Durasphere®EXP
Injectable Bulking Agent

Office Procedure Guide

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I. Overview

"Durasphere® EXP has become a key element in our arsenal against female urinary incontinence."

— Dr. Steven Bernstein, M.D.

Introduction

Durasphere® EXP is an injectable bulking agent containing pyrolytic carbon-coated graphite beads suspended in a water-based carrier gel. Pyrolytic carbon has long been used in implantable medical devices, including replacement heart valves, since the 1960s. Durasphere EXP is indicated for the treatment of women with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD).

There are many benefits to the office procedure.

Patient and Physician Benefits

- Improved patient perception of less invasive procedure and more comfortable setting
- Potential for lower patient out of pocket based on average 20% Medicare coinsurance[1]
- Increased office efficiencies for physician
  - Ability to attend to and treat more patients per day
  - No down time for hospital room turnover
  - Medicare reimbursement for Physician's Services is greater in office setting versus hospital[1]

Product Benefits

The body cannot degrade Durasphere's pyrolitic carbon-coated beads. The injectable beads are 90-120 microns, which is larger than the 80 micron threshold for migration.[2] No skin test or special handling is required. 65% of 70 patients tested maintained improved outcomes after five years.[3] Durasphere is the only bulking agent on the market that is not contraindicated for use in women with a fragile urethral mucosal lining.

Hospital to Office Transition

"Over the years, a transition has occurred as many physicians have shifted their practice from the hospital setting under general and regional anesthesia into their individual offices under local. Advantages of office-based therapy may include increased convenience and time efficiency for both the patient and physician, favorable patient perception of an office-based procedure, and potential cost savings to the patient."—Dr. Steven Bernstein, M.D.

Durasphere®EXP
Injectable Bulking Agent

Treat easily. Treat effectively.

Effective.

64.6% of patients maintained improved outcomes at 5 years.[3]

Permanent.

Pyrolitic carbon-coated beads cannot be degraded by the body.[2]

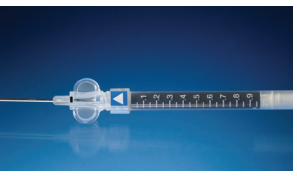
Versatile.

Can be injected using the periurethral or transurethral technique

Pencil Point Tip needle

- Designed to puncture, not cut or core.
- Side port delivery allows material to flow easier.
- Tapered 20-gauge needle tip. Reduces tissue trauma and injection site extravastion.*

*When compared to an 18-gauge injection needle



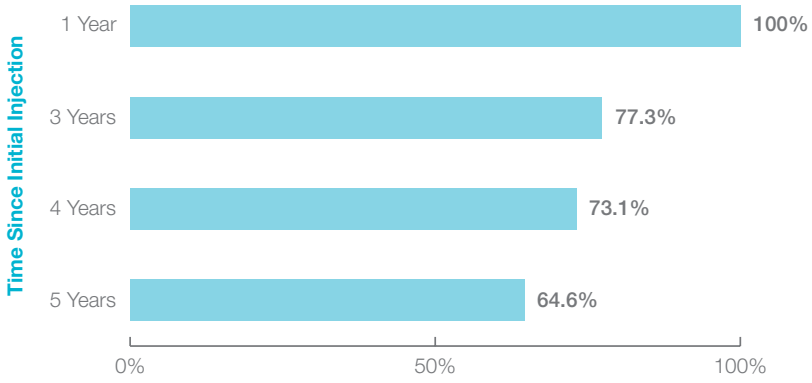
Injection force required to evacuate a syringe of bulking material

Product	Injection Force*
Original Durasphere	5268.6 gm
Coaptite®	5042.5 gm
Contigen®	3832.5 gm
Durasphere EXP	2647.5 gm

Durasphere® Post-Approval Study 5-Year Follow-up Data

The safety and efficacy of Durasphere Injectable Bulking Agent was determined through a clinical trial. As part of the FDA PMA approval for Durasphere, patients who were improved at 12 months post procedure were followed for an additional 4.2 years on average. (Average time from initial injection equals 5.2 years.) Following are the results of this post-market follow-up of 70 participants, 46 of which were followed for the full 5 years.[3]

Percent of Patients Maintaining Improved Outcomes*



*Four subjects received one additional injection procedure after entering into this post-approval study. Subjects who went on to a surgical intervention for stress urinary incontinence were categorized as not maintaining improved outcome for this analysis.

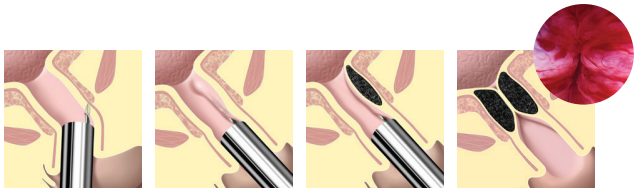
Ordering Information 800.258.3476

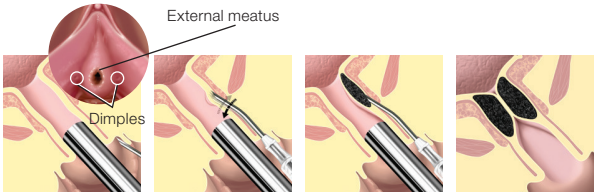
TRANSURETHRAL TECHNIQUE

Description	Order Number
Syringe size: 1 ml	890-215
Needle: 15 inch, pencil point tip, 20 gauge	890-209

PERIURETHRAL TECHNIQUE

Description	Order Number
Syringe size: 3 ml	890-216
Needle: 1.5 inch, spinal tip, 18 gauge	890-204





*Data on file at Carbon Medical Technologies, Inc.

