Spinal Cord Stimulation (SCS) Therapy: Fact Sheet

What is SCS Therapy?

Spinal cord stimulation (SCS) may be a life-changing[1] surgical option for patients to control their chronic neuropathic pain and may reduce the need for daily medicinal therapy.[2] It is a safe and effective therapy that has been in use for over 35 years. It has helped over 350,000[3] patients worldwide to find pain relief.

Typically, SCS is used for chronic pain when other treatments, such as physical therapy or drugs, have not been effective and offers a viable reversible treatment option.[4] Spinal cord stimulation cannot cure pain or eliminate its cause, but it can help relieve it.

SCS therapy is a reversible procedure, involving a small device called an implantable pulse generator (IPG) and thin wire(s), called lead(s). The IPG is positioned approximately 2.5 cm (1.5“) below the skin surface, usually in the abdomen, upper buttocks or below the collarbone; the leads are placed into the epidural space.

Most pain signals travel from the source of the problem or injury via nerve pathways to the spinal cord and then onto the brain. When the signals reach the brain, they are perceived as pain sensations. To help alleviate pain, the IPG electrically stimulates specific nerves in the spinal cord to mask the perception of pain signals that move along the spinal cord to the brain.

Clinical Indications for SCS Therapy

Common clinical indications for SCS therapy include:

- **Failed Back (Surgery) Syndrome (FBSS):** an umbrella term that describes residual pain that persists despite multiple spine surgeries or other interventions—such as spinal manipulation or nerve blocks—to reduce back and leg pain or repair neurological deficits.
- **Complex Regional Pain Syndrome (CRPS)**: a syndrome of various symptoms, most often caused by trauma, including burning pain, hyperaesthesia[i], swelling, hyperhidrosis[ii], and trophic changes in the skin and bone of the affected areas. Peripheral nerve stimulation may also be indicated for treatment.
- **Peripheral Neuropathy**: any disease/disorder of the peripheral nerves.

[i] Increased sensitivity of any of the sense organs, especially the skin to cold, heat, pain, etc.
[ii] Excessive and profuse perspiration.

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Clinical Effectiveness of SCS Therapy

Two randomised controlled trials have compared the effectiveness of SCS versus other pain management treatments, such as conventional medical management (CMM) and repeat back surgery.

Key findings from these twostudies concluded that:

- SCS is more likely than repeat back surgery to result in a successful outcome by standard measures of pain relief and treatment outcome.[5,c]
- SCS is significantly more successful than repeat operation, by multiple outcome measures, in selected patients with failed back surgery syndrome (FBSS).[5,c]
- In most cases, SCS eliminated the need for further spine surgery in patients identified as reoperation candidates by standard criteria. In contrast to reoperation, SCS provides patients the opportunity to undergo a therapeutic trial before the definitive procedure. Researchers also observed that patients randomised to SCS achieved success more often than those who crossed over to SCS after having had another low back operation. In patients suffering with persistent radicular pain (due to damage or injury to the spinal roots) following lumbosacral spine surgery, clinicians should offer SCS as an alternative to repeated operation before exhausting all surgical alternatives.[5,c]
- Comparing SCS and CMM with CMM alone in patients with FBSS, at 24 months of SCS treatment, selected FBSS patients report sustained pain relief, clinically important improvements in functional capacity and health-related quality of life, and satisfaction with treatment.[5,iii]

Two additional studies* may suggest that early SCS intervention is linked to higher success rates: such rates decrease from 85% with a delay of less than two years to approximately nine per cent if the delay is 15 years or longer.[6 (iv), 7 (v)]

[iii] One hundred failed back surgery syndrome patients were randomized to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. The patients continuing SCS (of 52 randomized to SCS) reported significantly improved leg pain relief ($P < 0.0001$), quality of life ($P \leq 0.01$), and functional capacity ($P = 0.0002$. At 24 months, 46 of 52 patients randomized to SCS and 41 of 48 randomized to CMM who were available, the primary outcome was achieved by 17 (37%) randomized to SCS versus 1 (2%) to CMM ($P = 0.003$) and by 34 (47%) of 72 patients who received SCS as final treatment versus 1 (7%) of 15 for CMM ($P = 0.02$).

[iv] 22 year retrospective review. Study group consisted of 410 patients (252 men, 58 women) with a mean age of 54 years and a mean follow-up period of 97.6 months. The study was conducted over 22 years.

[v] Patients (235) were followed up for periods ranging from 6 months to 15 years with a mean follow-up of 66 months. One hundred and eighty-nine patients received permanent devices; 111 (59%) of these patients continue to receive satisfactory pain relief. Aside from etiologies of pain syndromes as a prognostic factor, the authors have identified other parameters of success. In patients who have undergone previous surgical procedures, the shorter the duration of time to implantation, the greater the rate of success ($p < 0.001$).

