





# permamem®

HIGH-DENSITY

PTFE BARRIER MEMBRANE



### Polytetrafluoroethylene (PTFE) -

### stable, inert and biocompatible

In regenerative dentistry, polytetrafluoroethylene (PTFE) membranes have a long history and are used for more than 30 years¹. 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

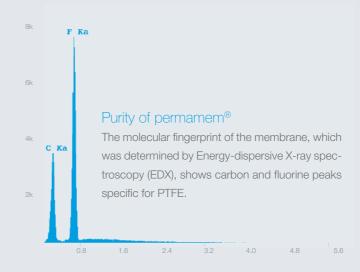
In the course of the evolution of GBR and Guided Tissue Regeneration (GTR), different types of membranes have evolved. In particular, for the regeneration of defects outside the ridge contour, the use of a non-resorbable, dimensionally stable membrane is recommended, because it offers a higher stability 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<sup>2</sup>.



### **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.



<sup>1</sup> 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.

# 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.

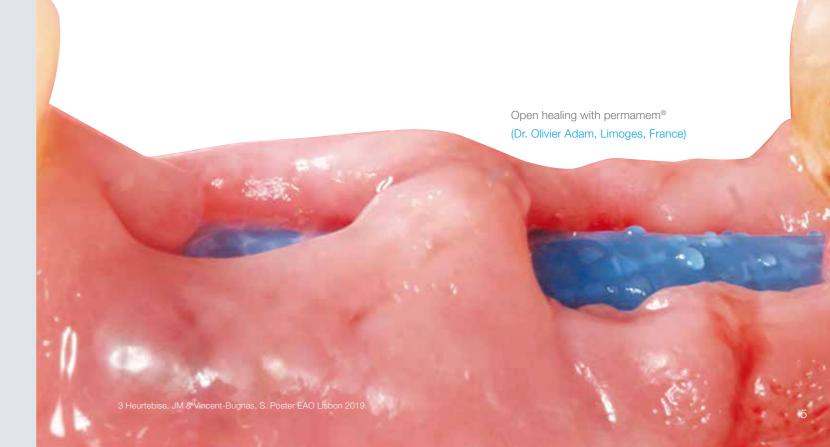
# IMPLANTOLOGY, PERIODONTOLOGY AND ORAL AND CMF SURGERY

- 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)

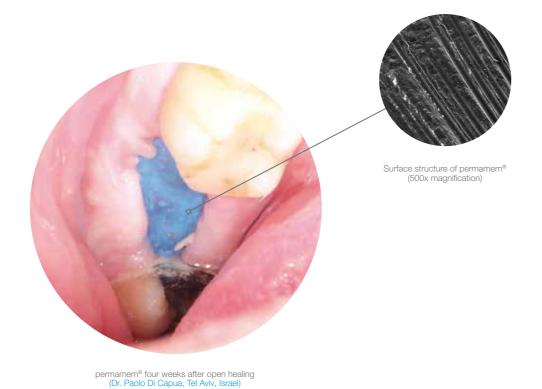


# Open healing in socketand ridge preservation<sup>3</sup>

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.



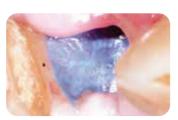
# **Less Plaque Accumulation**



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.



(Dr. Monica Turco, Bari, Italy)



permamem® two weeks after open healing 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).







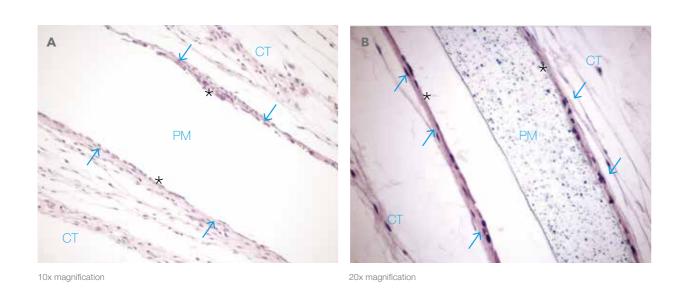
Membrane placement (left), situation six months post-operative at re-entry (mid) and after membrane removal (right)



# Proven biocompatibility and barrier function<sup>4</sup>

### 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.



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 continuous use for more than 30 days according to Directive 93/42/EEC.

