MEGA'GEN

bone & tissue regeneration

botiss biomaterials

permamem®

UPGRADE
HORIZONTAL/ VERTICAL GBR

HIGH-DENSITY
PTFE BARRIER MEMBRANE

barrier membrane

non-resorbable

synthetic

biocompatible

Polytetrafluoroethylene **(PTFE) – stable, inert** and **biocompatible**

In regenerative dentistry, polytetrafluoroethylene (PTFE) membranes have a long history and are used for more than 30 years[1]. PTFE is a synthetic, chemically stable and biologically inert fluoropolymer – it is able to resist biological (enzymatic) attack, does not stick and is biocompatible. During polymerization the gaseous tetrafluoroethylene is transformed into the polymeric polytetrafluoroethylene by the help of catalysts creating one of the most vigorous chemical bonds. Nowadays, PTFE membranes are mainly used for Guided Bone Regeneration (GBR).

PTFE barrier membranes **in regenerative dental medicine**

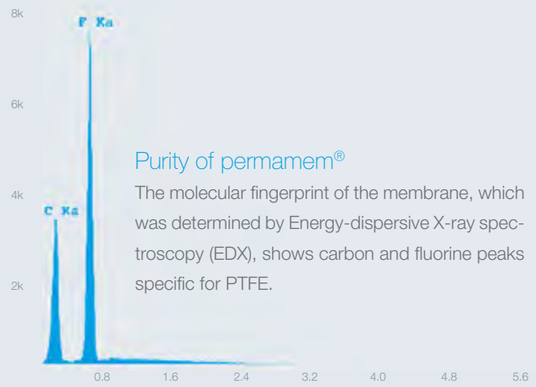
In the course of the evolution of GBR and Guided Tissue Regeneration (GTR), different types of membranes have evolved. In particular, for the regeneration of defects outside the ridge contour, the use of a non-resorbable, dimensionally stable membrane is recommended, because it offers a higher stability and superior space-maintaining properties compared to resorbable (collagen) membranes. In regenerative dental medicine, membranes made of PTFE are the most commonly used non-resorbable barrier membranes[2].

1 Gentile et al. Biotechnol J. 2011 Oct;6(10):1187-97.
2 Carbonell et al. Int J Oral Maxillofac Surg. 2014 Jan;43(1):75-84.

permamem®

NON-RESORBABLE MEMBRANE

permamem® is an exceptionally thin, non-resorbable and biocompatible membrane. It is composed of biologically inert, high-density PTFE, which acts as an efficient barrier against bacterial and cellular penetration, and can therefore be used for open healing in certain indications. In addition, an easy removal of the membrane is enabled as no adjacent tissue grows into it. permamem® maintains its structural characteristics both during the initial implantation and over the whole healing time.



Purity of permamem®

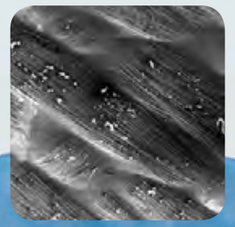
The molecular fingerprint of the membrane, which was determined by Energy-dispersive X-ray spectroscopy (EDX), shows carbon and fluorine peaks specific for PTFE.

Properties

- 100% synthetic PTFE barrier membrane
- Ultra-thin (~0.08 mm)
- Impervious to bacteria due to dense structure
- Exceptional 360° tear strength

ADVANTAGES DURING CLINICAL USE

- No need for primary soft tissue closure (indication-dependent)
- Supports space maintenance (as compared to collagen membranes)
- Easy recovery thanks to blue color
- Rounded edges for minimal tissue trauma
- Easy fixation with sutures or pins
- Either side may be placed towards the defect site



Indications:

permamem® is a temporarily implantable membrane
for use as a space-creating barrier in GBR and GTR.

