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.
When to consider using the Biomet® SpinalPak®
Non-Invasive Spine Fusion Stimulator System

What is the SpinalPak Stimulator System?

The SpinalPak Stimulator System is a proven, safe and effective
nonsurgical adjunctive treatment that helps promote the healing
of your spinal fusion.

What is the SpinalPak Stimulator System indicated for?

The SpinalPak Stimulator System is a non-invasive device indicated as an adjunct electrical treatment
to primary lumbar spinal fusion surgery for one or two levels.

The system 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 the patient’s treatment.

How does the SpinalPak Stimulator work?

A 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 Stimulator System may be prescribed to assist in healing the fusion by sending electrical impulses directly to
the spine that mimics the body’s natural healing process. It’s portable and designed for ambulatory
use and easy to operate, so your patients will be able to treat their lumbar spinal fusion while going
about their daily routine, or while sleeping.

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

**Technology:** Capacitive Coupling (CC)
**Delivery Method:** Pair of electrodes
**Signal:** 60kHz sinusoidal wave
**Recommended Treatment Time:** 24 hours/day for 270 days
**Device Weight:** 3.15 oz.
**Original FDA Approval Date:** 1999

Key Highlights:

- In 2016, the North American Spine Society (NASS) recommended capacitive coupling and direct current stimulation for posterolateral fusions in high-risk patients.¹
- Nearly 400,000 SpinalPak Stimulator Systems sold.²
- More than 30 years of proven clinical use.³
- Patient compliance data download to monitor success in heal rates.⁴
- Smallest and Lightest spine fusion stimulator device on the market weighing only 3.15 ounces.⁵
- Lightweight electrodes weigh less than an ounce allowing for minimal weight around the fusion site, and they can be comfortably worn under a brace.

Capacitive Coupled Technology is Supported by Pre-Clinical Results:

In this Pre-Clinical Study, Capacitive Coupling (CC) Technology was shown to promote upregulation of bone morphogenetic proteins (BMPs)⁶,

- In this in vitro pre-clinical study, upregulation of multiple BMPs was shown to occur with capacitive coupling (CC) stimulation in as little as 30 minutes of exposure with optimal upregulation occurring at 24 hours.

While the greatest expression of osteogenic BMPs was observed after 24 hours of CC stimulation, two to three times more upregulation was observed after just 30 minutes of CC stimulation and continued to increase in a dose dependent manner.

*Although not indicative of human clinical results, outcomes from pre-clinical research have been implicated in various models of bone repair.*

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¹Although not indicative of human clinical results, outcomes from pre-clinical research have been implicated in various models of bone repair.
In another Pre-clinical Study, Capacitive Coupling had Significantly Greater Cellular Proliferation at 24 hours than CMF & PEMF.\(^7,\ast\)

While the data and results presented within the pre-clinical study demonstrated the technology was shown to enhance, upregulate or increase certain biological factors it does not conclusively support any specific mechanism of action as it relates to device effectiveness, bone remodeling or healing outcomes.

**Mechanism of Action**

- CC signal transduction occurs through the regulation of calcium ions into the cell through the voltage gated calcium ion channels.
- CMF and PEMF signal transduction occurs through the regulation of intracellular calcium ions.

1) CC Stimulates Voltage Gated Calcium Ion Channels to Allow Calcium Ions to Enter Cells
2) Calcium Ions Then Activate Calmodulin (Protein)
3) Activated Calmodulin Leads to Increased Cell Proliferation

**DNA Production by Technology Across Four Time Points**

<table>
<thead>
<tr>
<th>Technology</th>
<th>30 minutes</th>
<th>2 hours</th>
<th>6 hours</th>
<th>24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC</td>
<td>17%</td>
<td>23%</td>
<td>25%</td>
<td>49%</td>
</tr>
<tr>
<td>PEMF</td>
<td>15%</td>
<td>17%</td>
<td>21%</td>
<td>22%</td>
</tr>
<tr>
<td>CMF</td>
<td>21%</td>
<td>22%</td>
<td>25%</td>
<td>30%</td>
</tr>
</tbody>
</table>

*Although not indicative of human clinical results, outcomes from pre-clinical research have been implicated in various models of bone repair. **The mechanism of action behind capacitive coupling (CC) technology is unknown, however, while the data and results presented within the pre-clinical study demonstrated the technology was shown to enhance, upregulate or increase certain biological factors it does not conclusively support any specific mechanism of action as it relates to device effectiveness, bone remodeling or healing outcomes.**
The SpinalPak Stimulator System is Supported by Clinical Results:

In one clinical study, overall success rate (Clinical and Radiographic) was

84.7% vs 64.9%  
84.7% in the SpinalPak Group vs 64.9% in the Placebo Group (P=0.0043).

In the same clinical study, the SpinalPak stimulator achieved statistically significant results demonstrated across several measurements:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>SpinalPak Group</th>
<th>Placebo Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterolateral fusion</td>
<td>89.1%</td>
<td>64.9%</td>
<td>0.006</td>
</tr>
<tr>
<td>Two-Level fusion + Internal Fixation</td>
<td>84%</td>
<td>58%</td>
<td>0.04</td>
</tr>
<tr>
<td>Diagnosed with DDD</td>
<td>86.5%</td>
<td>57.4%</td>
<td>0.002</td>
</tr>
</tbody>
</table>

In the same study, separate individual fusion procedure scores for clinical or radiological only were measured:

In one clinical study for posterolateral fusions, the SpinalPak stimulator demonstrated clinical or radiological healing outcomes as high as 92.7%.

§ The patients in the "Degenerative Disc Disease Only" group were patients that were initially diagnosed with DDD and underwent a one-to-two level spinal fusion surgery. In this study, the DDD group only consisted of 52 patients in the SpinalPak treatment group and 54 patients in the placebo group.

† Represents the radiological or clinical success rate for posterolateral fusion separately. Radiological results P=0.013; clinical results P=0.088. P values for the clinical success rate between 0.05 and 0.10 show a trend toward statistical significance.
Zimmer Biomet – Offering Solutions To Your Patients

Our goal is to heal each and every patient and get them back to their daily activities.

No other company offers as many electrical stimulation technologies as Zimmer Biomet. In fact, no other company offers more than one technology. Zimmer Biomet currently offers three: pulsed electromagnetic field (PEMF), capacitive coupling (CC), and direct current (DC).*

1. North American Spine Society Coverage Policy Recommendations: Electrical Stimulation for Bone Healing. 2016. North American Spine Society, 7075 Veterans Boulevard, Burr Ridge, IL 60527 USA. These recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations do not represent a “standard of care,” nor are they intended as a fixed treatment protocol.

2. Data on file at Zimmer Biomet - ZBDATA1_20

3. Data on file Zimmer Biomet - P850022


5. Data on file at Zimmer Biomet – P&R17341A


* For product information, please visit www.zimmerbiomet.com/bonehealing.

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. There are no known contraindications regarding the use of SpinalPak Spine Fusion Stimulator Systems. Rx Only - Prescription Only - Single Patient Use Only - Do Not Reuse.

FINANCIAL DISCLAIMER: In support of their research for or preparation of this work, one or more of the authors may have received remuneration from Zimmer Biomet.

For complete prescribing information including indications, usage, contraindications, warnings and precautions, please visit www.zimmerbiomet.com/bonehealing or call 1-800-526-2579 extension 6000. This material is intended for health care professionals. Distribution to any other recipient is prohibited. BNS232093L 05/20 ©2020 Zimmer Biomet.