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RM-2471

READ BEFORE USING
AlloFiber™ DBF
INSTRUCTIONS FOR USE
DONATED HUMAN TISSUE

CAUTION; TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically processed. Passes USP <71> Sterility Tests. AlloFiber™ 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

AlloFiber DBF is composed of cortical bone. The allograft is intended for single use in the repair of musculoskeletal defects. AlloFiber DBF is supplied in a variety of standard sized units designed for surgical use by qualified health care professionals (e.g., physicians, dentists, and/or podiatrists). The amount and size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size and type of defect. 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 FOR USE

Do not sterilize. Do not freeze. 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

Caution should be used in 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

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
- Disease transmission and 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

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".

Freeze-dried demineralized bone has been preserved using lyophilization (freeze-drying) to lower the total water content to 6% or less.

INSTRUCTIONS FOR USE

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 securely fixed to the host bone to aid in incorporation and to prevent displacement of the graft.
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 reconstitution solution for desired handling properties.
- Based upon surgeon 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.

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 pouch:

1. Peel open the outer pouch.
2. Pass the inner foil pouch into the sterile field.
3. Peel open the foil pouch and transfer the tissue to a basin.
4. Add desired amount of reconstitution solution.

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. Grasp the top and bottom of the container by placing fingers in the open area provided to remove it from the outer tray and pass it into the sterile field.
3. Remove the threaded cap by twisting.
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.

STORAGE

Store containers of freeze-dried tissue at ambient temperature. In order to maintain integrity of seal, do not refrigerate, 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.

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

AlloFiber DBF is aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing AlloFiber DBF 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 comments regarding the use of the tissue on the TissueTrace Tracking Form. Once completed, a system for electronic submission may be used and sent to MTFTTC@Sceris.com or returned using the self-addressed mailer. Copies of this information may be retained or provided to the local allograft representative.

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

Consult instructions for use

Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

PROCESSED BY:

mtfbiologics®

Processed by: Musculoskeletal Transplant Foundation
125 May Street, Edison, NJ 08837 USA
Within the United States: 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.
CTO: 100024

IF IMPORTED INTO CANADA, IMPORTED BY;

Stryker Canada ULC
2 Medicorum Place, Waterdown
Ontario, Canada, L8B 1W2
1-800-668-8323
CTO: 100261