Cem-Ostetic™
Berkeley Advanced Biomaterials

AUTHORIZED EC REPRESENTATIVE:
Orthopedix (BAB France)
29 Grande Rue,
54290 Neuviller-sur-Moselle
France
Phone: +33-(0)3 83724946

e-mail: ec@hydroxyapatite.com

DISTRIBUTED WORLDWIDE BY:
Berkeley Advanced Biomaterials
1933 Davis Street, Suite 307
San Leandro, CA 94577
U.S.A.
Phone: +1-510-883-1644
Fax: +1-510-883-1315
e-mail:us@hydroxyapatite.com

STERILE R 2 CE 0123

INSTRUCTIONS FOR USE

IMPORTANT PRODUCT INFORMATION

Please read before use

ENGLISH

These instructions-for-use refer specifically to Cem-Ostetic™ osteoconductive bone void filler formulated as a putty.

Materials

Cem-Ostetic™ contains calcium based inorganic compounds, which have been the subject of extensive clinical studies for more than 30 years that demonstrated their excellent biocompatibility. After it is implanted, Cem-Ostetic™ resorbs and is later replaced by natural bone. Significant resorption normally occurs within 12 weeks. Cem-Ostetic™ is a natural choice for sparing patients the trauma of autograft harvesting. It also provides a safe alternative to human or animal cadaver bone that completely eliminates the potential for disease transmission. The distilled sterile water contained in the vial is indicated to be poured into the jar containing the powder and mixed with it for one minute to form a viscous putty. Once mixed with water for 60 seconds, the putty can be placed in contact with other fluids, bone chips, or demineralized bone matrix to enhance bone reconstruction. It can also be molded into specific shapes. When mixed with the indicated amount of sterile distilled water, the putty hardens within 5 minutes.

Indications-For-Use

Cem-Ostetic™ is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.

The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The Cem-Ostetic™ paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. Cem-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs**.**

Contraindications

Cem-Ostetic™ is not designed or sold for any use except as indicated. Do not use Cem-Ostetic™ in the presence of any contraindication. Cem-Ostetic™ is contraindicated where the device is intended as structural support in the skeletal system (e.g. mandibular segment replacement). Other conditions representing relative contraindication include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

Precautions

Cem-Ostetic™ is not intended for load-bearing uses. It is important to ensure that the area where the putty has been implanted or injected be properly secured mechanically with rigid fixations to strengthen the surroundings. The entire volume of STERILE water contained in the vial **(about 0.4 cc of water per cc of powder)** should be mixed carefully for 60 seconds with the powder contained in the jar to form an implant with a volume about half of that of the powder. The putty will not harden if the powder placed in contact with blood or other liquids prior to mixing with water. The putty can be molded or injected during the first 3 minutes after the water is in contact with the powder. The putty will harden completely within 5 minutes. Respecting approximately a 4-to-10 water-to-powder volume ratio is important; changing this ratio will affect both hardening time and putty viscosity. Attempts should not be made to modify the putty or to change its shape after hardening has begun. It is important to maximize contact between existing bone and the putty to ensure proper bone regeneration.

The effect of Cem-Ostetic™ on patients with the following conditions is unknown:

- documented renal disease
- metabolic bone disease
- pregnancy and nursing
- radiation bone therapy
- long-term infection
- cardiovascular disease precluding elective surgery.

The effect of Cem-Ostetic™ in pediatric patients is not known. The effect of preparing Cem-Ostetic™ with any substance except for STERILE water (including antibiotics or serum) is not known.

Possible Complications

Successful results may not be achieved for every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure. Possible adverse effects may include but are not be limited to:

- wound complications including hematoma, edema, swelling and fluid accumulation, tissue thinning, bone fracture, infection, and other complications that are possible with any surgery
- fracture of the implant with or without generation of particulate debris
- bone deformity at the site.

Warnings

Content of package is STERILE unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.

Cem-Ostetic™ putty must be prepared within 60 minutes after opening the package. Exposure to humidity prior to mixing will compromise results.

Cem-Ostetic™ is opaque to x-rays. This may mask areas under or above the implant.

The putty must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Injection of the putty may cause pressurization that could lead to tissue fragments embolization or embolization of the device into the blood stream.

Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.

Mixing and Application

Step 1: **Open** both outer and inner pouches. Open the lid of the jar (that contains the powder) and the vial of sterile distilled water. The proper amount of water is pre-measured. Note that glass containers are naturally dark as a result of the gamma-sterilization process.

