Physician Manual

EBI® OsteoGen™

Bone Growth Stimulator

ZimVie

EBI BONE GROWTH STIMULATION

EBI® OsteoGen™
Bone Growth Stimulator


Symbol for “Do Not Reuse”

Symbol for “Sterilization using EtO”


Symbol for “See Instructions for Use”


Symbol for “Use by Date”


Symbol for “Date of Manufacture”

Symbol for “Batch Code”


Symbol for “Storage Temperature”

ZimVie

English

PHYSICIAN MANUAL

The purpose of this manual is to describe the principal characteristics of the EBI® OsteoGen Bone Growth Stimulator and describe methods for its use.

Attention is drawn to the section concerned with Implant Registration and the Conditions of Sale. All personnel responsible for the implantation of the Stimulator and for post-operative care should be familiar with these details.

The data herein may not agree in detail with previous catalog descriptions, illustrations and technical specifications as products are subject to modification, revision and improvement.

In the case of questions regarding the most current data publication, please contact your local sales representative, or call customer service at 1-800-526-2579.

TERMINOLOGY

"Generator" means the part of the Bone Growth Stimulator that produces a constant electrical current and includes the power source circuit.
"Lead" refers to the electrically conductive element that is insulated and connects to a cathode.
"Anode" refers to the electrically conductive platinum coated area of the generator case.
"Cathode" refers to the electrically conductive element which interfaces with body tissue.
"Bone Stimulator" refers to the entire device including the generator and attached lead.

LIST OF CONTENTS

The OsteoGen package contains:

EtO Gas Sterilized:

- Stimulator with pre-assembled cathode (straight or mesh)
- Mandrel for forming helix and gauging helix size
- Gauge for selection of helix size
- Sterilometer

Non-Sterile:

- Physician Manual and Full Prescribing Information
- Implant Registration Label
- Utility Label

Note: Models for OsteoGen- 20/M, OsteoGen- 40/M, OsteoGen- 20/ML, OsteoGen- 40/ML, DO NOT INCLUDE A GUAGE/MANDREL.

DESCRIPTION

OsteoGen- 20/S, OsteoGen- 20/M, OsteoGen- 20/F Bone Growth Stimulator is a solid state, constant current generator, producing a constant direct current of 20 microamperes. The Stimulator is powered by one lithium battery with a single or dual lead cathode configuration designed for use in long bone nonunions.

The electronics and power source are hermetically sealed within a medical grade titanium case, part of which is coated in platinum and acts as an anode (surface area approximately 200mm^2). The straight cathode consists of 25 cm of three-strand titanium wire terminating at one end with a titanium connector socket (OsteoGen- 20/S and OsteoGen- 20/SL), or permanently connected with a titanium crimp (OsteoGen- 20/F). The Mesh Cathode consists of two strands of titanium wire woven into a flexible grid with a nominal dimension of 1cm x 8cm, terminating at one end with a titanium connector socket (OsteoGen- 20/M and OsteoGen- 20/ML). The single lead configuration (for use in single nonunion sites) consists of 15 cm or 30 cm of drawn brazed stranded stainless steel/silver wire, insulated with silicone and terminating with a titanium connector pin.

The OsteoGen- 40/S, OsteoGen- 40/M, OsteoGen- 40/SL, and OsteoGen- 40/ML are solid state, constant current generators, producing a constant direct current of 40 microamperes which is divided between two leads of 20 microamperes each and powered by one lithium battery. The electronics and power course are hermetically sealed within a medical grade titanium case. An area on the generator of approximately 400mm^2 is platinum coated and functions as the anode. The dual lead configuration (for use in multiple nonunion sites) consists of 15cm or 30cm of drawn brazed stranded stainless steel/silver wire, insulated with silicone and terminating at each end with a titanium connector pin. The dual straight cathodes consist of 25 cm of three stranded titanium wire, terminating at each end with a titanium connector socket. The Mesh Cathodes consists of two strands of titanium wire woven into a flexible grid with nominal dimensions of 1cm x 8cm. The dual leads terminating at each end in a titanium connector socket, are connected to the generator.

