

**Obtryx® II**

Transobturator Sling System  
with PrecisionBlue™ Design

**Boston  
Scientific**

## Product Review for the Purchasing Committee



**Always there.**

*Dedicated to Women's Health*

*Urology and  
Women's Health*

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# Product Overview

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Obtryx<sup>®</sup> II Transobturator Sling System  
with PrecisionBlue<sup>™</sup> Design Summary

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# Obtryx® II Transobturator Sling System with PrecisionBlue™ Design

Obtryx II Sling System with PrecisionBlue Design is a transobturator sling with enhanced features that are designed to provide smooth sling placement, intra-operative adjustability with minimal tissue disruption and increased physician visualization that aids in precise sling placement.

## Smooth Sling Placement

Obtryx II Sling System is designed with thin dilator legs to allow ease of placement when traveling through the anatomy and transitioning around the bone. The plastic sleeves have smooth edges versus sharp edges; and the dilator legs allow untwisting of the sling when necessary.

## Intra-operative Adjustability with Minimal Tissue Disruption

Obtryx II Sling System is designed to allow inter-operative adjustability with minimal tissue disruption. The centering tab and dilator legs act as a system to allow the physician to adjust the sling intra-operatively according to their preferences. The centering tab not only marks the center of the sling, but is a tool to aid in tensioning. Physicians can use the dilator legs and centering tab to adjust the sling to achieve their desired tensioning.

## Increased Physician Visualization

Mesh color can obviously be advantageous in enhancing visibility. Obtryx II Sling System has blue mesh and dilator legs that can be seen during placement and cystoscopy to ensure the sling is placed according to physician preferences. The mesh color can also be beneficial if there was a need to view the sling post-surgery. There is no sleeve coverage in the suburethral segment, this allows the physician to see how the mesh implant sits against the urethra without having to pull back the sleeves.

## The Three Elements of PrecisionBlue Design



### Needle Design

- Needle tip length is designed to facilitate easier passage through varied anatomy
- Two needle configurations allow physicians to choose the needle that meets their preference

### Association Loop

- Designed to facilitate easy needle engagement and removal

### CURVED NEEDLE

- No sleeve coverage under the sub-urethral segment to allow for visibility and to aid in precise placement

