocedure van de **Essure**-micro-insert toegenomen pijn, krampen en bloedingen ervaart.
- Er bestaat een risico dat de **Essure**-micro-insert een perforatie van de wand van de eileider of de cornua uteri veroorzaakt. Dit kan ertoe leiden dat de micro-insert in de buikholte terechtkomt. Als gevolg hiervan kunnen postoperatieve pijn en/of verstoringen van de menstruatiecyclus of andere bijwerkingen optreden. Indien de patiënte ervoor kiest sterilisatie met een incisie of een andere chirurgische behandeling te ondergaan, kan hierbij een poging worden gedaan om de micro-insert uit de peritoneale holte te verwijderen indien de arts dit veilig acht. Wellicht is verwijdering van de micro-insert echter niet mogelijk indien de micro-insert niet door de arts zichtbaar kan worden gemaakt of indien hij/zij er geen toegang toe heeft.
- Er bestaat een risico dat plaatsing van de **Essure**-micro-insert slechts bij één eileider met goed gevolg verloopt. In dit geval is het mogelijk dat de patiënte te maken heeft met één micro-insert *in vivo*, waarop niet kan worden vertrouwd als permanent anticonceptiemiddel.
- Er bestaat een risico dat plaatsing van de **Essure**-micro-insert in geen van beide eileiders mogelijk is.
- Er bestaat een minimaal risico van overvloedige vloeistofabsorptie van de fysiologische zoutoplossing die wordt gebruikt om de baarmoeder te laten uitzetten voor het uitvoeren van de hysteroscopische behandeling.
- Zoals bij alle invasieve ingrepen kan de plaatsingsprocedure van de micro-insert een infectie veroorzaken. Een infectie kan schade veroorzaken aan de baarmoeder, de eileiders en de bekkenholte. Hiervoor kan behandeling met antibiotica nodig zijn; in zeldzame gevallen is ziekenhuisopname of operatief ingrijpen, zoals een hysterectomie, noodzakelijk.

C. Risico's die gepaard gaan met het dragen van de Essure-micro-insert

- Er bestaat een risico dat de **Essure**-micro-insert losraakt uit de eileiders. Deze verplaatsing kan betrekking hebben op expulsie (verplaatsing uit de eileider naar de baarmoederholte, de baarmoederhals of de vagina, of uit het lichaam) of migratie (verplaatsing naar het distale uiteinde van de eileider of vanuit de eileider naar de buikholte). Een aanvullend röntgenonderzoek kan nodig zijn om de locatie van de micro-insert(s) te bepalen en een operatief ingrijpen kan nodig zijn om de micro-insert(s) te verwijderen. Het verplaatsen van de micro-insert kan resulteren in zwangerschap, buitenbaarmoederlijke zwangerschap en/of pijn, verstoring van de menstruatiecyclus en andere bijwerkingen.
- Net zoals bij andere momenteel beschikbare methoden voor mechanische permanente anticonceptie (d.w.z. clips, ringetjes) is een operatie nodig om de **Essure**-micro-insert te verwijderen. Daarnaast is het mogelijk dat chirurgische verwijdering van de eileiders (salpingectomie) en van de baarmoeder (hysterectomie) noodzakelijk is.
- Er kunnen pijn en krampen in de buikstreek en het bekken optreden. Pijn en krampen kunnen vaker voorkomen tijdens de menstruatieperiode, tijdens en na seksueel contact of bij andere lichamelijke activiteiten.
- Het is mogelijk dat er bloedingen tussen de menstruatieperiode optreden en dat de menstruele bloedingen zwaarder zijn dan normaal.
- Het komt soms voor dat een vrouw spijt krijgt van haar beslissing om een behandeling voor permanente anticonceptie te ondergaan. Dit kan resulteren in een milde vorm van depressie of andere emotionele stoornissen.

D. Risico's die gepaard gaan met de follow-upbehandeling

- De straling die gebruikt wordt bij het röntgenonderzoek van het bekken dat drie maanden na plaatsing van de micro-insert dient te worden verricht om de plaats van de micro-insert te beoordelen, gaat gepaard met risico's. Ook kan het nodig zijn een **Essure**-bevestigingstest (HSG) te verrichten. De hoeveelheid straling tijdens het doorlichtingsgedeelte (<30 seconden) van de hysterosalpingogramprocedure bedraagt ongeveer 0,033 rad. Ter vergelijking: de straling bij een bariumklysma bedraagt 0,85 rad, hetgeen hoger is dan bij de vereiste **Essure**-bevestigingstest (HSG). De straling bij één röntgenfoto van het bekken is ongeveer gelijk aan de hoeveelheid waaraan een persoon gedurende één jaar als gevolg van natuurlijke straling blootstaat.
- De volgende extra risico's gaan gepaard met de eventueel te verrichten **Essure**-bevestigingstest (HSG): vasovagale respons; infectie; waardoor een behandeling met antibiotica en in zeldzame gevallen ziekenhuisopname nodig kan worden; intravasatie; perforatie van de baarmoeder; krampen en/of bloedingen in de baarmoeder; pijn of ongemak; en allergische reacties op latex. Naar verluidt heeft blootstelling aan latex in uitzonderlijke gevallen anafylactische reacties tot gevolg die tot de dood kunnen leiden.
- Het gebruik van contrastmiddel voor de uitvoering van de **Essure**-bevestigingstest (HSG) heeft bij sommige patiënten allergische reacties tot gevolg gehad. Een allergische reactie kan tot netelroos of een moeizame ademhaling leiden. Bij sommige personen kan zich een anafylactische reactie voordoen die de dood tot gevolg heeft.

E. Risico's die gepaard gaan met mogelijke latere ingrepen

- Patiënten bij wie een **Essure**-micro-insert wordt geplaatst, kunnen in de jaren daarna intra-uteriene behandelingen ondergaan waarbij gebruik wordt gemaakt van elektrische energie. Aanbevolen wordt elektrocauterisatie te vermijden bij chirurgische behandelingen van de cornua uteri en de eileiders. Bij alle andere behandelingen in het bekken dient elektrocauterisatie binnen 4 cm van de micro-insert te worden vermeden. Door de aanwezigheid van de **Essure**-micro-inserts kunnen er bij deze behandelingen risico's bestaan die op dit moment nog niet bekend zijn.
- Intra-uteriene ingrepen zoals endometriële biopsie, dilatatie en curettage, hysteroscopie (diagnostisch of operatief) met inbegrip van endometriële ablatie kunnen een onderbrekende werking uitoefenen op het vermogen van de micro-inserts om zwangerschap te voorkomen. Bovendien kunnen door de aanwezigheid van **Essure**-micro-inserts risico's bestaan bij deze behandelingen die op dit moment nog niet bekend zijn.
- Patiënten kunnen in de toekomst besluiten een behandeling voor in-vitrofertilisatie (IVF) te ondergaan om zwanger te worden. De effecten van de **Essure**-micro-inserts op het succes van in-vitrofertilisatie zijn niet bekend. Bij zwangerschap zijn de risico's van de micro-insert voor de patiënte, de foetus en het verloop van de zwangerschap onbekend.
- De **Essure**-micro-inserts zijn MRI-veilig en radiopaak. Ook zijn **Essure**-micro-inserts MRI-compatibel, met uitzondering van beeldvorming van het kleine bekken, waarbij artefacten kunnen optreden.
- **De mogelijkheid bestaat dat er tot dusver onbekende risico's bestaan.**

VIII. Aanwijzingen voor gebruik

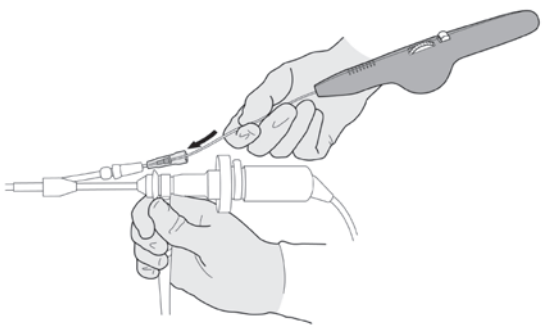
A. Vóór de plaatsingsprocedure van de micro-insert

1. De plaatsing van de micro-insert moet verricht worden gedurende dag 7-14 van de menstruatiecyclus (waarbij dag 1 de eerste dag van de bloeding is) teneinde de uitmondingen van de eileiders beter zichtbaar te kunnen maken en de kans te verkleinen dat de micro-insert bij een patiënte met een niet-gediagnosticeerde zwangerschap wordt geplaatst.
2. Binnen 24 uur vóór of onmiddellijk na de plaatsing van de micro-insert dient door een arts of daartoe aangewezen persoon een zwangerschapstest te worden uitgevoerd.
3. Het verdient sterke aanbeveling om één à twee uur vóór plaatsing van de micro-insert een NSAID (niet-steroïdaal anti-inflammatoir middel) zoals Indocid (oraal of door middel van een zetpil) toe te dienen, omdat uit klinische proeven blijkt dat de kans dat de plaatsing slaagt, aanzienlijk toeneemt bij gebruik van een NSAID. Wanneer alleen een paracervicaal block gebruikt wordt, kan ook Diazepam (oraal) of een vergelijkbaar middel 30 minuten vóór de behandeling worden verstrekt om de angst te verminderen.

B. Plaatsingsprocedure van de Essure-micro-insert

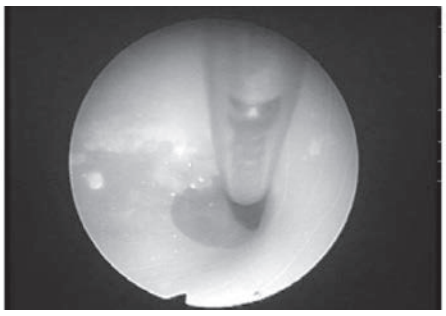
De **Essure**-micro-insert kan worden geplaatst tijdens een ambulante behandeling of een dagbehandeling. De plaatsingsprocedure van de micro-insert dient te worden uitgevoerd met gebruikmaking van steriele techniek. De hoeveelheid tijd om de plaatsingsprocedure van de micro-insert te voltooien mag niet meer dan 30 minuten bedragen.

1. Breng de patiënte in de lithotomiepositie.
2. Breng een speculum in de vagina in om toegang te krijgen tot de baarmoederhals. Behandel de baarmoederhals met Betadine of een andere geschikte antibacteriële oplossing volgens de gebruikelijke procedure.
3. De voorkeur gaat uit naar plaatselijke verdoving voor de implantatie van de micro-inserts. Er kan een paracervicaal block worden toegepast. Ook kan Midazolam (IV) of een vergelijkbaar middel worden toegediend om eventueel ongemak te voorkomen of te beperken.
4. Breng een steriele hysteroscoop waaraan een camera en een werkkanaal (≥5 French) is bevestigd, door de baarmoederhals in de baarmoederholte in. Verwijd de baarmoederhals zo nodig om het inbrengen te vergemakkelijken. Ter voorkoming van perforatie van de baarmoeder dient de behandeling te worden gestaakt indien er overmatige kracht moet worden uitgeoefend om de baarmoederhals te verwijden.
5. Uitzetting van de baarmoederholte dient te gebeuren door het infunderen van een fysiologische zoutoplossing via het werkkanaal van de hysteroscoop. Het wordt met klem aanbevolen om de fysiologische zoutoplossing op lichaamstemperatuur te brengen en onder invloed van de zwaartekracht in te brengen om krampen van de eileiders tot een minimum te beperken. Gedurende de gehele behandeling moet een optimale uitzetting van de baarmoeder bereikt en gehandhaafd worden. De gebruikelijke vloeistof-controleprocedures moeten tijdens de gehele behandeling worden gevolgd. De uitmondingen van de eileiders moeten door middel van hysteroscopische visualisering zichtbaar worden gemaakt.
6. Beide uitmondingen van de eileiders moeten vóór plaatsing van de **Essure**-micro-insert hysteroscopisch zichtbaar worden gemaakt en worden gecontroleerd. Er mag geen poging worden ondernomen om de micro-insert te plaatsen in de uitmonding van één eileider, tenzij redelijkerwijs te verwachten is dat de andere eileider doorgankelijk is.
7. Zodra de uitmondingen van de eileiders worden gelokaliseerd, brengt u de introducer door de afdichtdop van het werkkanaal van de hysteroscoop in. De afsluitkraan van het werkkanaal moet in de open stand blijven (het instrument en/of de introducer kunnen beschadigd worden als de afsluitkraan een van beide instrumenten afsluit). Steek het **Essure**-plaatsingssysteem door de introducer en voer het op door het werkkanaal van de hysteroscoop. Als de introducer met klep bij de eerste plaatsing van de micro-insert geen schade heeft opgelopen, kan deze in het werkkanaal blijven tijdens de **Essure**-procedure.



Breng de introducer doorheen de afdichtdop van het werkkanaal van de hysteroscoop, en plaats daarna het Essure-plaatsingssysteem door de introducer.

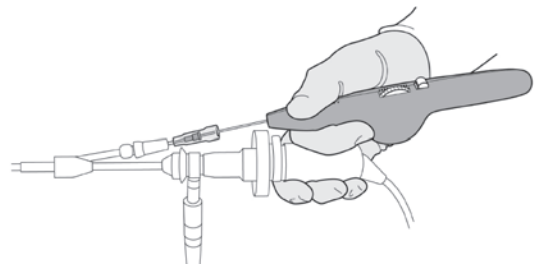
8. Voer het **Essure**-plaatsingssysteem met een langzame gestage beweging in de proximale eileider op om verkramping van de eileider te voorkomen. Voer het plaatsingssysteem op totdat de merkring op de plaatsingskatheter de uitmonding van de eileider bereikt. Deze visuele markering geeft aan dat de **Essure**-micro-insert de distale intramurale en proximale vernauwde segmenten van de eileider overbrugt, waarbij de buitencoil de utero-tubale overgang overbrugt. Dit is de ideale plaatsing voor de **Essure**-micro-insert.



Opvoeren totdat de zwarte merkring zich bij de uitmonding van de eileider bevindt. Dit is een visuele indicator voor de juiste plaatsing om te kunnen expanderen.

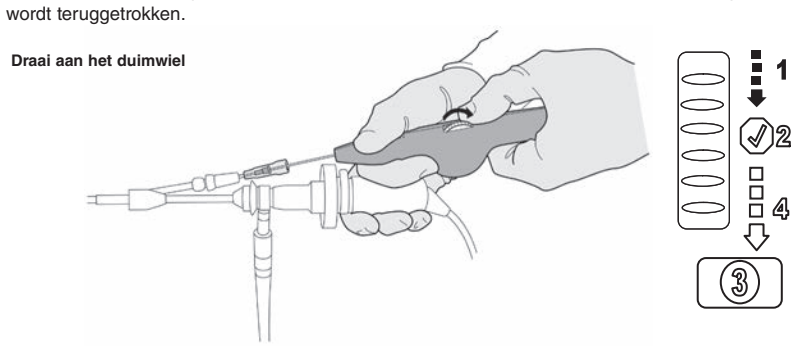
9. De juiste concentrische uitlijning van de plaatsingskatheter ten opzichte van het lumen van de eileider is gewaarborgd wanneer de katheter onder directe visualisering kan worden opgevoerd zonder grote weerstand. Weerstand bij het opvoeren is over het algemeen op twee manieren merkbaar: 1) aan de zwarte merkring op de buitenkant van de katheter is niet te zien dat deze zich in de richting van de uitmonding van de eileider beweegt en/of 2) de plaatsingskatheter buigt overmatig, zodat de arts geen voorwaartse druk op de katheter kan uitoefenen. Wanneer een dergelijke weerstand op de voorwaartse beweging van de katheter merkbaar is, dient men niet verder te proberen de micro-insert te plaatsen om perforatie van de baarmoeder of onverhoopte plaatsing in de uteriene musculatuur in plaats van in het lumen van de eileider te voorkomen. Een tweede **Essure**-bevestigingstest (HSG) is noodzakelijk om te bepalen of de eileider doorgankelijk is.

10. Indien het niet mogelijk is de katheter binnen enkele minuten tot de merkring op te voeren, kan, wanneer dit niet reeds is gebeurd, met een katheter een perfusietest worden uitgevoerd om te bepalen of de eileider doorgankelijk is. Indien de eileider geblokkeerd is of de katheter niet tot de merkring kan worden opgevoerd, moet de behandeling worden gestaakt. Indien het plaatsen van de **Essure**-micro-insert niet lukt na tien minuten canulatie per eileider, dient de behandeling te worden gestaakt.
11. Wanneer de katheter tot de merkring is opgevoerd, moet de micro-insert worden geplaatst. Hiertoe dient eerst de handgreep van de **Essure**-micro-insert tegen de camera van de hysteroscoop of tegen een ander vast voorwerp te worden gestabiliseerd om te voorkomen dat het **Essure**-systeem onverhoopt naar voren beweegt tijdens het terugtrekken van de plaatsingskatheter.



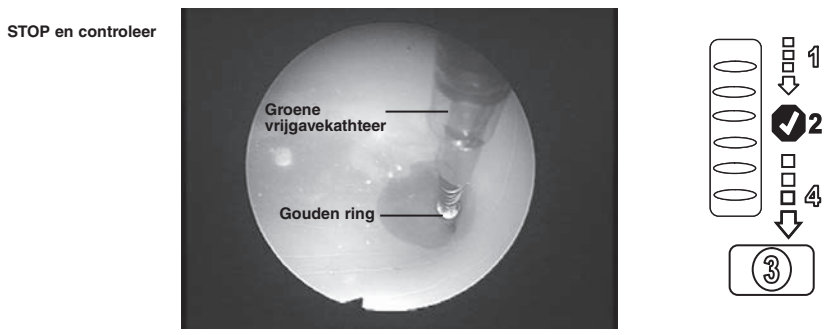
De handgreep tegen de kop van de camera of tegen een ander vast voorwerp stabiliseren om onverhoopt naar voren bewegen van het ***Essure****-systeem te voorkomen.*

12. Zorg dat de zwarte merkring zich bij de uitmonding van de eileider bevindt en draai het duimwiel op de handgreep naar u toe totdat het wiel niet meer draait. Deze handeling komt overeen met het symbool ⇩1 op de handgreep van het plaatsingssysteem. Dit vergemakkelijkt het terugtrekken van de plaatsingskatheter. U zult zien dat de zwarte merkring weg beweegt van de uitmonding van de eileider (in de richting van de hysteroscoop) en in het werkkanaal verdwijnt. Het terugtrekken van de plaatsingskatheter toont de ineengedraaide **Essure**-micro-insert. Er moet ongeveer 1 centimeter van de micro-insert (ineengedraaide coils) in de baarmoeder uitsteken wanneer de plaatsingskatheter wordt teruggetrokken.



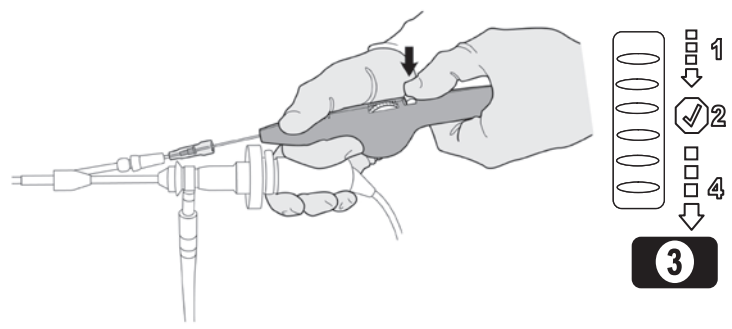
Draai aan het duimwiel om de katheter terug te trekken.

13. Om de juiste plaatsing te confirmeren, plaatst u de gouden merkring net buiten de uitmonding, die met het symbool ✓2 op de handgreep van het plaatsingssysteem overeenkomt. Visualisering van de gouden ring net buiten de uitmonding, zowel als de visualisering van de distale tip van de groene vrijgavekatheter zal de juiste plaatsing confirmeren. Indien meer dan 1 cm van de micro-insert zichtbaar is in de baarmoeder, dan moet de micro-insert opnieuw worden geplaatst door het gehele systeem, indien mogelijk, verder in de leider op te voeren.



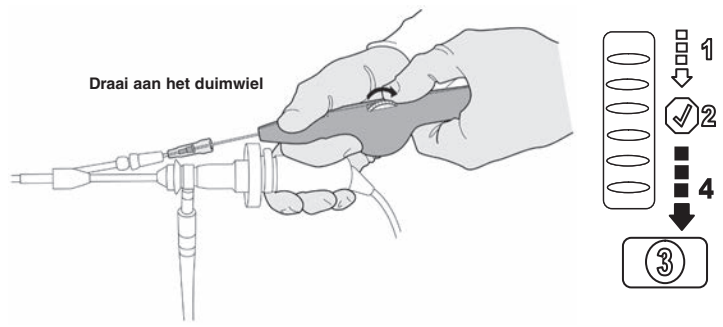
Visualiseer de gouden ring bij de uitmonding.

14. Druk de knop op de handgreep van het plaatsingssysteem in zodat het duimwiel verder kan worden gedraaid, wat overeenkomt met het symbool ③ op de knop op de handgreep.



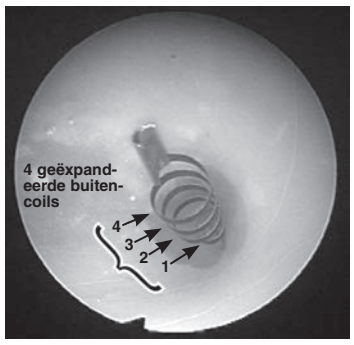
Druk op de knop zodat het duimwiel opnieuw kan draaien.

15. Draai het duimwiel naar u toe om de buitencoil van de micro-insert te expanderen die overeenkomt met het symbool ⇩4 op de handgreep van het plaatsingssysteem. Blijf aan het duimwiel draaien tot het niet meer ronddraait. Wanneer het duimwiel niet meer verder kan worden gedraaid en de geëxpandeerde buitencoils zijn zichtbaar, trekt u het systeem terug.



Draai aan het duimwiel om de buitencoil van de micro-insert te expanderen

16. De plaats van de geëxpandeerde **Essure**-micro-insert moet met behulp van hysteroscopische visualisatie worden bepaald. Idealiter moeten 3-8 geëxpandeerde buitencoils van de **Essure** micro-insert in de baarmoeder uitsteken.



Geëxpandeerde buitencoils van de **Essure***-micro-insert die in de baarmoeder uitsteken geven de ideale plaats aan.*

17. Indien de arts niet tevreden is met de plaatsing van de micro-insert op grond van het hysteroscopische beeld of indien de arts perforatie van de eileider(s) of de uterus vermoedt, moet(en) de micro-insert(s) op zijn (hun) plaats worden gehouden en wordt/worden beoordeeld aan de hand van een röntgenfoto van het bekken die, of een HSG dat, drie maanden na plaatsing van de micro-insert is gemaakt.

    WAARSCHUWING: NADAT DE MICRO-INSERT IN DE EILEIDER INGEBRACHT EN VRIJGEGEVEN IS, MAG NIET GEPROBEERD WORDEN DE MICRO-INSERT HYSTEROSCOPISCH TE VERWIJDEREN, TENZIJ ER TEN MINSTE 18 COILS VAN DE ESSURE-MICRO-INSERT IN DE BAARMOEDERHOLTE UITSTEKEN. Verwijdering van een dergelijke micro-insert moet onmiddellijk worden geprobeerd tijdens de poging tot plaatsing. Het kan echter onmogelijk blijken de micro-insert te verwijderen (zie deel XIII, Verwijdering van een **Essure**-micro-insert). Indien de micro-insert onverhoopt in de baarmoederholte en niet in de eileider is geëxpandeerd, dient de micro-insert uit de baarmoeder te worden verwijderd en dient vervolgens een nieuwe poging te worden ondernomen de micro-insert in de eileider te plaatsen.

18. De **Essure**-micro-insert kan nu op dezelfde wijze in de andere eileider worden geplaatst.

19. Noteer de lengte van de micro-insert die in de baarmoederholte uitsteekt en noteer daarbij eventuele kwesties m.b.t. het lokaliseren of bevestigen van de uitmonding van de eileiders of kwesties m.b.t. eventuele perforatie. Deze opmerkingen dienen genoteerd te worden in de status van de patiënte in verband met de beoordeling van de **Essure**-bevestigingstest *(zie onderstaand deel IX – Essure-bevestigingstest).*

20. **Herinner de patiënte eraan om gedurende de eerste drie maanden na de plaatsingsprocedure van de micro-insert een andere vorm van anticonceptie toe te passen (geen spiraaltje).**

21. Laat de patiënte drie maanden na de plaatsingsprocedure van de **Essure**-micro-insert terugkomen voor een **Essure**-bevestigingstest om de retentie en de plaats van de micro-inserts te beoordelen.

IX. Essure-bevestigingstest

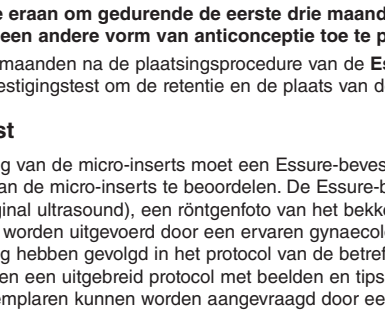
A. Drie maanden na plaatsing van de micro-inserts moet een Essure-bevestigingstest worden verricht om de retentie en de plaats van de micro-inserts te beoordelen. De Essure-bevestigingstests (transvaginale echografie (TVU, transvaginal ultrasound), een röntgenfoto van het bekken of een hysterosalpingogram (HSG)) mogen uitsluitend worden uitgevoerd door een ervaren gynaecoloog, echospecialist en/of radioloog die een opleiding hebben gevolgd in het protocol van de betreffende Essure-bevestigingstest. Tijdens de opleiding worden een uitgebreid protocol met beelden en tips voor het uitvoeren van de test verstrekt; aanvullende exemplaren kunnen worden aangevraagd door een kopie te downloaden van essure.com.

B. Voor de eerstelijns bevestigingstest kan er drie maanden na ongecompliceerde plaatsing van bilaterale micro-inserts ofwel een röntgenfoto van het bekken of een TVU worden gemaakt.

1. In de volgende omstandigheden mogen de röntgenfoto en de TVU niet als Essure-bevestigingstest worden gebruikt:
    a) Moeilijke plaatsingsprocedure met een of meer van de volgende factoren:
        (1) Bezorgdheid ten tijde van de plaatsing over een mogelijke perforatie als gevolg van overmatige kracht die tijdens de plaatsing van de micro-insert moest worden uitgeoefend en/of een plotseling verlies van weerstand.
        (2) Moeilijkheid bij de identificatie van de uitmonding van de eileiders tijdens de plaatsing als gevolg van anatomische variatie of technische factoren zoals slechte uitzetting, slechte verlichting of endometriummateriaal.
        (3) Onzekerheid van de chirurg omtrent de plaatsing.
    b) Proceduretijd > 15 minuten (scoop in scoop uit).
    c) Plaatsing met nul of > 8 uitstekende coils.
    d) Ongewone postoperatieve pijn, van voorbijgaande aard of persisterend, of begin op een bepaald moment na de procedure, zonder een andere aanwijsbare oorzaak.
2. Indien een röntgenfoto of echo niet aangewezen is, moet de patiënte een HSG ondergaan om de plaats van de micro-inserts en de occlusie van de eileiders te evalueren. Er kan geen transabdominale echo worden uitgevoerd in plaats van een TVU. Indien een evaluatie met behulp van een röntgenfoto of echo dubbelzinnig of niet bevredigend is, moet de patiënte een HSG ondergaan om de plaats van de micro-inserts en occlusie van de eileiders te evalueren.

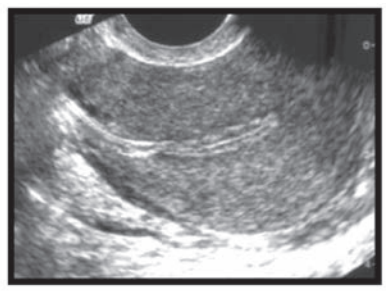
C. Transvaginale echo

1. Er moeten minimaal drie beelden worden gemaakt en ter documentatie worden bewaard.
    a) Een coronaal of schuin-coronaal beeld dat een deel van elke micro-insert in de cornua aantoont; gelabeld als 'verkennend beeld'.



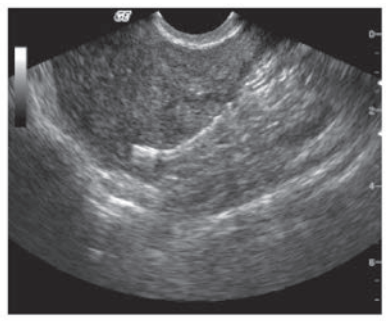
Bilaterale micro-inserts worden geïdentificeerd in dit transversale (coronale / schuin-coronale) beeld.

    b) Een coronaal of schuin-coronaal beeld van de lineaire as van de linker micro-insert inclusief het proximale uiteinde dat het myometrium kruist in de cornua (interstitiële deel van de eileider) of dat in aanraking is met de overgang van de eileiders naar de baarmoeder/serosa; gelabeld als 'links'.
    c) Een coronaal of schuin-coronaal beeld van de lineaire as van de rechter micro-insert die het myometrium kruist in de cornua (interstitiële deel van de eileider) of dat in aanraking is met de overgang van de eileiders naar de baarmoeder/serosa; gelabeld als 'rechts'.
    d) Alle drie beelden moeten op foto's worden vastgelegd en in de status van de patiënte geplaatst om een bevredigende retentie en plaats van de micro-inserts te documenteren.
2. Classificatie van de plaats van de micro-inserts
    a) Identificatie van de micro-inserts: In een enkel verkennend beeld moet een deel van elke micro-insert gevisualiseerd worden in de cornua in het coronale of schuin-coronale beeld om zich te vergewissen van een bilaterale plaatsing en het risico te verkleinen dat er een tweede beeld van dezelfde micro-insert wordt gemaakt. De lineaire as van de micro-inserts moet er relatief symmetrisch uitzien.
    b) Optimale plaats
    De plaats van de micro-inserts is optimaal wanneer het proximale uiteinde van de micro-insert in aanraking is met de baarmoederholte of het endometrium en de lineaire as zich binnen het myometrium in de cornua (interstitiële deel van de eileider) bevindt en gevisualiseerd kan worden bij de overgang van de eileiders naar de baarmoeder/serosa (USTJ, utero-serosal tubal junction) of waar hij deze kruist. Het deel van de micro-insert dat zich in de eileider bevindt, kan al dan niet gevisualiseerd worden. De lineaire as van de micro-insert moet gevisualiseerd worden om te bevestigen dat hij niet opgerold of langgerekt is.



Optimale plaats

    c) Bevredigende plaats
    De plaats van de micro-inserts is bevredigend wanneer het proximale uiteinde van de micro-insert distaal is ten opzichte van het endometrium, maar de lineaire as zich echter binnen het myometrium in de cornua (interstitiële deel van de eileider) bevindt en gevisualiseerd kan worden bij de overgang van de eileiders naar de baarmoeder/serosa of waar hij deze kruist. Het deel van de micro-insert dat zich in de eileider bevindt, kan al dan niet gevisualiseerd worden. De lineaire as van de micro-insert moet gevisualiseerd worden om te bevestigen dat hij niet opgerold of langgerekt is.

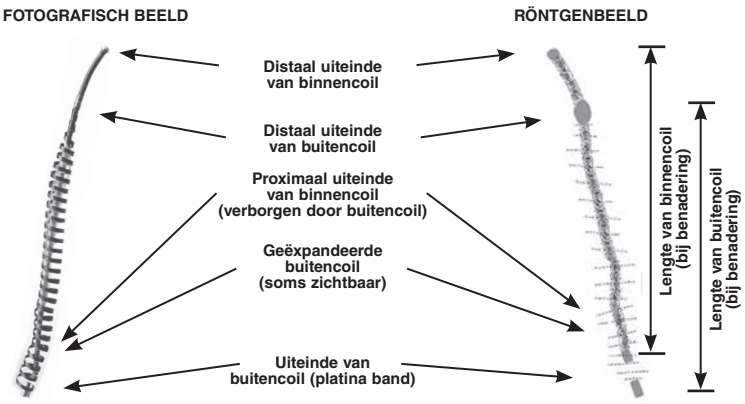


Bevredigende plaats

    d) Niet bevredigende plaats
        (1) De plaats van de micro-insert is niet bevredigend indien een deel van elke micro-insert in één verkennend beeld niet gevisualiseerd kan worden in de cornua in het coronale of schuin-coronale beeld.
        (2) Expulsie wordt vermoed indien een of beide micro-inserts in één enkel verkennend beeld niet geïdentificeerd kan/kunnen worden in de cornua in een coronaal beeld.
        (3) Distale plaatsing wordt vermoed indien het proximale uiteinde van de micro-insert zich niet in het myometrium in de cornua (interstitiële deel van de eileider) bevindt en niet in aanraking is met de USTJ of deze niet kruist.
        (4) Proximale plaatsing wordt vermoed indien meer dan 50% of de meerderheid van de micro-insert gevisualiseerd wordt in de baarmoederholte of indien de lineaire as van de micro-insert(s) gevisualiseerd wordt in het sagittale beeld van de middellijn.
        (5) Perforatie wordt vermoed indien de lineaire as van een of beide micro-inserts parallel is aan de longitudinale schaduw van het endometrium in het sagittale beeld, of indien de lineaire as van een micro-insert gevisualiseerd wordt waar deze het myometrium kruist in het sagittale beeld van de middellijn.
        (6) Niet-geclassificeerde positie: Indien de lineaire as van een micro-insert niet geïdentificeerd kan worden, wat erop kan duiden dat de micro-insert opgerold, verbogen of langgerekt is, wordt de plaats van de micro-insert niet bevredigend geacht. Indien de omgevende weke delen niet duidelijk gedefinieerd kunnen worden, wordt de positie niet bevredigend geacht.
3. Indien een evaluatie met behulp van een echo dubbelzinnig of niet bevredigend is, moet de patiënte een HSG ondergaan om de plaats van de micro-inserts en occlusie van de eileiders te evalueren.

D. Röntgenfoto van het bekken

1. Maak een beeld van de baarmoeder waarop beide Essure-micro-inserts duidelijk te zien zijn. Maak een aantekening van de ligging en de welving van de micro-inserts.



Corresponderend röntgenbeeld van de Essure-micro-insert

2. Evalueer de röntgenfoto van het bekken als volgt:
    a) Bevredigend: De micro-inserts blijken zich in het lumen van de eileiders te bevinden en de utero-tubale overgang te overbruggen en blijken relatief symmetrisch te zijn. Patiënten van wie de röntgenfoto's als 'bevredigend' worden beoordeeld, mogen beginnen te vertrouwen op de Essure-micro-insert als anticonceptiemiddel.
    b) Verdacht: Een of beide micro-inserts blijkt/blijken zich distaal of proximaal van de optimale plaats te bevinden, of kan/kunnen gedeeltelijk of geheel geperforeerd zijn door de eileider en/of blijkt/blijken relatief asymmetrisch te zijn. Patiënten van wie de röntgenfoto's als 'verdacht' worden beoordeeld, dienen de instructie te krijgen om een andere vorm van anticonceptie te blijven toepassen en een HSG te ondergaan.
    c) Niet bevredigend: Duidelijke intraperitoneale locatie of expulsie van de micro-insert.
3. Indien een evaluatie met behulp van een röntgenfoto dubbelzinnig of niet bevredigend is of de plaats van de micro-insert(s) verdacht is, moet de patiënte een HSG ondergaan om de plaats van de micro-insert(s) en occlusie van de eileiders te evalueren.

E. Gemodificeerde HSG's uitvoeren en beoordelen

1. Het HSG wordt uitgevoerd om de plaats van de Essure micro-insert(s) en de occlusie van de eileider(s) zo nodig nader te evalueren op grond van de bevindingen van de röntgenfoto of de echo. Volg de onderstaande instructies voor het uitvoeren en beoordelen van het HSG.
2. Uitvoering van het HSG – richtlijnen:
    a) Er dient een goede vulling van de cornua te worden verkregen zodat het silhouet van de baarmoederholte duidelijk te zien is.
    b) Plaats de doorlichtingsstraal zo dicht mogelijk bij de A/P-projectie.
    c) Dilateer de baarmoederhals niet tenzij dit noodzakelijk is; als dilatatie plaatsvindt, moet goede afdichting van de baarmoederhals gehandhaafd blijven.
    d) Neerwaartse tractie op het tenaculum aan de baarmoederhals kan nodig zijn bij patiënten die een baarmoeder in de middenpositie hebben. Verwijder het speculum vóór de doorlichting voor de beste visualisering van de anatomie van de baarmoeder.
    e) Neem minimaal zes röntgenfoto's om de plaats van de micro-insert en de occlusie van de eileiders te kunnen bepalen.
        (1) Röntgenfoto 1 – 'verkennende foto' – baarmoeder en micro-inserts zonder contrastmiddel.

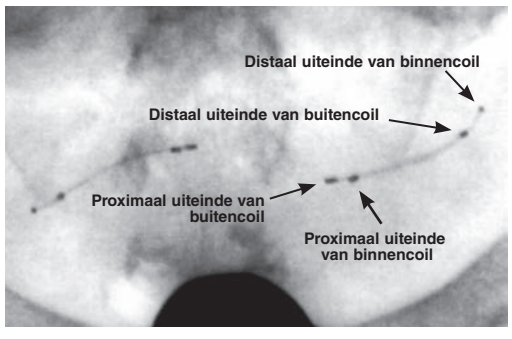
(2) Röntgenfoto 2 – minimale vulling van de holte – baarmoeder en micro-inserts met een geringe hoeveelheid contrastmiddel.

(3) Röntgenfoto 3 – gedeeltelijke vulling van de holte – baarmoeder en micro-inserts bijna vol met contrastmiddel.

(4) Röntgenfoto 4 – totale vulling van de holte – baarmoeder en micro-inserts wanneer de cornua uitgezet zijn met contrastmiddel.

(5) Röntgenfoto 5 en 6 – vergrotingen van de cornua uteri – micro-insert zonder eileider met rechter (5) en linker (6) cornua.

LET OP: Het verder verhogen van de druk in de baarmoeder dan nodig is voor röntgenfoto 4 moet vermeden worden om de patiënte onnodig ongemak te besparen en een vasovagale respons te voorkomen.



3. Beoordeling van de plaats van de micro-inserts
   a) Let tijdens de beoordeling op vier 'markeringen' op elk uiteinde van de binnen- en buitencoil. De distale markeringen hebben een vaste plaats ten opzichte van elkaar, maar de proximale markeringen kunnen van plaats veranderen of uitgerekt lijken vanwege de flexibiliteit van de buitencoil. De ideale plaats van de micro-inserts is daar waar de binnencoil de utero-tubale overgang kruist.
   b) De plaats van de micro-inserts beoordelen:
      (1) Expulsie of proximale plaatsing: De micro-insert is niet aanwezig of ≥ 50% van de binnencoil steekt in de baarmoederholte uit.
      (2) Bevredigende plaatsing: Het distale uiteinde van de binnencoil bevindt zich binnen de eileider en < 50% van de binnencoil steekt in de baarmoederholte uit of het proximale uiteinde van de binnencoil bevindt zich ≤ 30 mm in de eileider van welke plaats de cornua met contrastmiddel gevuld worden.
      (3) Distale plaatsing of perforatie: De micro-insert bevindt zich in de eileider maar het proximale uiteinde van de binnencoil bevindt zich > 30 mm distaal van de plaats waar de cornua met contrastmiddel worden gevuld, of de micro-insert is geheel of gedeeltelijk geperforeerd.
4. Beoordeling van de occlusie van de eileider
   a) Stel vast of het contrastmiddel zichtbaar is voorbij de micro-insert en ga na of er enige mate van proximale vulling van de eileider is zelfs indien er geen sprake is van occlusie van de eileider.
   b) Beoordeel de occlusie van de eileider:
      (1) Bevredigende occlusie: De eileider is geoccludeerd bij de cornua.
      (2) Bevredigende occlusie: Contrastmiddel te zien binnen de eileider maar niet voorbij het distale uiteinde van de buitencoil.
      (3) Niet bevredigende occlusie: Contrastmiddel te zien voorbij het distale uiteinde van de micro-insert of in de peritoneale holte.
5. Beoordeling van het vermogen op de micro-insert te vertrouwen
   a) Indien de plaats van de micro-insert en de occlusie van de eileider beide als bevredigend worden beoordeeld, dient de patiënte het advies te krijgen het gebruik van een andere anticonceptiemethode te staken.
   b) Indien de plaats van de micro-insert niet bevredigend is, dient de patiënte het advies te krijgen niet te vertrouwen op de micro-inserts als anticonceptiemiddel.
   c) Indien de plaats van de micro-insert bevredigend is, maar de occlusie van de eileider niet bevredigend is, dient de patiënte het advies te krijgen een andere anticonceptiemethode te blijven gebruiken. Herhaal het HSG na drie maanden. Indien de occlusie van de eileider nog steeds niet bevredigend is, dient de patiënte het advies te krijgen om niet te vertrouwen op de micro-inserts als anticonceptiemiddel.

X. Behandeling van een niet-bevredigende plaats van de micro-inserts

A. Niet-bevredigende plaats van de micro-inserts, zoals gediagnosticeerd met behulp van een hysterosalpingogram

1. Proximale plaats: meer dan 50% van de lengte van de binnencoil van de micro-insert(s) bevindt zich in de uterus.
2. Distale plaats: De micro-insert(s) bevindt (bevinden) zich in de eileider(s), maar het proximale uiteinde van de binnencoil is meer dan 30 mm verwijderd van het contrastmiddel dat de cornua uteri vult.
3. Volledige expulsie van micro-insert(s): micro-insert(s) niet in het lichaam aanwezig.
4. Perforatie: micro-insert(s) perforeren de eileider gedeeltelijk of geheel.
5. Intraperitoneale plaats van micro-insert(s): micro-insert(s) duidelijk buiten de eileider(s).

B. Behandeling van expulsie van micro-inserts of niet-bevredigende locatie van de micro-inserts

1. Bilaterale expulsie van micro-inserts met bilaterale occlusie: De patiënte moet advies krijgen over de mogelijkheid sterilisatie met een incisie te ondergaan of te vertrouwen op de bilaterale PTO voor anticonceptie, gezien de mogelijkheid van een vals-positieve diagnose van occlusie van de eileiders op grond van een **Essure**-bevestigingstest (HSG).
2. Bilaterale expulsie van micro-inserts met occlusie in één eileider en doorgankelijkheid in de andere eileider: Er kan overwogen worden de patiënte in aanmerking te laten komen voor een aanvullende plaatsing van een micro-insert om de nieuwe micro-insert te plaatsen in de eileider die doorgankelijk is zodat zij voor anticonceptie op één **Essure**-micro-insert en op PTO van de andere eileider kan vertrouwen. De patiënte moet advies krijgen over deze mogelijkheid, gezien de mogelijkheid van een vals-positieve diagnose van occlusie van de eileiders op grond van een **Essure**-bevestigingstest (HSG). De patiënte dient ook advies te krijgen over de mogelijkheid sterilisatie met een incisie te ondergaan.
3. Unilaterale expulsie van een micro-insert of een niet-bevredigende unilaterale plaats van de micro-insert (in het myometrium of de intraperitoneale holte) terwijl de plaats van de andere micro-insert bevredigend is: Als aan de hand van het **Essure**-bevestigingstest (HSG) blijkt dat de eileider geblokkeerd is van waaruit de micro-insert is verdreven of waar de micro-insert geplaatst had moeten zijn, kan de patiënte vertrouwen op de naar tevredenheid geplaatste micro-insert en PTO in de andere eileider, gezien de mogelijkheid van een vals-positieve diagnose van occlusie van de eileiders op grond van een **Essure**-bevestigingstest (HSG). De patiënte dient ook advies te krijgen over de mogelijkheid sterilisatie met een incisie te ondergaan.
4. Niet-bevredigende unilaterale plaats van een micro-insert (in het myometrium of de intraperitoneale holte) terwijl de plaats van de andere micro-insert bevredigend is: Indien de **Essure**-bevestigingstest (HSG) aantoont dat de eileider waarin de micro-insert zou moeten zijn geplaatst, doorgankelijk is, kan overwogen worden de patiënte de gelegenheid te geven terug te komen voor plaatsing van een aanvullende micro-insert om nogmaals een plaatsing te ondernemen. De patiënte dient ook advies te krijgen aangaande de mogelijkheid voor incisionele sterilisatie.
5. Unilaterale expulsie van een micro-insert; niet-bevredigende unilaterale plaats van een micro-insert (in het myometrium of de intraperitoneale holte); niet-bevredigende unilaterale plaats van een micro-insert in 'proximale plaats' (>50% van de lengte van de binnencoil bevindt zich in de baarmoeder) of 'distale plaats' (micro-insert in de eileider, maar het proximale uiteinde van de binnencoil is >30 mm verwijderd van het contrastmiddel dat de cornua uteri vult) terwijl de andere micro-insert zich op een niet-bevredigende plaats bevindt: De patiënte dient advies te krijgen over de mogelijkheid sterilisatie met een incisie te ondergaan. In alle gevallen kan een operatie met een incisie nodig zijn, als verwijdering van de micro-insert nodig wordt geacht en hysteroscopische verwijdering niet mogelijk is.
6. Indien een patiënte gekozen heeft voor sterilisatie met een incisie na een van de hierboven vermelde scenario's, moeten beide eileiders worden geoccludeerd ongeacht een eventueel achterblijvende micro-insert die zich op een bevredigende plaats bevindt. Er moet getracht worden een micro-insert te verwijderen indien de arts meent dat dit veilig kan worden gedaan; het kan echter onmogelijk blijken de micro-insert te verwijderen. Het gebruik van doorlichting tijdens de behandeling wordt aanbevolen om de plaats van de micro-insert(s) vóór en tijdens de behandeling te lokaliseren. Een poging de micro-insert te verwijderen mag niet langer duren dan 30 minuten.

XI. Behandeling van gevallen waarin de plaatsing van Essure-micro-inserts niet met goed gevolg is verlopen

In het geval dat de plaatsing van de micro-insert unilateraal of bilateraal niet met goed gevolg is verlopen, moet de patiënte worden verteld dat er geen permanente anticonceptiemethode tot stand is gekomen. Indien de patiënte kiest voor laparoscopische sterilisatie (d.w.z. afklemmen of gebruik van elektrocauterisatie), dienen beide eileiders afgeklemd of gecauteriseerd te worden, zelfs indien er een **Essure**-micro-insert in één eileider is geïmplanteerd. Het afklemmen of cauteriseren van de eileider(s) dient distaal van de **Essure**-micro-insert te gebeuren.

Indien de patiënte niet voor laparoscopische sterilisatie kiest, kan haar een **Essure**-bevestigingstest (HSG) worden aangeboden. Dit HSG kan plaatsvinden na de eerstvolgende menstruatie (vóór de ovulatie: dag 7-14 waarbij dag 1 de eerste dag van de menstruatie is) om te controleren of de eileiders doorgankelijk zijn. Indien wordt vastgesteld dat de eileiders doorgankelijk zijn, kan de arts de patiënte aanbieden plaatsing van een tweede micro-insert te proberen. Indien ook de tweede keer niet met goed gevolg verloopt, is het onwaarschijnlijk dat daaropvolgende pogingen wel zullen slagen. Indien de patiënte één micro-insert *in vivo* heeft, moet haar worden geadviseerd voor anticonceptie niet op de unilaterale micro-insert te vertrouwen.

Indien alleen unilaterale plaatsing tot stand gebracht is en de **Essure**-bevestigingstest (HSG) occlusie van de eileider (PTO) bevestigt, moet met de patiënte worden gesproken over de mogelijkheid te vertrouwen op deze ene micro-insert, gezien de mogelijkheid van een vals-positieve diagnose van PTO met behulp van een **Essure**-bevestigingstest (HSG). Occlusie van de eileiders wordt gedefinieerd als het falen van kleurstof om tijdens de **Essure**-bevestigingstest (HSG) door de baarmoederholte naar de peritoneale holte te vloeien. De patiënte dient ook advies te krijgen aangaande de mogelijkheid voor incisionele sterilisatie. Het verdient geen aanbeveling te trachten een unilateraal geplaatste micro-insert te verwijderen, tenzij de patiënte last heeft van (een) bijwerking(en) van de micro-insert.

XII. Verwijdering van een Essure-micro-insert

WAARSCHUWING: INDIEN DE MICRO-INSERT IS INGEBRACHT, MAG NIET WORDEN GETRACHT OM DEZE HYSTEROSCOPISCH TE VERWIJDEREN, TENZIJ ER TEN MINSTE 18 COILS VAN DE ESSURE-MICRO-INSERT IN DE BAARMOEDERHOLTE UITSTEKEN. In dat geval dient u de micro-insert onmiddellijk na het plaatsen te verwijderen. Verwijderen kan dan echter onmogelijk zijn. Bij het verwijderen van de micro-insert moeten de volgende stappen worden uitgevoerd.

1. Voer een grijptangetje door het werkkanaal van de hysteroscoop.
2. Grijp de buitencoil van de **Essure**-micro-insert vast. Probeer de buiten- en binnencoil van de micro-insert samen vast te klemmen.
3. Trek het grijptangetje en de hysteroscoop tegelijkertijd terug, zodat het gehele systeem gezamenlijk uit de baarmoeder wordt getrokken.
4. De buitencoil en/of de binnencoil van de **Essure**-micro-insert kunnen uitgerekt worden wanneer geprobeerd wordt de micro-insert te verwijderen.
5. Geef zo nodig een pijnstiller/verdovingsmiddel om het ongemak voor de patiënte te verminderen of te voorkomen.
6. Indien volledige verwijdering van de micro-insert tot stand wordt gebracht, moet getracht worden een andere **Essure**-micro-insert te plaatsen.
7. Als de arts er niet zeker van is dat de gehele **Essure**-micro-insert uit de eileider is verwijderd, mag er **GEEN** andere micro-insert in die eileider ingebracht worden en moet er na de plaatsing een röntgenfoto worden gemaakt om te bepalen of er een gedeelte van de micro-insert *in vivo* blijft.

Bij een ander scenario dan hierboven beschreven mag men alleen proberen een micro-insert te verwijderen indien de patiënte last heeft van bijwerkingen van de micro-insert of vraagt om verwijdering van de micro-insert.

Wanneer verwijdering van de micro-insert noodzakelijk geacht wordt, moet dit transabdominaal plaatsvinden (d.w.z. door laparotomie of laparoscopie).

Een resectie van de cornua van de proximale eileider is nodig als de micro-insert correct is geplaatst over de utero-tubale overgang.

Een **Essure**-micro-insert die onjuist is geplaatst of voorbij de utero-tubale overgang is geschoven, moet worden verwijderd via een traditionele, lineaire salpingotomie of een salpingectomie die wordt uitgevoerd via laparoscopie of laparotomie.

1. Om een lineaire salpingotomie uit te voeren, wordt een kleine incisie (ongeveer 2 cm lang) gemaakt langs de antimesenterische rand van de eileider, onmiddellijk boven de micro-insert.
2. Een algehele of gedeeltelijke salpingectomie kan worden uitgevoerd om de micro-insert te verwijderen met of zonder uitvoering van een traditionele sterilisatieprocedure van de eileider.

XIII. Patiënte-identificatiekaart

Elke patiënte bij wie een of meerdere **Essure**-micro-inserts zijn geïmplanteerd, krijgt een gelamineerde kaart die in een portemonnee past en waarop staat aangegeven dat bij haar een of meerdere **Essure**-micro-inserts zijn ingebracht. **De kaart zit in dit pakket bijgevoegd.** De kaart geeft bovendien aan dat er risico's zijn als de deelneemster in de toekomst intra-uteriene behandelingen of chirurgische ingrepen aan de voortplantingsorganen ondergaat.

XIV. Legenda van symbolen

STERILE EO	Het systeem is gesteriliseerd met gebruik van ethyleenoxidegas
LOT	Partijcode
	Niet opnieuw gebruiken
REF	Catalogusnummer
	Aandacht, zie gebruiksaanwijzing
	Uiterste gebruiksdatum
	Weg van hitte houden
	Niet gebruiken als verpakking is geopend of beschadigd
MR	Kan onder bepaalde omstandigheden met MRI worden gescand
EC REP	Europese gemachtigde
CE 0050	Hulpmiddel voldoet aan Europese Richtlijn 93/42/EEG
	Droog houden
CONT	Inhoud

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Permanente Empfängnisverhütung

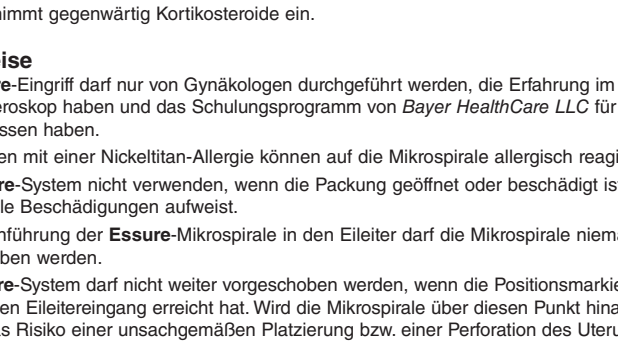
BAYER

GEBRAUCHSANWEISUNG

I. Beschreibung der Mikrospirale

Das **Essure**®-System zur permanenten Empfängnisverhütung besteht aus mehreren Komponenten. Die **Essure**-Mikrospirale ist eine sich dynamisch entfaltende Mikrospirale auf einem Führungsdraht und einem Freigabekatheter. Die komplette Einheit ist in einem Einführkatheter untergebracht. Dieses System (siehe Abb. 1) ist mit einem Griff verbunden, der die Einführung und das Einsetzen der Mikrospirale erleichtert. Außerdem wird das **Essure**-System mit einer Einführschleuse mit Ventil geliefert, die die **Essure**-Mikrospirale bei der Einführung durch den Gummiport des Hysteroskop-Arbeitskanals schützen soll (**DryFlow**® Einführschleuse).

Abb. 1
Essure-Einführsystem
mit den Symbolen für das Einsetzverfahren
(NICHT MASSSTABSGETREU)



II. Wirkmechanismus

Die **Essure**-Mikrospirale wird unter hysteroskopischer Kontrolle durch das **Essure**-System vorgeschoben, bis der proximale Bereich des Eileiterlumens erreicht ist. Wenn sich die **Essure**-Mikrospirale nach der Freigabe entfaltet, verankert sie sich automatisch im Eileiter. Des Weiteren führt die Mikrospirale zu einer erwünschten gutartigen Gewebereaktion, bei der Gewebe in die Mikrospirale hineinwächst und sie fest im Eileiter verankert. Diese gutartige Reaktion ist lokal begrenzt; sie führt zur Bildung von fibrösem Gewebe und damit zu einem Verschluss.

Jedes **Essure**-System wird steril (Sterilisation mit Ethylenoxid) zum einmaligen Gebrauch geliefert. Nicht mehrmals verwenden oder resterilisieren. Eine Resterilisation kann die ordnungsgemäße mechanische Funktion beeinträchtigen und könnte zu einer Verletzung der Patientin führen.

III. Indikationen

Das **Essure**-System dient der permanenten Empfängnisverhütung durch Eileiterverschluss mit einer Mikrospirale.

IV. Kontraindikationen

- Unsicherheit der Patientin, ihre Fertilität zu beenden
- Schwangerschaft oder Verdacht auf Schwangerschaft
- Geburt oder Terminierung einer Schwangerschaft im zweiten Trimester weniger als sechs Wochen vor Einsetzen der **Essure**-Mikrospirale
- Akute oder kurz zurückliegende Beckeninfektion
- Unbehandelte akute Zervizitis
- Ungeklärte oder starke vaginale Blutung
- Gynäkologisches Malignom (vermutet oder bekannt)
- Anormale Uterushöhle oder Eileiter, die eine Sichtbarmachung der Eileitereingänge und/oder Kanülierung des proximalen Eileiters erschweren oder verhindern
- Allergie gegenüber Kontrastmitteln (ein Hysterosalpingogramm ist möglicherweise 3 Monate nach Einsetzen der Mikrospirale erforderlich)
- Patientin nimmt gegenwärtig Kortikosteroide ein.

V. Warnhinweise

- Der **Essure**-Eingriff darf nur von Gynäkologen durchgeführt werden, die Erfahrung im Umgang mit dem Hysteroskop haben und das Schulungsprogramm von *Bayer HealthCare LLC* für diesen Eingriff abgeschlossen haben.
- Patientinnen mit einer Nickeltitan-Allergie können auf die Mikrospirale allergisch reagieren.
- Das **Essure**-System nicht verwenden, wenn die Packung geöffnet oder beschädigt ist oder wenn die Mikrospirale Beschädigungen aufweist.
- Bei der Einführung der **Essure**-Mikrospirale in den Eileiter darf die Mikrospirale niemals mit Gewalt vorgeschoben werden.
- Das **Essure**-System darf nicht weiter vorgeschoben werden, wenn die Positionsmarkierung auf dem Katheter den Eileitereingang erreicht hat. Wird die Mikrospirale über diesen Punkt hinaus vorgeschoben, besteht das Risiko einer unsachgemäßen Platzierung bzw. einer Perforation des Uterus oder des Eileiters.
- Bei einer Perforation des Eileiters oder bei Verdacht darauf muss der Eingriff abgebrochen werden. Bei einem sehr geringen Prozentsatz der Frauen, die an den klinischen **Essure**-Studien teilnahmen (1,8 % bzw. 12 von 682 Patientinnen), wurden durch die Spirale bedingte Eileiterperforationen festgestellt. Falls die Mikrospirale aufgrund einer Perforation entfernt werden muss, ist eine Laparoskopie oder ein anderer chirurgischer Eingriff erforderlich.
- Wenn die **Essure**-Mikrospirale nicht innerhalb von 10 Minuten nach versuchter Kanülierung erfolgreich in den betreffenden Eileiter eingesetzt werden kann, sollte der Versuch abgebrochen und möglicherweise zu einem späteren Zeitpunkt wiederholt werden.
- Sobald die Mikrospirale eingesetzt ist (d.h. vom Einführdraht getrennt wurde), darf eine hysteroskopische Entfernung nicht mehr versucht werden, es sei denn, 18 oder mehr Windungen der **Essure**-Mikrospirale reichen in die Uterushöhle. In diesem Fall sollte unmittelbar nach Einsetzen der Mikrospirale versucht werden, diese wieder zu entfernen. Ein Entfernen ist jedoch unter Umständen nicht möglich.
- Die Patientin muss alternative Verhütungsmittel verwenden, bis drei Monate nach Implantation der Mikrospirale durch eine Röntgenaufnahme eine zufriedenstellende Platzierung der Spirale nachgewiesen werden kann.
- Bei Patientinnen, die die **Essure**-Mikrospirale erhalten, ist nicht auszuschließen, dass sie in späteren Jahren mit elektrochirurgischen Verfahren intrauterin behandelt werden. Es wird empfohlen, bei chirurgischen Eingriffen an den Cornua uteri und den Eileitern auf Elektrokauterisierung zu verzichten. Bei allen anderen Eingriffen im Becken sollte bei Elektrokauterisierung ein Mindestabstand von 4 cm eingehalten werden. Aufgrund der vorhandenen **Essure**-Mikrospirale können bei solchen Eingriffen Risiken auftreten, die bislang noch nicht erkannt wurden.
- Sämtliche intrauterinen Eingriffe wie Biopsie des Endometriums, Ausschabung, diagnostische oder operative Hysteroskopie (einschließlich Ablation des Endometriums) können die empfängnisverhütenden Eigenschaften der Mikrospirale außer Kraft setzen. Ferner können aufgrund der vorhandenen **Essure**-Mikrospirale bei solchen Eingriffen Risiken auftreten, die bislang noch nicht erkannt wurden.
- Laboruntersuchungen und klinische Studien haben gezeigt, dass eine Ablation des Endometriums mit dem GYNECARE-THERMACHOICE*-Uterusballon-System, dem Hologic-NovaSure**-System zur Endometriumablation und dem Hydro ThermAblator*** von Boston Scientific sicher und effektiv durchgeführt werden kann, wenn sie unmittelbar im Anschluss an das Einsetzen der **Essure**-Mikrospirale erfolgt. Es wurden keine speziellen Studien zur Bewertung der Expulsionsrate der **Essure**-Mikrospirale bzw. der Empfängnisverhütungsrate nach einer Kombination des **Essure**-Verfahrens mit der Endometriumablation durchgeführt.
- Patientinnen können sich später für eine In-vitro-Fertilisation (IVF) entscheiden, um dennoch schwanger zu werden. Die Auswirkungen der **Essure**-Mikrospirale auf den Erfolg von IVF sind unbekannt. Welche Risiken die Mikrospirale bei einer Schwangerschaft für die Patientin, den Fötus und die Fortsetzung der Schwangerschaft darstellt, ist bisher nicht bekannt.

* Eine Marke von ETHICON, INC.
** Marke von Hologic, Inc.
***Marke der Boston Scientific Corporation

VI. Vorsichtsmaßnahmen

- Das Einsetzen der Mikrospirale sollte, wenn möglich, während der Tage 7 - 14 der proliferativen Phase des Menstruationszyklus erfolgen (wobei Tag 1 dem ersten Tag der Blutung entspricht), um die Sichtbarkeit der Eileitereingänge zu erhöhen und um die Möglichkeit des Einsetzens der Mikrospirale bei einer Patientin mit einer nicht diagnostizierten Schwangerschaft zu vermeiden.
- Abweichende anatomische Bedingungen im Uterus können das Einsetzen der **Essure**-Mikrospirale erschweren.
- Zur Vermeidung einer Uterusperforation sollte der Eingriff abgebrochen werden, wenn für die Zervixdehnung übermäßige Kraftanwendung erforderlich ist.
- Die beiden Eileitereingänge sollten identifiziert und vor dem Einsetzen der **Essure**-Mikrospirale mit dem Hysteroskop untersucht werden. Die Mikrospirale darf nur dann in einen Eileitereingang eingesetzt werden, wenn davon ausgegangen werden kann, dass auch der gegenüberliegende Eileiter zugänglich und durchgängig ist.
- Eine unmittelbar auf das Einsetzen der **Essure**-Mikrospirale folgende Ablation des Endometriums kann das Risiko einer postablativen PTL erhöhen. Es werden jedoch nur wenige Fälle berichtet, die Frauen mit Eileitersterilisation betreffen, bei denen eine Ablation des Endometriums durchgeführt wurde.
- Das **Essure**-System darf nicht vorgeschoben werden, wenn die Patientin starke Schmerzen oder Beschwerden verspürt.
- Das **Essure**-System muss kühl und trocken gelagert werden.

VII. Mögliche unerwünschte Nebenwirkungen

A. Schwangerschaft

Zu den Risiken gehören Schwangerschaft und Extrauterinschwangerschaft sowie die Risiken, die mit deren Behandlung verbunden sind. Wenn eine Patientin schwanger wird und eine intrauterine Schwangerschaft austragen will, sollte sie darauf hingewiesen werden, dass die Risiken der Mikrospirale für die Patientin, den Fötus und die Fortsetzung der Schwangerschaft nicht bekannt sind.

B. Risiken in Verbindung mit der Einsetzung der Mikrospirale

- Zur Vorbeugung oder Reduzierung der Beschwerden eignen sich Lokalanästhesie, orale Analgesie und Sedierung, regionale Anästhesie (d.h. spinal oder epidural), orale oder intravenöse Sedierung bei Bewusstsein oder eine Vollnarkose. Unabhängig von der Art der Betäubung können die Patientinnen normale Aktivitäten u.U. erst 12 bis 24 Stunden nach dem Eingriff wieder aufnehmen.
- Während und nach dem Einsetzen der Mikrospirale können Schmerzen, Krämpfe und Vaginalblutungen auftreten. In der Regel sind diese erträglich, vorübergehend und können mit Medikamenten erfolgreich behandelt werden.
- Während bzw. direkt nach dem Einsetzen der Mikrospirale besteht das Risiko, dass der Patientin übel wird oder sie erbricht. Diese Beschwerden sind vorübergehend und können im Bedarfsfall medikamentös behandelt werden.
- Am Tag des Eingriffs besteht für die Patientin Ohnmachtgefahr bzw. das Risiko einer vasovagalen Reaktion.
- Es besteht zudem das Risiko einer Perforation oder Dissektion des Eileiters oder der Cornua uteri. Durch eine solche Perforation oder Dissektion kann es zu Blutungen und Narbenbildung kommen; eine Behandlung ist jedoch meist nicht erforderlich.
- Es besteht das Risiko einer Uterusperforation durch das Hysteroskop, das **Essure**-System oder andere Instrumente, die während des Eingriffs verwendet werden. Es können Verletzungen des Darms, der Blase und der größeren Blutgefäße nicht ausgeschlossen werden. Falls solche Komplikationen auftreten, kann eventuell (wenngleich nicht wahrscheinlich) ein chirurgischer Eingriff erforderlich sein. Zur Vermeidung einer Uterusperforation sollte der Eingriff abgebrochen werden, wenn zur Dehnung der Zervix übermäßige Kraftanwendung erforderlich ist.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale ungewollt im Myometrium des Uterus und nicht im Lumen des Eileiters platziert wird. Wenn eine Mikrospirale bereits ordnungsgemäß in einem Eileiter eingesetzt wurde und dann versehentlich eine Platzierung im Myometrium erfolgt, kann der Arzt versuchen, eine dritte Mikrospirale einzusetzen, um den Eingriff abzuschließen. Wenn die Spirale nicht in beiden Eileitern eingesetzt werden kann, trägt die Patientin eine Mikrospirale im Eileiter und/oder eine Mikrospirale im Myometrium, so dass eine zuverlässige Empfängnisverhütung nicht gegeben ist. Wird die Mikrospirale im Myometrium eingesetzt, kann dies zu postoperativen Schmerzen oder anderen unerwünschten Nebenwirkungen führen. Wenn eine chirurgische Entfernung der Spirale(n) erforderlich ist, kann eine Salpingektomie oder Hysterektomie notwendig werden.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale zu weit distal im Eileiter platziert wird. Wenn eine Entfernung der Mikrospirale erforderlich ist, muss ein chirurgischer Eingriff (Laparoskopie oder Laparotomie) vorgenommen werden.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale zu weit proximal im Eileiter platziert wird. Wenn beim Einsetzen 18 oder mehr Windungen der **Essure**-Mikrospirale sichtbar sind, muss sofort versucht werden, die Mikrospirale wieder zu entfernen (siehe Abschnitt XIII - Entfernung der **Essure**-Mikrospirale). Wenn versucht wird die Mikrospirale zu entfernen, besteht die Möglichkeit, dass die Entfernung fehlschlägt oder dass die **Essure**-Mikrospirale bricht und ein Fragment der Mikrospirale *in vivo* verbleibt. Wenn eine Entfernung der Mikrospirale versucht bzw. erreicht wird, besteht zudem die Möglichkeit, dass die Patientin nach dem Einsetzen der **Essure**-Mikrospirale stärkere Schmerzen verspürt und Krämpfe und Blutungen auftreten.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale die Eileiterwand oder die Cornua uteri perforiert und in die Bauchhöhle gelangt. Infolgedessen kann es zu postoperativen Schmerzen bzw. Menstruationsstörungen oder anderen unerwünschten Nebenwirkungen kommen. Wenn die Patientin sich entscheidet, eine chirurgische Sterilisation oder einen anderen chirurgischen Eingriff vornehmen zu lassen, kann versucht werden, die Mikrospirale aus der Bauchhöhle zu entfernen, wenn der Arzt das Vorgehen für sicher hält. Wenn der Arzt die Mikrospirale jedoch nicht sehen oder erreichen kann, ist eine Entfernung der Mikrospirale eventuell nicht möglich.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale nur in einem Eileiter erfolgreich eingesetzt werden kann. In diesem Fall verbleibt bei der betroffenen Patientin eventuell nur eine Mikrospirale *in vivo*, die eine sichere Empfängnisverhütung nicht gewährleistet.
- Es besteht das Risiko, dass die **Essure**-Mikrospirale in keinen der beiden Eileiter eingesetzt werden kann.
- Es besteht ein geringfügiges Risiko einer exzessiven Absorbierung der physiologischen Kochsalzlösung, die bei einem hysteroskopischen Eingriff zur Dehnung des Uterus verwendet wird.
- Wie bei allen invasiven Eingriffen kann das Einsetzen der Mikrospirale eine Infektion verursachen. Eine Infektion kann zu Schäden an Uterus, Eileitern oder Beckenhöhle führen. Dies kann eine Behandlung mit Antibiotika oder in seltenen Fällen einen Krankenhausaufenthalt bzw. eine Operation einschließlich einer Hysterektomie erforderlich machen.

C. Risiken im Zusammenhang mit dem Tragen der Essure-Mikrospirale

- Es besteht die Gefahr, dass die **Essure**-Mikrospirale aus den Eileitern migriert. Bei dieser Migration kann es sich um eine Expulsion (Bewegung aus dem Eileiter in die Uterushöhle, Zervix oder Vagina oder aus dem Körper) oder um eine Migration im Körper (Wanderung in den Eileiter oder aus dem Eileiter in die Bauchhöhle) handeln. Unter Umständen sind zusätzliche Röntgenaufnahmen erforderlich, um den Sitz der Mikrospirale zu bestimmen, und gegebenenfalls eine Operation, um die Mikrospirale zu entfernen. Eine Migration der Mikrospirale kann zu Schwangerschaft, Extrauterinschwangerschaft bzw. zu Schmerzen und Menstruationsstörungen sowie anderen unerwünschten Nebenwirkungen führen.
- Wie bei anderen derzeit verfügbaren mechanischen Methoden zur permanenten Schwangerschaftsverhütung (z.B. Clips, Ringe) ist ein chirurgischer Eingriff erforderlich, wenn die **Essure**- Mikrospirale entfernt werden soll. Ferner kann eine chirurgische Entfernung der Eileiter (Salpingektomie) und des Uterus (Hysterektomie) erforderlich werden.
- Schmerzen im Bauch bzw. Beckenbereich und Krämpfe können auftreten. Es besteht eine größere Wahrscheinlichkeit, dass Schmerzen und Krämpfe während der Menstruation, während und nach dem Sexualverkehr oder bei anderen körperlichen Aktivitäten auftreten.
- Es kann zu Zwischenblutungen oder verstärkten Menstruationsblutungen kommen.
- Mitunter bedauern Patientinnen ihre Entscheidung für eine permanente Empfängnisverhütung und leiden infolge des Eingriffs unter leichten Depressionen oder anderen emotionalen Störungen.

D. Risiken im Zusammenhang mit den Nachuntersuchungen

- Beim Röntgen des Beckens, das drei Monate nach Einsetzen der Mikrospirale zur Kontrolle der Lage der Spirale notwendig ist, besteht ein Bestrahlungsrisiko. Eventuell ist ein bestätigender **Essure**-Test (HSG) erforderlich. Die Strahlenbelastung liegt bei der Fluoroskopieaufnahme (<30 Sekunden) eines Hysterosalpingogramms bei etwa 0,033 Rad. Die Strahlenbelastung bei einem Bariumeinlauf liegt im Vergleich dazu bei 0,85 Rad. Das ist mehr als für einen bestätigenden **Essure**-Test (HSG) erforderlich ist. Die Strahlenbelastung beim Röntgen des Beckenbereichs ist ungefähr gleichwertig mit der natürlichen Hintergrundstrahlung, die eine Person im Laufe eines Jahres aufnimmt.
- Mit dem bestätigenden **Essure**-Test (HSG) sind, falls erforderlich, folgende zusätzliche Risiken verbunden: vasovagale Reaktion, Infektion und dadurch gegebenenfalls Behandlung mit Antibiotika und in seltenen Fällen Krankenhausaufenthalt, Intravasation, Uterusperforation, Krämpfe bzw. Blutungen des Uterus sowie Schmerzen oder Beschwerden und allergische Reaktionen auf Latex. Beim Kontakt mit Latex wurde in einigen wenigen Fällen über anaphylaktische Reaktionen berichtet, die zum Tode führen können.

- Die Verwendung von Kontrastmitteln bei dem bestätigenden **Essure**-Test (HSG) wurde bei einigen Patientinnen mit allergischen Reaktionen in Zusammenhang gebracht. Allergische Reaktionen können zu Urtikaria und Atembeschwerden führen. Bei einigen Patientinnen kann eine anaphylaktische Reaktion nicht ausgeschlossen werden, die zum Tode führen kann.

E. Risiken im Zusammenhang mit potenziellen zukünftigen Eingriffen

- Bei Patientinnen, die die **Essure**-Mikrospirale erhalten, ist nicht auszuschließen, dass sie in späteren Jahren mit elektrochirurgischen Verfahren intrauterin behandelt werden. Es wird empfohlen, bei chirurgischen Eingriffen an den Cornua uteri und den Eileitern auf Elektrokauterisierung zu verzichten. Bei allen anderen Eingriffe im Becken sollte bei Elektrokauterisierung ein Mindestabstand von 4 cm eingehalten werden. Aufgrund der vorhandenen **Essure**-Mikrospirale können bei solchen Eingriffen Risiken auftreten, die bisher noch nicht erkannt wurden.
- Sämtliche intrauterinen Eingriffe wie Biopsie des Endometriums, Ausschabung, diagnostische oder operative Hysteroskopie (einschließlich Ablation des Endometriums) können die empfängnisverhütenden Eigenschaften der Mikrospirale außer Kraft setzen. Ferner können aufgrund der vorhandenen **Essure**-Mikrospirale bei solchen Eingriffen Risiken auftreten, die bislang noch nicht erkannt wurden.
- Patientinnen könnten sich später für eine In-vitro-Fertilisation (IVF) entscheiden, um dennoch schwanger zu werden. Die Auswirkungen der **Essure**-Mikrospirale auf den Erfolg von IVF sind unbekannt. Welche Risiken die Mikrospirale bei einer Schwangerschaft für die Patientin, den Fötus und die Fortsetzung der Schwangerschaft darstellt, ist bisher nicht bekannt.
- Die **Essure**-Mikrospirale ist MRT-sicher und röntgendicht. Die **Essure**-Mikrospirale ist außerdem mit Ausnahme der Beckenbildgebung, bei der Artefakte entstehen können, MRT-kompatibel.
- **Es ist nicht auszuschließen, dass noch unbekannte Risiken bestehen.**

VIII. Gebrauchsanleitung

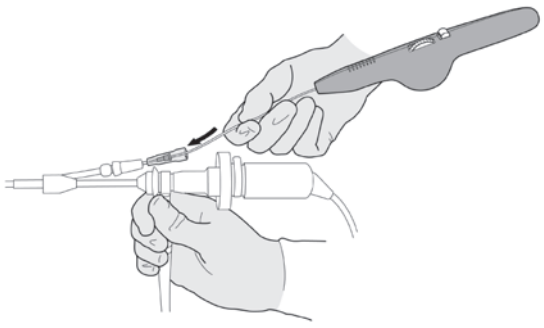
A. Vor Einsetzen der Mikrospirale

1. Das Einsetzen der Mikrospirale sollte, wenn möglich, während der Tage 7 - 14 der proliferativen Phase des Menstruationszyklus erfolgen (wobei Tag 1 dem ersten Tag der Blutung entspricht), um die Sichtbarkeit der Eileitereingänge zu erhöhen und um die Möglichkeit des Einsetzens der Mikrospirale bei einer Patientin mit einer nicht diagnostizierten Schwangerschaft zu vermeiden.
2. Innerhalb von 24 Stunden vor oder unmittelbar vor dem Eingriff zum Einsetzen der Mikrospirale sollte vom Arzt bzw. einem Beauftragten ein Schwangerschaftstest durchgeführt werden.
3. Ein bis zwei Stunden vor dem Einsetzen der Spirale sollte unbedingt ein nicht-steroidales Antiphlogistikum (NSAR) wie z.B. Indocid oral oder als Zäpfchen verabreicht werden, da in klinischen Studien gezeigt wurde, dass NSAR die Wahrscheinlichkeit einer erfolgreichen Platzierung wesentlich erhöhen. Wird nur ein Parazervikalblock verwendet, kann ferner zur Linderung von Angstgefühlen 30 Minuten vor dem Eingriff Diazepam (oral) oder ein ähnliches Mittel verabreicht werden.

B. Einsetzen der Essure-Mikrospirale

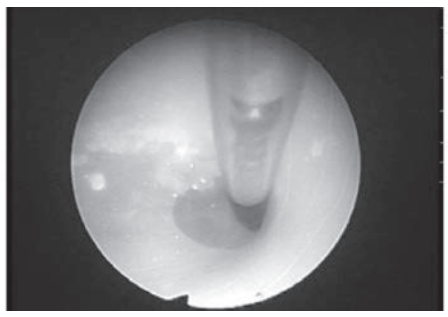
Die **Essure**-Mikrospirale kann ambulant oder in einer Tagesklinik eingesetzt werden. Dabei sind sterile Verfahren anzuwenden. Das Einsetzen der Mikrospirale sollte maximal 30 Minuten dauern.

1. Die Patientin in Steinschnittlage bringen.
2. Ein Spekulum in die Vagina einführen, um die Zervix zu erreichen. Die Zervix gemäß Protokoll mit Betadin oder einer anderen geeigneten antibakteriellen Lösung vorbereiten.
3. Für die Implantation der Mikrospirale sollte vorzugsweise eine Lokalanästhesie verwendet werden. Es kann ein Parazervikalblock gegeben werden. Zur Reduzierung oder Vermeidung von Beschwerden kann ggf. auch Midazolam (intravenös) oder ein ähnliches Mittel verabreicht werden.
4. Ein steriles Hysteroskop mit Kamera und Arbeitskanal (≥5 French) durch die Zervix in die Uterushöhle einführen. Gegebenenfalls die Zervix dehnen, um die Einführung zu erleichtern. Zur Vermeidung einer Uterusperforation sollte der Eingriff abgebrochen werden, wenn zur Dehnung der Zervix übermäßige Kraftanwendung erforderlich ist.
5. Die Uterushöhle sollte durch Infusion physiologischer Kochsalzlösung durch den Arbeitskanal des Hysteroskops gedehnt werden. Es wird dringend empfohlen, die physiologische Kochsalzlösung auf Körpertemperatur vorzuwärmen und mit Gefällezuführung zu infundieren, um Eileiterkrämpfe zu minimieren. Der Uterus muss sehr prall sein und während des Eingriffs in diesem Zustand gehalten werden. Während des Eingriffs sollten die üblichen Verfahren zur Flüssigkeitskontrolle eingehalten werden. Die Eileitereingänge sind mit Hilfe des Hysteroskops zu bestimmen.
6. Die beiden Eileitereingänge sollten identifiziert und vor dem Einsetzen der **Essure**-Mikrospirale mit dem Hysteroskop untersucht werden. Die Mikrospirale darf nur dann in einen Eileitereingang eingesetzt werden, wenn davon ausgegangen werden kann, dass auch der gegenüberliegende Eileiter zugänglich und durchgängig ist.
7. Nach der Identifizierung der Eileitereingänge die Einführschleuse durch die Verschlusskappe am Arbeitskanal des Hysteroskops einführen. Den Absperrhahn des Arbeitskanals geöffnet lassen (wenn der Absperrhahn an einem der Geräte geschlossen wird, kann das Gerät bzw. die Einführschleuse beschädigt werden). Das Einführsystem der **Essure**-Mikrospirale durch die Einführschleuse führen und im Arbeitskanal des Hysteroskops vorschieben. Die Einführschleuse mit Ventil kann während des ganzen **Essure**-Verfahrens im Arbeitskanal bleiben, wenn sie im Rahmen der ersten Platzierung der Mikrospirale nicht beschädigt wurde.



Die Einführschleuse durch die Verschlusskappe am Arbeitskanal des Hysteroskops einführen und dann das **Essure***-Einführsystem durch die Einführschleuse schieben.*

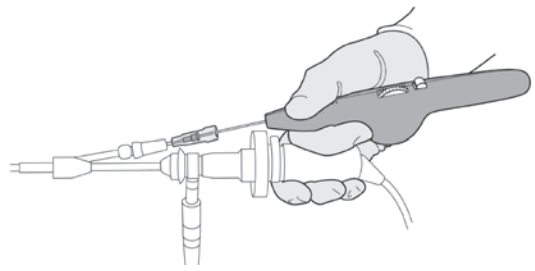
8. Das **Essure**-Einführsystem langsam und stetig in den proximalen Teil des Eileiters vorschieben, um Eileiterkrämpfe zu vermeiden. Das Einführsystem so weit vorschieben, bis die Positionsmarkierung des distalen Katheters den Eileitereingang erreicht. Diese optische Markierung weist darauf hin, dass die **Essure**-Mikrospirale vom distalen intramuralen bis zum proximalen isthmischen Abschnitt des Eileiters reicht und die äußere Spirale den uterotubaren Übergang abdeckt. Diese Position ist ideal zum Einsetzen der **Essure**-Mikrospirale.



Vorschieben, bis die schwarze Positionsmarkierung den Eileitereingang erreicht hat (optischer Hinweis für die richtige Einsetzposition).

