

Obtryx™ II

Transobturator Mid-Urethral Sling System

Boston
Scientific

Featuring
PrecisionBlue™ Design



Always there.

Dedicated to Women's Health

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

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**.

Advantage™ Mesh Characteristics¹

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

Commitment to Clinical Data

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

Prospective Study - Randomized Controlled Trial² 12 month follow-up

	Obtryx Halo System	Advantage™ System
Objective Cure* (p=0.577)	81% (68/84)	77% (67/87)
Subjective Cure (p=0.213)	98.8% (85/86)	92.6% (88/95)

Retrospective Study - Chart Review³ 18.1 month median follow-up

Obtryx Halo System	
Objective Cure (P <0.005)	98% (184/188)
No longer wearing pads (P <0.005)	93% (175/188)

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

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

CURVED NEEDLE

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

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

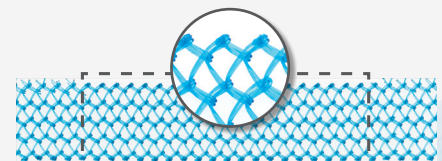
Centering Tab

- 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 is designed to potentially reduce irritation to the urethral wall.



Suburethral portion which sits under the urethra has de-tanged edges.

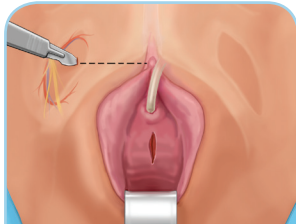
Advantage Mesh

Over 750,000 implanted to date

Procedural Steps

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

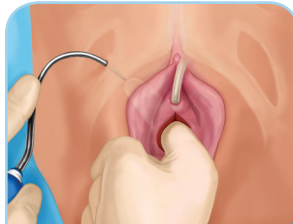
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Patient Preparation

- 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 inferior 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 ramus and adductor longus muscle meet. Repeat on the contralateral side.

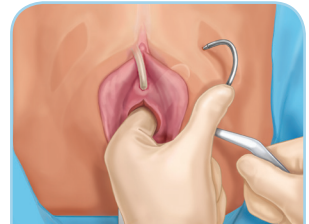
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Curved Needle - Insertion

- 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 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.

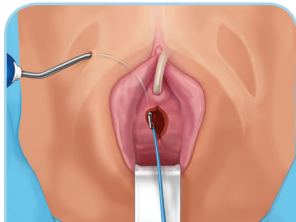
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Halo Needle - Insertion

- 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 to the thigh.
- Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
- Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

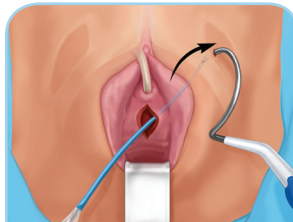
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Loop Engagement

- Engage one association loop to the distal end of the needle.

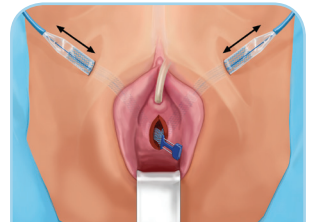
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Needle Removal

- 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.
- Cystoscopy may be performed at this time, to be determined at the physician's discretion.

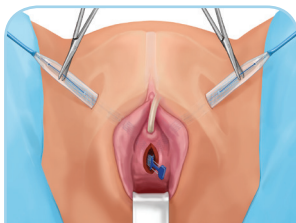
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Mesh Adjustment

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

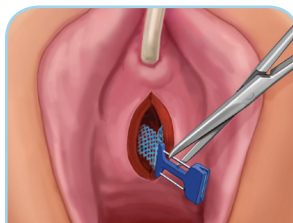
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Sleeve Removal

- 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.

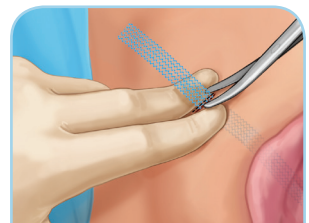
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Centering Tab Removal

- 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.

Ordering Information

Product Code	Description	Quantity
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

¹ 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

² Ross, Sue, Robert, Magali, et al. Transobturator Tape Compared with Tension-Free Vaginal Tape for Stress Incontinence, A Randomized Controlled Trial, *Obstetrics & Gynecology*, 114 (6), Dec 2009, 1287-93.

³ Litwiler S, et al. 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. AUGS 2009, Hollywood, FL

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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.

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