

## Foreword

Pain medicine physicians have long recognized the benefits of spinal cord stimulation in patients experiencing chronic, refractory neuropathic pain. Even for physicians with understanding and expertise in electrical neuromodulation therapies, it is a daunting task to remain knowledgeable of all aspects of spinal cord stimulation and maintain an updated reference list on this topic. Dr. Richard North and Ms. Jane Shipley's *Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain* has met the clear need for a readily available, fully referenced, peer-reviewed resource of information on spinal cord stimulation.

There is, arguably, no more qualified physician to write about spinal cord stimulation than Richard B. North, MD, Professor of Neurosurgery, Anesthesiology and Critical Care Medicine at The Johns Hopkins University School of Medicine. Dr. North has served as chairman of the Section of Pain of the American Association of Neurological Surgeons, is past president of the North American Neuromodulation Society, and has over 30 years of experience in the design, development, and implantation of devices for pain. In addition, he has trained hundreds of residents and scores of fellows at Johns Hopkins, and perhaps thousands of clinicians who have attended his lectures and studied his research. Lastly, Dr. North was the recipient of the 2007 Founders Award, presented by the American Academy of Pain Medicine and given to an individual for outstanding contributions to the basic or clinical science of pain medicine and for demonstration of clinical excellence or innovation in the practice of pain medicine. I cannot think of a more worthy recipient.

Before reading *Practice Parameters*, there are two terms that warrant defining. The first term is "parameter," which refers to a range of variations that might influence a choice. The practice parameters presented in this supplement are intended to support, and not restrict, the clinical decisions of pain medicine physicians using evidence-based criteria. Their sole objective is to increase the reader's expertise of spinal cord stimulation. The second term is "mentor," which refers to an

advisor, a counselor, or a role model. To me, a mentor also implies a personal relationship between a pupil and a respected teacher. Although I have never had the privilege of working directly with Dr. North in a clinical setting, I do know him through his writings, lectures, and working with him in the preparation of these *Practice Parameters*. He is truly a mentor to us all.

I would like to highlight the collaborative effort that was instrumental in the creation of *Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain*. The Neuromodulation Therapy Access Coalition (NTAC) is a newly formed coalition of medical specialty societies, medical device manufacturers, and patient advocates dedicated to ensuring appropriate patient access to neuromodulation therapies and the highest quality patient care. The NTAC was responsible for convening the interested parties and experts whose voices were essential in shaping this document. The NTAC has underwritten the publication of *Practice Parameters* and will play an ongoing role in disseminating this document. The NTAC, the many contributing medical society representatives and the organizations that have already endorsed this document (American Academy of Pain Medicine, International Spine Intervention Society, and North American Neuromodulation Society) feel that these *Practice Parameters* represent a balanced, evidence-based, and timely resource for clinicians. We are hopeful that the information contained within *Practice Parameters* will also ensure favorable insurance coverage and payment decisions with the ultimate effect of improving access to appropriate care for those patients requiring spinal cord stimulation.

It is with great pride and respect for Dr. North that the Editorial Board of Pain Medicine presents *Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain*.

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# Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain

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### Financial Disclosure

Neither Dr. North nor Ms. Shipley receives direct funding from the three manufacturers of spinal cord stimulation (SCS) systems; however, their employer, The Johns Hopkins University, has received research support from the three companies. Dr. North has received no funding or salary support for his contribution to this project. Ms. Shipley has received support from The North American Neuromodulation Society for her work on this project. The North American Neuromodulation Society receives support from the SCS manufacturers. Some Neuromodulation Therapy Access Coalition members are employed by the SCS manufacturers, as is disclosed in the list of contributors. All other members are disclosing any support from the SCS manufacturers.

Although coalition members have contributed their expertise to this project, neither the views nor the special interests of the SCS manufacturers have influenced the information presented in this document. The work of Dr. North and Ms. Shipley in compiling and editing this document is independent of industry influence. This statement, though straightforward, is, of course, impossible to prove. Indeed, one of the outside reviewers of this document conflated industry involvement with industry influence. Our submission of this document to a journal that follows the peer-review process—a process designed to identify bias—signals that we have taken every step possible to ensure that our presentation of these practice parameters is balanced and based on clinical reality as well as on information gained from the results of clinical trials.

### Acknowledgment

We thank The AGREE Collaboration [1] for publishing the *Appraisal of Guidelines Research & Evaluation (AGREE) Instrument*, which guided the development and evaluation of our practice parameters.

### ABSTRACT

*Introduction.* Physicians, policy makers, and other interested parties require a synthesized, critical,

and clear compilation of the following information to optimize spinal cord stimulation (SCS) for neuropathic pain: 1) indications and potential beneficial outcomes; 2) answers to key clinical questions; 3) cost/resource use implications; and 4) the quality and source of the evidence. This information must be nonjudgmental and noncoercive and have the sole objective of increasing the reader's expertise.

*Study Design.* Evidence-based literature review and consensus statement.

*Methods.* We consulted with experts to identify clinical-practice questions. Then, we conducted a critical literature review (MEDLINE, EMBASE, 1967 through March 2007) to grade treatment practices from “options” to “recommended.” We created a bibliographical database of all citations pertinent to each practice question. Several experts not otherwise involved reviewed the draft document.

*Results.* We answered 64 questions covering 1) indications; 2) potential beneficial outcomes; 3) prognostic factors; 4) patient selection for screening trial; 5) procedural risk management; 6) screening trial; 7) device options; 8) patient management; 9) factors affecting the delivery and quality of SCS treatment; and 10) cost-effectiveness. Most of our more than 300 references are cited multiple times (in each pertinent category). This is the first overview that seeks to categorize and place the entire SCS clinical literature at the disposal of the reader. It presents the first grading system that incorporates, among other evidence sources, an assessment of the likelihood of a favorable outcome based on the evidence provided by expert consensus combined with consideration of the risk and potential benefit of an action.

*Conclusions.* *The Practice Parameters for Spinal Cord Stimulation in the Treatment of Neuropathic Pain* answers important questions. It assesses supporting evidence and provides specific citations to enable the reader to conduct further study. The document will be updated regularly in a Web-based version.

*Key Words.* Spinal Cord Stimulation; Neuropathic Pain; Indications; Patient Selection; Outcomes; Prognostic Factors; Risk Management; Device Options; Patient Management; Delivery of Health Care; Quality of Health Care; Cost-Effectiveness

## Executive Summary

Spinal cord stimulation (SCS) is a reversible pain therapy applied with sophisticated techniques that include multi-output implanted pulse generators and a choice of electrodes, some of which can be placed percutaneously. Patients must pass an SCS screening trial before undergoing implantation of a permanent system. The technical goal of the screening trial is to achieve stimulation paresthesia at a subjectively comfortable level, overlapping a patient's topography of pain. Technical success, however, is not sufficient to ensure clinical success. Some patients with complete coverage of the topography of pain report little or no pain relief.

These practice parameters provide a synthesized, critical, and clear compilation of the information needed to optimize the use of SCS as a treatment of chronic neuropathic pain.

### Target Audience

- Health care providers adopting best practices for referral and treatment;
- Medical school faculty improving education and training;
- Scientists identifying research targets;
- Policy makers;
- Device manufacturers identifying research and development targets;
- Insurers quantifying and improving cost-effectiveness;
- Patients making informed decisions; and
- The general public.

Although the information in this document might influence or reinforce physician choices, it is not intended to be coercive or judgmental. The evidence that supports the clinical decisions and treatment options is presented and graded with the sole objective of increasing the confidence of clinicians who wish to incorporate this information into their practices. In addition, the information provided has important implications for the cost and consumption of health care resources, which will be appropriately noted.

These practice parameters will apply to the majority of patients; in each case, however, the answers (summarized below) to the clinical-practice questions are useful for individualizing treatment and are not meant to substitute for a clinician's best judgment.

### Neuropathic Pain Indications

- Failed back surgery syndrome (FBSS)

- Complex regional pain syndrome (CRPS) I and II
- "Other" (peripheral neuropathic pain, phantom limb/postamputation syndrome, postherpetic neuralgia, root injury pain, spinal cord injury/lesion)

### Potential Beneficial Outcomes

- Pain relief (with multiple measures of pain relief considered)
- Reduced consumption of health care resources (including medication)
- Improved ability to engage in the activities of daily living
- Improved quality of life
- Patient satisfaction with treatment
- Improvement in symptoms of depression
- Return to work in patients whose uncontrolled chronic pain was the only impediment to gainful employment
- Improved neurologic function might occur as an indirect benefit of pain control or discontinuation of other treatment

### Prognostic Factors

- Age: The safety and effectiveness of SCS in children is not established. Age-related infirmity might reduce the chances of a good outcome with SCS, but each patient must be assessed on an individual basis.
- Sex: No reason exists to exclude patients based on their sex.
- Pregnancy: The safety status of SCS during pregnancy remains to be established. The use of SCS must be balanced against known or potential adverse effects of alternative pain treatments.
- Life expectancy: An SCS system with an external stimulator might be more cost-effective than an implanted generator in a patient (e.g., one with terminal cancer) who has a very short life expectancy.
- Worker's compensation or litigation status: We have inadequate information to determine if worker's compensation or litigation status influences SCS outcome.
- Pain characteristics: Radicular or radiating neuropathic pain that 1) has an objective basis; 2) has a distribution consistent with the results of the physical examination and diagnostic studies; and 3) is linked to a specific diagnosis is most straightforward to treat. Treatable pain will be adequately relieved during a screening trial.

**Patient Selection for Screening Trial**

Information to determine a patient's suitability for a screening trial is gathered from the history, including pain location and intensity; physical examination; imaging studies; and a psychological evaluation (required before permanent implantation).

**Relative Contraindications to the Screening Trial**

- An unresolved major psychiatric comorbidity;
- The unresolved possibility of secondary gain;
- An active and untreated substance abuse disorder;
- Inconsistency among the history, pain description, physical examination, and diagnostic studies;
- Abnormal or inconsistent pain ratings;
- A predominance of non-organic signs (note that Waddell's signs are nonspecific);
- Alternative therapies with a risk–benefit ratio comparable to that of SCS remain to be tried;
- Pregnancy;
- Occupational risk;
- Local or systemic infection;
- Presence of a demand pacemaker;
- Presence of a cardioverter defibrillator;
- Foreseeable need for magnetic resonance imaging (MRI);
- Presence of a major comorbid chronic pain syndrome; or
- Anticoagulant or antiplatelet therapy.

**Contraindications to SCS Therapy**

- Inability to control the device;
- Nerve compression amenable to surgery causing a serious neurologic deficit;
- Gross instability at risk for progression;
- Coagulopathy, immunosuppression, or other conditions associated with an unacceptable surgical risk; or
- Need for therapeutic diathermy.

**Procedural Risk Management**

To reduce the general risk of SCS, discharge instructions must indicate when and how to contact the patient's physician, the device manufacturer, and emergency care providers.

**Risks Associated with SCS**

- Spinal cord or nerve injury;
- Dural puncture;
- Infection;
- Epidural hematoma;

- Electrode migration;
- Implanted pulse generator failure; and
- Electromechanical failure of lead or extension cable.

**Screening Trial**

The 3- to 8-day screening trial duplicates the definitive procedure and offers the most meaningful prognostic sign that SCS will succeed or fail.

A percutaneous catheter electrode placed under fluoroscopy provides easy access to multiple spinal levels and facilitates mapping of paresthesia/pain overlap to determine the optimal longitudinal level for the electrode.

A surgical plate/paddle electrode, however, might be required for screening if a percutaneous catheter electrode cannot access the epidural space satisfactorily, e.g., in a patient who has undergone a previous laminectomy or posterior fusion at the level of insertion. In addition, a surgical plate/paddle electrode might be useful to eliminate excessive side effects or provide sufficient pain/paresthesia overlap.

Anchoring an electrode for use during the screening trial and permanent stimulation thereafter reduces the cost of hardware in patients who have a successful trial but increases the cost of the screening procedure because the electrode must be inserted and removed (if necessary) in an operating room. Anchoring a trial electrode for potential permanent stimulation also increases incisional pain and requires the use of a percutaneous extension cable, which increases the risk of infection. On the other hand, a percutaneous catheter electrode designed solely for screening is relatively inexpensive, can be inserted under sterile conditions with fluoroscopy, and can be removed easily.

Using the same electrode for the screening trial and permanent stimulation eliminates the possibility that the replacement electrode will not reproduce the pain/paresthesia overlap. Using a new, permanent electrode, however, provides the opportunity to improve the screening-trial results.

Unless the trial electrode is routinely removed, a patient and clinician's bias that SCS will be successful could be bolstered by the expectation that the screening-trial electrode will become permanent and skew the results of the screening trial.

To control procedural pain during trial electrode placement, use a local anesthetic whenever possible. An unconscious patient cannot describe paresthesia coverage or react to changes in stimulation parameters or intraoperative events, which might increase the risk of neurologic injury.

Stimulator parameters are adjusted by a trained professional during the screening trial and after implantation to 1) find the best settings for patients to use as they pursue activities of daily life; 2) maximize comfortable pain/paresthesia overlap; and 3) minimize power requirements.

A successful screening trial results in at least 50% patient-reported pain relief despite appropriate (provocative) physical activity, with stable or reduced analgesic consumption and patient satisfaction.

If sufficient pain/paresthesia overlap does not occur during the screening trial, a repeat trial should be considered.

The screening trial provides important information that will dictate the choice of electrode and stimulator to be implanted and the optimum stimulating configuration.

Medicare and many third-party payers require a successful screening trial before implantation.

#### *Device Options*

For screening trials, specially designed, temporary (less costly) percutaneous electrodes are available, or either type of electrode designed for permanent use may be used with a temporary percutaneous extension cable.

The choice of electrode is determined by individual patient factors and individual clinical factors. Percutaneous catheter electrodes have as many as eight contacts and can be implanted singly, creating a one-dimensional array or multiply, creating a two-dimensional array. Surgical plate/paddle electrodes have as many as 16 contacts in one- or two-dimensional arrays.

