Surgical Technique Guide

EBI® OsteoGen™

Surgically Implanted Bone Growth Stimulator

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EBI® OSTEOGEN™ STIMULATOR MODELS

OsteoGen™ 40/M (Drawing A)
Model: 10-1348M
Two Leads (each 15 cm in length)
Two Mesh Cathodes (each 1 x 8 cm in length)
Connectors - Detachable at the generator and cathodes
Generator - 40 microamps (20μA per lead and cathode)

OsteoGen™ 40/S (Drawing B)
Model: 10-1348S
Two Leads (each 15 cm in length)
Two Straight Cathodes (each 25 cm in length)
Connectors - Detachable at the generator and cathodes
Generator - 40 microamps (20μA per lead and cathode)

OsteoGen™ 20/M (Drawing C)
Model: 10-1320M
One Lead (15 cm in length)
One Mesh Cathode (1 x 8 cm in length)
Connector - Detachable at the cathode
Generator - 20 microamps (20μA to the lead & cathode)

OsteoGen™ 20/S (Drawing D)
Model: 10-1320
One Lead (15 cm in length)
One Straight Cathode (25 cm in length)
Connector - Detachable at the cathode
Generator - 20 microamps (20μA to the lead & cathode)

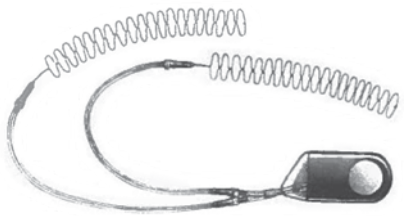
OsteoGen™ 20/F (Drawing D)
Model: 10-1318
One Lead (15 cm in length)
One Straight Cathode (25 cm in length)
Connector - Fused (Cathode is non detachable from the lead)
Generator - 20 microamps (20μA to the lead & cathode)

OsteoGen™ 20/SL (Drawing D)
Model: 10-1328S
One Lead (30 cm in length)
One Straight Cathode (25 cm in length)
Connector - Detachable at the cathode
Generator - 20 microamps (20μA to the lead & cathode)

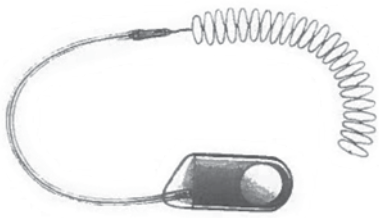
OsteoGen™ 20/ML (Drawing C)
Model: 10-1328M
One Lead (30 cm in length)
One Mesh Cathode (1 x 8 cm length)
Connector - Detachable at the cathode
Generator - 20 microamps (20μA to the lead & cathode)

OsteoGen™ 40/ML (Drawing A)
Model: 10-1322M
Dual Lead (30 cm in length)
Two Mesh Cathodes (each 1 x 8 cm in length)
Connector - Detachable at the cathodes
Generator - 40 microamps (20μA to the lead & cathode)

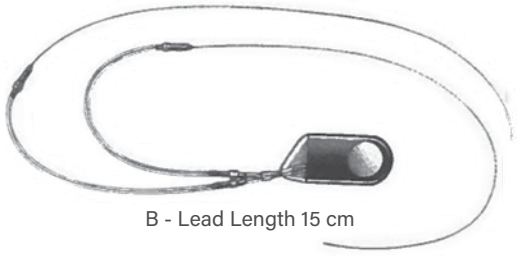
OsteoGen™ 40/SL (Drawing A)
Model: 10-1322S
Dual Lead (30 cm in length)
Two Mesh Cathodes (each 1 x 8 cm in length)
Connector - Detachable at the cathodes
Generator - 40 microamps (20μA to the lead & cathode)



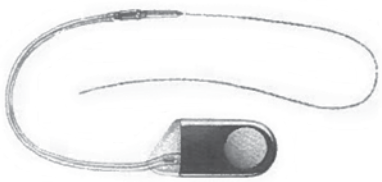
A - Lead length 15-30 cm



C - Lead length 15-30 cm



B - Lead Length 15 cm



D - Lead length 15-30 cm
Fused or Connected

INTRODUCTION

This surgical guide highlights the applications and implantation procedures for the EBI® OsteoGen™ Bone Growth Stimulators. Several applications and techniques are presented for the treatment of nonunions in long bones.

Efficacy

The effective use of direct current (DC) for the treatment of long bone nonunions is well documented in clinical studies.[1,2,3,4,*]

OsteoGen™ are useful adjuncts for treating long bone nonunions, where surgery is already planned or where patient noncompliance may be a factor with other noninvasive electrical stimulator technologies. Because the OsteoGen™ is implanted, the patient is assured of therapeutic treatment at the nonunion site.

OsteoGen™ is compatible with surgical treatments commonly used for management of transverse, segmented, and comminuted long bone nonunions of the femur, tibia, fibula, humerus, clavicle, ulna and radius. The OsteoGen™ may be used as an adjunct to internal/external fixation and can be used with autograft.

Current Density

The Mesh Cathode provides the same current density to the fusion site as the straight cathode, but with increased contact of the cathode to the graft and host bone. To accomplish this, the mesh cathode of the OsteoGen™ 20M, 20ML, 40M, & 40ML are fabricated from the same titanium filament as the triple strand titanium straight wire cathode of the OsteoGen™ 20S, 20SL, 20F, 40S, & 40SL models.

Although the dimensions of the mesh and straight cathodes appear different (1x8 cm grid vs. 25 cm straight cathode), the exposed surface area of both cathodes remain exactly the same. By maintaining the same exposed surface area between the mesh and straight cathode configuration, the same overall current density is maintained at the nonunion site with either cathode. What does change with the mesh cathode is the opportunity for contact between the cathode and the host bone graft material. The mesh cathode configuration increases the number of point to point contacts of the cathode to the nonunion site, thereby increasing the surface area available for stimulating bone union.

CATHODE CONFIGURATIONS

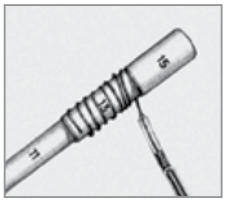
There are six cathode configurations, which are commonly utilized with OsteoGen™. Each corresponds to a different implantation technique for various long bone nonunion applications.

