

Press release

SORIN GROUP ANNOUNCES FDA APPROVAL OF NEW DEFIBRILLATION LEADS RANGE: ISOLINE™

Denver, CO, March 7, 2008 (HSMN NewsFeed) – ELA Medical Inc., a Sorin Group company, announces the U.S. Food and Drug Administration’s approval to market ISOLINE™¹, its latest generation of defibrillation leads.

Leads are insulated wires inserted through the vein as part of an implantable cardioverter defibrillator (ICD) or a pacemaker system. They are a key component of the implanted system. Connecting the device to the heart, the leads carry high voltage and electrical impulses from the implanted device to the heart when needed by the patient.

The ISOLINE™ defibrillation leads have a multi-lumen structure with a silicone body and include an ETFE protective coating placed around the cables leading to the electrodes. **This redundant insulation² is also made by a third layer of protection consisting of a polyurethane overlay to provide better abrasion resistance. Both ends of the defibrillator electrodes are securely connected to the cables.**

Abrasion resistance materials such as polyurethane have much better³ friction coefficients than other materials such as silicone. Avoiding lead abrasion is very important to maximize leads longevity and protect patients’ safety. Results in an internal study demonstrated that a similar lead with the same polyurethane overlay was **at least 201 times more resistant** to abrasion than a non-polyurethane coated lead.

“ISOLINE™’s FDA approval is a big step towards strengthening our position in the US market and offering a Cardiac Rhythm Management complete solution to patients and physicians”, said Fred Hrkac, President of Sorin Group’s Cardiac Rhythm Management (CRM) division.

ISOLINE™ leads are steroid eluting, dual coil defibrillation leads available in active and passive fixation models. A clinical trial showed that with a fully isodiametric **7.8 F** lead body, ISOLINE™ ensures very good manoeuvrability and overall handling characteristics. ISOLINE™ leads also offer EASYTURN™: **a quick lead placement system for positioning the lead and extending the helix with a single stylet**, and Easy Mapping to obtain pacing thresholds without helix extension.

The ISOLINE™ leads family was successfully launched two years ago in Europe. For more information on product performance, see the **“Sorin Group CRM Product Performance Report”** available on: www.sorin-crm.com.

¹ Active fixation models: Isoline 2CR5 (58 cm) IJ27U and 2CR6 (65 cm) IJ24U
Passive fixation models: Isoline 2CT5 (58 cm) IJ26U and 2CT6 (65 cm) IJ23U

² Redundant Insulation: ETFE coating, Silicone

³ Scheuer-Lesser, M. et al. Polyurethane Leads, pg 456, PACE vol. 6, March – April 1983

About the Sorin Group

The Sorin Group (Bloomberg: SRN.IM; Reuters: 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. The Sorin Group includes these brands: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellico and Bellico Soludia. At the Sorin Group 4,500 employees work to serve over 5,000 public and private treatment centers in more than 80 countries throughout the world.

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