

Company

Standard Bariatrics, Inc.

Drug or Device Name

Titan SGS®

Category

Medical Technology

Compound/Technical Name

Titan Standard Gastric Stapler

Trade Name

Titan SGS®

Date of Approval

04/28/2021

Therapeutic Categories

Implantable Staple - Titan SGS® 23cm powered endoscopic nonarticulating gastric surgical stapler (longest uninterrupted staple line).

Indications

The Titan SGS® linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation.

Background

Cincinnati-based Standard Bariatrics, Inc., an emerging leader in the bariatric surgery medical device field was founded in January 2014. The company formed to work on meeting the unmet clinical needs surrounding sleeve gastrectomy pouch creation. At the highest level of clinical need—the disease state of obesity—we started with one of the most undertreated disease states in medicine. Despite being the most successful treatment strategy, less than one percent of the 28 million surgically eligible patients who meet the criteria (BMI of 35+ with comorbidities) for bariatric surgery receive any form of a bariatric procedure. This is old news to bariatric surgeons. The thinking went, if we could find a way to make bariatric surgery seem like gallbladder surgery, which is perceived to be noninvasive and routine to stakeholders (patients, payors, primary care doctors), we might improve the attractiveness of bariatric surgery as a treatment strategy. This came out of the recognition that patients with post prandial right upper quadrant pain and gallbladder are more than likely to have their gallbladder removed even in the absence of an abnormality identified on workup. Why was there such a low threshold for cholecystectomy but such a high one for bariatric surgery? If we could tweak a bariatric surgery to make it significantly safer and more repeatable, the hope was we could lower the intervention threshold for the surgical treatment of obesity. After researching sleeve construction, we identified the following technical problem insight: It is hard to make a straight line in floppy, stretchy,

two-sided tissue. “Freehanding” with general purpose short staplers and a straight bougie results in a high degree of variation in sleeve pouch anatomy. With this, we identified an unmet clinical need that had a technical root cause. If we solved that technical problem, we had the chance to improve the consistency in anatomic output of the sleeve gastrectomy procedure and improve patient outcomes.

Development

The idea of a full-length gastric stapler came from our 1st generation Standard Clamp®, which held along the entire length of the stomach and was connected at both ends. This clamp design provided a unique architecture with broad patentable claims to develop the Titan SGS®. Once we realized that we had physics in our favor with this stronger clamp design, we explored developing a gastric stapler. We set up to develop a consistent, repeatable sleeve pouch anatomy to ensure that the pouch was the proper size, shape, and distances from key anatomic landmarks. We had market research results confirming consensus that surgeons made sleeves 1cm from the gastroesophageal junction, 3cm from the incisura angularis, and 5cm from the pylorus. During clinical sleeve cases with our Standard Clamp®, we identified the key anatomical landmarks and used a 60mm endo stapler through a 12mm trocar. This resulted in sleeves that were better than we were making before and more importantly primed the market for our Titan SGS® 23cm stapler. With 12,000 Standard Clamp clinical cases and results confirmed a curved sleeve shapes can be made from straight staple lines. Incorporating the clamp design in our Titan Stapler and following the same surgical technique, we could move the stomach relative to the stapler to align these anatomical landmarks resulting in a symmetrical shape stomach much like the virgin anatomy. Titan SGS® has now been used in over 2,000 clinical cases and the feedback from surgeons is that this stapler is disruptive and game-changing in the \$1B gastric stapling market.

Innovation

In October 2021, the FDA issued guidance on surgical staplers and staples for internal use. The new guidelines include labeling recommendations that cover the risks specifically associated with the crossing of staple lines. The legacy short staplers require 4-6 firings of a 60mm stapler that require crossing of staple lines and increasing the chances of a gastric leak. The Titan SGS® 23cm continuous 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. Bariatric surgeons are seeing benefits delivered to patients from the anatomy-based approach of Titan SGS® surgical stapler technology from Standard Bariatrics®, Inc. Since the first use in gastric sleeve surgery on August 24, 2021, the Titan SGS® has now been used in over 2,000 clinical cases and efficacy data continues to build. Surgeons who have used the Titan SGS® in sleeve gastrectomy are reporting less operative time and less post-op patient nausea. Surgeons are also describing clean staple lines and the ease of sleeve pouch reproducibility available by using the Titan SGS®. We believe that with improved outcomes, surgery will become the preferred treatment modality for both patients and referring physicians.

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See Company Fact Sheet

Attachments

- 1649553690Standard-Bariatrics-A-Biodesign-Story-BTSOT.pdf
- 1649554468FDA_Release_10.07.2021.pdf

- 1652382975Standard-Bariatrics-Company-Fact-Sheet.pdf
- 1649552418SBI-2100-A_Titan-SGS_Sheet_R10FA_DIGITAL.pdf
- 1652384729Pub_JT_part2_Bartimes.pdf