

*Implantable Spinal Fusion Stimulators
Physician's Manual &
Full Prescribing Information
SpF[®] PLUS-Mini, SpF[®]-XL IIb*

PHYSICIAN'S MANUAL1-7

Terminology1

Package Contents1

Description2

Typical Characteristics2-3

Directions for Use3

Pre-operative Instructions for Testing the SpF®3

Opening Instructions4

Insertion Technique4

Implantation Technique with Wave Cathode4

Implantation Technique with Mesh Cathode5

Explantation Technique5

Conditions of Sale5-6

Replacement Credit Policy6

Return Goods Policy6

Safety6

Calibration and Maintenance6

Storage6

Shelf Life6

Sterilization7

Implant Registration Form7

FULL PRESCRIBING INFORMATION7-9

Indications and Usage7

Description7-8

Contraindications8

Precautions8-9

MRI SAFETY, ARTIFACTS TESTING AND EFFICACY9-11

CLINICAL STUDIES12-14

Adverse Events14

UNIVERSAL SYMBOLS15

PHYSICIAN'S MANUAL

The purpose of this manual is to present and explain the principal characteristics of the SpF® Spinal Fusion Stimulators and to describe methods for their use.

Attention is drawn to the section concerned with Patient Registration and to the Conditions of Sale. All personnel responsible for the implantation of the stimulator and for postoperative care should be familiar with these details.

The data herein may not agree in detail with previous catalog descriptions, illustrations, and technical specifications, as products are subject to modification, revision and improvement.

In case of questions regarding the most current data publication, please contact your nearest Biomet, representative or call Biomet at 1-800-526-2579. Outside the United States, contact your local Biomet Distributor.

TERMINOLOGY

"Generator" refers to that part of the spinal fusion stimulator that produces a constant electrical current and includes the power source and electronic circuit.

"Lead" refers to the electrically conductive element that is insulated and connects to the cathode.

"Cathode" refers to the electrically conductive element, which interfaces with body tissue.

"Anode" refers to the electrically conductive platinum coated area of the generator case.

"Stimulator" refers to the generator and attached leads.

PACKAGE CONTENTS:

ETO Gas Sterilized:

- Stimulator with pre-assembled cathodes (preformed wave or mesh)
- Disposable Tester
- Sterilometer

Non-Sterile:

- Physician's Manual
- Implant Registration Form
- Full Prescribing Information Sheet
- Utility Label
- Patient Travel Card

DESCRIPTION

The **SpF PLUS-Mini** Implantable Spinal Fusion Stimulator is indicated as a spinal fusion adjunct to increase the probability of fusion success in 1 or 2 levels. The **SpF PLUS-Mini** and **SpF-XL IIb** Implantable Spinal Fusion Stimulators are indicated as a spinal fusion adjunct to increase the probability of fusion success in 3 or more levels.

For more detail, please see Typical Characteristics below or Full Prescribing Information on page 7.

Identification: (All with serial number marked on the case)

By Model:

“**SpF PLUS-Mini** (60 μ A/M)”

“**SpF PLUS-Mini** (60 μ A/W)”

“**SpF-XL IIb 2/DM**”

“**SpF-XL IIb 2/DW**”

TYPICAL CHARACTERISTICS

Case Material

Titanium

Power Source

One lithium manganese dioxide battery powers all **SpF** models.

Electronics: The **SpF PLUS-Mini** has a solid-state circuitry maintaining cathode current at a constant 60 microamperes regardless of changes in bone/tissue resistance over a range of 0-38,000 ohms. The **SpF-XL IIb** has solid-state circuitry maintaining cathode current at a constant 40 microamperes regardless of changes in bone/tissue resistance over a range of 0-40,000 ohms.

Hermeticity: Hermetically sealed and tested for leakage to method adapted from MIL STD 883A method 1014.1.

Anode: Circular platinum anode with a surface area of 400 mm² for the **SpF-XL IIb** and 600 mm² for the **SpF PLUS-Mini**.

