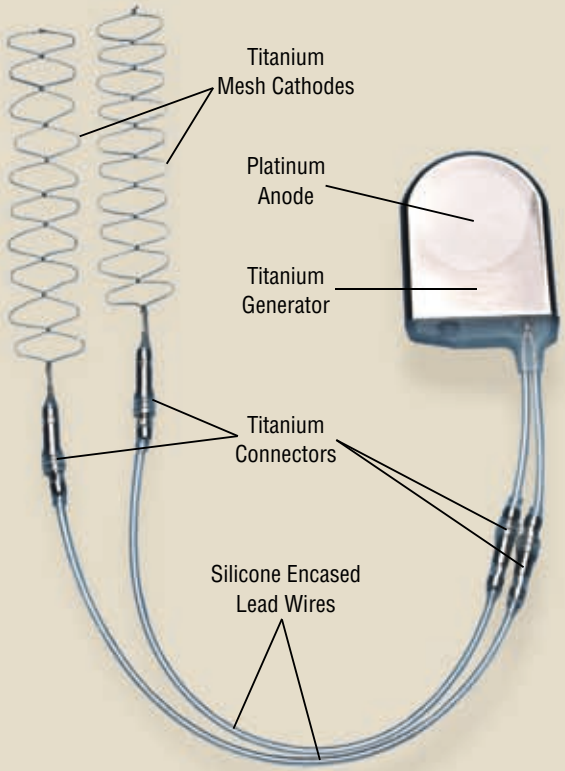
What is the SpF® Implantable Spine Fusion Stimulator?

Your doctor may prescribe* the SpF® Stimulator, an implantable electrical device that has been shown to increase the probability of fusion success[1, 2, 3, 4]. Electrical stimulation therapies have been used for more than 30 years to promote spinal fusion[4, 5]. Backed by clinical studies, the SpF® Stimulator is a proven, safe and effective adjunctive treatment that increases the probability of the healing of your fusion. The original device received initial FDA approval and was fully commercialized in 1987. Since then, over 100,000 devices have been implanted.



Educated Decisions

The information contained in this brochure is for educational purposes only. Biomet is not dispensing medical advice. Only you and your physician can decide the proper course of treatment and only your physician can make the proper medical judgment required to determine which products and procedures would be most suitable for your condition.

It is our goal to help physicians achieve successful outcomes, one patient at a time. We firmly believe that patients who are well informed are able to more accurately identify the symptoms they are suffering, better understand the conditions they are afflicted with, and work closely with their physicians in order to fully comprehend, and decide upon, a course of treatment.

1 Kane, W.J. Direct current electrical bone growth stimulation for spinal fusion. Spine (Phila Pa 1976), 1988.13(3): p. 363-5.
2 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.
3 Kucharzyk, D.W. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. Spine (Phila Pa 1976), 1999. 24(5): p. 465-8;discussion 469.
4 Source: SpF® Implantable Spinal Fusion Stimulator Technical Monograph, BSP196276L 05/10.
5 Dwyer, A.F. and Wickham, G.G. Direct current stimulation in spinal fusion. Med J Aust, 1974. 1(2): p. 73-5. P850035/S0333 SpF® PLUS-Mini (60 µA/W) and SpF® Plus-Mini (60 µA/M). P850035/S022 SpF®-XL IIb Implantable Spine Fusion Stimulator. P850035/S023 SpF®-XL IIb 2/DM and 2/DW

Indications: The SpF® PLUS-Mini Implantable Spine Fusion Stimulator is indicated as a spinal fusion adjunct to increase the probability of a 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.

* Rx Only. Caution: Federal law restricts this device to sale by or on the order of a physician.

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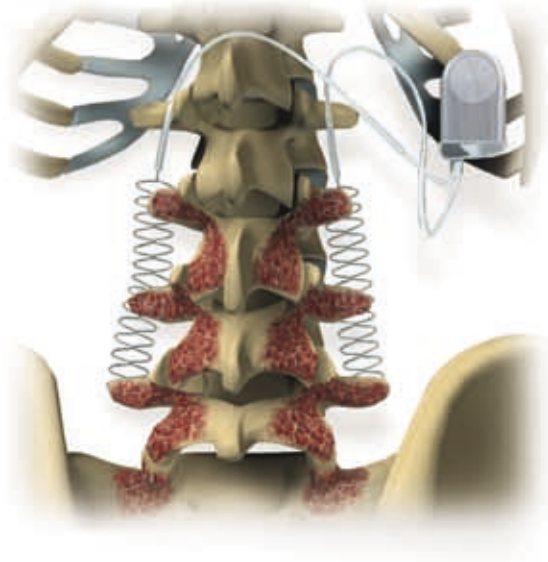
SpF® Implantable Spine Fusion Stimulators

Patient Brochure

How does the SpF® Implantable Spine Fusion Stimulator work?

The SpF® Implantable Spine Fusion Stimulator produces an electrical signal at the fusion site like the body typically generates to induce normal bone healing. Two thin wires known as “cathodes” are connected to a low-profile system generator near your surgical site. Upon implantation, the SpF® Stimulator is automatically activated and begins to deliver treatment. The SpF® Stimulator requires no maintenance during the course of your treatment and is virtually unnoticeable. Clinical investigations have shown that the SpF® Implantable Spine Fusion Stimulator increases the probability of fusion success rates, particularly in high-risk populations[1, 2, 3, 4].



What will the SpF® Implantable Spine Fusion Stimulator feel like?

The SpF® Implantable Spine Fusion Stimulator will not create any painful or electrical sensations. Some patients report that they can feel the device under their skin when they touch the area of implantation, but many patients say that they do not notice the device at all.

How will the SpF® Implantable Spine Fusion Stimulator affect my daily activities?

There are no special activity restrictions for patients with the SpF® Implantable Spine Fusion Stimulator; however, many surgeons will restrict their patient’s activities because of the fusion surgery. Swimming and bathing will not affect the device.

Do I need to have the SpF® Implantable Spine Fusion Stimulator removed?

The SpF® Implantable Spine Fusion Stimulator is designed to deliver approximately six months of continuous treatment. The generator may optionally be removed at the end of its useful life (approximately 24-weeks). If removal is desired, the explantation may be performed as an outpatient procedure utilizing local anesthetic.

Is it safe to travel with the SpF® Implantable Spine Fusion Stimulator?

The SpF® Implantable Spine Fusion Stimulator is provided with an identification card that may be used to inform TSA (Transportation Security Administration) of your device; however, most patients report that they travel through airport metal detectors without any problem.

Has the SpF® Implantable Spine Fusion Stimulator been proven and is it covered by insurance?

The SpF® Implantable Spine Fusion Stimulator is FDA approved and covered by most private health insurance providers, Medicare, and most state Medicaid programs, when deemed medically necessary and when all supporting documentation forms have been appropriately submitted.

Who can I talk to if I have a question?

Please consult your spine surgeon with any questions regarding the SpF® Implantable Spine Fusion Stimulator.