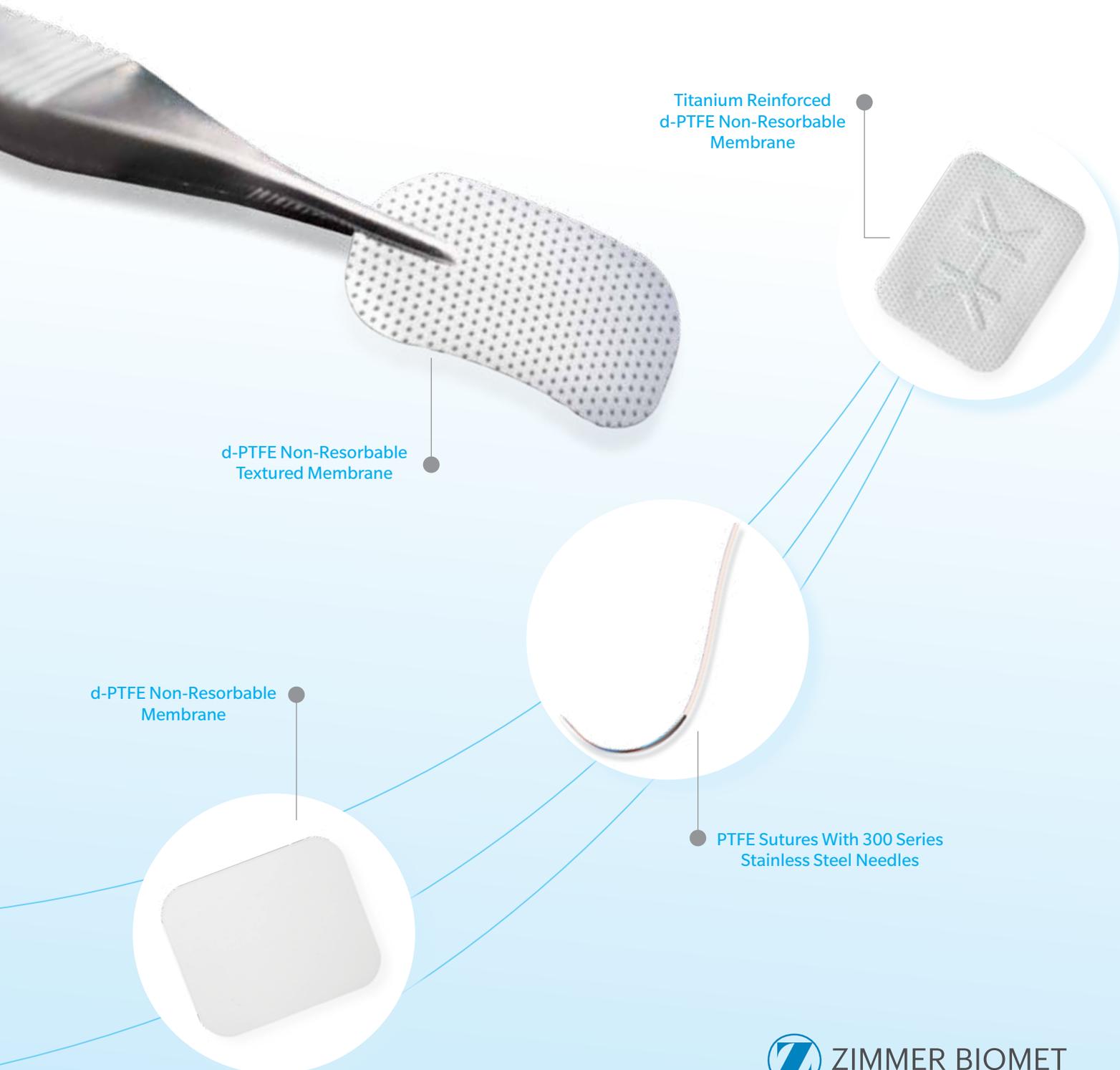


OsseoGuard[®] Non-Resorbables

Product Brochure



d-PTFE Non-Resorbable
Textured Membrane

Titanium Reinforced
d-PTFE Non-Resorbable
Membrane

d-PTFE Non-Resorbable
Membrane

PTFE Sutures With 300 Series
Stainless Steel Needles



ZIMMER BIOMET
Your progress. Our promise.

