

MTF ALLOGRAFT TISSUE 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 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 (e.g., physicians, dentists, and/or podiatrists). 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.

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. Trace amounts of Gentamicin, Primaxin and Amphotericin B antibiotics 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.

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.

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 vacuum inside the glass container is not intact. (Note: This is only applicable to freeze-dried tissues packaged in glass containers.)
- If the freeze-dried allograft container has been allowed to freeze or has otherwise been damaged.
- If the freeze-dried allograft has been rehydrated for more than 24 hours.
- If the frozen allograft has not been used within 24 hours of thawing or has been stored at temperatures that exceed recommended storage temperatures. (See "Frozen Bone and Soft Tissue")
- If the expiration date shown on the container label has passed.

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

Precautions

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. Bacterial infection at the site of grafting may occur. **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.**

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

Processing

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment.

- Tissue that is aseptically processed with no exposure to gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions" and "Passes USP <71> Sterility Tests".
- Tissue that is aseptically processed and treated with low-dose gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions. Treated with gamma radiation" and "Passes USP <71> Sterility Tests".

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.

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.

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.

FREEZE-DRIED BONE, FREEZE-DRIED DEMINERALIZED BONE AND FREEZE-DRIED SOFT TISSUE

Freeze-dried bone, freeze-dried demineralized bone and freeze-dried soft tissue have been preserved using lyophilization (freeze-drying) to lower the total water content to 6% or less.

Freeze-Dried Packaging Note: Tissues preserved by freeze-drying are packaged in nested plastic trays, screw top jars, glass bottles, plastic bottles, or flexible pouches. Some tissues may be wrapped in gauze prior to packaging. The gauze (if present) will be wrapped around the tissue or located at the bottom of the container and must be removed from the tissue prior to tissue implantation.

Storage

Store containers of freeze-dried tissue at ambient temperature. In order to maintain integrity of seal, 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.

Reconstitution/Rehydration Procedure

To obtain the best clinical results and prevent graft failure the procedure and recommendations listed below should be followed.

Preparation For Use

The decision to rehydrate MTF freeze-dried tissue prior to transplantation should be based upon the surgeon's preference. For tissues that are to be cut, shaped, drilled or used for weight bearing purposes, excessive force should not be applied to the lyophilized bone during manipulation or upon implantation. For ease of handling, it is recommended that freeze-dried soft tissue (i.e. tendon and ligaments) be rehydrated prior to use.

Recommended instruction for handling freeze-dried tissue:

- Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- It is common surgical practice to rehydrate freeze-dried tissue in an acceptable sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon preference.
- Patient sensitivity to antibiotics used to rehydrate allograft tissues should be checked prior to use. Concentration of antibiotic solutions should be less than normally indicated for I.V. administration.
- Use new solutions for each allograft.
- Sufficient solution should be prepared to completely cover the tissue.

- Tissues should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

Tissue packaged in nested plastic trays:

Open tissues packaged in nested plastic trays using the following procedure. Note: The inner and outer tray components are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft should be used promptly. Inner tray, alone, although a sterile barrier, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Grasp the pull-tab on the lid of the inner tray to remove it from the outer tray and pass it into the sterile field.
3. Peel back lid of inner tray. Transfer tissues to a sterile container for reconstitution.
4. Completely immerse the tissue in the reconstitution solution.
5. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze-dried bone and soft tissue allografts are packaged with gauze. If gauze is present with the tissue, remove gauze and discard.

Tissue packaged in screw top jar in plastic tray:

Open tissues packaged in a **screw top jar in a plastic tray** using the following procedure: Note: The inner jar and its outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft should be used promptly. Inner container, alone, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Grasp the top and bottom of the container by placing fingers in the open area provided to remove it from the outer tray and pass it into the sterile field.
3. Remove the threaded cap by twisting and breaking the tamper evident tab. Transfer tissues to a sterile container for reconstitution.
4. Completely immerse the tissue in the reconstitution solution.
5. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze-dried bone and soft tissue allografts are packaged with gauze. If gauze is present with the tissue, remove gauze and discard.

Tissue packaged in plastic bottle in plastic tray:

Open tissue packaged in a plastic bottle in plastic tray using the following procedure: Note: The inner bottle and the outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft tissue should be used promptly. Inner container, alone, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Remove the inner bottle from outer tray and pass it into the sterile field.
3. Remove the red cap and aluminum collar from the bottle. NOTE: fragments of the red cap may break off.
4. Remove the rubber stopper. Note: The container shall be held firmly on a hard surface while removing stopper to prevent spillage.
5. Deposit the contents of the bottle into a sterile container for reconstitution.
6. Completely immerse the tissue in the reconstitution solution.
7. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze dried bone and soft tissue allografts are packaged with gauze. If gauze is present with tissue, remove gauze and discard.

Tissues packaged in glass bottles

Open freeze-dried tissues packaged in glass bottles using the following procedure:

1. Remove aluminum cap from container and wipe entire stopper target area with betadine or 70% alcohol.
2. Using aseptic technique, deliver the reconstitution solution into the container by puncturing the stopper with a needle attached to a syringe, I.V. administration set, or

other appropriate delivery system. All components used for the delivery of the reconstitution solution must be sterile. Completely immerse the tissue in the reconstitution solution. The solution should be drawn into the vial by the vacuum inside of the container (this assures that vacuum is present). If the solution is not drawn into the vial, repeat the process with a different needle to assure coring of the stopper did not block the needle opening. Do not use tissue if vacuum does not appear to be present.

3. Remove rubber stopper with the aid of a large sterile clamp in order not to contaminate the opening of the bottle. Note: The container should be held firmly on a hard surface while removing the stopper to prevent spilling.
4. Deposit the contents of the bottle into a sterile container on the operative field. If desired by the surgeon, this container can be prefilled with an antibiotic solution (see above).
5. Completely immerse the tissue in the reconstitution solution.
6. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze-dried bone and soft tissue allografts are packaged with gauze. If gauze is present with the tissue, remove gauze and discard.

Tissue packaged in flexible pouches

This allograft has been aseptically packaged into sterilized packaging components. Use standard aseptic/sterile techniques to open the package and make ready for use.

1. Peel open the outer pouch.
2. Pass inner pouch to sterile field.
3. Peel open inner pouch.
4. Remove tissue.
5. Implant as per surgeon's preference.

Note: The decision to rehydrate MTF freeze-dried bone prior to transplantation should be based upon the surgeon's preference.

FROZEN BONE AND FROZEN SOFT TISSUE

Bone and soft tissues preserved by freezing have been stored at -40°C to -90°C until time of shipping, and are shipped on dry ice.

Storage

It is recommended that the frozen bone or soft tissue be stored on dry ice or in a -40°C to -90°C environment until time of surgery. Storage of a package containing allograft at or below -90°C or in 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 -39°C is acceptable. If the thawed tissue is not used within 24 hours of thawing it must be discarded. Packaged tissue thawed 2 hours or less may be returned to frozen storage provided the package seal has not been breached. 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

1. Cut open outer bag with non-sterile scissors and remove sterile peel pouch.
2. Open pouch using proper sterile technique.
3. Hand off inner vacuum-sealed bag into sterile field.
4. Cut open vacuum-sealed bag with sterile scissors and remove tissue.

Thawing

1. It is recommended that frozen allograft be placed into 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's preference.
2. The tissue thaw time is per surgeon's preference. Soft tissue only: remove remaining cloth layers (if present).
3. The allograft should then be rinsed 3 times in Lactated Ringers Solution or normal saline.

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



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