INDICATIONS AND USAGE

The OsteoGen is indicated in the treatment of long bone nonunions. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing. The original 1980 PMA included two clinical studies; neither was designed for long-term follow-up. In the first study (N=30) the patients were followed for a minimum of ten (10) years, with an overall follow-up rate of 48.2%. The long-term success rate was 66.7%. This calculation excludes the initial treatment successes not followed for ten (10) years (N=11). The second study (N=107) followed the patients for a minimum of four (4) years with an overall follow-up rate of 25.6%. The long-term success rate was 38.8%. This calculation excludes initial treatment successes not followed for four (4) years (N=58). In both studies, patients had difficult nonunion fractures: 0.7 and 1.5 number of average prior surgeries, average 28.4 and 24.3 months (median 26 and 16) disability since original injury, and 43.3% and 24.3% infected prior to treatment, respectively.

OsteoGen- 40/S, OsteoGen- 40/M, OsteoGen- 40/SL, and OsteoGen- 40/ML
These devices are only to be used to treat multiple nonunions or in a severely comminuted nonunion where a single cathode cannot span the entire breadth of the nonunion site. The OsteoGen- 40/S, OsteoGen- 40/M, OsteoGen- 40/SL, and OsteoGen- 40/ML must be used with both leads in place, each delivering 20 microamperes per lead.

CONTRAINDICATIONS

There are no known contraindications to the use of this device, however, due to insufficient clinical experience, it is not recommended that it be used in the following conditions: pathological fractures due to malignant tumors or in the presence of active osteomyelitis.

WARNINGS

Long-Term Biocompatibility:
While titanium has a clinical history of nearly thirty years of use, longer term effects of implantation in humans are unknown. Titanium does not contain nickel, chromium or cobalt, which have been known to provoke a hypersensitivity response in some patients. "Attempts to produce toxicity in experimental animals have usually failed and the fact that titanium has been used in cosmetic preparations and treatment of skin disorders testifies to its relative innocuousness."[1]

Direct Current in Vivo:
Animal Studies (in the rat) using capacitively coupled alternating current techniques have shown evidence of excessive bone formation.[2] The significance of these observations in humans is not known. Routine clinical observation extending over a twelve-year period in a limited number of patients treated with OsteoGen has not shown any evidence of excessive bone formation.

Pediatric Nonunions:
The safety and effectiveness of using this device in the pediatric population has not been determined. There has not been any lengthening of the leg bones observed using the OsteoGen device. Physicians are advised, however, to monitor these possible effects when using the OsteoGen device and the epiphysis is within the treatment area.

PRECAUTIONS

Electrosurgery:
Electrosurgical instruments are capable of producing radio frequency voltages of such magnitude that direct coupling can occur between the cautery tip and lead system of the generator. To preclude the possibility of damage to the generator electronics, electrosurgical equipment should not be used on the patient in the immediate vicinity of the implanted stimulator. If electrosurgery must be done after implantation of the device, leave the electrode/cathode in place so it remains connected and remove the generator, placing it outside of the body with a gloved hand. Only when electrosurgery is completed, place the generator back subcutaneously into the soft tissue.

Diathermy (Microwave, Shortwave or Ultrasonic):
Therapeutic diathermy should not be used in the treatment of a patient who has an OsteoGen implanted, since this equipment can also produce voltages which may cause damage to the electronics. Diathermy must never be applied over the site of any bone growth stimulator since high currents induced in the electrode lead can cause burning of the tissues in contact with the cathode (electrode tip).

Handling:
The energy source and electronics of the generator are heavily protected within the titanium case and will be unaffected by normal handling. However, the possibility of damage by mechanical shock, such as a drop onto a hard floor, cannot be precluded. Any unit subjected to this type of accident should not be implanted. Out of service units should be disposed of by industrial garbage disposal. Do not dispose of any unit in an open fire.