OsseoGuard PTFE Textured Membranes

Micro-Textured, High-Density PTFE Membrane

Features & Benefits*

Non-Resorbable

Does not resorb prematurely – you can better manage healing time

100% Dense (non-expanded) PTFE

Impervious to bacteria (pore size less than 0.3 μm)

Textured surface

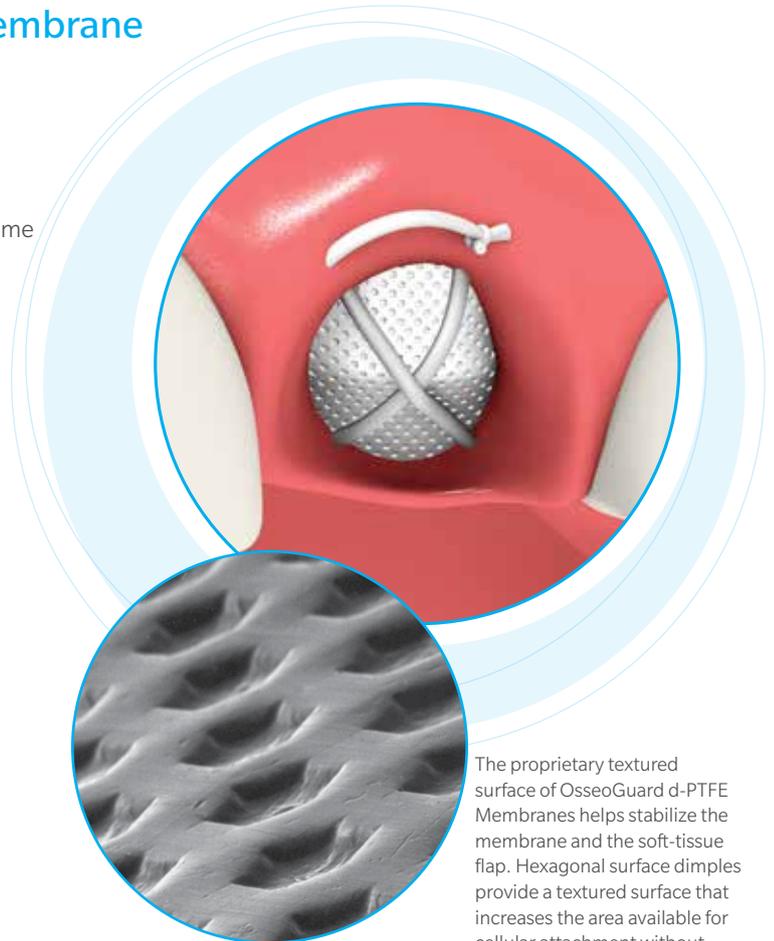
Increases membrane stabilization

Purposely leave the membrane exposed

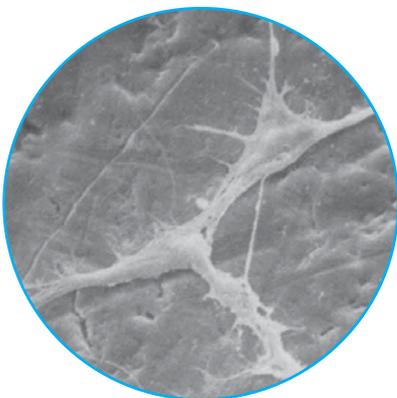
Preservation of the soft-tissue architecture and keratinized mucosa

Soft tissue attaches, but doesn't grow through the membrane

Exposed membrane allows for non-surgical removal; no anesthesia required



The proprietary textured surface of OsseoGuard d-PTFE Membranes helps stabilize the membrane and the soft-tissue flap. Hexagonal surface dimples provide a textured surface that increases the area available for cellular attachment without increasing porosity.



