CONTRAINDICATIONS
AFT is NOT intended to provide structural support of the bone during the healing process. AFT is also contraindicated 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
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- Osteomyelitis at the surgical site
- Septis 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

Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

CAUTIONS
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 antibiotic, Polysorbate-80, Ethanol, Methanol, Isopropanol and Hydrogen Peroxide may be present. 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 (see Donor Screening & Testing). Transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and extensive medical screening procedures. AFT is also contraindicated in the following circumstances:
- Disease transmission and undesirable immune response
- Patients requiring immediate radiation treatment post-operatively
- Vascular deficiency at the surgical site
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- Osteomyelitis at the surgical site
- Septis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

Samples from each donor lot of Sygnal DBM were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE
AFT is packaged in a stainless steel tube and is designed to be extruded from the tube directly into the operative site. AFT is available in two types of tubes: diverted end, and straight end. The diverted end tube is used at the beginning of the fill process and allows for the controlled delivery of the material to the intended site. The straight end is used to complete the fill. The following materials are suggested for use with AFT: 17 oz mallet, cannulated holder with stylet and outer stylet dimensions 0.162"-0.171", and stylet with outer dimensions 0.130"-0.132". Closed suction or drainage is recommended to prevent fluid accumulation in the wound.

DEVICE INFORMATION
AFT is composed of demineralized bone matrix (DBM), cortical cancellous bone mix (Chips/CBM) and sodium hyaluronate (NaHy). 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. DO NOT STERILIZE. 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 is added to the demineralized bone to improve the handling characteristics of demineralized bone. AFT is packaged and shipped in a stainless steel tube, which is also the applicator for the AFT.

The diverted end tube is used at the beginning of the fill process and allows for the controlled delivery of the material to the intended site. The straight end is used to complete the fill. The following materials are suggested for use with AFT: 17 oz mallet, cannulated holder with stylet and outer stylet dimensions 0.162"-0.171", and stylet with outer dimensions 0.130"-0.132". Closed suction or drainage is recommended to prevent fluid accumulation in the wound.

DEVICE INFORMATION
AFT is composed of demineralized bone matrix (DBM), cortical cancellous bone mix (Chips/CBM) and sodium hyaluronate (NaHy). 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. DO NOT STERILIZE. 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 is added to the demineralized bone to improve the handling characteristics of demineralized bone. AFT is packaged and shipped in a stainless steel tube, which is also the applicator for the AFT.
INSTRUCTIONS FOR USE—cont’d

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 the cannulation in the holder until the proximal flange rests on top of the handle.
6. Place styllet in the end of the tube.
7. Begin tapping styllet with a mallet, push approximately 1/8 of the bone out of the tube and into the implant site.
8. Pull the tube slightly out of the holding apparatus and rotate it 90 degrees.
9. Reinsert tube back into holder and resume emptying tube.
10. Continue to eject, rotate, reinsert and empty the diverted tube in the site, with various randomly selected diverted tip orientations.

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 ousseous defect periphery is completely filled. When defect is completely filled remove tube.

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

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.

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 tissues in accordance with current policies and procedures approved by the MTF Medical Advisory Board.

Donor blood samples taken at the time of recovery were tested by a CLIA licensed facility for:

- Hepatitis B surface antigen
- HIV-1/2 antibody
- Hepatitis B core antibody
- HTLV-I/II antibody
- Hepatitis C antibody
- Syphilis

In addition to the testing listed above, HIV 1 Nucleic Acid Amplification Testing (NAT) was performed. Furthermore, donors recovered on or after May 1, 2004 were tested for HCV utilizing the HCV NAT testing method. The results of all serologic testing were negative. The 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 1270 and Part 1271 Human Tissue Intended for Transplantation, as applicable. All procedures for donor screening, serologic and microbiologic testing, 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.

PRE-TREATMENT WITH LOW DOSE GAMMA IRRADIATION

All MTF tissues are recovered in operating rooms or other facilities with similar aseptic environments. It is the policy of the Foundation that all tissues be recovered in an aseptic fashion and maintained as such throughout their processing and distribution to the user. It is possible, however, for some tissues to demonstrate positive tissue cultures upon recovery as a result of factors relating to the recovery process. These tissues are then exposed to a low level (1.2 – 1.8 megarads) dose of gamma radiation prior to processing as a means of reducing bioburden. For these tissues, the container label will specify ‘PRE-TREATED WITH GAMMA IRRADIATION’.

PACKAGING & LABELING

AFT material 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. Because of potential violation of sterility, 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.

STORAGE

Store the AFT Tube at room temperature (15°C to 30°C). 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.

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. A TissueTrace® Tracking Form and peel-off labels have been included with each package of tissue. Record the patient name, the name and address of the transplant facility, allograft tissue information (using the peel-off labels) and comments regarding the use of the tissue on the TissueTrace® Tracking Form. Outside of the United States: Once completed, the bottom page of the form should be returned to MTF using the self-addressed, postage paid mailing. Copies of this information should be retained by the transplant facility for future reference. MTF will be responsible for the return of the peel-off labels.

REFERENCES:

1. Current Standards for Tissue Banking, American Associates of Tissue Banks, McLean, VA.

Processed by:

MTF® is a registered trademark of the Musculoskeletal Transplant Foundation, Edison, NJ USA.