### **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 Situation socket with permamem®. Fixation operative of the membrane by suturing of the marginal soft tissues



Situation two weeks post-



Situation four weeks postoperative after membrane removal



Situation six months postoperative before re-entry



Re-entry six months postoperative



After implant placement



Radiographic control following implant placement



Final prosthetic restoration



### **APPLICATION & FIXATION OF PERMAMEM® FOR OPEN HEALING**

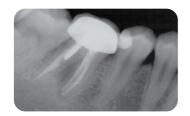
For membrane placement small mucoperiosteal pockets on the oral/buccal aspect of the alveolar socket can be prepared. To ensure membrane stability, permamem® should be trimmed extending three to five millimeters beyond the socket walls to cover the socket completely. A minimum distance of one millimeter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

**CLINICAL APPLICATION** of permamem®

### **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

Radiographic control



Re-entry four months postoperative





cap and wound closure



Radiographic control after final restoration

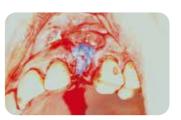
### **CLINICAL CASE BY**

# 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 Suturing, permamem® left in grafting with cerabone® and covering of the alveole and buccal bone wall with permamem®



place for open healing



Situation one week postoperative



Situation six months postoperative



Re-entry six months postoperative



Implant bed preparation



Site prepared for implant placement



Implant placement



Situation after implant placement before flap closure



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.

### 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 postoperative, occlusal view



Situation three weeks postoperative, lateral view



Situation after membrane removal three weeks post-operative



Situation four months postoperative, occlusal view



Situation four months postoperative, lateral view



Radiographic control four months post-operative



Re-entry four months postoperative



Final prosthetic restoration, occlusal view



Final prosthetic restoration, lateral view

### **CLINICAL CASE BY**

# Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

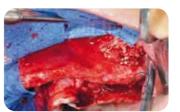
GBR of the edentulous maxillary ridge using permamem®, cerabone® and autologous bone chips



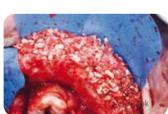
Atrophic maxillary ridge



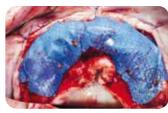
Fixation of permamem® to the ridge with titanium pins



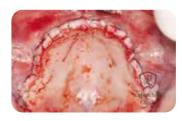
Sinus floor augmentation on both Placing of cerabone® mixed with sides of the maxilla autologous bone between the



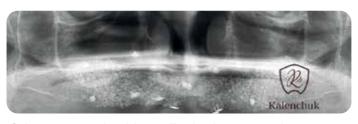
Placing of cerabone® mixed with autologous bone between the ridge surface and permamem® along the alveolar ridge



Covering and fixation of the graft with permamem®



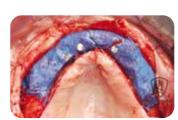
Tension free suturing of the mobilized soft tissue over the augmentation area



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<sup>®</sup>, Jason<sup>®</sup> membrane and cerabone<sup>®5</sup>



Initial clinical situation



Bone augmentation with cerabone® block



Covering with permamem® apically and fixation with titanium pins



Additional augmentation with cerabone® granules

### **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



Additional covering with Jason® membrane and fixation with titanium pins



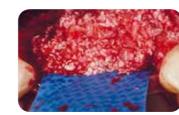
Suturing and primary wound



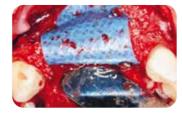
Clinical situation three weeks post-operative



Re-entry five months postoperative



Grafting with cerabone® mixed with autologous bone chips



permamem® immobilized with pins on the buccal side



Primary wound closure



Temporary prosthesis



Implant placement after membrane removal



Primary wound closure



Radiographic control six months after implant placement



Provisional restoration six months after implant placement



Situation four months postoperative



Re-entry four months postoperative, lateral view



Re-entry four months postoperative, occlusal view



Clinical situation at the time of final reconstruction



### **REMOVAL OF PERMAMEM® FOLLOWING GBR**

Following GBR, permamen® 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.



