Healthcare Professionals

Biomet® EBI®

Bone Healing System

Powered by Pulsed Electromagnetic Fields

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.

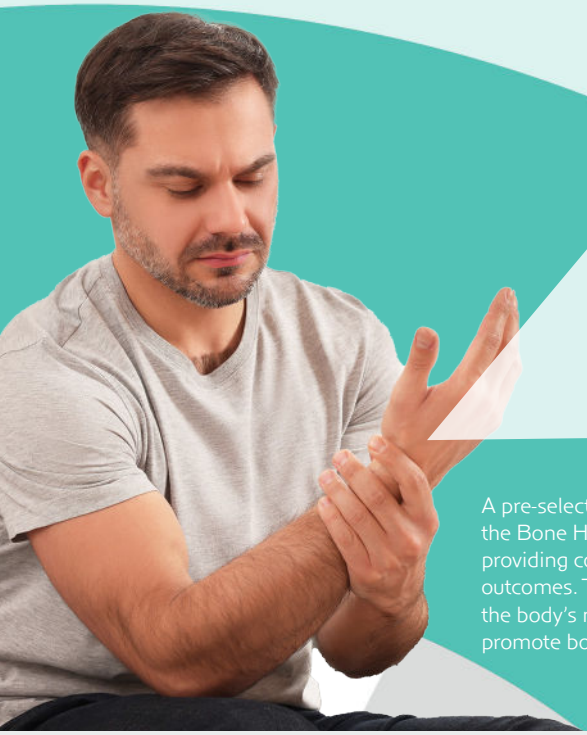
Specifications

- 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*]

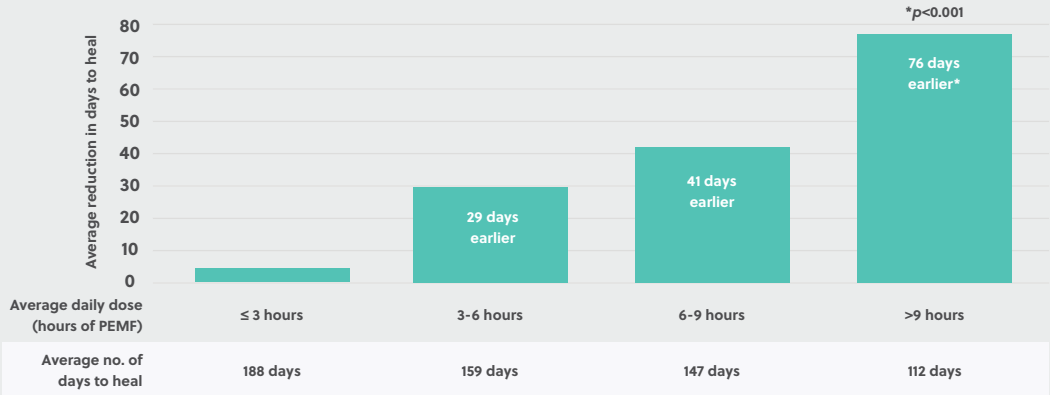


A pre-selected, flexible, hand-crafted treatment coil which accompanies the Bone Healing System is placed over the targeted treatment site, providing complete therapeutic coverage to achieve optimal healing outcomes. The area within the treatment coil is stimulated inducing the body's natural healing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

DOSE RESPONSE RELATIONSHIP FOR NONUNION FRACTURES[1]



Average daily dose (hours of PEMF)	≤ 3 hours	3-6 hours	6-9 hours	>9 hours
Average no. of days to heal	188 days	159 days	147 days	112 days

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+]

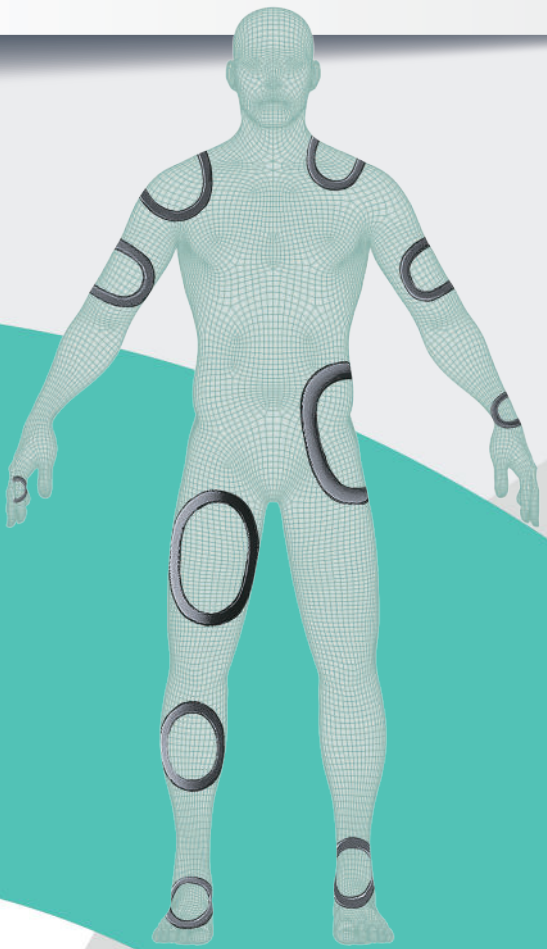
Tibia Nonunion Success Rate

87%

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

Overall Clinical and Radiographic Success Rate[5+]

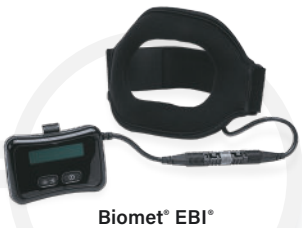
90%



The largest portfolio of clinically proven bone growth stimulation solutions.

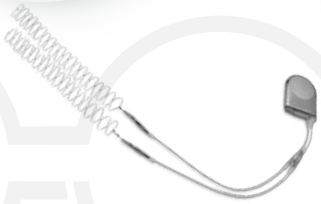
Biomet® SpinalPak®
Non-invasive Spine
Fusion Stimulator System

Biomet® OrthoPak®
Non-invasive Bone
Growth Stimulator System



Biomet® EBI®
Bone Healing System

EBI® OsteoGen™
Surgically Implanted
Bone Growth Stimulators



SpF®
Implantable Spinal
Fusion Stimulators

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References

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