Coil Placement Guide

Biomet® EBI® Bone Healing System

SFLX Treatment Coil

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SFLX Treatment Coil Placement Suggestions

The SFLX Treatment Coil is chosen by the prescribing physician and authorized representative based upon the anatomical location of the treatment location, the vertical length of the fracture nonunion, the field of coverage required and the physical size of the patient. The anatomic locations are suggested based on treatment coil size and configuration. The selection of a suitable treatment coil is specific to each patient and should take into account factors such as activity level, presence of a cast, patient body mass index (BMI), etc. This guide is designed to assist in the best application locations for various fracture nonunion or failed fusion types but is by no means a definitive guide for treatment coil placement on every possible fracture nonunion or failed fusion.

Use the table below to determine the recommended treatment coil based on the patient's individual fracture nonunion or failed fusion.

Catalog #	SFLX Coil Description	Minimum Maximum	M/L Flexion	Depth of Penetration	Vertical Fracture Length	Anatomical Location(s)
1068225	SFLX 1	Minimum Maximum	9 cm 13 cm	6.5 cm 5.5 cm	7 cm 6 cm	Metatarsals, Scaphoid, Metacarpals, Radius, Ulna
1068226	SFLX 2	Minimum Maximum	8 cm 11 cm	8 cm 7 cm	10 cm 10 cm	Humerus, Tibia, Fibula, Radius, Ulna
1068227	SFLX 2-1 (Elliptical)	Minimum Maximum	10 cm 12 cm	5 cm 4.5 cm	16 cm 14 cm	Tibia, Fibula, Radius, Ulna, Humerus
1068227	SFLX 2-1 (Saddle)	Minimum Maximum	8 cm 11 cm	8 cm 7 cm	10 cm 10 cm	Tibia, Fibula, Radius, Ulna, Humerus
1068228	SFLX 2-4	Minimum Maximum	8 cm 11 cm	8 cm 7 cm	10 cm 10 cm	Ankle
1068229	SFLX 3	Minimum Maximum	5 cm 9 cm	7 cm 5.5 cm	7 cm 6 cm	Radius, Ulna, Metatarsals, Distal Tibia/Fibula
1068235	SFLX 4	Minimum Maximum	9.25 cm 14.5 cm	10 cm 8 cm	12 cm 8 cm	Midshaft Femur, Tibia, Fibula, Humerus
1068236	SFLX 4-1 (Elliptical)	Minimum Maximum	12 cm 14 cm	6 cm 6 cm	22 cm 18 cm	Tibia, Fibula, Humerus, Radius, Ulna
1068236	SFLX 4-1 (Saddle)	Minimum Maximum	9.25 cm 14.5 cm	10 cm 8 cm	12 cm 8 cm	Tibia, Fibula, Humerus, Radius, Ulna
1068237	SFLX 4-4	Minimum Maximum	9.25 cm 14.5 cm	10 cm 8 cm	12 cm 8 cm	Ankle
1068224	SFLX 5	Minimum Maximum	13 cm 20 cm	12 cm 10 cm	10 cm 10 cm	Femur (Proximal or Midshaft)
1068239	SFLX Mini Coilette	Minimum Maximum	2.5 cm 3.5 cm	2.5 cm 2 cm	1.5 cm 1.5 cm	Phalanges
1068238	SFLX Coilette	Flat Elliptical Saddle	N/A N/A N/A	2.75 cm 3.5 cm 3.5 cm	4 cm 4 cm 2 cm	Clavicle, Metatarsals, Scaphoid, Distal Radius, Cuboid, Medial Lateral Malleolus
1068240	SFLX XL Coilette	Flat Elliptical Saddle	N/A 5 cm 7.5 cm	3.5 cm 4.25 cm 5.5 cm	6 cm 4 cm 4 cm	Foot, Hand, Small Bones
1068313	Black Velcro Strapping for SFLX Treatment Coilette					
1068314	Black Velcro Strapping for SFLX Treatment Coilette - Clavicle Application					

NOTE: For full prescribing information including indications, precautions, warnings, and product operation instructions please refer to the product manual available with all stimulation products.

