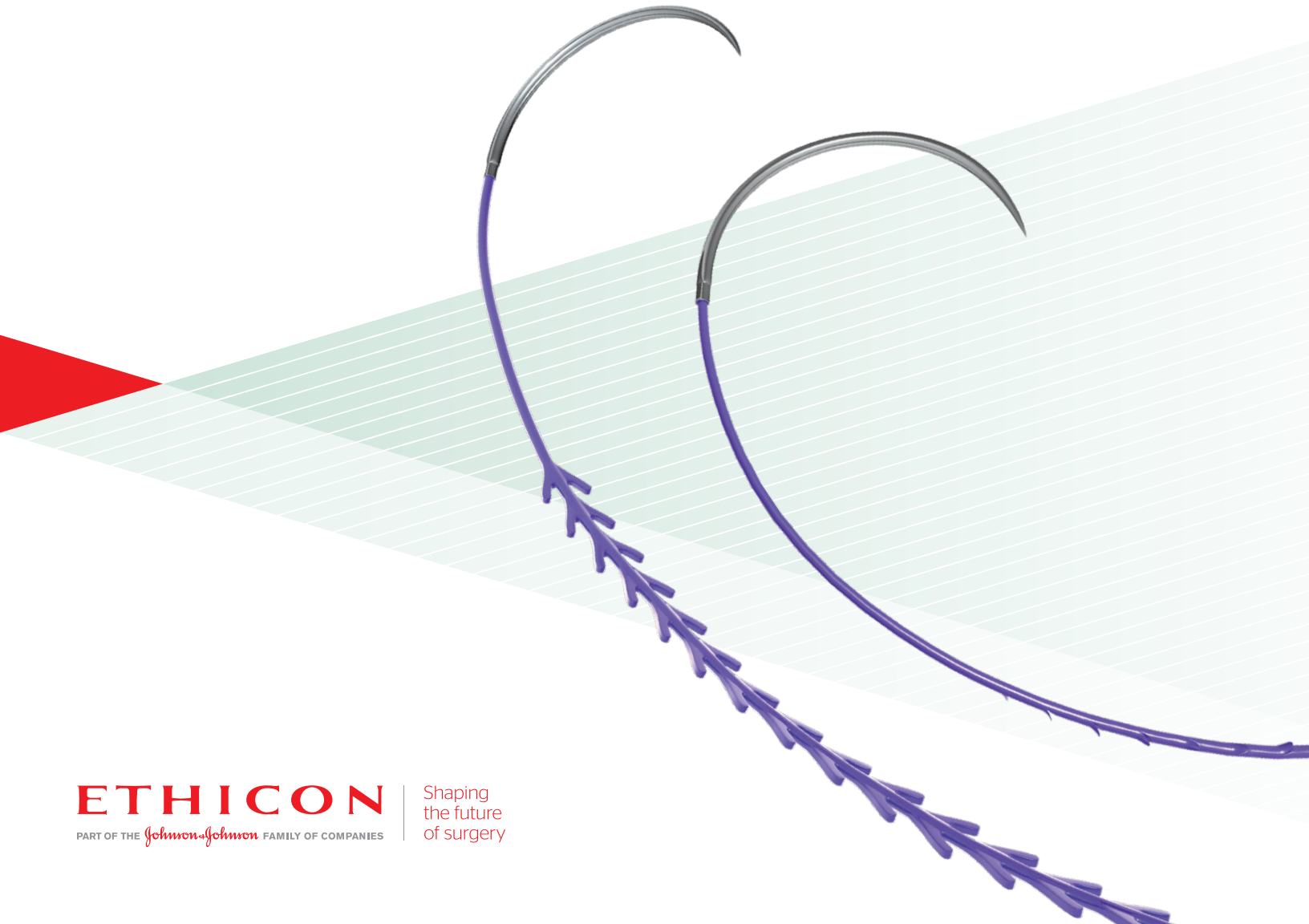
STRATAFIX™ Knotless Tissue Control Devices

