

AccelStim™
Bone Healing Therapy

PhysioStim™
Bone Healing Therapy

Patient's Guide to Understanding Bone
Growth Therapy for Nonunion Fracture
and Indicated Fresh Fracture Healing



 **ORTHOFIX®**






What is Bone Growth Therapy?

Some patients who experience bone injuries and spinal fusion surgery have difficulty healing. In many of these cases, there are certain health factors that may have impaired the natural healing process of the bones. To help overcome healing challenges, doctors commonly prescribe a treatment called bone growth therapy, otherwise known as bone growth stimulation.

Orthofix Bone Growth Therapy devices provide a safe, noninvasive treatment that helps promote healing in fractured bones and spinal fusions that have not healed or have difficulty healing. The devices stimulate the bone's natural healing process by sending low-level pulses of electromagnetic energy or ultrasound waves to the injury or fusion site.^{1,3-5}

Orthofix bone growth therapy devices have aided patients in bone healing since 1986.



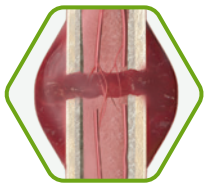
***“I feel alive again.
That is the stuff that
dreams are made of.”***

- Veronika, a PhysioStim device patient

How Does a Pulsed Electromagnetic Field (PEMF) Work?

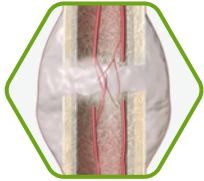
The PhysioStim™ devices provide a safe and effective non-surgical treatment to improve nonunion fracture healing. The devices use a pulsed electromagnetic field (PEMF) signal to induce a low-level electrical field at the fracture site which stimulates bone healing.^{1,2}

Phases of Bone Healing



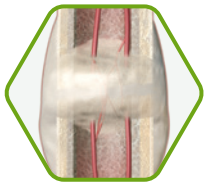
Stage 1: Hematoma

When a bone breaks, blood vessels in the bone and periosteum are torn and hemorrhage, and a hematoma (blood clot) forms at the fracture site. Tissue at the site becomes swollen and painful in response to inflammatory factors. New blood vessels begin to form to reestablish the blood supply.



Stage 2: Formation of soft callus

The body's inflammatory response attracts cells to the fracture site to remove the blood clot and bone debris. For healing to progress at this stage, the inflammatory response must stop. Cells begin reconstructing the bone by laying down matrix. Proteins and mineralization factors produced by the osteoblasts (bone forming cells) begin to consolidate into what is known as a soft callus.



Stage 3: Formation of hard callus

Osteoblasts (bone building cells) mineralize the bone matrix, converting soft callus into hard callus.



Stage 4: Remodeling

The bone is remodeled into a stronger bone by the action of osteoblasts (bone building cells) and osteoclasts (bone resorption cells). Eventually, the fracture callus is remodeled into a new shape which closely duplicates the bone's original shape and strength.

