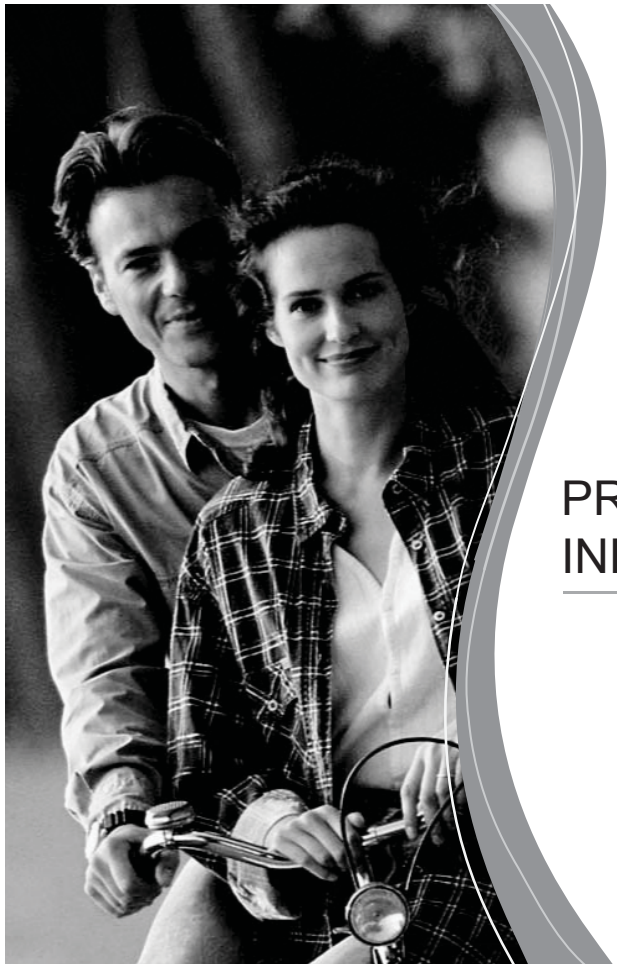

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PRECISION SPECTRA™ SYSTEM INFORMATION FOR PATIENTS

Part No. 90668560-01 Rev B

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Boston Scientific

Information for Patients

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

Part No. 90668560-01 Rev B

Copyright

Guarantees

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

Drawings are for illustration purposes only.

Refer to the Precision Spectra™ System Patient Trial Handbook, Precision Spectra System Remote Control Handbook, Charger Handbook, and Limited Warranty for additional instructions and information on your Spinal Cord Stimulation System.

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1 Safety Information

Indications for Use

The Boston Scientific Precision Spectra™ Spinal Cord Stimulator System (Precision System) is indicated as an aid in the management of 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 pain and leg pain.

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.

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Contraindications

Patients contraindicated for permanent 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

Warnings

UNAUTHORIZED MODIFICATION: 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.

Heat Due to Charging. Do 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 Belt or an adhesive patch, as shown in your Charger Handbook, may result in a burn. If you experience pain or discomfort, cease charging and contact Boston Scientific.

Magnetic Resonance Imaging (MRI). You should **not** be exposed to Magnetic Resonance Imaging (MRI). Exposure to this diagnostic technology may result in dislodgement of your Stimulator or leads, heating of the Stimulator, severe damage to the Stimulator electronics and/or increased voltage through the leads or Stimulator which can cause an uncomfortable or “jolting” sensation.

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

Diathermy. As an SCS patient, you should not have any form of diathermy either as treatment for a medical condition or as part of a surgical procedure. The high energy and heat generated by diathermy can be transferred through your stimulator system, causing tissue damage at the lead site and, possibly, severe injury or death. The Stimulator, whether it is turned on or off, may be damaged.

Cardiac Pacemakers. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators, such as pacemakers and implantable cardiac defibrillators (ICDs). Be sure your physicians are aware of your spinal cord stimulator before going forward with other implantable device therapies so that medical decisions can be made and appropriate safety measures taken.

Implant Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals.

Posture. Changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Keep the Remote Control with you at all times, and turn the stimulation down or off before making posture changes. If unpleasant sensations occur, the stimulation should be turned off immediately.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, or cause uncomfortable or jolting stimulation. 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 you request assistance to bypass the device. If you must proceed through the device, turn off the Stimulator and proceed with caution, and move 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

As you approach these devices, you may become aware of changing stimulation levels. In rare instances, you could experience an increase in stimulation level to the point that the sensation is uncomfortably strong or possibly “jolting.” If this happens, turn off the Stimulator. If the Stimulator suddenly turns off by itself, first move away from the area. Next, check the stimulation status with the

Remote Control by pressing the Unlock button and observing the screen. The implant may need to be recharged before stimulation can be restarted. Refer to your Charging Handbook for further information.

Always be aware of your surroundings, particularly near theft detectors/security screeners. Ask for assistance to go around these devices if you feel at all uncomfortable.

