

Limited Guarantee



PEMF and the Challenge of Healing in the Cervical Spine



Currently, a common form of surgery for treating cervical degenerative disc disease is cervical spine fusion, with approximately 200,000 cervical fusion procedures performed each year. A high-risk cervical fusion patient may have difficulty with successful bone fusion after surgery. Conditions that put a patient at risk for failed fusion may include smoking, multi-level fusion, allograft, diabetes, obesity, osteoporosis, chronic oral steroid use, and any metabolic bone disease. Electrical bone stimulation has been shown to overcome the challenges of bone graft incorporation in high-risk cervical spine fusion patients.

Although electricity's potential to aid bone healing was reported as early as 1841, it was not until the mid-1950s that scientists seriously studied the subject. Fukada's and Yasuda's discovery of the electric potential of bone provides overwhelming evidence of electricity's effect in promoting osteogenesis, particularly in long bone non-unions.

The use of electrical stimulation in the lumbosacral region was first attempted by Alan Dwyer of Australia.¹ In 1974, he reported successful initiation of graft incorporation in 11 of 12 fusion patients. Since that time, electrical stimulation has been shown to significantly increase the probability of bony arthrodesis in spinal fusions. The use of low energy, time-varying magnetic fields (commonly referred to as pulsed electromagnetic fields or PEMF) has been particularly successful when used adjunctively to fresh fusions. In a clinical trial with 323 high-risk cervical fusion patients, 84% fused successfully within six months of surgery.²

The Program

The Cervical-Stim® Limited Guarantee Program provides physicians, insurance payers and patients with a proven method to increase the potential for bone grafted (autograft and/or allograft) cervical spine fusion. The Limited Guarantee provides that radiographic fusion will occur or the fee paid for the Cervical-Stim unit will be refunded to the payer(s) of record.

Fusion is defined as >50% bony bridging on both the superior and inferior graft interfaces between adjacent vertebral bodies AND <4° angulation (motion) between adjacent fused vertebrae on flexion/extension lateral films AND absence of radiolucency.

Guidelines for Assessment of Bone Grafted Cervical Spine Fusion

Fusion, or the absence of fusion, will be determined radiographically by the prescribing physician's (or his/her appointed radiologist's) written evaluation of X-rays taken at least 180 days post-operatively. If that evaluation confirms the absence of fusion, the refund claim will be processed.

Eligibility Requirements

All bone grafted (autograft and/or allograft) cervical spine fusion cases for which Cervical-Stim is prescribed as an adjunct to surgery are eligible for the Cervical-Stim Limited Guarantee.

Guarantee Program Subject to the Following Conditions:

- Cervical-Stim is prescribed for an approved indication.
- The device is applied and treatment begins within 14 days of the most recent cervical fusion procedure for which it is prescribed.
- The Treatment Period with Cervical-Stim continues for a minimum of 180 consecutive days.
- The patient uses the device for at least 4 hours per day on at least 90% of the days from the day the device is first applied following surgery until the date of the radiographic assessment of fusion or absence of fusion.
- Radiographs to assess fusion, or the absence of fusion, are taken on or after the 180th day following the day the device is first applied following surgery.
- Payment is received by Orthofix within 45 days of invoicing date.
- Guarantee claims are received at Orthofix headquarters within one year after the Cervical-Stim device is first applied following surgery.
- Cervical-Stim devices deliberately rendered inoperable or altered in any way will be excluded from the guarantee program and will not be eligible for a refund.

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Claim Submission

A refund claim must be initiated and signed by the prescribing physician and be accompanied by:

- Radiographs taken prior to placement of the Cervical-Stim, and at the fusion evaluation date (180 days or beyond). Radiographs should be clearly marked with the patient's name, date, physician's name and any other pertinent identifying information.
- The prescribing physician's (or his/her appointed radiologist's) written evaluation of the radiographs taken prior to placement as compared to those taken at the fusion evaluation date.
- Originals or photocopies of the Cervical-Stim patient compliance reports from Day 1 of Cervical-Stim treatment through the evaluation date.
- The prescribed Cervical-Stim unit.

Please contact your Orthofix Sales Representative for assistance in preparing and submitting a refund claim.

- Claims must be received by Orthofix at its offices at 1720 Bray Central Drive, McKinney, Texas USA 75069 within one year after the Cervical-Stim device is first applied following surgery. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or Cervical-Stim devices.
- Call Toll-Free (800) 535-4492, Orthofix Customer Service, to arrange for Cervical-Stim device pick-up and return. The Cervical-Stim Limited Guarantee Program gives the payer(s) of record specific legal rights, and such person(s) may also have other rights which vary from State to State.

Indications

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.

Orthofix has the highest success rates in bone growth stimulation for spine fusion and non-operative salvage.

Warnings

1. 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.
2. Remove the Cervical-Stim prior to any imaging procedures (e.g., CT scan, MRI, etc.)

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 not help your healing process.

Adverse Effects

Adverse effects that may be experienced when using the Cervical-Stim 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.

References

- ¹ Dwyer, AF, "Direct Current Stimulation in Spinal Fusion," Medical Journal of Australia, Vol 1, No 1, 1974, p 73.
- ² Results from "Orthofix Inc. Randomized, Prospective, Controlled Clinical Trial of Pulsed Electromagnetic Field Stimulation for Cervical Fusion 2004"

For more information about Orthofix Bone Growth Stimulators, call Orthofix Customer Service at: (800) 535-4492.

For full prescribing information, please visit
www.orthofix.com