



Facts About Surgical Mesh to Treat Stress Urinary Incontinence

Urology Care
FOUNDATION™
*The Official Foundation of the
 American Urological Association*

The Urology Care Foundation and the American Urological Association (AUA) are concerned that patients are confused about the use of surgical mesh to treat Stress Urinary Incontinence (SUI). Surgical mesh is used to treat other health problems, such as hernias. The U.S. Food and Drug Administration (FDA) has issued safety statements on the use of mesh in several health problems. But surgically-placed mesh “slings” are safe and work well to treat SUI. In fact, they continue to be a standard treatment for SUI.

WHAT IS SUI?

SUI occurs when you leak urine (pee) when coughing, sneezing, laughing, or being physically active. Urine leaks because your pelvic floor muscles are stretched, weak or injured. It is a common problem – 1 in 3 women experience SUI. But SUI is not a “normal” part of aging. Not being able to control your bladder may cause you to be embarrassed. It may also make you want to avoid being active.

There are treatments that can help. In most people, urine leakage stops or is greatly reduced with treatment. There are many choices for treating and managing SUI. They include pelvic floor muscle exercises, lifestyle changes, medical devices and absorbent pads. For some people, these options may not be enough, and they may choose to have surgery.

For more information on all SUI treatment options, visit www.UrologyHealth.org/TreatSUI.

SURGICAL MESH IS A STANDARD TREATMENT FOR SUI

For women with SUI who choose to have surgery, mesh sling surgery is the most common. It is a less invasive surgery, and patients tend to heal sooner than with other surgeries to treat SUI. For this treatment, a strip of material (a “sling”) is placed under the tube that carries urine out of the body (the urethra). The sling gives support to help prevent urine leakage. (If your pelvic floor muscles weren’t weak or injured, they would provide this support.) Slings can be made from your own tissue, donor tissue or surgical mesh.

The American Urological Association’s guideline for SUI care lists mesh slings as a “standard” treatment for SUI. The AUA points to many scientific studies that support the use of mesh slings to treat SUI. Mesh sling surgery has high success rates for greatly reducing or stopping urine leakage.

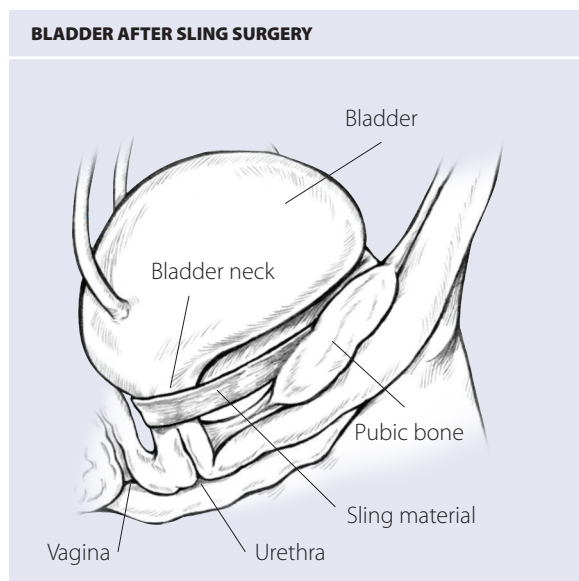
There are three kinds of mesh slings – transobturator, retropubic and mini-slings. All of these slings are safe and work well to treat SUI. Since mini slings are newer, studies to assess how well they work in the long-term are ongoing.

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As with all surgeries, side effects can result from sling surgery, whether the sling is made of your own tissue, donor tissue or mesh. These side effects can include difficulty urinating (peeing), or in rare cases, not being able to urinate at all. More serious side effects, such as damage to the bladder or urethra (the tube you pee through) are rare and might require further surgeries.

One possible side effect when using mesh for sling surgery is exposure of the mesh into the vagina after surgery. (Also called mesh erosion, this is when the mesh starts to be felt or seen from the vagina, often on the line where the cut was made for surgery.) This happens in about 2 out of 100 women within a year of having this surgery. In most cases, the exposure may be treated fairly easily. But some of these women require further surgery. Generally, the FDA found that long-lasting side effects from treating SUI with mesh seem to be rare.

Talking with a urologist or other female pelvic medicine reconstructive surgeon will help inform you about your options. That surgeon can talk to you about the risks and benefits of each treatment.



RECENT FDA SAFETY STATEMENTS ABOUT SURGICAL MESH

The Urology Care Foundation and the AUA are concerned that patients are confused about the use of surgical mesh to treat SUI versus the different use of surgical mesh to repair pelvic organ prolapse (POP). (POP is a health problem in which some organs, such as your uterus or bladder, drop into your vagina. This can cause a vaginal bulge and often a sense of pressure or discomfort.)