Cell Attachment

Although High-Density PTFE (d-PTFE) is inherently a non-stick material, cells attach to the outside of the d-PTFE membranes. Scanning electron micrographs of removed d-PTFE membranes reveal attached fibroblasts to the surface of the d-PTFE membranes.

Additionally, membrane removal of exposed d-PTFE membranes at 21-28 days often results in slight bleeding, which would indicate a biological attachment to the d-PTFE membrane.

Cellular attachment is important to create a seal around the edges of exposed d-PTFE membranes or to support primary closure in larger grafting applications.

*Data on file with manufacturer and available upon request.



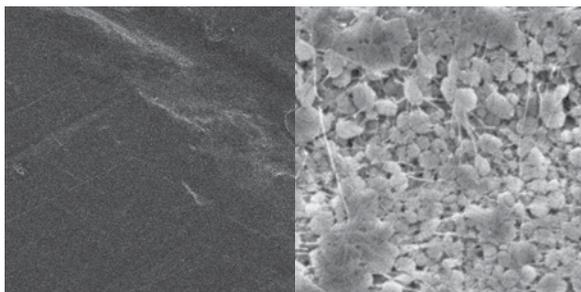
Impervious To Bacteria

In two separate studies treating a total of 696 extraction sites using d-PTFE membranes in an exposed technique, there were no reported infections.^{1,2}

A microbial barrier (strike-through) test was completed by an independent third party lab in accordance with US FDA Good Laboratory Practice (GLP) regulations. The purpose of the test was to verify that d-PTFE membranes were impervious to bacteria in an accelerated environment. *E. faecalis* was chosen as the challenge organism for its common presence in the oral environment, its spherical morphology, rapid growth, and its small size of 0.5 to 1.0 µm.

The challenge organism was placed on the d-PTFE membranes at a concentration of 2×10^7 colony forming units per membrane. Ten samples were placed on agar plates and incubated for 48 hours. Following incubation, membranes were removed and agar plates were further incubated for 48 hours, and then bacterial counts were completed on the area underneath the membranes. While all positive controls exhibited growth, all ten test articles exhibited zero growth on the agar plates underlying the d-PTFE membranes.*

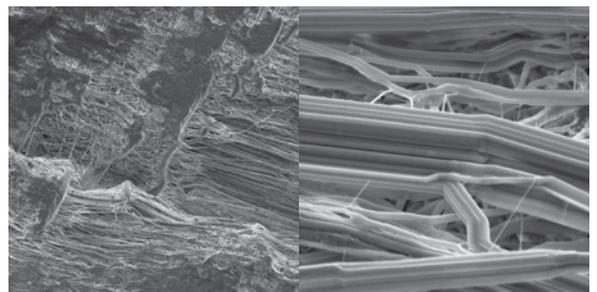
High-Density PTFE (d-PTFE)



Magnification x500

Magnification x20,000

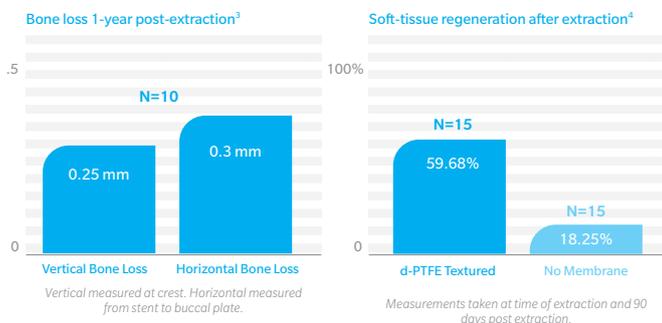
Expanded PTFE (e-PTFE)



Magnification x500

Magnification x20,000

Clinical Evidence: No reported infections in two separate studies totaling 696 extraction sites using d-PTFE membranes in an exposed technique.^{1,2}



Description	Item No.	Units (per box)
Textured 12 mm x 24 mm	TXR1224-1	1
	TXR1224-10	10
Textured 25 mm x 30 mm	TXR2530-1	1
	TXR2530-4	4

*Data on file with manufacturer and available upon request.

