Biomet® EBI® Bone Healing System
SFLX 5 Therapeutic Treatment Coil

When you see these symbols, immediately refer to the full prescribing information described within the User Manual and Packaging 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 growth stimulator 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.

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- 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.

1068318-01 Rev. D

SFLX 5 Therapeutic Treatment Coil Application

Application instructions for: SFLX 5 Treatment Coil applies to:

Description	Treatment Coil	Suggested Placement
SFLX 5	1068224	Femur – Proximal or Mid Shaft

Flexion Gauge Coil Tolerances for: SFLX 5 Treatment Coil

Flex Span	Min (5 cm)	Max (14.50 cm)
Maximum depth of penetration	12 cm	10 cm
Maximum fracture length	10 cm	10 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.

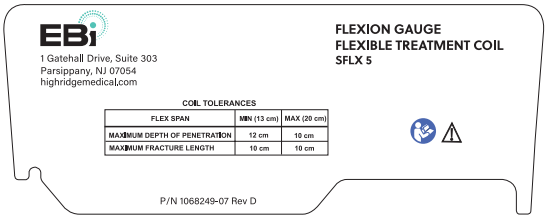
Flexion Gauge Instructions For SFLX 5 Treatment Coil

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

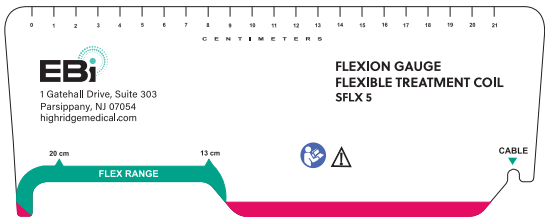
1. Place the treatment coil at the treatment site and shape for best fit. Treatment coil should be bent only in one direction. Do not kink or twist the coil.
2. Remove the shaped treatment coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge 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 of 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.

Center the SFLX 5 Coil over the fracture nonunion site. Conform the treatment coil and verify with the Flexion Gauge.

Front View



Back View



Not to Scale

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