



PURPOSEFULLY
DESIGNED

Durasphere[®] EXP

Injectable Bulking Agent

Durasphere[®] Procedural Technique

Durasphere[®] EXP

Injectable Bulking Agent

These instructions are for general use of this device in the treatment of female stress urinary incontinence and should not replace the directions for use (DFU). Variations in use may occur due to individual technique and patient anatomy.

STEP 1

Using standard procedure, prepare the patient for cystoscopy. Insert a cystoscope into the urethra. (For transurethral injection, use a 17 to 24 Fr. cystoscope with a minimum working channel of 5 Fr.)

STEP 2

Connect the Durasphere Syringe to the Carbon Medical Technologies Injection Needle and prime the needle.

WARNING: Do not inject Durasphere into blood vessels. Injection of Durasphere into blood vessels may cause vascular occlusion, platelet aggregation, infarction or embolic phenomena.

TRANSURETHRAL INJECTION



STEP 3

Advance the needle through the working channel of the cystoscope to the desired injection area.



STEP 4

Advance the needle to a point approximately 1 to 1 1/2 cm distal to the bladder neck and insert the needle tip under the mucosa. Advance the needle tip one half to one cm under the mucosal lining and begin injecting Durasphere. The longitudinal markings are in line with the beveled needle tip. Orient the bevel towards the center of the urethra. A bleb should be visible under direct vision with the cystoscope. If a bleb does not appear, withdraw the needle and reposition more superficially. Inject again.



STEP 5

After a bleb has been raised by the injection of Durasphere, reposition the needle away from the initial injection site. Repeat injection procedure until the bladder neck is closed. The procedure typically will require between 4 to 6 ml of Durasphere.

Go to Step 6

PERIURETHRAL INJECTION



STEP 3

Introduce the needle approximately 1 cm lateral to the urethral meatus.



STEP 4

Advance the needle through the perineum, parallel to the urethra, to the desired injection area (submucosal tissue of the proximal urethra). Proceed carefully during the injection procedure to avoid penetration of the urethral lining or bladder. Verify placement of the needle tip cystoscopically by gently moving the needle.



STEP 5

Inject Durasphere into the submucosal tissue until unilateral or circumferential closure is seen. If circumferential flow of material is being observed, continue injecting until complete coaptation of the bladder neck is seen with cystoscopic irrigation fluid on. If unilateral closure is observed, continue injecting until the submucosal tissue crosses the midline of the urethra. Remove the Injection Needle and repeat on the opposing side. Inject at the second location until coaptation of the bladder neck is seen with cystoscopic irrigation fluid on. Remove the injection needle.

Go to Step 6

STEP 6

Since the procedure is dependent on causing the mucosal lining of the bladder neck to balloon up, the treating physician should look for viable mucosal lining.

NOTE: If the Injection Needle is inserted into muscle rather than submucosal tissue, the Durasphere beads will not flow because muscle is too dense to accept the beads. The Durasphere gel will flow into muscle under extreme force. If this happens, Durasphere beads will clog the Injection Needle.

STEP 7

The physician may continue to use the Injection Needle and connect new Durasphere syringes to it or can use a new needle with each syringe of Durasphere.

CAUTION: After use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

NOTE: It is recommended that patients be kept in the setting or clinic where they receive their Durasphere injection until they are able to void on their own volition. In the event the patient experiences urinary retention, it can be managed by catheterization in the immediate post-injection phase and with clean intermittent catheterization should it persist.



DURASPHERE® EXP – INJECTABLE BULKING AGENT

Indication:

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.

The use of Durasphere with needles other than those recommended in the DFU may result in Durasphere beads clogging the injection needle.

Warnings:

Do not inject Durasphere into blood vessels. Injection of Durasphere into blood vessels may cause vascular occlusion, platelet aggregation, infarction or embolic phenomena.

Durasphere should not be used in patients with bladder neck or urethral strictures until such strictures have been corrected. Use of Durasphere on uncorrected strictures may cause occlusion.

The safety and effectiveness of Durasphere treatment during pregnancy has not been established. The effect of Durasphere on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effectiveness of Durasphere, is unknown. Therefore, the risks and benefits of the device in women of childbearing potential could be carefully assessed.

Durasphere containing pyrolytic carbon coated graphite beads is not visible under X-ray and requires magnetic resonance imaging (MRI) for visualization.

Precautions:

The treatment procedure and instrumentation associated with the injection of Durasphere carry a small risk of infection and/or bleeding, as do similar urologic procedures. The usual precautions associated with urologic procedures, specifically cystoscopy, should be followed.

Durasphere is supplied steam sterilized in sealed package and is intended for single use only. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged. Immediately return damaged product to Carbon Medical Technologies.

Do not re-sterilize. This may damage or distort contents. Unless the packaging is damaged, Durasphere will remain sterile until used.

Do not expose to organic solvents, ionizing radiation or ultraviolet light. This may damage or distort contents.

Rotate inventory so that product is used prior to the last day of the labeled month of the expiration date on package label.

After use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

Potential Complications:

Potential complications include acute retention, dysuria, urinary urgency, urinary tract infection, hematuria, non-acute retention, outlet obstruction (slow prolonged stream), excreted bulking material, GI (nausea, vomiting, diarrhea), genitourinary (infection, tenderness), urinary frequency, overbulking/abscess/cyst, infection, worsening of incontinence (onset of urge), neurological (headache), pelvic pain, allergic reaction to antibiotic, and fever.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

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

Ostomy Care
Continence Care
Wound & Skin Care
Urology Care

