PACKAGE INSERT
CORELINK GRAFT 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 musculoskeletal allograft may be used in a variety of orthopedic procedures. Tissue is supplied in a range of sizes for surgical use by licensed clinicians. All tissue is processed, packed, and freeze dried using aseptic technique, and is terminally sterilized by a validated electron beam or gamma irradiation process.

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 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.

PRECAUTIONS:
- Restricted to use by a licensed clinician.
- Trace amounts of Polymyxin B sulfate or Bacitracin may be present and caution should be exercised if the recipient is allergic to these antibiotics.

CAUTION:
- Under federal law, this device may only be sold by or on the order of physician

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.

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.

STORAGE:
Store freeze-dried grafts at ambient temperature in a clean, dry location.

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.

PREPARATION:

1. Using aseptic technique, peel open outer pouch.
2. Introduce inner-most pouch into sterile field.
3. To reconstitute, place implant in sterile basin and reconstitute with sterile isotonic solution per specific recommendations in the below table

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	RECOMMENDED GRAFT PREPARATION
CoreLink Cervical Spacer Machined Graft **CoreLink Posterior SI Allograft**	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.

INADEQUATE RECONSTITUTION MAY RESULT IN GRAFT BREAKAGE OR FRACTURE. DO NOT USE IF BROKEN OR DAMAGED.

Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise must be DISCARDED. Discard any unused implant in accordance with standard practice for disposal of human tissue.

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 pre-printed peel-off labels are included with each package of tissue. 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.

CONTACT INFORMATION

Please contact CoreLink
Toll free at 1-888-349-7808
to promptly report any unanticipated
or adverse events, or should you
require further information.

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