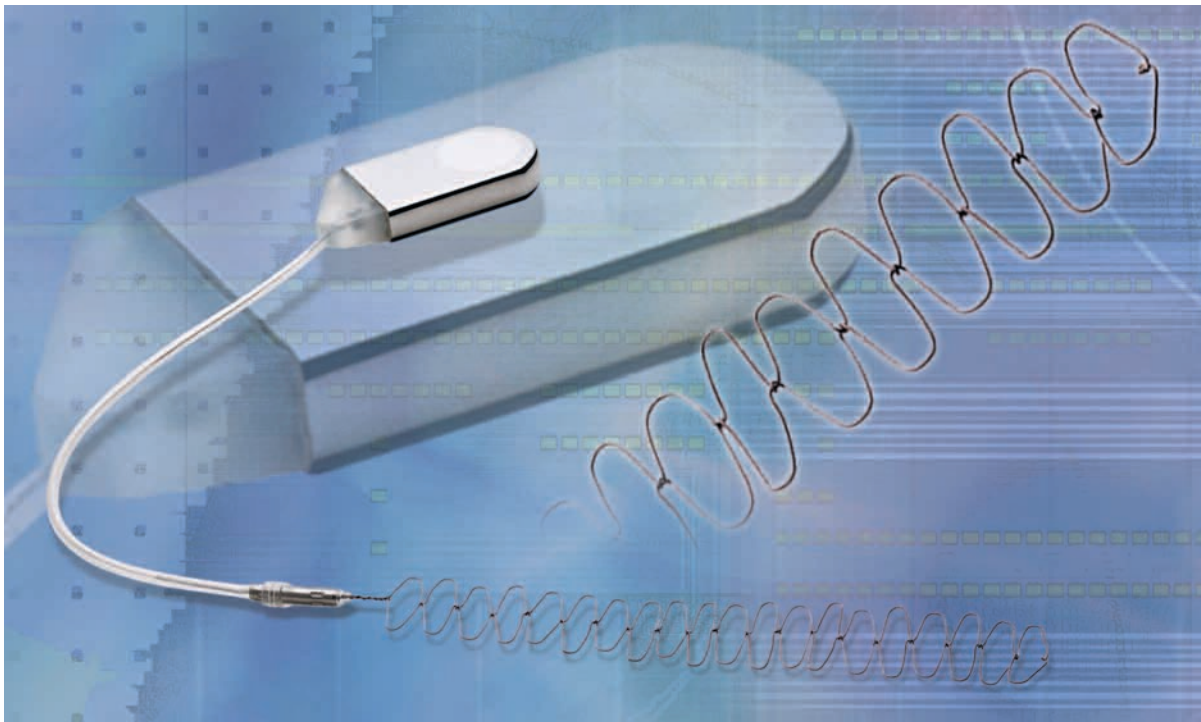


*OsteoGen™ Surgically Implanted
Bone Growth Stimulator*

Surgical Technique

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Introduction

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

Efficacy

The effective use of direct electrical current (DC) for treatment of nonunions is well documented.

The **OsteoGen** surgically implanted bone growth stimulator is a useful adjunct for treating nonunions where surgery is already planned or where patient noncompliance may be a factor with pulsed electromagnetic fields (PEMF). Because the **OsteoGen** is totally implanted, your patient is assured of the therapeutic treatment at the nonunion site.

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

Cathode Configurations

OsteoGen-M™

There are two cathode configurations, which are commonly utilized with the **OsteoGen-M** Implanted Bone Growth Stimulator. Each corresponds to a different implantation technique for various nonunion applications.

- “L” Configuration
- “M” Configuration

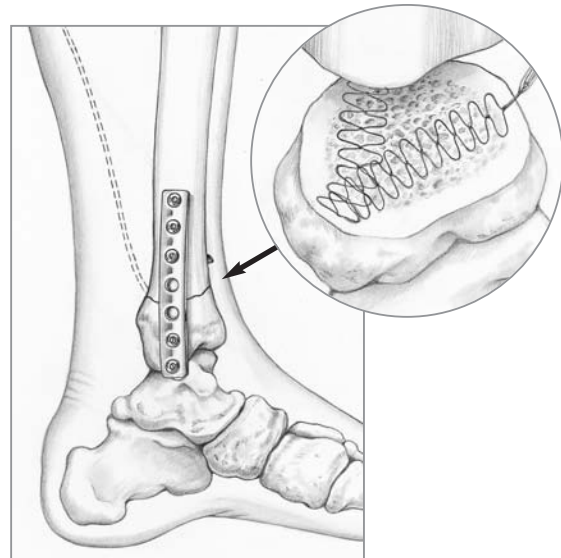
Current Density

The new 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-M** is fabricated from the same titanium filament as the triple strand titanium wire cathode of the straight **OsteoGen**.

Although the dimensions of the mesh cathode and straight cathode 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 configuration, the same overall current density is maintained at the fusion site with either cathode. What does change with the mesh cathode is the opportunity for contacts between the cathode and the host bone graft material. The mesh configuration increases the number of point to point contacts of the cathode to these critical areas, thereby increasing the surface area available for stimulating bone growth.