- Helix
- ZigZag
- Fishscale
- Straight
- L Configuration
- M Configuration

No matter which configuration is utilized, the electrical current emanating from the cathode traverses a cylindrical area approximately 5-8 mm in radius, creating a field of influence by the configuration. The cathode configuration and implementation technique ultimately chosen will be dependent upon surgical approach and the size of the area to be stimulated.

Helix Configurations

APPLICATION: Transverse, segmented, or comminuted nonunions, with or without bone graft augmentation.



There are three ways to utilize a helix configuration:

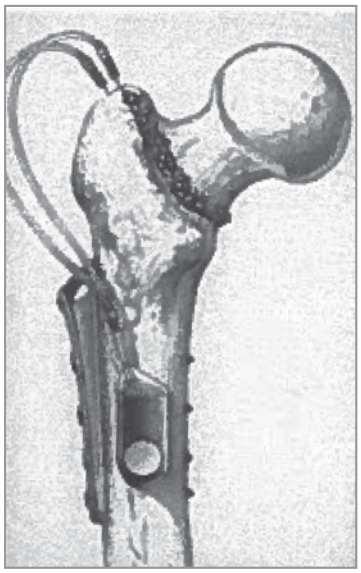
1) using a trough,

2) direct placement at nonunion site or

3) via drilled hole.

When using a trough, determine the appropriate trough depth and create the trough. Prepare a helix configuration by using the narrow end of the mandrel to ascertain the depth of the trough, then wrap the cathode around the corresponding diameter on the mandrel. If adjunctive cortical bone grafting is to be used, form a helix by wrapping the cathode around the cortical graft, which is then inserted into the trough.

The helix configuration can also be inserted lengthwise into a drilled hole or "channel" prepared to the diameter of the helix, or inserted directly into the nonunion site.



Femoral neck nonunion

Helix in drilled hole core

CATHODE CONFIGURATIONS (CONTINUED)

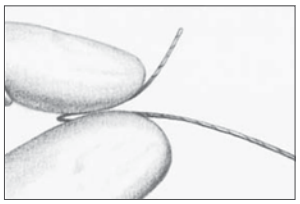
Zigzag Configuration

APPLICATION:

Compressive nonunions with parallel surfaces, with or without bone graft augmentation.

Prepare and flatten a helix configuration into an appropriate zigzag (sinusoidal) shape, and insert between the bone surfaces to be stimulated.

Straight or Fishscale into Drilled Hole Configuration



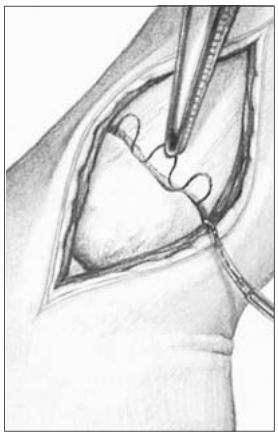
APPLICATION:

Nonunions where helix or zigzag configurations are too large or otherwise inappropriate; and for added control in preventing cathode contact with internal or external fixation.

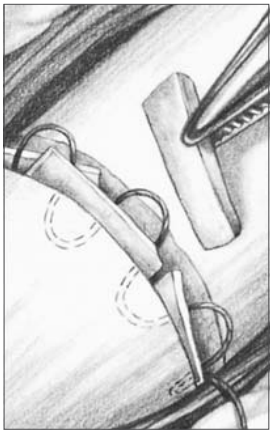
Prepare drilled holes across the nonunion site. The hole diameter must be sufficient to accommodate single cathode wire if using a single-insertion approach, or to accept slightly more than twice the cathode wire if using a "fishscale" woven approach. For maximum influence of electrical current, at least two drilled holes should be employed.

Another method of stimulating a nonunion is by placing drilled holes immediately adjacent and parallel to the surface of the nonunion. Weave the cathode wire back and forth between the drilled holes.

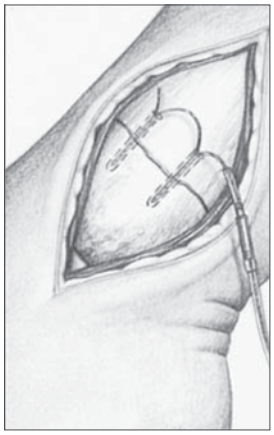
For single insertion, insert the cathode into the hole. Ensure that the connector is approximately 1 cm proximal or distal to the nonunion site. For "fishscale" insertion, create a "V" at one end of the cathode and insert into the first hole, then proceed on to the next hole. If an increased cathode contact surface area is required or desirable, as many holes can be drilled as can be accommodated by the cathode length in the procedure described.



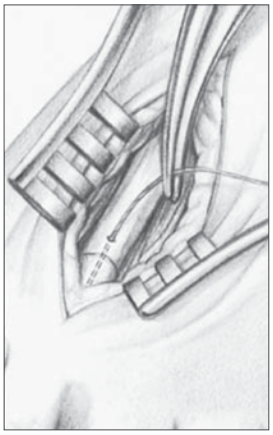
Zigzag into nonunion site



Zigzag with matchstick bone graft



Fishscale into drilled hole



Straight cathode into drilled hole

CATHODE CONFIGURATIONS (CONTINUED)

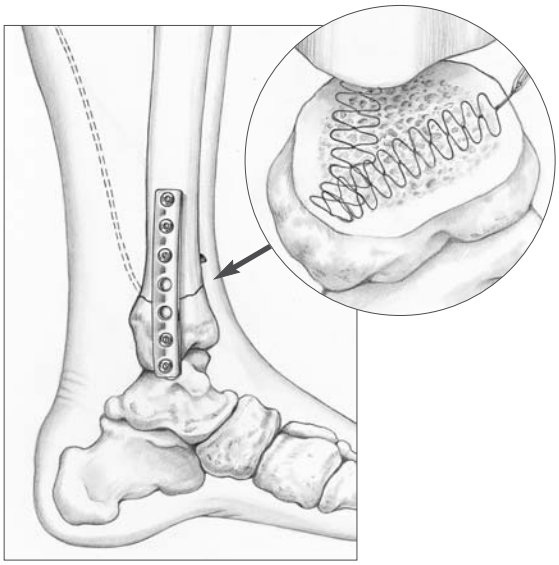
L Configuration

The L configuration is formed by bending the mesh cathode on itself at a 90-degree angle as illustrated in the diagram. This configuration allows increased surface area exposure of the cathode to the nonunion site while allowing for an area for internal fixation to cross the distal tibia nonunion site without making contact with the mesh cathode.

