PI -106 Rev 4, 02/2022

RM –2009

CAM

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

CAM is composed of freeze-dried articular cartilage. CAM is intended for the replacement of damaged or inadequate host cartilage as the result of natural or surgically created cartilage voids. 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. 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 freeze-dried allograft container has been allowed to freeze or has otherwise been damaged.
- If the expiration date on the container label has passed.

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.

Precautions

Caution should be used in the following conditions:

- Uncontrolled diabetes
- Local or systemic infection
- Inability to cooperate with and/or comprehend post-operative instructions

***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
- Deformity of cartilage at the site
- Disease transmission or 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 virus (HBV) surface antigen
- Hepatitis B virus 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 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.

Freeze-dried CAM

CAM has been preserved using lyophilization (freeze-drying) to lower the total water content to 6% or less.

Storage

Store the containers of CAM 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.

Preparation for Use

Recommended instruction for handling:

- Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- CAM must be rehydrated prior to use.

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

Instructions for Use

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The inner bottle and the outer foil pouch are sterilized. Use standard aseptic/sterile technique to open the package and make it ready for use.

1. Peel open the foil pouch and transfer the inner bottle as a single unit into the sterile field. Remove the white cap and aluminum collar from the bottle.
2. Remove the rubber stopper.
   Note: The container shall be held firmly on a hard surface while removing stopper to prevent spillage.
3. CAM may be mixed with 0.8 ml to 1.0 ml of sterile saline or liquid biologic. NOTE: Adding too little or too much liquid will result in a dry or runny paste, respectively.
4. CAM is now ready for use. Paste should be used within 60 minutes of mixing to minimize drying of the paste.

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 MTFTTC@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

 Consult instructions for use  Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

Processed and distributed by:

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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.

CAUTION: Restricted to use by a physician, dentist and/or podiatrist.

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