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 established guidelines. In addition, we encourage patients to contact their insurance company for details in regards to health care coverage.

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 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 1-866-543-9430 to discuss payment options and/or arrangements.

Q: Can I wear the device over a brace or collar? A: No. You have the flexibility to receive your treatment at a time and place that is convenient for you.

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 public and private 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: 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: 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 1-866-543-9430 to discuss payment options and/or arrangements.

Q: What if I don’t have insurance or need financial assistance? A: Please contact our Patient Care Billing Specialists at 1-866-543-9430 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.

**Subject to eligibility requirement.**

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**Frequently Asked Questions**

**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 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.

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**Physician Bone Healing Therapy**

The PhysioStim™ device is indicated for use as an adjunctive manual therapy to enhance the healing of fibular osteotomies. J Orthop Res. 2004;22(5):1086-93

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**Brief Prescribing Information:**

**SpinalStim Spinal Fusion Therapy**

The SpinalStim™ device is indicated as a spinal fusion adjunct to increase the probability of bone union and to decrease the risk of pseudarthrosis. In 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.

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**PhysioStim Bone Healing Therapy**

The PhysioStim™ device is intended for use as an adjunctive manual therapy to enhance the healing of fibular osteotomies. J Orthop Res. 2004;22(5):1086-93

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**Frequently Asked Questions**

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**Full prescribing information** is found in product labeling on our patient education website www.BoneGrowthTherapy.com or by calling Patient Services at 1-866-543-9430.

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**Caution:** Federal law (USA) restricts this device to sale by or on the order of a doctor.

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**BoneGrowthTherapy.com**

www.BoneGrowthTherapy.com or by calling 1-800-535-4492.
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 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 is my daily treatment time?**

A: The CervicalStim device is worn four hours a day. The SpinalStim device is typically worn for three hours a day.

**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.

**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 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 your 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.4 These high risk patients had multi-level fusions, were smokers, or both—all difficult fusions to heal.5

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<td>92.2%</td>
<td>36% Improvement</td>
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**Q: What are the clinical results of the SpinalStim device?**

A: The SpinalStim device was approved by the Food and Drug Administration (FDA) in 1996. 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.4,5 When treating failed fusion with the SpinalStim device, 67% of patients achieve successful fusion with no additional surgery.6,7 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

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**Q: What is my daily treatment time?**

A: The SpinalStim device is typically worn a minimum of two hours a day.

**Q: What is your 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.6

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**Q: Is bone growth therapy safe?**

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