



Peri-Strips Dry
*with Veritas Collagen Matrix
Staple Line Reinforcement*

CONFIDENCE AT THE STAPLE LINE

Strong from the start. Strong over time.*

BARIATRIC SURGERY¹

- ▶ Sleeve Gastrectomy
- ▶ Roux-en-Y
- ▶ Duodenal Switch
(Biliopancreatic Diversion with
Duodenal Switch (BPD/DS))

GENERAL SURGERY¹

- ▶ Colon/Colorectal
- ▶ Gastric/Small Bowel



*Pre-clinical data results may not correlate to results in humans.

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Applications & Procedures

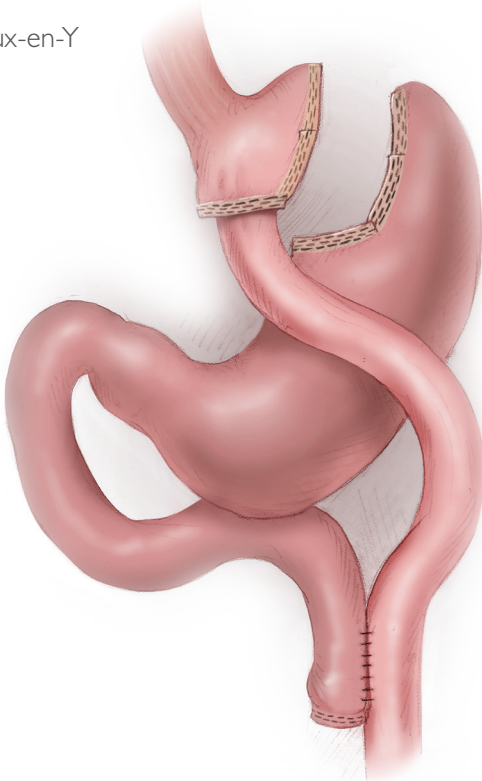
PERI-STRIPS DRY with VERITAS Collagen Matrix is derived from **bovine pericardium** and processed during manufacturing to produce a biocompatible, acellular, non-crosslinked collagen matrix that is immunologically inert.^{1,2*,3*}

PERI-STRIPS DRY with Veritas Collagen Matrix is intended to reinforce the staple line during repair of soft tissue deficiencies and can be used during bariatric, gastric, small bowel, colon and colorectal procedures.¹

