DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax:(781) 596-7896	03/28/2005 - 05/20/2005*
	FEI NUMBER 3001451463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Paul W. Warren, General Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corporation	500 Commander Shea Blvd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Quincy, MA 02171-1518	Distributor, Manufacturer, Sterilizer

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 WE OBSERVED:

OBSERVATION 1

The organization structure is not adequate to assure that quality system requirements are fully met.

Specifically, activities for the sale, shipment, receipt, control, and return of inventory are not adequately controlled through personnel actions, documentation, and associated procedures.

OBSERVATION 2

Products that do not conform to specifications are not adequately controlled.

Specifically:

A. [redacted] units of Taxus Express 2 (Material Number [redacted] Batch [redacted]) were shipped to [redacted] different customers direct from BSC Quincy, while on "Pending KDR Test Results" ship hold. The Taxus Express 2 units had failed initial KDR (Kinetic Drug Release) testing.

[redacted]

B. Three shipments of 45-233, Vaxcel Low Profile Ports, were made after the ship hold was

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received in this facility in Quincy, MA on 8/25/04. The sales reps were notified by BSC Quincy on 8/26/04. Products were either sold or provided as samples by the sales reps on 9/21/04, 12/14/04, and 2/15/2005. They include:

[redacted]

C. [redacted]atches of Symmetry product (i.e. Balloon Dilatation Catheter) from Sterilization load 0600006201 were released by BSC Quincy and shipped in September and October 2004 to BSC customers. BSC Quincy received partial release paperwork on 8/24, 9/3, and 9/8/2005 from BSC Galway releasing particular batches from specific delivery numbers from this sterilization load. However, Galway had not released these particular batches due to a PRR, Product Review Request, investigation being open for the Symmetry products. This PRR was closed 2/8/2005. There is no documentation of the [redacted] batches ever being released by Galway. At least [redacted] units from these [redacted] batches have been distributed.

OBSERVATION 3

There is no documentation of the disposition of nonconforming product.

Specifically, BSC Quincy closed ship hold 04-08-018 on 1/18/05 at their facility without accounting for the sales rep stock that was being returned to Quincy. The disposition of the product for hold 04-08-018 on the Notification of Shipping Hold Release dated 12/22/04 did not include "Sales Rep Inventory" a.k.a. Trunk Stock, when it was included on the original hold. The Quincy facility takes the orders from the sales reps, sends them product, tells them if there is a shipping hold, what to return via reservation number, and keeps track of the sales rep stock.

Annotation: Promised to correct.

OBSERVATION 4

Corrective and preventive action activities have not been documented, including investigations of causes of nonconformities, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and implementation of corrective and preventive actions.

Specifically:

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A. The following CAPAs did not include the necessary details to document the entire non-conforming condition:

   a. CAR 05-004, involving the shipment of [redacted] units of Taxus Express 2, which had failed initial KDR testing, did not include the actual occurrence dates, what actually happened (including the 3 other mistaken batch removals that were caught and put back into their original locations), and who was involved in the incident.
   b. CAR 04-052, involving transaction of ship hold product into finished goods, did not include the number of orders and units shipped.
   c. CAR 04-082, involving a product that was placed on ship hold, which BSC Quincy attempted to retrieve before leaving the facility, did not include the fact that the shipment was pulled back, had portions of the shipment replaced, and was refilled with product in inventory that was also on hold.
   d. CAR 04-120, involving demo product being returned, labeled not for human use, placed back into finished goods, and sold, did not list the product or quantity.
   e. CAR 05-013, involving release of product before LAL testing was completed, did not state in the CAPA form what product this CAPA involved.

   The local CAPA procedure, S842393-00, Rev. AU, states that: "The CAPA administrator will complete the first section of the form ... A detailed description of the Nonconformance, Potential Nonconformance, Preventive Action, or Action Item."

B. Not all e-mails of discussions and decisions made regarding CAPAs and PIRs were kept with the respective files.

   a. CAR 04-120 did not include the e-mail regarding the investigation.
   b. CAR 04-125 did not include the e-mail regarding future release of Symmetry products.

