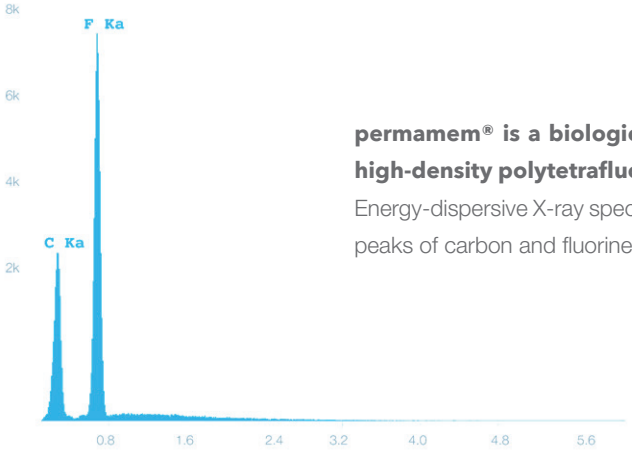

FAQ
requently asked uestions
permamem®
botiss
biomaterials

What is permamem® made of?



permamem® is a biologically inert and biocompatible membrane made of high-density polytetrafluoroethylene (PTFE).

Energy-dispersive X-ray spectroscopy (EDX) (molecular fingerprint) show characteristic peaks of carbon and fluorine, but no other phases are detectable.

In which indication(s) is the use of permamem® particularly beneficial?

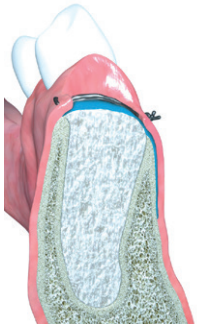
In which indication(s) may permamem® be preferred over a collagen membrane (Jason® membrane or collprotect® membrane)?

In general, permamem® can be used in the same indications as resorbable (collagen) barrier membranes.

However, due to the distinctive material properties, permamem® may be preferred over Jason® membrane or collprotect® membrane in some indications:

- For the regeneration of bone defects outside the ridge contour, permamem® may be preferentially used because of its higher form stability. The membrane maintains its structural integrity during implantation and over time. Compared to collagen membranes, permamem® has superior space-maintaining properties and capacity for cell occlusion.
- In socket and ridge preservation permamem® can be left exposed to the oral cavity as it acts as an efficient barrier against bacterial and cellular penetration thanks to its dense structure.
- Due to its synthetic character, permamem® is the membrane of choice for the treatment of patients with dietary or religious conflicts.

Can permamem® be left exposed to the oral cavity for open healing?



Open healing with permamem® in ridge preservation.

Yes, but only in certain indications. permamem® can be left exposed to the oral cavity as the membrane is made of non-porous high-density PTFE, which is impervious to bacteria and resistant to premature degradation.

However, open healing with permamem® is only indicated in socket and ridge preservation procedures. In GBR procedures, like horizontal and vertical ridge augmentation, permamem® should always be covered by the flap.

What are the advantages of open healing in socket/ridge preservation?

Since no primary wound closure is required, the soft tissue architecture and contours can be maintained. Thus, depending on the integrity of the bone walls of the socket, only minimal flap reflection for membrane placement and removal is needed.

In addition, the mucogingival line will not be displaced, the keratinized gingiva will be preserved and the vestibular depth will be maintained, thus improving aesthetics and patient comfort. Hence, permamem® can be a simple and efficient solution to cover and protect alveolar sockets following tooth extraction.

Why is open healing with permamem® only indicated for socket/ridge preservation?

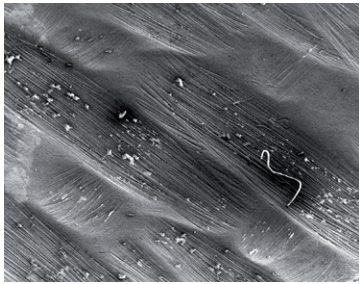
The specific anatomy (contained area) and comparatively quick healing time of the alveolar socket allow for open healing and a temporary covering with permamem®. It aims to support the natural healing process and promotes integration of the bone graft (in case the socket was grafted with a bone substitute material) without changing the natural soft tissue architecture. On the contrary, horizontal and vertical ridge augmentation require a longer healing period of the augmented bone.

