Tri-Membrane Wrap™/Tri-Membrane Wrap Restore™

triple-layer amniotic allograft membrane

Instructions for Use (IFU)

PRODUCT DESCRIPTION

Tri-Membrane Wrap™/Tri-Membrane Restore™ is a triple-layer human tissue allograft [Human Cellular and Tissue Based Product (HCT/P)] for transplantation regulated by the US Food and Drug Administration under 21 CFR Part 1271, containing amnion-chorion-amnion layers, derived from the amniotic membrane that serves as a barrier and provides protective covering for the wound.

PACKAGE CONTENTS

The product package contains the following items:

- One tissue graft, double packaged in sealed pouches
- Instructions for Use insert (this document)
- One set of supplemental tracking labels
- One allograft Tissue Tracking Record (TTR) card
- Note: To secure the product onto the wound, a non-adherent dressing is required and can be chosen by the clinician. This dressing is **NOT** provided by BLS Labs, LLC.

If any of these items are missing, please contact us at QA@blslabs.net or by calling 602-830-5100.

PREPARATION & APPLICATION

Open product box and remove the product pouch.

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

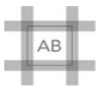
When ready to use, either tear open the inner pouch at the notch or cut the pouch at the notch to expose the graft.

Remove graft using dry, sterile gloves or forceps.

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

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

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



Ensure the HCT/P is secured in place by the Physician's choice of fixation.

STORAGE AND HANDLING

- Store product at ambient temperature (15-25°C, 59-77°F).
- Handle using aseptic techniques.
- It is the responsibility of the allograft holder to maintain tissue intended for transplantation in the appropriate storage conditons as listed in this IFU insert prior to transplant.

WARNINGS

- For single patient use only.
- To be used under the supervision of a qualified healthcare provider.
- Do not use if the product sterile barrier system or its packaging is compromised.
- Cannot be re-sterilized.

PRECAUTIONS

- The graft should not be applied in the presence of a live infection.

- BLS Labs, LLC makes no claims concerning the biological properties of this allograft tissue. All tissues have been collected, processed, stored, and distributed in compliance with US Food and Drug Administration (FDA) regulations governing human cells, tissues, and cellular and tissue-based products (HCT/Ps) to prevent the transmission of communicable diseases listed on page two. Current technologies may not preclude the transmission of communicable diseases.

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HCT/P RECORD TRACKING

Recipient records must be maintained for the purpose of tracking tissue post-transplant in accordance with The Joint Commission standards and the FDA requirements under 21 CFR Part 1271. Supplemental labels, which indicate the tissue ID number, are contained in this package for tracking processes. The allograft ID number must be recorded in the operative record. The provided Tissue Tracking Record (TTR) must be completed and returned to BLS Labs, LLC.

PROCESSING

The HCT/Ps are processed in accordance with FDA's Good Tissue Practice regulations in a controlled cleanroom environment, using processes designed to prevent contamination of the tissue, and to prevent the introduction, transmission, or spread of communicable diseases. The tissue products are sterilized using electron-beam irradiation for a Sterility Assurance Level of SAL10-6.

DONOR SCREENING, TESTING AND ELIGIBILITY

The donated human birth tissue has been determined to be eligible for transplantation by a licensed physician, the Medical Director of BLS Labs, LLC. In accordance with FDA regulations under 21 CFR Part 1271, the donor has been deemed to be free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases and other exclusionary disease conditions through review of donor records, including a medical/behavior risk assessment, medical records, and a recent physical examination. Additionally, testing of a qualified blood sample indicates that the donor is nonreactive or negative for the following communicable disease markers:

- Antibody to human immunodeficiency virus (HIV) types 1 & 2
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core (HBc total)
- Antibody to hepatitis C (HCV)
- Syphilis (RPR)*
- WNV NAT
- HCV NAT
- HIV NAT
- HBV NAT

*Tissues from a donor whose blood specimen is initially reactive for the non-treponemal screening assay, are cleared for transplantation use **only** when the confirmatory result from the treponemal specific assay is non-reactive. All laboratories performing donor screening tests for this product are registered with the FDA and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or equivalent requirements. Test kits used are approved and cleared by the FDA for screening blood specimens collected from living donors. A copy of the relevant medical records can be obtained from BLS Labs, LLC upon request.

ADVERSE REACTIONS

No adverse clinical reactions to this tissue product have been reported. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to BLS Labs, LLC at QA@blslabs.net or by calling 602-830-5100.

ALLOGRAFT TISSUE PROCESSED BY AND DONOR ELIGIBILITY DETERMINED BY:

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