

Stress Urinary Incontinence Urethral Bulking Agent



STRAIGHT Talk

With treatment options available for incontinence, women can now restore, and may improve 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 surgical correction becomes the next common option.

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.

How Does a Normal Bladder Work?

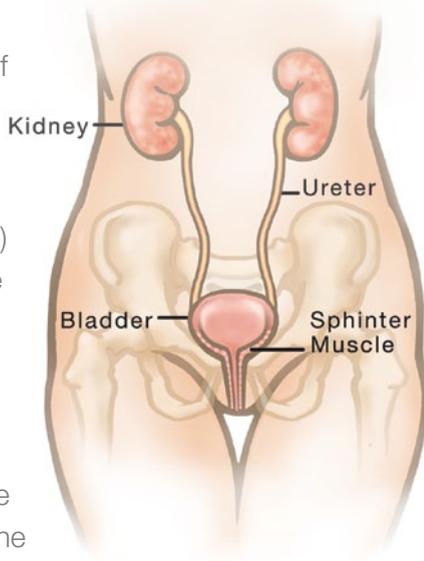
The bladder is a hollow organ in the lower abdomen. It stores urine; the liquid waste produced by the kidneys. Urine passes from each kidney into the bladder through a pair of tubes called ureters. Urine exits the bladder to the outside of the body through another tube called the urethra. The urethral 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. Damage, weakening or injury to either the muscles or nerves of the urethra can result in urinary continence.



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 or if you know incontinence is preventing you from enjoying your life, speak to your doctor. They will find the most effective treatment option for you.

Intrinsic Sphincter Deficiency (ISD) is a form of Stress Urinary Incontinence

One type of incontinence is stress urinary incontinence—it can develop slowly as you age, and may often be a result of childbirth. It can also occur with chronic or repetitive straining on the pubourethral ligament from things such as constipation, chronic coughing, or high impact aerobics. Other causes include menopause or hysterectomy.

ISD is a form of incontinence that happens when there is damage, weakening or injury to the muscles or nerves of the urethra. When ISD occurs, the muscles are no longer strong enough to retain urine.

Someone with ISD will notice leakage with:

- Laughing
- Sneezing
- Coughing
- Lifting
- Exercising
- Increasing abdominal pressure in any other way



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 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 that you understand your options. This brochure explains a minimally-invasive, non-surgical treatment using Coloplast's Durasphere® EXP which can provide relief from intrinsic sphincter deficiency.

Durasphere EXP is known as a “bulking agent,” a substance that helps the weak muscles of the bladder neck by adding bulk to the area, increasing the ability to resist urine leakage during exercise or other activities.

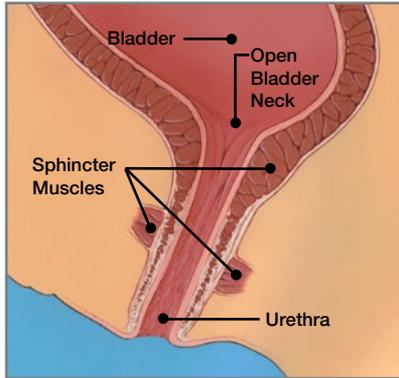
Durasphere EXP is a water-based gel, into which tiny carbon-coated beads are placed. It is a black, odorless, sand-like material, placed through a hollow needle into the middle layer of tissue surrounding the urethra. Once injected, the gel is dissolved by the body, leaving the tiny beads in place permanently. These tiny beads add “bulk” to the urethra muscles, allowing the bladder neck to close enough to stop urine from leaking. When you decide to empty your bladder the urethra expands, allowing urine to pass.



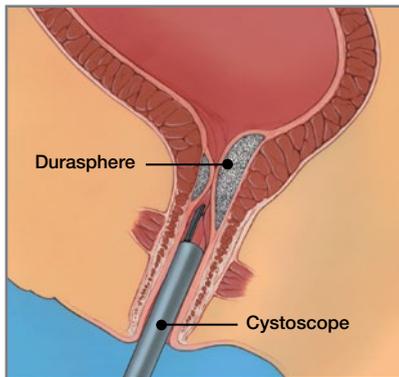
Durasphere EXP

These illustrations show how adding Durasphere EXP helps stop leakage by closing the bladder neck.

