

ABOUT STANDARD BARIATRICS

Standard Bariatrics, Inc., is a rapidly expanding medical device company focused on the development and commercialization of products for the surgical treatment of obesity. Driven by a passionate group of surgical innovators, the Cincinnati-based organization works hand in hand with bariatric surgeons to develop and release novel solutions designed to address the growing global epidemic of obesity.

THE STANDARD SLEEVE[®]

Surgical anatomy and symmetry are two of the critical factors affecting outcomes in laparoscopic sleeve gastrectomy (LSG). Standard Bariatrics offers surgeons a new standard in sleeve gastrectomy called the Standard Sleeve[®] that harmonizes techniques through product innovation. This anatomy-based approach (ABA) using purpose-built devices is a proven technique that simplifies visualization, reduces complexity, saves time and enables consistently optimal surgical sleeve anatomy.

TITAN SGS[®] KEY CLAIMS

55 second firing cycle to complete sleeve pouch anatomy

Source: U.S. Food and Drug Administration. (2021). Indications for Use. [510(k) No. K210278]. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210278.pdf

23cm staple line with no overlapping staples

Sources: (1) Goodman. (2020). Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection. Identification No. NCT04347837. Retrieved from <https://clinicaltrials.gov/ct2/show/NCT04347837>
(2) Salyer, C., Spuzzillo, A., Wakefield, D., Gomaa, D., Thompson, J., & Goodman, M. (2020 July). Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy. *Surgical Endoscopy*, 35(7), 4016–4021. <https://doi.org/10.1007/s00464-020-07858-0>

88% less bleeding at the staple line

Source: Standard Bariatrics, Inc. (n.d.). Comparison of Titan SGS to Ethicon Endo-Surgery ECHELON FLEX[™] GST tests on porcine model. *Acute Hemostasis Report QT-0367*. Internal data on file.

82% fewer malformed staples

Source: Standard Bariatrics, Inc. (2020 June) Comparison of Titan SGS to Ethicon Endo-Surgery ECHELON FLEX[™] GST. *Gastric Tissue Stapler Comparison Study QT-0372*. Identification No. NCT04086433. Retrieved from <https://clinicaltrials.gov/ct2/show/NCT04086433>

One (1) firing to complete the sleeve pouch anatomy

Source: Salyer, C. E., Thompson, J., Hoffman, A., Burstein, M. D., Enochs, P., Watkins, B. M., Kuethe, J., & Goodman, M. D. (2022). Multisite Study of Titan SGS Stapler in longitudinal gastric resection. *Surgical Endoscopy*. <https://doi.org/10.1007/s00464-022-09051-x>

OUR TEAM

Matt Sokany

President & Chief Executive Officer

Jonathan Thompson

Founder & Chief Medical Officer

Adam Dunki-Jacobs

Chief Technical Officer

Ronald Galovich

Chief Commercial Officer

Peter Donato

Chief Financial Officer

John McLaughlin

Vice President of Sales

BOARD OF DIRECTORS

Kurt Azarbarzin

Jonathan Thompson, MD

Matt Sokany

Karen Spilizewski

Douglas Reed, MD

Casey Tansey

SCIENTIFIC ADVISORY BOARD

John Morton, MD, MPH, FACS, FASMBS – Yale School of Medicine
Past-President, American Society for Metabolic and Bariatric Surgery
2014-2015

Helmuth Billy, MD – Dignity Health

Thomas Inge, MD, PHD – Ann & Robert H. Lurie Children's Hospital of Chicago

Paul Enochs, MD, FACS, FASMBS – WakeMed

Brad Watkins, MD, FACS, FASMBS – Overlake Medical Center & Clinic, Bellevue, WA

To learn more or to request training, contact:

RONALD GALOVICH

Chief Commercial Officer

513.620.7751 | ron@standardbariatrics.com



PRODUCT LINE

TITAN SGS®

The Titan SGS® stapler offers an elegant alternative for performing sleeve gastrectomy. The device is designed to help achieve more consistent and symmetrical sleeve pouch anatomy, setting patients up for the best possible outcomes.

FDA Clearance: <https://standardbariatrics.com/wp-content/uploads/2021/08/Titan-SGS-FDA-Clearance-Letter.pdf>

STANDARD CLAMP®

Successfully used in more than 12,000 surgical procedures, the Standard Clamp® is a laparoscopic surgical device designed to clamp the entire length of the stomach, enabling surgeons to plan and hold the staple line prior to dividing the stomach during laparoscopic sleeve gastrectomy. This ensures the creation of a more symmetrical, consistent sleeve pouch anatomy, setting patients up for the best possible outcomes.

