

SORIN GROUP: ELA MEDICAL RECEIVES FDA CLEARANCE FOR PACING TECHNOLOGY THAT REDUCES UNNECESSARY VENTRICULAR PACING

Company pioneers algorithm to prevent unnecessary ventricular stimulation; second-generation AAIsafeR 2 pacing mode manages all three degrees of heart block.

Milan May 4, 2005 – Drago Cerchiari, CEO of Sorin Group, announces that ELA Medical, a Sorin Group company, innovative leader in the development of cardiac rhythm management (CRM) implantable and diagnostic systems, received U.S. Food and Drug Administration (FDA) clearance for its new AAIsafeR™ 2 pacing mode. AAIsafeR 2 is ELA Medical's second-generation pacing mode that prevents unnecessary ventricular pacing, and is the first therapeutic-pacing alternative available in the United States. AAIsafeR 2 technology will be on display in ELA Medical's booth (#1215) at HEART RHYTHM 2005, the Heart Rhythm Society's Annual Scientific Sessions, being held May 4-7, 2005 in New Orleans.

Several recent clinical studies show that unnecessary right ventricular pacing increases a patient's risk of developing heart failure and atrial fibrillation. ELA Medical's Symphony® pacemakers, with AAIsafeR 2 mode, limit unnecessary ventricular stimulation to 0.1 percent in patients while they are not in heart block¹. Conventional pacemakers unnecessarily pace these same individuals 50-80 percent of the time.

ELA Medical's first-generation AAIsafeR pacing technology was launched in its Symphony pacing systems in September 2003 in Europe. The company received CE Mark earlier this year for its AAIsafeR 2 pacing technology.

"The ideal amount of unnecessary ventricular pacing is zero percent," said Malcolm Bersohn, M.D., Ph.D., electrophysiologist and professor of medicine at the University of California Los Angeles (UCLA) Medical Center. "AAIsafeR 2 is a promising technology because it comes remarkably close to meeting this objective. As a result, patients with intermittent heart block will experience both the benefits of atrial pacing and the safety of ventricular stimulation, if needed. AAIsafeR 2 will offer a dramatic reduction in ventricular pacing for a high percentage of patients."

Heart block is a disturbance of the heart's electrical conduction system that results in the inability of the heart's chambers to beat in sync. Three broad categories or degrees of heart block can occur. AAIsafeR 2 is the only algorithm that can detect and manage all three degrees of heart block. An estimated 60 percent of the pacemaker population can benefit from AAIsafeR 2 pacing². No other pacemaker can treat such a large patient population.

Protecting Pacemaker Patients from Heart Failure and Atrial Fibrillation

Each year more than 300,000 individuals in the United States receive a pacemaker to treat slow heart rates. Most patients receive pacemakers that pace both upper (atrium) and lower

¹ SAVE R pre-market clinical study results (September 2004). Cumulative percent pacing stored in the pacemaker data.

² Herzschr Elektrophys 2002; 13: 242-257. Danish, German and Swiss registry.

(ventricle) chambers of the heart. The Symphony pacemaker with AAsafeR 2 technology delivers ventricular pacing only when intrinsic cardiac impulses from the atrium are not conducted to the ventricle. When intrinsic cardiac conduction resumes, the Symphony AAsafeR 2 pacing system automatically reverts back to physiological atrial-based pacing. In addition, the Symphony AAsafeR 2 pacemaker is the only pacing system in the world that specifically manages atrioventricular (AV) conduction disorders that occur during exercise or at night.

The AAsafeR 2 pacing mode is already incorporated in previously implanted Symphony pacemakers. A software change to the pacemaker programmer unlocks this feature in thousands of patients who already have these devices implanted. ELA Medical has a unique tradition of providing design improvements to already implanted devices.

“ELA Medical is proud to once again pioneer the next evolution of pacing technology,” said Andre-Michel Ballester, president of the Sorin Group’s CRM business unit. “As of today, more than 10,000 patients worldwide already benefit from AAsafeR 2, a unique technology that can fulfill the need for more physiological pacing and deliver patient-tailored pacing therapy while reducing unnecessary ventricular stimulation.”

The Symphony AAsafeR 2 is a full-featured dual-chamber pacemaker that includes advanced therapeutic and diagnostic functions. There is a full suite of AV conduction diagnostics, including automatically stored electrograms (EGMs). With AAsafeR technology, device longevity could be extended by approximately two years. ELA Medical’s next implantable cardiac defibrillator (ICD), which the company plans to launch later this year, will also feature the AAsafeR 2 advanced-pacing mode.

HEART RHYTHM 2005: Unnecessary Ventricular Pacing/AAsafeR 2 Satellite Symposium

ELA Medical will hold a satellite symposium at HEART RHYTHM 2005 titled “AAsafeR 2: New Pacing Mode for the Next Decade.” This symposium will take place on Thurs., May 5, 2005, at the Hilton New Orleans Riverside from 6:00-7:15 a.m. CDT. During the symposium:

- Dr. Kenneth Ellenbogen of the Virginia Commonwealth University Medical Center in Richmond, Va. will present a literature review of pacing sick sinus syndrome patients.
- Dr. David Hayes of the Mayo Clinic in Rochester, Minn. will address the role unnecessary ventricular pacing has on the incidence of atrial fibrillation.
- Dr. Philippe Mabo of the Hôpital Pontchaillou-CHU in Rennes, France will highlight the clinical background and clinical cases of AAsafeR 2 technology.

Dr. Frédéric Anselme of the University Hospital in Rouen, France will discuss preliminary results of the SAVE R controlled study.

ELA Medical, a Sorin Group Company, designs and manufactures implantable pacemakers and ICDs, leads, Holter equipment and electrophysiology catheters and markets them in Europe, the U.S. and Japan.

The Sorin Group (Reuters code: SORN.MI), a world leader in the development of medical technologies for cardiac surgery, offers innovative therapies for cardiac rhythm management, interventional cardiology and the treatment of chronic kidney diseases. The companies of the Sorin Group are: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellco and Soludia. The Sorin Group has about 4,800 employees working at facilities in more than 80 countries throughout the world to serve over 5,000 public and private treatment centers.

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