Boston Scientific

Precision Spectra™ System Information for Prescribers

℞ ONLY

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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Copyright

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Trademarks

Precision Spectra is a trademark of Boston Scientific. Other brands and their products are trademarks or registered trademarks of their respective holders and should be noted as such.

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Refer to the *Indications for Use* for indications and related information.

Refer to the following Directions for Use (DFU) for device specific instructions: *Precision Spectra System Implantable Pulse Generator DFU, Surgical Leads DFU, Percutaneous Leads DFU, Precision Spectra System Clinician Remote Control DFU, Clinician Trial Manual, Precision Spectra System Programming Manual,* and *Programming Wand DFU*.

Refer to the *Limited Warranty* for warranty information.

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Device and Product Description

The Precision Spectra™ Spinal Cord Stimulation System consists of an Implantable Pulse Generator (IPG), temporary and permanent Percutaneous Leads, Surgical Paddle Leads, Lead Extensions, OR Cables, Trial Stimulator, Remote Control, Clinician Programmer, and Programming Wand, each packaged as a separate kit. Single use accessories and disposable tools are also included in these kits.

Features of the Precision Spectra System include:

- Stimulation electrode field navigation
- Thirty-two independent current-controlled electrodes
- Four programmable stimulation areas per program; sixteen possible programs
- Long-life operation
- High-range parameter capability
- Small size
- Two-foot programming range
- This product contains no detectable latex

Precision Spectra System Clinical Summary

Determination of the safety and effectiveness of the Precision Spectra System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The Precision Spectra System is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the Precision Spectra System for the treatment chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to support the effectiveness of the Precision Spectra™ System (Ohnmeiss et al. 1996, Villavincencio et al. 2000, Hassenbach SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was depicted from the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, a totally implantable spinal cord stimulator was used in association with a percutaneous and/or surgical lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Precision Spectra System.

The prospective study by Ohnmeiss et al. 1996, examined the long-term effectiveness of SCS in patients with intractable leg pain. Forty patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP (Sickness Impact Profile), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had greater than 50% improvement in pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study performed by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In this study, 27/41 patients, 66%, had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%), reported greater than 50% reduction in pain.

Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, one patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis performed by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the

treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. Five patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief.

There were 4 (10%) patients who underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: “On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?” 16/26 patients (62%) had greater than 50% pain relief with SCS. In this study, 2/16 (13%) had greater than 50% pain relief with opioids. Mean follow-up was 2.1 ± 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Eleven studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Precision Spectra™ System. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. The table below depicts the number of patients, the number of events, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that citations cover both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

Table 1: Summary of Risks Identified in the Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%
Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain Over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Clinical Experience-Safety

Clinical data has been collected during a clinical study of the Precision System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the Precision System. The follow-up period for the 26 implanted patients ranged from two weeks to six months. The following major adverse events were reported.

Table 2: Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced
Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

References

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Contraindications

Patients contraindicated for permanent Spinal Cord Stimulation (SCS) therapy are those who:

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

Safety Information

WARNING: Unauthorized modification to the medical devices is prohibited. System integrity could be compromised and harm or injury to the patient could occur if the medical devices are subjected to unauthorized modification.

Instructions for the Patient

Warnings

Heat Due to Charging. Patients should not charge while sleeping. This may result in a burn. While charging, the Charger may become warm. It should be handled with care. Failure to use the Charger with either the Charging Belt or an adhesive patch, as shown, may result in a burn. If patients experience pain or discomfort, they should cease charging and contact Boston Scientific.

Magnetic Resonance Imaging (MRI). Patients implanted with the Precision Spectra SCS system should not be subjected to MRI. MRI exposure may result in dislodgement of implanted components, heating of the neurostimulator, damage to the device electronics and/or voltage induction through the leads and Stimulator causing an uncomfortable or “jolting” sensation.

