BIOMET 3i

RegenerOss™ Allograft Putty

READ BEFORE USING

THE TISSUE WAS RECOVERED FROM DECEASED DONORS WHOSE LEGAL NEXT-OF-KIN HAS GIVEN PERMISSION FOR THE BONE TO BE DONATED. RECOVERY WAS PERFORMED USING ASEPTIC PROCEDURES. PROCESSING AND PACKAGING WERE PERFORMED USING ASEPTIC TECHNIQUES IN CONTROLLED CLEAN ROOM ENVIRONMENTS.

DO NOT STERILIZE

Description

RegenerOss™ Allograft Putty products contain human tissue (allograft bone) and are intended for transplantation. The allograft bone has been granulated, demineralized and provided in a lipid carrier. The lipid carrier used in the manufacture of RegenerOss products is extracted from soybean.

Use

RegenerOss products are to be used as a bone filling material for dental intraosseous and oral/maxillofacial defects including: localized ridge augmentations, extraction sockets, cystic defects, sinus lifts, peri-implant defects, defects associated with root resection or apicoectomy, and periodontal defects. The amount of RegenerOss products to be used should be based on the type of procedure and size of the graft site.

RegenerOss products have been processed aseptically and are ready to use. The RegenerOss products are provided in sterile syringes. The product is then packaged in two sterile peel pouches. The outer peel pouch can be used to aseptically transfer the sealed inner pouch to the sterile field. Follow these instructions:

1. Peel open outer pouch using proper sterile technique.
2. Pass inner pouch into sterile field.
3. Peel open inner pouch and remove product.
   Remove cap.
   Express from syringe.

RegenerOss products require no reconstitution prior to use. They do not require rehydration or any special preparation. Do not subject RegenerOss products or their packaging to additional disinfection or sterilization procedures. RegenerOss is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents on multiple patients. Empty or partially used containers should be disposed of in accordance with recognized procedures for discarding medical waste materials.

Prior to placing a dental implant, it is recommended to allow a healing period of approximately 4 months. Prosthetic restoration can be performed after an additional four-month healing period or confirmation of healing by radiographic analysis.

Patient Records

The clinic or hospital is responsible for maintaining recipient records for the purpose of tracing allograft tissue post-implantation. Ensure that the following information is recorded in the patient's medical record and the hospital implant records (1-3 are required and 4-10 are suggested):

1. Description of Tissue
2. Donor Identification Number
3. Product Code
4. Expiration Date
5. Quantity Implanted
6. Antibiotics Used
7. Description of Procedure
8. Date and Time of Procedure
9. Surgeon Name
   Any Other Pertinent Information

As a convenience, a Graft Tracing Record has been included to be completed at the time of the surgical procedure. A completed original is to be retained in the patient record and the copy sent back to Interpore Cross International, a Biomet company, as indicated on the enclosed Graft Tracing Record. If the entire tissue product was discarded, return the Graft Tracing Record and explain the reason for discard.

Once completed, return the bottom copy of the form using the self-mailer (or fax) to Interpore Cross International for our permanent records. File the top copy in the patient chart.

Contraindications

Contraindications customary to the use of bone grafts should be observed:
- osteomyelitis at the surgical site
- metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- severe renal dysfunction, sever liver disease
- high dose therapy with corticosteroids
- vascular impairment at the implant site
- active or latent infection is observed in or surrounding the implantation site

Warnings and Precautions

RegenerOss products are aseptically processed and remain aseptic during the stated shelf-life in an unopened and undamaged package. The product must be used before the expiration date. RegenerOss must not be used under any of the following conditions:

- If any of the package or product elements appear to be missing, tampered with or damaged;
- If the product label or identifying bar code is severely damaged, illegible, or missing;
- If the expiration date shown on the package label has passed.

Do not subject RegenerOss products or their packaging to disinfection or sterilization procedures. RegenerOss is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents on multiple patients. Empty or partially used containers should be disposed of in accordance with recognized procedures for discarding medical waste materials.

