Boston Scientific

Advancing science for life™

Solyx™

Single Incision Sling

YOUR GUIDE TO UNDERSTANDING

Stress Urinary Incontinence

The Solyx™ Single Incision Sling is a small 9 cm piece of polypropylene mesh that is placed under the urethra to provide additional support to reduce or eliminate leakage during physical activity.[1] The Solyx Sling allows for a less invasive procedure with only one small incision, providing support to treat your stess urinary incontinence (SUI).[2]

SUI is the involuntary loss of urine during physical activity such as coughing, laughing or sneezing. In women with SUI, weakened pelvic muscles and tissue have caused the bladder and urethra (the canal that carries urine from the bladder) to relax from their normal positions (see Figure 2). A mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity (see Figure 3).

In consultation with your physician, you will decide whether or not to have a mid-urethral sling procedure with the Solyx Single Incision Sling. Over 18 million women have stress urinary incontinence in the United States.[3] The Solyx Single Incision Sling is only one way to treat stress urinary incontinence. Your physician should provide you with recommended options for treating your incontinence and help you make the right treatment decision.

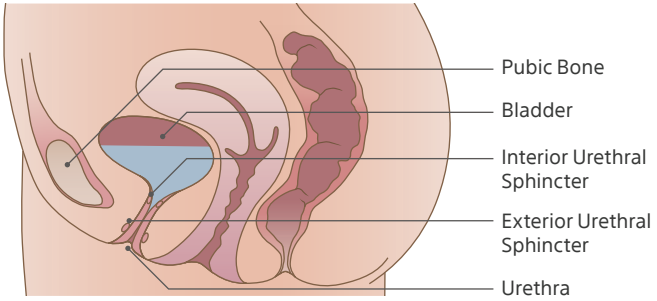


Figure 1 – A woman without stress urinary incontinence
The bladder and urethra must be well supported by the pelvic muscles and tissue in order to prevent involuntary urine loss

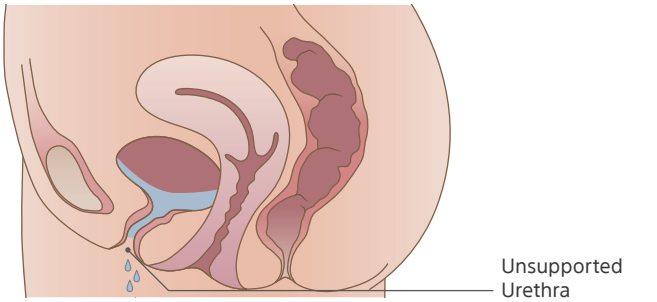


Figure 2 – A woman with stress urinary incontinence
Weakened pelvic floor muscles allow the urethra to drop from its normal position and leak urine when pressure is placed on your bladder

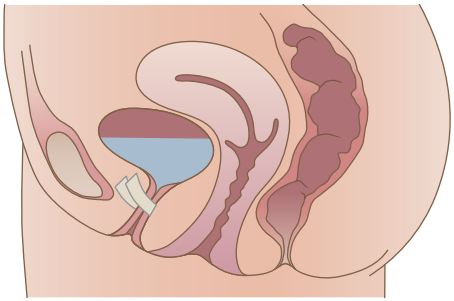
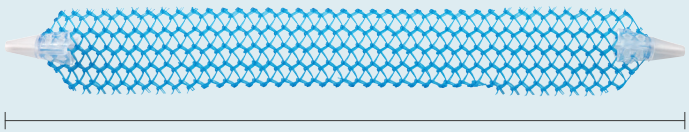


Figure 3 – A woman after a Solyx Sling repair
The Solyx Sling supports the urethra and prevents urine leakage

Benefits of the Solyx Single Incision Sling

Like other mid-urethral slings, the Solyx Single Incision Sling may help you become dry or lessen the amount of urinary leakage. It is a less invasive approach than the retropubic or transobturator approaches and requires only one, small incision instead of three. The Solyx procedure can be performed under local, regional or general anesthesia depending on what you and your physician decide.



