DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	06/10/2009 - 06/17/2009* FEI NUMBER 1000151187

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Todd C. Cantine, General Manager

FIRM NAME	STREET ADDRESS
American Catheter Corp	13047 S Highway 475
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34480-8503	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

A validated process was not revalidated when changes or process deviations occurred.

Specifically,

A. The Process Challenge Device (PCD) you used to validate/re-validate the sterilization process for the 9100 Series and 9100L Series Cholangiogram Catheters, and continue to use to monitor that process, has not been adequately proven to be an equivalent or superior sterility challenge by the scientific study, dated 10/02/01, which was conducted by the outside firm that designed/tested the PCD for you.

B. You did not qualify the heating room and installation of the heating room equipment as part the re-validation of your non-traditional EtO sterilization process for 9100 Series and 9100L Series Cholangiogram Catheters, and this process includes [redacted] (b)(4)

C. Your original validation and the re-validation, dated July 2005, which you are currently using to cover your process for sterilization of the 9100 Series and 9100L Series Cholangiogram Catheters feature different equipment than the equipment your are currently using for your sterilization process. Some differences are as follows.

   1. Current process uses [redacted] while validations lists [redacted]
   2. Current process uses [redacted] continuous temperature recorder, while validations list [redacted] (b)(4)

D. Individuals who perform re-validation of the firm's non-traditional sterilization process for 9100 Series and 9100L Series Cholangiogram Catheters are not fully knowledgeable of acceptance criteria.

Objectionable conditions regarding process validation were previously listed by FDA on 02/23/06.

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	Joshua J. Silvestri, Investigator	06/17/2009

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OBSERVATION 2

Procedures were not implemented for monitoring and control of process parameters for validated processes.

Specifically, you have not implemented the procedure covering the sterilization process for the 9100 Series and 9100L Series Cholangiogram Catheters, dated 04/05.

A. You are not using a continuous temperature recorder to keep record of the time and temperature during the [redacted] pre-conditioning step, as required by your written procedure, and the purpose of this step is to allow moisture to penetrate any spores present, which is required to allow the spores to be affected by the EtO gas.

B. On 06/17/09, I randomly selected 20 continuous temperature records and found 9 of 20 continuous temperature records covering the [redacted] portion of the sterilization process had deficiencies.

   a. I observed 8 of 20 do not show the devices were processed for a at least of [redacted] at a minimum temperature of [redacted] which is the time and temperature used to validate/re-validate the process.
   b. I observed 1 of 20 did not document in an observable way the start of the time cycle and, thus, did not show the process was run for a minimum of [redacted] at [redacted]
   c. Additionally, I observed 1 of 20 documented a period of time more than 6 hours longer than the typical [redacted] period; however the EO Gas Sterilizer Control Sheet covering that process documents exactly [redacted]

(b)(4)

OBSERVATION 3

Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been established, completed, and implemented.

Specifically,

A. Your Policy/Procedure #022, dated 07/05, references use of a Decision Matrix to determine if a product return is a complaint, but on 06/11/09 I observed there was no Decision Matrix in the procedure and the General Manager could not locate the document elsewhere. Further, the General Manager received a product return, dated 11/18/08, which reported the user could not open the product packaging, and the General Manager stated he determined it was not a complaint without using the Decision Matrix.

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B. Your Policy/Procedure #022 , dated 07/05, does not include requirements to respond in a timely manner, to collect the complainant's address information, or to collect information for MDR events regarding (1) whether the device failed to meet specifications, (2) whether the device was being used to treat or diagnose, and (3) the relationship of the device to the reportable event.

OBSERVATION 4

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements were not complete and implemented.

Specifically,

A. Your purchasing controls listed in Policy/Procedure #008, dated 07/05, section 4.1.1 Class A, are not complete because for all products considered "off-the-shelf" it only requires verification of the identity, quantity, and that there is no visually observable damage to these products, which does not evaluate products based on all quality specifications which may potentially affect the quality of your medical devices. One product you have classified as an "off-the-shelf" product is the Biological Indicator used to evaluate the effectiveness of the sterilization process performed on the 9100 Series and 9100L Series Cholangiogram Catheters.

