OSSIX® GRAFT

PARTICULATE ALLOGRAFT

ALLOGRAFT PACKAGE INSERT

DESCRIPTION

OSSIX™ Graft Particulate Allograft is comprised of cortical and/or cancellous bone matrix and may be used in a variety of orthopaedic, neurosurgical, reconstructive, periodontal, and oral maxillofacial procedures.

OSSIX™ Graft is supplied in a range of sizes and formats (Demineralized and Mineralized Cortical, Cancellous and Mix Cortical Cancellous Bone) supplied as Granules format.

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, 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 irradiation to ensure 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 are supplied freeze dried, or hydrated CellRight Technologies® 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 (DBM) will have a residual calcium level ≤8%. When applicable, a description of how the tissue is supplied (Freeze Dried or Hydrated DBM) 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 podiatrists.

Although this tissue has been tested and screened for human pathogens, processed under aseptic conditions, and sterilized using irradiation, 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

FREEZE-DRIED TISSUE - Maintain tissue at 15C - 30C 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.

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

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 the 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.
   b. Syringe – Deploy tissue through syringe.
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 physician's choice.
   b. Recommendation - Non-weight bearing osseous grafts should be reconstituted for a minimum of 30 minutes.
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.

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CONTRAINDICATIONS

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1. Active or latent infection at the surgical implantation site.
2. Sensitivity or allergies to any of the processing agents listed under the processing section of this document.
3. Use in immunocompromised patients.

RETURNS

With prior approval, unused, unopened tissue may be returned to OraPharma, provided OraPharma 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 OraPharma,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:
OraPharma, a division of
Bausch Health US, LLC
Bridgewater, NJ 08807 USA
To Order: 1-866-273-7846
Customer Service: 1-800-321-4576

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.

Processed By:

CellRight Technologies®
A Tissue Regenix Group Company
1808 Universal City Blvd
Universal City, TX 78148
210-659-9353
Fax: 210-659-9556
www.CellRightTechnologies.com

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
Illinois Registration No. 0319

CellRight Technologies® is Registered with the State Tissue Bank in:
Oregon;
Delaware

Distributed By:

OraPharma, a division of Valeant
Pharmaceuticals North America LLC
Bridgewater, NJ 08807
To order: 1-866-271-7846
Customer Service: 1-800-321-4576
orapharma@orapharma.com
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