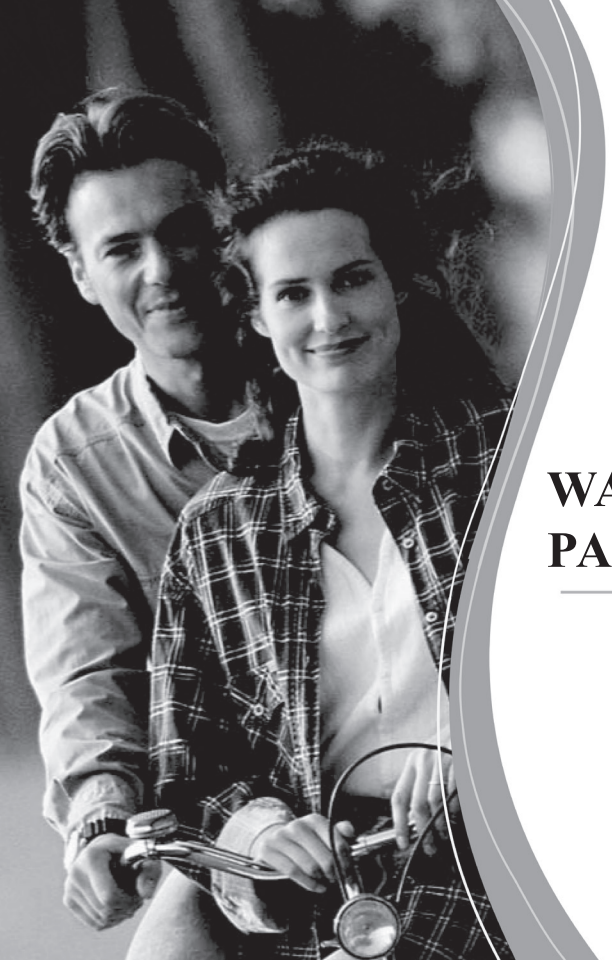

Boston Scientific

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WAVEWRITER ALPHA™ SYSTEM PATIENT TRIAL HANDBOOK

SC-6500-72 Patient Trial Kit
SC-5170 External Trial Stimulator
SC-5170R External Trial Stimulator (Refurbished)

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Patient Trial Handbook

℞ ONLY

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

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.

Trademark

WaveWriter Alpha™ is a trademark of Boston Scientific Corporation or its affiliates.

All other trademarks are the property of their respective owners.

Additional Information

Refer to the appropriate *Information for Patients* manual for your SCS System for indications for use, contraindications, warnings, precautions, adverse events, storage and handling, glossary, and information on contacting Boston Scientific.

Refer to the *Therapy Controller App Handbook* or *Remote Control Handbook* and *Charger Handbook* for your SCS System for device specific information and instructions not included in this handbook.

! USA Refer to the appropriate *Information for Patients* manual for your SCS system for FCC rules and clinical studies supporting the clinical use of the neuromodulation system.

Labeling Symbols

For an explanation of labeling symbols, refer to the Labeling Symbols document.

Warranty

For device warranty information, visit (www.bostonscientific.com/warranty).

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1 Introduction

Welcome to the “Trial Phase” of the Boston Scientific Spinal Cord Stimulation (SCS) pain management program. You are about to test a pain treatment therapy that could result in a dramatic change in your life and your lifestyle. The trial you have agreed to participate in is intended to give you and your physician a chance to evaluate 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 physician will also want to explore your feelings about a permanent SCS implant so that, together, you can determine whether long-term treatment with an applicable Boston Scientific spinal cord stimulation system 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.

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 during the trial phase, a small external trial stimulator (ETS), or **stimulator,** is connected to one or more 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, or **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 is 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.

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.

CAUTION: If your doctor approves of you driving during the trial, make sure to turn off the Trial Stimulator before getting behind the steering 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 increase in the strength of the stimulation. Keep the mobile device with Therapy Controller App or Remote Control with you at all times so that you can make adjustments quickly if necessary. Refer to your Therapy Controller App or Remote Control Handbook for instructions for use.

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 OR Cables (see “Disconnecting the Trial Stimulator” for information on disconnecting the OR Cables).

The position and stability of your Leads is a very important part of the trial experience. Remember when the Leads were placed along your spine, they were specifically located to provide pain coverage. You want the Leads to stay in place. To prevent the Leads from moving:

- Do not lift objects of more than 5 pounds.
- Do not engage in rigorous physical 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 are 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. The journal is made up of a brief questionnaire, a simple chart, and a therapy activity log. *Start your journal the first full day following surgery.*

Using Your Trial Equipment. Turn to this section when you are ready to learn about the many ways available for managing stimulation using the Therapy Controller App or 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 during the trial, but it may help you in the future.

2 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 will 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 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 Numerical Rating Scale (NRS), commonly used to measure the before-and-after pain levels of SCS trial patients. You may have completed a NRS before in your doctor's office or at a clinic. Once your NRS 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 is getting out of bed, washing the dishes, or walking the dog.
- Time: Fill in the approximate time (starting, during or ending) of the activity.
- NRS: Use this column to enter a Numerical Rating Scale pain score for what your pain level was during the activity. The NRS 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.
- Therapy ON (Program No.) or Therapy OFF: Indicate if stimulation was on or off during the activity. If you know which program or schedule you were using, write the program or schedule number (1, 2, 3, or 4).

3 Using the Trial Equipment

The Trial Stimulator System

Caution

- Keep the Trial Stimulator dry. It should not be exposed to moisture.
- Do not connect the Trial Stimulator to any other device except to the OR Cables provided with it.
- Keep the Trial Stimulator away from pets, pests, and children to avoid damage to the device.