C. PIR USD-2005-01-01 did not completely describe the events that occurred. It states only that several batches were inappropriately removed from the Quarantine location. The quantity and batch numbers that were mistakenly removed, which were caught and returned to their original locations, were not documented.

   The PIR procedures state that the owner of the PIR will verify that the PIR is accurate.

D. PIR USD 2004-10-02 does not include any documentation of verbal discussions between Galway and Quincy about the status of the product released prior to a recommendation made on 2/28/05 not to conduct a field action.

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Annotation: Under consideration.

OBSERVATION 5

The procedures addressing identification of corrective and preventive actions were not implemented.

Specifically, PIR USD 2005-01-01, Part IIIA, Global Medical/Clinical Assessment, did not answer the question from the Detection section appropriately. This section questions the physician's ability to detect a problem with a device. The rationale provided addresses the firm's ability to detect outliers before distribution.

The PIR procedures state that the owner of the PIR will verify that the PIR is accurate.

Annotation: Promised to correct within 30 days.

OBSERVATION 6

Changes in methods and procedures needed to correct and prevent identified quality problems are not implemented and effective.

Specifically, there have been multiple instances of shipments of product on hold to BSC customers, although these individual CARs have been verified for effectivity. Review of the 2004 and 2005 Corrective/Preventive Action Logs reveals at least 4 instances of shipments of products on hold: CAR 05-017, 05-004, 04-125, and 04-052.

The local CAPA procedure states "the corrective or preventative actions are verified and reviewed to ensure all actions taken have been effective." It also states that the CAPA file will consist of "evidence of implentation and evidence of verification and effectivity."

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OBSERVATION 7

Records of changes did not include a description of the change, the signature of the approving official(s), and the approval date.

Specifically:

A. PIR USD-2005-01-01 had 3 pages which included Part IV: PIR Team Input Approval and Part V: Recommendation for Field Action Approval.

   a. The original, which had section IV on page 8 of 10, includes printed titles and names for the 3 approving officials as well as the owner's original signature. The other 2 pages including this particular section are on page 9 of 11. These pages, which show the other 2 approving officials signatures, do not have the printed names and titles for all 3 approving officials.

   b. The original, in Section V, includes a check in the YES block for field action recommendation. The other 2 copies of this page do not have this block checked.

   Regarding these discrepencies, the owner, who is the Director of Quality Assurance, stated that she probably updated and reprinted an original prior to her signing the document.

B. A training record was altered for employee, [redacted] April 29, 2005, when first collected. On May 11, 2005, it was reviewed again, and it was noted that "TD" was added to some of the training boxes without explanation.

C. PIR USD-2005-01-01 had 2 original pages 9 of 10. The first page 9 of 10 includes original handwritten statements stating to see attached documents. The second page 9 of 10 includes an original signature of the FAC chairperson.

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OBSERVATION 8

Procedures for the control and distribution of finished devices have not been complete and implemented to ensure that only devices approved for release are distributed.

Specifically, a sales rep (M003) was not notified when a hold (#04-08-018) was received by BSC the same day the product was sent to M003. The list the firm uses to call the sales reps the following day includes sales reps who have received the product but not the sales reps who have been sold the product.

SOP BSC Rep Stock Ship Hold/Release Procedure, 90147555, Rev. AA, addresses only the product that the sales reps have received, but not product that they have been sold. This procedure states only to "Periodically check on RGA's (Return Goods Authorization) to see if closed." The procedures are not complete for regularly notifying sales reps, when they still have a ship hold product in their possession that was not returned.

In addition after a ship hold release form is received, the procedure allows the sales support staff to inform the sales reps that the RGA's are cancelled. This allows the ship hold to be released without the sales reps actually returning affected product.

Annotation: Promised to correct.

OBSERVATION 9

The acceptance status of product was not clearly identified.

Specifically:

A. Not all sales reps are notified when they sell product that is currently on hold. BSC does not have a procedure to notify sales reps when they have sold product that is on ship hold.

