INSTRUCTION MANUAL

Model 5505

USA CERVICAL-STIM MANUAL CS-1602

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

ORTHOFIX®

Assembled in the United States of America

Cervical-Stim Device Patent No.
U.S. 6,024,691
U.S. 5,743,844
U.S. 6,132,362

Cervical-Stim® Instruction Manual
Table of Contents

Device Box Components

1 – Cervical-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

Indication
Cervical-Stim® is a noninvasive, pulsed electromagnetic bone growth stimulator indicated as an adjunct to cervical fusion surgery in patients at high-risk for non-fusion.

Contraindication
There are no known contraindications for Cervical-Stim as an adjunct to cervical spine fusion surgery.

Warnings
- Do not use Cervical-Stim if you have a cardiac pacemaker or defibrillator because it may interfere with the operation of your pacemaker or defibrillator. If you use Cervical-Stim and it affects your pacemaker or defibrillator, it may injure your heart. Consult your cardiologist before using Cervical-Stim.
- Remove Cervical-Stim prior to any imaging procedures (e.g., CT scan, MRI, etc.). If you wear Cervical-Stim during these procedures, you could be injured, the imaging being produced may be ruined, and/or the Cervical-Stim could be damaged.

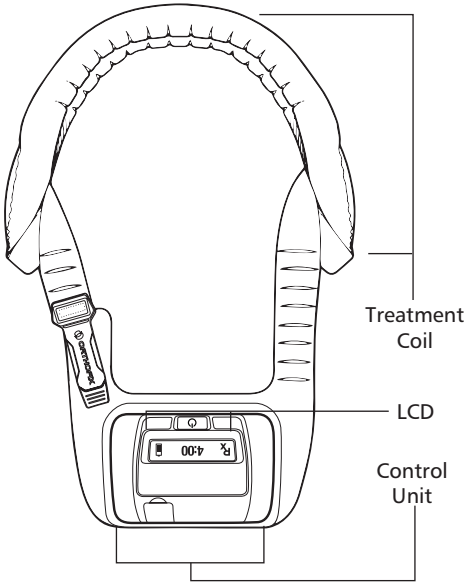
Precautions
- Avoid using Cervical-Stim if you do not understand the instructions your doctor has given you. If you use Cervical-Stim incorrectly, it may harm you or may not help your healing process.
- Cervical-Stim has not been evaluated in treating patients with the following conditions: osseous or ligamentous spinal trauma, spondylitis, Paget's disease, moderate to severe osteoporosis, metastatic cancer, renal disease, rheumatoid arthritis, uncontrolled diabetes mellitus, patients prone to vascular migraine headache, seizure, epilepsy, thyroid conditions, or neurological diseases.
- Animal reproductive studies performed with this device did not show any harmful effects in animals. However, the safety of this device for use on patients who are pregnant or nursing has not been established.

Adverse Effects Summary
Adverse effects may be experienced when using Cervical-Stim. These adverse effects may include increased pain, numbness and tingling, headache, migraines, and nausea. These effects may or may not be directly related to use of Cervical-Stim. Any adverse effects that are related to Cervical-Stim should stop when you discontinue use.

See the Adverse Effects Table for a list of all adverse events reported during the clinical study.

Device Information

Device Description
Cervical-Stim is an external device that generates a Pulsed Electromagnetic Field (PEMF) signal 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 5505

Cervical-Stim contains a Control Unit and a Treatment Coil in one integrated device. A micro-processor generates Cervical-Stim's electrical signal, which is a highly uniform, low-energy magnetic field sent from the treatment coil. When the coil is centered over the treatment area, the therapeutic Cervical-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
Cervical-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

Cervical-Stim can be turned on by pressing the On/Off Button on the Control Unit of the device.

