Physician Manual

Biomet® SpinalPak®

Non-invasive Spine Fusion Stimulator System

Complete Package Insert

Table of Contents

SYSTEM CONTENTS

- Electrodes
- Charger Cradle
- Rechargeable Battery Packs (2)
- Electrode Cover Patches
- Stimulator
- Device Holster
- Lead Wires - 20″ Lead Wire and 48″ Lead Wire
- Patient Manual
- Complete Manual and Package Insert
- A/C Power Adapter

IMPORTANT SAFEGUARDS

Read All Instructions Before Using

Save These Instructions

When using electrical products, basic safety precautions should always be followed:

ATTENTION: To reduce the risk of electric shock, fire or injury:

1. Do not use this product while bathing, showering or swimming.
2. Do not place or store this product where it can fall or be pulled into a tub or sink.
3. Do not immerse the stimulator, battery charger or battery pack in water or any liquid.
4. Do not reach for this product if it has fallen into water. Unplug from the wall outlet immediately.
5. Do not permit the battery charger to be connected to the stimulator when wet.
6. Do not touch the battery pack contacts when the battery charger is plugged into an outlet.
7. Never operate the battery charger if it has a damaged power cord, plug or if it is not working properly. Do not use if it has been dropped and damaged, or immersed into water. Contact the EBI® Customer Care team for return instructions.
8. Do not attempt to charge any other type of battery pack in the SpinalPak® battery charger.
9. Keep all cords away from heated surfaces.
10. Never insert any foreign object into any opening of the system.
11. Do not expose the stimulator or the battery charger to prolonged heat or direct sunlight. (Normal operating temperature range is 5°C to 38°C [41°F to 100°F], normal storage/ transport temperature is -15°C to 50°C [5°F to 122°F].)
12. Use this product only for its intended use as described in this manual.
13. The SpinalPak® has no installation, periodic maintenance requirements or user serviceable parts. If any of the replacement parts are damaged they must be replaced by the EBI® Customer Care team in order to avoid a hazard.
14. 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.

NOTE: Call the Customer Care team at 800-526-2579 with questions or concerns.

BIOMET® SPINALPAK® NON-INVASIVE SPINE FUSION STIMULATOR SYSTEM

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

Figure 1

This device is not intended for re-sale or re-distribution. Single patient use only.

Description

The SpinalPak® promotes (Figure 1) healing by inducing a low electrical current at the fracture nonunion site. The therapeutic signal generates a low energy electrical field by passing a specific current between the electrodes.

Electrical Requirements Battery And Charger

Input: 100-240 VAC 50/60 Hz 6 W
Output: 12 VDC 500mA
For use with the SpinalPak® rechargeable battery pack only (PN 1067720).

Battery rating: 3.7 VDC $\geq$ 800 mAh

Do not use the rechargeable battery pack supplied with this system in any other device. Use of the SpinalPak® battery pack in any other device may cause damage or malfunction to the battery pack and/or devices.

SYSTEM COMPONENTS

Stimulator

The SpinalPak® operates on a rechargeable battery pack, which allows for ambulatory use. It includes an audible and visible self-checking alarm mechanism to alert the patient if it is not functioning properly. The SpinalPak® is designed to store the patient's daily therapeutic treatment data which may be downloaded and read with the patient compliance software (See Patient Compliance Monitoring Page 10). Patients are encouraged to bring the stimulator to each follow-up visit with the prescribing physician to review how they are using their stimulator.

SYSTEM COMPONENTS

Battery And Battery Charger
The SpinalPak® includes two rechargeable battery packs. Upon receipt, it is recommended that the second battery pack be immediately placed into the charger and fully charged. In the meantime, the first battery pack may be used to begin the patient's treatment.

Note: The first battery pack may not provide a 24-hour treatment initially. It is recommended that the patient keep one battery pack in the battery charger to assure that it is fully charged and ready, and the other inserted into the stimulator. This will ensure continuous treatment as prescribed by the prescribing physician.