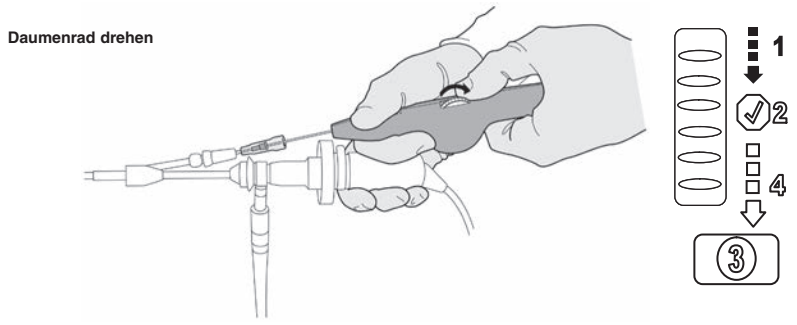
9. Eine richtige konzentrische Anordnung des Einführkatheters im Eileiterlumen ist dann gegeben, wenn der Katheter bei direkter Sicht ohne starken Widerstand weiter vorgeschoben werden kann. Ein Widerstand gegen weiteren Vorschub macht sich in der Regel auf zweierlei Weise bemerkbar: 1) Die schwarze Markierung an der Außenfläche des Katheters bewegt sich nicht weiter in Richtung Eileitereingang und/ oder 2) der Einführkatheter krümmt oder biegt sich stark und verhindert so, dass der Arzt weiteren Druck auf den Katheter ausüben kann. Wenn ein solcher Widerstand gegen eine Vorwärtsbewegung des Katheters festgestellt wird, sollte nicht weiter versucht werden, die Mikrospirale einzusetzen, da dann eine Uterusperforation nicht auszuschließen ist oder die Mikrospirale u.U. versehentlich im Muskelgewebe des Uterus und nicht im Eileiterlumen eingesetzt wird. Zur Untersuchung der Eileiterdurchgängigkeit ist während der Nachsorge ein bestätigender **Essure**-Test (HSG) erforderlich.

10. Kann der Katheter nach mehreren Minuten nicht zur Positionsmarkierung vorgeschoben werden, sollte die Durchgängigkeit des Eileiters mit Hilfe eines speziellen Katheters überprüft werden, sofern dies nicht bereits geschehen ist. Ist der Eileiter verschlossen oder kann der Katheter nicht bis zur Positionsmarkierung vorgeschoben werden, sollte die Behandlung abgebrochen werden. Wenn die Mikrospirale nicht spätestens 10 Minuten nach versuchter Kanülierung erfolgreich in den betreffenden Eileiter eingesetzt werden kann, sollte die Behandlung abgebrochen werden.
11. Wenn der Einführkatheter bis zur Positionsmarkierung vorgeschoben ist, kann die Mikrospirale eingesetzt werden. Dazu zuerst den Griff der **Essure**-Mikrospirale an der Hysteroskopkamera oder einem anderen unbeweglichen Gegenstand stabilisieren, damit das **Essure**-System nicht versehentlich beim Zurückziehen des Einführkatheters vorgeschoben wird.



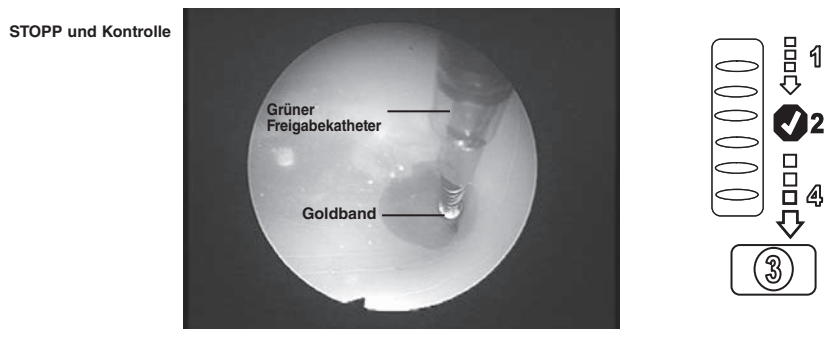
Griff am Kamerakopf oder einem anderen unbeweglichen Gegenstand stabilisieren, damit das **Essure***-System nicht versehentlich vorgeschoben wird.*

12. Wenn sichergestellt ist, dass sich die Positionsmarkierung am Eileitereingang befindet, das Daumenrad am Handgriff in Richtung des Bedieners drehen, bis sich das Rad nicht mehr drehen lässt. Dieser Vorgang entspricht dem Symbol ⇩1 auf dem Handgriff des Einführsystems. Dadurch wird das Zurückziehen des Einführkatheters erleichtert. Es kann beobachtet werden, wie sich die schwarze Positionsmarkierung vom Eileitereingang weg (in Richtung des Hysteroskops) bewegt und in den Arbeitskanal verschwindet. Beim Zurückziehen des Einführkatheters wird die rückgewickelte **Essure**-Mikrospirale sichtbar. Etwa 1 cm der Mikrospirale (rückgewickelte Spiralwindungen) sollte nach Zurückziehen des Einführkatheters im Uterus bleiben.



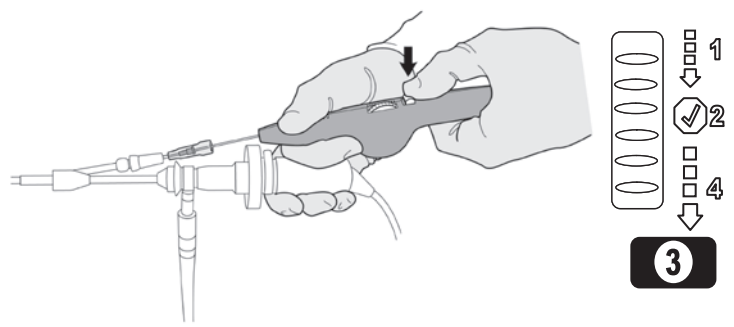
Daumenrad drehen, um den Katheter zurückzuziehen.

13. Zur Bestätigung der richtigen Position das goldene Markierungsband unmittelbar außerhalb des Eileitereingangs positionieren; dies entspricht dem Symbol ✓2 auf dem Handgriff des Einführ-systems. Das Erscheinen des Goldbands unmittelbar außerhalb des Eileitereingangs sowie das Erscheinen der distalen Spitze des grünen Freigabekatheters bestätigen die richtige Position. Sollte mehr als 1 cm der Mikrospirale im Uterus zu sehen sein, ist das ganze System ggf. weiter in den Eileiter zu bewegen, um die Mikrospirale anders zu positionieren, bevor der nächste Schritt ausgeführt wird.



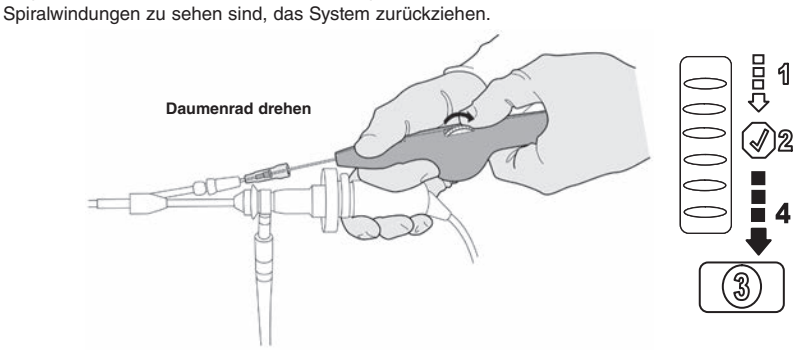
Goldband am Eileitereingang

14. Damit das Daumenrad weiter gedreht werden kann, auf den Knopf auf dem Handgriff drücken; dies entspricht dem Symbol ③ auf dem Handgriff.



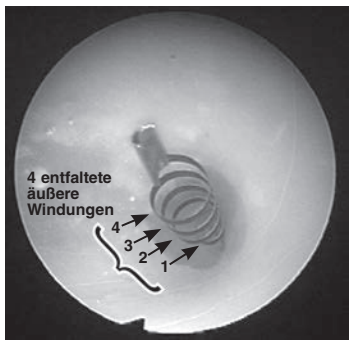
Auf den Knopf drücken, damit das Daumenrad wieder gedreht werden kann.

15. Das Daumenrad in Richtung des Bedieners drehen, um die äußere Spirale der Mikrospirale zu entfalten; dies entspricht dem Symbol ⇩4 auf dem Handgriff. Das Daumenrad so weit drehen, wie es geht. Wenn das Daumenrad nicht weiter gedreht werden kann und die entfalteten äußeren Spiralwindungen zu sehen sind, das System zurückziehen.



Daumenrad drehen, um die äußeren Windungen der Mikrospirale zu entfalten.

16. Die Position der eingesetzten **Essure**-Mikrospirale wird mit dem Hysteroskop kontrolliert. Im Idealfall bleiben 3 bis 8 entfaltete äußere Windungen der **Essure**-Mikrospirale frei im Uterus.



Die entfalteten äußeren Windungen der **Essure**-*Mikrospirale im Uterus zeigen, dass die Mikrospirale optimal platziert wurde.*

17. Wenn der Arzt auf Grund des hysteroskopischen Bildes nicht mit der Platzierung der Mikrospirale zufrieden ist bzw. eine Perforation des Eileiters oder Uterus vermutet, ist die Mikrospirale an ihrer Stelle zu lassen und drei Monate nach dem Eingriff durch eine Röntgenaufnahme des Beckens oder HSG zu beurteilen.

    ACHTUNG: NACH DEM EINSETZEN DER MIKROSPIRALE UND DEREN FREIGABE IM EILEITER DARF SIE NICHT MITHILFE DES HYSTEROSKOPS ENTFERNT WERDEN, ES SEI DENN, 18 ODER MEHR WINDUNGEN DER MIKROSPIRALE REICHEN IN DIE UTERUSHÖHLE. In diesem Fall sollte unmittelbar nach Platzierung der Mikrospirale versucht werden, diese wieder zu entfernen. Es ist jedoch nicht auszuschließen, dass eine Entfernung nicht möglich ist (siehe Abschnitt XII - Entfernung der **Essure**-Mikrospirale). Wenn die Mikrospirale jedoch unbeabsichtigt in die Uterushöhle eingesetzt wurde, sollte sie aus dem Uterus entfernt und ein weiterer Versuch unternommen werden, die Mikrospirale im Eileiter zu platzieren.
18. Den Vorgang zum Einsetzen der **Essure**-Mikrospirale im gegenüberliegenden Eileiter wiederholen.
19. Die Länge der in die Uterushöhle reichenden Mikrospirale sowie Probleme bei der Identifizierung oder Bestätigung der Eileitereingänge oder Bedenken in Bezug auf eine potenzielle Perforation vermerken. Diese Informationen im Krankenblatt der Patientin dienen als Bezugspunkt bei Überprüfung des bestätigenden **Essure**-Tests nach drei Monaten *(siehe Abschnitt IX - Bestätigender Essure-Test).*
20. **Die Patientin ist darauf hinzuweisen, dass in den nächsten drei Monaten nach Einsetzen der Mikrospirale alternative Mittel zur Empfängnisverhütung (außer einem IUP) verwendet werden müssen.**
21. Mit der Patientin muss drei Monate nach dem Einsetzen der **Essure**-Mikrospirale ein Termin für einen bestätigenden **Essure**-Test vereinbart werden, um Retention und Lage der Mikrospirale zu kontrollieren.

IX. Bestätigender Essure-Test

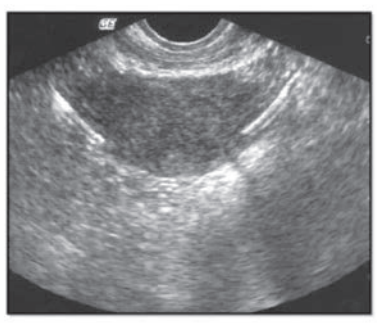
A. Drei Monate nach Einsetzen der **Essure**-Mikrospirale muss ein bestätigender **Essure**-Test durchgeführt werden, um Retention und Lage der Mikrospiralen zu kontrollieren. Die bestätigenden **Essure**-Tests (transvaginaler Ultraschall (TVU), Röntgenaufnahme des Beckens oder Hysterosalpingogramm (HSG)) müssen von einem erfahrenen Gynäkologen, Ultraschalldiagnostiker und/oder Radiologen mit Schulung im Protokoll des jeweiligen bestätigenden **Essure**-Tests durchgeführt werden. Bei der Schulung wird ein ausführliches Protokoll mit Abbildungen und Tipps für die Durchführung des Tests bereitgestellt; zusätzliche Exemplare können unter essure.com heruntergeladen werden.

B. Als erster bestätigender Test kann drei Monate nach einem komplikationslosen Eingriff zum Einsetzen bilateraler Mikrospiralen entweder eine Röntgenaufnahme des Beckens oder eine TVU-Aufnahme erstellt werden.

1. Röntgen- und TVU-Aufnahmen dürfen unter den folgenden Umständen nicht als bestätigender **Essure**-Test verwendet werden:
    a) Schwieriges Einsetzverfahren mit mindestens einem der folgenden Punkte:
        (1) Bedenken zum Zeitpunkt des Einsetzens, dass es aufgrund übermäßiger Kraftanwendung bei der Mikrospiralenfreigabe und/oder eines plötzlichen Widerstandsverlusts möglicherweise zu einer Perforation gekommen ist.
        (2) Schwierigkeiten bei der Identifizierung der Eileitereingänge aufgrund anatomischer Bedingungen oder technischer Faktoren wie unzureichender Dehnung, schlechter Lichtverhältnisse oder endometrialer Gewebereste.
        (3) Unsicherheit des Arztes bezüglich der Platzierung
    b) Eingriffsdauer > 15 Minuten (Einführung bis Entfernung des Hysteroskops).
    c) Nach der Platzierung reichen 0 oder > 8 Windungen in die Uterushöhle
    d) Ungewöhnliche postoperative Schmerzen (vorübergehend oder anhaltend) oder zu einem späteren Zeitpunkt einsetzende Schmerzen ohne feststellbare Ursache.
2. Wenn Röntgen oder Ultraschall kontraindiziert sind, muss eine HSG der Patientin durchgeführt werden, um die Lage der Mikrospiralen und den Eileiterverschluss zu beurteilen. Transabdominaler Ultraschall ist kein Ersatz für TVU. Wenn das Ergebnis der Röntgen- oder Ultraschallkontrolle nicht eindeutig oder nicht zufriedenstellend ist, muss eine HSG der Patientin durchgeführt werden, um die Lage der Mikrospiralen und den Eileiterverschluss zu beurteilen.

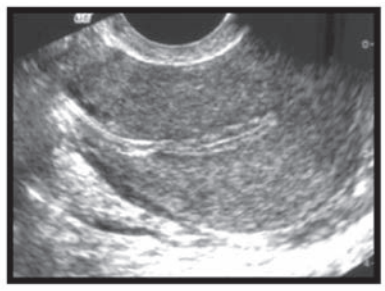
C. Transvaginaler Ultraschall

1. Es müssen mindestens drei Bilder angefertigt und für die Dokumentation aufbewahrt werden:
    a) Koronale oder schräg koronale Ansicht mit Abbildung eines Teils jeder Mikrospirale in den Gebärmutterhörnern, als „Aufklärungsaufnahme“ gekennzeichnet.



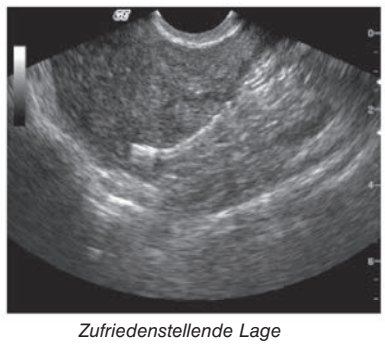
In dieser Queransicht (koronal/schräg koronal) sind bilaterale Mikrospiralen sichtbar.

    b) Koronale oder schräg koronale Abbildung der linearen Achse der linken Mikrospirale (einschließlich des proximalen Endes), die das Myometrium im Cornu (interstitieller Teil des Eileiters) durchquert oder den Eileiter-Übergang zur Uterus-Serosa berührt, als „links“ gekennzeichnet.
    c) Koronale oder schräg koronale Abbildung der linearen Achse der rechten Mikrospirale, die das Myometrium im Cornu (interstitieller Teil des Eileiters) durchquert oder den Eileiter-Übergang zur Uterus-Serosa berührt, als „rechts“ gekennzeichnet.
    d) Alle drei Bilder sollten auf Film aufgenommen und in die Krankenakte der Patientin aufgenommen werden, um die zufriedenstellende Retention und Lage der Mikrospiralen zu dokumentieren.
2. Klassifizierung der Lage der Mikrospiralen
    a) Identifizierung der Mikrospiralen: In einer einzigen Aufklärungsaufnahme (koronale oder schräg koronale Ansicht) muss ein Teil jeder Mikrospirale im Cornu sichtbar sein, um die bilaterale Platzierung zu gewährleisten und die Gefahr der doppelten Abbildung derselben Mikrospirale zu reduzieren. Die lineare Achse der Mikrospiralen sollte relativ symmetrisch aussehen.
    b) Optimale Lage
    Die Mikrospirale liegt optimal, wenn ihr proximales Ende die Uterushöhle oder das Endometrium berührt und sich die lineare Achse innerhalb des Myometriums im Cornu (interstitieller Teil des Eileiters) befindet und am Eileiter-Übergang zur Uterus-Serosa bzw. diesen durchquerend dargestellt werden kann. Der Teil der Mikrospirale, der sich im Eileiter befindet, kann möglicherweise nicht dargestellt werden. Die lineare Achse der Mikrospirale muss dargestellt werden, um zu bestätigen, dass sie nicht verdreht oder gedehnt ist.



Optimale Lage

    c) Zufriedenstellende Lage
    Die Lage der Mikrospirale ist zufriedenstellend, wenn sich das proximale Ende distal zum Endometrium befindet, während sich die lineare Achse innerhalb des Myometriums im Cornu (interstitieller Teil des Eileiters) befindet und am Eileiter-Übergang zur Uterus-Serosa bzw. diesen durchquerend dargestellt werden kann. Der Teil der Mikrospirale, der sich im Eileiter befindet, kann möglicherweise nicht dargestellt werden. Die lineare Achse der Mikrospirale muss dargestellt werden, um zu bestätigen, dass sie nicht verdreht oder gedehnt ist.



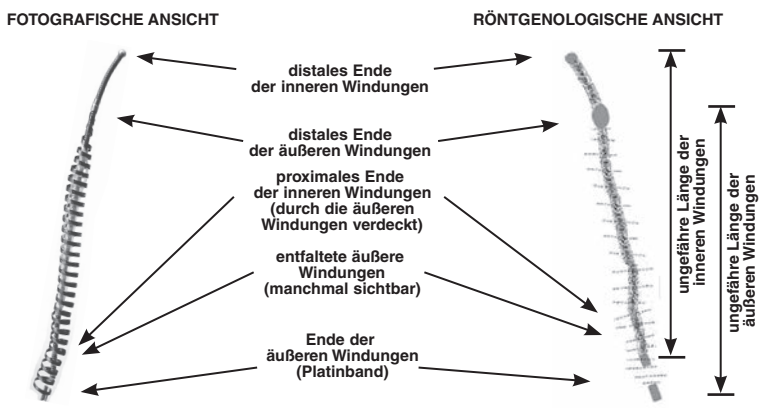
Zufriedenstellende Lage

    d) Unbefriedigende Lage
        (1) Die Lage der Mikrospirale ist unbefriedigend, wenn ein Teil einer Mikrospirale nicht in einer einzigen Aufklärungsaufnahme (koronale oder schräg koronale Ansicht) im Cornu sichtbar ist.
        (2) Wenn eine oder beide Mikrospiralen nicht in einer einzigen Aufklärungsaufnahme (koronale oder schräg koronale Ansicht) im Cornu sichtbar sind, besteht Verdacht auf eine Expulsion.
        (3) Wenn sich das proximale Ende der Mikrospirale nicht innerhalb des Myometriums im Cornu (interstitieller Teil des Eileiters) befindet und nicht den Eileiter-Übergang zur Uterus-Serosa durchquert oder berührt, besteht Verdacht auf eine distale Platzierung.
        (4) Wenn mehr als 50 % bzw. der größte Teil der Mikrospirale in der Uterushöhle sichtbar oder die lineare Achse der Mikrospirale/n in der sagittalen Mittellinienansicht sichtbar ist, besteht Verdacht auf eine proximale Platzierung.
        (5) Wenn die lineare Achse einer oder beider Mikrospiralen in der sagittalen Ansicht parallel zum Endometriumstreifen verläuft oder die lineare Achse einer Mikrospirale in der sagittalen Mittellinienansicht das Myometrium durchquert, besteht Verdacht auf eine Perforation.
        (6) Unbestimmte Lage: Wenn die lineare Achse einer Mikrospirale nicht identifiziert werden kann, was bedeutet, dass sie verdreht, verbogen oder gedehnt ist, wird die Lage als unbefriedigend eingestuft. Wenn das umliegende Weichgewebe nicht klar definiert werden kann, wird die Lage als unbefriedigend eingestuft.
3. Wenn das Ergebnis der Ultraschallkontrolle nicht eindeutig oder nicht zufriedenstellend ist, muss eine HSG der Patientin durchgeführt werden, um die Lage der Mikrospiralen und den Eileiterverschluss zu beurteilen.

D. Röntgenaufnahme des Beckens

1. Nehmen Sie ein Bild des Uterus auf, in dem beide **Essure**-Mikrospiralen deutlich zu sehen sind. Die Lage und Krümmung der Mikrospiralen sind zu vermerken.

Entsprechendes Röntgenbild der ***Essure***-*Mikrospirale*



2. Beurteilen Sie die Röntgenaufnahme des Beckens wie folgt:
    a) Zufriedenstellend: Die Mikrospiralen scheinen sich im Eileiterlumen zu befinden, den Eileiter-Übergang zur Uterus-Serosa zu überspannen und relativ symmetrisch zu liegen. Patientinnen, deren Röntgenaufnahmen als „zufriedenstellend” beurteilt werden, können beginnen, sich auf die **Essure**-Mikrospirale zur Empfängnisverhütung zu verlassen.
    b) Verdächtig: Eine oder beide Mikrospiralen scheinen distal oder proximal zur optimalen Position zu liegen, haben möglicherweise den Eileiter teilweise oder vollständig perforiert und/oder scheinen relativ asymmetrisch zu liegen. Patientinnen, deren Röntgenaufnahmen als „verdächtig” beurteilt werden, sind anzuweisen, weiterhin alternative Empfängnisverhütungsmethoden anzuwenden und sich einer HSG zu unterziehen.
    c) Unbefriedigend: Offensichtliche Lage der Mikrospirale in der Bauchhöhle oder Expulsion.
3. Wenn das Ergebnis der Röntgenkontrolle nicht eindeutig oder nicht zufriedenstellend oder die Lage der Mikrospiralen verdächtig ist, muss sich die Patientin einer HSG unterziehen, um die Lage der Mikrospiralen und den Eileiterverschluss zu beurteilen.

E. Durchführung und Auswertung einer modifizierten HSG

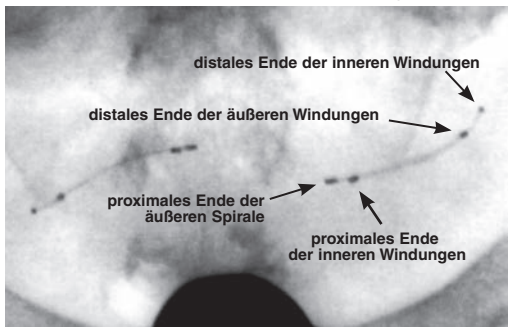
1. Die HSG dient zur weiteren Beurteilung der Lage der **Essure**-Mikrospirale und des Eileiterverschlusses, wenn dies aufgrund der Röntgen- oder Ultraschallbefunde notwendig ist. Beachten Sie bei der Durchführung und Auswertung der HSG die folgenden Richtlinien.
2. Durchführung der HSG – Richtlinien:
    a) Sorgen Sie für gute Füllung der Cornua, damit die Silhouette der Uterushöhle deutlich zu sehen ist.
    b) Bringen Sie den Fluoroskopiestrahl so nah zur A/P-Projektionsebene wie möglich.
    c) Dilatieren Sie die Zervix nur wenn nötig; achten Sie im Falle einer Dilatation auf eine gute Abdichtung der Zervix.
    d) Liegt der Uterus in Mittelposition, kann es erforderlich sein, die zervikale Zange nach unten zu ziehen. Entfernen Sie zur optimalen Darstellung der Uterusanatomie das Spekulum vor der Fluoroskopie.
    e) Nehmen Sie mindestens sechs Röntgenbilder auf, um die Lage der Mikrospiralen und den Eileiterverschluss zu beurteilen.
        (1) Röntgenbild 1 – „Aufklärungsaufnahme“: Uterus und Mikrospiralen ohne Kontrastmittel.
        (2) Röntgenbild 2 – Minimale Füllung der Uterushöhle – Uterus und Mikrospiralen mit kleiner Kontrastmittelmenge.

(3) Röntgenbild 3 – Teilweise Füllung der Uterushöhle - Uterus und Mikrospiralen fast vollständig mit Kontrastmittel gefüllt.

(4) Röntgenbild 4 – Vollständige Füllung der Uterushöhle - Uterus und Mikrospiralen bei mit Kontrastmittel gedehnten Cornua.

(5) Röntgenbilder 5 und 6 – Vergrößerung der Cornua uteri – Mikrospirale innerhalb des Eileiters mit rechtem (5) und linkem (6) Cornu.

VORSICHT: Der intrauterine Druck ist auf das für Röntgenbild 4 erforderliche Maß zu beschränken, um unnötige Beschwerden für die Patientin und eine vasovagale Reaktion zu vermeiden.



3. Beurteilung der Lage der Mikrospiralen
   a) Achten Sie bei der Beurteilung auf die vier „Markierungen“ an beiden Enden der inneren und äußeren Windungen. Der Abstand zwischen den distalen Markierungen ist unveränderlich, aber die proximalen Markierungen können aufgrund der Flexibilität der äußeren Spirale beweglich sein oder gestreckt erscheinen. Die Lage der Mikrospirale ist optimal, wenn die innere Spirale den Eileiter-Übergang zur Uterus-Serosa überquert.
   b) Lage der Mikrospiralen beurteilen:
      (1) Expulsion oder proximale Lage: Mikrospirale ist nicht vorhanden oder ≥ 50 % der inneren Spirale reicht in die Uterushöhle hinein.
      (2) Zufriedenstellende Lage: Das distale Ende der inneren Spirale befindet sich innerhalb des Eileiters und < 50 % der inneren Spirale reicht in die Uterushöhle hinein, oder das proximale Ende der inneren Spirale reicht ≤ 30 mm in den Eileiter ab dem Kontrastmittel im Cornu.
      (3) Distale Platzierung oder Perforation: Die Mikrospirale befindet sich im Eileiter, aber das proximale Ende der inneren Spirale liegt > 30 mm distal zum Kontrastmittel im Cornu, oder die Mikrospirale ist vollständig oder teilweise perforiert.
4. Beurteilung des Eileiterverschlusses
   a) Stellen Sie fest, ob Kontrastmittel über die Mikrospirale hinaus zu sehen ist, und nehmen Sie zur Kenntnis, ob der Eileiter proximal zum Teil gefüllt ist, auch wenn der Eileiter verschlossen ist.
   b) Eileiterverschluss beurteilen:
      (1) Zufriedenstellender Verschluss: Der Eileiter ist am Cornu verschlossen.
      (2) Zufriedenstellender Verschluss: Kontrastmittel ist im Eileiter zu sehen, jedoch nicht über das distale Ende der äußeren Spirale hinaus.
      (3) Unzufriedenstellender Verschluss: Kontrastmittel ist über das distale Ende der Mikrospirale hinaus oder in der Bauchfellhöhle zu sehen.
5. Beurteilung der Zuverlässigkeit
   a) Wenn sowohl Lage als auch Eileiterverschluss als zufriedenstellend bewertet werden, braucht die Patientin keine alternativen Mittel zur Empfängnisverhütung mehr zu verwenden.
   b) Wenn die Lage nicht zufriedenstellend ist, weisen Sie die Patientin an, sich nicht auf die Mikrospiralen zur Empfängnisverhütung zu verlassen.
   c) Wenn die Lage zufriedenstellend, jedoch der Verschluss nicht zufriedenstellend ist, weisen Sie die Patientin an, weiterhin alternative Methoden zur Empfängnisverhütung zu verwenden. Wiederholen Sie die HSG nach drei Monaten. Wenn der Verschluss immer noch unbefriedigend ist, weisen Sie die Patientin an, sich nicht auf die Mikrospiralen zur Empfängnisverhütung zu verlassen.

X. Management von unbefriedigender Mikrospiralenlage

A. Unbefriedigende Mikrospiralenlage nach Diagnose durch Hysterosalpingogramm

1. Proximale Lage: Mehr als 50 % der inneren Windungen der Mikrospirale(n) reichen in den Uterus.
2. Distale Lage: Die Mikrospiralen befinden sich im Eileiter, aber das proximale Ende der inneren Windungen liegt mehr als 30 mm vom Kontrastmittel der Cornua uteri entfernt.
3. Vollständige Expulsion der Mikrospiralen; Mikrospiralen nicht mehr im Körper vorhanden.
4. Perforation: Die Mikrospiralen haben die Eileiter teilweise oder vollständig perforiert.
5. Lage der Mikrospiralen in der Bauchhöhle; Mikrospiralen offensichtlich außerhalb der Eileiter.

B. Management von Mikrospiralenexpulsion oder unbefriedigender Mikrospiralenlage

1. Bilaterale Mikrospiralenexpulsion mit bilateralem Verschluss: Die Patientin sollte angesichts einer möglichen falsch-positiven Diagnose eines Eileiterverschlusses durch den bestätigenden **Essure**-Test (HSG) auf die Option einer inzisionalen Sterilisation aufmerksam gemacht bzw. in Bezug auf die Möglichkeit der Empfängnisverhütung mit dem bilateralen Verschluss beraten werden.
2. Bilaterale Expulsion der Mikrospirale mit Verschluss in einem Eileiter und Durchgängigkeit im gegenüberliegenden Eileiter: Für die Patientin sollte ein erneuter Eingriff zum Einsetzen einer Mikrospirale in Betracht gezogen werden, um die Spirale in dem Eileiter zu ersetzen, der durchgängig ist, damit sie sich zur Empfängnisverhütung auf eine **Essure**-Mikrospirale und den gegenüberliegenden proximalen Eileiterverschluss verlassen kann. Die Patientin sollte angesichts dieser Option auf die Möglichkeit einer falsch-positiven Diagnose eines Eileiterverschlusses beim bestätigenden **Essure**-Test (HSG) hingewiesen werden. Die Patientin sollte auch darauf hingewiesen werden, dass die Möglichkeit einer inzisionalen Sterilisation besteht.
3. Einseitige Expulsion der Mikrospirale oder einseitige unbefriedigende Lage der Mikrospirale (im Myometrium oder in der Bauchhöhle) mit kontralateraler Mikrospirale in zufriedenstellender Position: Wenn der bestätigende **Essure**-Test (HSG) einen Eileiterverschluss in dem Eileiter nachweist, aus dem die Mikrospirale ausgestoßen wurde oder in den die Spirale platziert werden sollte, kann sich die Patientin auf die zufriedenstellend positionierte Mikrospirale und den gegenüberliegenden proximalen Eileiterverschluss verlassen, allerdings mit der Einschränkung einer möglichen falsch-positiven Diagnose eines Eileiterverschlusses durch den bestätigenden **Essure**-Test (HSG). Die Patientin sollte auch darauf hingewiesen werden, dass die Möglichkeit einer inzisionalen Sterilisation besteht.
4. Einseitige, unbefriedigende Lage der Mikrospirale (im Myometrium oder in der Bauchhöhle) mit kontralateraler Mikrospirale in zufriedenstellender Position: Wenn beim bestätigenden **Essure**-Test (HSG) Durchgängigkeit in dem Eileiter nachgewiesen wird, in den die Mikrospirale eingesetzt werden sollte, kann der Patientin ein erneuter Eingriffsversuch zum Einsetzen der Mikrospirale angeboten werden. Die Patientin sollte auch darauf hingewiesen werden, dass die Möglichkeit einer inzisionalen Sterilisation besteht.
5. Einseitige Expulsion der Mikrospirale; einseitige, unbefriedigende Lage der Mikrospirale (im Myometrium oder in der Bauchhöhle); einseitige, unbefriedigende Lage der Mikrospirale in „proximaler Position” (>50 % der inneren Spirale reichen in den Uterus) oder „distaler Position” (Mikrospirale im Eileiter, aber das proximale Ende der inneren Windungen befindet sich >30 mm von der Kontrastmittelfüllung der Cornua uteri entfernt) mit kontralateraler Mikrospirale in unbefriedigender Position: Die Patientin sollte darauf hingewiesen werden, dass die Möglichkeit einer inzisionalen Sterilisation besteht. Wenn eine Entfernung der Mikrospirale notwendig erscheint und eine hysteroskopische Entfernung nicht möglich ist, kann in solchen Fällen eine inzisionale Operation notwendig sein.
6. Wenn sich eine Patientin bei einem der oben genannten Szenarien zu einer inzisionalen Sterilisation entschließt, sollten unabhängig von einer sich möglicherweise in zufriedenstellender Position befindlichen Mikrospirale beide Eileiter verschlossen werden. Der Arzt sollte versuchen, die Mikrospirale zu entfernen, wenn er der Ansicht ist, dass ein solches Unterfangen ohne Sicherheitsrisiko für die Patientin durchgeführt werden kann; unter Umständen ist eine Entfernung jedoch nicht möglich. Zum Auffinden der Mikrospirale(n) wird vor und während des Eingriffs der Einsatz eines intraoperativen Fluoroskopiegeräts empfohlen. Ein Entfernungsversuch sollte nicht länger als 30 Minuten dauern.

XI. Management von Fällen, in denen die Essure-Mikrospirale nicht erfolgreich eingesetzt werden konnte

Konnte die Mikrospirale in einem oder beiden Eileitern nicht erfolgreich eingesetzt werden, ist die Patientin darauf hinzuweisen, dass der Eingriff zur dauerhaften Empfängnisverhütung nicht erfolgreich war. Wenn sich die Patientin für eine laparoskopische Sterilisation entscheidet (d.h. für die Anwendung eines Clips oder einer Elektrokauterisierung), sollten beide Eileiter abgeklemmt oder kauterisiert werden, selbst wenn in einem Eileiter eine **Essure**-Mikrospirale implantiert ist. Ein Abklemmen oder Kauterisieren der Eileiter sollte distal zur **Essure**-Mikrospirale erfolgen.

Entscheidet sich die Patientin nicht für eine laparoskopische Sterilisation, kann ihr eine erneute Kontrolle durch einen bestätigenden **Essure**-Test (HSG) nach den nächsten Mensen angeboten werden (vor der Ovulation: Tag 7-14, wobei Tag 1 der erste Tag der Blutung ist), um die Durchgängigkeit des Eileiters zu prüfen. Wird festgestellt, dass der Eileiter durchgängig ist, kann der Arzt der Patientin anbieten, erneut ein Einsetzen der Mikrospirale zu versuchen. Schlägt auch der zweite Versuch zum Einsetzen der Mikrospirale fehl, ist bei weiteren Versuchen kaum noch mit Erfolg zu rechnen. Wenn bei der Patientin nur eine Mikrospirale *in vivo* vorhanden ist, muss sie darauf hingewiesen werden, dass der Verschluss eines Eileiters als Mittel zur Empfängnisverhütung nicht ausreicht.

Wenn nur in einem Eileiter eine Mikrospirale eingesetzt werden konnte und beim bestätigenden **Essure**-Test (HSG) ein proximaler Eileiterverschluss des gegenüberliegenden Eileiters nachgewiesen werden kann, ist mit der Patientin zu klären, ob sie sich auf die Funktion der einen Mikrospirale verlassen will, da die Möglichkeit eines falsch-positiv diagnostizierten proximalen Eileiterverschlusses beim bestätigenden **Essure**-Test (HSG) nicht auszuschließen ist. Ein Eileiterverschluss wird als Versagen des Farbstoffs definiert, beim bestätigenden **Essure**-Test (HSG) von der Uterushöhle in die Bauchhöhle zu gelangen. Die Patientin sollte auch darauf hingewiesen werden, dass die Möglichkeit einer inzisionalen Sterilisation besteht. Es wird nicht empfohlen, eine einseitig eingesetzte Mikrospirale zu entfernen, es sei denn, die Patientin leidet unter unerwünschten Nebenwirkungen der Mikrospirale.

XII. Entfernung der Essure-Mikrospirale

ACHTUNG: NACH DEM EINSETZEN DER MIKROSPIRALE DARF SIE NICHT MITHILFE DES HYSTEROSKOPS ENTFERNT WERDEN, ES SEI DENN, 18 ODER MEHR WINDUNGEN DER MIKROSPIRALE REICHEN IN DIE UTERUSHÖHLE. Die Entfernung einer Mikrospirale sollte unmittelbar nach dem Einsetzen versucht werden. Ein Entfernen ist jedoch unter Umständen nicht möglich. Wenn die Entfernung versucht wird, sind folgende Schritte einzuhalten:

1. Durch den Arbeitskanal des Hysteroskops ein Greifinstrument einführen.
2. Die äußere Windungen der **Essure**-Mikrospirale (nach Möglichkeit die äußeren und inneren Windungen zusammen) fassen.
3. Greifinstrument und Hysteroskop gleichzeitig zurückziehen, sodass das gesamte System zusammen aus dem Uterus entfernt wird.
4. Die äußere Windung bzw. die innere Windung der **Essure**-Mikrospirale kann sich beim Versuch der Entfernung der Mikrospirale dehnen und in die Länge ziehen.
5. Gegebenenfalls Analgesie oder Anästhesie verabreichen, um Beschwerden der Patientin zu verringern oder zu verhindern.
6. Wenn die Mikrospirale komplett entfernt werden konnte, sollte erneut versucht werden, eine andere **Essure**-Mikrospirale einzusetzen.
7. Wenn der Arzt nicht vollständig überzeugt ist, dass die gesamte **Essure**-Mikrospirale aus dem Eileiter entfernt wurde, darf **KEINE** weitere Mikrospirale in denselben Eileiter eingesetzt werden, und es ist nach dem Eingriff am Röntgenbild zu kontrollieren, ob Teile der Mikrospirale *in vivo* verblieben sind.

Außer im oben beschriebenen Szenario darf eine Entfernung der Mikrospirale nur versucht werden, wenn die Patientin unter unerwünschten Nebenwirkungen der Mikrospirale leidet oder eine Entfernung der Spirale verlangt.

Sollte eine Entfernung der Mikrospirale für erforderlich gehalten werden, ist ein transabdominaler Zugang (d.h. eine Laparotomie oder Laparoskopie) erforderlich.

Eine Cornua-Resektion des proximalen Eileiters ist erforderlich, wenn sich die Mikrospirale im uterotubaren Übergang befindet.

Eine falsch eingesetzte **Essure**-Mikrospirale oder eine Mikrospirale, die aus dem uterotubaren Übergang migriert ist, sollte durch einen laparoskopischen oder laparatomischen Eingriff mit konventioneller linearer Salpingostomie oder Salpingektomie entfernt werden.

1. Für eine lineare Salpingostomie ist eine kleine Inzision (Länge ca. 2 cm) an der antimesenterischen Grenze des Eileiters direkt über der Mikrospirale erforderlich.
2. Eine vollständige oder teilweise Salpingektomie zur Entfernung der Mikrospirale kann gleichzeitig oder unabhängig von einer konventionellen Eileitersterilisation durchgeführt werden.

XIII. Patientinnenausweis

Jeder Patientin mit implantierter **Essure**-Mikrospirale ist ein laminierter, scheckkartengroßer Patientinnenausweis auszuhändigen, aus dem zu entnehmen ist, dass ihr **Essure**-Mikrospiralen implantiert wurden. **Der Ausweis befindet sich in der Verpackung.** Auf dem Ausweis wird auch auf mögliche Risiken hingewiesen, mit denen bei späteren intrauterinen Eingriffen oder Operationen an den Geschlechtsorganen gerechnet werden muss.

XIV. Symbollegende

STERILE EO	Mit Ethylenoxidgas sterilisiert
LOT	Chargennummer
	Nicht wieder verwenden
REF	Katalognummer
	Achtung, siehe Gebrauchsanweisung
	Verfallsdatum
	Von Hitze fernhalten
	Nicht verwenden, wenn die Verpackung bereits geöffnet oder beschädigt ist.
MR	Bedingt MR-sicher
EC REP	Zugelassener Vertreter für Europa
CE 0050	Das Gerät erfüllt die Voraussetzungen der europäischen Richtlinie 93/42/EWG.
	Trocken lagern
CONT	Inhalt

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Für Bestellungen oder zur Meldung unerwünschter Nebenwirkungen wenden Sie sich bitte an die zuständige Bayer HealthCare LLC-Vertretung.

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Dansk

essure®

Permanent prævention

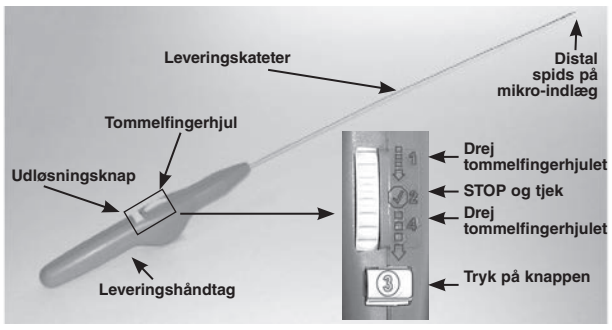
BAYER

BRUGSANVISNING

I. Beskrivelse af mikro-indlæg

Essure® permanent præventionssystem består af flere komponenter. **Essure** mikro-indlæg, som er et dynamisk ekspanderende mikro-indlæg, sidder på en leveringsledetråd og et udløsningskateter. Hele denne samling er indeholdt i et leveringskateter. Systemet (vist i figur 1) sidder på et håndtag, der letter levering og anlæggelse af mikro-indlægget. En ventilintroducer, **DryFlow**®, er også vedlagt **Essure** systemet. Den er beregnet på at hjælpe til med at beskytte **Essure** mikro-indlægget, mens dette føres gennem gummiporten på hysteroskopets arbejdskanal.

Figur 1
Essure leveringssystem
viser detalje af leveringsproceduresymboler
(IKKE I RETTE FORHOLD)



II. Handlingsmekanisme

Under hysteroskopisk fremstilling leverer **Essure** systemet et **Essure** mikro-indlæg til den proksimale del af tubalumen. Når **Essure** mikro-indlægget ekspanderer ved udløsning, forankrer det sig solidt i tuba uterina. Mikro-indlægget genererer dernæst en tilsigtet godartet vævsreaktion, hvilket resulterer i vævsindvækst i mikro-indlægget, der forankrer mikro-indlægget solidt i tuba uterina. Denne godartede vævsreaktion er lokal, fibrotisk og okklusiv.

Hvert **Essure** system er steriliseret med ethylenoxid og leveres sterilt kun til engangsbrug. Må ikke genbruges eller resteriliseres. Resterilisering kan påvirke ordentlig mekanisk funktion og kan resultere i skade på patienten.

III. Indikationer

Essure systemet er beregnet på anvendelse som et mikro-indlæg til okklusion af tubae med henblik på permanent prævention.

IV. Kontraindikationer

- Patienten er ikke sikker på, om hun ønsker at afslutte sin fertilitet.
- Graviditet eller mistanke om graviditet.
- Fødsel eller svangerskabsafbrydelse i andet trimester mindre end 6 uger før placering af et **Essure** mikro-indlæg.
- Aktiv eller nylig underlivsbetændelse.
- Ubehandlet akut cervicitis.
- Uforklarlig eller svær blødning fra vagina.
- Gynækologisk malignitet (mistænkt eller kendt).
- Kendt unormal uteruskavitet eller tubae, der gør fremstilling af tubaostierne og/eller kanylering af den proksimale del af tuba vanskelig eller umulig.
- Allergi over for kontraststoffer (et hysterosalpingogram kan være påkrævet tre måneder efter placering af mikro-indlægget).
- Patienter tager corticosteroider for øjeblikket.

V. Advarsler

- **Essure** proceduren bør kun udføres af erfarne hysteroskopister, der har gennemført Bayer HealthCare LLC uddannelsesprogrammet for denne procedure.
- Personer, som er allergiske over for nikkeltitan, kan have en allergisk reaktion over for mikro-indlægget.
- Anvend ikke **Essure** systemet, hvis pakningen er åben eller beskadiget. Anvend ikke systemet, hvis mikro-indlægget er beskadiget.
- Når **Essure** mikro-indlægget indføres i tuba, må mikro-indlægget (indlæggene) aldrig føres frem, hvis der mærkes stor modstand.
- Fortsæt ikke med at fremføre **Essure** systemet, når først placeringsmarkøren på katetret har nået tubaostiet. Fremføring forbi dette punkt kan resultere i utilfredsstillende placering af mikro-indlægget eller perforering af tuba/uterus.
- Hvis der sker perforering af tuba eller der er mistanke derom, skal forsøg på placering af **Essure** mikro-indlægget straks indstilles. En meget lille procentdel af kvinder i **Essure** kliniske undersøgelser (1,8 % eller 12/682 patienter) blev identificeret som havende anordningsrelaterede perforeringer af tuba. Fjernelse af det perforerende mikro-indlæg, hvis det er nødvendigt, vil kræve laparoskopi eller andre kirurgiske metoder.
- Hvis placeringsforsøgene for **Essure** mikro-indlægget ikke er lykkedes efter 10 minutter med forsøgt kanylering per tuba, bør tilfældet afsluttes og eventuelt planlægges til et senere tidspunkt.
- Når mikro-indlægget er placeret (dvs. adskilt fra leveringsledetråden), bør der ikke gøres forsøg på at fjerne mikro-indlægget hysteroskopisk, medmindre 18 eller flere spiraler på **Essure** mikro-indlægget når ind i uteruskaviteten. Fjernelse af et sådant mikro-indlæg bør forsøges umiddelbart efter placeringen. Fjernelse kan imidlertid være umulig.
- Patienten skal anvende alternativ prævention, indtil et røntgenbillede taget tre måneder efter placering af mikro-indlægget påviser, at mikro-indlægget sidder tilfredsstillende.
- Patienter, som får indlagt et **Essure** mikro-indlæg, kan efter nogle år blive tilbudt intrauterinzte behandlinger, der bruger elektrisk energi. Det anbefales, at elektrokaustik undgås i kirurgiske procedurer i cornua uteri og tubae. Alle andre procedurer i bækkenet bør undgå anvendelse af elektrokaustik inden for 4 cm fra mikro-indlægget. På grund af tilstedeværelsen af **Essure** mikro-indlæg kan der være risici forbundet med sådanne procedurer, der på nuværende tidspunkt ikke er klarlagt.
- Enhver intrauterin procedure som f.eks. endometrisk biopsi, D&C, hysteroskopi (diagnostisk eller operativ) herunder endometrisk ablation kan afbryde mikro-indlæggets evne til forebygge graviditet. Derudover kan tilstedeværelsen af **Essure** mikro-indlæg medføre risici forbundet med sådanne procedurer som på nuværende tidspunkt ikke er klarlagt.
- Laboratorie- og kliniske undersøgelser demonstrerede, at termisk endometrisk ablation af uterus kan foretages sikkert og effektivt med GYNECARE THERMACHOICE* uterinballonsystem, Hologic NovaSure ** endometrisk ablationssystem, og Boston Scientific Hydro ThermAblator ***umiddelbart efter **Essure** mikroindlæg placering. Ingen andre specifikke undersøgelser er blevet foretaget for at evaluere afstødnings- eller præventionsfrekvenser for **Essure** mikro-indlæg efter kombinerede samtidige **Essure** og endometriske ablationsprocedurer.
- Patienter kan muligvis bestemme sig til senere hen at gennemgå reagensglasbefrugtning (IVF) med det formål at blive gravid. **Essure** mikro-indlæggenes indvirkning på succes med IVF er ukendt. Hvis graviditet opnås, er risiciene ved mikro-indlægget for patienten, fosteret og graviditetens forløb ukendt.

* Varemærke tilhørende ETHICON, INC.
** Varemærke tilhørende Hologic, Inc.
*** Varemærke tilhørende Boston Scientific Corporation

VI. Forholdsregler

- Når det er muligt, bør placering af mikro-indlægget foretages i løbet af dagene 7-14 i menstruationscyklusen (hvor dag 1 repræsenterer den første blødningsdag) for at forstærke visualiseringen af tubaostierne og nedsætte muligheden for placering af et mikro-indlæg i en patient med udiagnosticeret graviditet.
- Uterus med usædvanlig anatomi kan gøre det vanskeligt at placere **Essure** mikro-indlæg.
- Med henblik på at nedsætte risikoen for perforering af uterus, bør proceduren afsluttes, hvis det er nødvendigt at anvende stor styrke for at opnå cervikal dilatation.
- Begge tubaostier bør identificeres og opnås adgang til gennem hysteroskopi inden placering af **Essure** mikro-indlægget. Der bør ikke gøres forsøg på at placere et mikro-indlæg i det ene tubaostium, medmindre der er rimelig forventning til, at den anden tuba er tilgængelig og åben.
- Foretagelse af endometrisk ablation umiddelbart efter placering af **Essure** mikro-indlæg kan øge risikoen for tubalt steriliseringssyndrom efter ablation, hvilket er en sjælden tilstand, som er blevet rapporteret hos kvinder med tubal sterilisering i anamnesen, som gennemgår endometrisk ablation.
- Fremfør ikke **Essure** systemet, hvis patienten føler usædvanlig smerte eller ubehag.
- Opbevar **Essure** systemet køligt og tørt.

VII. Mulige bivirkninger

A. Graviditet

Der er risiko for graviditet og ektopisk graviditet og risici forbundet med behandling af begge. Hvis patienten undfanger og vælger at fortsætte en intrauterin graviditet, bør hun informeres om, at risiciene ved mikro-indlægget for patienten, fosteret og graviditetens fortsatte forløb ikke kendes.

B. Risici forbundet med placeringsproceduren for mikro-indlæg

- Lokal anæstesi, oral analgesi/sedering, regional anæstesi (f.eks. spinal, epidural), oral eller bevidst (intravenøs) sedering eller generel anæstesi kan administreres til patienten for at forebygge eller nedsætte ubehag. Uanset typen af anæstesi vil patienter muligvis ikke være i stand til at genoptage normale aktiviteter i 12 til 24 timer efter proceduren.
- Smerte, kramper og vaginal blødning kan forekomme under og efter placeringen af mikro-indlægget. Disse hændelser er sædvanligvis tolerable, forbigående og kan behandles med succes med medicin.
- Under og/eller direkte efter placeringen af mikro-indlægget, er der risiko for at patienten kan få kvalme eller kaste op. Dette forventes at være forbigående og kan behandles med medicin efter behov.
- Patienter kan besvime eller få en vasovagal reaktion på proceduredagen.
- Der er risiko for perforering eller dissektion af tuba eller cornua uteri. Blødning og ardannelse kan resultere fra en sådan perforering eller dissektion; behandling er dog sædvanligvis ikke påkrævet.
- Der er risiko for perforering af uterus med hysteroskopet, **Essure** systemet eller andre instrumenter, der anvendes under proceduren med mulig beskadigelse af tarm, blære og større blodkar. Kirurgisk indgriben kan være påkrævet, men er usandsynlig, hvis en sådan skade skulle opstå. Med henblik på at reducere risikoen for perforering af uterus, bør proceduren afsluttes, hvis stor styrke er nødvendig for at opnå cervikal dilatation.
- Der er risiko for, at **Essure** mikro-indlægget utilsigtet placeres i myometrium af uterus og ikke i tubalumen. Hvis et mikro-indlæg allerede er korrekt placeret i en tuba, ud over utilsigtet placering i myometrium, kan lægen forsøge at placere et tredje mikro-indlæg for at afslutte proceduren. Hvis bilateral placering i tubae ikke opnås, kan det resultere i, at patienten har ét mikro-indlæg i tuba og/eller ét mikro-indlæg i myometrium, der ikke kan medregnes som prævention. Placering af mikro-indlægget i myometrium kan resultere i postoperativ smerte eller anden bivirkning. Hvis kirurgisk fjernelse af mikro-indlæg er påkrævet, kan det være nødvendigt at foretage salpingektomi eller hysterektomi.
- Der er risiko for, at **Essure** mikro-indlægget kan blive placeret for distalt i tuba. Hvis fjernelse af mikro-indlægget er nødvendig, vil kirurgi (laparoskopi eller laparotomi) være påkrævet.
- Der er risiko for, at **Essure** mikro-indlægget kan blive placeret for proksimalt i tuba. Hvis 18 eller flere spiraler på **Essure** mikro-indlægget er synlige på placeringstidspunktet, bør det øjeblikkeligt forsøges at fjerne mikro-indlægget (se afsnit XIII, Fjernelse af **Essure** mikro-indlæg). Hvis fjernelse af mikro-indlægget forsøges, er der mulighed for, at fjernelsen ikke vil være vellykket, eller at **Essure** mikro-indlægget går i stykker og efterlader en del af mikro-indlægget *in vivo*. Hvis fjernelse af mikro-indlægget forsøges og/eller opnås, er der ligeledes mulighed for, at patienten kan få øget smerte, kramper og blødning under og efter placeringsproceduren af **Essure** mikro-indlægget.
- Der er risiko for, at **Essure** mikro-indlægget kan perforere gennem tubavæggen eller cornua uteri, hvilket kan resultere i, at mikro-indlægget frigives ind i peritoneum. Postoperativ smerte og/eller menstruationsforstyrrelse eller anden bivirkning kan forekomme som et resultat. Hvis patienten vælger at få foretaget incisional sterilisation eller andet kirurgisk indgreb, kan det forsøges at genindfange mikro-indlægget fra peritoneum, hvis lægen vurderer, at dette kan gøres uden risiko. Genindfangning af mikro-indlægget er muligvis ikke muligt, hvis mikro-indlægget ikke kan fremstilles, eller lægen ikke kan opnå adgang dertil.
- Der er risiko for, at placering af **Essure** mikro-indlægget kun lykkes i den ene tuba. Hvis dette sker kan patienten ende med at have ét mikro-indlæg *in vivo*, der ikke kan regnes med som permanent prævention.
- Der er risiko for, at placering af **Essure** mikro-indlæg ikke vil være mulig i nogen af tubae.
- Der er minimal risiko for en for stor væskeabsorption af det fysiologiske saltvand, der bruges til distension af uterus med henblik på udførelse af hysteroskopien.
- Som det er tilfældet ved alle invasive procedurer, kan placeringen af mikro-indlægget forårsage en infektion. En infektion kan forårsage skade på uterus, tubae eller bækken. Dette kan kræve behandling med antibiotika eller sjældent, hospitalisering eller operation, herunder hysterektomi.

C. Risici forbundet med et implanteret Essure mikro-indlæg

- Der er risiko for, at **Essure** mikro-indlægget kan bevæge sig ud af tubae. Denne bevægelse kan være afstødning (bevægelse ud af tuba og ind i uterus/cervix/vagina eller ud af kroppen) eller vandring (bevægelse til den distale tuba eller ud af tuba og ind i peritoneum). Yderligere røntgenbilleder kan være påkrævet for at identificere mikro-indlæggenes position, og kirurgi kan være nødvendig for at fjerne mikro-indlægget (indlæggene). Hvis mikro-indlægget flytter sig kan det resultere i graviditet, ektopisk graviditet og/eller smerte/menstruationsforstyrrelser eller andre bivirkninger.
- Som det er tilfældet med aktuelt tilgængelige metoder for mekanisk, permanent prævention (f.eks. clips, ringe), vil det være nødvendigt at operere, hvis **Essure** mikro-indlægget skal fjernes. Desuden er det muligt, at kirurgisk fjernelse af tubae (salpingektomi) og uterus (hysterektomi) kan være nødvendig.
- Smerte og kramper i abdomen og pelvis kan forekomme. Smerte og kramper kan være mere sandsynlig under menstruation, under og efter samleje eller ved anden fysisk aktivitet.
- Blødning mellem menstruationer eller kraftigere end normal menstruationsblødning kan forekomme.
- Det kan ske, at en kvinde fortryder sin beslutning om at få foretaget permanent prævention og at hun oplever mild depression eller andre følelsesmæssige forstyrrelser som et resultat deraf.

D. Risici forbundet med efterundersøgelsesprocedurer

- Der er risiko for udsættelse for stråling forbundet med røntgen af bækkenet, som er påkrævet tre måneder efter placering af mikro-indlægget med henblik på at evaluere mikro-indlæggets position. Der kan også være et behov for en **Essure** bekræftelsestest (HSG). Der er ca. 0,033 rad i den fluoroskopiske del (<30 sekunder) af et hysterosalpingogram. Som et sammenligningsgrundlag er strålingseksponering fra et røntgen af colon 0,85 rad, der er højere end den påkrævede **Essure** bekræftelsestest (HSG). Mængden af strålingseksponering fra et røntgen af bækkenet er omtrent det samme som den mængde, en person ville modtage fra et år med naturlig baggrundsstråling.
- Følgende yderligere risici er forbundet med **Essure** bekræftelsestesten (HSG), hvis en sådan er nødvendig: vasovagal reaktion, infektion, der kan kræve behandling med antibiotika og i sjældne tilfælde hospitalisering, intravasation, perforering af uterus, krampe og/eller blødning i uterus, smerte og ubehag, og allergisk reaktion over for latex. Det er rapporteret, at eksponering for latex kan være forbundet med anafylaktiske reaktioner i sjældne tilfælde, der kan medføre døden.
- Brug af kontraststoffer til udførelse af **Essure** bekræftelsestest (HSG) er forbundet med allergisk reaktion hos nogle patienter. Allergisk reaktion kan resultere i nældefeber eller åndedrætsbesvær. Hos nogle personer kan en anafylaktisk reaktion forekomme, der kan medføre døden.

E. Risici forbundet med potentielle fremtidige procedurer

- Patienter, som får indlagt et **Essure** mikro-indlæg, kan efter nogle år blive tilbudt intrauterine behandlinger, der bruger elektrisk energi. Det anbefales, at elektrokaustik undgås i kirurgiske procedurer i cornua uteri og tubae uterinae. Alle andre procedurer i bækkenet bør undgå anvendelse af elektrokaustik inden for 4 cm fra mikro-indlægget. På grund af tilstedeværelsen af **Essure** mikro-indlæg kan der være risici forbundet med sådanne procedurer, der på nuværende tidspunkt ikke er klarlagt.
- Enhver intrauterin procedure som f.eks. endometrisk biopsi, D&C, hysteroskopi (diagnostisk eller operativ) herunder endometrisk ablation kan afbryde mikro-indlæggets evne til forebygge graviditet. Derudover kan tilstedeværelsen af **Essure** mikro-indlæg medføre risici forbundet med sådanne procedurer som på nuværende tidspunkt ikke er klarlagt.
- Patienter kan muligvis bestemme sig til senere hen at gennemgå reagensglasbefrugtning (IVF) med det formål at blive gravid. **Essure** mikro-indlæggenes indvirkning på succes med IVF er ukendt. Hvis graviditet opnås, er risiciene ved mikro-indlægget for patienten, fosteret og graviditetens forløb ukendt.
- **Essure** mikro-indlæg er MR-sikre og røntgenfaste. **Essure** mikro-indlæg er også MR-kompatible bortset fra imagografi af pelvis, hvor de kan forårsage visse artefakter.
- **Det er muligt, at ukendte risici eksisterer.**

VIII. Brugsanvisning

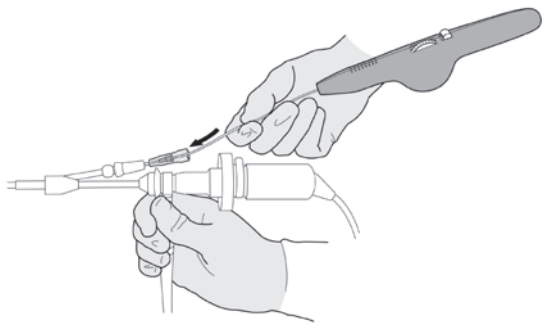
A. Før placeringsproceduren for mikro-indlægget

1. Placering af mikro-indlæg bør foretages i løbet af dagene 14-1 i menstruationscyklus (hvor dag 1 repræsenterer den første blødningsdag) for at forstærke visualiseringen af tubaostierne og nedsætte muligheden for placering af et mikro-indlæg i en patient med udiagnosticeret graviditet.
2. En graviditetstest foretaget af lægen eller en person udpeget af denne bør foretages inden for 24 timer før eller umiddelbart før placeringsproceduren for mikro-indlægget.
3. Administrering af et non-steroid anti-inflammatorisk lægemiddel (NSAID) som f.eks. Indocid (peroralt eller gennem suppositorium) anbefales stærkt en til to timer før placeringsproceduren af mikro-indlægget, da data fra kliniske forsøg viser, at brugen af NSAID'er signifikant øger sandsynligheden for en vellykket placering. Hvis der kun bruges en paracervikal blokade, kan Diazepam (PO) eller et lignende middel tilbydes 30 minutter før proceduren med henblik på at mindske angst.

B. Placeringsprocedure for Essure mikro-indlæg

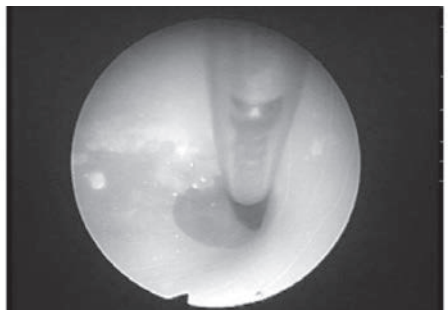
Placeringsproceduren for **Essure** mikro-indlæg kan udføres ambulant eller i en dagklinik. Steril teknik skal anvendes under placeringsproceduren for mikro-indlæg. Det tidsrum, der er nødvendigt for at fuldføre placeringsproceduren for mikro-indlæg, bør ikke overstige 30 minutter.

1. Lejr patienten i litotomi-stilling.
2. Indfør et spekulum i vagina for at opnå adgang til cervix. Afvask cervix med betadin eller en anden egnet antibakteriel opløsning i overensstemmelse med sædvanlig praksis.
3. Lokalanæstesi er den foretrukne metode ved implantation af mikro-indlæg. Der kan administreres en paracervikal blokade. Midazolam (IV), eller et lignende middel, kan også administreres for at forebygge eller mindske ubehag, efter behov.
4. Før et sterilt hysteroskop med påsat kamera og operationskanal (≥5 French) gennem cervix og ind i uteruskaviteten. Hvis det er nødvendigt, kan cervikal dilatation foretages for at tillade indføring. Med henblik på at forhindre perforering af uterus, bør proceduren afsluttes, hvis det er nødvendigt at anvende stor styrke for at opnå cervikal dilatation.
5. Distension af uteruskaviteten bør opnås med infusion af fysiologisk saltvand gennem hysteroskopets arbejdskanal. Det anbefales stærkt, at saltvandsopløsningen forvarmes til legemstemperatur og indføres under faldtilførsel for at minimere spasme i tubae. Der skal opnås og opretholdes meget god distension af uterus under hele procedurens varighed. Standard væskemonitoreringsprocedurer bør følges under hele proceduren. Tubaostierne bør identificeres ved hysteroskopisk fremstilling.
6. Begge tubaostier bør identificeres og opnås adgang til gennem hysteroskopi inden placering af **Essure** mikro-indlægget. Der bør ikke gøres forsøg på at placere et mikro-indlæg i det ene tubaostium, medmindre der er rimelig forventning om, at den anden tuba er åben.
7. Når tubaostium er identificeret, indføres introduceren gennem forseglingshætten på hysteroskopets arbejdskanal. Operationskanalens stophane skal blive stående i åben position (instrumentet og/ eller introduceren kan blive beskadiget, hvis stophanen lukkes på én af dem). Placér **Essure** leveringssystemet gennem introduceren og før det frem gennem hysteroskopets operationskanal. Hvis den ikke blev beskadiget under placeringen af det første mikro-indlæg, kan ventilintroduceren forblive i operationskanalen under **Essure** indgrebet.



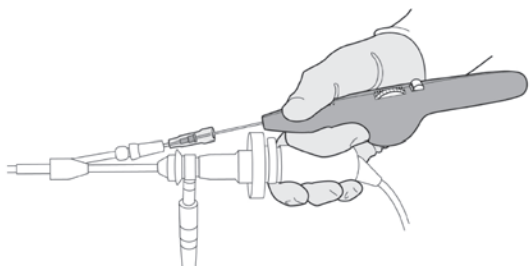
Indfør introduceren gennem forseglingshætten på hysteroskopets arbejdskanal, og placér derefter **Essure** *leveringssystemet gennem introduceren.*

8. Før **Essure** leveringssystemet ind i den proksimale del af tuba med en langsom, rolig bevægelse for at forhindre spasme i tuba. Før leveringssystemet frem, indtil placeringsmarkøren på leveringskatetret når tubaostiet. Denne visuelle markør angiver, at **Essure** mikro-indlægget spænder over det distale intramurale segment og det proksimale isthmussegment i tuba, og at den udvendige spiral spænder over overgangen mellem uterus og tuba (UTJ). Dette er den ideelle placering af **Essure** mikro-indlægget.



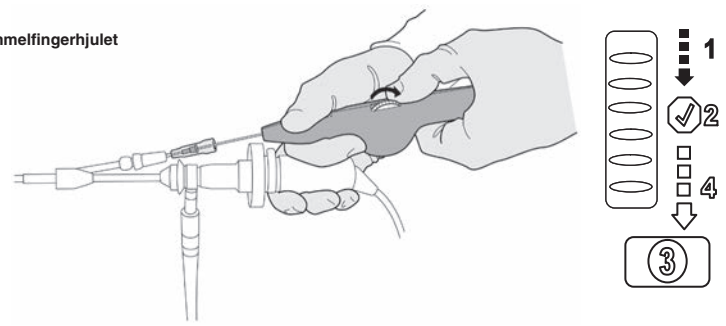
Fremfør, indtil den sorte placeringsmarkør er ved tubaostium. Dette er en visuel indikator for korrekt position til anlæggelse.

9. Korrekt koncentrisk tilpasning af leveringskatetret med tubalumen antydes af evnen til at kunne fremføre katetret under direkte visualisering uden usædvanlig modstand. Modstand ved fremføring er sædvanligvis tydelig på to måder: 1) den sorte markør på katetrets udvendige overflade observeres ikke at gå frem mod tubaostiet, og/eller 2) leveringskatetret bøjer eller bukker for meget, og forhindrer lægen i at føre katetersamlingen fremad. Når en sådan modstand observeres ved forsøg på at bevæge katetret fremad, bør der ikke gøres yderligere forsøg på at placere mikro-indlægget for at undgå muligheden for perforering af uterus eller utilsigtet placering af mikro-indlægget i uterusmuskulaturen, snarere end inden for tubalumen. Der bør foretages en **Essure** bekræftelsestest (HSG) for at afgøre, om tubae er åbne.
10. Hvis det ikke er muligt at fremføre katetret til placeringsmarkøren efter nogle minutter, kan man bruge en perfusionstest med et passagekateter, hvis et sådant ikke allerede er blevet anvendt, med henblik på at afgøre, om tuba er åben. Hvis tuba er blokeret eller katetret ikke kan føres frem til placeringsmarkøren, bør tilfældet afsluttes. Hvis placering af mikro-indlægget ikke er vellykket efter 10 minutter med forsøg på kanylering per tuba, bør tilfældet afsluttes.
11. Når leveringskatetret er blevet ført frem til placeringsmarkøren, anlægges mikro-indlægget. Dette gøres ved først at stabilisere håndtaget på **Essure** mikro-indlægget mod hysteroskopkameraet eller en anden fikseret genstand for at forebygge, at **Essure** systemet utilsigtet bevæger sig fremad under tilbagetrækning af leveringskatetret.



Stabilisér håndtaget mod kamerahovedet eller en anden fikseret genstand for at forebygge, at **Essure** *systemet utilsigtet bevæger sig fremad*

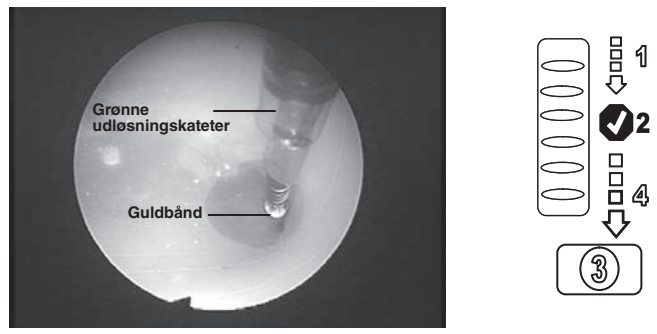
12. Når der er sikkerhed for, at den sorte placeringsmarkør er ved tubaostiet, drejes tommelfingerhjulet på håndtaget mod operatøren, indtil hjulet ikke længere drejer. Dette svarer til symbolet 1 på leveringssystemets håndtag. Dette letter tilbagetrækning af leveringskatetret. Man kan se den sorte positionsmarkør flytte sig væk fra tubaostiet (mod hysteroskopet) og forsvinde ind i operationskanalen. Tilbagetrækning af leveringskatetret eksponerer det nedvundne **Essure** mikro-indlæg. Ca. 1 cm af mikro-indlægget (nedvundne spiraler) skal kunne ses nå ind i uterus, når leveringskatetret er trukket tilbage.



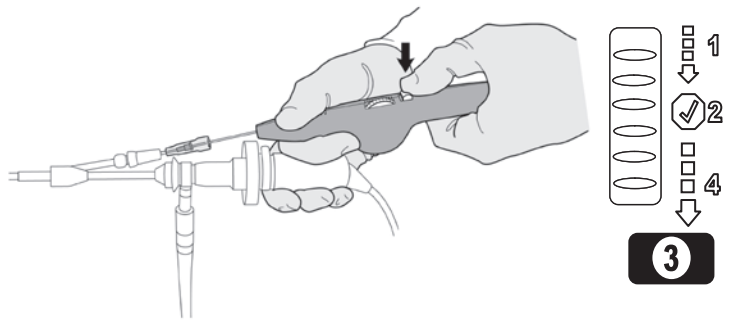
Drej tommelfingerhjulet for at trække katetret tilbage

13. For at sikre korrekt placering anbringes guldmarkørbåndet lige udenfor ostium, hvilket svarer til symbolet 2 på leveringssystememts håndtag. Visualisering af guldbåndet lige udenfor ostium, så vel som visualisering af den distale spids på det grønne udløsningskateter vil bekræfte korrekt placering. Hvis der kan ses mere end 1 cm af mikro-indlægget i uterus, skal mikro-indlægget omplaceres ved om muligt at flytte hele systemet længere ind i tuba, inden der fortsættes med næste trin.

Visualisér guldbånd ved ostium

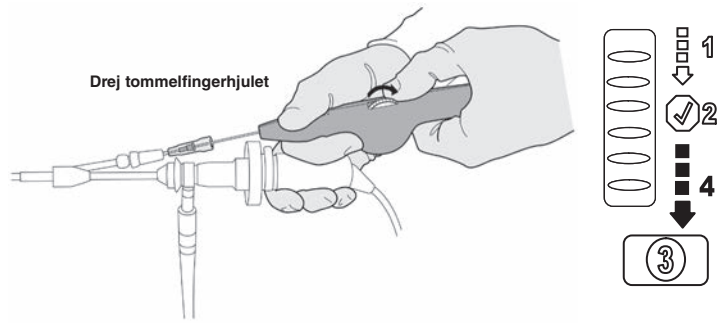


14. Tryk ned på knappen på leveringshåndtaget for at aktivere tommelfingerhjulet, så det kan roteres yderligere, hvilket svarer til symbolet 3 på håndtagets knap.



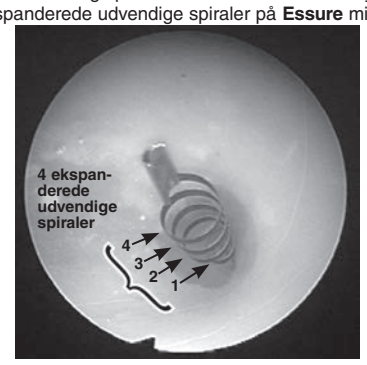
Tryk på knappen for at aktivere tommelfingerhjulet til at rotere igen.

15. Drej tommelfingerhjulet mod operatøren for at anlægge den udvendige spiral på mikro-indlægget, hvilket korresponderer til symbolet 4 på leveringssystemets håndtag. Fortsæt med at dreje tommelfingerhjulet indtil det holder op med at dreje. Når det ikke kan drejes mere,og de ekspanderede udvendige spiraler kan ses, trækkes systemet tilbage.



Drej tommelfingerhjulet for at aktivere mikro-indlæggets udvendige spiral

16. Det anlagte **Essure** mikro-indlægs position skal vurderes under hysteroskopisk fremstilling. Der bør ideelt være 3 til 8 ekspanderede udvendige spiraler på **Essure** mikro-indlægget, der når ind i uterus.



Ekspanderede udvendige spiraler på **Essure** *mikro-indlæg, der når ind i uterus, angiver ideel placering.*

17 Hvis lægen er utilfreds med mikro-indlæggets placering baseret på hysteroskopisk fremstilling, eller har mistanke om perforering af tuba eller uterus, bør mikro-indlægget (indlæggene) blive siddende og evalueres ved hjælp af røntgen af bækkenet eller HSG tre måneder efter placering af anordningen.

ADVARSEL: EFTER AT MIKRO-INDLÆGGET ER PLACERET OG FRIGIVET I TUBA, MÅ DER IKKE GØRES FORSØG PÅ AT FJERNE MIKRO-INDLÆGGET MED HYSTEROSKOPI, MEDMINDRE 18 ELLER FLERE SPIRALER AF Essure MIKRO-INDLÆGGET KAN SES NÅ IND I UTERUSKAVITETEN. Fjernelse af et sådant mikro-indlæg bør forsøges straks under placeringsforsøget. Fjernelse kan imidlertid være umulig (se afsnit XIII, Fjernelse af **Essure** mikro-indlæg). Hvis mikro-indlægget blev anlagt utilsigtet i uteruskaviteten og ikke i tuba, bør mikro-indlægget fjernes fra uterus og et nyt forsøg på at placere mikro-indlægget i tuba bør udføres.

18 Gentag placeringsproceduren for **Essure** mikro-indlægget i den kontralaterale tuba.

19. Notér længden på den del af mikro-indlægget, der når ind i uteruskaviteten, idet eventuelle observationer noteres vedrørende identifikation eller bekræftelse af enten tubaostium eller problemer vedrørende potentiel perforering. Disse bør noteres i patientjournalen til senere reference ved gennemgang af **Essure** bekræftelsestesten *(Se afsnit IX -* **Essure** *bekræftelsestest herunder)*.
20. **Mind patienten om, at denne skal bruge en alternativ form for prævention (bortset fra en spiral) i de første 3 måneder efter placeringsproceduren for mikro-indlægget.**
21. Aftal tid med patienten til en **Essure** bekræftelsestest tre måneder efter placeringsproceduren for **Essure** mikro-indlægget med henblik på at evaluere mikro-indlæggets retention og position.

IX. Essure bekræftelsestest

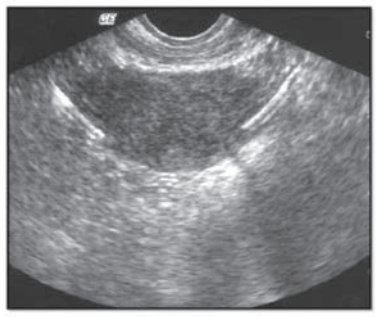
A. Der bør foretages en **Essure** bekræftelsestest tre måneder efter placering af mikro-indlægget med henblik på at evaluere mikro-indlæggets retention og position. **Essure** bekræftelsestests (transvaginal ultralyd (TVU), røntgen af bækkenet eller hysterosalpingogram (HSG)) bør kun udføres af en erfaren gynækolog, ultrasonograf og/eller en radiolog, der er undervist i den respektive protokol for **Essure** bekræftelsestest. I forbindelse med undervisningen leveres der en detaljeret protokol med billeder og tips til udførelse af testen. Ekstra kopier fås ved at downloade en kopi fra essure.com.

B. Ved den første bekræftelsestest kan der udføres enten et røntgen af bækkenet eller en TVU tre måneder efter et ukompliceret bilateral indgreb til placering af mikro-indlægget.

1. Røntgen og TVU bør ikke bruges som **Essure** bekræftelsestest under følgende omstændigheder:
   a) Vanskelig placeringsprocedure inklusive ét eller flere af følgende punkter:
      (1) Betænkelighed på placeringstidspunktet vedrørende mulig perforering på grund af for stor styrke under placering af mikro-indlægget og /eller et pludseligt tab af modstand.
      (2) Besvær med at identificere tubaostierne under placeringen på grund af anatomisk variation eller tekniske faktorer som f.eks. ringe distension, dårlige lysforhold eller endometrisk debris.
      (3) Kirurgen er usikker på placeringen.
   b) Indgrebstid > 15 minutter (skop ind-skop ud).
   c) Placering med nul eller > 8 spiraler, der når ind i uteruskaviteten.
   d) Unormale, postoperative, forbigående eller vedvarende smerter eller begyndende smerter efter indgrebet uden nogen identificerbar årsag
2. Hvis røntgen eller ultralyd ikke er indikeret skal patienten have foretaget en HSG for at evaluere mikro-indlæggets position og okklusionen af tuba. Trans-abdominal ultralyd kan ikke erstatte TVU. Hvis røntgen eller ultralydvurderingen er tvivlsom eller utilfredsstillende skal patienten have foretaget en HSG for at evaluere mikro-indlæggets position og okklusionen af tuba.

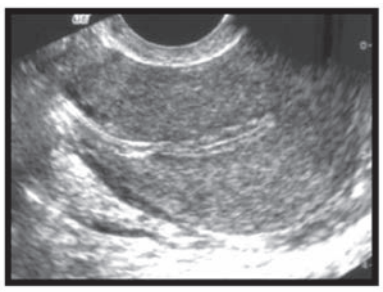
C. Transvaginal ultralyd

1. Der skal optages mindst tre billeder, der skal opbevares som dokumentation:
   a) Et koronalsnit eller skråt koronalsnit, der viser en del af hvert mikro-indlæg i cornua og markeret "Rekognosceringsbillede".



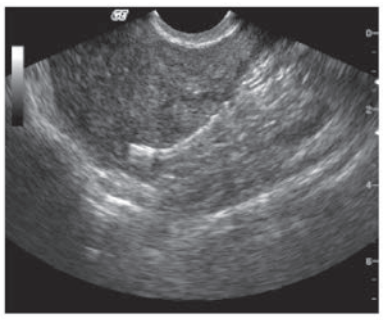
Bilaterale mikro-indlæg kan ses i dette tværgående (koronal/skråt koronalt) snit.

   b) Et koronal- eller skråt koronalsnit af den lineære akse af venstre mikro-indlæg inklusive den proksimale ende, der krydser myometrium i cornua (interstitiel del af æggelederen) eller i kontakt med overgangen mellem utero-serosa og tuba og markeret "venstre".
   c) Et koronal- eller skråt koronalsnit af den lineære akse af det højre mikro-indlæg, der krydser myometrium i cornua (interstitiel del af æggelederen) eller i kontakt med overgangen mellem utero-serosa og tuba og markeret "højre".
   d) Alle tre billeder bør tages på film og placeres i patientens lægejournal for at dokumentere tilfredsstillende retention og position af mikro-indlægget.
2. Klassifikation af mikro-indlæggets position
   a) Identifikation af mikro-indlæg: På et enkelt rekognosceringsbillede skal en del af hvert mikro-indlæg visualiseres i cornua i koronal- eller skrå koronalsnittet for at sikre bilateral placering og reducere risikoen for dobbelt billeddannelse af det samme mikro-indlæg. Mikro-indlæggenes lineære akse bør forekomme relativt symmetrisk.
   b) Optimal position
   Mikro-indlæggets position er optimal, hvis mikro-indlæggets proksimale ende er i kontakt med uteruskaviteten eller endometrium, og den lineære akse er inden i myometrium i cornua (interstitiel del af æggelederen) og kan visualiseres ved eller krydsende overgangen mellem utero-serosa og tuba (USTJ). Den del af mikro-indlægget, der er placeret i æggelederen, kan eller kan ikke visualiseres. Mikro-indlæggets lineære akse skal visualiseres for at bekræfte, at det ikke er snoet eller elongeret.



Optimal position

   c) Tilfredsstillende position
   Mikro-indlæggets position er tilfredsstillende, hvis mikro-indlæggets proksimale ende er distal for endometrium, dog er den lineære akse inden i myometrium i cornua (interstitiel del af æggelederen) og kan visualiseres ved eller krydsende overgangen mellem utero-serosa og tuba (USTJ). Den del af mikro-indlægget, der er placeret i æggelederen, kan eller kan ikke visualiseres. Mikro-indlæggets lineære akse skal visualiseres for at bekræfte, at det ikke er snoet eller elongeret.