Use With Internal/External Fixation:
When the Stimulator is used in conjunction with metal internal/external fixation devices, caution must be taken to prevent contact with the cathode and the metallic implant. If the cathode comes into contact with the metallic implant, a current dissipation could occur. This reduction of current density could affect the level of OsteoGen normally expected. Secondly, if the anode was to come into contact with the metal implant, possible corrosion could occur at the site of contact.

Use of a Second Stimulator:
Two or more treatments have been required in up to 3% of the patients reported in the clinical trials. That is, a complete union may not be achieved with the first Stimulator, necessitating the implantation of a second unit.

MRI:
The safety and effectiveness of the Stimulator during MRI procedures has not been established. MR imaging at close proximity to implanted devices may be associated with tissue heating, nerve stimulation or movement. **Warning:** The MR image of the area close to the generator may be distorted.

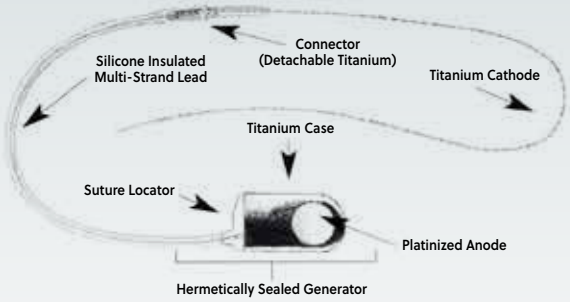
ADVERSE EFFECTS

At this date there are no known adverse effects.

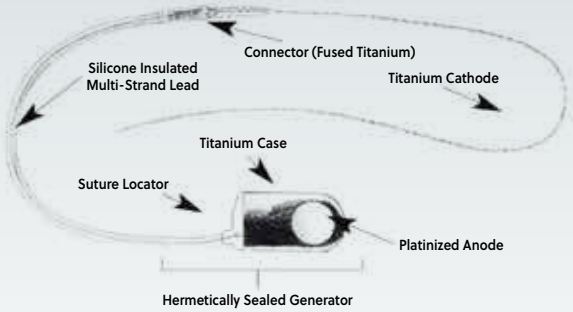
TYPICAL CHARACTERISTICS

Case Material: Medical grade pure titanium.

