



# 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.<sup>1,2,3</sup>

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).