Boston Scientific Corporation

510(k) Summary for Blue SUI Sling

OCT 10 2012

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename:	Obtryx II System
Common/usual name:	Surgical Mesh
Classification Name:	OTN – Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision 21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename:	Advantage , Advantage Fit & Lynx Systems Obtryx, Prefyx Systems
Common/usual name:	Surgical Mesh
Classification Name:	FTL- Mesh, Surgical, Polymeric 21 CFR 878.3300, Class II
Premarket Notification:	Boston Scientific Corporation, ▪ K020110 ▪ K040787

E. Device Description

The proposed sling is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a blue knitted polypropylene monofilament fiber mesh body implant, association loops, dilator legs, sleeves, leader loops, center tab and lead.

The proposed sling is packaged with (2) delivery devices (Halo or Curved) which are used in conjunction with the mesh assembly to place the mesh implant. Each of the delivery devices consist of a polymer handle and a stainless steel needle which extends from the handle. The tip of the needle has a slot which is used to attach the association loop of the mesh assembly.

F. Intended Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

G. Technological Characteristics

The proposed sling has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicates K020110 & K040787.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed sling is substantially equivalent to the predicate sling in terms of intended use, technological characteristics, and performance characteristics tested. The proposed sling is as safe, as effective, and performs as well as the predicate devices.

I. Non-Clinicial Testing

Material testing was performed to demostrate that the material properites are suitable for the intended use.

Bench testing was performed to demostrate that the device as manufactured meets performance specifications. Test results demostrate that the device meets the predetermine specifications and is acceptable for clinical use.

Biocompatiblity testing was performed in accordance to standard EN ISO 10993-1 for each of the patient contacting materials, and results demonstrate that the device is biocompatible for its intended use.

Conclusion:

Based on material, biocompatiblity, bench testing, and the proposed device labeling, the Obtryx II System is substantially equivalent to the identified predicate devices in terms of intended, use , safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 10 2012

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade/Device Name: Obtryx II System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: September 19, 2012
Received: September 20, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Boston Scientific Corporation

Indications for Use Statement

510(k) Number (if Known): K121754

Device Name: Obtryx II System

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

09 Oct 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121754

Traditional 510(k)
Obtryx II System

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
Urology/Woman's Health
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade Name: Blue SUI Sling
Dated: June 13, 2012
Received: June 14, 2012

JUL 30 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission we require the following:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 15, 2012

BOSTON SCIENTIFIC CORP.
UROLOGY/WOMAN'S HEALTH
100 BOSTON SCIENTIFIC WAY
M21
MARLBOROUGH, MASSACHUSETTS 01752
ATTN: JANET A. MCGRATH

510k Number: K121754

Received: 6/14/2012

Product: BLUE SUI SLING

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'mcgrathj@bsci.com'
Sent: Friday, June 15, 2012 7:54 AM
Subject: Relayed: K121754 ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mcgrathj@bsci.com'

Subject: K121754 ACK Letter

Sent by Microsoft Exchange Server 2007

47

SUBSORD K121754

Boston Scientific

Urology
Gynecology
100 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

June 13, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Subject: Premarket Notification- Traditional 510(k)
Device Name: Blue SUI Sling
Device Type: Surgical Mesh
Regulation Number: 21 CFR
Regulatory Class: II
Product Code: OTN
Panel: Obstetrics and Gynecology

Dear Sir/Madam,

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 510(k) Notification, 21 CFR 807.90(e), Boston Scientific Corporation (BSC) hereby submits this Original Traditional 510(k) and three copies (one electronic copy that is an exact duplicate of the original paper submission and two paper copies) for the "Blue SUI Sling ".

The proposed Blue SUI is (b)(4) and is very similar in terms of design and materials to a previously cleared Blue SUI Sling by Boston Scientific K040787. The proposed Mid Urethral Sling share principal characteristics, including:

- Identical indications for use
- Same fundamental design in that they consist of similar mesh assembly and identical delivery devices (alo and curved) designs.
- Same base materials used for the mesh implant, polypropylene

Per the recommendations in the Guidance for Industry and FDA Staff, "Format for Traditional and Abbreviated 510(k)'s" please refer to Cover Letter: Attachment A for a table summarizing the design and use of the device.

Boston Scientific Corporation considers its intent to manufacture and distribute this device to be confidential commercial information, and therefore exempt from public disclosure according to 21 CFR 807.95.

If you have any questions regarding this Premarket Notification, please contact me at (508) 683- 4726 or by facsimile at (508) 683-5827.

Sincerely,

Janet A. McGrath
Principal Specialist, Global Regulatory Affairs
Urology and Gynecology
Boston Scientific Corporation
e-mail: mcgrathj@bsci.com

Boston Scientific Corporation

Traditional 510(k): Premarket Notification

Blue SUI Sling

June 12, 2012

Device Panel: General Surgery

Branch: Office of Device Evaluation
Center for Devices and Radiological Health

Table of Contents

Section 1

Medical Device User Fee Cover Sheet (Form FDA 3601)

This section does not apply. Third-party review submissions are exempt from user fees.

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BOSTON SCIRNTIFIC CORP 100 BOSTON SCIENTIFIC WAY MARLBOROUGH MA 01752 US	Lisa Sullivan 2.1 E-MAIL ADDRESS lisa.sullivan@bsci.com 2.2 TELEPHONE NUMBER (include Area code) 508-683-4745 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-683-5827
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

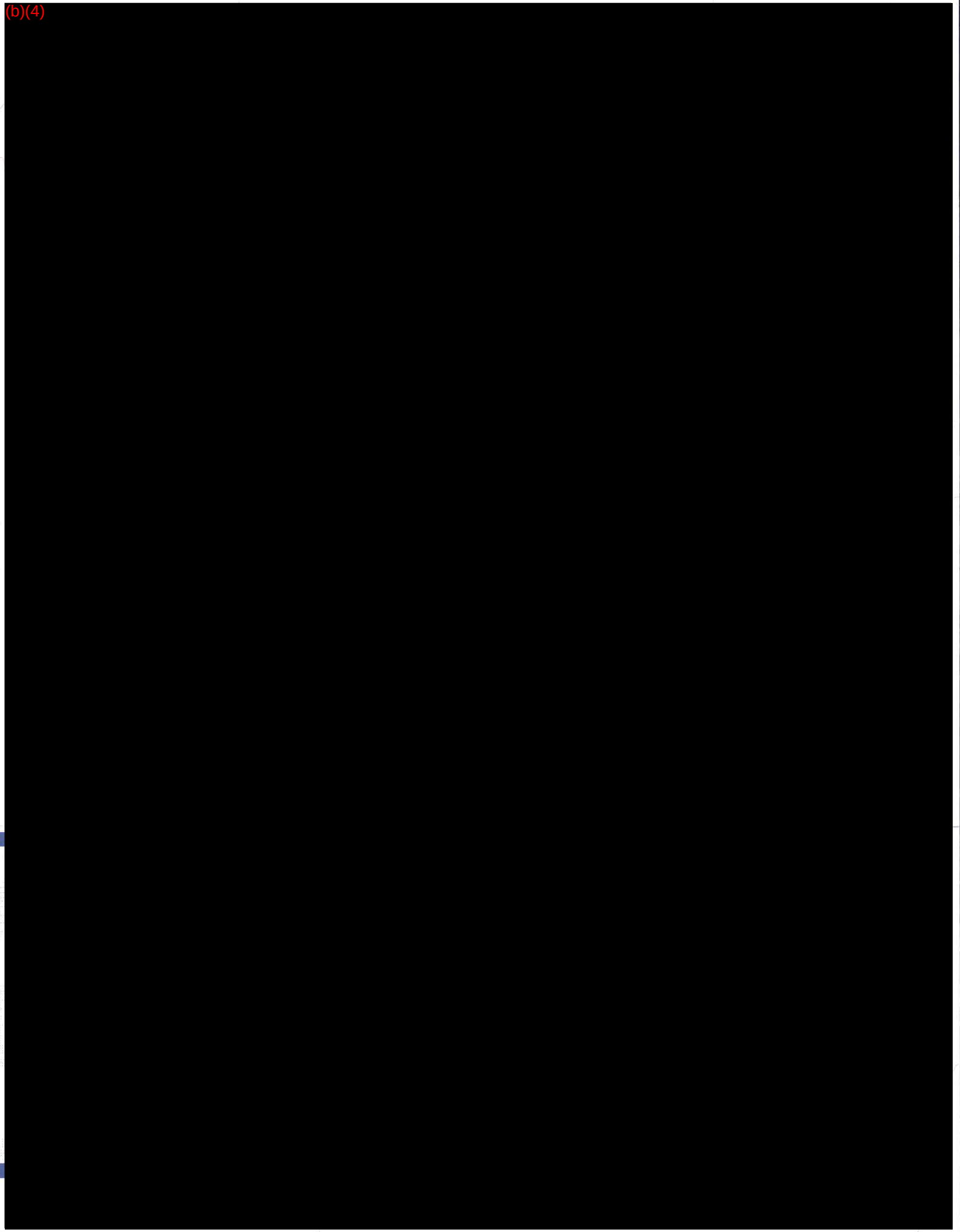
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 02-Mar-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet


(b)(4)

Section 2

CDRH Premarket Review Submission Cover Sheet

and

FDA Form 3674, Certificate of Compliance with ClinicalTrials.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
June 12, 2012	MD6060582-956733	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Boston Scientific Corporation	1225056 (operator/owner# 9912058)		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Urology /Woman's Health	(508) 683-4726		
Street Address	**FAX Number *(including area code)***		
100 Boston Scientific Way ,M21	(508) 683-5827		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Marlborough	Ma	01752	USA
Contact Name			
Janet A . McGrath			
Contact Title	**Contact E-mail Address**		
Principal Specialist Global Regulatory Affairs	mcgrathj@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FTL	2	FTL	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K020110	1	Advantage and Advantage Fit Systems Lynx Systems	1	Boston Scientific
2	K040787	2	Obtryx Systems (Halo & Curved)	2	Boston Scientific
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Surgical mesh

	Trade or Proprietary or Model Name for This Device		Model Number
1	Blue SUI Sling	1	M0068505110,M0068505111,M0068504110,M006850[illegible]
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OTN	878.3300	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Obstetrics/Gynecology		

Indications *(from labeling)*

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting form hypermobility and/or intrinsic sphincter deficiency.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

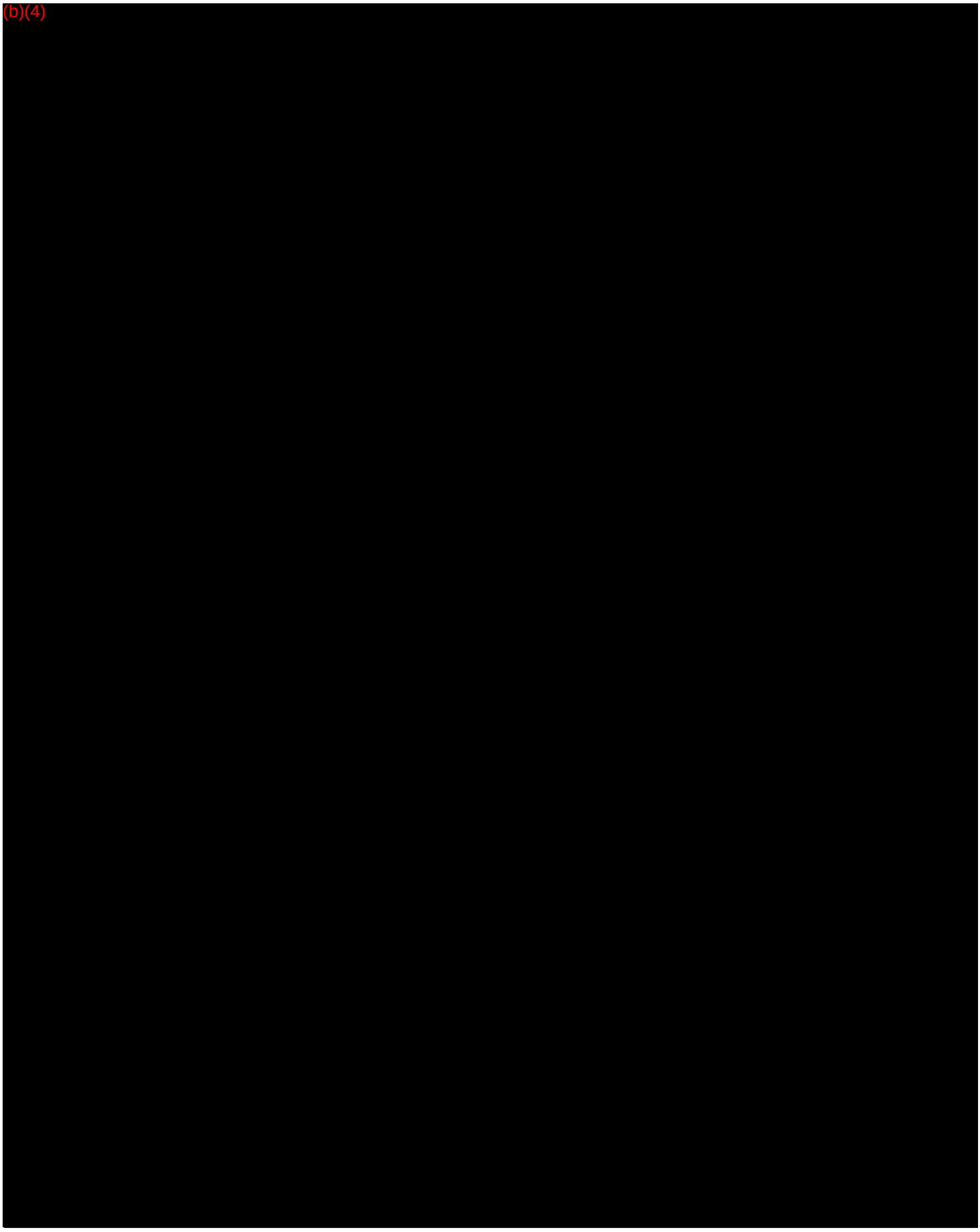
(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

FORM FDA 3514 (12/10) Add Continuation Page

(b)(4)



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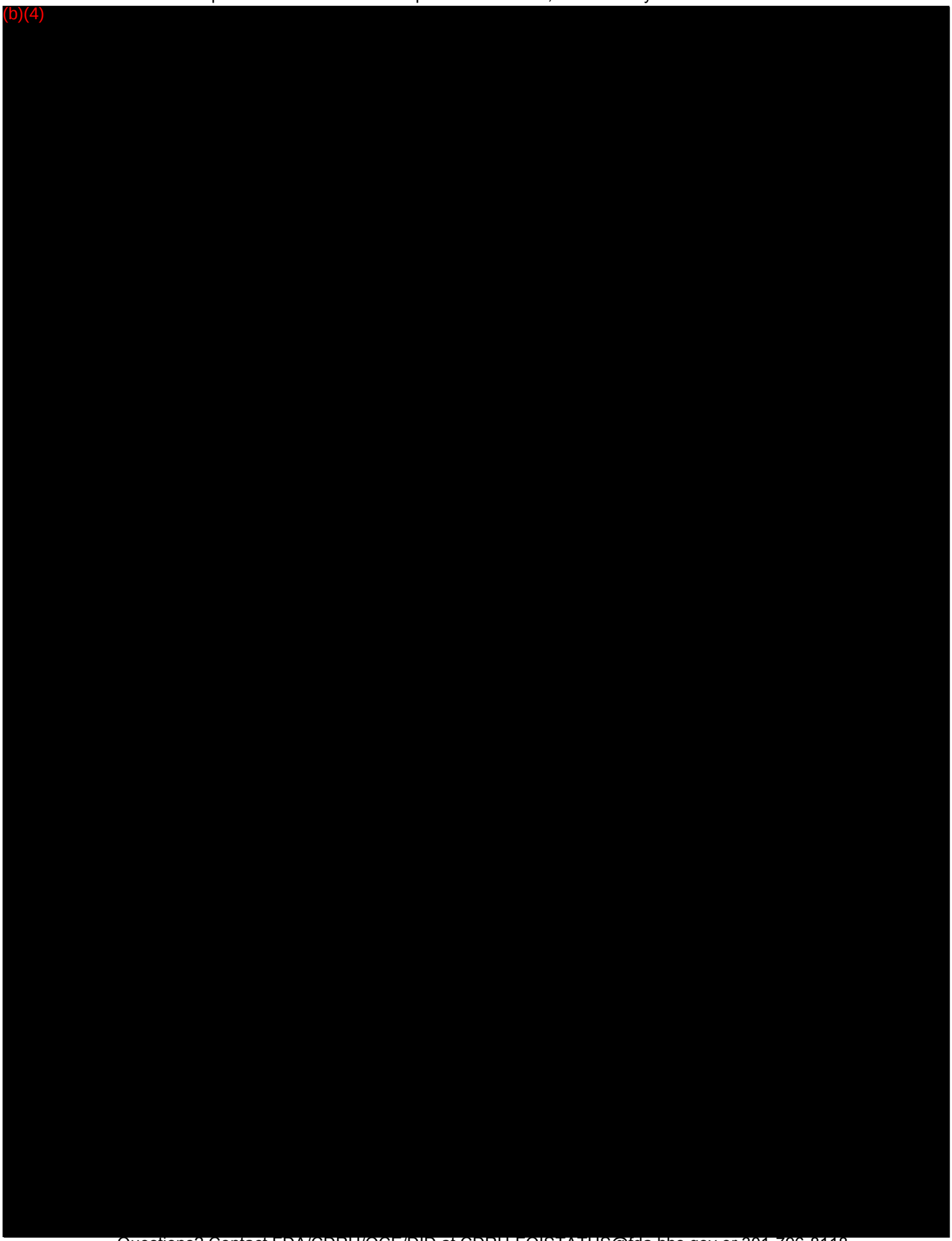

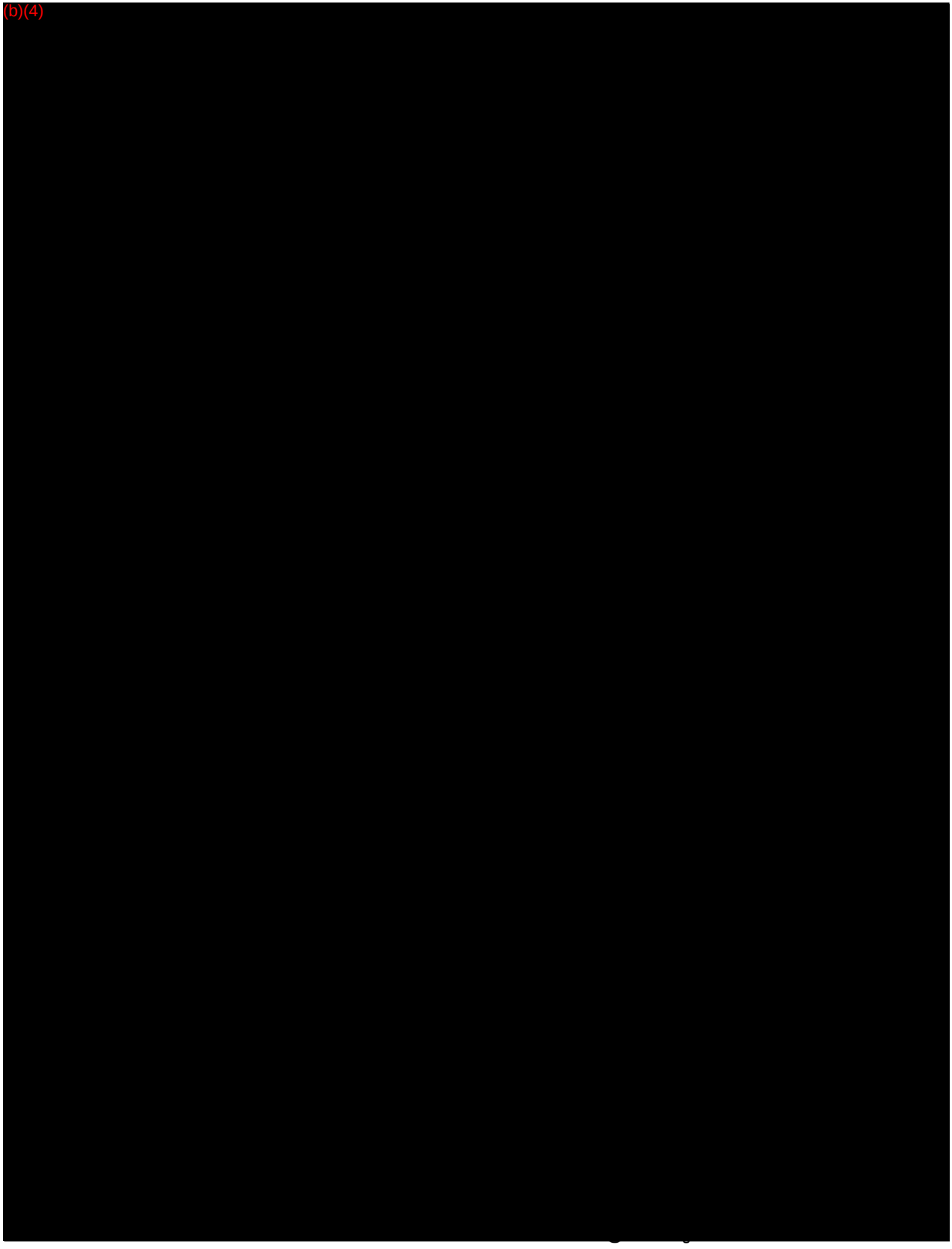
(b)(4)

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date -** This is the date of the application/submission which the certification accompanies.
3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification -** This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11 -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14. -** Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/11) (BACK)

Section 3

510(k) Cover Letter

Boston Scientific

Urology
Gynecology
100 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

June 13, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Subject: Premarket Notification- Traditional 510(k)
Device Name: Blue SUI Sling
Device Type: Surgical Mesh
Regulation Number: 21 CFR
Regulatory Class: II
Product Code: OTN
Panel: Obstetrics and Gynecology

Dear Sir/Madam,

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 510(k) Notification, 21 CFR 807.90(e), Boston Scientific Corporation (BSC) hereby submits this Original Traditional 510(k) and three copies (one electronic copy that is an exact duplicate of the original paper submission and two paper copies) for the "Blue SUI Sling ".

