

# Early Clinical Results Using GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement For Circular Staplers

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## Introduction

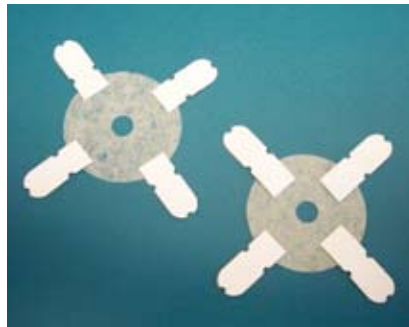
The Achilles heel of Roux-en-Y divided gastric bypass is the enteric anastomosis. Whether it be bleed, stricture, or leak a complication involving the anastomosis may result in untoward morbidity and/or mortality. This represents an opportunity for significant advancement in surgical technology.

Bioabsorbable staple-line reinforcements have been developed in an attempt to reduce the risk of staple-line complications. Although they have been shown to be effective in reducing linear staple line complications in a variety of surgical procedures, and circular staple line complications in colorectal surgery, no studies have examined their effects on outcomes in circular stapled anastomoses in bariatric surgery.<sup>1,2</sup>

## Purpose

The purpose of this study was to compare the incidence of anastomotic bleeding, leak, and stricture in laparoscopic divided gastric bypass patients with gastrojejunal anastomotic circular staple line reinforcement to those with no circular staple line reinforcement.

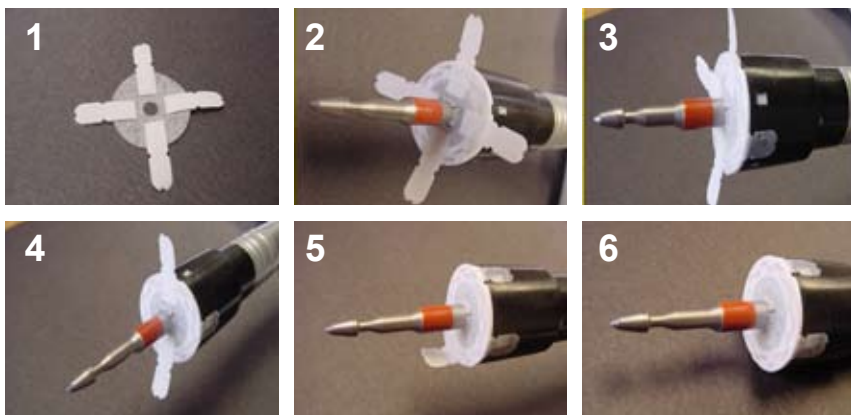
GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement



## Methods

We performed a retrospective review of prospectively collected data on 90 consecutive patients (Group A) who underwent laparoscopic Roux-en-Y divided gastric bypass using GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement (W. L. Gore & Assoc.) between May 2006 and January 2007. Complications measured were anastomotic bleed, stricture and anastomotic leak. Bleeding was defined as either the need for transfusion, reoperation or hemodynamic instability secondary to anastomotic hemorrhage. Stricture was defined as subjective dysphagia and/or patient food intolerance with subsequent endoscopic or radiographic evidence of anastomotic narrowing. Anastomotic leak was assessed by air insufflation at the time of surgery, limited water-soluble contrast upper GI on post-operative day 1, and abnormal drainage from a drain left in the area of the gastrojejunal anastomosis at the time of surgery. Results were compared to 269 consecutive patients (Group B) who underwent surgery prior to May 2006 without gastrojejunal anastomotic reinforcement.

All operations were performed by a single surgeon at a single institution with ante-gastric/ante-colic placement of the Roux limb. The end-to-end gastrojejunal anastomoses were fashioned using a 25mm Ethicon ILS® stapler. Stapler and anvil preparation and the tissue donuts from the procedure are shown below.