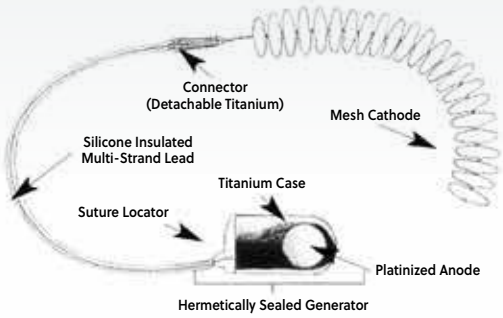
OsteoGen-20/S



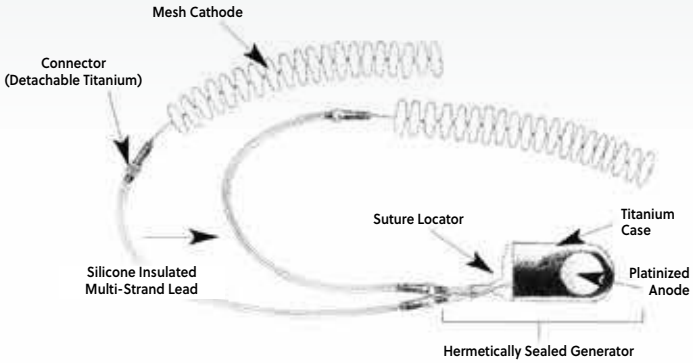
OsteoGen-20/F



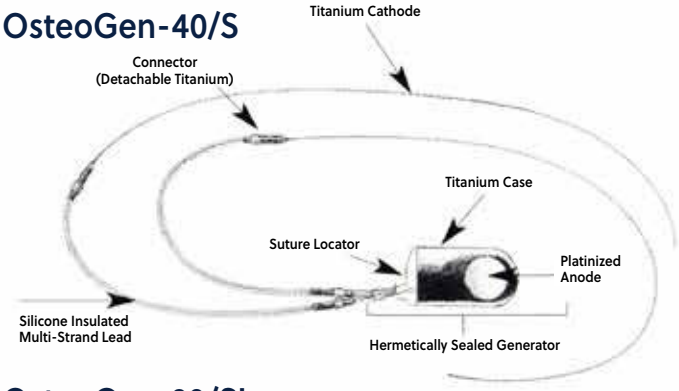
OsteoGen-20/M



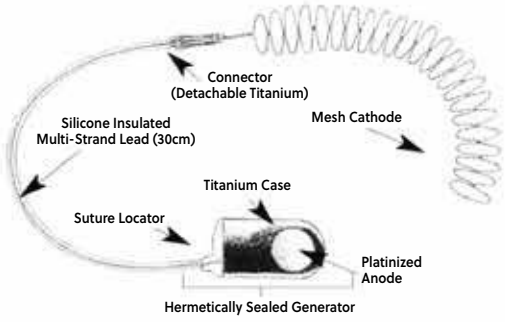
OsteoGen-40/M



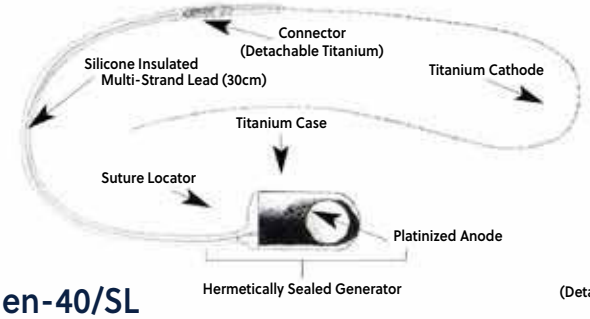
OsteoGen-40/S



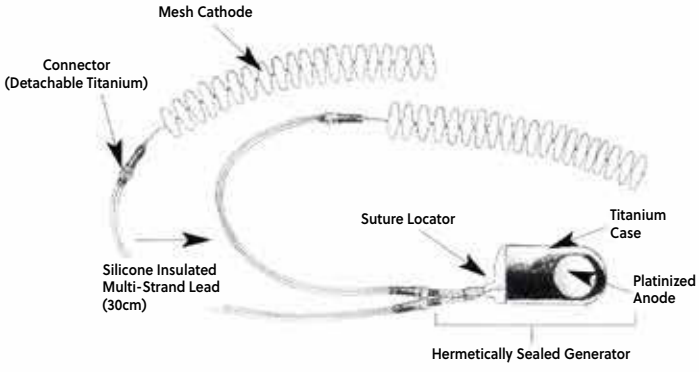
OsteoGen-20/ML



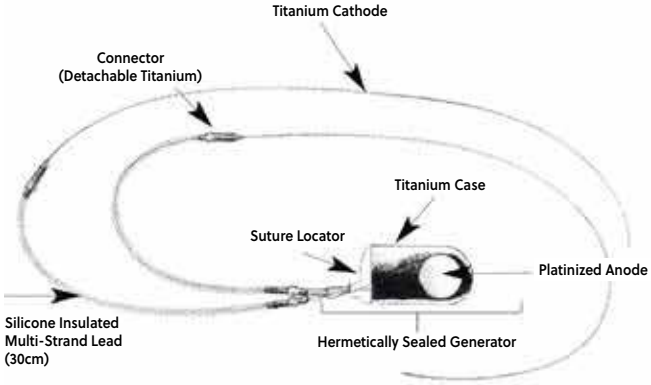
OsteoGen-20/SL



OsteoGen-40/ML



OsteoGen-40/SL



Power Source: One lithium battery with a rated capacity of 208 mAh minimum.

