Surmodics Receives FDA 510(k) Clearance for Pounce™ LP Thrombectomy System

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Addition to Pounce ™ thrombectomy platform with the low-profile (LP) model will allow for efficient clot removal in below-the-knee peripheral arteries (2 mm to 4 mm), expanding the addressable market for the Pounce ™ platform

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jun. 14, 2023-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Pounce™ LP (Low Profile) Thrombectomy System.

Introduced in 2021, the Pounce Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature in vessels 3.5 mm to 6 mm in diameter. The Pounce LP Thrombectomy System, a new addition to the Pounce platform, is indicated for use in vessels ranging from 2 mm to 4 mm in diameter, sizes typical of vessels found below the knee.

"We are excited to secure FDA clearance for the Pounce LP Thrombectomy System, which will extend the range of treatment for our Pounce platform to include removal of organized thrombotic or embolic occlusions in smaller vessels below the knee," said Gary Maharaj, President and Chief Executive Officer of Surmodics. "Catheter-directed thrombolysis in these vessels is limited against organized clot and requires ICU admission, while small-diameter aspiration thrombectomy devices may struggle to remove organized material in the distal lower extremity. By expanding the treatment range of the Pounce platform we are addressing tibial clots, an important component of treatment in this vulnerable patient population which fills a gap in care."

Mr. Maharaj added, "FDA clearance of the Pounce LP Thrombectomy System brings us one step closer to providing the complete mechanical thrombectomy solution for all peripheral arteries and demonstrates our commitment to leadership in this critical-needs space."

Surmodics expects to initiate limited market evaluation (LME) for the Pounce LP Thrombectomy System by the end of the first quarter of its fiscal 2024 (ending December 2023), with commercialization planned following completion of the LME.

About the Pounce Thrombectomy System

The Pounce system is the first mechanical thrombectomy device designed to promptly remove organized thrombus or embolus without the need for capital equipment, thrombolytics, or aspiration. Described as a "grab-and-go" solution, the Pounce system is both readily deployable and simple to use. The 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 that the Pounce LP system will bring prompt resolution of limb ischemia to more patients without the need for ICU admission and time-consuming, expensive adjunctive treatments, statements regarding the company in the future providing the complete mechanical thrombectomy solution for all peripheral arteries, the anticipation and timing of an LME for the Pounce LP system and subsequent commercialization, and regarding Surmodics' 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, 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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