StabiliT® ER²

English

BONE CEMENT

INSTRUCTIONS FOR USE

IMPORTANT INFORMATION – PLEASE READ BEFORE USE

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

DESCRIPTION

The StabiliT® ER² Bone Cement is a polymethylmethacrylate (PMMA) radiopaque bone cement. The StabiliT ER² Bone Cement is packaged in 2 sterile components. One component is a vial of a colorless, flammable liquid monomer that has sweet slightly acrid odor. The other component is a vial of fine powder. Hydroquinone is added to the liquid to prevent premature polymerization. N-Dimethyl-p-toluidine is added to promote cold curing of the finished therapeutic bone cement. The barium sulphate acts as a contrast medium for X-ray examination. When the powder and liquid are mixed, an exothermic reaction occurs resulting in a liquid that progressively hardens as a cement-like complex.

The composition of StabiliT ER² Bone Cement is

Powder	10.5 g of Sterile Powder
Polymethyl Methacrylate	69.50 % w/w
Barium Sulphate	30.00 % w/w
Benzoyl Peroxide	0.50 % w/w
Liquid	**4.2 g of Sterile Liquid**
Methyl Methacrylate	99.50 % w/w
N,N-Dimethyl-p-toluidine	0.50 % w/w
Hydroquinone	75 ppm

DIRECTIONS FOR USE

For proper mixing and use, follow the IFU for ER² Saturate Mixing System and StabiliT Vertebral Augmentation System (VAS).

CAUTION

Deviating from the mixing instructions in IFU (ER² Saturate Mixing System) will result in inadequate cement delivery.

CAUTION

Never arbitrarily alter the powder to liquid ratio.

Bone cements are sensitive to temperature. Any increase in temperature of the working environment, the cement components, or the mixing instrumentation reduces the times indicated in the tables below. Conversely, lower temperatures increase the times indicated in the tables below.

Table 1: Cement delivered using VAS.

Operation	Activity	Approximate Cumulative Time From Initiation Of Saturation At 23 °C (Minutes)
Saturation	Saturation of the powder	0-4
System Preparation	Attaching Cement Syringe to VAS	4-5
Working	Injection of cement into VB	See IFU (StabiliT Vertebral Augmentation System)
Setting	Bone Cement fully hardened	See IFU (StabiliT Vertebral Augmentation System)

Table 2: Effect of Ambient Temperature on Cement WITHOUT using VAS.

Temperature °F (°C)	Minimum Setting Time, Cement Only (Minutes)
81 (27)	35
73 (23)	51
66 (19)	82

INDICATIONS

The StabiliT ER² Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

CONTRAINDICATIONS

- This product is contraindicated with patients with coagulation disorders, or with severe pulmonary insufficiency.
- Product use is contraindicated with patients with extended vertebral collapse superior to 2/3 of the standard thickness, and destruction of the posterior wall with epidural extension of the pathologic tissue and clinical signs of medullar compression.
- PMMA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site where the cement is to be applied.
- This product should not be used in patients with sensitivity to any of the components of the PMMA bone cement.
- Evidence of safety for use of this material in children or during pregnancy or lactation has not been established.

WARNINGS

- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.
- Sterility is assured only if the unit container is not damaged or opened.
- Do not use after the expiration date.
- Store the package in a dry ventilated place at a temperature below 25ºC and away from strong light.
- Do not re-sterilize any of the components. Reconditioning refurbishing repair, modification, or resterilization of the device to enable further use is expressly prohibited as it may result in loss of function and/or infection.
- For an efficacious use of StabiliT ER² Bone Cement, the operator should have specific training and experience to be thoroughly familiar with the properties, handling characteristics, and application of the cement.
- Adverse patient reactions affecting the cardiovascular system have been associated with bone cements. 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 carefully for any change in blood pressure during and immediately following the application of bone cement
- The liquid is highly volatile and flammable. The operating room should be adequately ventilated to eliminate as much monomer vapor as possible. Additionally, care should be taken in the use of electrocautery in the presence of freshly implanted bone cement.
- Caution should be exercised during mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce irritation to the respiratory tract, eyes, and possibly the liver. Because soft contact lenses are quite permeable, personnel wearing contact lenses should not be near or involved in mixing the bone cement.
- Polymerization of this bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant.
- Avoid over pressurization of the bone cement because this may lead to extrusion of the bone cement beyond the site of its intended application and damage to the surrounding tissues.

