





# "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.



# **THE** Graft<sup>™</sup>**…**

Natural bone substitute Page 4 to 9

# THE Graft Collagen

Bone substitute with collagen Page 10 to 13

# **THE** Cover<sup>™</sup>

Resorbable collagen membrane Page 14 to 17

# **\*\*Open**Tex<sup>®</sup>

Non-resorbable PTFE membrane Page 18 to 21

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

PTFE Titanium reinforced membrane Page 22 to 25



Suture for dental implant surgery Page 26 to 29



## Science Speaks THE Graft<sup>™</sup>



# **THE** Graft<sup>™</sup>

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











#### Specifications

Description	Item NO.	Size / Volume ~		
THE Graft (S*) Granule 0.25 - 1.00mm	BG-A15	<b>≜</b> 0.36cc	0.15g	
	BG-A25	₫ 0.60cc	0.25g	
	BG-A05	₫ 1.20cc	0.50g	
	BG-A10	₫ 2.40cc	1.00g	
	BG-A20	₫ 4.80cc	2.00g	
	TG-AS25	<b>↓</b> 0.25cc	-	
	TG-AS05	<b>↓</b> 0.50cc	-	
	TG-AS10	<b>1</b> 1.00cc	-	
THE Graft (L*) Granule 1.00 - 2.00mm	BG-B05	₫ 1.80cc	0.50g	
	BG-B10	<b>≜</b> 3.60cc	1.00g	
	TG-BS25	<b>↓</b> 0.25cc	-	
	TG-BS05	<b>∔</b> 0.50cc	-	
	TG-BS10	<b>∔</b> 1.00cc	-	

\* S : small / L : large

#### Indications

BONE REPLACEMENT MATERIALS	GR/CC	Extraction socket with intact socket	Extraction socket with defective socket	Minor bone 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				•	•	

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

#### THE Graft™ Purity [3-4-5]

#### Is THE Graft™ safety material?

#### Proprietary virus inactivation process technology.

Thanks to highly efficient manufacturing process, THE Graft<sup>TM</sup> 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<sup>TM</sup> 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™ has a high purity.

The analysis result minimal residual protein, soft tissue, and organic bone matrix, proves that THE Graft™ is deproteinized enough for safe use.

Other than THE Graft<sup>TM</sup>, 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



[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

[4] Process Development of a virally-safe dental xenograft material from porcine bones, Dong-Myon Kim, Ho-Chang Kang, Hyung-Joon Cha, Jung Eun Bae, and In Seop Kim, Korean Journal of Microbiology [2016] Vol. 52, No.2, pp. 140-147

### **THE Graft™ Biocompatibility** [3-4-5]

#### « Getting closer to human bone »

THE Graft™ 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<sup>TM</sup> 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 liquids and cells spreading.

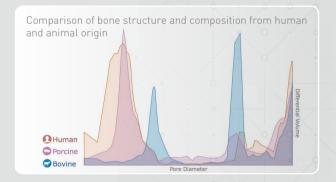
THE Graft™ provides the optimized bone architecture for cells adhesions and tissue regeneration.





Human bone

THE Graft™





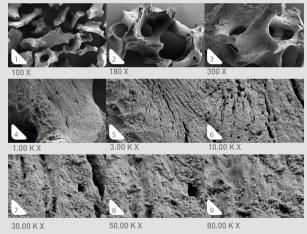
#### **THE Graft™ High Porosity** [3-4-5-6]

# 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  $\rightarrow$  100 $\mu$ m), are necessary to form blood vessels and induce both bone growth and reorganization around the graft material.
- **2** Micropores (diameter  $\leftarrow$  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 [3]

THE Graft<sup>TM</sup> 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



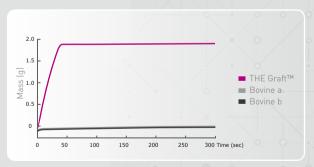
THE Graft™ has shown to have higher wettability than the compared xenografts. It suggests that THE Graft™ is relatively hydrophilic and can be easily wet by body fluids after implantation. Not only protein adsorption, but also the attachment, growth, and proliferation of various types of cells, including 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  $^{\text{TM}}$  was significantly higher than the bovine bone.

# 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.









TCB-01

TCB-02

TCB-03





TCB-05

TCB-06

# Specifications

THE Graft Collagen					
Description	Item NO.	Size / Volume	~		
THE Graft™ Collagen Block Type	TCB-01	7x7x7mm	0.34cc		
	TCB-02	8x9x10mm	0.72cc		
	TCB-03	10x11x12mm	1.32cc		
	TCB-05	5x5x5mm	0.125cc		
	TCB-06	5x5x10mm	0.250cc		



#### Characteristics of THE Graft™ Collagen

#### 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.



While retaining better handling properties, THE Graft<sup>TM</sup> 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







### Resorbable collagen membrane with high biocompatibility



THE Cover™ is a resorbable collagen membrane consisting of porcine-originated Type I Collagen.

