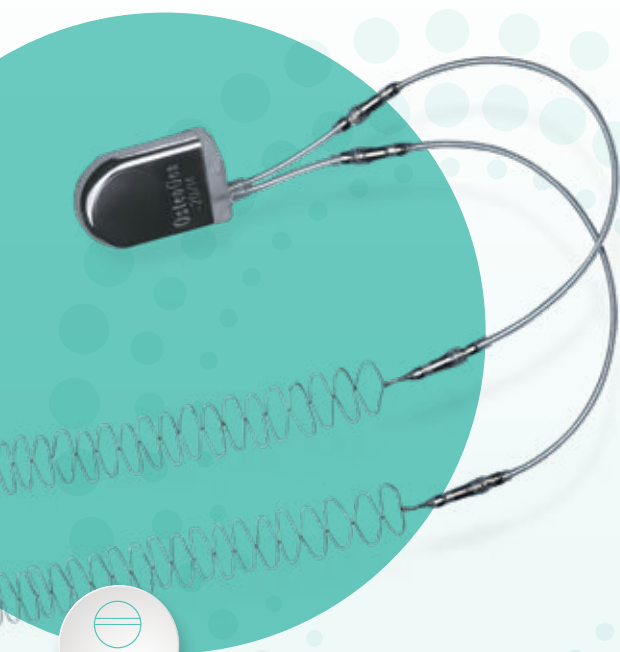




EBi[®] OsteoGen[™]

Surgically Implanted
Bone Growth Stimulator




Powered by
Direct Current
Technology

Frequently Asked Questions

FAQs

ABOUT

Why are bone growth stimulators prescribed?

Physicians may prescribe an implantable bone growth stimulator to aid in the bone healing process. OsteoGen™ Implantable Bone Growth Stimulators are FDA approved, clinically proven, safe, and effective devices that have been helping people heal for over 40 years.

What is an OsteoGen™ Implantable Bone Growth Stimulator?

An OsteoGen™ stimulator is a small, battery-powered, direct current electrical stimulation device implanted near the treatment site during a scheduled procedure. It provides constant, around-the-clock stimulation to promote bone growth that increases the chance of achieving a successful outcome.



How does the OsteoGen™ stimulator work?

The device's uniquely designed cathode(s) are placed in or around the treatment site with the generator implanted away from the cathode(s) during surgery. The area between and around the cathodes safely and effectively stimulate the body's natural healing mechanisms to promote bone growth.

USE

How can patients confirm the device is working?

Prior to implanting the device, the surgeon completes a pre-operative testing procedure to ensure the device is operational. Once implanted, the device is automatically activated and works continuously for 24 weeks (approximately 6 months).

How long are the OsteoGen™ stimulators intended to be worn?

The OsteoGen™ stimulators provide around-the-clock treatment for 24 weeks (approximately 6 months). After 24 weeks, the direct current electrical stimulation technology is automatically deactivated.

Will the OsteoGen™ stimulator affect a patient's daily activities?

There are no special activity restrictions for patients implanted with the OsteoGen™ stimulator; however, during recovery from surgery, the patient's activities may be limited based upon their surgeon's recommendations.

Does the OsteoGen™ stimulator need to be recharged?

No. The OsteoGen™ stimulator is a completely self-contained implantable device that lasts for the entire treatment period. It is designed to function for the duration of treatment and will not require recharging.

How can patients check their healing progress?

The prescribing surgeon will monitor the healing progress of the patient through x-rays or other imaging techniques. While the patient may not feel the stimulator actively treating, patients are encouraged to follow-up with their prescribing surgeon to view their progress.

CARE

Is it safe to travel through airport security with the OsteoGen™ stimulator implanted?

OsteoGen™ stimulators are designed to be safe for use with most airport security systems. However, it is important to inform and share an identification travel card with the Transportation Security Administration (TSA) personnel that the patient has an implantable device. The identification travel card is located inside the product packaging.

What happens to the device when treatment is complete?

After treatment completion, the device's electrical stimulation automatically deactivates. The generator may be optionally removed at any time after treatment is complete. If removal is desired, a simple and quick explantation is performed as an outpatient procedure utilizing a local anesthetic. An outpatient procedure is a surgery that takes place in one day and does not require an overnight stay. A local anesthetic is a drug that numbs a specific part of the body to prevent pain. It lasts a short period of time to allow patients to leave the same day after the removal.

Can patients receive a MRI scan with the stimulator implanted?

OsteoGen™ stimulators have not been studied in combination with Magnetic Resonance (MR) imaging and thus are not considered MR Safe. They are not intended to be scanned under any MR conditions while implanted.

Who do patients call with additional product questions or concerns?

Patients may call the EBI® Customer Care team at 800-526.2579.

MODELS

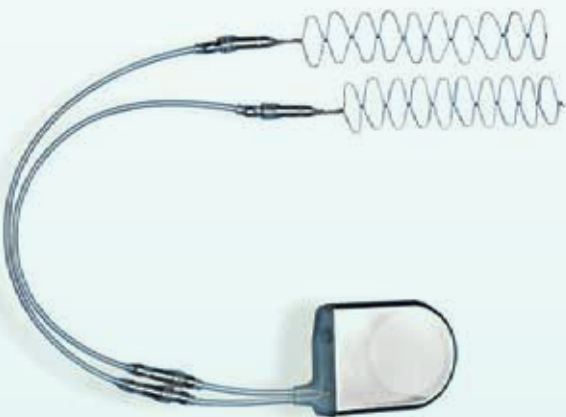
Are there different types of OsteoGen™ stimulators?

Yes. There are two available OsteoGen™ stimulator models which may be implanted based upon the type of nonunion and treatment location.

OsteoGen™ 20M: Single-lead, mesh cathode.



OsteoGen™ 40M: Dual-lead, mesh cathode



LEADING THE INDUSTRY IN BONE GROWTH STIMULATION

As the pioneer of bone growth stimulation, EBI has been leading the industry for almost half a century with the largest portfolio of clinically proven solutions and is dedicated to advancing their mission of helping people heal to restore their daily life.

EBI, LLC

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Legal Manufacturer

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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. All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Highridge Medical or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Highridge Medical. 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. HM0426 REV A 01/25. ©2025 EBI, LLC. All rights reserved.