Press Release

BIOTRONIK
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Page: 1/3

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BIOTRONIK Announces First Enrollments in New Study Evaluating Reduction of Thromboembolic Events via GoldTip Ablation

Trial to Demonstrate Efficacy of AlCath Flux eXtra Gold Ablation Catheter in Reducing the Incidence of Harmful Thromboemboli

BERLIN, Germany, January 14, 2015 – BIOTRONIK, a leading manufacturer of cardiovascular medical technology, announced today the first enrollments in its prospective, multi-center, international Reduce-TE Pilot study (Reduction of AF Ablation Induced Thrombo-Embolic Incidence). The study will assess the ability of the advanced irrigated ablation catheter AlCath Flux eXtra Gold to reduce the incidence of silent microemboli (SME). SME are a complication associated with catheter ablation of the pulmonary veins, a common treatment for atrial fibrillation (AF).[1] The BIOTRONIK ablation catheter features a GoldTip and a 3-D irrigation system which study investigators believe can diminish the number of SME via optimized cooling, thereby improving patient safety.

AF, the most common cardiac arrhythmia, is very often induced and maintained by incorrect electrical signals emanating from the pulmonary veins. An option for treating AF is to isolate the pulmonary veins (PVI) with radiofrequency therapy, causing the formation of scar tissue around the connections of the pulmonary veins to the heart's left atrium. The heat emerging from an ablation catheter is associated with the formation of SME. The vast majority of SME, however, are asymptomatic and consequently go undetected.[2]

"Even silent microemboli are undesirable, as they produce irreversible neural tissue damage and therefore could lead to impaired neurological function," explained the study's coordinating clinical investigator Dr. Dipen Shah, University Hospital, Geneva, Switzerland. "It is imperative that we study their origin and potential effects further. With clinical data from this single-arm non-inferiority pilot study, we will be better able to assess whether a catheter with an innovative GoldTip designed to enable a lower tip temperature could favourably affect the incidence of cerebral subclinical lesions compared to published results."

The Reduce-TE Pilot study will observe up to 125 patients; the primary endpoint of the study is to investigate the incidence of new microembolic lesions occuring after PVI. Study investigators seek to demonstrate that the AlCath Flux eXtra Gold ablation catheter is non-inferior compared to historical data from the literature regarding the incidence of thromboembolic lesions. An important secondary endpoint is to assess the impact of PVI on the patient's neurocognitive status, so patients will also undergo a neurocognitive status assessment before the procedure, between one and three days after PVI, and during a three-month follow-up.

"Unlike other ablation catheters used for PVI, the BIOTRONIK catheter features a GoldTip which delivers the same amount of energy as a standard platinum iridium tip, but loses its heat into the bloodstream more quickly due to gold's greater thermal conductivity," commented study investigators Dr. Josef Kautzner and Dr. Petr Peichl, Institute of Clinical and Experimental Medicine, Prague, Czech Republic. "Our hypothesis is that a catheter with a cooler tip may result in an even lower incidence of microemboli than is currently observed, and therefore increase patient safety."

"As our first foray into EP clinical trials, the Reduce-TE Pilot study exemplifies the commitment BIOTRONIK has made to the fast growing field of complex ablation procedures," stated Wolf Ruhnke, Vice President at BIOTRONIK. "The AlCath Flux eXtra Gold ablation catheter has already garnered praise for its refined control and 'full circle' when following complex patient anatomies. We are now eager to explore what additional safety benefits the uniform cooling facilitated by our signature GoldTip and unique 3-D irrigation system provides."

About BIOTRONIK
One of the world's leading manufacturers of cardio- and endovascular medical devices, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries by its global workforce of more than 5,600 employees. Several million patients have received BIOTRONIK implants designed to save and improve the quality of their lives, or have been treated with BIOTRONIK coronary and peripheral vascular intervention products. Since its development of the first German pacemaker in 1963, BIOTRONIK has engineered many innovations, including BIOTRONIK Home Monitoring®; the world's first 4 F-compatible 200mm peripheral stent; Orsiro, the industry's first hybrid drug-eluting stent; and the world's first implantable cardioverter-defibrillators and heart failure therapy devices with ProMRI® technology.

For more information, visit: www.biotronik.com

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[2] Gaita F et al. *Circulation*. 2010, 122 (1667–1673)

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