Obtryx™ II
Transobturator Mid-Urethral Sling System

Product Overview
Regulatory Information
Directions for Use
Obtryx II Transobturator Sling System with PrecisionBlue™ Design

The 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 to aid in precise sling placement.

Smooth Sling Placement
The 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; and the dilator legs allow untwisting of the sling when necessary.

Intra-operative Adjustability with Minimal Tissue Disruption
The 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. The Obtryx II Sling System has blue mesh and dilator legs that can be seen during placement and cystoscopy to help 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, which 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 device passage through the obturator foramen
- Two needle configurations allow physicians to choose the needle that meets their preference

**Association Loop**
- Designed to facilitate needle engagement and removal

**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

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

**CURVED NEEDLE**
A Comparative Transobturator Sling Matrix

The 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.

<table>
<thead>
<tr>
<th>Transobturator Device</th>
<th>Sling Delivery Force</th>
<th>Mesh Holding Force</th>
<th>Sleeve Removal Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston Scientific Obtryx™ II Sling System</td>
<td>1.60 lbs¹</td>
<td>2.69 lbs²</td>
<td>0.50 lbs¹</td>
</tr>
<tr>
<td>Boston Scientific Obtryx Sling System</td>
<td>3.45 lbs¹</td>
<td>2.67 lbs¹</td>
<td>2.98 lbs³</td>
</tr>
<tr>
<td>AMS MonArc™ Sling System</td>
<td>3.51 lbs¹</td>
<td>2.83 lbs¹</td>
<td>5.63 lbs³</td>
</tr>
<tr>
<td>Bard Align™ TO Sling</td>
<td>5.28 lbs¹</td>
<td>2.79 lbs¹</td>
<td>5.54 lbs¹</td>
</tr>
<tr>
<td>Gynecare TVT-O</td>
<td>4.23 lbs¹</td>
<td>2.59 lbs¹</td>
<td>2.18 lbs³</td>
</tr>
<tr>
<td>Gynecare TVT-Abbrevo™ System</td>
<td>5.15 lbs³</td>
<td>2.19 lbs³</td>
<td>3.76 lbs³</td>
</tr>
<tr>
<td>Coloplast Aris™ Sling</td>
<td>0.78 lbs¹</td>
<td>0.52 lbs¹</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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-O
- 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 and Bard Align TO Sling
- 77% less than TVT-O
- 87% less than TVT-Abbrevo System

For all comparisons: Data on file with Boston Scientific

¹ 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.
² Bench test sample size n=16. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.
³ 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.
## Characteristics of Transobturator Slings Systems

<table>
<thead>
<tr>
<th>Transobturator Device</th>
<th>Boston Scientific Obtryx™ II Sling System</th>
<th>Boston Scientific Obtryx Sling System</th>
<th>AMS MonArc™ Sling</th>
<th>Bard Align™ TO Sling</th>
<th>Gynecare TVT-O Sling</th>
<th>Gynecare TVT Ablbrevo™ Sling</th>
<th>Coloplast Aris™ Sling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trocar Design</strong>³</td>
<td>Two options - Halo and Curved</td>
<td>Two options - Halo and Curved</td>
<td>Three options - MonArc+, MonArc C, Standard MonArc</td>
<td>Two options - Halo and Hook</td>
<td>Helical passers with Winged Guided Insertion Zone tool</td>
<td>Helical passers with Winged Guided Insertion Zone tool</td>
<td>Two options - Flat curved and helical introducers</td>
</tr>
<tr>
<td><strong>Approach</strong>⁴</td>
<td>Outside In</td>
<td>Outside In</td>
<td>Outside In</td>
<td>Inside Out</td>
<td>Inside Out</td>
<td>Outside In</td>
<td></td>
</tr>
<tr>
<td><strong>Mesh edges/Features</strong>⁴</td>
<td>Tanged/De-tanged (heat sealed mid-section)</td>
<td>Tanged/De-tanged (heat sealed mid-section)</td>
<td>Tanged/Tensioning Suture</td>
<td>Tanged</td>
<td>Tanged</td>
<td>Tanged</td>
<td>Not tanged, sealed edges</td>
</tr>
<tr>
<td><strong>Mesh Thickness</strong>⁴</td>
<td>0.66 mm</td>
<td>0.66 mm</td>
<td>0.66 mm</td>
<td>0.62 mm</td>
<td>0.63 mm</td>
<td>0.63 mm</td>
<td>0.27 mm</td>
</tr>
<tr>
<td><strong>Pore Size</strong>⁴</td>
<td>1182 um</td>
<td>1182 um</td>
<td>1000 um</td>
<td>1160 um</td>
<td>1379 um</td>
<td>1379 um</td>
<td>374 um</td>
</tr>
<tr>
<td>**Fiber Size (diameter)**⁴</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.13 mm</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.08 mm</td>
</tr>
<tr>
<td>**Weight (g/M²)**⁴</td>
<td>100</td>
<td>100</td>
<td>110</td>
<td>81</td>
<td>100</td>
<td>100</td>
<td>70</td>
</tr>
<tr>
<td><strong>Mesh Color</strong>⁵</td>
<td>Blue</td>
<td>White</td>
<td>White</td>
<td>White</td>
<td>Blue</td>
<td>Blue</td>
<td>White</td>
</tr>
<tr>
<td><strong>Center Tab</strong>⁵</td>
<td>Plastic tab marks center and can be used to aid in intra-operative tensioning</td>
<td>Plastic tab marks center</td>
<td>Blue dot mark center</td>
<td>Peel off sticker marks center</td>
<td>No center tab, split in sleeve marks center</td>
<td>Plastic tab on suture loop marks center</td>
<td>No center tab</td>
</tr>
<tr>
<td><strong>Sleeve coverage at suburethral segment</strong>⁵</td>
<td>No sleeve coverage</td>
<td>Sleeve coverage</td>
<td>Covered, split in sleeve</td>
<td>Sleeve coverage</td>
<td>Covered, split in sleeve</td>
<td>Split in sleeve at center</td>
<td>No sleeve coverage on the entire sling</td>
</tr>
</tbody>
</table>