Sleeve gastrectomy



Roux-en-Y



Biological Staple Line Reinforcement

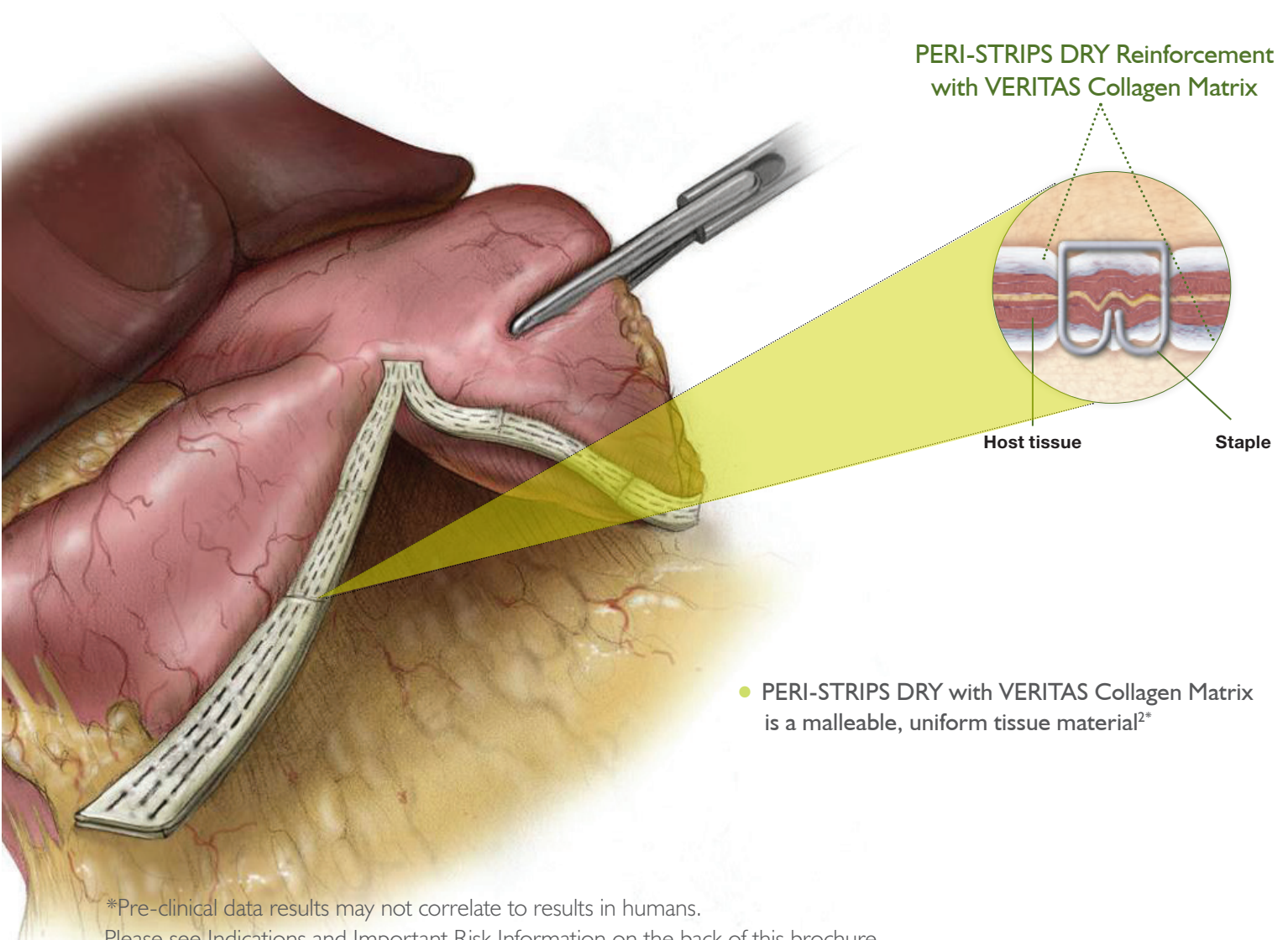
Your staple line buttressing options are synthetic PGA or a biological material. PERI-STRIPS DRY with VERITAS stands apart as a biological material that is shown to decrease the risk of staple line bleeding and leaking over synthetic PGA.^{4*}

Strong Biological Reinforcement

PERI-STRIPS DRY with VERITAS Collagen Matrix is created from a proprietary tissue manufacturing technique designed to provide **high levels of biocompatibility** (based on histological features^{2*}) while maintaining the **intrinsic suppleness and strength** of the material.^{2*}

- Strength over time at the staple line vs. synthetic PGA material⁵
- Reduced risk of staple line bleeding and leaks⁶⁻⁸
- Remodels in conjunction with the body's natural healing process⁹

Staple Line Reinforcement in Sleeve Gastrectomy Procedures



PERI-STRIPS DRY Reinforcement with VERITAS Collagen Matrix

Host tissue

Staple

- PERI-STRIPS DRY with VERITAS Collagen Matrix is a malleable, uniform tissue material^{2*}

*Pre-clinical data results may not correlate to results in humans. Please see Indications and Important Risk Information on the back of this brochure.



Gastric Staple Line Reinforcement - Clinical Meta-Analysis by Shikora et al¹⁰

The largest meta-analysis to date evaluating the outcomes for gastric staple line reinforcement was conducted through a systematic review of medical literature from 2000-2013.

There were **66,727** unique patients in the analysis. Data was extracted on **56,309** patients for leak and **41,864** patients for bleeding. These patients were included in 516 study arms, 301 for leak and 215 for bleed.

