Surmodics Receives FDA 510(k) Clearance for Pounce™ XL Thrombectomy System, Expanding the Pounce Thrombectomy Platform to Larger Peripheral Arteries up to 10 mm in Diameter

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The Pounce™ Thrombectomy Platform can now be used to remove clot from peripheral arteries as small as 2mm up to as large as 10 mm in diameter, broadening the platform's clinical utility and significantly expanding its addressable market

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 1, 2024-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Pounce™ XL Thrombectomy System.

The Pounce XL Thrombectomy System is indicated for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature in vessels 5.5–10 mm in diameter, making it suitable for iliac, femoral, and other arteries within this range. The Pounce XL Thrombectomy System dramatically increases the size range of the Pounce Thrombectomy Platform, which also includes the Pounce Thrombectomy System, indicated for 3.5–6 mm peripheral arteries, and the Pounce LP (Low Profile) Thrombectomy System, indicated for 2–4 mm peripheral arteries. The Pounce Thrombectomy System and Pounce LP Thrombectomy System were introduced in 2021 and 2024, respectively.

“Securing FDA clearance for the Pounce XL Thrombectomy System is a major step forward in Surmodics’ pursuit of a complete mechanical thrombectomy solution for all peripheral arteries, notably critically ischemic lower extremity vessels,” said Gary Maharaj, President and Chief Executive Officer of Surmodics. “The Pounce Thrombectomy Platform has already demonstrated its performance as a rapid, efficient solution for the removal of both acute and chronic thrombi and emboli in peripheral arteries without the use of thrombolytics. The addition of the Pounce XL Thrombectomy System to our Pounce Thrombectomy Platform demonstrates our commitment to setting the pace and direction of innovation in this critical space.”

Mr. Maharaj added, “Critically ischemic peripheral arteries often have older, organized clots that resist catheter-directed thrombolysis and aspiration thrombectomy. The Pounce Thrombectomy Platform allows physicians to rapidly restore blood flow regardless of clot morphology, which has the potential to reduce the need for follow-up procedures and additional thrombolytic therapy requiring ICU admission.”

Surmodics expects to initiate limited market release for the Pounce XL Thrombectomy System in the first half of 2025, with commercialization planned following the completion of the limited market release.

About the Pounce Thrombectomy Platform

The Pounce Thrombectomy System, Pounce LP Thrombectomy System, and Pounce XL Thrombectomy System are fully mechanical thrombectomy devices designed to promptly remove organized thrombus or embolus without the need for thrombolytics, aspiration, or capital equipment. 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 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.

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.

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 Pounce

XL Thrombectomy System significantly expanding its addressable market for the product platform, Surmodics' pursuit of a complete mechanical thrombectomy solution for all peripheral arteries, Surmodics' commitment to setting the pace and direction of innovation in mechanical thrombectomy solutions in peripheral arteries, expectations regarding the initiation of the limited market release and commercialization of the Pounce XL Thrombectomy System, 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 willingness of Premier members to adopt use of the Surmodics thrombectomy products, 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, 2023, 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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