

PACKAGING & LABELING

FlexHD is aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing FlexHD 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 container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- 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.

STORAGE

FlexHD 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.

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. 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 comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively a system for electronic submission may be used. *Within the United States:* Once completed, the bottom page of the form should be returned to MTF using the self-addressed, postage paid 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.

REFERENCES

1. Current Standards for Tissue Banking, AATB, McLean, VA.
2. Current Policies and Procedures of MTF, Edison, NJ.

Processed By:



125 May Street
Edison, NJ 08837
USA

Within the United States: 1.800.433.6576
Outside of the United States: 1.732.661.0202

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

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

These tissue forms are covered by the following US patent: US 7,723,108.

FlexHD® is a registered trademark of MTF.

MTF Musculoskeletal Transplant Foundation® is a registered trademark of the Musculoskeletal Transplant Foundation, Edison, NJ USA.

CTO: 100024

PI -31 Rev 10, 2/2011
RM -1098

READ BEFORE USING

FlexHD® Acellular Dermis

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests. FlexHD Is Not Terminally Sterilized. Do Not Sterilize.

THIS TISSUE WAS RECOVERED FROM A DONOR WITH DOCUMENTED PERMISSION FOR RECOVERY AND DONATION. 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

FlexHD is human allograft skin minimally processed to remove epidermal and dermal cells and is packaged in an ethanol solution. The process utilized preserves the extracellular matrix of the dermis. The resulting allograft serves as a framework to support cellular repopulation and vascularization at the surgical site.

INDICATIONS FOR USE

FlexHD is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is used for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects.

ADVERSE EFFECTS

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

- Local or systemic infection
- Dehiscence and/or necrosis due to poor revascularization
- 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.

PRECAUTIONS

When applied properly, FlexHD has been shown to support the migration of host cells from wound margins and surrounding tissue. Conditions that could potentially inhibit integration of FlexHD include, but are not limited to:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Low vascularity of the surrounding tissue
- Local or systemic infection
- Mechanical trauma
- Poor nutrition or poor general medical condition
- Dehiscence and/or necrosis due to poor revascularization
- Inability to cooperate with and/or comprehend post-operative instructions
- Infected or nonvascular surgical sites

CAUTIONS

Do not sterilize. No known sensitizing agents are present in this tissue. Trace amounts of ethanol may be present. FlexHD may be dipped in sterile solution prior to implantation to remove trace ethanol solution. NOTE: No β -lactam antibiotics are used during the processing of tissue in FlexHD.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

ALLOGRAFT INFORMATION

FlexHD is 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. **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

Standard accepted operative practices should be followed. FlexHD is packaged in a sterilized foil pouch that is designed to be passed directly into the sterile field.

1. Peel back the outer Tyvek Package and pass the inner foil pouch to the sterile field.
2. Remove FlexHD from the inner-foil pouch using sterile gloves/forceps.
3. Once the tissue has been removed from the inner pouch, discard the pouch and packaging solution outside of the sterile field.
4. FlexHD may be aseptically trimmed to fit the dimensions of the application site. The tissue can be shaped with scissors or scalpel and rolled or folded to desired thickness. At this point the FlexHD is ready for application in the surgical site.

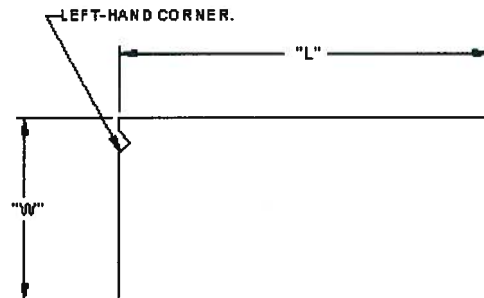
Once the foil pouch containing FlexHD has been opened and exposed, the tissue shall be transplanted within 30 minutes, otherwise, it can be maintained in a sterile saline bath and must be implanted or discarded within 24 hours provided the allograft is maintained in an aseptic environment.

Orientation

In order to discern the dermal side from the epidermal side, note that in most instances the epidermal side may have more pigmentation than the dermal side. For further verification, add a drop of blood to both sides of the graft and rinse with sterile saline. The dermal side will appear red and the epidermal side will appear pink.

To ensure proper orientation of FlexHD, position it so that the indicating notch is in the upper left-hand side of the tissue, facing left. This will assure that the epidermal side is facing up.

Every effort is made to ensure that all hair has been effectively removed from the skin allograft. If any hair is present, remove them before implantation. If they cannot easily be removed, please contact 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 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 CLIA licensed facility for:

- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1/2 antibody
- Syphilis

In addition to the testing listed above, HIV-1 and HCV Nucleic Acid Amplification Testing (NAT) were performed. The results of all serological testing were negative. This allograft tissue has been determined to be suitable for transplantation.

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 1270 and Part 1271 Human Tissue Intended for Transplantation, as applicable. All procedures for donor screening, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.