

Key differences in materials

In summary, **the study found significant differences between GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement and Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology in the animal model.** When choosing between types of staple line reinforcement, clinicians should consider that these differences in materials may impact patient outcomes.

GORE® SEAMGUARD® BIOABSORBABLE STAPLE LINE REINFORCEMENT

Material: PGA + TMC

67% polyglycolic acid (PGA)
33% trimethylene carbonate (TMC)

The copolymer of PGA and TMC provides strength, durability, flexibility, slower degradation and better contouring of the anatomical staple line

Minimal inflammation

Slower degradation creates minimal inflammatory response, especially during critical healing period.

Consistent thickness

Minimal change in material thickness after implantation, allowing for even pressure distribution over tissue.

Extensive clinical history and clinical studies

GORE® SEAMGUARD® Reinforcement has more than 60 published clinical papers and an extensive clinical history.

MEDTRONIC ENDO GIA REINFORCED RELOAD WITH TRI-STAPLE TECHNOLOGY

Material: PGA

100% polyglycolic acid (PGA)

Consists of stiff PGA only, there is no component to provide additional durability and slower degradation.

Significantly higher inflammation

Creates significantly higher inflammatory response at early post-operative time-points.

Material swells

After implantation, material swells to two to six times the original thickness, which may compromise staples and tissue.

Limited clinical history

No bariatric clinical studies designed to evaluate Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology.

For the complete study results, contact your Gore Sales Associate.

You can also visit goremedical.com/seamguard for more information.

This study was funded by W. L. Gore & Associates, Inc.



W. L. GORE & ASSOCIATES, INC.
Flagstaff, AZ 86004

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

goremedical.com

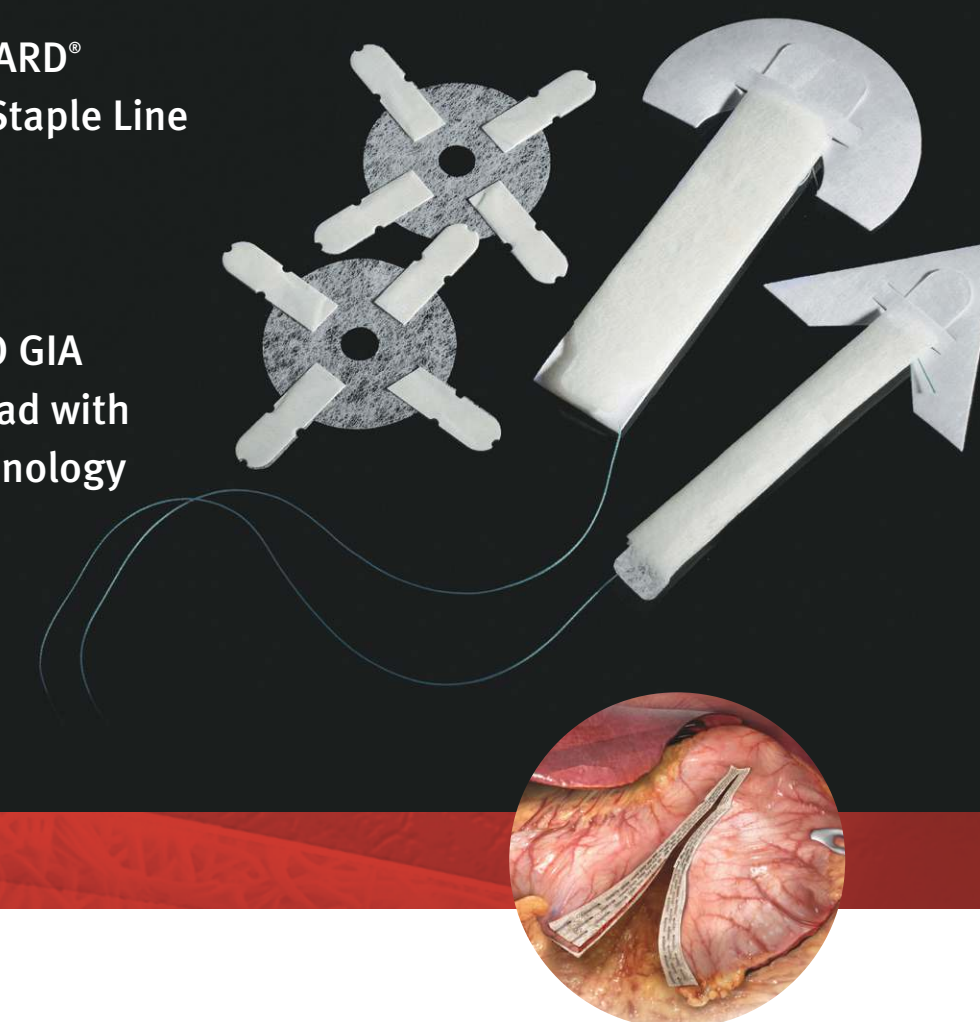
Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. REG
Products listed may not be available in all markets.
ENDO GIA is a trademark of Medtronic, Inc.
GORE®, SEAMGUARD®, and designs are trademarks of W. L. Gore & Associates.
© 2017 W. L. Gore & Associates, Inc. AW1208-EN2 AUGUST 2017