Leads/Cathodes:

Lead Configurations

Disconnects at both the Generator and Cathode (Dual)

The **SpF PLUS-Mini** and **SpF-XL IIb** lead wires consist of two 15 cm leads of drawn braided strand (DBS) wire, covered with silicone and are connected to the generator by a titanium connector. The **SpF PLUS-Mini** and **SpF-XL IIb** can each be disconnected at both the generator and cathode.

Cathode Configurations

Cathodes are available in two configurations: preformed wave and mesh.

Model	Configuration
SpF PLUS-Mini	12 cm [4 cm preformed wave (W)] or 1 x 4 cm mesh (M)
SpF-XL IIb	24 cm [8 cm preformed wave (W)] or 1 x 8 cm mesh (M)

Weight:

10g (approximately) for the **SpF PLUS-Mini** models.

7g (approximately) for the **SpF-XL IIb** models.

Dimensions:

39mm x 27mm x 4.7mm for the **SpF PLUS-Mini** models

36mm x 23mm x 5mm for the **SpF-XL IIb** models.

Operating Period:

The Stimulator is designed for implantation for a period of approximately 24-weeks, assuming implantation occurs prior to the "Use By" date.

DIRECTIONS FOR USE

The stimulator may be implanted in a variety of methods. The principle of implantation is to position as much of the cathode as possible so that the field formed is concentrated at the fusion site. The implanting surgeon should be familiar with the surgical technique detailed in the Physician's Manual.

PRE-OPERATIVE INSTRUCTIONS FOR TESTING THE SpF

Every **SpF** is tested before it leaves the manufacturing plant for functionality. Additionally, each device may be pre-operatively tested prior to implantation.

A sterile Implant Tester is included with each device and is contained in the inner packaging tray. The Implant Tester enables the user to functionally test the device pre-operatively. Once the devices have been implanted, postoperative monitoring is no longer available.

Located inside the packaging is a direct contact tester, which verifies functionality of the device at the time of removal from the inner packaging tray.

To test the **SpF PLUS-Mini** and **SpF-XL IIb** stimulators, please follow the 4 steps indicated below:

1. Remove the inner tray from the outer blister pack.
2. Place thumb on thumbprint symbol of inner tray.
3. Depress button and hold while turning inner tray over.
4. Check to see if orange light is on.

If light is on while button is depressed, the unit is functional and ready for use. If the light fails to turn on (after depressing the tester button), the unit is deemed inactive (fallen below 54 μ A or risen above 66 μ A for the **SpF PLUS-Mini** models or fallen below 35 μ A or risen above 45 μ A for **SpF-XL IIb** models) and should not be used (see page 6 for return instructions).

OPENING INSTRUCTIONS

Only the contents of the packaging inner tray are sterile. When introducing the sterile contents of the inner tray into a sterile field, grasp the tyvek "Peel Back" tab and slowly pull back to expose the sterile contents.

INSERTION TECHNIQUE

Regardless of the technique employed (see below for Implantation Technique), the surgeon must be cognizant of the following important guidelines:

Placement of Generator

- Prior to closure, the generator should be located just beneath the dorsal fascia in a tunnel, which can be created by blunt dissection along the paramedian region cephalad/caudal to the fusion area. Alternatively, the generator can be placed in soft tissue above the iliac crest.
- To avoid patient discomfort, care should be taken to place the generator in a comfortable tissue pocket so that rising of the skin contour is avoided or minimized.
- IT IS IMPORTANT TO ENSURE THAT THE ANODIC AREA OF THE GENERATOR IS IN SOFT TISSUE AND NOT AGAINST BONE as bone resorption can occur.
- The anodic area of the generator case should also be positioned 8-10 cm from the cathodes.
- In placing the generator case, consideration should also be given to subsequent removal of the generator and leads.