Step 2: **Pour** the water into the jar containing the powder. The jar can be used as a mixing container. **Add 0.4 to 0.5 cc (or milliliter) of water for each cc of powder to obtain usable consistency.** However, mixing may begin with a lesser amount of water to minimize excess fluid.

Powder Volume	Water Volume	Implant Volume
2.5 cc	1 cc	1.25 cc
5 cc	2 cc	2.5 cc
10 cc	4 cc	5 cc
15 cc	6 cc	7.5 cc
20 cc	8 cc	10 cc
30 cc	12 cc	15 cc

USE ONLY STERILE WATER
THE PUTTY WILL NOT HARDEN IF FIRST PLACED IN CONTACT WITH BLOOD OR OTHER LIQUIDS PRIOR TO MIXING WITH WATER. ALWAYS USE RECOMMENDED VOLUME OF WATER.

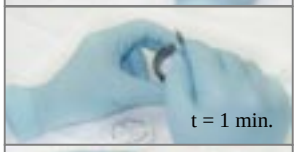
Table indicating the proper amount of water and powder that must be mixed to form a putty with consistent hardening times.

Step 3: **Mix thoroughly for 60 seconds using a spatula**. In contact with water, the powder will densify to form an implant with a volume **about half that of the powder volume.**

Step 1
Open Package

Step 2
Add Water

Step 3
Mix 60 Seconds



Step 4
Mold or Inject:
Complete in Fewer Than 2 Minutes

Step 4 - **Mold** the putty into the desired shape and let implant set. Alternatively, insert the putty into a syringe from the plunger side (pumping the putty from the needle orifice is more difficult) and inject it immediately into the void. For best results, this process must be completed within **2 minutes** after adding water to the powder. Once the putty begins to harden, it is no longer workable and may crack under pressure. To eliminate the potential for cracking the implant, the molding or injection process must be completed within 3 minutes after the water is first in contact with the powder. To repair or smoothen tiny cracks, a few drops of sterile water can be used.

Step 5: **Implant.** After 3 minutes (mixing and molding/injection are now complete), allow the putty to harden completely for additional 2 minutes, by letting it dry outside the body or by securing the surgical site mechanically after injection. The set material will appear somewhat dry and stable to the touch. Secure the surgical site after implanting to prevent micro-motion and implant migration. When excess fluid is present in the surgical field, the surgeon may allow up to 30 minutes for the material to set. Cauterization, suction, and application of bone wax (if needed) can be used to reduce bleeding. If the material has not set satisfactorily, remove the implant and start over with a new package of Cem-Ostetic™.

Storage Conditions

Store in a dry place at room temperature. Optimal Storage Conditions: 15-30˚C (59-86˚F), less than 70% relative humidity. DO NOT FREEZE OR ALLOW PACKAGE TO GO BELOW FREEZING TEMPERATURE (0°C/32F).

Shelf Life

The expiration date is printed on the label. DO NOT USE CEM-OSTETIC™ AFTER THE EXPIRATION DATE.

Disposal of Cem-Ostetic™

Cem-Ostetic™ is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

Ordering Information

Cem-Ostetic™ bone void filler is a sterile and osteoconductive bone graft substitute. Cem-Ostetic™ is provided with detailed instructions-for-use. The entire device is sterilized by gamma irradiation. Five volumes are available.

Cem-Ostetic™ bone void filler is packaged in plastic or glass jars. The pre-measured amount of water is packaged in a plastic vial. Both are sealed in translucent double pouches within an additional box for transport and storage. Included with this instructions-for-use leaflet are supplementary labels for patient documentation. The sterile jar containing the powder is designed to also serve the function of mixing container.

Cat. No.	Powder Volume	Description
CemO-02P	2.5 cc	Injectable Putty
CemO-05P	5 cc	Injectable Putty
CemO-10P	10 cc	Injectable Putty
CemO-20P	20 cc	Injectable Putty
CemO-30P	30 cc	Injectable Putty

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital.

Manufactured and distributed by Berkeley Advanced Biomaterials, Inc. San Leandro CA (USA).

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Cem-Ostetic™, and for the choice of post-operative follow-up procedures rests entirely with the physician. In case of complaint or for further information on the product and its uses, please contact Berkeley Advanced Biomaterials at the address printed on this information sheet.