

Spinal Cord Stimulation

Overview

Spinal cord stimulation is a therapy that masks pain signals before they reach the brain. A small device, similar to a pacemaker, is implanted in the body to deliver electrical pulses to the spinal cord. It helps people better manage their chronic pain symptoms and decrease their use of opioid medications. It may be an option if you suffer chronic back, leg or arm pain and have not found relief with other therapies.

What is a spinal cord stimulator?

A spinal cord stimulator (SCS) device is surgically placed under your skin and sends a mild electric current to your spinal cord (Fig. 1). A small wire carries the current from a pulse generator to the nerve fibers of the spinal cord. When turned on, the SCS stimulates the nerves in the area where your pain is felt. Pain is reduced because the electrical pulses modify and mask the pain signal from reaching your brain.

Some SCS devices use a low-frequency current to replace the pain sensation with a mild tingling feeling called paresthesia. Other SCS devices use high-frequency or burst pulses to mask the pain with no tingling feeling. A paresthesia-free setting is an option on most devices.

Stimulation does not eliminate the source of pain. It simply changes the way the brain perceives it. As a result, the amount of pain relief varies for each person. The goal for SCS is a 50 to 70% reduction in pain. However, even a small amount of pain reduction can be significant if it helps you perform daily activities and reduces the amount of pain medication you take. SCS does not improve muscle strength.

Stimulation does not work for everyone. Some patients may find the sensation unpleasant. In other cases it may not cover the entire pain area. For these reasons a trial stimulation is performed before the device is permanently implanted. If unsuccessful, the trial wires can be removed, leaving no damage to the spinal cord or nerves.

There are several types of SCS device systems. However, all have three main parts:

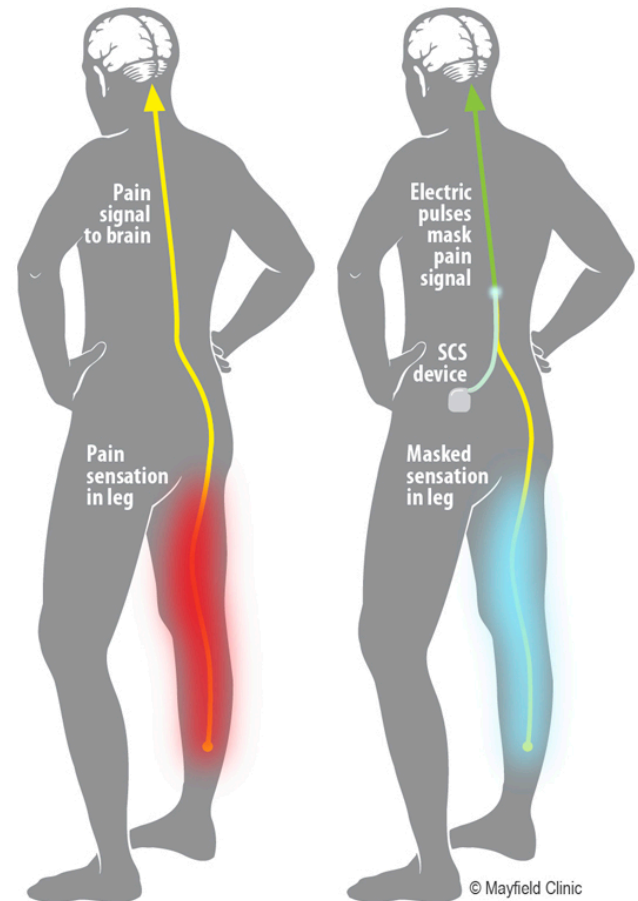


Figure 1. A spinal cord stimulator works by masking pain signals before they reach the brain. A stimulator device delivers electric pulses to electrodes placed over the spinal cord. Modified by the pulses, the pain signals are either not perceived or are replaced by a tingling feeling.

- A pulse generator with a battery that creates the electrical pulses.
- A lead wire with a number of electrodes (8-32) that delivers electrical pulses to the spinal cord.
- A hand-held remote control that turns the device on and off and adjusts the settings.