L Configuration

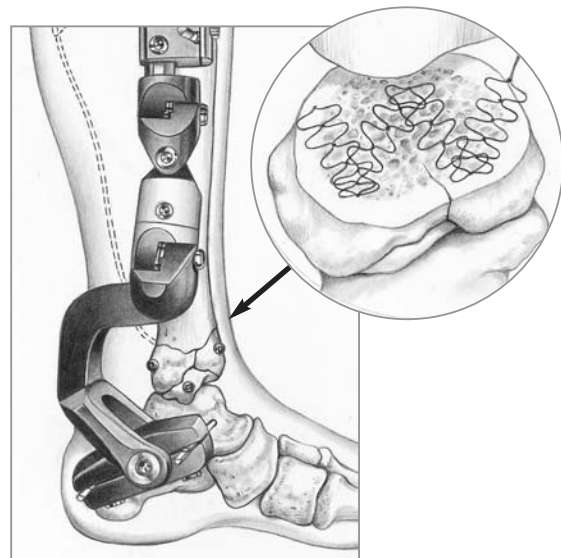
The L configuration is formed by bending the mesh cathode on itself at a 90-degree angle as illustrated in the diagram. This configuration allows increased surface area exposure of the cathode to the nonunion site while allowing for an area for internal fixation to cross the nonunion site without making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



Cathode Configurations (Continued)

OsteoGen and OsteoGen-F

There are three cathode configurations, which are commonly utilized with the **OsteoGen** Surgically Implanted Bone Growth Stimulator. Each corresponds to a different implantation technique for various nonunion applications.

- Helix
- Zigzag
- Straight or fishscale into drill hole

No matter which configuration is utilized, the electrical current emanating from the cathode traverses a cylindrical area approximately 5-8mm 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.

Helix Configuration

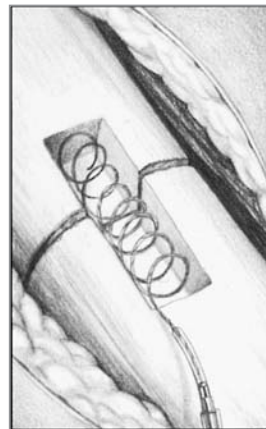
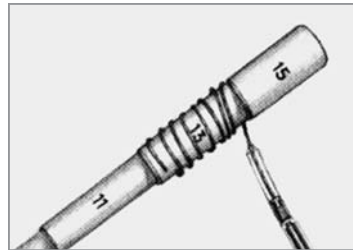
APPLICATION: Transverse, segmented, or comminuted nonunions, with or without bone graft augmentation.

There are three ways to utilize a helix configuration:

- 1) using a trough,
- 2) direct placement at fracture site or
- 3) via drill 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 drill hole or "channel" prepared to the diameter of the helix, or inserted directly into the nonunion site.



Helix in trough.

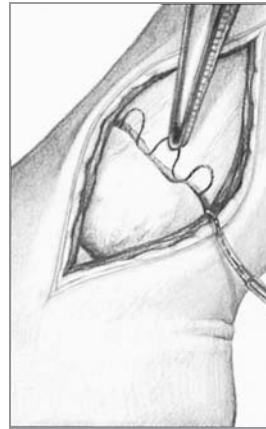
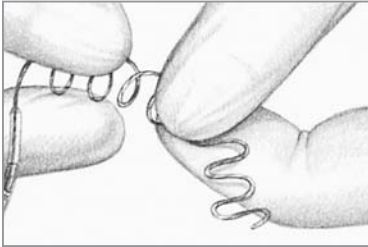


Helix in drill hole.

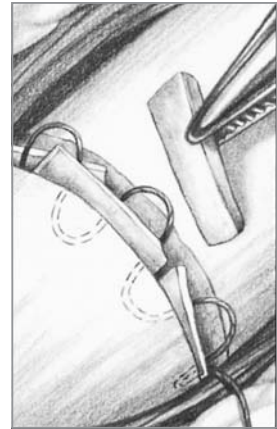
Zig-zag Configuration

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.



Zigzag with matchstick
bone graft.



Zigzag with matchstick
bone graft.

Cathode Configurations (Continued)

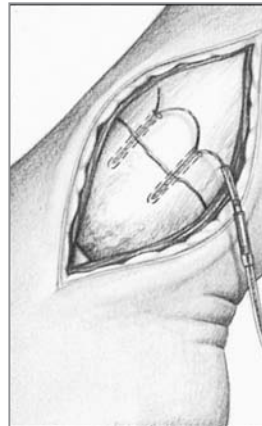
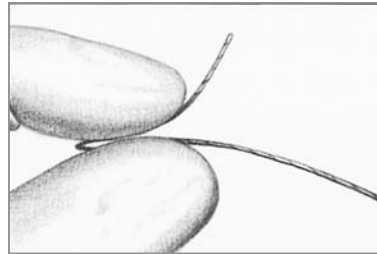
Straight or Fishscale Into Drill Hole Configuration

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

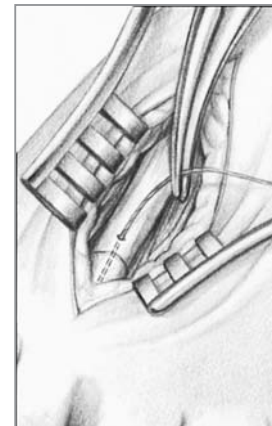
Prepare drill holes across the fracture site. Hole diameter must be sufficient to accommodate single cathode wire if using a single-insertion approach, or to accept slightly more than twice the cathode wire if using a “fishscale” woven approach. For maximum influence of electrical current, at least two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

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



Fishscale into drill hole.