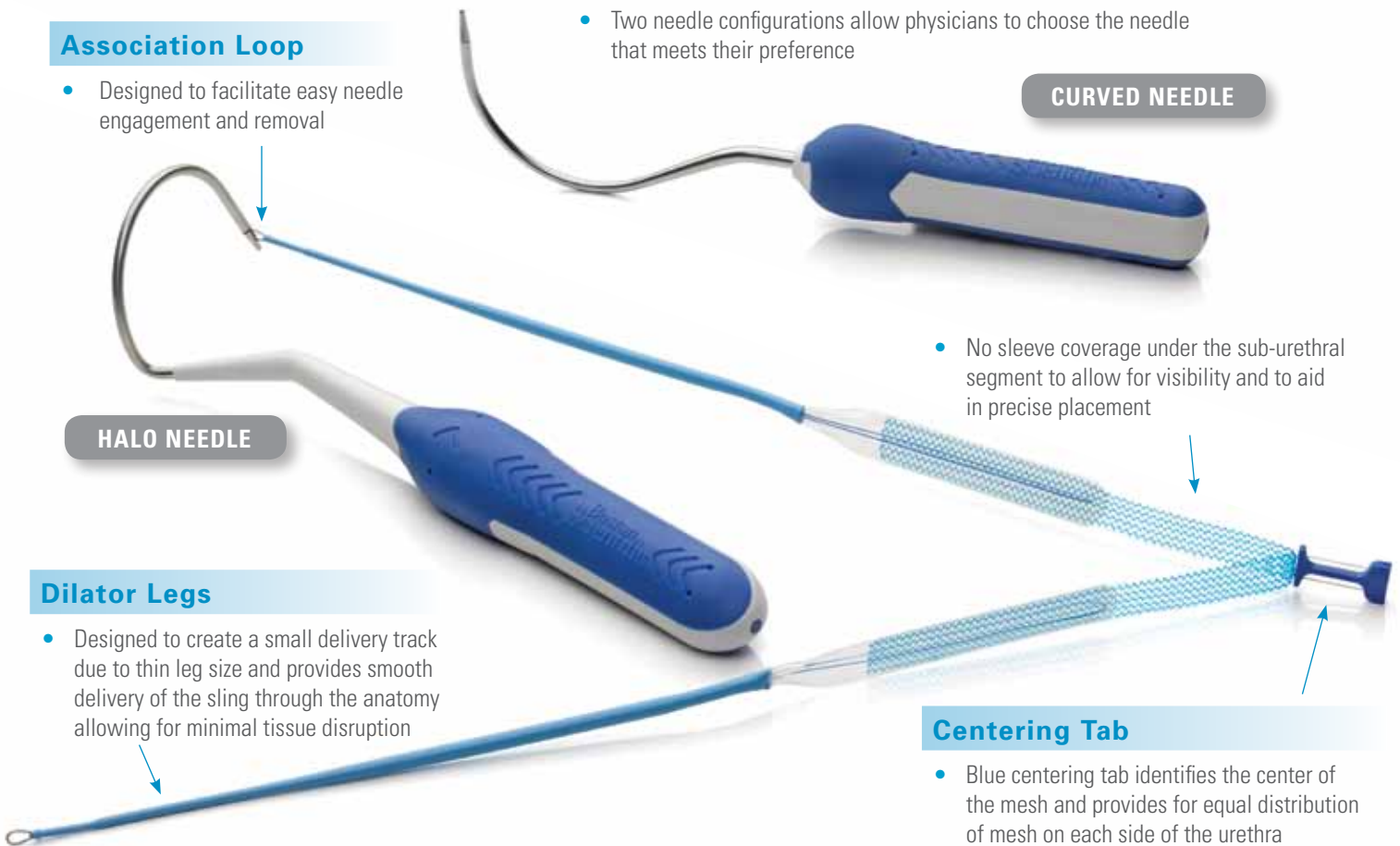
### HALO NEEDLE

### Dilator Legs

- Designed to create a small delivery track due to thin leg size and provides smooth delivery of the sling through the anatomy allowing for minimal tissue disruption

### Centering Tab

- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- The centering tab can be used to aid in tensioning the mesh implant





# Regulatory Information

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Regulatory Summary

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Boston Scientific  
Obtryx<sup>®</sup> II System Letter

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FDA 510K Clearance Letter  
for Obtryx II System

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Indications for Use Statement

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## Regulatory Summary

Regulation Medical Specialty	Obstetrics and Gynecology
Regulation Description	Surgical Mesh
Device Classification Name	Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision
Trade/Device Name	Obtryx® II System
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.
510(k) Number	K121754
Regulation Number	21 CFR §878.3300
Regulatory Class	II
Product Code	OTN
Clearance Date	October 10, 2012
Additional Information	Please refer to package insert provided with the product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

**Caution:** Federal Law (USA) restricts these devices 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 Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.



# Obtryx® II System Letter



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

October 18, 2012

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product Obtryx® II System - Transobturator Sling System with PrecisionBlue™ Design. ***This information is provided in response to your direct request for information concerning the regulatory status of these products within the USA and may not be used for any other purpose without the expressed written permission of Boston Scientific.***

M0068504110	Obtryx® II Transobturator Sling System - Curved	Single Unit
M0068504111	Obtryx II Transobturator Sling System - Curved	5 Pack
M0068505110	Obtryx II Transobturator Sling System - Halo	Single Unit
M0068505111	Obtryx II Transobturator Sling System - Halo	5 Pack

Obtryx® II System - Transobturator Sling System with PrecisionBlue™ Design is marketed in accordance with the U.S. Food and Drug Administration (FDA) regulations 21 CFR 878.3300. This product was cleared to market by the FDA on October 10, 2012 via 510(k) K121754. Attached you will find a copy of this clearance letter.

Please contact your local sales representative or Boston Scientific directly should you have any additional questions or require additional information.

