Surmodics Announces Outcomes from 160 Patients in PROWL Registry Evaluating Pounce™ Thrombectomy Platform in Treatment of Real-World Limb Ischemia Presentations

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Analysis of the all-comers PROWL Registry demonstrated high procedural success and safety in a cohort reflecting the real-world complexity of patients with symptomatic limb ischemia, over 40% of whom had symptoms lasting more than two weeks before intervention with the Pounce™ Platform.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 4, 2025-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that results from an analysis of 160 real-world patients with symptomatic infrainguinal limb ischemia from its PROWL registry study were presented on November 3rd at an industry-sponsored session at the 23rd Annual VIVA Conference in Las Vegas, NV. PROWL national co-principal investigators Dr. Sean Lyden and Dr. Joseph Campbell, and study investigator Dr. Peter Monteleone, presented the results.

PROWL is an open-label, retrospective, multi-center, U.S. registry of the Surmodics Pounce™ Thrombectomy Platform for the non-surgical removal of emboli and thrombi in the peripheral arterial vasculature. The registry is collecting real-world efficacy and safety outcomes data for endovascular interventions using the fully mechanical, non-aspiration-based Pounce Thrombectomy Platform for up to 500 patients at up to 30 sites. The core lab-adjudicated study is enrolling all patients treated with the Pounce Platform, including those with shortened life expectancy, history of cancer or COVID-19, prior interventions to the target limb, and symptom duration up to and beyond 28 days. Most patients in the subset were treated with the Pounce Thrombectomy System, indicated for use in peripheral arteries 3.5-6 mm in diameter.

The analysis examined subjects with symptomatic infrainguinal vessels followed through 30 days. The primary effectiveness endpoint, procedural success in target lesion(s) with or without adjunctive treatment, was 91.7%. The primary safety endpoint, incidence of device-related major adverse events (MAEs) from procedure to 30-day follow up, was 0.6% (N=1).

The vast majority (94.8%) of patients experienced final core lab adjudicated post-procedural TIPI 2-3 blood flow restoration. Device technical success, restoration of blood flow to the target lesion(s) with <50% residual obstruction without the need of other therapies, was 83.2%. Average Pounce Platform use time in the study was 24.1 minutes with a median of 2 passes per patient. Core lab adjudicated procedural thrombus removal was complete or substantial in 94.1% of patients upon procedure completion.

Previous studies of pharmacomechanical or aspiration thrombectomy for symptomatic limb ischemia only included patients with acute limb ischemia (symptom duration ≤14 days).[1-3] In the 160-patient PROWL registry cohort, 43.1% of patients presented with >2 weeks of symptoms, a reflection of the heterogeneous clinical presentations seen in real-world treatment of peripheral ischemia.[4]

In this diverse PROWL cohort of acute, subacute, and chronic thrombotic presentations, 78.8% of patients did not require adjunctive treatments (thrombolysis and/or thrombectomy) for clot removal following use of the Pounce Platform. Product use was well tolerated, with only 1 patient (0.6%) experiencing a device-related adverse event.* There were no reports of device related distal embolization.† All-cause major adverse events at 30 days post-procedure were major amputation (8.1%, N=13), clinically driven target lesion revascularization (7.5%, N=12), and death (4.4%, N=7). There were no device-related deaths.

“As reflected in the all-comers PROWL registry, a large share of PAD patients who require prompt removal of arterial blood clots have experienced symptoms well beyond two weeks,” said Dr. Campbell. “The exclusion of these patients from other studies of peripheral arterial thrombectomy is a serious limitation, as thrombus becomes more organized with age and increasingly resistant to thrombolytics and aspiration-based devices. Findings from the PROWL registry show that the Pounce Thrombectomy Platform is an effective, rapid, low-risk option for front-line endovascular treatment of limb ischemia across the diverse populations we see in clinical practice.”

“Real-world thromboembolic patients present with numerous uncontrollable factors, including tremendous variability in lesion characteristics and locations, medical history, symptom duration, and urgency,” said Dr. Lyden. “Data from the PROWL registry demonstrate that this device effectively addresses this variability, achieving rapid, efficient clot removal across a broad spectrum of clot chronicity and patient comorbidities. In nearly 80% of patients, no additional clot removal was required following use of the device, and procedural success exceeded 90%, outcomes that can translate to shorter procedure times, and reduced risk of complications.”

About the Pounce Thrombectomy Platform

The Pounce Thrombectomy Platform comprises the Pounce Thrombectomy System, Pounce LP (Low-Profile) Thrombectomy System, and the Pounce XL Thrombectomy System. All are FDA-cleared, fully mechanical thrombectomy devices designed to promptly remove organized thrombus or embolus without the need for thrombolytics, aspiration, or capital equipment. They are indicated for use in peripheral arteries 3.5-6 mm, 2-4 mm, and 5.5-10 mm in diameter, respectively.

Described as “grab-and-go” solutions, Pounce Thrombectomy Platform devices are both readily deployable and simple to use. The systems are composed of three components: a delivery catheter, a basket wire, and a funnel catheter. The basket wire is delivered via the delivery catheter 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 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 the statements regarding the potential number of patients and sites for the PROWL registry study and Surmodics' 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 outcome of the full PROWL registry study, 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, 2024, 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.

* Flow-limiting dissection followed by clinically driven target lesion revascularization
† Distal embolization requiring surgical procedure or obstructing one of the major downstream vessels >70% at the end of the procedure.

1. *Maldonado TS, Powell A, Wendorff H, et al. Safety and efficacy of mechanical aspiration thrombectomy for patients with acute lower extremity ischemia. J Vasc Surg. 2024;79(3):584-592.*
2. *de Donato G, Pasqui E, Sponza M, et al. Safety and efficacy of vacuum assisted thrombo-aspiration in patients with acute lower limb ischaemia: the INDIAN trial. Eur J Vasc Endovasc Surg. 2021;61(5):820-828.*
3. *Leung DA, Blitz LR, Nelson T, et al. Rheolytic Pharmacomechanical Thrombectomy for the Management of Acute Limb Ischemia: Results From the PEARL Registry. J Endovasc Ther. 2015;22(4):546-557*
4. *Howard DP, Banerjee A, Fairhead JF, Hands L, Silver LE, Rothwell PM. Population-based study of incidence, risk factors, outcome, and prognosis of ischemic peripheral arterial events: implications for prevention. Circulation. 2015;132(19):1805-1815.*

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