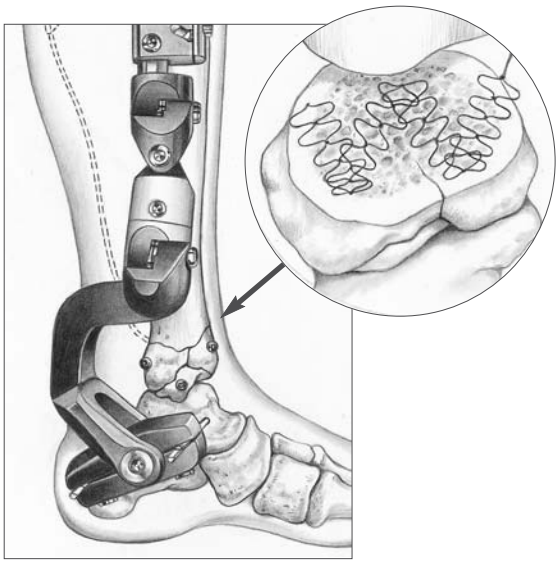
M Configuration

The M configuration is formed by bending the mesh cathode on itself multiple times at an angle of 45 degrees as illustrated in the diagram. The configuration allows maximum exposure of the cathode to the distal nonunion site.

To prevent contact between the fixation and the mesh cathode, the M configuration is best utilized when internal fixation is not planned across the nonunion site such as with plating and external fixation.



L configuration used in distal tibia nonunion with internal fixation



M configuration used in pilon fracture nonunion with external fixation

CATHODE CONFIGURATIONS (CONTINUED)

Adjunctive Bone Grafting for Cathode Configurations

Bone grafting may be used in conjunction with the OsteoGen™ stimulator. Ensure that the cathode is touching live bone proximally and distally.

Cancellous Bone Grafting

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

Cortical Bone Grafting

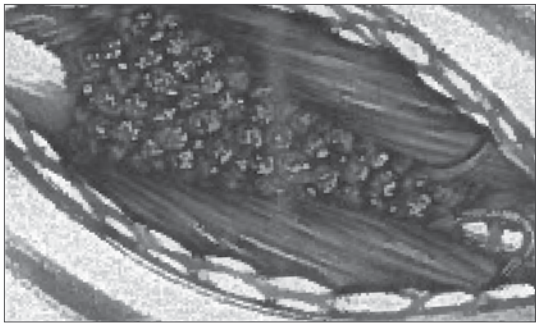
Cortical bone graft may be wrapped by the cathode in a helix configuration, and placed directly into the nonunion. Additional cancellous bone graft may be placed around the cortical graft.

Cortical "Matchstick" Grafts

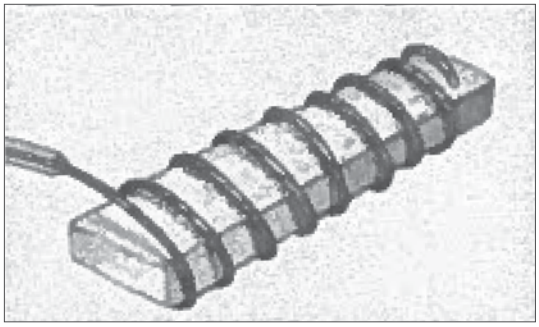
Cortical bone "matchsticks" may be used with the cathode in a zigzag configuration. Place graft material between the cathode and the surface area where new bony growth is required.

Onlay Bone Graft

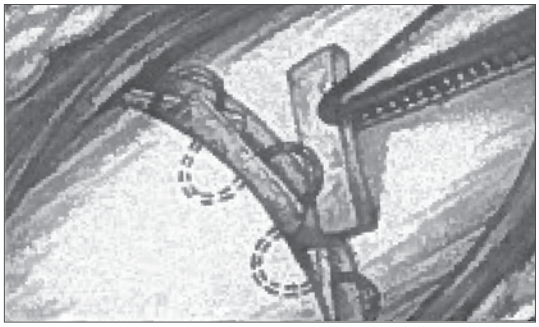
Onlay bone graft may be used with the OsteoGen™ Mesh Cathode. The Mesh Cathode is preformed 1x8 cm grid to facilitate placement of onlay bone graft.



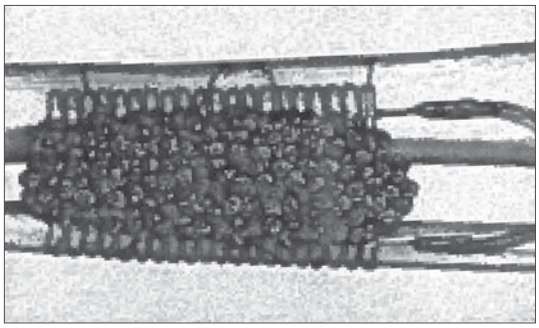
Helix with cancellous bone graft



Helix wrapped around cortical bone graft



Zigzag with matchstick bone graft



Mesh Cathode with onlay bone graft

OSTEOGEN™ STIMULATORS USE WITH BONE GRAFT AND FIXATION

Internal/External Fixation

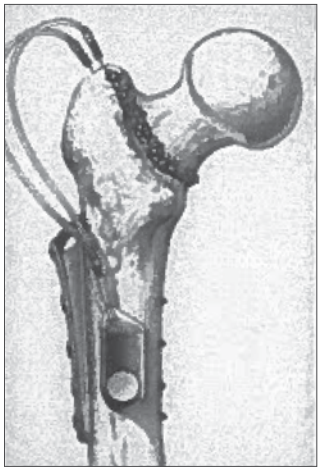
The same basic implantation procedure is utilized in the presence of both internal and external fixation.

NOTE: It is important to ensure that the OsteoGen™ does not come into physical contact with any metal or metallic fixation component, as this will impede deliverance of the therapeutic current to the nonunion site and possibly compromise clinical efficacy.

