INSTRUCTIONS FOR USE

INDICATIONS

The StabiliT Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertical augmentation or kyphoplasty technique. It is contraindicated where there is active or incompletely treated infection, at the site of bone grafting, and at the site of injection of any radiopaque material. This product is contraindicated with patients with coagulation disorders, or with severe pulmonary insufficiency.

DIRECTIONS FOR USE

The StabiliT Bone Cement is a polymethylmethacrylate (PMMA) radiopaque bone cement. The StabiliT Bone Cement and Saturate Mixing System is packaged sterile. Components include a vial of a colorless, flammable liquid containing Methyl Methacrylate and Polymethyl Methacrylate, and a colorless, flammable powder containing Barium Sulphate. The composition of StabiliT Bone Cement is as follows:

- Methyl Methacrylate 99.50 % w/w
- Polymethyl Methacrylate 69.50 % w/w

The Saturate Mixing System is intended for mixing of StabiliT Bone Cement. The Locking Syringe and Stopcock are sterilized by ethylene oxide gas. This device is intended to be used with the StabiliT Bone Cement and Saturate Mixing System.

CAUTION: Never arbitrarily alter the powder to liquid ratio.

NOTE: Bone cements are sensitive to temperature. Exceeding the recommended temperature range of 68°F to 77°F (20°C to 25°C) may result in incomplete polymerization. Conversely, lower temperatures increase the polymerization time.

Working Injection of cement into vertebral body

Use appropriate imaging techniques to confirm correct needle placement, absence of damage to surrounding structures and appropriate location of injected material.

Bladder fistula

Hematuria

Inadequate joining of the Syringe Filter to the Stopcock

Nerve entrapment and dysphasia due to extrusion of the cement

Heterotopic bone formation

Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 minutes. Some have progressed to cardiac arrest. Patients should be monitored for hypotension. Do not use damaged product. Before use, inspect the StabiliT Bone Cement and Saturate Mixing System for any defects.

The StabiliT Bone Cement is a single-use device that is sterilized and packaged in aseptic conditions. Sterility is assured only if the unit container is not damaged or opened.

Hypotensive reactions may occur following the injection of bone cement and should be monitored. The liquid is highly volatile and flammable. The operating room should be adequately ventilated to eliminate as much as possible the monomer fumes and particulate matter released during polymerization. Where applicable, personal protective equipment and personnel training should be made available. Personnel should be trained to recognize and handle adverse reactions, including signs of death, cardiac arrest, air embolism, and embolism of the lung.

During mixing, avoid contact dermatitis. Wearing a second pair of gloves and strict adherence to the mixing instructions may avoid contact dermatitis. Personal protective equipment should include mask, protective clothing, and gloves.

Carefully remove cap from top of Cement Syringe.

Draw 30cc of vacuum and rotate the Locking Syringe plunger to lock plunger in place.

If not already, rotate the Stopcock off lever towards the Locking Syringe to temporarily close off flow and secure the Locking Syringe to the Stopcock. Pointing the Cement Syringe luer down, tap the luer opening of the Cement Syringe to assure that little or no excess dried powder comes out of the Cement Syringe.

Approximate completion of saturation is 15 seconds. Once饱和 completion is observed, rotation of the Stopcock off lever downwards should be taken to open the flow to the Cement Syringe where the cement is to be applied.

Initiation of Saturation

The cement can be injected into the vertebral body as soon as the cement is yellow in color.

NOTE: Inadequate joining of the Syringe Filter to the Stopcock

NOTE: Diffusion of the resin outside the vertebral body:

Insertion

Techniques

Asceptic Processing

NOTE: Diffusion of the resin outside the vertebral body:

Insertion

Techniques