Patient Manual

Biomet® SpinalPak®

Non-invasive Spine Fusion Stimulator System

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WHY YOUR DOCTOR HAS PRESCRIBED THE BIOMET® SPINALPAK® NON-INVASIVE SPINE FUSION STIMULATOR SYSTEM

Following your spine fusion (back) surgery, your doctor has prescribed the SpinalPak® as an added treatment to your surgery. The SpinalPak® delivers a treatment signal to the area of your surgery. This manual provides instructions on how to use and care for your SpinalPak®. Please read this information carefully before using the stimulator. The safest and most effective use of the SpinalPak® depends upon following the instructions and care described below.

HOW THE SPINALPAK® WORKS

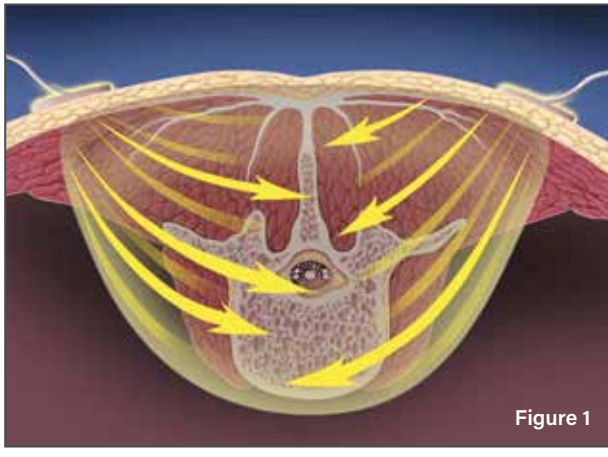

Figure 1

The SpinalPak® delivers an electrical treatment signal that is intended to help your back to heal, (see Figure 1). The signal operates at a high frequency; therefore, you should not feel the signal during your treatment. Two lightweight electrodes (conductors of electrical signals), which look like round bandages, are placed on your spine, four to six inches apart from one another, at the level of your back surgery. These electrodes, which are necessary for delivering the electrical signal to your surgery site, are easy to apply, and extremely lightweight.

The stimulator is battery operated with a rechargeable battery pack. Upon connection of the charged battery pack, the stimulator is automatically activated (turned on) and ready to deliver treatment.

YOUR SPINALPAK® KIT INCLUDES:

- Controller
- Electrodes
- Adhesive electrode cover patches to place over the electrodes to enhance electrode security to the skin (if needed) or for showering with the electrodes attached to the skin (if desired)
- Electrode lead wires to connect the electrodes to the SpinalPak®
- Two rechargeable battery packs
- Battery pack charger and cradle
- Patient Manual
- A device holster to wear the stimulator on the patient's waistband or belt

WEARING THE SPINALPAK®

The SpinalPak® has been specifically designed to be convenient to use, comfortable to wear, and safe to operate. You should begin using the SpinalPak® immediately after you have read the instructions for use and received instructions from your doctor.

SYSTEM COMPONENTS

Electrodes

A supply of electrodes is included with every assembly. The patient should replace electrodes every 1 to 7 days. Patients can order additional electrodes by calling 800-526-2579 and then dialing extension 6000.

Electrode Cover Patches

The electrode cover patches are water resistant and are intended to enhance electrode security to the skin, if needed, or for showering with the electrodes attached, if desired.

Device Holster

The device holster is designed to securely hold the SpinalPak® in place. It has a clip on the back which allows the patient to wear the device on their waistband or belt.

Lead Wires

Two different length lead wires are included with the SpinalPak®. The patient should choose the lead wire that best accommodates their needs for where they would like to wear the control unit. Additional lengths are available from the Customer Care team.

Treatment with the SpinalPak®

- Clean and dry your skin where the electrodes will be placed. Trimming (not shaving) body hair from the electrode application area is often helpful.
- Place one electrode on your skin, two to three inches to the left of the area of your surgery and a second electrode two to three inches to the right of the area of your surgery, so that the electrodes are four to six inches apart. (see Figure 2)

Depending upon your ability to move after surgery, it may be helpful to ask another person to assist you in placing these electrodes on your back. For information about how to apply the electrodes, see instructions for use on Page 8. Consult your surgeon or local representative if you have any questions about proper electrode placement.

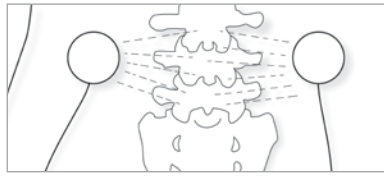

Figure 2

If your skin becomes abnormally red at the electrode sites, the electrodes should be moved to either immediately above or below the original sites. If the redness does not go away after 48 hours once the electrodes are removed, you should contact your doctor.

