

— *Clinical Performance with
Staple Line Reinforcement*

Scientific Literature Analysis
(n = 4689 patients)



PERFORMANCE
through innovation

Clinical Performance of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

Pooled Data from Studies included in this Scientific Literature Analysis		With GORE® SEAMGUARD® Product	Without GORE® SEAMGUARD® Product
Gastric Bypass Procedures (n=2593 patients with GORE® SEAMGUARD® Product)	Leak rate	0 – 0.7%	Up to 1.9% Up to 5.3% w/ competitive product
	Bleeding rate	0 – 0.75%	Up to 8.0%
	Fistula formation	0	Up to 12.5%
	Stricture rate	0% to 2.5%	Up to 10%
	Internal hernia rate	0 – 0.8%	Up to 2.9%
	Erosions	0	Up to 4% with competitive product
Sleeve Gastrectomy Procedures (n=1324 patients with GORE® SEAMGUARD® Product)	Leak rate	0 – 1.92%	Up to 5.88%
Colorectal Procedures (n=295 patients with GORE® SEAMGUARD® Product)	Leak rate	0 – 3.4% (including high risk anastomosis)	Up to 2.2%
	Bleeding rate	0	Up to 9.1%
	Stricture rate	0	
Solid Organ Resection (n=217 patients with GORE® SEAMGUARD® Product)	Leak rate	0 – 4%	Up to 57%
	Fistula formation	0	Up to 31%
Thoracic Procedures (n=260 patients with GORE® SEAMGUARD® Product)	Leaks – requiring reoperation	0	Up to 3.4% with competitive product

(n = 4689)

Refer to *Instructions For Use* for a complete description of all warnings, precautions, and contraindications. Products listed may not be available in all markets.

Data presented is pooled from various sources. No further data analysis has been done.

Clinical Performance of Staple Line Reinforcement

Ninh T. Nguyen, MD

From the Department of Surgery, Division of Gastrointestinal Surgery, University of California Irvine School of Medicine, Irvine, CA.

Introduction

The minimally invasive approach for thoracic and abdominal surgery has gained tremendous popularity over the past decade. At the current time, the majority of abdominal operations are being performed using laparoscopy, and a large number of thoracic cases are being performed via thoracoscopy. Important technological adjuncts that enable surgeons to perform minimally invasive surgery are linear and circular stapling devices. These stapling devices allow simultaneous stapling and sealing of the tissue, thus giving surgeons the ability to divide and transect a variety of tissues with ease. However, there are two major drawbacks to the stapling technology: the development of staple line bleeding and leaks. These potential complications can lead to significant postoperative morbidity and even mortality.

Currently, bariatric surgery is one of the most frequently performed general surgical operations in the U.S., and Roux-en-Y gastric bypass is the most commonly performed bariatric procedure. Potential life-threatening complications after laparoscopic gastric bypass include postoperative gastrointestinal bleeding and leaks. The incidence of intraabdominal and gastrointestinal bleeding after laparoscopic gastric bypass ranges from as low as 0.8% to as high as 9.4%.¹⁻⁵ The primary cause for gastrointestinal hemorrhage after laparoscopic gastric bypass is bleeding at the staple line. In Roux-en-Y gastric bypass, there are four potential anatomic sites for staple line hemorrhage: the gastrojejunostomy, gastric pouch, jejunojunostomy, and gastric remnant. A variety of intraoperative methods have been attempted to minimize staple line bleeding, including the use of staplers with shorter staple height and oversewing of the staple lines. Stapler load with shorter staple height provides added compression of the transected tissues; however, this must be balanced against the risk for staple malformation and staple line disruption. Oversewing of the staple line can be effective but technically difficult, time consuming, and creates additional tissue disruption.

Mechanisms of Staple Line Bleeding

It is important to understand the mechanisms for staple line bleeding in an effort to determine the best methods to minimize this complication. The sites for staple line bleeding include bleeding at the line of tissue transection or bleeding at the site where the individual staple penetrates the tissue. For example, bleeding during stapling of the gastric pouch in Roux-en-Y gastric bypass can be at the transected gastric pouch edge, which would be manifested as intraoperative staple line bleeding, or bleeding at the site of staple penetration, which would be manifested as intraoperative or postoperative gastrointestinal bleeding.