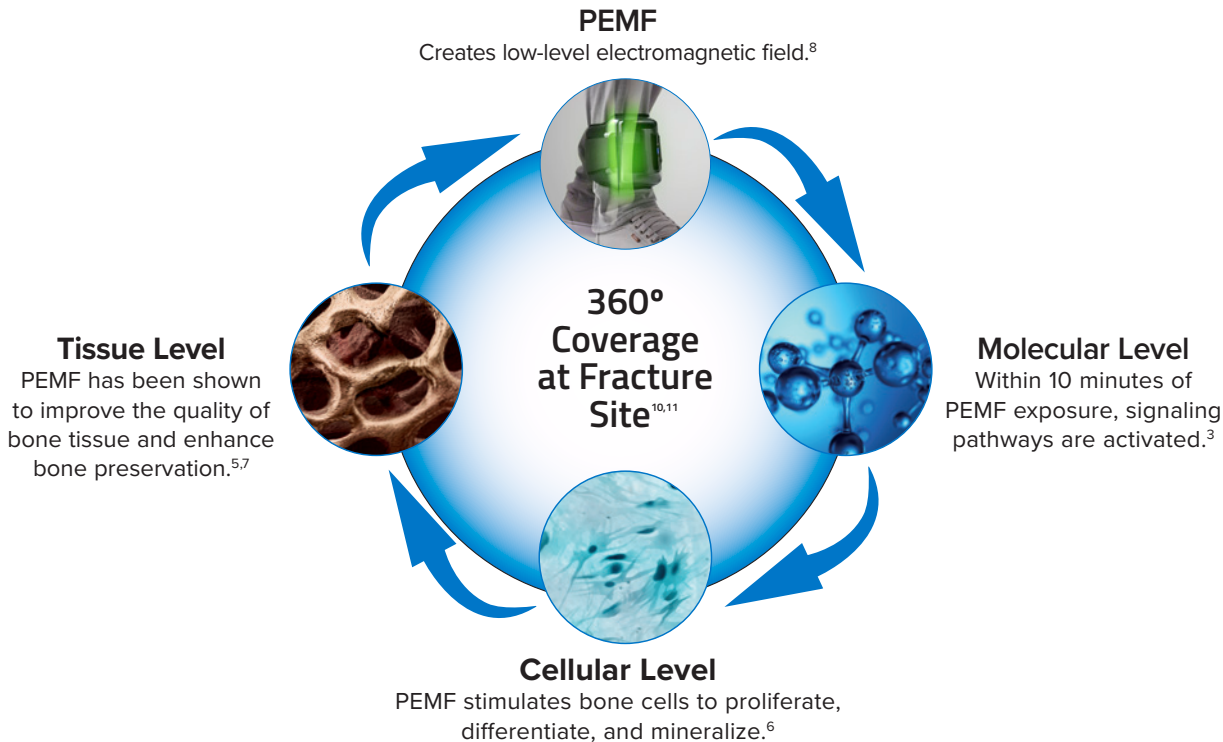


PEMF and the Healing Process

The result of these molecular, cellular and tissue processes is improved healing rates of a nonunion fracture.

Published preclinical research shows that PEMF affects the bone healing processes at the molecular, cellular and tissue levels.³⁻⁷ At the cellular level, the PEMF signal activates bone growth signaling pathways, which enhances bone formation (Stage 2 and 3 on page 5) by increasing both the bone building cell population and maturity.^{3,6} At the tissue level this leads to stronger, higher density bone.^{5,7}

The PEMF signal is produced from a coil built into a fabric garment of the PhysioStim device that is worn over the fracture site. The garment can be worn over clothing, casts, or internal and external surgical fixation devices.



The PhysioStim Device

The PhysioStim bone growth therapy device is FDA approved to be used for the treatment of nonunion fractures.¹ A nonunion is a fracture that has shown no visible signs of healing. For complete prescribing information, please visit our website at BoneGrowthTherapy.com. This single-piece device is lightweight, flexible and portable, allowing freedom of movement during treatment. The typical prescribed treatment time is three hours per day. An LCD and audible alarm provide important feedback during treatment such as the operational status, treatment time remaining, battery capacity, etc.

Product Features and Benefits:

