StabiliT® ER²

English

BONE CEMENT, SINGLE-LEVEL

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.

INDICATIONS

The StabiliT® ER² Bone Cement, Single-level is intended for:

- 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).
- The Saturate Mixing System is intended for mixing of StabiliT ER² Bone Cement.

DESCRIPTION

The StabiliT ER² Bone Cement is a polymethylmethacrylate (PMMA) radiopaque bone cement. The StabiliT ER² Bone Cement, Single-level is packaged sterile. Components include a vial of a colorless, flammable liquid monomer that has sweet slightly acrid odor, a Cement Syringe Assembly packed with fine powder, a locking syringe which provides a vacuum source and a Stopcock assembly. To the liquid component, Hydroquinone is added to prevent premature polymerization and N-Dimethyl-p-toluidine is added to promote cold curing of the finished therapeutic bone cement. To the powder component, barium sulphate is added to assist in visualization of bone cement under standard imaging. When the powder and liquid components 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	8 g of Sterile Powder
Polymethyl Methacrylate	69.50 % w/w
Barium Sulphate	30.00 % w/w
Benzoyl Peroxide	0.50 % w/w
Liquid	**3.2 g of Sterile Liquid**
Methyl Methacrylate	99.50 % w/w
N,N-Dimethyl-p-toluidine	0.50 % w/w
Hydroquinone	75 ppm

HOW SUPPLIED

The StabiliT ER² Bone Cement, Single-level is provided sterile. The powder is sterilized by ethylene oxide gas. The liquid is sterilized by filtration method and the outer surface of the vial is sterilized by ethylene oxide gas. The locking syringe and Stopcock are 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.

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 Use By Date.
- Do not use damaged product. Before use, inspect the StabiliT ER² Bone Cement, Single-level components and packaging to verify that no damage has occurred.
- Store the package in a dry ventilated place at a temperature below 25ºC and away from direct light.
- Do not re-sterilize and/or reuse any of the components. The StabiliT ER² Bone Cement, Single-level is for single use only. 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, Single-level, 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, Single-level, 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 kyphoplasty are:

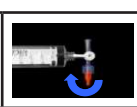
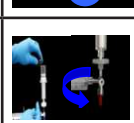
- Transitory fall in blood pressure
- Hemorrhage and hematoma
- Bursitis
- Heterotopic bone formation
- Thrombophlebitis
- Superficial or deep wound infection
- Short-term cardiac irregularities

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.
- Transitory worsening of pain due to heat released during polymerization
- Adhesions and stricture of the ileum due to heat released during polymerization
- Anaphylaxis
- Dysuria
- Pyrexia
- Hematuria
- Bladder fistula
- Nerve entrapment and dysphasia due to extrusion of the bone cement beyond its intended application

Potential adverse events associated with vertebroplasty or kyphoplasty include:

- Pneumonia
- Collapse of a vertebra adjacent to the one injected, due to osteoporotic disease
- Extravasation of cement into soft tissue
- 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
- Intercostal neuralgia
- Pneumothorax
- Fracture of a pedicle
- Diffusion of the resin outside the vertebral body: in the peripheral veins (pulmonary embolism), in the epidural plexus (myelopathy, radiculopathy), in the intervertebral disc.

	**Figure 1**: Components of StabiliT ER² Bone Cement, Single-level		**Figure 2**: Assemble Stopcock to Locking Syringe
	**Figure 3**: Rotate Stopcock handle to close off Locking Syringe		**Figure 4**: Draw 30cc of vacuum with off lever turned to the Locking Syringe, and rotate plunger to lock.
	**Figu re 5**: Securely join Syringe Filter luer and Stopcock		**Figure 6**: Pour entire contents of liquid vial of StabiliT ER² Bone Cement into Funnel BEFORE rotating Stopcock lever downwards.
	**Figure 7:** Saturation of powder as liquid progresses through the Cement Syringe is visible. **(Saturate fully)**		**Figure 8**: Separate Syringe Filter from Stopcock after saturation is complete (to syringe filter).
	**Figure 9**: Only remove Funnel and Syringe Filter immediately prior to use.		

DIRECTIONS FOR USE

For proper mixing and use, follow this IFU and StabiliT Vertebral Augmentation System (VAS) IFU.

