



Healthcare Professionals



SpF[®]
Implantable Spinal
Fusion Stimulators

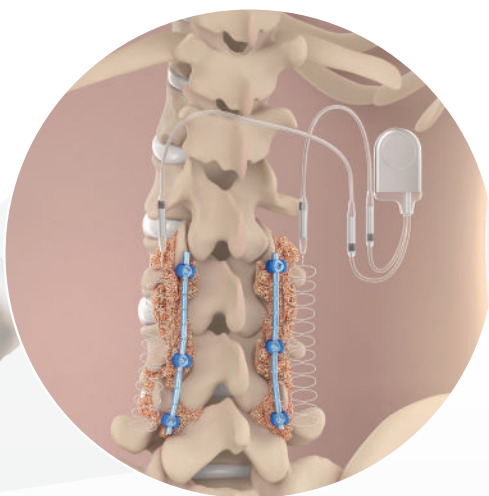
 Powered by Direct Current
Technology



How does the SpF® stimulator work?

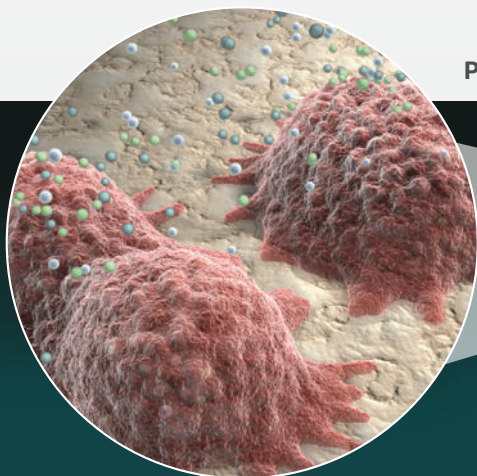
The SpF® stimulator delivers a clinically proven, low-level electrical stimulation technology called Direct Current (DC) through a pair of titanium cathodes. The uniquely designed cathodes are placed laterally over the transverse processes away from the vertebral bodies and implantable hardware on each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

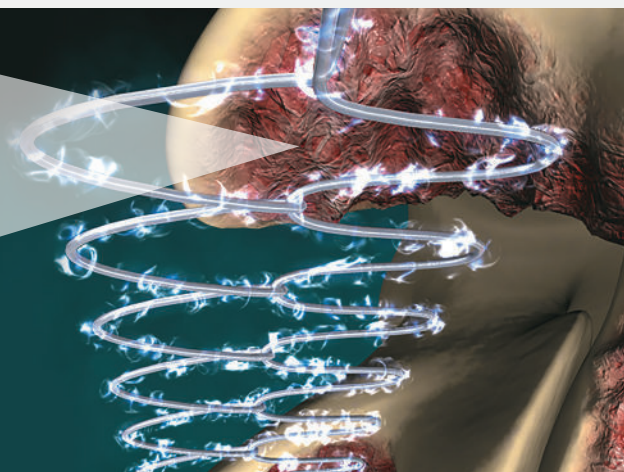


What pre-clinical data has been published on Direct Current technology?

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 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

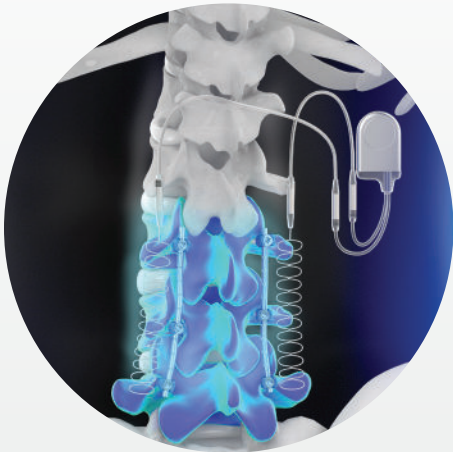
Statistically Significant Results in Uninstrumented Fusions

81% vs 54%

Success rate vs. 54% with no stimulation ($p=0.02$)³

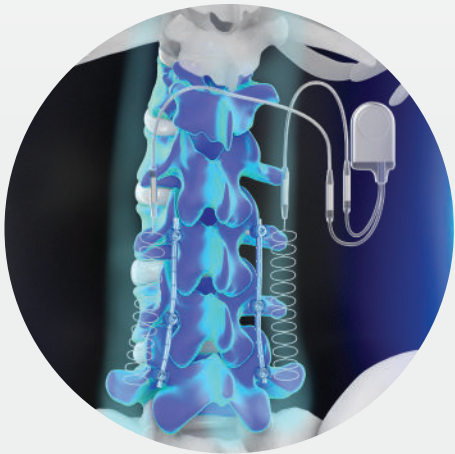
Available Models

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 and 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 cathode(s) embedded in the bone. The quick and simple removal is perfect for an Ambulatory Surgery Center (ASC) setting.



What is the SpF® implantable stimulator?

The SpF® implantable stimulator is an 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 and 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 Conditional: 1.5 and 3.0 Tesla
- Original FDA Approval Date: 1988
- Model: SpF® PLUS-Mini
 - Signal: 60 μ A
 - # of Levels: 1-2 levels
- Model: SpF®-XL IIb
 - Signal: 40 μ A
 - # of Levels: 3 or more levels



The largest portfolio of clinically proven bone growth stimulation solutions.

EBI, LLC

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Legal Manufacturer

EBI Patient Care, Inc.
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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.

+ The original DC clinical study which led to PMA approval yielded an overall success rate of 78% SS&ED.

Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at ebibonestimulador.com or by calling 800-526-2579. 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. All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to EBI or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of EBI. EB00243 REV A 06/26. ©2026 EBI, LLC. All rights reserved.



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