

Striate+™

Periodontal membrane

INTENDED USE

Striate+™ is a resorbable collagen barrier membrane intended for use in guided bone and tissue regeneration prior to implant placement, simultaneous with implant placement or for maxillary sinus augmentation.

INDICATIONS FOR USE

Striate+™ is indicated for use in the treatment of alveolar bone defects in oral and maxillofacial surgery.

DESCRIPTION

Striate+™ is a barrier membrane designed to protect the bone defect space from ingrowth of gingival tissue, provide a favorable environment for osteogenesis and maintains its barrier function long enough to allow for bone regeneration to occur.

Striate+™ is composed of purified type I collagen. Striate+™ is manufactured from porcine-derived raw materials, selectively sourced from Australian veterinary-certified animals and manufactured without crosslinking. Striate+™ is provided in a double blister pack and sterilized by gamma irradiation.

PROPERTIES

Striate+™ collagen membranes have a bilayer structure with a rough and a smooth side. The rough side, which is placed facing the bone defect, is composed of randomly distributed collagen bundles that provide a porous structure for migration of osteogenic cells. The smooth side, which faces the gingival tissue, is composed of parallel arrangements of densely packed collagen bundles that permit passage of fluids but act as a barrier to prevent the ingrowth of epithelial cells into the defect.

Striate+™ retains its structural integrity when wet and conforms to the contours of the defect. Striate+™ has sufficient tensile strength to be sutured or pinned in place, if required. Striate+™ is fully resorbed through normal physiological processes within 26 weeks. A second surgical procedure to remove the membrane is not required.

Striate+™ is classified as MR as it is composed of materials that are electrically non-conductive, non-metallic and non-magnetic.

CONTRAINDICATIONS

Striate+™ should not be used where there is evidence of active infection at the treatment site.

The use of Striate+™ in patients with known sensitivity to porcine-derived materials or collagen is contraindicated.

INSTRUCTIONS FOR USE

General principles of surgical practice and sterile handling should be followed. Striate+™ is provided in a double sterile barrier packaging. The inner tray is intended to be opened within a sterile field.

1. Prior to guided bone regeneration procedures, prophylactic antibiotic therapy and counselling the patient in good oral hygiene practices is recommended.
2. Following the completion of surgical procedure(s), bone defects are filled as required with bone graft or other void-filling material.

3. Trim Striate+™ to the required size using sterile technique. The membrane should significantly overlap the walls of the defect to assure adequate enclosure and prevent soft-tissue invasion. Striate+™ does not require pre-wetting.
4. Apply Striate+™ with the rough side of the membrane facing the bone defect and the smooth side facing the oral cavity.
5. Apply gentle pressure until the membrane is uniformly wet and conforming and adhering to the underlying surface.
6. To prevent membrane displacement, Striate+™ may be fixed in place with sutures or pins, if required.

POST-OPERATIVE CARE

Patients should be monitored closely in the initial post-operative period. The use of antibiotics and oral antiseptics following surgery is recommended.

Patients should be provided with guidance on the maintenance of good oral hygiene.

Destructive parafunctional habits (bruxism, clenching), attrition or excessive orthodontic appliances may impede healing. Patients should be provided with guidance on how to minimize damage to the treatment site.

WARNING/PRECAUTIONS

Striate+™ should only be used by qualified dentists and oral surgeons.

Striate+™ is a single-use product. Re-use may result in severe adverse reactions, illness or infection. Any unused product must be discarded.

Do not use the product if damaged or opened.

Striate+™ must be stored at room temperature (15-25°C) in a dry place.

Caution may be required when using Striate+™ in patients with compromised healing capacity due to:

- Uncontrolled metabolic disease (e.g. diabetes)
- Anti-coagulant / blood-thinning therapy
- Treatment with high doses of anti-inflammatory medications or bisphosphonates
- Autoimmune diseases
- Radiotherapy
- Heavy smoking

SIDE EFFECTS

Possible side effects or complications associated with the surgical procedure may include infection, localized tissue reaction (inflammation, wound dehiscence), membrane exposure, bleeding or pain.

INCIDENT REPORTING

Please contact the manufacturer, authorized representative, importer or distributor to report any serious incidents in relation to the use of Striate+™. The Summary of Safety and Clinical Performance (SSCP) for Striate+™ can be found on the European database for medical devices (EUDAMED).


(<https://ec.europa.eu/tools/eudamed/#/screen/home>)


PRODUCT RANGE


REF	Size
OCG-152	Striate+™ 15 x 20 mm
OCG-203	Striate+™ 20 x 30 mm
OCG-304	Striate+™ 30 x 40 mm
OCG-405	Striate+™ 40 x 50 mm

PATIENT IMPLANT CARD

A Patient Implant Card has been provided with this Striate+ Periodontal Membrane, together with an instructional leaflet on how to complete the card. Please ensure that you update the required fields and give the card to the patient for them to keep. Use the Billing and Implant label provided or ballpoint pen or other indelible ink to complete the required information.


 **European Union Authorized Representative:**
MDSS GmbH - Schiffgraben 41, 30175 Hannover, Germany

 **Swiss Authorized Representative:** MDSS CH GmbH - Laurenzenvorstadt 61, 5000 Aarau, Switzerland

 **European Importer:** MedEnvoy - Prinses Margrietplantsoen 33-Suite 123, 2595 AA The Hague, NL



























Swiss Importer: MedEnvoy – Gotthardstrasse 28, 6302 Zug, CH

 **Manufacturer:** Orthocell Ltd
Building 191 Murdoch University
South Street, Murdoch
Western Australia 6150
+61 8 9360 2888 www.orthocell.com

 **Distributed by:** Biohorizons
2300 Riverchase Center, Birmingham AL 35244, USA www.biohorizons.com

A paper IFU is available from your distributor, or you can make a request via the Orthocell website

SYMBOLS USED IN LABELLING

-  Manufacturer
-  Use-by date
-  Batch code
-  Catalogue number
-  Date of manufacture
-  Importer
-  Distributor
-  Authorized representative in the EU
-  Authorized representative in Switzerland
-  Sterilized using irradiation
-  Do not re-sterilize
-  Do not use if package is damaged
-  Double sterile barrier system
-  Keep away from sunlight
-  Keep dry
-  Temperature limit 15-25°C
-  Do not re-use
-  Consult instructions for use
-  Contains biological material of animal origin
-  Unique device identifier
-  Medical Device
-  Available on prescription only
-  Date of implantation
-  Name and address of institution/provider who performed the implantation
-  Patient Name
-  Patient information website address