



Spinal Cord Stimulation

Fact Sheet

SPINAL CORD STIMULATION OVERVIEW

Spinal cord stimulation (SCS) devices are approved by the U.S. Food and Drug Administration (FDA) as a method of pain control for the treatment of chronic pain of the arms, legs and trunk, or pain resulting from failed back surgery. Although it is not a cure, SCS therapy can be successful in reducing pain that is the result of dysfunction or damage to the nervous system caused by injury, disease or localized trauma.

Chronic pain is a largely under-treated and misunderstood disease that affects millions of people worldwide. It is defined as moderate to severe pain that persists for three or more months longer than would generally be expected for recovery to a specific disease, injury or surgery. According to The American Pain Foundation, chronic pain affects 76.5 million people in the U.S., while the National Institutes of Health estimates that chronic pain costs the U.S. economy \$100 billion a year in lost work time and medical expenses.

In their search for relief, patients often endure inadequate treatments and struggle with prescription painkillers. In a report issued by the U.S. Department of Health & Human Services, the number of narcotic, analgesic, drug abuse-related emergency room visits increased 20 percent over the course of one year, totaling 108,320 visits in 2002. The 45–54 age group experienced the largest increase (298 percent).

Neurostimulation studies have shown that SCS systems can often reduce pain by 50 percent or greater.¹⁻³ These patients are often able to reduce or eliminate their use of pain medications, such as analgesic opioids, which potentially have negative side effects, including dependency. By providing significant pain relief, SCS therapy enables many patients to increase their activity levels and improve their overall quality of life.⁴

WHAT ARE SPINAL CORD STIMULATORS?

Spinal cord stimulators are implanted neurostimulation devices that are similar in function and appearance to cardiac pacemakers, except that the electrical pulses are sent to the spinal cord instead of the heart. These “pacemakers for pain” interrupt the pain signals’ pathways to the brain by delivering low intensity electrical pulses to trigger selective nerve fibers along the spinal cord. Researchers theorize that stimulating these nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain, replacing feelings of pain with a more pleasant tingling sensation called *paresthesia*.

A spinal cord stimulation system includes:

- **Neurostimulator or generator**—a surgically implanted, battery-operated medical device that is like a pacemaker for pain
- **Leads**—one or more thin wires with several electrodes or contacts that carry mild electrical pulses from the neurostimulator to specific segments of the spinal cord
- **Patient controller**—a remote control device that turns the system on and off and allows patients to adjust stimulation within parameters set by physicians
- **Programmer**—a device that enables the doctor or clinician to adjust and fine-tune the stimulation programs

To have a spinal cord stimulator implanted, a patient undergoes a minor surgical procedure in which a lead or leads are placed in the epidural space next to the spine. Leads are positioned using a small needle or by making an incision and they are then connected to the generator, which serves as the power source. Once activated, the system’s programs are adjusted and fine-tuned to best control the patient’s pain. Patients use a controller that allows them to check the system’s battery, adjust the stimulation level, select from pre-set programs, and turn the system power on and off.

The neuromodulation division of St. Jude Medical is a technology leader in implantable neurostimulation therapies with nearly 30 years of experience and numerous technology firsts. More than 45,000 people in approximately 35 countries have St. Jude Medical neuromodulation devices managing their chronic pain.

PATIENT RESOURCES

Patients should always be encouraged to talk with their physicians or seek out pain management practitioners if they believe they are suffering from chronic pain. Information on how to locate a physician who treats pain can be found at www.PowerOverYourPain.com.

Indications for Use: Chronic, intractable pain of the trunk and limbs.

Contraindications: Demand-type cardiac pacemakers, patients who are unable to operate the system or who fail to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, cardioverter defibrillators, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Events: Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis).

User's guide must be reviewed prior to use for detailed disclosure.

Caution: U.S. federal law restricts this device to sale and use by or on the order of a physician.

FOR ADDITIONAL INFORMATION FOR PATIENTS OR JOURNALISTS:

- www.PowerOverYourPain.com
- www.NationalPainFoundation.org
- www.PainFoundation.org

Linked website disclaimer

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Sources:

¹ Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*. 2007 Nov;132(1-2):179-88.

² North RB, Kidd DH, Farrokhi F, Piantadosi S. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery*. 2005;56:98-107.

³ Burchiel KJ, Anderson VC, Brown FD, et al. Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. *SPINE*. 1996;21(23):2786-2794.

⁴ Advanced Neuromodulation Systems. Prospective, Multi-Centered, Single Arm Study to Evaluate the Safety and Effectiveness of Genesis™ Implantable Pulse Generator in Combination with ANS Percutaneous Leads for the Management of Chronic Pain of the Trunk and/or Limbs. Plano, Tex; 2006.

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