

Innovative Cardiovascular Solutions Announces Successful First Cases in European Clinical Study of EMBLOK Embolic Protection System

Milan, Italy – March 15, 2017 - [Innovative Cardiovascular Solutions](#) (ICS), a privately held medical device company pioneering novel solutions for embolic protection during transcatheter aortic valve replacement (TAVR), announced today successful first European clinical cases using the EMBLOK™ Embolic Protection System in patients undergoing TAVR procedures. The cases were performed by Drs. Azeem Latib and Matteo Montorfano under the direction of Dr. Antonio Colombo at San Raffaele Hospital in Milan, Italy.

TAVR is indicated for use in intermediate, high, and extreme risk patients with severe aortic stenosis. Its efficacy is currently being tested in low risk patients. However, numerous studies confirm that these procedures are associated with increased risk of neurological events as compared to conventional surgery, due to the embolic debris that enters the cerebral, abdominal and distal vasculature during the procedure. The EMBLOK system is the first circumferential aortic filter designed to fully capture and prevent embolic debris from reaching the brain and other vasculature during transcatheter valve procedures.

“The EMBLOK system is intended to provide complete cerebral protection during valve implantation and is very easy to position, deploy and retrieve,” said Dr. Latib. “It is the most intuitive filter I have ever used,” added Dr. Montorfano. Dr. Colombo further commented, “Of all the filters, this is the one I like the most, it is very straightforward to use.”

The company’s multi-center non-randomized feasibility study will evaluate subjects with severe native aortic valve stenosis who meet the commercially approved indications for TAVR. Study endpoints will include acute cerebral embolic burden and major adverse cardiac and cerebrovascular events (MACCE) at 30 days.

“We’re very encouraged the device exceeded physician expectations and performed well in the first clinical cases,” said R. Kevin Plemmons, ICS’s co-founder and CEO. “Interventional cardiologists and cardiovascular surgeons who perform left heart structural procedures demand the best care for their patients. We are pleased to meet this need with the first embolic system designed to offer both full collection and circumferential protection.”

The EMBLOK system is currently available for investigational use only and is not approved for sale.

About the EMBLOK Embolic Protection System

The EMBLOK system is the world’s first and only embolic protection device designed to offer full circumferential aortic collection while protecting the cerebral, abdominal and peripheral vasculature from embolic debris. In addition, the EMBLOK system incorporates an integrated 4 Fr radiopaque pigtail catheter which provides the physician constant visualization, while eliminating the need for constant dye injections to verify positioning. The entire system is 11 Fr

and allows two devices (i.e., embolic filter and pigtail catheter) to be deployed through a single puncture site.

About Innovative Cardiovascular Solutions (ICS)

ICS strives to develop novel solutions that offer full capture and protection from embolic material released during left-sided heart procedures. With the first product, the EMBLOK Embolic Protection System, the goal is to improve patient quality of life and lower overall healthcare costs that are associated with embolic risks.

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