

Capture™

Facet Fixation System



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A Note to Physicians

As with any percutaneous spinal procedure, good imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection, but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Capture Facet Fixation System for physicians experienced in interpreting biplanar fluoroscopic images of the lumbar spine and experienced in image-guided instrument placement.

Capture™ Facet Fixation System

Minimally invasive, bone-sparing surgical methods and load-bearing interbody fusion systems have dramatically altered the biomechanical demands placed on fixation systems, reducing the need for large complex spinal fixation constructs for many patients. The Capture Facet Fixation System is the perfect complement.

Implanted with intuitive percutaneous over-the-wire methods, the Capture system features superb implant control, excellent tactile response when seating the screw, head serrations to “grip” the bony cortex, and full-thread or lag screw options. In all, minimally complex, minimally invasive fixation.



Self-tapping design eliminates need for tapping in all but the hardest bone



Percutaneous over-the-wire surgical technique is atraumatic and efficient



Teeth on bony interface of screw head “grip” facet joint cortex

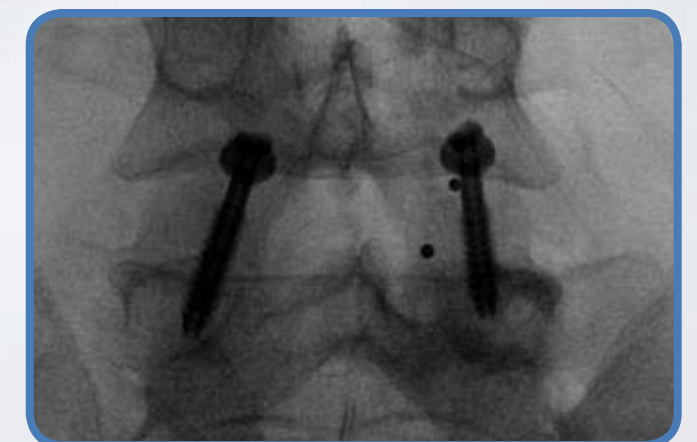


Fully threaded and lag screw options to meet clinical demands



T-top design provides rigid implant attachment to enhance control during implantation

90° head/shaft angle provides tactile response to indicate when screw is seated



Instruments

310-0010 Pin Introducer



430-0037 1.1mm Guide Pin



430-0030 Dilator



430-0029 EMG Cannula



430-0038 Palm Ratchet



430-0035 Drill Bit



430-0023 Drill Guide



430-0024 Tap



430-0025 Driver Shaft



430-0026 Driver Cannula



430-0027 Cannula Cleaner



430-0028 Screw Remover



300-1010 2.4mm Guide Pin



430-0031 Rasp



430-0032 Graft Spacer



301-0021 Push Rod



430-0022 Manual Drill



430-0034 Suction



Capture Facet Screw Surgical Technique

Patient Preparation and Positioning

Following the implantation of an interbody fusion construct, keep or position the patient prone (**FIG. 1**).

Anesthetize the patient appropriately.

Prior to surgery, the following recommendations should be followed:

- Administer a broad spectrum prophylactic antibiotic.
- Lateral and anterior/posterior (AP) imaging is required for this procedure. If biplane imaging is

not being used, swing the image intensifier under the table to ensure that no obstructions are present at the pathologic level in either AP or lateral views.

- Using the image intensifier, identify the pathologic level.
- Prep and drape the patient and C-arm image intensifier accordingly.



FIG. 1

Guide Pin Placement

Orient a C-arm to provide a true lateral image coplanar with the endplates of the level to be instrumented. Place the tip of the Pin Introducer, midline, against the patient's skin and x-ray. Alter the position of the Pin Introducer until the tip appears to be in line with a trajectory that encompasses a point immediately cephalad to the most dorsal projection of the target facet joint and projects into the next-most caudal pedicle (**FIGS. 2A & B**). Incise.

Place the tip of the Pin Introducer, with the bevel oriented dorsal, just inside the incision and alter the angle of the shaft to be coplanar with the previously noted trajectory (**FIG. 3**).

Orient the C-arm to provide a true AP image coplanar with the endplates of the level to be instrumented. Continue the advancement of the Pin Introducer along the previously established trajectory while using AP x-ray guidance to target the center of the inferior facet being fixated where it appears to intersect the superior endplate of the disc (**FIGS. 4A & B**). When bony contact is made,

modify the medial/lateral trajectory of the Pin Introducer shaft such that it is aligned with the center of the next-most caudal pedicle. Provisionally seat the Pin Introducer tip with a gentle Mallet tap.