Electronics: OsteoGen-20/S, OsteoGen-20/F, OsteoGen-20/M, OsteoGen-20/SL and OsteoGen-20/ML have a solid-state circuitry maintaining cathode current at a constant 20 (+/-2) microamperes regardless of changes in bone/tissue resistance over a range of 0-100,000 Ohms. OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML have solid state circuitry maintaining cathode current at a constant 40 (+/-2) microamperes divided between two leads, which must be used to deliver 20 microamperes each, regardless of changes in bone/tissue resistance over a range of 0-40,000 Ohms.

Hermeticity: To eliminate the possibility of fluid ingress-egress, the capsule is hermetically sealed and tested for leakage using a method adapted from MIL STD 883A method 1014.1.

Anode: Circular area on one side of case platinized for anodic function, surface area approximately 200 mm^2 for OsteoGen-20/S, OsteoGen-20/M, OsteoGen-20/F OsteoGen-20/SL, OsteoGen-40/SL and OsteoGen-20/ML and two sides of case for a total of approximately 400 mm^2 for OsteoGen-40/S, OsteoGen-40/M and OsteoGen-40/ML.

Lead Configurations and Cathodes

OsteoGen-20/S
Lead
- Single lead
- 15cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Single, detachable cathode
- Straight configuration
- 25cm in length
- Consists of three-strand titanium wire terminating at one end in a titanium connector socket

OsteoGen-20/M
Lead
- Single lead
- 15cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Single, detachable cathode
- Mesh configuration
- 1 x 8cm in length
- Consists of two strands of titanium wire terminating at one end in a titanium connector socket

OsteoGen-20/F
Lead
- Single lead
- 15cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and is permanently connected with a titanium crimp

Cathode
- Single, fused cathode
- Straight configuration
- 25cm in length
- Consists of three-strand titanium wire permanently connected with a titanium crimp

OsteoGen-40/S
Lead
- Dual lead, detachable at the generator
- 15cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Dual, detachable at the generator and cathodes
- Straight configuration
- 25cm in length
- Consists of three-strand titanium wire terminating at one end in a titanium connector socket

OsteoGen-40/M
Lead
- Dual lead, detachable at the generator
- 15cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Dual, detachable at the generator and cathodes
- Mesh configuration
- 1 x 8cm in length
- Consists of two strands of titanium wire terminating at one end in a titanium connector socket

OsteoGen-20/SL
Lead
- Single lead
- 30cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Single, detachable cathode
- Straight configuration
- 25cm in length
- Consists of three-strand titanium wire terminating at one end in a titanium connector socket

OsteoGen-20/ML
Lead
- Single lead
- 30cm in length
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Single, detachable cathode
- Straight configuration
- 1 x 8cm in length
- Consists of two strands of titanium wire terminating at one end in a titanium connector socket

OsteoGen-40/ML
Lead
- Dual lead, detachable at the generator
- 30cm in length total
- Single 15cm lead splits into two single leads ('Y' shape) for an additional 15cm each
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Dual, detachable at the generator and cathodes
- Mesh configuration
- 1 x 8cm in length
- Consists of two strands of titanium wire terminating at one end in a titanium connector socket

OsteoGen-40/SL
Lead
- Dual lead, detachable at the generator
- 30cm in length total
- Single 15cm lead splits into two single leads ('Y' shape) for an additional 15cm each
- Consists of drawn, brazed-stranded stainless steel/silver wire that is insulated with silicone and terminates with a titanium connector pin

Cathode
- Dual, detachable at the generator and cathodes
- Straight configuration
- 25cm in length
- Consists of three-strand titanium wire terminating at one end in a titanium connector socket

Identification: Each unit has the model and serial number engraved on the case.

Weight: OsteoGen-20/S, OsteoGen-20/F, OsteoGen-20/M OsteoGen-20/SL, OsteoGen-20/ML, OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML are 7 grams for generator only - no leads or cathode.

Dimensions: 36 mm x 23 mm x 5 mm. Generator only.