In 2011 and 2013, the FDA stated concerns about the use of transvaginal mesh to repair pelvic organ prolapse (POP) (<http://1.usa.gov/1HghbDi>). POP and SUI are different health issues with different surgical treatments. The surgeries that use mesh to treat each health issue have their own unique risks and benefits. Mesh to treat SUI is used differently than mesh for POP repair. SUI mesh is smaller and is placed in a different location than mesh used to repair POP.

In 2014, the FDA indicated that mesh for SUI does not carry the same risk as transvaginal mesh for POP (<http://1.usa.gov/1b4FEPF>). Mesh slings used to treat SUI are generally recognized to be safe, and long-lasting side effects are rare. Mesh slings are a standard treatment for SUI.

HAS THE FDA “RECALLED” SURGICAL MESH FOR SUI TREATMENT OR FOUND IT TO BE “DEFECTIVE”?

No. The FDA has not “recalled” any mesh slings to treat SUI or asked doctors to stop using it. It is still available for doctors to use. It has **not** been found to be “defective.”

To view the FDA’s “Information for Patients with SUI,” which includes a list of questions to ask your doctor, visit: <http://1.usa.gov/14eIwX8>.

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IF YOU HAVE HAD SURGERY WITH MESH TO TREAT SUI DO YOU NEED TO HAVE IT REMOVED?

Surgical mesh is designed to be a permanent implant. If you are not having any side effects, there is no need to remove the mesh. When mesh is removed, side effects can occur. These can include injury to tissue near the mesh or having your incontinence return or even be worse.

IF YOU ARE THINKING ABOUT SLING SURGERY, OR IF YOU HAVE UNDERGONE SLING SURGERY FOR SUI AND HAVE CONCERNS ABOUT THE USE OF MESH, THE UROLOGY CARE FOUNDATION OFFERS THIS ADVICE:

- Talk to a urologist about what options are best for you. A urologist or other female pelvic medicine reconstructive surgeon should be able to explain all of your treatment options and their risks and benefits. Feel free to ask them questions until you feel confident in the choice you make together about the treatment that is right for you.
- Before surgery, ask about which type of sling (mesh or human tissue) will be used. You should learn what results to expect and why this surgery is being recommended for you.
- Ask your doctor how often they have done this surgery, what training they have and what side effects their patients have seen.
- Learn about potential side effects and their cause. It is important to recognize bad side effects so they can be taken care of right away. Many side effects of sling surgery for SUI may not be related to the mesh. Some problems can happen with non-mesh sling surgeries as well. Talk with your doctor about what symptoms (such as bleeding, pain or problems urinating) need immediate attention.

IF YOU ARE THINKING ABOUT SLING SURGERY FOR SUI, HERE ARE SOME QUESTIONS YOU CAN ASK YOUR UROLOGIST OR OTHER FEMALE PELVIC MEDICINE RECONSTRUCTIVE SURGEON WHO SPECIALIZES IN TREATING INCONTINENCE:

- What type of sling material will be used – surgical mesh, donor tissue or my own tissue?
- Why are you suggesting this surgery for me?
- How many surgeries have you done with this kind of sling?
- What kind of training have you had for doing this kind of sling surgery?
- What kind of results can I expect?
- What side effects have your sling patients had? How often have you seen these side effects?
- Once I go home from the hospital, are there any symptoms I should let your office know about right away? (Some symptoms, such as bleeding, pain or problems urinating, may be need to be dealt with right away.)
- Since the mesh is a permanent implant, what kind of adjustments or modifications may be required over time?
- Are there other surgeries or treatments that could help me?
- What are some of the side effects of other surgeries and treatments?
- What kind of results could I expect with other surgeries and treatments?

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FOR MORE INFORMATION:

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) and American Urogynecologic Society (AUGS)

Frequently Asked Questions by Patients for Mid-urethral Slings for Stress Urinary Incontinence
www.sufu.org/docs/news/patient-FAQs-MUS-for-posting.aspx

U.S. Food and Drug Administration

Information for Patients for SUI
<http://1.usa.gov/14eIwX8>

Urology Care Foundation

It's Time to Talk about SUI campaign
www.UrologyHealth.org/SUI

Download our Patient Guide, Bladder Diary and other helpful materials and tools. Order any of our materials mailed to you at **www.UrologyHealth.org/Order**.

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