

The MedTech STRATEGIST

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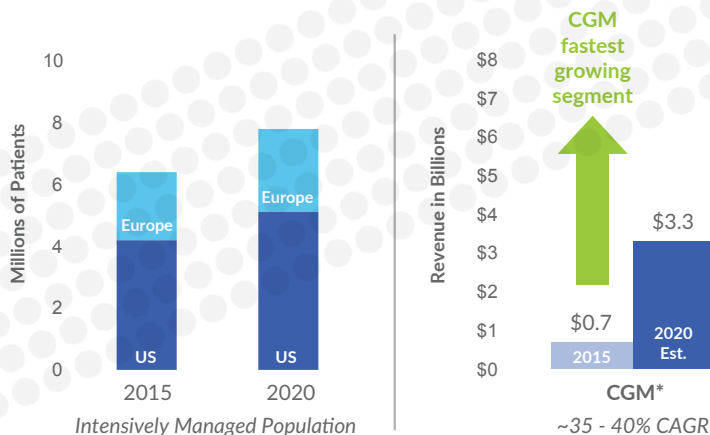
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YEAR FOUNDED

2016

WHO'S BEHIND IT

General surgeon Albert Huang, MD, a serial inventor who has developed and built laparoscopic, endoscopic and surgical tracking devices while a medical technology innovation fellow at The Methodist Hospital System/Weill Cornell Medical College and previously as director of product design at Integrated Bionics in Houston, TX

UNMET CLINICAL NEED

Identifying the ureter is a crucial initial step in abdominal and pelvic surgeries, because its location makes it susceptible to damage during a number of different procedures

SOLUTION

StimSite, a single-use hand-held device, delivers an electrical impulse that causes the ureter to contract so surgeons can identify its location and entire pathway

FUNDING TO DATE

\$350,000 seed round, provided by Houston Health Ventures and individual investors and a \$50,000 award from the MedTech Innovator Accelerator and Venture Competition. Currently seeking a \$3 million Series A round

ALLOTROPE MEDICAL: A SIMPLE SOLUTION FOR PROTECTING THE URETER DURING SURGERY

There are three million surgical procedures each year (in the US) in which there is a risk of injuring the ureter, and rates of injury are highest in minimally invasive cases, where up to 30% of OR time can be spent on trying to identify the ureter to spare it from harm. Allotrope Medical has developed an intuitive, battery-operated, single-use handheld device to help surgeons see the location of this hidden part of the anatomy.

by
MARY STUART



Albert Huang, MD, has always been an inventor. Growing up, he would tinker with cars and motorcycles and rebuild old audio equipment, he says, and that desire to fix things is why he chose general surgery among all medical specialties.

While participating in abdominal and pelvic surgeries as a surgery resident, on more than one occasion Huang became aware of the time and energy it took to identify the ureter, the tube that carries urine from the kidney to the urinary bladder, which is necessary so that surgeons can take steps to avoid inadvertently damaging it. There was constant checking and rechecking, he says, to determine, "Is that the structure? Am I getting close to it?"

The ureter is difficult to find because it is located in the retroperitoneum. It's behind a layer of tissues at the back of the abdominal wall, where it is very close to organs that are the targets of abdominal and pelvic surgeries; the colon and the ovaries, for example. There are approximately 3 million surgeries that pose a risk to the ureter, including gynecological and colorectal surgeries (and, to a lesser extent, vascular, urological and cancer-related procedures). The risk is highest for minimally-invasive procedures, which prevent surgeons from directly palpating tissue.

Across all of these procedures, the rate of injury is only about 2%, which sounds trivial. However, the consequences of damaging the ureter can be dire, including harmful strictures and scarring, urinary extravasation leading to peritonitis, or even the loss of kidney function. Fundamentally, the threat of ureteral injury is a significant stressor for surgeons.

Huang was assisting one day on a colon resection surgery, "and we were having a bear of a time identifying the ureter, which was impeding our ability to advance the operation." He says he happened to notice that the anesthesiologist was using a facial nerve stimulator on the patient's cheek to see if the chemical paralytic agent was working. Driving home that day, he mulled over what he had seen. He thought, "The ureter is smooth muscle. What if we could generate a contraction to help us identify where it is?"

Using off-the-shelf parts, Huang cobbled together a prototype of a handheld electrical stimulator with the idea of inducing a contraction in the ureter and was able to test it in the animal lab at Houston Methodist Hospital, where he was a surgery resident. The device was successful at achieving a visible contraction in the ureter, so in 2016 Huang left the hospital, was accepted to TMCx, the accelerator program of the Texas Medical Center, and founded **Allotrope Medical**.

