SPOTLIGHT ON TECHNOLOGY

A SUPPLEMENT TO *BARIATRIC TIMES*
VOL. 20, NO. 5–6 • MAY–JUNE 2023

BARIATRICTIMES.COM

Best Practices for Getting New Technology Through VAC and into the OR: A Titan SGS® Case Study

by JONATHAN THOMPSON, MD, FACS, FASMBS, and JOHN MAGAÑA MORTON, MD, MPH, MHA, FACS, FASMBS, DABOM, AGAF

Dr. Thompson is Assistant Professor of Surgery, Division Director of General Surgery and Bariatrics, West Chester Hospital in West Chester Township, Ohio; Medical Director of UC Health Weight Loss Center, Department of Surgery, University of Cincinnati College of Medicine in Cincinnati, Ohio; and Founder, Standard Bariatrics, Inc. in Cincinnati, Ohio. Dr. Morton is Professor and Vice-Chair, Division Chief, Bariatric and Minimally Invasive Surgery, Yale School of Medicine in New Haven, Connecticut; Inaugural Chair, Committee for Metabolic and Bariatric Surgery, American College of Surgeons; and Past-president, American Society for Metabolic and Bariatric Surgery, 2014–2015.

Bariatric Times. 2023;20(5–6 Suppl 2):S1–S4.

Jonathan Thompson, MD, FACS, FASMBS

John Magaña Morton, MD, MPH, MHA, FACS, FASMBS, DABOM, AGAF

ABSTRACT: Getting a breakthrough medical device through the United States (US) Food and Drug Administration (FDA) is the first step. Next up, hospital purchasing; materials management in the modern operating room (OR) is a complex process. Drs. Thompson and Morton break down the steps of navigating the value analysis process using the Titan SGS as a case study. Several surgeons relay their experiences with the value analysis process as well.

KEYWORDS: Sleeve gastrectomy, bariatric surgery, stapler, Titan, Titan SGS, stapling technique, single fire, obesity, weight loss surgery, staple line, value analysis, VAC

Few things are more painful to a surgeon than bringing new technology into the hospital. Most of us have touched that hot stove before. Value analysis and supply chain stakeholders in operating room (OR) materials management seem to have a pretty simple function—tell surgeons "no" when they ask for anything new.

In two articles previously published in *Bariatric Times'* Spotlight on Technology, my co-authors and I explored the process of innovation and how it is iterative and messy. Since becoming commercially available 18 months ago, each of the Titan SGS accounts has endured the stringent value analysis process and overcome what might seem like iron-clad stapling contracts.

In this article, John Morton, MD, an experienced supply chain committee member, and I have partnered to give surgeons an overview of the typical approach to introducing new technology into a hospital. We will use lessons from the experience of commercializing the Titan SGS as a field guide for navigating the value analysis process, including three best practices you can employ to champion new technology. Following the article are interviews with several surgeons on their experiences with the value analysis process for the Titan SGS.

Implementation is hard but possible, especially when considering the more than 8,000 cases of sleeve gastrectomy pouch creation[1] using the Titan SGS completed in the last 18 months.

THE VALUE ANALYSIS PROCESS

Previously, obtaining new technology for the OR was straightforward for surgeons. We wanted it. We got it. Unfortunately, this process has gone the way of usual and customary charges. The new process is much more involved and has multiple stakeholders (Figure 1). Overall, the value analysis process is not intended for easy adoption of a new device or

BT BARIATRIC TIMES
Clinical Developments and Metabolic Insights in Total Bariatric Patient Care

Sponsored by STANDARD BARIATRICS | Teleflex®

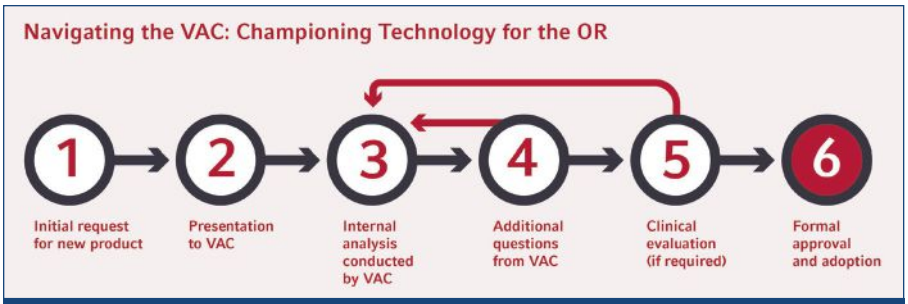

FIGURE 1. Generic value analysis process cycle

product and can therefore be burdensome.

