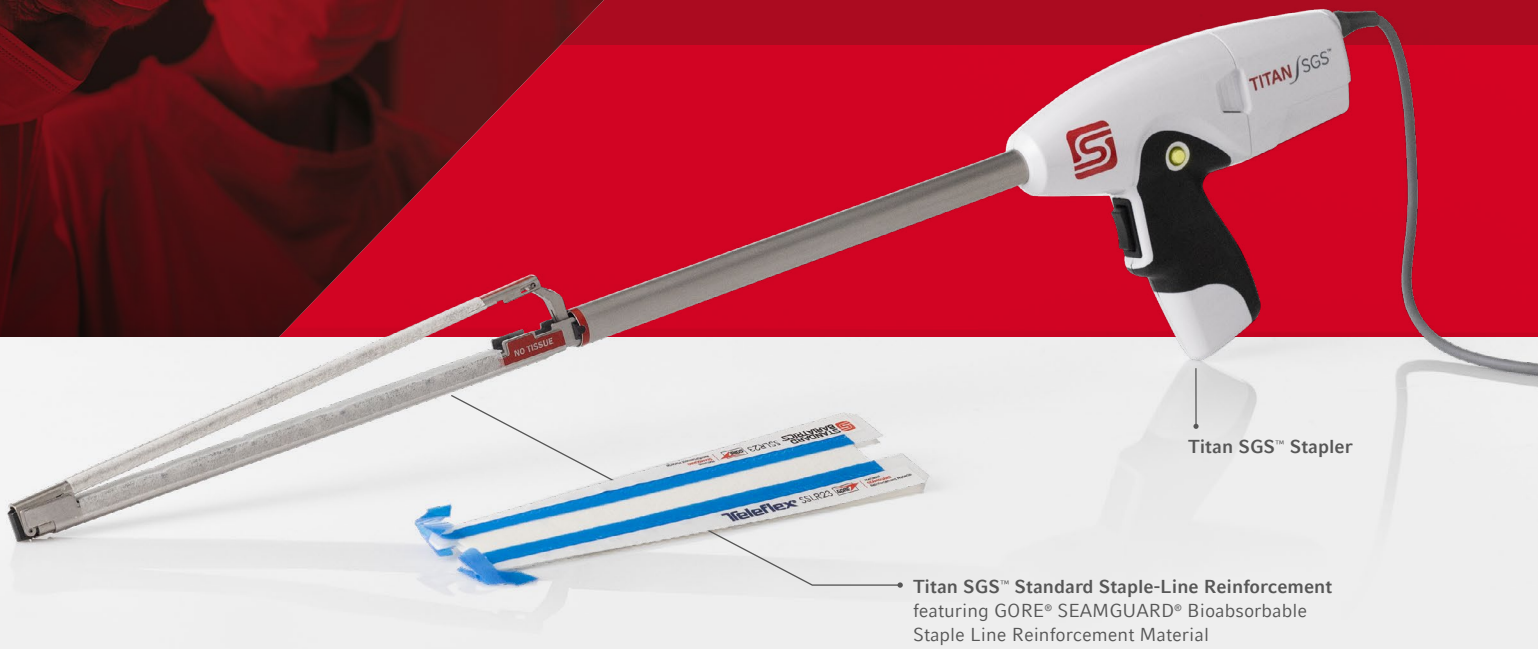
Titan SGS™ Standard Staple-Line Reinforcement *featuring GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material*



Titan SGS™ Stapler

Titan SGS™ Standard Staple-Line Reinforcement featuring GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material

Titan SGS™ Standard Staple-Line Reinforcement and Titan SGS™ Stapler

The Titan SGS™ Stapler, the only purpose-built stapler for gastric tissue with specific indication for sleeve pouch creation in bariatric procedures,[1] is now paired with GORE® SEAMGUARD® Reinforcement Material. This is the only*[2] staple line reinforcement (SLR) material proven to significantly reduce leaks in sleeve gastrectomy procedures.[3]

Paired for use in sleeve gastrectomy

Just as not all bariatric staplers are the same, not all staple line reinforcements are the same. The Titan SGS™ Stapler is a 23cm, single-fire stapler designed to deliver more consistent and symmetrical sleeve anatomy by enabling the Standard Sleeve™ Technique, an anatomy-based approach to sleeve gastrectomy.[1] It is now available with Titan SGS™ Standard Staple-Line Reinforcement featuring GORE® SEAMGUARD® Reinforcement Material.

