

YOUR GUIDE TO UNDERSTANDING
Stress Urinary Incontinence



What is Stress urinary incontinence?

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine. The problem afflicts approximately 18 million women in the United States.¹ It usually takes four to six years to see a healthcare professional for this condition.⁴

You are not alone.

What are some of the symptoms and how is it caused?

Stress urinary incontinence is the involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing or lifting. Incontinence occurs when the muscles that support the urethra (the tube that carries urine out of the body) are weakened or damaged. This can happen as a result of childbirth, trauma, hormone changes and many other reasons. You don't have to live like this. This type of incontinence can be treated both surgically or nonsurgically.



What are some treatment options?

Stress urinary incontinence can be treated in several ways, depending on the exact nature of the incontinence and its severity. As disease state and anatomy differ for each patient, outcomes may vary. Consult your physician for all available treatment options.

You and your physician may discuss:

Non-Surgical Options:

- Changes to your **diet** and fitness routine²
- Use of a **“pessary,”** which is a device designed to relieve symptoms when in place by holding up the vaginal walls. It is inserted vaginally and is removable.³
- **Physical therapy** such as Kegel exercises, designed to increase strength and maintain elasticity in the pelvic muscles

Surgical Options:

Including traditional mesh slings, single incision mini-slings, retropubic colposuspension and bulking

Potential Complications of Surgery

As with most surgical procedures, there are potential risks and complications associated with this SUI surgery. Your physician can further explain your specific risks based on your medical history and surgical approach used.

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
- Apathy (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)

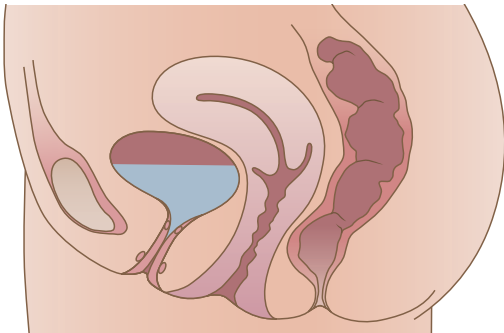
The following additional adverse events have been reported for the Solyx SIS System: Dysuria (painful/difficult urination), Hematuria (blood in the urine).

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.

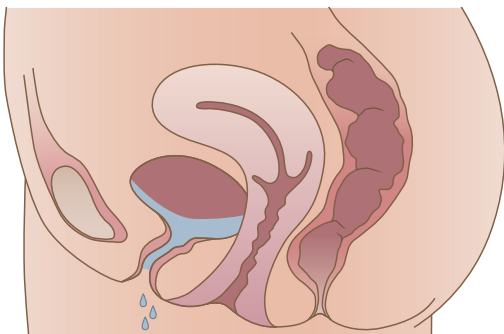
What type of SUI do I have?

One condition is called hypermobility, “hyper” means too much and “mobility” refers to movement, which can result from childbirth, previous pelvic surgery or hormonal changes. Hypermobility occurs when the normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping when any downward pressure is applied, resulting in involuntary leakage.

Another condition is called intrinsic sphincter deficiency, also sometimes referred to as ISD. This refers to the weakening of the urethral sphincter muscles or closing mechanism. As a result, the sphincter does not function normally regardless of the position of the bladder neck or urethra.



Normal functioning anatomy



Weakened pelvic floor muscles allow the urethra to drop from its normal position and leak urine when pressure is placed on your bladder

Glossary

Bulking – Procedure in which a bulking agent is injected under the urethra and bladder neck to treat stress urinary incontinence.

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.

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.

Pelvic Floor Reconstruction – The surgical repair of prolapse and incontinence. Surgical repair of pelvic support structures that can lead to pelvic organ prolapse and/or incontinence when weakened either via age related changes or trauma.

Pessary – A removable plastic device that is inserted into the vagina to hold prolapsed organs back in place.

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.

Sphincter Muscle – Muscles in the urethra that squeeze together and prevent urine from escaping the body involuntarily.

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 obturator regions.

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

Urethra – Tube that carries urine from the bladder outside of the body.

Frequently asked questions about SUI

Is it common to perform procedures with mesh?

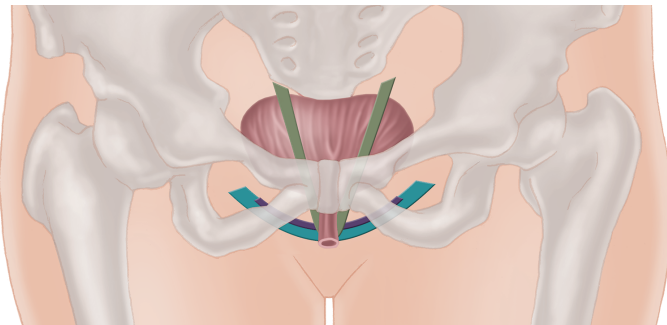
Polypropylene-based mesh devices have been a mainstay in many medical procedures for over 50 years, including in hernia and tendon repair, sutures, and wound closure. Advantage™ mesh is clinically studied and has been used in more than 1 million slings.⁴

How can a mid-urethral sling system help my incontinence?

A mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity, which may include but is not limited to: coughing, laughing, or lifting.

What are the types of sling options?

Many surgical options have been developed, 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. Consult your physician for all available treatment options.



● Retropubic ● Single incision sling ● Transobturator

How will my surgery be performed?

Your minimally invasive 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 the procedure.

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 and bandage the small incisions in the groin area (if applicable for your sling type) and the top of the vaginal canal.

What should I expect after surgery?

