INSTRUCTION MANUAL

USA SPINAL-STIM MANUAL SS-1602

Model 5212

DRAFT 5/02/16 - DO NOT DISTRIBUTE
FINAL WILL BE PROVIDED ONCE APPROVED

ORTHOFIX®

Assembled in the United States of America

Spinal-Stim Device Patent No.
U.S. 5,743,844
U.S. 6,132,362
U.S. 6,261,221

Spinal-Stim® Instruction Manual
Table of Contents

Device Box Components

1 – Spinal-Stim
1 – Power Supply
1 – Literature Pack

Orthofix Patient Services: 800-535-4492 or 214-937-2718
To learn more about Orthofix, please visit our website at www.orthofix.com.

Prescription Information

Indications
Spinal-Stim® is a noninvasive electromagnetic bone growth stimulator indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment of salvage of failed spinal fusion, where a minimum of nine months has elapsed since the last surgery.

Contraindication
Cardiac pacemakers may be adversely affected by exposure to PEMF. Use of this device is contraindicated where the individual has an implanted cardiac pacemaker.

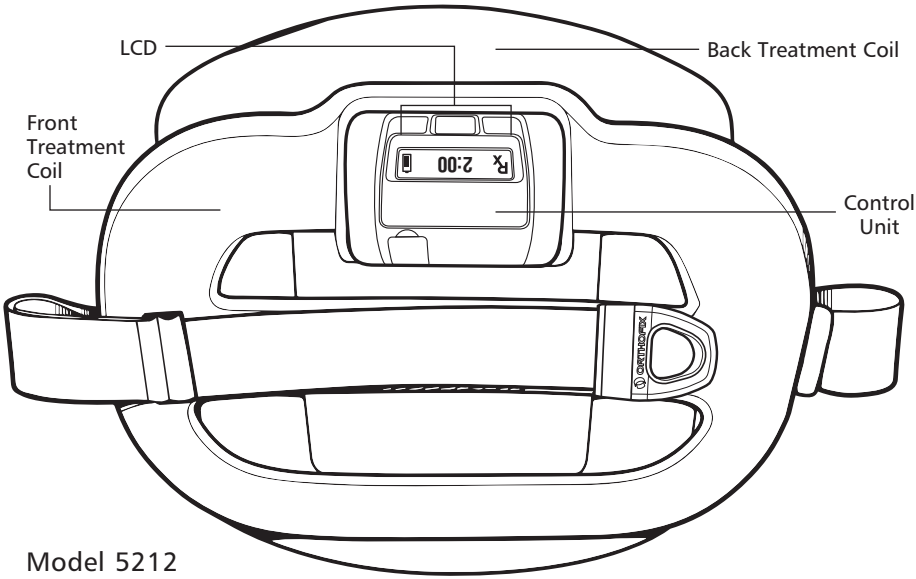
Warnings
- Although animal teratological studies performed with the device demonstrated no adverse findings, the safety of use of this device during pregnancy and nursing in humans has not been established.
- The safety and effectiveness of the use of this device on individuals lacking skeletal maturity have not been established.
- Animal studies conducted to date do not suggest any long-term adverse effects from the use of a similar device. However, long-term effects in humans are unknown.

Precautions
- This device should not be used if there are mental or physical conditions which preclude compliance with the physician and device instructions.
- This device has not been evaluated in treating patients with the following conditions: osseous or ligamentous spinal trauma, spondylitis, Paget's disease, moderate to severe osteoporosis, metastatic cancer, renal disease, and uncontrolled diabetes mellitus.
- The results of premarketing data from the randomized double-masked cohort indicate that inconsistent users (defined as those patients that used the device for less than an average of two hours per day) had success rates similar to those in the placebo group. Therefore, the use of the device for less than the minimum recommended usage may result in lower success rates.

Adverse Effects
Rare instances of reversible minor discomfort have been reported. These were: cumbersome or uncomfortable, minor tingling or pain, minor skin rash, insomnia, fainting, nausea/diarrhea, and polymenorrhea.

Device Information

Device Description
Spinal-Stim stimulator is an external device that generates a Pulsed Electromagnetic Field (PEMF) as a nonsurgical, prescription treatment to increase the chances of a successful fusion. The device is lightweight, adjustable, and portable, including a rechargeable battery that allows freedom of movement during treatment. A Liquid Crystal Display (LCD) and audible indicators provide important feedback during treatment. See "Device Operation" for more information.



Model 5212

Spinal-Stim contains a Control Unit and Treatment Coils in one integrated device. A micro-processor generates Spinal-Stim's electrical signal, which is a highly uniform, low-energy magnetic field sent from the treatment coils. When the coils are centered over the treatment area, the therapeutic Spinal-Stim PEMF signal is delivered through clothing and skin directly to the fusion site.