Sincerely,

Regulatory Affairs

enclosure

# FDA 510K Clearance Letter

OCT. 10. 2012 2:27PM

NO. 9916 P. 1/3



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  
100 Boston Scientific Way, M21  
MARLBOROUGH MA 01752

OCT 10 2012

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

OCT. 10. 2012 2:27PM

NO. 9916 P. 2/3

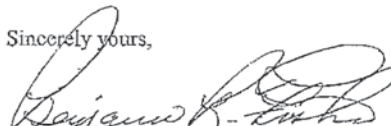
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of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

# Indications for Use Statement

OCT. 10. 2012 2:28PM

NO. 9916 P. 3/3

Boston Scientific Corporation

CONFIDENTIAL

## 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.

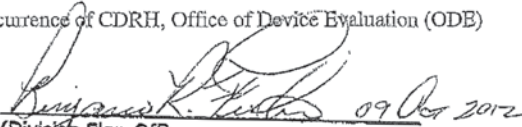
Prescription Use X  
(21 CFR 801 Subpart D)

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)

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

Traditional 510(k)  
Obtryx II System

# Directions For Use

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Obtryx<sup>®</sup> II System - *Curved Needle*

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Obtryx II System - *Halo Needle*

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# DFU: Obtryx® II System - Curved Needle

**Boston Scientific**


**Obtryx™ II System**  
**CURVED**

Transobturator Sling System  
with PrecisionBlue™ Design

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**Directions for Use**                      **2**

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90693849-01 Rev. D

2012-09

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DFU as of November 14, 2012. Current version of the DFU is included with the product.

# Obtryx™ II System

**CURVED**

Transobturator Sling System with  
PrecisionBlue™ Design

## Rx 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.

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### 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.

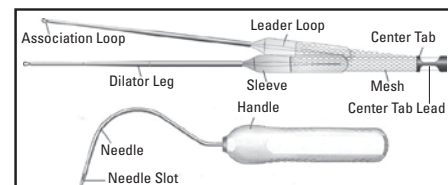


Figure 1: Parts Description

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.

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# DFU: Obtryx® II System - Curved Needle (cont.)

**WARNING**

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

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



**Figure 2: Association Loop Engagement**

- 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.
- Remove the association loop from the needle (see Figure 3).

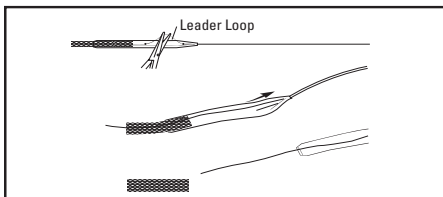


**Figure 3: Association Loop Removal**

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

**TENSION MESH/SLEEVE REMOVAL**

- Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
- Appropriately tension the mesh/sleeve according to physician preference.
- 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**

- 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.
- Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
- 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:

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- 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.

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**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.**



Catalog Number  
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Bestell-Nr.  
Numero di catalogo  
Catalogusnummer  
Referència



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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EU Authorized Representative  
Representante autorizado en la UE  
Représentant agréé UE  
Autorisierter Vertreter in der EU  
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Lot  
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Lot  
Charge  
Lotto  
Partij  
Lote



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



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



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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.  
A 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.

# DFU: Obtryx® II System - Curved Needle (cont.)



Do Not Resterilize  
No reesterilizar  
No 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.

