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 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.

Q: Will my insurance company pay for the device?

A: Coverage for the device may depend on the insurance plan you have chosen. If prescribing guidelines are met, the bone growth therapy device is accepted and approved by the majority of private and public health plans, including Medicare, Medicaid and workers' compensation plans. In addition, we encourage patients to contact their insurance company for details in regards to health care coverage.

Q: Does Orthofix pre-authorize the bone growth therapy device with my insurance company?

A: Orthofix will assist you in determining whether your health plan will cover the device, in accordance with the patient's benefit plan, before you receive the device.

Bone Healing Therapy Products:

Model 5313
PhysioStim™ device

Model 5314
PhysioStim™ device

Model 5315
PhysioStim™ device

Model 5302
PhysioStim™ device

Model 5303
PhysioStim™ device

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

A: In the event of an insurance denial, Orthofix's appeals processing department will appeal the denial 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 BoneGrowthTherapy.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 Patient Services line at **1-800-535-4492.**

* The results of preclinical studies may not be indicative of human clinical trials.

1. Mooney V. Pulsed electromagnetic fields: an adjunct to interbody spinal fusion surgery in the high risk patient. Surg Technol Int 1993, 2:405-410.
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. Patterson TE, Sakai Y, Grabiner MD, et al. Exposure of murine cells to pulsed electromagnetic fields rapidly activates the mTOR-signaling pathway. Bioelectromagnetics. 2006;27(7):535-44
5. 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
6. Orthofix patient registry. PMA P850007/S20. Data on file.
7. Selvamurugan N, Kwok S, Vasilov A, Jefcoat SC, Partridge NC. Effects of BMP-2 and pulsed electromagnetic field (PEMF) on rat primary osteoblastic cell proliferation and gene expression. J Orthop Res. 2007;25(9):1213-20
8. Ibiwoye MO, Powell KA, Grabiner MD. Bone mass is preserved in a critical-sized osteotomy by low energy pulsed electromagnetic fields as quantitated by in vivo micro-computed tomography. J Orthop Res. 2004;22(5):1086-93
9. Midura RJ, Ibiwoye MO, Powell, KA, et al. Pulsed electromagnetic field treatments enhance the healing of fibular osteotomies. J Orthop Res. 2005;23:1035-46
10. Zborowski M, Androjna C, Waldorff EI, Midura RJ 2015 Comparison of therapeutic magnetic stimulation with electric stimulation of spinal column vertebrae. IEEE Transactions on Magnetics 51(12): #5001009, doi: 10.1109/TMAG.2015.2458297
11. Data on file. Field mapping analysis conducted by M. Zborowski, Ph.D., Cleveland Clinic.

Guarantee Program

*Orthofix Bone Growth Therapy devices are prescribed with a Guarantee Program which states that radiographic progress will be shown in fracture healing or fusion healing, 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 devices with confidence, and most importantly, to assure our patients will have the maximum opportunity to heal.

**Subject to eligibility requirement.

Brief Prescribing Information:

SpinalStim Spinal Fusion Therapy
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.

CervicalStim Spinal Fusion Therapy
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.

PhysioStim Bone Healing Therapy
The PhysioStim™ device is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Use of this device is contraindicated where the individual has synovial pseudarthrosis. Demand type pacemaker operation may be adversely affected by exposure to pulsed electromagnetic fields. The safety and effectiveness of this device has not been established for individuals lacking skeletal maturity or individuals with a nonunion secondary to, or in connection with, a pathological condition. 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.BoneGrwothTherapy.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.

BoneGrowthTherapy.com
orthofix.com
1.800.535.4492

ORTHOFIX®

A Patient's Guide to **Bone Growth Therapy**

Frequently Asked Questions

ORTHOFIX®

Q: What is bone growth therapy, and how will it help me?

A: Bone growth therapy, commonly known as bone growth stimulation, is a safe, nonsurgical treatment your doctor has prescribed to improve your opportunity for a successful fusion or bone fracture healing. These devices 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.

