

Biomet® SpinalPak®
Non-Invasive Spine Fusion Stimulator System

A Patient's Guide



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Non-Invasive Stimulation
OPTIONS • EVIDENCE • EXPERIENCE



Why Your Doctor Has Prescribed the Biomet® SpinalPak® Stimulator

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

How the Biomet® SpinalPak® Stimulator Works

The Biomet® SpinalPak® Stimulator 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 dermal (skin) 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.

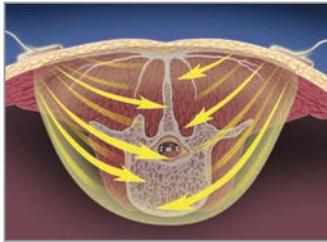


Figure 1

Your Biomet® SpinalPak® Stimulator Kit Includes

- Biomet® SpinalPak® Stimulator
- Extra electrodes (72R and LT-4500)
- Adhesive electrode retainer 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 Biomet® SpinalPak® Stimulator
- Two rechargeable battery packs
- Battery pack charger
- Patient Manual
- A device holster to wear the Biomet® SpinalPak® on the patient's waistband or belt

Wearing the Biomet® SpinalPak® Stimulator

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

System Components

Electrodes

There are two types of electrodes that are packaged with the Biomet® OrthoPak® Stimulator System assembly: 72R and LT-4500. The 72R electrodes have green writing on their packaging. The LT-4500 electrodes have black writing on their packaging. The 72R electrodes have a hydrogel that is stickier than the LT-4500 electrode hydrogel. The patient can use whichever electrodes best suit their skin type.

Electrode Covers

The electrode covers 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 Biomet® SpinalPak® Stimulator 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 Biomet® SpinalPak® Stimulator system. The patient should choose the lead wire that best accommodates their needs for where they would like to wear the control unit.

Treatment with the Biomet® SpinalPak® stimulator

- 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).

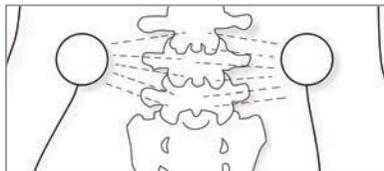


Figure 2

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. See

instructions for use on the electrode packet. Consult your local Biomet representative if you have any questions about proper electrode placement. If your skin becomes abnormally red at the electrode sites, the electrodes should be moved 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 Biomet® SpinalPak® Stimulator. 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.

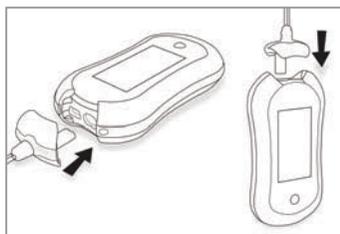


Figure 3

Operating Instructions

Both battery packs provided with the Biomet® SpinalPak® Stimulator are charged prior to being packaged. Upon receipt of the Biomet® SpinalPak® device, it is recommended that you take the second battery pack, place it into the charger 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 battery pack charger into a wall outlet (Figure 4). A green light on the AC adaptor will illuminate indicating power (Figure 5).

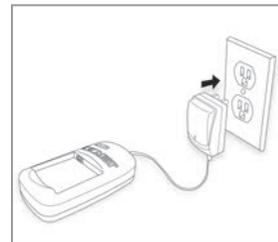


Figure 4

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.

Step 2:

Insert the charged battery pack into the Biomet® SpinalPak® Stimulator (Figure 6). The LED light will blink, indicating ready for use. Each symbol will be indicated on the screen and the alarm will flash and beep if the electrodes are not properly applied. To silence the audio alarm, press the button below the messaging screen. If the light does not blink, which indicates the battery is not charged, charge the battery pack (see CHANGING BATTERY PACKS below).

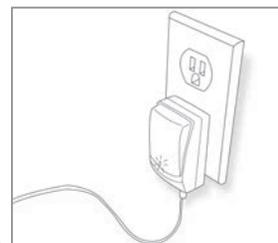


Figure 5

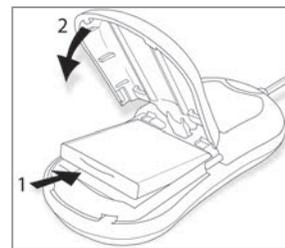


Figure 6

Step 3:

Attach electrodes as per instructions on the package, and as per TREATMENT WITH The Biomet® SpinalPak® section.

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 cable – If alarming continues after confirming connection, attach a new electrode lead wire.

Warning: Do not attempt to charge any other battery. Do not use the battery packs supplied with this unit in any other device. Use of the Biomet® SpinalPak® battery packs in any other device may cause damage or malfunction to the batteries and/or devices. Do not short circuit, overcharge, crush, mutilate, nail penetrate, heat, reverse the + or – terminals or disassemble the battery. Do not allow metal objects to come into contact with the battery terminals. These and any other abuses of the battery may cause serious injury and/or burns. To ensure proper charging and safety, use only the charger supplied with your device. Keep battery 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.