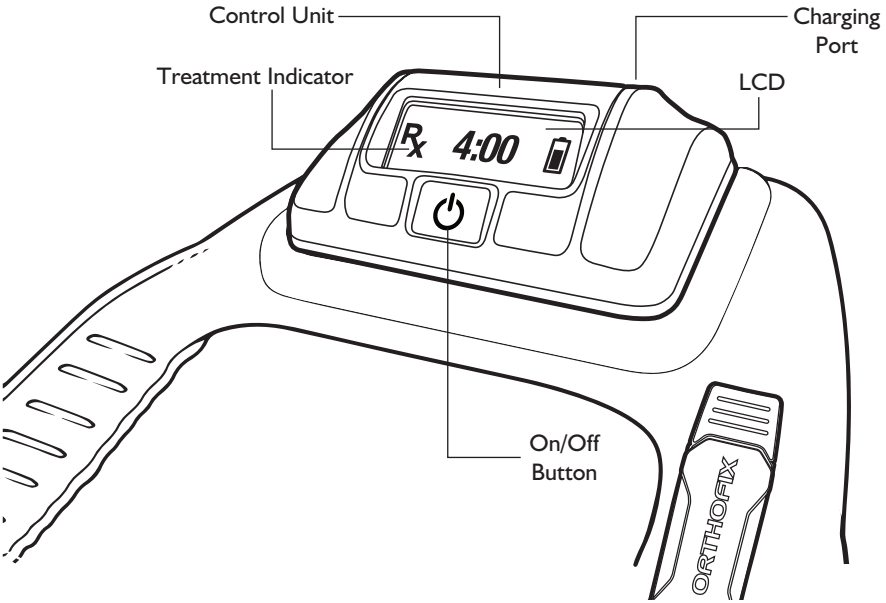
When the device is turned on, a status screen will display the number of days since the first use, the treatment status, and the compliance percentage.

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.

Cervical-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 this On/Off Button to light up the LCD.



Treatment Instructions

- Cervical-Stim should be worn for 4 hours each day as prescribed by a physician.
- Cervical-Stim may be used at any time of day that is most convenient for the patient.
- The device is programmed to reset daily at midnight Central Standard Time, unless adjusted by a physician or Orthofix representative for a different time zone or reset time.
- Hours worn before the reset time will be logged and stored in the device for daily use compliance.
- The overall treatment duration (months/weeks) will vary based on specific patient conditions as determined by a physician.
- Because Cervical-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

- Cervical-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 daily treatment time.
- When daily treatment is completed, the device will automatically turn off.

Charging the Battery

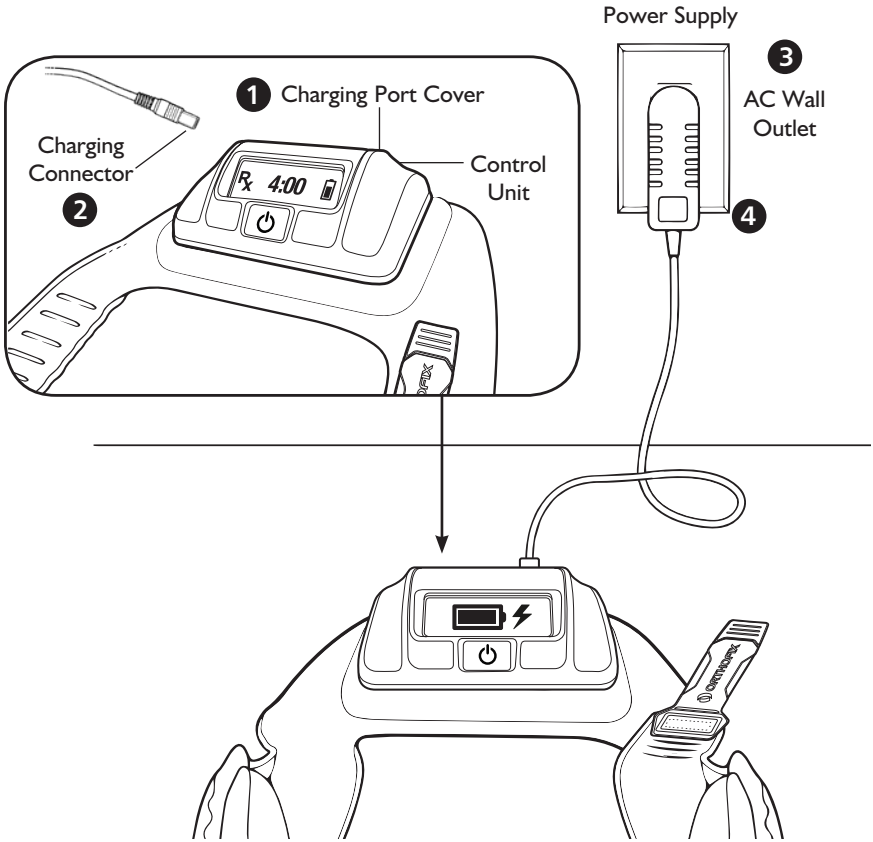
Cervical-Stim is powered by a rechargeable lithium-ion battery pack. A power supply to charge the battery is provided with the device. Use only the Orthofix power supply to charge the battery (Part no. Orthofix 20110412).

