



Patient
Frequently Asked Questions

Sling Surgery for Stress Urinary Incontinence

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What is Stress Urinary Incontinence (SUI)?

Q: What is Stress Urinary Incontinence and is it a common problem?

A: Stress Urinary Incontinence (SUI) is an involuntary loss of urine that occurs during physical activity, such as coughing, sneezing, laughing, or exercise. About 1 out of every 3 women experience urinary leakage at some time in their lives. Approximately one-third of women age 30 to age 60, and one-third of women under the age of 30, experience urinary incontinence.¹

Treatment options for SUI.

Q: What is a SLING for Stress Urinary Continance? And, how is it used?

A: It is a small strip or sling of a very soft and flexible synthetic material. A SLING becomes integrated in your tissues and forms a “hammock of support” under your urethra (tube where one urinates through) to support it when necessary. SLINGS have been developed by biomedical engineers and clinical researchers to be compatible with your tissues.

A SLING is usually about 0.6 inches wide and can vary in length depending on the approach from 3.4 inches to longer depending on the product used and your anatomy.²

Ask your physician for clinical study information on the SLING he or she recommends for you.

Q: What alternative procedures exist for Bladder Leakage?

A: Depending on the severity of your symptoms, your surgeon may recommend Pelvic Floor Training, surgical procedures such as fascial slings, minimally invasive SLING procedures, suspension procedures using other materials or sutures, or bulking agents.

Q: How do I know if a SLING is a good option for me?

A: This is a decision that should be made by you in consultation with your surgeon. You should discuss with your surgeon all of your options and which treatment plan is most appropriate for your specific medical situation. This is a personal choice that your surgeon is ready to discuss with you.

For moderate to severe BLADDER LEAKAGE primarily caused at time of exertion, of all of the techniques available, the synthetic mid urethral SLINGS have been shown to be the most effective treatment.³

Q: How is a SLING for Bladder Leakage placed?

A: The procedure can be performed on an outpatient basis under local anesthesia with IV sedation. A small vaginal incision of about 1.5 cm is made. Small instruments are passed to place the tension free mesh. No stitches are used to attach a tension-free sling to the tissue. Instead, tissue itself holds the sling in place initially. Eventually scar tissue forms in and around the SLING to keep it from moving. As with any medical procedure, complications from the surgery can occur.

Q: How long is the SLING surgery?

A: In most cases, the surgery should last less than 30 minutes⁴ and if your surgeon recommends, the procedure can be done under local anesthesia with IV sedation. SLING procedures are frequently outpatient procedures, in which case you may be returning home the same day of surgery. Many

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times, the SLING is part of another procedure and you may need additional surgery to support a dropped bladder, uterus or rectum. Your surgeon will discuss this with you.

Q: What can I expect during recovery?

A: Every patient's recovery experience is unique and you should consult your physician as to what he or she expects in your case. After undergoing a SLING surgery, you may feel sore for a short period of time. Please consult with your surgeon on activities to avoid during recovery to achieve optimal outcomes.

Q: What complications can occur with the use of SLINGS?

A: Your surgeon will explain the risks and benefits associated with vaginal mesh placement. Vaginal mesh placement can result in problems such as exposure (small amount of the SLING material exposed into the vagina), infection, irritation or inflammation. These problems can often be treated by your surgeon in his or her office as an outpatient procedure. More serious complications such as pain, infection, bleeding, organ perforation, urinary problems (such as urinary tract obstruction, retention, worsening incontinence or overactive bladder symptoms), erosion of the SLING through the urethra (tube you urinate through), or surrounding organs, migration or fistula formation can occur. These responses may require additional intervention by your surgeon or may require removal of all or part of the mesh.

Q: Will a SLING cure my incontinence symptoms with 100% certainty? And, if the SLING does not work, can I still have a different procedures?

A: There is no surgery for incontinence that has a 100% cure rate, but SLINGS for Bladder Leakage have been studied since the mid-90's and have shown to have high success rates of 80-95%.^{5,9,10,11,12} Other incontinence procedures are possible after SLING placement. If necessary, inform your surgeon about having a SLING when considering additional treatment options.

