

Bi-Ostetic™

Berkeley Advanced Biomaterials

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



INSTRUCTIONS FOR USE

IMPORTANT PRODUCT
INFORMATION

Please read before use

ENGLISH

These instructions-for-use refer specifically to
Bi-Ostetic osteoconductive bone void filler
formulated as granules or blocks

Description

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.

Intended Use

Bi-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 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.

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.

It is recommended to use Bi-Ostetic within one hour of opening the package. Bi-Ostetic is opaque to x-rays. This may mask areas under or above the implant on the radiograph.

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. Closed suction or drainage is recommended to prevent wound fluid accumulation.

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. The filler may extrude into soft tissues (e.g. facial applications or iliac crest backfill) and cause inflammation. Do not overfill the site.

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,
- implant fracture 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.

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

Optimal Storage Conditions: 15-30°C (59-86°F) in a secure and dry environment. DO NOT EXPOSE TO EXCESSIVE HEAT. Device may lose functionality if exposed to temperatures above 55°C (131°F).

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.

Other Information

Bi-Ostetic bone void filler is a sterile osteoconductive bone graft substitute. Bi-Ostetic is provided with detailed Instructions-for-use. 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.

Bi-Ostetic is a registered trademark of Berkeley Advanced Biomaterials, Inc.

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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. In case of complaint or for further information on the product and its uses, please contact Berkeley Advanced Biomaterials, Inc. at the address printed on this information sheet.