Use with Instrumentation

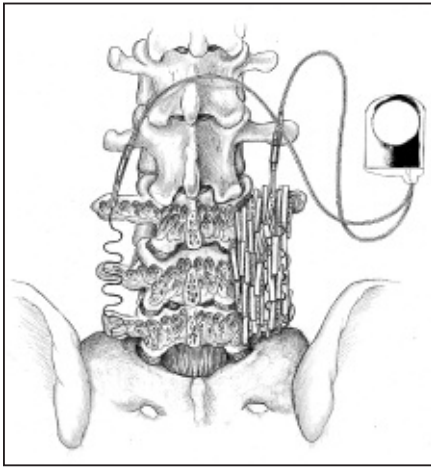
- All SpF® models are compatible for use with spinal instrumentation.
- Care should be extended to the cathode wires, so as not to touch any part of the spinal instrumentation. This may dissipate the effective dosage over the surface area of the instrumentation.

IMPLANTATION TECHNIQUE

Posterolateral Fusion (All models)

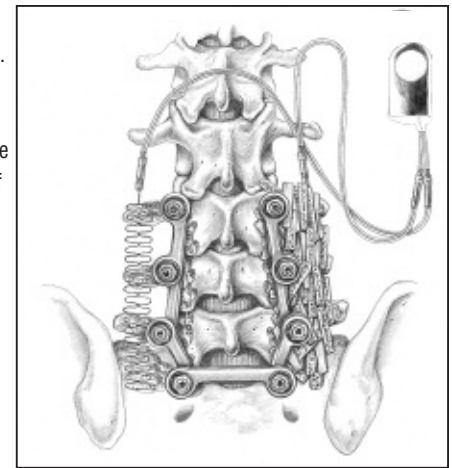
WAVE CATHODE

Follow your normal procedure for a posterolateral fusion. Prior to placing the bone graft, a cathode is laid between the transverse processes on either side of and within the decorticated area of the intertransverse ligament to cover the level or levels to be fused. For multi-level fusions with the SpF device each cathode is to be laid between the transverse processes one on each side of the spine to cover the levels to be fused. It is important that the cathodes are in contact with as much viable bone as possible. The bone graft is then placed in the usual fashion on and around the cathodes to form the fusion mass (pictured). Repeat on the other side of the spine. Care must be taken to ensure that the bare titanium cathodes are completely enmeshed in bone graft and are not lying in the soft tissue where flexing of the titanium may occur. Flexing of the bare titanium cathodes could result in breakage.



MESH CATHODE

Follow your normal procedure for a posterolateral fusion. Prior to placing the bone graft, one mesh cathode is placed on either side of the spine and within the decorticated area of the lateral gutter. This mesh cathode touches the transverse processes of the desired levels of fusion, ensuring that it is in contact with as much viable bone as possible. Bone graft is then placed as usual, especially on and around the cathode to form a fusion mass. Care must be taken to ensure that the bare titanium of the mesh cathode is not exposed in soft tissue, where flexing of the titanium may occur (i.e., the cathode must be completely enmeshed in bone graft). Flexing of the bare titanium could result in breakage.



EXPLANTATION TECHNIQUE

The generator may optionally be removed at the end of its useful life (approximately 24-weeks). Since the effects of long-term implantation of the generator have not been investigated, the surgeon should carefully weigh the risks versus the benefits of explantation when deciding whether to remove the device. Under sterile technique, with the use of a local anesthetic, and in conjunction with a recent anteroposterior film of the lumbar region, the generator is removed. Using a pair of forceps, take a firm hold of each lead separately and pull. The connector located on each lead is designed to pull apart on explantation, leaving the uninsulated titanium cathode wires enmeshed in bone.

NOTE: Single Use Only - Do Not Reuse.

CONDITIONS OF SALE

It is an express condition of sale that the purchaser and the patient become aware of the following:

Caution: The decision to implant a spinal fusion stimulator is purely a medical one determined in light of the special circumstances of each case. The manufacturer takes every care in the selection of components and in all steps of manufacturing, quality control, and packaging. However, due to the nature of the stimulator itself and the hostile environment in which it is used, the stimulator will ultimately cease to function, due to either predictable exhaustion of the power source or random, unpredictable failure of any component, including the power source.

