DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	07/09/2010 - 08/30/2010* FEI NUMBER 3000718335

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Susan Jezior Slane, Divisional Vice President, Quality, Compliance

FIRM NAME	STREET ADDRESS
Abbott Vascular, Inc.	400 Saginaw Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Redwood City, CA 94063-4749	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,

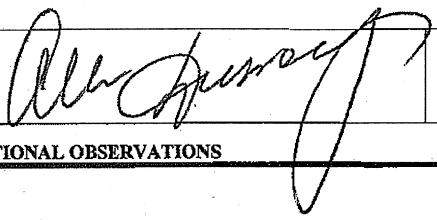
This is a repeat observation from the last inspection in January 2007.

1). Your firm has not submitted the following complaint incidents as Medical Device Reports within 30-days of receiving or otherwise becoming aware of information that your device StarClose SE® Vascular Closure System, Part #14679-01 or #14679-02, may have caused or contributed to a death or serious injury:

126713-1-1, 149041-1-1, 148502-1-1, 147249-2-1

2). Your firm has not submitted the following complaint incidents as Medical Device Reports within 30-days of receiving or otherwise becoming aware of information that your device Perclose® ProGlide™ Suture-Mediated Closure System, Part #12673-03, #12673-04, or #12673-05, may have caused or contributed to a death or serious injury:

151415-4-2, 151415-5-1, 151415-6-1, 151415-7-1, 151415-8-1,
130217-1-1, 136597-1-1, 136598-1-1, 136598-3-1, 136599-1-1,
136599-2-1, 136599-3-1.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Alla Dubrovsky, Investigator 	08/30/2010

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OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

This is a repeat observation from the last inspection in January 2007.

1). Your firm has not submitted the following complaint incidents as Medical Device Reports within 30-days of receiving or otherwise becoming aware of information that Manual Compression was applied after the use of your device StarClose SE® Vascular Closure System, Part #14679-01 or #14679-02, by operating physician to achieve full hemostasis:

134593-1-1, 133283-2-1, 143110-1-1, 135775-2-1, 135775-3-2,
136065-1-1, 133284-2-1, 126757-1-1, 126757-2-1, 126757-3-1,
126757-4-1, 126757-5-1, 126757-6-1, 115680-1-1, 115526-1-1.

2). Your firm has not submitted the following complaint incidents as Medical Device Reports within 30-days of receiving or otherwise becoming aware of information that Manual Compression was applied after the use of your device Perclose® ProGlide™ Suture-Mediated Closure System, Part #12673-03, #12673-04, or #12673-05, by operating physician to achieve full hemostasis:

138537-1-1, 137325-8-1, 131008-1-1, 130217-2-1, 129644-1-1,
129644-4-1, 128652-2-1, 110544-1-1, 110299-1-1, 110299-1-2,
110299-1-3, 108118-1-1, 107187-2-1, 106339-2-1, 106022-1-1.

3). Your firm failed to implement your procedure, (b) (4) (b) (4) - section 2.4 page 3 which states (b) (4) Your firm failed to implement guidelines stated in the meeting minutes of the teleconference with FDA and your firm on 4/10/2008 emailed by your firm to FDA, where your firm "acknowledged understanding of this."

4). Your firm failed to implement your procedure (b) (4) eff. 6/17/2010 - (b) (4)

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(b) (4) page 1 #A4 and page 2 #8 - that states that (b) (4)

"Difficult to Remove" was identified by your firm as a malfunction and the CAPA process (b) (4) was open on 1/7/2009.

I reviewed a complaints log for Abbott Vascular product StarClose SE, Part #14679-01 and #14679-02, from 3/11/2008 to 7/13/2010, which contained 1829 complaints total. 590 complaints had "Reported Dev Code" = "Difficult to Remove". I identified at least 255 complaints classified by the firm as not MDR Reportable event, where "Reported Dev Code" = "Difficult to Remove". At least 255 complaints with this failure mode were not reported. For example, complaint incident #134593-1-1.

At least 3 complaints with this failure mode were not reported when your product used was Perclose® ProGlide™ Suture-Mediated Closure System, Part #12673-03, #12673-04, and #12673-05. For example, complaint incident #143949-1-1.

OBSERVATION 3

An MDR report submitted to FDA did not include all information that was reasonably known to the manufacturer.

Specifically,

Your firm did not submit all information "reasonably known" and in possession of Abbott Vascular Chief Medical Officer and Abbott Vascular Regional Sales Representative, an employee of Abbott Vascular Commercial Organization, subject to a Complaint #126713-1-1 and MDR #2953144-2009-01905. This information was obtained from the operating physician, who used your product StarClose SE® Vascular Closure System on 4/29/2009 and the patient autopsy report (Complaint #126713-1-1 notes dated 12/15/2009 and 3/11/2010).

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OBSERVATION 4

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Your firm's complaint handling procedures failed to ensure that: complaints are processed in a uniform and timely manner; and complaints are adequately evaluated for MDR reportability.

