



Placement Guide



Biomet[®] EBI[®] Bone Healing System

SFLX Treatment Coil



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

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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 fracture nonunion, the vertical length of the fracture nonunion, the field of coverage required to treat the fracture nonunion 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		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



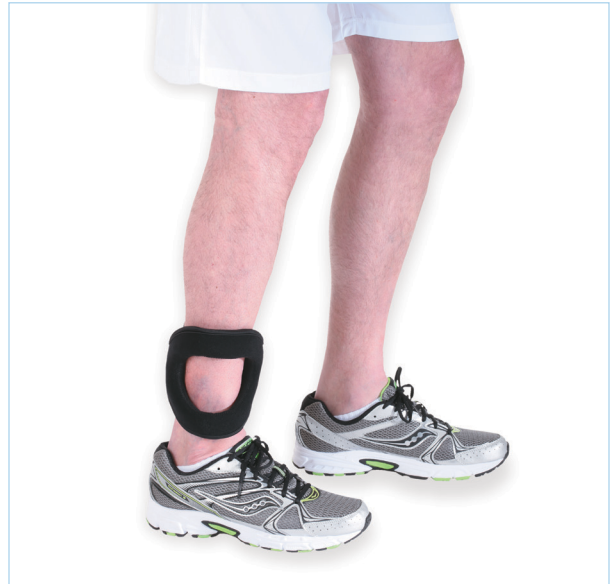
Distal Radius/Ulna



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



SFLX Treatment Coil Placement Guide

SIMPLE to use.

FAST device application.

PROVEN, clinically.

INDICATIONS: The Biomet EBI Bone Healing System - P790002/S028/S026 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 - P790005/S041.

USAGE: These device systems are durable therapeutic electrical devices intended for single patient use only under a prescription. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only - Single Use Only - Not for Re-Sale or Re-Distribution - Do Not Reuse.

CONTRAINDICATIONS: Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap) exists. Under certain conditions, electromagnetic stimulation could inhibit the output of some demand pacemakers or implantable defibrillators. Therefore, it is not recommended for patients with certain types of pacemakers or implantable defibrillators. Patients should be cautioned to avoid coming in close proximity to pacemaker or defibrillator wearers during stimulation. Use of these device systems on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.



For more information, visit [ZimVie.com](https://www.zimvie.com)

ZimVie

1 Gatehall Drive,
Suite 303
Parsippany, NJ 07054
1-800-526-2579



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A ZimVie Company
484 Calle E
Guaynabo, PR 00969 USA



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