We know that the goals of OR materials management are to improve patient outcomes and reduce overall procedure cost. These goals are shared with the surgeon who understands that healthcare value equals outcomes divided by cost.

Ultimately, for a device to be adopted, surgeons must become champions and prepare for what seems like a battle in the value analysis journey, arming ourselves with the clinical and economic data to shepherd our device of choice through the value analysis process. This is the first of three best practices: **become champions for our desired products by beginning the value analysis process well prepared**.

The value analysis process begins when a surgeon seeks a new or different product from what is currently available for the same job. If the desired product is not yet in the purchasing system, we can request it. A request then triggers a set of questions from the Value Analysis Committee (VAC) that need to be answered. See Table 1 for examples of commonly asked questions and responses about the Titan SGS®.

A surgeon who wants to introduce a new technology into their OR must take an active role in this process. We must become a champion for the device, our staff, the OR, and our patients.

This is a moment in the process where the device manufacturer becomes an ally. Sales representatives are well equipped to answer VAC questions, and although they cannot attend VAC meetings, they should be able to provide the necessary data to complete the value analysis submission.

In some cases, new technology does not represent a one-to-one product swap on a procedure card. Using the Titan SGS as an example, the job it helps a surgeon complete is not *stapling*, per se. The job is *sleeve gastrectomy pouch creation*.[2] Therefore, products used in sleeve gastrectomy pouch creation that the Titan SGS and its accessories will replace must be accounted for in a comparative analysis. That includes stapler handles, stapler reloads, staple line reinforcement products, bougies, hemostatic agents, sutures, and clips.

Since the equipment set varies widely from one OR to another and from one surgeon to another, information on what we use, with what frequency, and at what unit cost can usually be obtained from materials management staff. Since they do not perform sleeve gastrectomy pouch creation, we, as experts and champions, can apply the second best practice: **work in partnership with hospital administration to understand the true cost and potential savings of introducing the new technology.** This includes the cost of the device and accessories as well as OR time, length of stay, and other variables, illuminating the overall value and cost savings associated with the product package and procedure.

Following the initial request, written submission, presentation to and analysis by the VAC, and resolution of open questions, several outcomes are possible: denial, clinical evaluation or trial, additional VAC questions and subsequent analysis, and/or, ideally, formal approval and adoption.

Contracts are the last hurdle to consider. Since the Titan SGS is a stapler and there are endomechanical contracts and rebate programs, contracts are a common topic. Contracts and rebate programs come in many flavors, making this the third best practice: **understand both the limits and the opportunities with existing contracts**.

Most contracts include a no-cross-reference and/or new or breakthrough technology clause. Products determined by the local hospital system or group purchasing organization (GPO) to be no-cross-reference and/or new or breakthrough technology nullify the constraints of a contract. If there are purchasing minimums in the contract that might be affected by the reduced use of legacy stapling products, those can be addressed with increased revenue from more cases done in the same OR block, reduced overall procedural spend, and reduced length of stay.

In conclusion, value analysis plays an important role in controlling hospital costs and reducing waste. Believe it or not, we are on the same side, trying to improve patient outcomes and reduce costs. While the process of going from bench to bedside can be arduous, the ability to solve the value equation is too compelling to ignore. Surgeons need to understand the new product request/value analysis process. As champions, we can leverage device manufacturers' expertise in managing the value analysis and contract processes to reduce the strain of value analysis and thus increase the odds of successfully obtaining products that help improve surgical and patient outcomes.

INTERVIEW: JON SCHRAM, MD, FACS, FASMBS

How did you address the cost reduction challenge with VAC?

