

EP Vantage Interview - Boston Scientific remakes itself to face the future



[Elizabeth Cairns](#)

Boston Scientific is in a state of flux. Having suffered through a poor summer when its shares fell to their lowest level in 17 years, the company is looking to innovation and diversification to improve its lot. Before that can happen, though, it faces huge upheavals.

With a restructure that will see it split its cardiac device unit, a new chief executive starting next week, the launch of an entirely new type of implantable cardioverter-defibrillator (ICD), and steps towards entering the high-profile heart valves and renal denervation sectors, Boston Scientific is juggling a number of issues. Its ability to evolve into a new organisation capable of reversing its current stagnation will depend on how well it deals with all of these.

And change cannot come soon enough. Boston Scientific released its third-quarter results last week, and the situation is not good, with a net loss of \$725m compared with a profit of \$142m a year ago. Overall sales declined 7% to \$1.7bn, and most of the damage came from the company's core interventional cardiology division; revenue there fell 20% to \$494m, while cardiac rhythm sales dropped 8% to \$462m.

Shock

First among Boston Scientific's new adventures to reverse the decline is the US launch of its S-ICD. Like other ICDs it is implanted just under the patient's skin. However, it is unlike any other device on the market in that the pacing leads are also implanted subcutaneously, rather than threaded through the vasculature to reach the heart.

"It's a totally unique technology today in the marketplace," Tim Coutts, UK General Manager at Boston Scientific, tells *EP Vantage*. "Nothing goes inside the vascular structure, nothing goes inside the heart. It's completely subcutaneous." He says that delivering shocks through leads that go into the vascular tree is not the optimal method, but has hitherto been the only option available. Boston Scientific, and more importantly, physicians, "believe that this is the way of the future".

Indeed, recent safety concerns over transvascular pacemaker leads, including St Jude's Riata and Medtronic's Sprint Fidelis technologies, could boost uptake of the S-ICD. Analysts from Credit Suisse estimate that the device will increase Boston Scientific's share of the worldwide ICD market by around 2%, or \$140m.

But the device is not without issues; it has no anti-tachy pacing, meaning that unlike other ICD that are subtly able to maintain a regular heart beat, the S-ICD is a "shock-only" device. It cannot be used in patients with pacemakers and the energy required to shock the heart means not only is the device large, but shocking is more painful.

The S-ICD was developed by Cameron Health, and Boston Scientific paid an initial \$150m upfront for the company back in March, with the trigger being filing for FDA approval of the S-ICD. The approval, which came a year earlier than Boston Scientific expected, also sparked another \$150m milestone and could see Cameron's former shareholders getting sales based milestones of up to \$1.05bn over the next six years.

Late entrant

It is possible to get a flavour of the kind of company Boston Scientific is aiming to turn into from the new areas it is investigating. Previously heavily involved in revascularisation technologies such as drug-eluting stents, balloons and cardiac resynchronisation, the company is now - finally - moving into the two hottest areas in interventional cardiology: transcatheter aortic valve implantation (TAVI) and renal denervation.

Over the past five years or so Boston Scientific has been left in the dust by Edwards Lifesciences, Medtronic and St Jude Medical in these two crucial sectors. Edwards leads the TAVI field by a country mile, with two devices CE marked and the only valve on the US market; Medtronic has a valve in Europe and St Jude is expected to achieve this milestone any day now.

But the fact Boston Scientific is behind the two groups is partly due to strategy, Mr Coutts explains.

“Sometimes you want to go first,” he says, “and sometimes you’ve made a conscious decision to be a fast follower with the best technology.”

As with Cameron and the S-ICD, Boston Scientific liked the technology – called Lotus – so much that it bought its originator, Sadra Medical, for \$193m in 2011.

Boston Scientific has a lot of faith in Lotus, believing it can take share from established valves because it can be repositioned during the implantation procedure, and because it is better able to resist regurgitation – the backflow of blood from the aorta into the left ventricle. It is on course for CE mark and European launch next year.

As for renal denervation, Medtronic leads here with a technology approved in Europe in 2010, but St Jude, Covidien and two other smaller companies also have CE marked systems. Boston Scientific’s RDN device is set for European entry in 2013. With Oppenheimer analysts putting the renal denervation market at in excess of \$10bn in the US alone, Boston Scientific’s technology could be lucrative, but once again the company is late to the party.

Tricky conditions

Boston Scientific’s strategy of increasing its product offering through acquisitions is set to continue. “We’re quite an acquisitive company,” says Mr Coutts. In the last few weeks Boston Scientific has purchased BridgePoint Medical and Rhythmia Medical, bringing a catheter-based system to treat coronary chronic total occlusions, and mapping and navigation technology for use in electrophysiology procedures, respectively, Bridgepoint and Rhythmia are perhaps closer to Boston Scientific’s comfort zone.

Much of Boston Scientific’s recent activity is geared towards shoring up its troubled cardiac rhythm management (CRM) and interventional cardiology sections, which are splitting apart having previously made up its cardiac device division. But it is also attempting to remodel itself as a more diverse developer, reducing its reliance on these two areas that are facing tricky conditions across the board – for example, St Jude’s results, also released last week, showed an 8% drop in CRM and a 4% drop in cardiovascular sales compared with the third quarter of 2011.

When the former J&J exec Mike Mahoney, the company’s new CEO – its fourth in just over three years – takes his seat on November 1, he will be watched closely to see if Boston Scientific’s apparent effort to ape its rivals flies. With sales-limiting European austerity showing little sign of relaxing and the US medtech tax lurking around the corner, Boston Scientific’s long-awaited renaissance is unlikely to happen fast.

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