

Q: Will my insurance company pay for the device?

A: Coverage for the device depends upon your specific insurance plan. If coverage guidelines are met, the AccelStim and PhysioStim devices are 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.

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 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. If you have not already made prior payment arrangements and you receive a statement, please contact our Patient Care Billing Specialists at 1.800.535.4492 to discuss your 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 the FAQ section on Billing and Insurance Coverage at BoneGrowthTherapy.com for details.

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

A: Please contact our Patient Care Billing Specialists at 1.800.535.4492 to discuss questions about billing or financial assistance.

Q: Who do I call if I have questions?

A: You may call the Orthofix Patient Care line at 1.800.535.4492.

References

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

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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 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.

Brief Prescribing Information:

AccelStim Bone Healing Therapy

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 adult individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

The PhysioStim Device

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 www.BoneGrowthTherapy.com or by calling Patient Care at 1.800.535.4492.

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

Orthofix Recycles

Please contact Patient Care at 1.800.535.4492 or learn more on our website for further information on our free recycling program.



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A Patient's Guide to Bone Growth Therapy

Frequently Asked Questions for Nonunion Fractures & Indicated Fresh Fractures



PhysioStim™
Bone Healing Therapy



AccelStim™
Bone Healing Therapy



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

A: AccelStim device: No. Ultrasound waves cannot travel through casts, braces, air or clothing. The AccelStim transducer requires direct contact with skin along with the coupling gel provided with your device. If you have a cast, please contact Patient Care as an accessory may be available.

PhysioStim device: Yes, it can be worn over a cast, brace, and clothing without affecting the PEMF signal to the treatment area.

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 at 12:00 midnight, Central Time, unless adjusted for your time zone.

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

A: 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 1.800.535.4492 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.



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

A: 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.

Q: What should I do with my device once I've completed treatment?

A: You own the unit, so you can keep it or recycle it to 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 Care at 1.800.535.4492 or visit our website for further information on our free recycling program.

Q: How will I know if the device is working?

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

Q: Is bone growth therapy safe?

A: Yes. Our bone growth stimulation devices produce a signal like the one your own body generates to induce normal bone healing.

For full prescribing information, see the product manual that came with your device or visit BoneGrowthTherapy.com.

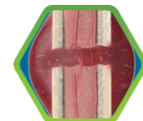
Q: How does bone growth therapy work?

A: Fracture healing is a complex metabolic process that depends on various factors. If these factors are inadequate or interrupted, the healing of fractures may be delayed or impaired.

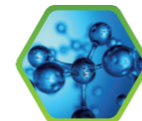
In cases of nonunion, where the fracture fails to show evidence of healing, or in patients who have undergone spinal fusion surgery, requiring additional treatment options, bone growth therapy may be prescribed by doctors.

Orthofix Bone Growth Therapy devices offer a safe, noninvasive treatment to promote healing in fractured bones and spinal fusions that have not healed or are struggling to heal. These devices stimulate the bone's natural healing process by emitting low-level pulsed electromagnetic or ultrasound waves, which can help the bone to heal more quickly.

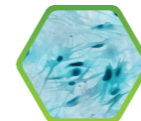
For more information on bone healing for the AccelStim and PhysioStim devices and how it works, visit BoneGrowthTherapy.com.



Hematoma



Formation of Soft Cells



Formation of Hard Cells



Remodeling

The FAQ sheet is provided for information purposes only and does not constitute medical advice, if you have any questions about your treatment plan, contact your physician or medical professional.

Q: What is my daily treatment time?

A: 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.

Q: Can I use the AccelStim device if I have a pacemaker?

A: The operation of active, implantable devices, such as cardiac pacemakers, may be adversely affected by 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.

Q: What if I run out of coupling gel?

A: If you need more gel, please call Patient Care at 1.800.535.4492.

Q: What if I do not place the AccelStim transducer in exactly the right spot?

A: Best results are achieved when the AccelStim transducer is placed at the location marked by your physician. Consult with your physician if you are unsure of where to place the transducer.