Clinical Support

A New Injectable Bulking Agent for Treatment of Stress Urinary Incontinence: Results of a Multicenter, Randomized, Controlled, Double-Blind Study of Durasphere®

Prepared by Coloplast

Journal of Urology, July, 2001

D. Lightner, C. Calvosa, R. Anderson, I. Klimberg, C.G. Brito, J. Snyder, D. Gleason, D. Killion, J. MacDonald, A.U. Khan, A. Diokno, L.T. Sirls and D. Saltzstein

Study Objectives:
Durasphere compared with bovine collagen (Contigen®) in the treatment of SUI due to ISD.

Methods:
Multicenter, randomized, controlled, double-blind trial was composed of 355 women diagnosed with SUI due to ISD.

All patients had a leak-point pressure of less than 90 cm H2O (average 51).

Results:
At 12 months after the first injection, the two materials were equivalent with respect to the improvement in continence grade and pad weight testing.

Less Durasphere was injected to obtain comparable clinical results (Durasphere 4.83 ml vs. Contigen 6.23 ml), and this was statistically significant with P-value = 0.001.

12 months after last injection, 80.3% of women treated with Durasphere showed improvement of one continence grade or more compared with 69.1% of women treated with Contigen. Though not statistically significant @ P-value = 0.162, the difference is directionally superior with Durasphere .

No skin test needed with Durasphere/Durasphere EXP.

Discussion:
“This study demonstrated the equivalent safety and efficacy of Durasphere compared with bovine collagen. It is anticipated that in ongoing post-approval studies, Durasphere will prove to be more durable.”

“Pelvic x-rays taken of study patients after injection, and repeated at one and two years after injection, demonstrated the stability of the bulking agent at the injection site…”

“Urethral bulking agents offer a less-invasive augmentation of the urethra than sling procedures and artificial sphincters.”

“Although bovine collagen injection therapy has proved to be a safe and effective form of treatment for ISD, the material has completely degraded within 9 to 19 months, requiring repeated injection to sustain its successful result. Durasphere, however, was designed to be permanent.”

Clinical Support

New Periurethral Bulking Agent for Stress Urinary Incontinence: Modified Technique and Early Results

Prepared by Coloplast

Journal of Urology, July, 2001

S. Madjar, C. Covington-Nichols, and C. Secrest

Study Objectives:

To present a modified injection technique for easier implantation of Durasphere®.

To present early results using this technique.

Methods:

Utilizes the standard transurethral injection technique in the office setting.

A single needle stick is made at the 4 o'clock position.

1.5 ml of 1% lidocaine is injected through the Durasphere injection needle into the site of injection.

Durasphere is injected immediately following the lidocaine without repositioning the needle.

Slight withdrawal or rotation of the needle if resistance is met.

The needle is left in place 10 seconds after complete coaptation is observed to decrease extravasation.

Patients are seen at 4 weeks following procedure.

Results:

Patients were in the age range of 46 to 83 (mean 69.4).

The procedure was well tolerated.

Excellent or good coaptation was achieved in 92% of injections.

More than 65% of the patients considered themselves to be improved or cured of stress urinary incontinence.

Discussion:

"Using the technique described, we were able to inject the agent with good urethral coaptation in the majority of our patients."

"The procedure is brief, well tolerated and can be performed using local anesthesia in an office setting."

"Complications were not noted…"

*Prepared by Coloplast on behalf of Carbon Medical Technologies, Inc.

II. Procedure

"Durasphere® EXP is a great, simple, minimally-invasive option for females with ISD who may have failed other therapies or are not satisfactory candidates for sling"

— Dr. Steven Bernstein, M.D.

