

Standard Bariatrics: Setting a New Standard in Stapling for Sleeve Gastrectomy

This is the second in a two-part series about the journey of a medical device startup to solve an unmet clinical need in bariatric surgery.

by JONATHAN THOMPSON, MD, FACS, FASMBS; MARISSA NOVACK, MD;
and AARON HOFFMAN, MD, FACS

Dr. Thompson is Founder & Chief Medical Officer at Standard Bariatrics, Inc. in Cincinnati, Ohio; Assistant Professor of Surgery Director, Division of WCH General Surgery and Bariatrics; Medical Director, UC Health Weight Loss Center, University of Cincinnati Department of Surgery in Cincinnati, Ohio. Dr. Novack is MIS Fellow, University at Buffalo, Department of Surgery in Buffalo, New York. Dr. Hoffman is Associate Professor, Jacobs School of Medicine in Buffalo, New York, and Division Chief, General Surgery, and MIS Fellowship Program Director.

Bariatric Times. 2022;19(5 Suppl 1):S1–S3.



Jonathan Thompson, MD,
FACS, FASMBS



Marissa Novack, MD



Aaron Hoffman, MD, FACS

ABSTRACT: The prevalence of obesity continues to rise in the United States (US), leading to an even greater number of bariatric procedures being performed every year. Sleeve gastrectomy is currently the most commonly performed bariatric surgery, with results being variable between hospitals and even surgeons. The discrepancies in sleeve anatomy can lead to reduced weight loss and postoperative complications. With these elements in mind, the US Food and Drug Administration (FDA)-cleared 230mm single-fire stapler was created to aid in standardization of the sleeve gastrectomy and improve patient outcomes.

KEYWORDS: Sleeve gastrectomy, bariatric surgery, stapler, stapling technique, single-fire, obesity, weight loss surgery, staple line

In April 2021, Standard Bariatrics (Cincinnati, OH) received United States (US) Food and Drug Administration (FDA) clearance to market the 230mm Linear Cutting Titan SGS® stapler (Figure 1). Titan SGS is the only surgical stapler studied in a clinical trial prior to FDA clearance and the only stapler on the market to have a sleeve gastrectomy indication.^{1,2}

In sleeve gastrectomy, Titan SGS is designed to enable a surgeon to perform a sleeve gastrectomy resection in a single firing of the stapler (Figures 2 and 3). This technique aids the surgeon in planning the ideal resection line, decreases variability in pouch formation, and saves operating room (OR) time.

We took a novel approach to designing an endocutter stapler. Instead of having different cartridge selections that apply to many different types of tissue, we measured the dynamics of the tissue to be stapled, then built a stapler from the ground up. We took tissue thickness measurements from fresh human gastric tissue at a pressure more in line with the pressure applied by staples in tissue.³ We also performed head-to-head comparative testing in fresh human gastric tissue. In this preclinical test, the Titan SGS staple line was shown to be superior in tests of staple line reliability, with fewer malformed staples (Figure 4) and better staple height to tissue thickness matching.⁴

In this same study, in addition to staple line reliability metrics, the burst pressure was highest in the Titan SGS group (Table 1).⁴

One-third of the staple line failures in competitor devices' staple lines occurred at the staple line crossings. This corresponds with the higher risk of malformed staples at



FIGURE 1. Titan SGS stapler and Titan Standard Power Unit

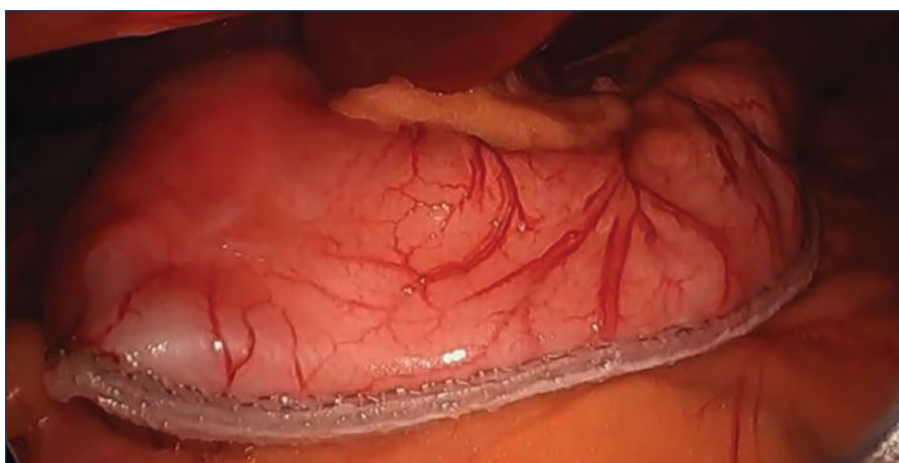


FIGURE 3. Image of Titan SGS stapler yielding a curved sleeve pouch anatomy

TABLE 1. Average pneumatic burst pressure testing of experimental staple lines in human gastric tissue