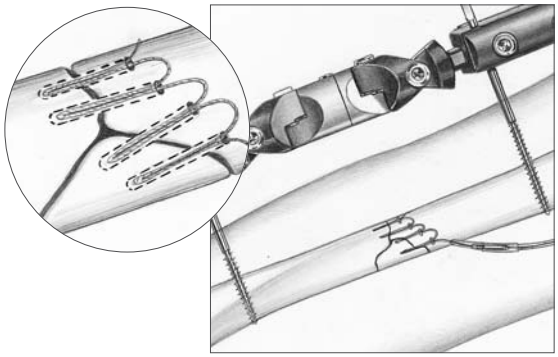
Preparation and Cathode Implantation

These procedures should be followed to ensure the performance of the OsteoGen™:

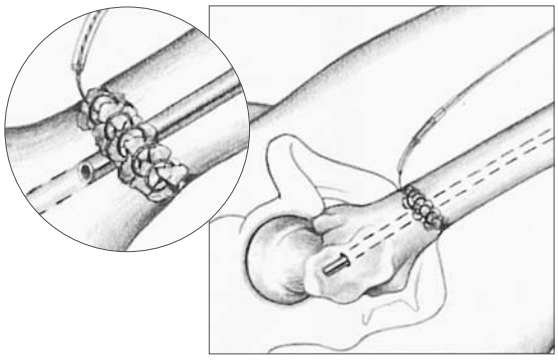
- Preparation should allow contact with viable bone at the proximal and distal ends of the nonunion site to encourage bony ingrowth.
- The connector between the cathode and the lead wire should be placed 1 cm distal or proximal to the nonunion site to avoid disruption of bony ingrowth (for optional generator removal).
- If the silastic covered lead wire crosses a joint, the joint should be immobilized to prevent disruption of the implant, possible cathode migration, or lead wire breakage from repetitive motion.
- Ensure that cathode placement is within the nonunion site and not in soft tissue. To help facilitate this, it may be necessary to suture around the lead wire (at the connector) into the soft tissue.



Proximal femur with bone graft



Fishscale into nonunion



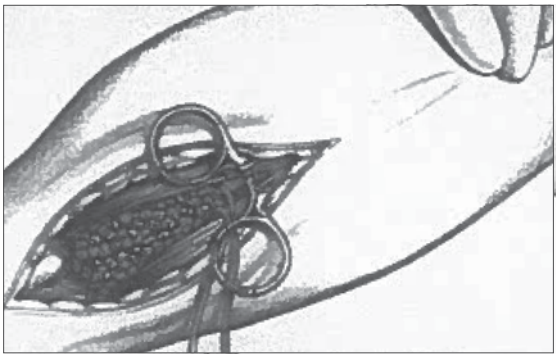
Helix with bone graft and IM nail fixation

OSTEOGEN™ STIMULATORS USE WITH BONE GRAFT AND FIXATION (CONTINUED)

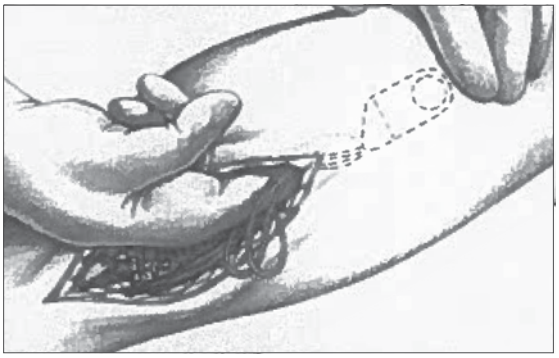
Generator Implantation

The following surgical implantation procedures will facilitate the implantation and optional removal of the OsteoGen™ generator:

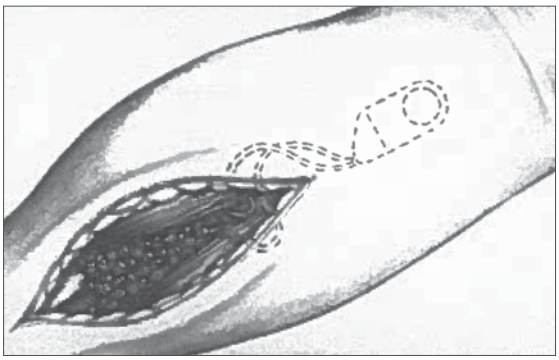
- The generator should be placed in subcutaneous tissue only (do not allow generator to touch bone) and does not require a separate incision.
- Position generator for optimum patient comfort; select an area that is protected from external irritation or impact, and unlikely to cause generator migration.
- The generator should be placed 8-10 cm away from the cathode. Placement closer than 8 cm may cause a build-up of new bone tissue at the proximal end of the cathode and connector site.
- The generator should not be implanted more than 4 cm or 1-1/2" deep to facilitate optional removal.
- The generator should not touch any metal or metallic component of the internal or external device, as this may dissipate the therapeutic current, impeding implant performance.
- 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 circular mark on the soft silastic portion of the generator.



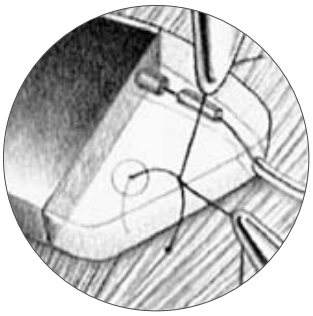
Create a pathway in subcutaneous tissue



Place OsteoGen™ generator subcutaneously in tissue 8-10 cm from cathode



OsteoGen™ generator in proper position



Generator sutured in place

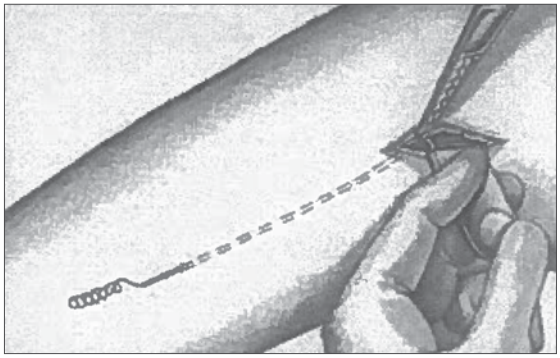
OSTEOGEN™ STIMULATORS USE WITH BONE GRAFT AND FIXATION (CONTINUED)

Generator Removal

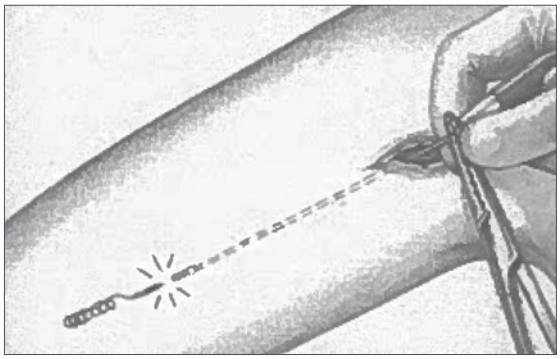
Once union has been established or the generator's power source has been exhausted (24 weeks post-implantation) the generator may be removed.