To learn more about bone growth stimulation, please visit our patient website at www.bonestimulation.com.

Device Life
Spinal-Stim provides daily treatments for up to 365 days. The physician determines the overall length of treatment (months/weeks) on an individual basis according to fusion healing progress.

Device Operation

Turning the Device On and Off

Spinal-Stim can be turned on by pressing and holding the On/Off Button on the Control Unit of the device until it beeps.

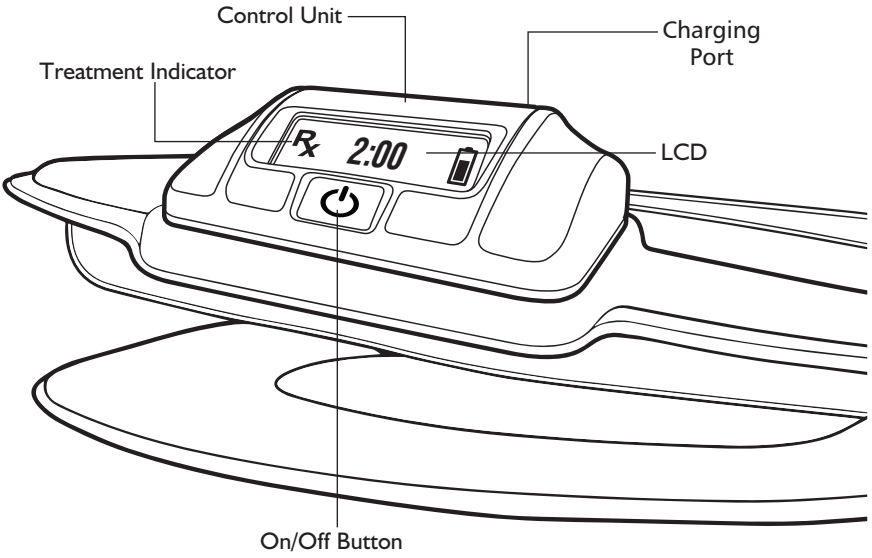
When the device is turned on, a status screen will display the number of days since the first use, the treatment status, and the compliance percentage.

The LCD will show the prescribed treatment time remaining and the battery status.

The flashing semicolon on the LCD screen and On/Off button indicate that the device is on and delivering treatment.

Spinal-Stim can be turned off by pressing and holding the On/Off Button on the Control Unit of the device until it beeps.

The On/Off Button on the Control Unit doubles as a Backlight to light up the LCD. In low light, press the On/Off Button to light up the LCD.



Treatment Instructions

- Spinal-Stim should be worn each day for the number of hours prescribed by a physician (a minimum of 2 hours/day).
- Spinal-Stim may be used at any time of day that is most convenient for the patient.
- The device is programmed to reset the treatment clock daily at midnight Central Standard Time, unless adjusted by a physician or Orthofix representative for a different time zone.
- Hours worn prior to the reset time will be logged and stored in the device for monitoring daily use compliance.
- The overall treatment duration (number of months/weeks) will vary based on specific patient conditions as determined by a physician.
- Because Spinal-Stim is lightweight and portable, treatment can be received while sitting, walking, reclining, sleeping, etc. However, since each patient is unique, the overall activity level should be based on physician instructions.

Timing of Treatment Sessions

- Spinal-Stim tracks the treatment time; this tracking (or timing) begins when the device is turned on and at least one minute of treatment is complete.
- The LCD shows a countdown of the daily treatment time remaining.
- To stop treatment at any point, simply press and hold the On/Off Button until you hear a beep.
- To resume treatment, press the On/Off button again.
- The countdown will resume at the remaining treatment time.
- When daily treatment is completed, the device will automatically turn off.

