**\*\*Open**Tex<sup>®</sup>

**\*\*OpenTex**\*-TR



**::Bio**Cover



812, 27, Dunchon-daero 457beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13219, Korea Tel: +82 2 548 1875 Made in Korea www.purgo-biologics.com EU Importer
Purgo Biologics Europe

1 Square Felix Bloch,
Pôle Activ' Ocean,
85300 Challans, France
Tel: +32 (0)2 28 10 61 02
E-mail: europe@purgobiologics.com
www.purgo-europe.com

EU Authorized Representatives
OBELIS S.A

Bd. Général Wahis, 53 1030 Brussels, Belgium Tel: +32 2 732 59 54 Fax: +32 2 732 60 03 E-mail: mail@bbefe.net www.obelis.net

THE Graft™ ,OpenTex®, OpenTex®-TR, Biotex®, THE Graft™ Collagen.









#### "Purgo focuses on Bone and Membrane only!"

Founded in 1999, Purgo Biologics strives to become one of the leading global companies in oral health care with its focus on safe biomaterials for soft tissue and bone regeneration.

Based on the specialized experiences accumulated by our outstanding research personnel, Purgo Research and Development Center based in Seoul is thriving to become the best in the world, specifically in the expertise of oral biomaterials for soft tissue and bone regeneration. All members in Research and Development Center are pursuing the optimized technical developments with various clinical studies, cooperative research with the governments, clinicians and educational institutions.

The solutions manufactured by Purgo are gaining fame throughout the world and Purgo's solutions are widely accepted by global dentists from more than 30 countries.

Our production site is complying with the most international quality standards and regularly inspected by international agencies. Each production stage of our biologics solutions are controlled from the selection of the raw material to the final product.





Natural bone substitute Page 4 to 9

## **THE** Graft<sup>™</sup> Collagen

Bone substitute with collagen
Page 10 to 13

## **OpenTex**

Non-resorbable PTFE membrane Page 14 to 17

## OpenTex®-TR

PTFE Titanium reinforced membrane Page 18 to 21



Suture for dental implant surgery Page 22 to 25

### **Bio**Cover<sup>™</sup>

Resorbable collagen membrane
Page 26 to 27



#### Science Speaks THE Graft



## **THE** Graft<sup>™</sup>**:::**

THE Graft<sup>™</sup> is a natural, porcine bone mineral matrix for bone reconstruction. It is produced by removal of all organic components from porcine bone. Due to its native structure THE Graft™ likens the physical and chemical aspects of mineralized matrix of human bone. When packed into a bone defect, THE Graft™ gradually resorbs and replaced with bone during the healing process. It is available in cancellous granules packaged in vial. THE Graft™ is sterilized using gamma irradiation.

Unique proprietary manufacturing process removes very effectively potential immunogenic organic elements keeping the natural structure of the matrix.

THE Graft™ quality and safety have been scientifically demonstrated with invitro, in-vivo studies, large case study reports and international randomized clinical research. Systematic review and meta-analysis are conducted on THE Graft™ worldwide. [1-2]

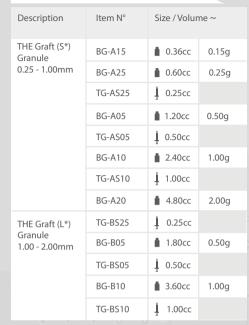
THE Graft<sup>™</sup> has established its fame throughout the world, both scientifically and clinically, becoming a popular bone regeneration material.







### Specifications



\*S:small / L:large

## Indications

THE Graft !!!

BONE REPLACEMENT MATERIALS	GR/CC		Extraction socket ith defective sock	Minor bone et augmentation	Major bone augmentation	Sinur floor elelation	Peri-implantitis
THE Graft™ Granules 0,25-1mm	0.25g~0,6cc		•				
THE Graft™ Granules 0,25-1mm	0.50g~1,2cc	•	•				
THE Graft™ Granules 0,25-1mm	1.00g~2,4cc	•	•	•	•	•	
THE Graft™ Granules 1-2mm	0.50g~1,8cc				•	•	
THE Graft™ Granules 1-2mm	1.00g~3,6cc				•	•	

THE Graft #



[1] Alveolar ridge regeneration of damaged extraction sockets using deproteinized porcine versus bovine bone minerals: A randomized clinical trial. 100 patients Clin Implant Dent Relai Res 2018 Jul 27. Epub 2018 Jul 27.

