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

OSTEOARTICULAR ALLOGRAFT BIO-IMPLANT

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

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 rinsed with a cryosolution and then frozen. Processing was performed under aseptic conditions, and the bio-implant is culture negative.

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 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 cryosolution with 10% dimethylsulfoxide (DMSO). Caution should be exercised if the patient has a known sensitivity to this reagent.

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.

Preservation Method	Storage Temperature	Special Conditions
Frozen	Store between -40°C and -80°C	Bio-implants may be stored between -20°C to -39°C for no more than six months.
		Do not store in a liquid nitrogen freezer or a refrigerator.

POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to, disease transmission, infection, allograft tissue rejection, allergic reaction to residual processing reagents, re-operation 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.

See Back for Graft Preparation Instructions

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GRAFT PREPARATION INSTRUCTIONS

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.
- There may be a sulfur-like smell detectable when the packaging is opened. This is an acceptable characteristic of DMSO and does not prevent clinical use of the allograft.

PREPARATIONS FOR USE:

Non-Sterile Team Member:

1. Open the outer peel pouch being careful not to touch the inner pouch.
2. Aseptically present the inner pouch to the sterile team member being careful to retain the outer peel pouch as well as the product label. The product label is NOT sterile.

Use sterile technique for the following:

1. Open the inner peel pouch. Note: the inner peel pouch may contain residual blood and/or fluid.
2. Remove and discard the gauze from the cut end of the bio-implant. The bio-implant is wrapped with one piece of gauze.
3. Transfer the bio-implant to a sterile basin and cover the bio-implant with warm (37-46°C) sterile saline. Antibiotics (surgeon's choice) may be added to the thawing solution.
4. Thaw the bio-implant. It is recommended to thaw for 30-60 minutes.

Once the bio-implant is thawed, it must be used during the current procedure or discarded. Do not refreeze or refrigerate the bio-implant after thawing has begun.

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, Virginia, 23453 USA
Source Establishment: LifeNet Health CTO #100038

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

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