OSSIX Agile™

Cross-Linked Pericardium Membrane

Instructions for Use

DESCRIPTION

OSSIX Agile™ is a biodegradable and biocompatible collagen membrane intended for use during the process of guided tissue and bone regeneration. It is produced from porcine pericardium by standardized and controlled manufacturing procedures. The pericardium is extracted from pigs subjected to veterinarian inspection and is purified to prevent hypersensitivity reactions; the collagen is cross-linked using a naturally-occurring sugar – D-ribose. OSSIX Agile™ is packaged in a sealed double blister contained in a paperboard box and is terminally sterilized by ethylene oxide (EtO).

OSSIX Agile™ is intended for use in adults and should only be used by trained dentists or oral surgeons.

PROPERTIES / ACTION

OSSIX Agile™ has been demonstrated to be biocompatible.

OSSIX Agile™ does not dissolve or disintegrate when wet and conforms easily and tightly to the shape of the alveolar ridge.

OSSIX Agile™ has a porous structure; the size of the pores is small enough to occlude gingival cells.

OSSIX Agile™ acts as a barrier: it provides a space for bone ingrowth and stabilizes and protects the bone grafting material that occupies this space.

If necessary, OSSIX Agile™ can be trimmed and can be fixated with resorbable suture material or with tacks or pins or screws.

Preclinical studies have shown slight to moderate degradation after 6 months. Thus, a second surgical intervention is not necessary to remove the membrane.

INTENDED USE / INTENDED PURPOSE

OSSIX Agile™ membrane alone or in combination with suitable augmentation materials (like autologous bone or other bone replacement materials) is indicated for immediate or delayed guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable membrane for:

1. Alveolar ridge augmentation and reconstruction,
2. Alveolar ridge preservation consequent to tooth extractions,
3. Over the window in sinus elevation procedures and for support of the Schneiderian membrane
4. In intrabony defects around teeth,
5. Guided tissue regeneration procedures in periodontal defects.

CONTRAINDICATIONS

OSSIX Agile™ 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, dermatomyositis, etc.
4. Patients with acute infection in the oral cavity or acute inflammation at the implantation site.
5. Patients with general diseases, where measures of stomatology, maxillo-facial surgery, implantology, periodontology, endodontology or other measures of oral surgery are contraindicated.

WARNINGS AND PRECAUTIONS

1. OSSIX Agile™ is for single use only. Re-use may result in infection, contamination and degradation of device performance.
2. Do not re-sterilize OSSIX Agile™.
3. Infection control and good oral hygiene should be achieved prior to surgical intervention.
4. Treatment of high-risk patients, such as: smokers, patients suffering from uncontrolled diabetes mellitus, and uncontrolled periodontal disease may be impaired.
5. The safety of treatment with OSSIX Agile™ in pregnant and nursing women and in children has not been established.

SIDE EFFECTS

1. Possible general complications might be caused by the surgical intervention itself, such as a recession of the gingiva followed by wound dehiscence, heavy gum bleeding, swelling of the soft tissue, temperature sensitivity, desquamation of the gingival epithelium in the area of the flap, a resorption or ankylosis of the treated dental root, a minor loss of crestal bone height, infections, pain or complications due to the use of anesthetics.
2. As with every implantation of exogenous material, infections may occur, or existing infections might be intensified by the implantation procedure.
3. The following adverse events are rare but cannot be ruled out: foreign body reactions, allergic reactions (e.g., erythema, swelling, induration and/or pruritus at the treatment site), inflammation due to prolonged resorption.

DIRECTIONS FOR USE

1. **General**
   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. 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 should be removed.
   - In GTR, the root surface should be carefully debrided and planed. Root conditioning should be considered.
   - The cortical plate can be perforated in order to allow osteogenic tissues from the bone marrow to colonize the regenerating site.
3. **Proper placement and containment of the device**
   - The blister packaging, which is sterile on the inside, can be removed from the outer carton in the unsterile operation area and shall be opened under sterile conditions. The inner packaging shall be removed in the sterile area. When the defect is prepared, the membrane can be removed from the inner packaging, maintaining sterility.
   - OSSIX Agile™ is of natural origin. Therefore, the collagen structure can be slightly wavy, and the membrane thickness and size may vary slightly in the dry material. These phenomena do not affect the quality or functionality of the membrane.
   - Trimming to the required dimensions: it is recommended that OSSIX Agile™ extends 2-3 mm beyond the margins of the defect.
   - OSSIX Agile™ shall be cut with sterile scissors over a sterile container.
   - The membrane can, if preferred, be hydrated before or after trimming in a 0.9% sterile saline solution until it becomes soft and flexible.
   - If clinically indicated, the site to be augmented may be filled with a space-maintaining material. The user should follow the manufacturer's instructions for the material used.
   - OSSIX Agile™ should be placed over the defect and slightly pressed down to hold it in place. The membrane will adhere to the underlying tissue; additional fixation of the membrane may be necessary to avoid its displacement due to strain or mobilization, and to prevent the shifting of the augmentation material used. The membrane can be sutured with resorbable suture material and with a non-cutting needle (fixation by overlying sutures by anchoring a mattress suture in the apical periosteum buccally and lingually), or it can be fixed to the bone with tacks or pins or screws.
4. **Site closure**
   - The mucoperiosteal flaps are sutured while ensuring that the tissue is not under tension. Do not compromise blood supply to the defect area.

POSTOPERATIVE REMINDERS

1. Depending upon the type and severity of the complications, as judged by the dental surgeon, membrane removal may be indicated.

2. If the membrane becomes exposed, the dehiscence usually heals by itself within several weeks. Membrane removal is usually not necessary. However, to minimize bacterial contamination rinsing with bactericidal solutions is recommended.

PATIENT CARE FOLLOWING TREATMENT

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

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

STORAGE AND HANDLING

1. The material should be handled using sterile gloves or sterile atraumatic instruments.
2. Do not use the membrane after the expiration date.
3. Do not use the membrane if it is torn or damaged.
4. OSSIX Agile™ is sterile if the packaging is unopened and undamaged. Do not use membrane if the sterile packaging is opened or damaged, because the function and safety of the product can no longer be guaranteed.
5. Any remaining or unused membrane can be disposed of with normal clinical waste, but local regulations must also be observed.
6. OSSIX Agile™ should be stored at temperatures between 15-25°C (59-77°F).

HOW SUPPLIED

1. OSSIX Agile™ is supplied in a double blister pack, for single use only. Each pack contains one membrane.
2. OSSIX Agile™ is available in four sizes: 10x12 mm, 15x20 mm, 20x30 mm and 30x40 mm.

Product size:	10±1 x 12±1 mm	15±1.5 x 20±2 mm	20±2 x 30±3 mm	30±3 x 40±4 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
https://www.datumdental.com/en/resources/clinicians/symbols-glossary/

SYMBOLS

Manufacturer

Authorized Representative in the European community /European Union

Use-by date

Batch code

Catalog number

	Importer
	Distributor
	Sterilized using ethylene oxide
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Double sterile barrier system
	Temperature limit
	Do not-reuse
	Consult instructions for use
	Caution
	Contains biological material of animal origin
	Medical device
	Unique device identifier
	Open here

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

Manufacturer
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