SKYE® BIOLOGICS

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WOUNDFIX™

ALLOGRAFT TISSUE INFORMATION & PREPARATION INSTRUCTIONS

Contents

This package contains a human tissue allograft [Human Cellular and Tissue Based Product (HCT/P)] for transplantation regulated by US Food and Drug Administration under 21 CFR Part 1271. In addition to this product insert, the following items are included in the product package:


1 Outer Box


1 Double Peel-Pouch (containing graft)


1 Allograft Tracking Record


1 Set of Supplemental Labels for Patient Documentation

CAUTION U.S. Federal law restricts this tissue to use by or on the order of a licensed physician. The use of the enclosed tissue for veterinary purposes is not permitted.

Product Description

WOUNDFIX™ is a sterile, dehydrated, human tissue allograft intended for homologous use as a wound covering.

Intended Use

WOUNDFIX™ is an amnion-only thin membrane allograft intended for use in the management of acute and chronic wounds. **WOUNDFIX™** may be applied and is intended for use as a wound covering, wrap or barrier, application to partial and full-thickness, acute and chronic wounds. **WOUNDFIX™** can be applied from the onset of the wound. Additional **WOUNDFIX™** may be applied for the duration of the wound, weekly, or at the discretion of the health care practitioner.

Storage & Handling

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

WOUNDFIX™ must be stored at ambient temperature (50-86°F /10-30°C) until ready for use.

The tissue product is for single patient, one time use only. Once opened, the tissue must be used immediately or disposed of appropriately.

Product has a 5 yr shelf life. Please refer to product ID label for expiry date.

Product must be recorded (see HCT/P Tracking section).

WOUNDFIX™ is packaged in a double peel-pouch and outer box. The inner peel-pouch and tissue are terminally sterilized via irradiation, and may be placed directly onto the sterile field.

Recommended Instructions For Use

NOTE These recommendations are designed only to serve as general guidelines. They are not intended to supersede any institutional protocols or professional clinical judgment concerning patient care.

PREPARATION & APPLICATION


1. Open product package and remove peel-pouch containing the graft.


2. Using aseptic technique, peel open outer pouch and place inner pouch onto the sterile field.


3. When ready to use, peel open pouch to expose the graft.


4. Remove graft using dry, sterile gloves or forceps.


5. Use forceps to apply the graft over the intended site. Achieve full contact.


6. Graft may be cut with scissors to apply over multiple sites.


7. It may be necessary to gently "brush" or "massage" edges to smooth wrinkles or folds that can occur during placement.


8. If desired, graft may be hydrated prior to application with sterile saline, for tight or hard to reach areas.

HCT/P Tracking

IMPORTANT NOTICE TO END-USER Recipient records must be maintained for the purpose of tracking tissue post-transplant per The Joint Commission and FDA requirements. The allograft ID number must be recorded in the operative record. Supplemental labels, which indicate the Tissue ID number, are contained in this package to aid in the tracking process and to provide the option for applying on patient medical records. The Allograft Tracking Record must be completed and returned to Skye Biologics Holdings, LLC.

Donor/Tissue Screening

The donor of the enclosed **DONATED HUMAN TISSUE** has been deemed free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases and other exclusionary disease conditions through the review of the donor's medical records, including medical/behavior risk assessment and a recent physical examination. The donor is deemed eligible for tissue donation by the tissue bank's Medical Director and the enclosed **DONATED HUMAN TISSUE** has been determined to be acceptable for transplantation use through a stringent quality assurance review process.

Additionally, testing of a qualified blood sample indicates that the donor is negative or nonreactive for the following communicable disease markers:

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

- HIV-1/2 Antibodies
- Nucleic Acid Test for HIV-1 RNA

HEPATITIS B VIRUS (HBV)

- HBV Surface Antigen
- HBV Core Antibody (Total)
- Nucleic Acid Test for HBV DNA

HEPATITIS C VIRUS (HCV)

- HCV Antibody
- Nucleic Acid Test for HCV RNA

HUMAN T CELL LYMPHOTROPHIC VIRUS I/II

- HTLV-I/II Antibody

SYPHILIS

- Rapid Plasma Reagin Screen*, or
- Treponemal Specific Test

WEST NILE VIRUS

- Nucleic Acid Test for WNV RNA**

* A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is deemed eligible for tissue donation only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

** As of June 2017, blood samples from donors acquired during the seasonal time period (June 1 to October 31 of each year) are tested with the WNV NAT Assay. Donors may be screened with the WNV NAT test outside the seasonal time period.

The non-required screening test for exposure to the virus listed below may have been performed on the donor. A negative / nonreactive result is not required for this test; however, all donors are evaluated on a case-by-case basis by the Medical Director.

CYTOMEGALOVIRUS

- CMV Antibody (Total)

All laboratories performing these tests are registered with FDA and certified to perform testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or equivalent requirements. Test kits used are approved and cleared (for screening blood specimens collected from living donors) by the FDA. A copy of the medical records can be obtained upon request.

Processing

The HCT/Ps are processed in a controlled environment using methods designed to prevent contamination of the tissues. Tissues are exposed to antibiotics at an initial processing step and subsequently subjected to multiple rinse steps using sterile saline. Final products are sized and packaged according to approved specifications and procedures and are terminally sterilized by E-Beam irradiation technology in accordance with ANSI/AAMI /ISO11137.

Precautions

- In order to reduce the risk of complications, the tissue should not be implanted in the presence of active infection.
- Although the tissue has been rinsed multiple times with sterile saline during processing, antibiotic residuals such as amphotericin, penicillin, streptomycin and neomycin may remain in the tissue.

Adverse Reactions

Inherent uncertainty exists in medical and social histories and laboratory testing may not detect known or unknown pathogens. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to Skye Biologics Holdings, LLC.

NOTE Skye Biologics Holdings, LLC. and Human Regenerative Technologies, LLC (HRT) make no claims concerning the biological properties of the tissue allograft. All tissues have been collected, processed, stored, and distributed in compliance with FDA regulations governing HCT/Ps. Although every effort has been made to ensure the allograft's safety, current technologies may not preclude the transmission of disease.

WARNINGS

Do not re-sterilize. Dispose of all open and unused portions of the product.

Each allograft is intended for single patient use, on a single occasion only.

Use is limited to specific health professionals (e.g. physicians).

Once the expiration date on the label has been reached, the allograft must be disposed of.

Do not use if the package integrity has been violated, opened or damaged, or if mishandling has caused possible damage or contamination. Do not use if seal is broken or compromised. Once the packaging has been compromised, the allograft should be implanted immediately or disposed of.

After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DONOR ELIGIBILITY DETERMINED & TISSUES PROCESSED BY
Human Regenerative Technologies, LLC

DISTRIBUTED BY Skye Biologics Holdings, LLC

FDA FEI: 3005340932 (FDA Establishment Identifier)

STATE OF CALIFORNIA TB License: CTB 00081043 (Tissue Bank)