

**GORE® SEAMGUARD®**

Bioabsorbable Staple  
Line Reinforcement



# CLINICAL PERFORMANCE WITH STAPLE LINE REINFORCEMENT

Scientific Literature Analysis (n = 8,142 patients)

*Together, improving life*



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# Clinical Performance of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

Pooled data from studies included in this scientific literature analysis*		With GORE® SEAMGUARD® Reinforcement	Without GORE® SEAMGUARD® Reinforcement
<b>Gastric bypass procedures</b>			
(n = 2,058 patients with GORE® SEAMGUARD® Reinforcement)	Leak rate <sup>1,3,4,7,9</sup>	0–0.7%	Up to 1.9% Up to 5.3% with competitive product
	Bleeding rate <sup>2,4,6,7,9</sup>	0–0.7%	Up to 15%
	Fistula formation <sup>1</sup>	0%	Up to 12.5%
	Stricture rate <sup>4,9,10</sup>	0–2.5%	Up to 10%
	Internal hernia rate <sup>5,8</sup>	0–0.8%	Up to 2.9%
	Erosions <sup>11</sup>	0%	Up to 4% with competitive product
<b>Sleeve gastrectomy procedures</b>			
(n = 5,328 patients with GORE® SEAMGUARD® Reinforcement)	Leak rate <sup>12-26,28-35</sup>	0–2.3%	Up to 5.88%
	Bleeding rate <sup>(12-14,16-18,22-24, 26,27,29,31-32,34-35)</sup>	0–5.5%	Up to 20%
<b>Colorectal procedures</b>			
(n = 266 patients with GORE® SEAMGUARD® Reinforcement)	Leak rate <sup>36-41</sup>	0–3.4% (including high risk anastomosis)	Up to 2.16%
	Bleeding rate <sup>36-38,40,41</sup>	0%	Up to 9.05%
	Stricture rate <sup>36-38,40,41</sup>	0%	
<b>Pancreatic procedures</b>			
(n = 200 patients with GORE® SEAMGUARD® Reinforcement)	Leak rate <sup>42-44,46,47,49-51</sup>	0–4%	Up to 57%
	Fistula formation <sup>45,48</sup>	0%	Up to 31%
<b>Thoracic procedures</b>			
(n = 260 patients with GORE® SEAMGUARD® Reinforcement)	Leaks <sup>52,53</sup> – Requiring reoperation	0%	Up to 3.4% with competitive product

(n = 8,142)

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.

\* A literature search was performed by an Information Specialist in May 2020 using the MEDLINE MEDLARS® Database, BIOSIS PREVIEWS® Database and EMBASE® Database. Limiters were: 10 years, English language, humans. Key words/phrases are on file.

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# SEAMGUARD® Bioabsorbable Reinforcement: A Historical Perspective of Staple Line Reinforcement

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## I. Introduction

W. L. Gore & Associates (Gore) completed the earlier version of this literature summary in 2013, which included data from 4,689 patients across, bariatric, colorectal, solid organ and thoracic surgery. These data were gathered from the earliest publications of staple line reinforcement and was especially relevant since the very first fully absorbable buttressing material was developed by Gore in 2003. Since 2013, the data have continued to expand and while SEAMGUARD® Bioabsorbable Reinforcement is present in over 85 published clinical studies, we can now present data on over 8,000 patients in this updated analysis of the key papers.

## II. Improving Patient Outcomes

Throughout surgical history, surgeons have continuously tried to improve on techniques, processes, instruments and materials with one goal in mind: improving patient outcomes. The development of the surgical staplers was a giant leap for our field and provided the path that eventually led to laparoscopic staplers. With every improvement in these devices, surgeons have been able to advance minimally invasive surgery further and further. Gallbladder surgery for the most part has been left to the novice, while the titans of surgery progressed the minimally invasive field into complex intestinal, solid organ and thoracic realms. In bariatric surgery alone, from 2014 to 2018, the number of cases has increased in the U.S. from 195,000 to 252,000 and to 394,000 worldwide, with sleeve gastrectomy becoming the most commonly performed procedure.<sup>1,2</sup> Although technically easier than the laparoscopic gastric bypass, the longer staple line of the sleeve and the higher intra-gastric pressure pushed the stapler mechanics further and further, leading to an increased risk of bleeding and leaks.<sup>3,4</sup> Despite improvements, we continue to realize the limitations of the surgical stapler. Our understanding of the stapler mechanics deepens, and we realize that rows of small, titanium staples create varying points of high and low pressure leading to areas at risk for bleeding, leaks and ischemia.<sup>5</sup> In an effort to prevent these risks, the majority of bariatric surgeons surveyed at the most recent Sleeve Gastrectomy Consensus Conference consider staple line buttressing acceptable.<sup>6</sup>