Systems with a non-rechargeable battery need to be surgically replaced every 2 to 5 years, depending on the frequency of use. Rechargeable battery systems may last 8 to 10 years or longer, but you must remember to charge the system daily.

The pulse generator has programmable settings. Some SCS devices are able to sense a change in body position (sitting vs. lying down) and adapt the stimulation level to your activity. Other systems have leads that can be independently programmed to cover multiple pain areas. Some send a sub-perception pulse with no tingling. Your doctor will select the best type of system for you.

Who is a candidate?

An evaluation of your physical condition, medication regime, and pain history will determine whether your goals of pain management are appropriate for SCS. A neurosurgeon, physiatrist, or pain specialist will review all previous treatments and surgeries. Because chronic pain also has emotional effects, a psychologist will assess your condition to maximize the probability of a successful outcome.

Patients selected for SCS usually have had chronic debilitating pain for more than 3 months in the lower back, leg (sciatica), or arm. They also typically have had one or more spinal surgeries.

You may be a candidate for SCS if:

- Conservative therapies have failed.
- You would not benefit from additional surgery.
- The pain is caused by a correctable problem and should be fixed.
- You do not want further surgery because of the risks or long recovery. Sometimes SCS may be chosen over a large, complex spine surgery.
- You do not have untreated depression or drug addiction; these should be treated prior to having a SCS.
- You have no medical conditions that would keep you from undergoing implantation.
- You have had a successful SCS trial.

SCS works better in the earlier stages of a chronic condition, before a cycle of pain-suffering-disability-pain is established.

An SCS can help lessen chronic pain caused by:

- **Chronic leg (sciatica) or arm pain:** ongoing, persistent pain caused by arthritis, spinal stenosis, or by nerve damage.
- **Failed back surgery syndrome:** failure of one or more surgeries to relieve persistent leg or arm pain, but not a technical failure of the original procedure.
- **Complex regional pain syndrome:** a progressive disease in which patients feel constant, chronic burning pain, typically in the foot or hand.
- **Arachnoiditis:** painful inflammation and scarring of the protective lining of the spinal nerves.
- **Other:** stump pain, angina, peripheral vascular disease, multiple sclerosis, or spinal cord injury.

Who performs the procedure?

Neurosurgeons and doctors who specialize in pain management (an anesthesiologist or physiatrist) implant spinal cord stimulators.

The surgical decision

Determining whether a spinal cord stimulator will be a good option for you is a two-step process. First, you must undergo a temporary trial to see if the device decreases your level of pain.

Stage 1. Trial SCS

Trial stimulation is a “test drive” to determine if an SCS will work for the type, location, and severity of your pain. It is performed at an outpatient center.

If you take blood-thinners, you are required to stop the medication 3 to 7 days prior to the trial.

A local anesthetic is given to numb the area in the lower back. Using X-ray fluoroscopy, a hollow needle is inserted through the skin into the epidural space between the bone and spinal cord. The trial lead is inserted and positioned over specific nerves. The wires are attached to an external generator worn on a belt (Fig. 2).

You will be sent home with instructions on how to use the trial stimulator and care for your incision site. Keep a written log of the stimulation settings during different activities and the level of pain relief. After 4 to 7 days, you will return to the doctor’s office to discuss permanently implanting the stimulator or removing the trial leads.

