
FAQ
requently asked estions
Jason® membrane
botiss
biomaterials

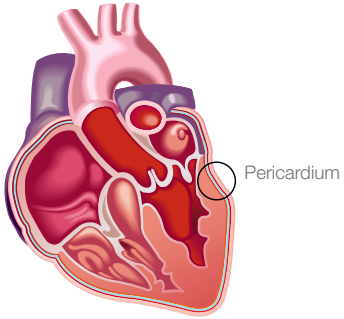
What is Jason® membrane made of and why is it of particular interest?

Jason® membrane is a native collagen membrane derived from porcine pericardium.

The pericardium is a double-layered tissue sac that surrounds and protects the heart, and allows volume changes by contraction and relaxation of the heart muscle. Imagine the human heart beats around 100.000 times a day, that's almost 40 million times per year! For every beat, the heart requires a similar effort as that needed to squeeze a tennis ball with one hand. The tissue consists of highly organized naturally cross-linked fibers of collagen type I/III. As known from the literature, the quantity, orientation, and the mechanical behavior of collagen from porcine pericardium has a higher homology to human than bovine pericardium has.[1]

During the production process, the natural collagen structure and composition is preserved, providing a solid membrane with excellent tear resistance (elasticity) and slow degradation (natural long stability).

botiss puts great value on the development of biomaterials that keep their original structure to support the best natural regeneration.



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

According to the concept of Guided Tissue- and Guided Bone Regeneration (GTR, GBR), a barrier membrane is placed to separate the slow proliferating osteoblasts from the fast proliferating epithelial and connective tissue cells, thus giving the bone cells time and space for differentiation and proliferation.

A separation facilitates the bony regeneration of the augmentation site. Several studies confirmed that the use of a bone grafting material in combination with a membrane may significantly enhance bone regeneration.[2,3,4] In addition, placement of a membrane is of particular importance when applying granulated materials, as this helps to avoid migration of particles.

However, membranes should also be used when working with allogenic bone blocks. Revascularization and remodeling of allogenic blocks take significantly more time compared to autogenous bone blocks.

Separation of hard and soft tissue through a collagen barrier membrane

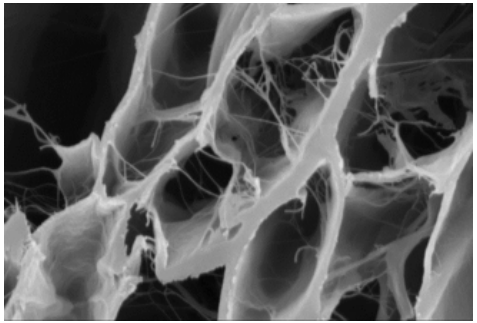
Is Jason® membrane a safe product?

Yes, Jason® membrane is a safe product which is manufactured from porcine pericardium in a standardized controlled purification process effectively removing all non-collagenous proteins and antigenic components.
The pericardium is extracted from veterinary controlled pigs destined for the food industry, and certified according to EN ISO 22442.

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

Is Jason® membrane artificially cross-linked?

No, Jason® membrane is not artificially cross-linked by chemical or physical additives. Chemical cross-linking has shown to slow down membrane degradation properties, but can also negatively affect the biocompatibility, tissue integration, and revascularization as shown for other collagen membranes.[5]



Honey-comb collagen arrangement of Jason® membrane

Nevertheless, Jason® membrane exhibits naturally cross-linked collagen as present in the tissue of origin.
Due to its natural honeycomb-like collagen arrangement, Jason® membrane shows a slowed degradation, offering a naturally long barrier function (see question on barrier function).

Why is the structure of Jason® membrane sometimes irregular?

Why are variances seen in the thickness or surface structure?

Jason® membrane is a native membrane and therefore, a natural product. It is produced from porcine pericardium by processing (cleaning) and freeze-drying the tissue.

Variances in the tissue structure or thickness that exist between different pericardia influence the appearance of the final product (Jason® membrane).

Of course, these variances are within the specifications (thickness of Jason® membrane ranges between 0.05 - 0.35 mm); the production process includes a quality control, meaning that products that are not within the specifications are removed.

