



Surmodics Announces Successful First Patient Use of Pounce™ Thrombectomy System

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Standalone arterial mechanical thrombectomy device removes 30 cm of subacute thrombus in first clinical case

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jul. 29, 2021--

Surmodics, Inc. (NASDAQ: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that J. Michael Bacharach, MD, vascular interventionalist/cardiologist at North Central Heart, a division of Avera Heart Hospital in Sioux Falls, South Dakota, successfully treated the first patient with the company's Pounce™ Thrombectomy System.

The procedure, completed last month, involved a patient presenting with increasing pain in the left leg and was diagnosed with an occluded superficial femoral artery (SFA). Three passes of the Pounce device removed 30 cm of subacute thrombus and blood flow was successfully restored. Eight additional cases have since been performed in the U.S., with positive outcomes reported following each procedure.

"Despite the challenge presented by this particular case, I couldn't have asked for anything more. The device's performance was really amazing," said Dr. Bacharach. "I was able to safely and effectively achieve a positive outcome for this patient with minimal blood loss and without the use of thrombolytics. I'm very excited about the results of this case. I'm a believer in the Pounce system!"

The Pounce Thrombectomy System, which received U.S. Food & Drug Administration (FDA) 510(k) clearance in Sept. 2020, is a mechanical thrombectomy device intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. Depending on the age and magnitude of the occlusion and the viability of the threatened limb, existing treatments for this condition may include catheter directed thrombolysis, surgical embolectomy, and/or percutaneous mechanical thrombectomy. In cases in which the occlusion has caused irreversible damage to the limb, acute limb ischemia can result in the amputation of a lower extremity.

"I am delighted that the Surmodics team is providing peripheral interventionalists with this innovative tool for treating arterial thrombotic occlusions," said Gary Ansel, MD, founder and former Chief Medical Officer of Embolitech, from which Surmodics acquired the technology and intellectual property behind the Pounce Thrombectomy System. "I also congratulate the company on its continued efforts to advance therapies for patients dealing with arterial thrombosis and peripheral arterial disease (PAD) while focusing on ease of use and efficiency for the physicians treating these patients."

"We are grateful for Dr. Bacharach and his partnership in performing this first case with the Pounce Thrombectomy System," said Gary Maharaj, President and Chief Executive Officer of Surmodics. "We are highly encouraged by his initial feedback. Having such a positive experience with this first case is a testament to this product and delivers on our timeline goal of getting our first successful case in third quarter of FY21. We look forward to the expansion of our evaluation efforts in the weeks ahead."

About the Pounce Thrombectomy System

The Pounce Thrombectomy System facilitates thrombus removal in peripheral vasculature without the added expense or commitment to any additional, external capital equipment. The device is comprised of three components: a 5 Fr basket delivery catheter, a basket wire assembly, and a trumpet assembly. After the basket wire assembly is delivered distal to the location of the thrombus, two nitinol self-expanding baskets are deployed to collect and entrain the clot into a trumpet-shaped nitinol wire mesh. With the clot entrained, the trumpet assembly is then collapsed into a 7 Fr guide sheath through which the clot is withdrawn and removed from the body.

About Peripheral Arterial Disease (PAD)

Worldwide, over 200 million people suffer from PAD¹, a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Twelve to 20 percent of Americans over 60 years old have PAD², which increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.³

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about future evaluations of the Pounce Thrombectomy System and the company's growth strategy, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at <https://surmodics.gcs-web.com> and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

References:

1. Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.
2. Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
3. National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

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