Not Annotated!

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	07/27/2005 - 08/26/2005*
	FEI NUMBER 3000204642

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brian R. Burns, Senior Vice President, Global Quality Assurance

FIRM NAME	STREET ADDRESS
Boston Scientific Corporation	1 Boston Scientific Place
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Natick, MA 01760-1536	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 WE OBSERVED:

OBSERVATION 1

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Specifically,

- Data trended monthly by Corporate for quarterly management review meetings does not include all quality issues.

  For example, complaints are trended monthly by rate and length of time open. The late submissions of Medical Device Reports (MDRs) is not included in the trending.

  The Manager of Corporate Quality Systems Compliance said Corporate trends metrics and timeliness. He said the details of the Product Inquiry Reports (PIRs) are tracked by the sites.

- Prior to June 2005, trends were not required to be reported by product family. Now, although they must be reported, if the site did not exceed their pre-set goal for overall complaint rate for the month, the data will be reported in green rather than red, so the reviewers may not realize there is a trend listed.

- The procedures for trending state only that trending must be done, but do not explain specifically what and how to trend data at the various BSC sites.

  For example, review of the data trended by the Wayne, NJ facility revealed discrepancies between their data and the comments included on the complaint forms (which are reviewed at the Marlboro, MA facility).

SEE REVERSE OF THIS PAGE		DATE ISSUED
	Elizabeth B. [illegible] Courtney M. Irving	08/26/2005

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OBSERVATION 2

Employees who manage, perform, and assess work affecting quality have not been provided the independence and authority to accomplish their work.

[redacted]

OBSERVATION 3

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically:

A. PIR # SJC-2005-01-01 initiated 12/3/2004:

The firm's recall of the Position Acquisition Module (PAM) as part of the RPM system (including 3 UPNs, all lots) was not reported to FDA. The device is used on patients receiving ablation for arrhythmias. The PAM does not meet IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment. During overheating testing, it was discovered that the 70V secondary of the PAM transformer failed short circuit testing, implying the possibility of a fire hazard. The Clinical Assessment for Severity is listed as Critical. The Field Action recommended is to conduct a recall. The recall is classified by Boston Scientific as Class III. This was approved by the FAC Chairperson on 1/24/2005. The equipment has been distributed to both US and OUS consignees.

B. PIR # SJC-2005-03-03 initiated 2/3/2005:

The firm's recall of the Signal Acquisition Module (SAM3) as part of the RPM system (including all UPNs starting with M004308300), was not reported to FDA. The device is used on patients receiving ablation for arrhythmias. The SAM3 does not meet IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment. During overheating testing, it was discovered that the secondary of the SAM3 transformer failed short circuit testing, implying the possibility of a fire hazard. The Clinical Assessment for Severity is listed as Critical. The Field Action recommended is to conduct a recall. The recall is classified by Boston Scientific as Class III. This was approved by the FAC Chairperson on 3/14/2005. The equipment has been distributed to both US and OUS consignees.

According to the Director of Corporate Quality Systems and Compliance, all Product Inquiry Reports (PIRs) are signed by the Senior Vice President of Global Quality Assurance, who is also the Field Action Committee (FAC) Chairperson, who is located here at BSC-Natick.

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OBSERVATION 4

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, Medical Device Reports (MDRs) were either not submitted or were submitted late in the following instances:

A. For Enteryx Procedure Kits:
- An MDR has not been submitted for complaint # 655872 dated 4/13/05 involving: patient had dysphagia with a subsequent dilatation.
- An MDR has not been submitted for complaint # 655874 dated 4/13/05 involving: patient with dysphagia and weight loss resulting in an EGD for which results have not been reported.
- Complaint # 650765 dated 12/8/04 was reported on 1/17/05 (10 days late)
- Complaint # 657183 dated 5/2/05 was reported on 6/3/05 (2 days late)

B. For Vaxcel Ports:
- Complaint # 640535 dated 3/17/04 was reported on 4/20/04 (4 days late)
- Complaint # 640726 dated 3/23/04 was reported on 4/23/04 (1 day late)

OBSERVATION 5

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, Medical Device Reports (MDRs) were either not submitted or were submitted late in the following instances:

A. For Vaxcel Dialysis Catheters:
- MDRs have not been submitted for complaint # 647741 dated 9/16/04 involving: five units with cuff separation and the catheter slipping out.
- An MDR has not been submitted for complaint # 642926 dated 11/9/04 involving: a patient's catheter which fell out at home.
- Complaint # 655187 dated 1/21/05 was reported on 4/4/05 (6 weeks late)
- Complaint # 655188 dated 1/21/05 was reported on 4/4/05 (6 weeks late)
- Complaint # 653673 dated 1/21/05 was reported on 3/25/05 (4 ½ weeks late)
- Complaint # 651774 dated 1/5/05 was reported on 3/4/05 (4 weeks late)
- Complaint # 655350 dated 2/13/05 was reported on 4/8/05 (3+ weeks late)
- Complaint # 653670 dated 2/15/05 was reported on 3/25/05 (8 days late)

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- Complaint # 653671 dated 2/16/05 was reported on 3/25/05 (1 week late)

B. For Vaxcel Ports:

- An MDR has not been submitted for complaint # 647625 dated 9/22/04 involving: Post placement could not flush or draw; the port was removed and replaced the same day.
- Complaint # 639511 dated 2/20/04 was reported on 12/17/04 (9 months late)
- Complaint # 639513 dated 2/20/04 was reported on 12/17/04 (9 months late)
- Complaint # 639514 dated 2/20/04 was reported on 12/17/04 (9 months late)
- Complaint # 656751 dated 11/24/03 was reported on 4/23/04 (4 months late)
- Complaint # 646924 dated 9/3/04 was reported on 1/27/05 (3 ½ months late)
- Complaint # 637445 dated 12/18/03 was reported on 4/8/04 (3+ months late)
- Complaint # 648812 dated 10/21/04 was reported on 1/14/05 (2 months late)
- Complaint # 648804 dated 10/21/04 was reported on 1/14/05 (2 months late)
- Complaint # 631548 dated 8/5/03 was reported on 10/30/03 (2 months late)
- Complaint # 640109 dated 3/3/04 was reported on 4/14/04 (12 days late)
- Complaint # 641509 dated 4/13/04 was reported on 5/18/04 (5 days late)

OBSERVATION 6

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

Specifically, it is unclear who is making final MDR determinations.