The prescription and implantation of a stimulator are beyond the control of the manufacturer. Biomet, makes no claim that in certain circumstances adverse human body reactions or medical complications will not follow the implantation of the stimulator or any part thereof, whether or not of the manufacturer's design and manufacture, and irrespective of method of surgical implantation or method of use.

Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique or implant to be utilized for an individual patient.

Biomet would like to thank Neil Kahanovitz, M.D., Donald Kucharzyk, D.O., and Ronald Wisneski, M.D. for their contribution in developing the techniques described herein.

Rx Only

REPLACEMENT CREDIT POLICY

In the event of a product failure due to manufacturing defect and/or failure of the product to perform according to specifications, a replacement stimulator will be provided only when all the following conditions are met:

1. The original unit was implanted prior to the "Use By" date indicated on the package.
2. The completed registration form was returned to Biomet within thirty (30) days of implantation.
3. The explanted generator was returned to Biomet within thirty (30) days of removal from the patient, together with a written report detailing the circumstances of its removal.

RETURN GOODS POLICY

1. Customers receiving damaged product or product that is deemed inactive for use (see page 3 Directions for Use) may return the product for full credit.
2. Unopened, un-expired product in the original packaging may be returned if returned ninety (90) days prior to expiration. A fee will be charged for restocking.
3. Opened product cannot be returned for credit.
4. Outdated or expired product cannot be returned for credit.

SAFETY

To eliminate the possibility of fluid ingress/egress, the generator case is hermetically sealed and tested for leakage to the method adapted from MIL STD 883A method 1014.1. Safety is further ensured by the use of biocompatible materials with a clinical history of safety in human implants. The titanium does not contain nickel, chromium, or cobalt, which have been shown to provoke a hypersensitivity response in some patients. Model designation and serial number are engraved into the generator case for ease of identification and traceability.

CALIBRATION AND MAINTENANCE

The **SpF** PLUS-Mini is preset to deliver a constant current of 60 ± 3 microamperes through load impedance variations of 0 to 38,000 ohms. The **SpF**-XL IIB is preset to deliver a constant current of 40 ± 2 microamperes through load impedance variations of 0 to 40,000 ohms. No adjustments are required for implantation. The stimulator may be used in conjunction with internal or external fixation devices, if desired. The stimulator is designed for implantation for a period of approximately 24-weeks, assuming implantation occurs prior to the expiration date.

STORAGE

The **SpF** should be stored at temperatures between 5° and 25°C (41° and 77°F).

SHELF LIFE

The **SpF** has a 24-month battery shelf life.

STERILIZATION

SpF Spinal Fusion Stimulators are Ethylene Oxide (EtO) gas sterilized. Sterilization data appears on the inner tray labeling. A sterilometer (color indicator), visible in the inner package, indicates exposure to EtO gas. The inner tray assembly should be carefully inspected to ensure that the seal has not been broken. Resterilization, if necessary, should be carried out using normal EtO procedures, but NOT in excess of 50°C. After sterilization, allow 72-hours for degassing in a warm (37°C) ventilated environment.

CAUTION: Do not resterilize by autoclave, liquid solution, gamma or ultraviolet radiation, and do not clean with ultrasonic cleaners.

IMPLANT REGISTRATION FORM

In accordance with international practice and regulatory legislation in some countries, a registration form is provided with each **SpF** Spinal Fusion Stimulator. The registration form, with duplicates, is included in the stimulator storage package. The purpose of this form is to maintain traceability of all units. It allows a center involved in the evaluation of a specific implanted stimulator to quickly gain access to pertinent data from the manufacturer. It is the responsibility of the implanting center to return the completed form to the manufacturer at the address shown on the form within thirty (30) days of implantation. The duplicates are for the patient's chart and physician's file.

