

# **BONE BANK**

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# **ALLOGRAFTS**

## **PROCESSED ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION**

READ BEFORE USING

THIS ALLOGRAFT UNIT IS DERIVED FROM HUMAN TISSUES VOLUNTARILY DONATED. THIS ALLOGRAFT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY.

CAUTION: RESTRICTED TO USE BY A PHYSICIAN, PODIATRIST OR DENTIST.

NO ADDITIONAL STERILIZATION STEP IS TO BE PERFORMED BY THE USER.

### **DESCRIPTION**

Bone Bank Allografts bone grafts are processed and prepared via a proprietary process by Texas Human Biologics, San Antonio, TX (THB). All recovery, processing and distribution costs were paid for in part by **BONE BANK ALLOGRAFTS**.

### **DONOR SCREENING AND TESTING**

Prior to processing, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by **BONE BANK ALLOGRAFTS**. All **BONE BANK ALLOGRAFTS** policies and procedures for donor screening, serologic and microbiologic testing meet current *Standards* established by the **American Association of Tissue Banks**. Contraindications for tissue donation include: presence of infectious disease, neurological degenerative disease, disease of unknown etiology, and exposure to toxic substances. The donor's medical/social history was also screened for HIV, Hepatitis and other relevant communicable disease agents in accordance with current United States Public Health Services Recommendations and FDA Federal Regulations and Guidance Documents.

Testing of donor blood and tissue samples began at the site of recovery and continued throughout processing. Donor blood samples taken prior to or at the time of recovery were tested by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and were found negative using FDA licensed tests for:

HBsAg	Hepatitis B Surface Antigen
HBc (Total)	Hepatitis B Core Total
HCV	Hepatitis C Antibody
HIV 1/2-Ab	Antibody to Human Immunodeficiency Virus Types 1 and 2
HTLV I/II	Human T-Lymphotropic Virus Types I and II
RPR/STS/FTA confirm.	Syphilis Detection
*HIV NAT	HIV Nucleic Acid Test
*HCV NAT	HCV Nucleic Acid Test
<b>Additional tests that may have been performed</b>	
HIV-1 Antigen (p24)	Antibody to Human Immunodeficiency Virus Type 1 p24 antigen
HIV by PCR	Human Immunodeficiency Virus DNA Detection by Polymerase Chain Reaction (PCR)
HBV NAT	HBV Nucleic Acid Test
CMV IgM or IgG Avidity	Cytomegalovirus Antibody Test

\* Tests will be performed on all donor blood samples recovered after 01/01/05.

The infectious disease test results, together with the consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, plasma dilution assessment, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by **BONE BANK ALLOGRAFTS** licensed physician and are sufficient to indicate that donor suitability criteria, current at the time of procurement, have been met. This tissue allograft is determined to be suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published at the time of recovery.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this human tissue are on file at **BONE BANK ALLOGRAFTS** and are available upon request.

### **PROCESSING**

Technical Quality Assurance standards are rigorously maintained by Texas Human Biologics (THB).

This graft was prepared from tissue procured from a cadaver donor using aseptic surgical techniques. Processing cleaning, cutting, sizing, shaping, container sterilization, and filling were performed using aseptic techniques in a controlled, ultra clean environment.

This allograft was prepared from tissues that were cleaned using sterile water, isopropyl alcohol, hydrogen peroxide, and Brij-35. Additional solutions for preparation may include hydrochloric acid, potassium phosphate monobasic, and potassium phosphate dibasic. Following processing, THB incorporates exposure to gamma irradiation at 19.8-24.2 kGy for Frozen, Freeze Dried and Saline packaged grafts, as a terminal sterilization methodology.

This aseptic handling of the tissue continues throughout processing and final release is based on a validated sterilization process with a SAL of  $10^{-6}$  in accordance with ISO 11137-2 Method 1.

### **PACKAGING AND LABELING**

Each graft distributed by **BONE BANK ALLOGRAFTS** is identified by its own unique serial number.

This graft is packaged in sterile, single patient use containers and the lot number (donor ID), expiration date, product code, size, and additional information are listed on the package label.

### **USE**

This allograft can be used in a number of orthopedic, spine and reconstructive applications. It can be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or it can be used by itself as a bone graft.

This package is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents of this package for multiple patients.

Preparation of the bone graft bed is important for graft incorporation and bone formation, as are other factors such as blood supply, source of marrow elements, loading, stability and absence of infection at the graft site.

### **PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS**

This allograft may contain trace amounts of processing solutions or reagents.

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors for **BONE BANK ALLOGRAFTS**. Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of an infectious disease through the use of this tissue graft is still possible.

Any adverse outcomes potentially attributable to this graft must be reported promptly to **BONE BANK ALLOGRAFTS**. Possible adverse effects include:

- 1) Complications associated with surgery such as hematoma, infection and other complications;
- 2) Incomplete or lack of bony growth at the treatment site;
- 3) Immune rejection of the introduced tissue; and
- 4) The transmission of known pathogens including Human Immunodeficiency Virus 1/2, Hepatitis B and C, Human T-Lymphotropic Virus 1 and 2, Syphilis, bacteria, and fungus.

