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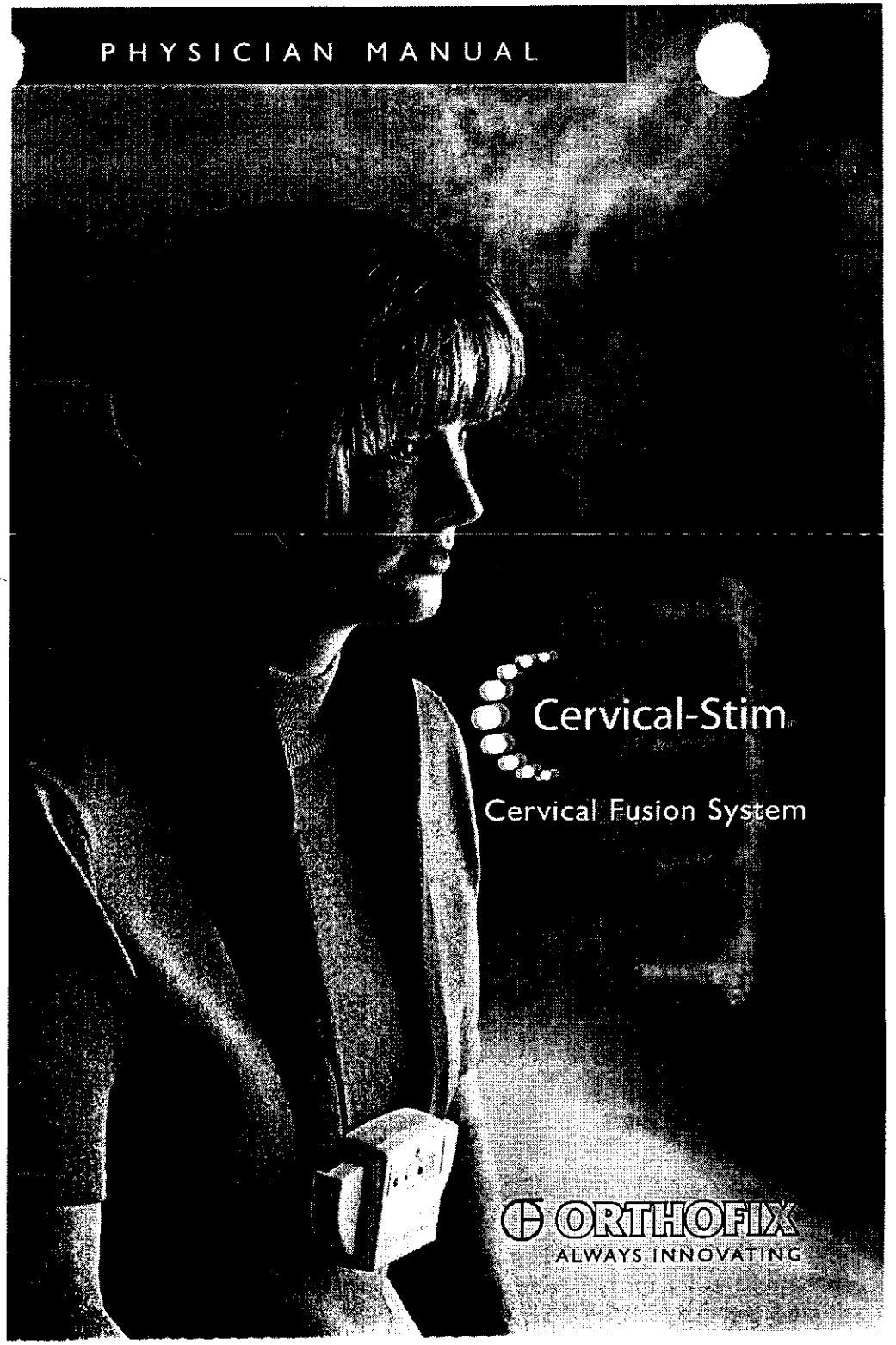
ORTHOFIX®
ALWAYS INNOVATING

PHYSICIAN MANUAL



Cervical-Stim

Cervical Fusion System

ORTHOFIX
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Cervical-Stim®
Physician Manual

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To learn more about Orthofix, please visit our website at www.orthofix.com.

