Stratafix™

Anatomy of a Barbed Suture

A comprehensive guide

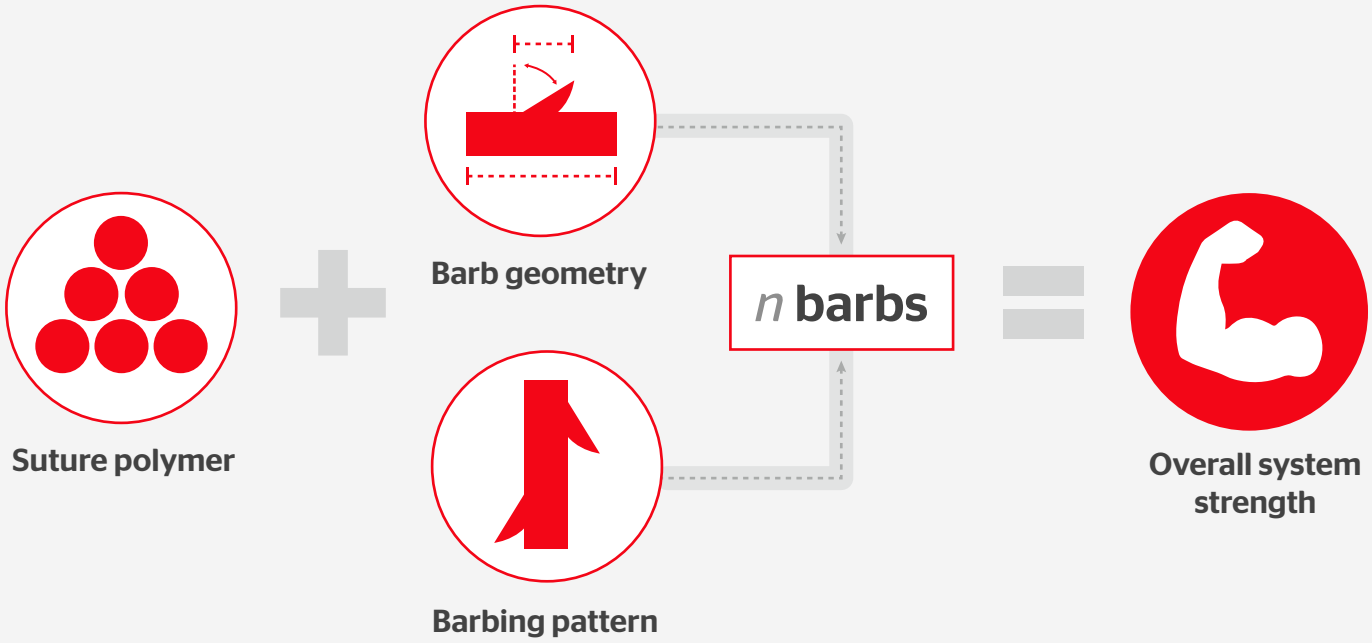
At first glance, choosing the proper barbed suture for a given procedure appears to depend on the same factors as traditional suture—polymer, absorption profile, out-of-package tensile strength, breaking strength retention (BSR), size (diameter), and needle type and length.

While some of the "decision criteria" used in selecting a traditional suture still apply, it is important to recognize that **barbed suture is a system of complex design features that work together to strike the right balance between strength and smooth tissue passage.[1]**

The following is a discussion of the core engineering and design principles that influence the overall performance of a barbed suture—and thus should be weighed when making a selection:

- **Suture polymer**
- **Barb geometry**
- **Barbing pattern**

Barb geometry and barbing pattern dictate the number of barbs, which, together with suture polymer, define the overall strength of the system.[1]



While some suture manufacturers suggest that a barbed suture's strength relies solely on the number of barbs, the overall strength arises from a multi-factorial system of polymer, barb geometry, and barbing pattern.

