Haemonetics Receives FDA Approval for Expanded Labeling of the VASCADE MVP® XL Venous Vascular Closure System

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VASCADE MVP XL now approved for larger sheaths used in market-leading PFA and LAAC technologies

BOSTON, March 30, 2026 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, today announced U.S. Food and Drug Administration (FDA) approval to expand the labeling for the VASCADE MVP® XL venous vascular closure system to include procedures using 10-14F inner diameter (ID) and up to 17F outer diameter (OD) procedural sheaths. With this label expansion, the VASCADE MVP XL system is approved for larger sheaths used in market-leading technologies for pulsed field ablation (PFA) and left atrial appendage closure (LAAC) to treat atrial fibrillation.

FDA approval was supported by clinical evidence from the AMBULATE EXPAND trial, a multicenter, prospective, single-arm, pivotal trial designed to evaluate the safety and effectiveness in technologies using 17F maximum OD procedural sheaths, such as PFA and LAAC. The study enrolled 77 patients at eight U.S. centers and demonstrated 0% major and 0% minor access site closure-related complications and a median time to ambulation (TTA) of 2.4 hours[1]. The study results were presented at the AF Symposium 2026 in Boston in February and published in the Journal of Cardiovascular Electrophysiology in March.

The VASCADE MVP XL system features a 25F diameter disc and 19 milligrams of resorbable, thrombogenic collagen and has been available in the U.S. for use with 10-12F ID and 15F maximum OD procedural sheaths. It is now the only extravascular venous closure system clinically proven in electrophysiology procedures using up to 17F OD procedural sheaths. With the VASCADE MVP XL system, there is no need for physicians to downsize a procedural sheath to a smaller size for closure, which can increase procedural time.

"VASCADE MVP XL has become the device of choice in advanced vascular closure, delivering differentiated clinical benefits and economic advantages for healthcare providers," said Ken Crowley, Vice President and General Manager, Interventional Technologies at Haemonetics. "With label expansion approval for fast-growing PFA and LAAC technologies, we are poised to accelerate our commercial strategy and momentum, with opportunities to support a greater number and broader range of procedures at hospitals and ambulatory surgical centers across the U.S."

Haemonetics' full portfolio of VASCADE® vascular closure systems features an innovative collapsible disc technology and a proprietary resorbable collagen patch designed to promote rapid hemostasis for interventional and electrophysiology procedures to help clinicians reduce the risk of complications, improve patient satisfaction, and enable same day discharge. In addition to the VASCADE MVP XL system, the portfolio includes the VASCADE system, designed for "small-bore" femoral arterial and venous closure with standard 5-7F ID procedural sheaths, and the VASCADE MVP® system, designed for "mid-bore" multi-access femoral venous closure with 6-12F ID procedural sheaths.

About Haemonetics

Haemonetics is a global medical technology company dedicated to improving the quality, effectiveness and efficiency of health care. Our innovative solutions addressing critical medical needs include a suite of hospital technologies designed to advance standards of care and help enhance outcomes for patients; end-to-end plasma collection technologies to optimize operations for plasma centers; and products to enable blood centers to collect in-demand blood components. To learn more about Haemonetics, visit **www.haemonetics.com**.

Cautionary Statement Regarding Forward-Looking Information

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Forward-looking statements in this press release may include, without limitation, statements regarding plans and objectives of management for the operation of Haemonetics, including statements regarding potential benefits associated with the expanded labeling of the VASCADE MVP XL venous vascular closure system and Haemonetics' plans or objectives related to the commercialization of such product enhancement. Such forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon Haemonetics' current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, product quality; market acceptance; the effect of economic and political conditions; and the impact of competitive products and pricing. These and other factors are identified and described in more detail in Haemonetics' periodic reports and other filings with the U.S. Securities and Exchange Commission. Haemonetics does not undertake to update these forward-looking statements.

[1] In Per Protocol population.

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