



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.

There are three preservation methods included in these instructions: Frozen, Freeze-Dried, and packaged with Preservon®. Please refer to the label to identify which preservation method was utilized for this bio-implant.

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
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 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.

Preservation Method	Storage Temperature	Special Conditions
Frozen	Refer to the label.	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.
Freeze-Dried/Preservon	Store at ambient temperature.	Do not freeze

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.

FREEZE-DRIED / PRESERVON BIO-IMPLANTS

OPENING INSTRUCTIONS:

- Non-Sterile Team Member:** Peel open outer tray foil lidstock and present inner contents to the **Sterile Team Member**.
- Sterile Team Member:**
 - If the bio-implant is packaged in a plastic tray, firmly grasp the "Peel Here" tab and remove from outer tray. If rehydration is preferred by the physician, place the bio-implant in a sterile basin and follow the appropriate preparations for use below.
 - If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is preferred by the physician, keep the bio-implant in the jar and follow the appropriate preparations for use below.

PREPARATIONS FOR USE

- Preservon:** It is recommended to rinse the bio-implant in sterile irrigant per physician preference.
- Freeze-dried:** If rehydrating, refer to the table below for the recommended rehydration instructions. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

FREEZE-DRIED	Allograft Bio-Implant Type	Recommended Rehydration Instructions
	Soft tissue (Fascia, Pericardium, Rotator Cuff)	Rehydrate for a minimum of 30 minutes.
All Other Allograft Bio-Implants	Rehydrate until required consistency and handling are achieved as per physician preference.	

FROZEN BIO-IMPLANTS

OPENING INSTRUCTIONS

Frozen (Sterile)

- Non-Sterile Team Member:** Open the outer peel pack and present the inner pouch to the **Sterile Team Member**.
- Sterile Team Member:** Firmly grasp the inner pouch and remove from outer peel pack. Peel open inner bag and place the bio-implant in a sterile basin.

Frozen (Non-Sterile)

- Non-Sterile Team Member:** Open the outer peel pack and remove the inner bag. **Do NOT present the inner or outer bag to the sterile field.**
- Open the inner bag and present the bio-implant to the **Sterile Field**.

PREPARATIONS FOR USE

Frozen (Sterile & Non-Sterile)

- Refer to the table below for the recommended thawing time based on bio-implant type. Thawing times are provided for three different thawing techniques.
- If solution soak technique is utilized, the following solutions may be used for thawing: antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.



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.

FROZEN	Allograft Bio-Implant Type	Room Temperature (Standing Air)	Warm Solution Soak (37°C – 42°C)	Room Temperature Solution Soak
	VertiGraft VG2	5 minutes	20 seconds	30 seconds
VertiGraft VG1 ALIF	15 minutes	20 seconds	2 minutes	
Fibular, Humeral, Femoral	15 minutes	60 seconds	2 minutes	
Other Allograft Tissue	30 minutes	5 minutes	10 minutes	

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.

Symbol Index

	Manufacturer
	Caution
	Single Use
	For use by a licensed clinician only
	Use by date
	Temperature Limitation
	Sterilized using irradiation
	Consult instructions for use
	Minimize excessive exposure to light and protect from excessive heat

LifeNet Health

1864 Concert Drive
Virginia Beach, VA 23453
Phone: 1-888-847-7831
Fax: 1-888-847-7832
www.LifeNetHealth.org

Allowash, Allowash XG, AngioGraft, Arthroflex, CardioGraft, Dermacell, FlexiGraft, I/C Graft Chamber, KinetiGraft, LifeNet, LifeNet Health, LifeNet Logo, LifeNet Health Plus Logo, Matracell, MatriGraft, Matrispine, Oracell, OraGraft, Osteocleanse, Preservon, and ReadiGraft are registered trademarks of LifeNet Health, Virginia Beach, VA. VertiGraft is a registered trademark of DePuy, Inc., a Johnson & Johnson Company. LifeNet Health allograft bio-implants are covered by one or more of the following US patents:

US5,531,791; US5,556,379; US5,797,871; US5,879,876; US5,976,104; US5,977,034;
US5,977,432; US6,024,735; US6,189,537; US6,200,347; US6,293,970; US6,305,379;
US6,326,188; US6,458,158; US6,511,509; US6,520,993; US6,534,095; US6,544,289;
US6,569,200; US6,734,018; US6,743,574; US6,902,578; US7,063,726; US5,820,581;
US7,338,757; US7,498,040; US7,498,041; US7,744,597; US D450,121; US D472,632;
US D472,633; US D472,634; US D472,971; US D472,972.