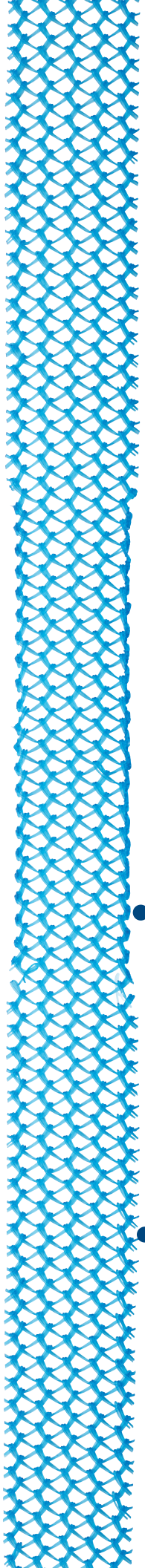
Boston Scientific

Advancing science for life™

Obtryx™ II

Transobturator Mid-urethral Sling System



Obtryx™ II

Transobturator Mid-urethral Sling System

Boston Scientific offers a full portfolio of solutions to treat stress urinary incontinence - giving you the control and confidence to treat patients with your preferred surgical approach.

Obtryx II Transobturator Mid-urethral Sling System features Advantage™ blue mesh, providing improved visibility and used in over 1 Million Advantage products.*

A smooth, de-tanged suburethral portion designed to maintain its integrity during tensioning and potentially reduce irritation to the urethral wall

Tanged edges outside of the suburethral portion designed to prevent mesh migration

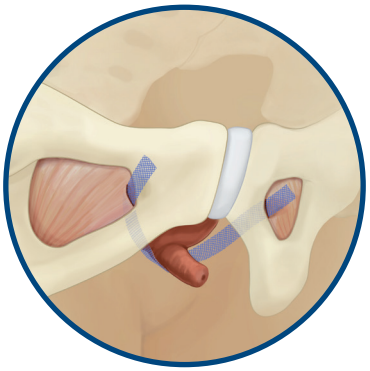
Improved visibility. Evidence based.

- The same mesh properties as our patented Advantage mesh, which is documented in more than 100 publications to date
- The easy-to-see, optical blue color is designed to help improve your visibility for more accurate intra-operative sling tensioning and may make it easier to locate post-operatively**

Trusted polypropylene mesh[1]

- Mesh thickness: 0.66 mm
- Pore size: 1182 µm
- Fiber size (diameter): 0.15 mm
- Weight: 100 g/m^2

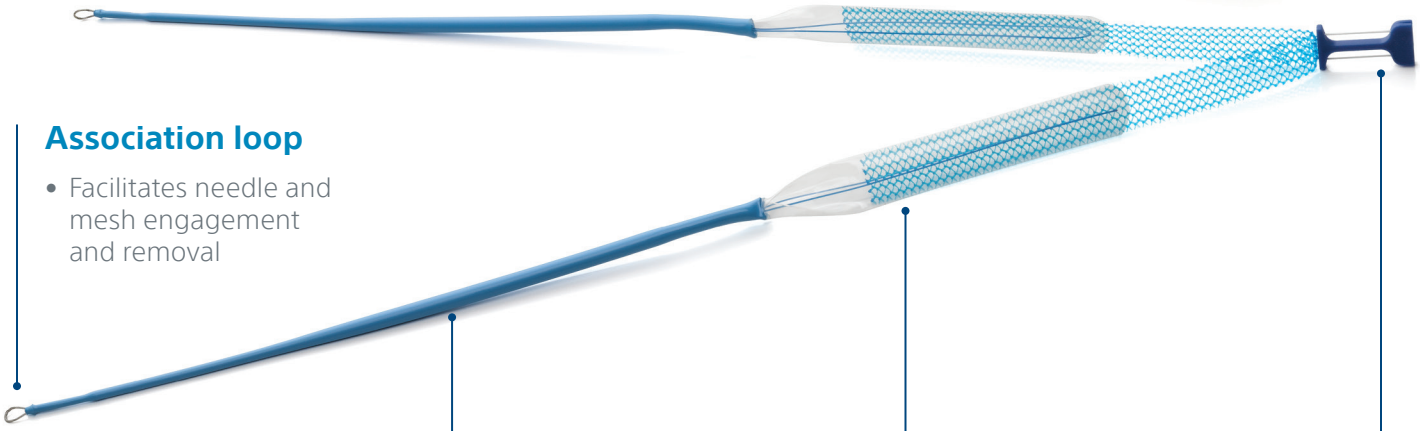
* Data on File at Boston Scientific.
** Based on physician feedback.



Transobturator approach

Needle

- Designed to facilitate transobturator device passage
- Two needle configurations (curved and halo) allow physicians to choose their preferred approach (curved and halo sold separately)



Association loop

- Facilitates needle and mesh engagement and removal

Blue dilator leg

- Designed to create a smooth transition from the needle to the mesh assembly
- Designed to improve intra-operative visibility
- Designed to minimize the force needed to deliver the mesh assembly through the patient's anatomy

Mesh assembly

- No sleeve coverage under the suburethral segment to allow for mesh visibility and to aid in precise placement
- Reduced plastic sleeve is designed to minimize the force needed to remove sleeves

Blue centering tab

Designed for proper alignment of the center of the mesh under the urethra. It also allows the physician to apply counter tension to the sling while preserving the mesh integrity.

Ordering Information

Product code	Description	Quantity
M006**850411**0	**Obtryx™ II Transobturator Sling System – Curved**	2 Delivery Devices and 1 Mesh Assembly
M006**850511**0	**Obtryx™ II Transobturator Sling System – Halo**	2 Delivery Devices and 1 Mesh Assembly

1. Moalli PA, Papas N, Menefee S, et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 May;19(5):655-63.

Caution: For Female Mid-Urethral Slings: Federal (US) law 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.

The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Apareunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), 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 following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. 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.

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 for availability in other markets.

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