CARBON MEDICAL TECHNOLOGIES, INC.

DURASPHERE® *FI*

Injectable Bulking Agent

DIRECTIONS 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.

CONTENTS

1ml or 3ml syringe of Durasphere (to be used only with Durasphere Injection Needles).

MODE OF ACTION

Durasphere achieves its intended effect by causing the submucosal lining of the anal canal along the dentate line to bulge or balloon up. Once this is accomplished, the rectal neck is then in better opposition than before the injection so the patient's ability to sense and hold feces will likely improve continence. 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 FOR USE

Durasphere is intended for the treatment of anal incontinence in men and women. Durasphere injections should be only initiated in patients who have documented symptoms of anal incontinence.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

Durasphere should not be injected into blood vessels. Injection of Durasphere into blood vessels may cause vascular occlusion, infarction or embolic phenomena.

PRECAUTIONS

The treatment procedure and instrumentation associated with the injection of Durasphere carry an inherent, yet minimal risk of infection and/or bleeding. The usual aseptic precautions associated with any surgical procedure in this area should be followed.

ADVERSE EVENTS

All patients can expect to experience some degree of transient pain from injection, possible discomfort with the first bowel movement, and minor spotting of blood. The symptoms are expected to resolve within twenty-four to forty-eight hours.

Adverse events associated with treatment may include, but are not limited to: worsened incontinence, fecal impaction, peri-anal irritation, sense of urgency to evacuate bowels, peri-anal abscess, anal stenosis or infection.

If injected in the blood vessels it may cause vascular occlusion, infarction or embolic phenomena.

INSTRUCTIONS FOR USE

To use Durasphere, physicians must be familiar with the use of injectable bulking agents and surgical procedures associated with the colo-rectal anatomy.

PRIOR TO USE

Durasphere is supplied steam sterilized in a 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.

The injection of Durasphere requires the following materials:

Durasphere Syringes (up to 15 ml of Durasphere may be injected into the submucosal tissue during a single injection procedure)

Durasphere Injection Needles (available in a variety of sizes)

INJECTION PROCEDURE

1. Per physician discretion, the patient may receive an enema the morning of the procedure to evacuate the rectum. Pre-operative antibiotics may be administered.
2. Administer a local anesthetic, which can be in the form of a standard pudendal nerve block at the level of the ischial spine or the perianal infiltration of a local anesthetic.
3. With the patient in a comfortable position, (preferably "Jack-Knife"), the scope is inserted to inspect the rectal neck and identify the dentate line.
4. Prior to injection, the injection sites should be swabbed with an anesthetic.
5. Introduce the injection needle perianally approximately 2 cm from the anal opening and advance the needle medially and upwards towards the submucosal tissue at or just above the dentate line. Digitally confirm needle placement in the submucosal tissue plane. Perforation of the anal mucosa could cause extravasation of the Durasphere material. If perforation occurs, reposition injection needle in a different location.
6. Slightly withdraw on the plunger to confirm that the needle tip is not in a blood vessel.
7. Inject the Durasphere into the tissue until the desired amount of bulking is achieved, using additional syringes of Durasphere as needed.

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. If this happens, Durasphere beads may clog the injection needle.

8. After obtaining the desired bulking effect, reposition the needle and repeat the injection procedure at additional locations as needed until the walls of the rectal neck can be seen, or felt, to oppose each other more effectively than prior to injection. The physician may continue to use the injection needle and connect new Durasphere syringes or can change needles if necessary.
9. After the procedure patients may be given a course of antibiotics and pain medications. Use of a stool softener may be recommended, as needed.

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

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.

HOW SUPPLIED

Durasphere is provided in individually packaged 1 ml or 3 ml syringes. The contents of Durasphere syringes are sterile and nonpyrogenic.

Do not use open or damaged packages. Do not use if packaging is not intact or if the syringes or needles appear to be damaged.

The Durasphere system consists of:

- Durasphere 1ml syringes, packaged individually, each containing approximately one ml sterile, injectable bulking material.
- Durasphere 3ml syringes, packaged individually, each containing approximately three ml sterile, injectable bulking material.
- Durasphere Injection Needles, packaged individually are sterile.

Durasphere is supplied steam sterilized in a 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.

STORAGE

There are no unusual storage instructions for the Durasphere or Injection Needles. The products should be at room temperatures, 60°F - 90°F (15°C - 32°C), prior to use.

Do not re-sterilize. Unless the packaging is damaged, the Durasphere and Injection Needles will remain sterile until used.

Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

WARNING

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.

WARRANTY

Carbon Medical Technologies 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 Carbon Medical Technologies' control directly affect the device and the results obtained from its use. Carbon Medical Technologies' obligation under this warranty is limited to the replacement of this device and Carbon Medical Technologies shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Carbon Medical Technologies 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 trademark of Carbon Medical Technologies, Inc.

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