PACKAGE INSERT

PREPARATION INSTRUCTIONS

All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (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 skin allograft may be used for temporary coverage of epithelial surface defects due to third degree burn or other causes.
Human musculoskeletal allograft (bone, tendon, cartilage) may be used in a variety of orthopedic, neurosurgical, reconstructive or periodontal 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, dentists, physician's assistants, nurse practitioners). All tissue is processed and packed using aseptic technique. Tissue may be fresh, fresh frozen, freeze dried, frozen, cryopreserved or may be packaged in saline. 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. The presence of gross infection at the transplantation site is a contraindication for use of skin 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 AlloPac®, CanPac, osteochondral cryopreserved fresh frozen grafts, intercalary grafts, and skin 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 sulfate, Bacitracin or Gentamicin 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)
- 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 will 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.

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.
Tissue in Peel Pouch Packaging: Graft may be in 2 or 3 pouches. The inner pouch(es) has 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.
Tissue in vacuum bottle: DO NOT USE IF VACUUM IS NOT PRESENT. Carefully remove the rubber top without touching the sterile inside of the bottle. Wipe bottle rim with a sterile alcohol swab. Transfer tissue onto sterile field.

GRAFT PREPARATION INSTRUCTIONS ARE INTENDED AS GUIDELINES AS PART OF ESTABLISHED SURGICAL TECHNIQUES. THEY ARE NOT INTENDED TO REPLACE OR CHANGE STANDARD PROCEDURES OR INSTITUTIONAL PROTOCOLS.

	GRAFT TYPE	GRAFT STORAGE	RECOMMENDED GRAFT PREPARATION *
FREEZE DRIED	Ground bone Crushed bone Cancellous products Fascia lata	Store freeze dried grafts at ambient temperature in a clean, dry location.	To reconstitute, place graft in sterile basin and cover with sterile isotonic solution for a maximum of 30 minutes, depending upon the size of the graft.
	Machined grafts (single & multi-piece)		To reconstitute, place graft in a sterile basin and cover with sterile isotonic solution. The recommended soak time is 1 minute, with a minimum of 30 seconds.
	Tricortical wedges Segments Struts 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. DO NOT USE IF BROKEN OR DAMAGED.		
FROZEN or CRYOPRESERVED	Cancellous products Tricortical wedges Segments Struts Cortical products Fascia lata	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 30-60 minutes, depending upon the size of the graft.
	Tendons AlloPac® CanPac Intercalary 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 30-60 minutes, depending upon the size of the graft. If removal of blood and morrow elements is desired, rinse 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 isotonic solution. The recommended thawing time is 30-60 minutes, depending upon the size of the tissue. 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.
	Cryopreserved skin	Store cryopreserved skin grafts at or below -40˚C	To thaw, place the skin or inner pouch in a sterile basin on a sterile field. Immerse the skin or inner pouch completely in warm sterile isotonic solution for a maximum of 5 minutes. Cryopreserved skin is preserved with 15% Glycerin in LR + Gentamicin/RPMI 1640. Grafts should be rinsed with sterile isotonic solution prior to transplant.
	DO NOT HANDLE OR MANIPULATE SOFT TISSUE GRAFTS UNTIL THAWING IS COMPLETE.		
SALINE	Costal cartilage	Store at room temperature in a clean, dry location.	No preparation is necessary.
FRESH/ Graft Utility	Joint Restoration grafts or Graft Utility Skin	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. Graft Utility Skin is stored in RPMI 1640 w/Glutamine + Gentamicin and should be rinsed in isotonic solution. **DO NOT USE WARM SOLUTION.**

*** Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise DISCARDED.**

RECORD KEEPING:
The FDA requires that allograft tissue be traceable from the donor to the recipient. The tissue bank is responsible for traceability from the donor to the consignee (transplantation facility), and the transplantation facility is responsible for traceability to the recipient. A *Transplantation Record & Feedback Form* and preprinted peel-off labels are included with each package of tissue. Record the patient name or ID number, 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.

CONTACT INFORMATION

Please contact AlloSource at 720.873.0208 or 800.557.3587 to promptly report any unanticipated or adverse events, or should you require further information.

AlloSource®

Health Canada CTO Registration Certificate Number 100134

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Non-Profit Organization
Accredited Member of the American Association of Tissue Banks