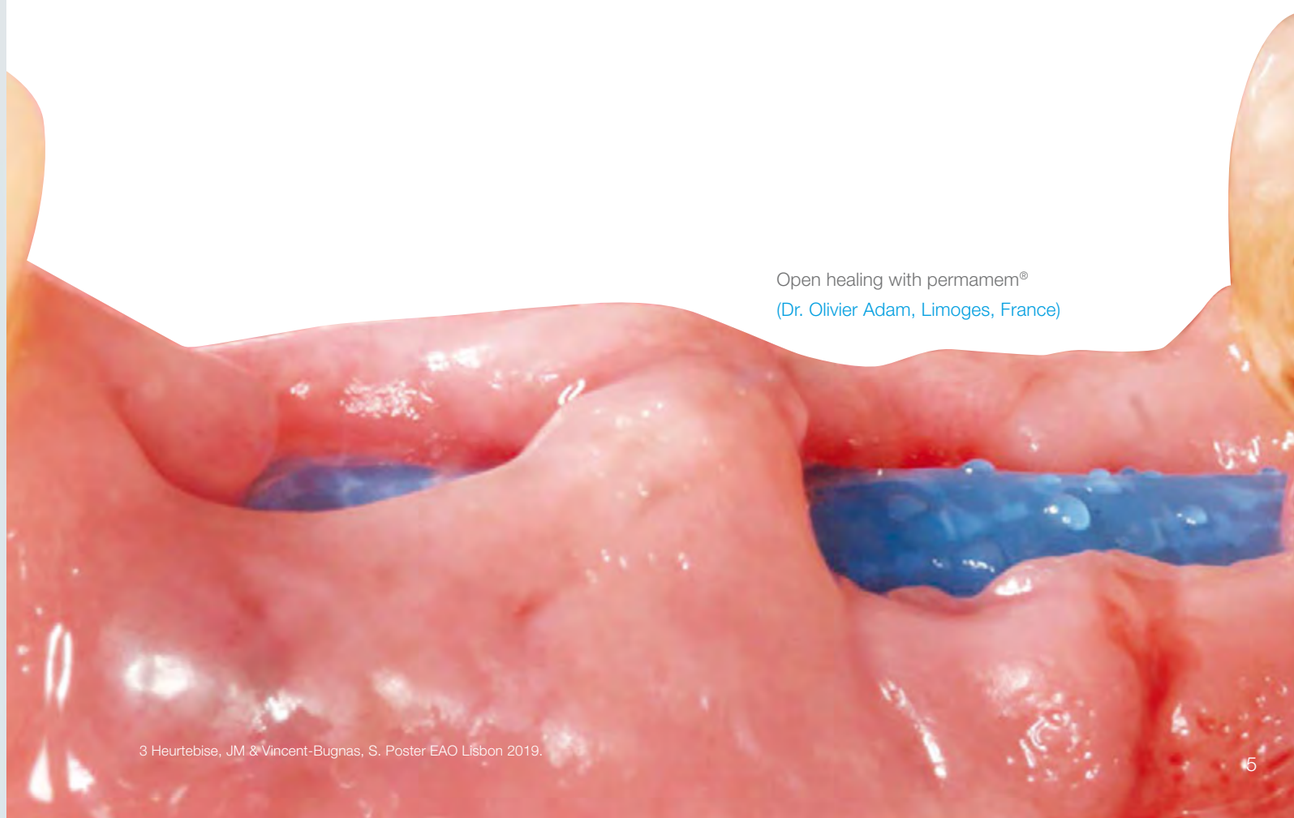
IMPLANTOLOGY, PERIODONTOLOGY AND ORAL AND CMF SURGERY

- Socket- and ridge preservation (open healing)
- Horizontal/vertical augmentation
- Fenestration and dehiscence defects
- Intraosseous defects (1 to 3 walls)
- Furcation defects (class I and II)

permamem®

Open healing in socket- and ridge preservation[3]