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. Slide the battery door on the back of the stimulator and remove the depleted battery (Figure 7).

B. Place the depleted battery pack into the battery charger for charging (Figure 8). A solid orange light on the charger 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 and reinserting it. If the orange light does not appear, contact Biomet.

C. Once the charger'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 (Figure 9) and place the fully charged battery pack into the Biomet® SpinalPak® Stimulator in order to commence treatment.

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

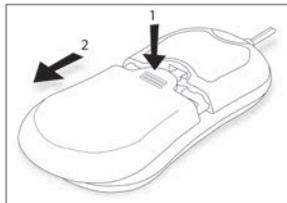


Figure 7

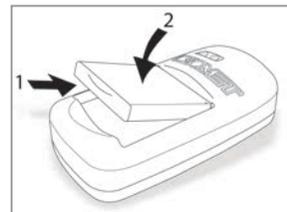


Figure 8

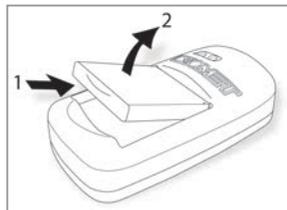


Figure 9

NOTE: Do not be concerned if the battery packs are inadvertently charged more than once or kept on the charger for a long period of time. The batteries cannot be overcharged. If the battery pack is in the battery pack charger and the battery pack is fully charged, the charger will terminate the recharging process. The charger, having no orange light when the charging is complete, will indicate this termination. Additional replacement battery packs are available by contacting Biomet.

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.

Text/ Symbol	Condition	Instructions
✓	Treating	Continue use
	Audible alarm engaged	If beeping, depress the button briefly to silence the alarm. Depress the button approximately 3 seconds to engage or disengage the audible alarm
	Low battery	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 Biomet for assistance.
	Device is connected to a pc	Device will not treat until USB cable is disconnected
	End of operation	Contact Biomet

Troubleshooting - Electrodes

- Change your electrodes every five to seven days. Different skin types will provide for a longer or shorter life of the electrodes. If the alarm indicates a disconnection, it is likely that either the cable connection is incomplete or the adhesive (gel) on the electrode is no longer working and the electrodes need changing. Check all cable connection points, to make sure that the electrode cable is tightly plugged into the top of the Biomet® SpinalPak® Stimulator (Figure 10) and that the cable connectors are completely inserted into both electrode connectors. If all the connections are made and the symbol indicates a disconnection, it is probably time to change the electrodes.

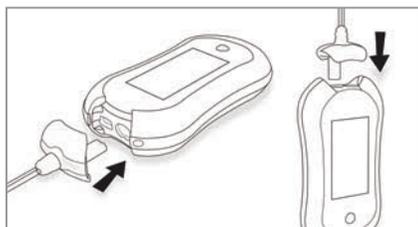


Figure 10

- Remove the old electrodes from your skin.
- Wash your skin gently with soap and water and pat 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 minutes.

Note: The Biomet® SpinalPak® Stimulator 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.

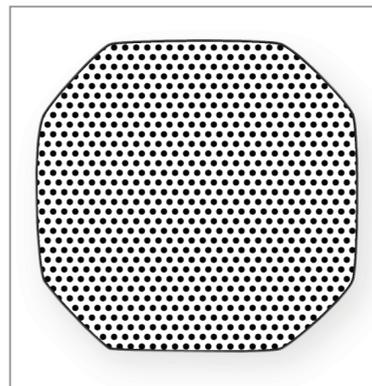


Figure 11

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

Caring For Your Biomet® SpinalPak® Stimulator

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

If You Have Questions

If you have questions about your Biomet® SpinalPak® Stimulator System or about any components within the System, contact Biomet domestically at 1-800-526-2579 or 1-973-299-9300 if calling from outside the United States. Representatives are available from 8:30 am to 5:00 pm (EST), Monday through Friday. At other times, please leave a clear message for a return call by the next business day.

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

Ordering Information

To order replacement supplies, please contact Biomet 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.



Single Patient Use/Prescription Only

Disposal Instructions

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

Indications for Use

The Biomet® SpinalPak® Stimulator is a noninvasive 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 Biomet® SpinalPak® Stimulator. 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 Biomet® SpinalPak® device. If there are any observable adverse changes in the pacemaker rhythm or output, the Biomet® SpinalPak® device should not be used.
- The safety and effectiveness of the Biomet® SpinalPak® Stimulator 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 Biomet® SpinalPak® device.

Precautions

- The safety and effectiveness of the Biomet® SpinalPak® Stimulator 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 Biomet® SpinalPak® Stimulator to water. 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 device function.
- Patients should be able to use the device in accordance with the instructions for use. If a patient cannot comply with these instructions for any reason, use of the device is not recommended.
- This system should only be used with components and parts recommended by Biomet. Other components and parts may not be compatible, and may damage the device.
- If any component does not function properly, contact Biomet. No attempt should be made to modify or repair the device.

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 Biomet® SpinalPak® device. 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.