Pre-clinical studies state, “An appropriate electrical stimulation applied in vivo could cause the local up-regulation of a number of osteogenic BMPs in a safe, effective, economical manner.”

The SpF® Implantable Spine Fusion Stimulator

A Proven Treatment for Posterolateral Lumbar Spine Fusions

PROVEN TECHNOLOGY
• In pre-clinical investigations, DC stimulation enhances the expression of several different osteoinductive growth factors, including BMP-2, BMP-6, and BMP-7.8

PROVEN CLINICAL HISTORY
• Over 100,000 implanted to date
• 50% increase in fusion rates over autograft alone
• Significantly improves fusion success rates particularly in patients with specific risk factors1,2,3,4

ECONOMICAL
• Cost-effective, particularly in multi-level fusions
• CPT and ICD-9 Codes

Providing a constant dose of electrical stimulation for a maximum of 6 months.6
Pre-clinical animal studies have shown the following:

**Bone Morphogenetic Protein (BMP) Expression**
Prospective animal study of posterolateral lumbar spine fusion comparing autograft to autograft with rhBMP-27

- Not all BMPs expressed immediately post-op
- Each BMP has a specific time and pattern of expression
- BMP-2 mRNA is expressed later and to a lesser extent than BMP-6
- **BMP-6 appears to play a unique role as the earliest bone morphogenetic protein expressed during spine fusion healing**

**Direct Current (DC) Stimulation: BMP mRNA Upregulation**
Prospective animal study of posterolateral lumbar spine fusion comparing autograft to autograft with direct current (DC) stimulation

- **DC Stimulation up-regulates the gene expression of BMP-2, BMP-6 and BMP-7**
- DC stimulation up-regulates the normal physiologic expression of not just one, but various factors
  - Allows synergistic relationships between growth factors
  - Enhances fusion success without the potential concerns associated with single growth factor treatments
- **Cathode placement against and across the decorticated transverse processes resulted in enhanced bone formation throughout the entire fusion mass rather than just along the transverse processes**

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6. P850035/S020/S022/S031/S033 Approved FDA Trade Names: SpF® PLUS-Mini (60 μA/W), SpF® PLUS-Mini (60 μA/V) and SpF® XL Implantable Spinal Fusion Stimulator. Certain models of the SpF® Implantable Spinal Fusion Stimulator have approved trade names preceded with “EBI” designating the former sponsor and/or applicant.

* Denotes significant difference.
** In vitro cellular and pre-clinical animal studies may not be indicative of human clinical outcomes.