Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX Mini Coilette
PN 1068318-09

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX Mini Coilette 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

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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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

The EBI 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%).

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CONTENTS

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

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1068318-09 Rev. B

FLEXION GAUGE INSTRUCTIONS FOR SFLX MINI TREATMENT COILETTE

Application Instructions for: SFLX Mini Coilette

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX Mini Coilette	1068239	Phalanges

Flexion Gauge Coil Tolerances for SFLX Mini Coilette

Flex Span	Min (2.5cm)	Max (3.5cm)
Maximum depth of penetration	2.5cm	2.0cm
Maximum fracture length	1.5cm	1.5cm

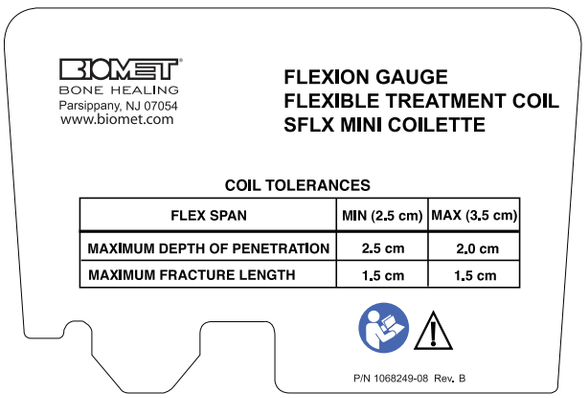
In order to ensure proper fit and efficacious treatment the Flexion Gauge should be employed to check for the proper shape.

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

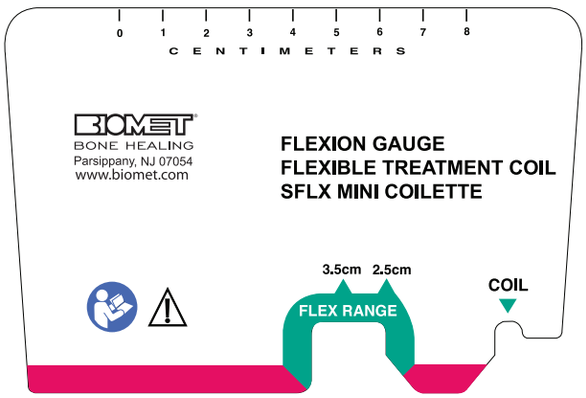
2. Remove the shaped treatment coilette and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked “FLEX RANGE”. Each Flexion Gauge has a chart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

3. If the treatment coilette edge does not fall within the green zone contact your Biomet representative for a suitable replacement and assistance.

Front View



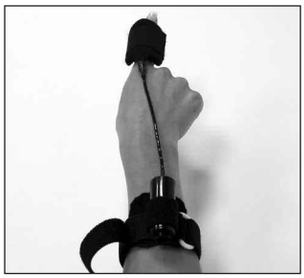
Back View



Not to scale

PHALANGE APPLICATIONS FOR SFLX MINI TREATMENT COILETTE INSTRUCTIONS

1. Slip wrist connector strap around wrist.

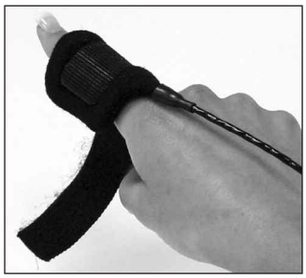


2. Adjust strap up or down arm until length of wire to SFLX Mini Treatment Coilette is properly placed.

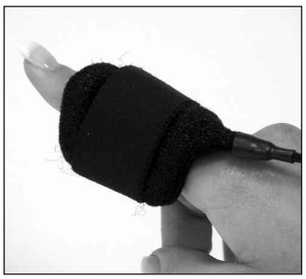
3. Feeding strap through ring, adjust and tighten securing strap to Velcro® hook.

4. Trim excess strap with scissors.

5. Adjust SFLX Mini Treatment Coilette to size by squeezing or opening.

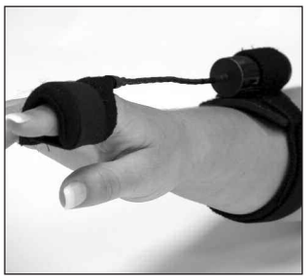


6. Secure the SFLX Mini Treatment Coilette in place by wrapping strap around finger and securing onto Velcro® hook.



7. Trim excess strap with scissors.

WARNING: Do not place the SFLX Mini Treatment Coilette over metallic splints or jewelry.



8. Connect link cable to wrist connector by inserting plug into jack. Begin treatment.

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

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX Coilette
PN 1068318-08

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX Coilette Therapeutic Treatment Coil

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INDICATIONS FOR USE

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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:

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

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FLEXION GAUGE INSTRUCTIONS FOR THE SFLX TREATMENT COILETTE

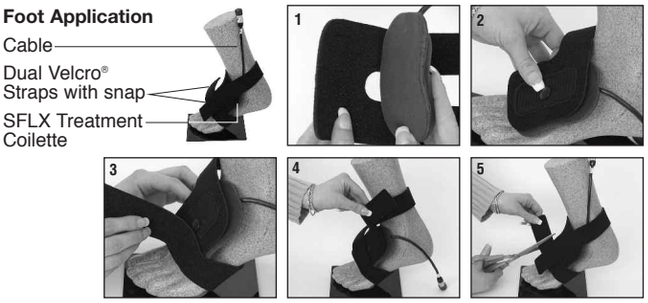
Application Instructions for: SFLX Treatment Coilette

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX Coilette	1068238	Metatarsals, Scaphoid, Distal Radius, Cuboid, M-L Malleous

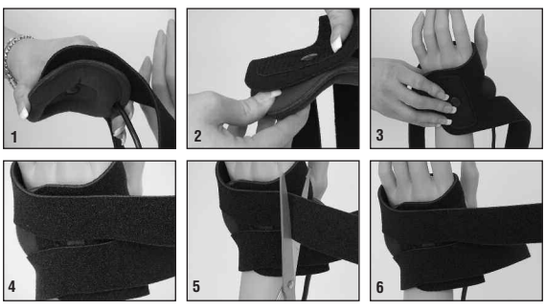
APPLICATION INSTRUCTIONS FOR THE SFLX TREATMENT COILETTE

Foot Application



1. Attach the SFLX Treatment Coilette to the strap by connecting it to the Velcro® hook provided on the strap.
2. Center the SFLX Treatment Coilette over the fracture site.
3. Wrap lower strap around bottom of foot and attach to Velcro® hook.
4. Wrap top strap around ankle and cable, and attach to Velcro® hook.
5. Adjust strap for comfort. Excess strap length may then be cut away. When treatment is completed for the day, remove the SFLX Treatment Coilette by loosening the straps. Leave the straps attached to the SFLX Treatment Coilette. It is ready for your next daily treatment.