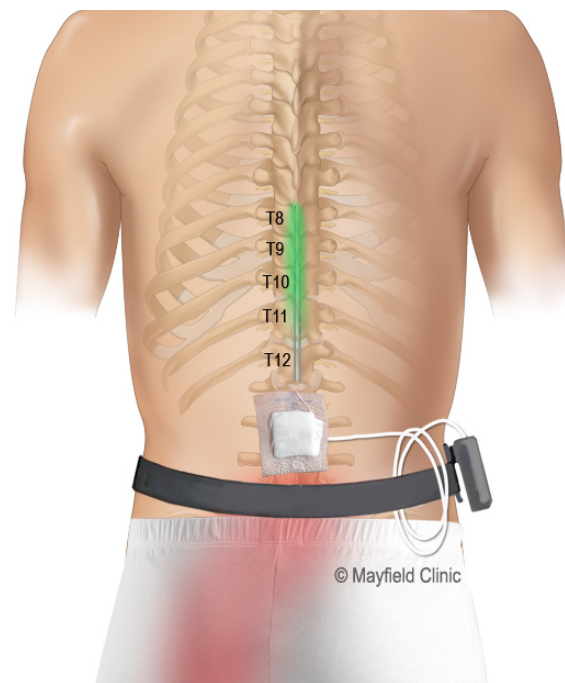


Figure 2. During a Trial SCS, temporary leads are placed in the spinal canal and a stimulator is worn on a belt. For several days you will test the device to see if it relieves your pain during various activities.

Stage 2. Permanent SCS

If the trial is successful and you experience greater than 50% improvement in pain, surgery can be scheduled to permanently implant the SCS.

What happens before surgery?

You may be scheduled for presurgical tests (e.g., blood test, electrocardiogram, chest X-ray) several days before surgery. In the doctor's office, you will sign consent and other forms so that the surgeon knows your medical history (allergies, medicines/vitamins, bleeding history, anesthesia reactions, previous surgeries). Inform your healthcare provider about all the medications (over-the-counter, prescription, herbal supplements) that you are taking.

Stop taking all non-steroidal anti-inflammatory medicines (Naprosyn, Advil, Motrin, Nuprin, Aleve, etc.) and blood thinners (Coumadin, Plavix, etc.) 1 to 2 weeks before surgery as directed by the doctor. In addition, stop smoking, chewing tobacco, and drinking alcohol 1 week before and 2 weeks after surgery, because these activities can cause bleeding problems. No food or drink is permitted past midnight the night before surgery.

Morning of surgery

- Shower using antibacterial soap. Dress in freshly washed, loose-fitting clothing.
- Wear flat-heeled shoes with closed backs.
- If you have instructions to take regular medication the morning of surgery, do so with small sips of water.
- Remove make-up, hairpins, contacts, body piercings, nail polish, etc.
- Leave all valuables and jewelry at home (including wedding bands).
- Bring a list of medications (prescriptions, over-the-counter, and herbal supplements) with dosages and the times of day usually taken.
- Bring a list of allergies to medication or foods.

Arrive at the hospital 2 hours before your scheduled surgery time (1 hour before at the outpatient surgery center) to complete the necessary paperwork and pre-procedure work-ups. An anesthesiologist will talk with you and explain the effects of anesthesia and its risks. An intravenous (IV) line will be placed in your arm.

What happens during surgery?

The surgery generally takes 1 to 2 hours.

Step 1: prepare the patient

You will lie on your stomach on the table and be given light sedation. Next, the areas of your back and buttock are prepped where the leads and generator are to be placed. Local anesthetic will be used to numb the incisions.

Step 2: place the leads

The electrode leads are inserted with the aid of fluoroscopy (a type of X-ray). A small skin incision is made in the middle of your back (Fig. 3), and the bony vertebra is exposed. A portion of the bony arch is removed (laminotomy) to allow room to place the leads. The leads are secured with sutures in the epidural space above the spinal cord (Fig. 4).

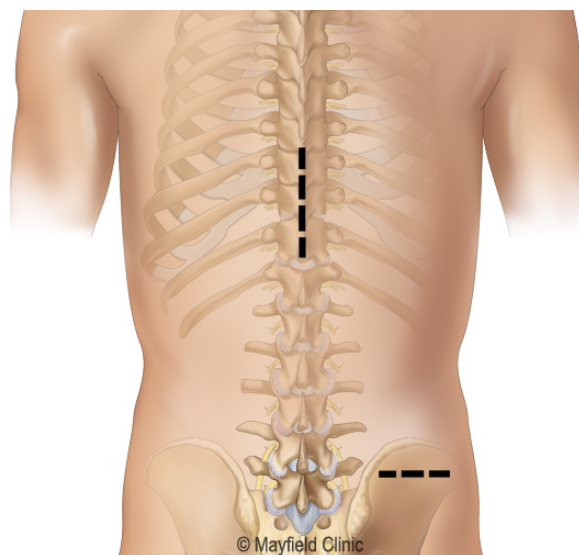


Figure 3. A skin incision is made in the middle of your back for the leads and another is made in your buttock for the generator.