OsseoGuard PTFE Titanium-Reinforced Membranes



Titanium-Reinforced, High-Density PTFE Membrane

The traditional frame design, incorporating delicate and strategically-placed titanium “struts”, has more than 25 years of clinical history and successful use in GBR. This innovative, hybrid design consists of a thin layer of expanded PTFE (e-PTFE) laminated to a textured d-PTFE membrane. In between these two layers lies a titanium framework. The titanium framework is a grade of titanium that has little to no memory. Once formed, the titanium-reinforced membrane will remain in that shape until mechanically altered.

Features and Benefits*

Less Titanium Bulk

Less is more - less titanium bulk allows for greater versatility in shaping and placement

Grade 1 titanium, lightweight framework

Easy to form in three dimensions and retains no memory, allowing for passive fit

Easy to trim and is compliant with the overlying soft tissues

Textured surface, d-PTFE backing

Prevents migration of bacteria into wound if exposed. Edges remain soft and supple to prevent flap complications.

Prevents tissue ingrowth making removal of membrane easier when compared to removal of titanium mesh

Can be molded and shaped for tenting and space maintenance

May be easily cut with scissors to custom-fit various defects

Two Different Handling Options

OsseoGuard d-PTFE Titanium-Reinforced is available in two handling options: TR250 or TR150. TR150 membranes are 40% thinner than TR250 membranes, providing clinicians another handling option in titanium-reinforced membranes.



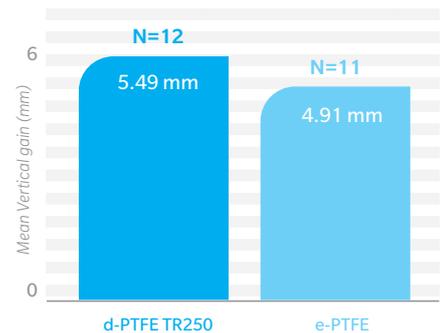
Designed for periodontal applications, large defects, and defects missing adequate bony architecture. Engineered to withstand exposure.



Membrane Insertion

Carefully open the outer tray of the double blister and aseptically remove the sterile inner tray containing the OsseoGuard Non-Resorbable Barrier Membrane in the sterile field. The sterile barrier membrane can then be removed from the sterile inner tray for usage during the surgical procedure. Handle the membrane only with sterile surgical gloves, which have been washed in sterile water to remove the talc, or with sterile atraumatic forceps. The membrane may be cut to the desired configuration. After trimming, there should be no sharp corners or rough edges. Note: For best results when using textured material, place dimples side up towards gingival tissue. To enhance space-making capability, the material may be stretched over the fingertips or a sterile instrument handle to create a dome shape, if desired. The membrane should be trimmed to extend 3-4 mm beyond the defect margins to provide adequate protection of the bone defect and enhance membrane stability. The membrane should be trimmed to remain at least 1 mm from adjacent, uninvolved teeth. If additional stability is desired, the membrane may be stabilized with sutures, surgical tacks or screws.

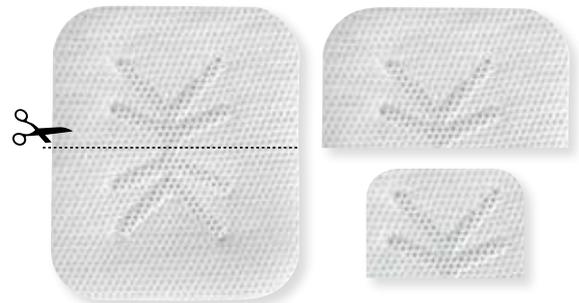
Clinical Evidence: Prospective randomized controlled trial to compare vertical ridge augmentation around implants using a titanium-reinforced e-PTFE membrane vs. a d-PTFE titanium-reinforced membrane⁵



Cutting and Trimming Instructions for Titanium-Reinforced Membranes

Because the membrane is a laminated product, care must be taken in trimming the membrane to fit smaller defects. The material, including the titanium strut, may be easily cut with surgical scissors. However, since OsseoGuard PTFE Titanium-Reinforced membranes are available in 15 different shapes and sizes, aggressive trimming of the membrane is not necessary. Although the product is designed to withstand trimming, over-trimming of larger membranes may result in delamination of the membrane.