---


⁵ MUS Sling Comparision Review
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.

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

closure
FDA 510K Clearance Letter

OCT. 10, 2012  2:27PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Ms. Janet A. McGraith
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

Oct 10 2012

Dear Ms. McGraith:

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/115809.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/115809.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](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 its Internet address [http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm](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

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 CDRII, Office of Device Evaluation (ODE)

Traditional 510(k)
Obtryx II System
Directions for Use - Curved Needle

Obtryx™ II Transobturator Sling System with PrecisionBlue™ Design

TABLE OF CONTENTS
WARNING ..............................................................................................................3
DEVICE DESCRIPTION .........................................................................................3
INDICATIONS FOR USE ........................................................................................3
CONTRAINDICATIONS .........................................................................................3
HOW SUPPLIED ....................................................................................................3
DIRECTIONS FOR USE ..........................................................................................4
TENSION MESH/SLEEVE REMOVAL .................................................................5
GENERAL WARNING ..........................................................................................5
POST PROCEDURAL WARNING ........................................................................5
ADVERSE EVENTS ................................................................................................6
PRECAUTIONS .....................................................................................................6
WARRANTY ...........................................................................................................7

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
Obtryx™ II System

Transobturator Sling System with PrecisionBlue™ Design

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.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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.

For current version refer to the DFU packaged with the product.

Prevent infections that would compromise healing.

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 bony tissues for placement through the obturator foramen.

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.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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.

The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

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

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.

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 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. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic rami at the 45° angle off the midline creating a pathway for delivery device placement.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic rami at the junction where the inferior pubic rami 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 fingertips on the distal end of the needle. Guide the distal end of the needle around the inferior pubic rami through the vaginal incision, maintaining contact with the finger.

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

Obtryx™ II System

Transobturator Sling System with PrecisionBlue™ Design

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.
DFU: Obtryx™ II Transobturator Mid-Urethral Sling System

Directions for Use: Curved Needle (cont.)

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).

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).

The occurrences of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

PRECAUTIONS

• The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, uterus, and bowel. Treatment of the erosion may require surgical removal.

• As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.

• Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.

• Bleeding can occur. Check carefully before releasing patient from the hospital.

• 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.

• Physician should determine when it is suitable for each patient to return to normal activities.

• Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.

• Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.

• The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

ADVERSE EVENTS

The following adverse events 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 response may occur.

• Tissue responses to the mesh implant could include:
  • erosion/exposure/ extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  • scarring/scar contracture
  • device migration
  • fistula formation and inflammation

The occurrences of these events may require surgical intervention and possible 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.

• Allergic reaction has been reported.

