PhysioStim™
Bone Healing Therapy

Redefining *your* ***Recovery*** *experience*

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

ORTHOFIX®

On the cover: Helen, a PhysioStim device patient, enjoys fishing and walking on the beach with her family.

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What is Bone Growth Therapy?

In some patients who have a fracture, the bone(s) may not mend properly and a nonunion results. To help overcome this healing challenge, doctors commonly prescribe a treatment called bone growth therapy, also known as bone growth stimulation.

Electrical currents have been used to heal bones since the mid-1800s. However, it wasn't until the1950s when scientists discovered that if a bone is bent or broken, it generates an electrical field. This low-level electrical field activates the body's own repair mechanism which, in turn, promotes bone healing. When this healing process fails to occur naturally, bone growth therapy can be used to help the process.[1-3]

Orthofix bone growth therapy devices have been prescribed since the late 1980s and provide a safe, noninvasive treatment that helps promote the healing of nonunion fractures 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 to the fracture site.[4-7]

"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?

Orthofix bone growth therapy devices create a low-level pulsed electromagnetic field, which helps promote the body's natural healing process.[1-3]

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 (blot 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.[5-9] 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.[5,8] At the tissue level this leads to stronger, higher density bone.[*7,9]

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.

PEMF
Creates low-level electromagnetic field.[*1]

Tissue Level
PEMF has been shown to improve the quality of bone tissue and enhance bone preservation.[*7,9]

Molecular Level
Within 10 minutes of PEMF exposure, signaling pathways are activated.[*5]

Cellular Level
PEMF stimulates bone cells to proliferate, differentiate, and mineralize.[*8]

The PhysioStim Device

The PhysioStim bone growth therapy device is FDA approved to be used for the treatment of nonunion fractures.[4] A nonunion is a fracture that has shown no visible signs of healing. For complete prescribing information, please visit our website at BoneGrowthTherapy.com.

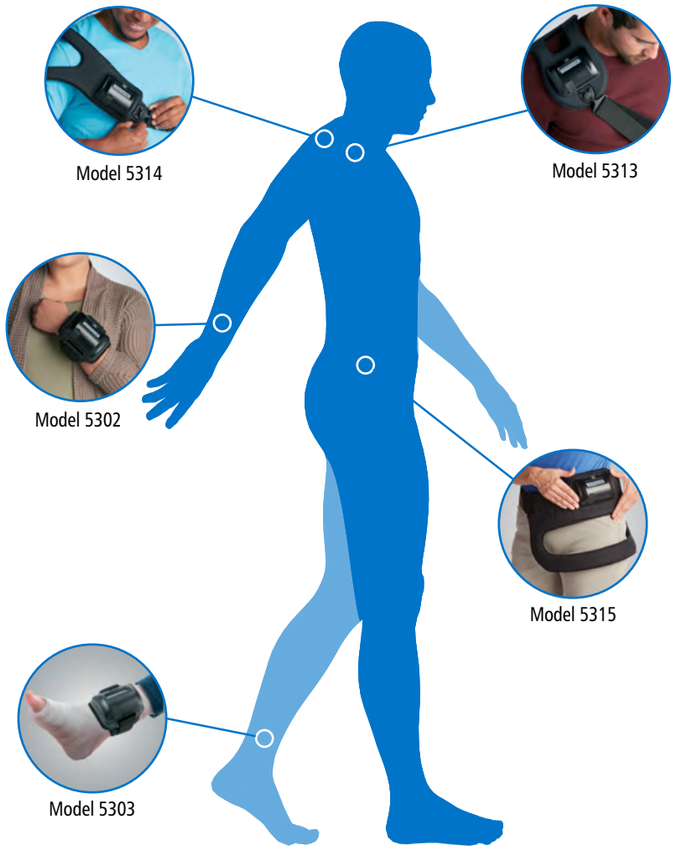
This single-piece device is lightweight, flexible and portable, allowing freedom of movement during treatment. The typical prescribed treatment time is three hours per day. An LCD and audible alarm provide important feedback during treatment such as the operational status, treatment time remaining, battery 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 fixation [10,11]
- Single-piece, cordless design that allows for ease of placement and patient mobility
- Effective delivery of treatment when worn over clothing, casts and boots
- Accompanied by the STIM onTrack™ Mobile App which provides patients with a treatment calendar, therapy reminder, outcome measurement questionnaires and additional educational resources

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.[4,10,12]



Healing Success in Common Nonunion Sites[12]	
Femur	84.2%
Fibula	91.4%
Metatarsal	90.9%
Tibia	89.0%
Ulna	96.1%
Radius	93.8%

Why Do Physicians Prescribe PhysioStim Devices?

