Resorbable Membrane - Collagen Membrane

A Product Description

Collagen membrane is a resorbable membrane to aid the regenerative healing of bone or bone/periodontal ligament defects of the oral cavity. Collagen membrane is designed to be a passive barrier which excludes epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur. Collagen membrane is sterilized in vacuum wrap by gamma-radiation.

B Indications for use

Collagen membrane is intended to be used during guided bone and guided tissue regeneration procedures as a biodegradable barrier membrane into bony defects surrounding teeth and on alveolar ridges.

- Periodontal/infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Guided bone regeneration (GBR) procedures
- Sinus lifts

C Contraindication

Collagen membrane should not be used for patients with

- A known allergy to collagen
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Chronic high dose therapy with corticosteroids.
- Osteomyelitis at the surgical site
- Vascular impairment at the implant site
- Severe renal dysfunction, liver disease

D Directions for use

1) Maintain sterile conditions throughout procedure.
2) Prepare a full thickness Mucoperiosteal flap.
3) Preserve interdental papillae and excise pocket epithelium.
4) Thoroughly scale and plane the root surface, and debride the defect of any granulomatous tissue.
5) Preserving a space under the membrane, trim the membrane for adequate defect coverage and cover the defect area completely.
6) Adapt the margins of the membrane to the alveolar bone.
7) If necessary, stabilize the membrane.
8) Suture mucoperiosteal flap over the material.

E Post-operative reminder

- Do close patient monitoring and professional prophylaxis at least biweekly for the first 8 weeks.
- Exposed material may be removed anytime post-operatively at the clinician's discretion.
- Post-operative management may also include antibiotic therapy at the clinician's discretion.
- If complications develop which can not be controlled by standard post-operative treatments, immediate membrane removal is recommended.
- In the event of tissue inflammation or evidence of infection, the membrane may be removed at the clinician's discretion.

F Precaution

- There can be patients having medical conditions which may pu them at increased risk for complications following periodontal surgery. Patients with a heart valve of other prosthetic device, heart valve defects (i.e., heart murmur, prolapsed mitral valve, history of rheumatic heart disease, etc.) or uncontrollable dia betes are specific examples.
- Effect on pediatric patient is not known.
- Effect on pregnant woman is not known.
- Collagen membrane containing bovine collagen may induce BSE risks

G Warning

- Single use only, do not re-sterilize or reuse.
- Collagen membrane should not be placed where active infection exists.
- Do not use if package is opened or damaged, or if expiration date has been passed.
- Use under sterilized condition.
- Open the product just before operation.
- Do not use patients who have a known allergy to collagen.

H Adverse reaction

- This membrane is a collagen product, and in very rare cases allergic reactions may occur.
- Possible complications with any periodontal surgery include thermal sensitivity, gingival recession, flap sloughing, resorptionor ankylosis of the treated root, some loss of crestal bone height, perforation or abscess formation, pain, swelling, inflammation, infection, gingival irregularities, and complications associated with the use of anesthesia.
- Depending on the type and severity of the complication, as judged by the clinician, membrane removal or antibiotic therapy may be required. (Please refer to the section on post-operative reminders.)

I Symbols

REF	Catalogue number	LOT	Batch code
	Do not re-use		Date of manufacture
	Caution		Use by date
STERILE R	Sterilized using irradiation		Manufacturer
1°C 30°C	Temperature limit		Do not resterilize
	Do not use if package is damaged and consult instructions for use		

J Storage condition

Storage in a dry room temperature
(recommended refrigerated storage below 4°C)

K Caution

The clinician must discuss the use of bovine animal tissue related products with patients who may object to their use one religious or ethical grounds, and inform the patient of the BSE risk of the device in advance of the procedure.

L Articles

REF	Size (mm)
GCM1020	10 x 20
GCM1520	15 x 20
GCM1530	15 x 30
GCM2030	20 x 30
GCM3040	30 x 40

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