HeliMEND™
Absorbable Collagen Membrane

Instructions for Use
**Indications**

HeliMEND™ absorbable collagen membrane is an absorbable, implantable material that is indicated for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.

**Description**

HeliMEND™ absorbable collagen membrane is a white, compressed, non-friable matrix fabricated from collagen derived from bovine deep flexor (Achilles) tendon. Bovine tendon is known to be one of the purest sources of Type I collagen that can be readily obtained and processed in commercial amounts. The HeliMEND™ membrane is completely absorbable, eliminating the need for the second surgical procedure often required to remove a non-resorbable membrane. The collagen is currently used for general and dental surgery as absorbable hemostatic agents and absorbable wound dressings.

Under scanning electron microscopy, HeliMEND™ absorbable collagen membrane has a morphology of condensed laminated sheets in cross-section and a textured surface. The HeliMEND™ membrane appears paper white in the dry state and translucent and non-slippery when wet. The HeliMEND™ membrane can be cut to any size or shape in the wet or dry state, without tearing or fragmenting.

HeliMEND™ absorbable collagen membrane has an effective pore size of 0.004 microns, which will help to retard epithelial downgrowth during early phases of healing. Being semi-occlusive, it allows essential nutrients to pass through the membrane. The HeliMEND™ membrane incorporates into the surrounding tissue and is generally absorbed within 4-8 weeks.

HeliMEND™ absorbable collagen membrane is sterilized using ethylene oxide gas.
Contraindications

- HeliMEND™ absorbable collagen membrane is contraindicated in patients who have acute infections or contaminated wounds in the oral cavity.
- HeliMEND™ absorbable collagen membrane is contraindicated in clinical situations where periodontal surgery should not be performed.
- HeliMEND™ absorbable collagen membrane is contraindicated in patients with a known history of allergic responses to collagen.
- HeliMEND™ absorbable collagen membrane is contraindicated in patients who are allergic to bovine-derived products.

Warnings

Clinicians should use care in screening their patients for any known allergies to collagen or bovine-derived products.

Hypersensitivity reactions or immune reactions did not occur during the clinical trials evaluating the collagen membrane. All patients in the clinical trial were prescreened by a series of dermal patch tests for possible sensitivity reaction to the collagen. No patient prescreened developed a sensitivity reaction. Additionally, patients were assessed for a potential immune response to the collagen by evaluating their blood preoperatively and at several time points postoperatively using an enzyme linked immunosorbent assay (ELISA). No significant difference was observed in antibody titers between patients who received the collagen matrix and those who did not.

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 HeliMEND™ absorbable collagen membrane.
Changes in Performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as to seek the services of a trained dental professional if there are any changes in the performance of the membrane (e.g., infection, pain, any other unusual symptoms that the patient has not been told to expect). If these conditions occur, the patient should be instructed to see a trained dental professional immediately.

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 diseases, indicating a history of anaphylactic reactions, autoimmune disease, uncontrolled diabetes or severe hypertension have not been implanted with the device; therefore the safety and effectiveness for these patients have not been demonstrated.

The safety and effectiveness of the device has not been evaluated in pregnant women or children. Therefore, caution should be used in these patients.

HeliMEND™ absorbable collagen membrane cannot be resterilized. Opened, unused HeliMEND™ membrane must be discarded.

HeliMEND™ absorbable collagen membrane is not intended for use on defects outside the indications stated.

HeliMEND™ absorbable collagen membrane has not been clinically evaluated in patients with conditions involving extremely severe defects with little remaining periodontium.

HeliMEND™ absorbable collagen membrane has not been clinically tested for use in regeneration of alveolar bone, either in preparation for
or in conjunction with the placement of endosseous (dental) implants, or in the treatment of failing implants.

The template material is NOT TO BE IMPLANTED. It is to be used only as an aid in shaping the HeliMEND™ absorbable collagen membrane.

**Adverse Reactions**

Possible complications which can occur with any periodontal surgery include swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis of the treated root, some loss of crestal bone height, infection, pain or complications associated with the use of anesthesia.

As with any type of surgical therapy, the patient may experience minor discomfort for a few days.

