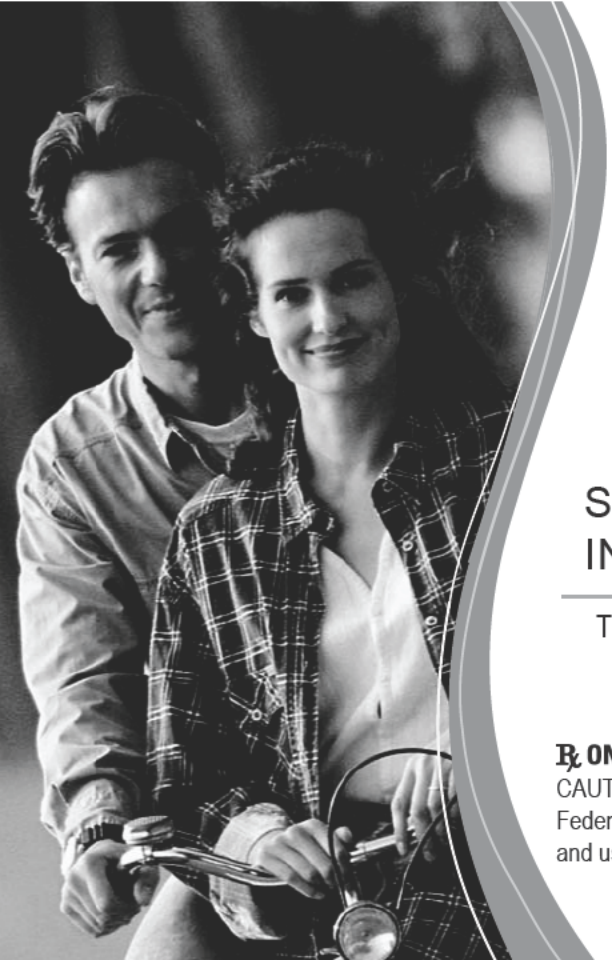

Boston Scientific

Advancing science for life™

SPINAL CORD STIMULATOR SYSTEM INFORMATION FOR PATIENTS

These instructions are intended for U.S. patients only.

℞ ONLY

CAUTION:

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

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Trademarks

All trademarks are the property of their respective holders.
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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.

Additional Information

Refer to the Directions for Use provided with your Patient Trial kit for Trial information.

Refer to your *Remote Control Handbook*, *Charger Handbook*, and *Limited Warranty* for additional instructions and information on your Spinal Cord Stimulator (SCS) System.

Throughout this manual, the name “Boston Scientific SCS System” refers to the following rechargeable SCS systems: Precision Spectra™, Precision™ Montage™, Precision Montage MRI, and Spectra WaveWriter™ SCS systems.

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1 Safety Information

Indications for Use

The Boston Scientific Spinal Cord Stimulator (SCS) Systems* are 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,
- Complex Regional Pain Syndrome (CRPS) Types I and II,
- Intractable low back pain and leg pain,
- Diabetic Peripheral Neuropathy of the lower extremities,
- Radicular pain syndrome,
- Radiculopathies resulting in pain secondary to failed back syndrome or herniated disc,
- Epidural fibrosis,
- Degenerative disc disease (herniated disc pain refractory to conservative and

surgical interventions),

- Arachnoiditis,
- Multiple back surgeries.

The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery.

*The Boston Scientific Spinal Cord Stimulator (SCS) Systems include the following:

- Precision™ System
- Precision Spectra™ System
- Precision Novi™ System
- Precision Montage™ MRI System
- Spectra WaveWriter™ System
- WaveWriter Alpha™ System
- WaveWriter Alpha™ Prime System

Note: *CRPS I was previously referred to as Reflex Sympathetic Dystrophy (RSD) and CRPS II was previously referred to as causalgia.*

Boston Scientific SCS System Clinical Summary

Determination of the safety and effectiveness of the Boston Scientific SCS System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The Boston

Scientific SCS 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 Boston Scientific SCS 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 Boston Scientific SCS 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 Boston Scientific SCS 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 Implantable Pulse Generator (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 Boston Scientific SCS System. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. Table 1 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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Subperception Therapy – Clinical Summary

Determination of the safety and effectiveness of the Boston Scientific Spinal Cord Stimulator (SCS) Systems for subperception therapy was based on a prospective, randomized, multicenter, crossover study with the primary endpoint of responder rate (proportion of subjects with 50% or greater improvement in overall pain) at 3 month post-device activation. A crossover design provided a within-subject comparison between the supra-perception and subperception settings.