Charging the Battery

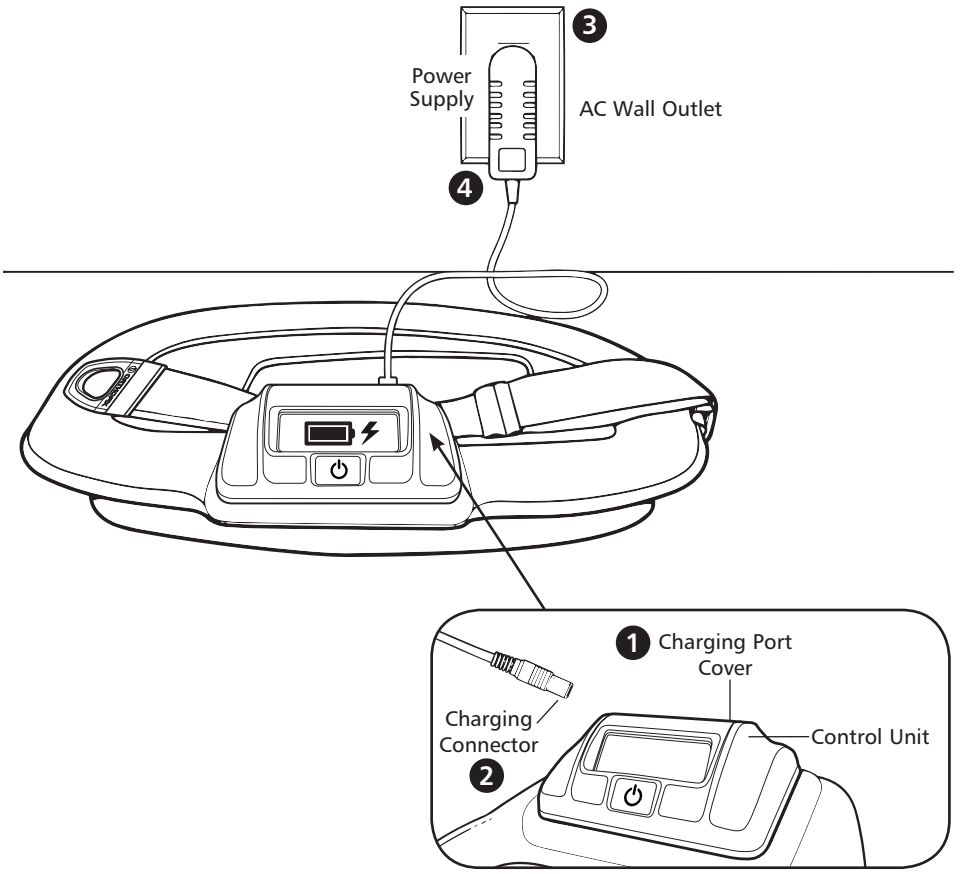
Spinal-Stim is powered by a rechargeable lithium-ion battery pack. A power supply to charge the battery is provided with the device. Use only the Orthofix power supply to charge the battery (Part no. Orthofix 20110412).

To ensure that the device is functioning properly, Spinal-Stim constantly monitors battery voltage and the electrical signal. The LCD will display a battery capacity symbol and the device will beep to alert the patient when the battery is low and will soon need to be recharged.

Spinal-Stim should be charged before the first use and every day after completing treatment. The device will not deliver treatment while charging.

Follow these steps to recharge the battery:

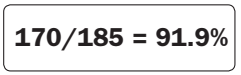
1. Open the Charging Port Cover.
2. Plug the Charging Connector into the Charging Port located on the Control Unit.
3. Plug the power supply into any standard AC Wall Outlet.
4. The LED on the power supply will light up green as an indicator that the AC Wall Outlet is delivering power.
5. The Control Unit LCD will display a battery symbol filling to verify that the device is charging. When the battery reaches a complete charge, a check mark symbol will be displayed next to the battery symbol. In addition, the device will beep once to alert the patient.
6. If the battery is fully depleted, it may require up to 4 hours to charge completely.
7. After charging is complete, remove the Charging Connector and replace the Charging Port Cover.



Visual and Audio Indicators

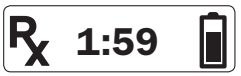
The LCD and audible beeps are designed to provide helpful information to the user. The screens, symbols, and beeps are explained below.

Compliance Screen



Compliance Screen – Displays a compliance percentage which is calculated by the number of full treatments days completed over the number of available treatment days. The treatments days available begin once the device has been delivered to the patient and a minute of treatment time has been established.

Treatment Screen



Treatment Screen – displays the treatment time remaining in hours and minutes. The timer counts down to zero until daily treatment is complete.

Treatment Complete

Daily Prescribed Treatment complete

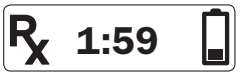
Charging Screen

Battery Charging – Battery symbol filling repeatedly verifies that the device is charging.

Charging Complete

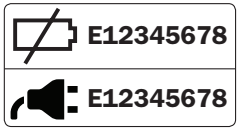
Charging Complete – Indicates when the battery is fully charged.

Low Battery Warning Screen



Low Battery – Displays along with three fast beeps when recharging is recommended.

Battery must be charged to turn on



Battery Empty – Indicates that the battery must be charged before treatment may continue.

