PROVIDER MANUAL

INSTRUCTIONS FOR USE

XSTIM SPINE FUSION STIMULATOR

Model 08-0041

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INTRODUCTION

Your doctor has prescribed this Xstim Bone Growth Stimulator System as an important part of your spine fusion surgery recovery plan. Your Xstim device was designed to be portable, convenient, and comfortable. Like a medication that you take every day, you won't feel the stimulation working but the healing therapeutic signal has been shown to benefit patients with daily use according to your doctor's directions.

Read this User's Manual carefully before using the device. Pay attention to the Safety Information and Warnings throughout the manual.

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

SAFETY INFORMATION

Read all instructions before using

Use the product only for its intended use.

The controller does not contain a power button. Xstim can only be powered on/powered off by connecting/disconnecting the battery to the controller.

Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.

In the case of a malfunction, contact Customer Service at **(844) 228-2067.** WARNING: Do not attempt to disassemble, repair or modify the device.

Do not use system components with any other devices. Do not submerge or expose the device to liquids.

Disconnect the Controller while bathing, showering, or swimming. Do not connect the battery charger to the wall outlet if wet.

If the battery charger has fallen into water, unplug from the wall outlet before retrieving. Do not operate the battery charger if it has a damaged power cord or has been dropped or immersed into water.

Do not short circuit, crush, penetrate or otherwise damage the battery or connect conductive materials across the battery terminals. These and other abuses can lead to serious injury or burns.

If the Controller is not being used, remove the battery. This will avoid indicators (visual, sound and vibration) from activating.

Do not expose the system to prolonged heat, sunlight or cold. Normal operating temperature is 5 to 40°C (41 to 104°F) . Normal storage and transport temperature is -29 to 60°C (-20 to 140°F).

There are two Controller lead cable lengths. If there is a situation where there is a risk of the longer lead wire causing strangulation, use the shorter length.

If anything happens that is unexpected or different to what is contained in these instructions, contact Customer Service at **(844) 228-2067**.

SYSTEM COMPONENTS

QUICK START INSTRUCTIONS

LEAD WIRE CABLE

1

Two Controller Lead Wires are supplied in the Xstim Product Case. Locate the Controller Lead Wire length that is most convenient for use:

Short Cable: 20 inches (0.5m)
Long Cable: 49 inches (1.25m)

CONTROLLER

2

Connect the other end of the Lead Wire Cable (largest connector) to the Controller.

See "Place the Electrodes" on the opposite page for proper placement.

