



CLARET MEDICAL SUBMITS MARKETING APPLICATION TO FDA FOR US CLEARANCE OF FIRST CEREBRAL PROTECTION SYSTEM FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

SANTA ROSA, Calif. – September 20, 2016 – [Claret Medical®](#), an innovator in filter-based cerebral embolic protection technologies, today announced its filing of a marketing application with the US Food and Drug Administration (FDA) for clearance of the [Sentinel® Cerebral Protection System](#) (CPS). The Sentinel CPS is the only device designed to protect the brain by capturing and removing debris dislodged during transcatheter aortic valve replacement (TAVR) that enters cerebral circulation and carries the potential for stroke. There are currently no cerebral embolic protection technologies available in the US to protect TAVR patients from cerebral embolic events.

The filing includes data from the recently completed SENTINEL pivotal IDE trial, a prospective, randomized, controlled, blinded study of 363 TAVR patients at 19 centers in the US and Germany. Trial endpoints included reduction in new ischemic cerebral infarcts, major adverse cardiac or cerebrovascular events, neurocognitive outcomes, and qualitative and quantitative histopathological findings. The SENTINEL trial allowed inclusion of all commercially available TAVR platforms available in the US.

Results from the recently published [CLEAN-TAVI blinded, randomized, controlled trial](#) in the [Journal of the American Medical Association \(JAMA\)](#) and the [MISTRAL-C randomized, controlled trial](#), published in [Eurointervention](#), showed that patients protected with the system had significantly fewer and smaller new ischemic cerebral infarcts following the procedure than unprotected patients. MISTRAL-C also demonstrated that the TAVR procedure created embolic debris in 100 percent of patients, which could have traveled to the brain if not for the protection offered by the Sentinel CPS.

“Our contribution in building significant new science will help the rapidly growing TAVR field embrace the critical role of cerebral protection in all left heart and endovascular procedures,” said [Claret Medical President and Chief Executive Officer Azin Parhizgar, PhD](#). “These studies incorporate a level of rigorous brain evaluation never before undertaken, including systematic and serial state-of-the-art 3-Tesla MRI neuroimaging of patients’ pre-existing cerebrovascular disease, as determined by a baseline MRI, as well as neurological, histopathological and neurocognitive evaluations. Assuming a positive outcome with the FDA, we look forward to making the Sentinel CPS available to interventional cardiologists and cardiovascular surgeons in the US soon.”

Stroke continues to be a devastating complication of TAVR and other endovascular procedures. Ischemic brain infarcts have been associated with adverse neurologic and cognitive

consequences, as well as dementia. In population-based studies, they have also been shown to increase the risk of future stroke by two- to four-fold.

The Sentinel CPS received the CE Mark in 2013 and, since then, more than 3,000 patients in Europe have been protected by a Claret Medical cerebral protection system.

About Claret Medical

Claret Medical™ is a privately-held company focused on innovative solutions for cerebral protection during structural heart interventions, vascular interventions, and cardiac surgery procedures. The company is currently focusing product development and clinical research on addressing the problem of stroke during TAVR, a significant unmet clinical need. For more information: www.claretmedical.com.

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