Hand Application



1. Shape and place the SFLX Treatment Coilette over the treatment site as instructed by your physician or Biomet representative.
2. Place the SFLX Treatment Coilette onto the Velcro® hook on the strap.
3. Place the SFLX Treatment Coilette over treatment site and bring straps around each side of thumb.
4. Secure Velcro® straps onto the Velcro® hook. Adjust for comfort.
5. Excess strap length may then be cut away.
6. When treatment is completed for the day, remove the SFLX Treatment Coilette by loosening the straps. Leave the straps attached. It is ready for your next daily treatment.

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.

BIOMET® SFLX TREATMENT COILETTE

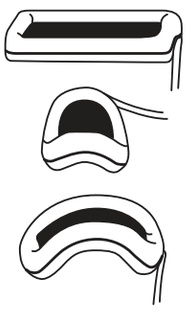
Specifications and Gauge Directions

SFLX Coilette Shape	Depth of Penetration	Vertical Fracture Length
Flat	2.75cm	4.0cm
Elliptical	3.5cm	4.0cm
Saddle	3.5cm	2.0cm

To insure proper fit and efficacious treatment with the SFLX Treatment Coilette:

1. Place the SFLX Treatment Coilette over the treatment site and shape for best fit. The treatment coilette must only be bent in one of two directions (long axis or short axis). Do not kink or twist the treatment coilette.
2. The shape of the treatment coilette will determine the specifications (see above).
3. Remove the treatment coilette and utilize the Flexion Gauge to verify the shape listed below.

Optional Shapes:



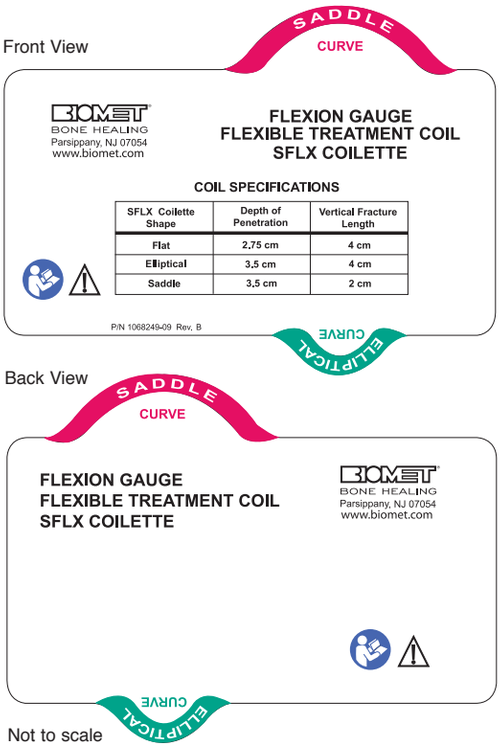
Flat Shape (see coil specifications above) The Flexion Gauge is not needed.

Elliptical Shape (see coil specifications above) Place the treatment coilette over the green portion of the gauge marked “elliptical.” The Coilette bend should not exceed the elliptical curve indicated on the Flexion Gauge.

Saddle Shape (see specifications above) Place the treatment coilette over the red portion of the gauge marked “saddle.” The treatment coilette bend should not exceed the saddle curve on the Flexion Gauge.

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 coilette at the treatment site and shape for best fit. Treatment coilette must only be bent in one of two directions: Long or short axis. Do not kink or twist the treatment coilette. The shape of the treatment coilette will determine the specifications.
2. Remove the shaped treatment coilette and utilize the Flexion Gauge to verify the acceptable bend according to the shape listed below.
3. If the treatment coilette shape does not fit the curve on the Flexion Gauge, contact your Biomet representative for a suitable replacement and assistance.



Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX Coilette for Clavicle Application PN 1068318-11

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX Coilette Therapeutic Treatment Coil for Clavicle Application

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CLAVICLE PLACEMENT APPLICATION INSTRUCTIONS

Application Instructions for: SFLX Treatment Coilette

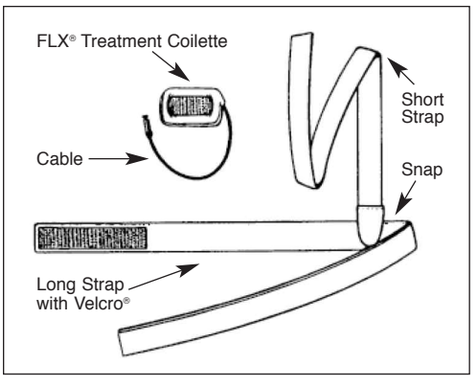
Applies to:

Description	Treatment Coil	Suggested Placement
SFLX Coilette	1068238 and 1068314 (strapping)	Clavicle

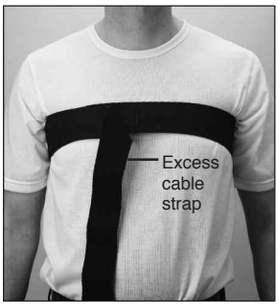
Flexion Gauge Specifications for SFLX Coilette

SFLX Coilette Shape	Depth of Penetration	Vertical Fracture Length
Flat	2.75cm	4cm

The SFLX Coilette for Clavicle placement requires a SFLX Treatment Coilette and strapping in order to be properly fitted over the affected torso and shoulder.



1. Place the SFLX Treatment Coilette and straps provided on a flat surface. The straps are provided snapped together. Notice that the strap with Velcro® is longer than the one without Velcro®.



2a. Wrap the long strap with Velcro® around your chest and back onto itself. Secure it in place with the Velcro®.

2b. Note, the snap should be located in the center of your back.