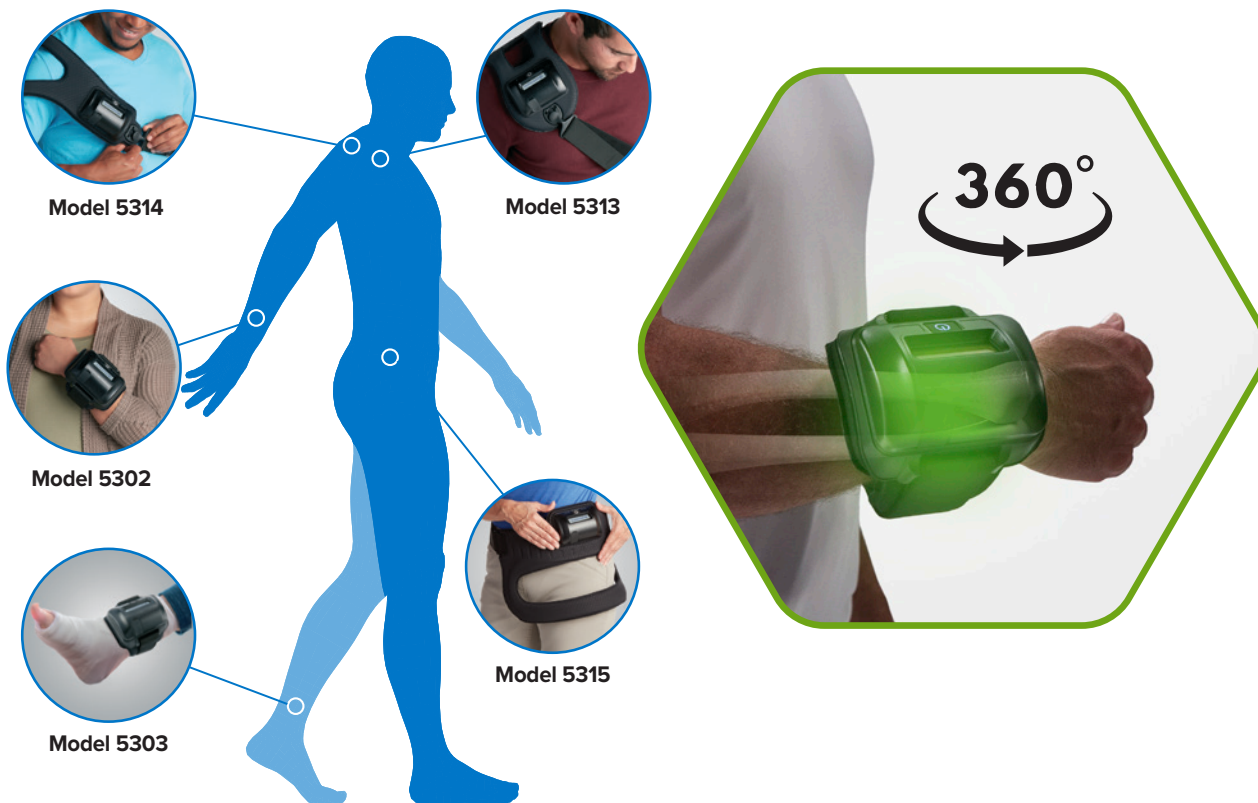
Variety of anatomically designed models

- 360 degrees of PEMF treatment around the fracture site that evenly penetrates across tissue, bone and fixation⁹⁻¹⁰
- Single-piece, cordless design that allows for ease of placement and patient mobility
- Effective delivery of treatment when worn over clothing, casts and boots



The PhysioStim Device

With high clinical success rates, the PhysioStim device provides 360 degrees of treatment coverage around the fracture site to aid in bone healing.^{1,9,11}



Why Do Physicians Prescribe PhysioStim Devices?

- #1 Prescribed Bone Growth Stimulator^{12,13}
- High clinical success rates^{1,2,11}
- Increases success rates in nonunion fracture patients^{1,2,11}
- PEMF signal covers 360 degrees around the fusion site that evenly penetrates across tissue, bone and fixation^{9,10}
- The STIM onTrack™ app and DIRECT™ Physician Portal allow physicians to monitor patient compliance data to prescribed treatments remotely.



Healing Success in Common Nonunion Sites¹¹

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



How Does Low-Intensity Pulsed Ultrasound (LIPUS) Work?

The AccelStim™ device provides a safe and effective nonsurgical treatment to improve nonunion fracture healing and accelerate the healing of indicated fresh fractures.* The device stimulates the bone's natural healing process by low-intensity pulses of ultrasound (LIPUS) waves to the fracture site.¹⁵⁻¹⁷

Phases of Bone Healing



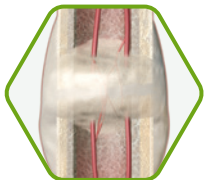
Stage 1: Inflammation

When a bone breaks, the body sends out signals for special cells to come to the injured area. These cells are known as osteoclasts (bone resorption cells). Some of these cells cause the injured area to become inflamed (red, swollen, and painful). This tells the body to stop using the injured part so that it can heal. Other cells come to this area during this stage and form a hematoma (blood clot) around the broken bone.



Stage 2: Formation of soft callus

Within days of the fracture, capillaries grow into the hematoma (blood clot), while phagocytic cells begin to clear away the dead cells. This stops the inflammatory response and begins the reconstructing of the bone which proteins and mineralization factors produced by osteoblasts (bone building cells) consolidate into what is known as soft callus.



Stage 3: Formation of hard callus

As osteoblasts (bone building cells) create new bone by adding minerals to transform soft callus into hard callus.