To ensure that the device is functioning properly, Cervical-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.

Cervical-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:

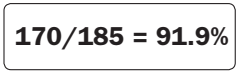
1. Open the Charging Port Cover.
2. Plug the Charging Connector into the Charging Port located on the Control Unit.
3. Plug the power supply into any standard AC Wall Outlet.
4. The LED on the power supply will light up green as an indicator that the AC Wall Outlet is delivering power.
5. The Control 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

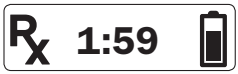
The LCD and audible beeps are designed to provide helpful information to the user. The screens, symbols, and beeps are explained below.

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

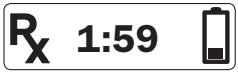
Charging Screen

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

Charging Complete

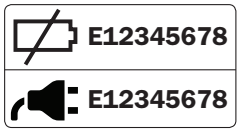
Charging Complete – Indicates when the battery is fully charged.

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 a treatment..

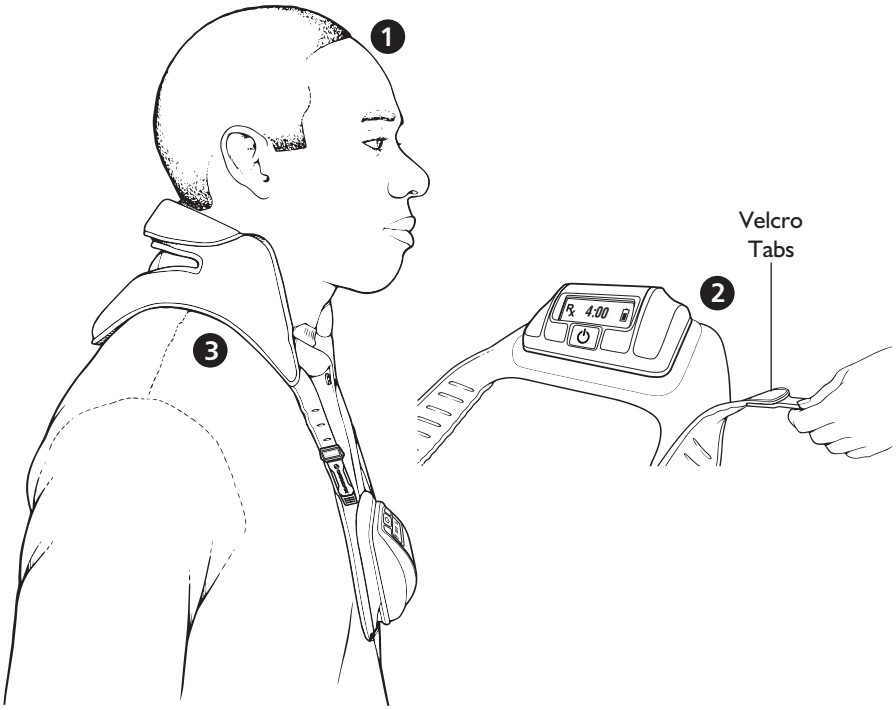
Exception Screen

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
Cervical-Stim may be worn over a brace, cervical collar, halo, or clothing. Proper treatment does not require direct contact with the body. However, the coil must be centered around the fusion site to be effective. Users can gently bend and shape the treatment coil to fit more comfortably around the neck.

