DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005* FEI NUMBER 1317056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John F. Watkins, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glens Falls, NY 12801-3864	Medical Device Manager

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 acceptance or rejection of incoming product were not established.

Specifically,

a) Quality Assurance Procedure #6V62 titled Incoming Inspection of Low Profile Plastic Port Subassemblies was incorrect to established product specification for dimensional height. Firm's product specifications for the port dimensional height single valve were established at [redacted] Firm's Incoming Inspection of Low Profile Plastic Port Subassemblies QA 6V62 and associated blueprint for the Port, LP, with Septum had a product specification for the port dimensional height single valve established at [redacted]

b) Quality Assurance Procedure #6V56 titled Incoming Inspection of Introducer / Sheath did not adequately define inspection / testing of the received Introducer / sheath for proper scoring to allow for the designed peeling activity.

Annotation: Promised to correct.

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been fully validated and approved according to established procedures.

Specifically,

a) Vaxcel PASV Low Profile Port with PASV valve devices are tested in-process per Manufacturing Operation Code #3043 using the [redacted] test to assure no bubble formation (leaks). Firm has not validated the [redacted] test.

b) Vaxcel PASV Low Profile Port with PASV valve devices product specification is 'no leaks at [redacted]

SEE REVERSE OF THIS PAGE	This is a modified document. Michael C. Ambrosi	DATE ISSUED MGS 05/06/2005

Attachment A 4

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005*
	FEI NUMBER 1317056
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED **TO:** John F. Watkins, Plant Quality Manager	
FIRM NAME Boston Scientific Corp	STREET ADDRESS 10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY Glens Falls, NY 12801-3864	TYPE ESTABLISHMENT INSPECTED Medical Device Manager

[redacted] Firm uses a product specification of '[redacted] test'. Firm has not validated the [redacted] test' against the established product specification [redacted] to assure the two product specification test methods are equivalent.

c) Vaxcel PASV Low Profile Port with PASV valve devices product specification is [redacted] test'. Firm releases product port assembly with valve at [redacted] is observed. Firm has not validated the [redacted] when no bubble is observed against the product specification of [redacted] test'.

Annotation: Promised to correct.

OBSERVATION 3

Procedures for acceptance or rejection of finished device production runs, lots, or batches were not established and implemented.

Specifically,

a) Vaxcel Low Profile, Mini, and Standard Chest Implant Ports with PASV valve were released and distribution without a final acceptance conducted post sterile or equivalent which assures that the device meets all specifications.

b) VAXCEL PASV PICCs were released and distribution without a final acceptance conducted post sterile or equivalent which assures that the device meets all specifications.

Annotation: Under consideration.

OBSERVATION 4

Acceptance procedures to ensure that specified requirements for in-process product are met were not established.

Specifically,

a) Quality Assurance Procedure #6W39 Rev.1 dated 4/30/04 was not adequately defined so that the quality assurance operator would conduct acceptance activity to assure that the correct proximal fitting red color is aligned with larger lumen.

Annotation: Corrected and verified.

ATTACHMENT # 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005* FEI NUMBER 1317056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John F. Watkins, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glens Falls, NY 12801-3864	Medical Device Manager

OBSERVATION 5

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically,

a) Audit of 38 MFG 100% Leak Test Ports, Port Traceability form Attachment A records which are covered by Manufacturing Operation Codes #3043 found that the leak test device history record failed to identify test method used, pressure, and time tested.

Annotation: Promised to correct.

OBSERVATION 6

Complaint handling procedures have not been implemented to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report.

Specifically,

a) Introducers/Sheaths [redacted] used in the Vaxcel Mini, Standard, & Low Profile Port with PASV valves had 7 (640938, 644265, 647007, 647080, 650077, 651813, 651815) of 21 complaints of malfunction involved with patient - procedure were not filed as MDR.

b) Vaxcel Mini & Standard Chest Implant Ports had 3 (639511, 639513, 639514) of 9 complaints of malfunction involved with patient - procedure was not filed as MDR.

OBSERVATION 7

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

Specifically,

a) Vaxcel 4.5Fr Dual Lumen PASV PICC Catheters were being recalled because the firm installed the smaller capacity proximal fitting onto the larger handling volume lumen and the larger capacity proximal fitting onto the smaller handling volume lumen during production which was not picked up during inspection.

SEE REVERSE OF THIS PAGE

This is a modified document.

