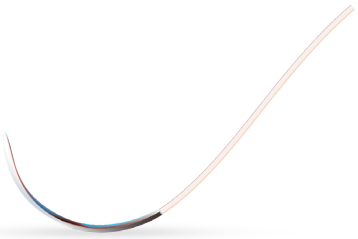
Product
Brochure

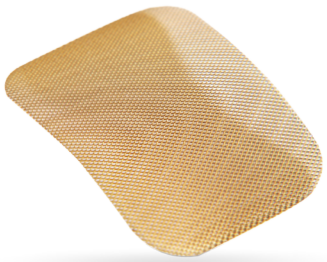
d-PTFE Non-Resorbable
Textured Membrane

OsseoGuard®
Non-Resorbables

d-PTFE Non-Resorbable Membrane



PTFE Sutures With 300 Series
Stainless Steel Needles



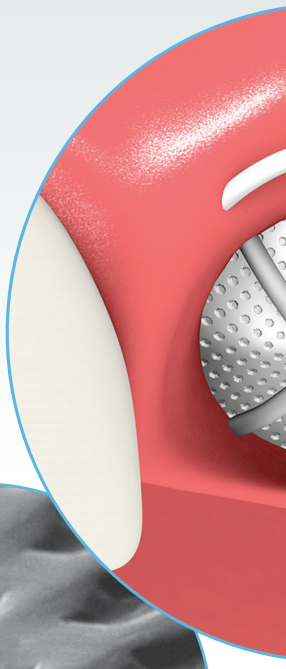
Titanium Mesh

Titanium Reinforced d-PTFE
Non-Resorbable Membrane

ZimVie

OsseoGuard PTFE Textured Membranes

Micro-Textured, High-Density PTFE Membrane



Features and Benefits*

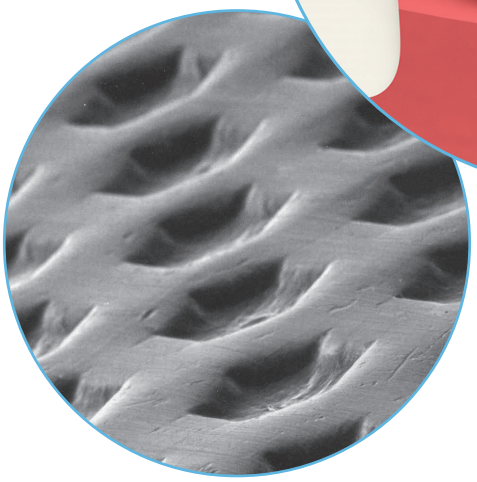
Non-resorbable
Does not resorb prematurely – you dictate healing time

100% Dense (non-expanded) PTFE
Impervious to bacteria (pore size less than 0.3 µm)

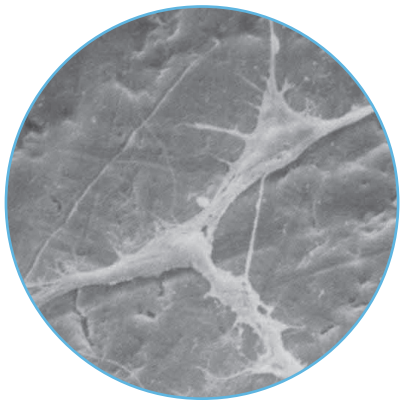
Textured surface
Increases membrane stabilization

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.

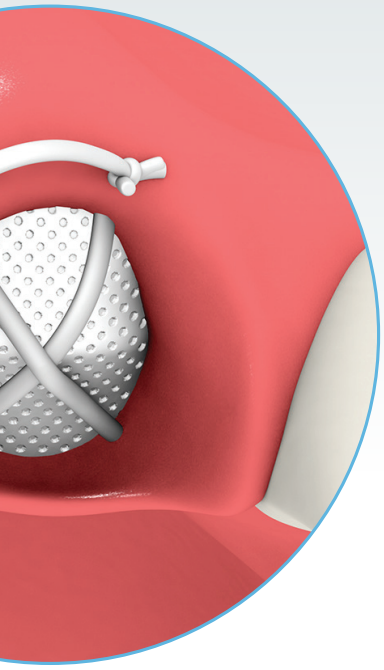


Cell attachment

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.



