

Common Questions



What is SCS?

Spinal cord stimulation (SCS) is the stimulation of your nerves by tiny electrical pulses. An implanted lead, which is powered by an implanted battery or receiver, is placed against your spinal cord. This system sends electrical pulses that block the pain messages to your brain. Some patients describe the feeling of SCS as “tingling.” SCS implantation is a reversible procedure that does not damage your spinal cord or nerves. Typically, patients who have success with SCS experience a 50% to 70% reduction in their pain.

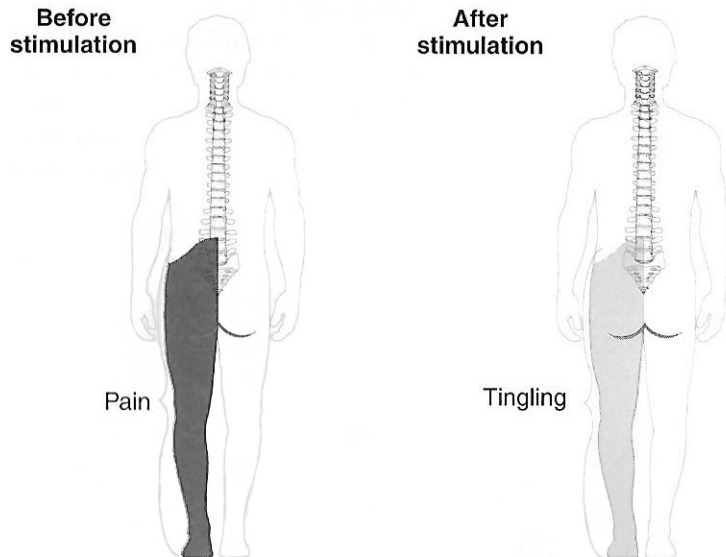


Figure 1. Pain reduction achieved with SCS

Is SCS new?

SCS is not new. It has helped thousands of patients worldwide since its beginnings in the early 1970s. Medtronic, the first to provide SCS systems, continues to apply medical technology to refine the system.

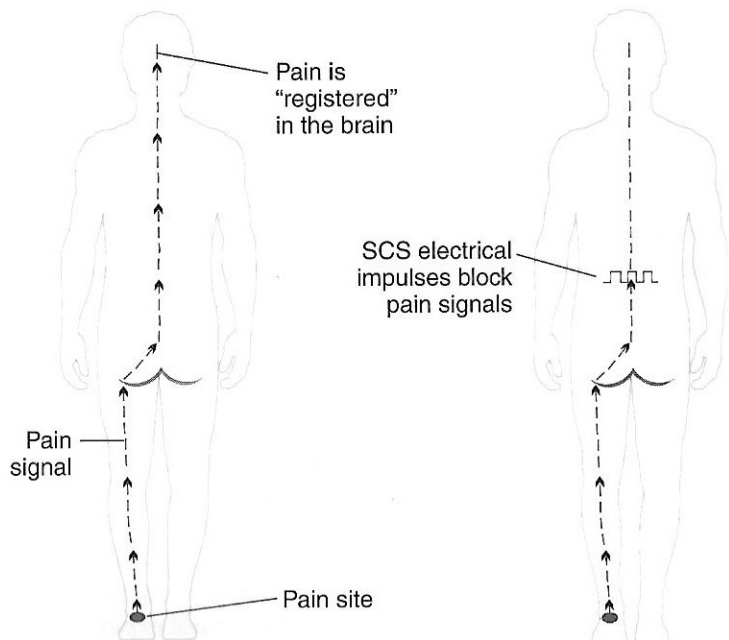
What does SCS feel like?

The sensation felt from SCS varies from patient to patient, but most report a tingling sensation in the area of their pain. Ideally, stimulation will provide a pleasant tingling sensation in the areas where you usually feel pain. However, SCS will not mask sharp pain from a new injury.

What is pain?

Understanding the concepts of pain will help you understand how the SCS system can help to relieve your pain.

Pain is a process. Pain receptors in your skin and other tissue send an impulse through the spine to the brain. It is the brain, not the point of injury, that registers the sensation of pain. This was an important discovery, because it taught doctors to control pain by preventing the impulses from reaching the brain. If the pain signals never reach the brain, the pain is not "felt."



Pain signal blocked by SCS impulses

SCS works because it uses electrical impulses to block or override messages before they reach the brain. According to the theory SCS is based on, pain can be controlled by masking the sensation with a tingling feeling. Think of SCS as the rubbing of your “funny bone” after you’ve bumped it. Rubbing masks the feeling of pain just as tingling masks the feeling of pain with the SCS system.

Why is my pain unique?