ELECTRODE LEAD WIRES

3

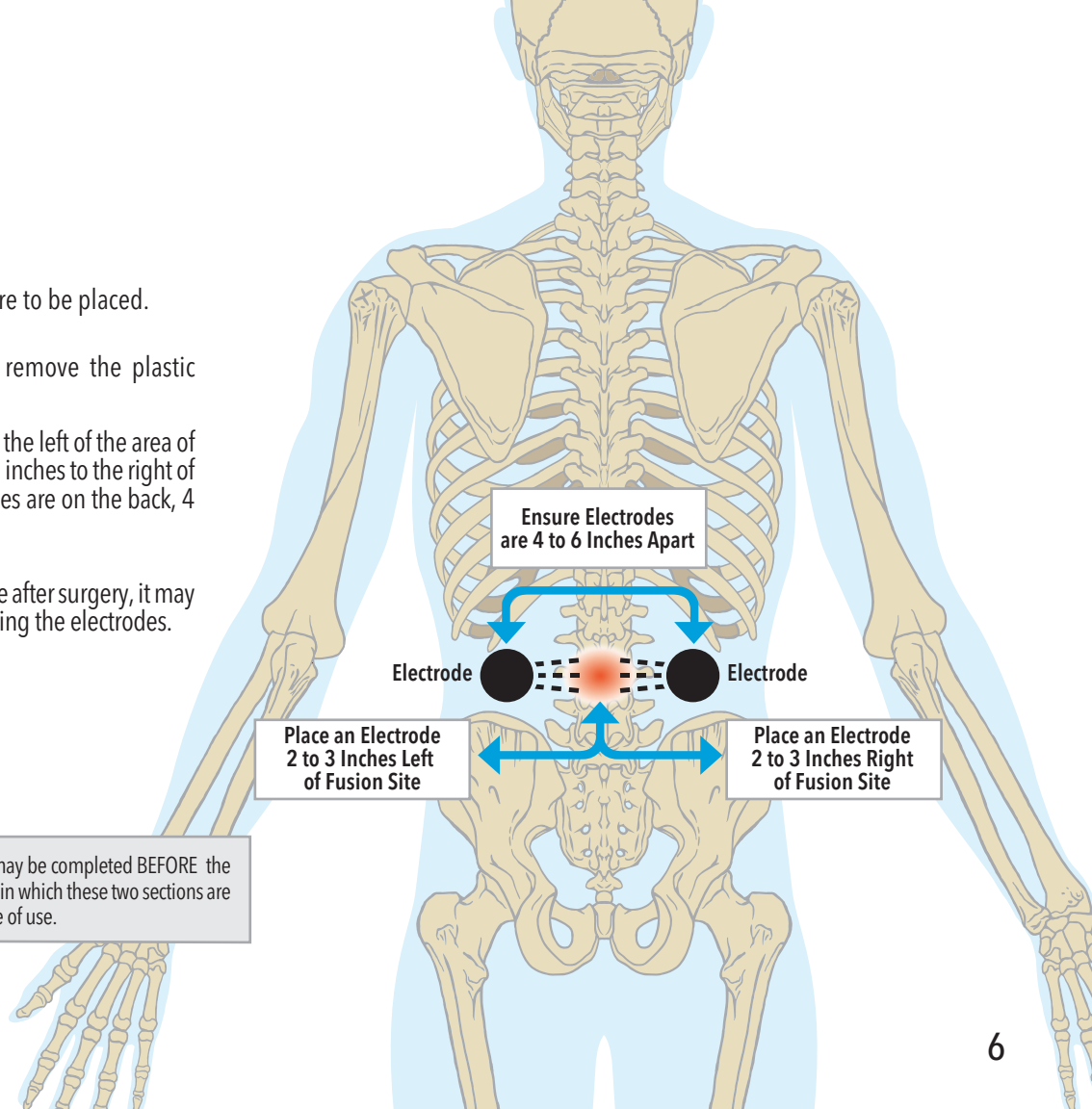
Connect the ends (2) of the Lead Wire Cable (female connectors) to the 2 pins (male connectors) of the Electrode Lead Wires.

For Optional Belt Clip Instructions see Page 10

PLACE THE ELECTRODES:

1. Clean and dry the skin where the electrodes are to be placed.
2. Remove the electrode from the pouch and remove the plastic backing material.
3. Place one electrode on the back, 2 to 3 inches to the left of the area of the spinal fusion and the second electrode 2 to 3 inches to the right of the area of the spinal fusion so that the electrodes are on the back, 4 to 6 inches apart.

Helpful Hint: Depending on your ability to move after surgery, it may be helpful to ask another person to assist in placing the electrodes.



Note: The "Place the Electrodes" Instruction Section (left) may be completed BEFORE the "Assemble the Xstim System" Instruction Section. The order in which these two sections are completed is dependent upon the users preference for ease of use.

For Battery Charging Instructions see Page 16

PRESCRIBING INFORMATION

Description

Xstim passes a specific current between the electrodes in order to promote healing by inducing a therapeutic, low level electrical current at the fusion site. Federal law restricts this device to sale by or on the order of a physician. Prescription (Rx) only. This device is not intended for re-sale.

Indications for Use

The Xstim Spine Fusion Stimulator is a noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. The device is for prescription use only, and intended for single patient use in adult patients only.

Contraindications

There are no known contraindications.

Warnings

Cardiac pacemakers or cardioverters may be adversely affected by Xstim. The concomitant use of Xstim 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 stimulator device. If there are any observable adverse changes in the pacemaker rhythm or output, Xstim should not be used.

The safety and effectiveness of Xstim in pregnant women have not been studied and the effects of Xstim 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 Xstim.

Precautions

The safety and effectiveness of Xstim in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of Xstim in these individuals are unknown: spondylitis, infection, Paget's disease, cancer, diabetes mellitus, renal disease, osteoporosis, trauma of the lumbar spine.

