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RM – 1973

Demineralized Cancellous Allograft in Q-PACK®

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 has been used in a variety of surgical applications and in combination with prosthetic devices. Demineralized Cancellous Allograft is packaged in Q-PACK and is ready for immediate use. 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 and detergents may be present. Demineralized Cancellous is packaged in an ethanol solution. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β-lactam antibiotics were used during the processing of this tissue.

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 container has been allowed to freeze or has otherwise been damaged.
- 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
- Neurological injury
- Vascular or visceral injury

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 is 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, 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. 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.

Storage

Store containers of the Demineralized Cancellous Allograft 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.

Instructions for Use:

Standard accepted operative practices should be followed.

Demineralized Cancellous Allograft should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
The inner pouch, its contents, and the inside of the outer pouch are sterile. The outside of the outer pouch is not sterile. Use standard aseptic/sterile technique to open the package

1. Peel open the outer Tyvek pouch and pass the inner foil pouch to the sterile field.
2. Peel open the inner foil pouch.
3. Remove the tissue from the foil pouch.
4. Note: if the tissue is provided in a plastic clamshell, remove the tissue from the clamshell
5. Once the tissue has been removed from the packaging, discard the packaging outside of the sterile field.

Note: Demineralized Cancellous Allograft packaged with Q-PACK technology is ready for immediate use. Per surgeon's preference, tissue may be rinsed in sterile saline solution prior to implantation.

The inner pouch alone provides a sterile and moisture barrier. Once the foil pouch containing Demineralized Cancellous Allograft has been opened, the implant should be used as soon as possible. Once removed from the pouch, the tissue has to be implanted within 20 minutes; otherwise, it has to be put under a sterile saline bath for at least 5 minutes before implanting it. The tissue placed under a sterile saline bath must be implanted or discarded within 24 hours provided the allograft is maintained in an aseptic environment.

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

Processed by:

MTF Musculoskeletal Transplant Foundation

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

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