



Patient Manual

Biomet® EBi®

Bone Healing System



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INTRODUCTION

Read all instructions before using electrical products.

Basic safety precautions should always be observed.

This manual presents a complete overview of how to use your Bone Healing System safely and effectively. The manual is intended to complement the one-on-one training you'll be receiving by a fully trained professional prior to starting your treatment. Please read through the entire manual before operating.

EBI is committed in providing every opportunity to you to achieve a successful outcome. If you have any questions or concerns regarding your Bone Healing System or one-on-one personal training please feel free to contact the EBI® Customer Care team or your local sales representative at any time.



Symbol Description

!	Warning		On/Off
*	Note	Rx Only	Rx Only Prescription Only
	Type BF Equipment		Manufacturer
==	Direct Current		Not for use by patients who are pregnant or becoming pregnant
~	Alternating Current		Not recommended for patients with with certain types of pacemakers or implantable defibrillators
	Attention –		Temperature range for storage and transportation
	See Instructions		Lithium Ion Battery – Recycle in compliance with local laws
	Non-ionizing Radiation		The Bone Healing System has not been tested for safety or been evaluated for heating in the MR environment
	Class II		
	Single Patient Use / Single Prescription		
	WEEE – Do not dispose of this device with household waste		
→ 	Charge Battery		
	Reset		
	Backlight		

WARNINGS

! Warnings: To reduce the risk of electric shock, fire or potential injuries please adhere to the following:

1. Do not use your Bone Healing System while bathing.
2. Do not place or store your Bone Healing System where it can fall or be pulled into a tub, sink or any pool of liquid.
3. Do not immerse or drop your Bone Healing System's control unit, treatment coil, AC Wall Adapter, in any liquid.
4. Do not reach for your bone healing system that has fallen into a liquid. Unplug from the wall outlet immediately.
5. Do not permit the AC Wall Adapter to be connected when wet.
6. Never touch the AC Wall Adapter contacts when the AC Wall Adapter is plugged into an AC Wall outlet.
7. Do not place the AC Wall Adapter in the bed with you if you are treating while you are sleeping.
8. Never operate your bone healing system if it has a damaged link cable, cord or plug, if it is not working properly, if it has been dropped and damaged, or immersed into any liquid. Contact EBI immediately for a replacement part(s).
9. Keep all electrical cords and cables away from heated surfaces.
10. Keep the Bone Healing System and its accessories away from small children. This device is not a toy and may be hazardous to children.

For example:

- A choking hazard may exist for detachable parts.
- Improper use could result in exposure to a treatment signal for which the risks of exposure to children have not been established.

WARNINGS (CONTINUED)

11. Never insert any object into any opening of your Bone Healing System.
12. Do not place your bone healing system's control unit in prolonged heat or direct sunlight. (Normal operating temperature range is 5°C to 38°C, [41°F to 100°F], 20-80% RH non-condensing, normal storage/transport temperature is -15°C to 60°C [5°F to 140°F]).
13. Use your bone healing system only for its intended use as prescribed by your physician and described in this manual.
14. The safe operation of Durable Medical Electrical Equipment requires adherence to special precautions regarding Electromagnetic Compatibility (EMC) in accordance with information provided in the physician manual.
15. No modification to this device is allowed for any reason whatsoever.
16. Routine use of bone healing systems for over 30 years has demonstrated that any known hazard associated with their use does not present an unreasonable risk of illness or injury when compared to the benefit of their use.
17. Use of your Bone Healing System for the spine and skull has not been evaluated or approved.

Battery Warning

CAUTION: The Bone Healing System control unit contains a permanently installed Lithium Ion battery. You must read and follow these safety instructions and warnings provided within this manual before using or charging the battery within your control unit.

- Do not attempt to open the control unit to access the battery or its internal electronic components for any reason. No unauthorized modification of the control unit is allowed.
- Never attempt to change, adjust or reverse the battery's polarity connections for any reason.
- Do not allow or permit the control unit or its permanently installed battery to be physically mishandled, abused, crushed, mutilated or penetrated by any metal object such as a nail.
- Never allow or permit any metal object to touch or contact the permanently installed battery's terminals.
- Never store the control unit or charge the battery in extreme temperatures.
- Never charge the battery unattended.
- Always keep the control unit away from children.

Battery Warning (continued)

Any abuse or misuse to the control unit or its permanently installed battery may result in serious personal injury and/or property damage.

EBI is not liable for any such abuse, misuse or resulting damage.

To ensure proper charging, **ONLY USE** the AC Wall Adapter supplied with your device system and follow the specific operating instructions provided within this manual. Always keep the control unit and its permanently installed battery dry. When all treatment has been completed, the control unit and permanently installed battery **MUST BE** disposed of properly. In the USA, disposal information may be obtained by contacting the Rechargeable Battery Recycling Corporation Hotline (RBRC) at 1-800-822-8837. Please contact local recycling authorities for proper disposal information and instructions if outside the USA. Never dispose in normal household waste or refuse.