- You are provided with two choices of stimulator lead wire lengths with the SpinalPak®. Select a length of stimulator lead wire in order to enhance your comfort while wearing the stimulator and receiving treatment.
- Insert the stimulator lead wire male connection into each female electrode lead wire connections.
- Insert the lead wire plug into the opening at the top of the stimulator. (see Figure 3).

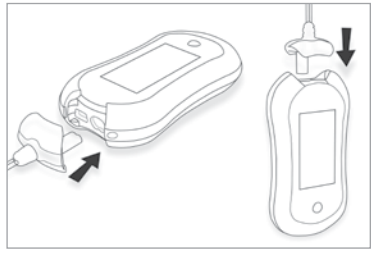

Figure 3

OPERATING INSTRUCTIONS

Both battery packs provided with the SpinalPak® are partially charged prior to being packaged. Upon receipt of the SpinalPak®, it is recommended that you take the second battery pack, place it into the charger cradle and charge fully. In the meantime, you may use the first battery pack to begin your treatment immediately. **Note:** The first battery pack may not provide a 24-hour treatment initially.

Step 1:

Plug the A/C adapter of the battery pack charger into a wall outlet (Figure 4). A green light on the A/C adapter will illuminate indicating power (Figure 5). Connect the A/C adapter and cradle.

Note: At room temperature, (24°C (75°F)), charging may take two to three hours. In warmer or colder temperatures, the battery may take longer to charge.

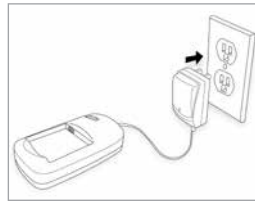

Figure 4

Step 2:

Following the arrows (1, 2), insert the charged battery pack into the SpinalPak® (Figure 6). The LED light will blink, indicating ready for use.

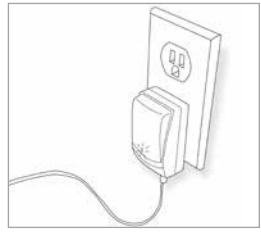

Figure 5

Each symbol will be indicated on the screen and the alarm will flash and beep if the electrodes are not properly applied.

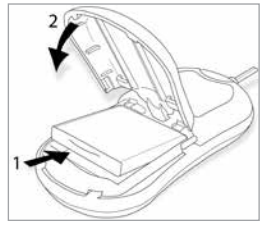

Figure 6

To silence the audio alarm, press the button below the messaging screen. If the light does not blink, this indicates the battery pack is not charged. Charge the battery pack (see CHANGING BATTERY PACKS below).

Step 3:

Attach electrodes as per instructions on pages 3 and 8.

Helpful Tips:
Loose electrodes – Confirm that both electrodes are in complete contact with clean, dry skin. Moisten or replace worn electrodes if necessary.
Incomplete circuit/disconnection – Check all connection points, confirming a snug fit.
Broken electrode lead wire – If alarm continues after confirming connection, attach a new electrode lead wire.

⚠ **Warning:** Do not attempt to charge any other battery pack. Do not use the battery packs supplied with this unit in any other device. Use of the SpinalPak® battery packs in any other device may cause damage or malfunction to the battery pack and/or devices. Do not short circuit, overcharge, crush, mutilate, nail penetrate, heat, reverse the + or – terminals or disassemble the battery pack. Do not allow metal objects to come into contact with the battery pack terminals. These and any other abuses of the battery pack may cause serious injury and/or burns. To ensure proper charging and safety, use only the charger supplied with your device. Keep battery pack dry. This battery pack must be disposed of properly. Disposal information can be obtained by contacting the Rechargeable Battery Recycling Corporation (RBRC) at 1-800-822-8837 in the US.

STEP 4: CHANGING BATTERY PACKS

Once daily, preferably at the same time every day to ensure treatment is continued without interruption, patients should do the following:

A. Depress the battery door latch (1) and slide the battery door on the back of the stimulator (2) and remove the depleted battery pack (Figure 7).

B. Following the arrows, place the depleted battery pack into the battery charger cradle for charging (Figure 8). A solid orange light on the charger cradle will illuminate indicating a proper connection. If no light appears on the charging cradle an error is indicated. If this occurs, try removing the battery pack from the charger cradle and reinserting it. If the orange light does not appear, contact the Customer Care team.

