Draft Professional Labeling

SpinalPak® Fusion Stimulator

Caution: Federal law restricts this device to sale by or on the order of a physician.

This device has been APPROVED by the U.S. Federal Food and Drug Administration for the indications described below.

INDICATIONS FOR USE

The SpinalPak® Fusion Stimulator is a noninvasive electric bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

DEVICE DESCRIPTION

The SpinalPak® Fusion Stimulator is a bone growth stimulator utilizing capacitive coupling technology.

The SpinalPak® Fusion Stimulator system consists of two primary components: (1) the Patient Kit, which includes the SpinalPak® Fusion Stimulator, the hydrogel electrodes, the electrode lead wires, and a supply of 9-volt batteries; and, (2) the Physician Test Meter (which remains with the physician). The SpinalPak® Fusion Stimulator is a lightweight (less than four oz.), battery operated, portable signal generator. It produces a sinusoidal waveform of five Volts Peak-to-Peak amplitude, at a frequency of 60 Kilohertz, which is delivered to the patient by two hydrogel electrodes

The stimulator has a two-color light emitting diode (LED) and an audible alarm system to monitor device function. If the stimulator is functioning properly, the LED will emit an intermittent green light. If the stimulator is not functioning properly, the LED light will change to red and an audible alarm signal will be activated. A continuous red light and audible alarm indicate that the battery voltage is too low for effective treatment. An intermittent red light and audible alarm indicate there may be poor electrode contact with the skin or a poor connection of the wires. The "ALARM ON-OFF" switch located on the face of the stimulator may be used to temporarily turn off the audible alarm system.

The SpinalPak® Fusion Stimulator also has an internal elapsed time accumulator that stores the number of days the device was used. The device will automatically deactivate after 270 days of accumulated therapy. A health care professional may use the Physician Test Meter to determine the number of days of device use and to evaluate the stimulator's current treatment voltage and amperage levels. The Physician Test Meter provides a visual display of this information.

WARNINGS

- Cardiac pacemakers or cardioverters may be adversely affected by the SpinalPak® Fusion 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 SpinalPak® device. If there are any observable adverse changes in the pacemaker rhythm or output, the SpinalPak® device should not be used.

- The safety and effectiveness of the SpinalPak® Fusion Stimulator 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 SpinalPak® device.

PRECAUTIONS

- The safety and effectiveness of the SpinalPak® Fusion Stimulator in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of the device in these individuals is therefore unknown:

    - spondylitis, infection, Paget's disease
    - cancer, diabetes mellitus, renal disease
    - trauma of the lumbar spine
    - osteoporosis

- The patient should be instructed to apply the electrode 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 with the physician.

- Do not submerge or expose the SpinalPak® Fusion 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, proper maintenance of the device, and replacing the electrodes every five to seven days are essential for proper device function.

- The patient 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 Biolectron, Inc. Other components and parts may not be compatible, and may damage the device.

- If any component does not function properly, contact Biolectron, Inc. at 1 (800) 524-0677. 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 SpinalPak® Fusion Stimulator for the indication listed above, skin irritation was the most common adverse effect associated with use of the 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.

CLINICAL STUDIES

A randomized, double-blinded clinical study was conducted to determine whether the SpinalPak® Fusion Stimulator increases the frequency of overall success (where overall success is defined as the combination of clinical and radiographic success) when compared to placebo (inactive) units, after primary (first-time) one or two level fusions within L3 to S1. All subjects had degenerative disc disease. Investigators were instructed to apply the SpinalPak® within three weeks of surgery. Subjects may have undergone a posterior lumbar interbody fusion (PLIF), an anterior lumbar interbody fusion (ALIF), a bilateral posterolateral fusion, or a combination of these procedures with or without internal fixation. Subjects were to be excluded from the study if they:

- Had a pathologic process at spine level
- Had a systemic disease that may affect fusion
- Had osseous trauma of the lumbar spine
- Were pregnant
- Had a cardiac pacemaker
- Were unable to understand or comply with study instructions
- Had moderate to severe osteoporosis (osteoporosis was subjectively defined by individual physicians)

Subjects were randomly assigned an active or inactive (placebo) stimulator. The subjects were instructed to use the device continuously, except for periods of personal hygiene, until the physician had determined a patient was considered to be an overall success or for a period of nine months (the maximum treatment duration time).