Normal charging temperature range is 50°F (10°C) to +95°F (35°C).

INDICATIONS, CONTRAINDICATIONS, USAGE AND ADVERSE EFFECTS

Indications:

The 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.

Contraindications:



1. Under certain conditions, electromagnetic stimulation generated by a bone healing system could inhibit the output of some demand pacemakers or implantable defibrillators. Therefore, it is not recommended for patients with certain types of pacemakers or implantable defibrillators. Patients should be cautioned to avoid coming in close proximity to pacemaker or defibrillator wearers during stimulation treatment. The use of bone healing systems on pregnant patients has not been evaluated; therefore, it is not recommended in these cases. The long term effects of exposure to low level magnetic fields created by bone healing systems are not known.



2. Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap exists).
3. Use of the Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.



4. The Bone Healing System has not been tested for safety or been evaluated for heating in the MR environment. The effects of MRI procedures and scans using MR systems has not been determined or established" therefore, MRI scans and procedures should not be performed on patients until the device system has been completely removed.

INDICATIONS, CONTRAINDICATIONS, USAGE AND ADVERSE EFFECTS (CONTINUED)

MR Unsafe-Not for MRI use!

Usage:

This Bone Healing System is a durable therapeutic electrical medical 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 Use Only - Not for Re-Sale or Re-Distribution - Do Not Reuse.

Adverse Effects:

The original Bone Healing System was approved and introduced in 1979. Since then, over 600,000 systems have been marketed. The safe and effective use of non-invasive bone growth stimulation devices over this time has clearly established their therapeutic benefit of use. In addition, all known hazards associated with the use of Bone Healing Systems do not present an unreasonable risk of illness or injury when compared to their therapeutic benefit and can be typically addressed by either modifying or terminating treatment.

WHAT DOES A BONE HEALING SYSTEM DO?

Your doctor has prescribed the Bone Healing System to help heal your fracture nonunion or failed fusion. The Bone Healing System is a proven, safe and effective medical device. The system consists of an anatomically configured flexible treatment coil that can be worn directly over a cast or worn over clothing or directly on the skin during treatment. The system's electronic controller once connected to the flexible treatment coil via a link cable sends a low-level electrical signal to the coil. The coil then converts this signal into a pulsating electromagnetic field which is delivered directly to your specific treatment site. The flexible coil is lightweight, easy to apply and wear. The Bone Healing System is portable, battery operated, easy to use and comes with an AC wall adapter for simple battery recharging. You'll be able to conveniently receive treatment while going about your normal daily activities, routine or even while sleeping.

WHAT DOES A BONE HEALING SYSTEM DO? (CONTINUED)

What comes in the System Kit?

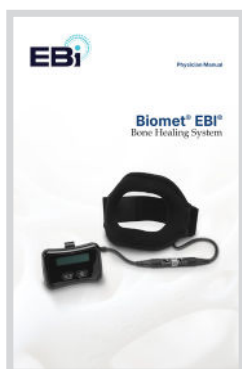
- Electronic control unit/controller - #1068233
- Controller to Coil Connector link cables:
 - “Zero” inch link cable - #1068210
 - 28 inch link cable - #1068215
- Belt - #1068222
- Clip Holder - #1068208
- AC Wall Adapter - #1068315
- Physician’s Manual
- Patient Manual

Bone Healing System Kit Contents





Physician Manual



Patient Manual



If at any point you need a replacement part for your Bone Healing System please contact the Customer Care team at 800-526-2579 and reference the part number next to the description of the item you need to order.

ADDITIONAL COMPONENTS

SFLX Flexible Therapeutic Treatment Coils

In addition to your Bone Healing System you have also received an SFLX flexible therapeutic treatment coil. The coil you have depends on the type and location of your fracture nonunion or failed fusion your doctor diagnosed. To properly apply your flexible treatment coil, please refer to the important user and safety instructions that were included with the coil when you received it.

International Wall Plug Blade Adapter Kit

An international wall plug blade adapter kit is available for patients who will be traveling outside the US and wish to continue their treatment while abroad. The part number is #1068317.



Extremity Band

An optional extremity band is also available if you would like to wear your Bone Healing System's electronic control unit closer to your treatment site, for example on your arm. When ordering the extremity band, reference part number #1068209 and it will be shipped to you with important user and safety instructions.



HOW DO I CONNECT MY CONTROL UNIT TO MY TREATMENT COIL?

First, connect the controller (A) to either the “Zero” inch or 28 inch Link Cable (B). Then connect Link Cable (B) to the Treatment Coil (C). The Link Cable selection depends on which cable length best fits your specific treatment needs.



HOW DO I START MY TREATMENT?

- 1. Place the treatment coil over your treatment site and adjust for a comfortable fit.

* **NOTE:** Please refer to the important user and safety instructions insert that came with your individual coil to adjust and complete proper application and placement.

- 2. Once the treatment coil is adjusted, refer to the table below to turn on your control unit.

