ADVANCED BIONICS

PATIENT TRIAL HANDBOOK

PRECISION

Spinal Cord Stimulation System

Patient Trial Handbook

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

9055078-001 Rev C

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 System components should only be serviced by Advanced Bionics. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair the components will void the warranty.

Guarantees

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

Registered trademarks

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Introduction

Welcome to the "Trial Phase" of the Advanced Bionics® Precision™ pain management program. You're about to test a pain treatment therapy that could result in a dramatic change in your life and your lifestyle. The trial you've agreed to participate in is intended to give you and your physician a chance to evaluate *spinal cord stimulation* (SCS) as an appropriate and effective long-term therapy option for your chronic pain.

At the end of the trial period (approximately one week) you and your physician will meet to discuss your experience with spinal cord stimulation. The doctor will also want to explore your feelings about a permanent SCS implant so that, together, both of you can determine whether long-term treatment with spinal cord stimulation is an appropriate option for you. To prepare yourself for this important decision, you may want to spend at least some of the trial period carefully evaluating spinal cord stimulation.

Contraindications: Patients who fail to receive pain relief during stimulation, do not meet psychological selection criteria, are poor surgical risks or are pregnant cannot be implanted with the permanent device.

What is Spinal Cord Stimulation?

Most pain signals travel from the source problem or injury area to nerve pathways to the spine, then up the spine and to the brain. SCS uses electrical stimulation of the spinal cord to block the

perception of those signals. To apply the stimulation, a small electrical pulse generator is connected to one or two wires, called leads, which are placed along your spinal cord. The stimulator, internal or external, sends pulses of a low electrical current to a series of metal contacts, called electrodes, located at the end of the lead(s). The "feeling" produced by this stimulation is a light sensation called *paresthesia*. Thousands of SCS patients consider paresthesia not only a pleasant substitute feeling, but also an effective and welcome relief from pain.

It's important to understand that spinal cord stimulation cannot *cure* pain or eliminate its cause. It does, however, provide control of and relief from certain types of pain over the area where the paresthesia is felt. Spinal cord stimulation is a treatment choice designed to provide you with the most effective pain relief over the widest pain area possible. When that goal is reached with the Precision™ system, you should experience good to excellent relief from chronic pain.

Caretaking During the Trial

To speed-up your recovery following the surgery, your physician might require bed rest for the first several hours after the surgery; administer antibiotics; schedule a mid-trial follow-up visit; and limit your physical activity, including driving.

If your doctor approves of you driving during the trial, always turn off the external Trial Stimulator before getting behind the wheel. Please ask for specific instructions about what you may do and should not do during the trial, and follow all instructions carefully!

Be aware that some changes in posture can cause a decrease or (at times) an uncomfortable increase in the strength of the stimulation. Keep the Remote Control with you at all times so that you can make adjustments quickly if necessary.

You can help the recovery process by:

- Keeping your incision dry. Be sure you understand instructions about cleaning the incision and sponge-bathing. You must not bathe or shower during the trial.
- Checking the wound occasionally for signs of redness or the presence of fluid.
- Notifying your physician's office if you develop a fever, or if you experience increased pain at the incision site.
- Limiting most physical activity during the trial.

During sleep, bathing or for comfort, turn off the Trial Stimulator, remove it from the pocket, and disconnect the leads (see “The Trial Stimulator” on page 10 for information on disconnecting the leads).

The position and stability of your leads is a vitally important part of the trial experience. Remember that, when they were placed along your spine, the leads were specifically located according to where you felt stimulation covering your pain. You want the leads to stay in place! So, to prevent them from moving:

- Do not lift objects of more than 5 pounds.
- Do not engage in rigorous activity such as twisting, bending or climbing.
- Do not raise your arms above your head.
- Do not pull or jiggle the leads.

Again, call your doctor if you have any questions about an activity that you’re not sure is appropriate for you during the trial.

How to Use This Manual During the Trial

You will probably want to refer to this manual often during the trial period. For that reason, the content is arranged in the order you are most likely to need it.