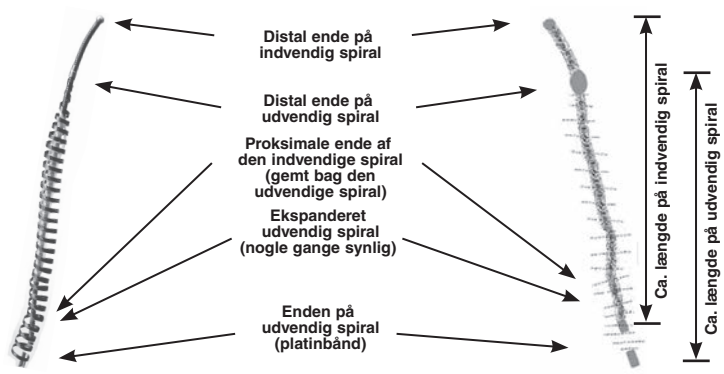
Tilfredsstillende position

   d) Utilfredsstillende position
      (1) Mikro-indlæggets position er utilfredsstillende, hvis en del af hvert mikro-indlæg ikke kan visualiseres i cornua i koronal- eller skrå koronalsnittet på ét rekognosceringsbillede.
      (2) Der er mistanke om afstødning, hvis det ene eller begge mikro-indlæg ikke identificeres i cornua i et koronalsnit på et enkelt rekognosceringsbillede.
      (3) Der er mistanke om distal placering, hvis den proksimale ende af mikro-indlægget ikke er placeret i myometrium i cornua (interstitiel del af æggelederen) og ikke krydser eller er i kontakt med overgangen mellem utero-serosa og tuba.
      (4) Der er mistanke om proksimal placering, hvis mere end 50 % eller størstedelen af mikroindlægget visualiseres i uteruskaviteten, eller hvis mikro-indlæggets/-indlæggenes lineære akse visualiseres i midtlinjens saggitalsnit.
      (5) Der er mistanke om perforering, hvis den lineære akse af det ene eller begge mikro-indlæg er parallelt/parallelle med livmoderslimhinden i saggitalsnittet, eller hvis den lineære akse af et mikro-indlæg visualiseres krydsende myometrium i midtlinjens saggitalsnit.
      (6) Ikke-klassificeret position: Hvis et mikro-indlægs lineære akse ikke kan identificeres, hvilket indikerer, at det er snoet, bøjet eller elongeret, betragtes mikro-indlægget position som utilfredsstillende. Hvis de omgivende bløddele ikke kan defineres tydeligt, betragtes positionen som utilfredsstillende.
3. Hvis røntgen eller ultralydvurderingen er tvivlsom eller utilfredsstillende skal patienten have foretaget en HSG for at evaluere mikro-indlæggets position og okklusionen af tuba.

D. Røntgen af bækkenet

1. Tag et billede af uterus, hvor begge **Essure** mikro-indlæg ses tydeligt. Mikro-indlæggenes leje og krumning bør noteres.

Tilsvarende røntgenbillede af **Essure** *mikro-indlæg*

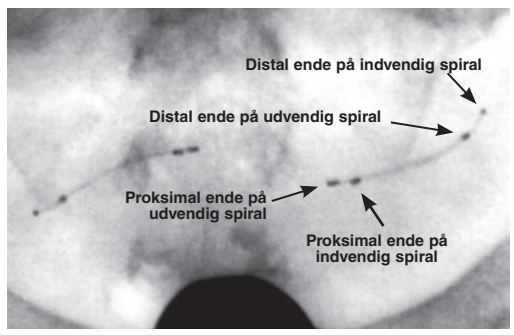


2. Evaluér røntgenbillede af bækkenet, som følger:
   a) Tilfredsstillende: Mikro-indlæggene ser ud til at være i tubalumen, spænder overgangen mellem uterus og tuba og ser ud til at være relativt symmetriske. Patienter, hvis røntgenbilleder skønnes at være "tilfredsstillende", kan begynde at stole på **Essure** mikro-indlægget som prævention.
   b) Suspekt: Et af mikro-indlæggene eller begge to ser ud til at være distalt eller proksimalt for den optimale position, eller de kan være delvist eller helt perforeret gennem tuba og/eller de forekommer relativt asymmetriske. Patienter, hvis røntgenbilleder skønnes at være "suspekt", bør meddeles at de skal fortsætte med alternativ prævention og gennemgå en HSG.
   c) Utilfredsstillende: Tydelig intraperitoneal mikro-indlæg position eller afstødning.
3. Hvis røntgenevalueringen er tvivlsom eller utilfredsstillende eller mikro-indlæggets position er suspekt, skal patienten have foretaget en HSG for at evaluere mikro-indlæggets position og okklusion af tuba.

E. Udførelse og evaluering af modificerede HSG'er

1. HSG udføres for yderligere at evaluere **Essure** mikro-indlæggets position og okklusion af tuba, hvis det skønnes nødvendigt baseret på røntgen- eller ultralydresultaterne. Følg instruktionerne nedenfor for at udføre og evaluere HSG.
2. Udførelse af HSG - Retningslinjer:
   a) Sørg for en god fyldning of cornua, således at silhuetten af uteruskaviteten ses tydeligt.
   b) Anbring fluoroskopistrålen så tæt på A/P projektionen som muligt.
   c) Dilatér ikke livmoderhalsen, medmindre det er nødvendigt. Hvis der forekommer dilatation, skal der opretholdes en god cervikal lukning.
   d) Nedadgående traktion på den cervikale tenaculum kan være påkrævet for patienter med uterus i midtposition. Fjern spekulum inden fluoroskopi for at opnå den bedste visualisering af livmoderens anatomi.
   e) Tag mindst seks røntgenbilleder for at vurdere mikro-indlæggets position og okklusion af tuba.
      (1) Røntgenbillede 1 – "Rekognosceringsbillede" - Uterus og mikro-indlæg uden kontrast.
      (2) Røntgenbillede 2 – Minimal fyldning af kaviteten – Uterus og mikro-indlæg med en lille mængde kontrast.
      (3) Røntgenbillede 3 – Delvis fyldning af kaviteten - Uterus og mikro-indlæg når den er næsten fuld af kontrast.
      (4) Røntgenbillede 4 – Total fyldning af kaviteten - Uterus og mikro-indlæg, når cornua er udspilet med kontrast.
      (5) Røntgenbillede 5 & 6- Forstørrelse af cornua uteri – Mikro-indlæg i tuba med højre (5) og venstre (6) cornua.

   FORSIGTIG: Undgå overdrevent intrauterint tryk ud over hvad der er nødvendigt for at frembringe røntgenbillede 4 for at undgå unødige gener for patienten samt vaso-vagal reaktion.



3. Vurdering af mikro-indlæggets position
   a) Notér fire "markører" ved hver ende af de indvendige og udvendige spiraler under evalueringen. Bemærk, at de distale markører er fastlagte i relation til hinanden, men at de proksimale markører kan flytte sig eller synes udstrakt på grund af den udvendige spirals fleksibilitet. Ideel position for mikro-indlægget er, når mikro-indlæggets indvendige spiral krydser overgangen mellem uterus og tuba.
   b) Vurdering af mikro-indlæggets position:
      (1) Afstødning eller proksimal position: Mikro-indlægget er ikke til stede, eller ≥ 50 % af den indvendige spiral når ind i uteruskaviteten.
      (2) Tilfredsstillende position: Den distale ende af den indvendige spiral er inden i tuba, og < 50 % af den indvendige spiral når ind i uteruskaviteten, eller den proksimale ende af den indvendige spiral er ≤ 30 mm inden i tuba fra hvor kontrast fylder cornua.
      (3) Distal placering eller perforering: Mikro-indlægget er i tuba, men den proksimale ende af den indvendige spiral er > 30 mm distal fra hvor kontrast fylder cornua, eller mikro-indlægget perforerer tuba helt eller delvist.
4. Vurdering af okklusion af tuba
   a) Afgør, om kontrasten er synlig i tuba ud over mikro-indlægget, og notér enhver grad af kontrastfyldning af proksimal tuba, også selv om tuba er okkluderet.
   b) Vurdér okklusionen af tuba:
      (1) Tilfredsstillende okklusion: 1 -Tuba er okkluderet ved cornua.
      (2) Tilfredsstillende okklusion: Kontrast ses inden i tuba, men ikke forbi den distale ende af den udvendige spiral.
      (3) Utilfredsstillende okklusion: 3 - Kontrast ses forbi den distale del af mikro-indlægget eller i peritoneum.

5. Vurdering af pålideligheden
   a) Hvis position og okklusion af tuba begge vurderes som tilfredsstillende, skal patienten instrueres i at ophøre med alternativ prævention.
   b) Hvis positionen er utilfredsstillende, skal patienten instrueres i ikke at stole på mikro-indlæggende som prævention.
   c) Hvis positionen er tilfredsstillende, men okklusionen er utilfredsstillende, skal patienten instrueres i at fortsætte med alternativ prævention. Gentag HSG efter tre måneder. Hvis okklusionen stadig er utilfredsstillende, skal patienten instrueres i ikke at stole på mikro-indlæggende som prævention.

X. Behandling af utilfredsstillende mikro-indlæg position

A. Utilfredsstillende mikro-indlæg position diagnosticeret ved hysterosalpingogram

1. Proksimal position: Mere end 50 % af længden på mikro-indlæggets (indlæggenes) indvendige spiral når ind i uterus.
2. Distal position: Mikro-indlægget (indlæggene) er i tuba, men den proksimale ende af den indvendige spiral er mere end 30 mm fra kontrastfyldningen af cornea uteri.
3. Fuldstændig afstødning af mikro-indlægget (indlæggene); mikro-indlægget (indlæggene) er ikke til stede i kroppen.
4. Perforering: mikro-indlægget (indlæggene) perforerer tuba delvist eller helt.
5. Mikro-indlæggets (indlæggenes) position er intraperitoneal; mikro-indlægget (indlæggene) er tydeligvis uden for tuba(e).

B. Behandling af afstødning af mikro-indlæg eller utilfredsstillende mikro-indlæg position

1. Bilateral afstødning af mikro-indlæg med bilateral okklusion: Patienten bør vejledes om muligheden for incisional sterilisation eller om at regne med hendes bilaterale proksimale okklusion af tuba (PTO) som prævention i lyset af muligheden for en falsk positiv diagnose om okklusion af tubae gennem **Essure** bekræftelsestest (HSG).
2. Bilateral afstødning af mikro-indlæg med okklusion i en tuba og åbenhed i den kontralaterale tuba: Patienten kan komme under overvejelse til endnu en mikro-indlæg procedure med henblik på at placere mikro-indlægget igen i den tuba, der er åben, således at hun kan regne med ét **Essure** mikro-indlæg og kontralateral PTO som prævention. Patienten bør vejledes vedrørende denne valgmulighed i lyset af muligheden for en falsk positiv diagnose om okklusion af tuba gennem **Essure** bekræftelsestest (HSG). Hun bør ligeledes vejledes om muligheden for at få udført incisional sterilisation.
3. Unilateral afstødning af mikro-indlæg eller utilfredsstillende unilateral mikro-indlæg position (i myometrium eller intraperitoneum) med kontralateralt mikro-indlæg i en utilfredsstillende position: Hvis **Essure** bekræftelsestest (HSG) påviser blokering i den tuba, hvorfra mikro-indlægget blev afstødt, eller hvor mikro-indlægget burde have været placeret, kan patienten regne med det tilfredsstillende placerede mikro-indlæg og det kontralaterale PTO i lyset af muligheden for en falsk positiv diagnose om okklusion af tuba gennem **Essure** bekræftelsestest (HSG). Hun bør ligeledes vejledes vedrørende muligheden for at få udført incisional sterilisation.
4. Utilfredsstillende unilateral mikro-indlæg position (i myometrium eller intraperitoneum) med kontralateralt mikro-indlæg i en tilfredsstillende position: Hvis **Essure** bekræftelsestest (HSG) påviser åbenhed i den tuba, der skulle have modtaget et mikro-indlæg, kan patienten få tilbudt muligheden for at komme igen senere for at forsøge endnu en placeringsprocedure for mikro-indlægget. Hun bør ligeledes vejledes vedrørende muligheden for at få udført incisional sterilisation.
5. Unilateral afstødning af mikro-indlæg; utilfredsstillende unilateral mikro-indlæg position (i myometrium eller intraperitoneum); Utilfredsstillende unilateral mikro-indlæg position i "Proksimal position" (>50 % af den indvendige spirallængde når ind i uterus) eller "Distal position" (mikro-indlægget er i tuba, men den proksimale ende af den indvendige spiral er >30 mm fra kontrastfyldningen af cornua uteri) med det kontralaterale mikro-indlæg i en utilfredsstillende position: Patienten bør vejledes vedrørende muligheden for at få udført incisional sterilisation. I alle tilfælde kan incisional kirurgi være påkrævet, hvis fjernelse af mikro-indlægget skønnes nødvendigt og hysteroskopisk fjernelse ikke er mulig.
6. Hvis en patient har valgt incisional sterilisation efter en af ovenstående scenarier, bør begge tubae okkluderes uanset om der er et mikro-indlæg til stede i en tilfredsstillende position. Det bør forsøges at genindfange et mikro-indlæg, hvis lægen vurderer, at det kan gøres uden risiko, men det kan være umuligt at genindfange mikro-indlægget. Det anbefales at bruge intraoperativ fluoroskopi til at identificere mikro-indlæggets (indlæggenes) position før og under kirurgi. Forsøg på genindfangning bør ikke overstige 30 minutter.

XI. Behandling af tilfælde med mislykket placering af Essure mikro-indlæg

I tilfælde af fejlslagen unilateral eller bilateral placering af mikro-indlæg, bør patienten informeres om, at hendes permanente prævention ikke er blevet fuldført. Hvis patienten vælger laparoskopisk sterilisation (f.eks. påføring af clips eller elektrokaustik), bør begge tuba clipses eller kauteriseres, også selv om en af tubae har et **Essure** mikro-indlæg implanteret. Clipsning eller kauterisering af tuba eller tubae bør udføres distalt for **Essure** mikro-indlægget.

Hvis patienten ikke vælger laparoskopisk sterilisation, kan hun tilbydes en **Essure** bekræftelsestest(HSG) efter næste menses (før ovulation: dag 7-14 hvor dag 1 repræsenterer første blødningsdag) med henblik på at afgøre åbenhed af tubae. Hvis der observeres åbenhed i tubae, kan lægen tilbyde patienten endnu et forsøg på placering af mikro-indlæg. Hvis det andet forsøg på placering af mikro-indlægget mislykkes, er det ikke sandsynligt at placering vil lykkes ved yderligere forsøg. Hvis patienten har et mikro-indlæg *in vivo*, bør hun rådes til ikke at stole på det unilaterale mikro-indlæg som prævention.

Hvis der kun blev opnået unilateral placering og **Essure** bekræftelsestest (HSG) bekræfter kontralateral PTO, bør patienten vejledes vedrørende muligheden for at stole på det ene mikro-indlæg, i lyset af muligheden for en falsk positiv diagnose om PTO gennem **Essure** bekræftelsestest (HSG). Okklusion af tuba defineres ved at farvestoffet ikke passerer fra uteruskaviteten og ind i peritoneum på tidspunktet for en **Essure** bekræftelsestest (HSG). Hun bør ligeledes vejledes om muligheden for at få udført incisional sterilisation. Et forsøg på at fjerne et unilateralt placeret mikro-indlæg kan ikke anbefales, medmindre patienten har bivirkninger med mikro-indlægget.

XII. Fjernelse af Essure mikro-indlæg

ADVARSEL: FJERNELSE AF MIKRO-INDLÆG BØR IKKE FORSØGES GENNEM HYSTEROSKOPI, NÅR FØRST MIKRO-INDLÆGGET ER PLACERET, MEDMINDRE 18 ELLER FLERE SPIRALER PÅ Essure MIKRO-INDLÆGGET NÅR IND I UTERUSKAVITETEN. Fjernelse af et sådant mikro-indlæg bør forsøges udført umiddelbart efter placering. Fjernelse kan imidlertid være umulig. Hvis fjernelse forsøges, bør følgende trin anvendes:

1. Indfør et gribeinstrument gennem hysteroskopets arbejdskanal.
2. Grib fat i den udvendige spiral på **Essure** mikro-indlægget. Prøv at tage fat samtidigt om den udvendige og den indvendige spiral på mikro-indlægget.
3. Træk gribeinstrumentet og hysteroskopet tilbage samtidigt, således at hele systemet trækkes tilbage fra uterus på en gang.
4. Der er mulighed for at den udvendige spiral og/eller den indvendige spiral på **Essure** mikro-indlægget kan strække sig eller forlænges, efterhånden som fjernelse af mikro-indlægget forsøges.
5. Administrer analgesi/anæstesi efter behov for at reducere eller forebygge ubehag for patienten.
6. Hvis der opnås fuldstændig fjernelse af mikro-indlægget, bør det forsøges at placere et andet **Essure** mikro-indlæg.
7. Hvis lægen ikke er helt sikker på, at hele **Essure** mikro-indlægget er fjernet fra tuba, bør et andet mikro-indlæg IKKE placeres i denne tuba og et røntgenbillede bør tages efter placeringen for at afgøre, om der stadig er et fragment af mikro-indlægget *in vivo*.

Bortset fra ovenstående scenarie bør fjernelse af mikro-indlæg kun forsøges, hvis en patient har en eller flere bivirkninger med mikro-indlægget, eller hvis hun forlanger fjernelse af mikro-indlægget.

Hvis det skønnes nødvendigt at fjerne mikro-indlægget, er transabdominal adgang (d.v.s. laparotomi eller laparoskopi) påkrævet.

Resektion af cornua af den proksimale del af tuba vil være nødvendig, hvis mikro-indlægget sidder korrekt henover overgangen mellem uterus og tuba (UTJ).

Et **Essure** mikro-indlæg, der er placeret forkert eller som er vandret forbi UTJ, bør fjernes med traditionel lineær salpingotomi eller salpingektomi opnået gennem laparoskopi eller laparotomi.

1. Lineær salpingotomi udføres via en lille incision (ca. 2 cm lang) langs tubas antimesenteriske grænse direkte over mikro-indlægget.
2. Total eller delvis salpingektomi kan udføres for at indhente mikro-indlægget sammen med, eller uafhængig af, udførelse af en traditionel sterilisationsprocedure i tubae.

XIII. Patient ID-kort

Enhver patient, der har fået et **Essure** mikro-indlæg implanteret, bør medgives et lamineret kort på størrelse med en pung, der angiver, at patienten har et **Essure** mikro-indlæg implanteret. **Dette kort vedlægges i denne pakning.** Kortet oplyser også, at der kan være risici forbundet, hvis patienten får foretaget fremtidige intrauterine procedurer eller kirurgi i kønsorganerne.

XIV. Tegnforklaring

STERILE EO	Steriliseret med ethylenoxid
LOT	Partikode
	Må ikke genbruges
REF	Katalognummer
	NB! Se brugsanvisningen
	Anvendes inden
	Hold væk fra varme
	Må ikke anvendes, hvis emballagen er åben eller beskadiget
MR	Kan anvendes i MR-scanningsmiljøer under visse betingelser
EC REP	Autoriseret europæisk repræsentant
CE 0050	Anordningen er i overensstemmelse med europæisk direktiv 93/42/EF
	Hold tørt
CONT	Indhold

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Kontakt den lokale Bayer HealthCare LLC repræsentant for at bestille produkter eller rapportere bivirkninger.

English Outside USA only

essure®
permanent birth control

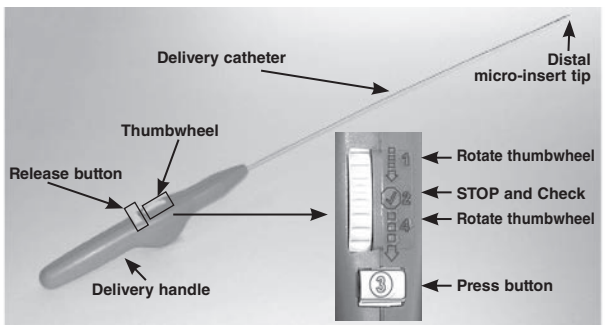
BAYER

INSTRUCTIONS FOR USE

I. Description

The **Essure**® Permanent Birth Control System is comprised of several components. The **Essure** micro-insert, a dynamically expanding micro-insert, is attached to a delivery wire and a release catheter. The entire assembly is sheathed within a delivery catheter. This system, (shown in Figure 1), is attached to a handle that facilitates micro-insert delivery and deployment. A valved **DryFlow**® Introducer is also provided with the **Essure** system. It is intended to help protect the **Essure** micro-insert as it is being passed through the rubber port of the hysteroscope working channel.

Figure 1
Essure Delivery System
Showing detail of placement procedure symbols
(NOT TO SCALE)



II. Mechanism of action

Under hysteroscopic visualisation, the **Essure** system delivers an **Essure** micro-insert to the proximal section of the fallopian tube lumen. When the **Essure** micro-insert expands on release, it acutely anchors itself in the fallopian tube. Subsequently, the micro-insert elicits an intended benign tissue response, resulting in tissue in-growth into the micro-insert that anchors the micro-insert firmly into the fallopian tube. This benign tissue response is local, fibrotic and occlusive in nature.

Each **Essure** system is sterilised using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilise. Resterilisation may adversely affect proper mechanical function and could result in patient injury.

III. Indications for use

The **Essure** system is intended for use as a tubal occlusion micro-insert for purposes of permanent contraception.

IV. Contraindications for use

- Patient uncertainty about her desire to end fertility.
- Pregnancy or suspected pregnancy.
- Delivery or termination of a second trimester pregnancy less than 6 weeks before **Essure** micro-insert placement.
- Active or recent pelvic infection.
- Untreated acute cervicitis.
- Unexplained or severe vaginal bleeding.
- Gynaecological malignancy (suspected or known).
- Known abnormal uterine cavity or fallopian tubes that makes visualisation of the tubal ostia and/or cannulation of the proximal fallopian tube difficult or impossible.
- Allergy to contrast media (a hysterosalpingogram may be required three months post-micro-insert placement).
- Patient currently taking corticosteroids.

V. Warnings

- The **Essure** procedure should only be performed by skilled hysteroscopists who have completed the Bayer Healthcare LLC training programme for this procedure.
- Persons allergic to nickel titanium may suffer an allergic reaction to the micro-insert.
- Do not use the **Essure** system if the package is open or damaged. Do not use if the micro-insert is damaged.
- When introducing the **Essure** micro-insert into the fallopian tube, never advance the micro-insert(s) against excessive resistance.
- Do not continue to advance the **Essure** system once the positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory micro-insert placement or tubal/uterine perforation.
- If a tubal perforation occurs or is suspected, do not continue with the **Essure** micro-insert placement attempt. A very small percentage of women in the **Essure** clinical trials (1.8% or 12/682 patients) were identified as having device related tubal perforations. Retrieval of perforating micro-inserts, if necessary, will require laparoscopy or other surgical methods.
- If **Essure** micro-insert placement attempts are not successful after 10 minutes of attempted cannulation per tube, the case should be discontinued and potentially rescheduled.
- Once the micro-insert has been placed (i.e., detached from the delivery wire), micro-insert removal should not be attempted hysteroscopically unless 18 or more coils of the **Essure** micro-insert are trailing into the uterine cavity. Removal of such a micro-insert should be attempted immediately following the placement. However, removal may not be possible.
- The patient must use alternative contraception until an x-ray performed three months post-micro-insert placement demonstrates satisfactory micro-insert location.
- Patients who undergo placement of the **Essure** micro-insert may, in future years, be offered intrauterine therapies that utilise electrical energy. It is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes. All other procedures in the pelvis should avoid the use of electrocautery within 4 cm of the micro-insert. Due to the presence of the **Essure** micro-inserts, there may be risks associated with such procedures that at this time have not been identified.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation, could interrupt the ability of the micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** micro-inserts could entail risks associated with such procedures that at this time have not been identified.
- Bench and clinical studies demonstrated that endometrial ablation of the uterus can be performed safely and effectively with the GYNECARE THERMACHOICE* Uterine Balloon System, the Hologic NovaSure** Endometrial Ablation System and the Boston Scientific Hydro ThermAblator*** **immediately following Essure** micro-insert placement. No specific studies have been conducted to evaluate **Essure** micro-insert expulsion or contraception rates following combined **Essure** and endometrial ablation procedures.
- Patients may decide, in future years, to undergo in vitro fertilisation (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the micro-insert to the patient, to the foetus and to the continuation of the pregnancy are unknown.

* Trademark of ETHICON, INC.
** Trademark of Hologic, Inc.
*** Trademark of Boston Scientific Corporation

VI. Precautions

- Whenever possible, micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding) in order to enhance visualisation of the fallopian tube ostia and decrease the potential for micro-insert placement in a patient with an undiagnosed pregnancy.
- Unusual uterine anatomy may make it difficult to place the **Essure** micro-inserts.
- In order to reduce the risk of uterine perforation, the procedure should be discontinued if excessive force is required to achieve cervical dilatation.
- Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is accessible and patent.
- Performing endometrial ablation immediately following placement of **Essure** micro-inserts may increase the risk of post-ablation tubal sterilisation syndrome, a rare condition that has been reported in women with a history of tubal sterilisation who undergo endometrial ablation
- Do not advance the **Essure** system if the patient is experiencing extraordinary pain or discomfort.
- Store the **Essure** system in a cool, dry place.

VII. Possible adverse effects

A. Pregnancy

There is a risk of pregnancy, ectopic pregnancy, and risks associated with the treatment for both. If the patient conceives and chooses to continue an intrauterine pregnancy, she should be informed that the risks of the micro-insert to the patient, to the foetus and to the continuation of the pregnancy are unknown.

B. Risks associated with the micro-insert placement procedure

- Local anaesthesia, oral analgesia/sedation, regional anaesthesia (i.e., spinal, epidural), oral or conscious (intravenous) sedation or general anaesthesia may be administered to the patient to prevent or reduce discomfort. Regardless of the type of anaesthesia, patients may not be able to resume normal activities for 12-24 hours following the procedure.
- Pain, cramping and vaginal bleeding may occur during and following the micro-insert placement procedure. Typically, these incidents are tolerable, transient and successfully treated with medication.
- During and/or directly following the micro-insert placement procedure, there is the risk that the patient will experience nausea or vomiting. This is expected to be transient and may be treated with medication as required.
- Patients may experience fainting or vasovagal response on the day of the procedure.
- There is a risk of perforation or dissection of the fallopian tube or uterine cornua. Bleeding and scarring may result from such a perforation or dissection; however, treatment is typically not required.
- There is a risk of uterine perforation by the hysteroscope, **Essure** system or other instruments used during the procedure with possible injury to the bowel, bladder and major blood vessels. Surgical intervention may be required, but is unlikely, if such injury were to occur. To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
- There is a risk that the **Essure** micro-insert may be inadvertently placed into the myometrium of the uterus and not into the fallopian tube lumen. If one micro-insert has already been properly placed in one fallopian tube, in addition to inadvertent placement into the myometrium, the physician may attempt to place a third micro-insert to complete the procedure. If bilateral fallopian tube placement is not achieved, this may result in the patient having one micro-insert in the fallopian tube and/or one micro-insert in the myometrium that cannot be relied upon for contraception. Placement of the micro-insert in the myometrium may result in post-operative pain or other adverse event. If surgical removal of the micro-insert(s) is required, salpingectomy or hysterectomy may be required.
- There is a risk that the **Essure** micro-insert may be placed too distally in the fallopian tube. If removal of the micro-insert is necessary, surgery (laparoscopy or laparotomy) will be required.
- There is a risk that the **Essure** micro-insert may be placed too proximally in the fallopian tube. If 18 or more coils of the **Essure** micro-insert are visible at the time of placement, an immediate attempt should be made to remove the micro-insert (see section XII, **Essure** micro-insert removal). If micro-insert removal is attempted, there is a possibility that the removal will not be successful or that the **Essure** micro-insert may break, leaving a fragment of the micro-insert *in vivo*. If micro-insert removal is attempted and/or achieved, there is also a possibility that the patient may experience increased pain, cramping and bleeding during and following the **Essure** micro-insert placement procedure.
- There is a risk that the **Essure** micro-insert may perforate through the tubal wall or uterine cornua, which could result in the micro-insert being released into the peritoneal cavity. Post-operative pain and/or menstrual disturbance or other adverse event may occur as a result. If the patient elects to undergo incisional sterilisation or other surgical intervention, micro-insert retrieval from the peritoneal cavity may be attempted if the physician believes it is safe to do so. However, micro-insert retrieval may not be possible if the micro-insert cannot be visualised or accessed by the physician.
- There is a risk that **Essure** micro-insert placement will only be achieved in one fallopian tube. If this occurs, patients may be left with one micro-insert *in vivo* that cannot be relied upon for permanent contraception.
- There is a risk that **Essure** micro-insert placement will not be possible in either fallopian tube.
- There is a minimal risk of excess fluid absorption of the physiologic saline fluid used for distension of the uterus, to perform the hysteroscopic procedure.
- As with all invasive procedures, the micro-insert placement procedure can cause an infection. An infection could cause damage to the uterus, fallopian tubes or pelvic cavity. This could require antibiotic therapy, or rarely, hospitalisation or surgery, including hysterectomy.

C. Risks associated with Essure micro-insert wearing

- There is a risk that the **Essure** micro-insert could move out of the fallopian tubes. This movement could be expulsion (movement out of the fallopian tube and into the uterine cavity/cervix/vagina or out of the body) or migration (movement to the distal fallopian tube or out of the fallopian tube and into the peritoneal cavity). Additional x-rays may be required to identify the location of the micro-insert(s), and surgery may be required to remove the micro-insert(s). Device movement could result in pregnancy, ectopic pregnancy and/or pain/menstrual disturbance or other adverse events.
- As with currently available methods of mechanical permanent contraception (i.e., clips, rings), if the **Essure** micro-insert is to be removed, surgery will be required. Further, it is possible that surgical removal of the fallopian tubes (salpingectomy) and uterus (hysterectomy) may be required.
- Abdominal/pelvic pain and cramping may occur. Pain and cramping may be a more likely occurrence during the menstrual period, during and after sexual intercourse or with other physical activity.
- Intermenstrual bleeding or heavier than normal menstrual bleeding may be experienced.
- Occasionally, a woman may regret her decision to undergo permanent contraception and experience mild depression or other emotional disturbances as a result.

D. Risks associated with follow-up procedures

- There is the risk of radiation associated with the pelvic x-ray that is required three months following micro-insert placement to evaluate micro-insert location. There may also be a need for an **Essure** Confirmation Test (HSG). There are approximately .033 rads in the fluoroscopic portion (< 30 seconds) of a hysterosalpingogram procedure. As a point of comparison, radiation exposure from a barium enema is 0.85 rads which is higher than the required **Essure** Confirmation Test (HSG). The amount of radiation exposure from one pelvic x-ray is about the same as the amount an individual would receive from one year of natural background radiation.
- The following additional risks are associated with the **Essure** Confirmation Test (HSG) procedure if needed: vasovagal response; infection, which may require antibiotic treatment and in rare cases could require hospitalisation; intravasation; perforation of the uterus; uterine cramping and/or bleeding; pain or discomfort; allergic reaction to latex. Latex exposure has been reported to be associated with anaphylactic reactions in rare cases, which may lead to death.
- The use of contrast media, used to perform the **Essure** Confirmation Test (HSG), has been associated with allergic reaction in some patients. Allergic reaction can result in hives or difficulty breathing. In some individuals, an anaphylactic response may occur which may lead to death.

E. Risks associated with potential future procedures

- Patients who undergo placement of the **Essure** micro-insert may, in future years, be offered intrauterine therapies that utilise electrical energy. It is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes. All other procedures in the pelvis should avoid the use of electrocautery within 4 cm of the micro-insert. Due to the presence of the **Essure** micro-inserts, there may be risks associated with such procedures that, at this time, have not been identified.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation, could interrupt the ability of the micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** micro-inserts could entail risks associated with such procedures that, at this time, have not been identified.
- Patients may decide, in future years, to undergo in vitro fertilisation (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the micro-insert to the patient, to the foetus and to the continuation of a pregnancy are unknown.
- The **Essure** micro-inserts are MR-safe and radiopaque. The **Essure** micro-inserts are also MR-compatible, except for pelvic imaging where they may cause some artefacts.
- **There is the potential that unknown risks exist.**

VIII. Directions for use

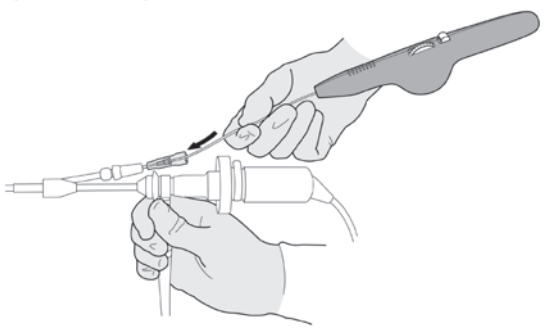
A. Prior to micro-insert placement procedure

1. Micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding), in order to enhance visualisation of the fallopian tube ostia and decrease the potential for micro-insert placement in a patient with an undiagnosed pregnancy.
2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to or immediately preceding the micro-insert placement procedure.
3. Administration of a non-steroidal anti-inflammatory drug (NSAID) such as Indocid (orally or via suppository) is strongly recommended one to two hours before the micro-insert placement procedure, since clinical trial data demonstrate that the use of NSAIDs significantly increase the likelihood of placement success. If using only a paracervical block, Diazepam (PO) or a similar agent may also be offered 30 minutes prior to the procedure to reduce anxiety.

B. Essure micro-insert placement procedure

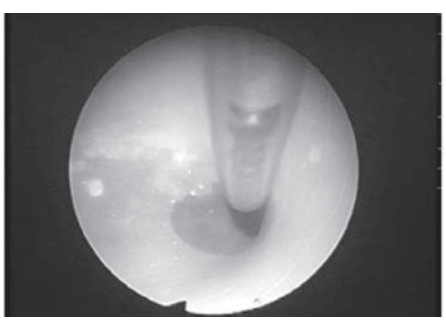
The **Essure** micro-insert placement procedure can be performed in an ambulatory or day surgery setting. Sterile techniques should be used during the micro-insert placement procedure. The amount of time required to complete the micro-insert placement procedure should not exceed 30 minutes.

1. Place the patient in the lithotomy position.
2. Introduce a speculum into the vagina to allow access to the cervix. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.
3. Local anaesthesia is the preferred method for implantation of the micro-inserts. A paracervical block may be administered. Midazolam (IV), or a similar agent, may also be administered to prevent or reduce discomfort if needed.
4. Insert a sterile hysteroscope, with attached camera and operating channel (≥ 5 French), through the cervix into the uterine cavity. If necessary, perform cervical dilation to allow insertion. In order to prevent uterine perforation, the procedure should be discontinued if excessive force is required to achieve cervical dilatation.
5. Uterine cavity distension should be accomplished with a physiologic saline infusion through the working channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature and introduced under gravity feed to minimise spasm of the fallopian tubes. Excellent uterine distension must be achieved and maintained throughout the procedure. Standard fluid monitoring procedures should be followed throughout the procedure. The fallopian tube ostia should be identified by hysteroscopic visualisation.
6. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is patent.
7. Once the fallopian tube ostia have been identified, insert the introducer through the sealing cap on the hysteroscope working channel. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if the stopcock closes on either device). Place the **Essure** delivery system through the introducer and advance through the operating channel of the hysteroscope. If undamaged from the first micro-insert placement, the valved introducer may remain in the operating channel throughout the **Essure** procedure.



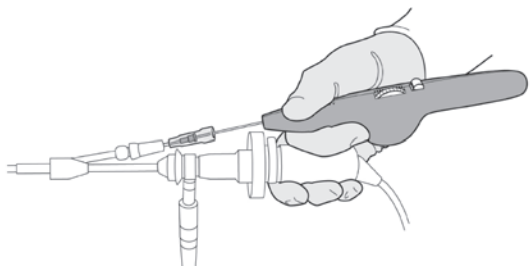
Insert the introducer through the sealing cap on the hysteroscope working channel, then place the **Essure** *delivery system through the introducer.*

8. Advance the **Essure** delivery system into the proximal fallopian tube with slow, steady movement to prevent tubal spasm. Advance the delivery system until the positioning marker on the delivery catheter reaches the fallopian tube ostium. This visual marker indicates that the **Essure** micro-insert is spanning the distal intramural to proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the **Essure** micro-insert.



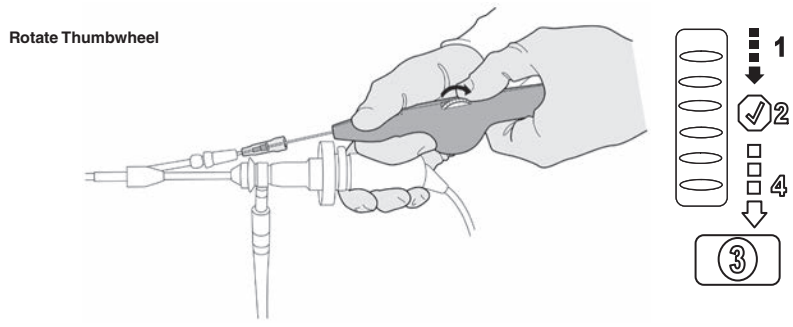
Advance until the black positioning marker is at tubal ostium. This is a visual indicator for proper position for deployment.

9. Proper concentric alignment of the delivery catheter with the tubal lumen is suggested by the ability to advance the catheter under direct visualisation without undue resistance. Resistance to advancement is usually apparent in two ways: 1) the black marker on the outside surface of the catheter is seen not to advance forward towards the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward motion of the catheter is observed, no further attempts should be made to place the micro-insert in order to avoid the possibility of uterine perforation or inadvertently placing the micro-insert in the uterine musculature rather than within the tubal lumen. A follow-up **Essure** Confirmation Test (HSG) should be undertaken to determine tubal patency.
10. If it is not possible to advance the catheter to the positioning marker after several minutes, a perfusion test with a patency catheter may be employed, if it has not already been utilised, to determine tubal patency. If the tube is blocked or the catheter cannot be advanced to the positioning marker, the case should be terminated. If micro-insert placement is not successful after 10 minutes of attempted cannulation per tube, the case should be terminated.
11. When the delivery catheter has been advanced to the positioning marker, deploy the micro-insert. To do so, first stabilise the handle of the **Essure** micro-insert against the hysteroscope camera or some other fixed object, to prevent inadvertent forward movement of the **Essure** system during retraction of the delivery catheter.



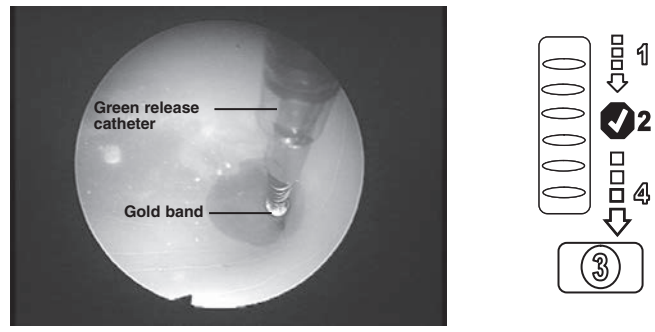
Stabilise handle against camera head or some other fixed object to prevent inadvertent forward movement of the **Essure** *system*

12. Being certain that the black positioning marker is at the fallopian tube ostium, rotate the thumbwheel on the handle toward you until the wheel no longer rotates. This operation corresponds to the symbol ⇩1 on the delivery system handle. This facilitates withdrawal of the delivery catheter. You will see the black positioning marker move away from the tubal ostium (towards the hysteroscope) and disappear into the operating channel. Withdrawal of the delivery catheter exposes the wound-down **Essure** micro-insert. Approximately 1 cm of the micro-insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn.



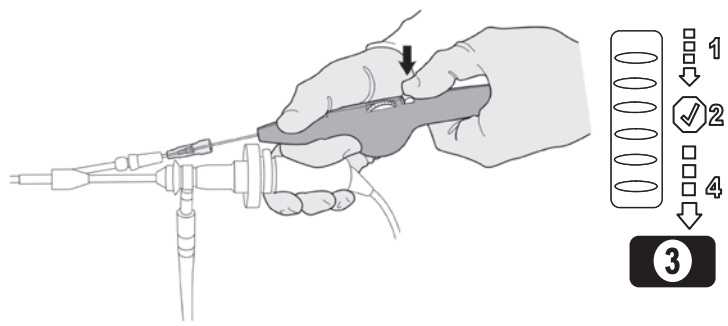
Rotate thumbwheel to retract catheter

13. To confirm proper positioning, place gold marker band just outside the ostium, which corresponds to the symbol ✓2 on the delivery system handle. Visualisation of the gold band just outside the ostium, as well as visualisation of the distal tip of the green release catheter, will confirm proper positioning. If more than 1 cm of the micro-insert is visible in the uterus, then the micro-insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to the next step.



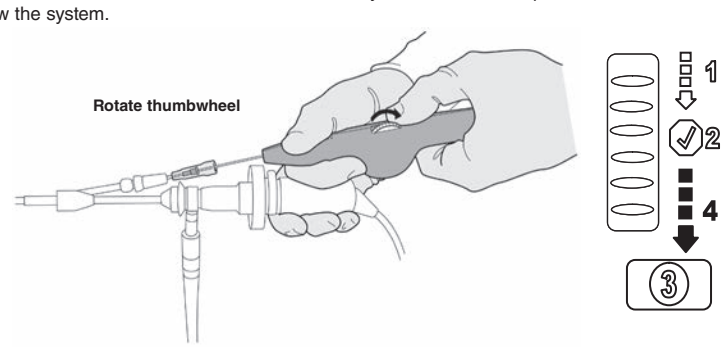
Visualise gold band at ostium

14. Press the button on the delivery handle to enable the thumbwheel to be further rotated, which corresponds to the symbol ③ on the handle button.



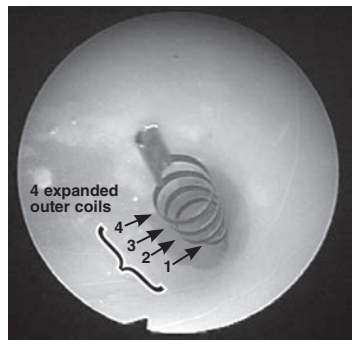
Press button to enable thumbwheel to rotate again.

15. Rotate the thumbwheel toward you to deploy the outer coil of the micro-insert, which corresponds to the symbol ⇩4 on the delivery system handle. Continue to rotate the thumbwheel until it stops rotating. When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, withdraw the system.



Rotate thumbwheel to deploy the outer coil of the micro-insert

16. The position of the deployed **Essure** micro-insert will be assessed under hysteroscopic visualisation. There should ideally be 3 to 8 expanded outer coils of the **Essure** micro-insert trailing into the uterus.



Expanded outer coils of the **Essure** *micro-insert trailing into the uterus indicates ideal placement*

17. If the physician is dissatisfied with the micro-insert's placement based on the hysteroscopic view, or suspects tubal or uterine perforation, the micro-insert(s) should be left in place and evaluated via pelvic X-ray or HSG three months post device placement.

    WARNING: AFTER THE MICRO-INSERT HAS BEEN PLACED AND RELEASED INTO THE FALLOPIAN TUBE, DO NOT ATTEMPT TO REMOVE THE MICRO-INSERT HYSTEROSCOPICALLY UNLESS 18 OR MORE COILS OF THE ESSURE MICRO-INSERT ARE TRAILING IN THE UTERINE CAVITY. Removal of such a micro-insert should be attempted immediately during the placement attempt. However, removal may not be possible (see section XIII, **Essure** Micro-insert Removal). If the micro-insert was inadvertently deployed in the uterine cavity and not into the tube, the micro-insert should be removed from the uterus and another attempt made at micro-insert placement in the tube.

18. Repeat the **Essure** micro-insert placement procedure in the contralateral fallopian tube.
19. Record the length of the micro-insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concerns regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the **Essure** Confirmation Test *(See Section IX - Essure Confirmation Test below)*.
20. **Remind the patient to use an alternative form of contraception (except an IUD) for the first 3 months following the micro-insert placement procedure.**
21. Schedule the patient for an **Essure** Confirmation Test three months following the **Essure** micro-insert placement procedure to evaluate micro-insert retention and location.

IX. Essure Confirmation Test

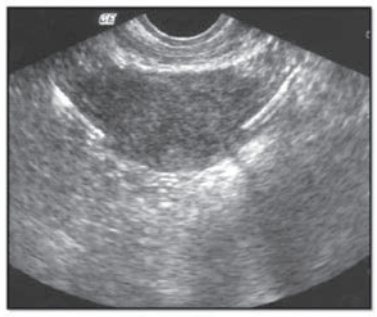
A. An **Essure** Confirmation Test should be performed three months after micro-insert placement to evaluate micro-insert retention and location. The **Essure** Confirmation Tests (transvaginal ultrasound (TVU), pelvic x-ray or hysterosalpingogram (HSG)) should be performed only by an experienced gynecologist, ultrasonographer and/or radiologist trained on the respective **Essure** confirmation test protocol. A detailed protocol with images and test performance tips is provided with training; additional copies may be obtained by downloading a copy from essure.com.

B. For the first-line confirmation test, either a pelvic x-ray or a TVU may be performed three months after an uncomplicated bilateral micro-insert placement procedure.

1. X-ray and TVU should not be used as the **Essure** Confirmation Test under the following circumstances:
   a) Difficult placement procedure including one or more of the following:
      (1) Concern at the time of placement of possible perforation due to excessive force required for micro-insert delivery and/or a sudden loss of resistance.
      (2) Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting or endometrial debris.
      (3) Surgeon is uncertain about placement.
   b) Procedure time > 15 minutes (scope in-scope out).
   c) Placement with zero or > 8 trailing coils
   d) Unusual post-operative pain, transient or persistent, or onset at some later time post procedure, without any other identifiable cause.
2. If X-ray or ultrasound is not indicated, patient must proceed to an HSG to evaluate micro-insert location and tubal occlusion. Trans-abdominal ultrasound cannot be substituted for TVU. If X-ray or ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to an HSG to evaluate micro-insert location and tubal occlusion.

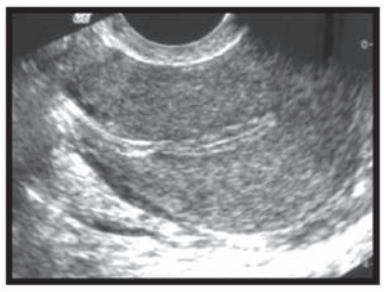
C. Transvaginal Ultrasound

1. A minimum of three images must be obtained and retained for documentation:
   a) A coronal or oblique coronal view demonstrating a portion of each micro-insert in the cornua labeled “scout image.”



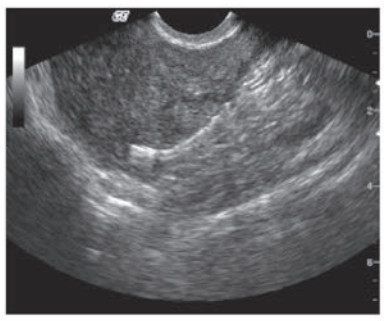
Bilateral micro-inserts are identified in this transverse (coronal / oblique coronal) view.

   b) A coronal or oblique coronal image of the linear axis of the left micro-insert including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the utero-serosal tubal junction and labeled “left.”
   c) A coronal or oblique coronal image of the linear axis of the right micro-insert crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the utero-serosal tubal junction and labeled “right.”
   d) All three images should be captured on film and placed in the subject’s medical record to document satisfactory micro-insert retention and location.
2. Classification of Micro-insert Location
   a) Micro-insert identification: In a single scout image, a portion of each micro-insert must be visualized in the cornua in the coronal or oblique coronal view to ensure bilateral placement and reduce the risk of duplicate imaging of the same micro-insert. The linear axis of the micro-inserts should appear relatively symmetric.
   b) Optimal Location
   Micro-insert location is optimal when the proximal end of the micro-insert is in contact with the uterine cavity or endometrium, and the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the utero-serosal tubal junction (USTJ). The portion of the micro-insert located in the fallopian tube may or may not be visualized. The linear axis of the micro-insert must be visualized to confirm it is not coiled or elongated.



Optimal Location

   c) Satisfactory Location
   Micro-insert location is satisfactory when the proximal end of the micro-insert is distal to the endometrium, however the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the utero-serosal tubal junction (USTJ). The portion of the micro-insert located in the fallopian tube may or may not be visualized. The linear axis of the micro-insert must be visualized to confirm it is not coiled or elongated.



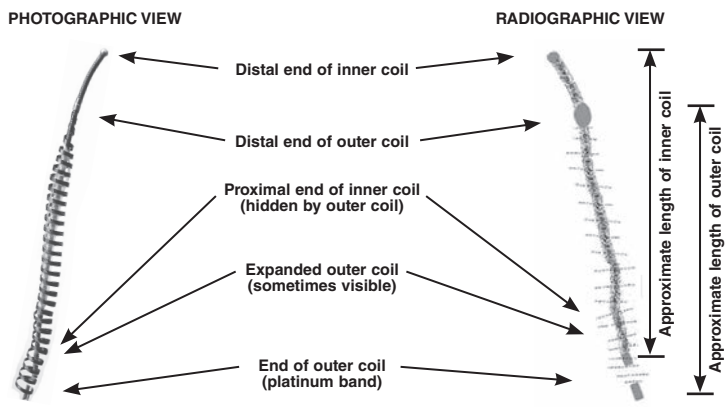
Satisfactory location

   d) Unsatisfactory Location
      (1) Micro-insert location is unsatisfactory if a portion of each micro-insert cannot be visualized in the cornua in the coronal or oblique coronal view in one scout image.
      (2) Expulsion is suspected if one or both micro-inserts are not identified in the cornua in a coronal view in a single scout image.
      (3) Distal placement is suspected if the proximal end of the micro-insert is not located in the myometrium in the cornua (interstitial portion of the fallopian tube), and not crossing or in contact with the USTJ.
      (4) Proximal placement is suspected if greater than 50% or the majority of the micro-insert is visualized in the uterine cavity or if the linear axis of the micro-insert(s) is visualized in the midline sagittal view.
      (5) Perforation is suspected if the linear axis of one or both micro-inserts are parallel to the endometrial stripe in the sagittal view, or if the linear axis of a micro-insert is visualized crossing the myometrium in the midline sagittal view.
      (6) Unclassified position: If the linear axis of a micro-insert cannot be identified, suggesting it is coiled, bent or elongated, micro-insert location is considered unsatisfactory. If the surrounding soft tissue cannot be clearly defined, position is considered unsatisfactory.
3. If ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to an HSG to evaluate micro-insert location and tubal occlusion.

D. Pelvic X-ray

1. Capture an image of the uterus with both Essure micro-inserts clearly seen. The lie and curvature of the micro-inserts should be noted.

Corresponding radiographic view of the Essure micro-insert

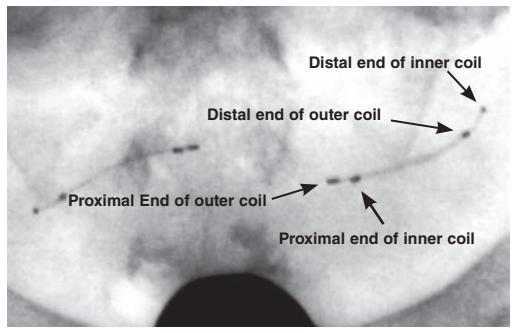


2. Evaluate pelvic X-ray as follows:
   a) Satisfactory: Micro-inserts appear to be in the tubal lumen and spanning the uterotubal junction, and appear relatively symmetrical. Patients whose X-rays are determined to be “satisfactory” may begin to rely on the Essure micro-insert for contraception.
   b) Suspicious: One or both of the micro-inserts appear to be distal or proximal to optimal position, or may be partially or completely perforated through the tube, and/or appear relatively asymmetrical. Patients whose X-rays are determined to be “suspicious” should be instructed to continue alternative contraception and undergo an HSG.
   c) Unsatisfactory: Obvious intraperitoneal micro-insert location or expulsion.
3. If x-ray evaluation is equivocal or unsatisfactory; or micro-insert location is suspicious, patient must proceed to an HSG to evaluate micro-insert location and tubal occlusion.

E. Performing and Evaluating modified HSGs

1. The HSG is performed to further evaluate Essure micro-insert location and fallopian tube occlusion if necessary based on the X-ray or ultrasound findings. Follow the instructions below for performing and evaluating the HSG.
2. Performing the HSG - Guidelines:
   a) Obtain good cornual filling so that the uterine cavity silhouette is clearly seen.
   b) Place fluoroscopy beam as close to A/P projection as possible.
   c) Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.
   d) Downward traction on cervical tenaculum may be required in for midpositional uteri. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.
   e) Take a minimum of six radiographs to assess micro-insert location and tubal occlusion.
      (1) Radiograph 1 – “Scout Film” - Uterus and micro-inserts without contrast.
      (2) Radiograph 2 – Minimal Fill of the Cavity – Uterus and micro-inserts with small amount of contrast.
      (3) Radiograph 3 – Partial Fill of the Cavity - Uterus and micro-inserts when nearly full of contrast.
      (4) Radiograph 4 – Total Fill of Cavity - Uterus and micro-inserts when the cornua is distended by contrast.
      (5) Radiographs 5 & 6- Magnifications of uterine cornua – Micro-insert within the fallopian tube with right (5) and left (6) cornua.

   CAUTION: Avoid excessive intrauterine pressure beyond Radiograph 4 to avoid undue patient discomfort and vaso-vagal reaction.



3. Assessing Micro-insert Location
   a) During evaluation, note four “markers” at each end of the inner and outer coils). Note that the distal markers are fixed in relation to one another, but the proximal markers may move or seem stretched because of the flexibility of the outer coil. Ideal micro-insert location is when the inner coil crosses the utero-tubal junction.
   b) Assess micro-insert location:
      (1) Expulsion or proximal placement: Micro-insert is not present or ≥ 50% of inner coil trailing into the uterine cavity.
      (2) Satisfactory placement: Distal end of inner coil is within the tube, with < 50% of inner coil trailing into the uterine cavity or proximal end of inner coil ≤ 30 mm into the tube from where contrast fills cornua.
      (3) Distal placement or perforation: Micro-insert is in tube but proximal end of inner coil > 30 mm distal from where contrast fills cornua or the micro-insert is completely or partially perforated.
4. Assessing Tubal Occlusion
   a) Determine whether the contrast is visible beyond the micro-insert and note any degree of proximal tubal filling even if the tube is occluded.
   b) Assess tubal occlusion:
      (1) Satisfactory occlusion: Tube is occluded at the cornua.
      (2) Satisfactory occlusion: Contrast seen within tube but not past distal end of outer coil.
      (3) Unsatisfactory occlusion: Contrast seen past the distal end of the micro-insert or in the peritoneal cavity.
5. Assessing Ability to Rely
   a) If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue alternative contraception.

b) If location is unsatisfactory, instruct patient to not rely on the micro-inserts for contraception.

c) If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain on alternative contraception. Repeat the HSG in three months. If occlusion is still unsatisfactory, instruct patient to not rely on the micro-inserts for contraception.

X. Management of Unsatisfactory Micro-insert Location (UML)

A. Unsatisfactory micro-insert location diagnosed by hysterosalpingogram

1. Proximal Location: more than 50% of the length of the inner coil of the micro-insert(s) is trailing into the uterus.
2. Distal Location: the micro-insert(s) is in the fallopian tube but the proximal end of the inner coil is more than 30 mm from the contrast filling the uterine cornua.
3. Complete micro-insert(s) expulsion: micro-insert(s) absent from the body
4. Perforation: micro-insert(s) partially or fully perforated.
5. Intraperitoneal micro-insert(s) location: micro-insert(s) obviously outside the fallopian tube(s).

B. Management of micro-insert expulsion or unsatisfactory micro-insert location

1. Bilateral micro-insert expulsion with bilateral occlusion: the patient should be counselled about the option to have incisional sterilisation or to rely on her bilateral PTO for contraception, in light of the potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG).
2. Bilateral micro-insert expulsion with occlusion in one tube and patency in contralateral tube: the patient may be considered for an additional micro-insert procedure to replace the micro-insert in the tube that is patent, so that she may be able to rely on one **Essure** micro-insert and contralateral PTO for contraception. The patient should be counselled regarding this option, in light of the potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG). She should also be counselled about the option to have incisional sterilisation.
3. Unilateral micro-insert expulsion or unsatisfactory unilateral micro-insert location (in myometrium or intraperitoneal cavity), with contralateral micro-insert in a satisfactory location: if the **Essure** Confirmation Test (HSG) demonstrates tubal blockage in the tube from where the micro-insert was expelled or where the micro-insert should have been placed, the patient may rely on the satisfactorily located micro-insert and the contralateral PTO, in light of the potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG). She should also be counselled regarding the option to undergo incisional sterilisation.
4. Unsatisfactory unilateral micro-insert location (in myometrium or intraperitoneal cavity) with contralateral micro-insert in a satisfactory location: if the **Essure** Confirmation Test (HSG) demonstrates tubal patency in the tube that should have been placed with a micro-insert, the patient may be offered the opportunity to return for an additional micro-insert placement procedure to re-attempt placement. She should also be counselled regarding the option to undergo incisional sterilisation.
5. Unilateral micro-insert expulsion; unsatisfactory unilateral micro-insert location (in myometrium or intraperitoneal cavity); unsatisfactory unilateral micro-insert location in “proximal location” (> 50% of inner coil length trailing into uterus) or “distal location” (micro-insert in fallopian tube, but proximal end of inner coil is > 30 mm from contrast filling the uterine cornua) with contralateral micro-insert in an unsatisfactory location: the patient should be counselled regarding the option to undergo incisional sterilisation. In all cases, if the micro-insert removal is deemed necessary and hysteroscopic removal is not possible, incisional surgery may be required.
6. If a patient has opted for incisional sterilisation following any of the above listed scenarios, both tubes should be occluded regardless of any remaining micro-insert that is in a satisfactory location. An attempt should be made to retrieve a micro-insert if the physician believes it can be done safely, however micro-insert retrieval may not be possible. Use of intra-operative fluoroscopy is recommended to identify the location of the micro-insert(s) prior to and during surgery. Attempted retrieval should not exceed 30 minutes.

XI. Management of cases with unsuccessful Essure micro-insert placement

In the event of unilateral or bilateral micro-insert placement failure, the patient should be informed that her permanent contraception has not been completed. If the patient chooses laparoscopic sterilisation (i.e., clip application or electrical cautery), both fallopian tubes should be clipped or cauterised even if one tube has the **Essure** micro-insert implanted in it. Clipping or cauterising of the tube or tubes should be performed distal to the **Essure** micro-insert.

If the patient does not select laparoscopic sterilisation, she may be offered an **Essure** Confirmation Test (HSG) after her next menses (pre-ovulatory: day 7-14 where day 1 represents the first day of bleeding) to determine tubal patency. If tubal patency is observed, the physician may offer the patient a second attempt at micro-insert placement. If a second attempt at micro-insert placement fails, the patient is unlikely to have success with subsequent attempts. If the patient has one micro-insert left *in vivo*, she should be counselled not to rely on the unilateral micro-insert for contraception.

If only unilateral placement was achieved and the **Essure** Confirmation Test (HSG) confirms contralateral proximal tubal occlusion (PTO), the patient should be counselled regarding the option to rely on the one micro-insert, in light of the potential for a false positive diagnosis of PTO by **Essure** Confirmation Test (HSG). Tubal occlusion is defined as the failure of dye to pass from the uterine cavity into the peritoneal cavity at the time of an **Essure** Confirmation Test (HSG). She should also be counselled about the option to have incisional sterilisation. An attempt to remove a unilaterally placed micro-insert is not recommended, unless the patient is experiencing an adverse event(s) with the micro-insert.

XII. Essure micro-insert removal

WARNING: MICRO-INSERT REMOVAL SHOULD NOT BE ATTEMPTED HYSTEROSCOPICALLY ONCE THE MICRO-INSERT HAS BEEN PLACED, UNLESS 18 OR MORE COILS OF THE ESSURE MICRO-INSERT ARE TRAILING INTO THE UTERINE CAVITY. Removal of such a micro-insert should be attempted immediately following placement. However, removal may not be possible. If removal is attempted, the following steps should be employed:

1. Introduce a grasping instrument through the hysteroscope working channel.
2. Grasp the outer coil of the **Essure** micro-insert. Try to grasp the outer and inner coil of the micro-insert together.
3. Pull back on the grasping instrument and the hysteroscope at the same time, so that the entire system is withdrawn from the uterus in concert.
4. The outer coil and/or the inner coil of the **Essure** micro-insert may stretch or elongate as micro-insert removal is being attempted.
5. As necessary, administer analgesia/anaesthesia to reduce or prevent patient discomfort.
6. If complete micro-insert removal is accomplished, an attempt should be made to place another **Essure** micro-insert.
7. If the physician is not completely satisfied that the entire **Essure** micro-insert has been removed from the fallopian tube, another micro-insert should **NOT** be placed in that tube and a post-placement x-ray should be taken to determine if a micro-insert fragment remains *in vivo*.

Other than the above described scenario, micro-insert removal should only be attempted if a patient is experiencing an adverse event(s) with the micro-insert or if she demands micro-insert removal.

Should micro-insert removal be deemed necessary, a transabdominal approach (i.e., laparotomy or laparoscopy) is required.

A cornual resection of the proximal fallopian tube will be required if the micro-insert is properly located across the utero-tubal junction (UTJ).

An **Essure** micro-insert that has been improperly placed or has migrated beyond the UTJ should be removed with traditional linear salpingotomy or salpingectomy accomplished via laparoscopy or laparotomy.

1. To perform a linear salpingotomy, a small incision (approximately 2 cm in length) is made along the antimesenteric border of the fallopian tube, directly overlying the micro-insert.
2. Total or partial salpingectomy can be performed to retrieve the micro-insert along with, or independent of, the performance of a traditional tubal sterilisation procedure.

XIII. Patient identification card

Each patient who has had **Essure** micro-insert(s) implanted should be given a laminated, wallet-sized card stating that she has **Essure** micro-insert(s) in place. **The card is enclosed in this package.** The card will additionally state that there may be risks associated with the participant undergoing future intrauterine procedures or surgery of the reproductive organs.

XIV. Legend of Symbols

STERILE EO	Sterilised using ethylene oxide
LOT	Batch code
	Do not reuse
REF	Catalogue number
	Attention, see Instructions for Use
	Use by
	Keep away from heat
	Do not use if package is open or damaged
MR	MR Conditional
EC REP	Authorised European Representative
CE 0050	Device complies with European Directive 93/42/EC
	Keep dry
CONT	Content

Manufactured by:
Bayer Healthcare LLC
1011 McCarthy Boulevard
Milpitas, CA 95035
USA
essure.com

European Authorised Representative:
Bayer Pharma AG
Müllerstr. 178
D-13353 Berlin
Germany

For product ordering or reporting of adverse events, please contact local Bayer Healthcare LLC representative.

Recyclable

Italiano

essure®

Controllo permanente delle nascite

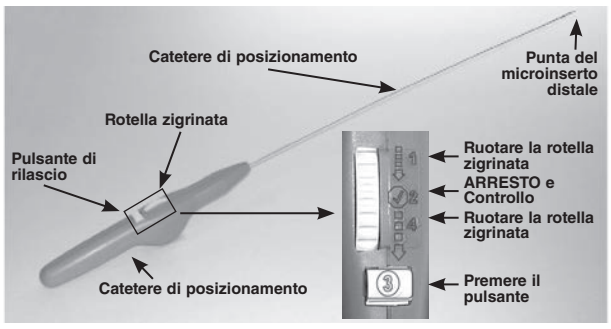
BAYER

ISTRUZIONI PER L'USO

I. Descrizione del microinserto

Il sistema di controllo permanente delle nascite **Essure**® è costituito da diversi componenti. Il microinserto **Essure**, un dispositivo ad espansione dinamica, è fissato ad un filo di posizionamento e ad un catetere di rilascio. Il gruppo è contenuto in una guaina all'interno di un catetere di posizionamento. Questo sistema (illustrato in Figura 1) è dotato di un'impugnatura che agevola il posizionamento e l'impianto del microinserto. Il sistema **Essure** comprende inoltre un introduttore dotato di valvola, l'introduttore **DryFlow**®, la cui funzione è di proteggere il microinserto **Essure** quando viene fatto passare attraverso l'apertura di gomma del canale operativo dell'isteroscopio.

Figura 1
Sistema di posizionamento Essure
con dettagli dei simboli relativi alla procedura di posizionamento
(NON IN SCALA)



II. Meccanismo di azionamento

Sotto visualizzazione isteroscopica, il sistema **Essure** consente l'impianto di un microinserto **Essure** nella sezione prossimale del lume della tuba di Falloppio. Quando al momento del rilascio il microinserto **Essure** si espande, si ancora ad angolo acuto nella tuba di Falloppio. Successivamente, il microinserto stimola una risposta tissutale positiva prevista che porta ad una endoproliferazione tissutale; ciò determina il saldo ancoraggio del microinserto nella tuba di Falloppio. Questa risposta positiva dei tessuti è di natura localizzata, fibrotica e occlusiva.

Ogni sistema **Essure** è sterilizzato con ossido di etilene, viene fornito sterile ed è esclusivamente monouso. Non riutilizzare o risterilizzare. La risterilizzazione potrebbe influire negativamente sull'accurato funzionamento meccanico del sistema **Essure** e potrebbe causare lesioni alla paziente.

III. Indicazioni per l'uso

Il sistema **Essure** è costituito da un microinserto indicato per l'occlusione delle tube a scopo di contraccezione permanente.

IV. Controindicazioni per l'uso

- Incertezza della paziente sul desiderio di interrompere in modo permanente la fertilità.
- Gravidanza o gravidanza sospetta.
- Parto o interruzione di una gravidanza nel secondo trimestre avvenuti meno di sei settimane prima del posizionamento del microinserto **Essure**.
- Infezione pelvica attiva o recente.
- Cervicite acuta non trattata.
- Emorragia vaginale grave o non spiegata.
- Tumore maligno ginecologico (sospetto o noto).
- Cavità uterina con anomalie note o tube di Falloppio che rendono difficile o impossibile la visualizzazione degli orifizi tubarici e/o l'incannulamento della tuba di Falloppio prossimale.
- Allergia ai mezzi di contrasto (tre mesi dopo il posizionamento del microinserto può essere necessaria un'isterosalpingografia).
- La paziente sta attualmente assumendo corticosteroidi.

V. Avvertenze

- La procedura **Essure** deve essere eseguita solo da medici esperti che hanno completato il programma formativo di *Bayer HealthCare LLC* Ilergici al nichel titanio possono presentare una reazione allergica al microinserto.
- Non usare il sistema **Essure** se la confezione è stata aperta o danneggiata. Non usare il microinserto se appare danneggiato.
- Durante l'introduzione del microinserto **Essure** nella tuba di Falloppio, non farlo avanzare se si avverte una resistenza eccessiva.
- Non continuare a far avanzare il sistema **Essure** quando il marker di posizionamento sul catetere raggiunge l'orifizio tubarico. L'ulteriore avanzamento può compromettere il posizionamento del microinserto o causare la perforazione tubarica/uterina.
- In caso di perforazione tubarica accertata o sospetta, interrompere il tentativo di posizionamento del microinserto **Essure**. Una piccolissima percentuale delle donne coinvolte negli studi clinici **Essure** (1,8% o 12/682 pazienti) ha riportato perforazioni tubariche correlate al dispositivo. La rimozione dei microinserti correlati a perforazione, se necessaria, richiede un intervento laparoscopico o chirurgico di altro tipo.
- Se non si riesce ad impiantare con successo il microinserto **Essure** dopo aver tentato di incannulare ciascuna tuba per 10 minuti, interrompere la procedura e fissare un altro appuntamento, se possibile.
- Una volta posizionato (cioè staccato dal filo di posizionamento), il microinserto non deve essere rimosso tramite isteroscopia, a meno che non vi siano 18 o più spirali del microinserto **Essure** poste più indietro nella cavità uterina. Se un microinserto si presenta in questo modo, la rimozione deve essere effettuata subito dopo il posizionamento. La rimozione, tuttavia, potrebbe non essere possibile.
- La paziente deve usare un metodo di contraccezione alternativo fino a tre mesi dopo l'impianto del microinserto quando, tramite radiografia, si procederà alla verifica del corretto posizionamento.
- Le pazienti sottoposte all'impianto del microinserto **Essure** possono, in futuro, usufruire di terapie intrauterine che utilizzano energia elettrica. Si raccomanda di evitare l'elettrocauterio in interventi chirurgici condotti sui corni uterini e sulle tube di Falloppio. Per qualsiasi altro intervento nella pelvi, l'uso dell'elettrocauterio va evitato entro 4 cm dal microinserto. A causa della presenza dei microinserti **Essure**, vi possono essere rischi associati a procedure che, al momento, non sono state identificate.
- Qualsiasi procedura intrauterina come la biopsia endometriale, la dilatazione e il raschiamento, l'isteroscopia (diagnostica o operativa) compresa l'ablazione endometriale potrebbe compromettere la capacità dei microinserti di impedire la gravidanza. La presenza dei microinserti **Essure** potrebbe, inoltre, comportare rischi associati a procedure che, al momento, non sono state identificate.
- Gli studi clinici e di laboratorio hanno dimostrato che l'ablazione endometriale dell'utero può essere eseguita efficacemente e in sicurezza con il sistema uterino a palloncino GYNECARE THERMACHOICE*, il sistema di ablazione endometriale Hologic NovaSure** e il Boston Scientific Hydro ThermAblator*** **immediatamente dopo** il posizionamento del microinserto **Essure**. Non è stato condotto alcuno studio specifico volto a valutare i tassi di espulsione o di contraccezione del microinserto **Essure** a seguito delle procedure combinate **Essure** e di ablazione endometriale.
- Le pazienti possono decidere in futuro di sottoporsi alla fecondazione in vitro per rimanere incinte. Gli effetti dei microinserti **Essure** sul successo della fecondazione in vitro non sono noti. In caso di gravidanza, i rischi del microinserto per la paziente, per il feto e per il proseguimento della gravidanza stessa non sono noti.

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** Marchio di fabbrica di Hologic, Inc.
*** Marchio di fabbrica di Boston Scientific Corporation

VI. Precauzioni

- Quando è possibile, il posizionamento del microinserto deve essere eseguito durante i giorni 7-14 del ciclo mestruale (dove il giorno 1 rappresenta il primo giorno di mestruazione) per ottenere una migliore visualizzazione degli orifizi delle tube di Falloppio e ridurre la possibilità di posizionamento del microinserto in una paziente con una gravidanza non diagnosticata.
- Un'anatomia uterina insolita può rendere difficoltoso il posizionamento dei microinserti **Essure**.
- Per ridurre il rischio di perforazione uterina, la procedura va interrotta se, per ottenere la dilazione cervicale, è necessario applicare una forza eccessiva.
- Prima di procedere al posizionamento dei microinserti **Essure** occorre identificare entrambi gli orifizi tubarici ed esaminarli tramite isteroscopia. Non collocare il microinserto in un solo orifizio tubarico senza aver prima accertato che vi siano sufficienti probabilità che la tuba opposta sia accessibile e pervia.
- L'esecuzione dell'ablazione endometriale immediatamente dopo il posizionamento del microinserto **Essure** può aumentare il rischio di sindrome da sterilizzazione tubarica post-ablazione, una condizione rara riportata in donne con anamnesi di sterilizzazione tubarica sottoposte ad ablazione endometriale.
- Non far avanzare il sistema **Essure** se la paziente avverte molto dolore o fastidio.
- Conservare il sistema **Essure** in luogo fresco e asciutto.

VII. Possibili effetti indesiderati

A. Gravidanza

Esiste il rischio di gravidanza e di gravidanza extrauterina con rischi associati al trattamento di entrambe le condizioni. Se la paziente rimane incinta e sceglie di portare avanti la gravidanza, deve essere informata che non sono noti i rischi del microinserto per se stessa, per il feto e per la continuazione della gravidanza.

B. Rischi associati alla procedura di posizionamento del microinserto

- È possibile somministrare alla paziente anestesia locale, analgesia/sedazione orale, anestesia regionale (ovvero spinale, epidurale), sedazione orale o cosciente (endovenosa), o anestesia generale per prevenire o ridurre il fastidio. Indipendentemente dal tipo di anestesia somministrato, le pazienti possono non essere in grado di riprendere le normali attività per 12-24 ore dopo la procedura.
- Durante o dopo la procedura di posizionamento del microinserto possono manifestarsi contrazioni muscolari, dolore e sanguinamento vaginale. In genere, queste manifestazioni sono tollerabili, transitorie e vengono trattate con successo mediante farmaci.
- Durante e/o subito dopo la procedura di posizionamento del microinserto, esiste il rischio che la paziente sia soggetta a nausea o vomito. Questi sintomi dovrebbero essere transitori e possono essere trattati con farmaci, secondo necessità.
- Le pazienti possono essere soggette a svenimento o a risposta vasovagale il giorno della procedura.
- Esiste il rischio di perforazione o dissezione della tuba di Falloppio o dei corni uterini, con possibile conseguente sanguinamento e formazione di cicatrici. Tuttavia, in genere non è necessario alcun trattamento.
- Esiste il rischio di perforazione uterina causata dall'isteroscopio, dal sistema **Essure** o da altri strumenti usati durante la procedura con possibili lesioni all'intestino, alla vescica e ad importanti vasi ematici. Nel caso si verifichino lesioni di questo tipo, può essere necessario, anche se poco probabile, intervenire chirurgicamente. Per ridurre il rischio di perforazione uterina, la procedura va interrotta se, per ottenere la dilazione cervicale, è necessario applicare una forza eccessiva.
- Esiste il rischio che il microinserto **Essure** possa essere inavvertitamente posizionato nel miometrio dell'utero anziché nel lume della tuba di Falloppio. Se un microinserto è già stato correttamente impiantato in una tuba di Falloppio, oltre all'inavvertito posizionamento nel miometrio, il medico può tentare di collocare un terzo microinserto per completare la procedura. Se non si ottiene il posizionamento bilaterale nelle tube di Falloppio, si può verificare la situazione, inefficace ai fini della contraccezione, in cui la paziente ha un microinserto nella tuba di Falloppio e/o un microinserto nel miometrio. Il posizionamento del microinserto nel miometrio può causare dolore o altri eventi indesiderati dopo la procedura chirurgica. Qualora occorra rimuovere i microinserti, potrebbe essere necessario eseguire una salpingectomia o una isterectomia.
- Esiste il rischio che il microinserto **Essure** possa essere collocato in posizione troppo distale nella tuba di Falloppio. Qualora si renda necessario rimuovere il microinserto, si dovrà procedere chirurgicamente (in laparoscopia o laparotomia).
- Esiste il rischio che il microinserto **Essure** possa essere collocato in posizione troppo prossimale nella tuba di Falloppio. Se al momento del posizionamento sono visibili 18 o più spirali del microinserto **Essure**, si deve procedere immediatamente alla rimozione del microinserto (vedere la sezione XIII, Rimozione del microinserto **Essure**). Nel tentativo di rimozione del microinserto esiste la possibilità che la rimozione non riesca o che il microinserto **Essure** si rompa e che un frammento di esso rimanga *in vivo*. Se si tenta di rimuovere il microinserto e/o si porta a termine la rimozione, esiste inoltre la possibilità che la paziente avverta dolore e contrazioni muscolari con sanguinamento durante e dopo la procedura di posizionamento del microinserto **Essure**.
- Esiste il rischio che il microinserto **Essure** possa perforare la parete tubarica o i corni uterini con conseguente sconfinamento del microinserto nella cavità peritoneale. In tal caso, dopo la procedura si possono manifestare dolore e/o disturbi mestruali o altri eventi indesiderati. Se la paziente sceglie di sottoporsi a sterilizzazione con resezione o legatura delle tube o un altro intervento chirurgico, si può tentare di recuperare il microinserto dalla cavità peritoneale, se il medico ritiene che sia sicuro farlo. Il recupero del microinserto può, tuttavia, non essere possibile se il medico non riesce a visualizzarlo o ad accedervi.
- Esiste il rischio che il posizionamento del microinserto **Essure** possa essere effettuato solo in una tuba di Falloppio. In tal caso, le pazienti possono rimanere con un microinserto *in vivo*, condizione tuttavia inefficace ai fini della contraccezione permanente.
- Esiste il rischio che il posizionamento del microinserto **Essure** non sia possibile in entrambe le tube di Falloppio.
- Esiste il rischio minimo che un eccessivo assorbimento di soluzione fisiologica, usata per la distensione dell'utero, impedisca la procedura isteroscopica.
- Come nel caso di tutte le procedure invasive, la procedura di posizionamento del microinserto può causare un'infezione, con conseguente danneggiamento dell'utero, delle tube di Falloppio o della cavità pelvica. In tal caso occorre somministrare una terapia antibiotica; raramente si procede all'ospedalizzazione o a interventi chirurgici, tra cui l'isterectomia.

C. Rischi associati all'uso del microinserto Essure

- Esiste il rischio che il microinserto **Essure** possa fuoriuscire dalle tube di Falloppio, per espulsione (dalla tuba con penetrazione nella cavità/cervice/vagina o fuoriuscita dal corpo) o per migrazione (verso il segmento distale della tuba di Falloppio o espulsione dalla tuba e penetrazione nella cavità peritoneale). Per identificare la posizione dei microinserti può essere necessario eseguire delle radiografie e, se necessario, procedere chirurgicamente per rimuoverli. Lo spostamento del dispositivo può causare gravidanza, gravidanza extrauterina e/o dolore/disturbi mestruali o altri eventi indesiderati.
- Analogamente agli attuali metodi meccanici di contraccezione permanente (ovvero clip, anelli), l'eventuale rimozione del microinserto **Essure** deve essere effettuata chirurgicamente. È inoltre possibile che sia necessaria la rimozione chirurgica delle tube di Falloppio (salpingectomia) e dell'utero (isterectomia).
- Possono manifestarsi contrazioni muscolari e dolore di natura addominale/pelvica. Esiste una maggiore probabilità di dolore e contrazioni muscolari durante il periodo mestruale, durante e dopo un rapporto sessuale o con altre attività fisiche.
- Esiste la possibilità di perdite ematiche tra i cicli mestruali o emorragia più abbondante del solito durante il periodo mestruale.
- Talvolta può accadere che la donna si penta di essersi sottoposta alla contraccezione permanente e che sia soggetta quindi ad una lieve depressione o ad altri disturbi emotivi.

D. Rischi associati alle procedure di follow-up

- Esiste il rischio di esposizione a radiazioni durante la radiografia pelvica necessaria a tre mesi dall'impianto del microinserto per valutarne la posizione. Può anche essere necessario un test di conferma (isterosalpingografia) **Essure**. La fluoroscopia (<30 secondi) effettuata in una procedura di isterosalpingografia contiene circa 0,033 rad. Come termine di confronto, un clisma baritato espone ad una dose di radiazioni pari a 0,85 rad, che è maggiore di quella richiesta dal test di conferma (isterosalpingografia) **Essure**. La quantità di radiazioni a cui espone una radiografia pelvica è approssimativamente pari alla quantità di radiazioni di fondo naturali a cui un individuo è esposto nel corso di un anno.
- Di seguito sono riportati i rischi associati al test di conferma (isterosalpingografia) **Essure**, se necessaria: risposta vasovagale; infezione, che può richiedere una terapia antibiotica e in casi rari ospedalizzazione; intravascolarizzazione; perforazione dell'utero; contrazioni uterine e/o sanguinamento; dolore e fastidio; reazione allergica al lattice. Sono stati riportati rari casi di associazione tra la reazione al lattice e reazioni anafilattiche che possono rivelarsi fatali.
- In alcuni pazienti, l'uso dei mezzi di contrasto, utilizzati per eseguire il test di conferma (isterosalpingografia) **Essure**, è stato associato ad una reazione allergica che può provocare orticaria o difficoltà respiratorie. In alcuni individui, si può verificare una reazione anafilattica che può causare decesso.