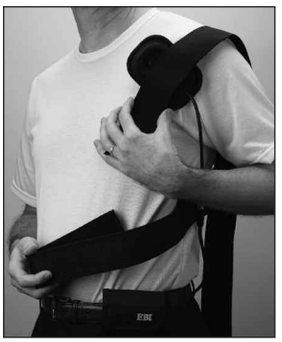
3. Pull the remaining short strap from behind your back over the shoulder on the treatment side.

4. Place the SFLX Treatment Coilette over the treatment site as instructed by the prescribing physician or Biomet representative.

5. Secure the SFLX Treatment Coilette in place by passing the strap over the Velcro® on the SFLX Treatment Coilette and onto the chest strap. Close the chest strap.

6a. Adjust for comfort. Excess shoulder and chest strap lengths may be then cut away.

6b. Common position.



7. When treatment is completed for the day, remove the SFLX Treatment Coilette by unhooking the strap from around your chest. Leave the strap over your shoulder secured to the SFLX Treatment Coilette and chest strap. Remove the SFLX Treatment Coilette. It is ready for your next daily treatment.

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

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX XL Coilette
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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

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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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

The EBI 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

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1068318-10 Rev. B

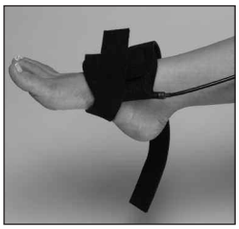
SFLX XL TREATMENT COILETTE FOOT APPLICATION

Application Instructions for: SFLX XL Treatment Coilette

Applies to:

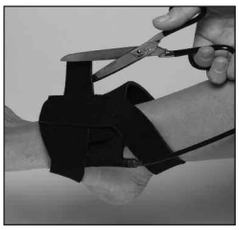
Description	Treatment Coil	Suggested Placement
SFLX XL Coilette	1068240	Foot, Hand, Small bones

1. Center the SFLX XL Treatment Coilette over the fracture nonunion site. Conform the treatment coil and verify with Flexion Gauge.



2. Wrap lower strap around bottom of foot and attach to Velcro® hook.

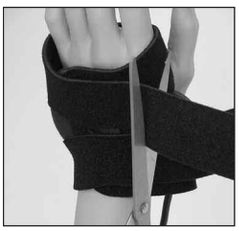
3. Wrap upper strap around ankle and cable. Attach to Velcro® hook.



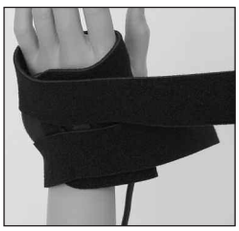
4. Adjust straps for comfort. Excess strap length may be cut away. When treatment is complete for the day, remove the coilette by loosening the straps.

SFLX XL TREATMENT COILETTE HAND APPLICATION

1. Center the coilette over the fracture nonunion site. Conform shape and remove. Verify treatment coil is conformed within treatment limit using Flexion Gauge. Secure upper proximal strap first. Wrap strap around hand and attach to Velcro® hook.



2. Secure lower distal strap by wrapping around fracture nonunion site and attaching to Velcro® hook. Cut away excess strap length.



3. Adjust straps for comfort. When treatment is complete for the day, remove the coilette by loosening the straps.

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 XL TREATMENT COILETTE

Flexion Gauge Specifications for SFLX Coilette

SFLX Coilette Shape	Depth of Penetration	Vertical Fracture Length
Flat	3.5cm	6cm
Eliptical	4.25cm	6cm
Saddle	5.5cm	4cm

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

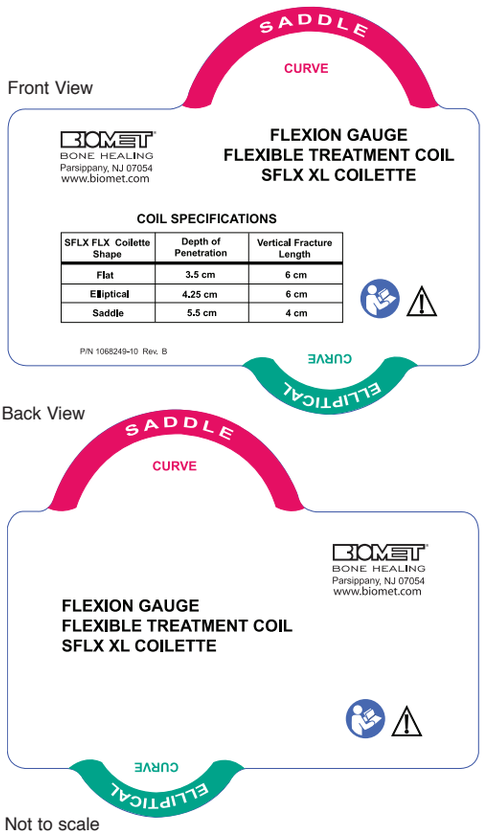
1. Place the treatment coilette at the treatment site and shape for best fit. The SFLX Treatment Coilette must only be bent in one of two directions. Long or short axis, see illustrations that follow. Do not kink or twist the treatment coilette. The shape of the treatment coilette will determine the specifications.
2. Remove the shaped treatment coilette and utilize the Flexion Gauge to verify the acceptable bend according to the shape listed below.
3. If the treatment coilette is flexed in excess of the green or red outlines, contact your Biomet representative for a suitable replacement and assistance.

Optional Shapes:

Flat Shape (see coil specifications above) The Flexion Gauge is not needed.

Elliptical Shape (see coil specifications above) Place the treatment coilette over the green portion of the gauge marked “elliptical.” The Coilette bend should not exceed the elliptical curve indicated on the Flexion Gauge.

Saddle Shape (see specifications above) Place the treatment coilette over the red portion of the gauge marked “saddle.” The treatment coilette bend should not exceed the saddle curve on the Flexion Gauge.



Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 1
PN 1068318-02

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX 1 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

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CONTRAINDICATIONS

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

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

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

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- Flexion Gauge
- User, Safety & Application Instructions

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1068318-02 Rev. B

SFLX 1 TREATMENT COIL APPLICATION
Application Instructions for: SFLX 1 Treatment Coil

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX 1	1068226	Metatarsals, Radius, Ulna, Scaphoid, Metacarpals

Flextion Gauge Coil Tolerances for SFLX 1 Treatment Coil

Flex Span	Min (9cm)	Max (13cm)
Maximum depth of penetration	6.5cm	5.5cm
Maximum fracture length	7cm	6cm

Center the SFLX 1 Coil over the fracture nonunion site. Conform the treatment coil and verify with the Flexion Gauge.

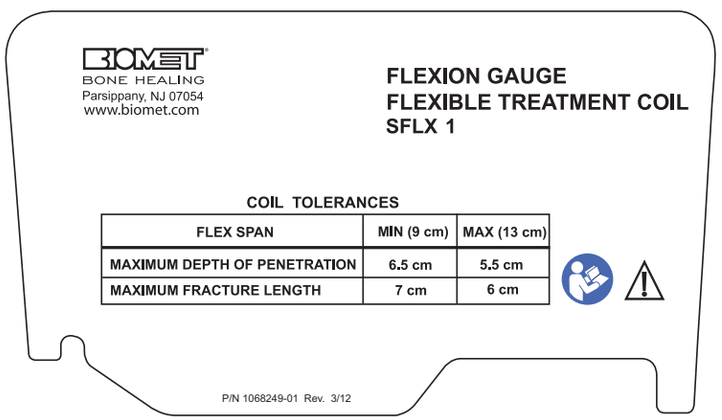
NOTE: During treatment, the position of the treatment coil may shift due to normal patient activity. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc). The treatment coil may be loosened and may need to be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

FLEXION GAUGE INSTRUCTIONS FOR SFLX 1 TREATMENT COIL

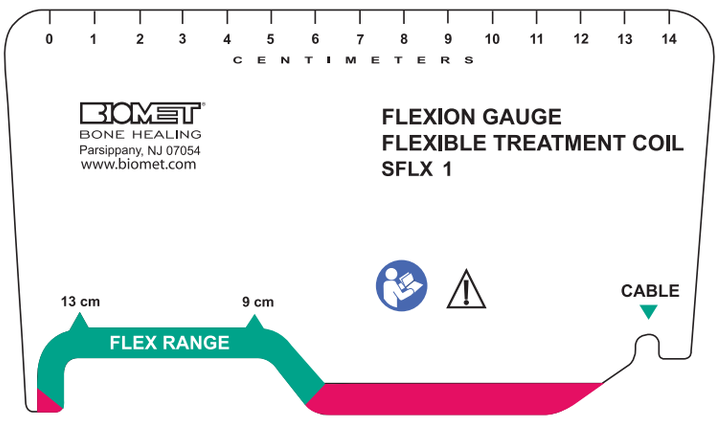
In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

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 Guage 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 your Biomet representative for a suitable replacement and assistance.

Front View



Back View



Not to scale

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 2
PN 1068318-03

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX 2 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.

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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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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:

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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.

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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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

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1068318-03 Rev. B

SFLX 2 TREATMENT COIL APPLICATION
Application Instructions for: SFLX 2 Treatment Coil

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX 2	1068226	Humerus, Tibia, Fibula, Radius, Ulna

Flextion Gauge Coil Tolerances for SFLX 2 Treatment Coil

Flex Span	Min (8cm)	Max (11cm)
Maximum depth of penetration	8cm	7cm
Maximum fracture length	10cm	10cm

Center the SFLX 2 Coil over the fracture nonunion site. Conform the treatment coil and verify with the Flexion Gauge.

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 2 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.
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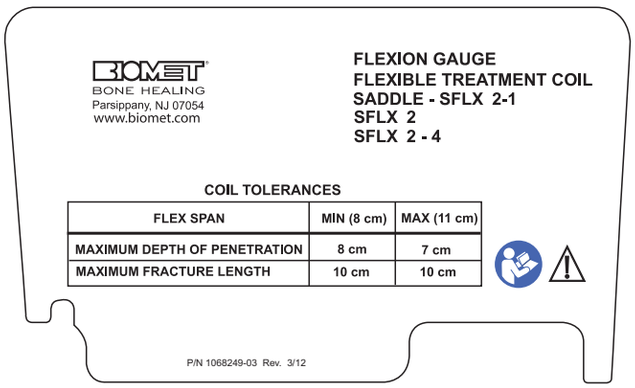
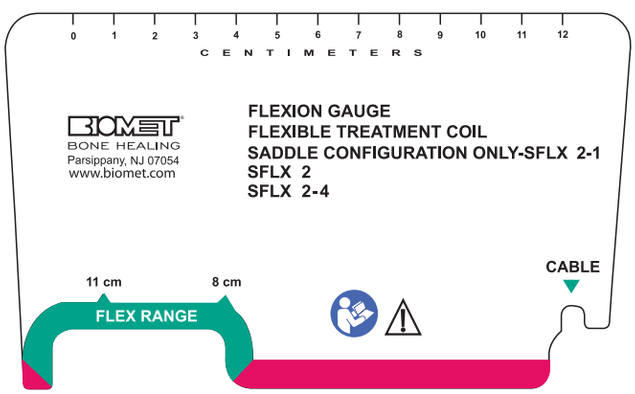


Back View



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Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 2-1 & 4-1
PN 1068318-04

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

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

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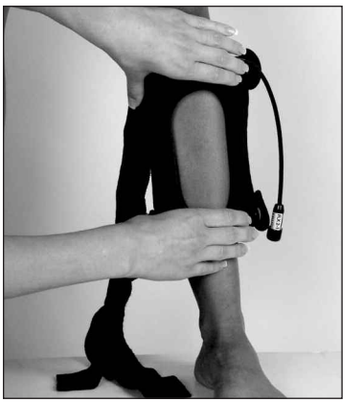
- Do Not Reuse.

1068318-04 Rev. B

SFLX 2-1 AND 4-1 TREATMENT COILS — LONG VERTICAL FRACTURE APPLICATION

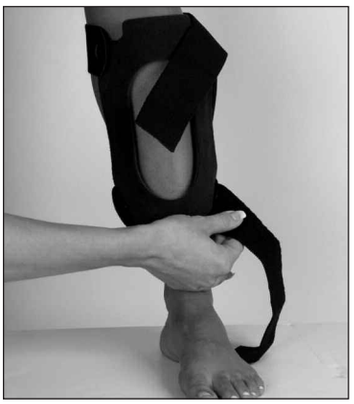
See Flexion Gauge Instructions for measuring the tolerances of the treatment coil on the following page.