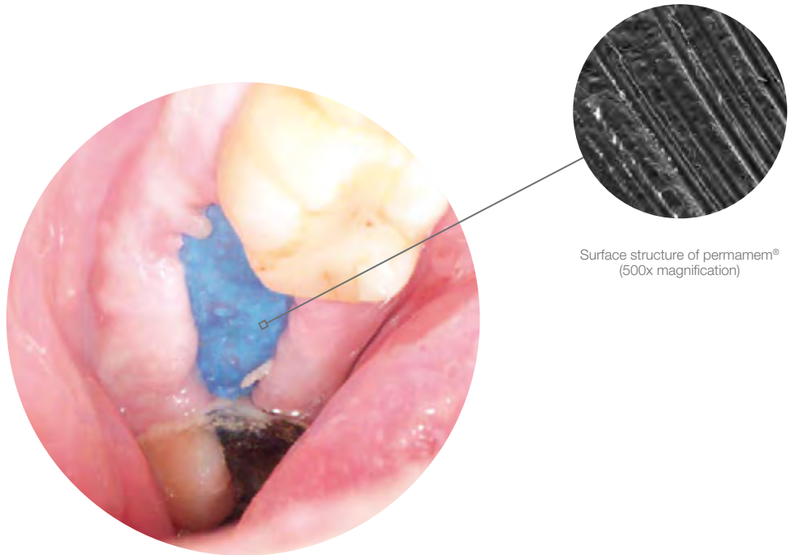
Since permamem® can be used for open healing in socket- and ridge preservation, primary wound closure is omitted and the soft tissue contours are maintained. The missing flap closure avoids displacement of the mucogingival line thus preserving the attached/keratinized gingiva. Likewise, the aesthetic outcome is improved as the non-surgical removal of the membrane after the healing time omits the need for big surgical incisions (vertical releasing incisions). After removal of permamem®, the primary healing process and the reepithelialization of the regenerated soft tissue is completed within about one month.



Open healing with permamem®
(Dr. Olivier Adam, Limoges, France)

3 Heurtebise, JM & Vincent-Bugnas, S. Poster EAO Lisbon 2019.

Less Plaque Accumulation

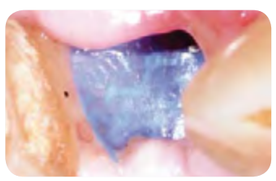


Surface structure of permamem®
(500x magnification)

permamem® four weeks after open healing
(Dr. Paolo Di Capua, Tel Aviv, Israel)

The inertness and denseness of permamem® prevents bacterial biofilm formation on the exposed outer membrane surface when permamem® is used for open healing (or got secondarily exposed due to a flap dehiscence). Thus, during membrane removal the risk for contamination of the augmented area by accumulated plaque is reduced and in addition, the retrieval of the membrane is facilitated.

permamem® two weeks after open healing
(Dr. Monica Turco, Bari, Italy)



permamem® five weeks after open healing
(Dr. Piero Papi, Rome, Italy)

permamem®

Easily removable thanks to minimal tissue ingrowth into the surface structure

Due to its low thickness and smooth surface, soft tissue attaches only superficially and does not grow into permamem® enabling easy removal. If permamem® is used for open healing, a surgical removal of the membrane is generally not necessary and the membrane can be easily removed with a pair of tweezers. Only if permamem® was used to treat a bone wall defect, a flap raising may be required to fully access the membrane for removal. If primary wound closure is obtained during membrane placement, opening of the surgical site will be necessary to remove the membrane.

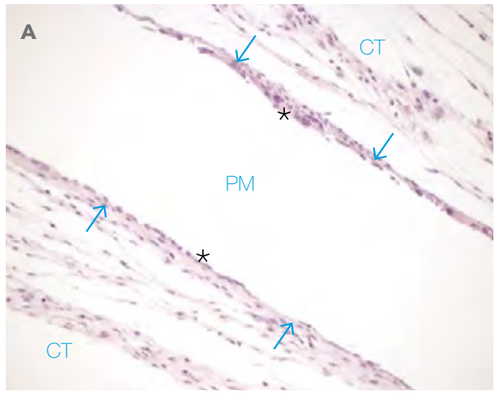
Removal of permamem® following horizontal GBR
(Dr. Algirdas Puišys, Vilnius, Lithuania).

