

THE SORIN GROUP UNVEILS ITS GROWTH STRATEGY FOR THE NORTH AMERICAN MARKET

Mitroflow inaugurates a brand new facility in Burnaby, Vancouver, that will design and manufacture tissue valves – The Sorin Group will leverage its global leadership in mechanical valves (800,000 implants worldwide) to grow in the market for tissue valves – An FDA authorization to market a new tissue valve in the United States is expected by 2007.

Vancouver (Canada), May 21, 2004 – The Sorin Group, a world leader in the cardiac surgery market, plans to strengthen its presence in North America, where it controls about 40% of the cardiopulmonary segment and about 20% of the mechanical cardiac valve segment. Growth in this market will be driven in part by the U.S. launch in 2007 of Mitroflow tissue valves manufactured at the factory that *Drago Cerchiari*, Sorin’s Chief Executive Officer, inaugurated today in Vancouver. The new facility which replaces the existing smaller one in the same town, will be able to produce in excess of 25,000 valves.

“Thanks to its high production capacity and technological excellence, the new Mitroflow plant will provide significant support for the strategy pursued by the Sorin Group with the goal of achieving a significant share of the North American market by 2008,” explained *Drago Cerchiari*, concluding that “We have achieved world leadership in the mechanical valve segment, and we believe that we enjoy equally strong growth prospects in the tissue valve market.”

The start of tissue valve production at the new Vancouver facility represents another step by the Sorin Group in a strategy designed to bring to the North American market innovative therapies to treat heart diseases already successfully introduced in Europe. It has been estimated that over 100,000 valve prostheses (about one-third mechanical valves) are implanted or repaired each year in the United States and Canada alone. The Sorin Group, through its recognized brand Carbomedics and Sorin Biomedica, is already a leader in mechanical valves (over 800,000 implants, with zero structural failures) and plans to increase its share of this market segment, which, owing in part to recent technological and clinical developments, has shown significant growth.

“Over the last several years, in the United States and Europe, there has been a steady increase in the number of tissue valves implanted. The use of tissue valves is growing not only because the superior hemodynamic performance of these valves has improved, but also because of recent clinical studies that have demonstrated extended durability of 15-17 years,” pointed out *Jim Trevor*, head of strategic marketing for the Sorin Group’s Cardiac Surgery Business Unit. Mitroflow’s production capacity, combined with the output of Sorin Biomedica, make the Sorin Group one of the few players in this market segment capable of satisfying all of the needs of the cardiac surgeon.

“The progress made by biomedical research in the field of valve prostheses is amazing, not only with regard to materials processing but also in the design of valves that are capable of delivering

maximum hemodynamic performance and durability,” said *Franco Vallana*, President of the Cardiac Surgery Business Unit. The key considerations in developing an implantable device such as a cardiac valve are the device durability, since, as is well known, a cardiac valve opens and closes an average of 40 million times a year and has to withstand very high blood-pressure levels, the easiness of implantation and optimal haemodynamic.

Mitroflow, a company established in 1982, was acquired by the Sorin Group when it bought CarboMedics. The new Vancouver plant has 150 employees, including 15 in R&D and 113 in manufacturing. “Our new facilities, which encompass every aspect of manufacturing, from treating the raw material (bovine pericardium) to designing and producing the valves, have a capacity of more than 25,000 valves a year. In 2003 Mitroflow obtained an IDE to begin clinical trials to gain FDA approval for the United States. Since then more than 100 patients have been already enrolled,” pointed out Eros Roncaia, Mitroflow’s Vice President.

Cardiac Valve Business – The world market for mechanical and tissue valves is valued at about \$810 million, with tissue valves accounting for \$405 million (66% sold in the United States). In the area of cardiac surgery, a market valued at more than \$2 billion worldwide, the Sorin Group is the leading producer of extracorporeal circulation systems, with a market share of more than 50%, and controls 40% of the world oxygenator market. In the market for mechanical cardiac valves, it has a penetration of close to 50% in Europe and 20% in North America. In the tissue valve segment, the Sorin Group has a market share of about 20% in Europe and expects to complete the procedures necessary to begin marketing these prostheses in America by 2007.

The presence of the Sorin Group in North America (a market that account for about 70% of worldwide demand) dates back to 1992, when it acquired the Cardiovascular Division of Pfizer Inc. This acquisition, which included Stöckert and Dideco, was followed by the purchases of COBE Cardiovascular, a company based in Denver, Colorado, in May 1999 and CarboMedics, a company based in Austin, Texas, in January 2003. “Today, the Group’s North American operations have more than 1,200 employees (28% of the Group’s entire staff). We are the largest non-USA group present in this market,” pointed out *Rodger Stewart*, President of the North American Region of the Sorin Group. “Today our efforts are also focused on the cardiac rhythm management business, an area in which, because of our ability to introduce increasingly sophisticated life-saving devices, we expect to double our market share over the next few years. In cardiac surgery, we plan to leverage our leadership position to exploit growth opportunities, particularly in the tissue valve segment.” In North America, the Sorin Group serves over 1,500 public and private treatment centers and generated aggregate revenues of about \$195 million in 2003. The positive trend that characterizes this market is continuing, with revenues up by about 8% in the first quarter of 2004 (on a comparable foreign exchange rate basis). Sorin expects to growth at an average annual rate of about 20% between 2003 and 2008 and achieve revenues of \$400 million.

The 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 disease. The companies of the Sorin Group are: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin, Sorin Biomedica, Belco and Soludia. The Sorin Group has over 4,800 employees working at facilities in more than 80 countries in every region of the world to serve over 5,000 public and private treatment centers.

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