Pain is experienced differently by everyone. Remember that your pain is unique. If your doctor has recommended SCS, you are most likely experiencing chronic intractable pain. The pain you feel is different from someone who has burned a hand or broken a leg. Your pain is called *neuropathic*, which means the pain is caused by actual damage to nerve tissue. It is often felt as a burning or stabbing pain. Another type of pain, *nociceptive* pain, is from external sources, for example, burning your hand. This type of pain is more responsive to traditional drug therapies.

Will SCS alone get rid of all my pain?

SCS is just one component in your pain therapy plan. SCS requires a strong patient commitment to effectively control pain. You must also participate in other therapies, such as physical therapy or spending extra time learning to operate the SCS equipment.

SCS does not eliminate the source of pain, so the amount of pain reduction varies from patient to patient. Some patients experience substantial pain relief, while others experience little or no benefit. Those patients who do not experience adequate relief generally will not receive a complete system as part of their pain therapy.

Who is a candidate for SCS Therapy?

The best candidates for SCS have severe, chronic pain in their legs. Patients with primarily leg pain and some back pain can also benefit. In general, the wider the pain, the more difficult it is for SCS to be effective. Most patients have tried other methods of pain control, but have not experienced sufficient pain relief.



Warning: Safety for use during pregnancy or delivery has not been established. Consult your doctor if this is a concern.

Who can be helped with SCS?

Generally, doctors consider the following when choosing to use SCS:

- More conservative therapies have failed (for example, epidural blocks).
- The doctor does not feel further surgeries would be beneficial.
- The patient has had a psychological screening.
- The patient has no untreated drug addictions.
- There are no contraindications to the SCS system (for example, the patient does not have a pacemaker).
- The patient has had a successful trial stimulation period.
- The patient has made a commitment to be an active participant in his/her recovery.

Will SCS work for me if I have been unsuccessful with TENS?

Your success with SCS cannot be measured by your past experience with TENS (transcutaneous electrical nerve stimulation). Both SCS and TENS are electrical stimulators. However, TENS is an external device that reduces pain by applying low-voltage electricity via electrodes placed over the skin.

TENS is more effective for less severe pain than for chronic pain. It creates much weaker and more localized stimulation than the implanted SCS system. Many patients find pain relief with SCS even if they have not had successful results with TENS. If you have further questions regarding the TENS system, please consult your doctor.

Is SCS safe?

Extensive clinical research has shown that the tiny electrical pulses from the SCS system cause no apparent damage to the nervous system. Likewise, research has shown that the materials in the electrodes and other implanted components are safe.

Are there any side effects to SCS?

SCS is not addictive and has no apparent side effects. Unlike some drugs used to control pain, SCS does not cause drowsiness, disorientation, or nausea. And, it treats only the area where there is pain rather than affecting the entire body.

What are the possible complications associated with the SCS system?

As with any surgery, there are risks involved with implantation. These risks are covered in the *Implant Surgery* section of this booklet. Some general complications that may be experienced with the system include:

- Risk of infection
- No stimulation or intermittent stimulation
- Stimulation in the wrong location
- Loss of pain relieving effect, which may return you to your underlying pain condition

If you experience any of these complications, consult your doctor immediately. It could mean the implanted lead has moved, there is a poor system connection, or the battery is depleted.

Will I experience any changes in sensation?

Generally, you will experience a fairly constant sensation of stimulation. However, you may feel changes in sensation with abrupt movements or shifts in posture. Don't be alarmed when you feel these changes in sensation—they are perfectly normal.

Will I be able to go back to my normal routine?

Many patients find they are able to resume former activities. Consult your physician before beginning any activity. It is important to remember that SCS is just one aspect of your pain therapy. You should work with your doctor to create a rehabilitation plan that works for you. This plan may include psychological, occupational, and physical therapy.

How long will the battery in the implantable pulse generator (IPG) last?

This time will vary by patient. The battery life of the implanted pulse generator (IPG) depends on how many hours a day the system is used, the intensity of the stimulation, and individual differences. The trial screening process will help you and your doctor decide whether an internally-powered or externally-powered system is best for your battery requirements.

The battery life of the IPG is dependent on your usage and the therapy programmed by your doctor. After the battery is depleted, you may need surgery to replace the IPG.

The external system uses a standard, external 9-volt battery. The battery is replaced approximately once a week, depending on individual use.

SCS System Components



There are two types of SCS systems:

- Fully implanted system with an internal power source
- Implanted system with an external power source

The main difference is the battery location. The internally-powered system uses a battery that is implanted beneath the skin; the externally-powered system uses a battery source that is worn outside the body. Some SCS systems are implanted using two leads. Your doctor will work with you to help you select the system that is most appropriate for your needs.