SpF Implantable Spinal Fusion Stimulators

Models: **SpF** PLUS-Mini and **SpF**-XL IIB

Rx Only

Full Prescribing Information

INDICATIONS

The **SpF** PLUS-Mini Implantable Fusion Stimulator is indicated as a spinal fusion adjunct to increase the probability of fusion success in 1 or 2 levels. The **SpF**-XL IIB Implantable Spinal Fusion Stimulators are indicated as a spinal fusion adjunct to increase the probability of fusion success in 3 or more levels.

USAGE

The **SpF** has only been studied as an adjunct for lumbar spinal surgery.

DESCRIPTION

The **SpF** PLUS-Mini is a solid state constant current generator producing a constant current of 60 microamperes and is powered by one lithium manganese dioxide battery. The electronics and power source are hermetically sealed within a titanium generator case; an area of approximately 600 mm² is platinum coated and functions as the anode.

The **SpF PLUS-Mini** lead wires consist of two 15 cm leads of drawn braided strand (DBS) wire covered with silicone and connected to the generator by a titanium connector. The cathodes are available in preformed wave or mesh configurations. In the preformed wave configuration, each lead is terminated in a 12 cm (4 cm preformed wave) uninsulated triple strand titanium wire which acts as a cathode and is connected to the insulated DBS lead by a titanium connector which disconnects at both the generator and cathode. The mesh cathode consists of two strands of titanium wire woven into a flexible grid with nominal dimensions of 1 cm x 4 cm.

SpF-XL IIb is a solid-state constant current generator producing a constant current of 40 microamperes and is powered by one lithium manganese dioxide battery. The electronics and power source are hermetically sealed within a titanium generator case--an area of approximately 400 mm² is platinum coated and functions as the anode.

The **SpF-XL IIb** lead wires consist of two 15 cm leads of drawn braided strand (DBS) wire covered with silicone and connected to the generator by a titanium connector. The cathodes are available in preformed wave or mesh configurations. In the preformed wave configuration, each lead is terminated in a 24 cm (8 cm preformed wave) uninsulated triple strand titanium wire which acts as a cathode and is connected to the insulated DBS lead by a titanium connector which disconnects at both the generator and cathode, or is permanently connected with a titanium crimp (fused lead configuration only). The mesh cathode consists of two strands of titanium wire woven into a flexible grid with nominal dimensions of 1 cm x 8 cm.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

Do not use with defibrillators.

PRECAUTIONS

Electrosurgery

Electrosurgical instruments are capable of producing radio frequency voltages of such magnitude that direct coupling can occur between the cautery tip and lead system of the generator. To preclude the possibility of burning of tissues adjacent to the electrode or damage to the generator electronics, electrosurgical equipment should not be used on the patient in the vicinity of the generator after the Stimulator has been implanted.

Diathermy

Therapeutic diathermy should not be used in the treatment of a patient who has an implanted stimulator, since this equipment can produce voltages, which may cause damage to the electronics. Diathermy must never be applied over the site of any bone stimulator implant since high currents induced in the electrode lead will cause burning of the tissues in contact with the electrode tip.

Handling

The energy source and electronics of the generator are well protected within the generator case and will be unaffected by normal handling. However, the possibility of damage by mechanical shock, such as a drop onto a hard floor, cannot be precluded. Any unit subjected to this type of accident should not be implanted. Do not disconnect the leads from the cathodes during the surgical procedure.

Use with Internal Fixation

If the stimulator is 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.

Placement of Generator

To avoid patient discomfort, care should be taken to place the generator in a comfortable tissue pocket so that rising of the skin contour is avoided or minimized.

Placement of Cathodes

The cathodes of the implantable spinal fusion stimulator must be positioned a minimum of 1 cm from nerve roots to reduce the possibility of nerve excitation during a MRI procedure.

MRI SAFETY INFORMATION, ARTIFACTS TESTING AND EFFICACY

MRI-SpF PLUS-Mini and SpF-XL IIb Models

Experiments conducted to assess magnetic field interactions, artifacts, and operational aspects of the implantable spinal fusion stimulators combined with experience in patients indicate that MR procedures may be performed safely in patients under the following conditions:

- MR static magnetic field of 1.5 Tesla or less.
- Maximum spatial gradient 250 gauss/cm for the **SpF PLUS-Mini** model and maximum spatial gradient 450 gauss/cm for the **SpF-XL IIb** model.
- Gradient magnetic fields of 20 Tesla/second or less.
- Maximum whole body averaged Specific Absorption Rate (SAR) of 1.1 W/kg for 25 minutes of imaging.