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:

- **Trial Stimulator**
- **Lead(s)—**An implantable wire that sends stimulation pulses to the spinal cord. You may have up to four Leads.
- **Remote Control—**A small battery powered device used to adjust stimulation.
  or
  Therapy Controller App—Software App used to adjust stimulation. Installed on a compatible mobile device.
- **OR Cable(s)—**Thin plastic-coated wire(s) used to attach the Trial Stimulator to the Lead.
- **Trial Belt—**A waist wrap/pocket for wearing the Trial Stimulator.

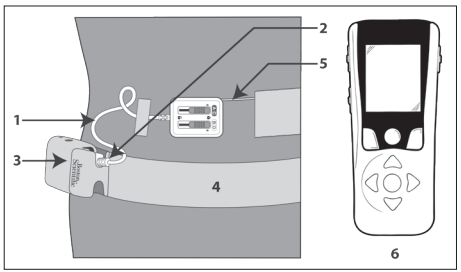


Table 1: Trial Equipment

1. OR Cable	4. Trial Belt
2. OR Cable Connection to Trial Stimulator	5. Lead
3. Trial Stimulator	6. Remote Control or Mobile Device with Therapy Controller App

Note: *Use only accessories supplied or approved by Boston Scientific.*
For the Trial Stimulator, use only the Patient Trial Belt supplied by Boston Scientific.

Taking Care of Your Trial Equipment

All of the items that were sent home with you from the hospital or out patient center are important to your trial success, so please follow the instructions listed. Refer to the instructions for use provided with your mobile device when using the Therapy Controller App.

- 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 are 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. Avoid all sources of water that can come into contact with the Remote Control and the Trial Stimulator.
- Always turn off the Trial Stimulator, remove it from the belt pocket, and disconnect and secure the OR Cables before taking a sponge bath.
- Carry your Temporary Patient Identification card (given to you by your healthcare provider) throughout the trial.

The Trial Stimulator

To turn therapy on or off, press the ON/OFF button on the Therapy Controller App or Remote Control. To minimize the movement of your Leads, it is preferable to use the Therapy Controller App or Remote Control. However, you may also turn the Stimulator on and off by pressing the ON/OFF button on the Trial Stimulator. When the Stimulator is on, the Therapy ON indicator light will blink green. When the batteries need replacement, the Battery Indicator Light will change from a flashing green light to a flashing yellow light.

CAUTION: Always turn the Stimulator off and decrease the strength of stimulation to zero before connecting or disconnecting your OR Cables.

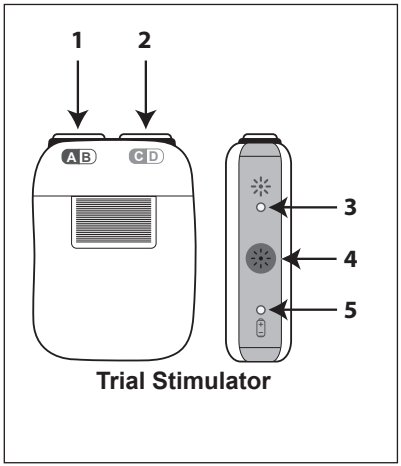


Table 2: Stimulator Connection

1. AB connector	4. Therapy ON/OFF
2. CD connector	5. Battery Indicator light
3. Therapy Indicator light	

Disconnecting the Trial Stimulator

The OR Cables connect the Leads to the Trial Stimulator. The Trial Stimulator has two connectors: AB and CD. Your healthcare provider may have placed identifying labels on the OR Cables before connecting them to matching plugs on the Trial Stimulator. Check the labels each time you need to connect to or disconnect from the Trial Stimulator.

Trial Stimulator Battery Replacement

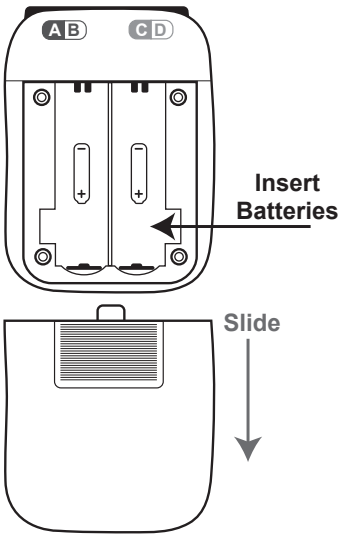
If your Trial Stimulator battery drains to a very low level, install new batteries right away.

Be sure that therapy is off (the therapy indicator light is not blinking) before opening the Trial Stimulator's battery compartment.

1. On the rear of the Trial Stimulator, push in slightly and slide down the battery compartment cover.

Note: *The serial and model number for your Trial Stimulator are visible when the battery compartment cover is removed.*

2. Remove the old batteries.
3. Place the two new AA batteries in the slots, matching the positive (+) and negative (-) markings in the compartment.
4. Align the battery compartment cover on the case and slide the cover into position until it snaps closed.



Both the Battery and Therapy ON indicator lights will emit an amber glow for 15 seconds, after which the Battery indicator light blinks green.

Trial Stimulator Battery Service Life

The External Trial Stimulator battery has a typical service life of 10 days.

Accessories

Washing the Trial Belt

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

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Boston Scientific
Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355 USA
+1-866-789-5899 in US and Canada
+1-661-949-4000, +1-661-949-4022 Fax
+1-866-789-6364 TTY
www.bostonscientific.com
Email: neuro.info@bsci.com

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