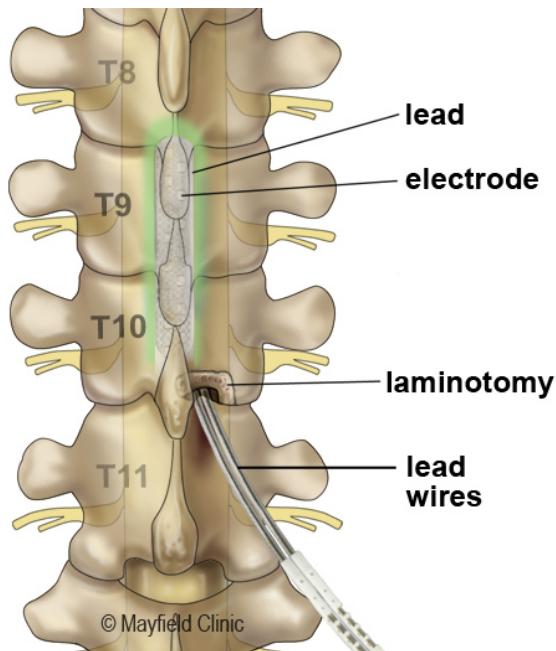


Figure 4. A laminotomy is made in the bone to allow room to place the leads. The leads are positioned in the epidural space above the spinal cord to deliver electrical current to the nerves.

Step 3: test stimulation

You will be awakened so that you can help the doctor determine how well the stimulation covers your pain pattern. Several stimulation settings will be tried, and you will be asked to describe the location of any tingling you feel. These settings will be used to program the pulse generator at the end of surgery, so your feedback is important to ensure the best pain relief.

In some cases, if the leads implanted during the trial are positioned perfectly, there is no need to reposition or insert new leads.

Step 4: tunnel the wire

Once the leads are in place, sedation is again given. The lead wire is passed under the skin from the spine to the buttock, where the generator will be implanted.

Step 5: place the pulse generator

A small skin incision is made below the waistline. The surgeon creates a pocket for the generator beneath the skin (Fig. 5). The lead wire is attached to the pulse generator. The generator is then correctly positioned within the skin pocket.

Step 6: close the incisions

The incisions are closed with sutures and skin glue. A dressing is applied.

What happens after surgery?

You will wake up in the recovery area. Your blood pressure, heart rate, and respiration will be monitored, and your pain will be addressed. Most patients are discharged home the same day or the following morning. The pulse generator will be programmed before you leave. You will be given written instructions to follow when you go home.

Discharge instructions

Discomfort

- Take pain medication as directed by your surgeon. Narcotics can be addictive and are used for a limited period of time.
- Narcotics can also cause constipation. Drink lots of water and eat high-fiber foods. Laxatives and stool softeners such as Dulcolax, Senokot, Colace, and Milk of Magnesia are available without a prescription.
- Ice your incision 3-4 times per day for 15-20 minutes to reduce pain and swelling.
- Spinal headaches may be caused by leakage of cerebrospinal fluid around the lead site. The leak often heals on its own. Lie flat and drink plenty of caffeinated non-carbonated fluids (tea, coffee).

Restrictions

- Do not bend, lift, twist your back or reach overhead for the next 6 weeks. This is to