Operating Period (Implant Life): Provided the OsteoGen is implanted prior to the "Use Before" date, it should deliver its full rated current for approximately 24 weeks.

SAFETY
The output parameters and electrical function of the Stimulator are unaffected by commonly occurring electrical interference and magnetic fields. Safety is further insured by the use of biocompatible materials with a clinical history of safety when used in human implants. Model designation and serial number are engraved into the case for ease of identification and traceability.

STORAGE
The generator should be stored at temperatures between 5°and 25°C (40° and 77°F)

SHELF LIFE
A "Use Before" date is located on the outer box (end label) and on the sterile pack label in the inner package. All OsteoGen have a 24-month battery shelf life.

STERILIZATION
The OsteoGen is supplied EtO gas sterilized. The sterilization data appears on the sterile inner pack. A color indicator, visible in the inner package, indicates exposure to ethylene oxide gas. The tray assembly should be carefully inspected to be sure that the seal has not been broken. Resterilization, if necessary, should be carried out using normal ethylene oxide procedures, but not in excess of 50°C. After resterilization, allow 72 hours for aeration in a warm (37°C) ventilated environment.

Caution: Do not resterilize by autoclave, liquid solutions, gamma or ultraviolet radiation; and do not clean by ultrasonic cleaners.

OPENING INSTRUCTIONS
Only the contents of the inner tray are sterile. When introducing the sterile contents of the inner tray into a sterile field, grasp the "Peel Back" tab and slowly pull back to expose the sterilized contents.

IMPLANT REGISTRATION FORM
In accordance with international practice and regulatory legislation in some countries, a registration form is provided with each OsteoGen. The registration form, with duplicates, is packed with this manual. The purpose of this form is to maintain traceability of all units. It allows a center involved in the evaluation of a specific implanted stimulator to quickly gain access to pertinent data from the manufacturer. It is the responsibility of the implanting center to return the completed Registration Form to the manufacturer at the address shown on the form within thirty days of implantation. The duplicate copies are for the patient's chart and physician's files.

PRINCIPLES OF OPERATION
The OsteoGen is a constant direct current generator intended for use as an adjunct in healing fractures of long bones. The unit is designed for total implantation for a period of approximately 24 weeks. The energy source consists of one lithium cell. The electronic circuitry acts as a self-adjusting variable resistance between the energy source and the load impedance (bone/tissue resistance) such that a constant current will flow regardless of changes in the load between the limits of 0-100,000 Ohms, 0-40,000 Ohms for the OsteoGen-40/S, OsteoGen-40/M, OsteoGen-40/SL and OsteoGen-40/ML.

PRE-IMPLANT TEST
Monitoring of current flow may be achieved by the use of the Implant Tester contained in the OsteoGen packaging prior to implantation ONLY.

PRE-OPERATIVE INSTRUCTIONS FOR TESTING THE OsteoGen
Each OsteoGen is tested for functionality before it leaves the manufacturing plant. Additionally, the device may be pre-operatively tested prior to implantation. A sterile Implant Tester is provided with each device and is contained in the inner tray/packaging of the OsteoGen. The Implant Tester will enable the user to test the device for functionality pre-operatively. Once the device has been implanted, post-operative monitoring is no longer required and can not be monitored with the ST-52 and ST72 Implant Testers.

The Implant Tester is activated ONLY when the outer packaging layer of the OsteoGen is removed. A magnet contained in the outer packaging keeps the battery disconnected from the circuitry in the generator. Once the outer packaging is removed, the OsteoGen is activated. Simply depress the Implant Tester button found on the tester and a light will turn on to signal that the unit is active/functional. If the light fails to turn on (after depressing the tester button), the unit is deemed inactive (fallen below 15 µA or risen above 25 µA for the 20 microampere devices and fallen below 35 µA or risen above 45 µA for the 40 microampere devices) and should not be used.

