

Take Control of Stress Urinary Incontinence



The information in this guide is not intended to replace any discussion with your doctor, or any of the materials he or she may give you. By taking the time to read this guide, you have already taken an important step towards correcting your incontinence and restoring the active lifestyle you've always enjoyed.

Acknowledgment

Coloplast would like to acknowledge and thank Matthew E. Karlovsky, M.D., for his partnership in the development of the information provided in this brochure.

With treatment options available for incontinence, women can now get back in control and restore their active lifestyle.

What is urinary incontinence?

Urinary incontinence is the involuntary loss of urine from the body. It affects over 13 million Americans, 85% of whom are women. Urinary incontinence that occurs with straining or with activities is known as stress urinary incontinence (SUI).

Typical activities that can provoke leakage of urine are running, jumping, coughing, sneezing, laughing, and even sexual intercourse. While incontinence is often considered an aspect of aging, in many cases it can be treated. Multiple treatment options exist for patients. If fluid restriction and pelvic floor muscle exercises do not improve a woman's urinary incontinence, then an incontinence pessary worn in the vagina may provide relief. When none of the above non-surgical options reduce symptoms, surgical correction may be considered.

How does a normal bladder work?

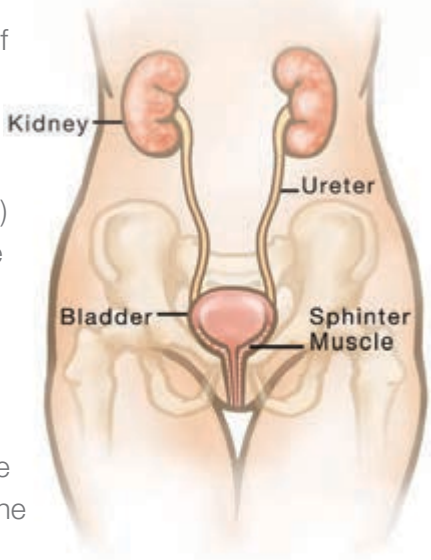
The bladder is a hollow organ in the lower abdomen. It stores urine; the liquid waste produced by the kidneys. Urine passes from each kidney into the bladder through a pair of tubes called ureters. Urine exits the bladder to the outside of the body through another tube called the urethra. The urethral opening lies under the clitoris, and above the vagina.

As the bladder fills with urine, pressure is exerted on the bladder wall and the desire to void is felt. This triggers the brain to send a message to the layer of muscle

that surrounds the inner lining of the bladder, forcing the muscle to contract (tighten) which forces the urine to flow out of the bladder.

At the same time, the sphincter muscle that surrounds the urethra relaxes,

letting the urine flow out of the body. This process requires both nerves and muscles working together to prevent urine leakage.



Are you showing signs of incontinence?

Below are some simple questions to help start a dialogue with your doctor:

Do you leak urine unexpectedly?

- Yes No

What is the severity of leakage?

- Mild (a few drops)
 Moderate (wet undergarments)
 Severe (wet clothing)

Do you leak urine when you:

- Cough? Sneeze? Laugh?
 Bend? Lift?
 Change positions (i.e. sitting or laying to standing)?
 Engage in sexual intercourse?

Do you leak urine continuously during the day?

- Yes No

Do you leak urine while sleeping?

- Yes No

Has urine leakage caused you to change your lifestyle?

- Yes No

If yes, how has your lifestyle changed?

- Limiting fluids Staying home
 Limiting clothing to dark clothes
 Stop exercising Other

If you answered yes to any of these questions incontinence may be preventing you from enjoying your life. Speak to your doctor to find the most effective treatment option for you.

What causes incontinence to occur?

There are many types of urinary incontinence, in this brochure we will only be discussing stress urinary incontinence.

Stress urinary incontinence can develop slowly with age, and may often be a result of childbirth. It can also occur with chronic or repetitive straining (constipation, chronic coughing, high impact aerobics), menopause or even a hysterectomy.

Damage, weakening or injury to the muscles supporting the urethra can result in stress urinary incontinence. It occurs when weak pelvic floor muscles, especially at the bladder neck opening and urethral sphincter, cannot reflexively tighten during times of increased pressure on the bladder and the urethra. This leads to the urine involuntarily escaping.

Stress urinary incontinence commonly occurs with:

- Laughing
- Sneezing
- Coughing
- Lifting
- Exercising
- Entering/exiting a vehicle
- Sexual intercourse
- Increasing abdominal pressure in any other way

Another type of stress incontinence is called Intrinsic Sphincter Deficiency (ISD). It occurs when the urethral sphincter, which opens and closes the bladder neck opening, does not function properly. Talk to your doctor to learn more about the type of incontinence you may have and available treatment options.



What to expect at the doctor's office

It is important to diagnose your incontinence correctly to ensure the appropriate treatment option is selected. Your physician will want a complete medical and surgical history, a list of all medication and supplements, as well as information about your urinary habits and all fluids consumed. It's important to accurately describe the problems you are having, such as when and under what conditions leakage occurs.

