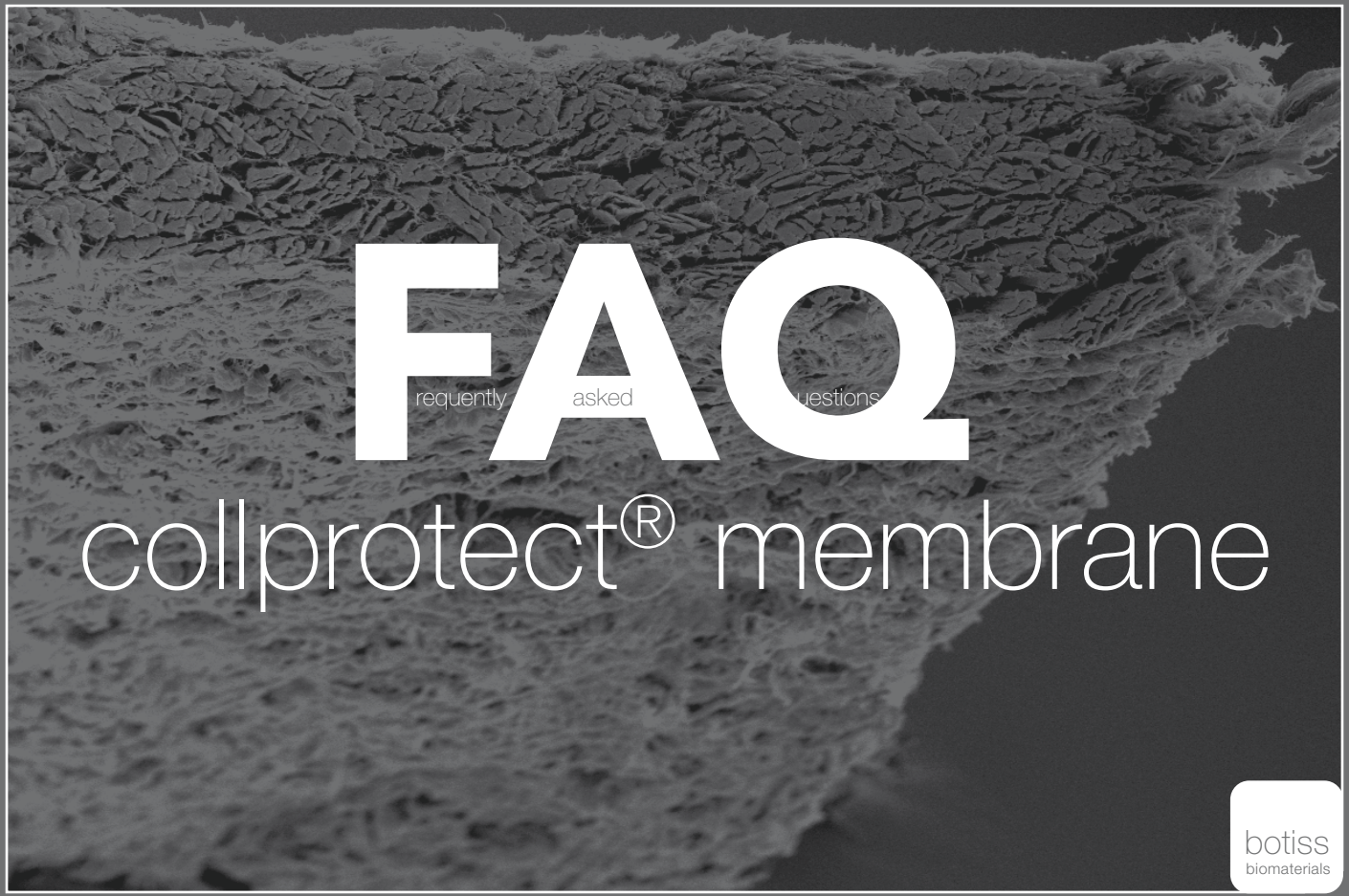
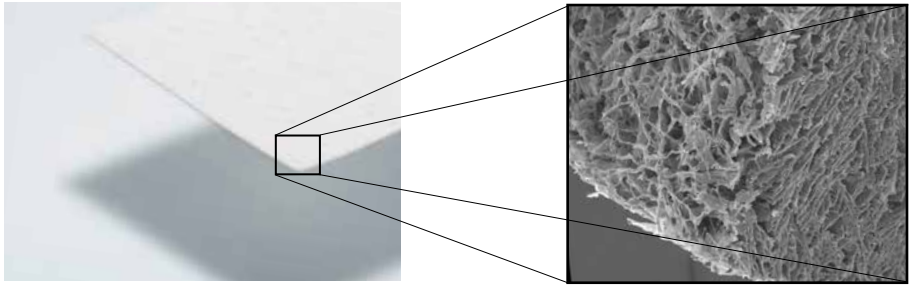

FAQ
requently asked uestions
collprotect® membrane
botiss
biomaterials

What is collprotect® membrane?

