stomdevice

ENGLISH

OSSIX® VOLUMAX

The Resorbable Collagen Membrane

Instructions for Use for OSSIX® VOLUMAX

DESCRIPTION

OSSIX® VOLUMAX is a biodegradable and biocompatible collagen membrane intended for use during the process of guided tissue and bone regeneration. It is produced by standardized and controlled manufacturing procedures.

The collagen is extracted from porcine tendons subjected to veterinarian inspection and is purified to prevent hypersensitivity reactions. OSSIX® VOLUMAX is packaged in a sealed double blister contained in a cardboard box and is terminally sterilized by ethylene oxide (EtO).

OSSIX® VOLUMAX is intended for a single use.

PROPERTIES

OSSIX® VOLUMAX has been demonstrated to be biocompatible. Animal and human clinical testing show a low potential to induce hypersensitivity.

OSSIX® VOLUMAX has a porous structure; the size of the pores is small enough to occlude gingival cells but large enough to allow the passage of fluids, nutrients and plasma proteins, which are necessary to support healing (see reference h below).

OSSIX® VOLUMAX is not self-supporting and therefore it is recommended for use in conjunction with support such as an autogenous bone graft, allograft, xenograft, osteoconductive and/or inductive bone substitute, or a mixture of these.

OSSIX® VOLUMAX does not dissolve or disintegrate when wet.

OSSIX® VOLUMAX conforms easily to the shape of the alveolar ridge.

An animal study has shown that OSSIX® VOLUMAX degradation is completed within approximately 6 months.

INDICATIONS

OSSIX® VOLUMAX is a resorbable collagen membrane intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

1. Ridge augmentation for later implant insertions.
2. Simultaneous ridge augmentation and implant insertions.
3. Ridge augmentation around implants inserted in delayed extraction sites.
4. Ridge augmentation around implants inserted in immediate extraction sites.
5. Alveolar ridge preservation consequent to tooth (teeth) extraction(s).
6. Over the window in lateral window sinus elevation procedures.
7. In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved.
8. In intra bony defects around teeth.
9. For treatment of recession defects, together with coronally positioned flap.
10. In furcation defects in multi rooted teeth.
11. Localized gingival augmentation.

CONTRAINDICATIONS

OSSIX® VOLUMAX must 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, dermatomyositisetc.

⚠ WARNINGS AND PRECAUTIONS

1. OSSIX® VOLUMAX is intended for a single use device. Do not re-sterilize OSSIX® VOLUMAX.
2. Treatment of high risk patients, such as: smokers, patients suffering from uncontrolled diabetes mellitus, and uncontrolled periodontal disease may be impaired.
3. The safety of treatment with OSSIX® VOLUMAX in pregnant and nursing women and in children has not been yet established.
4. The outcome of regenerative procedures may be impaired in patients suffering from untreated periodontitis. Infection control and good oral hygiene should be achieved prior to surgical intervention.

ADVERSE EVENTS

1. Post marketing experience with OSSIX® PLUS, which is a thinner version of the membrane, reveals an excellent safety profile.
2. Adverse reactions with OSSIX® PLUS collagen membrane were not observed.
3. Yet, as the membrane is of a collagen origin, allergic reactions (e.g. erythema, swelling, induration and/or pruritus at treatment site) may not be entirely excluded.

DIRECTIONS FOR USE

1. Special instructions for use in periodontology
   A basic requirement for successful periodontal 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. The bony defect should be exposed by full thickness mucoperiosteal flaps.
3. All soft tissues should be removed.
4. In GTR the root surface should be carefully debrided and planed. Root conditioning should be considered.
5. The cortical plate can be perforated in order to allow osteogenic tissues from the bone marrow to colonize the regenerating site.
6. By using sterile a-traumatic instruments and sterile gloves rinsed with sterile saline, OSSIX® VOLUMAX is removed aseptically from the package.
7. OSSIX® VOLUMAXshould be immersed (the inner blister can be used as a dish) for 30 seconds in sterile saline, to allow for its expansion to its final dimensions (10x12.5, 15x25 mm, 25x30 mm and 10x40 mm). Initial trimming to the estimated final size may be performed prior to sterile saline immersion.
8. Trimming to the required dimensions: it is recommended that OSSIX® VOLUMAX extends 3-4 mm beyond the margins of the defect. One-two mm of uncovered bone to adjacent teeth must be allowed.
9. OSSIX® VOLUMAX is cut with sterile scissors over a sterile container; try-in over the defect with a-traumatic instruments should be performed.
10. The site to be augmented should be filled with a space-maintaining material. The user should follow the manufacturer's instructions for the material used.
11. OSSIX® VOLUMAX should be secured under the lingual flap, then a bone graft placed, and the membrane carefully adapted over the defect. The membrane will adhere to the underlying tissue; additional fixation of the membrane should be considered. Fixation with screws or tacks or suturing through the membrane is not recommended as it may tear the membrane. Fixation with overlying sutures is advised. This may be achieved by anchoring a mattress suture in the apical periosteum buccally and lingually.
12. The mucoperiosteal flaps are sutured while ensuring that the tissue is not under tension. Do not compromise blood supply to the defect area.
13. In GTR, the use of a periodontal dressing may be considered.