Device Expired

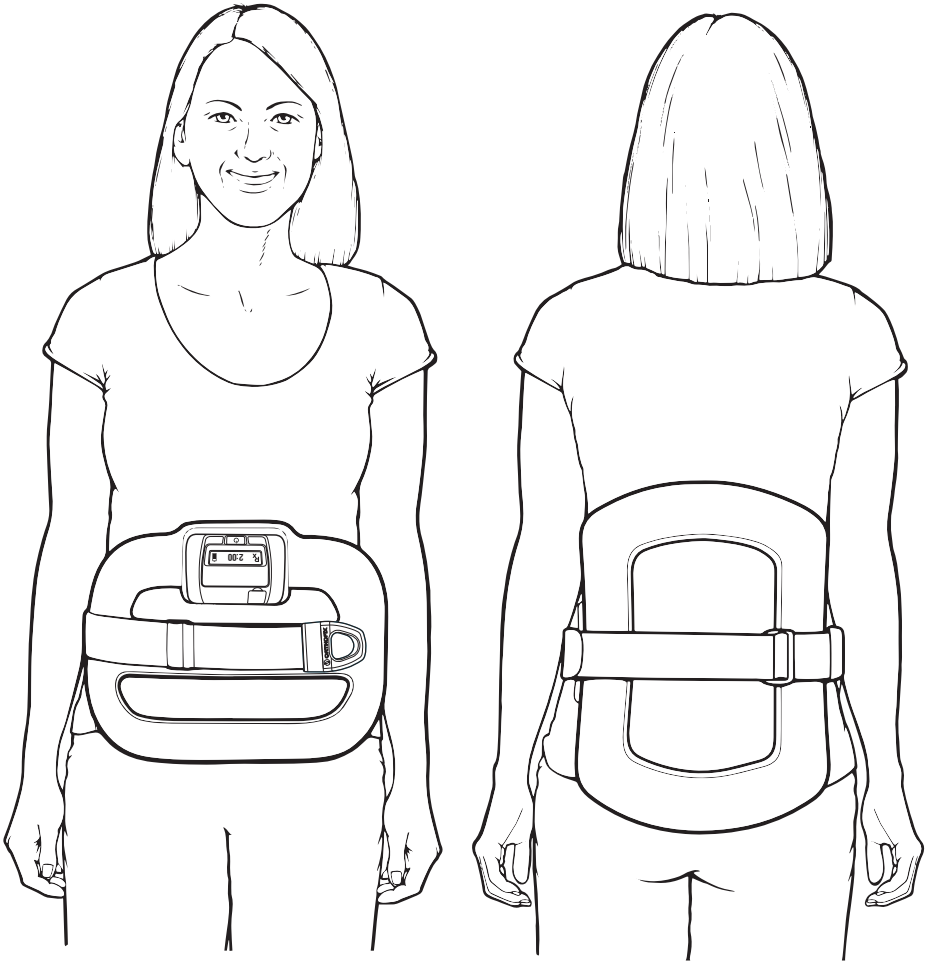
Device Expired – Display of a closed lock indicates the device has been available for treatment for 365 days and will no longer provide treatment.

Exception Screen

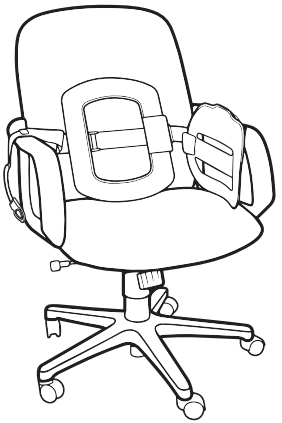
Exception Codes – Display of ERROR, any E codes (e.g., E01, E02), along with three slow beeps. Contact Patient Services at 800-535-4492 or 214-937-2718.

Wearing the Device

Spinal-Stim can be worn over bracing and clothing. Proper treatment does not require direct contact with the body. However, the coils must be centered around the fusion site to be effective. Users can gently bend and shape the treatment coils to fit more comfortably around the body.

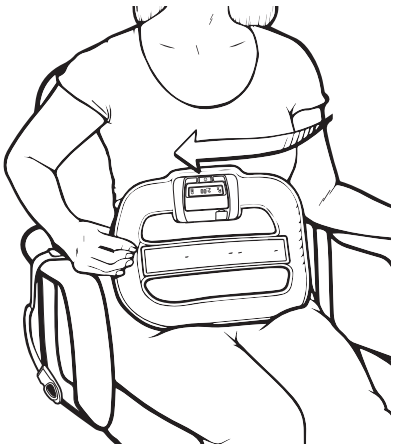


The following is the suggested method for wearing Spinal-Stim:



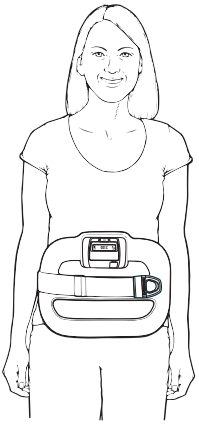
1. Rest the Back Coil of the device against the back of a chair and the Front Coil against the left arm of the chair. Let the Velcro® Strap hang over the right arm of the chair.

