

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. The Solyx Sling allows for a less invasive procedure with only one small incision, and it provides immediate support potentially reducing recovery time and post-operative pain compared to other mid-urethral slings.¹

Stress urinary incontinence (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 adults have stress urinary incontinence in the United States, 85% of these adults being women.² 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.

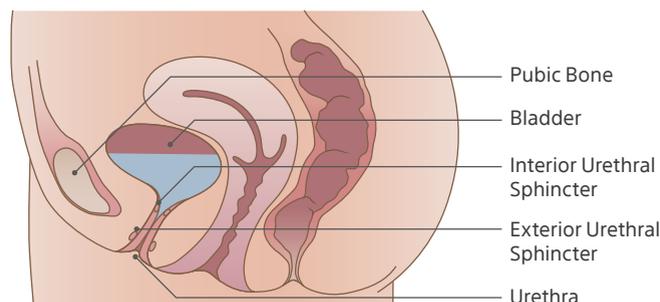


Figure 1 – A woman without stress urinary incontinence
The bladder and urethra must be well supported by the pelvic muscles and tissue in order to prevent involuntary urine loss

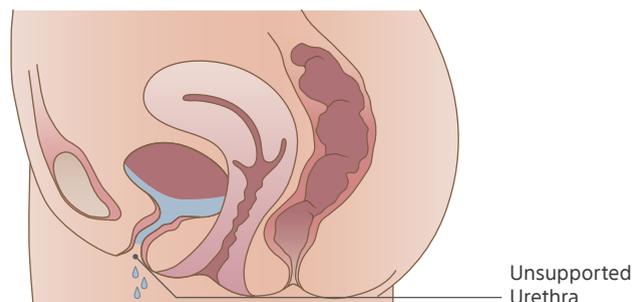


Figure 2 – A woman with stress urinary incontinence
Weakened pelvic floor muscles allow the urethra to drop from its normal position and leak urine when pressure is placed on your bladder

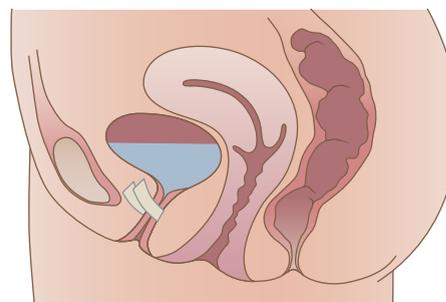
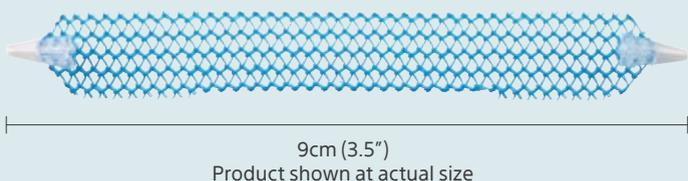


Figure 3 – A woman after a Solyx Sling repair
The Solyx Sling supports the urethra and prevents urine leakage

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.



In a post-market study, 98 out of 104 patients (94%) reported improvement at 3 years following treatment with Solyx.³ The study also showed that Solyx has similar safety and efficacy as a transobturator sling at 3-year follow up.³ Single incision slings have been associated with a better patient experience including earlier return to normal activities and earlier return to work than retropubic or transobturator slings.¹