Comparison of

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

and

Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology



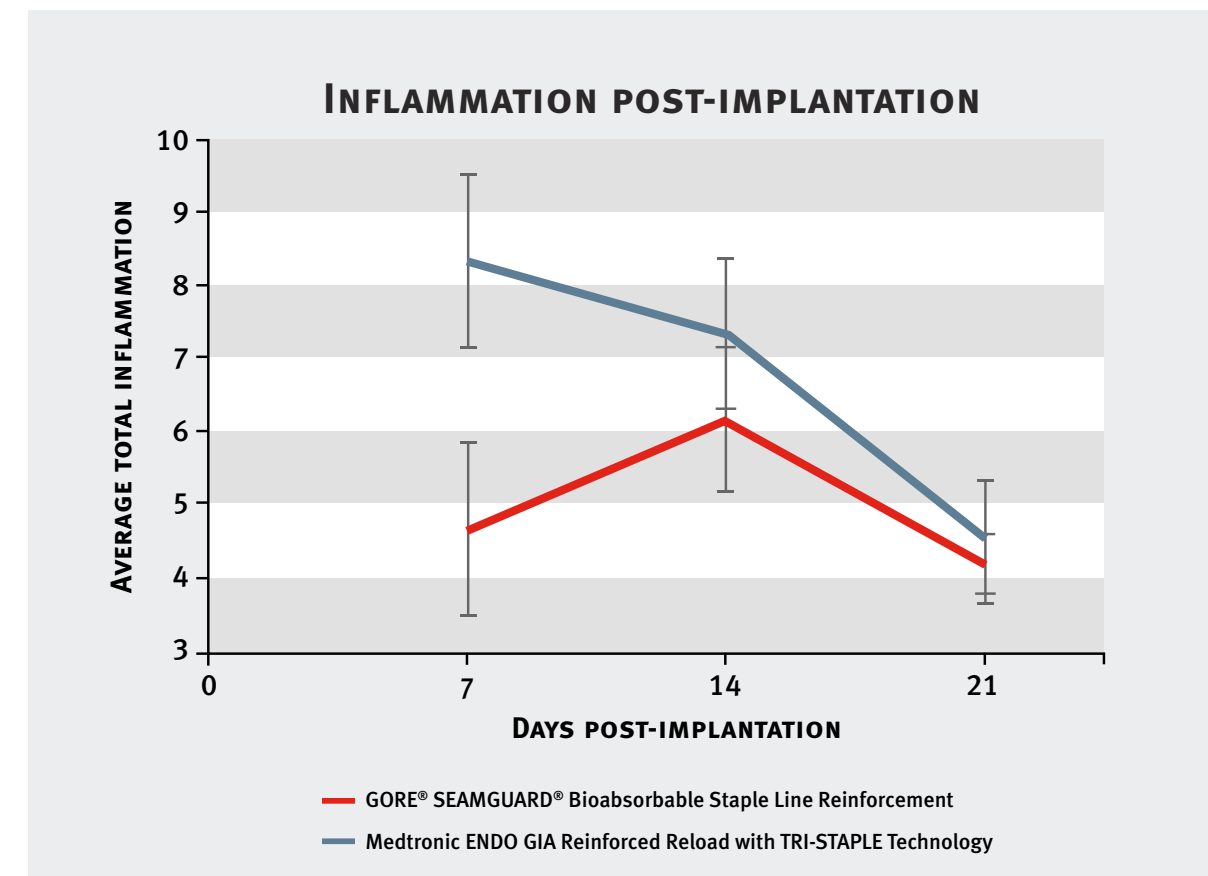
A porcine study was conducted to evaluate two staple line reinforcement devices, GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement and Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology, using the same stapler. At each of the three designated time points (7 days, 14 days, and 21 days), macroscopic observations were recorded and the the implant sites were evaluated histologically.

The complete study is documented in a technical paper, following are the key results.