PRECAUTIONS

- This device should only be used by licensed physicians with training in the clinical procedure in which it is being used.
- For proper use of the StabiliT ER² Bone Cement, the surgeon should have specific training, experience, and thorough familiarity with the use and application of this product.
- Use appropriate imaging techniques to confirm correct needle placement, absence of damage to surrounding structures and appropriate location of injected material.
- Percutaneous vertebroplasty or kyphoplasty procedures should only be performed in medical settings in which emergency decompressive surgery is available. It is essential to maintain strict sterile technique during the vertebroplasty or kyphoplasty procedure and during all phases of handling this product.
- Follow the handling and mixing instructions carefully to ensure that the cement has reached the appropriate consistency. This will prevent incompletely mixed material from either being injected or clogging the delivery device. Failure to follow the mixing instructions or premature injection of material may negatively affect the outcome of the procedure.
- Do not continue injection beyond the working time of the bone cement. Attempting to inject the material beyond the working time may result in failure of the delivery system.
- Wear safety glasses or a face shield when delivering the material. Follow handling and mixing instructions to avoid contact dermatitis. Wearing a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The liquid component is a powerful lipid solvent. Do not allow the liquid component to contact latex gloves.
- Dispose the powder component in an authorized waste facility. The liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred in a suitable container for disposal.

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

The most frequent adverse reactions reported with acrylic bone cement intended for vertebroplasty or kyphoplastyare

- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Superficial or deep wound infection
- Bursitis
- Short-term cardiac irregularities
- Heterotopic bone formation

Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include

- Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.
- Pyrexia
- Hematuria
- Dysuria
- Anaphylaxis
- Bladder fistula
- Transitory worsening of pain due to heat released during polymerization
- Nerve entrapment and dysphasia due to extrusion of the bone cement beyond its intended application
- Adhesions and stricture of the ileum due to heat released during polymerization

Potential adverse events associated with vertebroplasty or kyphoplasty include

- Pneumonia
- Intercostal neuralgia
- Collapse of a vertebra adjacent to the one injected, due to an osteoporotic disease
- Pneumothorax
- Extravasation of cement into soft tissue
- Fracture of a pedicle
- Rib fracture in patients with diffuse osteopenia, especially during thoracic vertebroplasty or kyphoplasty procedures, due to the significant downward force exerted during cannula insertion
- Compression of the spinal cord with paralysis or loss of feeling.
- Diffusion of the resin outside the vertebral body: in the peripheral veins (pulmonary embolism), in the epidural plexus (myelopathy, radiculopathy), in the intervertebral disc.

HOW SUPPLIED

The StabiliT ER² Bone Cement is sterile. The powder (10.5g) in a package is sterilized by ethylene oxide gas. The liquid (4.2g) is sterilized by filtration method and the outer surface of the vial in its package is sterilized by ethylene oxide gas. This device is intended for single use only. Do not resterilize. Do not use if the package is open or damaged.

STORAGE

The StabiliT ER² Bone Cement should be stored in its original packaging materials. Proper care should be taken to ensure that the StabiliT ER² Bone Cement will not be damaged. Store below 25°C and away from direct sunlight.

SYMBOL GLOSSARY

	Caution		Use By
	Consult Instructions for Use		Do not resterilize
EC REP	Authorized Representative in the European Community		Keep away from sunlight
STERILE EO	Sterilized using Ethylene Oxide		Keep away from moisture
STERILE A	Sterilized using Asceptic Processing Techniques		Flammable
LOT	Lot Number		Single Use Device DO NOT REUSE
REF	Catalog Number		Store below 25°C
	No Latex		Manufacturer
	Do not use if package is opened or damaged	QTY:	Quantity
℞ Only	Federal (USA) law restricts this device to sale by or on the order of a physician.		

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