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 — high-output sound or shock waves often used to treat gall stones and kidney stones
- electrocautery — the use of a heated electric probe to stop bleeding during surgery
- external defibrillation — the use of electrically charged paddles to restart the heart in an emergency
- radiation therapy — ionizing energy commonly used to treat cancer. Any damage to the device by radiation may not be immediately detectable.
- ultrasonic scanning — very high frequency sound waves used to produce images of internal organs or tissue for diagnostic purposes

- high-output ultrasound — high frequency sound waves which may be applied as physical therapy to treat certain bone/muscle injuries, or for muscle stimulation, or to improve blood flow

Before having procedures, medical therapies, or diagnostics, have your healthcare professional call our Customer Service department for proper instructions. Refer to “Contacting Boston Scientific” in this manual for contact information for your locality.

Automobiles and Other Equipment. Do not operate an automobile, other motorized vehicle, or any potentially dangerous machinery/equipment with therapeutic stimulation switched on. Turn off stimulation first. Sudden stimulation changes, if they occur, may distract you from attentive operation of the vehicle or equipment.

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

- Do not lift objects of more than five pounds.
- Do not engage in rigorous physical activity such as twisting, bending, or climbing.
- If new leads were implanted, do not raise your arms above your head.
- While undergoing patient trial, do not pull or jiggle the leads.

Temporarily, there may be some pain in the area of the implant as the incisions heal. If discomfort continues beyond two weeks, contact your physician.

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

Be sure to consult your physician before making any lifestyle changes due to decreases in pain.

Implant Location. Never attempt to change the orientation or “flip” (rotate or spin) the implant. Do not “finger” or play with the implant. If the implant flips over in your body it cannot be charged. If you know that the device has turned, or if stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system.

In some cases, the skin over your implant may become very thin over time. If this occurs, contact your physician.

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, consult your physician who may be able to restore stimulation by reprogramming the implant in the clinic or repositioning the lead during another operation.

Device Failure. Implants 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), turn off the Stimulator and contact your physician so that the system can be evaluated.

Operating Temperature. The operating temperature of the Trial Stimulator and Remote Control 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, be careful that the storage temperature does not exceed -20–60 °C (-4–140 °F).

Handle the system components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water which can come into contact with the devices. 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 the components. Refer to the Limited Warranty for additional information.

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 Stimulator 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 for information.

Remote Control, Charging System Cleaning. The charging system components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. The Remote Control 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.

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 physician should be contacted.

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:

- The lead(s) which deliver stimulation may move from their original implanted location, 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 battery leakage, device failure, lead

breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.

- Your body may react negatively to the materials used to manufacture the Stimulator or the leads. You may notice redness, warmth or swelling of the implant area.
- The skin over your implant may become thin and increasingly tender over time. A seroma may be formed.
- The most common surgical procedural risks are temporary pain at the implant site and infection. However, since the leads are placed in the epidural space, there is a small risk that spinal fluid may leak from the lead insertion site following surgery. Very rarely, you may develop an internal blood clot (hematoma) or blister (seroma); or you may experience epidural hemorrhage or paralysis. Your spinal cord may become compressed.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- MRI. Exposure to magnetic resonance imaging (MRI) can result in noticeable heat near the Stimulator or the leads; may distort or destroy the image needed for diagnosis; and may produce enough electromagnetic interference (EMI) to erase the Stimulator programming, destroy the leads, or cause the leads to move from their intended location.

- 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.
- You may experience painful electrical stimulation of your chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, your implant may move from its original position.
- You may experience weakness, clumsiness, numbness or pain below the level of implantation.
- You may experience persistent pain at the Stimulator or lead site.

In any event, you should contact your physician and inform him/her.

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.

Patient Identification Card

Ensure you have received your Temporary Patient Identification Card. If not, please call your healthcare professional. Keep your Temporary Patient Identification Card with you until you receive your permanent card.

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 provides the following indicator to inform you 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.

You should contact your health care provider upon receipt of the first message regarding the number of service days remaining.

IPG Battery 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.

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.

2 Contacting Boston Scientific

There are no user serviceable parts. If you have any questions, or need to contact Boston Scientific for any reason, you may do so in any of the following ways:

- Customer Service Phone: (866) 360-4747
- Customer Service Fax: (661) 949-4022
- Address:
  Boston Scientific Neuromodulation
  25155 Rye Canyon Loop
  Valencia, CA 91355

3 Glossary

ADHESIVE PATCH. Non-reactive skin patch designed to temporarily attach the Charger to the skin over the Stimulator site.

ADVERSE EFFECT. Undesirable result, such as side effect.

AMPLITUDE. The measure of the strength or level of delivered stimulation.

AREA. A location on the body such as right leg or left leg where stimulation will occur.

CABLE. Thin plastic coated wire(s) connecting the exposed portion of temporary lead(s) to the Trial Stimulator.

CARDIAC PACEMAKER. A small implantable device used to control the rhythm of the heart.

CHARGER. A portable device used to recharge the battery of the implanted stimulator.