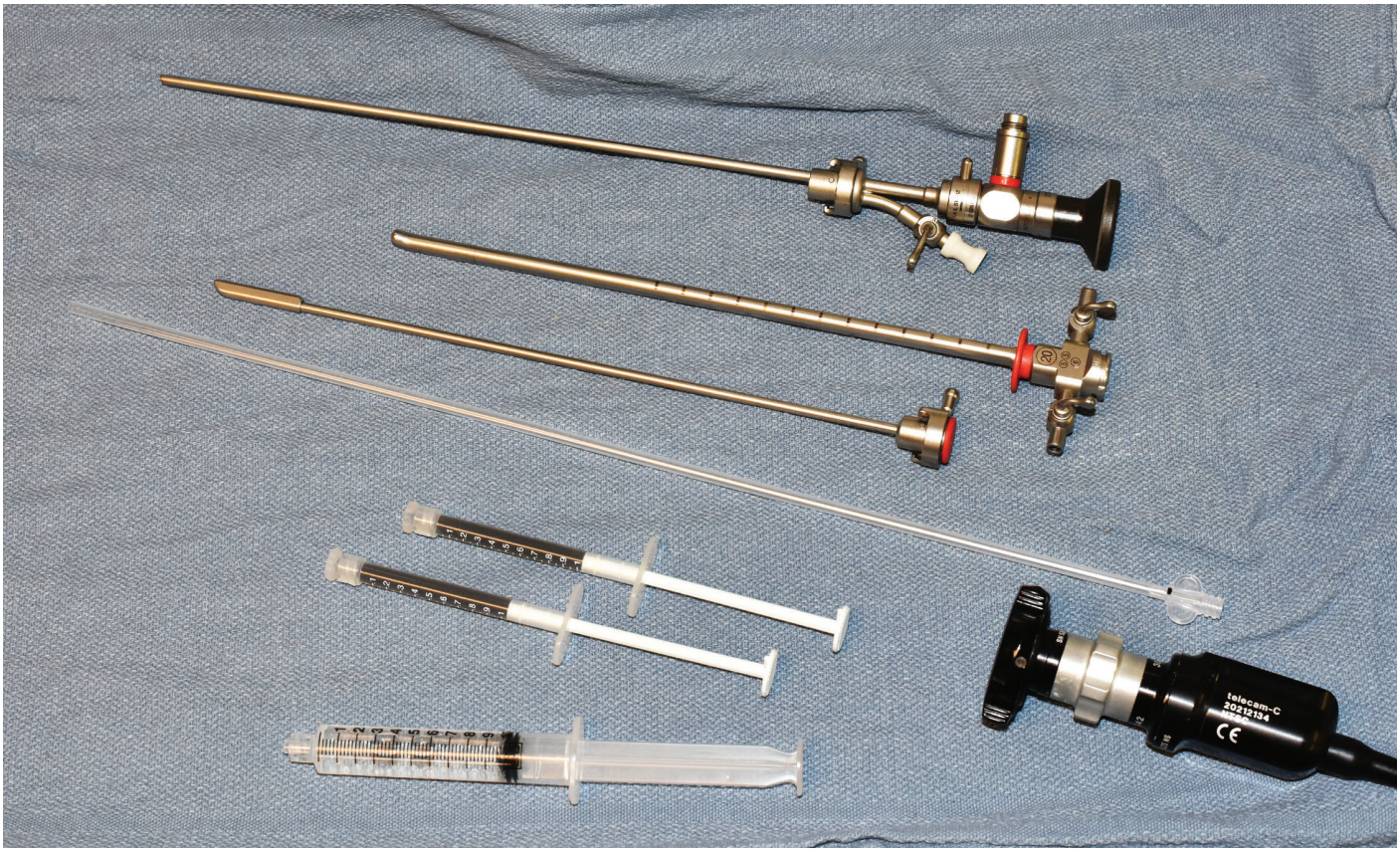
Procedure setup

The supplies and equipment needed to perform Durasphere® EXP procedures are the same as those required for cystoscopy:

- Lidocaine jelly
- Injectable either 0.25% bupivacaine or 1% lidocaine (without epi)
- Small syringe/needle to draw up bupivacaine/lidocaine
- Rigid cystoscope, 20 Fr with 30 degree lens, and light source
- Camera is recommended

Procedure Technique	REF	Product information
Transurethral technique	890-215:	Durasphere EXP 1 ml syringe
	890-209:	15” transurethral injection needle
Periurethral technique	890-216:	Durasphere EXP 3 ml syringe
	890-204:	1.5” periurethral injection needle

See information specific to the cystoscope for requirements.



Anesthesia

For most patients, the Durasphere® EXP procedure requires only local anesthesia. The following technique[3] has been used effectively in office procedures:

- Place the patient in the lithotomy position and prep the perineum with antiseptic.
- Insert 2% lidocaine jelly into the urethra; leave in place 5-10 minutes.
- Prime Durasphere EXP injection needle (REF #890-209) with 0.25% bupivacaine or 1% lidocaine (with or without epi) and place injection needle down the channel of cystoscope.
- Place cystoscope into the urethra, introduce injection needle into the submucosal tissue at the mid-urethra and inject 1-2 cc of lidocaine.

Rigid Cystoscopes

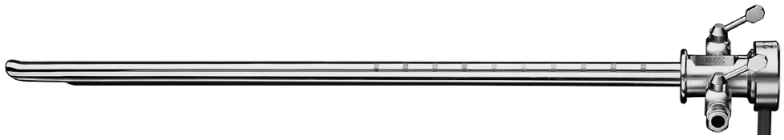
Rigid cystoscopes are manufactured in many sizes from different manufacturers, but basically they are similar and consist of the following parts: sheath, obturator, bridge, and the telescope.

SHEATH

Purpose: The sheath is the outermost rigid part of the instrument. It serves to protect the interchangeable telescopes which are delicate and expensive, and can be damaged if bent or dropped. The proximal end of the sheath has two irrigation ports, one for the introduction of the irrigation medium and the other for its egress. The distal end of the cystoscope sheath is cut away in a fenestration to permit the use of operative instruments. Opposite the fenestration, the sheath is beveled to enhance the comfort of introduction into the urethra.

Beveled tip

Fenestration – open window



Because irrigation fluid leaks at the urethral meatus until the fenestrated tip is completely inserted, this design makes working in the urethra difficult. Unlike cystoscopy sheaths, urethroscopy sheaths are cut flush at the distal end, having a shorter beak and no fenestration. This allows distention of the bladder neck and more complete visualization of the urethral walls.

Sheaths are available in various calibers, which are measured by their diameter, usually using the French (Fr) scale. The smallest diameter sheath for adults is a 17Fr. As the French (Fr) size increases, there is more room for the placement of instruments into the irrigation-working channel. Using a 20 Fr sheath allows the injection needle to be introduced into the sheath at the 6 o'clock position which greatly facilitates needle control during the procedure.