Subjects were considered to be an overall success only if they were determined to be radiographically successful and clinically successful at the final evaluation timepoint. An independent blinded review process confirmed radiographic assessments.

Of all subjects entered into the study, 2.6% experienced skin irritation.

Two hundred and fifteen subjects met all the protocol requirements and formed the core group for the data analysis. The effectiveness results described below were analyzed using a two-tail Fisher exact test.

The active (n=110) and placebo (n=105) subjects were evaluated to determine if the treatment groups were comparable, and to assure that a 24% loss to withdrawal and a 14% loss to censure (subjects completed the study, but did not comply with all protocol requirements) did not bias study results. The groups were compared using 63 demographic and clinical characteristics, such as age, gender, body mass index, tobacco and alcohol use, type of occupation and preoperative primary and secondary diagnoses. There were no statistically significant differences between these treatment groups. The treatment groups were also compared preoperatively using data from a 14-question pain and dysfunction patient self-assessment questionnaire. The analysis of the summed pain and dysfunction scores showed no statistically significant differences in the preoperative status of the treatment groups.

Table 2 compares success in the active and placebo subjects of the core group (n=215). An overall success requires an independent confirmation of radiographic successful outcome on the Final Assessment Case Report Form and also a successful clinical outcome on the Final Assessment Case Report. For each group the number of successes is shown. The p-value presented for "Overall Success" indicates statistical significance (a p-value of less than or equal to 0.05 denotes significance). The data were analyzed using a two-tail Fisher exact test.

Table 2
Frequency Of Success The Core Group, By Treatment (n = 215)

	Overall Success (Clinical AND Radiographic Success)	Clinical Success	Radiographic Success	Average PSAF Score Baseline/ 12 months
Active (N = 110)	87 (79%)	95 (85%)	94 (85%)	31.44/ 23.03
Placebo (N = 105)	64 (61%)	79 (75%)	82 (78%)	33.35/ 23.44
P-value	0.0018			

Note: A patient was considered to be a success in this study if he/she was considered both clinically and radiographically successful at the time of the final evaluation. Patient progress at the interim (follow-up) visits was not taken into consideration in making the final evaluation.

In the 215 core group, 87 active subjects (79%) achieved an overall success (defined as a combination of both physician described clinical success and also a radiographic successes

at the time of final evaluation) whereas 64 placebo subjects (61%) achieved overall success at the time of final evaluation. This difference in the rates of overall success (18.1%) was statistically significant (p=0.0018).

A subjective patient self-assessment form (PSAF) was also used to collect information about subjects' perceptions of their ability to function. Scores from PSAF show that there is no statistically significant difference between active and placebo subjects at PSAF scores baseline and at the time of final evaluation.

A number of subject characteristics and demographics may affect the frequency of overall success. A logistic regression analysis was conducted to determine if any variable(s) may have affected overall success. A logistic regression analysis tests whether any variable is statistically associated with success after controlling for the other variables, and provides an odds ratio to indicate the nature and strength of the relationship. A logistic regression was conducted using the following 13 variables that may have had an effect on the likelihood of a overall successful:

(1) the active device;
(2) history of prior surgery (treatment);
(3) gender;
(4) age;
(5) overweight;
(6) smoking;
(7) use of pre-operative medications, including steriodal and non-steriodal anti-inflammatory medications;
(8) a secondary diagnosis of herniated disc pulposus;
(9) a secondary diagnosis of spondylolysthesis;
(10) occupational type, such as sedentary employment or moderate/heavy labor;
(11) type of fusion, such as posterolateral or interbody;
(12) level of fusion (single or multiple); and
(13) the use of fixation hardware.

A logistic regression analysis determines whether any of the variables is statistically associated with success after controlling for the other variables, and provides an odds ratio to indicate the nature and strength of the relationship. This analysis was performed to determine if this variable was responsible for the outcome rather than the device being studied.

The following four variables were associated with frequency of overall success and were statistically significant: the active device, a history of prior surgery, fusion type, and smoking. The other variables, including the use of fixation hardware, were not significantly associated with overall success after controlling for the other variables. The analysis was then conducted with only the four identified variables, and is shown below in **Table 3**.