DATE ISSUED
m6 5
05/06/2005

Attachment 4 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005* FEI NUMBER 1317056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John F. Watkins, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glens Falls, NY 12801-3864	Medical Device Manager

OBSERVATION 8

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

Specifically,

a-1) Introducer/sheaths [redacted] used in the Vaxcel Mini, Standard, and Low Profile Port with PASV valve kits had 16 (636342, 641509, 642733, 644265, 645048, 647007, 647080, 652157, 652152, 652154, 650077, 651727, 651772, 651773, 651813, 651815) of 21 complaint / failure investigations which did not report root cause and follow up.

a-2) Vaxcel Low Profile Port With PASV valve kits had 2 (646860 & 649881) of 5 complaint/failure investigations which did not report root cause and follow up.

a-3) Vaxcel Mini & Standard Port with PASV valve kits had 6 (628403, 634224, 637445, 639511, 639513, 639514) of 9 complaint/failure investigations which did not report root cause and follow up.

a-4) Vaxcel PASV PICCs (IR/5/2) had 14 (634999, 636072, 636073, 636074, 636075, 636077, 636083, 634185, 641152, 641153, 641155, 641575, 641578, 641579) of 19 complaint/failure investigations which did not report root cause and follow up.

a-5) Vaxcel PASV PICCs (IR/5/1) had 4 (637687, 637500, 645956, 645957) of 5 complaint/failure investigations which did not report root cause and follow up.

a-6) Vaxcel PASV PICCs (CK/5/2) had 10 (635156, 635300, 637348, 637349, 637350, 637352, 637354, 637355, 644796, 645595) of 14 complaint/failure investigations which did not report root cause and follow up.

b-1) Introducer/sheaths [redacted] used in the Vaxcel Mini, Standard, and Low Profile Port with PASV valve kits had 12 (636342, 640042, 641509, 644265, 645048, 652157, 652152, 652154, 650077, 651727, 651813, 651815) of 21 complaints failed to request and obtain complainant product, failure to follow-up in a timely manner to get failed device, and/or GF RCM not following up to assure failed device is obtained from complainant.

b-2) Vaxcel Mini & Standard Port with PASV valve kits had 3 (639511, 639513, 639514) of 9 complaints failed to request and obtain complainant product, failure to follow-up in a timely manner to get failed device, and/or GF RCM not following up to assure failed device is obtained from complainant.

b-3) Vaxcel PASV PICCs (IR/5/2) had 4 (641576, 641575, 641578, 641579) of 9 complaints failed to request and obtain complainant product, failure to follow-up in a timely manner to get failed device, and/or GF RCM not following up to assure failed device is obtained from complainant.

b-4) Vaxcel PASV PICCs (IR/5/1) had 2 (645556 & 6455957) of 5 complaints failed to request and obtain complainant product, failure to follow-up in a timely manner to get failed device, and/or GF RCM not following up to assure failed device is obtained from complainant.

Attachment #4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005* FEI NUMBER 1317056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John F. Watkins, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glens Falls, NY 12801-3864	Medical Device Manager

OBSERVATION 9

Procedures have not been established to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems regulation.

Specifically,

a) Quality Assurance Procedure #6V87 requires that the original signed Port Traceability form completed during the QA inspection of assembled Vaxcel Chest Ports with Attached lock are removed from the device history record and replaced with a photocopy of the completed record in the device history record. Audit of 38 device history records for the Vaxcel Chest Ports Port Traceability forms found 13 photocopies present in the respective production device history record. Review found that the firm had 12 of the 13 original Port Traceability forms in a different folder in Regulatory Affairs but was unable to locate the 13th original lot #917111.

Annotation: Promised to correct.

OBSERVATION 10

Records of complaint investigations do not include device identifications and control numbers used.

Specifically,

a) Introducer /Sheath[redacted]and used in Vaxcel Mini, Standard, & Low Profile PASV Port with valve kits received as complaints had 6 (652157, 652152, 652154, 650077, 651813, 651815) of 21 which failed to list lot number of product.

b) Vaxcel Low Profile Chest Implant Ports had 2 (646355 & 648652) of 5 which failed to list lot number of product.

c) Vaxcel Mini & Standard Chest Implant Ports had 4 (634224, 639511, 639513, 639514) of 9 which failed to list lot number of product.

d) Vaxcel PASV PICCs (IR/5/2) had 12 (636072, 636073, 636074, 636075, 636077, 636083, 636084, 634185, 637896, 637898, 641153, 641155) of 19 which failed to list lot number of product.

e) Vaxcel PASV PICCs (IR/5/1) had 3 (637687, 637900, 639866) of 5 which failed to list lot number of product.

ATTACHMENT 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	04/12/2005 - 05/06/2005*
	FEI NUMBER 1317056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John F. Watkins, Plant Quality Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	10 Glens Falls Tech Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glens Falls, NY 12801-3864	Medical Device Manager

f) Vaxcel PASV PICCs (CK/5/2) had 9 (637349, 637350, 637352, 637354, 637355, 643025, 645595, 645593, 643023) of 14 which failed to list lot number of product.

*** DATES OF INSPECTION:**
04/12/2005(Tue), 04/14/2005(Thu), 04/15/2005(Fri), 04/19/2005(Tue), 04/21/2005(Thu), 04/22/2005(Fri), 05/06/2005(Fri)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Michael G Sinkevich, Investigator

SEE REVERSE OF THIS PAGE	This is a modified document.	DATE ISSUED MGS 05/06/2005

FORM FDA 483 (07/00) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 6 OF 6 PAGES

Attachment 4