



**EMBOLINE, INC. COMPLETES INITIAL HUMAN CLINICAL CASES WITH THE *EMBOLINER™*
*EMBOLIC PROTECTION CATHETER***

*Revolutionary Device Provides Total Embolic Protection During
Transcatheter Aortic Valve Replacement (TAVR) Procedures*

SANTA CRUZ, Calif. — June 5, 2018 — Emboline, Inc., an emerging medical device company with a [game-changing device for total embolic protection](#) during transcatheter aortic valve replacement (TAVR) procedures, announced today the successful completion of its initial series of human clinical cases using the Emboliner™ Embolic Protection Catheter. The initial procedures were performed at the Heart Center and the University of Dresden Hospital in Dresden, Germany as part of the SafePass™ clinical trial.

Cerebral embolism, which can lead to stroke or even death, is a known complication of TAVR. In carefully controlled studies, stroke rates related to TAVR have been shown to be as high as 27 percent. A reliable, simple-to-use aortic embolic protection system, like the Emboliner, is critical for the adoption and growth of TAVR procedures, especially in younger, lower-risk patients.

The SafePass trial will include up to 60 patients at up to five medical centers throughout Germany, the Netherlands and Israel. The trial will assess the safety and technical performance of the Emboliner and the data will be used to submit the device for European CE Mark approval.

“Trapping and removing embolic debris during TAVR is especially critical to improving the outcomes of these procedures,” said Prof. Dr. Axel Linke, the SafePass Principal Investigator and Chairman of the Department of Internal Medicine and Cardiology at the Heart Center, University of Dresden Hospital. “We are very encouraged by the initial results we are seeing from the Emboliner device, which has captured embolic debris in every patient in the clinical cases to date. The Emboliner’s unique design, which provides full-body embolic protection, is an important addition to the field of TAVR embolic protection.”

The novel Emboliner device is intended to not only provide more reliable cerebral embolic protection, but also complete protection of the arterial bed (both cerebral and non-cerebral vessels) utilizing a uniquely ported design that maintains tool access through the filter. Providing significant improvements on first-generation TAVR embolic protection solutions, The Emboliner has been designed to offer the following potential advantages:

- More effective coverage of all cerebral branches with fewer anatomical limitations
- Full-body embolic protection, capturing both cerebral and non-cerebral debris
- No requirement for an additional procedural access
- No interference with the TAVR delivery system and accessory devices
- An extremely user-friendly design with minimal added procedural time or complexity

“The initiation of our SafePass clinical trial will bring Emboline one step closer to achieving CE Mark approval and offering future TAVR patients a safer procedure,” said Scott Russell, Emboline’s President & CEO. “We believe that the Emboliner’s total embolic protection combined with its outstanding ease-of-use will offer physicians significant advantages over existing technologies.”

About Emboline, Inc.

Emboline, Inc., is a privately-held, emerging medical device company that has developed the Emboliner™ Embolic Protection Catheter, a game-changing embolic protection technology for TAVR



and other interventional procedures with embolic risks. The novel Emboliner™ device is intended to more reliably protect the cerebral system, while also capturing non-cerebral debris. Emboline's technologies are derived from intellectual property invented by Amir Belson, MD, founder of Neoguide Systems, Vascular Pathways, Zipline Medical, Qool Therapeutics, and others. For more information: www.emboline.com.

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