

biphasic bioabsorbable matrix for guided tissue and bone regeneration

General information

Biocompatible atelocollagen and the method of its preparation is the achievement of Hypro Otrokovice researchers, it is the proprietary technology of Hypro Otrokovice confirmed by the approved registration of the patent No: 276891 on 31December 1992. Hypro-Sorb® M is the result of many years experience and intensive research cooperation of Hypro Otrokovice s.r.o and Cardiophil Ltd scientific team, Hypro-Sorb® M is a bovine atelocollagen type I, non-cross linked membrane that has been especially prepared, purified and chemically modified utilizing the proprietary technology of Hypro Otrokovice, the material is biocompatible, apyrogenic, sterile for 5 years and fully resorbable in live tissue when implanted. Hypro-Sorb® M is a very effective haemostatic in addition to its excellent properties, Hypro-Sorb® M is well tolerated in the tissue. It is non-immunogenic, absorbable and supports the healing processes; Hypro-Sorb® M is completely bioresorbed within 6 months.

Activity

Hypro-Sorb® M has a specific activity to thrombocytes and releases clotting factors, which together with plasma binding factors promote fibrinogenesis. Other tissue interactions are the inhibition of collagenolytic activity of wound excretions, support of granulation, epithelisation, promotes soft tissue healing and Guided Tissue Regeneration-GTR. Hypro-Sorb® M is an excellent agent for Guided Bone Regeneration-GBR due to its potent release of growth factors (TGF and PDGF) from the highly concentrated thrombocytes. TGF and PDGF are natural peptides responsible for triggering of cell proliferation and Bone Regeneration.

Properties

- 99.9% collagen type I free of telopeptide.
- The especially designed 0.8mm thick biphasic membrane presents an excellent collagen type I matrix for bone integration on the rough porous side as well as for soft tissue adhesion and healing on the smooth matrix side.
- High degree of tissue biocompatibility with excellent wound healing characteristics.
- Quickly adaptable to the defect due to its potent hydrophilic property.
- Reduced risk by dehiscence formation due to the specially designed 0.8mm thick Matrix.
- Can be attached with pins and suturing material.
- Barrier function is sufficiently long and is completely bioresorbed within 6 months.
- Bioabsorbable a second operation for membrane removal is not necessary.
- Well documented atelocollagen safety and proven by clinical experience.
- Hypro-Sorb® M is a dual sterile Matrix.
- Unmistakably visible rough side and smooth side.

Indication group

Haemostatic, GTR / GBR

GTR/GBR

Guided tissue regeneration (GTR) has nowadays become an essential therapeutic procedure not only for the treatment of periodontal bone defects but also for bone and peri-implant defects, and for augmentation procedures prior to implant placement. In the latter situation, its sometimes termed Guided Bone Regeneration (GBR). The method of guided tissue regeneration (GTR), which began in the mid-1980s, became an important part of periodontal practice. Research results show that with the help of barrier membranes it is possible to prevent penetration of epithelial cells or fibroblasts into the bone defect and thus allow for gradual growth and reconstruction of the bone tissue. This procedure was applied in the cure of periodontal defects. The barrier helped the isolation of the defect with resulting reconstruction of cement, periodontal connection and the bone. During wide use of dental implants it became obvious that the GTR conception is useful for the cure of bone defects in the vicinity of implant. In such cases, the membrane prevents penetration of fibroblasts into the bone defect and bone cells have the necessary time for regeneration, either spontaneous or with the help of an augmentic agent. With GTR, it is now possible to regenerate the bone tissue in such a way that optimal conditions are created for introduction of an implant.

Indications

Hypro-Sorb® M membrane is used in maxillofacial surgery and implantology in the following applications:


- Cystectomy
- Segmental growing of alveolar tissue
- Lifting of the sinus bottom

- Resection of root upper part
- Filling of the alveolus after resections in protetic surgical practice
- Periimplantitis
- Furcation treatment
- Cleft lip and palate

Contraindication

Hypro-Sorb® M shall not be used inside bone fractures, when acrylate adhesives are applied, as it reduces the bonding strength.

Warning

 Hypro-Sorb® M is sterile. Check original packaging before opening. Do not use if packaging has been opened. Unused Hypro-Sorb® M cannot be re-sterilized.

Side effects

Immunogenicity of Hypro-Sorb® M was not observed at present. However, in the case of known allergy of patients to bovine products, it should not be excluded.

Handling instructions

1. Hypro-Sorb® M is trimmed to the desired size 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 to prevent a lateral ingrowth of gingival tissue.
3. The defect cavity is then filled loosely with Bone Substitute Material if indicated.
4. Hypro-Sorb® M is applied over the defect with its smooth side uppermost and held in place with moderate pressure. The quick saturation of the membrane with blood and exsudate permits perfect adaptation to the bone surface. Additional stabilization by means of pins maybe indicated for complex defects.
5. The flaps are sutured over the membrane closely and 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.

Postoperative care

In case of wound dehiscence with membrane exposure the usual antimicrobial precautions are recommended. Removal of the membrane is not necessary. The resorption time may be accelerated by external influences such as saliva, etc. The properties of collagen may favour rapid healing of the wound dehiscence.

Composition

This product is a naturally pure crystalline absorbable sterile bovine atelocollagen (99.9% collagen type I free of telopeptide).

Shelf life

The expiry date is written on every single packing. The product is safe for 5 years.

Storage conditions

Hypro-Sorb®M must be stored in a dry place and at a normal temperature. Hypro-Sorb®M is not damaged by temperatures from -25°C/-13°F to +50°C/+122°F. It needs to avoid direct sun light.

Packaging sizes

Hypro-Sorb® M biphasic membrane is available in the following sizes:

Cat. No.:	Name	Size	Description
030	Hypro-Sorb M	16 x 20 mm	biphasic barrier for GTR/GBR
031	Hypro-Sorb M	22 x 32 mm	biphasic barrier for GTR/GBR
032	Hypro-Sorb M	32 x 42 mm	biphasic barrier for GTR/GBR

Medical device of class III, Hypro-Sorb® was clinically tested and is certificated by notified body No. 1023, EC Certificate No. 09 0627 QS/NB, EC Design-Examination Certificate No. 09 0628 CN/NB.

Producer

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