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FLEX Vessel Prep™ System FLEX FIRST AV Registry 6-Month Data and the Hamburg Vessel Prep Experience Prior to Angioplasty presented at Charing Cross Symposium

Minneapolis, Minnesota – April 23, 2025 – VentureMed Group, Inc., a privately held leader in medical device innovations for arteriovenous (AV) access and peripheral arterial disease (PAD), announced data presented at the Charing Cross Symposium, April 23 – 25th, London, England. Overall, the real-world data represented in both presentations demonstrated the FLEX Vessel Prep™ (VP) System is designed to prepare the vessel to maximize outcomes, while minimizing complications.

Presentation 1: The FLEX FIRST AV Registry, 6-Month Findings

Ari Kramer, MD
Primary Investigator
Spartanburg Medical Center
Spartanburg, South Carolina

"The FLEX VP System has changed the way I approach resistant stenoses. This study confirms what I've seen firsthand—controlled-depth micro-incisions offer not only technical precision but also real clinical impact in reducing reinterventions. This is not just about another tool. FLEX represents a paradigm shift in how we think about vessel prep - moving from blunt force dilation to a more refined, surgical-style approach. It's precision endovascular medicine, and our patients deserve it."

The FLEX FIRST AV Registry 6-Month Real-World Results was a multi-center observational registry with 130 hemodialysis patients with AVF/ABG presenting with vascular access dysfunction.

The FLEX FIRST AV Registry 6-month results demonstrated procedural safety and clinically meaningful durability in a real-world patient population with challenging lesion types.

- **0 Serious Adverse Events through 1-month follow up**
- **70.7% overall target lesion primary patency at 6 months**
- **76.3% target lesion patency in Cephalic Arch Lesions**
- **100% technical success achieved in device delivery across all procedures**

Presentation 2: Vessel preparation prior to drug-coated angioplasty improves target lesion patency rates of hemodialysis vascular access

Robert Shahverdyan, MD
Vascular Access Medicine
Hamburg, Germany

"After using FLEX in over 70 patients and comparing it to high-, ultra-high pressure, and scoring balloons, the reintervention rates are clearly lower. The results we're seeing with FLEX aren't just good, they're consistent across access types, lesion locations, and patient profiles. It's my go-to prep method for resistant stenosis and it's changing how we approach access maintenance."

The role of Vessel Prep prior to drug-coated angioplasty results demonstrated an effective way to treat vascular access across a mix of locations/lesions.

The results of vessel preparation prior to drug-coated angioplasty with FLEX observed by Dr. Shahverdyan in Hamburg included:

- **Patency outcomes favored VP + DCB, target lesion primary patency (TLPP) rates at 6 and 12 months of 86.0% and 73.6%, respectively.**
- **Reinterventions per patient-year were significantly lower in the VP group (0.372) compared to POBA (0.695) and SB (0.917) ($p<0.0001$)**
- **In cephalic arch interventions at 12-months: 3 of 4 (75%) maintained TLPP vs 0 of 2 (0%) in POBA and 0 of 2 (0%) in SB groups.**
- **VP + DCB offers a promising alternative for the management of VA stenoses in real-world clinical settings.**

Why FLEX FIRST for vessel prep?

“We are grateful to Dr Kramer and Dr Shahverdyan for their tireless work and congratulate them on their well-run clinical studies. This data expands the foundation of successful evidence for the FLEX Vessl Prep device. AV Access patients, around the globe, deserve access to the technologies and algorithms demonstrated in these studies,” said Denis Harrington, President & CEO of VentureMed Group.

About VentureMed Group & FLEX Vessel Prep™ System

VentureMed Group, Inc. is a pioneering medical device company dedicated to advancing endovascular solutions for arteriovenous (AV) access and peripheral arterial disease (PAD) interventions. The company’s flagship technology, the **FLEX Vessel Prep™ System**, is designed to optimize vessel preparation using its proprietary **Kinetic Endovascular Micro-incision Creation (KEMIC) technology**. Unlike traditional balloon-based approaches that apply static pressure, KEMIC leverages-controlled motion and dynamic vessel apposition to create long, precise micro-incisions. As FLEX is pulled back through the vessel, the outward pressure of the struts ensures continuous contact with the vessel wall, while the pull-back motion of the blades generates a series of precise micro-incisions.

This unique mechanism facilitates luminal gain, may enhance drug uptake when used in combination therapy, and may reduce vessel trauma—ultimately lowering the risk of restenosis. FDA 510(k) cleared and CE Mark approved, FLEX is redefining vessel preparation and advancing treatment options for patients worldwide.

For more information, visit **www.VentureMedgroup.com**.