IMPLANTATION TECHNIQUES
Directions for Use: The Stimulator may be implanted using a variety of methods. The principle of implantation is to position as much of the cathode as possible in the area of the fracture so that the field formed is concentrated at the fracture site. Regardless of how the cathode is configured, the electrical current emanating from the cathode traverses a cylindrical area approximately 5-8 mm in radius, creating a field of influence which can be enhanced by the configuration. The cathode configuration and implantation technique ultimately chosen will be dependent upon surgical approach and the size of the area to be stimulated. The implanting surgeon should be familiar with the surgical technique, which is detailed in this manual. (Also available in "OsteoGen Surgically Implanted Bone Growth Stimulator Procedures for Surgical Use.")

Special note: Do not disconnect the cathode during the surgical procedure.

Mandrel/Depth Gauge Information

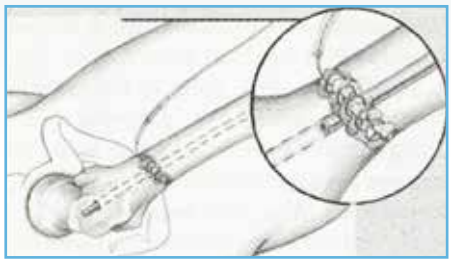
A mandrel/depth gauge is provided with the implantable stimulators for ease in shaping the straight cathode. For a long bone fracture, the depth gauge is used to measure the defect where the cathode will be placed. Using the corresponding section of the mandrel, the cathode is formed into a helix and placed into the bone defect. The mandrel is used to form a helix of the appropriate size.

Note: This is a suggested technique only.

After determining the size of the defect, prepare a helix configuration by wrapping the straight cathode around the corresponding diameter on the mandrel.

Cancellous bone graft may be used to fill in the area surrounding the straight cathode when using helix or zigzag configurations.

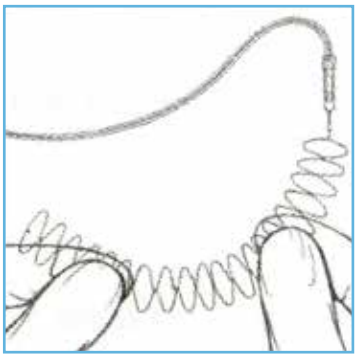
The helix configuration can be inserted directly into the nonunion site. The cathode should be placed where bone growth is desired, ensuring that the cathode is touching live bone proximally and distally.

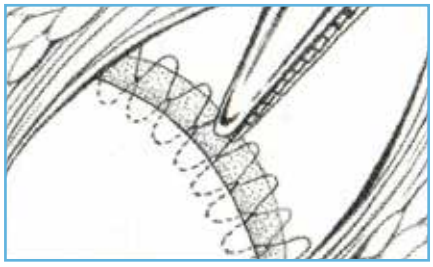


Bone Grafting may be used in conjunction with the OsteoGen stimulator.

Another method of stimulating a nonunion is to flatten a helix configuration into an appropriate zigzag (sinsoidal) shape and insert the cathode between the bone surfaces to be stimulated.

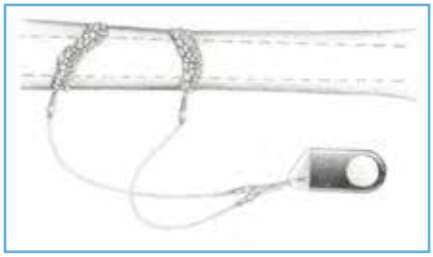
The OsteoGen devices with mesh cathode(s) comes in a preformed "mesh" configuration.





When implanting an OsteoGen with a mesh cathode it should be placed where bone growth is desired, ensuring that the cathode is touching live bone proximally and distally.

When implanting an OsteoGen with dual leads both cathodes (mesh or straight) should be placed where bone growth is desired, ensuring that the cathode is touching live bone proximally and distally.

