Boston Scientific

Boston Scientific Announces CE Mark Approval and European Launch for New Infinion™ 16 Percutaneous Lead for Precision Plus™ Spinal Cord Stimulator System

Paris, France and Miami Beach, FL (February 3, 2012) – Boston Scientific Corporation (NYSE: BSX) announces CE Mark 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 first patient implant in Europe using the Infinion™ 16 Lead was performed by Kliment Gatzinsky, M.D., Ph.D., and David Revesz, M.D., of the Neurosurgery Department at the Sahlgrenska University Hospital in Guldheden, Sweden.

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 announced the approval today at the World Institute of Pain (WIP) Congress, which runs from February 4 - 6 in Miami Beach. The Infinion 16 Lead is currently commercially available in the U.S. and will be introduced in CE Mark countries immediately.

SCS leads are designed to deliver electrical pulses from an implantable pulse generator to the spinal cord to mask pain signals to the brain (known as paresthesia). 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.

"I appreciate that for the first time, it is possible to place 16 contacts with a single percutaneous lead using a small insertion needle," said Dr. Gatzinsky. "This lead will provide me with more options to optimize the paresthesia coverage to bring relief for chronic pain patients." Dr. Revesz added, "The Infinion 16 Lead is very responsive, with excellent steering that allows easy placement in the target area."

Chronic pain is a debilitating condition that affects approximately 138 million people in Europe or more than one in five adults(1). Tens of thousands of patients with chronic pain have found that SCS systems help them manage their pain. SCS is a reversible therapy that manages pain through an implantable pulse generator and external devices that control therapy and charge the implant.

"The Infinion 16 Lead is the latest advance in SCS lead technology and an exciting addition to our unrivaled percutaneous lead portfolio," stated Maulik Nanavaty, Senior Vice President and President of the Boston Scientific Neuromodulation Division. "We believe that the European launch of the Infinion 16 Lead, coupled with increased awareness of pain management treatment alternatives, will allow us reach a wider patient population. Boston Scientific continues its commitment to innovation by offering pain management physicians more choices to help optimize pain relief for their patients."

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 investments in technology, clinical science, and world-class service, Boston Scientific Neuromodulation is committed to Making life smoother™ for physicians and patients.

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.

(1) United Nations World Population Monitoring 2001. United Nations Publication, 2001;1-80.

---

https://news.bostonscientific.com/infinion-16-scs-launch-europe