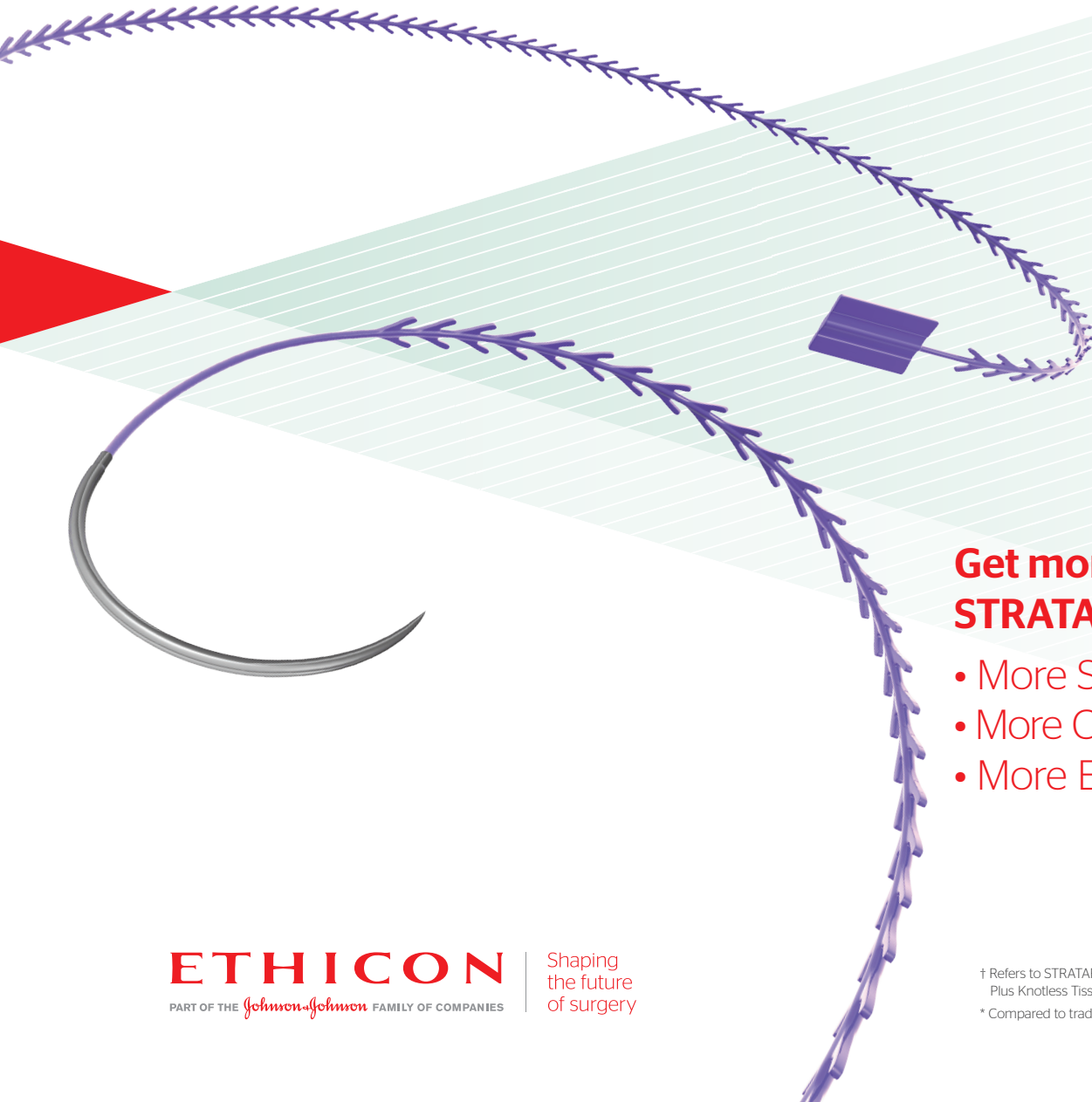


Stratafix™

STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device

The only knotless tissue control device that is appropriate for fascial closure^{1,2,†}



Get more with STRATAFIX™

- More Security *
- More Consistency *
- More Efficiency *

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Shaping
the future
of surgery

† Refers to STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device Only.
* Compared to traditional sutures.

What is important in **fascial closure**?

Strength

- After 14 to 28 days of healing, the fascia is self-supportive but still weak^{8,18}
- Fascia heals even slower in patients with co-morbidities such as diabetes—or due to other patient factors like smoking, poor nutrition, cancer, or AIDS^{8,18}
- Patient movement and intra-abdominal swelling increase abdominal pressure, placing added tension on the incision, and pulling the wound edges apart⁴

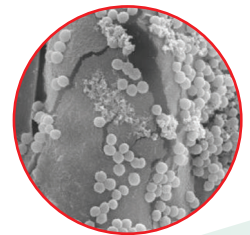
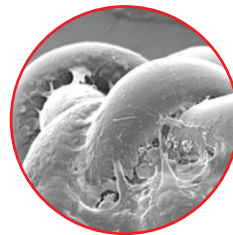
Up to **3.5%** of midline incisions result in dehiscence^{4,19}

