

The Facts About Boston Scientific Spinal Cord Stimulation

The health and safety of patients is our top priority. Our products meet FDA and other regulatory and international standards, as well as our own rigorous internal safety standards.



Commitment to Quality

Our products are designed to improve the health of patients. Safety monitoring is a constant process that begins with product design and development, and continues after our products are introduced to the market.



Proven Results

The safety and effectiveness of our spinal cord stimulation (SCS) systems are supported by multiple clinical studies.^{I-VI} These studies demonstrate effective long-term pain relief and a low rate of adverse events for SCS therapy when used appropriately.

SCS is a drug-free, non-addictive, FDA-approved therapy.

An estimated 1 in 5 adults suffer from pain, and another 1 in 10 adults are diagnosed with chronic pain globally each year.^{VII} Chronic pain causes millions to lose the ability to sleep, work and function normally. Because what works for one patient won't necessarily be the appropriate choice for another patient, managing chronic pain is complex and requires highly specialized care.



For decades, medications, including opioids, have been used as a first-line treatment regimen. While sometimes effective in treating patients' pain symptoms, they don't always work long term and also have an associated risk of being misused and abused.



Available for more than four decades, SCS is a proven, non-addictive therapeutic option for patients with certain types of chronic disabling pain. We speak to physicians regularly about the type of patients they believe may benefit from SCS; specifically, those for whom medications or surgery are not an option, or when the side effects of their current therapy are severely impacting their quality of life.

To date, more than 150,000 people worldwide have received a Boston Scientific SCS System to help provide long-term pain relief.



In a recent study, about 90% of patients implanted with a Boston Scientific SCS device for an average of four years reported they were “better” or a “great deal better” as a result of their SCS therapy.^I



Our newest SCS system is the first FDA-approved device which can deliver both paresthesia and paresthesia-free therapy at the same time, allowing patients to customize their stimulation. One clinical trial found that if patients are able to choose between paresthesia and paresthesia-free therapies, the number of patients whose pain was effectively controlled by SCS therapy increased by 62%.^{II}



A real-world study of more than 200 patients using the latest Boston Scientific SCS system at the last follow-up (mean 3 months), reported a 5.2-point drop in a patient’s pain score on a 10-point pain score scale. Further, about 40% of these patients also reported greater than 80% pain relief.^{VI}

We continue to focus on offering safe and effective products to manage chronic pain and advance SCS technology to improve patient outcomes. To do this, we are investing in ongoing clinical research and development of SCS devices. We are committed to delivering even greater pain relief and personalized therapy for each individual patient.

^INorth J. WHISPER: A Multicenter, Prospective Randomized Controlled Crossover Trial Evaluating Subperception SCS at ≤ 1.2 kHz. *NANS 21st Annual Meeting, January 11–14, 2018, Las Vegas, NV.*

^{II}Thomson S.J., Tavakkolizadeh M., Love-Jones S., Patel N.K., Gu J.W., Bains A., Doan Q., Moffitt M. 2018. Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial. *Neuromodulation* 2018; 21: 67–76North JM, Hong KJ, Cho PY.

^{III}Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation in Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial. *Neuromodulation*. 2016 Oct;19(7):731-737.

^{IV}Thomson S.J., Kruglov D., Duarte R.V. 2017. A Spinal Cord Stimulation Service Review From a Single Centre Using a Single Manufacturer Over a 7.5 Year Follow-Up Period. *Neuromodulation* 2017; 20: 589–599.

^VVeizi E, Hayek SM, North J, et al. Spinal cord stimulation (SCS) with anatomically guided (3D) neural targeting shows superior chronic axial low back pain relief compared to traditional SCS-LUMINA study. *Pain Med* 2017;18(8):1534–48.

^{VI}Metzger C. Outcomes Using an SCS Device Capable of Delivering Combination Therapy (Simultaneous or Sequential) and Advanced Waveforms/Field Shapes. *1st Joint Congress of the European INS Chapters. September 19–22, 2018, Nijmegen, The Netherlands.*

^{VII}Goldberg, Daniel S and Summer J McGee. “Pain as a global public health priority” *BMC public health* vol. 11 770. 6 Oct. 2011, doi:10.1186/1471-2458-11-770