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Media contact: Beth Bentley
bbentley@venturemedgroup.com
(210) 214-8482

Data Presented at ISET Shows Impressive Revascularization in Chronic Total Occlusions with FLEX Vessel Prep™ System

Minneapolis, MN, January 30, 2020 - VentureMed Group, Inc., a privately-held medical device innovator focused on vessel preparation for interventional treatment of peripheral arterial disease (PAD) and stenoses of arteriovenous (AV) fistulas and grafts, announced data presented at the International Symposium on Intervascular Therapy (ISET) Annual Conference, Jan. 22-24, in Hollywood, Florida.

Study Details and Findings

FLEX Vessel Prep System in Acute Results in Complex Vessel Anatomy
A multi-center retrospective review
Conducted on 185 real-world cases
Long (≥8cm) chronic total occlusions (CTO)

"Complex lesions in the femoral and popliteal arteries are common and if not prepared properly, can encounter dissections, embolizations and other complications," said Constantino Pena, MD, Medical Director of Vascular Imaging, Miami Cardiac and Vascular Institute. "Vessel preparation is a key component of a successful revascularization. The FLEX System delivers safe, easy and efficient vessel preparation that potentially delivers better outcomes and improved efficiencies in the lab."

Results in CTOs:

- Post-FLEX 34% mean luminal gain prior to treatment
- Sub-nominal inflation pressures averaged 4 atm
- Low rate (4%) and grade (A or B) of dissections in lesions averaging 20.8 cm
- No flow-limiting dissections, perforations, or embolization
- Provisional stenting in only 28% of cases

Revascularization was successful in all 185 CTOs reviewed with no major complications. Following treatment with the FLEX System, vessel compliance was noted to have improved due to the sub-nominal inflation pressures.

The FLEX System is designed to optimize revascularization of long, complex lesions by creating controlled depth micro-incisions along the entire length of mixed morphology and asymmetrical diseased vessels to prepare lesions for drug coated balloons (DCBs) or other therapies. The FLEX System engages into vessel lesions with adaptive expansion force and is pulled back through the vessel to create micro-incisions along the entire length of lesions. Typical results are acute luminal gain (~ 25%), increased vessel compliance (subsequent balloon inflation pressures of ~4 ATM's), low bail-out stent rates and reduced risk of dissections that require additional interventions. The

micro-incision pathways created with the FLEX System potentially enhance and facilitate drug access to diseased vessels.

“This real-world data continues to build a strong case that the FLEX System is a safe and effective vessel preparation option for long, complex morphologies. FLEX consistently demonstrates lower rates and grades of dissections, embolizations and other complications in leg revascularization procedures, while preparing vessels for endovascular therapies,” said J. Robert Paulson Jr., chief executive officer and president of the VentureMed Group.”

About VentureMed Group, Inc. and the FLEX VP System

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 Vessel Prep™ System optimizes treatment of long complex by safely creating micro-incisions to deliver acute lumen gain and vessel compliance for more effective PAD revascularization with other therapies. The FLEX VP System received CE Mark and 510(k) clearance from the US Food and Drug Administration. For more information, visit www.flexvesselprep.com.