



The TactiCath® Force-Sensing Ablation Catheter Technology Fact Sheet

Market Overview

Atrial fibrillation (AF) is the most prevalent cardiac rhythm disorder today, with more than six million people affected worldwide. In patients with AF, the heart beats irregularly due to abnormal electrical activity in its upper chambers. This irregular beating can cause symptoms such as shortness of breath, fatigue and dizziness, and can ultimately lead to stroke and heart failure.

Patients with AF have historically had two treatment options: pharmaceutical drugs with significant side effects and poor long-term effectiveness, or invasive ablation surgery in which lesions are created along the heart wall to cut off the abnormal electrical activity.

A new form of ablation therapy, called catheter ablation, promises to offer physicians and patients a less invasive approach with the potential for better outcomes and fewer negative side effects than traditional therapies. Many technologies have emerged over the last several years to accelerate the adoption of catheter ablation for AF, yet the procedure remains a highly complex and unpredictable.

A key factor slowing the adoption of catheter ablation for AF is the physician's inability to accurately control the contact force between the catheter tip and the beating heart wall. This inability results in a delicate balancing act between procedure safety and effectiveness, as the physician has to estimate – and frequently guess – the level of force applied. If the contact force is too great, the catheter tip may perforate the heart wall. If it is too slight, the procedure may be ineffective.

The TactiCath® Force-Sensing Ablation Catheter

Developed by Endosense, the TactiCath is the first force-sensing ablation catheter to give physicians a real-time, objective measure of tip-to-tissue contact force during the catheter ablation procedure. With the TactiCath, physicians can be assured that they are using just the right force for the right lesion creation.

The TactiCath is a high-end, 7 F sheath compatible, open irrigated, steerable ablation catheter that seamlessly integrates Endosense's proprietary Touch+® force-sensing technology in the catheter tip. It is supported by the TactiSys™ system, which is comprised of a graphical user interface, base station and splitter.

During the procedure, the physician threads the TactiCath through the patient's groin area to the upper chambers of the heart, where he or she will create targeted lesions along the heart wall. During lesion creation, the physician can view the TactiSys interface to see the exact amplitude

and direction of the forces applied, along with the Force-Time Integral™ (the calculation of force over time). Following the procedure, he or she then receives an automatically generated report documenting the forces applied during lesion creation.

Key TactiCath Features:

- Real-time, highly accurate tip-to-tissue contact force measurements
- Proven fiber optic sensor technology
- Sensitivity of less than 1 gram
- Shaft: 7 F, usable length 115 cm
- Tip electrode: 3.5 mm, open irrigated
- Electrode spacing: 2-5-2 mm
- Curve shape: 65 mm steering

Key TactiSys Features:

- Easy-to-read data and easy-to-interpret graphics
- Measurement and display of tip-to-tissue orientation
- Axial and lateral force measurement
- Force-Time Integral measurement (the calculation of force over time)
- Automatically generated procedure summary reports

Anticipated Benefits:

- A major positive impact on the safety and effectiveness of lesion creation during the AF ablation procedure
- Improved real-time decision-making, potentially shortening procedure times
- Simplified physician training

Touch+® Force-Sensing Technology

Touch+ is Endosense's proprietary fiber optic sensor technology, which provides highly accurate and sensitive force measurements at the catheter tip. Touch+ is based on a validated sensor technology used in the civil engineering and telecommunication fields.

Clinical Validation

Endosense's TactiCath ablation catheter and supporting TactiSys™ system have undergone extensive pre-clinical validation in the United States and Europe. The resulting pool of study data has created a solid foundation of evidence supporting the feasibility, safety and value of contact force sensing during catheter ablation.

Endosense's ongoing clinical research program currently includes the following studies.

TOCCATA

Launched in late 2008, TOCCATA (TOuCh+ for CATHeter Ablation) was a multi-center, prospective safety and performance study led by Principal Investigator Karl-Heinz Kuck, M.D., with the participation of 21 additional highly experienced investigators. Investigators used the TactiCath to perform catheter ablations on 76 patients, including 34 with paroxysmal atrial fibrillation. Primary safety and performance endpoints were met during the course of the study. In 12-month data presented during the Heart Rhythm 2010, TOCCATA abstract authors suggested room for a safer and more effective catheter ablation treatment in

the future, as retrospective analysis identified a statistically significant relationship ($p < 0.05$) between the contact force applied at ablation sites and the 12-month success of the procedure (median contact force applied in the non-recurrent patient group was 20g versus 11g in the recurrent patient group).

The EFFICAS Study Series

Launched in May 2010, EFFICAS is a study series intended to demonstrate that the use of contact force control during cardiac ablation utilizing the TactiCath force-sensing catheter results in superior outcomes as compared to ablations performed without a force sensor. EFFICAS I and EFFICAS II are single arm, multi-center, prospective pilot studies that will assess the clinical effectiveness of catheter ablation with and without the use of contact force control. Outcomes data from EFFICAS I and II will help in the design of future, larger, EFFICAS studies with clinical endpoints.

TOCCASTAR

TOCCASTAR is an investigational device exemption (IDE) trial designed to achieve Premarket Approval (PMA) of the TactiCath in the United States. Endosense expects to begin enrollment in TOCCASTAR in 2010.

Endosense's growing body of study data has been the subject of 16 abstracts presented at annual meetings of the Heart Rhythm Society, American College of Cardiology and American Heart Association.

Availability

The TactiCath and TactiSys were granted CE mark in October 2009 for the treatment of atrial fibrillation (AF) and supraventricular tachycardia (SVT). In April 2010, Endosense launched a second-generation product. The company's exclusive product distributor in Europe, Latin America, Canada, Africa and the Middle East is BIOTRONIK. The TactiCath is not currently available in the United States.

References

¹ Schmidt, B., et al., "TOCCATA Multi-Center Clinical Study: Irrigated RF Ablation Catheter with an Integrated Contact Force Sensor – Long-term Results," Heart Rhythm 2010.

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