The types of stimulator/power generators available are: 1) a radiofrequency receiver with no battery, requiring the patient to wear an external antenna and transmitter during stimulation; 2) a primary cell that requires surgical replacement when the battery is exhausted; and 3) a battery recharged by periodic use of an external radio frequency transmitter.

The factors that dictate the choice of stimulator/power generator are 1) the patient's ability to control the device; 2) the amount of power required; 3) patient convenience; and 4) patient cosmetic concerns.

#### *Patient Management*

##### **Potential Side Effects**

- A change in paresthesia corresponding to change in posture is normal and seldom causes a problem.

- Extraneous paresthesia or motor responses usually can be avoided by careful electrode implantation and postoperative adjustment or by the use of an insulated surgical plate/paddle electrode.
- Unless it is a symptom of infection, pain/irritation from any component of the system can generally be treated topically, but surgical revision is necessary in some cases.

##### **Possible Long-Term Adverse Events**

- Loss of pain/paresthesia overlap can be managed by reassigning contact combinations or revising the electrode.
- Loss or reduction of pain relief despite paresthesia coverage of pain can be treated with adjunct medical therapy.

##### **Adjunct Treatment**

- Baclofen and gabapentin can potentiate the therapeutic impact of SCS.
- All other pain treatments remain available.
- Adjunct treatment is beneficial if a patient's pain has a nociceptive component, which SCS is not expected to treat.

##### **SCS Patient Precautions**

- Avoid placing excessive strain on the system.
- Avoid bending, twisting, or lifting weights over 8 lb (1 gal) for the first 6 weeks after implantation.
- No scuba diving more than 10 m deep.
- No entry into hyperbaric chambers with the absolute pressure above 2.0 atmospheres.
- Disable the SCS system before entering electromagnetic fields produced by anti-theft devices or security screening systems.

##### **Medical Procedures Requiring**

###### **Special Precautions**

- Routine medical tests that might interact with, or be influenced by, the stimulator (e.g., cardiac monitoring)
- Radiation therapy that might capture the pulse generator in the active field
- Radiofrequency ablation or electrocautery
- Lithotripsy

##### **Medical Procedures Contraindicated after Implantation of an SCS System**

- MRI
- Ultrasound over the device
- Diathermy in all body locations

On/off time has a direct effect on battery longevity, but the impact of an imposed duty cycle on pain relief is unknown. In some patients, pain

relief persists for a week after the device is turned off; others must operate the stimulator continuously to obtain pain relief.

To receive appropriate emergency treatment, SCS patients are provided with identification cards from the device manufacturer that contain information on how to contact their physician and the manufacturer's representative.

Follow-up visits should occur as often as necessary to ensure safe and effective operation of the stimulator. The patient should have a postoperative surgical check and SCS adjustment, and on postoperative day 7 to 14, the patient should return for suture or staple removal and any needed additional adjustment. From that point forward, monthly visits should gradually taper to yearly visits.

Elective follow-up of a new patient who was implanted elsewhere should adhere to the routine that applies to any new patient. As is standard, a physician has the discretion to accept or reject any new patient. In emergencies, however, the patient might require immediate treatment.

#### *Factors Affecting the Delivery and Quality of SCS Treatment*

A physician who offers SCS therapy should have successfully completed residency or fellowship training or a preceptorship in SCS (including proctoring by an experienced clinician) in a setting with an adequate patient volume to include candidates for a full range of procedures.

#### *Cost-Effectiveness*

SCS is cost-effective in the treatment of FBSS and CRPS and might be cost-effective in the treatment of other neuropathic pain indications. The cost-effectiveness of SCS can be optimized by adjusting stimulation parameters to prolong battery life, minimizing the incidence of complications, improving equipment design, and careful patient selection.

### **Part I: Background and Development Process**

#### *Spinal Cord Stimulation (SCS)*

Pain has been treated with the application of electrical current since ancient times, when electricity was known only as a mysterious force generated by lightning and some types of fish and conducted through water. After the development of the Leyden jar in 1745 made it possible for physicians to control electrical current, the

therapeutic use of electrical stimulation spread throughout the Western world. With the advent of modern, empirical medicine in the 20th century, however, electrotherapy fell out of favor for most indications until it was revived following the 1965 publication of Melzack and Wall's gate control theory of pain [2].

By 1967, advances in implantable cardiac pacemaker technology enabled investigators to deliver electrical current directly to the spinal cord with surgically implanted electrodes and externally powered stimulators [3]. Today, SCS is a reversible pain therapy applied with sophisticated techniques that include multi-output implanted pulse generators and a choice of electrodes, some of which can be placed percutaneously.

The reversibility of SCS is one of its most important features; unlike the surgical procedures that are commonly performed to relieve pain, SCS does not ablate pain pathways or change a patient's anatomy.

SCS offers patients an additional advantage in that its routine screening trial emulates the definitive procedure before a patient undergoes implantation of a pulse generator. Thus, each patient provides "individually based observational evidence," which, when combined with the broader evidence, "should be used to demonstrate effectiveness and determine appropriate subsequent treatment." [4]

The most common indication for SCS in North America is chronic neuropathic pain, the subject of this document. In Europe, SCS is used most often to treat ischemic pain arising from intractable angina pectoris and to counteract the effects of peripheral vascular disease.

The clinical goals of SCS include

- Relief of pain, with an attendant positive impact on quality of life, health-related quality of life, ability to perform activities of daily living, and (when possible and appropriate) return to work; and
- Reduction in the use of medication.

The technical goal of SCS is to achieve stimulation paresthesia at a subjectively tolerable (comfortable) level, overlapping (covering) a patient's topography of pain [5]. This is a necessary condition for pain relief and can be lost if an electrode migrates, equipment fails, or the pain moves or expands to a new area. Non-invasive system adjustment might recapture pain/paresthesia overlap; however, surgical revision is sometimes necessary.

Technical success is not sufficient to ensure clinical success. Some patients with complete coverage of the topography of pain report little or no pain relief. This lack of relief might be evident during the screening trial, or the relief might be lost over time in the absence of a discernible technical problem. In rare instances, a patient will dislike the sensation of paresthesia and decide not to proceed with the therapy.

### Chronic Neuropathic Pain

Neuropathic pain results from injury to the nervous system. Many patients experience neuropathic pain as a component of pain with a mixed nature and origin, i.e., neuropathic pain commonly coexists with nociceptive or ischemic pain or both.

Patients with chronic pain often experience depression and anxiety, which exacerbates the negative emotional state characterized by the pain sensation and creates a vicious cycle of escalating pain and depression.

### Scope and Purpose

This document addresses

- The indications and potential beneficial outcomes of SCS as a treatment of chronic neuropathic pain;
- The clinical decisions involved in the use of SCS in the target patient population; and
- The quality and source of the evidence that informs these expectations and decisions.

The goal of this project is to provide physicians, policy makers, and other concerned individuals with a synthesized, critical, and clear compilation of the information they need to optimize the use of SCS treatment for chronic neuropathic pain.

Although the information in this document might influence or reinforce physician choices, it is not intended to be coercive or judgmental. The evidence that supports the clinical decisions and treatment options is presented and graded with the sole objective of increasing the confidence of clinicians who wish to incorporate this information into their practices. In addition, the information provided has important implications for the cost and consumption of health care resources, which will be appropriately noted.

These practice parameters will apply to the majority of patients; in each case, however, the answers to the clinical-practice questions are useful for individualizing treatment and are not meant to substitute for a clinician's best judgment.

### Current Best Evidence

... any statement to the effect that there is no evidence addressing the effect of a particular treatment is a non sequitur. The evidence may be extremely weak—the unsystematic observation of a single clinician, or generalization from only indirectly related physiologic studies—but there is always evidence [6].

In 1996, Sackett et al. defined evidence-based medicine as "... the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. **The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research** [emphasis added]. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice" [7].

Despite this clear emphasis on the *integration* of individual expertise and research evidence, some authors have adopted a definition of "evidence-based medicine" that privileges the results of clinical trials and discounts the weight of clinical experience [8], dismissing even the conclusions of acknowledged experts as "mere consensus" [9].

What, then, constitutes the proper hierarchy of evidence? Some investigators assert that the evidence provided by meta-analyses is of the highest quality. Shah [10], for example, notes that Benson and Hartz [11] claim that observational studies and randomized controlled trials (RCTs) "can produce similar estimates of the effects of treatment" and that Concato et al. [12] have shown that "meta-analyses of observational studies produce results that are similar to meta-analyses of randomized trials." Guyatt et al. [13], however, maintain that a single RCT provides better evidence than a systematic review of observational studies and point to a meta-analyses of observational studies [14] that concluded that hormone replacement therapy in women would lead to "a 50% reduction in relative risk of coronary events," whereas the Heart and Estrogen/Progestin Replacement Study RCT [15] found no such effect.

Despite their support for the practice of evidence-based medicine, Guyatt et al. acknowledge that, when making clinical decisions, "evidence is never enough" and the 'hierarchy' [of the strength of evidence for treatment decisions] is not absolute" [6]. Thus, as a practical matter, the type of evidence that informs clinical decisions ranges from the results of RCTs to expert opinion based on direct experience and on comparable

experience (or techniques) used in other medical specialties.

Therefore, the recommendations and options offered in this document reflect the current status of evidence-based practice of SCS. Because SCS elicits perceptible paresthesia, this evidence does not include the results of “blinded” studies.

Our grading system (see Table 1) sets a new standard for evidence-based clinical practice. In order for a standard to be useful in the evaluation of the evidence that helps us make rational decisions about the clinical care of patients, the standard itself must be rational, realistic, and practical. Thus, for example, a dictum from Medicare (the rationale for which is to be discussed separately) has the same practical value as the highest level of evidence. A risk–benefit calculation in combination with expert clinical opinion might likewise compensate for lacunae in the evidence supplied by the results of clinical trials. In our grading system, therefore, we are not suggesting that an “A” equals the highest level of evidence; instead, we define an “A” as a recommended or required clinical action that is valid, useful, or non-negotiable.

**Table 1** Evidence sources and strength of recommendations

Strength of recommendation	Evidence Sources/Rationale
<i>A = Recommended or required Valid, useful, or non-negotiable</i>	<ul style="list-style-type: none"> <li>• Well-designed randomized controlled trials (RCTs)</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Computer modeling studies corroborated by clinical data</li> <li>• Medicare requirement</li> <li>• Only option</li> </ul>
<i>B = Recommended Uncertain validity, apparently useful</i>	<ul style="list-style-type: none"> <li>• Well-designed clinical studies (prospective, nonrandomized cohort studies, case-control studies, etc.)</li> <li>• RCTs with design problems</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>
<i>C = Optional Undetermined validity, might be useful</i>	<ul style="list-style-type: none"> <li>• Flawed RCTs</li> <li>• Retrospective case series</li> <li>• Comparative studies with historical controls</li> <li>• Case reports</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a moderate likelihood of a favorable outcome</li> </ul>

Compared with other published grading systems [17–21], this scheme is simpler in that it has fewer levels, yet broader because it incorporates practical considerations, e.g., only option, risk–benefit.

### Practice Parameters Development Process

1. Review publications on the development of practice parameters (and “guidelines”) as well as publications purporting to present them for SCS.
2. Consult with experts to identify the appropriate clinical-practice questions (this includes delineating the points in patient care where the information is useful for individualizing treatment).
3. Review the literature to identify and grade (see Table 1) treatment practices on a continuum from “options” to “recommended.”
4. Determine search strategy (exclusion/inclusion criteria, languages, dates, databases, search terms, and sources, including specialty journals [e.g., *Neuromodulation: Technology at the Neural Interface*] and additional articles included in reference lists and from expert knowledge).
5. Conduct a literature search.
6. Consult with experts about accepted practice based on direct experience or the translation of experience from other disciplines (this activity, along with presentation of the reports in the literature, will be considered pretesting [piloting] of the recommendations and options presented).
7. Identify, summarize, and appraise the evidence supporting each option.
8. Write the first draft—completion date April 1, 2006.
9. Review the first draft (committee)—initial review period April 1 to May 1, 2006.
10. Reach consensus and resolve any substantive content differences through frank discussion and debate. Suggestions for minor changes (e.g., in terminology) will be filtered through the editor and adopted at his discretion.
11. Identify societies and individuals involved in the development process, including those involved in the external review (include in the final draft).
12. Identify any conflicts of interest (actual, potential, or potentially perceived) on the part of any group member and the sources of funding, support, or sponsorship for preparation of this document (include in the final draft).
13. Integrate comments into the second draft (completion date May 31, 2006).
14. Integrate comments into the third draft (completion date September 11, 2006).

**Table 2** Target audience

Audience	Use
Health care providers, including primary care physicians, neurologists, neurosurgeons, anesthesiologists, orthopedic surgeons, nurses, allied health care providers, and physiotherapists	Adopting best practices for referral and treatment
Medical school faculty	Improving education and training
Scientists	Identifying research targets
Policy makers	Informing policy decisions
Device manufacturers	Identifying research and development targets
Insurers	Quantifying and improving cost-effectiveness
Patients	Understanding options in order to make informed decisions
General public	General understanding

15. Integrate comments into the fourth draft (completion date November 15, 2006).
16. Determine the process for external review. Choose and contact external reviewers.
17. Send the draft to committee and external reviewers for comment.
18. Create three versions of the final document (see Table 2): 1) a complete version that includes findings as well as details about the document development process, the evidence, the bibliography, and the recommendation continuum; 2) a version that can be read quickly and includes only the recommendation continuum; and 3) a version written in a language suitable for the public.
19. Gain final approval.
20. Determine the review/update timing and process because guidelines are “never complete, always imperfect, and continually challenged . . . by new scientific investigation” [16].
21. Disseminate to the target publication, e.g., *Pain Medicine*, a stand-alone Website, and comprehensive guideline sites, such as <http://www.guidelines.gov>.