Inflammatory response

A significantly higher inflammatory response was observed for Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology devices compared to GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement at early post-operative time-points.* This was quantified by counting the acute inflammatory cells in 5 fields per section (10 fields per device) under 40x magnification. Inflammation was quantified using a modified International Organization for Standardization 10993-6:2009 / American Society for Testing and Materials (ISO / ASTM) scoring scale.



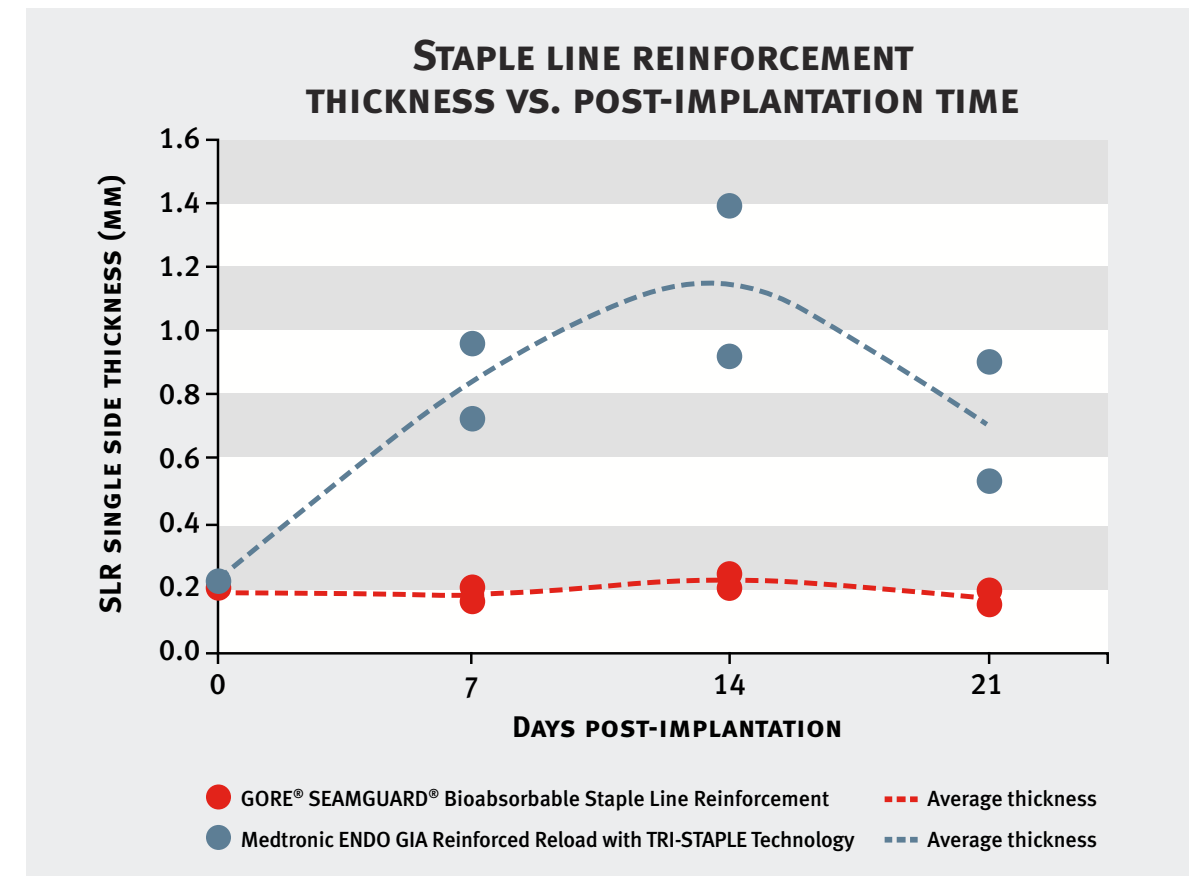
At Day 7 the Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology had a significantly greater inflammatory response than GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement.

At Days 14 and 21, while there was a trend of higher inflammation in the Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology group compared to the GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement group, this was not significantly different.

*Data on file.

Material thickness

A major observation in this study was the variation in the thickness of the device material after implantation, where some Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology devices increased to more than 500% of the original device thickness.