Table 3
Logistic Regression Analysis For The Core Group (n=215)

Variable	Odds Ratio	95% Confidence Interval	p-value
Prior Surgery	0.48	0.25 – 0.92	0.0276
Posterolateral Fusion	2.40	1.26 – 4.55	0.0073
Smoker	0.33	0.16 – 0.68	0.0024
Active Device	2.33	1.21 – 4.48	0.0110

This analysis showed that subjects with a history of prior surgery were less likely to achieve success, regardless of other factors (odds ratio = 0.48; p=0.0276). Subjects who had a posterolateral fusion were more likely to be overall successes, regardless of the other variables (odds ratio = 2.40, p=0.0073). Subjects who smoked were also less likely to achieve overall success (odds ratio = 0.33, p=0.0024). The subjects in the active group were more likely (odds ratio = 2.33) to achieve overall success regardless of their type of fusion, their prior history of surgery, or smoking. This odds ratio was statistically significant (p=0.0110).

The clinical results establish the SpinalPak® Fusion Stimulator may be used as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

INSTRUCTIONS FOR USE

Patients should be instructed in the proper use and daily maintenance of the device. All instructions below are also presented in the Patient Manual, which is included with every SpinalPak® unit.

1. Electrodes and Placement

The low profile hydrogel electrodes are mounted on a release liner and may be used for five to seven days.

The two electrodes should be placed on each side of the patient's spinal column. The electrodes should be placed four to six inches apart at the mid-fusion level.

2. Electrode Application

Remove the two hydrogel electrodes from the packaging. Moisten the entire gel area of each electrode with tap water applied by fingertip. Gently press the electrodes on

the patient's skin in the proper position as described above. Connect the electrodes to the electrode lead wire.

With use, the electrode gel area may dry out and the electrode may lose its contact with the skin. (This may cause the LED display to blink red intermittently, and cause an audible intermittent warning sound) . If this occurs, the electrode may be reapplied. Again moisten the entire gel area of the electrode with tap water. Reapply the electrode to the patient's skin.

Adhesive covers (provided in the Patient Kit) may be used to protect the electrodes during bathing or showering. The protective covers are provided to prevent the necessity of completely removing the adhesive electrodes and then re-applying them following personal hygiene.

3. Commencement of Treatment

Insert the electrode lead plug carefully into the jack at the top of the stimulator, and rotate it clockwise, as shown in Figure 1.

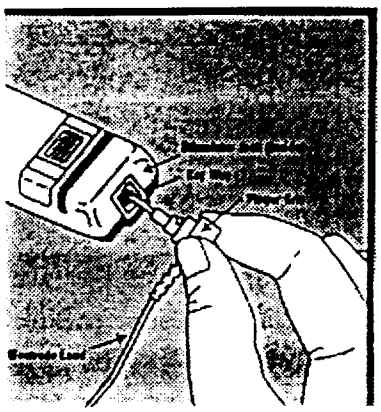


Figure 1

Open the battery compartment of the stimulator by sliding its cover down, as shown in Figure 2. Insert one of the supplied 9-volt alkaline batteries into the battery compartment. Replace the cover by pressing it down. The cover will snap into place.

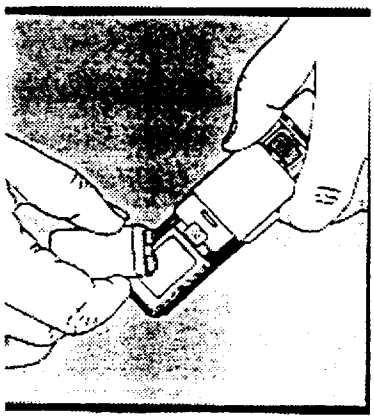


Figure 2

If the stimulator is functioning properly, there will be an intermittent green flashing light. This light means that the electrodes are properly applied, the battery is functioning, and the device is delivering a therapeutic current.

If the device is not functioning properly, an audible alarm and red light will appear. The type of alarm and red light will vary depending upon the cause of the problem.

If the audible alarm and red light are continuous, the battery voltage is too low. Insert a new battery, and properly dispose of the old battery.

If the audible alarm and red light are intermittent, the continuity of the circuit may have been interrupted. Confirm that the electrode lead is properly connected to the electrodes and the stimulator. Check that the electrodes are making proper contact with the skin, and reapply the electrodes if necessary. If the alarm and red light continue, replace the electrode lead. If the alarms stop, the original electrode lead may be defective. If the alarms continue, there may be a problem with the stimulator. Use a new stimulator.