Staple line Reinforcement

Staple line reinforcement was developed more than a decade ago in an effort to strengthen the integrity of the staple line and minimize bleeding. Staple line reinforcement employs a buttressing material that strengthens the staple line and provides a compressive effect on the staple line, leading to improve hemostasis. The mechanisms for improved hemostasis include protecting the tissue from injury by the individual staple and redistributing the pressure exerted by an individual staple over a wider surface area. By strengthening the staple line, staple line reinforcement material reduces the risk for staple line failure and bleeding while redistribution of pressure on the staple line improves hemostasis over the entire staple line.

The material used for staple line reinforcement is extremely important. Desirable characteristics of a staple line reinforcement material include strength with minimal and consistent thickness, and bioabsorbable properties. Bioabsorbability is an extremely important characteristic as nonabsorbable materials have been shown to cause localized indolent infection and tissue erosion.⁶ The GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is constructed from biocompatible copolymer and offers all of the above characteristics. It strengthens the staple line during the critical healing period and absorbs thereafter yet is thin enough that it adds only minimal thickness (0.5 mm) to the staple line.

Comments

Staple line reinforcement has been applied clinically to minimize intraoperative bleeding, to decrease the occurrence of postoperative air leaks for pulmonary resections, for transection of solid organs, and for all aspects of gastrointestinal surgery to decrease intraoperative bleeding and postoperative gastrointestinal hemorrhage and leaks. The scientific literature provided in this document summarizes the clinical experience with GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement in thoracic, colorectal, pancreatic, and bariatric surgery, and confirms the following findings:

- Pancreatic surgery - reduces postoperative pancreatic stump leak and perioperative bleeding.
- Gastrointestinal surgery – reduces intraoperative staple line bleeding, with a trend toward reduction in gastrointestinal hemorrhage and staple line leaks.
- Thoracic surgery – reduces postoperative pulmonary air leak.

In conclusion, surgeons performing thoracic or gastrointestinal surgery should consider the use of staple line reinforcement material as an adjunct in the prevention of intraoperative staple line bleeding, postoperative bleeding, and leak complications. The GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement has a proven safety record and an abundance of clinical literature supporting its clinical efficacy.

References

1. Mehran A, Szomstein S, Zundel N, Rosenthal R. Management of acute bleeding after laparoscopic Roux-en-Y gastric bypass. *Obesity Surgery* 2003;13(6):842-847.
2. Higa KD, Ho T, Boone KB. Laparoscopic Roux-en-Y gastric bypass: technique and 3-year follow-up. *Journal of Laparoendoscopic & Advanced Surgical Techniques* 2001;11(6):377-382.
3. Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Annals of Surgery* 2000;232(4):515-529.
4. Nguyen NT, Rivers R, Wolfe BM. Early gastrointestinal hemorrhage after laparoscopic gastric bypass. *Obesity Surgery* 2003;13(1):62-65.
5. Luján JA, Frutos MD, Hernández Q, et al. Laparoscopic versus open gastric bypass in the treatment of morbid obesity: a randomized prospective study. *Annals of Surgery* 2004;239(4):433-437.
6. Consten ECJ, Dakin GF, Gagner M. Intraluminal migration of bovine pericardial strips used to reinforce the gastric staple-line in laparoscopic bariatric surgery. *Obesity Surgery* 2004;14(4):549-554.

Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial.

Miller KA, Pump A.¹

24 patients with GORE® SEAMGUARD® Product	24 patients with no SLR	Significance
No leaks	1 intraoperative leak	
Fewer clips used (mean of 2)	Higher clips used (mean of 22)	*p<0.0001
Higher post-op hemoglobin (12.47 ± 1.7 mg/dL)	Lower post-op hemoglobin (11.1 ± 1.9 mg/dL)	*p<0.05
No fistulas	12.5% developed fistulas	p=0.2

Excerpts from Conclusions

“Intraoperative staple line bleeding was significantly reduced in our study group, as demonstrated by the significantly lower use of clip instruments in group 1 versus group 2.”

“The avoidance of a single severe complication would make its [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] use worth it.”

Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial.

Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE.²

17 patients with GORE® SEAMGUARD® Product	17 patients with no SLR	Significance
Lower mean blood loss (84 ± 50ml)	Higher mean blood loss (129 ± 63 ml)	*p<0.01
Fewer staple line bleeding sites (mean: 0 - 0.4)	Higher staple line bleeding sites (mean: 0.6 - 2.5)	*p<0.01
Less time to staple line hemostasis (mean: 1.2 min)	Greater time to staple line hemostasis (mean: 10.1 min)	*p<0.01
No transfusions	1 transfusion and reoperation	

Excerpts from Conclusions

“The use of glycolide copolymer staple-line reinforcement sleeves in patients undergoing laparoscopic gastric bypass is safe and significantly reduces staple-line bleeding sites and may reduce the incidence of gastrointestinal hemorrhage.”

Comparison of buttressing material in Roux-en-Y gastric bypass.

Žomerlel TA, Brown A, Bajric J, Kemmeter PR.³

142 patients with GORE® SEAMGUARD® Product	228 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No leaks	5.3% leak rate	p<0.05

Excerpts from Conclusions

“Despite the EBSG [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] group having a higher rate of comorbidities, the leak rate was lower compared to the PSDV [with SYNOVIS® PERI-STRIPS DRY® Product] group”

Bioabsorbable staple line reinforcement diminishes bleeding after laparoscopic Roux-en-Y gastric bypass

Onopchenko A.⁴

133 patients with GORE® SEAMGUARD® Product	127 patients with no SLR	Significance
0.75%	8.0% bleeding rate	*p=0.02

Excerpts from Conclusions

“Bioabsorbable staple line reinforcement significantly decreases clinical significant bleeding after gastric bypass.”

Retrospective review of laparoscopic Roux-en-Y gastric bypass technique using combination linear cutting stapler and hand-sewn gastrojejunal anastomosis with bioabsorbable staple line reinforcement.

Jackson KD, Price JM.⁵

402 patients with GORE® SEAMGUARD® Product
4 total leaks (0.99%), 1 leak from the pouch (0.2%), and 3 from gastro-jejunal anastomosis (0.7%)

Excerpts from Conclusions

“The use of linear-cutting with bioabsorbable SLR [staple line reinforcement], along with the double-layer closure of the common enterostomy is a safe and effective technique for gastric bypass.”

“This series demonstrates a significantly low rate of post-op leak, hemorrhage, and stricture formation, compared with other techniques described in the bariatric literature.”

Early experience with intraluminal reinforcement of stapled gastrojejunostomy during laparoscopic Roux-en-Y gastric bypass.

Saber AA, Scharf KR, Turk AZ, Elgamal MH, Martinez RL.⁶

40 patients with GORE® SEAMGUARD® Product	40 patients with no SLR	Significance
No bleeding	15% intraoperative bleeding rate	*p=0.0255
2.5% stricture rate	10% stricture rate	p=0.2007

Excerpts from Conclusions

“The use of intraluminal bioabsorbable glycolide copolymer staple-line reinforcement significantly reduces the incidence of gastrojejunal bleeding.”

Bioabsorbable glycolide copolymer staple-line reinforcement decreases internal hernia rate after laparoscopic Roux-en-Y gastric bypass.

Ahmed AR, Rickards G, Husain S, Johnson J, O'Malley W, Boss T.⁷

354 patients with GORE® SEAMGUARD® Product	1350 patients with suture only	Significance
0.8% internal hernia rate	2.9% internal hernia rate	*p=0.01

Excerpts from Conclusions

“In our opinion, SLR (staple line reinforcement) can therefore be used in LRYGBP procedures not only with the objective of decreasing gastrointestinal bleeding but also with the aim of reducing the postoperative IH (internal hernias) rate.”

Use of SEAMGUARD [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in laparoscopic gastric bypass to decrease postsurgical bleeding.

Rodríguez Velasco G, Mendía Conde E, Peromingo Fresneda R, et al.⁸

80 patients with GORE® SEAMGUARD® Product	45 patients with no SLR
No bleeding	6.7% bleeding rate

Excerpts from Conclusions

“Since we started using [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], we have no complications in relation to stomach section bleeding.”

Bioabsorbable staple line reinforcement for laparoscopic gastrointestinal surgery.

Nguyen NT, Longoria M, Chalifoux S, Wilson SE.⁹

22 patients with GORE® SEAMGUARD® Product undergoing Roux-en-Y gastric bypass

No leaks, intra-abdominal abscesses, or hemorrhages

Excerpts from Conclusions

“This study demonstrates that bioabsorbable glycolide copolymer staple line sleeves is safe and effective in prevention of intraoperative staple line bleeding and postoperative GI hemorrhage in 44 intra-abdominal GI operations (22 Roux-en-Y procedures).”

