

PACKAGE INSERT PREPARATION INSTRUCTIONS



**THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.
IT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY.**

This package contains an HCT/P (Human Cells, Tissues, and Cellular and Tissue Based Products) / CTO (Human Cell, Tissue, Organ) as defined by US Food and Drug Administration (FDA) 21 CFR Part 1271 and the Health Canada Cells, Tissues and Organs for Transplantation Regulations. All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US FDA regulations, and the Health Canada CTO Regulations and associated Standards (when applicable).

DESCRIPTION / USE:

Human musculoskeletal allograft (bone, tendon, cartilage) may be used in a variety of orthopedic, neurosurgical, or reconstructive procedures. Tissue is processed and preserved by a variety of techniques and is supplied in a range of sizes for surgical use by licensed clinicians (i.e., physicians, physician's assistants, nurse practitioners). All tissue is processed and packed using aseptic technique. Tissue may be fresh, fresh frozen, freeze dried, frozen, or cryopreserved. Some tissue may be terminally sterilized by a validated electron beam or gamma irradiation process. Fresh grafts are stored in a nutrient medium.

CONTRAINDICATIONS:

The presence of infection at the transplantation site is a contraindication for use of musculoskeletal allografts.

WARNINGS:

- **Human tissue has the potential to transmit infectious agents.** Donor screening, processing treatments, and laboratory testing follow stringent specifications to reduce the risk of infectious agent transmission.
- **Do not use** if the expiration date has been exceeded or if there is evidence of defects in package or label integrity.
- Do not sterilize or re-sterilize.
- It is the responsibility of the hospital or clinician to maintain tissue for transplantation according to recommended storage conditions. **Do not use** if tissue has not been stored according to the recommended STORAGE instructions.

ATTENTION:

- Due to the presence of blood and marrow components, fresh grafts and aseptic tissues, including osteochondral cryopreserved fresh frozen grafts, should not be considered sterile.
- Patients receiving any of the above grafts in a surgical procedure should be appropriately informed of the risk associated with these grafts.
- A prophylactic regimen of antibiotics, as used in arthroplasty, is highly recommended for fresh graft procedures.

PRECAUTIONS:

- Restricted to use by a licensed clinician.
- Trace amounts of Bacitracin, Amphotericin B, Ciprofloxacin HCl, Gentamicin Sulfate, Polymyxin B Sulfate, or Vancomycin HCl may be present and caution should be exercised if the recipient is allergic to these antibiotics.

DONOR ELIGIBILITY:

Donor eligibility (screening and testing) is performed in accordance with AATB Standards and FDA regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility has been determined by an AlloSource® Medical Director.

SEROLOGICAL TESTING:

Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at AlloSource at the address listed at the bottom of this document. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Antibody to Hepatitis C (HCV)
- Hepatitis C Virus (HCV NAT)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Virus (HBV NAT) (as required)
- Rapid Plasma Reagin or Serologic Test For Syphilis (RPR or STS)

Additional tests, including but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) may have been performed at the time of donor screening, and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed may be provided upon request.

MICROBIAL TESTING:

Tissue is subjected to microbiological testing at recovery and in the course of processing, and must be free of specific aerobic / anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.

MEDICAL DIRECTOR ASSESSMENT:

Donor eligibility determination is made by the AlloSource Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request to AlloSource at the address at the bottom of this document.

POTENTIAL COMPLICATIONS / ADVERSE REACTIONS:

Inherent uncertainty exists in medical and social histories and laboratory testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Loss of function or integrity of transplanted tissue with resorption, fragmentation, disintegration, and associated loss of continuity, displacement, bending, or fracture.
- Immune response to transplanted tissue.
- Transmission of known pathogens including Hepatitis B or C, Human T-cell Leukemia / Lymphotropic Virus, Human Immunodeficiency Virus 1 & 2, syphilis or bacteria.

- Transmission or causation of diseases of unknown etiology and characteristics.