### Literature Search Strategy

1. Databases: MEDLINE, EMBASE
2. Additional publications: specialty journals (e.g., *Neuromodulation: Technology of the Neural Interface*), books, articles included in reference lists and gleaned from expert knowledge
3. Inclusion criteria:
  - All Western European languages
  - Dates: 1967 through March 2007

4. Exclusion criteria: reviews, meta-analyses
5. Search terms (used with appropriate delineators): spinal cord stimulation, dorsal column stimulation, electrical stimulation

### Format

#### I. Areas Requiring Clinical Decisions

- Indications
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Potential beneficial outcomes
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Prognostic factors
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Patient selection for screening trial
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Procedural risk management
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Screening trial
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Device options
  - Specific questions and answers
  - Strength of Recommendation
  - Evidence sources
- Patient management
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Factors affecting the delivery and quality of SCS treatment
  - Specific questions and answers
  - Strength of recommendation
  - Evidence sources
- Cost-effectiveness
  - Specific questions and answers
  - Strength of recommendation
  - Evidence source(s)

#### II. Alphabetical Bibliography

#### External Review

This document was submitted to an external review by experts.

### External Review Process

Reviewers were nominated by committee members. Four agreed to participate. These reviewers assessed this document using the 26 assessment questions in the *Appraisal of Guidelines Research & Evaluation (AGREE) Instrument* [1]. Dr. North considered each comment and made appropriate changes.

### Reviewers

1. Clifford Goodman, MD
2. Samuel Hassenbusch, MD
3. John Loeser, MD
4. Woodrow A. Myers, Jr., MD, MBA

### Provision for Updating the Document

This document will be updated on a dedicated Website on the first day of each calendar quarter. The printed version of the document will be updated annually.

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## Part II: Practice Parameters—Questions, Answers, Evidence

### Indications

*Which neuropathic pain conditions have been treated successfully with spinal cord stimulation (SCS)?*

1. Failed back surgery syndrome (FBSS) or lumbosacral root injury pain (also known as “arachnoiditis”)

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Well-designed randomized controlled trials (RCTs)</li> <li>• Well-designed clinical studies</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

#### FBSS RCT

North RB, Kidd DH, Farrokhi F, Piantadosi S. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized, controlled trial. *Neurosurgery* 2005;56(1):98–106.

#### FBSS Long-Term<sup>1</sup> Follow-Up Studies

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<sup>1</sup>All patients at least 24 months' follow-up.

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2. Complex regional pain syndrome (CRPS) I (reflex sympathetic dystrophy) and CRPS II (causalgia)

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Well-designed RCTs</li> <li>• Well-designed clinical studies</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

#### CRPS RCTs

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#### CRPS Case Studies

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3. Other (peripheral neuropathic pain, phantom limb/postamputation syndrome, postherpetic neuralgia (PHN), root injury pain, spinal cord injury/lesion)

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Well-designed clinical studies</li> <li>• Case reports</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

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#### Potential Beneficial Outcomes

*What are the potential beneficial outcomes of the treatment of neuropathic pain with SCS?* (See below for assessment methodology.)

- Pain relief: The primary outcome measure of the success of SCS is patient-reported pain relief.
- Reduced consumption of health care resources: Patients in whom SCS is successful should be able to reduce or eliminate their intake of pain medication as well as their use of additional therapeutic procedures.
- Improvement in function as demonstrated by increased ability to engage in activities of daily living, e.g., walking, climbing stairs, sleeping, engaging in sex, driving a car, and sitting at a table
- Improvement in quality of life
- Patient satisfaction with treatment (would repeat treatment to achieve the same result)
- Improvement in symptoms of depression
- Improved neurologic function (lower extremity strength and coordination, sensation, bladder/bowel function) is not an expected direct benefit but might occur as an indirect benefit of pain control or discontinuation of other treatment (viz., opioids).
- Return to work: This is an expected beneficial outcome in patients whose uncontrolled chronic pain was the only impediment to gainful employment. Employment status depends on many factors beyond pain control, however,

including the patient's training and education, field of employment, work history, overall physical condition, and age. Furthermore, it is not unusual for SCS patients to have been disabled by their pain and unable to work for a significant period of time while they were unsuccessfully treated with other therapies before receiving SCS. Any significant unemployment period decreases the likelihood of return to work even after successful treatment. However, some SCS patients, as reported in the cited literature, do return to work, and it is reasonable to assume that when SCS treatment is offered earlier in the treatment continuum, more disabled patients will be able to return to work.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

#### Pain Relief

The arbitrary criterion of 50% pain relief has been used in reports on SCS for decades (see, e.g., Long DM, Erickson DE. Stimulation of the posterior columns of the spinal cord for relief of intractable pain. *Surg Neurol* 1975;4:134–41). For commentaries on this topic, see 1) North RB. The glass is half full. *Pain Forum* 1999;8(4):195–7; and 2) Simpson BA. Selection of patients and assessment of outcome. In Simpson BA, ed. *Electrical Stimulation and the Relief of Pain*. Amsterdam: Elsevier Science; 2003:236–47.

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### *How are the outcomes of SCS assessed?*

- Pain relief: 50% reduction in pain is commonly used as the threshold for success. This may be reported by the patient directly, as a percentage, or it may be calculated from numeric (e.g., 0–10) or visual analog scales (VAS). The results of these different measures might vary in the same patient; in any event, no measure of pain relief has been shown to be an absolute criterion for success or for proceeding to a permanent implant. Pain relief should be considered along with other outcomes, as follows.
- Ability to engage in activities of daily living: standard scales, e.g., the Oswestry Disability Index (disease-specific for low back pain) or the Sickness Impact Profile (general health)
- Work status: patient report
- Health care resource consumption, including the need for additional interventions, is measured by patient self-report, medical records, and/or tracking patient cross-over to an alternative treatment (e.g., from SCS to reoperation). Some instruments, such as the Medication Quantification Scale, might be useful in tracking consumption of specific health care resources.
- Improved neurologic function, as mentioned above, is not an expected direct benefit of SCS. The primary method of gaining information on changes in neurologic function is patient self-report; however, validated scales exist for some conditions (e.g., spinal cord injury).
- Patient satisfaction can only be determined from patient self-report.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

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#### *What measures can be taken to reduce bias in the collection of outcome data?*

Having a disinterested third party (a person not involved in patient care) collect follow-up data reduces bias.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

Aló KM, Redko V, Charnov J. Four year follow-up of dual electrode spinal cord stimulation for chronic pain. *Neuromodulation* 2002;5(2):79-99.

De Mulder PA, te Rijdt B, Veeckmans G, Belmans L. Evaluation of a dual quadripolar surgically implanted spinal cord stimulation lead for failed back surgery patients with chronic low back and leg pain. *Neuromodulation* 2005;8(4):219-24.

Devulder J, de Laat M, van Bastelaere M, Rolly G. Spinal cord stimulation: A valuable treatment for chronic failed back surgery patients. *J Pain Symptom Manage* 1997;13(5):296–301.

Fiume D, Sherkat S, Callovini GM, Parziale G, Gazzeri G. Treatment of the failed back surgery syndrome due to lumbo-sacral epidural fibrosis. *Acta Neurochir Suppl* 1995;64:116–8.

Koeze TH, Williams AC, Reiman S. Spinal cord stimulation and the relief of chronic pain. *J Neurol Neurosurg Psychiatry* 1987;50(11):1424–9.

Kumar K, Nath RK, Toth C. Spinal cord stimulation is effective in the management of reflex sympathetic dystrophy. *Neurosurgery* 1997;40(3):503–8.

Kupers RC, Van den Oever R, Van Houdenhove B, et al. Spinal cord stimulation in Belgium: A nation-wide survey on the incidence, indications and therapeutic efficacy by the health insurer. *Pain* 1994;56(2):211–6.

Leveque JC, Villavicencio AT, Bulsara KR, Ruvlin L, Gorecki JP. Spinal cord stimulation for failed back surgery syndrome. *Neuromodulation* 2001;4(1):1–9.

North RB, Ewend ME, Lawton MA, Piantadosi S. Spinal cord stimulation for chronic, intractable pain: Superiority of “multi-channel” devices. *Pain* 1991;44(2):119–30.

North RB, Kidd DH, Farrokhi F, Piantadosi S. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized, controlled trial. *Neurosurgery* 2005;56(1):98–106.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–94.

Ohnmeiss DD, Rashbaum RF, Bogdanffy GM. Prospective outcome evaluation of spinal cord stimulation in patients with intractable leg pain. *Spine* 1996;1;21(11):1344–50.

Segal R, Stacey BR, Rudy TE, Baser S, Markham J. Spinal cord stimulation revisited. *Neurol Res* 1998;20(5):391–6.

Sundaraj SR, Johnstone C, Noore F, Wynn P, Castro M. Spinal cord stimulation: A seven-year audit. *J Clin Neurosci* 2005;12(3):264–70.

Van Buyten J-P, van Zundert J, Vueghs P, Vanduffel L. Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium. *Eur J Pain* 2001;5(3):299–307.

Villavicencio AT, Leveque J-C, Rubin L, Bulsara K, Gorecki JP. Laminectomy versus percutaneous electrode placement for spinal cord stimulation. *Neurosurgery* 2000;46(2):399–405.

### Prognostic Factors

#### *Does patient age affect the potential benefit from SCS?*

The safety and effectiveness of SCS in children remains to be established. Age-related infirmity might reduce the chances of a good outcome with SCS, but each patient must be assessed on an individual basis.

Strength of recommendation	A
Evidence source(s)	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Only option (in some cases)</li> </ul>

#### Age Difference Found

Burchiel KJ, Anderson VC, Wilson BJ, et al. Prognostic factors of spinal cord stimulation for chronic back and leg pain. *Neurosurgery* 1995;36(6):1101–10.

#### No Age Difference Found

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: Challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58(3):481–96.

Kumar K, Toth C. The role of spinal cord stimulation in the treatment of chronic pain postlaminectomy. *Curr Pain Headache Rep* 1998;2:85–92.

Kumar K, Toth C, Nath RK, Laing P. Epidural spinal cord stimulation for treatment of chronic pain—Some predictors of success. A 15-year experience. *Surg Neurol* 1998;50(2):110–20.

May MS, Banks C, Thomson SJ. A retrospective, long-term, third-party follow-up of patients considered for spinal cord stimulation. *Neuromodulation* 2002;5(3):137–44.

***Does the patient’s sex affect the potential benefit from SCS?***

Although investigators have reported differences in outcome for men and women, no reason exists to exclude patients based on their sex.

The safety of SCS during pregnancy remains to be established (and must be balanced against the known or potential adverse effects of medication and other treatments for pain).

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**Sex Difference Found**

Fiume D, Sherkat S, Callovini GM, Parziale G, Gazzeri G. Treatment of the failed back surgery syndrome due to lumbo-sacral epidural fibrosis. *Acta Neurochir Suppl* 1995;64:116–8.

Kupers RC, Van den Oever R, Van Houdenhove B, et al. Spinal cord stimulation in Belgium: A nation-wide survey on the incidence, indications and therapeutic efficacy by the health insurer. *Pain* 1994;56(2):211–6.

North RB, Ewend ME, Lawton MA, Piantadosi S. Spinal cord stimulation for chronic, intractable pain: Superiority of “multi-channel” devices. *Pain* 1991;44(2):119–30.

North RB, Ewend MG, Lawton MT, Kidd DH, Piantadosi S. Failed back surgery syndrome: 5-year follow-up after spinal cord stimulator implantation. *Neurosurgery* 1991;28(5):692–9.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–95.

Shimoji K, Hokari T, Kano T, et al. Management of intractable pain with percutaneous epidural spinal cord stimulation: Differences in pain-

relieving effects among diseases and sites of pain. *Anesth Analg* 1993;77:110–6.

Sundaraj SR, Johnstone C, Noore F, Wynn P, Castro M. Spinal cord stimulation: A seven-year audit. *J Clin Neurosci* 2005;12(3):264–70.

Woo-Sam J, Lo S, Wilemon W. Sex differences in adaptation to peripheral electrostimulating surgical implants. *Arc Phys Med Rehab* 1972;53(9):425–9.

**No Sex Difference Found**

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: Challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58(3):481–96.

Kumar K, Toth C. The role of spinal cord stimulation in the treatment of chronic pain postlaminectomy. *Curr Pain Headache Rep* 1998;2:85–92.

Kumar K, Toth C, Nath RK, Laing P. Epidural spinal cord stimulation for treatment of chronic pain—Some predictors of success. A 15-year experience. *Surg Neurol* 1998;50(2):110–20.

Ohnmeiss DD, Rashbaum RF. Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain. *Spine J* 2001;1(5):358–63.

**Pregnancy (Sex Difference)**

Hanson JL, Goodman EJ. Labor epidural placement in a woman with a cervical spinal cord stimulator. *Int J Obstet Anesth* 2006;15(3):246–9.

Segal R. Spinal cord stimulation, conception, pregnancy, and labor: Case study in a complex regional pain syndrome patient. *Neuromodulation* 1999;2(1):41–5.

***Does life expectancy dictate how SCS is used?***

An SCS system with an external stimulator, as is used for screening trials, might be the most cost-effective method of SCS treatment in patients with a very short life expectancy (e.g., those with end-stage cancer).

Strength of recommendation	NA—information only
Evidence source(s)	NA

Hassenbusch SJ, Paice JA, Patt RB, Bedder MD, Bell GK. Clinical realities and economic considerations: Economics of intrathecal therapy. *J Pain Symptom Manage* 1997;14(suppl 3):S36–48.