Internal hernias after laparoscopic Roux-en-Y gastric bypass are prevented with Bioabsorbable SEAMGUARD® Material.

Allemang MT, Renton DB, Narula VK, et al.¹⁰

417 patients with GORE® SEAMGUARD® Product

No internal hernias

Excerpts from Conclusions

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be a possible way to prevent retro Roux hernias in patients undergoing laparoscopic Roux-en-Y gastric bypass.”

Clinical results using bioabsorbable staple line reinforcement for circular staplers.

Jones WB, Myers KM, Traxler LB, Bour ES.¹¹

138 patients with GORE® SEAMGUARD® Product	255 patients with no SLR	Significance
0.7% bleeding rate	1.1% bleeding rate	p=0.64
0.7% leak rate	1.9% leak rate	p=0.34
0.7% stricture rate	9.3% stricture rate	*p=0.0005

Excerpts from Conclusions

“Our results indicate that the use of circular staple line reinforcement at the gastrojejunal anastomosis in patients undergoing laparoscopic gastric bypass significantly decreases the incidence of anastomotic stricture and a composite end point of all anastomotic complications. On this basis, strong consideration should be given to the routine use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in patients undergoing laparoscopic divided gastric bypass with a circular stapled gastrojejunal anastomosis.”

Reduction in anastomotic strictures using bioabsorbable circular staple line reinforcement in laparoscopic gastric bypass.

Traxler LB, Scott JD, Cobb WIV, Carbonell A, Bour ES.¹²

596 patients with GORE® SEAMGUARD® Product	255 patients with no SLR	Significance
0.67% stricture rate	9.41% stricture rate	*p<0.0005

Excerpts from Conclusions

“Use of staple line reinforcement reduced the stricture rate by 92.9%.”

“The results here show that use of bioabsorbable circular staple line reinforcement on gastrojejunal anastomoses in laparoscopic RYGB significantly reduces the incidence of anastomotic stricture. Standard use of the bioabsorbable reinforcement on circular staple line anastomoses could be part of the solution to the most common complication in laparoscopic gastric bypass.”

Foreign material erosion after laparoscopic Roux-en-Y gastric bypass: findings and treatment.

Yu S, Jastrow K, Clapp B, et al.¹³

228 patients with GORE® SEAMGUARD® Product	153 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No erosions	6 erosions (4%)	p=0.003

Excerpts from Conclusions

“Non absorbable Peri Strips resulted in erosion.”

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is preferable because it does not erode.”

Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane.

Consten, ECJ, Gagner M, Pomp A, Inabnet WB.¹⁴

10 patients with GORE® SEAMGUARD® Product	10 patients with no SLR	Significance
No leaks		
Lower mean blood loss (120 ± 15 mL)	Higher mean blood loss (210 ± 20 mL)	*p<0.05
	2 had staple-line hemorrhages (10%)	
	1 had a subphrenic abscess (5%)	

Excerpts from Conclusions

“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.”

Strategic laparoscopic surgery for improved cosmesis in general and bariatric surgery: analysis of initial 127 cases

Nguyen NT, Smith BR, Reavis KM, Nguyen XM, Nguyen B, Stamos MJ.¹⁵

50 patients with GORE® SEAMGUARD® Product (26 were SLIC ‘strategic laparoscopic surgery for improved cosmesis’ patients)
No leaks
No other complications reported

The routine use of Seamguard® [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to reinforce the staple line during laparoscopic sleeve gastrectomy – a retrospective analysis of a large patient population.

Durmush E, Atik A, Ermerak G.¹⁶

170 patients with GORE® SEAMGUARD® Product	186 patients with suture
No leaks	1.6% leak rate
No other complications	

Excerpts from Conclusions

“It has been the experience of this centre that the addition of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in 170 patients has resulted in nil leaks or patient mortality.”

Robot-assisted sleeve gastrectomy for super-morbidly obese patients.

Ayloo S, Buchs NC, Addeo P, Bianco FM, Giulianotti PC.¹⁷

69 patients with GORE® SEAMGUARD® Product

No leaks

No other complications reported

Laparoscopic sleeve gastrectomy is a safe and effective bariatric procedure for the lower BMI (35.0–43.0 kg/m²) population.