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 Xstim to water. The patient must be instructed to remove Xstim 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 Xstim. Other components, parts and accessories may not be compatible, and may damage Xstim. If any component does not function properly, contact Customer Service at **(844) 228-2067**. No attempt should be made to modify or repair Xstim.

Patients should be able to use Xstim in accordance with the instructions for use. If a patient cannot comply with these instructions for any reason, use of Xstim is not recommended.

Adverse Events

During a multi-center clinical study of 349 patients treated with a device delivering either the same output parameters as Xstim for the indication listed above (177 active subjects) or no signal (172 placebo subjects), 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.

Recommended Usage

Xstim 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.

Use Environment

The Xstim is a prescription device in the USA and is intended for use in accordance with the directions of a healthcare provider. The device may be used in a healthcare facility setting or by a patient or lay operator in a home environment.

DIRECTIONS FOR USE

General

The stimulator and all of the following instructions have been specifically designed for safe, comfortable and easy use by a patient. They include the required assembly, operation, troubleshooting and maintenance (battery charging and cleaning) activities.

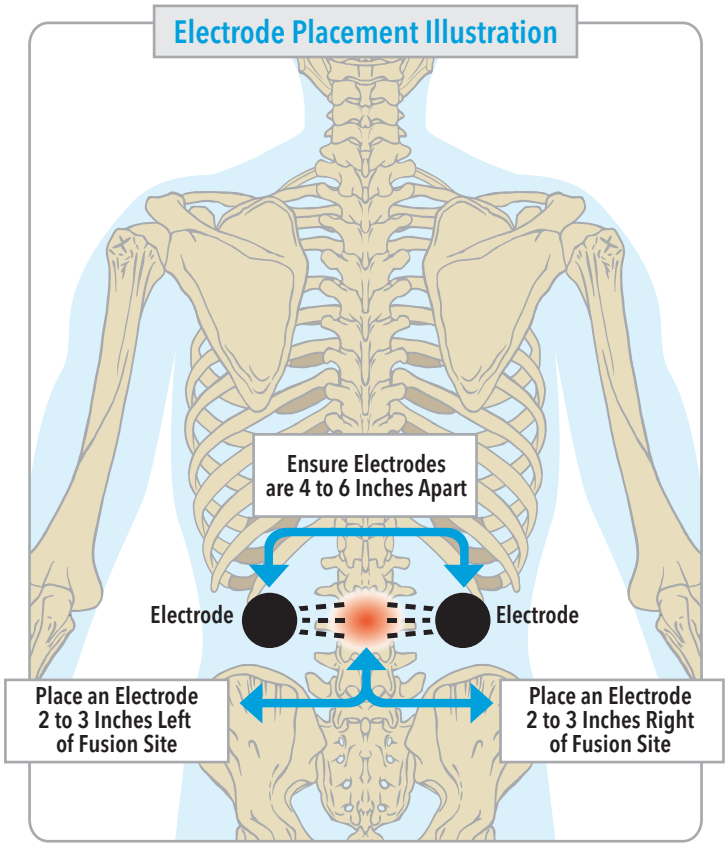
Begin using the stimulator immediately after reading the instructions for use and having received instructions from the prescribing physician.

The device is intended for use 24 hours per day until treatment is determined to be complete by the prescribing physician. Compliance with the instructions provided by the prescribing physician is critical to achieving effective treatment. Proper care of Xstim is also required for the proper function of Xstim.

The system has been designed to give 24 hours of treatment from a fully charged battery and routine charging and swapping of the 2 batteries every 24 hours will help ensure no inadvertent gaps in treatment. Indicators are provided to demonstrate the latest point at which a fully discharged battery will need recharging if treatment is to avoid being interrupted.

Examine the skin for signs of irritation when replacing the electrodes. If irritation is present, relocate the electrodes to a place adjacent to that site, but still within the guidance. Disconnect the Xstim Controller during bathing, showering or swimming, and reconnect as soon as practical following these activities. Either remove the electrodes or cover the electrodes with the electrode covers during showering.

