Healthcare Professional Brochure

SpF®

Implantable Spinal Fusion Stimulators

Powered by Direct Current Technology

What is the SpF® implantable stimulator?

The SpF® implantable stimulator is a class III, FDA approved, bone growth stimulation implant designed as an adjunctive therapy to aid in the healing of spinal fusions. It is a proven, safe and effective electrical bone growth stimulation therapy that has improved patient healing outcomes for over 35 years.

Features & Benefits

- The first and only bone growth stimulation implant to support spinal fusion outcomes.
- The unique, implantable bone growth stimulator allows surgeons to place the cathodes precisely over the targeted treatment site offering controlled treatment to the area where patient's need it most.
- The device provides constant, around-the-clock stimulation therapy, empowering surgeons to improve their patient's healing outcomes with no concern for compliance.
- The innovative cathode design enables increased surface area for active bone growth stimulation at the targeted treatment site.
- The optional generator removal is a simple and fast surgical procedure that can be performed in an Ambulatory Surgery Center (ASC).
- The sterilely packed implant improves operational efficiencies; no special instrumentation required.

Specifications

Technology: Direct Current (DC)
MRI Conditions: 1.5 & 3.0 Tesla
Original FDA Approval Date: 1988

- Model: SpF® PLUS-Mini
- Signal: 60 µA
- # of Levels: 1 – 2 Levels

- Model: SpF®-XL IIb
- Signal: 40 µA
- # of Levels: 3 or More Levels

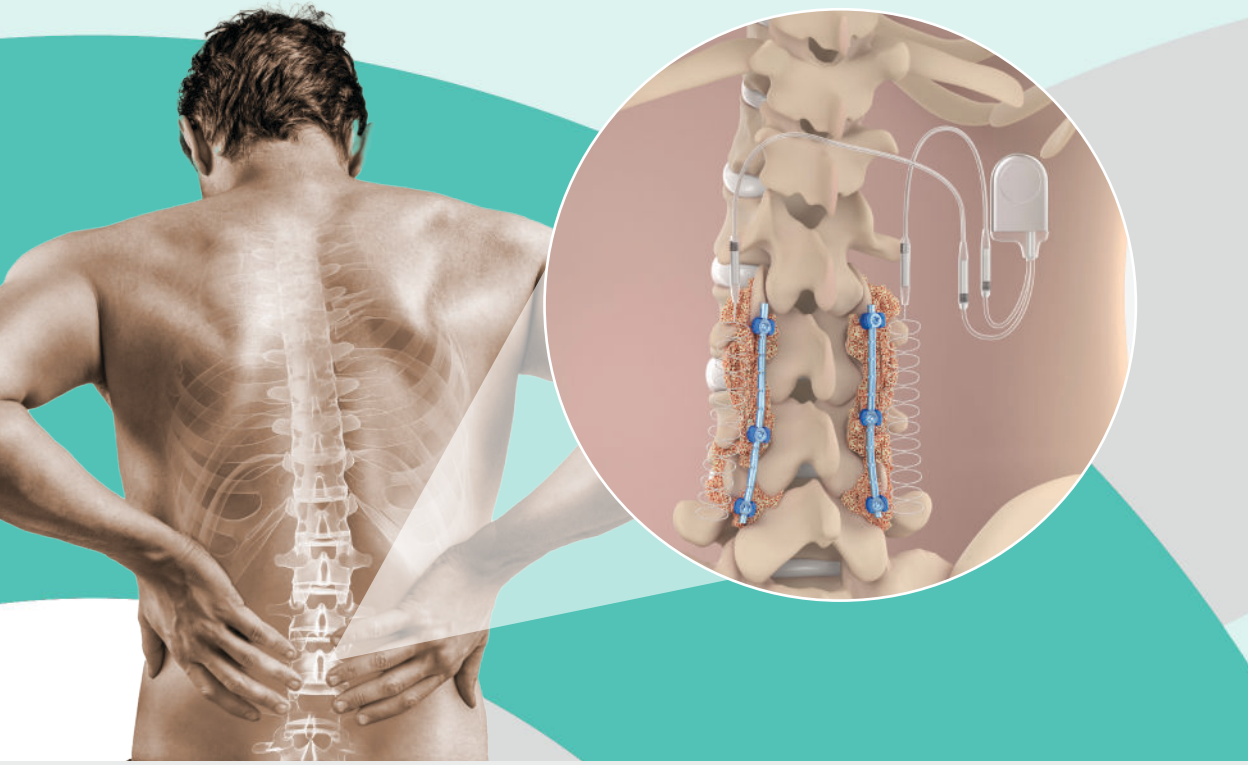
MR CONDITIONAL

Scan to
learn more

How does the SpF® stimulator work?

