# Surmodics Announces Global Approvals of .014" Low-Profile PTA Balloon Dilation Catheter

September 18, 2017

***The company received FDA 510(k) and CE Mark clearance***

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Sep. 18, 2017-- Surmodics, Inc. (NASDAQ: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, announced it has received U.S. Food and Drug Administration (FDA) 510(k) and CE Mark clearance for its .014" low-profile percutaneous transluminal angioplasty (PTA) balloon dilation catheter, designed for peripheral angioplasty procedures. The company is making this product available for distribution in the coming months.

Surmodics .014" PTA balloon catheter offers best-in-class deliverability and lesion crossing by leveraging the company's proprietary Serene ® hydrophilic coating, unmatched for low friction and particulates.[1] The company's proprietary balloon and catheter technology, combined with Surmodics' advanced processes, ensures ultra-low tip entry and crossing profile with smooth transitions, to achieve best-in-class product performance.

"Surmodics is focused on providing next-generation devices to address the growing need for minimally invasive treatment of peripheral artery disease," said Gary Maharaj, President and CEO of Surmodics. "We're confident this highly deliverable, low-profile PTA catheter will provide physicians an effective new tool for accessing and crossing even the most complex peripheral lesions."

The development of the Surmodics .014" low-profile PTA catheter is a step forward in the company's strategy to be a provider of whole-product vascular solutions for its medical device customers. Following acquisitions of Creagh Medical and NorMedix, Surmodics now has complete capabilities for design, development and high-volume manufacturing of a wide variety of highly differentiated balloon catheter and specialty catheter solutions.

With a complete suite of in-house capabilities at its state-of-the-art facility in Ballinasloe, Ireland, Surmodics controls every step of the manufacturing process to produce high-quality, reliable balloon catheters under rigorous testing. Surmodics' portfolio of balloon technologies includes the highest-pressure conventional balloons.[1]

**About Peripheral Artery Disease**

Worldwide, over 200 million people have peripheral artery disease (PAD),[2] 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 PAD.[3] PAD 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.[4]

**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) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total solutions, Surmodics' mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the company, 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 beliefs and expectations regarding the company's strategy to transform to a provider of whole-product solutions. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) our ability to successfully develop, obtain regulatory approval for, and commercialize our proprietary products; (2) our ability to achieve expected benefits from our acquisitions; and (3) 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, 2016, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at www.surmodics.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.

[1]Surmodics data on file

[2] Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.

[3]Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.

[4]National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170918005186/en/

Source: Surmodics, Inc.

Surmodics, Inc.

Andy LaFrence, 952-500-7000
ir@surmodics.com