Influx™

TRABECULAR BONE GRAFT

isto BIOLOGICS

Available through Isto Biologics
Processed by CellRight Technologies, LLC

ALLOGRAFT PACKAGE INSERT

DONATED HUMAN TISSUE

THIS ALLOGRAFT IS SUPPLIED STERILE

This human tissue allograft is processed and supplied by CellRight Technologies. All tissue was retrieved, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/Ps 21 CFR Part 1271), and applicable State regulations. The Donor has been determined to be eligible based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease screening, autopsy report (if performed), and physical exam. The Donor has been tested and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1 and Hepatitis C Virus Nucleic Acid Test (HIV 1/HCV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Additional tests, including but not limited to HTLV I/II and HBV Nucleic Acid Testing, may have been performed and were found to be acceptable for transplantation. U.S. Food and Drug Administration (FDA) licensed test kits are used when available. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing 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). A list of additional communicable disease test(s) performed will be provided upon request.

CellRight Technologies Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by CellRight Technologies. The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at CellRight Technologies and are available upon request.

Tissue has been sterilized, using Cobalt 60, to a SAL of 10^{-6} (Sterility Assurance Level). Allografts are processed using some or all of the following agents: physiological buffers, acids, alcohols, surfactants, Gentamicin Sulfate, and/or Vancomycin HCl, and traces may remain.

WARNINGS AND PRECAUTIONS

- Intended for use in one patient, on a single occasion only.
- Do not use if package integrity has been compromised. Once the user breaks the seal on the inner-most pouch, the tissue grafts must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized by your facility.
- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrist.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to CellRight Technologies.
- It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further Distribution or transplant.

STORAGE

Maintain tissue at room temperature (15°C - 30°C).

TISSUE PREPARATION

BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:

1. Any of the package elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed

If any of the above conditions exist or are suspected, this allograft should NOT be used.

PREPARATION OF Influx™ Trabecular Bone Graft

1. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
2. Remove tissue from Inner peel pouch.
3. Tissue may be maintained within the inner pouch or in a jar.
4. Rehydrate the tissue.
    - Jar- Unscrew the top. Rehydrate tissue in jar or transfer to a basin for rehydration.
    - Tissue may be rehydrated in a basin.

IMPORTANT!

5. Final determination of allograft reconstitution should be made by the physician prior to use.
6. 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°C to 10°C in an aseptic container for no longer than 6 hours.

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RETURNS

With prior approval, unused, unopened tissue may be returned provided ISTO Technologies Customer Service has authorized the return and issued a return authorization number. The responsible individual at your facility must obtain a Return Authorization Form from ISTO Technologies, complete the required information and provide a signature declaring the unopened tissue has been continuously stored according to instructions and that proper transportation has been utilized to ensure tissue integrity during the return.

Contact Customer Service at ISTO Technologies by email or phone.

Email: customerservice@istotech.com

Phone: 888.705.ISTO (4786)

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and mail to CellRight Technologies. 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 to provide this Information, which enables CellRight Technologies to maintain records for the purpose of tracing the tissue post-transplant.

ISTO RM336-D001

Available Through:

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