

## Press Release

### SORIN GROUP INITIATES MULTI-CENTER 'OPTION' STUDY IN EUROPE

***Study will enroll 450 patients in Europe and North America with the objective of demonstrating superiority of dual chamber implantable cardioverter defibrillators (ICDs) in patients with life-threatening tachyarrhythmias***

Paris, France – November 14, 2006. Sorin Group Cardiac Rhythm Management (CRM) Business Unit today announced the initiation of the OPTION (Optimal Antitachycardia Therapy in ICD Patients without Pacing Indication) clinical study in Europe. The primary objective of the study is to demonstrate that implantable dual chamber cardioverter defibrillators (ICDs) have greater efficacy than single chamber ICDs in reducing inappropriate shock delivery and have the same efficacy in reducing all cause patient mortality and hospitalizations due to cardiovascular events.

The multi-centre prospective, single blind, two-arm randomized OPTION study aims to demonstrate that patients implanted with dual chamber ICDs incorporating advanced features such as optimal dual chamber arrhythmia detection, a pacing mode that minimizes ventricular pacing and a slow ventricular tachycardia zone, have better outcomes in terms of inappropriate shock delivery, patient mortality and hospitalizations than patients with single chamber devices.

The first patients who were enrolled in the OPTION study in Germany, Portugal and in Italy were all implanted with Sorin Group's OVATIO™ dual chamber ICDs. OVATIO ICDs feature the innovative **PARAD@+** arrhythmia detection algorithm, **AAIsafeR™** mode that limits ventricular pacing and a slow ventricular tachyarrhythmia (VT) zone. All patients included in the study are randomized to either single chamber ICD therapy following standard clinical practice with an active monitoring zone ON to allow ventricular arrhythmia documentation, or to dual chamber detection and therapy in the slow VT zone (**BTO™**) with AAIsafeR switched on.

The principal study investigator, Dr. Christof Kolb, Deutsches Herzzentrum, Munich, Germany, commented, "We are confident that OPTION will significantly help us assess whether dual chamber ICD therapy gives clinical benefit to patients without a pacing indication. OVATIO DR innovative features and the design of the trial will enable us to investigate the impact of ICD therapy on the full range of ventricular tachyarrhythmias, including slow VTs, in combination with pacing backup in patients with impaired left ventricular function to avoid unnecessary ventricular stimulation. We also expect that the results of OPTION will help us in better selecting ICD candidates."

Another objective of the study is to determine how to best identify patients who could benefit from ICD therapy using Sorin Group's "**T-variability**" risk stratification method, a noninvasive Holter-based test that analyzes micro-volt variations that are linked to the development of life-threatening tachyarrhythmias.

Patient recruitment will be completed in 18 months. A follow-up phase of 27 months is scheduled after enrolment to allow monitoring of the development of AF and CHF. The OPTION study will enroll 450 patients in Europe, Canada and the US. Interim results will be published every 12 months.

Andre-Michel Ballester, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit commented, "As pioneers in dual chamber defibrillation therapy – ELA Medical implanted the world's first dual chamber ICD back in 1995 - Sorin Group takes it to heart to constantly demonstrate the clinical benefits of its innovative CRM technologies through upstream research as well as through post-release clinical studies. The OPTION study exemplifies our commitment to provide clinically tested solutions that can bring optimal treatment and better quality of life to patients with cardiac arrhythmias".

**Sorin Group:**

*Sorin Group Cardiac Rhythm Management Business Unit designs and manufactures implantable pacemakers and ICDs, leads and Holter equipment and markets them worldwide.*

*Sorin Group (Reuters code: SORN.MI), a world leader in the development of medical technologies for cardiac surgery, offers innovative therapies for cardiac rhythm dysfunctions, interventional cardiology and the treatment of chronic kidney disease. Sorin Group includes: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellco and Soludia. Sorin Group has more than 4,500 employees working at facilities in more than 80 countries throughout the world to serve over 5,000 public and private treatment centers.*

---

*For additional information, please visit our website: [www.sorin.com](http://www.sorin.com)*

**Martine Konorski**

Director, Global Communications, Cardiac Rhythm Management Business Unit

Tel. +33-1-46013605

e-mail: [martine.konorski@sorin.com](mailto:martine.konorski@sorin.com)

**Marilena Giavara**

Director, Investor Relations

Tel. +44-20-70038730

e-mail: [marilena.giavara@sorin.com](mailto:marilena.giavara@sorin.com)

**Francesca Caprari**

Director, Communications & Industry Affairs

Tel +39-02-6332322

e-mail: [francesca.caprari@sorin.com](mailto:francesca.caprari@sorin.com)

---