

READ BEFORE USING

OSTEOARTICULAR ALLOGRAFT TISSUE

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY
Aseptically Processed. Passes USP <71> Sterility Tests. Not
Terminally Sterilized.

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 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. 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.

Processing of refrigerated allografts includes removing any extraneous soft tissue. General appearance of the cartilage is "pearly white" and glistening, perhaps with only slight discoloration. Some areas of unusable cartilage may be present. The remaining cartilage would be used as allograft.

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

CAUTIONS

Trace amounts of Bacitracin/Polymyxin B or Gentamicin antibiotics 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. 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.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and 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 serological testing.

Use caution in the following circumstances:

- 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
- Incomplete skull growth
- Inability to cooperate with and/or comprehend post-operative instructions

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.

This allograft must not be used under any of the following conditions:

- If the frozen graft has not been used within 24 hours of thawing or has been stored at temperatures that exceed recommended storage temperatures.
- If the container seal is damaged, not intact or has any physical damage.
- If the container label or identifying bar code is severely damaged, not readable or is missing.
- If the innermost container is damaged, not intact or leaks.
- If the expiration date shown on the container label has passed.

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 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 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)
- HBV (NAT)

All infectious disease tests were negative. This allograft tissue has been determined to be suitable for transplantation.

DONOR SCREENING AND TESTING—cont'd

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.

STORAGE

It is recommended that the graft be shipped and stored on dry ice or in a minus -40°C to -90°C freezer until time of surgery. Storage of package containing graft at or below a minus -90°C freezer or liquid nitrogen (vapor or liquid phase) may compromise package integrity. Short term storage of less than six months at the user's facility at -20°C to -40°C is acceptable. Tissue that is thawed for more than two hours must be stored at 4°C to 8°C in a covered sterile container until ready for use. If the thawed tissue is not used within 24 hours of thawing it must be discarded. 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. If storage conditions or container seal have been compromised before intended use, the tissue should be discarded.

PREOPERATIVE PREPARATION

Preparation of the host bed is important for allograft incorporation. The host bed should be free of infection prior to grafting. Whenever possible, the allograft should be securely fixed to the host bone to aid in incorporation and to prevent displacement of the graft.

PREPARATION FOR USE

Open packaging using the following procedure. Note: The inner and outer pouches are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Cut open outer bag with non-sterile scissors and remove sterile peel pouch.
2. Open pouch using proper sterile technique.
3. Hand off sterile vacuum-sealed bag into sterile field.
4. Cut open vacuum-sealed bag with sterile scissors and remove tissue. Note: Some frozen bone and soft tissue allografts may be packaged with gauze. If gauze is present with tissue, remove gauze and discard.

THAWING

1. Place the graft in a sterile stainless steel basin or equivalent containing a warm (39°C+/-2°C) sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon preference.
2. The graft should remain in this solution for 15 to 20 minutes to allow full thawing. Soft tissue only: remove remaining cloth layers (if present).
3. The graft should then be rinsed 3 times in Ringers Lactate or sterile saline.
4. 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 in compliance with current FDA, AATB and other regulatory requirements.

Definitions of Label Symbols



See IFU



Do Not Reuse

Processed and distributed by:

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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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