

TRINITY EVOLUTION™ INSTRUCTIONS FOR USE

READ BEFORE USING DONATED HUMAN TISSUE

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR WHOSE LEGAL NEXT-OF-KIN HAS GIVEN PERMISSION FOR THE BONE AND CONNECTIVE TISSUE TO BE DONATED. 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

MUSCULOSKELETAL TRANSPLANT FOUNDATION (MTF) tissues are supplied in a variety of standard sized units designed for surgical use by qualified health care professionals (e.g., physicians, dentists, and/or podiatrists). Processed human bone and soft tissue have been used in a variety of surgical applications and in combination with prosthetic devices. 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

Trace amounts of Acetic Acid, Dimethyl Sulfoxide, Polysorbate-80, Ethanol, Polyoxyethylene (10) Phenol Ether 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.

Precautions

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF. 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 serological testing. Bacterial infection at the site of grafting may occur. **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.**

Contraindications

Tissues distributed by MTF are contraindicated in the following circumstances:

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Incomplete skull growth
- 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)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response

Aseptically Processed

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. The allografts are not terminally sterilized. Each allograft is aseptically processed and the finished product passes USP <71> Sterility Tests. **Do not subject allografts to additional sterilization procedures.** Do not use portions of an allograft from one container on multiple patients. Dispose of excess or unused 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 expiration date shown on the container label has passed.
- If the vial is received thawed.

- If not used within 2 hours after thawing or has been stored at a temperature not recommended.

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 MTF's Medical Advisory Board.

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

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

In addition to the testing listed above, HIV-1 and HCV Nucleic Acid Amplification Testing (NAT) were performed. The results of all serological testing 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 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.

Cryopreserved Tissue

Tissue prepared by cryopreserved processes has been stored in MTF at -185°C in Vapor Phase Liquid Nitrogen until time of shipping and are shipped on dry ice.

Storage

The recommended storage temperature is -70 to -80 degrees C. Short term storage of -58 to -70 degrees C for up to 2 weeks is acceptable. Tissues stored at -58 to -70 degrees C may be placed back into the recommended storage environment of -70 to -80 degrees C at any time during that period. This short-term storage temperature would also allow for any internal temperature fluctuations between -58 to -70 degrees C that may occur during long-term storage at -70 to -80 degrees due to cycling or opening freezer doors. 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.

Preparation for Use

Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination. The inner jar and its outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back the lid of the outer tray
2. Grasp the top and bottom of the container by placing fingers in the open area provided to remove jar from the outer tray and pass it into the sterile field.

Thawing:

3. Place the jar containing allograft and cryopreservation solution in a sterile stainless steel basin or equivalent containing a warm (35°C to 39°C) sterile irrigant (i.e. normal saline or 5% Dextrose in Lactated Ringer's Solution).
 4. The jar containing the allograft should remain in this solution until the contents of the jar flows freely upon inversion. The jar should be removed from the warm solution once free-flowing.
 5. The cryopreservation solution should be immediately decanted into a waste container taking care not to dispose of the allograft tissue.
 6. Add 5% Dextrose in Lactated Ringer's Solution to the jar to cover the material until ready for use.
 7. Decant 5% Dextrose in Lactated Ringer's Solution prior to use.
 8. Implant within 2 hours of thawing.
- 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.

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 stickers have been included with each package of tissue. The serial number and the tissue description have been preprinted on the peel off stickers. 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. **Within the United States:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed, postage paid mailer. Copies

of this information should be retained by the transplant facility for future reference. All recovery, processing and distribution costs were paid for by MTF, a non-profit organization. **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

1. Current Standards for Tissue Banking, AATB, McLean, VA.
2. Current Policies and Procedures of MTF, Edison, NJ.

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CAUTION: Restricted to use by a physician, dentist and/or podiatrist.

Patent pending.

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