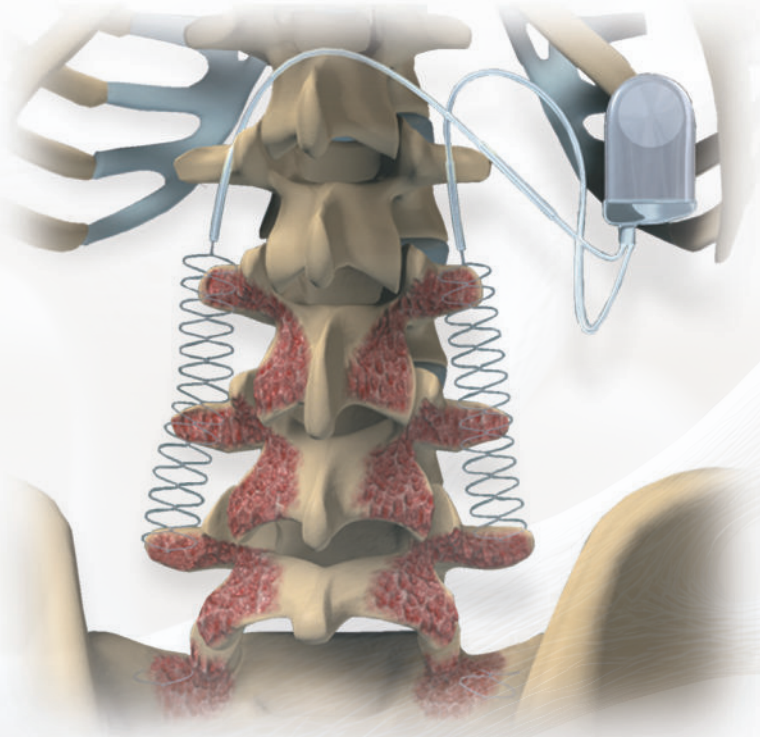
EBi

Surgical Technique Guide

SpF®

Implantable Spinal Fusion Stimulator



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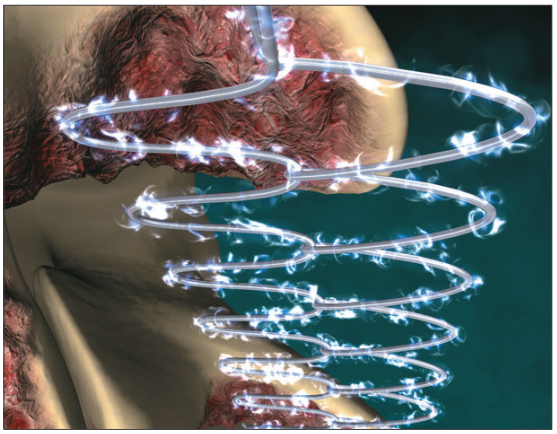
INTRODUCTION

