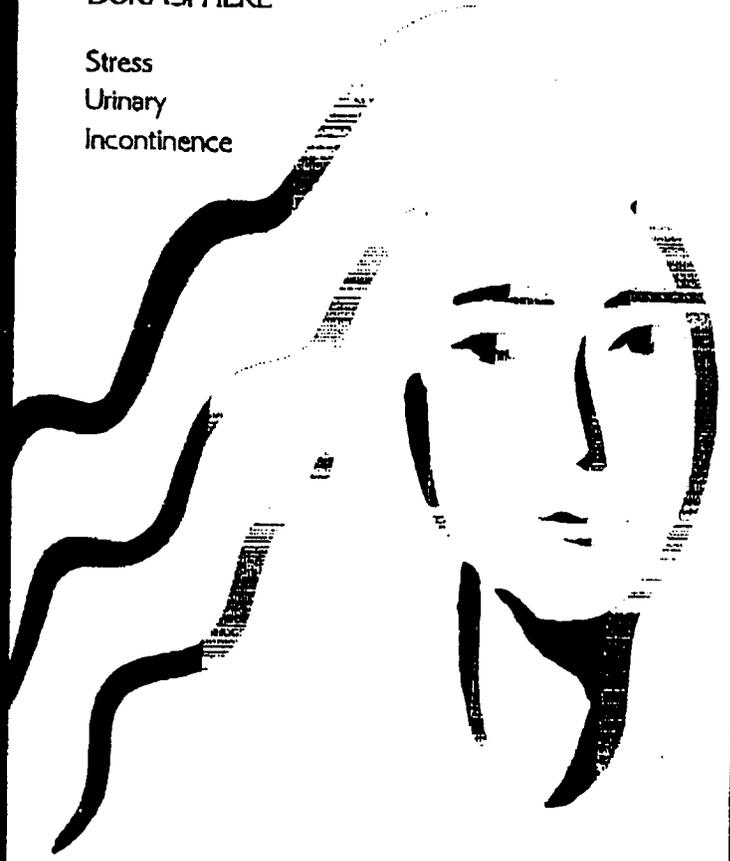


A PATIENT'S GUIDE
TO TREATMENT
WITH
DURASPHERE

Stress
Urinary
Incontinence



PATIENT BROCHURE



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Back Cover

Front Cover



Introduction

This brochure has been given to you to help you decide whether treatment with Durasphere™ is right for you. You should know about another, although more invasive surgical option that is available to treat your condition. This surgery repositions your bladder neck to restore the normal angle between your bladder and urethra. You should discuss other treatment options, along with any questions you have about the Durasphere procedure, with your Doctor before you decide to be treated.

 **DURASPHERE™**
SETTING THE STANDARD

What is Durasphere?

Durasphere is a material that is placed through a hollow needle into tissues around your bladder neck to cause them to fill out (bulking agent). It is used to help adult women who accidentally leak urine. Durasphere is a water-based gel into which tiny, carbon-coated beads are placed. It is a black, odorless, sand-like material.

How can Durasphere help me?

There are many reasons you might leak urine. Sometimes the muscles (urinary sphincter) surrounding the tube that carries urine to the outside of the body (urethra) aren't



strong enough to help hold back urine. This condition is called **Intrinsic Sphincter Deficiency** and is one of the causes of a type of incontinence called **Stress Incontinence**.

As a result of this condition, you may leak urine when you sneeze, cough, or exercise. Durasphere works by helping the muscles hold back urine.

How does Durasphere work?

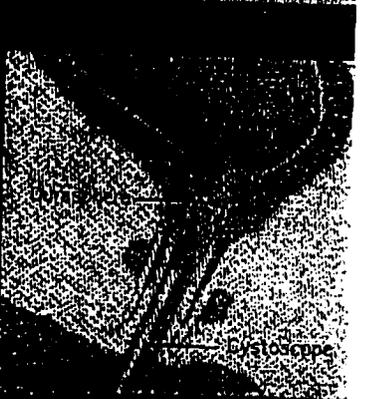
After it is placed, Durasphere helps the weak muscles of the bladder neck by adding bulk to the area. The added bulk allows the bladder neck to close enough to help stop urine from leaking. When you decide to empty your bladder, the opening from the bladder into the urethra expands, allowing urine to pass through.

These illustrations show how adding bulk with Durasphere helps stop leaking by closing the bladder neck.

Unaugmented urinary system with open bladder neck



Durasphere placement



Bladder neck after treatment with Durasphere



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

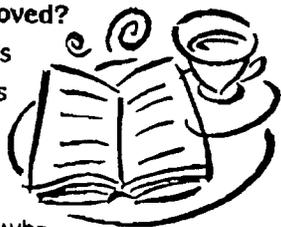
You could. About one-half of patients will need only one treatment. The time between treatment ranges from four to six months.

Will I become dry or improved after treatment?

Most people will benefit from treatment with Durasphere. Six out of 10 will be dry and nine 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.



Eight out of 10 patients who receive a single treatment are improved at 12 months following treatment. Five out of 10 patients who received two or more treatments are improved at 12 months following treatment.

Tell me more about what will happen during my treatment.

You will be given pain-deadening medication, similar to what you may have experienced before dental work. After the area is numb, a rigid, hollow tube called a cystoscope will be inserted into your urethra. This will allow your doctor to see the bladder neck area into which Durasphere will be placed. Next, a thin needle is inserted through the cystoscope and Durasphere is injected into the numbed areas. The cystoscope is then removed and the treatment is complete.

Will I feel pain?

After a local anesthesia will be given if you do not receive the numbing medication is administered. Medications may be given through your arm 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 will 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. This 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 leak out?

Yes. You may notice some black specks 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. 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).

Contraindications

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.

Warnings

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.

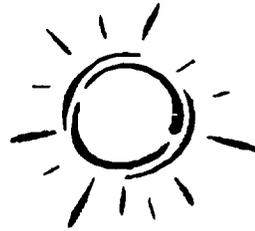
Precautions

Safety and effectiveness have not been proven in pregnant women or in women who have had children after receiving Durasphere. Long-term safety and effectiveness of Durasphere is being evaluated and is not yet known.

Adverse Events

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 more prolonged (greater than 24 hours) Durasphere-related symptoms such as: retention of urine or feeling of incomplete emptying lasting 7 days or less (16%), urgency to urinate (15%), 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 physician if symptoms last over 24 hours.

Glossary



Adverse event:
An undesirable event reasonably associated with the use of a device.

Bladder: A muscular organ in which urine is stored.

Bladder neck: The lower portion of the bladder, continuous with the urethra.

Bulking agent: A substance that is injected into tissues that causes those tissues to fill out or 'bulk'.

Catheter: A sterile, soft rubber tube that is inserted into bladder, through the urethra to drain urine.

Contraindications: Alerts the user to situations where the product should not be used because the risk of using the product outweighs the benefits.

Cystoscope: Instrument that is inserted through the urethra to examine the bladder and internal urethra.

Incontinence: The involuntary leaking of urine.

Precaution: Alerts the user to exercise special care necessary for the safe and effective use of the product.

Stricture: A narrowing of a passageway.

Urethra: A short, narrow tube that carries urine from the bladder to the outside of the body.

Urinary sphincter: A muscle that assists in controlling urine flow.

Warning: Alerts the user to potential serious outcomes.