The primary objective of this study was to demonstrate sustained clinically significant pain relief in patients with chronic pain when using the Boston Scientific SCS Systems at subperception amplitude.

Of the 197 subjects that provided consent to participate in the study, 136 were randomized to either receive subperception followed by supra-perception settings or vice versa for 90 days post-activation. The study cohort was comprised of subjects who have been treated successfully with paresthesia-inducing stimulation for at least six months.

Efficacy Outcomes

The study successfully met its primary effectiveness endpoint, demonstrating that the proportion of overall pain responders at 90 days post-activation with subperception settings is non-inferior compared to supra-perception settings at a statistically significant level ($p < 0.001$). The study also successfully demonstrated non-inferiority in the Per Protocol group indicating the robustness of the study.

At the end of the crossover period, subjects were asked to choose between supra-perception and subperception settings. Of the 70 subjects included in the primary effectiveness cohort, 53 subjects (76%) chose subperception whereas only 17 (24%) chose supra-perception as their preferred treatment settings. Additionally, 40 subjects (57%) preferred to keep both the stimulation treatments if given the option.

Safety Outcomes

A total of 27 adverse events were reported among 20 subjects across the entire study experience. Of the 27 adverse events, 12 were serious adverse events (SAEs) and 15 nonserious adverse events. All serious adverse events were unrelated to the study-device and/or study-procedure. There were no unanticipated events.

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). Patients with a Precision Spectra, Spectra WaveWriter, or Precision Montage MRI SCS System may be able to have an MRI examination when specific

conditions are met. These conditions are defined in the following supplemental manuals for your specific Boston Scientific Rechargeable SCS system:

- *ImageReady MRI Head Only Guidelines for Precision Spectra Spinal Cord Stimulator System*
- *ImageReady MRI Head Only Guidelines for Spectra WaveWriter Spinal Cord Stimulator System*
- *ImageReady MRI Full Body Guidelines for Precision Montage MRI Spinal Cord Stimulator System*

It is important that your Physician read this information in its entirety and determine all conditions are met before conducting and recommending an MRI examination.

The “ImageReady MRI Guidelines” manual for your specific Boston Scientific rechargeable SCS system can be found on the Boston Scientific websites (www.bostonscientific.com/MRI and www.bostonscientific.com/ImageReady).

Patients with a Precision Montage System (IPG Model Number SC-1120) should not be exposed to MRI.

External Devices. Boston Scientific external components (i.e., External Trial Stimulator and OR Cable, Remote Control and Accessories, Battery Charger) are **MR Unsafe**. They must not be taken into any MR environment such as the MRI scanner room.

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 sudden movements may cause decreases, or 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. If using therapy that does not produce a sensation (subperception), postural changes are less likely to affect you.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication.

You should avoid or exercise care around:

- Theft detectors, tag deactivators and RFID devices, such as those used at department stores, libraries, and other public establishments. If you must proceed through the detector, you should proceed with caution, ensuring to move through the center of the detector as quickly as possible.
- Security screeners, such as those used in Airport Security or at entrances to government buildings, including hand-held scanners. It is recommended that you request assistance to bypass the screener. If you must proceed through the security screener, proceed with caution, ensuring to move quickly through the security screener and staying as far from the screener as allowable.
- Power lines or power generators.
- Electric steel furnaces and arc welders.
- Large magnetized stereo speakers.
- Strong magnets.
- Automobiles or other motorized vehicles using a LoJack system or other anti-theft system that can broadcast a radio frequency (RF) signal. The high energy fields

produced by these systems may interfere with the operation of the Remote Control and its ability to control stimulation.

- Other sources of electromagnetic disturbance, such as RF transmitters at television or radio broadcast stations, Amateur Radio or Citizens Band radio transceivers, or Family Radio Service band transceivers.

Note: *When in close proximity, equipment that generates strong electromagnetic fields might cause uncomfortable or jolting stimulation or interfere with wireless communication even if they comply with CISPR requirements.*

Precautions

Physician training is required.

Prior Back Surgery. Only the Spectra WaveWriter, WaveWriter Alpha, and WaveWriter Alpha Prime SCS Systems have been evaluated for effectiveness in patients with intractable low back pain and leg pain without prior back surgery.

