REFLECTIVE ESSAY

Nicholas Edwards

Throughout my writing process in Written Communication for Engineers, I had the opportunity to refine my research skills in a professional setting. Through Dr. Marzluf's guidance, collaboration with Jason Coleman and K-State Libraries, and a highly engaging topic to explore, I found ENGL 415 to be a formative experience as I prepare for my new role post-graduation.

Since career exploration during high school courses, I've been enamored by the medical device development process, which frequently enters the news. In our diverse and changing world, individuals have continued to question oversight and regulation, asking powerful questions about the FDA's existing five-step device development process and its efficacy in the healthcare space. As I began narrowing my topic space, I quickly realized I wanted to bring attention to existing gaps in our process, synthesizing various perspectives (government, company, and research) to share with my peers.

Most of my research relied on several STEM-based databases accessed through K-State Libraries, including American Society for Testing and Materials Compass, Applied Science and Technology Abstracts, PubMed, and Gale Health and Medicine. Early in the semester, Jason Coleman visited our class to walkthrough strategies to find keywords related to our project. He shared ideas about using Advanced Search operators like 'and' or 'not' and quotation marks for collective terms like "stent migration" and "endoscopic sutures," which accelerated my ability to sort through devices unrelated to my scope. These were research techniques I had previously not needed, as the majority of my underclassman experience revolved around math equations on notebook paper, but found handy as I searched for analogous devices that had relied on the FDA's substantial equivalence process. I had previously not given much consideration to the keywords that I was plugging into our databases; in a world now adapting to artificial intelligence, better understanding how to use the tools we have at our disposal might just be golden key to career success.

One tool through K-State Libraries that I used for the first time was the interlibrary loan. I requested the article, *Nurses' use of the clinically aligned pain assessment tool: A mixed methods study* by Sandra Hagstrom, hoping to add more qualitative analysis for my Proposal Requirements. Although the source itself turned out to be too narrow in scope to the specific role of caregivers to be used in my report, I was excited to try this new technique. When researching, I find that sometimes we let initial roadblocks halt our progress: whether we are faced with a required subscription or way-too-technical journal, it can be easy to simply look in another direction. With this source, I outlined the reasons for requesting access and persevered past this initial fatigue – I would recommend students do the same, as often, exploring sources that counter our existing understanding of the material can be more beneficial than finding ones that don't.

The largest challenge in this process was identifying the criteria I used to include or exclude sources from my project. My engineering brain found value in the *Journal of Biomedical Materials Research* and *Biotextiles as Medical Implants*, as I recognize the peer-review process critical to work submitted in these journals; however, my Formal Report extends beyond the scientific concerns of the VICI VENOUS STENT System and into the raw, human nature of a failing healthcare system.

For many weeks, I scavenged databases wanting to find the exact price associated with a product recall and the specific number of individuals who filed complaints with the device through the FDA's Medical Device Recall center; I realized that I had been 'forcing' sources to fit into my narrative. In particular, the identified cost drawback identified in my Preliminary Short Report in Paunescu's *Budgets and Billing in Clinical Trials: DCT Considerations,* while replete with a strong list of references, was written with a find-the-loopholes-in-the-industry mindset. This offered a strong moment of learning for me – that all sources are written with a perspective in mind, and it is our duty to hold this perspective to root out bias that can reduce the value of our work. As I write this reflection piece, I see now that eight sources I used in my Preliminary Short Report, including *Stent migration following endoscopic suture fixation of esophageal self-expandable metal stents: a systematic review,* which formed the foundation of my project, were not used in the Formal Report at the end of the semester. This demonstrates my newfound ability to avoid finding sources that play directly into my hand, and instead, search the K-State Libraries Databases for all sources available.

This summer, I will begin my role as Manufacturing Development Program Associate with BD, helping improve process efficiency through quality and continuous improvement projects. Although the regulatory steps of Device Discovery and Pathway to Approval have long preceded my role, my research into the costs of product recalls can help inform the attention-to-detail that comes with this opportunity. I leave this Formal Report having a better understanding of how to skim through technical details, which will help as I read through operating manuals and Standard Operating Procedures; overcome roadblocks, which will be plentiful as my career progresses; and synthesize many perspectives into a single Proposal, a skill that our world desperately needs. I thank Dr. Marzluf and Jason Coleman for their work in helping students like me hone our research skills and build a strong, professional foundation. I've cherished the opportunity to conduct powerful research to broaden my understanding of the field I'll be leading change in, while challenging my existing understanding of what it means to research.