Membrane placement (left), situation six months post-operative at re-entry (mid) and after membrane removal (right)

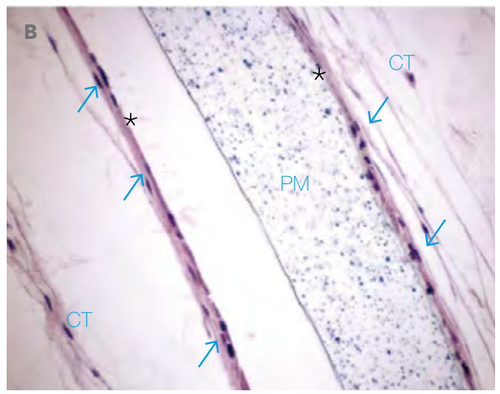
Proven biocompatibility and barrier function[4]

In vivo pre-clinical data on permamem®

After 30 days*, permamem® (PM) is well integrated into the surrounding tissue (connective tissue, CT) as shown by HE staining of histological sections, which points to an excellent biocompatibility. The healing of the membrane shows no signs of inflammation as demonstrated by only a thin layer (asterisks) of mononuclear cells (blue arrowheads) on the membrane surface. The found cell numbers were comparable between permamem® and an established collagen membrane (Jason® membrane, used as control). In addition, no cell penetration or soft tissue ingrowth into the PTFE membrane were detected during the observation period.



10x magnification



20x magnification

permamem® fulfills the requirements of biocompatibility according to EN ISO 10993 and EN ISO 7405. The membrane comes into contact with bone and soft tissue and is categorized as a medical device Class IIb for continous use for more than 30 days according to Directive 93/42/EEC.

4 Korzinskas et al. Int J Mol Sci. 2018 Sep 27;19(10).
*after subcutaneous implantation in mice

CLINICAL CASE BY

Dr. Alfonso Caiazzo, Salerno, Italy

Socket preservation with permamem® and cerabone®

Grafting of the extraction socket with small cerabone® granules

Covering of the augmented socket with permamem®. Fixation of the membrane by suturing of the marginal soft tissues

Situation two weeks post-operative

Situation four weeks post-operative after membrane removal

Situation six months post-operative before re-entry

Re-entry six months post-operative

After implant placement

Radiographic control following implant placement

Final prosthetic restoration

APPLICATION & FIXATION OF PERMAMEM® FOR OPEN HEALING

For membrane placement small mucoperiosteal pockets on the oral/buccal aspect of the alveolar socket can be prepared. To ensure membrane stability, permamem® should be trimmed extending three to five millimeters beyond the socket walls to cover the socket completely. A minimum distance of one millimeter to the adjacent teeth should be maintained. In this indication, permamem® can be passively stabilized by suturing of the marginal soft tissue.

CLINICAL CASE BY
Dr. Paolo Di Capua, Tel Aviv, Israel

Socket preservation with permamem® and maxgraft® granules


Situation before tooth removal


Situation after extraction of tooth 46


permamem® placed under the marginal soft tissue


Socket grafted with maxgraft® cancellous granules and covered with permamem®


Situation after membrane removal

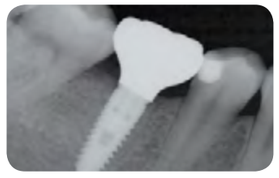

Re-entry four months post-operative


Situation after implant placement


After application of the healing cap and wound closure


Radiographic control


Final restoration


Radiographic control after final restoration

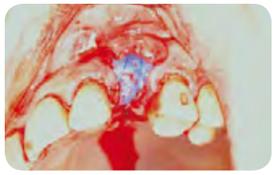
MEMBRANE REMOVAL FOLLOWING OPEN HEALING

If permamem® is used for open healing in socket- or ridge preservation, the membrane can be removed after approximately four weeks. This will provide sufficient time for the formation of the blood clot and a provisional matrix of woven bone in the alveole, which is the basis for the bony regeneration.