DIRECTIONS FOR USE



Placement of Electrodes

Clean and dry the skin where the electrodes are to be placed. Trimming (not shaving) body hair from the electrode application area is often helpful. Remove the electrode from the pouch and remove the plastic backing material from the electrode. Place one electrode on the back, **2 to 3 inches to the left** of the area of the spinal fusion and the second electrode **2 to 3 inches to the right** of the area of the spinal fusion so that the electrodes are on the back, **4 to 6 inches apart.**

Depending on your ability to move after surgery, it may be helpful to ask another person to assist in placing these electrodes. The patient should consult their prescribing physician if they have any questions or concerns regarding proper electrode placement.

If the 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.

If there are issues with the electrodes remaining in place, consider applying an electrode cover over the top of the electrode.

Electrode Care and Replacement

If removing the electrode temporarily for any reason, replace the plastic backing material to protect them. Before replacing them on the back, check to see that the surface is still clean and tacky. If not, apply a few drops of water to the skin facing surface and gently rub into the gel to help rehydrate. If this does not improve the surface properties, use a new pack of electrodes as supplied. Typically, a new set of electrodes may be required after a few days of use (1-7 days).

When supplies of electrodes are running low, contact Customer Service at **(844) 228-2067** for additional supplies.

Assembly of System

1. Choose the Controller lead wire length that is most convenient for use. This will depend on the location chosen to place or carry the Controller. Please ensure that the spare length of wire is not so long as to present a strangulation hazard.
2. Connect the end of the Controller lead wire (female connectors) to the 2 pins (male connectors) of the electrode lead wires. **Note:** This may be done before connecting the electrodes to the back if that is easier to manage.
3. Connect the other end of the Controller lead wire (largest connector) to the Controller.

Optional Controller Belt/Clothing Clip Accessory

If it is desired to attach the Controller to a belt, waistband or pocket, locate the belt clip and slide the controller into the belt clip and press down firmly to ensure fit. To remove the belt clip, hold the belt clip securely with one hand, the controller with the other hand, and simply pull it upwards until it is clear of the belt clip.

4. Insert a battery. The battery can only be properly inserted in one orientation. Once inserted, if the battery is sufficiently charged, the controller will automatically begin treatment as indicated on the home screen. If the battery is not sufficiently charged as indicated by a red level battery warning screen, try the other battery provided and charge the original.

Xstim will go through a self-check routine and will immediately start delivery of treatment. There is no on/off button. Please do not insert the battery until ready to start treatment. To stop treatment, remove the battery.

Normal Operation

When first connected, Xstim goes through a self-check routine which illuminates the "Xstim" logo on the splash screen before reaching a settled state. If everything is operating correctly, and the electrodes are properly applied to the skin, the Home Screen will appear on the display, indicating treatment is active.

HOME SCREEN MESSAGES AND NOTIFICATION INDICATORS

The home screen will enter sleep mode and go dark after 45 seconds. At any time, pressing the wake/sleep/mute button located on the top of the controller will illuminate the screen. While in sleep mode, if Xstim senses a change in state of normal operation, the relevant display message, along with an audible (beeping) indicator, and vibration indicator will automatically activate to provide notification of the changed state.

Session Time

Length of time in Hrs/Mins that the device has been active.

Battery Indicator

Indicates the battery percentage left in the device.

Calendar

Number of completed 24 hour sessions the device has been active.

HOME / TREATMENT ACTIVE SCREEN

INDICATORS AND TROUBLESHOOTING ACTIONS

The Battery Level, Error/Malfunction and Electrode Connection notifications also have an accompanying vibration and audible (beeping) indicator in case the display screen visual notifications are not visible. If notifications are not active for any reason, try the other battery and charge the original.

Session Time / Completed Sessions

Xstim dashboard screen is displayed when the device is in treatment mode. A complete session is equal to 24 hours in treatment mode, and time is only accumulated to the Session when the device is actively treating. When Session Time reached 24 hours, the Completed Sessions indicator will increase by 1 day and the Session Time will restart at 00:00.