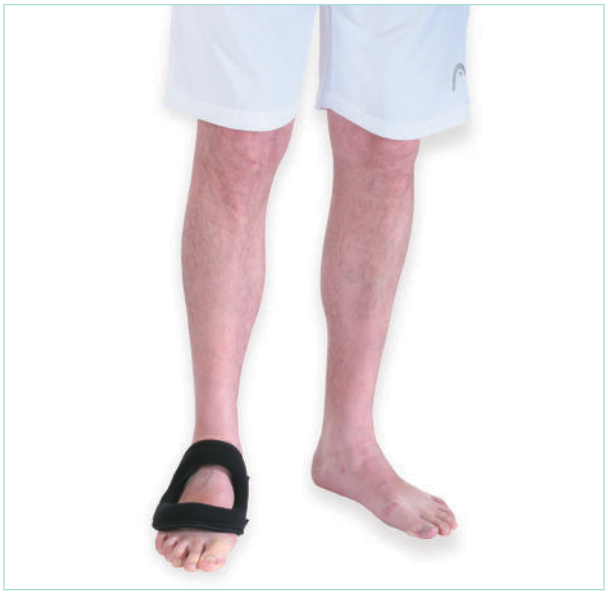
SFLX 1 Coil Placements (Catalog #1068225)

Midshaft Radius/Ulna

Distal Radius/Ulna

Metacarpals

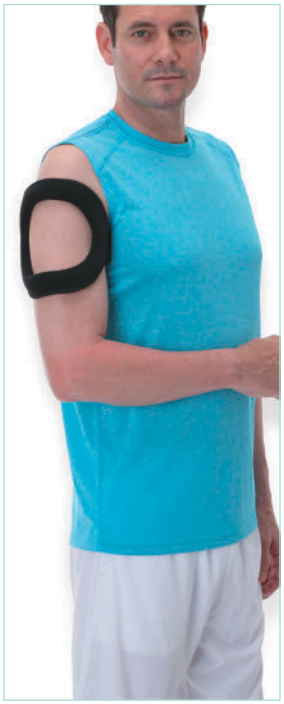
Scaphoid



Flex Span	Min (9 cm)	Max (13 cm)
Maximum Depth of Penetration	6.5 cm	5.5 cm
Maximum Fracture Length	7 cm	6 cm

SFLX 2 Coil Placements (Catalog #1068226)

Proximal Humerus



Distal Humerus

Proximal Radius/Ulna

Proximal Tibia/Fibula

Distal Tibia/Fibula

Flex Span	Min (8 cm)	Max (11 cm)
Maximum Depth of Penetration	8 cm	7 cm
Maximum Fracture Length	10 cm	10 cm

SFLX 2-1 (Elliptical) Coil Placements (Catalog #1068227)

Proximal Humerus

Midshaft Humerus

Radius/Ulna

Tibia/Fibula

Flex Span	Min (10 cm)	Max (12 cm)
Maximum Depth of Penetration	5 cm	4.5 cm
Maximum Fracture Length	16 cm	14 cm

SFLX 2-1 (Saddle) Coil Placements (Catalog #1068227)

Humerus

Radius/Ulna

Tibia/Fibula

Flex Span	Min (10 cm)	Max (12 cm)
Maximum Depth of Penetration	5 cm	4.5 cm
Maximum Fracture Length	16 cm	14 cm

SFLX 2-4 Coil Placements (Catalog #1068228)

Ankle

Ankle

Flex Span	Min (8 cm)	Max (11 cm)
Maximum Depth of Penetration	8 cm	7 cm
Maximum Fracture Length	10 cm	10 cm

SFLX 3 Coil Placements (Catalog #1068229)

Midshaft Radius/Ulna

Distal Radius/Ulna

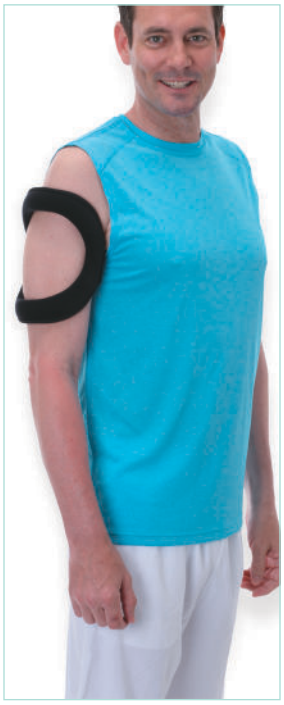
Metatarsals

Distal Tibia/Fibula

Flex Span	Min (5 cm)	Max (9 cm)
Maximum Depth of Penetration	7 cm	5.5 cm
Maximum Fracture Length	7 cm	6 cm

SFLX 4 Coil Placements (Catalog #1068235)

Humerus



Midshaft Femur

Proximal Tibia/Fibula

Proximal Tibia/Fibula

Flex Span	Min (9.25 cm)	Max (14.50 cm)
Maximum Depth of Penetration	10 cm	8 cm
Maximum Fracture Length	12 cm	8 cm