**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.

9



**EU Authorized Representative**

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



**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.**

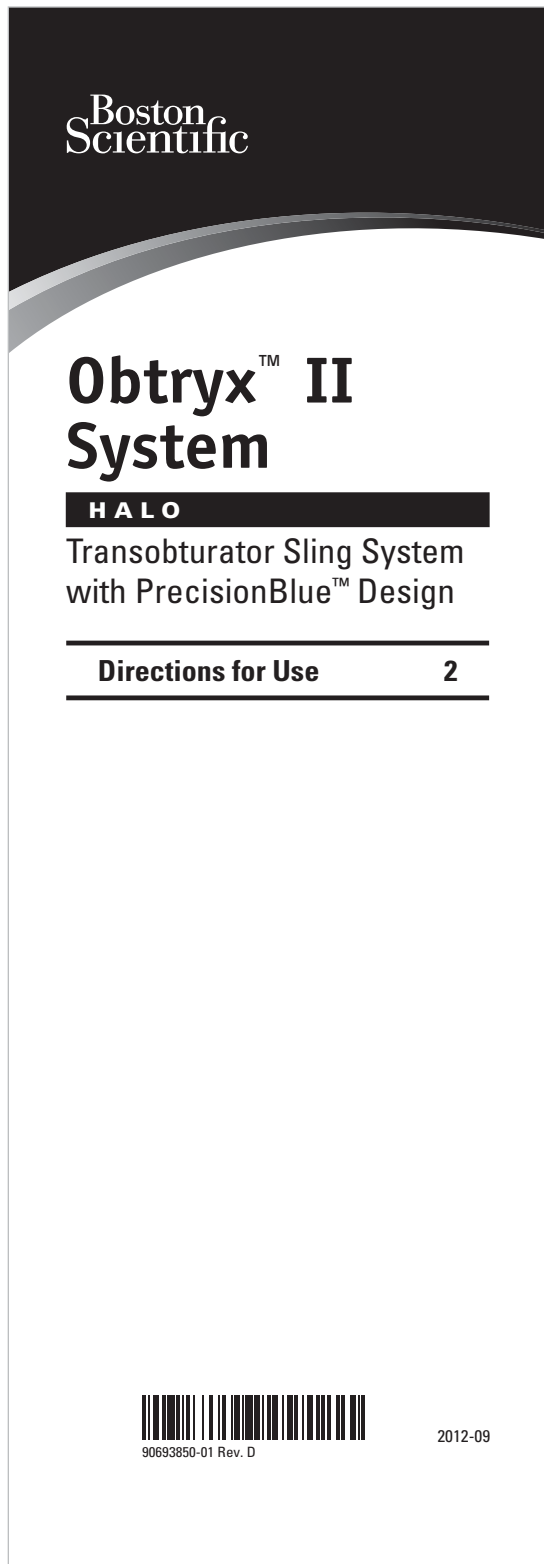


**Recyclable Package**

**CE 0197**

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# DFU: Obtryx II System - Halo Needle



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# DFU: Obtryx® II System - Halo Needle (cont.)

## Obtryx™ II System

**HALO**

Transobturator Sling System with PrecisionBlue™ Design

### Rx 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.

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#### 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.

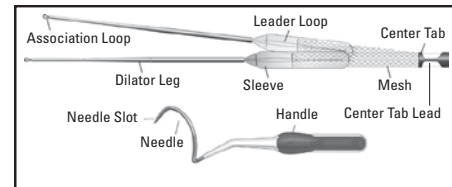


Figure 1: Parts Description

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 inferior 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

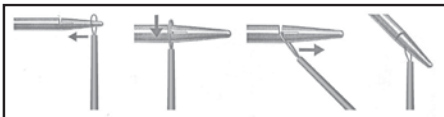
Pay careful attention to avoid the adductor longus tendon with the delivery device.

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**WARNING**

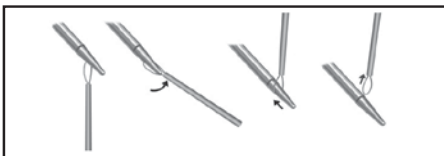
Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

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



**Figure 2: Association Loop Engagement**

- 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.
- Remove the association loop from the needle (see Figure 3).

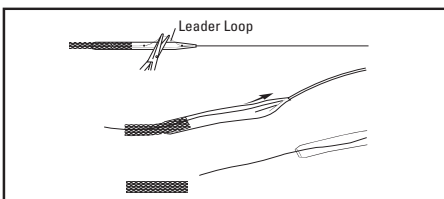


**Figure 3: Association Loop Removal**

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

**TENSION MESH/SLEEVE REMOVAL**

- Adjust the mesh/sleeve by pulling outward on the dilators so that the blue center tab is centered below the urethra.
- Appropriately tension the mesh/sleeve according to physician preference.
- 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**

- 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.
- Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
- Close all incisions per standard practice.

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**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.

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# DFU: Obtryx® II System - Halo Needle (cont.)

- 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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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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# Clinical/Scientific Data

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A Comparative Transobturator Sling Matrix

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Long Term Efficacy and Safety of the Obtryx<sup>®</sup>  
Transobturator Mid-Urethral Sling System for Treatment  
of Stress Urinary Incontinence in a Community Setting:  
An Analysis of Outcomes and Quality of Life

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## A Comparative Transobturator Sling Matrix

PrecisionBlue Design is a set of enhanced features designed to provide smooth sling placement, intra-operative adjustability with minimal tissue disruption and increased physician visualization that aids in precise sling placement.

