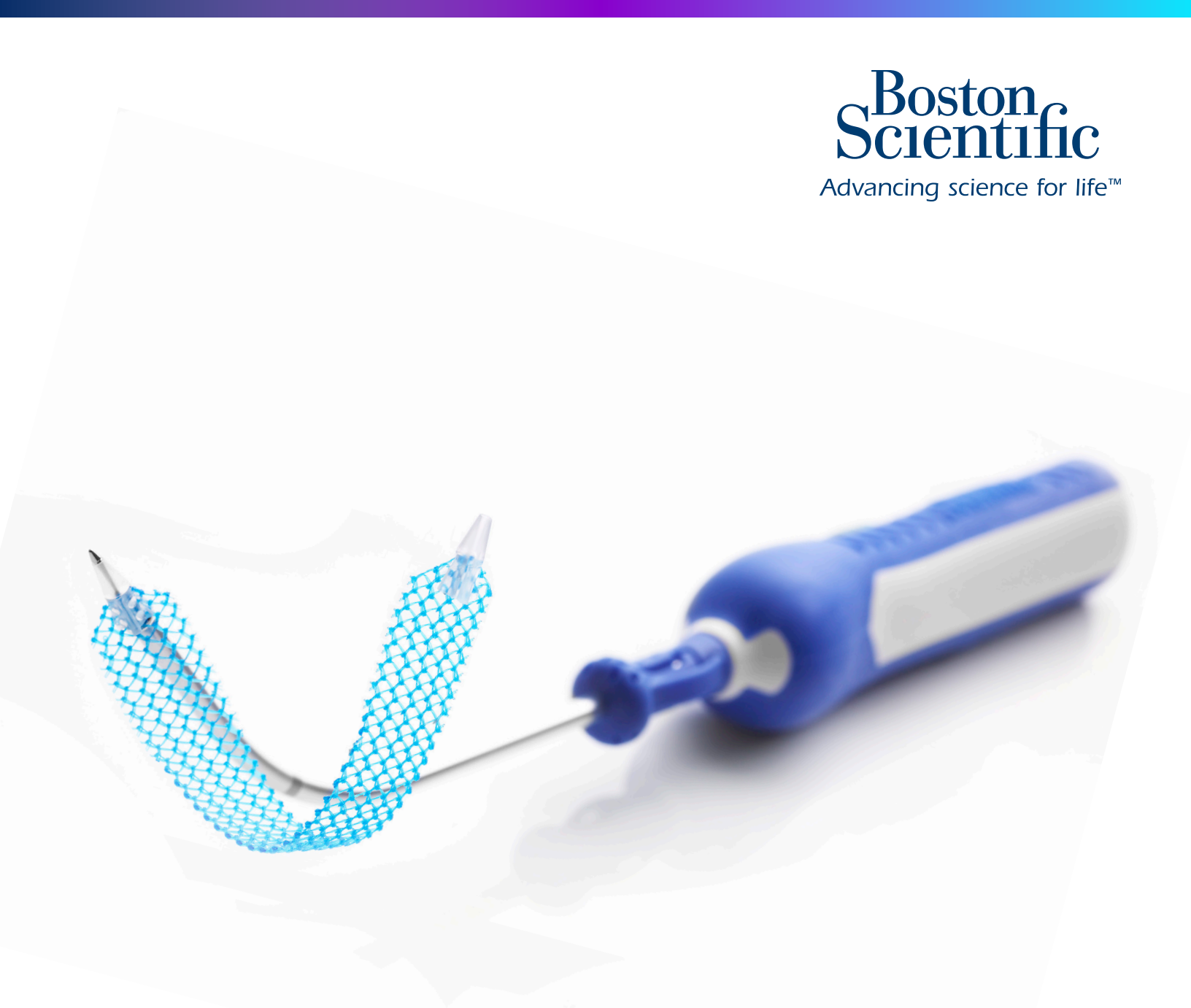
Boston Scientific

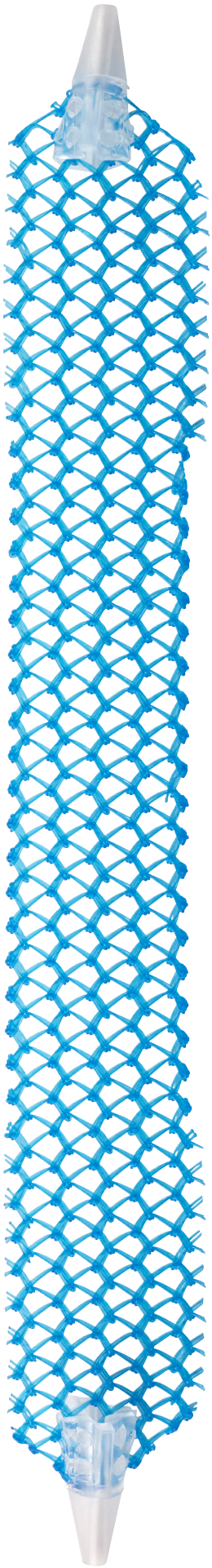
Advancing science for life™



Solyx™

Single Incision Sling System

Solyx Blue Sling System shown



Solyx™

Single Incision Sling System

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

Paired with the clinically supported Advantage™ clear or blue mesh, the Solyx Single Incision Sling System is designed with mesh characteristics, fixation, and adjustability in mind.

Improved visibility. Evidence based.

- The easy-to-see, optical blue color is designed to help improve visibility for more accurate intra-operative sling tensioning and may make it easier to locate postoperatively.
- Advantage mesh is documented in more than 100 publications to date and has been used in over 1 million Advantage products.

Trusted polypropylene mesh[1]

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

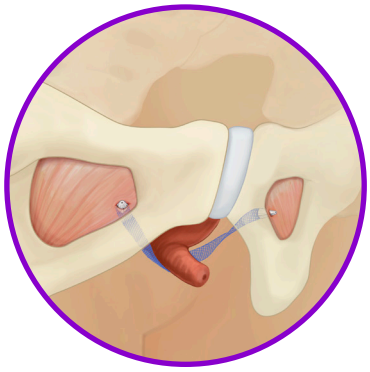
The smooth, de-tanged suburethral portion is designed to maintain its integrity during tensioning and potentially reduce irritation to the urethral wall

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

Solyx is designed for secure fixation while allowing for intra-operative tensioning and adjustments

- Carrier snap-fit on delivery device tip is designed to facilitate control during placement
