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VasoStar's vibrating guidewire takes aim at coronary artery blockages

A Cleveland-area startup is developing an electromagnetic vibrating catheter and guidewire system that could give interventional cardiologists a better means of pushing through serious coronary artery blockages called chronic total occlusions.

Mentor, Ohio-based VasoStar recently received a $1 million grant through Ohio's Third Frontier technology acceleration program that the company plans to use to fund the first human tests of its new innovative medical device. The company's technology has demonstrated safety in animal studies.

That funding is expected to take the company to the point of filing for U.S. Food and Drug Administration clearance of its device, which is projected for 2013, said Chief Operating Officer Stephanie Harrington.

VasoStar is a subsidiary of Frantz Medical Group, a device manufacturer that also has a venture arm that invests in and forms startups. VasoStar was formed in 2008 to license its core technology from an Israeli company, Harrington said. In addition to the Third Frontier grant, the company has received grant support from Cleveland Clinic's Global Cardiovascular Innovation Center and the National Institutes of Health.

The company thinks its device could provide a less-invasive and safer option to coronary artery bypass grafting (CABG), a procedure that can become necessary when plaque builds up in a patient's blood vessels and reduces blood flow to the heart. VasoStar's technology is designed to break through plaque formations called chronic total occlusions (CTOs) to place stents. About 10 percent of CTOs are treated with less-invasive interventional techniques and VasoStar's system could help increase that number and reduce invasive surgeries for heart disease or chronic chest pain that can lead to complications.

To break through CTOs using existing technology, a doctor must snake a guidewire through a patient's arteries up to the CTO in the heart. Once the guidewire has reached the CTO, the physician taps and turns the guidewire using her hand in an attempt to penetrate through the CTO to open up the vessel with follow-on therapy such as balloons and stents.

VasoStar's technology adds a high-frequency vibration at the end of the guidewire near the CTO, which allows the clinician to turn on the device for more force and tapping frequency. When the guidewire has penetrated through the CTO, the physician can turn off the electromagnetic power source and continue the procedure using the same guidewire to position balloons and stents.

"The main advantage of our approach is that it offers clinicians the ability to penetrate CTOs safely and effectively without significantly changing their conventional guidewire practices," Harrington said.

After obtaining 510(k) clearance in 2013, VasoStar expects to distribute the system through a larger company that sells vascular devices.

"Our goal is to retain the proprietary technology, regulatory responsibility and manufacturing while leveraging the sales and marketing reach of a global leader in vascular medical devices," Harrington said.