ACE SURGICAL SUPPLY CO., INC.

conFORM™ Resorbable Collagen MEMBRANE

CONFORM™ RESORBABLE COLLAGEN MEMBRANE

INSTRUCTIONS FOR USE

Intended Use:

ConForm™ Resorbable Collagen Membrane is a bioresorbable, implantable collagen material that is intended for use dental surgery procedures as a material for placement in the area of dental implant, bone defect or ridge reconstruction to aid in wound healing post surgery.

Description:

ConForm™ Resorbable Collagen Membrane is a white, nonfriable membrane matrix engineered from highly purified type I collagen fibers derived from bovine Achilles tendon. CONFORM(TM) Resorbable Collagen Membrane is resorbable which eliminates the need for a second surgical procedure that is normally required to remove a non-resorbable membrane.

ConForm™ Resorbable Collagen Membrane has a morphology of dense oriented fibers for mechanical strength. Macromolecular permeation studies have shown that the membrane is permeable to macromolecules. Its porosity is such that it effectively retards epithelial down growth and prevents gingiva connective cell migration into the wound site. The semi-permeability properties of the membrane permit the exchange of essential nutrients for wound healing.

ConForm™ Resorbable Collagen Membrane is sterilized by Ethylene Oxide and is for single use only.

Administration:

ConForm™ Resorbable Collagen Membrane is packaged in a double sterile pouch. The outer pouch should be opened carefully, allowing the inner pouch to be placed onto a sterile field. The membrane should be removed from the inner pouch with sterile gloves or instruments.

The bone defect is exposed by a mucoperiosteal flap and basic surgical procedures are performed (e.g. curettage). Space-making material such as autologous bone, demineralized bone matrix and ceramic materials may be used to fill the defect.

ConForm™ Resorbable Collagen Membrane can be placed either dry or hydrated. If the clinician prefers the handling characteristics of the hydrated collagen, the membrane can be hydrated in sterile water or saline solution for approximately five minutes prior to the final placement.

ConForm™ Resorbable Collagen Membrane can be trimmed to the size and shape of the defect in the dry or wet state using sharp, sterile scissors.

ConForm™ Resorbable Collagen Membrane should overlap the walls of the defect by at least 2 mm to allow complete bone contact and to prevent gingival connective tissue invasion below the material.

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.

Post-operative Procedures:

ConForm™ Resorbable Collagen Membrane is completely resorbable and should not be removed. Patients should rinse with an antimicrobial agent such as chlorhexidine gluconate (Peridex) twice daily for four weeks following surgery. Beginning 24 hours after surgery, the wound site may be additionally swabbed with a cotton-tipped applicator dipped in the antimicrobial agent.

The patient should refrain from brushing the treated area for two weeks following the surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Dental floss should not be used for four weeks following surgery. Coronal scaling and prophylaxis can be performed at follow-up visits, if indicated.

The patient should be seen seven to ten days following surgery for wound evaluation 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. The patient may return to normal oral hygiene routine.

ConForm™ Resorbable Collagen Membrane should be completely resorbed 26 to 38 weeks following surgery. However, probing and subgingival scaling should not be performed prior to six months following surgery to prevent damage to immature tissues. Other assessments of clinical health may be repeated, including plaque, bleeding and tooth mobility indices.

Contraindications:

ConForm™ Resorbable 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 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 ConForm™ Resorbable Collagen Membrane.

Precautions:

As with all surgical procedures, caution should be exercised when treating medically compromised patients such as patients receiving long-term steroidal therapy or currently taking anticoagulants. Patients with clinically significant systemic diseases, indicating a history of anaphylactic reactions, autoimmune diseases, uncontrolled diabetes or severe hypertension have not been implanted with the membrane; therefore, the safety and effectiveness for those patients have not been determined. Nor has it been evaluated in pregnant women, children and/or in patients with conditions involving extremely severe defects with little peridontium or bone.

ConForm™ Resorbable Collagen Membrane cannot be resterilized. Open, unused ConForm™ Resorbable Collagen Membrane must be discarded. *In vivo* stability may be adversely affected if re-sterilized.

Adverse Reactions:

Possible complications that can occur with any dental surgery include infection, 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 complications associated with the use of anesthesia. Minor discomfort may occur for a few days.

Safety:

The product is manufactured from bovine Achilles tendon, which is classified as tissues with no detected infectivity for Bovine Spongiform Encephalopathy, BSE (World Health Organization Guidelines). The bovine tendon is known to be one of the richest sources of type I collagen that is commercially available.

The manufacturing process for the product meets European Standards and International Standards for animal tissue sourcing, handling and inactivation of Spongiform Encephalopathy (SE) pathogens. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of SE pathogens.

A viral inactivation study for the product's manufacturing process was conducted by an independent laboratory. In this study key manufacturing steps were evaluated for their ability to inactivate the following viral strains: Bovine Viral Diarrhea (enveloped virus) and Porcine Parvoviradae (non-enveloped virus). The study results showed that each of the manufacturing steps evaluated, including the sodium hydroxide treatment, is effective in inactivating these viruses.

Storage:

The product should be stored at room temperature. Avoid excessive heat and humidity.

How Supplied:

One (1) membrane per package,
509-1520. conFORM 1.5cm x 2.0cm
509-2030. conFORM 2.0cm x 3.0cm
509-3040. conFORM 3.0cm x 4.0cm

Labeling Symbols

Symbols may be used on some international package labeling for easy identification.

Symbol for "Use Until Date"
Symbol for "Do Not Reuse"
Symbol for "See Instructions for Use"
STERILE EO Symbol for "Method of sterilization using Ethylene Oxide"
LOT Symbol for "Lot Number"
Rx only Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.
Symbol for "Temperature Limitation"

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