Up to **19%** of midline incisions develop surgical site infections (SSIs)^{5-7,19}

Up to **23%** of midline incisions result in incisional hernia^{5,7,19}

Address risk factors of infection

- Surgical site infection (SSI) increases the risk of dehiscence and incisional hernia.^{3,8,18} SSIs can extend the inflammatory phase, during which the tissue has essentially no strength⁹
- Bacterial colonization of the suture is a known risk factor for SSI⁹



Bacterial colonization is a potential complication of suture knots and braided sutures⁹

Technique

- Continuous closure combines efficiency with more consistent distribution of tension¹⁰, but has greater risk of wound dehiscence and bacteria travelling along the suture
- Interrupted closure is more time consuming but less likely to be compromised by a single break in the suture^{7,11,12}

The ideal choice for fascial closure would provide a high level of tension control, without compromising strength, security, and antibacterial protection.

STRATAFIX™ Symmetric PDS™ Plus

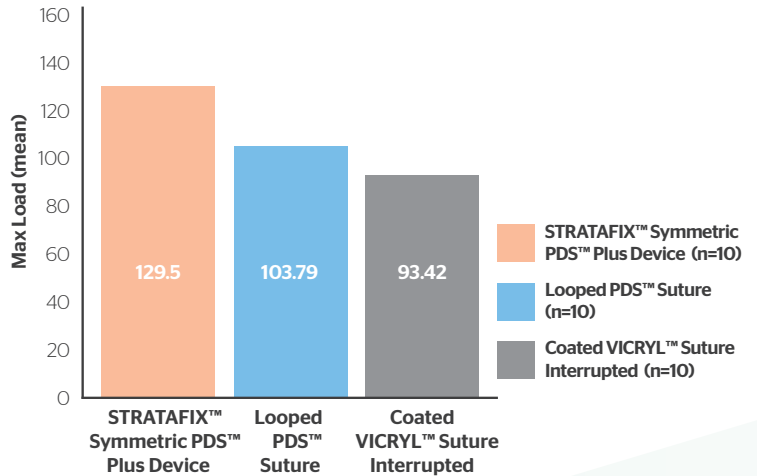
Knotless Tissue Control Device

Now achieve the efficiency and security of your wound closure without compromise.

Superior Strength

- STRATAFIX™ Symmetric PDS™ Plus Device demonstrated superior tissue holding strength compared to interrupted technique with Coated VICRYL™ (polyglactin 910) Suture, continuous technique with PDS™ II (polydioxanone) Looped Suture and V-LOC™ 180 Wound Closure Device^{1,13}
- Initial breaking strength superior to Traditional PDS™ Plus Antibacterial (polydioxanone) Suture¹⁴
- In ex-vivo studies, multiple cuts to the STRATAFIX™ Symmetric PDS™ Plus Device placed in fascia did not result in tissue separation¹⁵
- In pre-clinical animal studies, STRATAFIX™ Spiral PGA-PCL Knotless Tissue Control Device,^{*} STRATAFIX™ Spiral PDO Knotless Tissue Control Device,^{*} and STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device showed wound healing equivalent to traditional PDS™ Plus Antibacterial (polydioxanone) Suture at 7 and 21 days postsurgery.¹

Max Load Comparison for Tissue Holding in Fascia¹³



Address risk factors of infection

Provides antibacterial protection against pathogens commonly associated with SSIs^{14,16}

- Creates a zone of inhibition around the device¹⁷
- Shown in vitro to inhibit bacterial colonization of the device for 11 to 23 days¹⁷
- The only commercially available knotless tissue control - devices with antibacterial protection¹

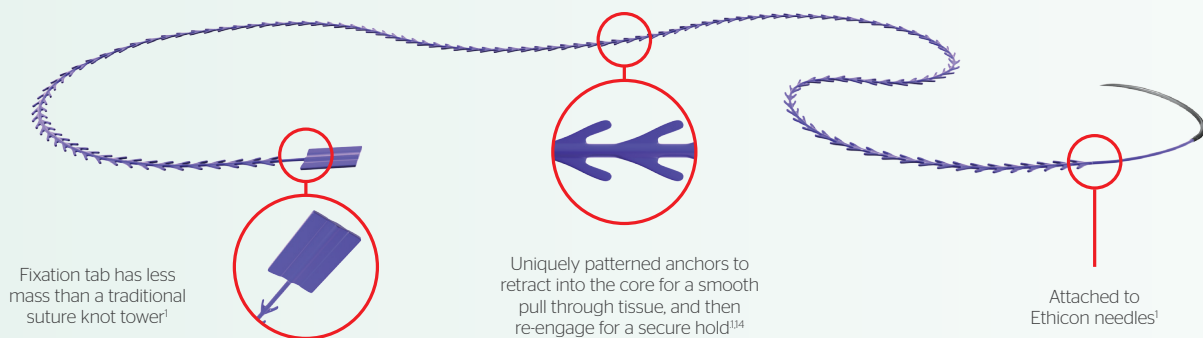


Demonstrated In vitro activity—
E coli: 11 days
S aureus: 23 days¹⁷

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

Technique

STRATAFIX™ Symmetric PDS™ Plus Device combines the benefits of interrupted and continuous suturing techniques¹



Only Ethicon offers a knotless tissue control device[†], with Plus **antibacterial** technology, that is appropriate for closing high-tension areas, such as **fascia**.^{1,2,14}











* This study was performed with a device of similar material and anchor design to a STRATAFIX™ Spiral Device.

