**Demineralized Bone Matrix**

**Berkeley Advanced Biomaterials**

**DISTRIBUTED BY:**
Berkeley Advanced Biomaterials
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**STERILE**

**INSTRUCTIONS FOR USE**

**IMPORTANT PRODUCT INFORMATION**

Please read before use

These instructions for use refer specifically to Demineralized Bone Matrix.

**Material**

Demineralized Bone Matrix (DBM) Human Allograft is produced from ground cortical bone.

**Storage Recommendation**

All tissue is freeze-dried. It is the user clinician’s responsibility to maintain tissue in appropriate storage conditions prior to transplant. Store between 2 and 40 °C (room temperature).

**Donor Selection**

All donor tissue is recovered, processed and distributed according to standards established by the American Association of Tissue Banks.

Donor screening following the Tissue Banks International 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 test kits in a CLIA certified lab, a serum sample from the donor has passed control testing by a CLIA certified lab.

**Precautions**

This allograft should not be implanted into sites with active or latent infection.

**Possible Contraindications**

- 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
- Treatment of vertebral compression fractures; a highly pressurized application of DBM into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.

**Usage**

This allograft may contain trace amounts of processing agents such as iodine, ethanol, or hydrogen peroxide.

**Sterility Control**

Tissue from this donor has passed bacteriological quality control testing by a CLIA certified lab.

**Possible Adverse Reactions**

An allograft may not elicit proper response from the recipient (e.g., fusion/union with adjacent tissue). It is possible for a host site to become infected. The allograft may not provide mechanical support and collapse, or 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. 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
- Treatment of vertebral compression fractures; a highly pressurized application of DBM into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.

**Reporting Adverse Reactions**

The surgeon is responsible for reporting all adverse reactions potentially attributed to the allograft within 30 days of the occurrence. In such a case, contact Berkeley Advanced Biomaterials at +1.510.883.0500.

**Warning**

- Unused allograft, whole or partial, may not be repackaged, or resterilized.
- This allograft is intended for single patient use only.
- 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 screening/testing procedures, this allograft has the potential to transmit infectious agents to the recipient.
- This allograft may contain trace amounts of processing agents such as iodine, ethanol, or hydrogen peroxide.

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The expiration date has passed.
The label has been removed or defaced.
Recommended storage conditions have not been met.

DBM IFU Rev. C (Mar 2005)
Spec: 50221
DBM Preparation for Use

1. Examine peel pack for package integrity. Do not use if there is evidence that the outer peel pack is damaged or sterility has been compromised.

2. The outer peel pack is not sterile. The inner bottle and the allograft it contains are sterile, provided the allograft packaging has not been compromised.

3. Aseptically present the bottle containing the allograft onto the sterile field.

4. Remove the safety seal band and cap.

5. Remove the stopper and pour contents from the bottle into a sterile preparation container. Mix for use. Allow the DBM to rehydrate for a minimum of 5 minutes with initial light mixing to wet all the particles prior to use.

6. We recommend that you obtain a swab culture of the allograft and submit it to your clinical laboratory for aerobic and anaerobic testing. If the surgeon desires, antibiotics may be added to the allograft in the preparation container prior to use.

7. If the DBM is not to be used within approximately 2 hours following rehydration, assure its continued sterility and refrigerate at approximately 2 to 8°C. Use rehydrated tissue within 24 hours or discard.

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 RETURN CARD in detail and return as indicated.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of DBM, 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 information sheet.