OBTURATOR

Purpose: Obturators can be introduced into the sheath to provide a smooth tip for insertion into the urethra. The closed obturator provides a solid intact tip for blind introduction and a visual obturator accommodates a telescope to allow the sheath to be introduced under vision.

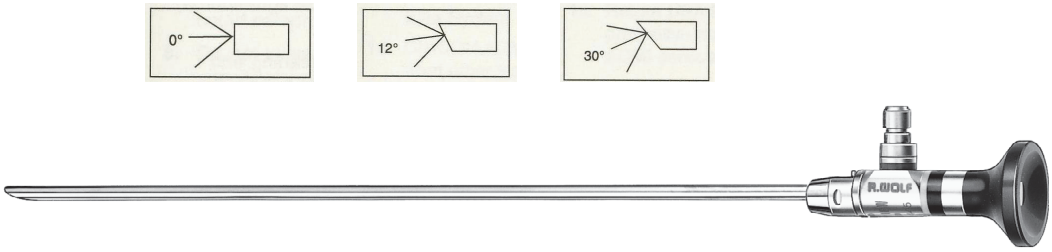
BRIDGE

Purpose: The bridge serves as a watertight connector between the telescope and the sheath. It may have one or two angled side-arms for introduction of instruments (e.g. injection needle) into the irrigation-working channel; the single breidge is preferred for transurethral injection of Durasphere®.

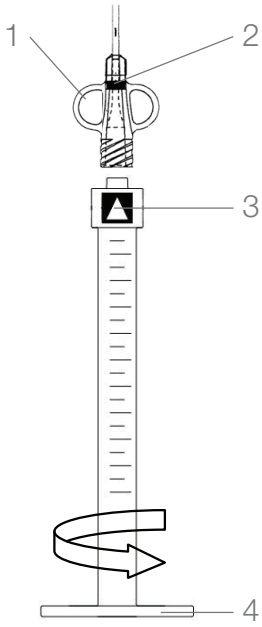
TELESCOPE

Purpose: The telescope carries the fiber optic illuminating system. Telescopes are available in several viewing angles, which are determined by the lens angle relative to the instrument's long axis.

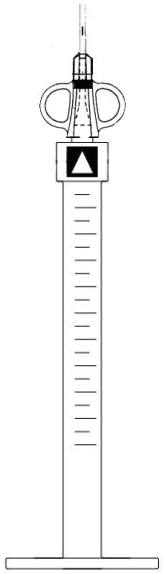
Lenses focused to look directly forward are 0° telescopes; a 30° telescope provides a forward oblique view, the 70°, a lateral view and the 120°, a retrograde view. The 30° view provides the best view of the injection needle which is situated below the telescope within the sheath.



Syringe/Needle Assembly

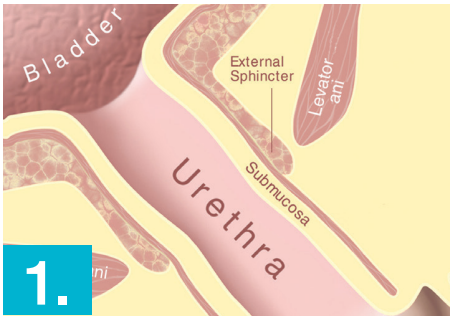


1. Use proper sterile technique when assembling the syringe to the needle
2. Hold the needle by its wings (1) with one hand.
3. With the other hand, grasp the syringe and align the arrow on the syringe tip (3) with the dark bar (2) located on the needle hub.
4. Turn the syringe to connect it to the needle hub.
5. Take the hand that is on the syringe and move it back to the wings of the syringe barrel (4). Finish tightening the syringe to the needle. This will require a full 360º rotation until the arrow is once again aligned with the dark bar locate on the needle.



- To attach additional syringes, remove used syringe and attach new syringe using the same technique outlined above.

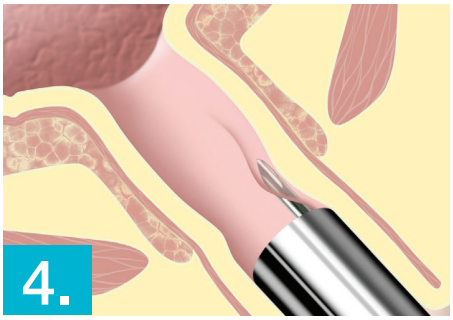
Transurethral Procedure



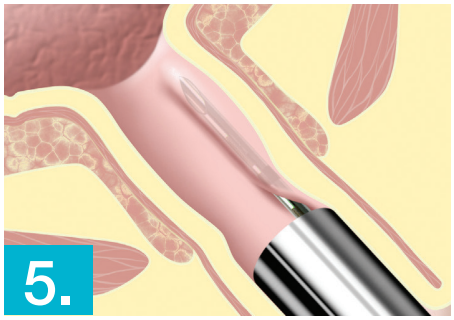
The objective of the procedure is to obtain closure from the bladder neck to mid-urethra by injecting Durasphere® EXP until the tissue surrounding the bladder neck coapts.

Using standard procedure, prepare the patient for cystoscopy. Attach a syringe to the injection needle and prime the needle. Insert the primed needle into the scope. Insert the scope into the urethra. At mid-urethra, choose a position betwen 4 and 8 o'clock

At the level o the mid-urethra, position the needle bevel toward the urethral lumen. Puncture tissue at a 45º angle until the bevel of the needle is covered in tissue. Do not insert past the bevel.