E. Rischi associati a eventuali procedure future

- Alle pazienti sottoposte all'impianto del microinserto **Essure** potrebbero, in futuro, essere proposte terapie intrauterine che utilizzano energia elettrica. Si raccomanda di evitare l'elettrocauterio in interventi chirurgici condotti sui corni uterini e sulle tube di Falloppio. Per qualsiasi altro intervento nella pelvi, l'uso dell'elettrocauterio va evitato entro 4 cm dal microinserto. A causa della presenza dei microinserti **Essure**, vi possono essere rischi associati a procedure che, al momento, non sono state identificate.
- Qualsiasi procedura intrauterina come la biopsia endometriale, la dilatazione e il raschiamento, l'isteroscopia (diagnostica o operativa) compresa l'ablazione endometriale potrebbe compromettere la capacità dei microinserti di impedire la gravidanza. La presenza dei microinserti **Essure** potrebbe, inoltre, comportare rischi associati a procedure che, al momento, non sono state identificate.
- Le pazienti possono decidere in futuro di sottoporsi alla fecondazione in vitro per rimanere incinte. Gli effetti dei microinserti **Essure** sul successo della fecondazione in vitro non sono noti. In caso di gravidanza, i rischi del microinserto per la paziente, per il feto e per il proseguimento della gravidanza stessa non sono noti.
- I microinserti **Essure** sono radiopachi e sicuri in procedure diagnostiche di risonanza magnetica. I microinserti **Essure** sono inoltre compatibili con la risonanza magnetica, tranne in esami di diagnostica per immagini sulla pelvi, dove possono causare artefatti.
- **Esiste la possibilità di rischi non noti.**

VIII. Istruzioni per l'uso

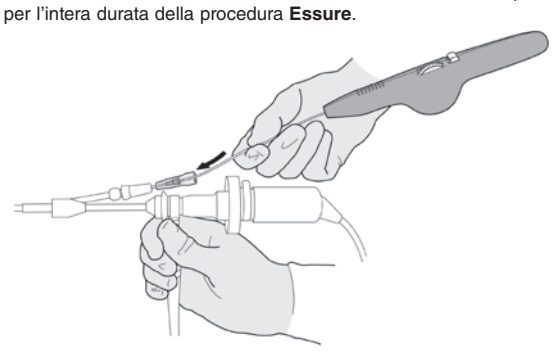
A. Prima della procedura di posizionamento del microinserto

1. Il posizionamento del microinserto deve essere eseguito durante i giorni 7-14 del ciclo mestruale (dove il giorno 1 rappresenta il primo giorno di mestruazione) per ottenere una migliore visualizzazione degli orifizi delle tube di Falloppio e ridurre la possibilità di posizionamento del microinserto in una paziente con una gravidanza non diagnosticata.
2. Un test di gravidanza (condotto da un medico o da un operatore medico-sanitario su ordine del medico) deve essere eseguito entro 24 ore prima o immediatamente prima della procedura di posizionamento del microinserto.
3. Poiché i dati ottenuti mediante studi clinici hanno dimostrato che l'uso di un farmaco antinfiammatorio non steroideo (FANS) aumenta notevolmente le probabilità di riuscita della procedura, si raccomanda vivamente la somministrazione di un FANS, ad esempio Indocid (per via orale o in supposte), una o due ore prima della procedura di posizionamento del microinserto. Se si usa solo un blocco paracervicale, 30 minuti prima della procedura è possibile somministrare anche Diazepam (PO) o un agente simile per ridurre l'ansia.

B. Procedura di posizionamento del microinserto Essure

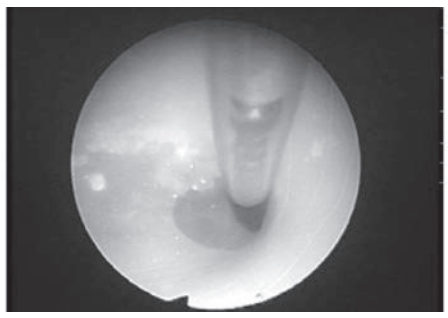
La procedura di posizionamento del microinserto **Essure** può essere eseguita in una struttura ambulatoriale o "day hospital". Durante la procedura di posizionamento del microinserto si deve usare una tecnica sterile. La durata della procedura di posizionamento del microinserto non deve essere superiore a 30 minuti.

1. Collocare la paziente nella posizione di litotomia.
2. Introdurre nella vagina uno speculo che consente l'accesso alla cervice. Medicare la cervice con Betadine o un'altra soluzione antibatterica idonea secondo la prassi normale.
3. L'anestesia locale è il metodo preferito per l'impianto dei microinserti. Si può somministrare un blocco paracervicale. Se necessario, si può somministrare anche Midazolam (per via endovenosa), o una soluzione simile, per prevenire o ridurre il fastidio.
4. Inserire un isteroscopio sterile, a cui sono fissati la telecamera e il canale operativo (≥ da 5 F), attraverso la cervice fino all'interno della cavità uterina. Se necessario, effettuare la dilatazione cervicale per agevolare l'inserimento. Per evitare la perforazione uterina, la procedura va interrotta se, per ottenere la dilazione cervicale, è necessario applicare una forza eccessiva.
5. La distensione della cavità uterina si ottiene con l'infusione di soluzione fisiologica attraverso il canale operativo dell'isteroscopio. Si raccomanda vivamente di riscaldare la soluzione fisiologica fino a raggiungere la temperatura corporea prima dell'infusione e di introdurla a caduta libera in modo da ridurre al minimo lo spasmo delle tube di Falloppio. È importante raggiungere una perfetta distensione uterina e mantenerla nel corso dell'intera procedura, seguendo inoltre le normali procedure di monitoraggio dei fluidi. Identificare gli orifizi delle tube di Falloppio mediante visualizzazione isteroscopica.
6. Prima di procedere al posizionamento dei microinserti **Essure** occorre identificare entrambi gli orifizi tubarici ed esaminarli tramite isteroscopia. Non collocare il microinserto in un solo orifizio tubarico senza aver prima accertato che vi siano sufficienti probabilità che la tuba opposta sia pervia.
7. Una volta identificati gli orifizi delle tube di Falloppio, inserire l'introduttore attraverso il cappuccio di tenuta presente sul canale operativo dell'isteroscopio. Il rubinetto del canale operativo deve rimanere in posizione aperta (il dispositivo e/o l'introduttore possono essere danneggiati se viene chiuso il rubinetto su uno o entrambi i dispositivi). Inserire il sistema di posizionamento **Essure** nell'introduttore e farlo avanzare attraverso il canale operativo dell'isteroscopio. Se non è stato danneggiato durante il primo posizionamento del microinserto, l'introduttore dotato di valvola può rimanere nel canale operativo per l'intera durata della procedura **Essure**.



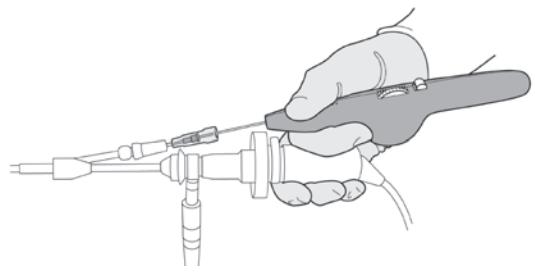
Inserire l'introduttore nel cappuccio di tenuta presente sul canale operativo dell'isteroscopio e poi inserire il sistema di posizionamento **Essure** *nell'introduttore.*

8. Far avanzare il sistema di posizionamento **Essure** nella tuba di Falloppio prossimale con un movimento lento e regolare per evitare lo spasmo tubarico. Far avanzare il sistema di posizionamento finché il marker sul catetere di posizionamento raggiunge l'orifizio della tuba di Falloppio. Questo marker visivo indica che il microinserto **Essure** sta estendendo il segmento intramurale distale fino all'istmo prossimale della tuba di Falloppio, con la spirale esterna distesa attraverso la congiunzione uterotubarica. Questa è la posizione ideale del microinserto **Essure**.



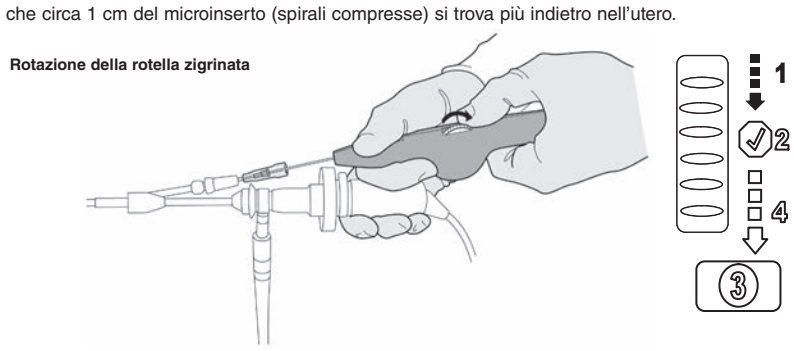
Far avanzare il sistema fino a quando il marker nero di posizionamento si trova in corrispondenza dell'orifizio tubarico. Questo è l'indicatore visivo della corretta posizione di impianto del sistema.

9. Il corretto allineamento concentrico del catetere di posizionamento con il lume della tuba è indicato dalla capacità di far avanzare il catetere con visualizzazione diretta senza eccessiva resistenza. La resistenza all'avanzamento si manifesta in genere in due modi: 1) il marker nero sulla superficie esterna del catetere non avanza verso l'orifizio tubarico, e/o 2) il catetere di posizionamento si piega o si flette eccessivamente, impedendo così al medico di spingere in avanti il gruppo del catetere. Quando si avverte tale resistenza all'avanzamento del catetere, si deve interrompere la procedura di posizionamento del microinserto per evitare la possibilità di perforazione uterina o l'involontario posizionamento del microinserto nella muscolatura dell'utero anziché nel lume della tuba. Per determinare la pervietà della tuba, eseguire un test di conferma (isterosalpingografia) **Essure**.
10. Se dopo diversi minuti non si riesce a far avanzare il catetere fino al marker di posizionamento, si può eseguire un test di perfusione con un catetere di pervietà, se non è già stato fatto, per determinare la pervietà tubarica. Se la tuba è ostruita o non si riesce a far avanzare il catetere fino al marker di posizionamento, interrompere la procedura. Se non si riesce ad impiantare con successo il microinserto dopo aver tentato di incannulare ciascuna tuba per 10 minuti, interrompere la procedura.
11. Impiantare il microinserto dopo aver fatto avanzare il catetere fino al marker di posizionamento. Stabilizzare innanzitutto l'impugnatura del microinserto **Essure** spingendola contro la telecamera dell'isteroscopio o un altro oggetto fisso per impedire un involontario movimento in avanti del sistema **Essure** durante il ritiro del catetere di posizionamento.



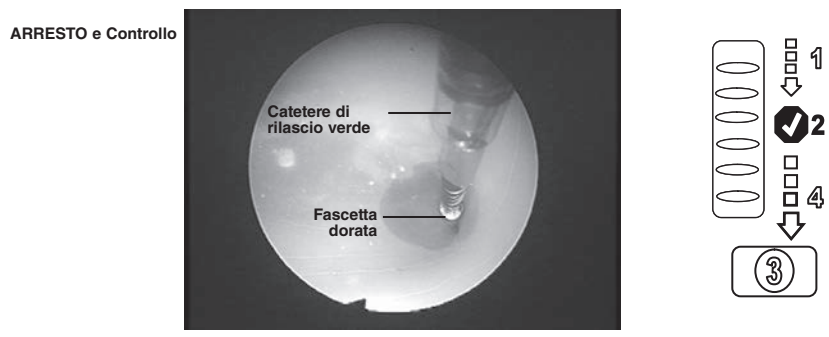
Stabilizzare l'impugnatura spingendola contro la testina della telecamera o un altro oggetto fisso per impedire un involontario movimento in avanti del sistema **Essure***.*

12. Dopo essersi accertati che il marker di posizionamento nero si trovi in corrispondenza dell'orifizio della tuba di Falloppio, ruotare la rotella zigrinata sull'impugnatura verso l'operatore, fermandosi quando la rotella non si muove più. Questa operazione corrisponde al simbolo 4 situato sull'impugnatura del sistema di posizionamento. In questo modo si agevola il ritiro del catetere di posizionamento . Si osserverà il marker di posizionamento nero allontanarsi dall'orifizio della tuba (verso l'isteroscopio) e scomparire nel canale operativo. Il ritiro del catetere di posizionamento espone il microinserto **Essure** compresso . Durante il ritiro del catetere di posizionamento, si dovrebbe notare che circa 1 cm del microinserto (spirali compresse) si trova più indietro nell'utero.



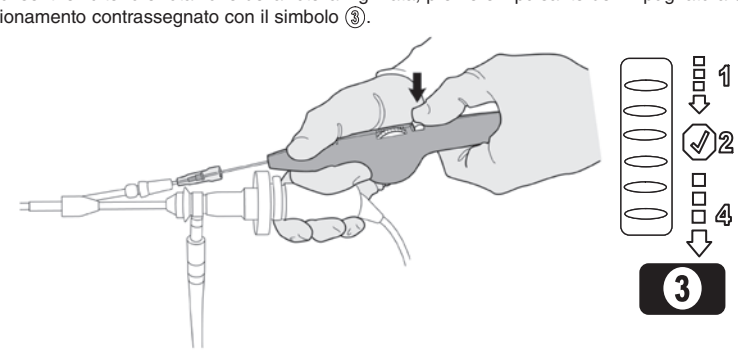
Rotazione della rotella zigrinata per il ritiro del catetere

13. Per confermare il corretto posizionamento, collocare la fascetta dorata del marker appena al di fuori dell'orifizio, che corrisponde al simbolo 2 sull'impugnatura del sistema di posizionamento. La visualizzazione della fascetta dorata appena al di fuori dell'orifizio e la visualizzazione della punta distale del catetere di rilascio verde confermerà il corretto posizionamento. Se nell'utero è visibile più di 1 cm di microinserto, prima di procedere all'operazione successiva riposizionare, se possibile, il microinserto spostando ulteriormente nella tuba l'intero sistema.



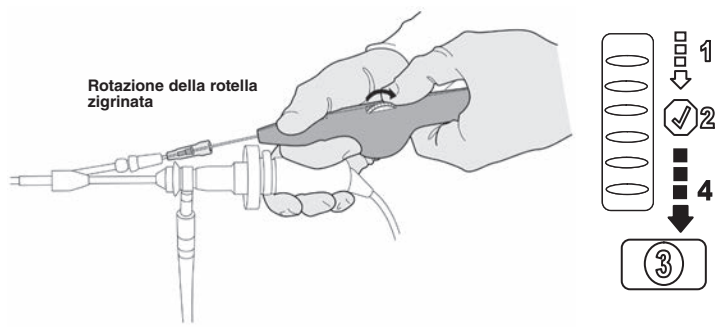
Visualizzazione della fascetta dorata in corrispondenza dell'orifizio

14. Per consentire l'ulteriore rotazione della rotella zigrinata, premere il pulsante dell'impugnatura di posizionamento contrassegnato con il simbolo 3.



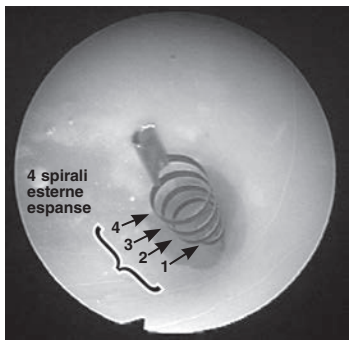
Per consentire alla rotella zigrinata di ruotare di nuovo, premere il pulsante.

15. Ruotare la rotella zigrinata verso l'operatore per impiantare la spirale esterna del microinserto, che corrisponde al simbolo 4 situato sull'impugnatura del sistema di posizionamento. Continuare a ruotare la rotella zigrinata fino a quando si arresta. Quando non è più possibile ruotare ulteriormente la rotella e le spirali esterne espanse diventano visibili, ritirare il sistema.



Ruotare la rotella per impiantare la spirale esterna del microinserto.

16. La posizione del microinserto **Essure** impiantato verrà valutata sotto osservazione isteroscopica. Idealmente, dovrebbero esserci da 3 a 8 spirali esterne espanse del microinserto più indietro nell'utero.



Spirali esterne espanse del microinserto **Essure** *più indietro nell'utero: questo assetto indica la posizione ideale*

17. Se il medico non è soddisfatto del posizionamento del microinserto in base alla visualizzazione isteroscopica, o sospetta la perforazione tubarica o uterina, deve lasciare il microinserto dove si trova ed eseguire una radiografia della pelvi o isterosalpingografia a tre mesi dalla procedura di posizionamento.

    AVVERTENZA - UNA VOLTA POSIZIONATO NELLA TUBA DI FALLOPPIO, IL MICROINSERTO NON DEVE ESSERE RIMOSSO TRAMITE ISTEROSCOPIA, A MENO CHE NON VI SIANO 18 O PIÙ SPIRALI DEL MICROINSERTO ESSURE POSTE PIÙ INDIETRO NELLA CAVITÀ UTERINA. Se un microinserto si presenta in questo modo, la rimozione deve essere effettuata immediatamente durante la procedura di posizionamento. La rimozione, tuttavia, può non essere possibile (vedere la sezione XIII, Rimozione del microinserto **Essure**). Se il microinserto è stato inavvertitamente impiantato nella cavità uterina anziché nella tuba, occorre rimuoverlo dall'utero e tentare nuovamente di posizionarlo nella tuba.
18. Ripetere la procedura di posizionamento del microinserto **Essure** nella tuba di Falloppio controlaterale.
19. Annotare la lunghezza della porzione di microinserto che si trova più indietro nella cavità uterina, rilevando eventuali particolari che identifichino o confermino uno degli orifizi tubarici o altre problematiche indicanti un'eventuale perforazione. Queste annotazioni devono essere fatte nella cartella clinica della paziente per riferimento futuro quando si esamina il test di conferma Essure *(vedere la successiva sezione IX , Test di conferma Essure).*
20. **Ricordare alla paziente di usare mezzi di contraccezione alternativi (ma non un contraccettivo intrauterino) per almeno i primi 3 mesi dopo la procedura di posizionamento del microinserto.**
21. Fissare un appuntamento con la paziente per sottoporla ad un test di conferma **Essure** a tre mesi dalla procedura di impianto del microinserto **Essure** per valutarne la posizione e la stabilità.

IX. Test di Conferma Essure

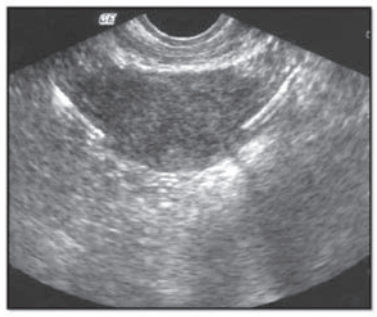
A. A tre mesi dall'impianto del microinserto occorre eseguire un Test di Conferma **Essure** per valutarne la posizione e la stabilità. I Test di Conferma **Essure** (ecografia transvaginale (TVU), radiografia pelvica o isterosalpingografia (HSG)) devono essere effettuati unicamente da un ginecologo, ecografista e/o radiologo esperto, formati sui rispettivi protocolli di test di conferma **Essure**. Un protocollo dettagliato con immagini e consigli per l'esecuzione del test viene fornito durante il training formativo; è possibile scaricare copie aggiuntive dal sito essure.com.

B. Per il test di conferma di prima linea, è possibile effettuare sia una radiografia pelvica sia un'ecografia transvaginale a tre mesi di distanza da una procedura di posizionamento bilaterale del microinserto priva di complicanze.

1. Nelle circostanze che seguono non si devono effettuare radiografie ed ecografie transvaginali come Test di Conferma **Essure**:
    a) Procedura di posizionamento difficoltosa, comprendente uno o più dei seguenti casi:
        (1) Sospetto al momento del posizionamento di possibile perforazione dovuta all'applicazione di una forza eccessiva e necessaria per il posizionamento del microinserto e/o improvvisa perdita di resistenza.
        (2) Difficoltà di identificazione degli orifizi tubarici durante il posizionamento a causa di variazioni anatomiche o fattori tecnici quali distensione insufficiente, illuminazione scarsa o depositi endometriali.
        (3) Incertezza del chirurgo riguardo al posizionamento.
    b) Tempo di intervento > 15 minuti (ingresso–uscita dell'isteroscopio).
    c) Posizionamento con zero o > 8 spirali più indietro nella cavità uterina.
    d) Insolito dolore postoperatorio, transitorio o persistente, o comparso dopo un certo tempo dall'intervento, senza alcun'altra causa identificabile.
2. Se radiografia o ecografia sono controindicate, la paziente deve essere sottoposta a isterosalpingografia per valutare il posizionamento del microinserto e un'eventuale occlusione tubarica. L'ecografia transaddominale non può sostituire quella transvaginale. Se radiografia o ecografia sono incerte o insoddisfacenti, la paziente deve essere sottoposta a isterosalpingografia per valutare il posizionamento del microinserto e un'eventuale occlusione tubarica.

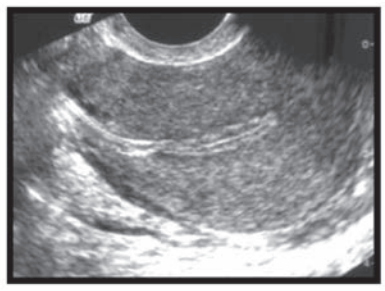
C. Ecografia transvaginale

1. Per la documentazione è necessario acquisire e salvare un minimo di tre immagini:
    a) Una vista coronale o coronale obliqua che mostri una porzione di ciascun microinserto nei corni etichettata come "immagine esplorativa".



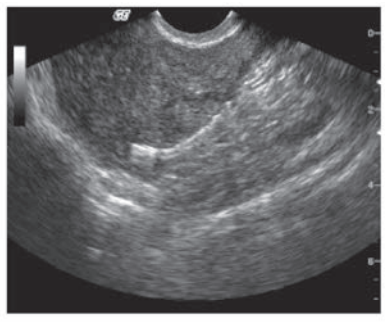
Questa vista trasversale (coronale / coronale obliqua) permette di identificare i microinserti bilaterali.

    b) Un'immagine coronale o coronale obliqua dell'asse lineare del microinserto di sinistra che comprenda anche l'estremità prossimale che attraversa il miometrio ai corni (porzione interstiziale della tuba di Falloppio) o in contatto con la congiunzione uterotubarica sierosa ed etichettata con "sinistra".
    c) Un'immagine coronale o coronale obliqua dell'asse lineare del microinserto di destra che attraversa il miometrio ai corni (porzione interstiziale della tuba di Falloppio) o in contatto con la congiunzione uterotubarica sierosa ed etichettata con "destra."
    d) Le tre immagini devono essere salvate su pellicola e archiviate nella cartella clinica della paziente al fine di documentare la posizione e stabilità soddisfacente del microinserto.
2. Classificazione della posizione del microinserto
    a) Identificazione del microinserto: in una singola immagine esplorativa, in vista coronale o coronale obliqua si deve visualizzare una porzione di ciascun microinserto nei corni, in modo da assicurare il posizionamento bilaterale e ridurre il rischio di effettuare una doppia acquisizione dello stesso microinserto. L'asse lineare dei microinserti deve apparire relativamente simmetrica.
    b) Posizione ottimale
    La posizione del microinserto è ottimale quando l'estremità prossimale del microinserto è a contatto con la cavità uterina o endometrio, e l'asse lineare è all'interno del miometrio ai corni (porzione interstiziale della tuba di Falloppio) e può essere visualizzato presso o attraverso la congiunzione uterotubarica sierosa (USTJ). La porzione di microinserto posta nella tuba di Falloppio potrebbe anche non essere visibile. L'asse lineare del microinserto deve essere visibile per confermare che non sia avvolto o disteso.



Posizione ottimale

    c) Posizione soddisfacente
    La posizione del microinserto è soddisfacente quando l'estremità prossimale del microinserto è distale rispetto all'endometrio, e tuttavia l'asse lineare è all'interno del miometrio ai corni (porzione interstiziale della tuba di Falloppio) e può essere visualizzato presso o attraverso la congiunzione uterotubarica sierosa (USTJ). La porzione di microinserto posta nella tuba di Falloppio potrebbe anche non essere visibile. L'asse lineare del microinserto deve essere visibile per confermare che non sia avvolto o disteso.



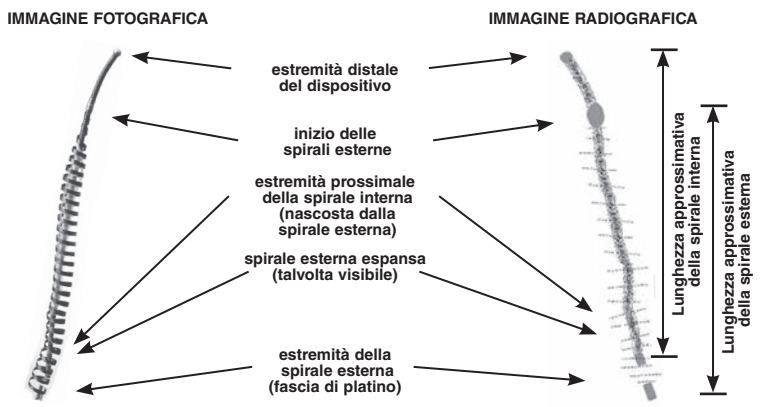
Posizione soddisfacente

    d) Posizione insoddisfacente
        (1) La posizione del microinserto è insoddisfacente se in un'immagine esplorativa, in vista coronale o coronale obliqua, non è possibile visualizzare una porzione di ciascun microinserto nei corni.
        (2) Si sospetta l'espulsione se uno o entrambi i microinserti non vengono identificati nei corni in vista coronale in una singola immagine esplorativa.
        (3) Si sospetta un posizionamento distale se l'estremità prossimale del microinserto non è posizionata nel miometrio ai corni (porzione interstiziale della tuba di Falloppio), e non attraversa né è in contatto con la congiunzione uterotubarica sierosa (USTJ).
        (4) Si sospetta un posizionamento prossimale se è possibile visualizzare più del 50% o la maggior parte del microinserto nella cavità uterina o se in vista sagittale mediana è possibile visualizzare l'asse lineare del/i microinserto/i.
        (5) Si sospetta una perforazione se in vista sagittale l'asse lineare di uno o entrambi i microinserti è parallelo alla striscia endometriale, o se in vista sagittale mediana si vede l'asse lineare di un microinserto attraversare il miometrio.
        (6) Posizione non classificabile: se non è possibile identificare l'asse lineare di un microinserto, il che suggerisce che esso è avvolto, piegato o disteso, la posizione del microinserto viene considerate insoddisfacente. Se non è possibile identificare chiaramente i tessuti molli circostanti, la posizione viene considerata insoddisfacente.
3. Se la valutazione radiografica è incerta o insoddisfacente, la paziente deve essere sottoposta a isterosalpingografia per valutare il posizionamento del microinserto e un'eventuale occlusione tubarica.

D. Radiografia pelvica

1. Acquisire un'immagine dell'utero con entrambi i microinserti **Essure** chiaramente visibili. Si devono notare la posizione e la curvatura dei microinserti.

Vista radiografica corrispondente del microinserto ***Essure***



2. Valutare la radiografia pelvica come segue:
    a) Soddisfacente: i microinserti sembrano trovarsi nel lume della tuba, distesi attraverso la congiunzione uterotubarica in relativa simmetria. Le pazienti la cui radiografia viene ritenuta "soddisfacente" possono iniziare a fare affidamento sul microinserto **Essure** come metodo di contraccezione.
    b) Sospetta: uno o entrambi i microinserti sembrano trovarsi in posizione distale o prossimale rispetto alla posizione ottimale, o possono aver perforato in parte o completamente la tuba, e/o si presentano in relativa asimmetria. Le pazienti la cui radiografia viene ritenuta "sospetta" devono essere invitate a continuare ad usare un metodo di contraccezione alternativo e sottoporsi a test di conferma (isterosalpingografia) **Essure**.
    c) Insoddisfacente: evidente collocazione del microinserto in posizione intraperitoneale o espulsione.
3. Se la radiografia è incerta o insoddisfacente, o se la posizione del microinserto è sospetta, la paziente deve essere sottoposta a isterosalpingografia per valutare il posizionamento del microinserto e un'eventuale occlusione tubarica.

E. Esecuzione e valutazione delle isterosalpingografie modificate

1. Il test di conferma (isterosalpingografia) **Essure** viene eseguito per valutare ulteriormente la posizione del microinserto **Essure** e l'occlusione delle tube di Falloppio, se necessario in base ai risultati della radiografia o ecografia pelvica. Nell'esecuzione e nella valutazione del test di conferma (isterosalpingografia) **Essure** occorre attenersi a quanto indicato di seguito.
2. Esecuzione del test di conferma (isterosalpingografia) **Essure** – Linee guida:
    a) Ottenere un buon riempimento dei corni in modo che il profilo della cavità uterina sia chiaramente visibile.
    b) Posizionare il fascio fluoroscopico quanto più vicino possibile alla proiezione antero–posteriore.
    c) Non dilatare la cervice, a meno che non sia necessario; in caso di dilatazione, mantenere una buona tenuta cervicale.
    d) In caso di utero in posizione retroflessa può essere necessaria una trazione verso il basso sull'uncino per tessuti applicato alla cervice. Per ottenere la miglior visualizzazione possibile dell'anatomia uterina rimuovere lo speculum prima della fluoroscopia.
    e) Per valutare la posizione del microinserto e l'occlusione delle tube occorre effettuare un minimo di sei radiografie.

(1) Radiografia 1 – “Ripresa esplorativa” – Utero e microinserti senza contrasto.

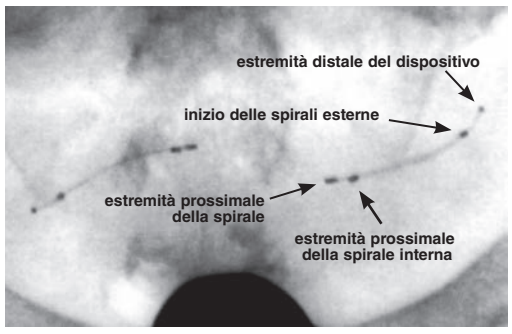
(2) Radiografia 2 – Riempimento minimo della cavità – Utero e microinserti con una piccola quantità di mezzo di contrasto.

(3) Radiografia 3 – Riempimento parziale della cavità – Utero e microinserti a utero quasi pieno di mezzo di contrasto.

(4) Radiografia 4 – Riempimento totale della cavità – Utero e microinserti con corni distesi dal mezzo di contrasto.

(5) Radiografie 5 e 6- Ingrandimenti dei corni uterini – Microinserti nelle tube di Falloppio, con corni destro (5) e sinistro (6).

ATTENZIONE: evitare un aumento eccessivo della pressione intrauterina superiore a quanto necessario a produrre la Radiografia 4,per risparmiare alla paziente un fastidio superfluo e una risposta vaso-vagale.



3. Valutazione della posizione del microinserto
   a) Durante la valutazione, notare i quattro “marker” a ogni estremità delle spirali (interna ed esterna). Notare che i marker distali sono in posizione fissa tra di loro, mentre i marker prossimali possono spostarsi o sembrare estesi a causa della flessibilità della spirale esterna. La posizione ideale del microinserto è quando la spirale interna attraversa la congiunzione uterotubarica.
   b) Valutare la posizione del microinserto:
      (1) Espulsione o posizionamento prossimale: il microinserto non è presente o ≥ 50% della spirale interna si trova più indietro nella cavità uterina.
      (2) Posizionamento soddisfacente: l’estremità distale della spirale interna è all’interno della tuba, con < 50% della spirale interna più indietro nella cavità uterina o l’estremità prossimale della spirale interna ≤ 30 mm nella tuba dal punto in cui il mezzo di contrasto riempie i corni uterini.
      (3) Posizionamento distale o perforazione: il microinserto è nella tuba, ma l’estremità prossimale della spirale interna > 30 mm in posizione distale dal punto in cui il mezzo di contrasto riempie i corni, oppure il microinserto è completamente o parzialmente perforato.
4. Valutazione dell’occlusione tubarica
   a) Determinare se il mezzo di contrasto sia visibile oltre il microinserto, e notare qualsiasi grado di riempimento con mezzo di contrasto della parte prossimale della tuba, anche nel caso in cui la tuba sia occlusa.
   b) Valutare l’occlusione tubarica:
      (1) Occlusione soddisfacente: la tuba è occlusa in corrispondenza dei corni.
      (2) Occlusione soddisfacente: il mezzo di contrasto è visibile all’interno della tuba, ma non oltre l’estremità distale della spirale esterna.
      (3) Occlusione insoddisfacente: il mezzo di contrasto è visibile oltre l’estremità distale del microinserto o nella cavità peritoneale.
5. Valutazione dell’affidabilità della contraccezione
   a) Se sia posizionamento sia occlusione tubarica vengono classificate soddisfacenti, invitare la paziente all’interruzione dell’uso del metodo di contraccezione alternativo.
   b) Se il posizionamento è insoddisfacente, avvertire la paziente di non fare affidamento sui microinserti per la contraccezione.
   c) Se il posizionamento è soddisfacente ma l’occlusione non è soddisfacente, invitare la paziente a continuare a usare un metodo di contraccezione alternativo. Ripetere l’isterosalpingografia dopo tre mesi. Se l’occlusione è ancora insoddisfacente, avvertire la paziente di non fare affidamento sui microinserti per la contraccezione.

X. Come regolarsi in caso di posizionamento insoddisfacente del microinserto

A. Posizione insoddisfacente del microinserto diagnosticata tramite isterosalpingografia

1. Posizione prossimale: oltre il 50% della lunghezza della spirale interna del microinserto è più indietro nell’utero.
2. Posizione distale: il microinserto è nella tuba ma l’estremità prossimale della spirale interna si trova ad oltre 30 mm dal mezzo di contrasto che riempie i corni uterini.
3. Completa espulsione del microinserto: il microinserto non è all’interno del corpo.
4. Perforazione: il microinserto ha sconfinato in parte o completamente.
5. Posizionamento intraperitoneale del microinserto: il microinserto si trova senza dubbio all’esterno della tuba di Falloppio.

B. Come regolarsi in caso di espulsione o posizionamento insoddisfacente del microinserto

1. Espulsione bilaterale del microinserto con occlusione bilaterale: in caso di diagnosi isterosalpingografica di occlusione prossimale bilaterale delle tube, considerata la probabilità di una falsa diagnosi positiva di occlusione tubarica nel corso del test di conferma (isterosalpingografia) **Essure**, è necessario informare la paziente della possibilità di scegliere come metodo contraccettivo la sterilizzazione con resezione o legatura delle tube.
2. Espulsione bilaterale del microinserto con occlusione di una tuba e pervietà della tuba controlaterale: la paziente può essere considerata per una ulteriore procedura di impianto per la sostituzione del microinserto nella tuba pervia; in questo modo, per evitare la gravidanza la paziente potrà fare affidamento su un microinserto **Essure** e sull’occlusione prossimale della tuba controlaterale. La paziente deve essere informata di questa possibilità, considerata la probabilità di una falsa diagnosi positiva di occlusione tubarica nel corso del test di conferma (isterosalpingografia) **Essure**. La paziente deve inoltre essere informata della possibilità di sottoporsi a sterilizzazione con resezione o legatura delle tube.
3. Espulsione unilaterale del microinserto o posizione unilaterale insoddisfacente del microinserto (nel miometrio o nella cavità intraperitoneale) con microinserto controlaterale collocato in posizione soddisfacente: se il test di conferma (isterosalpingografia) **Essure** dimostra l’ostruzione della tuba da cui il microinserto è stato espulso o nella quale lo si sarebbe dovuto collocare, la paziente può fare affidamento sul microinserto collocato in posizione soddisfacente e sull’occlusione prossimale della tuba controlaterale, considerata la probabilità di una falsa diagnosi positiva di occlusione tubarica nel corso del test di conferma (isterosalpingografia) **Essure**. La paziente deve inoltre essere informata della possibilità di sottoporsi a sterilizzazione con resezione o legatura delle tube.
4. Posizione unilaterale insoddisfacente del microinserto (nel miometrio o nella cavità intraperitoneale) con microinserto controlaterale collocato in posizione soddisfacente: se il test di conferma (isterosalpingografia) **Essure** dimostra la pervietà della tuba nella quale si sarebbe dovuto collocare un microinserto, si può prospettare alla paziente la possibilità di sottoporsi nuovamente alla procedura di impianto del microinserto. La paziente deve inoltre essere informata della possibilità di sottoporsi a sterilizzazione con resezione o legatura delle tube.
5. Espulsione unilaterale del microinserto; posizione unilaterale insoddisfacente del microinserto (nel miometrio o nella cavità intraperitoneale); collocazione unilaterale insoddisfacente del microinserto in “posizione prossimale” (>50% della lunghezza della spirale interna più indietro nell’utero) o in “posizione distale” (microinserto nella tuba di Falloppio mentre l’estremità prossimale della spirale interna si trova >30 mm dal mezzo di contrasto che riempie i corni uterini) con il microinserto controlaterale in posizione insoddisfacente: la paziente deve essere informata della possibilità di sottoporsi a sterilizzazione con resezione o legatura delle tube. In ogni caso, se si ritiene necessario rimuovere il microinserto e non è possibile farlo mediante isteroscopia, può essere necessario procedere chirurgicamente.
6. Se dopo aver considerato le possibilità su menzionate la paziente sceglie la sterilizzazione con resezione o legatura delle tube, occorre occludere entrambe le tube indipendentemente dalla presenza residua di microinserti in posizione soddisfacente. Se il medico ritiene di poterlo fare in modo sicuro, deve tentare di recuperare un microinserto, benché ciò possa non essere possibile. Prima e durante l’intervento chirurgico si raccomanda di usare la fluoroscopia intra-operatoria per identificare la posizione del microinserto. Il tentativo di rimozione non deve durare più di 30 minuti.

XI. Come regolarsi in casi di posizionamento insoddisfacente del microinserto Essure

Nel caso di mancato posizionamento unilaterale o bilaterale del microinserto, è necessario comunicare alla paziente che la procedura di contraccezione permanente non è stata completata. Se la paziente sceglie la sterilizzazione laparoscopica (ovvero applicazione di clip o elettrocauterio), entrambe le tube di Falloppio devono essere occluse con clip o cauterizzate anche se all’interno di una tuba è stato impiantato il microinserto **Essure**. L’occlusione con clip o la cauterizzazione della tuba o delle tube deve essere eseguita in un segmento distale rispetto al microinserto **Essure**.

Se la paziente non opta per la sterilizzazione laparoscopica, le si può proporre di sottoporsi al test di conferma (isterosalpingografia) **Essure** dopo il prossimo ciclo mestruale (fase pre-ovulatoria: giorni 7-14 dove il giorno 1 rappresenta il primo giorno di mestruazione) per determinare la pervietà tubarica. Se si rileva la pervietà tubarica, il medico può proporre alla paziente di sottoporsi ad un secondo tentativo di impianto del microinserto. Se neanche il secondo tentativo di impianto del microinserto riesce, è improbabile che ulteriori tentativi possano avere esito positivo. Se la paziente ha un solo microinserto rimasto *in vivo* le deve essere detto di non fare affidamento sul microinserto unilaterale come metodo contraccettivo.

Se è stato ottenuto solo l’impianto unilaterale del microinserto il test di conferma (isterosalpingografia) **Essure** conferma l’occlusione prossimale della tuba controlaterale, informare la paziente della possibilità di fare affidamento sul microinserto, considerata la probabilità di una falsa diagnosi positiva di occlusione prossimale tubarica nel corso del test di conferma (isterosalpingografia) **Essure**. Per “occlusione tubarica” si intende il mancato passaggio del mezzo di contrasto dalla cavità uterina nella cavità peritoneale al momento del test di conferma (isterosalpingografia) **Essure**. La paziente deve inoltre essere informata della possibilità di sottoporsi a sterilizzazione con resezione o legatura delle tube. Se la paziente non manifesta eventi avversi, si sconsiglia di tentare di rimuovere un microinserto posizionato su un solo lato.

XII. Rimozione del microinserto Essure

AVVERTENZA - UNA VOLTA POSIZIONATO, IL MICROINSERTO NON DEVE ESSERE RIMOSSO TRAMITE ISTEROSCOPIA, A MENO CHE NON VI SIANO 18 O PIÙ SPIRALI DEL MICROINSERTO POSTE PIÙ INDIETRO NELLA CAVITÀ UTERINA. Se un microinserto si presenta in questo modo, la rimozione deve essere effettuata immediatamente dopo il posizionamento. La rimozione, tuttavia, può non essere possibile. Se si tenta la rimozione, eseguire la procedura seguente:

1. Introdurre una pinza attraverso il canale operativo dell’isteroscopio.
2. Afferrare la spirale esterna del microinserto **Essure**. Cercare di afferrare la spirale esterna e quella interna del microinserto insieme.
3. Tirare contemporaneamente la pinza e l’isteroscopio, in modo da ritirare il sistema dall’utero per intero.
4. Durante il tentativo di rimozione del microinserto **Essure** è possibile che la spirale esterna e/o la spirale interna si estenda o si allunghi.
5. Somministrare agenti analgesici/anestetizzanti per ridurre o evitare il fastidio della paziente, secondo necessità.
6. Se si ottiene la rimozione completa del microinserto, tentare di impiantare un altro microinserto **Essure**.
7. Se il medico non è del tutto sicuro che il microinserto **Essure** sia stato rimosso per intero dalla tuba di Falloppio, **NON** deve tentare di impiantarne un altro in quella tuba e deve verificare tramite radiografia l’eventuale presenza di un frammento del microinserto *in vivo*.

Tranne che per le circostanze descritte in alto, il tentativo di rimozione del microinserto deve essere effettuato solo se la paziente manifesta eventi avversi associati alla presenza del microinserto o qualora ne richieda la rimozione.

Qualora si ritenga necessario procedere alla rimozione del microinserto, si deve scegliere l’approccio transaddominale (ovvero laparotomia o laparoscopia).

Se il microinserto è posizionato correttamente attraverso la congiunzione uterotubarica, sarà necessario ricorrere alla resezione del corno del segmento prossimale della tuba di Falloppio.

Un microinserto **Essure** in posizione errata o spostatosi oltre la congiunzione uterotubarica va rimosso mediante salpingotomia lineare tradizionale o salpingectomia effettuate in laparoscopia o laparotomia.

1. Per eseguire una salpingotomia lineare, praticare una piccola incisione (circa 2 cm di lunghezza) lungo il margine antimesenterico della tuba di Falloppio, direttamente soprastante il microinserto.
2. Per il recupero del microinserto si può eseguire una salpingectomia parziale o totale insieme alla procedura di sterilizzazione tubarica tradizionale o indipendentemente da questa.

XIII. Scheda di identificazione della paziente

Ad ogni paziente nella quale sia stato impiantato un microinserto **Essure** deve essere consegnata una scheda laminata in formato portafoglio su cui è indicato che nel soggetto è stato impiantato il microinserto **Essure**. **La scheda è fornita in dotazione in questa confezione.** La scheda indica inoltre la possibilità di rischi associati a procedure intrauterine future effettuate sul soggetto o ad interventi chirurgici sugli organi riproduttivi.

XIV. Spiegazione dei simboli

STERILE EO	Sterilizzato con ossido di etilene
LOT	Codice lotto
	Non riutilizzare
REF	Numero di catalogo
	Attenzione, vedere le istruzioni per l’uso
	Data di scadenza
	Tenere lontano da fonti di calore
	Non utilizzare se la confezione è aperta o danneggiata
MR	A compatibilità RM condizionata
EC REP	Rappresentante autorizzato per l’Europa
CE 0050	Dispositivo conforme alla direttiva europea 93/42/CEE
	Tenere al riparo dall’umidità
CONT	Contenuto

Prodotto da:
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Per ordinare il prodotto o per riportare eventi avversi, chiamare il rappresentante di zona Bayer HealthCare LLC

Riciclabile

PN-84731145, ART Rev. B

Norsk

essure®

Varig prevensjon

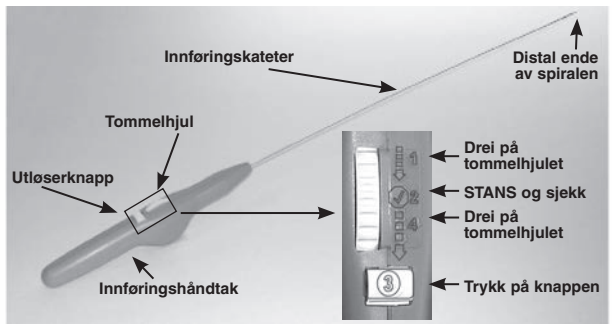
BAYER

BRUKSANVISNING

I. Beskrivelse av spiralen

Essure® varig prevensjonssystem består av flere komponenter. **Essure**-spiralen, en dynamisk ekspanderende spiral, festes til en styreline og et utløserkateter. Hele enheten er innkapslet i et innføringskateter. Dette systemet (vist på figur 1) festes til et håndtak som letter innføring og plassering av spiralen. Et **DryFlow**® ventilutstyrt innføringsrør inngår også i **Essure**-systemet. Det beskytter **Essure**-spiralen når den føres gjennom gummiåpningen på hysteroskopets arbeidskanal.

Figur 1
Essure innføringssystem
Med detaljutsnitt av symboler for plasseringsprosedyre
(ikke vist i riktig målestokk)



II. Virkningsmekanisme

Under hysteroskopisk visualisering leverer **Essure**-systemet en **Essure**-spiral til det proksimale området av eggledertumenet. Når **Essure**-spiralen ekspanderer ved utløsning, forankrer den seg umiddelbart i eggledern. Deretter fremkaller spiralen en mild tilsiktet vevsreaksjon som resulterer i at vevet gror inn i spiralen, noe som igjen gjør at spiralen forankrer seg permanent i eggledern. Denne milde vevsreaksjonen er lokal, fibrøs og okklusiv.

Hvert **Essure** system er sterilisert ved bruk av etylenoksid og leveres sterilt, kun til éngangsbruk. Må ikke brukes på nytt eller resteriliseres. Resterilisering kan ha uheldig innvirkning på mekanismen og føre til pasientskade.

III. Indikasjoner

Essure-systemet er indisert for bruk som en tubar okklusjonsspiral for varig prevensjon.

IV. Kontraindikasjoner

- Pasienten er usikker på om hun vil miste sin evne til å bli gravid.
- Graviditet eller mistanke om graviditet.
- Fødsel eller avslutning av en graviditet i andre trimester mindre enn seks uker før plassering av **Essure**-spiral.
- Aktiv eller nylig pelvisk infeksjon.
- Ubehandlet akutt cervicitt.
- Uforklarlig eller alvorlig vaginal blødning.
- Gynekologisk malignitet (mistenkt eller kjent).
- Kjent unormal livmorhule eller eggledere som gjør visualiseringen av eggledernes åpningene og/eller kanyleringen av den proksimale eggledern vanskelig eller umulig.
- Allergi mot kontrastmediet (et hysterosalpingogram kan være nødvendig tre måneder etter plassering av spiralen).
- Pasienten tar kortikosteroider i øyeblikket.

V. Advarsler

- **Essure**-prosedyren må kun utføres av personer som har erfaring med hysteroskopi og som har gjennomgått *Bayer HealthCare LLC* opplæringsprogram for denne prosedyren.
- Personer som er allergiske mot nikkeltitan kan få en allergisk reaksjon mot spiralen.
- **Essure**-systemet må ikke brukes hvis pakken er åpnet eller ødelagt. Må ikke brukes hvis spiralen er ødelagt.
- Ved innføring av **Essure**-spiralen i eggledern må det aldri brukes makt på spiralen(e) ved stor motstand.
- Du må ikke føre **Essure**-systemet videre etter at plasseringsmarkøren på kateteret har nådd tubaråpningen. Innføring utover dette punktet kan føre til utilfredsstillende spiralplassering eller tubar/uterin perforasjon.
- Hvis det oppstår, eller mistenkes, en tubar perforasjon, må du ikke fortsette plasseringen av **Essure**-spiral. En meget liten prosentdel av kvinner i **Essure** kliniske forsøk (1,8 % eller 12/682 pasienter) ble funnet å ha enhetsrelaterte tubare perforasjoner. Fjerning av perforerende spiraler vil, om nødvendig, kreve laparoskopi eller andre kirurgiske metoder.
- Hvis plassering av **Essure**-spiralen ikke lykkes etter 10 minutters kanylering per eggleder, bør prosedyren avsluttes og eventuelt nytt forsøk vurderes.
- Når spiralen er på plass (dvs. frakoplet styrelinen), må den ikke fjernes ved hjelp av hysteroskopi med mindre 18 eller flere kveiler på **Essure**-spiralen går inn i livmorhulen. Fjerning av slik spiral bør skje umiddelbart etter plassering. Det kan imidlertid være at fjerning er umulig.
- Pasienten må benytte annen prevensjon inntil røntgen, som tas tre måneder etter spiralplasseringen, viser tilfredsstillende spiralplassering.
- Pasienter som får plassert **Essure**-spiral kan i fremtiden tilbys intrauterin behandling som benytter elektrisk energi. Det anbefales at elektrokauterisasjon unngås i kirurgiske prosedyrer som utføres på cornua uteri og eggledere. For alle andre prosedyrer i pelvis må man unngå bruk av elektrokauterisasjon nærmere enn 4 cm fra spiralen. På grunn av tilstedeværelsen av **Essure**-spiralene kan det være risiko forbundet med prosedyrer som per i dag ikke er kartlagt.
- En intrauterin prosedyre som endometriebiopsi, dilatasjon og utskraping, hysteroskopi (diagnostisk eller operativt) medregnet endometrieablasjon kan skade spiralens evne til å hindre graviditet. I tillegg kan tilstedeværelsen av **Essure**-spiralene innebære risikoer assosiert med prosedyrer som per i dag ikke er kartlagt.
- Bench- og kliniske studier viste at endometrieablasjon av uterus kan utføres sikkert og effektivt med GYNECARE THERMACHOICE* livmorballongsystem, Hologic NovaSure** endometrieablasjonssystem og Boston Scientific Hydro ThermAblator*** **umiddelbart etter** plassering av **Essure**-spiralen. Ingen spesifikke studier er utført for å evaluere utstøtings- eller prevensjonsfrekvensen for **Essure**-spiralen etter kombinerte **Essure**- og endometrieablasjonsprosedyrer.
- Pasienter kan senere bestemme seg for å få utført in vitro-fertilisering (IVF) for å bli gravide. **Essure**-spiralenes påvirkning på hvorvidt en IVF blir vellykket eller ikke, er ikke kjent. Ved oppnådd graviditet er det ikke kjent om spiralen utgjør noen risiko for pasienten, fosteret og den videre graviditeten.

* Varemerke for ETHICON, INC.
** Varemerke for Hologic, Inc.
*** Varemerke for Boston Scientific Corporation

VI. Forholdsregler

- Spiralen bør om mulig settes inn i løpet av dag 7-14 av menstruasjonssyklusen (hvor dag 1 representerer første dag med blødning) for å styrke visualiseringen av eggledernes åpningene og redusere muligheten for plassering av spiralen hos en pasient med en udiagnostisert graviditet.
- Unormal livmoranatomi kan vanskeliggjøre plassering av **Essure**-spiralene.
- For å redusere faren for livmorperforasjon må prosedyren avsluttes hvis det er nødvendig å bruke makt for å oppnå cervikal dilatasjon.
- Begge tubaråpningene må identifiseres og evalueres hysteroskopisk før man fører inn **Essure**-spiralen. Det må ikke innføres en spiral i den ene tubaråpningen med mindre det er rimelig grunn til å anta at den andre eggledern er mottakelig og åpen.
- Utførelsen av endometrie-ablasjon umiddelbart etter plassering av **Essure**-spiralen, kan øke risikoen for post-ablasjon tubar steriliserings-syndrom, en sjelden tilstand som har vært rapportert i kvinner med tubar sterilisering-historie som gjennomgår endometrie-ablasjon.
- Før ikke **Essure**-systemet videre hvis pasienten opplever unormal smerte eller ubehag.
- **Essure**-systemet må oppbevares tørt og kjølig.

VII. Mulige bivirkninger

A. Graviditet

Det er risiko for graviditet og ektopisk graviditet og risikoer assosiert med behandlingen av begge. Hvis pasienten blir gravid og velger å fortsette en intrauterin graviditet, bør hun informeres om at det ikke er kjent om spiralen utgjør noen risiko for pasienten, fosteret og fortsettelsen av graviditeten.

B. Risikoer assosiert med plassering av spiralen

- Lokalbedøvelse, oral analgesia/sedasjon, regionalanestesi (f.eks. spinal, epidural), oral eller bevisst (intravenøs) sedasjon, eller totalbedøvelse kan gis pasienten for å forhindre eller redusere ubehag. Uavhengig av type anestesi kan pasienter være ute av stand til å gjenoppta normale aktiviteter de første 12-24 timene etter prosedyren.
- Smerter, kramper og vaginale blødninger kan oppstå under og etter plassering av spiralen. Disse hendelsene er vanligvis utholdelige, forbigående og kan behandles med medisinering med godt resultat.
- Under og/eller direkte etter plasseringen av spiralen er det en risiko for at pasienten vil oppleve kvalme eller oppkast. Dette forventes å være forbigående og kan behandles med medisinering etter behov.
- Pasienter kan oppleve besvimelse eller vasovagal respons på operasjonsdagen.
- Det er risiko for perforasjon eller disseksjon av eggledern eller cornua uteri. Blødninger og arrdannelse kan oppstå fra slik perforasjon eller disseksjon. Det er vanligvis ikke nødvendig med behandling.
- Det er en risiko for at livmoren kan perforeres av hysteroskopet, **Essure**-systemet eller andre instrumenter benyttet under prosedyren med mulig skade på tarm, blære og større blodkar. Hvis slik skade skulle oppstå, kan det være nødvendig med kirurgisk intervensjon, men dette er usannsynlig. For å redusere risikoen for livmorperforasjon bør prosedyren avsluttes hvis det er nødvendig å bruke makt for å oppnå cervikal dilatasjon.
- Det er risiko for at **Essure**-spiralen utilsiktet kan plasseres i livmorens myometrium og ikke i eggledernlumen. Hvis den ene spiralen allerede er korrekt plassert i eggledern, i tillegg til utilsiktet plassering i myometrium, kan legen forsøke å plassere en tredje spiral for å fullføre prosedyren. Hvis bilateral plassering i eggleder ikke oppnås, kan dette resultere i at pasienten har én spiral i eggledern og/eller én spiral i myometrium som ikke er pålitelig som prevensjon. Plassering av spiralen i myometrium kan resultere i post-operative smerter eller andre bivirkninger. Hvis kirurgisk fjerning av spiralen(e) er nødvendig, kan salpingektomi eller hysterektomi bli nødvendig.
- Det er en risiko for at **Essure**-spiralen kan plasseres for distalt i eggledern. Hvis spiralen må fjernes, er det nødvendig med operasjon (laparoskopi eller laparotomi).
- Det er en risiko for at **Essure**-spiralen kan plasseres for proksimalt i eggledern. Hvis 18 eller flere kveiler på **Essure**-spiralen er synlige på plasseringstidspunktet, må det umiddelbart gjøres et forsøk på å fjerne spiralen (se kapittel XIII, Fjerning av **Essure**-spiral). Hvis spiralen forsøkes fjernet, er det en mulighet for at fjerningen kan mislykkes eller at **Essure**-spiralen kan knekke og etterlate et fragment av spiralen *in vivo*. Hvis fjerning av spiralen forsøkes og/eller oppnås, er det også en mulighet for at pasienten kan oppleve økte smerter, kramper og blødninger under og etter plassering av **Essure**-spiralen.
- Det er en risiko for at **Essure**-spiralen kan perforere gjennom eggledervеggen eller cornua uteri som igjen kan resultere i at spiralen vandrer inn i bukhulen. Post-operative smerter og/eller menstruasjonsforstyrrelser eller andre bivirkninger kan oppstå som en følge av dette. Hvis pasienten velger å få utført kirurgisk sterilisering eller annet kirurgisk inngrep, kan man forsøke å fjerne spiralen fra bukhulen hvis legen anser at det er trygt å gjøre det. Fjerning av spiralen kan imidlertid være umulig hvis spiralen ikke kan visualiseres eller nås av legen.
- Det er en risiko for at plassering av **Essure**-spiralen bare kan oppnås i én eggleder. Hvis dette skjer, kan pasientene sitte igjen med én spiral *in vivo* som ikke er pålitelig som varig prevensjon.
- Det er en risiko for at plassering av **Essure**-spiralen ikke er mulig i noen av eggledern.
- Det er en minimal risiko for for høy absorbering av den fysiologiske saltoppløsningen, som brukes til utspiling av livmoren ved utføringen av den hysteroskopiske prosedyren.
- Som med alle invasive prosedyrer, kan prosedyren for plassering av spiral forårsake infeksjon. En infeksjon kan forårsake skade på livmoren, eggleder eller pelvisk hulrom. Dette kan nødvendiggjøre antibiotikabehandling, eller i sjeldne tilfeller innleggelse på sykehus eller operasjon, inkludert hysterektomi.

C. Risikoer forbundet med bruk av Essure-spiralen

- Det er en risiko for at **Essure**-spiralen kan bevege seg ut fra eggledern. Dette kan bety utstøting (bevegelse ut av eggledern og inn i livmorhulen/cervix/vagina eller ut av kroppen) eller migrering (bevegelse til den distale eggledern eller ut av eggledern og inn i bukhulen). Ytterligere røntgen kan være nødvendig for å lokalisere spiralen(e), og operasjon kan være nødvendig for å fjerne spiralen(e). Forflytning av enheten kan resultere i graviditet, ektopisk graviditet og/eller smerter/menstruasjonsforstyrrelser eller andre bivirkninger.
- Som med tilgjengelige metoder for mekanisk varig prevensjon (f.eks. klemmer, ringer), er det nødvendig med operasjon hvis **Essure**-spiralen skal fjernes. Videre er det mulig at kirurgisk fjerning av eggledern (salpingektomi) og livmor (hysterektomi) kan være nødvendig.
- Abdominale/pelviske smerter og kramper kan forekomme. Det er mer sannsynlig at smerter og kramper forekommer under menstruasjonsperioden, under og etter samleie eller ved annen fysisk aktivitet.
- Intermenstruell blødning eller kraftigere menstruasjonsblødning enn normalt kan oppleves.
- Av og til kan en kvinne angre på sin avgjørelse om å få utført varig prevensjon og kan oppleve lett depresjon eller andre følelsesmessige forstyrrelser som en følge av dette.

D. Risikoer forbundet med oppfølgingsprosedyrer

- Det er en risiko for stråling forbundet med den pelviske røntgenen som er nødvendig tre måneder etter plassering av spiral for evaluering av spiralplasseringen. Det kan også være behov for en **Essure** bekreftelsestest (HSG). Det finnes omtrent 0,033 rad i den fluoroskopiske delen (<30 sekunder) av en hysterosalpingogram-prosedyre. Til sammenligning er strålingseksponering fra ett bariumenema 0,85 rad, noe som er høyere enn den nødvendige **Essure** bekreftelsestest (HSG). Mengden strålingseksponering fra én pelvisk røntgen er omtrent samme mengde som en person ville utsettes for i løpet av ett års naturlig bakgrunnsstråling.
- Ytterligere risikoer forbundet med eventuell **Essure** bekreftelsestest (HSG)-prosedyre: vasovagal respons; infeksjon, som kan kreve antibiotikabehandling og i sjeldne tilfeller sykehusinnleggelse, intravasasjon; perforasjon av livmoren; livmorkramper og/eller blødninger; smerter eller ubehag og allergisk reaksjon på lateks. Det er rapportert om lateksеksponering forbundet med anafylaktiske reaksjoner i sjeldne tilfeller, noe som kan føre til død.
- Bruken av kontrastmedier for å utføre en **Essure** bekreftelsestest (HSG) har blitt forbundet med allergiske reaksjoner hos enkelte pasienter. Allergiske reaksjoner kan resultere i utslett eller åndedrettsproblemer. Hos enkelte individer kan det oppstå en anafylaktisk respons som kan føre til død.

E. Risikoer forbundet med mulige fremtidige prosedyrer

- Pasienter som får plassert **Essure**-spiral kan i fremtiden tilbys intrauterin behandling som benytter elektrisk energi. Det anbefales at elektrokauterisasjon unngås i kirurgiske prosedyrer som utføres på cornua uteri og eggledere. For alle andre prosedyrer i pelvis må man unngå bruk av elektrokauterisasjon nærmere enn 4 cm fra spiralen. På grunn av tilstedeværelsen av **Essure**-spiralene kan det være risiko forbundet med prosedyrer som per i dag ikke er kartlagt.
- En intrauterin prosedyre som endometriebiopsi, dilatasjon og utskraping, hysteroskopi (diagnostisk eller operativt) medregnet endometrie-ablasjon kan skade spiralens evne til å hindre graviditet. I tillegg kan tilstedeværelsen av **Essure**-spiralene innebære risikoer assosiert med prosedyrer som per i dag ikke er kartlagt.
- Pasienter kan senere bestemme seg for å få utført in vitro fertilisering (IVF) for å bli gravide. **Essure**-spiralenes påvirkning på hvorvidt en IVF blir vellykket eller ikke, er ikke kjent. Ved oppnådd graviditet er det ikke kjent om spiralen utgjør noen risiko for pasienten, fosteret og den videre graviditeten.
- **Essure**-spiraler kan trygt brukes sammen med MR og er radiopake. **Essure** spiralene er også MR-kompatible, bortsett fra ved bilder av pelvis, hvor de kan føre til artefakter.
- **Det kan finnes potensielle, ukjente risikoer.**

VIII. Bruksanvisning

A. Før plassering av spiral

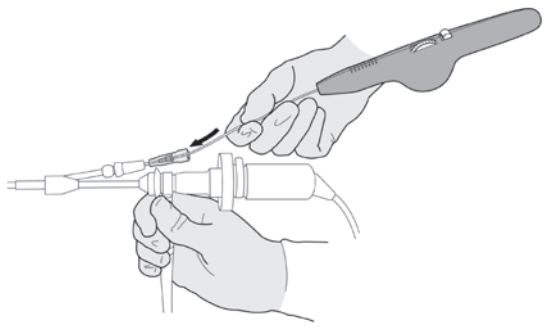
1. Spiralen bør plasseres i løpet av dag 7-14 av menstruasjonssyklusen (hvor dag 1 representerer første dag med blødning) for å styrke visualiseringen av eggledernes åpningene og redusere muligheten for plassering av spiralen hos en pasient med en udiagnostisert graviditet.

2. En graviditetstest utført av lege eller annen helseperson bør foretas innen 24 timer før eller rett før plasseringen av spiralen.
3. Administrasjon av NSAID-er (ikke-steroide antiinflammatoriske legemidler) som Indocid (oralt eller suppositorium), anbefales sterkt én til to timer før plassering av spiralen, siden kliniske studiedata viser at bruk av NSAID-er signifikant øker sannsynligheten for vellykket plassering. Hvis det bare brukes en paracervikalblokade, kan Diazepam (oralt), eller et tilsvarende middel, tilbys 30 minutter før prosedyren for å redusere engstelse.

B. Prosedyre for plassering av Essure-spiral

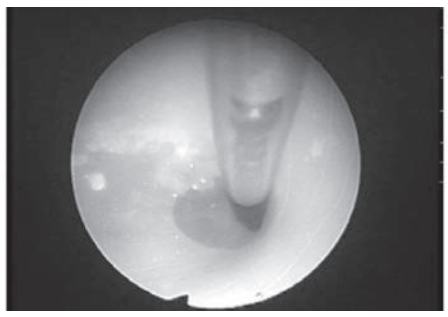
Prosedyren for plassering av **Essure**-spiralen kan utføres i polikliniske eller dagkirurgiske miljøer. Steriliteknikk må brukes under prosedyren for plassering av spiralen. Nødvendig tid for å gjennomføre plasseringen av spiralen bør ikke overstige 30 minutter.

1. Plassér pasienten i litotomiposisjon.
2. Innfør et spekulum i vagina for tilgang til cervix. Klargjør cervix med betadin eller annen egnet antibakteriell oppløsning i henhold til standard rutiner.
3. Lokalbedøvelse er den foretrukne metoden for implantasjon av spiralene. En paracervikalblokade kan administreres. Midazolam (IV), eller tilsvarende, kan også administreres etter behov, for å hindre eller redusere ubehag.
4. Sett inn et sterilt hysteroskop med kamera og operasjonskanal (≥ 5 French), gjennom cervix og inn i livmorhulen. Om nødvendig utføres en cervikal dilatasjon for å muliggjøre innføring. For å unngå livmorperforasjon må prosedyren avsluttes hvis det er nødvendig å bruke makt for å oppnå cervikal dilatasjon.
5. Utspiling av livmorhulen må utføres ved tilførsel av en fysiologisk saltoppløsning gjennom arbeidskanalen på hysteroskopet. Det anbefales på det sterkeste at saltoppløsningen forvarmes til kroppstemperatur og falltilført for å minimisere spasmer i eggledere. En god livmorutspiling må oppnås og opprettholdes gjennom hele prosedyren. Standardprosedyrer for væskemonitorering må følges gjennom hele prosedyren. Eggledеråpningene må identifiseres ved hysteroskopisk visualisering.
6. Begge tubaråpningene må identifiseres og evalueres hysteroskopisk før man fører inn **Essure**-spiralen. Det må ikke innføres en spiral i den ene tubaråpningen med mindre det er rimelig grunn til å anta at den andre egglederen er åpen.
7. Så snart egglederåpningen er identifisert, føres innføreren gjennom forseglingshetten på hysteroskopets arbeidskanal. Kranen på operasjonskanalen skal være åpen (enheten og/eller innføreren kan bli skadet hvis kranen stenges på en av enhetene). Før **Essure** innføringssystem gjennom innføreren og skyv det gjennom operasjonskanalen på hysteroskopet. Hvis den ventilutstyrte innføreren er uskadet etter første plassering av spiralen, kan den forbli i operasjonskanalen under hele **Essure**-prosedyren.



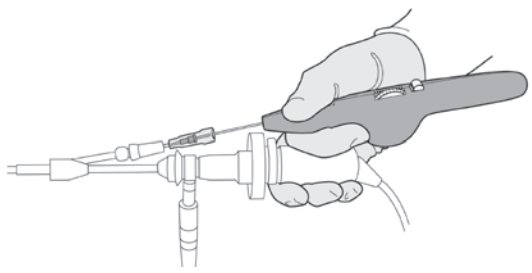
Før inn innføreren gjennom forseglingshetten på hysteroskopets arbeidskanal, og før deretter ***Essure****-innføringssystemet gjennom innføreren.*

8. Før **Essure**-innføringssystemet inn i den proksimale egglederen med en langsom, rolig bevegelse for å unngå tubare spasmer. Før innføringssystemet videre inntil plasseringsmarkøren på innføringskateteret når egglederåpningen. Denne visuelle markøren indikerer at **Essure**-spiralen spenner over de distale, intramurale til de proksimale, istmiske segmentene av egglederen, mens den ytre kveilen spenner over overgangen mellom livmor og eggleder (UTJ). Dette er den ideelle plasseringen av **Essure**-spiralen.



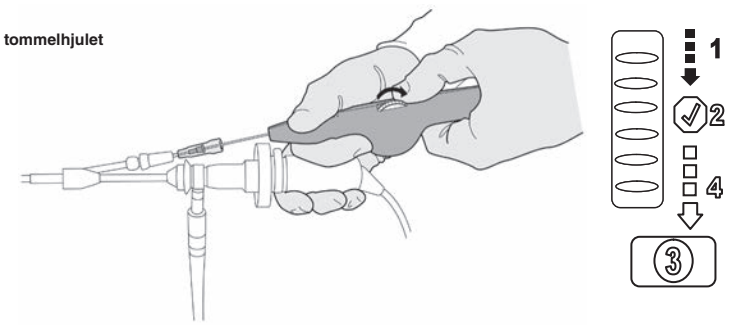
Føres videre til den svarte plasseringsmarkøren er ved tubaråpningen. Dette er en visuell indikator for korrekt posisjonering for innsetting.

9. Det tyder på korrekt konsentrisk tilpasning av innføringskateteret med tubarlumen når det er mulig å føre kateteret videre under direkte visualisering uten unødvendig motstand. Motstand mot videreføring vises vanligvis på to måter: 1) det kan observeres at den svarte markøren på den utvendige overflaten av kateteret ikke føres videre fremover mot tubaråpningen og/eller 2) innføringskateteret bøyes eller bendes overdrevent, og forhindrer derved legen i å føre kateterenheten videre fremover. For å unngå muligheten for livmorperforasjon eller utilsiktet plassering av spiralen i livmormuskulaturen i stedet for innenfor eggledеrlumenet, må det ikke gjøres ytterligere forsøk på å plassere spiralen når slik motstand mot videre fremføring av kateteret oppdages. Et oppfølgings-**Essure** bekreftelsestest (HSG) må utføres for å fastslå at eggledеrne er åpne.
10. Dersom det etter flere minutter ikke er mulig å føre kateteret videre til plasseringsmarkøren, kan det utføres en perfusjonstest med et kateter som påviser åpenhet, dersom det ikke allerede har blitt brukt, for å fastslå at eggleder er åpen. Dersom egglederen er blokkert eller kateteret ikke kan føres videre til plasseringsmarkøren, bør prosedyren avsluttes. Avbryt prosedyren hvis plassering av spiral ikke lykkes etter 10 minutter med kanyleringsforsøk per eggleder.
11. Spiralen settes inn når innføringskateteret er ført frem til plasseringsmarkøren. For å gjøre dette må håndtaket på **Essure**-spiralen først stabiliseres mot hysteroskop-kameraet eller annet fast objekt for å unngå utilsiktet, videre bevegelse av **Essure**-systemet under tilbaketrekking av innføringskateteret.



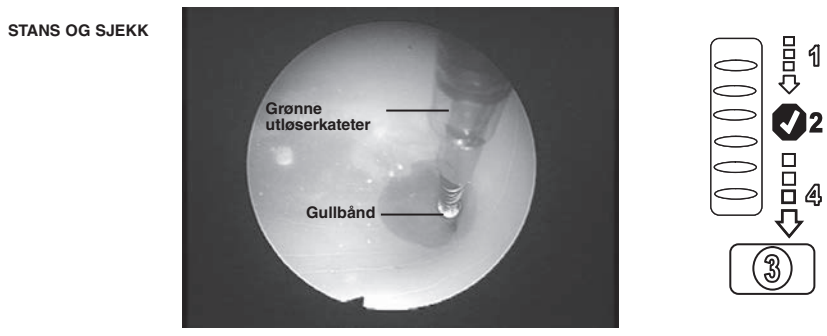
Stabiliser håndtaket mot kamerahodet eller annen fast gjenstand for å unngå utilsiktet, videre bevegelse av ***Essure****-systemet.*

12. Når det er fastslått at den svarte plasseringsmarkøren er ved egglederåpningen, dreies tommelhjulet på håndtaket mot deg inntil hjulet ikke kan gå lenger. Denne handlingen tilsvarer symbolet ⇩1 på innføringssystemets håndtak. Dette letter tilbaketrekkingen av innføringskateteret. Du vil se at den svarte plasseringsmarkøren beveger seg bort fra egglederåpningen (mot hysteroskopet) og forsvinner inn i operasjonskanalen. Tilbaketrekking av innføringskateteret blottlegger den avspente **Essure**-spiralen festet til utløserkateteret. Omtrent 1 cm av spiralen (avspente kveiler) må være synlig i livmoren når innføringskateteret er trukket tilbake.



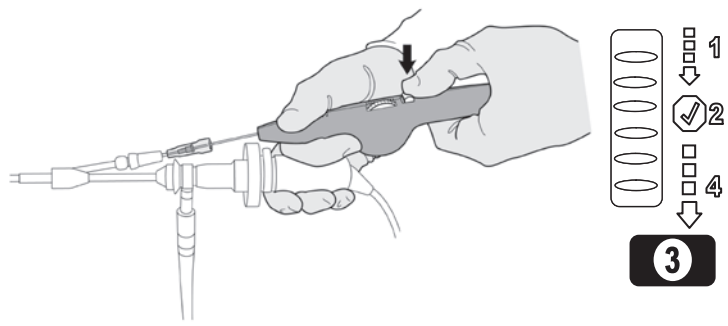
Drei tommelhjulet for å trekke kateteret tilbake

13. For å bekrefte riktig plassering, plasser det gullfargede markeringsbåndet like utenfor åpningen, noe som tilsvarer symbolet ✓2 på innføringssystemets håndtak. Riktig plassering bekreftes ved visualisering av gullbåndet like utenfor åpningen og visualisering av den distale enden av det grønne utløserkateteret. Hvis mer enn 1 cm av spiralen er synlig i uterus, skal spiralen omplasseres ved å skyve hele systemet lenger inn i egglederen, om mulig, før du går videre til neste trinn.



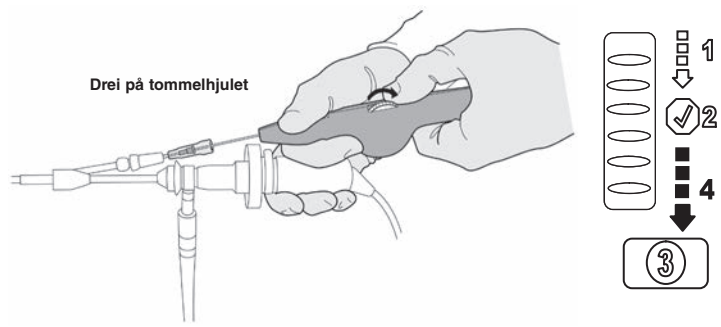
Visualiser gullbånd ved åpningen

14. Trykk på knappen på innføringshåndtaket slik at tommelhjulet kan dreies ytterligere, noe som tilsvarer symbolet ③ på håndtaksknappen.



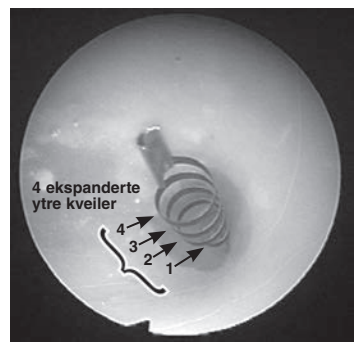
Trykk på knappen for å dreie tommelhjulet igjen

15. Drei tommelhjulet mot deg for å ekspandere den ytre kveilen på spiralen, noe som tilsvarer symbolet ⇩4 på håndtaket til innføringssystemet. Fortsett å dreie tommelhjulet til det ikke går lenger. Når tommelhjulet ikke kan dreies lenger og den ekspanderte ytre kveilen er synlig, dras systemet tilbake.



Vri på tommelhjulet for å ekspandere spiralens ytre kveil

16. Plasseringen av den innsatte **Essure**-spiralen vurderes ved hjelp av hysteroskopisk visualisering. Ideelt skal 3 til 8 ekspanderte ytre kveiler av **Essure**-spiralen gå inn i livmoren.



Ekspanderte ytre kveiler på ***Essure****-spiralen som går inn i livmoren angir ideell plassering*

17. Hvis legen etter hysteroskopisk vurdering er misfornøyd med plasseringen av spiralen eller har mistanke om livmorperforasjon, bør spiralen(e) forbli på plass og evalueres ved pelvisk røntgen eller HSG tre måneder etter plassering av enheten.

    ADVARSEL: NÅR SPIRALEN ER PLASSERT OG UTLØST I EGGLEDEREN, MÅ DU IKKE FORSØKE Å FJERNE SPIRALEN HYSTEROSKOPISK, MED MINDRE 18 ELLER FLERE KVEILER PÅ SPIRALEN GÅR INN I LIVMORHULEN. En slik spiral må forsøkes fjernet umiddelbart under plasseringsforsøket. Det kan imidlertid være umulig å fjerne denne (se kapittel XIII, Fjerning av **Essure**-spiral). Hvis spiralen ble utilsiktet plassert i livmorhulen og ikke i egglederen, må spiralen fjernes fra livmoren, og nytt forsøk på å plassere spiralen i egglederen må utføres.
18. Gjenta prosedyren for plassering av **Essure**-spiralen i den kontralaterale egglederen.
19. Registrér lengden på spiralen som går inn i livmorhulen, og notér eventuelle problemer med identifisering eller bekreftelse av enten tubaråpning eller andre forhold vedrørende mulig perforasjon. Disse bør føres i pasientens journal for senere referanse ved gjennomgang av en **Essure** bekreftelsestest *(Se kapittel VIII - Tre måneders* ***Essure*** *bekreftelsestest nedenfor).*
20. **Minn pasienten på å bruke annen prevensjon (unntatt spiral) de første 3 månedene etter plassering av spiralen.**

21. Sett opp time til pasienten for pelvisk røntgen tre måneder etter plassering av **Essure**-spiralen for å evaluere retensjon og plassering av spiralen.

IX. Essure bekreftelsestest

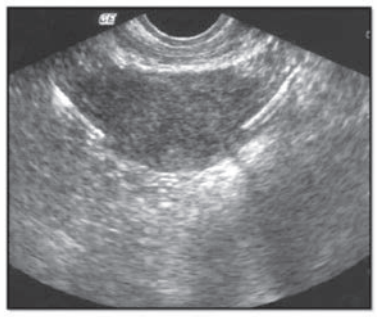
A. Det bør tas en **Essure** bekreftelsestest tre måneder etter plassering av spiralen for å evaluere spiralretensjon og –plassering. **Essure** bekreftelsestester (transvaginal ultralyd (TVU), pelvisk røntgen eller hysterosalpingogram (HSG)) skal kun utføres av en erfaren gynekolog, ultralydspesialist og/eller radiolog med opplæring i gjeldende **Essure** bekreftelsestest-protokoll. En detaljert protokoll med bilder og tips om testytelse gis gjennom opplæringen; flere kopier kan fås ved å laste ned en kopi fra essure.com.

B. Som første bekreftelsestest kan enten en pelvisk røntgen eller TVU gjøres tre måneder etter en ukomplisert bilateral spiralplassering.

1. Røntgen og TVU skal ikke brukes som **Essure** bekreftelsestest under følgende forhold:
   a) Vanskelig plassering med én eller flere av følgende:
      (1) Bekymring ved plasseringen om mulig perforasjon på grunn av for stor kraft nødvendig for levering av spiral og/eller plutselig tap av motstand.
      (2) Vanskelighet med identifikasjon av tubaråpning under plassering grunnet anatomisk variasjon eller tekniske faktorer som dårlig utspiling, dårlig belysning eller endometriale vevsavstøtninger.
      (3) Kirurg er usikker på plassering.
   b) Prosedyretid > 15 minutter (skop inn-skop ut).
   c) Plassering med null eller > 8 ekspanderte kveiler
   d) Uvanlig postoperativ smerte, forbigående eller vedvarende, eller som oppsto senere etter prosedyren, uten annen identifiserbar grunn.
2. Hvis røntgen eller ultralyd ikke er indikert, må pasienten videre til en HSG for å vurdere spiralplassering og okklusjon av eggledere. Transabdominal ultralyd kan ikke erstatte TVU. Hvis røntgen- eller ultralydvurdering er tvetydig eller utilfredsstillende, må pasienten videre til en HSG for å vurdere spiralplassering og okklusjon av eggledere.

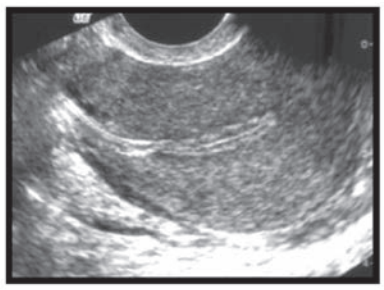
C. Transvaginal ultralyd

1. Minimum tre bilder må tas og oppbevares som dokumentasjon:
   a) Et koronalt eller oblikt koronalt bilde som viser en del av hver spiral i cornua, merket "speiderfilm".



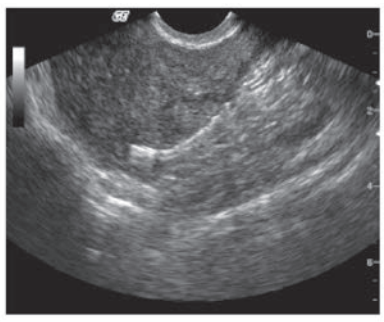
Bilaterale spiraler er identifisert i dette transverse (koronalt/oblikt koronalt) bildet.

   b) Et koronalt eller oblikt koronalt bilde av den lineære aksen til venstre spiral samt proksimalenden som krysser myometrium i cornua (interstitiell del av eggledereren) eller i kontakt med uterus serosa tubar junktur og merket "venstre".
   c) Et koronalt eller oblikt koronalt bilde av den lineære aksen til høyre spiral krysser myometrium i cornua (interstitiell del av eggledereren) eller i kontakt med uterus serosa tubar junktur og merkes "høyre".
   d) Alle tre bilder må tas opp på film og plasseres i pasientjournalen for å dokumentere tilfredsstillende spiralretensjon og plassering.
2. Klassifisering av spiralplassering
   a) Spiralidentifikasjon: I en enkel speiderfilm, må en del av hver spiral vises i cornua i koronal eller oblik koronal visning, for å sikre bilateral plassering og redusere risikoen for dobbelt bilde av samme spiral. Den lineære aksen til spiraler må virke relativt symmetrisk.
   b) Optimal plassering
   Spiralplassering er optimal når proksimalenden av spiralen er i kontakt med livmorhulen eller endometrium, og den lineære aksen er innen myometrium i cornua (interstitiell del av eggledereren) og kan vises ved eller kryssende utero serosa tubar junktur (USTJ). Delen av spiralen i eggledereren kan muligvis vise. Den lineære aksen til spiralen må vise for å bekrefte at den ikke er sammenkveilet eller utstrukket.



Optimal plassering

   c) Tilfredsstillende plassering
   Spiralplassering er tilfredsstillende når proksimalenden av spiralen er distalt til endometrium, men den lineære aksen er innen myometrium i cornua (interstitiell del av eggledereren) og kan vises ved eller kryssende utero serosa tubar junktur (USTJ). Delen av spiralen i eggledereren kan muligvis vise. Den lineære aksen til spiralen må vise for å bekrefte at den ikke er sammenkveilet eller utstrukket.

