Manufactured by:
Orthofix Inc.
1720 Bray Central Drive
McKinney, Texas 75069
Tel (469) 742-2500
(800) 535-4492

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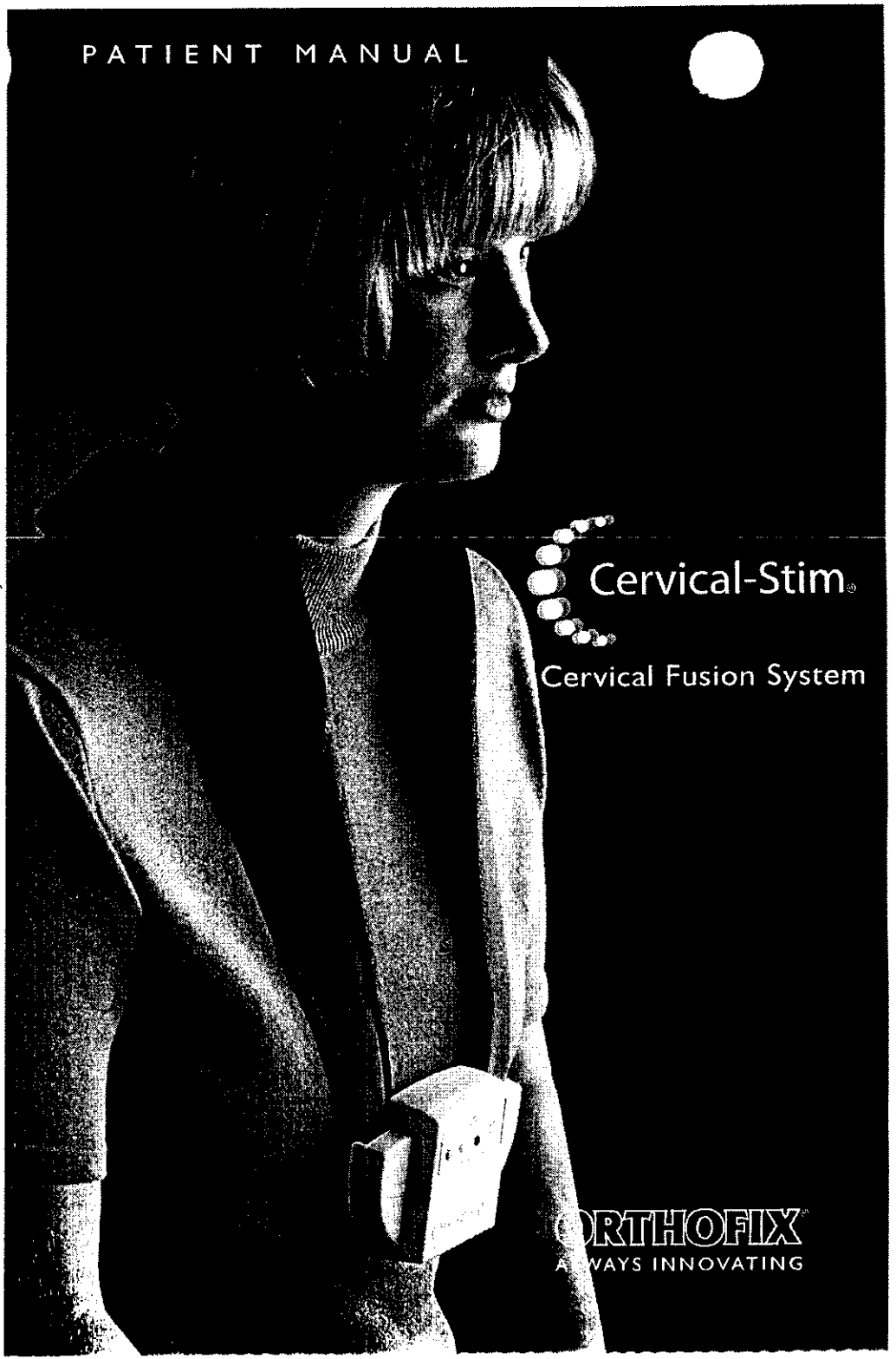
ORTHOFIX®
ALWAYS INNOVATING