Straight cathode into drill hole.

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

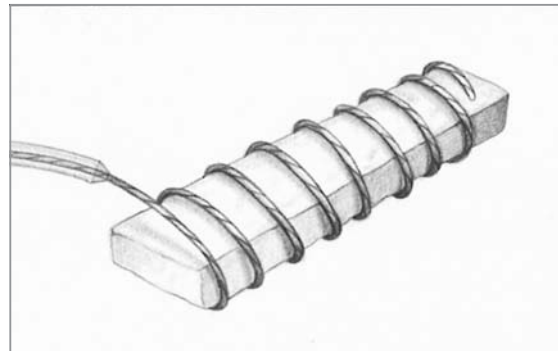
Cortical bone graft may be wrapped by the cathode in a helix configuration, and placed directly into a trough. Additional cancellous bone graft may be placed around the cortical graft.

Cortical “Matchstick” Grafts

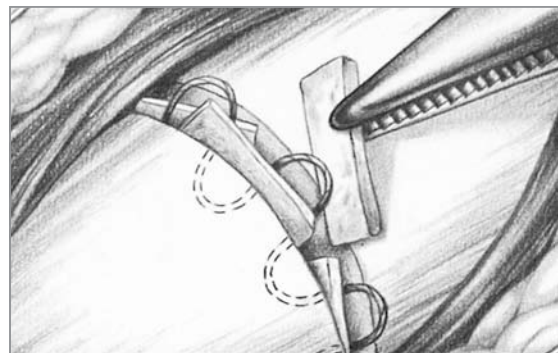
Cortical bone “matchsticks” may be used with the cathode in a zigzag configuration. Place graft material between the cathode and the surface area where new bony growth is required.



Helix in trough with cancellous bone graft.



Helix wrapped around cortical bone graft.



Zigzag with matchstick bone graft.

Cathode Configurations (Continued)

Internal/External Fixation

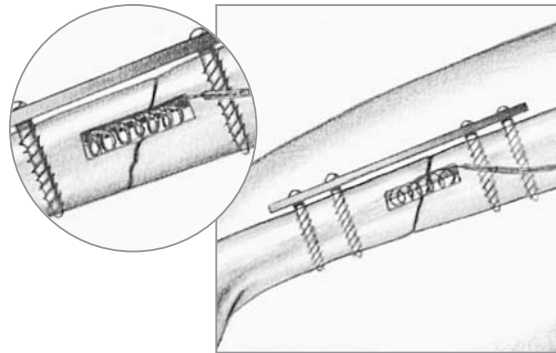
The same basic implantation procedure is utilized in the presence of both internal and external fixation.

NOTE: It is important to ensure that the **OsteoGen** Stimulator does not contact any metal, as this will impede deliverance of the therapeutic $20 \mu a$ to the fracture site and possible compromise clinical efficacy.

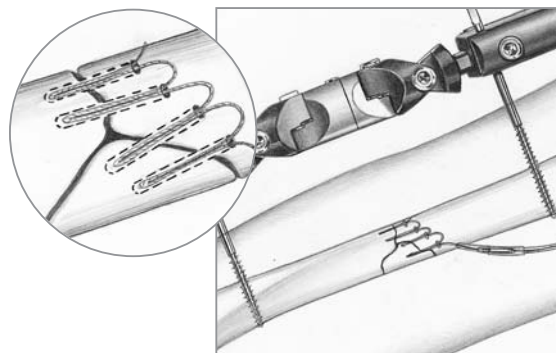
Trough Preparation and Cathode Implantation

These procedures should be followed to enhance the **OsteoGen** stimulator's performance:

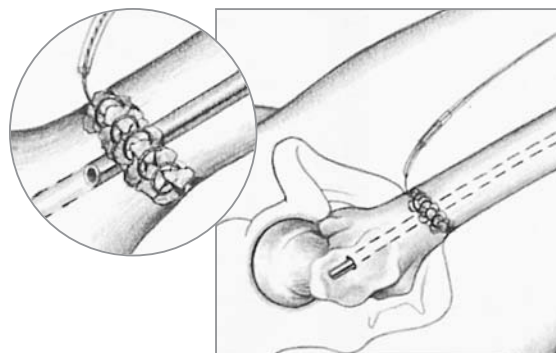
- Trough preparation should allow contact with viable bone at the proximal and distal ends of the nonunion site to encourage bony ingrowth.
- Trough positioning should be perpendicular to the nonunion site, but can be adjusted to an oblique angle if this is not possible.
- Trough size will be determined by the cortical thickness of the bone and the surgical requirements of each case.
- 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 (when the generator is removed).
- 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 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. In trough applications where the cathode will be implanted in a helix configuration within a trough, the end of the cathode can be placed in a pilot hole drilled at the proximal or distal end of the trough to hold the cathode in place.