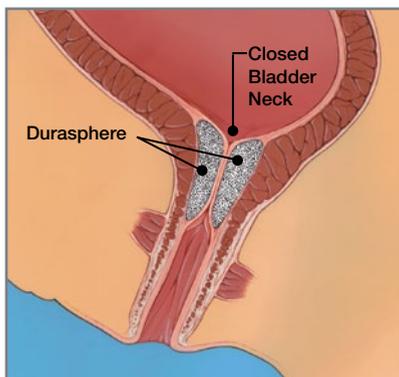
Untreated urinary system with open bladder neck



Durasphere® EXP placement



Bladder neck after treatment with Durasphere EXP



Frequently asked questions

Will I have more than one treatment? If so, when?

You could. About one-half of patients will need only one treatment. The time between treatment ranges from four to six months.

Will I become dry or improved after treatment?

Most people will benefit from treatment with Durasphere® EXP. 6 out of 10 will be dry and 9 out of 10 will be improved after treatment.

Will I stay dry or improved?

Most do. About two-thirds are improved at 12 months after treatment and about one-third are dry. 8 out of 10 patients who receive a single treatment are improved at 12 months following treatment. Five out of 10 patients who receive two or more treatments are improved at 12 months following treatment.

Tell me more about what will happen during the treatment.

- The procedure can usually be performed in under 20 minutes, and can be performed either as an in office procedure or an out-patient procedure in the hospital.
- The urethra will be numbed with a pre-injection prior to treatment with Durasphere EXP.
- Next, a thin needle is inserted through the cystoscope and Durasphere EXP is injected into the numbed areas. The cystoscope is then removed and the treatment is complete.

Will I feel pain?

More numbing medication will be given if you do. You will likely be discharged home with pain medication by your physician. If performed in the hospital, medications may be given through your vein so you will sleep during the procedure. With these medications it is unlikely that you would be aware of any pain.



Can I go home the same day as the treatment?

Yes. You will stay in the recovery area until you pass urine normally, usually within a few hours. If you can't urinate, a thin, soft rubber tube (catheter) will be placed into your bladder to help you. This procedure will be repeated until you pass urine normally.

What can I expect during the first 24 hours following the procedure?

You might have some pain when you urinate. You could also feel an urgency to urinate, even if there is little urine present. You may see some blood in your urine that could make it appear pinkish or reddish in color. Any discomfort should go away within the first 24 hours. If it does not, you should call your doctor. Can I go back to my usual activities when I get home? Your doctor will give you specific instructions regarding your activity level. You should avoid heavy lifting for a day or two. Most people return to their usual activities in one to two days.

Can Durasphere® EXP leak out?

Yes, you may notice some black specs or sand-like material in the toilet or on your pad after you urinate. This is normal and will go away in a few days.

What things should I know about before I decide to be treated?

There are several things to think about before making the decision to be treated with Durasphere EXP. They are classified as contraindications (risk greater than benefit), warnings (potential for serious harm), precautions (situations which involve special attention) and adverse events (conditions that are associated with the use of Durasphere EXP).

Are there any risks?

You should not have the procedure at this time if you have inflammation of the bladder (cystitis) or the urethra (urethritis) or other infection. Tell your doctor if you have pain and/or frequency when you urinate because these symptoms may be a sign of infection. After your infection has resolved, treatment can again be considered.

Narrowing of the bladder neck or urethra is called stricture. If you are treated when you have strictures, the urethra could be blocked and you may be unable to pass urine. Tell your doctor if you have to strain in order to start urinating, as this may be a symptom of stricture. Your doctor will be able to discuss the treatment options for strictures.

Safety and effectiveness have not been proven in pregnant women or in women who have had children after receiving Durasphere® EXP.

Conditions/symptoms such as urinary tract infection (UTI), retention of urine, urgency to urinate, painful urination and blood in the urine are common and expected events following treatment with bulking agents. Six out of 10 patients will experience mild and brief (less than 24 hours) symptoms. Some patients will experience prolonged (greater than 24 hours) Durasphere EXP related symptoms such as: retention of urine or feeling of incomplete emptying lasting 7 days or less (16%), urgency to urinate (13%), painful urination (12%), UTI (9%), retention of urine or feeling of incomplete emptying lasting for longer than 7 days (6%), or blood in the urine (6%). You should consult your doctor if symptoms last over 24 hours.

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.

Ostomy Care
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