SFLX 4-1 (Elliptical) Coil Placements (Catalog #1068236)

Humerus

Radius/Ulna

Tibia/Fibula

Flex Span	Min (12 cm)	Max (14 cm)
Maximum Depth of Penetration	6 cm	6 cm
Maximum Fracture Length	22 cm	18 cm

SFLX 4-1 (Saddle) Coil Placements (Catalog #1068236)

Humerus

Radius/Ulna

Tibia/Fibula

Flex Span	Min (12 cm)	Max (14 cm)
Maximum Depth of Penetration	6 cm	6 cm
Maximum Fracture Length	22 cm	18 cm

SFLX 4-4 Coil Placements (Catalog #1068227)

Ankle

Ankle

Flex Span	Min (9.25 cm)	Max (14.5 cm)
Maximum Depth of Penetration	10 cm	8 cm
Maximum Fracture Length	12 cm	8 cm

SFLX 5 Coil Placement (Catalog #1068224)

Proximal Femur

Flex Span	Min (13 cm)	Max (20 cm)
Maximum Depth of Penetration	12 cm	10 cm
Maximum Fracture Length	10 cm	10 cm

SFLX Mini Coilette Placement (Catalog #1068239)

Phalanges

Flex Span	Min (2.5 cm)	Max (3.5 cm)
Maximum Depth of Penetration	2.5 cm	2.0 cm
Maximum Fracture Length	1.5 cm	1.5 cm

SFLX Coilette Coil Placements (Catalog #1068238)

Clavicle*

Distal Radius

Scaphoid

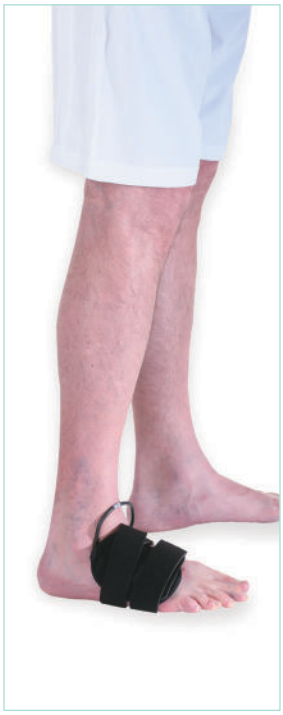
Scaphoid

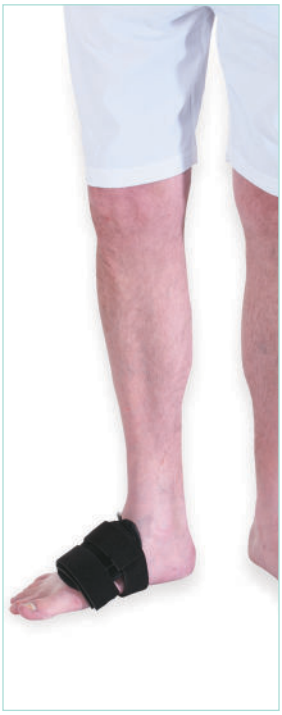
SFLX Coilette Shape	Depth of Penetration	Vertical Fracture Length
Flat	2.75 cm	4.0 cm
Elliptical	3.5 cm	4.0 cm
Saddle	3.5 cm	2.0 cm

*Clavicle Strap Required (Catalog #1068314)

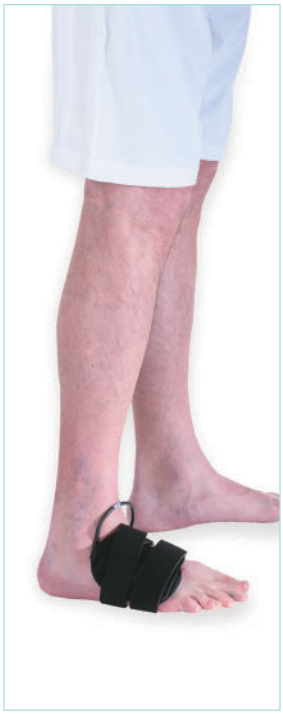
SFLX Coilette Coil Placements (Catalog #1068238) continued

