



Haemonetics Receives FDA Clearance For Expanded Use Of TEG® 6s Hemostasis Analyzer System In Adult Trauma Settings

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BRAINTREE, Mass., May 13, 2019 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative hematology solutions to drive better patient outcomes, announced today that it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand the medical indication of its [TEG® 6s Hemostasis Analyzer System](#) for use in adult trauma settings. This clearance builds on the current indication for the TEG 6s system in cardiovascular surgery and cardiology procedures, making it the first cartridge-based system available in the U.S. to evaluate the hemostasis condition in adult trauma patients. The site-of-care TEG 6s system provides actionable test results in as little as ten minutes.



The 510(k) clearance was based on clinical data from a multicenter, multistate trial of approximately 500 adult patients comparing the TEG® 5000 Hemostasis Analyzer System, which has been used in trauma for over a decade, to the next-generation TEG 6s system. The study collected more than 150,000 data points and showed that the TEG 6s system is reliable, substantially and analytically equivalent and test results can be interpreted like those from the TEG 5000 system when used in a trauma setting.

The TEG 6s system, comprised of the analyzer, disposable cartridges and software, provides rapid, comprehensive and accurate identification of a patient's hemostasis condition. Featuring an innovative, all-in-one cartridge, the TEG 6s system delivers viscoelastic test results without the complicated test preparation associated with traditional blood tests. The cartridge automatically mixes a small blood sample with reagents and runs up to four assays in parallel, lowering the potential for human error, allowing immediate test initiation and significantly reducing wait time for results so clinicians can quickly tailor treatment to a patient's specific needs.

"The TEG 6s system brings a new level of simplicity, consistency and speed to the coagulation testing process when every moment counts," said Eva Casamento, Haemonetics' Vice President, Global Marketing and Strategy, Hemostasis Management and Cell Salvage. "Acute care clinicians can quickly and confidently get a complete picture of a trauma patient's hemostasis condition right in the ER or trauma bay."

"The TEG 6s analyzer is an important tool for trauma centers needing fast access to information about critically injured patients," said Jan Hartmann, M.D., Haemonetics' Vice President, Medical Affairs. "What makes TEG 6s unique in trauma settings is the easy to operate cartridge-based system with rapid results at the site of care. The broad set of trauma-relevant parameters including LY 30, which measures clot lysis, allows clinicians to more accurately determine the best, tailored treatment option for each individual patient."

About Haemonetics

Haemonetics (NYSE: HAE) is a global healthcare company dedicated to providing a suite of innovative hematology 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. To learn more about Haemonetics, visit www.haemonetics.com.

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