Q: What is a suspension procedure?

A: For this procedure, an incision is made in your lower abdomen. Your surgeon then places stitches in the tissue near the bladder neck and secures the stitches to a ligament near your pubic bone (Burch procedure) or in the cartilage of the pubic bone itself (Marshall-Marchetti-Krantz procedure). This procedure involves an abdominal incision. It's done under general or spinal anesthesia.

Recent Communications From the FDA.

Q: What is a Public Health Notification?

A: A Public Health Notification is an important message from the FDA's Center for Devices and Radiological Health to the health care community describing a risk associated with the use of a medical device and providing recommendations on its use.

Q: What did the FDA say in its October 20, 2008 Public Health Notice?

A: On October 20, 2008, the FDA issued a Public Health Notification (PHN) regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The PHN provided recommendations and encouraged physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

Q: What has happened since the 2008 PHN?

A: In July 2011, the FDA issued an update to the October 2008 PHN. In this update, the FDA maintained that adverse events for POP mesh repair are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair. Although the PHN made mention of mesh for use in SUI repair, the FDA did not address this SUI treatment approach and communicated that further evaluation would be required prior to releasing any statement in that regard.⁶ The July 2011 notification continued to encourage physicians to seek specialized training in mesh procedures, to consider and to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications. For more information on the FDA Public Health Notification (PHN) please visit: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm>

On September 8-9, 2011, the FDA convened an Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to further address the safety and effectiveness of transvaginal surgical mesh used for repair of POP. The panel examined the use of transvaginal surgical mesh products to treat both pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

The panel recommended to the FDA that slings for the treatment of SUI are properly classified by the FDA with respect to risks and benefits offered. Regarding retropubic and TOT slings, the panel concluded that no additional post-market surveillance studies are necessary. Regarding mini-slings, the panel recommended pre-market studies for new devices and additional post-market studies.

Q: Are SLINGS FDA cleared for use to restore Continence?

A: Yes. There are different treatment options to restore continence. For Stress Urinary Incontinence (or BLADDER LEAKAGE), when conservative treatments are not helping, considering a SLING may be a good option. A SLING is considered one of the primary treatment options if alternative treatments fail⁷ and considered by many physicians to be the 'Standard of Care' or 'gold standard procedure'⁸ for Bladder Leakage. This is especially if you leak primarily with exertion such as coughing, laughing, exercising or sneezing etc. SLINGS have been studied since the mid-90's and have shown to have high success rates of 80-95%.^{5, 9, 10, 11, 12} Of the two major types of SLINGS (retropubic and transobturator), equivalency in success rates has been shown for both approaches with relatively low complication rates.¹³ In addition, another version called "MiniSlings" was introduced in 2007. They show efficacy and minimal complications similar to transobturator SLINGS but with shorter outcome data.¹⁴

Q: Has the FDA recalled SLINGS?

A: No, the FDA has not recalled SLINGS.

Q: I have a SLING (SURGICAL MESH) implanted for Bladder Leakage. Should I have it removed?

A: As with all important medical decisions, you should consult with your physician. There is no need to remove your SLING if you are satisfied with your surgery and are not having complications or symptoms. Because a SLING integrates in your own tissues, removal may cause complications or symptoms. The FDA recommends you continue with your annual and other routine check-ups and follow-up care. Patients should notify the surgeon if complications develop (persistent vaginal bleeding or discharge, pelvic or groin pain during sex).

Remember

While you're considering your treatment options, empower yourself and make an informed decision. This is a personal choice that your surgeon is ready to discuss with you, and plan for. Knowing your options can reduce your fear and strengthen your decision. Once you have read this information, consider visiting NAFC.org or PelvicHealthSource.com for additional information and be sure to consult with your surgeon to determine what option is right for you.

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- 7 Thuroff J et al. (2010) EAU Guidelines on Urinary Incontinence. *Eur Urol* 59:387-400
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