First U.S. Case Performed with Endosense’s TactiCath® Quartz Contact-Force Sensing Ablation Catheter

The Associated Press

GENEVA--(BUSINESS WIRE)--Feb 1, 2013--Endosense, a pioneer and leader in contact-force sensing technology focused on improving the efficacy and safety of catheter ablation for the treatment of cardiac arrhythmias, has announced that its new generation TactiCath Quartz contact-force sensing ablation catheter has been used for the first time in the United States by Dr. J. Michael Mangrum at University of Virginia Medical Center in Charlottesville, Va. The first U.S. case was performed on January 31 as part of an amended protocol of the company’s TOCCASTAR investigational device exemption (IDE) clinical study of the TactiCath (called the "TOCCASTAR Supplemental Clinical Study"). The supplemental study’s protocol is identical to that of original TOCCASTAR study, with the exception that the patients treated with the newer device will not be randomized.

“The TactiCath Quartz features several enhancements that have improved my ability to leverage contact-forcing sensing during the catheter ablation procedure,” said Dr. Mangrum. “I believe that the device represents another step forward for this exciting technology that, should it ultimately prove to be safe and effective, has the potential to become the gold standard in the catheter ablation treatment of cardiac arrhythmias.” The TactiCath Quartz, which received CE mark approval in June 2012 and was launched commercially in Europe by Endosense in December 2012, offers several key innovations over the previous TactiCath model. The device features a new force sensor that provides increased stability and precision and avoids the need for pre-procedure calibration; a significantly smaller equipment footprint; a user friendly graphical interface; and enhanced signal processing and digital output that facilitates connectivity with imaging devices and other equipment in the lab.

“The TactiCath Quartz brings several technical and functional advancements to the electrophysiology lab that further strengthen our leadership position in the field,” said Jan Keltjens, president, chief executive officer and chairman of Endosense. “Its use in the TOCCASTAR Supplemental Clinical Study will pave the way for us to continue to offer electrophysiologists and their patients the most advanced contact-force sensing technology available, once we achieve anticipated approval in the United States.” As announced on June 13, 2012, Endosense has completed enrollment in the original TOCCASTAR IDE clinical study. The company expects to use the results of the study to file a Premarket Approval (PMA) application to the U.S. Food and Drug Administration in the fourth quarter of 2013.

About Endosense Founded in Geneva in 2003, Endosense is a medical technology company focused on improving the efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias. The company pioneered the use

of contact-force measurement in catheter ablation with the development of the TactiCath, the first contact-force sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure. Endosense is backed by NDN Capital, Edmond de Rothschild Investment Partners, Neomed, Gimv, VI Partners, Sectoral Asset Management, Ysios Capital Partners and Initiative Capital Romandie. For more information, visit www.endosense.com.

Caution: In the United States, the TactiCath is an investigational device. Limited by Federal (or United States) law to investigational use.

CONTACT: ENDOSENSE MEDIA CONTACT/U.S.: Nobles Communications Laura Nobles, 310-795-0497 laura@noblescommunications.com or ENDOSENSE MEDIA CONTACT/EUROPE: Genevensis Communications Danièle Castle, +41 79 202 6667 info@genevensis.com KEYWORD: UNITED STATES EUROPE NORTH AMERICA NEW YORK SWITZERLAND INDUSTRY KEYWORD: SURGERY HEALTH CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES RADIOLOGY FDA SOURCE: Endosense Copyright Business Wire 2013 PUB: 02/01/2013 07:00 AM/DISC: 02/01/2013 07:00 AM http://www.businesswire.com/news/home/20130201005082/

Source URL (retrieved on *03/12/2014 - 1:30pm*):
http://www.mdtmag.com/news/2013/02/first-us-case-performed-endosense%E2%80%99s-tacticath%C2%AE-quartz-contact-force-sensing-ablation-catheter?qt-recent_content=0&qt-most_popular=0