

SINGLE PATIENT USE ONLY

SimpliDerm®

Hydrated Acellular Dermal Matrix

DONATED HUMAN TISSUE FROM U.S. TISSUE BANKS. THE RECOVERY AND PROCESSING WAS PERFORMED USING ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY STERILIZED TO A STERILITY ASSURANCE LEVEL OF 10⁻⁶ IN ITS FINAL PACKAGING.

DESCRIPTION

SimpliDerm® Hydrated Acellular Dermal Matrix (HADM) is a human skin allograft minimally processed to remove epidermal and dermal cells and then preserved in an irradiation protection solution. The process utilizes a proprietary and patented technology to preserve the remaining bioactive components and extracellular matrix of the dermis. The resulting acellular matrix is pre-hydrated without damage to the matrix components and is designed to be rinsed quickly in a sterile isotonic solution. The resulting allograft functions as a framework to support cellular repopulation and vascularization at the surgical site.

INDICATIONS FOR USE

SimpliDerm is to be used for the repair or replacement of damaged or insufficient integumental tissue. It may also be used for the repair, reinforcement, or supplemental support of soft tissue defects or any other homologous use of human integument. Each package of SimpliDerm is intended for use in one patient on a single occasion by a licensed physician.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

SimpliDerm was prepared from a donor determined to be eligible based on the results of screening and testing. Donors are screened for high-risk behavior and contraindications to transplant through medical/social history interview, review of medical records, physical assessment, and review of post-mortem-examination results (when applicable). Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS) and found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B virus (HBV NAT and HBsAg)
- Hepatitis B core antibody total (HBcAb)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma reagin (RPR) or other serological tests

Additional tests, including Human T-lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. A list of any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Berkeley Biologics, LLC in compliance with U.S. FDA regulations (21 CFR 1271) and American Association of Tissue Banks® (AATB®) Standards. The Medical Director determined final eligibility and acceptability for transplantation after review of donor screening and testing records.

CONTRAINDICATIONS

Use of SimpliDerm in patients exhibiting autoimmune connective tissue disease is not recommended. SimpliDerm should not be used in patients with sensitivities to processing agents (see WARNINGS).

WARNINGS

Potential adverse effects that may result from placement of SimpliDerm include, but are not limited to wound or systemic infection; seroma; dehiscence; hypersensitivity; allergic or other immune response; sloughing or failure of the graft; and disease transmission.

- Trace amounts of processing agents include, but are not limited to: gentamicin, maltodextrin and trehalose.
- Do not re-sterilize or reuse.

Extensive medical screening procedures have been used in the selection of all tissue donors (see Donor Screening and Testing). Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material may transmit infectious agents or diseases.

TRANSPORTATION, STORAGE AND HANDLING

The transplant facility or clinician must maintain the graft in the appropriate recommended storage conditions prior to implantation.

- SimpliDerm is shipped at ambient temperature and should be stored between 1°C and 25°C (33.8°F and 77°F).
- Do not freeze.

HOW SUPPLIED

SimpliDerm is supplied pre-hydrated and terminally sterilized. The graft is enclosed inside a sterile inner pouch, which is then enclosed in a secondary outer pouch. The outer pouch is contained inside a labeled box. Product thickness category and size are clearly marked on the label located on the foil pouch.

SimpliDerm is immersed in a proprietary irradiation protection solution that contains maltodextrin and trehalose which protects the biological materials of the allograft during the sterilization process. Any remaining solution may be rinsed off during allograft preparation (see INSTRUCTIONS FOR USE).

STERILITY

SimpliDerm is sterilized to a Sterility Assurance Level (SAL) of 10⁻⁶ using an internationally recognized validation method and a proprietary ionizing irradiation system.

PRECAUTIONS

SimpliDerm should not be used if:

- the expiration date shown on the labeling has passed,
- the package integrity is damaged or compromised,
- the labels or identifying barcodes are not legible or missing,
- the recommended storage conditions have not been maintained.

INSTRUCTIONS FOR USE

Minimum Equipment Required

- Sterile basin large enough to accommodate the SimpliDerm without bending.
- Sufficient sterile isotonic solution to completely submerge the graft.
- Sterile forceps or similar instrument.
- Sterile scissors, scalpels or similar instrument.

Preparation Procedure

It is important to utilize aseptic techniques when unpacking the allograft.

1. Peel open the outer pouch and aseptically introduce the sterile inner pouch containing the graft onto the sterile field.
2. With sterile gloves, peel open the inner pouch and gently remove SimpliDerm from the inner pouch. SimpliDerm may stick slightly to the inner pouch; this is normal.
3. Cover the graft with sufficient volume of room temperature or warm sterile isotonic solution to completely submerge the graft for a minimum of two (2) minutes. A sterile surgical instrument can be placed on the graft to aid in submersion and facilitate gentle movement of the tissue, if desired.
4. Once SimpliDerm is rinsed, it may be aseptically trimmed to desired dimensions.

NOTE: Once the inner pouch containing SimpliDerm has been opened, the allograft must be transplanted during that surgical procedure. DO NOT re-sterilize or repackage for next day use. Discard all opened and unused product.

ORIENTATION

SimpliDerm has two (2) distinct sides: a basement membrane and a dermal side. The basement membrane repels blood. The dermal side absorbs blood. When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. The allograft has a slit approximately 5 mm in length that when oriented vertically in the upper right corner indicates that the basement membrane is facing toward the user.

- Figure 1a – SimpliDerm with vertical slit oriented in upper right corner.
- Figure 1b – SimpliDerm with vertical slit oriented in upper left corner.

ADVERSE REACTIONS

The physician must promptly report any adverse reaction potentially attributable to SimpliDerm to Elutia Inc. at 877-651-2628.

TRACEABILITY

The FDA requires traceability from the donor to the recipient. The physician is responsible for completing the recipient records to ensure traceability. As a convenience, pre-printed peel-off labels are included with each allograft. Using the labels, record the allograft tissue identification information in the patient medical record. In addition, an Allograft Usage Report is included with the allograft. The physician is to complete the report and affix one of the pre-printed labels to it. Scan and email the completed report to AllograftUsage@Elutia.com.

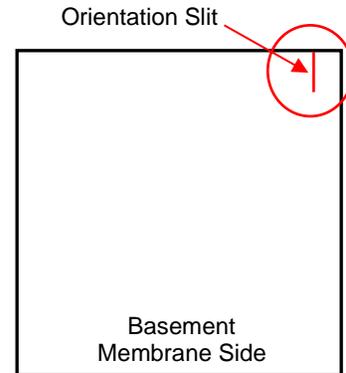


Figure 1a. SimpliDerm with vertical slit oriented in upper right corner.

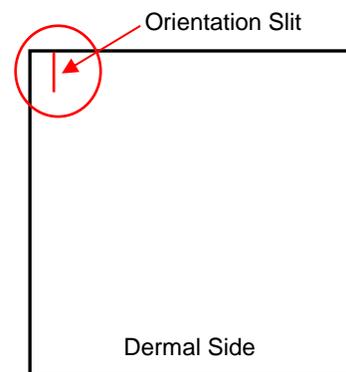


Figure 1b. SimpliDerm with vertical slit oriented in upper left corner.

Not to scale.

Processing and Release Performed By:



BERKELEY
BIOLOGICS

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FDA Registration No. 1000100754

Accredited by the AATB®.

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