



Surmodics Announces Successful First Patient Uses of Two Sublime™ Radial Access Platform Devices

April 1, 2021

Sublime™ Radial Access .014 RX PTA Dilatation Catheter, Sublime Radial Access Guide Sheath Deliver Outstanding Performance in Initial Physician Evaluations

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Apr. 1, 2021-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced the successful first uses with patients for two devices within its [Sublime™ Radial Access Platform](#): the Sublime™ Radial Access Guide Sheath and Sublime Radial Access .014 RX PTA Dilatation Catheter.

Dr. Constantino Pena, MD, Dr. Andrew Niekamp, MD, and Dr. Brian Schiro, MD, Interventional Radiologists at Baptist Health's Miami Cardiac & Vascular Institute, performed the first set of procedures utilizing the Sublime Radial Access Guide Sheath earlier this year. In early March, Dr. Osama A. Ibrahim, MD, FACC, utilized the Sublime Radial Access .014 RX PTA Dilatation Catheter in multiple cases, including a below-the-knee procedure which showcased the benefits of both Sublime products. Dr. Ibrahim performed his cases at the Ashchi Heart and Vascular Center in Jacksonville, Fla.

"We are thrilled and humbled to be the first facility to use the Sublime .014 RX PTA Dilatation Catheter, and our initial experience with this PTA catheter and the Sublime Radial Access Guide Sheath was outstanding. Delivery of the catheter was easy, even below-the-knee. The pushability, trackability, and crossability all were exceptional. We performed multiple inflations in the below-the-knee case and the crossing profile of the balloon was impeccable," said Dr. Ibrahim. "Our goal at Ashchi Heart and Vascular Center is to go radial-first for all cases. The Sublime platform products we evaluated could certainly aid us in this effort."

The Sublime Radial Access .014 RX PTA Catheter, which received FDA 510(k) clearance in August 2020, allows above- or below-the-knee access through a transradial approach by providing the longest working length (250 cm) on the market. Outer balloon diameters range from 2.0 mm to 4.0 mm with balloon lengths between 20 mm and 220 mm. The device is compatible with a 5 Fr guide sheath and is designed to provide the performance of an over-the-wire PTA catheter in an RX platform. Its proprietary reinforced shaft technology with flexible, kink-resistant construction and 250 cm hydrophilic coating are designed for optimal trackability and push through distal tortuosity.

The FDA-cleared Sublime Radial Access Guide Sheath is the industry's first 5 Fr sheath available in lengths up to 150 cm and sets a new standard for lower extremity treatment through a transradial approach. Designed to meet the specific demands of transradial access to the periphery, the Sublime Radial Access Guide Sheath incorporates a proprietary braiding technology and high metal composition within the shaft to provide a unique balance of kink resistance, flexibility, radial strength, and torque power. The device is also available with a 6 Fr outer diameter and 120 cm lengths.

"We are grateful to Dr. Pena, Dr. Niekamp, Dr. Schiro, and Dr. Ibrahim for performing these first cases with Sublime Radial Access Platform devices. The successful procedures are significant milestones for Surmodics and advance our efforts to enable below-the-knee procedures, or provide access for other peripheral treatments, using a transradial approach," said Gary Maharaj, President and CEO of Surmodics. "The numerous benefits of radial access—including cost savings, reduced risk of complications, and shorter length-of-stay—have been well researched¹. The lack of reliable tools to extend from the wrist to the tibials has limited the ability to standardize on a radial first approach. Our portfolio is quickly expanding and with industry-available complementary devices, this opens the door to adopting a radial-first strategy."

Radial artery access has been widely adopted for use in coronary procedures where devices have been developed to accommodate clinical need. However, the transradial approach for peripheral intervention has been limited by a lack of purpose-built devices that fulfill the needs of these procedures.²⁻⁵ Many available options are too short to reach the target treatment area from the radial access site, have outer diameters that are too large for the smaller radial artery, and are not specifically designed to navigate the long distances that are required when using the radial approach for lower periphery treatment.

The Sublime Radial Access .014 RX PTA Dilatation Catheter is indicated for PTA dilation of peripheral vasculature stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is contraindicated for use in the coronary arteries and the neurovasculature.

The Sublime Radial Access Guide Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neuro vasculature.

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 the expansion of the Sublime radial access portfolio 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, 2019, 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:

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Source: Surmodics, Inc.