If trimming the OsseoGuard PTFE TR250 25 x 30 Posterior, the recommended procedure is to cut the membrane in the central strut area (see right), resulting in two symmetrical pieces. Then trim around the outside edges as necessary. It is important to maintain a zone of 2-3 mm of intact membrane from the titanium framework in order to prevent delamination and to maintain a soft and supple edge. The textured side should face the soft tissue, although this may be reversed depending on operator preference.



Membrane Removal

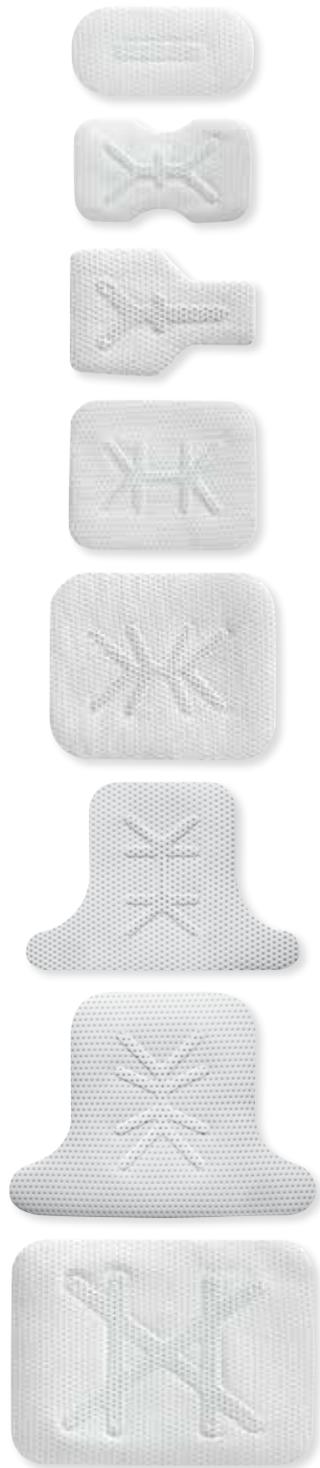
The membrane is not intended to remain in place as a permanent implant and should therefore be removed following the bone regeneration procedure. For socket grafting procedures, the membrane may be removed after 21 - 28 days. The membrane may be left longer depending on the defect size and type. When removal is desired, the membrane may be easily removed, if exposed, by grasping with forceps and gently removing it from the issue. Anesthesia may be provided to enhance patient comfort, but is usually not necessary. If primary closure is obtained at placement, surgical exposure will be required for removal. Following membrane removal, the regenerated tissue usually re-epithelializes within 14 to 21 days to complete the initial healing process. However, final bone maturation will not occur for 6 to 12 months. This time frame should be considered in treatment planning cases involving heavy prosthetic loading of regenerated bone.

*Data on file with manufacturer and available upon request.

OsseoGuard PTFE Titanium-Reinforced Membranes



Two Handling Options And 15 Different Shapes To Meet Your Clinical Needs



	Description	Item No.		Units (per box)
		TR250 (250 µm thick)	TR150 (150 µm thick)	
Anterior Extraction 12 mm x 24 mm	Designed for narrow single-tooth extraction sites, especially where one bony wall is missing	TR250AE-1	TR150AE-1	1
		TR250AE-2	TR150AE-2	2
Anterior Extraction 14 mm x 24 mm	Designed for single-tooth extraction sites, especially where one or more bony walls are missing	TR250AEY-1	TR150AEY-1	1
		TR250AEY-2	TR150AEY-2	2
Large Facial 17 mm x 25 mm	Designed for large buccal defects	TR250LF-1	TR150LF-1	1
		TR250LF-2	TR150LF-2	2
Posterior Extraction 20 mm x 25 mm	Designed for posterior extraction sites and limited ridge augmentation	TR250PE-1	TR150PE-1	1
		TR250PE-2	TR150PE-2	2
Posterior 25 mm x 30 mm	Designed for large bony defects, including ridge augmentation	TR250P-1	TR150P-1	1
		TR250P-2	TR150P-2	2
Small-T 25 mm x 36 mm	Designed for posterior extraction sites and limited ridge augmentation	TR250SMT-1	TR150SMT-1	1
		TR250SMT-2	TR150SMT-2	2
Large-T 30 mm x 41 mm	Designed for large bony defects, including ridge augmentation	TR250LGT-1	TR150LGT-1	1
		TR250LGT-2	TR150LGT-2	2
Ridge Augmentation X 30 mm x 40 mm	Designed for very large bony defects, including ridge augmentation	TR250RAX-1	TR150RAX-1	1
		TR250RAX-2	TR150RAX-2	2



