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READ BEFORE USING

TRINITY EVOLUTION®

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests. TRINITY EVOLUTION® Is Not Terminally Sterilized. Do Not Sterilize.

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 INDICTIONS FOR USE

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.

Trinity Evolution is an allograft intended for the treatment of musculoskeletal defects. 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 AND WARNINGS FOR USE

Do not sterilize. The tissue is exposed to processing solutions that may contain detergents and alcohol. In addition, Acetic Acid and Dimethyl Sulfoxide (DMSO10%) are used as well. Trace amounts of processing solutions may remain. Cautions should be exercised if the patient is allergic to any of these substances. NOTE: No antibiotics were used in the manufacturing process.

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.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening & Testing Section). 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.

PRECAUTIONS

Caution should be used for the following conditions:

- Uncontrolled diabetes
- Hypercalcemia
- Local or systemic infection
- Renal insufficiency
- 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)
- 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, particularly viable allografts

***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.**

ALLOGRAFT INFORMATION

Trinity Evolution is comprised of cancellous bone with a demineralized cortical bone component. Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment. During tissue processing and packaging this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. **Do not subject allograft to additional sterilization procedures.**

INSTRUCTIONS 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. **Note:** Trinity should not be implanted prior to thawing and until Steps 3-5 are complete.

1. Peel back the lid of the outer tray.
2. Place the unopened jar containing Trinity Evolution in a basin or water bath warmer containing warm sterile irrigant (saline or 5% Dextrose in Lactated Ringer's Solution; 35°C to 39°C; 95°F to 102.2°F)

Post-Thawing:

3. Once thawed, use sterile gauze to decant the cryopreservation solution.
4. Add 5% Dextrose in Lactated Ringer's Solution to the indicated fill line. Replace the cap until ready for use.
5. Prior to use, decant 5% Dextrose in Lactated Ringer's Solution (D5LR).
6. Implant within 2 hours of thawing.
   Note: Trinity EVOLUTION has been validated for a 2-hour window post-thaw for optimal cell viability.

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

The recommended storage temperature is -70 to -90 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 -90 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 -90 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.

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 virus, 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.

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

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

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