



CERVICAL-STIM®

A Patient's Guide to Bone Growth Stimulation



THE HEALING ADVANTAGE® GUARANTEED



Cervical-Stim is 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 Cervical-Stim as they strive to improve fusion rates for high risk patients. It also gives insurance providers who approve coverage for Cervical-Stim the assurance of a money back guarantee.

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

www.orthofix.com
www.spinestimulation.com

1720 Bray Central Drive
McKinney, Texas USA 75069

Bone Growth Stimulation | Biologics | MIS | Fusion | Bracing



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 bone growth 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 bone growth stimulator with my insurance company?

A: Yes, Orthofix will pre-authorize the device with your health plan.

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 receive a claim. If you have not already made prior payment arrangements and you receive a claim, please contact Customer Service at 1-800-535-4492 to discuss payment options and/or arrangements.

Q: What if I don't have insurance?

A: Please contact Customer Service at 1-800-535-4492 to discuss payment options. Orthofix also has a Patient 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: 1-800-535-4492.



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

Q: What is the Cervical-Stim® Bone Growth Stimulator, and how will it help me?

A: The Cervical-Stim spinal fusion system is a safe, nonsurgical treatment your doctor has prescribed to aid the healing of your cervical fusion. Cervical-Stim is a bone growth stimulator which uses a very 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-1800's. However, it wasn't until the 1950's 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.

Bone growth 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 Cervical-Stim is used following spine surgery in high risk patients, fusion success can be increased when compared to surgery without Cervical-Stim treatment.

Q: How long will it take to heal with Cervical-Stim?

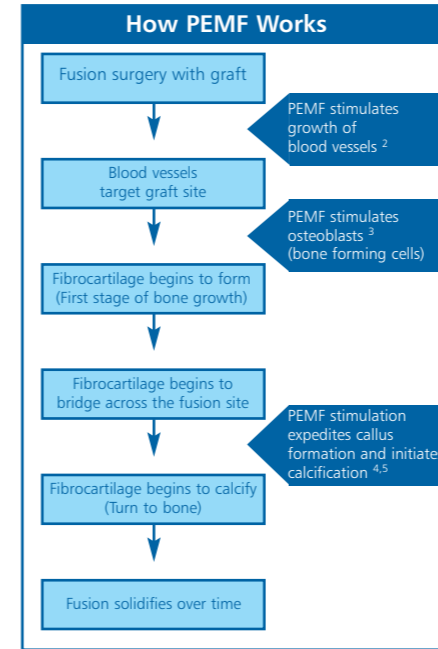
A: The healing process itself determines the duration of the treatment, and your doctor will closely monitor your progress. Your individual risk factors (such as smoking, multi-level fusion, and graft type) and your compliance in wearing Cervical-Stim will influence the duration of your treatment. To promote your healing, it is very important that you wear Cervical-Stim daily as prescribed. Your doctor may require that you bring the unit in on your follow-up visits to check your compliance. Most patients wear the device for three to six months.

Q: What difference has Cervical-Stim been shown to make?

A: Cervical-Stim was approved by the Food and Drug Administration (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 68% who fused without the treatment.¹ This 15% difference means that the bone growth stimulator improved their success rate 22%. Patients in the study were considered high risk if they had multi-level fusions, were smokers, or both—all more difficult fusions to heal. It's also important to note that fusion success rates were much lower (and slower to heal) for patients who didn't wear the device every day as prescribed by their doctor.

Q: How does Cervical-Stim work?

A: Using electricity, Cervical-Stim generates a low-level magnetic signal at the fusion site. This PEMF signal stimulates your own normal bone healing process which may be impaired or absent.



1. Foley, KT: Spine J. 2008 May-Jun; 8(3):436-42
 2. Yen-Patton GP et al.: J Cell Phys 1988;134:37-46
 3. McElhaney JH: J. Bone Joint Surg. 1967;49A:1561
 4. Marino AA and Becker RO: Nature 1970;228:473
 5. Midura RJ et al.: J Orthop Res. 2005;23(5):1035-46

Q: Is Cervical-Stim safe?

A: Yes. Cervical-Stim produces a signal like the one your own body generates to induce normal bone healing. The PEMF therapy emitted by Cervical-Stim 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. Cervical-Stim 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.

Well over 265,000 Orthofix patients have worn our spine stimulators to increase the probability of fusion success. For full prescribing information, see the manual that came with your device or visit www.spinestimulation.com.

Q: Can I wear Cervical-Stim with a TENS unit or cardiac pacemaker?

A: Cervical-Stim can be used with a TENS unit. If you have a cardiac pacemaker or defibrillator, it is important to consult your cardiologist before you use Cervical-Stim. Your cardiologist will run tests to determine whether Cervical-Stim therapy will affect your pacemaker or defibrillator.

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

A: You shouldn't feel the PEMF therapy. The Cervical-Stim unit is lightweight for a comfortable fit. It is powered with a rechargeable battery, which allows the unit to be portable. You can sit, stand, sleep, walk, recline, and drive while using Cervical-Stim. 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—typically four hours per day.

Q: Do I need to wear Cervical-Stim 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 allows you to receive your total prescribed treatment each day between the hours of 12:00 a.m. through 11:59 p.m. (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 Cervical-Stim over a neck collar?

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