Package Contents:

1- Cervical Stim® Cervical Fusion System

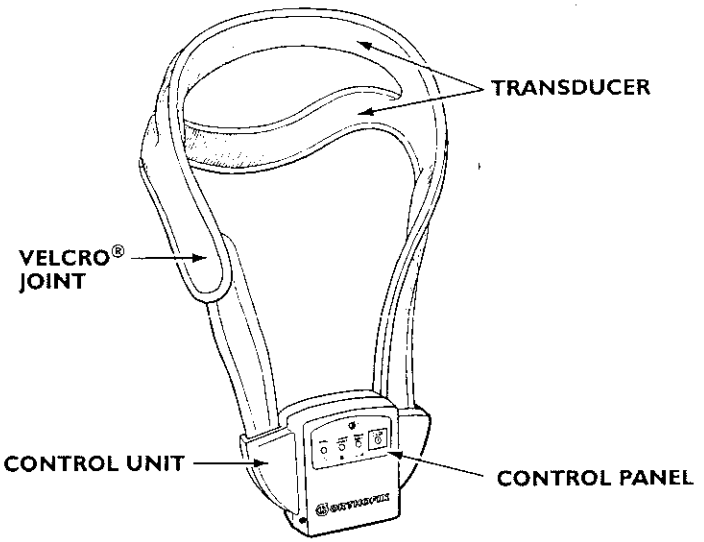
1- Literature Pack

1- Set 9-volt Batteries

Device Description

The Cervical-Stim® Cervical Fusion System is an external, low-level, Pulsed Electromagnetic Field (PEMF) device. It is a single-piece device that is lightweight, flexible and portable allowing freedom of movement during treatment. Colored lights and an alarm provide information during treatment (e.g. device is on, normal operation, battery low).

Cervical-Stim Cervical Fusion System



The Cervical-Stim is made up of a control unit and a treatment transducer. The control unit contains a micro-processor that generates the Cervical-Stim electrical signal. That signal is converted to a highly uniform, low-energy magnetic field by the treatment transducer. When the device is centered over the treatment area, the therapeutic PEMF signal is delivered directly to the fusion site.

To ensure that the device is functioning properly, the Cervical-Stim constantly monitors battery voltage and the electrical signal. If at any time during treatment, the device stops functioning properly, the red light will come on and the device will not provide treatment.

The Cervical-Stim is powered from a single 9-volt disposable battery. The device will provide approximately 5 days of treatment on one battery. Orthofix will provide a supply of batteries adequate to cover the patient's treatment time. When the red light flashes and the alarm sounds, the battery needs to be replaced. See "Battery Installation and Replacement" section for battery information. Refer to the "Lights and Alarms" table in the Troubleshooting Section for more information regarding the lights and their meaning or contact Orthofix Customer Service at (800) 535-4492.

Prescription Information

Indication

The 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.

Contraindications

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

Warnings

- The Cervical-Stim may interfere with the operation of a cardiac pacemaker or defibrillator. Consultation with the attending cardiologist is recommended.
- The Cervical-Stim should be removed prior to any imaging procedures (e.g., CT scan, MRI, etc.).

Precautions

- The Cervical-Stim should not be used if there are mental or physical conditions that may preclude compliance with physician or device instructions.
- The 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 teratological studies performed with this device did not show any adverse effects in animals. However, the safety of this device for use on patients who are pregnant or nursing has not been established.

Adverse Events

Adverse Events Reported at 6 Months by Treatment Group

	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.

Clinical Data Summary

Study Design

The Cervical-Stim clinical study was a controlled, randomized, parallel group study of 323 high-risk (smokers, multi-level or both and allograft) adult subjects with radiographic evidence of compressed cervical nerve roots and

symptomatic radiculopathy. The purpose of the study was to evaluate the safety and effectiveness of the PEMF Cervical-Stim device as an adjunct for high-risk patients who undergo cervical fusion. All subjects underwent anterior cervical discectomy and fusion using the Smith-Robinson technique with the Atlantis Plate. Subjects were randomly assigned to either the control group (standard treatment, n=160) or the treatment group (standard treatment plus the Cervical-Stim, n=163). Standard treatment was at the physician's discretion but typically included the standard hospital stay, use of a soft cervical collar, appropriate medications and physical therapy.

