


# BULLETIN



# AM SCIENTIFICS

ISSUE 707 - 2

**Skeletal Repair:Bi-Ostetic  
Void Filler**



Berkeley Advanced  
Biomaterials, Inc.

World Leader in Hydroxyapatite Solutions for Skeletal Repair

# Bi-Ostetic™ Bone Void Filler




# Bi-Ostetic™ Granules



- Easy-to-use
- 100% Synthetic Scaffold (Composed of 60% Hydroxyapatite and 40%  $\beta$ -Tricalcium Phosphate)
- 100% Resorbable (Six to Nine Months in Animal Tests and Clinical Studies)
- Osteoconductive and Biocompatible
- Radiopaque
- Sterilized by Gamma Irradiation (25 kGy Minimum Dose)

Bi-Ostetic™ is a biocompatible scaffold that quickly fills up bone voids. Bi-Ostetic™ provides a safe alternative to autograft and allograft surgery where harvest site morbidity, graft volume and potential for disease transmission are an issue. Clinical applications and animal models have shown gradual remodelling and replacement with new bone after surgery. The granules are packaged in a glass vial and provided with detailed instructions for use.

	Catalog No.	Qty/Dimension	Description
	BiO-02G	2.5 cc	Cancellous Granules; 0.5 - 1 mm Particle Size
	BiO-05G	5 cc	Cancellous Granules; 1 - 3 mm Particle Size
	BiO-10G	10 cc	Cancellous Granules; 1 - 3 mm Particle Size
	BiO-15G	15 cc	Cancellous Granules; 1 - 6 mm Particle Size
	BiO-30G	30 cc	Cancellous Granules; 1 - 6 mm Particle Size

Common use of Bi-Ostetic™ includes defect filling in total hip revision, spinal fusion, hand or foot surgery, fracture repair, joint reconstruction, cyst treatment and limb salvage.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital. Bi-Ostetic™ is a trademark of Berkeley Advanced Biomaterials, Inc. Manufactured and distributed by Berkeley Advanced Biomaterials, Inc. Berkeley, CA, USA.



**Berkeley Advanced  
Biomaterials, Inc.**

To order products from your local distributor, please contact Berkeley Advanced Biomaterials, Inc.  
901 Grayson Street, Suite 101, Berkeley, CA, 94710, U.S.A. Telephone: 510.883.0500 - Fax: 510.883.0511  
E-mail: [info@ostetic.com](mailto:info@ostetic.com) - Internet: [www.ostetic.com](http://www.ostetic.com) or [www.hydroxyapatite.com](http://www.hydroxyapatite.com)

# Bi-Ostetic Foam™

## Berkeley Advanced Biomaterials

AUTHORIZED EC REPRESENTATIVE:  
**Orthopedix (BAB, France)**  
 29 Grande Rue,  
 54290 Neuville-sur-Moselle  
 France  
 Phone: +33-(0)3 83724946  
 e-mail: ec@hydroxyapatite.com

DISTRIBUTED WORLDWIDE BY:  
**Berkeley Advanced Biomaterials**  
 901 Grayson Street, Suite 101  
 Berkeley, CA 94710  
 U.S.A.  
 Phone: +1-510-883-0500  
 Fax: +1-510-883-0511  
 e-mail: us@hydroxyapatite.com



Rx only

### INSTRUCTIONS FOR USE

#### IMPORTANT PRODUCT INFORMATION

Please read before use

ENGLISH

**These instructions-for-use refer specifically to Bi-Ostetic Foam™**

#### Materials and Device Description

Bi-Ostetic Foam™ is a sterile bone graft composed of purified fibrillar Type I collagen and Bi-Ostetic™ resorbable 60% hydroxyapatite 40% tricalcium phosphate granules. It functions as an osteogenic stimulus to which the patient's bone marrow can be added to, prior to implantation. Bi-Ostetic Foam™ is safe and has excellent biocompatibility. After it is implanted, the strip resorbs and is later replaced by natural bone. Bi-Ostetic Foam™ is a natural choice for sparing patients the trauma of autograft harvesting.

#### Indications-For-Use

Bi-Ostetic Foam™ is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous bone marrow prior to use at the physician's discretion. In weight bearing situations, Bi-Ostetic Foam is to be used in conjunction with internal or external fixation devices. The fracture defect treated should not exceed 30 mL.

#### Contraindications

Bi-Ostetic Foam™ is not sold for any use except as indicated. Do not use Bi-Ostetic Foam™ in the presence of any contraindication.