Bone growth therapy was initially used to stimulate the natural healing process in long bone fractures.[5] 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 spinal surgery in high risk patients, fusion success can be increased when compared to surgery without the treatment.[1,2]

Orthofix has two lines of Bone Growth Therapy Devices: Spinal Fusion Therapy and Bone Healing Therapy.

Q: What are the clinical results of the SpinalStim device?

A: The SpinalStim device 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.[1,2] When treating failed fusion with the SpinalStim device, 67% of patients achieve successful fusion with no additional surgery.[1,2] The SpinalStim device is the only bone growth therapy approved by the FDA for both lumbar spine fusion and non surgically treating a failed fusion.[1,2]

Lumbar Fusion Success Rate [1,2]

% Patients Fused

36% Improvement

Q: What are the clinical results of the CervicalStim device?

A: The CervicalStim device was approved by the FDA in 2004 and is the only device FDA approved for use as a noninvasive, adjunctive treatment option for cervical spine fusions.[3] 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] These high risk patients had multi-level fusions, were smokers, or both—all difficult fusions to heal.

Cervical Fusion Success Rate [3]

% Patients Fused

22% Improvement

Q: What are the clinical results of the PhysioStim device?

A: The PhysioStim device was approved by the FDA in 1986. Clinical studies showed the PhysioStim device helped eight out of every ten patients to heal. Clinical success rates for the PhysioStim device varied by fracture site.[5,6]

Proven Clinical Succes Rates [5,6]

for the PhysioStim device

Femur	82.4 %
Fibula	91.4 %
Metatarsal	90.9 %
Tibia	89.0 %
Ulna	96.1 %
Radius	93.8 %

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. To promote your healing, it is very important that you wear your bone growth therapy device daily as prescribed. Patients are instructed to wear their device until their doctor confirms they are healed. Although your treatment may vary, most patients wear the bone growth therapy device between three and nine months.

Q: How does bone growth therapy work?

A: Our devices generate a low-level electromagnetic field at the fusion or fracture site. This PEMF signal stimulates your own normal bone healing process which may be impaired or absent. The bone growth therapy device may be worn over a cast, brace or clothing without lessening its effectiveness.

Molecular

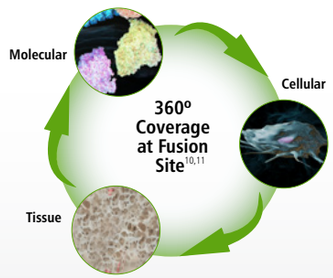
Within ten minutes of PEMF exposure, signaling pathways are activated.*[4]

Cellular

PEMF stimulates bone cells to proliferate, differentiate and mineralize.*[7]

Tissue

PEMF has been shown to improve the quality of bone tissue and enhance bone preservation.*[8,9]



Q: Is bone growth therapy safe?

A: Yes. Our bone growth therapy devices 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 bone growth therapy devices 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 800,000 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 BoneGrowthTherapy.com.

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

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

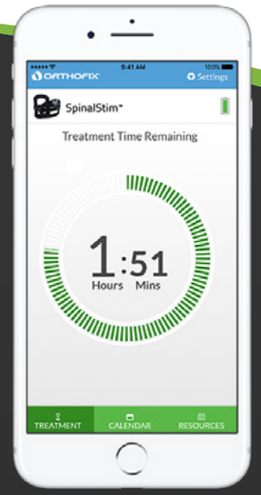
Q: What will treatment feel like? How will it affect my daily activities?

A: You should not 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.

- The SpinalStim device is typically worn a minimum of two hours a day.
- The CervicalStim device is worn four hours a day.
- The PhysioStim device is typically worn for three hours a day.



STIM onTrack™ Mobile App

Download on the App Store

STIM onTrack™ mobile app is a patient friendly mobile app that encourages you to adhere to treatment sessions set by your physician. If you choose to utilize this accessory, your Orthofix representative will help you download the STIM onTrack application to your smartphone at the time of device delivery.