Pediatric Use. The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Diathermy. Shortwave, microwave and/ or therapeutic ultrasound diathermy should not be used on SCS patients. The energy generated by diathermy can be transferred through the Stimulator system, causing tissue damage at the lead site and resulting in severe injury or death. The IPG, whether it is turned on or off, may be damaged.

Implanted Stimulation Devices. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators. The effects of implanted stimulation devices on neurostimulators is unknown.

Stimulator Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals. Do not implant the device if the case is damaged.

Postural Changes. Patients should be advised that changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Patients should be advised to turn down the amplitude or turn off the IPG before making posture changes.

Important: *If unpleasant sensations occur, the IPG should be turned off immediately.*

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, or cause uncomfortable or jolting stimulation. Patients should be counseled to avoid or exercise care around:

- Theft detectors or security screeners such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices. It is recommended that patients request assistance to bypass the device. If they must proceed through the device, the patient should turn off the Stimulator and proceed with caution, moving through the center of the screener as quickly as possible.
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers

Precautions

Physician training is required.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the Stimulator, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery (See “Instructions for the Physician” on page 11)
- external defibrillation
- radiation therapy (Any damage to the device by radiation may not be immediately detectable.)
- ultrasonic scanning
- high-output ultrasound

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 11. Ultimately, however, the device may require explantation as a result of damage to the device.

Automobiles and Other Equipment. Patients should not operate automobiles, other motorized vehicles, or potentially dangerous machinery/ equipment with therapeutic stimulation switched on. Stimulation must be turned off first. Sudden stimulation changes, if they occur, may distract patients from attentive operation of the vehicle or equipment.

Post Operative. During the two weeks following surgery, it is important that patients use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions:

- Patients should not lift objects of more than five pounds.
- Patients should not engage in rigorous physical activity such as twisting, bending, or climbing.
- If new leads were implanted, patients should not raise their arms above their head.

Temporarily, there may be some pain in the area of the implant as the incisions heal. Patients should be instructed that if discomfort continues beyond two weeks, they should contact their physician.

If patients notice excessive redness around the wound areas during this time, they should contact their physician to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Patients should consult their physician before making lifestyle changes due to decreases in pain.

Stimulator Location. Patients should never attempt to change the orientation or “flip” (rotate or spin) the Stimulator. Patients should not “finger” or play with the Stimulator. If the Stimulator flips over in the Patient’s body, it cannot be charged. If the Patient knows that the device has turned, or if stimulation cannot be turned on after charging, the Patient should contact his or her physician to arrange an evaluation of the system. In some cases, the skin over the Stimulator may become very thin over time. If this occurs, Patients should contact their physicians.

Lead Location. In some instances a lead can move from its original location, and stimulation at the intended pain site can be lost. If this occurs, Patients should consult their physician who may able to restore stimulation by reprogramming the Stimulator in the clinic or repositioning the lead during another operation.

Device Failure. Stimulators can fail at any time due to random component failure, loss of battery functionality, or lead breakage. If the device stops working even after complete charging (up to four hours), Patients should turn off the Stimulator and contact their physician so that the system can be evaluated.

Operating Temperature. The operating temperature of the Trial Stimulator, Remote Control, and Programming Wand is 10–40 °C (50–104 °F). For proper operation, do not use the Charger if the ambient temperature is above 35 °C (95 °F).

Storage, Handling and Transport. Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat.

If the Remote Control or the Charging System is to be stored for a period of time without batteries, the storage temperature should not exceed -20 to 60 °C (-4 to 140 °F).

Handle the system external components and accessories with care. Do not drop them or submerge them in water. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage these components. (See “Limited Warranty - IPG”.)

Upon completion of the Patient Trial, remove the batteries from the Trial Stimulator.

Component Disposal. Do not dispose of the Remote Control or Charger in fire. The battery in these devices can explode in fire. Dispose of used batteries in accordance with local regulations. The IPG should be explanted in the case of cremation, and returned to Boston Scientific. External devices to be disposed of per local regulatory requirements. Please contact your healthcare professional.