CLINICAL CASE BY
Dr. Marius Steigmann, Neckargemünd, Germany

Ridge preservation and reconstruction of the buccal wall using cerabone® and permamem®


Initial clinical situation showing bone wall defect


Following tooth extraction, socket grafting with cerabone® and covering of the alveole and buccal bone wall with permamem®


Suturing, permamem® left in place for open healing


Situation one week post-operative


Situation six months post-operative


Re-entry six months post-operative


Implant bed preparation


Site prepared for implant placement


Implant placement


Situation after implant placement before flap closure

Dr. med. dent./UMF Neumarkt Marius Steigmann, PhD, Neckargemünd, Germany

„With permamem® in an open healing procedure I have an attractive approach to regenerate the alveolar socket while keeping the natural soft tissue architecture. I have experienced excellent tissue compatibility of this membrane with almost no plaque accumulation."

CLINICAL CASE BY
Dr. Rainer Rannula, Tallinn, Estonia

Socket preservation with permamem® and collacone®

Situation after tooth extraction

Socket covered with permamem® after application of collacone® with no attempt to achieve primary wound closure

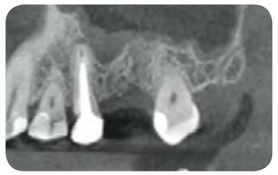
Situation three weeks post-operative, occlusal view

Situation three weeks post-operative, lateral view

Situation after membrane removal three weeks post-operative

Situation four months post-operative, occlusal view

Situation four months post-operative, lateral view



Radiographic control four months post-operative

Re-entry four months post-operative

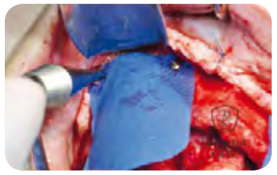
Final prosthetic restoration, occlusal view

Final prosthetic restoration, lateral view

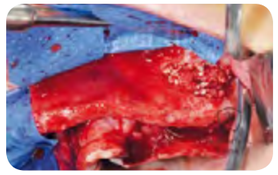
CLINICAL CASE BY
Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

GBR of the edentulous maxillary ridge using permamem®, cerabone® and autologous bone chips

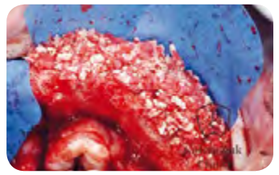
Atrophic maxillary ridge



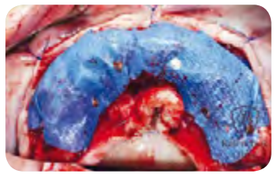
Fixation of permamem® to the ridge with titanium pins



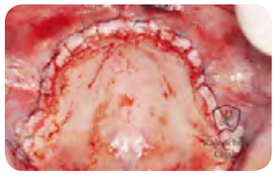
Sinus floor augmentation on both sides of the maxilla



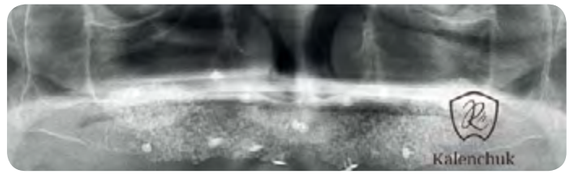
Placing of cerabone® mixed with autologous bone between the ridge surface and permamem® along the alveolar ridge



Covering and fixation of the graft with permamem®



Tension free suturing of the mobilized soft tissue over the augmentation area



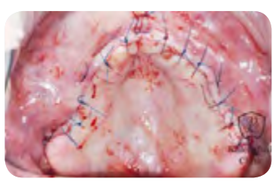
Orthopantomography of the maxilla after the augmentation

Maxillary ridge nine months after augmentation

permamem® and surrounding tissues at re-entry nine months post-operative

Grafted maxillary ridge after membrane removal nine months post-operative

Clinical situation of the maxillary ridge after implant placement



Wound closure

USE OF PERMAMEM® FOR GBR

Thanks to the smooth surface of permamem® no soft tissue attaches to it, however, a movement of the membrane may impair the regenerative process. Thus, in lateral or vertical GBR permamem® should always be immobilized at the defect site by sutures or ideally titanium pins.

