

## **Innovative Cardiovascular Solutions Announces First Use of its Next-Generation Emblok™ Embolic Protection System in European Feasibility Study**

*New System Significantly Increases Percentage of Patients Able to Receive Embolic Protection*

**Kalamazoo, Mich. – March 5, 2019 – [Innovative Cardiovascular Solutions, LLC \(ICS\)](#)**, a privately held medical device company, today announced the first clinical use of its next-generation Emblok™ Embolic Protection System in patients undergoing transcatheter aortic valve replacement (TAVR) procedures in its European feasibility study. The cases were successfully performed by primary investigator Dr. Federico De Marco at Policlinico San Donato (Milan, Italy).

“The prior generation demonstrated excellent performance, however we saw an opportunity to modify the device dimensions to be suitable for even more patients,” said R. Kevin Plemmons, CEO of ICS. “The next-generation Emblok system is appropriate for 97% of all TAVR patients, whereas other commercial embolic protection devices may not be suitable for all anatomies.”

In addition to offering protection to more patients, the next-generation Emblok system provides protection throughout the entire TAVR procedure. The embolic filter deploys before the TAVR catheter enters the aorta and remains deployed until the TAVR catheter is removed.

“I am excited to have one embolic protection system I can use across nearly all my TAVR patients to provide complete protection during the entire TAVR procedure,” said Dr. De Marco. “There is nothing like it on the market.”

The Emblok system is designed for use in TAVR and other structural heart procedures, which are associated with an increased risk of neurological events compared to conventional surgery due to embolic debris that is liberated throughout the procedure. The next-generation Emblok system is the first embolic protection system to fully protect the cerebral, abdominal and peripheral vasculature with complete circumferential aortic coverage to capture and remove the liberated embolic debris throughout the entire TAVR procedure.

“The system is easy to use and can integrate seamlessly in all stages of the TAVR procedure,” said Dr. Azeem Latib, Montefiore Medical Center (Bronx, New York) and scientific advisor for ICS. “With its 4 Fr radiopaque pigtail catheter, I have constant visualization which eliminates the need for unnecessary dye injections.”

The entire system is 11 Fr and allows both the embolic filter and integrated pigtail catheter to be deployed through a single femoral access site.

The Emblok system is available for investigational use only and is not approved for sale. The company plans to begin its U.S. early feasibility study later this year. Study endpoints will include acute cerebral embolic burden and major adverse cardiac and cerebrovascular events (MACCE) at 30 days.

### **About Innovative Cardiovascular Solutions (ICS)**

ICS is developing novel solutions that offer full capture and protection from embolic material released during left-sided heart procedures. With its first product, the Emblok Embolic Protection System, ICS’s goal is to improve patient quality of life and lower overall healthcare costs associated with embolic risks. To learn more, please visit [www.emblok.com](http://www.emblok.com).

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