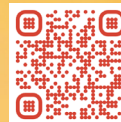


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FastWave Medical: Disrupting Arterial Calcium and the IVL Market

Minneapolis, MN

Contact:
Scott Nelson,
Co-founder and CEO

scott@
fastwavemedical.com

Arterial calcium can be dealt with using atherectomy tools to grind away debris from the inside of the vessel, but it is more challenging to remove from the medial layer of vessel tissue. Intravascular lithotripsy (IVL) addresses this discrepancy with an energy-based solution, and FastWave Medical is developing multiple IVL platforms that build upon currently available technology.

► COLIN MILLER

When plaque accumulates in the arteries over the years, it can form layers of calcium in the intimal and medial layers of the vessel. This calcific buildup often coincides with atherosclerosis and increases the risk of stroke and fatal cardiac events. Cardiovascular procedures are complicated by the presence of arterial calcium, and significant calcium burden can hinder balloon technologies from consistently dilating regions of the vessel.

Atherectomy is one of the most commonly used treatments for calcific arterial disease (CAD) and atherosclerosis, involving the mechanical debridement of plaque from the inner surface of the artery, yet current tools cannot eliminate deeper, medial deposits of calcium.

Fortunately for CAD patients, a technique known as intravascular lithotripsy (IVL) has emerged to address the calcium burden more thoroughly. In an IVL procedure, a balloon modified with

a series of ultrasonic transducers is advanced through the vessel, creating pressure waves that fracture calcium. Until recently, the only company offering IVL commercially has been **Shockwave Medical**, which posted revenue in excess of \$237 million in 2021 (representing 250% growth from the previous year), but **FastWave Medical** co-founder and CEO Scott Nelson believes his latest start-up can improve on already promising technology.

Nelson has spent most of his professional career in the cardiovascular device space, starting in large strategics such as CR Bard (now part of Becton Dickinson), Boston Scientific, and Medtronic. After that, Nelson led several early-stage health and wellness companies, including Touch Surgery (exited to Medtronic) and Joovv, a consumer light therapy start-up that has brought in \$20 million in top line solely from e-commerce. With some of his business partners, Nelson then formed

an accelerator called Big Sky Biomedical and spun out FastWave as a Delaware C Corp in February 2021.

Among other projects, Nelson had been tracking Shockwave's strong performance in the cardiovascular space, as well as CSI's (now Abbott) inter partes review process, noting, "Once the USPTO ruled almost overwhelmingly in favor of CSI, we took that as a signal that the IP landscape was potentially more open than most people might perceive." Since then, FastWave has sought to deliver IVL devices with greater benefit to both patients and physicians.

"It's rare to see such a specialized medical device company do as well as Shockwave has," says Nelson. Nevertheless, he and his team identified several areas of improvement, namely user friendliness, a more rupture-resistant and crossable balloon, and an

enhanced electrical system to create the cavitation inside the balloon that generates calcium-fracturing waves. Though necessary for IVL's mechanism of action, the electric emitters wired along the balloon add bulk and detract from the delivery catheter's ability to cross certain anatomy and reach the required position. According to Nelson, vascular surgeons and interventional cardiologists are accustomed to using balloons that are 150-200 mm long in the peripheral vasculature, yet Shockwave's balloon is only 60 mm, with its electrode configuration limiting greater lengths and thereby extending the duration of procedures with diffuse disease.

FastWave's balloon catheters are made more resilient by both their mechanical construction and the material chosen, aiming for a lower rupture rate than that of Shockwave's device, which is reported to be 10-15%. With a peripheral balloon costing \$3,000 and a coronary balloon costing \$5,000, the expense of balloon ruptures adds up quickly. Another known issue with delivering IVL catheters to the coronary arteries is coronary capture, or the stimulation of cardiac depolarization, which is desirable for the placement of pacemakers but not as an intended effect of vascular intervention. The sequelae of coronary capture are not well understood yet, but Nelson emphasizes caution, particularly when dealing with patients who have lower resting heart rates. To circumvent this risk, FastWave is developing a system with an alternative energy source, though no further details are available at this point.

The IVL market represents a more than \$9 billion market opportunity, by Nelson's estimate, encompassing peripheral and coronary cases as

well as valvular applications (calcium modification in the valves of the heart). The condition becomes more common with age, particularly in patients over 70 years old and especially in long-term smokers and those with diabetes or on dialysis. Though atherectomy

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—Scott Nelson

and angioplasty have more extensive adoption than IVL, neither approach is as effective for disrupting calcium in the medial layer of the vessel. In addition, physicians who are comfortable using IVL often do so to prepare arteries for the implementation of other devices, such as a drug-eluting stent, in cases of tight stenosis in a coronary artery.

IVL procedures are reimbursed "quite well, first and foremost for peripheral applications," in Nelson's words, with a temporary pass-through (TPT) code in place for the coronary market that expires this year, after which Nelson expects reimbursement to remain. FastWave is currently performing preclinical due diligence in preparation for a trial of its peripheral system as part of a 510(k) pathway, followed by first-in-human cases on the coronary side for an eventual PMA submission. The company is currently raising a Series B to fund these operations, after having raised a \$12 million Series A in August 2021 from Grand Pharma's VC arm, East Ocean Medical.

FastWave has multiple energy-based platforms in the pipeline for both peripheral and coronary indications, making it a strong candidate for acquisition by a major device manufacturer. "The company and the technology we're developing is best suited as a tuck-in for a strategic, so we've intentionally tried to move at an accelerated pace while keeping the amount of capital raised relatively minimal," explains Nelson. By working within a "build-to-buy" framework, he says there's less pressure to prove commercial traction or build out a large sales force, instead optimizing for speed of execution. In line with this goal, FastWave's team is minimal, relying on a network of consultants and freelancers, as well as key development partners such as Switchback Medical, a catheter developer and staked co-founder. Thanks to Switchback's vested interest in FastWave, the struggles of competing with larger clients for order precedence are greatly reduced. 

Posted on MyStrategist.com June 2, 2023