TISSUE PACKAGE INSERT

DESCRIPTION

DONATED HUMAN TISSUE. Tissue grafts are recovered from deceased human donors. All tissue is recovered, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB). Donor has been determined eligible by a Community Tissue Services (CTS) Medical Director at 349 S. Main St., Dayton, OH 45402 based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy (if performed) and physical exam. Donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, anti-HTLV I/II, HIV NAT, HCV NAT and syphilis. U.S. Food and Drug Administration (FDA) licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory registered with the FDA and certified under CLIA or equivalent requirements.

Demineralized tissue has been processed with HCL, alcohol, sodium phosphate (monobasic and dibasic) and traces may remain. Tissue has been processed using a proprietary method that has been validated to a Sterility Assurance Level (SAL) of 10^{-6}. Bacitracin and/or Polymyxin B traces may remain. Irradiated tissue is Gamma Irradiated with Cobalt 60.

WARNINGS AND PRECAUTIONS

1. Intended for use in one patient, on a single occasion only.
2. Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
3. Tissue may not be sterilized or re-sterilized.
4. This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
5. Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
6. Adverse outcomes potentially attributable to this tissue must be reported promptly to X-spine Systems, Inc.

STORAGE

FREEZE-DRIED TISSUE. Must be stored at ambient temperature or colder, not to exceed 48°C (120°F).

Tissue may not be stored at liquid nitrogen (LN2) vapor phase or LN2 liquid temperatures. It is the responsibility of the Tissue Dispensing Service and/or the end-user to maintain this tissue in appropriate storage conditions prior to transplant.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and fax to (937) 222-2538. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01,EP7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables the manufacturer to maintain records for the purpose of tracing the tissue post-transplant.

TISSUE PREPARATION

FREEZE-DRIED TISSUE

1. Inspect for package integrity and expiration date prior to opening.
2. Tissue in vacuum sealed jars: peel off metal cap and wipe rubber stopper with alcohol or betadine. Using a syringe, inject sufficient saline or air to release vacuum. If vacuum is present, plunger will be drawn down. DO NOT USE IF VACUUM IS NOT PRESENT. Remove rubber stopper with aid of sterile forceps.
3. Tissue in peel packages: peel outer package down and aseptically deliver inner package to the sterile field or sterile team member.
4. IMPORTANT! Crushed bone and soft tissue should be reconstituted for 30 to 45 minutes. Final determination of allograft reconstitution should be made by the physician prior to use.
5. Tissue should be used as soon as possible after reconstitution. If tissue is to be stored for longer than 2 hours after reconstitution, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.

X-spine Systems, Inc. and CTS make no claims concerning the biological or biomechanical properties of the provided tissue. X-Spine Systems, Inc. and CTS disclaim all liability and responsibility for any misuse of tissue provided for clinical application.

CONTACT

Please contact X-spine Systems, Inc. at (800) 903-0640 should you require further information, or visit www.x-spine.com.