The battery charger is designed to recharge the SpinalPak® battery packs only. Two LED (light emitting diode) lights monitor and indicate the operational status of the battery charger, a green A/C power indicator light and an orange charging status indicator light. The following table lists and describes the indications of the indicator lights:

Status	A/C Power Indicator Light	Charging Status Indicator Light on Cradle
No battery pack inserted (idle) on A/C powered battery charger	Solid green	Off
Battery pack in charging state	Solid green	Solid orange
Fully charged battery pack	Solid green	Solid green
A/C power deficiency	Off	Off
Error	Solid green	Off

Following Are Possible Error Conditions And Possible Resolutions

Error Conditions (flashes orange)	Possible Resolutions
Battery pack not properly connected to the charger	Remove and re-install the battery pack to ensure complete connection to the charger
Battery temperature is too low or high	Normal operating temperature is 5°C to 38°C [41°F to 100°F]
Battery voltage is too low	Contact the Customer Care team for a new battery pack

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 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 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.

FULL PRESCRIBING INFORMATION

Indications For Use
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.

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® device. If there are any observable adverse changes in the pacemaker rhythm or output, the device should not be used.

The safety and effectiveness of the SpinalPak® in pregnant women have 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 device.

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 adjacent to the original sites. If the reaction does not resolve after 48 hours after relocating the electrodes, the patient should be instructed to consult with the physician.

Do not submerge or expose the SpinalPak® to water. The patient must be instructed to remove the stimulator during bathing, showering or swimming.

Compliance with the treatment schedule, daily battery pack changes, and replacing the electrodes (1 to 7 days) as needed are essential for proper device function. This system should only be used with components and replacement parts supplied by EBI. Other components, parts and accessories may not be compatible, and may damage the device. If any component does not function properly, contact the Customer Care team. No attempt should be made to modify or repair the device.

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.

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 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.

DIRECTIONS FOR USE

Recommended Usage
The SpinalPak® is designed to deliver 270 days of continuous therapeutic treatment for 24 hours per day. The recommended daily therapeutic treatment is continuous for 24 hours.

Operating Instructions
The SpinalPak® has been specifically designed to be convenient to use, comfortable to wear, and safe to operate. Patients should begin using the SpinalPak® immediately after reading the instructions for use and having received instructions from their prescribing physician.

Begin treatment - Electrode Placement

- Clean and dry the skin where the electrodes will be placed. Trimming (not shaving) body hair from the electrode application area is often helpful.

- **Note:** To ensure electrode placement and adhesion, you may use one of the provided electrode retainer patches. Place one electrode two to three inches to the left of the area of the surgery and a second electrode two to three inches to the right of the area of the surgery so that the electrodes are four to six inches apart. See Figure 2. Depending on the patient's ability to move after surgery, it may be helpful for the patient to ask another person to assist them in placing the electrodes. See instructions for use on Page 10. The patient should consult their prescribing physician or the Customer Care team if they have any questions or concerns regarding proper electrode placement. If their skin becomes abnormally red at the electrode sites, the electrodes should be moved adjacent to the original sites. If the redness does not go away after 48 hours with the electrodes removed, the patient should contact their prescribing physician.

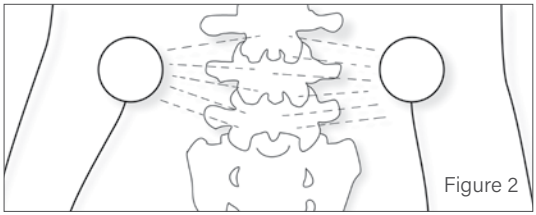


Figure 2

Tips:
Loose electrodes – Confirm that both electrodes are in complete contact with clean, dry skin. Please refer to electrode instructions for use located on page 10 of this manual and on the electrode packet.

Incomplete circuit/disconnection – Check all connection points, confirming a snug fit.

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

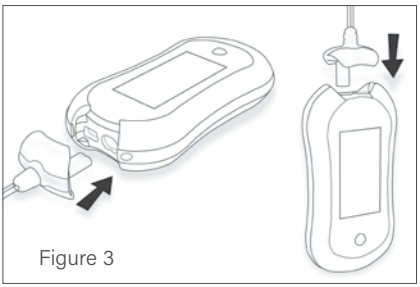


Figure 3

To begin treatment - Lead Wires

- The patient is provided with two stimulator lead wire lengths with the SpinalPak®. The patient should select the length of the stimulator lead wire in order to provide both convenience and comfort when wearing the stimulator during treatment.