Surface structure of Jason® membrane

The pericardium is a tissue sac; hence, it is really difficult to place it absolutely flat before freeze-drying.

Wrinkles are sometimes visible in the structure of Jason® membrane but do not influence the quality of the product or the clinical result. Nevertheless, if a clinician thinks that a membrane is of insufficient quality they can lodge a complaint.

Why is one side of the Jason® membrane marked with a G?

Does the Jason® membrane have two different sides?

Microscopically, Jason® membrane exhibits one rough, coarser surface and one slightly smoother side, corresponding to the natural conditions of the inner and outer surface of the natural pericardium.

The smoother, dense structured side (marked with a 'G') may be placed towards the gingiva to prevent soft tissue ingrowth. The rough side may be placed facing the bony defect to support the adhesion and ingrowth of osteoblasts, and hence the regeneration of the underlying defect.

However, since membrane stability is more dependent on the architecture of the collagen fibers rather than on the outer and inner surface, the membrane may be placed facing whichever way around without affecting the clinical outcome.

Jason® membrane is very thin,
is it mechanically stable?

Despite its low thickness of only ~0.15 mm, Jason® membrane demonstrates an outstanding multi-directional tear resistance due to its native collagen structure.

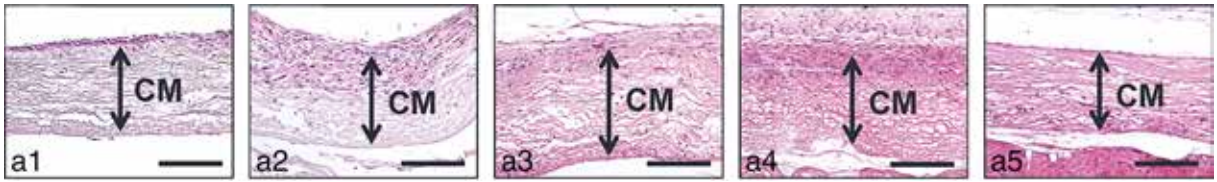
The porcine pericardium contains fine, wavy collagen fibers, which are multi-directionally orientated. This multidirectional structure results from the biomechanical force in the diastole preventing a hyperextension of the pericardium. Moreover, elastic fibers are associated with the collagen fibers.

The elastic fibers, together with the high degree of naturally cross-linked collagen are the basis for the high mechanical stability of Jason® membrane.

How long is the barrier function of Jason® membrane?

The indication, the way of application as well as differences in the metabolism of each patient affect the degradation rate of the collagen membrane. To follow the progression of resorption of Jason® membrane at different time points, animal experiments were performed as these tests cannot be realized in humans.
Subcutaneous implantation into mice demonstrated that Jason® membrane was intact after a period of 30 days.[6]
As the metabolic rate of mice is much higher compared to humans, the barrier function following implantation in humans will be significantly longer. In addition, remnants of the membrane were observed 12 weeks after implantation in dogs.[7]

Based on the preclinical data it can be assumed that Jason® membrane will be resorbed within three to six months following implantation. The different degradation properties of collagen membranes can be traced back to differences in the collagen organization, which have evolved in order to match the function of the original tissues, i.e. pericardium and dermis. In particular, the higher degree of naturally cross-linked collagen of the pericardium makes Jason® membrane more stable.



day 3 day 10 day 15 day 30 day 60

Pictures and data from Barbeck et al. 2014[6] showing the degradation of Jason® membrane after subcutaneous implantation in mice. Membrane is still intact after 60 days.

Can I use the double-layer technique when applying Jason® membrane?

Although Jason® membrane may be applied using the double-layer technique, there is no need to apply it in that way.

Clinicians using e.g. a commercially available bilayered membrane, such as Bio-Gide® sometimes find it useful to place two membranes in order to increase the barrier function. Jason® membrane, however, offers a sufficiently long barrier function, thereby providing adequate protection, even for extensive augmentative procedures. This can be advantageous, as a double layer of other commercially available collagen membranes may be quite thick and may impede a tension-free closure of the flap. Jason® membrane and even a double layer of Jason® membrane is comparably thin and therefore also suitable in situations where a tension-free closure is difficult (i.e. thin biotype).

