Bi-Ostetic™
Berkeley Advanced Biomaterials

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STERILE R 2 CE 0123

INSTRUCTIONS FOR USE

IMPORTANT PRODUCT INFORMATION

ENGLISH

Please read before use

These instructions-for-use refer specifically to Bi-Ostetic™ osteoconductive bone void filler formulated as porous granules.

Materials
Bi-Ostetic™ is a mixture with a nominal composition of 60% hydroxyapatite and 40% β-tri-calcium phosphate. These materials have been the topic of extensive clinical studies for a several decades. Bi-Ostetic™ is safe and has excellent biocompatibility. After it is implanted, the implant resorbs and is later replaced by natural bone. Bi-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
Bi-Ostetic™ is an osteoconductive bone substitute shaped as granules or blocks (cancellous, cortical or cortico-cancellous) 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 Bi-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 radio-opaque. Bi-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

Contraindications
Bi-Ostetic™ is not designed or sold for any use except as indicated. Do not use Bi-Ostetic™ in the presence of any contraindication. Bi-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
Bi-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 Bi-Ostetic™ on patients with the following conditions is unknown:
- documented renal disease
- pregnancy and nursing
- long-term infection
- metabolic bone disease
- radiation bone therapy
- cardiovascular disease precluding elective surgery.

The effect of Bi-Ostetic™ in pediatric patients is not known. The effect of mixing Bi-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,
- 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.
It is recommended to use Bi-Ostetic™ within one hour or opening the package.
Bi-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 and 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 Bi-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 Bi-Ostetic™ AFTER THE EXPIRATION DATE.
Bi-Ostetic™ is environment-friendly. No special disposal is necessary. Packaging material is recyclable.
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, San Leandro, CA (USA)
Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Bi-Ostetic™, and for the choice of post-operative follow-up procedures rests entirely with the physician.

Ordering Information
Bi-Ostetic™ bone void filler is a sterile osteoconductive bone graft substitute. Bi-Ostetic™ is provided with detailed instructions-for-use. The entire device is sterilized by gamma irradiation. Bi-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.	Quantity	Description
Porous Granules		
BiO-01G	1 cc	Cancellous Granules; < 1 mm in Particulate Size
BiO-02G	2.5 cc	Cancellous Granules; 0.5 - 1 mm in Particulate Size
BiO-05G	5 cc	Cancellous Granules; 1 - 3 mm in Particulate Size
BiO-10G	10 cc	Cancellous Granules; 1 - 3 mm in Particulate Size
BiO-15G	15 cc	Cancellous Granules; 1 - 6 mm in Particulate Size
BiO-20G	20 cc	Cancellous Granules; 1 - 6 mm in Particulate Size
BiO-30G	30 cc	Cancellous Granules; 1 - 6 mm in Particulate Size
BiO-60G	60 cc	Cancellous Granules; 1 - 6 mm in Particulate Size