Gluck B, Movitz B, Jansma S, Gluck J, Laskowski K.¹⁸

204 patients with GORE® SEAMGUARD® Product

No leaks

Single incision laparoscopic sleeve gastrectomy (SILS): a novel technique.

Saber AA, Elgamal MH, Itawi EA, Rao AJ.¹⁹

7 patients with GORE® SEAMGUARD® Product

No leaks

1% bleeding rate

Early experience with laparoscopic sleeve gastrectomy as a single-stage bariatric procedure.

Lewis CE, Dhanasopon A, Dutson EP, Mehran A.²⁰

42 patients with GORE® SEAMGUARD® Product

No leaks

How I do it. Laparoscopic sleeve gastrectomy for morbid obesity.

Moy J, Pomp A, Dakin G, Parikh M, Gagner M.²¹

135 patients with GORE® SEAMGUARD® Product

1.5% leak rate

Excerpts from Conclusions

“We believe that use of suture line buttressing material reduces the risk of perioperative bleeding and may reduce the risk of staple line failures resulting in leak.”

Laparoscopic vertical sleeve gastrectomy: efficacy of using Bioabsorbable SEAMGUARD [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement].

Chiasson PM, Burpee SE.²²

46 patients with GORE® SEAMGUARD® Product	46 patients with no SLR	Significance
No leaks		
No staple line oozing	13% had staple line oozing (had to oversee)	*p<0.05
No complications	2 patients required blood transfusion therapy	

Excerpts from Conclusions

“The safety and efficacy of the laparoscopic vertical sleeve gastrectomy is enhanced with the use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement].”

“Our study suggests that GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is effective in decreasing bleeding complications related to the long staple line associated with the LVSG.”

Evaluation of the sleeve gastrectomy as a single-stage treatment of morbid obesity.

Topart PA, Chazelet C, Verhaeghe P.²³

49 patients with GORE® SEAMGUARD® Product	183 patients with no SLR	214 patients with suture
No leaks	4.5% leak rate	3.3% leak rate
No other complications reported		

Comparison of staple-line leakage and hemorrhage in patients undergoing laparoscopic sleeve gastrectomy with or without the use of Bioabsorbable Seamguard® [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement].

Simon TE, Scott JA, Brockmeyer JR, Husain FA, Frizzi JD, Choi YU.²⁴

52 patients with GORE® SEAMGUARD® Product	68 patients with no SLR
1.92% leak rate	5.88% leak rate
No other complications	

Laparoscopic single-port sleeve gastrectomy for morbid obesity: preliminary series.

*Gentileschi P, Camperchioli I, Benavoli D, De Lorenzo N, Sica G, Gaspari AL.*²⁵

8 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Single-incision transumbilical laparoscopic sleeve gastrectomy.

*Saber AA, El-Ghazaly TH, Eliam A.*²⁶

6 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Laparoscopic sleeve gastrectomy: an Indian experience – Surgical technique and early results.

*Chowbey PK, Dhawan K, Khullar R, et al.*²⁷

~75 patients with GORE® SEAMGUARD® Product

No leaks

Excerpts from Conclusions

“Four patients required blood transfusion in the postoperative period for intraluminal bleeding manifested by melena and a fall hematocrit. We have thereafter used [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to reinforce the staple line. There has since been no evidence of staple-line bleed.”

Initial experience with robotic sleeve gastrectomy for morbid obesity.

*Diamantis T, Alexandrou A, Nikiteas N, Giannopoulos A, Papalambros E.*²⁸

19 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Gastroscoically controlled laparoscopic sleeve gastrectomy.

Köckerling F, Schug-Paß C.²⁹

38 patients with GORE® SEAMGUARD® Product

No leaks

Excerpts from Conclusions

“Thanks to the standardisation of this procedure using staple line reinforcement and intraoperative gastroscopic control, the complication rate can be reduced and the successful outcome of this stand-alone, weight-reduction operation can be optimized.”

“Staple line reinforcement with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] appears to reduce the risk for bleeding.”

Changes in lipid profiles in morbidly obese patients after laparoscopic sleeve gastrectomy (LSG).

Zhang F, Strain GW, Lei W, Dakin GF, Gagner M, Pomp A.³⁰

45 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Laparoscopic sleeve gastrectomy for morbid obesity with intra-operative endoscopic guidance. Immediate peri-operative and 1-year results after 25 patients.

