

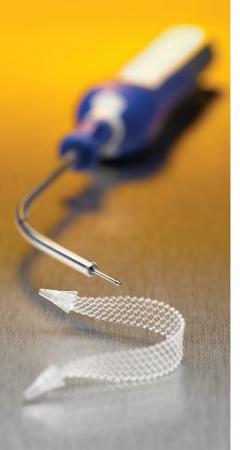
Advanced Control with Micro-Adjustability

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The Solyx[™] SIS System is a single incision sling system designed to be a potentially more efficient option in the treatment of stress urinary incontinence. The Solyx System is an innovative mid-urethral sling system that offers several advancements in delivery and tensioning – all built on the proven Advantage[®] Mesh platform. The result is sling placement progress towards reduced risk and dissection, and a more simplified procedure.

- Mesh assembly is composed of the proven Advantage Mesh polypropylene material
- Mesh is 9cm, as recommended by an anatomist
- Over 300,000 Advantage Mesh implant procedures have been performed to date



Delivery Device

- Designed to seat carrier where placed
- Ergonomic palm placement facilitates shaft angle follow-through

Mesh Carrier

- The barbs are in two stream-lined planes providing an aero-dynamic design intended to track smoothly through tissue
- Snap-fit to delivery device tip helps prevent premature carrier slip-off



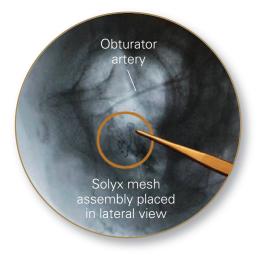
SIS SYSTEM

Mid-line marker facilitates guidance for accurate placement

The Solyx System Carrier Tip allows for

Advanced Control

The Single Incision Sling System designed with Micro-Adjustability



Mesh assembly placement is designed to be away from critical structures, such as the obturator bundle.



Suburethral Portion

Ability to Tighten

- Tensioning by delivery device advancement
- Carrier snap-fit on delivery device tip facilitates placement control

Ability to Loosen

- With carrier snap-fit on the delivery device tip, the delivery device is designed to allow retraction if needed
- Tanged lateral mesh may allow for loosening

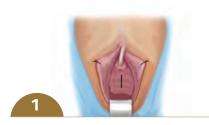
Note: Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment

De-tanged Polypropylene Material

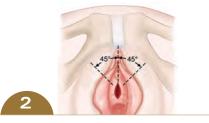
Designed to Reduce Irritation - 4cm mid-urethral portion is de-tanged to potentially reduce irritation to the anterior urethral wall

Resists Deformation - The suburethral portion of the mesh is de-tanged to resist deformation

Solyx[™] SIS System Procedure



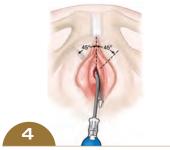
Prepare and drape the patient using standard surgical practice. Ensure the bladder is empty. Incise the anterior vaginal wall at the level of the mid-urethra approximately 1.0 to 1.5cm in length.



Dissect bilaterally to the interior portion of the inferior pubic ramus at a 45° angle off the midline creating a pathway for delivery device placement.



Place the mesh assembly onto the delivery device by placing the delivery device tip into the mesh carrier. NOTE: The mesh carrier should be pushed onto the delivery device tip until it is flush with the end of the delivery device shoulder. While placing the mesh carrier onto the delivery device, make sure that the mesh is oriented so that it lies on the outside curve of the delivery device. The mesh is now ready for placement.



Insert the delivery device into the dissection pathway targeting placement of the carrier at a 45° angle of the midline. Advance the delivery device towards the obturator foramen just lateral to the inferior pubic ramus until the midline mark on the delivery device is approximately at the midline position under the urethra.



Deposit the carrier by gripping the deployment mechanism with one hand and pulling the delivery device handle back with the other hand. This action will deposit the carrier into the surrounding obturator internus muscle tissue releasing it from the delivery device.



Repeat contralaterally. NOTE: Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment. Cystoscopy may be performed at the physician's discretion. Close incision according to usual methods.

Ordering Information

M00 68507 000	Solyx SIS System – (1 Delivery Device and 1 Mesh Assembly)
M00 68507 001	Solyx SIS System – (Box 5)

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician. Refer to package insert provided with these products for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using these products.

Boston Scientific

Delivering what's next.™

Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760-1537

Ordering Information 1.888.272.1001

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