

Answering Your Patients' Questions: Surgical Mesh Sling Surgery for Stress Urinary Incontinence

STRESS URINARY INCONTINENCE – THE BASICS

- ▶ Stress Urinary Incontinence (SUI) refers to urine leakage during activities that result in increased abdominal pressure, such as sneezing, coughing, physical exercise, lifting, bending and even changing positions.
- ▶ SUI is a very common condition – 1 out of 3 women have SUI
 - Less than half of women who have urinary incontinence have discussed their symptoms with their health care provider.
 - Any amount of leakage of urine is abnormal.
- Untreated, SUI can have significant impact on quality of life.
- ▶ For women choosing to undergo surgery, the sling procedure using synthetic polypropylene mesh is the most common surgery currently performed for SUI.
- ▶ The American Urological Association and other leading urological subspecialty societies support the use of mesh slings.

Many of your patients suffer from Stress Urinary Incontinence (SUI), yet research shows that less than half of those who suffer mention it their health care provider. When they do start talking about SUI treatments, many have been suffering for years. Patients who have tried non-surgical treatments and haven't gotten the results they want may start asking about surgical treatments, including mesh sling surgery.

Below, we have collected answers to the most frequently asked SUI patient questions.

WHAT TREATMENT OPTIONS ARE AVAILABLE FOR MY SUI?

There are many non-surgical strategies to help treat and manage SUI, including:

- pelvic floor muscle training
- lifestyle changes such as maintaining a healthy weight, fluid and diet management and smoking cessation
- absorbent pads

- urinary control devices such as pessaries or occlusive devices

For some people, these options may not be enough, and they may choose to have surgery. Current surgical options include:

- sling surgery
- bladder neck suspension (also called retropubic suspension or colposuspension)
- urethral bulking injection (helps better close off the urethra during times of increased pressure, significantly less effective than other surgeries)

For surgery, patients should consult with a urologist or other female pelvic medicine reconstructive surgeon to best understand their options.

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I HAVE HEARD THAT SURGICAL MESH ISN'T A SAFE TREATMENT FOR SUI. WHAT DO YOU THINK?

Surgical mesh is used to treat a number of health problems, most commonly hernia repair. Mid-urethral mesh sling surgery is the standard of care for women with moderate to severe SUI. Extensive data exist to support the use of mesh slings for the treatment of female SUI. The American Urological Association, the American Urogynecological Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) have all reiterated their support of mesh sling surgery to treat SUI.

Mesh sling surgery is a less invasive surgery than other options, and patients tend to recover quicker than with the alternative surgeries to correct SUI. (These alternatives include bladder suspension procedures and slings that are constructed using the patient's own tissue.)

Confusion about the use of mesh for SUI treatment is common due to reported concerns about the use of mesh in prolapse repair. Pelvic organ prolapse (POP) is a very different condition than SUI with a different surgical treatment. The surgeries that use mesh to treat POP and SUI are different and have their own unique risks and benefits. The products used in these surgeries are not identical. The mesh used to treat SUI is smaller and is placed in a different location than mesh used to repair POP.

A consultation with a urologist or other female pelvic medicine reconstructive surgeon can help inform your patients about their options, including the risks and benefits of different treatment options.

HAS THE FDA "RECALLED" VAGINAL MESH TO TREAT SUI OR FOUND IT TO BE "DEFECTIVE"?

No. The U.S. Food and Drug Administration (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 in suitable patients. It has not been found to be "defective."

IF I AM CONSIDERING A MESH SURGERY, WHAT QUESTIONS SHOULD I ASK THE SPECIALIST?

Both the Urology Care Foundation and the FDA have lists of questions to ask your specialist. You may download and print the Urology Care Foundation's Facts About Surgical Mesh to Treat Stress Urinary Incontinence, or just have your patients visit: www.UrologyHealth.org/Mesh.

Here are a few of the questions listed there:

- What type of sling material will be used – surgical mesh, donor tissue or your 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 do you have 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?
- 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?

