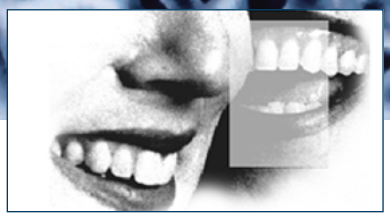
Hypro-Sorb® F



bilayer bioabsorbable barrier for guided tissue and bone regeneration

General information
Hypro-Sorb® F is a bovine atelocollagen type I, non-cross linked that has been especially purified and modificated (99.9% collagen type I free of telopeptides). After this process, the material is apyrogenic, sterile and fully resorbable by live tissue when implanted.

Description
Hypro-Sorb® F is a very effective haemostatic. In addition to its excellent properties, Hypro-Sorb® F is well tolerated in the tissue. It is non-immunogenic, absorbable and supports the healing processes;
Hypro-Sorb® F is completely bioresorbed within 6 months.

Activity
Hypro-Sorb® F 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 and epithelization and promotion of soft tissue healing.

Properties
- The bilayer 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 membrane side.
- High degree of tissue compatibility with excellent wound healing characteristics
- Quickly adaptable to the defect due to it is hydrophilic property
- Reduced risk of dehiscence formation
- Can be attached with pins and suturing material
- Barrier function is sufficiently long and is completely bioresorbed within 6 months
- Bioabsorbable; therefore, a second operation for membrane removal is not necessary
- Well documented and proven by many years of clinical experience

Indication group
GTR/GBR

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Guided tissue regeneration (GTR) has become an essential therapeutic procedure today, not only for the treatment of periodontal bone defects but also for bone and peri-implant defects. It is also used in augmentation procedures prior to implant placement, which is 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® F membrane is used in dental surgery and implantologyor for restitution of bone defects:
- Cystectomy
- Segmental growing of alveolar tissue
- Lifting of the sinus bottom
- Resection of upper root
- Filling of the alveolus after resections in protetic surgical practice
- Periimplantates
- Maxillofacial surgery

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

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

Side effects
Immunogenicity of Hypro-Sorb® F 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® F 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 Dexabone®.
4. Hypro-Sorb® F 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 exsudate 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 prescribedat 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 (99.9% crystalline) absorbable bovine sterile atelocollagen (99.9% collagen type I free of telopeptides).

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

Storage conditions
Hypro-Sorb® F must be stored in a dry place and at a normal temperature. Hypro-Sorb® 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® F bilayer membrane is available in the following sizes:

Cat.No.:	Name	Size	Description
HY 1520/2	Hypro-Sorb®	F 15x20 mm	bilayer barrier for GTR/GBR
HY 2030/2	Hypro-Sorb®	F 20x30 mm	bilayer barrier for GTR/GBR
HY 3040/2	Hypro-Sorb®	F 30x40 mm	bilayer barrier for GTR/GBR

Producer
HYPRO Otrokovice, s.r.o. Czech Republic, Europe

Medical device of class III, Hypro-Sorb® was clinically tested and is certificated by notified body No. 1023, EC certificate No. 04 0648 QS/ NB/a, EC type-examination certificate No. 04 0649 T/NB/a.