- High clinical success rates [4,12,15]
- Increases success rates in nonunion fracture patients [4,12,15]
- PEMF signal covers 360 degrees around the fusion site that evenly penetrates across tissue, bone and fixation [10,11]
- The STIM onTrack Mobile App and Orthofix Proprietary Physician Portal enables physicians to remotely view patient adherence to prescribed treatments.

#1 ORTHOFIX PEMF BONE GROWTH THERAPY DEVICES
PRESCRIBED
BONE GROWTH STIMULATORS [13,14]

STIM onTrack Mobile App

The STIM onTrack™ Mobile 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.

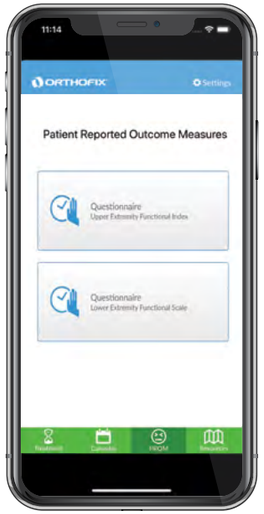
Features:

- Daily treatment reminders
- View a duplicate display of the device
- Tracks real-time usage data
- Links to educational patient resources
- Treatment calendars
- Quality of life questionnaire
  -Patient Reported Outcome Measure

Patient Reported Outcome Measure (PROM):

The PROM Tab on the STIM onTrack Mobile App enables patients to complete a specific standardized Patient Reported Outcome Measure (PROM) questionnaire to remotely share measures of their quality of life and/or functional well-being with their 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**
- The questionnaire available to complete is dependent on your type of bone growth therapy device prescribed for use
  - PhysioStim device with upper body placement-Upper Extremity Functionality Index (UEFI)
  - PhysioStim device with lower body placement-Lower Extremity Functional Scale (LEFS)



* 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

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 healing, 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 your bone growth therapy device with confidence.

**Subject to eligibility requirements.

THE Healing ADVANTAGE® GUARANTEE PROGRAM

"The simple things you appreciate. I can play with the grandchildren. I can go fishing again. I can run up and down barefoot. And it's wonderful."

- Helen, a PhysioStim device patient

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 Next Steps on our website at BoneGrowthTherapy.com.

Why doctors and patients choose Orthofix bone growth therapy devices:

- High clinical success rates
- Designed for patient comfort and ease of use
- 360 degrees of PEMF treatment
- Effective in the presence of internal and external fixation

Is bone growth therapy safe?

Yes. Our bone growth therapy device produces 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 device 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 a million Orthofix patients have worn our stimulators to increase the probability of healing success. For full prescribing information, see the manual that came with your device or visit www.BoneGrowthTherapy.com.

What will treatment feel like? How will it affect my daily activities?

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

Can I wear the device over a cast?

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.

How do I know if my device is working?

Both the blue treatment 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".

Commonly Asked Questions

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.

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 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.

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

Please contact our Patient Care Billing Specialists at 1-866-543-9340 to discuss payments options and to see if you may be eligible for the Orthofix patient financial assistance program for people who demonstrate financial need based on established guidelines.

When I am done with treatments, what do I do with my device?

Orthofix bone growth therapy devices should only be used by the person for whom it is prescribed. Bone Growth therapy devices expire after 365 days of treatment. The device is yours to keep once your treatment is complete. To help reduce waste, Orthofix is happy to help you recycle your bone growth therapy device after your treatment is complete and your physician has advised you to discontinue use. Please contact Patient Services at 1-800-535-4492 for further information on our free recycling program.

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.

Full prescribing information can be found in product labeling on our patient education website, BoneGrowthTherapy.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.

References

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

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Notes

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