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RM -730

READ BEFORE USING

AFT Allograft Filler Tube

GRANULAR GRAFT

AFT-DS Allograft Filler Tube

DONATED HUMAN TISSUE
CAUTION: DEVICE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
AFT Is Not Terminally Sterilized.

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

AFT Allograft Filler Tube consists of a stainless steel tube filled with a mixture of allograft tissue containing three components. The first component is cortical bone that has been ground and demineralized (DBM). The second component is cortical cancellous bone that has been milled (Chips/CBM). Both of these components are made from processed human bone. The third component is sodium hyaluronate, which is a naturally derived material that is biocompatible and biodegradable. The combination of DBM, the Chips and sodium hyaluronate results in a putty-like mixture for improved ease and flexibility of use during surgical application. AFT is available in two tube sizes. The AFT-DS tube has a 3.1 mm outer diameter. The larger AFT tube has a 4.0 mm outer diameter.

The allograft tissue contained in AFT is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. It can be used in the:

- Extremities
- Pelvis
- Spine

OSTEOINDUCTIVE POTENTIAL

The AFT Allograft Filler Tube contains osteoconductive allograft tissue, which has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final AFT product is assayed *in vivo* for osteoinductive potential. Standard testing performed in an athymic mouse must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

CONTRAINDICATIONS

The allograft tissue in AFT is not intended to provide structural support of the bone during the healing process.

CAUTIONS AND WARNINGS FOR USE

Do not sterilize. Do not freeze. Some tubes may be difficult to extrude. Excessive force should not be applied when tapping stylet with mallet. Tubes that require excessive force should be discarded.

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 are used during the processing of tissue in AFT products.

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

Closed suction or drainage is recommended to prevent fluid accumulation in the wound.

Use caution in the following circumstances:

- Patients requiring immediate radiation treatment post-operatively
- Vascular deficiency at the surgical site
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using AFT include, but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- 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.**

DEVICE INFORMATION

The allograft tissue mixture in AFT is composed of demineralized bone matrix (DBM), cortical cancellous bone mix (Chips/CBM) and sodium hyaluronate. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used in the DBM is cortical bone. The bone used in Chips/CBM is 80% cortical and 20% cancellous mixed. These tissues were treated with Gentamicin and were cleaned using ethanol and washed with purified water. The cortical bone in the DBM was demineralized using hydrochloric acid. The demineralized bone was then lyophilized to a controlled moisture content. The demineralized bone was combined with sterile-filtered sodium hyaluronate prior to packaging.

Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable. The sodium hyaluronate is mixed in a phosphate buffered saline and added to the bone components to improve the handling characteristics of the tissue. The tissue in AFT is packaged and shipped in a stainless steel tube, which is also the applicator for the tissue.

AFT Components	Size
Cortical Bone Particle Diameter in DBM	212 – 850 µm
Cortical Cancellous Bone Particle in Chips	212 – 850 µm
Sodium Hyaluronate Content (by weight in solution)	2%

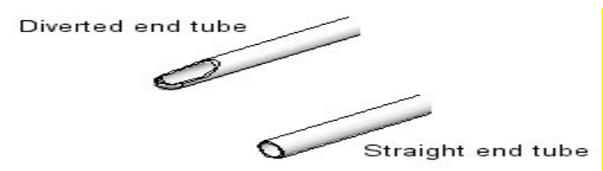
Some tissues are treated with low-dose gamma radiation. For these tissues the container label will state, "Treated with Gamma Radiation." Samples from each donor lot of AFT were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE

AFT tissue is packaged in stainless steel tubes and is designed to be extruded from the tube directly into the operative site. AFT is available in "diverted end" tubes and "straight end" tubes in outer diameters of either 3.1mm or 4.0mm. The straight end tubes are shorter in length and do not direct the flow of the discharged bone graft. The straight end tubes should be used for initial void filling and final void filling after diverted tubes are used. The diverted end tubes direct the flow of the discharged bone graft providing radial placement to the tube axis. Diverted end tubes must be rotated during the discharge of bone graft when a void is being filled.

Stylets that meet the following dimensions are required for usage with AFT in order to discharge bone graft from the tubes:

For 3.1mm tubes: stylet diameter ≤ 2.6mm and stylet length 211±10mm
For 4.0mm tubes: stylet diameter ≤ 3.3mm and stylet length 298±10mm



All AFT Allograft Filler Tubes must be rigidly supported by the proximal support washer at the tube outside diameter during the discharge of bone graft from the tube.

NOTE: This allograft has been aseptically packaged into sterilized packaging components. To make ready for use, open the package using aseptic/sterile techniques.

Straight tubes:

1. Peel back opening of outer pouch for a straight end tube.
2. Pass inner pouch to sterile field.
3. Peel back opening of inner pouch.
4. Remove AFT tube from inner pouch.
5. Pass the tube through a properly sized cannulation which supports the tube by the support washer and provides a mechanism for tube removal.
6. Place stylet in the end of the tube.
7. Use the stylet and mallet to discharge only enough material to initially fill a defect site without packing it, or to fill the small void remaining after use of a diverted tube requiring no more than 1/3 cc.

Diverted tubes:

1. Peel back opening of outer pouch for a diverted end tube.
2. Pass inner pouch to sterile field.
3. Peel back opening of inner pouch.
4. Remove AFT tube from inner pouch.
5. Pass the tube through a properly sized cannulation which supports the tube by the support washer and provides a mechanism for tube rotation and removal.
6. Place stylet in the end of the tube.
7. Use the mallet and stylet to discharge approximately 1/3cc of material out of the tube and into the defect site.
8. Use the rotation mechanism and rotate the tube 60-90 degrees.
9. Use the mallet and stylet to discharge another 1/3cc of material into the defect site.
10. Continue to rotate the tube 30-60 degrees and discharge 1/3cc of material into defect site until filled.
    NOTE: SOME TUBES MAY BE DIFFICULT TO EXTRUDE. DO NOT USE EXCESSIVE FORCE. DISCARD TUBES THAT REQUIRE EXCESSIVE FORCE.
11. Repeat steps 1 through 10 with additional diverted tubes until osseous defect periphery is filled.
12. Use a straight tube to fill the small void remaining after the final diverted tube requiring no more than 1/3cc.
13. 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.

STORAGE

Store AFT 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.

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.

VIRAL CLEARANCE AND INACTIVATION

The method for processing the DBM and Chips/CBM contained in the AFT was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses. The Chips/CBM processing methods were determined to provide some viral inactivation potential for a wide range of viruses. In comparison, the Chips/CBM processing methods provided less viral inactivation potential than the DBM processing methods; therefore, the risk for disease transmission for the Chips/CBM component is greater than the DBM component. However, the risk of disease transmission for these components remains low due to the multiple safeguards employed, i.e., donor selection, laboratory testing, and material processing.

PACKAGING & LABELING

The AFT tissue mixture is packaged in a steam-sterilized stainless steel tube. The filled tube is packaged in a sterilized heat-sealed foil pouch which is then placed into a sterilized outer pouch of Tyvek and plastic.

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

- If the container seal is damaged or not intact of 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.

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.

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:

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
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