SteriFuse™ DBM Putty and SteriFuse™ Crunch

PROCESSED ALLOGRAFT TISSUE PACKAGE INSERT

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

This human tissue allograft is supplied by **BONE BANK ALLOGRAFTS** (BBA) and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by **BONE BANK ALLOGRAFTS** in accordance with NOTA.

This allograft is supplied sterile.

REGULATORY CLASSIFICATION

SteriFuse™ DBM Putty and SteriFuse™ Crunch are human tissue products for transplantation. They are 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).

APPLICATIONS FOR USE

SteriFuse™ DBM Putty and SteriFuse™ Crunch are indicated 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 created from traumatic injury to the bone. These products provide a bone graft substitute that remodels into the recipient's skeletal system. They may be used independently or in combination with autologous tissue or other forms of allograft tissue.

This allograft is intended for single patient use only.

DONOR RECOVERY AND SCREENING

After authorization for donation is obtained, surgical recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, an autopsy review (if performed), serological screening, tissue recovery microbiology, and cause of death.
Each donor is tested and shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- HIV1/HCV Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus Type I Antibody (not required)
- Human T-Cell Lymphotropic Virus Type II Antibody (not required)

This testing is performed 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.

BONE BANK ALLOGRAFTS' Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by **BONE BANK ALLOGRAFTS**.

PROCESSING

Allograft tissues are processed in a controlled 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. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Note: Allograft tissues will naturally vary in color from white, off-white, pink, pale pink, and yellow to pale yellow. Occasional dark spots or localized discoloration is a normal occurrence.

CONTRAINDICATIONS

SteriFuse™ DBM Putty and SteriFuse™ 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

WARNINGS

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.

Do NOT reuse or re-sterilize.

PACKAGING AND LABELING

Each allograft distributed by **BONE BANK ALLOGRAFTS** is identified by its own unique serial number. Each Allograft is individually sealed in a peel back pouch and terminally sterilized. The package label includes graft details such as dimensions and/or volumes. Contents of the package are sterile unless the package is opened or damaged.

Warning: If the innermost pouch is compromised or shows evidence of being torn or opened, **DO NOT USE**!

SteriFuse™ DBM Putty and SteriFuse™ Crunch are supplied prehydrated and ready to use.

STORAGE OF STERIFUSE™ DBM PUTTY AND STERIFUSE™ CRUNCH

Maintain allograft at room temperature (15-30°C or 59-86°F). It is not necessary or recommended to refrigerate or freeze SteriFuse™ DBM Putty or SteriFuse™ Crunch. If allograft is refrigerated or frozen it must be thawed and warmed to room temperature prior to use. DO NOT EXPOSE TO EXCESSIVE HEAT. SteriFuse™ DBM Putty and SteriFuse™ Crunch will quickly lose functionality if exposed to temperature above 40°C (104°F).

EXPIRATION

See package label for expiration date or observe the above indications for alternate tissue storage.

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

USAGE INSTRUCTIONS

Prior to use: Examine SteriFuse™ DBM Putty or SteriFuse™ Crunch Package – Do Not Use SteriFuse™ DBM Putty or SteriFuse™ Crunch If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

If for any reason the SteriFuse™ DBM Putty or SteriFuse™ Crunch product is opened and not used, it should be disposed of properly or returned to BONE BANK ALLOGRAFTS by contacting Client Services and following appropriate return procedures. Document the reason for the non-use of the SteriFuse™ DBM Putty or SteriFuse™ Crunch product, indicate the disposition of the tissue on the enclosed Transplant Record, and return the record to BONE BANK ALLOGRAFTS.

RETURNS

If for any reason SteriFuse™ DBM Putty or SteriFuse™ Crunch must be returned, a return authorization is required from **BONE BANK ALLOGRAFTS** prior to shipping. It is the responsibility of the health care institution returning SteriFuse™ DBM Putty or SteriFuse™ Crunch to adequately package and label the tissue for return shipment.

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 pertinent hospital and patient medical records. 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 enclosed with each Allograft. Please attach one patient barcode label in the space provided and complete the requested information on the Transplant Record. Once completed, the bottom copy of the Transplant Record should be returned to **BONE BANK ALLOGRAFTS**. Copies of this information should be retained by the transplant facility for future reference.

POTENTIAL COMPLICATIONS

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.**

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.

DISPOSAL

SteriFuse™ DBM Putty and SteriFuse™ Crunch disposal shall be in accordance with local, state, and federal regulations for human tissue.

INQUIRIES

For additional information, to place an order, or to report adverse reactions, contact: **BONE BANK ALLOGRAFTS** Client Services at:

Phone: 800-397-0088
Fax: 210-696-7609

BONEBANK® ALLOGRAFTS

4808 RESEARCH DRIVE
SAN ANTONIO, TX 78240
(800) 397-0088
FDA Registration FEI: 3000779542

ALLOGRAFT TISSUE PROCESSED BY:
Texas Human Biologics
14805 Omicron Drive, Suite 200
San Antonio, Texas 78245

LB-155 R02 Eff. Date: May 27, 2015; CN# 15.105