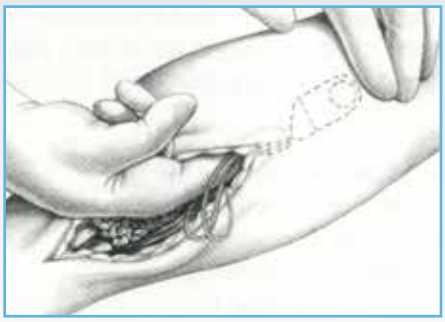


The OsteoGen devices with dual leads (40 microamperes) are only to be used to treat multiple nonunions or in a severely comminuted nonunion where a single cathode cannot span the entire breadth of the nonunion site. The OsteoGen devices with dual leads (40 microamperes) must be used with both leads in place, each delivering 20 microamperes per lead.

NOTES:
Care should be taken to prevent contact between the cathode and any other metal fixation devices which may be used (this may be accomplished with bone graft material). Such contact will increase the area of the cathode and will dissipate the current of 20 microamperes at the fracture site.

Generator Implantation:

1. The generator case should be placed in muscle or soft tissue and not against bone, with the anodic area of the case at least 8-10cm from the fracture site.
2. Position the generator for optimum patient comfort; selecting an area which is protected from external irritation or impact, and unlikely to cause component migration.
3. If generator migration is a concern, the generator can be sutured to soft tissue to maintain proper position. The suture can be placed through the indented recess on the soft silastic portion of the generator.
4. Without raising the surface contour of the skin over the generator, place the generator as close as possible to facilitate generator and lead removal subsequent to union.



EXPLANTATION TECHNIQUE

Once union has been established or the power source is exhausted (approximately 24 weeks) the generator may be removed. Explantation can be done in the office or clinic using local anesthesia. No special instrumentation is required. The pocket containing the generator should be reopened and the unit removed. Using a pair of forceps, take firm hold of the lead and pull steadily. The lead will separate from the cathode at the connector, leaving the titanium cathode enmeshed in new bone. When the OsteoGen-20/F is used, the lead wire should be held firmly and cut above the crimped connection.

For further information and advice in particular cases, contact your local sales representative or call Customer Service at 800-526-2579.

NOTES:
Do Not Re-Use

CONDITIONS OF SALE

It is an express condition of sale that the purchaser make them self and the patient aware of the following: The decision to implant a bone growth stimulator is a purely medical one determined in light of the special circumstances of each case. ZimVie takes every care in the selection of components and in all steps of manufacturing, quality control and packaging. However, due to the nature of the Stimulator itself, and the hostile environment in which it is used, the Stimulator will ultimately cease to function, due to either predictable exhaustion of the power source or random, unpredictable failure of any component, including the power source. As the prescription and implantation of a Stimulator are beyond the control of the manufacturer, ZimVie makes no claim that in certain circumstances, adverse human body reactions or medical complications will not follow the implantation of The Stimulator or any part thereof, whether or not of the manufacturer's design and manufacture, and irrespective of method of surgical implantation, or method of use.

REPLACEMENT CREDIT POLICY

In the event of a product failure due to manufacturing defect and/or failure of the product to perform according to specifications, a replacement Stimulator will be provided only when all of the following conditions are met:

1. The original unit was implanted prior to the "Use Before" date indicated on the package.
2. The completed registration form was returned to ZimVie within thirty (30) days of implantation.
3. The explanted generator is returned to ZimVie within thirty (30) days of removal from the patient, together with a written report detailing the circumstances of its removal.

RETURN GOODS POLICY

1. Customers receiving damaged product may return the product for full credit.
2. Unopened, unexpired product in the original packaging may be returned for full credit if returned 90 days prior to expiration.
3. Opened product cannot be returned for credit.
4. Outdated or expired product cannot be returned for credit.
5. Please direct returns to ZimVie, 1 Gatehall Drive, Suite 303, Parsippany, NJ 07054

Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

References

1. Leventhal, B.S., Titanium, a metal for surgery, JBJS 33A: 473-4 (1951).
2. McElhaney, J.M.H., and Stainaker, R., Electric Fields and Bone Loss of Disuse, J. Biomechanics Vol. 1, pp 47752 (1968).

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