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Redefine Recovery with Bone Healing Therapy

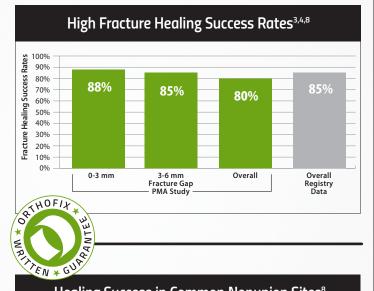
**ORTHOFIX**<sup>®</sup>

# Redefine Fracture Healing Recovery



PhysioStim<sup>™</sup> devices provide a safe and effective non-surgical treatment to improve nonunion fracture healing. These devices use a pulsed electromagnetic field (PEMF) signal to induce a low-level electrical field at the fracture site which stimulates bone healing.<sup>3-7</sup>

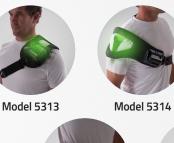
## **Proven Effective Therapy**



Healing Success in Common Nonunion Sites"	
Femur	84.2%
Fibula	91.4%
Metatarsal	90.9%
Tibia	89.0%
Ulna	96.1%
Radius	93.8%

### **Anatomically Designed Models**

- 360 degrees of PEMF treatment around the fracture site that evenly penetrates across tissue, bone and fixation<sup>9,10</sup>
- Single-piece, cordless design that allows for ease of placement and patient mobility
- Effective delivery of treatment when worn over clothing, casts and boots





814 Model 5302/5303





Model 5315

Model 5302/5303

#### **Commitment To Outcomes**



PhysioStim devices are accompanied by the STIM onTrack mobile app. The app includes a first-to-market feature that:

- Enables physicians to see how patients are adhering to their prescriptions in real-time
- Engages patients in their recovery process through treatment calendars, therapy reminders and educational resources

#### Brief Prescribing Information:

The PhysioStim<sup>®</sup> 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 Care at 1-800-535-4492.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

References: "The results of preclinical studies may not be indicative of human clinical trials. 1. iData Research Inc., U.S. Market for Spinal Implants and VCF (iDATA\_USSP17\_RPT), iData Research Inc, (www.idataresearch.net) 2017 2. iData Research Inc., U.S. Market for Orthopedic Tiauma Devices (iDATA\_USTR17\_RMS), iData Research Inc, (www.idataresearch.net) 2017 3. Garland DE, Moses B, Salver W. Fracture healing: Long-term follow-up of fracture non-inions treated with PEMFs. Contemp Orthop. 1991;22(3):295-302 4. PMA P850007. February 1986. 5. Marino, AA and Becker, RO: Prezoelectric effect and growth control in bone. Nature: 1970 October; 228: 473-74 6. McHange distribution on the human femur due to load. J Bone Joint Surg Am. 1967; 49(8): 1561-71 7. Midura RJ, Ibiwoye MO, Powell, KA, et al. Pulsed electro-magnetic field treatments enhance the healing of fibular osteotomies. J Onthop Res. 2005;23:1035-46 8. Orthofix patient registry. PMA P850007/S20. Data on file. 9. Data on file. Field mapping analysis conducted by M. Zborowski, Ph.D., Cleveland Clinic. 10. Navarro, M., Michiardi, A., Gastano, O., & Planell, J. (2008). Biomaterials in onthopaedics. Journal of the Royal Society Interface, 5(27), 1137-1158.



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