# Biomet® EBI® Bone Healing System
# SFLX 2-1 & 4-1 Therapeutic Treatment Coils

When you see these symbols, immediately refer to the full prescribing information described within the User Manual and Package Insert supplied with your non-invasive stimulator for more information. Please read the following helpful information listed below. This information will enable you to utilize this medical device safely and effectively. Retain this information for later use. This medical device is ONLY intended to be used with the non-invasive bone growthstimulator which was prescribed by your physician for your treatment.

## INDICATIONS FOR USE

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.

## USAGE

Follow the treatment schedule prescribed by your physician, normally ten (10) hours per day. Your compliance with the recommended ten (10) hours per day treatment is very important. A review of the original premarket clinical data demonstrated that less than the recommended use of this device possibly results in an increase in the time to heal your fracture nonunion. If you are unable to treat for ten continuous hours, it is recommended that you break up the total treatment time into more than one session. Please consult the general treatment instructions section contained within the User Manual and Packaging Insert supplied with your non-invasive stimulator for more information before beginning treatment.

## ATTENTION

This medical device 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. Treatment at home or in another appropriate or similar setting is acceptable. This medical device cannot be reprocessed, refurbished, disinfected, reused, sterilized, etc. with the intent to be used by another patient or for treatment other than prescribed.

## CONTRAINDICATIONS

A. Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap) exists.

B. Under certain conditions, electromagnetic stimulation could inhibit or impair the functioning of certain external, non-invasive and/or implanted, invasive active medical devices inclusive of "all active electrical and non-active conductive/metallic implants" as well as "worn medical devices" due to adverse events that may occur with other active electrical implants (e.g., Spinal Cord stimulators, Implantable Cardioverter-defibrillators, etc.) The impact or effect of pulsed electromagnetic fields generated by a non invasive bone growth stimulator on the function of other anatomical stimulators, pain pumps, insulin pumps, implanted spinal nerve stimulators and similar active devices has not been evaluated.

C. Use of the Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. 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. MR Unsafe-Not for MRI Use.

## WARNINGS

A. The long term effects of exposure to low level magnetic fields are not known. Routine use of these bone healing systems for over 30 years has indicated no known risks.

B. During the treatment of patients with open epiphyses, when the epiphysis is in the pulsing field, physicians are advised that the epiphyseal growth plates should be monitored for possible effects.

C. Use of the Bone Healing System for the spine and skull have not been evaluated.

D. To reduce the risk of potential injury:
   1. AVOID touching the AC Adapter contacts when the AC Adapter is plugged into an AC wall outlet.
   2. DO NOT charge the battery in bed if treating while sleeping.

E. The control unit is electrically live when connected with the AC Wall Adapter and plugged into an AC Wall outlet. To reduce the risk of serious injury by electric shock, patients are advised:
   1. DO NOT permit the AC Adapter to be connected when wet.
   2. DO NOT immerse the control unit, treatment coil, or the AC Wall Adapter in water or any liquid.

F. No unauthorized modification of this device is allowed for any reason whatsoever.

## PRECAUTIONS

The following conditions may compromise a successful treatment outcome.

A. Nonunion fractures with gaps in excess of 1.0cm.

B. Presence of fixation devices or instrumentation made from magnetic materials.

**PLEASE NOTE:** Most presently used internal or external fixation devices are constructed of 316L S.S., titanium alloys, and cobalt-chromium alloys which are non-magnetic and, therefore, compatible with the Bone Healing System.

## Adverse Effects

The Bone Healing System was FDA approved in 1979. Since then, more than 450,000 systems have been commercially distributed and prescribed to patients. Based on the results of an exhaustive historical search of the MAUDE and MDR Databases, the probability of an adverse event was extremely unlikely (.0062%).

The identified hazards associated with the use of non-invasive bone growth stimulation devices are comprehensive, well-known, understood and continue to clearly establish the benefits significantly outweighing the risks.

## CONTENTS

- SFLX Therapeutic Treatment Coil
- Flexion Gauge
- User, Safety & Application Instructions

Do not dispose of this device with household waste.

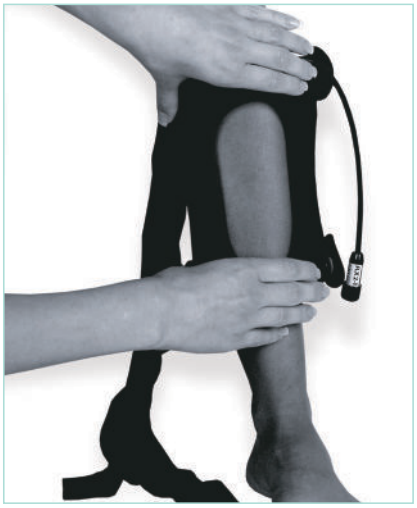
Rx Only - Prescription Only - Single Use Only
- Not for Re-Sale or Re-Distribution
- Do Not Reuse.

