FOR GENERAL PRACTITIONERS - FREQUENTLY ASKED QUESTIONS

What is a Spinal Cord Stimulation?

After several decades of use, Spinal Cord Stimulation (SCS) treatment is a well-established treatment [1] for the management of chronic intractable pain [2] with over 350,000 people successfully treated worldwide [3]. The SCS procedure should be carried out by an experienced specialist physician working as part of an interdisciplinary team. As with any surgical procedure, there are risks involved and potential side effects vary from patient to patient.

To assess whether a patient will receive benefit from permanent implantation of a SCS device, the patient will have a trial procedure first. Your patient will be implanted with temporary leads which will then be connected to an external trialling system. The trialling period can last between three days and three weeks, after which the leads and trialling system will be removed. The patient and their specialist will then assess the benefit to determine whether permanent implantation is likely to be successful. Usual criteria for a positive trial are > 50% pain relief and overall patient satisfaction.

Facts about Spinal Cord Stimulation:

It can be trialled first.
It is reversible.
It is covered by most private health insurers.**
It can lead to improved health outcomes, if considered at the onset of the patient's chronic pain. [4]
It is a more effective alternative to repeat operations or increased opioid use. [5]

** Always consult private health insurance for eligibility.

Contraindications for permanent SCS therapy are patients who [2]:

- Are unable to operate the SCS system
- Have failed trial stimulation by failing to receive effective pain relief
- Are poor surgical risks
- Are pregnant

Upon discharge, your patient will be given verbal and written instructions to avoid excessive lifting, twisting, or bending to prevent lead migration.

How does Spinal Cord Stimulation work?

In use for more than 40 years, spinal cord stimulation (SCS) delivers pulses of electricity directly to the nerves to interrupt pain signals before they reach the brain.

A small implantable pulse generator (IPG) and insulated wires are implanted into the body, near the spinal column. Metallic contacts at the end of each wire deliver electrical impulses to specific locations on the spinal cord to mask the pain signals.

With older SCS models, patients experience these electrical impulses as a gentle, tingling feeling called paraesthesia. With recent advances in waveform technology, your patient now has a choice over how they experience these electrical impulses. With some specific settings, the patient can achieve pain relief without any accompanying sensations [6].

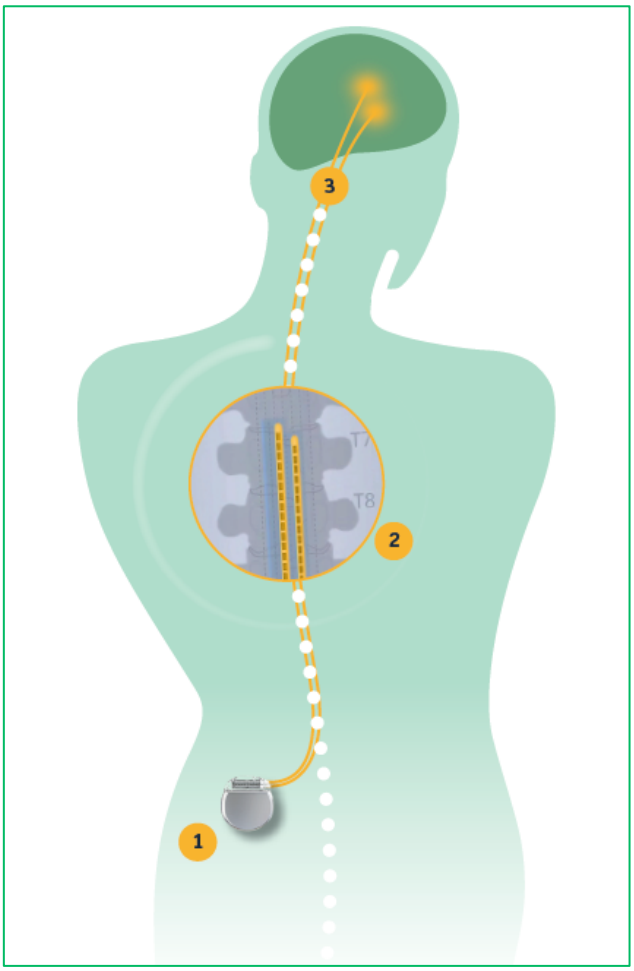

Image from Boston Scientific

What type of pain does Spinal Cord Stimulation work for?

