bone & tissue regeneration

botiss biomaterials

permamem®

HIGH-DENSITY
PTFE BARRIER MEMBRANE

barrier membrane

non-resorbable

synthetic

biocompatible

straumanngroup Certified Partner

Polytetrafluoroethylene **(PTFE) –**

stable, inert and **biocompatible**

Polytetrafluoroethylene (PTFE) is a synthetic, chemically stable and biologically inert fluoropolymer. During polymerization the gaseous tetrafluoroethylene is transformed into the polymeric polytetrafluoroethylene by the help of catalysts creating one of the most vigorous chemical bonds. PTFE is able to resist biological (enzymatic) attack, does not stick and is biocompatible. It has been employed for more than 30 years for numerous medical applications, including sutures, arterial grafts, filters and catheters[1]. In regenerative dentistry PTFE membranes have come a long way since they were first introduced for Guided Tissue Regeneration in the form of expanded PTFE membranes[2]. Nowadays, PTFE membranes are mainly used for Guided Bone Regeneration.

permamem®

Barrier membranes in regenerative dental medicine

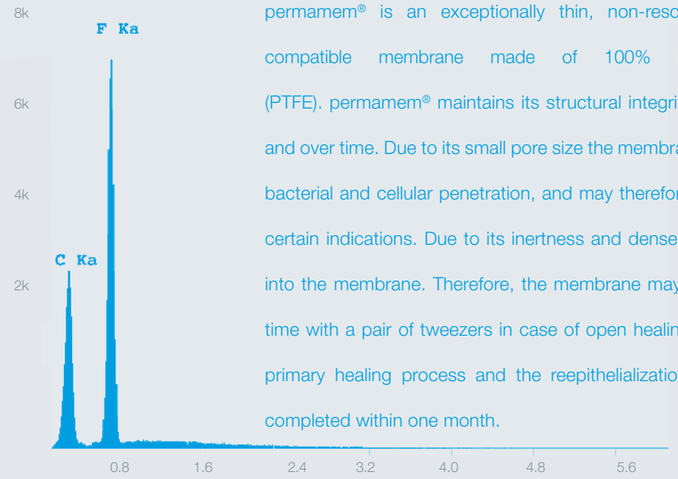
Guided Tissue- and Guided Bone Regeneration (GTR, GBR)

Guided Tissue- and Guided Bone Regeneration (GTR, GBR) are well-established techniques in modern dentistry to augment lost tissues around teeth and dental implants respectively[3]. The concept of these methods is the placement of a barrier membrane between the soft tissue and residual bone in order to prevent the fast-proliferating epithelial cells from populating the bony defect and to provide space and time for the migration of slow-dividing osteogenic or periodontal ligament cells into the defect area.

Guided bone regeneration (GBR)

In the course of the evolution of both techniques, different types of membranes have evolved. In particular, for the regeneration of defects outside the ridge contour, the use of a non-resorbable, volume 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 polytetrafluoroethylene (PTFE) are the most commonly used non-resorbable barrier membranes[4].

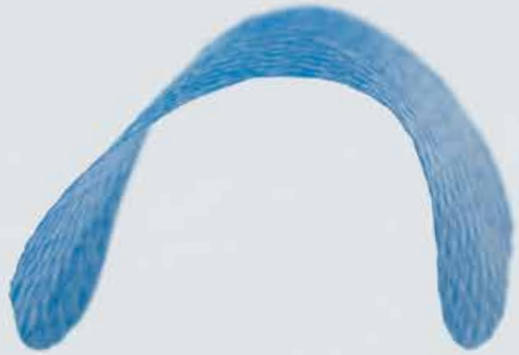
1 Maitz MF. Biosurface and Biotribology Volume 1, Issue 3, September 2015, Pages 161-176
2 Gentile et al. Biotechnol J. 2011 Oct;6(10):1187-97.
3 Retzepi M & Donos N. Clin Oral Implants Res. 2010 Jun;21(6):567-76.
4 Carbonell et al. Int J Oral Maxillofac Surg. 2014 Jan;43(1):75-84.