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Cervical-Stim®
Patient Manual

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

Glossary

adjunct/adjunctive: an additional therapy soon after the surgery

allograft: bone graft taken from another human

CT scan: Computerized Tomography Scan; a picture of structures within the body created by a computer that takes the data from multiple x ray images and turns them into pictures on a screen

defibrillator: an electrical device used to restore normal heartbeat by applying a brief electric shock

diabetes mellitus: a chronic disease in which the body has a lack of insulin and cannot make use of carbohydrates

electrocardiogram: a recording of the electrical activity of the heart

epilepsy: also know as "seizure disorder"; a pattern of seizures caused when the nerve cells in the brain fire electrical impulses at a rate of up to four times higher than normal

fusion: the joining of two bones into a single unit and thus eliminating motion between the two bones

high-risk patients: patients who have conditions or health concerns that may hinder normal bone healing/fusion; these can include smoking, bone depleting medications, osteoporosis, multi-level fusions, revision surgery, etc.

ligamentous spinal trauma: typically occurring in the cervical spine; generally brought about by extreme forces causing sudden forward or backward bending of the spine (e.g., whiplash)

metastatic cancer: type of cancer that spreads (i.e., metastasizes) from its original site to another area of the body

MRI: Magnetic Resonance Imaging; procedure that uses a magnet connected to a computer to create images of internal structures of the body

noninvasive: does not require placing an instrument or device through the skin or body orifice to get treatment

nonunion fracture: failure of the pieces of a broken bone to bond together

osseous: having to do with bone, consisting of bone, or resembling bone

osteoporosis: progressive disease that causes thinning of the bones with a decrease in bone mass

pacemaker: surgically implanted electronic device used to stimulate or regulate contractions of the heart muscle

Paget's disease: a chronic bone disorder that typically results in enlarged, deformed bones

PEMF: Pulsed ElectroMagnetic Field; a time-varying (pulsing) magnetic field; an external coil that produces a magnetic field through which an electrical charge is given

postoperative: following an operation

prospective randomized controlled clinical study: a forward-looking study involving human beings in which half of the patients are, at random, given a treatment and half are not

renal disease: permanent loss of most of the kidneys' ability to remove waste and maintain fluid and chemical balance in the body

rheumatoid arthritis: a chronic disease resulting in stiffness and inflammation of the joints, loss of mobility, weakness and deformity.

spondylitis: inflammatory disease of the spine; inflammation of one or more vertebrae of the spine

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
- 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 the Cervical-Stim and it affects your pacemaker or defibrillator, it may injure your heart. Consult your cardiologist.
- Remove the Cervical-Stim prior to any imaging procedures (e.g., CT scan, MRI, etc.). If you wear the 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 the Cervical-Stim if you do not understand the instructions your doctor has given you. If you use the Cervical-Stim incorrectly, it may harm you or may not help your healing process.
- 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 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
Adverse effects may be experienced when using the 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 the use of the Cervical-Stim. Any adverse effects that are related to the Cervical-Stim should stop when you discontinue use. The following table shows all adverse events that were reported during the clinical study.

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.