Subjects who met the following inclusion and exclusion criteria were eligible for participation in the study:

Inclusion Criteria

Adult male or female, 18-75 years old with radiographic evidence of compressed cervical nerve root(s), symptomatic radiculopathy, pain of 5 or greater on the Visual Analog Scale (VAS) and/or any muscle weakness and primary cervical spinal fusion performed using the Smith-Robinson technique with allograft bone and an anterior cervical plate. The fusion procedure must have been either multi-level (>1 fusion level) or the subject was a smoker (one pack/day or more) or both; and signed informed consent.

Exclusion Criteria

Traumatic cervical injury, posterior approach or revision fusion, autograft or bone substitute materials for graft source, history of vascular migraine headache or prone to uncontrolled seizures or epilepsy (controlled or uncontrolled) or any neurological diseases or injury; depressed immune system, regional conditions (Spondylitis, Paget's disease, rheumatoid arthritis), infection (systemic or local) within 2 weeks prior to surgery, systemic conditions (cancer, cardiac arrhythmia, thyroid disease, uncontrolled diabetes mellitus, renal disease/dysfunction, chronic steroid use or other conditions that may have affected bone metabolism), cardiac pacemakers, defibrillators, dorsal column stimulators, hearing aids, cochlear prostheses and cranial stimulators, subjects who were pregnant, nursing or had planned to become pregnant within 12 months, subjects that had participated in other clinical studies within the last 12 months, or had mental or physical conditions which may have precluded compliance with physician instructions.

Evaluation and Follow-Up

Follow-up visits were to have been performed at months 1, 2, 3, 6 and 12 and annually thereafter until the last subject enrolled reached 12 months.

Device Usage

Subjects assigned to the treatment group (Cervical-Stim) were instructed to wear the device for four hours per day for a minimum of three months postoperative. Surgeons could, at their discretion, extend the Cervical-Stim treatment up to six months postoperative.

Demographic Data

The subjects in this study had a mean age of 46.8 years (range 24 to 73 years). Of the 323 subjects, 148 (45.8%) were female and 175 (54.2%) were male. Three hundred one (93.2%) were Caucasian, while 17 (5.3%) were African American and 5 (1.6%) were Hispanic. One hundred fifty-nine (49.2%) were nonsmokers and 164 (50.8%) were smokers.

Baseline Demographic Characteristics

Variables	Number of Subjects (N = 323)	Control (n = 160)	Cervical-Stim (n = 163)	P-value[1]
Age (years)				
Mean	46.8	46.7	46.9	0.846
Range	24 – 73	26 – 72	24-73	
SD	9.3	9.2	9.4	
Gender				
Female	148(45.8%)	75 (46.9%)	73 (44.8%)	0.706
Male	175 (54.2%)	85 (53.1%)	90 (55.2%)	
Race				
Caucasian	301(93.2%)	150 (93.8%)	151 (92.6%)	0.703
African-American	17 (5.3%)	7 (4.4%)	10 (6.1%)	
Hispanic	5 (1.6%)	3 (1.9%)	2 (1.2%)	
Asian	0	-	-	
Other	0	-	-	
Smoking Status				
Nonsmoking	159 (49.2%)	79 (49.4%)	80 (49.1%)	0.958
Smoking	164 (50.8%)	81 (50.6%)	83 (50.9%)	

[1]. P-values of comparison tests between treatment groups using Student's t-test for numerical variables and Pearson χ^2 test for categorical variables.

Data Analysis and Results

The primary effectiveness endpoint was the increase in frequency of cervical fusion success by six months postoperatively as assessed by radiographic evidence. Secondary endpoints were neurological function, VAS pain assessment and Neck Disability Index. Safety was assessed by the frequency and severity of adverse events.