Stage 4: Bone Remodeling

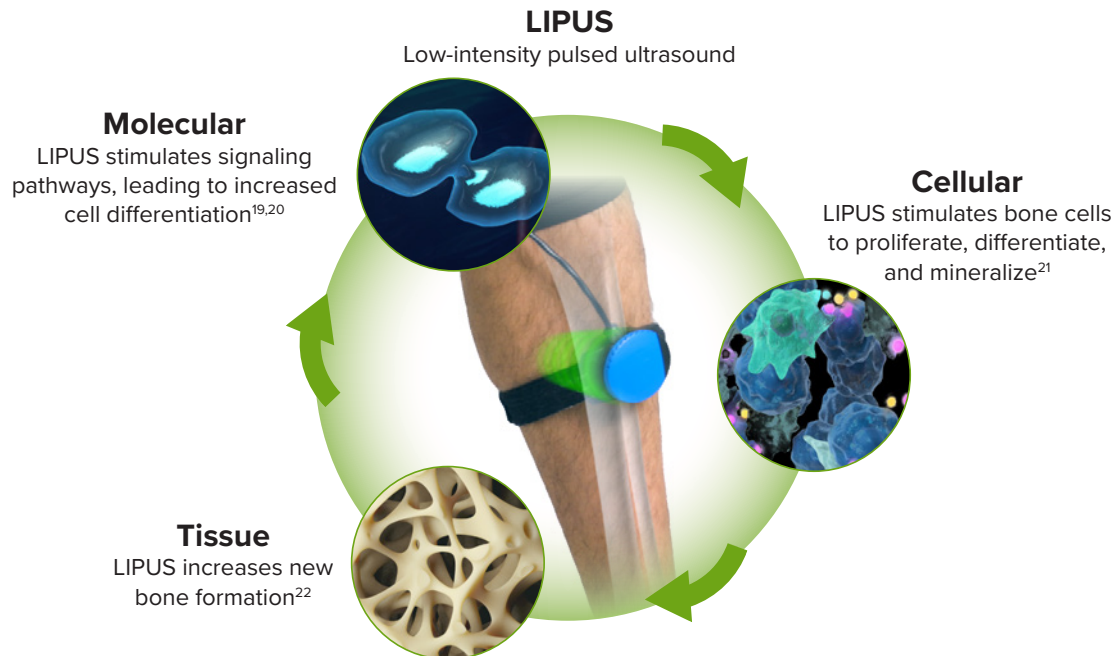
The bony callus is remodeled by osteoclasts (bone resorption cells) and osteoblasts (bone building cells) to create harder and stronger bone until it is completely healed and returned to its original shape.

LIPUS Amplifies Bone Healing

AccelStim accelerates fracture healing by alternating molecular and cellular mechanisms involved in each stage of the healing process.

Clinical studies have successfully shown to resolve 86%¹⁷ nonunion fractures and treatment induced a 38%¹⁶ acceleration in achieving the prospectively defined primary end-point of a combination of clinical and radiographic healing.¹⁴⁻¹⁸ LIPUS has been demonstrated to accelerate in vivo all stages of the fracture repair process (inflammation, soft callus formation, hard callus formation, and bone remodeling). The intensity and frequency of the applied LIPUS signal is effective to accelerate the osteogenetic process therefore reducing the healing times.

The LIPUS signal transmitted is an acoustic vibration with frequency above human auditory level, meaning the device is silent. The AccelStim device transmits this signal by means of an ultrasound transducer which is then applied to the area needing treatment.



The AccelStim Device

The AccelStim bone growth therapy device is FDA-approved to be used for the treatment of nonunion fractures and to accelerate the healing of specific fresh fractures.^{15-17,23} A doctor commonly prescribes an Orthofix bone growth therapy device to aid in the bone healing process for patients who have not healed or may have difficulty healing. For complete prescribing information, please visit our website at BoneGrowthTherapy.com.

The AccelStim device has a recommended prescribed daily treatment time of 20 minutes per day.

Product Features and Benefits:

Accelerates Fracture Healing Recovery

- Overall clinical success rate of 86%¹⁷ for nonunion fractures
- Lightweight, small, portable device,
- Rechargeable lithium ion battery
- Daily Treatment Calendar
- Audible and Visual feedback during treatment
- Automatic shut-off feature when a treatment is complete



**Accelerate Bone
Healing, Optimize
Patient Outcomes**



Why Do Physicians Prescribe the AccelStim Device?

- 38% Acceleration in Healing for indicated fresh fractures.¹⁶
- LIPUS direct signal to the fracture site.
- The STIM onTrack app and DIRECT Physician Portal allow physicians to monitor patient compliance data to prescribed treatments remotely.