Note: At lower lumbar levels, the pin introducer trajectory will typically pass dorsal to the spinous processes. However, at higher levels, it may be necessary to pass the Pin Introducer and subsequent instruments between the spinous processes to achieve the desired trajectory.



FIG. 3



FIG. 2A

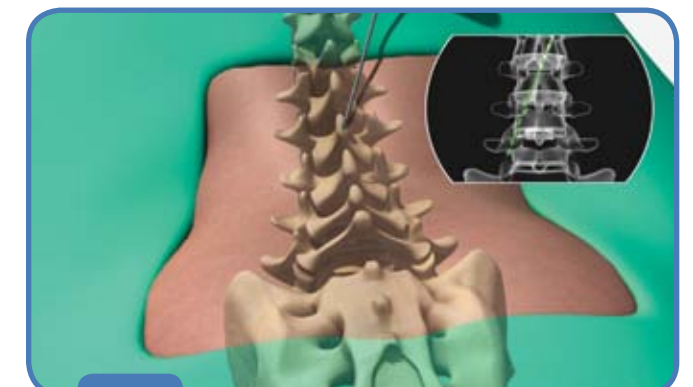


FIG. 4A

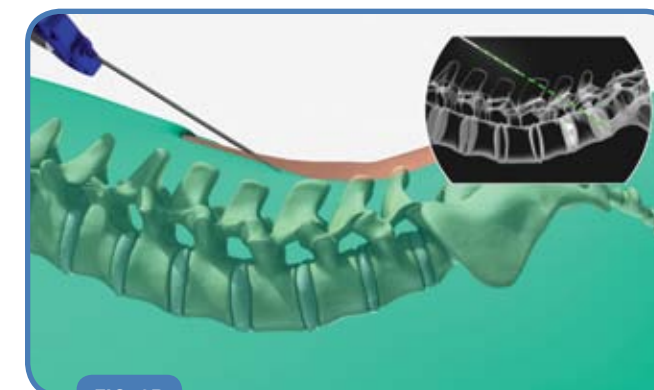


FIG. 2B



FIG. 4B

Revert to lateral x-ray and inspect the Pin Introducer tip position and shaft trajectory. The tip position should be immediately cephalad to the most dorsal projection of the facet joint, and the shaft trajectory should project anteriorly between the margins into the next-most caudal pedicle with the bevel dorsal (**FIG. 5**). If necessary, alter the tip position and/or trajectory until correct and re-seat the tip.

Note: Whenever alterations to the Pin Introducer tip position and/or trajectory are made, re-inspect the Pin Introducer with biplanar imaging to ensure good tip position and angle have been maintained in all planes.

Remove the central stylet from the Pin Introducer.

Place the sharp end of the Guide Pin through the Pin Introducer and abut it against the bone.

Note: A 1.1 mm Guide Pin is used for placement of the Capture screws.

Use AP x-ray to ensure the trajectory has not been altered. Pass a wire driver over the Guide Pin and grasp it approximately 4cm above the Pin Introducer handle. Activate the wire driver and advance the Guide Pin until x-ray shows the Guide Pin has traversed the facet and just entered the superior cortex of the pedicle (**FIG. 6**).

Revert to lateral imaging and continue advancing the Guide Pin until the tip, on x-ray, nears the caudal cortical and/or anterior margin of the pedicle (**FIG. 7**). The Guide Pin tip should not penetrate the lateral or caudal cortices of the pedicle.

Note: If a wire driver with wire collet is unavailable, the Guide Pin can be secured in a Jacobs chuck about 9" (20-25cm) from the sharp end.

Note: When fixating the L5/S1 facet joint, special care should be exercised to ensure quality x-rays can be obtained prior to fixating. The angulation of the L5/S1 disc and the opacity of the iliac crest and sacral ala can obscure visibility making the caudal aspect of the foramen difficult to observe.

Remove the wire driver and outer cannula of the Pin Introducer, leaving the Guide Pin in place.