## III. Staple Line Reinforcement

In an effort to redistribute this pressure across the entire staple line, Gore first developed staple line buttressing material for thoracic procedures. Although the original SEAMGUARD® Bioabsorbable Reinforcement did succeed in redistributing the pressure, with further research and development, improvements were made and its use was expanded to other surgical areas. SEAMGUARD® Bioabsorbable Reinforcement was created as a uniform, thin, scaffold of poly(glycolide:trimethylene carbonate) copolymer (PGA:TMC) that would provide added strength while native tissues healed and would allow for tissue ingrowth with complete absorption.<sup>7,8</sup>

SEAMGUARD® Bioabsorbable Reinforcement has had its fair share of competitors, none of which have established robust clinical data demonstrating their ability to reduce leaks and bleeding.

BAXTER PERI-STRIPS DRY® Staple Line Reinforcement (bovine pericardium) varies significantly in tissue thickness and there is about a 1.5x higher leak rate in sleeve gastrectomy when using this material compared to no staple line reinforcement at all.<sup>9</sup> However, uniformity is not the only requirement for success, and it has been demonstrated that material and structure are equally important. This was most evident with the introduction in 2009 of glycolide/dioxanone/trimethylene carbonate (COVIDIEN DUET TRS) that lasted only 3 years in the marketplace.

Medtronic then introduced a 100% polyglycolic acid material in 2014, but to date, there continues to be no peer-reviewed publications of its safety and effectiveness. Not to be left out, Ethicon, as the newcomer to the field, introduced a Polyglactin 910 (same material as their ETHICON VICRYL® Suture) and 2x polydioxanone (PDO) film material in 2020, and again, there are no long-term data to evaluate its safety and efficacy.

As a final staple line reinforcement technique, a number of surgeons continue to oversee the staple lines, with the idea that this is more cost-effective than utilizing buttressing material. However, oversewing increases the operative time without any significant decrease in the risk of leaks.<sup>10,11</sup> Furthermore, the variability in oversewing techniques between surgeons compromises analysis of this method for patient outcomes.<sup>12</sup> Conversely, this technique can actually increase the risk of complications and completely oversewing the staple line has been associated with an increased risk of revisional surgery.<sup>13</sup>

Compared to naturally derived buttressing materials, synthetic bioabsorbable materials offer consistent uniformity and absorption profiles without having to rely on surgeon suturing. As a result, synthetic buttressing use is standardized and reproducible, which reduces risks of technical misuse and complications.<sup>12</sup>

#### **IV. Cost Effectiveness**

As surgeons have continued to advance surgical techniques and outcomes, we have also been called upon to be caretakers of financial resources. Cost effectiveness has become instrumental in long-term viability of health care systems and the literature supports the role of staple line buttressing with SEAMGUARD® Bioabsorbable Reinforcement as a way to obtain this. Although we have heard that, “You have to spend money to make money,” the paradox that we need to spend money to save money has proven true. As mentioned previously, oversewing the staple line adds additional time to surgical procedures,<sup>11</sup> and the resultant loss of revenue with this delay can be significant.<sup>14</sup> Furthermore, the prevention of complications results in decreased length of stay, hospital readmissions and reoperations with substantial financial savings.<sup>11,12,15</sup>

#### **V. Conclusion**

Although minimally invasive surgery continuously evolves, some of our techniques, processes, devices and materials have proven the test of time, such as SEAMGUARD® Bioabsorbable Staple Line Reinforcement. As we continue to advance the field of surgery, we must focus on data-driven outcomes, which this clinical performance brochure nicely summarizes.

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# Gastric Bypass Procedures

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

Miller KA, Pump A.<sup>1</sup>

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

### Excerpts

“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.<sup>2</sup>

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

### Excerpts

“Staple misfire occurred in 1 (0.7%) of 143 total number of stapler loads used in the treatment group compared with 0 of 138 total number of stapler loads used in the control group.”