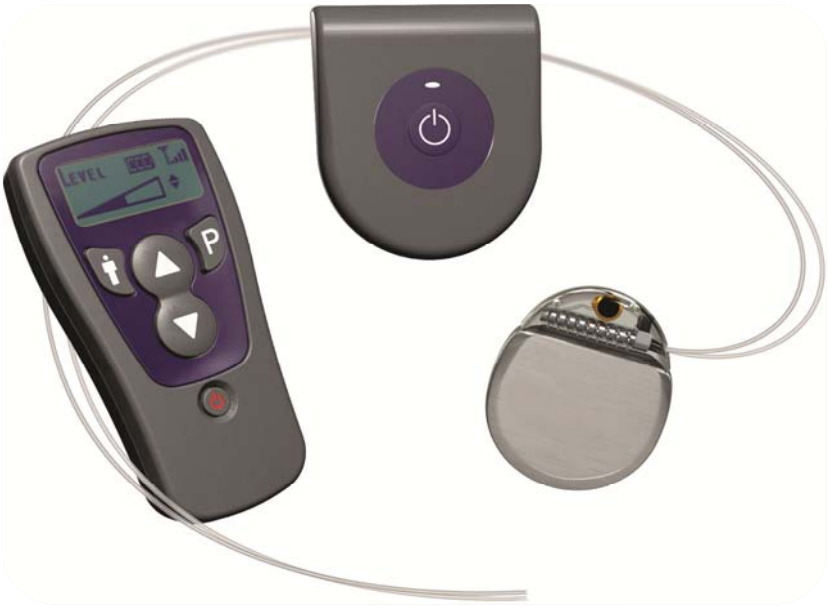
**Results from case studies are not predictive of results in other cases. Results in other cases may vary.*

The Precision™ Plus Spinal Cord System

The Precision Plus System, launched in 2005, is the world's first rechargeable implantable pulse generator (IPG). Today, more than 60,000 patients worldwide have been treated using this particular system.

Precision Plus is engineered to precisely target pain and maintain therapy over time as well as to fit the patient's lifestyle with its system features.

The implantable components of the Precision Plus System consist of the IPG, which is about 5 cm (2") long and less than 1.5 cm (1/2") thick, and the implantable lead(s).



FROM LEFT TO RIGHT, THE PRECISION™ PLUS SPINAL CORD SYSTEM CONSISTS OF A REMOTE CONTROL, A CHARGER, AND AN IMPLANTABLE PULSE GENERATOR (IPG).

- The IPG sends a very low electrical current to a series of metal contacts, called electrodes, at the end of the lead(s).
- Changing the current and other stimulation parameters delivered by the electrodes may help to relieve the patient's pain.
- Electrical pulses turn pain signals into a mild tingling sensation called *paresthesia*. Most patients describe the tingling as pleasant.
- Patients control the signal intensity by using the remote control, which can store up to four different stimulation programs.
- The different programs allow the patient to vary the settings for different pain problems, or different postures (sitting, laying down) at different times of day.

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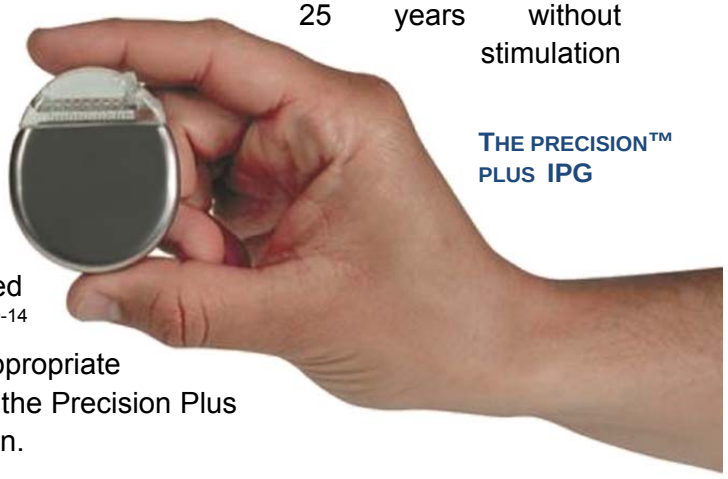
HOW SCS WORKS: ILLUSTRATION SHOWING AN EXAMPLE OF IPG PLACEMENT AND LEAD.

The Precision™ Plus System also includes a battery-charging device known as the charger. The charger is placed onto the skin where the IPG is implanted. Based on the patient's stimulation settings, one charge of the battery can last from one to two days and up to one month depending on the power output utilised.[8]

The Precision Plus System's features may help make a difference to both patients and health care systems.

- The first rechargeable system to market, the IPG of the Precision Plus has a special rechargeable battery that may last up to 25 years without needing to be replaced, based on stimulation parameters and usage.
  Previous IPGs were not rechargeable and often had to be replaced by a further surgical intervention.
  The average life of non-rechargeable SCS devices reported in the published literature is between one to five years.[10-14]
  While a minority of patients may not be appropriate for rechargeable SCS devices, the use of the Precision Plus System can be a more cost effective option.



THE PRECISION™ PLUS IPG

- The system comes with a cordless patient remote control with a wireless range of up to 60cm and a cordless charger, giving the patient more freedom to go about their normal daily activities.
- Zero-Volt™ is a battery technology. If for any reason a patient should forget to recharge their battery and it fully discharges, it does not matter how many times this occurs it will remain possible to recharge it without causing any battery damage. Avoiding damage to the battery means that it will not need to be replaced via another surgical intervention.
- As with any implanted lead or device, the body will naturally create scar tissue around it as part of the healing process. This scar tissue may reduce the amount of electrical current that can be delivered to the correct area of the spinal cord. This occurrence is known as increased "resistance." Precision Plus is the only system that can automatically adjust the amount of current delivered at each individual electrode to overcome any changes in resistance that may occur. This technology ensures that current is delivered to the correct area of the spine, so the patient will continue to receive and maintain the benefits of SCS therapy irrespective of impedance changes.

In summary, SCS therapy has advanced throughout the decades. In over 35 years of use, it has been proven to be a safe and effective therapy for chronic neuropathic pain patients who have failed conventional medical management.

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