

PACKAGING & LABELING

FlexHD Pliable PRE is aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing FlexHD Pliable PRE 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.

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 comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively a system for electronic submission may be used and sent to MFTTC@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.

Definitions of Label Symbols



See IFU



Do Not Reuse



Processed By: Musculoskeletal Transplant Foundation
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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. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtfbiologics.org.

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RM -2346

READ BEFORE USING

FlexHD Pliable PRE™

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests. FlexHD Pliable PRE Are 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

FlexHD Pliable PRE is human allograft skin minimally processed to remove dermal cells and is packaged in an ethanol solution. FlexHD Pliable PRE is processed from deep cut tissue from which the epidermal layer has been physically removed. The process utilized preserves the extracellular matrix of the dermis.

INDICATIONS FOR USE

FlexHD Pliable PRE is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and non-specific 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. FlexHD Pliable PRE 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.**

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
- 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

Conditions that could potentially inhibit integration of FlexHD Pliable PRE include, but are not limited to:

- Persistent inflammation
- Uncontrolled diabetes
- Pregnancy
- Poor vascularity of the surrounding tissue
- Sepsis, or infection in or around surgical site
- 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 surgical sites

CAUTIONS

Do not sterilize. Do not freeze. No known sensitizing agents are present in this tissue. FlexHD Pliable PRE is packaged in an ethanol solution and should be rinsed in a sterile solution prior to implantation. Care should be taken when using FlexHD Pliable PRE in conjunction with electrical equipment. NOTE: No antibiotics were used in the manufacturing process.

FlexHD Pliable PRE 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.**

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 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.

ALLOGRAFT INFORMATION

FlexHD Pliable PRE 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.

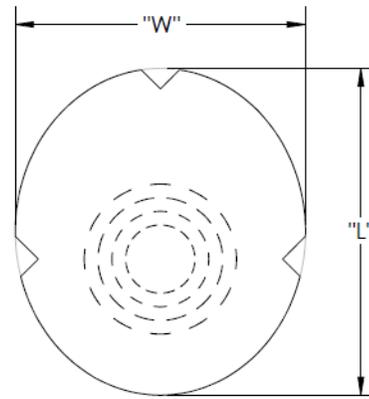
INSTRUCTIONS FOR USE

FlexHD Pliable PRE 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 FlexHD, including minimizing direct handling of FlexHD until ready to implant and ensuring frequent glove changes.

1. Peel back the outer Tyvek Package and pass the inner foil pouch to the sterile field.
2. In preparation for surgery with FlexHD, remove the graft from the package and place it in a sterile solution.
3. Following the initial soak, transfer FlexHD to an antibiotic solution until ready for implantation.
4. Once the tissue has been removed from the inner pouch, discard the pouch and packaging solution outside of the sterile field and away from electrosurgical equipment.
5. FlexHD Pliable PRE is designed to be used without requiring trimming, however, if required, FlexHD Pliable PRE may be aseptically trimmed to fit the dimensions of the application site. The tissue can be shaped with scissors or scalpel, per the surgeon’s preference. At this point, the FlexHD Pliable PRE is ready for application in the surgical site. It may be applied with either side of the tissue facing down.

Note: Concentration of antibiotic solutions should be less than normally indicated for I.V. administration. Toxicity and patient sensitivity to any antibiotics should be verified prior to use.



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
- HBV NAT
- HCV NAT

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, 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, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.

STORAGE

FlexHD Pliable PRE 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.