Do not attempt to fix the stimulator. Please contact Biolectron at 1-800-524-0677 or your sales representative.

An On/Off Switch on the stimulator controls the audible alarm, but not the visual alarm. The patient may elect to turn the audible alarm off if it would be disruptive, but the alarm should be re-activated as soon as practicable.

4. The Physician Test Meter

The health care professional may use the Physician Test Meter to monitor the number of days of device use, and to evaluate the stimulator's treatment voltage and current levels.

Before using the Physician Test Meter, make sure the stimulator has a new battery and the electrodes are properly placed on the patient's skin.

Remove the stimulator's battery compartment cover. Insert the Test Meter into the jack located inside the battery compartment of the stimulator, as shown in Figure 3.

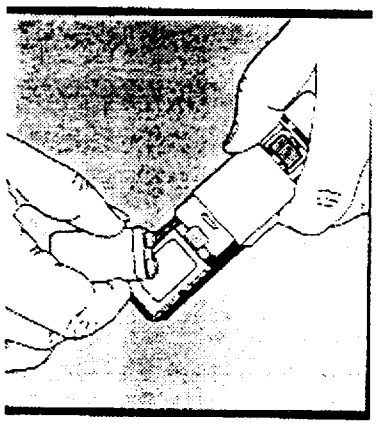


Figure 3

The voltage (VOLTS) is read first, then the current in milli-amperes (mAMPS), and then days (DAYS) by pressing the appropriate button on the front of the test meter. The test meter is operating only when the buttons are depressed.

The chart below describes the appropriate action to be taken based upon the meter readings.

BUTTON	VOLTAGE (VOLTS)	CURRENT (mAMPS)	APPROPRIATE ACTION
Reading	Between 3 & 6.3	Between 5 & 10	1. Normal treatment range.*
	Less than 3 or greater than 6.3**	Between 5 & 10	1. Check and correct the application of electrodes. 2. Insert a new battery. 3. If the voltage reading is still less than 3 volts or greater than 6.3 volts, proceed with treatment as current is within treatment range.
	"88.8"**	Less than 5 or greater than 10	1. Check and correct the application of the electrodes. 2. Insert a new battery. 3. If the current (mA) reading is still outside the range of 5 to 10 mA; the stimulator may be defective. Try a new stimulator.

* The essential requirement of the treatment signal is between 5 and 10 mA of current. The voltage is simply the driving force for the delivery of the current (mA).
** A value greater than 6.3 will be displayed as a flashing "88.8."

When the device has recorded 270 days of accumulated therapy, the SpinalPak® Fusion Stimulator will automatically cease to function. The red/green light indicators and the audible alarm will also cease to function.

PATIENT COUNSELING INFORMATION

The patient should be thoroughly instructed on how to properly use and care for the SpinalPak® Fusion Stimulator, and receive the patient labeling, 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 assure the proper function of the device and effective treatment.

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

Electrodes - The patient should be instructed to replace the electrodes every five to seven days, and to clean thoroughly the electrode sites 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 immediately above or below the original sites and to contact the physician within 48 hours. The patient should be evaluated periodically to assess the skin for sensitivity.

Alarms - The patient should be instructed to replace the battery if a continuous audible alarm and red light appear. If the audible and visual alarms are intermittent, the patient should be instructed to check that the electrode lead is connected, and to check that the electrodes are properly applied to the skin and to reapply if necessary. If the alarms continue after these checks, the patient should be instructed to contact Biolectron at 1-800-524-0677 or the sales representative.

On/Off Switch for the Audible Alarm - The patient should be instructed to keep the audible alarm system in the "On" position as often as practical, and to reset the alarm system if it has been switched to the "Off" Position as soon as practicable.

Bathing - The patient should be instructed to disconnect the stimulator unit during bathing, showering or swimming. It should be reconnected as soon as practical following these activities. The patient should also be instructed to either remove the electrodes, or to cover the electrodes with the protective adhesive covers (available through Biolectron), during bathing and showering.

STORAGE AND HANDLING

The SpinalPak® Fusion Stimulator should be stored in a cool and dry place. Do not use cleaning agents or solvents on any of the device components. The stimulator and electrode leads may be cleaned using a damp cloth.