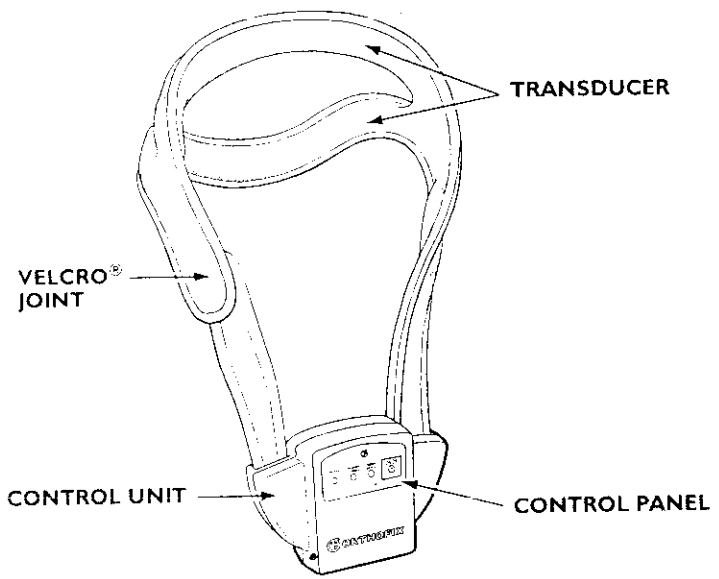
For more information regarding safety, refer to the section entitled "Clinical Data Summary".

Device Description

The Cervical-Stim® Fusion System is an external, low-level, pulsed electromagnetic field device intended to be worn after your cervical fusion surgery to increase your chances of a successful fusion. The Cervical-Stim has been designed with your comfort and convenience in mind. It is a single-piece device that is lightweight, flexible and portable. It allows you to move freely during your treatment. Colored lights and an alarm give you information during your treatment such as when the device is on and operating normally or when the battery is low, etc.

The Cervical-Stim is made up of a control unit and a treatment transducer. The control unit contains a computer chip that generates the electrical signal. That signal is converted to a uniform, low-energy magnetic field by the treatment transducer. By placing the device directly over the treatment area, the PEMF signal is delivered directly to your fusion site.

Cervical-Stim Cervical Fusion System



The Cervical-Stim constantly monitors battery voltage and the electrical signal to make sure it is working properly. If at any time during treatment, the device stops working properly, the red light will come on and the device will not give treatment.

The Cervical-Stim is powered from a 9-volt disposable battery. When you see a flashing red light and hear an alarm, 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.

Device Life

The Cervical-Stim can provide you with up to 270 daily treatments of four hours each. Your doctor will decide how long (weeks/months) your overall length of treatment will be.

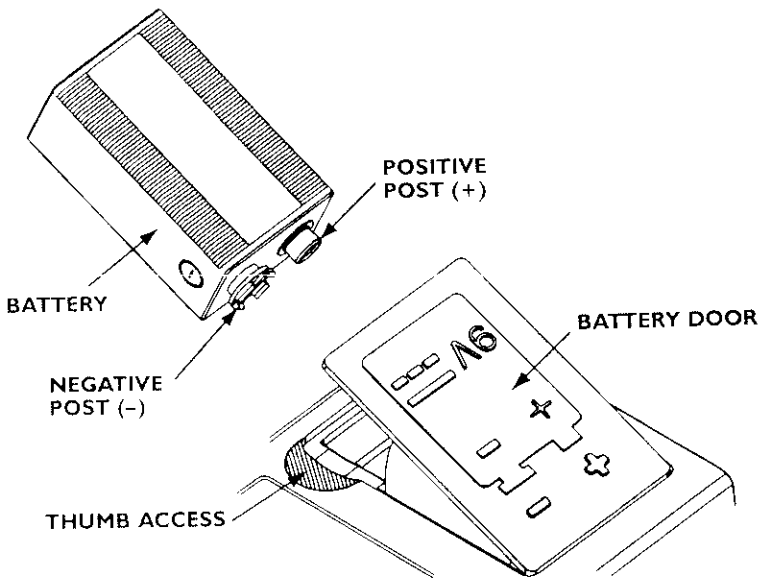
Treatment Time

The Cervical-Stim should be worn for four hours each 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). That is, if you use the device in a local time zone that is different from Central Standard Time, the internal clock inside the device may allow you to use the device for more than a single four hour treatment per day or it may prevent you from using the device late one day and then again the following morning for another four hour treatment. Call Orthofix Customer Service at (800) 535-4492 if you have this problem. You may turn the device 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. It is lightweight and adjustable. And because the Cervical-Stim is portable, you can get treatment while you are sitting, walking, reclining, sleeping, etc. However, since each patient is unique, your activity level should be based on your doctor's instructions. Not following your doctor's instructions can cause injury or diminish the effect of wearing the Cervical-Stim.