The proposed Blue SUI is (b)(4) and is very similar in terms of design and materials to a previously cleared Blue SUI Sling by Boston Scientific K040787. The proposed Mid Urethral Sling share principal characteristics, including:

- Identical indications for use
- Same fundamental design in that they consist of similar mesh assembly and identical delivery devices (alo and curved) designs.
- Same base materials used for the mesh implant, polypropylene

Per the recommendations in the Guidance for Industry and FDA Staff, "Format for Traditional and Abbreviated 510(k)'s" please refer to Cover Letter: Attachment A for a table summarizing the design and use of the device.

Boston Scientific Corporation considers its intent to manufacture and distribute this device to be confidential commercial information, and therefore exempt from public disclosure according to 21 CFR 807.95.

If you have any questions regarding this Premarket Notification, please contact me at (508) 683- 4726 or by facsimile at (508) 683-5827.

Sincerely,

Janet A. McGrath
Principal Specialist, Global Regulatory Affairs
Urology and Gynecology
Boston Scientific Corporation
e-mail: mcgrathj@bsci.com

Cover Letter: Attachment A

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? [A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? [A]		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Section 4

Indications for Use Statement

Indications for Use Statement

510(k) Number (if Known): _____

Device Name: Undetermined

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X____ (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Traditional 510(k)
Blue SUI Sling System

Section 5

510(k) Summary

510(k) Summary for Blue SUI Sling

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename:	Blue SUI Sling System
Common/usual name:	Surgical Mesh
Classification Name:	OTN – Mesh, Surgical, Polymeric 21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename:	Advantage , Advantage Fit & Lynx Systems Obtryx, Prefyx Systems
Common/usual name:	Surgical Mesh
Classification Name:	FTL- Mesh, Surgical, Polymeric 21 CFR 878.3300, Class II
Premarket Notification:	Boston Scientific Corporation, ▪ K020110 ▪ K040787

E. Device Description

The proposed sling is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a blue knitted polypropylene monofilament fiber mesh body implant, association loops, dilator legs, protective sleeves, leader loops, center tab and center tab lead.

Accessories

The proposed sling is packaged with other legally marketed accessories (e.g., Delivery Device; Class I exempt: 876.4730 Manual gastroenterology-urology surgical instrument and accessories).

F. Intended Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

G. Technological Characteristics

The proposed sling has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicates K020110 & K040787.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed sling is substantially equivalent to the predicate sling in terms of intended use, technological characteristics, and performance characteristics tested. The proposed sling is as safe, as effective, and performs as well as the predicate devices.

Section 6

Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*
(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as Regulatory Affairs Specialist of Boston Scientific Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
Urology and Gynecology

June 12, 2012
Date

[Premarket Notification (510(k) Number]: NA

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

Section 7

Class III Summary and Certification

This section does not apply.
The proposed device has been previously classified by FDA as Class II per 21 CFR 878.4810.

Section 8

Financial Certification or Disclosure Statement

This section does not apply.
No clinical studies were required in support of this premarket notification.

Section 9

Declarations of Conformity and Summary Reports

(b)(4)

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(b)(4)

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Section 10

Executive Summary

Section 10 Executive Summary

Overview:

The proposed device is a transobturator suburethral sling (b)(4) The key features of this new transobturator sling ar (b)(4) (b)(4) (b)(4)

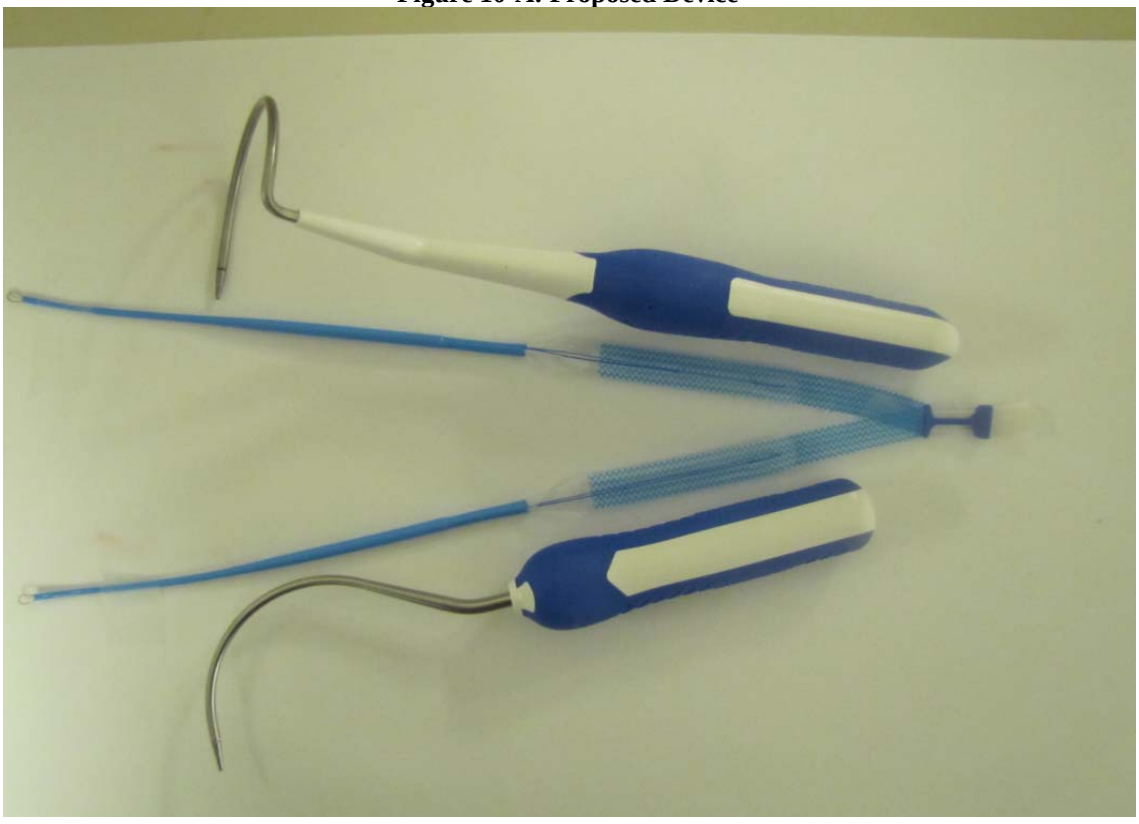
The modifications to the mesh assembly include: (b)(4)

This new sling will work with our current Obtryx® Halo and Obtryx® Curved delivery devices, cleared under K040787.

The proposed device (**Figure 10-A**) is a sterile, single use device consisting of:

- (1) Mesh assembly and
- (2) Delivery devices (Curved or Halo)

Figure 10-A: Proposed Device

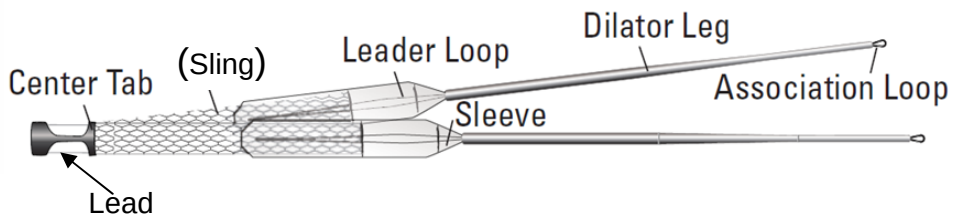


Section 10 Executive Summary *(Continued)*

Mesh Assembly:

The *mesh assembly* consists of: a sling (mesh implant), dilator legs with association loops, protective sleeves, leader loops, a center tab and center tab lead. **Figure 10-B** provides a diagram of the proposed device. The proposed mesh assembly is similar in design to predicates (K020110 & K040787) and **identical** in terms of current mesh characteristics and **intended use**.

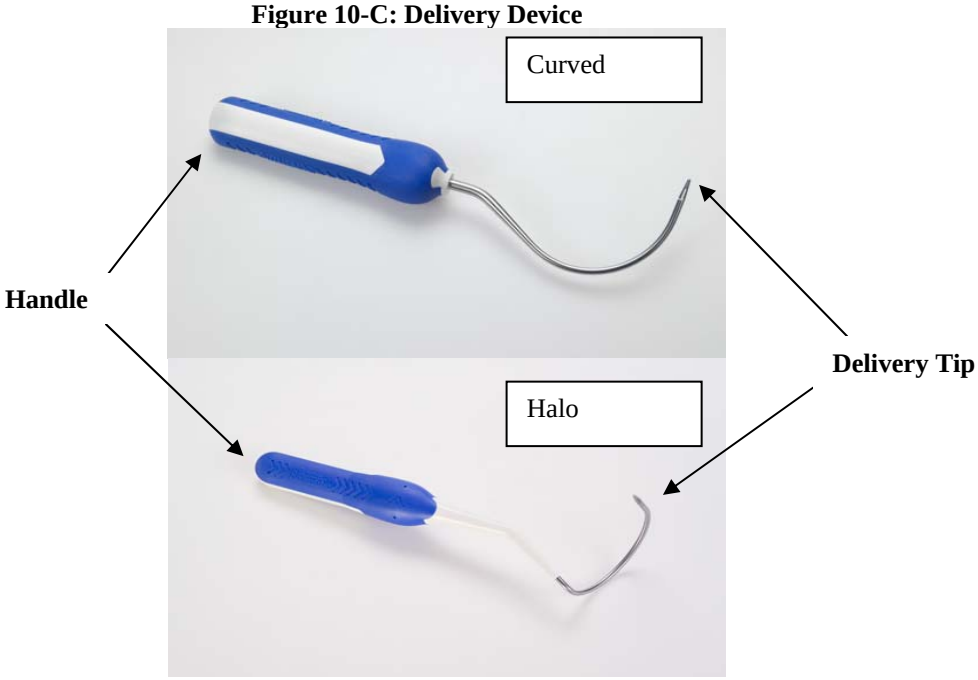
Figure 10-B: Mesh Assembly



Delivery Devices:

Two *delivery devices*, either Curved or Halo depending on the model, are included with each mesh assembly. Each delivery device consists of a molded handle at the proximal end with a curved shaft emanating from the handle which culminates in a formed 'needle' shape (either Curved or Halo) at the distal end (see **Figure 10-C**). The delivery devices are **identical** to those currently packaged with our previously cleared Obtryx® Slings (K040787, Curved & Halo).

Figure 10-C: Delivery Device

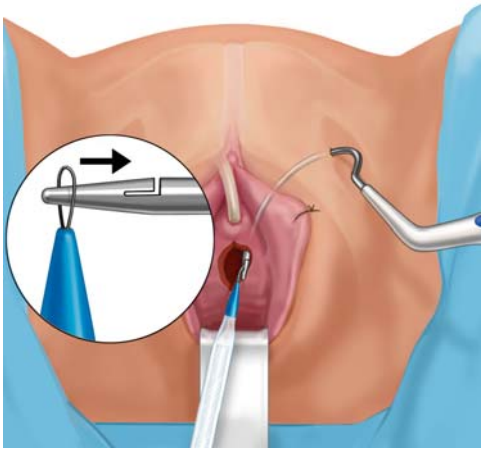


Section 10 Executive Summary *(Continued)*

Route of Placement:

The route of placement and attachment mechanism of the proposed sling are *identical* to that of the predicate (K040787, Obtryx). Using the included delivery devices, the physician places the sling to the suburethral region utilizing the transobturator placement method for the treatment of Stress Urinary Incontinence (SUI), which is identical to the predicate (K040787,Obtryx). As such, there is **no change in intended use.** **Figure 10-D** shows the placement of a suburethral sling using the Obtryx Halo delivery device.

Figure 10-D: Placement of the proposed and predicate (K040787,Obtryx)
Obtryx Halo shown



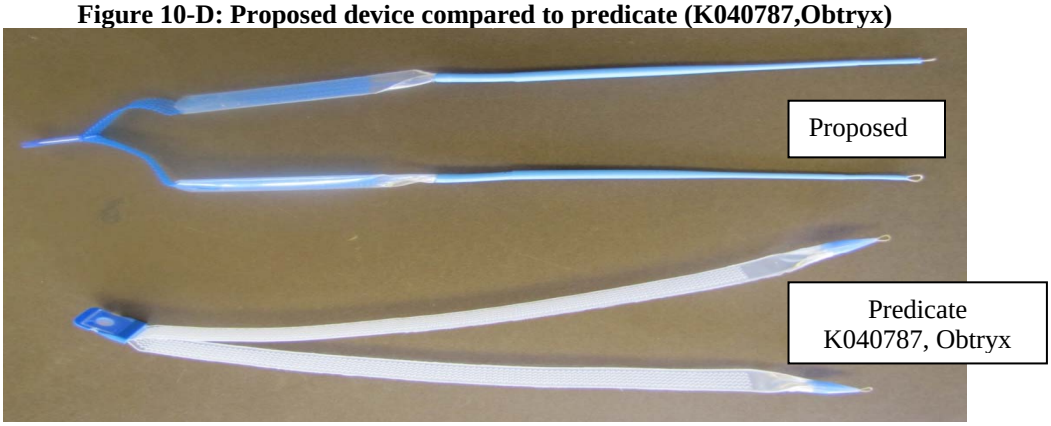
(b)(4)

Section 10 Executive Summary *(Continued)*

Discussion of Differences (Proposed and Predicate):

Design differences between the previously cleared BSC predicate (K040787, Obtryx) sling and the proposed device are described below. Reference **Figure 10-D** for a comparative photograph of the predicate and proposed devices. Table 10-1 on the next page provides a comparison of the predicate and proposed devices.

Figure 10-D: Proposed device compared to predicate (K040787,Obtryx)



Sling (Mesh Implant) Changes:

(b)(4)

[redacted]

Mesh Assembly Changes:

(b)(4)

[redacted]

Section 10 Executive Summary *(Continued)*

Direction for Use Changes:

(b)(4)

[redacted]

Table 10-1: Comparison of proposed to predicates

Feature	Predicate Devices (K020110& K040787)	Proposed Device
Placement		
Intended Use	The proposed device is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension.	The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.
Incision	Two transverse, groin incision and incision of anterior vaginal wall (K040787).	Identical to K040787
Route of placement	Introduces the delivery shaft percutaneously into a groin incision through the obturator membrane, behind the ischio-pubic ramus, and exits through the anterior vaginal wall incision. The association loop is attached to the tip of the delivery device needle slot and retracted back through the tissue, exiting the groin incision. This is repeated on the contralatral side (K040787).	Identical to K040787
Fixation method	To abdominal skin by friction/subsequent tissue in growth.	Identical to K020110 & K040787
Tensioning of sling	Physician option, patient dependent during surgery	Identical to K020110 & K040787

Feature	Predicate Devices (K020110& K040787)	Proposed Device
Centering Mechanism	Center tab (b)(4)	Center tab (b)(4) (b)(4)
Final Device Location	Suburethral	Identical to K020110 & K040787
Delivery Devices	Packaged with (2) Halo Or (2) Curved (K040787)	Identical to K040787
Mesh		
Mesh Properties: **Course /Inch** **Wale/Inch** **Fiber diameter (in.)** **Thickness (in.)**	(b)(4)	Identical to K020110 & K040787 (b)(4)
Mesh sling size		
Implant	Non-absorbable	Non-absorbable
Material	Polypropylene (b)(4)	Polypropylene (b)(4) (b)(4)
Colorant	None	
Mesh Assembly (materials)		
Dilator	(b)(4)	
Association loops		
Sleeve		
Leader Loops		
Center Tab		
Center Tab Lead		

Section 10 Executive Summary *(Continued)*

(b)(4) [redacted]

Performance Test Summary:

Functional testing was performed to demonstrate that the proposed device met the product specification requirements. Testing was performed in accordance with the FDA Guidance document, "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," issued on March 2, 1999. Several of these tests have standard test methods that were followed and declarations of conformity to those standards are located in Section 9. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] The performance testing reported in Section 19 demonstrate that the device performance is not affected by the sterilization process or accelerated aging and is acceptable for its intended use.

(b)(4) [redacted]

Substantial Equivalence:

We believe that a determination of "substantial equivalence" is supported, based on the comparative evaluation between the proposed sling and, the predicates (BSC) sling presented herein; inclusive of design, materials, performance characteristics and indications for use.

Section 11
Updates to predicate since clearance of (K020110 & K040787)

(b)(4)

(b)(4)

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(b)(4)

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(b)(4)

Section 12

Device Description

Section 12: Device Description

Product Performance/Device Design Overview

(b)(4)

The proposed mesh is identical to the predicate with the exception of (b)(4)
(b)(4)

(b)(4)

(b)(4) The device is still placed in the same manner, with minor instruction changes to account for the redesigned components.

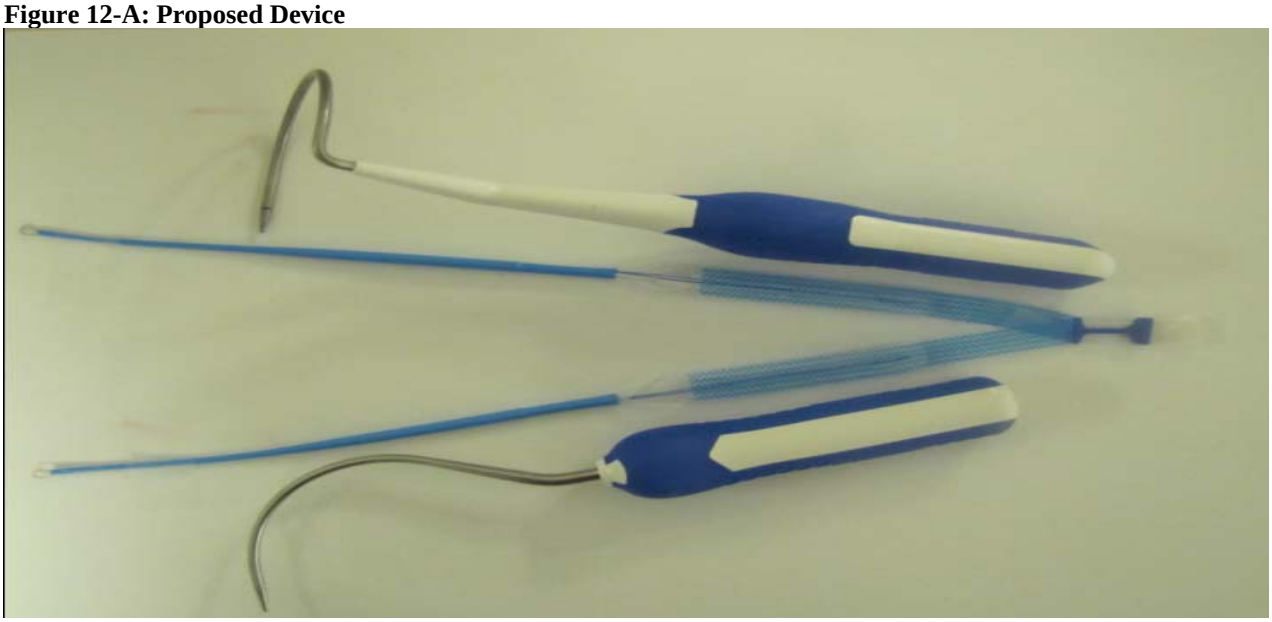
Table 12-1 lists the Proposed Devices.