JS: We saw a cost savings immediately. I'm one of five surgeons who does sleeve gastrectomies at our facility. When we looked at the cost of materials for the Titan SGS compared to the technique of the five surgeons at that time, there was a cost savings based on the average number of fires for each surgeon.

Is there anything else you want to share about your experience in using Titan SGS?

JS: It's a better technique for us for sure. Once the Titan SGS was introduced to our group, we adapted to the new technique and said, "We're not going back." Even the guys who do these with a robot would say, "I'm still going to use the Titan SGS when I do this procedure because it just creates a much better sleeve."

INTERVIEW: PAUL ENOCHS, MD AND JAIME BULL, PA

What's your personal experience and story working with VAC?

PE: We did have a little pushback with VAC like any time you have a new instrument. Our GPO provider was able to help us understand that the

TABLE 1. Economic and clinical value analysis frequently asked questions and responses for the Titan SGS®

PRIMARY FUNCTION: STAKEHOLDERS *(VALUE DRIVERS)*	KEY CHALLENGES/ OBJECTIONS	RESPONSES
Economic: Materials Manager, Supply Chain Cost *(OR time, productivity gains)*	How is the Titan SGS unique compared to current linear staplers?	**a)** The Titan SGS is the only stapler available in the US with a specific indication for sleeve pouch creation in bariatric procedures.[2] **b)** It is the first-of-its kind 23cm single-fire powered stapler,[3,4] designed to aid in standardization of sleeve gastrectomy. The longest general-purpose endocutter staplers are 6cm.
Clinical and Economic: OR Director, Director of Surgical Services, Finance *(total value [benefit over replacement], cost, clinical outcomes, strategic value)*	Does this product have lower/similar cost than current products in use?	**a)** True cost comparison is challenging, as it is surgeon/hospital specific. It is not a stapler-to-stapler comparison, but an "equipment to accomplish a job" comparison with the different techniques—anatomy-based vs. freehand sleeve. Supplies required to create a sleeve gastrectomy pouch must be considered (stapler/type and number of cartridges/buttress/clip applier/hemostatic sealant, etc.). A freehand sleeve creation can require up to 7 cartridges, compared to a single fire required by the Titan SGS.[3] **b)** Using the Titan SGS is associated with the reduction of OR time by over 20% per case,[5] which may allow for at least 1 additional case in a surgeon's OR block time. On average, hospital reimbursement for 1 sleeve gastrectomy procedure ranges from $9,700–18,000 nationally.*[6] **c)** Using the Titan SGS is associated with the reduction of an average LOS by 1 day,[5] which might have the potential to reduce overall cost of care. On average, hospital adjusted expenses are $2,883 per inpatient day nationally.[7]
Clinical and Economic: Hospital Contract Manager (*cost, product standardization)*	How is this new product better than the current alternatives? How does it support standardization?	**a)** Crossing staple lines leads to increased risk of leaks.[8] The Titan SGS delivers a 23cm staple line with no overlapping staples.[3,4] **b)** The Titan SGS aids in standardizing sleeve gastrectomy for consistent outcomes.[9] **c)** SET Data Collaborative has 8 sites contributing data, with over 2,100 Titan SGS cases with at least 30-day outcomes. OR time, LOS, and readmission are lower with the anatomy-based approach vs. freehand sleeve. Data is being prepared for peer-reviewed publication.[5]
Clinical: Surgeon, Head of Nursing (*ease of use, outcomes/clinical need, inventory management)*	Is there a cross-reference? Will this affect my contract compliance or my growth rebate? Does it allow me to remain compliant with my GPO agreement?	**a)** In 2023, the Titan SGS was awarded the Premier GPO contract (mid-contract cycle) recognizing the novel technology and overall outcomes. No cross-reference product from any other supplier is available. **b)** Most purchasing contracts have a new/novel technology clause to allow introduction of technologies that advance patient care. Provide this information to hospital administration to defend threats for contract compliance and rebates. **c)** While many hospitals have exclusionary stapling contracts mandating a certain level of use with the contracting vendor, these agreements allow noncontracted use up to a certain percentage or, importantly in this case, if the current vendor does not have a similar product. **d)** The VAC does not view innovative technology as must-have to keep up with other hospitals in a technology arms race. The VAC genuinely wants to know how this helps produce value which is a composite metric of cost, safety, efficacy, and efficiency. Partner with your hospital administration to demonstrate the value of the Titan SGS.

