ACTIGEN™
Verified Inductive Bone Matrix

PACKAGE INSERT

DONATED HUMAN TISSUE

ACTIGEN ALLOGRAFT IS SUPPLIED STERILE

ACTIGEN 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, Hepatitis C Virus, Hepatitis B Virus Nucleic Acid Test (HIV 1/HCV/*HBV* NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- *West Nile Virus Nucleic Acid Test (WNV NAT)

*Birth Tissue Only

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. U.S. Food and Drug Administration (FDA) licensed, approved, or cleared donor screening 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.

ACTIGEN has been sterilized utilizing a validated process to achieve an SAL of 10^{-6} (Sterility Assurance Level). Allografts are processed using some or all of the following agents: physiological buffers, acids, alcohols, surfactants, hydrogen peroxide, Gentamicin Sulfate, Vancomycin HCl, Amphotericin B, Polymyxin B, and/or Ciprofloxacin and traces may remain.

Tissues are supplied freeze dried, air dried, hydrated, or frozen. CellRight provides storage requirements in the package insert and on the final label that accompanies each graft. Additionally, osseous grafts may undergo demineralization. Grafts that have been demineralized will have a residual calcium level ≤8%. When applicable, a description of how the tissue is supplied (Freeze Dried, Air Dried, Hydrated or Frozen; Demineralized or Mineralized) is contained in the upper right-hand corner of the final label included with the graft.

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.
- ACTIGEN tissue may not be sterilized or re-sterilized by your facility.
- ACTIGEN 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.
- 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. Records must be maintained for the purpose of tracing tissue post-transplantation.

STORAGE

FREEZE-DRIED/AIR DRIED TISSUE/HYDRATED – Maintain tissue at ambient temperature (15-30C).

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 FREEZE DRIED VERIFIED INDUCTIVE MATRIX (VIM) FOR USE:

1. PRODUCT TYPE
    a. Freeze Dried VIM – Requires hydration prior to use. A label located on the container of product indicates the amount of solution to add.
2. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
3. The product is contained inside the inner pouch in a jar.
4. Remove container of product from the Inner peel pouch.
    a. Jar – Unscrew the top. (Freeze Dried VIM - add solution and mix) Remove the product from the jar. Mold into desired shape and press into defect.
    b. Product should be used as soon as possible to minimize drying of grafting material.
5. Irrigation resistant once molded and pressed into the defect.
6. For best results. The VIM must fill the defect and contact as much viable bone as possible.
7. Open, unused product may not be frozen and/or irradiated again once packaged has been opened.

RETURNS

With prior approval, unused, unopened tissue may be returned to CellRight provided CellRight personnel have authorized the return and issued a return authorization number. The responsible individual at your facility must obtain a Tissue Return Authorization Form from CellRight 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. This form must be completed for credit to be issued.

Contact Customer Service at CellRight Technologies by email or phone.

Email: CustomerCare@CellRightTechnologies.com

Phone: 1-210-659-9353

ADVERSE OUTCOMES

Adverse outcomes potentially attributable to this tissue must be reported promptly to CellRight Technologies.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and mail to CellRight Technologies. US 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.

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CellRight Technologies holds:
AATB Accreditation No. 00212
US FDA Registration No. 3009234552
Canadian Registration No. 100228
California Tissue Bank ID No. CNC80949
Florida License No. 212
Maryland Tissue Bank No. TB1898
New York State Tissue Bank ID No. 1779

CellRight Technologies is a Registered Tissue Bank in the following state(s):
Oregon
Delaware