Suture Polymer

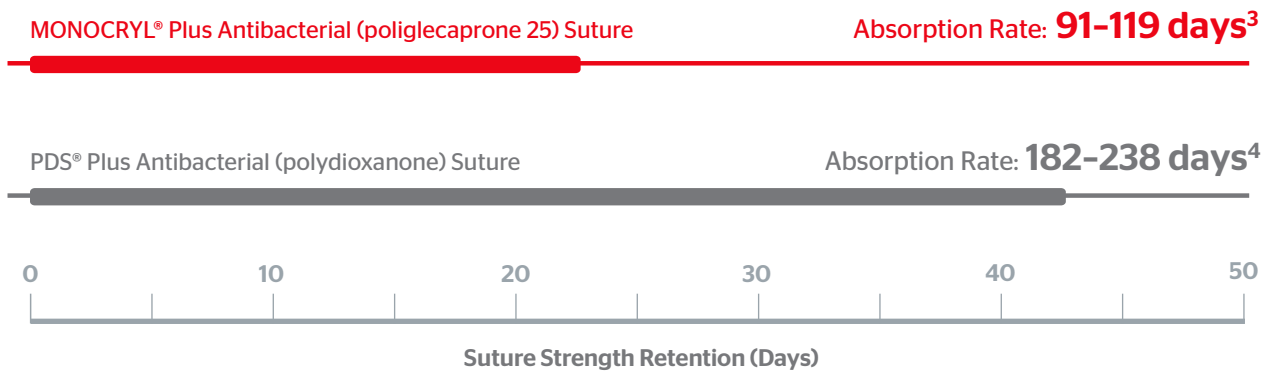
The importance of suture polymer cannot be overstated. The polymer ultimately defines the **short- and long-term strength** as well as the **intraoperative handling** of the barbed suture, just as it does with traditional suture.[2]

Different polymers have different **breaking strength retention (BSR)** and **absorption profiles** designed to meet the unique healing properties of the tissue layer being closed, as well as the kind of procedure being performed.[2] For example, a joint capsule closure necessitates a greater BSR and a longer absorption profile than a skin closure.

Breaking strength retention (BSR) = Suture's resistance to breaking under tension *in vivo*
Absorption profile = Rate and amount of time necessary for suture to be absorbed by the body, leaving no detectable trace in tissues

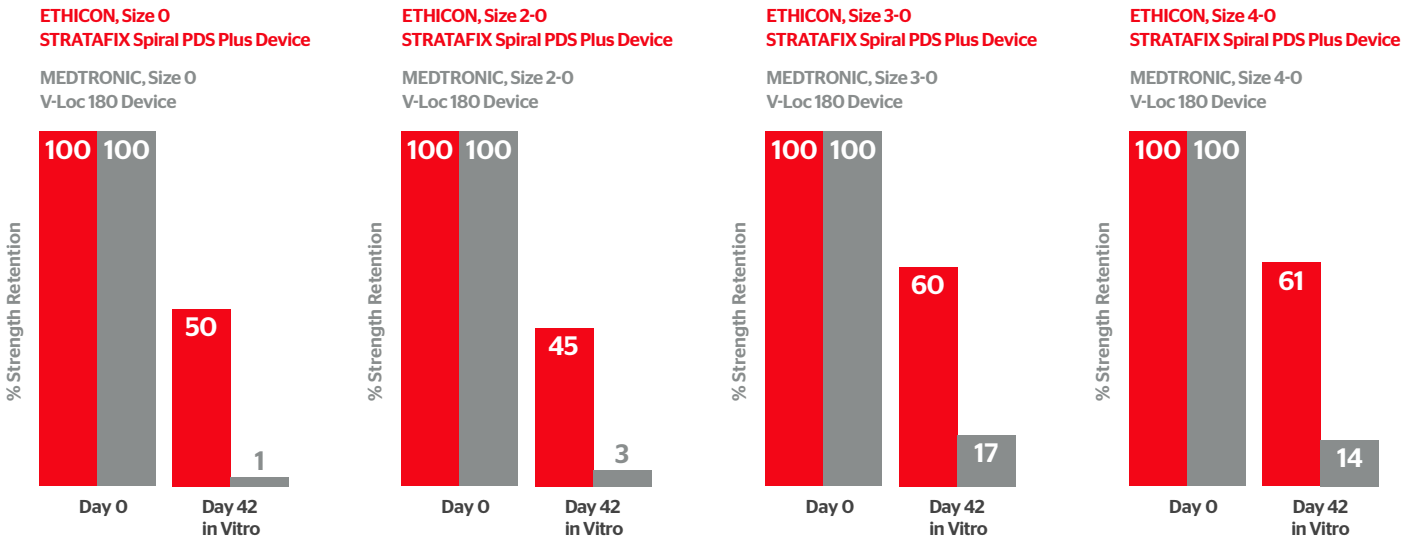
The strength you need for the choices you make

The STRATAFIX™ Knotless Tissue Control Device portfolio offers a variety of polymers of varying BSR and absorption profiles, including the trusted and proven Ethicon polymers MONOCRYL® (poliglecaprone 25) Suture and PDS® (polydioxanone) Suture.



