Instructions for Use

ReOss® Synthetic Biomaterial

DESCRIPTION

ReOss® is a hydrophilic, highly porous, resorbable, synthetic copolymer permeated with osteoconductive particles of Hydroxyapatite. It is configured as a multi-pore three - dimensional scaffold that creates an environment suitable for the infusion of blood and osteoblasts and is engineered to integrate with the physiochemical state of bone tissue.

INDICATIONS FOR USE

ReOss® Powder and Putty is indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites and sinus elevation grafting.

CONTRAINDICATIONS

Standard protocols are to be followed when taking a comprehensive medical/dental history.

- Uncontrolled diabetes.
- Severe vascular or neurological disease.
- Blood dyscrasias.
- Existing acute or chronic infections, especially at the site of use.
- Metabolic or systemic bone or calcium disorders.
- Severe degenerative bone disease.
- History of radiation to the treatment area.
- History of drug/alcohol abuse.
- History of allergic reactions to PLGA products
- Renal compromised patients.
- Uncooperative patient who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol.
- Pediatric patients.

HOW SUPPLIED

ReOss® is packaged for single use and sterilized by gamma irradiation.

Do not resterilize or reuse. The effects of multiple sterilization cycles could cause degradation to the product.

An expiration date is provided with shelf life if package is stored properly and is not damaged or opened. Product(s) must be used prior to expiration date. Inspect product prior to use.

INSTRUCTIONS FOR USE

These instructions for use of ReOss® are guidelines to be used in conjunction with established surgical techniques. Standard procedures for treatment of bone defects involving bone grafting and internal fixation should be followed. The results of bone grafting procedures are highly variable. When selecting the bone grafting material and the surgical technique to be utilized, the following factors should be taken into consideration:

- Bone quality and location of the defect;
- Anticipated load factor;
- Age of the patient;
- Suitable blood supply at graft site;
- Proper graft apposition;
- Complete coverage of the graft material to maintain material in situ.

For best results, care should be exercised to ensure the correct graft material is selected for the intended application.

Radiographic imaging of the defect is recommended to assess the location and extent of the defect to determine the optimum type and amount of ReOss® to be used.

Standard aseptic technique must be maintained to minimize the risk of post-operative complications.

Standard postoperative regimen as used when soft tissue and bone augmentation procedures should be followed. All cases must be treated in a manner consistent with individual patient profile, nature and extent of procedure.

PRECAUTIONS

ReOss® is not intended for load-bearing applications.

⚠ **WARNINGS**

Pre-treatment, treatment and post-treatment protocols should be followed as per standard treatment procedures.

Follow established protocols, including pre-and post-medication regimens prescribed to avoid infection, when/where necessary.

Avoid overfilling and do not disturb the material until hardened.

Soft tissue flap should approximate in a manner that establishes a tension-free closure of the surgical site.

If using ReOss® at the time of dental implant placement, additional healing time is recommended before loading dental implant.

In the unlikely event of an adverse reaction, report immediately according to established guidelines.

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Caution: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.

S40-082419 (5/17)