

OSSIX® PLUS
The Resorbable Collagen Membrane
Instructions for Use for OSSIX® PLUS

DESCRIPTION

OSSIX® PLUS is a biodegradable collagen membrane, obtained by standardized and controlled manufacturing procedures.

The collagen is extracted from porcine derived tendons that are subjected to veterinarian inspection and is purified to prevent hypersensitivity reactions. OSSIX® PLUS is packaged in a sealed double blister contained in a cardboard box and is terminally sterilized by Ethylene Oxide (EtO).

OSSIX® PLUS is packaged in a single membrane double blister pack, in which the outer blister contains a **template** material (not collagen) and the inner blister contains the **OSSIX® PLUS membrane**, for a single use.

PROPERTIES

OSSIX® PLUS has an excellent biocompatibility profile, resulting in a low potential to induce hypersensitivity.

OSSIX® PLUS has a porous structure; its pore size is occlusive for gingival cells yet permits the passage of fluids and plasma proteins, which assist in flap closure.

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

OSSIX® PLUS retains its structural integrity when wet.

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

An animal study has shown that OSSIX® PLUS degradation is completed within approximately 8 months.

INDICATIONS

OSSIX® PLUS biodegradable collagen membrane is 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 procedure.
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.

CONTRAINDICATIONS

OSSIX® PLUS must not be used in:

1. Patients with known collagen hypersensitivity.
2. Patients suffering from autoimmune disease and connective tissue disease, such as: systemic lupus erythematosus, dermatomyositis etc.



WARNINGS AND PRECAUTIONS

1. OSSIX® PLUS is intended for a single use device (membrane and template). Do not re-sterilize OSSIX® PLUS.
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® PLUS 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. Clinical and post marketing experience with Ossix™, the bovine counterpart, reveals an excellent safety profile during long term experience.
2. Adverse reactions with a porcine 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. The bony defect should be exposed by full thickness mucoperiosteal flaps.
2. All soft tissues should be removed.
3. In GTR the root surface should be carefully debrided and planed. Root conditioning should be considered.
4. The cortical plate can be perforated in order to allow osteogenic tissues from the bone marrow to colonize the regenerating site.
5. By using sterile a-traumatic instruments and sterile gloves after being rinsed with sterile saline, OSSIX® PLUS and the template material are removed aseptically from the package. In order to distinguish between the membrane and the template, the template is marked with the word "TEMPLATE".
6. OSSIX® PLUS is immersed (the inner blister can be used as a dish) for three minutes in saline, to allow for its expansion to its final dimensions (15x25 mm, 25x30 mm, 30x40 mm).
7. Trimming to the required dimensions: it is recommended that OSSIX® PLUS extends 3-4 mm beyond the margins of the defect. Therefore, the **template** should be trimmed respectively. One-two mm of uncovered bone to adjacent teeth must be allowed.
8. OSSIX® PLUS is cut with sterile scissors (over a sterile container) to fit the template and try-in over the defect with a-traumatic instruments should be performed.
9. The site to be augmented should be filled with a space-maintaining material. It is recommended to mix the material with blood to form a clot. It can be obtained by venous puncture or collected from the operated site.
10. OSSIX® PLUS should be secured under the lingual flap and a bone graft placed, then the membrane carefully adapted over the defect. The membrane will adhere to the underlying tissue thus there is no need for additional membrane's fixation.

11. The mucoperiosteal flaps are sutured while ensuring that the tissue is not under tension. Do not compromise blood supply to the defect area.
12. 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, e.g.: rinsing with chlorhexidine.
2. Postoperative patient's care, e.g.:
 - a. Soft diet, avoidance of contact with tongue, hard food or denture.
 - b. Avoid contact with heat that may cause early disintegration of the collagen matrix.

POSTOPERATIVE REMINDERS

1. Clinical experience with Ossix™ in the exposure area of Ossix™ membranes reveals no inflammatory signs following accidental exposure. Ossix™ is resistant to the oral environment and the exposed area is healed by connective tissue and epithelium covering the exposure within a few weeks.
Therefore, if accidental dehiscence occurs with OSSIX® PLUS, the site should only be followed up, without any specific treatment.
In case of immediate flap opening, suturing with resorbable (5-0) suture is recommended.
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® PLUS 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® PLUS should be performed after membrane's immersion in saline for 3 minutes.
4. Do not use the membrane in case that 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 will be discarded according to local regulations.
7. OSSIX® PLUS 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® PLUS is supplied as a single membrane, double blister pack, for a single use only. The pack contains one membrane and one template.
2. OSSIX® PLUS is available in 15x25 mm, 25x30 mm, 30x40 mm dimensions.

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

Symbols



Caution



Consult instructions for use



Do not use if package is damaged



Do not reuse



Use by/Expiration date



Lot/Batch number



Sterilized using ethylene oxide



Temperature limits



Authorized Representative in the European Community



Manufacturer



Catalog number

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

Manufacturer

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