Approved by: _____ **Date**: _____

LEAPBIOLOGICS

Demineralized Bone Matrix

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

STERILE R — 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 Demineralized Bone Matrix Putty and Crush-Mix

Donated Human Tissue. Tissue recovery was performed using aseptic techniques. Once processed, the tissue is sterilized by gamma irradiation.

Description
The implant is composed of 100% human bone tissue and does not contain any additive or extrinsic carrier. The bone is demineralized using a simple process that has been validated to perform viral inactivation.
The Demineralized Bone Matrix Putty is composed of demineralized cortical bone. The Demineralized Bone Matrix Crush-Mix is a mixture of Demineralized Bone Matrix Putty with mineralized cancellous chips. This set of Demineralized Bone Matrix products provides a variety of handling characteristics that can be chosen to fit the application.

Intended Use
The graft is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. It should be gently packed into bony voids or gaps of the skeletal system. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The graft provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. It can be mixed with autogenous bone marrow prior to use at the physician's discretion.

Contraindications
Do not use the graft in the presence of any contraindication. The graft is contraindicated where the graft is intended as structural support in the skeletal system. Other conditions representing relative contraindication include:
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- pregnancy
- 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 graft is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Contact distributor or manufacturer and do not use if packaging is damaged. Read expiration date before use. Do not use if expiration date has been exceeded.

It is recommended to use the graft within one hour of opening the package.
Dosage is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the graft.
While every effort has been made to ensure the quality of this allograft, Berkeley Advanced Biomaterials makes no claims concerning its biological or biomechanical properties. As with any allograft, despite strict screen-testing procedures, this allograft has the potential to transmit infectious agents to the recipient.
This allograft may contain trace amounts of processing/cleaning agents, such as iodine, ethanol, glycerol, or hydrogen peroxide.

Precautions
The graft is not intended for load-bearing uses. It is important to ensure that the area where the graft has been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the graft or to change its shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of the graft 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 implant must be secured to prevent potential migration or embolization of the graft into the blood stream. The implant should only be used in surgical procedures where bone grafts are adequately contained. The implant may extrude into soft tissues (e.g., facial applications or iliac crest backfill) and cause inflammation. Do not overfill the site.

Adverse Reactions
A graft may not elicit proper response from the recipient (e.g., fusion/union with adjacent tissue). It is possible for the host site to become infected. The graft may also lead to a deformity of the bone at the site. The graft may cause an inflammatory response. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of disease, including hepatitis and HIV.

Reporting Adverse Reactions
The surgeon is responsible for reporting all adverse reactions potentially attributed to the allograft within fifteen (15) days of the occurrence. In such a case, contact Berkeley Advanced Biomaterials at +1-510-883-0500.

Viral Inactivation
The processing methods were evaluated for their viral inactivation potential. A select panel of viruses representing various virus types, shapes, and genomes were evaluated. The tests demonstrated suitable viral inactivation potential of the processing methods. The product is also terminally sterilized by gamma sterilization to also ensure its biological sterility.

Donor Selection
All donor tissue is recovered, processed, and distributed according to standards established by the American Association of Tissue Banks. Donor screening exclusion criteria is performed via donor physical inspection, interview with a person who knew the donor, review of available medical records, and a review of autopsy findings (when applicable). Individuals considered to be at high risk for AIDs or hepatitis as defined by the FDA and CDC are excluded from donorship. Using FDA licensed, approved, or cleared test kits in a laboratory registered with the FDA and certified under CLIA or equivalent requirements, a serum sample from the donor has passed a hemodilution review and tested non-reactive for the following:
- Human immunodeficiency virus antibody (anti-HIV1 and anti-HIV2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Total antibodies to Hepatitis B core antigen (anti-HBc-total, IgG/IgM)
- Antibodies to the Hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Rapid plasma reagin (RPR) or serological tests for syphilis (STS)
- Nucleic acid test (NAT) for HBV

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.
Donor eligibility was performed by Alamo Biologics (AB), 5844 Rocky Point, San Antonio, TX; Solvita, 349 S. Main St., Dayton, OH; Berkeley Biologics (BB), 880 Harbour Way S., Suite 100, Richmond, CA; or AlloSource (AS), 6278 S. Troy Circle, Centennial, CO.

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. Open both outer and inner pouches. Open the container to dispense the graft. Follow accepted procedures for grafting with fixation. 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. Bone marrow aspirate can be added to the graft. The marrow aspirate 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. If the material is not positioned satisfactorily, remove the implant and start over with a new dose of the graft.

Storage Conditions

Store at ambient temperature in a secure and dry environment. Do not expose product to temperatures lower than 0°C (32°F) and greater than 50°C (122°F); product may lose functionality if exposed to temperatures outside this range for extended time periods. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Shelf Life and Disposal

The expiration date is printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. Packaging materials are recyclable. The graft comes sterile. Residual materials may be disposed with other medical waste.

Tissue Tracing

It is the responsibility of the user surgeon to complete recipient records for the purpose of tracing tissue post-transplant. Complete the enclosed ALLOGRAFT USAGE REPORT in detail and return as indicated.

Other Information

The implants are packed individually in containers 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 and an allograft usage report for traceability.

This allograft meets the criteria for regulation solely as a human cell, tissue, and cellular and tissue-based product (HCT/P) regulations under Section 361 of the Public Health Service Act and 21 CFR Part 1271. The implant therefore neither received a 510(k) medical device clearance nor is registered as a medical device. This product is solely registered as HCT/P with the Food and Drug Administration, Center for Biologics Evaluation and Research (CBER).

Note: Recipient records shall be maintained for the purpose of tracing tissue post-transplantation. Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of the graft, 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.