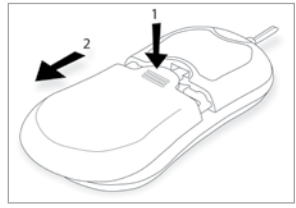

Figure 7

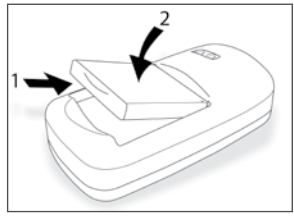

Figure 8

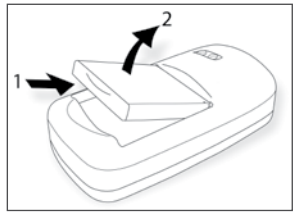

Figure 9

C. Once the charger cradle's orange light turns off and a solid green light appears, the battery pack is fully charged. Remove the battery pack from the battery charger cradle with a gentle lift (1, 2) on the battery tab, (Figure 9) and place the fully charged battery pack into the SpinalPak® in order to commence treatment.

D. There should always be one battery pack in the charger and one battery pack installed in the stimulator at all times, ensuring a fully charged battery pack every 24 hours as recommended.

NOTE: *Do not be concerned if the battery packs are inadvertently charged more than once or kept on the charger cradle for a long period of time. The battery pack cannot be overcharged. If the battery pack is in the battery pack charger cradle and the battery pack is fully charged, the charger will terminate the recharging process. The charger cradle will indicate this termination when the orange light does not illuminate. Additional replacement battery packs are available by contacting the Customer Care team..*

LCD SYMBOL DESCRIPTIONS AND INSTRUCTIONS

The alarm defaults to audible alarm. Press the button below the display on the front of the stimulator to silence the alarm. The light will continue to flash and the display will indicate the alarm condition.

Symbol	Condition	Instructions
✔	Treating	Continue use.
	Audible alarm engaged	If beeping, depress the button engaged briefly to silence the alarm. Depress the button approximately 3 seconds to engage or disengage the audible alarm.
	Low battery charge	Insert a charged battery pack.
	Disconnection of lead wire	Confirm that each electrode is properly applied on the skin. See the electrode pouch for instructions. Confirm that the lead wire is attached properly. Replace the lead wire if necessary.
	System error	Error in the stimulator – Contact the Customer Care team for assistance.
	Device is connected to a PC	Device will not treat until USB cable is disconnected.
	End of operation/ Treatment Completion	Contact the Customer Care team.

TROUBLESHOOTING - ELECTRODES

- Change your electrodes as required. Different skin types will cause a longer or shorter life of the electrodes. If the alarm indicates a disconnection, it is likely that either the lead wire connection is incomplete or the adhesive (gel) on the electrode is no longer working and the electrodes need changing. Check all lead wire connection points, to make sure that the electrode lead wire is tightly plugged into the top of the SpinalPak® (Figure 10) and that the lead wire connectors are completely inserted into both electrode connectors.

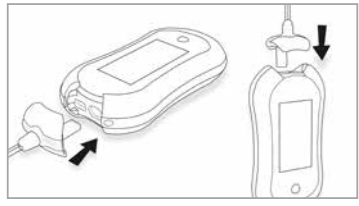

Figure 10

  If all the connections are made and the symbol indicates a disconnection, it is probably time to change the electrodes.
- Remove the old electrodes from your skin.
- Wash your skin gently with soap and water and dry.
- Remove two new electrodes from the packaging and store the liner for future use.
- Gently press the electrodes on your skin in the same place as before. Ask another person for help if you cannot reach the site easily. If your skin is very red, place the electrodes slightly above or below the original sites. Call your prescribing physician if the redness does not go away in 48 hours. It is normal to note a slight pinkness of the skin after removal of the previous pair of electrodes. This pinkness will fade within a short period of time.

NOTE: The SpinalPak® accurately records the number of days you receive treatment. This helps your doctor track your treatment.

HELPFUL TIPS

- Keep the audible alarm "ON" as much as possible. This alarm will help warn you of any problems with the device. During special occasions when you would like the device not to tell you audibly about stimulator problems, you may press the button for 3 seconds to turn off the audible alarm. It is recommended that you turn the audible alarm back "ON" as soon as possible by pressing the button for 3 seconds again.

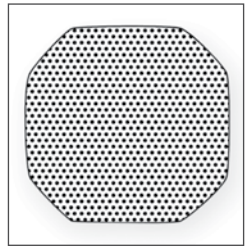

Figure 11

- Remove your SpinalPak® when you bathe, shower or swim. You should remove the electrodes or cover them with the additional adhesive cover patches provided, as shown in Figure 11 if you prefer to leave the electrodes attached to the skin during showering.
- Use the SpinalPak® up to 24 hours per day. Your doctor will tell you when to stop using it. After 270 continuous treatment days the SpinalPak® will automatically turn off.