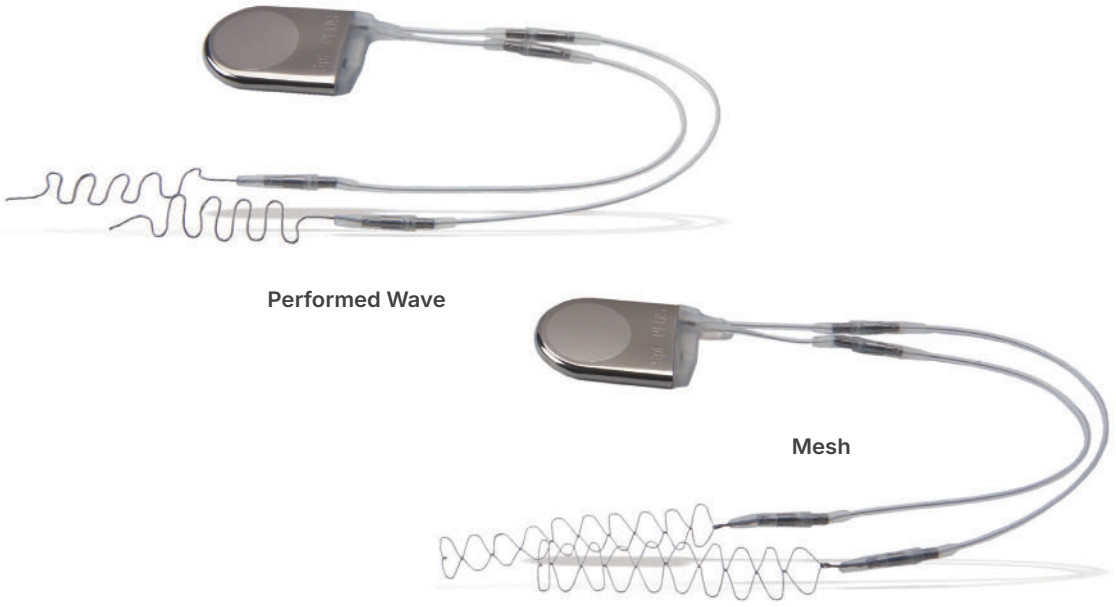
SpF® Bone Growth Stimulation

The concept of using electrical stimulation to affect bone growth began with Julius Wolff over 100 years ago. Over forty five years ago, all of the research that had been done on the response of bone to electrical stimulation led to Dr. Allan Dwyer's development of the first implantable bone growth stimulator for lumbosacral fusion. Since that time, many studies have conclusively demonstrated the efficacy of direct current stimulation improving the success rate of spinal fusions.



CATHODE CONFIGURATIONS

The following two cathode configurations are available for use with SpF® Implantable Spinal Fusion Stimulators:



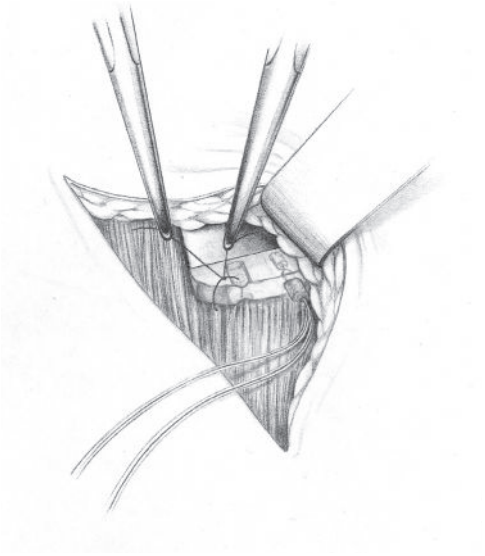
The use of each configuration is dictated by the specific fusion application and surgeon preference. The field of influence is approximately 5 to 8mm around the cathode and can be enhanced by the cathode configuration. The SpF® PLUS-Mini Stimulator delivers a constant direct current of 60µA. The two cathodes of the SpF® PLUS-Mini[1] each deliver 30µA of current. The SpF®-XL IIb produces a constant direct current of 40µA. The two cathodes of the SpF®-XL IIb each deliver 20µA of current.

Applications: Posterolateral lumbar fusion with or without internal fixation.

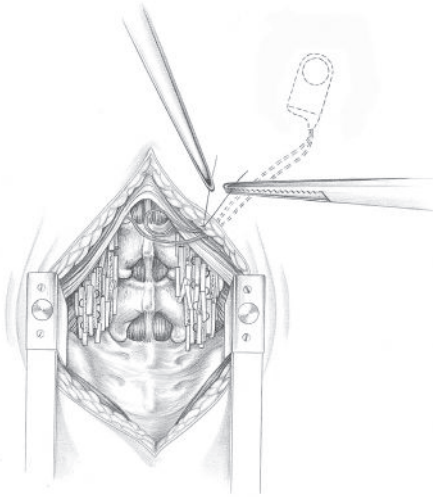
Place the cathode against the decorticated transverse processes of the levels to be fused, ensuring that the cathodes are contacting as much live bone as possible. Pack autograft on and around the cathodes.