## «Safety and purity are an important concern when using a biomaterial»

THE Graft™ Purity [3-4-5]

Is THE Graft<sup>™</sup> safety material?

Proprietary virus inactivation process technology. Thanks to highly efficient manufacturing process, THE Graft™ is free from any organic components that might be potential causes of infection or immune reaction. In addition the unique process helps preserve the physical properties of THE Graft™ with its native osseous structure. A large surface area is a key requirement for graft materials, and not only results in a larger surface region available for osteoblast cells attachment but also facilitates the exchange of nutrients and waste products, it allows greater amounts of blood, proteins, and growth factors to be absorbed onto the scaffold.

THE Graft<sup>™</sup> has a high purity.

The analysis result minimal residual protein, soft tissue, and organic bone matrix, proves that

THE Graft<sup>™</sup> is deproteinized enough for safe use.

Other than THE Graft™, such low values for organic residues are only found with bone graft material treated at high temperatures which may cause the detriment of the natural bone structure.



These results show that organic substances, including collagen and other organic compounds, were successfully removed from THE Graft™, which is thus not affected by issues associated with organic content. [3]



Is porcine bone safer than bovine?



THE Graft™ demonstrated a protein content lower than that of the natural bovine bone graft material. Bovine cancellous bone is Not Free of Zoonoses, such as BSE-Bovine Spongiform Encephalopathy. Porcine bone has a relatively low risk of zoonosis.

#### Less residual organic content for High purity



High purity means low organic matters

- ► High Surface Energy
- ▶ High Hydrophilicity

#### THE Graft<sup>™</sup> Biocompatibility [3-4-5]

« Getting closer to human bone »

THE Graft<sup>™</sup> is structurally similar to human bone. It has high possible level of porosity combined with a natural interconnectivity.

Safe & Biocompatible

The combination of porcine origin with the high level of purity enables predictable bone growth without risking an immunogenic reaction. In an In-Vitro study THE Graft™ was shown to encourage cell adhesion to the same extent as the compared DBBM (Deproteinized bovine bone matrix), and therefore offering optimal conditions for vital cell growth.

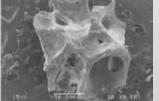


Porosity is an important factor in determining tissue-implant material integration.

High porosity leads to a quicker absorption of

High porosity leads to a quicker absorption of liquids and cells spreading. THE Graft™ provides the optimized bone architecture for cells adhesions and tissue regeneration.

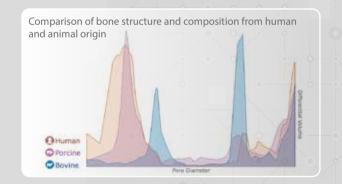






Human bone

THE Graft™





[3] Physicochemical characterization of porcine bone-derived grafting material and comparison with bovine xenografts for dental applications. Jung Heon Lee, Gyu Sung Yi, Jin Woong Lee, Deug Jeong Kim, School of Advanced Materials Science and Engineering, Sungkyunkwan University, Suwon, Korea 2SKKU Advanced Institute of Nanotechnology, Sungkyunkwan University, Suwon, Korea

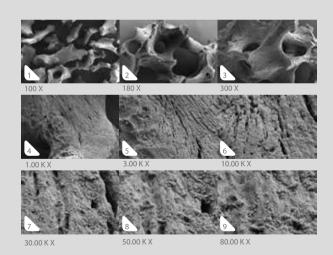
#### THE Graft™ High Porosity [3-4-5-6]

High porosity and early remodelling improve clinical performance.

The high porosity of THE Graft™ means a quicker absorption of fluids (e.g; blood) in comparison with DBBM. This not only facilitates the application of the material but also leads to early remodelling and improved clinical performance.