Fusion was assessed by radiographs at each visit:

Radiographic fusion was defined as $\geq$ 50% bony bridging on both the superior and inferior graft interfaces between adjacent vertebral bodies AND $\leq$ 4° angulation (motion) between adjacent fused vertebrae on flexion/extension lateral films AND absence of radiolucency.

Radiographic non-fusion was defined as < 50% bony bridging at either the superior or inferior graft interface OR > 4° angulation (motion) between adjacent fused vertebrae on flexion/extension lateral films OR presence of radiolucency.

For purposes of device evaluation, all films were scanned into a central database and reviewed by two independent, blinded orthopedic surgeons and a blinded, independent radiologist following completion of the entire study. Films were viewed and scored using a common protocol. All films at each time point were evaluated for amount of radiolucency, bony bridging and degree of motion as evidenced on the flexion/extension cervical spine films. A software program was used to calculate motion. Results obtained in this fashion were reviewed and verified by the reviewing orthopedic surgeons. The radiologist's diagnosis was considered definitive in the case of a disagreement between the two orthopedic surgeons.

Effectiveness Results

Of the 323 subjects who were randomized and received surgery, 240 were evaluable for the effectiveness analysis (Cervical-Stim treatment group, n=122; control group, n=118). Subjects were deemed unevaluable for the following reasons: non-existent or non-readable x-rays, subject non-compliance, protocol violations (inclusion criteria), graft collapse, broken internal hardware, early study exits due to minor adverse experiences, and one suicide attempt. The success or failure of these subjects is not known. These unavailable data could positively or negatively affect the overall success of the study. In order to assess the impact of the missing data, sensitivity analyses were performed. These included last observation carried forward and all missing data imputed as non-fusion. Both of these analyses showed that the results at six months were still statistically significantly different in favor of the Cervical-Stim group. In addition, the baseline demographic data from the evaluable population was compared to the demographic data of the missing subjects. The results of this analysis indicated there were no significant differences between the evaluable subjects and the non-evaluable subjects in 14 study variables including key demographics and clinical parameters.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was evidence of radiographic fusion at the 6 month time point postoperative. At the six month time point, 102 of the 122 evaluable subjects (84%) in the Cervical-Stim treatment group were judged to be fused versus 81 of the 118 evaluable subjects (69%) in the control group (p=0.0065).

Comparison of Radiographic Fusion Outcomes at Six Months

Treatment Group	Number of Subjects	Number of Subjects Fused	Fusion Rate (%)
Control	118	81	68.64
Cervical-Stim	122	102	83.61

These data show that for patients undergoing cervical fusion surgery, patients treated adjunctively with the Cervical-Stim experienced an increase in the frequency of radiographic fusion at six months when compared to the control group.

An additional analysis was performed to allow for the differences between the Cervical-Stim treatment group and the control group with respect to demographic characteristics (gender, age, diagnosis) and risk status (smoking, multilevel). The overall fusion rate in the Cervical-Stim group remained statistically significant after adjustment for each of these variables.

Long-term follow-up (12 months) showed no statistical difference between the two groups with respect to fusion. One hundred sixteen of the 125 evaluable subjects (92.8%) in the Cervical-Stim treatment group were judged to be fused at the long-term final endpoint, while 104 of the 120 evaluable subjects (86.7%) in the control group were judged to be fused.

Overall Radiographic Fusion Outcomes at 12 Months

Treatment Group	Number of Subjects	Number of Subjects Fused	Fusion Rate (%)
Control	120	104	86.67
Cervical-Stim	125	116	92.80

Note: The differences in long-term success rates between treatment groups is not statistically significant per Pearson x^2 test with the available sample size (x^2 = 2.5136, p = 0.1129).

Secondary Effectiveness Endpoints

Secondary endpoints evaluated changes in clinical symptoms. A "clinical success" with regard to symptoms was defined as no worsening in neurological function, an improvement in VAS pain assessment and no worsening in Neck Disability Index. A "clinical failure" with regard to symptoms was defined as failure for any one of these criteria. There was no statistically significant difference between the two groups with respect to the percent of subjects considered a "clinical success" at six months (p=0.8456) or at 12 months (p=0.1129).