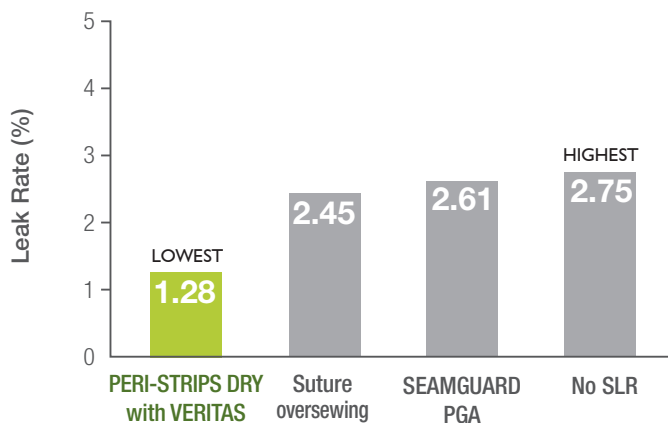
The three most commonly used SLR methods were compared

- 1** Oversewing reinforcement
- 2** Buttressing using PERI-STRIPS DRY / PERI-STRIPS DRY with VERITAS Collagen Matrix bovine pericardium
- 3** Buttressing using SEAMGUARD Bioabsorbable Staple Line Reinforcement glycolide copolymer PGA

16,967 articles were screened and **295** studies and abstracts were retained for data extraction.

Reinforcement type affects leak rate

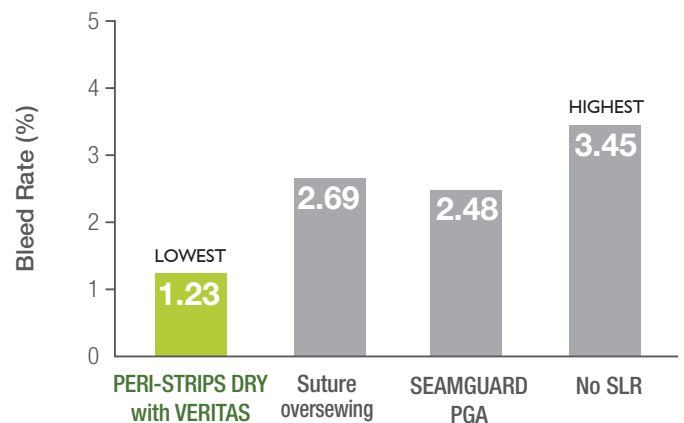
Reduced leak rate in sleeve gastrectomy/gastric bypass patients



PSDV vs oversuture and no SLR: $p < 0.001$
PSDV vs SEAMGUARD: $p < 0.01$

Reinforcement type affects bleed rate

Reduced bleed rate in sleeve gastrectomy/gastric bypass patients



PSDV vs no SLR: $p < 0.001$

PSDV vs SEAMGUARD: $p < 0.01$

PSDV vs oversuture: $p \leq 0.05$

SEAMGUARD vs no SLR: $p < 0.01$

This large meta-analysis demonstrated that in a population predominantly comprised of morbidly obese bariatric patients, excluding high risk revision patients, PERI-STRIPS DRY / PERI-STRIPS DRY with VERITAS Collagen Matrix (bovine pericardium) outperformed no staple line reinforcement, suture oversewing and synthetic buttress, SEAMGUARD Bioabsorbable Suture Line Reinforcement.

Please see Indications and Important Risk Information on the back of this brochure.

The Risk of Leaks in Bariatric Surgery

The event of bleeding or leakage in gastrointestinal and bariatric surgeries can result in devastating complications for the patient and lead to increased cost of care.^{10,11}

Laparoscopic Sleeve Gastrectomy - Clinical Publication by D'Ugo et al⁶

Retrospective multicenter study of **1162** patients from 2002 to 2012 focused on the comparative use of different techniques to evaluate reducing leak and bleeding along the staple line during **laparoscopic sleeve gastrectomy (LSG)**.

Of the **1162** LSG patients, there were **305** males and **857** females with a mean age of 43.7 ± 9.4 years (range 17-67 yr) and a mean body mass index (BMI) of 48 ± 6.4 kg/m² (range 35-84 kg/m²)

Effects of reinforcing the staple line

- 1** The study indicated that staple line reinforcement with PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix significantly reduced the risk of postoperative leaks compared to all other groups in the study.
- 2** Postoperative bleeding was significantly lower with staple line reinforcement than without any buttressing along the staple line in LSG.