If spinal instrumentation is used, care must be taken to ensure that the cathodes DO NOT contact the metal fixation device as this may compromise its functionality, performance and/or cause a reduction in current density which could affect the rate of osteogenesis. Pack autograph on and around the cathodes, with additional graft used to insulate the cathode from the metal fixation device.

GENERATOR PLACEMENT



Suture placed through the suture marker



Subcutaneous pocket sutured

Prior to closure, the generator should be placed just beneath the dorsal fascia in a tunnel which can be created through the primary incision by using a blunt dissection along the paramedian region cephalad to the fusion area. The generator may also be placed in the soft tissue above the iliac crest. To avoid patient discomfort, facilitate generator removal and ensure optimum SpF® Stimulator function, the following should be considered:

1. When placing the generator, DO NOT allow the generator to directly contact bone.

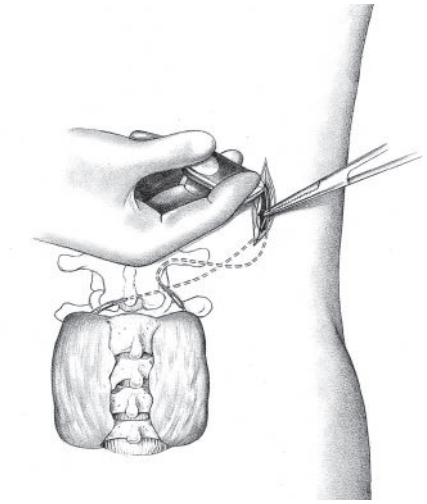
2. Position the generator for maximum patient comfort and:
   - Protect it from external irritation or impact
   - Palpate it without raising the skin contour
   - Facilitate removal as an outpatient procedure under local anesthetic

3. Place the generator 8 to 10 cm away from the cathodes.

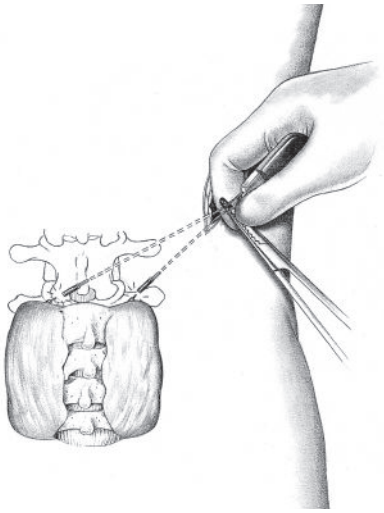
4. DO NOT allow the generator to contact metal fixation devices as this may dissipate the current.

5. Suture the generator to soft tissue to maintain proper position and prevent generator migration by placing a suture through the marker on the soft silastic portion of the generator.

GENERATOR EXPLANTATION



Generator removed through a small incision



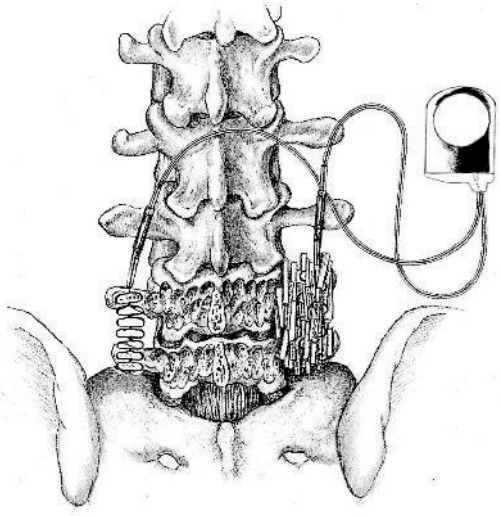
Insulated lead wire wrapped around clamp

It is recommended that the generator be removed at the end of its useful life (approximately 24 weeks). Since the effects of long term implantation have not been investigated, the surgeon should carefully weigh the risks versus the benefits of explantation when deciding whether to remove the device. The explantation may be performed as an outpatient procedure utilizing local anesthetic.