- Sling is tensioned by delivery device advancement and retraction
- Mesh assembly is designed to be placed away from critical structures, such as the obturator bundle
- Balanced anchors result in pull-out force of 6.43 lbs on each side

Note: Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment



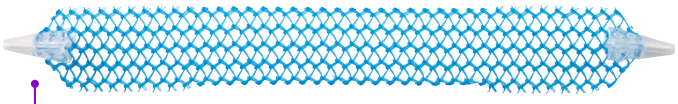
Single incision approach

Mid-line marker

Designed to facilitate guidance for accurate placement

Delivery device

- Designed to seat carrier where placed
- Ergonomic handle with non-skid grip



Mesh carrier

- The barb design is intended to track smoothly through tissue
- Mesh stays connected to trocar until desired tension is achieved

Solyx Blue Sling System shown

Ordering information

Product code	Description	Quantity
M00**6850701**0	**Solyx™ Blue Single Incision Sling System**	1 Delivery Device and 1 Mesh Assembly
M00**6850700**0	**Solyx™ Single Incision Sling System**	1 Delivery Device and 1 Mesh Assembly

1. Moalli PA, Papas N, Menefee S, Albo M, Meyn L, Abramowitch SD. Tensile properties of five commonly used mid-urethral slings relative to the TVT. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:655-663.

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.

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