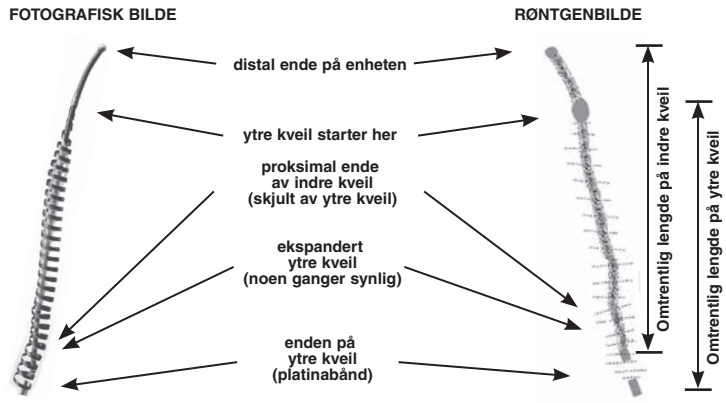


Tilfredsstillende plassering

   d) Utilfredsstillende plassering
      (1) Spiralplassering er utilfredsstillende hvis en del av spiralen ikke kan vises i cornua i koronal eller oblik koronal visning i en speiderfilm.
      (2) Utstøtning mistenkes hvis en eller begge spiraler ikke er identifisert i cornua i en koronal visning i en enkel speiderfilm.
      (3) Distal plassering mistenkes hvis proksimalenden av spiralen ikke er plassert i myometrium i cornua (interstitiell del av eggledereren), og ikke krysser eller er i kontakt med USTJ.
      (4) Proksimal plassering mistenkes hvis mer enn 50 % eller mesteparten av spiralen vises i livmorhulen eller hvis den lineære aksen til spiralen(e) vises i midtlinje sagittal visning.
      (5) Perforasjon mistenkes hvis den lineære aksen til en eller begge spiraler er parallell med endometrialstripen i den sagittale visningen, eller hvis den lineære aksen til en spiral vises kryssende myometrium i midtlinje sagittal visning.
      (6) Uklassifisert posisjon: Hvis den lineære aksen til en spiral ikke kan identifiseres, som antyder at den er kveilet, bøyd eller utstrukket, er spiralplassering utilfredsstillende. Hvis omkringliggende mykt vev ikke tydelig kan defineres, betraktes posisjonen som utilfredsstillende.
3. Hvis ultralydvurdering er tvetydig eller utilfredsstillende, må pasienten videre til en HSG for å vurdere spiralplassering og okklusjon av eggledere.

D. Pelvisk røntgen

1. Ta et bilde av livmoren som viser begge **Essure**-spiralene tydelig. Plassering og krumning av spiralene skal registreres.



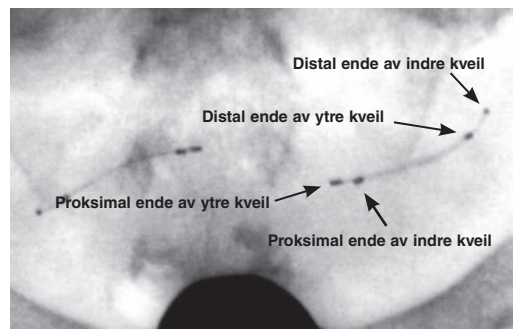
*Tilsvarende radiografisk visning av **Essure**-spiral*

2. Pelvisk røntgen evalueres som følger:
   a) Tilfredsstillende: Spiralene er i tubarlumenet og spenner over overgangen mellom livmoren og eggledere, og synes relativt symmetriske. Pasienter med røntgen som fastsettes som "tilfredsstillende" kan begynne å stole på **Essure**-spiralen som prevensjon.
   b) Mistenkelig: En eller begge spiralene synes å være distale eller proksimale i forhold til optimal plassering, eller kan være helt eller delvis perforert gjennom eggledere, og/eller synes relativt asymmetriske. Pasienter med røntgen som fastsettes som "mistenkelig" bør bes om å fortsette med annen prevensjon og få utført en HSG.
   c) Utilfredsstillende: Tydelig intraperitoneal spiralplassering eller utstøting.
3. Hvis røntgenevaluering er tvetydig eller utilfredsstillende, eller spiralplassering er mistenkelig, må pasienten videre til en HSG for å vurdere spiralplasseringen og okklusjon av eggledere.

E. Utføring og evaluering av modifiserte HSG-er

1. HSG utføres for å evaluere **Essure** spiralplassering og eggleder okklusjon om nødvendig, basert på røntgen eller ultralydresultater. Følg instruksjonene under for utføring og evaluering av HSG.
2. Utføre HSG - Retningslinjer:
   a) Få god oppfylling av cornua, slik at livmorhulens silhuett vises tydelig.
   b) Fluoroskopistrålen bør være så nær A/P projeksjon som mulig.
   c) Ikke utvid cerviks uten at det er nødvendig; hvis utvidelse skjer, opprettholde god cervikal tetning.
   d) Nedadgående traksjon på den cervikale tenakulum kan være nødvendig for pasienter med midtposisjonert livmor. Fjern spekulum før fluoroskopi for best visning av livmoranatomi.
   e) Ta minst seks røntgenbilder for å vurdere spiralplassering og okklusjon av eggledere.
      (1) Røntgenbilde 1 – "Speiderfilm" – Livmor og spiraler uten kontrastvæske.
      (2) Røntgenbilde 2 – Minimal fylling av livmorhulen – Livmor og spiraler med små mengder kontrastvæske.
      (3) Røntgenbilde 3 – Delvis fylling av livmorhulen – Livmor og spiraler når nesten fullt med kontrastvæske.
      (4) Røntgenbilde 4 – Fullstendig fylling av livmorhulen – Livmor og spiraler når cornua er utspilt med kontrastvæske.
      (5) Røntgenbilder 5 & 6 – Forstørrelser av cornua uteri – Spiral innen eggleder med høyre (5) og venstre (6) cornua.

   FORSIKTIG: Unngå for stort trykk i livmoren etter Røntgenbilde 4 for å unngå unødvendig ubehag for pasienten og vasovagal reaksjon.



3. Vurdere spiralplassering
   a) Under evaluering, legg merke til fire "markører" på hver ende av indre og ytre kveiler. Legg merke til at distale markører er faste i forhold til hverandre, men de proksimale markørene kan beveges eller virke strukket på grunn av fleksibiliteten til den ytre kveilen. Idéell spiralplassering er når den indre kveilen krysser livmorens tubarjunktur.
   b) Vurdere spiralplassering:
      (1) Utstøtning eller proksimal plassering: Spiralen er ikke til stede eller ≥ 50 % av den indre kveilen etterfølger inn i livmorhulen.
      (2) Tilfredsstillende plassering: Distalenden av den indre kveilen er innen eggledereren, med < 50 % av den indre kveilen etterfølgende inn i livmorhulen eller proksimalenden av den indre kveilen ≤ 30 mm inn i eggledereren hvor kontrasten fyller cornua.
      (3) Distal plassering eller perforasjon: Spiral er i eggledereren, men den proksimale enden av den indre kveilen er > 30mm distalt fra der som kontrast fyller cornua eller spiralen er fullstendig eller delvis perforert.
4. Vurdere okklusjon av eggledere
   a) Fastslå om kontrasten er synlig utover spiralen og legg merke til om det er noen proksimal fylling av eggleder, selv om eggledereren er okkludert.
   b) Vurdere okklusjon av eggleder:
      (1) Tilfredsstillende okklusjon: Eggledereren er okkludert ved cornua.
      (2) Tilfredsstillende okklusjon: Kontrast sett innen eggleder, men ikke utover distalenden av den ytre kveilen.
      (3) Utilfredsstillende okklusjon: Kontrast sett utover distalenden av spiralen eller i peritonealhulen.
5. Vurdere påliteligheten
   a) Hvis både plassering og okklusjon av eggleder er tilfredsstillende, gi pasienten beskjed om å avslutte annen prevensjon.
   b) Hvis plassering er utilfredsstillende, gi pasienten beskjed om å ikke stole på spiralen som prevensjon.
   c) Hvis plassering er tilfredsstillende, men okklusjon er utilfredsstillende, gi pasienten beskjed om å fortsette bruk av annen prevensjon. Gjenta HSG om tre måneder. Hvis okklusjon er utilfredsstillende, gi pasienten beskjed om å ikke stole på spiralen som prevensjon.

X. Håndtering av utilfredsstillende spiralplassering

A. Utilfredsstillende plassering av spiral diagnostisert ved hysterosalpingogram

1. Proksimal plassering: mer enn 50 % av lengden på den indre kveilen på spiralen(e) går inn i livmoren.
2. Distal passering: spiralen(e) er i eggleder, men den proksimale enden på den indre kveilen er mer enn 30 mm fra den kontrastoppfylte cornu uteri.
3. Full utstøting av spiralen(e); spiralen(e) har forsvunnet ut av kroppen.
4. Perforasjon: spiralen(e) perforerer eggleder helt eller delvis.
5. Intraperitoneal plassering av spiralen(e); spiralen(e) er klart utenfor eggleder(ne).

B. Håndtering av spiralutstøting eller utilfredsstillende spiralplassering

1. Bilateral spiralutstøting med bilateral okklusjon: Med hensyn til muligheten for en falskt positiv diagnose på tubar okklusjon ved en **Essure** bekreftelsestest (HSG), bør pasienten informeres om muligheten til å få utført en kirurgisk sterilisering eller å stole på sin bilaterale PTO (proksimal tubar okklusjon) som prevensjon.
2. Bilateral spiralutstøting med okklusjon i én eggleder og åpenhet i den kontralaterale egglederen: Pasienten kan vurderes med hensyn til en ny spiral-prosedyre for å erstatte spiralen i den egglederen som er åpen, slik at hun skal kunne stole på én **Essure**-spiral og kontralateral PTO som prevensjon. Med hensyn til muligheten for en falskt positiv diagnose på tubar okklusjon ved en **Essure** bekreftelsestest (HSG), bør pasienten informeres om denne muligheten. Hun bør også informeres om muligheten til å få utført en kirurgisk sterilisering.
3. Unilateral spiralutstøting eller utilfredsstillende spiralplassering (i myometrium eller intraperitonealt hulrom) med kontralateral spiral plassert tilfredsstillende: Dersom **Essure** bekreftelsestest (HSG) viser tubar blokkering i egglederen fra der hvor spiralen ble utstøtt eller der hvor spiralen skulle vært plassert, kan pasienten stole på den korrekt plasserte spiralen og den kontralaterale PTO, med hensyn til muligheten for en falskt positiv diagnose på tubar okklusjon ved **Essure** bekreftelsestest (HSG). Hun bør også informeres om muligheten til å få foretatt kirurgisk sterilisering.
4. Utilfredsstillende unilateral spiralplassering (i myometrium eller intraperitonealt hulrom) med kontralateral spiralplassering: Dersom **Essure** bekreftelsestest (HSG) viser tubar åpenhet i egglederen hvor det skulle vært en spiral, kan pasienten tilbys muligheten til å komme tilbake for en ny spiralplassering. Hun bør også informeres om muligheten til å få foretatt kirurgisk sterilisering.
5. Unilateral spiralutstøting; utilfredsstillende unilateral spiralplassering (i myometrium eller intraperitonealt hulrom); utilfredsstillende unilateral spiralplassering i "proksimal plassering" (>50 % av indre kveil lengde går inn i livmor) eller "distal plassering" (spiralen i eggleder, men proksimal ende på den indre kveilen er >30 mm fra kontrastoppfylt cornu uteri) med kontralateral spiral plassert utilfredsstillende: Pasienten bør informeres om muligheten til å få foretatt en kirurgisk sterilisering. For alle tilfeller gjelder det at dersom fjerning av spiral er nødvendig og hysteroskopisk fjerning er umulig, kan kirurgisk inngrep være nødvendig.
6. Dersom en pasient har valgt kirurgisk sterilisering etter noen av scenariene ovenfor, må begge eggledere okkluderes uavhengig av om den andre spiralen er tilfredsstillende plassert. Det bør gjøres et forsøk på å fjerne en spiral dersom legen finner det trygt. Det kan imidlertid vise seg umulig å fjerne spiralen. Det anbefales bruk av intra-operativ fluoroskopi for å identifisere plasseringen av spiralen(e) før og under inngrepet. Forsøk på fjerning må avbrytes etter 30 minutter.

XI. Håndtering av tilfeller med utilfredsstillende Essure-spiralplassering

I tilfeller med unilateral eller bilateral feilplassering av spiral, må pasienten informeres om at hennes varige prevensjon ikke er gjennomført. Dersom pasienten velger laparoskopisk sterilisering (dvs. klemmepåføring eller elektrokauterisasjon), må begge eggledere avklemmes eller kauteriseres selv om den ene egglederen har implantert **Essure**-spiral. Klemming eller kauterisasjon av egglederen eller -lederne må utføres distalt for **Essure**-spiralen.

Hvis pasienten ikke velger laparoskopisk sterilisering, kan hun tilbys en **Essure** bekreftelsestest (HSG) etter neste mensperiode (pre-ovulatorisk: dag 7-14 hvor dag 1 representerer den første blødningsdagen) for å fastslå tubar åpenhet. Dersom det bekreftes tubar åpenhet, kan legen tilby pasienten et nytt forsøk på plassering av spiral. Hvis et nytt forsøk på plassering av spiral mislykkes, er det lite trolig at pasienten vil lykkes ved ytterligere forsøk. Hvis pasienten har én spiral igjen *in vivo* bør hun rådes til ikke å stole på den unilaterale spiralen som prevensjon.

Dersom det kun var unilateral plassering som ble oppnådd og en **Essure** bekreftelsestest (HSG) bekrefter kontralateral PTO, bør pasienten informeres om muligheten for å stole på den ene spiralen med hensyn til muligheten for en falskt positiv diagnose på PTO ved **Essure** bekreftelsestest (HSG). Tubar okklusjon defineres ved at fargestoffet ikke passerer fra livmorhulen og inn i bukhulen på det tidspunkt en **Essure** bekreftelsestest (HSG) blir utført. Hun bør også informeres om muligheten til å få utført en kirurgisk sterilisering. Forsøk på fjerning av en unilateralt plassert spiral anbefales ikke med mindre pasienten opplever bivirkning(er) med spiralen.

XII. Fjerning av Essure-spiral

ADVARSEL: FJERNING AV SPIRAL MÅ IKKE UTFØRES HYSTEROSKOPISK NÅR SPIRALEN ER PLASSERT, MED MINDRE 18 ELLER FLERE KVEILER PÅ ESSURE-SPIRALEN GÅR INN I LIVMORHULEN. En slik spiral må forsøkes fjernet umiddelbart etter plassering. Det kan imidlertid være at fjerning er umulig. Hvis det blir gjort forsøk på fjerning, utføres følgende trinn:

1. Før et gripeinstrument gjennom hysteroskopets arbeidskanal.
2. Grip den ytre kveilen på **Essure**-spiralen. Prøv å gripe den ytre og indre kveilen på spiralen samtidig.
3. Trekk både gripeinstrumentet og hysteroskopet tilbake samtidig, slik at hele systemet trekkes ut av livmoren samtidig.
4. Den ytre kveilen og/eller den indre kveilen på **Essure**-spiralen strekkes eller forlenges ved forsøk på fjerning av spiral.
5. Administrér analgesia/anestesi etter behov for å redusere eller unngå pasientubehag.
6. Hvis en komplett fjerning av spiral gjennomføres, bør et nytt forsøk på plassering av **Essure**-spiral utføres.
7. Hvis legen ikke er helt sikker på at hele **Essure**-spiralen er fjernet fra egglederen, må det **IKKE** plasseres en ny spiral i den egglederen, og et røntgen må tas etter plasseringen for å fastslå om det finnes spiralfragment igjen *in vivo*.

Med unntak av scenariet beskrevet ovenfor, må fjerning av spiral kun forsøkes hvis en pasient opplever bivirkning(er) med spiralen eller hvis hun krever fjerning av spiralen.

Hvis fjerning av spiral ansees som nødvendig, er en transabdominal tilnærming (dvs. laparotomi eller laparoskopi) nødvendig.

En cornual reseksjon av den proksimale egglederen vil være nødvendig dersom spiralen er korrekt plassert på overgangen mellom livmor og eggleder.

En **Essure**-spiral som er feilplassert eller har vandret vekk fra overgangen mellom livmor og eggleder, må fjernes ved bruk av tradisjonell lineær salpingotomi eller salpingektomi gjennomført ved lapasorskopi eller laparotomi.

1. For å utføre en lineær salpingotomi må et lite snitt (omtrent 2 cm) lages langs den antimesenteriske grensen av egglederen, rett over spiralen.
2. Full eller delvis salpingektomi kan utføres for å fjerne spiralen samtidig med, eller uavhengig av, gjennomføring av en tradisjonell prosedyre for tubar sterilisering.

XII. Pasient-ID-kort

Alle pasienter som har fått implantert **Essure**-spiral(er), bør få et laminert kort i kredittkortstørrelse som opplyser at hun har **Essure**-spiral(er) innsatt. **Kortet er lagt ved denne forpakningen.** Kortet vil i tillegg opplyse at det kan innebære noen risiko dersom deltakeren får utført fremtidige intrauterine prosedyrer eller kirurgiske inngrep i forplantningsorganene.

XIV. Symbolforklaring

STERILE EO	Sterilisert ved bruk av etylenoksid
LOT	Partikode
	Må ikke brukes på nytt
REF	Katalognummer
	Forsiktig, se bruksanvisning
	Anvendes før
	Må holdes vekk fra varmekilder
	Må ikke brukes hvis pakken er åpen eller skadet
MR	Betinget MR-sikker
EC REP	Autorisert EU-representant
CE 0050	Enheten oppfyller kravene i EU-direktiv 93/42/EF
	Må holdes tørr
CONT	Innhold

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For produktbestilling eller rapportering av bivirkninger, vennligst kontakt den lokale representanten

PN-84731145, ART Rev. B

Português

essure®

Contraceptivo permanente

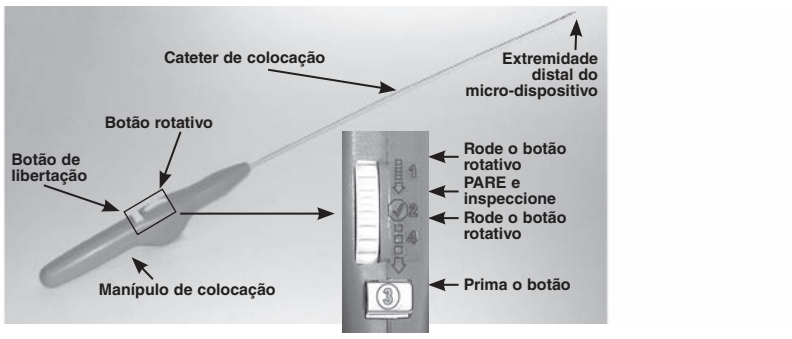
BAYER

INSTRUÇÕES DE UTILIZAÇÃO

I. Descrição do Micro-dispositivo

O Sistema Contraceptivo Permanente **Essure**® compreende vários componentes. O micro-dispositivo **Essure**, um micro-dispositivo de expansão dinâmica, está ligado a um fio de colocação e a um cateter de libertação. Todo o conjunto está coberto por um cateter de colocação. Este sistema (apresentado na Figura 1) está ligado a um manípulo que facilita a colocação e o accionamento do micro-dispositivo. Com o sistema **Essure**, também é fornecido um introdutor de válvula, o introdutor **DryFlow**®. Este destina-se a ajudar a proteger o micro-dispositivo **Essure** quando o mesmo é passado através do orifício em borracha do canal de trabalho do histeroscópio.

Figura 1
Sistema de colocação Essure
A apresentar pormenor dos símbolos do procedimento de colocação
(NÃO À ESCALA)



II. Mecanismo de Acção

O sistema **Essure**, sob visualização histeroscópica, coloca um micro-dispositivo **Essure** na secção proximal do lúmen da trompa de Falópio. Quando o micro-dispositivo **Essure** é expandido durante a libertação, fica firmemente fixo à trompa de Falópio. Posteriormente, o micro-dispositivo suscita uma resposta benigna intencional dos tecidos, a qual resulta em crescimento para o interior do micro-dispositivo, o que o prende firmemente à trompa de Falópio. Esta resposta benigna do tecido é local, fibrótica e de natureza oclusiva.

Cada sistema **Essure** é esterilizado por óxido de etileno e é fornecido esterilizado apenas para uma única utilização. Não reutilizar nem resterilizar. A resterilização pode afectar adversamente o funcionamento mecânico adequado e pode resultar em lesões para a doente.

III. Indicações de Utilização

O sistema **Essure** destina-se a ser utilizado como um micro-dispositivo de oclusão tubária para fins de contracepção permanente.

IV. Contra-indicações à Utilização

- Incerteza da doente quanto ao seu desejo de terminar a fertilidade.
- Gravidez ou suspeita de gravidez.
- Parto ou interrupção da gravidez no segundo trimestre, menos de 6 semanas antes da colocação do micro-dispositivo **Essure**.
- Infecção pélvica activa ou recente.
- Cervicite aguda não tratada.
- Sangramento vaginal inexplicado ou grave.
- Tumor maligno ginecológico (suspeito ou conhecido).
- Cavidade uterina ou trompas de Falópio reconhecidamente anormais, tornando a visualização dos óstios tubários e/ou a canulação da porção proximal da trompa de Falópio difícil ou impossível.
- Alergia aos meios de contraste (pode ser necessário um histerossalpingograma três meses após a colocação do micro-dispositivo).
- A doente está actualmente a tomar corticosteróides.

V. Advertências

- O procedimento **Essure** só deve ser realizado por histeroscopistas experientes que tenham concluído o programa de formação da Bayer HealthCare LLC para este procedimento.
- As doentes que tenham alergia ao níquel-titânio podem sofrer uma reacção alérgica ao micro-dispositivo.
- Não utilize o sistema **Essure** se a embalagem estiver aberta ou danificada. Não utilize se o micro-dispositivo estiver danificado.
- Quando introduzir o micro-dispositivo **Essure** na trompa de Falópio, nunca faça avançar o(s) micro-dispositivo(s) contra resistência excessiva.
- Não continue a avançar o sistema **Essure** depois de o marcador de posicionamento do cateter ter alcançado o óstio tubário. O avanço para além deste ponto pode resultar em colocação insatisfatória do micro-dispositivo ou em perfuração tubária/uterina.
- Em caso de ocorrência, ou suspeita de ocorrência, de perfuração tubária, não prossiga com a tentativa de colocação do micro-dispositivo **Essure**. Nos ensaios clínicos do **Essure**, foi identificada uma percentagem muito reduzida de mulheres (1,8% ou 12/682 doentes) com perfurações tubárias relacionadas com o dispositivo. Se necessário, a recuperação de micro-dispositivos causadores de perfuração exige laparoscopia ou outros métodos cirúrgicos.
- Se as tentativas de colocação do micro-dispositivo **Essure** não tiverem êxito ao fim de 10 minutos de tentativa de canulação por trompa, o caso deve ser terminado e potencialmente adiado.
- Uma vez introduzido o micro-dispositivo, ou seja, uma vez separado do fio de colocação, não se deve tentar a sua remoção por via histeroscópica, a menos que 18 ou mais hélices do dispositivo **Essure** estejam no interior da cavidade uterina. A remoção de tal micro-dispositivo deve ser tentada imediatamente após a colocação. No entanto, a remoção pode não ser possível.
- A doente deve usar um contraceptivo alternativo até que uma radiografia feita três meses após a colocação do micro-dispositivo demonstre uma localização satisfatória do micro-dispositivo.
- Às doentes sujeitas a colocação do micro-dispositivo **Essure** podem, no futuro, ser propostas terapias intra-uterinas que utilizem energia eléctrica. Recomenda-se evitar a utilização do electrocautério em procedimentos cirúrgicos realizados nos cornos uterinos e nas trompas de Falópio. Todos os outros procedimentos na pélvis devem evitar a utilização do electrocautério a menos de 4 cm do micro-dispositivo. Dada a presença dos micro-dispositivos **Essure**, podem existir riscos associados a esses procedimentos que, de momento, não foram identificados.
- Quaisquer procedimentos intra-uterinos, tais como biópsia do endométrio, dilatação e curetagem, histeroscopia (de diagnóstico ou cirúrgica), incluindo ablação do endométrio, podem interromper a capacidade dos micro-dispositivos prevenirem a gravidez. Além disso, a presença de micro-dispositivos **Essure** pode acarretar riscos associados a esses procedimentos, os quais, de momento, não foram identificados.
- Estudos clínicos e laboratoriais demonstraram que a ablação do endométrio do útero pode ser executada eficazmente e com segurança com o Sistema de Balão Uterino GYNECARE THERMACHOICE*, o Sistema de Ablação do Endométrio NovaSure** da Hologic e o Hydro ThermAblator*** da Boston Scientific **imediatamente após** a colocação do micro-dispositivo **Essure**. Não foram realizados estudos específicos para avaliar as taxas de expulsão ou de contracepção de micro-dispositivos **Essure** depois da realização de procedimentos combinados com micro-dispositivos **Essure** e de ablação do endométrio.
- No futuro, as doentes podem decidir-se a serem sujeitas a fertilização *in vitro* (FIV) para engravidarem. Desconhecem-se os efeitos dos micro-dispositivos **Essure** sobre o êxito da FIV. Em caso de gravidez, desconhecem-se os riscos para a doente, para o feto e para a continuação da gravidez decorrentes do micro-dispositivo.

* Marca comercial da ETHICON, INC.
** Marca comercial da Hologic, Inc.
*** Marca comercial da Boston Scientific Corporation

VI. Precauções

- Sempre que possível, a colocação do micro-dispositivo deve ser realizada entre o 7.º e o 14.º dias do ciclo menstrual (onde o 1.º dia representa o primeiro dia de sangramento), a fim de melhorar a visualização dos óstios tubários e diminuir as probabilidades de colocação de um micro-dispositivo numa doente com gravidez não diagnosticada.
- As variações anatómicas uterinas podem dificultar a colocação dos micro-dispositivos **Essure**.
- A fim de reduzir o risco de perfuração uterina, o procedimento deve ser terminado no caso de ser necessária força excessiva para obter dilatação cervical.
- Antes de prosseguir com a colocação de micro-dispositivos **Essure**, ambos os óstios tubários devem ser identificados e avaliados histeroscopicamente. Não deve ser feita qualquer tentativa para colocar um micro-dispositivo num óstio tubário, a menos que existam probabilidades aceitáveis da outra trompa ser acessível e não obstruída.
- A realização da ablação do endométrio imediatamente após a colocação dos micro-dispositivos **Essure** pode aumentar o risco do síndroma de esterilização tubária pós-ablação, uma situação rara que tem sido descrita em mulheres com antecedentes de esterilização tubária após a realização de ablação do endométrio.
- Não faça avançar o sistema **Essure** se a doente tiver dores ou desconforto invulgares.
- Conserve o sistema **Essure** num local fresco e seco.

VII. Possíveis Efeitos Adversos

A. Gravidez

Existem riscos de gravidez e de gravidez ectópica e riscos associados aos tratamentos de ambas as condições. No caso de a doente conceber e optar por prosseguir a gravidez intra-uterina, deve ser informada de que os riscos do micro-dispositivo para a doente, para o feto e para a continuação da gravidez são desconhecidos.

B. Riscos Associados ao Procedimento de Colocação do Micro-dispositivo

- A fim de prevenir ou reduzir o desconforto, pode ser administrada à doente anestesia local, analgesia/sedação oral, anestesia regional (ou seja, espinal, epidural), sedação oral ou consciente (intravenosa) ou anestesia geral. Independentemente do tipo de anestesia, as doentes podem não estar em condições de recomeçarem as suas actividades normais durante 12 a 24 horas após o procedimento.
- Podem ocorrer dores, cãibras e sangramento vaginal durante e após o procedimento de colocação do micro-dispositivo. De modo geral, estes incidentes são toleráveis, passageiros e tratados com êxito com fármacos.
- Durante e/ou imediatamente após o procedimento de colocação do micro-dispositivo, existe o risco de a doente sentir náuseas ou vómitos. Normalmente, estes sintomas são passageiros e podem ser tratados, se necessário, com fármacos.
- No dia do procedimento, as doentes podem sentir desmaio ou resposta vasovagal.
- Existe o risco de perfuração ou dissecção da trompa de Falópio ou dos cornos uterinos. A perfuração ou dissecção pode resultar em sangramento e cicatrização; no entanto, de modo geral, não é necessário tratamento.
- Existe o risco de perfuração uterina pelo histeroscópio, pelo sistema **Essure** ou por outros instrumentos utilizados durante o procedimento, com possíveis lesões do intestino, bexiga e vasos sanguíneos importantes. Em caso de ocorrência de tais lesões, pode ser necessária intervenção cirúrgica, se bem que pouco provável. A fim de reduzir o risco de perfuração uterina, o procedimento deve ser terminado no caso de ser necessária força excessiva para a obtenção da dilatação cervical.
- Existe o risco de o micro-dispositivo **Essure** ser inadvertidamente colocado no miométrio do útero, e não no lúmen da trompa de Falópio. No caso de já ter sido devidamente colocado um micro-dispositivo numa das trompas de Falópio, depois de colocar inadvertidamente um micro-dispositivo no miométrio, o médico pode tentar colocar um terceiro micro-dispositivo para completar o procedimento. No caso da colocação bilateral nas trompas de Falópio não ter sido conseguida, o resultado final poderá ser a colocação de um micro-dispositivo na trompa de Falópio e/ou outro micro-dispositivo no miométrio, situação com a qual a paciente não pode contar para fins contraceptivos. A colocação do micro-dispositivo no miométrio pode resultar em dor pós-operatória ou outra reacção adversa. No caso de ser necessária a remoção cirúrgica do(s) micro-dispositivo(s), pode ser necessária uma salpingectomia ou uma histerectomia.
- Existe o risco de o micro-dispositivo **Essure** ser colocado de forma demasiado distal no interior da trompa de Falópio. No caso de ser necessária a remoção do micro-dispositivo, é necessária cirurgia (laparoscopia ou laparotomia).
- Existe o risco de o micro-dispositivo **Essure** ser colocado de forma demasiado proximal no interior da trompa de Falópio. No caso de serem visíveis 18 ou mais hélices do micro-dispositivo **Essure** no momento da colocação, deve ser imediatamente realizada uma tentativa de remoção do micro-dispositivo (ver a secção XIII, Remoção de Micro-dispositivos **Essure**). No caso de ser tentada a remoção do micro-dispositivo, existe a possibilidade da remoção não ter êxito ou do micro-dispositivo **Essure** se quebrar, deixando um fragmento do micro-dispositivo *in vivo*. No caso de ser tentada e/ou obtida a remoção do micro-dispositivo, também existe a possibilidade da doente experimentar aumento da dor, das cãibras e do sangramento durante e após o procedimento de colocação do micro-dispositivo **Essure**.
- Existe o risco de o micro-dispositivo **Essure** poder perfurar a parede tubária ou os cornos uterinos, o que poderia resultar no desprendimento do micro-dispositivo para a cavidade peritoneal. Como resultado, podem ocorrer dores e/ou distúrbios menstruais ou outras reacções adversas. No caso de a doente optar por esterilização incisional, ou outra intervenção cirúrgica, pode ser tentada a recuperação do micro-dispositivo da cavidade peritoneal se o médico considerar ser seguro fazê-lo. No entanto, a recuperação do micro-dispositivo pode não ser possível se este não puder ser visualizado nem acedido pelo médico.
- Existe o risco de a colocação do micro-dispositivo **Essure** apenas ser obtida numa trompa de Falópio. Se o mesmo ocorrer, as doentes podem ficar com um micro-dispositivo *in vivo*, com o qual não poderão contar para contracepção permanente.
- Existe o risco de a colocação do micro-dispositivo **Essure** não ser possível em qualquer uma das trompas de Falópio.
- Existe um risco mínimo de absorção excessiva do soro fisiológico usado para distensão do útero, para a realização do procedimento histeroscópico.
- Tal como com todos os procedimentos invasivos, o procedimento de colocação do micro-dispositivo pode provocar uma infecção. Uma infecção pode ocasionar danos no útero, trompas de Falópio ou cavidade pélvica. Isto pode exigir tratamento com antibióticos ou, raramente, internamento hospitalar ou cirurgia, incluindo histerectomia.

C. Riscos Associados ao Uso do Micro-dispositivo Essure

- Existe o risco de o micro-dispositivo **Essure** se deslocar para o exterior das trompas de Falópio. Esta deslocação pode ser devida a expulsão (movimento para fora da trompa de Falópio e para o interior da cavidade uterina/colo uterino/vagina ou para o exterior do corpo) ou a migração (movimento para a porção distal da trompa de Falópio ou para fora da trompa de Falópio e para o interior da cavidade peritoneal). Podem ser necessárias radiografias adicionais para identificar a localização do(s) micro-dispositivo(s), podendo ser necessária cirurgia para remover o(s) mesmo(s). A deslocação do dispositivo pode resultar em gravidez, gravidez ectópica e/ou dor/distúrbios menstruais ou outras reacções adversas.
- Tal como com os métodos actualmente disponíveis de contracepção mecânica permanente (ou seja, grampos, anéis), no caso de o micro-dispositivo **Essure** ter de ser removido, é necessária cirurgia. Além disso, é possível que seja necessária a remoção cirúrgica das trompas de Falópio (salpingectomia) e do útero (histerectomia).
- Podem ocorrer dores e cãibras abdominais/pélvicas. As dores e as cãibras podem ocorrer com maior probabilidade durante o período menstrual, durante e após o coito ou com outras actividades físicas.
- Pode ocorrer sangramento intermenstrual ou sangramento mais abundante do que o normal.
- Ocasionalmente uma doente pode arrepender-se da sua decisão de se sujeitar a contracepção permanente e como resultado, sentir uma ligeira depressão ou outras perturbações emocionais.

D. Riscos Associados aos Procedimentos de Acompanhamento

- Existe o risco de radiação associado à radiografia pélvica, que é necessária três meses após a colocação do micro-dispositivo para avaliar a localização do mesmo. Também poderá ser necessário realizar um teste de confirmação do **Essure** (HSG). Existem aproximadamente 0,033 rads na porção fluoroscópica (< 30 segundos) do procedimento do histerossalpingograma. Como termo de comparação, a exposição a radiação derivada de um clister com bário é de 0,85 rads, o que é superior à do teste de confirmação do **Essure** (HSG). O montante da exposição a radiação resultante de uma radiografia pélvica é aproximadamente o mesmo que um indivíduo recebe durante um ano de radiação natural de fundo.
- Os seguintes riscos adicionais estão associados ao procedimento do teste de confirmação do **Essure** (HSG), caso seja necessário: resposta vasovagal; infecção, a qual pode necessitar de tratamento com antibióticos e em casos raros, pode exigir internamento hospitalar; intravazamento; perfuração do útero; cãibras uterinas e/ou sangramento; e dor ou desconforto; e reacção alérgica ao látex. Foram descritos casos raros de exposição ao látex associada a reacções anafilácticas que podem conduzir à morte.
- Em algumas doentes, a utilização de meios de contraste, usados na realização do teste de

confirmação do **Essure** (HSG), foi associada a reacções alérgicas. A reacção alérgica pode resultar em urticária ou dificuldades respiratórias. Em algumas pessoas, pode ocorrer uma reacção anafiláctica susceptível de conduzir à morte.

E. Riscos Associados a Potenciais Procedimentos Futuros

- Às doentes sujeitas a colocação do micro-dispositivo **Essure** podem, no futuro, ser propostas terapias intra-uterinas que utilizem energia eléctrica. Recomenda-se evitar a utilização do electrocautério em procedimentos cirúrgicos realizados nos cornos uterinos e nas trompas de Falópio. Todos os outros procedimentos na pélvis devem evitar a utilização do electrocautério a menos de 4 cm do micro-dispositivo. Dada a presença dos micro-dispositivos **Essure**, podem existir riscos associados a esses procedimentos que, de momento, não foram identificados.
- Os procedimentos intra-uterinos, tais como biópsia do endométrio, dilatação e curetagem, histeroscopia (de diagnóstico ou cirúrgica), incluindo ablação do endométrio, podem interromper a capacidade dos micro-dispositivos prevenirem a gravidez. Para além disso, a presença de micro-dispositivos **Essure** pode acarretar riscos associados a esses procedimentos, os quais, de momento, não foram identificados.
- No futuro, as doentes podem decidir-se por serem sujeitas a fertilização *in vitro* (FIV) para engravidarem. Desconhecem-se os efeitos dos micro-dispositivos **Essure** sobre o êxito da FIV. Em caso de gravidez, desconhecem-se os riscos para a doente, para o feto e para a continuação da gravidez decorrentes do micro-dispositivo.
- Os micro-dispositivos **Essure** são seguros em ambiente de RM e radiopacos. Os micro-dispositivos **Essure** também são compatíveis com a RM, excepto no que se refere à imagiologia pélvica, em que podem causar alguns artefactos.
- **Poderão eventualmente existir riscos desconhecidos.**

VIII. Instruções de Utilização

A. Antes do Procedimento de Colocação do Micro-dispositivo

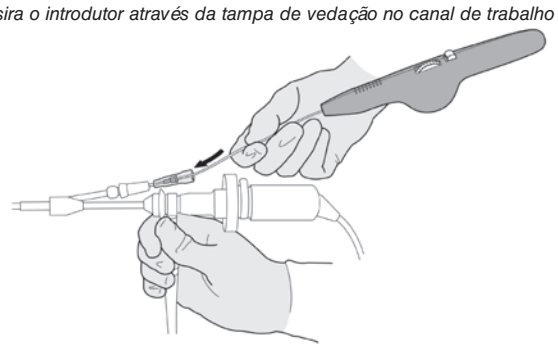
1. A colocação de micro-dispositivos deve ser realizada entre o 7.º e o 14.º dia do ciclo menstrual (onde o 1.º dia representa o primeiro dia de sangramento), a fim de melhorar a visualização dos óstios tubários e diminuir as probabilidades de colocação de um micro-dispositivo numa doente com gravidez não diagnosticada.
2. O médico ou uma pessoa por si designada deve administrar um teste de gravidez, o qual deve ser realizado nas 24 horas anteriores, ou imediatamente antes, do procedimento de colocação do micro-dispositivo.
3. Recomenda-se fortemente a administração de um fármaco anti-inflamatório não esteróide (AINE), tal como o Indocid (por via oral ou em supositório) uma a duas horas antes do procedimento de colocação do micro-dispositivo, dado que os dados dos ensaios clínicos demonstram que a administração de AINE aumenta significativamente a probabilidade de sucesso da colocação. No caso de apenas usar um bloqueio paracervical, e para reduzir a ansiedade, também pode ser administrado Diazepam (PO), ou outro agente semelhante, 30 minutos antes do procedimento.

B. Procedimento de Colocação do Micro-dispositivo Essure

O procedimento de colocação do micro-dispositivo **Essure** pode ser realizado num contexto de cirurgia em ambulatório. Deve ser empregue uma técnica estéril durante o procedimento de colocação do micro-dispositivo. O tempo necessário para concluir o procedimento de colocação do micro-dispositivo não deve ultrapassar 30 minutos.

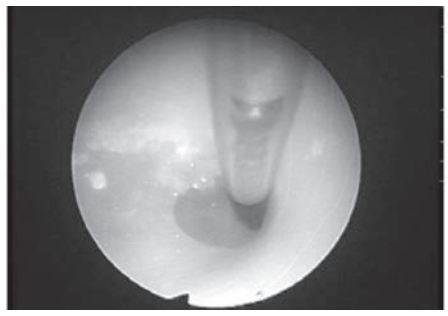
1. Coloque a doente em posição de litotomia.
2. Introduza um espéculo na vagina para permitir o acesso ao colo uterino. Prepare o colo uterino com Betadine, ou outra solução antibacteriana adequada, em conformidade com a prática normalizada.
3. A anestesia local constitui o método preferido para implantação dos micro-dispositivos. Pode ser administrado um bloqueio paracervical. Caso necessário, também pode ser administrado Midazolam (IV), ou outro agente semelhante, para prevenir ou reduzir o desconforto.
4. Introduza um histeroscópio estéril, com câmara acoplada e um canal de trabalho (≥ 5 French), através do colo uterino até ao interior da cavidade uterina. Caso seja necessário, proceda à dilatação cervical para permitir a introdução. A fim de prevenir a perfuração uterina, o procedimento deve ser terminado caso seja necessária uma força excessiva para obter a dilatação cervical.
5. A distensão da cavidade uterina deve ser realizada com uma infusão de soro fisiológico através do canal de trabalho do histeroscópio. Recomenda-se vivamente que o soro fisiológico seja previamente aquecido até à temperatura do corpo e introduzido por gravidade, a fim de minimizar os espasmos das trompas de Falópio. Deve obter-se e manter-se uma distensão uterina excelente durante todo o procedimento. Devem ser seguidos procedimentos normalizados de monitorização de fluidos durante todo o procedimento. Os óstios das trompas de Falópio devem ser identificados por visualização histeroscópica.
6. Antes de prosseguir com a colocação de micro-dispositivos **Essure**, ambos os óstios tubários devem ser identificados e avaliados histeroscopicamente. Não deve ser feita qualquer tentativa de colocação de um micro-dispositivo num óstio tubário a menos que existam probabilidades aceitáveis de a trompa oposta estar desobstruída.
7. Uma vez identificados os óstios das trompas de Falópio, insira o introdutor através da tampa de vedação do canal de trabalho do histeroscópio. A torneira de paragem do canal de trabalho deve permanecer na posição aberta (o dispositivo e/ou o introdutor podem ser danificados se a torneira de paragem se fechar em qualquer um dos dispositivos). Passe o sistema de colocação **Essure** através do introdutor e faça avançar através do canal de trabalho do histeroscópio. Se não estiver danificado após a colocação do primeiro micro-dispositivo, o introdutor de válvula pode permanecer no canal de trabalho durante a totalidade do procedimento **Essure**.

Insira o introdutor através da tampa de vedação no canal de trabalho do



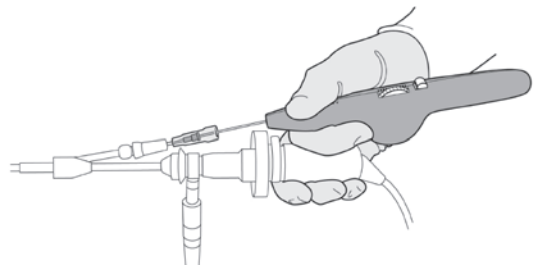
histeroscópio e, em seguida, passe o sistema de colocação **Essure** *através do introdutor.*

8. Faça avançar o sistema de colocação **Essure** para o interior da porção proximal da trompa de Falópio com movimentos lentos e contínuos para prevenir espasmos tubários. Faça avançar o sistema de colocação até o marcador de posicionamento do cateter de colocação atingir o óstio da trompa de Falópio. Este marcador visual indica que o micro-dispositivo **Essure** abrange os segmentos intramural distal e ístmico proximal da trompa de Falópio, com a hélice exterior abrangendo a junção útero-tubária. Esta constitui a posição ideal do micro-dispositivo **Essure**.



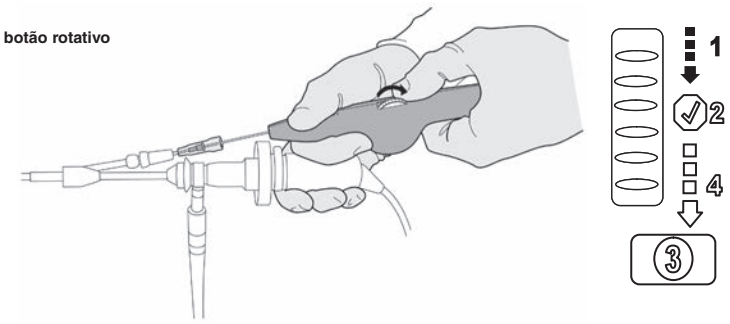
Faça avançar até o marcador negro de posicionamento estar no óstio tubário. Este é um indicador visual da posição correcta para expansão.

9. O correcto alinhamento concêntrico do cateter de colocação com o lúmen tubário é sugerido pela possibilidade de fazer avançar o cateter sob visualização directa sem demasiada resistência. De modo geral, a resistência ao avanço revela-se de duas maneiras: 1) não se vê o marcador negro na superfície exterior do cateter avançar em direcção ao óstio tubário e/ou 2) o cateter de colocação dobra ou flecte excessivamente, impedindo desse modo que o médico aplique pressão para diante no conjunto do cateter. Sempre que for observada tal resistência ao movimento para diante do cateter, não devem ser feitas novas tentativas para colocar o micro-dispositivo, a fim de evitar a possibilidade de perfuração uterina ou de colocação involuntária do micro-dispositivo na musculatura uterina e não no interior do lúmen tubário. Deve ser realizado um teste de confirmação do **Essure** (HSG) de acompanhamento para determinar a permeabilidade tubária.
10. Se, após vários minutos, não for possível fazer avançar o cateter até ao marcador de posicionamento, pode ser empregue um teste de perfusão com um cateter de desobstrução, caso não tenha sido já utilizado, para determinar a permeabilidade tubária. No caso de a trompa se encontrar obstruída, ou do cateter não poder ser avançado até ao marcador de posicionamento, o caso deve ser terminado. No caso de a colocação do micro-dispositivo não ter êxito ao fim de 10 minutos de tentativas de canulação por trompa, o caso deve ser terminado.
11. Quando o cateter de colocação tiver sido avançado até ao marcador de posicionamento, accione o micro-dispositivo. Para isso, estabilize primeiro o manípulo do micro-dispositivo **Essure** contra a câmara do histeroscópio ou outro objecto fixo para prevenir movimentos involuntários para diante do sistema **Essure** durante a retracção do cateter de colocação.



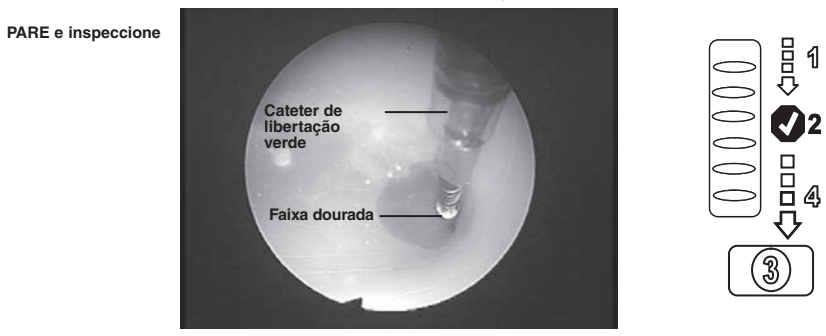
Estabilize o manípulo contra a cabeça da câmara ou outro objecto fixo para prevenir movimentos involuntários para diante do sistema **Essure**

12. Certificando-se de que o marcador negro de posicionamento se encontra no óstio da trompa de Falópio, rode o botão rotativo do manípulo para si, até que o botão deixe de rodar. Esta operação corresponde ao símbolo ⇩1 no manípulo do sistema de colocação. Isto facilita a remoção do cateter de colocação. Verá o marcador negro de posicionamento afastar-se do óstio tubário (na direcção do histeroscópio) e desaparecer no canal de trabalho. A remoção do cateter de colocação expõe o micro-dispositivo **Essure** retraído. Deve aparecer aproximadamente 1 cm do micro-dispositivo (hélices retraídas) pendendo para o interior do útero quando o cateter de colocação for removido.



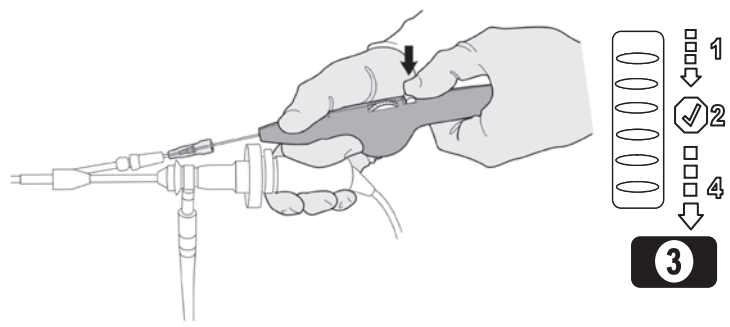
Rode o botão rotativo para retrair o cateter

13. Para confirmar o posicionamento correcto, coloque a faixa dourada de marcação imediatamente fora do óstio, o que corresponde ao símbolo ⓿2 no manípulo do sistema de colocação. A visualização da faixa dourada imediatamente fora do óstio, assim como a visualização da extremidade distal do cateter de libertação verde, confirmará o posicionamento adequado. Se mais de 1 cm do micro-dispositivo for visível no útero, o micro-dispositivo deve ser reposicionado ao avançar a totalidade do sistema ainda mais no tubo, se possível, antes de avançar para o próximo passo.



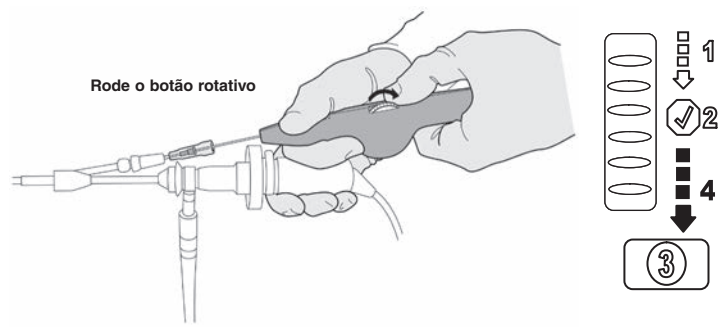
Visualize a faixa dourada no óstio

14. Prima o botão no manípulo do sistema de colocação para permitir que o botão rotativo seja rodado ainda mais, o que corresponde ao símbolo ③ no botão do manípulo.



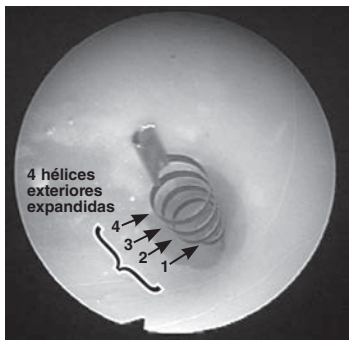
Prima o botão para permitir que o botão rotativo seja novamente rodado

15. Rode o botão rotativo para si para accionar a hélice externa do micro-dispositivo, o que corresponde ao símbolo ⇩4 no manípulo do sistema de colocação. Continue a rodar o botão rotativo até que o mesmo deixe de rodar. Quando o botão rotativo não puder mais ser rodado e as hélices externas expandidas forem visíveis, retire o sistema.



Rode o botão rotativo para accionar a hélice externa do micro-dispositivo

16. A posição do micro-dispositivo **Essure** accionado será avaliada através de visualização histeroscópica. Em condições ideais, devem existir entre 3 a 8 hélices exteriores expandidas do micro-dispositivo **Essure** a pender para o interior do útero.



As hélices exteriores expandidas do micro-dispositivo **Essure** *pendendo para o interior do útero indicam a colocação ideal*

17. No caso de o médico não ficar satisfeito com a colocação do micro-dispositivo com base apenas na visualização histeroscópica, ou suspeitar de perfuração tubária ou uterina, o(s) micro-dispositivo(s) deve(m) ser deixado(s) no lugar e avaliado(s) através de uma radiografia pélvica ou de um HSG três meses após a colocação do dispositivo.

    ADVERTÊNCIA: DEPOIS DE O MICRO-DISPOSITIVO TER SIDO COLOCADO E LIBERTADO NA TROMPA DE FALÓPIO, NÃO TENTE REMOVER O MICRO-DISPOSITIVO HISTEROSCOPICAMENTE, A MENOS QUE 18 OU MAIS HÉLICES DO MICRO-DISPOSITIVO ESSURE PENDAM PARA A CAVIDADE UTERINA. A remoção de um micro-dispositivo nesta situação deve ser tentada imediatamente após a tentativa de colocação. No entanto, a remoção pode não ser possível (consulte a secção XIII, Remoção de Micro-dispositivos **Essure**). No caso de o micro-dispositivo ter sido inadvertidamente expandido na cavidade uterina e não na trompa, o micro-dispositivo deve ser removido do útero e deve ser feita uma nova tentativa de colocação do micro-dispositivo na trompa.
18. Repita o procedimento de colocação do micro-dispositivo **Essure** na trompa de Falópio contralateral.
19. Registe o comprimento do micro-dispositivo que pende para o interior da cavidade uterina, anotando todas as dificuldades de identificação ou confirmação de qualquer dos óstios tubários ou as preocupações relacionadas com a potencial perfuração. Estas anotações devem ser incluídas na ficha da doente para consulta ulterior, durante a análise do teste de confirmação do **Essure** *(Secção IX – Teste de Confirmação do Essure, abaixo).*
20. **Relembre a doente para que use um método contraceptivo alternativo (com excepção de um DIU) durante os primeiros 3 meses após o procedimento de colocação do micro-dispositivo.**
21. Marque um teste de confirmação do **Essure** para três meses após o procedimento de colocação do micro-dispositivo **Essure** para avaliar a retenção e localização do micro-dispositivo.

IX. Teste de Confirmação do Essure

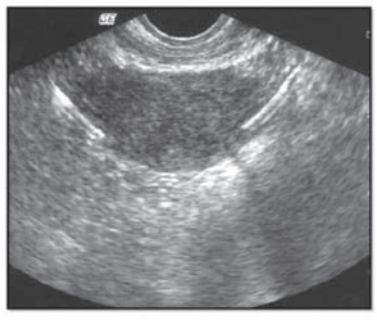
A. Deve ser realizado um teste de confirmação do **Essure** três meses após a colocação do micro-dispositivo para avaliar a retenção e localização do micro-dispositivo. Os testes de confirmação do **Essure** [ecografia transvaginal (ETV), radiografia pélvica ou histerossalpingograma (HSG)] devem apenas ser realizados por um ginecologista, ecografista e/ou radiologista experientes, devidamente formados no protocolo do respectivo teste de confirmação do **Essure**. Um protocolo detalhado com imagens e sugestões de execução do teste é fornecido juntamente com a formação; é possível obter exemplares adicionais ao transferir uma cópia a partir do site essure.com.

B. Para o teste de confirmação de primeira linha, pode ser realizada uma radiografia pélvica ou uma ETV três meses após um procedimento de colocação bilateral de micro-dispositivos sem complicações.

1. Não se deve recorrer a radiografia e ETV como o teste de confirmação do **Essure** nos seguintes casos:
    a) Procedimento difícil de colocação, incluindo uma ou mais das seguintes situações:
        (1) Receio, no momento da colocação, de possível perfuração devido a força excessiva necessária durante a colocação do micro-dispositivo e/ou perda súbita de resistência.
        (2) Dificuldade em identificar os óstios tubários durante a colocação devido a variação anatómica ou factores técnicos como fraca distensão, iluminação deficiente ou detritos do endométrio.
        (3) Incerteza do cirurgião relativamente à colocação.
    b) Tempo do procedimento superior a 15 minutos (da introdução à remoção do endoscópio).
    c) Colocação com zero ou menos de 8 hélices pendentes
    d) Dores inusitadas no pós-operatório, passageiras ou persistentes, ou ocorrência de dores em qualquer altura após o procedimento, sem qualquer outra causa identificável.
2. Se uma radiografia ou ecografia não for indicada, a doente tem de realizar um HSG para avaliar a localização do micro-dispositivo e a oclusão tubária. Uma ecografia transabdominal não pode ser substituída por ETV. Se a avaliação da radiografia ou ecografia for ambígua ou insatisfatória, a doente tem de realizar um HSG para avaliar a localização do micro-dispositivo e a oclusão tubária.

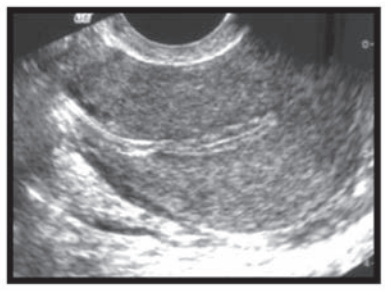
C. Ecografia transvaginal

1. É necessário obter e conservar um mínimo de três imagens para efeitos de documentação:
    a) Uma vista coronal ou coronal oblíqua apresentando uma parte de cada micro-dispositivo nos cornos uterinos designada "imagem de referência."



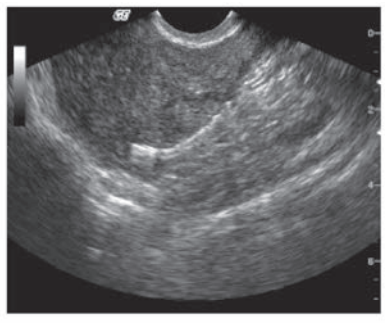
Os micro-dispositivos bilaterais estão identificados nesta vista transversal (coronal/coronal oblíqua).

    b) Uma imagem coronal ou coronal oblíqua do eixo linear do micro-dispositivo da esquerda, incluindo a extremidade proximal, a cruzar o miométrio nos cornos uterinos (parte intersticial da trompa de Falópio) ou em contacto com a junção tubária útero-serosa e designada "esquerda."
    c) Uma imagem coronal ou coronal oblíqua do eixo linear do micro-dispositivo da direita a cruzar o miométrio nos cornos uterinos (parte intersticial da trompa de Falópio) ou em contacto com a junção tubária útero-serosa e designada "direita."
    d) Todas as três imagens devem ser capturadas em película e colocadas na ficha médica da doente para documentar a retenção e localização satisfatórias do micro-dispositivo.
2. Classificação da Localização dos Micro-dispositivos
    a) Identificação dos micro-dispositivos: numa imagem única de referência, uma parte de cada micro-dispositivo tem de ser visualizada nos cornos uterinos na vista coronal ou coronal oblíqua para garantir o posicionamento bilateral e reduzir o risco de imagens em duplicado do mesmo micro-dispositivo. O eixo linear dos micro-dispositivos deve parecer relativamente simétrico.
    b) Localização Ideal
    A localização do micro-dispositivo é ideal quando a extremidade proximal do micro-dispositivo está em contacto com a cavidade uterina ou endométrio e o eixo linear está no interior do miométrio nos cornos uterinos (parte intersticial da trompa de Falópio) e pode ser visualizado sobre ou a cruzar a junção tubária útero-serosa (JTUS). A parte do micro-dispositivo localizada na trompa de Falópio pode ou não ser visualizada. O eixo linear do micro-dispositivo tem de ser visualizado para confirmar que não está enrolado ou alongado.



Localização ideal

    c) Localização Satisfatória
    A localização do micro-dispositivo é satisfatória quando a extremidade proximal do micro-dispositivo está distal em relação ao endométrio, mas o eixo linear está no interior do miométrio nos cornos uterinos (parte intersticial da trompa de Falópio) e pode ser visualizado sobre ou a cruzar a junção tubária útero-serosa (JTUS). A parte do micro-dispositivo localizada na trompa de Falópio pode ou não ser visualizada. O eixo linear do micro-dispositivo tem de ser visualizado para confirmar que não está enrolado ou alongado.

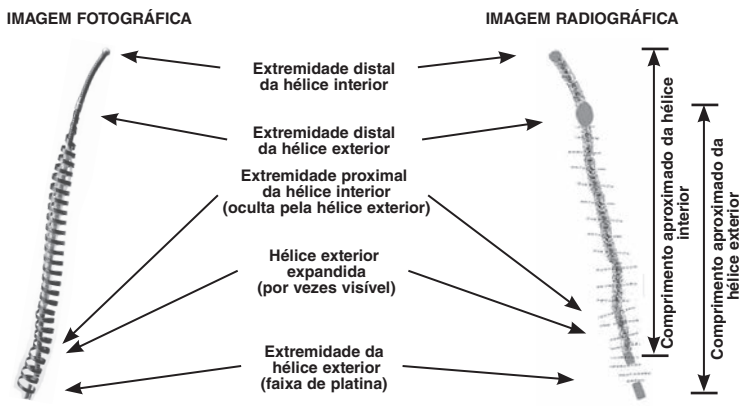


Localização satisfatória

    d) Localização Insatisfatória
        (1) A localização dos micro-dispositivos é insatisfatória se uma parte de cada micro-dispositivo não puder ser visualizada nos cornos uterinos na vista coronal ou coronal oblíqua numa imagem de referência.
        (2) Deve suspeitar-se de expulsão se um ou ambos os micro-dispositivos não forem identificados nos cornos uterinos numa vista coronal numa imagem única de referência.
        (3) Deve suspeitar-se de colocação distal se a extremidade proximal do micro-dispositivo não estiver situada no miométrio nos cornos uterinos (parte intersticial da trompa de Falópio) e não estiver a cruzar ou em contacto com a JTUS.
        (4) Deve suspeitar-se de colocação proximal se mais de 50% ou a maioria do micro-dispositivo for visualizada na cavidade uterina ou se o eixo linear do(s) micro-dispositivo(s) for visualizado na vista sagital de linha média.
        (5) Deve suspeitar-se de perfuração se o eixo linear de um ou ambos os micro-dispositivos estiver paralelo à faixa do endométrio na vista sagital ou se o eixo linear de um micro-dispositivo for visualizado a cruzar o miométrio na vista sagital de linha média.
        (6) Posição não classificada: se o eixo linear de um micro-dispositivo não puder ser identificado, sugerindo que está enrolado, dobrado ou alongado, a localização do micro-dispositivo é considerada insatisfatória. Se os tecidos moles adjacentes não puderem ser claramente identificados, a posição é considerada insatisfatória.
3. Se a avaliação da ecografia for ambígua ou insatisfatória, a doente tem de realizar um HSG para avaliar a localização do micro-dispositivo e a oclusão tubária.

D. Radiografia pélvica

1. Capture uma imagem do útero com ambos os micro-dispositivos **Essure** claramente visíveis. A posição e a curvatura dos micro-dispositivos devem ser anotadas.



Vista radiográfica correspondente do micro-dispositivo ***Essure***

2. Avalie a radiografia pélvica da seguinte forma:
    a) Satisfatória: os micro-dispositivos parecem estar dentro do lúmen tubário e abrangendo a junção útero-tubária, parecendo relativamente simétricos. As doentes cujas radiografias forem consideradas "satisfatórias" podem começar a ter confiança no micro-dispositivo **Essure** para contracepção.
    b) Suspeita: um ou ambos os micro-dispositivos parecem distais ou proximais em relação à posição ideal, ou podem ter perfurado parcial ou completamente a trompa e/ou parecem relativamente assimétricos. As doentes cujas radiografias forem consideradas "suspeitas" devem ser aconselhadas a prosseguirem com a contracepção alternativa e a fazerem um HSG.
    c) Insatisfatória: localização intraperitoneal evidente ou expulsão do micro-dispositivo.
3. Se a avaliação da radiografia for ambígua ou insatisfatória, ou se a localização do micro-dispositivo for suspeita, a doente tem de realizar um HSG para avaliar a localização do micro-dispositivo e a oclusão tubária.

E. Realização e Avaliação de HSG modificados

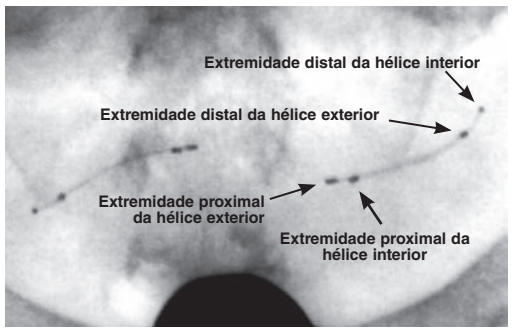
1. O HSG é realizado para melhor avaliar a localização do micro-dispositivo **Essure** e a oclusão da trompa de Falópio, caso necessário, com base nas conclusões sobre a radiografia ou ecografia. Siga as instruções adiante para realizar e avaliar o HSG.
2. Realização do HSG – Linhas de orientação:
    a) Obtenha um bom enchimento córneo de modo a que o contorno da cavidade uterina seja claramente visto.
    b) Situe o feixe fluoroscópico o mais próximo possível da projecção A/P.
    c) Não dilate o colo do útero a não ser que seja necessário; se ocorrer dilatação, mantenha um bom selo cervical.
    d) Pode ser necessária tracção descendente sobre o tenáculo cervical para úteros em posição intermédia. Retire o espéculo antes da fluoroscopia para a melhor visualização da anatomia uterina.
    e) Faça um mínimo de seis radiografias para avaliar a localização do micro-dispositivo e a oclusão tubária.
        (1) Radiografia 1 – "Película de Referência" – Útero e micro-dispositivos sem contraste.
        (2) Radiografia 2 – Enchimento Mínimo da Cavidade – Útero e micro-dispositivos com uma pequena quantidade de contraste.

(3) Radiografia 3 – Enchimento Parcial da Cavidade – Útero e micro-dispositivos quando praticamente cheios com contraste.

(4) Radiografia 4 – Enchimento Total da Cavidade – Útero e micro-dispositivos quando os cornos forem distendidos pelo contraste.

(5) Radiografias 5 e 6 – Ampliações dos cornos uterinos – Micro-dispositivo na trompa de Falópio com os cornos direito (5) e esquerdo (6).

ATENÇÃO: evitar pressão intra-uterina excessiva após a Radiografia 4 para evitar desconforto desnecessário da doente e reacção vasovagal.



3. Avaliação da Localização do Micro-dispositivo
   a) Durante a avaliação, observe quatro "marcadores" em cada extremidade das hélices interior e exterior. Observe que os marcadores distais são fixos um em relação ao outro, mas os marcadores proximais podem deslocar-se ou parecer esticados devido à flexibilidade da hélice exterior. A localização ideal do micro-dispositivo verifica-se quando a hélice interior atravessa a junção útero-tubária.
   b) Avalie a localização do micro-dispositivo:
      (1) Expulsão ou colocação proximal: o micro-dispositivo não está presente ou 50% ou mais da hélice interior pendem para o interior da cavidade uterina.
      (2) Colocação satisfatória: a extremidade distal da hélice interior está dentro da trompa, com menos de 50% da hélice interior a pender para o interior da cavidade uterina ou com a extremidade proximal a uma distância igual ou inferior a 30 mm na trompa do ponto em que o contraste enche os cornos.
      (3) Colocação distal ou perfuração: o micro-dispositivo encontra-se na trompa, mas a extremidade proximal da hélice interior está numa posição distal a mais de 30 mm do ponto em que o contraste enche os cornos ou o micro-dispositivo está completa ou parcialmente perfurado.
4. Avaliação da Oclusão Tubária
   a) Determine se o contraste é visível para além do micro-dispositivo e observe qualquer grau de enchimento da porção proximal da trompa, mesmo se a trompa estiver oclusa.
   b) Avalie a oclusão tubária:
      (1) Oclusão satisfatória: a trompa encontra-se oclusa nos cornos.
      (2) Oclusão satisfatória: contraste visível na trompa, mas não para além da extremidade distal da hélice exterior.
      (3) Oclusão insatisfatória: contraste visível para além da extremidade distal do micro-dispositivo ou na cavidade peritoneal.
5. Avaliação do Potencial de Confiança
   a) Se a localização e a oclusão tubária forem ambas consideradas satisfatórias, aconselhe a doente a interromper a contracepção alternativa.
   b) Se a localização for insatisfatória, aconselhe a doente a não confiar nos micro-dispositivos para contracepção.
   c) Se a localização for satisfatória, mas a oclusão for insatisfatória, aconselhe a doente a prosseguir com a contracepção alternativa. Repita o HSG após três meses. Se a oclusão continuar a ser insatisfatória, aconselhe a doente a não confiar nos micro-dispositivos para contracepção.

X. Tratamento da Localização Insatisfatória de Micro-dispositivos (LIM)

A. Localização Insatisfatória de Micro-dispositivos Diagnosticada por Histerossalpingograma

1. Localização Proximal: mais de 50% do comprimento da hélice interior do(s) micro-dispositivo(s) pende para o interior do útero.
2. Localização Distal: O(s) micro-dispositivo(s) encontra(m)-se na trompa de Falópio, mas a extremidade proximal da hélice interior está a mais de 30 mm do contraste que enche os cornos uterinos.
3. Expulsão completa do(s) micro-dispositivo(s); micro-dispositivo(s) ausente(s) do corpo.
4. Perfuração: o(s) micro-dispositivo(s) perfuraram a trompa de Falópio parcial ou completamente.
5. Localização intraperitoneal do(s) micro-dispositivo(s); micro-dispositivo(s) claramente no exterior da(s) trompa(s) de Falópio.

B. Tratamento da Expulsão de Micro-dispositivos ou da Localização Insatisfatória de Micro-dispositivos

1. Expulsão bilateral de micro-dispositivos com oclusão bilateral: Tendo em conta a possibilidade de um diagnóstico falso-positivo de oclusão tubária com o teste de confirmação do **Essure** (HSG), a doente deve ser aconselhada sobre a opção de fazer uma esterilização incisional ou de confiar na sua oclusão tubária proximal (OTP) bilateral para contracepção.
2. Expulsão bilateral de micro-dispositivos com oclusão de uma trompa e permeabilidade da trompa contralateral: A doente pode ser considerada para um procedimento adicional de colocação de micro-dispositivos para recolocação do micro-dispositivo na trompa permeável, de modo a poder confiar no micro-dispositivo **Essure** e na OTP contralateral para contracepção. Tendo em conta a possibilidade de um diagnóstico falso-positivo de oclusão tubária com o teste de confirmação do **Essure** (HSG), a doente deve ser aconselhada sobre esta opção. Também deve ser aconselhada sobre a opção de esterilização incisional.
3. Expulsão unilateral do micro-dispositivo ou localização unilateral insatisfatória do micro-dispositivo (no miométrio ou na cavidade intraperitoneal) com o micro-dispositivo contralateral em localização satisfatória: Tendo em conta a possibilidade de um diagnóstico falso-positivo de oclusão tubária com o teste de confirmação do **Essure** (HSG), no caso de o teste de confirmação do **Essure** (HSG) demonstrar um bloqueio tubário da trompa de onde tiver sido expulso o micro-dispositivo, ou da trompa onde o micro-dispositivo deveria ter sido colocado, a doente pode confiar no micro-dispositivo com localização satisfatória e na OTP contralateral. Também deve ser aconselhada sobre a opção de esterilização incisional.
4. Localização insatisfatória unilateral do micro-dispositivo (no miométrio ou na cavidade intraperitoneal) com o micro-dispositivo contralateral em localização satisfatória: No caso de o teste de confirmação do **Essure** (HSG) demonstrar a permeabilidade tubária da trompa onde deveria ter sido colocado um micro-dispositivo, a doente pode ser convidada a regressar para nova tentativa de colocação do micro-dispositivo. Também deve ser aconselhada sobre a opção de esterilização incisional.
5. Expulsão unilateral do micro-dispositivo; localização unilateral insatisfatória do micro-dispositivo (no miométrio ou na cavidade intraperitoneal); localização unilateral insatisfatória do micro-dispositivo em "Localização Proximal" (> 50% do comprimento da hélice interior pendendo para o útero) ou em "Localização Distal" (micro-dispositivo na trompa de Falópio mas a extremidade proximal da hélice interior está > 30 mm do contraste que enche os cornos uterinos) com o micro-dispositivo contralateral em localização insatisfatória: A doente deve ser aconselhada sobre a opção de esterilização incisional. Em todos os casos, se a remoção do micro-dispositivo for considerada necessária e a remoção histeroscópica não for possível, pode ser necessária cirurgia incisional.
6. No caso de uma doente optar por esterilização incisional na sequência de qualquer dos cenários acima enumerados, ambas as trompas devem ser oclusas, independentemente da permanência de qualquer micro-dispositivo em localização satisfatória. No caso de o médico o considerar seguro, deve ser feita uma tentativa de recuperação do micro-dispositivo, se bem que essa recuperação possa não ser possível. Recomenda-se a utilização de fluoroscopia intra-operatória para identificar a localização do(s) micro-dispositivo(s), antes e durante a cirurgia. A tentativa de recuperação não deve ultrapassar 30 minutos.

XI. Tratamento de Casos Mal Sucedidos de Colocação de Micro-dispositivos Essure

Na eventualidade de insucesso de colocação unilateral ou bilateral dos micro-dispositivos, a doente deve ser informada de que a sua contracepção permanente não foi concluída. No caso de a doente escolher a esterilização laparoscópica (ou seja, aplicação de grampos ou electrocauterização), ambas as trompas de Falópio devem ser grampeadas ou cauterizadas, mesmo que uma trompa tenha o micro-dispositivo **Essure** implantado. A aplicação de grampos ou cauterização de uma ou ambas as trompas deve ser realizada de forma distal ao micro-dispositivo **Essure**.

No caso de a doente não optar pela esterilização laparoscópica, pode ser convidada a fazer um teste de confirmação do **Essure** (HSG) após a menstruação seguinte (pré-ovulatório: 7.º-14.º dias, onde o 1.º dia representa o primeiro dia de sangramento) para determinar a permeabilidade tubária. No caso de se observar permeabilidade tubária, o médico pode convidar a doente para uma segunda tentativa de colocação dos micro-dispositivos. Em caso de falha da segunda tentativa de colocação dos micro-dispositivos, é improvável que a doente tenha êxito com tentativas ulteriores. No caso de a doente ter um micro-dispositivo *in vivo*, deve ser aconselhada a não confiar no micro-dispositivo unilateral para contracepção.

Tendo em conta a possibilidade de um diagnóstico falso-positivo de oclusão tubária com o teste de confirmação do **Essure** (HSG), no caso de apenas ter sido obtida colocação unilateral, e do teste de confirmação do **Essure** (HSG) confirmar oclusão tubária proximal (OTP), a doente deve ser aconselhada sobre a opção de confiar num micro-dispositivo. A oclusão tubária é definida como a incapacidade do contraste passar da cavidade uterina para a cavidade peritoneal durante o teste de confirmação do **Essure** (HSG). Também deve ser aconselhada sobre a opção de esterilização incisional. Não se recomenda qualquer tentativa de remoção de um micro-dispositivo colocado unilateralmente, a menos que a doente apresente reacção adversa ao micro-dispositivo.

XII. Remoção de Micro-dispositivos Essure

ADVERTÊNCIA: UMA VEZ O MICRO-DISPOSITIVO COLOCADO, A REMOÇÃO HISTEROSCÓPICA DO MICRO-DISPOSITIVO NÃO DEVE SER TENTADA, A MENOS QUE 18 OU MAIS HÉLICES DO MICRO-DISPOSITIVO ESSURE PENDAM PARA O INTERIOR DA CAVIDADE UTERINA. A remoção de tal micro-dispositivo deve ser tentada imediatamente após a colocação. No entanto, pode não ser possível a remoção. Em caso de tentativa de remoção, devem ser seguidos os seguintes passos:

1. Introduza um instrumento de aperto através do canal de trabalho do histeroscópio.
2. Prenda a hélice exterior do micro-dispositivo **Essure**. Tente prender simultaneamente as hélices exterior e interior do micro-dispositivo.
3. Puxe simultaneamente o instrumento de aperto e o histeroscópio, de modo a que todo o sistema seja removido em conjunto do útero.
4. À medida que é tentada a remoção do micro-dispositivo **Essure**, a hélice exterior e/ou a hélice interior podem esticar ou alongar.
5. Se necessário, administre analgesia/anestesia para reduzir ou prevenir o desconforto da doente.
6. No caso de ser obtida a remoção completa do micro-dispositivo, deve ser feita uma tentativa de colocação de outro micro-dispositivo **Essure**.
7. No caso de o médico não ficar completamente persuadido de que todo o micro-dispositivo **Essure** foi removido da trompa de Falópio, **NÃO** deve ser colocado outro micro-dispositivo nessa trompa, devendo ser feita uma radiografia após a colocação para determinar se algum fragmento de micro-dispositivo permanece *in vivo*.

Para além do cenário acima descrito, a remoção do micro-dispositivo só deve ser tentada se a doente apresentar reacções adversas ao micro-dispositivo ou se solicitar a remoção do micro-dispositivo.

No caso de a remoção do micro-dispositivo ser considerada necessária, é preciso uma abordagem transabdominal (ou seja, laparotomia ou laparoscopia).

No caso de o micro-dispositivo estar devidamente localizado sobre a junção útero-tubária (JUT), é necessária uma ressecção córnea da porção proximal da trompa de Falópio.

Um micro-dispositivo **Essure** que tenha sido incorrectamente colocado, ou que tenha migrado para além da JUT, deve ser removido por salpingotomia linear tradicional, ou por salpingectomia realizada com laparoscopia ou laparotomia.

1. Para realizar uma salpingotomia linear, faz-se uma pequena incisão (com aproximadamente 2 cm de comprimento) ao longo do bordo anti-mesentérico da trompa de Falópio que cobre directamente o micro-dispositivo.
2. Pode ser realizada uma salpingectomia total ou parcial para recuperar o micro-dispositivo, em simultâneo ou independentemente da realização de um procedimento tradicional de esterilização tubária.

XIII. Cartão de Identificação da Doente

Todas as doentes com micro-dispositivos **Essure** implantados devem receber um cartão plastificado tamanho carteira declarando ter o(s) micro-dispositivo(s) **Essure** implantado(s). **O cartão vem incluído nesta embalagem.** Além disso, o cartão adverte para o facto de poderem existir riscos associados a futuros procedimentos uterinos ou cirurgia dos órgãos reprodutivos.

XIV. Legenda dos Símbolos

STERILE EO	Esterilizado por óxido de etileno	MR	RM condicionada
LOT	Código do lote	EC REP	Representante autorizado na Europa
	Não reutilizar	CE 0050	O dispositivo está em conformidade com a Directiva 93/42/CE
REF	Número de catálogo		
	Atenção, consultar as Instruções de Utilização		Manter seco
	Prazo de validade	CONT	Conteúdo
	Manter afastado do calor		
	Não utilizar se a embalagem estiver aberta ou danificada		

Fabricado por:
Bayer HealthCare LLC
1011 McCarthy Blvd.
Milpitas, CA 95035
USA
essure.com

Representante Autorizado na Europa:
Bayer Pharma AG
Müllerstr. 178
D-13353 Berlin
Alemanha

Para encomenda de produtos ou participação de reacções adversas, contacte o representante local da Bayer HealthCare LLC.

PN-84731145, ART Rev. B

Svenska

essure®

Permanent födelsekontroll

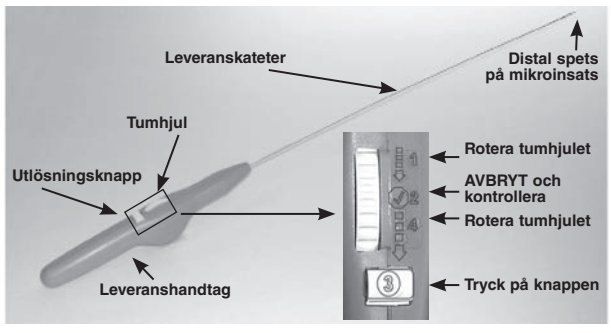
BAYER

BRUKSANVISNING

I. Beskrivning av mikroinsats

Essure® permanent system för födelsekontroll innefattar flera komponenter. **Essure** mikroinsats, som är dynamiskt expanderande, är fäst vid en leveranstråd och en utlösningskateter. Anordningen i sin helhet är inkapslad i en leveranskateter. Systemet (som visas i figur 1) är fäst vid ett handtag som är till för att underlätta leverans och placering av mikroinsatsen. Med **Essure**-systemet levereras också en introduceranordning försedd med ventiler, **DryFlow**® introducer, som är avsedd att skydda **Essure**- mikroinsatsen då den passeras genom gummiporten till hysteroskopets arbetskanal.

Figur 1
Essure-leveranssystem
med detaljer avseende placering av procedursymboler
(EJ SKALENLIG)



II. Verkningsmekanism

Essure-systemet levererar under hysteroskopi en **Essure** mikroinsats till den proximala delen av äggledarens lumen. **Essure** mikroinsats expanderar efter utlösning och hakar fast i äggledaren. Därefter framkallar mikroinsatsen en avsiktlig godartad vävnadsreaktion, så att vävnad växer in i mikroinsatsen och förankrar denna stadigt i äggledaren. Den godartade vävnadsreaktionen är lokal, fibrotisk och ocklusiv till sin natur.

Varje **Essure**-system är steriliserat med etylenoxid och tillhandahålls sterilt för engångsbruk. Produkten får inte återanvändas eller resteriliseras. Resterilisering kan påverka korrekt mekanisk funktion och medföra patientskada.

III. Indikationer för användning

Essure-systemet är avsett att användas som mikroinsats för tubarocklusion, i syfte att uppnå permanent födelsekontroll.

IV. Kontraindikationer för användning

- Patienten är osäker på beslutet att ända sin fertilitet.
- Graviditet, eller misstänkt graviditet.
- Förlöst eller avbruten graviditet i andra trimestern mindre än sex veckor innan **Essure** mikroinsats implanteras.
- Aktiv eller nyligen inträffad bäckeninfektion.
- Obehandlad akut cervicit.
- Oförklarad eller svår vaginal blödning.
- Gynekologisk malignitet (misstänkt eller erkänd).
- Erkänd onormal livmoderhåla eller onormala äggledare som medför att visualisering av äggledaröppningarna och/eller kanalisering av den proximala äggledaren blir svår eller omöjlig.
- Allergi mot kontrastmedel (ett hysterosalpingogram kanske krävs tre månader efter placeringen av mikroinsatsen).
- Patienter som för tillfället tar kortikosteroider.