What is it made of?

collprotect® membrane is a native collagen membrane made of porcine dermis, that is intended for dental bone and soft tissue regeneration.

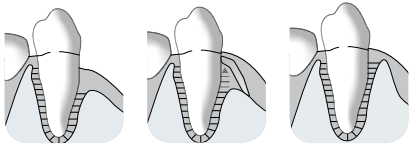
The membrane consists of parallel aligned, naturally cross-linked fibers of collagen type I/III and has a thickness of about 0.4 mm. The natural hemostatic effect of collagen supports early wound healing. The open pores in the three-dimensional, homogenous structure facilitate fast ingrowth of blood vessels and accelerate the integration into the surrounding tissue.



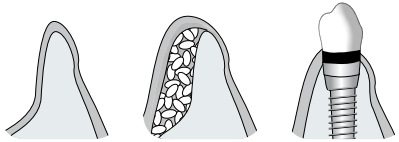
Why do I need a membrane for the regeneration of bone defects?

The concept of Guided Tissue- and Guided Bone Regeneration (GTR, GBR) is based on the placement of a barrier membrane to separate slow proliferating osteoblasts from fast proliferating epithelial and connective tissue cells. A spatial separation facilitates bony regeneration of the augmentation site by giving bone cells time and space to divide and to differentiate.
Placement of a membrane is of particular importance when applying particulate bone substitute materials, as this helps to avoid particle migration.

Guided Tissue Regeneration (GTR)

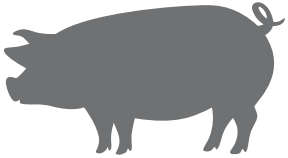


Guided Bone Regeneration (GBR)



Why is porcine dermis used as source for the manufacturing of collprotect® membrane?

Pig skin shows remarkable similarities to human skin, such as structure, hair follicle content, thickness, pigmentation, as well as collagen- and lipid composition[1,2]. The high homology to human skin results in a very high acceptance by the human body. In addition, porcine dermis shows dense parallel, aligned fibers, qualifying it as a source for dental barrier membranes.



Is collprotect® membrane a safe product?

Yes, collprotect® membrane is a safe product. It is manufactured from porcine dermis in a validated and controlled production process that removes all cells, non-collagenous and antigenic components, while the natural collagen structure of the dermis is being preserved.

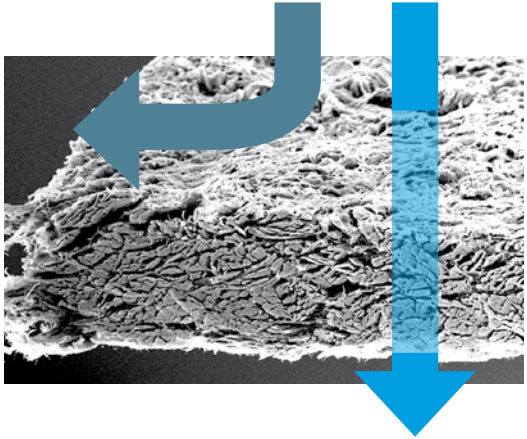
The intense purification process includes defatting of the tissue and treatment with different chemical agents that are used to eliminate possible pathogens as well as cellular and potentially immunogenic components. Following lyophilization, the end product is sterilized by gamma irradiation. The entire manufacturing process is subjected to a quality management system that is in accordance with ISO 13485 and is regularly monitored by independent institutions and authorities.

I can see little pores on the membrane surface.

Where do they come from?

The tiny holes on the membrane surface are pores that originate from the hair follicles of the porcine skin.

They appear once the hairs have been removed. Compared to the dense collagen structure of the membrane body, the areas of the transmembranous pores show a rather tender and fibrous collagen structure. The pores facilitate the ingrowth of blood vessels, resulting in fast vascularization of the underlying defect area as proven by histological findings[3].



Does collprotect® membrane have two different sides?

collprotect® membrane exhibits a quit homogenous structure that corresponds to the natural conditions of the dermis, thus the membrane can be placed either side facing towards the defect.

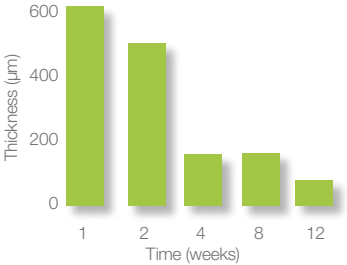
Is collprotect® membrane artificially cross-linked?

No, collprotect® membrane is not artificially cross-linked by chemical or physical additives. Chemical cross-linking has shown to slow down membrane degradation, but can also negatively affect the biocompatibility, tissue integration, as well as revascularization of collagen membranes[4]. Therefore, botiss offers only collagen membranes that keep their native collagen structure.