Bi-Ostetic Foam™ is contraindicated in patients with a history of severe allergies manifested by a history of anaphylaxis and known allergies to bovine collagen, in patients known to be undergoing desensitization injections to meat products, as these injections can contain bovine collagen, in children and pregnant women, in operative sites with inflammatory bone diseases such as osteomyelitis, for fractures of the epiphyseal plate, in sites with severe vascular or neurological impairment proximal to the graft site, in the presence of metabolic or systemic bone disorder, or in contaminated wounds with existing acute or chronic infections.

#### 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.

#### Surgical Procedure

All procedures should be performed in the operative room under aseptic conditions. Follow accepted procedures for grafting with fixation. Bone marrow is obtained by the standard bone marrow collection techniques, and the donor sites include iliac crest, fracture, or other sites. Exercise care not to collect blood. If marrow from the fracture site is used, it is important that the marrow has not been contaminated.

Transfer strips to a sterile tray followed by the addition of sterile saline, then allow them to hydrate for 1 to 3 minutes. To another sterile tray add 1cc of bone marrow for 1-3 strips, 2cc for 4-6 strips, 3cc for 7-9 strips, or 4cc for 10-12 strips. After hydration, transfer the strip(s) to the tray containing marrow and coat all surfaces of the strip(s) with marrow. The strips may be used as is or molded into desired shapes. It is important to mold gently to avoid crushing the granules or damaging the marrow cells. The defect site should be filled as completely as possible.

#### General Information on Using

Bi-Ostetic Foam™ is a bone graft substitute comprised of highly purified Type 1 collagen and hydroxyapatite/tricalcium phosphate granules. It functions as an osteogenic stimulus to which the patient's bone marrow may be added prior to implantation. The bone graft mimics the composition of natural bone and is biocompatible. Bi-Ostetic Foam™ provides an osteoconductive environment for new bone formation. When coated with autogenous bone marrow, the osteoinductive and osteogenic properties of Bi-Ostetic Foam™ enable it to be used as a substitute for autogenous bone graft, thus eliminating the need to subject the patient to the potential attendant morbidity as well as the harvesting-related complications and pain associated with the second surgery. The purified fibrillar collagen component has a high constituent of purified bovine tendon Type 1 collagen. The mineral component is a biphasic mixture of beta tricalcium phosphate and hydroxyapatite. The HAP/TCP particles are formed by a sintering process into irregularly shaped granules of 0.5-1.0 mm in diameter. The purified fibrillar collagen and HA/TCP composite serves as the matrix for the osteogenesis process to occur, in situ, the collagen and beta-tricalcium phosphate components of the ceramic are resorbed and replaced by new bone, similar to the resorption and remodeling with autogenous bone.

#### Warnings

Bi-Ostetic Foam™ contains bovine collagen and must not be used in patients with a history of allergies to any bovine products, including but not limited to injectable collagen, collagen implants, hemostatic sponges and collagen based sutures, because these patients are likely to have hypersensitivity to bovine collagen in Bi-Ostetic Foam™. Hypersensitivity reactions reported with the use of other products containing bovine collagen include erythema, swelling, induration, and/or urticaria at implantation sites.

Bi-Ostetic Foam™ does not possess sufficient mechanical strength for load-bearing uses. It is important to ensure that the implantation site has been properly secured mechanically with standard internal fixation. External stabilization alone is not sufficient.

#### Precautions

The safety and efficacy of Bi-Ostetic Foam™ have not been established in patients with pathological fractures caused by severe degenerative bone disease, pre-existing severe vascular or neurological disease in the affected limb as a result of uncontrolled diabetes, alcoholism, or other pathology, or in patients with clinically significant immune-mediated-systemic disease or disease of bone. The safety of using Bi-Ostetic Foam™ in pregnant women or in children has not been established.

Bi-Ostetic Foam™ is intended for use by surgeons familiar with bone grafting and internal fixation techniques. Care should be exercised to avoid a load directly on the implant.

Read expiration date before use. Do not use if expiration date has been exceeded.

DO NOT USE if packaging is damaged, as sterility of the contents cannot be assured.

Dosage is for SINGLE USE ONLY. DO NOT resterilize or re-use.

**Adverse Reactions**

Possible adverse reactions may include but are not limited to the following: total resorption of the graft, malunion, pseudoarthrosis, hypersensitivity, bleeding at the bone marrow aspiration site, thrombophlebitis, embolus, loss of fixation, neurological complication, and deformity at site. As with any other orthopedic and grafting procedures, wound complications may occur which include hematoma, edema, swelling and fluid accumulation, tissue thinning, infection, or other complications, that are possible with any surgery.

**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 Foam™ AFTER THE EXPIRATION DATE.

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

Bi-Ostetic Foam™ is a registered trademark of Berkeley Advanced Biomaterials, Inc. Manufactured and distributed by Berkeley Advanced Biomaterials, Berkeley, CA (USA)

**Note:** Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Bi-Ostetic Foam™, and for the choice of post-operative follow-up procedures rests entirely with the physician.

