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 guidelines.

**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 is 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 is supplied prehydrated and ready to use.

**STORAGE OF STERIFUSE™ DBM**

Maintain allograft at room temperature (15-30°C or 59-86°F). It is not necessary or recommended to refrigerate or freeze SteriFuse™ DBM. 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 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 Package – Do Not Use SteriFuse™ DBM 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 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 product and 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 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 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.

**DISPOSAL**

SteriFuse™ DBM 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

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

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.