



ENDOSENSE LAUNCHES THE TOCCASTAR IDE STUDY OF ITS TACTICATH®  
FORCE-SENSING ABLATION CATHETER

GENEVA – January 12, 2011 – [Endosense](#), a medical technology company focused on improving the efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias, has announced first patient enrollment in the TOCCASTAR (TactiCath Contact Force Ablation Catheter Study for Atrial Fibrillation) clinical study at Na Homolce Hospital, Prague, Czech Republic, by study investigator Petr Neuzil, M.D.

TOCCASTAR is a prospective, randomized, multi-center, investigational device exemption (IDE) clinical trial designed to evaluate the effectiveness and safety of the [TactiCath<sup>1</sup> force-sensing ablation catheter](#) for the treatment of symptomatic paroxysmal atrial fibrillation (AF). Results of the study will be used to support a Premarket Approval Application (PMA) to the U.S. Food and Drug Administration (FDA) for clearance of the TactiCath catheter and accompanying TactiSys system.

TOCCASTAR will be conducted at up to 30 centers in the United States and Europe. Three hundred patients will be randomized on a one-to-one basis for treatment with Endosense's force-sensing TactiCath or a catheter approved by the FDA for paroxysmal AF. The study's primary effectiveness endpoint will measure acute procedural success as well as chronic freedom from symptomatic AF, atrial tachycardia and atrial flutter at 12 months. The safety endpoint will report the incidence of device-related serious adverse events. In addition, TOCCASTAR will assess the contribution of real-time contact force information to procedural effectiveness during ablation compared to conventional radiofrequency (RF) irrigated catheters.

“This is a very exciting time for Endosense, as we embark on this critical step toward regulatory clearance for the TactiCath in the United States,” said Eric Le Royer, Endosense president and chief executive officer. “Based on the significant and growing foundation of clinical evidence we have built with the TactiCath contact force-sensing catheter, as well as our commercial success in Europe, we expect the results of TOCCASTAR to continue to

demonstrate the great potential of contact force sensing to profoundly improve and expand the catheter ablation treatment of cardiac arrhythmias.”

AF is the most common cardiac rhythm disorder today, affecting more than six million people worldwide. AF patients are typically treated with pharmaceutical drugs that are frequently ineffective and may cause side effects, or they undergo invasive surgery. TOCCASTAR will explore a new catheter ablation treatment option for patients who have symptomatic paroxysmal (sudden and temporary) AF and who are resistant or intolerant to at least one Class I-IV anti-arrhythmic drug.

“The ability of physicians to control contact force during ablation procedures has long been a missing link in catheter ablation, and the consequence of this has been an historic trade off between procedure safety and effectiveness,” said Vivek Reddy, M.D., TOCCASTAR principal investigator and director of the Cardiac Arrhythmia Service, The Mount Sinai Medical Center, New York. “TOCCASTAR is a landmark study in that its results may pave the way for contact force sensing to become the new standard of care in radiofrequency catheter ablation, a development that would finally address this issue and ultimately help improve safety, effectiveness and access to the procedure.”

### **About Catheter Ablation and the TactiCath**

During catheter ablation, the electrophysiologist uses a catheter to create a series of lesions along the heart wall to disrupt abnormal electrical activity. With no way to objectively measure the contact force between the catheter tip and beating heart wall, the electrophysiologist has to estimate – and frequently guess – the level of force required. This creates a delicate balancing act between procedure effectiveness and safety, as too little force may render the procedure ineffective and too great a force may perforate the heart wall. Endosense’s TactiCath is the first and only commercialized force-sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure. Launched outside of the United States in April 2010, the second generation TactiCath is now used by electrophysiologists across Europe. A [growing body of evidence](#) has reinforced the value of force sensing in improving patient outcomes of catheter ablation procedures and has supported the TactiCath’s potential to improve the effectiveness, safety and accessibility of catheter ablation treatment of cardiac rhythm disorders, including AF. BIOTRONIK is the exclusive distributor of the TactiCath in Europe, Latin America, Canada, Africa and the Middle East. The TactiCath is not yet available in the United States.

## **About Endosense**

Founded in Geneva in 2003, Endosense is a medical technology company focused on improving efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias. The company has pioneered the use of contact force measurement in catheter ablation, with the development of its proprietary Touch+<sup>®</sup> sensor technology. Endosense's flagship product is the TactiCath, the first force-sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure.

Endosense is backed by 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](http://www.endosense.com).

<sup>1</sup>Caution: TactiCath is an investigational device. Limited by Federal (or United States) law to investigational use.

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