For more than 20 years† GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material has created an unrivaled legacy of clinical performance.[3-7] Two decades of robust clinical literature detail GORE® SEAMGUARD® Reinforcement Material leak protection and bleeding reduction.[7]

* Considering all systematic review and meta-analysis of published articles only that distinguish between types of staple line reinforcement as of January 2024.
† First commercial marketing authorization, U.S. Food and Drug Administration in April 2003.

Strengths of GORE® SEAMGUARD® Reinforcement Material

0.39% LEAK RATE in the U.S.[3]

5 MILLION+ devices implanted[2]

85+ CLINICAL STUDIES published and peer-reviewed[2]

STANDARD BARIATRICS™ | Teleflex™

Titan SGS™ Standard Staple-Line Reinforcement featuring GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material

A Closer Look at GORE® SEAMGUARD® Reinforcement Material

Designed to protect against leaks

GORE® SEAMGUARD® Reinforcement Material has a significantly lower leak rate compared to other laparoscopic sleeve gastrectomy methods as shown in a systematic review consisting of 148 papers and more than 40,600 patients.[3]

A comparison of laparoscopic sleeve gastrectomy leak rate percentages in the U.S. among five staple line reinforcement (SLR) types:[3]

GORE® SEAMGUARD® Reinforcement Material	**0.39%**
SUTURE reinforcement by over sewing alone	**0.7%**
NO SLR no reinforcement	**1.3%**
SEALANT reinforcement with tissue sealant	**1.8%**
BPS reinforcement with nonabsorbable bovine pericardial strips	**1.5%**

Engineered to protect against bleeding and reduce bleeding complications

Randomized prospective data has shown that GORE® SEAMGUARD® Reinforcement significantly reduces bleeding in gastric bypass procedures.[5,6]

GORE® SEAMGUARD® Reinforcement Material provides a matrix that blood can infiltrate.[8] Platelets within the patient's blood stick together and create a clot to decrease bleeding. The material:

- Conforms to the staple line anatomy[8]
- Reduces blood flow by applying pressure[8]
- Provides a matrix for blood to start clotting[8]

Potential to reduce overall postoperative complication costs

GORE® SEAMGUARD® Reinforcement Material provides reliable protection from surgical complications associated with leaks and bleeding following the laparoscopic sleeve gastrecomy, along with reduced reoperations and readmissions.[3-7, 9]

1 510(k) No. K210278. The Titan SGS linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation. 2021. Database Product Search (March 2023, Product Code: GDW).
2 Data on file 2022; W. L. GORE & Associates, Inc; Flagstaff, AZ.
3 Gagner M, Kemmeter P. Comparison of laparoscopic sleeve gastrectomy leak rates in five staple-line reinforcement options: a systematic review. *Surgical Endoscopy* 2020;34(1):396-407.
4 Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D. Clinical and economic evaluation of absorbable staple line buttressing in sleeve gastrectomy in high-risk patients. *Obesity Surgery* 2016;26(8):1710-1716.
5 Miller KA, Pump A. Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial. Surgery for *Obesity & Related Diseases* 2007;3(4):417-422.
6 Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE. Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial. *Archives of Surgery* 2005;140(8):773-778.
7 W. L. Gore & Associates, Inc. Clinical Performance with Staple Line Reinforcement. Scientific Literature Analysis (n = 8142 patients). Flagstaff, AZ: W. L. Gore & Associates, Inc; 2021. [Literature summary]. 2161018-EN.
8 GORE Medical. (n.d.). Bleeding - Protects against bleeds. GORE Medical GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Data Review – Bleeding. https://www.goremedical.com/products/seamguard---bleeding. Accessed 30 January 2024.
9 Zambelli-Weiner A, Brooks E, Brolin R, Bour ES. Total charges for postoperative leak following laparoscopic sleeve gastrectomy. Presented at Obesity Week 2013: The American Society for Metabolic and Bariatric Surgery and the Obesity Society Joint Annual Scientific Meeting; November 11-16, 2013; Atlanta, GA. A-305-P.

For more information about the Titan SGS™ Stapler and Titan SGS™ Standard Staple-Line Reinforcement, visit standardbariatrics.com/titansgs/slr

For more about GORE® SEAMGUARD® Reinforcement Material, visit goremedical.com/products/seamguard

To place an order: orders@standardbariatrics.com

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