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FLEX Vessel Prep™ System Receives New Indication to Address In-Stent Restenosis

Minneapolis, MN, October 21, 2020 – VentureMed Group, Inc. (VentureMed), a privately-held medical device innovator in vessel preparation for interventional treatment of peripheral arterial disease (PAD) and stenoses of arteriovenous (AV) fistulas and grafts, announced today that the U.S. Food and Drug Administration (FDA) cleared the Company's FLEX Vessel Prep™ System for use in the treatment of in-stent restenosis (ISR) in the peripheral vasculature.

Patients undergoing peripheral vascular interventions often receive a balloon-expandable or self-expanding stent to keep the artery open as part of a standard percutaneous transluminal angioplasty (PTA) and/or drug-coated balloon (DCB) angioplasty procedure. Within two years of undergoing stent implantation for femoropopliteal disease, nearly 30 to 40% of patients experience excessive tissue growth inside the surface of the stent and a recurrence of the narrowed artery which restricts blood flow (e.g., in-stent restenosis).

The FLEX Vessel Prep System safely and effectively modifies plaque and fibrous stenoses by creating controlled-depth micro-incisions of any length to release the circumferential tension to improve vessel compliance and increase lumen gain. Eric A. Secemsky, MD, MSc, FACC, Director of Vascular Intervention at Beth Israel Deaconess Medical Center, stated "modifying the obstructive neointimal tissue that frequently forms within peripheral stents is clinically challenging, but essential to effectively restore blood flow and maintain vessel patency. The novel way in which the FLEX System incises along the entire length of challenging ISR lesions appears to help facilitate and optimize treatment of these vessels, including the delivery of drug-coated therapies."

"This expanded ISR indication for FLEX provides physicians with a safe and effective tool to address an increasingly common and difficult condition that can result from the implantation of stents to treat femoropopliteal disease," said J. Robert Paulson, Jr., president and chief executive officer of VentureMed. "FLEX allows physicians to modify plaque and prepare diseased vessels of any length to optimize their choice of definitive revascularization therapy, and now as part of treating patients with femoropopliteal ISR, helping to reduce the risk of recurrent ISR."

About VentureMed and the FLEX VP System

VentureMed develops and markets innovative endovascular medical devices to solve unmet medical needs in the treatment of peripheral arterial disease and stenoses of arteriovenous fistulas and grafts. The FLEX Vessel Prep™ System was designed to modify plaque safely and predictably by creating long, controlled micro-incisions along the entire length of complex lesions of varying morphology. The FLEX VP System has 510(k) clearance from the US Food and Drug Administration and CE marking for marketing and sale in the European Union. For more information, visit www.flexvesselprep.com.