AFT Allograft Filler Tube  
AFT-DS Allograft Filler Tube

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. 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 osseous defects or osseous defects created surgically. Patients requiring immediate radiation treatment post-operatively and/or damage to the bony spine structure for initial and final void filling are the indications. 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

Device Information  
The allograft tissue mixture in AFT is composed of demineralized bone matrix (DBM), 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. The tissue was 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.

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. Trace amounts of processing solutions may be used during the processing of tissue in AFT products. Extensive medical screening procedures have been used in the collection 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 if closed suction or drainage is recommended to prevent fluid accumulation in the wound. Use caution in the following circumstances:

- 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.
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

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 seal 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 recipient 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 MTFPTTC@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.

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

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