



PHYSICIAN IMPLANT MANUAL

Implantable Pulse Generator
model SC1100

PRECISION
Spinal Cord Stimulation System



Physician Implant Manual

9055100-001 Rev E

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Introduction

Manual Overview

This manual provides basic information for the implantation and operation of the Precision™ Implantable Pulse Generator (IPG), SC Model 1100. This information includes an overview of accessories for programming and powering the IPG, clinical and surgical considerations, storage and handling requirements, and relevant precautions concerning an implanted neurostimulator. Additional information on system components and operation can be found in the BionicNavigator™ Software Guide.

Device Description

The Advanced Bionics® Precision implantable pulse generator system is intended to treat chronic pain by electrically stimulating the spinal cord. The multi-channel, multi-electrode device capability provides flexibility in conjunction with ease of programming. A rechargeable battery increases IPG longevity and output capability while reducing size and device replacement surgeries. The implant is controlled by a handheld Remote Control, and can be engaged by a clinician computer using proprietary BionicNavigator software. Periodically, the implant battery requires replenishing with an RF charging device provided in the Patient Take Home Kit SC-6000.

Features

- Stimulation electrode field navigation
- Sixteen independent current-controlled electrodes
- Four programmable stimulation areas per program; four possible programs
- Long-life operation
- High-range parameter capability
- Small size
- Two-foot programming range

Indications for Use

The Advanced Bionics PRECISION™ 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 System Clinical Summary

Determination of the safety and effectiveness of the PRECISION System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The PRECISION 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 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 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 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 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 2 weeks to 6 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

Safety Instructions

Warnings

Magnetic Resonance Imaging (MRI). Patients implanted with the Precision 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.

Implant 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. 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, ensuring to 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

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 implant, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery: *Do not use monopolar cautery.*
- external defibrillation
- radiation therapy
- ultrasonic scanning
- high-output ultrasound

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 15. 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

Cell Phones. While we don't anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time.

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 exercise or attempt to move heavy objects, and avoid deep bending and stretching. 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.

Implant Location. Never attempt to change the orientation or "flip" 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 implant and contact your physician so that the system can be evaluated.

Storage. 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).

Handling. Handle the system 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 the components. (See “Limited Warranty” on page 50.)

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 Advanced Bionics.

Remote Control Battery. Do not try to use a AA (1.5-volt) battery in the Remote Control unit. The control will only operate with the special 3.6-volt battery available from Advanced Bionics.

Remote Control, Charging System Cleaning. The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning.

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 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.
- Tissue reaction to implanted materials can occur.
- Skin erosion or seroma at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, spinal cord compression, 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 implant may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.