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FLEX Vessel Prep™ System Data Presented at New Cardiovascular Horizons Conference Shows Key Findings including Luminal Gain

Toledo, Ohio, June 4, 2019 - VentureMed Group, Inc., 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 new data presented at the 20th Annual New Cardiovascular Horizons (NCVH) Annual Conference, May 29-31, in New Orleans, Louisiana.

FLEX iDissection Study Results Presentation

The study utilized intravascular ultrasound (IVUS) to assess the reduction in the rate and severity of dissections in peripheral arteries when the FLEX Vessel Prep System was used prior to angioplasty.

"Dissections are grossly under-appreciated on angiogram when compared with IVUS. Percutaneous transluminal balloon angioplasty (PTA) causes dissections and stretching of the vessel to restore blood flow. However, the severity and depth of the dissections can contribute to restenosis." said lead investigator Nicolas W. Shammas, MD, MS, EJD, FACC, FSCAI, research director, Midwest Cardiovascular Research Foundation in Davenport, Iowa. "This is a positive signal as these results showed a low rate of dissection after using the FLEX VP System with the majority of those dissections being lesser in depth and circumference."

Study details and findings:

- 15 patients were evaluated by angiogram and IVUS following treatment of femoropopliteal de novo or no-stent restenosis with the FLEX VP System and PTA.
- The patients had an average median baseline percentage stenosis of 77%, an average lesion length of 64 ± 33mm, 40% had moderate/severe calcified vessels (PACSS score ≥ 3), 40% were diabetic. Claudication was present in 73% of the patients.
- Angiogram and IVUS images were obtained at baseline, post-FLEX VP System, and post-adjunctive PTA to evaluate the presence and grade of dissections. There were significantly fewer new dissections, as well as lower gradations in the circumference and depth patterns of new dissections, post-FLEX VP System and adjunctive PTA.
- The majority of new dissections post-PTA, following vessel prep with the FLEX VP System, involved mostly the intima, the inner most layer of the vessel, (78.4%) and were <180° in circumference (81.1%). Vessel prep involving only the layers superficial to the internal elastic lamina may prevent restenosis.

FLEX VP System Comparative Review Data Presentation

A Comparative Review of the FLEX VP System in the Treatment of Femoropopliteal Lesions of Differing Lengths - real-world data of 443 femoropopliteal cases.

"This data highlights the importance of the unique FLEX VP mechanism of action that provides acute luminal gain and improved vessel compliance to reduce PTA balloon opening pressures leading to meaningful clinical results," said Jason A. Yoho, MD, Interventional Cardiologist at the Heart and Vascular Institute of Texas. "This real-world data on the use of the FLEX VP System is clinically relevant and important as we continue to evaluate options that may help patients achieve better clinical outcomes."

Study details and finding:

- Real-world data of 443 femoropopliteal cases reported from 104 operators in 70 health systems treating lesions of varying lengths (less than or equal to 8mm or greater than 8 mm).
- The mean 28% improvement in luminal gain achieved by the FLEX VP System alone was consistent regardless of lesion length.
- Low PTA balloon opening pressures (averaging 4.7atm) suggest the FLEX VP System positively improves vessel compliance.
- The FLEX VP System creates an ideal environment for PTA of choice and was shown to safely and effectively facilitate PTA of femoropopliteal stenosis of differing lengths.

"The data from these clinical studies assessing the use of the FLEX VP System provides physicians with important information as they develop effective tools to help improve outcomes for patients. The results of the FLEX iDissection study and this post-market surveillance data continues to build a strong case for the use of the FLEX VP System to facilitate PTA of choice and deliver positive outcomes," said J. Robert Paulson Jr., chief executive officer and president of the VentureMed Group.

About VentureMed Group, Inc. and the FLEX VP System

Founded in 2012, the VentureMed Group, Inc. develops and markets innovative endovascular medical devices to solve unmet medical needs in the treatment of PAD and stenoses of AV fistulas and grafts. The Flex VP System facilitates an ideal environment for treating PAD and AV fistulas and grafts by safely creating linear, parallel micro-incisions in plaque of any length to deliver acute lumen gain and vessel compliance enabling better clinical outcome for patients. The true vessel prep FLEX technology is currently indicated for use in femoropopliteal arteries and restoring access to AV fistulas and grafts. The FLEX VP System received CE Mark in 2015 and 510(k) clearance from the US Food and Drug Administration in 2016. For more information, visit www.flexvesselprep.com.