Connection Issue

If the "Disconnected Electrodes or Wires" notification screen is illuminated, treatment is not being provided and Xstim notifications will be activated. To troubleshoot, please check the following possible causes:

1. Check all connections to ensure they are complete:
   - Check to ensure that the electrodes are attached securely to the skin (see the "Placing the Electrodes" section for details). Press firmly against the skin to form a secure attachment.
   - Check to ensure that each (2) Electrode Lead Wire is securely fastened to the two ends of the Cable Lead Wire.
   - Check to ensure that the connector of the Cable Lead Wire (cable end with single connector) is securely inserted into the Controller.
2. If all connections are complete then the device will detect that the resistance provided by the electrode gel and/or patient's body is outside of Xstim's operating range. It is most likely that this could result from:
   - The electrodes being too dry. Moisten them by applying a small amount of water onto the skin facing surface and gently rubbing it into the surface.
   - The electrodes reaching the end of their useful life (approximately 1 to 7 days). Use fresh electrodes.
   - Make sure the skin is clean and completely dry before re-applying the electrodes.
   - The skin is dehydrated. Skin resistance changes throughout the day as a body's hydration level changes. Remove Xstim and hydrate well by drinking water before re-applying Xstim.

If these suggested troubleshooting actions do not eliminate the "disconnected" notification, contact Customer Service at **(844) 228-2067**.

Notification Indicator Light

Notification Indicator Symbols

Audible & Vibration Active

Audible & Vibration Muted

Pictured:
Audible and Vibration Active

DISCONNECTED SCREEN

HOME SCREEN BATTERY INDICATOR

The battery meter displayed on the home screen has 4 segments, each segment representing 25% battery life.

Segment 4
76-100%

Segment 3
51-75%

Segment 2
26-50%

Segment 1
0-25%

When the battery reaches 25% remaining capacity, the battery meter will turn red.

BATTERY REPLACEMENT AND CHARGING

Replace Battery

When the battery reaches 5% remaining capacity, the battery meter will turn red and the audible (beeping) and vibration alerts will automatically activate, indicating that the battery should be replaced with a more fully charged battery immediately to avoid any chance of interruption to treatment. **Best practice** is to have one battery charging at all times while the other battery is connected to the controller and providing treatment. To avoid gaps in treatment ensure that a fully charged battery is always available.

Battery Charging

Charge the battery at room temperature (24°C (75°F)). Charging may require up to 3.5 hours for a full charge. Charging time may vary in warmer or colder temperatures. The indicator light on the charging station will glow green while charging and all three circles will be illuminated when fully charged.

To charge battery, insert the depleted battery into the charging station and ensure it is fully seated. Connect the power supply to the charging station then insert the plug into a standard wall outlet. The use of any power supply not supplied by Xstim Inc. can cause excessive heat, damage to the circuit, and shorten the life of the battery.

To remove the depleted battery from the Xstim controller, simultaneously press both battery release buttons located on each side of the Xstim controller, and gently guide the battery downward until it is clear of the controller. If the battery is already removed, locate the battery to be charged, then connect it to the charging station. The battery can only be properly inserted into the charging station in one orientation.

The indicator light on the charging station will glow green while charging and all three circles will be illuminated when fully charged.

Battery Charge Percentages:

Yellow Shading=Flashing Lights

- Charging Station Light 1 Flashing: 0-30%
- Charging Station Light 2 Flashing: 31-60%
- Charging Station Light 3 Flashing: 61-99%
- All 3 Battery Lights Solid Green: 100%

ERROR ICONS

Error Contact Customer Service

If the "Error Contact Customer Service" icon illuminates on the display screen, remove the battery and replace the battery. If the problem persists, contact Customer Service at **(844) 228-2067.**

CONTACT CUSTOMER SERVICE SCREEN

End of Life

After 270, twenty four hour treatment days of use, Xstim will no longer operate, indicated by the "End of Product Life" display screen on the controller. Remove the battery and refer to disposal instructions.

END OF PRODUCT LIFE SCREEN

WAKE /SLEEP/ MUTE

Multi-Function Wake/Sleep/Mute Button

If audible/vibration (A/V) notification occurs, a short press will mute the A/V for 5 minutes. If Xstim has entered sleep mode and the display screen is not illuminated, a short press will re-illuminate the display screen for 45 seconds.

WAKE/SLEEP/MUTE BUTTON

PATIENT COUNSELING INFORMATION

Controller On/Off

To power on the Controller, connect the battery to the controller. To power off the Controller, disconnect the battery.

