FAQ

requently asked uestions

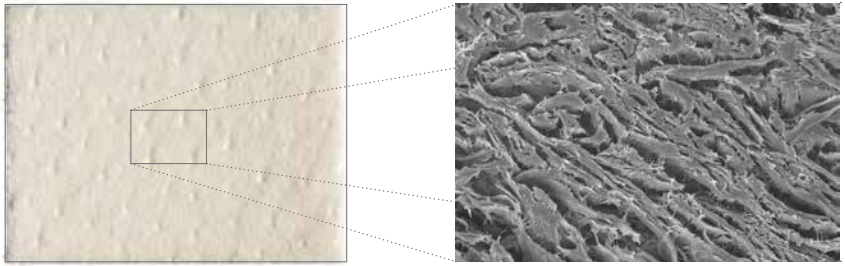
mucoderm®

botiss
biomaterials

What is mucoderm® and what is it composed of?

mucoderm® is a xenogenic acellular matrix that offers a safe alternative to autologous soft tissue grafts (subepithelial connective tissue and free gingival graft) in dental soft tissue grafting procedures.

mucoderm® is a natural matrix with an average thickness of 1.2 - 1.7 mm consisting of porcine collagen type I and III, which is not artifically cross-linked. It acts as a scaffold for soft tissue cells and blood vessels and has superior handling properties, such as tear resistance and volume stability.



Where does mucoderm® originate from?

How is mucoderm® manufactured?

mucoderm® originates from pig skin. To be more precise, it is derived from porcine dermis. For the manufacture of the collagen matrix the skin of veterinary controlled pigs is harvested. Afterwards the skin is cleaned in a multi-stage process, that preserves the original collagen structure of the tissue. Lastly, the final product is cut to size, packed and gamma sterilized.

This processing results in a three-dimensionally stable matrix that strongly resembles the human connective tissue.

Is mucoderm® a safe product?

The certified, standardized multi-stage cleaning process of mucoderm® effectively removes all non-collagenous proteins, cells and potential immunogens and infectious agents, such as bacteria viruses resulting in a safe product composed of pure collagen type I/III.

mucoderm® is a medical device regulated according to EC-guidelines. Manufacturing of mucoderm® is subject to a quality control system based on international standards (e.g. EN ISO 13485), and is regularly audited by the notified body and authorities.

The biocompatibility of mucoderm® was proven *in vitro* demonstrating a significantly higher viability of gingival fibroblasts, endothelial cells, and osteoblasts on mucoderm® compared to the control group ($p<0.05$)[1,2].

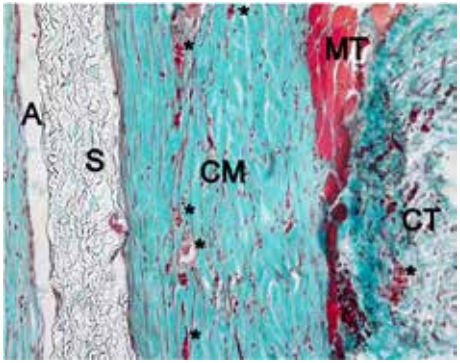
What happens to mucoderm® after implantation?

Is mucoderm® resorbable?

mucoderm® is characterized by an open porous collagen structure[3,4] that makes it an ideal scaffold for the ingrowth of blood vessels and cells, and promotes fast tissue integration and revascularization.

Tissue integration and matrix degradation were analyzed in an animal study. After implantation in rats, mucoderm® showed extensive ingrowth of blood vessels after only two weeks as well as an inflammation-free healing with superficial cell invasion. In the following four to eight weeks, a continuous degradation with increasing homogeneous cell distribution was observed. After eight weeks, 20% of the original matrix volume were still present as scaffold for the formation and reorganization of the connective tissue. Twelve weeks after implantation in rats, mucoderm® was almost completely replaced by newly formed connective tissue[3].

Animal data and human histological findings suggest that mucoderm® can be completely remodeled within six to nine months.