• Known risks of surgical procedures for the treatment of incontinence include:
  • pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  • infection
  • detrusor instability
  • complete failure of the procedure
  • voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  • bruising, bleeding (vaginal, hematoma formation)
  • abscess
  • vaginal discharge
  • dehiscence of vaginal incision
  • edema and erythema at the wound site
  • perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The effects of this procedure and the patients may again become incontinent.
• 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.
Directions for Use: Curved Needle (cont.)

Sterilized using ethylene oxide.

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

Argentina Local Contact
Contacto local en Argentina
Lokaler Kontakt Argentinien
Contacto local por l’Argentina
Contacto local na Argentina

Brazil Local Contact
Contacto local en Brasil
Lokaler Kontakt Brasilien
Contacto local no Brasil

EC REP EU Authorized Representative
Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

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

ARG Argentina Local Contact
Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

BRA Brazil Local Contact
Para informações de contato da Boston Scientific do Brasil Ltda, por favor, acesse o link www.bostonscientific.com/bra

Legal Manufacturer
Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.
Recyclable Package

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
Directions for Use: Halo Needle

**Obtryx II System**

**HALO**

Transobturator Sling System with PrecisionBlue™ Design

**TABLE OF CONTENTS**

- WARNING ................................................. 3
- DEVICE DESCRIPTION ............................. 3
- INDICATIONS FOR USE ............................ 3
- CONTRAINDICATIONS .............................. 3
- HOW SUPPLIED ......................................... 3
  - Handling and Storage ............................ 4
- DIRECTIONS FOR USE ............................. 4
  - Prior to Use ......................................... 4
- WARNING ................................................. 4
- TENSION MESH/SLEEVE REMOVAL .......... 5
- GENERAL WARNING ............................... 5
- POST PROCEDURAL WARNING ................. 6
- ADVERSE EVENTS ...................................... 6
- PRECAUTIONS ......................................... 6
- WARRANTY .............................................. 7

Dual manufactured product; no change in content as of January 11, 2017.

For current version refer to the DFU packaged with the product.
Directions for Use: Halo Needle (cont.)

**Obtryx™ II System**

**Transobturator Sling System with PrecisionBlue™ Design**

**Warning**

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 re-use, reprocess or re-sterilize. Re-use, reprocessing or re-sterilization 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. Re-use, reprocessing or re-sterilization 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 urethral 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.

**Steps to Use**

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
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.
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.
7. Ensure 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.

**Warning**

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

**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.

**Figure 2**
3. Once proper tension is achieved, cut the leader loop that is on the appropriate side of the center tab to release the tab from the mesh. Remove the association loop leaving the mesh in place. Repeat on the other side. (See Figure 4.

4. 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 subcutaneously, facing outward.

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

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.

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:

• Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with anticoagulants or antiplatelet agents.
• Patients with hypertonic bladders or vesicoureteral reflux.
• 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 a suburethral sling implantation procedure.
• User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
• Good surgical practices should be followed for management of contamination or infected wounds.
• Mesh is considered a permanent implant. Removal of mesh or correction of mesh-related complications may involve multiple surgeries.

• Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

POST PROCEDURAL WARNING
• If subsequent infection occurs, follow appropriate medical intervention practices.
• The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

ADVERSE EVENTS
The following adverse events 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 response may occur.
• Tissue responses to the mesh implant could include:
  • erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  • scarring/scar contracture
  • device migration
  • fistula formation and inflammation
• The occurrence of these events may require surgical intervention and possible 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.
• Allergic reaction has been reported.

Known risks of surgical procedures for the treatment of incontinence include:

• pain, ongoing pain (pelvic, vaginal, groin/high, dyspareunia)
• infection
• detrusor instability
• complete failure of the procedure
• voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
• bruising, bleeding (vaginal, hematoma formation)
• abscess
• vaginal discharge
• dehiscence of vaginal incision
• edema and erythema at the wound site
• perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

PRECAUTIONS
• The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, uterus, and bowel. Treatment of the erosion may require surgical removal.
• As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, steroid usage, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), chronic bladder, etc., or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
• Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
• Bleeding can occur. Check carefully before releasing patient from the hospital.
• 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.

Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Directions for Use: Halo Needle (cont.)

- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- 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. 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.

Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Obtryx™ II Transobturator Mid-Urethral Sling System

Notes
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.

All images are owned by Boston Scientific.

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 these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

For more information:
www.pelvic-floor-institute.com