Compliance

Compliance with device use and care is critical to ensure proper Xstim function and delivery of effective treatment.

Battery

Change the battery approximately every 24 hours or as indicated by Xstim. Charge the spare battery immediately upon removal or at least when indicated by the critical battery level display message.

Electrodes

Replace the electrodes when needed and clean the electrode application sites thoroughly with soap and water and dry the site before applying the electrodes.

Skin Irritation

Examine the skin for irritation or excessive redness when replacing the electrodes. If irritation or excessive redness is present, relocate the electrodes adjacent to the original sites. The patient should be evaluated periodically to assess the skin for sensitivity.

Bathing

Disconnect Xstim during bathing, showering, or swimming. Xstim should be reconnected as soon as practical following these activities. Either remove the electrodes, or cover the electrodes with the protective electrode covers, during showering.

PRODUCT CARE

Cleaning Instructions

Use a damp cloth to clean the Xstim system (excluding the electrode skin facing surfaces). Do not use detergents or other cleaning products.

Disposal

The battery is a lithium-ion rechargeable battery. The Xstim device is for single patient use only and is not reusable. It cannot be re-sold or used on multiple patients. When treatment is complete, as indicated by the "End of Product Life" message displayed on the device screen, or by the determination of the prescribing physician, dispose of the device according to local regulations. Xstim Customer Care or the prescribing physician may be contacted for assistance with disposal.

CLINICAL INFORMATION

Xstim Inc. referenced the P850022/S009 (SpinalPak) clinical study to establish a reasonable assurance of safety and effectiveness for its noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. A logistic regression analysis, performed as part of the SpinalPak study, determined that age and sex were not significantly associated with overall clinical and radiographic success after controlling for other variables. The effects of race and ethnicity were not evaluated. That study was randomized, double-blinded, multi-center clinical study of 349 patients treated with the SpinalPak® spine fusion device, a device delivering the same output parameters as Xstim, was conducted to determine if the SpinalPak® spinal fusion device increases the frequency of overall success (where overall success is defined as the combination of both clinical and radiographic success) when compared to placebo (inactive) units, after primary (first-time) one or two-level fusion surgeries within L3 to S1. All subjects had degenerative disc disease. Investigators were instructed to apply the spinal fusion device 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 a 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 the 349 subjects enrolled in the clinical study and who used the device at least once (177 active subjects and 172 placebo subjects), nine experienced skin irritation and cited this as a reason to withdraw from the study (2.6%). Of these nine subjects, four were in the active group and five were in the placebo group. Three other subjects withdrew from the study because of adverse events: one placebo had a wound infection (non-device related); one placebo had back spasms; and one active was not progressing.

Eight subjects who completed the study experienced adverse events:

1. Leg pain (placebo);
2. Recurrent pain due to over-activity (placebo);
3. Post-surgical wound seroma (active);
4. Superficial wound disruption from a staple reaction (placebo);
5. Pedicle fracture - screw removed (placebo);
6. A pedical screw placement (active);
7. An aneurysm clipping (placebo); and
8. A cluneal nerve neuroma at the graft site (active).

These eight subjects continued in the study and were included in the effectiveness analyses.

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-tailed 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 1 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 overall, clinical, and radiographic 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).

TABLE 1: FREQUENCY OF SUCCESS THE CORE GROUP, BY TREATMENT (N=215), (P-VALUE = 0.0018)

Subject Group	Overall Success (Clinical & Radiographic)	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 success 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 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 an overall successful outcome:

Variables:

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 steroids and NSAIDS
8. a secondary diagnosis of herniated disc pulposus;
9. a secondary diagnosis of spondylolisthesis;
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 2.