- Insert the stimulator lead wire male connection into each female electrode lead wire connection.

- Insert the lead wire plug into the opening at the top of the stimulator. See Figure 3.

OPERATING INSTRUCTIONS

Both battery packs provided with the SpinalPak® are charged prior to being packaged and distributed. Upon receipt of the SpinalPak®, it is recommended that the second battery pack be immediately placed into the charger cradle and completely charged. In the meantime, the first battery pack may be used to begin your treatment immediately. Note: The first battery pack may not provide a complete 24-hour treatment initially.

Step 1: Following the arrows, insert the charged battery pack (1, 2) into the SpinalPak® (Figure 4). The LED light on top of the device will blink, indicating power. Each symbol will be indicated on the display and the alarm will flash and beep if the electrodes are not properly applied. To silence the audio alarm press the button below the display.

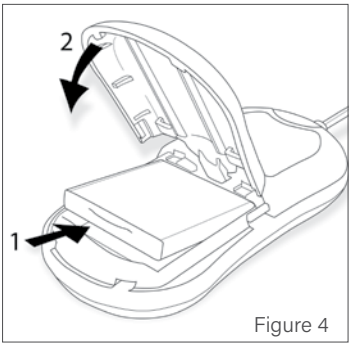
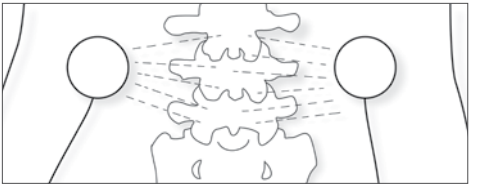


Figure 4

If the light does not blink, which indicates that the battery pack is not charged, change the battery pack (See Charging the Battery Pack below).

Step 2: Attach electrodes as per instructions on Page 10, and as per "To Begin Treatment - Electrode Placement" section on page 6.



Charging the Battery Pack

Charge the battery pack at room temperature (24°C (75°F)). Charging may require two to three hours. Charging may vary in warmer or colder temperatures.

Step 1: Plug the battery pack charger and cradle into a wall outlet (Figure 5). A green light on the A/C adaptor will illuminate indicating power (Figure 6).

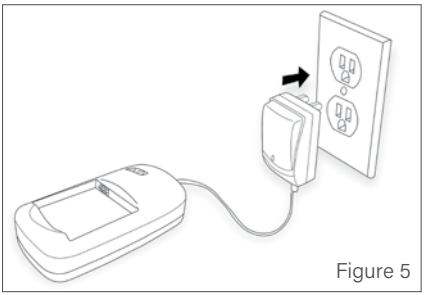


Figure 5

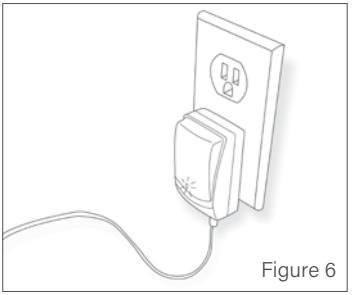


Figure 6

Step 2: Changing Battery Packs
Each day, preferably at the same time to ensure treatment is continued without interruption, patients should do the following:

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

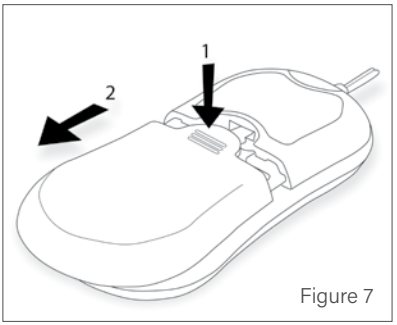


Figure 7

B. Following the arrows, place the depleted battery pack into the battery charger cradle (1, 2) for charging (Figure 8). A solid orange light on the charger cradle will illuminate, indicating the battery is charging. 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.