A FORMAL REPORT EXPLORING THE ADDITION OF ENDOSCOPIC SUTURING AS AN ANTI-MIGRATION FEATURE FOR BOSTON SCIENTIFIC'S VICI VENOUS STENT SYSTEM

Submitted To:

Lance Bates

Senior Vice President and President, Interventional Cardiology Therapies

Boston Scientific

Submitted By:

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Boston Scientific

May 3 2024

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3 May 2024

Lance Bates
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Subject: Completed Formal Report Exploring Endoscopic Suturing

Dear Mr. Bates:

I am honored to share the following report, "A formal report exploring the addition of endoscopic suturing as an anti-migration feature for Boston Scientific's VICI VENOUS STENT System," which was approved on March 15, 2024, by Sr. Product Manager, Nick Johnson, who oversees the device development team for the VICI VENOUS STENT System. This report includes key research highlights about the potential testing and analysis of endoscopic suturing.

This report demonstrates the success of endoscopic suturing as an anti-migration feature in existing devices and provides Boston Scientific with a comparison matrix of potential synthetic and natural biomaterials to be used as suture materials. This report is divided into five sections: applications of endoscopic suturing on the market (p. 6), biomaterials that can be used as sutures (p. 9), cost analysis (p. 13), government regulations (p. 15) and a recommendation on the implementation of sutures to the existing device (p. 18).

If continued research into the VICI VENOUS STENT System is approved, the next step is organizing a new, cross-disciplinary research and development team to begin testing polypropylene as an endoscopic suture biomaterial, as it demonstrated the best device potential throughout the research process. Boston Scientific will be able to leverage the FDA's Premarket Notification 510(k) for an accelerated concept-to-market timeline to return the life-saving device to patients in-need while mitigating costs associated with the product recall.

As a member of the VICI VENOUS STENT System's Research and Development Team, I am grateful and honored for the opportunity to further the device design process to meet the needs of our patients. I would like to thank Mr. Johnson and Asif Ashraful, R&D Engineer II, for their continued support of my research during the last few months.

I am looking forward to hearing feedback about this report. Please do not hesitate to reach out to share your thoughts about the future of the VICI VENOUS STENT System.

Sincerely,

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ILLUSTRATIONS

INTRODUCTION TO THE DISCUSSION

Boston Scientific has separated itself from competitors in the medical device industry by its value-centered approach, “dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world” (Boston Scientific, 2024). With a suite of products in every specialty from vascular surgery to interventional radiology, Boston Scientific leads the way in meeting unmet patient needs with its team of 45,000 employees. With every new product launch, our team shares a deep sense of pride in developing life-saving technologies for our global community. The recent recall of the VICI VENOUS STENT System provides an opportunity for Boston Scientific to reaffirm its values and commitment to continuous improvement, ensuring the patients who drive our work are put first.

As a member of the VICI VENOUS STENT System’s Research and Development Team, I have in-depth knowledge about the current device’s technical specifications, clinical trial results, and potential to change to the world. Despite thousands of successful implementation procedures that have supported patients fighting iliofemoral occlusion, the VICI VENOUS STENT System has migrated away from its target region in many patients. Without an anti-migration feature, the device succumbs to high shear forces which can dislodge its stent structure and could lead to fatalities. This problem has led to a device recall which has pulled the device from the market without a plan for patients currently relying on the device or patients expected to undergo device implementation.

On March 9, 2024, I submitted a proposal to research endoscopic suturing as an anti-migration device feature to combat this issue and prevent stent migration. One week later, on March 15, 2024, the proposal was approved, and I began researching the implementation of endoscopic suturing to the existing stent structure, with the following key objectives:

1) Review the Instructions for Use of many existing stent-based devices that employ sutures as an anti-migration feature to understand the market.
2) Research the U.S. Food and Drug Administration’s five-step Device Development Process to better understand regulatory standards.
3) Create a comparison matrix of several biomaterials to select the candidate that best addresses the root cause of the device recall.

This report reflects my research into this up-and-coming technology. First, the report analyzes current uses of endoscopic suturing for device fixation. Next, the report explores several biomaterials that could be used as sutures. Then, the report includes a discussion on costs and government regulations to assess the feasibility of continued investment. Finally, the report will recommend one biomaterial for research and development testing.

RESEARCH AND DEVELOPMENT INTO ENDOSCOPIC SUTURING

For the addition of any new device feature, preclinical research and feasibility studies are critical before clinical testing. Key research in this report outlines the background of endoscopic suturing, several biomaterials that can be used as suture materials, and the mechanical addition of the feature to the existing stent structure.

Background to Endoscopic Suturing

Sutures have traditionally been used in medical settings to close incisions created during surgery. Composed of absorbable and nonabsorbable biomaterials, sutures are vigorously tested for biocompatibility, the ability of a material to be in contact with a living system and not produce harmful effects. Within the last decade, additional applications for sutures have been explored, including the termination of arteriovenous fistulas, the closure of endoscopic perforations, and stent fixation (Stavropoulos, Modayil, & Friedel, 2015). The recent development of endoscopic sutures as a stent fixation or anti-migration device feature is demonstrated in Figure 1, where endoscopic sutures mechanically tie the implanted stent to the inner walls of its target blood vessels.