**Other Information**

Bi-Ostetic Foam™ is a sterile bone graft substitute. Bi-Ostetic Foam™ is sterilized by gamma irradiation. Bi-Ostetic Foam™ is packaged individually 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™

## Berkeley Advanced Biomaterials

AUTHORIZED EC REPRESENTATIVE: DISTRIBUTED BY:

**Orthopedix (BAB, France)**  
29 Grande Rue,  
54290 Neuville-sur-Moselle France  
Phone: +33-(0)3 83724946

e-mail: ec@hydroxyapatite.com

**Berkeley Advanced Biomaterials**  
901 Grayson Street, Suite 101  
Berkeley, CA 94710 USA  
Phone: +1-510-883-0500  
Fax: +1-510-883-0511  
www.hydroxyapatite.com

**STERILE R**  **0086 Rx only**

### 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 or blocks.**

#### 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. Closed suction or drainage is 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.

#### 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 of 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. The filler may extrude into soft tissues (e.g. facial applications or iliac crest backfill) and cause inflammation.

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.

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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.

#### 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. 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.



# Use of Bi-Ostetic™ Granules for Repair of Tibial Plateau Fracture

Berkeley Advanced Biomaterials

Case Report – B2



**Figure 1**

**Preoperative: AP view demonstrates a lateral depressed tibial plateau fracture.**



**Figure 2**

**Four Weeks Postoperative: AP view demonstrates reduction and fixation of the fracture as well as bone graft materials in fracture site.**

## Case Study B2

### *History*

An 80-year-old woman presented with pain and swelling of the right knee after a fall. She was unable to walk or stand on that leg. She had no previous history of injury to the right knee. Radiographs demonstrated a lateral depressed tibial plateau fracture classified as AO 41-B2.1 (Fig. 1).

### *Treatment*

The fracture was treated with open reduction and internal fixation. Given the bone loss at the fracture site and the poor bone quality, the decision was made to augment the fixation with the use of Bi-Ostetic™ granules. A volume of 10ml Bi-Ostetic™ granules was inserted into the metaphyseal defect of the fracture site. Wound closure was performed following irrigation (Fig. 2).



**Figure 3**

**12 Weeks Postoperative: AP view demonstrates blurring around the implants indicating ongoing graft remodeling and incorporation.**



**Figure 4**

**15 Months Postoperative: AP view demonstrates the well-healed fracture with excellent graft incorporation.**

### ***Postoperative Results and Outcome***

The patient had an unremarkable postoperative course. No allergic reactions, toxic effects, skin rash or high fever were observed. The concentrations of both serum calcium and phosphate were within normal limits. The wound healed well with no prolonged drainage noted. By 12 weeks, X-rays demonstrated fracture healing as well as blurring around the edge of the implants indicating ongoing graft resorption and remodeling (Fig. 3). The functional recovery of the patient's right knee was satisfactory and she was able to walk as before.

By 15 months, X-rays showed that the majority of the implanted bone graft has been remodeled and incorporated (Fig. 4). The patient was able to walk without any discomfort.

### ***Summary***

Use of Bi-Ostetic™ granules in the treatment of depressed tibial plateau fracture with osteoporotic bone allowed for augmentation of the poor quality bone in the region of the fracture site. By 12 weeks, the fracture had healed without collapse or displacement and signs of graft incorporation were observed. By 15 months, the majority of the granules were resorbed and incorporated. This case demonstrates the safe and effective use of Bi-Ostetic™ for tibial plateau fracture.



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Consult the package insert for complete labeling information. For more information about Berkeley Advanced Biomaterials products, visit our web site at [www.hydroxyapatite.com](http://www.hydroxyapatite.com). Cem-Ostetic is a trademark of and manufactured by Berkeley Advanced Biomaterials, Inc.

901 Grayson Street, Suite 101 - Berkeley, CA, U.S.A. 94710  
Telephone: 510.883.0500 - Fax: 510.883.0511

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Established in 1984, AM SCIENTIFICS LTD is active in marketing and distribution of high quality wound care, medical skin care devices and implants destined for use in hospitals, clinics and medical practices.

AM SCIENTIFICS is Exclusive Swiss Distributor for **AlloDerm**®, **Cymetra**™, **JUC**™ and other plastic, burn surgery & dermatology products and is active in most European Union (EU) countries.



AM SCIENTIFICS LIMITED

P.O. Box 507  
CH -1212 Grand-Lancy 1  
Geneva – Switzerland  
T:+41 (0)223011794, F:+41 (0)223011795  
M: +41 (0)763372100  
[www.am-scientifics.com](http://www.am-scientifics.com)  
[marketing@am-scientifics.com](mailto:marketing@am-scientifics.com)