Raptos® Jar

TISSUE PACKAGE INSERT

SEE BACK FOR ALLOGRAFT TRACKING FORM

BONE GRAFTING

RAPTOS® JAR

Allograft Bone Particulates

This allograft is derived from voluntarily donated human tissues. It is intended for single patient, single use only. All tissue has been sourced by Vivex Biologics, Inc. 2430 NW 116th Street, Bldg 3, Miami, FL 33167, operating in accordance with the American Association of Tissue Banking (AATB) Standards and the applicable regulations set forth by the US Food and Drug Administration (FDA).

All tissue has been processed by Regenx operating in accordance with the Standards for Tissue Banking of the American Association of Tissue Banks (AATB) and Food and Drug Administration (FDA) regulations.

USE/DESCRIPTION

Raptos® Jar products are used in situations where a human allograft is appropriate, such as dental bone grafting procedures. **Raptos® Jar** particulates are, low-dose, gamma irradiated particles of allogeneic human bone.

Procurement: **Raptos® Jar** are declared acceptable for transplant. All tissue meets stringent donor screening and laboratory testing to reduce the risk of transmitting infectious disease.

Processing: The processing of **Raptos® Jar** consists of a strict, quality-controlled procedure that involves thorough cleaning and gentle preservation of the tissue.

CONTRAINDICATIONS

The presence of infection at the transplantation site is a contraindication for use of musculoskeletal allografts.

Contraindications customary to the use of bone grafts should be observed. In addition, **Raptos® Jar** should not be used in patients with:

- Osteomyelitis at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction
- Severe liver disease
- High-dose therapy with corticosteroids
- Vascular impairment at the implant site

WARNINGS

- Discard grafts when mishandled, or when possible contamination of the graft has occurred.
- Return to the supplier, any package in which the sterile barrier has been compromised.
- Do not re-sterilize.
- Unused bone should be properly discarded.
- Single patient use only.

PRECAUTIONS

- Federal law (USA) restricts use to licensed clinicians
- Trace amounts of Polymyxin B Sulfate, or Bacitracin may be present and caution should be exercised if the recipient is allergic to these antibiotics.

HANDLING AND PREPARATION

Graft preparation instructions are intended as guidelines as part of established surgical techniques.

They are not intended to replace or change standard procedures or institutional protocols.

CAUTION

All preparation should be performed using aseptic technique. In order to obtain the **Raptos® Jar**, peel the outer tyvec lid back, twist off the plastic lid from the plastic vial and remove the **Raptos® Jar** onto a sterile field. Once the packaging has been opened, the tissue must either be transplanted or discarded. It is recommended that **Raptos® Jar** be reconstituted prior to use by covering with sterile isotonic solution for approximately 15 minutes, (30 minutes maximum) using aseptic/sterile technique.

Rehydration can also be achieved by mixing **Raptos® Jar** with the patient's blood. Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise DISCARDED.

DONOR ELIGIBILITY

Donor eligibility (screening and testing) is performed in accordance with AATB Standards and FDA regulations.

Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor has been determined to be eligible by a Vivex Biologics Director at 2430 NW 116th Street, Bldg 3, Miami, FL 33167.

SEROLOGICAL TESTING

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at Vivex Biologics. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Antibody to Hepatitis C (HCV)
- Hepatitis C Virus (HCV NAT)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Virus (HBV NAT)
- Hepatitis B Surface Antigen (HBsAg)
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) may have been performed at the time of donor screening, and were found to be negative or non-reactive. A list of additional communicable disease test(s) performed will be provided upon written request to Citagenix at the address provided.

MICROBIAL TESTING

Tissue is subjected to microbiological testing at recovery and in the course of processing, and must be free of specific aerobic/anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.

MEDICAL DIRECTOR ASSESSMENT

Donor eligibility determination is made by a Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request to Citagenix at the address provided.

POTENTIAL COMPLICATIONS / ADVERSE REACTIONS

As with any surgical procedure, the possibility of infection exists. Although the bone processing is designed to eliminate antigenic properties of the graft, the possibility of such rejection is present in any allograft procedure. Re-operation could be necessary to correct adverse effects. **Raptos® Jar** products remain sterile as long as the package is not opened and/or damaged. The graft must be used before the expiration date. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the graft. Patients should be instructed in the limitations of the graft and should be taught to govern their activities appropriately.

Appropriate placement and retention are critical factors in the avoidance of potentially adverse effect on graft performance.

Adverse reactions should be immediately reported to Citagenix as with all biological products, it is not possible to give an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening and laboratory testing. It is the responsibility of the hospital or clinician to maintain tissue for transplantation according to recommended storage conditions. Do not use if tissue has not been stored according to the recommended storage instructions.

STORAGE REQUIREMENTS

- Store at ambient temperature
- Do not freeze

DOCUMENTATION

A distinct identification lot code has been associated with **Raptos® Jar** that relates the product to associated records. The consignee is responsible to maintain recipient records for the purpose of tracking tissues post-transplantation. If you, the consignee, assigns a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the identifier designated by REGENX.

Please contact Citagenix to report any unexpected or adverse events, or for any additional product related information.

	Symbol for «Use-by date»
	Symbol for «Do not re-use»
	Symbol for «Do not resterilize»
	Symbol for «Do not use if the product sterilization barrier or it's packaging is compromised»
	Symbol for «Caution (see instructions for use)»
	Symbol for «Sterilized using irradiation»
	Symbol for «Batch code»
	Symbol for «Manufacturer»
℞ ONLY	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.
	Symbol for «Catalog number»
	Manufacturer: **REGENX** 1034 Pearl Street, Brockton, MA 02301 Telephone: 800-441-3100 Fax: 800-583-3150

ACE Surgical Supply Co Inc. Health Canada CTO Registration: 100235

CITAGENIX

The Regen Company

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CITAGENIX
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BONE GRAFTING

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Allograft Bone Particulates

ALLOGRAFT TRACKING FORM

In order to comply with these requirements, please complete ALL fields on this form and return to REGENX via fax at 1-800-583-3150

FDA Regulations and Joint Commission Standards require tissue tracking systems in all hospitals, clinics and doctor's offices using allografts for transplantation.

Patient ID:
(DO NOT PROVIDE PATIENT NAME) _____

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