

Boston Scientific Receives European Regulatory Approval For New Precision Spectra™ Spinal Cord Stimulator System

NATICK, Mass., Dec. 7, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark approval and has begun the European market launch of the Precision Spectra™ Spinal Cord Stimulator (SCS) System. The Precision Spectra System is the world's first and only SCS system with 32 contacts and 32 dedicated power sources and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain. The first commercial implant of the Precision Spectra System was performed last month by Dr. Simon Thomson, Consultant in Pain Medicine and Neuromodulation, at the Basildon and Thurrock University Hospitals in the United Kingdom.

Chronic pain affects one in five adults in Europe, or about 95 million people 15 to 64 years of age. 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.

Designed to manage chronic pain, spinal cord stimulators deliver electrical pulses from an implantable pulse generator to leads with stimulating contacts. These electrical pulses mask pain signals traveling to the brain. Until now, SCS systems have offered a maximum of 16 contacts and two lead ports, with each lead port allowing the placement of one lead. By providing 32 contacts and four lead ports—twice that of any other SCS system—the Precision Spectra System offers more coverage of the spinal cord for the management of chronic pain. Additional lead ports also give physicians more flexibility to treat their patients' pain at time of implant and more flexibility to adapt to changing pain patterns in the future.

"Over the past 30 years, SCS systems have evolved from four to eight to 16 contacts. At each step, we have seen an improvement in our ability to cover pain," said Dr. Thomson. "Now, by doubling the number of contacts to 32 while providing a dedicated power source for each contact, the Precision Spectra System advances our ability to provide pain relief."

"The Precision Spectra System is a major milestone in the advancement of SCS therapy," said Maulik Nanavaty, president of the Neuromodulation business at Boston Scientific. "Our innovation is focused on pain relief and the Precision Spectra System demonstrates our commitment to providing improved pain relief to a broader spectrum of chronic pain patients."

Boston Scientific plans to make significant investment in several clinical trials and build upon its current portfolio of chronic pain management and neuromodulation solutions.

The company has recently begun the following trials:

- **OPTIONS Trial:** A prospective, multi-center, single arm study to further characterize the benefits of having a 32 contact option using the Precision Spectra System.
- **MAP Trial:** A cross-sectional, multicenter study to identify the prevalence of multiple areas of pain in SCS-eligible patients with certain diseases.

In addition to the Precision Spectra System, the Boston Scientific Neuromodulation business has recently launched several new products and has received expanded regulatory indications for products approved in Europe. These include:

- Head-only MRI Conditional CE Mark Approval for the Precision™ Plus SCS System
- Peripheral Nerve Stimulation CE Mark Approval for the Precision Plus SCS System
- Vercise™ Deep Brain Stimulator System CE Mark Approval for Parkinson's Disease
- Infinion™ 16 Percutaneous Lead for SCS

The Precision Spectra SCS System is currently under review by the U.S. Food and Drug Administration, and is not available for sale in the United States.

About Boston Scientific Neuromodulation

Boston Scientific Neuromodulation is the innovation leader in implantable pain management technology. 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 SCS, visit www.pain.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 60,000 patients worldwide have been treated using Boston Scientific

SCS systems. When compared to non-rechargeable SCS systems, rechargeable SCS devices may offer clinical benefits by extending therapeutic longevity and therefore avoiding frequent replacement surgeries and complications that may arise from repeated surgeries.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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, regulatory approvals, clinical trials, product performance and importance, 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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