Bi-Ostetic™ Foam
Berkeley Advanced Biomaterials

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

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 Bi-Ostetic™ Foam

Description
Bi-Ostetic™ Foam is a sterile bone graft composed of purified fibrillar Type I collagen and Bi-Ostetic™ (60% hydroxyapatite - 40% tricalcium phosphate) resorbable granules. This device is safe and has excellent biocompatibility. After it is implanted, the graft resorbs and is later replaced by natural bone.

Intended 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, posterolateral 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. In weight bearing situations, the graft is to be used in conjunction with internal or external fixation devices. The fracture defect treated should not exceed 30mL.

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.

Warnings
Bi-Ostetic™ Foam is sterilized by gamma irradiation. 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. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the device.
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.
The implant must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
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. Do not overfill the defect site.
Do not over-pressurize the defect site since this may lead to fat embolization or embolization of the device material into the bloodstream.
The effect of mixing the device with any substance except for STERILE water or saline is not known.
Do not over-pressurize the device, as it may lead to extrusion of the device beyond the site of its intended application and damage surrounding application.

Adverse Reactions
Possible adverse reactions may include but are not limited to the following: total resorption of the graft, malunion, pseudoarthrosis, hypersensitivity, 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.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. 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. Initial debridement and wound management should be performed in an open fracture. Exercise care to minimize periosteal stripping. Strips can be hydrated with STERILE saline (about 1:1 ratio). Allow strips to rehydrate for three minutes. The strips may be used as is or molded to fill the defect shape. The defect site should be filled as completely as possible.

Storage Conditions
Optimal Storage Conditions: 15-30˚C (59-86˚F) in a secure and dry environment. DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT. Graft will quickly lose functionality if exposed to temperature above 55˚C (131˚F).

Shelf Life and Disposal
The expiration date is printed on the label. DO NOT USE Bi-Ostetic Foam AFTER THE EXPIRATION DATE. Packaging materials are recyclable. Residual materials may be dispensed with other medical waste.

Other Information
Bi-Ostetic™ Foam is a sterile bone graft substitute. Bi-Ostetic™ Foam is packaged individually in vials. The container is 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.

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. 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 leaflet.

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Description
Bi-Ostetic™ Foam Putty is a sterile bone graft composed of purified fibrillar type I collagen and 60% hydroxyapatite - 40% tricalcium phosphate resorbable granules. This device, formulated as putty, is safe and has excellent biocompatibility. After it is implanted, the graft resorbs and is later replaced by natural bone.

Intended Use
Bi-Ostetic™ Foam Putty 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, posterolateral 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. In weight bearing situations, the graft is to be used in conjunction with internal or external fixation devices. The fracture defect treated should not exceed 30mL.

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Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. 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. Initial debridement and wound management should be performed in an open fracture. Exercise care to minimize periosteal stripping. The putty can be hydrated with approximately a 10:6 ratio of hydration fluid. Allow the putty to hydrate for at least 3 minutes. The putty may be molded to fill the defect shape.

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).

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