“Although this study did not conclusively demonstrate that the use of staple line reinforcement sleeves lowers the rate of GI hemorrhage, we found that intraoperative staple line bleeding was significantly reduced. In this trial, we noted an 84% reduction in staple line bleeding sites at gastric tissue, an 83% reduction in staple line bleeding sites at jejunal tissue, and a 100% reduction in staple line bleeding sites at mesenteric tissue with the use of the staple line reinforcement sleeves.”

“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.”

\* *P* values less than 0.05 (\**P* < 0.05) represent statistically significant data.

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

Zomerlei TA, Brown A, Bajric J, Kemmeter PR.<sup>3</sup>

142 patients with GORE® SEAMGUARD® Reinforcement	228 patients with BAXTER PERI-STRIPS DRY® Product	Significance
No leaks	5.3% leak rate	* <i>P</i> < 0.05

### Excerpts

“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 BAXTER PERI-STRIPS DRY® Product] group.”

## 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.<sup>4</sup>

40 patients with GORE® SEAMGUARD® Reinforcement	40 patients with no SLR	Significance
No bleeding	15% intraoperative bleeding rate	* <i>P</i> = 0.0255
2.5% stricture rate	10% stricture rate	<i>P</i> = 0.2007

### Excerpts

“Since most of the cases of bleeding were managed intraoperatively, there was no significant difference between the two groups regarding estimated intraoperative blood loss or postoperative hematocrit values.”

“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.<sup>5</sup>

354 patients with GORE® SEAMGUARD® Reinforcement	1,350 patients with suture only	Significance
0.8% internal hernia rate	2.9% internal hernia rate	* <i>P</i> = 0.01

### Excerpts

“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.”

“It may be argued that the use of SLR is not cost effective, particularly because of the low IH rates in some recent studies. However, the follow-up time in one of these studies was short (9 months). Moreover, our opinion is that, in the light of the costs of hospital or outpatient visits for unexplained episodic abdominal pain, tests ordered to investigate the pain, and, eventually, reoperation, prophylactic use of SLR may save money.”

\* *P* values less than 0.05 (\**P* < 0.05) represent statistically significant data.



## 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.<sup>6</sup>

**80 patients with**

**GORE® SEAMGUARD® Reinforcement**

**45 patients with no SLR**

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No bleeding

4.44% bleeding rate

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### Excerpts

“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.<sup>7</sup>

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

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No leaks, intra-abdominal abscesses or hemorrhages

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### Excerpts

“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.<sup>8</sup>

**417 patients with GORE® SEAMGUARD® Reinforcement**

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No internal hernias

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### Excerpts

“[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.<sup>9</sup>

<b>138 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>255 patients with no SLR</b>	<b>Significance</b>
0.7% bleeding rate	1.1% bleeding rate	<i>P</i> = 0.64
0.7% leak rate	1.9% leak rate	<i>P</i> = 0.34
0.7% stricture rate	9.3% stricture rate	* <i>P</i> = 0.0005

### Excerpts

“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 W IV, Carbonell A, Bour ES.<sup>10</sup>

<b>596 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>255 patients with no SLR</b>	<b>Significance</b>
0.67% stricture rate	9.41% stricture rate	* <i>P</i> < 0.0005

### Excerpts

“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.<sup>11</sup>

<b>228 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>153 patients with BAXTER PERI-STRIPS DRY® Product</b>	<b>Significance</b>
No erosions	6 erosions (4%)	* <i>P</i> = 0.003

### Excerpts

“Non absorbable Peri Strips resulted in erosion.”

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

\* *P* values less than 0.05 (\**P* < 0.05) represent statistically significant data.

BAXTER and PERI-STRIPS DRY are trademarks of Baxter Healthcare Corporation.

