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RM-2559

vallos® Allograft Granules

INSTRUCTIONS FOR USE
READ BEFORE USING
DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests.

vallos Allograft Granules 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 INDICATIONS FOR USE

vallos® Allograft Granules are composed of cortical bone, cancellous bone, or a blend of cortical and cancellous bone which has been milled and freeze-dried. Variations may include mineralized or demineralized tissue. The allograft is intended for single use in the repair of musculoskeletal defects. 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 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. 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.

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

Conditions that could potentially inhibit integration of vallos Allograft Granules, but are not limited to:

- Uncontrolled diabetes
- Low vascularity of the surrounding tissue
- Local or systemic infection
- Dehiscence and or necrosis due to poor revascularization
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS

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

- Infection of the soft tissue and/or bone (osteomyelitis)
- Immune response of non-infectious cause, including fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of newly formed bone
- 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.**

ALLOGRAFT INFORMATION

vallos Allograft Granules are comprised of cortical and/or cancellous bone which have been milled and freeze-dried, and some variations may also have been demineralized. During tissue processing and packaging, this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. **Do not subject the allograft to additional sterilization procedures.**

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”.

PREPARATION FOR USE

The decision to rehydrate tissue prior to transplantation should be based upon the surgeon’s preference.

Recommended instructions for handling:

- Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- It is recommended to rehydrate the entire amount of freeze-dried tissue provided with fluid for desired handling properties.
- Based upon the surgeon’s preference, hydrated allograft may be further manipulated.
- Tissue should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

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 placed securely against the host bone to aid in incorporation and to prevent displacement of the graft.

INSTRUCTIONS FOR USE

Note: The inner jar and inside/interior of the foil pouch are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

Open the allograft tissue in a pouch:

1. Peel open the foil pouch using aseptic technique.
2. Present the jar to the sterile field.
3. Unscrew the jar lid, breaking the protective sticker, to access the tissue.
4. Tissue may be reconstituted in the jar, or if desired, transfer tissue to a basin.
5. Add desired amount of reconstitution solution.

STORAGE

Freeze-dried bone has been preserved using lyophilization (freeze-drying) to lower the residual moisture level to 6% or less by weight. 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.

DONOR SCREENING & TESTING

Prior to donation the donor’s medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissue 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 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, 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 meet or exceed current standards established by the American Association of Tissue Banks.

PACKAGING & LABELING

vallos Allograft Granules are aseptically packaged in a sterilized jar. The jar containing vallos Allograft Granules is inside a sealed sterilized foil pouch. The sealed foil pouch is labeled and then placed inside a carton. This allograft must not be used under any of the following circumstances:

- If the seal of the foil pouch is not intact or has any physical damage.
- If the finished goods label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the container has passed.

Once the foil pouch seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

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 comment regarding the use of the tissue on the TissueTrace Tracking Form. Alternately, 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 transplant facility 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

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

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

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