ORGANOGENESIS

SimpliGraft®

Dehydrated Amnion Allograft

DONATED HUMAN TISSUE

DESCRIPTION

SimpliGraft is a dehydrated, terminally sterilized, single -layer amniotic membrane sheet derived from donated human placental membrane. SimpliGraft retains its native extracellular matrix (ECM) scaffolding and proteins. The allograft is aseptically packaged in a double layer pouch and provided sterile.

INTENDED USE

SimpliGraft is intended for use as a protective barrier in the management of acute and chronic wounds. SimpliGraft may be applied to protect a variety of partial- and full-thickness acute and chronic wounds, such as dermal ulcers, and wounds with exposed tendon, muscle, joint capsule, and bone. SimpliGraft can be applied from the onset and for the duration of the wound, with subsequent application at the discretion of the health care practitioner. SimpliGraft will naturally be broken down and resorbed into the wound and is not intended to be removed.

CAUTION: This product is restricted to sale by or on the order of a physician or properly licensed practitioner. Not intended for veterinary use.

CONTRAINDICATIONS

SimpliGraft is contraindicated for:

- use on clinically infected wounds.
- surgical implantation sites with active or latent infection.

DONOR ELIGIBILITY

Communicable disease testing was performed by a laboratory registered with the 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. The testing was conducted using FDA licensed, approved, or cleared donor screening tests where applicable. The records of this testing are maintained at Xtant Medical Holdings, Inc. The following required testing was performed and found to be negative or non-reactive;

- HBsAg (Hepatitis B Surface Antigen)
- HBcAb (Hepatitis B Core Total Antibody)
- HBV-NAT (Hepatitis B Nucleic Acid Test)
- HCV (Hepatitis C Antibody)
- HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2)
- Syphilis
- HIV-1 NAT (HIV-1 Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test)
- WNV NAT

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I and II (HTLV I & II) may have been performed at the time of donor screening and were found to be acceptable for transplantation by the Medical Director. A list of additional communicable disease test(s) performed will be provided upon request.

The donor was determined to be eligible by a Xtant Medical Holdings, Inc. Tissue Bank Medical Director after review of these test results, donor risk assessment questionnaire, physical examination, and other available relevant donor records.

ADVERSE EVENTS AND REACTIONS

Inherent uncertainty exists in medical and social histories and lab testing which may not detect known or unknown pathogens.
Therefore, the following complications may occur with tissue transplantation:

- Transmission of diseases of unknown etiology;
- Immune rejection of implanted HCT/P.

Report any adverse outcomes to Organogenesis Inc. immediately.

PROCESSING

Technical quality assurance standards are rigorously maintained by Xtant Medical Holdings, Inc. SimpliGraft is processed using aseptic techniques in a controlled environment. Final product is terminally sterilized using a validated electron beam irradiation process.

STORAGE

SimpliGraft must be stored between 15°C to 30°C (59°F-86°F) prior to transplantation. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

WARNINGS & PRECAUTIONS

SimpliGraft is processed and packaged using aseptic techniques and terminally sterilized. The allograft must be handled in an aseptic manner to prevent contamination. As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, aseptic processing, and terminal electron beam irradiation of final product.

- **Single patient, single use only.**
- **Do not sterilize or re-sterilize.**
- **Do not freeze.**

<u>Do not use if:</u>

- the package integrity has been violated, opened, or damaged, or if mishandling has caused possible damage or contamination.
- if any seal is broken or compromised.
- expiration date has been exceeded, as indicated by the product label.
- the tissue has not been stored according to the recommended storage instructions.

- Return all compromised or flawed packaging to Organogenesis Inc.
- Once opened, allografts must be used immediately or discarded.
- Store product between 15°C-30°C (59°F-86°F).
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician.

- The healthcare professional is responsible for informing the patient of the risks associated with his/her treatment and the possibility of complications or adverse reactions.

DO NOT USE ALLOGRAFT IF EXPIRED.

ALLOGRAFT PREPARATION

Step 1: Remove the pouch containing the allograft from the box.

Step 2: Inspect the pouches for any holes, tears, or incomplete seals.

Step 3: Using aseptic technique, peel open the outer pouch and present the inner sterile pouch to the sterile field, when required.

Step 4: Wait to open the inner pouch until ready to place the allograft.

Step 5: Remove the allograft from the sterile pouch and place directly onto the wound or into a basin at the discretion of the practitioner. Normal saline, water for injection, Lactated Ringers, or an antibiotic solution of the physician's preference may be utilized.

Step 6: SimpliGraft can be applied at the onset of the wound, with subsequent application at the discretion of the healthcare provider. SimpliGraft is not intended to be removed.

Step 7: Affix SimpliGraft using preferred fixation method at the discretion of the healthcare provider.

Step 8: Apply a non-adherent, non-occlusive dressing directly over SimpliGraft followed by a secondary dressing specific to the wound type.

HCT/P TRACKING

Recipient records must be maintained for the purpose of traceability per 21 CFR 1271, which requires the documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities."

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to provide Xtant Medical Holdings, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix them on the TUR card and applicable recipient records. Complete the TUR card and mail to Xtant Medical Holdings, Inc. Even if the tissue has been discarded for any reason, the TUR completed with the allograft identification information and reason for discard needs to be returned to Xtant Medical Holdings, Inc.

ADVERSE REACTION OUTCOME AND COMPLAINT REPORTING

Adverse reaction outcomes potentially attributable to the allograft or other complaints must be promptly reported to Organogenesis Inc. at 1-888-432-5232.

RETURN POLICY

Please contact Customer Service at 1-888-432-5232 for information regarding Organogenesis Inc. Tissue Return Policy.

DISCLAIMER

Organogenesis Inc. and Xtant Medical Holdings, Inc. warrant that the allograft will conform to the specifications set forth herein provided that the allograft is handled, stored, and implanted by healthcare providers according to the requirements set forth herein or as provided in writing. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to Organogenesis Inc.

Distributed by:
Organogenesis Inc.
150 Dan Road
Canton, MA 02021
P: (888) 432-5232
Organogenesis.com

Manufactured by:
Xtant Medical Holdings, Inc.
664 Cruiser Lane
Belgrade, MT 59714
P: (888)-886-9354
Xtantmedical.com

Single Use Only

Store Between15°C to 30°C

Consult instructions for use