FDA Clearance: <https://standardbariatrics.com/wp-content/uploads/2021/08/Standard-Clamp-23cm.FDA-Clearance-Letter.pdf>

STANDARD TROCAR®

The Standard Trocar® is part of the complete solution for performing gastric stapling during laparoscopic procedures. Its bladeless technology is specifically designed to meet the needs of the bariatric surgeon looking to utilize the Titan SGS®. The 19mm sterile single-use access port is designed to gain access and introduce Titan SGS into the abdomen for laparoscopic procedures.

FDA Clearance: <https://standardbariatrics.com/wp-content/uploads/2021/08/Standard-Trocar.FDA-Clearance-Letter.pdf>

STANDARD BOUGIE® 38FR

Designed for use with the Titan SGS® stapler the Standard Bougie® 38FR allows surgeons to achieve precise anatomical alignment and protect the incisura angularis during sleeve pouch creation.

FDA Clearance: <https://standardbariatrics.com/wp-content/uploads/2021/08/Standard-Bougie-38Fr.FDA-Clearance-Letter.pdf>

To learn more or to request training, contact:

RONALD GALOVICH

Chief Commercial Officer

513.620.7751 | ron@standardbariatrics.com



standardbariatrics.com

ADDITIONAL CLAIMS AND FACTS

CLAIMS	SOURCES
You can complete the sleeve pouch anatomy in a single firing...	Goodman. (2020). Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection. Identification No. NCT04347837. Retrieved from https://clinicaltrials.gov/ct2/show/NCT04347837
...reducing the risk of anatomy variations associated with multiple, overlapping short-cartridge staple lines	Toro, J., Lin, E., Patel, A., Davis, S., Sanni, A., Urrego, H., Sweeney, J., Srinivasan, J., Small, W., Mittal, P., Sekhar, A., & Moreno, C. (2014 Sept. 1). Association of Radiographic Morphology with Early Gastroesophageal Reflux Disease and Satiety Control after Sleeve Gastrectomy. <i>Journal of the American College of Surgeons</i> , 219(3), 430–438. https://doi.org/10.1016/j.jamcollsurg.2014.02.036
Illustration of closed staple heights along device. Use on tissues easily compressible to the labeled closed staple heights.	No source needed
Titan SGS® was cleared after a successful 62-patient multi-center trial in longitudinal gastric stapling.	Goodman. (2020). Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection. Identification No. NCT04347837. Retrieved from https://clinicaltrials.gov/ct2/show/NCT04347837
The Titan SGS® first-of-its-kind design offers surgeons performing sleeve gastrectomy procedures the industry's longest continuous staple cutline of 23 centimeters.	Goodman. (2020). Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection. Identification No. NCT04347837. Retrieved from https://clinicaltrials.gov/ct2/show/NCT04347837
With a purposeful design, driven by the needs of today's bariatric surgeon performing sleeve gastrectomy, Titan SGS® provides real-time audio and visual feedback, graduated staple height formation, tissue-sensing technology and a firing cycle optimized particularly for the patient's gastric tissue during gastrectomy pouch creation.	U.S. Food and Drug Administration. (2021). Indications for Use. [510(k) No. K210278]. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210278.pdf Gomaa, D., Thompson, J., & Goodman, M. (2021 July). Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy. <i>Surgical Endoscopy</i> , 35(7), 4016–4021. https://doi.org/10.1007/s00464-020-07858-0 Yeo, E., Thompson, J., Hanseman, D., Dunki-Jacobs, A., Thompson, B., Goodman, M., & Diwan, T. (2020, Nov. 28). Increased staple loading pressures and reduced staple heights in laparoscopic sleeve gastrectomy reduce intraoperative bleeding. <i>Surgery</i> , 169(5), 1110–1115. https://doi.org/10.1016/j.surg.2020.10.045
While every patient's anatomy is different, the Titan SGS® long staple line enables surgeons to plan and place staples in one firing, minimizing variations often associated with the current use of multiple overlapping short-cartridge staple firings.	Toro, J., Lin, E., Patel, A., Davis, S., Sanni, A., Urrego, H., Sweeney, J., Srinivasan, J., Small, W., Mittal, P., Sekhar, A., & Moreno, C. (2014 Sept. 1). Association of Radiographic Morphology with Early Gastroesophageal Reflux Disease and Satiety Control after Sleeve Gastrectomy. <i>Journal of the American College of Surgeons</i> , 219(3), 430–438. https://doi.org/10.1016/j.jamcollsurg.2014.02.036
But achieving ideal anatomy can be especially challenging in gastric tissue.	Toro, J., Lin, E., Patel, A., Davis, S., Sanni, A., Urrego, H., Sweeney, J., Srinivasan, J., Small, W., Mittal, P., Sekhar, A., & Moreno, C. (2014 Sept. 1). Association of Radiographic Morphology with Early Gastroesophageal Reflux Disease and Satiety Control after Sleeve Gastrectomy. <i>Journal of the American College of Surgeons</i> , 219(3), 430–438. https://doi.org/10.1016/j.jamcollsurg.2014.02.036
The design ensures more consistent staple formation across the entire 23-centimeter cutline for improved staple-line strength and fewer malformed staples than competitive staplers that offer short cartridges for more general surgical use.	Goodman. (2020). Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection. Identification No. NCT04347837. Retrieved from https://clinicaltrials.gov/ct2/show/NCT04347837 Salyer, C., Spuzzillo, A., Wakefield, D., Gomaa, D., Thompson, J., & Goodman, M. (2021 July). Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy. <i>Surgical Endoscopy</i> , 35(7), 4016–4021. https://doi.org/10.1007/s00464-020-07858-0 Yeo, E., Thompson, J., Hanseman, D., Dunki-Jacobs, A., Thompson, B., Goodman, M., & Diwan, T. (2020, Nov. 28). Increased staple loading pressures and reduced staple heights in laparoscopic sleeve gastrectomy reduce intraoperative bleeding. <i>Surgery</i> , 169(5), 1110–1115. https://doi.org/10.1016/j.surg.2020.10.045

