

**THE Graft**  <sup>TM</sup>

 **Purgo** Dental  
Biologics  
Solution

## Science Speaks THE Graft™



# THE Graft™

THE Graft™ is a natural, porous bone mineral matrix. It is produced by removal of all organic components from porcine bone. Due to its natural structure the anorganic bone mineral of THE Graft™ likens physical and chemical aspects of mineralized matrix of human bone. When packed into a bone defect, THE Graft™ gradually resorbs and is 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 in-vitro, in-vivo studies, large case study reports and international randomized clinical research. Systematic review and meta-analysis are conducted on THE Graft™ worldwide. [7-8]

THE Graft™ has established its fame throughout the world, both scientifically and clinically, becoming the favourite bone regeneration material.





## Specifications

Description	Item N°	Size / Volume	
THE Graft (S*) Granule 0.25 - 1.00mm	BG-A25	■ 0.60 cc	0.25 g
	TG-AS25	↓ 0.25 cc	
	BG-A05	■ 1.20 cc	0.50 g
	TG-AS05	↓ 0.50 cc	
	BG-A10	■ 2.40 cc	1.00 g
	TG-AS10	↓ 1.00 cc	
	BG-A20	■ 4.80 cc	2.00 g
THE Graft (L*) Granule 1.00 - 2.00mm	BG-B05	■ 1.80 cc	0.50 g
	TG-BS05	↓ 0.50 cc	
	BG-B10	■ 3.60 cc	1.00 g
	TG-BS10	↓ 1.00 cc	

\* S : small / L : large

\*\* Syringe packaging is CE pending

## Indications

BONE REPLACEMENT MATERIALS	GR/CC						
		Extraction socket with intact socket	Extraction socket with defective socket	Minor bone augmentation	Major bone augmentation	Sinur floor elevation	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™ Purity [1-2-3]

### Is THE Graft™ safe 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. This unique process preserves most of the physical properties of the native porcine osseous structure of THE Graft™. 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™, such lower 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.



#### 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



[1] Physicochemical characterization of porcine bone-derived grafting material and comparison with bovine xenografts for 6 dental applications. Jung Heon Lee, Gyu Sung Yi, Jin Woong Lee, Deug Joong Kim, School of Advanced Materials Science and Engineering, Sungkyunkwan University, Suwon, Korea - J Periodontal Implant Sci. 2017 Dec;47(6):388

[2] Effect of the calcination temperature on the composition and microstructure of hydroxyapatite derived from human and animal bone, M. Figueiredo, A. Fernando, G. Martins, J. Freitas, F. Judas, H. Figueiredo - Ceramics International Volume 36, Issue 8, December 2010, Pages 2383-2393 (2016)140-147

## THE Graft™ Biocompatibility [1-2-3-4]

### « Getting closer to human bone »

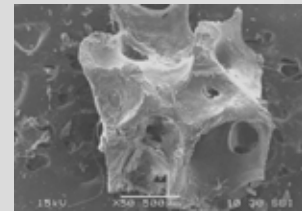
The Graft™ is structurally similar to human bone. It has high possible level of porosity combined with a natural interconnectivity.

### Safe & Biocompatible

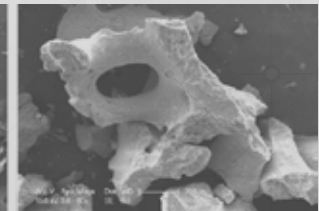
The combination of porcine origin with the high level of purity enables predictable bone growth without risking an immunogenic reaction. The high biocompatibility of THE Graft™ has been confirmed by an in-vitro cell study. THE Graft™ therefore encourages cell adhesion to the same extent as the established natural DBBM and offers 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™