HANDLING AND PREPARATION:

CAUTION: All preparation should be performed using aseptic technique. Once the packaging has been opened, the tissue must either be transplanted or discarded. **Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise discarded.**

Tissue in Peel Pouch Packaging: Graft may be in 2 or 3 pouches. The inner pouch(es) has/have been sterilized. Using aseptic technique, peel outer pouch and introduce innermost pouch onto sterile field. Thaw frozen grafts in accordance with the instructions below. With sterile scissors, open inner pouch.

	GRAFT TYPE	GRAFT STORAGE	GRAFT PREPARATION
FREEZE DRIED	Cancellous products Fascia lata	Store freeze dried grafts at room temperature in a clean, dry location.	To reconstitute, place graft in sterile basin and cover with sterile isotonic solution for 15 to 30 minutes, depending upon the size of the graft.
	Tricortical wedges Machined grafts Cortical products		To reconstitute, place graft in sterile basin and cover with sterile isotonic solution for approximately 30 minutes.
INADEQUATE RECONSTITUTION MAY RESULT IN GRAFT BREAKAGE OR FRACTURE.			
FROZEN or CRYOPRESERVED	Tendons Intercalary grafts	Musculoskeletal tissue may be stored at -20°C to -40°C if used within 6 months, otherwise store at or below -40°C.	To thaw, place the innermost pouch in a sterile basin on a sterile field. Immerse inner pouch completely in warm, sterile isotonic solution. The recommended thawing time is 30 to 60 minutes, depending upon the size of the graft. If removal of blood and marrow elements is desired, rinse the graft completely using high-pressure lavage with an isotonic solution.
	Osteochondral Cryopreserved Fresh frozen grafts		To thaw, place the innermost pouch in a sterile basin on a sterile field. Immerse inner pouch completely in warm, sterile isotonic solution. The recommended thawing time is 30 to 60 minutes, depending upon the size of the graft. Osteochondral cryopreserved fresh frozen grafts are preserved with a 10% (v/v) solution of DMSO in a nutrient medium. Grafts should be rinsed with sterile isotonic solution prior to transplant.
DO NOT HANDLE OR MANIPULATE SOFT TISSUE GRAFTS UNTIL THAWING IS COMPLETE.			
FRESH/ Graft Utility	Osteochondral allografts (OCA)	The recommended storage temperature for fresh grafts is 1° to 10°C. DO NOT expose graft to freezing temperatures or heat.	Fresh grafts are stored in a nutrient medium. Using high-pressure lavage with an isotonic solution, rinse graft completely to remove storage media, blood and marrow elements. Manipulate / shape the graft on the sterile field. Keep graft moist with a cold or room temperature sterile isotonic solution until time of transplant. DO NOT USE WARM SOLUTION.

RECORD KEEPING:

Regulatory bodies such as the US FDA and Health Canada require that allograft tissue be traceable from the donor to the recipient. The tissue bank (source establishment) is responsible for traceability from the donor to the consignee (transplantation facility, clinician or hospital), and the transplantation facility is responsible for the traceability to the recipient. A Transplantation Record & Feedback Form and pre-printed peel-off labels are included with each package of tissue. The lot number provided on the labels contains the donor identification number and graft serial number. Record patient identifier, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the Transplantation Record & Feedback Form. Return the completed form to AlloSource and retain a copy in the patient medical record. If the tissue has been discarded, please return the Transplantation Record & Feedback Form to AlloSource with the graft identification information and reason for discard.

<p>PROCESSED BY:</p> <p>AlloSource 6278 South Troy Circle Centennial, CO 80111 800-557-3587 (Toll free)</p> <p>A Non-Profit Organization</p> <p>Accredited Member of the American Association of Tissue Banks</p> <p>Health Canada CTO Registration Number 100134</p>	<p>DISTRIBUTED BY</p>  <p>JRF ORTHO</p> <p>6746 S Revere Pkwy, Ste B-125 Centennial, Colorado 80112</p> <p>A Non-Profit Organization</p> <p>CONTACT INFORMATION Please contact JRF Ortho at 877.255.6727 to promptly report any unanticipated or adverse events, or should you require further information.</p>	<p>For end users in Canada Affix chart label here for Donor Identification Code and Expiration Date per CTO regulations 31.3 and 31.20</p>
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