

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

A: 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 Services as an accessory may be available.

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 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.

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 Services line at 1-800-535-4492.

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

1. Nolte PA, van der Krans A, Patka P, Janssen IMC, Ryaby JP, Albers GHR. Low-intensity pulsed ultrasound in the treatment of nonunions. J Trauma. 2001;51(4):693-703.
2. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. J Bone Joint Surg. 1997;79- A(7):961-973.
3. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. J Bone Joint Surg. 1994;76- A(1):26-34.
4. Parvizi J, Wu CC, Lewallen DG, Greenleaf JF, Bolander ME. Low-intensity ultrasound stimulates proteoglycan synthesis in rat chondrocytes by increasing aggrecan gene expression. J Orthop Res: official publication of the Orthopaedic Research Society. 1999;17 (4): 488e494. <https://doi.org/10.1002/jor.1100170405>. PubMed PMID: 10459753
5. Azuma Y, Ito M, Harada Y, Takagi H, Ohta T, Jingushi S. Low-intensity pulsed ultrasound accelerates rat femoral fracture healing by acting on the various cellular reactions in the fracture callus. J Bone Miner Res. 2001;16(4):671-80.
5. Gurkan UA, Akkus O. The mechanical environment of bone marrow: a review. Ann Biomed Eng. 2008; 36(12): 1978e1991. <https://doi.org/10.1007/s10439-008-9577-x>. PubMed PMID: 18855142
6. Wang, Y.; Peng, W.; Liu, X.; Zhu, M.; Sun, T.; Peng, Q.; Zeng, Y.; Feng, B.; Zhi, W.; Weng, J.; et al. Study of bilineage differentiation of human-bone-marrow-derived mesenchymal stem cells in oxidized sodium alginate/N-succinyl chitosan hydrogels and synergistic effects of RGD modification and low-intensity pulsed ultrasound. Acta Biomater. 2014, 10, 2518-2528.
7. PMA P210035. May 2022.

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.

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



A Patient's Guide to Bone Growth Therapy

Frequently Asked Questions



ORTHOFIX Recycles

Please contact Patient Services at 1-800-535-4492 for further information on our free recycling program.



Orthofix.com
BoneGrowthTherapy.com

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AccelStim™

Bone Healing Therapy



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

A: The AccelStim Bone Growth Therapy Device provides non-invasive 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.⁷ 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.

Q: What should I do with my AccelStim 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 Services at 1-800-535-4492 for further information on our free recycling program.



Tibia/Fibula 89.6%⁸



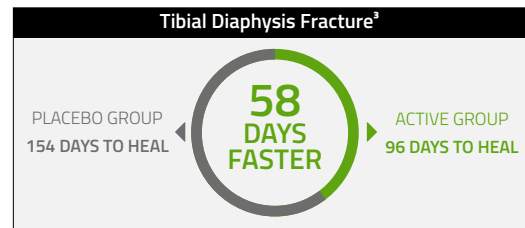
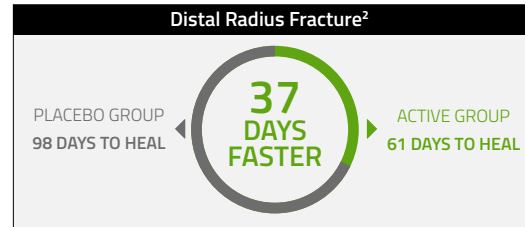
Hand/Wrist 91.8%⁹



Scaphoid 92.2%¹⁰

Q: Will AccelStim help heal my fracture?

A: Clinical studies show that nonunion fractures (breaks not healing on their own) healed at a high rate of 86%^{1,7} and sped up healing of indicated fresh fractures (newly broken bone) by 38%.^{2,3,7}



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

A: Your device is working properly 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.

Q: What if I can't do my treatment at the same time every day?

A: It is better to do daily treatment than to skip a treatment day. Resume treatment at the same time the following day as your schedule allows.

Q: How long will it take to heal?

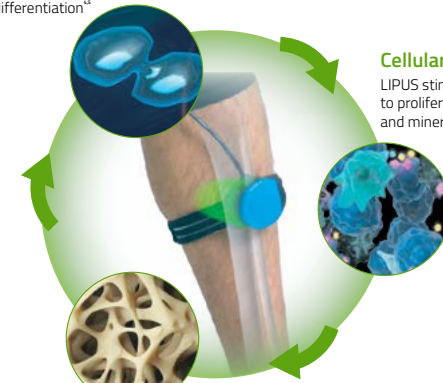
A: The healing process itself determines the duration of the treatment, and your doctor will closely monitor your progress. To promote your healing, it is very important that you wear your bone growth therapy device daily as prescribed. Patients are instructed to wear their device until their doctor confirms they are healed. Although your treatment may vary, most patients wear the bone growth therapy device between three and nine months.

Q: Will having two or more treatments per day result in better or faster healing?

A: Clinical studies have evaluated the effectiveness of the AccelStim device with one 20-minute treatment per day. Multiple or longer-duration daily treatments have not been studied.

Molecular:

LIPUS stimulates signaling pathways, leading to increased cell differentiation⁴



Cellular:

LIPUS stimulates bone cells to proliferate, differentiate, and mineralize⁵

Tissue:

LIPUS increases new bone formation⁶

Q: What if I miss a treatment?

A: If a treatment is missed, try to get back on a schedule as soon as possible. To stay consistent with your treatments, check the daily treatment calendar on your device to identify a convenient time to use the AccelStim device each day and help you take an active role in your bone healing recovery.

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 Services at 1-800-535-4492.

Q: Is the AccelStim device treatment painful?

A: Most patients do not feel anything at the treatment site, while some patients report experiencing a tingling sensation. Please contact Patient Services at 1-800-535-4492 with questions or comments.

Q: What is my daily treatment time?

A: Your doctor will prescribe a daily treatment time based on your needs. The AccelStim device is typically worn daily for 20-minutes per treatment.

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.