2. Sit in the chair.



3. Pull the Front Coil toward you and let it rest on top of your legs.

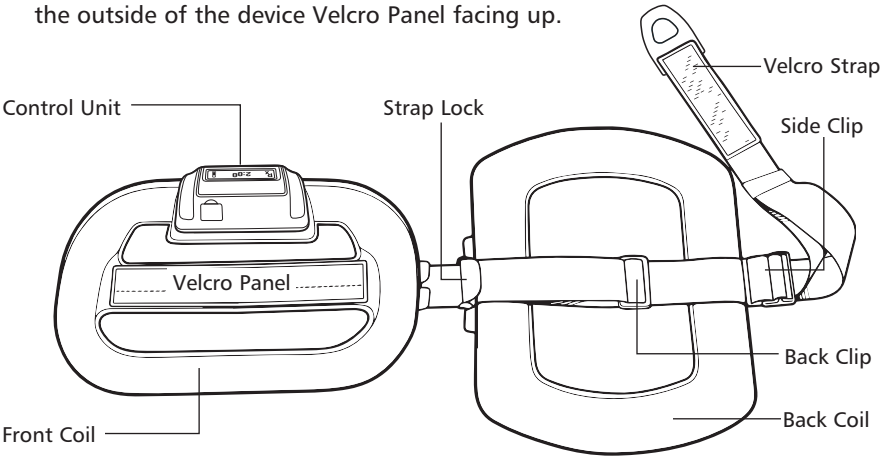
4. Locate the Velcro Strap and pull it snugly across your body and attach it to the Velcro Panel on the Front Coil.



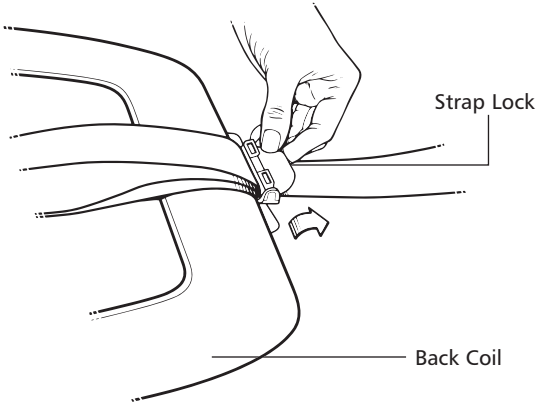
Sizing the Device
For minor size adjustments, adjust the placement of the front Velcro Strap. For further adjustments, follow the steps below.

1. Place Spinal-Stim around the body to determine how much adjustment is needed.
   - Note: when properly adjusted, the coils should be centered on the body. The Control Unit should be in front, LCD facing up.

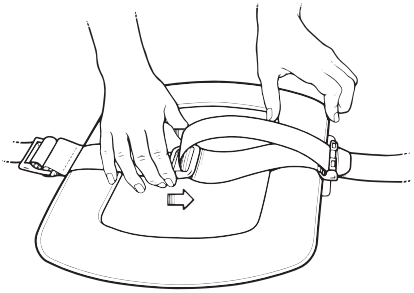
2. If a significant size adjustment is needed, lay the unit flat with the outside of the device Velcro Panel facing up.

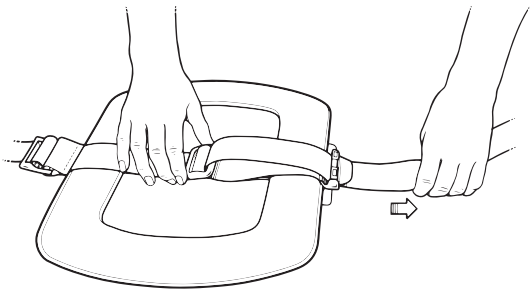


3. To adjust the Back Coil, open the Strap Lock.



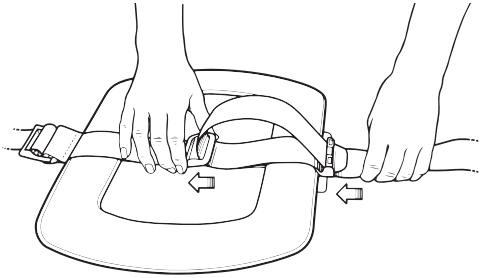
4. If **more** strap length is needed to make the device bigger, slide the Back Clip toward the Strap Lock. Pull the excess strap through the Strap Lock.

