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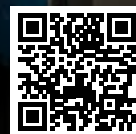
Richard Hendrick
COO

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Virtuoso Surgical

Endoscopic Surgery, Reimagined



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Virtuoso's technological innovation paves the way for new forms of treatment, all through a single port that is less than one centimeter in diameter



The introduction of endoscopy was a breakthrough in the history of modern medical science. The technique of exploring internal areas of the human body with a lighted tube gave surgeons the ability to non-invasively map parts and perform surgeries that were not possible before. The invention of the first fiber optic endoscope in 1957 further widened the scope of endoscopic surgery. Since then, companies have developed several techniques and tools to simplify the procedure, but even today the inherent limitation of endoscopes remains the same: rigid endoscopes offer very little maneuverability once inside the human body. Headquartered in Nashville, Tennessee, Virtuoso Surgical is bringing a breakthrough technology into this realm by delivering two robotically controlled, needle-sized manipulators through rigid endoscopes.

Virtuoso Surgical's system replaces single, straight tools in many rigid endoscopic procedures, enabling surgeons to grasp, manipulate, and cut tissues with unparalleled bi-manual dexterity. This capability gives surgeons the ability to perform advanced rigid endoscopic surgery—a task often limited by the tool and the surgeon's experience with it. "The endoscopic tool used to be a stick with a scalpel or scissor at the tip. It's like the surgeon is operating with one hand tied behind his back simply because he's using a scope. We're giving surgeons the ability to use their other hand, and you can imagine what that does for them," says Robert Webster, president and CTO of Virtuoso Surgical.



performing a new procedure that removes the entire pulp of the prostate (called enucleation of the prostate). The enucleation procedure has gained some traction, and there have been many randomized controlled trials with remarkable results. Yet, it is only performed in around two- to four-percent of patients. The reason: it is a difficult procedure to perform because the surgeons can't retract tissue.

New Horizons in Endoscopy—Pushing the Envelope on Innovation

Virtuoso Surgical helps overcome what was thought to be the limitation of endoscopy while fuelling easier adoption and harnessing the access and visibility that endoscopic devices offer. “Endoscopic surgery has evolved a lot from the past,” says S. Duke Herrell, the chief medical officer at Virtuoso, who is a urologic surgeon and pioneer in robotic surgery and minimally invasive surgical approaches. Herrell started his career during the early days of laparoscopy. “There was a lot of discussion at the time about what could be done with laparoscopy,” the doctor recalls. In the late nineties, a few surgeons worked together to take laparoscopy forward. “Despite the potential of laparoscopic surgery, certain procedures were still limited by the skills or training of the surgeon. They were so challenging to perform and hence were never going to translate out widely to the care of patients across the world,” Herrell states.

In the early 2000s, the DaVinci surgical robot changed the laparoscopy game by giving surgeons the ability to dextrously move and retract within the human body. The addition of robotics to laparoscopy was a major leap forward that greatly aided the performance and simplicity of laparoscopic surgeries.

Today, Virtuoso is helping push the envelope of minimally invasive surgery once again with its rigid



endoscopic system. Rigid endoscopes are currently used in almost every area of surgery, including neurologic, thoracic, orthopedic, urologic, and gynecologic procedures. The Virtuoso system enhances the traditional rigid endoscope by adding robotically controlled tools that are fully compatible within the operating-room workflow. Their solution brings the stability and dexterity of robot-assisted surgery to rigid endoscopy by providing surgeons better control of their instruments during complicated procedures. It reduces the need for awkward and potentially dangerous endoscope movements, and it enables surgeons to manipulate tissues almost as though their hands are inside the body.

For example, consider the surgery involving BPH, where an enlarged prostate blocks the flow of urine from the bladder. As a widely performed procedure, BPH surgery generally involves the removal of excess prostate tissue with an electric loop. Over the last decade, surgeons have begun

This is where the Virtuoso difference comes into play. Any surgeon equipped with Virtuoso's device can undertake the procedure with greater ease and confidence.

The Technology Behind the Product

Virtuoso has designed manipulators that are many times smaller than the robotic surgical instruments used in laparoscopy. This enables the surgeon to use dextrous, forceful tools that can operate in areas of the body that were previously unreachable. Virtuoso's technological innovation paves the way for new forms of treatment, all through a single scope that is less than one centimeter in diameter.