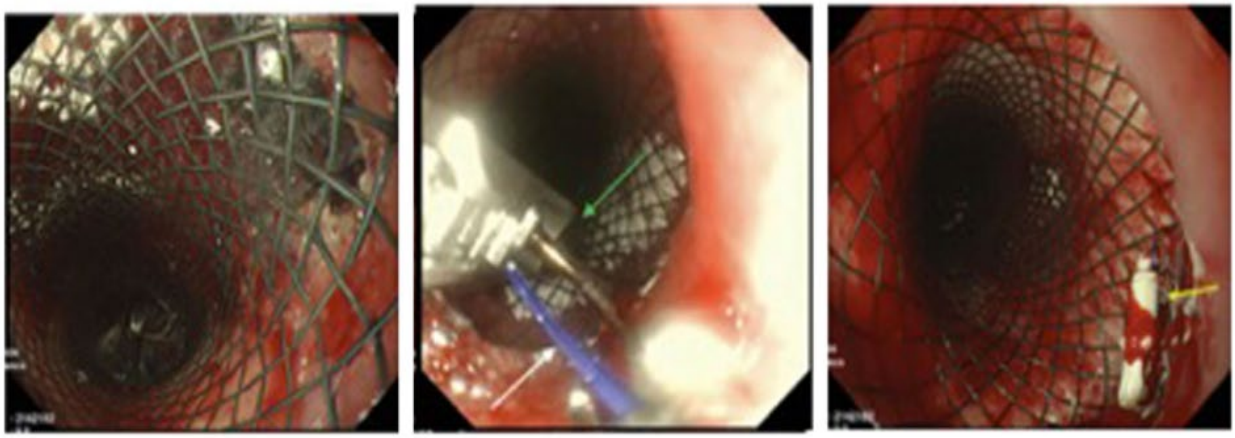

Figure 1: Stent-Based Endoscopic Suturing

Adapted from *Endoscopic suturing device with Overstitch for esophagealstent fixation*, by Li, Xuan; Zhang, Weifeng; Zhang, Guoxin. 2019, *Digestive Endoscopy.*

Stent-Based Applications of Endoscopic Suturing on the Market

Although non-surgical applications for endoscopic suturing continue to expand, several devices currently demonstrate the success of endoscopic suturing as an anti-migration feature. The following devices can provide foundational knowledge and clinical data to assist in research and development efforts.

G-SURG GERDx

G-SURG GmbH has designed GERDx, a device used to combat gastro-esophageal reflux disease (GERD) within the digestive tract. This device delivers one to three endoscopic sutures along the gastric lining to prevent acid regurgitation in the esophagus (Weitzendorfer et al., 2018). Initially, the sutures failed in 50% of patients; however, after the suture size was decreased from 2.0 to 0.0, the sutures were over 95% successful (Weitzendorfer, et al., 2018). Figure 2 depicts the implementation process of endoscopic suturing in the GERDx device.

GERDx uses polyamide, a monofilament non-absorbable suture, which is explored later in this report as a biomaterial candidate for endoscopic sutures. As a result, there exists an excess number of in-patient studies to assess the short and long-term biocompatibility concerns of polyamide.

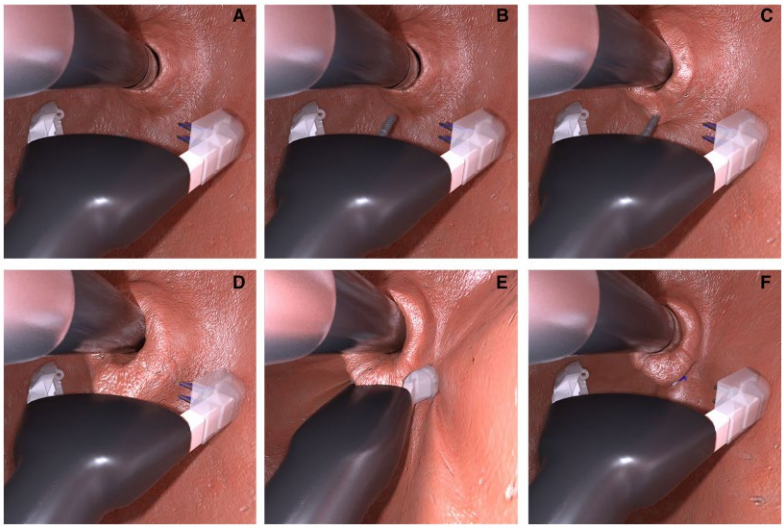

Figure 2: Endoscopic Sutures in G-SURG GmbH's GERDx

Adapted from *Clinical feasibility of a new full-thickness endoscopic plication device (GERDx) for patients with GERD: results from a prospective trial*, by Weitzendorfer, M.; Spaun, G. O.; Antoniou, S. A.; Witzel, K.; Emmanuel K.; Koch, O. O. 2018, *Surgical Endoscopy.*

CR BARD Endoscopic Technologies:

In Bard's CR BARD Endocinch Plication, endoscopic sutures were again used to support the implantation of a device used to prevent GERD in upper gastrointestinal endoscopy. Initial trials demonstrated an over seventy-five percent success rate of device fixation because of the endoscopic sutures, statistics that reflect successful anti-migration efforts (Byrne, et al.). However, the Endocinch ultimately was considered a failed device as patients didn't experience significantly reduced rates of GERD (Mahmood & Ang, 2007).

