

# The MedTech STRATEGIST

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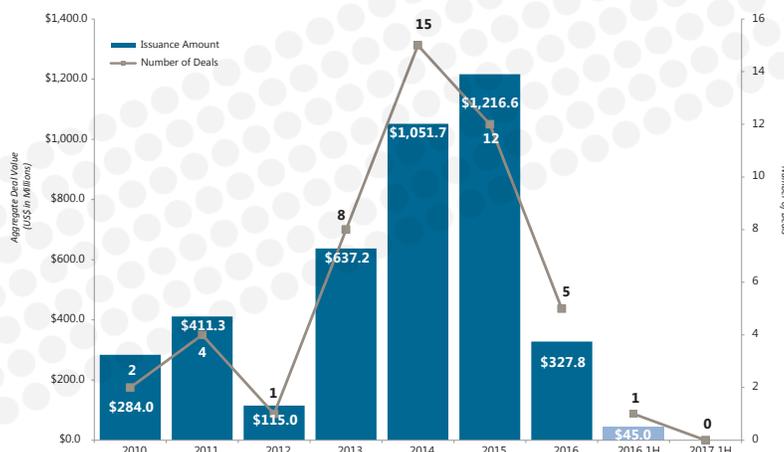
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LOUISVILLE  
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#### YEAR FOUNDED

2014

#### WHO'S BEHIND IT

Donna Ford-Serbu, co-founder and also SVP, Lead Management, Spectranetics; Kristin Johnson, the former Director, Disruptive Products and Technologies, Covidien; co-founder William Gregg, with 25 years in the medical device industry gained at Fisher Imaging and Covidien; and mechanical engineer Dirk Johnson, a co-founder who's co-founded several other businesses across the medical, consumer, industrial, and aerospace industries

#### UNMET CLINICAL NEED

Laparoscopic specimen removal, now that morcellators are labeled with a black box warning

#### SOLUTION

XCOR, a new minimally invasive cutting system that contains the specimen in the body, is fast, easy-to-use, and results in higher-quality specimens for pathology studies

#### FUNDING TO DATE

Seed round of \$3.5 million

#### MEDICAL ADVISORS

Eric R. Sokol, MD, Associate Professor of Gynecology-Urogynecology at the Stanford University Medical Center



## EXIMIS SURGICAL: FILLING A GAP IN LAPAROSCOPIC TISSUE REMOVAL

*The notorious morcellator, a tool for the laparoscopic removal of uterine fibroids and other tissues, has largely gone into disuse since the FDA issued a black box warning about the devices because of their potential for spreading cancerous cells. Eximis Surgical is filling the gap with a laparoscopic device that it says will not only be safe, but will also offer procedural advantages and result in higher quality tissue specimens for analysis.*

by  
MARY STUART



In June 2017, early-stage start-up **Eximis Surgical LLC** was the winner of a \$25,000 award as the top company in the value category of the MedTech Innovator Competition. MedTech Innovator is a global, nonprofit competition and accelerator for companies in the medical device, digital health, and diagnostic industries. Eximis Surgical made the cut—from 600 companies originally vetted—into the final four, and was ultimately deemed to have the best medical value proposi-

*It's counterproductive, says Johnson, if, at the end of a laparoscopic procedure, a large incision has to be made to remove the specimen from the body.*

tion for its laparoscopic specimen removal device, offering a replacement—with improvements—for the tarnished morcellator product category.

The history of morcellators is notorious, largely because of the efforts of Amy Reed, MD, an anesthesiologist, and her husband, Hooman Noorchasm, MD, a surgeon. Dr. Reed died in May 2017 from an aggressive type of cancer that was spread as a result of the removal of her uterus four years earlier, which was done with a morcellator, a rotating cutter in common use at the time that was designed to shred tissue so that large specimens could be removed through small incisions. The morcellator was never intended to be used to remove cancerous tumors; however, cancer sometimes lurks undetected, and what

are thought to be benign uterine fibroids sometimes turn out to be malignant tumors. In Dr. Reed's case, she had an aggressive form of uterine cancer that had gone undiagnosed before her hysterectomy, and the morcellation procedure to remove her uterus spread those cancerous cells inside her body, negatively impacting her prognosis. Other women with similar experiences came forward after Dr. Reed's story was published in the *Wall Street Journal*. The Reeds campaigned to get industry and the FDA to stop the use of these devices, and were successful. **Johnson & Johnson** removed its morcellator from the market, and the FDA issued a black box warning against the use of morcellators.