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

X-ray and CT scans may damage the Stimulator if stimulation is on. X-Ray and CT Scans are unlikely to damage the Stimulator if stimulation is turned off.

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.

Subperception Therapy. Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months.

Automobiles and Other Equipment. If you are using therapy that generates paresthesia you should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation turned on. Stimulation must be turned off first in such cases. Any sudden stimulation changes may distract you from proper operation of the vehicle, machinery, or equipment. For therapy that does not generate paresthesia (i.e., subperception therapy) it is less likely that sudden stimulation changes resulting in distraction could occur while having stimulation on when operating moving vehicle, machinery, and 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 2.5 kilograms (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 5–40 °C (41–104 °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 and External Trial Stimulator Cleaning.

As an operator of the external devices, you should perform only the following service and maintenance tasks on the external devices:

- Changing the battery
- Charging the battery
- Cleaning

Ensure that the devices are not in use while performing service and maintenance tasks.

The charging system components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. The Remote Control and External Trial Stimulator 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. Do not clean any of the accessories while they are directly or indirectly connected to a power outlet.

Cell Phones and Other Portable RF Communication Devices. Interference caused by cell phones is not anticipated, but the full effects of interaction with cell phones are unknown at this time. Portable RF communications equipment (for example, mobile phones) should be kept a minimum distance of 6 inches (15 cm) from the area of the implanted device. If interference does occur, move the cell phone away from the Stimulator or turn off the phone. If there is a concern or a problem is encountered, contact your healthcare provider.

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. Tissue reaction to implanted materials can occur. In some cases, the formation of reactive tissue around the lead in the epidural space can result in delayed onset of spinal cord compression and neurological/sensory deficit, including paralysis. Time to onset is variable, possibly ranging from weeks to years after implant.
- 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 disturbance may cause the device to malfunction and affect stimulation.
- MRI. Exposure to magnetic resonance imaging (MRI) can result in discomfort or injury due to heat near the Stimulator or the leads, tugging or vibration of the implanted system, induced stimulation, damage to the device requiring its replacement and may distort the image needed for diagnosis.
- 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.
- Changes in blood glucose levels in response to any adverse event.

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

Note: *Diabetic patients may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may*

be greater in diabetic patients, particularly those with inadequate pre-operative glycemic control.

FCC Rules

The following is federal government communications regulation information about the Boston Scientific Spinal Cord Stimulator 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 electromagnetic disturbance, and (2) This device must accept any electromagnetic disturbance received including electromagnetic disturbance that may cause undesired operation.

The Boston Scientific SCS 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.

Quality of Wireless Service

Low Frequency RF Inductive Link

The IPG, that is part of your Boston Scientific SCS System, uses a Half-Duplex, direct point-to-point,

primary-secondary communication system to communicate with the Remote Control (Low Frequency RF Inductive Link). This communication system has the following characteristics:

- Typical range:
  - » 36 inches (91.4 cm) between Remote Control and Stimulator with 95% or higher communication success rate. Beyond this range, the Remote Control is more likely to experience difficulty communicating commands to the Stimulator.
- Timing: Once a command is initiated by the user, the system will respond in less than 1.5 seconds.
- Telemetry failures:
  - » The signal to noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Signal to noise measurement is retried up to three times in case of insufficient range or the presence of electromagnetic disturbances. User is notified of the communication failure after 3 failed attempts.
  - » Packet and message errors are verified for accuracy. Any erroneous packets/ messages are rejected and re-sent up to 3 times. User is notified of the communication failure after 3 failed attempts.
  - » User may re-try the command or follow on-screen instructions for telemetry help.

When the Remote Control is unable to communicate a command to the Stimulator, it will display a "Communication Failed" screen and provide two options: Retry and Telemetry Help. The Retry option resends the last command. The Telemetry Help option assists you in discovering an optimal position to hold the Remote Control to ensure communication with the Stimulator. You may test the Remote Control in different positions and observe which positions produce an acceptable number of signal bars. Refer to the "Telemetry Help" section of the *Remote Control Handbook*. Common sources of electromagnetic disturbance such as television and computer monitors can reduce this range. Reduction of range may occur when in close proximity of sources of electromagnetic disturbance such as:

- Television and computer monitors
- Short range electronic RFID tracking systems such as badge scanners and parking lot scanners

Reduction of range may also occur within 18 feet of another Boston Scientific SCS System. Refer to the tables in the "Electromagnetic Compatibility" section to determine the recommended separation distances between the Boston Scientific SCS System and other transmitters.