V. Varningar

- **Essure**-ingreppet bör endast utföras av utbildade hysteroskopister som slutfört *Bayer HealthCare LLC* utbildningsprogram för detta ingrepp.
- Personer som är allergiska mot nickeltitan kan uppleva allergisk reaktion mot mikroinsatsen.
- **Essure**-systemet ska inte användas om förpackningen är öppnad eller skadad. Får ej användas om mikroinsatsen är skadad.
- Om man upplever ett kraftigt motstånd får man vid införande av **Essure** mikroinsats aldrig forcera in denna.
- Fortsätt inte att föra **Essure**-systemet längre in då placeringsmarkeringen på katetern har nått fram till äggledarens mynning. Vidare införande förbi denna punkt kan orsaka felaktig placering av mikroinsatsen eller perforation av äggledaren/livmodern.
- I det fall man misstänker eller kan fastställa att äggledaren perforerats ska man inte försöka fortsätta med placering av **Essure** mikroinsats. En väldigt liten procentandel av kvinnorna i **Essures** kliniska undersökningar (1,8 % eller 12 av 682 patienter) upptäcktes ha instrumentrelaterade äggledarperforationer. Om perforerande mikroinsatser måste avlägsnas ska det utföras med laparoskopi eller annan kirurgisk metod.
- Om försök att placera **Essure** mikroinsats ej är framgångsrikt efter försök till kanylering i 10 minuter per äggledare ska ingreppet avbrytas och eventuellt senareläggas.
- När mikroinsatsen väl har placerats (dvs. lösgörs från leveranstråden) ska inga försök göras att avlägsna denna på hysteroskopisk väg om inte minst 18 av spiralerna i **Essure** mikroinsats når in i livmoderhålan. Om detta krav är uppfyllt ska försök att avlägsna mikroinsatsen utföras omedelbart efter placeringen. Det är dock möjligt att det inte går att avlägsna mikroinsatsen.
- Patienten måste använda ett alternativt preventivmedel tills röntgen tre månader efter placeringen visar att mikroinsatsen är korrekt placerad.
- Patienter som genomgår placering av **Essure** mikroinsats kan i framtiden komma att erbjudas intrauterin behandling med hjälp av elektrisk energi. Vi rekommenderar att diatermibehandling ej används under kirurgiska ingrepp i livmodercornua och äggledare. Under samtliga andra eventuella bäckeningrepp som utförs ska användning av diatermi undvikas inom en radie av 4 centimeter från mikroinsatsen. På grund av närvaron av **Essure** mikroinsats(-er) kan dessa ingrepp vara förenade med risker som ännu ej är kända.
- Alla intrauterina ingrepp som t.ex. endometriumbiopsier, skrapningar, hysteroskopi (diagnostisk eller operativ) inklusive endometriumablation kan störa mikroinsatsernas förmåga att förhindra graviditet. Vidare kan närvaron av **Essure** mikroinsats(-er) vid dessa ingrepp medföra komplikationer som ännu ej är kända.
- Laboratorie- och kliniska studier har demonstrerat att endometriumablation av livmodern säkert och effektivt kan utföras med GYNECARE THERMACHOICE* livmoderballongsystem, Hologic NovaSure** endometriumablationssystem och Boston Scientific Hydro ThermAblator*** **omedelbart efter** utplacering av **Essure** mikroinsatser. Inga specifika studier har utförts för att utvärdera **Essure**-mikroinsatsens utstötnings- eller födelsekontrollsfrekvens efter förfaranden som kombinerar **Essure** och endometriumablation.
- Patienter kan i framtiden besluta sig för att genomgå provrörsbefruktning för att bli gravida. De eventuella (bi-)effekterna av **Essure** mikroinsatser på provrörsbefruktning är okända. Om graviditet uppstår är det okänt vilka risker som uppstår för patienten, fostret och för graviditetens fortsatta förlopp till följd av mikroinsatsen.

* Varumärke som tillhör ETHICON, INC.
** Varumärke som tillhör Hologic, Inc.
*** Varumärke som tillhör Boston Scientific Corporation

VI. Försiktighetsåtgärder

- Om så är möjligt, bör placeringen av mikroinsatsen utföras under dag 7-14 av menstruationscykeln (där dag 1 representerar blödningens första dag) för att visualiseringen av äggledaröppningarna ska maximeras, och för att minimera risken för att en patient med odiagnostiserad graviditet utsätts för implantation av mikroinsatserna.
- Om livmoderns anatomi avviker från det normala kan placeringen av **Essure** mikroinsats försvåras.
- För att minska risken för livmoderperforation ska ingreppet avbrytas om orimligt mycket kraft krävs för att uppnå cervikal dilatation.
- Båda äggledaröppningarna ska identifieras och utvärderas med användning av hysteroskopi innan placering av **Essure** mikroinsats påbörjas. Försök inte att placera en mikroinsats i ena äggledarens mynning såvida det inte skäligen kan förväntas/står bortom rimligt tvivel att motstående äggledare är tillgänglig och öppen.
- Om endometriumablation utförs omedelbart efter utplacering av **Essure** mikroinsatser kan det öka risken för steriliseringssyndrom i äggledaren efter ablationen, vilket är ett sällsynt tillstånd som har rapporterats hos kvinnor med historik av äggledarsterilisering som undergår endometriumablation.
- Försök inte att föra **Essure**-systemet längre in om patienten upplever betydande smärta och obehag.
- **Essure**-systemet ska förvaras i en kall och torr miljö.

VII. Potentiella biverkningar

A. Graviditet

Det finns risk för graviditet och utomkvedshavandeskap och även risker förenade med behandling av båda dessa tillstånd. Om patienten blir gravid och väljer att fortgå med en intrauterin graviditet ska hon informeras om att eventuella risker som mikroinsatsen kan medföra för fostret, patienten eller det fortlöpande havandeskapet är okända.

B. Risker förenade med mikroinsatsens placeringsprocedur

- Såväl lokal anestesi som peroral analgetika/sedering, regional anestesi (dvs. ryggmärgsbedövning, epiduralblockad), peroral eller vaken (intravenös) sedering eller allmän narkos kan ges patienten i syfte att förebygga eller lindra eventuella obehag. Oavsett vilken typ av bedövning som används är det möjligt att patienten inte kommer att vara förmögen att återuppta normala aktiviteter under 12 till 24 timmar efter ingreppet.
- Smärta, kramper och vaginala blödningar kan förekomma under och efter placering av mikroinsatsen. I regel är dessa symptom uthärdliga, övergående och kan behandlas framgångsrikt med medicinering.
- Under och/eller direkt efter placeringen av mikroinsatsen finns det en risk för att patienten kommer att uppleva illamående och kräkningar. Detta förväntas vara övergående och kan behandlas med medicinering allt efter behov.
- Patienter kan uppleva svimning eller vasovagal reaktion under dagen då ingreppet äger rum.
- Det finns en risk för perforation eller dissektion av äggledaren eller livmodercornua. Sådan perforation eller dissektion kan ge upphov till blödningar eller ärrbildning, men som regel finns inget behov av behandling.
- Det finns även risk för att hysteroskopet, **Essure**-systemet eller andra instrument som används under ingreppet orsakar perforation av livmodern vilket eventuellt kan medföra skador på tarmpaketet, urinblåsan och större blodkärl. Kirurgiska ingrepp kan i sällsynta fall krävas om sådana skador skulle uppstå. För att minska risken för perforation av livmodern ska ingreppet avbrytas om orimligt mycket kraft skulle krävas för att uppnå cervikal dilatation.
- Det finns risk för att **Essure** mikroinsats oavsiktligt fastnar i livmoderns myometrium, och inte i äggledarens lumen. Om en mikroinsats redan framgångsrikt placerats i den ena av äggledarna, och en dessutom oavsiktligt hamnat i myometrium, kan läkaren försöka att placera en tredje mikroinsats för att fullfölja ingreppet. Om det inte lyckats att placera mikroinsatsen i båda äggledarna kan det leda till att patienten har en mikroinsats i äggledaren och/eller en mikroinsats i myometrium. Eventuell mikroinsats i myometrium är inte tillförlitlig som preventivmedel. Placering av mikroinsatsen i myometrium kan medföra postoperativa smärtor eller andra biverkningar. Om det blir nödvändigt att på kirurgisk väg avlägsna mikroinsatsen/-erna kan salpingektomi eller hysterektomi krävas.
- Det finns en risk för att **Essure** mikroinsats placeras alltför distalt inne i äggledaren. Om det bedöms nödvändigt att avlägsna mikroinsatsen kan kirurgiska ingrepp (laparoskopisk kirurgi eller laparotomi) krävas.
- Det finns en risk för att **Essure** mikroinsats placeras alltför proximalt i äggledaren. Om 18 eller fler spiralfjädrar av **Essure** mikroinsats är synliga vid tiden för implantering, ska ett omedelbart försök göras att avlägsna mikroinsatsen (se kapitel XIII, Att avlägsna **Essure** mikroinsats). I samband med försök att avlägsna mikroinsatsen finns det risk för att detta misslyckas eller att **Essure** mikroinsats går sönder, vilket kan resultera i att ett fragment av mikroinsatsen blir kvar *in vivo*. Om mikroinsatsen framgångsrikt har avlägsnats eller om försök gjorts för att uppnå detta, är det också möjligt att patienten upplever ökad smärta, kramper och blödningar under och efter implanteringen av **Essure** mikroinsats.
- Det finns risk för att **Essure** mikroinsats perforerar äggledarväggen eller livmodercornua, vilket kan resultera i att mikroinsatsen utlöses i peritonealhålan. Postoperativa smärtor och/eller störningar i menstruationen eller andra biverkningar kan uppstå som ett resultat av detta. Om patienten väljer att genomgå kirurgisk sterilisering eller annat kirurgiskt ingrepp, kan mikroinsatsen avlägsnas från peritonealhålan om läkaren bedömer detta som riskfritt. Om läkaren inte kan komma åt mikroinsatsen eller visualisera den, kan dock avlägsnande vara omöjligt.
- Det finns risk för att placering av **Essure** mikroinsats bara lyckas i den ena av äggledarna. Skulle detta vara fallet kan patienten komma att ha en mikroinsats kvar *in vivo* som inte går att förlita sig på för permanent födelsekontroll.
- Det finns risk för att placering av **Essure** mikroinsats inte går att genomföra i någondera av äggledarna.
- Det finns en minimal risk för alltför stor vätskeabsorption av den fysiologiska koksaltlösning som används för att utvidga livmodern under det hysteroskopiska ingreppet.
- I likhet med alla invasiva ingrepp föreligger risk för infektion vid placering av mikroinsatsen. En infektion kan orsaka skador på livmoder, äggledare eller bäckenhåla. Detta kan i sin tur kräva behandling med antibiotika eller, i sällsynta fall, sjukhusvistelse eller kirurgiskt ingrepp, inklusive hysterektomi.

C. Risker med användning av Essure mikroinsats

- Det finns en risk för att **Essure** mikroinsats vandrar ut ur äggledarna. Denna vandring kan vara antingen bortstötning (vandring ut ur äggledaren och in i livmoderhålan/livmoderhalsen/vagina eller ut ur kroppen) eller migration (vandring mot den distala delen av äggledaren eller ut ur äggledaren och in i peritonealhålan). Ytterligare röntgen kan krävas för att lokalisera mikroinsatsens/mikroinsatsernas position och det kan bli nödvändigt med ett kirurgiskt ingrepp för att avlägsna den/dem. Om anordningen börjar vandra kan detta leda till graviditet, utomkvedshavandeskap, och/eller smärta/menstruationsstörningar eller andra biverkningar.
- I likhet med andra typer av system för mekanisk permanent födelsekontroll (dvs. clips, ringar) är det nödvändigt med ett kirurgiskt ingrepp för att avlägsna **Essure** mikroinsats. Vidare är det möjligt att avlägsnande på kirurgisk väg av äggledarna (salpingektomi) och livmodern (hysterektomi) kan bli nödvändig.
- Mag-/bäckensmärtor och kramper kan förekomma. Det är mer sannolikt att smärta och kramper uppträder under menstruationen, vid samlag och efter samlag, eller i samband med andra fysiska aktiviteter.
- Patienten kan vidare komma att uppleva mellanblödningar eller menstruationsblödningar som är mer rikliga än normalt.
- Det händer då och då att kvinnan ångrar sitt beslut att välja permanent födelsekontroll och kan då uppleva mildare depressioner eller andra emotionella störningar som ett resultat av detta.

D. Risker som är förknippade med uppföljningsprocedurer

- Strålningsrisk föreligger i samband med den bäckenröntgen som krävs för att utvärdera mikroinsatsens placering, tre månader efter implanteringen av mikroinsatsen. En **Essure** bekräftelsetest (HSG) kan också behövas. Det finns cirka 0,033 rad i det fluoroskopiska skedet (<30 sekunder) vid ett hysterosalpingogram-ingrepp. Som jämförelse kan nämnas utsattheten för strålning vid ett bariumlavemang ligger på 0,85 rad, vilket är högre än för den **Essure** bekräftelsetest (HSG) som krävs. Mängden strålning som en patient utsätts för vid bäckenröntgen är ungefär lika stor som den mängd en person utsätts för varje år genom naturlig bakgrundsstrålning.
- Följande ytterligare risker är förenade med med ingreppet i samband med **Essure** bekräftelsetest (HSG), om detta skulle befinnas nödvändigt: Vasovagal reaktion; infektion som kan komma att kräva en antibiotikakur och i sällsynta fall kan leda till sjukhusvistelse; intravasation; perforation av livmodern; kramper och/eller blödningar i livmodern; smärta eller obehag; och allergisk reaktion mot latex. Exponering för latex har i vissa sällsynta fall sagts vara förknippad med anafylaktisk reaktion, vilket kan leda till döden.
- Användning av de kontrastmedel som nyttjas vid **Essure** bekräftelsetest (HSG) har hos vissa patienter varit förknippad med allergisk reaktion. Allergisk reaktion kan leda till utslag (urticaria) eller andningssvårigheter. Hos vissa personer kan anafylaktisk reaktion uppstå, och detta kan leda till döden.

E. Risker förknippade med eventuella framtida åtgärder

- Patienter som genomgår placering av **Essure** mikroinsats kan i framtiden komma att erbjudas intrauterin behandling med hjälp av elektrisk energi. Vi rekommenderar att diatermibehandling ej används under kirurgiska ingrepp i livmodercornua och äggledare. Under samtliga andra eventuella bäckeningrepp som utförs ska användning av diatermi undvikas inom en radie av 4 centimeter från mikroinsatsen. På grund av närvaron av **Essure** mikroinsats(-er) kan dessa ingrepp vara förenade med risker som ännu ej är kända.

- Alla intrauterina ingrepp som t.ex. endometriumbiopsier, skrapningar, hysteroskopi (diagnostisk eller operativ) inklusive endometriumablation kan störa mikroinsatsernas förmåga att förhindra graviditet. Vidare kan närvaron av **Essure** mikroinsats(-er) vid dessa ingrepp medföra komplikationer som ännu ej är kända.
- Patienter kan i framtiden besluta sig för att genomgå provrörsbefruktning för att bli gravida. De eventuella (bi-)effekterna av **Essure** mikroinsatser på provrörsbefruktning är okända. Om graviditet uppstår är det okänt vilka risker som uppstår för patienten, fostret och för graviditetens fortsatta förlopp till följd av mikroinsatsen.
- **Essure** mikroinsatser är MR-säkra och röntgentäta. **Essure** mikroinsatser är vidare MR-kompatibla, förutom i bäckenområdet där de kan orsaka vissa artefakter.
- **Det finns även risk för att ännu ej kända risker föreligger.**

VIII. Bruksanvisning

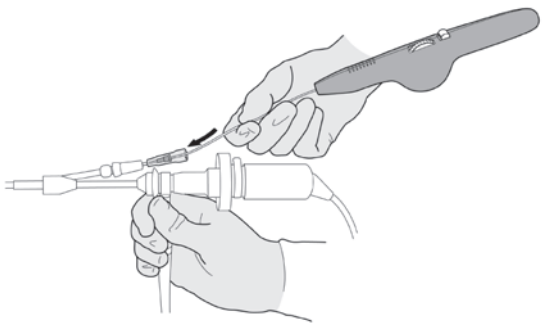
A. Före placering av mikroinsatsen

1. Placeringen av mikroinsatsen bör utföras under dag 7-14 av menstruationscykeln (där dag 1 representerar blödningens första dag) för att visualiseringen av äggledaröppningarna ska maximeras, och för att minimera risken för att en patient med odiagnostiserad graviditet utsätts för implantation av mikroinsatserna.
2. Ett graviditetstest bör göras under överinseende av ansvarig läkare eller annan behörig personal och ska genomföras inom 24 timmar eller omedelbart före placeringen av mikroinsatsen.
3. Vi rekommenderar starkt att NSAID:er (icke-steroida antiinflammatoriska medel) såsom Indocid (peroralt eller med suppositorium) ges till patienten en till två timmar före placering av mikroinsatsen, eftersom kliniska rön påvisar att användning av NSAID:er betydligt ökar sannolikheten för framgångsrik placering. I det fall enbart paracervikalblockad används, kan patienten ges Diazepam (peroralt) eller liknande medel trettio minuter före ingreppet, i ångestdämpande syfte.

B. Placering av Essure mikroinsats

Placeringen av **Essure** mikroinsats kan utföras ambulatoriskt, eller i en dagcentermiljö. Under placeringen ska steril teknik användas. Det ska inte krävas mer än 30 minuter för att slutföra placeringen av mikroinsatsen.

1. Placera patienten i litotomiläge.
2. För in ett spekulum i vagina för att få tillträde till livmoderhalsen. Preparera livmoderhalsen med betadine eller annan ändamålsenlig antibakteriell lösning i enlighet med praxis.
3. Lokal anestesi är den metod som är att föredra vid implantering av mikroinsatserna. Paracervikalblockad kan göras. Midazolam (IV) eller liknande medel kan också ges till patienten för att förebygga eller lindra eventuella obehag.
4. För in ett sterilt hysteroskop med fastsatt kamera och arbetskanal (≥5 Fr), genom cervix till livmoderhålan. Genomför vid behov cervikal dilatation för att medge införande. För att undvika risken för livmoderperforation ska ingreppet avbrytas om orimligt mycket kraft krävs för att uppnå cervikal dilatation.
5. Utvidgning av livmoderhålan bör utföras med infusion av fysiologisk koksaltlösning genom hysteroskopets arbetskanal. Vi rekommenderar starkt att koksaltlösningen förvärms till kroppstemperatur och introduceras med självtryck, för att minimera spasmer i äggledarna. Utvidgning av livmodern måste ske med utmärkt resultat och bibehållas under hela ingreppet. Följ standardrutiner för övervakning av patientens vätskeabsorption under hela ingreppet. Använd hysteroskopisk visualisering för att identifiera äggledarnas båda öppningar.
6. Båda äggledaröppningarna ska identifieras och utvärderas med användning av hysteroskopi innan placering av **Essure** mikroinsats påbörjas. Försök inte att placera en mikroinsats i ena äggledarens mynning såvida det inte skäligen kan förväntas/står bortom rimligt tvivel att motstående äggledare är öppen.
7. När äggledaröppningarna har identifierats förs introduceranordningen in genom tillslutningslocket på hysteroskopets arbetskanal. Arbetskanalens avstängningskran bör förbli i det öppna läget (enheten och/eller introducern kan skadas om avstängningskranen stängs på endera enheten. Placera **Essure** leveranssystem i introducern och för det vidare genom arbetskanalen på hysteroskopet. Om den ventilförsedda introduceranordningen inte skadats vid den första placeringen av mikroinsatsen, kan den förbli i arbetskanalen under hela **Essure**-proceduren.

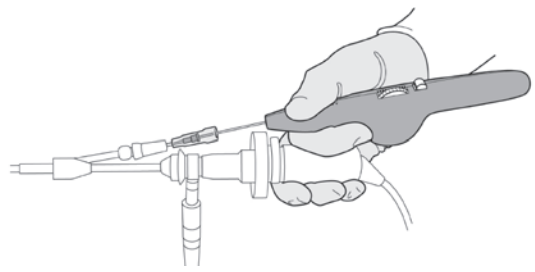


För in introduceranordningen genom tillslutningslocket på hysteroskopets arbetskanal och placera sedan **Essure** *leveranssystem i introduceranordningen.*

8. För långsamt och stadigt in **Essure** leveranssystem i den proximala äggledaren så att tubarspasm förebyggs. För in leveranssystemet tills placeringsmarkeringen på leveranskatetern ligger jäms med äggledarens mynning. Denna synliga markering indikerar att **Essure** mikroinsats nu sträcker sig från det distalt intramurala segmentet till det proximalt istmiska segmentet av äggledaren, med den yttre spiralen utsträckt längs den uterotubala förbindelsen. Detta är den optimala placeringen av **Essure** mikroinsats.

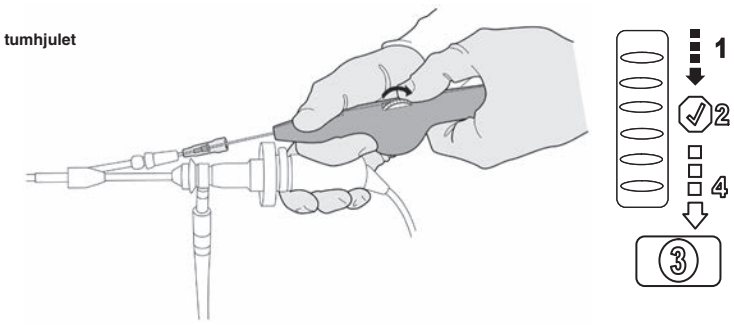
För in tills den svarta placeringsmarkeringen är vid äggledarens mynning. Detta utgör en synlig indikator för korrekt position före placering.

9. Att leveranskatetern och äggledarens lumen är koncentriskt korrekt placerade i förhållande till varandra indikeras av att det är möjligt att utan alltför stort motstånd föra in katetern under direkt visualisering. Vanligtvis finns två saker som visar på motstånd: 1) man ser att den svarta markeringen på kateterns ytterhölje inte förs fram till äggledarmynningen, och/eller 2) leveranskatetern böjer sig eller viker sig alltför mycket och hindrar därigenom läkaren från att öka trycket framåt på kateteranordningen. När sådant motstånd mot vidare avancemang observeras hos katetern ska inga ytterligare försök göras att placera mikroinsatsen; detta för att undvika risken för perforation av livmodern eller att mikroinsatsen av misstag placeras i livmoderns muskulatur istället för i äggledarnas lumen. En uppföljande **Essure**-bekräftelsetest (HSG) ska genomföras för att bedöma äggledarnas öppenhet.
10. Om det efter flera minuter är omöjligt att föra katetern fram till placeringsmarkeringen ska, såvida detta inte redan skett, ett perfusionstest med en patencitetskateter genomföras, för att kontrollera graden av öppenhet hos äggledaren. Avbryt ingreppet om äggledaren är blockerad eller om katetern inte kan föras fram till placeringsmarkeringen. Ingreppet ska även avbrytas i det fall placering av mikroinsatsen inte lyckats efter 10 minuters försök till kanylering per äggledare.
11. När leveranskatetern väl nått fram till placeringsmarkeringen, placeras mikroinsatsen. Börja med att stabilisera handtaget på **Essure** mikroinsats mot kameran på hysteroskopet, eller annat fixerat föremål för att förebygga att **Essure**-systemet av misstag rör sig framåt då leveranskatetern dras tillbaka.



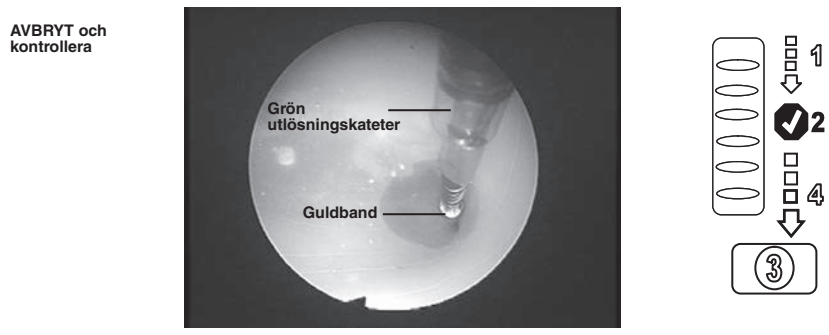
Stabilisera handtaget mot kamerahuvudet eller något annat fixerat föremål för att förebygga att **Essure***-systemet oavsiktligt rör sig framåt*

12. När du försäkrat dig om att den svarta placeringsmarkeringen befinner sig vid äggledarens mynning ska du rotera tumhjulet på handtaget mot dig själv tills hjulet har slutat att rotera. Denna åtgärd motsvaras av symbolen ⇩1 på leveranssystemets handtag. Detta gör det lättare att dra tillbaka leveranskatetern. Du kommer att se att den svarta placeringsmarkeringen flyttas bort från äggledarens mynning (mot hysteroskopet) och försvinner in i arbetskanalen. Då leveranskatetern dras tillbaka blottas den nedtryckta **Essure**-mikroinsatsen. Cirka 1 centimeter av mikroinsatsen (nedtryckta spiralfjädrar) ska vara synlig innanför livmodern då leveranskatetern har dragits tillbaka.



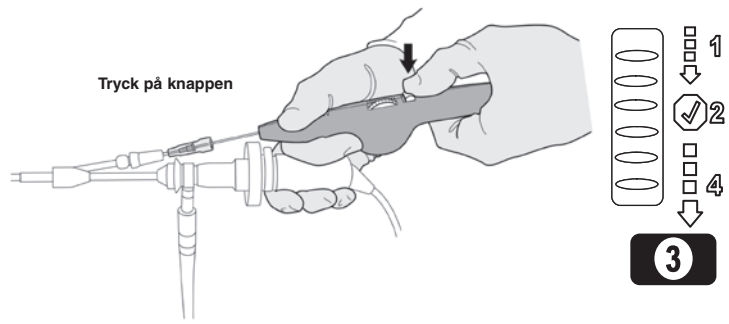
Rotera tumhjulet för att dra tillbaka katetern

13. För att bekräfta korrekt placering, sätt guldmarkeringsbandet precis utanför mynningen, vilket motsvarar symbolen ✓2 på leveranssystemets handtag. Visualiseringen av guldbandet precis utanför mynningen liksom visualiseringen av den gröna utlösningskateterns distala spets kommer att bekräfta korrekt placering. Om mer än 1 cm av mikroinsatsen är synlig utanför uterus, bör läget för mikroinsatsen ändras genom att flytta hela systemet ytterligare in i äggledaren om möjligt, innan fortsättning till nästa steg.



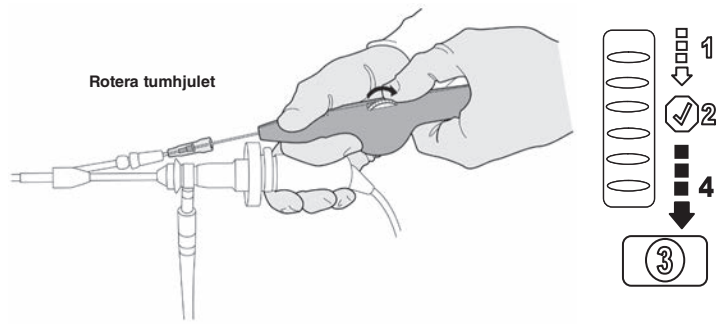
Visualisera guldbandet vid mynningen

14. Tryck på leveranshandtagets knapp så att tumhjulet kan ytterligare roteras, vilket motsvarar symbolen ③ på handtagets knapp.



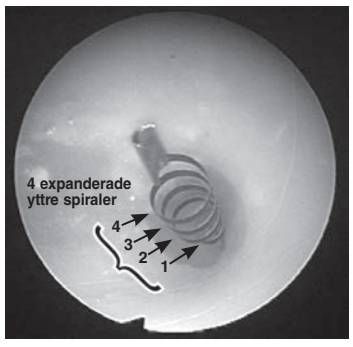
Tryck på knappen så att tumhjulet åter kan rotera.

15. Rotera tumhjulet mot dig för att lossa mikroinsatsens yttre spiralfjäder, vilket motsvarar symbolen ⇩4 på leveranssystemets handtag. Fortsätt att rotera tumhjulet tills det inte kan rotera längre. När tumhjulet inte kan roteras något ytterligare och de expanderade yttre spiralfjädrarna är synliga, dras systemet tillbaka.



Rotera tumhjulet för att lossa mikroinsatsens yttre spiralfjäder

16. **Essure** mikroinsats ska då den placerats fastställas med hysteroskopisk visualisering. Optimal position innebär då att 3 till 8 av **Essure** mikroinsats expanderade yttre spiralfjädrar befinner sig inne i livmodern.



Expanderade yttre spiralfjädrar inne i livmodern indikerar att **Essure** *mikroinsats är optimalt placerad.*

17. Om läkaren är missnöjd med mikroinsatsens placering utifrån vad han/hon ser i hysteroskopet, eller misstänker perforation av livmodern eller äggledarna, ska mikroinsatsen/-erna lämnas kvar på plats och utvärderas via bäckenröntgen eller HSG tre månader efter det att anordningen placerats.

    VARNING: NÄR MIKROINSATSEN VÄL HAR PLACERATS OCH UTLÖSTS I ÄGGLEDAREN SKA INGA FÖRSÖK GÖRAS ATT PÅ HYSTEROSKOPISK VÄG AVLÄGSNA MIKROINSATSEN, SÅVIDA INTE MINST 18 AV SPIRALERNA I ESSURE MIKROINSATS NÅR IN I LIVMODERHÅLAN. Avlägsnande av en sådan mikroinsats bör påbörjas omedelbart under placeringsförsöket. Det är dock möjligt att det inte går att avlägsna mikroinsatsen (se kapitel XIII, Att avlägsna **Essure** mikroinsats). Om mikroinsatsen oavsiktligt placerats i livmoderhålan och inte i äggledaren ska den avlägsnas från livmodern. Gör därefter ytterligare ett försök att placera en mikroinsats i äggledaren.
18. Upprepa placeringen av **Essure** mikroinsats i den motstående äggledaren.
19. Dokumentera hur mycket av mikroinsatsen som befinner sig inne i livmoderhålan och lägg märke till eventuella svårigheter med att bedöma eller bekräfta var och en av äggledarnas öppningar, eller misstankar om eventuell perforation. Dessa uppgifter ska noteras i patientjournalen för senare referens vid utvärdering av **Essure** bekräftelsetest *(se kapitel IX – Essure bekräftelsetest nedan)*.
20. **Påminn patienten om att hon måste använda en alternativ form av preventivmedel (dock ej spiral) under de 3 första månaderna efter det att mikroinsatsen placerats.**
21. Schemalägg ett tillfälle tre månader efter det att **Essure**-mikroinsatsen har placerats för ett **Essure** bekräftelsetest i syfte att kontrollera att mikroinsatsen sitter kvar och för att fastställa dess placering.

IX. Essure bekräftelsetest

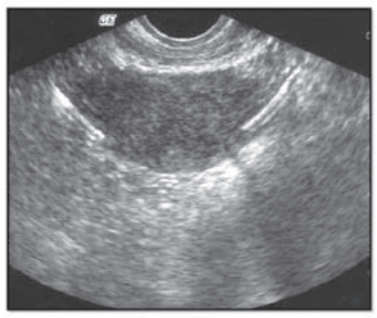
A. Ett **Essure** bekräftelsetest ska genomföras tre månader efter placeringen av mikroinsatsen för att bedöma om mikroinsatsen sitter kvar och för att fastställa dess placering. **Essure** bekräftelsetest (transvaginalt ultraljud (TVU), bäckenröntgen eller hysterosalpingogram (HSG)) får endast utföras av en erfaren gynekolog, ultrasonografist och/eller radiolog som fått utbildning i respektive **Essure** bekräftelsetestprotokoll. Ett detaljerat protokoll med bilder och tips för testprestanda medföljer utbildningen. Ytterligare kopior kan fås på beställning från essure.com

B. Företrädesvis kan bekräftelsetestet antingen utgöras av en bäckenröntgen eller en TVU som genomförs 3 månader efter en okomplicerad bilateral placering av mikroinsatsen.

1. Röntgen och TVU bör inte användas som **Essure** bekräftelsetest under följande omständigheter:
    a) Svår placering, inklusive ett eller flera av nedanstående:
        (1) Misstanke om möjlig perforation vid tiden för placering, på grund av att för stor kraft krävdes för att placera mikroinsatsen och/eller att motståndet plötsligt försvann.
        (2) Identifiering av äggledarens öppning komplicerades under placeringen, antingen på grund av anatomisk variation eller tekniska faktorer som t.ex. otillfredsställande utvidgning, bristfälliga ljusförhållanden eller endometriska restprodukter.
        (3) Kirurgen är osäker på placeringen.
    b) Ingreppets tid > 15 minuter (skop in-skop ut).
    c) Placering med inga eller > 8 spiraler inne i livmoderhålan
    d) Ovanlig post-operativ smärta, övergående eller persisterande, eller debut vid någon senare tid efter ingreppet, utan någon annan identifierbar anledning.
2. Om röntgen eller ultraljud inte är indicerat måste patienten gå vidare till ett HSG för att bedöma placeringen av mikroinsatsen och äggledarocklusion. Transabdominellt ultraljud kan inte användas i stället för TVU. Om röntgen eller ultraljudsbedömning är oklar eller otillfredsställande måste patienten gå vidare till ett HSG för att bedöma placeringen av mikroinsatsen och äggledarocklusion.

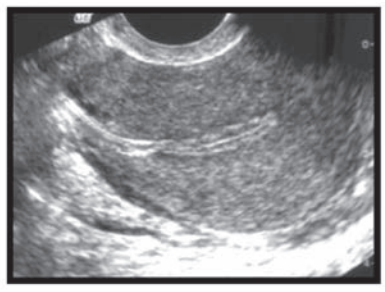
C. Transvaginalt ultraljud

1. Minst tre bilder måste tas och behållas för dokumentation:
    a) En koronal- eller sned koronalprojektion som visar en del av varje mikroinsats i cornua med beteckningen ”scoutbild”.



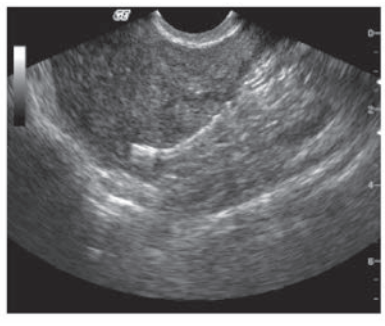
Bilaterala mikroinsatser identifieras i denna transversala (koronal/sned koronal) projektion .

    b) En koronal eller sned koronal bild av den linjära axeln på den vänstra mikroinsatsen inklusive den proximala änden som korsar myometrium i cornua (den interstitiala delen av äggledaren) eller är i kontakt med uterus serosa tubarförening med beteckningen ”vänster”.
    c) En koronal eller sned koronal bild av den linjära axeln på den högra mikroinsatsen som korsar myometrium i cornua (den interstitiala delen av äggledaren) eller är i kontakt med uterus serosa tubarförening med beteckningen ”höger”.
    d) Alla tre bilderna bör tas på film och placeras i patientens medicinska journal för att dokumentera att mikroinsatsen sitter kvar och dess placering.
2. Klassificering av mikroinsatsens placering
    a) Identifiering av mikroinsatsen: I en enstaka scoutbild, måste en del av varje mikroinsats visualiseras i cornua i den koronala eller sneda koronala projektionen för att säkerställa bilateral placering och minska risken för duplicerad bildtagning av samma mikroinsats. Mikroinsatsernas linjära axlar ska se relativt symmetriska ut.
    b) Optimal placering
    Placeringen av mikroinsatsen är optimal när den proximala änden av mikroinsatsen är i kontakt med livmoderhålan eller endometrium, och den linjära axeln är inne i myometrium i cornua (den interstitiala delen av äggledaren) och kan synas vid eller korsande uterus serosa tubarförening (utero-serosal tubal junction, USTJ). Den del av mikroinsatsen som befinner sig i äggledaren kan eventuellt inte visualiseras. Mikroinsatsens linjära axel måste kunna visualiseras för att bekräfta att den inte är fjädrad eller utsträckt.



Optimal placering

    c) Tillfredsställande placering
    Placeringen av mikroinsatsen är tillfredsställande när den proximala änden av mikroinsatsen är distalt om endometrium, med den linjära axeln inuti myometrium i cornua (den interstitiala delen av äggledaren) och kan visualiseras vid eller korsande uterus serosa tubarförening (utero-serosal tubal junction, USTJ). Den del av mikroinsatsen som befinner sig i äggledaren kan eventuellt inte visualiseras. Mikroinsatsens linjära axel måste kunna visualiseras för att bekräfta att den inte är fjädrad eller utsträckt.

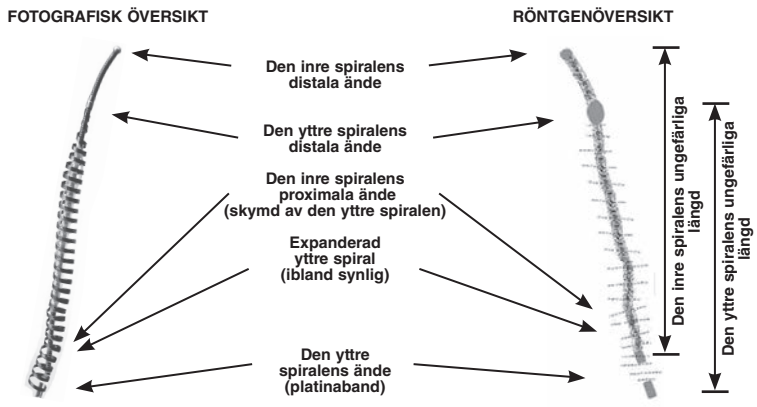


Tillfredsställande placering

    d) Otillfredsställande placering
        (1) Placeringen av mikroinsatsen är otillfredsställande om en del av varje mikroinsats inte kan visualiseras i cornua i den koronala eller sneda koronala projektionen i en scoutbild.
        (2) Bortstötning misstänks om en eller båda mikroinsatserna inte identifieras i cornua i en koronal projektion i en enda scoutbild.
        (3) Distal placering misstänks om den proximala änden av mikroinsatsen inte är placerad i myometrium i cornua (den interstitiala delen av äggledaren), och inte korsar eller är i kontakt med USTJ.
        (4) Proximal placering misstänks om mer än 50 % eller den större delen av mikroinsatsen visualiseras i livmoderhålan eller om mikroinsatsens/-ernas linjära axel visualiseras i mittlinjens sagittalprojektion.
        (5) Perforation misstänks om den linjära axeln hos en eller båda mikroinsatserna är parallella med endometrieskiktet i den sagittala projektionen, eller om en mikroinsats linjära axel ses korsa myometrium i mittlinjens sagittala projektion.
        (6) Oklassificerad position: Om en mikroinsats linjära axel inte kan identifieras, vilket antyder att den är fjädrad, böjd eller utsträckt, bedöms mikroinsatsens placering som otillfredsställande. Om den omgivande mjukvävnanden inte kan definieras tydligt bedöms positionen som otillfredsställande.
3. Om ultraljudsbedömning är oklar eller otillfredsställande måste patienten gå vidare till ett HSG för att kontrollera mikroinsatsens placering och tubarocklusion.

D. Bäckenröntgen

1. Ta en bild av livmodern med båda **Essure**-mikroinsatserna tydligt synliga. Mikroinsatsernas läge och kurvatur ska noteras.



Motstående röntgenprojektion av ***Essure*** *mikroinsats*

2. Bedöm bäckenröntgenbilder enligt följande:
    a) Tillfredsställande: Mikroinsatserna ser ut att vara i äggledarens lumen och utsträckta längs den uterotubala förbindelsen, och ser ut att vara relativt symmetriska. Patienter vars röntgenbilder bedöms vara ”tillfredsställande” kan börja förlita sig på **Essure** mikroinsats för födelsekontroll.
    b) Misstänkt: En av eller båda mikroinsatserna ser ut att befinna sig distalt eller proximalt om optimal position, eller kan vara delvis eller helt perforerade genom äggledaren, och/eller ser ut att vara relativt asymmetriska. Patienter vars röntgenbilder bedöms vara ”misstänkta” ska anvisas att fortsätta med alternativ födelsekontroll och att genomgå ett HSG.
    c) Otillfredsställande: Tydlig intraperitoneal placering av mikroinsatsen eller bortstötning.
3. Om röntgenbedömningen är oklar eller otillfredsställande, eller om mikroinsatsens placering är misstänkt, måste patienten gå vidare till ett HSG för att bedöma mikroinsatsens placering och tubarocklusion.

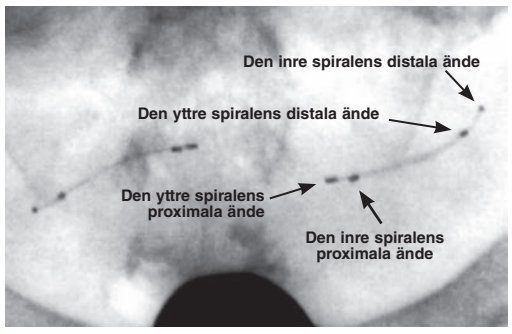
E. Utföra och bedöma modifierade HSG:er

1. HSG utförs för att ytterligare bedöma **Essure** mikroinsatsens placering och äggledarocklusion om så anses nödvändigt baserat på röntgen- eller ultraljudsfynd. Följ anvisningarna nedan om hur man utför och bedömer HSG.
2. Utföra HSG – riktlinjer:
    a) Åstadkom god fyllning av cornua så att livmoderhålans silhuett syns tydligt.
    b) Placera fluoroskopistrålen så nära AP-projektionen som möjligt.
    c) Dilatera inte livmoderhalsen i onödan; om dilatation inträffas ska en god cervikal tätning upprätthållas.
    d) En nedåtriktad dragning på cervikalt tenakulum kan krävas för en mittpositionerad livmoder. Avlägsna spekulum före fluoroskopi för att få bästa möjliga visualisering av livmoderns anatomi.
    e) Ta minst sex röntgenbilder för att bedöma mikroinsatsens placering och tubarocklusion.
        (1) Röntgenbild 1 – ”Scoutfilm” – Livmodern och mikroinsatser utan kontrast.
        (2) Röntgenbild 2 – Minimal fyllning av hålan – Livmodern och mikroinsatser med liten mängd kontrast.
        (3) Röntgenbild 3 – Delvis fyllning av hålan – Livmodern och mikroinsatser när hålan är nästan full med kontrast.

(4) Röntgenbild 4 – Total fyllning av hålan – Livmodern och mikroinsatser när cornua är uttänjd av kontrast.

(5) Röntgenbild 5 och 6 – Förstoringar av livmodercornua – Mikroinsats inuti äggledaren med höger (5) och vänster (6) cornua.

FÖRSIKTIGHET! Undvik onödigt kraftigt intrauterint tryck efter röntgenbild 4 så att patienten inte utsätts för obehag och vasovagal reaktion.



3. Bedömning av mikroinsatsens placering
   a) Under bedömningen, observera fyra ”markörer” vid varje ände på de inre och yttre spiralerna). Observera att de distala markörerna är fixerade i relation till varandra, men att de proximala markörerna kan ha förflyttat sig eller verkar utsträckta på grund av den yttre spiralens flexibilitet. Optimal placering av mikroinsatsen är när den inre spiralen korsar den uterotubala förbindelsen.
   b) Bedöma mikroinsatsens placering:
      (1) Bortstötning eller proximal placering: Mikroinsatsen saknas eller ≥ 50 % av den inre spiralen når in i livmoderhålan.
      (2) Tillfredsställande placering: Den distala änden av den inre spiralen är inuti äggledaren, och < 50 % av den inre spiralen når in i livmoderhålan eller den proximala änden av den inre spiralen är ≤ 30 mm in i den äggledare från vilken kontrast fyller cornua.
      (3) Distal placering eller perforation: Mikroinsatsen är inne i äggledaren men den proximala änden av den inre spiralen är > 30 mm distalt från där kontrast fyller cornua eller mikroinsatsen är helt eller delvis perforerad.
4. Bedöma tubarocklusion
   a) Fastställ om kontrast är synligt bortom mikroinsatsen och notera eventuell grad av proximal tubal fyllning även om äggledaren är ockluderad.
   b) Bedöm tubarocklusion:
      (1) Tillfredsställande ocklusion: Äggledaren är ockluderad vid cornua.
      (2) Tillfredsställande ocklusion: Kontrast kan ses inuti äggledaren men inte förbi den distala änden av den yttre spiralen.
      (3) Otillfredsställande ocklusion: Kontrast kan ses förbi den distala änden av mikroinsatsen eller i peritonealhålan.
5. Bedöma förmågan att förlita sig
   a) Om placeringen och tubarocklusionen båda bedöms vara tillfredsställande, ska patienten anvisas att avbryta alternativ födelsekontroll.
   b) Om placeringen är otillfredsställande ska patienten anvisas att inte förlita sig på mikroinsatsen för födelsekontroll.
   c) Om placeringen är tillfredställande med ocklusionen är otillfredsställande ska patienten anvisas att fortsätta med alternativ födelsekontroll. Upprepa HSG om tre månader. Om ocklusionen fortfarande är otillfredsställande ska patienten anvisas att inte förlita sig på mikroinsatserna för födelsekontroll.

X. Tillvägagångssätt vid otillfredsställande position av mikroinsats

A. Otillfredsställande position för mikroinsatsen diagnostiserad med hjälp av hysterosalpingogram

1. Proximal position: mer än 50 % av den inre spiralens längd på mikroinsatsen/-erna når in i livmodern.
2. Distal position: Mikroinsatsen/-erna befinner sig i äggledaren men den proximala änden av den inre spiralen befinner sig mer än 30 mm från kontrastmedlet som fyller livmodercornua.
3. Fullständig bortstötning av mikroinsatsen/-erna; mikroinsatsen/-erna finns ej längre i kroppen.
4. Perforation: mikroinsats/-erna är helt eller delvis perforerande.
5. Mikroinsatsen/-erna i intraperitonealt läge; mikroinsatsen/-erna befinner sig uppenbart utanför äggledarna.

B. Tillvägagångssätt vid bortstötning eller otillfredsställande position av mikroinsats

1. Bilateral bortstötning av mikroinsatserna och bilateral ocklusion: Patienten bör informeras om alternativet med incisionell sterilisering eller att hon kan förlita sig på sin bilaterala PTO (proximal tubarocklusion) som preventivmedel med hänsyn till den potentiella risken för en falsk positiv diagnos av tubarocklusion från **Essure** bekräftelsetest (HSG).
2. Bilateral bortstötning av mikroinsatserna med ocklusion i ena äggledaren och öppenhet i den motstående äggledaren: Ytterligare mikroinsats-implantering bör övervägas för patienten för att ersätta mikroinsatsen i den öppna äggledaren så att hon kan förlita sig på en **Essure** mikroinsats samt PTO i motstående äggledare som antikonceptionsmetod. Patienten bör informeras om denna valmöjlighet eftersom det finns en potentiell risk för falsk positiv diagnos av tubarocklusion från **Essure** bekräftelsetest (HSG). Hon bör även upplysas om att incisionell sterilisering också är ett alternativ.
3. Unilateral bortstötning av mikroinsatsen eller en unilateral otillfredsställande position av mikroinsatsen (i myometrium eller i intraperitonealhålan) men med en tillfredsställande position för mikroinsatsen i den motstående äggledaren: Om resultatet från **Essure** bekräftelsetest (HSG) uppvisar blockering i den äggledare från vilken mikroinsatsen bortstöttes eller där mikroinsatsen skulle ha placerats, kan patienten förlita sig på den mikroinsats vars placering är tillfredsställande och PTO hos den motstående äggledaren, med hänsyn till risken för falsk positiv diagnos av tubarocklusion från **Essure** bekräftelsetest (HSG). Hon bör även upplysas om att incisionell sterilisering också utgör ett alternativ.
4. Otillfredsställande unilateral position för mikroinsatsen (i myometrium eller i intraperitonealhålan) men med motstående äggledares mikroinsats belägen i tillfredsställande position: Om resultaten från **Essure** bekräftelsetest (HSG) uppvisar tubaröppenhet i den äggledare som skulle fått en mikroinsats implanterad kan patienten erbjudas möjlighet att komma tillbaka vid ett senare tillfälle för att göra ett nytt försök att implantera en mikroinsats. Hon bör även upplysas om att incisionell sterilisering också utgör ett alternativ.
5. Unilateral bortstötning av mikroinsatsen; otillfredsställande position (i myometrium eller i intraperitonealhålan) för mikroinsatsen i ena äggledaren; otillfredsställande position för mikroinsatsen i ena äggledaren i “Proximalläge” (>50 % av den inre spiralens längd når in i livmodern) eller “Distalläge” (mikroinsatsen befinner sig i äggledaren men den proximala änden på dess inre spiral ligger >30 mm från kontrastmedlet som fyller livmodercornua) med motstående äggledares mikroinsats i otillfredsställande position: Patienten bör upplysas om att incisionell sterilisering finns som ett alternativ. I samtliga fall då det bedöms som nödvändigt att avlägsna mikroinsatsen och avlägsnande på hysteroskopisk väg inte är genomförbart, kan ett incisionellt ingrepp bli nödvändigt.
6. Om en patient har valt incisionell kirurgi efter något av ovanstående scenarion bör båda äggledarna ockluderas oavsett om det finns mikroinsatser kvar i tillfredsställande position. Om läkaren bedömer det som genomförbart utan att kompromissa med säkerheten ska försök göras att avlägsna mikroinsatsen, men det är dock möjligt att det inte går att genomföra. Användning av intra-operativ fluoroskopi rekommenderas för att identifiera mikroinsatsen/-ernas position före och under ingreppet. Försök till avlägsnande ska inte pågå längre än 30 minuter.

XI. Tillvägagångssätt i händelse av otillfredsställande placering av Essure mikroinsats

I sådana fall då placering av mikroinsatsen misslyckats, unilateralt eller bilateralt, ska patienten informeras om att hon ännu inte har permanent födelsekontroll. Om patienten väljer laparoskopisk sterilisering (dvs. clipsapplicering eller diatermi) ska båda äggledarna förses med clips eller kauteriseras, även om ena äggledaren har en **Essure** mikroinsats implanterad. Clipsapplicering eller kauterisering av äggledarna ska utföras distalt i förhållande till **Essure** mikroinsats.

Om patienten inte väljer laparoskopisk sterilisering kan hon erbjudas en **Essure** bekräftelsetest (HSG) efter sin nästa menstruation (före ägglossning: dag 7 till 14 där dag 1 representerar blödningens första dag) för att fastställa äggledarnas öppenhet. Om öppenhet hos äggledarna kan fastställas kan läkaren erbjuda patienten ett nytt försök att implantera mikroinsatsen. Om ett andra försök till implantering av mikroinsats misslyckas, är det osannolikt att patienten kommer att lyckas med därpå följande försök. Om patienten har en mikroinsats kvar *in vivo* ska hon tillrådas att inte förlita sig på den unilaterala mikroinsatsen som preventivmetod.

Om placering i endast en äggledare lyckades, och resultatet från **Essure** bekräftelsetest (HSG) bekräftar befintlig proximal ocklusion i motstående äggledare (PTO) ska patienten tillrådas att det är möjligt att förlita sig på en av mikroinsatserna, med reservation för potentiellt felaktig PTO-positiv diagnos från **Essure** bekräftelsetest (HSG). Tubarocklusion definieras som färgämnets oförmåga att passera från livmoderhålan till peritonealhålan under en **Essure** bekräftelsetest (HSG). Hon bör även upplysas om att incisionell sterilisering också är ett alternativ. Försök att avlägsna en unilateralt placerad mikroinsats rekommenderas inte såvida inte patienten upplever negativa bieffekter från mikroinsatsen.

XII. Att avlägsna Essure mikroinsats

VARNING: NÄR MIKROINSATSEN VÄL HAR PLACERATS OCH UTLÖSTS I ÄGGLEDAREN SKA INGA FÖRSÖK ATT AVLÄGSNA DEN PÅ HYSTEROSKOPISK VÄG GÖRAS, SÅVIDA INTE MINST 18 AV SPIRALERNA I ESSURE MIKROINSATS NÅR IN I LIVMODERHÅLAN.

Om detta krav är uppfyllt ska försök att avlägsna mikroinsatsen utföras omedelbart efter placeringsförsöket. Det är dock möjligt att det inte går att avlägsna mikroinsatsen. Vid försök till avlägsnande ska man gå tillväga på följande sätt:

1. För in ett greppinstrument genom hysteroskopets arbetskanal.
2. Greppa tag i den yttre spiralen på **Essure** mikroinsats. Försök att ta ett grepp om både den inre och den yttre spiralen på mikroinsatsen.
3. Dra tillbaka greppinstrumentet och hysteroskopet samtidigt, så att hela systemet dras ut ur livmodern tillsammans.
4. Den yttre och/eller den inre spiralen på **Essure** mikroinsats kan komma att tänjas ut eller förlängas i samband med försök att avlägsna mikroinsatsen.
5. Ge analgetika/anestesi för att förebygga eller lindra obehag hos patienten, allt efter behov.
6. Om det går att framgångsrikt avlägsna mikroinsatsen fullständigt ska försök göras att föra in en annan **Essure** mikroinsats.
7. Om läkaren inte är fullkomligt övertygad om att **Essure** mikroinsats i sin helhet har avlägsnats från äggledaren ska han/hon **INTE** placera en annan mikroinsats i denna äggledare. Efter ingreppet tas en röntgenbild för att avgöra om fragment av mikroinsatsen fortfarande finns kvar *in vivo*.

Förutom ovan beskrivna scenario ska mikroinsatsen avlägsnas endast om en patient lider av biverkningar på grund av mikroinsatsen eller om hon kräver att mikroinsatsen ska avlägsnas.

Om det bedöms som nödvändigt att avlägsna mikroinsatsen måste ett transabdominellt tillvägagångssätt (laparotomi eller laparoskopi) användas.

En resektion av cornua, proximalt i äggledaren är nödvändig om mikroinsatsen befinner sig korrekt placerad längs med den uterotubala förbindelsen.

En **Essure** mikroinsats som har placerats på fel ställe eller har migrerat bortom den uterotubala förbindelsen ska avlägsnas med hjälp av traditionell linjär salpingotomi eller salpingektomi, vilket görs med hjälp av laparoskopi eller laparotomi.

1. Vid användning av linjär salpingotomi ska en mindre incision (ungefär 2 cm lång) göras längs med äggledarens antimesenteriska gräns, precis ovanför mikroinsatsen.
2. Total eller partiell salpingotomi kan utföras för att avlägsna mikroinsatsen i samband med, eller oberoende av, en traditionell äggledarsterilisering.

XIII. Patientkort

Samtliga patienter som fått **Essure** mikroimplantat ska få ett laminerat kort som passar i plånboken, vilket ska ange att hon har **Essure** mikroinsats(-er) implanterad(e). **Kortet bifogas i denna förpackning.** På kortet förklaras dessutom att det kan finnas risker för patienten i samband med framtida livmoderingrepp eller kirurgiska ingrepp i fortplantningsorganen.

XIV. Symbolförklaringar

STERILE EO	Steriliserad med etylenoxid
LOT	Batchkod
	Får ej återanvändas
REF	Katalognummer
	OBS! Se bruksanvisningen
	Använd före
	Förvara produkten på avstånd från värme
	Produkten får inte användas om förpackningen har öppnats eller skadats
MR	MR-säker under vissa villkor
EC REP	Auktoriserad europeisk representant
CE 0050	Produkten uppfyller kraven i EU-direktivet 93/42/EC
	Förvaras torrt
CONT	Innehåll

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Auktoriserad representant för Europa:
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För beställning av produkter eller rapportering om biverkningar/ komplikationer, var vänlig kontakta lokal representant för Bayer HealthCare LLC

PN-84731145, ART Rev. B

Suomi

essure®

Pysyvä raskauden ehkäisy

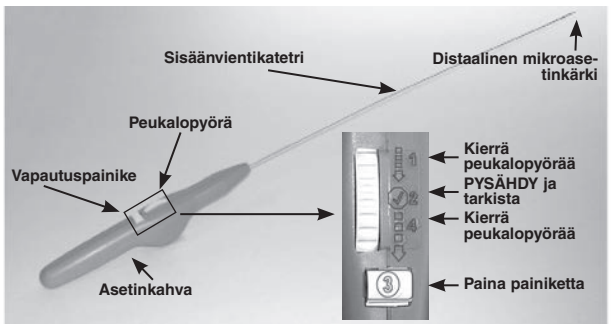
BAYER

KÄYTTÖOHJEET

I. Mikroistutteen kuvaus

Essure®- pysyvä ehkäisymenetelmä koostuu useista komponenteista. Dynaamisesti laajentuva **Essure**-mikroistute on kiinnitetty asennusjohtimeen ja vapautuskatetriin. Koko rakenne on asennuskatetrin sisällä. Tämä järjestelmä (kuvassa 1) kiinnitetään kahvaan, jolla mikroistute voidaan asentaa ja vapauttaa. **Essure**-järjestelmän mukana toimitetaan myös venttiilillä varustettu **DryFlow**®-asennuslaite. Sen tarkoituksena on suojata **Essure**-mikroistutetta, kun se pujotetaan hysteroskoopin työskentelykanavan kumiportin läpi.

Kuva 1
Essure-asennusjärjestelmä
asennustoimenpidemerkkeineen
(EI OIKEASSA MITTAKAAVASSA)



II. Toimintamekanismi

Essure-järjestelmä asentaa **Essure**-mikroistutteen hysteroskooppiohjauksessa munanjohtimen luumenin proksimaaliosaan. Kun **Essure**-mikroistute laajentuu sen vapauttamisen jälkeen, se ankkuroituu akuutisti munanjohtimeen. Tämän jälkeen mikroistute saa aikaan benignin kudosreaktion, joka aiheuttaa kudoksen kasvamista mikroistutteeseen, mikä puolestaan ankkuroi mikroistutteen tukevasti munanjohtimeen. Tämä benigni kudosreaktio on paikallinen, fibroottinen ja munanjohtimen sulkeva.

Jokainen **Essure**-järjestelmä on steriloitu etyleenioksidilla ja toimitetaan steriilinä. Se on kertakäyttöinen. Ei saa käyttää uudestaan tai steriloida uudestaan. Uudelleensterilointi voi heikentää sen mekaanisia ominaisuuksia, mikä voi johtaa potilasvahinkoon.

III. Käyttöaiheet

Essure-järjestelmä on tarkoitettu käytettäväksi munanjohtimen sulkevana mikroistutteena, joka on pysyvä raskauden ehkäisymenetelmä.

IV. Vasta-aiheet

- potilaan epävarmuus pysyvästä raskauden ehkäisystä
- raskaus tai epäilty raskaus
- synnytys tai toisen kolmanneksen aikana keskeytetty raskaus 6 viikon sisällä ennen **Essure**-mikroistutteen asettamista
- aktiivinen tai äskettäinen infektio lantiossa
- hoitamaton akuutti kohdunkaulan tulehdus
- selittämätön tai voimakas verenvuoto emättimestä
- gynekologinen maligniteetti (epäilty tai tunnettu)
- kohtuontelon tai munanjohtimien epänormaalius, joka tekee munanjohtimien kohtuaukon näkemisen tai munanjohtimien proksimaaliosan kanyloimisen vaikeaksi tai mahdottomaksi
- allergisuus varjoaineille (hysterosalpingografia on ehkä suoritettava kolme kuukautta mikroistutteen asentamisen jälkeen)
- potilas käyttää parhaillaan kortikosteroideja

V. Varoitukset

- **Essure**-toimenpiteen saavat suorittaa vain hysteroskopiaan hyvin perehtyneet lääkärit, jotka ovat suorittaneet tätä toimenpidettä koskevan *Bayer HealthCare LLC* -koulutusohjelman.
- Nikkelititaanille allergisilla henkilöillä voi esiintyä allerginen reaktio mikroistutteelle.
- **Essure**-järjestelmää ei saa käyttää, jos pakkaus on avoin tai vahingoittunut. Ei saa käyttää, jos mikroistute on vahingoittunut.
- Kun **Essure**-mikroistute asennetaan munanjohtimeen, sitä ei saa väkisin työntää eteenpäin.
- **Essure**-järjestelmää ei saa työntää eteenpäin, kun katetrin asennusmerkki on saavuttanut munanjohtimen aukon. Jos järjestelmää työnnetään tätä kauemmas, seurauksena voi olla mikroistutteen sijoittuminen väärään kohtaan tai munanjohtimen tai kohdun perforaatio.
- Jos munanjohdin puhkeaa tai puhkeamista epäillään, **Essure**-mikroistutteen asennustoimenpidettä ei saa jatkaa. Hyvin pienellä prosenttimäärällä **Essure**:n kliinisiin kokeisiin osallistuneista naisista (1,8 % eli 12/682 potilaalla) todettiin välineeseen liittyviä munajohtimen puhkeamisia. Puhkeamisia aiheuttaneiden mikroistutteiden poistaminen tarvittaessa vaatii laparoskopiaa tai muita kirurgisia toimenpiteitä.
- Jos **Essure**-mikroistutteen asettaminen ei onnistu 10 minuutin sisällä johdinta kohti kanylointiyrityksen alusta lähtien, toimenpide on keskeytettävä ja siirrettävä mahdollisesti myöhempään ajankohtaan.
- Kun mikroistute on sijoitettu paikoilleen (ts. irronnut asennusjohtimesta), sen poistamista ei tulee yrittää hysteroskooppisesti, ellei vähintään 18 **Essure**-mikroistutteen kierukan kierrettä ulotu kohtuonteloon. Mikroistutteen poistaminen tulee suorittaa heti sijoittamisen jälkeen. Poistaminen voi kuitenkin olla mahdotonta.
- Potilaan on käytettävä toista ehkäisymenetelmää, kunnes mikroistutteen tyydyttävä sijainti voidaan varmistaa 3 kuukautta istutteen asettamisen jälkeen otetusta röntgenkuvasta.
- Potilaille, joille on asennettu **Essure**-mikroistute, voidaan myöhemmin tarjota kohdunsisäistä hoitoa, jossa käytetään sähköenergiaa. Suosittelemme elektrokauterisaation välttämistä kohdunsarven ja munanjohtimien kirurgisissa toimenpiteissä. Kaikissa muissa lantion alueen toimenpiteissä tulee välttää elektrokauterisaatiota 4 cm:ä lähempänä mikroistutetta. **Essure**-mikroistutteiden vuoksi näihin toimenpiteisiin voi liittyä tällä hetkellä tuntemattomia riskejä.
- Mikä tahansa kohdunsisäinen toimenpide, kuten endometriumbiopsia, laajennus, kaavinta, hysteroskopia (diagnostinen tai operatiivinen) tai endometriumablaatio, voi häiritä mikroistutteiden ehkäisykykyä. **Essure**-mikroistutteiden vuoksi näihin toimenpiteisiin voi liittyä tällä hetkellä tuntemattomia riskejä.
- Simulointitestit ja kliiniset kokeet ovat osoittaneet, että kohdun endometrinen ablaatio voidaan suorittaa turvallisesti ja tehokkaasti GYNECARE THERMACHOICE* -kohdunsisäisen pallojärjestelmän, Hologic NovaSure** -endometriumablaatiojärjestelmän ja Boston Scientific Hydro ThermAblator** -järjestelmän avulla **välittömästi Essure**-mikroistutteen asettamisen jälkeen. **Essure**-mikroistutteen irtautumistiheyden tai ehkäisyn tehokkuuden arvioimiseksi ei ole tehty erityisiä tutkimuksia samanaikaisten **Essure**- ja endometriumablaatiotoimenpiteiden suorittamisen jälkeen.
- Potilaat voivat halutessaan käyttää myöhemmin keinohedelmöitystä. **Essure**-mikroistutteiden vaikutusta keinohedelmöityksen onnistumiselle ei tunneta. Jos potilas tulee raskaaksi, mikroistutteen aiheuttamia riskejä potilaalle, sikiölle ja raskauden jatkumiselle ei tunneta.

* ETHICON. INC:n tavaramerkki.
** Hologic Inc:n tavaramerkki
*** Boston Scientific Corporationin tavaramerkki

VI. Varotoimet

- Mikäli mahdollista, mikroistutteet tulee sijoittaa kuukautiskierron 7.-14. päivän aikana (kierron 1. päivä on kuukautisvuodon ensimmäinen päivä), jolloin munanjohtimen aukot ovat parhaiten näkyvissä ja mikroistutteen asettaminen potilaalle, jonka raskaus on jäänyt diagnosoimatta, on epätodennäköisempää.
- Kohdun epätavallinen anatomia voi vaikeuttaa **Essure**-mikroistutteiden asettamista.
- Kohdun perforaatioriskin vähentämiseksi toimenpide tulee keskeyttää, jos kohdunkaulan laajentuminen vaatii liiallista voimaa.
- Molemmat munanjohtimien aukot tulee tunnistaa ja arvioida hysteroskooppisesti ennen **Essure**-mikroistutteiden asettamista. Mikroistutetta ei tule sijoittaa munanjohtimen aukkoon, ellei toiseen munanjohtimeen sisäänpääsyä ja sen avoimuutta ole tarkistettu.
- Endometrisen ablaation suorittaminen välittömästi **Essure**-mikroistutteiden asettamisen jälkeen voi lisätä ablaationjälkeisen munajohtimiin liittyvän steriloitumisen oireyhtymän riskiä, jota on harvinaisena tilana raportoitu naisilla, joilla tiedetään esiintyneen munajohtimiin liittyvää steriloitumista ja joille suoritetaan endometriumablaatio.
- **Essure**-järjestelmää ei saa työntää eteenpäin, jos potilaalla on kovia kipuja tai epämiellyttäviä tuntemuksia.
- **Essure**-järjestelmä on säilytettävä viileässä ja kuivassa tilassa.

VII. Mahdolliset haittavaikutukset

A. Raskaus

On olemassa raskauden ja kohdun ulkopuolisen raskauden riski sekä niiden hoitoon liittyvät riskit. Jos potilas tulee raskaaksi ja päättää jatkaa kohdunsisäistä raskautta, hänelle tulee kertoa, että mikroistutteen aiheuttamia riskejä potilaalle, sikiölle ja raskauden jatkumiselle ei tunneta.

B. Mikroistutteen asennustoimenpiteeseen liittyvät riskit

- Paikallispuudutus, suun kautta annettu kipulääkitys/sedaatio, aluepuudutus (selkäydin- tai epiduraalipuudutus), suun kautta annettu tai suonensisäinen sedaatio (potilaan ollessa tajuissaan) tai yleisanestesia voidaan suorittaa potilaalle epämiellyttävien tuntemusten estämiseksi tai vähentämiseksi. Anestesian laadusta riippumatta potilaat eivät ehkä pysty palaamaan normaalitoimiin 12-24 tunnin kuluessa toimenpiteen jälkeen.
- Mikroistutteen asennustoimenpiteen aikana tai sen jälkeen voi esiintyä kipua, kouristuksia ja emätinvuotoa. Nämä ovat yleensä siedettäviä, tilapäisiä ja lääkityksellä hoidettavia.
- Mikroistutteen asettamistoimenpiteen aikana tai heti sen jälkeen potilaalla voi esiintyä pahoinvointia tai oksennuksia. Tämä on tilapäistä ja helposti hoidettavissa lääkityksellä.
- Potilaat voivat pyörtyä tai kokea vasovagaalisen kollapsin toimenpidepäivänä.
- On olemassa munanjohtimen tai kohdunsarven perforaation tai dissektion riski. Perforaatiosta tai dissektiosta voi aiheutua verenvuotoa tai arpeutumista, mutta ne eivät yleensä vaadi hoitoa.
- Kohtu voi perforoitua hysteroskoopilla, **Essure**-järjestelmällä tai muilla toimenpiteessä käytetyillä instrumenteilla, ja perforaatio voi vaurioittaa sisäelimiä, virtsarakkoa tai suuria verisuonia. Tällaisten vaurioiden korjaaminen voi vaatia kirurgista hoitoa, mutta se on epätodennäköistä. Kohdun perforaatioriskin vähentämiseksi toimenpide tulee keskeyttää, jos kohdunkaulan laajentaminen vaatii liiallista voimaa.
- **Essure**-mikroistutteet voidaan sijoittaa vahingossa kohdun lihaskerrokseen, eikä munanjohtimen aukkoon. Jos toinen mikroistute on sijoitettu asianmukaisesti munanjohtimeen, lääkäri voi kohdun lihaskerrokseen tahattomasti asennetun istutteen lisäksi koettaa kolmannen mikroistutteen asettamista. Jos istutteita ei voida asentaa kummallekin puolelle, potilaalla voi olla yksi mikroistute munanjohtimessa ja toinen kohdun lihaskerroksessa. Tämä ei ole tyydyttävä ehkäisymenetelmä. Mikroistutteen sijoittaminen kohdun lihaskerrokseen voi aiheuttaa leikkauksen jälkeistä kipua tai muita haittavaikutuksia. Jos mikroistute on poistettava kirurgisesti, salpingektomia tai hysterektomia voi olla tarpeen.
- **Essure**-mikroistutteet voidaan sijoittaa tahattomasti liian distaalisesti munanjohtimeen. Jos mikroistute on poistettava, voidaan tarvita kirurgista toimenpidettä (laparoskopiaa tai laparotomiaa).
- **Essure**-mikroistutteet voidaan sijoittaa vahingossa liian proksimaalisesti munanjohtimeen. Jos **Essure**-mikroistutteesta näkyy vähintään 18 kierrettä asennushetkellä, se on yritettävä poistaa välittömästi (katso kohtaa XIII, **Essure**-mikroistutteen poisto). Jos mikroistute yritetään poistaa, poistaminen voi epäonnistua tai **Essure**-mikroistute voi särkyä, jolloin mikroistutteesta jää osa *in vivo*. Jos mikroistute koetetaan poistaa tai poistetaan, potilaalla voi esiintyä voimakkaampia kipuja, kouristuksia ja verenvuotoa **Essure**-istutteen asennustoimenpiteen aikana tai sen jälkeen.
- **Essure**-mikroistute voi puhkaista munanjohtimen seinämän tai kohdunsarven, mistä voi seurata mikroistutteen siirtyminen vatsaonteloon. Seurauksena voi olla leikkauksen jälkeistä kipua, kuukautishäiriöitä tai muita haittavaikutuksia. Jos potilas valitsee leikkaussterilisaation tai muita kirurgisia toimenpiteitä, mikroistute voidaan yrittää poistaa vatsaontelosta, jos lääkäri uskoo poistotoimenpiteen olevan turvallisen. Mikroistutetta ei kuitenkaan voida poistaa, jos mikroistute ei ole näkyvissä tai lääkäri ei pääse siihen käsiksi.
- **Essure**-mikroistute voidaan ehkä sijoittaa vain toiseen munanjohtimeen. Tässä tapauksessa potilaalla on vain yksi mikroistute *in vivo*, eikä se ole luotettava, pysyvä ehkäisymenetelmä.
- **Essure**-mikroistutetta ei ehkä voida sijoittaa kumpaankaan munanjohtimeen.
- On olemassa erittäin pieni riski, että hysteroskopiatoimenpiteessä kohdun laajentamiseen käytettyä fysiologista keittosuolaliuosta absorboituu elimistöön liikaa.
- Kuten kaikista invasiivista toimenpiteistä, mikroistutteen asennustoimenpiteestä voi aiheutua infektio. Infektio voi vahingoittaa kohtua, munanjohtimia tai lantio-onteloa. Se voi vaatia antibioottihoitoa ja harvoissa tapauksissa sairaalahoitoa tai leikkausta, mukaan lukien hysterektomian.

C. Essure-mikroistutteen käyttöön liittyviä riskejä

- **Essure**-mikroistutteet voivat siirtyä pois munanjohtimista. Tämä siirtyminen voi olla poistuminen (siirtyminen pois munanjohtimesta kohtuonteloon, kohdunkaulaan, emättimeen tai ulos kehosta) tai liikkuminen (siirtyminen distaaliseen munanjohtimeen tai pois munanjohtimesta vatsaonteloon). Mikroistutteiden sijaintikohdan tunnistaminen voi vaatia lisää röntgenkuvia ja niiden poistaminen voi vaatia leikkauksen. Mikroistutteen siirtyminen voi aiheuttaa raskauden, kohdun ulkopuolisen raskauden tai kipua, kuukautishäiriöitä tai muita haittavaikutuksia.
- Kuten muidenkin saatavilla olevien mekaanisten, pysyvien ehkäisyvälineiden (klipsien, renkaiden) poistaminen, **Essure**-mikroistutteen poistaminen vaatii leikkausta. Munanjohtimet ja kohtu voidaan joutua poistamaan kirurgisesti (salpingektomia tai hysterektomia).
- Vatsa- tai lantiokipuja ja kouristuksia voi esiintyä. Kipujen ja kouristusten esiintyminen on todennäköisempää kuukautisten yhteydessä, yhdynnän aikana tai sen jälkeen tai muun liikunnan aikana.
- Välivuotoa tai normaalia runsaampia kuukautisia voi myös esiintyä.
- Potilas voi joskus katua päätöstään hankkia pysyvän raskauden ehkäisymenetelmän ja tämän vuoksi kokea lievää masennusta tai muita mielialahäiriöitä.

D. Seurantatoimenpiteisiin liittyvät riskit

- Mikroistutteen sijainti varmistetaan kolme kuukautta istutteen asettamisen jälkeen otetusta lantion röntgenkuvasta, mihin sisältyy säteilyvaara. **Essure**-vahvistustestiä (HSG) voidaan myös tarvita. Hysterosalpingografiatoimenpiteen fluoroskopiaosassa (kesto <30 sekuntia) käytetään noin 0,033 radia. Vertailukohteena voidaan käyttää paksusuolen varjoainetutkimusta, jossa säteilyaltistuma on **Essure**-vahvistustestiä (HSG) korkeampi eli 0,85 radia. Säteilyaltistuman määrä yhdessä lantion röntgenkuvassa on lähes sama kuin mitä potilas saa vuoden aikana luonnollisesta taustasäteilystä.
- Mahdollisesti tarvittavaan **Essure**-vahvistustestiin (HSG) liittyy mm. seuraavat riskit: vasovagaalinen reaktio; infektio, joka voi vaatia antibioottihoitoa ja harvoissa tapauksissa sairaalahoitoa; verisuonen sisälle joutuminen; kohdun perforaatio; kohdun supistelu tai verenvuoto; kipu ja arkuus ja allerginen reaktio lateksille. Lateksille altistumiseen on ilmoitettu liittyvän harvoissa tapauksissa anafylaktisia reaktioita, jotka voivat johtaa kuolemaan.
- **Essure-**vahvistustestissä (HSG) käytettyyn varjoaineeseen on todettu liittyvän allergisia reaktioita joillakin potilailla. Allergiset reaktiot voivat aiheuttaa nokkosihottumaa ja hengitysvaikeuksia. Joillakin yksilöillä voi esiintyä anafylaktisia reaktioita, jotka voivat johtaa kuolemaan.

E. Myöhempiin toimenpiteisiin mahdollisesti liittyvät riskit

- Potilaille, joille on asennettu **Essure**-mikroistute, voidaan myöhemmin tarjota kohdunsisäistä hoitoa, jossa käytetään sähköenergiaa. Suosittelemme elektrokauterisaation välttämistä kohdunsarven ja munanjohtimien kirurgisissa toimenpiteissä. Kaikissa muissa lantion alueen toimenpiteissä tulee välttää elektrokauterisaatiota 4 cm:ä lähempänä mikroistutetta. **Essure**-mikroistutteiden vuoksi näihin toimenpiteisiin voi liittyä tällä hetkellä tuntemattomia riskejä.
- Mikä tahansa kohdun sisäinen toimenpide, kuten endometriumbiopsia, laajennus, kaavinta, hysteroskopia (diagnostinen tai operatiivinen) tai endometriumin ablaatio, voi häiritä mikroistutteiden ehkäisykykyä. **Essure**-mikroistutteiden vuoksi näihin toimenpiteisiin voi liittyä tällä hetkellä tuntemattomia riskejä.
- Potilaat voivat halutessaan käyttää myöhemmin keinohedelmöitystä. **Essure**-mikroistutteiden vaikutusta keinohedelmöityksen onnistumiselle ei tunneta. Jos potilas tulee raskaaksi, mikroistutteen aiheuttamia riskejä potilaalle, sikiölle ja raskauden jatkumiselle ei tunneta.
- **Essure**-mikroistutteet ovat turvallisia magneettikuvauksissa ja röntgenpositiivisia. **Essure**-mikroistutteet eivät häiritse magneettikuvausta lukuun ottamatta lantiokuvauksia, joissa ne voivat aiheuttaa artefakteja.
- **Tuntemattomia riskejä voi myös esiintyä.**

VIII. Käyttöohjeet

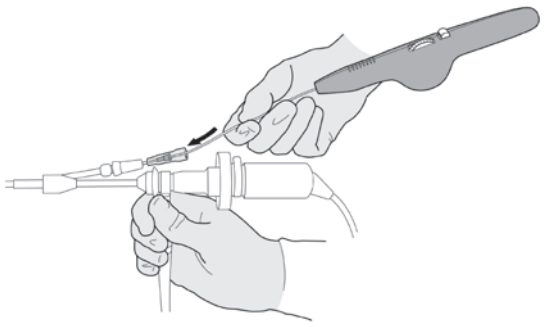
A. Ennen mikroistutteen asennustoimenpidettä

1. Mikroistutteet tulee asentaa kuukautiskierron 7.-14. päivänä (kierron 1. päivä on kuukautisvuodon ensimmäinen päivä), jolloin munanjohtimien aukot ovat paremmin näkyvissä ja mikroistutteen asettaminen potilaalle, jonka raskaus on jäänyt diagnosoimatta, on epätodennäköisempää.
2. Lääkärin tai muun hoitohenkilön tulee suorittaa raskaustesti 24 tunnin sisällä tai välittömästi ennen mikroistutteen asennustoimenpidettä.
3. On erittäin suositeltavaa antaa steroideihin kuulumatonta tulehduskipulääkettä, kuten Indocidia (suun kautta tai peräpuikkona), 1-2 tuntia ennen mikroistutteen asennustoimenpidettä, koska kliinisten tutkimusten tulokset ovat osoittaneet, että steroideihin kuulumattomien tulehduskipulääkkeiden käyttö parantaa merkittävästi asettamisen onnistumistodennäköisyyttä. Jos käytetään pelkästään paraservikaalipuudutusta, voidaan antaa diatsepaamia tai vastaavaa valmistetta suun kautta 30 minuuttia ennen toimenpidettä sedatiivina.

B. Essure-mikroistutteen asennus

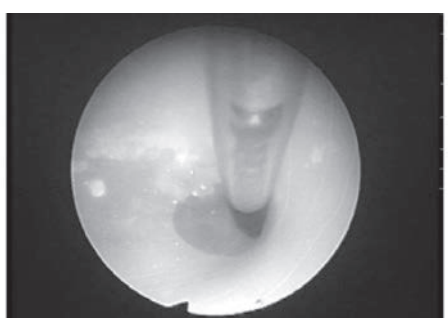
Essure-mikroistutteen asennustoimenpide voidaan suorittaa polikliinisesti tai päiväkirurgisena toimenpiteenä. Steriiliä menetelmää on käytettävä mikroistutteen asennustoimenpiteen aikana. Mikroistutteen asennustoimenpiteen ei tulee kestää yli 30 minuuttia.

1. Aseta potilas litotomia-asentoon.
2. Aseta tähystin emättimeen kohdunkaulan avaamiseksi. Valmistele kohdunkaula betadiinilla tai muulla antibakteerisella liuoksella vakiokäytännön mukaisesti.
3. Paikallispuudutus on suositeltava menetelmä mikroistutteiden asennustoimenpiteissä. Paraservikaalipuudutusta voidaan myös käyttää. Midatsolaamia (laskimonsisäisesti) tai muuta vastaavaa lääkitystä voidaan käyttää tarvittaessa potilaan epämukavuuden vähentämiseksi tai poistamiseksi.
4. Aseta steriili hysteroskooppi, johon on kiinnitetty kamera ja työskentelykanava (≥ 5 F), kohdunkaulan kautta kohtuonteloon. Suorita tarvittaessa kohdunkaulan laajennus. Kohdun perforaatioriskin minimoimiseksi toimenpide tulee keskeyttää, jos kohdunkaulan laajentaminen vaatii liiallista voimaa.
5. Kohtu on laajennettava fysiologisella keittosuolaliuoksella hysteroskoopin työskentelykanavan kautta. Suosittelemme, että keittosuolaliuos lämmitetään ruumiin lämpötilaan ja siirretään kohtuun painovoimalla munanjohtimien kouristelun minimoimiseksi. Kohtu on pidettävä hyvin laajennettuna koko toimenpiteen ajan. Toimenpiteen aikana on käytettävä vakiomenetelmiä nestemäärien seurantaan. Munanjohtimien ot aukot tulee tunnistaa hysteroskoopin kautta.
6. Molemmat munanjohtimien aukot tulee tunnistaa ja arvioida hysteroskooppisesti ennen **Essure**-mikroistutteiden asettamista. Mikroistutetta ei tule sijoittaa munanjohtimen aukkoon, ellei toisen munanjohtimen avoimuudesta ole kohtalaista varmuutta.
7. Kun munanjohtimen aukko on tunnistettu, työnnä sisäänvientiväline hysteroskoopin työskentelykanavan suojakannen läpi. Työskentelykanavan hanan on pysyttävä auki-asennossa (väline ja/tai sisäänvientikatetri voi vahingoittua, jos hana pääsee sulkemaan jommankumman). Vie **Essure**-sisäänvientikatetri asennusvälineen läpi ja työnnä se hysteroskoopin työskentelykanavan läpi. Jos venttiilillinen sisäänvientiväline on vahingoittumaton ensimmäisen mikroistutteen sisäänviennin jälkeen, se voi jäädä työskentelykanavaan koko **Essure**-toimenpiteen ajan.