Among the total **1162** patients undergoing LSG, **973** utilized staple line reinforcement.

% Rate of Leak Episodes (n=1162)	% Rate of Bleeding Episodes (n=1162)
0.3% PERI-STRIPS DRY w/ VERITAS	0% PERI-STRIPS DRY w/ VERITAS
3.2% GORE	1.6% GORE
7.8% COVIDIEN	1.3% COVIDIEN
3.0% OVER-SEWING	1.4% OVER-SEWING
4.8% NO SLR	13.7% NO SLR

The authors of this study had no commercial associations that might be a conflict of interest.



Peri-Strips Dry

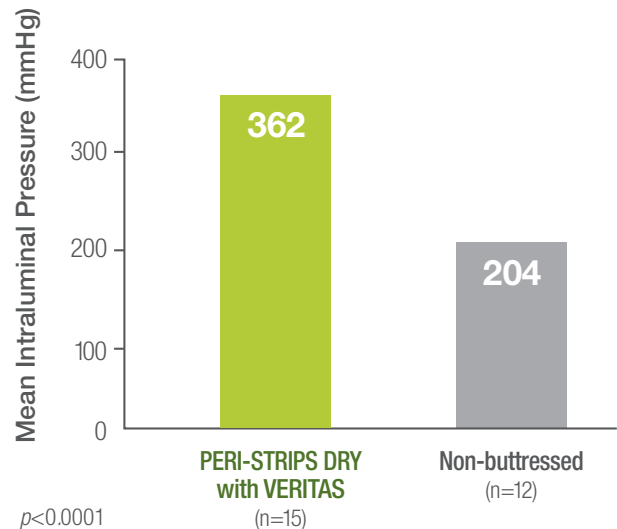
with Veritas Collagen Matrix
Staple Line Reinforcement

Strong From the Start (Burst Strength)^{12*}

An experimental study evaluating staple line seam integrity at intraluminal pressures in the immediate postoperative period with a canine model demonstrated:

- Regardless of the operative techniques, the buttressed ileocolic anastomoses showed higher bursting pressures^{12*}
- Buttressed anastomoses never ruptured at the staple line^{12*}

Higher Mean Burst Pressure^{12*}



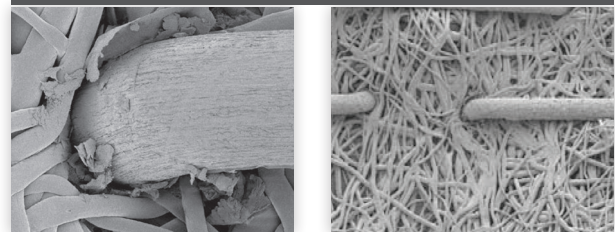
Enhanced Reapproximation

Staple Reapproximation in Laboratory Testing^{13*}

PERI-STRIPS DRY with VERITAS Collagen Matrix



SEAMGUARD Material



SEM (scanning electron microscopy) shows the PERI-STRIPS DRY with VERITAS Collagen Matrix material to be a smooth, dense membrane which readily reapproximates around individual staples of a buttressed intestinal staple line. In contrast, the SEAMGUARD Bioabsorbable material is highly porous (metal staples, 25x mag).^{13*}

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Over 20 Years of Proven Clinical History

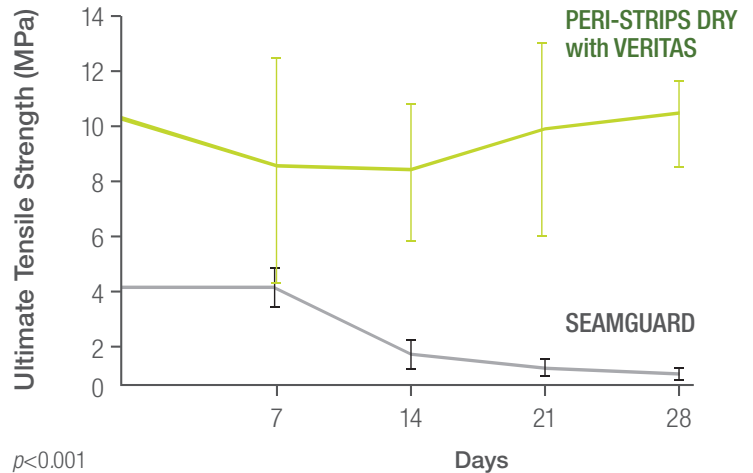
Over 20 years and 2.2 million implants later, PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix / PERI-STRIPS DRY Staple Line Reinforcement continue to have a proven clinical history.^{6,10}

