

## Press Release

### **SORIN GROUP EXPANDS ITS PRESENCE IN THE JAPANESE MARKET BY INTRODUCING ADVANCED DEFIBRILLATION THERAPY**

***First implants of ALTO®2 Implantable Cardioverter Defibrillator (ICD) Performed by Leading Medical Institutions.***

**Tokyo, October 4, 2006** — Sorin Group today announced the full market launch and first implants of the ALTO® 2 line of implantable cardioverter defibrillators (ICDs). The ALTO 2 devices are the first ELA Medical's ICDs to be released in Japan.

The single chamber and dual chamber models ALTO 2 VR and DR ICDs received regulatory and reimbursement approval from the Ministry of Health, Labor and Welfare (MHLW). Both ICD models are immediately available.

It is estimated that 80,000 people die from sudden cardiac arrest every year in Japan. Sudden cardiac arrest (SCA) is a condition caused by life-threatening arrhythmias such as ventricular tachycardia (VT) and ventricular fibrillation (VF). ALTO 2 ICDs are intended for patients at risk for SCA. Those highly-advanced devices are capable of accurately detecting and appropriately treating fast rhythm disorders through mild stimulation (anti-tachycardia pacing) or higher energy shocks.

The first implants of ALTO 2 were successfully performed by Dr. Akihiro Yoshida MD, Cardiovascular Internal Medicine, Kobe University Hospital, and by Dr. Katsumi Matsumoto, MD, and Dr. Kohei Matsushita, MD, in the Department of Cardiovascular Internal Medicine headed by Dr. Toshiyuki Ishikawa, Associate Professor, Yokohama City University Hospital, (Japan).

Dr. Ishikawa declared: "In addition to being the best-in-class arrhythmia discrimination algorithm, PARAD+ is the only arrhythmia management feature that integrates a true dual chamber architecture offering me a comprehensive monitoring of the two chambers of the heart. This exclusive specificity will enable me to better manage all my ICD patients".

The small size of ALTO 2 ICDs (12 mm thin) offers both improved patient comfort and ease of implant for the physician.

Inappropriate therapies remain a major issue for ICD patients. Studies have shown that up to 35% of patients<sup>1</sup> and up to 50% of young patients still receive unnecessary shocks<sup>2</sup>. For patients with ICDs, the possibility of receiving a shock can cause anxiety or depression, which can negatively impact their quality of life. In fact, up to 38% of ICD patients experience significant anxiety<sup>3</sup>.

Featuring the highly-regarded PARAD® + arrhythmia detection function, ALTO 2 DR has a 99%<sup>4</sup> specificity (only one out of 100 shocks delivered may be unnecessary), thus offering unrivalled discrimination of ventricular tachyarrhythmias and reduction in the number of inappropriate shock therapies.

PARAD+ also allows a unique management of slow ventricular tachycardias (VTs). Slow VTs are ventricular tachyarrhythmias of less than 150 beats per minute that can have serious consequences on patients with impaired heart pumping function. With ALTO 2, these slow VTs are appropriately treated through mild stimulation (anti-tachycardia pacing).

“We are pleased to bring the ALTO 2 ICD line to Japanese patients and provide them with state-of-the-art therapeutic solutions against sudden cardiac arrest. The approval of this life-saving device is the result of a fruitful collaboration with MHLW, the Japanese regulatory body.

Since its creation in 1988, ELA Medical Japan, a Sorin Group company, has marketed small, advanced cardiac pacemakers that are widely acknowledged as offering optimal pacing therapy to patients. Today’s introduction of ALTO 2 ICDS expands Sorin Group’s cardiac rhythm management product offering and is a testament of Sorin Group’s determination to better serve the needs of Japanese cardiologists and electrophysiologists and their patients”, said Nam Lee, Sorin Group Vice-President, Japan & Asia-Pacific and Sorin Group Japan President.

**ELA Medical:**

*ELA Medical, part of Sorin Group, designs and manufactures implantable pacemakers and ICDs, leads, and Holter equipment and markets them in Europe, the U.S. and Japan.*

**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 Solutia. Sorin Group has more than 4,700 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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<sup>3</sup> Samuel F. Sears, Jr, PhD; Julie B. Shea, MS, RNCS; Jamie B. Conti, MD. How to Respond to an Implantable Cardioverter-Defibrillator Shock. Circulation. 2005;111:e380-e382.

<sup>4</sup> Hintringer F. et al. Comparison of the Specificity of Implantable Dual Chamber Defibrillator Detection Algorithms. PACE, 2004, vol.27: 976-982