The effects of MRI procedures using MR systems and conditions above these levels have not been determined.

MRI procedures must only be performed according to the following guidelines:

- Plain films (radiographs) must be obtained to assess the site of the implanted **SpF** prior to the MRI examination to verify that there are no broken leads present.
- If this cannot be reliably determined, then the potential risks and benefits to the patient requiring the MRI examination must be carefully assessed in consideration of the possibility of excessive heating to develop in the leads.
- The patient must be continuously observed during the MRI procedure and instructed to report any unusual sensations including any feelings of warming, burning, or neuromuscular excitation or stimulation.
- If these occur, the MRI procedure must be discontinued.

Static Magnetic Field of MR Systems

A patient with a **SpF** device may safely undergo an MRI procedure using a shielded MR system with a static magnetic field of 1.5 Tesla or less (maximum spatial gradient 250 gauss/cm for the **SpF PLUS-Mini** model and maximum spatial gradient 450 gauss/cm for the **SpF-XL IIb** model).

Gradient Magnetic Fields of MR Systems

Pulse sequences (e.g., echo planar imaging techniques or other rapid imaging pulse sequences), gradient coils or other techniques, and procedures that exceed a gradient magnetic field of 20 Tesla/second must not be used for MRI procedures. The use of unconventional or non-standard MRI techniques must be avoided. Standard or conventional pulse sequences (e.g., spin echo, fast spin echo, gradient echo, etc.) may be used for MRI examinations.

Radio Frequency (RF) Fields of MR Systems

MRI procedures must not exceed exposures to RF fields greater than a whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 25 minutes of imaging. The use of unconventional or non-standard MRI techniques must be avoided.

MRI Artifacts

Artifacts for the **SpF** have been characterized using a 1.5 Tesla MR system (maximum spatial gradient 250 gauss/cm for the **SpF PLUS-Mini** model and maximum spatial gradient 450 gauss/cm for the **SpF-XL IIb** model) and various pulse sequences. This information is indicated on the table that follows. Based on this information, implantation of the SpF (i.e., with reference to the center of the device) a distance of at least 5-8 cm from the imaging area of interest is likely to maintain the diagnostic quality of the MRI examination. Artifact size is dependent on the type of pulse sequence used for imaging (e.g., larger for gradient echo pulse sequences and smaller for fast spin echo pulse sequences), the direction of the frequency encoding direction (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view. Positional errors and artifacts on MR images may be larger for MR systems with static magnetic field strengths greater than 1.5 Tesla or smaller for MR systems with lower static magnetic fields strengths using the same imaging parameters.

Implant the **SpF** as far as possible from the spinal canal and bone graft is desirable since this will decrease the possibility that artifacts will affect this area of interest on MRI examinations. The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of the **SpF** compared to the use of other imaging techniques.

The implantable spinal fusion stimulator was positioned parallel to the static magnetic field of the MR system for all conditions indicated below. MRI was performed using a 1.5 Tesla MR system (maximum spatial gradient 450 gauss/cm). Signal void values are indicated in millimeters squared.

Table Key: (T1-SE, T1-weighted spin echo; GRE, gradient echo or FISP, Siemens version of the gradient echo pulse sequence; N/A, not applicable; values for artifact size indicated in mm²; Note that the T1 and the T2 values for the gadolinium-doped saline.)

