STERIMATRIX™ ACELLULAR DERMAL ALLOGRAFT TISSUE PACKAGE INSERT

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

SteriMatrix 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

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) as defined by US FDA 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.

APPLICATIONS FOR USE

This allograft may be used for the repair, replacement or supplement of damaged or inadequate integumental tissue, or for any additional homologous uses of human integument.

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, bases, 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.

CONTRAINDICATIONS

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

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 sterilize.

PACKAGING AND LABELING

Each allograft distributed by **BONE BANK ALLOGRAFTS** is identified by its own **distinct graft identification code.** The allograft is packaged in a pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. 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!**

Allografts are supplied hydrated in saline (0.9%).

STORAGE OF PACKAGED TISSUES

Maintain allograft at room temperature (59-86°F or 15-30°C). No refrigeration necessary.

EXPIRATION

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

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

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.

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

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

Prepare the allograft for use using the following procedures:

1. Open the outer container to expose and remove the 1st inner peel pouch.
2. Open the 1st inner peel pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
3. Open the sterile sealed pouch and deliver the graft to a sterile field.

If for any reason the graft 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 graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to BONE BANK ALLOGRAFTS.

No further hydration required.

RETURNS

If for any reason tissue 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 the tissue 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 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 **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, 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

Allograft 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

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(800) 397-0088
FDA Registration FEI: 3000779542

ALLOGRAFT TISSUE PROCESSED BY:
Texas Human Biologics
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LB-274 R00 Eff. Date: March 21, 2016; CN# 15.157