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FORTRESS™ RADIOPAQUE BONE CEMENT

08/2019

(Polymethyl Methacrylate, Methyl Methacrylate-styrene copolymer and Barium sulfate)

IMPORTANT INFORMATION ON FORTRESS™ RADIOPAQUE BONE CEMENT
Please Read Before Use

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON FORTRESS™ RADIOPAQUE BONE CEMENT

DESCRIPTION

FORTRESS™ Radiopaque Bone Cements (FORTRESS™ and FORTRESS-Plus™) are radiopaque, self-curing, PMMA bone cements used to perform percutaneous vertebral augmentation procedures such as vertebroplasty or kyphoplasty. FORTRESS™ is packaged in two sterile components. One component is a vial containing 16.4g (full dose) or 8.2g (half dose) of monomer. The monomer is a colorless, flammable liquid material with a very distinctive odor of the following composition:

Methyl Methacrylate	99.0% w/w
N:N Dimethyl-p-toluidine	1.0% w/w
Hydroquinone	60 ppm

Hydroquinone is added to prevent premature polymerization. N:N Dimethyl-p-toluidine is added to initiate polymerization at operating room temperatures. The liquid component is sterilized by filtration methods.

The other component is a bottle containing 40.0g (full dose) or 20.0g (half dose) of powder polymer with the following composition:

Polymethyl Methacrylate / Methyl Methacrylate-styrene copolymer	72.0% w/w
Benzoyl peroxide	0.7% w/w
Barium sulfate	28.0% w/w

Barium sulfate is added to make the material radiopaque. The powder component is sterilized by gamma irradiation.

All components are single use and not re-sterilizable. Do not use if packaging is opened or damaged.

INDICATIONS

FORTRESS™ Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with the REVLOK® or CREO® Fenestrated Screw System for posterior fixation, FORTRESS™ Radiopaque Bone Cements are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. FORTRESS™ Radiopaque Bone Cements are limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

WARNINGS

Read and understand these instructions. Familiarization with the bone cement prior to use is important.

Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.

FORTESS™ Radiopaque Bone Cement is intended for single patient use. DO NOT re-use or re-sterilize. Sterility is assured only if the package is unopened and undamaged.

For safe and effective use of FORTRESS™ Radiopaque Bone Cement, the surgeon should be familiar with the material properties, handling characteristics and the application of the material and devices used for mixing and dispensing the material. FORTRESS™ Radiopaque Bone Cement should only be used by physicians familiar with percutaneous cement delivery, vertebroplasty and kyphoplasty.

FORTRESS™ Radiopaque Bone Cement is not recommended for patients that do not exhibit a pathologic condition, such as osteoporosis or a tumor that would impair the ability of the patient to heal using conservative treatment methods. Give proper consideration to other conventional therapies prior to performing percutaneous vertebroplasty or kyphoplasty. It is the responsibility of the physician to determine the appropriate procedure, technique and device for each individual patient.

Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. Loosening of the bone cement may occur due to the development of fibrous tissue between the bone cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.

Monomer is highly flammable. The operating room should be provided with adequate ventilation to eliminate concentrated monomer vapor. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the vapors which may produce respiratory irritation, irritation to the eyes and possibly the liver. Personnel wearing contact lenses should NOT be near or involved in mixing this material.

The liquid component is a powerful lipid solvent. It is recommended that all operating room staff who comes in contact with the material double glove to lessen the risk of contact dermatitis which may occur in susceptible individuals after long term exposure to the monomer. Wearing double gloves and adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. The liquid component should not be allowed to come in contact with rubber or latex gloves.

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.

Monomer can cause hypersensitivity in susceptible persons which may produce an anaphylactic response.

Use in Pregnancy: Although the results of animal studies with similar materials have been negative, the safety of PMMA materials in pregnancy, children, or by women of childbearing potential has not been established and requires that the potential benefits must be weighed against the possible hazards to the mother, child, or fetus.

Adverse reactions in patients due to bone cements have affected the cardiovascular system and in some cases hypotensive reactions have resulted in cardiac arrest. Patients should be monitored for any change in blood pressure and pulse rate during and immediately following treatment with bone cement.

Precautions should be taken to detect and rectify the transitory fall in blood pressure that may occur when bone cement is introduced into a patient.