- ▼ THE Cover<sup>™</sup> is a resorbable membrane originated from a pure Type I Collagen, and it's highly biocompatible and cell-friendly since chemical crosslinking agent was not used.
- There are two types of THE Cover™;
   THE Cover™ Flex offering easy handling experiences and THE Cover™ Stiff more favorable for space maintenance.



THE Cover™ Flex





# Benefits

- Easy-to-handle
- Hydrophilic
- Space maintenance
- Good flexibility and extension

#### Specifications

<b>THE</b> Cover <sup>™</sup>					
Description	Item NO.	Unit Size			
THE Cover™	BP3-1520	15mm x 20mm			
Flex	BP3-2530	25mm x 30mm			
	BP3-3040	30mm x 40mm			
THE Cover™	BP5-1520	15mm x 20mm			
Stiff	BP5-2530	25mm x 30mm			
	BP5-3040	30mm x 40mm			





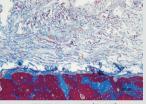
15 x 20mm

#### THE Cover™ Biocompatibility and Safety

THE Cover™ is a resorbable collagen membrane consisting of porcine originated Type I Collagen. It is safe and has high biocompatibility as manufactured by an inherent physical crosslinking method (Self-Assembly Technology) of Purgo without using any chemical crosslinking agents.

#### In-vivo beagle experiment (Masson Trichrome)\*[11]



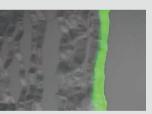


THE Cover™ (Flex)

THE Cover™ (Stiff)

#### Infiltration Test





THE Cover™ (Flex)

THE Cover™ (Stiff)

# THE Cover™ Hydrophilicity and Morphology maintenance

THE Cover™ is hydrophilic and has excellent adhesion as it maintains its shape even after being left at room temperature for more than 30 minutes after hydration.

#### Dehydration Test (After 30min)

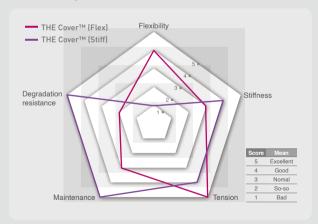




THE Cover™ (Flex)

THE Cover™ (Stiff)

#### Radial Graphs





#### THE Cover™ Flex

THE Cover™ Flex can cover a irregular surface with high flexibility.

It has practically useful extension and offers convenient handling.

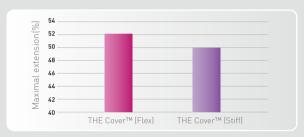
#### or THE Cover™ Stiff

**THE Cover™ Stiff** is favorable for space maintenance with its high stiffness and ability to maintain space.

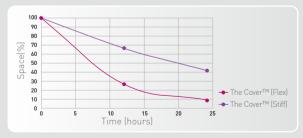
It is strongly resistant to biodegradation and suitable for indication that requires a longer time for bone maturation.



#### **Extension**



#### **Collagenase degradation**



#### **Flexibility**



THE Cover™ (Flex)



THE Cover™ (Stiff)

#### Maintenance



THE Cover™ (Flex)



THE Cover™ (Stiff)

#### Make smart decision with smart alternative!



# **\*\*OpenTex**®

OpenTex® Non-Resorbable PTFE Membrane is a pure medical-grade polytetrafluoroethylene (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]



#### The Evolution of PTFE Membrane





#### Non-Resorbable 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**

# **\*\*Open**Tex<sup>®</sup>

Item NO.	Size	Packaged	Shape Image
OpenTex_T01	24 mm x 30 mm	1 EA	
OpenTex_T02	17 mm x 25 mm	1 EA	

### **OpenTex® Main Features**



#### Non-Resorbable

- 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.



# Minimally Invasive

- 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.



#### Withstands Exposure

- Protect the tissue regeneration site.
- Regenerated underlying tissue can be evaluated.
- Provide a proper environment for the growth of blood vessel and osteogenic cells.

## OpenTex® Benefits



Soft Tissue Obtaining



Aesthetic Implant Restoration



Natural Saliva Passage



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.