Description	Item No.		Units (per box)	
	TR250 (250 µm thick)	TR150 (150 µm thick)		
Ridge Augmentation K 30 mm x 40 mm	Designed for very large bony defects, including ridge augmentation	TR250RAK-1	TR150RAK-1	1
		TR250RAK-2	TR150RAK-2	2
Ridge Augmentation K 40 mm x 50 mm	Designed for the largest bony defects, including ridge augmentation	TR250RAKL-1	TR150RAKL-1	1
		TR250RAKL-2	TR150RAKL-2	2
Perio Narrow 13 mm x 19 mm	Designed to fit periodontal defects in the anterior	TR250PN-1	TR150PN-1	1
		TR250PN-2	TR150PN-2	2
Perio Wide 13 mm x 18 mm	Designed to fit periodontal defects in the posterior	TR250PW-1	TR150PW-1	1
		TR250PW-2	TR150PW-2	2
Trans Crestal 24 mm x 38 mm	Designed for bony defects between adjacent teeth, including ridge augmentation	TR250TCS-1	TR150TCS-1	1
		TR250TCS-2	TR150TCS-2	2
Trans Crestal 38 mm x 38 mm	Designed for large bony defects between adjacent teeth, including ridge augmentation	TR250TCL-1	TR150TCL-1	1
		TR250TCL-2	TR150TCL-2	2
Posterior Ridge 38 mm x 38 mm	Designed for large bony defects, including distal extension of the posterior ridge	TR250PR-1	TR150PR-1	1
		TR250PR-2	TR150PR-2	2

OsseoGuard PTFE Suture

Non-Resorbable PTFE Soft Monofilament Suture

All OsseoGuard PTFE Sutures have 300 series stainless steel needles, the gold standard material for suture needles.

Features and Benefits*

100% Medical Grade PTFE

Biologically inert

Monofilament

Does not allow bacteria wicking into the surgical site

Soft

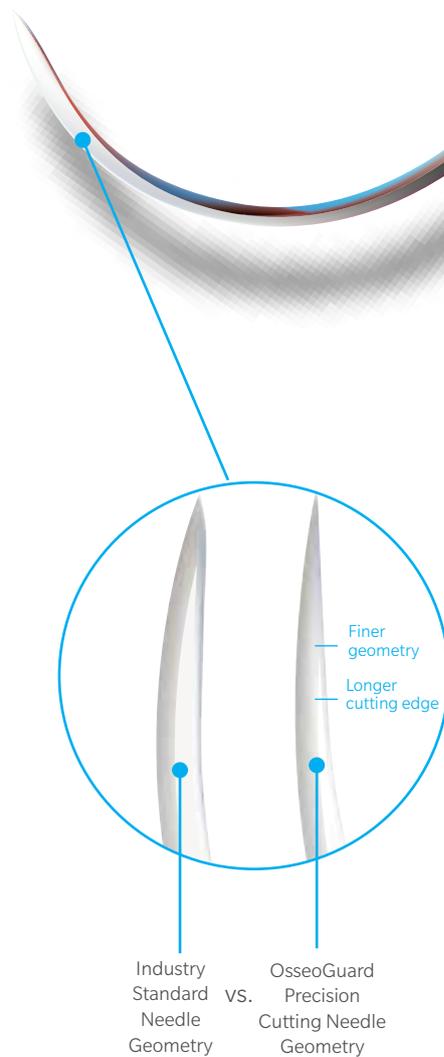
Comfortable for patients

Very low package memory

Excellent handling, knots securely

Non-resorbable

Keeps the surgical site reliably closed



*Data on file with manufacturer and available upon request.