Table 12-1: Proposed Device Model Numbers

Product UPN #	Description
M0068505110	Blue SUI Sling (single) (Halo)
M0068505111	Blue SUI Sling (5-pack) (Halo)
M0068504110	Blue SUI Sling (single)(Curved)
M0068504111	Blue SUI Sling (5-pack)(Curved)

The proposed device will be packaged with (2) delivery devices (Curved or Halo), to facilitate sling placement. The delivery device is a Class I Exempt per 21CFR 876.4730-Manual Gastroenterology-Urology Surgical Instrument and Accessories. **Figure 12-A** shows the proposed device and both delivery devices.

Figure 12-A: Proposed Device



Section 12: Device Description *(Continued)*

The device description for the proposed device, provided in this section, has been divided into the following parts: Sling (mesh implant), Mesh Assembly, Delivery Device and Packaging.

Sling (mesh implant)

The proposed sling is manufactured from the identical non absorbable synthetic material (polypropylene) as the predicate devices (K020110 & K040787). (b)(4) (b)(4) (b)(4) **Table 12-2** Mesh Product Characteristics includes a detailed listing of the design and performance characteristics of the proposed mesh implant.

The proposed mesh implant contains a "detanged" section along the length of each side of the sling. (b)(4) (b)(4) Reference **Figure 12-B** and **12-C** Mesh Edge and Sling. (b)(4) (b)(4) (b)(4) The route of placement of the proposed sling is ***identical to the predicate*** (Obtryx, K040787) as it is intended for use as a suburethral sling for transobturator placement.

Figure 12-B Mesh Edge

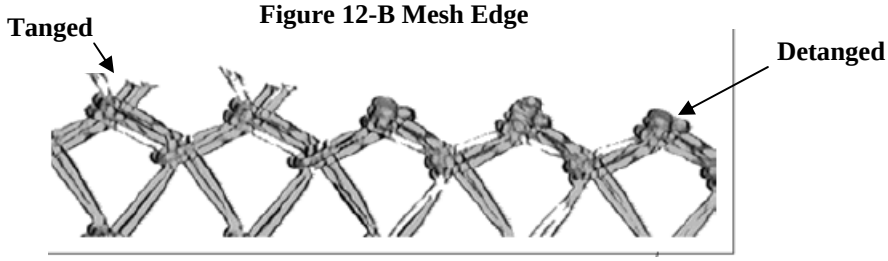
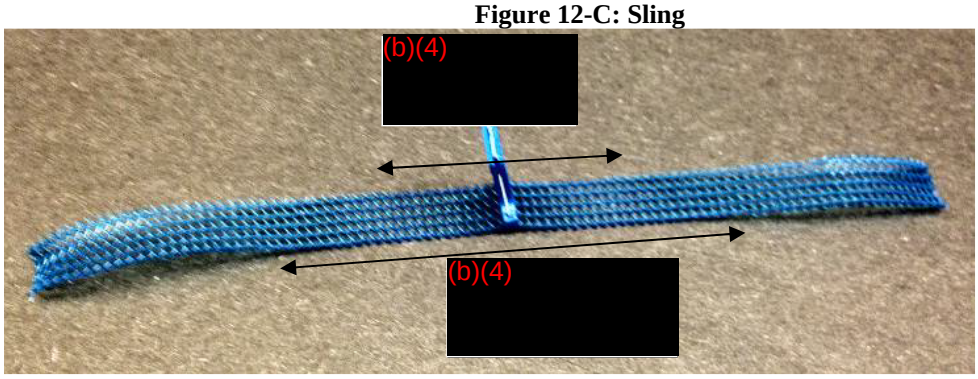


Figure 12-C: Sling



Section 12: Device Description *(Continued)*

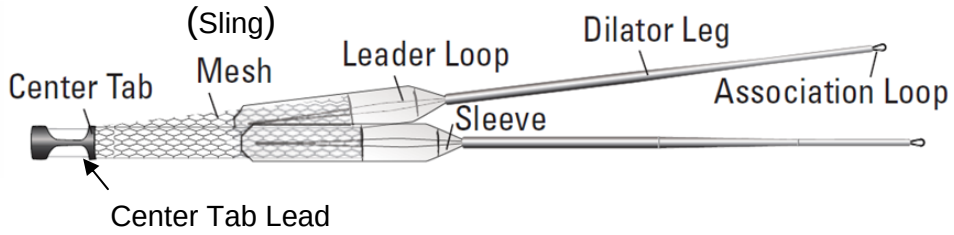
Table 12-2: Product Characteristics of the Proposed Mesh

Device Characteristic	Proposed Mesh Design
Mesh material Color	Polypropylene Blue
Mesh weave characteristics	Knit
(b)(4)	[redacted]

Section 12: Device Description *(Continued)*

Mesh Assembly

Figure 12-D: Mesh Assembly



The proposed mesh assembly is a sterile, single use device consisting of (1) sling (mesh implant), (2) (b)(4) dilator legs with (b)(4) association loops, (2) (b)(4) sleeve ends, each with a (b)(4) leader loop, and a (b)(4) center tab with a (b)(4) lead line.

Each side of the mesh assembly has a dilator leg with an association loop, a protective sleeve and leader loop. (b)(4)

(b)(4)

(b)(4)

(b)(4) The improved center tab design marks the center of the sling and aids in physician tensioning.

During delivery, the association loop of the mesh assembly is loaded onto the distal end of the delivery device needle tip slot for placement of the sling through the obturator foremen. Once placed, the sling can be adjusted under the mid line of the urethra by the center tab. After adjustments are finalized, the leader loops are cut from each leg assembly and dilators are removed. Once placement of the sling is complete, the center tab is removed by cutting the center tab lead from the sling implant.

Table 12-3 includes a detailed list of the characteristics of the proposed Mesh Assembly.

Section 12: Device Description *(Continued)*

Table 12-3: Product Characteristics of the Proposed Mesh Assembly

Device Characteristic	Proposed Mesh Assembly Design
(b)(4)	

Delivery Devices

The delivery devices are designed to facilitate the passage of the proposed sling through bodily tissues until sling placement is achieved at the appropriate sub-urethral location. The delivery devices are Class I Exempt per 21CFR 876**.**4730- Manual Gastroenterology-Urology Surgical Instrument and Accessories.

Two delivery devices (either Curved or Halo) are included with each mesh assembly and are **identical** to the current delivery devices cleared under #K040478 (Obtryx). Each delivery device has a (b)(4) handle at the proximal end, a (b)(4) curved shaft emanating from a handle which culminates in a formed 'needle' shape (either Curved or Halo) at the distal end. See **Figure 12-E** for a comparison of the Curved and Halo Delivery Devices.

Section 12: Device Description *(Continued)*

The delivery tip of the needle has a slot which is used to attach the association loop securely to the mesh assembly in preparation for sling placement. (b)(4)

(b)(4)

(b)(4) ee **Figure 12-F**.

Figure 12-E: Delivery Device

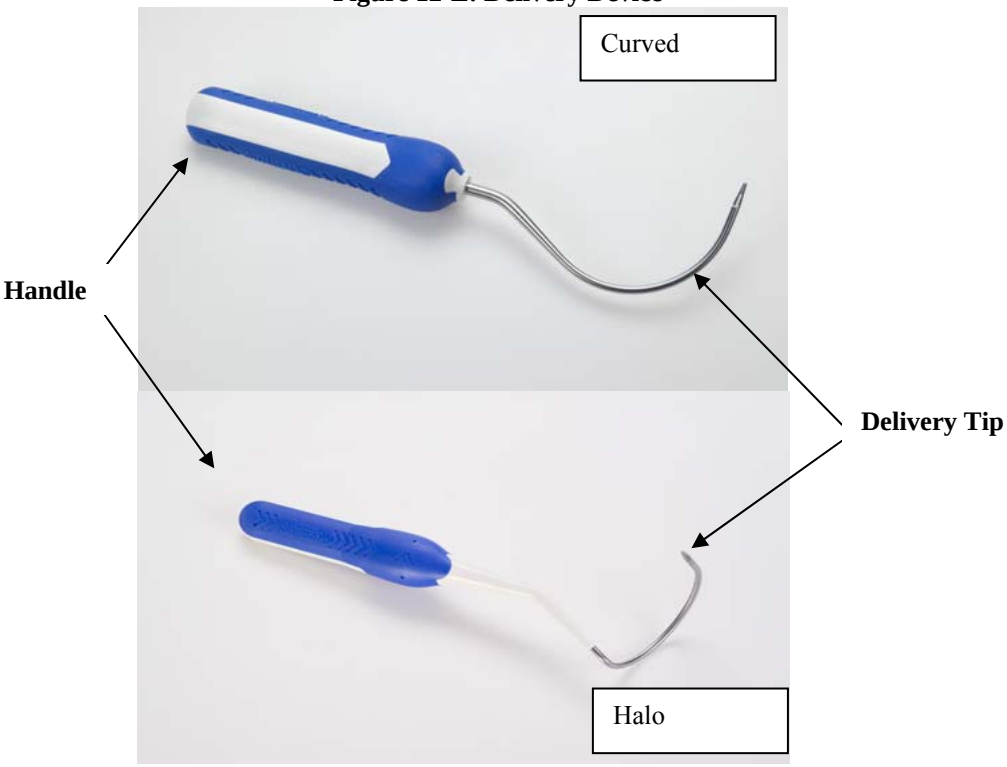


Figure 12-F Delivery Needle Tip to Association Loop Connection

Table 12-4 provides a list of the materials and description of functionality for each component of the Mesh Assembly and Delivery Devices.

Section 12: Device Description *(Continued)*

(b)(4)

Section 12: Device Description *(Continued)*

Packaging

Identical to the (BSC) predicate, the proposed device packaging consists of a rigid (b)(4) base, (b)(4) tray insert, Tyvek® lid, and outer shelf box. The mesh assembly is placed in a Tyvek envelope along with two delivery devices which are placed in the tray base and held in place by a tray insert. The Tyvek lid is placed on top of the insert and then heat sealed. The sealed tray is placed inside the outer shelf box along with the directions for use. Labels are placed on both the Tyvek lid and the outer shelf box. A description of the packaging components and their materials is provided in **Table 12-5.** See Packaging **Drawings 12-1 & 2** for packaging configuration.

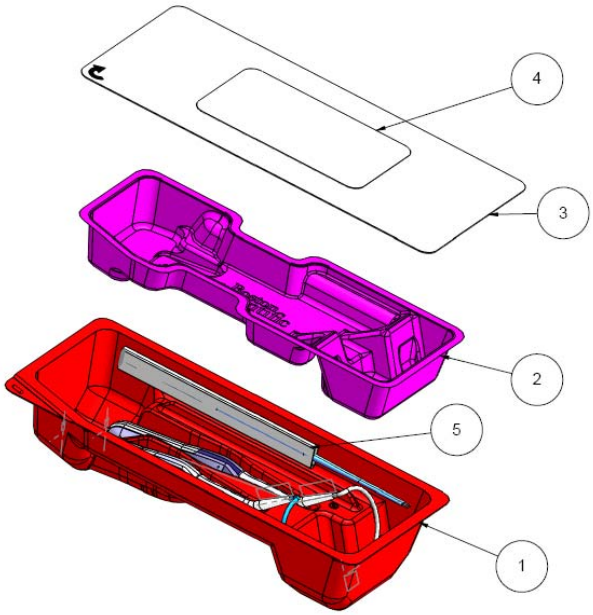
Table 12–5 Packaging Components

Item #	Description	Material	Function
1	Tray Base	(b)(4)	Packaging to protect product during shipping and to maintain product sterility
2	Tray insert		Packaging to protect mesh assembly/ delivery device during shipping. The insert fits inside the tray base on top of the components, to minimize the movement during shipping.
3	Tyvek Lid		Packaging to protect product during shipping, permits EO gas penetration during sterility cycle, and maintains product sterility for labeled shelf life.
4	Label		Label with human readable information: Model #, Description, Contents, Sterility, Manufacturer Name and address etc.
5	Tyvek Envelope		Packaging to protect product during shipping, permits EO gas penetration during sterility cycle.
6	Label		Label with human readable information: Model #, Description, Contents, Sterility, Manufacturer Name and address etc.
7	Outer Shelf Box		Outer Shelf Box provides secondary package to protect product.
8	Directions For Use		Labeling provided with product including: Indications for Use, Contraindications, Warnings, Precautions, and Instructions for Use.

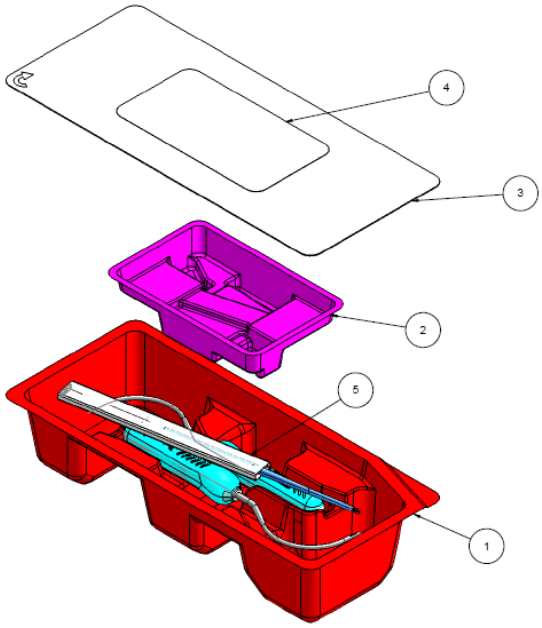
Section 12: Device Description *(Continued)*

Drawing 12-1: Packaging, Tray Base, Insert & Lid

Halo

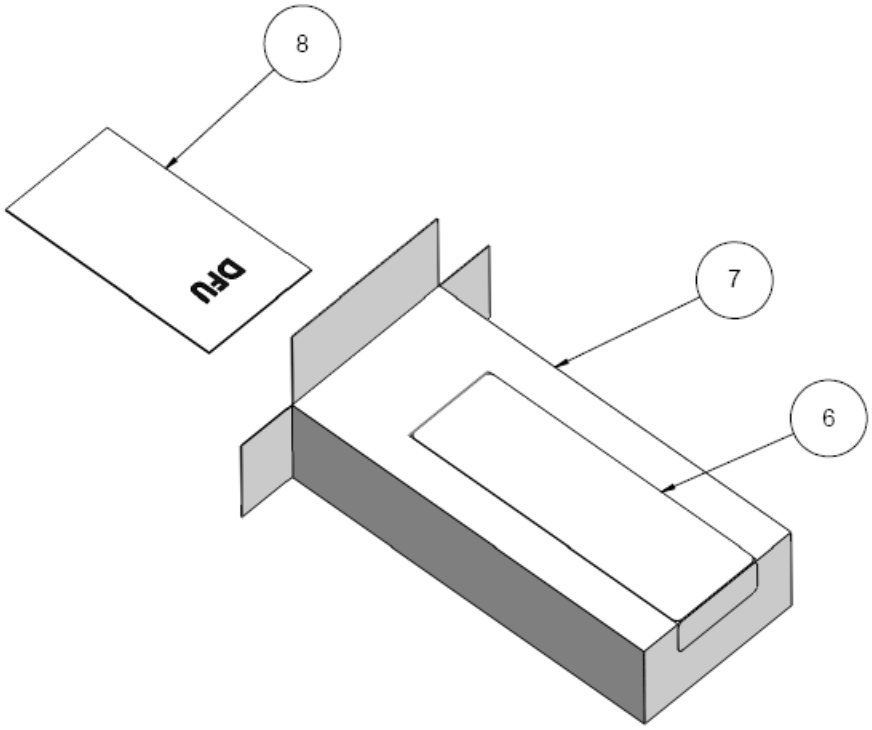


Curved



Section 12: Device Description *(Continued)*

Drawing 12-2: Packaging, DFU, Tray Assembly, Shelf Carton



Section 13

Substantial Equivalence Discussion

Section 13: Substantial Equivalence Discussion

For purposes of establishing 'substantial equivalence', the proposed device was compared to the following predicate devices, Referenced in Table 13-1.

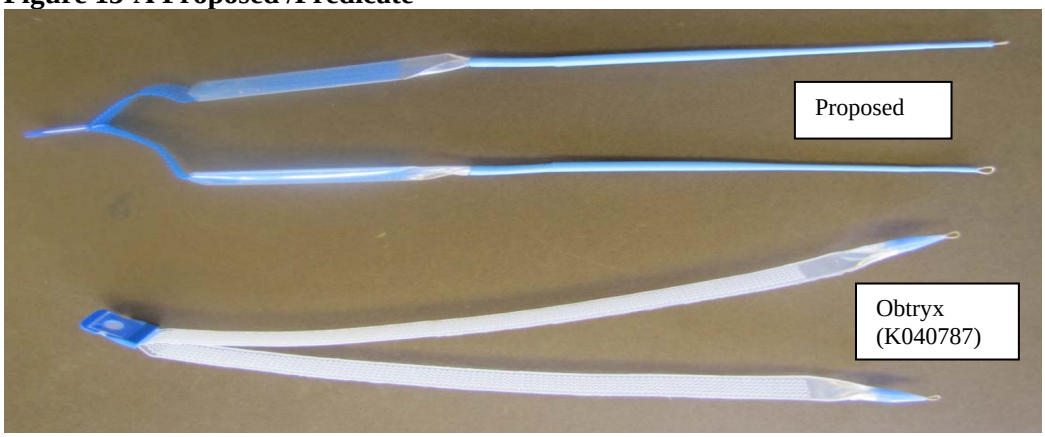
Table 13-1: Predicate Devices for Establishing 'Substantial Equivalence'

Device Name	510(k) Submitter/holder	510(k) #/ Clearance Date
Surgical Mesh	Boston Scientific Corporation (BSC)	K020110 Cleared Apr 3, 2002
Surgical Mesh (Obtryx)	Boston Scientific Corporation (BSC)	K040787 Cleared Apr 14, 2004

As compared to BSC previously cleared devices (K020110 & K040787 (Obtryx)) the proposed device is similar in design, equivalent in **intended use,** and **identical** in terms of current mesh characteristics**. Figure 13-A** shows the proposed and predicate devices.

(b)(4)

Figure 13-A Proposed /Predicate

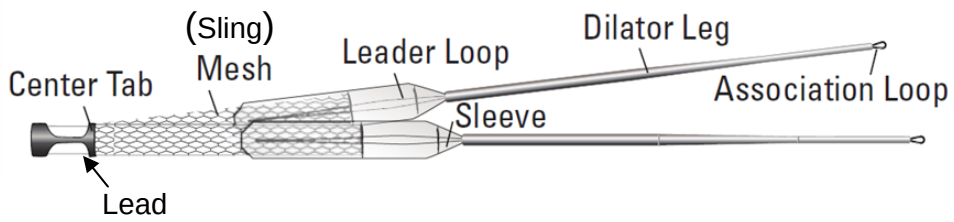


The proposed and predicate devices are the same/similar in the following areas:

- Identical mesh (b)(4)
- Identical mesh characteristics
- Equivalent Intended Use
- Identical Placement Route as Obtryx (K040787)
- Similar design and fundamental technology

Section 13: Substantial Equivalence Discussion (*Continued)*

Figure 13-B: Mesh Assembly



Sling

The proposed sling is constructed of the (b)(4) as the predicate sling. An additional (b)(4) has been added to the base material of the proposed device (b)(4)

(b)(4)

[redacted]

Section 13: Substantial Equivalence Discussion (*Continued)*

Mesh Assembly

The (2) disposable protective sleeves are used to protect and maintain sling integrity during placement and during adjustment via the center tab. The protective sleeves on the predicate device cover the entire length of the mesh. The protective sleeves for the proposed sling (b)(4) [redacted]

The dilators of the mesh assembly (b)(4) [redacted] owever, the placement of the device is the same with minor instruction updates to account for the change in components. Association loops are located on the end of the dilator to facilitate sling placement utilizing the slotted tip of the delivery device needle, identical to the predicates (K040787,Obtryx).

Delivery Device

The delivery devices (Halo or Curved) supplied with the proposed mesh assembly are identical to the current Boston Scientific delivery devices packaged with the sling (K040787,Obtryx). These devices are classified as Class I Exempt: 21CFR 876**.**4730 manual gastroenterology-urology surgical instrument and accessories.

Placement

Identical to the predicate, (K040787) the propose device is placed percutaneously with either the Curved or Halo devices, depending on physician preference and patient anatomy.

Both the proposed and the predicate device (K040787,Obtryx) attach the association loop of the mesh assembly onto the distal end of the delivery device needle tip slot and pass the sling percutaneously through the obturator foramen/muscle/membrane, tracking around the inferior pubic ramus (behind the pubic bone) exiting the incision site. The procedural steps are repeated on the contralateral side. Upon final sling adjustment, the leader loops of the proposed device are cut from each leg assembly and the dilator/sleeves are removed, and the center tab is cut and removed.

