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Press Release

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WERFEN RECEIVES US FDA 510(k) CLEARANCE FOR ROTEM® SIGMA COMPLETE CARTRIDGE FOR USE IN TRAUMA

—Extends ROTEM sigma Testing to Trauma, Supporting Rapid Viscoelastic Testing Bleeding Management—

Bedford, MA, November 17, 2026 — Werfen today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the ROTEM *sigma* complete cartridge to assess peri-operative hemorrhage and/or thrombosis in trauma. The new indication extends the use of the ROTEM *sigma* viscoelastic testing system beyond cardiovascular surgery and liver transplantation, enabling bleeding management in the trauma setting within the United States. See full Indications for Use below.

Traumatic injury is responsible for approximately 10% of deaths worldwide, and uncontrolled bleeding remains one of the leading causes of potentially preventable death following severe trauma.[1–3] Trauma-induced coagulopathy presents an additional challenge, requiring rapid assessment and timely intervention to support patient management.[4] Early evaluation of coagulation status is critical in these time-sensitive situations, and current trauma management guidelines recommend viscoelastic testing as part of a goal-directed approach to bleeding management and coagulation support.[5–7]

"Trauma teams are required to make critical treatment decisions within minutes, when every moment matters," said Bill Crandell, Vice President, Commercial Operations, North America at Werfen. "The clearance of the ROTEM *sigma* complete cartridge for use in trauma expands access to rapid, actionable coagulation information at the point of care, helping make informed treatment decisions during trauma resuscitation. This milestone underscores our commitment to bleeding management and providing clinicians with innovative tools that support timely, evidence-based care."

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ROTEM *sigma* is a fully automated viscoelastic testing system that delivers real-time assessment of clot initiation, clot firmness, and clot stability at the point of care. By providing timely information about a patient's coagulation status, the system supports individualized treatment strategies during critical bleeding events. ROTEM *sigma* results should be interpreted together with the patient's clinical condition and other laboratory tests.

Designed to simplify testing and streamline workflow, ROTEM *sigma* incorporates a fully automated cartridge-based system with closed-tube direct sampling, designed to minimize manual handling steps and reduce operator-dependent variability. Additional features of the ROTEM *sigma* include automated assay initiation, integrated quality control, continuous internal system monitoring, intuitive touchscreen operation, and room-temperature cartridge storage. Reduced operator interaction is designed to simplify implementation across a variety of acute care settings. Large, easy-to-interpret TEMograms and live viewing with GEMweb® Live provide clinicians with real-time visibility into coagulation dynamics.

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Indications for Use

The ROTEM sigma Thromboelastometry System is a fully integrated and automated in vitro diagnostic system designed to monitor and analyze a patient's coagulation status by measuring the viscoelastic properties of a 3.2% citrated venous or arterial whole blood sample. The ROTEM sigma system is indicated for use with adult patients 21 years and older where a semiquantitative evaluation of their blood coagulation properties is desired, in the point of care and laboratory settings. The ROTEM sigma system is not intended for use in pre-hospital trauma settings.

Coagulation evaluations on the ROTEM sigma system with ROTEM sigma complete are used to assess peri-operative hemorrhage and/or thrombosis in trauma. Coagulation evaluations on the ROTEM sigma system with ROTEM sigma complete + hep are used to assess peri-operative hemorrhage and/or thrombosis in cardiovascular surgery and liver transplantation.

The ROTEM sigma system includes the following assays contained in single use, multichannel cartridges; ROTEM sigma complete (INTEM C, EXTEM C, FIBTEM C, APTEM C) and ROTEM sigma complete + hep (INTEM C, EXTEM C, FIBTEM C, HEPTEM C):

INTEM C is used for the assessment of coagulation via the intrinsic pathway in citrated whole blood samples.

EXTEM C is used for the assessment of coagulation via the extrinsic pathway in citrated whole blood samples.

FIBTEM C is used for the assessment of coagulation via the extrinsic pathway in citrated whole blood samples, after blocking platelet contribution to clot firmness.

HEPTEM C is used for the assessment of coagulation via the intrinsic pathway in citrated whole blood samples, after inactivating heparin.

APTEM C is used for the assessment of coagulation via the extrinsic pathway in citrated whole blood samples, after blocking fibrinolysis.

Results from the ROTEM sigma should not be the sole basis for a patient diagnosis; ROTEM sigma results should be considered along with a clinical assessment of the patient's condition and other laboratory tests.

For in vitro Diagnostoc Use.
For use by healthcare professionals only.

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About Werfen's Acute Care Diagnostics Portfolio

The ROTEM *sigma* system is part of Werfen's integrated and comprehensive ACD product portfolio—helping clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure accreditation compliance and improve operational efficiency in hospital acute care settings. For Whole Blood Hemostasis testing, ROTEM viscoelastic testing systems, the GEM Hemochron™ 100 system, and the VerifyNow™ platelet-reactivity testing system inform key clinical decisions regarding transfusion, bleeding risk and heparin dose adjustment during surgical and interventional procedures along with a clinical assessment of the patient's condition and other laboratory tests. For Blood Gas testing, the GEM Premier systems, including GEM Premier 7000, 5000 and 3500 systems, and the Avoximeter™ 1000 portable CO-Oximeter, simplify POC operations by automating key labor- and skill-intensive tasks, including quality management and system maintenance. Complementing these testing systems, GEMweb Plus 500 Custom Connectivity provides centralized management of analyzers, operators and data, while GEMweb Live consolidates results from connected Werfen systems on a single screen for real-time viewing in the cardiovascular operating room. From Cardiovascular Operating Rooms and Catheterization Labs to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based systems with Werfen's integrated data management solutions, help hospitals improve efficiency and enhance patient care.

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Werfen (www.werfen.com), founded in 1966, is a worldwide developer, manufacturer and distributor of specialized diagnostic instruments, related reagents, automation workcells, and data management solutions for use primarily in hospitals and independent clinical laboratories. The Company's clinical areas of focus include Hemostasis, Acute Care, Transfusion, Autoimmunity, and Transplant.

Werfen's Acute Care portfolio includes the new GEM Premier 7000 with iQM3, the GEM® Premier™ 5000 with iQM®2, GEM Premier 3500 system with iQM, GEM Premier ChemSTAT™ system, ROTEM® viscoelastic testing systems, Hemochron™ systems, VerifyNow™ platelet function testing system, and Avoximeter™1000 CO-Oximeter, GEMweb® Plus 500 Custom Connectivity and GEMweb Live.

The Hemostasis portfolio includes ACL TOP® Family 50 Series and ACL TOP Family Hemostasis Testing Systems, ACL AcuStar® system, ACL Elite® systems, HemoCell™ Specialized Lab Automation, HemoHub™ Intelligent Data Manager, along with the comprehensive line of HemosIL® assays.

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