DermaPure® Decellularized Dermal Allograft

DESCRIPTION
DermaPure® Decellularized Dermal Allografts are produced from donated human tissue intended for transplant. All tissue is retrieved, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB) and U.S Federal Regulations CFR 21 part 1270 and 1271.

DermaPure® Decellularized Dermal Allograft provides a scaffold for the body’s repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument.

DONOR SCREENING / TESTING
Donors have been determined to be eligible for donation by Community Tissue Services at 349 S. Main St., Dayton, OH 45402. A Medical Director (licensed physician) evaluates donors for eligibility. Donor eligibility is based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical exam.

Infectious disease testing is performed by a laboratory registered with the U.S. Food and Drug Administration (FDA) and certified under CLIA standards or equivalent requirements. Test kits are FDA licensed or approved for donor testing. The following test criteria were met for this allograft:

<table>
<thead>
<tr>
<th>Required Infectious Disease Tests and Acceptable Result</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood Test</strong></td>
<td><strong>Acceptable Result</strong></td>
</tr>
<tr>
<td>HIV I/II Antibody: Human Immunodeficiency Virus Type I/II</td>
<td>Negative/ Non-reactive</td>
</tr>
<tr>
<td>HBsAG: Hepatitis B Surface Antigen</td>
<td>Negative/ Non-reactive</td>
</tr>
<tr>
<td>HbcAB: Hepatitis B Total Core Antibody</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>HIV NAT: Human Immunodeficiency Virus Nucleic Acid Test</td>
<td>Negative/ Non-reactive</td>
</tr>
<tr>
<td>HCVAb: Hepatitis C Virus Antibody</td>
<td>Negative/ Non-reactive</td>
</tr>
<tr>
<td>RPR/STS for Syphilis</td>
<td>Negative/ Non-reactive</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| *Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.*

PROCESSING / STERILIZATION
Tissue is processed aseptically in a clean-room environment using a validated method to remove the epidermis, cells, and cell remnants. Preparation exposes the skin to antibiotics—gentamicin, nystatin, vancomycin, imipenem, polymixin B, cefazolin —and processing reagents including sodium dodecyl sulphate, DNase, RNase, and glycerol. Tissue is treated to reduce residual content of reagents, however traces may remain.

**NOTE: Follow instructions for allograft preparation prior to application.**

Tissue labeled as STERILE R has been sterilized using gamma irradiation to a Sterility Assurance Level (SAL) of $10^{-6}$.

STORAGE

<table>
<thead>
<tr>
<th>Storage Method</th>
<th>Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient</td>
<td>Do not freeze</td>
</tr>
<tr>
<td></td>
<td>Protect from excessive heat</td>
</tr>
<tr>
<td></td>
<td>Must use once opened</td>
</tr>
</tbody>
</table>

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/ or End User Clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

**DermaPure® TISSUE PREPARATION**

1) Inspect for package integrity and expiration date prior to opening.
2) Peel outer package open and aseptically deliver inner package to the sterile field or sterile team member.
3) Partially fill two sterile basins with normal saline or isotonic solution of choice.
4) DermaPure® should not be immersed in solution that is greater than 98.6°F or 37°C. A key component of DermaPure®’s intact extracellular matrix is collagen. At higher temperatures collagen may be denatured, altering important essential properties.
5) Remove the allograft from inner package and discard packaging mesh. IMPORTANT: DO NOT implant packaging mesh.
6) Immerse the allograft in the first sterile basin for 5 minutes, providing periodic gentle agitation.
7) Transfer the allograft into the second basin and immerse for 5-10 minutes, with periodic gentle agitation.
8) DermaPure® should be used as soon as possible after opening. If the allograft is to be stored for longer than 2 hours after opening, it should be refrigerated at 34°F - 50°F (immersed in normal saline or isotonic solution) in an aseptic container no longer than 24 hours.

