

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 as allowed by the medical policy carrier. If appeals are exhausted and your contracted provider has denied medical necessity, you may contact our Patient Service Representatives at 1-800-535-4492 to discuss payment options and/or arrangements.

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

A: Please contact our Patient Service Representatives at 1-800-535-4492 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 Service

THE **Healing** ADVANTAGE[®]

Physio-Stim is prescribed with a Guarantee Program which provides that radiographic progress will be shown in fracture healing, or the feepaid for the unit will be refunded to the payer(s) of record.** This permits physicians to prescribe and insurance providers to approve our osteogenesis stimulation with confidence, and most importantly, to assure our patients will have the maximum opportunity to heal.



***Subject to eligibility requirements*

Proven Clinical Success Rates for Physio-Stim⁶

Femur	84.2%
Fibula	91.4%
Metatarsal	90.9%
Tibia	89.0%
Ulna	96.1%
Radius	93.8%

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. Yen-Patton GP, et al. Endothelial cell response to pulsed electromagnetic fields: stimulation of growth rate and angiogenesis in vitro. *J Cell Physiol.* 1988 Jan; 134(1): 37-46
3. McElhaney, JH: The charge distribution on the human femur due to load. *J Bone Joint Surg Am.* 1967; 49(8): 1561-71
4. Marino, AA and Becker, RO: Piezoelectric effect and growth control in bone. *Nature.* 1970 October; 228: 473-74
5. 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
6. Orthofix patient registry. PMA P850007/S20. Data on file.



Brief Prescribing Information:

The Physio-Stim[®] 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.bonestimulation.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.

For more information,
contact your local representative



Toll Free: (800) 863-1769

or call Orthofix Patient Services at
800-535-4492
www.orthofix.com
www.bonestimulation.com



3451 Plano Parkway • Lewisville, Texas 75056

PS-1411-PL-US © Orthofix Holdings, Inc. 09/2014



A Patient's Guide to Osteogenesis Stimulation Questions & Answers



Q: What is the Physio-Stim® osteogenesis stimulator and how will it help me?

A: The Physio-Stim osteogenesis stimulator is a safe, nonsurgical treatment which your physician has prescribed to aid the healing of your fracture. The stimulator uses a very low-strength pulsed electromagnetic field (PEMF) to activate the body's natural healing process.

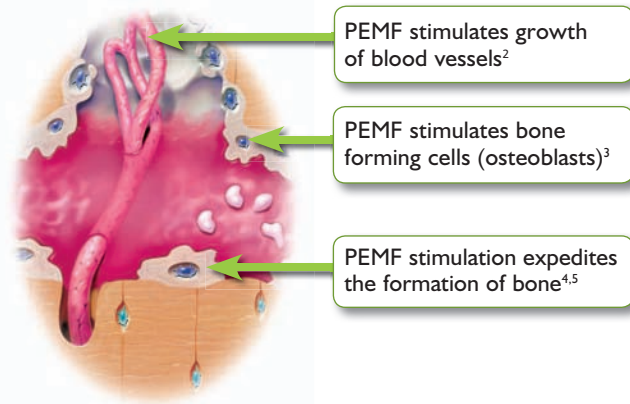
Electrical currents have been used to heal broken bones since the mid-1800's. However, it wasn't until the 1950's that scientists made an important discovery. When human bone is bent or broken, it generates an electrical field. This low level electrical field activates the body's internal repair mechanism,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

In some patients, this healing process is impaired or absent. The fracture fragments may not mend properly, and a nonunion results. The osteogenesis stimulation provided by Physio-Stim has proven very successful in treating fracture nonunions. In clinical studies, Physio-Stim helped 8 out of every 10 patients to heal.¹



Q: How does Physio-Stim work?

A: Using electricity, Physio-Stim generates a low level magnetic signal at the fracture site. PEMF stimulates the bone healing process, which may be impaired or absent. The unit may be worn over a cast, external fixator, orthopedic brace, or clothing without lessening its effectiveness.



Q: Is Physio-Stim safe?

A: Yes. Physio-Stim produces a signal at the fracture site like the one your own body would generate to induce normal bone healing. The PEMF emitted by Physio-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. Thousands of patients have worn Physio-Stim to heal their nonunions. Physio-Stim may be safely used with fixation devices, such as screws, plates, or pins, or even in fractures where there is infection. You should not wear the device if you have a demand type pacemaker.

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

A: You won't feel the PEMF therapy, and the Physio-Stim unit is lightweight and adjustable for a comfortable fit. It is powered with a battery, which allows the unit to be portable. You can sit, stand, sleep, walk, recline, and drive while using Physio-Stim. With your physician's approval, you can resume a normal activity level.

Q: What is my daily treatment time?

A: Physio-Stim treatment is based on daily therapy schedule. The treatment time is three hours per day.

Q: Do I need to wear the Physio-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 for treatment each day between the hours of 12:00 a.m. through 11:59 p.m. Central Time. 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 Physio-Stim if I am pregnant?

A: The effect of PEMF treatment has not been studied during pregnancy or nursing. Therefore, if you are pregnant or nursing, you should consult your doctor before using Physio-Stim.



Q: Can I wear Physio-Stim with a cardiac pacemaker?

A: If you wear a pacemaker, you should consult your doctor before using Physio-Stim. Physio-Stim may interfere with demand type pacemakers.

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

A: The healing process determines the duration of the treatment, and your physician will closely monitor your progress. To promote healing, it is very important that you wear Physio-Stim daily as prescribed. Your doctor may require that you bring your unit in on your follow-up visits to check your compliance. Although your treatment may vary, most patients wear the device between four and eight months.

Q: How often will I need to charge the battery?

A: It is strongly recommended that the device be recharged after completing daily treatment. The Physio-Stim will not deliver treatment while charging.

Q: Will my insurance company pay for the device?

A: Insurance policies are different depending on the plan you have chosen. The osteogenesis stimulator is accepted and approved by the majority of health plans and workers compensation plans. Guidelines are established for payment through your commercial, Medicare, or Medicaid coverage.

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

A: Yes, Orthofix will verify and estimate your benefits to help you in determining coverage by your health plan before you receive the device.