Removal of the generator can be performed as an outpatient procedure utilizing local anesthetic. Because the generator is implanted subcutaneously at a maximum depth of 4 cm or 1-1/2", it can be easily palpated to determine precise position. Local anesthetic can then be instilled. Simple dissection will permit accessibility of the generator. Upon resecting a pathway to the generator, a surgical clamp can be placed on or about the lead wire and a gentle, steady pull applied. A gentle pull will then disengage the generator and lead wire from the connector without disrupting the new bony ingrowth surrounding the cathode. The cathode and part of the connector will remain in place. When the OsteoGen™ 20/F is used, the lead wire should be held firmly and cut above the crimped connection.

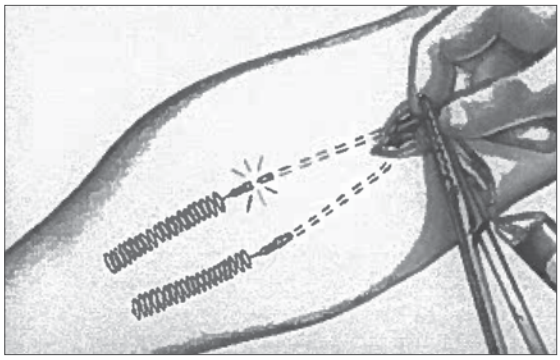
Please refer to the explantation technique contained within the OsteoGen™ Manual – PN 193102L for full instructions.[5]



Create an incision and grasp OsteoGen™ generator and lead wire



Remove OsteoGen™ gererator with a steady pull



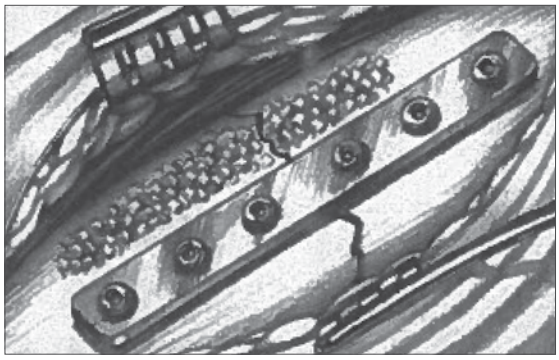
Remove OsteoGen™ generator with a steady pull

SURGICAL TECHNIQUES

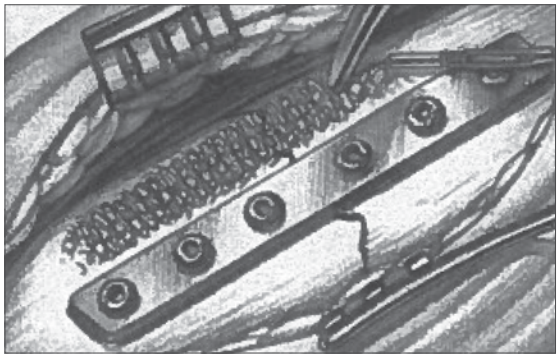
Transverse Humerus Nonunion

(Adjunct to internal fixation, with cancellous bone graft)
After the nonunion has been reduced according to procedure for the internal fixation device selected, a small amount of the periosteum is stripped to help facilitate nonunion healing.

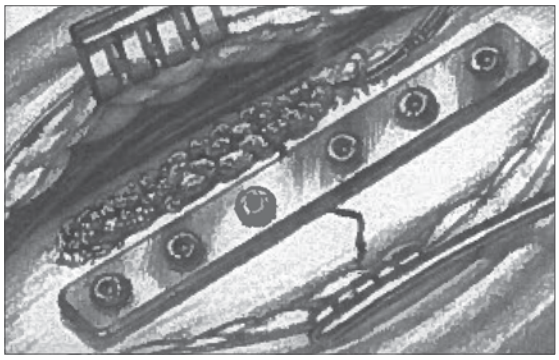
Once the periosteum is decorticated, the OsteoGen™ cathode is layed on top of the stripped outer cortex. At this point, bone graft (cancellous) is carefully placed on top of the device cathode. (If the cathode is at risk of coming in direct contact of the metal fixation, bone graft should be used to insulate the areas where they are in close proximity.) The generator can now be inserted into a subcutaneous pocket created (with a hemostat or dissecting scissors) 8-10 cm away from the cathode. Avoid placing the generator too close to the elbow joint, as this may cause excessive movement of the lead wire and potential migration of the cathode.



Prepared for cathode and graft placement



Mesh catode placed on prepared site



Cancellous graft on top of mesh catode

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

SURGICAL TECHNIQUES (CONTINUED)

Segmented Tibia Nonunion

(Adjunct to external fixation)

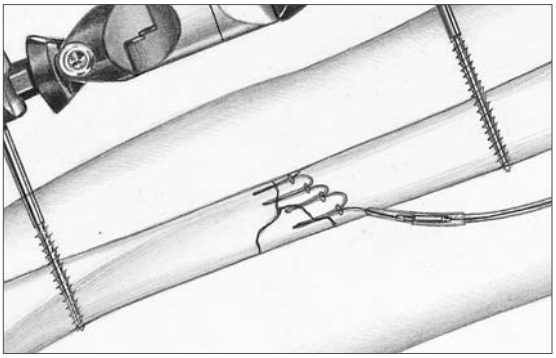
In segmented tibia nonunions, the cathode may be wrapped around a bone fragment or formed into a fishscale configuration and placed between fragments, and the nonunion fixated according to the procedure for the device selected.