Clinical data indicates the need for good surgical principles and techniques in delivery of bone cement. Postoperative infection is a serious condition and may require removal of the implanted bone cement. Postoperative infection may occur immediately or not manifest for several years.

Use high quality motorized C-arm fluoroscopy, high quality biplanar fluoroscopy or real-time CT to guide needle insertion. Place the needle tip in the anterior third of the vertebral body.

Polymerization of bone cement is an exothermic reaction, which occurs while it is hardening in situ. The released heat may damage bone or other surrounding tissues. The long term effect to surrounding tissues exposed to the exothermic temperatures produced by the polymerization process is not known.

Patient positioning should be maintained until the completion of the polymerization process of the bone cement to achieve proper fixation. The polymerization process may vary due to room temperature and delivery system.

Be aware that treating multiple levels may increase the risk of sudden drop in blood pressure, particularly if more than three vertebral levels are treated in a single operation.

Delivery of excessive bone cement may lead to extrusion of the bone cement beyond the intended application area and cause damage to surrounding tissues and the circulatory system.

DO NOT deliver bone cement into a vertebral body without appropriate imaging techniques such as high quality lateral fluoroscopic guidance.

Long-term effects of bone cement in pathological fractures of the vertebral body have not been established.

Leaks can also occur when injecting if the needle is in a vein or if unseen microfractures are prevalent.

If bone cement is seen outside of the vertebral body or in the circulatory system during percutaneous vertebroplasty or kyphoplasty, immediately stop the injection.

Consider carefully the risk/benefit analysis for patients with malignant conditions who also have epidural extension or malignant collapse, in view of risk of precipitating cord compression. Ensure that immediate surgical support is available.

Consider carefully the risk/benefit analysis for patients with traumatic burst fractures with disruption of the posterior vertebral body.

Adverse reactions affecting the cardiovascular system have been attributed to leakage of unpolymerized monomer into the circulatory system. Data indicates that the monomer undergoes rapid hydrolysis to methacrylic acid, and that a significant fraction of the circulating methacrylate is in the form of free acid rather than the methyl ester. Correlation between changes in circulating concentrations of methyl methacrylate/methacrylic acid and changes in blood pressure has not been established. Use proper technique to avoid laminations in the material as well as entrapping air.

Hypotensive reactions were reported to occur after introduction of bone cement between 10 to 165 seconds with duration of 30 seconds to 5-6 minutes. The patient should be monitored during and after the introduction of bone cement for any change in blood pressure, especially if the patient is prone to high blood pressure and/or cardiovascular abnormalities.

PRECAUTIONS

This product should not be used after the expiration date printed on the package label. This device may not be safe or effective beyond its expiration date.

Follow the handling and mixing instructions to avoid contact dermatitis. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication.

Adequately ventilate.

Do not introduce other substances or foreign materials into this product.

Do not modify the mixing ratios in any form. Modification of the composition can cause unpredictable handling characteristics, increased exposure to the monomer component, increased risk of venous embolization and unpredictable final performance properties.

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of similar acrylic bone cements for vertebroplasty or kyphoplasty include:

- Myocardial infarction
- Cardiac arrest
- Cerebrovascular accident
- Cardiac embolism
- Pulmonary embolism
- Hypertension
- Hypotension
- Anaphylaxis
- Nerve entrapment

The most frequent adverse events reported are:

- Transitory fall in blood pressure

- Thrombophlebitis
- Trochanteric bursitis
- Trochanteric separation
- Hemorrhage and hematoma
- Surgical wound infection
- Superficial or deep wound infection
- Heterotopic bone formation
- Short-term cardiac conduction irregularities

Other adverse events reported are:
- Pyrexia due to an allergy to the bone cement
- Hematuria
- Dysuria
- Bladder fistula
- Delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application
- Adhesions and stricture of the ileum due to the heat released during polymerization

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.

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 physician must be aware of these possible reactions and be prepared to treat them if they are encountered.