CLINICAL CASE BY

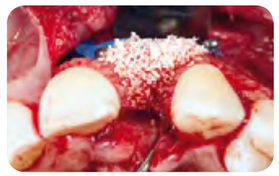
Dr. Pedro Lázaro, Madrid, Spain

Horizontal ridge augmentation with permamem®, Jason® membrane and cerabone®[5]

Initial clinical situation

Bone augmentation with cerabone® block

Covering with permamem® apically and fixation with titanium pins

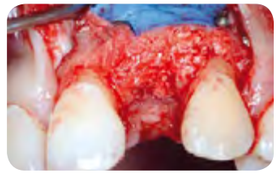


Additional augmentation with cerabone® granules

Additional covering with Jason® membrane and fixation with titanium pins

Suturing and primary wound closure

Clinical situation three weeks post-operative



Re-entry five months post-operative

Implant placement after membrane removal

Primary wound closure

Radiographic control six months after implant placement

Provisional restoration six months after implant placement

REMOVAL OF PERMAMEM® FOLLOWING GBR

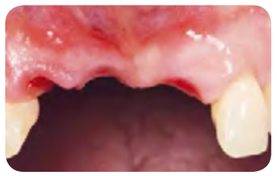
Following GBR, permamem® can be removed after approximately six months depending on the dimensions of the augmented bone defect and integration/remodeling time of the used bone grafting material.

5 González Ruiz, A. et al. Poster EuroPerio Amsterdam 2018.

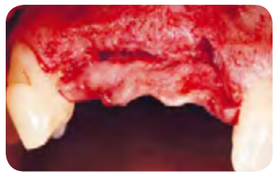
CLINICAL CASE BY

Prof. Dr. Stefan Fickl, Fürth and Würzburg, Germany

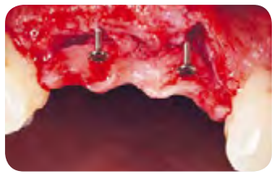
Vertical ridge augmentation with permamem®, cerabone® and autologous bone chips



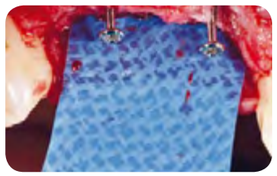
Pre-surgical situation



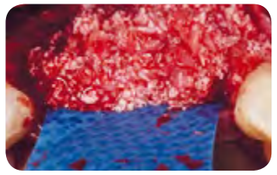
Intra-operative view



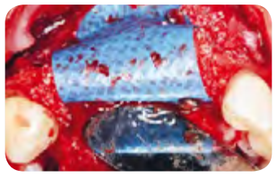
Insertion of tenting screws



permamem® placed at the palatal aspect



Grafting with cerabone® mixed with autologous bone chips

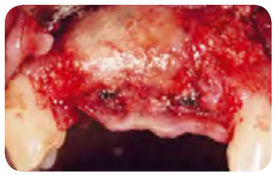


permamem® immobilized with pins on the buccal side

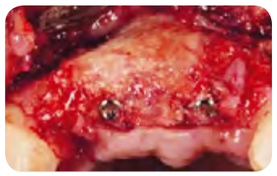
Primary wound closure

Temporary prosthesis

Situation four months post-operative



Re-entry four months post-operative, lateral view



Re-entry four months post-operative, occlusal view

Clinical situation at the time of final reconstruction

USE OF PERMAMEM® FOR VERTICAL GBR

For additional support of the membrane in vertical ridge augmentation procedures, permamem® can be applied using the tent pole screw technique.

AUGMENTATION WITH CERABONE® MIXED WITH AUTOLOGOUS BONE

Adding autologous bone chips to the bone substitute stimulates bone formation due to the osteoinductive and osteogenetic properties of autologous bone.

