Healthcare Professionals

Biomet® OrthoPak®

Non-invasive Bone Growth Stimulator System

Powered by Capacitive Coupling Technology

What is the OrthoPak® stimulator?

The Biomet® OrthoPak® Non-invasive Bone Growth Stimulator is a class III, FDA approved, non-invasive bone growth stimulation device designed as an adjunctive therapy to aid in the healing of established nonunions.

Features & Benefits

- The small, non-invasive, intuitive device encourages patients to treat compliantly on the go while improving their healing outcomes.
- The lightweight, flexible, Soft-Touch® electrodes weigh less than an ounce, minimizing unwanted weight around the treatment site.
- The flexible placement of the Soft-Touch® electrodes optimizes precise stimulation, penetrating evenly across the targeted treatment area.
- The Soft-Touch® electrodes may be comfortably and discreetly worn under clothing or a brace.
- The OrthoPak® stimulator is backed by statistically significant pre-clinical, scientific research and clinical evidence which demonstrated improved clinical outcomes.

Specifications

- Technology: Capacitive Coupling (CC)
- Signal: 60kHz sinusoidal wave
- Delivery Method: Soft-Touch® electrodes
- Device Weight: 3.15 oz.
- Original FDA Approval Date: 1986

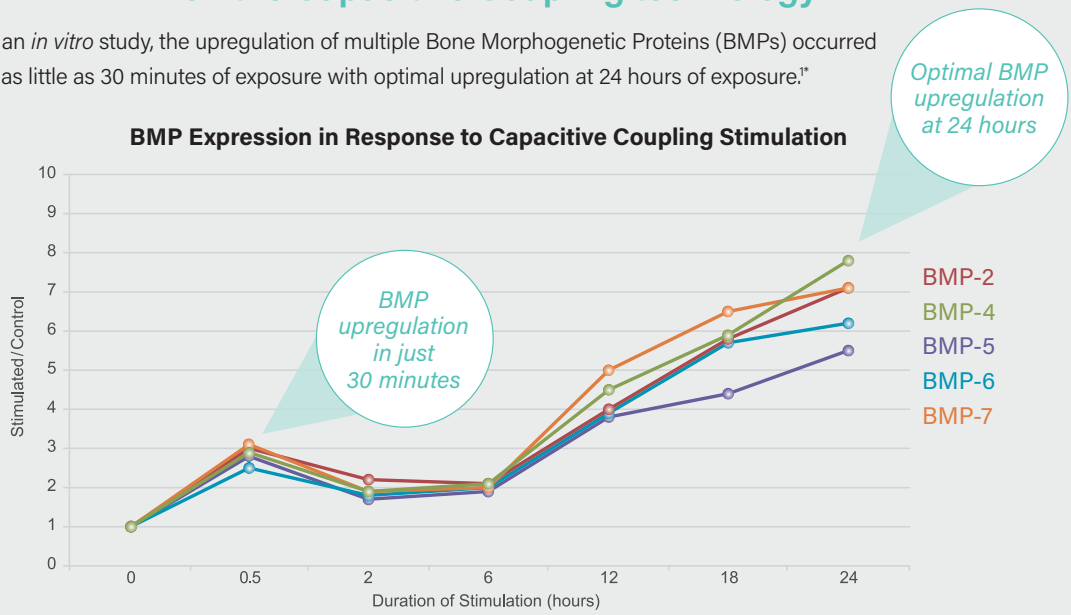
How does the OrthoPak® stimulator work?

The OrthoPak® stimulator is the original, first-in-class, nonsurgical bone growth stimulation device that utilizes Capacitive Coupled (CC) electrical stimulation technology to improve fracture nonunion outcomes.

The Soft-Touch® hydrogel electrodes are placed on each side of the treatment site; 180 degrees apart from one another. The OrthoPak® device sends low-level electrical impulses to the site through a pair of electrodes creating a favorable environment for bone regeneration.

What type of pre-clinical data has been published on the Capacitive Coupling technology?

