



EBR Systems Announces First Commercial Implants of WiSE Technology

The World's Only Wireless Pacing System for Heart Failure

SUNNYVALE, Calif—March 08, 2016 08:00 AM—EBR Systems, Inc. today announced the first commercial implants of WiSE Technology, the world's only wireless endocardial pacing system for cardiac resynchronization therapy (CRT). CRT is a proven therapy that reduces mortality and improves clinical outcomes in people suffering from heart failure. The implants were performed in James Cook University Hospital, UK and Na Homolce Hospital, Czech Republic.

WiSE Technology is an implantable pacing system capable of delivering energy to the heart without using a pacing lead (or wire) to conduct the energy. It was designed to address the persistent limitations of current CRT systems; where approximately 30-40% of patients who receive a conventional CRT device fail to respond to therapy or suffer lead-related failures.

Preliminary results from the SELECT-LV study, where patients were implanted with WiSE Technology, demonstrated improvement in 81% of patients who had previously failed conventional CRT treatment.

“What is most promising about the WiSE Technology is that we pace from the endocardial, or inside surface of the left ventricle which is a more physiological way to depolarize the myocardium,” said Prof. Petr Neuzil, Head of Cardiology at Na Homolce Hospital. “This mimics the natural activation of the heart, and may explain why it benefits patients who previously failed treatment.”

Conventional CRT devices use a wired lead to deliver pacing pulses to the left ventricle. These leads can break or otherwise fail, leading to complications in

roughly 10-12% of cases. Furthermore, their design limits the locations where the heart can be paced.

“By eliminating the need for a left ventricular lead, we now have the ability to target the exact site where we pace the heart,” said Dr. Simon James, Consultant Cardiologist at James Cook University Hospital. “By selecting a patient-specific pacing site, we expect to be able to increase the number of patients who respond to this therapy.”

Around 20% of patients who receive a CRT device already have a conventional pacemaker or defibrillator implanted. Studies have demonstrated they are at a higher risk of complications during an upgrade to a conventional CRT system. WiSE Technology has the potential to simplify the whole upgrade process and to reduce complications including infections and lead dislodgements.

“Patients benefit from CRT devices by improving their quality of life and increasing their chances of survival,” said Trudie Lobban MBE, Founder & CEO of Arrhythmia Alliance International, the patient advocacy group. “The WiSE Technology offers new hope for the thousands of patients who have suffered complications or failed to respond to conventional treatment.”

All patients implanted with the WiSE Technology will be enrolled in the WiCS-LV Post Market Surveillance Registry. This is an international, multi-center registry, designed to study the safety and performance of the technology up to 5 years post-implant.

“There is significant interest in the long term efficacy of this and all leadless technology, within the medical community,” said Prof. Nick Linker, President of British Heart Rhythm Society and Chair of the MHRA’s Expert Advisory Group on leadless devices. “The Group recognizes the importance that all implants are captured within a formal post-approval study during these early years, to help us understand the performance of the technology under real-world conditions of use. We are therefore pleased to see EBR Systems conduct this registry to continue to evaluate the WiSE CRT Technology.”

About EBR Systems

EBR Systems is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective pacing through Wireless Stimulation

Endocardially (WiSE). The company's patented, proprietary technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications and reliability issues in cardiac rhythm disease management. The Company's initial product eliminates the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring CRT. Future products will address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

The Company's wireless pacing system is not currently available for use in the United States.

About Heart Failure and Cardiac Resynchronization Therapy (CRT)

Heart failure affects more than five million Americans and 22 million people worldwide and is the most costly disease in the US, estimated at more than \$40 billion annually and growing. CRT is a treatment for heart failure that uses an implantable pacemaker to improve the pumping efficiency of the heart by synchronizing the left and right ventricles of the heart. Studies have demonstrated successful CRT therapy improves symptoms and reduces hospitalizations and mortality.

Contacts

for EBR Systems, Inc.

Kevin Knight, 214-732-9392

kknightpr@gmail.com