1068318-04 Rev. D

# SFLX 2-1 and 4-1 Therapeutic Treatment Coils – Long Vertical Fracture Application

See Flexion Gauge Instructions for measuring the tolerances of the treatment coil on the following page.

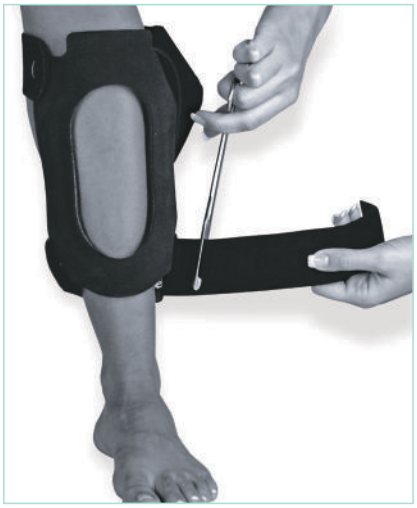
Used for long vertical fracture lengths; comminuted and segmented fracture nonunion applications.



1. Position treatment coil so that it is centered within the entire fracture length according to the prescribing physician instructions. Make sure the treatment coil is firmly in place before securing straps.

2. Bring top and bottom straps around back to opposite side.

3. Press strap onto Velcro® hook. Readjust both straps for a secure, comfortable fit. DO NOT over tighten.



4. Cut excess straps to size.

## Application Instructions for SFLX 2-1 and SFLX 4-1 Treatment Coils applies to:

| Description | Part Number | Suggested Placement |
|---|---|---|
| SFLX 2-1 | 1068227 | Tibia, Fibula, Radius, Ulna, Humerus |
| SFLX 4-1 | 1068236 | Humerus, Tibia, Fibula, Radius, Ulna |

# Coil Configuration Converting Elliptical to Saddle Shapes

The SFLX 2-1 and 4-1 treatment coils come in an elliptical format as pictured above.

To convert to a saddle configuration remove the straps and flatten the treatment coil. Rotate the coil 90°.

Complete the conversion to a saddle format by conforming the coil to the intended anatomic location and affix the straps at the new poles. Wrap straps around and cut lengths according to need.

## Flexion Gauge Instructions For SFLX 2-1 and SFLX 4-1 Treatment Coils

### Flexion Gauge Coil Tolerances for SFLX 2-1

| Flex Span | Min (10 cm) | Max (12 cm) |
|---|---|---|
| Maximum depth of penetration | 5 cm | 4.5 cm |
| Maximum fracture length | 16 cm | 14 cm |

### Flexion Gauge Coil Tolerances for SFLX 4-1

| Flex Span | Min (10 cm) | Max (12 cm) |
|---|---|---|
| Maximum depth of penetration | 6 cm | 6 cm |
| Maximum fracture length | 22 cm | 18 cm |

**NOTE:** During treatment, the position of the treatment coil may shift due to normal patient activity. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc). The treatment coil may be loosened and may need to be repositioned back to a comfortable location before tightening the straps, completing the adjustment.

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

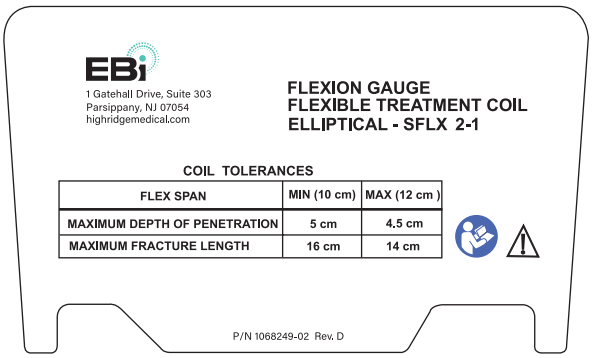
1. Place the SFLX Treatment Coil at the treatment site and shape for best fit. The Treatment Coil should be bent only in one direction. Do not kink or twist the Treatment Coil.

2. Remove the shaped SFLX Treatment Coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked "FLEXION RANGE." Each Flexion Gauge has a chart at Treatment Coil tolerances with depth of penetration data.

3. If the coil edge does not fall within the green zone, contact an EBI® representative for a suitable replacement and assistance.

