



## **SORIN GROUP LAUNCHES WORLD'S SMALLEST IMPLANTABLE CARDIOVERTER DEFIBRILLATORS IN EUROPE**

### **OVATIO DR Includes AAIsafeR Pacing Technology that limits Ventricular Pacing.**

**Paris, France – January 16, 2006** - ELA Medical, a Sorin Group Company and innovative leader in the development of cardiac rhythm management (CRM) implantable and diagnostic systems, announced today the European introduction of OVATIO™ implantable cardioverter defibrillators (ICDs). Sorin Group's new family of ICDs comprises a dual chamber, OVATIO DR and a single chamber model, OVATIO VR.

An implantable cardioverter-defibrillator is designed to quickly detect a life-threatening, rapid heartbeat - a ventricular tachyarrhythmia - coming from the lower chamber of the heart. It converts the abnormal rhythm back to normal by delivering anti-tachycardia pacing pulses or an electrical shock to the heart. An ICD can prevent sudden cardiac arrest, the leading cause of death in Europe with an estimated 400,000 deaths each year.

OVATIO devices are the world's smallest ICDs (29 cc; 11 mm thin). Physiologically-shaped and long-lasting, OVATIO ICDs also offer 34 joules of maximum output, which is useful for patients whose defibrillation threshold is particularly high and who may require more energy to terminate life-threatening arrhythmias.

The OVATIO ICD family includes innovative features dedicated both to pacing and arrhythmia management and advanced diagnostic features that offer significant patient benefits. Dual chamber OVATIO DR includes two exciting features: AAIsafeR and PARAD+.

### **AAIsafeR, Monitoring and Promoting the Patient's Natural Rhythm**

OVATIO DR features the latest generation of ELA's exclusive AAIsafeR™ pacing mode. AAIsafeR promotes natural heart activity by limiting unnecessary stimulation in the right ventricle, which prevents onset and progression of heart failure.

With AAIsafeR mode, OVATIO DR ICD continuously monitors the patient's intrinsic atrioventricular (AV) conduction and delivers ventricular pulses only when necessary. The patient's AV conduction can fully be documented through detailed statistics and intracardiac EGMs (IEGMs). AAIsafeR reduces the amount of ventricular pacing to less than 0.2 percent in ICD patients with intrinsic conduction. Conventional dual-chamber ICDs unnecessarily pace this patient population 50 percent of the time. AAIsafeR pacing technology has been available in Europe since September 2003.

## **PARAD+ (P And R Arrhythmia Detection), delivering therapies only when needed**

Since it is important that ICD patients not only receive appropriate therapies but also receive them only when necessary, OVATIO DR includes PARAD®+, the most specific ventricular arrhythmia detection software available to patients worldwide today.

PARAD®+ is intended to protect patients from inappropriate shocks which may result from misclassified supraventricular tachyarrhythmias (SVTs).

While SVTs have been reported to trigger 55% to 69% of inappropriate shocks, PARAD+ demonstrated a 99% overall specificity with out-of-the-box settings in a study recently published.

OVATIO DR is therefore capable of accurately diagnosing SVTs 99% of the time, thus drastically reducing the number of inappropriate shocks.

OVATIO DR is also capable of detecting and treating the full spectrum of tachyarrhythmias through painless anti-tachycardia pacing (ATP). The device's capability to terminate the slowest (100 bpm) as well as the fastest (up to 255 bpm) ventricular tachyarrhythmias offers ICD patients the comfort of painless therapy.

The first post-launch OVATIO implant was performed at the Medizinische Klinik und Poliklinik of Heidelberg Germany in the department of Internal Medicine by Dr. med. Alexander Bauer. The patient implanted with the first OVATIO VR was an 82-year-old woman who suffered from ischemic cardiomyopathy.

Dr. Bauer declared: "The implant procedure went very smoothly. The shape and size of OVATIO VR made it easy to implant. Programming the ICD was also extremely simple with the user-friendly new OVATIO programming software." Dr. Bauer also commented on OVATIO DR saying that "minimal ventricular pacing technology is a must-have feature of today's ICDs. The uniqueness of AAIsafeR lies in its exclusive and fully documented monitoring of the AV conduction".

To make post-implant office visits faster, OVATIO ICDs are supported by a completely new programming software that is ten times faster than previous versions. This, along with ELA's unique Online Help that gives assistance in programming OVATIO parameters and the intuitive and user-friendly display of critical patient information, significantly shorten follow-up time.

"The introduction of the OVATIO family reflects Sorin Group's drive to develop cutting-edge tachyarrhythmia management systems that are capable of respecting the heart's natural rhythm and bringing significant patient benefits. Although OVATIO ICDs are technologically sophisticated devices, they have been designed to simplify implant and followup procedures " said Andre-Michel Ballester, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit.

### **Information about the Sorin Group:**

*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 diseases. Sorin Group includes: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellco and Soludia. Sorin Group has about 4,700 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) and [www.elamedical.com](http://www.elamedical.com)

Internal data from Ovatio DR Clinical Release Report

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