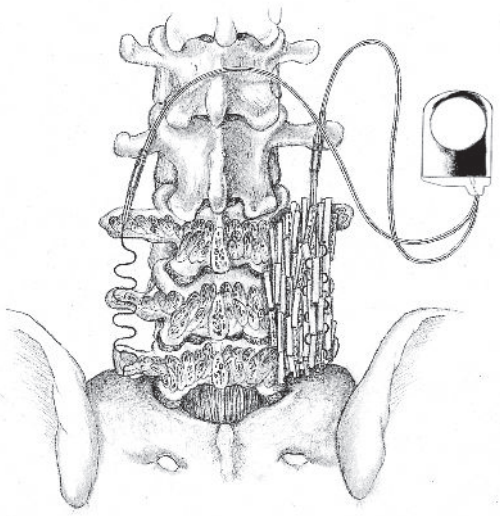
When the generator is implanted subcutaneously it can be easily palpated to determine the precise position. Under sterile technique and with the use of local anesthetic, simple dissection will permit access to the generator for removal.

Using a pair of forceps, take hold of each lead separately and wrap it around the forceps. Gently and steadily pull the generator and lead until they detach from the cathode. The cathodes will remain embedded in the bony fusion mass. The wound is then closed using standard closure procedure.

SURGICAL TECHNIQUES



SpF® PLUS-Mini
with mesh cathodes



SpF® PLUS-Mini
with wave cathodes

To address varying surgeon preference, this surgical guide highlights the applications and implant procedures of the SpF® PLUS-Mini and SpF®-XL IIb Implantable Spinal Fusion Stimulators as an adjunct to fusion success with and without spinal instrumentation.

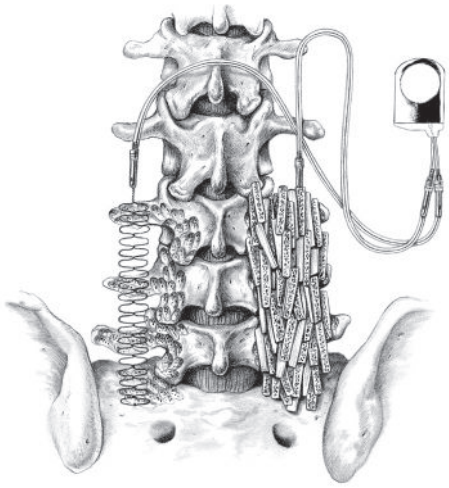
Single Level Fusion - SpF® PLUS-Mini

Using a lateral or midline surgical approach, single level fusion can be achieved by placing a cathode on the decorticated transverse processes so the cathodes are contacting the superior and inferior vertebrae to be fused. Pack bone graft on and around the cathodes to form a fusion mass, making sure the cathodes are completely embedded in the fusion mass. The generator can then be placed as previously described.