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

1. To put on Cervical-Stim, simply slip the device over your head.
2. For a wider opening, detach the Velcro® Tab near the control unit and place over your head.
3. The device does not need to be tight against the back of the neck; it should rest comfortably on your shoulders.



Device Accessories

An accessory available to the patient is an 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.

Certain patients may benefit from the use of a Comfort Collar with Cervical-Stim. Please contact Patient Services at 800-535-4492 or 214-937-2718 to order a Comfort Collar.

Device Use and Care

- Cervical-Stim is a technologically advanced electronic device and should be handled with care. Dropping or other mishandling of Cervical-Stim may damage the device and it may stop working.
- For safe usage, follow manufacturer instructions when using Cervical-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 Cervical-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 Cervical-Stim device, follow these instructions:

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

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

- DO NOT expose Cervical-Stim to direct sunlight for long periods of time.
- DO NOT expose Cervical-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 Cervical-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 Cervical-Stim instruction manual should be taken with you to quickly and easily identify the device for security personnel. Do not wear or operate Cervical-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. Cervical-Stim is for single patient use.

Cervical-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 Cervical-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.

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

Clinical Information

Clinical Data Summary

The Cervical-Stim was studied in humans to evaluate its safety and effectiveness as a therapy added to routine care (adjunct therapy) for high-risk patients having a cervical fusion surgery for degenerative conditions. Patients were high-risk if they were a smoker (one pack per day or more) and/or had a multi-level fusion surgery (more than one level).

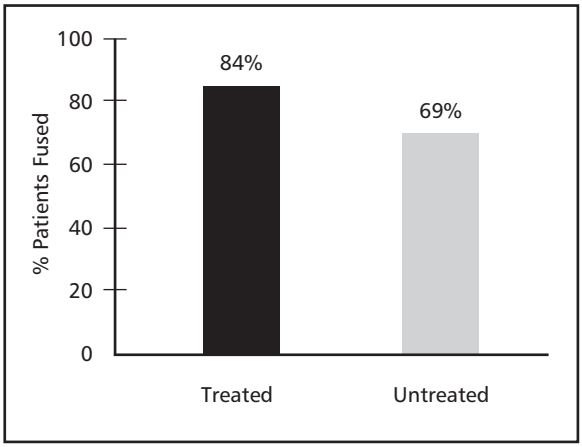
The 323 patients were randomly assigned, to one of two groups: either the control group (routine care only) or the treatment group (Cervical-Stim + routine care). One hundred and sixty (160) patients were assigned to the control group and 163 patients were assigned to the Cervical-Stim group. Patients wore the Cervical-Stim unit for 4 hours each day either for 4 continuous hours or in one hour sessions.

Safety and effectiveness was evaluated by measuring the following:

- rate and severity of adverse events
- rate of cervical fusion by six months after surgery as determined by x-ray

Eighty-four percent (84%) of the Cervical-Stim group were fused by six months (102/122 patients) versus only 69% of the control group (81/118 patients). This is a 15% difference between these two groups and is statistically significant (meaningful); p=0.0065. That is, more patients fused in the Cervical-Stim group than in the control group.

Clinical Trial: Overall Success Rate



The rate of patients who came back for their six month examinations and x-rays was 74% for the Cervical-Stim group and 73% for the control group. Patients who did not come back for scheduled examinations could not be evaluated; thus their success or failure is not known. These unavailable data could have a positive or negative effect on the overall success of this study.

One hundred and twelve (112) patients reported a total of 157 adverse (negative) effects for both groups combined at six months after surgery. There was no significant (meaningful) difference in the total number of adverse events or the number of patients reporting effects in the control group and the Cervical-Stim group nor in the numbers of patients in each group who experienced an adverse event. The adverse effects that may be experienced include: increased pain, numbness and tingling, headache, migraines and nausea. These effects may or may not be directly related to the use of the Cervical-Stim.