Remote Control, Charging System, External Trial Stimulator and Wand Cleaning. The charging system components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. The Remote Control, External Trial Stimulator and Programming Wand can be cleaned using a mild detergent applied with a lightly dampened cloth or tissue. Residue from soapy detergents should be removed with a cloth lightly dampened with water. Do not use abrasive cleansers for cleaning. Cleaning wipes for the External Trial Stimulator can also be ordered through Boston Scientific customer service.

Cell Phones. While we do not anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time. If there is a concern or a problem is encountered, the patients should contact their physician.

Adverse Effects

Potential risks are involved with any surgery.

The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur.
- Skin erosion at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, lead dislodgement.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, the Stimulator may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

In any event, instruct the patient to contact their physician to inform him/her.

Instructions for the Physician

Implanted Stimulation Devices. If such implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies.

Postural Changes. Depending on the activity level of the patient, postural changes may affect stimulation intensity. Instruct patients to keep the Remote Control on hand at all times, and ensure that they understand how to adjust stimulation levels. Refer to Postural Changes in the Instructions for Patients section of this manual, page 7, for additional information.

Medical Devices/Therapies. If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, or high-output ultrasound:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.

Sterilization

All Precision Spectra™ System implantable and surgical components are sterilized with ethylene oxide.

- Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not resterilize the package or the contents. Obtain a sterile package from Boston Scientific.
- Do not use if the product is past the labeled expiration date.
- All components are for single use only. Do not reuse.
- Do not use if package is opened or damaged
- Do not use if labeling is incomplete or illegibl

WARNING: *Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.*


For Single Use Only.
Do Not Reuse.


Do Not Resterilize


Do not use if package is damaged

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

FCC Rules

The following is federal government communications regulation information about the Precision Spectra™ Spinal Cord Stimulation System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The Precision Spectra™ System components should only be serviced by Boston Scientific. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair the components will void the warranty.

Changes of modifications to this product not authorized by Boston Scientific Corporation could void the FCC Certification and negate your authority to operate this product.

Technical Service

Boston Scientific has highly trained service professionals located worldwide to assist you. The Technical Service Department is available to provide technical consultation 24 hours a day.

In North America, please call (866) 566-8913 to speak to a representative.

End of Programmed Service

The Precision Spectra™ System IPG software is programmed to end service after 12 years. As the IPG nears the end of the programmed period, the Precision Spectra System Remote Control and Precision Spectra System Clinician Programmer provide the following indicators to inform the user that the end of the programmed period is approaching:

- Remote Control - Approximately six months before the end of the programmed period, the Remote Control displays a weekly message indicating the number of service days remaining. Approximately one month before the end of the programmed period, the message displays daily.
- Clinician Programmer - When less than six months of service period remain, an indicator displays on the Connect screen of the Clinician Programmer. When end of the programmed period has been reached, a message displays when connecting to the Stimulator to indicate that the end of the programmed period has been reached and programming is not allowed.

Patients should contact their health care provider upon first receiving a message regarding the number of programmed service period days remaining.

IPG Batttery Life

The rechargeable battery in the Precision Spectra System IPG should provide at least five years of service.[1] The IPG recharge interval at typical settings is at least 30 days.[2] Over time, the IPG battery will need more frequent recharges. Like all rechargeable batteries, use over time and repeated recharge cycles reduce the maximum charge capacity of the IPG battery.

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[1] The expected years of battery operation are defined as the longer of either:
A. Typical case: the time at which therapy cannot be maintained with daily charging.
OR
B. High energy case: when the maximum recharge interval has decreased by more than 50 % from the initial recharge interval.

[2] This estimated recharge interval is based on the following assumptions:
- The Precision Spectra IPG is newly implanted and at the beginning of it's charging life.
- The IPG has been programmed to the following settings: Current amplitude: 4 mA; Pulse Width: 300 µs; Pulse Rate: 50 Hz and Impedance: 750 Ohms.
  NOTE: Your actual settings may vary, thus varying the number of days for your recharge interval.

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90668515-01 REV A 2012-04