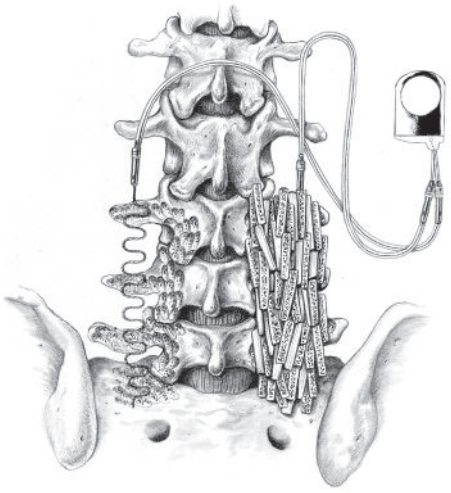
Two Level Fusions - SpF® PLUS-Mini

The transverse processes are stripped subperiosteally with care so as to maintain the integrity of the intertransverse ligament. The lateral wall of the facet joint complex is cleaned of all adherent tissue, and decortication is carried out between the tip of the transverse processes medially to the lateral wall of the facet joint complex. Prior to placing bone graft on the decorticated transverse processes a cathode is laid between the transverse processes on each side of the spinous process to cover the levels to be fused. It is important that each cathode is in contact with as much viable bleeding bone as possible. Bone graft is then placed in the usual fashion completely covering each cathode to form the fusion mass, making sure the cathodes are completely embedded in the fusion mass. The generator can then be placed as previously described.

SURGICAL TECHNIQUES (CONTINUED)



SpF®-XL IIb
with mesh cathodes



SpF®-XL IIb with
preformed wave cathodes

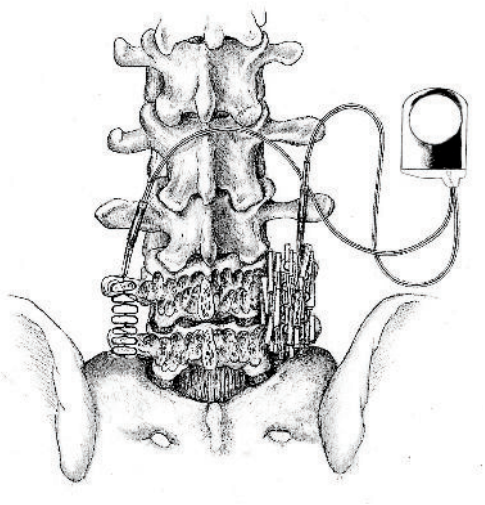
Three or More Levels - SpF®-XL IIb Mesh Cathode or Wave Cathode

A lateral or midline approach may be used. In the lateral approach the fascia should be incised approximately two-finger breadths lateral to the midline, curving toward the sacrum at the sacral junction. The avascular plane between the paraspinal muscle should be developed and carried anteriorly to the transverse processes and/or sacral ala. In the midline approach, a standard subperiosteal dissection should be performed. In either approach the laminae, spinous processes, lateral and medial facets and the tips of the transverse processes are exposed.

Prior to placing bone graft on the decorticated transverse processes, a mesh cathode is laid between the transverse processes on each side of the spinous process to cover the levels to be fused. It is important that each cathode is in contact with as much viable bleeding bone as possible. Bone graft is then placed in the usual fashion completely covering each cathode to form the fusion mass. The generator is then placed in soft tissue as previously described.

Care must be taken to ensure that the bare titanium cathodes are not exposed in soft tissue where flexing of the titanium may occur, but are encompassed within the fusion mass. Flexing of the bare titanium cathodes could result in their breakage.

LUMBOSACRAL FUSION ADJUNCT TO INTERNAL FIXATION



SpF® PLUS-Mini
with mesh cathodes

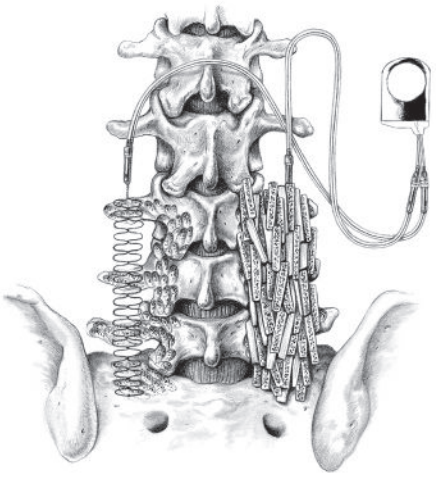
One or Two Levels - SpF® PLUS-Mini

This procedure is ideal in cases where bone growth stimulation must be combined with the need for immediate spinal stability.

A lateral or midline approach may be used, depending on the surgeon's preference. Following insertion of the spinal instrumentation according to the manufacturer's recommended procedure, decorticate the bone to create a viable bleeding bed along the transverse processes to be fused.