Create a pathway in subcutaneous tissue.



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

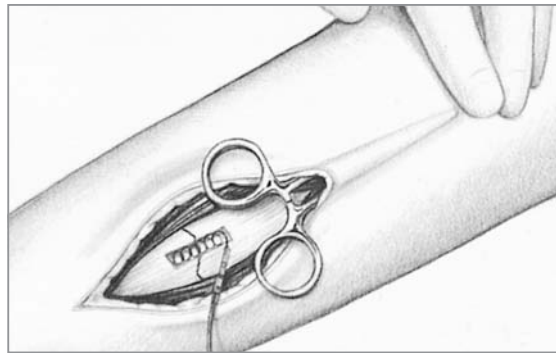


OsteoGen generator in proper position.

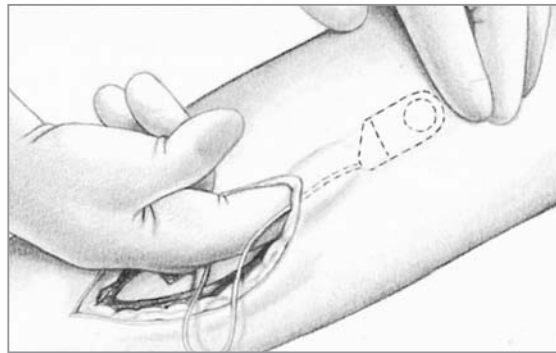
Generator Implantation

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

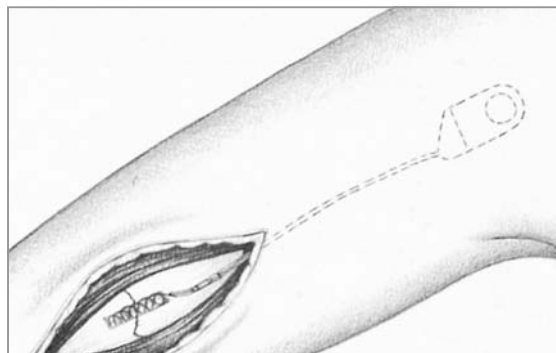
- Generator should be placed in subcutaneous tissue only (do not allow generator to touch bone) and does not require a separate incision.
- Position generator for optimum patient comfort; selecting an area which is protected from external irritation or impact, and unlikely to cause component migration.
- Generator should be placed 8-10 cm away from the cathode. Placement closer than 8 cm may cause build-up up new bone tissue at the proximal end of the cathode at the connector site.
- Generator should not be implanted more than 4 cm or 1-1/2" deep to facilitate removal.
- Generator should not touch metal of internal or external fixation devices as this may dissipate the therapeutic 20 μ A 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.

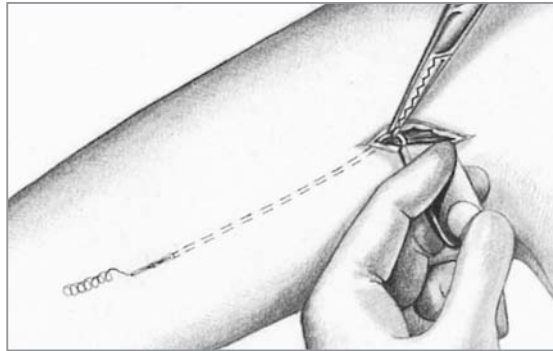


OsteoGen generator in proper position.

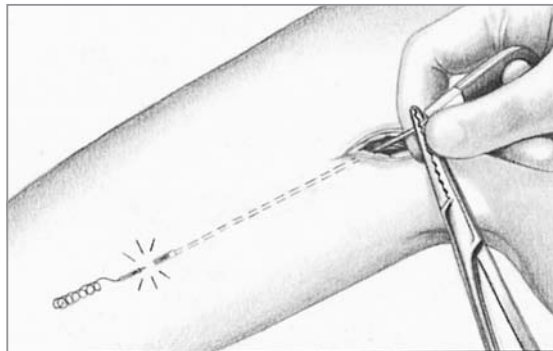
Generator Removal

Removal of the **OsteoGen** generator is recommended. 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, 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.



Create an incision and grasp generator and lead wire.



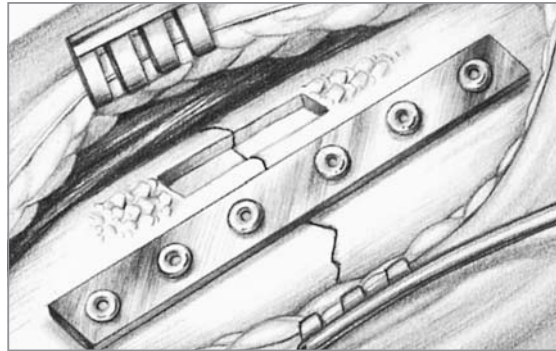
Remove **OsteoGen** generator with a steady pull.

