Sterile Decellularized Dermis

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
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 (SAL) of 10⁶ 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 (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, disease transmission, infection, allograft tissue rejection, allergic reaction to residual processing reagents, reoperation and/or death.

Donor screening are used as available. The following test criteria were met for the donor of this allograft bio-implant:

<table>
<thead>
<tr>
<th>REQUIRED INFECTIOUS DISEASE TESTING</th>
<th>ACCEPTANCE CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBcAb: Hepatitis B Total Core Antibody</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HBsAg: Hepatitis B Surface Antigen</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HCV NAT: Hepatitis C Virus Nucleic Acid Test</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HCVAb: Hepatitis C Antibody</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HBV NAT: Hepatitis B Virus Nucleic Acid Test*</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
<tr>
<td>RPR/STS or Equivalent: Syphilis</td>
<td>CONFIRMATORY</td>
</tr>
<tr>
<td>HTLV III Ab: Human T-Lymphotrophic Virus Types III Antibody**</td>
<td>NEGATIVE/NON-REACTIVE</td>
</tr>
</tbody>
</table>

*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.

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to the label.</td>
<td>Do not freeze or refrigerate.</td>
</tr>
<tr>
<td></td>
<td>Store in its original cardboard sleeve.</td>
</tr>
<tr>
<td></td>
<td>Minimize excessive exposure to light and protect from excessive heat.</td>
</tr>
</tbody>
</table>

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.

Preparation of the bone graft bed is important for graft incorporation and bone formation, as are other factors such as blood supply, source of marrow elements, loading, stability and absence of infection at the graft site. The volume of graft material used in each procedure is determined by the judgment of the clinician.

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 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.