How does the membrane behave after hydration?

Do I have to fix Jason® membrane?

In order to maximize the adhesion properties, it is recommended to wet the membrane shortly before application. The membrane is hydrophilic and hydrates rapidly in blood or sterile saline. The excellent ability of Jason® membrane to adhere to the defect site without sticking together guarantees optimal and easy handling.

In many cases, Jason® membrane may be used without fixation due to excellent adhesion properties. **Nevertheless, the multidirectional strength and tear resistance of the Jason® membrane permit the use of a wide range of fixation tools, such as sutures, pins and screws.**

Therefore, Jason® membrane can also be applied in the sausage technique. Furthermore, pinning of the membrane can also help to prevent dislocation/migration of bone substitute particles.

Can I leave Jason® membrane exposed?

What happens if a dehiscence occurs?

In case of a dehiscence of Jason® membrane, the wound usually heals without complications by formation of free granulation tissue. Nevertheless, exposure of the Jason® membrane should always be avoided, since fast bacterial resorption can occur, which significantly reduces the barrier function of the membrane.

Due to its low thickness, Jason® membrane is particularly sensitive to premature (bacterial) degradation in case of exposure. The alternative use of collprotect® membrane, mucoderm® or a non-resorbable, bacteria-resistant membrane (permamem®) may be recommended in cases of open healing (e.g. in socket preservation). In situations of incomplete or unstable wound closure due to insufficient flap mobilization, covering of the membrane with Jason® 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 a minor part of the membrane is exposed. In particular, in block augmentation with allografts, a membrane exposure should always be avoided and the correct soft tissue management enabling a tension free closure of the flap is of utmost importance.

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

Both membranes are made of porcine collagen, but originate from different tissues. collprotect® membrane is derived from porcine dermis, whereas Jason® membrane originates from porcine pericardium. Therefore, they differ in their collagen structure, affecting their resorption properties and barrier function.

collprotect® membrane has a mid-term barrier function and resorbs within a shorter time frame when compared to Jason® membrane, which demonstrates a prolonged barrier function and resorption time.[6,7]

In addition, the two membranes differ in their thickness.

collprotect® membrane has a thickness of ~0.4 mm, while Jason® membrane is only ~0.15 mm thick. Both membranes are quite stiff in dry condition but exhibit a good surface adaptation after hydration and allow fixation by pins or sutures.

Nevertheless, Jason® membrane provides superior biomechanical properties, i.e. a much higher tensile strength compared to collprotect® membrane.

For this reason, Jason® membrane may be preferred in techniques requiring fixation of the membrane, i.e. in the sausage technique.

Are there differences in the indications recommended for the use of collprotect®- and Jason® membrane?

In which cases would Jason® membrane be preferred?

The recommended indications are based on the differences in barrier function and thickness of the two membranes.
Jason® membrane offers a naturally long barrier function that is especially beneficial for the regeneration of larger defects or application in more extended augmentative procedures.
Typical indications where a longer barrier function is desirable are block augmentation, vertical- and horizontal augmentation, as well as sinus floor elevation with additional lateral augmentation.
Moreover, application of the very thin Jason® membrane is preferred for use in patients with a thin biotype, and permits soft tissue closure of the defect, especially where tension-free closure of the flap tends to be difficult.

Can an inflammatory reaction (swelling, redness) occur after application of Jason® membrane?

Jason® 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 Jason® membrane is EO treated to ensure its sterility. The biocompatibility of Jason® membrane has been confirmed in several preclinical and clinical studies.[7]

Nevertheless, intolerance symptoms and allergic reactions to porcine collagen may occur in extremely rare cases and therefore cannot be ruled out completely.

In case of suspected allergy against porcine collagen, Jason® membrane should not be applied.

Can I resterilize Jason® membrane?

NO!

Resterilization is neither allowed nor possible.

Jason® 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 causes a negative modification of the biomechanical properties and application benefits. In case of resterilization, botiss assumes no liability for the product.

Literature:

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