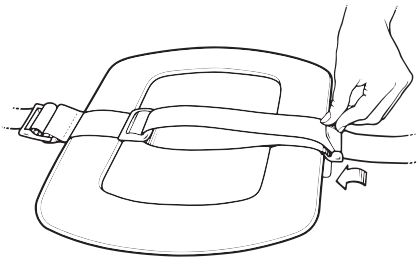




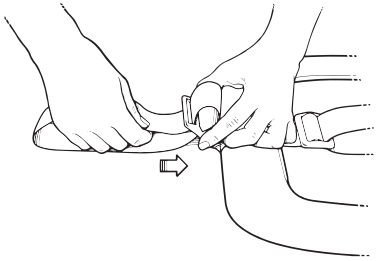
5. If **less** strap length is needed to make the device smaller, push the desired amount of strap through the Strap Lock. Slide the Back Clip away from the Strap Lock to tighten the excess strap.

6. Close the Strap Lock.

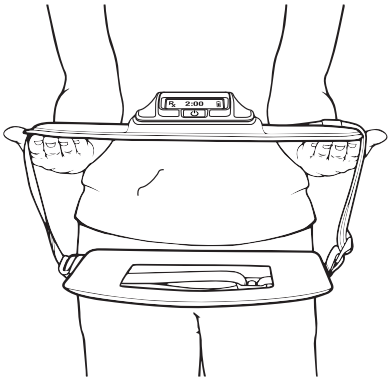




7. On the back coil, adjust the Velcro Strap by pulling more or less elastic strap through the Side Clip.



8. When properly adjusted, the Spinal-Stim straps will be approximately the same length on each side.



Device Accessories

Certain body types may benefit from the use of suspenders with Spinal-Stim. Please contact Patient Services at 800-535-4492 or 214-937-2718 to order suspenders.

An accessory available to the patient is a user friendly mobile application which allows the patient to easily monitor their device use. This may be downloaded to the patient's smartphone. Reference the Patient Guide to the Orthofix Stim App.

Device Use and Care

- Spinal-Stim is a technologically advanced electronic device and should be handled with care. Dropping or other mishandling of Spinal-Stim may damage the device and it may stop working.
- For safe usage, follow manufacturer instructions when using Spinal-Stim.
- Use of the device in any other manner could have harmful effects and/or void the warranty.
- The use of accessories other than those specified may result in increased emissions or decreased immunity of the device.
- Inspect the device prior to each use for wear or deterioration.
- Do not use the device if it does not appear to be in suitable condition.
- Do not attempt to open or disassemble Spinal-Stim as there are no user serviceable parts inside.
- CAUTION: STRANGULATION HAZARD – Keep the Power Supply cord out of the reachof children.

Care and Cleaning

When cleaning the Spinal-Stim device, follow these instructions:

- Clean the device by wiping surfaces with a damp, soft cloth (wet with water only). Do not sterilize Spinal-Stim.
- DO NOT expose Spinal-Stim to excessive moisture.
- DO NOT use solvents or alcohol-based liquids (anti-bacterial cleaners, hand sanitizers, perfume, etc.) to clean Spinal-Stim.

Storage

Unpacked Storage:

Temperature range: within -25°C to 60°C, in up to 93% relative humidity non-condensing.

Packed Storage, Shipping, and Transport:

Temperature range: -40°C and 60°C, between 10% and 100% relative humidity including condensation at pressures between 500hPA and 1060hPA in a safe manor.

Operating Environment:

Temperature range: within +5° C to +40°C,
15-93% relative humidity non-condensing, and 700-1060 hPA.

Spinal-Stim is designed for a storage life of twelve months plus one year of usage.

- DO NOT expose Spinal-Stim to direct sunlight for long periods of time.
- DO NOT expose Spinal-Stim to excessive heat or cold.
- Avoid storing the device in areas prone to extreme temperatures, such as an enclosed automobile or trunk.

Travel

When traveling by air, it is recommended to pack Spinal-Stim with checked luggage. If taken onboard the airplane, it should be turned off when passing through security screening equipment, as the device could be damaged. The Spinal-Stim instruction manual should be taken with you to quickly and easily identify the device for security personnel. Do not wear or operate Spinal-Stim while onboard the airplane.

Disposal

After treatment is complete and a physician advises you to discontinue use, you may dispose of the device according to your local governing ordinances or recycling plans. You may also contact Orthofix Patient Services regarding recycling.

Spinal-Stim is a Class III medical device (prescription only) that cannot be sanitized or used by another person.

Dispose of the device properly to prevent injury.

DO NOT dispose of Spinal-Stim in an incinerator. This device contains lithium batteries.

Service

If you have questions concerning the device or require any assistance, please call 800-535-4492 (U.S. only) or 214-937-2718. There are no user serviceable parts. Notify Orthofix for any servicing needs.