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

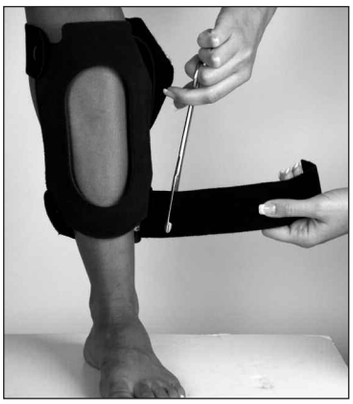


1. Position treatment coil so that it is centered within the entire fracture length according to the prescribing physician instructions. Make sure the treatment coil is firmly in place before securing straps.

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



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



4. Cut excess straps to size.

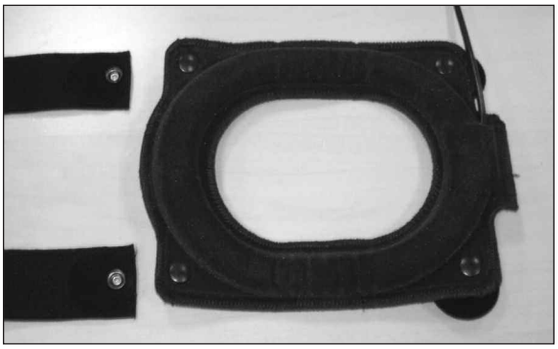
Application Instructions for SFLX 2-1 and SFLX 4-1 Treatment Coils

Applies to:

Description	Treatment Coil	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 to the left.



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 (10cm)	Max (12cm)
Maximum depth of penetration	5cm	4.5cm
Maximum fracture length	16cm	14cm

Flexion Gauge Coil Tolerances for SFLX 4-1

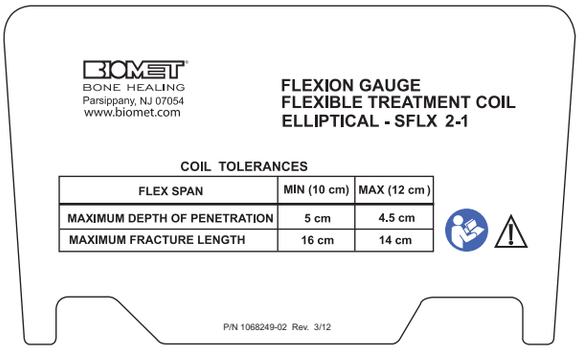
Flex Span	Min (12cm)	Max (14cm)
Maximum depth of penetration	6cm	6cm
Maximum fracture length	22cm	18cm

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.

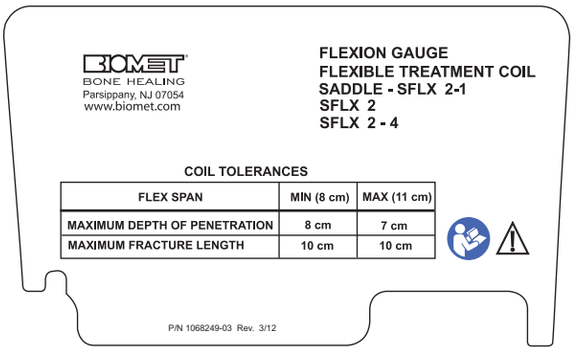
In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

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 your Biomet representative for a suitable replacement and assistance.

