FAQs: Spinal Cord Stimulation

Fact Sheet

FREQUENTLY ASKED QUESTIONS ABOUT SPINAL CORD STIMULATION

Q: What is spinal cord stimulation?

A: Spinal cord stimulation (SCS) devices are approved by the U.S. Food and Drug Administration (FDA) to target and treat chronic pain of the arms, legs and trunk, or pain resulting from failed back surgeries. SCS therapy uses an implanted device and thin wires with electrodes to deliver low levels of electrical energy to nerve fibers, replacing the pain with a tingling sensation called paresthesia.

Q: Is SCS a cure for chronic pain?

A: SCS is not a cure, but it can be successful in reducing chronic pain that is the result of dysfunction or damage to the nervous system caused by injury, disease or localized trauma (e.g., an infection or surgery). Pain is a reaction to signals sent from a pain source through the nerves in the spinal cord to the brain. SCS interrupts the pain signals' pathway to the brain by delivering low-intensity electrical impulses to selected nerve fibers along the spinal cord. SCS replaces areas of pain with what has been described as a more pleasant tingling sensation.

Q: Who are the best candidates for SCS?

A: The best candidates are individuals with chronic, neuropathic pain who have unsuccessfully tried less aggressive pain therapies, ranging from exercise and over-the-counter medications to nerve blocks, systemic opioids and surgery. A number of factors affect whether a patient is a good candidate for SCS. These include the patient's diagnosis and medical history, as well as the severity, location and type of pain.

Q: What devices are included in an SCS system?

A: An SCS system includes the following items:

- *Neurostimulator or generator*—A battery-operated medical device that is surgically implanted, somewhat like a pacemaker
- *Lead*—A thin wire with several electrodes or contacts that carry mild electrical pulses from the neurostimulator to targeted areas of the spinal cord (more than one lead may be used)
- *Patient controller*—A remote control device that the patient uses to turn the system on and off and select among preset pain-relief stimulation programs
- *Programmer*—A device that a doctor or clinician uses to set up the stimulation programs that run on the patient's neurostimulator

Q: How many patients are implanted with St. Jude Medical SCS systems?

A: Over 45,000 patients have been implanted with St. Jude Medical systems to alleviate their chronic pain. These patients live in more than 35 countries around the world.

St. Jude Medical, Inc.
Global Headquarters
One Lillehei Plaza
St. Paul, MN 55117

sjm.com

Media Contacts

Denise Landry
Tel: 972-309-8000
dlandry@sjm.com

Guy Davis
Tel: 972-309-8000
gdavis@sjm.com

Q: How is an SCS system implanted?

A: When an SCS system is implanted, one or more leads are inserted into the epidural space of the spinal cord. This is done through a small needle or, in some cases, by performing minor surgery. The placement of the leads and their electrodes in the epidural space is dictated by the patient's pain pattern. The other ends of the leads are then passed under the skin and connected to the neurostimulator, which is implanted just underneath the skin, usually in the buttock or abdomen.

Q: After an SCS system is implanted, how is it set up to relieve a patient's pain?

A: An SCS system can be adjusted by a physician or clinician with an external programmer that communicates with the implanted neurostimulator. In this way, the stimulation can be fine-tuned to best control the patient's pain. The patients themselves receive a remote control device that allows them to check the neurostimulator's battery, adjust stimulation within parameters set by the physician and turn the power on and off.

Q: Can a patient try SCS before getting a system permanently implanted?

A: Normally, SCS is administered on a trial basis before permanent implantation. The system's lead or leads are inserted into the patient for the trial and a special neurotransmitter is given to the patient to wear externally during this time. After the trial period, the patient, in consultation with the doctor, will decide whether or not to permanently implant the system.

Q: Is SCS the same as neurostimulation or neuromodulation?

A: Neuromodulation covers a broad group of therapies that includes neurostimulation (electricity) and drug pumps to modulate pain or minimize dysfunction. Neurostimulation refers to therapies that treat disorders of the nervous system by sending electrical impulses to the spinal cord or a specific nerve. Spinal cord stimulation, peripheral nerve stimulation, and deep brain stimulation are all types of neurostimulation therapies.

Q: How can I found out more information about spinal cord stimulation?

A: For more information on spinal cord stimulation or to locate a pain physician, visit www.PowerOverYourPain.com.

Q: What are the benefits of SCS to the patient?

A: SCS is cost effective, has limited side effects and is completely reversible. Implantation of the system is also a relatively simple procedure. When used successfully, SCS systems can provide these benefits to patients:

- Significantly improve pain relief
- Reduce use of medications such as analgesic opioids
- Increase activity levels and improve quality of life

Patients can use SCS systems around the clock, if necessary. Depending on the system, patients can control the intensity of the stimulation. With more advanced and full-featured systems, patients can choose among multiple programs tailored for their use and can fine-tune these programs within pre-programmed safety limits. St. Jude Medical systems with MultiStim® enable patients to run different stimulation programs to achieve the best possible pain relief throughout the day and night, as well as during specific activities.

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sjm.com

Media Contacts

Denise Landry
Tel: 972-309-8000
dlandry@sjm.com

Guy Davis
Tel: 972-309-8000
gdavis@sjm.com

Q: What are some of the limitations and restrictions with SCS?

A: SCS is a pain therapy, and it does have some limitations in certain cases, including these possible occurrences:

- Loss of effective pain stimulation and reduction in pain relief due to possible movement of the leads
- Changes in tissue around the electrodes causing a reduction in pain relief
- Too much stimulation resulting in an uncomfortable sensation
- Loss of pain relief over time, sometimes due to changes in stimulation coverage or changes in pain location
- Equipment failure

These conditions can often be overcome and successful pain therapy continued, depending on the cause and whether the SCS system is flexible enough to sustain the therapy. Having an SCS system does involve some restrictions. For example, patients are advised not to drive or operate heavy machinery while their SCS system is providing stimulation. In addition, things like metal detectors (such as those at airports) and antitheft devices may detect SCS devices. Therefore, patients must carry identification cards to help them pass through checkpoints that use these kinds of detection devices.

Q: What are some of the complications associated with SCS?

A: SCS is a pain therapy with a low risk of complications. Complications can include:

- Allergic reaction to the system components
- Pain at the implant site
- Local skin erosion over the implant

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.

SOURCES FOR STATISTICS AND INFORMATION:

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

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