To learn more or to request training, contact:

RONALD GALOVICH

Chief Commercial Officer

513.620.7751 | ron@standardbariatrics.com



[standardbariatrics.com](https://www.standardbariatrics.com)

ADDITIONAL CLAIMS AND FACTS, *continued*

CLAIMS	SOURCES
The Titan SGS® design may result in a more secure staple line and fewer chances of leaks, as evidenced with higher burst pressures.	Salyer, C., Spuzillo, A., Wakefield, D., Gomaa, D., Thompson, J., & Goodman, M. (2021 July). Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy. <i>Surgical Endoscopy</i> , 35(7), 4016–4021. https://doi.org/10.1007/s00464-020-07858-0
Because Titan SGS® takes approximately half the time to create the staple line,	U.S. Food and Drug Administration. (2021). Premarket Notification. (510(k) No. K210278). Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210278 Varban, O. A., Niemann, A., Stricklen, A., Ross, R., Ghaferi, A. A., Finks, J. F., & Dimick, J. B. (2017, Aug.). Far from Standardized: Using Surgical Videos to Identify Variation in Technique for Laparoscopic Sleeve Gastrectomy. <i>Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A</i> , 27(8), 761–767. https://doi.org/10.1089/lap.2017.0184
...it can also potentially improve procedure time and operational efficiencies.	Salyer, C. E., Thompson, J., Hoffman, A., Burstein, M. D., Enochs, P., Watkins, B. M., Kuethe, J., & Goodman, M. D. (2022). Multisite Study of Titan SGS Stapler in longitudinal gastric resection. <i>Surgical Endoscopy</i> . https://doi.org/10.1007/s00464-022-09051-x Varban, O. A., Niemann, A., Stricklen, A., Ross, R., Ghaferi, A. A., Finks, J. F., & Dimick, J. B. (2017, Aug.). Far from Standardized: Using Surgical Videos to Identify Variation in Technique for Laparoscopic Sleeve Gastrectomy. <i>Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A</i> , 27(8), 761–767. https://doi.org/10.1089/lap.2017.0184
Potential improvement in resolution of GERD and nausea	Thompson, J., Dhar, V., Hanseman, D., Watkins, B., Morton, J., & Diwan, T. (2017). Anatomy-based laparoscopic sleeve gastrectomy reduces gastroesophageal reflux disease compared to laparoscopic sleeve gastrectomy with bougie. <i>Surgery for Obesity and Related Diseases</i> , 13(10). https://doi.org/10.1016/j.soard.2017.09.242
Highly variable techniques and device usage yield inconsistent pouch anatomy, thus bariatric surgeons have been able to achieve the ideal tubular sleeve anatomy less than 40% of the time, resulting in inconsistent patient outcomes including GERD and nausea.	Toro, J., Lin, E., Patel, A., Davis, S., Sanni, A., Urrego, H., Sweeney, J., Srinivasan, J., Small, W., Mittal, P., Sekhar, A., & Moreno, C. (2014, May 7). Association of Radiographic Morphology with Early Gastroesophageal Reflux Disease and Satiety Control after Sleeve Gastrectomy. <i>Journal of the American College of Surgeons</i> , 219(3), 430–438. https://doi.org/10.1016/j.jamcollsurg.2014.02.036

To learn more or to request training, contact:

RONALD GALOVICH

Chief Commercial Officer

513.620.7751 | ron@standardbariatrics.com



standardbariatrics.com