Collagen Graft 2

A Product description

Collagen Graft2 is a Resorbable Tissue Regeneration inducer used for the protecting the surgical area and assisting the tissue defects or implants procedures. Product is composed of collagen and secures a soft tissue space in the form of a porous sponge in a bi-layer Product is composed of collagen and increases soft tissue in the form of a porous sponge in a bi-layer. Also, collagen graft 2 is provided with gamma sterilization.

B Indication for use

Collagen Graft 2 Resorbable periodontal tissue regeneration inducer that protects the surgical area and helps regenerate periodontal tissue

- Ridge preservation (open healing)
- Keratinized tissue augmentation
- Recovery of keratinized mucosa
- Root coverage

C Contraindication

General contraindications are as follows, but are determined by the practitioner in each case $\,$

- Collagen allergy symptoms
- Endocrine dysfunction
- (hypothyroidism and hyperthyroidism, parathyroid dysfunction, adrenal cortical dysfunction)
- Circulatory disease (angina plexus, myocardial infarction, congestive heart failure, chronic cardiomyopathy, High and low blood pressure, etc.)
- Respiratory diseases (bronchial asthma, etc.)
- Kidney disease, hematodyscrasia
- Bone disease (osteoporosis, osteomalacia, Behcet's disease, etc.)
- Collagen disease
- Pregnant women, menstruation, drug addiction, alcoholism, allergic diseases, etc.

D Directions for use

- 1) Maintain sterile conditions throughout procedure.
- Cut the product using a sterilized instrument for the implantation site.
- Check the location of the product before implantation and place it on the implant site.
- 4) Close enough to dead space.
- 5) Finish with minimal suture
- 6) Be careful of product deformation due to pressure when sealing

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 poste-operative treatments, immediate material removal is recommended
- In the event of tissue inflammation or evidence of infection, the material may be removed at the clinician's discretion

F Precaution

- -There can be patients having medical conditions which may put them at increased risk for complication 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 diabetes are examples.
- Effect on pediatric patient is not known.
- Effect on pregnant woman is not known.

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 sponge 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, some loss of bone, 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.)

■ Symbols

| REF | Catalogue number | LOT | Batch code |
|-------------|--|-----------|---------------------------------|
| (2) | Do not re-use | ~ | Date of manufacture |
| \triangle | Caution | | Use by date |
| 1°C 30°C | Temperature limit | | Manufacturer |
| | Do not resterilize | STERILE R | Sterilized using irradiation |
| (SQ) | Do not use if package is damaged and consult | | |

J Caution

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

instructions for use

K Articles

| REF | Size(mm) | Thickness(mm) | |
|----------|----------|---------------|--|
| PSD10C | Ø10 | | |
| PSD1010 | 10x10 | | |
| PSD1020 | 10x20 | 3 | |
| PSD1520 | 15x20 | | |
| PSD2030 | 20x30 | | |
| PSD10CM | Ø10 | | |
| PSD1010M | 10x10 | | |
| PSD1020M | 10x20 | 2 | |
| PSD1520M | 15x20 | | |
| PSD2030M | 20x30 | | |
| PSD10CL | Ø10 | | |
| PSD1010L | 10x10 | | |
| PSD1020L | 10x20 | 2.5 | |
| PSD1520L | 15x20 | | |
| PSD2030L | 20x30 | | |

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