# Sleeve Gastrectomy Procedures

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.<sup>12</sup>

10 patients with GORE® SEAMGUARD® Reinforcement	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 (20%)	
	1 had a subphrenic abscess (10%)	

## Excerpts

“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.<sup>13</sup>

50 patients with GORE® SEAMGUARD® Reinforcement (26 were SLIC [strategic laparoscopic surgery for improved cosmesis] patients)
No leaks
No other complications reported

## Short-term outcomes of sleeve gastrectomy for morbid obesity: Does staple line reinforcement matter?

Durmush EK, Ermerak G, Durmush D<sup>14</sup>

332 patients with GORE® SEAMGUARD® Reinforcement	186 patients with no SLR	Significance
No leaks	1.61% (3 patients)	*P = 0.045
No bleeds	0.53% (1 patient)	

## Excerpts

“Patients in whom synthetic PGA:TMC staple line reinforcement material was applied during LSG had no postoperative leaks or hemorrhages from the staple line. The difference in leak rate between the reinforcement-material group and the no-reinforcement-material group was significant (P = 0.045).”

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

Ayloo S, Buchs NC, Addeo P, Bianco FM, Giulianotti PC.<sup>15</sup>

### 69 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

No other complications reported

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## Laparoscopic sleeve gastrectomy is a safe and effective bariatric procedure for the lower BMI (35.0–43.0 kg/m<sup>2</sup>) population.

Gluck B, Movitz B, Jansma S, Gluck J, Laskowski K.<sup>16</sup>

### 204 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

1.0% bleeding rate

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

Saber AA, Elgamal MH, Itawi EA, Rao AJ.<sup>17</sup>

### 7 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

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

Lewis CE, Dhanasopon A, Dutson EP, Mehran A.<sup>18</sup>

### 42 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

2.38% bleeding rate

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

Moy J, Pomp A, Dakin G, Parikh M, Gagner M.<sup>19</sup>

### 135 patients with GORE® SEAMGUARD® Reinforcement

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1.5% leak rate

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### Excerpts

“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.<sup>20</sup>

<b>46 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>46 patients with no SLR</b>	<b>Significance</b>
No leaks		
No staple line oozing	13% had staple line oozing (Had to oversew)	* <i>P</i> < 0.05
No complications	2 patients required blood transfusion therapy	

### Excerpts

“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.<sup>21</sup>

<b>49 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>183 patients with no SLR</b>	<b>214 patients with suture</b>
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]

TSimon TE, Scott JA, Brockmeyer JR, Husain FA, Frizzi JD, Choi YU<sup>22</sup>

<b>52 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>68 patients with no SLR</b>
1.92% leak rate	5.88% leak rate
0% bleeding rate	0% bleeding rate

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

Gentileschi P, Camperchioli I, Benavoli D, De Lorenzo N, Sica G, Gaspari AL.<sup>23</sup>

### 8 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

No other complications

---

## Single-incision transumbilical laparoscopic sleeve gastrectomy.

Saber AA, El-Ghazaly TH, Eliam A.<sup>24</sup>

### 6 patients with GORE® SEAMGUARD® Reinforcement

---

No leaks

No other complications

---

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

Chowbey PK, Dhawan K, Khullar R, et al.<sup>25</sup>

### ~75 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

No bleeds

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### Excerpts

“Four patients required blood transfusion in the postoperative period for intraluminal bleeding manifested by melena and a fall [in] 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.<sup>26</sup>

### 19 patients with GORE® SEAMGUARD® Reinforcement

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No leaks

No other complications

---

## Gastroscoically controlled laparoscopic sleeve gastrectomy.

Köckerling F, Schug-Paß C.<sup>27</sup>

### 38 patients with GORE® SEAMGUARD® Reinforcement

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2.6% bleeding rate

2.6% stenosis

---

#### Excerpts

“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.<sup>28</sup>

### 45 patients with GORE® SEAMGUARD® Reinforcement

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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.<sup>29</sup>

### 25 patients with GORE® SEAMGUARD® Reinforcement

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0% leak rate

0% bleeding rate

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#### Excerpts

“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.<sup>30</sup>

### 157 patients with GORE® SEAMGUARD® Reinforcement

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1.27% leak rate

No post-operative bleeding reported

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

Ramon J, Puig S, Pera M, et al.<sup>31</sup>

### 17 patients with GORE® SEAMGUARD® Reinforcement

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0% bleeding rate

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### Excerpts

“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.<sup>32</sup>

### 100 patients with GORE® SEAMGUARD® Reinforcement

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1% leak rate

2% bleeding rate

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## Comparison of laparoscopic sleeve gastrectomy leak rates in five staple line reinforcement options: A systematic review

Gagner M, Kemmeter P<sup>33</sup>

### 4,100 patients with GORE® SEAMGUARD® Reinforcement

### 16,632 patients with no SLR

### Significance

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0.73% leak rate

1.89% leak rate

\**P* < 0.0001

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### Excerpts

“Systematic review of 148 included studies representing 40,653 patients found that the leak rate in LSG was significantly lower using APM [absorbable polymer membrane] staple line reinforcement than over-sewing, BPS [bovine pericardial strips] reinforcement or no reinforcement.”



