

THE Cover[™]

#BioCover

****Open**Tex[®]

****OpenTex***-TR

Botex



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







"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[™]**:::**

Natural bone substitute
Page 4 to 9



Bone substitute with collagen
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THE Cover[™]

Resorbable collagen membrane
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∷ BioCover[™]

Resorbable collagen membrane
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::OpenTex[®]

Non-resorbable PTFE membrane Page 20 to 23

****OpenTex***-TR

PTFE Titanium reinforced membrane
Page 24 to 27



Suture for dental implant surgery
Page 28 to 31



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 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[™] 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*)	BG-A15	₫ 0.36cc	0.15g		
Granule 0.25 - 1.00mm	BG-A25	₫ 0.60cc	0.25g		
	TG-AS25	1 0.25cc	-		
	BG-A05	₫ 1.20cc	0.50g		
	TG-AS05	∮ 0.50cc	-		
	BG-A10	₫ 2.40cc	1.00g		
	TG-AS10	1 1.00cc	-		
	BG-A20	₫ 4.80cc	2.00g		
THE Graft (L*)	TG-BS25	1 0.25cc	-		
Granule 1.00 - 2.00mm	BG-B05	₫ 1.80cc	0.50g		
	TG-BS05	↓ 0.50cc	-		
	BG-B10	₫ 3.60cc	1.00g		
	TG-BS10	1 1.00cc	-		

* S : small / L : large

Indications

THE Graft !!!

THE Graft !!!

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 GraftTM, 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™ 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.

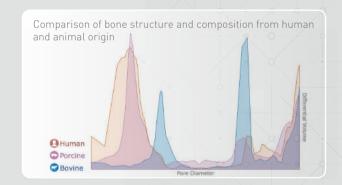
THE Graft™ provides the optimized bone architecture for cells adhesions and tissue regeneration.





Human bone

THE Graft™





[3] Physicochemical characterization of porcine bone-derived grafting material and comparison with bovine xenografts for dental applications. Jung Heon Lee, Gvir Sing Woogle Lee, Pour Leone Kim School Lee, Pour Leone Lee, Pour Le 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

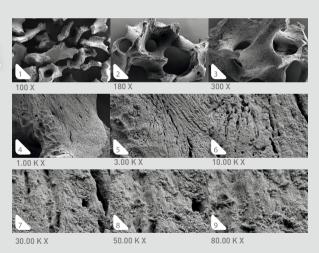
THE Graft™ High Porosity [3-4-5-6]

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.

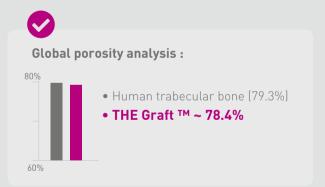
High level of porosity was demonstrated with particle pore structure test, particle size distribution test and total porosity tests.





THE Graft™ Structure:

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

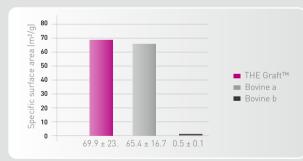


THE Graft™ Hydrophilicity

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

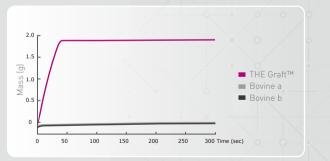


THE Graft™ has shown to have higher wettability than the compared xenografts. It suggests that THE Graft™ is relatively hydrophilic and can be easily wet by body fluids after implantation. Not only protein adsorption, but also the attachment, growth, and proliferation of various types of cells, including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

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.



TCR-01



TCR-02







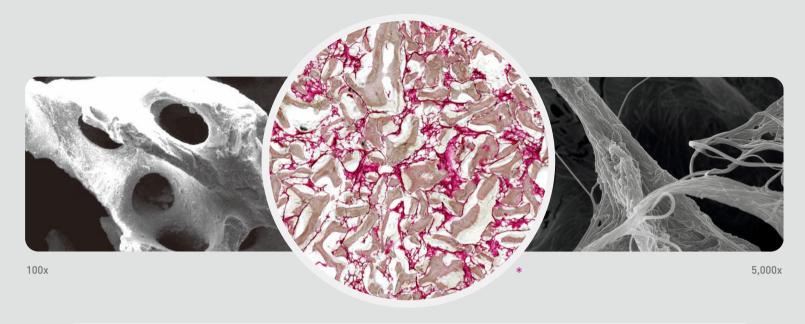




TCR-03

Specifications

THE Graft Collagen						
Description Item NO. Size / Volume ~						
THE Graft™	TCB-01	7x7x7mm	0.34cc			
Collagen Block Type	TCB-02	8x9x10mm	0.72cc			
	TCB-03	10x11x12mm	1.32cc			
THE Graft™	TCR-01	5x3x8 mm	0.22cc			
Collagen Ring Type	TCR-02	5x4x9mm	0.26cc			
	TCR-03	5x5x10mm	0.29cc			





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.

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.

Resorbable collagen membrane with high biocompatibility



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

- ▼ THE Cover™ 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.







