

Spinal-Stim® Non-operative Salvage Limited Guarantee



PEMFs and the Challenge of Non-operative Salvage of Failed Spine Fusion

Low back pain is a common and debilitating affliction that may ultimately culminate with spine fusion surgery. The lumbar spine region of the body is recognized as one of the slowest and most difficult areas in which to achieve solid arthrodesis. Pseudarthrosis is seen in up to one-third of all fusion cases^{1,2,3,4} despite advances in surgical methodology and instrumentation.

Low-energy, time-varying magnetic fields (commonly referred to as pulsed electromagnetic fields or PEMFs) have been proven effective in promoting bony arthrodeses in spine fusion patients. A number of clinical studies have demonstrated that PEMF treatment is an effective substitute for surgical revision of lumbar region pseudarthrosis.^{5,6,7}

Fewer incumbent risks and complications are associated with this therapy, and a dramatic cost reduction is met.

As a leader in the field of advanced devices for bone healing, Orthofix has witnessed the growing acceptance of Spinal-Stim as a safe, useful, and cost-effective treatment for the management of spine fusions. The Spinal-Stim Non-operative Salvage Limited Guarantee Program permits physicians to prescribe and providers to approve PEMF therapy with confidence, and patients to be assured of healing.

The Program

The Spinal-Stim Non-operative Salvage Limited Guarantee Program provides physicians, insurance carriers and patients with a proven method to increase the potential for bone grafting in established lumbar region pseudarthroses. *The Program provides that radiographic fusion* will occur or 100% of the fee paid for the Spinal-Stim unit will be refunded to the payer(s) of record.*

Guidelines for Assessment of Bone Grafted Lumbar Spinal 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 270 days after Spinal-Stim treatment began. If that evaluation confirms the absence of fusion, the refund claim will be processed.

Eligibility Requirements

All bone grafted (autograft and/or allograft) lumbar spinal fusion cases for which Spinal-Stim is prescribed as a non-operative salvage, are eligible for the Spinal-Stim Non-operative Salvage Limited Guarantee Program, subject to the following conditions:

- The appropriate Spinal-Stim is prescribed for an approved indication.
- At the time of device placement, visible graft remains intact and has not resorbed, as documented by radiograph.
- The individual wearing the unit does not have an implanted cardiac pacemaker.
- The treatment period with Spinal-Stim continues for a minimum of 270 consecutive days.

- The patient uses the Spinal-Stim for a minimum of 6 hours per day on at least 90% of the days from the day the device is first applied 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 270th day following the day the Spinal-Stim is first applied.
- A pre-numbered Certificate of Limited Guarantee is signed by the patient (to acknowledge the patient's understanding of the terms and conditions of the program) and returned to Orthofix along with the Assignment of Benefits form prior to initial treatment.
- Full payment is received by Orthofix within 45 days of invoicing date.
- Guarantee claims are received at Orthofix headquarters within one year after the Spinal-Stim device is first applied.
- Spinal-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.

Claim Submission

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

- a. Radiographs taken prior to placement of the Spinal-Stim, and at the fusion evaluation date (270 days or beyond). Radiographs should be clearly marked with the patient's name, date, physician's name and any other pertinent identifying information.
- b. 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.
- c. Originals or photocopies of the Spinal-Stim patient compliance reports from Day 1 of Spinal-Stim treatment through the evaluation date.
- d. The prescribed Spinal-Stim unit.

Please contact your Orthofix Territory Manager 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 Spinal-Stim device is first applied. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or Spinal-Stim devices.

Call Toll-Free (800) 535-4492, Orthofix Customer Service, to arrange for Spinal-Stim device pick-up and return.

The Spinal-Stim Non-operative Salvage 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.

* Fusion will be considered to have occurred if the physician's evaluation indicates 50% graft incorporation visible (confirmed) on a plain radiograph.

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Indications

Spinal-Stim is a non-invasive electromagnetic bone growth stimulator indicated as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion, minimum nine months postoperative.

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

Contraindications

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 teratologic studies performed with a similar device demonstrated no adverse findings, the safety of this device during pregnancy and nursing in humans has not been established.
- The safety and effectiveness 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 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 Orthofix Premarketing Data for 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.
- Spinal-Stim for the treatment of the skull has not been evaluated.

Adverse Effects

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

References

- Lane, JM and Muschler, GF. 1992. "Spinal Fusion: Principles of Bone Fusion." *The Spine*, 3d ed. 2 vols., ed. RH Rothman and FA Simeone. Philadelphia, PA: WB Saunders Company.
- Mooney, V. 1990. "A Randomized Double-Blind Prospective Study of the Efficacy of Pulsed Electromagnetic Fields for Interbody Lumbar Fusions." *Spine* 15 (7): 708-712.
- Kane, WJ. 1988. "Direct Current Electrical Bone Growth Stimulation for Spinal Fusion," *Spine* 13 (3): 363.
- Sims, WA. "Experience with Electrical Bone Growth Stimulation for Spinal Fusion." Presented at the annual meeting of the Clinical Orthopaedic Society, 1985.
- Lee, K. "Clinical Investigation of the Spinal-Stim System, Open Trial Phase: Pseudarthrosis Stratum." Presented at the annual meeting of the American Academy of Orthopaedic Surgeons, 1989.
- Simmons, JW, et al. "The Effect of Post-Operative Pulsing Electromagnetic Fields on Lumbar Fusion: An Open Trial Phase Study." Presented at the annual meeting of the North American Spine Society, 1989.
- Simmons, JW 1985. "Treatment of Failed Posterior Lumbar Interbody Fusion (PLIF) of the Spine with Pulsed Electromagnetic Fields." *Clinical Orthopaedics* 193: 127.

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

www.orthofix.com
www.treatmyback.com



For full prescribing information, see Physician Manual, or contact Orthofix at 1.800.535.4492