

READ BEFORE USING

OSTEOCHONDRAL 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 Penicillin G, Streptomycin sulfate, NCTC Medium 135, Amphotericin B as Fungizone® in 0.85% saline, vitamins, Fetal Calf Serum/BSE free, and Dulbecco's Modified Eagle Medium (DMEM) 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.

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. 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 tissue is stored outside 1°C to 10°C temperature range.
- 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.

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 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.

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 available at the time of release, 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.

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.

STORAGE

Remove the package of allograft tissue from the insulated shipping container. Store the allograft tissue at 1°C to 10°C until time of surgery, **DO NOT FREEZE**. 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. Handle the package containing the allograft tissue with care. Osteochondral allografts are packaged individually in a triple layered configuration consisting of an outer pouch, peelable middle pouch and inner pouch. The inner pouch contains the tissue with storage/transport media. Note: Fat and/or bone particulates may be present in the media and do not affect the functionality of the allograft tissue. Please refer to the rinsing instructions provided for proper rinsing of allograft prior to implantation.

INSTRUCTIONS 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.

Step 1: Cut open outer bag with non-sterile scissors and remove peel pouch using aseptic technique. Note: **Care should be taken to cut only the outer pouch.**

Step 2: Using sterile technique, peel open middle peel pouch and remove inner pouch. Note: The inner bag contains a small tube, which has been sealed.

Step 3: Using sterile scissors, cut the tubing on the inner pouch and pour off the storage/transport media.

Step 4: Using sterile scissors, cut open the bottom of the inner pouch and place the allograft tissue into a sterile basin containing sterile irrigant (i.e. normal saline or Lactated Ringers Solution).

Tissue Rinsing Procedure

1. Once the osteochondral allograft has been removed from the packaging and transferred to the basin of sterile irrigant (i.e. normal

saline or Lactated Ringers Solution), the allograft must be rinsed to remove excess storage/transport media that remain on the surface of the allograft. Antibiotics may be used with the irrigant according to surgeon preference.

2. To optimize cell viability and reduce the possibility of contamination, the osteochondral allograft must be implanted as soon as possible after it has been rinsed and shaped. The allograft should be implanted within six hours of removal of storage/transport media or discarded.
3. If the allograft is not implanted immediately, place the basin containing the allograft and sterile irrigant on ice and cover with a sterile drape. **DO NOT ALLOW THE ALLOGRAFT TO REMAIN AT ROOM TEMPERATURE OR TO DEHYDRATE.**
4. Immediately before implantation, rinse the allograft in the sterile irrigant for a minimum of 1 minute. During fashioning, rinse the allograft thoroughly using sterile irrigant. **THE ALLOGRAFT MUST REMAIN MOIST AT ALL TIMES PRIOR TO IMPLANTATION.**
5. 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

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