Summary of MRI Artifact Information for the **SpF-XL IIb** model

Parameter	Condition #1	Condition #2	Condition #3	Condition #4
Signal Void Size (mm ²)	16,762	8,918	19,769	12,630
Static Magnetic Field (T)	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	GRE(FISP)	GRE(FISP)
TR(msec)	500	500	3	3
TE(msec)	20	20	1	1
Flip Angle	N/A	N/A	55°	55°
Bandwidth	16kHz	16kHz	16kHz	16kHz
Field of View (cm)	30	30	30	30
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10mm	10mm	10mm	10mm
Imaging Plane	parallel	perpendicular	parallel	perpendicular
Phantom Filler	fluid	fluid	fluid	fluid

Summary of MRI Artifact Information for the **SpF PLUS-Mini** model

Parameter	Condition #1	Condition #2	Condition #3	Condition #4
Signal Void Size (mm ²)	7,618	5,813	21,871	14,908
Static Magnetic Field (T)	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	GRE(FISP)	GRE(FISP)
TR(msec)	500	500	100	100
TE(msec)	20	20	15	15
Flip Angle	N/A	N/A	50°	50°
Bandwidth (HZ/pixel)	100Hz	100kHz	100kHz	100kHz
Field of View (cm)	30	30	30	30
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10mm	10mm	10mm	10mm
Imaging Plane	parallel	perpendicular	parallel	perpendicular
Phantom Filler	fluid	fluid	fluid	fluid

Nerve Excitation

The cathodes of the implantable spinal fusion stimulator must be positioned a minimum of 1 cm from nerve roots to reduce the possibility of nerve excitation during a MRI procedure.

Torque

To minimize the possibility of magnetically induced torque during MR imaging, the stimulator should be oriented with its broad face (39mm x 27mm plane for the **SpF PLUS-Mini** and 36mm x 23mm plane for the **SpF-XL IIb**) parallel to the body and to the static field lines inside the bore.

CLINICAL STUDIES

Two clinical studies, one randomized and the other non-randomized, were conducted to support the indications and usage of the **SpF** Implantable Spinal Fusion Stimulator 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.

Randomized Study

The randomized study consisted of 99 patients who underwent spinal fusion surgery and received either an **SpF-4** device or had no device implanted. For analysis purposes, the data from these 99 patients were divided into two groups. Group A patients were from investigators who entered four or more patients (N= 63 patients) in accordance with the requirements of the randomization protocol as defined in the study (minimum of 2 treated and 2 control patients). Group B patients (N=36 patients) were from investigators who failed to meet the randomization criteria (less than 2 treated and 2 control patients).

Within the Group A patient population, there were a total of 34 **SpF-4** treated patients (26 males, 8 females) with a mean age of 39.79 years (S.D. 10.63) and 29 patients in the control group (20 males, 9 females) with a mean age of 39.66 years (S.D. 11.50). The spinal fusion success rate for the Group A treated patients was 81% versus 54% for the control group. This result was statistically significant at $p=0.026$ (Fisher's Exact test, one-tail). The mean follow-up time for Group A for the original PMA result was 12.97 months (S.D. 3.92) post spinal fusion surgery. Post-approval results showed a 75% spinal fusion success rate for the treated group versus 55% for the controls. The post-approval results showed a numerically better observed result for fusion rate among the **SpF-4** treated group, but this difference was not statistically significant ($p=0.087$). There were no patients lost to follow-up for this group. Patients in Group A were followed for a mean of 42 months (S.D. 24.26) post spinal fusion surgery.

At the time of the PMA, only 26 of the 36 Group B patients were available for analysis. Results showed 100% of the control patients fused ($n=10$) and 81% of the treatment group fused ($n=16$). The mean follow-up time for Group B for the original PMA result was 12.77 months (S.D. 3.40) post spinal fusion surgery. Post-approval study follow-up of Group B showed a spinal fusion success rate of 100% for the control patients ($n=11$) and 75% of the treated group ($n=19$). The post-approval study follow-up rate was 97% for the 36 Group B patients with a mean follow up time of 39 months (S.D. 19.13).

When the fusion results of Group A and Group B were combined, the difference was not statistically significant although there was a numerically better observed result for fusion rate among **SpF-4** treated patients. For the post-approval study Group A and Group B combined data there was no statistically significant difference between the **SpF-4** and control group.