In wrapping the cathode around a bone fragment, select a fragment, which will permit positioning of the lead wire connection 1 cm distal or proximal to the nonunion site to facilitate later generator removal. If placing the cathode between fragments, the helix configuration may be prepared using the mandrel. When placing the cathode, ensure that it does not contact any metal of the fixation device. The generator is inserted into a subcutaneous pocket created with a hemostat or dissecting scissors 8-10 cm away from the cathode.

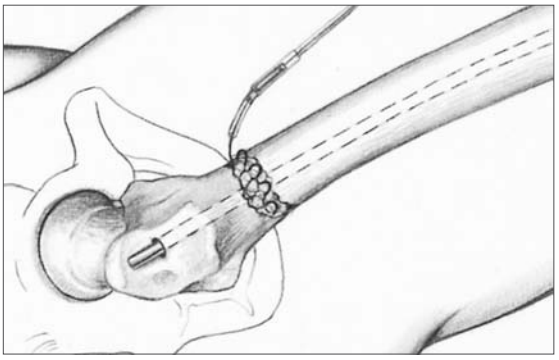
Femoral Nonunion

(Adjunct to intramedullary nail fixation, with cancellous and cortical bone graft)

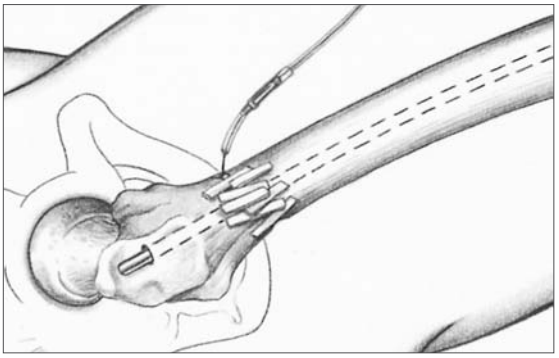
In those cases where bone graft is anticipated to be added in an atrophic femoral nonunion, addition of electrical stimulation can facilitate union. After reduction of the nonunion according to procedure for IM nailing, place cancellous bone graft into the nonunion site where the cathode is to be positioned to ensure insulation of the cathode from the metal IM nail. Prepare the cathode in either a helix or zigzag configuration and insert into the nonunion site. Autograft cortical bone "matchsticks" may be added as desired to facilitate bony union.
The generator can then be inserted into a subcutaneous pocket created with a hemostat or dissecting scissors 8-10 cm away from the cathode. If migration of the cathode is a concern, use a suture to secure connector to the soft tissue.



Fishscale into segmented bone



IM nail fixation with cancellous graft



IM nail fixation with cortical matchstick graft

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

SURGICAL TECHNIQUES (CONTINUED)

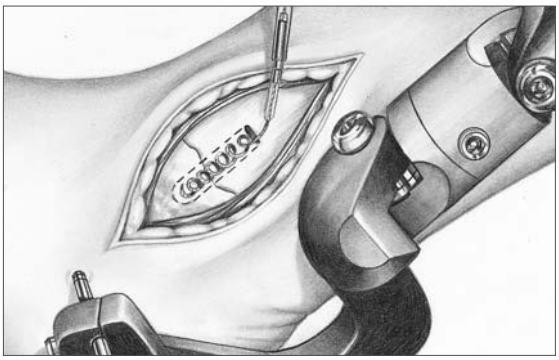
Distal Tibia Nonunion
(Adjunct to internal or external fixation)

The nonunion may be treated with the OsteoGen™ in any one of the five configurations as dictated by the situation and surgical preference. It may be helpful to pre-drill the area, providing temporary fixation before performing final reduction and fixation.

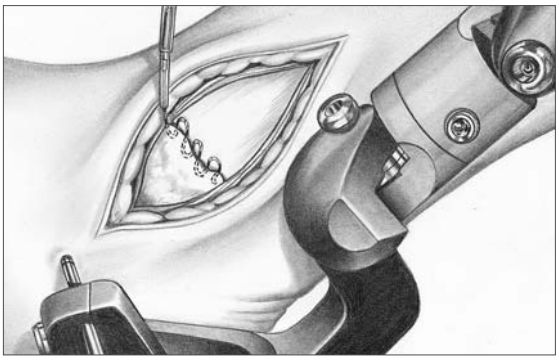
Helix Configuration (Straight Cathode):
Use the mandrel to form an appropriate helix configuration, then locate and drill a hole that is slightly larger than the diameter of the helix perpendicular across the nonunion site. Make sure the cathode will not contact the internal or external fixation device when inserted into the drilled hole.

Zigzag Configuration (Straight Cathode):
Prepare the cathode in an appropriate zigzag configuration. Position the cathode between the parallel bony surfaces, away from the metal fixation device, prior to final compressive fixation. Compressive forces will secure cathode position.

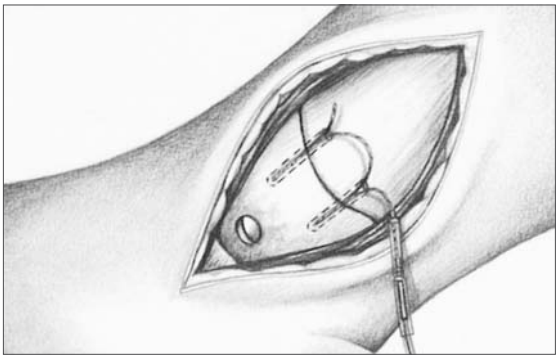
Drilled Hole Configuration (Straight Cathode):
Position at least two drilled holes perpendicular across the nonunion site, and insert the cathode into each hole using either the single insertion or woven insertion technique. After the cathode has been implanted, the generator can be inserted into a subcutaneous pocket created with a hemostat or dissecting scissors 8-10 cm away from the cathode.