Energy-dispersive X-ray spectroscopy (EDX) of permamem®: molecular fingerprint. Characteristic peaks of carbon and fluorine. No other phases detectable.

permamem® is an exceptionally thin, non-resorbable, biologically inert and biocompatible membrane made of 100% high-density polytetrafluoroethylene (PTFE). permamem® maintains its structural integrity both during the initial implantation and over time. Due to its small pore size the membrane acts as an efficient barrier against bacterial and cellular penetration, and may therefore be left in place for open healing in certain indications. Due to its inertness and denseness, adjacent tissue does not grow into the membrane. Therefore, the membrane may be easily removed after the healing time with a pair of tweezers in case of open healing. After removal of permamem®, the primary healing process and the reepithelialization of the regenerating soft tissue is completed within one month.

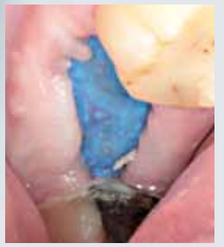
non-resorbable barrier membrane



permamem® –

engineered for open healing in socket/ridge preservation

Open healing with permamem® in socket or ridge preservation enables maintenance of the soft tissue architecture and contours since no primary wound closure is required. Due to the missing flap closure, the mucogingival line will not be displaced and the attached/keratinized gingiva will be preserved. The non-surgical removal of the membrane after the healing time omits the need for big surgical incisions (vertical releasing incisions), thus improving aesthetics.

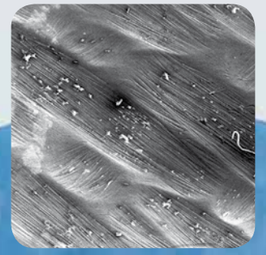


permamem® left in place for open healing, Dr. Paolo Di Capua, Tel Aviv, Israel

Properties

- 100 % synthetic PTFE barrier membrane
- Ultra-thin (~0.08 mm)
- Impervious to bacteria due to dense structure
- Easily removable due to minimal tissue ingrowth into the surface structure
- No need for primary soft tissue closure
- 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

permamem®



Surface structure of permamem®

(SEM 30x magnification)

Indications:

Implantology, Periodontology and Oral and CMF Surgery

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

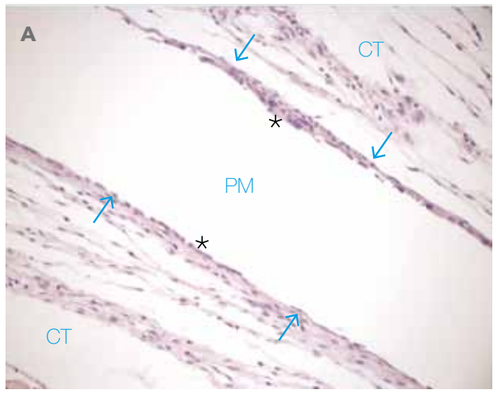
In vivo pre-clinical data on permamem®

Proven biocompatibility

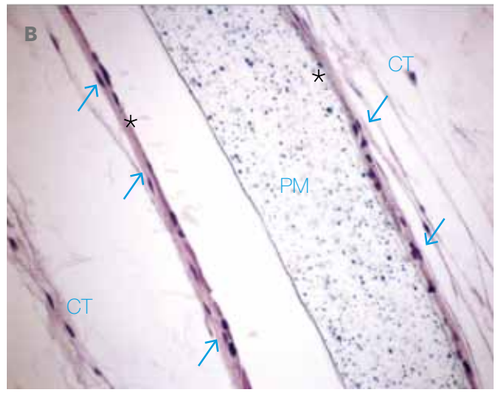
in a mouse model

Dr. M. Barbeck, Berlin-Brandenburg Center for Regenerative Therapies, Charité – University Medical Center, Berlin, and S. Stojanovic, Prof. Dr. S. Najman, Faculty of Medicine, University of Nis, Serbia

The biocompatibility of permamem® was examined following subcutaneous implantation into mice. HE-staining of histological sections at 30 days show permamem® (PM) well integrated into the surrounding tissue (connective tissue, CT) pointing to an excellent biocompatibility. Only a thin layer (asterisks) of mononuclear cells (blue arrowheads) was found at the membrane surfaces indicating its non-inflammatory properties.



10x magnification



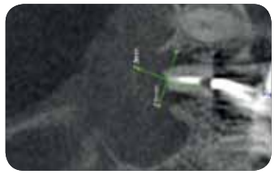
20x magnification

permamem® fulfills the requirements of biocompatibility according to EN ISO 10993-1 and EN ISO 7405. The membrane comes into contact with bone and soft tissue and is categorized as a medical device Class IIa according to Directive 93/42/EEC.

