SPINALSTIM® SPINAL FUSION THERAPY

THE Healing ADVANTAGE®

ORTHOFIX WRITTEN GUARANTEE

The SpinalStim™ Device Certificate of Limited Guarantee

The SpinalStim device is prescribed with a Guarantee Program if fusion is not shown, as described in and under the terms below, or the fee paid for the unit will be refunded to the payer(s) of record.* This permits physicians to prescribe and insurance providers to approve our bone growth therapy with confidence.

Bone growth therapy was initially used to stimulate the natural healing process in long bone fractures.[1] The treatment proved so successful that scientists studied its effectiveness in healing spinal fusions. The results showed that, when bone growth therapy is used following spine surgery in certain high risk patients, fusion success can be increased when compared to surgery without the treatment. Consistent users wore the SpinalStim device at least 2 hours a day for up to 270 days of treatment.[2-4]

The SpinalStim device is the only bone growth therapy approved by the FDA for both lumbar spine fusion and non-surgically treating spinal pseudarthrosis, reducing the need for revision surgery.[2-4] The SpinalStim device uses a low-level, pulsed electromagnetic field (PEMF) to help activate the body's natural healing process. Patients should wear the SpinalStim device as prescribed by their physician.

Terms and Conditions of the SpinalStim Device Limited Guarantee

Eligibility Requirements

- The SpinalStim device is prescribed for an FDA approved indication.
- The SpinalStim device treatment begins within 30 days of the lumbar fusion procedure for which it is prescribed. (Applies to adjunct use.)
- The patient uses the SpinalStim device for at least 2 hours per day for a minimum treatment period of 270 days.
- The patient must be at least 90% compliant with the SpinalStim device treatment which is from the time the device was applied until the date of the radiographic assessment.

Guidelines for for Assessment and Additional Eligibility Requirements

- All eligibility requirements are fulfilled and met.
- Fusion, or the absence of fusion, will be determined by the written evaluation of X-ray, CT, or other radiographic images by the prescribing physician (or his/her radiologist) taken at least 270 days after the SpinalStim device treatment began. (Fusion will be considered to have occurred if the physician's evaluation indicates 50% graft incorporation visible on a radiograph.)
- Full payment has been received by Orthofix.
- Compliance will be determined by the treatment of record stored on the SpinalStim device.
- The SpinalStim device Limited Guarantee claims must be received at Orthofix within one year after the SpinalStim device treatment began.
- If a SpinalStim device is deliberately rendered inoperable or altered in any way will be excluded from the guarantee and will not be eligible for a refund.

Claim Submission

For additional information regarding the SpinalStim device Limited Guarantee program, please contact Orthofix Patient Services at (800) 535-4492 or 3451 Plano Parkway, Lewisville, TX 75056. Claim submission, appropriate documentation, and returned device must be received within one year after the SpinalStim device treatment began. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or SpinalStim devices. This limited guarantee gives the payer(s) of record specific legal rights, and such person(s) may also have other rights, which vary from State to State. Orthofix reserves the right to discontinue or modify the SpinalStim device Limited Guarantee Program at any time.

*Subject to eligibility requirement. Refund of payment is not applicable for Wholesale Orders since the Certificate and Guarantee may not be transferred to another physician, patient, or payer. Orthofix must be the direct supplier of the device to the patient for the Limited Guarantee to be applicable.

1. Garland DE, Moses B, Salver W. Fracture healing: Long-term follow-up of fracture nonunions treated with PEMFs. Contemp Orthop. 1991;22(3):295-302. 2. PMA P850007/S6. February 1996. 3. Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields of interbody lumbar fusions. Spine. 1990 July; 15(7):708-12. 4. Simmons JW Jr, Mooney V, Thacker I. Pseudarthrosis after lumbar spine fusion: nonoperative salvage with pulsed electro-magnetic fields. Am J Orthop. 2004;33(1):27-30

Brief Prescribing Information:

The SpinalStim™ device is indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment of salvage of failed spinal fusion, where a minimum of nine months has elapsed since the last surgery.

Cardiac pacemakers may be adversely affected by exposure to pulsed electromagnetic fields. Use of this device is contraindicated where the individual has an implanted cardiac pacemaker. The safety and effectiveness of this device has not been established for individuals lacking skeletal maturity. The safety of this device for use on patients who are pregnant or nursing has not been established. Rare instances of reversible minor discomfort have been reported.

Full prescribing information can be found in product labeling on our patient education website www.BoneGrowthTherapy.com or by calling Patient Services at 1-800-535-4492.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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BoneGrowthTherapy.com
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1.800.535.4492

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