

FLEX Vessel Prep 12 Month AV Registry Data and 12 Month Belong PAD Data Shows Benefit to Micro-incisions Before Balloon or DCB Treatment

Minneapolis, MN, December 6, 2022 - VentureMed Group, Inc., a privately held medical device innovator in access management for arteriovenous (AV) fistulas and grafts and vessel preparation for interventional treatment of peripheral arterial disease (PAD) announced data presented at the VEITH Symposium, Nov. 15-19th, New York, New York. Overall, the data presented demonstrated that FLEX Vessel Prep used prior to balloon angioplasty improves 12-month outcomes both in PAD and AV fistulas and grafts.

Presentation 1: FLEX Vessel Prep™ System: Clinical Outcomes And Utility In HD Access Practice - AV Registry 12-Month Study Results

John E. Aruny, MD
Primary Investigator,
Dialysis Access Institute,
Orangeburg, SC.

“AV Access management is a critical component of successfully treating AV patients over time”, said John Aruny, MD, Primary Investigator, Dialysis Access Institute, Orangeburg, SC. “The FLEX AV Registry 12-month outcomes shows that utilizing FLEX Vessel Prep provides more time between interventions and continues to excel in the very difficult cephalic arch lesions.”

The FLEX Vessel Prep™ System AV Registry Clinical Study was a single arm, prospective study conducted in 8 centers in the United States with 114 real world patients.

The FLEX AV Registry 12-month outcomes demonstrate sustained patency across most patients and exceptional results specifically in the Cephalic Arch.

- **49% patency for all AVF patients (comparable historical data 26%)**
- **59.7% patency for cephalic arch lesions (comparable historical data 0-33.9%)**
- **AVG's had average time to TLR of 228 days (41.2% patency at 9 months)**
- **No observed SAE's**



Presentation 2: Late Breaking Trial with FLEX Vessel Prep™ System and DCB's Show Better 12-Month Results With FemPop (Belong Study)

Eric A. Secemsky, MD, MSc, RPVI, FACC, FSCAI, FSVM

Director | Vascular Intervention | Beth Israel Deaconess Medical Center

Section Head | Interventional Cardiology and Vascular Research | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology | Beth Israel Deaconess Medical Center

Assistant Professor of Medicine | Harvard Medical School.

“Vessel preparation has become a necessary step for better patient outcomes”, said Eric Secemsky, MD, Director of Vascular Intervention, Beth Israel Deaconess Medical Center. “Vessel preparation in PAD with FLEX creating longitudinal micro-incisions prior to DCB therapy had impressive freedom from clinically driven target lesion revascularization and looks to improve outcomes by lowering balloon inflation pressures and potentially enhancing drug delivery,”

The Belong Study 12 Month PAD Results with FLEX Vessel Prep™ System prior to DCB was a Single Center, Single-arm, prospective study conducted with 41 patients in Fribourg, Switzerland.

12 Month Efficacy Results:

- **97.5% (39/40) Freedom From CD-TLR**
- **84.2% (32/38) Freedom From Target Lesion Restenosis via Duplex (PSV>2.5) ***
 - **14/32 pt had stents**
- **100% Freedom From Major Amputation**

About VentureMed Group, Inc., and the FLEX Vessel Prep™ System

The VentureMed Group, Inc. develops and markets innovative endovascular medical devices to solve unmet medical needs in the treatment of stenoses of AV fistulas and grafts and PAD. The FLEX VP™ System is a unique, non-balloon-based approach to optimizing revascularization by creating long controlled-depth micro-incisions that release circumferential tension to improve vessel compliance and enable luminal gain with less vessel trauma that may cause restenosis. FLEX was designed to provide controlled and predictable pre-treatment to optimize outcomes in complex stenoses & lesions of any length or vessel morphology. The FLEX VP System received CE Mark and 510(k) clearance from the US Food and Drug Administration.

For more information, visit www.VentureMedgroup.com.