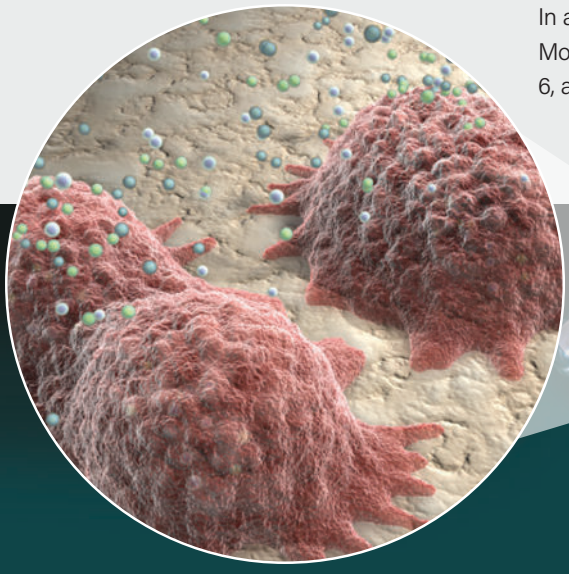
The SpF® stimulator delivers a clinically proven, low-level electrical stimulation technology called Direct Current (DC) through a pair of titanium cathodes. The uniquely designed cathodes are placed laterally over the transverse processes away from the vertebral bodies and implantable hardware on each side of the fusion site.

Direct Current technology generates a constant electrical current surrounding the cathodes to safely and effectively induce the body's natural healing mechanisms to promote bone growth at the targeted fusion site. The DC technology has been shown pre-clinically to cause a faradic reaction. The faradic reaction results in decreased oxygen tension (leading to a decrease in osteoclasts), increased pH (leading to an increase in osteoblasts), and provides a favorable osteogenic environment to enhance bone formation and healing.*



What pre-clinical data has been published on Direct Current technology?

In an *in vitro* study, the upregulation of multiple Bone Morphogenetic Proteins (BMPs) including BMPs 2, 6, and 7 were observed.[1+]



Proven Upregulation of Multiple BMPs
BMPs 2, 6, and 7

What human clinical outcomes are there to support the use of the SpF® stimulator?

The SpF® stimulator is supported by statistically significant level 1 clinical results and is proven to improve fusion success rates, particularly in patients with specific risk factors.[2,3,4]

Success Rate in Patients with Previous Back Surgery

100% vs 79%

Success rate vs. 79% with no stimulation (p=0.02)[3]

Overall Success Rate in Instrumented Lumbrosacral Fusions

96% vs 85%

Success rate vs. 85% with no stimulation (p=0.02)[3]

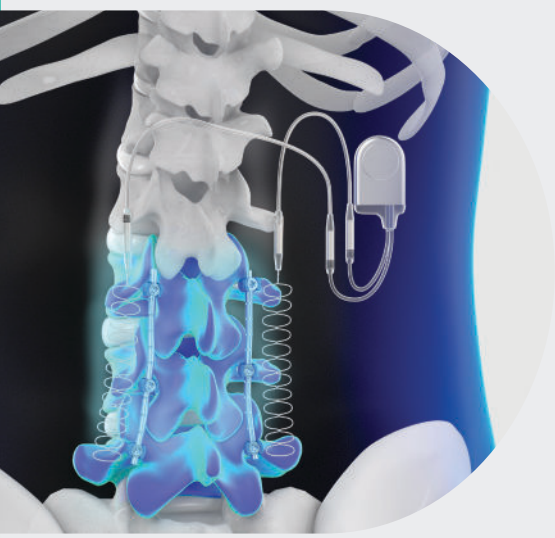
Statistically Significant Results in Uninstrumented Fusions

