Biomet® SpinalPak®

Non-invasive Spine Fusion Stimulator System

Frequently Asked Questions

ABOUT

Why are spinal fusion stimulators prescribed?

Physicians may prescribe a bone growth stimulator to aid in the spinal fusion healing process. The Biomet® SpinalPak® Non-invasive Spine Fusion Stimulator System is an FDA approved, clinically proven, nonsurgical treatment device prescribed by physicians for over 25 years to aid in the healing of spinal fusions.

How does the SpinalPak® work?

The Soft-Touch® electrodes that accompany the SpinalPak® are placed four to six inches apart adjacent to the fusion site. The Soft-Touch® electrodes deliver a safe and scientifically proven stimulation technology called capacitive coupling. The area surrounding the electrodes is stimulated inducing the body's natural healing mechanisms to safely and effectively promote bone growth at the targeted fusion site.

How can patients confirm the device is working?

When the device is properly activated, the blinking check mark on the controller display indicates treatment has started. If the system is not properly activated and/or the system's components accidently disengage, an audible and visual alert will prompt the patient that the device is not functioning properly.

USE

How long is the SpinalPak® worn?

The SpinalPak® is a unique, nonsurgical spinal fusion device that may be utilized continuously each day following surgery to help promote the recovery process. The prescribing physician will determine a customized treatment for the patient and when to discontinue treatment.

Can the SpinalPak® be used by pregnant or nursing women?

The effects of the stimulation treatment have not been studied during pregnancy or nursing so the prescribing physician should be consulted prior to use.

Can the SpinalPak® be worn with a pacemaker?

The use of the SpinalPak® and a pacemaker or cardioverter can be assessed on an individual basis. The SpinalPak® is not contraindicated for patients with pacemakers, however, it is recommended a cardiologist evaluate any potential interaction prior to use.

How often do the battery packs need to be replaced?

The battery packs last 24 hours. It is recommended to change the battery pack daily.

How often should the electrodes be replaced?

The disposable Soft-Touch® electrodes are intended to be replaced at leisure within 1-7 days. With continuous use, the hydrogel on the electrodes may dry out. The patient may renew the electrodes by dampening the gel area on the electrode or may order and replace the electrodes.

CARE

How may additional supplies be ordered?

Additional supplies including the Soft-Touch® electrodes and optional cover patches may be ordered free of charge by calling the EBI® Customer Care team at 800-526-2579.

Can the SpinalPak® be worn while traveling?

Yes. The SpinalPak® is comfortable and discreet and may be worn while traveling to continue therapeutic benefits while on the go. If traveling with the SpinalPak® on an airplane, it is recommended to remove the device prior to going through security at the airport and to keep the Patient Manual with the device at all times.

What happens to the device when treatment is complete?

Once the prescribing physician has determined treatment completion, the device may be disposed according to local governing ordinances. The EBI® Customer Care team may also be contacted at 800-526-2579 to support device disposal.

How should the SpinalPak® be stored and cleaned?

When not in use, the SpinalPak® should be stored in a cool and dry place. A damp cloth may be used to clean the device. Cleaning products or detergents should not be used.

Who do patients call with additional product questions or concerns?

Patients may call the EBI® Customer Care team at 800-526-2579.

COVERAGE

Is the SpinalPak® covered by insurance?

Each patient has a different insurance coverage policy. The SpinalPak® is covered by Medicare, Medicaid, and most commercial healthcare plans along with worker's compensation.

Does the SpinalPak® need to be pre-authorized?

If pre-authorization is required, EBI® will verify the patient's eligibility and benefit levels to obtain an advanced pre-authorization prior to the patient receiving the device.

Is there additional support provided for patients with financial concerns?

Yes. EBI® has a dedicated Patient Advocacy Group to assist all SpinalPak® patients with financial concerns. The patient may call the Patient Advocacy Group directly at 888-236-3652.

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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