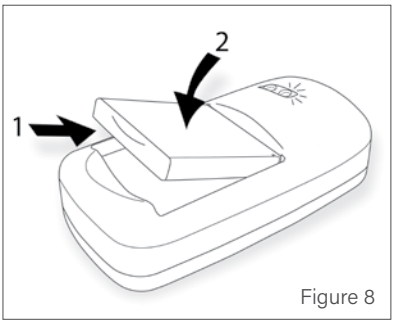


Figure 8

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 (1, 2) from the battery charger cradle with a gentle lift on the battery tab (Figure 9) and place the fully charged battery pack into the SpinalPak® in order to commence treatment.

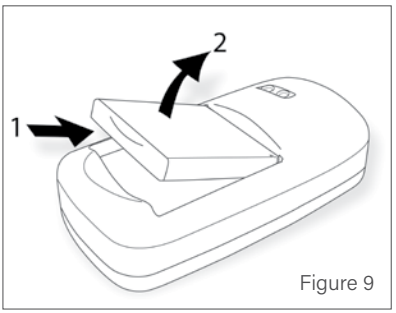


Figure 9

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 packs 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 cradle will indicate termination of charging when the orange light is not illuminated. Additional replacement battery packs are available by contacting the Customer Care team.

BUTTON FUNCTIONS

Alarm On/Off Button

The SpinalPak® is activated as soon as a charged battery pack is inserted. The button located below the LCD display enables or disables the audible alarm. During an alarm condition, depressing the button quickly (0.5 seconds) will temporarily disable the audible alarm. Depressing the button for a longer period of time (3 seconds) will toggle the audible alarm between enabled and disabled. Patients should be advised to leave the audible alarm enabled as frequently as possible in order to assure the fully prescribed treatment. A speaker symbol will be indicated on the LCD display when the alarm is enabled.

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. After silenced, the light will continue to flash and the display will indicate the alarm condition.

Symbol	Condition	Instructions
✔	Treating	Continue use.
	Audible alarm	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 charge	Insert a charged battery pack.
	Disconnection	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.
	Stimulator is connected to a PC	Stimulator will not treat until USB cable is disconnected
	End of operation/ Treatment Completion	Contact the Customer Care team

TREATMENT COMPLETION

Therapeutic treatment should not be suspended until fusion occurs or until such time as a determination is made by the prescribing physician. The device is programmed to deliver 270 continuous days of therapeutic treatment and automatically discontinues operation after the 270 days.

PATIENT COMPLIANCE MONITORING

The SpinalPak® contains embedded software which allows the display of patient specific history data including usage and therapeutic treatment times. This data may be downloaded to a personal computer for viewing, storage and/or print out via the use of Compliance Data Download Software. Please call your local sales representative to obtain more information.

ORDERING INFORMATION

To order supplies, contact the Customer Care team. See page 2 “Important Safeguards” for contact information.

The following information is necessary to expedite any inquiry:

- Patient name
- Physician name
- Address to send replacement parts (patient home, MD office, etc.)

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

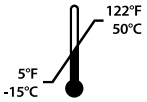
SYMBOL DESCRIPTION


Attention see instructions


Alternating Current


Direct Current


Type B



Storage/Transport temperature limits


Class II

Non Sterile


Manufacturer


WEEE


Single Patient Use

Rx only Prescription Only


Warning: The concomitant use of the stimulator and a pacemaker or cardioverter must be assessed by a cardiologist on an individual basis with an Electrocardiogram (EKG).


Caution: The safety of this device used during pregnancy and nursing in humans has not been established.

EQUIPMENT CLASSIFICATION

- Stimulator - Internally powered by rechargeable batteries
- Charger - Class II, Type B
- Ordinary Equipment without protection against ingress of water
- Equipment not suitable for use in presence of flammable anesthetic mixture with air or oxygen or nitrous oxide.
- Mode of operation - continuous

CLEANING INSTRUCTIONS

Use a damp cloth for cleaning any part of the SpinalPak®. Do not use cleaning products or detergents.

