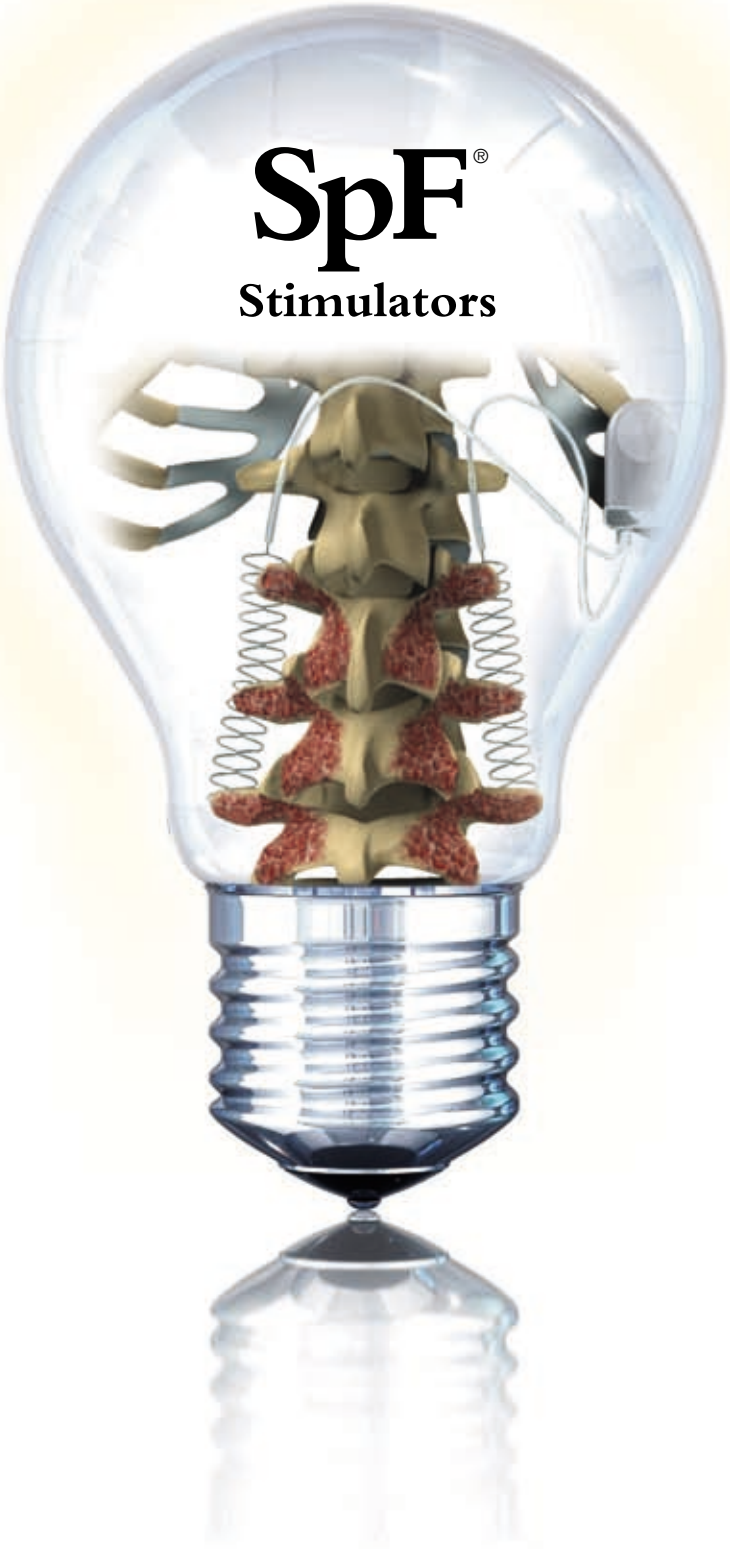
Innovation that Stands the Test of Time



The SpF® Implantable Spine Fusion Stimulator

A Proven Treatment for Posterolateral Lumbar Spine Fusions

PROVEN CLINICAL HISTORY

- Over 100,000 implanted to date
- 50% increase in fusion rates over autograft alone[1]
- Significantly improves fusion success rates particularly in patients with specific risk factors[1, 2, 3, 4]

PROVEN TECHNOLOGY

- DC stimulation enhances the expression of several different osteoinductive growth factors, including BMP-2, BMP-6, and BMP-7 in preclinical investigations[5, 6]

ECONOMICAL

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

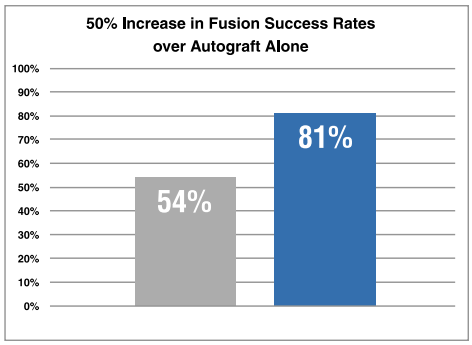
Providing a constant dose of electrical stimulation for approximately 6 months[7]