Comparison of bone structure and composition from human and animal origin

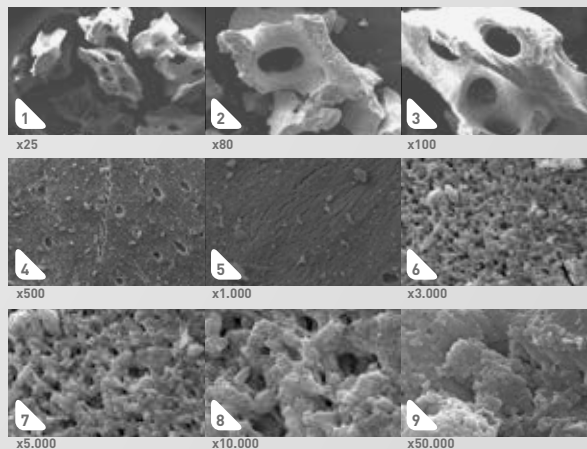


## THE Graft™ High Porosity [1-2-3]

High porosity and early remodelling improve clinical performance.

The High porosity of THE Graft™ means a quicker absorption of liquids (e.g; blood) in comparison with DBBM. This not only facilitates the application of the material but also leads to a quicker post-implantation incorporation.

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



### THE Graft™ Structure :

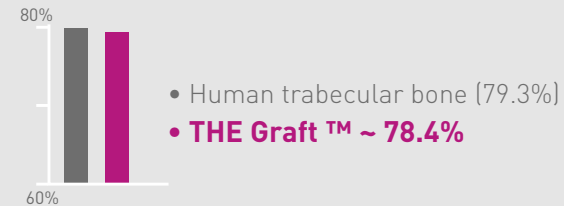
**1** -Macropores ( diameter  $\rightarrow$  100  $\mu$ m ), are necessary to form blood vessels and induce both bone growth and reorganization around the graft material.

**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, composed of sub-100-nm grains with a large amount of nanoscale pores present between the grains contrast.



### Global porosity analysis:



## THE Graft™ Hydrophilicity [2-5-6]

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

The wettability of THE Graft™ turned out to be higher than compared existing xenografts, which 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.

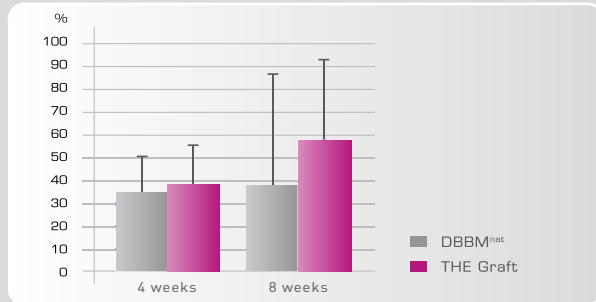
This high wettability of THE Graft™ suggests that it may have advantages in terms of protein adsorption and the resulting cell adhesion and proliferation processes after implantation.

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

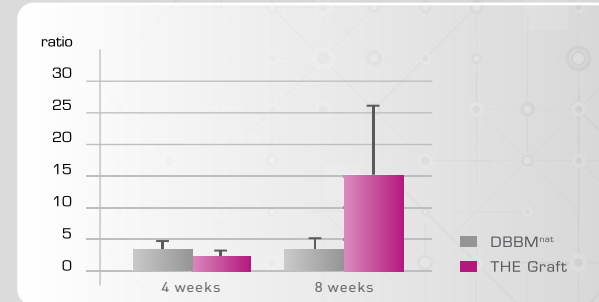


These results show that organic substances, including collagen and other organic compounds, were successfully removed from THE Graft™, which is thus not affected by issues associated with the organic content.

### Vital bone



### Lamellar/woven bone (bone quality)



At all time points, THE Graft™ demonstrated an equal or higher proportion of newly formed vital bone than natural DBBM (left). After 8 weeks, the test group with THE Graft™ showed a much better bone quality compared with the control group with DBBM illustrated by a higher proportion of lamellar vs. woven bone (right).



[5] Internal test results PURGO data files

**THE Graft** ™

**OpenTex**™

**OpenTex**™<sup>TR</sup>

**Blotex**™

**BioCover**™



**Purgo** Dental  
Biologics  
Solution

**Purgo Biologics Inc.**

E-607, 700, Pangyo-ro, Bundang-gu,  
Seongnam-si, Gyeonggi-do, Korea (13516)

Tel: +82 (2) 548-1875

Made in KOREA

[www.purgobiologics.com](http://www.purgobiologics.com)

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