Overview: The Trial Journal. This section describes the SCS Trial Journal which is included at the back of this manual. The journal is made up of a brief questionnaire, a simple chart, and a stimulation activity log. *Start your journal the first full day following surgery.*

Using the Medical Equipment. Turn to this section when you're ready to learn about the many ways available for managing stimulation using the Remote Control unit to program the Trial Stimulator. Depending upon the instructions you receive from your doctor you may not need all of the information here. But it may help you in the future.

Safety Instructions. This section covers information you should be aware of (especially) if you are under medical care for other conditions, or if your doctor does not restrict your activities outside the home.

Questions and Answers. This section addresses typical questions that you and other SCS patients have when first beginning therapy.

Overview: The Trial Journal

All trials or tryouts require careful record keeping of times or scores, and your SCS trial is no exception. In order for you and your doctor to decide to move on to the next step—a permanent implant— you'll both need a way to review the details of each of your SCS trial days. The easiest way to do that is with the help of a journal. Your journal, which can be found at the back of this manual, consists of the following:

Pain Profile

You may think of the Pain Profile as a way to make a starting point for this trial and for the journal. The simple questions you answer here will establish a detailed, personal description of your pain condition. The profile includes a simple graph called a Visual Analog Scale (VAS), commonly used to measure the before-and-after pain levels of SCS trial patients. You may have completed a VAS before in your doctor's office or at a clinic. Once your VAS score is marked, it becomes an important tool for determining your progress at the end of the trial.

The Journal

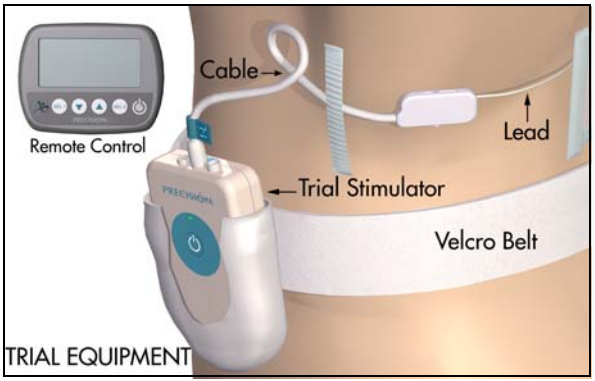
Seven log pages are included in your journal. We suggest that you begin keeping the log starting with the **first full day** following your surgery. An explanation of the columns follows:

- Activity: Please name the activity whether it's getting out of bed, washing the dishes, or walking the dog.
- Time: Fill in the approximate time (starting, during or ending) of the activity.
- VAS: Use this column to enter a Visual Analog Scale pain score for what your pain level was during the activity. The VAS score is a number between zero (0) and ten (10), where 10 is the worst pain imaginable and 0 is no pain. Rate the pain level you had while doing the activity.
- STIM ON (Program No.) or STIM OFF: Indicate if stimulation was on or off during the activity. If you know which program you were using, write the program number (1, 2, 3 or 4).

Using the Medical Equipment

The Trial Stimulator System

The Trial Stimulator is a temporary external spinal cord stimulator that is connected to the lead(s) placed along the spinal cord. You will use this external system to test how effective stimulation is in relieving your pain.



The Trial System includes:

- **Lead**—An implantable cable that sends stimulation pulses to the spinal cord.
- **Remote Control**—A small battery powered computer used to adjust stimulation.
- **Cable(s)**—Thin plastic cable(s) used to attach the Trial Stimulator to the lead.
- **Velcro® Belt**—A belt used to hold the Trial Stimulator (optional).

Taking Care of Your Trial Equipment

All of the items that were sent home with you from the hospital are important to your trial success. So please follow the instructions listed.

- Handle the Trial Stimulator and the Remote Control with care. These items are well-designed, quality-tested electronic components. However, they can be damaged if they're dropped on a hard surface.
- Never submerge the Trial Stimulator or the Remote Control in water, or leave them outside in the rain, extreme heat, or extreme cold.
- Always turn off the Trial Stimulator, remove it from the belt pocket, and disconnect and secure the leads before taking a sponge bath.
- Carry your Temporary Patient Identification card (given to you by your healthcare provider) throughout the trial.

Note: *This information covers most of what you need to be aware of during the trial. For additional precautionary information, see "Safety Instructions" on page 22. Please read the section carefully.*

The Trial Stimulator

You may turn off the Trial Stimulator by pressing its power on/off button, or by pressing the power button on the Remote Control unit. When the stimulator is on, the indicator light will blink

Always turn the stimulator off before connecting or disconnecting your lead wires.

