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 insurance 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?
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 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 bonestimulation.com for details.

Q: What if I don’t have insurance or need financial assistance?
A: Please contact our Patient Care Billing Specialists at 1-866-543-9430 to discuss payment options. Orthofix also has a patient financial assistance program for people who otherwise have difficulty receiving treatment. Please contact our Patient Care Billing Specialists at 1-866-543-9430 to discuss payment options. Please visit bonestimulation.com for details.

Q: Who do I call if I have questions?
A: You may call the Orthofix Patient Services line at 1-800-535-4492.

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.

Bone Healing Therapy Products:

- **Model 3313**
  - Physio-Stim device
  - For non-fusion; there are no known contraindications.

- **Model 3314**
  - Physio-Stim device
  - For non-fusion; there are no known contraindications.

- **Model 3315**
  - Physio-Stim device
  - For non-fusion; there are no known contraindications.

- **Model 3202**
  - Physio-Stim device
  - For non-fusion; there are no known contraindications.

- **Model 3303**
  - Physio-Stim device
  - For non-fusion; there are no known contraindications.

Physio-Stim Bone Healing Therapy

The Physio-Stim® device is indicated for the treatment of an established nonunion acquired secondary to trauma, including screws and spinous process, where the width of the nonunion defect is less than one-half the width of the bone to be healed. A treatment is considered to be established when the fracture site shows no visibly progressive signs of healing.

Use of this device is contraindicated when the individual has a local or systemic soft tissue infection. The device is contraindicated for use on patients who have a cardiac pacemaker. The safety and effectiveness of this device have not been established for individuals lacking skeletal integrity. 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 printed labeling on our patient education website www.bonestimulation.com or by calling our Patient Services at 1-866-535-4492. Caution: Federal law restricts this device to sale by or on the order of a physician.
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 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.

Spinal Fusion Therapy Products

Q: What are the clinical results with SpinalStim?
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 SpinalStim, 67% of patients achieve successful fusion with no additional surgery.1,3 SpinalStim 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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<td>74.4%</td>
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<td>36% Improvement</td>
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Q: What are the clinical results with CervicalStim?
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.1 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.1 These high risk patients had multi-level fusions, were smokers, or both—all difficult fusions to heal.

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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.

- **Cellular**
  - PEMF stimulates bone cells to proliferate, differentiate and mineralize.4

- **Tissue**
  - PEMF has been shown to improve the quality of bone tissue and enhance bone preservation.5

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 700,000 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 bonestimulation.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 Physio-Stim device is typically worn for three hours a day.

Q: What are the clinical results with Physio-Stim?
A: The Physio-Stim device was approved by the FDA in 1986. Clinical studies showed Physio-Stim helped 8 out of every 10 patients to heal. Clinical success rates for Physio-Stim varied by fracture site.3,6

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