*Hospital reimbursements for sleeve gastrectomy are ranges based on DRG codes for a sleeve gastrectomy procedure with no complications/comorbidities, with complications/comorbidities, and with major complications/comorbidities.
OR: operating room; US: United States; LOS: length of stay; DRG: Diagnosis Related Group; GPO: Group Purchasing Organization; VAC: Value Analysis Committee

Titan SGS doesn't fall into the same constraints as a 60mm stapler.

How did you address the cost reduction challenge with VAC?

JB: We were able to show cost reduction not only from operative time, but also from showing some savings, as well as fewer staple loads, less buttressing, and better outcomes.

PE: By showing that we could use fewer staple loads in each case, using the Titan SGS was actually a cost reduction. The clinical benefit of it was enough, in my mind, that even if it was cost neutral or even cost a little more, it would probably be okay.

Have you observed any benefits of using the Titan SGS technology for you? For your patients?

JB: I can sing praises of the Titan SGS all day long from a lot of different perspectives, but I think the biggest thing is postoperative Day 1 on the floor. It does appear that patients are having less nausea, and they're more apt to want to drink more. They're not feeling the reflux and nausea.

PE: In the United States (US) Food and Drug Administration (FDA) trial, we only did about 20 cases, but we were getting calls from the physician assistants and nurses on the floor saying, "What are you doing differently? These patients seem better—they have less nausea, they have less reflux," and they didn't even know we were doing something different.

In the OR, I can tell you, and we've made presentations about the Titan SGS before, and you can put your two staple lines right next to each other on the screen and have a Titan SGS staple line on this screen and a non-Titan SGS staple on the other screen. You look at the two and it's a night and day difference. You can actually see a beautiful smooth staple line of a Titan SGS and this jagged one, even if you're trying to make it look good, with a non-Titan SGS staple line.

INTERVIEW: JOHN S. OLDHAM JR., MD, FACS, FASMBS, DABS

What's your personal experience working with VAC regarding cost reduction?

JO: My technique has evolved over the years. First, starting out with sleeves, I would use a double-sided buttress. Sometimes, I would even oversew. Then, with cost of the buttress, I went to a single-sided buttress, and even without buttress for a while. I did see a bit of bleeding, so I went back to a single-sided buttress. Then, with the Titan SGS, it's been very hemostatic. I went from a single-sided buttress to no buttress with the Titan SGS. That has helped to reduce cost. I use fibrin sealant on the staple line. Years ago, I was using 10mLs, and now with the Titan SGS, I am using 2mLs. The Titan SGS, timewise, has a much quicker OR time and is more efficient.

Overall, we are doing more outpatient surgeries and are able to do that with less nausea and reflux that I'm seeing, and they're able to go home the same day much easier than before. It's very nice to see that dry staple line and not have to put clips, cauterize the staple line, and oversew it. Very nice.

FIGURE 2. The Titan SGS® stapler

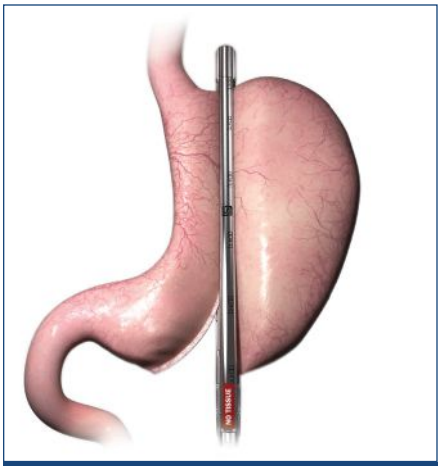

FIGURE 3. Graphic depiction of the Titan SGS applied to the stomach

What was your initial reaction when you started using Titan SGS?