Before you are discharged from the hospital, you may be given a prescription for an antibiotic and/or pain medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. 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 within 2 to 4 weeks, with no strenuous activity for up to 6 weeks.

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. Please consult your physician about your specific surgery and situation to learn more on what you may expect.

Is this procedure covered by insurance?

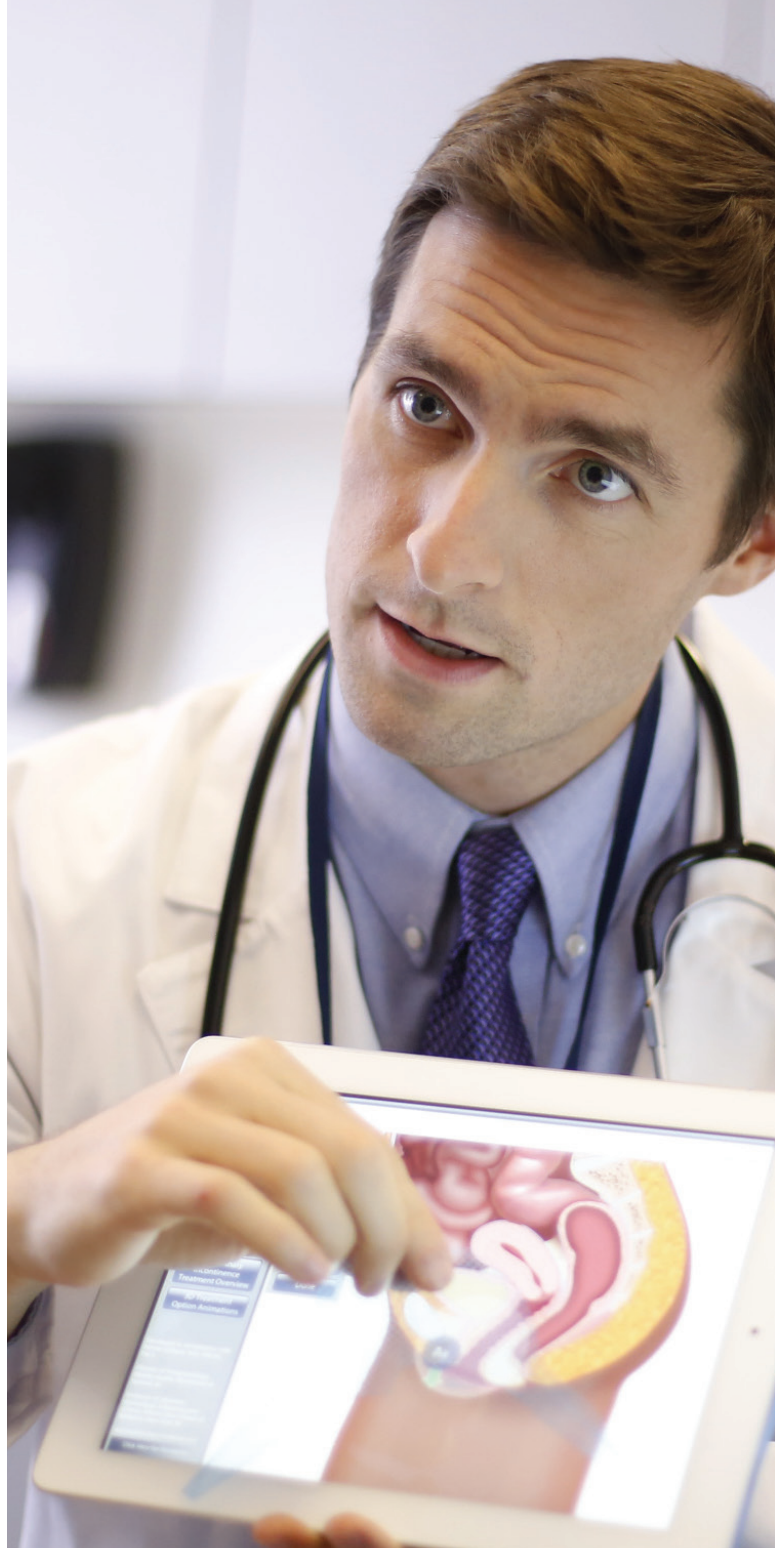
Most insurance plans cover the surgical treatment of stress urinary incontinence. Check with your insurance company to determine your specific coverage.

REFERENCES:

1. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in U.S. Women: 2010 to 2050. *Obstet Gynecol.* 2009 Dec;114(6):1278-1283. doi: 10.1097/AOG.0b013e3181c2ce96. PMID: 19935030.
2. <https://www.voicesforpfd.org/bladder-control/sui-treatment/> Accessed June 2021
3. <https://www.voicesforpfd.org/about/pessaries/> Accessed June 2021
4. Data on File at Boston Scientific.

Voiding diary example

Date:	Fluids		Urinated in toilet (number of times)	How much? (small, medium, or large amount)	Did you feel a strong urge to urinate?	Leaked urine (number of times)	How much? (small, medium, or large amount)	Activity when leaking
	What kinds?	How much?						
Example:	water	2 cups	✓	medium	no	✓	small	running
6am - 8am								
8am - 10am								
10am - 12pm								
12pm - 2pm								
2pm - 4pm								
4pm - 6pm								
6pm - 8pm								
8pm - 10pm								
10pm - 12am								
12am - 2am								
2am - 4am								
4am - 6am								



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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 Delivery Devices are intended for use as an aid in insertion, placement, fixation, and anchoring of the 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 Aparaunia (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:** The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered: 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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