

Hemosphere Receives CE Mark Approval for the HeRO[®] Graft

Opens European Union Market for Future Growth Opportunities Building Upon HeRO[®] Graft's Success in the United States

EDEN PRAIRIE, MINN--([BUSINESS WIRE](#))—[Hemosphere](#), Inc. announced today that it has received CE Mark and ISO 13485 Certification for the HeRO[®] Graft, a vascular access graft for hemodialysis patients.

“CE Mark approval of the HeRO Graft allows us to build upon the already successful commercialization of the HeRO Graft in the U.S.,” said Patrick Wethington, Hemosphere President and CEO. “Receiving CE and ISO 13485 Certification demonstrates the commitment Hemosphere has towards developing world-class quality systems and auditing processes that position us for future incremental sales growth.”

“Obtaining CE Certification for the HeRO Graft and ISO Certification are significant milestones for Hemosphere,” stated Laurie Lynch, Ph.D., Hemosphere’s Head of Quality and Regulatory Assurance. “These certifications signify that we have met the clinical, quality, and performance requirements of the Medical Device Directives (MDD) and demonstrates that the quality systems the company has in place achieve the rigorous performance standards required by the MDD.”

The HeRO (Hemodialysis Reliable Outflow) Graft is clinically proven to reduce costly infections by 69% compared to hemodialysis catheters. The HeRO Graft is an alternative to catheters for ESRD hemodialysis “catheter-dependent” patients with central venous stenosis – a blockage of the central veins that inhibits blood flow. Since its introduction, over 4,000 hemodialysis patients have received the HeRO Graft in the United States. Unlike catheters, the HeRO Graft is implanted completely under the skin, which reduces infection risk.

About Hemosphere:

Hemosphere, Inc., is leading innovation and collaboration in the global development and commercialization of technologies that revolutionize care and restore quality of life for end-stage renal disease patients with compromised vasculature. For more information on Hemosphere, Inc. and the HeRO Graft, visit the company’s website at www.herograft.com

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