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ENGLISH

OSSIX™ BONE

Bone grafting material

Instructions for Use

DESCRIPTION

OSSIX™ BONE is a sterile, biocompatible bone grafting material aimed to fill, augment, or reconstruct periodontal and bony defects of the maxillo-facial complex.

OSSIX™ BONE is composed of 80% crystalline hydroxylapatite and 20% porcine collagen that are constructed together to form a porours spongious matrix. The product is sterilized by ethylene oxide.

MODE OF ACTION

OSSIX™ BONE is an osteoconductive bone grafting material that serves as a scaffold for bone-forming cells when placed into bony gaps during maxillofacial surgery. With time, the OSSIX™ BONE matrix is resorbed and replaced by new bone as part of the natural healing process. Preclinical studies demonstrated that 50% or greater implant material remain at the 6-month time point.

PROPERTIES

OSSIX™ BONE has been demonstrated to be biocompatible.

OSSIX™ BONE consists of hydroxylapatite particles integrated in a porous lattice of cross-linked collagen fibers, which readily absorbs body fluids, allowing it to take the shape of the defect and to adhere to the surrounding tissues. Furthermore, the collagen lattice holds together the hydroxylapatite particles, prevents migration from the defect site, and facilitates the handling of the graft.

OSSIX™ BONE is recommended for use in conjunction with a resorbable dental barrier membrane (e.g. OSSIX® PLUS, OSSIX® VOLUMAX).

INDICATIONS FOR USE

OSSIX™ BONE is intended for the following uses:

- Augmentation or reconstructive treatment of the alveolar ridge;
- Filling of periodontal defects;
- Filling of defects after root resection, apicoectomy and cystectomy;
- Filling of extraction sockets to enhance preservation of the alveolar ridge;
- Elevation of the maxillary sinus floor;
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR);
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

CONTRAINDICATIONS

OSSIX™ BONE should not be used in:

1. Patients with known collagen hypersensitivity.
2. Patients with sensitivity to porcine-derived materials.
3. Patients suffering from autoimmune diseases and connective tissue diseases, such as: systemic lupus erythematosus, dermatomyositis etc.
4. Patients with acute or chronic infection (osteomyelitis) at the surgical site.
5. Patients with vascular impairment at the implant site.
6. Patients with uncontrolled periodontal disease.
7. In patients that have received or are currently receiving treatment with bisphosphonates.
8. OSSIX™ BONE should not be used in the presence of infected wounds at the site of implantation.

⚠ **WARNINGS AND PRECAUTIONS**

- OSSIX™ BONE is intended for a single use only. Do not re-sterilize or reuse.
- OSSIX™ BONE should only be used by trained dentists or oral surgeons.
- Use in areas where the graft can be adequately contained.
- Infection control and good oral hygiene should be achieved prior to surgical intervention.
- Do not overfill defects.
- Do not leave defect open.
- The device should be secured with a barrier membrane and/or with overlying (periosteal) sutures or fixation screws to prevent motion and migration.
- Do not compromise blood supply to the defect area.
- Do not use if package is opened or damaged or if expiration date has been exceeded.
- OSSIX™ BONE is not intended for immediate load-bearing. Mechanical loading (compression loading) of OSSIX™ BONE augmented areas is possible after 6 months, at the earliest.
- OSSIX™ BONE should be used with special caution in patients with:
  - Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia, osteoporosis, severe renal dysfunction, severe liver disease)
  - High dose corticosteroid therapy
  - Radiotherapy
  - Immunosuppressive therapy
  - Organ transplants
  - Autoimmune disease
  - Compromised immune system such as primary immunodeficiency or secondary immunodeficiency (cancer, myelofibrosis, AIDS, etc.)
  - Heavy smoking

  The outcome of the regenerative procedures in these patients may be impaired.
- Effect on pediatric patients is not known.
- The safety of treatment with OSSIX™ BONE in pregnant and nursing women patients has not been established.

ADVERSE EVENTS

1. As OSSIX™ BONE contains collagen, allergic reactions (e.g. erythema, swelling, induration and/or pruritus at treatment site) may not be entirely excluded.
2. Possible complications with any surgery in the oral and maxillofacial region include: infection, flap slough, perforation, abscess formation, bone loss, pain, soft tissue irregularities, and complications associated with the use of anesthesia.