Disconnecting the Trial Stimulator

The Trial Stimulator has connectors for both left and right leads, and a third connector for a patch electrode. Whether you have one or two leads, your doctor probably placed identifying labels on the lead wires before connecting them to matching plugs on the stimulator. These labels are intended to make it as easy as possible for you to connect the wires properly. *Remember to check the label(s) each time you need to reconnect the leads.*

Note: *If you were given a patch electrode for stimulation, an extra one is provided in case the adhesive wears out. When connecting a new patch electrode, be sure to plug it securely into the connector.*

The Remote Control

The Remote Control unit is your direct link to choices available for tailoring spinal cord stimulation to suit your comfort and convenience requirements. *Keep the Remote Control with you at all times in a pocket, purse, or in your immediate vicinity.*

The Remote Control is used to:

- Turn stimulation ON and OFF
- Change stimulation levels
- Activate or save new programs

Each button function label shown on the screen is related to the control button below it.

Basic Operation

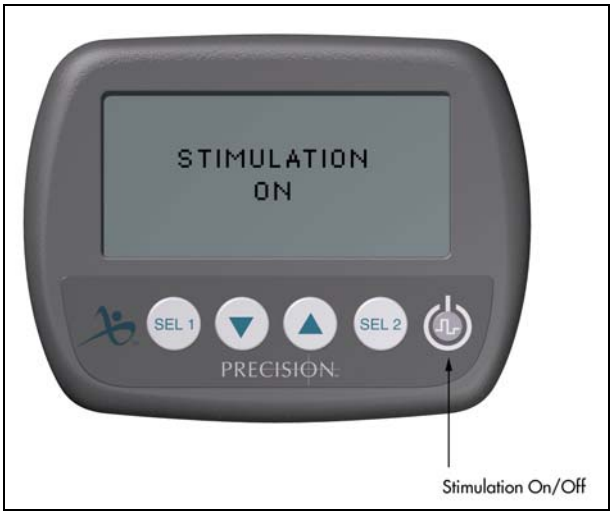
When it is not being used the Remote Control is in a “sleep” mode. Press any button and the Remote Control will wake up and look for the stimulator. Once connected, you can make adjustments. When you are done, the Remote Control will go to sleep after 60 seconds.

Good communication between the implant and the Remote Control is very important. This is the reason you’ll often see the message “Connecting...” while you are adjusting the stimulation. This is normal because the Remote Control continually checks for the stimulator.

Note: *If you have trouble communicating with the stimulator, the message “No Response” will appear on the Remote Control screen. See “Help” on page 26 for more information.*

Stimulation On and Off

The Remote Control uses a “dedicated” stimulation on/off switch. You may press the stimulation power button *at any time* to immediately turn stimulation on or off. You don’t have to be concerned about whether or not the Remote Control is awake.



Stimulation Level Control

A few seconds after stimulation is turned on, the Remote Control displays the main screen. From here, you may press the ▼[down] or ▲ [up] button to adjust the stimulation level (or intensity) until you're comfortable. The main screen controls all stimulation, whether you have one area of pain control... or more than one.

Note: • *In some cases, health professionals can give you control over more than one stimulation area.*

• *Multiple area control is available only if your system has been programmed to deliver stimulation to separate areas. If you do not have separate area control (for example, left leg vs.right leg) but feel that separate control might improve your stimulation therapy, speak to your health professional about this at your next visit.*

Selecting Areas (for Stimulation Control)

1. From the main screen, press the **SEL 1** button as necessary to cycle through your programmed areas. Each area is given a number (1 through 4) or a name, for example LeftArm.

Note: *If you only have one area of control, then that one area will appear each time you press* **SEL 1**.

2. When the named or numbered area that you want to adjust is displayed, press ▼ or ▲ to change the stimulation level for that area.

Selecting Programs (for Stimulation Control)

Your Remote Control can store up to four stimulation programs which may have been set up by your healthcare professional. Each saved program will have certain differences in the settings. These differences allow you to vary your stimulation in many ways. You may have been encouraged to try and compare specific programs for different circumstances or times in your daily routine. This is especially helpful during the trial period. Program flexibility gives you and your healthcare professional a way to continually "fine-tune" your therapy.