It may be beneficial to track your voiding habits in a journal to share with your physician. This 3-day voiding diary should include information such as what you drink, number of times you urinate and if you have episodes of leakage.

A voiding diary is provided for your use at the back of this pamphlet.



Common tests used to diagnose incontinence

- **Urinalysis**—testing of the urine sample
- **Stress test**—fluid inserted into the bladder to check for leaking
- **Post-void residual**—measures the amount of urine left in your bladder after urinating
- **Cystoscopy**—use of a scope to examine your bladder
- **Urodynamics**—testing that measures:
 - › Amount of urine in the bladder before urinating
 - › Force of the urine as it leaves the body
 - › Internal pressure of the bladder as it fills with urine
 - › Control of the urethral sphincter muscles

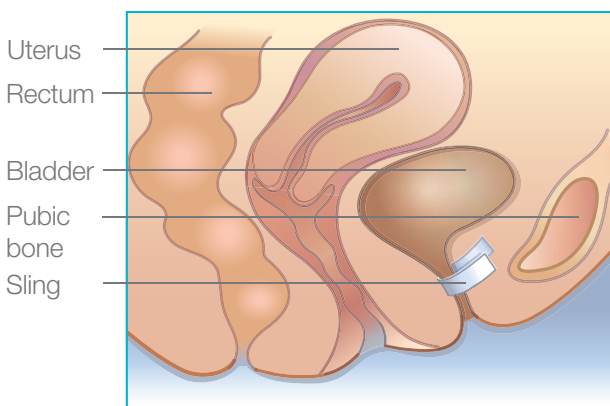
Treatment options

If you have been diagnosed with stress urinary incontinence, it is important to understand your options. This brochure explains a surgical treatment option that can provide relief.

However, surgery is not suitable for everyone, and you should discuss all solutions available with your doctor.

Non-surgical options are pelvic muscle exercises, protective under garments, behavioral therapies, catheters, vaginal pessaries and bulking injections.

Surgical options are open bladder neck suspensions, and sling procedures. A sling procedure corrects stress incontinence by placing a small strip of synthetic or biologic material beneath the urethra, and like a backboard, it supports the urethra during straining maneuvers or other activities, and can prevent leakage from occurring.

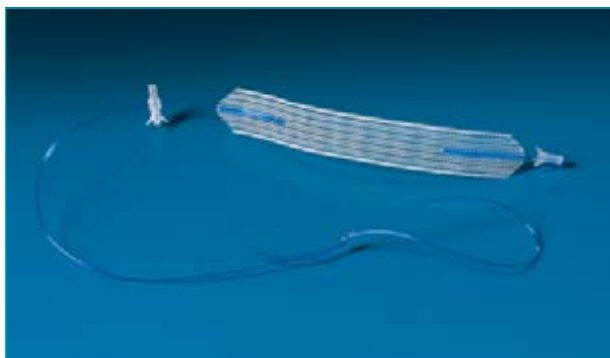


What happens during the surgery?

A sling procedure is the most common minimally invasive surgical option to correct stress urinary incontinence. It is usually performed as an outpatient procedure in under 30 minutes, however an overnight stay may be necessary.

There are a variety of approaches to place a sling, since there are many different types of slings available. The type of sling chosen is based on a number of factors, including the severity of incontinence, prior pelvic surgery, patient and physician preference.

This brochure discusses the Altis® Single Incision Sling System. This procedure is performed under local, regional, or general anesthesia. The Altis sling is made from a polypropylene light-weight mesh. The combination of sling and tissue ingrowth under the urethra becomes the new substructure for urethral support.



Coloplast Altis® sling.

In general, placing the sling involves the following steps:

- A small incision will be made in the vagina
- The sling is inserted into the incision and placed under the urethra
- The sling has anchors on each side to provide holding power during tissue ingrowth
- Finally, the sling is adjusted specifically for your body

After the sling is properly positioned, it forms a cradle under your urethra, which provides support, helping to prevent urine from escaping during activities or straining.

What happens after the surgery?

Your doctor will discuss post-operative instructions and recovery time with you. In general, expect a period of time to refrain from exercise, physical activity, straining and sexual activity. It is important to know that following a sling procedure, future pregnancies may negate the effects of the surgical procedure, and you may once again become incontinent.

Although every patient's recovery is different, there are general recovery guidelines that apply to most sling procedures. A sling procedure is a minimally invasive surgery; however, an overnight hospital stay may be required. You may experience some minor discomfort and fatigue during the first 24 to 72 hours after surgery.

Your doctor will provide specific details about your individual recovery process, and he or she may have other recommendations based on your individual needs. Please follow your physician's directions closely.

Your body needs to heal properly from the surgery and allow the sling material to incorporate within your body's natural tissue.

Should any problems occur after surgery, contact your physician immediately. This is especially important if a high temperature occurs, or if the surgical area becomes excessively painful, red or inflamed.

Are there any risks?