## Clinical and Economic Evaluation of Absorbable Staple Line Buttressing in Sleeve Gastrectomy in High-Risk Patients

Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D<sup>34</sup>

<b>86 patients with GORE® SEAMGUARD® Reinforcement*</b>	<b>116 patients with no SLR</b>	<b>Significance</b>
2.3% leaks (No surgery required however)	3.5% (3 reoperations required)	
No bleeds	8.6% bleeding	† <i>P</i> = 0.005

### Excerpts

“It was remarkable that the buttressing group had no bleeding at all and was clearly protected from this complication.”

“Staple line reinforcement with absorbable material reduces bleeding in high-risk population. Therefore, this type of material can also result in cost-savings.”

## A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients

Barreto TW, Kemmeter PR, Paletta MP, Davis AT<sup>35</sup>

<b>860 patients with GORE® SEAMGUARD® Reinforcement†</b>	<b>373 patients with imbrication (Seromuscular suturing)</b>	<b>269 patients with BPS</b>
0.3% leaks	0.3%	1.5%
5.5% bleeding	3.8%	5.9%

### Excerpts

“Although we did not find statistically significant differences in our primary outcome variables of leaks and bleeds, we did see a trend towards a higher leak rate in the [bovine pericardial strips] group, compared to the imbrication or [absorbable polymer membrane] groups (*P* = 0.08).”

“Despite a liberal definition of bleeding, postoperative bleed rates were not statistically different between groups, but did make our rates appear high at 3.8–5.9%.”

\*Decreased hospital stay see “Hospital Savings” section.

† *P* values less than 0.05 (*\*P* < 0.05) represent statistically significant data.

‡ Decreased reoperation and readmittance rate see “Hospital Savings” section.

# Colorectal Procedures

## 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.<sup>36</sup>

### 30 patients with GORE® SEAMGUARD® Reinforcement

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No leaks, bleeding or strictures

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#### Excerpts

“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.<sup>37</sup>

69 patients with GORE® SEAMGUARD® Reinforcement	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

“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. The incidence of wound infection and anastomotic narrowing were the same.”

## 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.<sup>38</sup>

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### 25 patients with GORE® SEAMGUARD® Reinforcement

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No bleeding or other complications during the surgical procedure

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#### Excerpts

“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.”

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

Portillo G, Franklin ME II.<sup>39</sup>

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### 117 patients with Circular GORE® SEAMGUARD® Reinforcement

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

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#### Excerpts

“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.<sup>40</sup>

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### 20 patients with Circular GORE® SEAMGUARD® Reinforcement

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No leaks, bleeding or anastomotic stenosis

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#### Excerpts

“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.<sup>41</sup>

### **5 patients with Circular GORE® SEAMGUARD® Reinforcement**

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No leaks, bleeding or anastomotic stenosis

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#### **Excerpts**

“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.”

“Although the sample of 5 patients is small and the follow-up is short, these cases bolster the results of other studies with linear stapler line reinforcement.”

# Pancreatic Procedures

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

Jimenez RE, Mavanur A, Macaulay WP.<sup>42</sup>

13 patients with GORE® SEAMGUARD® Reinforcement	18 patients with no SLR	Significance
No leaks	39% leak rate	* <i>P</i> = 0.025

### Excerpts

“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 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. A retrospective review of 14 cases.