Furthermore, open healing in case of a GBR procedure may harbor the risk of an infection of the grafting material, as the membrane may not be able to completely protect the grafted area over the entire healing time. Hence, in order to ensure an undisturbed healing period, permamem® should always be completely covered by the flap in those indications.

After which healing time do I have to remove permamem®?

permamem® should be removed in accordance with the indication. For extraction socket regeneration procedures, the membrane can be removed after 3–4 weeks. This will provide sufficient time for the formation of a blood clot followed by a provisional matrix of woven bone in the alveole, which is the basis for the bony regeneration[1]. In case of larger bone defects and augmentations with bone substitute material, the membrane can usually be removed after approximately 6 months.

During open healing or in the case of a secondary exposure, will soft tissue grow over permamem®?



Surface structure of permamem®
(SEM 30x magnification).

Due to its inertness and denseness, adjacent soft tissue will only attach superficially and will not grow into or over the membrane. Therefore, a non-surgical removal of the membrane is possible in open healing procedures.

Similarly, in case of a secondary exposure, i.e. a flap dehiscence, there will be no re-epithelialization over the membrane. For further advices concerning soft tissue management in case of a flap dehiscence, see question below.

How can permamem® be removed?

Is a second surgery required to remove the membrane?

If permamem® is intentionally left exposed (no primary wound closure), a surgical removal of the membrane is not necessarily required. However, this largely depends on how the membrane was immobilized and how much of the membrane was covered by the flap, i.e. if raising of a flap is required to fully access the membrane for removal. In general, after open healing, the removal of permamem® may be easily performed with a pair of tweezers. Topical anesthesia can be applied to improve patient comfort.

If primary wound closure is obtained during membrane placement, opening of the surgical site will be required to remove the membrane. After the removal of permamem®, the primary healing process and re-epithelialization of the soft tissue will be completed within about one month.

If permamem® becomes exposed because of a flap dehiscence, do I have to remove the membrane immediately?

In case of a flap dehiscence, permamem® does not necessarily need to be removed immediately and may be left in place as the membrane provides a barrier against bacterial penetration protecting the underlying bone from bacterial colonization.

In general, permamem® can be left in place if a) no swelling and/or infection is present and b) if the margins of the membrane are still covered by the flap. The patient should be enrolled in a continuous recall to monitor the exposure (weekly control) and should be instructed to rinse with antiseptic mouthwash (0.2% Chlorhexidine) every eight hours[2,3,4].

Does permamem® have two distinct sides?

No. permamem® can be positioned with either side facing towards the bone defect and soft tissue respectively.

Can I re-sterilize permamem®?

NO!

permamem® is intended for single use only. Re-sterilization will modify the material properties and carries the risks of disease transmission. In case of re-sterilization, botiss assumes no liability for the product.

Can permamem® provoke allergic/intolerance reactions?

permamem® is made of high-density polytetrafluoroethylene (PTFE), which is a non-resorbable, biologically inert and biocompatible material. The biocompatibility of permamem® has been confirmed in an animal trial[5]. In addition, PTFE has been employed for many years in numerous medical applications, including sutures, arterial grafts, filters and catheters demonstrating its excellent biocompatibility.

Thus, the risk of an allergic or intolerance reaction to permamem® can be considered negligible.

I have worked with Cytoplast™ PTFE barrier membranes before.

What are the differences to permamem®?

Cytoplast™ PTFE barrier membranes (TXT-200) and permamem® are both made of non-expanded PTFE (dense PTFE) and are temporarily implantable materials for the use as space-maintaining barriers in the treatment of dental bone defects. Moreover, both membranes have been engineered for open healing in socket preservation procedures requiring no primary soft tissue closure.

The main differences of the two membranes are related to thickness and structure.
permamem® with a thickness of ~0.08 mm is substantially thinner than Cytoplast™ (~0.2 mm in thickness), providing different handling experiences. Although very thin, permamem® offers an exceptional 360° tear strength providing the membrane with a very high stability.
Furthermore, Cytoplast™ TXT-200 has two distinct sides, i.e. a textured and a smooth side, and thereof, have to be placed in a specific direction. **permamem® with virtually two identical sides can be placed with either side orientated towards the bone defect.**

The membrane sometimes exhibits thin dark blue lines and/or black spots.