Greater long-term strength retention vs. Medtronic's V-Loc™ 180 Absorbable Wound Closure Device

At an equivalent size, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device, which is made from PDS (polydioxanone), provides 6 weeks of tissue support while Medtronic's V-Loc™ 180 Device, which is made from Maxon™ Suture, provides support for only 3 weeks.[5,6]



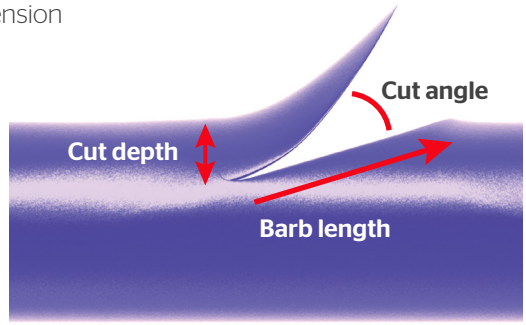
Barb Geometry

The geometry of the individual barbs affects two kinds of strength of a barbed suture:

- **Tensile strength:** the suture's resistance to breaking under tension
- **Tissue-holding strength:** the suture's ability to hold onto tissue under tension

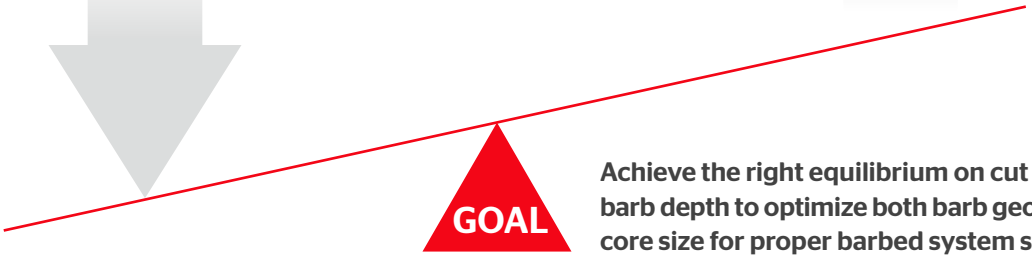
There are three design principles that influence barb geometry— and therefore strength[1]:

- **Cut depth** – Increasing cut depth increases the barb's tissue-holding strength, but decreases the device's tensile strength because less core remains
- **Cut angle** – Decreasing cut angle makes the barbs thinner and therefore more flexible, for potentially smoother tissue passage
- **Barb length** – Ultimately, barb length is a product of cut depth and angle



DECREASING
the cut angle and cut depth =
Smaller barb, but larger core

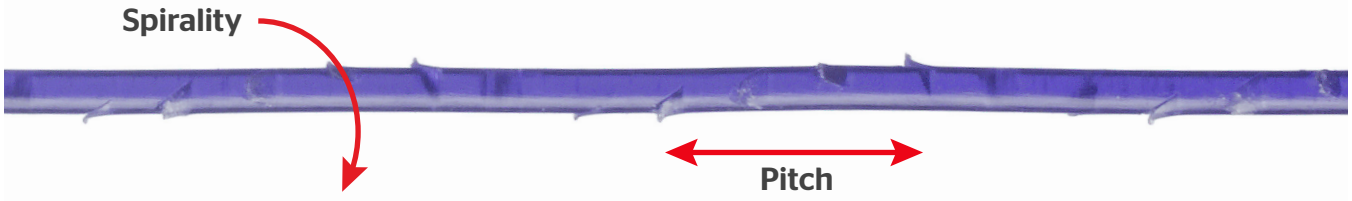
INCREASING
the cut angle and cut depth =
Larger barb, but smaller core