ELECTRODE INSTRUCTIONS FOR USE

Do not open outer packet until ready to use.

1) Tear open packet.
2) Remove electrode from clear plastic backing liner.
3) Wet finger with tap water and moisten entire gel area.
4) Place electrode on skin.
5) Connect electrode to electrode lead.

Renewal

1) With continuous use, electrodes may dry out.
2) To renew, wet finger with tap water and moisten entire gel area.
3) Reapply electrode to skin.

Store in a cool place

CARING FOR YOUR SPINALPAK®

- Do not use cleaning products or detergents on any part of SpinalPak® components. Please use a damp cloth.
- Do handle the SpinalPak® carefully. Dropping or rough handling can cause damage.
- Store the SpinalPak® in a cool and dry place when you are not wearing it.
- Contact the Customer Care team if you believe that any component has been damaged or is operating improperly.

IF YOU HAVE QUESTIONS

If you have questions about your SpinalPak® or about any components within the assembly, contact the Customer Care team at 800-526-2579.

IMPORTANT: *Any and all medical questions must be directed to your doctor.*

ORDERING INFORMATION

To order replacement supplies, please contact the Customer Care team directly. The following information is necessary to expedite any orders:

- Patient name
- Physician name
- Address to send the replacement supplies (patient's home, MD office, etc.)

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Prescription Only.

Single Patient Use

DISPOSAL INSTRUCTIONS

When treatment has concluded as determined by the prescribing physician, EBI requests that the patient dispose the SpinalPak® according to local statutes and regulations.

Indications for Use
The SpinalPak® is a non-invasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

Warnings
- Cardiac pacemakers or cardioverters may be adversely affected by the SpinalPak®. The concomitant use of the device and a pacemaker or cardioverter must be assessed on an individual basis, such as with an electrocardiogram, prior to use. The patient should be referred to a cardiologist for monitoring of pacemaker function while wearing the active SpinalPak®. If there are any observable adverse changes in the pacemaker rhythm or output, the SpinalPak® should not be used.
- The safety and effectiveness of the SpinalPak® in pregnant women has not been studied, and the effects of the device on the mother or the developing fetus are unknown. A patient who is either pregnant or is intending to become pregnant should be referred to her doctor prior to treatment with the SpinalPak®.

Precautions
- The safety and effectiveness of the SpinalPak® in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of the device in these individuals are unknown:
  - spondylitis, infection, Paget's disease
  - cancer, diabetes mellitus, renal disease
  - trauma of the lumbar spine
  - osteoporosis
- Apply the electrodes after the skin has been cleaned and dried. If erythema develops at the electrode sites, the electrodes should be relocated either immediately above or below the original sites. If the reaction does not resolve after 48 hours after relocating the electrodes, the patient should be instructed to consult the prescribing physician.
- Do not submerge or expose the SpinalPak® to water or any liquid. The patient should be instructed to remove the stimulator during bathing, showering or swimming.
- Compliance with the treatment schedule, daily battery changes, and replacing the electrodes (from 1 to 7 days) as needed is essential for proper stimulator function.
- Patients should be able to use the stimulator in accordance with the instructions for use. If a patient cannot comply with these instructions for any reason, use of the stimulator is not recommended.
- This system should only be used with components and parts recommended by the Customer Care team. Other components and parts may not be compatible, and may damage the stimulator.
- If any component does not function properly, contact the Customer Care team. No attempt should be made to modify or repair the stimulator.

Adverse Events
During a multi-center clinical study of 349 patients treated with the device for the indication listed above, skin irritation was the most common adverse effect associated with the use of the SpinalPak®. It occurred in 9 patients (2.6% of the trial population) — 4 patients treated with the active device and 5 patients treated with the placebo device.

Options

The industry's most comprehensive options:

- PEMF, CC and DC
- Anatomy specific coils
- Wear-time choice

Evidence

- Backed by proven science
- Multiple scientific papers
- The proof is in the patient

Experience

Recognized as an industry pioneer, EBI has helped over one million people.

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Parsippany, NJ 07054
800-526-2579

Legal Manufacturer
EBI Patient Care, Inc.
484 Calle E
Guaynabo, PR 00969 USA

Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. The SpinalPak® is a non-invasive spine fusion stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. No known contraindications. Rx Only. Single Patient Use Only. Do Not Reuse. P/N 1067796-00 REV H. HM0654 REV A 04/25.