Strong Over Time (Tensile Strength)^{5*}

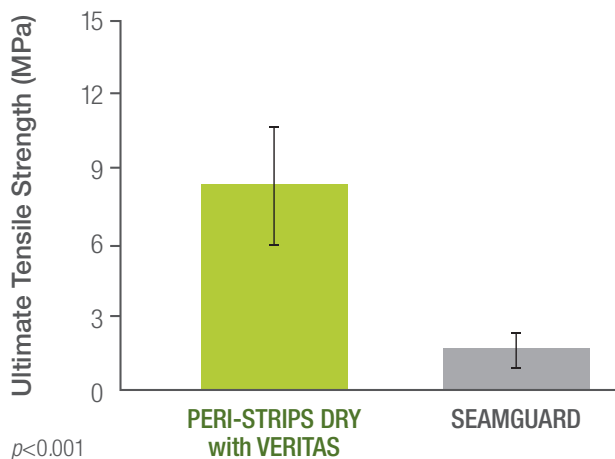
Samples of PERI-STRIPS DRY with VERITAS Collagen Matrix and SEAMGUARD were placed in sterile saline and incubated at 37°C for 0, 7, 14, 21, or 28 days. **The in vitro study showed no significant decrease in tensile strength over time with PERI-STRIPS DRY with VERITAS.^{5*}**

- After 7 days in sterile saline at 37°C, both buttress materials showed no statistically significant change in tensile strength
- However, there was a significant decrease in tensile strength of the SEAMGUARD Bioabsorbable material between day 7 and day 14 and thereafter

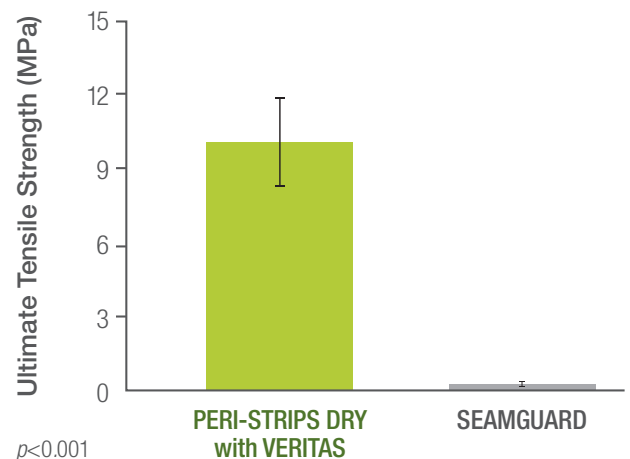
Mean Tensile Strength Over Time^{5*}



Day 14 Tensile Strength^{5*}



Day 28 Tensile Strength^{5*}



Gore's SEAMGUARD is composed of a glycolide and trimethylene carbonate copolymer and claims to be absorbed into the body within 6 to 7 months of implantation.¹⁴ The comparative study above between PERI-STRIPS DRY with VERITAS and SEAMGUARD demonstrates that the ultimate tensile strength (UTS) of PERI-STRIPS DRY with VERITAS was always higher than SEAMGUARD over a 28 day time period.⁵ The UTS is the maximum stress that a sample achieves throughout a tensile test and is generally the stress applied to the sample immediately before it fails.