Treatment Success at 3 Years (n=104)³

94.2%
of women reported
improvement in SUI

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

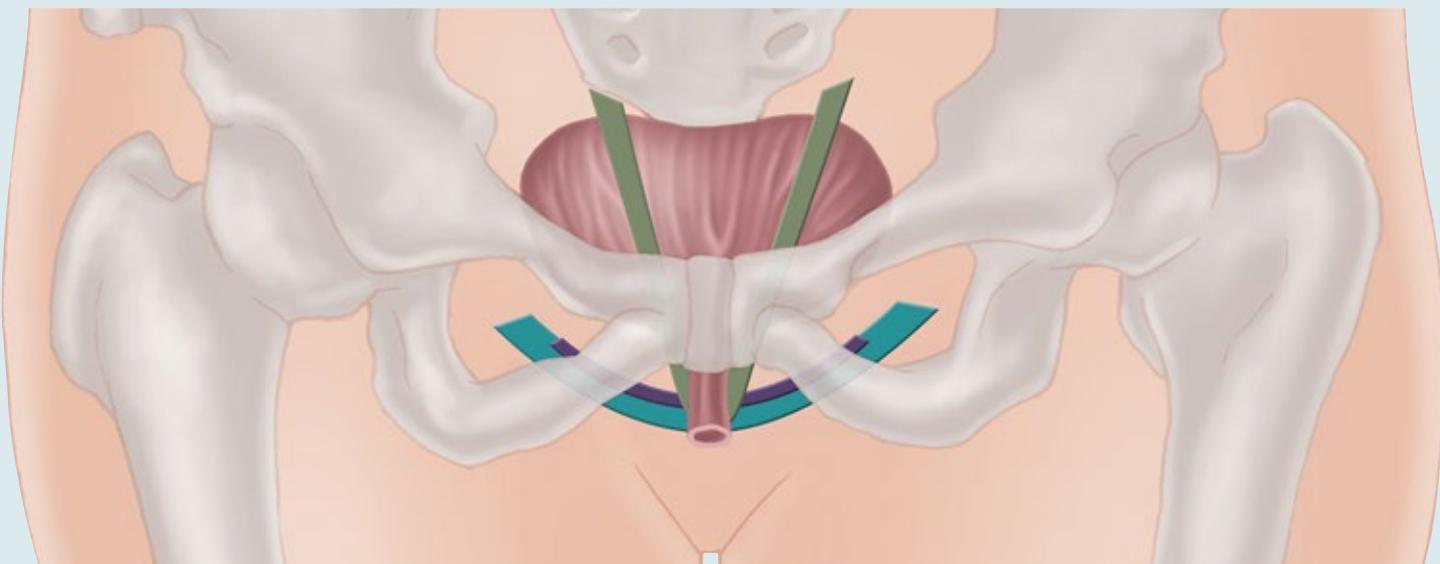


Figure 4
The Solyx Sling minimizes the mesh footprint and number of incisions as compared to retropubic and transobturator slings

● Retropubic ● Single incision sling ● Transobturator

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?

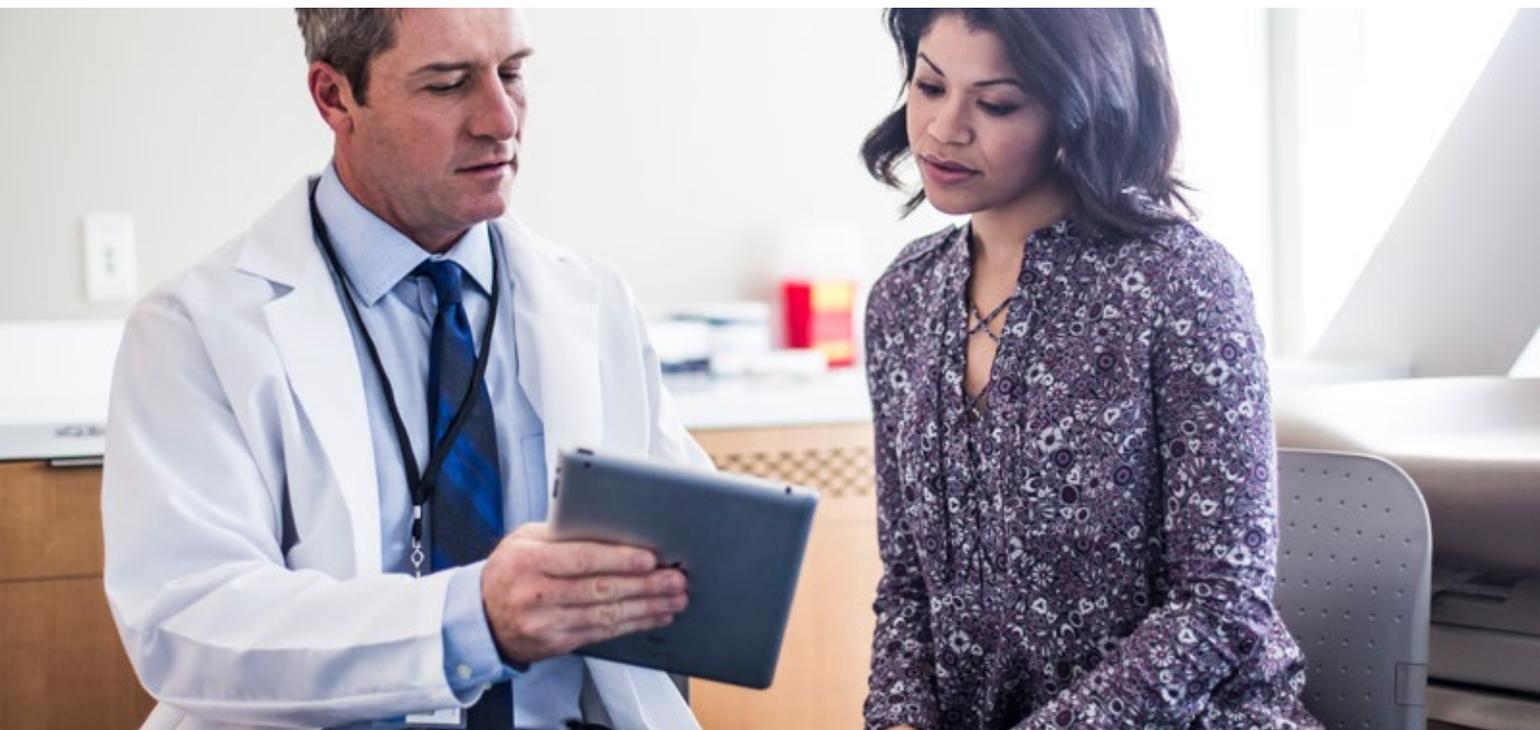
No, there are no medication alternatives. SUI is an anatomic problem often treated with surgery.