STANDARD BARIATRICS TITAN SGS (N=15)	MEDTRONIC SIGNIA™ POWERED STAPLER WITH TRI-STAPLE™ TECHNOLOGY (N=18)	ETHICON ECHELON POWERED PLUS WITH GST RELOADS (N=17)
159.8mmHg	128mmHg	102.1mmHg

junctions (Figure 4). Since the Titan SGS has one continuous staple line, its use eliminated the increased leak risk associated with crossing staple lines.

Titan SGS was built through rigorous research and development, beginning with characterization of the target tissue. Standard Bariatrics continues to make research a priority, testing different versions

of the Titan SGS device in the same excised human stomach model. Our goal is to understand the phenomenon of staple height auto-adjustment and optimize stapler design to take advantage of it.⁵

Increased FDA regulations of surgical staplers released on October 8, 2021, reclassified certain FDA Class I surgical staplers to a more stringent FDA Class II.

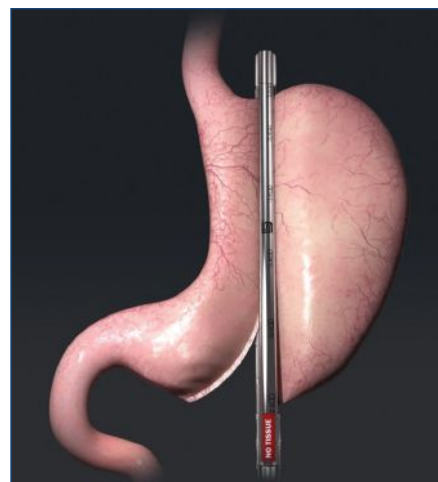


FIGURE 2. Graphic demonstration of Titan SGS applied to the stomach

In addition, in their final order, the FDA mandated labeling of staplers to include “risks specifically associated with the crossing of staple lines.”⁶ The FDA published a concurrent letter to healthcare providers and labeling guidance for the medical device industry clarifying this risk, stating, “Be aware that there is a risk of increased leak rates when staple lines are crossed, even if there may be clinical circumstances when it is clinically necessary or appropriate to do so.”^{6–8}

Titan SGS seems to be a breakthrough in sleeve gastrectomy. Given the positive experimental results, we look forward to future studies looking at the clinical impact, particularly on leak rate, in large registry programs, such as the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).

FUNDING

This supplement was sponsored by Standard Bariatrics, Inc.

DISCLOSURES

Dr. Thompson is Founder & Chief Medical Officer at Standard Bariatrics, Inc. Dr. Hoffman is a Proctor for and has received future options in Standard Bariatrics, Inc. Dr. Novack reports no conflicts of interest relevant to the content of this article.

REFERENCES

1. US Food and Drug Administration. Indications for Use. (510)(k) No.

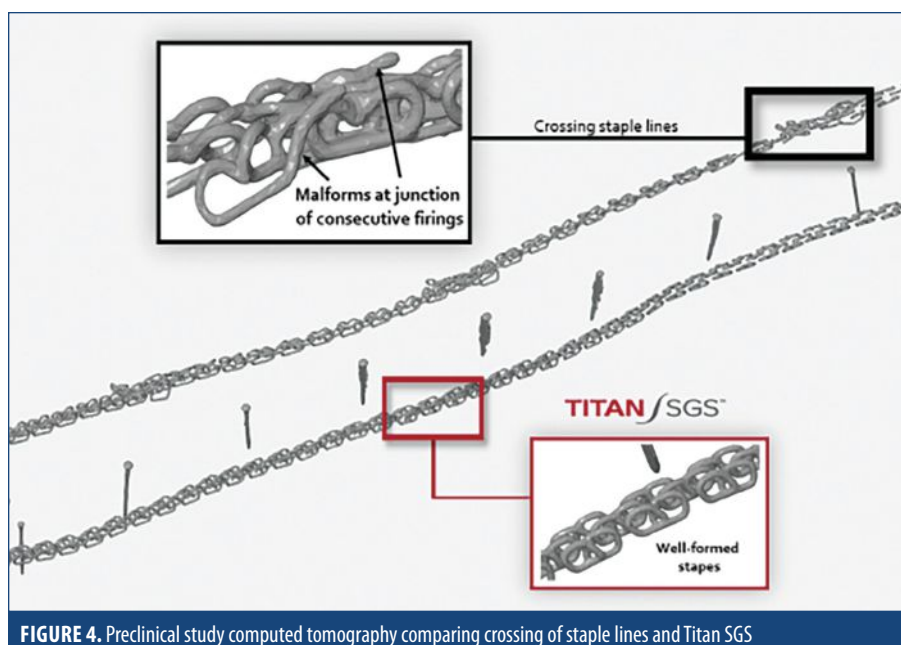
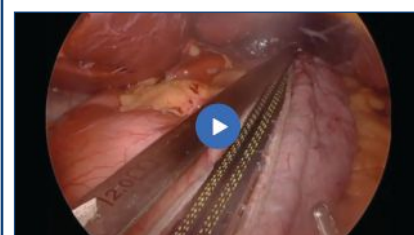