Surgical Techniques

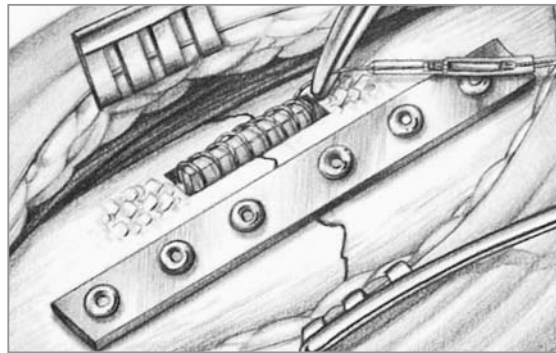
Transverse Humerus Nonunion (Adjunct to internal fixation, with cortical and cancellous bone graft)

After the nonunion has been reduced according to procedure for the internal fixation device selected, fibrous tissue is resected to permit preparation of a trough sufficient to accept the helix cathode configuration wrapped around a segment of cortical bone graft.

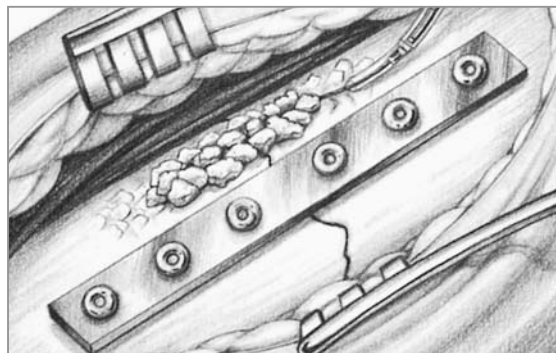
Prepare the helix by wrapping the cathode around an appropriately sized cortical bone graft, and place the graft and helix into the trough. After the cathode and graft are impacted, additional cancellous bone graft may be placed on the outer cortex if desired. If the cathode is at risk of contacting any part of the metal fixation device, cancellous bone graft can be used to insulate areas where they are in close proximity. The generator can be inserted into a subcutaneous pocket, created (with a hemostat or dissecting scissors) 8-10 cm away from the cathode. Avoid placing the generator close to the elbow joint as this may cause excessive movement of the lead wire and potential migration of the cathode.



Trough prepared for cathode and graft placement.



Helix cathode and cortical graft in trough.



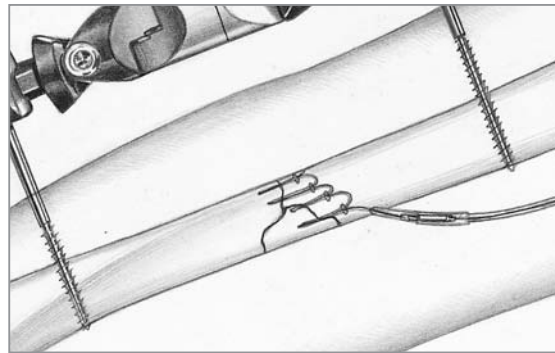
Cancellous graft on top of cortical graft.

Surgical Techniques (Continued)

Segmented Tibia Nonunion (Adjunct to external fixation)

In segmented 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 procedure for the device selected.

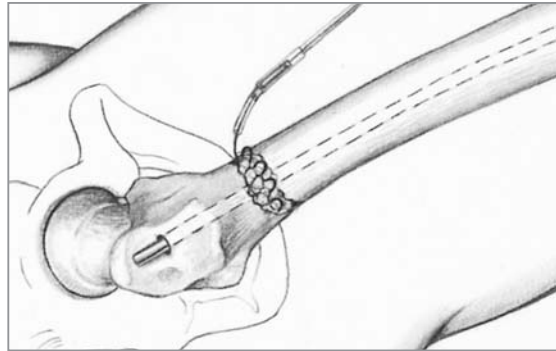
In wrapping the cathode around a bone fragment, select a fragment, which will permit positioning of the lead wire connection 1 cm distal or proximal to the nonunion site to facilitate later generator removal. If placing the cathode between fragments, the helix configuration may be prepared using the 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.



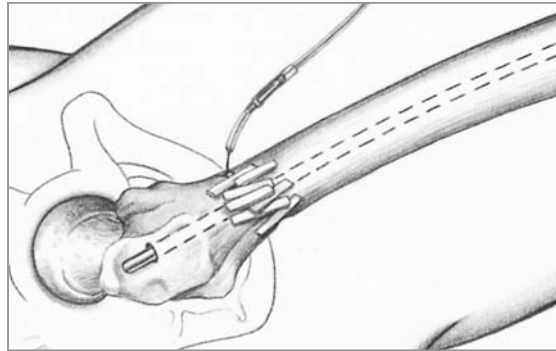
Fishscale into segmented bone.

Atrophic Femur 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 healing. 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 enhance 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.



IM nail fixation with cancellous graft.



IM nail fixation with cortical matchstick graft.