BIOMET® SPINE

50% Increase in Fusion Success Rates over Autograft Alone in an Uninstrumented Model[1]

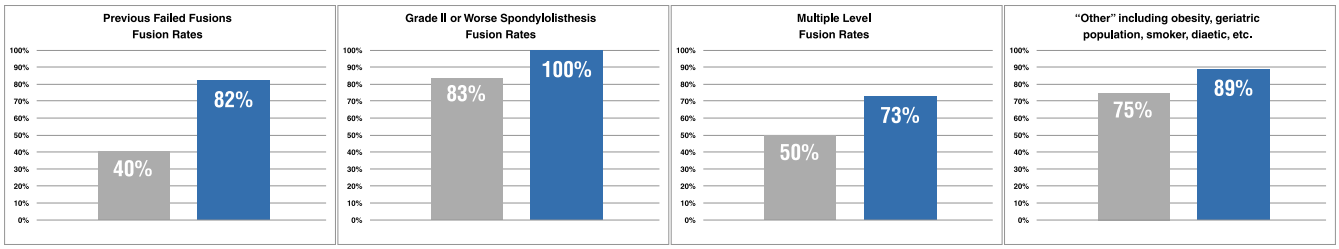
No SpF® Stimulator

SpF® Stimulator Treated Patients



- Randomized Prospective Controlled Trial[1]
- An "ethical substitution" for a human double blind study (did not want to implant inactive units in patients)
- Produced precisely matched cohorts of patients
- Radiographic fusion assessed by blinded independent radiologists achieved in 25 of 31 DC-treated patients (81%), but only 15 of 28 control patients "in situ" (54%) (See figure left)

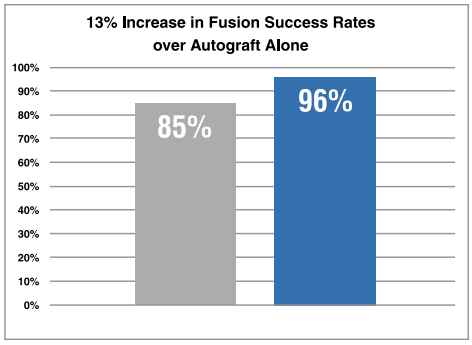
Difficult to Fuse Patient Studies



11-13% Increase in Fusion Success Rates with an SpF® Stimulator compared to without an SpF® Stimulator in difficult to fuse patients in an Instrumented Model[2, 3]

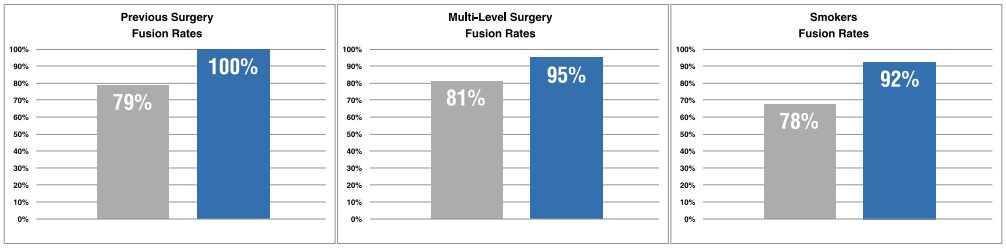
No SpF® Stimulator

SpF® Stimulator Treated Patients



- Instrumented compared to instrumented with an SpF® Stimulator in difficult to fuse patients
- Overall 96% of stimulated patients fused compared to 85% of unstimulated patients. (See figure left)[2]
- In a separate study, instrumented alone had a 87% fusion success rate; whereas Instrumented with SpF® direct current technology had a 96% fusion success rate[3]

Difficult to Fuse Patient Studies



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1 Kane, W.J. Direct current electrical bone growth stimulation for spinal fusion. Spine (Phila Pa 1976), 1988.13(3): p. 363-5.
2 Rogozinski, A. and Rogozinski, C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. Spine (Phila Pa 1976), 1996. 21(21): p. 2479-83.
3 Kucharzyk, D.W. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. Spine (Phila Pa 1976), 1999. 24(5): p. 465-8;discussion 469.
4 Source: SpF® Implantable Spinal Fusion Stimulator Technical Monograph, BSP196276L 05/10.
5 Fredericks, D.C., Smucker, J., Petersen, E.B., Bobst, J.A., Gan, J.C., Simon, B.J., and Glazer, P. Effects of direct current electrical stimulation on gene expression of osteopromotive factors in a posterolateral spinal fusion model. Spine (Phila Pa 1976), 2007. 32(2): p. 174-81.
6 *In vitro* cellular and pre-clinical studies may not be indicative of human clinical outcomes.
7 P850035/S020/S022/S031/S033 Approved FDA Trade Names: SpF® PLUS-Mini (60 µA/W), SpF® PLUS-Mini (60 µA/M) and SpF® XL IIb 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.