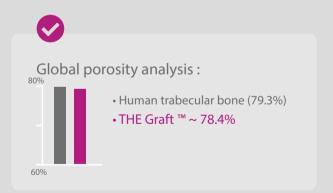
High level of porosity was demonstrated with particle pore structure test, particle size distribution test and total porosity tests.





#### THE Graft™ Structure :

- 1 -Macropores (diameter > 100µm), are necessary to form blood vessels and induce both bone growth and reorganization around the graft material.
- 2 -Micropores (diameter <10  $\mu$ m), are required for the penetration of body fluids, ion transportation, the attachment of osteoblasts, and the precipitation of newly formed HA.
- 3 -Nanopores are characterized by dimension of less than 100 nanometers pores size between grains. Nano-porosity increases bone graft permeability to the physiological fluids and cells adhesion.



#### THE Graft™ Hydrophilicity

THE Graft™ consists of a unique inter-connecting pore system that ensures an efficient fluid intake and permits the migration of cells. This pore system and high surface energy enhance the osteoconduction process.

The SSA of THE Graft™ was similar with the values measured for the «bovine bone a» and significantly larger than the «bovine bone b». Considering that both THE Graft™ and «the bovine bone a» had a similar surface morphology and pore size distribution with a substantial amount of nanoscale pores. we believe that this difference in the SSA was closely related to the nano/microscale structure of the bone graft materials.

#### Specific surface area

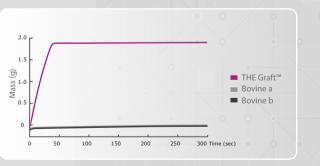


THE Graft™ has shown to have higher wettability than the compared xenografts. It suggests that THE Graft™ is relatively hydrophilic and can be easily wet by body fluids after implantation. Not only protein adsorption, but also the attachment, growth, and proliferation of various types of cells, including osteoblasts, have been reported to be significantly affected by the wettability of the material surface.

This high wettability of THE Graft™ suggests that it may have advantages in terms of protein adsorption and the resulting cell adhesion and proliferation processes after implantation.

The content of the organic component of THE Graft™ was somewhat lower than compared existing xenografts.

Wetting mass of the graft materials as a function of time.



This result indicates that the wettability of THE Graft™ was significantly higher than the bovine bone.





## THE Graft :: Collagen

Biocompatible and safe natural bone grafting material, THE Graft™ Collagen is just the science itself!

THE Graft™ Collagen block is composed of porcine derived bone mineral matrix from cancellous bone and atelocollagen from porcine tendon. THE Graft™ Collagen is a bone graft intended to fill, augment, and/or reconstruct periodontal, oral, and maxillofacial defects.

THE Graft™ Collagen bone mineral matrix is similar to physical and chemical aspects of human bone mineralized matrix. Hydrated collagen components have viscosity that facilitate for blending bone mineral matrix. With this characterization, THE Graft™ Collagen can be trimmed and/or molded to the various defect shapes and can be fixed in bone defect site.

As time passes, THE Graft™ Collagen is partially transformed by the osteoclast and osteoblast cells





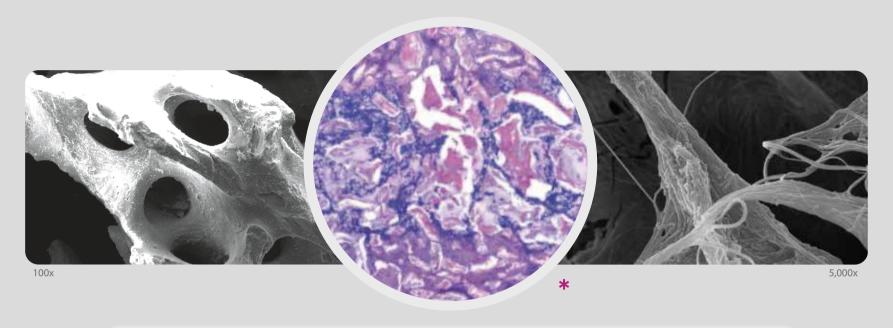


### Specifications

THE Graft™ Collagen

#### **THE** Graft<sup>™</sup> **!!!** Collagen Item N° Size/Measure Description THE Graft™ TCB-01 7x7x7 mm 0.34cc Collagen Block Type TCB-02 8x9x10 mm TCB-03 10x11x12 mm 1.32cc TCR-01 5x3x8 mm 0.22cc

Ring Type 5x4x9 mm TCR-02 0.26cc TCR-03 5x5x10 mm 0.29cc





#### 1 Easily Moldable

Made of THE Graft™ granules and collagen,
THE Graft™ Collagen is easier to mold than THE Graft™ granules alone.
Therefore, THE Graft™ Collagen has better handling property compared to that of THE Graft™, making it possible to adapt grafting materials to various shapes of the defect site with more ease.

