



RESORBABLE COLLAGEN SURGICAL MEMBRANE FOR DIRECT TISSUE REGENERATION

GDT BIOMEMBRANE

INSTRUCTIONS FOR USE

PURPOSE:

GDT BioMembrane is a bovine atelocollagen type I, non-cross linked material, that has been especially purified and modified (99.9% collagen type I free of telopeptides). After this process, the material is apyrogenic, sterile and fully resorbable by living tissue when implanted.

INDICATIONS:

- Implantation of defects in the bone tissue;
- Restoration of congenital and acquired defects of bone and soft tissues;
- Sinus-lifting;
- Cystectomy;
- Resection of the root apex;
- Filling of defects after the removal of cysts;
- Closure of perforations of the maxillary sinus and perforation of the lower jaw canal;
- Removal of the tooth (complicated/uncomplicated); as a stabilizer of the clot.

FEATURES:

Resorbable GDT BioMembrane membrane is a type I collagen (dermis) contains no additional cross-linking agents. The membrane is highly biocompatible, preventing proliferation and migration of the epithelium, creating optimal conditions for guided bone regeneration. The structure of collagen can safely close the bone defect. The material is completely resorbed without fibrous degeneration.

DIRECTIONS FOR USE:

1. GDT BioMembrane is trimmed to the desired size by using scissors.
2. The membrane should overlap the walls of the defect by at least 2-3 mm, in order to achieve complete coverage of the bone and thus prevent a lateral ingrowth of gingival tissue.
3. The defect cavity is then filled loosely with bone substitute material such as Bovine bone graft.
4. GDT BioMembrane is applied over the defect with its smooth side uppermost and held in place with moderate pressure. The saturation of the membrane with blood and exudate permits perfect adaptation to the bone surface. Additional stabilization by means of pins may be indicated for complex defects.
5. The flaps are closely sutured over the membrane and should be free of tension (e.g., using single sutures, mattress sutures). The wound should, whenever possible, be completely closed.
6. During the healing phase stress in the wound area from prosthetic pressure or palpation should be avoided. Intensive mechanical oral hygiene should be replaced by antibacterial rinsing (e.g., with chlorhexidine) for the first 3 weeks. Antibiotic therapy is prescribed at the discretion of the clinician.

Biodegradation of membranes is 4-5 months.

STERILITY:

Radiation sterilization by radiation 18 ± 3.0 kGy.

STORAGE:

GDT BioMembrane is intended for single use only; once opened it must be used or discarded. This product cannot be resterilized. Do not use after the expiry date mentioned on the outer package. Store in a dry and dark place in tightly closed containers at temperature (+5°C...+25°C). Avoid contact with moisture! Don't freeze!

PACKAGING:

Membrane (sterile flask) in a blister pack – 1 pcs.

15x15mm	Ref: GD-BM1515
25x25 mm	Ref: GD-BM2525
30x40 mm	Ref:GD-BM3040



STERILE R

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.