Benefits

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

Specifications

THE Co	ver™
Description	Item N

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	



30 x 40 mm

25 x 30mm 15 x 20mm

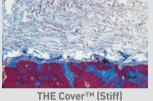
THE Cover™ Flex

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]





Infiltration Test





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)

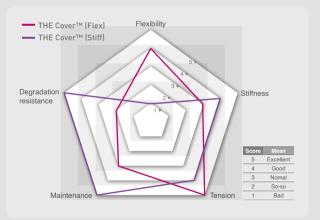




THE Cover™ (Flex)

THE Cover™ (Stiff)

Radial Graphs



THE Cover™ Flex or THE Cover™ Stiff

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

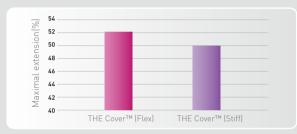
It has practically useful extension and offers convenient handling.

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

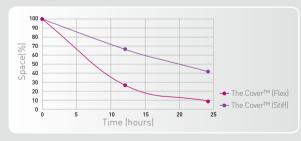
It is strongly resistant to biodegradation and suitable for indication that requires a longer time for bone maturation.



Extension

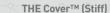


Collagenase degradation



Flexibility







Maintenance







THE Cover™ (Stiff)

* [11] In-vitro test: Cross-sections of confocal images showing infiltration of bovine serum albumin (BSA-488) after 48h

Adaptable Resorbable Collagen Membrane



BioCover™ 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









20 x 30 mm 15 x 25 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™).

Biomatlante

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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

::OpenTex®

Item NO.	Size	Packaged	Shape Image
OpenTex_01	24 mm x 30 mm	1 EA	
OpenTex_0105	24 mm x 30 mm	5 EA	
OpenTex_02	17 mm x 25 mm	1 EA	
OpenTex_0205	17 mm x 25 mm	5 EA	

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.



- 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
- 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®

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.

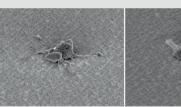


General Oral Bacteria

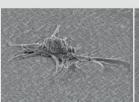


24 Hours for five cells adhesion cases on OpenTex® surface (SEM : Scanning Electron Microscope)

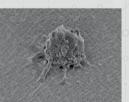
The matter is **PORE SIZE**











[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]



PTFE Titanium reinforced membrane



Indications

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







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



12 x 24 mm

OpenTex-TR P05







14 x 24 mm

OpenTex-TR_P06 OpenTex-TR_P07

30 x 40 mm

OpenTex®-TR Benefits

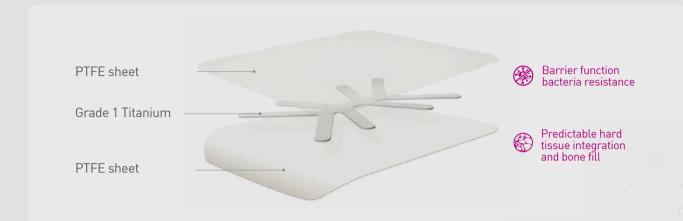
1 Optimal rigidity and strength for space making OpenTex®-TR is optimal product which is able to be trimmed easily and it is solid enough for space making since it is reinforced with titanium frame.

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.
- igoplus Provide with little memory of Titanium frame, which enables easy placement of the membrane.
- Ability to withstand exposure.

 2°

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



Item NO.	USP Size	Length (cm)	Needle Length (mm)	Circle	Point Type
BT3016	3-0	45	16	3/8	∇
BT3019	3-0	45	19	3/8	∇
BT4013	4-0	45	13	3/8	∇
BT4016	4-0	45	16	3/8	∇
BT4019	4-0	45	19	3/8	∇
BT5013	5-0	45	13	3/8	∇
BT5016	5-0	45	16	3/8	∇
BTP4013	4-0	45	13	1/2	0
BT301955	3-0	55	19	3/8	∇
BT301655	3-0	55	16	3/8	∇
BT401655	4-0	55	16	3/8	∇
BT401955	4-0	55	19	3/8	∇
BT501655	5-0	55	16	3/8	∇
BT401355	4-0	55	13	3/8	∇
BT501355	5-0	55	13	3/8	∇

2

Biotex® Main Features & Benefits

Suture

1 High pliability (PTFE)

• Tying and bending more at ease with less unintended

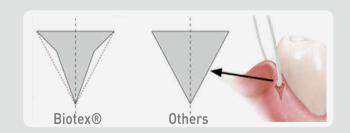
2 No room for little plaque

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

Needle

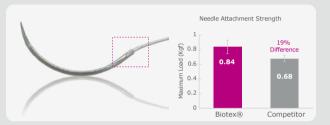
1 Slim reverse cutting needle tip

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



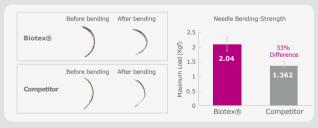
2 Strong Attachment

- 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.



Tab

entangling, and allows easy release of the suture.

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

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

'Race Track' shape

needle holder clip.

Designed to prevent suture from

