

Boston Scientific

## **PRECISION™ PLUS SPINAL CORD STIMULATOR System Receives CE Mark Approval as MRI Conditional**

PARIS, August 28, 2012 /PRNewswire/ --

Boston Scientific Corporation (NYSE: [BSX](#)) has received CE Mark approval for use of its PRECISION™ PLUS SPINAL CORD STIMULATOR (SCS) System in patients with the system and are in need for magnetic resonance imaging (MRI) head-only scans. The PRECISION PLUS SCS System is the world's first rechargeable SCS device. This approval provides physicians with an additional diagnostic option for patients with chronic intractable pain.

"As spinal cord stimulation becomes more widespread for control of severe disabling refractory pain, it is great to know that -- should the need arise -- head-only MRI scans can be safely performed in patients with the PRECISION PLUS SCS System," said Dr. Simon Thomson FPMRCA, consultant in pain medicine and neuromodulation at Basildon and Thurrock University Hospitals in the United Kingdom.

Chronic intractable pain is continuous pain that has lasted more than six months. 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. Chronic pain affects one in five adults in Europe, or about 95 million people 15 to 64 years of age.

"We are pleased to announce that patients implanted with the PRECISION PLUS SCS System will now be able to undergo MRI head scans," said Michael Onuscheck, senior vice president and president of Europe, Middle East and Africa at Boston Scientific. "We understand the need to provide physicians the necessary options to be able to manage their patients' care and believe this new MRI labeling will play a role for them."

Spinal cord stimulation is a reversible therapy that manages pain through an implantable pulse generator (IPG) and thin wires called electrodes, or "leads," that are implanted in the spinal column. The device electrically stimulates specific nerves of the spinal cord to mask the brain's perception of specific pain signals that move up the spinal cord. To date, about 350,000 patients with chronic pain have been treated worldwide with SCS therapy.

### **About the PRECISION™ PLUS SCS System**

The PRECISION PLUS SCS System was approved in the United States in 2004 and received approval in Europe and Canada in 2005. The system is the world's first rechargeable IPG. Today, more than 60,000 patients worldwide have been treated using this system. When compared to non-rechargeable SCS systems, rechargeable SCS systems may offer clinical benefits by extending therapeutic longevity and therefore avoiding frequent replacement surgeries and complications that may arise from repeated surgeries.

All cited trademarks are the property of their respective owners. Caution: The law restricts these devices to sale by or on the order of a physician. Inactions, contraindications, warnings, and instructions for use can be found on the product labeling supplied with each device. Information is for use only in countries with applicable health authority product registrations.

### **About Boston Scientific Neuromodulation**

Boston Scientific Neuromodulation is an 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 PRECISION PLUS SCS System technology, visit <http://www.ControlYourPain.com>.

### **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: <http://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 markets for our products, new product indications, 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.

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