



Surmodics Announces Successful Early Clinical Use of Pounce™ XL Thrombectomy System, Suitable for Non-Surgical Removal of Thrombi and Emboli from Iliac and Femoral Arteries

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With the addition of the Pounce™ XL Thrombectomy System, indicated for use in 5.5–10 mm peripheral arteries, the Pounce™ Thrombectomy Platform can now rapidly remove acute or chronic clot throughout the lower extremity without aspiration, thrombolysis, or capital equipment.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Feb. 3, 2025-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced the successful early clinical use of its Pounce™ XL Thrombectomy System. The Pounce XL Thrombectomy System received U.S. Food and Drug Administration (FDA) 510(k) clearance in September 2024, and is currently in limited market release (LMR), with full commercial launch planned following completion of the LMR.

Surmodics Pounce Thrombectomy systems are intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. The new Pounce XL Thrombectomy System is indicated for use in vessels ranging from 5.5–10 mm in diameter, sizes typical of iliac and femoral arteries. The Pounce XL System complements the Pounce and Pounce LP Thrombectomy Systems, which are indicated for 3.5–6 mm and 2–4 mm vessels, respectively.

University of Pittsburg Medical Center (UPMC) Hamot vascular surgeon Dr. Walter Rizzoni successfully used the new Pounce XL Thrombectomy System to restore blood flow in a thrombosed stent graft 8 mm in diameter. This marks Dr. Rizzoni's first case using the innovative device at the Erie, Pa. hospital.

"The Pounce XL Thrombectomy System removed a significant amount of chronic material during our first use," said Dr. Rizzoni. "In that respect, its performance was right in line with our experience using the Pounce and Pounce LP Systems."

"We're excited about the positive feedback we've received from early users of the Pounce XL System," said Gary Maharaj, President and Chief Executive Officer of Surmodics. "The addition of this larger-profile device to the Pounce Thrombectomy Platform fulfills our goal of providing physicians a standalone solution for rapid removal of acute or chronic peripheral arterial clot throughout the lower extremity. With hospitals under growing pressure to reduce costs, we believe the standalone Pounce Thrombectomy Platform may help reduce the need for hospitalizations and follow-up procedures."

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. The Pounce XL Thrombectomy System is currently pending full commercial release.

Described as "grab-and-go" solutions, Pounce Thrombectomy Platform systems are readily deployable and simple to use. Each system is 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 the PROWL registry

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.

On January 29, 2025, early results from the PROWL registry were presented at the 20th annual Leipzig Interventional Course (LINC) in Leipzig, Germany. Subset analysis of 74 PROWL patients with symptoms of limb ischemia demonstrated 97.1% TIPI 2-3 procedural flow restoration, with 79.7% of subjects not receiving additional thromboemboli removal treatment post Pounce or Pounce LP System use.* Four in ten (40.5%) patients in the cohort presented with symptoms of subacute (15-28 days) or chronic (>28 days) limb ischemia, a marked difference from previous studies of pharmacomechanical or aspiration peripheral arterial thrombectomy limited to ≤14-day limb ischemia.¹⁻³

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 regarding the expectation of full commercial launch of the Pounce XL Thrombectomy System following completion of the LMR, our belief that the standalone Pounce Platform may help reduce the need for hospitalizations and follow-up procedures, 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 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.

* No patient data for the Pounce XL System was available from the LINC subset analysis.

1. 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.

2. 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.

3. 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.

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