SORIN GROUP RECEIVES REGULATORY APPROVAL FOR NEW GENERATION MRI COMPATIBLE PACING SYSTEM IN JAPAN

*KORA 100 pacemakers feature Automatic MRI Mode exclusively available in Sorin devices*

**Tokyo, Japan, February 6, 2015** – Sorin Group, (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announced today that it has received approval from Japan’s Pharmaceutical and Medical Devices Agency (PMDA) for its new KORA 100 pacing system with automatic magnetic resonance imaging mode (MRI mode).

Pacemakers are usually implanted in elderly patients, a population prone to other medical conditions that typically require MRI examinations for optimal diagnosis and management. KORA 100 SR and DR pacemakers, when implanted with the Sorin BEFLEX pacing lead(s), enable implanted patients to safely undergo an MRI scan.

During an MRI scan pacemakers need to operate in asynchronous mode which exposes the patient to potential cardiac arrhythmias. This mode usually needs to be programmed by a cardiologist prior to and after the MRI scan which leaves the patient in asynchronous mode for a longer period of time than required by the MRI scan itself.

Unlike other pacemakers, KORA 100 ensures that asynchronous mode is activated for the least amount of time. Once Auto MRI mode is activated, the KORA 100 automatically adjusts its settings when the MRI field is detected. This ensures the safe operation of the device during an MRI scan. The device senses when a patient leaves the magnetic field and returns to its initial operating mode within five minutes. The Automatic MRI mode feature is patented and available exclusively in Sorin Group pacemakers.

The KORA 100 pacing system builds on Sorin’s legacy of proactively managing common cardiovascular comorbidities. The clinical results of the ANSWER study demonstrate that the SafeR™ pacing mode results in a 51% risk reduction of cardiac death or HF hospitalization. Moreover, the recently introduced Sleep Apnea Monitoring (SAM) function, a clinically validated diagnostic tool, allows for screening severe sleep apnea which is a significant comorbidity and risk factor related to heart failure and atrial fibrillation.

“The regulatory approval of our next-generation pacemaker marks a significant milestone for Sorin Group in Japan where there is strong demand for MRI compatible medical devices. We believe that KORA 100 with its unique automatic MRI mode, combination of therapeutic solutions, small size and extended longevity, will bring proven benefits to Japanese patients and physicians. Leveraging on our collaboration with our established business partner, Japan Lifeline, we will be able to achieve our market objectives and reinforce our leadership position”, said Stefano Di Lullo, Sorin Group, President CRM Business Unit.

The KORA 100 pacing system will be distributed in Japan by Japan Lifeline Co., Ltd.
About Sorin Group
Sorin Group (www.sorin.com) is a global medical device 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 over 3,500 employees worldwide, the Company focuses on two major therapeutic areas: Cardiac Surgery (cardiopulmonary products for open heart surgery and heart valve repair or replacement products) and Cardiac Rhythm Management (pacemakers, defibrillators and non-invasive monitoring to diagnose and deliver anti-arrhythmia therapies as well as cardiac resynchronization devices for heart failure treatment). Every year, over one million patients are treated with Sorin Group devices in more than 100 countries.

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References

1. BEFLEX models RF45D (52 cm) and RF46D (58 cm).
2. SORIN MRI Solutions implant manual.
4. Available on KORA 100 DR