The most common indications for SCS include failed back surgery syndrome (FBSS) with radicular pain, complex regional pain syndrome (CRPS), peripheral neuropathy, phantom limb pain, angina, and ischemic limb pain [7]. It can be used to treat patients with more than one pain area including patients with back or neuropathic pain [8]. BSC devices are specifically on-label to aid in the management of chronic intractable pain [2].

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 (increased sensitivity of any of the sense organs, especially the skin to cold, heat, pain, etc.), swelling, hyperhidrosis (excessive and profuse perspiration), 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.

What type of pain does Spinal Cord Stimulation not work for?

There are indications for SCS that have little reported evidence of success and are unlikely to work [9]. They include pain associated with spinal cord injury, central pain of non-spinal cord origin, avulsive brachial plexopathy and nociceptive axial pain following surgery [9]. The interested reader is also directed to the 2014 Neuromodulation Appropriateness Consensus Committee Guidance document for a detailed discussion of patient selection criteria [10].

What is reprogramming and how is this organised?

To optimise the therapy delivered by an SCS device, stimulation parameters (electrode configuration, amplitude, pulse width and frequency) are adjusted by a BSC representative post-operatively in an inpatient setting. If further adjustment is required, the patient is encouraged to schedule an appointment with their treating physician, at which time the BSC representative will also be present for additional programming. Your patient will be able to adjust their stimulation using their remote control. Typically, patients will see their BSC representative regularly after implantation to finetune the settings, and then as needed with time.

Your patient will also be given contact details of their local BSC representative to assist in the scheduling of programming appointments at the clinic and to help address any stimulator related enquiries.

What scans can/can't a patient have? MRI, X-Ray, CT, SPECT, Ultrasound etc.

Patients can undergo imaging methods such as X-Rays, CT scans, PET scans and diagnostic ultrasounds if stimulation is turned off five minutes prior to the scan [11-13].

In addition, the Precision Montage™ MRI System provides access to full-body MRI scans, under specified conditions, for people who meet the eligibility requirements. Other SCS systems have varying limitations related to MRI scans. For a detailed list of up-to-date eligibility requirements, please refer to our Directions for Use: http://www.bostonscientific.com/manuals.

A non-exhaustive list of interaction advice is also given with the above link. If in doubt, please contact your local NSW Boston Scientific Representative, Denise Winkler 0408 930 966 or BSN Customer Service Team, Toll free: 1800 245 559 for further advice.

What precautions are there with other surgical procedures?

Like other active implantable devices, there are specific contraindications, warnings and precautions that may apply to your SCS patient when considering other surgical procedures, as some modalities may damage the device and/or cause patient injury. Please refer to our most up-to-date guidance on our Directions For Use: http://www.bostonscientific.com/manuals or call our BSN Customer Service Team, Toll free: 1800 245 559 for further advice.

How long does the internal battery last? What to do at EOL?

Rechargeable Devices:

The rechargeable batteries in the Precision Montage™ MRI Spinal Cord Stimulator System and the Precision Spectra™ Spinal Cord Stimulator System should provide at least five years and up to 25 years or more of service [11, 13]. The Precision Montage™ MRI and Precision Spectra™ systems are programmed to end service after 12 years. Approximately six months before the end of the programmed period, the Remote Control displays a weekly message indicating the number of service days remaining. Approximately one month before the end of the programmed period, the message displays daily [11, 13].

Primary Cell Devices:

The Precision Novi™ Primary Cell Spinal Cord Stimulator System is approximately 5.2 years at nominal settings [12].