Helix in drilled hole at nonunion site



Zigzag into nonunion site



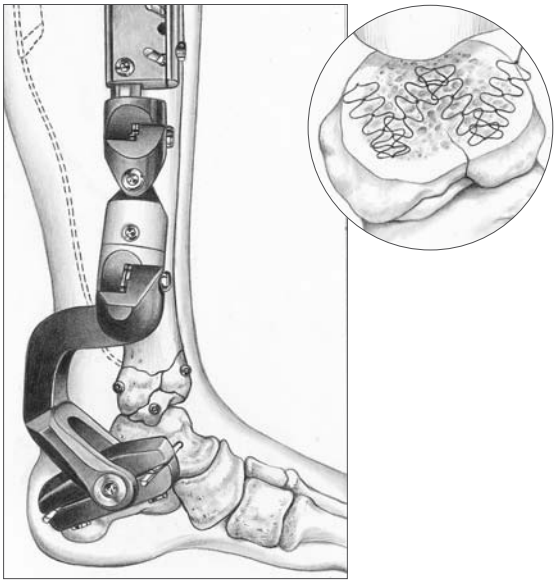
Fishscale into drilled hole

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

SURGICAL TECHNIQUES (CONTINUED)

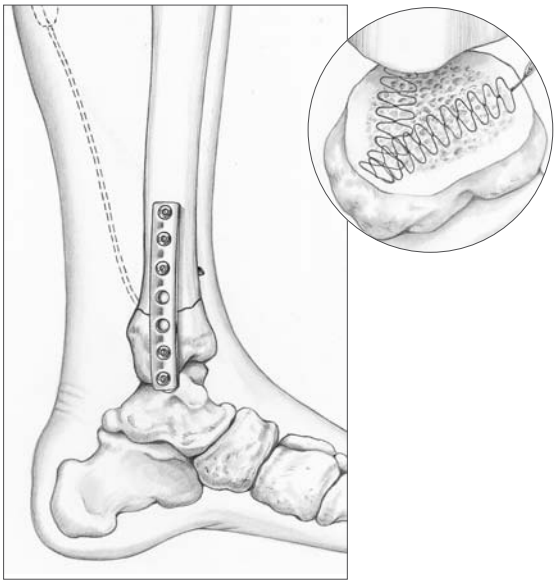
M Configuration (Mesh Cathode):
Prepare the bony surfaces of the nonunion to allow for optimal subchondral bone exposure. In cases of previous infection, perform thorough debridement and irrigation of all devitalized tissue. Then, stabilize the nonunion in the desired position and place one pin across it for temporary fixation.

Place the external fixation device at this time, stabilizing the nonunion in proper alignment. Remove the temporary pin and distract the nonunion. Place the M configuration mesh cathode across the entire nonunion site to provide maximal exposure of the mesh cathode to the nonunion site to promote healing in these challenging nonunions requiring external fixation.



M configuration used in pilon nonunion with external fixation

L Configuration (Mesh Cathode):
Prepare the two bony surfaces of the nonunion to allow for optimal subchondral bone exposure. Then, place a pin across the ankle nonunion for preparation for an interfragmentary screw. Next, use the cannulated drill to over-drill the pin. Place the L configuration mesh cathode across the nonunion while directly visualizing that the mesh cathode is not touching the pin. Next, place a partially threaded cannulated screw over the pin to provide maximal compression of the nonunion, with the mesh cathode within the nonunion site to promote healing. Then for further support, use plate fixation across the nonunion.



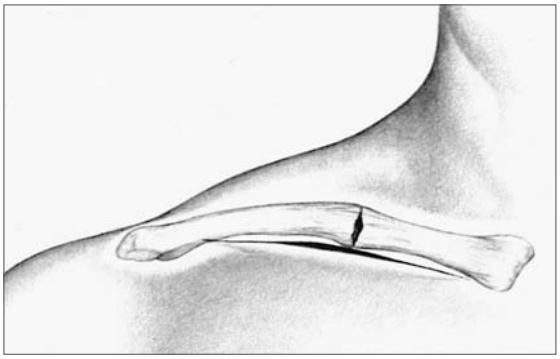
L configuration used in distal tibia nonunion with internal fixation

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

SURGICAL TECHNIQUES (CONTINUED)

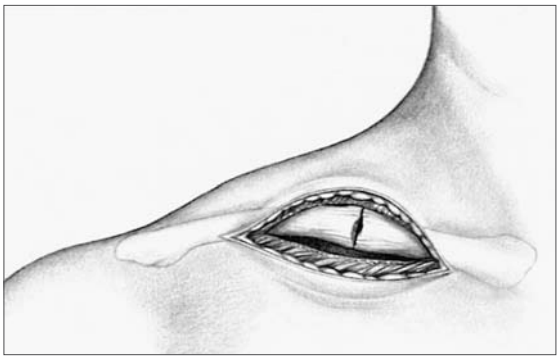
Clavicle Nonunion
(Adjunct to internal fixation with bone graft)

- A standard exposure to the clavicle is made, and soft tissue dissection carried down to the site of nonunion.



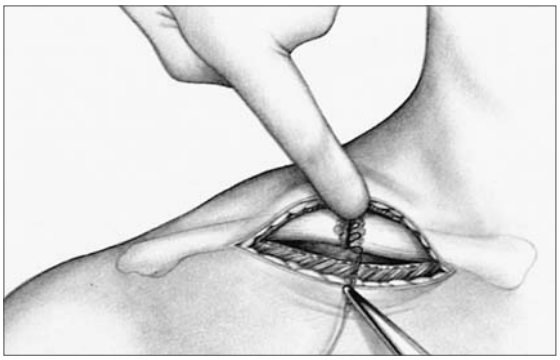
A standard exposure to the clavicle is made

  - The deep tissues are exposed with subperiosteal dissection. The callus may be resected in order to contour a flat surface for placement of the internal fixation.



The deep tissues are exposed with subperiosteal dissection

- The nonunion site is debrided and reduced. The cathode is then contoured into either the zigzag or helix configuration and placed between the bone fragments (if any). Make sure that the cathode is touching live, viable bloody bone. Alternatively, the fragments may be reduced and a fishscale configuration technique may be used to cross the nonunion site. The cathode should be placed into the specific nonunion configuration.