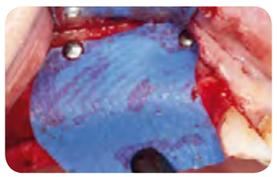
CLINICAL CASE BY

Dr. Stavros Pelekanos, Athens, Greece

Horizontal ridge augmentation with permamem®, cerabone® and autologous bone chips

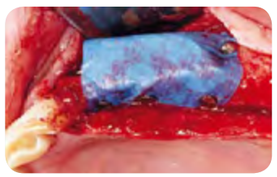
Atrophic alveolar ridge

Preparation of cortical bleeding points

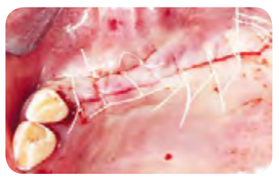


permamem® fixed with pins on the buccal aspect

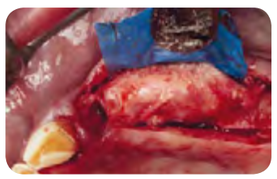
Grafting with cerabone® mixed with autologous bone chips



permamem® pinned on the palatal side to cover the bone grafting material



Primary wound closure



Re-entry and membrane removal six months post-operative

Placed implants, occlusal view

Placed implants, lateral view

Wound closure

Stable situation 18 months post-operative

Radiographic control with final prosthetic restoration

Dr. Ziv Mazor, Raanana, Israel

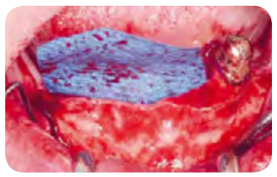
„I have used the „blue“ membranes in different indications and found them to be user friendly and very satisfactory.“

CLINICAL CASE BY

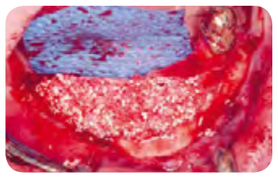
Dr. Bálint Molnár, Budapest, Hungary

Horizontal ridge augmentation with permamem®, cerabone® and autologous bone chips

Pre-operative situation



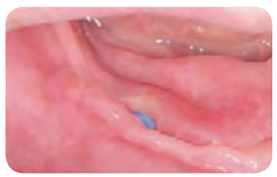
Intra-operative view; permamem® fixed on the lingual side



Site grafted with cerabone® mixed with autologous bone chips

permamem® placed to fully cover the grafted site; fixation of the membrane at the buccal aspect

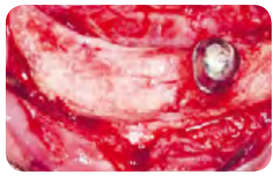
Primary wound closure



Small soft tissue dehiscence after one week

Closure of the dehiscence

Re-entry and membrane removal six months post-operative



Situation after membrane removal showing good integration of the bone graft

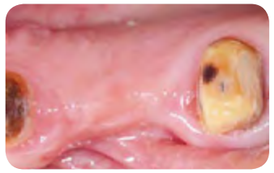
MANAGEMENT OF SOFT TISSUE DEHISCENCE

Since permamem® provides a barrier against bacterial penetration protecting the underlying bone from bacterial colonization, the membrane does not necessarily need to be removed immediately in case of a soft tissue dehiscence.
In general, permamem® can be left in place, if no swelling and/or infection is present and if the margins of the membrane are still covered by the flap.
To monitor the exposure, the patient should be enrolled in a continuous recall (weekly control) and should be instructed to rinse with antiseptic mouthwash (0.2% Chlorhexidine) every eight hours.

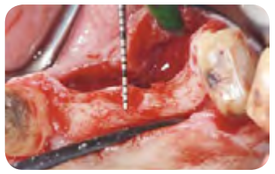
CLINICAL CASE BY

Dr. Serhat Aslan, Izmir, Turkey

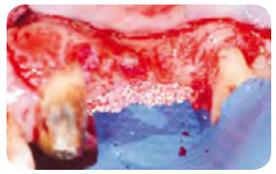
Lateral ridge augmentation with permamem®, cerabone® and autologous bone chips



