

## READ BEFORE USING

# FlexHD® PLIABLE

## Acellular Dermis

### DONATED HUMAN TISSUE

**CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY. Aseptically Processed. Passes USP <71> Sterility Tests. FlexHD PLIABLE Is 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

FlexHD PLIABLE is human allograft skin minimally processed to remove dermal cells and is packaged in an ethanol solution. Flex HD PLIABLE tissue 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 with the intent to address the issues of specific and non-specific inflammatory response. FlexHD PLIABLE is supplied as solid sheets, and may/may not contain additional perforations, fenestrations or a combination of the two.

FlexHD PLIABLE is used for the replacement of damaged or inadequate integumental tissue for the repair, reinforcement or supplemental support of soft tissue defects.

## 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. FlexHD PLIABLE 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 in conjunction with electrical equipment.

FlexHD PLIABLE 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 & 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 integration of FlexHD PLIABLE 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 human skin include but are not limited to:

- Local or systemic infection
- Failure of integration into the surrounding tissue
- Specific or non-specific 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

FlexHD PLIABLE 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. 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 discard regulated medical waste materials.

## INSTRUCTIONS FOR USE

FlexHD PLIABLE 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 the sterile solution.
3. Following the initial soak, transfer the 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 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 tissue is ready for application in the surgical site.

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

**Orientation:** The surgeon may prefer to orient the graft (if applicable). To orient FlexHD PLIABLE, position it so that the indicating notch (if included) in the upper left-hand side of the tissue, is facing left. In this instance, the epidermal side is facing up.

## STORAGE

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

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.

## PACKAGING & LABELING

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

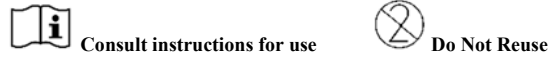
Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off

stickers), and comment regarding the use of the tissue on the TissueTrace Tracking Form. Alternately, a system for electronic submission may be used and sent to [MTFTTC@Sceris.com](mailto: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



### For Translation of Instructions for Use

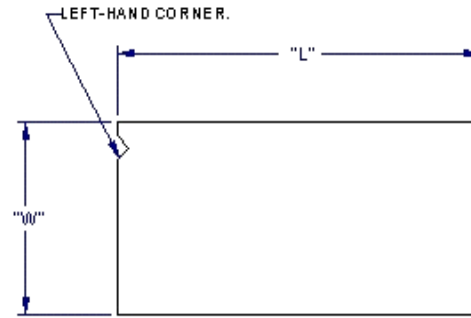


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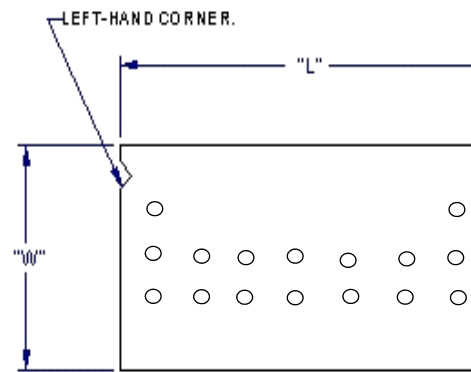
All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

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

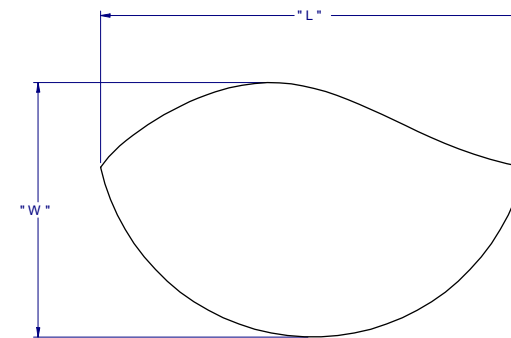
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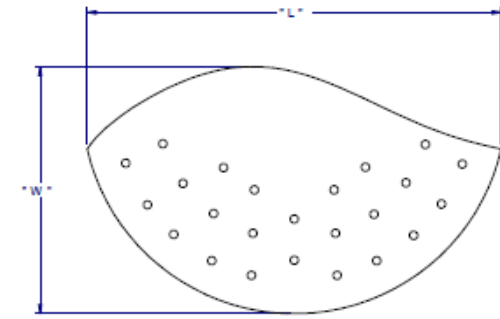
FlexHD PLIABLE



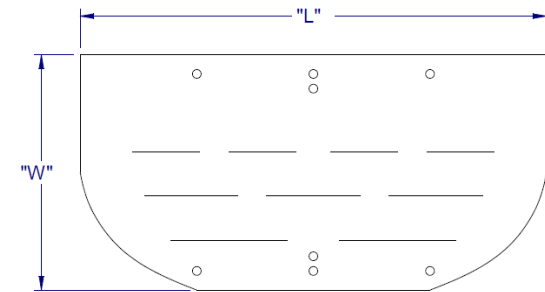
FlexHD PLIABLE Perforated



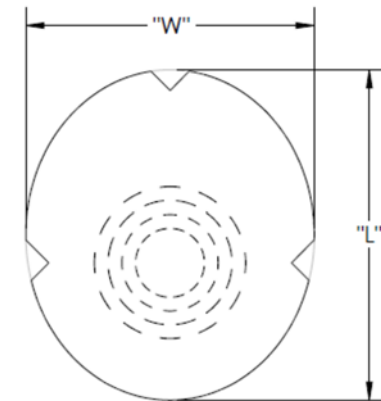
FlexHD Shaped PLIABLE



FlexHD PLIABLE Shaped Perforated



FlexHD PLIABLE MAX



FlexHD PLIABLE PRE