Section 13: Substantial Equivalence Discussion (*Continued)*

(b)(4)

[redacted]

Labeling

Minor modifications were required to the Directions for Use for the proposed device to account for the device modifications and changes in names of the components. An outcome of a clinical literature review also added the word "perforation" to the precautions section.

In addition, the Intended Use statement has been shortened. The intended use for the predicate device states that the device is intended:

> "for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension."

The intended use for the proposed device is identical, with the exception of the removal of the text in blue. Although shortened, both the predicate and proposed devices have the same intended use.

A draft of the proposed device Directions For Use (DFU) is attached to **Appendix 14-A**. Changes are highlighted in yellow for ease of review. Predicate labeling is attached in **Appendix 14-B**.

Substantial Equivalence

A determination of substantial equivalence is supported by the evidence collected during the comparison of the physical and functional characteristics of the proposed and predicate slings, which were previously 'cleared' by FDA through the 510(k) process. Reference **Table 13-2** for a comparison of the proposed and predicate devices.

Section 13: Substantial Equivalence Discussion (*Continued)*

Table 13-2: Comparison of Proposed and Predicate Devices

Feature	Predicate Devices (K020110& K040787)	Proposed Device
Mesh		
(b)(4)		
Material (Mesh)	Polypropylene (b)(4) - (b	Polypropylene (b)(4) (b
Colorant	(b)(4)	
Mesh Assembly (Materials)		
Dilator	(b)(4)	
Association Loops		
Sleeve		
Leader Loops		
Center Tab		
Centering Tab Lead		

Section 13: Substantial Equivalence Discussion (*Continued)*

Table 13:-2 Comparison of proposed to predicates (continued)

Placement		
Intended Use	Intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension.	The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.
Incision	Two transverse, groin incision and incision of anterior vaginal wall (K040787).	Identical to K040787
Route of placement	Introduces the delivery shaft percutaneously into a groin incision through the obturator membrane, behind the ischio-pubic ramus, and exits through the anterior vaginal wall incision. The association loop is attached to the tip of the delivery device needle slot and retracted back through the tissue, exiting the groin incision. This is repeated on the contralatral side (K040787).	Identical to K040787
Fixation method	To abdominal skin by friction/subsequent tissue in growth.	Identical to K020110 & K040787
Tensioning of sling	Physician option, patient dependent during surgery	Identical to K020110 & K040787
Centering Mechanism	Center tab attached to mesh sleeve.	Center tab attached to sling by lead line
Final Device Location	Suburethral	Identical to K020110 & K040787
Delivery Devices	Packaged with 2 (Halo Or Curved) (K040787)	Identical to K040787

Section 13: Substantial Equivalence Discussion (*Continued)*

Summary of Substantial Equivalence Statement

The 510(k) "Substantial Equivalence" Decision-Making Process, as outlined in ODE Guidance Document No. K86-3, "Guidance on the CDRH Premarket Notification Review Program," was used to determine substantial equivalence of the proposed device to the predicate devices.

Please refer to the decision tree from the 510(k) "Substantial Equivalence" Decision Making process (Detailed), Figure 13-C, at the end of this section. The answers to the following questions lead to a determination that the proposed device is substantially equivalent to the predicate device.

a) Does new device have same indication statements?
No . A change in the language of the intended use statement has been made in that it has been shortened from what it was cleared in (K020110 & K040787); however both intended use statements are equivalent.

b) **Do the difference alter the intended therapeutic/diagnostic/etc. effect (in deciding, may consider impact on safety and effectiveness)?**
No. Although the intended use statement is shortened, all of the delivery placement routes cleared in (K020110 & K04787) **are identical in intended use** to place the sling to the suburethral area for treatment of stress urinary incontinence (SUI) as the proposed device.

c) Does new device have same technological characteristics, e.g. design, materials, etc.?
No. The proposed device has added a blue colorant to the (b)(4). In addition, the proposed device has incorporated (b)(4) (b)(4) (b)(4) Although the materials are different, the proposed device has similar technological and design characteristics when compared to the predicates (K020110 & K0470787).

d) Could the new characteristics affect safety or effectiveness?
Yes . The new design enhancements of the proposed device require performance testing and the new materials selected require additional biocompatibility testing to ensure safety and effectiveness.

Section 13: Substantial Equivalence Discussion (*Continued)*

e) Do the new characteristics raise new type of safety of effectiveness questions?
No. As the proposed device has similar design and materials these do not raise new type of the safety of effectiveness questions.

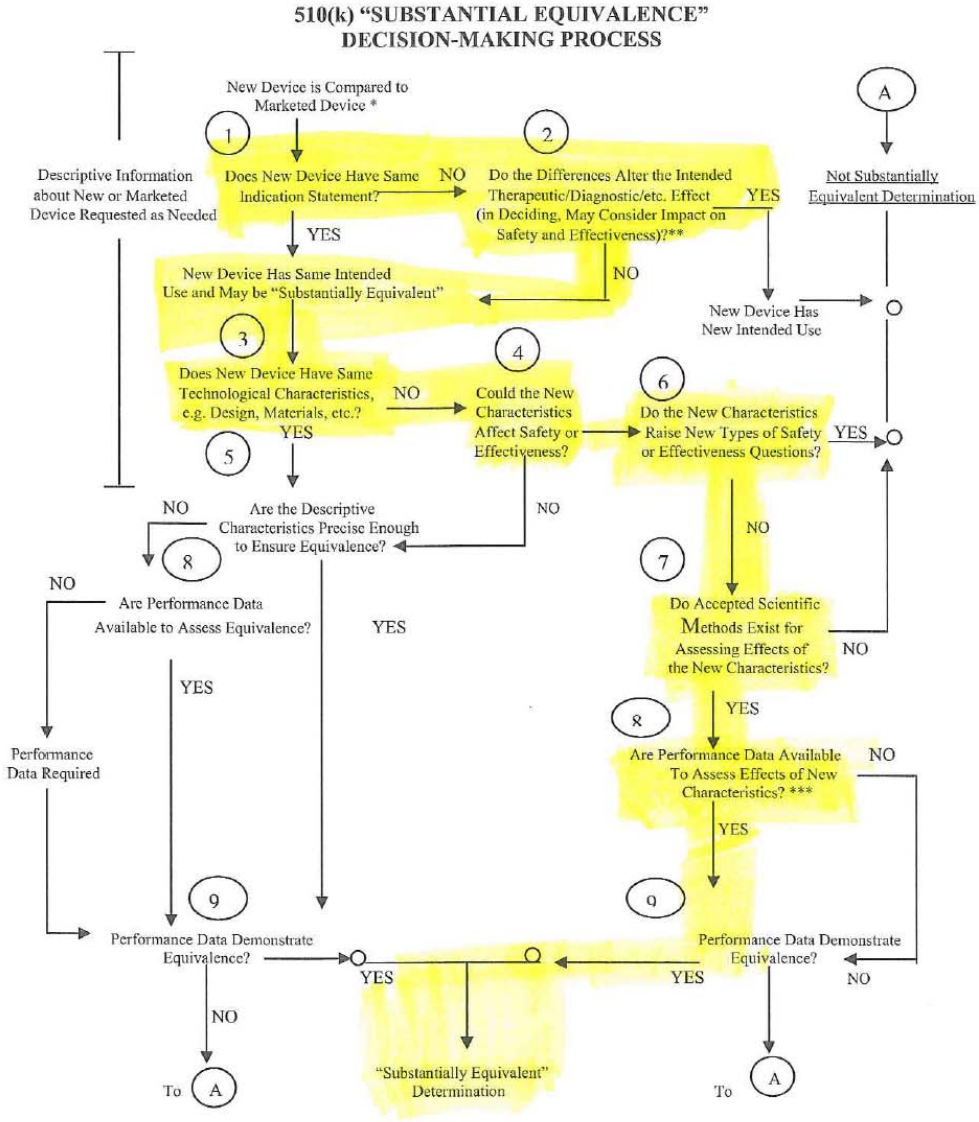
f) Do accepted scientific methods exist for assessing effects of the new characteristics?
Yes. The results of performance testing are provided in Section 19 Performance testing and testing results for the materials are presented in Section 16 Biocompatibility.

e) Performance data demonstrate equivalence?
Yes. The results of performance testing demonstrate that the proposed device is substantially equivalent to the predicate sling.

In summary, we believe that a determination of "substantial equivalence" is supported, based on the comparative evaluation between the proposed sling, the BSC slings, presented herein; inclusive of design, materials, performance characteristics and indications for use.

Section 13: Substantial Equivalence Discussion (*Continued)*

Figure 13-C



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Section 14

Proposed Labeling

Section 14: Proposed Labeling

Directions for Use

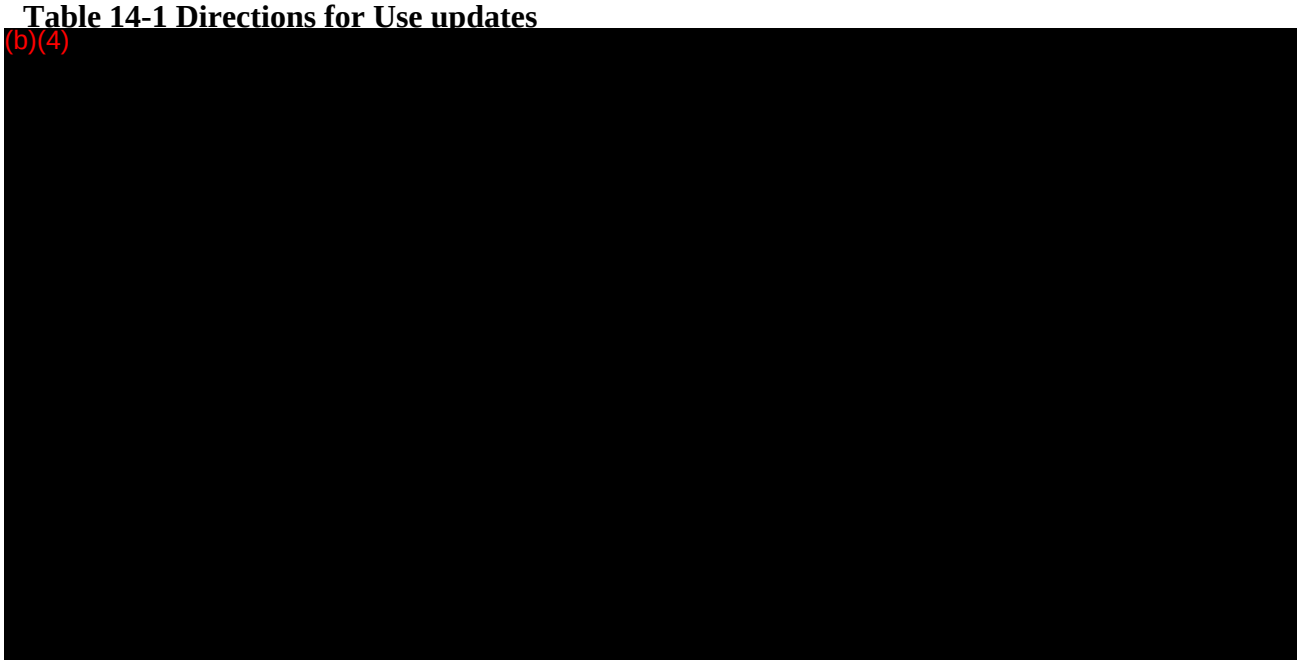
As discussed in Section 11, minor modifications were made to the direction for use which included general instructions, precautions, potential complications and warnings associated with the proper use of the sling since the clearance of the predicate BSC Obtryx (K040787). Assessments of the changes were conducted in accordance with FDA's Guidance document "Deciding When to Submit A 510(k) for a Change to an Existing Device. Dated January 10,1997", utilizing Flow Chart A Labeling. The changes do not require a submission to the agency as these changes were incorporated for clarity to insure safe and effective use.

Modifications to DFU for Proposed Device

Minor modifications were required to the Directions for Use for the proposed device to account for the device modifications and changes in names of the components. Based on a clinical literature review and usability study, additional updates were made to the following sections of the proposed DFU, directions for use, general warnings, potential complications, and precautions, reference **Table 14-1**.

Table 14-1 Directions for Use updates

(b)(4)



(b)(4)

In addition the Intended Use Statement has been shortened. The intended use for the predicate device states that the device is intended:

> "for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension."

The intended use for the proposed device is identical, with the exception of the removal of the text in blue. Although shortened, both the predicate and proposed devices have the same intended use.

A draft of the proposed device Directions For Use (DFU) is Attached in Appendix 14-A Proposed Labeling. Changes are highlighted in yellow for ease of review. Predicate labeling is attached in Appendix 14-B.

Appendix 14-A

Proposed Device Labeling

Proposed Directions For Use

Boston Scientific

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use **2**

90693850-01 Rev. B

2012-06

TABLE OF CONTENTS

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693950-01B

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

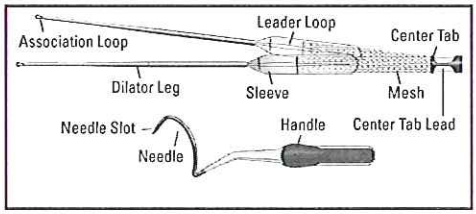


Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle for the patient's left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.
5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

Boston Scientific (Master Brand Template 9in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693850-01B

7. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

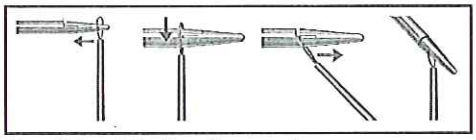


Figure 2: Association Loop Engagement

8. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
9. Remove the association loop from the needle (see Figure 3).

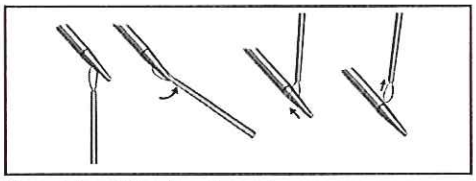


Figure 3: Association Loop Removal

10. Repeat Steps 4-9 on the contralateral side with the second needle.
11. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
12. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

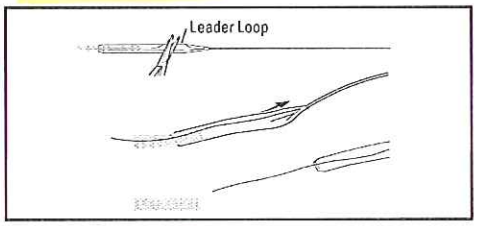


Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions according to usual methods.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).

- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.

- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ II System.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy is not required, but can be done at the surgeon's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pelvic and vaginal pain, dyspareunia, vaginal bleeding, vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site, have been reported due to suburethral sling procedure.
- It has also been reported that groin pain, orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of hematoma.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693650-01B

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration or perforation of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693850-01B

REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Katalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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Représentant agréé UE
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Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

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Fabricant légal
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Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

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Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

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Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
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Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS
Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

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No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

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No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

EC REP **EU Authorized Representative**

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA

Do not use if package is damaged.

Recyclable Package

CE 0197

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693850-01B

Boston Scientific

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use 2

90693849-01 Rev. B

2012-06

TABLE OF CONTENTS

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01B

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

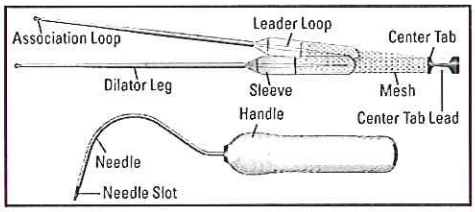

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hand's forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

5. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

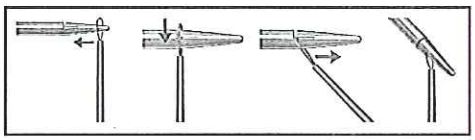

Figure 2: Association Loop Engagement

6. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
7. Remove the association loop from the needle (see Figure 3).

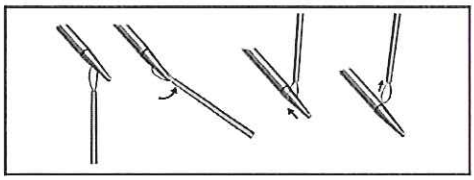

Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.
9. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
10. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

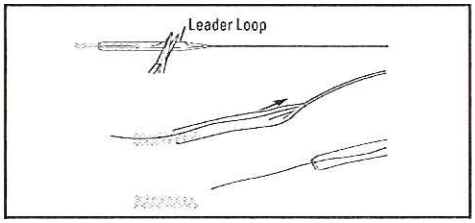

Figure 4: Tension Mesh/Sleeve Removal

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- If subsequent infection occurs, the entire mesh may have to be removed or revised.
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POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
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Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01B

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Charge
Lotto
Partij
Lote

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Produktnummer
Codice prodotto
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Número do Produto

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Confezione riciclabile
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Embalagem Reciclável

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Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken
Apenas para uma única utilização. Não reutilize.

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Do Not Resterilize
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Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

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STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

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FRANCE

AUS **Australian Sponsor Address**

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PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Manufactured for:
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One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

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Recyclable Package

CE 0197

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Proposed Lid Labels

Boston Scientific

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Contents **(1)**

(1) Mesh Assembly
(2) Delivery Devices

REF Catalog No. 850-510	Use By YYYY-MM

Obtryx™ II Halo REF 850-510 LOT 0000000000	**Obtryx™ II Halo** REF 850-510 LOT 0000000000
Obtryx™ II Halo REF 850-510 LOT 0000000000	**Obtryx™ II Halo** REF 850-510 LOT 0000000000

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

CE 0197

UPN Product No. M0068505110	LOT 0000000000
	STERILE EO **Sterilized using ethylene oxide.**

90677198-01A 90693833-01A

Boston Scientific

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Contents **(1)**

(1) Mesh Assembly
(2) Delivery Devices

REF Catalog No. 850-410	Use By YYYY-MM

Obtryx™ II Curved REF 850-410 LOT 00000000000	**Obtryx™ II Curved** REF 850-410 LOT 0000000000
Obtryx™ II Curved REF 850-410 LOT 0000000000	**Obtryx™ II Curved** REF 850-410 LOT 0000000000

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

CE 0197

UPN Product No. M0068504110	LOT 0000000000
	STERILE EO **Sterilized using ethylene oxide.**

90677198-01A 90693831-01A

Proposed Carton Labels

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation.

Contents (1)

(1) Mesh Assembly

Dispositivo de malla, Bandelette tressée, Mesh-Vorrichtung, Gruppo rete, Netconstructie, メッシュ・アセンブリ, Netsamling, Διάταξη πλέγματος, Unidade de Rede, Nätmontering, Hálószerkezet, Síťka s příslušenstvím, Zestaw siatki, Nettsamling, Tel Düzeneği

(2) Delivery Devices

Dispositivos de administración, Dispositifs de mise en place, Einbringvorrichtungen, Dispositivi di erogazione, Inbrenginstrumenten, デリバリー・デバイス, Indføringsanordninger, Συσκευές προώθησης, Dispositivos de Colocação, Insättningsanordningar, bevezetőeszközök, zavaděče, Elementy wprowadzające, Leveringsenheter, Aktarım Cihazları

STERILE EO **Sterilized using ethylene oxide.**

REF **Catalog No.** 850-510

Use By YYYY-MM

Obtryx™ II System
HALO
REF 850-510
LOT 0000000000

Obtryx™ II System
HALO
REF 850-510
LOT 0000000000

Obtryx™ II System
HALO
REF 850-510
LOT 0000000000

+M0068505110+

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

CE 0197

+$$8010000000000000+V

UPN Product No. M0068505110 LOT 0000000000

Obtryx™ II System
HALO

REF 850-510

YYYY-MM

90713045-01A

90693832-01A

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design

Contents (5)

(1) Mesh Assembly

Dispositivo de malla, Bandelette tressée, Mesh-Vorrichtung, Gruppo rete, Netconstructie, メッシュ・アセンブリ, Netsamling, Διάταξη πλέγματος, Unidade de Rede, Nätmontering, Hálószerkezet, Síťka s příslušenstvím, Zestaw siatki, Nettsamling, Tel Düzeneği

(2) Delivery Devices

Dispositivos de administración, Dispositifs de mise en place, Einbringvorrichtungen, Dispositivi di erogazione, Inbrenginstrumenten, デリバリー・デバイス, Indføringsanordninger, Συσκευές προώθησης, Dispositivos de Colocação, Insättningsanordningar, bevezetőeszközök, zavaděče, Elementy wprowadzające, Leveringsenheter, Aktarım Cihazları

REF Catalog No.	850-511
Use By	YYYY-MM
UPN Product No. M0068505111 LOT 00000000000	STERILE EO Sterilized using ethylene oxide.