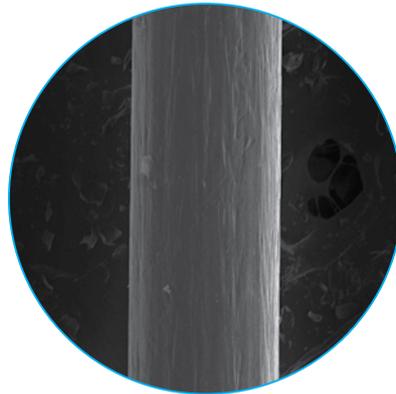


The Soft Monofilament

Smooth Monofilament Rod

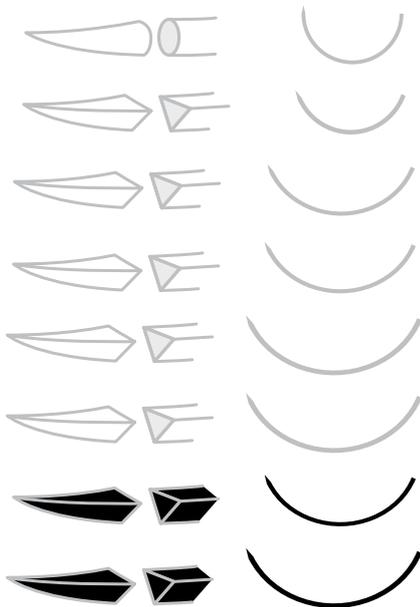
Non-wicking monofilament construction

Soft and comfortable for patients



OsseoGuard PTFE Suture
350x Magnification

OsseoGuard PTFE Suture



Description	Item No.	Units (per box)
USP 4-0, 13 mm, 1/2 circle round body taper point	OS4013PE	12
USP 4-0, 13 mm, 3/8 circle precision reverse cutting	OS4013PR	12
USP 3-0, 16 mm, 3/8 circle precision reverse cutting	OS3016	12
USP 4-0, 16 mm, 3/8 circle precision reverse cutting	OS4016	12
USP 2-0, 19 mm, 3/8 circle precision reverse cutting	OS2019	12
USP 3-0, 19 mm, 3/8 circle precision reverse cutting	OS3019	12
USP 3-0, 16 mm, 3/8 circle precision reverse cutting black	OS3016B	12
USP 3-0, 19 mm, 3/8 circle precision reverse cutting black	OS3019B	12

