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Collagen Membrane

Pericardium Collagen Membrane

Instructions for use
Gebrauchsinformation
Mode d'emploi
Istruzioni per l'uso
Instrucciones para el uso

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Collagen Membrane

Intended Use and Properties

Collagen Membrane is a completely resorbable collagen membrane to be used in stomatology and maxillo-facial surgery, implantology, periodontology, oral surgery and endodontology to support guided tissue and bone regeneration, for covering implants and for periodontal tissue regeneration.

Collagen Membrane is produced from porcine pericardium in a standardized, controlled purification process. The pericardium is extracted from veterinarily controlled pigs, carefully purified, degreased, lyophilized and sterilized by ethylene oxide gas treatment.

Collagen Membrane will be completely soaked with blood, while its structure and stability are maintained. Therefore a tight and form-fit adaptation to the bone is guaranteed. If necessary, a fixation with resorbable suture material or with nails or pins is possible.

When it is dry, Collagen Membrane is a white, tight and tear-proof collagen matrix, with a very dense fibre structure. Individual elastic fibres run between the fibrils of type 1 collagen fibres. When it gets wet, Collagen Membrane can become translucent. The dense layer of fibres slows down the ingrowth of gingival fibroblasts thus encouraging the proliferation of bone-forming cells. Nutritive substances can penetrate through Collagen Membrane.

Collagen Membrane is usually completely resorbed within 12 weeks after implantation. Therefore, there is no need to remove the membrane in a second surgical intervention.

The low antigenicity of Collagen Membrane, its excellent biocompatibility and the extreme tensile strength allow for a safe and simple use in stomatology and maxillo-facial surgery, implantology, periodontology, oral surgery and endodontology.

Composition and Package Sizes of Collagen Membrane

10 cm^2 of Collagen Membrane contains:
- 30 - 40 mg collagen type I
- 5 – 10 mg ultra pure water

The following sizes are available:
- 15 x 20 mm
- 30 x 40 mm
- 20 x 30 mm

Collagen Membrane is sterilized by gassing with ethylene oxide and supplied in a double sterile packaging.

Indications

Collagen Membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration.
- in case of surgical bone defects and bone wall defects
- in the context of sinus floor augmentation and for support of the Schneiderian membrane
- in the context of maxillary ridge augmentation
- in the context of maxillary ridge reconstruction for prosthetic treatment
- in the context of a treatment of fenestration defects
- in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects)
- in case of dehiscence defects
- after apicectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

Contraindications

Collagen Membrane must not be used for patients suffering from
- acute infections in the oral cavity or acute or chronic inflammation at the implantation site
- general diseases, where measures of stomatology, maxillo-facial surgery, implantology, periodontology, endodontology or other measures of oral surgery must not be performed
- known hypersensitivity to porcine collagen

Use During Pregnancy and Lactation

There are no studies concerning the use of Collagen Membrane during pregnancy and lactation and about its influence on human fertility. During pregnancy and lactation the surgeon should weigh the benefit for the mother against the potential risk to the child before using Collagen Membrane.

Application for Children and Elderly Patients

There is no indication that special precautions are necessary relating to the age of the patients.

Further Instructions for Use

Collagen Membrane should only be used by physicians who are familiar with the techniques of guided bone and tissue regeneration on the basis of a pertinent qualification.

Collagen Membrane is of natural origin. Therefore, the collagen structure can be slightly wavy, and the membrane thickness may vary slightly in the dry material. These phenomena do not affect the quality or functionality of Collagen Membrane.

Collagen Membrane has a bi-layer structure. The smooth side with the tighter structure is marked „G" at the edge and should lie towards the gingival or soft tissue side. The rougher side of Collagen Membrane should point to the bone.

Collagen Membrane can be cut with a pair of scissors - maintaining sterility- to the required shape and size of the defect to be treated in dry and, if required, also in wet state. It may be helpful to use appropriate templates for defining the required surface of Collagen Membrane. Collagen Membrane should overlap the defect walls by at least 2 - 3 mm. In this way, Collagen Membrane is closely attached to the bone, and a lateral ingrowth of gingival connective tissue can be prevented.

