DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	09/09/2013 - 11/05/2013* FEI NUMBER 3008002452

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James G. Leitl, Senior VP/GM Medical Specialties

FIRM NAME	STREET ADDRESS
Carefusion 2200 Inc	75 North Fairway Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vernon Hills, IL 60061	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

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

Specifically,

Carefusion has been aware since August 2011 of debris/particulate matter issues associated with the Denver Ascites Shunt and Percutaneous Access Kit with Ascites Shunt. Carefusion opened (b) (4) and completed its investigation and identified corrective and preventive actions. A review of the CAPA identified inadequate investigation of the product failures. For example, the firm failed to analyze particulate matter/debris observed on the shunts and inside the peritoneal catheter/tubing to identify the nature/ physical/ chemical composition of the debris in order to determine the source of the debris/ particulate matter. The device labeling warning identifies presence of debris/particulate matter as a significant safety and effectiveness concern that may cause occlusion and thrombosis amongst other safety and effectiveness concerns.

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,

From August 25, 2011 to September 2013, Carefusion received the following thirty-two complaints pertaining to particulate/debris matter for its Denver Ascites Shunt and Percutaneous Access Kit with Ascites Shunt:

(b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Paola S. Barnett, Investigator

DATE ISSUED: 11/05/2013

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(b) (4) [redacted]

The kits are provided sterile for use. Device labeling warning identifies presence of debris/particulate matter as a significant safety and effectiveness concern that may cause occlusion and thrombosis amongst other safety and effectiveness concerns. MDR reports were never submitted to the FDA.

OBSERVATION 3

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by a designated individual.

Specifically,

Review of MDR complaint investigation (b) (4) [redacted] that describes "Babies head of penis was cut due to scissors not rounded out at tip properly. Bleeding involved", revealed Carefusion failed to eliminate device failure as a contributing factor. For example, the investigation failed to determine whether the supplier of the scissor was manufacturing scissors according to specification. Further, Carefusion failed to ascertain whether the circumcision scissor specification is per a clinician requirement/clinical standards/clinical specifications and whether Carefusion incoming inspection acceptance criteria is based on clinical relevance.

OBSERVATION 4

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically,

Since August 2011, Carefusion received thirty-two complaints for particulate/debris matter issues associated with the Denver Ascites Shunt and Percutaneous Access Kit with Ascites Shunt. A review of ten of the thirty-two complaint investigations from 8/25/2011-6/05/2013 documented the following boiler plate language "A review of complaint data identified a previous complaint with a similar failure mode. Review of the previous complaint investigation noted corrective actions including remedial training and improved CME (controlled manufacturing environment) requirements, were implemented for the

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previous complaint". Carefusion could not locate this "previous complaint" and its associated complaint investigation and corrective actions referenced in these ten complaint investigations.

OBSERVATION 5

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically,

Supplier evaluations conducted of Level I suppliers were reviewed and deemed acceptable by Carefusion despite relevant quality system requirements not being met. For example, pertinent quality system questions on "The Supplier Self Audit Questionnaire" for two Level I suppliers of finished goods were not completed by the suppliers but were reviewed and approved by Carefusion without any further followup.

OBSERVATION 6

Requirements that must be met by suppliers have not been adequately established.

Specifically,

Supplier corrective actions are not always demonstrating that supplier corrective actions are verified and following CAPA requirements.

For example:

Carefusion initiated supplier corrective action (b) (4) to their supplier for occlusion MDR complaints reported for the Mask Air Entrainment Adult 50/CS used with nebulizers. The evaluation by the supplier confirmed that the 50% Jet dilutor component (b) (4) was occluded thereby preventing the flow of air. The evaluation included a root cause and determined corrective actions. For example supplier corrective action included "operator is reviewing every part using the attached visual aid". The supplier corrective action lacked documentation of verification of corrective action. The vendor response was determined to be acceptable by Carefusion on 06/10/2013.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct by 11/25/2013.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct by 11/25/2013.
Observation 5:	Promised to correct by 11/25/2013.	Observation 6:	Promised to correct by 11/25/2013.

*** DATES OF INSPECTION:**
09/09/2013(Mon), 09/10/2013(Tue), 09/11/2013(Wed), 09/12/2013(Thu), 09/13/2013(Fri), 09/17/2013(Tue), 09/18/2013(Wed), 09/19/2013(Thu), 11/05/2013(Tue)

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