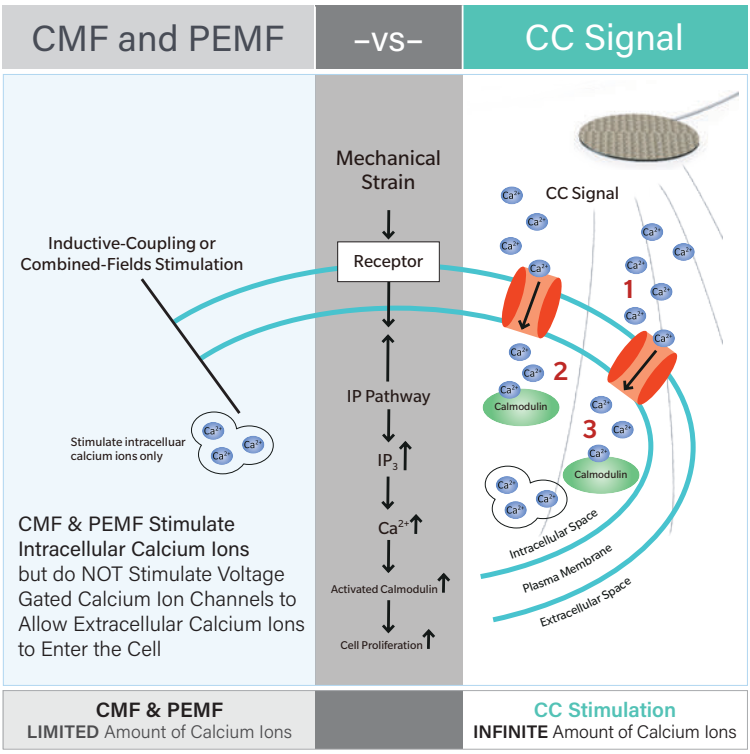
In an *in vitro* study, the upregulation of multiple Bone Morphogenetic Proteins (BMPs) occurred in as little as 30 minutes of exposure with optimal upregulation at 24 hours of exposure.[1*]



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.[1*]

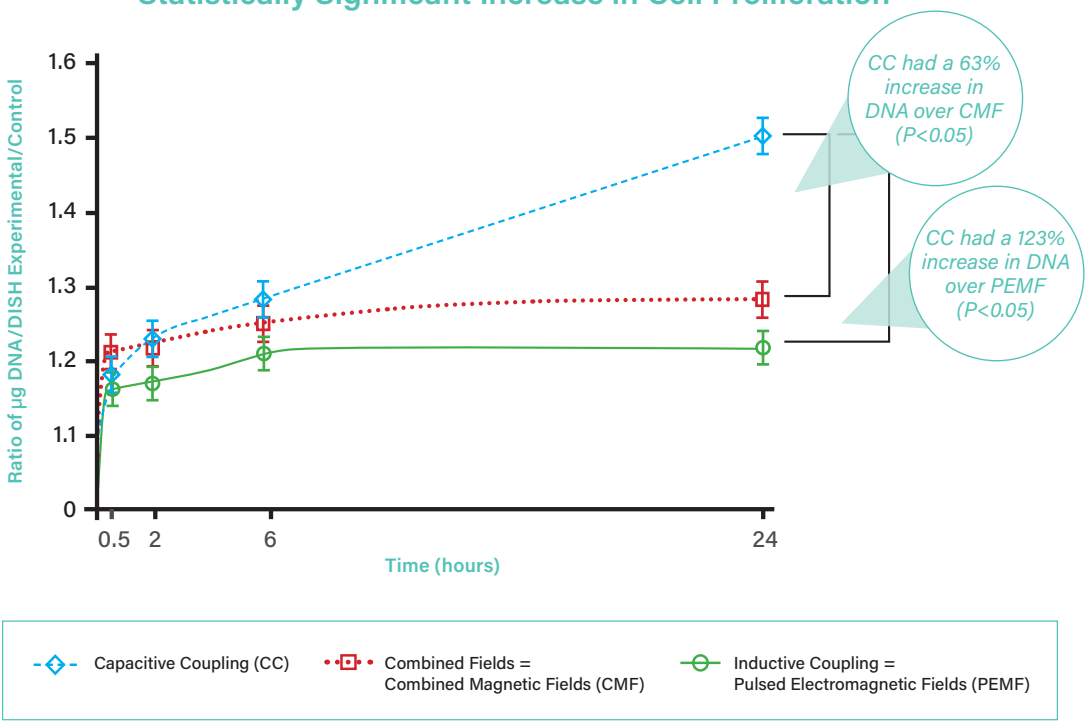
How is Capacitive Coupling (CC) different than other electrical stimulation technologies?

Another pre-clinical study demonstrated the difference between electrical stimulation technologies and how they work at a molecular level.



Capacitive Coupled technology was shown to stimulate an infinite amount of calcium ions by stimulating both intracellular and extracellular stores of calcium which leads to increased cell proliferation and ultimately more bone growth.[2]*

Statistically Significant Increase in Cell Proliferation



What human clinical outcomes are there to support the use of the OrthoPak® stimulator?