Achieve the right equilibrium on cut angle and barb depth to optimize both barb geometry and core size for proper barbed system strength

Barbing Pattern

The spirality and pitch of the barbing pattern also influence the overall suture system strength.[1]



Spirality is defined as how tight the spiral pattern is around the device, much like threads on a screw
Pitch is the spacing between barbs, represented by barbs per unit length

STRATAFIX™ Knotless Tissue Control Devices

The right balance of polymer, barb geometry, and barbing pattern to deliver optimal system strength

Medtronic claims that the dual-angle cut and the greater number of barbs on V-Loc™ Wound Closure Device results in greater tissue-holding strength. However, the chart below demonstrates the unique combination of factors that allows **STRATAFIX Knotless Tissue Control Devices to provide comparable strength – with fewer barbs**.[7,8]

	STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device (size 4-0) 	V-Loc™ 180 Absorbable Wound Closure Device (Maxon™ Suture) (size 4-0) 
Tissue-Holding Strength (Time 0)[7*†]	**26.9 lbf**	**23.4 lbf**
Polymer BSR at Day 42[5‡]	**61%**	14%
Geometry Barb Depth[9§]	**30% of full-strand diameter**	20% of full-strand diameter
Geometry Cut Angle[10]	**~ 21°**	Angle #1: ~ 45°, Angle #2: ~ 5°
Pitch (Barbs per Unit Length)[11]	**1.7 barbs per mm**	2.3 barbs per mm

	STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device (size 3-0) 	V-Loc™ 180 Absorbable Wound Closure Device (Maxon™ Suture) (size 3-0) 
Tissue-Holding Strength (Time 0)[8*†]	**50.9 lbf**	**61.4 lbf**
Polymer BSR at Day 42[5‡]	**60%**	17%
Geometry Barb Depth[9§]	**25% of full-strand diameter**	18% of full-strand diameter
Geometry Cut Angle[10]	**~ 23°**	Angle #1: ~ 35°, Angle #2: ~ 6°
Pitch (Barbs per Unit Length)[11]	**1.2 barbs per mm**	1.8 barbs per mm

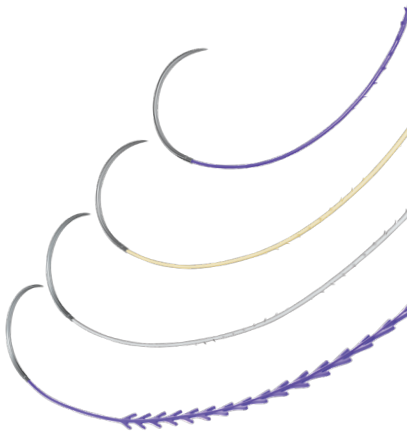
By incorporating proven polymers with an extended BSR and optimized barb depth, STRATAFIX Knotless Tissue Control Devices deliver statistically equivalent tissue-holding strength to Medtronic's V-Loc™ Wound Closure Devices.

*No statistical difference in tissue-holding strength despite the numerical difference.
†In porcine subcuticular tissue ‡In vitro §3.5 mils for STRATAFIX Spiral PDS Plus Device; 2.4 mils for V-Loc™ 180 Device

STRATAFIX™ Knotless Tissue Control Devices

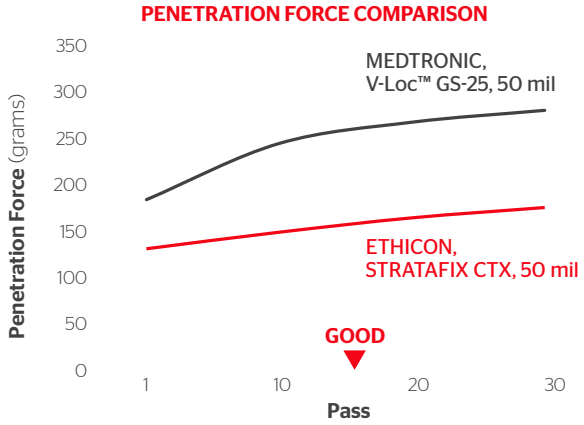
Everything you expect from the leader in Wound Closure

Only Ethicon's 130-year legacy of proven innovation can elevate barbed sutures to the next level—with trusted Ethicon polymers, superior needle performance,[2,12,13] and exclusive Plus Antibacterial Technology.