The patient is to be made aware of general risks associated with treatment and possible adverse effects. There are no guarantees regarding biological or biomechanical properties of the provided product.

### **CONTRAINDICATIONS**

Contraindications for the use of this allograft include;

- 1) The presence of infection at the surgical site and/or distant foci of infections that may spread to the surgical site;
- 2) Uncooperative patient or a patient with neurologic disorders who is incapable of following directions, including weight control and activity levels;
- 3) Pregnancy; and
- 4) Disorders or diseases which may impair bone formation.

### **STORAGE**

**Storage of Frozen Tissue:** Store frozen tissue at temperatures colder than  $-40^{\circ}$  C. **NOTE:** If the allograft is to be stored at a temperature between  $-20^{\circ}$  C and  $-40^{\circ}$  C, limit storage to a period not to exceed (6) six months.

**Storage of Freeze Dried & Saline Packaged Tissues:** Maintain allograft at ambient temperature ( $59-86^{\circ}$  F or  $15-30^{\circ}$  C). No refrigeration necessary.

## RETURNS

If for any reason tissue must be returned, a return authorization is required from **BONE BANK ALLOGRAFTS** prior to shipping. Frozen grafts are not returnable. It is the responsibility of the health care institution returning the tissue to adequately prepare and identify the tissue for return shipment.

## EXPIRATION

See package label for expiration date. It is the responsibility of the Tissue Dispensing Service and/or the end user to maintain this allograft in the appropriate storage conditions prior to transplant.

## USAGE INSTRUCTIONS

### **Before Usage: Examine Allograft Package – Do Not Use This Allograft 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.
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

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

### **Preparation of Allografts in 2 layer Peel-Packs for Use:**

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded. Used allograft containers should be disposed of in accordance with recognized procedures for discarding medical waste material.

1. Open tissues packaged in peel-packs using the following procedures:
  - a) Open the outer non-sterile moisture barrier to expose and remove the 1<sup>st</sup> inner peel pouch.
  - b) Using appropriate aseptic technique, open the 1<sup>st</sup> inner peel pouch and deliver the innermost sterile sealed pouch containing the graft material to the sterile field.
  - c) Using sterile technique, open the sterile sealed pouch and deliver the graft to the sterile field for rehydration.
  - d) If the graft is packaged in saline, utilize sterile scissors to open the fluid filled inner pouch and deliver the graft to a sterile basin.

**If for any reason the graft is opened and not utilized, it should be disposed of properly or returned to BONE BANK ALLOGRAFTS. Document the reason for the graft not being utilized and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to BONE BANK ALLOGRAFTS.**

2. Rehydrate tissue using the following method:

#### **SALINE PACKAGED TISSUES:**

No further hydration required.

#### **FREEZE DRIED TISSUES:**

***ALL FREEZE DRIED TISSUE MUST BE REHYDRATED FOR A MINIMUM OF 60 MINUTES. EXTENDED REHYDRATION TIME (UP TO 4 HOURS) IS RECOMMENDED FOR ANY TISSUE TO BE CUT, SHAPED, OR WEDGED TO REDUCE THE CHANCE OF FRACTURING.***

1. Place the graft in a basin with sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for a **minimum of 60 minutes**.
2. **Extended rehydration time (up to 4 hours)** is recommended for any tissue to be cut, shaped or wedged to reduce the chance of fracturing.
3. **Allografts must be used within six hours** after rehydrating if the allograft is stored at room temperature. If refrigerated and stored between 2° C and 8° C within six hours after rehydrating, the allograft may be used within 24 hours (including rehydration time). Graft must be stored with proper precautions to prevent contamination.

#### **FROZEN TISSUES:**

NOTE: Before use, the allograft must be thawed using aseptic technique. The allograft must not be refrozen after thawing.

1. Thaw tissue using one of the following methods:
  - a) **Slow Thaw Method:** Approximately 24 hours prior to surgery, move the packaged allograft from freezer to refrigerator (2° C to 8° C). Do not open the package until immediately before use. When needed for surgery, follow the unwrapping procedure and proceed as described below. Refrigerated tissue must be used within 24 hours or discarded.
  - b) **Quick Thaw Method:** Follow the instructions for removing allograft from packaging. Immerse the allograft in sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for 30 to 60 minutes. The solution used for thawing may be warmed to a maximum of 40° C for rapid thawing. **DO NOT MICROWAVE THE GRAFT.**
2. Allografts must be used promptly after thawing and must not be refrozen. Allografts must be used within six hours after thawing if the allograft is stored at room temperature. If refrigerated between 2° C and 8° C within six hours after thawing, the allograft may be used within 24 hours (including thaw time), if stored with proper precautions to prevent contamination.

## 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 labeled 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 hospital, name of the transplanting physician, date and type of surgery, name of the nurse filling out the Transplant Record and any comments. 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.

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**4808 RESEARCH DRIVE**

**SAN ANTONIO, TX 78240**

**(800) 397-0088**

**FDA Registration FEI: 3000779542**

Tissue processed by:

**Texas Human Biologics**  
14805 Omicron Drive, Suite 200  
San Antonio, Texas 78245

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