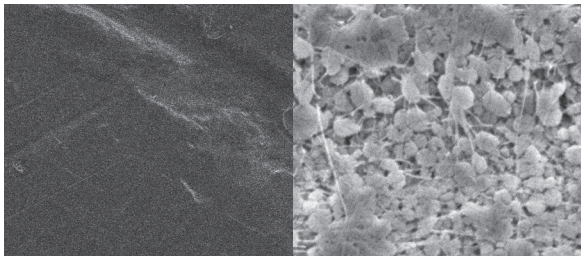
Impervious to bacteria

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 U.S. 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.

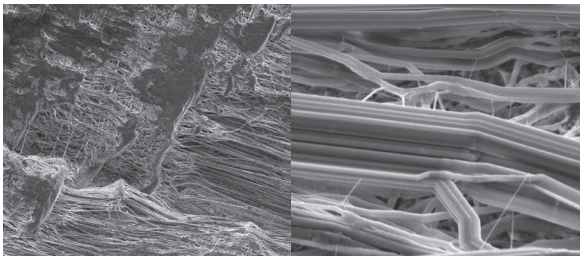
The challenge organism was placed on the d-PTFE membranes at a concentration of 2×10^7 colony forming units per membrane. Ten samples were placed on agar plates and incubated for 48 hours. Following incubation, membranes were removed and agar plates were further incubated for 48 hours, and then bacterial 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

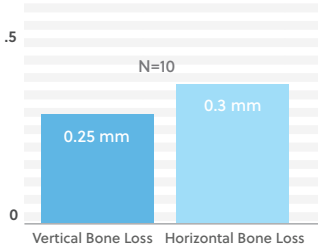
Expanded PTFE (e-PTFE)



Magnification x500 Magnification x20,000

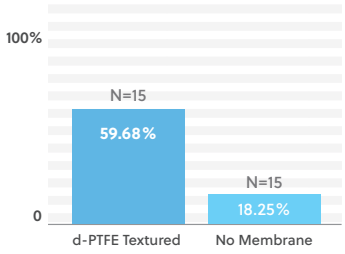
Clinical Evidence: No reported infections in two separate studies totaling 696 extraction sites using d-PTFE membranes in an exposed technique.[1,2]

Bone loss 1-year post-extraction[3]



Vertical measured at crest. Horizontal measured from stent to buccal plate.

Soft-tissue regeneration after extraction[4]



Measurements taken at time of extraction and 90 days post extraction.

	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.

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

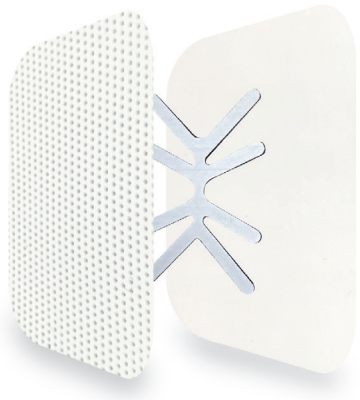
Grade 1 titanium, lightweight framework

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



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

Can be molded and shaped for tenting and space maintenance

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

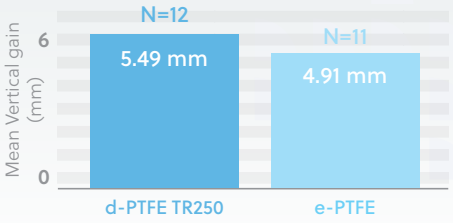
Two Different Handling Options

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.