Transobturator Device	Sling Delivery Force	Mesh Holding Force	Sleeve Removal Force
<b>Boston Scientific Obtryx® II Sling System</b>	<b>1.60 lbs<sup>1</sup></b>	<b>2.69 lbs<sup>2</sup></b>	<b>0.50 lbs<sup>1</sup></b>
Boston Scientific Obtryx® Sling System	3.45 lbs <sup>1</sup>	2.67lbs <sup>1</sup>	2.98 lbs <sup>1</sup>
AMS MonArc® Sling System	3.51 lbs <sup>1</sup>	2.83 lbs <sup>1</sup>	5.63 lbs <sup>1</sup>
Bard Align® TO Sling	5.28 lbs <sup>1</sup>	2.79 lbs <sup>1</sup>	5.54 lbs <sup>1</sup>
Gynecare TVT-0	4.23 lbs <sup>1</sup>	2.59 lbs <sup>1</sup>	2.18 lbs <sup>1</sup>
Gynecare TVT-Abbrevo® System	5.15 lbs <sup>3</sup>	2.19 lbs <sup>3</sup>	5.31 lbs <sup>3</sup>
Coloplast Aris® Sling	0.78 lbs <sup>1</sup>	0.52 lbs <sup>1</sup>	N/A

### The Obtryx II Sling System requires

- 54% less delivery force than the MonArc Sling
- 70% less than Bard Align TO Sling
- 62% less than TVT-0
- 69% less than Gynecare TVT-Abbrevo Sling

**without sacrificing holding force.**

### The Obtryx II Sling System requires

- 91% less sleeve removal force than the MonArc Sling, Gynecare TVT-Abbrevo Sling and Bard Align TO Sling
- 77% less than TVT-0

## Characteristics of Transobturator Slings Systems

Transobturator Device	Boston Scientific Obtryx® II Sling System	Boston Scientific Obtryx® Sling System	AMS MonArc® Sling	Bard Align® TO Sling	Gynecare TVT-O Sling	Gynecare TVT Abbrevio® Sling	Coloplast Aris® Sling
Trocar Design <sup>4</sup>	Two options - Halo and Curved	Two options - Halo and Curved	Three options - MonArc+, MonArc C, Standard MonArc	Two options - Halo and Hook	Helical passers with Winged Guided Insertion Zone tool	Helical passers with Winged Guided Insertion Zone tool	Two options - Flat curved and helical introducers
Approach <sup>5</sup>	Outside In	Outside In	Outside In	Outside In	Inside Out	Inside Out	Outside In
Mesh edges/ Features <sup>4</sup>	Tanged/ De-tanged (heat sealed mid-section)	Tanged/ De-tanged (heat sealed mid-section)	Tanged/ Tensioning Suture	Tanged	Tanged	Tanged	Not tanged, sealed edges
Mesh Thickness <sup>4</sup>	0.66 mm	0.66 mm	0.66 mm	0.62 mm	0.63 mm	0.63 mm	0.27 mm
Pore Size <sup>4</sup>	1182 um	1182 um	1000 um	1160 um	1379 um	1379 um	374 um
Fiber Size (diameter) <sup>4</sup>	0.15 mm	0.15 mm	0.15 mm	0.13 mm	0.15 mm	0.15 mm	0.08 mm
Weight (g/M <sup>2</sup> ) <sup>4</sup>	100	100	110	81	100	100	70
Mesh length <sup>5</sup>	22 cm	44 cm	50 cm	48 cm	48 cm	12 cm	60 cm
Mesh Color <sup>5</sup>	Blue	White	White	White	Blue	Blue	White
Center Tab <sup>5</sup>	Plastic tab marks center and can be used to aid in intra-operative tensioning	Plastic tab marks center	Blue dot mark center	Peel off sticker marks center	No center tab, split in sleeve marks center	Plastic tab on suture loop marks center	No center tab
Sleeve coverage at suburethral segment <sup>5</sup>	No sleeve coverage	Sleeve coverage	Covered, split in sleeve	Sleeve coverage	Covered, split in sleeve	Split in sleeve at center	No sleeve coverage on the entire sling

<sup>1</sup> Bench test sample size n=4. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.

