

Q: Will my insurance company pay for the device?

A: Insurance policies are different depending on the plan you have chosen. If guidelines are met, the osteogenesis stimulator is accepted and approved by the majority of private and public health plans, including Medicare, Medicaid and workers' compensation plans.

Q: Does Orthofix pre-authorize the osteogenesis stimulator with my insurance company?

A: Yes, Orthofix will assist you in determining coverage by your health plan before you receive the device.



Q: What happens if my insurance company denies the claim?

A: If this happens, the claim will be pursued by our appeals processing department on your behalf. If all appeals are exhausted and your contracted provider has denied medical necessity, you may contact our Patient Care Billing Specialists at 1-866-543-9340 to discuss payment options and/or arrangements.

Q: Can I pay my patient responsibility (coinsurance/deductible) online?

A: Yes. If your insurance has determined that you have a coinsurance/deductible, you will receive a bill with instructions for payment. Please visit bonestimulation.com for details.

Q: What if I don't have insurance or need financial assistance?

A: Please contact our Patient Care Billing Specialists at 1-866-543-9340 to discuss payment options. Orthofix also has a patient financial assistance program for people who demonstrate financial need based on established guidelines.

Q: Who do I call if I have questions?

A: You may call the Orthofix Customer Service line at **1-800-535-4492**.

1. 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.
2. Simmons JW, Mooney V, Thacker I. Pseudarthrosis after lumbar spine fusion: non-operative salvage with pulsed electromagnetic fields. *American Journal of Orthopedics*, 2004 Jan;33(1):27-30.
3. Foley K, et al. randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *The Spine Journal*. 2008 May/June;8:436-442.
4. Bassett C, et al. Fundamental and practical aspects of therapeutic uses of pulsed electromagnetic fields (PEMFs). *Critical Reviews in Bio Med Eng*, 1989;17:470-484.
5. Yen-Patton GP, et al. Endothelial cell response to pulsed electromagnetic field *Journal of Cellular Physiology*. 1988;134:37-46.
6. PMA P850007/S6
7. PMA P030034

**THE HEALING ADVANTAGE®
GUARANTEED**

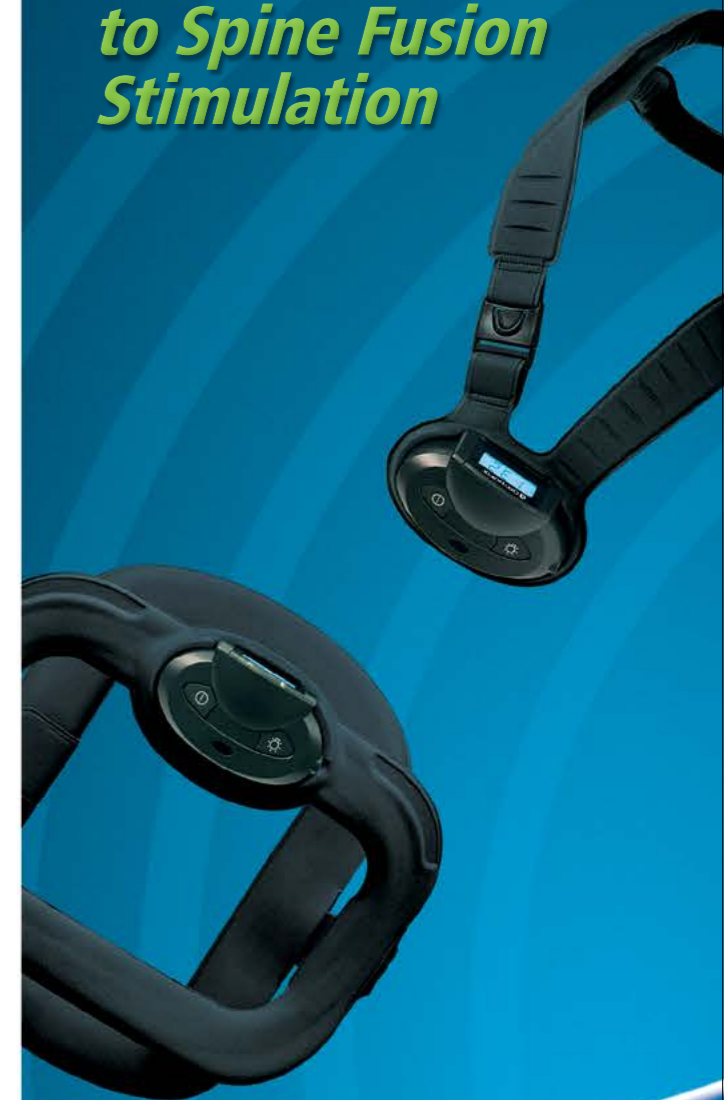


Spinal-Stim and Cervical-Stim are prescribed with a Guarantee Program which refunds to payors the fees paid for the device if radiographic fusion does not occur in compliant patients. This gives physicians added confidence in prescribing Orthofix devices as they strive to improve fusion rates for high risk patients. It also gives insurance providers who approve coverage the assurance of a money back guarantee.

**For more information,
contact your local representative
or call Orthofix Customer Service
800-535-4492**

**orthofix.com
bonestimulation.com**

A Patient's Guide to Spine Fusion Stimulation



Q: What is osteogenesis stimulation, and how will it help me?

A: The Spinal-Stim and Cervical-Stim spinal fusion systems are safe, nonsurgical treatments your doctor has prescribed to aid the healing of your spinal fusion. These osteogenesis stimulators use a low-strength pulsed electromagnetic field (PEMF) to activate the body's natural healing process.