The device components should be handled with care. Damage may occur if the device is inappropriately handled or abused.

The stimulator must not be submerged or exposed to water.

If you have any questions regarding the SpinalPak® Fusion Stimulator, please call one of our customer service representatives at 1-800-524-0677.

Biolectron, Inc.
25 Commerce Drive
Allendale, NJ 07401

Biolectron, Inc.
SpinalPak® Patient Education Brochure

COVER HEAD:	SpinalPak® Fusion Stimulator
SUBHEAD:	A Patient's Guide
LOGO:	Biolectron
NOTE INSIDE:	Caution: Federal law restricts this device to sale by or on the order of a physician.

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

How SpinalPak® Works
SpinalPak® delivers an electrical signal that is intended to help your back to heal. The signal operates at a high frequency, therefore you should not feel the signal during your treatment with the SpinalPak®. Two lightweight electrodes (conductors of electrical signals), which look like round Band-Aids®*, are placed on your spine, four to six inches apart from one another, at the level of your back surgery. These dermal (skin) electrodes are easy to apply, are extremely lightweight, and are a necessary component in delivering the electrical signal to your surgery site. The stimulator is battery operated. Upon insertion of the 9-volt battery, the unit is automatically activated (turned-on), and is always "on" as long as the battery is not used up, and the electrodes are placed on the skin.

Your SpinalPak® Kit consists of:
- SpinalPak® Fusion Stimulator
- Extra Electrodes
- Additional adhesive electrode covers to enhance electrode security (if needed)
- Electrode lead wires (to connect the electrodes to the SpinalPak® device)
- 9-volt batteries.

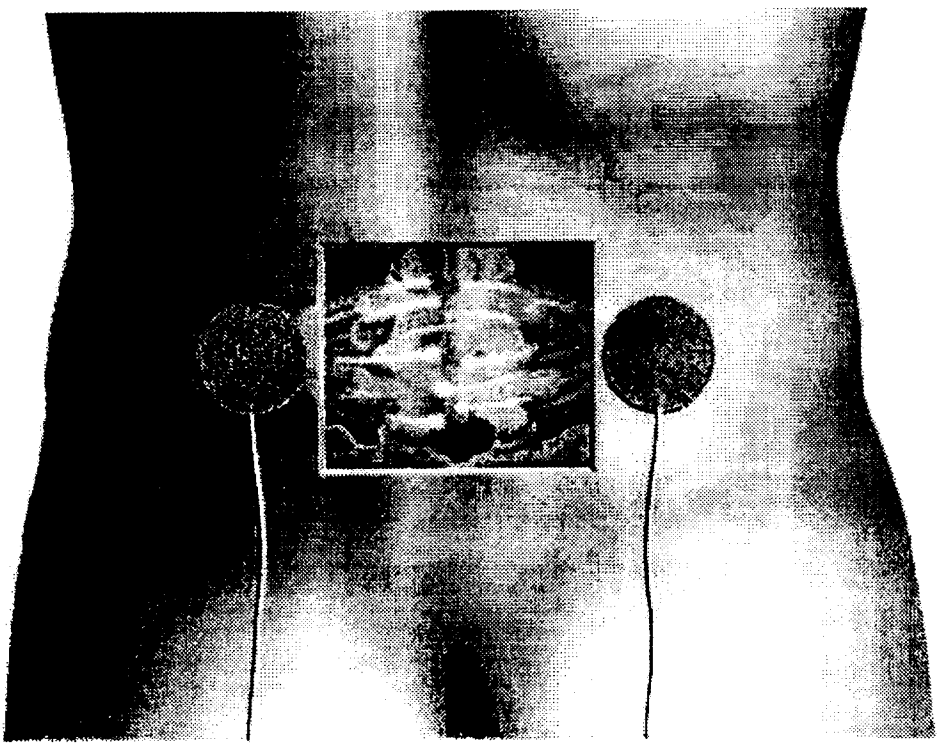
* Band-Aids® is a Registered Trademark of Johnson and Johnson

Wearing SpinalPak®

- SpinalPak® has been designed so that it is convenient to use, comfortable to wear, and safe to operate. You should begin using SpinalPak® immediately after you have read the instructions for use.