+M0068505111+

+$$8050000000000000000+V

CE 0197

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

90713955-01A

90724359-01A

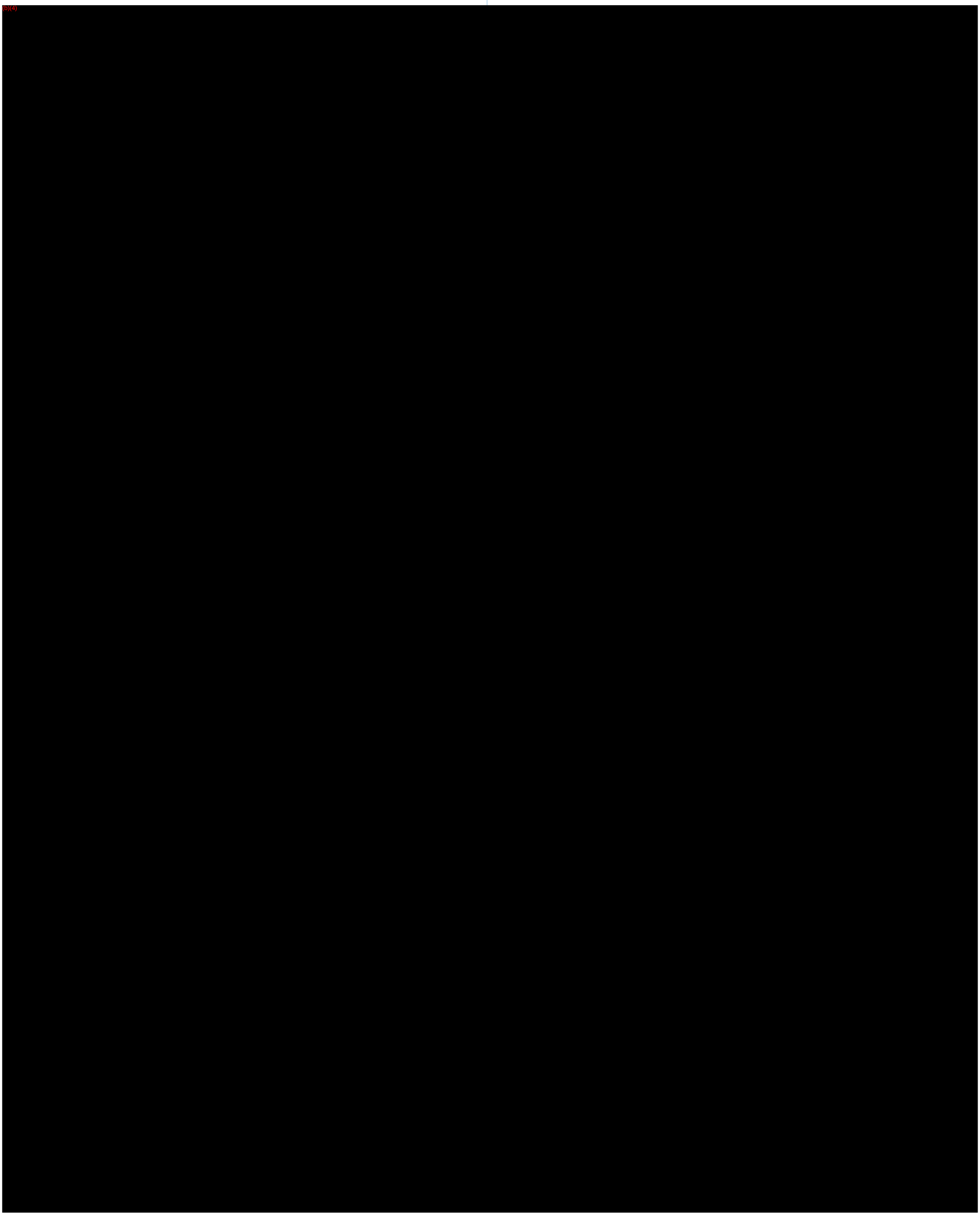
Obtryx™ II System

HALO

REF 850-511

YYYY-MM

(b)(4)



Carton Image Enlarged

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation, Product Description Translation.

Contents (1)

(1) Mesh Assembly

Dispositivo de malla, Bandelette tressée, Mesh-Vorrichtung, Gruppo rete, Netconstructie, メッシュ・アセンブリ, Netsamling, Διάταξη πλέγματος, Unidade de Rede, Nätmontering, Hálószerkezet, Síťka s příslušenstvím, Zestaw siatki, Nettsamling, Tel Düzeneği

(2) Delivery Devices

Dispositivos de administración, Dispositifs de mise en place, Einbringvorrichtungen, Dispositivi di erogazione, Inbrenginstrumenten, デリバリー・デバイス, Indføringsanordninger, Συσκευές προώθησης, Dispositivos de Colocação, Insättningsanordningar, bevezetőeszközök, zavaděče, Elementy wprowadzające, Leveringsenheter, Aktarım Cihazları

STERILE EO **Sterilized using ethylene oxide.**

REF **Catalog No.** 850-410

Use By YYYY-MM

Obtryx™ II System CURVED
REF 850-410
LOT 0000000000

Obtryx™ II System CURVED
REF 850-410
LOT 0000000000

Obtryx™ II System CURVED
REF 850-410
LOT 0000000000

+M0068504110+

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

CE 0197

+$$8010000000000000+V

UPN Product No. M0068504110 LOT 0000000000

Obtryx™ II System CURVED

REF 850-410

YYYY-MM

90713045-01A

90693830-01A

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design, Transobturator Sling System with PrecisionBlue™ Design

Contents (5)

(1) Mesh Assembly

Dispositivo de malla, Bandelette tressée, Mesh-Vorrichtung, Gruppo rete, Netconstructie, メッシュ・アセンブリ, Netsamling, Διάταξη πλέγματος, Unidade de Rede, Nätmontering, Hálószerkezet, Síťka s příslušenstvím, Zestaw siatki, Nettsamling, Tel Düzeneği

(2) Delivery Devices

Dispositivos de administración, Dispositifs de mise en place, Einbringvorrichtungen, Dispositivi di erogazione, Inbrenginstrumenten, デリバリー・デバイス, Indføringsanordninger, Συσκευές προώθησης, Dispositivos de Colocação, Insättningsanordningar, bevezetőeszközök, zavaděče, Elementy wprowadzające, Leveringsenheter, Aktarım Cihazları

REF Catalog No. 850-411

Use By YYYY-MM

UPN Product No. M0068504111 LOT 00000000000

STERILE EO Sterilized using ethylene oxide.

+M0068504111+

+$$8050000000000000+V

CE 0197

Made in USA:
North Port Industrial Park
2301 Centennial Blvd.
Jeffersonville, IN 47130 USA

90713955-01A

90724354-01A

Obtryx™ II System

CURVED

REF 850-411

YYYY-MM

(b)(4)

Carton Image Enlarged

Appendix 14-B

Predicate Labeling
Obtryx K040787

Predicate Directions For Use

Boston Scientific

ENGLISH
FRANÇAIS
DEUTSCH
ITALIANO
ESPAÑOL
NEDERLANDS
PORTUGUÊS

Obtryx™ System - Curved

Transobturator Mid-Urethral System

Kontakt den nærmeste Boston Scientific kundeserviceafdeling, hvis en dansk kopi af brugsanvisningerne ønskes. Spørg efter reservedel nr.: 90106923-02

Επικοινωνήστε με το γραφείο εξυπηρέτησης της Boston Scientific αν οι Οδηγίες Χρήσης απαιτείται να είναι στα Ελληνικά. Ζητήστε τον αριθμό ανταλλακτικού: 90106923-03

Kontakta Boston Scientific kundtjänst om ni behöver ett exemplar av en svensk bruksanvisning. Fråga efter del nummer: 90106923-05

℞ ONLY **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

DIRECTIONS FOR USE

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx™ Sling System - Curved is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

DIRECTIONS FOR USE

Prior to Use

The Obtryx™ Sling System - Curved is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx Sling System - Curved allows the operator a percutaneous approach utilizing a transobturator technique. **See Figure 1** for parts description.

ENGLISH

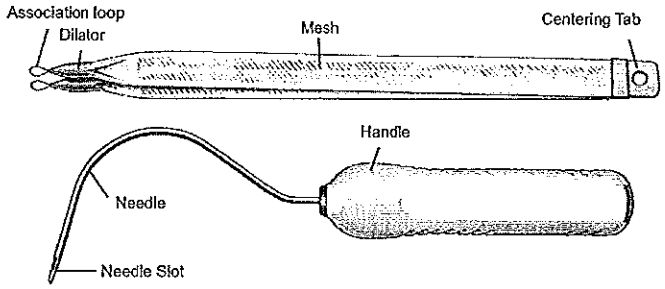


Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING: Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING: If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hands forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

WARNING: Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

5. Engage one (1) association loop to the distal end of the needle **(see Figure 2)** protruding through the vagina.

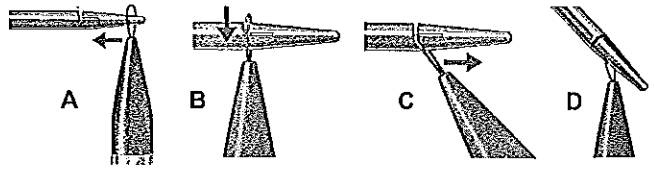


Figure 2: Association Loop Engagement

6. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue centering tab positioned suburethrally, facing outward.
7. Remove the association loop from the needle **(see Figure 3).**

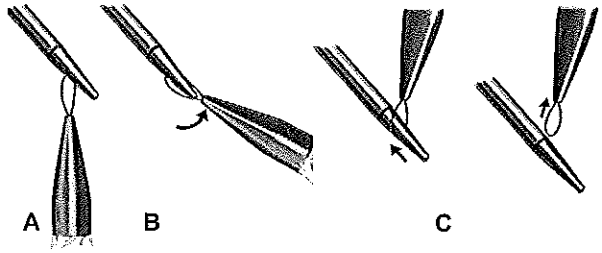


Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.
9. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
10. Next see section **"Tension Mesh/Sleeve Removal."**

Tension Mesh/Sleeve Removal

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue centering tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Grasp the blue centering tab and cut the tab through the center of the punch hole **(see Figure 4)** ensuring that both halves of the blue tab are completely removed from the vaginal canal.

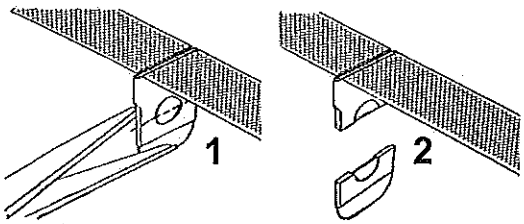


Figure 4: Tension Mesh/Sleeve Removal

4. Pull outwards on the dilators to remove the sleeve leaving the mesh in place.
5. Verify the tension of the mesh and adjust as necessary.
6. Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
7. Close all incisions according to usual methods.

GENERAL WARNING:

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).
  - Patients with blood coagulation disorder.
  - Patients with compromised immune system or any other conditions that would compromise healing.
  - Patients with renal insufficiency and upper urinary tract obstruction
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ Sling System - Curved.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy is not required, but can be done at the surgeon's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pelvic and vaginal pain, dysparenia, vaginal bleeding, vaginal discharge, dehiscence of vaginal incision, edema and erythema at the wound site have been reported due to suburethral sling procedure.
- It has also been reported that groin pain, orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of hematoma in the obturator foramen.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.

- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

STORAGE

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

UPN Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Contents
Contenido
Conteneu
Inhalt
Contenuto
Inhoud
Conteúdo

AUS Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

REF Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as instruções de Utilização

EC REP EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT Lot
Lote
Lot
Charge
Lotto
Partij
Lote

STERILE EO Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Boston Scientific

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

AUS Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

EC REP EU Authorized Representative

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

Do not use if package is damaged.

Recyclable Package

CE 0197

90106923-01 Rev. E

2010-06

Boston Scientific

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NEDERLANDS
PORTUGUÊS

Obtryx™ System - Halo

Transobturator Mid-Urethral System

Kontakt den nærmeste Boston Scientific kundeserviceafdeling, hvis en dansk kopi af brugsanvisningerne ønskes. Spørg efter reservedel nr.: 90116525-02

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Kontakta Boston Scientific kundtjänst om ni behöver ett exemplar av en svensk bruksanvisning. Fråga efter del nummer: 90116525-05

℞ ONLY **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

DIRECTIONS FOR USE

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx™ Sling System - Halo is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

DIRECTIONS FOR USE

Prior to Use

The Obtryx™ Sling System - Halo is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx Sling System - Halo allows the operator a percutaneous approach utilizing a transobturator technique. **See Figure 1** for parts description.

ENGLISH

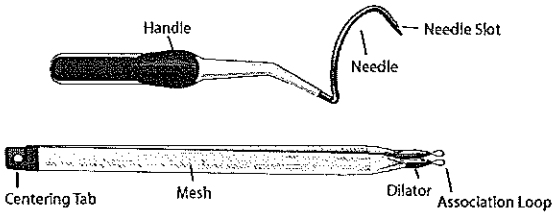

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING: Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING: If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle for the patient's left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.
5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

WARNING: Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

7. Engage one (1) association loop to the distal end of the needle **(see Figure 2)** protruding through the vagina.

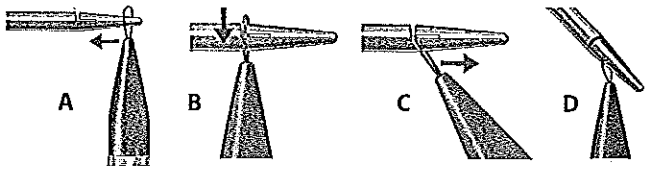

Figure 2: Association Loop Engagement

8. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue centering tab positioned suburethrally, facing outward.
9. Remove the association loop from the needle **(see Figure 3).**

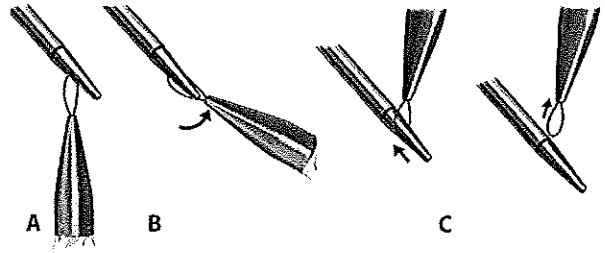

Figure 3: Association Loop Removal

10. Repeat Steps 4-9 on the contralateral side with the second needle.
11. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
12. Next see section **"Tension Mesh/Sleeve Removal."**

Tension Mesh/Sleeve Removal

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue centering tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Grasp the blue centering tab and cut the tab through the center of the punch hole **(see Figure 4)** ensuring that both halves of the blue tab are completely removed from the vaginal canal.

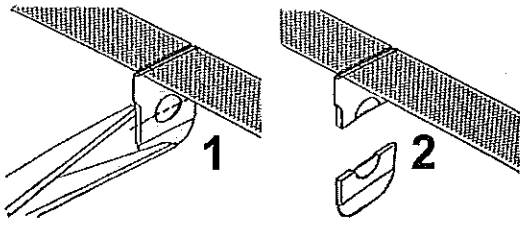

Figure 4: Tension Mesh/Sleeve Removal

4. Pull outwards on the dilators to remove the sleeve leaving the mesh in place.
5. Verify the tension of the mesh and adjust as necessary.
6. Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
7. Close all incisions according to usual methods.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).
  - Patients with blood coagulation disorder.
  - Patients with compromised immune system or any other conditions that would compromise healing.
  - Patients with renal insufficiency and upper urinary tract obstruction.
  - Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ Sling System - Halo.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy is not required, but can be done at the surgeon's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pelvic and vaginal pain, dysparenia, vaginal bleeding, vaginal discharge, dehiscence of vaginal incision, edema and erythema at the wound site, have been reported due to suburethral sling procedure.
- It has also been reported that groin pain, orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of hematoma in the obturator foramen.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

STORAGE

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

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UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo

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Adresse du promoteur australien
Adresse des australischen Sponsors
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Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
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Apenas para uma única utilização. Não reutilize.

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Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter la mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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LOT
Lot
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Lot
Charge
Lotto
Partij
Lote

STERILE EO
Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

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Emballage recyclable
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Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

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USA Customer Service 888-272-1001

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CE 0197

90116525-01 Rev. E

2010-06

Predicate Lid Labels

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Contents

(1) Obtryx™ System Halo

Sistema Obtryx™ Halo, Système Obtryx™ - Halo, Obtryx™ System - Halo, Sistema Obtryx™ Elicoidale, Obtryx™ System Cirkelvormig, Obtryx™ システム － ハロー ハロー, Obtryx™ system - Halo, Σύστημα Obtryx™ - Φωτοστέφανο, Sistema Obtryx™ - Halo, Obtryx™-system - Halo, Obtryx™ rendszer – Halo, Systém Obtryx™ - Halo, System Obtryx™ - Halo, Obtryx™ system ring, Obtryx™ 系统 - 环状, Obtryx™ 할로(halo) 시스템, Obtryx™ Sistemi - Halo

Consult instructions for use.

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STERILE EO **Sterilized using ethylene oxide.**

For single use only. Do not reuse.

℞ **ONLY**

2 STERILIZE **Do Not Resterilize**

REF **Catalog No.** 850500

UPN **Product No.** M0068505000

LOT 1ML0023001

Use By 2010 - 02

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Obtryx™	UPN	M0068505000
	LOT	1ML0023001
		2010 - 02

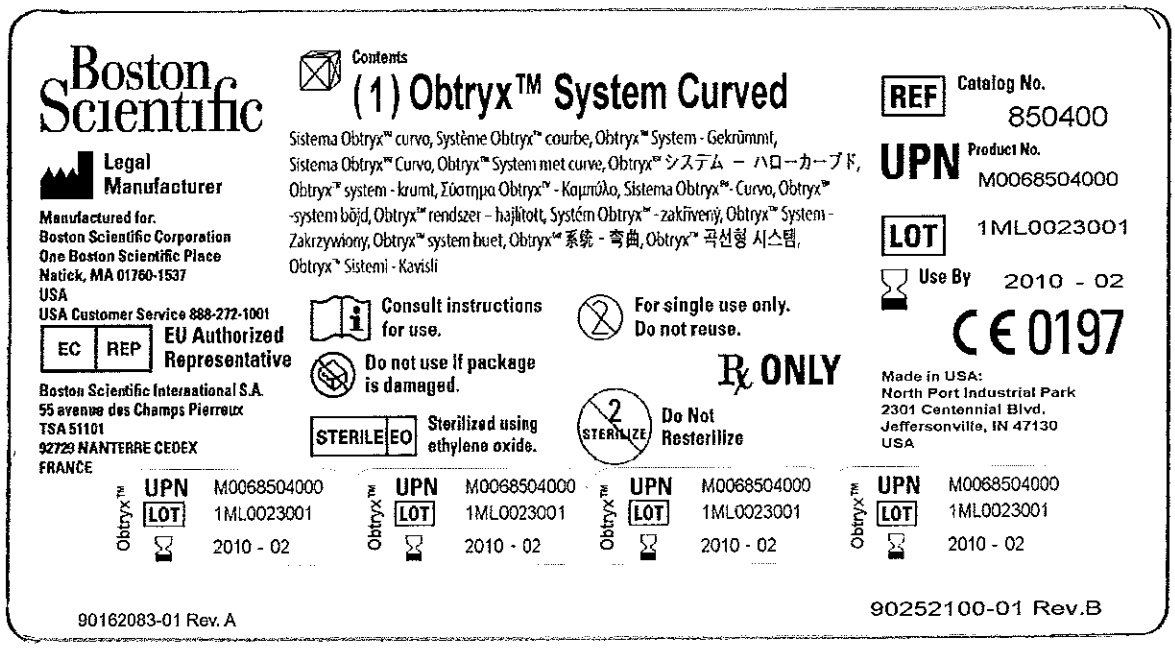
Obtryx™	UPN	M0068505000
	LOT	1ML0023001
		2010 - 02

Obtryx™	UPN	M0068505000
	LOT	1ML0023001
		2010 - 02

Obtryx™	UPN	M0068505000
	LOT	1ML0023001
		2010 - 02

90162083-01 Rev. A

90252116-01 Rev.B



Predicate Carton Labels

Obtryx™ - *Halo*
Transobturator Mid-Urethral Sling System

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Obtryx™ - *Halo*
Transobturator Mid-Urethral Sling System

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PN1002434 B

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REF Catalog No. 850500

UPN Product No. M0068505000

2 STERILIZE Do Not Resterilize

For single use only. Do not reuse.

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Do not use if package is damaged.