Kristin Johnson, a co-founder of Eximis Surgical, had occasionally encountered the use of morcellators during her 17 years at Covidien, most recently as director of Disruptive Products and Technologies, an internal Covidien incubator. "I didn't run across them too often," she recalls, "but when I did, I was surprised that they didn't follow the model of other surgeries in terms of containment. And I did see the need for a better solution." Johnson left Covidien at the end of 2013, and the story of Dr. Reed was the inspiration for her and several compatriots—Donna Ford-Serbu, SVP, Lead Management, Spectranetics; William Gregg, who has 25 years of experience in the medical device industry gained at Fisher Imaging and Covidien; and mechanical engineer Dirk Johnson (Johnson's husband) who has co-founded several other businesses across the medical, consumer, industrial, and aerospace industries—to found Eximis Surgical.

Notes Johnson, “It is a very sad story, but Dr. Reed and her husband were successful at getting the morcellator removed from practice.” At the same time, she says, “Now surgeons who were relying on these devices to remove large specimens without creating large incisions did not have a solution to do so.” That meant many more hysterectomies, for example, would be done abdominally, with the extra expenses occasioned by surgery, a longer hospital stay, and the need for more pain management.

“Minimally invasive surgery has gained a lot of traction,” says Johnson, “and a lot of that has been driven recently by the adoption of robotics.” But it’s counterproductive, she notes, if, at the end of a laparoscopic procedure, a large incision has to be made to remove the specimen from the body. “That didn’t make sense to us. We felt there was an urgent need to create a safe and easy way to remove these surgical specimens through a small incision.”

Johnson says that rather than improve upon the morcellator category—and some companies have attempted to do so, by creating containment bags around the morcellators—the company had an opportunity to redefine the problem and address not only the safety issues of morcellators, but other limitations as well. At the top of their list of desired attributes, Johnson notes, were safety, speed, and ease of use. “The specimen had to be contained. That was non-negotiable. Morcellators are time consuming and fatiguing. We could improve upon that.” It can take a surgeon an hour or longer to remove a specimen with a morcellator, and the surgeon’s time and effort isn’t the only issue; this keeps patients under anesthesia for long periods of time, at a cost to the hospital, which might be able to

do another procedure in that length of time, she says. “We wanted to develop something that’s fast and easy.”

The company is now finalizing prototypes for preclinical testing of a device called the *XCor*, which consists of slicing wires (the number varies, according to the product and intended use), preplaced in a containment bag. The surgeon places the bag containing the wires inside the patient, loads the specimen into the bag, exteriorizes the bag opening, and connects it to an instrument that applies mechanical and electrical energy to the wires. The wires pull from the bag through the tissue and into the instrument, leaving behind clean-cut segments of tissue. (On the Eximis website, two side-by-side photos compare *XCor* specimens, which look like slices of raw bacon, to those of morcellators, depicted by a bowl of what looks like ground meat.) The surgeon then reaches into the bag and removes the segments, all through an incision smaller than 2.2 cm.

“From the surgeon’s perspective, it fits nicely into their clinical workflow,” says Johnson. They are used to placing tissues into—and removing tissues from—specimen bags. “We have just added a step of connecting a connector and pushing a button. It is easy, simple, and instead of up to an hour or longer, we believe we will enable removal in five minutes. And we have optimized the device so that it’s low temperature.” She adds, “From the surgeon’s perspective, the difference between five minutes of pushing a button and up to an hour with a morcellator is big.”

*XCor* yields an unexpected benefit as well. “When we began showing these clean-cut segments to surgeons, they told us that these were significantly higher quality tissues for pathological

assessment than a morcellated specimen, and therefore would likely be used in procedures where a morcellator otherwise would have not.”

Eximis Surgical is at an early stage (as are most of the MedTech Innovator contestants) and is now working on finalizing the device’s design and getting it into surgeons’ hands for preclinical testing. It has also engaged manufacturing partners. The company aims to get to first-in-human studies and a 510(k) *de novo* submission in the next two years.

Eximis’ initial target markets are the “vacant morcellator markets,” says Johnson, i.e., laparoscopic hysterectomy, myomectomy, nephrectomy, and some benign general surgery applications, or “any case where a large specimen needs to be removed through a small incision,” which Johnson believes offers a total addressable market of \$2 billion.

The company anticipates that the upfront costs of the *XCor* will be comparable to those of morcellators offered in containment bags, but with additional economic advantages in terms of shorter and easier procedures, and perhaps the ability to perform more surgeries in a minimally invasive fashion.

In the future, Johnson believes the *XCor* platform can be integrated into robotic procedures, “enabling a surgeon to complete the entire surgery with the robot.” The company also foresees additional surgical applications for *XCor* that weren’t necessarily the province of morcellators in the past.

Eximis Surgical has raised \$3.5 in seed funding, the majority from Angel investors, many of whom are experienced medical device professionals or executives. The company will be looking for a \$4.5 million Series A round at the end of 2017. 📌