This device is placed in an internal environment subject to high shear forces, like the iliofemoral veins targeted by the VICI VENOUS STENT System and is also delivered as a feature of a stent-based device, making it a strong point of comparison to highlight the potential and future success of endoscopic suturing.

Boston Scientific's WallFlex Biliary Transhepatic Stent System

The industry has expanded to use sutures in endovascular applications, including right here at Boston Scientific, with the WallFlex Biliaty Transhepatic Stent System. The device is covered in a silicone polymer designed to prevent occlusion of the bile duct with a self-expandable stent system (Peteresen, et al., 2013). Boston Scientific implemented a polyester suture at one end of the device to allow for easy device re-positioning or removal. The stent ends on the exterior surface of the sphincters were also flared to support fixation (Martinez, Puc, & Quiros, 2011). An endoscopic image of this stent being mechanically attached to the blood vessel in the WallFlex device is depicted in Figure 3.

Ultimately, the device shares many similarities to the potential redesign of the VICI VENOUS STENT System, with the need to prevent stent migration in a difficult-to-reach region. Should the Research and Development team be permitted to further explore endoscopic suturing as an anti-migration feature, Boston Scientific has an analogous, successful device to provide initial clinical data and save in-house resource costs.

Figure 3: WallFlex Biliary Transhepatic Stent System Implementation

Adapted from *WallFlex Biliary RX Stents: Fully, partially, and uncovered self-expanding metal stents*, by Boston Scientific. 2023.

These three devices are examples of how endoscopic suturing is currently used as anti-migration features on the market, knowledge that could form the foundation of further research and development into the VICI VENOUS STENT System.

Biomaterial Candidates

Endoscopic sutures are composed of biomaterials, which are biomaterials used within the human body that do not lead to negative health effects. Several biomaterials should be evaluated during the initial stages of the Device Development Process to better understand long-term biomaterial-tissue interactions. The following section explores five commonly used suture biomaterials.

Polyglycolic acid

Polyglycolic acid (PGA) was one of the first biomaterials ever used in suturing, present in Covidien's Dexon, Deknatel's Biondek, and Dynek's Biovek devices. PGA's ability to tightly pack together in a rigid structure contributes to its high strength as a monofilament, making it highly suitable for narrow vessels (Chu, 2013). As a biomaterial, PGA is also commonly linked as a copolymer with poly-lactic acid (PLA), as found in Johnson & Johnson's Vicryl suture, which has been found to decrease inflammation and increase the rate of absorption with nearby tissue (Afewerki, Harb, Stocco, Ruiz-Esparza, & Lobo, 2023). This would be key for the narrow vasculature targeted by the VICI VENOUS STENT System, as high inflammation would cause adverse tissue effects which would increase the likelihood of device migration.

Poly(lactic-co-glycolic acid)

Poly(lactic-co-glycolic acid) (PLGA) is a copolymer synthesized from PLA and PGA, leveraging homopolymer benefits to create an improved composite structure. PLGA has been used in sutures developed by Parlodel LAR due to its amorphous structure, which can be manipulated by adjusting its homopolymer ratios to extend/shorten its degradation rate and solid/glassy appearance (Blasi, 2019). This functionality would provide a wide range of tools for the research and development team to consider within a single biomaterial, as each homopolymer ratio produces unique characteristics. Also, PLGA can breakdown into microparticles when exposed to water, a characteristic leveraged when designing absorbable sutures for short-term uses (Blasi, 2019). For the VICI VENOUS STENT System redesign, hydrolysis may be highly undesirable, as the sutures will need to remain in-tact for extended periods of time.

Polyester

Polyethylene terephthalate (PET, also known as polyester) is used in the Mersilene Polyester Fiber Suture, a braided suture designed for cardiovascular and neurovascular applications. Independent studies show a non-tear success rate of over 80% for Mersilene's Polyester Fiber Suture, making it one of the most popular surgical sutures on the market today (Melvin, Litsky, & Juncosa-Melvin, 2016). PET was found to have medium to high levels of inflammation when analyzed in-vivo by the FDA but demonstrated "no macroscopic indication of adverse systemic effects at any time" during several animal studies (Margerrison, 2020). However, any prominent inflammation in surrounding tissue might lead to suture failure.