- The Post Market Compliance Specialist who reviews complaints for the Oncology product line within the Endosurgery group for Medical Device Reportability, said the Manager for Post Market Compliance for Endosurgery reviews all of the complaints that are determined to be reportable, but not the ones that are not reportable.
- The Senior Post Market Compliance Specialist who reviews complaints for Endosurgery products said that regardless of whether the complaints are reportable or not, they are passed on to the Manager for Post Market Compliance for Endosurgery and to a physician for the ultimate decision.
- The Manager for Post Market Compliance for Endosurgery said she reviews every reportable complaint for Endosurgery, but not complaints that are determined not to be MDR reportable.
- The Manager for Post Market Compliance for Endosurgery also said all Enteryx complaints go to the Associate Medical Director, Endoscopy Division, Endosurgery Clinical Affairs unless it is clearly not a clinical issue. This review by the MD is not documented.

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OBSERVATION 7

Complaint handling procedures have not been established to ensure that all complaints are processed in a uniform and timely manner.

Specifically,

A. There are inconsistent times from the date the complaint was phoned in to the date it was entered into the computer system. The Corporate SOP for Complaint Handling S841052-00 rev. AJ, states that "**ALL employees** shall forward any BSC Product Concern to a Complaint Call Center **within 72 hours or less** of Becoming Aware of the concern".

651507 phoned in on 1/9/04, was entered on 12/29/04 (11 ½ months later)
655188 phoned in on 1/21/05, was entered on 3/29/05 (9 ½ weeks later)
655187 phoned in on 1/21/05, was entered on 3/29/05 (9 ½ weeks later)
654222 phoned in on 1/21/05, was entered on 3/8/05 (6 ½ weeks later)
655350 phoned in on 2/13/05, was entered on 4/1/05 (6 ½ weeks later)
653673 phoned in on 1/21/05, was entered on 2/23/05 (4 ½ weeks later)
656542 phoned in on 3/31/05, was entered on 4/27/05 (4 weeks later)
656902 phoned in on 4/27/05, was entered on 5/6/05 (2+ weeks later)
657472 phoned in on 5/3/05, was entered on 5/18/05 (2+ weeks later)
657473 phoned in on 5/3/05, was entered on 5/18/05 (2+ weeks later)
656899 phoned in on 4/21/05, was entered on 5/6/05 (2+ weeks later)
656901 phoned in on 4/21/05, was entered on 5/6/05 (2 weeks later)
657183 phoned in on 5/2/05, was entered on 5/12/05 (10 days later)
653824 phoned in on 2/17/05, was entered on 2/26/05 (9 days later)
660560 phoned in on 7/15/05, was entered on 7/24/05 (9 days later)
655971 phoned in on 4/7/05, was entered on 4/15/05 (8 days later)
653670 phoned in on 2/15/05, was entered on 2/23/05 (8 days later)
656774 phoned in on 4/28/05, was entered on 5/4/05 (1 week later)
653671 phoned in on 2/16/05, was entered on 2/23/05 (1 week later)
655837 phoned in on 4/7/05, was entered on 4/13/05 (6 days later)
658261 phoned in on 6/2/05, was entered on 6/7/05 (5 days later)
654048 phoned in on 3/1/05, was entered on 3/3/05 (4 days later)

B. The Date Reported (the date a BSC employee learned of a complaint) has been listed incorrectly:

655653 has both a date reported and a phoned in date of 4/8/05, however a comment in the complaint states that the findings were reported to BSC on 3/30/05.
653671 has a phoned in date of 2/16/06, however a date reported of 2/23/05.

C. There are inconsistencies in tracking open vs. closed complaints, and tracking whether or not any information is still

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outstanding.

- The Post Market Compliance Specialist for the Oncology product line said the Principal Post Market Compliance Specialist audits the closed complaints by the close out date and that they may or may not still be under investigation.
- The Post Market Compliance Specialist for the Oncology product line also said she has a manual process for following up on complaints: she keeps a folder with copies of email messages regarding questions that are still pending on complaints. She said she does not look at the Investigation Closed Date and does not know who enters that date.
- We observed numerous complaints listing Investigation Closed Dates which were prior to the Post Market Compliance Specialists receiving all information regarding their investigation.
- The Post Market Compliance Group at the Complaint Management Center (CMC) is responsible for the MDR determination, according to the Corporate SOP for MDR Reporting. The close out of this investigation is not always documented in the comments on the computer generated complaint form

* **DATES OF INSPECTION:**
07/27/2005(Wed), 07/28/2005(Thu), 07/29/2005(Fri), 08/02/2005(Tue), 08/03/2005(Wed), 08/04/2005(Thu), 08/24/2005(Wed), 08/25/2005(Thu), 08/26/2005(Fri)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Elizabeth B. Griffin, Engineer/Investigator

Courtney N. Long, Investigator

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	08/26/2005