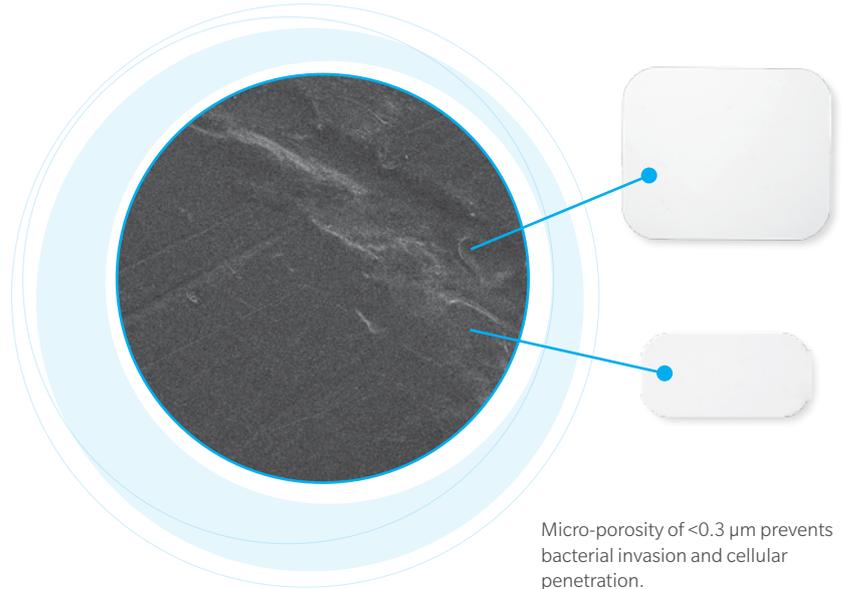
OsseoGuard PTFE Non-Textured Membranes



Non-Textured, Non-Resorbable High-Density PTFE Membrane

High-density PTFE membrane in a cost effective configuration

The OsseoGuard Non-Textured PTFE Membranes have similar characteristics as the OsseoGuard Textured, aside from the textured surface.



Micro-porosity of $<0.3 \mu\text{m}$ prevents bacterial invasion and cellular penetration.

Features and Benefits*

Non-Resorbable

Won't resorb prematurely – you can better manage healing time

100% Dense (non-expanded) PTFE

Impervious to bacteria (pore size less than $0.3 \mu\text{m}$)

Can be left exposed

Less surgical time, preservation of soft-tissue architecture and keratinized mucosa

Soft tissue attaches, but doesn't grow through the membrane

Exposed membrane allows for non-surgical removal; no anesthesia required

Designed for predictable and aesthetic outcome

Most cost effective OsseoGuard PTFE membrane



Description	Item No.	Units (per box)
Non-Textured 12 mm x 24 mm	NTXR1224-10	10
Non-Textured 25 mm x 30 mm	NTXR2530-4	4

*Data on file with manufacturer and available upon request.

References

1. Barboza EP, Stutz B, Ferreira VF, Carvalho W. Guided bone regeneration using nonexpanded polytetrafluoroethylene membranes in preparation for dental implant placements - a report of 420 cases. *Implant Dent.* 2010;19:2-7.
2. Hoffman O, Bartee BK, Beaumont C, Kasaj A, Deli G, Zafiroopoulos GG. Alveolar bone preservation in extraction sockets using non-resorbable d-PTFE membranes: A retrospective non-randomized study. *J Periodontol.* 2008;79:1355-1369.
3. Fotek PD, Neiva RF, Wang HL. Comparison of dermal matrix and polytetrafluoroethylene membrane for socket bone augmentation: a clinical and histologic study. *J Periodontol.* 2009;80:776-785.
4. Barboza EP, Francisco BS, Ferreira VF. Soft tissue enhancement using non-expanded PTFE membranes without primary closure [abstract]. Presented at the 2008 Research Forum Poster Session. Annual Meeting of the American Academy of Periodontology (AAP) in Seattle, WA, September 6-9, 2008.
5. Ronda M, Rebaudi A, Torelli L, Stacchi C. Expanded vs. dense polytetrafluoroethylene membranes in vertical ridge augmentation around dental implants: a prospective randomized controlled clinical trial. *Clin Oral Impl Res.* 2014 Jul;25(7):859-66.



Contact us at 1-800-342-5454 or visit
zimmerbiometdental.com



Zimmer Biomet Dental
Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: +1-561-776-6700
Fax: +1-561-776-1272

+31(0) 577 - 46 1927 | www.implacom.nl

Unless otherwise indicated, as referenced herein, all trademarks are the property of Zimmer Biomet; and all products are manufactured by one or more of the dental subsidiaries of Zimmer Biomet Holdings, Inc. and marketed and distributed by Zimmer Biomet Dental and its authorized marketing partners. OsseoGuard PTFE products are manufactured by Osteogenics Biomedical, Inc. For additional product information, please refer to the individual product labeling or instructions for use. Product clearance and availability may be limited to certain countries/regions. This material is intended for clinicians only and does not comprise medical advice or recommendations. Distribution to any other recipient is prohibited. This material may not be copied or reprinted without the express written consent of Zimmer Biomet Dental. ZBINST0040 REVA 08/19 ©2019 Zimmer Biomet. All rights reserved.

