

Study: Medtronic Anatomically-Designed Catheters Reduce Lab Time Required for Pulmonary Vein Isolation by 35 Percent

Data from FAST-PVI Study Presented at Cardioslim 2010

MINNEAPOLIS, & NICE, France, Jun 18, 2010 (BUSINESS WIRE) --Data from the FAST-PVI study, supported by Medtronic, Inc. (NYSE: MDT), shows lab time using anatomically-designed ablation catheters are more than one-third (35 percent) faster than traditional point-by-point focal ablation procedures in achieving pulmonary vein isolation (PVI). PVI is the cornerstone catheter procedure to treat paroxysmal atrial fibrillation (PAF). The anatomically shaped Arctic Front(R) Cardiac CryoAblation Catheter and advanced radiofrequency (RF) Pulmonary Vein Ablation Catheter(R) (PVAC) allowed physicians to more efficiently isolate the pulmonary veins than do focal RF catheters. Acute PVI success rate for the anatomical catheters was 99 percent. The data were released at Cardioslim 2010, the 17th World Congress in Cardiac Electrophysiology and Cardiac Techniques.

The Arctic Front is approved in Europe to treat paroxysmal atrial fibrillation (AF); PVAC is approved in Europe to treat supraventricular tachycardia (SVT). Both catheters are under investigational use in the United States. Arctic Front is under U.S. Food and Drug Administration (FDA) review for paroxysmal AF and PVAC for the treatment of continuous AF.

"FAST-PVI is the first study quantifying procedure time efficiency improvements associated with the use of anatomically designed catheter ablation systems," said Gunnar Klein, M.D., Ph.D., Hannover Medical School (Medizinische Hochschule Hannover - MHH) in Hannover, Germany. "The shorter and more predictable procedure times allows me to better manage lab time and treat more patients."

The goal of catheter ablation is to isolate the pulmonary vein to stop the rapid beating of the upper heart chambers by ablating (or blocking) the conduction pathways that trigger atrial fibrillation (AF). Catheter ablation is a minimally invasive procedure that is recommended after commonly prescribed drugs have failed to achieve acceptable results in symptomatic patients. Previously, AF ablation procedures could only be performed with a time-consuming point-by-point focal ablation technique to create individual lesions to block AF conductivity. Now, anatomically shaped catheters can efficiently create lesions with fewer applications because they have been designed specifically for isolating the pulmonary vein.

The retrospective FAST-PVI study compared procedure time using anatomically-designed catheter ablation systems with procedure times of point-by-point focal systems. Results from nine German centers and 444 procedures showed that using anatomical catheters for PVI allows for more efficient procedures, reduced cath lab occupancy time and faster physician procedure time. Of the 245 procedures using anatomical Arctic Front and PVAC catheters, overall staff time lowered by 36 percent ($p < 0.001$), fluoroscopy time was reduced by 33 percent ($p < 0.001$) and physician procedure time was reduced by 37 percent ($p < 0.001$). Using anatomical catheters achieved an average lab use time of 170 minutes compared to 262 minutes for point-by-point focal ablation, or a 35 percent time reduction ($p < 0.001$). Results with anatomical catheters were compared to the 199 patients receiving point-by-point focal ablation with an acute PVI success rate of 99 percent.

About Arctic Front and PVAC

The Arctic Front Cardiac CryoAblation Catheter System uses cryoablation, or freezing technology. A coolant is released into the catheter's balloon to freeze and ablate the tissue; freezing helps the balloon maintain contact with the tissue. The Medtronic Ablation Frontiers Cardiac Ablation System, a leading advancement from

currently available RF ablation tools, includes an RF generator (or heated energy source) and three anatomically shaped ablation catheters, including the PVAC.

About Medtronic

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