CONTRAINDICATIONS

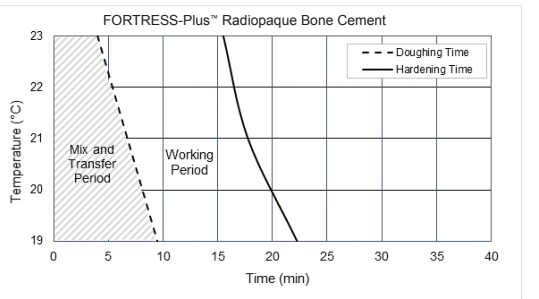
The use of FORTRESS™ Radiopaque Bone Cement is contraindicated in patients with:
- The presence of active or incompletely treated infection at the site where the bone cement is applied
- Allergies or sensitivity to methyl methacrylate or any of the chemical compositions of the product
- Traumatic fractures of the vertebra that are nonpathological in nature
- Cardiopulmonary disease
- Coagulation disorders
- Severe vertebral body collapse (vertebra plana)
- Prophylaxis with no evidence of acute fracture
- Clinically effective medical therapy

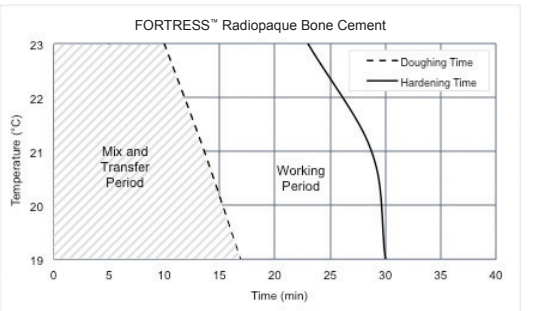
DIRECTIONS FOR USE

A dose is prepared by adding the entire contents of the liquid monomer to the entire contents of the powder. Do not add the powder to the liquid monomer.

1. Using sterile technique and under sterile conditions, empty the entire contents of the powder component into a sterile, inert mixing device.
2. Add the entire contents of the liquid monomer to the powder. Mix the material by following the device manufacturer's instructions or until the powder is completely saturated with the liquid monomer and the material reaches the desired consistency. The handling characteristics and setting time of the material may vary with temperature, mixing technique and humidity. Refer to the graphs and table below for additional information.
3. Determine the preferred method or procedure for bone cement delivery into the patient and, if applicable, follow the device manufacturer's instructions.

Doughing and Hardening Times





Handling Characteristics of FORTRESS™ Radiopaque Bone Cements at 23°C

Time Point	Activity	Approximate Elapsed Time from Initiation of Mixing	
		FORTRESS-Plus™	FORTRESS™
Mixing Period	Period to mix liquid and powder components	0 – 40 seconds	0 – 60 seconds
Transfer Period	Period during which cement can be transferred to delivery system	40 seconds – 3 minutes	1 – 10 minutes
Doughing Time	Time point at which cement separates cleanly from latex gloved finger	3 minutes	10 minutes
Working Period	Period during which cement may be safely injected into bone void	3 – 15 minutes	10 – 23 minutes
Hardening Time	Time point at which cement is too hard to effectively inject with delivery device	15 minutes	23 minutes

Hardening time may vary; the user should be aware of the behavior of the material and the operating room conditions.

HOW SUPPLIED

Individual Unit

Full Dose: One sterile package containing one bottle with 40.0g of powder polymer and one vial with 16.4g of liquid monomer.

Half Dose: One sterile package containing one bottle with 20.0g of powder polymer and one vial with 8.2g of liquid monomer.

SAFE DISPOSAL

The polymer component may be disposed in an authorized waste facility. The liquid component can be evaporated under a vented hood or absorbed by an inert material for disposal.

STORAGE

Warning: Flammable

Store below 25°C (77°F) and protect from light.

Device meets pyrogen limit specifications.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871).

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

SYMBOL TRANSLATION			
REF	REFERENCE NUMBER		USE BY (YYYY-MM-DD)
LOT	LOT NUMBER		DO NOT USE A DAMAGED PRODUCT
QTY	QUANTITY		PROTECT FROM LIGHT
STERILE R	STERILIZED BY GAMMA IRRADIATION (Powder Component)		ATTENTION, SEE INSTRUCTIONS FOR USE
STERILE A	STERILIZED BY FILTRATION (Liquid Component)		UPPER TEMPERATURE LIMIT 25° C 77° F
STERILE EO	STERILIZED BY ETHYLENE OXIDE (Contents of Blister Pack)		FLAMMABLE
	SINGLE USE ONLY		MANUFACTURER