***Does a patient’s worker’s compensation status or involvement in litigation have an impact on reported SCS outcome?***

We have inadequate information to determine if a patient’s worker’s compensation status or involvement in litigation influences SCS outcome.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

**Worker’s Compensation Status or Involvement in Litigation Considered**

Kim SH, Tasker RR, Oh MY. Spinal cord stimulation for nonspecific limb pain versus neuropathic pain and spontaneous versus evoked pain. *Neurosurgery* 2001;48(5):1056–64.

Kumar K, Toth C. The role of spinal cord stimulation in the treatment of chronic pain postlaminectomy. *Curr Pain Headache Rep* 1998;2:85–92.

Kumar K, Toth C, Nath RK, Laing P. Epidural spinal cord stimulation for treatment of chronic pain—Some predictors of success. A 15-year experience. *Surg Neurol* 1998;50(2):110–20.

Ohnmeiss DD, Rashbaum RF. Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain. *Spine J* 2001;1(5):358–63.

Sundaraj SR, Johnstone C, Noore F, Wynn P, Castro M. Spinal cord stimulation: A seven-year audit. *J Clin Neurosci* 2005;12(3):264–70.

Van Buyten J-P, Van Zundert J, Vueghs P, Vanduffel L. Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium. *Eur J Pain* 2001;5(3):299–307.

***What are the characteristics of the pain that is most likely to be treated successfully by SCS?***

- The pain is radicular or radiating rather than axial in distribution (predominant low back pain is more difficult to treat) and neuropathic rather than nociceptive in nature.
- The pain has an objective basis and a distribution consistent with the results of the physical

examination and diagnostic, e.g., imaging, studies.

- The painful condition is linked to a specific diagnosis.
- Objective findings predominate (as opposed to functional, nonphysiologic signs).
- The pain is adequately relieved during an SCS screening trial (see Screening Trial section).

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

Fiume D, Sherkat S, Callovini GM, Parziale G, Gazzeri G. Treatment of the failed back surgery syndrome due to lumbo-sacral epidural fibrosis. *Acta Neurochir Suppl* 1995;64:116–8.

Kim SH, Toska RR, Oh MY. Spinal cord stimulation for nonspecific limb pain versus neuropathic pain and spontaneous versus evoked pain. *Neurosurgery* 2001;48(5):1056–64.

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: Challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58(3):481–96.

Kumar K, Nath R, Wyant GM. Treatment of chronic pain by epidural spinal cord stimulation: A 10-year experience. *J Neurosurg* 1991;75(3):402–7.

Kumar K, Toth C, Nath RK, Laing P. Epidural spinal cord stimulation for treatment of chronic pain—Some predictors of success. A 15-year experience. *Surg Neurol* 1998;50(2):110–20.

Lang P. The treatment of chronic pain by epidural spinal cord stimulation—A 15 year follow up: Present status. *Axon* 1997;18(4):71–3.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–95.

Waddell G, McCulloch JA, Kummel EG, Venner RM. Nonorganic physical signs in low back pain. *Spine* 1980;5:117–25.

**Prognostic Factors: Miscellaneous**

Hord ED, Cohen SP, Cosgrove GR, et al. The predictive value of sympathetic block for the success of spinal cord stimulation. *Neurosurgery* 2003;53(3):626–32.

Kumar K, Nath R, Wyant GM. Treatment of chronic pain by epidural spinal cord stimulation: A 10-year experience. *J Neurosurg* 1991;75(3):402–7.

Sindou MP, Mertens P, Bendavid U, Garcia-Larrea L, Mauguier F. Predictive value of somatosensory evoked potentials for long-lasting pain relief after spinal cord stimulation: Practical use for patient selection. *Neurosurgery* 2003;52(6):1374–83.

**Patient Selection for Screening Trial*****What position should SCS occupy on the treatment continuum?***

SCS is a minimally invasive therapy. Thus, appropriate non-invasive therapies should have failed or be contraindicated before a patient undergoes an SCS screening trial. Likewise, an SCS trial should precede ablative therapies (e.g., sympathectomies in CRPS patients) and major reconstructive procedures (e.g., reoperation in selected FBSS patients). Some investigators report that the success of SCS decreases as the number of prior interventions a patient has undergone increases and/or as the length of time since the onset of pain increases.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

**Negative Impact Found for Number of Prior Interventions**

Kumar K, Toth C, Nath RK, Laing P. Epidural spinal cord stimulation for treatment of chronic pain—Some predictors of success. A 15-year experience. *Surg Neurol* 1998;50(2):110–20.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–95.

North RB, Kidd DH, Farrokhi F, Piantadosi S. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized, controlled trial. *Neurosurgery* 2005;56(1):98–106.

**Negative Impact Found for Time since Pain Onset**

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: Challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58(3):481–96.

Kumar K, Toth C. The role of spinal cord stimulation in the treatment of chronic pain postlaminectomy. *Curr Pain Headache Rep* 1998;2:85–92.

**No Impact Found for Duration of Symptoms**

May MS, Banks C, Thomson SJ. A retrospective, long-term, third-party follow-up of patients considered for spinal cord stimulation. *Neuromodulation* 2002;5(3):137–44.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–95.

***What tests are used to reveal information about a patient's physical suitability to proceed to the screening trial?***

- **History:** The specialist to whom the SCS patient is referred will review the patient's history pertaining to the neuropathic pain condition (e.g., for a patient with FBSS, operative records will provide critical information on the indications for prior lumbosacral surgical procedures). The history should include information on the patient's medications, allergies, and comorbid pain conditions.
- **Pain location and intensity:** The patient should characterize the pain in detail, indicate its location on a pain map or drawing (for comparison with areas of stimulation paresthesia if the patient proceeds to a screening trial), and rate its intensity with a validated numeric rating or VAS.
- **Physical examination:** In some pain states, especially early in their course, it is possible that no abnormalities will appear during a thorough physical examination. Any abnormalities and/or physical signs (e.g., Waddell has described non-specific, "nonorganic physical signs in low back pain") that do appear, however, should be evaluated for consistency with the patient's pain. The examination might reveal potentially disabling neurologic deficits and/or somatic or functional components of the pain.

- **Imaging studies:** Magnetic resonance imaging (MRI) and, as appropriate, flexion-extension X-rays, computed tomography, myelography, and/or discography can reveal abnormalities concordant with the patient's pain complaint and any surgically remediable cause of significant neurologic deficit. An MRI should be performed in any patient with suspected stenosis, disk herniation, or other anatomic abnormality that will increase the procedural risk of SCS (see section on Procedural Risk Management below). Some clinicians order an MRI before a patient undergoes any SCS procedure to gain information about the depth of dorsal cerebrospinal fluid and the position of the spinal cord, both of which vary among individuals. This information allows clinicians to optimize electrode selection, placement, and adjustment. Others, however, consider a routine preprocedure MRI an unnecessary increase in the cost of SCS therapy.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

### History

Deyo RA, Rainville J, Kent DL. What can the history and physical examination tell us about low back pain? *JAMA* 1002;268:760–65.

Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: Medical and behavioral assessment. *Clin J Pain* 2001;17(3):206–14.

Van de Kelft, De la Porte C. Long-term pain relief during spinal cord stimulation. The effect of patient selection. *Qual Life Res* 1994;3(1):21–7.

### Pain Map

North RB, Fowler KR, Nigrin DA, Szymanski RE, Piantadosi S. Automated pain drawing analysis by computer-controlled, patient-interactive neurological stimulation system. *Pain* 1992;50:51–7.

Parker H, Wood PL, Main CL. The use of the pain drawing as a screening measure to predict

psychological distress in chronic low back pain. *Spine* 1995;20:236–43.

Ransford AO, Cairns D, Mooney V. The pain drawing as an aid to the psychologic evaluation of patients with low back pain. *Spine* 1976;1:127–34.

### Physical Examination

Fishbain DA, Cole B, Cutler RB, et al. A structured evidence-based review on the meaning of nonorganic physical signs: Waddell signs. *Pain Med* 2003;4(2):141–81.

Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: Medical and behavioral assessment. *Clin J Pain* 2001;17(3):206–14.

Waddell G, McCulloch JA, Kummel EG, Venner RM. Nonorganic physical signs in low back pain. *Spine* 1980;5:117–25.

Villavicencio AT, Burneikiene S. Elements of the pre-operative workup, case examples. *Pain Med* 2006;7:S35–46.

### Imaging Studies

Holsheimer J, den Boer JA, Struijk JJ, Rozeboom AR. MR assessment of the normal position of the spinal cord in the spinal canal. *AJNR Am J Neuroradiol* 1994;15(5):951–9.

Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: Medical and behavioral assessment. *Clin J Pain* 2001;17(3):206–14.

### Miscellaneous

Eisenberg E, Backonja MM, Fillingim RB, et al. Quantitative sensory testing for spinal cord stimulation in patients with chronic neuropathic pain. *Pain Pract* 2006;6(3):161–5.

Frank ED, Menefee LA, Jalali S, et al. The utility of a 7-day percutaneous spinal cord stimulator trial measured by a pain diary: A long-term retrospective analysis. *Neuromodulation* 2005;8(3):162–70.

### *What are the psychological characteristics of patients most likely to benefit from SCS?*

We lack sufficient information to predict SCS outcome from the result of a pretreatment psychological evaluation, but SCS, as is the case for every interventional pain treatment, is reserved for patients with no evident unresolved major psychiatric comorbidity.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

### *Is it beneficial to conduct a psychological evaluation?*

The psychological evaluation provides patient selection information by identifying the small percentage of patients who might benefit from psychological treatment before undergoing SCS therapy or in whom SCS therapy might be complicated by psychological factors.

Just as organic disease can influence the results of psychological testing (by influencing a patient's state of mind), underlying psychological factors can influence the course of organic disease. Thus, it is common for patients with chronic pain to have secondary, if not premorbid, psychological comorbidities, and it is routine for a mental health professional to determine if a candidate for SCS has such comorbidities or is engaging in inappropriate drug use.

Medicare requires a psychological evaluation before SCS implantation, and many private insurers follow this example.

Strength of recommendation	A
Evidence source	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Medicare requirement</li> </ul>

### *When should the psychological evaluation take place?*

Some practitioners perform a percutaneous screening trial before the psychological evaluation takes place; however, the psychological evaluation can reveal a reason to postpone the screening trial or other information that would be beneficial at the initial stage of treatment.

The psychological evaluation must, however, occur before a patient undergoes a screening trial with a surgically placed electrode (a percutaneous

electrode anchored for potential use in a permanent system or an electrode implanted via laminectomy or laminotomy) or before a patient receives a complete implanted SCS system.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Medicare requirement</li> </ul>

Beltrutti D, Lamberto A, Barolat G, et al. The psychological assessment of candidates for spinal cord stimulation for chronic pain management. *Pain Pract* 2004;4(3):204–21.

Brandwin MA, Kewman DG. MMPI indicators of treatment response to spinal epidural stimulation in patients with chronic pain and patients with movement disorders. *Psychol Rep* 1982;51:1059–64.

Burchiel KJ, Anderson VC, Wilson BJ, et al. Prognostic factors of spinal cord stimulation for chronic back and leg pain. *Neurosurgery* 1995;36(6):1101–10.

Carlsson AM. Personality characteristics of patients with chronic pain in comparison with normal controls and depressed patients. *Pain* 1986;25(3):373–82.

Daniel MS, Long C, Hutcherson WL, Hunter S. Psychological factors and outcome of electrode implantation for chronic pain. *Neurosurgery* 1985;17(5):773–6.

Doleys DM, Klapow J, Hammer M. Psychological evaluation in spinal cord stimulation therapy. *Pain Rev* 1997;4:189–207.

Dumoulin K, Devulder J, Castille F, et al. A psychoanalytic investigation to improve the success rate of spinal cord stimulation as a treatment for chronic failed back surgery syndrome. *Clin J Pain* 1996;12(1):43–9.

Kupers RC, Van den Oever R, Van Houdenhove B, et al. Spinal cord stimulation in Belgium: A nation-wide survey on the incidence, indications and therapeutic efficacy by the health insurer. *Pain* 1994;56(2):211–6.

Levita E, Rilan M, Waltz JM. Psychological effects of spinal cord stimulation: Preliminary findings. *Appl Neurophysiol* 1981;44(1-3):93-6.

Long DM, Erickson D, Campbell J, North R. Electrical stimulation of the spinal cord and peripheral nerves for pain control. A 10-year experience. *Appl Neurophysiol* 1981;44(4):207-17.

Nelson DV, Kenington M, Novy, DM, Squitieri P. Psychological selection criteria for implantable spinal cord stimulators. *Pain Forum* 1996;5:93-103.

Nielson KD, Adams JE, Hosobuchi Y. Experience with dorsal column stimulation for relief of chronic intractable pain: 1968-1973. *Surg Neurol* 1975;4:148-52.

North RB, Kidd DH, Wimberly RL, Edwin D. Prognostic value of psychological testing in patients undergoing spinal cord stimulation: A prospective study. *Neurosurgery* 1996;39(2):301-10.

Olson KA, Bedder MD, Anderson VC, Burchiel KJ, Villanueva MR. Psychological variables associated with outcome of spinal cord stimulation trials. *Neuromodulation* 1998;1(1):6-13.

Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: Medical and behavioral assessment. *Clin J Pain* 2001;17(3):206-14.

Williams DA. Psychological screening and treatment for implantables: A continuum of care. *Pain Forum* 1996;5:115-7.

***What tests can be used to reveal information about a patient's psychological characteristics and baseline functional status?***

Published examples include

- Minnesota Multiphasic Personality Inventory with Wiggins content scales;
- Symptom Checklist-90-R;
- Derogatis Affects Balance Scale;
- Chronic Illness Problem Inventory;
- Spielberger State-Trait Anxiety Scale and State-Trait Anger Scale;
- Beck Depression Inventory;
- Locus of Control Scale;
- Absorption Scale;
- McGill Pain Questionnaire;
- Social Support Questionnaire;
- Sickness Impact Profile;
- Oswestry Disability Index; and
- Roland Morris Questionnaire.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

#### **Minnesota Multiphasic Personality Inventory**

Brandwin MA, Kewman DG. MMPI indicators of treatment response to spinal epidural stimulation in patients with chronic pain and patients with movement disorders. *Psychol Rep* 1982;51:1059-64.

