PHYSIOSTIM™
BONE HEALING THERAPY

ORTHOFIX WRITTEN GUARANTEE

The PhysioStim Device Certificate of Limited Guarantee

The PhysioStim™ device is prescribed with a Guarantee Program if healing is not shown, as described in and under the terms below, or the fee paid for the unit will be refunded to the payer(s) of record.* 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 PhysioStim device provides patients with a safe, non-surgical treatment to improve fracture healing of specific nonunion fractures. The device uses a low-level, pulsed electromagnetic field (PEMF) to help activate the body's natural healing process. Scientists studied the effectiveness and determined an overall clinical success rate of 80 percent (up to 88 percent for fracture gaps less than 3mm) for consistent users of the PhysioStim device. Consistent users were defined as patients that wore the PhysioStim device at least 3 hours a day for up to 180 days of treatment.[1-2] Patients should wear the PhysioStim device as prescribed by their physician.

Terms and Conditions of the PhysioStim Device Limited Guarantee

Eligibility Requirements

- The PhysioStim device must be prescribed for a FDA approved indication.
- The patient must use the PhysioStim device for at least three hours per day for a minimum treatment period of 180 days.
- The patient must be at least 90% compliant with the PhysioStim 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 PhysioStim 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 PhysioStim device.
- The PhysioStim device Limited Guarantee claims must be received at Orthofix within one year after the PhysioStim device treatment began.
- If a PhysioStim device is deliberately rendered inoperable or altered in any way will be excluded from the guarantee and will not be eligible for a refund.

Claim Submission

For additional information regarding the PhysioStim 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 one year after the PhysioStim 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 PhysioStim 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 P850007. February 1986. 2. Garland DE, Moses B, Salver W. Fracture healing: Long-term follow-up of fracture nonunions treated with PEMFs. Contemp Orthop. 1991;22(3):295-302

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.

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BoneGrowthTherapy.com
orthofix.com
1.800.535.4492

ORTHOFIX®