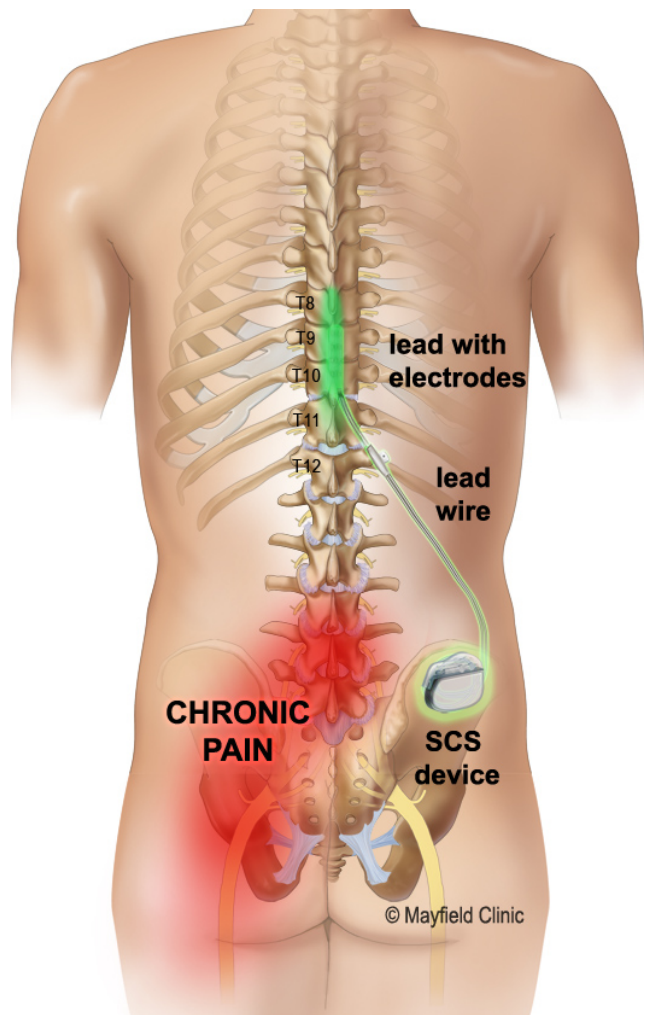


Figure 5. The SCS generator pocket is created below the waist, under the skin of the buttock.

prevent the leads from moving out of place until it heals.

- Do not lift anything heavier than 5 pounds for 2 weeks after surgery.
- No strenuous activity for the next 2 weeks including yard work, housework and sex.
- Do not drive until your follow-up appointment. You may ride in a car for short distances of 45 minutes or less if necessary.
- Do not drink alcohol for 2 weeks after surgery or while you are taking narcotic medication.

Incision Care

- Wash your hands thoroughly before and after cleaning your incision to prevent infection.
- You may shower the day after surgery.
- Gently wash the incision covered in Dermabond (skin glue) with soap and water. Pat dry. Inspect and wash the incision daily.
- Do not submerge or soak the incision in water (bath, pool or tub).

- Do not apply any lotions or ointments over the incision.
- Some drainage from the incision is normal. A large amount of drainage, foul smelling drainage, or drainage that is yellow or green should be reported to your surgeon's office immediately.
- Fluid may accumulate under the skin around the leads or the device, creating a visible swelling (seroma). Call the doctor if this occurs.

Activity

- Avoid sitting for long periods of time.
- Get up and walk 5-10 minutes every 3-4 hours. Gradually increase your walking time, as you are able.

When to Call Your Doctor

- Fever over 101.5° F (unrelieved by Tylenol)
- Unrelieved nausea or pain
- Incision complications
- Sudden severe back pain, sudden onset of leg weakness and spasm, loss of bladder and/or bowel function - **this is an emergency** - go to a hospital and call your surgeon.

Recovery

Approximately 10 days after surgery you will come to the office to have the sutures or staples removed. Programming of the pulse generator can be adjusted at this time if needed. It is important to work with your doctor to adjust your medications and refine the programming of the stimulator.

Your pain specialist and device representative will work with you to fine-tune adjustments to the SCS.

What are the results?

The results of SCS depend on careful patient selection, successful trial stimulation, proper surgical technique, and patient education. Stimulation does not cure the condition that is causing pain. Rather, it helps patients manage the pain. SCS is considered successful if pain is reduced by at least half.

Published studies of spinal cord stimulation show good to excellent long-term relief in 50 to 80% of patients suffering from chronic pain [1-6]. One study reports that 24% of patients improved sufficiently to return to gainful employment or housework with stimulation alone or with the addition of occasional oral pain medication [7].

SCS therapy is reversible. If a patient decides at any time to discontinue, the electrode wires and generator can all be removed.