Membrane Insertion

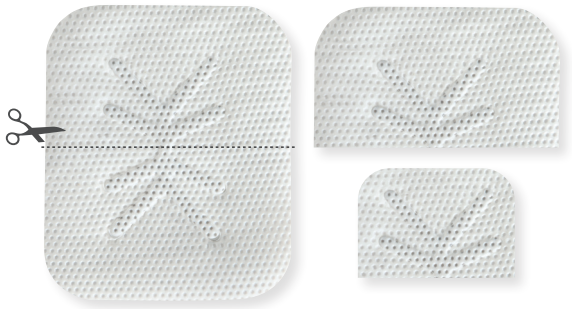
Carefully open the outer tray of the double blister and aseptically remove the sterile inner tray containing the OsseoGuard Non-Resorbable Barrier Membrane in the sterile field. The sterile barrier membrane can then be removed from the sterile inner tray for usage during the surgical procedure. Handle 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 membrane[5]



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.

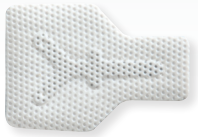
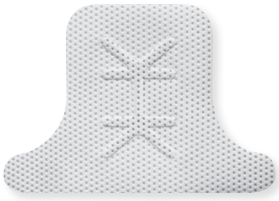
Membrane Removal

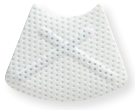
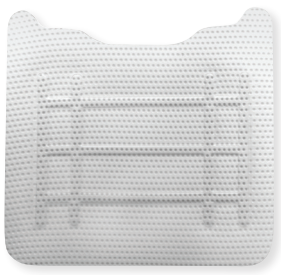
The membrane is not intended to remain in place as a permanent implant and should therefore be removed following the bone regeneration procedure. For socket grafting procedures, the membrane may be removed after 21 - 28 days. The membrane may be left longer depending on the defect size and type. When removal is desired, the membrane may be easily removed, if exposed, by grasping with forceps and gently removing it from the tissue. 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.

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

* Data on file with manufacturer.

OsseoGuard PTFE Non-Textured Membranes

Non-Textured, Non-Resorbable High Density PTFE Membranes

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

Features and Benefits*

Non-resorbable
Won't resorb prematurely – you dictate healing time

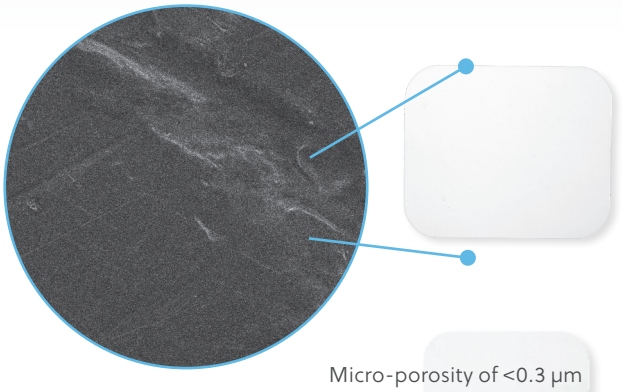
100% dense (non-expanded) PTFE
Impervious to bacteria (pore size less than 0.3 µm)

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



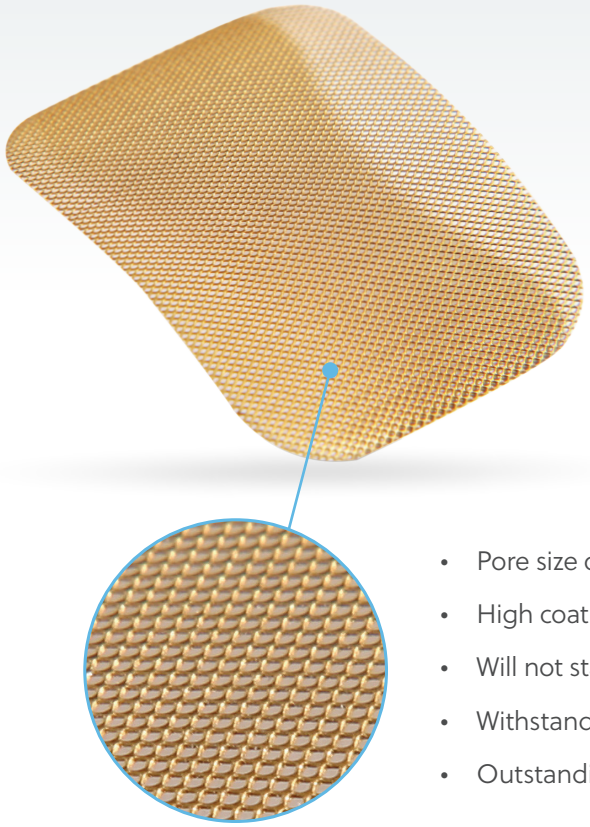
Micro-porosity of <0.3 µm prevents bacterial invasion and cellular penetration.