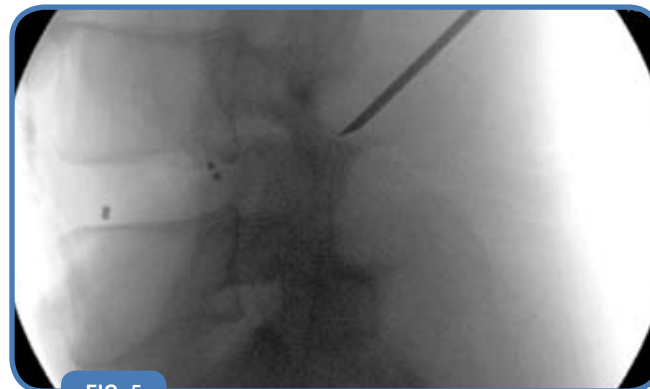


FIG. 5

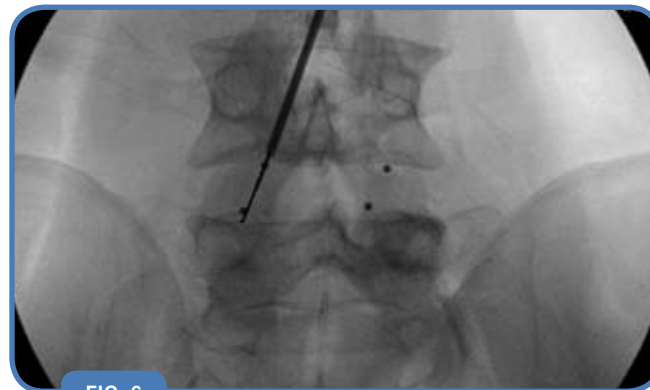


FIG. 6

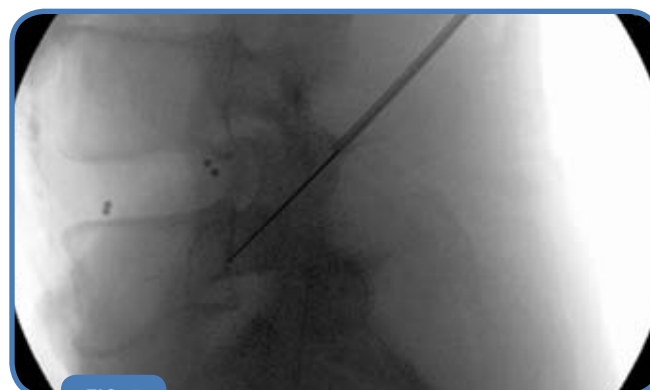


FIG. 7

EMG Cannula Placement

The Capture system can be inserted directly through the soft tissue or through a cannula. If cannula use is not desired continue to the next step, drilling.

If placement through a cannula is desired, pull back on the collar of the Palm Ratchet, insert the Dilator into the handle, and release the collar (**FIGS. 8A & B**).

Advance the Dilator through the EMG Cannula until an audible click is heard and the EMG Cannula is secured to the Dilator (**FIG. 9**).

Pass the assembly over the Guide Pin and through the tissue until the Dilator tip contacts the facet (**FIG. 10**).

Note: If resistance is felt when advancing the Dilator and EMG Cannula, x-ray to ensure correct trajectory and that Guide Pin is not being inadvertently deformed.

Grip the EMG Cannula below the slits and remove the Dilator leaving the EMG Cannula and Guide Pin in place.

Note: The EMG Cannula is constructed of plastic and is radiolucent. It will insulate the operative site from surrounding tissues in the event EMG stimulation of the instruments and/or Capture screws is desired.