** In Vivo. In an animal model.

† Refers to STRATAFIX™ Symmetric PDS™ Plus Device only.

STRATAFIX™ Symmetric PDS™ Plus

Knotless Tissue Control Device

Needle		Length	3-0	2-0	0	1
19 mm, 3/8 Circle, Reverse Cutting, PS-2		45 cm	SXPP1A101			
24 mm, 3/8 Circle, Reverse Cutting, PS-1		45 cm	SXPP1A100			
36 mm, 1/2 Circle, Reverse Cutting, OS-6		45 cm			SXPP1A200	SXPP1A201
26 mm, 1/2 Circle, Taper Point, SH		45 cm	SXPP1A410	SXPP1A409		
26 mm, 1/2 Circle, Taper Point, CT-2		45 cm		SXPP1A408	SXPP1A407	
36 mm, 1/2 Circle, Taper Point, CT-1		45 cm		SXPP1A403	SXPP1A401	SXPP1A404
40 mm, 1/2 Circle, Taper Point, CT		45 cm			SXPP1A406	SXPP1A405
48 mm, 1/2 Circle, Taper Point, CTX		45 cm			SXPP1A402	SXPP1A400
36 mm, 1/2 Circle, Taper Point, Ethiguard® Safety Needle, CTB-1		45 cm				SXPP1A301
48 mm, 1/2 Circle, Taper Point, Ethiguard® Safety Needle, CTXB		45 cm			SXPP1A302	SXPP1A300

References: 1. Ethicon, STRATAFIX™ Knotless Tissue Control Device Claims Matrix 060056-170214 EMEA, Data on File. 2. *Ethicon Wound Closure Manual*. 2007. Ethicon, Inc. 3. Franchi et al. Incisional Hernia in Gynecologic Oncology Patients: A 10-Year Study. *Obstet Gynecol*. 2001;97:696. 4. van Ramshorst GH, Nieuwenhuizen J, Hop WC, et al. Abdominal wound dehiscence in adults: development and validation of a risk model. *World J Surg*. 2010;34(1):20-27. 5. Millbourn D, Cengiz Y, Israelsson LA. Effect of stitch length on wound complications after closure of midline incisions: a randomized controlled trial. *Arch Surg*. 2009;144(11):1056-1059. 6. Petrosillo N, Drapeau CM, Nicastrì E, et al. ANPIO. Surgical site infections in Italian hospitals: a prospective multicenter study. *BMC Infect Dis*. 2008;8:34. 7. Seiler CM, Bruckner T, Diener MK, et al. Interrupted or continuous slowly absorbable sutures for closure of primary elective midline abdominal incisions: a multicenter randomized trial (INSECT: ISRCTN24023541). *Ann Surg*. 2009;249(4):576-582. 8. Dubay DA, Franz MG. Acute wound healing: the biology of acute wound failure. *Surg Clin North Am*. 2003;83(3):463-481. 9. Edmiston CE, Seabrook GR, Goheen MP, et al. Bacterial adherence to surgical sutures: can antibacterial-coated sutures reduce the risk of microbial contamination? *J Am Col Surg*. 2006;203:481-489. 10. Poole GV Jr. Mechanical factors in abdominal wound closure: the prevention of fascial dehiscence. *Surgery*. 1985;97(6):631-640. 11. Boutros S, Weinfeld AB, Friedman JD. Continuous versus interrupted suturing of traumatic lacerations: a time, cost, and complication rate comparison. *J Trauma Inj Infect Crit Care*. 2000;48(3):495-497. 12. Wong NL. Review of continuous sutures in dermatologic surgery. *J Dermatol Surg Oncol*. 1993;19:923-931. 13. Data on file, Ethicon, Inc. Minitab for Claims Study 2015. 14. STRATAFIX™ Symmetric PDS™ Plus IFU. 15. Ethicon, AST-2013-0056 Performance Testing of STRATAFIX™ Symmetric PDS™ Size2-0 suture device for Tissue Holding Strength with Multiple Incision Defects to Measure Gapping. Data on File. April 2013. 16. PDS™ Plus IFU. 17. Ethicon Inc. Notebook 4203, In Vitro Efficacy Evaluation of STRATAFIX™ Symmetric PDS™ PLUS Sutures treated with Triclosan, Jan 2013, Data on File. 18. Douglas. The Healing of Aponeurotic Incisions. *Br J Surg*. 1952;40:79. 19. Van't Riet et al. Meta-analysis of techniques for closure of midline abdominal incisions. *Br J Surg*. 2002;89:1350

Please always refer to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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