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. Mesh surgery for SUI is considered the gold standard or best surgical option. Advantage™ mesh has treated nearly 800,000 patients.⁶

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, potential complications include pain, discomfort/irritation, voiding dysfunction (having difficulty with urination), mesh extrusion/exposure, infection, vaginal discharge, and bleeding or bruising. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. For any questions on these potential complications, or additional information listed at the end of the brochure, please ask your doctor.

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, but mid-urethral slings for bladder leakage have been studied since the mid-1990s and have shown to have high success rates of 80-95%.^{1,3-5}

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.

1. Mostafa A, Lim CP, Hopper L, et al. Single-incision mini-slings versus standard mid-urethral 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.
2. Loss of Bladder Control poster. AUA, Urology Care Foundation website. www.urologyhealth.org/home/educational-materials/loss-of-bladder-control-poster. Accessed December 14, 2018.
3. White AB, Kahn BS, et al. A Prospective Parallel Cohort, Multi-Center Study of the Solyx™ Single Incision Sling System Vs. the Obtryx™ II Sling System for the Treatment of Women with Stress Urinary Incontinence: 3 Year Results, paper presented to American Urogynecologic Society Annual Congress; 2018 Oct 9-13; Chicago, IL.
4. Chevrot A, Droupy S, Coffin G, et al. Long-term efficacy and safety of tension free vaginal tape in a historic cohort of 463 women with stress urinary incontinence. *Int Urogynecol J*. 2017 Jun;28(6):827-33.
5. Litwiller SE. Long term efficacy and safety of the Obtryx Sling for treatment of stress urinary incontinence in a community setting: an analysis of outcomes and quality of life. *J Pelvic Med Surg*. 2009; 12(5):353.
6. Cox, A., S. Herschorn, and L. Lee. Surgical management of female SUI: is there a gold standard? *Nat Rev Urol*, 2013. 10(2): p. 78-89.

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.

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: Local irritation at the wound site and/or a foreign body response may occur; Erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue Erosion (presence of mesh material within the organs surrounding the vagina) Extrusion (presence of mesh material within the vagina); Scarring/scar contracture (tightening of tissue); Device migration (implant moves from the original implantation site); Fistula formation (a hole/passage that develops through the wall of organs); Inflammation (redness, heat, pain or swelling resulting from surgery); The occurrence of these events may require surgical intervention and possible removal of the entire mesh. Like all foreign bodies, the mesh may potentiate an existing infection; Excess tension may cause temporary or permanent lower urinary tract obstruction and retention; Allergic reaction has been reported; Known risks of surgical procedures for the treatment of incontinence include: Pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia (pain during intercourse); Infection, including abscess; Detrusor instability (involuntary contraction of the bladder wall); Complete failure of the procedure, voiding dysfunction (Difficulty with urination): (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder); Bruising, bleeding (vaginal, hematoma formation (pooling of blood beneath the skin)); Abscess; Vaginal discharge; Dehiscence of vaginal incision (opening of the incision after surgery); Edema (fluid retention in the body) and erythema at the wound site (redness of the skin); Perforation or laceration of vessels, nerves, bladder or urethra may occur during placement (damage to nerve, vessel, bladder, or urethra) The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

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 complication 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.

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