81% vs 54%

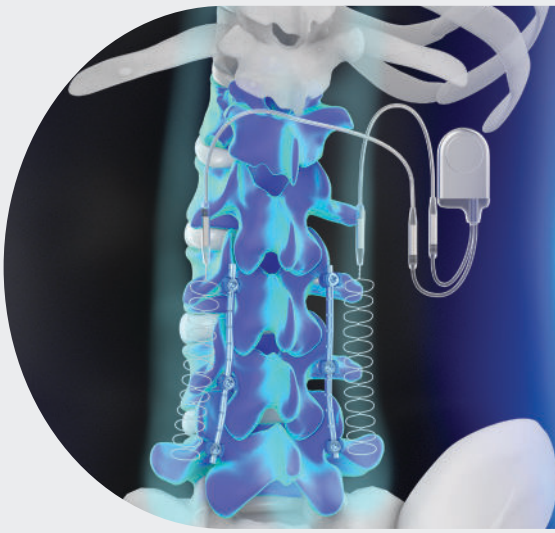
Success rate vs. 54% with no stimulation (p=0.02)[2]

Available Models

SpF® stimulators may be utilized as an adjunct to open spinal fusions and are available to order in two sizes to support both single and multilevel fusions.



SpF® PLUS-Mini: Intended to increase the probability of fusion success in 1 or 2 levels.



SpF®-XL IIb: Intended to increase the probability of fusion success in 3 or more levels.

Cost Effective

The SpF® stimulator may assist in reducing the overall spine fusion surgery costs by increasing the probability of fusion success rates.[2,3,4]

Implantation & Explantation Codes

Physician

CPT Code	Description
20975	Electrical stimulation to aid bone healing; invasive
20680	Removal of implant; deep

Ambulatory Surgery Center & Hospital Outpatient

CPT Code	Description
20680	Removal of implant; deep

Optional, Quick, Simple, Generator Removal May Be Performed in an ASC

After 6 months, the generator may be optionally removed, leaving the cathodes embedded in the bone. The quick and simple removal is perfect for an Ambulatory Surgery Center (ASC) setting.

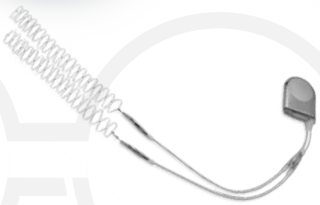
The largest portfolio of clinically proven bone growth stimulation solutions.

Biomet® SpinalPak®
Non-invasive Spine
Fusion Stimulator System

Biomet® OrthoPak®
Non-invasive Bone
Growth Stimulator System

Biomet® EBI®
Bone Healing System

EBI® OsteoGen™
Surgically Implanted
Bone Growth Stimulators



SpF®
Implantable Spinal
Fusion Stimulators

References

1. Fredericks, D.C., Smucker, J., Petersen, E.B., Bobst, J.A., Gan, J.C., Simon, B.J., and Glazer, P. Effects of direct current electrical stimulation on gene expression of osteopromotive factors in a posterolateral spinal fusion model. Spine (Phila. Pa 1976), 2007. 32(2): p. 174-81.
2. Kane, W.J., Direct Current Electrical Bone Growth Stimulation for Spinal Fusion. Spine (Phila. Pa 1976), 1988.13(3): p. 363-5.
3. Rogozinski, A. and Rogozinski, C. Efficacy of Implanted Bone Growth Stimulation in Instrumented Lumbosacral Spinal Fusion. Spine (Phila. Pa 1976), 1996. 21(21): p. 2479-83.
4. SpF® Implantable Spinal Fusion Stimulator Technical Monograph. BSP196276L. Parsippany, NJ: Biomet Spine; 2010.

*Although not indicative of human clinical results, outcomes from pre-clinical research have been implicated in various models of bone repair.

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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 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. The 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 stimulation is not recommended for patients with implantable pacemakers, defibrillators or pregnant patients. 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. HM0676 REV A 05/25.