



20 YEARS OF CLINICAL HISTORY.

Minimizing complications.
Maximizing outcomes.



GORE® BIO-A®
Tissue Reinforcement

GORE® SEAMGUARD®
Bioabsorbable Staple Line Reinforcement

Together, improving life



As pioneers of mid-term bioabsorbable mesh technology with a targeted mid-term absorption period of six to seven months, we are persistent in the pursuit of perfecting material science as a solution, so surgeons have more options when assessing the risk for complications and supporting concomitant hiatal hernia repairs for laparoscopic sleeve procedures.

As an innovative 3D mid-term bioabsorbable web scaffold for soft tissue reinforcement, our configured device is designed to support generation of quality tissue fast in hiatal/paraesophageal repairs. For this application, more than 130,000 GORE® BIO-A® Tissue Reinforcement devices have been sold. In addition, clinical literature cites more than 1,850 repairs that show GORE® BIO-A® Tissue Reinforcement is an excellent choice in soft tissue repair* The hiatal hernia configured device is ideal for reinforcement of a concomitant hiatal hernia during sleeve gastrectomies.

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* Data on file, W. L. Gore & Associates, Inc; Flagstaff, AZ.

Supporting patients with a single, effective procedure

Observations of hiatal hernia repair in combination with sleeve gastrectomy.

- Excess weight loss (EWL) in patients undergoing hiatal hernia repair was significantly higher at six months compared to patients undergoing sleeve gastrectomies alone.
- Improvement in patient reported gastroesophageal reflux disease (GERD) symptoms.
- High patient satisfaction post-operatively.

"I started using GORE® BIO-A® Tissue Reinforcement because we wanted the additional confidence that our suture hiatoplasty was going to be secure enough to allow for better healing of that repair. Having the GORE® BIO-A® Tissue Reinforcement scaffolding present has given us more confidence that repair was being bolstered.

We saw success when using [Gore 3D PGA:TMC web scaffold] during our staple line reinforcements so we felt it would be beneficial for hiatal repairs. This gave us confidence in the near term that it would cut down on recurrences in that area of the hiatoplasty.

We have always had confidence in Gore products overall, no fears of mesh migration into the esophagus or that it will disappear overnight."
– John P. Scott, M.D., FACS

*"As a bariatric surgeon, I repair any (hiatal hernia) bigger than two to three centimeters."
– John P. Scott, M.D., FACS*

GORE® BIO-A® Tissue Reinforcement

An innovative 3D mid-term bioabsorbable web scaffold for soft tissue reinforcement that is designed to support generation of quality tissue fast.

- GORE® BIO-A® Tissue Reinforcement has low recurrence rates when used in hiatal hernia repair.¹⁻³
- Long-term results after laparoscopic sleeve gastrectomy with concomitant posterior cruroplasty: Five-year follow-up.⁴
- Comparative study evaluating Hiatal hernia repair with concomitant laparoscopic sleeve gastrectomy.

With GORE® BIO-A® Tissue Reinforcement

Hernia recurrence

4.3%

Sutures without reinforcement

Hernia recurrence

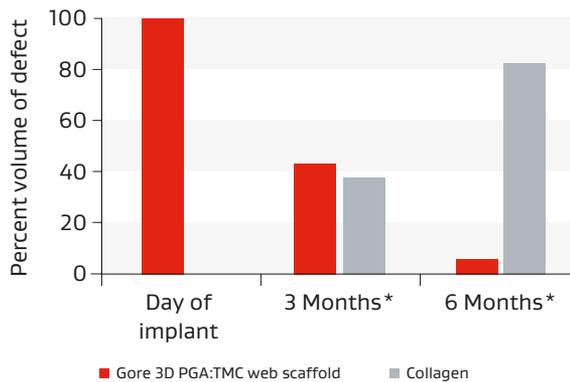
18.4%

“Since there are risks with surgery, we discuss those with all of our patients, including risks of dissection, benefits, how it would affect GERD, reflux, etc. If patients ask about the mesh or express concerns, we tell them that GORE® BIO-A® Tissue Reinforcement is a bioabsorbable material and will not erode into an organ, so these fears are not a significant concern with this mesh and/or specific to a hiatal hernia repair with GORE® BIO-A® Tissue Reinforcement.” – John P. Scott, M.D., FACS



With our 3D mid-term bioabsorbable technology, the patient's own cells migrate into the 3D web scaffold and begin generating vascularized soft tissue within one to two weeks. The Gore 3D PGA:TMC web scaffold gradually is absorbed, usually in six to seven months, and replaced by the patient's own Type I collagen.