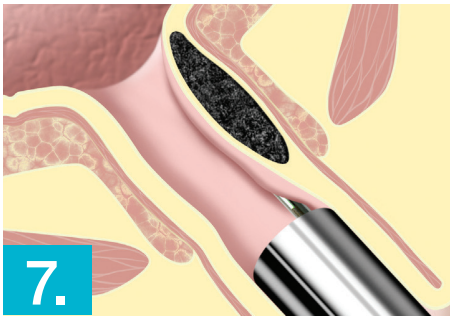


Re-angle the scope back parallel to the urethra. Advance approximately 1-2 cm and administer local anesthesia. Repeat on opposite side.

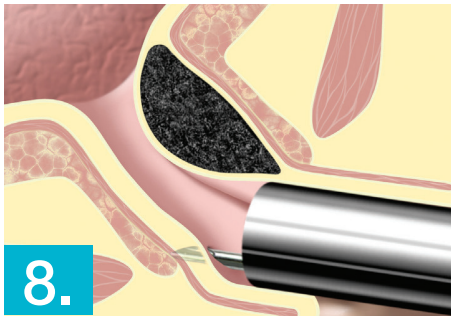


Using the circumferential markings on the needle as a guide, tunnel the needle tip toward the bladder neck 1-2 cm, depending on the approximated length between the mid-urethra and bladder neck. After tunneling, the needle tip should lie at the proximal urethra.

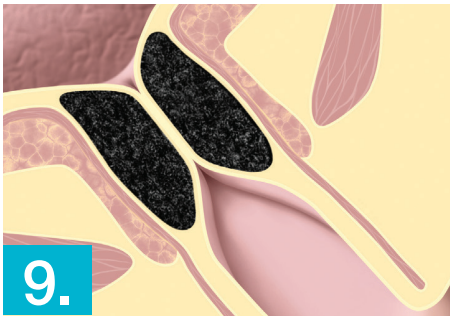
Begin injecting Durasphere EXP using consistent, moderate thumb pressure on the plunger. The flow should be even and smooth, similar to priming the needle.



The submucosal lining should begin to rise at the site during the injection. By rotating the bevel up and down, the flow of Durasphere EXP can be directed. Continue to inject Durasphere EXP in to this site until the bulge has crossed the midline of the urethra if possible.

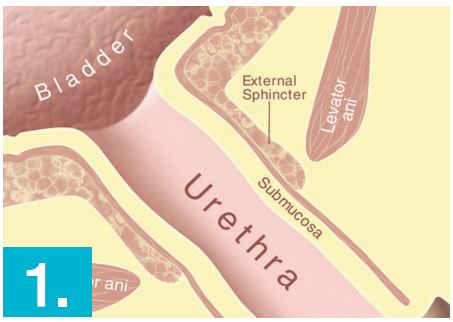


It may be necessary to choose an opposing site for injection. Repeat steps 3 through 7 at a second injection site if necessary. Most procedures will require approximately 4 ml of Durasphere EXP.

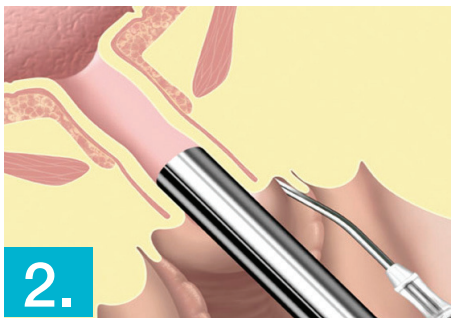


Continue to inject Durasphere EXP until the tissue surrounding the bladder neck coapts. The bladder neck should be closed when viewed with cystoscopic irrigation.

Periurethral Procedure



The objective of the procedure is to obtain closure from the bladder neck to mid-urethra by injecting Durasphere® EXP until the tissue surrounding the bladder neck coapts. Using standard procedure, prepare the patient for cystoscopy.



Along the periurethral sinus, there are two dimples, each located at the 3 and 9 o'clock position within 1 cm of the meatus. Position the needle tip at the dimple with the needle hup parallel to the scope. *NOTE: the proximal half of the needle will be angled away from the scope.*

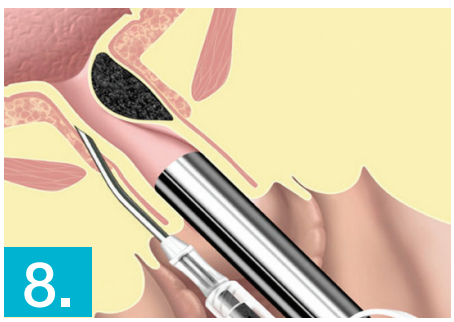
Penetrate the tissue and continue to advance the needle approximately 3 cm, keeping the needle hub parallel with the scope. The 15° bend guides the tip in an arc to the submucosal tissue between the lamina propria and the muscularis.

After advancing, the needle tip should lie in the proximal urethra.

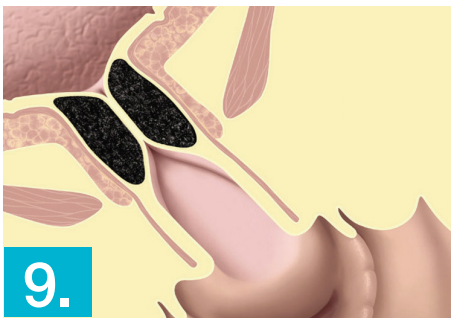
To verify placement of the needle tip in the submucosal tissue plane, look through the scope while gently wiggling the distal hub of the needle. Only the local area at the needle tip should tent.

