CERVICALSTIM™
SPINAL FUSION THERAPY

THE Healing ADVANTAGE®

ORTHOFIX WRITTEN GUARANTEE

The CervicalStim™ Device Certificate of Limited Guarantee

The CervicalStim device is prescribed with a Guarantee Program if fusion is not shown, as described in and under the terms below, 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, and helps increase the patient's opportunity to heal.

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 CervicalStim device at least 4 hours a day for up to 180 days of treatment. The healing success rate was statistically significant over a measurement period of 6 months.[2-3]

The CervicalStim device is the only bone growth therapy approved by the FDA as a noninvasive, adjunctive treatment option for cervical fusion.[2-3] The CervicalStim device uses a low-level, pulsed electromagnetic field (PEMF) to help activate the body's natural healing process. Patients should wear the CervicalStim device as prescribed by their physician.

Terms and Conditions of the CervicalStim Device Limited Guarantee

Eligibility Requirements

- The CervicalStim device must be used in accordance with the approved Indication for Use stated in the product labeling (i.e. Instructional Manual).
- The CervicalStim device treatment begins within 30 days of the fusion procedure for which it is prescribed.
- The patient uses the CervicalStim device for at least 4 hours per day for a minimum treatment period of 180 days.
- The patient must be at least 90% compliant with the CervicalStim device treatment from the time the device was applied until the date of the radiographic assessment.

Guidelines 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 180 days (6 months) after the CervicalStim 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 CervicalStim device .
- The CervicalStim device Limited Guarantee claims must be received at Orthofix within one year after the CervicalStim device treatment began.
- CervicalStim devices 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 CervicalStim 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 CervicalStim device treatment began. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or CervicalStim 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 CervicalStim 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 P030034. December 2004.
3. Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. Spine J. 2008;8(3):436-44

Brief Prescribing Information:

The CervicalStim™ device is indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fusion; there are no known contraindications.

Do not use this device if you have a cardiac pacemaker or defibrillator. Remove the device prior to any imaging procedures. The safety of this device for use on patients who are pregnant or nursing has not been established. Adverse effects may include increased pain, numbness and tingling, headache, migraines and nausea; these effects may or may not be directly related to use of the device.

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.

P/N 20122283 Rev. AD 2021-01-12

BoneGrowthTherapy.com
orthofix.com
1.800.535.4492

ORTHOFIX®