Striate+

Instructions for use

Implantable Collagen Membrane

Striate+[™] is a biocompatible, sterile, resorbable collagen barrier membrane intended for use in guided bone and guided tissue regeneration procedures.

Indications for use

Striate+™ is indicated for use in:

- Augmentation around implants placed in immediate extraction sockets:
- Augmentation around implants placed in delayed extraction sockets;
- Filling of bone defects after root resection or removal of retained teeth;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in intra-bony periodontal defects.

Description

Striate** is composed of purified collagen of porcine origin and is produced using quality-controlled manufacturing processes. Raw materials are selectively sourced from thin Australia from veterinary-certified anim is and manufactured without crosslinking a sints. Striate** is packed in double blister pack in sterilized by irradiation.

Properties

Striate** is a barrier membrane designed to protect the bone defect space from ingrowth of gingival tissue and provide a favorable environment for osteogenesis, and to persist long enough to allow sufficient time for bone regeneration to occur.

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 a loose distribution of collagen bundles that provides an open scaffold which allows entry 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 ingrowth of epithelial cells into the defect. Animal studies have shown that Striate+" provides an eff barrier, allowing bone regeneration to o cur in the defect space, and is then complet in resorbed into the surrounding tissu.

Striate+** retains its structural integing when wet, while conforming to the consumer of the defect. Striate+** has sufficient in the ength to be sutured or pipped in p. -2 if required.

Contraindica or

Striate+ $^{\text{M}}$ should not be used there is evidence of active in a new treatment site.

The us of Striate in patients with known senitive to porce-derived materials or lagen a continuidated.

Dir tions for use

General principles of surgical practice and as is technique should be adhered to.

- Prior to guided bone and tissue regeneration procedures, anti-infective therapy to eradicate any bacterial infection and counseling of the patient in good oral hygiene is highly recommended.
- Surgically expose the bone defect and create a mucoperiosteal flap suitable for wound closure. Debride and plane the root surface carefully. Adequate debridement

- and implant surface disinfection should be achieved before bone augmentation around implants in peri-implantitis bone defects.
- Fill the bone defect with bone graft or other void-filling material, taking care not to overfill the defect. Void fillers and implants must be adequately localized or fixed in place prior application of the Striate* membrane.
- 4. Trn Striate+** to the required size using steri. "chnique. The membrane should signi antly overlap the walls of the defect sure adequate enclosure and prevent soft-tissue invasion. Striate+** does not require pre-wetting.
- Apply Striate+™ over the defect and apply gentle pressure until the membrane is uniformly wet and conforming and adhering to the underlying surface. The rough side of the membrane is placed facing the bone defect and the smooth side faces the oral cavity.
- To avoid the formation of excessive junctional epithelium when treating periodontal defects, it is important to adapt Striate+** closely to the treated tooth.
 - To prevent membrane displacement, Striate+™ may be fixed in place with sutures or pins, if required.
- Use the previously created mucoperiosteal flap to close the wound over the membrane.
- Complete wound closure is recommended but not essential. Excess tension to achieve wound closure may increase the risk of dehiscence and should be avoided

Post-operative care

 Patients should be monitored closely in the initial post-operative period. The use of prophylactic antibiotics and oral antiseptics following surgery is recommended. Good oral hygiene is essential in the period following implantation and dental practitioners should provide additional guidance to patients on maintenance of oral hygiene post- treatment.

- 2. Post-operative symptoms may include swelling, pain or mild inflammation and dental practitioners should provide guidance to patients in appropriate symptom management.
- Exposure of the Striate+™ membrane through wound dehiscence may occur and generally resolves spontaneously. Membrane removal is usually not required. In the event of membrane exposure, prophylactic treatment with antiseptic rinses to minimize the risk of bacterial contamination is recommended.
- 4. Allow sufficient time for bone regeneration before surgical re-entry.
- Destructive parafunctional habits (bruxism. clenching), attrition or existing orthotic appliances may impede repair if in contact with the site of repair. In that case, dental practitioners should provide guidance to the patient in how to minimize damage to the treatment site

Precautions

Striate+™ should only be used by qualific dentists and oral surgeons trained in quic bone and tissue regeneration procedures. Caution and close patient monitoring during the post-operative period may be required

when using Striate+™ in patients with impacts on healing capacity including due to:

- · Uncontrolled metabolic disease (e.g. diabetes, thyroid disorders)
- · Anti-coagulant / blood-thinning therapy

- · Treatment with high doses of antiinflammatory medications or bisphosphonates
- · Connective tissue diseases Autoimmune diseases
- Radiotherapy
- · Heavy smoking

Adverse reactions

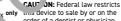
Complications that may be associated with the surgical procedure such as infection, dehiscence. membrane exposure, swelling, bleeding or pain should be discussed with the patient prior the procedure.

Adverse reactions to porcine-derive col membranes in dental procedures ar extre rare, but immune reactions are possit

Patients should be monitored closs in the initial post-operative period to ide ify and address any adverse reactions #1 nav oc

Storage and . ling

Store Striato+™ in original packaging at controll room tem, rature (15-25°C/59-77°F) in a dry blace.



only true device to sale by or on the order of a dentist or physician

rentation

Striace+™ is supplied in a double PETG/Tyvek tray contained in a labeled cardboard box.

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

Symbols used in labelling

Use-by date

LOT

Batch code

REF

Catalogue number

Date of manufacture



istributor



Sterilized using irradiation Double sterile barrier system



Do not desterilize



Do not re-use



Do not use if the blister packaging is damaged or opened.

FU-0000124 v6.0 (11 JAN 23)



Keep dry



Keep away from sunlight



Temperature limit 15-25°C/59-77°F

Contains biological material of animal origin Consult instructions for use





Medical Device



Unique device identifier



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