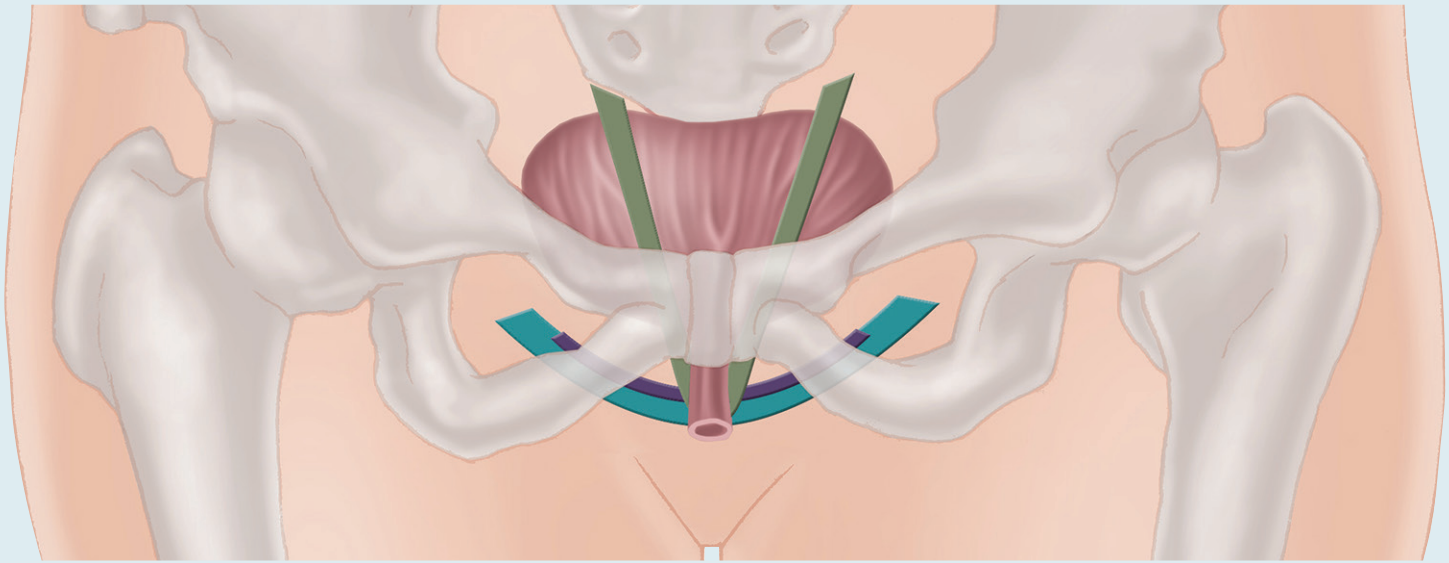
9cm (3.5")
Product shown at actual size

In a post-market study, 98 out of 104 patients (94%) reported improvement at 3 years following treatment with Solyx.[4] The study also showed that Solyx has similar safety and efficacy as a transobturator sling at 3-year follow up.

Treatment Success at 3 Years (n=104)[4]

94.2%
of women reported improvement in SUI

94.2%
of women didn't leak during a cough test



Retropubic Single incision sling Transobturator

Figure 4
The Solyx Sling minimizes the mesh footprint and number of incisions as compared to retropubic and transobturator slings

Frequently asked questions about the Solyx™ Single Incision Sling

What are the types of sling options?

Many surgical options have been developed, including retropubic, transobturator and single incision slings (see glossary), the difference being how the mesh material is placed under the urethra. Your doctor will recommend which anchoring location is right for you. As disease state and anatomy differ for each patient, outcomes may vary.

Are there medications to treat stress urinary incontinence?

No, there are no FDA approved medication alternatives. SUI is an anatomic problem often treated with surgery.

Is it common to perform procedures with mesh?

