CITAGENIX
The Regen Company

RAPTOS®

**TISSUE IN THIS PRODUCT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.
IT IS INTENDED FOR SINGLE PATIENT, SINGLE OCCASION USE ONLY.
ALL DONATED TISSUE IS PROCURED FROM DONERS IN THE UNITED STATES OF AMERICA.**

*** All tissue has been collected, processed, stored and distributed according to the Current Standards for Tissue Banking of the American Association of Tissue Banks (AATB) and Food and Drug Administration (FDA) Regulations.**

DESCRIPTION
Raptos freeze dried particles are 100% human allograft bone products. Raptos particle syringes are available with cortical, cancellous, cortico-cancellous or demineralized cortical bone. Raptos is provided in a specially designed syringe which enables rehydration in the syringe with saline or patient's blood. Raptos is aseptically processed and provided in a powder and chip form, sterile, single patient use package.

SURGICAL USE
Caution: Raptos is restricted to use by a physician, podiatrist, or dentist. Raptos can be used in orthopedic, neurosurgical, reconstructive, and periodontal bone grafting procedures. It can be used by itself as a bone graft or in conjunction with autologous bone and other forms of allograft bone. Raptos has been tested for sterility and is ready for use. Do not subject the product to additional disinfection or sterilization procedures. Raptos is intended for single patient use only. In order to prevent contamination of the graft, any open and unused Raptos must be discarded and not used in other patients.
Effective use of Raptos is dependent on the preparation of the surgical site. Factors such as blood supply, availability of marrow, stability of the surgical site, and absence of infection are important criteria for graft incorporation and new bone formation. The amount of Raptos used for each procedure is determined by the physician.

CONTRAINDICATIONS
Without any prescription by your surgeon, Raptos shall not be used in bacteria infected area or infected area surrounding the surgical area.

INSTRUCTIONS
Raptos should be opened into a sterile area and Raptos requires rehydration prior to use. To open packaging:

I. Usage with Syringe
1. Remove syringe pouch from the package.
2. Transfer the sterile inner pouch into a sterile field, using sterile techniques.
3. Remove the outside orange color cap.
4. Rehydrate contents in the syringe with patient's blood or saline using a plunger.
5. After particulate has been thoroughly hydrated, express excess fluid through yellow filter cap.
6. Remove yellow filter cap and loosely fill site.
7. Dispose of any unused product in accordance with recognized procedures to discard regulated medical waste materials.

II. Usage without Syringe
1. Remove syringe pouch from the package.
2. Transfer the sterile inner pouch into a sterile field, using sterile techniques.
3. Remove the outside orange color cap.
4. Empty desired amount of particulate into sterile dappen dish.
5. Thoroughly hydrate particulate with patient's blood or saline.
6. A sterile spatula, curette or a plastic carrier can be used to carry the particulate to site.
7. Dispose of any unused product in accordance with recognized procedures to discard regulated medical waste materials.

Sterile technique must be followed to minimize the possibility of post-operative complications. The amount of product to be used is dependent on the type of procedure and size of the defect, and is determined by the physician. To avoid cross-contamination of graft recipients, the contents of the Raptos syringe must NOT be used on multiple patients. Partially used and completely used Raptos syringes must be disposed of in accordance with recognized procedures for discarding medical waste materials.

PACKAGING AND LABELING
Raptos is packaged in sterile, single-patient use syringes that have been modified for product delivery. Raptos is provided in an open bore syringe. The sterile syringe is packaged in two sealed blister pouches. The pouches and box contain labels that indicate product description, serial number (donor ID), expiration date, product code, and additional information.

STORAGE
Store Raptos at room temperature (1˚C to 30˚C) in a clean, dry place. Do not expose to extreme heat. No refrigeration or freezing is required. Do not use the product in a cold or frozen state as this may affect the handling. Allow cold product time to reach room temperature before use. Use product before the expiration date indicated on the box as well as on the outer blister pouch. It is the responsibility of the tissue dispensing service and/or end-user clinician to maintain the product in appropriate storage conditions prior to implantation, if intended for transplantation.