<sup>2</sup> Bench test sample size n=15. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.

<sup>3</sup> Bench test sample size n=4. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.

<sup>4</sup> Moali, Pamela, et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT™ *Int Urogynecol J* (2008) 19:655–663 DOI 10.1007/s00192-007-0499-1

<sup>5</sup> MUS Sling Comparison Review

## Long Term Efficacy and Safety of the Obtryx® Transobturator Mid-Urethral Sling System for Treatment of Stress Urinary Incontinence in a Community Setting: An Analysis of Outcomes and Quality of Life

PRESENTED AT

### AMERICAN UROGYNECOLOGIC SOCIETY (AUGS)

■ ANNUAL MEETING ■

September 23 - 26, 2009 ■ Hollywood, FL

**Presentation Title:** LONG TERM EFFICACY AND SAFETY OF THE OBTRYX® TRANSOBTURATOR MID-URETHRAL SLING SYSTEM FOR TREATMENT OF STRESS URINARY INCONTINENCE IN A COMMUNITY SETTING: AN ANALYSIS OF OUTCOMES AND QUALITY OF LIFE

**Author Block:** Scott E. Litwiller, Sandra S. Seidel, John T. Whitaker, Curt R. Powell  
Eastern Oklahoma Continence Center, Tulsa, OK

#### Background

The Obturator sling is a first line treatment in the management of genuine stress incontinence (GSI). While most surgeons performing this surgery are in private practice, most series have come from tertiary referral centers and may not reflect the results seen in a community practice setting. This study reports the objective results and quality of life indices of the Obtryx Sling in a private practice setting.

We sought to retrospectively assess the outcomes of patients undergoing the Obtryx Transobturator Mid-Urethral Sling System in a community setting by two busy fellowship trained urologists and wanted to answer:

- How do the outcomes in the private sector compare to “Centers of Excellence”?
- What degree of long term continence can be anticipated with the Obtryx Sling?
- What is the impact on the quality of life of women undergoing treatment using the Obtryx Sling?
- What is the complication rate of this procedure in the private sector?
- Can the addition of an intra-operative cough stress test enhance the outcomes of the procedure?

#### Objective

Over the past 13 years, the polypropylene sling has assumed a dominant role in the management of the female with stress urinary incontinence

For a number of reasons, the Obturator approach to sling placement has been an evolution in this technique that has made the mid-urethral sling a safer and well accepted alternative to retropubic sling placement

- It appears to reduce the risk of bladder or bowel injury
- It appears to be more forgiving in respect to voiding dysfunction
- It can easily be performed as an outpatient procedure under Intravenous sedation.

While most surgeons performing the obturator sling procedure are in private practice, most series have come from “Centers of Excellence” and do not accurately reflect the results seen in a busy community practice.

## Long Term Efficacy and Safety of the Obtryx® Transobturator Mid-Urethral Sling System for Treatment of Stress Urinary Incontinence in a Community Setting: An Analysis of Outcomes and Quality of Life

### Materials & Methods

Over a three year period, 1472 patients underwent placement of an Obtryx Transobturator Mid-Urethral Sling System by two fellowship trained private practitioners.

Of those patients, 271 underwent Obtryx Sling placement alone or in conjunction with hysterectomy for reasons other than prolapse.

In this retrospective study, inclusion criteria were stress urinary incontinence, no concomitant prolapse, age over 18, and placement of sling alone. Exclusion criteria were urge incontinence alone, detrusor hypo-contractibility, and inability to assume lithotomy position. All patients reported GSI, but patients with mixed incontinence (55.9%) were not excluded when their primary complaint was GSI.

All patients underwent pre-op physical exam and multi-channel urodynamics. Pre-op physical exam included supine and standing assessment of pelvic organ prolapse, assessment of the ability to assume the exaggerated lithotomy position, and Q-tip assessment of urethral hypermobility. Multi-channel urodynamics included filling cystometry, measurement of valsalva leak-point pressure, pressure flow measurement of voiding function, measurement of post-void residual (sonographic) and EMG assessment of voiding function.

Chart review was used to evaluate surgical details, post-operative exam parameters and pad use. Blinded validated quality of life questionnaires (UDI-6, IIQ-7, and VAS Quality of life) were used to assess subjective outcomes.

