Reinforce with Confidence

PERFORMANCE through innovation

SEAMGUARD™ BIOABSORBABLE
STAPLE LINE REINFORCEMENT
Reduces Leaks.

Most clinical data literature supporting leak reduction

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

<table>
<thead>
<tr>
<th>Group</th>
<th>% of Leak Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>593 patients with GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement</td>
<td>0.5%</td>
</tr>
<tr>
<td>83 patients with Suture</td>
<td>1%</td>
</tr>
<tr>
<td>205 patients with Bovine Pericardium</td>
<td>2%</td>
</tr>
<tr>
<td>892 patients without Reinforcement</td>
<td>3%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Group</th>
<th>% of Leak Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>47 patients with GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement</td>
<td>0.5%</td>
</tr>
<tr>
<td>36 patients with no reinforcement</td>
<td>3%</td>
</tr>
</tbody>
</table>

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

3GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement significantly reduced leaks compared to no reinforcement, *p=0.01

“The use of an Absorbable buttress material during performance of a sleeve gastrectomy reduces the incidence of postoperative leaks by 3 fold.” Gagner

“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
Reduces Bleeding.

Most clinical data literature supporting bleeding reduction

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.** 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.** showed significantly reduced bleeding in gastric bypass procedures (p<0.05)*
  - Less clips used
  - Higher post-op hemoglobin

• **Consten et al.** showed significantly reduced bleeding in sleeve gastrectomies (p<0.05)*
  - 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
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)

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![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.](image)
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

*Data on File.
References


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