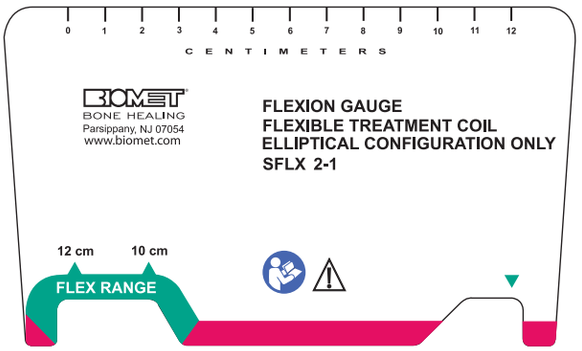
Front View



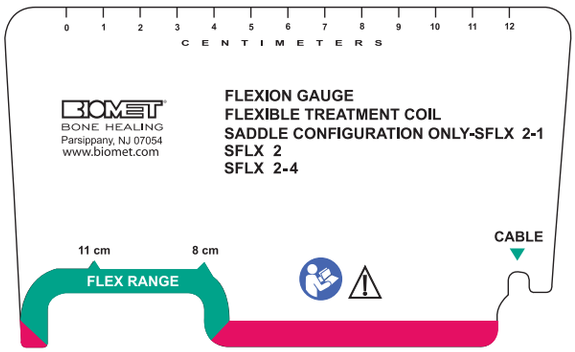
Front View



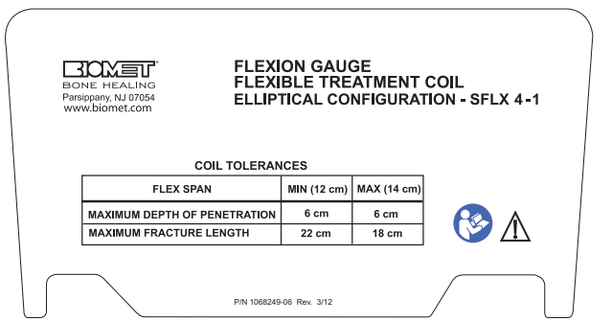
Back View



Back View



Front View



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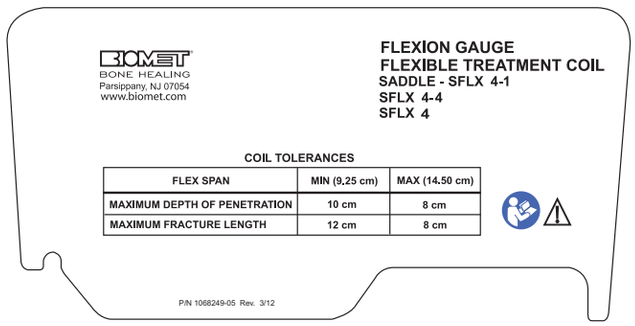
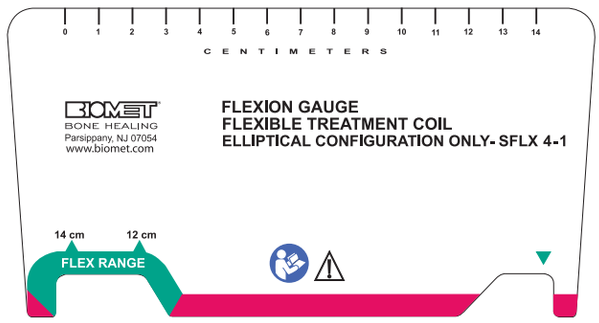
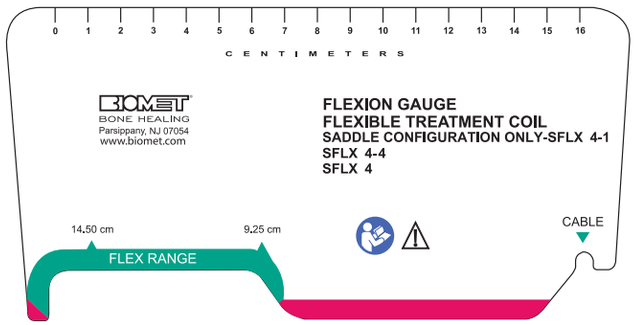


Back View



Not to scale

Back View



Not to scale

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 2-2 & 4-4
PN 1068318-05

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX 2-4 and 4-4 Therapeutic Treatment Coils

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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

The EBI 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

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1068318-05 Rev. B

SFLX 2-4 AND 4-4 TREATMENT COIL – ANKLE APPLICATION

Application Instructions for: SFLX 2-4 and SFLX 4-4 Treatment Coils

Applies to:

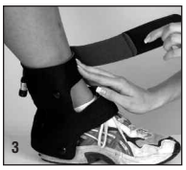
Description	Treatment Coil	Suggested Placement
SFLX 2-4	1068228	Ankle
SFLX 4-4	1068237	Ankle

See Flexion Gauge Instructions for measuring the tolerances of the coil

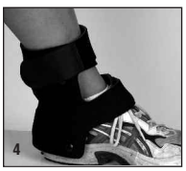
NOTE: Position SFLX Treatment Coil. Make sure the SFLX Treatment Coil is secured in the strapping before tightening straps.

1. Position SFLX Treatment Coil over the fracture nonunion site at the back of the ankle (for ankle application) according to the prescribing physician instructions. Make certain the SFLX Treatment Coil is flush with the bottom of the foot. Make sure the SFLX Treatment Coil is firmly in place before securing straps.

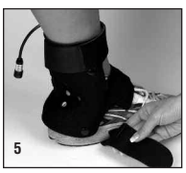
2. Both top and bottom straps are then positioned over the front of the ankle.



3. Fasten straps into place by pressing strap onto Velcro® hook.



4. Readjust both straps for a secure, comfortable fit opposite the Velcro® hook before cutting excess straps to size. DO NOT over tighten.



5. Optional: If the treatment coil migrates upward, you may use the additional provided strap to secure it. Simply fasten one end of the strap to the medial (inside seam) side of the ankle, bring strap under the foot and back around to the lateral (outside) side of ankle. Fasten strap into place by pressing strap onto Velcro® hook.

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 2-4 AND SFLX 4-4 TREATMENT COILS

Flexion Gauge Coil Tolerances for SFLX 2-4

Flex Span	Min (8cm)	Max (11cm)
Maximum depth of penetration	8cm	7cm
Maximum fracture length	10cm	10cm

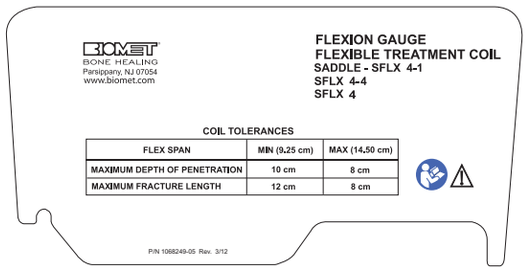
Flexion Gauge Coil Tolerances for SFLX 4-4

Flex Span	Min (9.25cm)	Max (14.50cm)
Maximum depth of penetration	10cm	8cm
Maximum fracture length	12cm	8cm

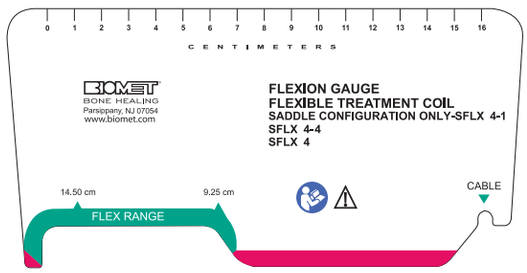
In order to ensure proper fit and efficacious treatment the Flexion Gauge should be employed to check for the proper shape.

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 the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite treatment coil edge should fall within the green zone in the area marked “FLEXION RANGE”. Each Flexion Gauge has a chart of treatment coil tolerances with depth of penetration data.
3. If the SFLX Treatment Coil edge does not fall within the green zone contact your Biomet representative for a suitable replacement and assistance.

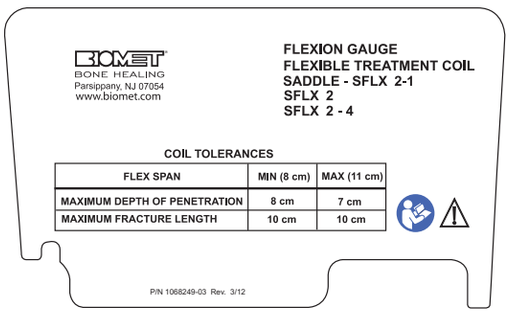
Front View



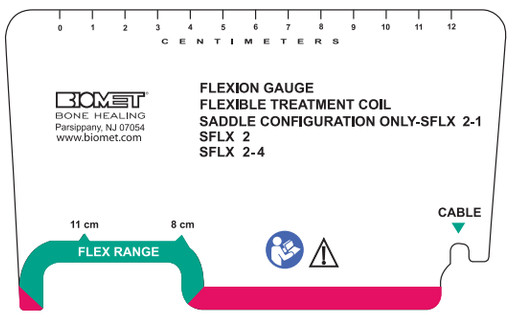
Back View



Front View



Back View



Not to scale

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 3
PN 1068318-06

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX 3 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

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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.

