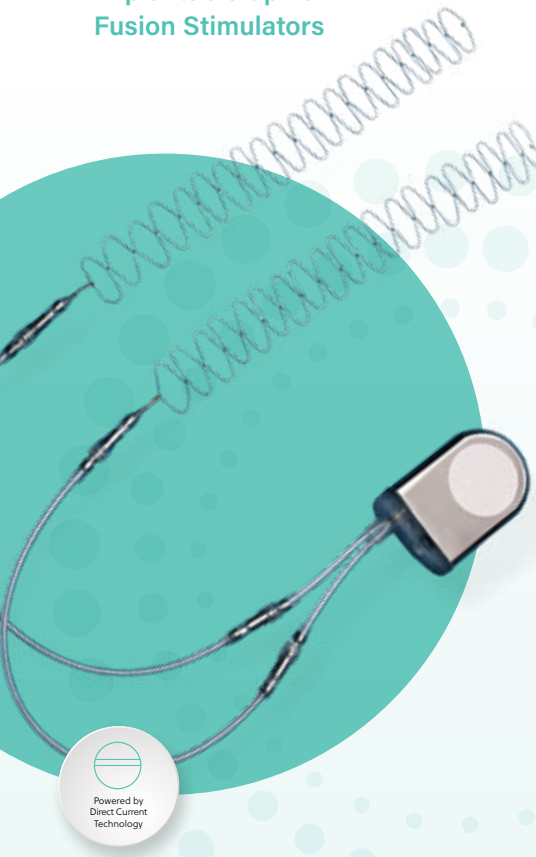
SpF®

Implantable Spinal Fusion Stimulators



Frequently Asked Questions

ABOUT

Why are implantable spinal fusion stimulators prescribed?

Physicians may prescribe an implantable bone growth stimulator to aid in the spinal fusion healing process. SpF® Implantable Spinal Fusion Stimulators are FDA approved, clinically proven, safe, and effective devices that have been helping people heal for over 35 years.

What is a SpF® Implantable Spinal Fusion Stimulator?

A SpF® stimulator is a small, battery-powered, direct current electrical stimulation device implanted near the fusion site during a spinal fusion procedure. It provides constant, around-the-clock stimulation to promote bone growth that increases the chance to achieve a successful fusion outcome.

How does the SpF® stimulator work?

The device's uniquely designed cathodes are placed on either side of the fusion site, and the generator is implanted away from the cathodes during surgery. The area between and around the cathodes safely and effectively stimulate the body's natural healing mechanisms to promote bone growth.

USE

How can patients confirm the device is working?

Prior to implanting the device, the surgeon completes a pre-operative testing procedure to ensure the device is operational. Once implanted, the device is automatically activated and works continuously for 24 weeks (approximately 6 months).

How long are the SpF® devices intended to be worn?

The SpF® stimulators provide around-the-clock treatment for 24 weeks (approximately 6 months). After 24 weeks, the direct current electrical stimulation technology is automatically deactivated.

Will the SpF® stimulator affect a patient's daily activities?

There are no special activity restrictions for patients implanted with the SpF® stimulator; however, during recovery from spinal fusion surgery, the patient's activities may be limited based upon their surgeon's recommendations.

Does the SpF® stimulator need to be recharged?

No. The SpF® stimulator is a completely self-contained implantable device that lasts for the entire treatment period. It is designed to function for the duration of treatment and will not require recharging.

How can patients check their healing progress?

The prescribing surgeon will monitor the healing progress of the patient's spinal fusion through x-rays or other imaging techniques. While the patient may not feel the stimulator actively treating, patients are encouraged to follow-up with their prescribing surgeon to view their progress.

CARE

Is it safe to travel through airport security with the SpF® stimulator implanted?

SpF® stimulators are designed to be safe for use with most airport security systems. However, it is important to inform and share an identification travel card with the Transportation Security Administration (TSA) personnel that the patient has an implantable device. The identification travel card is located inside the product packaging.

What happens to the device when treatment is complete?

After treatment completion, the device's electrical stimulation automatically de-activates. The generator may be optionally removed at any time after treatment is complete. If removal is desired, a simple and quick explantation is performed as an outpatient procedure utilizing a local anesthetic. An outpatient procedure is a surgery that takes place in one day and does not require an overnight stay. A local anesthetic is a drug that numbs a specific part of the body to prevent pain. It lasts a short period of time to allow patients to leave the same day after the removal.

Can patients receive a MRI scan with the stimulator implanted?

Yes. The SpF® stimulators are considered Magnetic Resonance (MR) Conditional, which means they are safe to scan under very specific conditions. Scan the QR code to learn more detailed information about the conditions that are appropriate for scanning with the different device models.

Who do patients call with additional product questions?

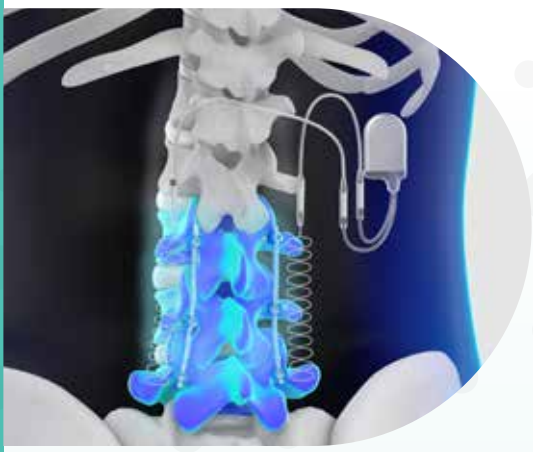
Patients may call the EBI® Customer Care team at 800-526.2579.

MODELS

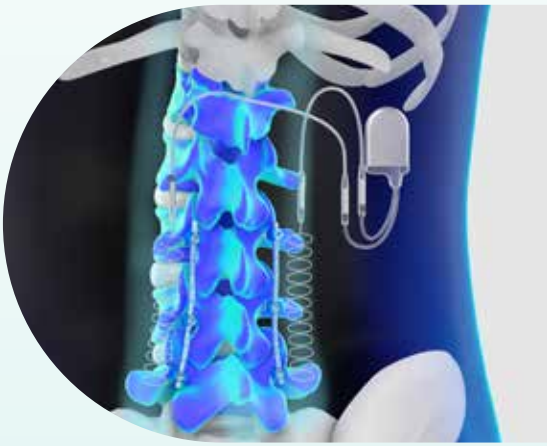
Are there different types of SpF® stimulators?

Yes. There are two available SpF® stimulator models which may be implanted based upon the number of levels a surgeon is intending to fuse.

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.



LEADING THE INDUSTRY IN BONE GROWTH STIMULATION

As the pioneer of bone growth stimulation, EBI has been leading the industry for almost half a century with the largest portfolio of clinically proven solutions and is dedicated to advancing their mission of helping people heal to restore their daily life.

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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. 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. 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. HM0366 REV B 03/25.