Surgical Techniques (Continued)

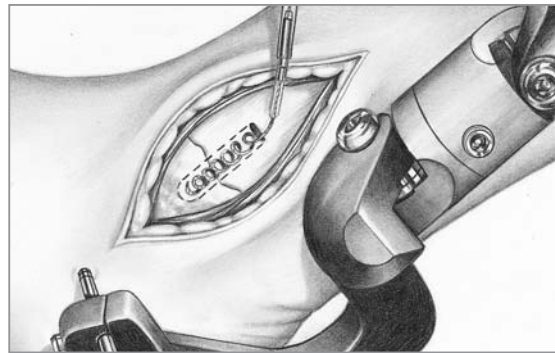
Distal Tibia/Ankle Nonunion (Adjunct to internal or external fixation)

The nonunion may be treated with the **OsteoGen** Surgically Implanted Bone Growth Stimulator 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.

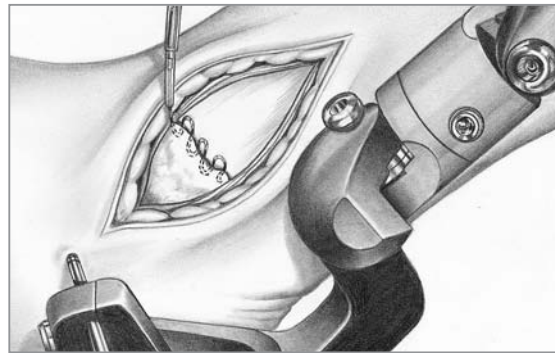
HELIX CONFIGURATION: Use the mandrel to form an appropriate helix configuration, then locate and drill a hole perpendicular across the nonunion site which is slightly larger than the diameter of the helix. Make sure the cathode will not contact the internal or external fixation device when inserted into the drill hole.

ZIGZAG CONFIGURATION: 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.

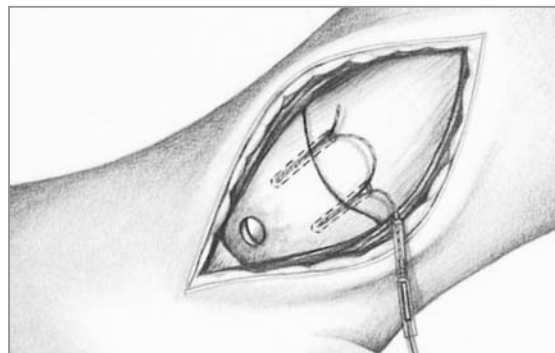
DRILL HOLE CONFIGURATION: Position at least two drill holes perpendicular across the nonunion site, and insert the cathode into each hole using either the single insertion or woven insertion technique. After the cathode has been implanted, the generator can be inserted into a subcutaneous pocket created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



Helix in drill hole at nonunion site.



Zigzag into nonunion site.

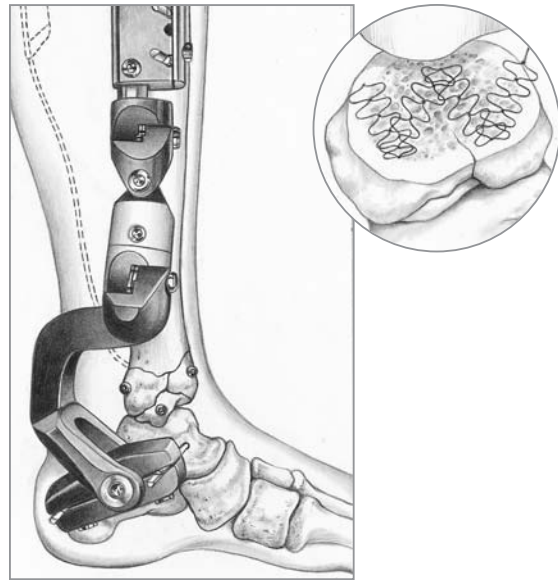


Fishscale into drill hole.

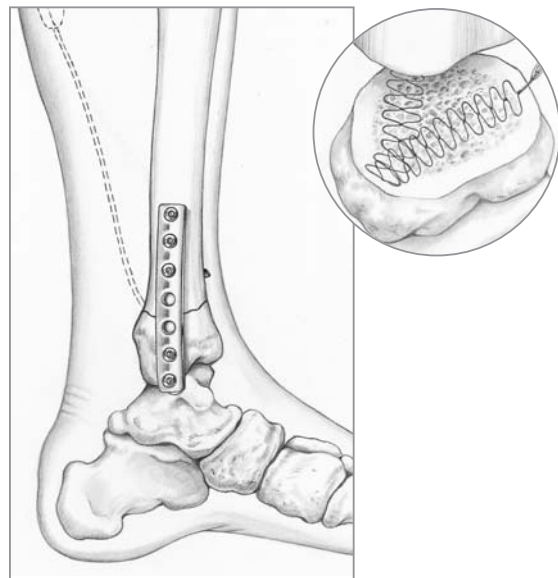
M CONFIGURATION: Prepare the bony surfaces of the nonunion to allow for optimal subchondral bone exposure. In cases of previous infection, perform thorough debridement and irrigation of all devitalized tissue. Then hold the ankle in the desired position and place one pin across it for temporary fixation.

Place the external fixation device at this time, holding the ankle in proper alignment. Remove the temporary pin and distract the ankle 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 and accelerate healing in these challenging nonunions requiring external fixation.

L CONFIGURATION: 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 ankle 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 ankle nonunion, with the mesh cathode within the nonunion site to promote and accelerate healing. Then for further support use plate fixation across the nonunion.



M configuration used in ankle nonunion with external fixation.



L configuration used in ankle nonunion with internal fixation.

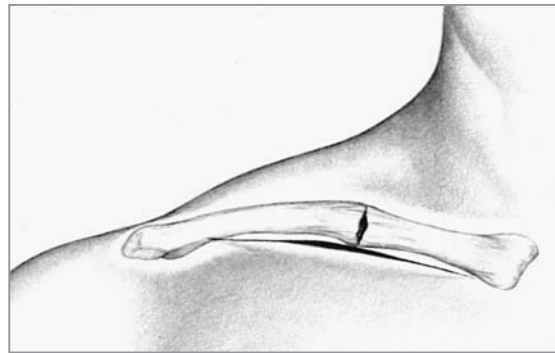
Surgical Techniques (Continued)

Clavicle Nonunion

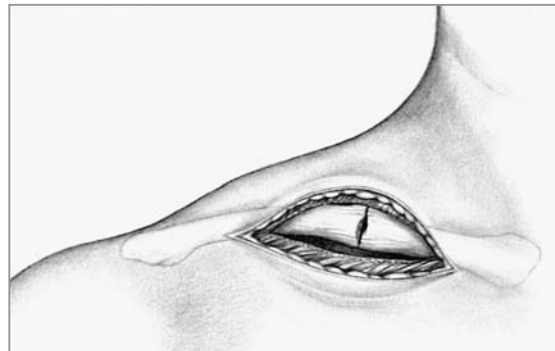
(Adjunct to internal fixation with bone graft)

The following surgical procedures will facilitate the implantation of the **OsteoGen**.

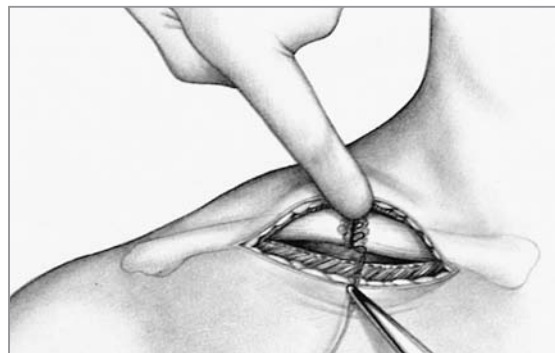
- A standard exposure to the clavicle is made, and soft tissue dissection carried down to the site of nonunion.
- The deep tissues are exposed with subperiosteal dissection. The callus may be resected in order to contour a flat surface for placement of the internal fixation.
- The site of nonunion is debrided and reduced. The cathode is then contoured into either the zigzag or helix configuration and placed between the fracture fragments making sure that the cathode is touching live, viable bloody bone. Alternatively, the fragments may be reduced and the fishscale (see Cathode Configurations) technique may be used to cross the fracture site. The cathode should be placed into the specific fracture configuration.



A standard exposure to the clavicle is made.

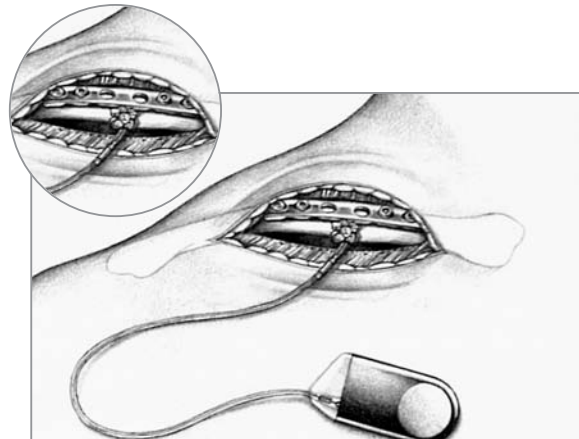


The deep tissues are exposed with subperiosteal dissection.

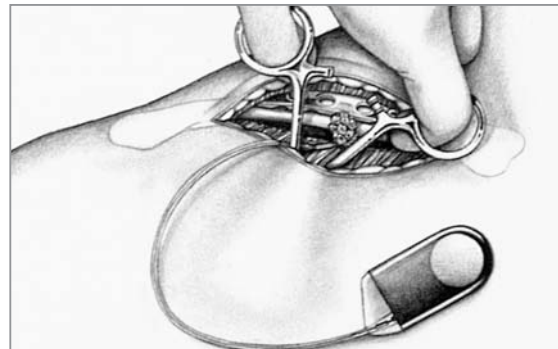


Cathode placed between fracture fragments.

