CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Use caution in the following circumstances:

- Disulfide and or necrosis due to poor revascularization
- 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 may occur despite careful donor selection and labelling, including serology and nucleic acid testing (NAT). 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)
- Immune response of non-infectious cause, including fever
- Deficiency 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

Allograft Information

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” and “Passes USP <71> Sterility Tests”.

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 nestable plastic trays, screw top jars, 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 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 some applications, such as bone, cartilage, nerve, or other tissues, it may be cut, shaped, drilled or used for weight bearing purposes. Excessive force should not be applied to the lyophilized bone during manipulation or implantation. For ease of handling, it is recommended that freeze-dried soft tissue (i.e. tendon and ligaments) be rehydrated prior to use.

Recommended instructions 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 surgical 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 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 in 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 of the outer tray and lift the inner tray 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 in 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.

Tissue packaged in sterile plastic trays:

Open tissues packaged in sterile 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.

Reconstitution/Rehydration Procedure

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

- Thoroughly rinse the package of tissue in a sterile irrigant to completely cover the tissue.
- Gently remove the gauze if present. 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.

Use caution in the following circumstances:

- Fever
- Uncontrolled diabetes
- Note: The inner jar and its outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.
- Local or systemic infection

Use caution in the following circumstances:
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.

**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.

**FROZEN BONE AND FROZEN SOFT TISSUE**

Bone and soft tissues preserved by freezing have been stored at -40ºC to -90ºC 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 -40ºC to -90ºC environment until time of surgery. Storage of a package containing allograft at below -90ºC or in liquid nitrogen (vapor or liquid phase) may compromise package integrity. Short-term storage in liquid nitrogen (vapor or liquid phase) may compromise package integrity. Short-term storage in a short-term storage environment until time of surgery. Storage of a package containing allograft at or below -90ºC or in liquid nitrogen (vapor or liquid phase) may compromise package integrity. Short-term storage in a short-term storage environment until time of surgery. Storage of a package containing allograft at or below -90ºC or in liquid nitrogen (vapor or liquid phase) may compromise package integrity.

**Preparation for Use**

1. Cut open outer bag with non-sterile scissors and remove sterile peel pouch.

2. Open the peelable pouch using proper sterile technique.

3. Pass 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 (39ºC +/- 2ºC) sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon’s preference.

2. The thaw time shall be 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.

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

Additional testing of SARS-CoV-2, 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, 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, including laboratory testing, 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 comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively, a system for electronic submission may be used and sent to MTFTrace@3cern.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.

**Definitions of Label Symbols**

Consult instructions for use

Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

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 technologies which may be found on the MTF web site www.mtfbiologics.org/patents. MTF Musculoskeletal Transplant Foundation®, MTF Biologics® and Tissue Trace® are registered trademarks of the Musculoskeletal Transplant Foundation, Edison, NJ, USA. ©2021 Musculoskeletal Transplant Foundation. CTO: 100024

MTF Biologics

125 May Street   Edison, NJ 08837 USA

Within the United States: 800.433.6576

Outside of the United States: +1.732.661.0202

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

Process distributed by: Musculoskeletal Transplant Foundation

1232 Mid-Valley Drive Jessup, PA 19044 USA

With the United States: 800.433.6576

Outside of the United States: +1.732.661.0202