TABLE 2: 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 spine fusion stimulator delivering the same output parameters as Xstim may be used as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

TECHNICAL INFORMATION

Equipment Classification	• Stimulator - Internally powered by rechargeable batteries • Charger - Class II, Type B • IP22 Degree of ingress protection provided by Xstim Controller Enclosure • Equipment not suitable for use in presence of flammable anesthetic mixture with air or oxygen or nitrous oxide. • Mode of operation – continuous
Output Waveform	• 60kHz ±10% sinusoidal waveform
Transport and Storage Conditions	• Transport Temperature: -29°C to 60°C • Transport Humidity: 0%-85% Relative Humidity • Atmospheric Pressure: 70~106 kPa
Operating Conditions	• Working Temperature: +5°C to +40°C • Operating Humidity: 15 to 90% humidity • Atmospheric Pressure: 70~106 kPa
Battery	• 3.7 V LiPo: 3,000 mAH Capacity
Power Supply	• Manufacturer: Keerda • Model No. DZ010DLL050200U • AC Input: 100-240 Vac, 50-60Hz • DC Output: 5V, 2A

COMPLIANCE

Compliance Declaration:

ANSI AAMI ES60601-1 05 & A1 12	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2-2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-11 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 62133-2	Lithium-ion Battery Performance
ISO 10993-5 and ISO 10993-10	Cytotoxicity (ISO 10993-5), Irritation (10993-10) & Sensitization (10993-10)
ISO 62304-2006	Medical device software – Software life cycle processes
ISO 14971	Medical devices - Application of risk management to medical devices
ISO 13485	Medical devices–Quality management systems–Requirements for regulatory purposes

SYMBOL DESCRIPTIONS

Content Quantity

Follow Instructions for Use

Date of Manufacture

Manufacturer

Prescription Only

Single Patient Multiple Use

Temperature Limit

Keep Dry

Storage Humidity Range

Pressure Range

Recycle Electronic Equipment

Degree of Ingress Protection
Provided by Xstim Controller Enclosure

Type BF Applied Part

Fragile

This Side Up

Audible & Vibration Active

Audible & Vibration Muted

Unique Device Identification

Catalog or Part Number

Serial Number

Lot Number

ELECTROMAGNETIC COMPATIBILITY

Xstim is intended for use in the Home Healthcare Environment (Restaurants; cafes; shops; stores; markets; schools; churches; libraries), outdoors (streets; sidewalks; parks), domiciles (permanent or temporary), vehicles; stations; airports; museums and theaters. Xstim is intended for use in the electromagnetic environment specified in the subsequent charts. The customer or user of the Xstim should ensure that it is used in such an environment.

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Xstim could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Xstim System including cables specified by Xstim. Otherwise, degradation of the performance of this equipment could happen.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Electromagnetic Environment - Guide
RF Emissions CISPR 11		Group 1, Class B
Harmonic Emissions IEC 61000-3-2		Class A
Voltage Fluctuations/ Emission Oscillations IEC 61000-3-3		Yes

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Immunity Test	Test Level IEC 60601	Compliance Level	Electromagnetic Environment - Guide
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15kV Air		
Electrical Fast Transient/ Burst IEC 61000-4-4	±2kV 100 kHz Repetition Frequency		
Surge IEC 61000-4-5	1kV		
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 (A/m)		
Voltage Dips, Short Interruptions & Voltage Variations on Power Supply Input Lines IEC 61000-4-11	Voltage Dips: Percent U(t): 95% Cycles: 0.5 Sync Angle: 0°, 45°, 90°,135°, 180°, 225°, 270°, 315° Cycles: 1 Sync Angle: 0°	Voltage Dips: Percent U(t): 30% Cycles: 25 (50Hz), 30 (60Hz) Sync Angle: 0°	Voltage Interruptions: Percent U(t): 95% Cycles: 250 (50Hz), 300 (60Hz) Sync Angle : 0°

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Immunity Test	Test and Compliance Levels		
Conducted RF IEC 61000-4-6	3 V; 150kHz - 80MHz. 3V RMS outside the ISM band, 6V RMS: ISM amateur radio bands between 150kHz - 80MHz 1% frequency step 80% Am @ 1kHz		
Radiated RF IEC 61000-4-3	Immunity Level 27 V/m Frequency: 385 MHz Pulse Modulation: 18Hz	28 V/m Frequency: 450 MHz ±5Hz deviation: 1kHz sine Frequency: 810/870/930 MHz Pulse Modulation: 18Hz Frequency: 1720/1845/1970 MHz Pulse Modulation: 217Hz Frequency: 2450 MHz Pulse Modulation: 217Hz	9 V/m Frequency: 710/745/780 MHz Pulse Modulation: 217Hz Frequency: 5240/5500/5785 MHz Pulse Modulation: 217Hz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