How long is the barrier function of the collprotect® membrane?

The indication, way of application as well as differences in the metabolism of each single patient affect the degradation rate of a collagen membrane. To follow the progression of collprotect® membrane resorption, animal experiments were performed as these tests cannot be realized in humans.

Subcutaneous implantation in mice has demonstrated a significant degradation of collprotect® membrane after 15 days[5]. In a preclinical study on rats, collprotect® membrane was degraded within four to eight weeks[6]. As the metabolic rate of small rodents is much higher compared to humans, the barrier function following implantation in humans will be significantly longer.



The diagram display degradation times of the membrane, obtained from *in vivo* data in an experimental rat model.[6]

Based on the preclinical data it can be assumed that collprotect® membrane will be resorbed in humans within two to three months following implantation.

Can I apply collprotect® membrane in the double-layer technique?

Yes, however there is no need to apply it that way. Clinicians who have experience with Bio-Gide® sometimes find it useful to place two membranes as a double-layer in order to increase the barrier function. If a longer barrier time is needed, the use of Jason® membrane is recommended. Jason® membrane is a pericardium membrane that offers a sufficiently long barrier function even for extensive augmentative procedures[4].

What is the difference between collprotect®- and Jason® membrane?

Both membranes are made of porcine collagen, but originate from different tissues. Furthermore, they differ in their membrane thickness and barrier function.

collprotect® membrane	Jason® membrane
Porcine dermis	Porcine pericardium
~0.4 mm	~0.15 mm
Intermediate barrier function (~2-3 months)	Naturally long barrier function (~3-6 months)

In dry condition, both membranes are slightly stiff but exhibit a good surface adaptation following hydration. collprotect® membrane is an optimal barrier membrane for smaller to middle-size defects. Jason® membrane on the other hand, provides superior biomechanical properties, a much higher tensile strength and may be preferred in techniques requiring fixation i.e. the sausage technique.

For which indications would collprotect® membrane be preferred?

collprotect® membrane is an allrounder that can be used for all common CMF-surgical procedures but because of its shorter barrier function in comparison to Jason® membrane, **it is the membrane of choice for the regeneration of smaller to middle-size defects, as well as periodontal defects.**

collprotect® membrane is indicated for:

- Sinus lift and coverage of Schneiderian membrane perforation
- Socket preservation
- Horizontal ridge augmentation
- Fenestration/dehiscence defects
- Intraosseous defects (1 to 3 walls)
- Furcation defects (class I and II)

How does collprotect® membrane behave after hydration?

Do I have to fix the membrane?

The membrane is hydrophilic meaning it takes up blood or sterile saline rapidly. The excellent ability to adhere to the defect site without sticking together enables optimal and easy handling of the membrane.

For better adhesion, the membrane can be wetted shortly before application but in many cases, the membrane is placed in dry condition and without fixation. Placement of a dry membrane gives stability and allows easy filling and contouring of the defect while in the meantime the membrane starts to hydrate and can easily be folded over the defect.

What else do I have to keep in mind when applying collprotect® membrane?

collprotect® membrane cut to shape and size in dry condition.
Photo: R. Cosgarea

When applying collprotect® membrane, the membrane should extend the defect area 2-3 mm to ensure optimal covering. In addition, the membrane can be cut to the right defect shape and size prior to hydration or after (but the latter is more challenging).

Can I leave collprotect® membrane exposed?

What happens if a flap dehiscence occurs?

In general, collprotect® membrane should always be covered by the flap.

In case of a dehiscence, the wound usually heals without complications by formation of free granulation tissue.

Nevertheless, an exposure should always be avoided, since fast bacterial resorption can occur, which significantly reduces the barrier function of the membrane. In situations of insecure wound closure, covering of the membrane with a collagen fleece may protect the healing area and promote a fast secondary healing and wound closure. Please note, this can only be recommended in certain indications and only if just minor parts of the membrane are exposed.

Can an inflammatory reaction occur after application of collprotect® membrane?

collprotect® membrane is made of porcine collagen. Due to the high homology to human collagen, it has a very low antigenicity. During the extensive wet chemical cleaning procedure, all potential antigenic components are removed. After packaging, the collprotect® membrane is gamma irradiated to ensure its sterility.

Nevertheless, intolerance symptoms and allergic reactions to collagen, which are extremely rare may occur and therefore, cannot be ruled out completely. In case of suspected allergy against porcine collagen, collprotect® membrane should not be used.

Can I resterilize collprotect® membrane?

The membrane is not approved for resterilization. This is indicated by symbols on the packaging and in the IFU. Autoclaving or dry heat sterilization destroys the native collagen structure, which impairs the biomechanical properties of the device. In case of resterilization, botiss assumes no liability for the product.

Literature:

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