Striate+™

INSTRUCTIONS FOR USE

DESCRIPTION

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

Striate+™ is a highly purified collagen membrane of porcine origin produced using quality-controlled manufacturing processes. Raw materials are sourced exclusively from within Australia and collected at certified facilities under strict quality controls. The collagen is purified to remove materials that may elicit antigenic reactions. Striate+™ is manufactured with no crosslinking to ensure a highly biocompatible product.

Slight variations in the appearance of Striate+™ due to the biological origin of the membrane do not influence its clinical performance.

PROPERTIES

Striate+™ is designed to protect the bone defect space from ingrowth of gingival tissue to provide a favorable environment for osteogenesis and 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 is composed of a random, loose distribution of collagen bundles that provides a scaffold for cellular ingrowth and the smooth side is composed of parallel arrangements of densely packed collagen bundles that permits passage of fluids but acts as a barrier to cellular ingrowth.

Striate+™ is hydrophilic, conforming to the contours of the defect, and may be sutured or pinned in place if required. A second surgical procedure to remove the membrane is not needed. Animal studies have shown that Striate+™ is still visible 5-13 weeks after implantation but is fully resorbed through normal physiological processes within 26 weeks.

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
- Localized ridge augmentation for later implantation
- Alveolar ridge reconstruction for prosthetic treatment
- Filling of bone defects after root resection, cystectomy, removal of retained teeth
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in periodontal defects.

DIRECTIONS FOR USE

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

1. 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.
2. 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.
3. Fill the bone defect with bone graft or other void-filling material, taking care not to over-fill the defect. Void fillers and implants must be adequately localized or fixed in place prior to application of the Striate+™ membrane.
4. 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.
5. 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.
6. To avoid the formation of excessive junctional epithelium when treating periodontal defects, it is important to adapt Striate+™ closely to the treated tooth.
7. To prevent membrane displacement, Striate+™ may be fixed in place with sutures or pins, if required.
8. Use the previously created mucoperiosteal flap to close the wound over the membrane.
9. 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

1. 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.
3. 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.
5. 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.

LIMITATIONS OF USE

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.

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 to the procedure.

Adverse reactions to porcine-derived collagen membranes in dental procedures are extremely rare, but immune reactions are possible.

Patients should be monitored closely in the initial post-operative period to identify and address any adverse reactions that may occur.

Precautions

Striate+™ should only be used by qualified dentists and oral surgeons trained in guided 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 anti-inflammatory medications or bisphosphonates
- Connective tissue diseases
- Autoimmune diseases
- Radiotherapy
- Heavy smoking

PATIENT IMPLANT CARD

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

STORAGE AND HANDLING

Store Striate+™ in its original packaging at controlled room temperature (15°-25°C) in a dry place.

PRESENTATION

Striate+™ is supplied in PETG/Tyvek double blister pack contained in a labelled 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

If you have any concerns or questions about this product, please contact Orthocell or your Distributor.

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

Distributed by:
BioHorizons
2300 Riverchase Center
Birmingham AL 35244
USA
biohorizons.com

SYMBOLS USED IN LABELLING

- Use-by date
- Batch code
- Catalogue number
- Date of manufacture
- Importer
- Distributor
- Sterilized using irradiation
- Double sterile barrier system
- Do not resterilize
- Do not re-use
- Do not use if package is damaged or opened
- Keep dry
- Keep away from sunlight
- Temperature limit 15-25°C/59-77°F
- Consult instructions for use
- Unique device identifier
- Medical device
- Contains biological material of animal origin
- Available on prescription only