PentOS OI™
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 ≤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 ambiant temperature.

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. Remove DBM 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.

Symbols may be used on some international package labeling for easy identification.

	Consult instructions for Use
	Sterilized Using Irradiation
	Do not use if the product sterilization barrier or its packaging is compromised
	Do not re-sterilize
	Do Not Reuse
	Temperature Limitation
	Manufacturer
℞ ONLY	Symbol for «Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist»

BONE GRAFTING

PENTOS OI™

Family of Osteoinductive Products

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The Regen Company

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ALLOGRAFT TRACKING FORM

FDA Regulations and joint Commission Standards require tissue tracking systems in all hospitals, clinics and doctor's offices using allografts for transplantation. In order to comply with these requirements, please complete ALL fields on this form and return to CellRight Technologies via fax or email.

Fax: 210-659-9556 E-mail: quality@cellrighttechnologies.com

Patient's Last Name: _____ First: _____ MI: _____

Age: _____ Sex: _____ Patient ID: _____

Hospital/Clinic/Doctor's Office: _____

City: _____ State/Prov.: _____ Zip/Postal Code _____

Physician: _____ Surgery Date: _____

Surgical Procedure: _____

Completed by: _____ Date: _____

Comments: _____

_____

Place peel-off label for up to 4 allografts or write tissue ID# in the spaces provided.
One patient, one procedure per tracking form.
Retain this completed document with the patient's file.

Allograft Tissue ID#

_____

OR Place Peel-Off Label Here