The arms of the Virtuoso tool, robotically-controlled concentric nested metal tubes made out of nitinol—invented by Robert Webster and others at Johns Hopkins—are super elastic, capable of bending to a much greater degree than conventional metals without deforming. Nitinol also has a shape-memory property, which means that

when it is put in a curved shape and heated, the alloy returns to that curved shape while retaining its elasticity. Each component tube of the manipulators is curved, and they slide inside each other, like a tv antenna. This allows them to bend and twist in such a way that they function like tentacles, without the need to use pull wires or levers to control them. Because of the concentric nitinol tubes, the arms exert significant force; the surgeon's tools can scale down to a 1-mm size and still have the ability to manipulate tissue at that scale with dexterity. The system is able to deliver a host of surgical tools through a rigid endoscope, including laser fibers of different types, bipolar and monopolar electrosurgery tools, scalpels, scissors, baskets, suction/irrigation, etc.

The Making of Virtuoso, and the Path Ahead

The origin of the company is a beautiful story about the collaboration between Webster and Herrell, who are also the cofounders with others of the Vanderbilt Institute for Surgery and Engineering (VISE), and the company's chief operating officer, Richard Hendrick. Together, these three invented and patented the Virtuoso device. Driven by a desire to improve the tools available to surgeons in the operating room, and to assure that their invention would actually assist patients and surgeons, the trio ventured into commercializing their technology outside of their laboratory. As COO, Richard Hendrick is the lead engineer on the project, leading a dedicated team of eight internal engineers, and the company's outside engineering consultants, to commercialize this technology.

In surgical robotics, one of the biggest challenges is often that robotics experts lack the clinical understanding that surgeons possess. Robotics-development can easily get too focused in engineering complexities and lose sight of both the patient and the surgeon. To overcome this, Virtuoso has


leveraged clinical input from Dr. Herrell, developing the technology with a focus on both the patient and the surgeon. Another major advantage of Virtuoso is its strong relationship with Vanderbilt University and the Vanderbilt University Medical Center. Their physicians, including Dr. Lara Harvey—an assistant professor of obstetrics and gynecology—and Dr. Fabien Maldonado—an associate professor of medicine, thoracic surgery, and mechanical engineering—have been able to significantly advance the development and performance of the Virtuoso system. The team at Virtuoso gets many surgeon perspectives and feedback on how the device should work, how it can be used, how the device controls work, and on top of it, what a surgeon is actually looking for, all in order to optimize the system. The collaboration, and the input from multispecialty interventionalists, surgeons, and other doctors, have helped Virtuoso to greatly improve their technology.

In terms of development and regulatory compliance, Virtuoso has completed what they call a “feature freeze” in their second prototype. This means that the basic parameters of the device have been established, allowing them to proceed to the next round of prototype development and to proceed with the regulatory-approval process. The company has recently filed its first FDA submission, an application seeking formal Breakthrough Device designation and treatment during the regulatory process.

All of the R&D behind the technology directly influences the company's market position. The Company is currently working with a Boston-based consulting firm, Fletcher Spaght, Inc., to examine in great detail the market receptivity of their technology. Based on the initial work done by Fletcher Spaght, and based on the known clinical benefits of the underlying technology, the company is confident that the market demand for their system will be strong.

The company is currently raising capital through an offering of preferred shares, through SEC Regulation A+. From the company's perspective, Regulation A+ is a good way for start-ups to raise capital. It is a relatively new statutory pathway that has not been explored by medical-device start-ups. Also, with the company's share structure, Virtuoso is able to solve some of the risks involved in early-stage investing, particularly for angels and other individuals. The shares are intended to generate returns comparable to historic VC portfolio returns while protecting individual investors from follow-on dilution. “The money that we're currently raising will be used to continue the development of the next prototype of the device for the regulatory approval process with the FDA, and to begin the testing and validation of the system and device itself,” adds Mark Pickrell, the company's chief administrative officer. The company has received grants from the U.S. National Institutes of Health and the State of Tennessee, totalling around \$3.5 million, and the company has received angel investments of approximately \$4 million.

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Virtuoso's technology is backed by a team of doctors, engineers, entrepreneurs, and investors, who choose to work on this project and support it because of the value that it will provide to both patients and surgeons. Ultimately, the value of the Virtuoso system is a function of the efficacy and utility of the Virtuoso device itself, which is a quantum leap forward for existing, and new, endoscopic procedures and techniques. 

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The annual listing of 10 companies that are at the forefront of providing Surgical solutions and impacting the industry