To hydrodissect, inject fluid into the site. Temporary bulking of the tissue should occur. If not seen, reposition more superficially and repeat injection of a small amount of fluid. Switch to the Durasphere EXP syringe when the needle is in the proper position.

Begin injecting Durasphere EXP using consistent, light pressure on the plunger. While injecting, bulking of the tissue should be apparent. If circumferential closure of the bladder neck is occurring, continue to inject until complete coaptation is achieved.



If the Durasphere EXP product is not flowing circumferentially, continue to inject into the site until the bulge has crossed the midline of the urethra. Reposition the needle on the opposing side and continue injecting. Most procedures will require approximately 4 ml of Durasphere EXP.



Continue to inject Durasphere EXP until the tissue surrounding the bladder neck coapts. The bladder neck should be closed when viewed with cystoscopic irrigation.

Frequently Asked Questions

What is Durasphere® EXP?

Durasphere EXP is an injectable bulking agent that is composed of pyrolytic carbon-coated beads suspended in a water-based carrier gel. It is indicated for the treatment of adult women with Stress Urinary Incontinence (SUI) due to Intrinsic Sphincter Deficiency (ISD).

Is a skin test required prior to placing Durasphere EXP?

No, a skin test is NOT required. No allergic responses or hypersensitivity have been experienced with Durasphere EXP to necessitate a skin test.

What are the long-term results?

At a mean follow-up of 5 years, 65% of the 70 Durasphere EXP patients who were improved at one year stated that they continued to be improved or dry as a result of their treatment(s) with Durasphere EXP.[3]

Is Durasphere EXP reimbursed?

The Durasphere EXP procedure is covered by most health insurance payers. However, it is important to remember that reimbursement for all medical procedures is dependent upon the payer, type of insurance, and any contractual relationships between the payer and the provider. Payer coverage of a medical procedure is normally defined by medical necessity criteria, which likely includes diagnosis and procedure codes. Providers should consult their payer organizations regarding their local policies. Prior authorization is recommended.

Payer coverage of the Durasphere EXP procedure is often limited to Stress Urinary Incontinence (SUI) due to Intrinsic Sphincter Deficiency (ISD). The appropriate codes for this coverage scenario are:
CPT® Code 51715 – endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
HCPCS Code L8606 – injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe
ICD-9-CM Diagnosis Code 599.82 – Intrinsic (urethral) Sphincter Deficiency (ISD)
ICD-9-CM Diagnosis Code 625.6 – Stress Incontinence, Female
Note: for insurance claims submission, report 3 units if using a 3 ml periurethral syringe, or 1 unit for every 1 ml transurethral syringe used.

Is a special scope needed for Durasphere EXP injections?

No; both the transurethral and periurethral techniques require a standard cystoscope. However, because the cystoscope guides the needle in the transurethral procedure, a straight working channel is required for this technique. It is helpful to use a sheath without fenestration on the ventral end, as fenestration opening allows irrigation to exit the sheath outside the meatus, rendering the irrigation useless for distending the urethra.

It is helpful to use a 19/20 French sheath without fenestration, a 30 degree lens, and a single bridge. While many physicians are comfortable using a simple scope, some physicians prefer to use “injection scopes,” which are specifically designed for this type of procedure; excellent results can be achieved with either device.

Why do I occasionally have difficulty injecting the bulking agent into the tissue?

Ensure the needle is attached as tightly as possible to the syringe by holding the wings and giving it an extra turn after tightening. The gel in the material takes the path of least resistance. Under pressure, if the connection is not airtight, gel will leak, increasing the concentration of beads in the syringe and proximal end (nub end) of the needle, causing them both to clog. When clearing a clogged needle, always use a 1 ml syringe filled with fluid.

It is possible that the needle tip is located in dense muscle tissue rendering it difficult to inject. If there is pressure resistance, withdraw the needle slightly, reposition more superficially and try again.

Where are the best injection sites?

For the transurethral technique, experienced users suggest choosing a position at the mid-urethra between 3 and 9 o’clock. After making the initial puncture at mid-urethra, tunnel the needle tip toward the bladder neck 1-2 cm, depending on the approximate length between mid-urethra and bladder neck. These locations are generally the most successful for the primary injection site. It has typically been found that the most effective injection is the first injection.

For the periurethral technique, medial and lateral to the meatus there are two dimples, each located at the 3 and 9 o’clock position. Locate the side that is most comfortable for you as the starting point. If coaptation is not achieved, introduce the injection needle on the opposite side to achieve coaptation of the proximal urethra.

How much Durasphere® EXP is injected?

The objective of the procedure is to obtain closure of the bladder neck to mid-urethra (proximal urethra) by injecting Durasphere EXP until the tissue surrounding the proximal urethra coapts. Approximately 4 ml are used per procedure to achieve coaptation and may be accomplished with one or multiple sites.

How is Durasphere EXP packaged?