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:

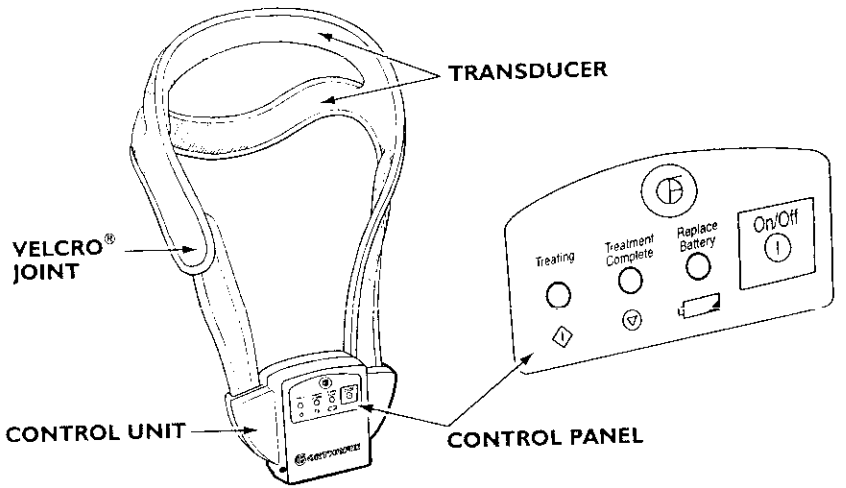
- Open battery door at thumb access
- Align battery post as shown
- Insert battery and snap shut

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 your Cervical-Stim on and off by pressing the On/Off button on the control panel. You should see a flashing green light. This means that the device is on and functioning normally. If you do not see the flashing green light, check the battery installation. If the device still does not work, contact Orthofix Customer Service.



Timing of Treatment Sessions

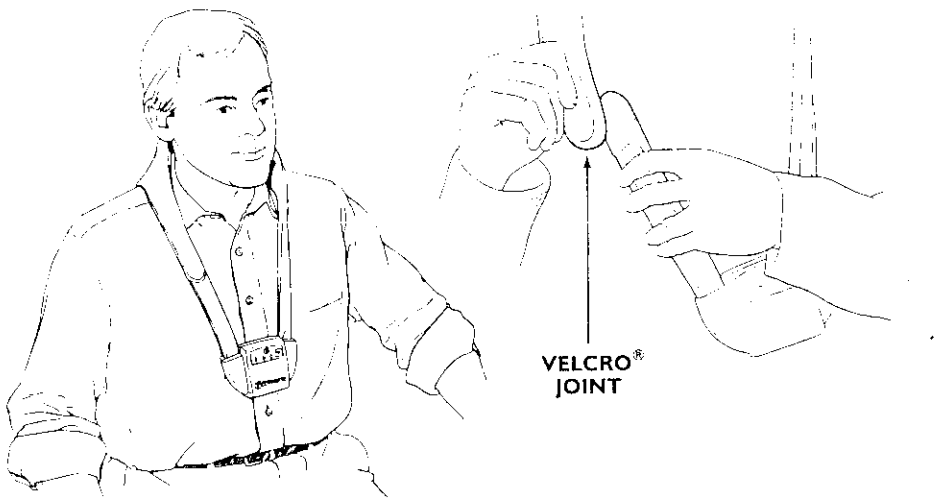
The Cervical-Stim automatically times your treatment sessions. The timing begins when the device is turned on and worn for a minimum of 65 minutes. At the end of four hours of treatment in a day, the device will turn itself off. To stop treatment before the end of a session, simply press the On/Off button.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

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. Dispose of the device in accordance with your 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.

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, similar to a coin toss, 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 6 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.

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 and
- 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.

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.

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.

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.