### ILS STAPLER PREPARATION

1. Select a SEAMGUARD® product disc and identify the side with adhesive backing paper
2. Place disc onto stapler with adhesive backing paper facing body of stapler
3. Remove adhesive backing paper and fix tab to stapler
4. Repeat for opposite side, being careful to align disc on stapler
5. Continue with remaining tabs
6. SEAMGUARD product completely affixed to stapler



### ANVIL PREPARATION

1. Slide disc over anvil shaft with adhesive backing paper facing the anvil
2. Remove backing paper and press tabs onto anvil face
3. SEAMGUARD product completely affixed to anvil



### STAPLER DONUTS

A total of 4 "donuts" are identified in the EEA stapler: 2 soft tissue donuts and 2 SEAMGUARD product donuts

## Results

In Group A there has been no incidence of either bleed, stricture or leak with a mean follow-up of 7 months (3-10 months). In Group B the incidence of anastomotic bleeding, leak, and stricture was 1.1%, 1.9% and 9.3%, respectively, with a mean follow-up of 20 months (10-30 months). There was a statistically significant difference in the development of anastomotic stricture between the two groups (A: 0/90 vs. B: 25/269,  $p = 0.0011$ ); differences in bleeding or leak were not statistically significant ( $p = 0.56$  and  $p = 0.34$ , respectively).

## Discussion

Enteric anastomotic integrity is essential to successful outcomes in bariatric surgery. Complications in the form of bleeding, stricture or leak are the fear of both patients and surgeons alike.

SEAMGUARD product is composed of a porous structure of a synthetic, fully bioabsorbable polyglycolic acid/trimethylene carbonate copolymer fiber. They have been shown to retain > 70% of original tensile strength for 4 to 6 weeks post placement and are completely absorbed by 6 months.

The integrity and bursting strength of stapled anastomoses of the gastric pouch have been shown to be significantly higher when using bioabsorbable linear staple line reinforcement<sup>1</sup>. The effects of SEAMGUARD product in end-to-end anastomoses in colorectal surgery revealed no incidence of anastomotic leak or bleeding; stricture was not examined<sup>2</sup>.

The benefits of circular staple-line reinforcement in bariatric surgery have not previously been examined. Perhaps in no other field is the integrity of the anastomosis more important than bariatric surgery. This is due largely in part to both the availability of bariatric surgeons' outcomes to a discriminating patient population committing to elective surgery and the devastating effects of anastomotic complications on patients that are routinely ill preoperatively.

Our findings support the routine use of SEAMGUARD product in bariatric surgery. Early 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 leak, bleeding, and stricture. Prior to their routine use, anastomotic stricture was present in nearly 1 out of 10 patients that underwent laparoscopic Roux-en-Y divided gastric bypass at our institution, resulting in a significant number of patients needing endoscopic dilation. We have identified no strictures since we changed our operative technique to include SEAMGUARD product. This has had an almost immediate effect on our clinical practice. Coupled with the reduction of bleeding and leak, this has encouraged us to continue to routinely use SEAMGUARD product on our patients undergoing Laparoscopic Roux-en-Y divided gastric bypass.

## Conclusion

**The routine use of SEAMGUARD product in patients undergoing laparoscopic Roux-en-Y divided gastric bypass with a circular stapled gastrojejunal anastomosis has led to a significant reduction in postoperative gastrojejunal stricture formation. In addition, a trend indicating a reduction in anastomotic bleeding and leak have also been identified with use of this product. As a result, strong consideration should be given to the routine use of this product in bariatric surgical procedures.**

## References

1. Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The Science of Stapling and Leaks. *Obesity Surgery*. 2004;14:1290-1298.
2. Franklin ME, Berghoff KE, Arellano PP, Trevino JM, Abrego-Medina D. Safety and Efficacy of the Use of Bioabsorbable Seamguard in Colorectal Surgery at the Texas Endosurgery Institute. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques*. 2005; 15: 9-13.

Poster Presented at The Emerging Technologies Session,  
SAGES Annual Meeting, April 22, 2007

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