To select and activate programs:

1. Press the **SEL 2 [NEXT]** button from the main screen to go to the program screen.
2. Press the **SEL 1 [SEL]** button as necessary to choose the program you want to activate.

3. Once the desired program is highlighted, press ▼ **[ACT]** and that program will start running after a couple of seconds.

Note: *You might not have all four programs saved in your Remote Control. Empty program slots will have an * (asterisk) symbol beside the program number. If you try to activate an empty program, nothing will happen.*

Once you've selected and activated a program, you can adjust its stimulation level using the ▼ and ▲ buttons.

If you make a stimulation level adjustment and decide that you prefer it, go back and select the program again, then press ▲ **[SAVE]**. The program will be updated with the new level.

You may also save changes to any empty (*) program slot if one is available.

Battery Information

Remote Control:

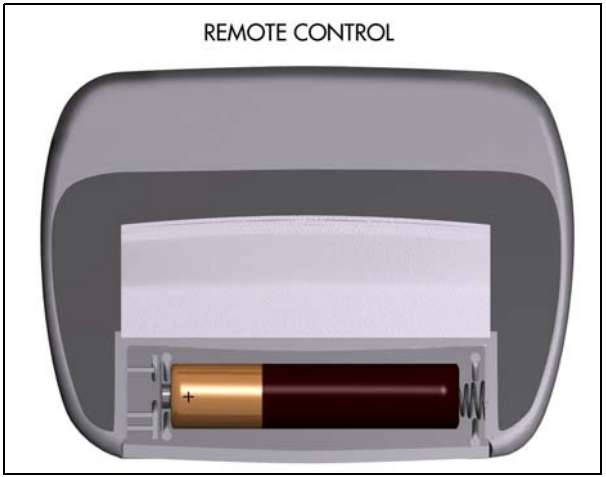
Following the low battery message you will only be able to turn the implant on and off. If you try to use any button except the power button, you will be reminded “Replace Remote Battery ON/OFF ONLY.”

The battery for your Remote Control is a special 3.6-volt battery available only from Advanced Bionics. Do not attempt to use a 1.5-volt AA battery in the Remote Control.

If you do not have an extra battery in your Trial Kit, call Advanced Bionics Customer Service Department at (866) 566-8913 to request a new battery.

To replace the Remote Control battery

1. On the rear of the remote, slide the battery compartment lock lever to the left to unlock the cover.
2. Press down on the ridged area below the lever using your thumb to release the cover.
3. Open the cover and remove the old battery.
4. Replace the new battery in the slot, matching the positive and negative markings.
5. Close the compartment by sliding the lock lever to the right.



The Remote Control will connect and reload information from the stimulator in approximately 30 seconds.

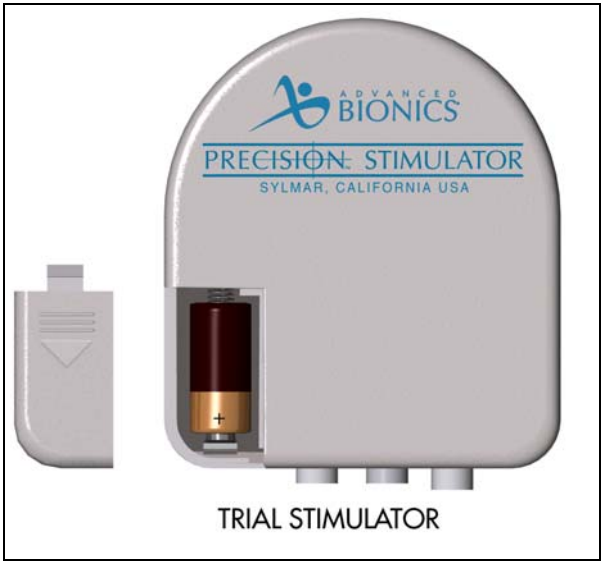
Trial Stimulator:

If the message “REPLACE STIMULATION BATTERY” appears on the Remote Control screen accompanied by a three-beep alarm, press **SEL2 [OK]** to acknowledge the message, then install a new battery right away.

The battery for your Trial Stimulator is a 6-volt battery (lithium Duracell 28L). This type of battery can be purchased at most drug and convenience stores.