Polypropylene

Polypropylene (PP) is a nonabsorbable monofilament used in Johnson & Johnson's Ethicon PROLENE sutures, which can be used for cardiovascular and neurovascular tissue repair (Johnson & Johnson MedTech, 2024). The crystallization mechanism for producing polypropylene allows for a wide range of molecular weight-to-strength ratios, meaning that polypropylene has been selected for sutures produced by Covidien, Deknatel, SURU International and B. Braun (Chu, 2013). These devices can offer a plethora of in-vivo data, which distinguishes PP from other researched biomaterials.

Polyamide

Another monofilament polymer material, polyamide (PA), produces Nylon. One key advantage of PA is its high molecular weight, which creates a durable material that can withstand high forces, like the forces found in the iliofemoral veins (Orion Sutures India PVT LTD, 2024). For endoscopic sutures, Nylon 66 and Nylon 6 have been used in several devices, including Ethicon's Nurolon and Dynek's Nylene; however, studies show they have been "reported to lose strength after implementation" (Chu, 2013). Any decrease in strength post-implementation would increase the likelihood of device migration, suggesting that selecting polyamide as the suture biomaterial might come with an elevated risk.

Mechanical Properties

When evaluating biomaterials for biomedical applications, the mechanical properties associated with each biomaterial are important. Within the iliofemoral region, the endoscopic sutures need to be durable enough to withstand shear forces, while also light enough to avoid unintentionally occluding the walls of the vessel. As a result, the selected biomaterial needs to have a high tensile strength and a low density. Additionally, the hard-to-reach vasculature has increased curvature and turbulent blood flow, suggesting that a high elastic modulus and a low coefficient of friction would not inhibit blood flow in the target region. Table 1 summarizes key mechanical properties of the five biomaterials analyzed for the VICI VENOUS STENT System's endoscopic sutures, in addition to biological properties identified in predicate devices. Each characteristic is scaled on the following color/metric scheme: green (advantage, 3 points), yellow (neutral, 2 points), and red (disadvantage, 1 point).

Table 1: Comparison Matrix of Biomaterial Mechanical and Biological Properties

	PGA	PLGA	PET	PP	PA
Polymer Type	Natural	Natural	Synthetic	Synthetic	Synthetic
Absorbable?	Yes	Yes	No	No	No
Biocompatible?	Yes	Yes	Yes	Yes	Yes
Density (kg/m^3)	1250	1340	1380	1000	1140
Tensile Strength (MPa)	59	5	80	25	40
Elastic Modulus (MPa)	3500	1370	3250	3000	2900
Coefficient of Friction	0.5	0.5	0.2	0.2	0.5
Proven Predicate Device?	Many	Some	Some	Many	Many
Additional Notes	Decreases local inflammation	Water causes polymer breakdown	Causes local inflammation	Adaptable weight-to-strength ratio	Loses strength post-implantation
Total	22	14	20	**25**	22

When comparing the biological and mechanical properties of the biomaterials, there are many advantages and disadvantages associated with each option; however, this research suggests that PP is best suited to be used as an endoscopic suture material in the VICI VENOUS STENT System,

Mechanical Addition

Like many endoscopic procedures, the VICI VENOUS STENT System is delivered to its target region through a catheter-based procedure that is tracked under UV fluoroscopy. Physicians will make an incision in the inguinal region and use the VICI VENOUS STENT Delivery System to slowly wind the device throughout the vasculature towards its target region. The VICI VENOUS STENT Delivery System is depicted in Figure 4 as a collection of ten components (Boston Scientific, 2019).

The outer shaft has a hollow interior where the stent is loaded onto the guidewire, which enables the stent to enter the vasculature. This design feature sets the VICI VENOUS STENT System up for success, should endoscopic suturing continue to be tested, as a suture plication device can be loaded in the same way, like G-SURG's GERDx device.

Additionally, an endoscopic camera can easily be added to the tip of the guidewire system, to provide physicians with a high-level view of the internal blood vessel structure. This technology is already present in many of Boston Scientific's devices, including the SpyGlass DS II Direct Visualization System and the HABIB EndoHPB Bipolar Radio-frequency Catheter. The VICI VENOUS STENT System is already well-designed for the addition of endoscopic suturing as an anti-migration feature.