Safety

The adverse events observed in this study are shown in the Adverse Events Table presented in the Prescription Information section. At six months, the numbers of subjects who experienced one or more adverse events is similar in the two groups. A total of 14 severe events were reported in 13 subjects; nine of the subjects were in the Cervical-Stim treatment group and five subjects were in the control group. These events included experiences such as increased pain, shortness of breath, dizziness, unrelated trauma and injury, unrelated death, surgical complication and adjacent level pathology. For the nine subjects in the Cervical-Stim treatment group, all severe adverse events were, in the judgment of the investigators, definitely or probably unrelated to the device.

Safety data obtained between the six month visit and the final contact with each subject indicate that 57 adverse events were experienced by a total of 51 subjects between both groups. The number of subjects who experienced one or more adverse events is similar in the two groups. None of the adverse events reported between the six month visit and the final contact were severe and are similar to those reported at six months.

Device Life

The Cervical-Stim can provide up to 270 consecutive (daily) treatments of four hours each. The overall length of treatment will be determined by the physician based on the patient and progress toward fusion.

Treatment Time

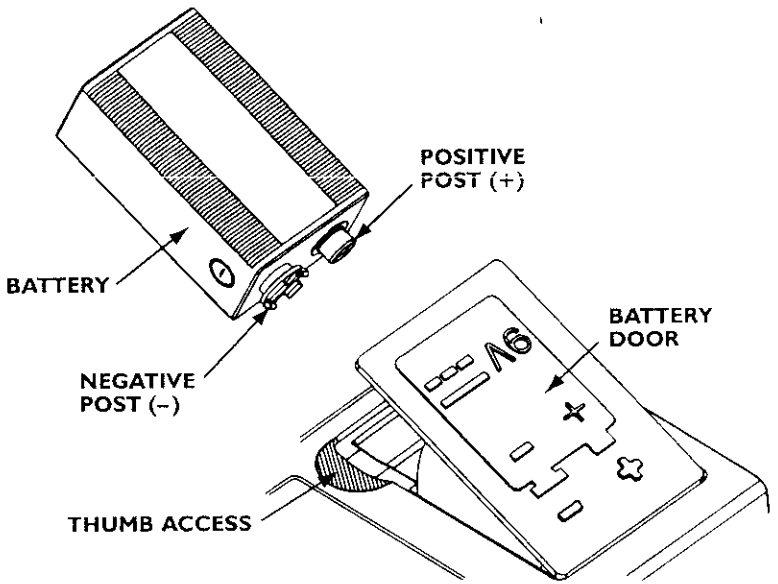
The Cervical-Stim should be worn for four hours per day. The device will automatically turn off when four hours of treatment is reached in a 24-hour day (based on midnight to midnight Central Standard Time). The device may be turned off at any time by simply pressing the On/Off button on the control panel.

The Cervical-Stim may be used at any time of day that is convenient for the patient. It is lightweight and adjustable. And because the Cervical-Stim is 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 your instructions.

Battery Installation and Replacement

To install the battery, turn the device off by pressing the On/Off button. Open the battery door located on the back of the control unit. Remove the battery if one is already there. Replace it with a new 9-volt battery as shown in the drawing. Close the battery door. If the battery posts (+ and -) are not properly aligned, the battery door will not close. The Cervical-Stim should now be ready for treatment.

Important: Battery must be inserted as shown:
- Open battery door at thumb access
- Align battery posts as shown
- Insert battery and snap shut