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Peri-Strips Dry

with Veritas Collagen Matrix
Staple Line Reinforcement

Remodeling vs. Resorption

Tissue Integration Through Remodeling

Unlike PERI-STRIPS DRY, which is a permanent, crosslinked collagen matrix, PERI-STRIPS DRY with VERITAS Collagen Matrix is a non-crosslinked matrix designed to remodel.^{9*}

Remodeling of PERI-STRIPS DRY with VERITAS Collagen Matrix entails two simultaneous processes that occur during the course of normal wound healing:^{9*,15*,16*}

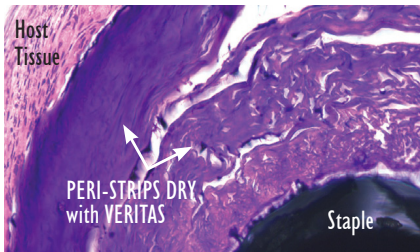
- Degradation of the VERITAS Collagen Matrix scaffold
- Deposition of new tissue and blood vessels

Although degradation is an important aspect of the remodeling process, it is a spontaneous chemical process of decomposition that is not controlled by the body.^{15*} **VERITAS Collagen Matrix exhibits favorable remodeling characteristics, such as scaffold degradation and new blood cell deposition, that occur during normal wound healing.**^{15*}

“VERITAS acts as a scaffold that, with time, becomes infiltrated with host cells and supports angiogenesis.”

— B. Oray^{2*}

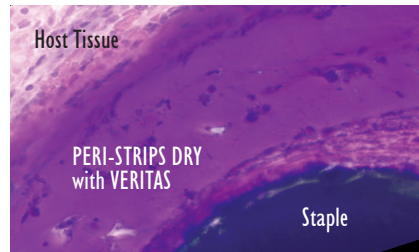
Replaced over time by tissue that is histologically indistinguishable from host tissue^{17*}



Time Zero

The acellular nature of the PERI-STRIPS DRY with VERITAS implant clearly distinguishes it from the surrounding tissue.

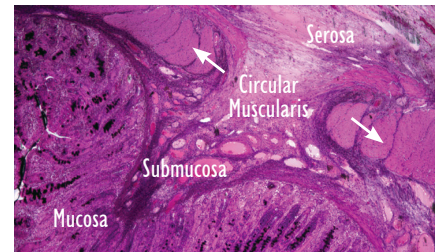
(Porcine model, 20x orig mag)



Three Days Post-Implant

Early signs of remodeling are evidenced by the infiltration of host cells into the PERI-STRIPS DRY with VERITAS acellular implant.

(Porcine model, 40x orig mag)



Six Weeks Post-Implant

The PERI-STRIPS DRY with VERITAS implant appears to be completely remodeled into histologically indistinguishable host tissue.

(Porcine model, 40x orig mag)

*As demonstrated in an animal model. Pre-clinical data results may not correlate to results in humans. Please see Indications and Important Risk Information on the back of this brochure.

Preparation and Application

Preparation and Application¹

1

GEL BOTH STRIPS

Apply a continuous bead of PSD Gel to the center of both sides of the loading unit.



2

WEDGE LOADING UNIT

The plastic loading unit contains two strips of bovine pericardium secured on each side of a foam spacer. Gently push the PERI-STRIPS DRY with VERITAS Collagen Matrix loading unit into the jaws of the stapler and slide the foam insert out of loading unit.

With the Covidien stapler, be careful to ensure that the end of the yellow guard is positioned above the assembly clip.

Note: PERI-STRIPS DRY with VERITAS can be used immediately or allowed to remain between the forks of the stapler loading unit until surgery. For optimal results, PERI-STRIPS DRY with VERITAS should be used within 60 minutes of its application to the stapler.

Ethicon stapler



Covidien stapler



3

REMOVE PLASTIC SHEATH / HOLD CLOSED

Remove the plastic sheath by sliding it straight off in a continuous motion. Wipe off any excess gel from both sides of the foam insert. Leave the stapler locked on the foam insert until ready to use.

PERI-STRIPS DRY with VERITAS Collagen Matrix can be used immediately or allowed to remain between the jaws of the stapler loading unit until surgery. For optimal results, PERI-STRIPS DRY with VERITAS Collagen Matrix should be used within 60 minutes of its application to the stapler.





Peri-Strips Dry

with Veritas Collagen Matrix
Staple Line Reinforcement

Primary Components

PERI-STRIPS DRY with VERITAS Collagen Matrix is composed of two primary components: the PERI-STRIPS DRY with VERITAS Collagen Matrix plastic loading unit and the PSD Gel.¹ The plastic loading unit contains two strips of dehydrated bovine pericardium secured on each side of a foam spacer by the plastic loading unit. PSD Gel is a hydrogel which creates a temporary bond between the strips and the forks of the stapler and promotes rehydration of the strips.