ELECTROMAGNETIC COMPATIBILITY

A. The use of accessories, cables or replacement parts other than those supplied by EBI may result in increased emissions or decreased immunity of the equipment or system.

B. This equipment should not be used adjacent to or stacked upon other equipment.

C. Portable and mobile RF communications equipment can adversely affect the operation of Medical Electrical Equipment.

D. In the event this equipment interferes with the operation of other equipment, or experiences interference from other equipment, to continue treatment, it will be necessary to move the SpinalPak® away from the source of the interference as indicated in Table 4.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The SpinalPak® is intended for use in the electromagnetic environment specified below. The customer or the user of the SpinalPak® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	The SpinalPak® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Class B**	The SpinalPak® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Not applicable**	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	**Not applicable**	

Table 2

Guidance and manufacturers declaration - electromagnetic immunity

The SpinalPak® is intended for use in the electromagnetic environment specified below. The customer or the user of the SpinalPak® should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 610004-2	± 6 kV contact ± 8 kV air	Group 1	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Class B	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Not applicable	Not applicable	

Table 3

Guidance and manufacturers declaration - electromagnetic immunity

The SpinalPak® is intended for use in the electromagnetic environment specified below. The customer or the user of the SpinalPak® should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	**Not applicable**	**Not applicable**	
Radiated RF IEC 61000-4-3	**3 V/m** **80 MHz to 2.5 GHz**	**1 V/m**	Portable and mobile RF communications equipment should be used no closer to any part of the SpinalPak®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5 \sqrt{P}$ 80 MHz to 800 MHz $d = 7 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 80 MHz and 800 MHz, the higher frequency applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SpinalPak® is used exceeds the applicable RF compliance level, the SpinalPak® device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SpinalPak®.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the SpinalPak®

The SpinalPak® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SpinalPak® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communications equipment (transmitters) and the SpinalPak® as recommended below, according to the maximum power output of the communications equipment.

Rated maximum output power of transmitter	Separation distance (meters) according to frequency of transmitter		
W	150 kHz to 80 MHz $d = 3.5\sqrt{P}$	80 MHz to 800 MHz $d = 3.5\sqrt{P}$	800 MHz to 2.5 GHz $d = 7\sqrt{P}$
0.01	.35	.35	.7
0.1	1.1	1.1	2.21
1	3.5	3.5	7
10	11.06	11.06	22.13
100	35	35	70

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

PATIENT COUNSELING INFORMATION

The patient should be thoroughly instructed on how to properly use and care for the SpinalPak®, and receive the Patient Manual, which provides detailed instructions. A summary of the key points in the patient labeling is provided below.

Compliance The patient should be instructed that compliance with device use and care is critical to ensure the proper function of the device and effective treatment.

Battery The patient should be instructed to insert a charged battery pack in the stimulator every 24 hours.

Electrodes The patient should be instructed to replace the electrodes when needed and to clean the electrode sites thoroughly with soap and water prior to applying the electrodes.

Skin Irritation The patient should be instructed to examine the skin for irritation when replacing the electrodes. If irritation is present, the patient should be instructed to relocate the electrodes adjacent to the original sites. The patient should be evaluated periodically to assess the skin for sensitivity.

Alarms See LCD Symbol Descriptions and Instructions (page 14). The patient should be instructed to keep the audible alarm system engaged as often as practical and to reset the alarm system if it has been toggled to the disengaged position as soon as practical.

Bathing The patient should be instructed to disconnect the stimulator during bathing, showering or swimming. It should be reconnected as soon as practical following these activities. The patient should also be instructed to remove or cover the electrodes with the electrode cover patches during showering.

STORAGE AND HANDLING

The SpinalPak® should be stored in a cool and dry place. The device components should be handled with care. Damage may occur if the device is inappropriately handled or abused.

DISPOSAL INSTRUCTIONS

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

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

SpinalPak® Bone Growth Stimulator
Complete Manual and Package Insert

To learn more about this product,
contact your local Sales Representative today.

EBI, LLC
1 Gatehall Drive, Suite 303
Parsippany, NJ 07054
800-526-2579

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