Product Brochure

A versatile portfolio to meet your wound closure needs



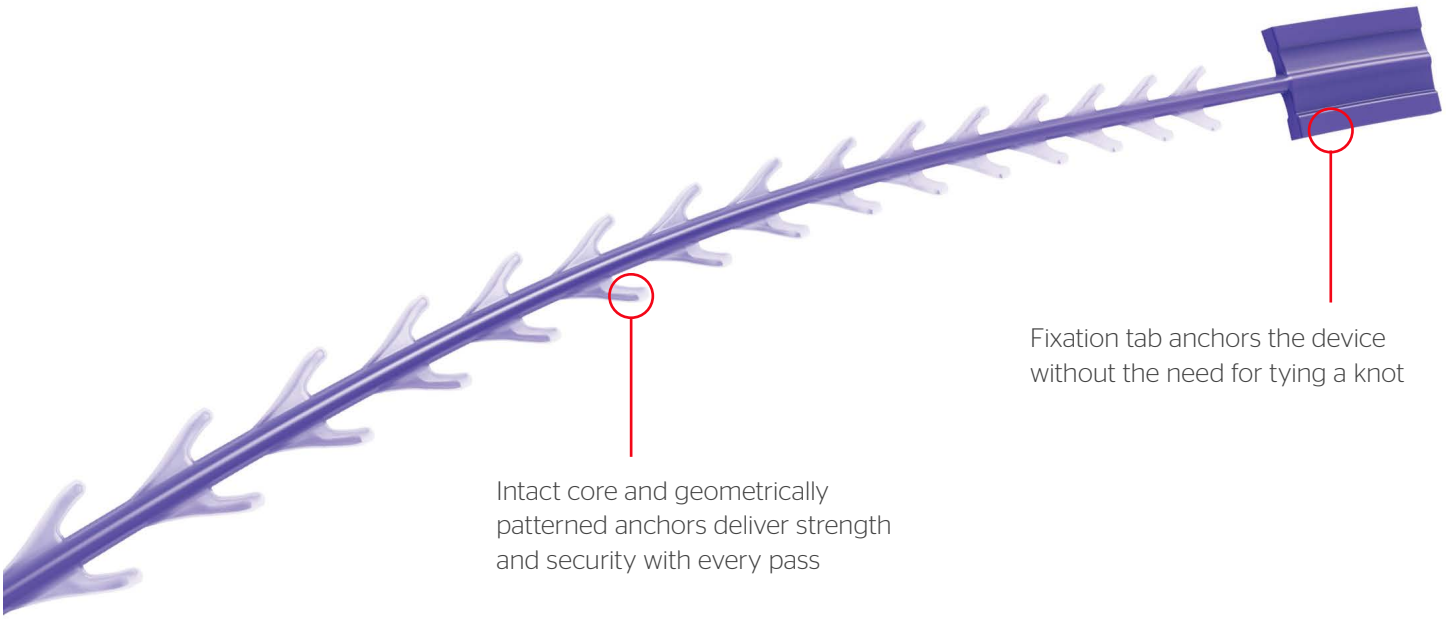
ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Shaping the future of surgery

STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices

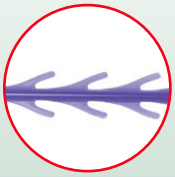
Only Ethicon offers a knotless tissue control device that is appropriate for closing high-tension areas, such as fascia[1-7]



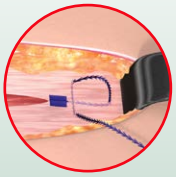
Fixation tab anchors the device without the need for tying a knot

Intact core and geometrically patterned anchors deliver strength and security with every pass

Symmetric



Pressed **symmetrical anchors** maintain the core of the device



Superior tissue-holding strength compared to interrupted technique with Coated VICRYL® (polyglactin 910) Suture, continuous technique with PDS® II (polydioxanone) Suture, and V-Loc™ 180 Wound Closure Device[1]

STRATAFIX Symmetric PDS Plus Device offers **Plus Antibacterial Technology** to address a known risk factor for surgical site infection (SSI)[7*]

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

References: 1. 100326296: Time Zero Tissue Holding - Competitive Claims Comparisons for STRATAFIX Knotless Tissue Control Devices vs Various Products. 2015. Ethicon, Inc. **2.** Ethicon study AST-2011-0210. Study to evaluate the tissue holding performance at time zero of DOLFIN PDS PLUS barbed suture sizes 1 and 2-0 vs dyed PDS II Plus suture sizes 1 and 2-0 in a continuous stitch pattern—Project DOLFIN 11822, version 1. Approved on July 15, 2011. **3.** Ethicon study AST-2011-0341. Performance testing of DOLFIN PDS PLUS size 3-0 suture—tissue holding 10 cm incision. Approved on August 22, 2011. Ethicon, Inc. **4.** Ethicon study PSE 09-0204, project number 11822. Exploratory histological and biomechanical evaluation of DOLFIN following closure of the ventral abdominal wall in a porcine model at 7±1 days. Approved on July 7, 2010. Ethicon, Inc. **5.** Ethicon study PSE 10-0012, project number 11822. Model development: histological and biomechanical evaluation of 3-0 DOLFIN barbed suture prototypes, 3-0 Quill suture, and 3-0 V-loc suture at 7±1 days following closure of the ventral abdominal wall in a rabbit model. Approved on August 8, 2011. Ethicon, Inc. **6.** Performance Testing of STRATAFIX SYMMETRIC PDS PLUS Size 0 & 1 Devices – Initiation Strength in Porcine Tissue. AST-2013-0603. Ethicon, Inc. **7.** Ming X, Rothenburger S, Nichols MM. In vivo and in vitro antibacterial efficacy of PDS Plus (polidioxanone with triclosan) suture. *Surg Infect (Larchmt).* 2008;9(4):451457.

