JUNE MEDICAL UK

DURASPHERE®

Injectable Bulking Agent

CE 0086

INSTRUCTIONS FOR USE

DESCRIPTION

Durasphere is a sterile, nonpyrogenic injectable bulking material composed of pyrolytic carbon coated beads suspended in a water based carrier gel containing beta glucan.

MODE OF ACTION

Durasphere is injected sub-mucosally at the bladder neck. The injection of Durasphere creates increased tissue bulk and subsequent coaptation of the bladder neck and/or urethra. Over time collagen is deposited around the pyrolytic carbon coated beads. The final bulking result derives from the combination of the pyrolytic carbon coated beads and the body's own collagen.

INDICATIONS

Durasphere is intended for use in the treatment of urinary incontinence due to stress incontinence; a poor or nonfunctioning bladder outlet mechanism that may be helped by a locally injected bulking agent. Durasphere therapy should be initiated in patients who have shown no improvement in their urinary incontinence for at least 12 months.

CONTRAINDICATIONS

Durasphere must not be used in patients with an acute condition involving cystitis, urethritis or infection.

WARNINGS

- Durasphere should not be injected 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.
- For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

PRECAUTIONS

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

ADVERSE EVENTS

All patients can expect to experience some degree of dysuria, hematuria, urgency and frequency in the 24 hours immediately following injection of Durasphere. Most patients will have spontaneous resolution of these symptoms by the end of the 24 hours. Those who do not should contact their treating physician.

Some patients can expect to experience urinary retention as a result of Durasphere injection therapy. It can be managed by catheterization in the immediate post-injection phase and with clean intermittent catheterization should it persist. As a general rule, patients will be kept in the hospital or clinic where they receive their Durasphere injection until they are able to void on their own volition.

Adverse events associated with treatment may include but are not limited to: worsened incontinence; urinary retention; urinary tract infection; and/or localized responses (including swelling, erythema, induration, infection, necrosis, or abscess formation).

INSTRUCTIONS FOR USE

PRIOR TO USE

Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. DO NOT USE if damaged. Return damaged product to JUNE MEDICAL UK Ltd.

The injection of Durasphere requires the following materials:

- Durasphere Syringes
- Durasphere Injection Needles

PROCEDURE

1. Up to 10 ml of Durasphere may be injected into the sub-mucosal tissues of the urethra and/or bladder neck during a single injection procedure.
2. Using standard procedure, prepare the patient for cystoscopy. Using direct visualization in the urethra with a cystoscope, inject a local anesthetic into the proximal urethra.
3. Connect the Durasphere Syringe to the sterile Injection Needle and prime the needle. Introduce the needle approximately 1 cm lateral to the urethral meatus.
4. Advance the needle through the perineum, parallel to the urethra, to the desired injection area (submucosal tissue of the proximal urethra). The 15-degree angle of the needle guides the tip in an arc to the submucosal lining of the proximal urethra. Proceed carefully during the needle placement and injection procedure to avoid penetration of the urethral lining or bladder. Verify placement of the needle tip cystoscopically by gently moving the needle.
5. Inject Durasphere into the submucosal tissue using consistent light thumb pressure on the plunger until unilateral or circumferential closure is seen. This is typically accomplished by injecting 1 or 2 positions around the urethra. The patient's history of incontinence procedures should be taken into consideration when determining the injection location and volume. Initiate the procedure on one side of the urethra (typically at the 3 or 9 o'clock position). Inject with slow and consistent thumb pressure.
    - If circumferential flow of material is being observed, continue injecting until complete coaptation of the bladder neck is seen with cystoscopic irrigation fluid on. Average injection volume is approximately 3mls. Remove the injection needle.
    - If unilateral closure is observed, continue injecting until the submucosal tissue crosses the midline of the urethra (approximate injection volume is 1.5ml). 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 (approximate injection volume is 1.5ml). Total Injection volume is approximately 3mls. Remove the injection needle.
6. 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 and government requirements.

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.

NOTE: If incontinence persists after initial injection or if improvement is followed by recurrence of symptoms, treatment may be repeated after sufficient time has passed to evaluate prior to retreatment but in no case shall the patient be retreated within 7 days of previous treatment.

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HOW SUPPLIED

Durasphere is provided in individually packaged 3ml syringes. The contents of Durasphere syringes are sterile and nonpyrogenic.

The Durasphere system consists of:

Product	Contents	Appropriate Needle(s)	Latex Free
Durasphere 3ml syringe Catalog # 030971	Approximately 3ml of Durasphere Injectable Bulking Agent	Durasphere 1.5 in. (38.1mm) Injection Needle Catalog # 101086	YES

CAUTION: The use of Durasphere with needles other than those recommended in this IFU may result in Durasphere beads clogging the injection needle.

STORAGE

There are no special storage instructions for Durasphere or Injection Needles. The products should be at room temperature, 15 °C - 32 °C (59 °F - 90 °F), prior to use.

Do not resterilize. Unless the package has been opened or damaged, Durasphere and Injection Needles will remain sterile until used or expired.

Do not expose to organic solvents, ionizing radiation or ultraviolet light.

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the manufacturer's directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of this device and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Prices, specifications and model availability are subject to change without notice.

Durasphere® is a registered trademark of Carbon Medical Technologies, Inc.

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