What are the risks?

No surgery is without risks. General complications of any surgery include bleeding, infection, blood clots, and reactions to anesthesia. Specific complications related to SCS may include:

- Undesirable changes in stimulation (can possibly be related to cellular changes in tissue around electrodes, changes in electrode position, loose electrical connections, and/or lead failure)
- Epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis (can be caused by placing a lead in the epidural space during a surgical procedure)
- Battery failure and/or battery leakage
- Cerebrospinal fluid leak
- Persistent pain at electrode or stimulator site
- A pocket of clear fluid (seroma) at the implant site. Seromas usually disappear by themselves but may require a drain.
- Lead migration, which can result in changes in stimulation and reduction in pain relief
- Allergic response to implant materials
- Generator migration and/or local skin erosion
- Paralysis, weakness, clumsiness, numbness, or pain below the level of implantation

Conditions for which you might need additional surgery include movement of the lead, breakage of the lead or extension wire, or (in rare cases) mechanical failure of the device. Reasons for removal of the device include infection and failure to relieve pain.

Sometimes scar tissue develops around the electrode and can make the stimulation less effective.

Living with a stimulator

Once the SCS has been programmed, you are sent home with instructions for regulating the stimulation by controlling the strength and the duration of each stimulation period. Your doctor may alter the pulse width, amplitude, and frequencies on follow-up visits if necessary.

The pulse generator has programmable settings:

1. Frequency (rate): number of times stimulation is delivered per second. Too few pulses results in no sensation. Too many results in a washboard or bumpy effect.
2. Pulse width: the area the stimulation will cover.
3. Pulse amplitude: determines threshold of perception to pain.

The handheld programmer lets you turn the stimulator on and off, select programs, and adjust the strength of the stimulation. Most people are given multiple programs to achieve the best possible pain relief at any point throughout the day

or during specific activities. You can use your spinal cord stimulator around the clock if necessary.

Some people feel differences in stimulation intensity depending on their position (e.g., sitting versus standing). This is caused by variations in the spread of electricity as you change positions and is normal.

Just like a cardiac pacemaker, your stimulator cannot be damaged by devices such as cellular phones, pagers, microwaves, security doors, and anti-theft sensors. Be sure to carry your Implanted Device Identification card when flying, since the device is detected at airport security gates. Department store and airport security gates or theft detectors may cause an increase or decrease in stimulation when you pass through the gate. This sensation is temporary and should not harm your system. However, as a precaution, you should turn off your system before passing through security gates.

The various SCS systems have different restrictions to their use with MRI, ultrasound, defibrillator, electrocautery, diathermy, and cardiac pacemakers. Be sure to know the limitations of your specific SCS device. Also, chiropractic manipulation may cause the lead to move. Consult your surgeon first.

Sources & links

If you have more questions, please contact New England Neurological Associates at 978-687-2321.

Sources

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Links

www.spine-health.com
www.controlyourpain.com
www.tamethepain.com
www.poweroveryourpain.com
www.nevro.com

Glossary

laminotomy: surgical cutting of the laminae or vertebral arch of the vertebra.

lead: a small medical wire that has electrodes at one end. Electrical current passes from a battery, along the wire, to the electrodes. Two types: percutaneous and surgical leads.

fluoroscopy: an imaging device that uses x-ray or other radiation to view structures in the body in real time, or "live". Also called a C-arm.

percutaneous: by way of the skin (e.g., injection).

peripheral nerve stimulation: a surgical treatment for pain in which specific nerves are stimulated rather than the general area of the spinal cord.

sciatic nerve: nerve located in the back of the leg which supplies the muscles of the back of the knee and lower leg and sensation to the back of the thigh, part of the lower leg, and the sole of the foot.

sciatica: pain that courses along the sciatic nerve in the buttocks and down the legs. Usually caused by compression of the 5th lumbar spinal nerve.

seroma: a mass formed by the collection of tissue fluids following a wound or surgery.

spinal hygroma: an accumulation of cerebrospinal fluid under the skin, which produces a visible swelling, caused by leakage around a catheter, drain, or shunt.



updated > 12.2018

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