



Healthcare Professionals



Biomet® EBI® Bone Healing System



What is the Bone Healing System?

The Biomet® EBI® Bone Healing System is a class III, FDA approved, non-invasive bone growth stimulation device designed as an adjunctive therapy to aid in the healing of nonunion fractures, failed fusions, and congenital pseudarthrosis.

Features & Benefits

- The only bone growth stimulator with three distinct indications: providing surgeons options to treat various conditions with one clinically proven, safe and effective nonsurgical device.
- The small, lightweight, easy-to-use nonsurgical device empowers patients to treat compliantly on the go while improving their healing outcomes.
- The flexible, hand-crafted, therapeutic treatment coil options in 12 different shapes and sizes provide complete, 360-degree coverage around the treatment area.
- The therapeutic treatment coils may be comfortably and discreetly worn over clothing, bracing, or a cast.
- The Bone Healing System is backed by statistically significant pre-clinical, scientific research and clinical evidence which demonstrated improved clinical outcomes.



Specifications

- Technology: Pulsed Electromagnetic Field (PEMF)
- Signal: 15Hz
- Delivery Method: Flexible treatment coils
- Device Weight: 6.70 oz.
- Original FDA Approval Date: 1979

How does the Bone Healing System work?

The Biomet® EBI® Bone Healing System delivers a clinically proven, low-level electrical stimulation technology called a Pulsed Electromagnetic Field (PEMF) through a complete complement of flexible, hand-crafted treatment coils designed to treat the entire appendicular system.

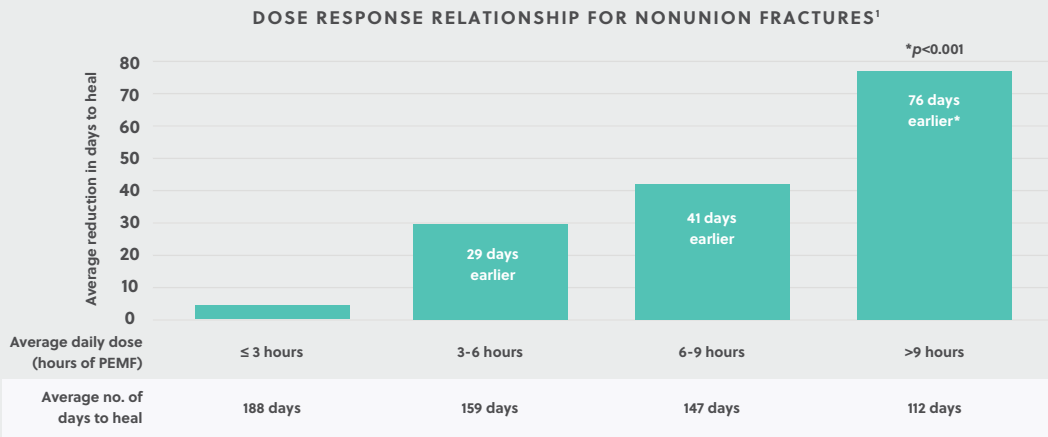
Pre-clinical evidence has demonstrated the mechanism of action behind PEMF technology involves the upregulation of factors that modulate normal bone healing. PEMF increases a number of factors such as TGF-β1, BMP-2 and BMP-4, which are normal physiological regulators of the various stages of bone healing, including angiogenesis, chondrogenesis and osteogenesis.^{1,2,3,4*}



A pre-selected, flexible, hand-crafted treatment coil which accompanies the Bone Healing System is placed over the targeted treatment site, providing complete therapeutic coverage to achieve optimal healing outcomes. The area within the treatment coil is stimulated inducing the body's natural healing mechanisms to safely and effectively promote bone growth at the targeted treatment site.

What type of clinical data has been published on the Pulsed Electromagnetic Field technology to demonstrate a dose response?

In a follow-up dose response study, treatment with the Bone Healing System resulted in significantly earlier healing when used for >9 hours/day.⁵



The data demonstrates a correlation between the average daily dose of PEMF and the reduction in time to heal for nonunion fractures. Patients that treated **>9 hours/day** exhibited a significantly earlier healing time, **76 days earlier**, than patients that treated for ≤3 hours/day.⁵

76 Days Earlier Healing

Patients using the PEMF device for more than 9 hours per day achieved successful fracture repair an average of 76 days earlier than patients who treated for an average of 3 hours or less per day.⁵ The overall reported success rate for patients treated with the Bone Healing System was as high as 89.6%.⁵⁺

6 Day Reduction In Time To Heal^{5*}

Linear regression analysis indicated a 6-day reduction in time to heal was achieved for each additional hour of average daily stimulation.