Bluetooth® Low Energy Technology

The Remote Control (SC-5261) uses Bluetooth Low Energy technology to communicate between the Remote Control and a compatible mobile device. This communication system has the following characteristics:

- Typical range:
  - » 39.4 inches (1 m) with 95% or higher communication success rate.

The quality of this wireless communication can vary depending on the environment (operating room, recovery room or home).

Data will be resent if not successfully received on either the Remote Control or the compatible mobile device. If there are sources of high interference, you may have a slow connection, difficulty pairing devices, or both. If you experience any of these, you may need to decrease the distance between the connected devices. For information on how to improve connection issues, refer to “Troubleshooting Wireless Coexistence Issues” on page 30.

Wireless Security

Low Frequency RF Inductive Link

The Boston Scientific SCS System has a short range inductively coupled telemetry system. A Remote Control has to be linked with a stimulator to allow communication. The Stimulator will not respond to any device that it is not linked to. There are additional mechanisms that ensure the integrity of the communicated data.

Bluetooth Low Energy Technology

The Remote Control uses passkey pairing to establish a connection with a single mobile device. Only one Remote Control may communicate with a compatible mobile device at the same time. Once pairing is completed the Remote Control and compatible mobile device communication channel is encrypted using AES-CCM encryption.

Wireless Technology Information

Low Frequency RF Inductive Link

Frequency Band: 119 – 131 kHz
Modulation type: FSK
Effective Radiated Power: 0.05 mW (-13 dBm) maximum
Magnetic Field Strength (at 3 m distance): 46 µA/m

Bluetooth Low Energy Technology

Frequency Band: 2.402 to 2.4800 GHz
Modulation Type: GFSK
Effective Radiated Power (at 20 cm distance): 21.1 mW typical
Magnetic Field Strength (at 3 m distance): ~ 0.0003 A/m maximum
Protocol: Bluetooth Low Energy technology (Version 4.1)

Troubleshooting Wireless Coexistence Issues

If you experience issues with the wireless communication behavior between the Remote Control, IPG or compatible mobile device, try the following steps to correct the behavior:

- Decrease the distance between the two devices if possible
- Move the devices so they are within line of sight of each other
- Relocate the devices away from other equipment or devices that may be causing interference
- Close the application on the compatible mobile device and allow the Remote Control to cycle off, wait a few minutes and try connecting the two devices again

Note: *Do not operate other wireless communications equipment (such as laptops, tablets, cell phones, cell phone boosters, Wi-Fi routers, or cordless phones), or microwave ovens at the same time and in close proximity to the two devices you are trying to pair or use. Wireless communications*

equipment and microwave ovens can affect the ability to pair and or the performance of the communications link between the Remote Control and compatible mobile devices.

Wireless Charging Information:

Charging Frequency: 77 – 90 kHz

The charging distance between the Charger and the IPG is between 0.5 to 2 cm. Centering the charger over the stimulator ensures the shortest charging time. The Charger will beep as it searches for the IPG and will stop beeping when it is aligned with the IPG. Refer to the instructions provided in the "*Charging Your Stimulator*" Section of the *Charger Handbook* for instructions on aligning the Charger.

Essential Performance

Failure of the external electrical components will not result in an unacceptable risk to the user.

Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic immunity			
The Boston Scientific SCS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Boston Scientific SCS System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: Remote Control and Charger: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV ETS: ± 2 kV, ± 4 kV, ± 8 kV Contact: Remote Control and Charger: ± 8 kV ETS: ± 6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. **Note:** Applies to external devices.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.
NOTE U_T *is the a.c. mains voltage prior to application of the test level.*			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Boston Scientific SCS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Boston Scientific SCS System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	Professional healthcare facility environment and home healthcare environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 M Hz to 2,7 GHz	Professional healthcare facility environment and home healthcare environment. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol shown below: 
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Boston Scientific SCS System is used exceeds the applicable RF compliance level above, the Boston Scientific SCS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Boston Scientific SCS System.			