DIRECTIONS FOR USE

1. **Special instructions for use in periodontology**

   A basic requirement for successful periodontal, dental implants' placement or other oral surgical treatment includes eradicating the underlying bacterial infection as well as adequate oral hygiene. Therefore, prior to surgical intervention, patients must receive a hygiene phase of treatment, consisting of oral hygiene instructions, scaling and root planing, and occlusal adjustment when indicated. A postoperative maintenance phase can help to ensure long-term therapeutic success.

2. **Site preparation**
   - The bony defect should be exposed by full thickness mucoperiosteal flaps.
   - All soft tissues and granulation tissue should be removed.
   - In periodontal defects, the roots should be thoroughly debrided and planed. Root conditioning is optional.

3. **Proper placement and containment of the device**
   - Using sterile atraumatic instruments and sterile gloves rinsed with sterile saline, OSSIX™ BONE is removed aseptically from the package.
   - The matrix should be placed in direct contact with well vascularized, bleeding bone surfaces using sterile instruments (e.g., tweezers).
   - The cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
   - OSSIX™ BONE (dry or wet) may be cut to the required size with sterile scissors or scalpel. If necessary, OSSIX™ BONE can be slightly molded in situ using a spatula or similar instrument.
   - Do not overfill defects.
   - Once placed in the defect, OSSIX™ BONE should be hydrated with patient's blood coming from the surgical site, until the entire device changes its color from white to red.
   - For improved bone formation in large osseous defects with one or two bony walls, OSSIX™ BONE may be covered with a cell occlusive membrane (e.g., OSSIX® PLUS, OSSI® VOLUMAX).
   - OSSIX™ BONE should be secured with a barrier membrane and/or with overlying (periosteal) sutures or fixation screws to prevent motion and migration.

4. **Site closure**
   - When closing the wound, the soft tissue flap should completely cover the implanted OSSIX™ BONE, and should be fixed by sutures to prevent motion and migration. If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
   - Do not compromise blood supply to the defect area and do not leave the defect open.

5. **Postoperative Reminders**
   - OSSIX™ BONE does not require a second surgery for removal of the matrix.
   - OSSIX™ BONE is not intended for immediate load-bearing. Mechanical loading (compression loading) of OSSIX™ BONE augmented areas is possible after 6 months, at the earliest.
   - In case of immediate flap opening, suturing with resorbable (5-0) suture is recommended.

6. **Patient care following treatment**
   1. The success of any surgical treatment depends on fulfilling the directions for use along with guiding the patient, as follows:
   2. Preoperative patient's education regarding adequate oral hygiene and meticulous prophylaxis.
   3. Postoperative patient's care, e.g.:
      - **a.** Soft diet.
      - **b.** Avoidance of contact with tongue, hard food or denture.
      - **c.** Avoidance of contact with hot temperature food or liquids that may cause early disintegration of the collagen matrix.
      - **d.** Following suture removal, rinse with chlorhexidine for one minute twice a day or according to the chlorhexidine manufacturer's instructions.

STORAGE AND HANDLING

1. OSSIX™ BONE should be used by skilled periodontists or oral surgeons.
2. The material should be handled using sterile gloves and sterile atraumatic instruments.
3. Do not use OSSIX™ BONE in the event that it is damaged.
4. Do not use OSSIX™ BONE, in the event that the sterile packaging is opened and/or damaged. Re-sterilization is not possible.
5. Any remaining / unused product should be discarded according to local regulations.
6. OSSIX™ BONE should be stored at temperatures between 15-30°C (59-86°F).
7. Do not use the OSSIX™ BONE after the expiration date.

HOW SUPPLIED

1. OSSIX™ BONE is supplied in a double blister pack and is intended for single use only. Each pack contains one device.
2. OSSIX™ BONE is available in three sizes: 0.125 cc (5x5x5 mm), 0.25 cc (5x5x10 mm), and 0.5 cc (5x10x10 mm).

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed health care professional.

The symbols glossary is provided electronically at http://www.ossixdental.com/products/symbol-glossary

For any further assistance/support/questions, please contact the local distributor or manufacturer.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