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

**Procedural Steps**

1. **Patient Preparation**
   - Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
   - Incise the anterior vaginal wall and dissect bilaterally to the interior portion of the inferior pubic ramus.
   - Create a vertical skin incision large enough to insert tip of one incision perpendicularly to the anus at the junction where the inferior pubic ramus and adductor longus muscle meet. Repeat on the contralateral side.

2. **Curved Needle - Insertion**
   - Grasp the device handle and insert one needle through one incision, piercing through the obturator muscle.
   - Turn the handle at a 45° angle medial towards the midline. Place the needle tip into the skin incision perpendicular to the anus at the junction where the inferior pubic ramus and adductor longus muscle meet. Repeat on the contralateral side.

3. **Sleeve Removal**
   - Engage one association loop to the distal end of the needle.
   - 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.

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.

5. **Mesh Adjustment**
   - Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that the ends retract into the skin incisions.
   - Appropriate tensioning of the mesh is confirmed at this time, as determined by the physician’s discretion.

6. **Closing**
   - Close all incisions according to usual methods.

7. **Centering Tab Removal**
   - Grasp the device handle and insert one needle through one incision, piercing through the obturator muscle.
   - Turn the handle at a 45° angle medial towards the midline. Place the needle tip into the skin incision perpendicular to the anus at the junction where the inferior pubic ramus and adductor longus muscle meet. Repeat on the contralateral side.

8. **Urethra**
   - 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.

**Ordering Information**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>M006404110</td>
<td>Obtryx™ II Transobturator Sling System - Curved</td>
<td>Single Unit</td>
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<tr>
<td>M006404111</td>
<td>Obtryx™ II Transobturator Sling System - Curved</td>
<td>5-Pack</td>
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<tr>
<td>M006405110</td>
<td>Obtryx™ II Transobturator Sling System - Halo</td>
<td>Single Unit</td>
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<td>Obtryx™ II Transobturator Sling System - Halo</td>
<td>5-Pack</td>
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DHU03 WMEA
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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<tbody>
<tr>
<td>Objective Cure*</td>
<td>81% (68/84)</td>
<td>77% (67/87)</td>
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<tr>
<td>Subjective Cure</td>
<td>98.8% (96/98)</td>
<td>92.6% (98/107)</td>
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</tbody>
</table>

Retrospective Study - Chart Review
18.1 month median follow-up

<table>
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<tbody>
<tr>
<td>Objective Cure</td>
<td>98% (184/188)</td>
<td></td>
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<tr>
<td>No longer wearing pads</td>
<td>P &lt;0.005</td>
<td>93% (175/188)</td>
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</tbody>
</table>

* Cure defined as less than 1 gram urine leak in standardized pad test.

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

Obtryx II designed with blue Advantage Mesh

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.

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 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

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

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-tanged mesh will potentially reduce irritation to the anterior urethral wall.

Advantage Mesh
Over 500,000 implanted to date

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