STRATAFIX™ Knotless Tissue Control Devices

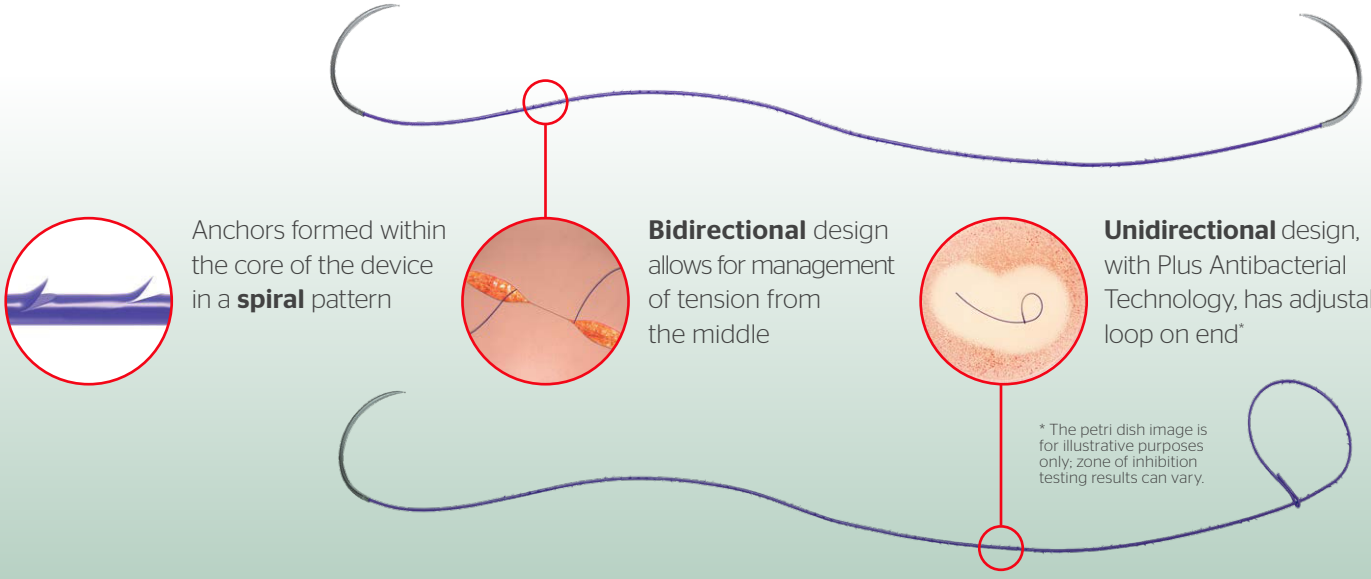
A broad range of bidirectional and unidirectional devices offers the smooth glide of a traditional suture and Plus Antibacterial Technology[1-7]

STRATAFIX™ Spiral PGA-PCL Knotless Tissue Control Device
STRATAFIX™ Spiral Polypropylene Knotless Tissue Control Device
STRATAFIX™ Spiral PDO Knotless Tissue Control Device
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices
STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices

Spiral anchor configuration provides a secure, 3-dimensional hold[1-7]

Anchors retract into the core for a smooth pull through tissue, then re-engage for a secure hold[1-7]

STRATAFIX Spiral Devices and STRATAFIX Spiral Devices with Plus Antibacterial Technology



Anchors formed within the core of the device in a **spiral** pattern

Bidirectional design allows for management of tension from the middle

Unidirectional design, with Plus Antibacterial Technology, has adjustable loop on end*

