Sterile Decellularized Dermis

Instructions for Use

LifeNet Health

1864 Concert Drive | Virginia Beach, VA 23453, USA
1.888.847.7831 (inside the U.S.) | +1.757.464.4761 (outside the U.S.)
www.LifeNetHealth.org

Source Establishment: LifeNet Health CTO #100038

EN

STERILE DECELLULARIZED DERMIS

Read this entire package insert carefully prior to use.

Federal law (U.S.A.) restricts this allograft bio-implant for use by a licensed clinician only.

DESCRIPTION

Decellularized dermis was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The dermis was processed using a proprietary technology, which safely renders the dermal matrix acellular without compromising the biomechanical properties for its intended surgical applications. Decellularized dermis achieves a sterility assurance level (S.A.L.) of 10^{-6} via gamma irradiation and is preserved with glycerol.

INDICATIONS FOR USE

Decellularized dermis serves as a scaffold which is suitable for the reinforcement of damaged or inadequate integumental tissue at the surgical site.

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, Lincomycin, Polymyxin B Sulfate, and/or Vancomycin), N-Lauroyl Sarcosinate (detergent), Benzonase® or Denarase® (recombinant endonuclease), 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, loss of bio-implant structural integrity, reoperation and/or death.
Promptly report any adverse event(s) or outcome(s) potentially attributable to the decellularized dermis (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 decellularized dermis under appropriate conditions prior to further distribution or implantation. Dermis must be stored as listed in the table below.

Storage Temperature	Special Conditions
Refer to the label.	Do not freeze or refrigerate.
	Store in its original cardboard sleeve.
	Minimize excessive exposure to light and protect from excessive heat.

The packaging may contain a temperature sensitive dot that will turn from white to pink or red if the upper temperature limit has been exceeded. Do not use the decellularized dermis if the temperature dot appears to be a color other than white.

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.

PLEASE READ THESE INSTRUCTIONS AS THEY ARE DIFFERENT THAN THOSE FOR TRADITIONAL CRYOPRESERVED SKIN ALLOGRAFTS.

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.
- Any unused dermis must be discarded.
- Inspect the dermis, 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.
  - When the temperature dot is present, do not use the dermis if the dot appears to be a color other than white.
- Use aseptic technique at all times.
- Do not sterilize.
- Keep the dermis stored according to recommended storage instructions until preparing it for implantation.

ORIENTATION: Decellularized dermis has two physically distinct sides; a reticular side and a papillary side. In general, when applied, the papillary side will face up while the reticular side is placed against the surgical wound or the most vascularized tissue. The dermis is packaged with the papillary side visible through the clear side of the packaging.

PREPARATIONS FOR USE

1. **Non-Sterile Team Member:** Open the cardboard sleeve and retrieve the pouch from within.
2. Aseptically open the outer peel pack and present inner pouch to the **Sterile Team Member.**
3. **Sterile Team Member:** To maintain orientation of the dermis, the papillary side should be marked with a sterile marker immediately after opening the inner pouch. **The dermis is packaged with the papillary side visible through the clear side of the packaging.**
   Dermis: Open the inner peel pouch and remove the dermis along with its slip sheet. Remove the slip sheet prior to application.
   Biowashers™: Open the inner peel pouch and remove the dermis while maintaining orientation of the individual grafts. Biowashers do NOT have a slip sheet.
4. **NOTE: Rinsing is not required prior to application, however it may improve handling.** If a rinse is preferred by the physician, continue to the rinse instructions below.

If not used immediately, keep dermis moist until implantation.

Rinse Instructions (Optional)

5. **Non-Sterile Team Member:** Prepare a sterile rinse basin with enough sterile isotonic solution (e.g., sterile saline) to completely cover the dermis. **CAUTION: Ensure the rinse solution does not exceed 42°C as this may damage the dermis.**
6. **Sterile Team Member:** After opening the packaging per the instructions above, remove the dermis from the slip sheet and immerse the dermis in sterile isotonic solution for a minimum of 1 minute. Ensure the dermis is completely submerged in solution during the rinse.
7. Keep the dermis completely submerged in sterile isotonic solution until needed.

The maximum sterile isotonic solution exposure time for decellularized dermis is 4 hours.

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 with 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/SWAI 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 or SWAI.

Symbol Index	
	Manufacturer, Produttore, Fabricante, Fabricant, 製造商, 제조 업체, Hersteller
	Caution, Attenzione, Precaución, Attention, 警示, 경고, Achtung
	Single Use, Monouso, Un único uso, Usage unique, 單次使用, 1회용, Einmalgebrauch
	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, Nur für den Gebrauch durch einen zugelassenen Arzt bestimmt
	Use by date, Usare entro la data di scadenza, Fecha de caducidad, Utiliser avant le, 在此日期前使用, 유효일, Verwendbar bis
	Temperature Limitation, Limiti di temperatura, Límite de temperatura, Limitations de températures, 溫度限制, 온도 제한, Temperaturgrenze
	Sterilized using irradiation, Sterilizzato mediante radiazioni, Esterilizado mediante irradiación, Stérilisé par irradiation, 已使用射線進行除菌, 방사선을 이용해 멸균함, Durch Strahlung sterilisiert
	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, Gebrauchsanweisung lesen
	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, Vor übermäßiger Lichtexposition und übermäßiger Hitze schützen