**BEST NEW TECHNOLOGY SOLUTION
- ULTRASOUND -**

STIM onTrack Mobile App

A Smarter Approach to Therapy Management

The STIM onTrack app is a patient-friendly accessory available for you to use with your Orthofix Bone Growth Therapy device that encourages you to adhere to treatment sessions prescribed by your physician. It features a daily treatment reminder and a device usage calendar to help you take an active role in your bone healing recovery. Studies show that patients who are more involved with their follow-up care have an overall better recovery experience and better outcomes. At the time of device delivery, your Orthofix representative will help you download the application to your mobile device.

Features:

- Daily Treatment Reminders
- Treatment Calendar to display daily usage to help patients stay on schedule with their treatments
- Patient Reported Outcome Measure
- Educational Patient Resources and Connecting
- Message with our Patient Care team for help ensure patients understand their treatment regimens

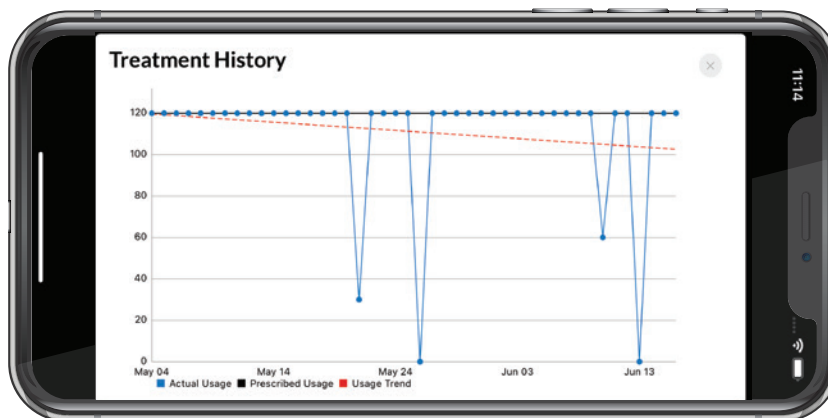
*Your Recovery, Simplified
Stay on Track with
STIM onTrack.*



Patient Reported Outcome Measure (PROM):

The Charts Tab on the STIM onTrack app includes Treatment Compliance and Patient Reported Outcome Measure (PROMs) tools which enable you to share the treatment history, your quality of life, and functional status. The details displayed are from information provided throughout your treatment and can be shared with your prescribing Physician.

- These questionnaires are validated tools that are widely used by healthcare providers
- The responses may be used by your healthcare provider to assist in understanding your current overall recovery status**
- If the PhysioStim or AccelStim device is prescribed, the Upper Extremity Functional Index (UEFI) and the Lower Extremity Functional Scale (LEFS) are available. The location of your bone fracture will determine which questionnaire is applicable. This will be discussed at the time of your device fitting with your Bone Growth Therapy representative



* STIM onTrack mobile app is available as an accessory for U.S. model devices only

** Information collected via the STIM onTrack mobile app is not intended for the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease.





Orthofix Guarantee Program

Some patients who experience bone injuries and spinal fusion surgery have difficulty healing. In many of these cases, there are certain health factors that may have impaired the natural healing process of the bones. To help overcome healing challenges, doctors commonly prescribe a treatment called bone growth therapy, otherwise known as bone growth stimulation.

Orthofix Bone Growth Therapy devices provide a safe, noninvasive treatment that helps promote healing in fractured bones and spinal fusions that have not healed or have difficulty healing. The devices stimulate the bone's natural healing process by sending low-level pulses of electromagnetic energy or ultrasound waves to the injury or fusion site.^{1,3-5 23}

Orthofix Bone Growth Therapy devices are prescribed with a Guarantee Program which states that when prescribed for an approved FDA indication and when other eligibility requirements are met, radiographic progress will be shown in fracture healing or fusion, or the fee paid for the unit will be refunded to the payer(s) of record** or, at the direction of the originally prescribing physician, a one-time replacement unit can be provided.

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 requirements.





Commonly Asked Questions

Below are common questions asked by real patients, just like you!

Am I a candidate for bone growth therapy?

Doctors may prescribe bone growth therapy for patients who are experiencing bone healing complications resulting in a nonunion.

What happens after my doctor prescribes a bone growth therapy device?

If your doctor prescribes an Orthofix bone growth therapy device, an Orthofix representative will contact you to schedule an appointment – either at your doctor’s office or at your home to explain the benefits of the device, how it works, insurance requirements, and to ensure that it is properly fitted. For a complete guide of what to expect after a device has been prescribed for you, watch our Patient Fitting Video located under FAQs & Resources on our website at BoneGrowthTherapy.com.