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(2) zavaděče

(1) Zestaw siatki
(2) Elementy wprowadzające

(1) Nettsamling
(2) Leveringsenheter

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(2) 递送装置

(1) 메시 어셈블리
(2) 삽입 기구

(1) Tel Düzeneği
(2) Aktarım Cihazları

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LOT 1ML0023001

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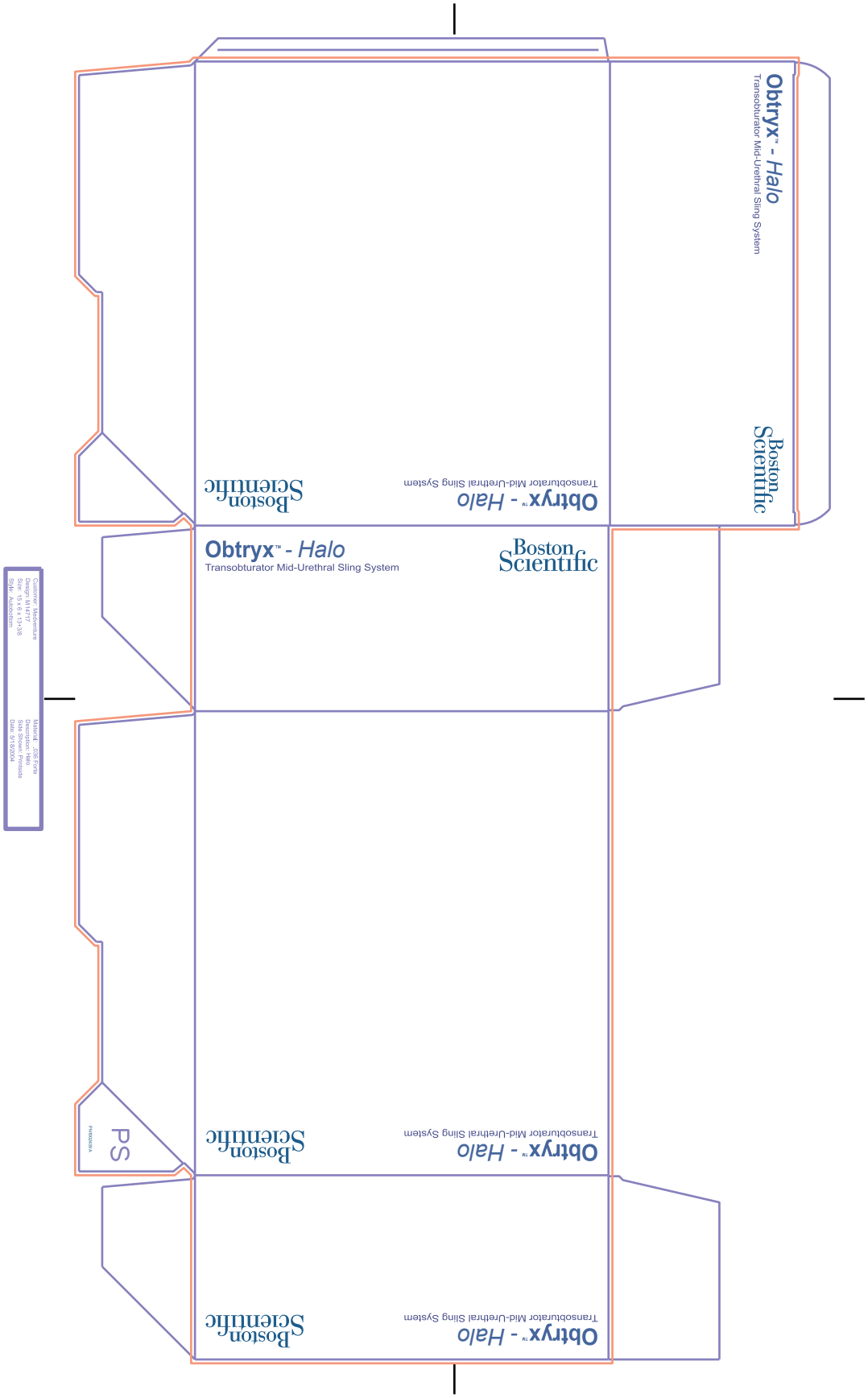
+M00685050001

+$$80102101ML00230011A

90252128-01 Rev. B

810095-05 Rev. B



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(5) Obtryx™ System Halo

Sistema Obtryx™ Halo, Système Obtryx™ - Halo, Obtryx™ System - Halo, Sistema Obtryx™ Elicoidale, Obtryx™ System Cirkelvormig, Obtryx™ システム － ハロー ハロー, Obtryx™ system - Halo, Σύστημα Obtryx™ - Φωτοστέφανο, Sistema Obtryx™ - Halo, Obtryx™-system - Halo, Obtryx™ rendszer - Halo, Systém Obtryx™ - Halo, System Obtryx™ - Halo, Obtryx™ system ring, Obtryx™ 系统 - 环状, Obtryx™ 할로(halo) 시스템, Obtryx™ Sistemi - Halo

REF Catalog No. 8505001

UPN Product No. M0068505001

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(2) デリバリー・デバイス

(1) Netsamling
(2) Indføringsanordninger
(1) Διάταξη πλέγματος
(2) Συσκευές προώθησης
(1) Unidade de Rede
(2) Dispositivos de Colocação
(1) Nätmontering
(2) Insättningsanordningar
(1) Hálószerkezet
(2) bevezetőeszközök
(1) Sítka s příslušenstvím
(2) zavaděče

(1) Zestaw siatki
(2) Elementy wprowadzające
(1) Nettsamling
(2) Leveringsenheter
(1) 网片组件
(2) 递送装置
(1) 메시 어셈블리
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(1) Tel Düzeneği
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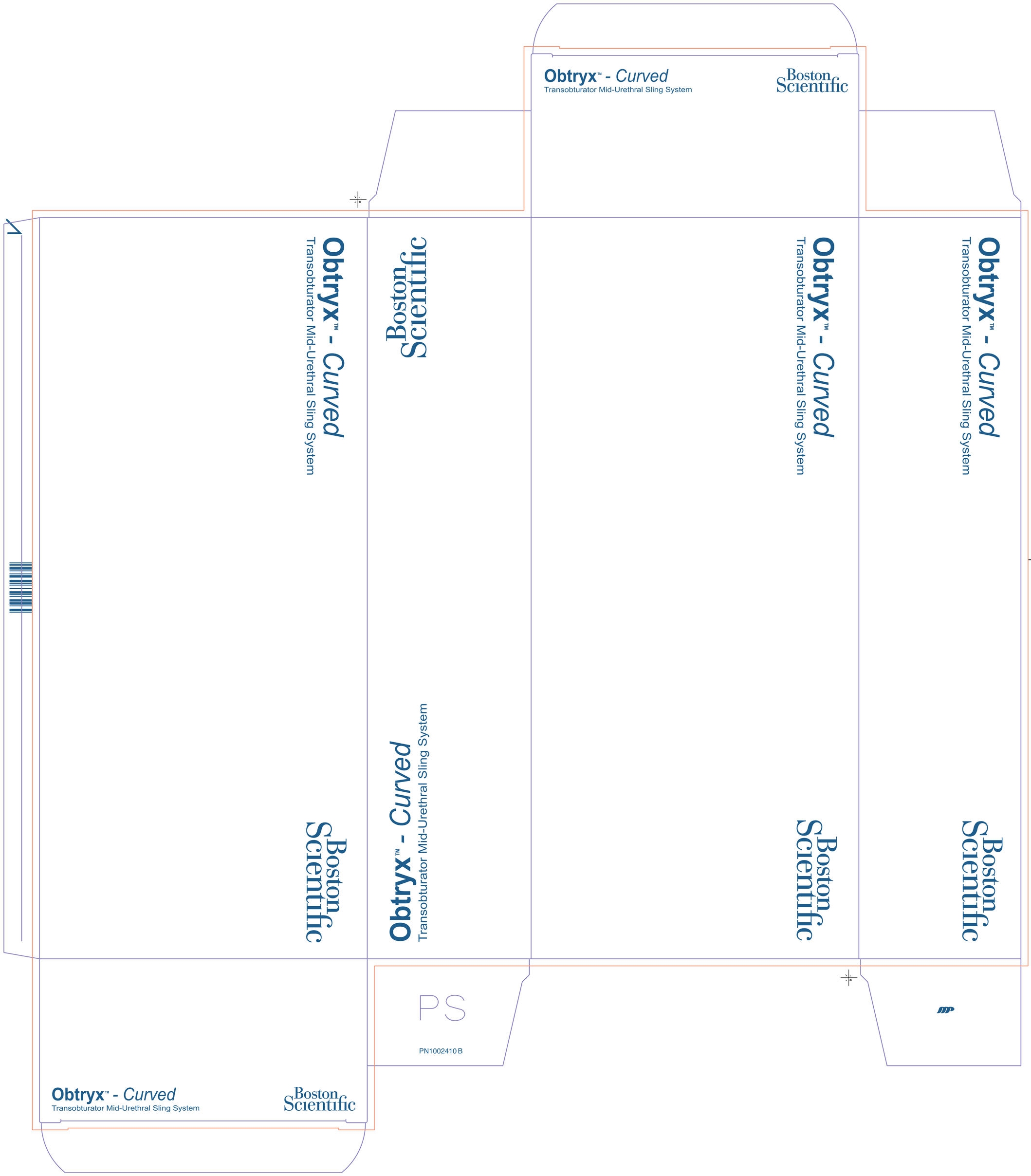
+M00685050012

+$$80502101ML00230012F

90252128-02 Rev. B

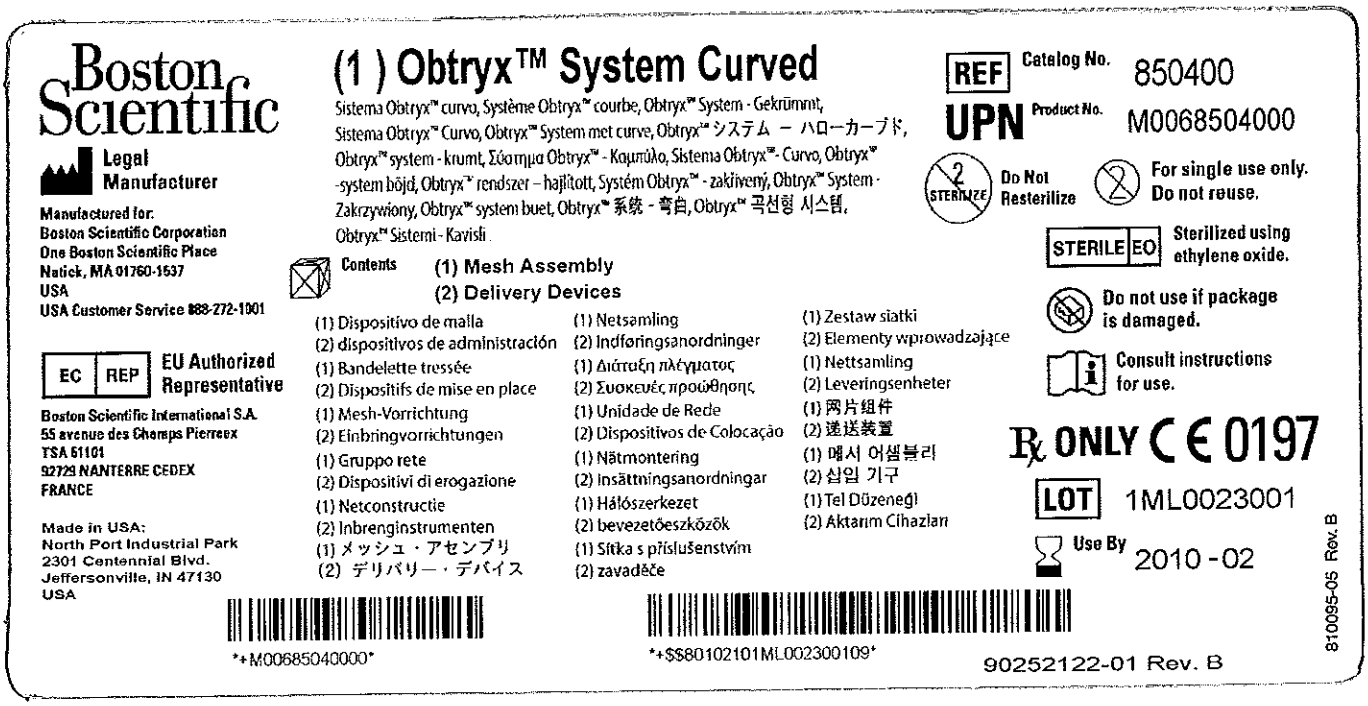
810095-05 Rev. B



PMS 541 BLUE
WATERBASE

Customer: Medventure	Material: .024 SBS
Design: m14705	Description: PN1002410
Size: 5+3/4 x 2+7/8 x 13	Side Shown: Printside
Style: Reverse Tuck	Date: 03/04/2004

MP Graphics # 8472 (Item#) PN1002410 B



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(1) Obtryx™ System Curved

Sistema Obtryx™ curvo, Système Obtryx™ courbe, Obtryx™ System - Gekrümmt, Sistema Obtryx™ Curvo, Obtryx™ System met curve, Obtryx™ システム – ハローカーブド, Obtryx™ system - krumt, Σύστημα Obtryx™ - Καμπύλο, Sistema Obtryx™- Curvo, Obtryx™ -system böjd, Obtryx™ rendszer – hajlított, Systém Obtryx™ - zakřivený, Obtryx™ System - Zakrzywiony, Obtryx™ system buet, Obtryx™ 系统 - 弯曲, Obtryx™ 곡선형 시스템, Obtryx™ Sistemi - Kavisli

REF Catalog No. 850400

UPN Product No. M0068504000

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(1) Mesh-Vorrichtung
(2) Einbringvorrichtungen
(1) Gruppo rete
(2) Dispositivi di erogazione
(1) Netconstructie
(2) Inbrenginstrumenten
(1) メッシュ・アセンブリ
(2) デリバリー・デバイス

(1) Netsamling
(2) Indføringsanordninger
(1) Διάταξη πλέγματος
(2) Συσκευές προώθησης
(1) Unidade de Rede
(2) Dispositivos de Colocação
(1) Nätmontering
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(1) Hálószerkezet
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(2) zavaděče

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(1) Tel Düzeneği
(2) Aktarım Cihazları

+M00685040000

*+$$80102101ML002300109+

90252122-01 Rev. B

810095-05 Rev. B

Obtryx™ - *Curved*
Transobturator Mid-Urethral Sling System

Boston Scientific

Obtryx™ - *Curved*
Transobturator Mid-Urethral Sling System

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PN100241R-02-A

Obtryx™ - *Curved*
Transobturator Mid-Urethral Sling System

Boston Scientific

Obtryx™ - *Curved*
Transobturator Mid-Urethral Sling System

Boston Scientific

Material: .036 Forte
Description: Helical / Curved
Side Shown: Printside
Date: 03/23/2004

Customer: Mectventure
Design: M14717
Size: 15 x 6 x 13+3/8
Style: Autobottom

Section 15

Sterilization and Shelf Life

Section 15: Sterilization and Shelf Life

STERILIZATION

(b)(4)

Method: Ethylene Oxide (EtO) Sterilization

Sterility Assurance Level: (b)(4)

Residuals: Residual levels of ethylene oxide, ethylene chlorohydrin will comply (b)(4)
(b)(4)

Sterilization Validatio and Monitoring:

The sterilization validation and routine sterilization monitoring will (b)(4)
(b)(4)

Pyrogenicity: (b)(4)

SHELF-LIFE

Functional testing on the proposed device was completed fo (b)(4)
(b)(4)

Section 15: Sterilization and Shelf Life *(Continued)*

The temperature was selected based upon table below defining the accelerated aging time (in days) for specific product shelf life periods based on the Arrhenius equation (Q10 theory below), the assumption of ambient storage condition at (b)(4) (b)(4) (b)(4) eference, **Table 15-1** Accelerated Aging Parameters.

Table 15-1 Accelerated Aging Parameters

Samples	Accelerated Aging Temperature	% Humidity(RH)	Accelerated Age Exposure Time to Simulate
			6 Months
Bulk Mesh	(b)(4)		
Mesh Assembly			

Arrhenius equation
Accelerated aging is based on the assumption that chemical reactions follow the Arrhenius reaction rate function. Based on modeling kinetics of materials, this function states that a 10°C increase or decrease in temperature of a homogenous process results in a 2x or 1/2x change, respectively, in the rate of a chemical reaction (Q10=2). This applies to shelf life as the equation

$$t = \frac{T}{2^{\frac{(b-a)}{10}}}$$

where t is the time required for product to be in an elevated temperature, T is the shelf life period being sought or claimed, b is the elevated temperature being used (°C), and a the ambient storage temperature (°C) expected for standard product storage.

This equation is a generalization that reaction rates of chemical processes double in rate for every 10°C increase in temperature.

Section 16

Biocompatibility

Section 16: Biocompatibility

Introduction:

The proposed device consists of the following:

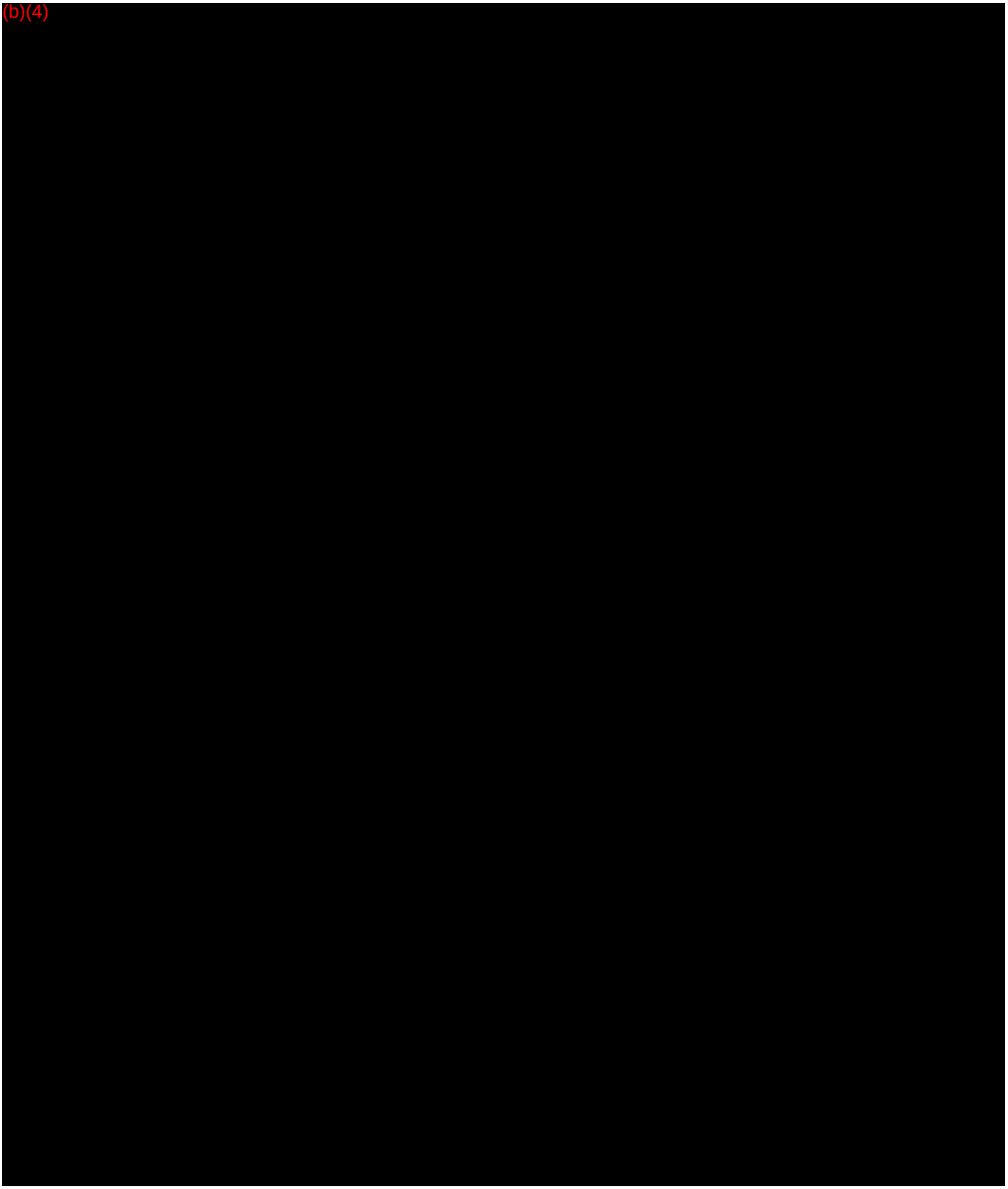
- One mesh assembly, consisting of:
  - One polypropylene sling implant;
  - Two protective sleeves with leader loops;
  - Two dilators with association loops;
  - One center tab with lead;
- Two delivery devices (either Curved or Halo).

