

READ BEFORE USING

Allograft Dermal Matrix (ADM)

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
Not Terminally Sterilized. Do Not Sterilize.

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

DESCRIPTION AND INDICATIONS FOR USE

AlloPatch® Pliable, AlloPatch® Pliable Meshed, FlexHD® Meshed and SomaGen® Meshed are human allograft dermal matrices (ADM) minimally processed to remove dermal cells and is packaged in an ethanol solution. AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD® Meshed and SomaGen Meshed tissues are processed from a deep cut tissue from which the epidermal layer has been physically removed. The process utilized preserves the extracellular matrix of the dermis with the intent to address the issues of specific and non-specific inflammatory response. The resulting allograft serves as a framework to support cellular repopulation and vascularization at the surgical site.

AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed are used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue such as complex wounds, diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous use. AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed are provided pre-meshed to maximize wound coverage. FlexHD Meshed should not be used for Abdominal Wall Repair, Hernia Repair or other procedures in which substantial tensile strength is needed. In those instances, FlexHD STRUCTURAL should be used.

CAUTIONS AND WARNINGS FOR USE

Do not sterilize. Do not freeze. Trace amounts of Gentamicin, Cefazolin, Chlorhexidine, Peracetic Acid, Ethanol and Propylene Glycol may be present. Caution should be exercised if the patient is allergic to any of these substances. AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen are packaged in an ethanol solution and should be rinsed in a sterile solution prior to implantation. Care should be taken when using AlloPatch Pliable, FlexHD Meshed and SomaGen in conjunction with electrical equipment.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening & Testing Section). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur.

PRECAUTIONS

Conditions that could potentially inhibit the integration of AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed include, but are not limited to:

- Uncontrolled diabetes
- Low vascularity of the surrounding tissue
- Local or systemic infection
- Dehiscence and/or necrosis due to poor revascularization
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using ADM include but are not limited to:

- Local or systemic infection
- Failure of integration into the surrounding tissue
- Specific or nonspecific immune response to some component of the graft

***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

AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed are composed of an acellular dermal matrix. During tissue processing and packaging, this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. In addition, the allograft was tested and met an MTF standard for an acceptable Endotoxin limit. **Do not subject allograft to additional sterilization procedures.**

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.

INSTRUCTIONS FOR USE

ADM is packaged in a sterilized foil pouch that is designed to be passed directly into the sterile field. Employ best practices with aseptic “no touch” technique when handling ADM, including minimizing direct handling of ADM until ready to implant and ensuring frequent glove changes.

Ensure the wound site has been debrided and prepared prior to graft placement.

1. Peel back the outer Tyvek package and pass the inner foil pouch to the sterile field.
2. In preparation for surgery with ADM, remove the graft from the package and place it in sterile solution (i.e., saline or antibiotic solutions) for a minimum of 5 minutes, slightly agitating during the soak.
3. Discard the pouch and packaging solution outside of the sterile field and away from electrosurgical equipment.
4. ADM may be aseptically trimmed to fit the dimensions of the application site, appropriate for tension-free application and maximum contact with wound bed. Do not mesh the tissue. The tissue can be shaped with scissors or scalpel, per surgeon’s preference. The tissue is provided per-meshed to maximize wound coverage.

ORIENTATION

The surgeon may prefer to orient the graft. If a specific orientation is desired, the epidermal facing side vs. dermal side of AlloPatch Pliable can be discerned by positioning the graft with the indicating notch in the upper left-hand side of the tissue. See Figure below.

STORAGE

AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed should be stored at ambient temperature. No refrigeration or freezing is required. 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.

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 tissues 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 core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 NAT
- HCV NAT
- HBV NAT

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.

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The infectious disease test results, consent, 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, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.

PACKAGING & LABELING

AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed and SomaGen Meshed are aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing AlloPatch Pliable, AlloPatch Pliable Meshed, FlexHD Meshed or SomaGen Meshed is inside a sealed sterilized Tyvek pouch. The Tyvek pouch is sealed, labeled and then placed inside an envelope. This allograft must not be used under any of the following circumstances:

- If the pouch seal is damaged or not intact or has any physical damage.
- If the pouch label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the pouch label has passed.

Once a pouch 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. Once completed, a system for electronic submission may be used and sent to MTFTTC@Sceris.com or returned using the self-addressed mailer. Copies of this information may be retained or provided to the local allograft representative.

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



See IFU



Do Not Reuse

For Translations of Instructions for Use



www.mtfbiologics.org



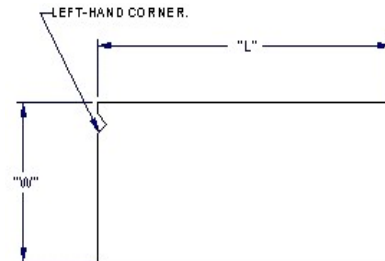
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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization

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

MTF tissue forms and products are protected by one or more issued or licensed technologies which may be found on the MTF website www.mtfbiologics.org/patents. MTF Musculoskeletal Transplant Foundation®, MTF Biologics®, Tissue Trace®, AlloPatch® and SomaGen® are registered trademarks of the Musculoskeletal Transplant Foundation, Edison, NJ USA.

AlloPatch Pliable:



AlloPatch Pliable Meshed, SomaGen Meshed, and FlexHD Meshed:

