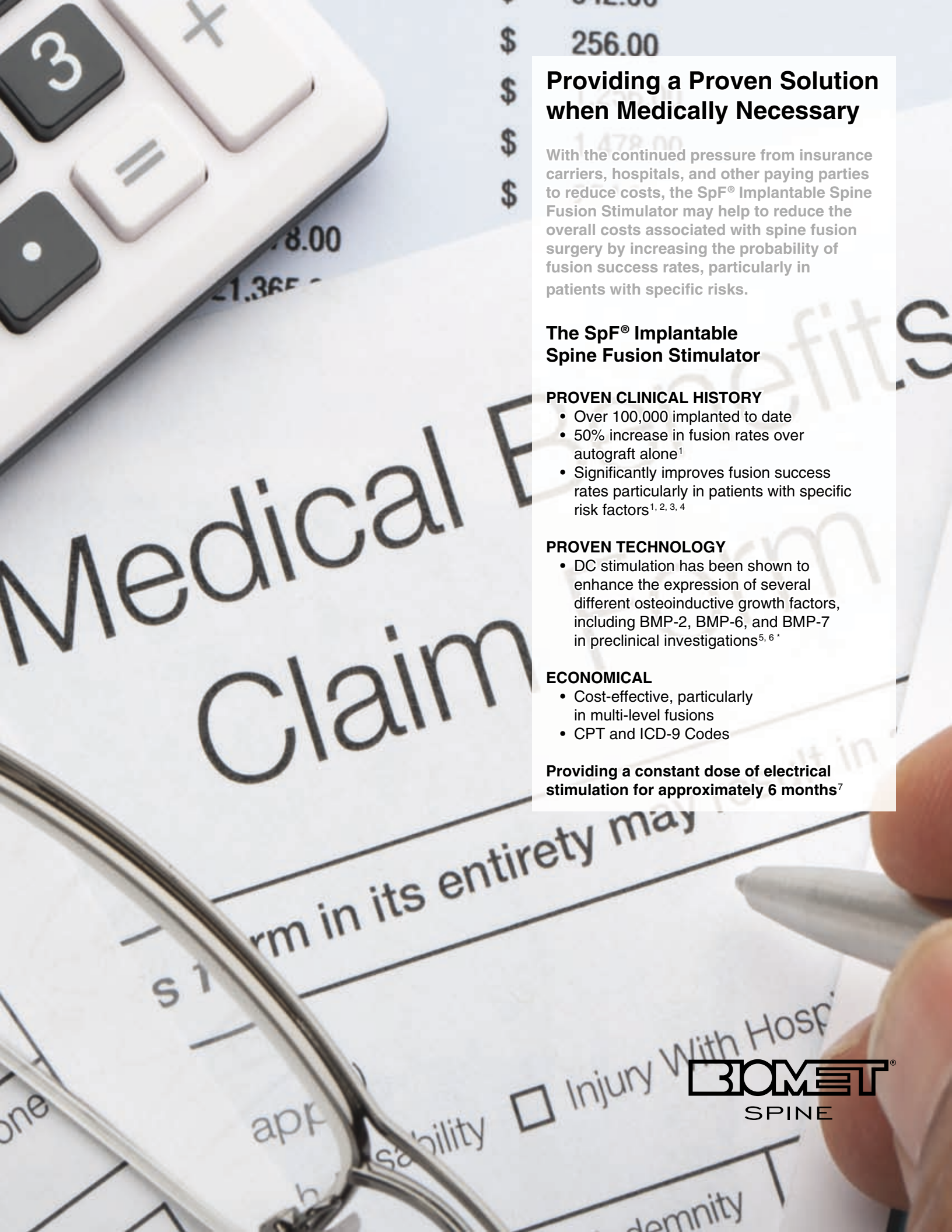

Providing a Proven Solution when Medically Necessary

With the continued pressure from insurance carriers, hospitals, and other paying parties to reduce costs, the SpF® Implantable Spine Fusion Stimulator may help to reduce the overall costs associated with spine fusion surgery by increasing the probability of fusion success rates, particularly in patients with specific risks.

The SpF® Implantable Spine Fusion Stimulator

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 has been shown to enhance 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

Medically Necessary Spine Fusion Stimulation Solution

Health insurance companies provide coverage only for health-related services that they define or determine to be **MEDICALLY NECESSARY**, which can be defined as a treatment, test, or procedure that is necessary for a patient's health or to treat a diagnosed medical problem.

Use of the SpF® Implantable Spine Fusion Stimulators may be considered **COST EFFECTIVE**, as they **increase the probability of fusion success** in patients with specific risk factors[1, 2, 3, 4]; thereby potentially avoiding additional surgeries and follow up.

Private Health Insurance Coverage

Major health insurance plans vary; however, most plans consider the SpF® Implantable Spine Fusion Stimulators **MEDICALLY NECESSARY** for spinal fusion surgery in individuals at high risk for pseudoarthrosis, including, but not limited to those with **ONE OR MORE** of the following risk factors for fusion failure:

- One (1) or more previously failed spinal fusion(s); **OR**
- Grade II or Grade III or worse spondylolisthesis; **OR**
- Diabetes; **OR**
- Renal disease; **OR**
- Other metabolic diseases where bone healing is likely to be compromised or growth is poor; **OR**
- Long-term systemic steroid use (e.g. daily enteral or parenteral use for greater than three (3) months)
- Fusion to be performed at two (2) or more levels; **OR**
- Current smoker or even history of tobacco use; **OR**
- Morbid obesity; **OR**
- Alcoholism or history of alcoholism; **OR**
- Significant osteoporosis which has been demonstrated on radiographs; **OR**

SpF® Implantable Spine Fusion Stimulators are often covered by the following providers when deemed **MEDICALLY NECESSARY** (when at least two or more of the risk factors listed above are present):

Aetna	GroupHealth	Regence
Anthem	HealthPartners	United Healthcare/Oxford
BlueCross BlueShield	Medica	UPMC Health
Cigna	Mountain State Medical	WellChoice
Fallon Community Health Plan	Presbyterian	Wellmark
And many others!		

Centers for Medicare and Medicaid Services Coverage

Effective July 1, 1996, the **Centers for Medicare and Medicaid Services** state that the SpF® Implantable Spine Fusion Stimulator is **MEDICALLY NECESSARY**, and therefore covered for the following indications:

- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to:
  - Previously failed spinal fusion at the same site; **OR**
  - Multiple level fusion

Reimbursement Codes

CPT Codes	Implantation 20975	Explantation (superficial) 20670	Explantation (deep) 20680
ICD-9 Codes	Implantation 78.9 + 9	Explantation 78.6 + 9	

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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.
8 SpF® Stimulator Surgical Technique BSP196967L Rev. 03/10.
* *In vitro* cellular and pre-clinical results may not be indicative of human clinical outcomes.