



## **ENDOSENSE REINFORCES CLINICAL LEADERSHIP IN CONTACT-FORCE SENSING WITH A RANGE OF NEW STUDY DATA AT HEART RHYTHM 2011**

GENEVA – May 9, 2011 – [Endosense](#), a Swiss medical technology company focused on improving the efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias, has further advanced its clinical leadership in the field of contact-force sensing with a host of new study data supporting its [TactiCath® ablation catheter](#)<sup>1</sup>. Presented in six separate abstracts at last week’s Heart Rhythm 2011 in San Francisco, the data included groundbreaking findings from the company’s EFFICAS I post-market clinical trial that shed fundamentally new insights into the relationship between catheter tip-to-tissue contact force and early pulmonary vein isolation (PVI) line reconduction.

“EFFICAS I represents the most rigorous and detailed investigation ever conducted on the role of contact force during catheter ablation, and its findings are truly remarkable,” said Karl-Heinz Kuck, M.D., Asklepios Klinik St. Georg, Hamburg, Germany. “For the first time, we have clearly demonstrated a direct correlation between low contact force and post-operative PVI line reconduction at three month follow-up. The implications are significant, as we now have the opportunity to use the information gathered in EFFICAS I to pinpoint optimal levels of contact force in EFFICAS II.”

The first in a series, EFFICAS I is a 45-patient, single-arm, prospective, multi-center European clinical trial designed to demonstrate the correlation between contact forces applied during pulmonary vein isolation (PVI) and atrial fibrillation (AF) treatment efficacy at three months. While investigators performed the procedure with the TactiCath, they were blinded to contact force measurements; however, the contact forces applied were recorded. Patients were re-assessed with a mapping catheter at three months to identify potential gaps in the PVI lines. Contact force parameters from initial procedures were then analyzed to determine the relationship with lesion formation.

In “Low Catheter-Tissue Contact Force Results in Late PV Reconnection - Initial Results from EFFICAS I,” study investigators unveiled to Heart Rhythm 2011 attendees data from 13 patients treated by seven operators at two centers with 926 radiofrequency ablations.<sup>2</sup> At

three-month follow-up, they found a predictive relationship between low force time integral (the accumulated energy delivered per ablation) at first ablation and early gap occurrence following PVI.<sup>2</sup> They also concluded that the use of low contact force may result in early gap formation on the posterior heart wall.<sup>2</sup>

Full results from EFFICAS I will be applied to EFFICAS II, in which investigators will take full advantage of the real-time, objective TactiCath contact-force control features to improve their ablation technique during lesion creation. Now enrolling patients, the EFFICAS II study will measure reduction in PVI gaps as well as procedural improvements as compared to EFFICAS I.

Additional TactiCath study abstracts presented at Heart Rhythm 2011 further validated the relationship between contact force and procedure efficacy and safety while also exploring new modes of contact-force visualization. Among the key findings, investigators concluded that:

- Parameters of low catheter tip-to-tissue contact force are associated with a higher rate of AF recurrence in patients at 12-month follow-up, as evidenced by long-term results of the TOCCATA clinical study<sup>3</sup>;
- Contact-force measurement with the TactiCath is safe and effective, and it provides a significant reduction in radiofrequency (RF) time as compared to standard irrigated-tip catheters<sup>4</sup>;
- The risk of steam pops when applying high contact force and moderate radiofrequency power is poorly predicted by a number of variables, including initial impedance, impedance, decrease during radiofrequency ablation, electrode tissue angle, systolic contact force, diastolic contact force and force-time integral<sup>5</sup>; and
- New contact-force and force-time-integral mapping and visualization techniques may help electrophysiologists identify potential areas of PVI line reconnection that contribute to long-term AF recurrence<sup>6,7</sup>.

“Endosense has long been committed to building indisputable scientific evidence supporting the value of contact-force sensing and the TactiCath, and today we are very proud to be leading the industry with a clinical program that is unrivaled in its breadth, depth and contribution to clinical practice,” said Eric Le Royer, president and chief executive officer of Endosense. “We look forward to continuing our leadership in this area to firmly position contact-force control as the standard of care for the treatment of cardiac arrhythmias.”

Endosense has a history of clinical leadership in the field of contact-force sensing. Since its first abstract on the TactiCath was presented at Heart Rhythm 2006, [more than 30 clinical publications](#) have appeared in peer-reviewed journals or been presented at major medical society meetings across the world. Endosense is currently conducting several post-market clinical studies of the TactiCath as well as the TOCCASTAR investigational device exemption clinical trial, which commenced in January 2011 and is rapidly enrolling patients.

### **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 force-sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure. Launched in April 2010 with a full release in September 2010, the second generation of the novel device has been used across Europe to treat more than one thousand patient cases of atrial fibrillation (AF) and supraventricular tachycardia (SVT). Endosense is currently conducting several post-market clinical studies aimed at proving the superiority of the TactiCath force-sensing catheter over standard irrigated catheters, as well as the TOCCASTAR investigational device exemption (IDE) clinical trial. The company is also executing an open platform strategy to integrate its technology into a range of three-dimensional cardiac mapping systems. BIOTRONIK is the exclusive distributor of the TactiCath in Europe, Latin America, Canada, Africa and the Middle East.

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

<sup>2</sup> Reddy, V. et al. "Low Catheter-Tissue Contact Force Results in Late PV Reconnection - Initial Results from EFFICAS I." Heart Rhythm 2011, AB12-1.

<sup>3</sup> Shah D., et al. "Contact Force During Ablation Predicts AF Recurrence at 12 Months." Heart Rhythm 2011, PO6-61.

<sup>4</sup> Dello Russo, A., et al. "Catheter Contact Force in Atrial Fibrillation Ablation: What Benefit Can We Learn?" Heart Rhythm 2011, PO5-135.

<sup>5</sup> Ikeda, A. et al. "Predictors of Steam Pop During Radiofrequency Ablation at High Contact Force and Moderate RF Power in Canine Beating Heart." Heart Rhythm 2011, PO2-156.

<sup>6</sup> Rashed, K. et al. “Magnetic Resonance Imaging Analysis of Tissue-contact Force Following Catheter Ablation for Paroxysmal Atrial Fibrillation.” Heart Rhythm 2011, AB15-1

<sup>7</sup> Vijaykumar, R. et al. “Spatiotemporal Distribution of Catheter-Tissue Contact Force Across the Left Atrium During Pulmonary Vein Isolation.” Heart Rhythm 2011, PO6-85.

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