Recommended separation distances between portable and mobile RF communications equipment and the external components of the Boston Scientific SCS System
The Boston Scientific SCS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Boston Scientific SCS System can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the external components of the Boston Scientific SCS System.
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - electromagnetic emissions		
The Boston Scientific SCS System is intended for use in the electromagnetic environment specified below. The customer or user of the Boston Scientific SCS System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guide**
RF emissions CISPR 11	Group 1	The Boston Scientific SCS System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Boston Scientific System is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Manufacturer's declaration for proximity fields			
The Remote Control (SC-5261) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of the Remote Control can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Remote Control as recommended below, according to the maximum output power of the communications equipment.			
Proximity Test	**IEC 60601 Test 4th Edition Level**	**Compliance Level**	**Electromagnetic Environment Guide**
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended separation distance d = 0.3 m
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
IEC 61000-4-3	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	Recommended separation distance d = 0.3 m
	2450 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
NOTE: For the frequency bands in this table, use the specified recommended separation distance. The recommended minimum separation distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the Remote Control (SC-5261) apply to all other frequencies within the specified ranges.			

RFID Spec Per AIM 7351731 (02.23.207 Edition)	Frequency	Test Level (RMS)
ISO 14223	134.2 kHz	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m
ISOAEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m
ISO 18000-3 Mode 3	13.56 MHz	12 A/m
ISO/IEC 18000-7	433 MHz	3 V/m
ISO/IEC 18000-63 Type C[a]	860-960 MHz	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m
a See Annex L, Guidance for healthcare organizations and RFID providers.		
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from various structures, objects, and people. (a) Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. (b) Over the frequency range 150 kHz and 80 MHz, field strengths should be less than 3 V/m.		

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 Boston Scientific SCS System IPG software is programmed to end service after 12 years. As the IPG nears the end of the programmed period, the 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.

Rechargeable IPG Battery Life

The Boston Scientific rechargeable SCS System's programming software gives your healthcare provider an estimate of charging time based on 24 hours per day of stimulation at the programmed settings. Depending on your program parameters, you may expect daily recharging times from as low as 10 minutes up to four hours, or weekly recharging times from as low as one hour up to four hours. If you do not recharge your implant, stimulation will eventually stop until you charge again.

The rechargeable battery in the Boston Scientific System's IPG should provide at least five years of service.[1] Battery life is dependent on your stimulation settings and conditions. In most cases, the Stimulator will need to be recharged at intervals ranging from once a week to once a month. 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. Your implant will need surgical replacement when stimulation can no longer be maintained with routine charging.

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.

Checking Stimulation Status

Because stimulation therapy should not be felt by patients receiving subperception therapy, patients should use the following procedure to check stimulation therapy status.

To check if stimulation therapy is **ON**:

Press the unlock/lock button on the side of the remote at any time, even if the Remote Control is in sleep mode.

The remote control screen should display either the Therapy **ON** icon or the Therapy **OFF** icon.

If stimulation therapy is **OFF**, press the button again to turn stimulation therapy **ON**.

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 Corporation
  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 is targeted to treat pain.

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 DISTURBANCE. Any electromagnetic phenomenon which can degrade the performance of a device or system.

ELECTROMAGNETIC INTERFERENCE (EMI). Degradation of the performance of a transmission channel or system caused by an electromagnetic disturbance.

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.

NON-PARESTHESIA. Absence of paresthesia. Also referred to as paresthesia free. See paresthesia definition.

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. Sensation that may be produced by stimulation.

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

PERCEPTION. A sensation that may be produced by stimulation at certain programmable settings.

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 designed for efficient charging.

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.

SCHEDULES. A schedule is a configuration of Programs and Wait Periods that are automatically cycled, either randomly or in a sequence, at defined time intervals. Schedules are designed to increase ease-of-use during the Spectra WaveWriter Trial. With automatic cycling of programs, you can experience different types of therapy from delivery of different waveforms, without using their remote control.

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, pulsating electrical signal delivered to a nerve by a device.

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.

SUBPERCEPTION. A term used to describe stimulation therapy that does not produce a sensation at certain programmable settings. This is also referred to as paresthesia independent or paresthesia free.

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

THERAPY. Patterns of stimulation used to reduce the awareness of pain. Therapy can be programmed at perception or subperception.

THERAPY RATING. The patient-recorded feedback on the therapy treating pain. You can record this feedback in your Remote Control at any time. The Therapy Rating feature is used by your physician to optimize your stimulation therapy. The Therapy Rating feature is available only with the Spectra WaveWriter SCS system.

ZERO VOLT™. Battery technology allowing the Boston Scientific rechargeable IPG to be completely discharged without causing battery failure or degradation.

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Boston Scientific

Advancing science for life™

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