PERI-STRIPS DRY with
VERITAS Collagen Matrix



PSD Gel Adhesive for
PERI-STRIPS DRY with VERITAS Collagen Matrix

Defining Confidence at the Staple Line: PERI-STRIPS DRY Reinforcement with VERITAS Collagen Matrix



Ordering Information

	Endoscopic Linear Staplers	Size	Cartridge Color	PSDV Standard Order #
ETHICON	ENDOPATH ETS 45 Endoscopic Transecting	45	Gr Wh Bl Gr	PSD4506ETSVCE
	ENDOPATH ETS Flex 45	45	Gr Wh Bl Gr	PSD4506ETSVCE
	ENDOPATH EZ 45	45	Bl Gr	PSD4506EVCE
	ENDOPATH ETS Flex 60	60	Wh Bl Gr	PSD6006ETSVCE
	Echelon 45 ENDOPATH Stapler	45	Gr Wh Bl Gl Gr	PSD4506ECHVCE
	Echelon 60 ENDOPATH Stapler	60	Wh Bl Gl Gr Bl	PSD6006ECHVCE
	Echelon FLEX 45 ENDOPATH	45	Gr Wh Bl Gl Gr	PSD4506ECHVCE
	Echelon FLEX 60 ENDOPATH	60	Wh Bl Gl Gr Bl	PSD6006ECHVCE
COVIDIEN	Endo GIA™ Universal Straight/Rotulator 30	30	Gr Wh Bl	PSD3006UVCE
	MultiFire Endo GIA™ 30	30	Gr Wh Bl	PSD3006UVCE
	Endo GIA™ Reloads with Tri-Staple™ Technology	30	Gr Ta Pu	PSD3006UVCE
	Endo GIA™ Universal Straight 45	45	Gr Wh Bl Gr	PSD4506UVCE
	Endo GIA™ Universal Rotulator 45	45	Wh Bl Gr	PSD4506UVCE
	Endo GIA™ Reloads with Tri-Staple™ Technology	45	Bl Pu	PSD4506UVCE
	Endo GIA™ Universal Straight/ Rotulator 60	60	Wh Bl Gr	PSD6006UVCE
	Endo GIA™ Reloads with Tri-Staple™ Technology	60	Bl Pu	PSD6006UVCE
INTUITIVE	EndoWrist Stapler 30 for da Vinci Xi	30	Gr Wh Bl Gr	PSD3006UVCE
	EndoWrist Stapler 45 for da Vinci Xi	45	Wh Bl Gr	PSD4506ETSVCE
	EndoWrist Stapler 45 for the da Vinci Si	45	Bl Gr	PSD4506ETSVCE
ETHICON	Open Linear Staplers	Size	Cartridge Color	PSDV Standard Order #
	PROXIMATE Linear Cutter 55	55	Wh Bl Gr	PSD5506EVCE
	USSC ILA 52	52		PSD5506EVCE
	PROXIMATE Linear Cutter 75	75	Bl Ye Gr	PSD7506EVCE
	USSC ILA 75	75		PSD7506EVCE
PROXIMATE Linear Cutter 100	100	Bl Gr	PSD10006EVCE	
COVIDIEN	GIA™ DST 60	60	Wh Bl Gr	PSD6006UDSTVCE
	GIA™ DST 80	80	Bl Gr	PSD8006UDSTVCE
	GIA 80	80		PSD8006UVCE
	GIA 90	90		PSD9006UVCE
	PI 90	90		PSD9006PIVCE
	GIA™ DST 100	100	Bl Gr	PSD10006EVCE

Cartridge Color Key

Wh White

Bl Blue

Gl Gold

Gr Green

Bl Black

Ye Yellow

Pu Purple

Gr Gray

Ta Tan

For questions or ordering information: <http://www.baxter.com/contact-us>

Please see Indications and Important Risk Information on the back of this brochure.



