PI -143 Rev 1 01/2021

RM –2339

fiberFUSE™

INSTRUCTIONS FOR USE
READ BEFORE USING
DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests.

fiberFUSE allograft 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

fiberFUSE™ Advanced is composed of freeze-dried demineralized cortical fibers and mineralized cancellous granules. fiberFUSE Strip is composed of freeze-dried demineralized cortical fibers and mineralized cancellous granules that are molded into specific sizes. The allograft is intended for single use in the repair of musculoskeletal defects. The description of the tissue, serial number, expiration date, product code, size and/or amount, and additional information are printed on the allograft container label.

CAUTIONS AND WARNINGS

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. Do not use portions of an allograft from one container on multiple patients. Do not sterilize. Trace amounts of Gentamicin may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solutions may remain. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β-lactam antibiotics were used during the processing of this tissue.

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.

PRECAUTIONS

Conditions that could potentially inhibit integration of fiberFUSE 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 tissues include but are not limited to:

- Infection of the soft tissue and/or bone (osteomyelitis)
- Immune response of non-infectious cause, including fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of newly formed bone
- Disease transmission or undesirable immune response

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

fiberFUSE allografts are composed of demineralized cortical fibers and mineralized cancellous granules. 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 the allograft to additional sterilization procedures.**

PREPARATION FOR USE

The decision to rehydrate tissue prior to transplantation should be based upon the surgeon's preference.

Recommended instructions for handling:

- Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- It is recommended to rehydrate the entire amount of freeze-dried tissue provided with fluid for desired handling properties.
- Based upon the surgeon's preference, hydrated allograft may be further manipulated.
- Tissue should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

Preparation of the host bed is important for allograft incorporation. The host bed should be free of infection prior to grafting. Whenever possible, the allograft should be placed securely against the host bone to aid in incorporation and to prevent displacement of the graft.

INSTRUCTIONS FOR USE

Note: the allograft tissue in contained either in a screw top jar in plastic tray or in a foil pouch within a tyvek pouch. For tissue in a jar, the inner jar and its outer tray are sterilized. For tissue in a pouch, the inner foil pouch and inside wall of the outer tyvek pouch are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

Open the allograft tissue in a jar and tray:

1. Peel back lid of outer tray. NOTE: Once tray is opened, allograft should be used promptly as the inner container, alone, is not intended for storage of allograft and may not provide an adequate moisture barrier.
2. Present the outer tray to the sterile field.
3. Grasp the top and bottom of the jar and remove the threaded cap by twisting.
4. Add desired amount of reconstitution solution.

Open the allograft tissue in a pouch:

1. Peel open the outer pouch.
2. Present the inner foil pouch to the sterile field.
3. Peel open the foil pouch and transfer tissue to a basin.
4. Add desired amount of reconstitution solution.
5. For the strip, rehydrate in basin for 5-10 minutes, no longer than 20 minutes.

NOTE: Small amounts of residual salts in the form of white precipitate may be observed in the jar or may be noticeable on the surface of the fibers. The white precipitate is a by-product of the chemical processing and freeze-drying steps that the allograft tissue is subjected to. Following hydration, white residue should no longer be noticeable on the tissue.

Hydration guide for fiberFUSE Advanced:

fiberFUSE Unit size	Hydration guideline
1cc	1-2cc
2.5cc	2-3cc
5cc	4-5cc
10cc	7-8cc

STORAGE

Freeze-dried bone has been preserved using lyophilization (freeze-drying) to lower the residual moisture level to 6% or less by weight. Store containers of freeze-dried tissue at ambient temperature. In order to maintain integrity of seal, do not freeze. 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. If storage conditions or container seal have been compromised before intended use, the tissue should be discarded.

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 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, 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

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

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

Once a 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.

Definitions of Label Symbols

 Consult instructions for use

 Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

mtfbiologics®

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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.

CTO: 100024

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