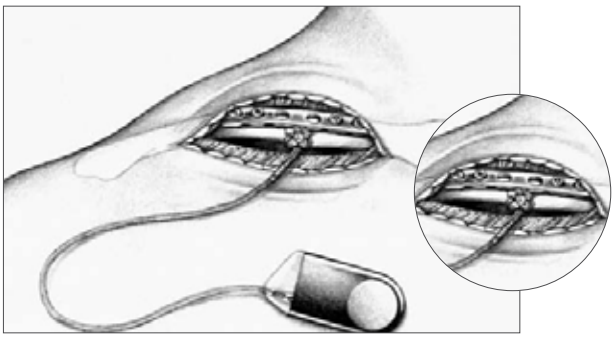


Cathode placed between bone fragments (if any)

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

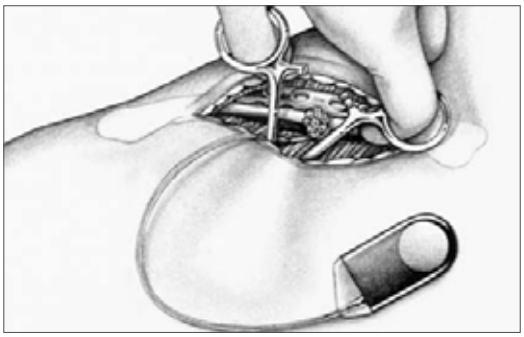
SURGICAL TECHNIQUES (CONTINUED)

- Bone graft can be placed at the nonunion site. Caution must be taken to prevent contact of the cathode with the metal fixation implant. A small reconstructive plate can be placed either anteriorly or superiorly so that a stable configuration can be achieved. The cathode can then be placed along the inferior clavicle.



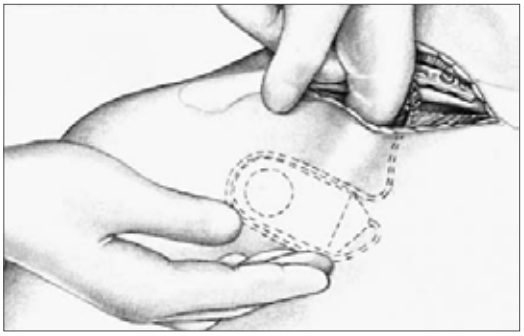
Bone graft placed between the cathode and the internal fixation

- A subcutaneous pocket is prepared with blunt dissection above the prepectoral fascia of the chest wall, allowing the OsteoGen™ generator to be placed 8-10 cm away from the cathode location.



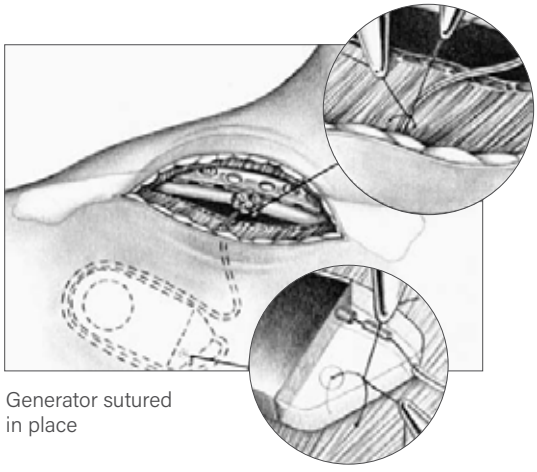
A subcutaneous pocket is prepared with blunt dissection

- The connecting lead wire may be shortened by wrapping it around the generator as shown.



Example of the generator placed in a subcutaneous pocket

- Additional stability to the configuration can be achieved by sewing the lead wire in place to the pectoral fascia adjacent to the clavicle, and by suturing the generator in place to the fascia in its subcutaneous pocket. The wound/incision can then be closed in the surgeon's preferred manner.



Generator sutured in place

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

IMPORTANT PRODUCT INFORMATION

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 visible progressive signs of healing.

EFFECTIVENESS
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 overall follow-up rate of 25.6%. The long-term success rate was 38.8%. This calculation excludes the 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 24 and 16) disability since original injury, and 43.3% and 24.3% infected prior to treatment, respectively.

OsteoGen™ 20/S, 20/F, 20/M, 20/SL & 20/ML Stimulators
These single lead devices should be used to treat a single nonunion and maintain a constant current of 20 microamps at the cathode.

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

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 fracture due to malignant tumors or in the presence of active osteomyelitis.

WARNINGS
Long-Term Biocompatibility
While titanium has had a clinical history of over 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."[6]

Direct Current *in Vivo*
Animal studies (in the rat) using capacitively coupled alternating current techniques have shown evidence of excessive bone formation.[7] The significance of these observations in humans is not known. Routine clinical observation extending over a twelve-year period on a limited number of patients treated with the OsteoGen™ Bone Growth Stimulator System 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 electrosurgey 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 in 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 responded 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. MRI imaging at close proximity to implanted devices may be associated with tissue heating, nerve stimulation or movement. ***Warning:*** The MRI image of the area close to the generator may be distorted.

Adverse Effects
At this date there are no known adverse effects.

FURTHER INFORMATION

For further information, please contact EBI® Customer Care at 800-526-2579

For full prescribing information, please consult the physician manual P/N 193102L Rev. H.

Caution: Federal Law (U.S.A.) restricts this device to sales by or on the order of a surgeon. Rx only.

ORDERING INFORMATION

Product Information

P/N	Description
10-1320	OsteoGen™-20/S
10-1328S	OsteoGen™-20/SL
10-1318	OsteoGen™-20/F
10-1320M	OsteoGen™-20/M
10-1328M	OsteoGen™-20/ML
10-1348M	OsteoGen™-40/M
10-1322M	OsteoGen™-40/ML
10-1348S	OsteoGen™-40/S
10-1322S	OsteoGen™-40/SL

EBI, as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. EBI and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

1. 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.

2. Dunn AW, Rush GA. Electrical stimulation in treatment of delayed union and nonunion of fractures and osteotomies. Southern Medical Journal. 1984;77 (12):1530-1534.

3. P.J. Cundy et. al. A Ten-Year Review of Treatment of Delayed Union and Nonunion with an Implanted Bone Growth Stimulator. Clin Orthop Relat Res. 1990 Oct;(259):216-22.

4. Data on file at ZimVie – P790005

5. EBI® OsteoGen™ Surgically Implanted Bone Growth Stimulator Manual – PN 193102L

6. Leventhal, B.S., Titanium, a metal for surgery, JBJS 33A: 473-4 (1951).

7. McElhaney. J.M.H.. and Stainaker R., Electric Fields and Bone Loss of Disuse. J. Biomechanics Vol. I, pp 47752 (1968).

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