# BIOLAB Membrane Wrap™

amniotic allograft membrane

## Instructions for Use

### PRODUCT DESCRIPTION

**BioLab Membrane Wrap™** is a human tissue allograft derived from the amniotic membrane that provides structural tissue to advance soft tissue repair, replacement, and reconstruction.

**Membrane Wrap™** is a 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.

### PACKAGE CONTENTS

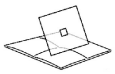
The product package contains the following items:

- One tissue graft, double packaged in sealed pouches
- Instructions for Use insert (this document)
- One set of supplemental Tracking Labels
- One allograft Tracking Record card

If any of these items are missing, please contact BioLab Sciences.

### PREPARATION & APPLICATION

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



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

When ready to use, open the inner pouch to expose the graft.

Remove graft using dry, sterile gloves or forceps.

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

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.

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).
- Product shall be handled using aseptic techniques.

### 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.
- Do not re-sterilize.

### PRECAUTIONS

- The graft should not be applied in the presence of live infection.
- BioLab Sciences makes no claims concerning the biological properties of this allograft tissue. 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.

## HCTP RECORD TRACKING

Recipient records must be maintained for the purpose of tracking tissue post-transplant per The Joint Commission and the FDA requirements. Supplemental labels, which indicate the tissue ID number, are contained in this package to aid in the tracking process. The allograft ID number must be recorded in the operative record. The provided Tissue Tracking Record must be completed and returned to BioLab Sciences.

## PROCESSING

The HCT/Ps are processed in a controlled cleanroom environment, using processes designed to prevent contamination of the tissue, introduction, transmission, or spread of communicable diseases.

The tissue products are sterilized using electron-beam irradiation.

## DONOR SCREENING, TESTING AND ELIGIBILITY

The donated human tissue has been determined to be eligible for transplantation by a licensed physician, the Medical Director of BioLab Sciences. The donor has been deemed 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 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)*
- HCV NAT
- HIV NAT
- HBV NAT

* Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal specific (confirmatory) assay is non-reactive.

All laboratories performing these tests 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 medical records can be obtained 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 BioLab Sciences.

## ALLOGRAFT TISSUE PROCESSED BY:

BioLab Sciences, LLC.

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FDA FEI (FDA Establishment Identifier)#: 3014573577

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