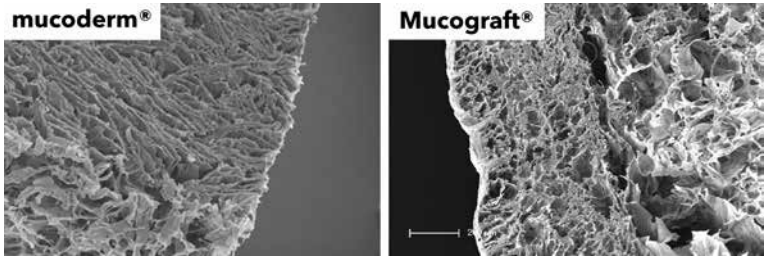


Complete degradation of mucoderm® after twelve weeks healing period in rats with newly formed connective tissue.[3] (Masson Goldner, magnification 200×).
CM: collagen matrix, MT: muscle tissue, *: blood vessel
CT: connective tissue, S: spacer, A: artefact.

What differentiates mucoderm® from other commercially available collagen matrices?

mucoderm® is a native, monolayer matrix meaning it has a homogenous three-dimensional collagen structure comparable to that of the connective tissue or free gingival graft (CTG/FGG) harvested from the palate. It is designed for use in all dental indications, where soft tissue is missing and needs to be regenerated or thickened.

The structure of mucoderm® is compact yet porous. mucoderm® is mechanically- and volume stable exhibiting the same thickness in dry and wet condition. Most matrices do not show a monolayer composition. Mucograft® for example is made of two components; a compact and a spongy part that have been joined together and thus requires particular handling experiences.

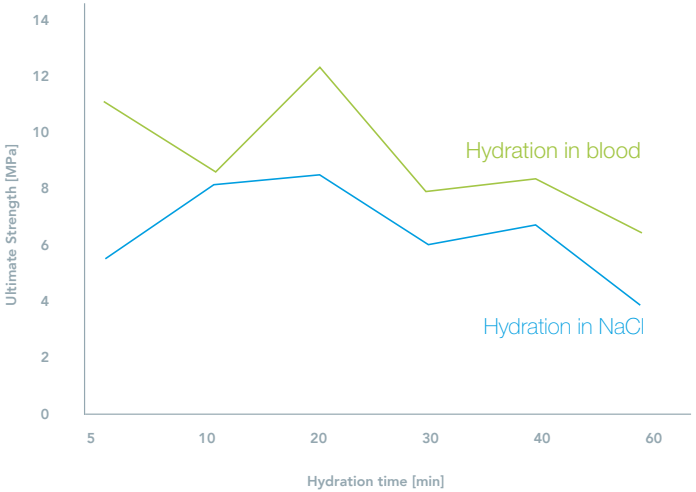


Structure of mucoderm® (left) and Mucograft® (right)[5]

Do I have to hydrate mucoderm® prior to application?

mucoderm® should always be hydrated before use. Hydration should be performed in sterile saline solution or patient blood for five to 20 minutes, depending on the desired flexibility of the matrix.

The flexibility of mucoderm® increases with hydration time. The hydration of mucoderm® and other collagen matrices and the influence on their biomechanical properties were analyzed in a comparative study by Kasaj and colleagues. The study indicated that a prolonged hydration (30 to 60 minutes) hardly affects the biomechanical properties (stability/integrity) of the collagen matrix[5].



What are the key points for the handling of mucoderm®?

Trimming

Size and shape of the matrix should be adapted to the defect. After hydration, mucoderm® can easily be trimmed to the desired size with a scalpel or scissors. Rounding off the edges of mucoderm® can prevent perforation of the gingival tissue during flap closure.

For covering of multi-recession defects, the size of the matrix can be extended by cutting mucoderm® on alternating sides (mesh-graft technique) and pulling it.

Positioning

Both sides of the matrix are comparable, since mucoderm® shows a homogenous structure. Therefore, no attention needs to be paid to the orientation during application.

Immobilization

Following application, mucoderm® should always be immobilized to avoid micro-movements and ensure undisturbed revitalization, e.g. ingrowth of vessels and cells.

When preparing a split flap, mucoderm® should be sutured to the intact periosteum to ensure close contact between the matrix and the periosteal wound bed. Single interrupted or cross-sutures may be used; the use of resorbable sutures is recommended. In case of vestibuloplasty, when increasing the height of the residual alveolar ridge and thereby the size of the denture bearing area, a split flap is prepared as well. mucoderm® is adapted to the exposed periosteal wound bed and tightly fixed by cross-sutures as well as single interrupted stiches.