Symbol	Purpose	Location
 On/Off Button	Press once to turn on/off	Button on the right
 Backlight/Reset	Press once and release for the display's backlight to come on	Button on the left beneath



* **NOTE:** If you hold down the backlight button for two beeps, the control unit will reset its internal clock to 00:00 treatment time for the day.

HOW DO I START MY TREATMENT? (CONTINUED)

3. The display on your control unit will scroll through the following five messages.

FIRST MESSAGE:

**EBI RECOMMENDS
10 HOURS PER DAY**

Your compliance with the recommended 10 hours per day treatment is very important. A review of the clinical data demonstrated that less than the recommended use may possibly result in an increase in time to heal. After you have used your Bone Healing System for one full treatment session, the control unit will display the following:

SECOND MESSAGE:

**PATIENT USAGE
AVG HR/DAY 00:00**

How many hours per day on average you used your system.

THIRD MESSAGE:

**PATIENT USAGE
DAYS USED 000**

How many days you have used your system.

FORTH MESSAGE:

**PATIENT USAGE
DAYS USED 000**

How many days you have not used your system.

FIFTH MESSAGE:

**TREATING 0:00
BATTERY ■■■**

The last message will display that you are “TREATING “and for how long. This message also displays a “BATTERY” icon to show you how much charge remains in your control unit’s battery.

4. After your Bone Healing System is operational and your treatment has started, you can wear your control unit wherever is most comfortable and convenient. Your Bone Healing System comes with a belt-clip so you can clip and attach the control unit to your waistband or belt. You can also request an optional extremity band from the Customer Care team if you would like to wear the controller closer to your treatment site, for example on your arm.

* **NOTE:** The control unit must not be worn on the coil.

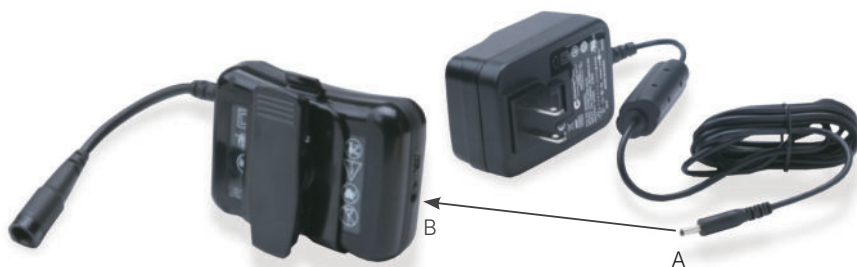
5. After 10 hours of use, your Bone Healing System’s electronic control unit will automatically turn off.

* **NOTE:** Your Bone Healing System’s electronic controller is designed to store your daily usage (treatment) information. This information is extremely important to your doctor in determining your treatment compliance. It’s recommended that you bring your Bone Healing System and flexible treatment coil to each follow-up visit to allow your doctor to review your healing progress.

IMPORTANT: Any medical questions regarding your treatment **MUST** be addressed by your doctor.

HOW DO I CHARGE MY BATTERY?

1. In order to charge your Bone Healing System's battery, connect the AC Wall Adapter (A) to the control unit (B) as shown:



2. Then, plug the AC Wall Adapter into an appropriate AC Wall outlet.

* **NOTE:** You are able to treat and charge at the same time. The display on the control unit will indicate that you are still treating, but will also indicate that the battery is charging. The battery may take up to 3.5 hours to fully charge.



CLEANING INSTRUCTIONS

The Control Unit

The control unit and charger can be cleaned by wiping with a damp cloth and mild soap. Do not immerse in water or use solvents or other cleaning agents. Do not machine wash or dry.

Therapeutic Treatment Coils

Clean with mild soap and water by wiping with a damp cloth. Do not immerse in water or any liquid. Do not machine wash or dry.

* **NOTE:** Please make sure your controller is disconnected from the AC Wall Outlet before cleaning.

TREATMENT COMPLETION

You should continue to use your Bone Healing System until healing occurs or until your physician recommends you discontinue its use. Your Bone Healing System's control unit is programmed to deliver a maximum of 270 days of treatment within a 400 day window. When 270 days of treatment or 400 days are reached, treatment automatically stops and the following message will be displayed: "SYSTEM ENDPOINT CALL CUSTOMER SERVICE".

DISPOSAL

When your treatment has concluded as determined by your doctor, EBI requests that you properly dispose your Bone Healing System according to local statutes and regulations.

WHAT IF I HAVE QUESTIONS

If you have questions about your Bone Healing System, its operation, components, replacement parts etc. please contact the Customer Care team directly at 800-526-2579 if calling outside the United States. Representatives are available from 8:30am to 5:30pm (EST), Monday through Friday. At all other times, please leave a clear and concise message along with contact information for a return call by the next business day.

For full prescribing information please visit ebibonestimulator.com or call 800-526-2579.

Options

The industry's most comprehensive options:

- PEMF, CC and DC
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- Wear-time choice

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- Multiple scientific papers
- The proof is in the patient

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