Fordyce WE, Bigos S, Battie M, Fisher L. MMPI scale 3 as a predictor of back injury report: What does it tell us? *Clin J Pain* 1992;8:222-6.

Moore J, Armentrot D, Parker J, Kiviahian D. Empirically derived pain-patient's MMPI subgroups: Prediction of treatment outcome. *J Behav Med* 1986;9:51-63.

#### **Symptom Checklist-90-R**

Derogatis LR. *Symptom-Checklist-90-R: Scoring and Procedures Manual I for the Revised Version*. Pearson Assessments: Eagan, NM; 1977.

#### **Derogatis Affects Balance Scale**

Derogatis LR. *The Affect Balance Scale*. Clinical Psychometric Research: Baltimore, MD; 1975.

#### **Chronic Illness Problem Inventory**

Kames LD, Naliboff BD, Heinrich RL, Schag CC. The Chronic Illness Problem Inventory: Problem-oriented psychosocial assessment of patients with chronic illness. *Int J Psychiatry Med* 1984;14(1):65-75.

Romano JM, Turner JA, Jensen MP. The Chronic Illness Problem Inventory as a measure of dysfunction in chronic pain patients. *Pain* 49(1):71-75, 1992.

#### **Spielberger State-Trait Anxiety Scale and State-Trait Anger Scale**

Spielberger C. *The State-Trait Anxiety Inventory*. New York, NY: Academic Press; 1970.

Spielberger C. *Manual for the State-Trait Anxiety Inventory (STAI)*. Palo Alto, CA: Consulting Psychologists Press; 1983.

Spielberger CD, Johnson EH, Russell EF, et al. The experience and expression of anger: Construction and validation of an anger expression scale. In: Chesney MA, Rosenman RH, eds. *Anger*

and Hostility in Cardiovascular and Behavioral Disorders. Washington, DC: Hemisphere Publishing Corp; 1985:5–30.

#### Beck Depression Inventory

Beck A, Steer RA, Garbin M. Psychometric properties of the BDI: Twenty-five years of evaluation. *Clin Psychol Rev* 1988;8(1):77–100.

Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Arch Gen Psychiatry* 1961;4:561–71.

Novy DM, Nelson DV, Berry LA, Averill PM. What does the Beck Depression Inventory measure in chronic pain?: A reappraisal. *Pain* 1995;61:261–71.

#### Locus of Control Scale

Lau RR, Ware JF, Jr. Refinements in the measurement of health-specific locus-of-control beliefs. *Med Care* 1981;19(11):1147–58.

Wallston BS, Wallston KA, Kaplan GD, Maides SA. Development and validation of the Health Locus of Control (HLC) Scales. *J Consult Clin Psychol* 1976;44:580–5.

#### Absorption Scale

Tellegen A, Atkinson G. Openness to absorbing and self-altering experiences (“absorption”), a trait related to hypnotic susceptibility. *J Abnorm Psychol* 1974;83:268–77.

#### McGill Pain Questionnaire

Melzack R. The McGill Pain Questionnaire: Major properties and scoring methods. *Pain* 1975;1:277–99.

Turk DC, Rudy TE, Salovey P. The McGill questionnaire reconsidered: Confirming the factor structure and examining appropriate uses. *Pain* 1985;21:385–97.

#### Social Support Questionnaire

Sarason IG, Levine HM, Barsham RB, Sarason BR. Assessing social support: The Social Support Questionnaire. *J Pers Soc Psychol* 1983;44:127–39.

#### Sickness Impact Profile

Bergner M, Bobbitt RA, Carter WB, Gibson BS. The Sickness Impact Profile: Development and final revision of a health status measure. *Med Care* 1981;19:787–805.

#### Oswestry Disability Index

Fairbank JC, Davies JB, Couper J, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66:271–3.

#### Roland Morris Questionnaire

Gronbald M, Jarvinen E, Hurri H, Hulpi M, Karaharju EO. Relationship of the Pain Disability Index (PDI) and the Oswestry Disability Questionnaire (ODQ) with three dynamic physical tests in a group of patients with chronic low back and leg pain. *Clin J Pain* 1994;10:197–203.

#### Fear-Avoidance Belief Questionnaire

Waddell G, Newton M, Henderson I, Somerville D, Main C. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance in chronic low back pain and disability. *Pain* 1993;52:157–68.

#### *Can serious psychological morbidities escape detection by the psychological examination?*

Yes, e.g., conversion disorder.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

Ferrante FM, Rana MV, Ferrante MA. Conversion disorder mimicking Dejerine-Roussy syndrome (thalamic stroke) after spinal cord stimulation. *Reg Anesth Pain Med* 2004;29(2):164–7.

Parisod E, Murray RF, Cousins MJ. Conversion disorder after implant of a spinal cord stimulator in a patient with a complex regional pain syndrome. *Anesth Analg* 2003;96(1):201–6.

#### *What clinical, physical, or psychological patient factors are relative contraindications that would reasonably cause a clinician to defer, delay, or modify the screening trial?*

- An unresolved major psychiatric comorbidity
- The unresolved possibility of secondary gain
- An active and untreated substance abuse disorder
- Inconsistency among the patient's history, pain description, physical examination, and diagnostic studies
- Abnormal or inconsistent pain ratings
- A predominance of non-organic signs (e.g., Waddell's signs)

- Alternative therapies with a risk–benefit ratio comparable to that of SCS remain to be tried
- Pregnancy
- Occupational risk (e.g., employment requires climbing ladders or operating certain machinery or vehicles)
- Local or systemic infection
- Presence of a demand pacemaker
- Presence of a cardioverter defibrillator
- Foreseeable need for an MRI
- Presence of a major comorbid chronic pain syndrome
- Anticoagulant or antiplatelet therapy

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

Contraindications are widely reported in descriptions of study designs.

***What clinical, physical and/or psychological patient factors are absolute contraindications to SCS therapy?***

- Inability to control the device
- For patients with a diagnosis of FBSS:
  - nerve compression (e.g., disc, stenosis) amenable to surgery and causing a serious neurologic deficit
  - gross instability at risk for progression
- Coagulopathy, immunosuppression, or other conditions associated with an unacceptable surgical risk
- Need for therapeutic diathermy

Strength of recommendation	A
Evidence source(s)	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

Contraindications are widely reported in descriptions of study designs.

***Procedural Risk Management***

***How can the general risk of SCS be reduced?***

The risk of an adverse event arising from a medical procedure is always reduced when appropriate precautions are taken. In addition, patients’ discharge instructions must include information about when and how to contact their physicians, the device manufacturer, and emergency care providers.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

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***What risks are associated with SCS?***

Spinal cord or nerve injury, dural puncture, epidural hematoma, infection, wound or skin breakdown, electrode migration, implanted pulse generator failure, and electromechanical failure of lead or extension cable.

*Spinal cord or nerve injury: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of spinal cord injury following SCS treatment, and how can this risk be reduced? (See also hematoma, below.)*

- Incidence: rare
- Time to appearance of symptoms: variable
- Treatment: surgical decompression as necessary
- Usual resolution and impact on therapy: variable
- Worst case adverse sequelae: paralysis, bladder/bowel/sexual dysfunction
- Risk reduction: Before implanting a surgical plate/paddle electrode and in cases of suspected stenosis or another anatomic condition that might increase risk, obtain an MRI of the target spinal levels. (For more information on the pros and cons of obtaining an MRI before the screening trial, see “What tests are used to reveal information about a patient’s physical suitability to proceed to the screening trial?” in

the sections Prognostic Factors and Patient Selection for Screening Trial.)

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Consensus</li> <li>• Cohort studies</li> <li>• Retrospective case series</li> <li>• Case reports</li> </ul>

*Dural puncture: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of dural puncture following SCS treatment, and how can this risk be reduced?*

- Incidence: less than 5%.
- Time to appearance of symptoms: variable, generally within a few hours.
- Treatment: bed rest, hydration, and administration of caffeine; if these are ineffective, consider an epidural blood patch.
- Usual resolution and impact on therapy: Usually not symptomatic, but if so, bed rest could compromise the screening trial.
- Worst case adverse sequelae: headache, subdural hematoma.
- Risk reduction: Use an anesthetic technique that allows the patient to provide feedback during electrode insertion or implantation. When possible, avoid needle placement in areas with pre-existing scarring. In cases of suspected stenosis or another anatomic condition that might increase risk and before implanting a surgical plate/paddle electrode, obtain an MRI of the target spinal levels.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Consensus</li> <li>• Cohort studies</li> <li>• Retrospective case series</li> <li>• Case reports</li> </ul>

#### Dural Puncture

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*Epidural hematoma: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of hematoma following SCS treatment, and how can this risk be reduced?*

- Incidence: rare
- Time to appearance of symptoms: variable (minutes to days)
- Treatment: urgent or emergent surgical evacuation
- Usual resolution and impact on therapy: If treated in time, the problems caused by a hematoma might resolve; electrode removal obviously interrupts SCS therapy.
- Worst case adverse sequelae: paralysis
- Risk reduction: Review the patient's coagulation history, medications, and preoperative blood studies. Monitor the patient closely for a reasonable period of time. Some clinicians observe patients overnight, believing the risk reduction offered by this measure outweighs the expense.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Consensus</li> <li>• Cohort studies</li> <li>• Retrospective case series</li> <li>• Case reports</li> </ul>

Abejón D, Reig E, del Pozo C, Contreras R, Insausti J. Dual spinal cord stimulation for complex pain: Preliminary study. *Neuromodulation* 2005;8(2):105–11.

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*Infection: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of infection following SCS treatment, and how can this risk be reduced?*

- Incidence: approximately 5%
- Time to appearance of symptoms: typically weeks to months, but can be overnight post-procedure or, at the other extreme, several years if the infection arises from hematogenous seeding or slow-growing bacteria
- Treatment: Culture a specimen to guide antibiotic therapy, remove any involved portion of the SCS system (infections limited to the skin over the implant may be treated without removing the underlying, noninvolved implant), and administer an appropriate course of antibiotics. Note that the system will not function with any part removed, and eradicating the infection is easier if the foreign body implant is removed in its entirety.
- Usual resolution and impact on therapy: Infection usually resolves with appropriate treatment. During the time the SCS system is removed, the patient must be treated for pain by other means. The SCS system can be reimplanted when the infection clears.
- Worst case adverse sequelae: paralysis, death
- Risk reduction: Use normal sterile techniques, maintain sterile dressing during the screening trial phase, administer prophylactic intravenous antibiotics before permanent implantation.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Consensus</li> <li>• Cohort studies</li> <li>• Retrospective case series</li> <li>• Case reports</li> </ul>

Abejón D, Reig E, del Pozo C, Contreras R, Insausti J. Dual spinal cord stimulation for complex pain: Preliminary study. *Neuromodulation* 2005;8(2):105–11.

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- Wound or Skin Breakdown (Incidence, Prevention, etc.)**
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- Percutaneous catheter electrode migration: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of percutaneous catheter electrode migration following SCS treatment, and how can this risk be reduced?*
- Incidence: variable depending upon implantation technique
  - Time to appearance of symptoms: immediate to decades
  - Treatment: Non-invasively reassign contact combination if possible; if ineffective, revise the electrode.
  - Usual resolution and impact on therapy: Minor displacement usually can be addressed noninvasively; major displacement requires revision. After fibrous tissue encapsulation occurs, revision might be more difficult, e.g., requiring laminectomy or laminotomy.
  - Worst case adverse sequelae: inability to recapture pain/paresthesia overlap.
  - Risk reduction: Applying silicone elastomer adhesive during anchoring has been reported to prevent longitudinal electrode migration. (This is not necessary or possible with some anchors and techniques, and alternatives are under development.) During system implantation,

avoid increasing mechanical stress by avoiding unnecessary bends of small radius and superfluous connectors. Subject to patient preference and surgical judgment, avoid crossing a mobile joint or body segment with subcutaneous lead wire or extension cable, e.g., a thoracic electrode encounters more stress and strain if connected to an upper buttock pulse generator than if connected to a lateral abdominal generator.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Well-designed clinical study</li> </ul>

*Surgical plate/paddle electrode migration: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of surgical plate/paddle electrode migration following SCS treatment, and how can this risk be reduced?*

- Incidence: Surgical plate/paddle electrodes resist migration after encapsulation.
- Time to appearance of symptoms: immediate, i.e., before encapsulation.
- Treatment: Non-invasively reassign contact combination if possible; if ineffective, revise electrode.
- Usual resolution and impact on therapy: Minor displacement usually can be addressed noninvasively; major displacement requires revision.
- Risk reduction: Some surgeons suture surgical plate/paddle electrodes directly to the dura, but this requires exposing a larger area, which is problematic, and might add mechanical stress. Some use an anchoring/strain relief sleeve to secure the emerging lead wire to the spine. Using absorbable sutures eliminates the continued focal stress that can be caused by non-absorbable sutures after the electrode becomes encapsulated. During system implantation, avoid increasing mechanical stress by avoiding unnecessary bends of small radius and superfluous connectors. Subject to patient preference

and surgical judgment, avoid crossing a mobile joint or segment with subcutaneous lead wire or extension cable, e.g., a thoracic electrode encounters more stress and strain if connected to an upper buttock pulse generator than if connected to a lateral abdominal generator.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> <li>• Consensus</li> </ul>

#### Electrode Migration (Incidence, Prevention, etc.)

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*Implanted pulse generator failure: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of implanted pulse generator failure, and how can this risk be reduced?*

- Incidence: rare, with the exception of battery depletion
- Time to appearance of symptoms: variable, albeit battery depletion is more or less predictable
- Treatment: revision as necessary
- Usual resolution and impact on therapy: resolves upon revision; interrupts therapy pending revision

- Worst case adverse sequelae: infection complicating replacement, necessitating removal of the entire system
- Risk reduction: careful choice of generator

Strength of recommendation	B
Evidence sources	• Consensus

*Electromechanical failure of lead or extension cable: What is the incidence, time to appearance of symptoms, usual resolution and impact on therapy, and worst case adverse sequelae of electromechanical failure of the lead or extension cable following SCS treatment, and how can this risk be reduced?*

- Incidence: rare
- Time to appearance of symptoms: variable
- Treatment: revision as necessary
- Usual resolution and impact on therapy: Surgical revision restores SCS therapy.
- Worst case adverse sequelae: Failure of the lead wire portion of an electrode assembly can require replacement of the entire assembly.
- Risk reduction: Avoid using extra connectors (a potential source of failure that adds mechanical stress to the adjacent cable or lead wire). If extra connectors are used, locate them at or near existing points of fixation. Create service loops from slack, redundant cable or lead wire and place them in locations where they can provide strain relief (e.g., within the fibrous pocket beneath the pulse generator). Subject to patient preference and surgical judgment, avoid crossing mobile segments of the body with cable or lead wire, so as to reduce motion-stress from postural changes; e.g., in patients with low thoracic electrodes, place the pulse generator in the flank or lateral abdomen at the same level as the electrode anchor.