Care must be taken so that the cathodes DO NOT contact the metal internal fixation devices. In addition, the graft may be used to create a wall of insulation between the cathodes and the metal fixation device. The generator can then be placed as previously described.

LUMBOSACRAL FUSION ADJUNCT TO INTERNAL FIXATION (CONTINUED)



SpF®-XL IIb
with mesh cathodes

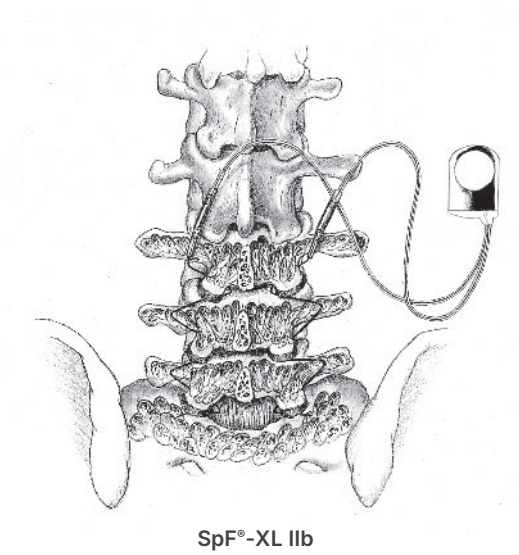
Three or More Levels - SpF®-XL IIb

This procedure is ideal in cases where bone growth stimulation must be combined with the need for immediate spinal stability.

A lateral or midline approach may be used, depending on the surgeon's preference.
Following insertion of the spinal instrumentation according to the manufacturer's recommended procedure, decorticate the bone to create a viable bleeding bed along the transverse processes to be fused.

Care must be taken so that the cathodes DO NOT contact the metal internal fixation devices.
Pack bone graft on and around the cathodes. In addition, graft may be used to create a wall of insulation between the cathodes and the metal fixation device. The generator can then be placed as previously described.

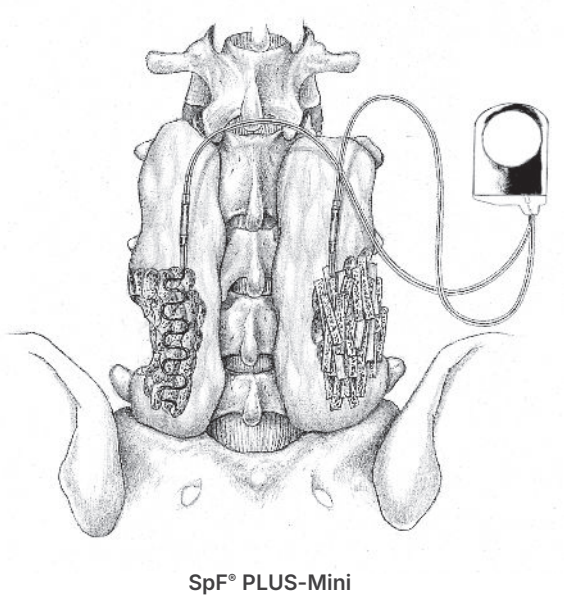
COMBINED FACET AND INTERTRANSVERSE FUSION



SpF®-XL IIb
with preformed wave cathodes

The opposing surfaces of the facet joints are denuded. The proximal end of the uninsulated titanium cathode is wedged into the facet and packed with bone graft. The graft acts as an anchor by holding the cathode in place. The remaining cathode is placed on top of the transverse processes. These steps are repeated on the other side of the spine. The generator can then be placed as previously described.

PSEUDARTHROSIS REPAIR



SpF® PLUS-Mini
with preformed wave cathodes

SpF® PLUS-Mini and SpF®-XL IIb

A lateral or midline approach may be used. Identify and decorticate the pseudarthrosis to expose bleeding cancellous bone. Remove fibrous tissue taking care not to damage the underlying dura. The debridement of the fibrous tissue should be performed completely to bleeding cancellous bone for the entire pseudarthrosis defect.

