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MARKET TRACK

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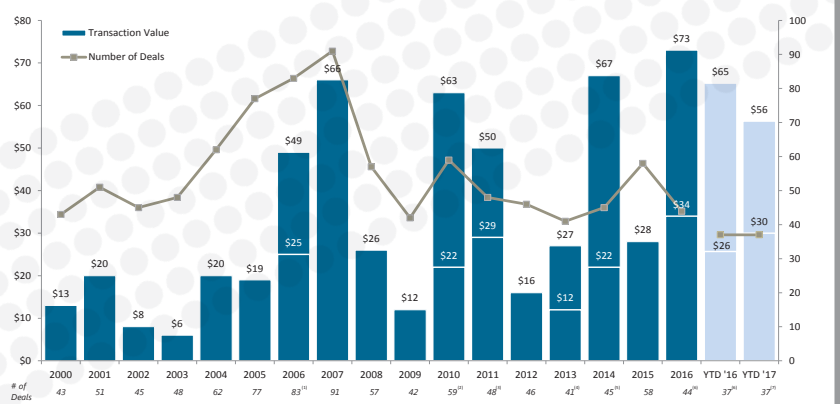
US Device and Diagnostic M&A: 2000 – 2017 YTD



ICHOR VASCULAR:
BRINGING THE BENEFITS OF A MINIMALLY INVASIVE PROCEDURE TO ARTERIAL EMBOLECTOMY

Acute limb ischemia, the sudden occlusion of a peripheral artery by clot or other embolic material, is a life- and limb-threatening condition that affects a significant number of people. Less than stellar outcomes after surgical arterial embolectomy haven't improved in 30 years, despite the implementation of multidisciplinary team approaches to managing the condition. ICHOR Vascular hopes to change that with an easy-to-use, one-size-fits-all percutaneous device.

by
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YEAR FOUNDED

2014

WHO'S BEHIND IT

Founders are Troy Long, MD, a practicing vascular interventional radiologist at Minneapolis Radiology Associates, and chairman Jeffrey Blair, formerly the CEO of Corpak MedSystems and the contract research organization NAMSA

UNMET CLINICAL NEED

A nonsurgical way to treat acute limb ischemia and significant embolic events

SOLUTION

Panacea, a percutaneous one-size fits all (above-the-knee and below-the-knee) arterial embolectomy system

FUNDING

$15 million from Cleveland Clinic's Global Cardiovascular Innovation Center and private individuals

Troy Long, MD, an interventional radiologist at Minneapolis Radiology Associates, is part of a multidisciplinary practice where interventionalists work alongside vascular surgeons. He has participated in many surgical arterial embolectomies over the years, procedures that treat patients with acute limb ischemia whose arteries have become suddenly occluded by blood clots or other embolic materials. Despite the team's efforts to refine the procedure, Long says patient outcomes haven't changed in 30 years. In these patients, 30-day amputation rates are as high as 30% and 30-day mortality rates are 15-44%.

Despite efforts to refine arterial embolectomy surgeries, outcomes haven't changed in 30 years, Long says.

Acute limb ischemia (of the lower limbs) has an incidence of 9-16 cases per 100,000 people and is different from critical limb ischemia (CLI). (*See "New Interventions for Critical Limb Ischemia,"* The MedTech Strategist, *November 27, 2017.)* Acute limb ischemia often arises secondary to atherosclerosis, when clots break off and embolize to the periphery (or less often, from the embolization of other materials), completely occluding an artery.

There is an urgency to rapidly treat the patient, as compared to CLI, because CLI develops over time, and collateral circulation often takes up the slack to protect tissues from ischemia. Such is not the case with an arterial occlusion caused by sudden embolization or organized clot. The nature of the clot is different as well, tending to be more soft and fresh than the lesions treated in CLI, and also different from clots in the brain.

Long set out improve outcomes by developing a percutaneous procedure that would avoid the complications of a surgical incision and general anesthesia in these patients, yet achieve the procedural success of surgery. He says, "We know the Fogarty balloon works. But how can I replicate, without surgery, the parameters that work well in surgical embolectomy?"

Long says he was able to identify a solution on paper, but the real challenges came after a few prototypes were built by his own efforts. "I could see how the technology would work, but the engineering artistry in getting these components to work inside of a 7F system became the real challenge, not to mention the funding challenges that come with building prototypes and testing them repeatedly."

