

TRINITY ELITE®

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 ELITE 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 ELITE 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. 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.

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 were used in the manufacturing process.

Caution should be used for the following conditions:

- 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

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.

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

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 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 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 surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1/2 antibody
- Syphilis
- HIV -1 (NAT)
- HCV (NAT)

All infectious disease tests 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 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, 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 at MTF in -185°C in Vapor Phase Liquid Nitrogen until time of shipping and is 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. 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.

Preparations 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 ELITE 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 ELITE 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.

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 MTF@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.

Definitions of Label Symbols



See IFU



Do Not Reuse

Processed and distributed by:



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.

Trinity ELITE® Sizes

Part #	Sizes	Volume
410001	Small	1.2cc
410002	Medium	5.3cc
410003	Large	10.6cc
410004	Extra Large	16cc

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

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtf.org. Trinity ELITE® is a registered trademark of Orthofix® Inc., Lewisville, TX, USA.

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