# Reinforce with Confidence



PERFORMANCE through innovation





### Reduces Leaks.

#### Most clinical data literature supporting leak reduction<sup>1</sup>

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement has the most published clinical literature supporting the reduction in leaks in a variety of minimally invasive surgeries, as highlighted below.

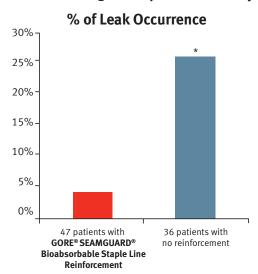
### Meta-analysis of leak following sleeve gastrectomy<sup>2</sup>

#### % of Leak Occurrence 3.5 3. 2.5 2 1.5 1 0.5 593 patients 83 patients 205 patients 892 patients with Bovine with GORE® without **SEAMGUARD®** Pericardium Reinforcement Bioabsorbable Staple Line Reinforcement

<sup>2</sup>GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement significantly reduced leaks compared to no reinforcement, \*p=0.005

"The use of an Absorbable buttress material during performance of a sleeve gastrectomy reduces the incidence of postoperative leaks by 3 fold." Gagner<sup>2</sup>

### Use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to prevent pancreatic leak following distal pancreatectomy<sup>3</sup>



GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement significantly reduced leaks compared to no reinforcement, \*p=0.01

"The use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is quickly becoming a common adjunct in distal pancreas resections.

Our study shows a lower incidence of pancreatic leak after distal pancreatectomy with the use of this staple line reinforcing product." Imagawa<sup>3</sup>

### Reduces Bleeding.

#### Most clinical data literature supporting bleeding reduction<sup>1</sup>

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement has the most published clinical literature supporting a significant reduction in bleeding in a variety of minimally invasive procedures. Among these clinical papers are the following three randomized studies:

- Miller et al.4 showed significantly reduced bleeding in gastric bypass procedures (p<0.05)\*
  - Lower mean blood loss
  - Fewer staple line bleeding sites
  - Less time to staple line hemostasis
- Nguyen et al.<sup>5</sup> showed significantly reduced bleeding in gastric bypass procedures (p<0.05)\*
  - Less clips used
  - Higher post-op hemoglobin
- Consten et al.<sup>6</sup> showed significantly reduced bleeding in sleeve gastrectomies (p<0.05)\*</li>
  - Lower mean blood loss

No hemorrhages, transfusions or reoperations when GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement was used in any of the studies above.

\*When comparing the use of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement and no reinforcement

"These early results may show that [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] reduces staple-line hemorrhage and leakage. This may have contributed to shorter hospital stay, decreased costs and lower morbidity after laparoscopic bariatric surgery." Consten et al<sup>6</sup>

## Safe and Reliable.

#### Strength over time

- Provides strength to the staple line during the critical healing process
- Reinforcement material bioabsorption process should be complete by six to seven months
- 1:1 tissue replacement

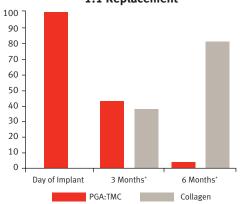
#### Strong, yet thin

- 0.4 mm total nominal thickness (max of 0.5 mm)
- Consistent and uniform with minimal staple line interference
- The open, highly interconnected 3D pore structure facilitates cell infiltration and growth

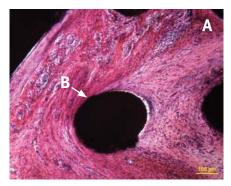
#### **─** 100% bioabsorbable

 Reinforcement constructed from Polyglycolic acid:Trimethylene carbonate (PGA:TMC)

#### Volume of Material = Volume of Tissue: 1:1 Replacement<sup>7</sup>



\*Cells & Blood Vessels Make Up Remaining Volume



GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement in a staple line at six months [10x, A-Native Tissue, B-Staple]. The bioabsorbable material is surrounded and infiltrated by a bland fibrovascular tissue with no signs of inflammation, making it safe and compatible with host tissue. Over approximately six to seven months, the material is absorbed by the body.

## A Legacy of Performance.

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is a bioabsorbable staple line reinforcement material specifically engineered to reduce the incidence of perioperative leaks and bleeding in a variety of open and minimally invasive surgeries.\*

Gore performance. Backed by experience. Supported by successful patient outcomes. Reinforced over the years by numbers. And further proof of why we say with pride, "Material really does matter."

The proven legacy of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement includes:

More than 1,000,000 devices implanted



- More than 10 years of performance
- More than 50 papers documenting the successful use of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement in bariatric, colorectal, thoracic and other procedures¹



#### References

- W. L. Gore & Associates, Inc. Clinical Performance with Staple Line Reinforcement. Scientific Literature Analysis (n = 4689 patients). Flagstaff, AZ:
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- Yamamoto M, Hayashi MS, Nguyen NT, Nguyen TD, McCloud S, Imagawa DK. Use of Seamguard to prevent pancreatic leak following distal pancreatectomy. Archives of Surgery 2009;144(10):894-899.
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- Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE. Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial. Archives of Surgery 2005;140(8):773-778.
- Consten, ECJ, Gagner M, Pomp A, Inabnet WB. Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane. *Obesity Surgery* 2004;14(10):1360-1366.
- Morales-Conde S, Flores M, Fernández V, Morales-Méndez S. Bioabsorbable vs polypropylene plug for the 'Mesh and Plug' inguinal hernia repair. Poster presented at the 9th Annual Meeting of the American Hernia Society; February 9-12, 2005; San Diego, CA.



