AccelStim™
Bone Healing Therapy

THE Healing ADVANTAGE®

The AccelStim Device Certificate of Limited Guarantee

The AccelStim™ device is prescribed with a Guarantee Program which provides that if healing is not shown, then, as described in the terms and conditions below, either 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 helps increase a patient's opportunity to heal.

The AccelStim device provides patients with a safe, non-surgical treatment to improve the healing of established nonunion fractures 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.[1] The device uses a low intensity pulsed ultrasound (LIPUS) to help activate the body's natural healing process. Scientists studied the effectiveness of LIPUS and determined an overall clinical success rate in the treatment of nonunion fractures of 86%. These patients wore the device 20 minutes per day for an average of 152 days (22 weeks) of treatment.[2] Patients should wear the AccelStim device as prescribed by their physician.

Terms and Conditions of the AccelStim Device Limited Guarantee

Eligibility Requirements

- The AccelStim device must be prescribed for an FDA approved indication (see Brief Prescribing Information below).
- The patient must use the AccelStim device for at least 20 minutes per day for a minimum treatment period of 180 days.
- The patient must be at least 90% compliant with the AccelStim device treatment from the time the device was applied until the date of the radiographic assessment.

Guidelines for Assessment and Additional Eligibility Requirements

- All eligibility requirements must be fulfilled and met.
- Radiographs (baseline and current) to assess the progression of bony union will be required. Progression of bony union comparison radiographs must be taken prior to the AccelStim device application (baseline) and on the evaluation date (current) after the minimum treatment period. Progression of bony union will be determined by the prescribing physician's (or physician's appointed radiologist) written evaluation of radiographs.
- Progression of bony union is considered to have occurred if the physician's evaluation indicates the following on any radiographic view:
  - cortical and/or trabecular bridging with modification of the radiolucent gap
  - overall callus progression
- Full payment for the device must have been received by Orthofix.
- Compliance will be determined by the treatment of record stored on the AccelStim device.
- The AccelStim device Limited Guarantee claims must be received by Orthofix within 18 months after the AccelStim device treatment began.
- If an AccelStim device is deliberately rendered inoperable or altered in any way it will be excluded from the guarantee and will not be eligible for a refund.
- The Guarantee Program is void if alternative interventions occur during the 180-day treatment period. If alternative intervention is needed, a new 180-day treatment period begins.

Claim Submission

For additional information regarding the AccelStim device Limited Guarantee program, please contact Orthofix Patient Services at (800) 535 4492 or 3451 Plano Parkway, Lewisville, TX 75056. Claim submission, appropriate documentation, and returned device must be received within 18 months after the AccelStim device treatment began. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or devices. This limited guarantee gives the payer(s) of record specific legal rights, and such person(s) may also have other rights, which vary from state to state. Orthofix reserves the right to discontinue or modify the AccelStim device Limited Guarantee Program at any time.

* Subject to eligibility requirements. Refund of payment is not applicable for Wholesale Orders since the Certificate and Guarantee may not be transferred to another physician, patient, or payer. Orthofix must be the direct supplier of the device to the patient for the Limited Guarantee to be applicable.

1. PMA P210035

2. Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH. Low-intensity pulsed ultrasound in the treatment of nonunions. J Trauma. 2001;51(4):693-703.

Brief Prescribing Information:

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. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing. Some patients may be sensitive to the ultrasound gel.

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.

Orthofix.com
BoneGrowthTherapy.com

P/N 20126755 Rev AB 2022-02-28
AS-2104 © Orthofix US LLC 2/2022

ORTHOFIX®