STERILIZATION
Raptos is intended for single patient use only and was aseptically manufactured. After the complete processing and packaging procedure, Raptos has been sterilized by Electron Beam Irradiation. This irradiation procedure has been validated to reduce the level of bacterial and fungal contamination. DO NOT RE-STERILIZE.

WARNINGS AND PRECAUTIONS
The following warnings and precautions must be observed.
- To avoid the use of a potentially contaminated package, this product must not be used under any of the following condition:
  - If the box seals or the blister pouch seals are not intact.
  - If contamination is suspected.
  - If the product label on the box or the outer blister pouch appears to be missing or tampered with.
  - If the expiration date indication on the label has passed.
- If any of the above conditions exist or are suspected to exist, please notify Citagenix Inc. and return the product.
- Extensive medical screening of tissue donors has been conducted. However, transmission of infectious agents may occur in spite of rigorous screening, processing, and testing procedures.
- Adverse outcomes potentially attributable to the product must be promptly reported to Citagenix Inc.
- Once the Raptos product is removed from the packaging it should be rehydrated within 24 hours and can be stored up to 4 hours prior to use.

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 eligibility has been determined by the Medical Director of the tissue bank (as identified on the product's outer packaging).

SEROLOGICAL TESTING
The following required testing was performed and found to be negative or non-reactive. Additional tests may have been performed at the time of donor screening, and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request. Serological testing is performed using FDA-licensed test kit by a laboratory registered with 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 42CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services(CMS).
- Antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Nucleic acid test (NAT) for the hepatitis B (HBV)
- Total antibodies to hepatitis B core antigen (anti-HBc-total, meaning IgG and IgM)
- Antibodies to the hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Syphilis(a non-treponemal or treponemal-specific assay may be performed)

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 processing or transplantation.

PATIENT RECORD AND TRACING
Product recipient records must be maintained by the physician, transplant facility or hospital for the purpose of tracing tissue post-implantation. A Raptos Traceability record and peel-off chart labels have been included in the packaging of this product. This record must be completed at the time of the surgical procedure. Please record the name and address of the transplant facility, physician name, allograft tissue information (use a chart label), and comments on use of the Raptos. A copy of this form should be retained by the transplant facility or physician for future reference. The completed form must mailed or faxed back to your distributor. Even if the entire tissue product is discarded the Raptos Traceability record must be filled out, the reason for discarding the product must be noted and the record mailed or faxed back to your distributor.

LABELING SYMBOLS:
Symbols may be used on some package labeling for easy identification.

	Symbol for «Do Not Reuse»
	Symbol for «See Instructions for Use»
	Symbol for method of sterilization using irradiation
	Symbol for «Temperature Limitation»

Raptos 200 - 850 µm bone particles					
Size	Cortical bone	Cancellous bone	Cortico-Cancellous Blend	Demineralized Cortical bone	Demin./Min. Cortical bone
0.25cc	COR02S-02	CAN02S-02	CCB02S-02	DCB02S-02	DMC02S-02
0.5cc	COR02S-05	CAN02S-05	CCB02S-05	DCB02S-05	DMC02S-05
1cc	COR02S-10	CAN02S-10	CCB02S-10	DCB02S-10	DMC02S-10

Raptos 850 to 1,500 µm bone particle size				
Size	Cortical bone	Cancellous bone	Cortico-Cancellous Blend	Demineralized Cortical bone
0.25cc	COR08S-02	CAN08S-02	CCB08S-02	DCB08S-02
0.5cc	COR08S-05	CAN08S-05	CCB08S-05	DCB08S-05
1cc	COR08S-10	CAN08S-10	CCB08S-10	DCB08S-10

Raptos is distributed in Canada by:

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Health Canada CTO Registration: 100084

Processed by: HansBiomed Corp.
64, Yuseong-Daero 1628beon-gil, Yuseong-gu, Daejeon, Republic of Korea (34054)
Tel. 82-42-478-9001 Fax 82-42-478-9006
Health Canada CTO Registration: 100201