For the use of Collagen Membrane, the general principles of sterile working and of patient medication must be followed.
- After the exposure of the defect, the necessary surgery is performed.
- The resulting bone defect is then filled, with suitable augmentation material (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials), if clinically indicated
- The outer packaging, which is sterile on the inside, can be removed from the outer carton by an assistant in the unsterile operation area and be opened under sterile conditions. The inner packaging, which is sterile on the inside and on the outside, is then handed to a member of the surgery team in the sterile area. When the bone defect is prepared, Collagen Membrane can be removed from the inner packaging - maintaining sterility.
- Collagen Membrane can be cut to size with a pair of scissors - maintaining sterility. Collagen Membrane should overlap the defect walls by at least 2 - 3 mm.
- Collagen Membrane is placed over the defect and slightly pressed down to hold it in place. The time for pressing it down depends on the extent of the bleeding. The adhesion to the bone surface results from the welling up and geling of the collagen fibres in contact with blood. Collagen Membrane can be applied in dry and wet state. Should you prefer the wet use of the membrane, the membrane must be rehydrated in sterile saline before the application.
- The complete soaking of Collagen Membrane with blood and exudates allows for a perfect adaptation and adhesion to the defect structure or the augmentate and for the creation of a blood coagulum under the membrane.
- Due to its good tensile strength, Collagen Membrane can be sutured with resorbable suture material and with a non-cutting needle, or it can be fixed to the bone or the neck of the tooth with nails or pins. A fixation of Collagen Membrane may be necessary to avoid its displacement due to strain or mobilisation, and to prevent the shifting of the augmentation material used.
- For wound closure the mucoperiosteal flap is repositioned over the membrane tightly and without tension, and sutured. Collagen Membrane should be completely covered by the mucoperiosteal flap to prevent any accelerated resorption due to exposure.
- After surgery, the patient should perform oral hygiene according to the doctor's instructions.

Special Instructions Concerning the Use in Periodontology

- The basis for a successful periodontal treatment is the control of bacterial infection by means of debridement (removal of the granulation tissue, subgingival curettage, scaling, smoothing of the tooth roots etc.), an antibiotics therapy, if necessary, and by a sufficient oral hygiene of the patient according to the instructions of the attending dentist. Please note that as little soft tissue as possible should be removed to guarantee the best possible wound closure. The surgery should be preceded by a hygiene phase with an instruction of the patient and another evaluation of the clinical situation by the dentist. To ensure long-term success of the therapy, a post-operative conservation phase with pertinent patient instructions by the dentist should follow.
- To avoid the formation of a crevicular epithelium effectively, Collagen Membrane must be modelled closely to the tooth or the neck of the tooth, and be fixated by suture material, nails or pins, if necessary.

Dosage

The quantity of Collagen Membrane needed depends on the individual anatomic conditions and the applied implant, if any.

Collagen Membrane is applied on the bone defect in the required size, the defect walls should be overlapped by 2 – 3 mm. Collagen Membrane can be cut to size with a pair of scissors. Suitable sterile templates can be helpful to define the required size.

Adverse Reactions

- Rare cases of allergic reactions to the collagen membrane cannot be ruled out.
- In extremely rare cases intolerance symptoms against collagen might occur.
- In rare cases the tissue might react with an inflammation due to a prolonged resorption.
- As with every exogenous material, existing infections might be intensified by the implantation of Collagen Membrane.
- Possible general complications might be caused by the surgical intervention itself, such as a recession of the gingiva, heavy gum bleeding, swelling of the soft tissue, temperature sensitivity, desquamation of the gingival epithelium in the area of the flap, a resorption or ankylosis of the treated dental root, a minor loss of crestal bone height, infections, pain or complications due to the use of anaesthetics.

Interactions with Other Medicinal Products and methods

The effectiveness of Collagen Membrane can be reduced by aggregation inhibitors and anticoagulants, since they might impair the creation of the blood coagulum under the membrane.

No interactions in magnetic resonance imaging are known, neither are they to be expected in view of the biochemical composition of the Collagen Membrane.

Warnings, Precautionary Measures

- Collagen Membrane is elastic and adheres to the bone. For space maintenance and to encourage the regeneration of bone, Collagen Membrane can be used with other suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials).
- An exposure of Collagen Membrane during the healing phase might shorten the resorption time.
- Collagen Membrane is only indicated for the applications listed above. The membrane has not been clinically examined for patients with extremely severe surgical, implantological, endodontological or periodontal defects
- Patients must be informed about possible contraindications, adverse reactions and precautionary measures according to the attending physician's responsibility. In case of any post-operative problems such as pain, infections or other unusual symptoms, the patient should turn to a dentist immediately.
- Patients with severe general diseases (such as a poorly stabilized pancreatic diabetes, severe hypertension, severe peripheral artery occlusive disease (PAOD), carcinoma or autoimmune diseases) or patients who have to undergo a long-term steroid treatment or anticoagulative therapy, must be treated with special care - as in all surgical treatment.

Storage

Collagen Membrane must be stored at temperatures below 30° C. Collagen Membrane must not be used after the expiry date.