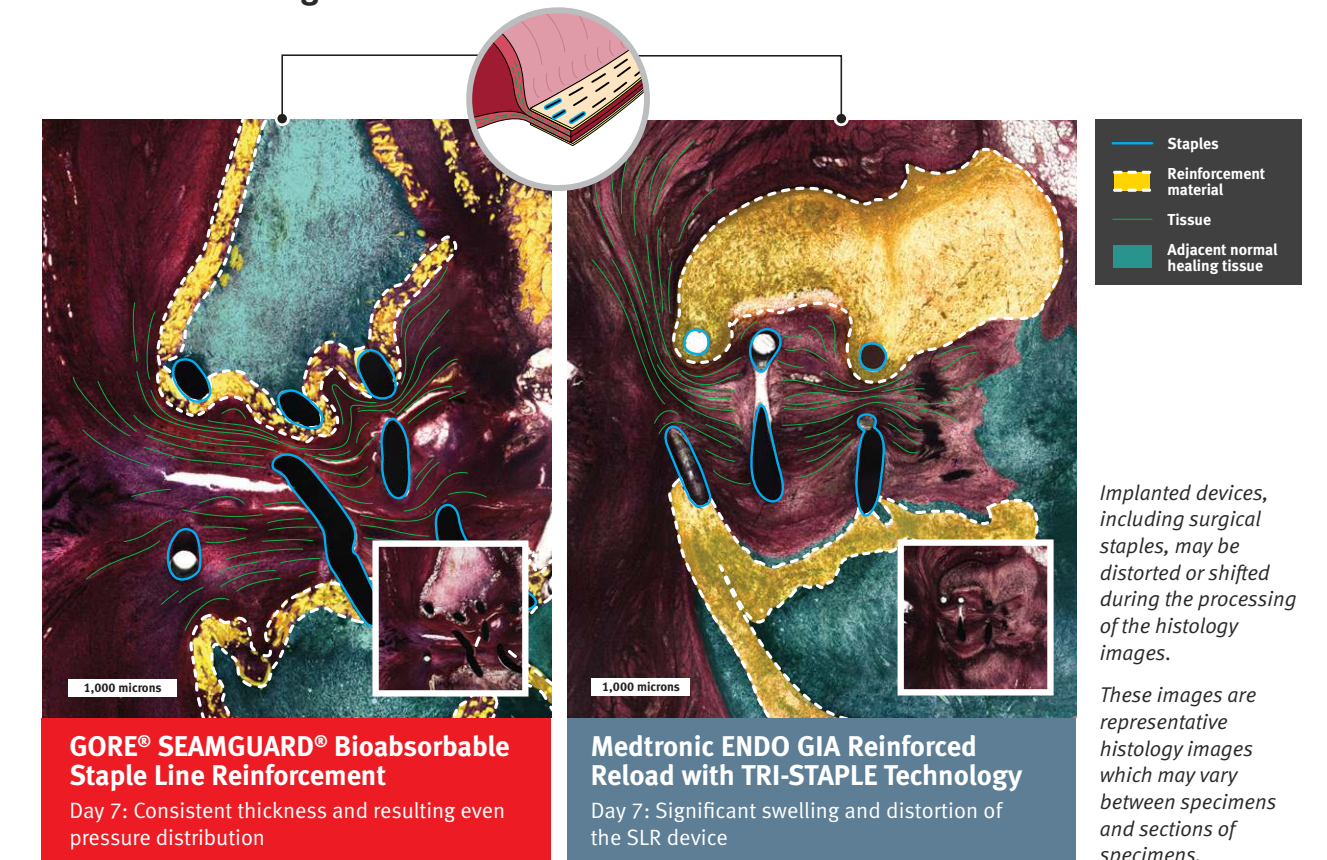
Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology material thickness increased 2x–6x, going from 0.22 mm pre-implantation, to 0.73–0.96 mm at Day 7, 0.92–1.39 mm at Day 14, and 0.54–0.91 mm at Day 21.

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement maintained a consistent thickness over 21 days, with minimal variation from the nominal thickness of 0.2 mm (0.18 mm at Day 7, 0.22–0.24 mm at Day 14, and 0.18 mm at Day 21).

At all time points there were at least two samples.

Staple line reinforcement shape

Note the significant differences in the shape of the staple line reinforcement, shown in the images below.



Material stiffness

Pre-implantation bench-top testing demonstrated significant differences in the material stiffness. The Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology material stiffness of 140 MPa being more than a magnitude greater than the GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement stiffness of 11 MPa. This is due to the use of very stiff PGA fibers in the Medtronic device as compared to softer PGA / TMC fibers in the Gore device (shown in table below). Because GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is more elastic, it allows it to better conform to the staples and soft tissue anatomy. This results in a staple line reinforcement that more closely matches the anatomical contours of the staple line.

| COMPARISON OF MECHANICAL PROPERTIES PRE-IMPLANTATION | | |
|--|--------------------------------|---|
| | GORE® SEAMGUARD® Reinforcement | Medtronic ENDO GIA Reinforced Reload with TRI-STAPLE Technology |
| Fiber modulus of elasticity | 0.5 GPa | 6.0 GPa |
| SLR modulus of elasticity | 11 MPa | 140 MPa |