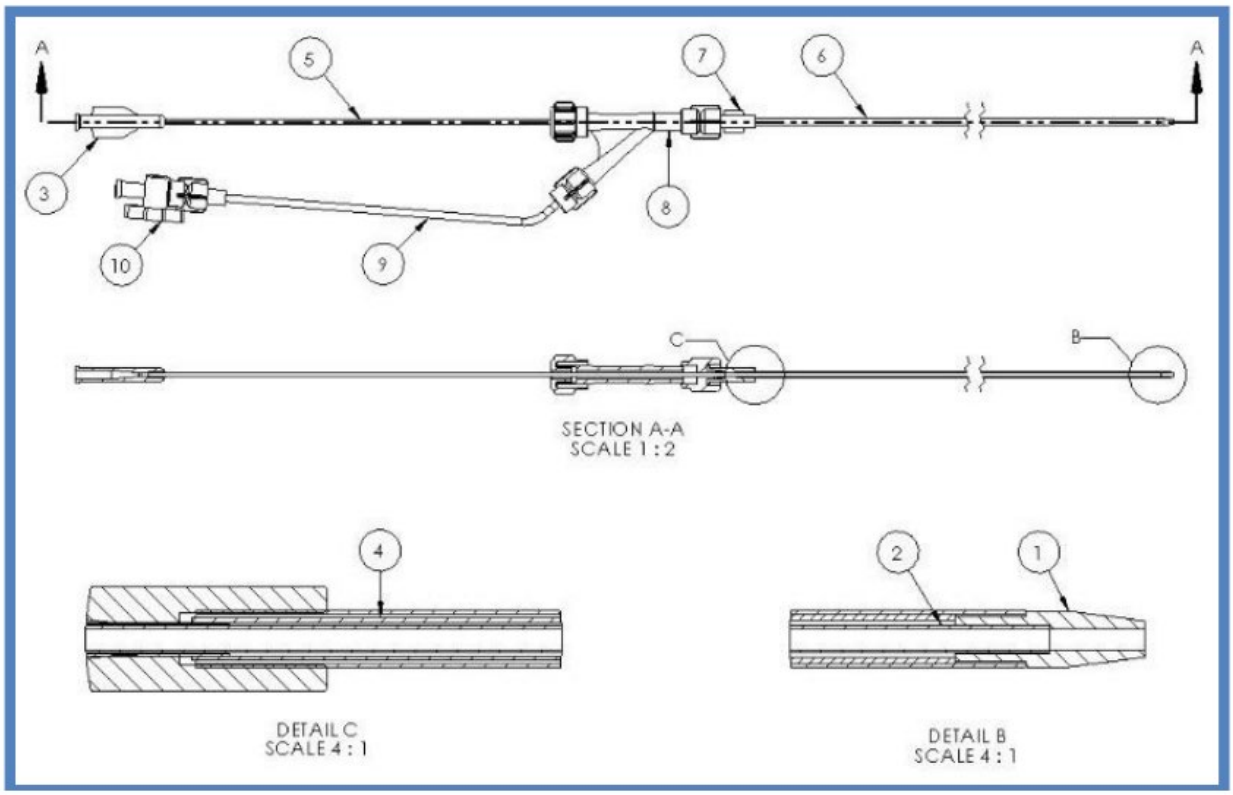

Figure 4: VICI VENOUS STENT Delivery System

Adapted from *STE-IFU-005 Rev. A Instructions for Use for the VICI VENOUS STENT*, by Boston Scientific. 2019. (1) Nosecone, (2) Inner Shaft, (3) Inner Shaft Hub, (4) Mid Shaft, (5) Mid Shaft Hypotube, (6) Outer Shaft, (7) Outer Shaft Hub, (8) Rotating Hemostasis Valve, (9) Extension Line, (10) 1-Way Stop Cock.

COSTS

Despite the countless benefits associated with further device development, a cost analysis can be an important factor in making decisions from a financial perspective. There are several strategies that can be used to mitigate the costs that arise from device development and the initial product recall.

Device Development Costs

The five-step Device Development Process from the FDA will result in a long-term investment for Boston Scientific. Adjusted for inflated resource costs, the Medical Device Manufacturers Association (MDMA) estimates the total cost of the process for a new medical device to be around $120,000,000. (Makower, Denend, & Meer, 2010). Since the initial product launch of the VICI VENOUS STENT System, this total expense can only be expected to increase. These estimated costs can be further broken down into the following sections:

1. Nonclinical: 30% (~ $36,000,000)
    a. Step 1: Device Discovery and Concept
    b. Step 2: Preclinical Research Prototype
2. Clinical (~$24,000,000)
    a. Step 3: Pathway to Approval
3. Pathway to Approval (~$60,000,000)
    a. Step 4: FDA Device Review

Although the VICI VENOUS STENT System is not new to the market, the documentation and testing associated with each stage in the FDA Device Development Process treats each application as a device they have not seen before.

Recall Costs

Using available FDA data on medical device product recalls, the Harvard Business School developed an algorithm to assess the impact recalls have on companies. Findings not only assessed the financial damages assessed by the FDA, but also the impacts on company innovation and the increased submission of premarket approvals from competitors in the space. These findings estimate a loss of around $90,000,000 upfront for the company (Kost, 2019). As for the money spent re-building company reputation and handling of patient lawsuits, Philips estimated a loss of around $825,000,000 in 2022 (Zipp, 2022). This device was for a Class I recall, the same process that Boston Scientific is undergoing. While it will be impossible to predict or assess long-term company damage, Boston Scientific needs to be prepared to take on analogous costs.