The production of all RegenerOss products is performed in environmentally controlled conditions and under rigorous quality controls. The DBM component is processed with 50 units/mL Bacitracin, 500 units/mL Polymyxin B, Isopropyl Alcohol, Hydrochloric Acid, Sodium Phosphate Buffer, Hydrogen Peroxide and Allowash® solution, and may contain traces of these processing agents.

RegenerOss products must be appropriately placed and/or fixed according to the clinical requirements for the specific procedure to avoid potentially adverse effects.

Care should be taken to avoid overfilling the defect site with RegenerOss. Excessive pressure or tension on the overlying tissue by an overfilled defect could cause the wound to re-open.

Each lot of DBM incorporated into RegenerOss Allograft Putty is assayed for its osteoinductive potential. The assay measures the proliferation of SAOS human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductive index). Results of the assay have been correlated with results from implantation of DBM into athymic rat muscle, which demonstrated a correlation coefficient of 0.850 ($p<0.0005$) and accurately predicted the *in vivo* osteoinductivity in 25 donor lots.[1] Additionally, clinical results using DBM with >0.20 and ≤0.20 (osteoinductive index) demonstrated a significant difference in healing as evaluated by radiography, 92% and 33% healing, respectively.[2]

The combination of DBM and the carrier has not been evaluated for osteoinductivity; therefore it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in-vitro* "SAOS" bioassay will correlate with human clinical performance of RegenerOss products.

1. Adkisson HD, Strauss-Schoenberger J, Gillis M, Wilkins R, Jackson M, and Hruska KA. Rapid Quantitative Bioassay of Osteoinduction. J Ortho Res, 2000, 18:503-511.
2. Wilkins RM, Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture, Advances in Tissue Banking. 1999 3:113-124

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of infectious diseases through the use of this tissue graft is still possible. Infection at the graft site may also occur. Any adverse outcomes potentially attributable to RegenerOss products must be reported promptly to Biomet 3i at 800-443-8166.

Storage

RegenerOss products should be stored in a clean, dry place at ambient temperature. Keep out of direct sunlight and do not freeze. It is the responsibility of the tissue dispensing service and user facility/clinician to maintain any tissue in appropriate conditions prior to use.

Production

Tissue Processing Procedures:

RegenerOss products are produced by a validated proprietary production process. Tissue processing is completed in accordance with procedures recommended by the American Association for Tissue Banks (AATB). The lipid carrier has been irradiated with a Cobalt 60 source.

Summary of Donor Records:

The completed donor chart for the enclosed tissue (including but not limited to, serology results, recovery culture results, medical and social history evaluation and hemodilution calculation that was conducted by or contract tested by and for the tissue provider) has been approved for transplantation by the tissue provider's Medical Director.

Donor Screening and Testing:

Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues. The tissue provider's policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the AATB. Contraindications for tissue donation include, but are not limited to, the following: presence of infectious disease, malignant disease, neurological degenerative diseases, disease of unknown etiology, and exposure to toxic substances. The donor's medical/social history was also screened for HIV high risk factors in accordance with current United States Public Health Services Recommendations for the Prevention of HIV Transmission through Tissue and Organ Donation.

Testing of donor blood and tissue samples began at the site of recovery and continued throughout processing. Donor blood samples taken at the time of recovery were tested and found negative (acceptable) for the following:

- Hepatitis B surface antigen (HBsAg)
  Hepatitis B core antibody (anti-HBc)
  Hepatitis C antibody (anti-HCV)
- Human immunodeficiency virus Type 1 and Type 2 antibodies (anti-HIV-1 and anti-HIV-2)
- Human T-lymphotropic virus Type 1 and Type 2 antibodies (anti-HTLV-1 and anti-HTLV-2)
- Syphilis (RPR or FTA)
- Nucleic Acid Testing (NAT) for HIV-1
- NAT for HCV

The individual tissues collected at recovery were subject to microbiological testing and determined to be free of specific aerobic/ anaerobic microorganisms and fungal contaminants whose presence would preclude the tissue from transplantation.

The above tests were performed by laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

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For additional information call
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