

## Press Release

### **SORIN GROUP ANNOUNCES REGULATORY APPROVAL AND FIRST IMPLANTS OF NEW-PLATFORM FACIL AND REPLY PACEMAKERS IN JAPAN**

***The FACIL and REPLY families of pacemakers, based on an entirely new platform, offer the latest Sorin Group technology for bradycardia in a compact 8cc device.***

**Tokyo, July 3, 2009** – Sorin Group, (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announced today the Ministry of Health, Labor and Welfare (MHLW) approval to market the FACIL™ and REPLY™ families of dual and single chamber rate responsive pacemakers.

The FACIL and REPLY families are based on the latest Sorin Group bradycardia platform. The FACIL pacemaker is an 8cc device, with no compromise on longevity. REPLY offers the complete range of therapies in FACIL with the addition of SafeR™, the first algorithm able to switch between AAI (atrial-based pacing) and DDD (dual chamber pacing) modes. Both pacemaker families offer advanced therapy options for atrial fibrillation (AF) prevention, recommendations for optimal programming of the system, innovative functions to automate implant and follow-up procedures, and functions specifically designed for patient safety.

Dr. Kei Tawarahara (Cardiovascular Division of Hamamatsu Redcross Hospital, Tokyo, Japan) implanted the first FACIL pacemaker in Japan on March 1<sup>st</sup>, 2009.

The FACIL pacemaker will leverage the success of the REPLY family, first implanted in Japan, by Dr. Yuji Nakazato, Professor of Cardiology at Juntendo University Hospital. Dr. Nakazato commented: "The 2007 ESC Guidelines on cardiac pacing and the 2008 ACC/AHA/HRS Guidelines for Device-Based Therapy emphasize the importance of reducing unnecessary ventricular pacing. The REPLY pacemaker with SafeR is able to promote the natural rhythm of this patient, reducing ventricular pacing to a very low percentage. The combination of SafeR, automatic features and good longevity all inside an 8cc pacemaker makes this device the most suitable choice for most of my patients."

SafeR technology was first introduced in Europe in September 2003 with AAISafeR™, which has been shown to reduce unnecessary ventricular pacing in both Sinus Node Disease and unselected AV Block patients.<sup>1</sup> Unnecessary pacing in the right ventricle has been shown to significantly enhance the risk of patients developing heart failure and atrial fibrillation.<sup>2</sup>

"The REPLY and FACIL families, based on Sorin Group's latest generation pacing platform, bring the best of our bradycardia technology to the market and offer a complete range of options for the treatment of bradycardia patients in Japan. Thanks to the REPLY and FACIL families, Sorin Group reinforces its commitment to enhance the standard of care through improved therapies and the delivery of innovative technology in Cardiac Rhythm Management", said Stefano Di Lullo, President of Sorin Group Cardiac Rhythm Management Business.

The REPLY and FACIL pacemakers will be distributed in JAPAN by Japan Lifeline Co. Ltd. a leading distributor of medical devices based in Tokyo.

## About the Sorin Group

Sorin Group ([www.sorin.com](http://www.sorin.com)) is a global company and a leader in the treatment of cardiovascular diseases. The Company develops, manufactures and markets medical technologies for cardiac surgery and for the treatment of cardiac rhythm disorders. With 3,500 employees worldwide, the Group focuses on three major therapeutic areas that include: cardiopulmonary bypass (extracorporeal circulation and autotransfusion systems), cardiac rhythm management, and heart valve repair and replacement. Every year, over 1 million patients are treated with the devices of Sorin Group in more than 80 countries.

For more information, please visit: [www.sorin.com](http://www.sorin.com), [www.sorin-crm.com](http://www.sorin-crm.com) or contact:

**Martine Konorski**

Director, Corporate Communications

Sorin Group

Tel: +33 (0)1 46 01 33 78

Mobile: +33 (0)6 76 12 67 73

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

**Carla Vidra**

Investor Relations

Sorin Group

Tel: +39 02 69969716

e-mail: [carla.vidra@sorin.com](mailto:carla.vidra@sorin.com)

(1) Pioger G, Leny G., Nitzsche R; Ripart A. AIsafeR Limits Ventricular Pacing in Unselected Patients. PACE 2007; 30: S66-S70)

(2) Epstein, Andrew E et al. ACC/AHA/HRS

2008 Guidelines for Device-Based Therapy for Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Journal of the American College of Cardiology. Volume 51, No. 21, 2008.