Strength of recommendation	B
Evidence sources	• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of favorable outcome

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#### Foreign Body Reaction

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#### Screening Trial

##### *Does a screening trial provide valid patient selection information?*

Because the SCS screening trial duplicates the definitive procedure (the therapeutic effects, side effects, and patient–control interface), it offers the most meaningful prognostic sign that SCS will succeed or fail. A patient who reports sufficient and satisfactory pain relief during a screening trial of reasonable duration (see below) with stable or reduced analgesic use and a concordant increase in activity should be offered a permanent implant. Thus, as its name implies, the screening trial fulfills both a screening and a trial function.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Medicare requirement</li> </ul>

##### *Does the length of a screening trial affect its ability to provide valid information?*

Valid information about pain/paresthesia coverage and pain relief can be obtained soon after the trial begins. Gaining valid information about the patient's degree of acceptance of the therapy, however, requires more time as does gathering information that supports the patient's report of pain relief (an appropriate reduction in medication consumption and increase in physical activity).

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

##### *What is the optimum length of a screening trial?*

A trial of 3–8 days generally provides sufficient information yet is short enough to reduce the likelihood of infection. Some practitioners, however, conduct trials of up to 3 weeks in duration. Others, in some circumstances, conduct an “on-table” trial

and implant the SCS system immediately after testing.

The advantage of on-table testing is that it obviates the need for a second procedure. The disadvantage is that the abbreviated trial could fail to provide information adequate to predict a short-term failure, which would require a second procedure to reverse the unwarranted implantation of the system.

(Reminder: This information applies to patients with neuropathic, not ischemic pain. In the latter case, clinical practice might differ.)

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

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***What type of electrode should be used for the screening trial?***

Percutaneous electrode placement under fluoroscopy provides access to many levels of the spine with the use of a single epidural needle. This allows mapping of paresthesia/pain overlap to determine the optimal longitudinal level for the electrode. A surgical plate/paddle electrode inserted by laminectomy or laminotomy limits this access and, thus, compromises mapping. Accordingly, most screening trials involve the placement of a percutaneous catheter electrode.

A surgical plate/paddle electrode is required for screening if a percutaneous catheter electrode fails to access the epidural space satisfactorily. A surgical plate/paddle electrode might also be useful if a percutaneous catheter electrode causes excessive

side effects or fails to provide sufficient pain/paresthesia overlap to allow assessment of the potential for SCS to provide pain relief.

In a minority of patients, e.g., those in whom a previous laminectomy or posterior fusion blocks access to the epidural space or in whom the target area (viz., C1) is otherwise inaccessible, it is evident from the outset that the screening trial will require a surgical plate/paddle electrode.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Only option (in some cases)</li> </ul>

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***What is the impact of anchoring the screening electrode at the time of implantation for chronic use if the screening trial is successful?***

**Expense**

Anchoring an electrode for use during the screening trial and permanent stimulation there-

after reduces the cost of hardware in patients who have a successful trial but increases the cost of the screening procedure (see Setting below). On the other hand, a percutaneous catheter electrode designed solely for screening can be less expensive than electrodes designed to be implanted.

### Setting

Inserting a temporary, unanchored percutaneous catheter electrode for the screening trial simply requires sterile conditions and fluoroscopy. In contrast, anchoring a screening trial electrode for potential permanent stimulation requires a surgical incision in an operating room, which increases expense and scheduling difficulty. Should a trial fail, the unanchored percutaneous catheter electrode can be removed easily; removal of an internally anchored electrode must take place in an operating room.

### Outcome

Using the same electrode for the screening trial and permanent stimulation eliminates the possibility that the replacement electrode will not reproduce the pain/paresthesia overlap captured during the screening trial. Implanting a new, permanent electrode in a patient who has gained experience through the screening trial, however, might give the clinician the opportunity to improve upon the results of the screening trial.

Anchoring a trial electrode for potential permanent stimulation increases incisional pain (which could confound the interpretation of the trial's success) and requires the use of a percutaneous extension cable, which increases the risk of infection.

It is reasonable for a patient and clinician to anticipate that an implanted SCS system will provide successful therapy (why otherwise would they participate in the screening trial?); yet this expectation could obfuscate evidence to the contrary during the short-term length of the trial. Expecting the screening trial electrode to become part of the chronic stimulation system could reinforce this positive expectation and, thus, could cause the patient to report a false-positive trial result or the clinician to interpret questionable results in an unwarranted positive light. This source of bias is easily avoided by adopting the practice of always removing the trial electrode.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome</li> </ul>

### *What should be done to control procedural pain during trial electrode placement?*

Whenever possible, screening trials should take place using a local anesthetic. Under general anesthetic, the unconscious patient cannot describe paresthesia coverage or react to changes in stimulation parameters or intraoperative events, which might increase the risk of neurologic injury. In some cases, however, a general anesthetic might be necessary (e.g., for cervical electrode placement of a surgical plate/paddle electrode).

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Only option (in some cases)</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

### *What adjustment options are available and when and where should adjustment of stimulation parameters take place?*

Parameter adjustment requires the assistance of a trained professional and might require specialized equipment. Adjustment takes place during the screening-trial period and after SCS implantation. The goal is to find settings for patients to use as they pursue activities of daily life. The technical goal is to maximize coverage of pain areas with comfortable or tolerable stimulation paresthesia. Minimizing power requirements is an additional goal, to the extent that battery life is important.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

Aló KM, Yland MJ, Kramer DL, Charnov JH, Redko V. Computer assisted and patient interactive programming of dual octrode spinal cord stimulation in the treatment of chronic pain. *Neuromodulation* 1998;1(1):30–45.

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***What determines the perception threshold of stimulation paresthesia?***

- Perception threshold increases with increasing distance of the electrode from the spinal cord, i.e., with increasing depth of the dorsal cerebrospinal fluid and with increasing distance of the electrode from the dura.
- The mediolateral position of the electrode in the spinal canal relative to the physiologic midline influences the perception threshold (which is significantly reduced by lateral asymmetry of less than 1 mm).
- The distance between contacts.
- The size and orientation of the fibers stimulated.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Computer modeling studies</li> </ul>

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Holsheimer J, Wesselink WA. Optimum electrode geometry for spinal cord stimulation: The narrow bipole and tripole. *Med Biol Eng Comput* 1997;35(5):493–7.

***What determines which area is covered by paresthesia?***

- The spinal level of the electrode(s)
- The position of the electrode with respect to the physiologic midline
- The distance of the electrode(s) from the spinal cord
- Individual patient anatomic variance
- The configuration of the electrode(s) and contacts
- The stimulation parameters (pulse width, rate, amplitude)

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Clinical studies</li> <li>• Computer modeling studies</li> </ul>

Barolat G, Massaro F, He J, Zeme S, Ketcik B. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. *J Neurosurg* 1993;78(2):233–9.

Holsheimer J, Nuttin B, King GW, et al. Clinical evaluation of paresthesia steering with a new system for spinal cord stimulation. *Neurosurgery* 1998;42(3):541–7.

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Holsheimer J, Wesselink WA. Effect of anode-cathode configuration on paresthesia coverage in spinal cord stimulation. *Neurosurgery* 1997;41:654–60.

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#### *What constitutes a successful screening trial?*

The generally accepted definition of a successful screening trial is 50% pain relief reported by the patient, despite appropriate (provocative) physical activity, with stable or reduced analgesic consumption. Patient satisfaction is, of course, an additional necessary condition for proceeding.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

#### *When should a screening trial be repeated?*

If the screening trial was technically inadequate (pain/paresthesia overlap was not sufficient), a repeat trial should be considered.

Strength of recommendation	NA—information only
Evidence sources	NA

#### *Are there additional reasons to conduct a screening trial?*

The screening trial provides important information that will dictate the choice of electrode and stimulator to be implanted and the optimum stimulating configuration.

Medicare and many third-party payers require a successful screening trial before implantation.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Medicare requirement</li> </ul>

#### *Device Options*

##### *What types of SCS electrodes are available?*

- For screening trials, specially designed, temporary (less costly) percutaneous electrodes are available, or either type of electrode designed for permanent use may be used with a temporary percutaneous extension cable.
- Percutaneous catheter electrodes have as many as eight contacts. Implantation of a single electrode produces a one-dimensional contact array. Implantation of multiple electrodes can create a two-dimensional contact array.
- Surgical plate/paddle electrodes have as many as 16 contacts in one- or two-dimensional contact arrays.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature on device options

##### *What factors dictate the choice of electrodes for permanent implantation?*

Individual patient factors: Patients who are satisfied with the result of the screening trial with the percutaneous catheter electrode might choose it for the permanent implant. During implantation in children who have yet to reach their full stature, provisions for growth should be considered. In obese patients, percutaneous catheter electrode placement using specially designed Tuohy needles might be advantageous. Insulated surgical plate/paddle electrodes protect susceptible patients from painful or uncomfortable extraneous stimulation (see below: “What advantages do percutaneous catheter electrodes and surgical plate/paddle electrodes offer?”).

Individual clinician factors: Sometimes the choice of electrode follows the choice of technique. A

surgeon, for example, might place a surgical plate/paddle electrode if this is perceived to be the best option. An anesthesiologist or physiatrist, on the other hand, would be expected to use the percutaneous technique.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature on device options

***What advantages do percutaneous catheter electrodes and surgical plate/paddle electrodes offer?***

**Pain/paresthesia mapping:** A percutaneous electrode offers relatively easy access to multiple spinal levels and, thus, facilitates paresthesia mapping. A surgical plate/paddle electrode, however, might be required for screening if a percutaneous catheter electrode cannot access the epidural space satisfactorily, e.g, in a patient who has undergone a previous laminectomy or posterior fusion at the level of insertion.

**Fracture:** There is no inherent difference in the fracture rate for these electrodes.

**Migration:** Longitudinal or lateral migration of an electrode (either a single electrode or one of a pair) can reduce or eliminate pain/paresthesia overlap. Because of its shape, a surgical plate/paddle electrode resists migration once it is encapsulated in fibrous tissue, and, if it has multiple columns of contacts, these are fixed in position with respect to one another. A percutaneous catheter electrode, on the other hand, retains a greater potential to migrate, even after encapsulation. To the extent that migration of percutaneous catheter electrodes can be avoided with the new anchoring techniques referenced herein, this issue is mitigated.

**Extraneous stimulation:** According to one case series with blinded, internal controls, the dorsal insulation on a surgical plate/paddle electrode prevents uncomfortable extraneous stimulation, viz., of nerve fibers in ligamentum flavum, seen in a small fraction of patients.

**Insertion/removal:** Placement of a surgical plate/paddle electrode requires a laminectomy or laminotomy; its removal requires laminotomy. Insertion/removal of the percutaneous catheter electrode does not require laminectomy or laminotomy. Thus, the pain associated with insertion

of a plate/paddle electrode might be greater than that experienced after insertion of a percutaneous catheter electrode.

**Electrode revision:** The scarring that occurs after electrode implantation is greater for surgical plate/paddle electrodes than for percutaneous catheter electrodes; this can present a greater problem if the electrode requires revision.

**Targeting specific sites**

- One RCT and one case series found that, in the treatment of low back and leg pain, compared with the use of percutaneous catheter electrodes at the same spinal level, the use of an insulated surgical plate/paddle electrode improves pain/paresthesia coverage, pain relief, and clinical outcome. Many case series have reported successful treatment of low back and leg pain with both electrode designs.
- Nonrandomized, but controlled, trials concluded that in patients with axial low back pain, an electrode with a single column of contacts placed on the midline affords coverage superior to that provided by a dual column of contacts (created with 1) percutaneous catheter electrodes implanted in parallel or 2) a single surgical plate/paddle electrode). Clinical outcomes, however, were assessed only for the dual column configurations, and they were comparable to those reported in the SCS literature in general. Many large case series report good outcomes with dual column electrodes.
- Modeling studies indicate that the use of a transverse tripole electrode with three columns that allow lateral anodes to bracket a central cathode and, thus, reduce segmental side effects might be advantageous. Limited clinical outcome studies have been reported for this configuration.

**Power requirement:** A surgical plate/paddle electrode requires less power than a percutaneous electrode with the same contact areas and spacing; therefore, the use of a surgical plate/paddle electrode increases the time before surgical battery replacement or recharging is required.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• RCT</li> <li>• Well-designed clinical studies</li> <li>• Consensus</li> </ul>

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Yearwood TL. Tripolar neurostimulator array in the cervical epidural space for the treatment of bilateral lower extremity pain [Abstract]. *Neuromodulation* 2006;9(1):18–9.

