

A WOMAN'S GUIDE TO STRESS URINARY INCONTINENCE





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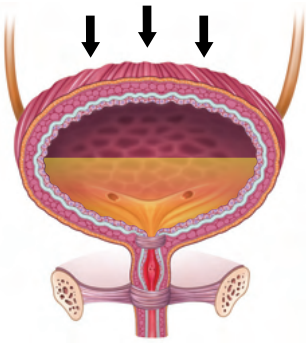
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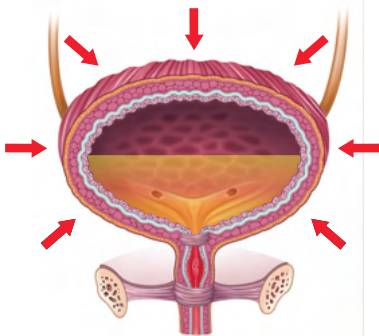
WHAT IS URINARY INCONTINENCE?

The bladder and urethra are supported by a group of pelvic muscles and connective tissue. As these muscles weaken, the bladder and urethra lose their support and move out of position, allowing urine to leak. It is misconceived to be a normal part of aging. In fact, it can happen at any age and is common but not normal.



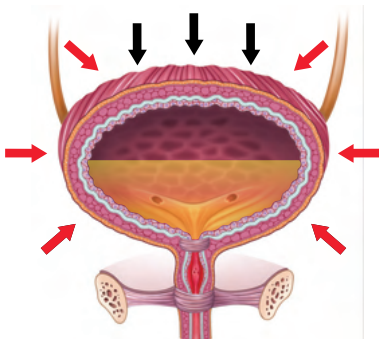
Stress Urinary Incontinence (SUI)

Involuntary leakage of urine due to increased pressure on the bladder from physical activities, such as coughing, sneezing, laughing, and heavy lifting.



Urge Incontinence

Involuntary leakage due to a sudden and intense urge to urinate.



Mixed Incontinence

A combination of stress and urge incontinence.

WHAT CAUSES STRESS URINARY INCONTINENCE?



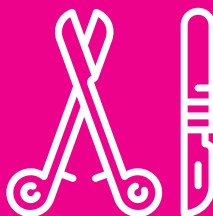
**PREGNANCY
& CHILD BIRTH**



MENOPAUSE



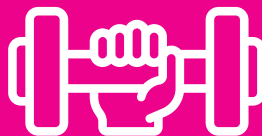
OBESITY



**PREVIOUS
PELVIC
SURGERY**



SMOKING



**LONG-TERM
HIGH IMPACT
ACTIVITIES**

WHAT ARE THE SYMPTOMS OF STRESS URINARY INCONTINENCE?

If you answer “**YES**” to any of the questions below, you may be living with Incontinence.

Do you leak urine unexpectedly?

Do you leak urine when coughing, sneezing, laughing, bending or lifting?

Do you continuously leak urine with little movement?

Do you avoid intimacy because you might leak urine?

Do you wear pads to protect against leaks?

Do you avoid certain activities because you fear leaking?

TREATMENT OPTIONS

Below are a few options that may be considered for the treatment of SUI. Discuss with your physician what treatment option will work best for you.

A **self-management** option is to do Kegel exercises consisting of a series of pelvic exercises to help increase the strength of the pelvic floor. This may help in mild cases of incontinence.

A **pessary** is a removable device that is inserted into the vagina against the vaginal wall and urethra to support the bladder neck. This helps reposition the bladder and/or urethra to reduce SUI.

Bulking agents consist of a bio-compatible substance injected around the urethra to narrow the urethra. The effects of a bulking agent are usually temporary, and the cure rates are lower compared to surgery.

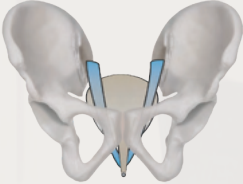
Surgery is used to help rebuild and restore support under the bladder and the urethra using a sling implant. Surgery has the highest success and cure rate compared to other treatment options.