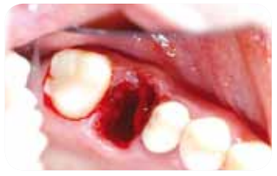
CLINICAL CASE BY

Dr. Rainer Rannula, Tallinn, Estonia

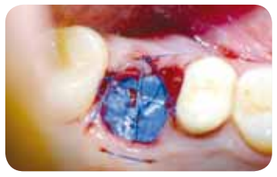
Socket preservation with permamem®



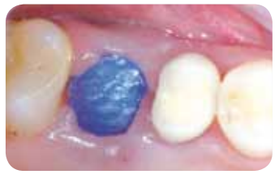
Preoperative CT



Situation after tooth extraction



Socket covered with permamem® after application of collacone®

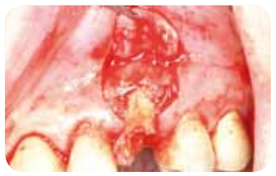


Clinical situation three weeks post-operative

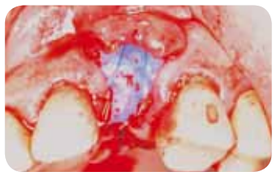
CLINICAL CASE BY

Dr. Marius Steigmann, Neckargemünd, Germany

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



Clinical situation with broken tooth and bone dehiscence



Socket preservation with cerabone® and permamem®. permamem® sutured to the periosteal flap

Suturing. permamem® left exposed on the coronal aspect

Healing one week post-surgical

With permamem® in an open healing procedure I have an attractive approach to regenerate the alveolar socket while keeping the natural soft tissue architecture.

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

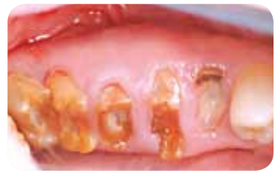
OPEN HEALING & MEMBRANE REMOVAL

Due to its small pore size permamem® acts as an efficient barrier against bacterial and cellular penetration, and may therefore be left in place for open healing in socket- and ridge preservation. The membrane should be removed after 3-4 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.

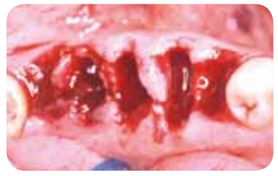
CLINICAL CASE BY

Dr. David Botond Hangyási, Szeged, Hungary

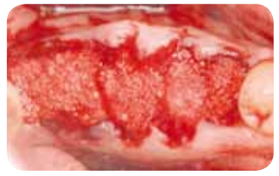
Multiple socket preservation using permamem® and collacone® max



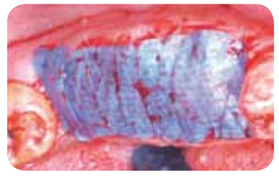
Pre-surgical situation



Situation after tooth extraction



Sockets grafted with collacone® max



Grafted sockets covered with permamem®

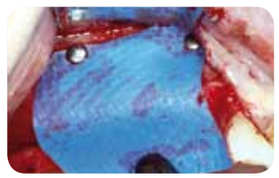
CLINICAL CASE BY

Asst. Prof. Stavros Pelekanos, University of Athens, Greece

Horizontal ridge augmentation using cerabone® and permamem®

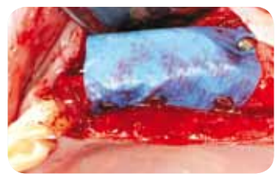
Atrophic alveolar ridge

permamem® cut into shape

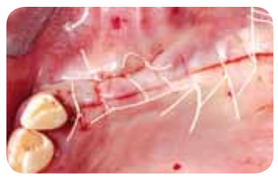


permamem® fixed with pins on the buccal side

cerabone® granules mixed with autologous bone chips and applied to the defect



permamem® fixed with pins on the palatal aspect



Primary wound closure

APPLICATION & FIXATION

To ensure membrane stability and protection of the bone grafting material, permamem® should extend three to four milimeters beyond the margins of the bone defect after placement. A minimum distance of one millimeter to the adjacent teeth should be maintained. It is recommended to fix permamem® with sutures, screws or pins.

Product Specifications

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

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

Innovation. **360° Regeneration.** Aesthetics.

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