Strategies to Mitigate Cost

Despite the product recall of the VICI VENOUS STENT System, there are several ways that Boston Scientific can work to mitigate company expenses. Many company competitors, including Medtronic, Abbott, and Baxter, have yet to submit any premarket approval (PMA) documentation for devices that enter this unique landscape, highlighting the opportunity cost that Boston Scientific can continue to invest in to generate unparalleled profit. A few ways that Boston Scientific can mitigate the device development and recall costs include:

- Continuing to invest in the prevention of iliofemoral occlusion, as its untapped market potential remains, despite the product recall.
- Selecting polypropylene as the biomaterial of choice for Research and Development, due to its numerous advantages over other analyzed biomaterials.
- Leveraging clinical trial data from existing medical devices like the Endocinch Plication, GERDx, and WallFlex Biliary Transhepatic Stent System to understand common device pitfalls.

These strategies may offer ways to combat the rising costs that product recalls have on a medical device company's revenue; however, creativity and innovation will be required to further analyze the intangible expenses incurred as our relationships with many patients become strained.

GOVERNMENT REGULATIONS

The device development process is heavily regulated by the United States Food and Drug Administration (FDA), who oversee the development, analysis, and regulation of medical devices on the market.

FDA Device Development Process

Every medical device that hits the market has undergone extensive testing through clinical trials, steps that are outlined by the FDA's five-step Device Development Process (U.S. Food and Drug Administration, 2024). Figure 5 illustrates this Device Development Process, which details the required documentation, verification, and validation required for formal market approval and release of a new medical device. This Figure can provide a visual process to simply a complex pathway including many involved parties.

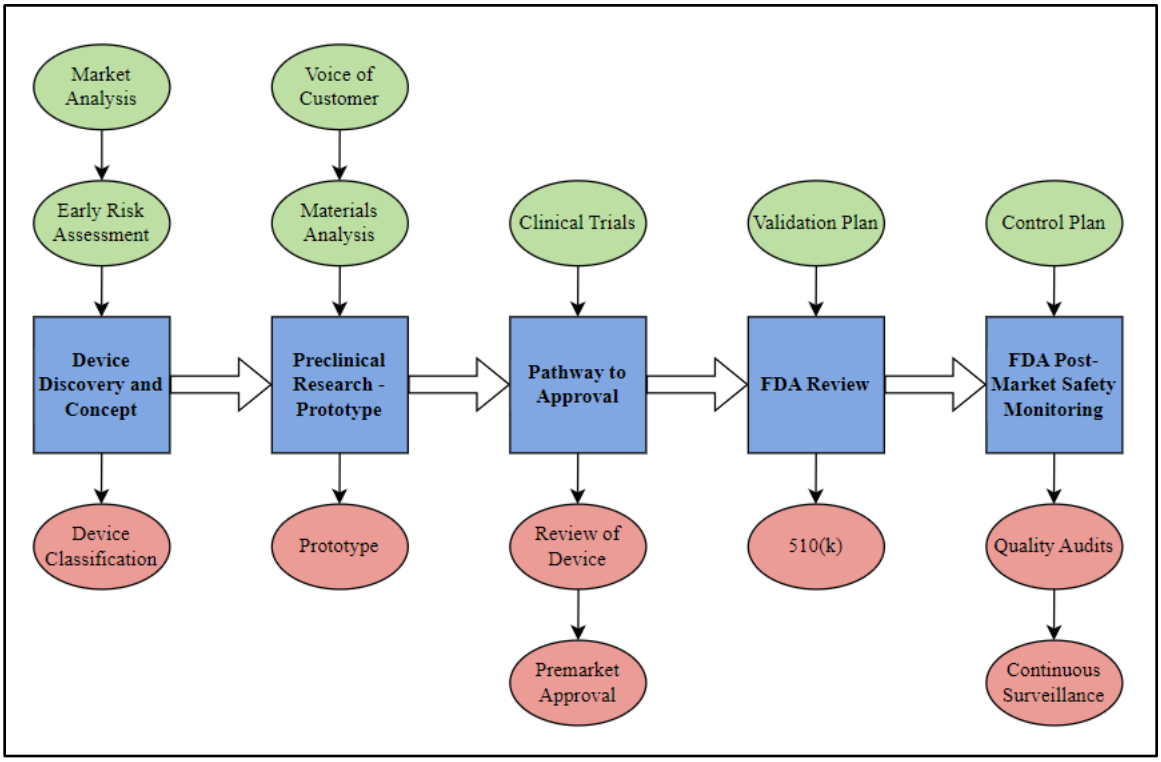

Figure 5: FDA Device Development Process Flowchart

Device Discovery and Concept

In this step, research and development teams generate an idea, brainstorm its associated risk, and weigh the costs of device investment.

Preclinical Research Prototype

In this step, companies develop numerous device prototypes to identify the features that best meet functional and design requirements.

