Spinal Cord Stimulation Systems (Neurostimulators)

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Device Overview

Spinal cord stimulation (SCS) systems are indicated for chronic pain due to Complex Regional Pain Syndrome (CRPS), failed back surgery syndrome (FBSS), nonsurgical back pain, and diabetic peripheral neuropathy. Selection of an SCS system is complicated by the variety of options, components, and "various levels of invasiveness, selectivity, longevity, and adjustability." [1,2] A trial whereby the electrodes/leads are implanted in the epidural space along with simulation applied to determine suitability followed by implantation upon a successful trial, which is at least a 50% decrease in pain or analgesic use, functional outcomes, and patient satisfaction. [3] Factors for the selection of SCS system are efficacy and cost. [4] Several systems are available on the market, "each with its own unique features, indications, and limitations."

FDA Approval

There are several SCS systems on the market. FDA 510(k) Premarket approval for various SCS stimulators may be searched by supplier and/or name here. [4,5]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS
Engage key specialties including surgeons (neuro, spine), pain management physicians, operating room nurses, and value analysis leaders.

CONSIDER GUIDELINES FOR USE
Develop 'criteria for use' guidelines for patient selection and procedures, sharing pricing & reimbursement information.

UNDERSTAND CONCERNS
Continue conversations with key specialties, leverage physician peer to peer conversations to understand decision making.

CONNECT

SEEK CLINICAL IMPACT
Review data & physician utilization by procedure to support improved quality of care, patient outcomes, and compare efficacy.

CONDUCT ANALYSIS
Compare costs of each system and available components (for example, rechargeable vs non). Include reimbursement and outcomes information.

DETERMINE POPULATION
Work with key stakeholders to determine appropriate patients & favorable conversion rates (from trial to implantation).

COMMUNICATE

EDUCATE AND TRAIN
Provide written and hands-on training with each SCS system. Engage suppliers for support of specific products.

PLAN AHEAD
Share 'criteria for use' guidelines, evidence, and data to support decision making. Include rationale for initiative when communicating to end users.

FOLLOW-UP FOR FEEDBACK
Create on-going feedback loop for challenges, ideas, recognition of wins, & further opportunities. Review agreed upon metrics at a regular cadence.

Clinical Insights: HealthTrust Physician Advisors

A panel of orthopedic spine and anesthesia specialists within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of SCS devices. [6]

Physician Advisor Insights

Anesthesia

- **To select device, consider the evidence and patient preferences, number of lead ports, and ability to recharge.**
- **"Tunneled permanent implanted lead" may be an option, but trial failure and incision site are considerations before choosing this method.**
- **Most SCS devices were deemed to be comparable, and physician preferences may be based on "company comfort" and which device was used during training.**

Orthopedic spine

- **Choice utilized may be based on device selected by pain management physician during trial phase and "a mix of representative competency/support and clinical quality".**

Additional comments

- **When considering direct implantation, determine if there is insurance coverage on direct implantation of SCS device without trial period.**

Clinical Evidence

Evidence within this category primarily compares products to conventional therapy and are industry-sponsored. Variations on magnetic resonance imaging (MRI) conditions/compatibility and burst definitions exist among systems. Evidence comparing products to one another is limited. More studies comparing types of waveforms (traditional, burst, or high frequency) is needed. A sample of the available evidence is provided below.

A 2023 systematic review and meta-analysis of 8 studies (N=893 patients) by Zhou et al. compared SCS to conventional management for chronic pain. Studies showed SCS plus conventional management reduced visual analog scale pain and McGill Pain questionnaire scores ($p=0.0005$ and $p<0.0001$, respectively). Quality of life scores were increased for all measures (SF-36, Oswestry Disability Index, and EQ-5D; $p<0.05$ for all). The randomized controlled trials (RCTs) were graded as Level I to II, or strong evidence, for the role of SCS for neuropathic pain. Limitations include heterogeneity, difference in stimulation types, vendor differences, and "specific surgical implantation settings." [7]

See Reference section for complete listing of research sources.

A 2013 systematic review of 6 RCTs by Grider et al. supported efficacy of SCS devices for short (less than or equal to 12 months) and long term (more than 12 months) pain relief for patients with FBSS (Level I to II; strong evidence) and high frequency stimulation (Level II to III; moderate evidence). The evidence for burst stimulation (Level IV) and adapative stimulation (level V) is low. [1]

In a 2023 analysis of real-world data of 7000 patients undergoing an SCS system trial prior to implantation, Venkatraman et al. reported that the use of a mobile platform led to 90.1% trial success and 80.4% permanent implantation success. Overall, 72.4% of patients had a permanent SCS placed as well as significant decreases in pain. Limitations include "single procedure," lack of long-term data, United States data and health care system, lack of sociodemographic information, lack of medication details, no control comparator, and response bias on surveys. [8]

A **2020 systematic review/meta-analysis of 11 studies by Karri et al.** compared different waveforms (burst vs. tonic, burst vs. high frequency, tonic vs. high frequency) of SCS in refractory chronic low back pain. The analysis reported burst stimulation "is superior" to tonic, but more studies are needed to gauge the "superiority" of other waveforms. [9]

Professional Society Statements & Clinical Practice Guidelines

American Society of Regional Anesthesia and Pain Medicine (2023)

The committee published position statements on trial simulation and patient selection for SCS systems available here. Additionally, the committee adds an "on-table trial", or trial leading straight to implantation without the traditional observation, "cannot fulfill all the objectives of a true SCS trial" since it cannot adequately assess "clinical benefit." They note there may be situations or patient factors where a traditional trial is bypassed to go to implantation. [10]

American Society of Pain and Neuroscience (2022)

The organization released guidance on patient selection considerations for SCS therapy available here. The guidelines focus on patients with bleeding disorders, allergic/immunologic responses to implants, and high infection risk. [11]

Summary

1

Evidence suggests SCS systems manage chronic pain in certain patient populations. High quality studies are needed to determine efficacy of different stimulation waveforms/types (such as burst and high frequency) and factors influencing SCS success.

2

Due to the costs and multiple SCS systems available, work to develop a goal related to intended use and patient selection, sharing price and reimbursement information as well as clinical data.

3

Since selection of SCS system is influenced by physician preference, engaging physician champions to assist with conversations among peers will be particularly helpful when developing criteria for use.

References

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