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VentureMed Group receives FDA 510(k) clearance for FLEX Scoring Catheter

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VentureMed Group, Ltd., a medical device company based in northwest Ohio, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the commercial distribution of a new surgical device for treating peripheral artery disease (PAD). It's called the FLEX Scoring Catheter® and was developed by ProMedica Vascular Surgeon John Pigott, MD, as an alternative to balloon-based scoring with a one-size-fits-all platform technology. Dr. Pigott founded VentureMed Group, which specializes in the development and commercialization of innovative and cost-effective endovascular medical devices.

FLEX, which received CE Mark in Europe in 2015, provides interventionalists with a device that allows them to care for patients with severely blocked arteries that might not be effectively treated with traditional balloon procedures.

"Using FLEX prior to balloon angioplasty in our first-in-man trial, we were able to show statistically significant improvement in ankle-brachial index scores at 30 days," said Dr. Pigott, chief science officer, VentureMed Group, Ltd. "Benefits for PAD patients may include fewer dissections and improved results at procedure completion. In fact, we continue to see encouraging data from early adopters across the European Union."

How the FLEX Scoring Catheter works

The FLEX Scoring Catheter surgical device is inserted through the patient's artery to a point just below the blockage. The surgeon pulls a thumb lever that exposes three precision micro-blades that are mounted at the tip of the catheter. As the catheter is drawn through the plaque, the micro-blades make continuous scores, relaxing the plaque. Next, an angioplasty balloon is inflated to open up the artery, allowing blood to flow freely.

"FLEX deploys quickly and is easy to use, saving the interventionalist procedural time," said Gary Smith, chief executive officer, VentureMed Group, Ltd. "Priced at a third of the cost of similar devices, it is an excellent vessel preparation tool for use with balloon angioplasty."

What is PAD?

Approximately 12 million people in the United States have PAD, the narrowing or blockage of the vessels that carry blood from the heart to the legs. PAD is usually caused by a buildup of plaque in the vessels and results in leg pain, difficultly walking, numbness or weakness in the legs. Left untreated, it could lead to amputation, heart attack and stroke.

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