PI -143 Rev 0

RM –2339

fiberFUSE™ DBM

INSTRUCTIONS FOR USE

READ BEFORE USING

DONATED HUMAN TISSUE

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 Indication for Use

fiberFUSE™ DBM is composed of freeze-dried demineralized cortical fibers and non-demineralized cancellous granules. 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.

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.

This allograft must not be used under any of the following conditions:

- If the container seal is damaged, or not intact.
- If the container has any physical damage.
- If the container label or identifying bar code is severely damaged, not readable or is missing.
- If the freeze-dried allograft container has been allowed to freeze or has otherwise been damaged.
- If the expiration date shown on the container label has passed.

Caution should be used for the following conditions:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal insufficiency
- History of or active Pott's disease
- Sepsis or infection in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

Precautions

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.

Adverse Effects

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

- Infection of 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 the 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.**

Processing

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment.

- Tissue that is aseptically processed with no exposure to gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions" and "Passes USP <71> Sterility Tests".
- Tissue that is aseptically processed and treated with low-dose gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions. Treated with gamma radiation" and "Passes USP <71> Sterility Tests".

Donor Screening and Testing

Prior to donation, the donor's medical/social history was 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

All infectious disease tests 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 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.

Preoperative Preparation

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.

Freeze-dried bone

Freeze-dried bone has been preserved using lyophilization (freeze-drying) to lower the residual moisture level to 6% or less by weight.

Storage

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.

Preparation for Use

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

Recommended instruction 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 on surgeon's preference, hydrated allograft may be further manipulated.
- Tissues should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

Instructions for Use

Note: The allograft tissue is 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 the outer tray is opened, allograft should be used promptly as 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 the tissue to a basin.
4. Add desired amount of reconstitution solution.

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. This 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.

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 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

 See IFU

 Do Not Reuse

Processed by:

mtfbiologics

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Represented by:

ORTHOFIX®

Orthofix Inc.
3451 Plano Parkway
Lewisville, TX 75056
USA

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.

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