How should the post-operative care be carried out?

To ensure optimal conditions for undisturbed and excellent healing, it is essential to avoid any mechanical trauma of the treated site following surgery. Accordingly, patients should be instructed not to brush their teeth at the respective side for about four weeks. Plaque prevention can be achieved by mouth rinsing with a ~0.2% chlorhexidine solution. **Postoperatively, the patient should be recalled weekly for plaque control and healing evaluation.**

What are the clinical indications of mucoderm®?

The matrix is indicated for the augmentation of soft tissue around natural teeth and dental implants[6-11] for:

- Recession coverage
- Augmentation/thickening of the soft tissue
- Broadening of the attached gingiva
- Socket sealing

What are the limitations for the use of mucoderm®?

There are biological limitations for the use of the material. In each of the mentioned indications a revascularization of the matrix must be ensured, either from the tissue above (flap) or from the bottom side by suturing to the underlying periosteum. In general, thin flaps may oppose revascularization of mucoderm®, hence an application of mucoderm® in such cases is not recommended. Another contraindication is, if a sufficient flap mobilization and tension-free closure of the flap over the matrix cannot be achieved.
A successful treatment of Miller class I and II defects have been described for mucoderm® [6,7]. Overall, the success rates of the treatment of defects in the maxilla are higher than for mandibular defects.

When mucoderm® is used for the augmentation of the attached gingiva, a band of at least 1 mm of keratinized tissue should be present to provide the biological information for the regeneration in the grafted site.
mucoderm® can be an alternative to autologous soft tissue transplants in a variety of indications. However, is not indicated in situations where even the use of autologous grafts is unpredictable.

Which surgical technique shall be used when treating recession defects?

mucoderm® can be used in combination with all common mucogingival surgical techniques, including coronally advanced flaps and tunnel techniques. Notably, the coronally advanced flap or the modified coronally advanced flap ensure a good view on the prepared donor bed and facilitate the coronal repositioning of the flap over the matrix. When applying mucoderm® for recession coverage, special attention must be paid to achieve sufficient flap mobilization as well as tension-free and complete closure.

For recession coverage, mucoderm® may also be used in conjunction with enamel matrix derivatives (Emdogain®). Adding Emdogain® to root coverage procedures with mucoderm® may improve soft tissue healing and attachment quality[12-14].

Can mucoderm® be left exposed?

Are there clinical situations which allow open healing?

mucoderm® can be left exposed for open healing in situations, in which revitalization from the surrounding or underlying wound bed is ensured.

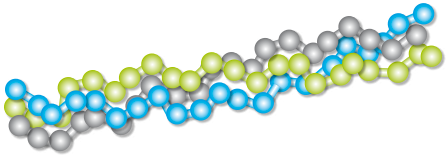
Open healing is feasible i.e. for vestibuloplasty, if mucoderm® is sutured and closely fixed to the periosteum. This technique is indicated to facilitate an increase in the width of the attached gingiva but does not thicken the tissue. Open healing is also possible in situations, in which only minor parts of the matrix are exposed. This might be the case in soft tissue augmentation around implants, when the matrix is mostly covered by the flap. In these situations, revascularization is ensured by the surrounding margins of the flap. Open healing is also indicated when using mucoderm® for socket sealing. Please note, that the resorption time of mucoderm® depends on the extent of exposure and will be accelerated during open healing due to bacterial degradation.

Exposure should always be avoided when treating recession defects. A close flap is also recommended when simultaneously applied with bone grafting materials.

Can an allergic reaction (swelling, redness) occur after application of mucoderm®?

mucoderm® is made of porcine collagen. **Thanks to the high homology to human collagen, mucoderm® has a very low antigenicity.** Moreover, the extensive cleaning process removes all potential antigenic components. However, intolerance symptoms and allergic reactions to collagen may occur and therefore, cannot be ruled out completely although they are extremely rare.

In case of suspected allergy against porcine collagen, mucoderm® shouldn‘t be applied.



Where can I find additional information about the product and how to use it?

You can find more information and clinical cases about mucoderm® on indication-matrix.com

If you are interested in additional handling and application tips please have a look into the mucoderm® surgical guide or visit our website at botiss-dental.com

For additional assistance, please contact us directly at: pm@botiss.com

Literature:

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