# DEMINERALIZED BONE MATRIX (DBM) ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

**READ BEFORE USING**

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. PROCESSING AND PACKAGING WERE ASEPTICALLY COMPLETED IN A CLEANROOM FACILITY. STERILIZATION VIA GAMMA IRRADIATION WAS USED IN THE PROCESS.

## DESCRIPTION AND APPLICATIONS FOR USE

This Demineralized Bone Matrix (DBM) allograft is comprised of 100% human bone, provided in a Putty or Crunch (putty and cortical-cancellous bone) formulation to be used at the discretion of qualified medical professionals (e.g. physicians, dentists and/or podiatrists). This DBM allograft is intended for use in bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects caused by traumatic injury to the bone. This product provides a bone graft substitute that remodels into the recipient's skeletal system. It may be used independently or in combination with autologous tissue or other forms of allograft tissues.

## REGULATORY CLASSIFICATION

This allograft is a human tissue product for transplantation. It is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271), State regulations, and the Standards of the American Association of Tissue Banks (AATB).

**Caution: Federal Law restricts this product to sale by or on the order of a licensed practitioner. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.**

## DONOR RECOVERY AND SCREENING

After legal authorization or consent for donation is obtained, recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments.

Blood samples from each donor are tested by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are approved by the FDA for testing cadaveric specimens where applicable. Donor test results were shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- HIV1 Nucleic Acid Test (NAT)
- Hepatitis C Virus Antibody
- HCV Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- HBV Nucleic Acid Test (NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

The following test(s) may have also been performed and shown to be **negative or nonreactive**:

- Human T-Cell Lymphotropic Virus Type I and II Antibody (required for international)
- West Nile Virus Nucleic Acid Test (NAT)

Donor medical and social history, physical assessment, autopsy results (if performed), infectious disease testing, tissue cultures, cause of death and all other available medical records have been evaluated by a licensed physician and determined to meet all donor eligibility requirements for transplantation as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. All testing and medical release records are maintained by Bone Bank Allografts**.**

## PROCESSING

Allograft tissues are processed in a controlled cleanroom environment using methods designed to prevent contamination and cross contamination. Proprietary physiological buffers, acids, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Antibiotics were not used in the processing of these allografts. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

DBM allograft tissues will naturally vary in color from pale yellow to tan. Occasional dark spots or localized discoloration are normal occurrences.

## WARNINGS AND PRECAUTIONS

Careful donor screening, laboratory testing, tissue processing, and gamma irradiation have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens. Disease screening methods are limited; therefore, certain diseases may not be detected.

Possible complications may occur with any surgical procedure including, but not limited to pain, bacterial infection, hematoma, incomplete or lack of bony growth at treatment site. As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist.

**All adverse outcomes potentially attributed to the allograft must be promptly reported to Bone Bank Allografts and to the Distributor listed on the container label, if applicable.**

**This allograft is intended for <u>single patient use only</u>.**
**Do NOT reuse or sterilize.**
**Do NOT refrigerate or freeze product.**

**Do Not Use This Allograft If:**

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. Product label or identifying bar code is severely damaged, illegible or missing.
3. Expiration date shown on the package label has passed.
4. Allograft has not been stored according to storage temperature requirements.

## CONTRAINDICATIONS

DBM Putty and Crunch are contraindicated where the product is intended as structural support in load-bearing bone and in articulating surfaces. Other conditions representing relative contraindication include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors

## PACKAGING AND LABELING

Each DBM allograft is identified by its own unique serial number and packaged in a plastic syringe placed in a two-layer pouch configuration. Tissue must be removed from the syringe prior to implantation.

The package container label includes graft details such as distributor name, address, phone number and product dimensions and/or volumes. **Contents of the package are sterile unless the package is opened or damaged.**

## TRANSPORT, STORAGE AND EXPIRATION

DBM allografts are shipped at ambient temperatures. Upon receipt product should be removed from the shipping container and stored at room temperature (59-86°F or 15-30°C). No refrigeration necessary.

See package label for expiration date.

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

## USAGE INSTRUCTIONS

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded.

1. Open allograft packaging for use by following the below procedures. Use proper aseptic technique to open and deliver the allograft to the sterile field:

   a) Cut or tear open the non-sterile outermost moisture barrier and remove associated labeling materials.
   b) Peel open the outer pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Peel open the sterile sealed pouch and deliver the graft to a sterile field.
   d) Remove plastic cap on syringe and apply even force on the plunger to extrude the DBM from the syringe onto the sterile field.

If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

## PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. ***IMPORTANT NOTICE TO END-USER:*** Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:

1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, distinct graft identification code, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the bottom copy of the Transplant Record should be returned to the address indicated. Copies of this information should be retained by the transplant facility for future reference.

Donor Eligibility Determination and Processing By:
Bone Bank Allografts
5335 Castroville Road
San Antonio, TX 78227
(800) 397-0088
FDA Registration FEI: 3000779542

All recovery, processing and distribution costs were reimbursed in part by Bone Bank Allografts in accordance with NOTA