Surmodics Announces Results from Sex-Specific Analysis of the PROWL Registry Study of Real-World Limb Ischemia Patients Treated with the Pounce™ Thrombectomy Platform

October 29, 2025 at 4:15 PM EDT

Analysis of 160 patients with acute, subacute, or chronic symptoms of thrombotic limb ischemia receiving thromboemboli removal treatment with the Pounce™ Thrombectomy Platform demonstrated high procedural success across sexes, 91.3% technical success in women.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 29, 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 a sex-specific analysis of 160 real-world acute, subacute, and chronic thrombotic limb ischemia patients from its PROWL registry study were presented by Dr. Peter Monteleone at the 37th Annual TCT Symposium in San Francisco, CA.

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. The full results of the PROWL registry will be presented on November 3, 2025, at the VIVA Vascular Symposium. On October 28, 2025, study investigator Dr. Monteleone, on behalf of the PROWL investigators and National Co-Principal Investigators Dr. Sean Lyden, Chairman of the Department of Vascular Surgery, Cleveland Clinic, and Dr. Joseph Campbell, Interventional Cardiologist, OhioHealth, presented results from a sex-specific analysis of the 160-patient infrainguinal PROWL subset. Most patients in this subset were treated with the Pounce Thrombectomy System, indicated for use in peripheral arteries 3.5-6 mm in diameter.

The analysis examined a subset of 160 patients (60 female, 100 male) who received Pounce Platform treatment in symptomatic, infrainguinal vessels, followed through 30 days. Procedural success, defined as restoration of pulsatile flow in the target lesion(s) with or without adjunctive treatment (patient level success), was achieved in 94.7% of female and 89.9% of male patients (p=0.3765). Technical success, defined as restoration of blood flow to the target lesion(s) with <50% residual obstruction without the need to initiate catheter-directed thrombolysis or to proceed to open surgery or other endovascular thrombectomy devices (lesion-level success), was achieved in 91.4% and 78.3% of target lesions for female and male patients, respectively, and reflected a significant difference between groups (p=0.0261).

Core lab adjudicated thrombus removal was complete or substantial in 93.8% of female patients and 94.3% of male patients, including 71.4% of female patients and 78.9% of male patients following use of the Pounce Thrombectomy Platform. These differences were not statistically significant between groups. Arterial flow improved in 97.2% of female patients and 93.4% of male patients (TIPI Grade 2/3). The composite outcome of freedom from all-cause major adverse events (MAEs), comprising mortality, major amputation, and clinically driven target lesion revascularization, was seen in 73.3% of female patients and 86.0% of male patients (p=0.0599).

Most previous studies of aspiration thrombectomy for symptomatic acute limb ischemia excluded patients with symptom duration greater than 14 days, and did not report on the presence of subacute or prolonged limb ischemia among these patients.[1-3] In this 160-patient PROWL registry subset, 41.7% of female patients and 44% of male patients presented with >2 weeks of symptoms, a reflection of the heterogeneous clinical presentations seen in real-world treatment of peripheral ischemia.[4]

There was a high level of acuity among both women and men in the cohort. Nearly half (48.5%) of women, and 47.3% of men, presented with Rutherford acute limb ischemia classification IIb or III, indicating immediately threatened limbs.

“Use of the Pounce Thrombectomy Platform achieved high procedural success in both women and men, with significantly greater technical success in women,” said Dr. Monteleone. “However, women experienced a trend toward less favorable clinical outcomes than men. These findings are consistent with prior evidence of elevated risk for female patients receiving limb ischemia interventions.”

In a 2020 analysis of 58,165 patients from the National Inpatient Sample, Hassan et al. identified female sex as an independent predictor of major adverse events in acute or symptomatic chronic limb ischemia requiring peripheral intervention (adjusted odds ratio, 1.36; 95% CI, 1.12–1.65; p = 0.002).[5]

Dr. Monteleone added, "Acute limb ischemia is a hugely morbid and expensive disease, with enormous variability in patient presentation, clot characteristics, and the anatomic locations of these clots. This variability has made endovascular management of ALI very challenging using the thrombectomy tools previously available to us. The Pounce Thrombectomy Platform is revolutionary—it gives physicians a reliable endovascular-first option for treating complex thromboembolic clots in high-risk patients without surgical embolectomy."

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 patents and sites for the PROWL registry study, the expectation that the full results of the PROWL registry will be presented on November 3, 2025, at the VIVA Vascular Symposium, 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.

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