Where does it come from and do I have to care for it?

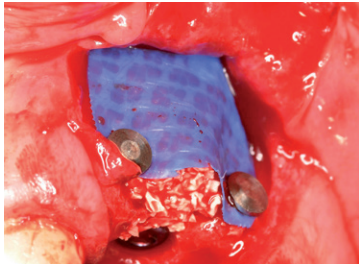
Irregularities of the structure and color of permamem® are due to technical reasons and do not affect the quality and functionality of the membrane.

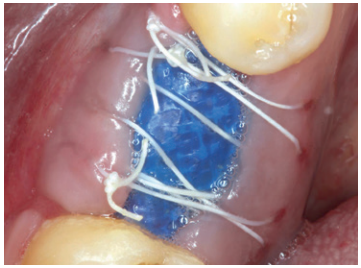
The unique manufacturing process of permamem® utilizes a cross-pattern lamination process containing oriented PTFE film plies. On occasion, the plies will be stacked yielding a typical laminate design, characterized by blue lines. By this means, an exceptional 360° tear strength of the membrane is created. Since ultra-thin plies are used, a constant thickness of the membrane within the range of 0.08 ± 0.04 mm will be maintained.

Occasionally black spots appear in the membrane. These are accumulations of the blue color that are formed during coloring of the white PTFE film plies.

Do I have to immobilize permamem® after application?

Yes, it is always recommended to properly fix permamem® by sutures, pins or screws, as the soft tissue, i.e. the flap, only attaches superficially to permamem®, as well as to avoid micro-movements of the membrane that may promote soft tissue perforation. In open healing procedures (i.e. socket/ridge preservation), the membrane may also be passively immobilized by sutures.



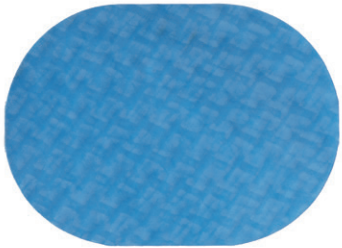


permamem® fixed by pins (left, Dr. Dávid Botond Hangyási, Hódmezővásárhely, Hungary) or sutures (right, Dr. Ziv Mazor, Raanana, Israel).

What is the shelf life of permamem®?

The shelf life of permamem® is three years from the date of manufacture.

The expiry date can be found on the outer cardboard box of the product, on the inner packaging label and on the patient record label.



Why is permamem® blue?

Is there any advantage of the blue color?

The blue color distinguishes permamem® from white, resorbable membranes and facilitates the recovery of the membrane during re-entry for membrane removal.

Literature:

1. Bartee BK Extraction site reconstruction for alveolar ridge preservation. Part 2: membrane-assisted surgical technique. J Oral Implantol. 2001;27(4):194-7.
2. Belleggia F Exposure of a dense PTFE membrane in a GBR procedure: Proposal of a treatment protocol Poster XXII International Congress 7-8/2/2014, Milan, Italy
3. Maridati PC, Cremonesi S, Fontana F, Cicciù M, Maiorana C. Management of d-PTFE Membrane Exposure for Having Final Clinical Success. J Oral Implantol. 2016 Jun;42(3):289-91. doi: 10.1563/aaid-joi-D-15-00074. Epub 2015 Aug 24.
4. Maridati P, Cremonesi S, Fontana F, Maiorana C. Treatment of a dense PTFE membrane exposure: a case report Poster Clin. Oral Impl. Res. 25 (Suppl. 10), 2014.
5. Korzinskas T, Jung O, Smeets R, Stojanovic S, Najman S, Glenske K, Hahn M, Wenisch S, Schnettler R, Barbeck M. In Vivo Analysis of the Biocompatibility and Macrophage Response of a Non-Resorbable PTFE Membrane for Guided Bone Regeneration. Int J Mol Sci. 2018 Sep 27;19(10):2952.