perFORM™

Collagen Membrane

INSTRUCTIONS FOR USE

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

INDICATIONS FOR USE

perFORM™ 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

perFORM™ is composed of purified collagen of porcine origin and is produced using quality-controlled manufacturing processes. Raw materials are selectively sourced from within Australia from veterinary-certified animals and manufactured without crosslinking agents. perFORM™ is packed in double blister packs and sterilized by irradiation.

PROPERTIES

perFORM™ 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.

perFORM™ 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 perFORM™ provides an effective barrier, allowing bone regeneration to occur in the defect space, and is then completely resorbed into the surrounding tissue.

perFORM™ retains its structural integrity when wet, while conforming to the contours of the defect. perFORM™ has sufficient tensile strength to be sutured or pinned in place if required.

CONTRAINDICATIONS

perFORM™ should not be used if there is evidence of active infection at the treatment site.

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

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 perFORM™ membrane.
4. Trim perFORM™ 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. perFORM™ does not require pre-wetting.
5. Apply perFORM™ 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 perFORM™ closely to the treated tooth.
7. To prevent membrane displacement, perFORM™ 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 perFORM™ 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.

PRECAUTIONS

perFORM™ 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 perFORM™ in patients with impacts on healing capacity 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

ADVERSE REACTIONS

Complications that may be associated with the surgical procedure such as infection, swelling, bleeding, dehiscence 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.

STORAGE AND HANDLING

Store perFORM™ in its original packaging at controlled room temperature (15-25°C/59°-77°F) in a dry place.

℞ only

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.

PRESENTATION

perFORM™ is supplied in a PETG/Tyvek double blister pack contained in a labelled cardboard box.

perFORM™ size variants

Ref	Size
perf1520	15 x 20 mm
perf2030	20 x 30 mm
perf3040	30 x 40 mm

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

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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
- Medical device
- Contains biological material of animal origin
- Unique Device Identifier