

Surmodics Announces Successful First Patient Uses of Sublime™ Radial Access .018 RX PTA Dilatation Catheter

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Latest addition to the Sublime™ Radial Access Platform expands market opportunity by increasing size offering to treat larger vessels and providing the shaft length needed to treat more distal lesions using a radial approach

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Sep. 29, 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 clinical uses of the Sublime™ Radial Access .018 RX PTA Dilatation Catheter.

Ankur Lodha, MD perfomed the first procedures with the device at Cardiovascular Institute of the South's office-based catheterization lab in Lafayette, LA. Subsequently, Imraan Ansaarie, MD, FCCP, FSCAI utilized the Sublime Radial Access .018 RX PTA Dilatation Catheter in cases at Advanced Endovascular Institute of St. Augustine, FL. The device is the latest addition to the Sublime Radial Access Platform, joining the Sublime Radial Access Guide Sheath and the Sublime Radial Access .014 RX PTA Dilatation Catheter.

"Sublime Radial Access RX PTA Dilatation Catheters will allow physicians to treat the most distal blockages in the foot with just radial access. This will help us perform more complex interventions via this approach which was not possible prior," said Dr. Lodha.

"This Sublime Radial Access .018 RX PTA Dilatation Catheter is a great addition to the current devices available for minimal arterial access lower extremity intervention (MáLEI) procedures," added Dr. Ansaarie.

The Sublime Radial Access .018 RX PTA Dilatation Catheter, which received FDA 510(k) clearance in June 2021, allows above- or below-the-knee access through a transradial approach by providing the longest working length (220 cm) on the market. Outer balloon diameters range from 2.0 mm to 6.0 mm, allowing for treatment in larger vessels, with balloon lengths between 20 mm and 220 mm. With a proprietary shaft construction incorporating a flexible distal segment, a supportive proximal segment, and a mid-shaft that transitions from supportive to flexible, the Sublime .018 RX PTA Dilatation Catheter is designed to provide improved pushability, trackability and crossability in an RX platform.

"We are thrilled that Dr. Lodha and Dr. Ansaarie pioneered these first cases with the Sublime Radial Access .018 RX PTA Dilatation Catheter," said Gary Maharaj, president and CEO of Surmodics. "The lack of reliable tools has limited the ability to standardize on a radial first approach. We are quickly expanding our portfolio of radial access devices. This enables more physician practices to adopt a radial-first strategy."

The numerous benefits of radial access—including cost savings, reduced risk of complications, improved patient satisfaction, and shorter length-of-stay—have been well researched. 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, or 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 .018 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.

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, 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:

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