FIGURE 4. Preclinical study computed tomography comparing crossing of staple lines and Titan SGS



VIDEO 1: The Titan SGS stapler produces a hemostatic and consistent staple line by using graduated staple height formation optimized for gastric tissue.

<https://vimeo.com/699170255>



VIDEO 2: Although the Titan SGS stapler is a straight device, it produces a gently curved sleeve similar to the original anatomy of the stomach's greater curvature. This video shows the first human 230mm stapled sleeve gastrectomy in the world, performed by Dr. Aaron Hoffman (SUNY Buffalo) in August 2020 at Buffalo General Medical Center in Buffalo, New York.

<https://vimeo.com/699171036>

1. K210278). 28 Apr 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210278.pdf. Accessed 13 Apr 2022.
2. Salyer CE, Thompson J, Hoffman A, et al. Multisite study of Titan SGS Stapler in longitudinal gastric resection. *Surg Endosc*. 2022;1–8. Published online ahead of print.
3. Yeo E, Thompson J, Hanseman D, et al. Increased staple loading pressures and reduced staple heights in laparoscopic sleeve gastrectomy reduce intraoperative bleeding. *Surgery*. 2021;169(5): 1110–1115.
4. Salyer C, Spuzzillo A, Wakefield D, et al. Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy. *Surg Endosc*. 2021;35(7): 4016–4021.
5. Salyer C, Spuzzillo A, Wakefield D, et al. Endocutter staple height auto-adjusts to tissue thickness. *J Surg Res*. 2021;267:705–711.
6. Federal Register: The Daily Journal of the United States Government. General and plastic surgery devices; reclassification of certain surgical staplers. 8 Oct 2021. www.federalregister.gov/documents/2021/10/08/2021-22041/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers. Accessed 13 Apr 2022.
7. US Food and Drug Administration. CFR—Code of Federal Regulations Title 21. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=878.4740>. Accessed 12 Apr 2022.
8. US Food and Drug Administration. UPDATE: Safe use of surgical staplers and staples—letter to health care providers. 7 Oct 2021. <https://www.fda.gov/medical-devices/letters-health-care-providers/update-safe-use-surgical-staplers-and-staples-letter-health-care-providers>. Accessed 13 Apr 2022. **BT**

Copyright © 2022 Matrix Medical Communications. All rights reserved. This article did not undergo peer review by the Bariatric Times editorial advisory board. Opinions expressed by authors, contributors, and advertisers are their own and not necessarily those of Matrix Medical Communications, the editorial staff, or any member of the editorial advisory board. Matrix Medical Communications is not responsible for accuracy of dosages given in the articles printed herein. The appearance of advertisements in this journal is not a warranty, endorsement, or approval of the products or services advertised or of their effectiveness, quality, or safety. Matrix Medical Communications disclaims responsibility for any injury to persons or property resulting from any ideas or products referred to in the articles or advertisements. For reprint information and pricing, contact Matrix Medical Communications. Bariatric Times (ISSN 1551-3572) is published 12 times yearly by Matrix Medical Communications. The journal is printed by LSC Communications, Shepherdsville, Kentucky.



Printed in the United States of America on acid-free paper.



Matrix Medical Communications • 1595 Paoli Pike • Suite 201 • West Chester, PA 19380

ONE

ONE Device.

ONE Firing.

ONE Staple Line.

ONE Textbook Curve.

TITAN SGS® STAPLER