With working prototypes in hand, he began to consider manufacturability, regulatory strategies, the cost of the system vs. reimbursement, and other commercial considerations normally outside a physician's purview. "While I had working prototypes and intellectual property I had no idea what to do with it, and none of the big companies had any interest in a prototype, my napkin, or my IP," says Long.

That's when he reached out to his old acquaintance, Timothy Blair, who is a 25-year veteran of the medical device space and managing director of strategic partnerships at the global medical research organization NAMSA. "NAMSA supports medical device companies all over the world through preclinical testing, biocompatibility, clinical research, and regulatory/compliance services all aimed at bringing medical innovations to the bedside more efficiently, with less risk, and with more predictability to the development process," says Blair

Blair is leading some new models for NAMSA, organizing global disciplines and resources to better support early-stage medtech innovation invented by physicians or other entrepreneurs. The goal is to help them develop those ideas in a time- and cost-efficient process to the point where a multinational might want to co-develop the project, or to perhaps de-risk the project enough to attract investors.

Blair took Long's project under NAMSA's wing, helping him found **ICHOR Vascular Inc.** in 2014, and began mapping out a detailed plan for commercialization. "Medical device development is a high risk proposition in a highly regulated industry. In my opinion, too many good ideas fail to reach the bedside because the early planning is missing, the milestones are misunderstood, inventors miscalculate how far they will need to take devices before investors or strategics take note, and inventors fail to partner with "been-there-done-that" partners or leaders," says Blair. Indeed, NAMSA embarked on its early-stage strategy to help start-ups overcome their lack of experience.

ICHOR Vascular's *Panacea* technology, is about six months away from market clearance, according to Long. The *Panacea* system has three components: a 7F sheath with a distal occlusion balloon; a 7F guide catheter with a disposable and recoverable 10 mm nitinol funnel-shaped basket; and an 014 rapid exchange compliant balloon that can expand up to 10 mm (a 10F system will also be available for the venous indication). It's a single-procedure, one-size-fits-all device for treating vessels above and below the knee.

Blair is leading some new models for NAMSA, organizing global disciplines and resources to better support early-stage medtech innovation invented by physicians or other entrepreneurs.

The sheath enters the vessel via percutaneous access, and its occlusion balloon is inflated to control and regulate arterial out-flow. The 7F guide catheter is inserted through the sheath and deployed in a manner similar to a stent; the operator pulls the sleeve back and the basket opens to gain good wall apposition proximal to the clot. The 014 embolectomy balloon crosses the lesion and sweeps the vessel as far down as the ankle if necessary, just as the Fogarty balloon would in the surgical procedure. Instead of sweeping back to the surgical incision, the *Panacea* sweeps embolic debris back to the recoverable funnel. After sufficient thrombus is removed, everything is pulled back into the sheath, out of the body into the sterile field, and the angiogram is performed to check for reperfusion.

Probably the most frequent question the company gets from clinicians, Blair says, is "How much clot can I put in the basket?" The procedure can be repeated several times because the clinician is able to maintain sheath and wire access, which is not always true of other aspiration technologies. The clinician observes what's been removed and makes repeated sweeps if necessary, followed by angiography to determine whether there is reperfusion (which is not an option for surgical embolectomy). If not, the basket is rinsed out and the procedure can be repeated as many times as necessary to get the vessel cleared of debris until reperfusion is achieved.

Blair notes that the device has been studied in four *in vivo* models to challenge the device in different sizes of vessels and clot types. ICHOR is also developing novel clot models that allow it to use fewer animals in comparing the effectiveness of *Panacea* against other devices. "We can look at time to reperfusion, amount of clot retrieved, distal embolization rates, and amount of blood loss to begin understanding how it will work in the real world," says Blair. "We'll even apply some translational science, taking these endpoints from the bench into *in-vivo* models. Upon market clearance we expect to translate this into real world clinical data," he adds. The company has identified four or five centers of excellence where it plans to start building these real world datasets, once it has 510(k) clearance for *Panacea*.

It's unusual for a start-up to do these kinds of translational studies at this stage, but, says, Blair, "When we surveyed physicians and multinational companies to learn what would help them reach a 'buy' decision, they asked for comparative effectiveness on different types of devices in different types of vessels—arterial, venous, big vessel and small vessel." Blair says the company is making sure to listen carefully to the marketplace during development "to make sure we are testing and building the right clinical data even before market clearance." That's the leg-up an organization like NAMSA can offer to an early-stage start-up.