THE Graft™

Purgo Dental Biologics Solution

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“Feel the Clinical Freedom on Science and Safety”

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.

Availability of words may vary from country to country.

Science Speaks THE Graft

THE Graft™

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™ 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. [1-2]

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

[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.

[2] Randomized clinical trial of maxillary sinus grafting using deproteinized porcine and bovine bone mineral. 16 Patients clin implant dent relai Res. 2017; 19[1]: 140-150

Specifications

Description	Item N°	Size / Volume ~	
THE Graft (S*) Granule 0.25 - 1.00mm	BG-A25	0.60cc	0.25g
	TG-AS25	0.25cc	
	BG-A05	1.20cc	0.50g
	TG-AS05	0.50cc	
	BG-A10	2.40cc	1.00g
	TG-AS10	1.00cc	
	BG-A20	4.80cc	2.00g
THE Graft (L*) Granule 1.00 - 2.00mm	TG-BS25	0.25cc	
	BG-B05	1.80cc	0.50g
	TG-BS05	0.50cc	
	BG-B10	3.60cc	1.00g
	TG-BS10	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™ 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™ 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.

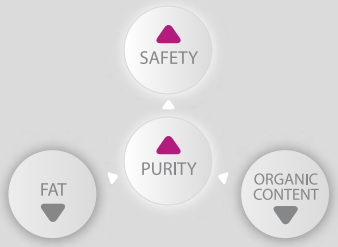
Other than THE Graft™, such low values for organic residues are only found with bone graft material treated at high temperatures which may cause the detriment of the natural bone structure.

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]

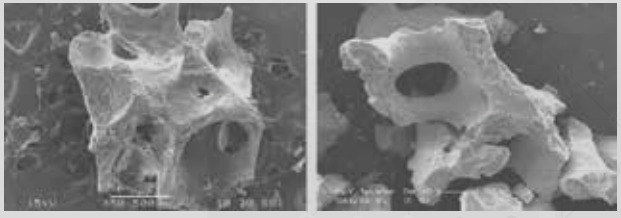
« Getting closer to human bone »

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

Safe & Biocompatible

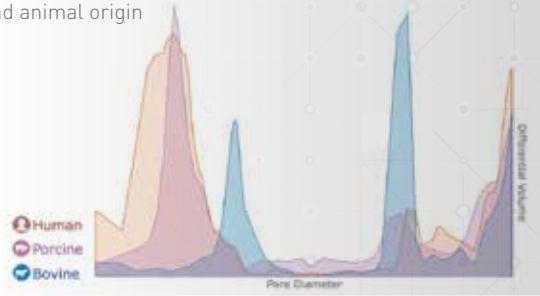
The combination of porcine origin with the high level of purity enables predictable bone growth without risking an immunogenic reaction. In an In-Vitro study THE Graft™ was shown to encourage cell adhesion to the same extent as the compared DBBM (Deproteinized bovine bone matrix), and therefore offering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

Comparison of bone structure and composition from human and animal origin



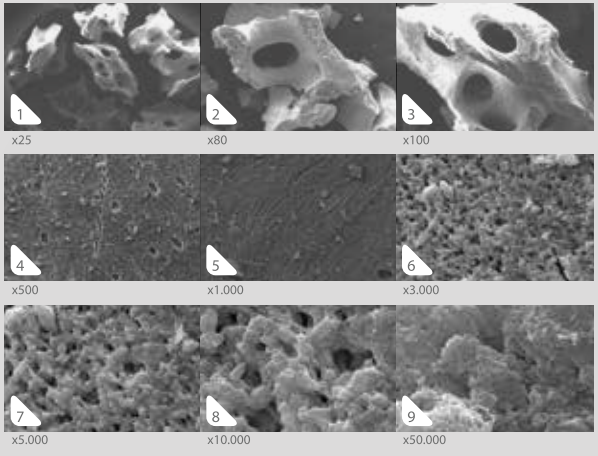
[5] Effect of the calcination temperature on the composition and microstructure of hydroxyapatite derived from human and animal bone, M. Figueiredo, A. Fernando, G. Martins, J. Freitas, F.Judas, H. Figueiredo - Ceramics International Volume 36, Issue 8, December 2010, Pages 2383-2393 [2016]140-147

THE Graft™ 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 µm), 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.

Global porosity analysis :

- Human trabecular bone (79.3%)
- **THE Graft ™ ~ 78.4%**

[6] Osteogenic effect of low-temperature-heated porcine bone particles in a rat calvarial defect model., Go A 1, Kim SE, Shim KM. Lee SM, Choi SH, Son JS, Kang SS . J Biomed Mater Res A. 2014 Oct:102(10):3609-17. doi: 10.1002/jbm.a.35022. Epub 2013 Nov 18.

THE Graft™ Hydrophilicity [3]

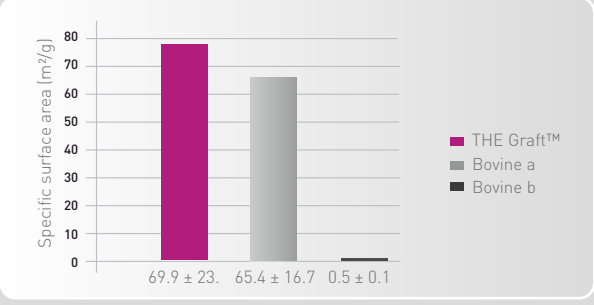
THE Graft™ consists of a unique inter-connecting pore system that ensures an efficient fluid intake and permits the migration of cells. This pore system and high surface energy enhance the osteoconduction process.

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.

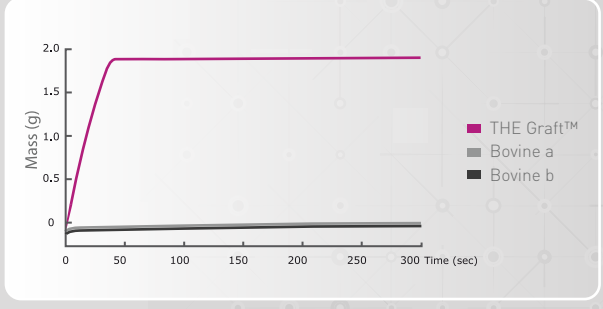
THE Graft™ has shown to have higher wettability than the compared xenografts. It suggests that THE Graft™ is relatively hydrophilic and can be easily wet by body fluids after implantation. Not only protein adsorption, but also the attachment, growth, and proliferation of various types of cells, including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

Specific surface area



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™

THE Graft™ Collagen

OpenTex®

OpenTex®-TR

Biotex®

BioCover™

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