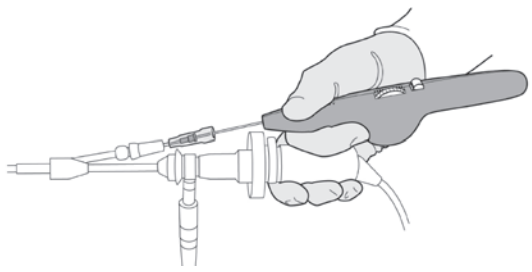
*Vie sisäänviejä hysteroskoopin työskentelykanavan suojakannen läpi ja vie sen jälkeen **Essure**-asennusjärjestelmä sisäänviejän läpi.*

8. Työnnä **Essure**-sisäänvientijärjestelmä proksimaaliseen munanjohtimeen hitaasti ja tasaisesti munanjohtimien lihaskouristusten välttämiseksi. Työnnä sisäänvientijärjestelmää, kunnes katetrin asennusmerkki saavuttaa munanjohtimen aukon. Tämä visuaalinen merkintä osoittaa, että **Essure**-mikroistute ulottuu kohdunseinämästä munanjohtimen proksimaaliseen solaan ja ulkokierukka ulottuu kohdun ja munanjohtimen yhdyskohtaan. Tämä on **Essure**-mikroistutteen paras sijoituskohta.



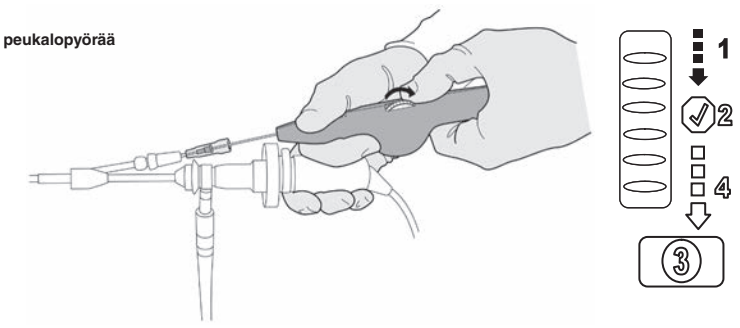
Työnnä eteenpäin, kunnes musta asennusmerkki on munanjohtimen aukon kohdalla. Tämä on näkyvä merkki, joka osoittaa oikean sijaintikohdan.

9. Asennuskatetrin samankeskisyys munanjohtimen aukon kanssa on saavutettu, jos katetria voidaan siirtää eteenpäin suorassa näkötarkkailussa ilman ylimääräistä vastusta. Vastus tuntuu katetria siirrettäessä kahdella tavalla: 1) katetrin ulkopinnan musta merkki ei siirry eteenpäin munanjohtimen aukkoa kohti ja/tai 2) asennuskatetri taipuu tai vääntyy liikaa ja estää siten lääkäriä työntämästä katetrijärjestelmää eteenpäin. Kun tällaista vastusta tuntuu katetria eteenpäin työnnettäessä, mikroistutetta ei saa yrittää sijoittaa, koska seurauksena voi olla kohdun perforaatio tai mikroistutteen tahaton sijoittuminen kohtulihakseen munanjohtimen sijasta. **Essure**-vahvistustesti (HSG) tulee suorittaa toimenpiteen jälkeen munanjohtimen avoimuuden tarkistamiseksi.
10. Jos katetria ei saada työnnettyä eteenpäin asennusmerkkiin saakka usean minuutin yrittämisen jälkeen, voidaan suorittaa perfuusiotesti avoimuuskatetrilla munanjohtimien avoimuuden selvittämiseksi, jos testiä ei ole vielä suoritettu. Jos munanjohdin on tukossa tai katetria ei voida siirtää eteenpäin asennusmerkkiin saakka, toimenpide tulee keskeyttää. Jos mikroistutteen asettaminen ei onnistu 10 minuutin kuluessa johdinta kohti kanylointiyrityksen alusta lähtien, toimenpide on lopetettava.
11. Kun asennuskatetri on työnnetty asennusmerkkiin saakka, mikroistute vapautetaan. Se tapahtuu vakauttamalla ensin **Essure**-mikroistutteen kahva hysteroskoopin kameraa tai muuta kiinteää esinettä vasten **Essure**-järjestelmän tahattoman eteenpäin siirtymisen estämiseksi asennuskatetrin takaisin vetämisen aikana.



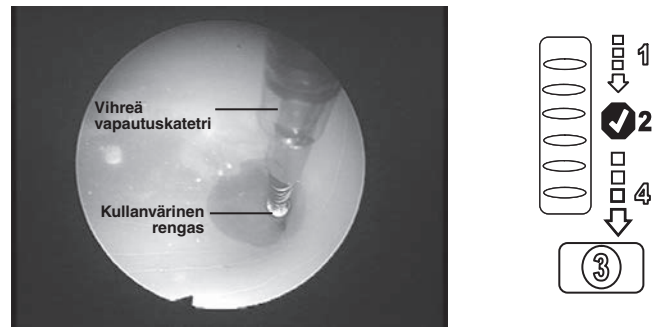
*Tue kahva kamerapäätä tai muuta kiinteää esinettä vasten **Essure**-järjestelmän tahattoman eteenpäin liikkumisen estämiseksi*

12. Kun olet varma, että musta asennusmerkki on munanjohtimen aukossa, kierrä kahvan peukalopyörää itseäsi kohti, kunnes pyörä ei enää kierry. Tämä liike vastaa merkkiä ⇩1 asennusjärjestelmän kahvassa ja helpottaa asennuskatetrin pois vetämistä. Näet mustan asennusmerkin siirtyvän pois munanjohtimen aukosta (hysteroskooppia kohti) ja häviävän työskentelykanavaan. Asennuskatetrin siirtyminen taaksepäin tuo esiin kokoon kiertyneen **Essure**-mikroistutteen. Noin 1 cm mikroistutteesta (kokoon kiertyneet kierteet) tulee näkyä kohdussa, kun asennuskatetri vedetään pois.



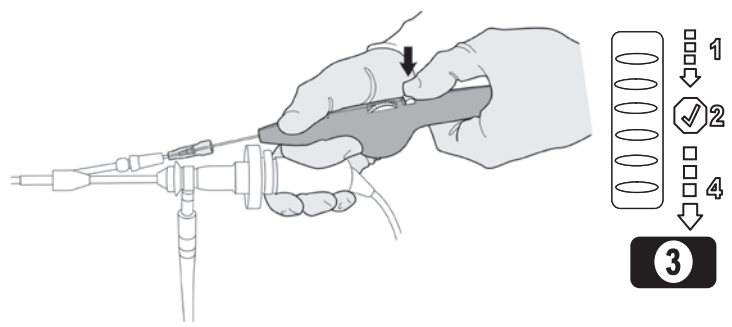
Kierrä peukalopyörää katetrin takaisin vetämiseksi

13. Asianmukaisen sijainnin varmistamiseksi sijoita kullanvärinen rengas välittömästi aukon ulkopuolelle, mikä vastaa sisäänvientijärjestelmän kahvassa olevaa merkkiä ✓2. Tarkista näönvaraisesti sekä kullanvärisen renkaan sijainti välittömästi aukon ulkopuolella että vihreän vapautuskatetrin distaalikärjen sijainti. Mikäli yli 1 cm mikroistutetta on näkyvissä kohdun sisällä, mikroistute tulee asentaa uudelleen siirtämällä koko järjestelmä mikäli mahdollista kauemmaksi munanjohtimeen ennen seuraavaa vaihetta.



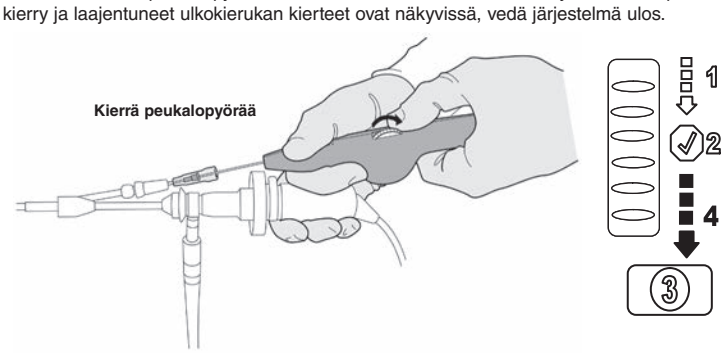
Tarkista näönvaraisesti kullanvärisen renkaan sijainti aukon kohdalla.

14. Paina asennuskahvan painiketta, jolloin voit kiertää peukalopyörää edelleen siten, että se on kohdakkain asennuskahvan painikkeessa olevan merkin ③ kanssa



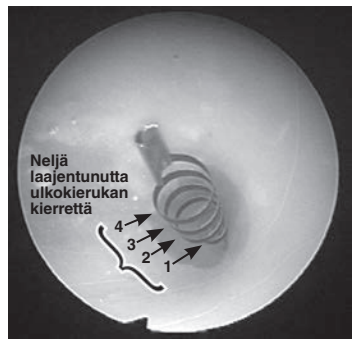
Paina painiketta, jotta peukalopyörää voidaan kiertää uudelleen

15. Kierrä peukalopyörää itseesi päin, jolloin mikroistutteen asennuskahvan merkkiä ⇩4 vastaava ulkokierukka irtoaa. Jatka peukalopyörän kiertämistä, kunnes se lakkaa kiertymästä. Kun peukalopyörä ei enää kierry ja laajentuneet ulkokierukan kierteet ovat näkyvissä, vedä järjestelmä ulos.



Kierrä peukalopyörää mikroistutteen ulkokierukan vapauttamiseksi.

16. Asennetun **Essure**-mikroistutteen asento tarkistetaan hysteroskoopilla. Parhaassa tapauksessa 3-8 laajentunutta **Essure**-mikroistutteen ulkokierukan kierrettä ulottuu kohtuun.



Essure-*mikroistutteen laajentuneet, kohtuun ulottuvan ulkokierukan kierteet ilmaisevat, että sijoituskohta on paras mahdollinen*

17. Jos lääkäri ei ole tyytyväinen mikroistutteen sijaintiin hysteroskooppikuvan perusteella tai jos hän epäilee munanjohtimen tai kohdun perforaatiota, mikroistutteet tulee jättää paikalleen ja tilanne tulee tarkistaa lantion alueen röntgenkuvasta tai **Essure**-vahvistustestillä (HSG) kolmen kuukauden kuluttua.

    VAROITUS: KUN MIKROISTUTE ON SIJOITETTU PAIKOILLEEN JA VAPAUTETTU MUNANJOHTIMESSA, SEN POISTAMISTA EI TULE YRITTÄÄ HYSTEROSKOOPPISESTI, ELLEI VÄHINTÄÄN 18 ESSURE-MIKROISTUTTEEN KIERUKAN KIERRETTÄ ULOTU KOHTUONTELOON. Mikroistutteen poistaminen tulee suorittaa heti sijoitustoimenpiteen aikana. Poistaminen voi kuitenkin olla mahdotonta (katso kohtaa XIII, **Essure**-mikroistutteen poisto). Jos mikroistute avautui vahingossa kohtuontelossa eikä munanjohtimessa, se tulee poistaa kohdusta ja on yritettävä sijoittaa uusi mikroistute munanjohtimeen.
18. Toista **Essure**-mikroistutteen asennustoimenpide vastakkaisen puolen munanjohtimeen.
19. Kirjaa kohtuun ulottuvan mikroistutteen pituus ja muut kummankin munanjohtimien aukon tunnistukseen tai vahvistukseen liittyvät seikat sekä mahdolliseen perforaatioon liittyvät ongelmat. Ne tulee kirjata sairauskertomukseen viitteeksi **Essure**-vahvistustestin tuloksen arviointia varten *(katso jäljempänä kohtaa IX, Essure-vahvistustesti).*

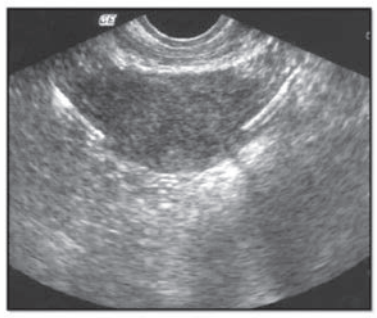
20. **Muistuta potilasta siitä, että hänen tulee käyttää muuta ehkäisymenetelmää (lukuun ottamatta kierukkaa) ensimmäisten kolmen kuukauden aikana mikroistutteen asennustoimenpiteestä.**
21. Varaa potilaalle aika **Essure**-varmistustestiin kolme kuukautta **Essure**-mikroistutteen asettamisen jälkeen mikroistutteen paikallaan pysymisen ja sijainnin arvioimiseksi.

IX. Essure-vahvistustesti

A. Essure-vahvistustesti tulee tehdä kolme kuukautta mikroistutteen asettamisen jälkeen mikroistutteen paikallaan pysymisen ja sijainnin arvioimiseksi. Vain kokenut gynekologi, ultraääniteknikko ja/tai radiologi, joka on saanut vastaavan **Essure**-vahvistustestin suorittamiseen liittyvän koulutuksen, saa tehdä **Essure**-vahvistustestin (transvaginaalinen kaikututkimus (TVU), lantion röntgenkuva tai hysterosalpingografia (HSG)). Kuvilla varustettu yksityiskohtainen toimenpideprotokolla ja testin suorittamista koskevia ohjeita annetaan koulutuksen yhteydessä. Lisää kopioita voi ladata osoitteesta essure.com.

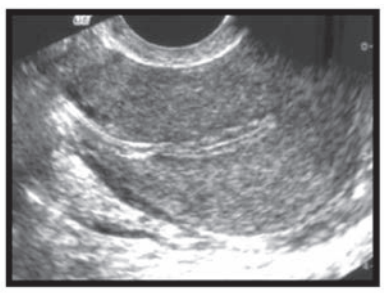
B. Ensimmäisenä vahvistustestinä voidaan tehdä joko lantion röntgenkuvaus tai transvaginaalinen kaikukuvaus kolme kuukautta mikroistutteen ongelmattoman molemminpuolisen asettamisen jälkeen.
1. Röntgenkuvausta tai transvaginaalista kaikukuvausta ei pitäisi käyttää **Essure**-vahvistustestinä seuraavissa tilanteissa:
   a) Asettamistoimenpiteen suorittamiseen liittyi yksi tai useampia seuraavista ongelmista:
      (1) Asettamisen aikana on epäilty mahdollista perforaatiota, sillä mikroistutteen asettamiseen tarvittiin liiallista voimaa tai sen aikana vastus antoi äkkiä periksi.
      (2) Asettamisen aikana oli vaikeuksia paikantaa munanjohtimen aukko anatomian poikkeavuuden tai teknisten vaikeuksien, kuten huonon laajenemisen, heikon valaistuksen tai endometriumin kudosjätteen, vuoksi.
      (3) Toimenpiteen suorittaja ei ollut varma oikeasta asetuskohdasta.
   b) Toimenpiteen kesto > 15 minuuttia (hysteroskoopin sisäänviennistä sen poistamiseen).
   c) Asetus siten, että näkyvissä on 0 kierrettä tai > 8 kierrettä
   d) Poikkeava, ohimenevä tai itsepintainen postoperatiivinen kipu, joka alkaa toimenpiteen aikana tai myöhemmin sen jälkeen ilman muuta ilmeistä syytä.
2. Jos röntgen- tai kaikukuvaus ei ole aiheellinen, potilaalle on tehtävä hysterosalpingografia mikroistutteen paikantamiseksi ja munanjohtimen okkluusion arvioimiseksi. Transabdominaalinen kaikukuvaus ei korvaa transvaginaalista kaikukuvausta. Jos röntgen- tai kaikukuvauksen tulos on epävarma, potilaalle on tehtävä hysterosalpingografia mikroistutteen paikantamiseksi ja munanjohtimen okkluusion arvioimiseksi.

C. Transvaginaalinen kaikukuvaus
1. On otettava vähintään kolme kuvaa, jotka tallennetaan.
   a) Koronaalinen tai koronaalinen viistonäkymä, jossa kohdunsarvissa näkyy osa kutakin mikroistutetta. Tämä kuva tallennetaan nimellä ”pilottikuva”.



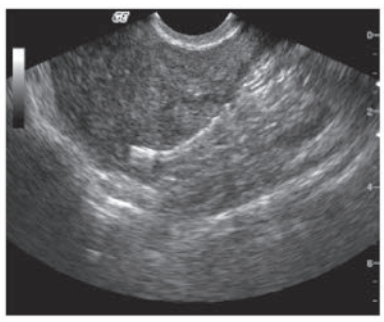
Molempien puolien mikroistutteet näkyvät tässä poikittaiskuvassa (koronaalinen / koronaalinen viistonäkymä).

   b) Koronaalinen tai koronaalinen viistokuva vasemmanpuolisen mikroistutteen aksiaalisuunnassa mukaan lukien sen proksimaalipää, joka kulkee myometriumin poikki kohdunsarvessa (munanjohtimen interstitiaalinen osa) tai kontaktissa kohdun limakalvon ja munanjohtimen liittymäkohdassa, merkittynä ”vasen”.
   c) Koronaalinen tai koronaalinen viistokuva oikeanpuolisen mikroistutteen aksiaalisuunnassa mukaan lukien sen proksimaalipää, joka kulkee myometriumin poikki kohdunsarvessa (munanjohtimen interstitiaalinen osa) tai kontaktissa kohdun limakalvon ja munanjohtimen liittymäkohdassa, merkittynä ”oikea”.
   d) Kaikki kolme näkymää pitää tallentaa filmille ja tallentaa potilaan sairauskertomukseen mikroistutteen asianmukaisen sijainnin ja säilymisen dokumentoimiseksi.
2. Mikroistutteen sijainnin luokitus
   a) Mikroistutteen sijainnin tunnistaminen: Jokaisessa pilottikuvassa on oltava näkyvissä mikroistutteen osa kohdunsarvissa koronaalisessa tai koronaalisessa viistokuvassa, jotta varmistetaan, että istutteet on asennettu molemmille puolille ja että samaa mikroistutetta ei kuvanneta uudestaan. Mikroistutteiden pituusakseleiden pitäisi näyttää suhteellisen symmetrisiltä.
   b) Optimaalinen sijainti
   Mikroistutteen sijainti on optimaalinen, kun sen proksimaalipää ulottuu kohtuonteloon tai endometriumiin ja sen pitkittäisakseli sijaitsee kohdunsarvessa (munanjohtimen interstitiaalisessa osassa) ja voidaan nähdä kohdun limakalvon ja munanjohtimen yhtymäkohdassa tai ulottuvan sen poikki. Munanjohtimessa sijaitseva mikroistutteen osa voi näkyä tai olla näkymätön. Mikroistutteen pituusakselin pitää näkyä, jotta varmistetaan, että se ei ole kiertynyt tai pidentynyt.



Optimaalinen sijainti

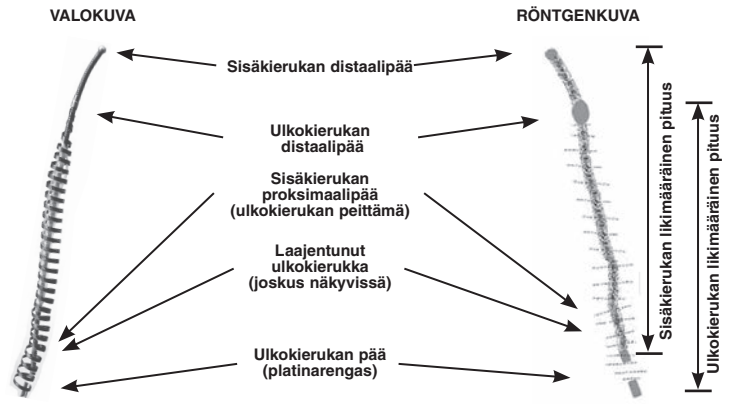
   c) Tyydyttävä sijainti
   Mikroistutteen sijainti on tyydyttävä, kun sen proksimaalipää sijaitsee endometriumiin distaalipuolella, mutta sen pitkittäisakselin pitää kuitenkin sijaita kohdunsarvessa (munanjohtimen interstitiaalisessa osassa) ja pitkittäisakseli voidaan nähdä kohdun limakalvon ja munanjohtimen yhtymäkohdassa tai ulottuvan sen poikki. Munanjohtimessa sijaitseva mikroistutteen osa voi näkyä tai olla näkymätön. Mikroistutteen pituusakselin pitää näkyä, jotta varmistetaan, että se ei ole kiertynyt tai pidentynyt.



Tyydyttävä sijainti

   d) Epätyydyttävä sijainti
      (1) Mikroistutteen sijainti on epätyydyttävä, jos kummankaan mikroistutteen osaa ei näy kohdunsarvissa koronaalisessa tai koronaalisessa viistonäkymässä yhdessäkin pilottikuvassa.
      (2) Ulostyöntymistä on syytä epäillä, jos yhtä tai kumpaakaan mikroistutetta ei näy kohdunsarvessa koronaalinäkymässä yhdessä pilottikuvassa.
      (3) Distaalista sijaintia on syytä epäillä silloin, jos mikroistutteen proksimaalipää ei sijaitse kohdunsarvien myometriumissa (munanjohtimen interstitiaalisessa osassa) eikä näy kohdun limakalvon ja munanjohtimen yhtymäkohdassa tai näy ulottuvan sen poikki.
      (4) Proksimaalista sijaintia voi epäillä, jos enemmän kuin 50 % eli suurin osa mikroistutteesta näkyy kohtuontelossa tai jos mikroistutteen tai -istutteiden pituusakseli näkyy keskiviivan sagittaalinäkymässä.
      (5) Perforaatiota on syytä epäillä, jos yhden tai kummankin mikroistutteen pituusakseli on yhdensuuntainen endometriumin reunan kanssa sagittaalinäkymässä tai jos mikroistutteen pituusakseli näkyy ulottuvan myometriumin poikki keskiviivan sagittaalinäkymässä.
      (6) Luokittelematon sijainti: Jos mikroistutteen pitkittäisakselia ei voi määrittää, minkä syynä voi olla, että se on kiertynyt, taipunut tai venynyt, mikroistutteen sijaintia on pidettävä epätyydyttävänä. Jos ympäröivää pehmytkudosta ei voida tarkasti määrittää, sijaintia on pidettävä epätyydyttävänä.
3. Jos mikroistutteen sijainti kaikukuvauksen perusteella on epävarma tai epätyydyttävä, potilaalle on tehtävä hysterosalpingografia mikroistutteen paikantamiseksi ja munanjohtimen okkluusion arvioimiseksi.

D. Lantion röntgenkuvaus
1. Ota röntgenkuva kohdusta, jossa molemmat **Essure**-mikroistutteet näkyvät selvästi. Mikroistutteiden sijainti ja käyryys huomioidaan.

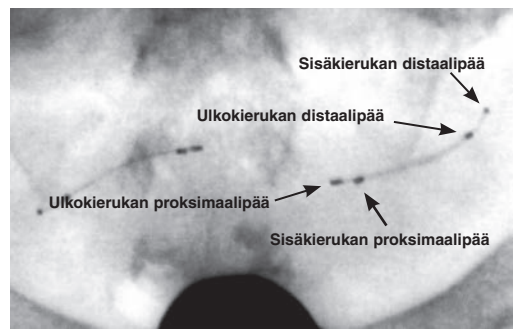


***Essure**-mikroistute ja sitä vastaava röntgenkuva*

2. Lantion alueen röntgenkuva tulkitaan seuraavasti:
   a) Tyydyttävä: Mikroistutteet näyttävät sijaitsevan munanjohdinten luumeneissa ja ulottuvat kohdun ja munanjohtimen yhtymäkohtaan. Istutteet näyttävät suhteellisen symmetrisiltä. Potilaat, joiden röntgenkuva tulkitaan ”tyydyttäväksi”, voivat ehkä luottaa **Essure**-mikroistutteeseen ehkäisyvälineenä.
   b) Epäilyttävä: Yksi tai kumpikin mikroistute näyttää olevan parhaan mahdollisen sijainnin distaali- tai proksimaalipuolella ja on saattanut puhkaista munanjohtimen osittain tai täysin tai näyttää suhteellisen epäsymmetriseltä. Potilaita, joiden röntgenkuvat arvioidaan ”epäilyttäviksi”, tulee neuvoa jatkamaan muiden ehkäisymenetelmien käyttöä ja käymään hysterosalpingografiassa.
   c) Epätyydyttävä: Mikroistutteet sijaitsevat selvästi vatsaontelossa tai ovat työntyneet pois.
3. Jos röntgenkuvauksen tulos on epävarma tai epätyydyttävä, potilaalle on tehtävä hysterosalpingografia mikroistutteen paikantamiseksi ja munanjohtimen okkluusion arvioimiseksi.

E. Modifioidun hysterosalpingografian suorittaminen ja tulkinta
1. Hysterosalpingografia suoritetaan **Essure**-mikroistutteen sijainnin ja munanjohtimen sulkeutumisen määrittämiseksi tarvittaessa röntgenkuvan tai kaikukuvauksen löydösten perusteella. Noudata jäljempänä esitettyjä hysterosalpingografian suorittamista ja tulkintaa koskevia ohjeita.
2. Hysterosalpingografian suorittamista koskevat ohjeet:
   a) Kohdun profiilin tulee näkyä selvästi ja kohdunsarvien tulee täyttyä kunnolla.
   b) Fluoroskopiasäteen tulee olla mahdollisimman lähellä etu-/takaprojektiota kohtuun nähden.
   c) Älä laajenna kohdunsuuta, ellei se ole välttämätöntä. Jos se laajenee, se on pidettävä tiiviisti suljettuna.
   d) Kohtua voidaan vetää alaspäin kohtupihdeillä, jos kohtu on keskiasennossa. Poista spekula ennen läpivalaisua, jotta kohdun anatomia näkyy selvästi.
   e) Ota vähintään kuusi kuvaa mikroistutteen sijainnin ja munanjohtimien okkluusion arvioimiseksi.
      (1) Kuva 1 – Pilottikuva - Kohtu ja mikroistutteet ilman varjoainetta.
      (2) Kuva 2 – Kohtuontelon minimaalinen täyttö - Kohtu ja mikroistutteet kuvattuna pienellä määrällä varjoainetta.
      (3) Kuva 3 – Kohtuontelon osittainen täyttö - Kohtu ja mikroistutteet kuvattuna lähes täydellä määrällä varjoainetta.
      (4) Kuva 4 – Kohtuontelon täysi täyttö - Kohtu ja mikroistutteet kuvattuna siten, että kohdunsarvet ovat varjoaineen laajentamat.
      (5) Kuvat 5 ja 6 – Kohdunsarvien suurennuskuva - Mikroistutteet sijaitsevat oikeassa (5) ja vasemmassa (6) kohdunsarvessa.

VAROITUS: Vältä liiallista kohtuontelon painetta kuvia 5 ja 6 otettaessa välttääksesi aiheuttamasta potilaalle liiallista kipua ja vasovagaalisen reaktion.



3. Mikroistutteen sijainnin tulkinta
   a) Tulkitessasi kuvaa kiinnitä huomiota neljään ”merkkiin” sisä- ja ulkokierukan molemmissa päissä. Huomaa, että distaaliset merkit ovat kiinteässä suhteessa toisiinsa, mutta että proksimaaliset merkit saattavat liikkua tai vaikuttaa venyneiltä ulomman kierukan joustavuuden vuoksi. Mikroistutteen sijainti on ihanteellinen silloin, kun sisäkierukka sijaitsee kohdun ja munanjohtimen yhtymäkohdan poikki.
   b) Mikroistutteen sijainnin tulkinta:
      (1) Ulostyöntyminen tai proksimaalinen sijainti: Mikroistutetta ei näy tai ≥ 50 % sisäkierukasta ulottuu kohtuonteloon.
      (2) Tyydyttävä sijainti: Sisäkierukan distaalipää sijaitsee munanjohtimessa ja < 50 % sisäkierukasta ulottuu kohtuonteloon tai sisäkierukan proksimaalipää sijaitsee ≤ 30 mm munanjohtimessa kohdasta, josta varjoaine täyttää kohdunsarvet.
      (3) Distaalinen sijainti tai perforaatio: Mikroistute sijaitsee munanjohtimessa mutta sisäkierukan proksimaalipää > 30 mm distaalisesti kohdasta, jossa varjoaine täyttää kohdunsarvet tai mikroistute on perforoinut munanjohtimen kokonaan tai osittain.

4. Munanjohtimen okkluusion tulkinta
   a) Määritä, onko varjoainetta näkyvissä mikroistutteen sijaintikohdan distaalipuolella ja huomioi proksimaalisen munanjohtimen mahdollinen täyttyminen munanjohtimen okkluusiosta huolimatta.
   b) Munanjohtimen okkluusion tulkinta
      (1) Tyydyttävä okkluusio: Munanjohdin on sulkeutunut kohdunsarven kohdalla.
      (2) Tyydyttävä okkluusio: Munanjohtimessa näkyy varjoainetta, mutta sitä ei näy ulomman kierukan distaalipuolella.
      (3) Epätyydyttävä okkluusio: Varjoainetta näkyy mikroistutteen distaalipään distaalipuolella tai vatsaontelossa.
5. Ehkäisyn luotettavuuden arviointi
   a) Jos sekä mikroistutteen sijainti että munanjohtimen okkluusio on tyydyttävä, potilasta voidaan neuvoa lopettamaan muiden ehkäisymenetelmien käyttö.
   b) Jos mikroistutteiden sijainti on epätyydyttävä, kehota potilasta olemaan luottamatta mikroistutteisiin ehkäisymenetelmänä.
   c) Jos mikroistutteen sijainti on tyydyttävä mutta munanjohtimen okkluusio on epätyydyttävä, kehota potilasta käyttämään muita ehkäisymenetelmiä. Toista hysterosalpingografia kolmen kuukauden kuluttua. Jos okkluusio on edelleen epätyydyttävä, kehota potilasta olemaan luottamatta mikroistutteisiin ehkäisymenetelmänä.

X. Mikroistutteen epätyydyttävän sijainnin käsittely

A. Mikroistutteen epätyydyttävän sijainnin diagnosointi hysterosalpingografian avulla

1. Proksimaalinen sijainti: yli 50 % mikroistutteen sisäkierukasta ulottuu kohtuun.
2. Distaalisijainti: Mikroistute on munanjohtimessa, mutta sisäkierukan proksimaalipää on yli 30 mm:n etäisyydellä kohdunsarvea täyttävästä varjoaineesta.
3. Mikroistutteet ovat tulleet ulos kehosta. mikroistutteet eivät näy kehon sisällä.
4. Perforaatio: mikroistute on perforoitunut osittain tai kokonaan.
5. Mikroistutteet ovat selvästi vatsaontelossa; mikroistutteet selvästi munanjohtimien ulkopuolella.

B. Mikroistutteen poistumisen tai epätyydyttävän sijainnin käsittely

1. Molemminpuolinen mikroistutteen poistuminen ja molemminpuolinen munanjohtimen sulkeutuminen: Potilaalle tulee ilmoittaa, että hänelle voidaan suorittaa leikkaussterilisaatio tai että hän voi luottaa molemminpuoliseen munanjohdinten proksimaaliseen sulkeutumiseen ehkäisymenetelmänä, koska **Essure**-vahvistustesti (HSG) voi antaa virheellisen positiivisen diagnoosin munanjohdinten sulkeutumisesta.
2. Molemminpuolinen mikroistutteen poistuminen, toisen munanjohtimen sulkeutuminen ja vastakkaisen puolen avoimuus: Potilaalle voidaan suorittaa toinen mikroistutteiden asennustoimenpide avoimeen munanjohtimeen, jotta potilas voisi luottaa yhteen **Essure**-mikroistutteeseen ja vastakkaisen puolen munanjohtimen proksimaaliseen sulkeutumiseen ehkäisymenetelmänä. Potilasta tulee informoida tästä vaihtoehdosta, koska **Essure**-vahvistustesti (HSG) voi antaa virheellisen positiivisen diagnoosin munanjohdinten sulkeutumisesta. Potilasta tulee informoida myös leikkaussterilisaation mahdollisuudesta.
3. Toisen puolen mikroistute poistunut tai toisen puolen mikroistutteen sijainti epätyydyttävä (kohdun lihaskerroksessa tai vatsaontelon sisällä) ja vastakkaisen puolen mikroistutteen sijainti on tyydyttävä: Jos **Essure**-vahvistustesti (HSG) osoittaa munanjohtimen olevan suljettu sillä puolella, josta mikroistute on poistunut tai johon mikroistute olisi pitänyt sijoittaa, potilas voinee luottaa tyydyttävästi sijoitettuun mikroistutteeseen ja vastakkaisen puolen munanjohtimen proksimaaliseen sulkeutumiseen, koska **Essure**-vahvistustesti (HSG) voi antaa virheellisen positiivisen tuloksen munanjohtimen sulkeutumisesta. Potilasta tulee informoida myös leikkaussterilisaation mahdollisuudesta.
4. Toisen puolen mikroistutteen sijainti epätyydyttävä (kohdun lihaskerroksessa tai vatsaontelon sisällä) ja vastakkaisen puolen mikroistutteen sijainti tyydyttävä: Jos **Essure**-vahvistustesti (HSG) osoittaa munanjohtimen olevan avoimen sillä puolella, johon mikroistute olisi pitänyt sijoittaa, potilaalle voidaan tarjota mahdollisuus toiseen mikroistutteen asennustoimenpiteeseen. Potilasta tulee informoida myös leikkaussterilisaation mahdollisuudesta.
5. Toisen puolen mikroistute on tullut ulos kehosta; toisen puolen mikroistutteen sijainti on epätyydyttävä (kohdun lihaskerroksessa tai vatsaontelossa); toisen puolen mikroistutteen epätyydyttävä sijainti ”proksimaalisijainnissa” (>50 % sisäkierteestä ulottuu kohtuun) tai ”distaalisijainnissa” (mikroistute on munanjohtimessa, mutta sisäkierteen proksimaalipää on >30 mm:n etäisyydellä kohdunsarven täyttävästä varjoaineesta) ja vastakkaisen puolen mikroistutteen sijainti on epätyydyttävä: Potilasta tulee informoida leikkaussterilisaation mahdollisuudesta. Kaikissa tapauksissa, joissa mikroistute on poistettava eikä hysteroskooppinen poistaminen ole mahdollista, voidaan tarvita kirurgista toimenpidettä
6. Jos potilas valitsee leikkaussterilisaation joissakin yllä mainituista tilanteista, molemmat munanjohtimet tulee tukkia, vaikka potilaalla olisikin mikroistute, jonka sijainti on tyydyttävä. Mikroistute tulee yrittää poistaa, jos lääkäri uskoo sen olevan turvallista. Mikroistutteen poistaminen ei kuitenkaan ole aina mahdollista. Mikroistutteiden sijaintikohdan tunnistamiseen ennen leikkausta ja sen aikana suositellaan toimenpiteen aikana suoritettavaa läpivalaisua. Mikroistutteen poistamiseen ei tulee käyttää yli 30 minuuttia.

XI. Essure-mikroistutteen asennustoimenpiteen epäonnistumisen käsittely

Jos toisen puolen tai molempien puolien mikroistutteiden sijoitus epäonnistuu, potilasta tulee informoida, että pysyvää ehkäisyä ei ole saavutettu. Jos potilas valitsee laparoskooppisen sterilisaation (eli klipsien tai elektrokauterin käytön), molemmat munanjohtimet tulee katkaista tai kauterisoida, vaikka munanjohtimeen olisikin asennettu **Essure**-mikroistute. Munanjohtimen katkaisu tai kauterisaatio tulee suorittaa **Essure**-mikroistutteen distaalipuolella.

Jos potilas ei valitse laparoskooppista sterilisaatiota, hänelle voidaan tarjota **Essure**-vahvistustestiä (HSG) seuraavien kuukautisten jälkeen (ennen ovulaatiota: kuukautiskierron 7.-14. päivänä [kun kierron ensimmäinen päivä on ensimmäinen vuotopäivä]) munanjohtimien avoimuuden tarkistamiseksi. Jos munanjohtimen todetaan olevan avoimen, lääkäri voi tarjota potilaalle toista mikroistutteen asennusyritystä. Jos toinen mikroistutteen asennusyritys epäonnistuu, lisätoimenpiteet eivät todennäköisesti onnistu tälle potilaalle. Jos potilaalle on jätetty yksi mikroistute *in vivo*, potilaan ei tulee luottaa toisen puolen mikroistutteeseen ehkäisymenetelmänä.

Jos mikroistute asennetaan vain toiselle puolelle ja **Essure**-vahvistustesti (HSG) vahvistaa vastakkaisen puolen munanjohtimen proksimaalisen tukkeutumisen, potilasta tulee informoida mahdollisuudesta luottaa yhteen mikroistutteeseen ottaen huomioon sen, että **Essure**-vahvistustesti (HSG) voi antaa virheellisen positiivisen diagnoosin munanjohdinten proksimaalisesta sulkeutumisesta. Munanjohtimen katsotaan olevan tukossa, kun varjoainetta ei pääse kohtuontelosta vatsaonteloon **Essure**-vahvistustestin (HSG) aikana. Potilasta tulee informoida myös leikkaussterilisaation mahdollisuudesta. Toiselle puolelle sijoitetun mikroistutteen poistamisyritystä ei suositella, ellei potilaalla esiinny haittavaikutuksia mikroistutteen johdosta.

XII. Essure-mikroistutteen poisto

VAROITUS: MIKROISTUTTEEN POISTAMISTA EI TULEE YRITTÄÄ HYSTEROSKOOPPISESTI MIKROISTUTTEEN ASETTAMISEN JÄLKEEN, ELLEI VÄHINTÄÄN 18 ESSURE-MIKROISTUTTEEN KIERUKAN KIERRETTÄ ULOTU KOHTUONTELOON. Mikroistutteen poistaminen tulee suorittaa heti sijoittamisen jälkeen. Poistaminen voi kuitenkin olla mahdotonta. Poistaminen tulee suorittaa seuraavien vaiheiden mukaisesti:

1. Vie tartuntainstrumentti sisään hysteroskoopin työskentelykanavan kautta.
2. Tartu **Essure**-mikroistutteen ulkokierteeseen. Koeta tarttua sekä mikroistutteen ulko- että sisäkierteeseen.
3. Vedä tartuntainstrumenttia ja hysteroskooppia taaksepäin samanaikaisesti siten, että koko järjestelmä tulee ulos kohdusta samanaikaisesti.
4. **Essure**-mikroistutteen ulko- ja sisäkierukka voi venyä tai pidentyä mikroistutteen poistamisyrityksen aikana.
5. Vähennä tai poista potilaan epämukavuus tarvittaessa kipulääkityksellä tai anestesialla.
6. Jos mikroistute saadaan poistettua kokonaan, lääkärin tulee yrittää asentaa toinen **Essure**-mikroistute.
7. Jos lääkäri ei ole varma, että koko **Essure**-mikroistute on poistettu munanjohtimesta, toista mikroistutetta **EI** tulee sijoittaa kyseiseen munanjohtimeen ja sijoittamisen jälkeinen röntgenkuva tulee ottaa, jotta voidaan tarkistaa, onko osa mikroistutteesta *in vivo*.

Lukuun ottamatta yllä kuvattua vaihtoehtoa, mikroistute tulee yrittää poistaa vain, jos potilaalla esiintyy haittavaikutuksia mikroistutteen johdosta tai jos hän vaatii mikroistutteen poistamista.

Jos mikroistute on poistettava, siihen on käytettävä vatsan kautta suoritettavaa toimenpidettä (laparoskopiaa tai laparotomiaa).

Proksimaalinen munanjohdin vaatii sarven resektion, jos mikroistute on sijoitettu kunnolla kohdun ja munanjohtimen yhtymäkohtaan.

Essure-mikroistute, jota ei ole sijoitettu kunnolla tai joka on siirtynyt kohdun ja munanjohtimen yhdyskohtaa kauemmas, tulee poistaa laparoskopian tai laparotomian avulla suoritettua tavallista lineaarista salpingotomiaa tai salpingektomiaa käyttäen.

1. Lineaarista salpingotomiaa suoritettaessa tehdään pieni viilto (noin 2 cm) munanjohtimen antimesenteeriselle laidalle, hieman mikroistutteen yläpuolelle.
2. Osittainen tai täydellinen salpingektomia voidaan suorittaa mikroistutteen poistamiseksi perinteisen sterilisaatiotoimenpiteen yhteydessä tai itsenäisenä toimenpiteenä.

XIII. Potilaan tunnistuskortti

Jokaiselle potilaalle, jolle on asennettu **Essure**-mikroistute, tulee antaa laminoitu, luottokortin kokoinen kortti, jossa hänellä todetaan olevan **Essure**-mikroistute. **Kortti toimitetaan tässä pakkauksessa.** Kortissa todetaan myös, että tälle potilaalle suoritettaviin kohdunsisäisiin toimenpiteisiin tai lisääntymiselinten leikkauksiin voi liittyä riskejä.

XIV. Merkkien selitykset

STERILE EO	Steriloitu etyleenioksidilla
LOT	Eräkoodi
	Ei saa käyttää uudelleen
REF	Luettelonumero
	Huomio, lue käyttöohjeet
	Käytettävä ennen
	Suojattava lämmöltä
	Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.
MR	Magneettikuvaukseen liittyvää turvallisuustietoa
EC REP	Valtuutettu edustaja
CE 0050	Tuote on direktiivin 93/42/EY vaatimusten mukainen
	Säilytettävä kuivana
CONT	Sisällys

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Tuotetilaukset tai haittavaikutuksia koskevat ilmoitukset ottaa vastaan paikallinen Bayer HealthCare LLC edustaja.

Ελληνικά

essure®

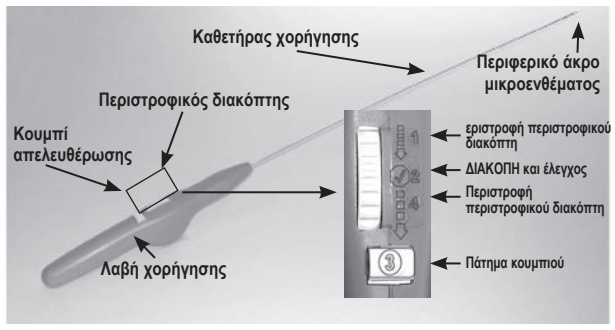
Μόνιμη αντισύλληψη

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

I. Περιγραφή του μικροενθέματος

Το σύστημα μόνιμης αντισύλληψης Essure® αποτελείται από διάφορα εξαρτήματα. Το μικροένθεμα Essure, ένα δυναμικά εκπτυσσομενο μικροένθεμα, είναι προσαρτημένο σε ένα σύρμα χορήγησης και έναν καθετήρα απελευθέρωσης. Ολόκληρη η διάταξη βρίσκεται μέσα σε ένα περίβλημα εντός ενός καθετήρα χορήγησης. Το σύστημα αυτό (απεικονίζεται στο Σχήμα 1) είναι προσαρτημένο σε μια λαβή που διευκολύνει τη χορήγηση και την έκπτυξη του μικροενθέματος. Με το σύστημα Essure παρέχεται επίσης ένας εισαγωγέας DryFlow® με βαλβίδα. Προορίζεται για να βοηθήσει στην προστασία του μικροενθέματος Essure καθώς διαβιβάζεται μέσω της ελαστικής θύρας του καναλιού εργασίας του υστεροσκοπίου.

Σχήμα 1
Σύστημα χορήγησης Essure
Εμφάνιση λεπτομερειών συμβόλων διαδικασίας τοποθέτησης
(ΔΕΝ ΕΙΝΑΙ ΣΕ ΚΛΙΜΑΚΑ)



II. Μηχανισμός δράσης

Υπό υστεροσκοπική απεικόνιση, το σύστημα Essure χορηγεί ένα μικροένθεμα Essure στην εγγύς μοίρα του αυλού της σάλπιγγας. Όταν το μικροένθεμα Essure εκπτύσσεται κατά την απελευθέρωση, στερεώνεται υπό οξεία γωνία στη σάλπιγγα. Ακολούθως, το μικροένθεμα προκαλεί μια επιδιωκόμενη καλοήθη ιστική απόκριση, με αποτέλεσμα την ιστική είσφρυση εντός του μικροενθέματος που στερεώνει το μικροένθεμα σταθερά εντός της σάλπιγγας. Αυτή η καλοήθης ιστική απόκριση είναι τοπική, ινώδους και αποφρακτικής φύσης.

Κάθε σύστημα Essure αποστειρώνεται με χρήση οξειδίου του αιθυλενίου και παρέχεται αποστειρωμένο για μία μόνο χρήση. Μην το επαναχρησιμοποιείτε και μην το επαναποστειρώνετε. Η επαναποστείρωση ενδέχεται να επηρεάσει αρνητικά τη σωστή μηχανική λειτουργία του συστήματος και να οδηγήσει σε τραυματισμό της ασθενούς.

III. Ενδείξεις χρήσης

Το σύστημα Essure προορίζεται για χρήση ως μικροένθεμα απόφραξης των σαλπίγγων για σκοπούς μόνιμης αντισύλληψης.

IV. Αντενδείξεις χρήσης

- **Αβεβαιότητα της ασθενούς σχετικά με την επιθυμία της για διακοπή της γονιμότητας.**
- **Κύηση ή υποψία για κύηση.**
- **Τοκετός ή τερματισμός κύησης στο δεύτερο τρίμηνο σε διάστημα λιγότερο από 6 εβδομάδες πριν από την τοποθέτηση του μικροενθέματος Essure.**
- **Ενεργή ή πρόσφατη πυελική λοίμωξη.**
- **Μη θεραπευθείσα οξεία τραχηλίτιδα.**
- **Ανεξήγητη ή βαριά κολπική αιμορραγία.**
- **Γυναικολογική κακοήθεια (υποψία ή γνωστή).**
- **Γνωστή ανωμαλία της μητριαίας κοιλότητας ή των σαλπίγγων που καθιστά την απεικόνιση των σαλπιγγικών στομίων ή/και την καθετηρίαση της εγγύς μοίρας της σάλπιγγας δύσκολη ή αδύνατη.**
- **Αλλεργία στα σκιαγραφικά μέσα (ενδέχεται να απαιτείται υστεροσαλπιγγογραφία τρεις μήνες μετά την τοποθέτηση του μικροενθέματος).**
- **Ασθενείς που επί του παρόντος παίρνουν κορτικοστεροειδή.**

V. Προειδοποιήσεις

- **Η διαδικασία Essure θα πρέπει να εκτελείται μόνον από πεπειραμένους ειδικούς στην υστεροσκόπηση, οι οποίοι έχουν ολοκληρώσει το πρόγραμμα εκπαίδευσης Bayer HealthCare LLC για τη διαδικασία αυτή.**
- **Άτομα αλλεργικά σε κράματα νικελίου-τιτανίου ενδέχεται να παρουσιάσουν αλλεργική αντίδραση στο μικροένθεμα.**
- **Μη χρησιμοποιείτε το σύστημα Essure αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. Μη χρησιμοποιείτε εάν το μικροένθεμα έχει υποστεί ζημιά.**
- **Κατά την εισαγωγή του μικροενθέματος Essure στη σάλπιγγα, μην προωθείτε ποτέ το(α) μικροένθεμα(τα) εάν συναντήσετε υπερβολική αντίσταση.**
- **Μη συνεχίσετε την προώθηση του συστήματος Essure όταν ο δείκτης τοποθέτησης στον καθετήρα φθάσει στο στόμιο της σάλπιγγας. Η προώθηση πέρα από το σημείο αυτό θα μπορούσε να έχει ως αποτέλεσμα μη ικανοποιητική τοποθέτηση του μικροενθέματος ή διάτρηση της σάλπιγγας/μήτρας.**
- **Εάν συμβεί ή υποψιάζεστε ότι έχει συμβεί διάτρηση της σάλπιγγας, μη συνεχίσετε την απόπειρα τοποθέτησης του μικροενθέματος Essure. Ένα πολύ μικρό ποσοστό γυναικών στις κλινικές δοκιμές Essure (1,8% ή 12/682 ασθενείς) αναγνωρίστηκαν ότι είχαν διατρήσεις των σαλπίγγων που σχετίζονται με τη συσκευή. Η ανάκτηση των διατρητικών μικροενθεμάτων, εάν είναι απαραίτητη, θα χρειαστεί λαπαροσκόπηση ή άλλες χειρουργικές μεθόδους.**
- **Εάν οι απόπειρες τοποθέτησης του μικροενθέματος Essure δεν είναι επιτυχείς μετά από 10 λεπτά απόπειρας καθετηριασμού ανά σάλπιγγα, θα πρέπει να τερματιστεί η διαδικασία και ενδεχομένως να επαναπρογραμματιστεί.**
- **Μετά την τοποθέτηση του μικροενθέματος (δηλ. την αποσύνδεσή του από το σύρμα χορήγησης), δεν θα πρέπει να επιχειρηθεί αφαίρεση του μικροενθέματος υστεροσκοπικά, εκτός εάν έχουν ήδη εισχωρήσει 18 ή περισσότερα σπειράματα του μικροενθέματος Essure μέσα στη μητριαία κοιλότητα. Θα πρέπει να επιχειρηθεί αφαίρεση ενός τέτοιου μικροενθέματος αμέσως μετά την τοποθέτηση. Ωστόσο, η αφαίρεση ενδέχεται να μην είναι δυνατή.**
- **Η ασθενής πρέπει να χρησιμοποιεί εναλλακτικές μεθόδους αντισύλληψης έως ότου καταδειχθεί ικανοποιητική θέση του μικροενθέματος με ακτινογραφία που θα εκτελεστεί τρεις μήνες μετά την τοποθέτηση του μικροενθέματος.**
- **Στις ασθενείς που υποβάλλονται σε διαδικασία τοποθέτησης του μικροενθέματος Essure ενδέχεται, τα επόμενα έτη, να παρασχεθεί δυνατότητα ενδομήτριων αγωγών που χρησιμοποιούν ηλεκτρική ενέργεια. Συνιστάται η αποφυγή της ηλεκτροκαυτηρίασης σε χειρουργικές διαδικασίες που πραγματοποιούνται στο μητριαίο κέρας και τις σάλπιγγες. Όλες οι άλλες διαδικασίες που πραγματοποιούνται στην πύελο θα πρέπει να αποφεύγουν τη χρήση ηλεκτροκαυτηρίασης εντός 4 cm του μικροενθέματος. Λόγω της παρουσίας των μικροενθεμάτων Essure, ενδέχεται να υπάρχουν κίνδυνοι που σχετίζονται με συναφείς διαδικασίες, οι οποίοι δεν έχουν αναγνωριστεί προς το παρόν.**
- **Τυχόν ενδομήτρια διαδικασία όπως για παράδειγμα ενδομήτρια βιοψία, διαστολή και απόξεση, υστεροσκόπηση (διαγνωστική ή εγχειρητική) συμπεριλαμβανομένης της ενδομήτριας εκτομής θα μπορούσε να διακόψει την ικανότητα των μικροενθεμάτων για την πρόληψη της κύησης. Επιπλέον, η παρουσία των μικροενθεμάτων Essure θα μπορούσε να συνεπάγεται κινδύνους που σχετίζονται με τέτοιες διαδικασίες, οι οποίοι δεν έχουν αναγνωριστεί προς το παρόν.**
- **Εργαστηριακές και κλινικές μελέτες κατέδειξαν ότι είναι δυνατό να εκτελεστεί με ασφάλεια και αποτελεσματικότητα ενδομήτρια εκτομή της μήτρας με το σύστημα ενδομήτριου μπαλονιού THERMACHOICE* της GYNECARE, το σύστημα ενδομήτριας εκτομής NovaSure** της Holargic και το σύστημα ThermAblator*** της Boston Scientific αμέσως μετά την τοποθέτηση του μικροενθέματος Essure. Δεν έχουν διεξαχθεί ειδικές μελέτες για την αξιολόγηση της εξώθησης του μικροενθέματος Essure ή των ποσοστών αντισύλληψης μετά από συνδυασμένες διαδικασίες Essure και ενδομήτριας εκτομής.**
- **Οι ασθενείς ενδέχεται να αποφασίσουν, τα επόμενα έτη, να υποβληθούν σε εξωσωματική γονιμοποίηση (IVF) για να μείνουν έγκυες. Οι επιδράσεις των μικροενθεμάτων Essure στην επιτυχία εξωσωματικής γονιμοποίησης δεν είναι γνωστές. Εάν επιτευχθεί κύηση, οι κίνδυνοι από το μικροένθεμα για την ασθενή, το έμβρυο και τη συνέχιση της κύησης δεν είναι γνωστοί.**

***Εμπορικό σήμα της ETHICON, INC.**
**** Εμπορικό σήμα της Hologic, Inc.**
***** Εμπορικό σήμα της BostonScientific Corporation**

VI. Προφυλάξεις

- **Όποτε είναι δυνατό, η τοποθέτηση του μικροενθέματος θα πρέπει να εκτελείται κατά τις ημέρες 7-14 του εμμηνορροϊκού κύκλου (όπου η ημέρα 1 αντιπροσωπεύει την πρώτη μέρα αιμορραγίας) προκειμένου να ενισχύεται η απεικόνιση των στομίων των σαλπίγγων και να μειωθεί το ενδεχόμενο τοποθέτησης του μικροενθέματος σε ασθενή με αδιάγνωστη κύηση.**
- **Τυχόν ασυνήθης ανατομία της μήτρας ενδέχεται να καταστήσει δυσχερή την τοποθέτηση των μικροενθεμάτων Essure.**
- **Προκειμένου να μειωθεί ο κίνδυνος διάτρησης της μήτρας, η διαδικασία θα πρέπει να τερματιστεί εάν απαιτείται υπερβολική δύναμη για την επίτευξη διαστολής του τραχήλου.**
- **Θα πρέπει να αναγνωριστούν αμφότερα τα στόμια των σαλπίγγων και να εκτιμηθούν υστεροσκοπικά πριν προχωρήσετε στην τοποθέτηση του μικροενθέματος Essure. Δεν πρέπει να γίνει καμία απόπειρα τοποθέτησης μικροενθέματος στο ένα στόμιο σάλπιγγας εκτός εάν αναμένεται εύλογα ότι η αντίπλευρη σάλπιγγα είναι προσπελάσιμη και βατή.**
- **Η εκτέλεση ενδομήτριας εκτομής αμέσως μετά την τοποθέτηση των μικροενθεμάτων Essure ενδέχεται να αυξήσει τον κίνδυνο εμφάνισης συνδρόμου σαλπιγγικής στείρωσης μετά από εκτομή, μια σπάνια κατάσταση, η οποία έχει αναφερθεί σε γυναίκες με ιστορικό σαλπιγγικής στείρωσης που υποβάλλονται σε ενδομήτρια εκτομή.**
- **Μην προωθείτε το σύστημα Essure εάν η ασθενής παρουσιάζει υπέρμετρο πόνο ή δυσφορία.**
- **Φυλάσσετε το σύστημα Essure σε δροσερό και ξηρό χώρο.**

VII. Πιθανές ανεπιθύμητες ενέργειες

A. Κύηση

Υπάρχει κίνδυνος κύησης και έκτοπης κύησης καθώς και κίνδυνοι που σχετίζονται με τη θεραπεία και των δύο. Εάν η ασθενής συλλάβει και επιλέξει να συνεχίσει μια ενδομήτρια κύηση, θα πρέπει να ενημερωθεί ότι οι κίνδυνοι από το μικροένθεμα για την ασθενή, το έμβρυο και τη συνέχιση της κύησης δεν είναι γνωστοί.

B. Κίνδυνοι σχετιζόμενοι με την διαδικασία τοποθέτησης μικροενθεμάτων

- **Είναι δυνατό να χορηγηθεί τοπική αναισθησία, από του στόματος αναλγησία/καταστολή, περιοχική αναισθησία (δηλ. νωτιαία, επισκληρίδιος), από του στόματος ή εν συνειδήσει (ενδοφλέβια) καταστολή ή γενική αναισθησία στην ασθενή για την πρόληψη ή τη μείωση της δυσφορίας. Ανεξαρτήτως από τον τύπο της αναισθησίας, οι ασθενείς ενδέχεται να μην είναι σε θέση να αρχίσουν πάλι τις φυσιολογικές δραστηριότητες τους επί 12-24 ώρες μετά τη διαδικασία.**
- **Ενδέχεται να εμφανιστεί πόνος, κράμπες και κολπική αιμορραγία κατά τη διάρκεια και μετά τη διαδικασία τοποθέτησης μικροενθέματος. Τυπικά, τα συμβάντα αυτά είναι ανεκτά, παροδικά και υποβάλλονται σε επιτυχή θεραπεία με φαρμακευτική αγωγή.**
- **Κατά τη διάρκεια ή/και άμεσα μετά τη διαδικασία τοποθέτησης μικροενθέματος, υπάρχει ο κίνδυνος η ασθενής να παρουσιάσει ναυτία ή έμετο. Αυτός αναμένεται να είναι παροδικός και μπορεί να υποβληθεί σε θεραπεία με φαρμακευτική αγωγή, όπως απαιτείται.**
- **Οι ασθενείς ενδέχεται να παρουσιάσουν λιποθυμία ή αγγειοπνευμονογαστρική απόκριση την ημέρα της διαδικασίας.**
- **Υπάρχει κίνδυνος διάτρησης ή διαχωρισμού της σάλπιγγας ή του μητριαίου κέρατος. Ενδέχεται να προκληθεί αιμορραγία και ουλοποίηση από μια τέτοια διάτρηση ή διαχωρισμό. Ωστόσο, δεν απαιτείται τυπικά θεραπεία.**
- **Υπάρχει κίνδυνος διάτρησης της μήτρας από το υστεροσκόπιο, το σύστημα Essure ή άλλα όργανα που χρησιμοποιούνται κατά τη διάρκεια της διαδικασίας με πιθανή βλάβη στο έντερο, την κύστη και σε μείζονα αιμοφόρα αγγεία. Ενδέχεται να απαιτηθεί χειρουργική επέμβαση, αλλά δεν είναι πιθανό, εάν επρόκειτο να συμβεί μια τέτοια βλάβη. Για να μειωθεί ο κίνδυνος διάτρησης της μήτρας, η διαδικασία θα πρέπει να τερματιστεί εάν απαιτείται υπερβολική δύναμη για την επίτευξη διαστολής του τραχήλου.**
- **Υπάρχει κίνδυνος τοποθέτησης από λάθος του μικροενθέματος Essure μέσα στο μυομήτριο και όχι στον αυλό της σάλπιγγας. Εάν έχει ήδη τοποθετηθεί σωστά ένα μικροένθεμα στη μία σάλπιγγα, εκτός από την κατά λάθος τοποθέτηση στο μυομήτριο, ο ιατρός μπορεί να επιχειρήσει την τοποθέτηση ενός τρίτου μικροενθέματος για την ολοκλήρωση της διαδικασίας. Εάν δεν επιτευχθεί αμφοτερόπλευρη τοποθέτηση στις σάλπιγγες, αυτό ενδέχεται να έχει ως αποτέλεσμα η ασθενής να έχει ένα μικροένθεμα στη σάλπιγγα ή/και ένα μικροένθεμα στο μυομήτριο, το οποίο δεν μπορεί να παρέχει αξιόπιστη αντισύλληψη. Η τοποθέτηση του μικροενθέματος στο μυομήτριο ενδέχεται να έχει ως αποτέλεσμα μετεγχειρητικό πόνο ή άλλη ανεπιθύμητη ενέργεια. Εάν απαιτείται χειρουργική αφαίρεση του(ων) μικροενθέματος(ων), ενδέχεται να απαιτηθεί σαλπιγγεκτομή ή υστερεκτομή.**
- **Υπάρχει κίνδυνος ενδεχόμενης τοποθέτησης του μικροενθέματος Essure πάρα πολύ περιφερικά μέσα στη σάλπιγγα. Εάν είναι απαραίτητη η αφαίρεση του μικροενθέματος, θα απαιτηθεί χειρουργική επέμβαση (λαπαροσκόπηση ή λαπαροτομή).**
- **Υπάρχει κίνδυνος ενδεχόμενης τοποθέτησης του μικροενθέματος Essure πάρα πολύ κεντρικά μέσα στη σάλπιγγα. Εάν 18 ή περισσότερα σπειράματα του μικροενθέματος Essure είναι ορατά κατά τη στιγμή της τοποθέτησης, θα πρέπει να επιχειρηθεί άμεσα αφαίρεση του μικροενθέματος (δείτε την ενότητα XIII, Αφαίρεση μικροενθέματος Essure). Εάν επιχειρηθεί αφαίρεση του μικροενθέματος, υπάρχει πιθανότητα μη επιτυχούς αφαίρεσης ή ενδεχόμενης ρήξης του μικροενθέματος Essure, αφήνοντας ένα θραύσμα του μικροενθέματος *in vivo*. Εάν επιχειρηθεί ή/και επιτευχθεί αφαίρεση του μικροενθέματος, υπάρχει επίσης δυνατότητα να παρουσιαστεί αυξημένος πόνος, κράμπες και αιμορραγία στις ασθενείς κατά τη διάρκεια και μετά τη διαδικασία τοποθέτησης του μικροενθέματος Essure.**
- **Υπάρχει κίνδυνος ενδεχόμενης διάτρησης του μικροενθέματος Essure μέσω του τοιχώματος της σάλπιγγας ή του μητριαίου κέρατος, το οποίο θα είχε ως αποτέλεσμα την απελευθέρωση του μικροενθέματος στην περιτοναϊκή κοιλότητα. Ενδέχεται να παρουσιαστεί μετεγχειρητικός πόνος ή/και διαταραχή της εμμήνου ρύσης ή άλλη ανεπιθύμητη ενέργεια. Εάν η ασθενής επιλέξει να υποβληθεί σε στείρωση μέσω χειρουργικής τομής ή σε άλλη χειρουργική επέμβαση, μπορεί να επιχειρηθεί ανάκτηση του μικροενθέματος από την περιτοναϊκή κοιλότητα εάν ο ιατρός πιστεύει ότι η ενέργεια αυτή είναι ασφαλής. Ωστόσο, η ανάκτηση του μικροενθέματος ενδέχεται να μην είναι δυνατή εάν δεν είναι δυνατή η απεικόνιση ή προσπέλαση του μικροενθέματος από τον ιατρό.**
- **Υπάρχει κίνδυνος η τοποθέτηση του μικροενθέματος Essure να επιτευχθεί μόνο στη μία σάλπιγγα. Εάν συμβεί αυτό, οι ασθενείς μπορεί να φέρουν μόνο ένα μικροένθεμα ίη νίνο, το οποίο δεν μπορεί να παρέχει αξιόπιστη μόνιμη αντισύλληψη.**
- **Υπάρχει κίνδυνος η τοποθέτηση του μικροενθέματος Essure να μην είναι δυνατή σε καμία από τις δύο σάλπιγγες.**
- **Υπάρχει ελάχιστος κίνδυνος απορρόφησης περίσσειας υγρού του φυσιολογικού ορού που χρησιμοποιείται για τη διάταση της μήτρας, για την εκτέλεση της υστεροσκοπικής διαδικασίας.**
- **Όπως συμβαίνει με όλες τις επεμβατικές διαδικασίες, η διαδικασία τοποθέτησης του μικροενθέματος μπορεί να προκαλέσει λοίμωξη. Μια λοίμωξη θα μπορούσε να προκαλέσει βλάβη στη μήτρα, τις σάλπιγγες ή την πυελική κοιλότητα. Αυτό θα μπορούσε να απαιτήσει αντιβιοτική αγωγή ή σπανίως, νοσηλεία ή χειρουργική επέμβαση, συμπεριλαμβανομένης της υστερεκτομής.**

C. Κίνδυνοι σχετιζόμενοι με την παραμονή του εμφυτευμένου μικροενθέματος Essure

- **Υπάρχει κίνδυνος μετακίνησης του μικροενθέματος Essure έξω από τις σάλπιγγες. Η μετακίνηση αυτή θα μπορούσε να είναι εξώθηση (μετακίνηση έξω από τη σάλπιγγα και μέσα στη μητριαία κοιλότητα/στον τράχηλο/στον κόλπο ή έξω από το σώμα) ή μετανάστευση (μετακίνηση προς την περιφερική σάλπιγγα ή έξω από τη σάλπιγγα και μέσα στην περιτοναϊκή κοιλότητα). Ενδέχεται να απαιτηθούν επιπλέον ακτινογραφίες για την αναγνώριση της θέσης του(ων) μικροενθέματος(ων) και διενέργεια χειρουργικής επέμβασης για την αφαίρεση του(ων) μικροενθέματος(ων). Η μετακίνηση της συσκευής θα μπορούσε να έχει ως αποτέλεσμα κύηση, έκτοπη κύηση ή/και πόνο/διαταραχή της εμμήνου ρύσης ή άλλες ανεπιθύμητες ενέργειες.**
- **Όπως συμβαίνει με τις μεθόδους μηχανικής μόνιμης αντισύλληψης που υπάρχουν σήμερα διαθέσιμες (δηλ. κλιπ, δακτύλιοι), εάν πρόκειται να αφαιρεθεί το μικροένθεμα Essure, θα απαιτηθεί χειρουργική επέμβαση. Περαιτέρω, είναι δυνατό να απαιτηθεί χειρουργική αφαίρεση των σαλπίγγων (σαλπιγγεκτομή) και της μήτρας (υστερεκτομή).**
- **Ενδέχεται να παρουσιαστεί κοιλιακός/πυελικός πόνος και κράμπες. Ο πόνος και οι κράμπες ενδέχεται να είναι ένα πιο πιθανό συμβάν κατά τη διάρκεια της περιόδου εμμήνου ρύσης, κατά τη διάρκεια και μετά τη σεξουαλική επαφή ή με άλλη φυσική δραστηριότητα.**
- **Ενδέχεται να παρουσιαστεί αιμορραγία μεταξύ εμμήνων ρύσεων ή εντονότερη από τη συνηθισμένη έμμηνο ρύση.**
- **Ενίοτε, μια γυναίκα ενδέχεται να μετανιώσει για την απόφαση της να υποβληθεί σε μόνιμη αντισύλληψη και να παρουσιάσει ως αποτέλεσμα ήπια κατάθλιψη ή άλλες συναισθηματικές διαταραχές.**

D. Κίνδυνοι σχετιζόμενοι με τις διαδικασίες παρακολούθησης

- **Υπάρχει ο κίνδυνος ακτινοβολίας, ο οποίος σχετίζεται με την πυελική ακτινογραφία που απαιτείται τρεις μήνες μετά την τοποθέτηση του μικροενθέματος για την αξιολόγηση της θέσης του. Ενδέχεται να υπάρχει επίσης ανάγκη για τεστ επιβεβαίωσης Essure (HSG). Υπάρχουν περίπου 0,33 rad στο ακτινοσκοπικό τμήμα (<30 δευτερόλεπτα) μιας διαδικασίας υστεροσαλπιγγογραφήματος. Ως σημείο σύγκρισης, η έκθεση σε ακτινοβολία από κλύσμα βαρίου είναι 0,85 rad, η οποία είναι υψηλότερη από το απαιτούμενο τεστ επιβεβαίωσης Essure (HSG). Η ποσότητα έκθεσης σε ακτινοβολία από μια πυελική ακτινογραφία είναι περίπου η ίδια με την ποσότητα που θα ελάμβανε ένα άτομο κατά τη διάρκεια ενός έτους φυσικής ακτινοβολίας υποβάθρου.**
- **Οι ακόλουθοι επιπλέον κίνδυνοι σχετίζονται με τη διαδικασία τεστ επιβεβαίωσης Essure (HSG), εφόσον χρειαστεί: αγγειοπνευμονογαστρική απόκριση, λοίμωξη, η οποία ενδέχεται να χρήζει αντιβιοτικής θεραπείας και σε σπάνιες περιπτώσεις θα μπορούσε να χρήζει νοσηλείας, ενδαγγείωση, διάτρηση της μήτρας, κράμπες στη μήτρα ή/και αιμορραγία, πόνο ή δυσφορία και αλλεργική αντίδραση στο λάτεξ. Η έκθεση στο λάτεξ έχει αναφερθεί ότι σχετίζεται με αναφυλακτικές αντιδράσεις σε σπάνιες περιπτώσεις, οι οποίες ενδέχεται να οδηγήσουν σε θάνατο.**

- **Η χρήση σκιαγραφικών μέσων, τα οποία χρησιμοποιούνται για την εκτέλεση τεστ επιβεβαίωσης Essure (HSG), έχει συσχετιστεί με αλλεργική αντίδραση σε ορισμένες ασθενείς. Η αλλεργική αντίδραση μπορεί να προκαλέσει κνίδωση ή δύσπνοια. Σε ορισμένα άτομα, ενδέχεται να παρουσιαστεί μια αναφυλακτική απόκριση, η οποία ενδέχεται να οδηγήσει σε θάνατο.**

Ε. Κίνδυνοι σχετιζόμενοι με πιθανές μελλοντικές διαδικασίες

- **Στις ασθενείς που υποβάλλονται σε διαδικασία τοποθέτησης του μικροενθέματος Essure ενδέχεται, τα επόμενα έτη, να παρασχεθεί δυνατότητα ενδομήτριων αγωγών που χρησιμοποιούν ηλεκτρική ενέργεια. Συνιστάται η αποφυγή της ηλεκτροκαυτηρίασης σε χειρουργικές διαδικασίες που πραγματοποιούνται στο μητριαίο κέρας και τις σάλπιγγες. Όλες οι άλλες διαδικασίες που πραγματοποιούνται στην πύελο θα πρέπει να αποφεύγουν τη χρήση ηλεκτροκαυτηρίασης εντός 4 cm του μικροενθέματος. Λόγω της παρουσίας των μικροενθεμάτων Essure, ενδέχεται να υπάρχουν κίνδυνοι που σχετίζονται με τέτοιες διαδικασίες, οι οποίοι δεν έχουν αναγνωριστεί προς το παρόν.**
- **Τυχόν ενδομήτρια διαδικασία όπως για παράδειγμα ενδομήτρια βιοψία, διαστολή και απόξεση, υστεροσκόπηση (διαγνωστική ή εγχειρητική) συμπεριλαμβανομένης της ενδομήτριας εκτομής θα μπορούσε να διακόψει την ικανότητα των μικροενθεμάτων για την πρόληψη της κύησης. Επιπλέον, η παρουσία των μικροενθεμάτων Essure θα μπορούσε να συνεπάγεται κινδύνους που σχετίζονται με τέτοιες διαδικασίες, οι οποίοι δεν έχουν αναγνωριστεί προς το παρόν.**
- **Οι ασθενείς ενδέχεται να αποφασίσουν, τα επόμενα έτη, να υποβληθούν σε εξωσωματική γονιμοποίηση (IVF) για να μείνουν έγκυες. Οι επιδράσεις των μικροενθεμάτων Essure στην επιτυχία εξωσωματικής γονιμοποίησης δεν είναι γνωστές. Εάν επιτευχθεί κύηση, οι κίνδυνοι από το μικροένθεμα για την ασθενή, το έμβρυο και τη συνέχιση της κύησης δεν είναι γνωστοί.**
- **Τα μικροενθέματα Essure είναι ασφαλή σε σχέση με τη μαγνητική τομογραφία και ακτινοσκιερά. Τα μικροενθέματα Essure είναι επίσης συμβατά με τη μαγνητική τομογραφία, εκτός από την πυελική απεικόνιση, όπου ενδέχεται να προκαλέσουν κάποια παράσιτα.**
- **Υπάρχει το ενδεχόμενο ύπαρξης άγνωστων κινδύνων.**

VIII. ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

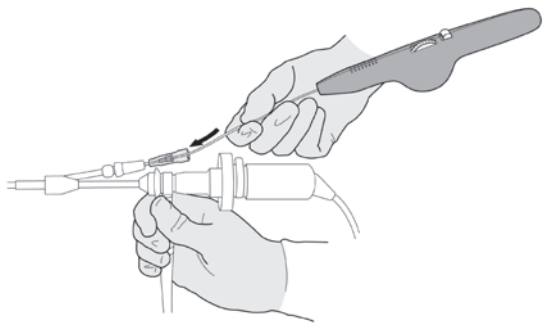
Α. Πριν από τη διαδικασία τοποθέτησης μικροενθέματος

1. **Η τοποθέτηση του θα πρέπει να εκτελείται κατά τις ημέρες 7-14 του εμμηνορροϊκού κύκλου (όπου η ημέρα 1 αντιπροσωπεύει την πρώτη μέρα αιμορραγίας) προκειμένου να ενισχύεται η απεικόνιση των στομίων των σαλπίγγων και να μειωθεί το ενδεχόμενο τοποθέτησης του μικροενθέματος σε ασθενή με αδιάγνωστη κύηση.**
2. **Θα πρέπει να διεξαχθεί τεστ εγκυμοσύνης από τον ιατρό ή καθορισμένο αντιπρόσωπο του, μέσα σε 24 ώρες πριν ή αμέσως πριν από τη διαδικασία τοποθέτησης του μικροενθέματος.**
3. **Συνιστάται ιδιαίτερα η χορήγηση ενός μη στεροειδούς αντιφλεγμονώδους φαρμάκου (ΜΣΑΦ), όπως το Incocid (από του στόματος ή υπόθετο), μία έως δύο ώρες πριν από τη διαδικασία τοποθέτησης του μικροενθέματος, επειδή τα δεδομένα των κλινικών δοκιμών καταδεικνύουν ότι η χρήση των ΜΣΑΦ αυξάνει σημαντικά την πιθανότητα επιτυχίας της τοποθέτησης. Εάν χρησιμοποιείται μόνον παρα-αυχενικός αποκλεισμός, μπορεί επίσης να παρασχεθεί διαζεπάμη (PO) ή ένας παρόμοιος παράγοντας, 30 λεπτά πριν από τη διαδικασία για τη μείωση του άγχους.**

Β. Διαδικασία τοποθέτησης του μικροενθέματος Essure

Η διαδικασία τοποθέτησης του μικροενθέματος Essure μπορεί να εκτελεστεί σε περιβάλλον περιπατητικών διαδικασιών ή ημερήσιων χειρουργικών επεμβάσεων, θα πρέπει να χρησιμοποιείται άσηπτη τεχνική κατά τη διάρκεια της διαδικασίας τοποθέτησης του μικροενθέματος. Το χρονικό διάστημα που απαιτείται για την ολοκλήρωση της διαδικασίας τοποθέτησης του μικροενθέματος δεν θα πρέπει να υπερβαίνει τα 30 λεπτά.

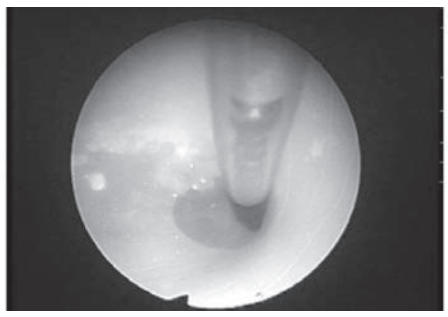
1. **Τοποθετήστε την ασθενή στη θέση λιθοτομής.**
2. **Εισαγάγετε ένα μητροσκόπιο στον κόλπο για να επιτραπεί η πρόσβαση στον τράχηλο. Προετοιμάστε τον τράχηλο με βάμμα ιωδίου (betadine) ή άλλο κατάλληλο αντιβακτηριακό διάλυμα σύμφωνα με την τυπική πρακτική.**
3. **Η τοπική αναισθησία είναι η προτιμώμενη μέθοδος για την εμφύτευση των μικροενθεμάτων. Μπορεί να χορηγηθεί παρα-αυχενικός αποκλεισμός. Μπορεί επίσης να χορηγηθεί μιδαζολάμη (ΕΦ) ή ένας παρόμοιος παράγοντας, για την πρόληψη ή τη μείωση της δυσφορίας, εάν χρειαστεί.**
4. **Εισαγάγετε ένα αποστειρωμένο υστεροσκόπιο, με προσαρτημένη κάμερα και κανάλι λειτουργίας (≥ 5 French), μέσω του τραχήλου στη μητριαία κοιλότητα. Εάν είναι απαραίτητο, εκτελέστε διαστολή του τραχήλου για να επιτραπεί η εισαγωγή. Προκειμένου να προληφθεί ο κίνδυνος διάτρησης της μήτρας, η διαδικασία θα πρέπει να τερματιστεί εάν απαιτείται υπερβολική δύναμη για την επίτευξη διαστολής του τραχήλου.**
5. **Η διάταση της μητριαίας κοιλότητας θα πρέπει να επιτυγχάνεται με έγχυση φυσιολογικού ορού μέσω του καναλιού εργασίας του υστεροσκοπίου. Συνιστάται ιδιαίτερα η προθέρμανση του διαλύματος φυσιολογικού ορού στη θερμοκρασία του σώματος και η εισαγωγή του μέσω βαρύτητας για την ελαχιστοποίηση του σπασμού των σαλπίγγων. Πρέπει να επιτυγχάνεται εξαιρετική διάταση της μήτρας και να διατηρείται καθόλη τη διάρκεια της διαδικασίας. Πρέπει να ακολουθούνται τυπικές διαδικασίες παρακολούθησης των υγρών καθόλη τη διάρκεια της διαδικασίας. Τα στόμια των σαλπίγγων θα πρέπει να αναγνωρίζονται με υστεροσκοπική απεικόνιση.**
6. **Θα πρέπει να αναγνωριστούν αμφότερα τα στόμια των σαλπίγγων και να εκτιμηθούν υστεροσκοπικά πριν προχωρήσετε στην τοποθέτηση του μικροενθέματος Essure. Δεν πρέπει να γίνεται καμία απόπειρα τοποθέτησης μικροενθέματος στο ένα στόμιο σάλπιγγας, εκτός εάν αναμένεται εύλογα ότι η αντίπλευρη σάλπιγγα θα είναι βατή.**
7. **Μόλις αναγνωριστούν τα στόμια των σαλπίγγων, εισαγάγετε τον εισαγωγέα μέσω του πώματος στεγανοποίησης του καναλιού εργασίας του υστεροσκοπίου. Η στρόφιγγα του καναλιού εργασίας πρέπει να παραμείνει στην ανοικτή θέση (η συσκευή ή/και ο εισαγωγέας ενδέχεται να υποστούν ζημιά αν η στρόφιγγα κλείσει σε οποιαδήποτε από τις συσκευές). Τοποθετήστε το σύστημα χορήγησης Essure μέσω του εισαγωγέα και προωθήστε το μέσω του**



καναλιού λειτουργίας του υστεροσκοπίου. Εάν ο εισαγωγέας με βαλβίδα είναι άθικτος από την πρώτη τοποθέτηση του μικροενθέματος, μπορείτε να παραμένει στο κανάλι εργασίας σε όλη τη διάρκεια της διαδικασίας Essure.

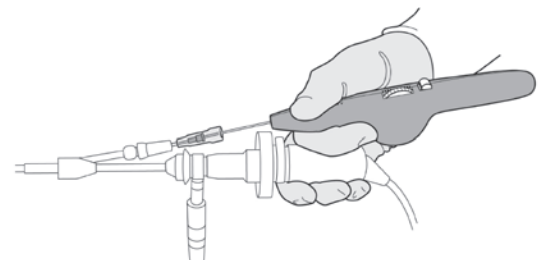
Εισαγάγετε τον εισαγωγέα μέσω του πώματος στεγανοποίησης στο κανάλι μικροενθέματος εργασίας του υστεροσκοπίου και μετά τοποθετήστε το σύστημα χορήγησης **Essure** *μέσω του εισαγωγέα.*

8. **Προωθήστε το σύστημα χορήγησης Essure στην εγγύς μοίρα της σάλπιγγας με αργή, σταθερή κίνηση για την πρόληψη του σπασμού της σάλπιγγας. Προωθήστε το σύστημα χορήγησης έως ότου ο δείκτης τοποθέτησης στον καθετήρα χορήγησης φθάσει στο στόμιο της σάλπιγγας. Αυτός ο οπτικός δείκτης υποδεικνύει ότι το μικροένθεμα Essure καλύπτει την περιφερική ενδοτοιχωματική έως την εγγύς ισθμική μοίρα της σάλπιγγας, με το εξωτερικό σπείραμα να καλύπτει την υστεροσαλπιγγική συμβολή. Αυτή είναι η ιδανική τοποθέτηση για το μικροένθεμα Essure.**



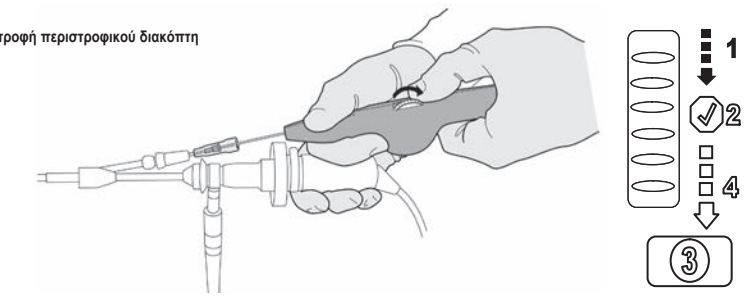
Προωθήστε έως ότου ο μαύρος δείκτης τοποθέτησης βρεθεί στο στόμιο της σάλπιγγας. Αυτό αποτελεί οπτική ένδειξη για τη σωστή θέση για έκπτυξη.