Table 16-1 provides a comparison of the patient-contacting materials for the proposed device and the (b)(4) (b)(4) (b)(4) (b)(4) The delivery devices (Curved and Halo) are identical to those cleared under #K040787. Further discussion regarding the biocompatibility of previously-cleared materials is provided on the next page.

Table 16-1: Comparison of Patient-Contact Materials- Proposed Device and Reference Device

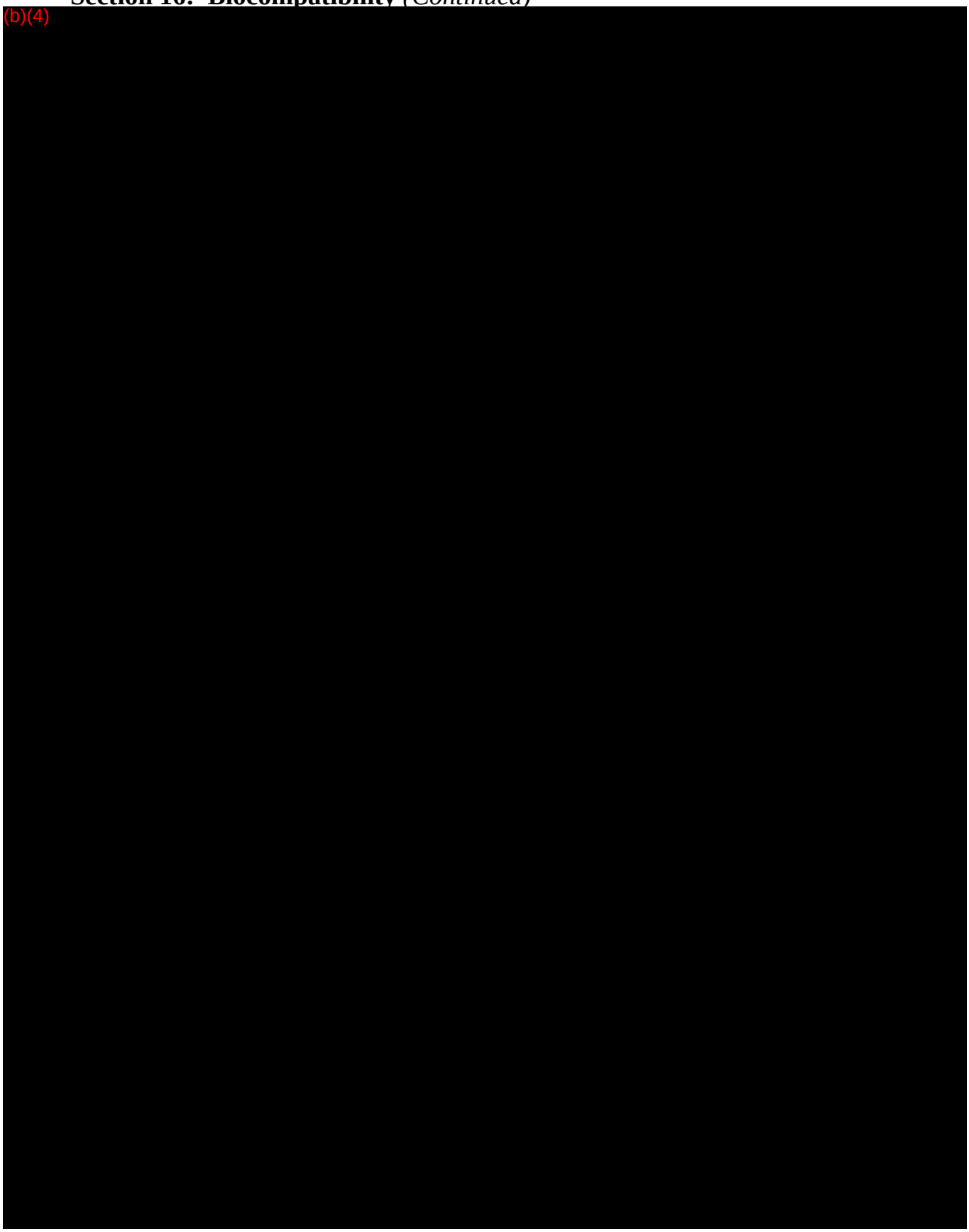
Component	(b)(4)
Sling Implant	
Protective Sleeve	
Leader Loop	
Dilator	
Association Loop	

(b)(4)



Section 16: Biocompatibility *(Continued)*

(b)(4)



Section 16: Biocompatibility *(Continued)*

Biocompatibility data for the patient-contacting portion of the delivery devices is on file with Boston Scientific.

Biocompatibility of New Components/Materials:

Testing was conducted to demonstrate biocompatibility of the (b)(4) in compliance with the requirements of ISO 10993-1. The (b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 16-2 provides a summary of the testing which demonstrates biocompatibility of the (b)(4)

Copies of the biocompatibility reports referenced in **Table 16-2** are provided in Appendix 16-A.

Table 16-2: Summary of Biocompatibility Tests Performed for Proposed Device

Test Performed / Applicable ISO 10993 Part No.	Test Facility & Report Number	Extract/ Conditions*	Results (Pass/Fail/Other)
(b)(4)			

Section 16: Biocompatibility *(Continued)*

(b)(4)

Appendix 16-A

Biocompatibility Reports

(b)(4) Study Report

(b)(4) Study Report

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(b)(4) Study Report

Appendix 16-B

(b) (4) [redacted] Certificate

(b)(4)

Section 17

Software

This section does not apply.
The proposed device does not contain software.

Section 18

Electromagnetic Compatibility and Electrical Safety

This section does not apply.
The proposed device is not the source nor does it have the ability to conduct electromagnetic or electrical energy to the patient.

Section 19

Performance Testing – Bench

Section 19: Performance Testing

Purpose

The purpose of the testing summarized in this section is to demonstrate that the proposed sling is "substantially equivalent" to the predicate Boston Scientific slings (K020110, K040787).

Performance testing

(b)(4)

Tests Performed

The tests performed on the proposed sling were driven by the product characterization list provided in the FDA Guidance document, "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," issued on March 2, 1999. Several of these tests have standard test methods that were followed and declarations of conformity to those standards are in Section 9.

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Section 20

Performance Testing – Animal

This section does not apply.
No animal studies were required in support of this premarket notification.

Section 21

Performance Testing – Clinical

This section does not apply.
No clinical studies were required in support of this premarket notification

(b)(4) FDA Review

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 14, 2012

BOSTON SCIENTIFIC CORP.
UROLOGY/WOMAN'S HEALTH
100 BOSTON SCIENTIFIC WAY
M21
MARLBOROUGH, MASSACHUSETTS 01752
ATTN: JANET A. MCGRATH

510k Number: K121754

Product: BLUE SUI SLING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: mcgrathj@bsci.com
Sent: Tuesday, August 14, 2012 1:30 PM
Subject: Relayed: K121754 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

mcgrathj@bsci.com (mcgrathj@bsci.com)

Subject: K121754 AI Letter

K121754/S1

Boston Scientific

Urology
Gynecology
100 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

August 13, 2012

FDA CDRH DMC
AUG 14 2012
Received
126

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20850

Subject: Premarket Notification –Traditional 510(k) – **K121754 – Amendment 1**
Device Name: Obtryx II System (Blue SUI Sling)
Device Type: Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision
Regulation Number: 21 CFR 878.3300
Regulatory Class: II
Product Code: OTN
Panel: Obstetrics and Gynecology

Dear Dr. Becky Robinson,

On June 12, 2012 Boston Scientific Corporation (BSC) submitted Traditional 510(k), K121754, for the Blue SUI Sling. On August 01, 2012 we received FDA's deficiency letter via fax, dated July 30, 2012 in response to the Blue SUI Sling (K121754). As requested by FDA we have updated the device name of the device from "Blue SUI Sling" To Obtryx II System".

Enclosed please find two copies of Boston Scientific's responses to FDA's letter dated July 30, 2012.

Boston Scientific Corporation considers its intent to manufacture and distribute this device to be confidential commercial information, and therefore exempt from public disclosure according to 21 CFR 807.95.

If you have any questions regarding this Premarket Notification, please contact me at (508) 683-4726 or by facsimile at (508) 683-5827.

Sincerely,

Janet A. McGrath
Principal Specialist, Global Regulatory Affairs
Urology and Gynecology
Boston Scientific Corporation
e-mail: mcgrathj@bsci.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/13/2012	MD6060582-956733	K121754

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Boston Scientific Corporation	1225056 (operator/owner # 9912058)		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Urology /Woman's Health	(508) 683-4726		
Street Address	**FAX Number *(including area code)***		
100 Boston Scientific Way ,M21	(508) 683-5827		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Marlborough	Ma	01752	USA
Contact Name			
Janet A . McGrath			
Contact Title	**Contact E-mail Address**		
Principal Specialist Global Regulatory Affairs	mcgrathj@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Additional information requested in response to FDA's deficiency letter date July 30,2012 for K121754 (Blue SUI Sling).

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FTL	2	FTL	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K020110	1	Advantage and Advantage Fit Systems , Lynx Systems	1	Boston Scientific
2	K040787	2	Obtryx Systems (halo & curve)	2	Boston Scientific
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, female, multi-incision

	Trade or Proprietary or Model Name for This Device		Model Number
1	Obtryx II System	1	M0068505110,M0068505111,M0068504110,M0068504[illegible]
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OTN	21 CFR 878.3300	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
Obstetrics/Gynecology		

Indications *(from labeling)*

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(b)(4) Responses to FDA Questions

(b)(4) Responses to FDA Questions

(b)(4) Responses to FDA Questions

(b)(4) Responses to FDA Questions

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(b)(4) Responses to FDA Questions

(b)(4) Responses to FDA Questions

Boston Scientific

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use **2**

90693849-01 Rev. C

2012-08

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01C_pretrans

TABLE OF CONTENTS

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

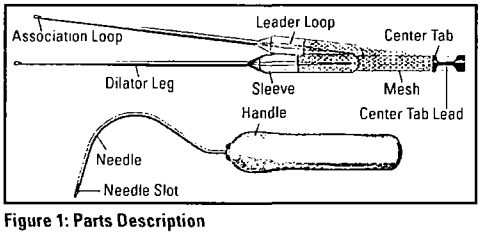

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hand's forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

5. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

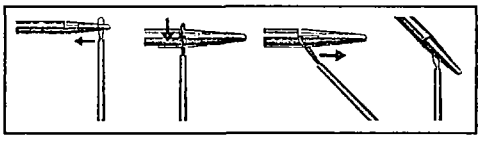

Figure 2: Association Loop Engagement

6. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
7. Remove the association loop from the needle (see Figure 3).

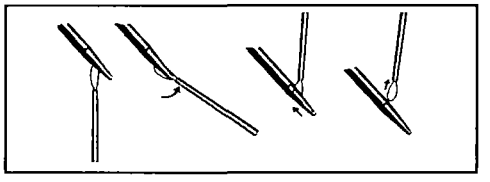

Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.
9. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
10. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

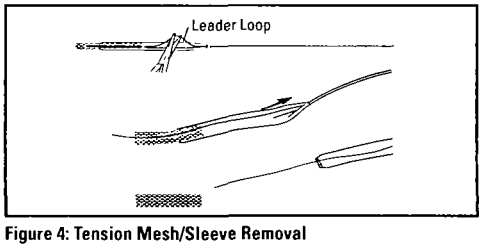

Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions according to usual methods.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).
  - Patients with blood coagulation disorder.
  - Patients with compromised immune system or any other conditions that would compromise healing.

- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.
- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ II System.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy is not required, but can be done at the surgeon's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site have been reported due to suburethral sling procedure.
- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration or perforation of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use
Consultar las instrucciones de uso
Consulter le mode d'emploi
Gebrauchsanweisung beachten
Consultare le istruzioni per l'uso
Raadpleeg instructies voor gebruik
Consulte as Instruções de Utilização

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EC REP
EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U E

Legal Manufacturer
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Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT
Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS
Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse
Para un solo uso. No reutilizar
À usage unique. Ne pas réutiliser
Für den einmaligen Gebrauch. Nicht wieder verwenden
Esclusivamente monouso. Non riutilizzare
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken
Apenas para uma única utilização. Não reutilize

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged
No usar si el envase está dañado
Ne pas utiliser si l'emballage est endommagé.
Ber beschadigter Verpackung nicht verwenden
Non usare il prodotto se la confezione è danneggiata
Niet gebruiken als de verpakking is beschadigd
Não utilize se a embalagem estiver danificada

Sterilized using ethylene oxide
Esterilizado por óxido de etileno
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert
Sterilizzato con ossido di etilene
Gesteriliseerd met ethyleenoxide
Esterilizado por óxido de etileno

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92729 NANTERRE CEDEX
FRANCE

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BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0197

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01C_pretrans

Boston Scientific

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use **2**

90693850-01 Rev. C

2012-08

TABLE OF CONTENTS

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

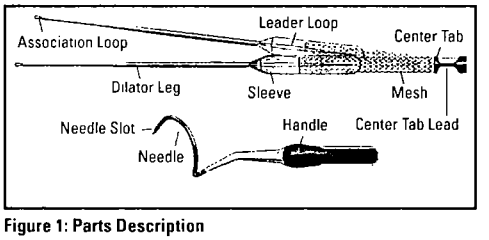

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle for the patient's left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.
5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

7. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

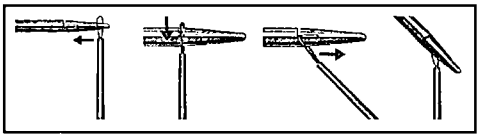

Figure 2: Association Loop Engagement

8. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
9. Remove the association loop from the needle (see Figure 3).

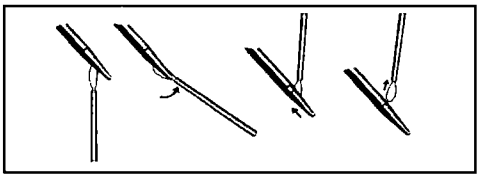

Figure 3: Association Loop Removal

10. Repeat Steps 4-9 on the contralateral side with the second needle.
11. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
12. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

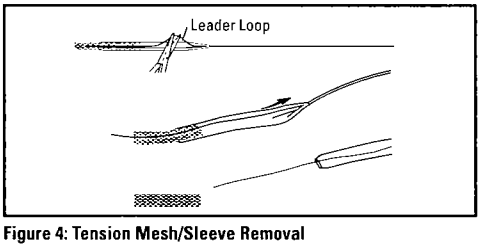

Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions according to usual methods.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).

- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.

- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ II System.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy is not required, but can be done at the surgeon's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site, have been reported due to suburethral sling procedure.
- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration or perforation of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

WARRANTY

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Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged.
No usar si el envase está dañado
Ne pas utiliser si l'emballage est endommagé.
Bei beschadigter Verpackung nicht verwenden
Non usare il prodotto se la confezione è danneggiata
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada

Sterilized using ethylene oxide
Esterilizado por óxido de etileno.
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Mit Ethylenoxid sterilisiert
Sterilizzato con ossido di etilene
Gesteriliseerd met ethyleenoxide
Esterilizado por óxido de etileno

EC REP **EU Authorized Representative**

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AUS **Australian Sponsor Address**

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PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

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One Boston Scientific Place
Natick, MA 01760-1537
USA

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Recyclable Package

CE 0197

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693850-01C_pretrans

NSIDERATIONS PRIOR TO SURGICAL REPAIR

If you are considering surgery for stress urinary incontinence your physician may ask you questions about your medical history, to ensure you are a candidate for this type of procedure. Some of these contraindications, warnings/potential complications, and post procedural events associated with surgery for stress urinary incontinence are listed below as a reference for you. You should consult your physician for a complete understanding of this information to determine whether this procedure is right for you.

INTENDED USE / INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Contraindications

A mesh implant is contraindicated in the following patients:

- Pregnant patients, patients with the potential for future growth or patients who are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

WARNINGS / POTENTIAL COMPLICATIONS

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

- Women planning future pregnancies.
- Overweight women (weight parameters to be determined by the physician).
- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.
- Vaginal and urinary tract infection should be treated prior to implantation.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI).

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due o incomplete support or overactive bladder.

In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence or vaginal incision, nerve damage, edema and erythema at the wound site, have been reported due to suburethal sling procedure.

- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.*

POST PROCEDURE

- Should dysuria, bleeding or other problems occur, contact your physician immediately.
- In the event that infection presents post procedure, the entire mesh may have to be removed or revised.
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
- Tissue responses to the implant could include: local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion/ exposure, device migration, complete failure of the procedure resulting in incontinence due to incomplete support or overactive bladder.

*For "Obtryx® Transobturator Mid-Urethral Sling System" procedure only

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effect, Warnings and Precautions prior to using this product.

Individuals depicted are models and included for illustrative purposes only.

Boston Scientific

Delivering what's next.™

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

WH-10234-AA 30M 8/12

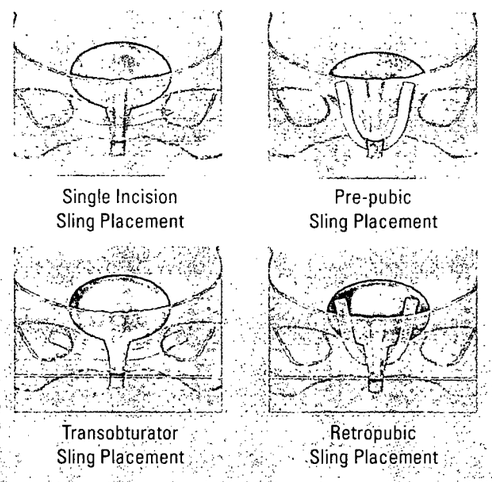
How can a mid-urethral sling system help my incontinence?

A mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity, which may include but is not limited to: laughing or lifting. Providing support that mimics the normal anatomy should prevent urine from leaking or reduce the amount of leakage.

What are the types of sling options?

Many surgical options have been developed, the difference being how the mesh material is placed under the urethra. Your doctor will recommend which anchoring location is right for you.

Sling Placement Options



Single Incision Sling Placement

Pre-pubic Sling Placement

Transobturator Sling Placement

Retropubic Sling Placement

What should I expect after surgery?

most patients resume moderate activities within 2 to 4 weeks...

Before your discharge from the hospital, you may be given a prescription for an antibiotic and/or pain medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. At the discretion of your physician, most patients resume moderate activities within 2 to 4 weeks, with no strenuous activity for up to 6 weeks.

When will I stop leaking?

Most women see results right after the procedure. Talk with your physician about what you should expect. ***You are on your way!***

Visit www.voicesforpfd.org for additional educational resources.

incontinence

YOUR GUIDE TO STRESS URINARY INCONTINENCE

commonly asked questions, down-to-earth answers

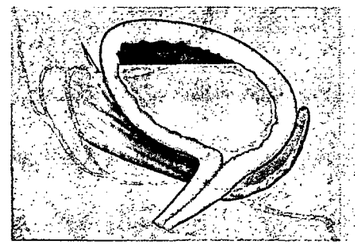
What is stress urinary incontinence?

Urinary incontinence is defined as the involuntary leakage of urine. The problem afflicts approximately 18 million adults in the United States, 85% of them being women. You are not alone! It usually takes 4–6 years to see a healthcare professional for this condition.

What type of stress urinary incontinence do I have?

One condition is called hypermobility, ("hyper" means too much and "mobility" refers to movement) which can result from childbirth, previous pelvic surgery or hormonal changes. Hypermobility occurs when the normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping when any downward pressure is applied, resulting in involuntary leakage.

Another condition is called intrinsic sphincter deficiency, usually called ISD. This refers to the weakening of the urethral sphincter muscles or closing mechanism. As a result, the sphincter does not function normally regardless of the position of the bladder neck or urethra.



Normal functioning anatomy

A weakening of the muscles supporting the urethra causes the urethra to drop during physical activity, resulting in urine leaking.

Remember, millions of women are going through exactly what you are. Seeing your physician and knowing your options are the first steps.

What are some of the symptoms?

You don't have to live like this.

Stress urinary incontinence is the involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing, or lifting. Incontinence occurs when the muscles that support the urethra (the tube that carries urine out of the body) are weakened or damaged. This can happen as a result of childbirth, trauma, hormone changes and many other reasons. You don't have to live like this. This type of incontinence can be treated both surgically or nonsurgically.

What are some treatment options?

Stress urinary incontinence can be treated in several ways, depending on the exact nature of the incontinence and its severity.