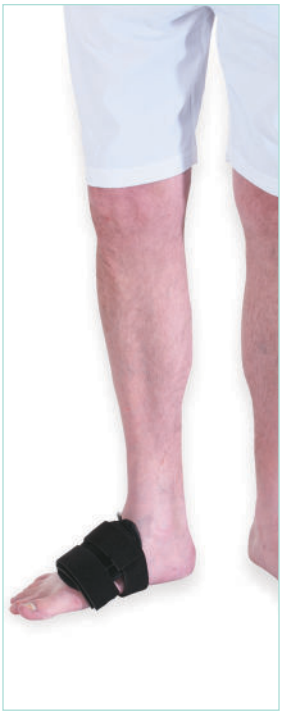
Metatarsals





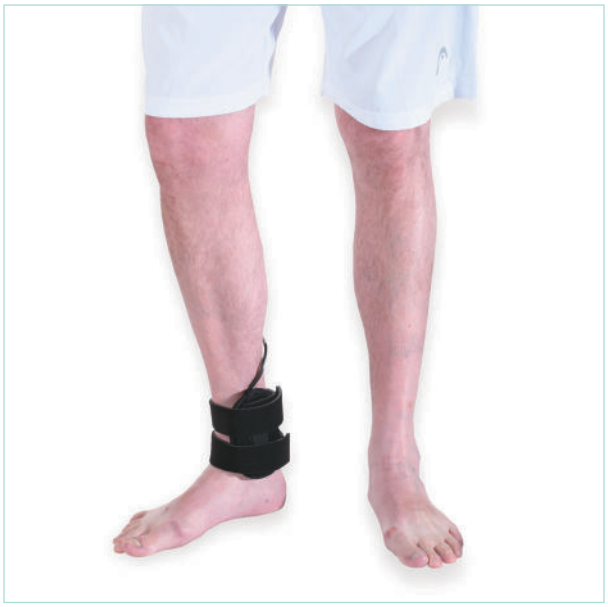
Cuboid





Lateral Malleolus

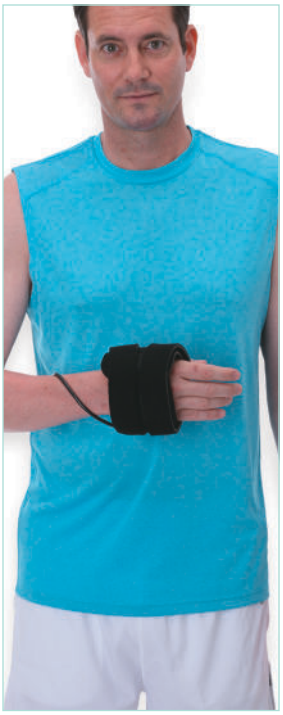
Medial Malleolus



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

SFLX XL Coilette Coil Placements (Catalog #1068240)

Hand



Small Bones

Foot

Foot

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

Coil Placements Over a Cast

Radius/Ulna (SFLX 1) Catalog #1068225

Radius/Ulna (SFLX 2) Catalog #1068226

Tibia/Fibula (SFLX 2) Catalog #1068226

Metatarsals (SFLX 3) Catalog #1068229

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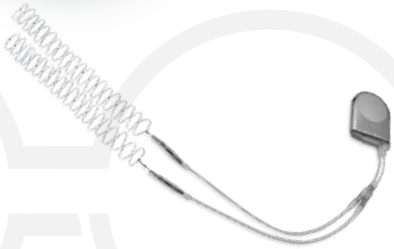

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Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. The Biomet® EBI® Bone Healing System is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. Contraindicated for nonunion fractures in which a synovial pseudarthrosis exists. Electromagnetic PEMF stimulation is contraindicated for use by patients with implantable pacemakers or defibrillators. The Bone Healing System is not MR safe. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. The SpinalPak is a non-invasive spine fusion stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. No known contraindications. Rx Only. Single Patient Use Only. Do Not Reuse. The OrthoPak is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. Contraindicated if the individual has synovial pseudarthrosis. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. OsteoGen stimulators are indicated in the treatment of long bone nonunions. No known contraindications. Not recommended with the following conditions: pathological fractures due to malignant tumors or active osteomyelitis. Federal Law (U.S.A.) restricts these devices to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. SpF stimulators are indicated as a lumbar spinal fusion adjunct to increase the probability of fusion success in one or two levels or three or more levels. Do not use with defibrillators. If the stimulators are used in conjunction with metal internal fixation devices, no metallic part of the stimulator should be allowed to come into contact with the fixation device; this includes minimally invasive surgical-MIS procedures. Any surgical implantation procedure such as minimally invasive surgical-MIS procedures requiring the SpF's cathodes to be disconnected from their corresponding leads prior to or during implantation. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. This material is intended for health care professionals. Distribution to any other recipient is prohibited.. HM0698 REV A 04/25.