LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

Biolieve™ Placental Membrane

INSTRUCTIONS FOR USE

Read this entire package insert carefully prior to use.

Federal law (USA) restricts this allograft for use by a licensed clinician only.

DESCRIPTION

Biolieve is comprised of the whole placental membrane derived from donated human birth tissue that retains the amnion, chorion and trophoblast layers. Biolieve is minimally processed and disinfected using a proprietary decellularization technology that safely renders the placental membrane acellular for its intended surgical applications. Biolieve is terminally sterilized and achieves a sterility assurance level (SAL) of 1 x 10^{-6} utilizing gamma irradiation.

INDICATIONS FOR USE

Biolieve is intended to serve as a protective covering or barrier for tendons, ligaments and nerves during soft tissue repair.

CONTRAINDICATIONS

The contraindications include, but are not limited to:

- Areas with active or latent infection.
- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or processing reagents listed in this package insert.

WARNINGS AND PRECAUTIONS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft, the potential for transmission of infectious agents exists.

This graft may contain residuals of antibiotics (Lincomycin, Polymyxin B Sulfate, and/or Vancomycin), N-Lauroyl Sarcosinate (detergent), and/or Benzonase® or Denarase® (recombinant endonuclease). Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to, infection, allergic reaction to residual processing reagents, and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to the allograft (See **COMPLAINTS AND RETURNS** section).

DONOR SCREENING AND TESTING

All donors have been screened and tissues acquired, processed, stored, tested and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical examination, relevant medical records, including previous medical history, and laboratory test results.

All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft:

Required Infectious Disease Testing	
Test	Acceptance Criteria
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody	Negative/Non-Reactive
WNV NAT: West Nile Virus Nucleic Acid Test*	Negative/Non-Reactive
CMV Ab: Cytomegalovirus Antibody	Negative/Non-Reactive

*Required only for donors acquired between June 1 and October 1. Performed as required by international laws and regulations.

STORAGE REQUIREMENTS

The distributor, intermediary and/or end-user clinician or facility is responsible for storing Biolieve under appropriate conditions prior to further distribution or implantation. Biolieve must be stored as listed in the table below.

The packaging contains a thermal sensitive dot that will turn from white to pink or red if the upper temperature limit has been exceeded. Do not use if the temperature dot appears to be a color other than white or if the thermal dot appears to have been tampered with.

Storage Temperature	Special Conditions
Freeze-dried - Store between 10°C to 30°C.	Do not freeze or refrigerate. Store in its original cardboard sleeve. Protect from excessive heat.

TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, a Graft Implant Tracking Card has been enclosed to assist in the post-implantation tracking. Please refer to the enclosed card for additional instructions.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 1-757-464-4761 ext. 2000 (outside of the U.S.) and have the graft's identification number available (see label).

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties and/or performance of the graft.

GENERAL INSTRUCTIONS:

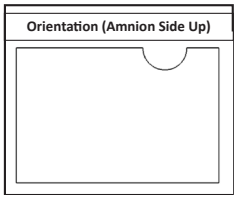
- Use on a single occasion for a single patient only.
- Once the packaging is opened, the graft must be used for the current procedure or discarded.
- Any unused portion of the graft must be discarded.
- Inspect the graft, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the graft is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
  - Do not use if the thermal dot appears to be a color other than white.
- Use aseptic technique at all times.
- Do not re-sterilize.
- Keep the graft stored according to recommended storage instructions until preparing it for application.

PREPARATIONS FOR USE:

1. **Non-Sterile Team Member:** Open the cardboard sleeve and retrieve the pouch from within.
2. Aseptically open the outer peel pack and present inner peel pouch to the **Sterile Team Member.**
3. **Sterile Team Member:** Open the inner peel pouch and place graft onto the sterile field.
4. **Sterile Team Member:** Orient the graft ensuring that the amnion side is facing up. Rotate the graft until the notch is located in the upper right. See the diagram below for reference.
5. **Sterile Team Member:** Trim graft if needed. The graft may be implanted dry or rehydrated. Position the graft so the chorion membrane is facing towards the more vascular tissue and the amnion side creates a barrier to preserve mobility. Orientation may vary based on surgical application.
6. Secure graft in the surgical site, and ensure graft is fully hydrated.
   NOTE: Graft may be hydrated with sterile saline, sterile water, or autologous fluids.

Do not allow the rehydration solution to exceed 42°C, as this may damage the graft.

The duration for rehydration prior to implantation/use must not exceed 30 minutes. After rehydration, do not allow the graft to dry.



WARRANTY STATEMENT

Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by LifeNet Health.

Manufactured by: LifeNet Health, 1864 Concert Drive, Virginia Beach, Virginia, 23453 USA
Source Establishment: LifeNet Health CTO #100038

For patent information, please visit: www.lifenethealth.org/patents