### PROCEDURAL TECHNIQUE:

- IV Sedation / General Anesthesia
- Antibiotic prophylaxis: 1st generation cephalosporin
- 0.25% Marcaine w/epinephrine infiltrated
- Cough stress conducted at maximum cystometric capacity
- Patient given 5mg Furosemide to facilitate voiding trials
- Patient released to home after voiding

### Results

271 patients were included in the retrospective evaluation, with a median of 18.1 months follow-up. 83 patients had less than 6 months follow-up, and were not included in the data reviewed. The remaining 188 patients were included in the pre-op and post-op evaluation. The median age of the patients was 57.3 (28-87.9).

Preoperatively, patients reported a median of 5 leakage episodes per day, with 86% wearing a median of 3 saturated pads per day. 55.9% reported urge incontinence. Preoperative UDI-6, IIQ-7 and QOL scores were 7, 9 and 8 respectively. Median pre-operative PVR was 37mL (0 – 147).

Pre-Op Parameters (N=188)	
Median Age	57.3 (28-87.9)
Urethral Hypermobility Present	151 (80.3%)
Stress Incontinence Alone	83 (44.1%)
Mixed Incontinence	105 (55.9%)
Leakage Episodes Per Day	5 (median)
Preoperative Daily Pad Use	Avg=3, 86% of patients
Preoperative UDI-6 (median)	7
Preoperative IIQ-7 (median)	9
Preoperative VAS-QOL (Median)	8
Preoperative PVR (median)	37 mL (0-147)

## Long Term Efficacy and Safety of the Obtryx® Transobturator Mid-Urethral Sling System for Treatment of Stress Urinary Incontinence in a Community Setting: An Analysis of Outcomes and Quality of Life (cont.)

### Results

The majority of patients (89.4%) underwent sling with IV sedation using a cough stress test to adjust sling tension. Median length of surgery was 20 minutes (18 – 35) with 10.6% of patients undergoing concomitant hysterectomy under general anesthesia. Median blood loss was 30mL (0 – 100).

At a median of 18.1 months post-op, 98% of patients are cured of stress incontinence and 93% never wear pads. Urge incontinence resolved in 51% of patients (N=105) with 2% of patients (N=188) reporting urgency post op. Of those reporting post op urgency, 17% are taking antimuscarinic medications. Median postoperative UDI-6, IIQ-7 and QOL parameters were 3, 0 and 1 respectively (P<0.005). Postoperative PVR was a median of 10mL.

There were no complications involving bladder or urethral perforation and no thigh or groin pain. Two patients suffered a vaginal sling exposure. One resolved with topical estrogen therapy, and the other required intra-operative excision and remains continent. One patient experienced vaginal pain due to bridging of the sling across the vaginal fornix. This was excised in the OR and the pain resolved and the patient remains continent. One patient required post-op sling lysis for voiding dysfunction. She remains continent. There was no post-op retention.

Intra-Op Parameters N=188	
Patients Undergoing Concomitant Hyst.	10.6% (20)
Procedure Under IV Sedation	89.4% (168)
Median Length of Surgery	20 minutes (18-35)
Estimated Blood Loss	30 cc (0-100)
Home Same Day without Catheter	95.7% (180)

Post-Op Parameters (N=188)	
Median Follow-Up	18.1 months
Cured of Stress Incontinence	184 (98%)
Resolution of Urge Incontinence	54/105 (51%)
Post-op De-Novo Urgency	4/188 (2%)
Percent no Longer Wearing Pads	175 (93%)
Post-operative UDI-6 (median)	3
Post-operative IIQ-7 (median)	0
Post-operative VAS -QOL (Median)	1
Post-operative PVR (median)	10 mL

Complication		Comments
Bladder or Urethral Perforation	0	
Bleeding >250cc	0	
Adductor or Thigh Pain	0	
Wound Infection	0	
Retention >24 hrs	0	
Sling Exposure	2	1 treated with topical estrogen RX, 1 required operative excision, still continent
Vaginal Pain	1	Bridging of the sling across the vaginal fornix, excised in OR, pain resolved, still continent
Sling Lysis for Voiding Dysfunction	1	Patient perceived objectionable slow stream, incised and still continent
Total	4 / 271 (1.5%)	

Obtryx and Obtryx II both use Advantage® Mesh. Obtryx II uses Advantage Mesh in blue.