Electrical currents have been used to heal bones since the mid-1800s. However, it wasn't until the 1950s that scientists made an important discovery. When human bone is bent or broken, it generates an electrical field. This low-level electrical field activates the body's internal repair mechanism which, in turn, stimulates bone healing.

Osteogenesis stimulation therapy was initially used to stimulate the natural healing process in long bone fractures. The treatment proved so successful that scientists studied its effectiveness in healing spinal fusions. The results showed that, when osteogenesis stimulation is used following spine surgery in high risk patients, fusion success can be increased when compared to surgery without the treatment.^{1,2}

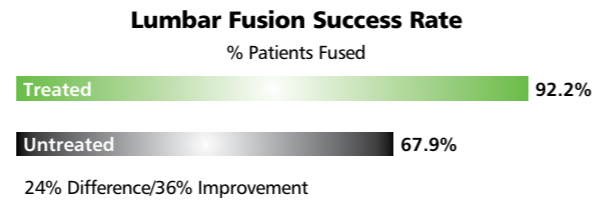


Cervical-Stim is the only FDA-approved device for cervical spine fusions.



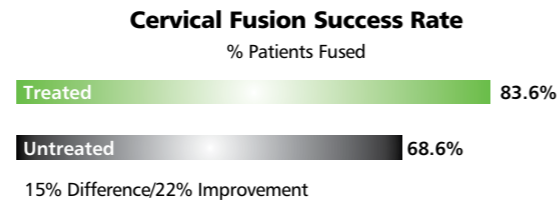
Q: What are the clinical results with Spinal-Stim?

A: Spinal-Stim was approved by the Food and Drug Administration (FDA) in 1990. In a clinical study with 195 lumbar (lower back) fusion patients, 92% fused successfully after receiving our PEMF stimulation, compared with 68% who fused without the treatment.^{1,6} When treating failed fusion with Spinal-Stim, 67% of patients achieve successful fusion with no additional surgery.^{2,6}



Q: What are the clinical results with Cervical-Stim?

A: Cervical-Stim was approved by the FDA in 2004. In a clinical study with 240 high-risk cervical fusion patients, 84% fused successfully within six months of surgery after receiving PEMF stimulation, compared with 69% who fused without the treatment.^{3,7} These high risk patients had multi-level fusions, were smokers, or both—all difficult fusions to heal.

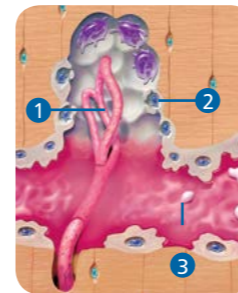


Q: How long will it take to heal?

A: The healing process itself determines the duration of the treatment, and your doctor will closely monitor your progress. Your individual risk factors (such as smoking, multi-level fusion, and graft type) and your compliance in wearing the device will influence the duration of your treatment. To promote your healing, it is very important that you wear your stimulator daily as prescribed. Patients are instructed to wear their stimulator until their doctor confirms they are healed. Your doctor may ask you to bring the device to follow-up visits to check your compliance.

Q: How does osteogenesis stimulation work?

A: Our stimulators generate a low-level magnetic field at the fusion site. This PEMF signal stimulates your own normal bone healing process which may be impaired or absent.



How PEMF Works^{4,5}

- 1 PEMF stimulates growth of blood vessels
- 2 PEMF stimulates bone forming cells (osteoblasts)
- 3 PEMF stimulates the formation of bone

Q: Is osteogenesis stimulation safe?

A: Yes. Our stimulators produce a signal like the one your own body generates to induce normal bone healing. The PEMF therapy emitted by our devices was specially designed with your safety in mind, and is similar in strength to what you're exposed to naturally from the magnetic field of the earth. Our osteogenesis stimulators may be safely used with surgical hardware. The effect of PEMF treatment during pregnancy or nursing has not been studied; consult with your doctor if you suspect you may be pregnant.

More than 700,000 Orthofix patients have worn our stimulators to increase their probability of healing success. For full prescribing information, see the manual that came with your device or visit www.bonestimulation.com.

Q: Can I wear the device with a cardiac pacemaker?

A: Using Spinal-Stim with an implanted cardiac pacemaker or defibrillator is contraindicated, while it's a warning with Cervical-Stim. It's important to consult your cardiologist, who can run tests to determine whether the device will affect your specific pacemaker model.

Q: What will treatment feel like? How will it affect my daily activities?

A: You shouldn't feel the PEMF therapy. The devices are lightweight for a comfortable fit, and powered with a rechargeable battery, which allows the unit to be portable. You can sit, stand, sleep, walk, recline, and drive while using the stimulator. With your doctor's approval, you can resume a normal activity level while wearing the device.

Q: What is my daily treatment time?

A: Your doctor will prescribe a daily treatment time based on your needs. Spinal-Stim is typically worn a minimum of two hours a day and Cervical-Stim is worn four hours a day.

Q: Do I need to wear the device at the same time each day?

A: No. You have the flexibility to receive your treatment at any time during the day. The device has a built-in 24 hour clock which resets daily at 12:00 midnight, Central Time, unless adjusted for your time zone. Additionally, you may choose to break your total daily prescribed treatment into a number of shorter sessions lasting **at least one hour each**, in accordance with your doctor's instructions.

Q: Can I wear the device over a brace or collar?

A: Yes, it can be worn over an orthopedic brace, soft collar or clothing without affecting the PEMF signal as it travels through the body to the fusion site.