Resorbable Membrane - Collagen Membrane 2

A Product information

1. Product name: Collagen Membrane 2
2. Classification name: Barrier, intra oral, resorbable

B Product description

This medical device is a resorbable dental membrane made of bovine-derived collagen. By securing a space in the area where bone regeneration is required, it prevents the downward movement of soft tissue to help the periodontal tissue regeneration, and it is absorbed after a certain period of time, so there is no need for secondary surgery to remove the product.

C Intended purpose

It is a resorbable membrane that helps to regenerate periodontal tissue, so there is no need for secondary surgery to remove it.

D Precautions during use

1. Warning
   1) This product is a sterile product, so make sure that the sterile state is maintained during the procedure, and do not use the product whose expiration date has passed.
   2) Use the product after examining the packaging for damage or contamination of the product and checking the expiration date. Do not use expired, damaged of contaminated products.
   3) Single-use only, do not re-sterilize or re-use.
   4) Only qualified medical professionals must administer the surgery.
2. Contraindications
   1) Collagen Membrane 2 should not be used for patients with
      ① Metabolic diseases (diabetes, etc.)
      ② Endocrine dysfunction (hypothyroidism, hyperthyroidism, parathyroid dysfunction, adrenal cortex disease, etc.)
      ③ Circulatory diseases (angina, myocardial infarction, congestive heart failure, chronic valvular disease, hypertension, hypotension, etc.)
      ④ Respiratory disease (bronchial asthma, etc.)
      ⑤ Kidney disease, blood disease
      ⑥ Bone disease (osteoporosis, osteomalacia, Behcet's disease, marble disease, etc.)
      ⑦ Diffuse collagen disease
      ⑧ Pregnant women, during menstruation, drug addiction, alcoholism, allergic diseases, etc.
   2) The following cases are generally considered contraindicated unless there is an improvement in symptoms.
      ① If there is a severe inflammatory disease in the oral cavity
      ② In case of impacted tooth, cyst, residual root, tumor, etc.
      ③ If there is a history of poor healing
      ④ When the amount of alveolar bone is small (vertical to the buccal path)
      ⑤ In case of poor alveolar bone quality (osteoporosis, osteomalacia, Behcet disease, etc.)
      ⑥ In case of bone defect of adjacent abutment
3. General precautions
   1) Surgery carries a risk of infection. An aseptic environment and standard procedures should be followed to prevent cross-contamination.
4. Precautions for undesirable effects
   1) This product is a collagen product, and in very rare cases allergic reactions may occur.
   2) After using the product, complications such as foreign body reaction, inflammation, edema, adhesions, and subgaleal seromas may occur.
   3) Depending on the type and severity of the complications, as judged by clinician, membrane removal or antibiotic therapy may be required.
   4) Redness, edema, and tissue loss may occur if the product is exposed inadvertently during suturing, so remove it when exposed.
5. Patient conditions
   1) Do not use a patient who has the potential to cause side effects. Special att

E Directions for use

1. Precaution before use
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      ① The surgical technique for the implantation of this product requires a special and complicated procedure. Formal training on product implantation is recommended.
      ② The operator must be fully aware of the surgical method using the surgical instrument of this product, clinical indications, and precautions.
      ③ Decide on the appropriateness of the location for this product to be implanted and the location for local surgery. Before using this product, it is necessary to establish a treatment plan through appropriate radiographic measurement and direct palpation, and establish a treatment plan through visual inspection of the implantation site.
      ④ Select and prepare a model with specifications suitable for the surgical site and purpose.
      ⑤ Check whether the expiration date of the product has expired.
      ⑥ Check the inner packaging of the product. Since the inner packaging is sealed and sterilized, do not use if damaged.
      ⑦ Check if there are any factors that may impair the surgical result.
   2) Establishment of patient treatment plan
      ① Medical evaluation
         a. Investigation of an appropriate medical history
         b. Surgeon review of patient's investigation
         c. Physical and therapeutic evaluation
         d. Medical advice or clinical pathological examination, if necessary
      ② Establishment of radiological plan
         a. Established by apical imaging, occlusal picture, panoramic picture, cephalolateral picture, conventional tomography, CT scan, MRI, etc.
   3) Sterilization of surgical instruments
      ① Instruments used for surgical procedures in hospitals are strictly sterilized according to the procedure, and contamination is prevented after sterilization
2. Treatment procedures
   1) Prepare a fill thickness mucoperiosteal flap.
   2) Preserve interdental papillae and excise pocket epithelium.
   3) After accurately measuring and leveling the treatment area, check the size and prepare the product.
   4) Open the product after checking the type and size of the product specified on the packaging and label.
   5) Cut the product using a sterile instrument to fit the treatment site.
   6) Check the location of the product before treatment, and place it on the treatment site.
   7) Cut the product to be in contact with the bone at least 2mm and cover the edge of the defect to prevent the soft tissue of the gingiva from penetrating downward.
   8) Adapt the margins of the membrane to the alveolar bone.
   9) When a load is applied or it is judged that there is movement, fixing may be necessary to prevent displacement of the product.
   10) Suture mucoperiosteal flap over the product.
3. Storage after use
   1) The product after use is legally disposed of as medical waste.
   2) Do not re-sterilize.

F Storage

Store at room temperature (1°C ~ 30°C)

G Expiration Date

2 years from manufacture date

H Number of uses

Single-use sterile medical device, do not re-use

I Packing Unit

1EA

J Symbol

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
	Consult instructions for use		Do not use if package is damaged and consult instructions for use

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