Huang notes that the need to identify the ureter during surgery is well recognized, and the placement of stents or catheters is one commonly applied strategy to increase the safety of procedures. However, in and of themselves, stents don't prevent injury. Although they stiffen the ureter (which makes it easier to find upon palpation), it is still possible to inadvertently nick or even fully transect the ureter. But stents do make it easier to detect injury intraoperatively so the ureter can be repaired. The placement of stents involves calling in a urologist and significantly affects the profitability of procedures. Says Huang, "So stents are

not that effective, they're not easy to use, and literature shows that it costs about \$1200 to place them each time with no reimbursement." The placement of stents and the addition of OR time and resources spent on other methods of ureter identification (which include time-consuming dissections, stent or catheter placements, or injections of contrast agents like indocyanine green), result in increased costs without properly addressing the issue.

Allotrope Medical's *StimSite* is a handheld, single-use, battery operated device that a surgeon can reach for during both minimally invasive and open procedures if it becomes difficult to find the ureter (see *Figure 1*). The surgeon simply places the tip of the device in the vicinity of the ureter, pushes a button and an electrical impulse causes a characteristic contraction that throws the ureter into relief (it looks like a night crawler, Huang says). "You are able to see the full length of the ureter towards the kidney and the bladder each time you elicit that contraction, even if it is behind other tissues." The company has filed 8 patents in the US, EU and China, protecting its system and methods for ureter detection and smooth muscle stimulation via electrical stimulation (with expanded clinical and technologic applications).

There are no other smooth muscle tissues in that part of the body, so the device effect is specific to the ureter. Huang also notes that while patients undergoing minimally invasive and robotic surgeries in the abdomen receive neuromuscular-blocking agents, which paralyzes skeletal muscles so that the working space in the body can be inflated with air, smooth muscles are not affected. "You get a zero percent false positive rate with our device. If you see a contraction of this nature in this part of the body, you are certain that it is the ureter."

The company has developed the alpha prototype of *StimSite*, and is preparing to work with a contract manufacturer to complete the manufacturing design and aging process required to get the device ready for the FDA. Huang anticipates being able to follow a 510(k) pathway through the FDA using nerve stimulators as predicates. Allotrope is now looking to raise a \$3 million Series A round to achieve FDA clearance and advance the technology to the market by early 2019.

Huang's market research has identified gynecological surgery as the best launching point for *StimSite*, for several reasons. First, it accounts for 50% of the cases of surgical ureteral damage, because the pelvic ureter is the most susceptible segment of the ureter. Also, because general ob-gyns spend more time in the clinic than they do in surgery, they would be more likely to adopt an adjunctive device that increases their confidence in the safety of a procedure. "Leadership told us they would have a higher adoption rate. They do the vast majority of hysterectomies, but don't operate every day." Huang acknowledges that surgeons who do minimally invasive surgery day in, day out are more comfortable working in that part of the body and are less likely to use *StimSite*. "But they have told me that there are cases where this issue starts to slow them down, because of the presence of scar tissue for example, and that they would like to have it available in the OR."

Two high-volume procedures that Allotrope will initially target are hysterectomy (750,000 procedures in the US) and colon resections (300,000 cases). While the alpha prototype is a handheld, standalone device, the company also plans on working with robotics

Figure 1

***StimSite* for Intraoperative Ureter Identification (Alpha Prototype)**



Source: Allotrope Medical

companies to incorporate *StimSite* into their platforms.

The healthcare economics of Allotrope's device are positive says Huang. *StimSite* has a projected ASP of approximately \$250, a fraction of the unreimbursed \$1200 cost of placing ureteral stents. Additional savings will be realized in decreased surgery times (through the elimination of current methods of ureter identification) and increased safety, especially if surgeons don't have to prolong procedures in order to do slow dissections to identify the ureter, repair a damaged ureter, or worse, address the medical—and legal—ramifications of a damaged ureter that's not discovered until after the patient leaves the hospital.

Allotrope Medical is at a very early stage, but so far, it has gained positive recognition at every step along the way. It was accepted into the Houston JLABS incubator of **Johnson & Johnson**, was voted as having the top innovation of the entire event at the annual SAGES surgical conference in March, and at the annual meeting of Advamed in late September, Allotrope was awarded second place in the Medtech Innovator competition, out of 600 competing companies across the world. 📌