Polypropylene-based mesh devices have been a mainstay in many medical procedures for over 50 years, including in hernia and tendon repair, sutures, and wound closure. Advantage™ mesh is clinically supported and has been used in more than 1 million slings.[1]

How will my surgery be performed?

Your minimally invasive single incision sling procedure is estimated to only take 30 - 45 minutes. Your doctor will determine the type of anesthesia you will have during the procedure. Once the anesthesia takes effect, your doctor will begin. A small incision will be made in the vaginal area. Next, the synthetic mesh implant is placed to create a “sling” of support under the urethra. When your doctor is satisfied with the position of the mesh, he or she will close the small vaginal incision. The Solyx Sling procedure is usually performed as an outpatient procedure, in which case, most patients return home the same day.

What should I expect after surgery?

Before you are discharged from the hospital, you may be given a prescription for pain medication to relieve any discomfort you may experience. At the discretion of your physician, there may be some physical restrictions, such as heavy lifting and pelvic rest, and most patients resume moderate activities shortly after the procedure. The goal of surgery is to restore your quality of life allowing you to resume life the way you want to live it.

What are the potential complications of surgery?

As with any surgical procedure for the treatment of incontinence, Solyx surgery could also result in potential complications. For a complete list of potential complications, see the end of the brochure and consult your physician about your specific surgery and situation.

When will I stop leaking?

Most women see results right after the procedure. Talk with your physician about what you should expect.

Will a mid-urethral sling cure my incontinence symptoms with 100% certainty?

There is no surgery for incontinence that has a 100% cure rate. In a post-market study, 98 out of 104 patients (94%) reported improvement at 3 years following treatment with Solyx.[4]

Is this procedure covered by insurance?

Most insurance plans cover the surgical treatment of stress urinary incontinence. Check with your insurance company to determine your specific coverage.

Glossary

Hypermobility – A condition associated with stress urinary incontinence in which loss of urethral support and stability impacts ability of the urethra to close during a stress event, such as coughing, laughing or lifting.

Intrinsic Sphincter Deficiency ("ISD") – Refers to the weakening of the urethral sphincter muscles or closing mechanism.

Minimally Invasive Surgery – A procedure that minimizes surgical incisions and reduces trauma to the body.

Pelvic Floor – A group of muscles that form at the base of the pelvis and support pelvic organs.

Retropubic Colposuspension – Procedure used to treat stress incontinence by suspending a sagging bladder neck and urethra to the pubic bone.

Retropubic Sling Placement – Refers to surgical delivery of a traditional mid-urethral sling which includes both transvaginal and abdominal incisions, leaving a graft material suspending the bladder neck and extending behind the pubic bone.

Single Incision (Mini) Sling Placement – Refers to surgical delivery of a mini mid-urethral sling through a single vaginal incision.

Stress Urinary Incontinence – The involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing or lifting.

Traditional Mesh Slings – Refers to a full-length sling that utilizes the ingrowth of surrounding tissue to remain in place and support the urethra to reduce stress urinary incontinence.

Transobturator Sling Placement – Refers to surgical delivery of a traditional mid-urethral sling which includes transvaginal and groin incisions, leaving a graft material suspending the bladder neck and extending through the inner thigh.

Transvaginal Surgery – Surgery that is approached through an incision in the vagina.

Learn more at chooseyou.com

REFERENCES:

1. Data on file at Boston Scientific.
2. Mostafa A, Lim CP, Hopper L, et al. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. *Eur Urol*. 2014 Feb;65(2):402-27.
3. Wu, Hundley, Andrew et al. Forecasting the Prevalence of Pelvic Floor Disorders in U.S. Women 2010 to 2050. *ACOG*, VOL. 114, NO. 6, DECEMBER 2009
4. White, AB, Kahn BS, et al. Prospective study of a single-incision sling versus a transobturator sling in women with stress urinary incontinence: 3-year results, *AJOG*, Oct 2020

