PI -120 Rev 0, Date
RM -2271

CartiMax™

Viable Cartilage Allograft

INSTRUCTIONS FOR USE

READ BEFORE USING
DONATED HUMAN TISSUE

THIS TISSUE WAS RECOVERED FROM DECEASED DONORS FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THE RECOVERIES WERE PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS. ACCESSORY COMPONENTS ARE STERILIZED BY GAMMA RADIATION.

Description

CartiMax Viable Cartilage Allograft is a kit composed of Viable Cartilage Fibers (Fibers), Cartilage Allograft Matrix (CAM), and CartiMax Accessories (Accessories). The Accessories include a strainer cap and a spatula. The Fibers and the CAM are mixed together using the Accessories; the result is a product with a putty-like consistency.

The amount and size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size of the defect. The description of the tissue, serial numbers, expiration dates, product codes and additional information are printed on the allograft container labels.

Indication for Use

CartiMax is intended for the replacement of damaged or inadequate host cartilage as the result of natural or surgically created cartilage voids.

Cautions and Warnings

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY.
Do not use the allograft(s) or accessories from one kit on multiple patients.

Do not sterilize. 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 any of the container seals are damaged or not intact.
- If any of the containers have physical damage.
- If any of the container labels or identifying bar codes are severely damaged, not readable or are missing.
- If the use by and or expiration dates on the kit and or container labels have passed.

CartiMax should be used by the date indicated on the top of the kit box. Trace amounts of Gentamicin, Primaxin, Amphotericin B antibiotics, Dimethyl Sulfoxide (DMSO 10%), and Dexamethazone Sodium Phosphate may be present. Caution should be exercised if the patient is allergic to any of these substances.

Caution should be used in the following conditions:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal insufficiency
- History of or active Pott's disease
- Sepsis, or infection in or around the surgical site
- 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. Transmission of infectious diseases may occur despite careful donor selection and laboratory testing. Bacterial infection at the site of grafting may occur.

Adverse Effects

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

- Infection of cartilage, 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

***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.**

Aseptically Processed

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment. Each Allograft is aseptically processed and the finished product passes USP <71> Sterility Tests.

- 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".
  Do not subject allografts to additional sterilization procedures.

Donor Screening and Testing

Prior to donation, the donors' 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)

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.

Storage

The CartiMax storage temperature requirement is -70°C (-94°F) or below. It is the responsibility of the transplant facility or clinician to maintain the

tissue in the appropriate storage conditions. If storage conditions or container seals have been compromised before intended use, the tissue should be discarded.

Instructions for Use

Allograft tissues and accessories should be maintained in an aseptic environment at all times to prevent the possibility of contamination. Use standard aseptic/sterile technique to open the packages and make ready for use. **Note:** CartiMax should not be prepared prior to thawing the Fibers.

Preparation of the Fibers:

1. Remove the three (3) contents from the kit box. Viable Cartilage Fibers (Fibers), Cartilage Allograft Matrix (CAM) and CartiMax Accessories.
2. Using standard aseptic/sterile technique, open the packaging of the three contents and place into the sterile field. Put the CAM and Accessories to the side.
3. *Thawing the fibers.* Place the unopened jar containing the Fibers in a basin with warm sterile irrigant (saline or 5% Dextrose in lactated Ringer's Solution; Thaw time is approximately 20 minutes (35°C to 39°C; 95°F to 102.2°F) until all ice dissolves. Thawing at cooler temperature may extend thawing time. **Note: Decant per procedure below immediately after thawing.**
4. Immediately after thawing the Fibers, remove the cap. Put the strainer cap on the jar of the Fibers.
5. *Decant the solution from the Fibers.* Drain the fluid from the Fibers by inverting the jar and tapping on the bottom of the jar several times. After turning the jar upright, tap the bottom of the jar to the table top to return the fibers to the bottom of the jar.
6. *Rinse the Fibers.* Remove the strainer cap from the jar of the Fibers and fill jar with sterile irrigant (saline or 5% Dextrose in Lactated Ringer's Solution).
7. Put the strainer cap back on the jar of the Fibers. Decant the sterile irrigant following the instruction from step 5. After repeating Step 5 once, the fibers are now ready to be mixed with CAM.
8. *Open the CAM Bottle.* Remove the white cap, aluminum collar and rubber stopper from the CAM bottle. Hold the container firmly on a hard surface while removing the stopper to prevent spillage.
9. *Mix the CAM and the Fibers.* Pour the CAM into the jar of Fibers. Using the spatula, mix the CAM and Fibers together, creating a putty-like consistency
10. Mold CartiMax into the desired shape. CartiMax Viable Cartilage Allograft is now ready for implantation.

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


See IFU


Do Not Reuse


Expiration Date

Method of Sterilization: Irradiation (Accessories)

Processed and distributed by:
Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837
USA

MTF contact 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. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

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