



Haemonetics Announces CE Mark Certification for the SavvyWire® Pre-Shaped Pressure Guidewire

July 30, 2024

BOSTON, July 30, 2024 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, today announced CE Mark certification and the first commercial European procedures for the SavvyWire® Pre-Shaped Pressure Guidewire. The SavvyWire guidewire is the world's first and only sensor-guided 3-in-1 solution for Transcatheter Aortic Valve Implantation (TAVI), designed to improve procedural efficiency with predictable wire performance, hemodynamic measurement and left-ventricular (LV) pacing capabilities.



The certification will allow Haemonetics, which added the SavvyWire guidewire to its product portfolio with its acquisition of OpSens Inc. in December 2023, to engage in the next steps of country-specific entrance of the SavvyWire guidewire into the European Union (EU) and other geographies that recognize CE marking. The first commercial European procedures using the SavvyWire guidewire were performed this month at Hôpital Haut-Lévêque du Centre Hospitalier Universitaire (CHU) de Bordeaux, France, and at Catharina Ziekenhuis Eindhoven in The Netherlands.

The SavvyWire guidewire is engineered to uniquely support multiple steps over the same guidewire, reducing procedural device exchanges, providing stable aortic valve delivery and positioning while continuously monitoring cardiac hemodynamics. Additionally, it has been designed to enable reliable LV pacing without need for adjunct devices or venous access for conventional right ventricular pacing during TAVI procedures.

"More than 20 years after the first introduction of TAVI in France, the SavvyWire guidewire brings unique capabilities to European markets to help further streamline and optimize the procedure through efficient, predictable wire performance and LV pacing," said Dr. Lionel Leroux from CHU Bordeaux. Professor Thomas Modine of CHU Bordeaux added, "This wire marks an important step in the assessment of TAVI patients. With one wire in the same position, there are less manipulations and we are enabled to continuously monitor the patient's haemodynamics."

According to Professor Pim Tonino from Catharina Ziekenhuis Eindhoven, "The SavvyWire guidewire raises the standard for hemodynamic measurements throughout the TAVI procedure, enabling physicians to make important procedural decisions immediately without having to exchange devices."

"CE Mark certification for the SavvyWire guidewire is a key step in our strategic international expansion, as we continue to broaden our leadership and impact by creating greater access to critical interventional technologies that advance healthcare standards," said Stewart Strong, President, Global Hospital at Haemonetics. "We look forward to leveraging our strong global commercial infrastructure to bring the SavvyWire guidewire's fiber optic sensor technology to Europe, the Middle East and Africa, and enable more physicians to optimize TAVI procedures to improve patient outcomes."

About Haemonetics

Haemonetics (NYSE: HAE) is a global healthcare company dedicated to providing a suite of innovative medical products and solutions for customers, to help them improve patient care and reduce the cost of healthcare. Our technology addresses important medical markets: blood and plasma component collection, the surgical suite and hospital transfusion services. Haemonetics' Global Hospital business provides a range of solutions to address the needs of hospitals, including Interventional Technologies for electrophysiology and interventional cardiology, and Blood Management Technologies that include diagnostics to help inform treatment decisions, technologies to help avoid unnecessary allogeneic transfusions and solutions to help optimize management of blood products. 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 SavvyWire guidewire 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 global 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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