Considerations Prior to Surgical Repair: If you are considering surgery for stress urinary incontinence your physician may ask you questions about your medical history, to ensure you are a candidate for this type of procedure. Some of these contraindications, warnings/ potential complications, and adverse events associated with stress urinary incontinence are listed below as a reference to you. You should consult your physician for a complete understanding of this information and to determine whether this procedure is right for you.
Intended Use / Indications for Use: The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The Solyx SIS Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Solyx SIS surgical mesh during urogynaecological procedures.
Contraindications: A mesh implant is contraindicated in the following patients: Pregnant patients, patients with the potential for future growth or patients who are considering future pregnancies; Any patients with soft tissue pathology into which the implant is to be placed; Patients with any pathology that would compromise implant placement; Patients with any pathology, such as blood supply limitations or infections that would compromise healing.
Adverse Events: The following adverse events and known risks have been reported due to suburethral (beneath the urethra) mesh sling placement, any of which may be ongoing, but are not limited to: Abscess (swollen area within the body tissue, containing a buildup of pus), Allergic reaction to the implant, Apareunia (inability to perform sexual intercourse), Bleeding from the vagina, Hematoma formation (bruising), Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Dehiscence of vaginal incision (opening of the incision after surgery), De novo detrusor instability (involuntary contraction of the bladder wall leading to an urge to urinate), Dyspareunia (pain during sexual intercourse), Edema and erythema at the surgical site (swelling and redness), Fistula formation (a hole/passage that develops through the wall of the organs) that may be acute or chronic, Foreign body reaction (body's response to the implant) that may be acute or chronic, Infection, Inflammation that may be acute or chronic (redness, heat, pain or swelling at the surgical site as a result of the surgery), Irritation (redness or pain) at surgical site, Leg weakness (muscle weakness), Mesh contracture (mesh shrinkage), Erosion into the following organs: urethra, bladder, or other surrounding tissues and exposure/extrusion into the vagina (when the mesh goes through the vagina into other organs or surrounding tissue), Pain or discomfort to the patient's partner during intercourse, Pain/Ongoing Pain/Severe/Chronic Pain in the pelvis, vagina, groin/thigh, and suprapubic area that may be acute or chronic (pain or ongoing pain just above the pubic bone, pelvis, vagina, groin/thigh area that may be severe and could last for a long time), Pain with intercourse that may not resolve, Perforation or laceration of vessels, nerves, bladder, urethra or bowel (a hole in or damage to these or other tissues that may happen during placement), Scarring, scar contracture (tightening of the scar), Stone formation (as a result of mesh erosion/exposure/extrusion in the urethra or bladder where the mesh is exposed to urine, mineral deposits may form along the mesh, also known as stones), Tissue contracture (tightening of the tissue), Voiding dysfunction: incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention (involuntary leakage of urine or reduced or complete inability to empty the bladder from the mesh being implanted too tightly beneath the urethra). The following additional adverse events have been reported for the Solyx SIS System: Dysuria (painful/difficult urination), Hematuria (blood in the urine).
The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may be permanent after surgery or other treatments. 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.
General Warning: Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure; Mesh is considered a permanent implant. 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.
Post Procedure Warning: If subsequent infection occurs, follow appropriate medical intervention practices; Patients should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.
Precautions: The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal; As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g.diabetes, steroid usage, etc.), or active infection in or near the surgical site. These pathophysiologic processes should be understood and should not be ignored when considering if the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route; Patients should be counseled when to resume both normal and/ or vigorous activities (heavy lifting, exercise), and intercourse following the procedure; Consult with your physician immediately if you experience painful urination, bleeding, or any other problems following surgery. Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician trained in use of surgical mesh 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 labelling 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.
All images are the property of Boston Scientific. All trademarks are the property of their respective owners. Individuals depicted are models and included for illustrative purposes only. For Customer Service please call: 1.888.272.1001

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

WH-632004-AC JUL2021

Boston Scientific
Advancing science for life™