Gore 3D PGA:TMC web scaffold replaced by tissue

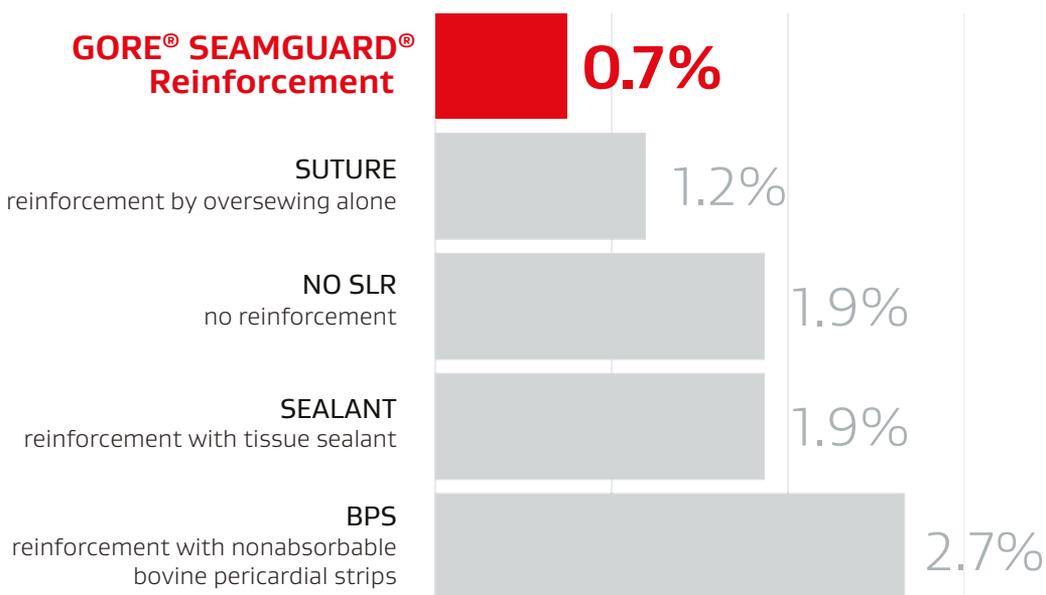


* Cells and blood vessels make up remaining volume.
GORE® BIO-A® Hernia Plug.

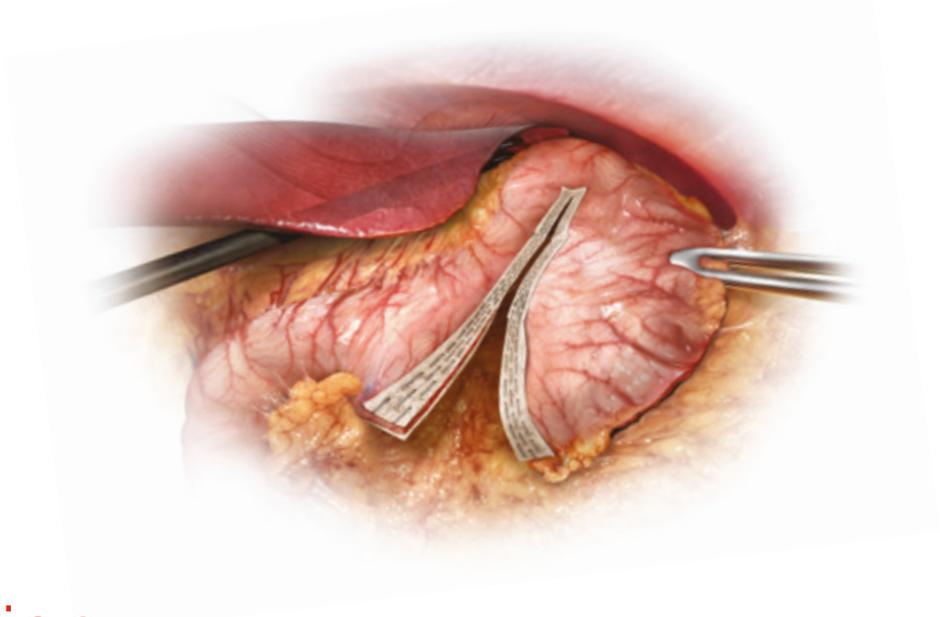
GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

The only* staple line reinforcement proven to significantly reduce leaks in sleeve gastrectomy procedures to minimize complications.

A comparison of leak rate percentages among five staple line reinforcement types:⁵

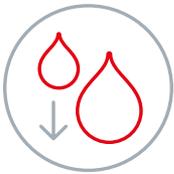


* Considering all systematic reviews and meta-analysis of published articles only, that distinguish between types of staple line reinforcement.



Proven protection

In numerous clinical studies and in thousands of patients, GORE® SEAMGUARD® Reinforcement has demonstrated unrivaled protection that no other technology can match.



35% less bleeding
than no reinforcement on average⁶



4+ million
devices implanted*



15+ years
of clinical human data



85+ clinical studies
published and peer-reviewed*

* Data on file 2021, W. L. Gore & Associates, Inc; Flagstaff, AZ.

References

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4. Boru CE, Coluzzi MG, de Angelis F, Silecchia G. Long-term results after laparoscopic sleeve gastrectomy with concomitant posterior cruroplasty: 5-year follow-up. *Journal of Gastrointestinal Surgery* 2020;24(9):1962-1968.
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Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

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