



Haemonetics Announces FDA Approval of PerQseal® Elite Vascular Closure System

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BOSTON, Oct. 19, 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 of the PerQseal® Elite vascular closure system for large-bore arterial procedures. The approval expands Haemonetics' portfolio of clinically-differentiated large-bore closure devices for structural heart and endovascular procedures in the U.S., following the company's acquisition of Vivasure Medical Limited in January 2026.

The PerQseal Elite system provides sutureless, large-bore vascular closure following structural heart and endovascular procedures performed with 14 – 22F sheaths. Its fully bioabsorbable patch seals arteriotomies up to 26F from within the vessel, enabling near-instantaneous hemostasis and leaving nothing permanent behind. Physicians can confirm hemostasis while maintaining guidewire access, with the flexibility to reposition or recover the system until implant release. Results from the prospective, single-arm, multicenter ELITE arterial study demonstrated 0% major complications per VARC-3 and a mean time to hemostasis of less than one minute.¹ In 2025, PerQseal Elite received CE Mark approval in Europe for both arterial and venous indications.

"FDA approval represents an important milestone in our strategy to bolster our presence and growth in advanced vascular closure, with new and meaningful innovation to meet evolving procedural needs," said Jan Hartmann, M.D., Senior Vice President and Chief Medical Officer at Haemonetics. "PerQseal Elite has the potential to further simplify minimally invasive procedures such as TAVR, while supporting patient comfort and experience. We are pleased to offer physicians and their patients in the U.S. this novel, patch-based approach to large-bore vascular closure."

Professor Nicolas van Mieghem, MD, co-investigator of the ELITE study clinical trials and interventional cardiologist at ZOL Hospital in Genk, Belgium, said, "I have found PerQseal Elite to be easy to adopt and intuitive to use, with rapid hemostasis being a particularly notable feature. In both the ELITE study and our early clinical experience, it has integrated well into procedural workflows for large-bore arterial interventions."

Clinical data related to PerQseal Elite will be presented and discussed by Haemonetics at the Transcatheter Cardiovascular Therapeutics® (TCT) Conference at the end of October.

1. VARC-3 major device-related vascular access site complications through 30 days. See PerQseal® Elite Instructions for Use.

About Haemonetics

Haemonetics is a global medical technology company dedicated to improving the quality, effectiveness and efficiency of health care. Our Apheresis business features proprietary technologies designed to enhance safety, yield, donor satisfaction and operational efficiency for plasma and blood collectors around the world. Our MedSurg business offers Blood Management Technologies designed to help inform treatment decisions and optimize the management of blood products, and Interventional Technologies, including advanced vascular closure systems and sensor-guided technologies, designed to drive procedural effectiveness and elevate the patient experience. 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 PerQseal Elite vascular closure system and Haemonetics' plans or objectives related to the commercialization of such product. 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.

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