Durasphere EXP comes in a 1ml and 3 ml syringe. The 1ml syringe is designed for use with the transurethral technique and the 3ml syringe is designed for use with the periurethral technique.
The 3 ml syringe is not intended to be used transurethrally through the 15 inch needle because the long needle requires higher pressure, which is produced by the 1 ml syringe, to effectively open the tissue pocket at the tip of the 15 inch needle. The 3 ml syringe does not provide adequate pressure. The 3 ml syringe is intended for use with the 1.5 inch periurethral needle.

What are the guidelines for retreatment?

Retreatment may be considered when the initial injection does not result in the patient becoming dry. It is best to wait for a period of 90 days from the previous procedure to allow the material and tissue to heal properly. During this time, the carrier gel is replaced by the body's own collagen. If a retreatment is attempted to soon, the patient may lose some of the benefit of the existing bulking material.

What adverse events are uniquely associated with Durasphere® EXP injection therapy?

Durasphere EXP has no adverse events that are different than those associated with cystoscopy and other injectable bulking agents. Adverse events related to Durasphere that were reported by >5% of patients during the clinical study included: retention, dysuria, urinary urgency, urinary tract infection, and hematuria. See our directions for use for more detail.

Can a Foley catheter be used to treat retention following a Durasphere EXP procedure?

Yes, Foley catheters can be used without concerns of molding or stress on the bulked areas. It is important to use the smallest sized catheter possible. Another very effective way of dealing with retention is intermittent catheterization.

Can Durasphere EXP be used after other incontinence procedures?

Yes. Durasphere EXP has effectively been used in conjunction with surgical incontinence procedures as well as after a failed bulking procedure using a different product.

Can Durasphere EXP be removed?

If you choose to remove Durasphere EXP, this can be done by making a small incision or puncture in the bulked musoca.

Does Durasphere EXP migrate?

The targeted Durasphere EXP bead size ranges from 90 to 212 microns, which is larger than the 80-micron threshold for particle size associated with migration issues.[2]

How does Durasphere EXP affect MRI and X-ray images?

MRI: Durasphere EXP beads are non-metallic and inert. Therefore, an MRI's radio frequency is absorbed by the bead and does not produce scatter. MRIs have been successfully performed on patients who were implanted with the beads. No artifacts were created, no scatter was observed and there was no adverse impact on the quality of the magnetic resonance scanning.

X-ray: Durasphere EXP pyrolytic carbon-coated graphite beads are not radio-opaque, and therefore do not show up on x-rays.

MSDS information can be requested by calling Coloplast Customer Service.

III. Physician Procedure

"Durasphere® EXP has given us the opportunity to 'tweak' results after suboptimal stabilization procedures and to offer significant therapy to patients who were otherwise not considered candidates for treatment."

— Dr. Steven Bernstein, M.D.

Durasphere® EXP Injection Therapy An Office Procedure

Written by Steven Bernstein, M.D.

Dr. Bernstein is a female incontinence specialist in Minneapolis. In his focused practice Dr Bernstein utilizes tools for behavioral modification, pharmachotherapy, anatomic correction and neuromodulation. He has been using Durasphere as a tool to address intrinsic sphincter deficiency since 2004, initially in the hospital setting but exclusively in the office since 2006.

Disclosure: This training is sponsored by Coloplast. Dr. Bernstein was compensated for this summary.

PATIENT SELECTION

Key indications for Durasphere injection are the presence of ISD in patients who have undergone sling procedure with satisfactory stabilization but suffer from persistent SUI (which we refer to as 'sling rescue') and patients who are not considered satisfactory candidates for pubovaginal sling.

PROCEDURAL SETUP

The office set-up is very basic. It begins with the standard 20 French cystoscope, 30 degree lens and single bridge. The use of a camera and monitor is recommended but not required. Standard irrigation and prep are used.

Additions to the standard cysto setup include local anesthetic (as previously described) and the Coloplast injection needle (part # 890-209). We open two syringes of Durasphere EXP to have on our table and have a third ready to open if necessary; the syringe caps are removed prior to beginning the procedure.

As part of the preparation we remove the needle sheath and prime the needle with local. At this point the patient is brought into the procedure room.

In our office we have a nurse to assist, as per routine cysto cases. Once the case begins, however, the physician handles all of the syringes and needles during the procedure. The only exception to this is if the third Durasphere syringe is required; the nurse will then open that package and place it on the procedure table.

INJECTION PROCEDURE

Informed consent is reviewed. The patient is placed in the low lithotomy position and a sterile prep is performed.

Lubricating jelly is used either with or without anesthetic. Cystoscopy is performed to establish the location of the patient's anatomic landmarks. The bladder is drained and the scope is withdrawn.

The needle, previously primed with local, is then placed into the sheath. Care is exercised to ensure that the needle remains at the 6 o'clock position in the sheath and that the tip is not advanced beyond the end of the cystoscope. The scope containing the needle is then introduced into the bladder. The needle is advanced just beyond the tip of the scope and the camera is focused on the tip. The tip is rotated into the 9 o'clock position.

The scope is angled 45 degrees to the patient's longitudinal axis. With moderate irrigation flow the scope is gradually withdrawn to the level of the bladder neck and proximal urethra. It is useful to 'lay' the needle tip on the urethral mucosa at this point as you begin to 'slide' the needle proximally toward its destination in the mid urethra. Once in the midurethra we notify the patient that they are about to experience the first of the two "mosquito bites" to the urethra and the needle is advanced into the periurethral tissue. Initial travel is several mm on the 45 degree axis, after which the needle is angled more parallel to the patient's longitudinal axis and advanced several additional mm. The local anesthetic is then carefully injected in a slow, gentle manner. Development of a 'bleb' of local should be visible through the scope. Blanching of the urethral mucosa suggest that the injection is slightly superficial to the ideal plane. Difficulty with infusion suggests that needle placement is somewhat deep to the intended plane. Care is exercised to refrain from overdistension of the bleb which could result in rupture. The needle is withdrawn back into the sheath and the bladder is emptied through the sheath.