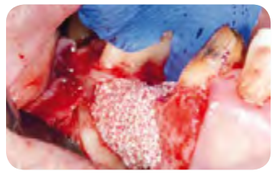
Pre-operative situation



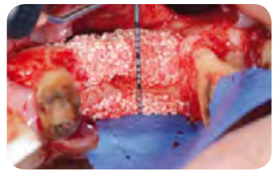
Intra-operative view



Bone augmentation with cerabone® mixed with autologous bone chips at the oral side



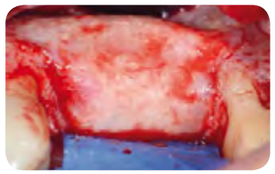
Bone augmentation at the buccal aspect



Occlusal view

Augmented area covered by permamem® and membrane fixation with titanium pins

Situation after membrane removal six months post-operative



After membrane removal, occlusal view

After implant placement

Final prosthetic restoration

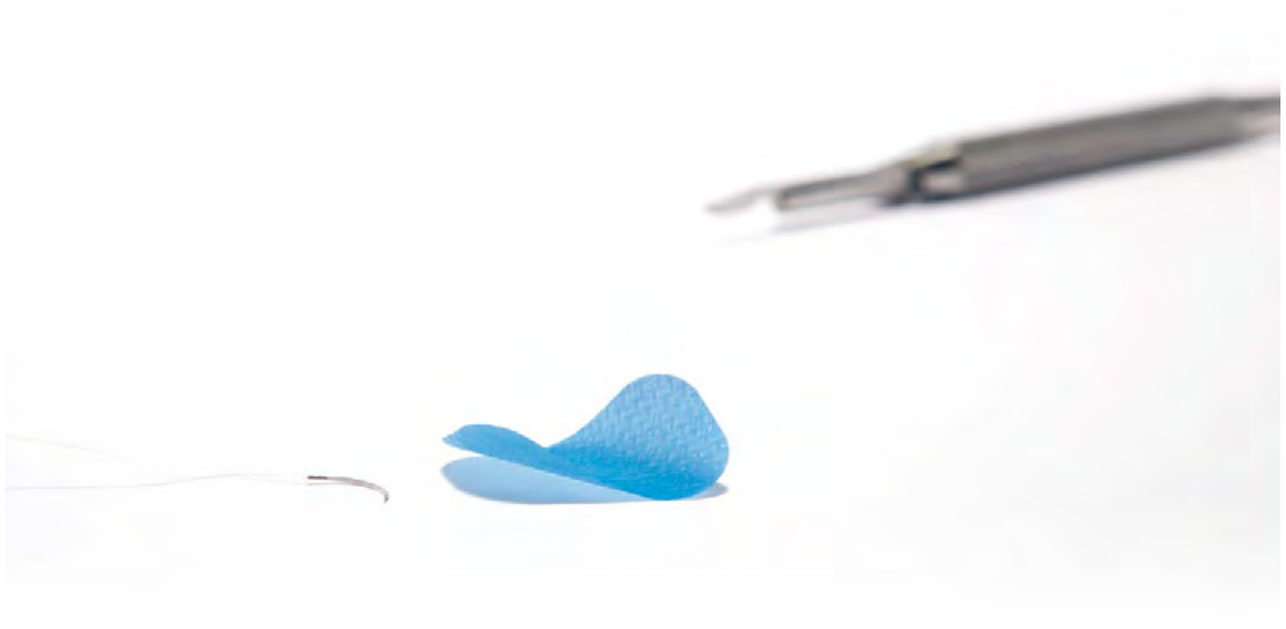
Dr. Serhat Aslan, Izmir, Turkey

„Honestly, removal of the non-resorbable barriers are taking lots of effort and with permamem® it is so easy. permamem® is so thin and soft – in my opinion, this is a major advantage when a clinician is dealing with the thin alveolar mucosa."

Product Specifications

permamem® is delivered sterile and is intended for single use only.

Art.-No.	Size	Content
801520	15x20 mm	1 membrane
802030	20x30 mm	1 membrane
803040	30x40 mm	1 membrane



bone & tissue regeneration

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soft tissue

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Rev.: PMen-02/2019-10