Healthcare Professional Brochure

EBI® OsteoGen™

Surgically Implanted Bone Growth Stimulator

Powered by Direct Current Technology

What is the OsteoGen™ implantable stimulator?

The OsteoGen™ implantable stimulator is a class III, FDA approved, implantable bone growth stimulation device designed as an adjunctive therapy to aid in the healing of nonunion fractures. It is a proven, safe and effective bone growth stimulation therapy that has been improving patient outcomes for over 40 years.

Features & Benefits

- The first and only long bone growth stimulation implant to support fracture nonunion healing outcomes.
- The unique, implantable stimulator allows surgeons to place the cathodes precisely over the targeted treatment site offering controlled treatment to the area where patient's need it most.
- The device provides constant, around-the-clock stimulation therapy, empowering surgeons to improve their patient's healing outcomes with no concern for compliance.
- The innovative cathode design enables increased surface area for active stimulation at the targeted treatment site.
- The optional generator removal is a simple and fast surgical procedure that can be performed in an Ambulatory Surgery Center (ASC).
- The sterilely packed implant improves operational efficiencies; no special instrumentation required.

Specifications

Technology: Direct Current (DC)
Original FDA Approval Date: 1980

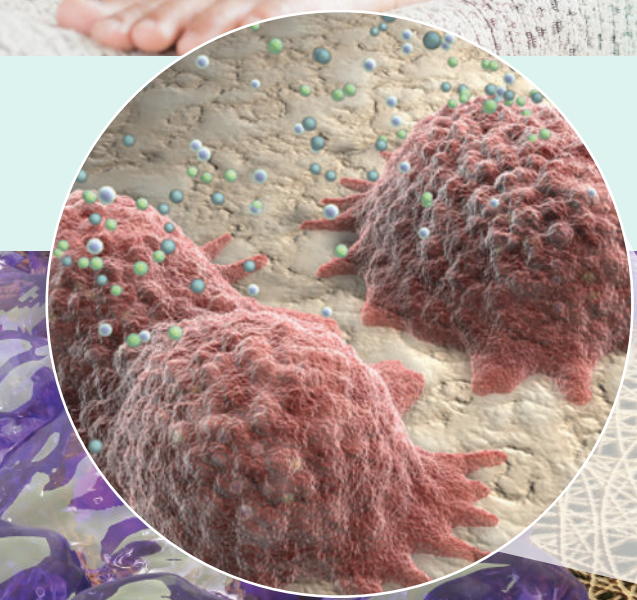
- Model: OsteoGen™ Single-lead
- Signal: 20 µA
- Cathode length: 8cm

- Model: OsteoGen™ Dual-lead
- Signal: 40 µA (20 µA per cathode)
- Cathode length: 8cm

How does the OsteoGen™ stimulator work?

The OsteoGen™ stimulator delivers a clinically proven, low-level electrical stimulation technology called Direct Current (DC) through a titanium cathode(s). The uniquely designed cathode(s) are placed in or around the treatment site with the generator implanted away from the cathode(s) during surgery. Direct Current technology generates a constant electrical current between and around the cathode(s) to safely and effectively induce the body's natural healing mechanisms to promote bone growth at the targeted treatment site. The DC technology has been shown pre-clinically to cause a faradic reaction. The faradic reaction results in decreased oxygen tension (leading to a decrease in osteoclasts), increased pH (leading to an increase in osteoblasts), and provides a favorable osteogenic environment to enhance bone formation and healing.*

What pre-clinical data has been published on Direct Current technology?



In an *in vitro* study, the upregulation of multiple Bone Morphogenetic Proteins (BMPs) including BMPs 2, 6, and 7 were observed.[1+]

Proven Upregulation of Multiple BMPs
BMPs 2, 6, and 7

What human clinical outcomes are there to support the use of the OsteoGen™ stimulator?

High clinical success rates were achieved with the OsteoGen™ stimulator.

United Fracture Success Rates as High as 84% with Normal Bone Remodeling and No Long-term Effects[3+]

84%

Overall Success Rate Demonstrated for Fracture Nonunions[2]

86%

Available Models

OsteoGen™ stimulators are available to order with a single or dual-lead mesh cathode to support a variety of long bone nonunions.

10-1320M	OsteoGen™ – 20/M	(20µA)
10-1348M	OsteoGen™ – 40/M	(40µA)

Implantation & Explantation Codes

Physician

CPT Code	Description
20975	Electrical stimulation to aid bone healing; invasive
20680	Removal of implant; deep

Ambulatory Surgery Center & Hospital Outpatient

CPT Code	Description
20680	Removal of implant; deep

Optional, Quick, Simple, Generator Removal May Be Performed in an ASC

After 6 months, the generator may be optionally removed, leaving the cathode(s) embedded in the bone. The quick and simple removal is perfect for an Ambulatory Surgery Center (ASC) setting.

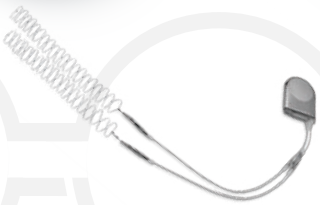
The largest portfolio of clinically proven bone growth stimulation solutions.

Biomet® SpinalPak®
Non-invasive Spine
Fusion Stimulator System

Biomet® OrthoPak®
Non-invasive Bone
Growth Stimulator System

Biomet® EBI®
Bone Healing System

EBI® OsteoGen™
Surgically Implanted
Bone Growth Stimulators



SpF®
Implantable Spinal
Fusion Stimulators

References

1. 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.
2. Paterson DC, Lewis GN, Cass CA. Treatment of delayed union and nonunion with an implanted direct current stimulator. Clin Orthop Relat Res. 1980 (148) may:117-128.
3. PJ Cundy, FRACS, DC Paterson, MD, FRCS, FRACS. A Ten-year Review of Treatment of Delayed Union and Nonunion With an Implanted Bone Growth Stimulator.

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

+The original DC clinical study which led to PMA approval yielded an overall success rate of 78% SS&ED.

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Complete prescribing information including full indications, contraindications, warnings and precautions associated with the use of these devices may be found online at highridgemedical.com or by calling 800-526-2579. The SpinalPak is a non-invasive spine fusion stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. No known contraindications. Rx Only. Single Patient Use Only. Do Not Reuse. The OrthoPak is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. Contraindicated if the individual has synovial pseudarthrosis. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. The Bone Healing System is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. Contraindicated for nonunion fractures in which a synovial pseudarthrosis exists. Electromagnetic stimulation is not recommended for patients with implantable pacemakers, defibrillators or pregnant patients. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. OsteoGen stimulators are indicated in the treatment of long bone nonunions. No known contraindications. Not recommended with the following conditions: pathological fractures due to malignant tumors or active osteomyelitis. Federal Law (U.S.A.) restricts these devices to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. SpF stimulators are indicated as a lumbar spinal fusion adjunct to increase the probability of fusion success in one or two levels or three or more levels. Do not use with defibrillators. If the stimulators are used in conjunction with metal internal fixation devices, no metallic part of the stimulator should be allowed to come into contact with the fixation device; this includes minimally invasive surgical-MIS procedures. Any surgical implantation procedure such as minimally invasive surgical-MIS procedures requiring the SpF's cathodes to be disconnected from their corresponding leads prior to or during implantation. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Rx Only. Single Patient Use Only. Do Not Reuse. This material is intended for health care professionals. Distribution to any other recipient is prohibited.