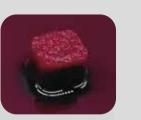
#### 2 Optimal osteoconductivity

While retaining better handling properties, THE Graft™ Collagen is able to form sufficient osseous tissue for implant placement and maintain natural volume and great adhesion property which lead to minimum chair time.

#### **3** Predictable clinical results

With great hydrophilicity, THE Graft™ Collagen stabilizes the clot and aids in revascularization of the grafting material in the defect area to increase cell migration efficiency to the minreal substrate. As a result, fast bone formation can be expected, as well as a predictable clinical result.

It is advantageous for shape and space maintenance







\* Invivo histological evaluation: Rats were sacrified at 8 weeks.

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#### Make smart decision with smart alternative!



## **::OpenTex**®

OpenTex® Non-Resorbable PTFE Membrane is a pure medical-grade polyte-trafluoroethylene (PTFE) sheet with inert biological features and predictable barrier effect. Due to the smooth surface and small pore size, OpenTex® PTFE Membrane resists the incorporation of bacteria into its structure and eases the removal of the membrane.

Non-resorbable membrane is sustainable for surgical procedure with no primary closure. OpenTex® Membrane is ideal for space-making feature providing enough space for host cells to adhere to grafting materials. OpenTex® is supplied sterile for single use only and available in various sizes. [7]



implant placement.

#### The Evolution of PTFE Membrane







#### Indications

#### GBR (Guided Bone Regeneration)

- Simultaneous use of GBR membrane and implants.
- Augmentation around implant placed in immediate extraction sites or delayed extraction sockets.

#### GTR (Guided Tissue Regeneration)

• Filling of bone defects after root resection, removal of cysts, and removal of retained teeth.





## Specifications





[7] Alveolar ridge preservation using an open membrane approach for sockets with bone deficiency: A randomized controlled clinicat trial Dong-Joo Sung DOS, MSD1 1 Hyun-Chang Lim DOS, PhD2 I Dong-Woon Lee DOS, Ph01 Clin Implant Dent Relat Res.

#### OpenTex® Main Features



- · 100% medical grade PTFE membrane.
- ·Biologically inert and chemically non-reactive.
- ·Healing procedure is not interfered with membrane absorption.



## Microporous

- ·Promote the gingival tissue attachment.
- ·Enhances ease in the interstitial fluid circulation.
- · Resist the bacteria infection and fibroblast cells migration.



#### Withstands Exposure

- ·Rapid recovery of soft tissue. ·Primary Closure is not necessary.
- ·Virtually impervious to bacteria.
- Minimum flap reflection or dissection. Safe from bacteria infection, even in the event of the exposure.
- · Protect the tissue regeneration
- Regenerated underlying tissue can be evaluated.
- Provide a proper environment for the growth of blood vessel and osteogenic cells.

#### OpenTex® Benefits



Soft Tissue Obtaining



Natural Saliva Passage



Aesthetic Implant Restoration



Minimally Invasive

#### OpenTex® Strenghts

1 Stability:

Non-resorbable PTFE Membrane offers enough healing time to bone regenerative process.

2 Biologically inert:

PTFE is soft tissue friendly so it is ideal material as a barrier for bone regenerative process.

3 Withstands to exposure :

PTFE Membrane withstands to exposure since it is impervious to bacteria due to their barrier function.

#### Characteristics of OpenTex® [8]

Impervious to Bacteria

Most of Oral Bacteria is larger than 1um. OpenTex® is micro-porous material that has the pore size small enough to prevent bacterial infiltration.