To view the FDA's Information for Patients with SUI, visit:
<http://1.usa.gov/14elwX8>.

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WHAT IF I ALREADY HAVE HAD SURGERY WITH MESH TO TREAT MY SUI? SHOULD I HAVE THE MESH 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 recurrent incontinence.

If you are experiencing side effects that you did not experience prior to mesh surgery, it is important that you have a follow-up visit with the surgeon to discuss these symptoms. The majority of the time, these side effects can be easily addressed by the specialist without surgical intervention.

WHY DO I SEE SO MANY ADS ABOUT MESH ON THE TV? THERE MUST BE A REAL PROBLEM, RIGHT?

A lot of misconceptions have been created by trial lawyer advertisements looking for clients to represent. There is also confusion about the use of mesh for SUI treatment due to FDA statements about the use of mesh to repair pelvic organ prolapse (POP). In 2013 and 2014, the FDA stated concerns about the use of transvaginal mesh to repair POP (<http://1.usa.gov/1HghbDi>). (POP is a health problem in which some organs, such as your uterus or bladder, fall into the vagina. This can cause a vaginal bulge and often a sense of pressure or discomfort.)

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.

More recently, the FDA indicated that mesh for SUI does not carry the same risk as transvaginal mesh for POP repair. In 2016, the FDA put transvaginal mesh for POP in a higher risk category than mesh for SUI. Read the FDA's final rule at: <http://1.usa.gov/1ne31wL>. The FDA clearly states that this rule does not apply to mesh for SUI.

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.

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MORE INFORMATION FOR HEALTH CARE PROVIDERS:

American Urological Association

Position Statements on the *Use of Vaginal Mesh for the Surgical Treatment of SUI* and POP

www.AUAnet.org/about/vaginal-mesh-for-sui.cfm

Guideline for the Surgical Management of Female SUI

www.AUAnet.org/education/guidelines/incontinence.cfm

SUFU and AUGS

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) and American Urogynecologic Society (AUGS) *Position Statement on Mesh Midurethral Slings (MUS) for Stress Urinary Incontinence:*

<http://www.sufuorg.com/resources.aspx>

U.S. Food and Drug Administration

Considerations About Surgical Mesh For SUI

<http://1.usa.gov/1ukqsEx>

Information for Health Care Providers for SUI

<http://1.usa.gov/11j4G9F>

Urology Care Foundation

SUI Monograph and SUI Pocket Reference

www.UrologyHealth.org/SUI, click on "for Health Care Providers."

Surgical Mesh for Stress Urinary Incontinence

www.UrologyHealth.org/MeshHCP

MORE INFORMATION FOR PATIENTS:

SUFU and AUGS

Frequently Asked Questions by Patients for Mid-urethral Slings for Stress Urinary Incontinence: <http://www.sufuorg.com/docs/guidelines/Patient-FAQs-MUS-for-posting.aspx>

U.S. Food and Drug Administration

Information for Patients

<http://1.usa.gov/14eIwX8>

Urology Care Foundation

For referral to a urologist:

www.UrologyHealth.org/FindAUrologist

Choose "incontinence" as a "special interest area" to find urologists who are interested in treating SUI.

It's Time to Talk about SUI campaign

www.UrologyHealth.org/SUI, click on Patients.

Surgical Mesh for SUI Fact Sheet

www.UrologyHealth.org/Mesh

For more information, contact:

Urology Care Foundation

1000 Corporate Blvd.

Linthicum, MD 21090

1-800-828-7866

UrologyHealth.org

You may download this and print this fact sheet yourself from UrologyHealth.org/MeshQ. For copies of other printed materials about urologic conditions, visit UrologyHealth.org/Order or call 800-828-7866.

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National Headquarters: 1000 Corporate Boulevard, Linthicum, MD 21090

Phone: 410-689-3990 • Fax: 410-689-3878 • 1-800-828-7866 • info@UrologyCareFoundation.org • www.UrologyHealth.org