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

INSTRUCTIONS FOR USE

ALLOGRAFT BIO-IMPLANT

Read this entire package insert carefully prior to use.

Federal law (USA) restricts this allograft bio-implant for use by a licensed clinician only

DESCRIPTION
This allograft bio-implant was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The bio-implant was cleaned and disinfected through a proprietary process and terminally sterilizedvia gamma irradiation.

STERILE R Bio-implants that are indicated as sterile on the label are sterilized via low-dose gamma irradiation and achieve a sterility assurance level (SAL) of 10^{-6}.

INDICATIONS FOR USE
This allograft bio-implant is intended for implantation.

CONTRAINDICATIONS
The contraindications include, but are not limited to:
- 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 bio-implant, the potential for transmission of infectious agents exists.

This bio-implant may contain residuals of antibiotics (Bacitracin, Gentamicin and/or Polymyxin B Sulfate), alcohol, surfactants, and/or glycerol. 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, allograft tissue rejection, allergic reaction to residual processing reagents, reoperation and/or death.

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

DONOR SCREENING AND TESTING
All donors have been screened and tissues recovered, 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 bio-implant 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 assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).

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 bio-implant:

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

* Not required for donors recovered prior to December 16, 2016. Performed as required by international laws and regulations.
**Not required for donors recovered after March 31, 2010. Performed as required by International laws and regulations.

STORAGE REQUIREMENTS
The distributor, intermediary and/or end-user clinician or facility is responsible for storing this allograft bio-implant under appropriate conditions prior to further distribution or implantation. Bio-implants must be stored as listed in the table below.

Storage Temperature	Special Conditions
Store at ambient temperature	Do not Freeze

FINAL GRAFT TESTING
Product is tested for osteoinductive potential. Findings from this testing are not necessarily predictive of human clinical results.

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.

GENERAL INSTRUCTIONS:
- Use on a single occasion for a single patient only.
- Once the packaging is opened, the bio-implant must be used for the current procedure or discarded.
- Inspect the bio-implant, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the bio-implant is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- Use aseptic technique at all times.
- Do not sterilize.
- Keep the bio-implant stored according to recommended storage instructions until preparing it for implantation.

OPENING INSTRUCTIONS
1. Non-Sterile Team Member: Peel open outer pouch and present inner contents to the Sterile Team Member.
2. Sterile Team Member: Firmly grasp the inner pouch and remove from outer pouch.
3. Remove the bio-implant from the inner pouch and place in a sterile basin.

PREPARATIONS FOR USE:
If rehydration is preferred by the physician, rehydrate until desired consistency and handling are achieved. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

Rehydration with the patient's own blood is recommended to achieve optimal consistency and handling.

3a. Cover the bio-implant with a minimum of 5 cc of blood for a 50 mm strip and a minimum of 10 cc of blood for a 100 mm strip.

3b. Allow the blood to absorb into the bio-implant and coagulate until desired consistency and handling are achieved.

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, LifeNet Health has enclosed a Graft Implant Tracking Card 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 LifeNet Health Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 00+1-757-464-4761 ext. 2000 (outside the U.S.) and have the bio-implant's identification number available (see label).

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, VA 23453

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www.LifeNetHealth.org

Source Establishment: LifeNet Health CTO #100038