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

References: 1. 100326296: Time Zero Tissue Holding - Competitive Claims Comparisons for STRATAFIX Knotless Tissue Control Devices vs Various Products. 2015. Ethicon, Inc. **2.** Ethicon study AST-2012-0331. Tissue gapping under tension of porcine cadaveric skin incisions closed with Stratafix Spiral in comparison to Monocryl in both interrupted and continuous stitching patterns. Approved on August 24, 2012. Ethicon, Inc. **3.** Vakil JJ, O'Reilly MP, Sutter EG, Mears SC, Belkoff SM, Khanuja HS. Knee arthrotomy repair with a continuous barbed suture: a biomechanical study. *J Arthroplasty.* 2011;26(5):710-713. **4.** Eickmann T, Quane E. Total knee arthroplasty closure with barbed sutures. *J Knee Surg.* 2010;23(3):163-167. **5.** Levine BR, Ting N, Della Valle CJ. Use of a barbed suture in the closure of hip and knee arthroplasty wounds. *Orthopedics.* 2011;34(9):e473-e475. doi: 10.3928/01477447-20110714-35. **6.** Einarsson JI, Chavan NR, Suzuki Y, Jonsdottir G, Vellinga TT, Greenberg JA. Use of bidirectional barbed suture in laparoscopic myomectomy: evaluation of perioperative outcomes, safety, and efficacy. *J Minim Invasive Gynecol.* 2011;18(1):92-95. **7.** Moran ME, Marsh C, Perrotti M. Bidirectional-barbed sutured knotless running anastomosis v classic Van Velthoven suturing in a model system. *J Endourol.* 2007;21(10):1175-1178.

STRATAFIX™ Knotless Tissue Control Devices

The only commercially available knotless tissue control devices with antibacterial protection — designed to address a known risk factor associated with surgical site infection (SSI)

Plus Sutures have been shown in vitro to inhibit colonization of the suture for **7** days or more, including bacteria commonly associated with surgical site infection (SSI). [1-3]

PROVEN EFFECTIVE AGAINST: [2-3]

- ✓ *Staphylococcus aureus*
- ✓ *Staphylococcus epidermidis*
- ✓ *Escherichia coli**
- ✓ *Klebsiella pneumoniae**
- ✓ *Methicillin-resistant Staphylococcus epidermidis (MRSE)*
- ✓ *Methicillin-resistant Staphylococcus aureus (MRSA)*
- ✓ ***PDS® Plus Antibacterial (polydioxanone) Suture and MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture only**

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

Triclosan Coated Sutures are now supported by:

Centers for Disease Control and Prevention (CDC)

Guideline for the Prevention of Surgical Site Infections 2017*

"Consider the use of triclosan-coated sutures for the prevention of SSI." [4]

World Health Organization (WHO)

Global Guidelines for The Prevention of Surgical Site Infection*

The panel suggests the use of triclosan coated sutures for the purpose of reducing the risk of SSI, independent of the type of surgery.[5]

American College of Surgeons Surgical Infection Society (ACS & SIS)

Surgical Site Infection Guidelines, 2016 Update*

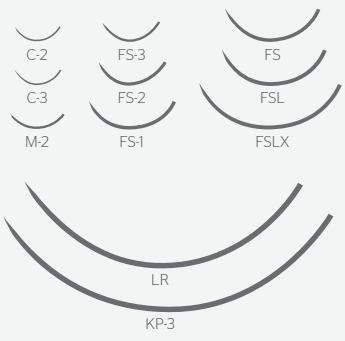
The use of triclosan coated suture is recommended for wound closure in clean and clean-contaminated abdominal cases when available.[6]

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

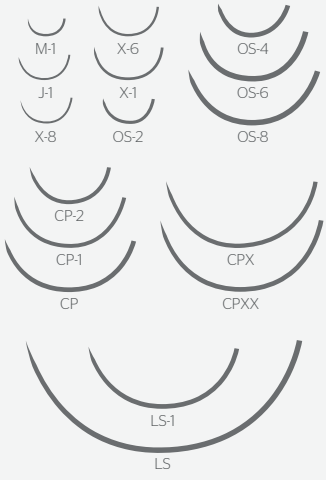
Ethicon Needle Types

REVERSE CUTTING

3/8 CIRCLE



1/2 CIRCLE



PRECISION POINT

REVERSE CUTTING

CONVENTIONAL CUTTING

References: 1. Rothenburger S, Spangler D, Bhende S, Burkley D. In vitro antimicrobial evaluation of coated Vicryl Plus Antibacterial Suture (coated polyglactin 910 with triclosan) using zone of inhibition assays. *Surg Infect (Larchmt).* 2002;3 (suppl):S79-S87. **2.** Ming X, Rothenburger S, Yang D. In vitro antibacterial efficacy of Monocryl Plus Antibacterial Suture (poligelcaprone 25 with triclosan). *Surg Infect (Larchmt).* 2007;8(2):201-207. **3.** Ming X, Rothenburger S, Nichols MM. In vivo and in vitro antibacterial efficAcy of PDS Plus (polidioxanone with triclosan) suture. *Surg Infect (Larchmt).* 2008;9(4):451-457. **4.** 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. **5.** 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. **6.** 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.

 116249-190610