	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.

OsseoGuard Titanium Mesh

Titanium Nitride-Coated Mesh



Features and Benefits*

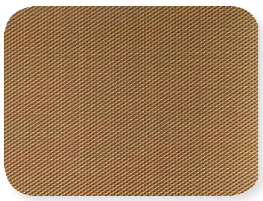
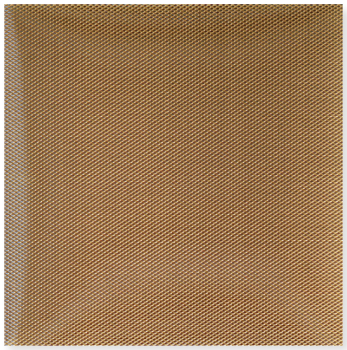
Ultra-thin; 0.2 mm thick
Designed to make primary closure easier to achieve

0.5 mm pore size
Contains most graft materials

Highly inert, non-reactive, non-stick nitride coating
Designed to improve tissue release upon removal

Can be repeatedly sterilized by autoclave
Unused portions are not wasted

- Pore size of 0.5 mm contains graft material while allowing tissue ingrowth
- High coating density with no pores to hold contaminants
- Will not stain or corrode
- Withstands acids, bases, solvents, and high temperatures
- Outstanding wear resistance

	Description	Item No.	Units (per box)
	Titanium Mesh 25 mm x 34 mm	TIM2534-1	1
	Titanium Mesh 45 mm x 45 mm	TIM4545-1	1

*Data on file with manufacturer.

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OsseoGuard PTFE Sutures

Non-Resorbable PTFE Soft Monofilament Sutures

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

Features and Benefits*

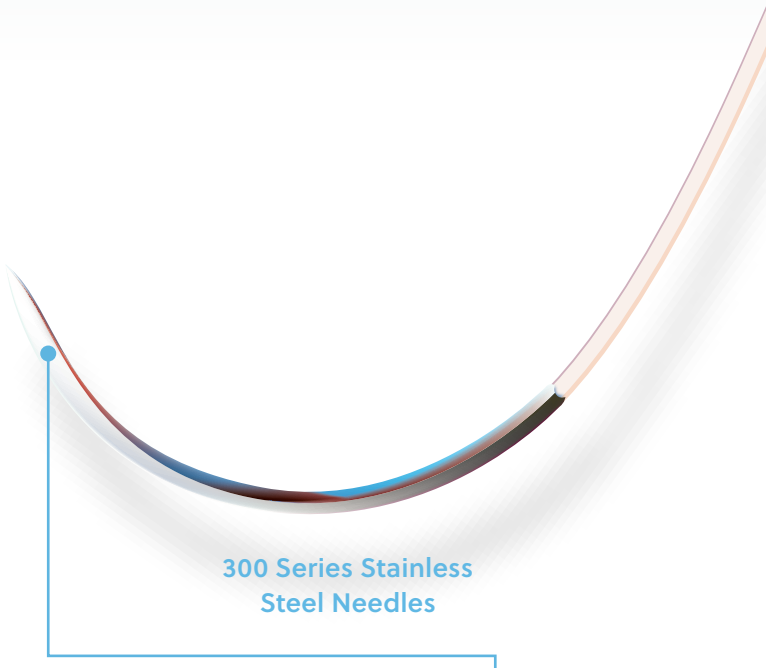
100% medical grade PTFE
Biologically inert