What human clinical outcomes are there to support the use of the Bone Healing System?

High clinical success rates were achieved for some of the most difficult to treat locations.

Scaphoid Nonunion Success Rates As High As

92%

A follow-up study in upper extremities demonstrated clinical healing outcomes as high as 92%⁶⁺

Fifth Metatarsal Nonunion Success Rates As High As

100%

A clinical study focused on fifth metatarsal nonunions demonstrated clinical healing outcomes as high as 100%⁷⁺

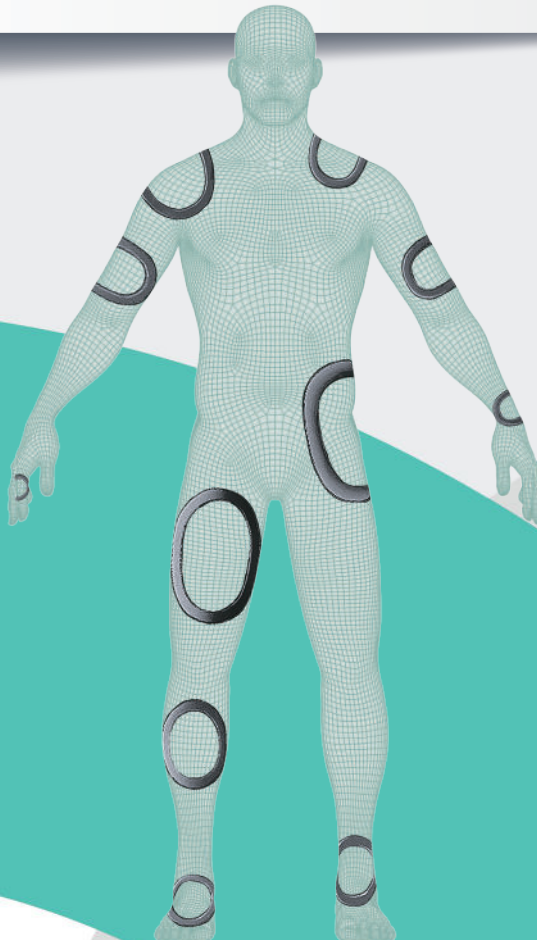
Tibia Nonunion Success Rate

87%

Another clinical study in lower extremities demonstrated clinical healing outcomes as high as 87%⁸⁺

Overall Clinical and Radiographic Success Rate⁵⁺

90%



The largest portfolio of clinically proven bone growth stimulation solutions.



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Legal Manufacturer

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References

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- + The original PEMF clinical study under the supervision of C.A.L. Bassett, M.D., Sc.D. which led to PMA approval in 1979 yielded an overall functional union success rate of 76%.

Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. The SpinalPak is a non-invasive spine fusion stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. No known contraindications. Rx Only. Single Patient Use Only. Do Not Reuse. The OrthoPak 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. Contraindicated if the individual has synovial pseudarthrosis. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. The Bone Healing System is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. Contraindicated for nonunion fractures in which a synovial pseudarthrosis exists. Electromagnetic PEMF stimulation is contraindicated for use by patients with implantable pacemakers or defibrillators. The Bone Healing System is not MR safe. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. OsteoGen stimulators are indicated in the treatment of long bone nonunions. No known contraindications. Not recommended with the following conditions: pathological fractures due to malignant tumors or active osteomyelitis. Federal Law (U.S.A.) restricts these devices to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. SpF stimulators are indicated as a lumbar spinal fusion adjunct to increase the probability of fusion success in one or two levels or three or more levels. Do not use with defibrillators. If the stimulators are used in conjunction with metal internal fixation devices, no metallic part of the stimulator should be allowed to come into contact with the fixation device; this includes minimally invasive surgical-MIS procedures. Any surgical implantation procedure such as minimally invasive surgical-MIS procedures requiring the SpF's cathodes to be disconnected from their corresponding leads prior to or during implantation. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. This material is intended for health care professionals. Distribution to any other recipient is prohibited. All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Highridge Medical or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Highridge Medical. HM0440 REV A 01/25. ©2025 EBI, LLC. All rights reserved.