YOUR PROCEDURE

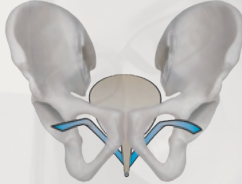
Your minimally invasive mid-urethral sling procedure uses a half-inch wide strip of mesh under the urethra to help rebuild support to prevent urine leakage. The procedure is most commonly performed as an outpatient surgery, and usually takes less than 30 minutes. The type of Desara® sling used and the method of placement will depend on your condition and your physician's preference.

Desara® sling products can be placed in three general ways:

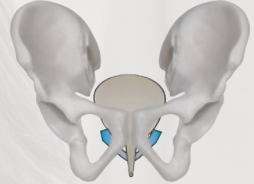
RETROPUBIC



TRANSOBTURATOR



SINGLE INCISION



Standard Desara® mid-urethral slings are placed with a single vaginal incision and two external skin incisions in either the lower abdomen, just above the pubic bone, (Retropubic) or in the groin area near the bikini line (Transobturator).

The Desara® One single incision sling (SIS) requires only one incision in the vagina, and no external skin incisions. In addition, Desara® One SIS is much shorter in length compared to a standard Desara® mid-urethral sling. Single incision slings may have a lower cure rate compared to standard mid-urethral slings.

In order to place Desara®, instruments are used to pass Desara® through the vaginal incision and place it within your abdomen where it will rest just below your urethra, creating a backboard for support. Just as your mattress needs a box spring for support, your urethra also needs a firm backboard of support to maintain bladder control. The Desara® sling then acts like a scaffolding for your tissue to grow into. The sling and tissue in-growth will provide support to the urethra and help you regain continence.

IS THE PROCEDURE SAFE & EFFECTIVE?

The minimally invasive mid-urethral sling procedure is the most studied surgery and is considered the standard procedure to treat stress urinary incontinence with over 2,000 articles published about it^{1,2}. The procedure has demonstrated its effectiveness^{1,3,5} and patient satisfaction⁵.

YOUR SURGICAL SLING DESARA®

The surgical mesh sling used in your procedure is called Desara®. It is a sling made of Polypropylene (PP), which is a well accepted and commonly used material for surgical implants. This material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients globally⁶ and it has significantly and favorably impacted the field of surgery^{7,8}. A large majority of sutures are made of polypropylene⁶.



WHY USE A MESH IMPLANT?

Implants are used in virtually all fields of medicine to reinforce weakened tissue⁶. Implants are used for ligament and tendon repair, vascular grafts, craniofacial reconstruction, face contour augmentation, suture material, joint and spinal implants⁶.



DAY OF SURGERY

Mid-Urethral Sling surgeries are commonly outpatient surgeries performed under intravenous (IV) sedation or general anesthesia, in either the hospital or an outpatient surgery center. Most patients can go home the same day of surgery, but some may require an overnight stay at the hospital. This is dependent on your health and if your sling procedure was a part of a bigger surgery (such as correcting prolapse).



AFTER THE SURGERY

After surgery, you will be in a recovery room for a couple hours until the anesthesia wears off, and you are able to empty your bladder. If you have trouble emptying your bladder, you may have to use a catheter temporarily. It is common for patients to have trouble emptying their bladder after surgery but this is usually only temporary.

POST OPERATIVE CARE

You have just undergone a mid-urethral sling operation for the treatment of stress urinary incontinence. You are now on the road to recovery and a new continent lifestyle. You play a pivotal role in your recovery and the long-term success of the surgery.

The sling is made of a loosely knitted polypropylene mesh material. Over the next several weeks, your own tissues will grow into the sling material and make it much more stable and secure. This “tissue in-growth” process begins a few days after your procedure and lasts for weeks. Therefore, it is recommended that you restrict your activity for at least 4 weeks after the operation. Restrictions and special instructions for this post-operative period are listed below:

If you do not already have a follow-up appointment, please call your doctor's office to schedule one for some time 2 to 4 weeks after the surgery.

URINATING

Most patients will be able to urinate (void) before leaving the hospital. If you have to go home with a catheter, you will be asked to return to your doctor's office the next morning for a “voiding trial.”

ACTIVITY

Routine activities such as getting dressed, shaving legs, etc., are fine. Low impact exercise such as stretching, “easy” Yoga, Pilates moves, and walking is OK. Avoid swimming, biking and high-impact aerobics for 4 -6 weeks.