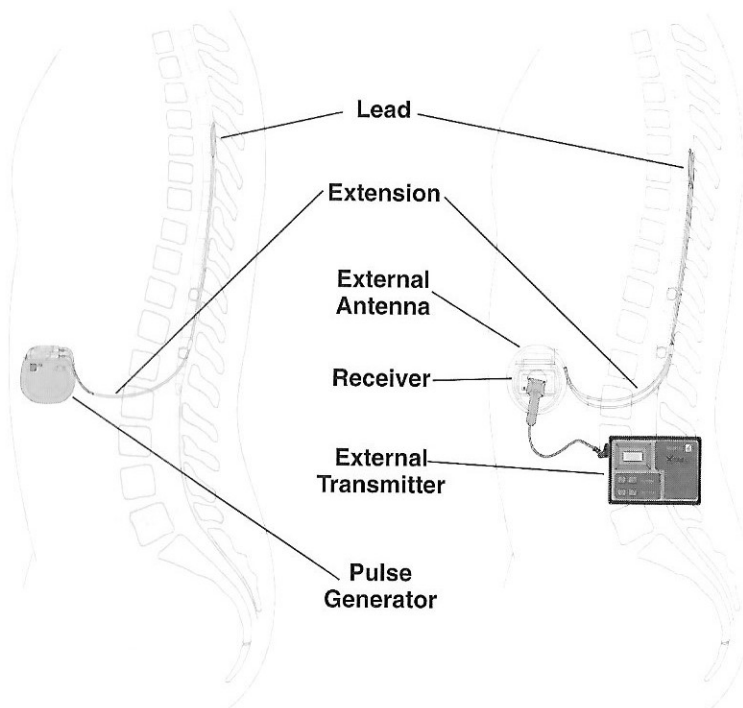
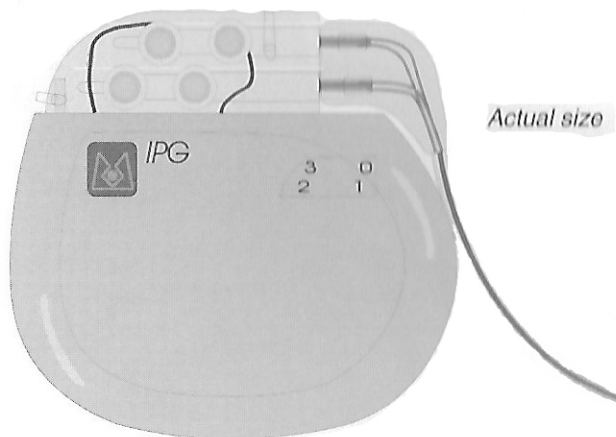


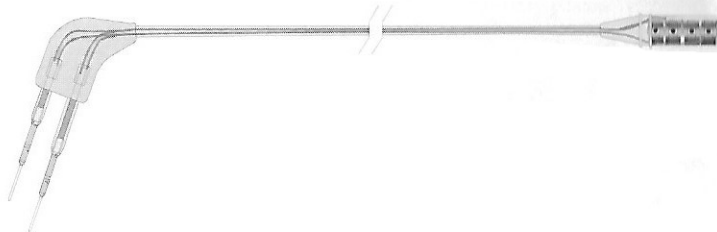
Figure 3. SCS systems with internal (left) and external (right) power sources

Internally-Powered System

Implantable Pulse Generator (IPG) – In a fully implanted system, the IPG is the device that sends exact, electrical pulses to your spinal cord to control your pain. The IPG contains a special battery and electronics to create these pulses. The device, which is about 2½ inches across and less than ½ inch thick, is most frequently placed under the skin in your abdomen or upper buttock.



Extension – The extension is a small cable about 20 inches long that is placed under the skin and connects the lead to the IPG.



Lead – The lead is a small cable about 11 inches long that is placed under the skin. It contains a set of electrodes through which the electrical stimulation is delivered to the spinal cord. A typical lead is pictured below.



Trial Screening Procedure

The trial screening procedure consists of a short test stimulation period in the operating room and an evaluation period of several days. During the evaluation period, your doctor determines your response to SCS. If you experience an adequate level of pain relief and are comfortable with the system, your doctor will implant a complete system.

The goals of trial screening are to:

- Determine if stimulation will cover your pain
- Determine the level of your pain relief
- Give you an opportunity to experience the system
- Assess your battery requirements

Lead-Implant Surgery

The lead-implant surgery:

- Is a surgical procedure
- Involves the use of a special needle or a special surgical procedure to insert the lead
- Is typically performed under local anesthesia
- Lasts approximately 1 to 2 hours
- Is performed in a hospital or outpatient surgical center
- Typically requires that patients be admitted the morning of surgery
- Typically requires a hospital stay ranging from same-day to 3 days

Neurostimulator Implant Surgery Procedure

If the trial screening is successful, you and your doctor will make arrangements for implanting the complete system.