Monofilament
Does not allow bacteria wicking into the surgical site

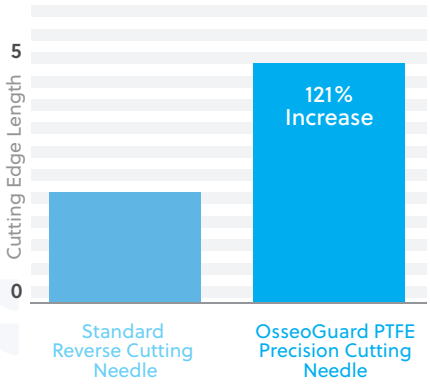
Soft
Comfortable for patients

Very low package memory
Excellent handling, knots securely

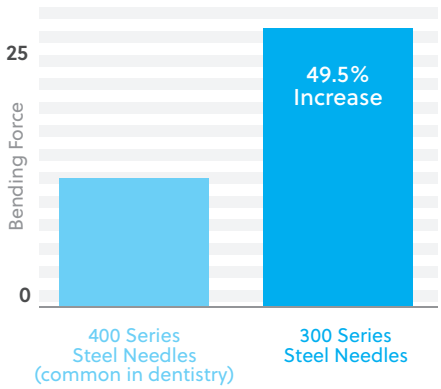
Non-resorbable
Keeps the surgical site reliably closed

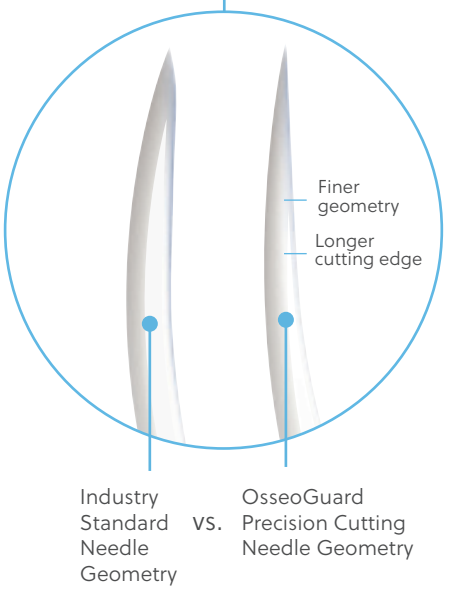


Cutting Edge Length*



Resistance to Bending*



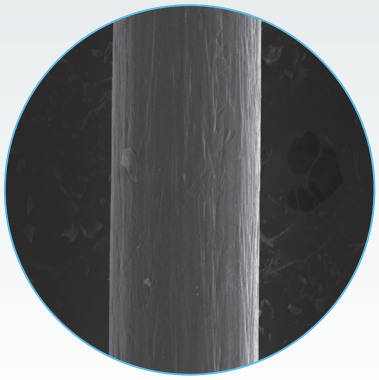


*Data on file with manufacturer.

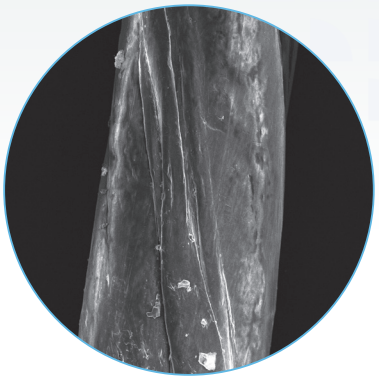
The soft monofilament

- Smooth monofilament rod
- Non-wicking monofilament construction
- Soft and comfortable for patients

OsseoGuard PTFE Suture vs. a Competitor's PTFE Suture



OsseoGuard PTFE Suture
350x Magnification



Competitor PTFE Suture
350x Magnification

	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

* Data on file with manufacturer.

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, Zafiropoulos 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.

For more information, visit ZimVie.com

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