

Boston Scientific Receives FDA Approval for New Infinion™ 16 Percutaneous Lead for Precision Plus™ Spinal Cord Stimulator System

World's first and only 16-contact percutaneous lead provides innovative, new option for physicians to treat chronic pain

NATICK, Mass. and LAS VEGAS, Dec. 8, 2011 /[PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) announces U.S. Food and Drug Administration (FDA) approval of the Infinion™ 16 Percutaneous Lead for its Precision Plus™ Spinal Cord Stimulator (SCS) System, the first rechargeable SCS device for chronic pain management. The Infinion 16 Lead is the world's first and only 16-contact percutaneous lead and the latest innovation in Boston Scientific's comprehensive percutaneous lead portfolio. The Company is introducing the Infinion 16 Lead at the North American Neuromodulation Society (NANS) meeting, which begins today in Las Vegas.

(Photo: <http://photos.prnewswire.com/prnh/20111208/NE19468>)

SCS leads are designed to deliver electrical pulses from an implantable pulse generator to the spinal cord to mask pain signals to the brain. Until now, percutaneous leads have offered a maximum of eight stimulating contacts. By providing twice the number of contacts than any previous percutaneous lead, the Infinion 16 Lead is designed to offer more coverage of the spinal cord for the management of chronic pain.

"When a single percutaneous lead is the best choice for my patient, the Infinion 16 Lead is a useful new option that lets me cover more of the spinal cord than ever before," said Marshall Bedder, M.D., Director of Interventional Pain at Pacific Medical Centers in Seattle. "For the first time, I can now place 16 contacts through a single, small insertion needle with just one lead placement."

"The Infinion 16 Lead is the latest advance in lead technology and an exciting new addition to our unrivaled percutaneous lead portfolio," stated Maulik Nanavaty, Senior Vice President and President of Boston Scientific's Neuromodulation Division. "With the launch of the Infinion 16 Lead, Boston Scientific continues its commitment to innovation by offering pain management physicians more choices to help optimize pain relief for their patients."

SCS evaluation device to be discussed at NANS

At the NANS conference, several pain management physicians will discuss their clinical use of Boston Scientific's Observational Mechanical Gateway (OMG™) Connector. The OMG Connector is a novel device designed to allow patients with a failed or sub-optimal SCS trial to evaluate Boston Scientific's Precision Plus System with SmoothWave™ Technology as an alternative therapy.

"Switching to another drug when the first one fails to deliver the desired patient benefit is standard medical practice," said Michael Stanton-Hicks, M.D., Vice-Chairman of the Anesthesiology Institute at the Cleveland Clinic. "The OMG Connector now gives me that capability with my SCS trial patients."

"The OMG device has enabled me to treat patients using SCS in certain instances where those patients failed trials using other SCS systems," said Stephen Pyles, M.D., of the Florida Pain Clinic in Ocala. "The OMG is a tool SCS practitioners should use to provide their SCS patients with every opportunity for success."

More than 75 million Americans suffer from chronic pain, according to the American Pain Foundation. Tens of thousands of patients with chronic pain have found that SCS systems help them manage their pain. Spinal Cord Stimulation is a reversible therapy that manages pain through an implantable pulse generator and external devices that control therapy and charge the implant.

About Boston Scientific Neuromodulation

Boston Scientific Neuromodulation is an innovation leader in implantable pain management technology. The Precision Plus Spinal Cord Stimulator System, powered by SmoothWave Technology, uses pulses of electricity delivered directly along nerve fibers through the spinal cord to mask pain signals to the brain. Through its investments in technology, clinical science, and world-class service, Boston Scientific Neuromodulation is committed to Making life smoother™ for physicians and patients. For more information on Precision Plus technology, visit <http://www.ControlYourPain.com>.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding new product launches and launch cadence, future innovation, regulatory approvals, clinical trials, product performance and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

CONTACT: Eric Olson
336-293-4393 (office)
Media Relations
Boston Scientific Corporation
eric.olson@bsci.com

Sean Findlen
617-520-7268 (office)
Media Relations
Weber Shandwick
sfindlen@webershandwick.com

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/news-releases?item=95991>