**Frequently Asked Questions**

**Q: What is the STIM onTrack mobile app and how will it help?**

The STIM onTrack mobile app is a patient-friendly experience designed to help you take an active role in your bone healing recovery. It features a daily treatment reminder and a device usage calendar to help you keep an active role in your bone healing recovery and better outcomes. At the time of device delivery your Orthofix representative will help you download the application to your mobile device.

**Q: Will my insurance company pay for the device?**

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 Medicare, Medicaid and workers’ compensation plans. In the event of an insurance denial, Orthofix’s appeals plan will cover the device, in accordance with the patient’s plan will cover the device, in accordance with the patient’s benefit plan, before you receive the device.

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

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 your 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?**

Yes. If your insurance has determined that you have financial need based on established guidelines, please contact our Patient Care Billing Specialists at 1-866-543-9340 to discuss payment options and/or arrangements.

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

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.

**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.**

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**Brief Prescribing Information:**

**SpinalStim® Spinal Fusion Therapy**

The SpinalStim™ device is indicated as an adjunct to conventional fusion surgery in patients who seek for non-fusion; there are no known contraindications.

Do not use the 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.

**Physician Bone Healing Therapy**

The Physiostim™ device is indicated for the treatment of an established nonunion associated secondary to trauma, excluding vertebral 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.

The SpinalStim™ device is indicated as a spinal fusion adjunct to increase the probability of fusion success and as a complimentary treatment of surgical fusion failure, where a minimum of nine months has elapsed since 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 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.

**Cerviostim® Spinal Fusion Therapy**

The Cerviostim™ device is indicated as an adjunct to cervical fusion surgery in patients who seek for non-fusion; there are no known contraindications.

Do not use the 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.

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**Bone Growth Therapy**

Brief Prescribing Information:

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Bone growth therapy was initially used to stimulate 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. Scientists made an important discovery. When human bone is bent or broken, it generates an electrical field. 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 fusion, fusion success can be increased when compared to surgery without the treatment. 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. 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 fusion, fusion success can be increased when compared to surgery without the treatment.1,2

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. 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 fusion, 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.3 When treating failed fusion with the SpinalStim device, 67% of patients achieve successful fusion with no additional surgery.4 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.5

Lumbar Fusion Success Rate

% Patients Fused
Treated 92.2%
Untreated 67.9%

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. 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.6 High risk patients had multi-level fusions, were smokers, or both—all difficult fusions to heal.

Cervical Fusion Success Rate

% Patients Fused
Treated 83.6%
Untreated 68.6%

22% Improvement

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.7,8

Cellular
PEMF stimulates bone cells to proliferate, differentiate and mineralize.7,8

Tissue
PEMF has been shown to improve the quality of bone tissue and enhance bone preservation.9,10

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.1,5

Proven Clinical Success Rates

for the PhysioStim device

Fracture

Femur 82.4 %
Ulna/Radial 89.0 %
Tibia 99.2 %
Intercondylar 96.1 %
Metatarsal 97.8 %

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 especially 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.

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.

Bone Healing Therapy Products:

Spine Fusion Therapy Products: