

COLLAGUIDE™ COLLAGEN MEMBRANE

DESCRIPTION

The CollaGuide™ Collagen Membrane is a translucent, non-friable collagen membrane derived from bovine hide. CollaGuide™ Collagen Membrane is resorbable which eliminates the need for a second surgical procedure that is normally required to remove a non-resorbable membrane.

CollaGuide™ Collagen Membrane has a morphology of dense fibers for mechanical strength. Its dense fibrous structure creates porosity designed to retard epithelial downgrowth and prevent gingiva connective cell migration into the wound site.

INDICATIONS

CollaGuide™ Collagen Membrane is indicated for:

- simultaneous use of GBR-membrane and implants.
- augmentation around implants placed in immediate extraction sites.
- 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.
- guided tissue regeneration procedures in periodontal defects.

CONTRAINDICATIONS

The CollaGuide™ Collagen Membrane is contraindicated in patients who have:

- acute infections or contaminated wound in the oral cavity
- known allergy to collagen of animal origin or other bovine derived products
- clinically significant renal, hepatic, cardiac, endocrine, hematologic, autoimmune or systemic disease, which in the physician's judgment, will prevent safe implantation or likely healing

WARNING

Clinicians should use extra care in screening their patients for any known allergies to collagen or bovine derived products. Hypersensitivity reactions have been noted with the use of other products containing bovine collagen; therefore, the possibility exists of developing a local sensitivity response to the CollaGuide™ Collagen Membrane.

PRECAUTIONS

- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.

- Single patient use only. **Do not resterilize.** Discard all open and unused portions of the CollaGuide™ Collagen Membrane
- Rinse surgical gloves to remove any glove powder prior to handling the CollaGuide™ Collagen Membrane.
- In case of membrane exposure during the healing phase the resorption time may be accelerated.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that device is hydrated prior to cutting, trimming or placement.

ADVERSE REACTIONS

Possible complications that can occur with any dental surgery can include infections, swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis, with loss of crestal bone height, pain, or complication associated with the use of anesthesia. Minor discomfort may occur for a few days.

INSTRUCTIONS FOR USE

Preparation

1. General principles of sterile handling and patient medication must be followed when using the CollaGuide™ Collagen Membrane. The device is packaged in double sterile trays. The outer tray should be opened carefully, allowing the inner tray to be placed onto the sterile field. The membrane should be removed from the inner tray using sterile gloves or instruments.
2. The periodontal or bone defect is exposed by creating a mucoperiosteal flap and basic surgical procedures are performed (e.g. curettage). The clinician should perform thorough debridement and good planing of the defect. Space-making material such as autologous bone, demineralized bone matrix and ceramic materials may be used to fill the defect. As much tissue as possible should be preserved to allow for primary closure of the wound and correct positioning of the flaps.

Hydration and Placement Procedure

1. Hydrate the CollaGuide™ Collagen Membrane in an excess of sterile saline for approximately 5 minutes prior to final placement.
2. The CollaGuide™ Collagen Membrane can be trimmed to the size and shape of the defect in the hydrated state using sharp, sterile scissors.
3. The CollaGuide™ Collagen Membrane should overlap the walls of the defect by at least two (2) mm to allow complete bone contact and prevent gingival connective tissue invasion below the material.
4. Fixation of the membrane may be indicated to avoid displacement due to loading or mobilization. The membrane can be sutured in place using absorbable sutures and a non-cutting needle. Resorbable tacks can also be used to affix the membrane. The mucoperiosteal flap is sutured over the collagen membrane and the wound should be closed completely to avoid accelerated resorption due to membrane exposure.

Postoperative Procedure

1. CollaGuide™ Collagen Membrane is completely resorbable and should not need to be removed. To minimize bacterial contamination, patients should rinse with an antimicrobial agent such as chlorhexidine gluconate (Peridex) twice daily for four weeks following surgery.
2. The patient should refrain from brushing for two weeks following surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Dental floss should not be used prior to four weeks following surgery. Coronal scaling and prophylaxis can be performed at follow-up visits, if indicated.
3. The patient should be seen seven to ten days following surgery for wound reevaluation and removal of any closing sutures or periodontal packing. These follow-up visits should be repeated every two weeks thereafter, up to eight weeks following surgery.
4. Probing and subgingival scaling should not be performed prior to six (6) months following surgery to prevent damage to immature tissues. Other assessments of clinical health may be repeated, including plaque, bleeding and tooth mobility indices. The CollaGuide™ Collagen Membrane should resorb within eight (8) months.

HOW SUPPLIED

The CollaGuide™ Collagen Membrane is supplied in a tray-in-tray configuration, with one membrane per package. CollaGuide™ Collagen Membrane is sterilized by ethylene oxide and is for single use only.

STORAGE

Store at controlled room temperature (15-25°C) and in a dry place.

CAUTION:

Federal (U.S.A.) law restricts this product to sale by or on the order of a physician.

CollaGuide™ Collagen Membrane

Distributed by:
Riemser, Inc.
P.O. Box 12339
Research Triangle Park, NC 27709-2339
Phone: 888-237-2767
www.RIEMSERdental.com

Manufactured by:
Kensley Nash Corporation
Exton, PA 19341 USA
Phone: 800-524-1984
www.kensleynash.com