CHARGER BASE STATION. A holder/power supply that supports the Charger and keeps it in a ready state for recharging the implant.

CHARGING SYSTEM. The Charging System consists of a Charger Base Station, Charger, Power Supply, Charging Belt and adhesive patches. The system is used for recharging the implanted stimulator.

CONTROL BUTTONS. Buttons located on the Remote Control; used for adjusting stimulation settings.

DIATHERMY. A therapeutic procedure used to heat body tissue by high-frequency electromagnetic currents.

DISPLAY. The Remote Control screen.

ELECTRICAL PULSE GENERATOR. Also called an implantable pulse generator (IPG or Stimulator); used to send electrical pulses to the spinal cord.

ELECTRICAL STIMULATION. The energy created by a pulse generator.

ELECTROMAGNETIC INTERFERENCE (EMI). Electromagnetic signals that interfere with a variety of electrical signals including spinal cord stimulation.

IDLE MODE. A time-out period when the Remote Control is not being used. Also known as sleep mode.

IMPLANT. Small electrical pulse generator used to control stimulation.

INCISION. Small surgical cut or opening in the skin.

INDICATOR. A signal light used on the Trial Stimulator and the IPG Charger.

IPG. Implantable Pulse Generator.

LABELS. Adhesive tags placed on the trial lead cables to show where to attach the cables to the Trial Stimulator.

LEAD. An insulated surgically implanted wire that sends electrical stimulation pulses from a pulse generator to the spinal cord.

LEAD MIGRATION. The movement of a lead away from its original location.

LEVEL. Term often used to identify the amplitude or strength of stimulation pulses.

MRI. Magnetic Resonance Imaging; the use of a nuclear magnetic resonance spectrometer to produce electronic images of tissues and organs.

NUMERICAL RATING SYSTEM (NRS). A simple graph used to measure the before-and-after pain levels of SCS trial patients.

OPTIONS. Methods for adjusting stimulation beyond amplitude, or level, using the Remote Control. Your healthcare provider may or may not provide you with all available options.

PAIN PROFILE. A record or documentation of pain locations, occurrence, and intensity. A pain “chart” for determining therapy.

PARESTHESIA. Tingling sensation produced by electrical stimulation.

PATCH ELECTRODE. An adhesive patch placed on the skin and attached to the Trial Stimulator only when trial leads are not used.

PATIENT IDENTIFICATION CARD. A wallet size card that lists the patient name, physician name, Stimulator model and serial number.

PERMANENT IMPLANT. A stimulator system, pulse generator and leads, implanted in the body and maintained by a pulse generator battery Charging System.

PRECAUTION. Generally, situations that you should be aware of in order to avoid potentially uncomfortable stimulation sensations and/or damage to your stimulation system.

PROGRAM. Combination of one or more stimulation patterns for one or more areas.

PULSE WIDTH. The length of time each stimulation pulse lasts. An option setting available from the Remote Control.

QUICKCHARGE TECHNOLOGY. Enhancements to the IPG charging circuitry provide 1.4 times the rate of charging compared to the Precision™ charging system when the charger is placed 1 cm or less from the IPG.

RATE. The number of times–per-second (speed) at which stimulation pulses are delivered to the spinal cord. An option setting available from the Remote Control.

REMOTE CONTROL. A battery powered hand-held computer used to adjust stimulation.

SAVE. The Remote Control button command used to store a newly created or modified stimulation program.

SLEEP MODE. A time-out period when the Remote Control is not being used. Also known as idle mode.

SPINAL CORD STIMULATION (SCS). A method of applying electrical pulses to the spinal cord to block/mask pain signals to the brain.

STIMULATION. When used as a therapy for pain, an artificially applied, low-level, pulsating electrical signal delivered to a nerve by a device. Felt as a tingling or pulsating sensation in the area of pain and perceived enough to reduce the awareness of pain.

STIMULATION COVERAGE. Area on the body where stimulation occurs. (See Area.)

STIMULATOR. Small implantable electrical pulse generator used to provide stimulation.

SUBCLAVICULAR. Below the collarbone.

SURELIFE BATTERY. Battery technology allowing the Precision Spectra™ IPG to be completely discharged without causing battery failure or degradation.

SYSTEM FAILURE. Inability of spinal cord stimulator system to deliver stimulation.

TRIAL JOURNAL. Questionnaire, chart and activity log used to record information during the Trial Phase.

TRIAL SCREENING. Temporary evaluation of electrical stimulation of the spinal cord.

TRIAL STIMULATOR. An electrical pulse generator used during the Trial Phase of SCS therapy evaluation.

TRIAL STIMULATOR SYSTEM. Precision Spectra™ system components used during a limited time to evaluate SCS therapy. The Trial Stimulator System consists of an External Trial Stimulator (ETS), temporary or permanent lead(s), lead cable(s), the Remote Control, and a Velcro Belt.

WARNING. Potential hazards that you must be aware of to avoid serious situations that may cause injury or death.

WIDTH. See Pulse Width.

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