Diamantis T, Alexandrou A, Pikoulis E, et al.³¹

25 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Excerpts from Conclusions

“Concerning the measures to reduce the bleeding rate or the chance for a post-operative leakage from the staple line, we regularly use the [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] material, which has been shown to provide effective protection against these fearful complications.”

“Having used this material as of today for all our LSGs and for all of our last LRYGBPs, we have encountered no post-operative bleeding. Last but not least, the post-operative leakage rates from the staple line, which is by far the most fearful complication after LSG, was also zero.”

Laparoscopic sleeve gastrectomy: a retrospective review of 1- and 2-year results.

Jacobs M, Bisland W, Gomez E, et al.³²

157 patients with GORE® SEAMGUARD® Product

1.27% leak rate

No post-operative bleeding reported

Laparoscopic sleeve gastrectomy for morbid obesity using a staple line reinforcement material.

Ramon J, Puig S, Pera M, et al.³³

17 patients with GORE® SEAMGUARD® Product

No leaks

No other complications

Excerpts from Conclusions

“The absence of hemorrhagic complications in this series may be related to the use of a staple-line reinforcement.”

Laparoscopic sleeve gastrectomy: our first 100 patients.

Nath A, Leblanc KA, Hausmann MG, Kleinpeter K, Allain BW, Romero R.³⁴

100 patients with GORE® SEAMGUARD® Product

1% leak rate

Safety and efficacy of the use of bioabsorbable Seamguard [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in colorectal surgery at the Texas Endosurgery Institute.

Franklin ME II, Berghoff KE, Arellano PP, Trevino JM, Abrego-Medina D.³⁵

30 patients with GORE® SEAMGUARD® Product

No leaks, bleeding, or strictures

Excerpts from Conclusions

“It has been used in obesity surgery and pulmonary surgery as staple line reinforcement with good results. As such, we believe that [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be ideal to use in colorectal surgery as an aid during the healing process of an anastomosis and may help prevent anastomotic bleeding and staple line disruption.”

“There were no clinical leaks, no strictures, and no bleeding in our early postoperative follow-up period. The use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] as a staple line reinforcer appears to be safe and may be useful in preventing anastomotic leakage, bleeding, and intraluminal stenosis.”

Surgical outcomes after colonic and colon rectal anastomosis with and without using buttressing material Seamguard® (Gore) [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement]: a retrospective study of 301 cases by a single surgeon.

Ramanujam PS, Ramanujam KP, Griffin KM.³⁶

69 patients with GORE® SEAMGUARD® Product	232 patients with no staple line reinforcement	Significance
No leaks	2.2% leak rate	p=0.27
No post-operative bleeding	9.1% bleeding rate	*p=0.0026

Excerpts from Conclusions

“Our study showed very favorable results from using [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] for colorectal anastomosis. There were not any leaks when [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] was used and the hemostasis was excellent.”

Bioabsorbable staple-line reinforcement to reduce staple-line bleeding in the transection of mesenteric vessels during laparoscopic colorectal resection: a pilot study.

de la Portilla F, Zbar AP, Rada R, et al.³⁷

25 patients with GORE® SEAMGUARD® Product

No bleeding or other complications during the surgical procedure

Excerpts from Conclusions

“Cost of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be offset by avoiding extra time to oversee bleeding sites and the possible cost of treating intraabdominal hemorrhage that may include blood transfusion and prolongation of hospital stay.”

Laparoscopic colorectal surgery and the use of staple line reinforcement materials.

Franklin ME, Glass JL, Trevino JM, Arellano PP, Abrego-Medina D.³⁸

29 patients with GORE® SEAMGUARD® Product

No leaks, bleeding, strictures, or other complications

Excerpts from Conclusions

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] appears to aide in preventing leaks, bleeding and may result in a more widely patent anastomosis [in laparoscopic colorectal surgery].”

Clinical results using bioabsorbable staple-line reinforcement for circular stapler in colorectal surgery: a multicenter study

Portillo G, Franklin ME II.³⁹

117 patients with Circular GORE® SEAMGUARD® Product

3.4% leak rate, however they all occurred in very low resections (6 cm or less)

Excerpts from Conclusions

“The use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in colorectal open and laparoscopic surgery may result in a lower incidence of anastomotic leakage.”

“This showed that [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] material is safe and may reduce the rate of postoperative anastomotic leakage, especially in challenging cases.”