- Place two electrodes on your skin, the first two to three inches to the left of the area of your surgery, and another two to three inches to the right of the area of your surgery. Depending on your ability to move after your surgery, it may be helpful to ask another person to help you place these electrodes on your back. With your fingertip, wet the entire gel area of the electrode with tap water. Consult your doctor should you have questions about proper electrode placement.

  Make sure you apply the electrodes after your skin has been cleaned and dried. 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 after moving the electrodes, you should call your doctor.



- Connect the electrodes to the stimulator using the lead wires provided. Choose the shortest lead wires possible to connect to the SpinalPak® Fusion Stimulator where you wish to wear the stimulator on your body. Put the electrode lead plug carefully into the jack at the top of the stimulator, and turn it clockwise, see Figure 1.

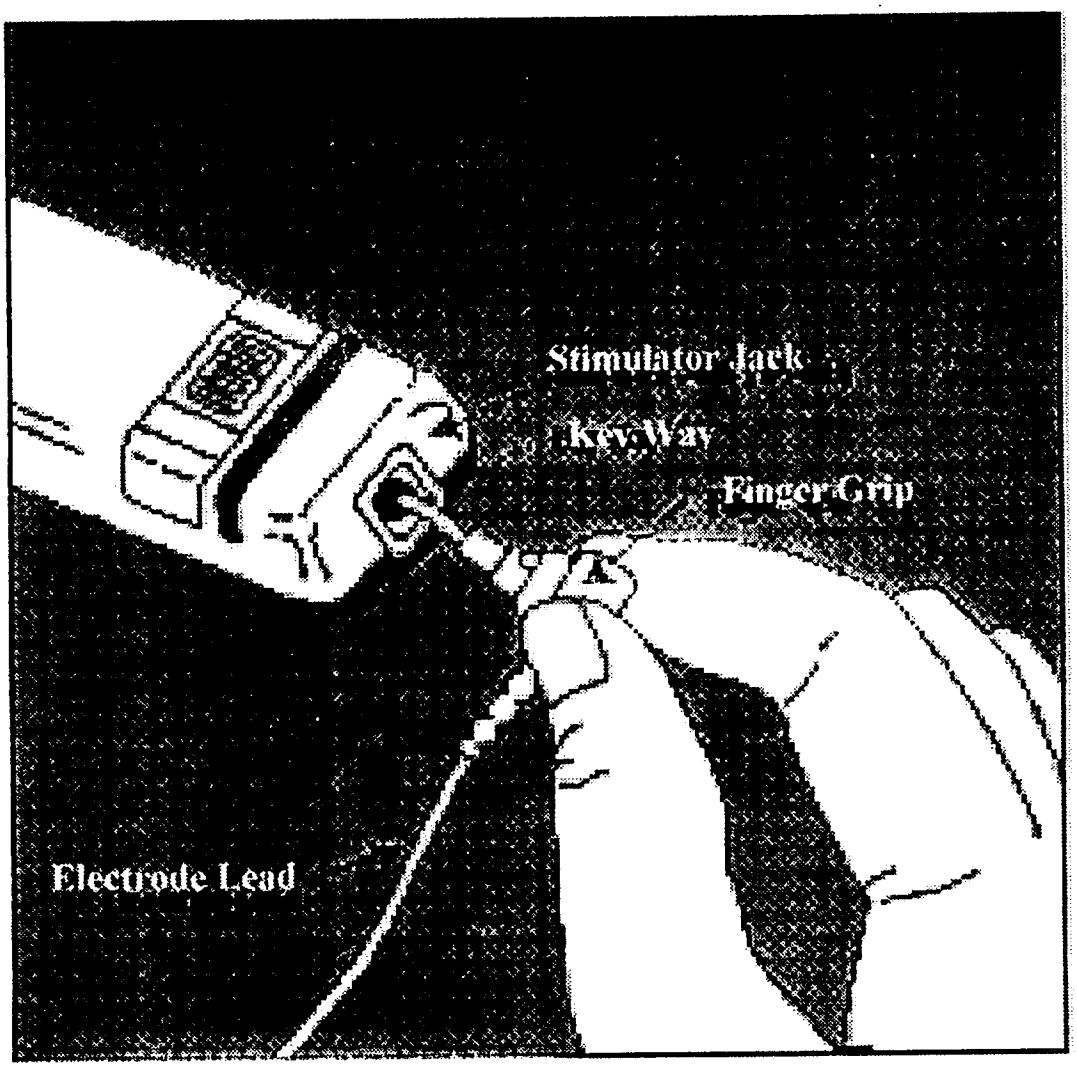


Figure 1

- Insert a new 9-volt alkaline battery every day.