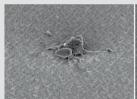
General Oral Bacteria

**1** μm

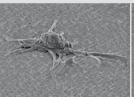
The matter is **PORE SIZE** 

24 Hours for five cells adhesion cases on OpenTex® surface

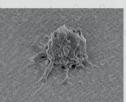
(SEM : Scanning Electron Microscope)











#### 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]





#### PTFE Titanium reinforced membrane



# Indications

- Extraction socket reconstruction
- Bone regeneration
- Where primary closure isn't possible

# Primary Closure HHH





#### Specifications

**Openlex*-TR				
Item NO.	Size	Shape Image		
OpenTex-TR_P01	17 mm x 25 mm			
OpenTex-TR_P02	24 mm x 30 mm			
OpenTex-TR_P03	17 mm x 25 mm			
OpenTex-TR_P05	12 mm x 24 mm			
OpenTex-TR_P06	14 mm x 24 mm			
OpenTex-TR_P07	30 mm x 40 mm			

## **OpenTex®-TR Main Features**





OpenTex-TR P06

OpenTex-TR P07

OpenTex-TR P05

# 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 easily.

# **Characteristics of OpenTex®-TR**



- 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
- ❷ BIOLOGICALLY INERT
- ✓ NO TANGLE
- **⊘** EASY KNOTTING







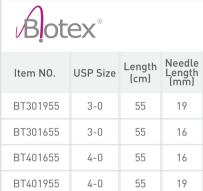
# Indications

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

### Specifications

BT501655

BT401355



5-0

4-0

55

55

16

13

Point Type

 $\nabla$ 

 $\nabla$ 

Circle

3/8

3/8

3/8

3/8

3/8

3/8

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

#### **Suture**

### 1 High pliability (PTFE)

• Tying and bending more at ease with less unintended loosening.

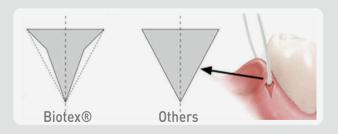
### 2 No room for little plaque

• It dispels the possibility of any bacterial infection as well as the plaque formation and any other factors that prevent healing process.

#### Needle

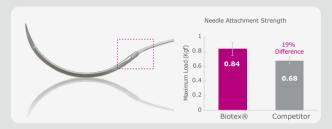
# 1 Slim reverse cutting needle tip

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



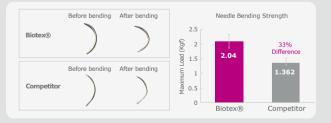
### 2 Strong Attachment

- 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.



#### 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

#### Tab

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

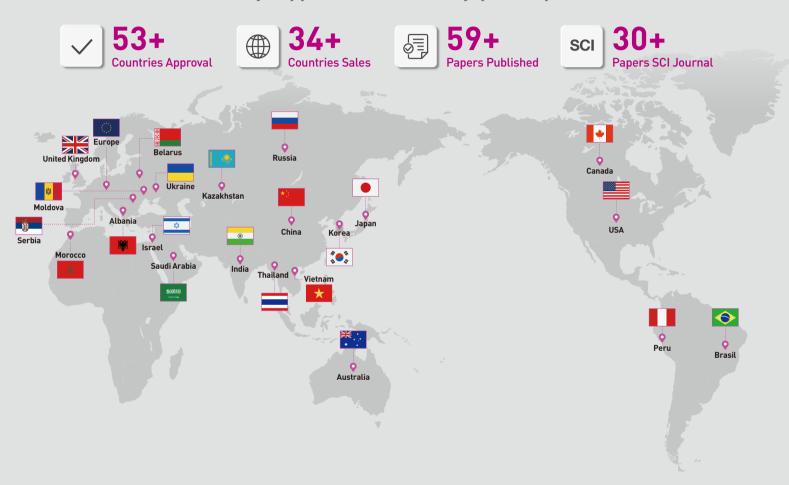
#### 'Race Track' shape

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

# **Indication Guide**

	BONE	GRAFT	MEMBRANE			SUTURE	
Classification	Xenograft	Xenograft with collagen	Resorbable collagen membrane		Non-resorbable PTFE		PTFE Suture
	THE Graft	THE Graft Collagen	THE Cover Flex	THE Cover Stiff	OpenTex	OpenTex-TR	Biotex
Management of contained extraction socket	•	•	•				•
Management of non-contained extraction socket	•	•		•	•	•	•
Augmentation of minor bone defect	•	•	•				•
Augmentation of major bone defect	•			•	•	•	•
Sinus floor augmentation	•	•	•	•			•
Periodontal defects	•	•	•	•			•
Peri-implantitis	•	•	•	•			•
Immediate implant	•	•	•	•			•
Soft tissue volume	•	•	•	•			•

# Scientifically supported and clinically-proven products



# **THE** Graft<sup>™</sup>**::**



**THE** Cover<sup>™</sup>

**\*\*Open**Tex®

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

Botex®



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