

Spinal Cord Stimulation (SCS)

Media Backgrounder

What is SCS therapy?

Spinal Cord Stimulation, or SCS, may offer hope for many of the millions of people who suffer from chronic pain.¹ SCS sends electrical impulses that activate nerve fibres along the spinal cord, masking the pain messages travelling to the brain.¹ When this happens, the painful sensation is replaced with a tingling sensation.² Typically, SCS is used for chronic pain when other treatments, such as physical therapy or drugs, have not been effective.³ SCS has helped over 400,000 patients worldwide to find pain relief and may offer hope for many of the estimated 100 million people in Europe who suffer from chronic pain.^{4,5}

SCS may be prescribed for⁶:

- **Failed Back Surgery Syndrome (FBSS):** a term which describes lingering pain that persists despite multiple spine surgeries or other medical interventions—such as spinal manipulation or nerve blocks.
- **Complex Regional Pain Syndrome (CRPS):** is a chronic (lasting greater than six months) pain condition that most often affects one limb, such as an arm, leg, hand, or foot, usually after an injury. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous systems.⁶
- **Peripheral Neuropathy:** develops when nerves in the body's extremities – such as the hands, feet and arms – are damaged. This can cause numbness and tingling in the feet or hands, burning, stabbing or shooting pain in affected areas, loss of balance and coordination and muscle weakness, especially in the feet.⁷

How does SCS work?

SCS 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 below the skin surface, usually in the upper buttocks or below the collarbone. The leads are placed into the epidural space (the space between the walls of the vertebral canal and the dura mater of the spinal cord). 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.

The burden of chronic pain in Europe and the cost savings with SCS

Chronic pain can undermine the ability to lead a productive working and social life and has a significant impact on European economies. It is estimated that chronic pain may cost up to €300 billion to European healthcare systems and 90% of this can be attributed to costs such as lost productivity and social security and welfare payments.⁸

SCS has the potential to save costs compared with conventional medical management, even with the initial implantation cost.⁹ Improved management of chronic pain promises to generate tangible savings for health systems both in the short as well as the longer term.¹⁰

In the long term, SCS costs are lower because non-SCS patients consume more healthcare resources such as drug therapy, rehabilitation services, and other therapies for pain control. For example, FBSS patients who respond to SCS can potentially return to work, achieve increased pain control and ultimately a better quality of life.¹¹

Cost-effectiveness analyses and clinical studies have shown that SCS is more cost-effective in comparison to other conventional pain therapies one to three years post implant for patients with failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).¹²

Boston Scientific and SCS

Boston Scientific SCS Systems are designed to help maintain therapy over time. Our advanced technologies help adapt the stimulation, which may help maintain the therapy that people with SCS receive.



Figure 1: The Boston Scientific SCS portfolio

Precision Spectra™ ¹³	Precision Novi™ ¹⁴	Precision Montage™ ¹⁵
<ul style="list-style-type: none"> The world's first and only SCS system with 32 contacts, 32 dedicated power sources, and Illumina 3D™ Programming Technology The software is based on a computer model that takes into account 3D anatomical structures, including the conductivity of the spinal cord and surrounding tissue. The physician can select a desired location on the spinal cord and the programming software creates a customised stimulation field to mask the pain of the person with chronic pain. 	<ul style="list-style-type: none"> World's Smallest 16-Contact High-Capacity Primary Cell Device Expands Spinal Cord Stimulator System Offering. The enhanced shape of the Precision Novi implant is designed to provide a new level of comfort to patients with pain treated using primary cell therapy. Precision Novi is powered by Illumina 3D™ Software that enables physicians to target pain precisely with point-and-click simplicity. 	<ul style="list-style-type: none"> Precision Montage™ MRI providing access to full-body MRI scans. Precision Montage delivers Multiple Waveforms, all powered by Illumina 3D. The Precision Montage™ System offers customized relief to patients with chronic pain while also enabling safe access to full body magnetic resonance imaging (MRI) in a 1.5 Tesla environment when conditions of use are met.