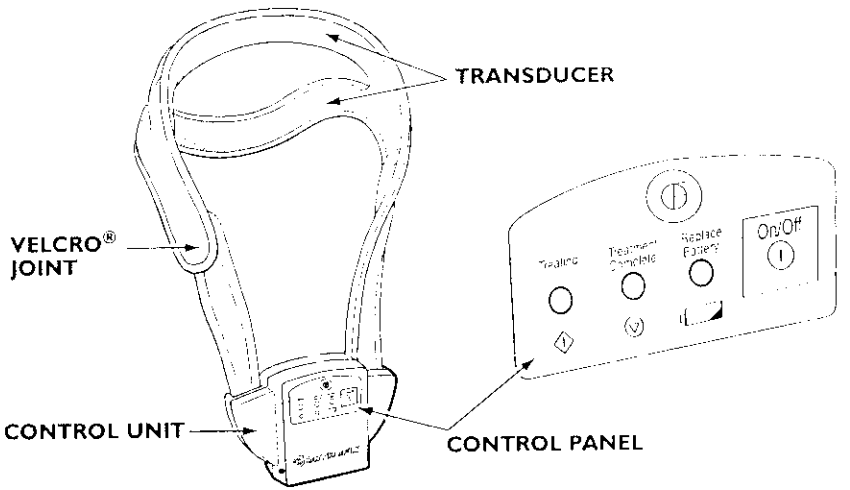


Note: Dispose of batteries properly to prevent injury.
Do not throw into fire.
Do not attempt to recharge the Cervical-Stim batteries.
Do not short circuit. That is, do not let the battery come in contact with metal (for example, a penny or aluminum foil). Doing this may cause the battery to get hot and cause injury.

Device Operation

Turning the Device On and Off

Turn the Cervical-Stim on and off by pressing the On/Off button on the control panel. A flashing green light means that the device is on and functioning normally. If the green light does not flash, check the battery installation. If the device still does not work, contact Orthofix Customer Service.



Timing of Treatment Sessions

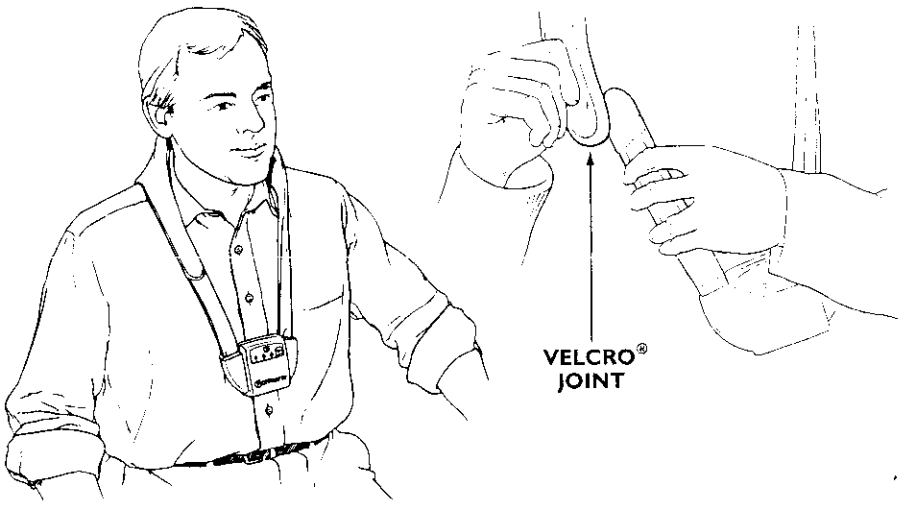
The Cervical-Stim automatically times treatment sessions. The timing begins when the device is turned on and worn for a minimum of 65 minutes. At the end of four hours of treatment in a day, the device will turn itself off.
To stop treatment before the end of a session, simply press the On/Off button.
To restart treatment, press the On/Off button again.

Note: the device should be worn at least 65 minutes at a given time for an accurate timing of the treatment session. If the device is worn less than 65 minutes, the timer resets to "0".

Wearing the Device

The Cervical-Stim is intended for the cervical spine and may be worn with or without a brace. For better comfort, clothing should be worn between the skin and the Cervical-Stim.

To use the Cervical-Stim, simply slip the device over the head so that it rests comfortably against the neck and shoulders (see figure below). Or, the device may be unhooked at the Velcro® joint Be sure to close the Velcro opening or the device could fall off.



Care and Cleaning

The Cervical-Stim is a sophisticated electronic device and should be handled with care. Dropping or other mistreatment of the Cervical-Stim may cause damage to the device.

DO NOT expose the Cervical-Stim to direct sunlight for long periods of time. The device control unit may be damaged.

