

St. Jude Medical Enrolls First Patient in Next-Generation Quadra Study

Business Wire

The MultiPoint Pacing study is designed to show improved effectiveness for patients when pacing multiple locations of the heart



St. Jude Medical, Inc., a global medical device company, today announced first enrollment of its MultiPoint™ Pacing clinical study to build upon its first- to-market Quadripolar Pacing System. Patients will be implanted with the Quadra Assura MP™ cardiac resynchronization therapy defibrillator (CRT-D) and Quartet® lead to assess pacing in multiple locations in the heart.

“This study represents our commitment to investing in product innovation and clinical evidence to ensure an increasing number of patients continue to respond to, and appropriately benefit from, CRT.”

The study will evaluate outcome benefits such as improved hemodynamics (blood flow) and cardiac function in heart failure patients who receive cardiac resynchronization therapy (CRT). MultiPoint pacing provides the ability to deliver

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two left ventricular (LV) pacing pulses, either simultaneously or sequentially, rather than the standard single pulse for each pacing cycle (heartbeat). This may be beneficial in further increasing the responder rates to CRT because it may capture a larger area of the cardiac anatomy by engaging areas around already damaged tissue.

“The MultiPoint Pacing trial is a study of patients who may not receive benefit or are unresponsive to standard CRT single-point pacing. We are evaluating whether MPP can increase the potential for a successful CRT outcome by pacing in multiple locations in the heart,” said Gery Tomassoni, M.D., director of electrophysiology at Baptist Health Lexington in Lexington, Ky.

The prospective, randomized, double-blind, multi-center clinical study will enroll more than 500 patients at 50 centers in the U.S. Implanted patients will receive the single pacing pulse available with the existing quadripolar systems for the first three months. After three months, patients will be classified as being responders or non-responders to single-point CRT pacing and then will be randomized to either a single or multi-point pacing group. Patients will be monitored for an additional six months, at which time responder rates will be compared between patients receiving MultiPoint pacing and single point pacing.

“The Quadra Assura MP device builds upon the robust platform available with the current St. Jude Medical quadripolar technology and provides additional tools that may improve the CRT responder rate even further,” said Dr. Mark Carlson, chief medical officer and senior vice president of research and clinical affairs for the St. Jude Medical Implantable Electronic Systems Division. “This study represents our commitment to investing in product innovation and clinical evidence to ensure an increasing number of patients continue to respond to, and appropriately benefit from, CRT.”

Cardiac resynchronization therapy can be delivered by an implantable cardioverter defibrillator (ICD) to resynchronize the beating of the heart's lower chambers (ventricles), which often beat out of sync in heart failure patients. [Studies](#) [1] have shown that CRT can improve the quality of life for many patients with heart failure, a progressive condition in which the heart weakens and loses its ability to pump an adequate supply of blood.

According to the Heart Failure Society of America, heart failure affects [nearly 5 million](#) [2] people in the U.S. and approximately 400,000 to 700,000 new cases are diagnosed each year.

Visit St. Jude Medical during The Heart Rhythm Society's 34th Annual Scientific Sessions next week at booth #1003 for more information on our quadripolar technology. The MultiPoint Pacing clinical study is conducted under an [Investigational Device Exemption \(IDE\) from the U.S. Food and Drug Administration \(FDA\)](#) [3].

About St. Jude Medical

St. Jude Medical develops medical technology and services that focus on putting

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more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com [4].

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