Restore Your Confidence
A Woman’s Guide to Correcting Stress Urinary Incontinence

Ask your physician about the Desara® Family of Products

For more information please call
Caldera Medical
866.422.5337
YOU ARE NOT ALONE
Stress Urinary incontinence is the involuntary leakage of urine that affects over 15 million Americans, most of whom are women. This embarrassing condition can seriously affect all aspects of life – social, work and sex life. This guide is designed to inform you about Female Stress Urinary Incontinence and the surgical treatment options. With minimally invasive techniques available, you no longer need to live with this condition.

WHAT IS STRESS URINARY INCONTINENCE?
The bladder and urethra are supported by a group of pelvic muscles and connective tissue. As the muscles that support the bladder and urethra weaken, the bladder and urethra lose their support and move out of position, allowing urine to escape. By applying pressure to the abdomen through coughing, sneezing, laughing, lifting and exercising, you may leak urine. This common condition is called Stress Urinary Incontinence or SUI. SUI is the most common type of incontinence to affect women and it is estimated that one in three women will suffer the effects of SUI at some point in their life. It is also commonly misconceived to be a normal part of aging. In fact, it can happen at any age.

THREE TYPES OF INCONTINENCE
• Stress Incontinence - Involuntary leakage of urine with cough, sneeze, or exertion.
• Urge Incontinence - Sudden and involuntary leakage of urine due to a powerful urge to urinate.
• Mixed Incontinence - Involuntary leakage of urine with sneeze, cough, exertion and urgency.

TALK TO YOUR PHYSICIAN ABOUT THE DESARA FAMILY OF PRODUCTS TODAY!
A few questions you should ask your physician:
• Will Desara help manage my incontinence?
• What should I expect during the Desara procedure?
• What will the normal recovery time be?
• What are the risks and benefits of having the Desara procedure?

Useful Resources:
• American Urogynecological Society (AUGS) / Voices for PFD: http://www.voicesforpfd.org/
• AUGS Guidelines and Statements: http://www.augs.org/p/cm/ld/fid=202
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These diagrams compare a normal female pelvis to one with SUI. Notice in the diagram demonstrating SUI, the bladder has slipped out of place and the urethra is no longer in the correct position.

**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 events.1 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 patients 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.

1FDA’s Urogynecologic Surgical Mesh Implants Website: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm

**SYMPTOMS**
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 have sudden urges to urinate and trouble holding your urine?
• Do you wear pads to protect against leaks?
• Have your daily activities been affected by your leakage of urine?

**WHAT CAUSES SUI?**
The pelvic muscles and connective tissue are weakened by:
• Pregnancy
• Child Birth
• Menopause
• Previous Pelvic Surgery
• Obesity
• Smoking

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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 urethra to reduce SUI.

Bulking agents consist of a collagen or a biocompatible substance injected around the urethra to reinforce the surrounding tissues. 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. Surgery has the highest success and cure rate compared to other treatment options.

• 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.

• Use over-the-counter pain medicine such as Tylenol or Advil for pain control. A prescription narcotic pain medication may be prescribed by your doctor if necessary. Please contact your doctor if your pain is not adequately controlled.

• Do not have intercourse, douche, or place anything in the vagina for six weeks after surgery.

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

• 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.

CONGRATULATIONS ON YOUR DECISION TO GET YOUR LIFE BACK!

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POST-OPERATIVE CARE

You have just undergone a sub-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 sometime 2 to 4 weeks after the surgery.

• 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.”

• For 4 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.

• Routine activities such as getting dressed, shaving legs, etc., are fine. Low impact exercise such as stretching, “easy” Yoga or Pilates moves, and aerobic exercise limited to walking is OK. In fact, WALKING IS ENCOURAGED!! Avoid swimming, biking and high-impact aerobics.

YOUR RECOVERY

Even though you may feel well, your body needs time to heal, allowing your body’s tissue to incorporate the sling. You should avoid sexual intercourse, heavy straining and lifting for approximately 4 weeks after surgery. Strenuous activity or returning to certain activities too soon may negate the outcome of the procedure. Pain from the procedure is usually minimal. Some pain after surgery is normal and is to be expected. Your physician may prescribe medication to help with pain and an antibiotic to help prevent infection. A catheter may be inserted to drain urine from your bladder. Depending on your recovery process your physician will decide on the length of time this will be needed.
**FREQUENTLY ASKED QUESTIONS**

**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. Limited data are available beyond this point.

**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.

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**INFORMATION ON SURGICAL MESH PROCEDURES**

The mesh procedure used to treat stress urinary incontinence (SUI) is different than that used to treat another common women’s health condition, pelvic organ prolapse (POP). Procedures using mesh to correct both POP and SUI were the subject of an FDA Safety Communication in July 2011. After further review of clinical studies for SUI, an FDA panel concluded that retropubic and transobturator slings, such as Desara, have been extensively studied, and that the safety and effectiveness of these devices is well-established.

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**YOU NO LONGER NEED TO BE EMBARRASSED!**
Thousands of women have chosen Desara and are enjoying the freedom and control that it provides. With the minimally invasive techniques that are available today, there is no reason to live with incontinence! Improve the quality of your life and restore your active lifestyle.

Please ask your physician for more information on how the Desara Family of Products can help you.

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- Menopause
- Previous Pelvic Surgery
- Obesity
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