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RM –1383

TRINITY EVOLUTION®

INSTRUCTIONS FOR USE
READ BEFORE USING - DONATED HUMAN TISSUE

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

Trinity Evolution is a cryopreserved, viable cellular allograft containing cancellous bone and demineralized cortical bone designed for surgical use by qualified health care professionals. Processed human bone has 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.

Indication for Use

Trinity Evolution is an allograft intended for the treatment of musculoskeletal defects.

Contraindications

Contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to the following reagents listed under the Cautions & Warnings in the IFU

Cautions and Warnings

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. **Do not use portions of an allograft from one container on multiple patients. Do not sterilize.** 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.

Trace amounts of Acetic Acid and Dimethyl Sulfoxide (DMSO 10%) may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solutions may remain. NOTE: No antibiotics are used during the processing of tissue.

Caution should be used for 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

Precautions

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF. 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.

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
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of the newly formed bone
- Disease transmission or 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.**

Aseptically Processed

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment. Each allograft is aseptically processed and the finished product passes USP <71> Sterility Tests. **Do not subject allografts to additional sterilization procedures.**

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 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
- Hepatitis B virus core antibody
- Hepatitis C virus (HCV) antibody
- HBV NAT
- HIV-1/2 antibody
- Syphilis
- HIV -1 NAT
- HCV NAT

All infectious disease test results passed acceptability screening. 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 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, including laboratory testing meet or exceed current standards established by the American Association of Tissue Banks.

Storage

The recommended storage temperature is -70 to -85 degrees C. Short term storage of up to -40 degrees C for up to 4 weeks is acceptable. Tissues stored at up to -40 degrees C may be placed back into the recommended storage environment of -70 to -85 degrees C at any time during that period. This short-term storage temperature would also allow for any internal temperature fluctuations between -40 to -69 degrees C that may occur during long-term storage at -70 to -85 degrees due to cycling or opening freezer doors. Only pull the frozen tissue from the freezer when ready to thaw and implant. 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. Do not implant the tissue prior to thawing.

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 (35ºC 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. Use sterile gauze or the optional strainer to decant the cryopreservation solution into a waste container.
6. Add 5% Dextrose in Lactated Ringer's Solution to the jar to cover the material. Replace the cap and invert the vial twice to suspend tissue until ready for use.
7. Decant 5% Dextrose in Lactated Ringer's Solution into a waste container prior to use.

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. 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. Alternatively 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 in compliance with current FDA, AATB and other regulatory requirements.

Definitions of Label Symbols

 See IFU

 Do Not Reuse

Processed and distributed by: Musculoskeletal Transplant Foundation

125 May Street
Edison, NJ 08837
USA

MTF contact within the United States: 800.433.6576
Outside of the United States: +1.732.661.0202

Represented by:

Orthofix Inc.
3451 Plano Parkway
Lewisville, TX 75056
USA

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

CAUTION: Restricted to use by a physician, dentist and/or podiatrist. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

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