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Silicon Valley startup Cardiva raises $11M to back expansion of its vascular closure tech

By Stacy Lawrence, Staff Writer

Cardiva Medical Inc. of Santa Clara, Calif., has raised $11 million to expand its U.S. marketing of its FDA-approved Vascade vascular closure system and to fund a pivotal trial for an investigational device specifically in vascular closure after electrophysiology procedures.

The vascular access management startup also markets the Catalyst Manual Compression Assist Device, which first launched in 2005 with the most recent iteration cleared by the FDA in 2009. This latest infusion brings the total equity and debt raised by Cardiva to $41 million.

After electrophysiology

The pivotal trial is for a newly disclosed investigational vascular closure device that is for use after electrophysiology procedures. The study is already underway and expected to report out this year with a PMA submission to follow. The trial is randomized against standard-of-care, which is manual compression that typically requires up to six hours of bed rest following an EP procedure.

The study, known as AMBULATE, aims to get patients up and walking sooner with the investigational device than SOC, with effective vessel closure that more rapidly minimizes the chances of subsequent bleeding, which is a common complication.

Principal investigators on this trial include Andrea Natale, the executive medical director of the Texas Cardiac Arrhythmia Institute; Mintu Turakhia, an Associate Professor at Stanford University School of Medicine; and Steve Compton of the Alaska Heart and Vascular Institute.

"What we've done is identify a significant unmet clinical need, which is closure for mid-bore vein procedures that fall into the range of six to 12 French inner diameter access sheaths. Essential procedures that would fall in this category are cardiac ablation, left atrial closure, venous stent procedures. As a category, this is a procedure group which is growing in the double-digits, in particular EP cardiac ablation procedures," John Russell, Cardiva President and CEO, told *BioWorld MedTech*.

"What most of these procedures have in common is that they use multiple access sites in the femoral vein. The sheaths are larger than what is used in today's standard arterial closure procedures and the patients are on significant anticoagulation," he added, noting later that "We believe that this is the first-of-its-kind trial in this space."

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>
> John Russell
> President and CEO, Cardiva

After the catheter

Cardiva already markets a handful of products and has achieved four consecutive years of revenue growth, although its revenues remain undisclosed. Vascade drives most of that growth with Catalyst II and Catalyst III contributing as well to sales.

Vascade is an extravascular, bioabsorbable femoral access closure system. It is fully integrated and based on Cardiva's collapsible disc technology integrated with a thrombogenic, resorbable collagen patch. It is used for closure after femoral vein access in catheter-based, interventional arterial procedures. Vascade deposits that small, collagen patch on the outside of the arterial puncture site. The biomaterial enhances the clotting cascade.

"Vascade is the only closure device to demonstrate statistically significant improvement in access site complications versus manual compression in a multi-center, randomized, controlled clinical trial," said Russell. "The trial was called RESPECT,

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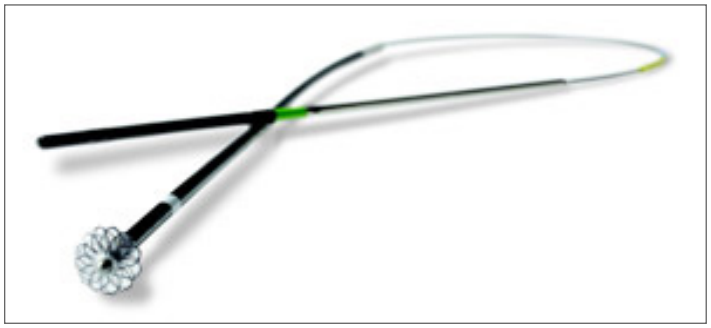
which we ran for our PMA approval for Vascade originally. That improvement in complications was in addition to demonstrating improvement in time to hemostasis and time to ambulation, which are the traditional metrics for closure devices."

He added that the global market for arterial closure is about $600 million with only four commercial players, with Cardiva being the only private company among them.

The startup, which was founded about 15 years ago, first marketed its Catalyst device. The recent iterations are intended as an improvement over manual compression, reducing mean hold time by more than 50 percent and time to ambulation by more than 20 percent.

Catalyst II is coated with kaolin and chitosan used to promote coagulation by activating the clotting cascade and causing platelet aggregation, while Catalyst III adds a protamine sulfate coating that is intended to neutralize the anticoagulant heparin.

Cardiva investors include PTV Healthcare Capital, Canepa Healthcare and affiliates of Luther King Capital Management.



Vascade vascular closure system; Cardiva Medical Inc.

"This additional investment reflects enthusiasm from our investors for the continued high rate of sales growth of Vascade, as well as for the exciting potential of our mid-bore vein closure program," summed up Russell. "With the AMBULATE Trial, we are fortunate to have a world-class group of investigators." ♦