Each day, (preferably at the same time), you should:

- Remove the battery compartment cover as shown in Figure 2.
- Insert one of the supplied, new 9-volt batteries, and throw away or recycle the old battery.
- Replace the cover by pressing it down. It will snap into place.
- Check to see that the stimulator's indicator light is flashing "green" on the front of the unit. This shows that the unit is operating properly, and that the

device is sending the therapeutic signal. If the indicator light flashes "red", see the "Warning Section" to try to figure out what is wrong.

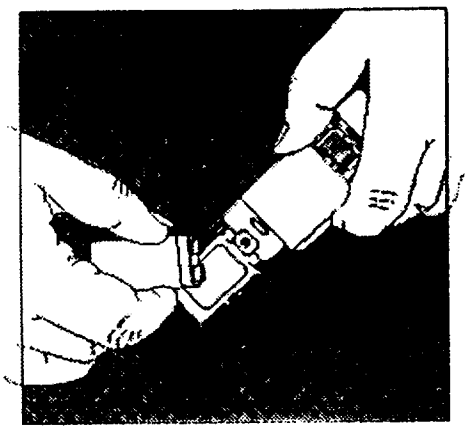


Figure 2

- Change your electrodes every five to seven days. Different skin types will provide for longer or shorter life of the electrodes. If the indicator starts and stops flashing "red" 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 lead wire is tightly plugged into the top of the SpinalPak® device, and that the lead wire connectors are completely inserted into both electrode connectors. If all the connections are made and the indicator light continues to flash "red," it is probably time to change the electrodes.

    - Remove the old electrodes from your skin by wetting your fingertips with tap water, and gently peeling back the electrode. DO NOT abruptly tear the electrode off the skin.
    - Wash your skin gently with soap and water and pat dry.
    - Remove two new electrodes from the packaging.
    - Thoroughly moisten the entire gel area of each electrode with tap water applied with your fingertip.
    - Gently press the electrodes on your skin in same place as before. You may need help putting the electrodes on your back. Ask another person for help if you cannot reach your back easily. If your skin is very red, place the electrodes slightly above or below the original sites, and call your doctor 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.

- Use SpinalPak® up to 24 hours per day. Your doctor will tell you when to stop using it. After 270 days of use, your SpinalPak® will automatically turn off.

NOTE:

The SpinalPak® Spine Fusion Stimulator accurately records the number of days you receive treatment. A special monitor records and displays this information for your doctor. This helps your doctor track your treatment.

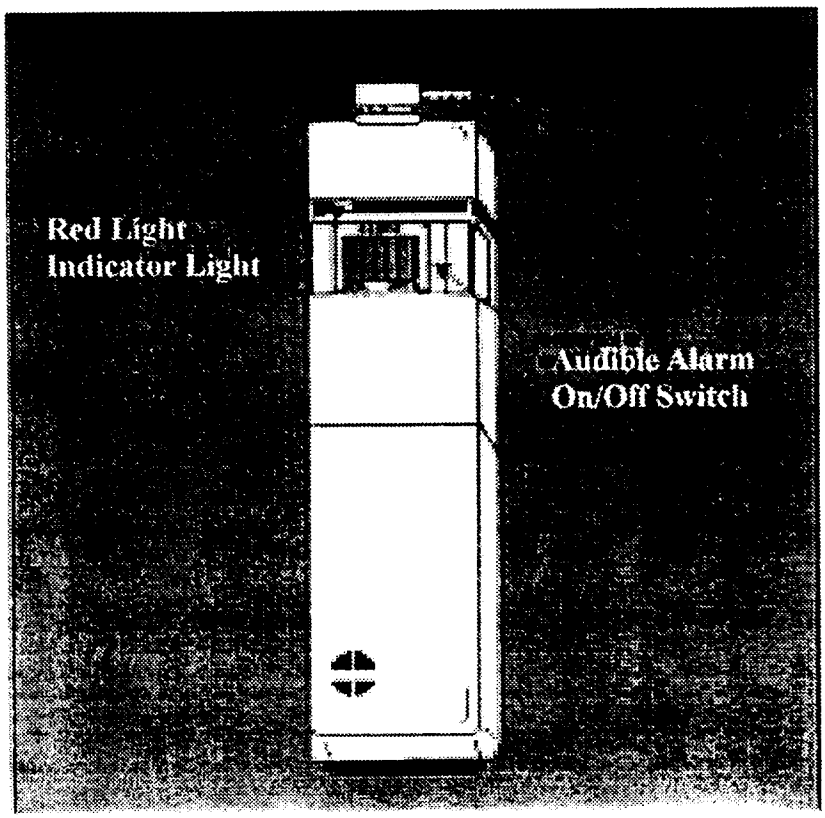
Indicator Light:

- A flashing green light indicates that the device is working properly. A flashing or constant "red" light and an audible alarm signal (a signal that you can hear) alert you to any problems. The alarm you can hear can be turned off using the "ON/OFF" switch on the front of the device. This switch does not affect the indicator light, see Figure 3.

- If the red light and audible alarm do not go away, first try replacing the wire to your electrodes. If the alarms stop, your electrode wire may have been defective. If the alarms do not stop, there may be a problem with your SpinalPak® stimulator. Do not try to fix the stimulator. Call Biolectron 1 (800) 524-0677.

Tip:
Keep the audible alarm system in the "On" position as much as possible. This alarm will help warn you to any problems with the device. During special occasions when you would like the device not to tell you audibly about stimulator problems, you may set the switch to the "Off" position. It is recommended that you turn the unit be back "On" as soon as possible.

- Remove your SpinalPak® when you bathe, shower or swim. You should also either remove the electrodes, or cover them with the additional adhesive covers provided if



you prefer to leave the electrodes attached to the skin during bathing and showering.

Figure 3

Caring for Your SpinalPak®

- Don't use cleaning products or detergents on any part of SpinalPak®. You just need a damp cloth.
- Do handle SpinalPak® carefully. Dropping or rough handling can cause damage.
- Store SpinalPak® in a cool and dry place when you are not wearing it.
- Contact Biolectron at 1 (800) 524-0677 if you believe that the device has been damaged or is operating improperly.

Warning Signals

- Flashing green light: the stimulator is working properly
- Constant Red light and Constant audible beeping: Replace battery.
- Flashing Red light and intermittent beeping: The circuit is incomplete, check all connection points, including electrode to skin interface.

Tip:

Loose Electrodes – Make sure that both electrodes are in complete contact with your skin. Remoisten or replace worn electrodes if necessary.

Incomplete Circuit – Check all connection points, insuring tight fit of lead wire into top of SpinalPak® device, and adequate touching of lead wire pin into electrode wire receptacle.

Broken Electrode Lead – If you have checked the electrodes and the connections and the flashing red light and audible alarms continue, a break in the lead wire may be responsible. Remove the old electrode lead. Turn the lead counterclockwise and then pull out. Attach a new electrode lead into the jack. An extra electrode lead is provided in the kit.

If the alarm still continues, please call Biolectron at 1-800-524-0677.

If You Have Questions

If you have questions about your SpinalPak® contact Biolectron Customer Service toll-free at **(800) 524-0677** 24 hours a day, seven days a week.

IMPORTANT: <u>Any/All medical questions must be directed to your doctor.</u>

INDICATIONS FOR USE

The SpinalPak® Fusion Stimulator is a noninvasive bone growth stimulator indicated for use 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® Fusion 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 SpinalPak® device. If there are any observable adverse changes in the pacemaker rhythm or output, the SpinalPak® device should not be used.

- The safety and effectiveness of the SpinalPak® Fusion Stimulator 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 SpinalPak® device.

PRECAUTIONS

- The safety and effectiveness of the SpinalPak® Fusion Stimulator in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of the device in these individuals is therefore unknown:

    - spondylitis, infection, Paget's disease
    - cancer, diabetes mellitus, renal disease
    - trauma of the lumbar spine
    - osteoporosis

- Apply the electrode 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 with the physician.

- Do not submerge or expose the SpinalPak® Fusion 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, proper maintenance of the device, and replacing the electrodes every five to seven days are 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.

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- If any component does not function properly, contact Biolectron, Inc. at 1 (800) 524-0677. 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 SpinalPak® Fusion Stimulator for the indication listed above, skin irritation was the most common adverse effect associated with the use of the 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.

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