BioSkin

ALLOGRAFT TISSUE INFORMATION AND 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:

- One (1) Outer Box
- One (1) Double Peel-Pouch (containing the graft)
- One (1) Allograft Tracking Record
- One (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 physician. The use of the enclosed tissue for veterinary purposes is not permitted.

PRODUCT DESCRIPTION

BioSkin amniotic membrane product is a STERILE dehydrated human tissue allograft intended for homologous use to cover and protect recipient's tissues.

HANDLING

BioSkin 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.

- BioSkin is for single patient, one time use only.
- Once opened, BioSkin must be used immediately or disposed of appropriately.
- Product use must be recorded (see HCT/P TRACKING section).

STORAGE

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or end user to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. Maintain the graft in its original packaging and at ambient temperature (50-86°F / 10-30°C) until ready for use.

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

1. Remove the allograft from its box packaging.
2. Using aseptic technique, peel open the outer pouch and present the inner peel-pouch onto the sterile field. (BioSkin is the translucent sheet inside the inner pouch.)
   NOTE: The inner peel-pouch and product are sterile.
3. Peel open the inner pouch over a sterile basin to expose the graft.

APPLICATION

4. Using dry, sterile forceps, apply the graft over the intended site. Achieve full contact.
   TIP: The drier the surface to be covered with the graft, the easier the application.
5. It may be necessary to gently "brush" or "massage" the membrane at the edges to smooth-out wrinkles or folds that can occur during graft placement.
6. If desired, graft may be hydrated prior to application with sterile saline, for tight or hard to reach areas.

   NOTE: Once the package is opened, the graft should be used immediately or disposed of appropriately.

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 tissue 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 the patient records. The *Allograft Tracking Record* must be completed and returned to Human Regenerative Technologies, LLC (HRT).

TISSUE ORIGIN

The tissue is obtained aseptically at Cesarean birth delivery, which is performed by a licensed OB/GYN physician in a hospital operating room environment.

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 (WNV)
  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, are 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 (from June 1st to October 31st of each year), will be tested with the WNV NAT assay. Donors may be screened with the WNV NAT test outside of 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 using E-Beam irradiation technology in accordance with ANSI/AAMI/ISO 11137.

PRECAUTIONS

- In order to reduce the risk of complications, BioSkin should not be implanted in the presence of active infection.
- Although the tissue has been rinsed several 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 BioSkin must be reported immediately to Human Regenerative Technologies, LLC (HRT).

NOTE: Human Regenerative Technologies, LLC (HRT) makes 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 safety of the allograft, current technologies may not preclude the transmission of disease.

WARNINGS
Do not re-sterilize.
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.
The expiration date is indicated on the product label. Do no use if the expiration date has been reached.
Store at ambient temperature and keep away from excessive heat. **DO NOT FREEZE.**
Each allograft is intended for single patient use, on a single occasion only.
Use is limited to specific health professionals (e.g. physicians).
No veterinary use is permitted.
AFTER USE OR EXPIRATION, 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 and Tissue Processed and Distributed by:
Human Regenerative Technologies, LLC (HRT)