You and your physician may discuss:

- ☐ Changes to your diet and fitness routine
- ☐ Physical therapy including pelvic floor muscle training
- ☐ Vaginal pessaries
- ☐ Surgical options including traditional mesh slings, single incision mini-slings, retropubic colposuspension, and bulking.

This guide will focus on surgical procedures.

How will my surgery be performed?

Your minimally-invasive sling procedure is estimated to only take 30–45 minutes.

Your doctor will determine the type of anesthesia you will have during the procedure. Once the anesthesia takes effect, your doctor will begin the procedure.

A small incision will be made in the vaginal area. Next, the synthetic mesh is placed to create a "sling" of support around the urethra.

When your doctor is satisfied with the position of the mesh, he or she will close and bandage the small incisions in the groin area (if applicable for your sling type) and the top of the vaginal canal.

(b)(4) Study Report

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(b)(4) Study Report

Section 5

510(k) Summary

510(k) Summary for Blue SUI Sling

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename:	Obtryx II System
Common/usual name:	Surgical Mesh
Classification Name:	OTN – Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision 21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename:	Advantage , Advantage Fit & Lynx Systems Obtryx, Prefyx Systems
Common/usual name:	Surgical Mesh
Classification Name:	FTL- Mesh, Surgical, Polymeric 21 CFR 878.3300, Class II
Premarket Notification:	Boston Scientific Corporation, ▪ K020110 ▪ K040787

E. Device Description

The proposed sling is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a blue knitted polypropylene monofilament fiber mesh body implant, association loops, dilator legs, sleeves, leader loops, center tab and lead.

The proposed sling is packaged with (2) delivery devices (Halo or Curved) which are used in conjunction with the mesh assembly to place the mesh implant. Each of the delivery devices consist of a polymer handle and a stainless steel needle which extends from the handle. The tip of the needle has a slot which is used to attach the association loop of the mesh assembly.

F. Intended Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

G. Technological Characteristics

The proposed sling has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicates K020110 & K040787.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed sling is substantially equivalent to the predicate sling in terms of intended use, technological characteristics, and performance characteristics tested. The proposed sling is as safe, as effective, and performs as well as the predicate devices.

I . Non-Clinicial Testing

Material testing was performed to demostrate that the material properites are suitable for the intended use.

Bench testing was performed to demostrate that the device as manufactured meets performance specifications. Test results demostrate that the device meets the predetermine specifications and is acceptable for clinical use.

Biocompatiblity testing was performed in accordance to standard EN ISO 10993-1 for each of the patient contacting materials, and results demonstrate that the device is biocompatible for its intended use.

Conclusion:

Based on material, biocompatiblity, bench testing, and the proposed device labeling, the Obtryx II System is substantially equivalent to the identified predicate devices in terms of intended, use , safety and effectiveness.

Section 4

Indications for Use Statement

Indications for Use Statement

510(k) Number (if Known): _____

Device Name: Obtryx II System

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b)(4) Standard Data Reports

(b)(4) Standard Data Reports

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
Urology/Woman's Health
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade Name: Blue SUI Sling
Dated: June 13, 2012
Received: June 14, 2012

JUL 30 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission we require the following:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For

guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf. The purpose of this document is to assist Agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Dr. Becky Robinson at (301) 796-6532. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elaine H. Blyskun

Elaine H. Blyskun
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

K121754/S2 V1

OCT 10 2012

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade/Device Name: Obtryx II System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: September 19, 2012
Received: September 20, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Boston Scientific Corporation

Indications for Use Statement

510(k) Number (if Known): K121754

Device Name: Obtryx II System

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

09 Oct 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121754

Traditional 510(k)
Obtryx II System

* * * COMMUNICATION RESULT REPORT (OCT. 10. 2012 2:28PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : OCT. 10. 2012 2:24PM				
FILE MODE	OPTION	ADDRESS	RESULT	PAGE
9916 MEMORY TX		5086835827	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 10 2012

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade/Device Name: Obtryx II System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: September 19, 2012
Received: September 20, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

(b)(4) FDA Review

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 20, 2012

BOSTON SCIENTIFIC CORP.
UROLOGY/WOMAN'S HEALTH
100 BOSTON SCIENTIFIC WAY
M21
MARLBOROUGH, MASSACHUSETTS 01752
ATTN: JANET A. MCGRATH

510k Number: K121754

Product: BLUE SUI SLING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: mcgrathj@bsci.com
Sent: Thursday, September 20, 2012 11:32 AM
Subject: Relayed: K121754 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

mcgrathj@bsci.com (mcgrathj@bsci.com)

Subject: K121754 AI Letter

K121754/S2

Boston Scientific

FDA CDRH DMC

SEP 20 2012

Received

September 19, 2012

U.S Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Premarket Notification –Traditional 510(k) – **K121754 – Amendment 2**
Device Name: Obtryx II System (Blue SUI Sling)
Device Type: Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision
Regulation Number: 21 CFR 878.3300
Regulatory Class: II
Product Code: OTN
Panel: Obstetrics and Gynecology

Dear Dr. Becky Robinson,

On June 12, 2012 Boston Scientific Corporation (BSC) submitted Traditional 510(k), K121754, for the Blue SUI Sling. On August 13, 2012 BSC sent a response to FDA's with regards to a deficiency letter received for K121754, dated July 30, 2012. On September 10, 2012 BSC received a second deficiency letter via fax dated September 6, 2012 for a request for additional information. As requested by FDA we have provided the additional information requested.

Enclosed please find two copies and one original of Boston Scientific's responses to FDA's deficiency letter dated September 6, 2012, received September 10, 2012.

Boston Scientific Corporation considers its intent to manufacture and distribute this device to be confidential commercial information, and therefore exempt from public disclosure according to 21 CFR 807.95.

If you have any questions regarding this Premarket Notification, please contact me at (508) 683-4726 or by facsimile at (508) 683-5827.

Sincerely,

Janet A. McGrath
Principal Specialist, Global Regulatory Affairs
Urology and Gynecology
Boston Scientific Corporation
e-mail: mcgrathj@bsci.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09/19/2012	MD6060582-956733	K121754

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & *HDE Supplement*			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Boston Scientific Corporation	1225056(operator/owner # 9912058)		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Urology/Woman's Health	(508)683-4726		
Street Address	**FAX Number *(including area code)***		
100 Boston Scientific Way , M21	(508) 683-5827		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Marlborough	MA	01752	USA
Contact Name			
Janet A. McGrath			
Contact Title	**Contact E-mail Address**		
Principal Specialist Global Regulatory Affairs	mcgrathj@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☒ Other Reason *(specify)*:

Additional information requested in response to FDA's deficiency letter dated September 6, 2012 for Obtryx II (Blue SUI Sling) K121754.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FTL	2	FTL	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K020110	1	Advantage and Advantage Fit Systems, Lynx Systems	1	Boston Scientific Corporation
2	K040787	2	Obtryx Systems (curved & halo)	2	Boston Scientific Corporation
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

mesh,surgical,synthetic, urogynecologic, for stress urinary incontinence, female , multi-incision

	Trade or Proprietary or Model Name for This Device		Model Number
1	Obtryx II System, Curved, Single Unit	1	M0068504110
2	Obtryx II System, Curved, 5 Pack	2	M0068504111
3	Obtryx II System, Halo, Single Unit	3	M0068505110
4	Obtryx II System, Halo, 5 Pack	4	M0068505111
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OTN	21 CFR 878.3300	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Obstetrics/Gynecology

Indications *(from labeling)*

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(b)(4) Response to FDA Questions

(b)(4) Response to FDA Questions

(b)(4) Response to FDA Questions

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(b)(4) Response to FDA Questions

(b)(4) Response to FDA Questions

Boston Scientific

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use **2**

90693849-01 Rev. D

2012-09

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01D_pretrans

TABLE OF CONTENTS

Obtryx™ II System

CURVED

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

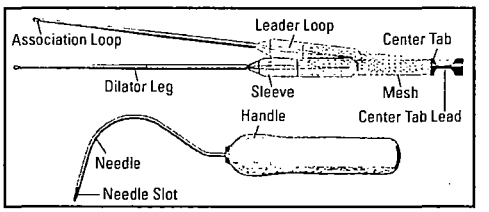

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hand's forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01D_pretrans

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

5. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

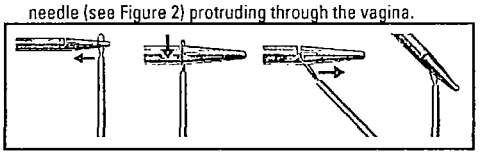

Figure 2: Association Loop Engagement

6. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
7. Remove the association loop from the needle (see Figure 3).

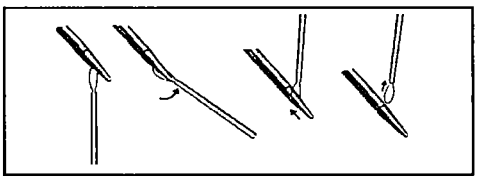

Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.
9. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
10. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

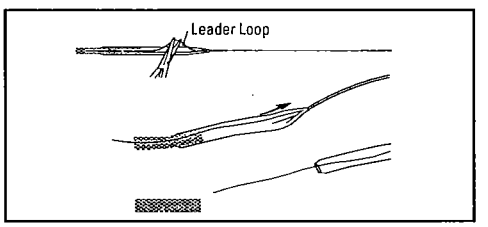

Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead *located on the side of the center tab to release the tab from* the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions per standard practice.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

- Women planning future pregnancies.
- Overweight women (weight parameters to be determined by the physician).
- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.

- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ II System.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy may be done at the physician's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site have been reported due to suburethral sling procedure.
- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration or perforation of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr
Numero di catalogo
Katalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo

EC REP
EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT
Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS
Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden
Esclusivamente monouso. Non riutilizzare
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken
Apenas para uma única utilização. Não reutilize

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd
Não utilize se a embalagem estiver danificada

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693849-01D_pretrans

EC REP **EU Authorized Representative**

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0197

Boston Scientific

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

Directions for Use **2**

90693850-01 Rev. D

2012-09

TABLE OF CONTENTS

Obtryx™ II System

HALO

Transobturator Sling System with PrecisionBlue™ Design

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

WARNING

Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from *hypermobility and/or intrinsic sphincter deficiency.*

CONTRAINDICATIONS

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

Boston Scientific (Master Brand Template 3in x 9in Global, 90106040 AK), DFU, MB, Obtryx II System, Global, 90693850-01D_pretrans

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

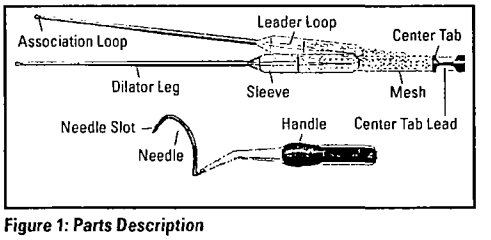

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING

If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle for the patient's left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.
5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

WARNING

Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING

Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

7. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

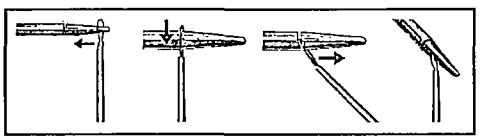

Figure 2: Association Loop Engagement

8. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.
9. Remove the association loop from the needle (see Figure 3).

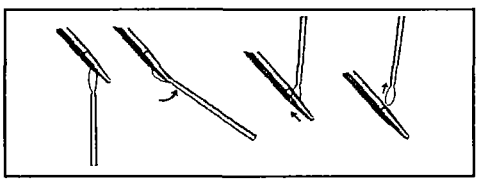

Figure 3: Association Loop Removal

10. Repeat Steps 4-9 on the contralateral side with the second needle.
11. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
12. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

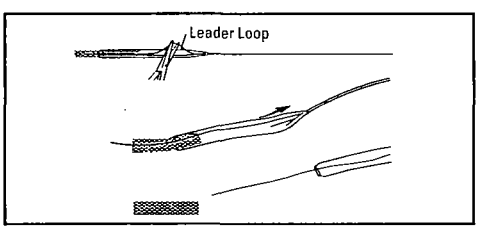

Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions per standard practice.

GENERAL WARNING

- The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
  - Women planning future pregnancies.
  - Overweight women (weight parameters to be determined by the physician).
  - Patients with blood coagulation disorder.
  - Patients with compromised immune system or any other conditions that would compromise healing.
  - Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.
- Vaginal and urinary tract infection should be treated prior to implantation.
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx™ II System.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

PROCEDURAL WARNING

- Cystoscopy may be done at the physician's discretion.

POST PROCEDURAL WARNING

- If subsequent infection occurs, the entire mesh may have to be removed or revised.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

POTENTIAL COMPLICATIONS

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site, have been reported due to suburethral sling procedure.

- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration or perforation of any vessels, nerves, bladder and bowel.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counselled to refrain from heavy lifting, exercise and intercourse for a minimum of four (4) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização


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À usage unique. Ne pas réutiliser.
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Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize

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CONSIDERATIONS PRIOR TO SURGICAL REPAIR

If you are considering surgery for stress urinary incontinence your physician may ask you questions about your medical history, to ensure you are a candidate for this type of procedure. Some of these contraindications, warnings/potential complications, and post procedural events associated with surgery for stress urinary incontinence are listed below as a reference for you. You should consult your physician for a complete understanding of this information to determine whether this procedure is right for you.

INTENDED USE / INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Contraindications

A mesh implant is contraindicated in the following patients:

- Pregnant patients, patients with the potential for future growth or patients who are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

WARNINGS / POTENTIAL COMPLICATIONS

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

- Women planning future pregnancies.
- Overweight women (weight parameters to be determined by the physician).
- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling placement.
- Vaginal and urinary tract infection should be treated prior to implantation.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI).

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence or vaginal incision, nerve damage, edema and erythema at the wound site, have been reported due to suburethal sling procedure.
- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding.*

POST PROCEDURE

- Should dysuria, bleeding or other problems occur, contact your physician immediately.
- In the event that infection presents post procedure, the entire mesh may have to be removed or revised.
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
- Tissue responses to the implant could include: local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion/exposure, device migration, complete failure of the procedure resulting in incontinence due to incomplete support or overactive bladder.

*For "Obtryx® Transobturator Mid-Urethral Sling System" procedure only

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effect, Warnings and Precautions prior to using this product.

Individuals depicted are models and included for illustrative purposes only.

Boston Scientific
Delivering what's next.™

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One Boston Scientific Place
Natick, MA 01760-1537

WH-10234-AA 30M 10/12

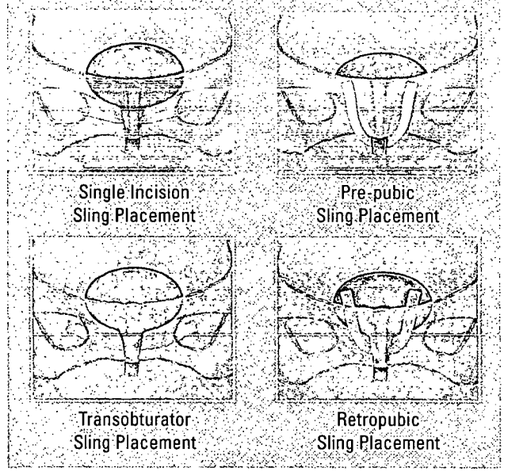
Q: How can a mid-urethral sling system help my incontinence?

A: A mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity, which may include but is not limited to: laughing or lifting. Providing support that mimics the normal anatomy should prevent urine from leaking or reduce the amount of leakage.

Q: What are the types of sling options?

A: Many surgical options have been developed, the difference being how the mesh material is placed under the urethra. Your doctor will recommend which anchoring location is right for you. As disease state and anatomy differs for each patient, outcomes may vary. Consult your physician for all available treatment options.

Sling Placement Options



Q: What should I expect after surgery?

most patients resume moderate activities within 2 to 4 weeks...

A: Before your discharge from the hospital, you may be given a prescription for an antibiotic and/or pain medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. At the discretion of your physician, most patients resume moderate activities within 2 to 4 weeks, with no strenuous activity for up to 6 weeks.

Q: When will I stop leaking?

A: Most women see results right after the procedure. Talk with your physician about what you should expect. ***You are on your way!***

Visit www.voicesforpfd.org for additional educational resources.

incontinence

YOUR GUIDE TO STRESS URINARY INCONTINENCE

frequently asked questions

frequently asked questions, down-to-earth answers

Q: What is stress urinary incontinence?

A: Urinary incontinence is defined as the involuntary leakage of urine. The problem afflicts approximately 18 million adults in the United States, 85% of them being women. You are not alone! It usually takes 4–6 years to see a healthcare professional for this condition.

Q: What are some of the symptoms?

A: Stress urinary incontinence is the involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing, or lifting. Incontinence occurs when the muscles that support the urethra (the tube that carries urine out of the body) are weakened or damaged. This can happen as a result of childbirth, trauma, hormone changes and many other reasons. You don't have to live like this. This type of incontinence can be treated both surgically or nonsurgically.

You don't have to live like this.

For more information, visit the FDA's Urogynecologic Surgical Mesh website at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm

Q: What are some treatment options?

A: Stress urinary incontinence can be treated in several ways, depending on the exact nature of the incontinence and its severity. As disease state and anatomy differs for each patient, outcomes may vary. Consult your physician for all available treatment options.

You and your physician may discuss:

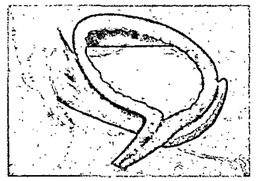
- Changes to your diet and fitness routine
- Physical therapy including pelvic floor muscle training
- Vaginal pessaries
- Surgical options including traditional mesh slings, single incision mini-slings, retropubic colposuspension, and bulking.

This guide will focus on surgical procedures.

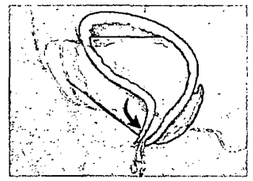
Q: What type of stress urinary incontinence do I have?

A: One condition is called hypermobility, ("hyper" means too much and "mobility" refers to movement) which can result from childbirth, previous pelvic surgery or hormonal changes. Hypermobility occurs when the normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping when any downward pressure is applied, resulting in involuntary leakage.

Another condition is called intrinsic sphincter deficiency, usually called ISD. This refers to the weakening of the urethral sphincter muscles or closing mechanism. As a result, the sphincter does not function normally regardless of the position of the bladder neck or urethra.



Normal functioning anatomy



A weakening of the muscles supporting the urethra causes the urethra to drop during physical activity, resulting in urine leaking.

Q: How will my surgery be performed?

A: Your minimally-invasive sling procedure is estimated to only take 30–45 minutes. Your doctor will determine the type of anesthesia you will have during the procedure. Once the anesthesia takes effect, your doctor will begin the procedure.

A small incision will be made in the vaginal area. Next, the synthetic mesh is placed to create a "sling" of support around the urethra.

When your doctor is satisfied with the position of the mesh, he or she will close and bandage the small incisions in the groin area (if applicable for your sling type) and the top of the vaginal canal.

Q: What are the potential risks and complications of surgery?

A: As with most surgical procedures, there are potential risks and complications associated with surgery. Your physician can further explain your specific risks based on your medical history and surgical approach used. Some potential adverse reactions related to surgical correction for stress urinary incontinence include:

- Pain/Discomfort/Irritation
- Inflammation (redness, heat, pain, or swelling resulting from surgery), edema (swelling caused by fluid retention) and erythema (redness of the skin)
- Infection, including abscess
- Bleeding (vaginal) and hematoma formation (pooling of blood beneath the skin)
- Mesh erosion (presence of mesh material within the organs surrounding the vagina)
- Mesh extrusion (presence of mesh materials within the vagina)
- Fistula formation (a hole/passage that develops between organs or anatomic structures that is repaired by surgery)
- Foreign body (allergic) reaction to mesh implant
- Urinary incontinence (involuntary leaking of urine)
- Urinary retention/obstruction (involuntary storage of urine/blockage of urine flow)
- Voiding dysfunction (difficulty with urination)
- Vaginal discharge
- Wound dehiscence (opening of the incision after surgery)
- Nerve damage
- Detrusor stability (involuntary construction of the detrusor muscle while the bladder is filling)
- Device migration, complete failure of the device
- Dyspareunia (pain during intercourse)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Janet A. McGrath
Principal Specialist, Global Regulatory Affairs
Boston Scientific Corporation
Urology/Woman's Health
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

SEP 06 2012

Re: K121754
Trade Name: Obtryx II System
Dated: August 13, 2012
Received: August 14, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally-marketed predicate device because you did not completely respond to the deficiencies listed in our July 30, 2012 letter. To complete the review of your submission we require the following:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket

Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf. The purpose of this document is to assist Agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Dr. Becky Robinson at (301) 796-6532. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elaine H. Blyskun

Elaine H. Blyskun
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health