Spinal-Stim has not been evaluated with regard to use with specific implantable electronic medical devices. Please consult your physician prior to use of the Spinal-Stim with implantable electronic medical devices.

Clinical Information

Clinical Data Summary
Spinal-Stim was studied in human clinical trials to evaluate its safety and effectiveness as a therapy added to standard post-surgical care (referred to as the "adjunct clinical trial"). A separate phase of the clinical trial (referred to as the "failed fusion clinical trial") examined patients with fusions that had not healed (pseudarthrosis) after a lumbar fusion surgery. The patients in both clinical studies had risk factors.

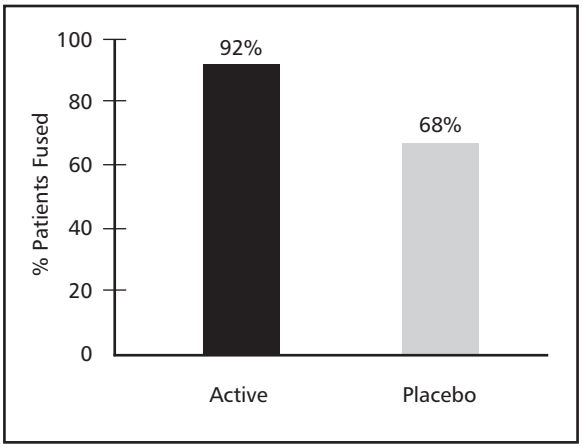
Adjunct Clinical Trial
Spinal-Stim has been tested in a clinical study involving 54 surgeons at 31 centers. This clinical investigation contained a prospective randomized double-masked trial of PEMF efficacy. Spinal-Stim was tested as a surgical adjunct in patients undergoing a first attempt at lumbar fusion. At one year postoperative, patients using active devices on a consistent daily regimen (an average of at least two hours per day) developed solid fusion in 92.2% of the cases.1 Patients consistently using placebo (inactive) devices developed solid fusion in 67.9% of the cases. This 35% increase in treatment effect is statistically significant, and is realized regardless of:

At one year after the fusion surgery, patients using active devices on a consistent daily regimen (an average of at least two hours per day) developed solid fusion in 92% of the cases. Patients consistently using placebo devices developed solid fusion in 68% of the cases.

- Number of levels
- Graft type
- Internal fixation
- Gender
- Vertebral level
- Smoking
- Age

The success rate for patients in the randomized double-masked phase for whom success or failure status is known at four years after treatment with the Spinal-Stim for all subjects (consistent and inconsistent users combined) was 63% (n=88) as compared with 83% in this phase of the clinical trial (i.e., one year postoperative).

Adjunct Clinical Trial: Overall Success Rate



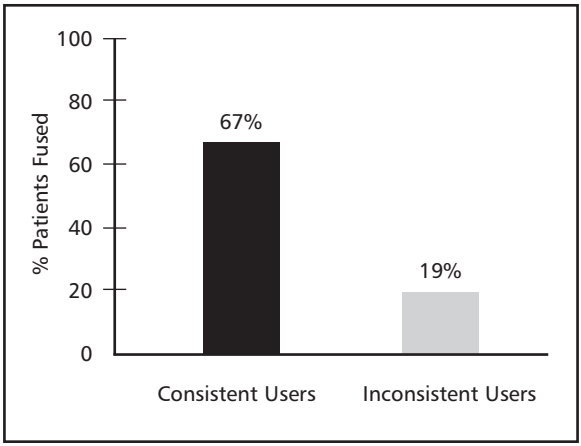
Consistent users (n=64) of the device in this phase had an initial success rate of 92.2% with a success rate of 70% after four years (a 24% reduction). Inconsistent users (n=34) and the entire placebo group (n=97) had an initial success rate of 65% with a success rate of 50% after four years (again, a 24% reduction). Long-term follow-up data indicates the success rate differentials between active and placebo units are maintained over time. Long-term, consistent Spinal-Stim users benefit with a 40% increase in fusion success, when compared to inconsistent and placebo device users. Based on this analysis, the reduction in long-term success rates appears unrelated to treatment with the Spinal-Stim. During this four year period, 10% of the original patients in the randomized double-masked phase were lost to follow-up and are not reflected in these success rates.

Failed Fusion Clinical Trial

Spinal-Stim was also tested for nonoperative salvage in patients presenting with established pseudarthrosis of lumbar fusion in an open trial. Without additional regrafting of fusion surgery, 67% of these cases reached a successful fusion with consistent (an average of at least 2 hours per day) PEMF treatment.[2]

Spinal-Stim reduced smoking and multi-level fusion as risk factors in failed fusion patients. Consistent users showed a 67.2% success rate in non-smokers and a slightly lower 66.7% success rate in smokers. Users with failed single level fusions showed a 68% success rate and a slightly lower 66% success rate for failed multi-level fusions.

