

# News Release

## CONTACTS:

J.C. Weigelt  
Investor Relations  
Tel 651 756 4347  
[jweigelt@sjm.com](mailto:jweigelt@sjm.com)

Denise Landry  
Media Relations  
Tel 972 309 8085  
[dlandry@sjm.com](mailto:dlandry@sjm.com)

Guy Davis  
Media Relations  
Tel 972 526 8227  
[gdavis@sjm.com](mailto:gdavis@sjm.com)

## **St. Jude Medical Announces FDA Clearance for Industry-First Neurostimulation Lead Delivery System for the Management of Chronic Pain**

Innovative Epiducer system allows introduction of multiple neurostimulation leads through a single entry point

ST. PAUL, Minn. – July 12, 2011 – St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the U.S. Food and Drug Administration (FDA) clearance and limited market release of the Epiducer™ lead delivery system for neurostimulation therapy. This first-of-its-kind system allows physicians to place multiple neurostimulation leads through a single entry point.

Designed to reduce procedural complexities and enhance efficiency, the Epiducer lead delivery system reduces the need for multiple incisions typically required to place more than one neurostimulation lead utilized in [spinal cord stimulation](#) (SCS) therapy for the [management of chronic pain](#). The system also allows physicians to introduce St. Jude Medical S-Series™ paddle leads through a percutaneous entry. Before the Epiducer system, the placement of paddle leads was only possible through a laminotomy, a more invasive surgical procedure that typically requires removal of part of the vertebral bone.

In addition, this minimally invasive system enables physicians to deliver one, two or three different leads through a single entry point to configure and optimize the therapy for each patient. This allows for the management of complex and multifocal pain patterns such as low back pain combined with leg pain.

“The Epiducer lead delivery system represents an important paradigm shift and step forward enabling physicians to configure patient-specific systems utilizing multiple lead arrays to treat complex multifocal pain, and we are excited to bring it to the U.S. market,” said Chris Chavez, president of the St. Jude Medical Neuromodulation Division. “This innovative system is already available in Europe, Australia and Canada, and physician feedback has been very positive regarding this new capability to deliver multiple lead configurations less invasively.”

Created with a highly radiopaque material to provide easy fluoroscopic visualization, the Epiducer system is the newest addition to the St. Jude Medical product portfolio which includes many industry firsts including:

- World’s smallest neurostimulator for chronic pain – the [Eon Mini™](#) spinal cord stimulator
- First-of-its-kind five-column paddle lead – the [Penta™ lead](#)
- Unique mechanical locking lead anchor designed to enhance procedural efficiency – the [Swift-Lock™ anchor](#)

Neurostimulation (also called spinal cord stimulation) is used for managing chronic pain of the trunk and

limbs and pain from back surgeries that have failed. Mild electrical pulses are carried from the neurostimulator to a lead or leads that are placed in the epidural space near the spine to interrupt or mask the transmission of pain signals to the brain. Electrodes on the lead can be programmed to meet each individual patient's needs. More information can be obtained about neurostimulation therapy at [www.PowerOverYourPain.com](http://www.PowerOverYourPain.com).

Chronic pain affects millions worldwide. According to a new report from the Institute of Medicine (IOM) of the National Academies, chronic pain affects an estimated 116 million American adults — more than the total affected by heart disease, cancer, and diabetes combined. Pain also costs the nation up to \$635 billion each year in medical treatment and lost productivity. Noting that much of this pain is preventable or could be better managed, the IOM report calls for coordinated national efforts of public and private organizations to create a cultural transformation in how the nation understands and approaches pain management and prevention. The study was mandated by Congress and sponsored by the National Institutes of Health. The IOM provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. Visit the IOM site for more on their "[Relieving Pain in America](#)" report.

### **Three Decades of Leading-Edge Neurostimulation Technology**

For more than 30 years, the St. Jude Medical Neuromodulation Division has developed new technologies to treat [chronic pain](#) and other neurological disorders. Today more than 75,000 patients in 40 countries have been implanted with St. Jude Medical neurostimulation systems. Focused on research, St. Jude Medical is developing new technologies to address a growing list of neurological disorders. Clinical studies are currently underway or results being reported currently for Parkinson's disease, essential tremor, migraine headaches, major depressive disorder, and others.

### **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](http://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 January 1, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended April 2, 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.