The PMA and post-approval study follow-up results for the Group A and Group B are summarized in Table 1. Combined Group A and Group B data are summarized in Table 2.

Table 1
Group A (N=63 patients)

	PMA Result		Post-Approval Study Result	
	Control	Treatment	Control	Treatment
Fused	15	25	16	24
Not Fused	13	6	13	8
Lost to Follow-up	1	2	0	0
Deceased	0	0	0	1
No Fusion Performed	0	1	0	1
	p = .026†		p = .087†	
Success Rate *	54%	81%	55%	75%

Group B (N=36 patients)

	PMA Result		Post-Approval Study Result	
	Control	Treatment	Control	Treatment
Fused	10	13	11	5
Not Fused	0	3	0	8
Lost to Follow-up	1	4	0	1
Deceased	1	0	1	0
No Fusion Performed	2	0	2	0
Omit-Non-Protocol	1	1	1	1
Success Rate *	100%	81%	100%	74%

† Fisher's Exact Test, one tail/ * Calculated by: Fused ÷ Fused plus Not Fused within each group.

Table 2
Group A and Group B (N=63 + 36 = 99 patients)

	PMA Result		Post-Approval Study Result	
	Control	Treatment	Control	Treatment
Fused	25	38	27	38
Not Fused	13	9	13	13
Lost to Follow-up	2	6	0	1
Deceased	1	0	1	1
No Fusion Performed	2	1	2	1
Omit-Non-Protocol	1	1	1	1
Success Rate *	66%	81%	68%	75%

* Calculated by: Fused ÷ Fused plus Not Fused within each group.

Non-Randomized Study

There were a total of 367 patients enrolled in the non-randomized portion of the study (Table 3). At the time the PMA was submitted, there were 116 patients that had a final outcome result and 251 patients were still being followed. The 116 patients showed a 93% spinal fusion success rate. The mean follow-up time for the patients from the original PMA result was 12.02 months (S.D. 2.42). The post-approval study success rate for the 116 patient group was 89%; the post-approval study follow-up rate was 81% (19% lost to follow-up) with a mean follow-up time of 53 months (S.D. 28.51) post

(cont'd)

fusion/implantation. The post-approval study results from the non-randomized 251 patients showed a post-implant spinal fusion success rate of 84%, with a mean follow-up time of 51 months (S.D. 26.6). The post-approval study follow-up rate for this group was 80% (20% lost to follow-up). Within the 367 non-randomized study population there were 204 males and 163 females with a mean age of 44.49 years (S.D. 11.99).

Table 3

	Non-Random, N=116 patients		Non-Random N=251 patients	Non-Random N=367 patients (116 + 251)
	PMA Result	Post-Approval Study Result	Post-Approval Study Result	Post-Approval Study Result
Fused	108	84	170	254
Not Fused	8	10	32	42
Lost to Follow-up	0	19	43	62
Deceased	0	3	4	7
Omit	0	0	2	2
Success Rate *	93%	89%	84%	86%

* Calculated by: Fused ÷ Fused plus Not Fused within each group.

ADVERSE EVENTS

In randomized and non-randomized clinical studies involving 493 patients using the model SpF-4, twenty-two adverse events (4%) were reported. Eight were related to lead breakage. In addition, there were seven reported events of discomfort; five reported cases of infection and two events related to battery life. A change to a new lead material was made in response to eight incidents of reported lead breakage (connecting the generator to the titanium cathode). There were 206 patients enrolled into the study subsequent to the change to the new lead material. These patients were followed for a mean of 42.84 months (S.D. 26.46) post implantation with no additional incidents of lead breakage reported in the trial.

Universal Symbols



Symbol for "Do Not Reuse"



Symbol for "Sterilization using EtO"



Symbol for "Attention, See Instructions for Use"



Symbol for "Use by Date"



Symbol for "Date of Manufacture"



Symbol for "Storage Temperature"



Symbol for "Catalog Number"



Symbol for "Serial Number"



Symbol for "Prescription Only"