FIRST NORTH AMERICAN TRIAL RESULTS REINFORCE THE SAFETY AND HEMODYNAMIC PERFORMANCE OF SORIN’S SOLO SMART PERICARDIAL AORTIC VALVE

Solo Smart offers the superior hemodynamics of a stentless valve combined with a stented valve’s ease of implantation

MILAN, June 24, 2015 – Sorin Group, (Reuters Code: SORN.MI), a global medical company and a leader in the treatment of cardiovascular diseases, announced positive one-year safety and efficacy data from a North American prospective trial of Freedom Solo Stentless Pericardial Aortic Valve.1 The trial results, which are available online at the European Journal of Cardio-Thoracic Surgery website, were used to obtain FDA approval of Solo Smart in June 2014.

In clinical use since 2004, Freedom Solo is a stentless biological prosthesis that provides optimum blood flow and can be implanted faster than other available stentless valves due to a single suture line technique. Solo Smart is based on the same technology platform, but includes a removable stent for straightforward implantation and optimal positioning.

251 patients with aortic valve disease from 15 centers across North America were included in the trial. The mean age was 74.7 ± 7.5 years and concomitant procedures, primarily coronary artery bypass grafting (CABG), were performed in 61.9% of patients at time of implantation. Preoperatively, 54% of patients had NYHA functional class III or IV symptoms.

The study demonstrated excellent hemodynamics in terms of Mean Pressure Gradients and Effective Orifice Area at implantation that remained stable up to 1 year. One-year mean gradients for valve sizes 19, 21, 23, 25 and 27 mm were 11.7, 7.8, 6.3, 4.6 and 5.0 mmHg, respectively. At one-year follow-up, 96% of patients (181/189) were in NYHA class I or II functional status, and freedom from structural valve deterioration was 99.5%.

“Aortic valve stenosis is the third most frequent heart disease and leads to approximately 100,000 aortic valve replacements and 15,000 deaths each year in North America. We welcome new technologies that can help us improve patient survival and quality of life. To this end, we were pleased to see these data reinforce the excellent safety profile and hemodynamic benefit observed in previous trials of the Solo valve,” said lead author David Heimansohn, M.D., St. Vincent’s Heart Center, Indianapolis, Indiana. “Despite the older age, comorbidities and overall risk profile associated with this population, these patients experienced excellent recoveries after one year. The Solo Smart valve keeps the native aortic and annular functional capacity intact, unlike a stented valve. There is no other valve like it available today.”
The positive results were consistent with an earlier trial by Grubitzsch et al. of 804 patients that showed beneficial survival, morbidity and functional status outcomes with Solo up to three years following surgery. In this trial, a significant decrease in left ventricular mass index was observed between discharge and one year, and remained stable thereafter. Another recent paper published by Thalmann, et al followed 277 patients out to five years with 100% freedom from structural valve deterioration.

“Sorin is committed to developing groundbreaking cardiovascular devices that help cardiac surgeons deliver a precise, tailored solution for each patient,” said Michel Darnaud, President Cardiac Surgery Business Unit, Sorin Group. “In addition to providing clinical benefit and improved convenience for the patient and surgeon, a stentless procedure that takes less time to perform is more cost-effective for the hospital and the healthcare system overall.”


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 3,900 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 arrhythmias 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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