Pugliese R, Maggioni D, Sansonna F, et al.<sup>43</sup>

7 patients with GORE® SEAMGUARD® Reinforcement	7 patients with no SLR	Significance
No leaks at 30 days post-op	57% leak rate	* <i>P</i> = 0.0349

### Excerpts

“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.<sup>44</sup>

29 patients with GORE® SEAMGUARD® Reinforcement	11 patients with no SLR	Significance
3.5% leak rate	36% leak rate	* <i>P</i> = 0.005

### Excerpts

“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.<sup>45</sup>

<b>7 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>2 patients with no SLR</b>
No leaks or fistulas	2 fistulas

### Excerpts

“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.<sup>46</sup>

<b>47 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>38 patients with no SLR</b>	<b>Significance</b>
4% leak rate	26% leak rate	* <i>P</i> = 0.01

### Excerpts

“In our 2 leaks with use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], 1 patient eventually required another operation to close an unresolved leak, and oversewing of the stump remnant was used. The other patient was treated nonoperatively without incident.”

“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.<sup>47</sup>

<b>10 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>18 patients with no SLR</b>	<b>Significance</b>
No leaks	33% leak rate	<i>P</i> = 0.062

### Excerpts

“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.<sup>48</sup>

### 7 patients with

**GORE® SEAMGUARD® Reinforcement**

No fistulas

### 51 patients with no SLR

31% developed fistulas

### Excerpts

“In 7 patients treated with a linear stapler associated with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], we obtained a good postoperative course without fistula.”

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

Consten EC, Gagner M.<sup>49</sup>

### Case study with GORE® SEAMGUARD® Reinforcement

No bleeding or leaks

### Excerpts

“Bioabsorbable staple line reinforcement material [GORE® SEAMGUARD Reinforcement] 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.”

# Thoracic Procedures

## 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.<sup>50</sup>

<b>23 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>59 patients with BAXTER PERI-STRIPS DRY® Product</b>	<b>Significance</b>
No leaks requiring reoperation	3.4% leak rate – required reoperation	
7-day average air leak duration	12-day average air leak duration	<i>P</i> = 0.08

### Excerpts

“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.<sup>51</sup>

### **237 major pulmonary resections – Most with GORE® SEAMGUARD® Reinforcement**

No direct comparison results

### Excerpts

“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. . .”



# Hospital Savings

## Clinical and Economic Evaluation of Absorbable Staple Line Buttressing in Sleeve Gastrectomy in High-Risk Patients

Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D<sup>34</sup>

<b>Economic Analysis Characteristics</b>	<b>86 patients with GORE® SEAMGUARD® Reinforcement</b>	<b>116 patients without SLR</b>	<b>Significance</b>
Hospital stay (Day)	4.2 ± 0.9	5.2 ± 3.8	* <i>P</i> = 0.005
Operative time (Min)	155 ± 29	142 ± 29	* <i>P</i> = 0.002
Buttressing cost (€)	746 ± 137	0 ± 0	* <i>P</i> < 0.001
Intraoperative costs (€)	1678 ± 315	1546 ± 316	* <i>P</i> = 0.002
Extraoperative costs (€)	3384 ± 766	4479 ± 4734	* <i>P</i> = 0.0035
Overall cost during initial stay (€)	5808 ± 844	6026 ± 4756	* <i>P</i> < 0.001
Rehospitalization costs (€)	5043 ± 6240	6394 ± 4986	<i>P</i> = 0.53
Overall cost (€)	5984 ± 1658	6246 ± 4986	* <i>P</i> < 0.001

### Excerpts

“Regarding overall costs, the use of absorbable buttressing membranes seems to bring another economic benefit in high-risk population. Indeed, control group costs were higher even when rehospitalizations for complications within six months were included in the analysis.”

“SLR can be considered a cost-effective measure and this does not include the social costs of leak and bleeding to the patient.”

