# Cem-Ostetic™ **Berkeley Advanced Biomaterials**

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# INSTRUCTIONS FOR USE

# **IMPORTANT PRODUCT INFORMATION**



Please read before use

# These instructions-for-use refer specifically to Cem-Ostetic<sup>™</sup> osteoconductive bone void filler formulated as granules or blocks.

#### Materials

Cem-Ostetic  $\ensuremath{^{\text{TM}}}$  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, the implant 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.

## Indications-For-Use

Cem-Ostetic™ is an osteoconductive bone substitute shaped as granules or blocks that are 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 granules or blocks may be pressed into the void or into the surgical site by hand. The Cem-Ostetic™ granules or blocks provide void filling material that acts as a temporary support medium. The granules or blocks are not intended to provide structural support during the healing process. The implant is radioopaque. 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 granules or blocks have been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of Cem-Ostetic™ on patients with the following conditions is unknown:

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

# **BLOCKS AND GRANULES**

The effect of Cem-Ostetic™ in pediatric patients is not known. The effect of mixing Cem-Ostetic™ with other substances (e.g. 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,
- implant fracture 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.

It is recommended to use Cem-Ostetic™ within one hour or opening the

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

Granules or blocks must be secured to prevent potential migration or embolization of the device into the blood stream. The implants should only be used in surgical procedures where bone grafts are adequately contained.

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

## Application

Step 1: Open both outer and inner pouches. Open the container. Note that glass containers are naturally dark as a result of the gamma-sterilization process.

Step 2: Implant. 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 use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new dose 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.

### Shelf Life and Disposal

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

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

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

Cem-Ostetic™ is a registered trademark of Berkeley Advanced Biomaterials, Inc. Manufactured and distributed by Berkeley Advanced Biomaterials, 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.

## Ordering Information

Cem-Ostetic<sup>™</sup> bone void filler is a sterile osteoconductive bone graft substitute. Cem-Ostetic<sup>™</sup> is provided with detailed instructions-for-use. The entire device is sterilized by gamma irradiation. Cem-Ostetic™ bone void filler is packaged in vials that 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.

Cat. No.	Qty	Description
Porous Granules		
CemO-01G	1 cc	Cancellous Granules; < 1 mm Particle Size
CemO-02G	2.5 cc	Cancellous Granules; 0.5 - 1 mm Particle Size
CemO-05G	5 cc	Cancellous Granules; 1 - 3 mm Particle Size
CemO-10G	10 cc	Cancellous Granules; 1 - 3 mm Particle Size
CemO-15G	15 cc	Cancellous Granules; 1 - 6 mm Particle Size
CemO-30G	30 cc	Cancellous Granules; 1 - 6 mm Particle Size
CemO-60G	60 cc	Cancellous Granules; 1 - 6 mm Particle Size
Porous Blocks		
CemO-XYZ151505P	15x15x5mm	Cancellous Parallelepiped
CemO-XYZ151515P	15x15x15mm	Cancellous Cube
CemO-XYZ202005P	20x20x5mm	Cancellous Parallelepiped
CemO-XYZ202010P	20x20x10mm	Cancellous Parallelepiped
CemO-XYZ201010P	20x10x10mm	Cancellous Parallelepiped
CemO-XYZ251010P	25x10x10mm	Cancellous Parallelepiped
CemO-XYZ301010P	30x10x10mm	Cancellous Parallelepiped
CemO-DZ1505P	Ø15x5mm	Cancellous Disk
CemO-DZ2010P	Ø20x10mm	Cancellous Disk
CemO-DZ2020P	Ø20x20mm	Cancellous Cylinder
CemO-DZ2510P	Ø25x10mm	Cancellous Disk
CemO-DZ4010P	Ø40x10mm	Cancellous Disk
CemO-DZ5010P	Ø50x10mm	Cancellous Disk