- Bone graft can be placed at the nonunion site. Caution must be taken to prevent contact of the cathode with the metal implant. Bone graft should be placed between the cathode and the internal fixation. A small DCP or a reconstructive plate can be placed either anteriorly or superiorly so that stable configuration can be achieved. The cathode can be placed along the inferior clavicle.
- 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.
- The connecting lead wire may be shortened by wrapping it around the generator as shown.



Bone graft placed between the cathode and the internal fixation.



A subcutaneous pocket is prepared with blunt dissection.



Example of the generator placed in a subcutaneous pocket.

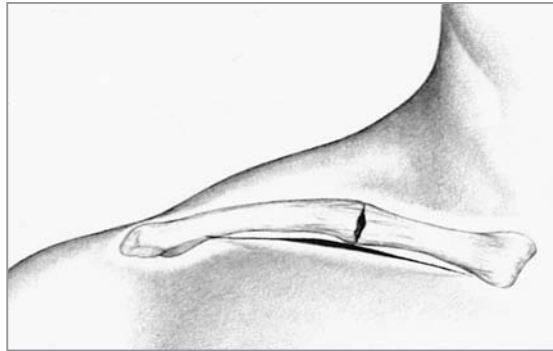
Surgical Techniques (Continued)

Clavicle Nonunion

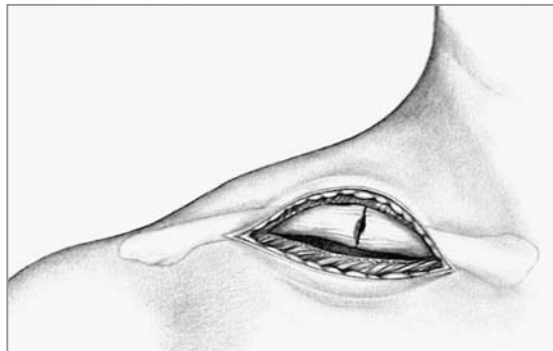
(Adjunct to internal fixation with bone graft)

The following surgical procedures will facilitate the implantation of the **OsteoGen**.

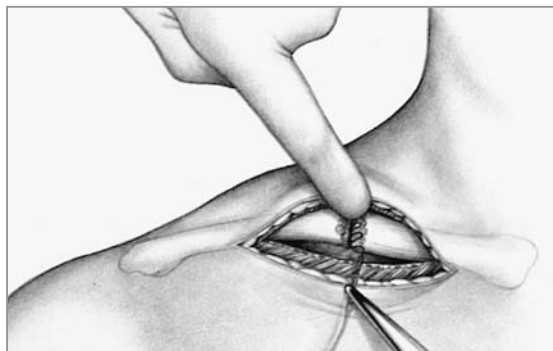
- A standard exposure to the clavicle is made, and soft tissue dissection carried down to the site of nonunion.
- The deep tissues are exposed with subperiosteal dissection. The callus may be resected in order to contour a flat surface for placement of the internal fixation.
- The site of nonunion is debrided and reduced. The cathode is then contoured into either the zigzag or helix configuration and placed between the fracture fragments making sure that the cathode is touching live, viable bloody bone. Alternatively, the fragments may be reduced and the fishscale (see Cathode Configurations) technique may be used to cross the fracture site. The cathode should be placed into the specific fracture configuration.



A standard exposure to the clavicle is made.



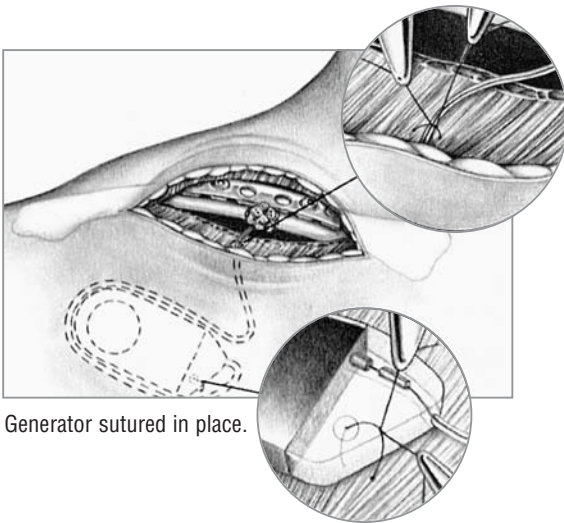
The deep tissues are exposed with subperiosteal dissection.



Cathode placed between fracture fragments.

Clavicle Nonunion (continued)

- 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 can then be closed in the surgeon's preferred manner.



Generator sutured in place.

INDICATIONS AND USAGE: The Stimulator is indicated in the treatment of long-bone nonunions. A nonunion is considered to be established when there is no visibly progressive signs of healing.

The original 1980 PMA included two (2) 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 to 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.

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 AND PRECAUTIONS: Certain warnings and precautions apply. For full prescribing information, please consult package insert.

For more information, please contact your Biomet Trauma representative at 1-800-526-2579.

Further Information

This brochure describes the surgical technique used by George Shybut, M.D. and Brian Donley, M.D. Biomet Trauma, as the manufacturer and distributor of this device and/or implant and their surgical consultants do not recommend this or any other surgical technique for use on a patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

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