B. You did not implement the purchasing controls outlined in your Policy/Procedure #008, dated 07/05, section 4.3 Receiving Inspection, which require creating Receiving History records. On 06/16/09, I reviewed your Receiving History records and found no record to cover receipt of Biological Indicators, which are used to evaluate the effectiveness of your sterilization process for 9100 Series and 9100L Series Cholangiogram Catheters.

C. You did not implement the purchasing controls outlined in your Policy/Procedure #008, dated 07/05, section 4.1 Supplier Evaluation and Selection, which requires establishment of an Approved Vendor List featuring each supplier and each component or service to be listed. The Approved Vendor List does not include the laboratory which performs Bioburden testing during re-validation of the sterilization process for 9100 Series and 9100L Series Cholangiogram Catheters. Further, the Applied Vendor List is not approved and dated for implementation.

Objectionable conditions regarding purchasing controls were previously listed by FDA on 02/23/06.

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OBSERVATION 5

Procedures to ensure that equipment is routinely calibrated and maintained were not implemented.

Specifically,

A. You have not implemented your Policy/Procedure #014, Equipment Maintenance, dated 07/05, to establish a Master Maintenance List to cover the following equipment, which require routine maintenance according to their respective Operation Instructions manuals. This equipment is used to seal packaging used to establish and/or maintain the sterility of the 9100 Series and 9100L Series Cholangiogram Catheters.

1. [redacted] sealer
2. [redacted] sealer

B. You have not implemented your Policy/Procedure #015, Equipment Calibration, dated 06/09, to include the thermometer portion of the incubator unit on the Master Equipment Calibration List required by the procedure. The incubator is used to analyze Biological Indicators used to evaluate the effectiveness of each sterilization run and used to validate/re-validate the sterilization process.

C. Additionally, your Master Equipment Calibration List requires the [redacted] sealer to be calibrated every [redacted] while the Operation Instructions manual recommends an annual calibration, and you did not present any justification for this difference.

(b)(4)

Observations related to equipment maintenance/calibration were previously listed by FDA on 02/23/06.

OBSERVATION 6

Quality audits were not conducted at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, your firm's Policy/Procedure #004, dated 07/05, states Quality Audits will be conducted once every [redacted] but on 06/10/09 your General Manager identified the most recent Quality Audit, which was dated 01/09/07. According to your procedure, on 06/10/09 your firm was overdue to conduct a Quality More by more than 11 months. Additionally, you did not document the audit was conducted using the form referenced in your procedure.

(b)(4)

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OBSERVATION 7

Management reviews were not conducted at defined intervals.

Specifically, your firm's Policy/Procedure #003, dated 07/05, states a Management Review will be conduced [redacted] but the records of Management Reviews provided by your General Manager on 06/10/09 do not include any records of Management Reviews since 06/2002.

(b)(4)

Additionally, you have not designated a Management Representative and documented such designation.

OBSERVATION 8

The written MDR procedure does not include an internal system which provides for timely transmission of complete medical device reports to FDA.

Specifically, your firm's MDR procedure listed in Policy/Procedure #022, dated 07/05, does not ensure that you submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (1) a reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or (2) a reportable event for which FDA made a written request.

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Observation Annotations

Observation 1:	Under consideration.	Observation 2:	Under consideration.
Observation 3:	Promised to correct within 1 week.	Observation 4:	Under consideration.
Observation 5:	Under consideration.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct within 30 days.	Observation 8:	Promised to correct within 30 days.

*** DATES OF INSPECTION:**
06/10/2009(Wed), 06/11/2009(Thu), 06/12/2009(Fri), 06/16/2009(Tue), 06/17/2009(Wed)

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