# 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 APPLICATION** of permamem®

### **CLINICAL CASE BY**

### Dr. Stavros Pelekanos, Athens, Greece

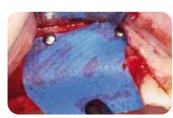
Horizontal ridge augmentation with permamem®, cerabone® and autologous bone chips



Atrophic alveolar ridge



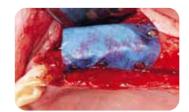
Preparation of cortical bleeding



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 postoperative



Radiographic control with final prosthetic restoration

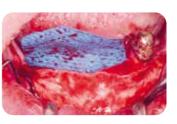
### **CLINICAL CASE BY**

# Dr. Bálint Molnár, Budapest, Hungary

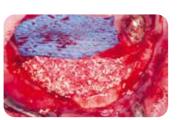
Horizontal ridge augmentation with permamem®, cerabone® and autologous bone chips



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 Primary wound closure the grafted site; fixation of the membrane at the buccal aspect

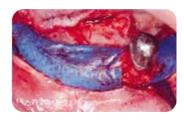




Small soft tissue dehiscence after one week



Closure of the dehiscence



Re-entry and membrane removal six months post-operative



Situation after membrane removal showing good integration of the bone graft

### Dr. Ziv Mazor, Raanana, Israel

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

### **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

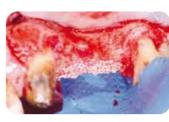
Lateral ridge augmentation with permamem®, cerabone® and autologous bone chips







Intra-operative view



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



Bone augmentation at the buccal Occlusal view aspect

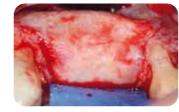




Augmented area covered by permamem® and membrane fixation with titanium pins



Situation after membrane removal six months post-operative



After membrane removal, occlusal view



After implant placement



Final prosthetic restoration

### Dr. Serhat Aslan, Izmir, Turkey

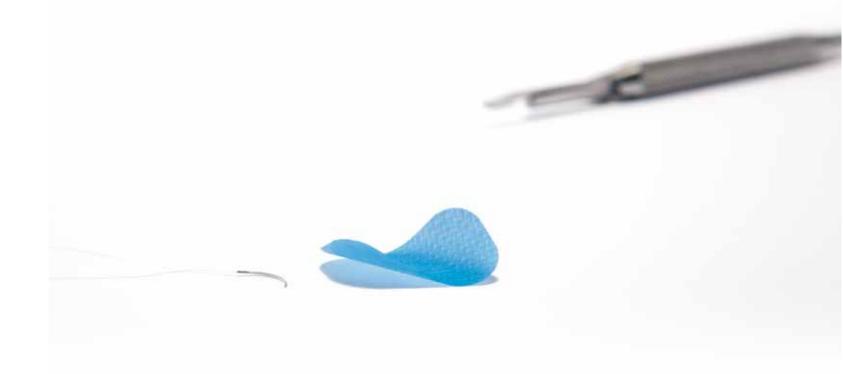
"Honestly, removal of the non-resorbable barriers are taking lots of effort and with permamem® it is so easy. permamem® is so thin and soft - in my opinion, this is a major advantage when a clinician is dealing with the thin alveolar mucosa."



# Product Specifications

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

ArtNo.	Size	Content
801520	15x20 mm	1 membrane
802030	20x30 mm	1 membrane
803040	30x40 mm	1 membrane







# Innovation. Regeneration. Aesthetics.

soft tissue

education

hard tissue

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