# Allograft Bio-Implant
# Instructions for Use

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Source Establishment: LifeNet Health CTO #100038

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## 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.

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.

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 (Gentamicin, and/or Vancomycin), 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.*

| 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 |

### 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.

### 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:
1. Non-Sterile Team Member: Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.
2. Sterile Team Member:
   a. 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.
   b. 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:
3a. Preservon: It is recommended to rinse the bio-implant in sterile irrigant per physician preference.
3b. 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.

| | Allograft Bio-Implant Type | Room Temperature (Standing Air) |
|---|---|---|
| FREEZE-DRIED | 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. |

**FREEZE-DRIED / PRESERVON® BIO-IMPLANTS**

### OPENING INSTRUCTIONS:
Frozen (Sterile)
1. Non-Sterile Team Member: Open the outer peel pack and present the inner pouch to the Sterile Team Member.
2. 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)
1. 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.
2. Open the inner bag and present the bio-implant to the Sterile Field.

### PREPARATIONS FOR USE
Frozen (Sterile & Non-Sterile)
3. Refer to the table below for the recommended thawing time based on bio-implant type. Thawing times are provided for three different thawing techniques.
4. 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.

| | Allograft Bio-Implant Type | Room Temperature (Standing Air) | Warm Solution Soak (37°C – 42°C) | Room Temperature Solution Soak |
|---|---|---|---|---|
| FROZEN | VertiGraft VG2 | 5 minutes | 20 seconds | 30 seconds |
| | VertiGraft VG1 ALIF | 15 minutes | 60 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, Produttore, Fabricante, Fabricant, 製造商, 제조 업체 |
| | Caution, Attenzione, Precaución, Attention, 警示, 경고 |
| | Single Use, Monouso, Un único uso, Usage unique, 單次使用, 1회용 |
| | For use by a licensed clinician only, Solo per uso da parte di un medico autorizzato, Uso restringido a médicos con licencia, Pour utilisation par un médecin agréé uniquement, 僅供持有執照醫師使用, 면허가 있는 임상의만 사용 가능함 |
| | Use by date, Usare entro la data di scadenza, Fecha de caducidad, Utiliser avant le, 在此日期前使用, 유효일 |
| | Temperature Limitation, Limiti di temperatura, Límite de temperatura, Limitations de températures, 溫度限制, 온도 제한 |
| | Sterilized using irradiation, Sterilizzato mediante radiazioni, Esterilizado mediante irradiación, Stérilisé par irradiation, 已使用射線進行除菌, 방사선을 이용해 멸균함 |
| | Consult instructions for use, Consultare le istruzioni per l'uso, Consulte las instrucciones de uso, Consulter les instructions d'utilisation, 請參閱使用指示, 사용 전 설명서 필독 |
| | Minimize excessive exposure to light and protect from excessive heat, Ridurre il più possibile l'esposizione alla luce e proteggere da eccessivo calore, Reduzca al mínimo la exposición excesiva a la luz y protéjalo del calor excesivo, Conserver à l'abri de la lumière et d'une chaleur excessive, 儘可能減少暴露在陽光下，並避免過度加熱, 빛에 노출을 최소화하고 과도한 열로부터 보호하십시오 |

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