InterCollagen® Guide

Porcine Derived Collagen Membrane

DEVICE DESCRIPTION

InterCollagen® Guide is a resorbable collagen membrane, derived from porcine pericardium. InterCollagen® Guide is intended for periodontal and/or dental surgical procedures as a barrier membrane restricting the entry of rapidly proliferating non-osteogenic cells within the bone defect while allowing the ingrowth of slow-growing bone forming cells. The membrane is a bio-resorbable barrier which eventually is remodeled and/or incorporated by the host tissue.

InterCollagen® Guide is substantially resorbed within 15 weeks after implantation. It is adaptable and easy to handle. It can be trimmed to the desired size and conforms easily when hydrated. The product is terminally sterilized via gamma irradiation.

INDICATIONS FOR USE

InterCollagen® Guide alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) can be used in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures as a biodegradable barrier for:

- in the context of a treatment of fenestration defects
- in case of dehiscence defects
- after apicoectomy and resection of retained teeth
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

INSTRUCTIONS FOR PREPARATION

InterCollagen® Guide is to be used by licensed dentists or oral surgeons only. When handling the product, general principles of sterile handling, safety, hygienic clinical practice, and patient medication must be followed.

Opening the Product

- The package should be inspected prior to use to confirm the sterile barrier has not been compromised. Ensure the presence of a red sticker on the package to identify the product is sterile.
- Do not use unless the integrity of the package can be verified.
- Do not use if the expiration date has been exceeded.
- Do not remove the membrane from packaging until just prior to implantation. Avoid contact between the membrane and unsterile objects. Do not leave the membrane in the open air.

Site Preparation

- Raise the mucoperiosteal flap to expose the bone defect. Follow basic requirements for successful surgical procedures (e.g. hygiene phase of treatment, curettage).
- Fill the bone defect with a graft material such as allograft, autogenous, xenogenic, or synthetic bone substitute at the discretion of the clinician. Do not overfill the defect; remove any excess residual material.
- Trim the membrane to fit the defect using sterile scissors. Trimming can be conducted in dry form or after wetting with the patient's blood or sterile 0.9% saline. The membrane may be easier to manipulate when dry.
- Use the membrane to overlap the walls of the defect by at least 2.0 mm to allow complete bone contact and to prevent migration of gingival connective tissue below the membrane. To avoid contamination, minimize contact of the membrane with other parts of the oral cavity, including saliva.
- Apply the membrane over the defect site with moderate pressure and cover the edges of the membrane with soft tissue.
- Secure the membrane in place with sutures or by means of sufficient contact with the mucoperiosteal flap to avoid displacement and mobilization, ensuring the membrane remains in place during healing.
- Suture the mucoperiosteal flap over the membrane.
- The membrane can be sutured with resorbable suture material and with a non-cutting needle.
- Ensure there is closure of the soft tissue flap covering the membrane without any tension.

Patient Care Following Treatment

- Patients should be monitored closely for any adverse reactions.
- The clinician should inform the patient to refrain from any activity that could cause mobilization or displacement of the membrane.
- In the event the membrane becomes exposed, the dehiscence typically heals by itself within a few weeks and removal of the membrane may not be necessary unless there is evidence of infection. However, the clinician may recommend the patient use an antibacterial treatment until wound closure to reduce the risk of bacterial contamination.
- Four to six months of healing time is recommended prior to surgical exposure.

CONTRAINDICATIONS

Conditions representing contraindications include:

- Patients with a known hypersensitivity to porcine collagen
- Any systemic disorder or disease that involves an unacceptable increase in the postoperative risk for complications
- Presence of infected wounds, acute or chronic infection (e.g. osteomyelitis) at the surgical site or surrounding area

ADVERSE EFFECTS

- Dehiscence with early membrane exposure
- Bleeding
- Bone loss
- Flap Sloughing
- Hematoma
- Swelling at the surgical site
- Increased sensitivity or pain
- Local inflammation

STERILIZATION

InterCollagen® Guide is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. InterCollagen® Guide is non-pyrogenic and is single use only.

PRECAUTIONS

- A basic requirement for a successful periodontal treatment is prevention of bacterial infection and adequate oral hygiene. Therefore, prior to surgical intervention, patients must receive dental and oral hygiene treatment. After the surgery, postoperative care should be maintained.
- Effect on pediatric patients is not known.
- Effect on patients with pre-existing disease conditions (e.g. metabolic bone disorder, cardiovascular disease, autoimmune disease) or prior exposure to radiation therapy is not known.
- Safety and effectiveness in pregnant or breastfeeding women have not been established.

WARNINGS

- Before using the membrane, screen patients to determine whether they have a history of hypersensitivity to porcine collagen or porcine products.
- If the product, labeling, or packaging is compromised in any way, do not use the membrane.
- Do not re-sterilize or reuse in more than one surgical case or on more than one patient.
- Discard any unused portions of the membrane.
- Strictly adhere to sterile protocol during the implantation of the membrane. Improper handling of the membrane may contaminate the membrane and affect the sterility.
- In case of early exposure of the membrane, resorption time may be accelerated.

CAUTION

United States Federal law restricts this device to sale by or on the order of a licensed dentist.

MR (Magnetic Resonance) Statement

InterCollagen® Guide has not been evaluated for safety and compatibility in the MR environment. InterCollagen® Guide has not been tested for heating or migration in the MR environment.

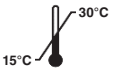
Rx Only

STORAGE AND HANDLING

InterCollagen® Guide should be stored in a dry, clean, and well-ventilated place at ambient temperature (15-30°C/59-86°F), protected from direct sunlight. The membrane should be handled using sterile gloves or sterile instruments.

EXPIRATION DATE: 1 year

LABELING SYMBOLS

 CAUTION, CONSULT ACCOMPANYING DOCUMENTS	 DO NOT RE-USE	 BATCH CODE
 USE BY	 CATALOG NUMBER	 MANUFACTURER
 DATE OF MANUFACTURER	 STERILIZED USING IRRADIATION	 TEMPERATURE LIMITATION
Rx Only PRESCRIPTION ONLY	 CONSULT INSTRUCTION FOR USE	 DO NOT RESTERILIZE
 DO NOT USE IF PACKAGE IS DAMAGED	 KEEP AWAY FROM SUNLIGHT	 KEEP DRY
 MEDICAL DEVICE	 TRANSLATED BY: Apex Translations 123 B West Water Street Plymouth, NC 27062, USA	
SYMBOLS		

Manufactured by

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