B. BSC had 9 Shipping holds not signed by an employee in the Quality Department in BSC Quincy upon arrival of the holds at the firm. The W1 Quincy Trans Shipping Hold procedures, S800294-01, Rev. AP and AN, both state that "a representative of the QA group will review the form and sign the Shipping hold form whether or not the form is signed from the initiating site." It does not state that only shipping holds for Quincy will be signed. The QA group checks the SAP

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computer system for all holds that arrive at [redacted] The nine shipping holds that were not signed include:

- 04-08-009 Amendment dated 9/23/04 f[redacted]
- 05-02-007 dated 2/9/05 from[redacted]
- 05-02-018 Amendment dated 3/22/0[redacted]
- 05-02-018 Amendment dated 3/16/05[redacted]
- 05-02-018 Amendment dated 2/24/05[redacted]
- 05-02-018 dated 2/23/05[redacted]
- 05-03-006 dated 3/3/05 f[redacted]
- 05-03-017 dated 3/17/05[redacted]
- 05-03-018 dated 3/22/05[redacted]

[redacted] Shipping Hold, S800294-01, Rev. AP, states that a representative of the QA group will review the form and sign the shipping hold form.

Annotation: Promised to correct.- Part A; Reported Corrected, Not Verified - Part B

OBSERVATION 10

The corrective and preventive action procedures addressing the investigation of the cause of nonconformities relating to product, processes, and the quality system were not implemented.

Specifically, copies were not maintained of complete copies of PIRs, which were used to obtain approval signatures. Only signature pages were retained. The signature pages were attached as faxed documents or e-mailed documents. They did not always print out in the same format as the original PIR.

The local and corporate PIR procedures state the PIR shall be filed in its local CAPA file with all other documents generated in the course of generating the PIR and obtaining approval.

Annotation: Promised to correct.

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OBSERVATION 11

Required records are not retained for at least 2 years from the date of release of the device for commercial distribution.

Specifically, the Emergency FREP Pull Lists, otherwise known as the ZV29 Forms, are discarded. These forms document the physical movement of finished goods and show who entered them into the SAP computer system.

Annotation: Under consideration.

OBSERVATION 12

Employees have not been adequately trained.

Specifically, the training file for a Distribution Associate/Overstock and Replenishment employee [redacted] does not show adequate documentation of training on procedures relating to everyday job duties. The training file shows [redacted] was trained on S808448-01, Put Away Procedure, as a corrective action to CAR 05-004, only on the day his employment was terminated.

Annotation: Under consideration.

OBSERVATION 13

Employee training is not fully documented.

Specifically, there is no documentation of sales reps attending an overview of the BSC Quincy facility and its functions at BSC Quincy. This overview includes a presentation and handouts, including the BSC Sales Rep Stock Guidelines, covering inventory maximums, how to order, return, and handle recalled products, and what SAP functions are.

Annotation: Under consideration.

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OBSERVATION 14

Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device.

Specifically, CAR 05-013 did not update the procedure "Processing of Sterile Finished Goods [redacted] Sterilized," 6000019-05, Rev. AR. The non-conformance involved product which had [redacted] sterilized. The corrective action plan states to update the procedure 6000019-01, which referred to [redacted] processed products. Procedure 6000019-05, which refer[redacted] processed products, has not been updated. The CAPA verification was completed on 3/18/05.

Annotation: Reported corrected, not verified.

OBSERVATION 15

Quality audits did not verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, BSC did not record the number of ship holds reviewed during the audits for 2004 and 2003. The Internal Audit procedure, S808614-01, states the audit report will be formatted to include audit scope - detailing procedures and documents reviewed.

Annotation: Promised to correct.

* **DATES OF INSPECTION:**
03/28/2005(Mon), 03/29/2005(Tue), 03/31/2005(Thu), 04/01/2005(Fri), 04/04/2005(Mon), 04/06/2005(Wed), 04/08/2005(Fri), 04/13/2005(Wed), 04/15/2005(Fri), 04/19/2005(Tue), 04/21/2005(Thu), 04/22/2005(Fri), 04/26/2005(Tue), 04/27/2005(Wed), 04/28/2005(Thu), 04/29/2005(Fri), 05/03/2005(Tue), 05/04/2005(Wed), 05/10/2005(Tue), 05/11/2005(Wed), 05/12/2005(Thu), 05/13/2005(Fri), 05/20/2005(Fri)

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Carla C. Cummins, Investigator

Darin S. Wiegers, Investigator

Elizabeth B. Griffin, Investigator

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