Place the cathodes into the pseudarthrosis defect where bone growth is desired, achieving as much contact between the cathode and viable bone as possible. The cathodes must be completely within the pseudarthrosis site; therefore, they may contact each other. Bone graft is then placed on and around the cathodes making sure the cathodes are insulated from soft tissue contact. The generator can then be placed as previously described.

INDICATIONS

The SpF® PLUS-Mini is indicated as a spinal fusion adjunct to increase the probability of fusion success in one or two levels. The SpF®-XL IIb is indicated as a spinal fusion adjunct to increase the probability of fusion success in three or more levels.

Contraindications

Any case where SpF® could come into contact with metallic implant components (i.e., those that contain Titanium, Cobalt Chrome and Stainless Steel). Any surgical implantation procedure such as minimally invasive surgical-MIS procedures requiring the SpF® cathodes to be disconnected from their corresponding leads prior to or during implantation since this may seriously compromise the electrical performance of the implantable stimulator's cathodes to deliver a constant current to the fusion site as intended.

Warnings

Do not use with defibrillators. Certain precautions apply. For full prescribing information, please consult the physician manual (i.e., IFU). PN 1067632L Rev. K.

Usage and Intended Use

SpF® stimulators have only been studied as an adjunct for lumbar spinal surgery, Posterolateral Fusion (All models). Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only - Prescription Only - Single Use Only - Do Not Reuse.

ORDERING INFORMATION

P/N	Description and Device Name
10-1335M	SpF® - XL llb 8cm mesh cathode - 40 Microamp Device
10-1335W	SpF® - XL llb 8cm wave cathode - 40 Microamp Device
10-1398M	SpF® PLUS-Mini Mesh Cathode - 60 Microamp Device
10-1398W	SpF® PLUS-Mini Wave Cathode - 60 Microamp Device

FURTHER INFORMATION

Two clinical studies, one randomized and the other non-randomized, were conducted to support the indications and usage of the SpF® as a spinal fusion adjunct to increase the probability of fusion success.

The entry criteria included the following: (a) one or more previous failed spinal fusion(s); (b) grade II or worse spondylolisthesis; (c) extensive bone grafting necessary for a multiple level fusion; or (d) other high risk factors for failure of fusion, including gross instability, obesity, degenerative osteoarthritis, previous fusion surgery, or previous disc surgery. The criteria used for determining success was based on radiographic fusion. A number of radiographic techniques were used to evaluate fusion. The radiographic assessment of fusion was confirmed by an independent radiologist[1].

For success rates, please consult the physician manual.
P/N 1067632L Rev. K

Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

For further information, please contact the
Customer Care Team at 800-526-2579

SpF® Implantable Spinal Fusion Stimulators

To learn more about this product, contact your local Sales Representative today.

1. P850035/S031, June 2007, approval to market & commercially distribute the stimulator under the trade name SpF® PLUS 60/W & SpF® PLUS 60/M. Subsequently filed and received approval under P850035/S033, September 2008 to change the trade name to SpF® PLUS-Mini (60 µA/W) & SpF® PLUS-Mini (60 µA/M) i.e., the SpF® PLUS-Mini.

2. P850035/S020 August 1996, approval to market & commercially distribute the stimulator under the trade name SpF®-XL IIb Implantable Spinal Fusion Stimulator followed by P850035/S022, April 1997, approval to market & commercially distribute the stimulator under the trade name SpF®-XL IIb Implantable Spinal Fusion Stimulator.

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Legal Manufacturer
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Guaynabo, PR 00969 USA

Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at ebibonestimulator.com or by calling 800-526-2579. SpF® stimulators are indicated as a lumbar spinal fusion adjunct to increase the probability of posterolateral 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. 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. P/N 196067L REV L. EB00145 REV A 03/26.

Learn more
ebibonestimulator.com