

## **Boston Scientific Receives FDA And CE Mark Approval For New CoverEdge™ Surgical Leads For The Precision Spectra™ Spinal Cord Stimulator (SCS) System**

### **World's First 32-contact SCS Surgical Leads Designed to Provide More Focused Pain Relief for Patients with Chronic Pain**

MARLBOROUGH, Mass., Oct. 21, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) and CE Mark approval for the CoverEdge™ 32 and CoverEdge™ X 32 Surgical Leads, the world's first 32-contact surgical leads designed to blanket the spinal cord for unprecedented pain coverage. Designed for use with the Precision Spectra™ Spinal Cord Stimulator (SCS) System, the CoverEdge Surgical Leads are powered by the Illumina 3D™ Software, a proprietary, anatomy-based computer model for precise pain targeting. Boston Scientific is introducing the CoverEdge Surgical Leads at the Congress of Neurological Surgeons (CNS) this week in Boston.

Previous surgical leads have delivered pain therapy with a maximum of 16 independent contacts. By offering 32 contacts – each powered by a dedicated power source – CoverEdge Surgical Leads are designed to deliver more focused coverage of the spinal cord for more pain relief. Available in two configurations, the CoverEdge 32 Surgical Lead features 32 tightly spaced contacts in four columns for precise pain targeting. The CoverEdge X 32 Surgical Lead offers the broadest span on the market among multi-column paddles.

"I see the CoverEdge Surgical Leads as a game changer for patients," said Giancarlo Barolat, M.D., medical director of Barolat Neuroscience in Denver. "Because it provides greater coverage of the spinal cord, I believe this product will give patients, especially those with low back pain or pain in multiple areas, a better opportunity for relief."

The combination of the CoverEdge Surgical Leads with the Precision Spectra SCS System and Illumina 3D Software is designed to deliver spinal cord stimulation in new ways. For example, a key challenge in SCS therapy is stimulating the neural target without stimulating undesired areas. By taking into account the conductivity of 3D anatomical structures and physician placement of the SCS leads, the Illumina 3D Software is designed for simple point-and-click pain targeting. Click [here](#) for more information on the CoverEdge Leads, or download images [here](#).

"At Boston Scientific, we are dedicated to advancing the science of pain relief," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "The new CoverEdge Surgical Leads allow surgeons to utilize the full potential of our innovative Precision Spectra SCS System and offer their patients an opportunity for excellent pain relief. The introduction of the Precision Spectra System in 2013 has changed the way many physicians treat their patients with chronic pain."

More than 100 million Americans suffer from chronic pain. Living in constant pain for an extended period of time can have a devastating impact on quality of life for many patients. Without relief, or the hope for relief, many patients lose the ability to sleep, work, and function normally. Spinal cord stimulators deliver electrical pulses from an implantable pulse generator to leads with stimulating contacts. These contacts provide pain relief by masking pain signals traveling to the brain.

### **About Boston Scientific Neuromodulation**

Boston Scientific is the innovation leader in implantable pain management technology. Through investments in technology, clinical science and world-class service, Boston Scientific is committed to Innovation Focused on Pain Relief™. For more information on SCS, visit [www.ControlYourPain.com](http://www.ControlYourPain.com). In 2004, Boston Scientific launched the world's first rechargeable SCS device, the Precision™ System, which was also the world's first 16-contact implantable SCS device. Today more than 80,000 patients worldwide have been treated using Boston Scientific SCS systems.

### **About Boston Scientific**

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit [www.bostonscientific.com](http://www.bostonscientific.com) and connect on [Twitter](#) and [Facebook](#).

### **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, regulatory approvals, product performance and impact 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.

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