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D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

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- SFLX Therapeutic Treatment Coil
- Flexion Gauge
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1068318-06 Rev. B

SFLX 3 TREATMENT COIL APPLICATION
Application Instructions for: SFLX 3 Treatment Coil

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX 3	1068229	Radius, Ulna, Metatarsals, Distal Tibia/Fibula

Flextion Gauge Coil Tolerances for SFLX 3 Treatment Coil

Flex Span	Min (5cm)	Max (9cm)
Maximum depth of penetration	7cm	5.5cm
Maximum fracture length	7cm	6cm

Center the SFLX 3 Coil over the fracture nonunion site. Conform the treatment coil and verify with the Flexion Gauge.

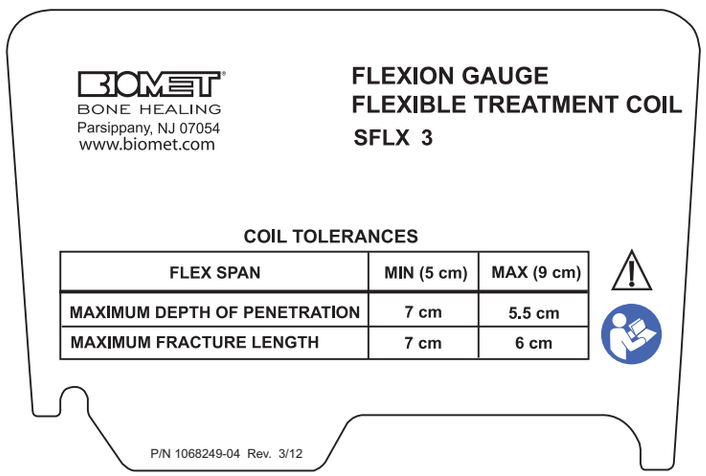
NOTE: During treatment, the position of the treatment coil may shift due to normal patient activity. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc). The treatment coil may be loosened and may need to be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

FLEXION GAUGE INSTRUCTIONS FOR SFLX 3 TREATMENT COIL

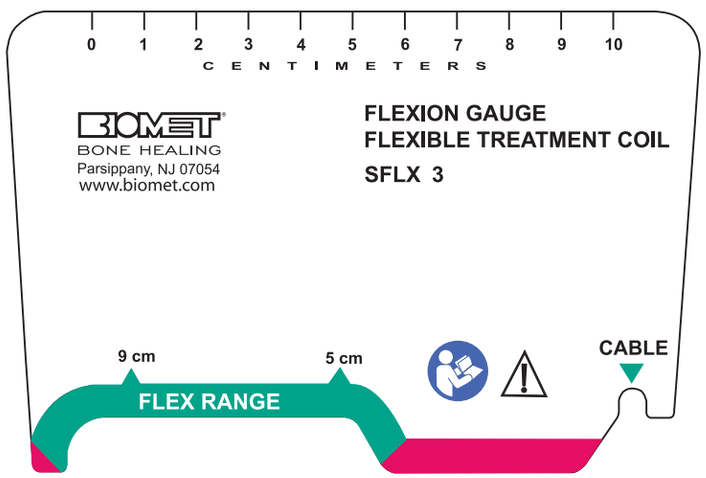
In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

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 Guage 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 your Biomet representative for a suitable replacement and assistance.

Front View



Back View



Not to scale

Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 4
PN 1068318-07

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System SFLX 4 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.

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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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

The EBI 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

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1068318-07 Rev. B

SFLX 4 TREATMENT COIL APPLICATION
Application Instructions for: SFLX 4 Treatment Coil

Applies to:

Description	Treatment Coil	Suggested Placement
SFLX 4	1068235	Midshaft Femur, Tibia/Fibula, Humerus

Flextion Gauge Coil Tolerances for SFLX 4 Treatment Coil

Flex Span	Min (9.25cm)	Max (14.50cm)
Maximum depth of penetration	10cm	8cm
Maximum fracture length	12cm	8cm

Center the SFLX 4 Coil over the fracture nonunion site. Conform the treatment coil and verify with the Flexion Gauge.

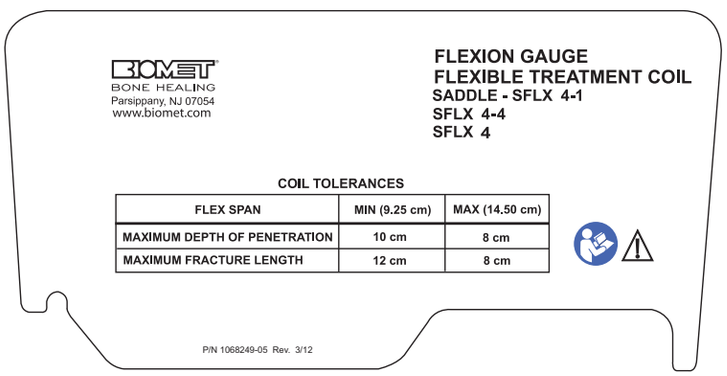
NOTE: During treatment, the position of the treatment coil may shift due to normal patient activity. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc). The treatment coil may be loosened and may need to be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

FLEXION GAUGE INSTRUCTIONS FOR SFLX 4 TREATMENT COIL

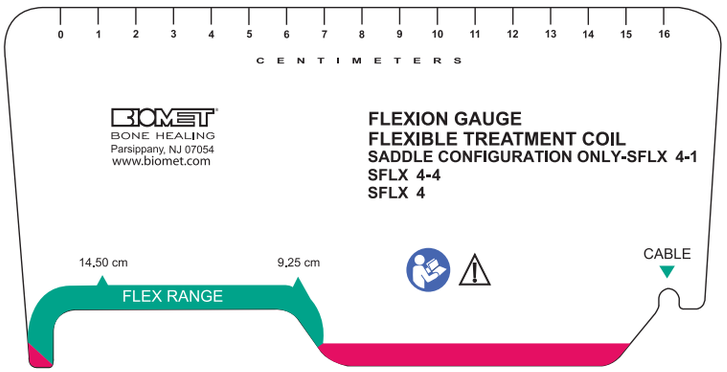
In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

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 Guage 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 your Biomet representative for a suitable replacement and assistance.