DO NOT expose the Cervical-Stim to excessive heat. In warm climates, the temperature in a car or trunk can exceed 160°F / 71°C. Excessive heat can damage the control unit of the device.

DO NOT expose the Cervical-Stim to excessive moisture. Moisture can damage the electronic components of the device and the device may stop working.

To clean the device, wipe lightly with a soft cloth dampened with water only.

Travel

Patients should be advised that when traveling by air, it is best to check the Cervical-Stim with the luggage. If the device is taken on board the airplane, it should not be worn when passing through passenger screening devices. The Cervical-Stim could be damaged. The Cervical-Stim user manual should be taken to quickly and easily identify the device for any security personnel.

Storage

The Cervical-Stim should be stored within 14°F to 122°F (-10° C to 50° C)
The Cervical-Stim operating temperature range should be within 41°F to 104°F (+5° C to 40° C)
Relative Humidity: Up to 95%, non-condensing

Battery Disposal

Dispose of batteries properly to prevent injury.
Do not throw into fire.

Device Disposal

The Cervical-Stim is for single patient use. The patient should dispose of the device in accordance with local refuse laws. DO NOT dispose of the Cervical-Stim in an incinerator. Incineration could cause injury.

Trouble Shooting

The lights and alarms are there to give you helpful information.
See the table below for the lights and alarms, and what they mean.

Cervical-Stim Lights and Alarms

Indication	Meaning
all lights on / continuous alarm for 3 seconds	power-on self test; device is initializing - no action required
steady yellow light / continuous alarm	power-on self test error; contact Orthofix Customer Service
flashing green light	normal treatment in progress
alarm for 5 seconds /green light off or flashing yellow light	daily/total treatment is complete
flashing red light and alarm	replace battery (see battery installation section)
steady red light / continuous alarm	"Field Fault" condition contact Orthofix Customer Service

If you have any questions about the use of the Cervical-Stim please call Orthofix Customer Service at (800) 535-4492.

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Conformance to Standards

The Orthofix Cervical-Stim Cervical Fusion System conforms to the following worldwide series of standards:

UL 60601 - Medical Electrical Equipment, General Requirements for Safety; (including Electromagnetic Compatibility and Interference)

IEC 60601 - Medical Electrical Equipment, Safety Requirements for Medical Electrical Systems (including Electromagnetic Compatibility and Interference)

Orthofix Compliance Printer Instructions

Patient Compliance Monitoring

Orthofix bone growth stimulators provide the treating physician with a monitoring system to track patient compliance. This system assists the physician during the therapy period by ensuring that the patient is receiving the treatment necessary for a successful outcome.

The accumulated treatment time per day over the course of treatment is retained in a special physician-accessed memory within the device for monitoring patient compliance. This memory will retain data which have accumulated for up to 365 treatment days. The compliance data may be output from the device and printed in a calender format, or simply verified without a hardcopy printout.

A. Access with Printer

The physician may request a printout of the compliance data at any time during patient treatment. It can be initiated by attaching and powering up the printer, and momentarily depressing the power switch.

Important: To avoid battery drainage, the memory must be cleared OR the On/Off button must be depressed after a printout has been taken.

B. Access without a Printer

To monitor compliance without a detailed printout, depress and hold the Orthofix logo button on the unit while momentarily depressing the On/Off button. The green LED will light if the prescribed daily treatment time was met on at least 90% of the days since last cleared. The red LED will light if the patient has not been in compliance since last checked.

Clearing the Patient Compliance Memory

Memory may be cleared immediately following a compliance check (A. or B. above). To clear the memory, the Orthofix logo button is pressed and held for 5 seconds. The unit will beep 3 times indicating memory is about to clear. After the 3 beeps, the memory will clear.

The Compliance Printer

Function and Use of Each Part

- **Power Switch**
  Used to turn power On/Off.
- **Paper Feed Switch**
  This switch is used to feed the heat sensitive paper continuously. Press it lightly.
- **Paper Cutter**
  This is used to tear off the heat sensitive roll paper. Tear off the paper by pulling it in the arrow direction.