Pathway to Approval

In this step, the device is tested in pre-clinical and clinical testing environments, providing key insight to its safety and performance.

FDA Device Review

In this step, data is gathered from throughout the device development process and submitted to the FDA for review.

Post-Market Device Safety Monitoring

In this step, the FDA shares its plan for device surveillance after commercialization.

Premarket Notification 510(k)

Despite its lengthy Device Development Process, the FDA has developed numerous ways to accelerate technological innovation. Within the regulatory process for this testing, Boston Scientific has the option to apply for pre-market approval in numerous different ways, including traditional Premarket Approval, the De Novo Pathway, and the Premarket Notification 510(k). Each process is subject to individual inspection and standards; however, the Premarket Notification 510(k) accelerates the FDA Device Review, if substantial equivalence is sufficiently demonstrated between the subjected device and existing devices (Lefkovich, 2018). The FDA finds substantial equivalence if a new device "is as safe and effective as the predicate," encouraging companies to use existing technologies as a foundation for their research and development (U.S. Food and Drug Administration, 2024).

By maintaining the existing nitinol stent structure of the VICI VENOUS STENT System and continuing the use the device in the iliofemoral region, Boston Scientific can properly meet the following criteria to use the Premarket Notification 510(k):

1. The device has the same intended use as the predicate;
2. The device has different technological characteristics and does not raise questions of safety and effectiveness; and
3. The information submitted to the FDA demonstrates that the device is at least as safe and effective as the legally marketed device.

Despite annual concerns about the balance between innovation and patient safety, the Premarket Notification 510(k) continues to be the primary source of new device applications, comprising over ninety-eight percent of device applications submitted since 2014 (Collins, 2023).

As the initial design of the VICI VENOUS STENT System will be quickly approved as "substantially equivalent" to its updated design, the five-step Device Development Process can be greatly decreased in length and cost, ensuring Boston Scientific can focuses its resources on the identification of the best biomaterial to be used for endoscopic suturing in the device.

CONCLUSIONS & RECOMMENDATIONS

Conclusions

This report assesses the feasibility of further research into Boston Scientific's VICI VENOUS STENT System following its device recall in August of 2021. Through the opportunity to engage in this project and advocate for the VICI VENOUS STENT System, I have arrived at the following takeaways:

1. The Endocinch Plication, GERDx, and WallFlex Biliary Transhepatic Stent System demonstrate the clinical and in-vivo success of endoscopic sutures as a device anti-migration feature.
2. Based on its mechanical and biological properties, polypropylene is the best suited biomaterial to undergo testing as a device suture.
3. Although medical device development costs continue to rise, Boston Scientific will be at a greater financial loss without addressing the product recall.
4. The FDA's Premarket Notification 510(k) provides a unique, accelerated pathway to get the VICI VENOUS STENT System on the market as quickly as possible using its earlier device as substantially equivalent.
5. Leveraging the existing outer shaft of the VICI VENOUS STENT Delivery System provides an easy route of implementation for endoscopic sutures in the iliofemoral region.

Recommendations

Regarding my research conclusions, I strongly recommend that Boston Scientific continues to invest in the VICI VENOUS STENT System, as it maintains a market advantage over its competitors based on the absence of rival premarket documentation and the FDA's accelerated Premarket Notification 510(k). With several existing devices successfully using endoscopic suturing as an anti-migration feature, Boston Scientific would not be forced to restart the FDA Device Development Process, instead, leveraging existing data to meet unmet patient needs. Additionally, the existing VICI VENOUS STENT Delivery System offers a simple way to implement endoscopic suturing using existing Boston Scientific Technology.

Second, I recommend that Boston Scientific develops a cross-disciplinary Research and Development team that includes the existing Device Development Team, including myself and Asif Ashraful, R&D Engineer II, as well as experts from within the biomaterial field, like John T. Favreau, Principal R&D Engineer and Technical Lead. This team will leverage shared resources, like data from the WallFlex Transhepatic Stent System, to unify endoscopic suturing and our existing stent-based device. The development of this team will be critical in mitigating the costs associated with the FDA's Device Development Process and kickstarting testing into PP to assess its feasibility as a suturing biomaterial.

Lastly, I recommend that this Research and Development team begin testing and analysis of polypropylene as the biomaterial used as the endoscopic suture. Mechanically, polypropylene has a low density, high elastic modulus, and low coefficient of friction, three characteristics that are ideal for the iliofemoral vasculature. The nonabsorbable, synthetic device is used in many existing applications, such as Johnson & Johnson's Ethicon PROLENE sutures and can be adapted to a wide range of molecular weight-to-strength ratios, offering immense opportunity for research.

Should my recommendations be considered, I believe that Boston Scientific will be best prepared to rebuild the trust of its many, global patients who continue to push our team to our shared vision: transforming lives through innovation.

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