BioMed ENT

FDA Establishment Identifier
FEI:3041532372

INSTRUCTIONS FOR USE
READ BEFORE USING DONATED HUMAN TISSUE

This allograft was recovered from voluntarily donated human tissue. All tissue has been collected, processed, stored, and distributed in accordance with applicable regulations of the U.S. Food and Drug Administration (FDA) and Health Canada's Cells, Tissues and Organs for Transplantation (CTO) Regulations.

Description and Indications for Use

BioMed ENT tissues are supplied in a variety of standard-sized units intended for surgical use by qualified healthcare professionals, including physicians, dentists, podiatrists, and other licensed medical professionals, for use in recipients. Human tissue for transplantation shall not be offered, distributed, or dispensed for veterinary use.

Processed human bone and soft tissue have been used in a variety of surgical applications, including use in combination with prosthetic devices. The amount and size of allograft necessary for a surgical procedure are based on the individual surgeon's preference and the size and type of defect being treated. The tissue description, serial number, expiration date, product code, size and or amount, and additional required 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 resterilize.

Trace amounts of the following processing agents may be present: Betadine, hydrogen peroxide, isopropyl alcohol, Triton X-100, hydrochloric acid (demineralized or DBM), and phosphate buffer (demineralized or DBM). Use caution if the patient has known sensitivity or allergy to any of these substances.

Dispose of excess or unused tissue and all packaging that has come into contact with the tissue in accordance with recognized procedures for regulated medical waste.

Do not use this allograft under any of the following conditions:
- The container seal is damaged or not intact
- The container shows evidence of physical damage
- The container label or identifying barcode is missing, unreadable, or severely damaged
- A freeze-dried allograft has been rehydrated for more than 24 hours
- The expiration date on the container label has passed

Precautions

Extensive medical screening procedures are used in the selection of all tissue donors. Despite careful donor screening and serological testing, transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of Creutzfeldt-Jakob disease (CJD), may occur. Bacterial infection at the graft site is also a possible risk.

Within the United States, adverse outcomes attributable to the tissue must be promptly reported to BioMed ENT. Outside the United States, adverse outcomes must be reported to the local representative.

Contraindications

Tissues distributed by BioMed ENT may be contraindicated in the following circumstances:
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes or hyperglycemia
- Severe degenerative bone disease
- Pregnancy
- Renal compromise
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Incomplete skull growth
- Inability to comply with or understand post-operative instructions

Possible Complications

Possible adverse effects or complications associated with the use of human tissue include, but are not limited to:
- Infection of soft tissue and or bone, including osteomyelitis
- Fever
- Bone deformity at the graft site
- Incomplete bone ingrowth, delayed union, or non-union
- Accidental aspiration or removal of particulate graft material when used in the oral cavity
- Fracture of newly formed bone
- Disease transmission or undesirable immune response

Processing

Processing and packaging are performed under controlled aseptic conditions in a Class 1000 environment. All bone allografts are terminally sterilized using a minimum radiation dose of 15.8 kGy.

Donor Screening and Testing

This allograft was prepared from a donor determined to be suitable based on donor screening and testing results. Donors are evaluated through medical and social history interviews, review of medical records, physical assessment, and review of post-mortem examination results when applicable.

Tissue from this donor has passed bacteriological testing performed by a CLIA-certified laboratory. Communicable disease testing was performed by a laboratory registered with the FDA and certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 CFR Part 493, or deemed compliant by the Centers for Medicare and Medicaid Services (CMS). Testing results were negative or non-reactive for, at minimum:
- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1 and HIV-2 antibodies
- Syphilis
- HIV-1, HCV, and HBV nucleic acid testing (NAT), including Ultrio

Additional testing, including but not limited to Human T-Cell Lymphotropic Virus Types I and II (HTLV I and II), may have been performed and found acceptable for transplantation. A complete list of additional communicable disease tests performed is available upon request.

Donor eligibility determination was made by KDNA Life Sciences, LLC in compliance with U.S. FDA regulations under 21 CFR Part 1271. Final eligibility and suitability for transplantation were determined by the Medical Director following review of all donor screening and testing records.

Donor Eligibility Determination and Tissue Processing

Donor eligibility determination and tissue processing are performed by KDNA Life Sciences, located at 512 E. Madison Avenue, Suite A1, Belgrade, Montana 59714. KDNA Life Sciences is registered with the U.S. Food and Drug Administration under FDA Establishment Identifier (FEI) 3020499006 and holds CTO Registration Certificate No. 3020499006. The facility can be reached by phone at (406) 209-8766 and by fax at (406) 518-2225.

Distributor Information
BioMed ENT
757 N. Water Street, Suite 300
Milwaukee, WI 53202
Phone: (414) 616-117
Email: info@biomed-ent.com

FREEZE-DRIED MUSCULOSKELETAL TISSUE PREPARATION FOR USE

Freeze-dried bone and freeze-dried demineralized bone and pericardium have been preserved using lyophilization (freeze-drying) to lower the total water content to 6% or less.

Storage

Store freeze-dried allografts in a clean, dry environment at ambient temperature 50 to 86 degrees Fahrenheit (10 to 30 degrees Centigrade). 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

Allograft tissue should be maintained in an aseptic environment at all times to reduce the possibility of contamination. To obtain the best clinical results and prevent graft failure, the procedure and recommendations below should be followed.

- Using aseptic technique, peel open the outer package.
- Introduce inner-most pouch into sterile field. Cut the pouch on one end and place the allograft into a sterile basin. If product is packaged in a jar, introduce the jar to the sterile field. If product is packaged in a syringe, introduce the syringe to the sterile field.
- It is common surgical practice to rehydrate freeze-dried tissue in a sterile isotonic solution. At the surgeon's discretion, the following autologous fluids may also be used to hydrate the implant: blood, bone marrow aspirate and platelet rich plasma. Antibiotics of the physician's preference may be added to the solution. Sufficient solution should be prepared to completely cover the allograft. INADEQUATE RECONSTITUTION MAY RESULT IN GRAFT BREAKAGE OR FRACTURE.
- Rehydration times vary by graft type. Allograft particulate shall be reconstituted for a minimum of 10 minutes. Promptly dispose of unused, rehydrated tissue after the procedure it was rehydrated for.
- Implant per surgeon's preference.
- Discard any unused implant in accordance with standard practice for disposal of human tissue.

Disclaimer: BioMed ENT and KDNA Life Sciences will not be liable for any damages, whether direct or indirect, special, incidental or consequential resulting from improper use of this allograft. The instructions for use are specific, and BioMed ENT & KDNA waives all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the allograft tissue included with this insert.

ALLOGRAFT TISSUE UTILIZATION RECORD (TUR)

The Joint Commission and the US FDA requires tissue tracing systems in all facilities using allograft tissue for transplantation. It is the responsibility of the tissue dispensing service, distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. In order to comply with these requirements, please complete this form.

File a copy in the patient's chart and return the TUR to BioMed ENT. If any tissue is discarded, please notate reason in the comments section.

Affix Label Here

Faculty:
Address:
Surgery Date/Time:
Physician:
Procedure:
Patient ID:
Comment:

Entered By:

MUST BE RETURNED

FILL OUT AND RETURN TO ONE OF THE FOLLOWING

BioMed ENT | 757 N Water Street, Suite 300 | Milwaukee, WI | 53202
FAX: (210) 855-3872
EMAIL: info@biomed-ent.com