Cem-Ostetic®
Berkeley Advanced Biomaterials

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

STERILE R — RADIATION STERILIZED

SINGLE USE ONLY

℞ Only

DO NOT RESTERILIZE

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 moldable putty

Description
Cem-Ostetic is a bio-engineered mixture of calcium-based inorganic compounds. After it is implanted, Cem-Ostetic resorbs and is later replaced by natural bone. 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 to form a viscous putty. Once mixed with water for 60 seconds, the putty can be placed in contact with 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 begins hardening after 2 minutes.

Intended 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 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. It is biocompatible and resorbs in the body as bone in-growth 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. The implant will not function if the implanted site is not well vascularized. The implant is contraindicated where it 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

Warnings
The entire device is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
Dosage is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the device.
Cem-Ostetic putty must be prepared within one hour after opening the package. Exposure to excessive heat or humidity prior to mixing components will compromise results.
Cem-Ostetic is opaque to x-rays. This may mask areas under or above the implant on the radiograph.

Precautions
Cem-Ostetic is not intended for load-bearing uses. It is important to ensure that the area where the putty has been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Cem-Ostetic is not intended for treatment of vertebral compression fractures and iliac crest backfill. Highly pressurized applications of the putty into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown. 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. The filler may extrude into soft tissues (e.g. facial applications or illiac crest backfill) and cause inflammation. Do not overfill the site.
The entire volume of sterile water contained in the vial should be quickly mixed with the powder contained in the jar to form a dough. The dough must then be kneaded by hand to ensure that the water is properly mixed with the powder. The putty will not harden if the powder is first placed in contact with blood or other liquids prior to mixing with water. The putty can be molded during the first 3 minutes after the water is in contact with the powder. Past these 3 minutes, the implant must be left alone for at least 2 minutes so that it can harden properly; changing the shape of the implant will make it crumble. Implant preparation takes a total of about 5 minutes. Using all the water from the vial is important. Using less water will compromise the hardening. Using more water will increase viscosity (increasing the risk of having the paste leak or embolize) and will increase the hardening time (the dough may actually not harden). Again, do not attempt to change the shape of the dough once hardening has begun (3 minutes after first contact between the water and the powder) or it will crumble. It is very important to maximize contact between existing bone and the putty to ensure proper bone regeneration. The effect of implanting the device in 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.

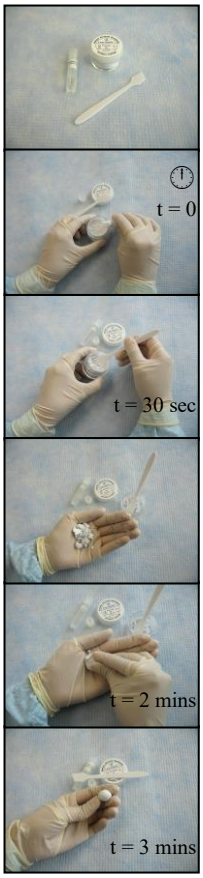
The effect of Cem-Ostetic in pediatric patients is not well documented. The effect of mixing the powder with any substance except for STERILE water (including antibiotics or serum) is not known. Closed suction or drainage is highly recommended to prevent wound fluid accumulation.

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 and are not limited to:
- wound complications including hematoma, edema, seroma, 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 and loss of contour at the site.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

Mixing and Application



Step 1
Open Package.

Step 2
Add Water.

Step 3
Mix 30 Seconds.

Step 4
Transfer Dough into Hand.

Step 5
Knead by Hand.
Mold Implant.
Complete in Fewer
Than 2 Minutes.

Step 6
Let Implant Harden for
3 Minutes.

Step 1: **Open** both outer and inner pouches. Open jar of powder and vial of distilled water. The proper amount of water to add is pre-measured.
Step 2: **Pour entire amount of water** into jar containing the powder. The jar can be used as a mixing container.
Step 3: **Mix thoroughly for 30 seconds using spatula**.
Step 4: Once the powder is wet, it forms a dough. Remove dough from the jar and **transfer it into the hand.**
Step 5: Knead dough firmly until it becomes homogenous.
Quickly mold putty into desired shape or pack into surgical site and let implant harden. 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 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 6: **Let implant harden for at least 2 minutes** either letting it dry on the preparation table or secure implant mechanically in the surgical site. The set material will appear somewhat dry and stable to the touch. Secure the implanted site to **prevent micro-motion and implant migration**. When excess fluid is present in the surgical field, 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 dough has not set satisfactorily, remove the implant and start over with a new package of Cem-Ostetic.

Powder	Implant
1 g	1 cc
2.5 g	2.5 cc
5 g	5 cc
10 g	10 cc
15 g	15 cc
20 g	20 cc

Nominal quantities of Cem-Ostetic powder and putty.

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.

Storage Conditions

Optimal Storage Conditions: 15-30˚C (59-86˚F) in a secure and dry environment. DO NOT FREEZE. The water vial may crack if package goes below freezing temperature (0°C/32˚F). DO NOT EXPOSE DEVICE TO EXCESSIVE HEAT. Device may lose functionality if frozen or exposed to temperatures above 55˚C (131˚F).

Shelf Life and Disposal

The expiration date is printed on the label.
DO NOT USE AFTER THE EXPIRATION DATE.
Cem-Ostetic is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

Other Information

Cem-Ostetic bone void filler is a sterile and osteoconductive bone graft substitute. The product is provided with detailed instructions-for-use.
Cem-Ostetic is packaged in plastic or glass jars. The components are sealed in translucent pouches and placed in 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. The spatula can be used to mix the components.

Cem-Ostetic is a registered trademark of Berkeley Advanced Biomaterials.
Note: Responsibility for proper selection of patients, adequate training, experience in the choice and placement of the implant, 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.