To replace the Trial Stimulator battery:

1. On the rear of the unit, press down on the ridged area and slide to release the cover.
2. Open the cover and remove the old battery.
3. Replace the new battery in the slot, matching the positive and negative markings.
4. Close the compartment by sliding the cover in the opposite direction.



Safety Instructions

Warnings

Pregnancy. The safety considerations of SCS devices for use during pregnancy are unknown. If you become pregnant, turn off the External Trial Simulator when you become aware of your condition and consult your physician.

Diathermy. As an SCS patient, you must 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 the leads, causing tissue damage at the lead site and, possibly, severe injury or death.

Posture. Some changes in posture may cause decreased or uncomfortable increased stimulation levels. Keep the Remote Control with you at all times in order to be ready to adjust stimulation for unexpected changes.

Electromagnetic Interference. Avoid or exercise care around electromagnetic fields generated by:

- Theft detectors and security screeners (usually located at stores, airports, libraries, and government buildings)
- Power lines and power generators
- Electric steel furnaces, arc welders, and other heavy duty industrial electric equipment

- 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 External Trial 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 power button and observing the screen.

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

MRI. You must **not** be exposed to Magnetic Resonance Imaging (MRI). Exposure to this diagnostic technology may result in dislodgement of your lead(s) and/or increased voltage through the leads which can cause an uncomfortable or "jolting" sensation.

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

- lithotripsy
- electrocautery

- external defribrillation
- radiation therapy
- ultrasonic scanning
- high-output ultrasound

Before having procedures, medical therapies, or diagnostics, have your healthcare professional call our Customer Service department at (866) 566-8913 for proper instructions.

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

Adverse Effects

Potential risks are involved with any surgery. The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur.
- Skin erosion at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, lead dislodgement.

Help

Stimulation

No Stimulation

1. When stimulating, the Trial Stimulator status light will blink. If it is not blinking, toggle the power button on the Trial Stimulator or the Remote Control. When the Remote Control receives confirmation from the Trial Stimulator, it will flash “Stimulation On.”
2. When the status light is blinking and you still do not feel stimulation:
    a. Check to make sure the lead cable is properly connected to the stimulator. Turn the stimulator “off” before adjusting the cables, and then turn it back “on.”
    b. If you were provided a skin patch electrode, check that it is properly secured to your skin. Make sure to turn the stimulation off first, and then back on.
    c. Try turning up the level of the stimulation. If this does not bring on stimulation, turn it back down.
3. When the status light will not blink and you do not feel stimulation, replace the Trial Stimulator battery.
4. Call your physician’s office if the above steps do not solve the problem.

Stimulation Increases or Decreases on Its Own

1. Stimulation can change depending on body position (lying down, standing or bending).
2. Always keep the Remote Control with you, so that you can adjust your stimulation levels as needed.

Stimulation Coverage is in a Different Area Than at the Doctor's Office

1. If stimulation is moved, and you did not activate a different program, you should call your doctor. It is possible that the leads may have moved during the trial.

Remote Control Display

"Remote Battery Low" on the Display

1. The battery in your Remote Control needs to be replaced using the Advanced Bionics 3.6 Volt battery. Do not use a AA battery. Call Advanced Bionics Customer Service department at (866) 566-8913 or your physician's office to obtain a new battery.

"No Response" on the Display

1. When the Remote Control displays "No Response," it cannot find the Trial Stimulator because of orientation or interference. Move the remote closer and try again. Call our Customer Service Department at (866) 566-8913 if the problem continues.

"Action Unsuccessful" on the Display

1. When the Remote Control displays "Action Unsuccessful," press [OK] and try the action again. If pressing [OK] does not clear the message, call your physician's office.

Accessories

Washing the Velcro® Belt

1. Wash the belt with mild soap and warm water.

Contacting Advanced Bionics

If you have any other questions, or need to contact Advanced Bionics for any reason, you may do so in any of the following ways:

- Customer Service Phone: (866) 566-8913
- Customer Service Fax: (661) 362-1503
- Address: Advanced Bionics® Corporation
  Pain Management Division
  Mann Biomedical Park
  25129 Rye Canyon Loop
  Valencia CA 91355

IMAGINE the Possibilities®

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