HEAVY LIFTING

For 4 - 6 weeks you should not lift, push, or pull any objects weighing more than 8 -10 lbs (about the weight of a gallon of milk). You should not be carrying groceries, the laundry basket, or operating a vacuum cleaner during this time.

SEXUAL INTERACTION

Do not have intercourse, douche, or place anything in the vagina for six weeks after surgery, or until your surgeon says it is ok.

BOWEL MOVEMENTS

Do not strain when trying to have a bowel movement. You may need to use a stool softener after your surgery. If you are getting constipated and need suggestions about treating the constipation. Please call your doctor's office.

DISCHARGE

It is normal to have a minimal amount of vaginal discharge, which may last up to six weeks following surgery. This discharge may be bloody or may be yellow in color. Please call if you think it is excessive or if you have concerns about your incisions.

HYGIENE

You may shower when you get home, but do not take a bath or go swimming for 4 - 6 weeks following surgery.

FAQ

Will future pregnancies affect the results of my sling?

Future pregnancies may negate the outcome of your sling procedure. Another procedure may be needed to regain continence.

Will I need to stay in the hospital after the procedure?

A hospital stay is usually not required for this procedure; however, depending on your condition, your physician may require you to stay overnight. If you are having another procedure performed at the same time, you may be required to stay longer. Ask your physician about what to expect.

How long does the sling procedure last?

The mesh material is permanent; however, the durability of mesh repair for urinary incontinence depends on many factors. Most clinical studies have collected outcomes data for only 1-2 years; these studies suggest that the majority of women who undergo mesh repair for incontinence report their symptoms as less bothersome compared to before their surgery. The mid-urethral sling has been studied as long in follow-up as any other procedure for SUI and has demonstrated superior safety and efficacy. This includes a recent 17 year follow-up study.

Can the procedure be redone?

Yes, a sling procedure can be repeated if necessary. Due to scarring after your original mesh repair procedure, repeat surgeries may be more complicated.

When will I see results?

In most cases, you will see results immediately after the procedure with little pain or discomfort. Many women are able to return to their daily activities within several days.



What about the information I have heard about mesh usage?

The FDA has recently stopped the sale of transvaginal mesh used in a different surgical procedure called Pelvic Organ Prolapse (POP) repair after considering it equivalent⁹ but not superior to other alternatives¹⁰. Transvaginal mesh used for Vaginal Prolapse is larger and placed in a different location than the midurethral sling mesh. Because mesh is used in both procedures, transvaginal mesh for prolapse and midurethral sling mesh for treatment of incontinence, there may be some confusion about the use of the term "mesh".

Transvaginal mesh for POP is no longer available because of the FDA decision but mid-urethral slings have NOT been affected and the FDA has determined them to be safe and effective¹¹.

Mid-urethral slings were approved in Europe in 1990 and in the United States in 1998, helping millions of women with SUI regain control of their lives since then. Prospective studies have followed patients with implanted mid-urethral slings for 17 years showing excellent durability and safety of the procedure¹².

This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years having the full support of the main Female Pelvic Medicine organizations in the US (AUGS and SUFU)¹³ and being used by >99% of their members¹⁴.

Risks:

Surgery carries some risks. If you experience vaginal discharge, redness or pain at the incision sites, pain that is severe or lasts longer than expected, slow urination flow, or the inability to urinate, it may be a sign of complications. Contact your physician immediately. You should discuss with your physician your recovery process, expected results, and the potential complications associated with having a Desara procedure.

WARNINGS AND PRECAUTIONS

Potential adverse reactions are those associated with surgery using implantable mesh materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, inflammation, fistula formation, and mesh exposure, erosion, or extrusion*. Punctures or laceration of vessels, nerves, bladder, urethra or bowel may occur during mesh placement and may require surgical repair.

*Extrusion of the mesh into the vagina is one of the most common adverse events¹⁵. You may be able to be treated in your doctor's office. In some cases, treatment may occur in the operating room. Be sure to discuss all treatment options with your physician. If mesh is exposed on the surface of the vagina, sexual intercourse may be painful for both you and your partner.

Sling procedures should not be performed on:

- Patients who are pregnant or planning future pregnancies.
- Patients with a urinary tract infection or with an infection in the operative field.
- Infants, children, or any patient with future growth potential.

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