

# 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 suitable 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

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.

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, hydrogen peroxide, Gentamicin Sulfate, Vancomycin HCl, Amphotericin B, Polymyxin B, and/or Ciprofloxacin and traces may remain.

Tissues may be supplied freeze 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  $\leq 8\%$ . When applicable, a description of how the tissue is supplied (Freeze Dried 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.
- 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.
- 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

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

**FREEZE-DRIED TISSUE** - Maintain tissue at ambient temperature.

**FROZEN TISSUE** – Maintain tissue at -40°C or colder. Short term storage of up to 6 months is acceptable if tissue is maintained at -20°C to -39°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
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

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

## PREPARATION OF HYDRATED DEMINERALIZED BONE MATRIX (DBM) AND FREEZE DRIED INDUCTIVE CARRIER MATRIX (ICM) FOR USE:

1. PRODUCT TYPE
  - a. Hydrated DBM is Ready to use – does not require thawing or rehydration.
  - b. Freeze Dried ICM – 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, syringe, or other storage container.
4. Remove container of product from the Inner peel pouch.
  - a. Jar – Unscrew the top. (Freeze Dried ICM - add solution and mix) Remove the product from the jar. Mold into desired shape and press into defect.
  - b. Syringe – Remove protective cap from syringe tip or remove the syringe end cap completely. Apply pressure to the plunger to extrude the DBM. Mold into desired shape and press into defect.
5. Irrigation resistant once molded and pressed into the defect.
6. For best results. The DBM must fill the defect and contact as much viable bone as possible.

**PREPARATION OF FREEZE-DRIED ALLOGRAFT TISSUE FOR USE**

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 in a jar, syringe, or other storage container.
  - a. Jar – Unscrew the top. Rehydrate tissue in jar or transfer tissue to a basin for rehydration.
  - b. Syringe – Rehydrate tissue in syringe or transfer to a basin for rehydration.
4. Rehydrate the tissue, when applicable.
  - a. Final determination of allograft reconstitution should be made by the physician prior to use. Rehydrate using a sterile isotonic solution or solution of physicians' choice.
  - b. Recommendation - Non-weight bearing osseous grafts and soft tissue should be reconstituted for a minimum of 30 minutes.
  - c. Recommendation - Weight bearing grafts should be reconstituted approximately 1 hour.
  - d. Recommendation – Grafts that are to be manipulated by drilling or cutting or require force to insert may require a longer period of reconstitution prior to manipulation to reduce the chance of fracturing.
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°C to 10°C in an aseptic container for no longer than 6 hours.
6. **IMPORTANT!** Peel away and remove all internal packaging materials, if present, from the graft (i.e. gauze or mesh) prior to implantation.

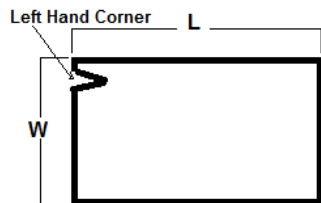
**PREPARATION OF FROZEN ALLOGRAFT TISSUE FOR USE**

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. Remove tissue from inner package and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
4. Tissue should remain in solution until thawed. Tissue thawing temperature should not exceed ambient or room temperature. **DO NOT MICROWAVE.**
5. Tissue should be used as soon as possible after thawing. If tissue is to be stored for longer than 2 hours after thawing, it should be refrigerated at 1°C to 10°C in an aseptic container for no longer than 6 hours.
6. Do not refreeze product if thawed.
7. **IMPORTANT!** Peel away and remove all internal packaging materials, if present, from the graft (i.e. gauze or mesh) prior to implantation.

**FROZEN DERMIS ORIENTATION**

Frozen Dermis has two distinct sides, the side that would have been oriented nearest the basement membrane of the epithelium, referred to in this document as the "Basement Membrane" side and the side oriented toward the donor's adipose, referred to as the "Dermal" side.

To determine the orientation of Frozen Dermis, position the graft so the indication notch is in the upper left-hand side of the tissue, facing left. This will assure that the basement membrane side is facing up.



Every effort is made to ensure all hair has been effectively removed from the allograft. If any hair is present, remove them before implantation. If they cannot be easily removed, please contact CellRight Technologies.

**RETURNS**

ChoiceSpine is committed to honoring the altruism of tissue donation. In accordance with this commitment, ChoiceSpine may accept returned allografts based on stringent criteria. Please contact ChoiceSpine Customer Service for tissue return criteria and a required return authorization number.

ChoiceSpine Customer Service  
865-243-3383  
customerservice@choicespine.com

**ADVERSE OUTCOMES**

Adverse outcomes potentially attributable to this tissue must be reported promptly to ChoiceSpine's Quality/Regulatory Department, phone: 865-246-3333, fax: 865-588-4045.

**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.

**Distributed By:**



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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. CPI73TP141TS145