JO: When you first see that nice, straight staple line with the Titan SGS—and I do telesurgery, and the surgeons see it for the first time, and they're like, "Wow." It's just that nice—and to see it be very hemostatic, and not having to cross staple lines. There's always a concern about crossing staple lines, with leaks and bleeding in those areas. Also, there's the concern of spiraling or twisting of the sleeve. We just don't see any of that with the Titan SGS. Getting that consistent sleeve for every patient is very nice. Seeing that exact same sleeve every single time—where we're not having to free fire with the multiple firings of the stapler, which could be six or seven firings of a 60mm stapler.

When most surgeons see it, they're saying, "Wow, what a nice, straight staple line and not getting any spiraling." It just looks so much better than with the multiple firings. Especially in the fundus, if the surgeon gets off track, it is much easier to leave some retained fundus, possibly, when you're doing these multiple firings. With the Titan SGS, since you've got it all lined up and you can check it all out before the firing, you have your sleeve with the Titan SGS clamp down, and you have the view of your sleeve before you fire. You can't do that with the multiple firings of the 60mm stapler. You're doing it as you go. You can always see that before you fire the Titan SGS, and if you ever need to reposition it, you can do that.

I do robotic as well and use the Titan SGS there. I had to go to the Titan SGS pretty quickly on those cases. It's just better overall, being more hemostatic with shorter OR times, less bleeding, less nausea, and less heartburn. You pretty much see these right off the bat.

INTERVIEW: AARON HOFFMAN, MD, FACS

What do you think about the VAC approval process?

AH: Number one is that the VAC approval needs to be shepherded and promoted by the surgeon. It shouldn't be left to the committee—it has to be surgeon driven. The VAC approval needs the sponsor of a surgeon who believes in the technology. It's clear that if there's not a surgeon advocate and they just say, "Oh no, another bariatric stapler," then I would say that the chances of it getting through the VAC on the first try are very low. You need a surgeon to take this personally and explain that patients will benefit from the technology.

There is a significant time savings with the Titan SGS compared to standard laparoscopic sleeve and certainly robotic sleeve, and hospitals have a very hard time valuing the minutes per case in the OR. They still struggle with that. To run the OR with anesthesia, the scrub tech, the nurse—all those costs are underrecognized by the hospital. Time savings is hard for the hospital or VAC to understand because they're usually just looking at the device costs and not the overall contribution margin, and that's something I think the VACs need to understand.

Interviews were edited for length and clarity.

FUNDING

This supplement was sponsored by Teleflex, Inc.

DISCLOSURES

Drs. Thompson, Morton, Enochs, Hoffman, Schram and Oldham are paid consultants for Teleflex and members of the Titan SGS Scientific Advisory Board. Jaime Bull is a paid consultant for Teleflex.

REFERENCES

1. Data on file. Teleflex Inc.
2. United States Food and Drug Administration. Titan SGS is a sterile, single patient use instrument used for longitudinal transection and resection of the gastric tissue for sleeve gastrectomy pouch creation. Source: 510(k) No. K210278. 28 Apr 2021. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210278.pdf.
3. Salyer CE, Thompson J, Hoffman A, et al. Multisite study of Titan SGS stapler in longitudinal gastric resection. *Surg Endosc*. 2022;36(8):6285–6292.
4. Salyer C, Goodman M, Kuethe J, et al. Multisite study of Titan SGS stapler in longitudinal gastric resection. 2021.
5. Standard Bariatrics, Inc. Multisite comparison of Titan SGS to existing surgical staplers in sleeve gastrectomy. (Unpublished raw data). Qualitee 360 Report. 2022. Retrieved from Metabolic and Bariatric Surgery Accreditation and Quality Program database.
6. Centers for Medicare and Medicaid Services. FY2023 Wage Index Home Page. https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy2023-wage-index-home-page. Accessed 10 May 2023.
7. 1999–2021 American Hospital Association Annual Survey. Copyright 2021 by Health Forum, LLC, an affiliate of the American Hospital Association. Accessed 18 May 2023.
8. United States Food and Drug Administration. Surgical staplers and staples for internal use – labeling recommendations. 8 Oct 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labelingrecommendations. Accessed 16 May 2023.
9. Thompson J, Novack M, Hoffman A. Standard Bariatrics: Setting a new standard in stapling for sleeve gastrectomy. *Bariatric Times*. 2022;19(5 Suppl 1):S1–S3. BT

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