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

Some patients who experience bone injuries and spinal fusion surgery have difficulty healing. In many of these cases, there are certain health factors that may have impaired the natural healing process of the bones. To help overcome healing challenges, doctors commonly prescribe a treatment called bone growth therapy, otherwise known as bone growth stimulation.

AccelStim device: The AccelStim device provides noninvasive therapy for healing nonunions and accelerating time to healing of fresh, closed, posteriorly displaced distal radius fractures or closed or grade I open tibial diaphysis fractures. The AccelStim device transmits a low-intensity ultrasound signal to the fracture site through coupling gel, with little or no sensation felt by the patient during the treatment. Low-intensity pulsed ultrasound has been shown in in-vitro and in-vivo studies to stimulate cells to produce growth factors and proteins that are important to bone healing.

PhysioStim device: The PhysioStim device provides a safe, noninvasive option for treating fractures that are difficult to heal. With high clinical success rates, the PhysioStim device provides 360 degree of treatment coverage around the fracture site. The device assists in fracture healing by delivering a pulsed electromagnetic field (PEMF) signal to the targeted fracture site.

Will AccelStim help heal my fracture?

Clinical studies show that nonunion fractures (breaks not healing on their own) healed at a high rate of 86%¹⁷ and sped up healing of indicated fresh fractures (newly broken bone) by 38%.¹⁶

How long will it take to heal?

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 to nine months.

Can I wear the device over a cast, brace, or clothing?

AccelStim device: No. Ultrasound waves cannot travel through cast, braces, air, or clothing. The AccelStim transducer requires direct contact with skin and the use of the supplied coupling gel (included with your device).

PhysioStim device: Yes, it can be worn over clothing, casts, or internal and external surgical fixation devices without affecting the PEMF signal as it travels through the body to the fracture site.

Can I use AccelStim if I have a pacemaker?

The operation of active, implantable devices such as cardiac pacemakers may be adversely affected by the close exposure to the AccelStim device. If you have a pacemaker, talk with your doctor or a cardiologist to find out if AccelStim is right for you.

How will I know if the device is working?

AccelStim device: Your device is properly working when you see the display screen counting down from 20 minutes during each treatment. Your physician will update you on your healing status at follow-up appointments.

PhysioStim device: Both the blue indicator light and the colon between hours and minutes on the display screen will flash to show active status. Once your daily treatment is complete, a check mark will show up on the display screen next to the “Rx”.

What is my daily treatment time?

Your doctor will prescribe a daily treatment time based on your needs:

AccelStim device: The AccelStim device is typically worn for 20 minutes a day

PhysioStim device: The PhysioStim device is typically worn for three hours per day.

Who do I call if I have questions?

You may call the Orthofix Patient Care line at 800.535.4492.

Will my insurance company pay for the device?

Coverage for the device depends upon your specific insurance plan. If coverage guidelines are met, the AccelStim and PhysioStim device is accepted and approved by the majority of private and public health plans, including Medicare, Medicaid and workers' compensation plans. Some plans include a deductible, copayment, or other coinsurance amount. In addition, we encourage patients to contact their insurance company for details in regards to health care coverage.

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

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.

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 our Patient Care Billing Specialists. If you have not already made prior payment arrangements and you receive a statement, please contact our Patient Care Billing Specialists at 800.535.4492 to discuss your payment options and/or arrangements.

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

Please contact our Patient Care Billing Specialists at 800.535.4492 to discuss questions about billing or financial assistance.

Is treatment painful? How will it affect my daily activities?

AccelStim device: Most patients do not feel anything at the treatment site, while some patients report experiencing a tingling sensation. Please contact Patient Care at 800.535.4492 with questions or comments.

PhysioStim device: You should not feel the PEMF therapy. The device is lightweight for a comfortable fit, and powered with a rechargeable lithium battery, which allows the unit to be portable. You can sit, stand, sleep, walk, recline, and drive while using the PhysioStim device. With your doctor's approval, you can resume normal activity level while wearing the device.

What if I run out of coupling gel?

If you need more gel, please call Patient Care at 800.535.4492.



Brief Prescribing Information

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.

The **AccelStim™ device** is indicated for the non-invasive treatment of established nonunions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

Full prescribing information can be found in product labeling on our patient education website BoneGrowthTherapy.com or by calling Patient Care at 800.535.4492.

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



References

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

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