

Costal Cartilage Allograft

INSTRUCTIONS FOR USE READ BEFORE USING DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
MTF Biologics Costal Cartilage Allografts Are NOT Terminally Sterilized. Do Not Sterilize.

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

MTF Biologics costal cartilage allograft is human allograft costal cartilage that is minimally processed. Profile® costal cartilage allograft is stored in a triple layer packaging configuration inside a carton. Extearna™ is stored in a triple layer packaging configuration. Tissue color for both Profile and Extearna may vary from donor to donor due to physiologic differences.

Profile® Costal cartilage allograft is intended for use in cosmetic and reconstructive rhinoplasty procedures.

Extearna™ Costal cartilage allograft is intended for use in microtia reconstruction. Both Profile and Extearna may also be used in other procedures as needed to supplement, augment or repair cartilaginous defects.

Cautions and Warnings

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.

Do not thaw, rinse or soak in warm (> ambient temperature) solutions.

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 allograft has not been used within 24 hours of thawing or has been stored at temperatures that exceed recommended storage temperatures. (See "Storage" section)
- If the expiration date shown on the container label has passed.

Use caution in the following circumstances:

- Uncontrolled diabetes
- Low vascularity and/or ischemia of the surrounding tissue
- Local or systemic infection
- Inability to cooperate with and/or comprehend post-operative instructions

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 laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur.

Adverse Effects

Possible adverse effects of using human tissues include but are not limited to:

- Local or systemic infection
- Specific or non-specific Immune response to some component of the graft

***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.**

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 treated with low-dose gamma radiation and then aseptically processed 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 virus (HBV) surface antigen
- HBV core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 NAT
- HCV NAT
- HBV NAT

Additional testing of SARS-CoV-2, HTLV I & II and/or West Nile Virus (as applicable) may have been performed. All infectious disease tests passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, authorization, 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.

Storage

It is recommended that the frozen 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 costal cartilage allograft be placed into a sterile stainless steel basin or equivalent containing an ambient temperature 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. However, for Profile, a thaw time of 10 minutes for Profile costal cartilage segments and 5 minutes for Profile costal cartilage sheets is recommended. For Extearna, a thaw time of 20 minutes is recommended.

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 MTFBTC@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

For Translation of Instructions for Use



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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.

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