The neurostimulator surgery:

- Is a surgical procedure
- Involves minor incisions for neurostimulator and connections
- Follows the general characteristics of the lead-implant surgery listed on page 15

You will be under local or general anesthesia. Your doctor makes an incision in your skin, usually in the abdomen. The IPG or receiver is placed below the skin, and the lead is connected to the IPG or receiver via the extension.

Will I have pain following the surgery?

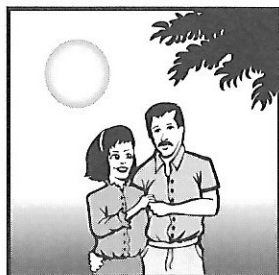
Yes, you will feel some discomfort at both the incision site (in your back) and the IPG or receiver site for several days. “Incisional pain” feels like a bruise, but it heals quickly. You may also experience pain at the IPG or receiver implant site 2 to 6 weeks after the surgery. This pain, caused by forming scar tissue, happens with any type of implant surgery. It is your body’s natural response to the implant. Once the scar tissue forms, the pain will begin to disappear. Use ice to reduce swelling and pain for 24 hours after surgery. Follow your doctor’s or nurse’s instructions for using ice.

What risks are associated with the SCS surgery?

- | | |
|-------------------------|---------------------------|
| ■ Bleeding | ■ Infection |
| ■ Headache | ■ Allergic reactions |
| ■ Hardware difficulties | ■ Failure to relieve pain |
| ■ Spinal cord injury | ■ Paralysis |

Complication risk is low; please discuss this with your doctor.

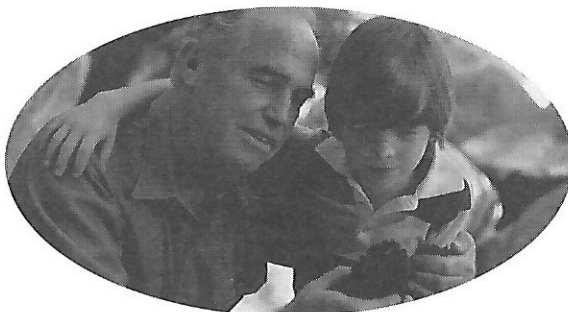
Living with Your SCS System



Will an SCS system limit my activities?

Generally no, but you should always follow your doctor's instructions for activity restrictions. During the first six to eight weeks following the implantation, you will need to avoid lifting, bending, and twisting movements. This allows time for scar tissue to form and anchor the lead. Use normal caution after the initial six to eight weeks. Continue following guidelines for good back care. Certain strenuous activities (for example, moving or lifting heavy objects) may break or move the lead. Consult your doctor before beginning any strenuous activity.

To reduce the risk of damaging your SCS system, you must also avoid certain medical procedures (for example, MRI (magnetic resonance imaging)) and take special precautions with electronic systems and items that contain magnets (for example, theft and security detectors found in libraries and airports). Otherwise, you can safely use household appliances, such as microwaves, TVs, computers, cellular phones, and other items, without fearing interference with your SCS system.



How can SCS help me in my day-to-day activities?

The SCS system may help you increase activities:

- Traveling
- Resuming sexual activity
- Working at your home or job
- Recreation such as walking, hiking, gardening, or fishing

Can I drive a car with my SCS system?

To help ensure safe operation of your vehicle or any equipment you are operating, turn your stimulator OFF. Do *not* drive or use equipment with your stimulator ON. If you are driving a vehicle or operating power tools, a change in stimulation could cause you to lose control of your vehicle or equipment. Initially, long car trips are not recommended because you should avoid sitting for long periods of time.

Will I have problems with my SCS system?

Problems with the SCS system are rare. Strictly follow your doctor's instructions about proper body positioning, lifting, twisting, bending, stretching, and activity levels to minimize problems. It is also important to keep all follow-up appointments as scheduled. Some patients build a tolerance to SCS, and the stimulation effect is reduced or lost. The reasons are not clearly understood. Contact your doctor if you experience changes in stimulation or pain.

Will I feel the SCS system inside me?

The IPG or receiver does not make any noise. It may be felt as a small bulge under your skin. It does not normally show through your clothes. The device is about 2½ inches wide, 2 inches tall, and ½ inch thick. It is usually implanted in the lower abdomen or buttock, where it is most comfortable and least visible. Discuss placement with your doctor before surgery; together you will decide the best location for the IPG or receiver.