ZimVie

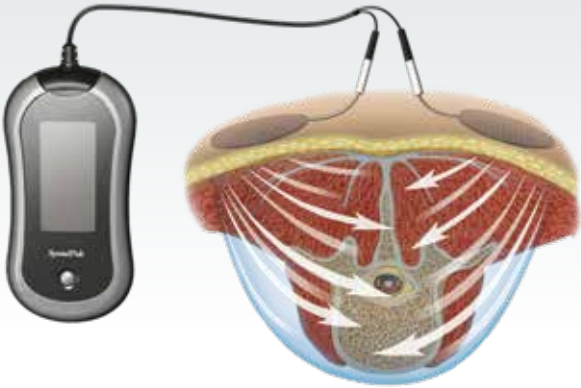
Biomet® SpinalPak®

Non-invasive Spine
Fusion Stimulator System

Patient Information

EBI BONE GROWTH STIMULATION

Frequently Asked Questions



How does the Biomet® SpinalPak® Non-invasive Spine Fusion Stimulator System work?

Spinal fusion joins one or more lumbar vertebrae to eliminate motion, increase stability, and to try to reduce pain. Following spinal fusion surgery, in the lower (lumbar) spine, the SpinalPak may be prescribed to assist in healing the fusion by sending electrical impulses directly to the spine that mimics your body's natural healing process. It is portable for ambulatory use and easy to operate, so you'll be able to treat your lumbar spinal fusion while going about your daily routine, or while sleeping. Results will vary due to health, weight, activity, and other variables. Not all patients are candidates for this medical device. Only a medical professional can determine the treatment appropriate for your specific condition.

Two lightweight electrodes similar in size to a quarter are placed on your back adjacent to the surgical site. The electrodes are easy to apply and are lightweight. The SpinalPak is battery operated with a rechargeable battery pack. Upon connection of the charged battery pack, the SpinalPak is automatically activated and ready to deliver therapeutic treatment.

How long will I have to treat with the device?

The SpinalPak is designed to deliver 270 days of continuous therapeutic treatment. The recommended treatment time is 24 hours per day. Certain risk factors such as smoking, obesity, diabetes, osteoporosis, undergoing a multi-level surgery or a revision spinal surgery may factor into the duration of your treatment.

How do I know the system is working?

You should not feel the SpinalPak as it delivers the treatment signal to the fusion site; however, some patients may feel a slight sensation. When the system is treating, you'll see a battery symbol and check mark on the stimulator's display screen. Please refer to the patient manual for a description of each symbol that may appear on the display screen. If you have any questions, please contact a Customer Care Representative at 1-800-526-2579 extension 6000.

Can I use the system while wearing a back brace over my fusion site?

Yes. The SpinalPak's electrodes can be worn comfortably underneath a back brace.

I have a pacemaker. Can I use the system?

The use of a pacemaker or cardioverter must be assessed on an individual basis. ZimVie recommends that you consult with your cardiologist, who can monitor your pacemaker with an electrocardiogram while you are wearing the SpinalPak.

Is the system MRI safe?

MRI scans and procedures should not be performed until the SpinalPak Stimulator System has been completely removed.

Is the system safe to use during pregnancy?

Use of the SpinalPak during pregnancy has not been evaluated; therefore it is not recommended.

Will my insurance cover the cost of the device?

Insurance coverage varies depending on your insurance plan. The SpinalPak is generally recognized by Medicare, Medicaid, workers compensation as well as private and public health plans. ZimVie's Patient Advocacy Group is available to assist you and discuss any questions regarding insurance coverage, deductibles and potential out-of-pocket expenses. You may contact our Patient Advocacy Group at 1-888-236-3652.

What is the process for obtaining a SpinalPak?

You can only obtain the SpinalPak with a doctor's prescription.

Who do I contact if I have questions or need to order supplies?

Customer Care Representatives are ready to answer your questions, and can be reached at 1-800-526-2579 extension 6000.

*Not actual patients.

Biomet® SpinalPak®

Non-invasive Spine Fusion
Stimulator System

Following your spine fusion surgery, your doctor may prescribe the SpinalPak, a proven, safe, and effective nonsurgical adjunctive treatment that helps promote the healing of your fusion.

A Name You Can Trust

ZimVie non-invasive stimulation devices trace their lineage to Electro-Biology, Inc. (EBI), an industry pioneer that introduced the world's first FDA approved electrical non-invasive bone growth stimulation device more than 40 years ago. ZimVie's extensive sales and customer service support helps both physicians and patients obtain access to appropriate therapeutic treatment technologies and works with each patient to optimize and monitor compliance, track progress and assist with insurance reimbursement.

INDICATIONS: The Biomet SpinalPak Non-invasive Spine Fusion Stimulator System is a non-invasive Spine Fusion stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels - P850022/S017.

USAGE: The SpinalPak is designed to deliver 270 days of continuous therapeutic treatment for 24 hours per day. The recommended daily therapeutic treatment is continuous for 24 hours. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.
Rx Only - Prescription Only - Single Patient Use Only - Do Not Reuse

CONTRAINDICATIONS: There are no known contraindications regarding the use of the SpinalPak.

For complete prescribing information including warnings and precautions, please refer to the Biomet SpinalPak Non-invasive Spine Fusion Stimulator System Complete Manual and Package Insert PN1067795-00 or call 1-800-526-2579 extension 6000.

For more information, visit ZimVie.com

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