Front View



Back View



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Package Insert Containing Important User, Safety & Application Instructions for the:

SFLX 5
PN 1068318-01

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the 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 **Biomet**® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

D. The **Biomet**® EBI 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 **Biomet**® EBI 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 **Biomet**® EBI Bone Healing System.

ADVERSE EFFECTS

The EBI 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%).

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1068318-01 Rev. B

SFLX 5 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

Flextion Gauge Coil Tolerances for SFLX 5 Treatment Coil

Flex Span	Min (13cm)	Max (20cm)
Maximum depth of penetration	12cm	10cm
Maximum fracture length	10cm	10cm

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

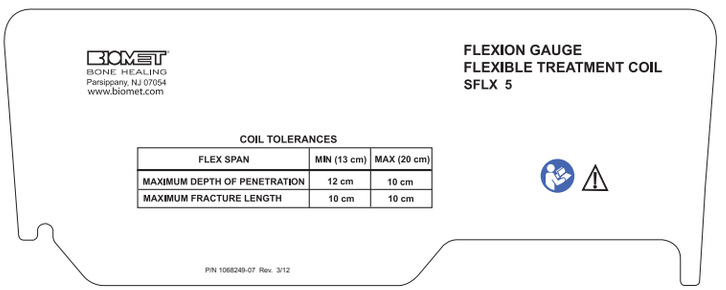
NOTE: During treatment, the position of the treatment coil may shift due to normal patient activity. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc). The treatment coil may be loosened and may need to be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

FLEXION GAUGE INSTRUCTIONS FOR SFLX 5 TREATMENT COIL

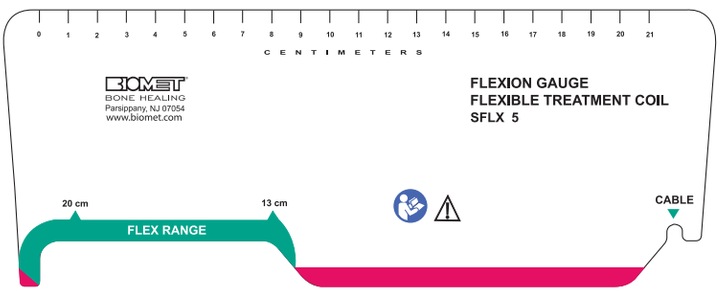
In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be employed to check for the proper shape.

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 Guage 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 your Biomet representative for a suitable replacement and assistance.

Front View



Back View



Not to scale

Package Insert Containing Important User, Safety & Application Instructions for the:

Extremity Band
Therapeutic Treatment Coil
PN 1068318-12

IMPORTANT USER, SAFETY & APPLICATION INSTRUCTIONS

For the Biomet® EBI Bone Healing System Extremity Band 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

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CONTRAINDICATIONS

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

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PRECAUTIONS

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ADVERSE EFFECTS

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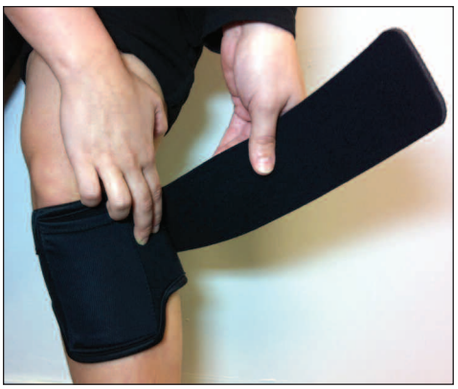
1068318-12 Rev. B

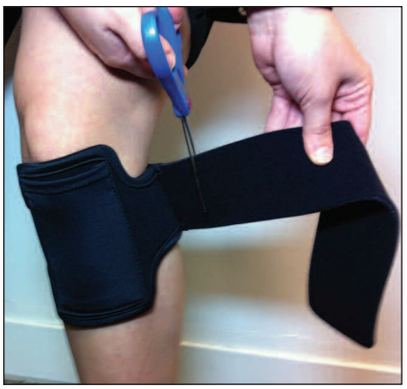
EXTREMITY BAND — UPPER AND LOWER EXTREMITY APPLICATION
Application Instructions for: Extremity Band

Applies to:

Description	Part Number	Suggested Placement
Extremity Band	1068209	Upper and lower extremity applications

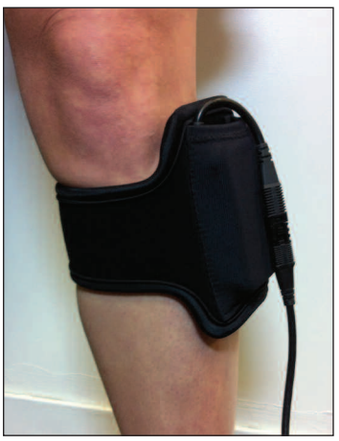
The Extremity Band is an accessory which may be helpful when wearing the controller for treating fracture nonunions in the upper or lower extremities. The band facilitates for convenient placement of the controller closer to the treatment area (as opposed to wearing at the waist). Once applied and adjusted for comfort, excess strap lengths may then be cut away as illustrated below.

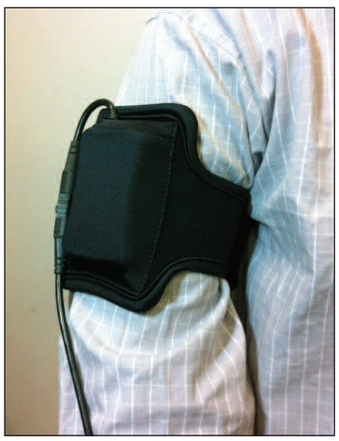

Extremity band being applied


Extremity band being trimmed


Unit being inserted into sleeve

Most common applications would be for treatment of foot/ankle or hand/wrist fracture nonunions.





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