Media Contact:
Hospital Contact
Phone Number
Email Address

FOR IMMEDIATE RELEASE

[INSERT HOSPITAL NAME] Offers First Catheter Ablation Therapy Approved in the U.S. with Direct Contact Force Technology for Treatment of Atrial Fibrillation

[INSERT HOSPITAL NAME] First in [INSERT REGION] to Offer New FDA-Approved Therapy with Direct Contact Force Technology for Treatment of Atrial Fibrillation

[INSERT HOSPITAL NAME] Offers Latest Advancement in the Treatment of Patients with Atrial Fibrillation

City, State, Date – **[INSERT HOSPITAL NAME]** has become the first in **[REGION]** to offer the THERMOCOOL® SMARTTOUCH® Catheter, the first catheter approved by the FDA in the U.S. to feature direct contact force technology for the treatment of patients with atrial fibrillation, or Afib. This novel innovation enables doctors to accurately control the amount of contact force applied to the heart wall during radiofrequency catheter ablation procedures.

"Consistent and stable application of contact force against the heart wall has been demonstrated to have a significant impact on patient outcomes during catheter ablation. The THERMOCOOL® SMARTTOUCH® Catheter provides critical contact force information to help confirm that we are applying the intended amount of pressure with the catheter throughout the duration of the procedure so that optimal outcomes can be achieved, said [FULL NAME], MD, [TITLE] at [HOSPITAL NAME]. "Without this technology, doctors have to estimate the amount of force being applied to the heart wall through other indirect measures that have been shown not to be as effective."[1]

During a minimally invasive catheter ablation procedure, doctors insert a therapeutic catheter through a small incision in the groin where it is then weaved up to the heart through a blood vessel. Once it reaches the left upper chamber of the heart (atrium), the catheter delivers radiofrequency energy to the heart wall to create lesions that block faulty electrical impulses that can cause heart rhythm disorders. Providing doctors with the ability to apply stable contact force during catheter ablation has been shown to improve patient outcomes as poor tissue contact may result in incomplete lesion formation that could result in the need for additional treatment, and too much contact force may result in tissue injury, which may lead to complications.[2-5]

One-year results from a clinical trial that studied the safety and effectiveness of the device showed that patients experienced a 74 percent success rate after treatment with the THERMOCOOL® SMARTTOUCH® Catheter. Importantly, data from the trial showed higher success rates the longer physicians stayed within a targeted contact force range, with one-year results demonstrating an 88 percent success rate when physicians stayed within a targeted range greater than or equal to 85 percent of the time.[6]

An estimated three million Americans suffer from Afib, a progressive disease that increases in severity and frequency if left untreated, and can lead to chronic fatigue, congestive heart failure and stroke.[7] While most Afib patients today are treated with drugs, about half of patients are not able to control their abnormal heart rhythm with drugs or find they cannot tolerate the side

effects. When medication proves to be unsuccessful, the American College of Cardiology and the American Heart Association suggest catheter ablation be considered as a safe and effective treatment option.[8] Clinical studies show that success rates for Afib treatments such as catheter ablation decrease the longer the disease is left untreated so earlier intervention is recommended.

[INSERT INFORMATION ABOUT ELECTROPHYSIOLOGY PROGRAM AND TEAM]

[INSERT HOSPITAL BOILERPLATE]

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[1] Nakagawa H, Kautzner J, Natale A, et al. Locations of high contact force during left atrial mapping in atrial fibrillation patients: electrogram amplitude and impedance are poor predictors of electrode-tissue contact force for ablation of atrial fibrillation. Circ Arrhythm Electrophysiol 2013;6:746-53.

[2] Marijon E, Fazaa S, Narayanan K, Guy-Moyat B, Bouzeman A, Providencia R, et al (2013) Real-time contact force sensing for pulmonary vein isolation in the setting of paroxysmal atrial fibrillation: procedural and one-year results. Journal of Cardiovascular Electrophysiology (published online October 2013).

[3] Carmo P, Pulido Adrago P, Cavaco D, Bello Morgado F, Candeias R, Aldmeida S, et al. (2012) Determination of the contact force during ablation of atrial fibrillation: Inter-operator variability. Cardiostim (abstract # 136P_86).

[4] Kuniss M, Lehinhant S, Pajitnev D, Zaltsberg S, Greiss H, Berkowitsch A, et al (2013) Clinical success of conventional vs. contact force-controlled radiofrequency catheter ablation of atrial fibrillation: clinical outcome after 12 months. Heart Rhythm Society (abstract # AB35-04).

[5] Stabile G, Solimene F, Calo L, Anselmino M, Castro A, Pratola C, et al (2013) Impact of catheter-tissue contact force on pulmonary veins isolation acute procedural parameters. Heath Rhythm Society (abstract # PO03-130).

[6] Natale A (2013, May). Ablation of Symptomatic Paroxysmal Atrial Fibrillation Using Novel Contact Force Catheter: SMART-AF Trial. Data presented at the Heart Rhythm Society's 34th Annual Scientific Sessions in Denver, CO.

[7] Naccarelli GV, Varker H, Lin J, Schulman KL. Increasing prevalence of atrial fibrillation and flutter in the United States. Am J Cardiol.2009;104:1534-1539.

[8] Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. J Interv Card Electrophysiol. 2012 Mar;33(2):171-257. doi: 10.1007/s10840-012-9672-7.

THERMOCOOL® Navigation Catheters are approved for drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® Systems (excluding NAVISTAR® RMT THERMOCOOL® Catheter).