Having a procedure to correct stress urinary incontinence with a synthetic sling can cause some known risks, including:

- Vaginal extrusion
- Erosion (e.g. vaginal, urethral)
- Dyspareunia (i.e. painful intercourse)
- Sling migration
- Infection
- Pain
- Hematoma
- Scarring
- Transient or permanent urinary retention/obstruction
- Urethral obstruction
- Voiding dysfunction
- Nerve injury
- Vascular injury
- Bladder, bowel, urethra, vessel and/or nerve perforation

You should consult with your doctor to discuss these risks in detail.

Mesh used to correct incontinence may cause pain. You may also be able to feel the mesh inside of the vagina; when this occurs, the mesh may interfere with intimate sexual activity. Other risks you may experience are an increase in the need to urinate, or your urine flow may be slower. You may also not be able to urinate naturally following the procedure. This result may be temporary, but it may last a month or longer. If this occurs, you may need to have a catheter inserted to help you urinate, or you may need another operation to have the sling clipped or cut. Depending upon the severity of your symptoms, it may be necessary to undergo repeat surgery in an attempt to relieve your symptoms

You may have a reaction to the sling material itself. Another potential complication is infection, which may require treatment with antibiotics. Talk to your doctor about these risks and reactions.

It is important that you understand and consider the potential risks of a permanent implant as well as the benefits when choosing the best treatment option for you.



FDA Information

On October 20, 2008, FDA issued a Public Health Notification on serious complications associated with surgical mesh placed through the vagina to treat pelvic organ prolapse and stress urinary incontinence. Subsequently, on July 13, 2011, FDA released a safety communication update on transvaginal placement of surgical mesh for Pelvic Organ Prolapse.

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/default.htm>

Ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:*

- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- Are you planning to use mesh in my surgery?
- What are the alternatives to surgical mesh repair, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- What if the mesh surgery doesn't correct my problem?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?

Voiding diary

The voiding diary on the following pages is an important tool to help you and your physician better identify your condition and choose the best treatment for you. *Please complete it as accurately as possible for three days (day ☀ and night 🌙).*

How to complete:


- Each day, begin recording upon rising in the morning and continue for a full 24 hours.
- List all fluid intake.
- List each time you go to the bathroom to urinate, and record the amount of urine in ounces (any container can be used to measure output—but be consistent each time). If unable to measure, list as small, medium or large amount.
- In the “Leakage amount” column, write a 1, 2 or 3 to record the volume of leakage.
- If you changed a pad or any protective garments, mark that column with an “X.”
- In the “Activity” column, write down what you were doing when the leakage occurred. For example: coughing, sneezing, laughing, walking, sleeping, etc.

Bring this brochure and the completed diary when meeting with your physician.



Coloplast

Voiding Diary – Day 3

Time A.M. 	Fluid intake (amount of liquid in ounces)	Voided amount in ounces or S/M/LG	Leakage amount 1=damp 2=wet but not dripping 3=soaked or dripping	Changed pads or protective garments (mark with an "x")	Activity during leakage

Time P.M. 	Fluid intake (amount of liquid in ounces)	Voided amount in ounces or S/M/LG	Leakage amount 1=damp 2=wet but not dripping 3=soaked or dripping	Changed pads or protective garments (mark with an "x")	Activity during leakage

Insurance coverage

In most cases, Medicare and private insurance plans cover sling procedures. Consult with your insurance carrier before seeing your physician to find out the specific criteria for coverage. The reimbursement specialist at your doctor's office may also be able to help with this.



Returning to an active lifestyle

Many women find it difficult to talk about incontinence due to potential embarrassment about the subject or the intimate nature of the problem. There are many options for treating or managing incontinence and it is important to discuss all of the options with your doctor.

By treating your incontinence successfully, you are getting back in control and are free to return to the active lifestyle you have always enjoyed.

Learn more about treatment options for stress urinary incontinence and how Coloplast can make your life easier.

www.straighttalk.net
www.us.coloplast.com

Coloplast – Your partner in women's health care

Coloplast is a Danish company, globally represented in 33 countries, with a 50-year legacy of listening and responding to the needs of our customers. We develop, manufacture and market medical devices and services in ostomy care, wound care, and surgical urology and continence care, striving to improve the quality of life for people. With a continuously evolving portfolio of women's health products, Coloplast is working to provide solutions that help improve quality of life for women globally.

Reference:

- ¹ Juma S, Brito C G (2009, February). Aris Transobturator Sling: Three Years Follow-Up. Poster session presented at the 2009 Society of Urodynamics and Female Urology (SUFU) Annual Meeting, Henderson, NV.

Ostomy Care
Urology & Continence Care
Wound & Skin Care



Coloplast Corp.
Minneapolis, MN 55411
1.800.258.3476
usmedweb@coloplast.com
www.us.coloplast.com

The Coloplast logo and Altis are registered trademarks of Coloplast A/S.
© 2013. All rights reserved. Coloplast Corp., Minneapolis, MN USA.

M2468N 08.13