Most comprehensive portfolio of barbed sutures

- 170+ codes in a variety of lengths and sizes for open, laparoscopic, and robotic procedures
- Three anchor technologies (unidirectional spiral, bidirectional spiral, and symmetric) for maximum versatility
- Only barbed suture appropriate for closing high-tension areas, such as fascia[14,15]*
- Available in short-term, long-term, and non-absorbable polymers to suit multiple tissue types



Paired with premium Ethicon needles[12,13]

- Superior penetration and strength compared to V-Loc™ and Quill™ needles
- Resistant to bending and breaking
- Penetrate tissue smoothly

Only barbed suture portfolio with exclusive Plus Antibacterial Technology

- Triclosan technology is now supported by World Health Organization (WHO) Global Guidelines for the Prevention of Surgical Site Infection, a Centers for Disease Control and Prevention (CDC) Guideline, and American College of Surgeons & Surgical Infection Society (ACS & SIS) Surgical Site Infection Guidelines, 2016 Update[16-18†]

†The WHO, CDC, and ACS & SIS guidelines on reducing the risk of SSIs are general to triclosan-coated sutures and are not specific to any one brand.

- Available in Spiral and Symmetric codes

STRATAFIX™ Spiral Plus Knotless Tissue Control Device

◀ 11 days against *E. coli*, 23 days against *S. aureus**

V-Loc™ Wound Closure Device

The petri dish image is for illustrative purposes only, zone of inhibition testing results can vary.

*Applies only to STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device. The third-party trademarks used herein are trademarks of their respective owner.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References: 1. Nawrocki J. Technical Memo: Explanation on the Science Behind the Anchors on Knotless Tissue Control Devices. 2017. Ethicon, Inc. **2.** Ethicon Wound Closure Manual. Ethicon, Inc. **3.** MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture Instructions for Use. Ethicon, Inc. **4.** PDS® Plus Antibacterial (polydioxanone) Suture Instructions for Use. Ethicon, Inc. **5.** Report for Assessment of Real Time In-Vitro BSR Testing of STRATAFIX Spiral PDS Plus, STRATAFIX Spiral Monocryl PLUS, V-Loc 90 and V-Loc 180 barbed suture devices. 100552029. July 14, 2017. Ethicon, Inc. **6.** V-Loc™ 180 Absorbable Wound Closure Device Instructions for Use. Medtronic. **7.** Nonnenmann H. Performance Testing Report for STRATAFIX Spiral PDS Plus – Mechanical Testing. November 2016. Ethicon, Inc. **8.** Report for Assessment of Benchtop Tissue Holding Strength of STRATFIX Spiral PDS PLUS, STRATAFIX Spiral Monocryl PLUS, V-Loc 90 and V-Loc 180 barbed suture devices. 100559286. July 19, 2017. Ethicon, Inc. **9.** ADAPTIV 100541512. Measurement of V-Loc Suture Dimensions and Comparisons to Claims Within EP2335889B1. Ethicon, Inc. **10.** Measurement of V-Loc Suture Dimensions. 100584728. October 27, 2017. Ethicon, Inc. **11.** Scogna R. STRATAFIX™ Spiral PDS™ Plus vs. V-Loc™ 180: Comparison of Devices. May 2017. Ethicon, Inc. **12.** Technical Memo CT12-009. December 12, 2012. Ethicon, Inc. **13.** Technical Memo CT09-022. January 20, 2010. Ethicon, Inc. **14.** STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device Instructions for Use. Ethicon, Inc. **15.** Time Zero Tissue Holding - Competitive Claims Comparisons for STRATAFIX Knotless Tissue Control Devices vs Various Products (100326296). 2015. Ethicon, Inc. **16.** Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA Surg.* doi:10.1001/jamasurg.2017.0904. **17.** Global guidelines on the prevention of surgical site infection. World Health Organization website. http://www.who.int/gpsc/ssi-prevention-guidelines/en/. Accessed March 23, 2017. **18.** Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. *J Am Coll Surg.* 2016;224:59-74.

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