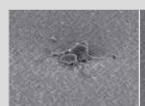
Biocompatible, OpenTex® facilitates cell adhesion on the surfaces.

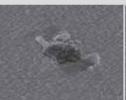
Test performed shows that the surface of OpenTex® is not toxic causing cells to adhere well on the surface.

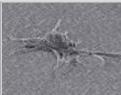
24 Hours for five cells adhesion cases on OpenTex® surface (SEM: Scanning Electron Microscope)

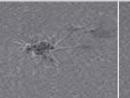


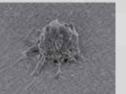
The matter is **PORE SIZE** 











[8] Review of pore sizes effect on OpenTex®/OpenTex®-TR PTFE Membrane

#### Make smart decision with smart alternative!



# :: OpenTex®-TR

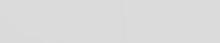
Membrane is composed of 100% polytetrafluoroethylene (PTFE) sheet and grade 1 titanium frame, which are biologically inert and tissue compatible.

OpenTex®-TR Non Resorbable PTFE Membrane with titanium frame is designed to have a suitable surface structure and porosity to prevent integration and passage of bacteria within the interstices of the material, while maintaining space for host cells adhesion to the device.

OpenTex®-TR provides a favorable environment for neovascularization and healing of defects, through repopulating the bone derived cells and protecting the bony defects from migration of the gingival tissue derived cells.

Since the adequate space maintenance is critical to this procedure, the membrane is sufficiently stiff to prevent spontaneous collapse, but also flexible enough to easily conform to tissue contours and reduce perforations of overlying soft tissue. [9]





#### Indications

#### 01.

Extraction socket reconstruction

#### 02.

Bone regeneration

#### 03.

Where primary closure isn't possible

#### Primary Closure







## Specifications

<b>::Open</b> Tex®	<b>∷OpenTex</b> °-⊤R				
Item N°	Size				
OpenTex-TR_01	17 mm x 25 mm				
OpenTex-TR_02	24 mm x 30 mm				
OpenTex-TR_03	17 mm x 25 mm	<u> </u>			
OpenTex-TR_05	12 mm x 24 mm				
OpenTex-TR_06	14 mm x 24 mm				
OpenTex-TR_07	30 mm x 40 mm				



#### OpenTex®-TR Main Features



Non-Resorbable



Optimal rigidity for space maintenance

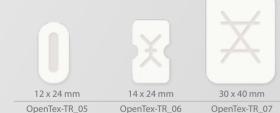




17 x 25 mm

OpenTex-TR\_01 OpenTex-TR\_02

OpenTex-TR\_03



#### OpenTex®-TR Benefits

1 Optimal rigidity and strength for space making OpenTex®-TR is optimal product which is able to be trimmed easily and it is solid enough for space making since it is reinforced with titanium frame.

2 Diverse embedded titanium frame OpenTex®-TR is designed in various shapes to meet surgeon's demand.

**3** Excellent tissue interaction Its micro porous structure helps the tissue interaction.

4 Easy of use OpenTex®-TR can be trimmed easily and also removed

#### Characteristics of OpenTex®-TR





Barrier function bacteria resistance



Predictable hard tissue integration and bone fill

- Membrane can be molded and shaped for tenting and space maintenance.
- The rigidity of the membrane is enhanced to be used for space maintenance.
- Provides additional stability in large, non-space-making osseous defects.
- Provide with little memory of Titanium frame, which enables easy placement of the membrane.
- Ability to withstand exposure.

### Minimal memory, No tangle, and Superior handling



Biotex® Non-Resorbable PTFE Suture is comprised of a single-arm, non-resorbable monofilament suture with a stainless-steel surgical needle connected to the suture. The suture is uncoated, undyed and sterile for single use only, composed of 100% PTFE.

