HUMAN CRYOPRESERVED
OSTEOARTICULAR ALLOGRAFT

DONATED HUMAN TISSUE

REstricted TO USE BY OR ON THE ORDER OF A
LICENSED HEALTHCARE PROFESSIONAL (physician,
dentist, podiatrist, optometrist, nurse practitioner or physician
assistant).

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The Cryopreserved Osteoarticular Allograft is aseptically recovered with consent from qualified donors. The allograft is processed using aseptic techniques and exposed to an antibiotic solution (containing Gentamicin and either Vancomycin or Bacitracin). The allograft is aseptically packaged in a tear pouch within a peel pouch configuration, secured in an outer container and frozen. The inner pouch contains traces of a 15% glycerol solution, which acts as a cryoprotectant during initial freezing.

INTENDED USE
The Cryopreserved Osteoarticular Allograft is intended for reconstruction of the musculoskeletal system.

CONTRAINDICATIONS
The Cryopreserved Osteoarticular Allograft is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, or glycerol.

DONOR ELIGIBILITY
The Cryopreserved Osteoarticular Allograft is recovered from a qualified donor and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The donor has been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the screening and testing have been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donor has been deemed suitable for transplantation.

Communicable disease testing is performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests are found to be nonreactive or negative:

**Human Immunodeficiency Virus (HIV)**
- HIV-1/2 Antibodies (HIV-1/2-Ab)
- Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

**Hepatitis B Virus (HBV)**
- HBV Surface Antigen (HBsAg)
- HBV Core Antibody (IgG & IgM) (HBcAb)
- Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)

**Hepatitis C Virus (HCV)**
- HCV Antibody (HCVAb)
- Nucleic Acid Test for HCV RNA (HCV NAT)

**Human T Cell Lymphotrophic Virus I/II* (if performed)**
- HTLV-I/II (Antibody HTLV-I/II-Ab)

**Syphilis**
- Rapid Plasma Reagin (RPR) Screen
- T. Pallidum IgG T. pallidum IgG

*A donor with a reactive result for the HTLV-I/II Antibody test is cleared for transplantation use only when the result from a confirmatory assay is nonreactive.

**A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

**Cytomegalovirus**
- CMV Ab (IgG & IgM)

**Epstein Barr Virus**
- EBV Ab (IgG & IgM)

**Toxoplasma gondii**
- Toxoplasma Ab (IgG & IgM)

**Trypanosoma cruzi**
- T. cruzi Ab (IgG & IgM)

**WARNINGS**
The donor of the Cryopreserved Osteoarticular Allograft has been screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). The Cryopreserved Osteoarticular Allograft is processed using aseptic techniques and microbiologically tested. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

**DO NOT RE-FREEZE** the allograft by any method.

**FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY**

**DO NOT STERILIZE** the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

**PRECAUTIONS**
The Cryopreserved Osteoarticular Allograft is processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.
ADVERSE EVENTS
Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE
The Cryopreserved Osteoarticular Allograft must be transferred to a monitored freezer which maintains the temperature at -20°C or colder for short term storage (less than 6 months) or -40°C or colder for long term storage (until expiration date on graft). It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION
ONCE THE TEAR POUCH SEAL HAS BEEN OPENED, the allograft must be used within 24 hours, or otherwise discarded.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

THE OUTERMOST POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

The Cryopreserved Allograft must be thawed prior to use. Thawing time is approximately one (1) hour and is accomplished by complete immersion of the allograft in sterile normal saline or sterile isotonic solution of choice.

Do not manipulate the allograft until it is completely thawed and pliable. Premature manipulation of the allograft may result in its fracture.

Step 1: Remove the pouch containing the allograft from the outer container.
Step 2: Inspect the pouch packaging.
Step 3: Locate a black or blue/green surgical suture. The black surgical suture indicates Right side and the blue/green surgical suture indicates Left side
Step 4: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the operative field.
Step 5: Locate the tear notch on the pouch, tear open, and place the allograft into the thawing container.
Step 6: Aseptically pour sterile solution into the thawing container until the allograft is completely immersed. Antibiotics of the End-User’s preference may be added to the solution if desired. THE ALLOGRAFT MUST BE RINSED IN SOLUTION TO ALLOW REMOVAL OF THE GLYCEROL PRIOR TO USE.

Step 7: Once completely thawed and pliable, the allograft is ready for use.

If the allograft is labeled with a sidedness orientation, the allograft should also have a corresponding surgical suture indicating the sidedness. The black surgical suture indicates the allograft was recovered from the right anatomical side and the blue/green surgical suture indicates the allograft was recovered from the left anatomical side.

In the event that the allograft is not implanted within 2 hours of reconstitution, place the allograft into a sterile basin containing the solution of choice and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape and double wrap the sealed basin with sterile waterproof wrappers. Store in the refrigerator at 1 to 10°C for no longer than 24 hours.

RECIPIENT INFORMATION
Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-User or the Clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to UMTB Biomedical, Inc., scan and e-mail to turs@umtb.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING
Adverse outcomes potentially attributable to the Cryopreserved Osteoarticular Allograft or other complaints should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783.

RETURNED GOODS POLICY
Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from UMTB Biomedical, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.