

READ BEFORE USING

CRYOPRESERVED HUMAN SKIN ALLOGRAFT

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Not Terminally Sterilized. Do Not Sterilize.

DESCRIPTION AND INDICATIONS FOR USE

This allograft was prepared from skin that was procured aseptically from a deceased donor. Allograft skin is procured, processed, and packaged in a clean, climate-controlled environment. Procurement, processing, and packaging are performed using aseptic technique appropriate for a sterile surgical environment as recommended by current AORN "Recommended Practices for Surgical Tissue Banking". The skin allograft has been cooled at a controlled rate to the frozen state and is provided in tissue culture medium in 10 to 15% glycerol. This allograft has been treated with Gentamicin, Nystatin, glycerol, and RPMI-1640 with L-glutamine, and may contain trace amounts of antibiotics and other processing solutions.

Samples from this allograft were tested for microorganisms using USP <61> Microbial Limits test and EP section 2.6.13 Microbial Examination of Non-sterile Products (Test for Specified Micro-organisms). Please note that despite careful recovery and processing techniques designed to reduce or eliminate skin contaminants, allograft skin is supplied as non-sterile and may contain bacteria. Human skin allografts may be used for temporary coverage of epithelial surface defects (e.g., due to third degree burns, other dermal denudations or skin breakdown) in highly selected circumstances after careful review of the availability and desirability of using skin autograft, xenograft or other prosthetic materials. Human skin allografts may also be used to serve as a barrier against environmental particulate and bacteriologic contaminants, and against evaporative or direct loss of body fluids. These grafts are intended to remain grafted to the patient for no more than 30 days.

CAUTIONS AND WARNINGS FOR USE

Trace amounts of Gentamicin, Nystatin, RPMI-1640 with L-glutamine, and glycerol may be present. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β -lactam antibiotics are used during the processing of tissue in this allograft.

Extensive medical screening procedures have been used in the selection of all MTF tissue donors (see Donor Screening & Testing). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial or viral infection from the allograft at the site of grafting may occur. The potential to transmit cytomegalovirus through skin allografts has been reported.

PRECAUTIONS

The presence of infection at the transplantation site is a contraindication for the use of this allograft. This allograft may contain trace amounts of processing agents listed in the Cautions section of this insert. This Human Skin Allograft should not be used in patients sensitive or allergic to these specific agents.

ADVERSE EFFECTS

Allograft dermal incorporation with subsequent rejection syndrome and sloughing of allograft may occur. As with any grafting procedure, bacterial infection at the graft site may occur postoperatively and may not be apparent for months after grafting.

Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

ALLOGRAFT INFORMATION

Skin allografts are supplied in a non-sterile foil package designed to help maintain the integrity of the graft during shipping. Each allograft is stored inside a plastic peel pouch, the contents of which are for single-patient, single use only. The shape of the skin allograft is an irregular rectangle and the surface area is indicated on the package label. The average thickness of this skin

allograft is approximately 0.012-0.018 inches but may vary. Each allograft is provided either non-meshed or meshed as indicated on the package label.

INSTRUCTIONS FOR USE

Open the outer non-sterile foil package and remove the plastic peel pouch containing the skin allograft. Care should be taken to avoid contaminating sterile fields or instruments with the non-sterile surfaces of the foil package and its inner pouches. Before use, the allograft must be thawed using aseptic technique. Rapid re-warming is very important. The allograft must not be refrozen after thawing.

Suggested Method:

1. The allograft should be thawed rapidly by aseptically transferring the graft from the inner package into a sterile basin containing sterile 0.9% sodium chloride solution at 20°C to 37°C.
2. Gently swirl the graft within the warm saline solution. Thawing should take place in two minutes or less.
3. Rinse allograft in sterile 0.9% sodium chloride with 2-3 changes of rinse solution in order to remove glycerol, nutrient medium and antibiotics.
4. Remove and discard the supportive mesh material from each side of the graft.
5. After thawing and rinsing, wrap the allograft in sterile saline saturated gauze until use.
6. Non-Meshed Allograft
If meshing is desired by end user, the allograft may be meshed prior to application; however, such use opens the wound surface to potential bacterial colonization. Appropriate caution should be maintained to monitor and control infection at the graft site.
Meshed Allograft
Grafts are provided pre-meshed at a ratio of 2:1. Further meshing by end user is not recommended.
7. Allografts must be used within six hours after thawing if the allograft is stored at room temperature. If refrigerated in the range of 2°C to 8°C within six hours after thawing, the allograft may be used within 24 hours (including thaw time) only if stored with proper precautions to prevent contamination.

NOTE: If it is advantageous for the user to thaw the skin within its packaging, the thawing steps above (Steps 1 & 2) may be substituted by the placement of the packaged graft(s) into a 20°C to 37°C sterile water bath. Transfer the primary (inner) pouches from the outer foil pouch into the water bath. Observe the grafts for complete thawing (absence of crystallized liquid the pouch). The thawed graft(s) can then be aseptically introduced into the rinse solution at Step 3 and the process completed from there as outlined.

Alternative methods for thawing may be considered based on end user needs. Any such alternative methods should be verified by the end user to comply with specific facility and industry standards and requirements. The amount of allograft needed is based on the condition and size of the epithelial defect. Preparation of the host bed is important and it should be debrided free of dead or necrotic tissue, pus and bacterial flora. Using aseptic technique, the allograft should be placed with the dermal side of the allograft applied to the recipient bed. The allograft should be flattened and applied and then steps taken to discourage displacement.

NOTE: Once the inner container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

STORAGE

Store this cryopreserved allograft at -40°C or colder. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

DO NOT USE IF DRY ICE IS NOT PRESENT UPON RECEIPT FROM MTF.

DONOR SCREENING & TESTING

Prior to donation the donor's medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissue in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:

- Hepatitis B virus (HBV) surface antigen
- HBV antibody
- Hepatitis C virus (HCV) antibody

• HIV-1/2 antibody

• HBV NAT



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Additional testing of SARS-CoV-2 virus, HTLV I & II and/or West Nile Virus (as applicable) may also have been performed. All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, authorization, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening meet or exceed current standards established by the American Association of Tissue Banks.



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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

PACKAGING & LABELING

Skin allografts are supplied in a non-sterile foil package designed to help maintain the integrity of each individual graft during shipping. Each allograft is stored inside a separate plastic peel pouch between two pieces of supportive netting, the contents of which are for single-patient, single use only.

NOTE: Remove and discard netting before use.

This allograft must not be used under any of the following circumstances:

1. The allograft has been prematurely thawed.
2. The frozen allograft has not been stored according to storage temperature requirements as specified on the allograft container label.
3. If the container seal is damaged or not intact or physical damage is noted;
4. If the container label or identifying bar code is severely damaged, not legible or is missing; or
5. If the expiration date shown on the container label has passed.

Once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comment regarding the use of the tissue on the TissueTrace Tracking Form. Alternately, a system for electronic submission may be used and sent to MTFTTC@Sceris.com. **Within the United States:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. **Outside of the United States:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

Note: Not all tissue forms are available for International distribution.

Definitions of Label Symbols



Consult instructions for use



Do Not Reuse

For Translation of Instructions for Use

CAUTION: Restricted to use by a physician and/or podiatrist.

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