Shelf Life / Sterility

The use-by date is printed on the folding box and on the sterile inner packaging. Collagen Membrane must not be used after the expiry date.

Collagen Membrane is sterile if the packaging is unopened and undamaged. Should the packaging be damaged, Collagen Membrane must not be used. The contents of unused, yet opened or damaged, packets must not be resterilized and should therefore be discarded.

Information

For further information, please contact your supplier or the manufacturer directly.

Information Update

06/2010

Symbols

STERILE EO	Sterilisation with ethylene oxide		Not for reuse
LOT	Batch ID		Use by
	Note the instructions for use	30 °C	Maximum storage temperature 30 °C
REF	Catalogue Number		Manufacturer
CE 1275	Conformity mark	®	Registered trademark
	Do not resterilize		Do not use if package is damaged
	Keep away from sunlight		

Responsible manufacturer

aap Biomaterials GmbH, Lagerstr. 11-15, 64807 Dieburg, Germany

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Collagen Membrane

Zweckbestimmung und Eigenschaften

Collagen Membrane ist eine vollständig resorbierbare Kollagenmembran zum Einsatz in der Mund-, Kiefer- und Gesichtschirurgie, Implantologie, Parodontologie, Oralchirurgie und Endodontie zur Unterstützung der gesteuerten Knochen- und Geweberegeneration, Implantatabdeckung und parodontalen Geweberegeneration.

Collagen Membrane wird in einem standardisierten, kontrollierten Reinigungsprozess aus Schweineperikard hergestellt. Das Perikard wird von tierärztlich kontrollierten Schweinen gewonnen, sorgfältig gereinigt, entfettet, lyophilisiert und mittels Ethylenoxidbegasung sterilisiert.

Collagen Membrane wird von Blut unter Erhaltung der Struktur und Stabilität vollständig durchfeuchtet. Somit ist eine dichte und formschlüssige Anpassung an die Knochenwandung gewährleistet. Eine Fixierung mit resorbierbarem Nahtmaterial oder Nägeln bzw. Pins ist bei Bedarf möglich.

Collagen Membrane ist im trockenen Zustand eine weiße, dichte und reißfeste Kollagenmatrix, die sich durch eine dichte Faserstruktur auszeichnet. Zwischen Fibrillen aus Kollagen Typ I verlaufen einzelne elastische Fasern. In feuchtem Zustand kann Collagen Membrane transluzent werden. Die dichte Faserschicht verzögert das Einwachsen von gingivalen Fibroblasten und begünstigt dadurch die Proliferation von knochenbildenden Zellen. Wichtige Nährstoffe können durch Collagen Membrane penetrieren.

Collagen Membrane wird in der Regel innerhalb von 12 Wochen nach Implantation vollständig resorbiert. Damit entfällt die Notwendigkeit, die Membrane in einem zweiten chirurgischen Eingriff wieder entfernen zu müssen.

Die geringe Antigenität und hervorragende Biokompatibilität sowie die hohe Reißfestigkeit von Collagen Membrane erlauben die sichere und einfache Handhabung beim Einsatz in der Mund-, Kiefer- und Gesichtschirurgie, Implantologie, Parodontologie, Oralchirurgie und Endodontie.

Zusammensetzung und Packungsgröße von Collagen Membrane

10 cm^2 Collagen Membrane enthalten:
- 30 - 40 mg Kollagen Typ I
- 5 – 10 mg Reinstwasser

Es werden folgende Größen angeboten:
- 15 x 20 mm
- 30 x 40 mm
- 20 x 30 mm

Collagen Membrane wird mittels Ethylenoxidbegasung sterilisiert und in einer doppelt sterilen Verpackung bereitgestellt.

Anwendungsgebiete

Collagen Membrane ist allein oder in Kombination mit geeigneten Augmentierungsmaterialien (z. B. autogener Knochen, allogene, xenogene oder alloplastische Knochenersatzmaterialien) indiziert für die sofortige oder verzögerte gesteuerte Gewebe- und Knochenregeneration
- bei chirurgischen Knochendefekten und Knochenwanddefekten
- im Rahmen einer Sinusbodenaugmentation und zur Unterstützung der Schneiderschen Membrane
- im Rahmen einer Kieferkammaugmentation
- im Rahmen einer Kieferkammrekonstruktion für die prothetische Versorgung
- im Rahmen der Behandlung von Fenestrationsdefekten
- bei parodontalen Knochendefekten (ein- bis dreiwandige Defekte, Furkationsdefekte Klasse I, II)
- bei Dehiszensdefekten
- nach Wurzelspitzenresektion, Zystenentfernung, Entfernung retinierter Zähne und Resektion sonstiger Knochenschäden