Interview: Jean Luc Budillon – Head of Cardiac Surgery Division & Country Manager, LivaNova France

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The October 2015 merger between Houston, TX-based Cyberonics and Milan, Italy-based Sorin has led the creation of LivaNova, a medical device manufacturer active in the fields of cardiac surgery, neuromodulation and cardiac rhythm management. With three operating headquarters, France is home to the Cardiac rhythm management (CRM) division. Jean Luc Budillon talks about the company's exciting initiatives in CRM and Cardiac surgery, and explains why even with the company's international strategy, maintaining R&D and production capabilities in France remains a priority.

How has the recent merger between Sorin and Cyberonics, announced last year, affected development in France, which currently acts as the CRM business center?

The merger officially took place on October 19, 2015. We have now established a forward-looking vision to work together as a cohesive group. The headquarters for CRM will remain in Clamart, France, with our cardiac surgeries business centered in Italy, and our neuromodulation division in Houston. These are the "three pillars," as we refer to them, on which we define our work as a company. The European headquarters of Cyberonics were initially in Brussels, and we are currently working to transition operations to France.

Following the merge, the company grew from an estimated worth of nearly one billion Euros (1.1 billion USD) to 1.3 billion Euros (1.4 billion USD). Currently, our CRM business makes up around 25 percent of total revenue, cardiac surgeries represents just over half of all business activity, and the remainder is dedicated to neuromodulation. The company now operates almost 50 percent of all activity in Europe, about a quarter of activity out of the US in Texas, with other global sites accounting for the remainder.

You joined what was then the Sorin Group over two years ago. What have been the key achievements and developments for the Cardiac surgery business unit globally and specifically in France?

Prior to this position, I was the VP general manager of Philips Healthcare in France, a company for which I worked for nearly 20 years. Moving from such a large corporation, to an SME in the process of developing, was quite a change for me. I have enjoyed the agility and the efficiency that comes with my current job, after spending the best part of two decades in a different environment. That is not to say that the transition has not come without its own unique set of challenges. In 2012, due to an earthquake in Italy, one of our facilities had to halt production for six months, and we have been working ever since to stabilize the company. Bringing the company back to its working capacity of 2011 has been one of my priorities at LivaNova. We accomplished this goal in 2015. In addition, over the past few years we have executed a strategic reorganization of our different businesses as the company has grown.

I feel a particular sense of pride working for a European company, with factories across the continent, and particularly one in France. As a European company, we are open to partnerships and new possibilities. Our identity is critical if we are to compete amongst the international competition. The main challenge for LivaNova, but an objective that we have been accomplishing successfully, is to continue transitioning from an SME to a large international company. Bringing our employees together and promoting a company strategy has been fundamental to our success amidst constant growth and change. There are three new potential markets, namely sleep apnea, mitral valves in carbomedics, and developments in heart failure treatments, which represent a horizon of new opportunities.

June 2015 saw the European launch of the KORA 250, your next-generation full-body MRI-compatible pacemaker. What other products do you plan to launch in the coming years that will cement your leadership position in your different focus areas within CRM?

In addition to KORA 250, we have launched a new defibrillator called Platinium. This has been a success, establishing new market share for the company in France, and ultimately leading to an increase in production capabilities. Platinium is a new range of implantable cardiac defibrillators (ICDs) and cardiac resynchronization therapy devices (CRT-Ds) that is making an impact in the market thanks to breakthrough technology offering unmatched longevity. The CRT devices guarantee a lifespan ranging over ten years, while standard products currently on the market have a lifespan reaching only four to five years, allowing for considerable improvements in wellbeing of patients.

LivaNova is also actively launching new oxygenators in the Cardiac surgery market, primarily for extensive procedures such as transplants. The process takes time, considering the phase-out of outdated devices, and tailoring new oxygenators to meet the needs of each individual facility. We are introducing memory recording rings, Memo Record 3D, which have been warmly welcomed by physicians in France, facilitating the procedure of implanting our carbomedic mitral valves. These rings alone have brought LivaNova a 50 percent increase in market share, and as more cardiac centers incorporate LivaNova technologies, this trend will only increase.

In the sutureless market, LivaNova has received approval in Europe and the US for the Perceval Sutureless Heart Valve (Perceval), which is a unique self-anchoring frame that enables the surgeon to replace the diseased valve without suturing it into place. The functional component of the valve is comprised of bovine pericardium mounted on an elastic alloy frame. Clinical results of patients implanted with Perceval have shown significant reduction in surgical procedure times, as well as a minimization of topical scaring as compared with traditional cardiac surgical methods.

Further demonstrating the breadth of products available through LivaNova, the company is launching a product targeting epilepsy, called AspireSR. LivaNova is unique in the French market as a company focusing on neuromodulation, and primarily on treatments dedicated toward epilepsy. As this is a relatively new market, continuing development is a priority of the company for the near future.

Last year the company invested in HighLife and Caisson. What importance do such new ventures play in your business model and in sustaining continued growth?

LivaNova invests substantially in R&D. In the Clamart branch specifically there is a division called “New Ventures” where we present new research developments. We work closely with research facilities as well as university hospitals in France to continue developing new products. New Ventures is part of LivaNova’s growth strategy, and in continued collaboration with Cyberonics, the

company is looking to expand global R&D capabilities. Dedication to research and development is one of the key values of LivaNova. It will allow us to continue to offer breakthrough technologies and is an integral part of the company's international growth strategy.

Every year LivaNova devices treat over one million patients in over 100 countries. With France operating as the group's CRM operating headquarters, as well as a major manufacturing site, what is the strategic importance of your French operations?

The Clamart center employs 500 specialists. Compared to some of the more established names in our industry, this may not seem particularly noteworthy, but LivaNova is proud of the size and impact of its French center. As far as development centers specializing in medical devices are concerned, the capacity of the Clamart center is enormous. Even with the company's international strategy, maintaining R&D and production capabilities in France remains a priority. Our flagship facility in France, can be used to the company's advantage, particularly when it comes to inviting researchers and specialists to collaborate on our projects. As many companies globalize and outsource production to emerging markets, we take great pride in maintaining production capabilities in Europe.

Both Sorin and Cyberonics were well-established companies with brand recognition. What is the strategy to raise awareness on what LivaNova stands for?

At the heart of our name, LivaNova, is a belief in a new life, and new beginnings. There are challenges to establish a company identity while at the same time developing our name throughout France. We are making efforts to continue increasing awareness around our company and our new ventures, something that requires both diligence as well as patience. Under our new name, we can promote our company philosophy and strategy in a new way, and this is a great opportunity to extend beyond our expertise in cardiac treatments, demonstrating our commitment to the Group´s various sectors.

In the coming years, LivaNova is preparing to expand into new treatment sectors, including developments for sleep apnea. We are working on devices specifically focusing on the detection of sleep apnea, and with this research, we can move forward with new developments for pacemakers and implants in order to treat the disorder. We are also concentrating on more fully understanding the causes of heart failure with a goal for LivaNova to establish itself as a market leader by 2018 for research and development in the field.

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