When the Novi™ battery is nearing depletion, the IPG will enter the Elective Replacement mode. The Elective Replacement Indicator (ERI) will appear on the Remote Control and Clinician Programmer. Failure to replace the IPG may lead to reduced programming capabilities, limited communication with the stimulator and stimulation not being available soon. The stimulator must be replaced to continue to receive stimulation. Batteries that have lasted 12 months or more without entering ERI mode will have a minimum of 4 weeks between entering ERI mode and reaching End of Battery life (EoBL). Surgery is required to replace the IPG at EoBL, although the leads may stay in place while the stimulator is exchanged.

Patients should contact their health care provider upon first receiving a message regarding the number of service days remaining (Montage™, Spectra™) or when they receive the ERI message (Novi™).

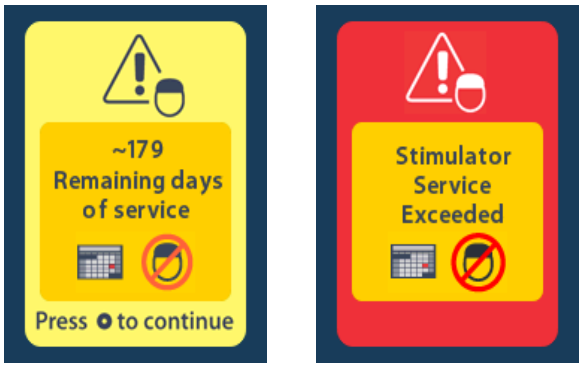

Figure 1:

Figure 2:

Precision Novi™ Remote Control
Elective Replacement Indicator (ERI) warning message (left) and End of Battery Life (EoBL) warning message (right).

Who to contact if they need further information?

For local product and programming support, please contact your NSW BSC Representative, Denise Winkler on 0408 930 966 during business hours. For technical enquiries, please contact our Customer Service Team, who will direct your enquiry to the most suitable member of our Neuromodulation team.

Toll free (within Australia): 1800 245 559, press #2 at the prompt.

Where can a GP learn more about the device?

For up-to-date Directions for Use, please visit: http://www.bostonscientific.com/manuals

References:

[1] K. Kumar *et al.*, "The effects of spinal cord stimulation in neuropathic pain are sustained: A 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation," *Neurosurgery,* vol. 63, no. 4, pp. 762-768, 2008.

[2] Boston Scientific, "Precision Spectra™ System Indications For Use: Directions for Use," 90970620-04 REV AB 2018-06.

[3] *Data on file.*

[4] E. S. Krames, S. Monis, L. Poree, T. Deer, and R. Levy, "Using the SAFE principles when evaluating electrical stimulation therapies for the pain of failed back surgery syndrome," (in eng), *Neuromodulation,* vol. 14, no. 4, pp. 299-311; discussion 311, Jul-Aug 2011.

[5] National Institute for Health and Clinical Excellence, "Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin," in "Technology appraisal guidance [TA159]," 2008.

[6] J. M. North, K.-S. J. Hong, and P. Y. Cho, "Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation in Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial," *Neuromodulation: Technology at the Neural Interface,* 2016.

[7] C. Yampolsky, S. Hem, and D. Bendersky, "Dorsal column stimulator applications," *Surgical neurology international,* vol. 3, no. Suppl 4, pp. S275-S289, 2012.

[8] National Institute for Health and Clinical Excellence, "Spinal cord stimulation for chronic pain of neuropathic or ischemic origin," in "NICE technology appraisal guidance," National Health Service, London 2008.

[9] L. Atkinson *et al.*, "Recommendations for patient selection in spinal cord stimulation," *Journal of Clinical Neuroscience,* vol. 18, no. 10, pp. 1295-1302, 2011.

[10] T. R. Deer *et al.*, "The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee," (in eng), *Neuromodulation,* vol. 17, no. 6, pp. 515-50; discussion 550, Aug 2014.

[11] Boston Scientific, "Precision Montage™ System Information for Prescribers: Directions for Use," 91053246-04 REV A 2017-02.

[12] Boston Scientific, "Precision Novi™ System Information for Prescribers: Directions for Use," 90962628-03 Rev AB 2018-07.

[13] Boston Scientific, "Precision Spectra™ System Information for Prescribers: Directions for Use," 90970880-04 REV AB 2018-07.

CAUTION: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.

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