1). Your procedure (b) (4) " rev. P page 13 or rev. N page 18 - "MDR Decision Tree" is inadequate. The block diagram is missing decision branches influencing MDR reportability decisions. This procedure is used by your firm to assess reportability to FDA for product complaints received for Abbott Vascular devices: StarClose SE® Vascular Closure System and Perclose® ProGlide™ Suture-Mediated Closure System.

2). The following Abbott Vascular procedures define (b) (4) the procedures sections including but not limited to (b) (4) page 1, (b) (4) " page 3 section "(b) (4) ". These procedures are used by your firm to assess reportability to FDA for product complaints received for Abbott Vascular devices: StarClose SE® Vascular Closure System and Perclose® ProGlide™ Suture-Mediated Closure System.

However, your firm received guidelines given by FDA during teleconference with your firm on 4/10/2008. As stated in the meeting minutes emailed by your firm to FDA, "FDA clarified that every time manual compression is used as a result of a closure device, whether the device malfunetioned, or there was an issue with patient anatomy, or the user, it is an intervention to prevent a serious injury, and must be reported. Abbott acknowledged understanding of this."

3). Your firm failed to establish adequate expectations and requirements for the Sales Representatives, your employees of the Commercial Organization, with respect to Complaints Handling to ensure that complaints are processed in a uniform and timely manner and complaints are adequately evaluated for MDR reportability.

Your procedure, (b) (4) ", provides inadequate direction to

your Sales Force, including but not limited to timely investigations, follow-up, and a number of attempts to communicate with the Product Performance Group ("PPG") to ensure that material information is received by PPG and communicated to FDA timely.

Your training procedures, (b) (4) " and computer based training (b) (4) rev 3/14/2008 - "(b) (4) " appear not to address requirements of the follow-up communication delivered/received to/by PPG, number of attempts, and the time frame.

The following complaint incidents were not investigated timely:
#126713-1-1 reported as MDR #2953144-2009-01905.
#127146 reported as MDR #2953144-2009-00614 (Recall of 2009).
#149041-1-1 reported as MDR #2953144-2010-01170.
#148502-1-1
#147249-2-1
#149645-1-1

OBSERVATION 5

Procedures for corrective and preventive action have not been adequately established.

Specifically,

Your firm failed to implement your procedure (b) (4) - "CAPA Investigation" - when investigating the root-cause and identifying actions needed to correct and prevent recurrence of nonconformities and other quality problems subject to complaint incident #126713-1-1 open on 4/30/2009, reported as MDR #2953144-2009-01905 on 12/16/2009, and CAPA #67904 for your product StarClose SE® Vascular Closure System.

Your procedure (b) (4) - "CAPA Investigation" page 3 states:
"(b) (4) "

Your CAPA investigation was incomplete. The record of CAPA (b) (4) does not include the list of potential root-causes and the justification for rejection as such. Specifically, your firm failed to identify the root-causes, including but not limited to: the Sales Representative not providing material

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information, known to him, to the analyst timely, not confirming the receipt of the material information, and insufficient follow-up of the complaint investigation.

The following complaint incidents were not investigated timely, and records show similar root-causes:
#127146-1-1 reported as MDR #2953144-2009-00614 (Recall of 2009);
#149041-1-1 reported as MDR #2953144-2010-01170;
#148502-1-1, #147249-2-1, #149645-1-1,
#151415-x-x reported as MDR #2953144-2010-01276 to #2953144-2010-01280.

OBSERVATION 6

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically,

On 7/12/2010 during my tour of the manufacturing line of your product StarClose SE® Vascular Closure System Lot (b) (4) in the clean room I observed an assembler at the station (b) (4)-Packaging. The assembler was performing tasks outlined in the work instruction procedure "(b) (4) (b) (4) effective 5/25/2010 specifically covering the tasks to avoid foreign particles getting caught on the device.

The actions performed as observed: the assembler wiped a StarClose SE® device with an alcohol wipe, then touching the lid open the lid of the yellow waste container, located within the work area, with her gloved hand to dispose the wipe, then continued performing the next task on the device without changing the glove. The yellow container was equipped with foot pedal. I observed the same at least twice.

Your procedure (b) (4) does not outline a task covering proper wipe disposal into the waste container as to not to return foreign particles from the lid of the yellow waste container back to the device.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Under consideration.
Observation 3:	Promised to correct.	Observation 4:	Under consideration.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.

*** DATES OF INSPECTION:**
07/09/2010(Fri), 07/12/2010(Mon), 07/14/2010(Wed), 07/19/2010(Mon), 07/20/2010(Tue), 07/22/2010(Thu), 07/23/2010(Fri), 07/28/2010(Wed), 08/05/2010(Thu), 08/06/2010(Fri), 08/11/2010(Wed), 08/18/2010(Wed), 08/24/2010(Tue), 08/30/2010(Mon)

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