

New data presented at WIP 2014 demonstrate sustained low back pain relief with the Boston Scientific Precision Spectra™ Spinal Cord Stimulator System [EN]

Advanced Illumina™ 3D Programming Software Provides Highly Significant Pain Relief in Study Patients

New retrospective data highlighting the Boston Scientific Corporation (NYSE: BSX) Precision Spectra™ Spinal Cord Stimulator (SCS) System demonstrate the device provided sustained and highly significant relief of low-back pain six months after implantation. Results were presented at the World Institute of Pain (WIP) 7th World Congress in Maastricht, The Netherlands May 7-10, 2014.

Precision Spectra is the first SCS System designed to improve pain relief using the innovative and highly advanced Illumina 3D Software, a three dimensional anatomy-driven computer model. 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.

The retrospective study of 213 patients at 13 centers is focused on patients with chronic pain who were treated with the Precision Spectra SCS System. To date, 140 patients have reached six months post-implant. Results include:

- Sustained and highly significant reduction in pain from an average baseline score of 7.15, on a 10-point scale, to an average score of 2.93 at six months post-implant (n=140).
- In those patients with only low-back pain (N=62), sustained and highly significant reduction of low back pain, from an average baseline score of 7.53, on a 10-point scale, to an average of 3.45 at six months post-implant.
- In those patients with severe low back pain (N=38, baseline score of 8 or greater on a 10-point scale), sustained and highly significant reduction in pain, from an average score of 8.78 at baseline to 3.68 at 6 months post-implant.

"The goal of SCS is sustained pain relief, and individuals with chronic back pain are among the most difficult to treat," said Salim Hayek, M.D., Ph.D., chief, Division of Pain Medicine at University Hospitals of Cleveland. "In this study, these retrospective results demonstrate that the Precision Spectra System is maintaining effective therapy for these challenging patients out to six months post-implant."

Boston Scientific also initiated the full European launch of the Precision Spectra Clinician Programmer, a mobile, touchscreen tablet powered by an Intel® Core™ i5 Processor.¹ The new Precision Spectra Clinician Programmer provides clinicians with a sleek, powerful and easy-to-use device to drive the advanced Illumina 3D Software.

Chronic pain affects 95 million people in Europe and more than 100 million people in the United States.^{2,3} Living in constant pain for an extended period of time can have a devastating impact on quality of life for many patients. 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. By providing 32 contacts – twice the number of contacts available with other SCS systems – the Precision Spectra System offers more coverage of the spinal cord for the management of chronic pain.

"Boston Scientific specifically developed the Precision Spectra System to achieve better therapy outcomes," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "These six-month results demonstrate our dedication to improving the lives of patients with chronic pain through meaningful innovation. We look forward to the long-term outcomes of this ongoing clinical study."

The clinical data presented at WIP are part of a robust clinical program that has been established to characterize further the benefits of the Precision Spectra System in providing pain relief. Other initiatives include RELIEF, a global registry for long term assessment of neuromodulation therapy for pain, and OPTIONS, a prospective, multi-center study of the Precision Spectra System.

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 a Boston Scientific SCS System. 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.

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