

Limited Guarantee



PEMF and the Challenge of Healing in the Lumbar Spine

Low back pain is a common but often debilitating affliction that results in more than 55,000 lumbar spine fusions annually.¹ This region of the body is recognized as one of the slowest and most difficult in which to achieve arthrodesis, as demonstrated by the occurrence of pseudarthrosis in as many as one-third of all fusion cases^{2,3,4,5} despite advances in methodology and instrumentation. Electrical stimulation has shown promising results in overcoming the challenges of bone graft incorporation in the lumbar spine.

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.⁶ 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.

The Program

The Spinal-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) lumbar spinal fusion. *The Limited Guarantee provides that radiographic fusion* will occur or 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 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) lumbar spinal fusion cases for which Spinal-Stim is prescribed as an adjunct to surgery are eligible for the Spinal-Stim.

Guarantee Program, subject to the following conditions:

- Spinal-Stim is prescribed for an approved indication.
- The device is applied and treatment begins within 30 days of the most recent lumbar fusion procedure for which it is prescribed.
- 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 device for at least 2 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 270th day following the day the device is first applied following surgery.
- A pre-numbered original Certificate of Limited Guarantee is signed by the patient (to acknowledge the patient's understanding of program terms and conditions) and returned to Orthofix along with the Assignment of Benefits Form.
- 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 following surgery.
- 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 following surgery. 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 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 fusion 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 Pre-marketing 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

- National Council of Health Statistics, 1987.
- 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.
- Dwyer, AF. 1974. "Direct Current Stimulation in Spinal Fusion." *Medical Journal of Australia* 1 (1): 73

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