***How many contact combinations are available?***

The number of possible bipolar contact combinations ranges from 50 on an electrode with four contacts to 6050 on an electrode with eight contacts. The number of possible combinations soars to the millions for electrodes with 16 contacts, which exceeds the number of combinations that can be tested in a timely fashion, even with the aid of computerized adjustment.

Strength of recommendation	NA—information only
Evidence sources	NA

***What factors dictate the choice of contact configuration?***

The results of computer modeling studies and clinical studies guide the contact configuration strategy, which aims to maximize pain/paresthesia overlap, the range of clinically useful stimulation, and battery life.

Strength of recommendation	A
Evidence source	<ul style="list-style-type: none"> <li>• Computer modeling studies</li> <li>• Well-designed clinical studies</li> </ul>

Aló KM, Redko V, Charnov J. Four year follow-up of dual electrode spinal cord stimulation for chronic pain. *Neuromodulation* 2002;5(2):79–99.

Bennett DS, Aló KM, Oakley J, Feler CA. Spinal cord stimulation for Complex Regional Pain Syndrome I (RSD). A retrospective multicenter experience from 1995–1998 of 101 patients. *Neuromodulation* 1999;2(3):202–10.

Leclercq TA. Electrode migration in epidural stimulation: Comparison between single electrode and four electrode programmable leads. *Pain* 1984;20(suppl 2):78.

Law JD. Spinal stimulation: Statistical superiority of monophasic stimulation of narrowly separated, longitudinal bipoles having rostral cathodes. *Appl Neurophysiol* 1983;46(1–4):129–37.

North RB, Ewend ME, Lawton MA, Piantadosi S. Spinal cord stimulation for chronic, intractable pain: Superiority of “multi-channel” devices. *Pain* 1991;44(2):119–30.

North RB, Kidd DH, Olin J, et al. Spinal cord stimulation for axial low back pain: A prospective, controlled trial comparing dual with single percutaneous electrodes. *Spine* 2005;30(12):1412–8.

***What types of stimulator/power generators are available?***

Implanted generators are available with three types of power source:

- A radiofrequency receiver with no battery, requiring the patient to wear an external antenna and transmitter during stimulation;
- A primary cell that requires surgical replacement when the battery is exhausted; and
- A rechargeable battery requiring only occasional use of a radiofrequency transmitter.

Generators have multiple outputs connected to individual electrode contacts. Most deliver single-channel (as opposed to multichannel) stimulation, i.e., they cannot simultaneously deliver different voltage or current levels to different electrode contacts, although they might do so sequentially.

Strength of recommendation	NA—information only
Evidence sources	NA

***What factors dictate the choice of stimulator/power generator?***

The patient’s ability to control the device, which can be limited by age (too young) or age-related infirmity (too old)

During implantation in children who have yet to reach their full stature, provisions for growth should be considered.

The amount of power required, which influences battery depletion and might be a factor even for rechargeable batteries, which must eventually be replaced

Patient convenience

Patient cosmetic concerns

Grade	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

Deer T, Kim C, Bowman R, et al. Initial experience with a new rechargeable generator: A report of twenty systems at 3 months status postimplant in patients with lumbar postlaminectomy syndrome [Abstract]. *Neuromodulation* 2006;9(1):9–10.

Devulder J, De Laat M, Rolly G. Dual channel electrostimulation in pain. *Acta Neurol Belg* 1998;98(2):195–8.

North RB, Ewend ME, Lawton MA, Piantadosi S. Spinal cord stimulation for chronic, intractable pain: Superiority of “multi-channel” devices. *Pain* 1991;44(2):119–30.

North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–94.

Oakley J, Krames E, Weiner R, et al. Bilateral current fractionalization in spinal cord stimulation [Abstract]. *Neuromodulation* 2006;9(1):17–8.

Stultz M. Quality of life, function and pain relief attributed to two types of spinal cord stimulation systems: Result of a patient survey. *Pain Digest* 1999;9:348–52.

### **Patient Management**

***What are the possible side effects of SCS treatment and how are these managed/avoided?*** (See also section on procedural risks above.)

**Postural changes:** Changes in paresthesia intensity and/or location corresponding to the patient’s changes in posture are normal. Information about this phenomenon should be stressed during patient education and can be demonstrated within hours of placement of a temporary electrode. Most patients comment on postural changes and adjust quickly; some complain short-term, but patients rarely mention the phenomenon at long-term follow-up. Some patients appreciate their ability to control stimulation amplitude with simple postural changes; new SCS systems with multiple

program options might help the few who regard this as a problem to avoid the phenomenon.

**Unwanted stimulation:** Extraneous, local segmental paresthesia or motor responses usually can be avoided by careful electrode implantation technique and postoperative adjustment. The choice of electrode can be important; implanting an insulated surgical plate/paddle electrode can be advantageous.

**Generator site pain:** Pain/irritation from the extension lead or connector, or at the site of the pulse generator, is generally self-limited, unless of course it is a symptom of infection. The external antenna used in radio frequency-coupled devices can irritate the skin. Topical therapy usually suffices, but surgical revision is necessary in some cases.

**Difficulty urinating:** Occasionally, patients report difficulty urinating while stimulation is on; this is resolved by turning the unit off temporarily.

Strength of recommendation	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

Henderson JM, Schade CM, Sasaki J, Caraway D, Oakley J. Prevention of mechanical failures in implanted spinal cord stimulation systems. *Neuromodulation* 2006;9:183–91.

Rosenow JM, Stanton-Hicks M, Rezai AR, Henderson JM. Failure modes of spinal cord stimulator hardware. *J Neurosurg Spine* 2006;5(3):183–90.

### **Postural Changes**

Barolat G, Schwartzman R, Woo R. Epidural spinal cord stimulation in the management of reflex sympathetic dystrophy. *Stereotact Funct Neurosurg* 1989;53(1):29–39.

Olin JN, Kidd DH, North RB. Postural changes in spinal cord stimulation thresholds. *Neuromodulation* 1998;1(4):171–5.

### **Unwanted Stimulation**

North RB, Lanning A, Hessels R, Cutchis PN. Spinal cord stimulation with percutaneous and plate electrodes: Side effects and quantitative comparisons. *Neurosurg Focus* 1997;2(1:3):1–5.

### **Generator Site Pain**

Barolat G, Schwartzman R, Woo R. Epidural spinal cord stimulation in the management of

reflex sympathetic dystrophy. *Stereotact Funct Neurosurg* 1989;53(1):29–39.

#### Difficulty Urinating

North RB, Fischell TA, Long DM. Chronic stimulation via percutaneously inserted epidural electrodes. *Neurosurgery* 1977;1(2):215–8.

#### Foreign Body Reaction

See “What risks are associated with SCS?” above.

#### *What long-term adverse events can occur, and how are these managed?*

- Loss of pain/paresthesia overlap (with or without a sign of electrode migration): First, reassign contact combinations (anodes/cathodes/off); should this fail, the electrode might require revision.
- Loss of pain relief when paresthesia continues to cover the painful area: Treat with adjuvant medical therapy.

Grade	B
Evidence sources	Weighing risk versus potential benefit and expert consensus reveals a good likelihood of a favorable outcome

#### Loss of Pain/Paresthesia Overlap (see also Electrode Migration under Procedural Risk Management)

Bennett DS, Aló KM, Oakley J, Feler CA. Spinal cord stimulation for Complex Regional Pain Syndrome I (RSD). A retrospective multicenter experience from 1995–1998 of 101 patients. *Neuromodulation* 1999;2(3):202–10.

#### Loss of Pain Relief

Barolat G, Schwartzman R, Woo R. Epidural spinal cord stimulation in the management of reflex sympathetic dystrophy. *Stereotact Funct Neurosurg* 1989;53(1):29–39.

Lang P. The treatment of chronic pain by epidural spinal cord stimulation—A 15 year follow up: Present status. *Axon* 1997; 71–3.

#### Other

Barbara G, De Giorgio R, Stanghellini V, et al. Relapsing ulcerative colitis after spinal cord stimulation: A case of intestinal neurogenic inflammation? *Gastroenterology* 1999;117(5):1256–7.

Katz PG, Greenstein A, Severs SL, Zampieri TA, Sahni KS. Effect of implanted epidural stimulator on lower urinary tract function in spinal cord injured patients. *Eur Urol* 1991;20:103–6.

Kemler MA, Barendse GA, Van Kleef M. Relapsing ulcerative colitis associated with spinal cord stimulation. *Gastroenterology* 1999;117(1):215–7.

Loubser PG. Adverse effects of epidural spinal cord stimulation on bladder function in a patient with chronic spinal cord injury pain. *J Pain Symptom Manage* 1997;13(5):251–2.

Meyer F, Sandvoss G. Compound acetabulum fracture caused by overstimulation with a PISCES system [German]. *Zentralbl Neurochir* 1990; 51(3):174–5.

#### *Patient Management: Device Interaction*

##### Cardiac Device Interaction Clinical Studies

Ekre O, Borjesson M, Edvardsson N, Eliasson T, Mannheimer C. Feasibility of spinal cord stimulation in angina pectoris in patients with chronic pacemaker treatment for cardiac arrhythmias. *Pacing Clin Electrophysiol* 2003;26(11):2134–41.

Ferrero P, Grimaldi R, Massa R, et al. Spinal cord stimulation for refractory angina in a patient implanted with a cardioverter defibrillator. *Pacing Clin Electrophysiol* 2007;30:143–6.

##### Cardiac Device Interaction Case Reports/Series

Andersen C, Oxhøj H, Arnsbo P. Management of spinal cord stimulators in patients with cardiac pacemakers. *Pacing Clin Electrophysiol* 1990; 13(5):574–7.

Colini Baldeschi G, Del Giudice GB, Scotti E, et al. Spinal cord stimulation in neuropathic pain of the lower limbs in a patient with Behcet’s disease and permanent cardiac DDD pacing. *Panminerva Med* 2004;46(3):199–200.

Iyer R, Gnanadurai TV, Forsey P. Management of cardiac pacemaker in a patient with spinal cord stimulator implant. *Pain* 1998;74(2–3):333–5.

Monahan K, Casavant D, Rasmussen C, Hallet N. Combined use of a true-bipolar sensing implantable cardioverter defibrillator in a patient having a prior implantable spinal cord stimulator for intractable pain. *Pacing Clin Electrophysiol* 1998;21: 2669–72.

Romano M, Brusa S, Grieco A, et al. Efficacy and safety of permanent cardiac DDD pacing with

contemporaneous double spinal cord stimulation. *Pacing Clin Electrophysiol* 1998;21(2):465-7.

Romano M, Zucco F, Baldini MR, Allaria B. Technical and clinical problems in patients with simultaneous implantation of a cardiac pacemaker and spinal cord stimulator. *Pacing Clin Electrophysiol* 1993;16:1639-44.

Schimpf R, Wolpert C, Herwig S, et al. Potential device interaction of a dual chamber implantable cardioverter defibrillator in a patient with continuous spinal cord stimulation. *Europace* 2003;5(4):397-402.

**What adjunct treatment is available?**

Baclofen and gabapentin can potentiate the pain relief achieved with SCS. Because we have no indication of cross-tolerance between SCS and other pain treatments, all pain treatments remain available. The use of adjunct treatment is beneficial if a patient's pain has a nociceptive component, which SCS is not expected to treat.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**Long-Term Follow-Up Studies**

van Buyten J-P, van Zundert J, Vueghs P, Vanduffel L. Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium. *Eur J Pain* 2001;5(3):299-307.

Lind G, Meyerson BA, Winter J, Linderoth B. Intrathecal baclofen as an adjuvant therapy to enhance the effect of spinal cord stimulation in neuropathic pain: A pilot study. *Eur J Pain* 2004;8:377-83.

**Experimental Study**

Wallin J, Cui JG, Yakhnitsa V, et al. Gabapentin and pregabalin suppress tactile allodynia and potentiate spinal cord stimulation in a model of neuropathy. *Eur J Pain* 2002;6(4):261-72.

**What precautions should patients take in their daily lives after implantation of an SCS system?**

- Avoid placing excessive strain on the system.

- Avoid bending, twisting, or lifting weights over 8 lb (1 gal) in the immediate postoperative period (up to 6 weeks) before the device becomes encapsulated in fibrous tissue.
- No scuba diving more than 10 m deep.
- No entry into hyperbaric chambers with the absolute pressure above 2.0 atmospheres.
- Disable the SCS system before entering electromagnetic fields produced by anti-theft devices, metal detectors, or other security screening systems.

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**Case Report**

Eisenberg E, Waisbrod H. Spinal cord stimulator activation by an antitheft device. Case report. *J Neurosurg* 1997;87(6):961-2.

**What medical procedures must be conducted with special precautions during the screening trial and after implantation of an SCS system?**

- Routine medical tests that might interact with, or be influenced by, the stimulator (e.g., cardiac monitoring) should be avoided, if possible, during the screening trial and interpreted judiciously after implantation.
- Radiation therapy that might include the implanted pulse generator in the active field
- Radio frequency ablation and electrocautery
- Lithotripsy

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**What medical procedures are contraindicated after implantation of an SCS system?**

- MRI: the manufacturers of SCS devices warn that MRI can cause serious patient injury or death.

- Ultrasound over the device
- Diathermy in all body locations

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**MRI Case Reports**

De Andres J, Valia JC, Cerda-Olmedo G, et al. Magnetic resonance imaging in patients with spinal neurostimulation systems. *Anesthesiology* 2007;106:779–86.

Kiriakopoulos ET, Tasker RR, Nicosia S, Wood ML, Mikulis DJ. Functional magnetic resonance imaging: A potential tool for the evaluation of spinal cord stimulation: Technical case report. *Neurosurgery* 1997;41(2):501–4.

Liem LA, van Dongen VC. Magnetic resonance imaging and spinal cord stimulation systems. *Pain* 1997;70(1):95–7.