# A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients

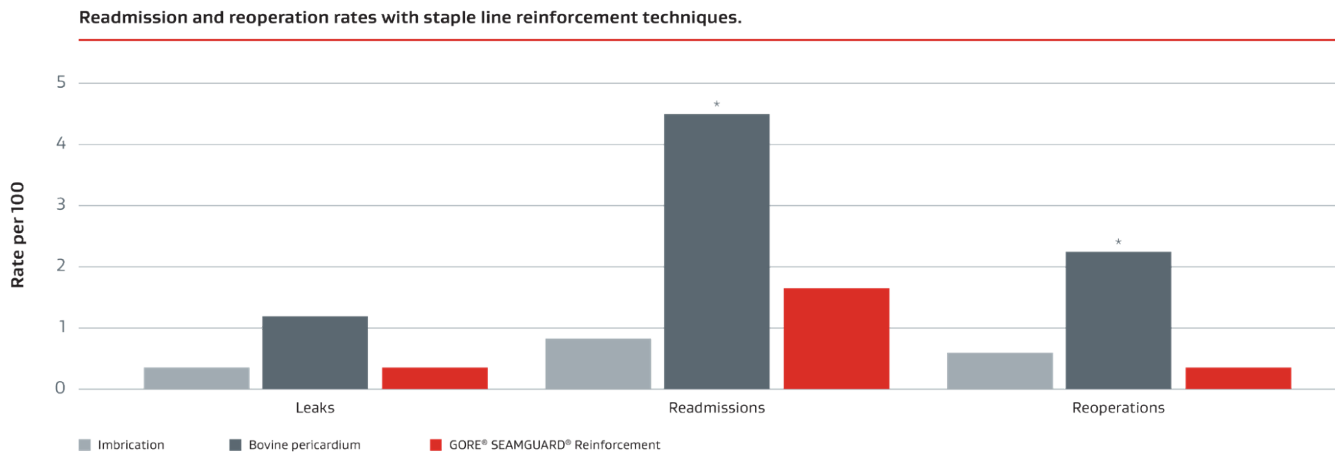
Barreto TW, Kemmeter PR, Paletta MP, Davis AT<sup>35</sup>

## 1,502 PATIENTS FROM THE SAME INSTITUTION WERE COMPARED

373 patients (24.8%) reinforced with imbrication

269 patients (17.9%) reinforced with bovine pericardial strips (BPS)

860 patients (57.3%) reinforced with GORE® SEAMGUARD® Reinforcement (APM)



Rates of adverse events by percent of gastric leaks ( $P = 0.08$ ), hospital readmissions ( $P = 0.001$ ) and reoperations ( $P = 0.01$ ). Bovine pericardium use resulted in significantly higher readmissions and reoperations compared to the other two techniques.

### Excerpts

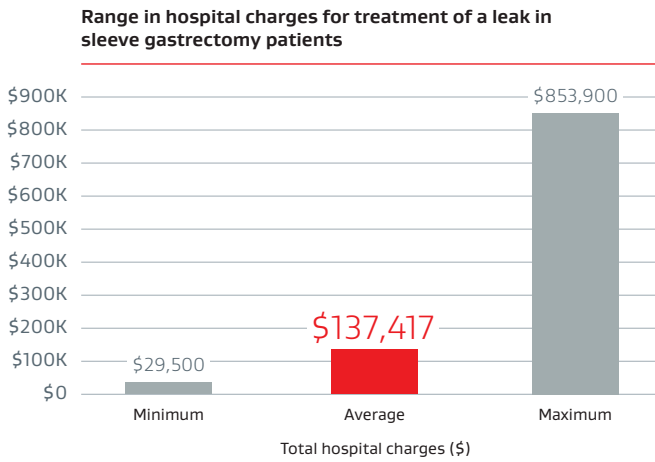
“Additionally, our study demonstrated statistically higher rates of reoperation and readmission in the BPS group, with leak being the primary indication for reoperation and >25 % of readmissions being related to a leak.”

“This study demonstrated that BPS is associated with significantly higher readmission and reoperation rates with a trend towards a higher leak rate.”

\* This study demonstrated that bovine pericardium (BPS) is associated with significantly higher readmission and reoperation rates with a trend towards a higher leak rate.

# Total Charges for Post-Operative Leak Following Laparoscopic Sleeve Gastrectomy

Zambelli-Weiner A, Brooks E, Brolin R, Bour ES<sup>52</sup>



Sleeves with GORE® SEAMGUARD® Reinforcement		Sleeves with any staple line reinforcement	
200 sleeve cases	.7% leak rate <sup>33</sup>	200 sleeve cases	1.5% leak rate <sup>33</sup>
X		X	
1.4 leaks	\$93,451/leak <sup>53</sup>	3 leaks	\$93,451/leak <sup>53</sup>
X		X	
\$130,831		\$280,353	



# \$149,522

Potential reduced charges\*†

\* For every 200 cases.

† Does not consider bleeding complication charges or other associated complication charges.

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