

iDissection Classification Study to Evaluate Dissection Rate of FLEX Dynamic Scoring Catheter™

- **New study to determine if the FLEX Dynamic Scoring Catheter™ reduces dissections and the need for bailout stents in peripheral arteries**
- **15 patients to be evaluated by Dr. Nicolas W. Shammam at the UnityPoint Trinity in Bettendorf, Iowa**
- **More than 12 million people in the US and 30 million people worldwide are affected by Peripheral arterial disease (PAD)¹**

Toledo, Ohio, November 6, 2018 - VentureMed Group, Inc., a medical device company that develops and markets innovative interventional vascular solutions, announced the initiation of a new study to determine if the FLEX Dynamic Scoring Catheter™ reduces dissections and the need for bailout stents in peripheral arteries. The study entitled “*Arterial Dissections Following FLEX Scoring and Adjunctive Balloon Angioplasty: Intravascular Ultrasound Assessment and Correlation with Angiographic Findings*” will utilize intravascular ultrasound (IVUS) to identify the health of the vessel after treatment.

Nicolas W. Shammam, MD, Founder and Director of the Midwest Cardiovascular Research Foundation in Davenport, Iowa is the principal investigator for the study. This study is the second iDissection study performed by Dr. Shammam. The first study revealed that after atherectomy, in the peripheral arteries, significant dissections are more visible by a ratio of 6:1 when using IVUS in comparison to the typical angiogram. Deducing that the presence and severity of dissection after atherectomy may have been underestimated, especially for deeper dissections which are associated with recurrent restenosis, recoil, and possibly acute closure.²

“After the indicative results of the initial iDissection study, I am motivated to look for vessel prep devices that further reduce the need for provisional stenting,” said Dr. Shammam. “I am optimistic about the ability of the FLEX Catheter to reduce the rate of high-grade dissections and looking forward to the evaluation.”

Using IVUS, the new study will evaluate the dissection rates of 15 patients following treatment of femoropopliteal de novo or no-stent restenosis by the FLEX Dynamic Scoring Catheter™ and plain old balloon angioplasty (POBA).

“VentureMed Group is honored to be working with such an esteemed interventionalist and outstanding laboratory. In over 400 registry case report forms, from multiple physicians that have

reported on the performance of the FLEX Dynamic Scoring Catheter™, we have seen low rates of minor dissections, less stents, and lower balloon inflation pressures required for lesion effacement. As we embark on this new adjudicated study, we are confident Dr. Shammam will experience similar results.” said John Pigott, MD, FACS, Jobst Vascular Institute, Promedica Healthcare Systems and Founder and Chief Science Officer of VentureMed Group. “We are anticipating improved outcomes that the FLEX positively impacts results as a safe and effective means of vessel prep in this iDissection study, along with future studies.”

VentureMed Group will be exhibiting at Vascular Interventional Advances (VIVA), and the VEITH Symposium during the month of November.

About Peripheral Arterial Disease

Peripheral Arterial Disease (PAD) is a narrowing of the peripheral arteries caused by a hardening of the arteries. More than 12 million people in the US and 30 million people worldwide are affected by PAD. It most commonly affects the arteries of the pelvis and legs, including the femoral and popliteal arteries. Left untreated, patients with PAD are five times more at risk for limb amputation.¹

References:

1. Stay in Circulation: Campaign Materials: Facts about Peripheral Arterial Disease (P.A.D.). Nhlbi.nih.gov. https://www.nhlbi.nih.gov/health/educational/pad/materials/pad_extfctshg_general.html. Published 2018. Accessed November 5, 2018.
2. Nicolas W. Shammam, MD, MS, et al (2018). *Intravascular Ultrasound Assessment and Correlation With Angiographic Findings Demonstrating Femoropopliteal Arterial Dissections Post Atherectomy: Results From the iDissection Study*. [online] Journal of Invasive Cardiology. Available at: <https://evtoday.com/2018/07/11/study-evaluates-ivus-for-detecting-dissections-in-femoropopliteal-vessels-after-pta> [Accessed 5 Nov. 2018].

###

About the FLEX Dynamic Scoring Catheter™

The FLEX Catheter creates long parallel linear scores in all plaque morphologies to prepare an ideal vessel environment to facilitate angioplasty. Its dynamic technique safely scores difficult, diseased vessels, providing vessel compliance and acute lumen gain.

About VentureMed Group, Inc.

VentureMed Group is a medical device company, founded in 2012, that develops and markets innovative medical devices for the interventional vascular industry. The company’s FLEX Dynamic Scoring Catheter™ is a safe and effective vessel preparation device engineered to create parallel micro-incisions, prepping the vessel for angioplasty. The FLEX Dynamic Scoring Catheter™ is cleared for sale in the US and carries CE Mark for sales in EU. For more information, visit www.FlexVesselPrep.com.

Contact:

Gary L. Smith, CEO

VentureMed Group, Inc.

614-296-4213

gsmith@venturemedgroup.com