Allotech, LLC

enCore Allograft Package Insert

DESCRIPTION / USE:

Human allograft bone may be used in a variety of dental reconstructive, regenerative, 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. The tissue is donated human tissue. All tissue is processed and packaged using aseptic technique, freeze dried, and terminally sterilized.

CONTRAINDICATIONS:

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

WARNING:

- **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 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, 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 a licensed Medical Director.

SEROLOGICAL TESTING:

The following required testing was performed and found to be negative or non-reactive. Additional tests 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. 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. Serological testing is performed by a CLIA certified laboratory using tests approved by the FDA where applicable:

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

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) and/or nucleic acid test (NAT) for the hepatitis B virus (HBV) may have been performed at the time of donor screening, and were found to be acceptable for transplantation.

MICROBIAL TESTING AND TERMINAL STERILIZATION:

Prior to packaging, 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. Following packaging, tissue is terminally sterilized by e-beam irradiation to a minimum sterility assurance level (SAL) of 10^{-6}.

MEDICAL DIRECTOR ASSESSMENT:

The Medical Director or designee for the Recovery Agency, as well as the Medical Director for the tissue bank responsible for determining donor eligibility, 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.

DIRECTIONS FOR HANDLING AND PREPARATION:

CAUTION: All preparation should be performed using aseptic technique. *Carefully open the outer tray of the single blister and aseptically remove the sterile inner container holding the ground bone matrix. The sterile ground bone matrix can then be removed from the sterile inner container for usage during the surgical procedure.* Once the packaging has been opened, the tissue must either be transplanted or discarded. The tissue is intended for use in one patient, on a single occasion only.

Graft Type	Graft Storage	Graft Preparation
Ground Bone	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 15-30 minutes, depending on the size of the graft

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's initials and/or patient ID or medical record number, the transplantation facility name and address, the allograft tissue lot number (using the peel-off stickers) and comments regarding the use of the tissue on the *Transplantation Record & Feedback Form*. Return the completed form to Allotech and retain a copy in the patient medical record. If the tissue has been discarded, please return the *Transplantation Record & Feedback Form* to Allotech with the graft identification information and reason for discard.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Expiration Date		Single use only
	Lot Number		Catalog Number
	Method of Sterilization Using Irradiation		
	Attention, see instructions for use		

Red indicator label indicates exposure to irradiation

All tissue has been collected, processed, stored, and distributed according to the Standards for Tissue Banks (AATB) and Food and Drug Administration (FDA) Regulations.

Responsible Tissue Banks:

Source Establishment, Determines Donor Suitability & Processing:
AlloSource, 6278 S. Troy Circle, Centennial, CO 80111
(Ph) 720.873.0213
Health Canada CTO Registration Certificate Number: 100134

Source Establishment & Processing:
Allotech, LLC, 4620 71st Street, Bldg 78-79, Lubbock, TX 79424
Health Canada CTO Registration Certificate number: 100211

Distribution:
Osteogenics Biomedical, Inc., 4620 71st Street, Bldg 78-79, Lubbock, TX 79424

CONTACT INFORMATION: Please contact Allotech at 888.796.1923 or 806.796.1923 to promptly report any unanticipated or adverse events, or should you require further information.

Retain this information for your records. TB IFU-001 Rev2017-03