1. It is important to read the IFU for StabiliT VAS and the precautions prior to device operation.
2. Remove the following components from the StabiliT ER² Bone Cement, Single-level:
   a. Cement Syringe with powder and attached Funnel and Syringe Filter
   b. Stopcock with Cap
3. Be sure all air is pushed out of the Locking Syringe prior to attaching to Stopcock.
4. Securely attach the Stopcock to the Locking Syringe at the middle luer connector of the Stopcock.
5. If not already, rotate the Stopcock off lever towards the Locking Syringe to temporarily close off flow and secure orange cap to Stopcock.
6. Draw 30cc of vacuum and rotate the Locking Syringe plunger to lock plunger in place. **Caution**: Do not apply more than or less than 30cc vacuum. Device malfunction may occur during cement delivery.
7. Ensure the Funnel is secured to the Cement Syringe and the cap is secured to the Funnel.
8. Rotate powder filled Cement Syringe back and forth while rolling to mix powder.
9. Gently tap the tip of syringe filter against table top for 10 seconds
10. Carefully remove cap from top of Cement Syringe.
11. Firmly attach the powder filled Cement Syringe, Funnel and Syringe Filter to the Stopcock and the Locking Syringe with the plunger locked at 30 cc volume (see Figure 5). **NOTE**: Inadequate joining of the Syringe Filter to the Stopcock can result in poor cement mix and device malfunction.
12. Open the liquid glass vial and pour the entire contents into the Funnel and immediately rotate the Stopcock off lever DOWNWARDS towards the orange cap per Figure 6. **Caution**: Be careful when breaking glass vial of liquid monomer. Be careful when pouring liquid into the Funnel to avoid injury. **Caution**: Ensure the entire contents of the liquid ampule are emptied into the Cement Syringe/ Funnel without spilling prior to applying vacuum.
13. Immediately start the timer on the MultiPlex Controller by pressing the ENTER button on the MultiPlex Controller (per MultiPlex Controller Operators Manual). **NOTE**: Closely observe the progression of the monomer liquid as it saturates through the powder. When the liquid reaches the Syringe Filter luer and no excess monomer present in Funnel, the saturation of the powder with monomer is complete (approximately 20 seconds). **Caution**: Only apply vacuum for the prescribed period of time. If longer or shorter duration is used, device malfunction may occur during cement delivery. Immediately separate the Syringe Filter from the Stopcock to relieve vacuum pressure
14. ONLY after 4:00 minutes (or 9:00 minutes if room temperature is ≤67°F (≤19°C)) has elapsed on the MultiPlex Controller timer, remove the Syringe Filter and Funnel from the Cement Syringe and wipe excess cement off the top of the Cement Syringe. **NOTE**: Proceeding without allowing 4:00 minutes (or 9:00 minutes if room temperature is ≤67°F (≤19°C)) to elapse will result in poor cement mix and device malfunction.
15. 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. **NOTE**: If dry powder is observed coming out of the Cement Syringe, the saturation was not complete and a new cement mix should be performed and the MultiPlex Controller timer should be reset by pressing "Remix" on the MultiPlex Controller.
16. Connect the Master Syringe of the StabiliT VAS Hydraulic Assembly to the Cement Syringe per StabiliT VAS IFU. Ensure the threads are fully engaged. **CAUTION**: Deviating from the mixing instructions in this IFU will result in inadequate cement delivery. **CAUTION**: Never arbitrarily alter the powder to liquid ratio. **CAUTION**: 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 ºF (ºC)	Minimum Setting Time, Cement Only (Minutes)
81 (27)	35
73 (23)	51
66 (19)	82

STORAGE & HANDLING

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

SYMBOL GLOSSARY

	Caution		Use By		Do not resterilize
	Consult Instructions for Use		Store below 25°C		Do not use if package is opened or damaged
EC REP	Authorized Representative in the European Community		Keep away from sunlight	2	Single Use Device DO NOT REUSE
STERILE EO	Sterilized using Ethylene Oxide		Keep away from moisture		Manufacturer
STERILE A	Sterilized using Asceptic Processing Techniques		Flammable	QTY:	Quantity
LOT	Lot Number		No Latex	REF	Catalog Number
℞ Only	Federal (USA) law restricts this device to sale by or on the order of a physician.				

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