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*Biomet® EBI Bone Healing System®*

## Patient Information Brochure



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## *What is the Biomet EBI Bone Healing System?*

The Bone Healing System is a proven, safe and effective device for the treatment of fracture nonunions and failed fusions. It consists of an anatomically configured therapeutic treatment coil, which is placed directly over your fracture nonunion or failed fusion to help promote healing.

A nonunion is considered to be established when there are no visibly progressive signs of healing.



## *The Bone Healing Process*

Bone is one of the tissues within the human body capable of healing itself when damaged, in much the same way as skin and other tissues. When you fracture a bone, the body naturally produces low level electric impulses that help to heal the fracture site. Occasionally, the fracture may not heal on its own. This will result in what is called a nonunion. The Bone Healing System is a proven, safe, and effective method for promoting the healing of fracture nonunions and failed fusions.

## *How does the Bone Healing System Work?*

Your doctor has prescribed the Bone Healing System that is intended to help heal your fracture nonunion or failed fusion. The Bone Healing System is a proven, safe and effective device that consists of an anatomically configured treatment coil that is placed over a cast or directly onto the skin. An electronic control unit sends a pulsating electromagnetic field to the fracture nonunion or failed fusion site. The coil is easy to apply and is lightweight. The Bone Healing System is battery operated, portable, and easy to operate. You will be able to treat your fracture nonunion or failed fusion while going about your daily routine, relaxing or while sleeping. Results will vary due to health, weight, activity and other variables. Not all patients are candidates for this medical device. Only a medical professional can determine the treatment appropriate for your specific condition.

## *How long will I have to treat with the device?*

The Bone Healing System has a recommended daily treatment time of 10 hours per day. Certain risk factors such as smoking and instrumentation may factor into the duration of your treatment. Zimmer Biomet recommends that your doctor closely monitor your healing progress to determine how long you should treat with the device. It is important that you use the device as prescribed.

## *How do I know the system is working?*

The Bone Healing System has been designed so that it's convenient to use, comfortable to wear and safe to operate. You will not feel the Bone Healing System therapy as it delivers the therapeutic treatment signal to the nonunion or failed fusion site. When the system is properly activated, the device's LCD display will illuminate with the words TREATING and the backlight button will flash. Please refer to the patient manual for a description of each symbol that may appear on the display screen. If you have any questions, please contact Zimmer Biomet's Customer Care line at 1-800-526-2579 extension 6000.

## *Is the system MRI safe?*

MRI scans and procedures should not be performed until the Bone Healing System has been completely removed.

## *Is the system safe to use during pregnancy?*

Use of the Bone Healing System during pregnancy has not been evaluated; therefore it is not recommended.

## *I have a pacemaker. Can I use the Bone Healing System?*

No. The use of a pacemaker or cardioverter with the Bone Healing System is contraindicated and not recommended.





\*Not actual patients.

### *Will my insurance cover the cost of the device?*

Insurance coverage varies depending on your insurance plan. The Bone Healing System is generally accepted by Medicare, Medicaid and workers compensation, as well as by some private and public health plans. Zimmer Biomet's Patient Advocacy Group is available to assist you and discuss any questions regarding insurance coverage, deductibles and potential out-of-pocket expenses. You may contact our Patient Advocacy Group at 1-888-236-3652

### *What is the process for obtaining an Bone Healing System?*

You can only obtain the Bone Healing System with a doctor's prescription.

### *Who do I contact if I have questions?*

Zimmer Biomet Customer Care Representatives are ready to answer your questions at 1-800-526-2579 extension 6000.

## Zimmer Biomet - A Name You Can Trust

Zimmer Biomet non-invasive stimulation devices trace their lineage to Electro-Biology, Inc. (EBI), an industry pioneer that introduced the world's first FDA approved electrical non-invasive bone growth stimulation device more than 40 years ago. Zimmer Biomet's extensive sales and customer service support helps both physicians and patients obtain access to appropriate therapeutic treatment technologies and works with each patient to optimize and monitor compliance, track progress and assist with insurance reimbursement.

### View the Patient Video

To learn more about the how to properly wear the Bone Healing System , please visit: <https://zimmerbiomet.tv/videos/2225>

**INDICATION:** The Biomet EBI Bone Healing System is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. A nonunion is considered to be established when there are no visibly progressive signs of healing - P790002/S028.

**USAGE:** The recommended daily treatment dosage is normally 10 hours per day. The maximum recommended therapeutic treatment period is nine months (approximately 270 days). This device system is a durable therapeutic electrical device intended for single patient use only under a prescription. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only - Prescription Only - Single Patient Use Only - Not for Re-Sale or Re-Distribution - Do Not Reuse.

**CONTRAINDICATIONS:** Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap) exists. Under certain conditions, electromagnetic stimulation could inhibit or impair the functioning of certain external, non-invasive and/or implanted, invasive active medical devices. Use of the Biomet EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases. MR unsafe – Not for MRI Use.

For complete prescribing information including contraindications, warnings, and precautions, please refer to the Biomet EBI Bone Healing System Physician Manual and Package Insert PN1068220-00 or call 1-800-526-2579 extension 6000.



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