Clinical success with regard to symptoms was evaluated by the following:

- no worsening in neurological function
- an improvement in pain
- no worsening in Neck Disability Index

Based on the criteria above, there was no major difference between the control group and the Cervical-Stim group in clinical success. An equal number of patients in both groups showed an improvement in their clinical condition after surgery, regardless of treatment.

Long-term x-ray information collected at 11 months after surgery or later showed no meaningful difference in fusion rate between the Cervical-Stim treatment group and the control group who received rountine care alone.

The results of this study show that the use of the Cervical-Stim is both safe and effective in increasing the frequency of fusion by six months after surgery in high-risk subjects having cervical fusion.

[1] Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. The Spine Journal. 2008 May-Jun;8(3):436-442

Adverse Events Reported at 6 Months by Treatment Group
Control Group (n=160) Cervical-Stim Group (n=163)

	Control Group (n=160)		Cervical-Stim Group (n=163)	
Adverse Events	**# (%) of Events**	**# (%)[1] of Patients Experiencing the Event**	**#[*] (%) of Events**	**# (%)[1] of Patients Experiencing the Event**
Increased Neck Pain	10 (14.9)	9(5.6)	16(17.8)	15(9.2)
Shoulder/Arm Pain	10(14.9)	9(5.6)	16(17.8)	16(9.8)
Re-Injury to Cervical Spine	10(14.9)	8(5,0)	9(10.0)	9(5.5)
Adjacent level pathology	3(4.5)	3(1.9)	8(8.8)	8(4.9)
Surgical Complications	2(3.0)	2(1.3)	7(7.7)	5(3.1)
LBP/Lumbar pathology	8(11.9)	8(5.0)	5(5.5)	5(3.1)
Trauma/Injury(not cervical)	2(3.0)	2(1.3)	5(5.5)	4(2.5)
Numbness/Tingling	6(8.9)	6(3.8)	4(4.4)	4(2.5)
Headache/Migraine	2(3.0)	2(1.3)	4(4.4)	4(2.5)
Nonspecific/Unrelated Pain	2(3.0)	2(1.3)	3(3.3)	3(1.8)
Nausea	0	0	2(2.2)	2(1.2)
Dizziness/Vertigo	2(3.0)	2(1.3)	1(1.1)	1(0.6)
Rash/Discoloration	0	0	1(1.1)	1(0.6)
Rapid/Irregular Heartbeat	0	0	1(1.1)	1(0.6)
Shortness of Breath	0	0	1(1.1)	1(0.6)
Ringing in Ears	0	0	1(1.1)	1(0.6)
Neurologic Symptom/Stroke	1(1.5)	1(0.6)	1(1.1)	1(0.6)
Lump in Throat	0	0	1(1.1)	1(0.6)
Diagnosis of Diabetes	0	0	1(1.1)	1(0.6)
Diagnosis of Breast Cancer	0	0	1(1.1)	1(0.6)
Seizure	0	0	1(1.1)	1(0.6)
Death, Unrelated	0	0	1(1.1)	1(0.6)
Tenderness	1(1.5)	1(0.6)	0	0
Screw Broken	1(1.5)	1(0.6)	0	0
Graft Collapse	1(1.5)	1(0.6)	0	0
Carpal Tunnel Syndrome	2(3.0)	2(1.3)	0	0
Choking Sensation	1(1.5)	1(0.6)	0	0
Cardiac Symptoms	1(1.5)	1(0.6)	0	0
Nephrotic Syndrome	1(1.5)	1(0.6)	0	0
Suicide Attempt	1(1.5)	1(0.6)	0	0
TOTAL	67	47[2]	90	58[2]

[1] % expressed as number of patients experiencing the event / total number of patients in the group
[2] Some patients experienced multiple adverse events

[*] There were several adverse events that were more frequently observed in the Cervical-Stim group than in the control group. Given the types of events, it is unlikely that these adverse events are related to the treatment.

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

Cervical-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 Cervical-Stim Osteogensis 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.

Orthofix Inc.
3451 Plano Parkway
Lewisville, Texas 75056
Tel 214-937-2718

Patient Services
800-535-4492 toll free

www.bonestimulation.com
www.orthofix.com

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