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

Cryopreserved Skin Allograft

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 was processed from donated human skin, resulting from the generous gift of an individual or his/her family. This graft was disinfected using an antibiotic regimen, cryogenically preserved and then is maintained at temperatures between -40°C to -80°C until used for application. Processing was performed under aseptic conditions.

INDICATIONS FOR USE

This allograft is intended for burn and wound applications.

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 application. 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 (Gentamicin and/or Vancomycin), alcohol, chlorhexidine, and/or cryosolution consisting of a culture medium and glycerol. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents. This graft was processed without ß-lactam antibiotics.

STORAGE REQUIREMENTS

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

Preservation Method	Storage Temperature	Special Conditions
Cryopreserved	Store frozen at temperatures between -40°C to -80°C.	Do not store in a liquid nitrogen freezer or a refrigerator.

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 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:

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.

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 (see COMPLAINTS AND RETURNS section).

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.

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 dermis must be used for the current procedure or 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 dermis 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 graft stored according to recommended storage instructions until preparing it for application.
- Once the graft is thawed, it must be used for the current procedure or discarded.
- Do not refreeze the graft after thawing has begun.
- If multiple skin grafts are being used, they may be thawed and soaked together.

PREPARATIONS FOR USE:

1. *Non-Sterile Team Member:* Open box to expose the inner thermal container.
2. Lift the thermal container's lid and remove envelope from the dry ice.
3. Open the envelope and retrieve the pouch from within.
4. Aseptically open the outer peel pack and remove the inner pouch containing the graft.
5. Open the inner peel pouch and place graft onto the *Sterile Field.*
6. *Sterile Team Member:* Place graft in a sterile basin (see option below if sterile basins are not available). Fill the sterile basin with enough sterile solution to completely submerge the graft. Allow graft to thaw for 2 minutes. **Do not allow the solution to exceed 42°C as this may damage the graft.**
7. **After the 2 minutes has elapsed, place the graft into a second sterile basin. Fill the second basin with enough sterile solution to completely submerge the graft. Do not allow the solution to exceed 42°C.**
8. **Allow the graft to soak in the second basin of sterile solution for 2 minutes. Carefully remove the double mesh lining prior to applying and securing the graft to the patient**

Optional Thaw and Soak Procedure if Sterile Basins are not available:
If sterile basins are not available, the graft may be thawed and soaked in its inner pouch. When following the instructions above, place enough sterile solution in the inner pouch to completely submerge the graft. Do not allow the solution to exceed 42°C. Utilize the same thaw and soak times as instructed above, replacing the sterile solution in the inner pouch between the thaw and soak. Carefully remove the double mesh lining prior to applying and securing the graft to the patient.

Do not allow the graft to dry. Keep the graft completely submerged in the sterile solution until it is time for application.

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 00+1-757-464-4761 ext. 2000 (outside of the U.S.) and have the graft'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 or SWAI.

SWAI
Skin and Wound Allograft Institute

Prepared by: The Living Legacy Foundation
1730 Twin Springs Road, Suite 200, Baltimore, Maryland 21227
www.llf.org
410-242-7000/800-641-HERO

Manufacturer/Source Establishment: LifeNet Health
1864 Concert Drive Virginia Beach, VA 23453, USA
CTO # 100038