

Limited Guarantee



PEMFs: A Twenty-Year Record of Success

Low-energy, time-varying magnetic fields (commonly referred to as pulsed electromagnetic fields or PEMFs) have been proven effective in promoting bony arthrodeses in fracture non-unions. The application of PEMF has been scientifically proven to be as effective as surgical intervention with bone grafts.^{1,2,3}

As a leader in the field of advanced devices for bone healing, Orthofix has witnessed the growing acceptance of PEMF technology as a safe, useful, and cost-effective treatment for the management of fractures. The Physio-Stim Limited Guarantee Program permits physicians to prescribe and providers to approve PEMF therapy with confidence, and patients to be assured of healing.

The Program

The Physio-Stim Limited Guarantee Program provides physicians, insurance carriers and patients with a proven method to promote healing of fracture non-unions. *The Program guarantees that radiographic and/or subsequent complete bony union will be shown in fracture non-unions or the fee paid for the Physio-Stim unit will be refunded to the payer(s) of record.*

Guidelines for Assessment of Healing Progress

Progression of bony union,* or the absence of progression, and complete bony union,** or the absence of complete bony union, will be determined by the prescribing physician's (or physician's appointed radiologist's) written evaluation of X-rays taken prior to fitting of the Physio-Stim unit and again at Day 120 (or beyond) and 180 days, respectively of Physio-Stim treatment (evaluation date). If evaluations confirm the absence of progression by 120 days or the absence of complete bony union by 180 days, the refund claim will be processed.

Eligibility Requirements

All non-union cases for which Physio-Stim is prescribed are eligible for the Physio-Stim Limited Guarantee Program, subject to the following conditions:

- Physio-Stim is prescribed for an approved indication that meets the following criteria:
 - a. Fracture gap is less than one-half the width of the bone to be treated, not to exceed 1 cm.
 - b. Synovial pseudarthrosis is not present.
- Treatment with Physio-Stim continues for a minimum of 120 consecutive days for determination of progression of

bony union or treatment with Physio-Stim continues for a minimum of 180 consecutive days for determination of complete bony union.

- The patient uses the device for a minimum of 3 hours per day on at least 90% of the days from the day the patient is fitted with the unit until the date of the prescribing physician's radiographic assessment that there is an absence of progression of bony union (minimum of 120 days) or absence of complete bony union (minimum of 180 days).
- Radiographs to assess the progress of bony union are taken prior to fitting and at Day 120 (or beyond) of Physio-Stim treatment or radiographs to assess complete bony union are taken prior to fitting and at Day 180 (or beyond) of Physio-Stim treatment.
- A Certificate of Limited Guarantee is signed by the patient (to acknowledge the patient's understanding of the terms and conditions of the program) and returned to Orthofix along with the Assignment of Benefits form.
- Full payment is received at Orthofix within 45 days of invoicing date.
- Guarantee claims are received at Orthofix headquarters within one year after the Physio-Stim device is applied.
- Physio-Stim devices deliberately rendered inoperative or altered in any way will be excluded from the guarantee program and will not be eligible for a refund.

Claim Submission

Contact your Orthofix Territory Manager for assistance in preparing and submitting a refund claim.

- All claims must be accompanied by:
 - a. Original radiographs of the affected site (in comparable projections) prior to the day of fitting of the Physio-Stim unit and at the evaluation date. Radiographs should be clearly marked with the patient's name, date, physician's name, and any other pertinent identifying information.
 - b. The prescribing physician's written evaluation of the radiographic series at the evaluation date.
 - c. Originals or photocopies of Physio-Stim patient compliance reports from Day 1 of Physio-Stim treatment through the evaluation date.
 - d. The prescribed Physio-Stim unit.

*Progression of bony union is determined by cortical bridging and/or trabecular bridging with modification of the radiolucent gap on any radiographic view and the overall callus progression shown from baseline (X-ray prior to fitting of Physio-Stim device).

**Complete bony union is determined by bicortical bridging and trabecular bridging on any radiographic view with no motion present (X-ray prior to fitting of Physio-Stim device).

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- Claims must be received by Orthofix at its offices at 1720 Bray Central Drive, McKinney, Texas 75069 within 60 days of the evaluation date and not more than 18 months from date prescribed. Orthofix is not responsible for lost, delayed, misdirected or improperly addressed claims or Physio-Stim devices.
- Call Toll-Free (800) 535-4492, Orthofix Customer Service, to arrange for Physio-Stim device pick-up and return.
- Physicians will receive written notification of the final disposition of all claims within 45 days of claim receipt. Refund will be made within 60 days of Orthofix's receipt of a guarantee claim by Orthofix.

The Physio-Stim Limited Guarantee Program gives the payer(s) of record specific legal rights, and such person(s) may also have other rights which vary from State to State.

Indications

Physio-Stim is indicated for the treatment of an established non-union secondary to trauma, excluding vertebrae and all flat bones, where the width of the non-union defect is less than one-half the width of the bone to be treated. A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

The original Pre-marketing Data reported an 80 percent success rate among 126 patients (135 non-union fractures) who averaged greater than 3 hours of daily treatment. The average duration of non-union in these difficult fractures was 2.6 years, with an average of 2.6 prior surgical procedures per fracture. The success rate of Physio-Stim treatment for non-union repair demonstrated no statistically significant change over long term follow-up.

Contraindications

Use of this device is contraindicated where the individual has synovial pseudarthrosis.

Warnings

- a. The safety and effectiveness of using this device on individuals lacking skeletal maturity is not known.
- b. In the presence of a malaligned non-union, careful consideration of using this device must be undertaken on an individual basis; treatment with this device is not intended to alter or affect the degree of malalignment.
- c. Demand type pacemaker operation may be adversely affected by exposure to pulsed electromagnetic fields. Physicians should not prescribe Physio-Stim for applications

which may place the transducer in proximity to the pacemaker. Further screening by the attending cardiologist is recommended (e.g., electrocardiogram).

- d. Animal studies conducted to date do not suggest any long-term adverse effects from use of this device. However, long-term effects in humans are unknown.
- e. The safety and effectiveness of using this device with a non-union secondary to, or in conjunction with a pathological condition have not been established.

Precautions

- a. Non-union fractures with gaps exceeding one centimeter have not been evaluated under PEMF therapy.
- b. Physio-Stim treatment of the spine and skull has not been evaluated.
- c. Although animal teratological studies performed with this device demonstrated no adverse findings, the safety of use of this device by pregnant and nursing humans has not been established.
- d. This device should not be used if there are mental or physical conditions which preclude patient compliance with the physician and device instructions.

Adverse Effects

Rare instances of reversible minor discomfort have been reported, such as cumbersome or uncomfortable fit, minor tingling or pain, and minor skin rash.

References

1. Bassett, CAL. 1989. "Fundamental and Practical Aspects of Therapeutic Uses of Pulsed Electromagnetic Fields (PEMFs)." *Critical Reviews in Biomedical Engineering* 17 (5): 451.
2. Zoltan, Jon D. 1986. "Electrical Stimulation of Bone: An Overview." *Seminars in Orthopaedics* 1 (4)
3. Bassett, CAL, et al. 1981. "Treatment of Ununited Tibial Diaphyseal Fractures with Pulsing Electromagnetic Fields." *Journal of Bone and Joint Surgery* 63-A: 511-523
4. Garland, Douglas, et al. 1991. "Long-Term Follow-up of Fracture Non-Unions Treated with PEMFs." *Contemporary Orthopaedics* 22 (3)

For more information about Orthofix Bone Growth Stimulators, call Orthofix Customer Service at 800-535-4492.