Surmodics Announces First Patient Enrolled in PROWL Registry Study Using the Pounce™ Thrombectomy System

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Registry to enroll up to 500 patients at up to 30 sites, collecting real-world outcomes data for the Pounce ™ Thrombectomy System

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Apr. 20, 2023-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced enrollment of the first patient in PROWL, the Pounce™ Thrombectomy System Retrospective Registry.

PROWL is an open-label, retrospective, multi-center, U.S. registry of the Surmodics Pounce system for the non-surgical removal of emboli and thrombi in the peripheral arterial vasculature. The registry will collect real-world efficacy and safety outcomes data for endovascular interventions using the Pounce system for up to 500 patients at up to 30 sites. Dr. Sean Lyden, Chairman of the Department of Vascular Surgery, Cleveland Clinic, and Dr. Joseph Campbell, Interventional Cardiologist, OhioHealth, are National Co-Principal Investigators. The first site to enroll a patient in the registry study was Baton Rouge General Medical Center, Baton Rouge, La.

“We are delighted to be the first site to enroll a patient in the PROWL registry,” said Dr. Joseph Griffin, Vascular Surgeon, Vascular Specialty Center, LLC and Baton Rouge General Medical Center. “In our experience, the Pounce system promptly removes peripheral arterial clot in a single treatment session while reducing the need for thrombolytic drugs and subsequent ICU stays. We’re eager to help track outcomes in this important study.”

“We’ve long needed better tools to help us resolve acute limb ischemia in a simple and effective manner, without the use of multiple adjunctive treatments,” he added. “In this respect, our experience with the Pounce system has been quite positive.”

PROWL’s primary efficacy endpoint is procedural success, while the primary safety endpoint is the incidence of device-related major adverse events (MAEs) through 30 days.

“Acute limb ischemia from arteries blocked by thrombus or embolus is an urgent threat to both limb and life,” said Gary Maharaj, President and CEO of Surmodics, Inc. “With hospitals increasingly short on staff and beds, physicians need a simple and effective tool that lets them restore arterial flow right on the table without resorting to time-consuming and costly adjunctive treatments. We are confident the PROWL registry will demonstrate these exceptional attributes of the Pounce system in real-world clinical practice.”

About the Pounce Thrombectomy System

The Pounce Thrombectomy System is composed of three components: a 5 Fr delivery catheter, a basket wire, and a funnel catheter. The basket wire is delivered distal to the location of the thrombus, deploying two nitinol self-expanding baskets. The baskets capture the clot and are retracted into the nitinol collection funnel. With the clot entrained, the system is withdrawn into a minimum 7 Fr guide sheath through which the clot is removed from the body.

About Acute Limb Ischemia (ALI)

ALI is characterized by a sudden decrease in arterial perfusion to the limb, with a potential threat to limb survival, requiring urgent evaluation and management. Common causes include embolization due to cardiac dysrhythmia or thrombus from pre-existing peripheral artery disease.[1] ALI is associated with 30-day amputation and mortality rates as high as 30% and 11.5%, respectively.[2] ALI-related interventions may account for up to 16% of the case volume for vascular surgeons and be accompanied by hospitalization costs of $26,000–$29,000.[2] Interventional radiologists and interventional cardiologists also treat ALI.

About Surmodics, Inc.

Surmodics is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention 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 modification and drug-delivery coating technologies, along with its device design, development, and manufacturing capabilities. The company's mission is 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 Securities and Exchange Commission.

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 number of patients and sites expected to be involved in the PROWL registry, the anticipated outcomes of the PROWL registry, 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 willingness of patients and facilities to participate in the PROWL registry, the ability to complete the PROWL registry, the results of the PROWL registry, and 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, 2022, 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.

1. Björck M, Earnshaw J, Acosta S, et al. European Society for Vascular Surgery (ESVS) 2020 clinical practice guidelines on

the management of acute limb Ischaemia. Eur J Vasc Endovasc Surg. 2020; 59(2):173e218.
2. Gupta R, Siada SS, Bronsert M, Al-Musawi MH, Nehler MR, Jeniann AY. High Rates of Recurrent Revascularization in Acute Limb Ischemia–A National Surgical Quality Improvement Program Study. Ann Vasc Surg. 2022;87:334-342.

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Surmodics Investor Inquiries:
Jack Powell, Investor Relations
ir@surmodics.com

Surmodics Public Relations Inquiries:
pr@surmodics.com

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