Sorin Group Announces FDA 510(K) Clearance for the New Sorin CONNECT(TM) Perfusion Charting System

Business Wire

Sorin Group, a global medical company and a leader in the treatment of cardiovascular diseases, announced today the 510(k) clearance for commercialization of Sorin CONNECT TM, Sorin Group's new innovative and intuitive perfusion electronic charting system.

The new Sorin CONNECT perfusion electronic charting system allows real-time data recording and trends visualization aimed to support clinicians and institutions in their perfusion management and documentation goals, during and after cardiac surgery. During the surgical case, all relevant information related to the patient and perfusion are electronically collected from Sorin's heart lung machines and autotransfusion systems, as well as a variety of other patient monitoring devices, allowing the creation of an electronic medical record for each patient. After surgery, statistical tools are easily available for queries and analysis, supporting clinicians' efforts towards hospital quality management and practice improvement programs.

Electronic Medical Records (EMR) have been proven to improve quality of patient care, decrease human errors associated with medical practice and control healthcare expenditures. Adoption of Electronic Medical Records (EMR) is expected to significantly and rapidly increase in the near future, starting with the United States. The Obama administration mandated to have all medical records in the United States converted to the electronic format by 2014. While the United States are early adopters of digital technologies and will continue to drive adoption faster than other geographies, due to the rapidly changing health care scenario, Europe and emerging countries are expected to follow closely.

"CONNECT makes data management during Cardiopulmonary simple and the addition of GDP Monitor TM (Goal Directed Perfusion) offers a new level of physiological control in line with Goal Directed Therapy", said Paul Exton, Sr. Clinical Perfusionist at University Hospital South Manchester, Manchester, United Kingdom.

Sorin CONNECT was launched in Toledo, Spain during the 15 th European Congress on Extracorporeal Circulation Technology, held on June 12 th – 15 th 2013. The U.S. launch is planned to happen at the Amsect Best Practices, which will take place in San Antonio, Texas on October 9-12.

"The commercial availability of Sorin CONNECT represents an important milestone of Sorin Group's strategic innovation program. We are excited to launch the first element of an entirely new Cardiopulmonary System (CP) connecting our disposable products to our HLMs, providing clinicians and institutions an unprecedented solution for their Cardiopulmonary patients", said Michel Darnaud, Sorin Group,

President Cardiac Surgery Business Unit.

Sorin's CONNECT platform is based on the world's leading Sorin Group Heart Lung Machine (HLM) technology, S5 and C5.

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