- SOFT HANDLING
- BIOLOGICALLY INERT
- ✓ NO TANGLE
- **EASY KNOTTING**







#### Indications

- Bone grafting procedures
- Periodontal surgery
- Guided tissue regeneration
- Ridge augmentation
- Implant surgery
- Soft tissue grafts

## Specifications

<b>B</b> ote	<b>(</b> ®					
Item N°	USP Size	Length	Needle Length (mm)	Circle	Point Type	
BT3019	3-0	45	19	3/8	$\nabla$	
BT3016	3-0	45	16	3/8	$\nabla$	
BT4016	4-0	45	16	3/8	$\nabla$	
BT4019	4-0	45	19	3/8	$\nabla$	
BT5016	5-0	45	16	3/8	$\nabla$	
BT4013	4-0	45	13	3/8	$\nabla$	
BT5013	5-0	45	13	3/8	$\nabla$	
BTP4013	4-0	45	13	1/2	0	

7

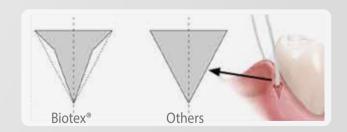
#### Biotex® Main Features & Benefits [10]

#### Suture

- 1 High pliability (PTFE)
- Tying and bending more at ease with less unintended loosening.
- 2 No room for little plaque
- It dispels the possibility of any bacterial infection as well as the plaque formation and any other factors that prevent healing process.

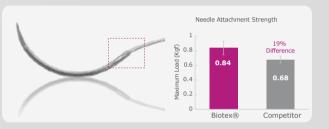
#### Needle

- 1 Slim reverse cutting needle tip
- Precision slim cut triangular needle for small penetration area and smooth suturing.
- Minimize damage to surrounding soft tissue.



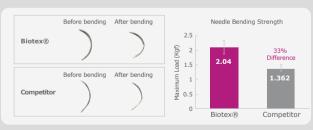
#### 2 Strong Attachment

- Advanced technology for strong needle attachment.
- Smooth and firm connection between needle and thread.
- Rapid healing process due to the reduced bleeding from needle insertion.



#### 3 Strong Needle

- 33% higher strengths are required to bend needle in same degree compared to other product.
- High rigidity of the needle resists to bent stress during suturing.



#### Needle holding clip

Designed to hold the needle in place, also allows for secure and easy release of the suture needle from its package.



#### Sturdy & Flexible Transparent Cover

Protect and give clear visibility of suture and needle. Soft and sturdy cover effectively protect the suture.

Allows surgeon to easily grasp and remove the suture needle from its needle holder clip.

#### 'Race Track' shape

Designed to prevent suture from entangling, and allows easy release of the suture.



#### Benefits

- Soft and comfortable for patients
- Soft texture for patient comfort
- Reliable closure period
- Superior handling: provides flexibility in the positioning of a square knot. Easy to tie Easy to remove Nonwicking: Elimination of bacterial wicking usually associated to monofilament
- Maintains tensile strength
- PFOA free

#### Adaptable Resorbable Collagen Membrane



BioCover<sup>™</sup> is a resorbable collagen membrane consisting porcine tissues which are similar to human collagen phylogenetically. BioCover™ resorbable collagen membrane offers excellent handling, easy adaptation to bone graft materials and less time consumption in surgery.

- FLEXIBLE & ADAPTABLE
- STRONG ENOUGH FOR SUTURE
- CROSSLINKED FOR DESIRED BARRIER DURABILITY





#### Benefits

- Biocompatible and safe
- Excellent Handling
- Great tissue adhesion
- Cell occlusive
- Strong enough to suture

## Specifications

## **::Bio**Cover

Item N°	Unit Size
PG0701EZC1525	15 x 25 mm
PG0702EZC2030	20 x 30 mm
PG0703EZC3040	30 x 40 mm







## Indications

BioCover™ is intended for use in periodontal and dental surgery procedures as a material for placement in the area of periodontal defect, dental implant, bone defect or ridge reconstruction to aid in wound healing post surgery. Considering BioCover™ indications and resorption time, it is recommended to combine the membrane with bone graft to new bone healing by osteoconduction (THE Graft™).



Manufacturer Biomatlante

Purgo Biologics Europe

5 rue Edouard Belin, Z.A, Les IV Nations, 44360, Vigneux-de-Bretagne, France Tel. +33 (0)2 25 02 00 09 Fax. +33 (0)2 28 02 00 10 www.biomatlante.com

1 Square Felix Bloch, 85300 Challans, France