9. **Η σωστή συγκεντρική ευθυγράμμιση του καθετήρα χορήγησης με τον αυλό της σάλπιγγας υποδηλώνεται από τη δυνατότητα προώθησης του καθετήρα υπό άμεση απεικόνιση χωρίς υπέρμετρη αντίσταση. Η αντίσταση στην προώθηση γίνεται συνήθως εμφανής με δύο τρόπους: 1) ο μαύρος δείκτης στην εξωτερική επιφάνεια του καθετήρα διαπιστώνεται ότι δεν προωθείται προς τα εμπρός προς το στόμιο της σάλπιγγας ή/και 2) ο καθετήρας χορήγησης λυγίζει ή κάμπτεται υπερβολικά, παρεμποδίζοντας έτσι τον ιατρό στην εφαρμογή πίεσης προς τα εμπρός στη διάταξη του καθετήρα. Όταν παρατηρείται τέτοια αντίσταση στην κίνηση του καθετήρα προς τα εμπρός, δεν θα πρέπει να γίνονται περαιτέρω απόπειρες για την τοποθέτηση του μικροενθέματος προκειμένου να αποφευχθεί η πιθανότητα διάτρησης της μήτρας ή ακούσιας τοποθέτησης του μικροενθέματος στο μυϊκό σύστημα της μήτρας αντί για εντός του αυλού της σάλπιγγας, θα πρέπει να διενεργηθεί τεστ επιβεβαίωσης Essure (HSG) παρακολούθησης για τον προσδιορισμό της βατότητας της σάλπιγγας.**
10. **Εάν δεν είναι δυνατή η προώθηση του καθετήρα προς το δείκτη τοποθέτησης μετά από μερικά λεπτά, μπορεί να χρησιμοποιηθεί μια δοκιμασία διάχυσης με έναν καθετήρα βατότητας, εάν δεν έχει ήδη χρησιμοποιηθεί, για τον προσδιορισμό της βατότητας της σάλπιγγας. Εάν η σάλπιγγα έχει αποφραχθεί ή δεν είναι δυνατή η προώθηση του καθετήρα προς το δείκτη τοποθέτησης, θα πρέπει να τερματιστεί η επέμβαση. Εάν δεν είναι επιτυχής η τοποθέτηση του μικροενθέματος μετά από 10 λεπτά απόπειρας καθετηριασμού ανά σάλπιγγα, θα πρέπει να τερματιστεί η επέμβαση.**
11. **Μετά την προώθηση του καθετήρα χορήγησης προς το δείκτη τοποθέτησης, προχωρήστε στην έκπτυξη του μικροενθέματος. Για να το επιτύχετε αυτό, σταθεροποιήστε πρώτα τη λαβή του μικροενθέματος Essure πάνω στην κάμερα του υστεροσκοπίου ή σε κάποιο άλλο σταθερό αντικείμενο για την πρόληψη της ακούσιας κίνησης προς τα εμπρός του συστήματος Essure κατά τη διάρκεια της απόσυρσης του καθετήρα χορήγησης.**



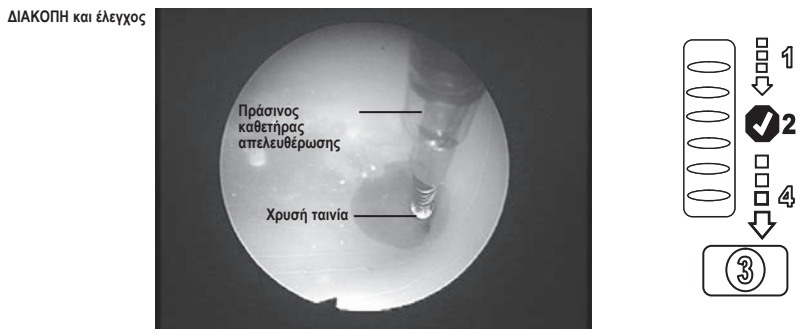
Σταθεροποίηση της λαβής πάνω στην κεφαλή της κάμερας ή σε κάποιο άλλο σταθερό αντικείμενο για την πρόληψη της ακούσιας κίνησης προς τα εμπρός του συστήματος Essure

12. **Αφού βεβαιωθείτε ότι ο μαύρος δείκτης τοποθέτησης βρίσκεται στο στόμιο της σάλπιγγας, περιστρέψτε τον περιστροφικό διακόπτη της λαβής προς το μέρος σας έως ότου ο τροχός σταματήσει να περιστρέφεται. Αυτή η λειτουργία αντιστοιχεί στο σύμβολο ⇩1 στη λαβή του συστήματος χορήγησης. Αυτή η ενέργεια διευκολύνει την απόσυρση του καθετήρα χορήγησης. Θα δείτε τον μαύρο δείκτη τοποθέτησης να απομακρύνεται από το στόμιο της σάλπιγγας (προς το υστεροσκόπιο) και να εξαφανίζεται στο κανάλι εργασίας. Η απόσυρση του καθετήρα χορήγησης αποκαλύπτει το συμπτυγμένο μικροένθεμα Essure. Όταν αποσύρετε τον καθετήρα χορήγησης, θα πρέπει να εμφανίζεται μέσα στη μήτρα τμήμα περίπου 1 cm του μικροενθέματος (συμπτυγμένα σπειράματα).**



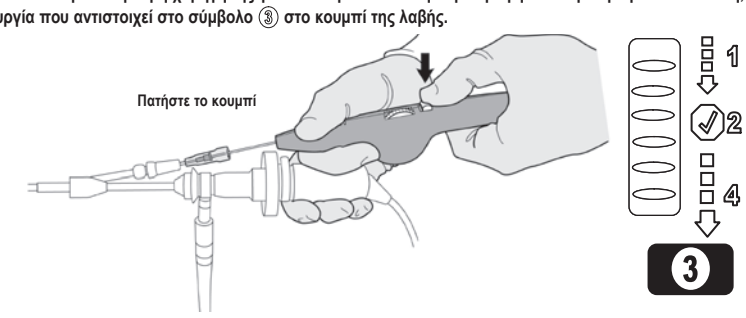
Περιστροφή του περιστροφικού διακόπτη για απόσυρση του καθετήρα

13. **Για να επιβεβαιωθεί η σωστή τοποθέτηση, τοποθετήστε τη χρυσή ενδεικτική ταινία λίγο έξω από το στόμιο, λειτουργία που αντιστοιχεί στο σύμβολο ✓2 στη λαβή του συστήματος χορήγησης. Ο ακτινοσκοπικός έλεγχος της χρυσής ταινίας έξω από το στόμιο, καθώς και ο ακτινοσκοπικός έλεγχος του περιφερικού άκρου του πράσινου καθετήρα απελευθέρωσης θα επιβεβαιώσει τη σωστή τοποθέτηση. Αν είναι ορατό στη μήτρα περισσότερο από 1 cm μικροενθέματος, το μικροένθεμα θα πρέπει να επανατοποθετηθεί με περαιτέρω μετακίνηση ολόκληρου του συστήματος μέσα στη σάλπιγγα, εφόσον είναι εφικτό κάτι τέτοιο, πριν προχωρήσετε στο επόμενο βήμα.**



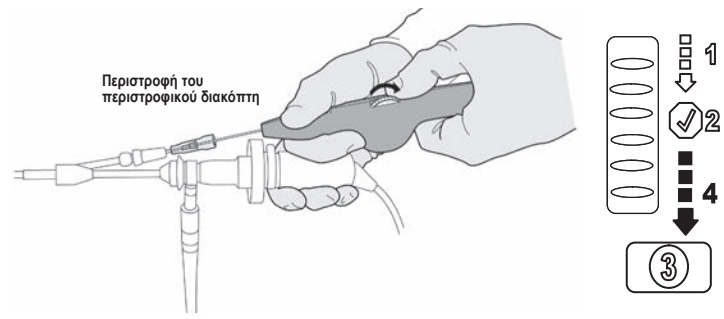
Ακτινοσκοπισμός εντοπισμός της χρυσής ταινίας στο στόμιο

14. **Πατήστε το κουμπί στη λαβή χορήγησης για να επιτραπεί πάλι η περιστροφή του περιστροφικού διακόπτη, λειτουργία που αντιστοιχεί στο σύμβολο ③ στο κουμπί της λαβής.**



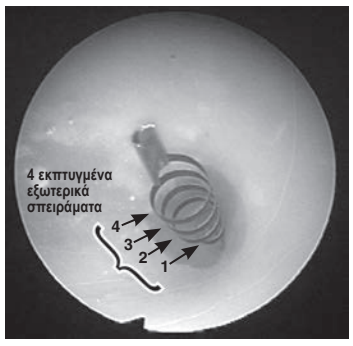
Πατήστε το κουμπί για να επιτραπεί πάλι η περιστροφή του περιστροφικού διακόπτη

15. **Περιστρέψτε τον περιστροφικό διακόπτη προς το μέρος σας για να εκπτύξετε το εξωτερικό σπείραμα του μικροενθέματος, λειτουργία που αντιστοιχεί στο σύμβολο ⇩4 της λαβής του συστήματος χορήγησης. Συνεχίστε να περιστρέφετε τον περιστροφικό διακόπτη έως ότου σταματήσει να περιστρέφεται. Όταν ο περιστροφικός διακόπτης δεν μπορεί να περιστραφεί άλλο και τα εκπτυγμένα εξωτερικά σπειράματα είναι ορατά, αποσύρετε το σύστημα.**



Περιστροφή του περιστροφικού διακόπτη για έκπτυξη του εξωτερικού σπειράματος του μικροενθέματος

16. **Η θέση του εκπτυγμένου μικροενθέματος Essure θα εκτιμηθεί υπό υστεροσκοπική απεικόνιση. Θα πρέπει να υπάρχουν ιδανικά 3 έως 8 εκπτυγμένα εξωτερικά σπειράματα του μικροενθέματος Essure εντός της μήτρας.**



Η εισχώρηση εκπτυγμένων εξωτερικών σπειραμάτων του μικροενθέματος **Essure** *εντός της μήτρας υποδεικνύει ιδανική τοποθέτηση*

17. **Αν ο ιατρός δεν είναι ικανοποιημένος με την τοποθέτηση του μικροενθέματος βάσει της υστεροσκοπικής εικόνας ή αν υποπτεύεται διάτρηση της σάλπιγγας της μήτρας το(α) μικροένθεμα(τα) πρέπει να αφαιρεθεί(ούν) στη θέση του(ς) και να γίνει αξιολόγηση με πυελική ακτινογραφία ή τεστ επιβεβαίωσης (HSG) τρεις μήνες μετά την τοποθέτηση της συσκευής.**

    ΠΡΟΕΙΔΟΠΟΙΗΣΗ: ΜΕΤΑ ΤΗΝ ΤΟΠΟΘΕΤΗΣΗ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ ΚΑΙ ΤΗΝ ΑΠΕΛΕΥΘΕΡΩΣΗ ΤΟΥ ΜΕΣΑ ΣΤΗ ΣΑΛΠΙΓΓΑ, ΜΗΝ ΕΠΙΧΕΙΡΗΣΕΤΕ ΤΗΝ ΑΦΑΙΡΕΣΗ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ ΥΣΤΕΡΟΣΚΟΠΙΚΑ ΕΚΤΟΣ ΕΑΝ ΕΧΟΥΝ ΗΔΗ ΕΙΣΧΩΡΗΣΕΙ 18 'Η ΠΕΡΙΣΣΟΤΕΡΑ ΣΠΕΙΡΑΜΑΤΑ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ Essure ΣΤΗ ΜΗΤΡΙΑΙΑ ΚΟΙΛΟΤΗΤΑ.
    Θα πρέπει να επιχειρηθεί αφαίρεση ενός τέτοιου μικροενθέματος αμέσως κατά τη διάρκεια της απόπειρας τοποθέτησης. Ωστόσο, η αφαίρεση ενδέχεται να μην είναι δυνατή (δείτε την ενότητα XIII, Αφαίρεση μικροενθέματος Essure). Εάν η έκπτυξη του μικροενθέματος έγινε κατά λάθος στη μητριαία κοιλότητα και όχι μέσα στη σάλπιγγα, θα πρέπει να αφαιρέσετε το μικροένθεμα από τη μήτρα και να επιχειρήσετε εκ νέου τοποθέτηση του μικροενθέματος στη σάλπιγγα.
18. **Επαναλάβετε τη διαδικασία τοποθέτησης του μικροενθέματος Essure στην αντίπλευρη σάλπιγγα.**
19. **Καταγράψτε το μήκος του μικροενθέματος που έχει εισχωρήσει εντός της μητριαίας κοιλότητας, σημειώνοντας τυχόν θέματα σχετικά με την αναγνώριση ή την επιβεβαίωση είτε του στομίου της σάλπιγγας είτε τυχόν ανησυχίες που αφορούν τη δυνητική διάτρηση. Αυτά θα πρέπει να σημειωθούν στα αρχεία των ασθενών για επακόλουθη αναφορά όταν ανασκοπείται η εξέταση επιβεβαίωσης Essure** *(δείτε την ενότητα IX – Εξέταση επιβεβαίωσης* **Essure**, *παρακάτω).*
20. **Υπενθυμίστε στην ασθενή να χρησιμοποιεί εναλλακτική μέθοδο αντισύλληψης (εκτός από ενδομήτριο σπείραμα) για τους πρώτους 3 μήνες μετά τη διαδικασία τοποθέτησης του μικροενθέματος.**
21. **Προγραμματίστε την ασθενή για εξέταση επιβεβαίωσης Essure τρεις μήνες μετά τη διαδικασία τοποθέτησης του μικροενθέματος Essure για την αξιολόγηση της συγκράτησης και της θέσης του μικροενθέματος.**

IX. Εξέταση επιβεβαίωσης Essure

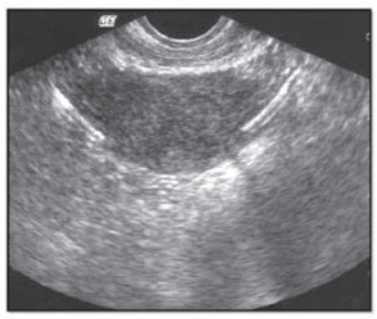
A. Τρεις μήνες μετά την τοποθέτηση του μικροενθέματος θα πρέπει να εκτελεστεί εξέταση επιβεβαίωσης Essure για την αξιολόγηση της συγκράτησης και της θέσης του μικροενθέματος. Οι εξετάσεις επιβεβαίωσης Essure (διακολπικό υπερηχογράφημα (transvaginal ultrasound, -TVU), πυελική ακτινογραφία ή υστεροσαλπιγγογραφία (HSG)) θα πρέπει να διενεργούνται μόνο από έμπειρο γυναικολόγο, τεχνικό υπερηχογραφίας ή/και ακτινολόγο εκπαιδευμένο στο αντίστοιχο πρωτόκολλο της εξέτασης επιβεβαίωσης Essure. Λεπτομερές πρωτόκολλο με εικόνες και συμβουλές για την απόδοση της εξέτασης παρέχεται με την εκπαίδευση. Μπορεί να πραγματοποιηθεί λήψη επιπλέον αντιγράφων από τον ιστότοπο essure.com.

B. Για την εξέταση επιβεβαίωσης πρώτης γραμμής, μπορεί να διενεργηθεί είτε πυελική ακτινογραφία είτε διακολπικό υπερηχογράφημα (TVU) τρεις μήνες μετά από μια διαδικασία αμφίπλευρης τοποθέτησης του μικροενθέματος που πραγματοποιείται χωρίς επιπλοκές.

1. **Η ακτινογραφία και το διακολπικό υπερηχογράφημα (TVU) δεν θα πρέπει να χρησιμοποιούνται ως εξέταση επιβεβαίωσης Essure υπό τις ακόλουθες συνθήκες:**
    - **a) Δύσκολη διαδικασία τοποθέτησης, συμπεριλαμβανομένων ενός ή περισσότερων από τα ακόλουθα:**
        - **(1) Κατά το χρόνο τοποθέτησης, ανησυχία για δυνητική διάτρηση λόγω απαίτησης άσκησης υπερβολικής δύναμης για τη χορήγηση του μικροενθέματος ή/και ξαφνικής απώλειας αντίστασης.**
        - **(2) Δυσκολία εντοπισμού των σαλπιγγικών στομίων κατά την τοποθέτηση λόγω ανατομικής απόκλισης ή τεχνικών παραγόντων, όπως πτωχή διάταση, υποβέλτιστος φωτισμός ή υπολείμματα στο ενδομήτριο.**
        - **(3) Ο χειρουργός δεν είναι σίγουρος αναφορικά με την τοποθέτηση.**
    - **b) Διάρκεια διαδικασίας > 15 λεπτά (εισαγωγή-εξαγωγή ενδοσκοπίου).**
    - **c) Τοποθέτηση χωρίς σπειράματα ή με > 8 σπειράματα.**
    - **d) Ασυνήθιστος μετεγχειρητικός πόνος, παροδικός ή εμμένων, ή ο οποίος εμφανίζεται σε μεταγενέστερο χρόνο μετεγχειρητικά, χωρίς οποιοδήποτε άλλο αναγνωρίσιμο αίτιο.**
2. **Αν η διενέργεια ακτινογραφίας ή υπερηχογραφήματος δεν ενδείκνυται, η ασθενής πρέπει να προχωρήσει σε πραγματοποίηση υστεροσαλπιγγογραφίας (HSG) προκειμένου να αξιολογηθεί η θέση του μικροενθέματος και η απόφραξη των σαλπίγγων. Το διακοιλιακό υπερηχογράφημα δεν μπορεί να υποκατασταθεί από διακολπικό υπερηχογράφημα (TVU). Αν τα αποτελέσματα της ακτινογραφίας ή του υπερηχογραφήματος είναι διφορούμενα ή μη ικανοποιητικά, η ασθενής πρέπει να προχωρά σε διενέργεια υστεροσαλπιγγογραφίας (HSG) προκειμένου να αξιολογείται η θέση του μικροενθέματος και η απόφραξη των σαλπίγγων.**

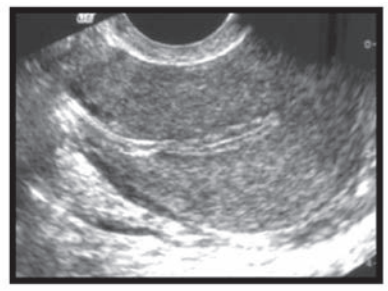
C. Διακολπικό υπερηχογράφημα

1. **Πρέπει να ληφθούν και να διατηρηθούν προς τεκμηρίωση τουλάχιστον τρεις εικόνες:**
    - **a) Μια στεφανιαία ή λοξή στεφανιαία προβολή, η οποία καταδεικνύει ένα τμήμα κάθε μικροενθέματος στο κέρας, με την επισήμανση «εικόνα ανίχνευσης».**



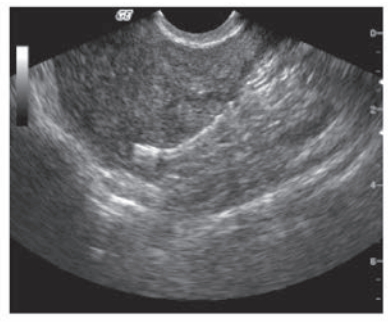
Αμφίπλευρα μικροενθέματα εντοπίζονται σε αυτήν την εγκάρσια (στεφανιαία / λοξή στεφανιαία) προβολή.

    - **b) Μια στεφανιαία ή λοξή στεφανιαία εικόνα του γραμμικού άξονα του αριστερού μικροενθέματος συμπεριλαμβανομένου του εγγύς άκρου που διασχίζει το μυομήτριο στο κέρας (διάμεσο τμήμα της σάλπιγγας) ή που εφάπτεται της συμβολής ορογόνου μήτρας και σαλπίγγων, με την επισήμανση «αριστερά».**
    - **c) Μια στεφανιαία ή λοξή στεφανιαία εικόνα του γραμμικού άξονα του δεξιού μικροενθέματος συμπεριλαμβανομένου του εγγύς άκρου που διασχίζει το μυομήτριο στο κέρας (διάμεσο τμήμα της σάλπιγγας) ή που εφάπτεται της συμβολής ορογόνου μήτρας και σαλπίγγων, με την επισήμανση «δεξιά».**
    - **d) Και οι τρεις εικόνες θα πρέπει να αποτυπώνονται σε φιλμ και να φυλάσσονται στον ιατρικό φάκελο της ασθενούς προκειμένου να τεκμηριώνεται η ικανοποιητική συγκράτηση και θέση του μικροενθέματος.**
2. **Ταξινόμηση της θέσης του μικροενθέματος**
    - **a) Ταυτοποίηση του μικροενθέματος: Σε μία μόνο εικόνα ανίχνευσης, ένα τμήμα κάθε μικροενθέματος πρέπει να απεικονίζεται στο κέρας στη στεφανιαία ή τη λοξή στεφανιαία προβολή προκειμένου να διασφαλίζεται η αμφίπλευρη τοποθέτηση και να μειώνεται ο κίνδυνος διπλής απεικόνισης του ίδιου μικροενθέματος. Ο γραμμικός άξονας των μικροενθεμάτων θα πρέπει να εμφανίζεται σχετικά συμμετρικός.**
    - **b) Βέλτιστη θέση**
      Η θέση του μικροενθέματος είναι βέλτιστη όταν το εγγύς άκρο του εφάπτεται της μητριαίας κοιλότητας ή του ενδομητρίου και ο γραμμικός άξονας βρίσκεται εντός του μυομητρίου στο κέρας (διάμεσο τμήμα της σάλπιγγας) και μπορεί να απεικονιστεί είτε να εφάπτεται της συμβολής ορογόνου μήτρας και σαλπίγγων (USTJ) είτε να τη διασχίζει. Το τμήμα του μικροενθέματος που βρίσκεται στη σάλπιγγα μπορεί να απεικονίζεται ή όχι. Ο γραμμικός άξονας του μικροενθέματος πρέπει να απεικονίζεται προκειμένου να επιβεβαιώνεται ότι δεν έχει συστραφεί ή επιμηκυνθεί.



Βέλτιστη θέση

    - **c) Ικανοποιητική θέση**
      Η θέση του μικροενθέματος είναι ικανοποιητική όταν το εγγύς άκρο του βρίσκεται περιφερικά του ενδομητρίου αλλά ο γραμμικός άξονας βρίσκεται εντός του μυομητρίου στο κέρας (διάμεσο τμήμα της σάλπιγγας) και μπορεί να απεικονιστεί είτε να εφάπτεται της συμβολής ορογόνου μήτρας και σαλπίγγων (USTJ) είτε να τη διασχίζει. Το τμήμα του μικροενθέματος που βρίσκεται στη σάλπιγγα μπορεί να απεικονίζεται ή όχι. Ο γραμμικός άξονας του μικροενθέματος πρέπει να απεικονίζεται προκειμένου να επιβεβαιώνεται ότι δεν έχει συστραφεί ή επιμηκυνθεί.

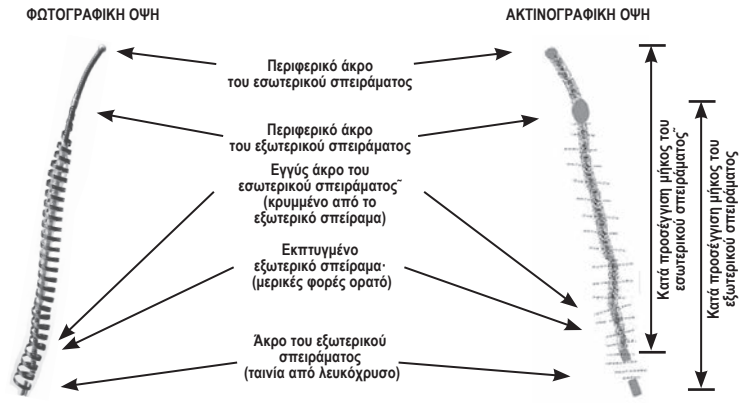


Ικανοποιητική θέση

    - **d) Μη ικανοποιητική θέση**
        - **(1) Η θέση του μικροενθέματος είναι μη ικανοποιητική αν κάποιο τμήμα κάθε μικροενθέματος δεν μπορεί να απεικονιστεί στο κέρας στην στεφανιαία ή τη λοξή στεφανιαία προβολή, στην εικόνα ανίχνευσης.**
        - **(2) Εξώθηση του μικροενθέματος πιθανολογείται αν το ένα ή και τα δύο μικροενθέματα δεν εντοπίζονται στο κέρας στη στεφανιαία προβολή μίας μόνο εικόνας ανίχνευσης.**
        - **(3) Περιφερική τοποθέτηση πιθανολογείται αν το εγγύς άκρο του μικροενθέματος δεν βρίσκεται εντός του μυομητρίου στο κέρας (διάμεσο τμήμα της σάλπιγγας) και δεν διασχίζει ούτε εφάπτεται της συμβολής ορογόνου μήτρας και σάλπιγγας (USTJ).**
        - **(4) Εγγύς τοποθέτηση πιθανολογείται αν περισσότερο από το 50% ή το μεγαλύτερο μέρος του μικροενθέματος απεικονίζεται στη μητριαία κοιλότητα ή αν ο γραμμικός άξονας του (των) μικροενθέματος(ων) απεικονίζεται στην οβελιαία προβολή μέσης γραμμής.**
        - **(5) Διάτρηση πιθανολογείται αν ο γραμμικός άξονας ενός ή και των δύο μικροενθεμάτων είναι παράλληλος προς τη γραμμή του ενδομητρίου στην οβελιαία όψη ή αν ο γραμμικός άξονας ενός μικροενθέματος απεικονίζεται να διασχίζει το μυομήτριο στην οβελιαία προβολή μέσης γραμμής.**
        - **(6) Μη ταξινομημένη θέση: Αν ο γραμμικός άξονας ενός μικροενθέματος δεν μπορεί να προσδιοριστεί, κάτι που υποδηλώνει ότι έχει συστραφεί ή επιμηκυνθεί, η θέση του μικροενθέματος θεωρείται μη ικανοποιητική. Αν ο περιβάλλων μαλακός ιστός δεν μπορεί να προσδιοριστεί σαφώς, η θέση του μικροενθέματος θεωρείται μη ικανοποιητική.**
3. **Αν τα αποτελέσματα της υπερηχογραφικής αξιολόγησης είναι διφορούμενα ή μη ικανοποιητικά, η ασθενής πρέπει να προχωρά σε διενέργεια υστεροσαλπιγγογραφίας (HSG) προκειμένου να αξιολογείται η θέση του μικροενθέματος και η απόφραξη των σαλπίγγων.**

D. Πυελική ακτινογραφία

1. **Λάβετε μια εικόνα της μήτρας με αμφότερα τα μικροενθέματα Essure να φαίνονται καθαρά. Θα πρέπει να σημειώνεται η θέση και η καμπυλότητα των μικροενθεμάτων.**



Αντίστοιχη ακτινογραφική όψη του μικροενθέματος **Essure**

2. **Αξιολογήστε την πυελική ακτινογραφία ως ακολούθως:**
    - **a) Ικανοποιητική: Τα μικροενθέματα φαίνονται ότι είναι στον αυλό της σάλπιγγας, καλύπτουν την υστεροσαλπιγγική συμβολή και εμφανίζονται σχετικά συμμετρικά. Οι ασθενείς, των οποίων οι ακτινογραφίες προσδιορίζονται ότι είναι «ικανοποιητικές» μπορούν να αρχίζουν να βασίζονται στο μικροένθεμα Essure για αντισύλληψη.**
    - **b) Ύποπτη: Ένα ή αμφότερα τα μικροενθέματα φαίνονται ότι είναι περιφερικά ή εγγύς στη βέλτιστη θέση ή μπορεί να έχουν διατρήσει μερικώς ή εντελώς μέσω της σάλπιγγας ή/και να εμφανίζονται σχετικά ασύμμετρα. Στις ασθενείς των οποίων οι ακτινογραφίες προσδιορίζονται ότι είναι «ύποπτες» θα πρέπει να δίνονται οδηγίες να συνεχίζουν μια εναλλακτική μέθοδο αντισύλληψης και να υποβάλλονται σε υστεροσαλπιγγογραφία (HSG).**
    - **c) Μη ικανοποιητική: Εμφανής ενδοπεριτοναϊκή θέση ή εξώθηση του μικροενθέματος.**
3. **Αν τα αποτελέσματα της ακτινογραφικής αξιολόγησης είναι διφορούμενα ή μη ικανοποιητικά ή αν η θέση του μικροενθέματος είναι ύποπτη, η ασθενής πρέπει να προχωρά σε διενέργεια υστεροσαλπιγγογραφίας (HSG) προκειμένου να αξιολογείται η θέση του μικροενθέματος και η απόφραξη των σαλπίγγων.**

E. Εκτέλεση και αξιολόγηση τροποποιημένων υστεροσαλπιγγογραφιών (HSG)

1. **Η υστεροσαλπιγγογραφία εκτελείται για την περαιτέρω αξιολόγηση της θέσης του μικροενθέματος Essure και της απόφραξης της σάλπιγγας αν αυτό απαιτείται βάσει των ακτινογραφικών ή των υπερηχογραφικών ευρημάτων. Ακολουθήστε τις παρακάτω οδηγίες για την εκτέλεση και την αξιολόγηση της υστεροσαλπιγγογραφίας (HSG).**
2. **Εκτέλεση της υστεροσαλπιγγογραφίας (HSG) – Κατευθυντήριες οδηγίες:**
    - **a) Το περίγραμμα της μητριαίας κοιλότητας θα πρέπει να διακρίνεται σαφώς με καλή πλήρωση του κέρατος.**
    - **b) Η δέσμη της ακτινοσκόπησης σε σχέση με τη μήτρα θα πρέπει να είναι όσο το δυνατόν πιο κοντά στην Π/Ο προβολή.**
    - **c) Ο τράχηλος δεν πρέπει να διατείνεται. Εφόσον λάβει χώρα διάταση, διατηρήστε καλή στεγανοποίησή του.**
    - **d) Ενδέχεται να απαιτηθεί έλξη προς τα κάτω στο τραχηλικό άγκιστρο σε ασθενείς των οποίων η μήτρα βρίσκεται σε μέση θέση. Αφαιρέστε το μητροσκόπιο πριν από την ακτινοσκόπηση για την καλύτερη απεικόνιση της ανατομίας της μήτρας.**

e) Λάβετε τουλάχιστον έξι ακτινογραφίες για την αξιολόγηση της θέσης του μικροενθέματος και της απόφραξης των σαλπίγγων.

(1) Ακτινογραφία 1 – «Φιλμ ανίχνευσης» - Η μήτρα και τα μικροενθέματα χωρίς σκιαγραφικό μέσο.

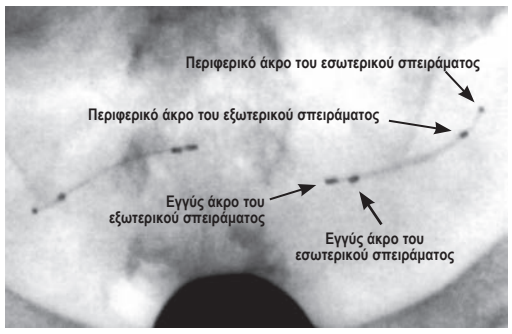
(2) Ακτινογραφία 2 – Ελάχιστη πλήρωση της κοιλότητας – Η μήτρα και τα μικροενθέματα με μικρή ποσότητα σκιαγραφικού μέσου.

(3) Ακτινογραφία 3 – Μερική πλήρωση της κοιλότητας - Η μήτρα και τα μικροενθέματα όταν η μητριαία κοιλότητα είναι σχεδόν πλήρης σκιαγραφικού μέσου.

(4) Ακτινογραφία 4 – Ολική πλήρωση της κοιλότητας - Η μήτρα και α μικροενθέματα με όταν το κέρας έχει διαταθεί από το σκιαγραφικό μέσο.

(5) Ακτινογραφίες 5 & 6- Μεγεθύνσεις του μητριαίου κέρατος – Το μικροένθεμα εντός της σάλπιγγας με το δεξιό (5) και το αριστερό (6) κέρατο.

ΠΡΟΣΟΧΗ: Η υπερβολική ενδομήτρια πίεση, πέραν από αυτήν που απαιτείται για τη λήψη της Ακτινογραφίας 4, θα πρέπει να αποφεύγεται, ώστε να αποφευχθεί η μη αναγκαία δυσφορία της ασθενούς και η αγγειοπνευμονογαστρική αντίδραση.



3. Αξιολόγηση της θέσης του μικροενθέματος

a) Κατά την αξιολόγηση, σημειώστε τους τέσσερις «δείκτες» σε κάθε άκρο των εσωτερικών και των εξωτερικών σπειραμάτων). Σημειωτέον ότι οι περιφερικοί δείκτες είναι σταθεροί σε σχέση με τη μεταξύ τους θέση, αλλά οι εγγύς δείκτες ενδέχεται να μετακινηθούν ή να φαίνονται τεντωμένοι λόγω της ελαστικότητας του εξωτερικού σπειράματος. Η ιδανική θέση του μικροενθέματος επιτυγχάνεται όταν το εσωτερικό σπείραμα διασχίζει την υστεροσαλπιγγική συμβολή.

b) Αξιολόγηση της θέσης του μικροενθέματος:

(1) Εξώθηση ή εγγύς τοποθέτηση: Το μικροένθεμα δεν υπάρχει ή το ≥ 50% του εσωτερικού σπειράματος έχει εισχωρήσει στη μητριαία κοιλότητα.

(2) Ικανοποιητική τοποθέτηση: Το περιφερικό άκρο του εσωτερικού σπειράματος βρίσκεται εντός της σάλπιγγας, με < 50% του εσωτερικού σπειράματος να έχει εισχωρήσει στη μητριαία κοιλότητα ή το εγγύς άκρο του εσωτερικού σπειράματος βρίσκεται ≤ 30 mm εντός της σάλπιγγας από όπου το σκιαγραφικό μέσο πληροί το κέρας.

(3) Περιφερική τοποθέτηση ή διάτρηση: Το μικροένθεμα βρίσκεται εντός της σάλπιγγας αλλά το περιφερικό άκρο του εσωτερικού σπειράματος βρίσκεται > 30mm περιφερικά από το σημείο όπου το σκιαγραφικό μέσο πληροί το κέρας ή το μικροένθεμα έχει υποστεί πλήρη ή μερική διάτρηση.

4. Αξιολόγηση της απόφραξης των σαλπίγγων

a) Προσδιορίστε αν το σκιαγραφικό μέσο είναι ορατό πέραν από το μικροένθεμα και σημειώστε οποιονδήποτε βαθμό εγγύς πλήρωσης των σαλπίγγων ακόμα και αν η σάλπιγγα είναι αποφραγμένη.

b) Αξιολόγηση της απόφραξης των σαλπίγγων:

(1) Ικανοποιητική απόφραξη: Η σάλπιγγα είναι αποφραγμένη στο κέρας.

(2) Ικανοποιητική απόφραξη: Το σκιαγραφικό μέσο διακρίνεται εντός της σάλπιγγας αλλά όχι πέρα από το περιφερικό άκρο του εξωτερικού σπειράματος.

(3) Μη ικανοποιητική απόφραξη: Το σκιαγραφικό μέσο διακρίνεται πέρα από το περιφερικό άκρο του μικροενθέματος ή στην περιτοναϊκή κοιλότητα.

5. Αξιολόγηση της απόδοσης

a) Αν τόσο η θέση του μικροενθέματος όσο και η απόφραξη των σαλπίγγων θεωρείται ικανοποιητική, ζητήστε από την ασθενή να διακόψει την εναλλακτική μέθοδο αντισύλληψης.

b) Αν η θέση του μικροενθέματος είναι μη ικανοποιητική, ζητήστε από την ασθενή να μην βασιστεί στα μικροενθέματα ως μέθοδο αντισύλληψης.

c) Αν η θέση του μικροενθέματος είναι ικανοποιητική αλλά η απόφραξη είναι μη ικανοποιητική, ζητήστε από την ασθενή να συνεχίσει την εναλλακτική μέθοδο αντισύλληψης. Επαναλάβετε την υστεροσαλπιγγογραφία (HSG) σε τρεις μήνες. Αν η απόφραξη εξακολουθεί να είναι μη ικανοποιητική, ζητήστε από την ασθενή να μην βασιστεί στα μικροενθέματα ως μέθοδο αντισύλληψης.

X. ΑΝΤΙΜΕΤΩΠΙΣΗ ΤΗΣ ΜΗ ΙΚΑΝΟΠΟΙΗΤΙΚΗΣ ΘΕΣΗΣ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ

A. Διάγνωση με υστεροσαλπιγγογραφία μη ικανοποιητικής θέσης του μικροενθέματος

1. Εγγύς θέση: περισσότερο από 50% του μήκους του εσωτερικού σπειράματος του(ων) μικροενθέματος(ων) έχει εισχωρήσει μέσα στη μήτρα.
2. Περιφερική θέση: Το(α) μικροένθεμα(α) βρίσκεται στη σάλπιγγα αλλά το εγγύς άκρο του εσωτερικού σπειράματος απέχει περισσότερο από 30 mm από το σκιαγραφικό μέσο που πληροί το μητριαίο κέρας.
3. Πλήρης εξώθηση του(ων) μικροενθέματος(ων), το(ο) μικροένθεμα(τα) δεν υπάρχει(ουν) στο σώμα
4. Διάτρηση: το(α) μικροένθετο(α) έχει(ουν) διατρήσει τη σάλπιγγα μερικώς ή πλήρως.
5. Ενδοπεριτοναϊκή θέση του(ων) μικροενθέματος(ων), το(α) μικροένθεμα(α) είναι προφανώς εκτός της(ων) σάλπιγγας(ων).

B. Αντιμετώπιση της εξώθησης του μικροενθέματος ή της μη ικανοποιητικής θέσης του μικροενθέματος

1. <u>Αμφοτερόπλευρη εξώθηση του μικροενθέματος με αμφοτερόπλευρη απόφραξη</u>: θα πρέπει να ενημερωθεί η ασθενής σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή ή να βασιστεί στην αμφοτερόπλευρη ΑΕΣ (απόφραξη εγγύς σάλπιγγας) για αντισύλληψη, εν όψει του ενδεχόμενου για μια ψευδώς θετική διάγνωση απόφραξης των σαλπίγγων με τεστ επιβεβαίωσης Essure (HSG).
2. <u>Αμφοτερόπλευρη εξώθηση του μικροενθέματος με απόφραξη στη μία σάλπιγγα και βατότητα στην αντίπλευρη σάλπιγγα</u>: Η ασθενής μπορεί να ληφθεί υπόψη για επιπλέον διαδικασία τοποθέτησης μικροενθέματος για την επανατοποθέτηση του μικροενθέματος στη σάλπιγγα που είναι βατή, έτσι ώστε να μπορεί να βασιστεί στο ένα μικροένθεμα Essure και στην αντίπλευρη ΑΕΣ για αντισύλληψη. Η ασθενής θα πρέπει να ενημερωθεί σχετικά με την επιλογή αυτή, εν όψει της δυνατότητας για μια ψευδώς θετική διάγνωση απόφραξης των σαλπίγγων με τεστ επιβεβαίωσης Essure (HSG). Θα πρέπει να ενημερωθεί επίσης σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή.
3. <u>Ετερόπλευρη εξώθηση του μικροενθέματος ή μη ικανοποιητική θέση του ετερόπλευρου μικροενθέματος (στο μυομήτριο ή στην ενδοπεριτοναϊκή κοιλότητα) με το αντίπλευρο μικροοένθεμα σε ικανοποιητική θέση</u>: Εάν το τεστ επιβεβαίωσης Essure (HSG) καταδεικνύει απόφραξη της σάλπιγγας από όπου εξωθήθηκε το μικροένθεμα ή όπου θα έπρεπε να είχε τοποθετηθεί το μικροένθεμα, η ασθενής μπορεί να βασίζεται στο ικανοποιητικά τοποθετημένο μικροένθεμα και στην αντίπλευρη ΑΕΣ, εν όψει του ενδεχόμενου για μια ψευδώς θετική διάγνωση απόφραξης των σαλπίγγων με τεστ επιβεβαίωσης Essure (HSG). Θα πρέπει να ενημερωθεί επίσης σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή.
4. Μη ικανοποιητική θέση του ετερόπλευρου μικροενθέματος (στο μυομήτριο ή στην ενδοπεριτοναϊκή κοιλότητα) με το αντίπλευρο μικροένθεμα σε ικανοποιητική θέση: Εάν το τεστ επιβεβαίωσης Essure (HSG) καταδεικνύει βατότητα της σάλπιγγας στην οποία θα έπρεπε να έχει τοποθετηθεί ένα μικροένθεμα, μπορεί να δοθεί η δυνατότητα στην ασθενή να επανέλθει για μια επιπλέον διαδικασία τοποθέτησης του μικροενθέματος για εκ νέου απόπειρα τοποθέτησης, θα πρέπει να ενημερωθεί επίσης σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή.
5. <u>Εξώθηση ετερόπλευρου μικροενθέματος. μη ικανοποιητική θέση ετερόπλευρου μικροενθέματος (στο μυομήτριο ή στην ενδοπεριτοναϊκή κοιλότητα), μη ικανοποιητική θέση ετερόπλευρου μικροενθέματος στην "εγγύς θέση" (>50% του μήκους του εσωτερικού σπειράματος ένει εισχωρήσει στη μήτρα) ή στην "περιφερική θέση" (το μικροένθεμα βρίσκεται στη σάλπιννα αλλά το εγγύς άκοο του εσωτερικού σπειράματος απέχει >30 mm από το σκιαγραφικό μέσο που πληροί το μητριαίο κέρας) με το αντίπλευρο μικροένθεμα σε μη ικανοποιητική θέση</u>: Η ασθενής θα πρέπει να ενημερωθεί σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή. Σε όλες τις περιπτώσεις, εάν κρίνεται απαραίτητη η αφαίρεση του μικροενθέματος και η υστεροσκοπική αφαίρεση δεν είναι δυνατή, ενδέχεται να απαιτηθεί χειρουργική επέμβαση με τομή.
6. Εάν μια ασθενής έχει επιλέξει στείρωση με χειρουργική τομή μετά από οποιοδήποτε από τα σενάρια που αναφέρονται παραπάνω, θα πρέπει να αποφραχθούν αμφότερες οι σάλπιγγες ανεξαρτήτως της παρουσίας οποιουδήποτε μικροενθέματος που βρίσκεται σε ικανοποιητική θέση. θα πρέπει να επιχειρηθεί η ανάκτηση ενός μικροενθέματος εάν ο ιατρός πιστεύει ότι μπορεί να γίνει με ασφάλεια, ωστόσο η ανάκτηση του μικροενθέματος ενδέχεται να μην είναι δυνατή. Συνιστάται η χρήση διεγχειρητικής ακτινοσκόπησης για την αναγνώριση της θέσης του(ων) μικροενθέματος(ων) πριν και κατά τη διάρκεια της χειρουργικής επέμβασης. Η απόπειρα ανάκτησης δεν θα πρέπει να υπερβαίνει τα 30 λεπτά.

XI. Αντιμετώπιση περιπτώσεων με μη επιτυχή τοποθέτηση μικροενθέματος Essure

Σε περίπτωση αποτυχίας τοποθέτησης ετερόπλευρου ή αμφοτερόπλευρου μικροενθέματος, θα πρέπει να ενημερωθεί η ασθενής ότι δεν έχει ολοκληρωθεί η μόνιμη αντισύλληψη της. Εάν η ασθενής επιλέξει λαπαροσκοπική στείρωση (δηλ. εφαρμογή κλιπ ή ηλεκτροκαυτηρίαση), θα πρέπει να εφαρμοστούν κλιπ ή να καυτηριαστούν αμφότερες οι σάλπιγγες, ακόμα και εάν έχει εμφυτευτεί το μικροένθεμα Essure στη μία σάλπιγγα. Η εφαρμογή κλιπ ή η καυτηρίαση της σάλπιγγας ή των σαλπίγγων θα πρέπει να εκτελείται περιφερικά προς το μικροένθεμα Essure.

Εάν η ασθενής δεν επιλέξει λαπαροσκοπική στείρωση, μπορεί να της παρασχεθεί η δυνατότητα τεστ επιβεβαίωσης Essure (HSG) μετά την επόμενη έμμηνο ρύση της (προ-ωοθυλακιοωορρηκτική: ημέρα 7-14 όπου η ημέρα 1 αντιπροσωπεύει την πρώτη ημέρα αιμορραγίας) για τον προσδιορισμό της βατότητας των σαλπίγγων. Εάν παρατηρηθεί βατότητα των σαλπίγγων, ο ιατρός μπορεί να παρέχει στην ασθενή τη δυνατότητα δεύτερης απόπειρας τοποθέτησης του μικροενθέματος. Εάν αποτύχει μια δεύτερη απόπειρα τοποθέτησης του μικροενθέματος, η ασθενής είναι απίθανο να έχει επιτυχία στις επακόλουθες απόπειρες. Εάν έχει παραμείνει στην ασθενή ένα μικροένθεμα *in vivo* θα πρέπει να ενημερωθεί να μη βασίζεται στο ετερόπλευρο μικροένθεμα για αντισύλληψη.

Εάν έχει επιτευχθεί μόνον ετερόπλευρη τοποθέτηση και το τεστ επιβεβαίωσης Essure (HSG) επιβεβαιώσει αντίπλευρη απόφραξη της εγγύς σάλπιγγας (ΑΕΣ), θα πρέπει να ενημερωθεί η ασθενής σχετικά με την επιλογή να βασίζεται στο ένα μικροένθεμα, εν όψει του ενδεχόμενου για μια ψευδώς θετική διάγνωση της ΑΕΣ με τεστ επιβεβαίωσης Essure (HSG). Η απόφραξη της σάλπιγγας ορίζεται ως η αποτυχία διόδου της χρωστικής από τη μητριαία κοιλότητα εντός της περιτοναϊκής κοιλότητας κατά στιγμή διενέργειας του τεστ επιβεβαίωσης Essure (HSG). θα πρέπει να ενημερωθεί επίσης σχετικά με την επιλογή να υποβληθεί σε στείρωση με χειρουργική τομή. Δεν συνιστάται απόπειρα αφαίρεσης ενός ετερόπλευρα τοποθετημένου μικροενθέματος, εκτός εάν η ασθενής παρουσιάζει τυχόν ανεπιθύμητες ενέργειες με το μικροένθεμα.

XII. Αφαίρεση μικροενθέματος Essure

ΠΡΟΕΙΔΟΠΟΙΗΣΗ: ΜΕΤΑ ΤΗΝ ΤΟΠΟΘΕΤΗΣΗ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ, ΔΕΝ ΘΑ ΠΡΕΠΕΙ ΝΑ ΕΠΙΧΕΙΡΗΘΕΙ ΑΦΑΙΡΕΣΗ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ ΥΣΤΕΡΟΣΚΟΠΙΚΑ, ΕΚΤΟΣ ΕΑΝ ΕΧΟΥΝ ΉΔΗ ΕΙΣΧΩΡΗΣΕΙ 18 Ή ΠΕΡΙΣΣΟΤΕΡΑ ΣΠΕΙΡΑΜΑΤΑ ΤΟΥ ΜΙΚΡΟΕΝΘΕΜΑΤΟΣ Essure ΜΕΣΑ ΣΤΗ ΜΗΤΡΙΑΙΑ ΚΟΙΛΟΤΗΤΑ. Θα πρέπει να επιχειρηθεί αφαίρεση ενός τέτοιου μικροενθέματος αμέσως μετά την τοποθέτηση. Ωστόσο, η αφαίρεση ενδέχεται να μην είναι δυνατή. Εάν επιχειρηθεί αφαίρεση, θα πρέπει να εφαρμοστούν τα ακόλουθα βήματα:

1. Εισαγάγετε ένα εργαλείο σύλληψης μέσω του καναλιού εργασίας του υστεροσκοπίου.
2. Συλλάβετε το εξωτερικό σπείραμα του μικροενθέματος Essure. Προσπαθήστε να συλλάβετε μαζί το εξωτερικό και το εσωτερικό σπείραμα του μικροενθέματος.
3. Τραβήξτε προς τα πίσω το εργαλείο σύλληψης και το υστεροσκόπιο ταυτόχρονα, έτσι ώστε να αποσυρθεί από κοινού ολόκληρο το σύστημα από τη μήτρα.
4. Το εξωτερικό σπείραμα ή/και το εσωτερικό σπείραμα του μικροενθέματος Essure μπορεί να εκταθούν ή να επιμηκυνθούν καθώς επιχειρείται η αφαίρεση του μικροενθέματος.
5. Ανάλογα με τις ανάγκες, χορηγήστε αναλγησία/αναισθησία για τη μείωση ή την πρόληψη της δυσφορίας της ασθενούς.
6. Εάν επιτευχθεί η πλήρης αφαίρεση του μικροενθέματος, θα πρέπει να επιχειρηθεί η τοποθέτηση ενός άλλου μικροενθέματος Essure.
7. Εάν ο ιατρός δεν είναι πλήρως ικανοποιημένος από την αφαίρεση ολόκληρου του μικροενθέματος Essure από τη σάλπιγγα, ΔΕΝ θα πρέπει να τοποθετηθεί ένα άλλο μικροένθεμα στη σάλπιγγα αυτή και θα πρέπει να ληφθεί μια ακτινογραφία μετά την τοποθέτηση για να προσδιοριστεί εάν παραμένει τυχόν τεμάχιο μικροενθέματος *in vivo*.

Εκτός από το σενάριο που περιγράφεται παραπάνω, θα πρέπει να επιχειρηθεί αφαίρεση του μικροενθέματος μόνον εφόσον η ασθενής παρουσιάζει ανεπιθύμητη(ες) ενέργεια(ες) με το μικροένθεμα ή απαιτεί αφαίρεση του μικροενθέματος.

Εάν κρίνεται απαραίτητη η αφαίρεση του μικροενθέματος, απαιτείται διακοιλιακή προσέγγιση (δηλ. λαπαροτομή ή λαπαροσκόπηση).

Εάν το μικροένθεμα έχει τοποθετηθεί σωστά κατά πλάτος της υστεροσαλπιγγικής συμβολής (ΥΣΣ) θα απαιτηθεί εκτομή κέρατος της εγγύς μοίρας της σάλπιγγας.

Ένα μικροένθεμα Essure που έχει τοποθετηθεί εσφαλμένα ή έχει μεταναστεύσει πέρα από την ΥΣΣ θα πρέπει να αφαιρείται με παραδοσιακή γραμμική σαλπιγγοτομή ή σαλπιγγεκτομή, η οποία επιτυγχάνεται μέσω λαπαροσκόπησης ή λαπαροτομής.

1. Για την εκτέλεση μιας γραμμικής σαλπιγγοτομής, γίνεται μια μικρή τομή (μήκους περίπου 2 cm) κατά μήκος του αντιμεσεντερικού ορίου της σάλπιγγας, απευθείας υπερκείμενη του μικροενθέματος.
2. Μπορεί να εκτελεστεί ολική ή μερική σαλπιγγεκτομή για την ανάκτηση του μικροενθέματος σε συνδυασμό με ή ανεξάρτητα από την εκτέλεση της καθιερωμένης διαδικασίας σαλπιγγικής στείρωσης.

XIII. ΚΑΡΤΑ ΤΑΥΤΟΤΗΤΑΣ ΑΣΘΕΝΟΥΣ

Σε κάθε ασθενή στην οποία είχε(αν) εμφυτευτεί μικροένθεμα(τα) Essure θα πρέπει να δίνεται μια πλαστικοποιημένη κάρτα μεγέθους πορτοφολιού, η οποία αναφέρει ότι φέρει μικροένθεμα(τα) Essure. Η κάρτα εσωκλείεται στη συσκευασία αυτή. Η κάρτα θα αναφέρει επιπλέον ότι ενδέχεται να υπάρχουν κίνδυνοι που σχετίζονται με το ενδεχόμενο η συμμετέχουσα να υποβληθεί σε μελλοντικές ενδομήτριες διαδικασίες ή χειρουργική επέμβαση στα όργανα αναπαραγωγής.

XIV. ΕΠΕΞΗΓΗΣΗ ΣΥΜΒΟΛΩΝ

STERILE EO	Αποστειρωμένο με οξείδιο του αιθυλενίου	MR	Ασφαλές υπό προϋποθέσεις κατά τη χρήση με συστήματα μαγνητικού συντονισμού
LOT	Κωδικός παρτίδας		
	Μην επαναχρησιμοποιείτε	EC REP	Εξουσιοδοτημένος αντιπρόσωπος για την Ευρώπη
REF	Αριθμός καταλόγου	CE 0050	Η συσκευή είναι σύμφωνη με την Ευρωπαϊκή οδηγία 93/42/ΕΚ
	Προσοχή, δείτε τις οδηγίες χρήσης		
	Ημερομηνία λήξης		Διατηρείτε στεγνό
	Διατηρείτε μακριά από θερμότητα	CONT	Περιεχόμενο
	Μη χρησιμοποιείτε το προϊόν εάν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά		

Κατασκευάζεται από την:
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Εξουσιοδοτημένος αντιπρόσωπος για την Ευρώπη:
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D-13353 Berlin
Γερμανία

Για παραγγελίες προϊόντων ή αναφορά ανεπιθύμητων ενεργειών, παρακαλούμε επικοινωνήστε με τον τοπικό αντιπρόσωπο της Bayer HealthCare LLC.

Ανακυκλώσιμο

PN-84731145, ART Rev. B

10.7 Appendix 7: Patient Information Brochure

Your complete Guide to the Essure® Procedure

When you're done having children, consider Essure® permanent birth control

YOUR COMPLETE GUIDE TO THE ESSURE® PROCEDURE

essure®

FOR MORE INFORMATION

Visit essure.com

or call 1-888-842-2937

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Your Complete Guide: The Essure Procedure

GLOSSARY

Anesthesia: Medically-induced partial or complete loss of sensation in all or part of the body. Loss of sensation may occur with or without loss of consciousness.

Cervix: The passageway that connects the vagina with the uterus.

Contraceptive: Any process, device, or method that reduces the likelihood of pregnancy.

Ectopic Pregnancy: The development of a fertilized egg outside the uterus, such as in a fallopian tube. Ectopic pregnancies can be dangerous and possibly life-threatening.

Essure Insert: The small, soft, flexible device that is placed in your fallopian tubes for permanent pregnancy prevention.

Fallopian Tubes: The tubes that carry the eggs from the ovaries to the uterus.

General Anesthesia: Medication that induces total loss of consciousness and sensation.

Hysterosalpingogram (HSG): An X-ray of the uterus and fallopian tubes after they have been filled with contrast dye.

Hysteroscope: A telescopic instrument that is used to view the inside of the uterus.

In Vitro Fertilization (IVF): Fertilization of an egg outside the body. Once fertilized, the egg is placed into the uterus.

Intrauterine Device (IUD)/Intrauterine Contraceptive (IUC): A medical device that is placed in the uterus for temporary prevention of pregnancy.

Local Anesthetic: Medication that is applied or injected to numb a certain part of the body.

NovaSure® Endometrial Ablation: A procedure that removes the lining of the uterus to lighten or stop your periods.

Occlusion: An obstruction or a closure of a passageway or a vessel.

Tubal Ligation: A form of permanent birth control by means of cutting, tying, burning or clipping the fallopian tubes so that they are blocked.

Uterus: The womb, where a developing fetus grows.

Vasectomy: Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).

WHAT IS ESSURE?

Essure is a permanent birth control procedure that works with your body to create a natural barrier against pregnancy. The Essure procedure involves placing soft, flexible inserts into your fallopian tubes. Over a period of about three months, tissue forms around the inserts. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs and prevents conception.

Essure insert – Actual size

Essure may be right for you if:

- You are certain you do not want any more children.
- You desire a permanent form of birth control.
- You would like to stop worrying about getting pregnant.
- You prefer a method or procedure that
  - Is simple and does not take a lot of time.
  - Can be done in your doctor's office.
  - Does not require surgery or exposure to its potential risks.
  - Does not contain any hormones.

Essure is NOT right for you if:

- You suspect you are pregnant.
- You have only one fallopian tube.
- You have one or both fallopian tubes closed or obstructed.
- You have had your "tubes tied" (tubal ligation).
- You are allergic to contrast dye used during x-ray exams.
- You are unwilling to undergo the Essure Confirmation Test.
- You are uncertain about ending your fertility.

You should delay having the Essure procedure if:

- You are or have been pregnant within the past 6 weeks.
- You have had a recent pelvic infection.
- You are in the second half (weeks 3 and 4) of your menstrual cycle. During that time, there is an increased risk of being pregnant prior to having the Essure procedure.

You should speak to your doctor if:

- You are taking or receiving therapy that suppresses your immune system. Examples include chemotherapy or corticosteroids, such as prednisone. Therapy that suppresses the immune system may make the Essure procedure less effective for birth control.
- You have, or think you may have, a nickel allergy.

Talk to your Doctor about the Essure procedure and whether it is right for you.

IMPORTANT: Essure inserts do not protect against HIV or other sexually transmitted diseases.

Your Complete Guide: The Essure Procedure

THE BENEFITS OF ESSURE

Highly Effective
The Essure procedure is 99.83% effective based on five-year clinical study data.

Available for Over 10 Years
Since FDA approval in 2002, over half a million women have relied on Essure.

Non-Surgical Procedure
Essure is a simple procedure that can be done in 10 minutes in your doctor's office.

Non-Hormonal
Essure inserts do not contain or release hormones.

No General Anesthesia Required
You can remain fully conscious during the procedure.

Quick Recovery
Most women return to normal activity within one to two days.

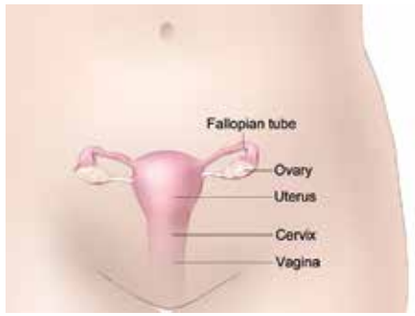
Benefit of Confirmation
An Essure Confirmation Test will verify that the inserts are placed correctly so that you can rely on Essure for birth control.

ESSURE PROCEDURE OVERVIEW

Step 1

Placing the Essure inserts

The Essure procedure is usually performed in your doctor's office. During the procedure, the doctor will place a tiny insert into each of your fallopian tubes. The inserts are soft and flexible, and are delivered with a tube through your vagina and cervix, and into your fallopian tubes. No incisions are needed.



Step 2

Waiting for the natural barrier to form

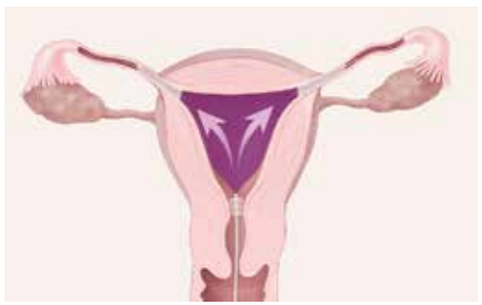
Over the next 3 months, your body will form tissue around the Essure inserts. The tissue forms a natural barrier within the fallopian tubes. The barrier prevents sperm from reaching the eggs that are produced every month. During the 3-month period, you **must** continue using another form of birth control to prevent pregnancy.

Since Essure does not contain hormones that interfere with your body's menstrual cycle, your ovaries will continue to release eggs. Since the eggs cannot be fertilized, they are simply absorbed back into your body.

Step 3

Essure Confirmation Test

After 3 months, a doctor will administer the Essure Confirmation Test. The test will verify that the inserts are in their correct location and your fallopian tubes are blocked. The doctor will use contrast dye and a special type of x-ray during the confirmation test.



IMPORTANT: FOR SOME WOMEN, IT MAY TAKE LONGER THAN 3 MONTHS FOR ESSURE TO COMPLETELY BLOCK THE FALLOPIAN TUBES, REQUIRING A REPEAT CONFIRMATION TEST AT 6 MONTHS. YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. UNTIL YOU RECEIVE CONFIRMATION FROM YOUR DOCTOR, YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY.

Your Complete Guide: The Essure Procedure

WARNINGS, PRECAUTIONS AND OTHER POTENTIAL RISKS

WARNING: Be sure you are done having children before you undergo the Essure procedure. Essure is a permanent method of birth control.

- **The younger a woman is when she chooses to end her fertility, the more likely she is to regret her choice later.**

WARNING: You must continue to use another form of birth control until you have your Essure Confirmation Test and your doctor tells you that you can rely on Essure for birth control.

- You can rely on Essure for birth control only after your doctor has reviewed your Essure Confirmation Test results and told you that you may rely. If you rely on Essure for birth control before having your Essure Confirmation Test, you are at risk of getting pregnant.
- Talk to your doctor about which method of birth control you should use for the 3 months after the procedure. Some women can remain on their current birth control. Other women, such as those using an intrauterine device or contraceptive (IUD or IUC), will need to switch to another method.
- It can take longer than three months for the Essure procedure to be effective. In rare cases, it has taken up to 6 months. Make sure to continue using an alternate form of birth control up until your doctor has reviewed your Essure Confirmation Test results and confirmed that you can rely on Essure for birth control.

Risks: During the Essure procedure

- You may experience mild to moderate pain.
- Your doctor may be unable to place one or both Essure inserts correctly.
- In rare cases, part of an Essure insert may break off. Your doctor may remove the piece or let it leave your body during your period.
- In rare cases, part of an Essure insert may puncture the fallopian tube. Surgery may be necessary to repair the puncture.
- Your body may absorb a large amount of the salt water solution used during the procedure.
- Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.

Risks: Immediately following the procedure

- You may experience mild to moderate pain and/or cramping, vaginal bleeding, and pelvic or back discomfort for a few days after the procedure. Some women experience nausea and/or vomiting or fainting. You should arrange to have someone available to take you home after the procedure.
- In rare instances, an Essure insert may be expelled from the body. This is usually detected during the Essure Confirmation Test.

Risks: During the Essure Confirmation Test

- Because the Essure Confirmation Test requires an x-ray, you will be exposed to very low levels of radiation. This is standard with most x-rays.
- In rare instances, women may experience spotting and/or infection.

Risks: Long-term

- **There are reports of chronic pelvic pain in women, possibly related to Essure.**
- **There are reports of the Essure insert migrating into the lower abdomen and pelvis. If this happens, it may be necessary to surgically remove the migrated device.**
- No birth control method is 100% effective. There is a chance that you can become pregnant after completing the Essure procedure. In the original premarketing studies for Essure, no pregnancies were reported for women who had the Essure inserts for up to 5 years. Although successful pregnancies have been reported with Essure devices in place, if you do become pregnant, the risks to you, the fetus, the pregnancy and childbirth are unknown.
- Women who have the Essure procedure are more likely to have an ectopic pregnancy if they get pregnant. Ectopic pregnancy is when the pregnancy occurs outside of the uterus. The pregnancy usually happens in one of the fallopian tubes. Ectopic pregnancies can be very serious or life-threatening.
- If you have the NovaSure® procedure, a procedure that removes the lining of the uterus to lighten or stop menstrual bleeding, after the Essure procedure, it is unknown if this will affect the blockage in your tubes, and your risk of pregnancy may increase.
- The Essure insert is made of materials that include a nickel-titanium alloy. Once placed inside the body, small amounts of nickel are released from the inserts. Patients who are allergic to nickel may have an allergic reaction to the inserts. Symptoms include rash, itching and hives.

Unknown Risks:

- The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.
- The safety and effectiveness of reversing the Essure procedure are not known.
- The safety and effectiveness of in vitro fertilization (IVF) after the Essure procedure are not known.
- The risks to you and your fetus if you get pregnant after the Essure procedure are not known.

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WHAT TO EXPECT WITH ESSURE

Preparing for your procedure

Your doctor will schedule your Essure procedure for a time soon after your menstrual period ends. This will make it easier for your doctor to see the openings of your fallopian tubes and place the inserts.

The day of your procedure

You will take a pregnancy test before or on the day of your procedure. This will ensure you are not pregnant. Your doctor may also give you medication to take 1 to 2 hours before your procedure to help you relax and open (dilate) your fallopian tubes. This will also help to reduce cramping. Talk to your doctor about the types of medications that are right for you.

During your procedure

Your doctor will first insert an instrument called a speculum inside your vagina. The speculum helps the doctor widen the opening and see inside. Then your doctor will insert a narrow, telescope-like instrument (hysteroscope) through your cervix and into your uterus. A camera attached to the hysteroscope sends video images to a video monitor that lets your doctor see inside your uterus. A salt water solution is used to expand the uterus. This makes it easier for your doctor to find the openings of your fallopian tubes.

The Essure insert is attached to the end of a small, flexible tube that passes through the hysteroscope and into your fallopian tube. Once the insert is placed, the tube is removed.

The procedure is then repeated to place an insert into your other fallopian tube. The entire process usually takes less than ten minutes.

Your doctor will schedule you for an Essure Confirmation Test for 3 months after the procedure.

IMPORTANT: Not all women will achieve successful placement of both Essure inserts. Fewer than 1 out of 12 women are not able to have one or both of the inserts placed. If this occurs, talk to your doctor about a second Essure procedure.

After your procedure

Most women are able to leave the doctor's office about 45 minutes after the procedure is completed. Most return to normal activities within one to two days. Call your doctor if you experience pain, bleeding, fever, vaginal discharge, or other symptoms following the procedure.

It takes about 3 months (sometimes longer) for your body to produce tissue around the inserts and form a barrier to prevent pregnancy. During that time you can still get pregnant. You must rely on another type of birth control to prevent pregnancy during this time period.

IMPORTANT: YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. UNTIL YOU RECEIVE CONFIRMATION FROM YOUR DOCTOR, YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY.

The Essure Confirmation Test
The Essure Confirmation Test verifies that the inserts are in the correct location and that your fallopian tubes are completely blocked.

The Essure Confirmation Test is a type of x-ray exam involving little to no pressure or discomfort. Although the test is similar to the HSG (hysterosalpingogram) test used to diagnose and treat infertility, it is considerably more comfortable.

During the test, a radiologist injects a special contrast dye into your uterus. The dye is visible on x-rays. This lets the radiologist look at your fallopian tubes to confirm that the inserts are properly placed and that your tubes are blocked.

ESSURE PATIENT ID CARD AND PROCEDURES AFTER ESSURE

After your Essure procedure, you will be given an Essure ID card. The ID card tells doctors and others that you have Essure inserts. Show the card when undergoing any procedure involving your uterus or fallopian tube. These include an MRI, D&C, hysteroscopy, endometrial biopsy, or endometrial ablation. Body areas near the inserts may be obscured when they are seen on x-rays, MRIs and other imaging.

IMPORTANT: Women with Essure inserts who undergo MRI procedures should tell their doctor they have been implanted with Essure inserts.

FREQUENTLY ASKED QUESTIONS

Can I trust Essure to prevent pregnancy?
Yes, the Essure procedure is 99.83% effective, based on the original premarketing studies for Essure.

Pregnancies have been reported among the hundreds of thousands of women who have completed the procedure since it became commercially available. Many of those pregnancies were a result of not having completed the procedure (for example not undergoing the Essure Confirmation Test) or not following instructions. In some cases, the Essure Confirmation Test results were misinterpreted by the person reading the test.

Is Essure painful?
There may be some pain associated with placing Essure. Some women report mild discomfort, pain, and cramping during or after the placement procedure. Symptoms may be similar to what they might experience in their normal monthly cycle. There are reports of chronic pelvic pain in women, possibly related to Essure.

Is Essure reversible?
No, the Essure procedure is not reversible. Like having your tubes tied or a vasectomy for men, Essure is permanent birth control. You need to be sure you are done having children before you decide to have the Essure procedure.

Will I still get my period after the Essure procedure?
Yes, you will still have a period. Some women find that their period may become slightly lighter or heavier after the procedure. These changes are often temporary. They may also be due to you stopping your previous hormonal birth control, rather than the Essure procedure.

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What are the Essure inserts made of?
The inserts are made from polyester fibers, nickel-titanium and stainless steel. These same materials have been used for many years in cardiac stents and other medical devices placed in other parts of the body.

Is Essure covered by my insurance?
Some or all of the costs of the Essure procedure are covered by most insurance providers. When the Essure procedure is done in a doctor's office, your cost may be as low as the usual co-pay amount for an office visit/procedure. This depends on your insurance plan.

Review your insurance coverage with your doctor and provider before having the procedure. When you speak with your insurance provider, ask for your plan's specific coverage and reimbursement guidelines for hysteroscopic sterilization (code 58565). This is the code that most plans use to categorize the Essure procedure. Specify if the procedure will be done in a doctor's office, clinic, hospital, etc. The location may affect the amount you will need to cover out of your own pocket.

QUESTIONS TO ASK YOUR DOCTOR

If you are considering having the Essure procedure, here are some questions you might ask your doctor:

- Is Essure right for me compared to other birth control methods?
- Where will my Essure procedure be performed?
- What type of medications will be used before and/or during my procedure?
- How should I prepare?
- What are my options if both inserts cannot be placed on the first attempt?
- How do I schedule my Essure Confirmation Test?
- Can I continue to use my current method of birth control until I have the results of my Essure Confirmation Test?

HOW ESSURE PERFORMED IN CLINICAL STUDIES

The effectiveness and safety of Essure was measured in clinical studies in the United States, Australia, and Europe. Over 700 women between the ages of 21 and 45 were studied.

Was Essure effective in preventing pregnancy?
The primary goal of any birth control method is to prevent pregnancy. Every birth control method has a measured effectiveness rate.

In the original Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to 5 years. The effectiveness rate with Essure was estimated to be 99.83%.

Was the Essure placement procedure successful?
In only a few instances (fewer than 1 out of 12 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes.

The majority of women (96.5%) were able to achieve complete blockage of their fallopian tubes within the expected 3-month period. A small percentage of women (3.5%) took up to 6 months.

Was the Essure procedure safe?
In the original premarketing study, some women reported mild to moderate adverse events during and after the procedure. During the procedure, the most common problem reported was mild to moderate pain (9.3% of women). Some of the women in the study reported moderate pain (12.9% of women) and/or cramping (29.6% of women) on the day of the procedure. A smaller percentage of women reported nausea/vomiting (10.8%) and vaginal bleeding (6.8%). Eighty-eight percent (88%) of women rated tolerance of the placement procedure as good, very good, or excellent.

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HOW ESSURE HAS PERFORMED OUTSIDE OF CLINICAL TRIALS BETWEEN 2002 AND 2010

Pregnancies have been reported with “real world” use of Essure. The table below shows the number of **reported** pregnancies and the most likely reason the pregnancy occurred. The actual number of pregnancies in women with Essure may be higher.

Pregnancies Reported With Essure, 2002-2010*

Potential Contributing Factor	Within The U.S. Number (%)***	Outside the U.S. Number (%)****	Total Number (%)
Patient did not comply with instructions	213 (32%)	16 (18%)	229 (31%)
Essure insert perforated fallopian tube**	91 (14%)	4 (5%)	95 (13%)
Essure inserts were not placed correctly**	32 (5%)	13 (15%)	45 (6%)
Doctor did not comply with instructions	22 (3%)	13 (15%)	35 (5%)
Pregnant at time of placement	26 (4%)	6 (7%)	32 (4%)
Essure Confirmation Test misinterpreted or incomplete**	28 (4%)	0 (0%)	28 (4%)
Essure insert was expelled from the fallopian tube**	20 (3%)	4 (5%)	24 (3%)
Fallopian tube was open/ unobstructed**	19 (3%)	1 (1%)	20 (3%)
Unable to determine cause	209 (32%)	31 (35%)	240 (32%)
Total	**660 (100%)**	**88 (100%)**	**748 (100%)**

* Number of pregnancies reported worldwide since commercial launch in 2001 through the end of 2010. Over that time period, 497,306 Essure kits were sold. This works out to be a “reported” pregnancy rate of 0.15%. The “true” overall pregnancy rate is unknown, because the actual number of pregnancies and the number of devices actually implanted is not known.

** Most of these pregnancies are due to Essure Confirmation Tests that were misinterpreted. In most cases, the Essure inserts were not properly placed but the x-ray indicated that fallopian tubes were blocked.

*** Only HSG was used for these procedures.

**** TransVaginal Ultrasound, HSG, and/or x-ray were acceptable confirmation tests.

Many pregnancies reported by women who had the Essure procedure were preventable. For example, the patient or physician did not follow the Instructions for Use. So it is important that you follow the instructions provided to you by your doctor.

Make sure to:

- Continue to use an alternative form of birth control for at least 3 months following the placement of the Essure inserts.
- See your doctor to have your Essure Confirmation Test 3 months after your Essure inserts are placed.
- Have your doctor confirm that you can rely on Essure inserts for your birth control.

COMPARISON OF PERMANENT BIRTH CONTROL METHODS

The following table provides information about a variety of permanent birth control methods. It includes data on the percentage of women likely to become pregnant within a year and five years while utilizing that method. For a complete list, visit the FDA website at www.fda.gov and search for the Birth Control Guide.

ESSURE

Soft, flexible inserts are delivered through the vagina and uterus and placed in each fallopian tube. A natural barrier forms around the inserts and prevents sperm from reaching the eggs.

No incision is necessary to deliver or place the inserts. General anesthesia is not necessary during the procedure.

Failure rate*
- 0.3 out of 1,000 women at 1 year
- 1.7 out of 1,000 women at 5 years

Recovery Time
1–2 days or sooner

Pain/discomfort
- Cramping
- Discharge

Proof that method was effective
Yes. Three months after the procedure, the Essure Confirmation Test confirms correct insert location and blockage of the fallopian tubes.

TUBAL LIGATION[5]

The fallopian tubes are blocked so that sperm is unable to reach the eggs. One of three methods is used to block the tubes:

- Clamping with metal clips or plastic rings that remain in the body.
- Cutting away a section of the tube.
- Burning a portion of the tube.

The procedure requires an incision and is performed under general anesthesia. Gas is used to expand the abdomen. Stitches or staples are then used to close the incision.

Failure rate*
- 5.5 out of 1,000 women at 1 year
- 13.1 out of 1,000 women at 5 years
- 18.5 out of 1,000 women at 10 years

Recovery time
4–6 days

Pain/discomfort
- Cramping
- Discharge
- Pain at the incision area
- Bruising near the incision area
- Bloated abdomen and/or sharp pains in the neck or shoulder (due to gas used)
- Tired and achy feeling

Proof that method was effective
None.

*Expected number of pregnancies with this method over time.

VASECTOMY (MEN)

The two vas deferens tubes that propel sperm through the urethra are tied in two places with permanent sutures. Between the ties, the tubes are severed using one of three methods:

- Burning a portion of the tube.
- Cutting the tube.
- Blocking the tube with clips or clamps that remain in the body.

The scrotal area is shaved and cleaned with an antiseptic solution. An incision or puncture is made into the scrotum (the sac containing the testicles). Stitches or staples are used to close the cuts.

Failure rate*
- 7.4 out of 1,000 women at 1 year
- 11.3 out of 1,000 women at 5 years

Recovery time
2-3 days

Pain/discomfort
- Bruising
- Pain and swelling in the testicles

Proof that method was effective
Yes. A follow-up sperm count test is performed 3 months after the vasectomy to confirm no sperm are evident.

*Expected number of pregnancies with this method over time.

COMPARISON OF TEMPORARY BIRTH CONTROL METHODS

The following table provides information on a variety of temporary birth control methods. It includes data on the percentage of women likely to become pregnant within a year while utilizing that method. For a complete list, visit the FDA website at www.fda.gov and search for the Birth Control Guide.

Not all temporary methods of birth control listed below can be used during the 3-month waiting period before the Essure Confirmation Test. Talk to your doctor about which form of temporary birth control is right for you.

ORAL CONTRACEPTIVES (COMBINATION ESTROGEN/PROGESTIN PILL)

An estrogen/progestin-based pill that suppresses ovulation.

Failure rate*
80 out of 1,000 women

Risks
Dizziness, nausea, changes in menstruation, mood, and weight gain. Rare events include cardiovascular disease, including high blood pressure, blood clots, heart attack, and stroke.

Routine
Must be taken daily.

ORAL CONTRACEPTIVES (PROGESTIN-ONLY PILL)

A progestin-based pill that inhibits fertilization.

Failure rate*
80 out of 1,000 women

Risks
Irregular bleeding, weight gain, breast tenderness, and less protection against ectopic pregnancy.

Routine
Must be taken daily.

INJECTION (DEPO PROVERA®)

A progestin-containing injection that inhibits ovulation and fertilization.

Failure rate*
30 out of 1,000 women

Risks
Irregular bleeding, weight gain, breast tenderness, and headaches.

Routine
One injection every 1-3 months.

VAGINAL CONTRACEPTIVE RING (NUVARING®)

A flexible ring inserted in the vagina that releases progestin and estrogen to prevent ovulation and fertilization.

Failure rate*
80 out of 1,000 women

Risks
Vaginal discharge, vaginitis, irritation, and other risks similar to those posed by oral contraceptives.

Routine
Inserted by the woman and kept in place for 3-week intervals. If expelled for more than 3 hours during the 3-week interval, another method of birth control must be used.

*Expected number of pregnancies with this method over time.

PATCH (ORTHO EVRA®)
A patch worn on the body that releases progestin and estrogen to prevent ovulation and fertilization.

Failure rate*
80 out of 1,000 women

Risks
Similar to the oral estrogen-progestin pill

Routine
A new patch must be applied every week other than the week of the menstrual period.

IUD/IUC (MIRENA®)
A device placed in the uterus (by a doctor) that emits hormones, preventing ovulation.

Failure rate*
2 out of 1,000 women

Risks
Ovarian cysts, pelvic inflammatory disease, perforation of the uterus, embedding into the uterus, cramps, bleeding, miscarriage, premature birth, breast cancer, nausea, mood swings, headaches, nervousness, inflammation/pain of vagina/uterus, back pain, weight gain, acne, hypertension, and changes in menstrual cycle.

Routine
Remains in place for 1 to 5 years.

IUD/IUC (PARAGUARD®)
A device placed in the uterus (by a doctor) that releases copper, preventing ovulation and fertilization.

Failure rate*
8 out of 1,000 women

Risks
Pelvic inflammatory disease, perforation of the uterus, embedding into the uterus, cramps, bleeding, vaginal discharge, allergic reaction, expulsion, anemia, ectopic pregnancy, life-threatening infection, miscarriage, premature birth, Wilson's disease, vaginal infection, inflammation/pain of vagina/uterus, back pain, pain during sex, fainting, and changes in menstrual cycle.

Routine
Remains in place for 1 to 10 years.

*Expected number of pregnancies with this method over time.

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MALE CONDOM
A sheath placed over the penis that prevents passage of sperm.

Failure rate*
150 out of 1,000 women

Risks
Irritation, allergic reactions, and reduced effectiveness if used with oil-based lubricants.

Routine
Applied immediately before intercourse and used only once.

FEMALE CONDOM
A lubricated sheath placed in the vagina to prevent sperm from entering the uterus.

Failure rate*
210 out of 1,000 women

Risks
Irritation and allergic reactions.

Routine
Applied immediately before intercourse and used only once.

DIAPHRAGM WITH SPERMICIDE
A dome-shaped rubber disk with a flexible rim that covers the cervix. The disk prevents sperm from reaching the uterus. A spermicide must be applied to the dome of the diaphragm before insertion.

Failure rate*
160 out of 1,000 women

Risks
Irritation, allergic reactions, urinary tract infection, and risk of toxic shock syndrome.

Routine
Inserted before intercourse and left in place for 6 to 24 hours afterward. For repeated intercourse, spermicide must be added without removing the diaphragm.

SPERMICIDE
A foam, cream, jelly, film, suppository or tablet containing a sperm-killing chemical (nonoxynol-9).

Failure rate*
290 out of 1,000 women

Risks
Irritation, allergic reactions, and urinary tract infections.

Routine
Instructions vary. Inserted 5 to 90 minutes before intercourse and usually left in place for at least 6 to 8 hours afterward.

PERIODIC ABSTINENCE/RHYTHM METHOD
Deliberately refraining from having sexual intercourse during times when pregnancy is more likely.

Failure rate*
250 out of 1,000 women

Risks
None

Routine
Requires continuous monitoring of ovulation cycle and body temperature.

Data adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition*. New York, NY: Ardent Media; 2007.

*Expected number of pregnancies with this method over time.

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