Failed Fusion Clinical Trial: Overall Success Rate



The four year success rates for these patients in the open trial, non-operative salvage phase for all subjects (consistent and inconsistent users combined) was 39% (n=119) as compared with 57% in this phase of the original clinical trial (i.e., one year postoperative). Consistent users (n=93) of the device in this phase had a success rate of 44% after four years. Inconsistent users (n=26) of the device in this phase had a success rate of 19% after four years.

The reduction in success rates from the time of commercial marketing compared with those at four years showed a similar percentage decrease (31%) to those in the randomized double-masked trial. During this four year period, 6% of the original patients in the open phase were lost to follow-up and are not reflected in these success rates.

[1]Mooney, V., "A Randomized Double-Blind Prospective Study of the Efficacy of Pulsed Electromagnetic Field for Interbody Lumbar Fusions", SPINE, Vol. 15, No. 7, P708, 1990.

[2]Simmons, JW, Hayes, MA, Christensen, KD, Dwyer, AP, Koulisis, CW, Kimmich, SJ: "The Effect of Postoperative Pulsed Electromagnetic Fields on Lumbar Fusion: Open Trial Study". Presented at the Annual Meeting of the North American Spine Society, Quebec City, Canada, 2 July 1989.

Equipment Classification

Device Symbol Descriptions

Symbol	Meaning	Symbol Location
	Attention – Refer to Instruction Manual	Device and Device Box
	Type BF Applied Part	Device and Device Box
	On/Off	Device
	Prescription Only	Device
	Storage Temperature Range	Device Box
	Year of Manufacture for Active Device	Device and Device Box
	Manufacturer	Instruction Manual
	Not for General Waste	Device and Device Box
	Keep Dry	Device and Device Box
	FCC Mark	Device and Device Box
	CE Mark	Device and Device Box
	Storage Humidity Limits	Device and Device Box
	EU Authorized Representative	Instruction Manual
	Catalog Number	Device and Device Box
	Serial Number	Device and Device Box

Spinal-Stim Classifications

- Product Family Name: Orthofix PEMF Device
- Internally powered equipment
- Type BF applied part
- IEC 60529 enclosure rating: IP22
- Mode of operation: intermittent operation
- This device is non-sterile. It does not require sterilization.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- The battery charger is considered double insulated with Class II construction throughout.

Compliance Statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

IMPORTANT! Changes or modifications not expressly approved by Orthofix, Inc. could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAN ICES-3 (B)/NMB-3(B)

This equipment complies with radiation exposure limits set forth for uncontrolled environment.

Information regarding Electromagnetic Compatibility and Immunity

Spinal-Stim complies with IEC 60601-1-2 for electromagnetic compatibility (EMC). Spinal-Stim needs special precautions regarding EMC and needs to be used in accordance with the EMC information provided in this manual. Wireless communications equipment such as home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect Spinal-Stim. These types of equipment should be kept at least 0.198 m (7.8 in) away from Spinal-Stim.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warranty

Orthofix Inc. warrants the Spinal-Stim Osteogenesis Stimulator to be free from defects in materials and workmanship for one year from the date of first use. Provided that all terms and conditions of this Limited Warranty are complied with, Orthofix Inc. will replace defective components.

This Limited Warranty applies to the product only under normal use and does not cover any damage or defect caused by accident, misuse, abuse, fire, flood, and acts of God, or by any alteration, tampering, repair, or attempted repair by anyone other than Orthofix Inc. This warranty only applies to the patient for whom the product is prescribed and is not assignable or transferable.

Defective products covered by this Limited Warranty must be returned to Orthofix Inc., Attention: Orthofix Returns. You must call a Patient Services representative or your local distributor to obtain the Return Authorization number and address prior to returning the product.

Except as specifically required by applicable law, the foregoing warranty is in lieu of all other warranties, expressed or implied, and Orthofix Inc. specifically disclaims any and all warranties of merchantability or fitness for a particular purpose. Under no circumstances shall Orthofix Inc., its authorized representative, affiliated, or subsidiary companies be liable for special, consequential, or incidental damages. The sole remedy with respect to any defective product shall be limited to replacement.

This Limited Warranty may not be extended or modified except in writing by Orthofix Inc. No sales person, representative, distributor or physician is authorized to make or consent to any extension or modification of the terms of this Limited Warranty.

For additional information and/or device assistance, contact Orthofix Patient Services at 800-535-4492 or 214-937-2718.

RX Only

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

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