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#### Configured For Endoscopic Staplers

ENDOPATH® ETS 45 Endoscopic Transecting White, Blue, Green ENDOPATH® ETS 45 Endoscopic Transecting White, Blue, Green ENDOPATH® ETS Flex 45 ENDOPATH® ETS Flex 45 ENDOPATH® ETS Flex 45 ENDOPATH® ETS Flex 60 Echelon 45 ENDOPATH® Stapler Echelon 60 ENDOPATH® Stapler Echelon 60 ENDOPATH® Stapler Echelon 60 ENDOPATH® Stapler Echelon FLEX 60 ENDOPATH® Stapler White, Blue, Gold, Green Echelon FLEX 60 ENDOPATH® Stapler Echelon FLEX 60 ENDOPATH® Stapler Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green BSGEC60 / 12BSGEC60* Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green BSGEC60A / 12BSGEC60A* Endo GIA™ Universal Straight 45 White, Blue BSGUSS45B / 12BSGUSS45B
ENDOPATH® ETS Flex 45  ENDOPATH® EZ 45  ENDOPATH® EZ 45  ENDOPATH® EZ 45  ENDOPATH® ETS Flex 60  Echelon 45 ENDOPATH® Stapler  Echelon 60 ENDOPATH® Stapler  Echelon 61 ENDOPATH® Stapler  Echelon 62 ENDOPATH® Stapler  Echelon 64 ENDOPATH® Stapler  Echelon 65 ENDOPATH® Stapler  Echelon 66 ENDOPATH® White, Blue, Gold, Green  Echelon 67 ESGEC60 / 12BSGEC60*  Echelon 68 ENDOPATH® White, Blue, Gold, Green  Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green  Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green
Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green 1BSGEC60A / 12BSGEC60A*
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Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green 1BSGEC60A / 12BSGEC60A*
Echelon FLEX 60 ENDOPATH® White, Blue, Gold, Green 1BSGEC60A / 12BSGEC60A*
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Endo GIA™ Universal Roticulator 45 White, Blue 1BSGUSS45B / 12BSGUSS45
Endo GIA™ Universal Straight 45 Green 1BSGUSS45G / 12BSGUSS45
Endo GIA™ Universal Roticulator 45 Green 1BSGUSS45G / 12BSGUSS45
Endo GIA™ Universal Straight 60 White, Blue 1BSGUSS60B / 12BSGUSS60
Endo GIA™ Universal Roticulator 60 White, Blue 1BSGUSS60B / 12BSGUSS60
Endo GIA™ Universal Straight 60 Green 1BSGUSS60G / 12BSGUSS60
Endo GIA™ Universal Straight 60 White, Blue 1BSGUSS60B / 12BSGUSS60B /
Š Configured specifically for the Covidien Endo GIA™ Reloads with Tri-Staple™ Technology
Endo GIA™ Ultra Universal Staplers Purple 1BSGTRI45P / 12BSGTRI45P
Endo GIA™ Ultra Universal Staplers Purple 1BSGTRI60P / 12BSGTRI60P
Endo GIA™ Ultra Universal Staplers Black 1BSGTRI45B / 12BSGTRI45B
Endo GIA™ Ultra Universal Staplers Black 1BSGTRI60B / 12BSGTRI60B

<sup>\*</sup> Twelve packages per box

#### Configured For Open Staplers

	STAPLING DEVICE	CATALOGUE NUMBER
Ethicon Endo-Surgery	PROXIMATE® Linear Cutter 55 (Staplers: TLC55, TCT55; Reloads: TCR55, TRT55)	10BSGPROX55
	PROXIMATE® Linear Cutter 75 (Staplers: TLC75, TCT75, TCD75; Reloads: TCR75, TRT75, TRD75)	10BSGPROX75
	PROXIMATE® Linear Cutter 100 (Staplers: TLC10, TCT10; Reloads: TCR10, TRT10)	10BSGPROX100
Covidien Autosuture	GIA <sup>™</sup> DST 60 (Stapler: GIA6038S; Reload: GIA6038L) (Stapler: GIA6048S; Reload: GIA6048L)	10BSGDST60
	GIA™ DST 80 (Stapler: GIA8038S; Reload: GIA8038L) (Stapler: GIA8048S; Reload: GIA8048L)	10BSGDST80
	GIA™ DST 100 (Stapler: GIA10038S; Reload: GIA10038L) (Stapler: GIA10048S; Reload: GIA10048L)	10BSGDST100

#### Configured For Circular Staplers

	STAPLING DEVICE	CATALOGUE NUMBER
Ethicon Endo-Surgery	ENDOPATH® 25 and Proximate 25 (Staplers: ECS25, CDH25, SDH25)	1BSGC25
	ENDOPATH® 29 and Proximate 29 (Staplers: ECS29, CDH29, SDH29)	1BSGC2829
	ENDOPATH® 33 and Proximate 33 (Staplers: ECS33, CDH33, SDH33)	1BSGC3334
e	CEEA 25 (Staplers: 110214L, 111985)	1BSGC25
	CEEA 28 (Staplers: 110238L, 111987)	1BSGC2829
	CEEA 31 (Staplers: 110276L, 111989)	1BSGC31
sutur	CEEA 34 (Stapler: 111981)	1BSGC3334
Covidien Autosuture	DST Series™ CEEA 25 (Staplers: EEA25, EEAXL25, EEA2535, EEAXL2535, EEAORVIL25)	1BSGC25
Covid	DST Series™ CEEA 28 (Staplers: EEA28, EEAXL28, EEA2835, EEAXL2835)	1BSGC2829
	DST Series™ CEEA 31 (Staplers: EEA31, EEAXL31)	1BSGC31
	DST Series™ CEEA 34 (Staplers: EEA34, EEAXL34)	1BSGC3334