



SORIN GROUP INNOVATES IN THE HEMODYNAMIC MANAGEMENT OF HEART FAILURE WITH THE EUROPEAN INTRODUCTION OF ITS NEW GENERATION CARDIAC RESYNCHRONIZATION THERAPY PRODUCTS.

VENICE, ITALY - October 4, 2005 - Sorin Group Cardiac Rhythm Management (CRM) Business Unit, an innovative leader in the development of cardiac rhythm management therapies, announced today at the Venice Arrhythmias 2005 Congress, **the European launch of OVATIO™ CRT and NewLiving™ CHF, respectively its new cardiac resynchronization therapy defibrillator (CRT-D) and pacemaker (CRT-P) for the treatment of heart failure patients.**

Heart failure is a major cardiac condition affecting **10 million Europeans¹** and more than **22 million people worldwide²** and is expected to almost triple in 2020. According to the European Cardiology Society (ESC) approximately 40% of heart failure patients could benefit from cardiac resynchronization devices (CRT-Ds and CRT-Ps)³. Cardiac resynchronization therapy (CRT) aims at increasing cardiac pump efficiency by resynchronizing the contractions of the ventricles. Under the new 2005 ESC heart failure guidelines, cardiac resynchronization devices have been designated as standard-of-care treatment (Class 1A) for indicated heart failure patients already on optimal medical therapy.

With OVATIO (CRT-D) and NewLiving (CRT-P), Sorin Group CRM is the first to provide **cardiac resynchronization therapy that delivers optimal hemodynamic performance**. The heart is seen as a blood pump as well as a ticking clock, so that information on the hemodynamic status of a patient complements that on rhythm to achieve customized diagnosis and treatment.

OVATIO (CRT-D) ensures delivery of resynchronization therapy at higher pacing rates while providing antitachycardia protection against slow ventricular tachycardias (VTs)

OVATIO, Sorin Group CRM's latest **generation of cardiac resynchronization defibrillators** is the **smallest CRT-D device available on the market (30 cc), for enhanced patient comfort**. OVATIO is indicated in heart failure patients who might be at risk for Sudden Cardiac Death (SCD) as it resynchronizes ventricular contractions and delivers defibrillation support when necessary.

Sudden cardiac death is a sudden loss of heart function which is due most of the time to ventricular tachycardia (VT) or ventricular fibrillation (VF). According to AHA statistics⁴ **in congestive heart failure people, SCD occurs six to nine times more often than in the general population.**

Heart failure patients display a higher incidence of slower dangerous rhythms (slow VTs)⁵. For these patients, the challenge arises of ensuring 100% resynchronization at exercising pacing rates, thereby imposing no limitations on patient activity and lifestyle, while retaining the ability to discriminate slow VTs which may need treatment.

OVATIO addresses this challenge with its **unique Brady-Tachy Overlap (BTO™) zone**, accurately discriminating VTs as slow as 100 beats per minute whilst maintaining 100% cardiac resynchronization support in the same rate range. OVATIO offers a full range of options to optimize CRT and to treat dangerous ventricular tachycardias between 100 and 255 beats per minute.

OVATIO also includes PARAD®+, the most specific ventricular arrhythmias detection software available to patients worldwide today. PARAD+ demonstrated a 99% overall specificity in a study recently published⁶. PARAD+ is intended to protect heart failure patients from inappropriate shocks which may result from atrial fibrillation (AF), a common comorbidity of heart failure that affects about 10% to 30% of all heart failure patients⁷. PARAD+ has been shown to decrease the patient's individual risk of receiving inappropriate therapy due to AF to only 0.3 percent⁸.

Dr. John M. Morgan, from Wessex Cardiac Unit, at Southampton General Hospital in the UK believes that *“Brady-Tachy Overlap (BTO) will set the standard for flexibility of therapies in CRT-D patients”*.

To complement its CRT systems and left ventricular over-the-wire and stylet-driven SITUS® lead system, Sorin Group is also introducing its latest generation defibrillation leads, the Isoline™ lead range. Building on twenty years of experience in pacing leads, Isoline leads combine carbon tip and steroid elution with dual-coil technology to achieve outstanding electrical characteristics.

NewLiving (CRT-P) with Peak Endocardial Acceleration (PEA™) hemodynamic sensor ensures automatic therapy optimization for CRT patients.

The NewLiving system includes a dedicated right ventricular pacing and sensing lead which also integrates the **exclusive PEA contractility sensor**. Continuous monitoring of PEA allows the device to automatically optimize the timing and activation sequence of the heart chambers to deliver maximum hemodynamic benefit to the patient.

Continuous automatic optimization reduces the need for time-consuming echocardiographic assessment and simplifies patient follow-up, while ensuring self-adjustment of resynchronization therapy for each patient. *“New Living opens up a new method for determination of the optimal pacing configuration for each heart failure patient”* confirms Pr. Jacques Clémenty, Department of Cardiology, at Hôpital du Haut-Lévêque, University of Bordeaux, France.

“The introduction of OVATIO (CRT-D) and NewLiving (CRT-P), with their unique PEA and BTO functions, shows our continued commitment to advancing cardiac resynchronization therapy and delivering meaningful innovation in heart failure treatment. OVATIO and NewLiving truly reflect the innovative leadership of Sorin Group in hemodynamic management of heart failure” declared Andre-Michel Ballester, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit.

About Sorin Group:

Sorin Group CRM Business Unit designs and manufactures implantable pacemakers and ICDs, leads and Holter equipment and markets them worldwide.

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.

For additional information, please visit our website: www.sorin.com

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References:

1. Cleland JG, Swedberg K, Follath F et al. The EuroHeart Failure Survey Programme- A Survey of the Quality of Care Among Patients with Heart Failure in Europe. Part 1: Patient Characteristics and Diagnosis. *Eur Heart J* 2003;24:442-463
2. Heart Failure Facts and Figures. OU Medical Center. www.oumedcenter.com [last accessed 26-09-05]
3. Swedberg k., Cleland J., Dargie H., et al. The Task Force for the diagnosis and treatment of CHF of the European Society of Cardiology. *Eur Heart J* 2005;26:1115-40; full guidelines online at www.escardio.org/knowledge/guidelines/Chronic_heart_failure.htm
4. Heart Disease and Stroke Statistics – 2005 Update, American Heart Association.
www.americanheart.org/downloadable/heart/1105390918119HDSSStats2005Update.pdf [last accessed 22-09-05]
5. Sadoul N., Mletzko R., Anselme F. et al. Internal sub analysis (375 patients) of the IDEF08 Slow VT study. Incidence and Clinical Relevance of Slow Ventricular Tachycardia in Implantable Cardioverter-Defibrillator Recipients: An International Multicenter Prospective Study. IDEF 08 publication.
6. Hintringer F. et al. Comparison of the Specificity of Implantable Dual Chamber Defibrillator Detection Algorithms. *PACE*, 2004, vol.27: 976-982
7. Stevenson WG, Stevenson LW. Atrial fibrillation in heart failure. *N Engl J Med* 1999;341:910-1.
8. R Mletzko, F Anselme, D Klug, W Schoels, R Bowes, N Iscolo, R Nitzsché, N Sadoul On behalf of the "Slow VT Study" Investigators. Enhanced Specificity of a Dual Chamber ICD Arrhythmia Detection Algorithm by Rate Stability Criteria. *PACE* 2004;vol.27:1113-1119

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