Striate+™

CE 2797

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 favourable 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 form 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, so a second surgical procedure to remove the membrane is not required.

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

CONTRAINDICATIONS

Striate+™ should not be used if 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 existing orthotic appliances may impede healing. Patients should be provided with guidance on how to minimise damage to the treatment site.

WARNING/PRECAUTIONS

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

Striate+™ is a single-use product. 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, inflammation, wound dehiscence, membrane exposure, bleeding or pain.

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INCIDENT REPORTING

Please contact the manufacturer, UK Responsible Person, 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

UK Responsible Person:
QCS International
Unit 9 Cumbernauld Business Park
WardPark Rd, Glasgow G67 3JZ, UK
ukrp@qcsl.co.uk

UK Importer: MedEnvoy UK Limited
85 Great Portland Street, First Floor
London W1W 7LT, United Kingdom

Manufacturer:
Orthocell Ltd
Building 191 Murdoch University
South Street, Murdoch
WA 6150 Australia
+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
LOT	Batch code
REF	Catalogue number
	Date of manufacture
	Importer
	Distributor
EC REP	Authorized representative in the EU
CH REP	Authorized representative in Switzerland
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Double sterile barrier system
	Keep away from sunlight
	Keep dry
	Temperature limit
	Do not re-use
	Consult instructions for use
BIO	Contains biological material of animal origin
UDI	Unique device identifier
MD	Medical device
℞ ONLY	Available on prescription only
	Date of implantation
#	Name and address of institution/provider who performed the implantation
?	Patient name
	Patient information website address

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Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Alison Carleton	Regulatory Affairs Associate	13-Jul-2022 15:24 (GMT+8)
Review	Monique Cannon	Quality Director	13-Jul-2022 17:56 (GMT+8)
Send for Approval	Alison Carleton	Regulatory Affairs Associate	31-Mar-2023 13:29 (GMT+8)
Approve	Daniel McKie	Quality Assurance Manager	31-Mar-2023 13:30 (GMT+8)
QA Approval	Daniel McKie	Quality Assurance Manager	31-Mar-2023 13:30 (GMT+8)