The patient's left side is treated in an identical manner with the injection site at the 3 o'clock position. Again, the bladder is emptied upon completion of the injection.

A Durasphere EXP syringe is then loaded onto the needle. Care is exercised to ensure that the syringe is well-secured. The needle is then primed until Durasphere is just visible at the needle's port. The needle is loaded back into the sheath at the 6 o'clock position and advanced into the bladder.

As per the injection with local, the needle is carefully 'dragged' back along the urethra at the 9 o'clock position to the level of the midurethra. The previous puncture site is often visible and can be utilized. The needle is then advanced into the periurethral tissue at 45 degrees for several mm and then longitudinally for several additional mm. The Durasphere EXP is then injected in a slow, gentle manner. Progress of the bleb is directly visualized through the scope. In most cases the entire syringe is injected. Ideally, the bleb should reach, or even cross, the midline.

Once the right side of the urethra is addressed the bladder is emptied, the syringe is replaced with the second Durasphere® syringe and treatment is performed on the patient's left side in an identical manner. The bladder is drained and the scope is withdrawn.

In the rare case of significant bleeding, direct pressure can be applied from the vaginal side for several minutes with excellent results.

POST-PROCEDURAL CARE

Patients are encouraged to return to their usually daily activities. Tub use and sexual intimacy are avoided for 48 hours. Although antibiotic use varies, our practice is to provide a single quinolone tablet upon completion of the procedure. Follow-up is arranged for one month.

The patient is advised that she may see some hematuria and/or Durasphere beads for the next several days; parameters of normal are given. Precautions about the rare case of post-procedure urinary retention are also given.

Disclosure

Steven Bernstein, MD is a paid consultant of Coloplast Corp.

This training is sponsored by Coloplast. This training is not approved for continuing education credit but it is intended to supplement each physician's education and training. Nothing in this training is a substitute for a physician's medical judgment, which may vary based upon each individual patient's circumstances. Before using any product discussed in this training, a physician must review all relevant product information, including indications, contraindications, warnings, precautions and adverse events—as well as the instructions for use and surgical protocol, as applicable.

IV. Reimbursement and Ordering Information

"Coloplast has done a great job providing support of the product and our practice."

— Dr. Steven Bernstein, M.D.

Reimbursement and Ordering Information

Coding Procedures
Many payers limit coverage for injectable bulking agents to patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). In these instances, ISD should be listed as the primary diagnosis and stress incontinence as the secondary diagnosis.

Diagnosis Codes	ICD-9 code: 599.82	Intrinsic (urethral) Sphincter Deficiency (ISD)
	ICD-9 code: 625.6	Stress Incontinence, Female
Injection Procedure Code	CPT code: 51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
Bulking Agent Code	HCPCS code: L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

For reimbursement and health insurance information, please contact us_reimbursement_inquiry@coloplast.com.

Durasphere EXP Ordering Information

TRANSURETHRAL TECHNIQUE

Description	Order Number
Syringe size: 1 ml	890-215
Needle: pencil point tip Size: 15 inch, 20 gauge	890-209

PERIURETHRAL TECHNIQUE

Description	Order Number
Syringe size: 3 ml	890-216
Needle: bent spinal tip Size: 1.5 inch, 18 gauge	890-204

Call Customer Service to order: 1.800.258.3476

References:

1. Federal Register Vol. 79 No. 219 Department of Health and Human Services, CMS, 42 CFR Parts 403, 405, 410, et al. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule … & Other Revisions to Part B for CY 2015; Final Rule, November 13, 2014
2. Lightner D, Calvosa C, Andersen R, Klimberg I, Gilberto-Brito C, Snyder J, Gleason D, Killion D, MacDonal J, Khan A U, Diokno A, Sirls L T, Saltzstein D. A new injectable bulking agent for the treatment of stress urinary incontinence: results of a multicentre, randomized, controlled, double-blind study of Durasphere. Elsevier Science Inc. 2001
3. Madjar S, Covington-Nichols C and Secrest C. New periurethral bulking agent for stress incontinence: Modified technique and early results. Journal of Urology. July 2003

DURASPHERE INJECTABLE BULKING AGENT BRIEF STATEMENT

Indications:
Durasphere is indicated for use in the treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency (ISD).

Contraindications:
Durasphere must not be used in patients with acute cystitis, urethritis, or other acute genitourinary infection.

Warnings / Precautions:
Do not inject Durasphere into blood vessels. This may cause vascular occlusion, platelet aggregation, infarction or embolic phenomena.

Adverse Events:
Adverse events related to Durasphere that were reported by >5% of patients during the clinical study include: retention, dysuria, urinary urgency, urinary tract infection and hematuria.

See the Instructions for Use for detailed information regarding the implant procedure. Warnings /precautions, adverse reactions, prior to using this product.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

CAUTION: Federal (USA) law restricts this device to sale by, or on, the order of a physician.

Coloplast Corp., 1601 West River Road North, Minneapolis, MN 55411 USA

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