“The overall clinical leak rate of 3.4% was similar to previously reported rates for all colon anastomoses, but it was markedly lower than the rates of about 6%–12% or higher usually associated with low resections.”

The use of bioabsorbable staple line reinforcement for circular stapler (BSGC Seamguard [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement]) in colorectal surgery.

Franklin JR, Portillo G, Glass JL, Gonzalez J II.⁴⁰

20 patients with Circular GORE® SEAMGUARD® Product

No leaks, bleeding, or anastomotic stenosis

Excerpts from Conclusions

“The initial data is very promising and has encouraged us to continue using this device [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] on further patients.”

The use of bioabsorbable staple line reinforcement for circular stapler (BSG SEAMGUARD [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement]) in colorectal surgery.

Franklin ME II, Ramila GP, Treviño JM, et al.⁴¹

5 patients with Circular GORE® SEAMGUARD® Product

No leaks, bleeding, or anastomotic stenosis

Excerpts from Conclusions

“Several authors agree the use of [GORE® SEAMGUARD® Reinforcement] seems to be safe and may be useful in preventing anastomotic leakage, bleeding, and potentially intraluminal stenosis.”

“The inflammatory response was felt to be significantly less than that normally seen at this postoperative phase.”

Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy.

Jimenez RE, Mavanur A, Macaulay WP.⁴²

13 patients with GORE® SEAMGUARD® Product	18 patients with no SLR	Significance
No leaks	39% leak rate	*p=0.025

Excerpts from Conclusions

“We conclude that staple line reinforcement is a simple and effective method of reducing pancreatic stump leakage after distal pancreatectomy.”

“We believe that the standard individual staples by themselves can “cut” through the pancreatic tissue without effectively achieving any compression or seal. The reinforcement acts as a scaffold for the individual staples, preventing them from cutting through the tissues and allowing even tension distribution along the closure line.”

Staple line reinforcement with bioabsorbable mesh reduces leak rate following distal pancreatectomy.

Thaker RI, Matthews BD, Linehan DL, Strasberg SM, Eagon JC, Hawkins WG.⁴³

16 patients with GORE® SEAMGUARD® Product	19 patients with no SLR	Significance
No leaks	26% leak rate	*p=0.03

Excerpts from Conclusions

“Bioabsorbable mesh reinforcement of the staple line lowered our pancreatic leak rate and was not associated with increased complications.”

Laparoscopic distal pancreatectomy. A retrospective review of 14 cases.

Pugliese R, Maggioni D, Sansonna F, et al.⁴⁴

7 patients with GORE® SEAMGUARD® Product	7 patients with no SLR	Significance
No leaks at 30 days post-op	57% leak rate	*p=0.0349

Excerpts from Conclusions

“It should be emphasized that after introducing reinforcement of the staple line with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in this study, no leak has been observed within 30 days from surgery.”

Absorbable mesh reinforcement of a stapled pancreatic transection line reduces the leak rate with distal pancreatectomy.

Thaker RI, Matthews BD, Linehan DC, Strasberg SM, Eagon JC, Hawkins WG.⁴⁵

29 patients with GORE® SEAMGUARD® Product	11 patients with no SLR	Significance
3.5% leak rate	36% leak rate	*p=0.005

Excerpts from Conclusions

“Mesh reinforcement of the stapled pancreatic transection line reduced the pancreatic leak rate after distal pancreatectomy.”

“We conclude that incorporation of mesh into the stapled transection line is safe and holds considerable promise as a method to reduce the pancreatic leak rate after open and laparoscopic distal pancreatectomy”

Totally laparoscopic Roux-en-Y duct-to-mucosa pancreaticojejunostomy after middle pancreatectomy.

Rotellar F, Pardo F, Montiel C, et al.⁴⁶

7 patients with GORE® SEAMGUARD® Product	2 patients with no SLR
No leaks or fistulas	2 fistulas

Excerpts from Conclusions

“Buttressing the staple line with absorbable material seems to be effective in preventing pancreatic fistula after distal pancreatectomy when compared with standard stapling alone.”

Use of Seamguard [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to prevent pancreatic leak following distal pancreatectomy.

Yamamoto M, Hayashi MS, Nguyen NT, Nguyen TD, McCloud S, Imagawa DK.⁴⁷

47 patients with GORE® SEAMGUARD® Product	38 patients with no SLR	Significance
4% leak rate	26% leak rate	*p=0.01

Excerpts from Conclusions

“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.”

Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy.

Mavanur A, Takata M, Macaulay WP, Orlando R III, Piorkowski RJ, Jimenez RE.⁴⁸

10 patients with GORE® SEAMGUARD® Product	18 patients with no SLR	Significance
No leaks	33% leak rate	p=0.062

Excerpts from Conclusions

“Staple line reinforcement is a simple and effective method of reducing pancreatic stump leakage after distal pancreatectomy. The economic impact of lower leak rates is reflected in significantly shorter hospital stays.”

Laparoscopic distal pancreatectomy results on a consecutive series of 58 patients.

Melotti G, Butturini G, Piccoli M, et al.⁴⁹

7 patients with GORE® SEAMGUARD® Product	51 patients with no SLR
No fistulas	31% developed fistulas

Excerpts from Conclusions

“In 7 patients treated with a linear stapler associated with Seamguard, we obtained a good postoperative course without fistula.”

The use of bioabsorbable seamguard [GORE® SEAMGUARD® Reinforcement] during laparoscopic appendectomy.

Tucker JG, Copher JC, Reilly JP, Fitzsimmons TR.⁵⁰

33 patients with GORE® SEAMGUARD® Product
No bleeding or leaks

Excerpts from Conclusions

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is a safe and effective adjunct to endoscopic mesoappendiceal stapling which prevents intraoperative and postoperative staple line bleeding.”

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is a rapid, reliable adjunct to endoscopic stapling, which provides complete hemostasis along the mesenteric staple line when used during laparoscopic appendectomy.”

Bioabsorbable glycolide copolymer staple line reinforcement for laparoscopic appendectomy.

Saber AA, Boros M, Rao A.⁵¹

46 patients with GORE® SEAMGUARD® Product

No bleeding or leaks

Excerpts from Conclusions

“Laparoscopic appendectomy using endoscopic linear stapler with bioabsorbable glycolide copolymer reinforcement is a safe and efficient procedure for acute appendicitis.”

Perioperative outcome of laparoscopic left lateral liver resection is improved by using staple line reinforcement technique: a case report.

Consten ECJ, Gagner M.⁵²

Case study with with GORE® SEAMGUARD® Product

No bleeding or leaks

Excerpts from Conclusions

“Staple line reinforcement with the absorbable polymer membrane has the potential to decrease staple line hemorrhage and bile leakage.”

“Staple line reinforcement with the absorbable polymer membrane might lead to the elimination of more expensive reoperations associated with staple line hemorrhage and bile leakage of longer hospital stays, or of intermittent radiologic procedures for drainage.”

Staple line reinforcement in laparoscopic distal pancreatectomy diminishes pancreatic duct leak and hemorrhage.

Consten ECJ, Gagner M.⁵³

Case study with with GORE® SEAMGUARD® Product

No bleeding or leaks

Excerpts from Conclusions

“Bioabsorbable staple line reinforcement material provides staple line reinforcement without requiring the implantation of a permanent prosthetic material. It diminishes perioperative bleeding and possibly pancreatic duct leaks. Concerns over possible long-term complications such as migration, erosion, calcification and infection are reduced.”

Reducing airleaks in lung volume reduction surgery: is there a difference between two different buttresses?

Abunasra H, Oey I, Simpson L, Solly S, Martin-Ucar A, Waller DA.⁵⁴

23 patients with GORE® SEAMGUARD® Product	59 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No leaks requiring reoperation	3.4% leak rate – required reoperation	
7 day average air leak duration	12 day average air leak duration	p=0.08

Excerpts from Conclusions

“The perioperative cost-effectiveness of LVRS can be improved by technical modifications including the change of stapling practice and buttressing material.”

Video-assisted thoracic surgery (VATS) lobectomy: 13 years’ experience.

Congregado M, Merchan RJ, Gallardo G, Ayarra J, Loscertales J.⁵⁵

237 major pulmonary resections – most with GORE® SEAMGUARD® Product
No direct comparison results

Excerpts from Conclusions

“Another potential cause of morbidity is air leakage, the water-seal test should always be performed to check that the bronchial suture is watertight, and reinforcement can be used where necessary. In our opinion, adoption of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] could minimize this complication...”

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W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

goremedical.com

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