Obtryx™ II
Transobturator Mid-Urethral Sling System

Featuring PrecisionBlue™ Design
Commitment to Clinical Data

Boston Scientific is committed to providing clinical data across its Advantage Mesh mid-urethral sling products.

**PrecisionBlue Design** is a set of 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.

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### Advantage™ Mesh Characteristics

- Mesh thickness: 0.66 mm
- Pore size: 1182 μm
- Fiber size (diameter): 0.15 mm
- Weight (g/m²): 100

The Obtryx II System designed with blue Advantage Mesh

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### Commitment to Clinical Data

Boston Scientific is committed to providing clinical data across its Advantage Mesh mid-urethral sling products.

#### Prospective Study - Randomized Controlled Trial

12 month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Obtryx Halo System</th>
<th>Advantage™ System</th>
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</thead>
<tbody>
<tr>
<td>Objective Cure*</td>
<td>81% (68/84)</td>
<td>77% (67/87)</td>
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<tr>
<td>(p=0.577)</td>
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<tr>
<td>Subjective Cure</td>
<td>98.8% (85/86)</td>
<td>92.6% (88/95)</td>
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<td>(p=0.213)</td>
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* Cure defined as less than 1 gram urine leak in standardized pad test.

#### Retrospective Study - Chart Review

18.1 month median follow-up

<table>
<thead>
<tr>
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<th>Obtryx Halo System</th>
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<tbody>
<tr>
<td>Objective Cure</td>
<td>98% (184/188)</td>
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<tr>
<td>(P&lt;0.005)</td>
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<tr>
<td>No longer wearing pads</td>
<td>93% (175/188)</td>
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<tr>
<td>(P&lt;0.005)</td>
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</table>
Blue mesh and dilator legs for better physician visualization, as compared to white or clear colored slings

**Needle Design**
- Needle tip length is designed to facilitate transobturator device passage
- Two needle configurations allow physicians to choose the needle that meets their preference

**Association Loop**
- Designed to facilitate easy 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**

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**The Blue Advantage™ Mesh is a Polypropylene Material**
Polypropylene has been proven over the years to be biocompatible in many medical applications. The blue Advantage Mesh has a suburethral segment that is de-tanged. This unique heat sealed edge is smoother allowing for these potential benefits:

- Reduced risk that the mesh will experience deformation during tensioning. The suburethral mesh segment is designed to maintain its integrity.
- The de-tangled mesh is designed to potentially reduce irritation to the urethral wall.

**Advantage Mesh**
Over 750,000 implanted to date
Procedural Steps

Obtryx™ II Transobturator Mid-Urethral Sling System with PrecisionBlue™ Design

1. **Patient Preparation**
   - Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
   - 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 ramus at the 45 degree angle off the midline creating a pathway for delivery device placement.
   - 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 rami and adductor longus muscle meet. Repeat on the contralateral side.

2. **Curved Needle - Insertion**
   - Grasp the device handle and insert one needle through one skin incision, piercing through the obturator muscle and obturator membrane.
   - Turn the handle at a 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 ramus through the vaginal incision, maintaining contact with the finger.

3. **Loop Engagement**
   - Engage one association loop to the distal end of the needle.

4. **Needle Removal**
   - Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra with the blue centering tab positioned suburethrally, facing outward.
   - Remove the association loop from the needle.
   - Repeat Step 2 through Step 4.

5. **Mesh Adjustment**
   - The mesh/sleeve assembly is not twisted and lies flat under the urethra with the blue centering tab positioned suburethrally, facing outward.
   - Appropriately tension the mesh/sleeve assembly according to physician preference.

6. **Sleeve Removal**
   - 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.

7. **Centering Tab 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.

8. **Closing**
   - Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that the ends retract into the skin incisions.
   - Close all incisions according to usual methods.

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### Ordering Information

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<th>Product Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>M0068504110</td>
<td>Obtryx™ II Transobturator Sling System - Curved</td>
<td>Single Unit</td>
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<tr>
<td>M0068504111</td>
<td>Obtryx™ II Transobturator Sling System - Curved</td>
<td>5 Pack</td>
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<tr>
<td>M0068505110</td>
<td>Obtryx™ II Transobturator Sling System - Halo</td>
<td>Single Unit</td>
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<tr>
<td>M0068505111</td>
<td>Obtryx™ II Transobturator Sling System - Halo</td>
<td>5 Pack</td>
</tr>
</tbody>
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By selecting the option 850411 for Obtryx II Transobturator Sling System, you are confirming that you have the legal right to purchase these devices.

**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.

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.