GUIDELINES FOR THE PATIENT

The success of any surgical treatment depends on fulfilling the directions for use along with guiding the patient, as follows:

1. Preoperative patient's education regarding adequate oral hygiene and meticulous prophylaxis
2. Postoperative patient's care, e.g.:
   - Soft diet, avoidance of contact with tongue, hard food or denture.
   - Avoidance of contact with hot temperature food or liquids that may cause early disintegration of the collagen matrix.
   - Following suture removal, rinsing with chlorhexidine for one minute twice a day or according to the manufacturer's instructions.

POSTOPERATIVE REMINDERS

1. Clinical experience with OSSIX® PLUS, which is a thinner version of the membrane, reveals no inflammatory signs following accidental exposure. The membrane degrades slowly in the oral environment and the exposed area is covered by connective tissue and epithelium within a few weeks (see references a-h below).
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.
3. Depending upon the type and severity of the complications, as judged by the dental surgeon, membrane removal may be indicated.

STORAGE AND HANDLING

1. OSSIX® VOLUMAX should be used by skilled, experienced and/or trained dental surgeons.
2. The material should be handled using sterile gloves or sterile a-traumatic instruments.
3. Placement of OSSIX® VOLUMAX should be performed after membrane's immersion in saline for 30 seconds.
4. Do not use the membrane if it is torn and/or damaged.
5. Do not use the membrane, in the event that the sterile packaging is opened and/or damaged.
6. Any remaining / unused membrane should be discarded according to local regulations.
7. OSSIX® VOLUMAX should be stored at temperatures between 15-30°C (59-86°F).
8. Do not use the membrane after the expiration date.

HOW SUPPLIED

1. OSSIX® VOLUMAX is in a double blister pack, for single use only. Each pack contains one membrane.
2. OSSIX® VOLUMAX is available in four sizes: 10x12.5 mm, 15x25 mm, 25x30 mm and 10x40 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.

Symbols
Symboles
Simboli
Symbole
Símbolos
Símbolos



Caution
Attention
Attenzione
Vorsicht
Precaución
Cuidado



Consult instructions for use
Consulter le mode d'emploi
Consultare le Istruzioni per l'uso
Gebrauchsanweisung beachten
Consulte las instrucciones de uso
Ver instruções de uso



Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé
Non utilizzare in presenza di danni alla confezione
Bei beschädigter Verpackung nicht verwenden
No utilizar si el envase está dañado
Não usar se a embalagem estiver danificada



Do not reuse
Ne pas réutiliser
Monouso
Nicht wieder verwenden
No reutilizar
Não reutilizar



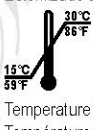
Use by
Utiliser avant
Utilizzare entro
Verfalldatum
Fecha de caducidad
Usar até



Batch code
Code du lot
Codice lotto
Chargencode
Código de lote
Código do lote



Sterilized using ethylene oxide
Stérilisé à l'oxyde d'éthylène
Sterilizzazione con ossido di etilene
Sterilisiert mit ETO
Producto esterilizado mediante óxido de etileno
Esterilizado com óxido de etileno



Temperature limits
Températures limites d'utilisation
Limiti di temperatura
Temperaturbegrenzung
Límite de temperatura
Limites de temperatura



Authorized Representative in the European community
Représentant autorisé pour la Communauté européenne
Rappresentante autorizzato per l'Unione Europea
Autorsierter bevollmächtigter in der Europäischen Union
Representante autorizado en la Unión Europea
Representante autorizado na Comunidade Europeia



Manufacturer
Fabricant
Produttore
Hersteller
Fabricante
Fabricante



Catalog number
Numéro de catalogue
Numero di catalogo
Katalognummer
Número de catálogo
Número de catálogo

REFERENCES
RÉFÉRENCES
RIFERIMENTI BIBLIOGRAFICI
REFERENZEN
REFERENCES
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https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