## Conclusions

- The Obtryx® Obturator Sling represents a safe and effective long term treatment option for the patient with stress urinary incontinence or mixed incontinence with a predominantly stress component
- For this quality of life disease, the Obtryx Sling affords a definite improvement in all quality of life indices as measured by validated questionnaires
- The results achieved in this private practice setting favorably compares to those in currently reported series from tertiary “Centers of Excellence”
- Limitations of this study are certainly found in its retrospective nature, and in the tendency for private based patients to avoid long term follow up when either doing exceedingly well or exceedingly poorly

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

**Caution:** Federal Law (USA) restricts these devices 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 Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

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Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537  
[www.bostonscientific.com/gynecology](http://www.bostonscientific.com/gynecology)

**Ordering Information**  
1.888.272.1001

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# Reimbursement Guide

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Obtryx<sup>®</sup> II Transobturator Sling System  
with PrecisionBlue<sup>™</sup> Design

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# Reimbursement for Obtryx® II Transobturator Sling System with PrecisionBlue™ Design

## Is this product reimbursable by insurance?

The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare reimbursement for sling operation for stress incontinence procedures are available online at [www.bostonscientific.com/reimbursement](http://www.bostonscientific.com/reimbursement). For additional coding and reimbursement information, contact your local Territory Manager or the Women's Health Reimbursement Help Desk at [UroWH.reimb@bsci.com](mailto:UroWH.reimb@bsci.com) or 1-508-683-4022.

## What is the Medicare Pass-Through Code (aka C-code or HCPCS)?

The Medicare Pass-Through Code for this product is C1771 (*repair device, urinary, incontinence, with sling graft*).

## Is this a patient-chargeable product?

Yes. The appropriate Revenue Code for Obtryx II Sling System with PrecisionBlue is 278 - Medical/Surgical Supplies and Devices-Other Implants. Medicare does not dictate a provider's charge structure or how it itemizes those charges. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g. operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic charge. Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific supply. However, Medicare does require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

## Relevant Reimbursement Codes:

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

## Reimbursement



### Relevant Reimbursement Codes:

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Procedure Name	APC Code	CPT® Code	ICD-9-CM Procedure Code	ICD-9-CM Diagnosis Code	Possible MS-DRG Assignment <sup>1</sup>
Sling Procedure	0202	57288 – Sling operation for stress incontinence (eg, fascia or synthetic)	59.4 – Suprapubic sling operation 59.71 – Levator muscle operation for urethrovesical suspension 59.79 – Other repair of stress incontinence	625.6 – Stress incontinence, female 599.82 – Intrinsic (urethral) sphincter deficiency (ISD) 599.81 – Urethral hypermobility	748 – Uterine and Adnexa Procedures for Nonmalignancy with CC/MCC1 662 – Minor bladder procedures with major complication or comorbidity (MCC) 663 – Minor bladder procedures with complication or comorbidity (CC) 664 – Minor bladder procedures without MCC/CC

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For additional coding and reimbursement questions please contact our Women’s Health Reimbursement Help Desk at [UroWH.reimb@bsci.com](mailto:UroWH.reimb@bsci.com) OR 1-508- 683-4022.



# Ordering Information

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## Ordering Information

Obtryx® II  
Transobturator Sling System  
with PrecisionBlue™ Design

### New Product Codes

Product Code	Product Name
M0068504110	Obtryx® II Transobturator Sling System - Curved, Single Unit
M0068504111	Obtryx II Transobturator Sling System - Curved, 5 Pack
M0068505110	Obtryx II Transobturator Sling System - Halo, Single Unit
M0068505111	Obtryx II Transobturator Sling System - Halo, 5 Pack





<sup>†</sup>The patient's medical record must support the existence and treatment of the complication or comorbidity.  
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All other trademarks are property of their respective owners.

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Data on file. Bench test results may not necessarily be indicative of clinical performance. Results from case studies are not predictive of results in other cases. Results in other cases may vary.



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[www.pelvic-floor-institute.com](http://www.pelvic-floor-institute.com)

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

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