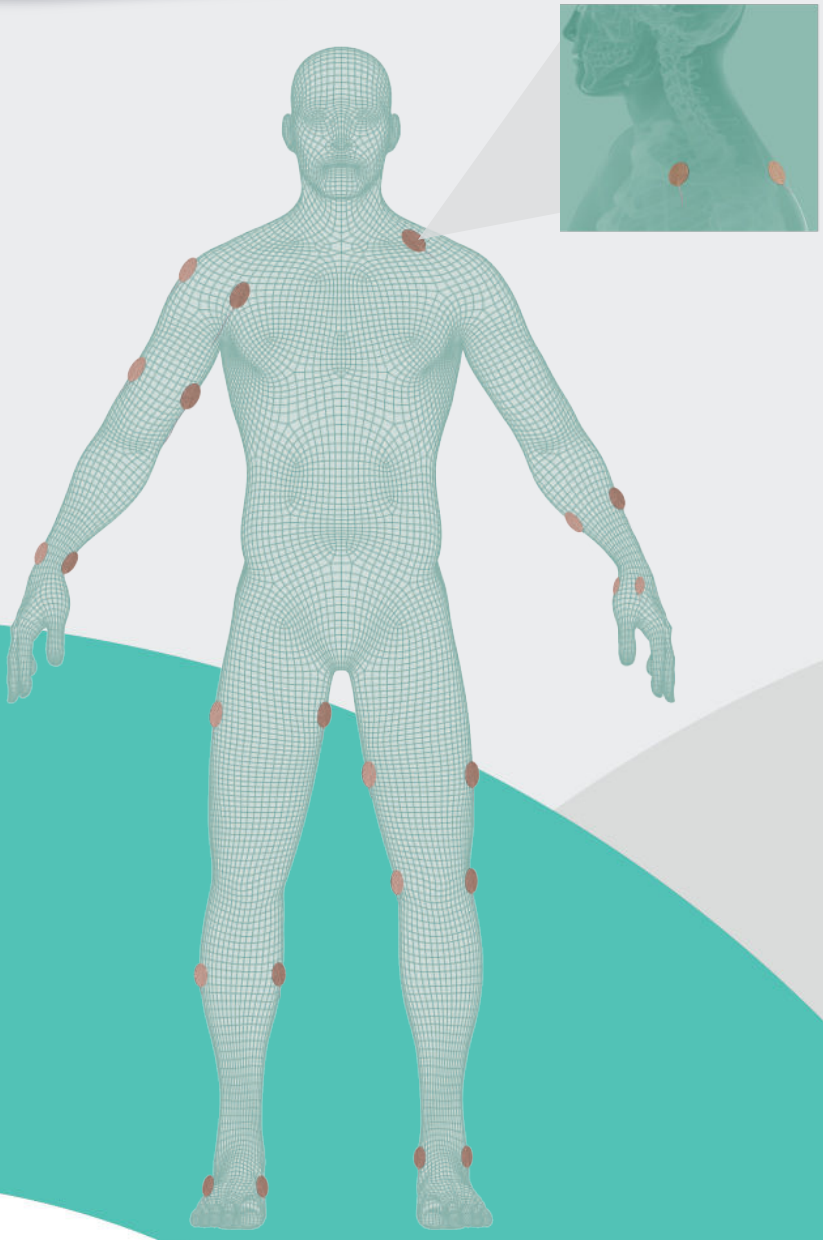
The OrthoPak® stimulator is supported by statistically significant level 1 clinical results.

Success Rates as high as

77%[3]

Statistically Significant Improvement in Healing Outcomes

60% Improvement[4]



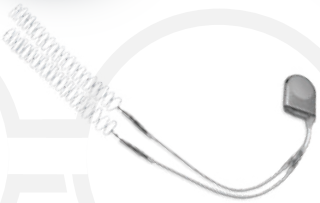
The largest portfolio of clinically proven bone growth stimulation solutions.

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

EBI, LLC
1 Gatehall Drive, Suite 303
Parsippany, NJ 07054
800-526-2579

Legal Manufacturer
EBI Patient Care, Inc.
484 Calle E
Guaynabo, PR 00969 USA

References

1. Wang Z, Clark CC, Brighton CT. Up-regulation of bone morphogenetic proteins in cultured murine bone cells with use of specific electric fields. J Bone Joint Surg Am. 2006;88(5):1053-1065.
2. Brighton CT, Wang W, Seldes R, Zhang G, Pollack SR. Signal transduction in electrically stimulated bone cells. J Bone Joint Surg Am. 2001;83-A(10):1514 1523.
3. Brighton CT, Pollack SR. Treatment of recalcitrant non-union with a capacitively coupled electrical field. A preliminary report. J Bone Joint Surg Am. 1985;67(4):577-585.
4. Scott, G. and King JB. A prospective double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. J Bone Joint Surg Am 1994; 76-A(6):820-26. The original PMA approval was based upon a clinical study efficacy of 72.5%.

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

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 PEMF stimulation is contraindicated for use by patients with implantable pacemakers or defibrillators. The Bone Healing System is not MR safe. 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.