To feed paper, first depress the green "ONLINE" switch. Wait for the red "OFFLINE" indicator to light prior to depressing the "FEED SWITCH".

Before printing, depress the green "ONLINE" switch and wait for the green "ONLINE" LED to light.

Note: Use the paper feed switch to feed out the heat sensitive roll paper. If the paper was pulled out by hand, always feed it one line with the paper feed switch before starting printing.

Operating Instructions For Compliance Printer

Connection to the Power Source

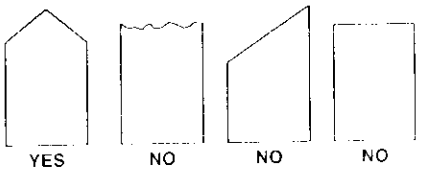
Power is supplied to the Compliance Printer by the accessory adapter.

Loading the Heat Sensitive Roll Paper

Use the special Compliance Printer heat sensitive roll paper.

1. When there is only a small amount of heat sensitive roll paper remaining, a red line appears at the side. When this red line appears, pull out the old paper by hand and load a new roll of heat sensitive paper as indicated below.

2. Cut the end of the new roll of the heat sensitive paper as shown:



3. While inserting the end of the heat sensitive roll paper in the direction of the arrow, press and hold the paper feed switch until the paper is fed out. Since the outside of the heat sensitive roll paper is coated with a heat sensitive agent, pay careful attention to the front and back of the paper.

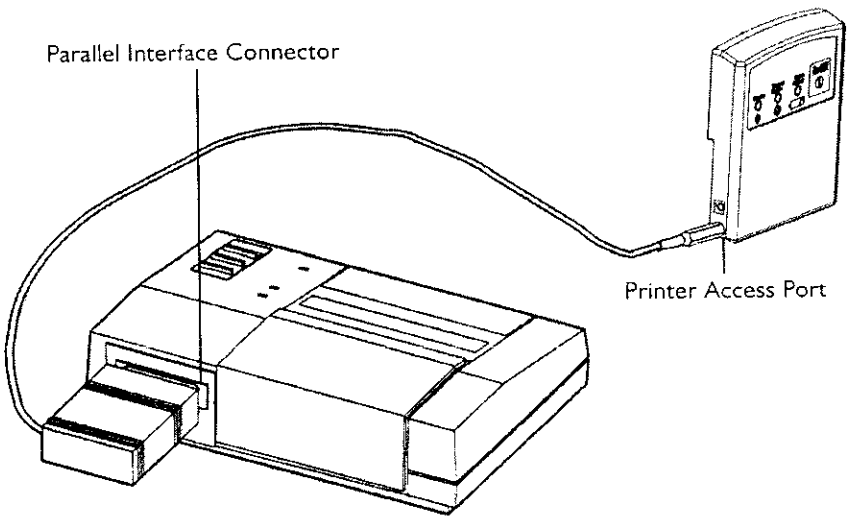
Heat Sensitive Roll Paper

Handling Precautions

- The heat sensitive roll paper is special paper which is discolored by thermochemical reaction.
- Since the paper is vulnerable to heat, moisture, light, etc., whether used or unused, it should be stored in a cool, dry place.
- Touching the paper with perspiring hands will leave fingerprints on the paper and/or make the recordings blurry.
- Rubbing the paper with a hard object will discolor the paper.
- When gluing the paper, generally use a water solvent glue. Starch, composite glue, etc., is suitable.
- Since adhesive tape will discolor heat sensitive paper, hold the back of the paper with double sided tape, etc.
- Do not let the paper touch vinylchloride film for an extended period of time. The recordings will become discolored.
- If diazo process or moist copies are attached immediately after copying, the heat sensitive paper will be discolored.
- Organic solvents will discolor the paper.
- For long-term record keeping, it is recommended that you photocopy the printout.

For additional paper rolls, contact Orthofix Customer Service at (800) 535-4492.

Connecting the Cables



Warranty Information

Orthofix Inc. warrants the Cervical-Stim® bone growth 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 the Customer Service Representative at 1-800-535-4492 or your local distributor to obtain the Return Authorization (RA) 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 doctor 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 Customer Service at (800) 535-4492.