St. Jude Medical Issues Physician Communication about QuickSite and QuickFlex LV CRT Leads

ST. PAUL, Minn. – April 4, 2012 – St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced it is proactively informing physicians about visual observations of externalized conductors on the silicone end of QuickSite® and QuickFlex® Left-Ventricular (LV) Leads, used to connect Cardiac Resynchronization Therapy (CRT) devices to the heart.

There have been no reports of patient injury or loss of therapy due to externalized conductors in these leads, but as a conservative measure, St. Jude Medical is communicating with physicians about the incidence rate so they have the most updated lead performance information with which to make important patient care decisions. The company will no longer sell these lead models. It is important to note, however, that the overall safety and reliability of QuickSite and QuickFlex leads continues to be comparable to currently available CRT leads from other manufacturers.

A copy of the physician letter and additional information about these leads can be found on sjmprofessional.com.

An LV lead (a thin, coated wire) is placed on the lower left chamber of the heart (the left ventricle) to stimulate the two sides of the heart to beat in synchronization with each other, which helps the heart to beat more efficiently. These left-ventricular leads are intended to improve the efficiency of the heart in patients with heart failure, but are not responsible for delivering immediate life-sustaining pacing or life-saving defibrillation therapy. If an LV lead were to fail, the other leads attached to the patient’s device would continue to deliver life-saving therapy.

St. Jude Medical has confirmed 39 cases of externalized conductors, out of 171,000 QuickSite and QuickFlex leads sold worldwide, resulting in a current reported incidence rate of 0.023 percent, or 2.3 in 10,000. Because these leads continue to function normally, the company expects that this rate is under-reported. Based on an analysis of leads returned to the company and recent fluoroscopic images of implanted leads still in clinical use, St. Jude Medical estimates that 3 to 4 percent of QuickSite and QuickFlex leads may exhibit externalized conductors. As a result of this estimated rate, the company felt it was prudent to communicate with physicians about the externalized conductors at this time.

This medical device advisory does not affect the company’s continued sale of its newer QuickFlex µ (micro) or Quartet® LV leads, which are fully insulated using Optim® insulation along the entire length of the lead body. Optim insulation is a hybrid material that combines the biostability and flexibility of high-performance silicone rubber with the strength, tear resistance and abrasion resistance of polyurethane, to provide increased durability and flexibility. There have been no reports or observations of externalized conductors.
conductors in these newer Optim-insulated leads, out of over 65,000 of these leads sold worldwide since 2008.

An externalized conductor occurs when the cable, or conductor, from inside the lead wears through the outer silicone insulation around the lead and appears outside the insulation body. This can be visualized on an x-ray or fluoroscopic image; however, these cables are protected by an additional layer of insulation, and therefore can continue to function properly if an externalization occurs.

About St. Jude Medical

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

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management's current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company's control and the risk factors and other cautionary statements described in the Company's filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.