**DermaPure® APPLICATION**

1) Place the allograft onto the wound bed, with the basement membrane side outer-most, cut the tissue tab off. Secure the allograft with liquid skin adhesive, sterile adhesive strips, staples or sutures if needed.
2) Place a non-adherent contact layer over the allograft and cover with a secondary dressing to maintain a moist environment. Leave dressing in place for 5 – 7 days.

**ADVERSE EFFECT**

As with any allograft tissue, some risk of disease transmission exists. Adverse effects may include but are not limited to: infection, allergic reaction to residual processing reagents, immune response to allograft tissue, or loss of integrity/functionality of tissue. Caution should be used if the patient has a known sensitivity to any of the reagents/antibiotics listed in this insert.
DermaPure® ORIENTATION

1) DermaPure® has a distinct basement membrane (outer) and dermal surface (inner). When applied to the wound bed the dermal surface should be placed in contact with the wound bed, with the basement membrane side facing up. (See illustration below)

2) Prior to removing the allograft from the basin check the surface orientation. The basement membrane surface is outer-most when the tissue tab is positioned on the top right edge. (See illustration below)

3) Remove the allograft from the basin. Remove any remaining packaging materials from the allograft.

4) Keeping the allograft in the correct orientation, (basement membrane outermost), trim the allograft to the dimensions of the wound with sterile instruments.

PROPER GRAFT ORIENTATION

- Place the allograft so that it appears as pictured below (Fig 1.0)

- With the allograft tissue tab positioned in the top right corner as shown, the dermal surface is now on the underside of the allograft—adjacent to the wound bed—with the basement membrane outer-most.

- This is the correct orientation for placement on the wound bed. (Fig 1.0)

![Tissue tab](image)

WARNINGS/ PRECAUTIONS

- Intended for use in one patient, on a single occasion only.
- Do not use if package integrity has been compromised.
  - Once the user breaks the package seal, the allograft must be transplanted or discarded.
  - Do not use past expiration date listed on the product label.
- Do not sterilize or re-sterilize the allograft.
- This allograft is intended for use by qualified healthcare specialists such as physicians or podiatrists.
- Although this allograft has been tested and screened for human pathogens and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse events potentially attributable to this allograft must be reported promptly to Community Tissue Services at (800) 684-7783.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and fax to Community Tissue Services at (937) 222-2538. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables Community Tissue Services to maintain records for the purpose of tracing the tissue post-transplant.

CUSTOMER SERVICE

Please contact Tissue Regenix Inc. at (855) 452-0133 should you require additional information.

Community Tissue Services makes no claims concerning the biological or biomechanical properties of the provided tissue. Community Tissue Services disclaims all liability and responsibility for any misuse of tissue provided for clinical application. Community Tissue Services is accredited by the American Association of Tissue Banks. Community Tissue Services – Center for Tissue, Innovation and Research is ISO 13485:2003 certified. Health Canada Registration: 100076.

DEFINITION OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Read Instructions for Use" /></td>
<td>Read Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Single Patient Use Only" /></td>
<td>Single Patient Use Only</td>
</tr>
<tr>
<td><img src="image" alt="Store at Ambient Temperature" /></td>
<td>Store at Ambient Temperature</td>
</tr>
<tr>
<td><img src="image" alt="For use by licensed professional only" /></td>
<td>For use by licensed professional only</td>
</tr>
<tr>
<td><img src="image" alt="Gamma irradiated for sterility" /></td>
<td>Gamma irradiated for sterility</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

Manufactured and Distributed by Community Tissue Services for Tissue Regenix Wound Care Incorporated

Community Tissue Services
Center for Tissue, Innovation and Research
2900 College Drive
Kettering, Ohio 45420 1-800-684-7783

Tissue Regenix Wound Care Incorporated
2611 North Loop 1604 West, Suite 201
San Antonio, TX 78258
1-855-452-0133
www.tissueregenixus.com

DermaPure® is a trademark of TRX Wound Care Limited, Swillington, Leeds LS26 8XT, United Kingdom.