Peri-Strips Dry

with Veritas Collagen Matrix
Staple Line Reinforcement

PERI-STRIPS DRY with VERITAS Collagen Matrix and PSD Gel Indications for Use

PERI-STRIPS DRY with VERITAS Collagen Matrix Indications For Use:

PSD-V is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

PSD-V can be used for reinforcement of staple lines during bariatric surgical procedures.

PSD-V can be used for reinforcement of staple lines during gastric, small bowel, colon, and colorectal procedures.

Contraindications:

The use of PSD-V is contraindicated in patients with known sensitivity to bovine material.

Adverse Reactions:

As with any surgical procedure, adverse reactions are possible and include but are not limited to: infection, rejection, erosion, and allergic reaction.

For safe and proper use of this device refer to the complete Instructions for Use.

PSD Gel Indications For Use:

PSD Gel is intended to be used only with Peri-Strips Dry (PSD) as a temporary bonding agent during applications indicated in the PSD Instructions for Use.

Contraindications:

PSD Gel is not designed, sold, or intended for use except as indicated. Use only as a temporary bonding agent with Peri-Strips Dry.

For safe and proper use of this device refer to the complete Instructions for Use.

References:

1. PERI-STRIPS DRY with VERITAS Collagen Matrix Instructions for Use. **2.** Oray BN, Kelly S, Konobeck T, Lambert A, Mooradian DL. Novel propylene oxide-treated bovine pericardium as soft tissue repair material and potential scaffold for tissue engineering. *Surgical Technology International XVIII*. **3.** Data on file. Baxter Healthcare Inc. **4.** Spector D, Perry Z, Konobeck T, Mooradian D, Shikora S. Comparison of hemostatic properties between collagen and synthetic buttress materials used in staple line reinforcement in a swine splenic hemorrhage model. *Surg Endosc*. 2011;25(11):148-152. **5.** Data on file. SI-0107. Synovis Surgical Innovations. **6.** D'Ugo S, Gentileschi P, Benavoli D, et al. Comparative use of different techniques for leak and bleeding prevention during laparoscopic sleeve gastrectomy: a multicenter study. *Surg Obes Relat Dis*. 2013 Nov 12. [Epub ahead of print] **7.** Stamou KM, Menenakos E, Dardamanis D, et al. Prospective comparative study of the efficacy of staple line reinforcement in laparoscopic sleeve gastrectomy. *Surg Endosc*. 2011;25(11):3526-3530. **8.** Shikora SA, Kim JJ, Tarnoff ME. Comparison of permanent and nonpermanent staple line buttressing materials for linear gastric staple lines during laparoscopic Roux-en-Y gastric bypass. *Surg Obes Relat Dis*. 2008;4(6):729-734. **9.** Deeken C, Melman L, Jenkins E, Greco S, Frisella M; Matthews B; Histologic and biomechanical evaluation of crosslinked and non-crosslinked biologic meshes in a porcine model of ventral incisional hernia repair. *J Am Coll Surg*. 2011;212(5):880-888. **10.** Shikora SA, Mahoney CB. Clinical benefit of gastric staple line reinforcement (SLR) in gastrointestinal surgery: a meta-analysis. *Obes Surg*. 2015; 25:1133-1141. **11.** Data on file. AS-0012R. Synovis Surgical Innovations. **12.** Gaertner WB, Hagerman GF, Potter MJ, Karulf RE. Experimental evaluation of a bovine pericardium-derived collagen matrix buttress in ileocolic and colon anastomoses. *J Biomed Mater Res B Appl Biomater*. 2010;92(1):48-54. **13.** Data on file. Synovis Surgical Innovations. **14.** Gore Medical. Instructions For Use For: GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement. Mar. 2008. **15.** Melman L, Jenkins E, Hamilton NA, et al. Early biocompatibility of crosslinked and non-crosslinked biologic meshes in a porcine model of ventral hernia repair. *Hernia*. 2011;15(2):157-164. **16.** Hsu A, Mustoe TA. The principles of wound healing. Elsevier website. Available at: <http://www.elsevieradvantage.com/samplechapters/9780323034708/9780323034708.pdf>. Accessed May 22, 2015. **17.** Data on file. AS-0004R. Synovis Surgical Innovations.

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