# Flexion Gauge for Measuring the Tolerances of the Treatment Coil

Front View

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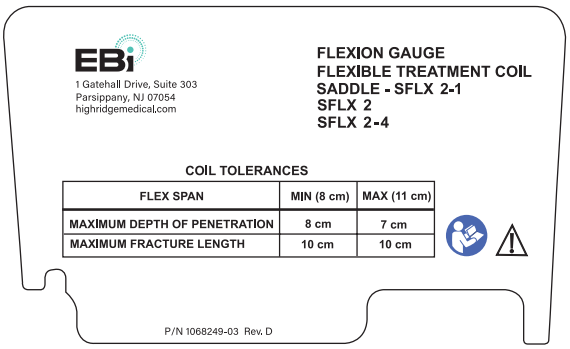


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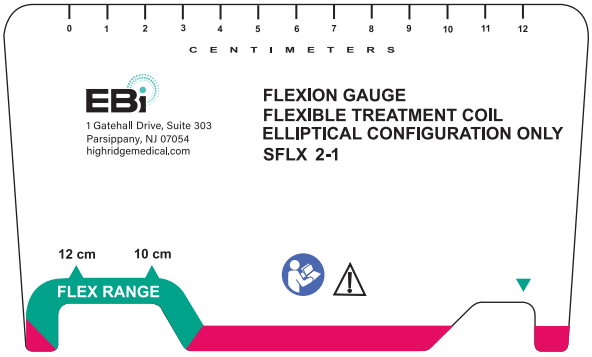


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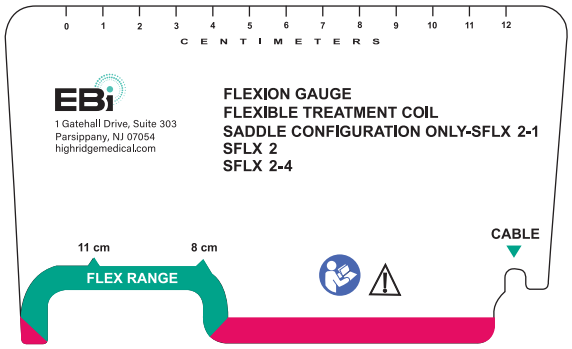


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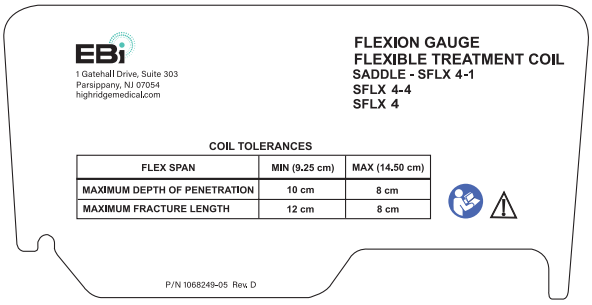


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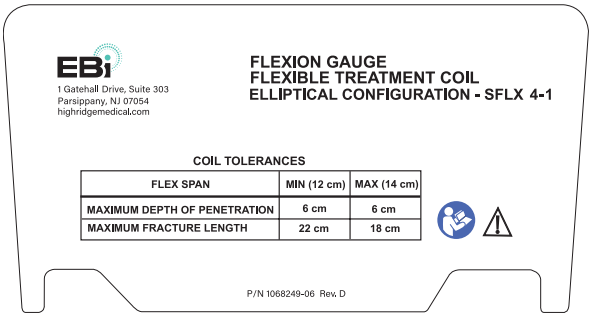


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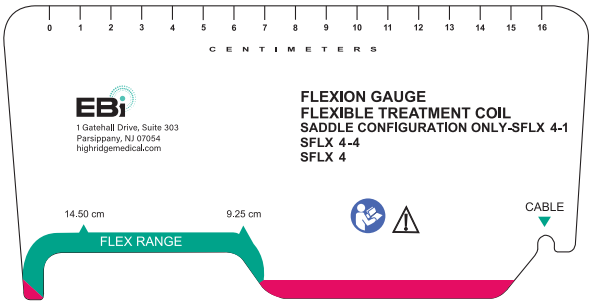


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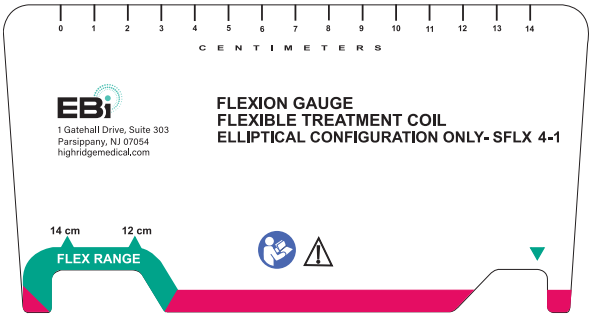


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Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. The Biomet® EBI® Bone Healing 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.  P/N 1068318-04 REV D. HM0688 REV A 04/25. 