PACKAGE INSERT

PREPARATION INSTRUCTIONS

JRFORTHO

All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the Association for Advancing Tissue and Biologics (AATB) and Food and Drug Administration (FDA) regulations

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

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. 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 Polymyxin B, Bacitracin, Gentamicin Sulfate, Amphotericin B, Penicillin G Sodium, or Streptomycin Sulfate 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, hospital records, infectious disease screening, autopsy report (if performed), and physical exam of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility has been determined by a Solvita Medical Director at 349 S Main Street, Dayton, Ohio 45402.

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, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). 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 Solvita. The following required testing was performed and found to be negative or nonreactive:

- 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)
- 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 Solvita Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request to Solvita.

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.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Solvita.

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 >0 to 37°C 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 >0˚ 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.**

TISSUE TRACKING:
An Allograft Tracking Form and preprinted peel-off labels are included with each package of tissue. Complete the Allograft Tracking Form and return to Solvita. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient record must be maintained for the purpose of tracing tissue post-transplantation. If the tissue has been discarded, please return the Allograft Tracking Form to Solvita with the graft identification information and reason for discard (to be confirmed with JRF).

Solvita is accredited by the Association for Advancing Tissue and Biologics. Solvita is ISO 13485 certified. Health Canada Registration: 100076.

Processed to JRF Ortho specifications by:
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