Schueler BA, Parrish TB, Lin J-C, et al. MRI compatibility and visibility assessment of implantable medical devices. *J Magn Reson Imaging* 1999; 9(4):596–603.

Shah RV, Smith HK, Chung J, Hegazi A, Racz GB. Cervical spinal cord neoplasm in a patient with an implanted cervical spinal cord stimulator: The controversial role of magnetic resonance imaging. *Pain Phys* 2004;7:273–8.

**Should on/off time be imposed?**

On/off time (the duty cycle) has a direct effect on battery longevity (or on the recharging interval), but the impact of an imposed duty cycle on pain relief is unknown. In some patients, pain relief persists for a week after the device is turned off; others must operate the stimulator continuously to obtain pain relief.

Strength of recommendation	NA—information only
Evidence sources	NA

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain:

Challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006; 58(3):481–96.

Monhemius R, Simpson BA. Efficacy of spinal cord stimulation for neuropathic pain: Assessment by abstinence. *Eur J Pain* 2003;7(6):513–9.

**How can an SCS patient receive appropriate emergency treatment?**

All SCS patients are provided with identification cards from the device manufacturer that contain information on how to contact the implanting physician and the manufacturer’s representative, both of whom maintain pertinent patient records.

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**What is the appropriate number and timing of follow-up visits for SCS patients?**

Follow-up visits should occur as often as necessary to ensure the safe and effective operation of the stimulator. Thus, the patient should have a post-operative surgical check and SCS adjustment, and on postoperative day 7 to 14, the patient should return for suture or staple removal and any needed additional adjustment. From that point forward, monthly visits should gradually taper to yearly visits.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**When and how is it appropriate to provide routine follow-up care for an SCS patient who was implanted elsewhere?**

Elective follow-up of a new patient who was implanted elsewhere should adhere to the routine that applies to any new patient. (For example, before an appointment is scheduled, the patient

should provide sufficient information to allow the new physician to form an opinion about whether the patient could benefit from the physician's help.) As is standard in every field of medicine, a physician has the discretion to accept or reject any new patient.

In emergencies (e.g., an obvious implant-related infection), however, the patient might require immediate treatment.

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> <li>• Only option (in some cases)</li> </ul>

**Factors Affecting the Delivery and Quality of SCS Treatment**

*Does the setting (e.g., hospital vs free-standing clinic) in which it is delivered have an impact on the outcome of SCS therapy?*

No definitive evidence is available.

Strength of recommendation	NA
Evidence sources	NA—see Bibliography for relevant literature

Kupers RC, Van den Oever R, Van Houdenhove B, et al. Spinal cord stimulation in Belgium: A nation-wide survey on the incidence, indications and therapeutic efficacy by the health insurer. *Pain* 1994;56(2):211–6.

Lazorthes Y, Siegfried J, Verdie JC, Casaux J. Chronic spinal cord stimulation in the treatment of neurogenic pain. Cooperative and retrospective study on 20 years of follow-up [French]. *Neurochirurgie* 1995;41(2):73–86.

*How can a physician best be trained to offer SCS treatment?*

A physician who offers SCS therapy should have successfully completed residency or fellowship training or a preceptorship in SCS (including procuring by an experienced clinician) in a setting with

an adequate patient volume to include candidates for SCS and for a full range of alternative procedures. Such a setting will allow the physician to gain experience in patient selection (including behavioral evaluation) for each procedure, even if the physician does not provide direct care in every situation.

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

*Does physician experience (i.e., number of years/number of procedures per year) have an impact on SCS outcome?*

No pertinent studies have been performed for SCS, but, for other therapies/conditions, retrospective studies show that high patient volume and increased physician experience correlate positively with improved patient outcome.

Strength of recommendation	B
Evidence sources	<ul style="list-style-type: none"> <li>• Weighing risk versus potential benefit and expert consensus reveals a good likelihood of favorable outcome</li> </ul>

**Cost-Effectiveness**

*Is SCS cost-effective in the treatment of FBSS?*  
Yes.

Strength of recommendation	A
Evidence sources	<ul style="list-style-type: none"> <li>• Well-designed RCTs</li> <li>• Well-designed clinical studies</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**Estimates of Annual Cost of Nonsurgical Treatment**

Bell GK, Kidd D, North RB. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage* 1997;13:286–95.

de Lissovoy G, Brown RE, Halpern M, Hassenbusch SJ, Ross E. Cost effectiveness of long-term intrathecal morphine for pain associated with failed back syndrome. *Clin Ther* 1997;19:96–112.

Luo X, Pietrobon R, Sun SX, Liu GG, Hey L. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States. *Spine* 2004;29:79–86.

Straus BN. Chronic pain of spinal origin: The costs of intervention. *Spine* 2002;27(22):2614–19.

**RCT**

North RB, Kidd D, Shipley J, Taylor R. Spinal cord stimulation versus reoperation for failed back surgery syndrome: A cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery* 2007;61(2):361–9.

**Clinical Trials**

Blond S, Buisset N, Dam Hieu P, et al. Cost-benefit evaluation of spinal cord stimulation treatment for failed-back surgery syndrome patients [French]. *Neurochirurgie* 2004;50(4):443–53.

Health Technology Assessment Information Service [a branch of a World Health Organization collaborating center]. Spinal cord (dorsal column) stimulation for chronic intractable pain, Plymouth Meeting, PA, ECRI, October, 1993.

Kumar K, Malik S, Deneria D. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: Cost-effectiveness analysis. *Neurosurgery* 2002;51(1):106–16.

**Modeling Study**

Bell GK, Kidd D, North RB. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage* 1997;13:286–95.

**Cost Descriptions Lacking Comparators**

Bel S, Bauer BL. Dorsal column stimulation (DCS): Cost to benefit analysis. *Acta Neurochir* 1991;52(suppl):121–3.

Budd K. Spinal cord stimulation: Cost-benefit study. *Neuromodulation* 2002;5(2):75–8.

Devulder J, de Laat M, van Bastelaere M, Rolly G. Spinal cord stimulation: A valuable treatment for chronic failed back surgery patients. *J Pain Symptom Manage* 1997;13(5):296–301.

**Is SCS cost-effective in the treatment of CRPS?**

Yes.

Grade	A
Evidence sources	<ul style="list-style-type: none"> <li>• Well-designed RCTs</li> <li>• Well-designed clinical studies</li> <li>• Weighing risk versus potential benefit and expert consensus reveals a high likelihood of a favorable outcome</li> </ul>

**RCT**

Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology* 2002;59:1203–9.

**Is SCS cost-effective in the treatment of other (cervical root injury pain, thoracic root injury pain, PHN, postamputation pain, peripheral neuropathic pain, spinal cord injury, spinal cord lesion) neuropathic pain syndromes?**  
No definitive evidence is available.

Strength of recommendation	NA
Evidence sources	NA—see Bibliography for relevant literature

**Low Back Pain**

Raphael JH, Southall JL, Gnanadurai TV, Treharne GJ, Kitas GD. Chronic mechanical low back pain: A comparative study with intrathecal opioids drug delivery. *Neuromodulation* 2004;7(4):260–6.

**Unspecified Indications**

Willis KD. A simple approach to outcomes assessment of the therapeutic and cost-benefit success rates for spinal cord stimulation therapy. *Anesthesiol Clin North America* 2003;21(4):817–23.

**How can the cost-effectiveness of SCS be optimized?**

- Adjusting stimulation parameters to optimize battery life (the impact of rechargeable batteries on cost-effectiveness remains to be studied)

- Minimizing the incidence of complications, especially those that require removal and replacement of an implanted system
- Improving equipment design
- Careful patient selection and improving patient selection criteria
- Offering SCS before ablative therapies, such as sympathectomy, dorsal root gangliectomy, or repeat operation

Grade	NA—information only
Evidence sources	NA—see Bibliography for relevant literature

#### Adjusting Stimulation Parameters to Optimize Battery Life

North RB, Brigham DD, Khalessi A, et al. Spinal cord stimulator adjustment to maximize implanted battery longevity: A randomized controlled trial using a computerized, patient-interactive programmer. *Neuromodulation* 2004;7(1):13–25.

#### Minimizing the Incidence of Complications

Kumar K, Wilson JR, Taylor RS, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. *J Neurosurg Spine* 2006;5(3):191–203.

#### Improving Equipment Design

See Device Options section above.

#### Careful Patient Selection and Improving Patient Selection Criteria

See Patient Selection section above.

### Systematic Reviews, Meta-Analyses, Recommendations

Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Phys* 2007;10(7):7–111.

Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: A 20-year literature review. *J Neurosurg Spine* 2004;100(3):254–67.

Carter ML. Spinal cord stimulation in chronic pain: A review of the evidence. *Anaesth Intensive Care* 2004;32(1):11–21.

Grabow TS, Tella PK, Raja SN. Spinal cord stimulation for complex regional pain syndrome: An evidence-based medicine review of the literature. *Clin J Pain* 2003;19(6):371–83.

Henderson JM, Schade CM, Sasaki J, Caraway DL, Oakley JC. Prevention of mechanical failures in implanted spinal cord stimulation systems. *Neuromodulation* 2006;9(3):183–91.

Kumar K, Buchser E, Linderroth B, Meglio M, Van Buyten J-P. Avoiding complications from spinal cord stimulation: Practical recommendations from an international panel of experts. *Neuromodulation* 2007;10(1):24–33.

Mailis-Gagnon A, Furlan AD, Sandoval JA, Taylor R. Spinal cord stimulation for chronic pain. *Cochrane Database of Systematic Reviews* 2004; Issue 3. Art. No.: CD003783. DOI: 10.1002/14651858.CD003783.pub2.

Middleton P, Simpson B, Maddern G. Spinal cord stimulation (neurostimulation): An accelerated systematic review. AERSNIP-S R Report No. 43. 2003. Adelaide, South Australia, Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S).

Taylor RS. Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: Results of a systematic review and meta-analysis. *J Pain Symptom Manage* 2006;31(4 suppl):S13–9.

Taylor RS, Taylor RJ, Van Buyten J-P, 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;27:370–8.

Taylor RS, Van Buyten J-P, Buchser E. Spinal cord stimulation for complex regional pain syndrome: A systematic review of the clinical and cost-effectiveness literature and assessment of prognostic factors. *Eur J Pain* 2006;10(2):91–101.

Taylor RS, Van Buyten J-P, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: A systematic review and analysis of prognostic factors. *Spine* 2005;30(1):152–60.

Turner JA, Loeser JD, Bell KG. Spinal cord stimulation for chronic low back pain: A systematic literature synthesis. *Neurosurgery* 1995;37:1088–96.

Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. *Pain* 2004;108(1):137–47.

Wetzel FT, Hassenbusch S, Oakley JC, et al. Treatment of chronic pain in failed back surgery patients with spinal cord stimulation: A review of current literature and proposal for future investigation. *Neuromodulation* 2000;3(2):59–74.

## Glossary

**Anode**—a stimulating contact programmed as a positive pole, which attracts negative ions.

**Cathode**—a stimulating contact programmed as a negative pole, which attracts positive ions. Compared with an anode, a cathode more readily attains the amplitude stimulation threshold that initiates action potential generation (depolarization); thus, cathodal effects predominate in SCS.

**Guarded cathode**—an array in which two contacts programmed as anodes bracket a contact programmed as a cathode. The boundary created by the anodes for the depolarizing effect of the cathode helps define the area of paresthesia. In general (statistically), patients prefer a guarded cathode array.

**Channel**—a multichannel generator allows simultaneous delivery of pulses of different amplitude to different contacts. (A programmable generator that allows rapid sequential delivery of pulses to different contacts is not, strictly speaking, a multichannel device; instead it is a “gated single channel” generator.)

**Contact**—the electrically conductive portion of the electrode. An individual contact can be programmed as an anode, a cathode, or neither (i.e., off).

**Contact combination**—anode or cathode or off assignment of contacts.

**Electrode**—an assembly comprising contacts, wire, insulating spacers, catheters, and backing material. “Electrode” is generally applied to the part of the assembly that contains the contacts (with “lead” used to describe the wire leading between the electrode and the power source). Using “electrode” to refer solely to a contact is imprecise because it ignores the other components of the assembly. Using “lead” to refer to an electrode is inappropriate; the electrode does not lead anywhere.

**Electrode array**—the arrangement of electrodes, which can (for example) be longitudinal or transverse; single, dual, or triple; end-to-end or parallel.

**Lead**—the insulated wire that connects (leads) the power source to the electrode contacts. (This term is often, but confusingly, used to refer to an electrode assembly.)

**“Monopolar” stimulation**—the misnomer “monopolar stimulation” (stimulation, of course, requires two poles) refers to the use of the metallic case of an implanted generator as a remote anode. Thus, the electrode has only one contact that is stimulated (i.e., one pole) as a cathode.

**Paresthesia**—a tingling sensation caused by SCS. In order for SCS to provide pain relief, it is generally necessary for the paresthesia to overlap the pain. Such overlap, however, does not guarantee pain relief. Achieving pain/paresthesia overlap is, thus, a necessary, but not sufficient, condition for pain relief.

**Percutaneous catheter electrode**—an electrode that can be inserted through a needle, in a manner that is less invasive than laminectomy or laminotomy.

**Surgical plate/paddle electrode**—also known as a laminectomy, laminotomy, or insulated electrode. Because of their shape, paddle or plate electrodes must be inserted via laminectomy or laminotomy. Because they do not rotate, the dorsal surface can be insulated. Because they are insulated, surgical plate/paddle electrodes reduce the incidence of extraneous stimulation, in particular that attributable to recruitment of dorsal structures.

**Stimulation parameters**—the amplitude, width, and repetition rate of stimulation pulses. See also *contact combination*.

## Acronyms

FBSS = failed back surgery syndrome

MRI = magnetic resonance imaging

PHN = postherpetic neuralgia

RCT = randomized controlled trial

SCS = spinal cord stimulation

VAS = visual analog scale

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