Spontaneous exfoliation of the material may occur in the immediate postoperative period if the HeliMEND™ membrane is not adequately covered by the mucogingival flap.

**Preparation for Use**

- Open outer blister tray and remove sterile inner template “envelope” containing the sterile HeliMEND™ membrane. (see Fig. 1)
- Open sterile inner template “envelope” containing the HeliMEND™ membrane. (see Fig. 2)
- Carefully remove the implantable HeliMEND™ membrane from template “envelope.” (see Fig. 3)
- The template is a convenience item to assist in shaping the HeliMEND™ membrane. (see Fig. 4)
- The template is **not implantable** and must be discarded following modification of the HeliMEND™ membrane.
- The HeliMEND™ membrane is then placed over the defect.
Administration

It is advisable that only clinicians trained in related treatment planning and in the technique of placing periodontal membranes should use HeliMEND™ absorbable collagen membrane.

HeliMEND™ absorbable collagen membrane is packaged in a sterile configuration. HeliMEND™ absorbable collagen membrane is packaged inside a sterile piece of high density, medical grade polyethylene which can be used as a template to help trim the membrane to the desired shape. The embossed pattern on the template will distinguish it from the membrane. The absorbable collagen membrane and template material should be removed from their packaging using sterile gloves or instruments.

Mucoperiosteal incision flaps are developed in the site to be treated. The incision should be sulcular when possible. The clinician should perform thorough debridement. As much tissue as possible should be preserved to allow for primary closure of the wound and correct positioning of the flaps.

The HeliMEND™ 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 prior to final placement.

The product can be trimmed to the size and shape of the defect in the dry or wet state using sharp, sterile scissors. However, if using the template material to assist in material shaping, gross modification of the membrane should be performed in the dry state. An approximate shape can be cut from the template and modified to fit the given defect. The template is then placed against the absorbable collagen membrane and a duplicate shape is trimmed from the membrane. The template material is a convenience item to assist in shaping HeliMEND™ absorbable collagen membrane. It is not implantable and must be discarded following modification of the membrane.
The HeliMEND™ membrane is placed over the defect and as close to the tooth as possible. The absorbable collagen membrane should extend a minimum of 2-3 mm beyond the bony defect apically, mesially and distally. Additional trimming of the membrane may be performed, avoiding sharp corners that could perforate overlying tissue. The HeliMEND™ membrane can be sutured in place if desired using absorbable sutures and a non-cutting needle. Gingival flaps should be coronally positioned over the defect and the absorbable collagen membrane. The mucoperiosteal flap should completely cover the absorbable collagen membrane if possible and be sutured in place.

**Postoperative Procedures**

The HeliMEND™ membrane is fully absorbable and should not be removed.

Periodontal packing may be applied to the wound site. While this is a matter of clinician preference, care must be taken not to overcompress the area. Post-Operative care should include the following minimum steps:

Patients should rinse with an antimicrobial agent such as chlorhexidine gluconate twice daily for four weeks following surgery. The wound site may additionally be swabbed with a cotton-tipped applicator dipped in the antimicrobial agent.

The patient should refrain from brushing the treated area for two weeks following surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Instruction will be dependent on an evaluation of wound healing. 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.

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 six to eight weeks following surgery. The patient may then return to a normal oral hygiene routine.

The HeliMEND™ membrane should be completely absorbed 8 weeks following surgery. However, probing and subgingival scaling should not be performed prior to six months following surgery to prevent damage to immature regenerated tissues. Other assessments of clinical health may be repeated, including plaque, bleeding and tooth mobility indices.

**Storage**

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

**How supplied**

Individually packaged in a variety of sizes:

- 15 mm x 20 mm 1/box
- 20 mm x 30 mm 1/box
- 30 mm x 40 mm 1/box

**Caution**

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.
**Labeling Symbols**

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

- Use Until Date
- Do Not Reuse
- See Instructions for Use
- Sterilization method using ethylene oxide gas
- Peel Here
- Lot Number

**Rx ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufacturer
HeliMEND™ is manufactured by Integra LifeSciences Corporation for Miltex, Inc.

PRODUCT INFORMATION DISCLOSURE

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