Clinical data

- The Lumina study involved 213 patients across multiple sites and demonstrated¹⁶:
 - Highly significant low back pain relief that was maintained over 24 months after initial implant
 - A highly significant improvement in NRS ($p < 0.0001$) pain score in patients with severe low back pain
 - Pain scores with a difference of 65% between baseline pain and 24 months after implant

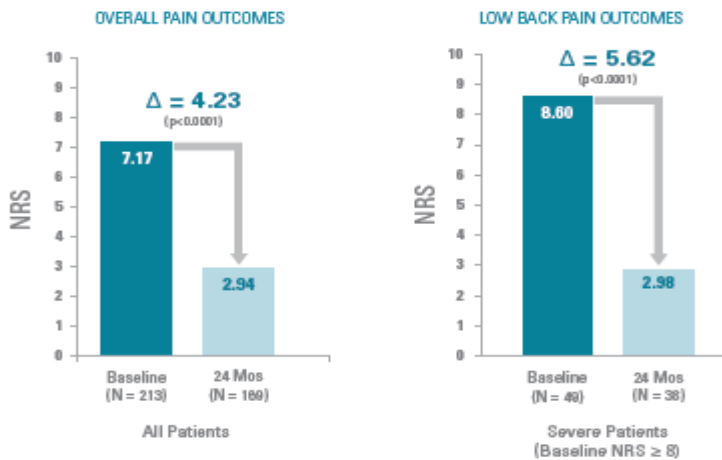
BETTER OUTCOMES WITH ILLUMINA 3D™

70%

Illumina 3D Technology has proven to provide 70% better **low back pain relief** than our previous generation system.

Sustained Pain Relief with Illumina 3D

In the LUMINA multi-center observational study of 213 consecutive Precision Spectra patients across 13 sites, highly significant pain relief was maintained out to 24 months.



This pain relief, Powered by Illumina 3D, is now available in a complete portfolio of devices to treat the varying needs of your unique patients.

For more information on Boston Scientific in SCS, visit <http://www.bostonscientific.com/en-EU/medical-specialties/pain-medicine/products.html>

Media contact

Rosie Ireland
Corporate Communications
Specialist Europe
Boston Scientific
+44 7585 403359
rosie.ireland@bsci.com

References

- 1 Kumar, 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;132:179–188.
- 2 Simpson, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technology Assessment* 2009;13:178:1-176.
- 3 Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin Technology appraisal guidance [TA159] Published date: 22 October 2008
<https://www.nice.org.uk/guidance/ta159/chapter/1-Guidance>
- 4 Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment” by Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D and published in the [European Journal of Pain](https://doi.org/10.1007/s10286-006-0111-1) 2006;10(4):287-333 (11).
- 5 American Association of Neurological Surgeons, 2008. Available at :
<http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Spinal%20Cord%20Stimulation.aspx>
- 6 Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Technology appraisal guidance Published: 22 October 2008 www.nice.org.uk/guidance/ta159
- 7 NHS Choices. Peripheral neuropathy <http://www.nhs.uk/conditions/Peripheral-neuropathy/Pages/Introduction.aspx> (Accessed May 2017)
- 8 Pain Proposal: Improving the Current and Future Management of Chronic Pain. A European Consensus Report 2010
- 9 Manca A et al. Quality of life, resource consumption and costs of spinal cord stimulation vs. conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *Eur J of Pain*. 2008
- 10 Pain Proposal: Improving the Current and Future Management of Chronic Pain. A European Consensus Report 2010
- 11 Kumar KR et al. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: cost effectiveness analysis. *Neurosurgery* 2002; 51:1:106–116.
- 12 Taylor. RS et al. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. *J Pain Symptom Manage*. 2004;27:37-78
- 13 Boston Scientific news release: [Boston Scientific Launches Precision Spectra™ Spinal Cord Stimulator System In The United States](#)
- 14 Boston Scientific news release: [Boston Scientific launches the Precision NOVI™ Spinal Cord Stimulator System in Europe](#)
- 15 Boston Scientific news release: [Boston Scientific Receives U.S. FDA Approval for Precision Montage™ MRI Spinal Cord Stimulator System](#)
- 16 Boston Scientific [LUMINA data](#) presented at the 19th annual meeting of the [North American Neuromodulation Society](#)



The Precision Spectra™ SCS System with Image Ready MRI Technology is "MR-Conditional" only when exposed to the MRI environment under the specific conditions defined in the Image Ready™ MRI Guidelines for Precision Spectra Spinal Cord Stimulator System.

Indications for Use: Boston Scientific Neuromodulation Spinal Cord Stimulator Systems are indicated as an aid in the management of chronic intractable pain.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

NM-487713-AA NOV2017

©2017 Boston Scientific Corporation or its affiliates. All rights reserved.