FIG. 8A



FIG. 8B

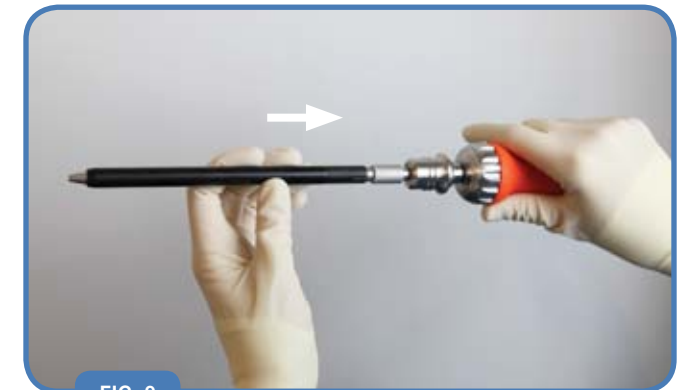


FIG. 9

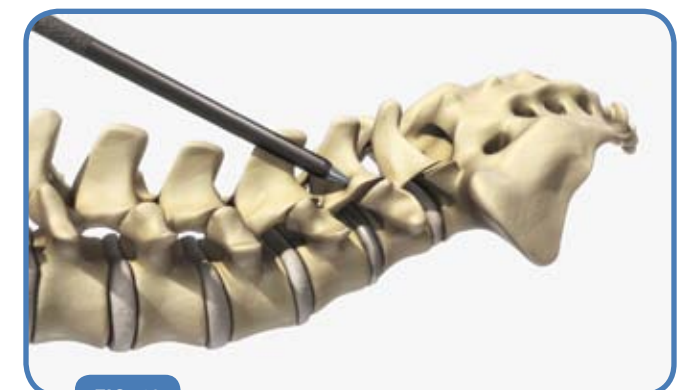


FIG. 10

Drilling

Sequentially place the Drill Bit and Drill Guide over the Guide Pin until they contact the facet (**FIGS. 11 & 12**).

Note: If resistance is felt when advancing the Drill Bit or Drill Guide, x-ray to ensure correct trajectory and that the Guide Pin is not being inadvertently deformed.

Pass the wire driver over the Guide Pin and grasp the Drill Bit.

Note: The Drill Bit is configured for use with a pin collet or Jacobs chuck. If a wire driver with pin collet is unavailable, the Drill Bit can be secured in a Jacobs chuck prior to placement over the Guide Pin.

Note: If a wire driver with pin collet or power drill with Jacob's chuck is unavailable, a Manual Drill Bit that fits into the Palm Ratchet is provided in the set.

Using AP x-ray guidance, activate the wire driver and advance the Drill Bit until it is seen to just penetrate the superior cortical margin of the pedicle (**FIG. 13**).

Revert to lateral imaging and continue advancing the Drill Bit until the tip, on x-ray, nears the caudal cortical and/or anterior margin of the pedicle (**FIG. 14**).

Note: While drilling, continually monitor the position of the Guide Pin tip to ensure it does not inadvertently advance.



FIG. 11

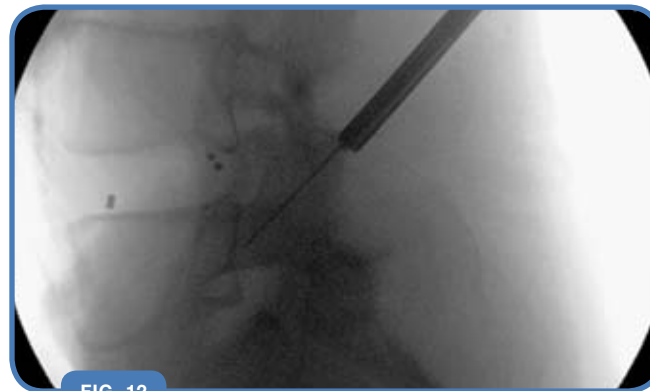


FIG. 12



FIG. 13

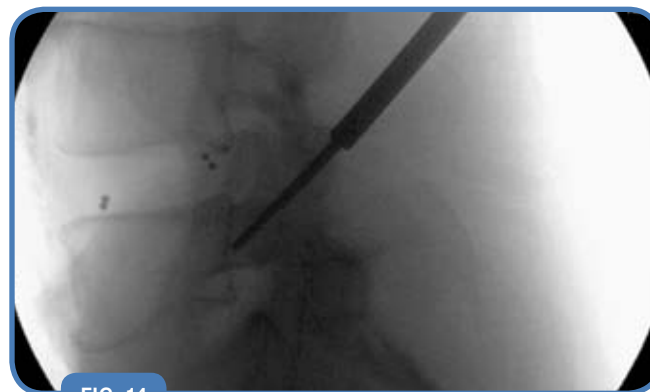


FIG. 14

Note the advancement of the etch lines and numbers on the Drill Bit in relation to the Drill Guide. They are used to select the appropriate screw length. After reaching the final drilling depth, note which line is nearest the top of the Drill Guide. If the most distal line on the Drill is near the top of the Drill Guide, a 25mm screw is selected; if the center line, a 30mm screw; and if the most proximal line, a 35mm screw (**FIG. 15**).

Maintain the position of the Guide Pin and sequentially remove the wire driver, Drill Bit, and Drill Guide.

Note: The Capture screws are self-tapping. However, in the event the facet is exceptionally sclerotic and additional bony removal is desired, an optional Tap is supplied in the set. To tap, place the Tap in the Palm Ratchet. Pass the assembly over the Guide Pin. Apply a small amount of downward pressure and rotate the Tap in a clockwise direction until it traverses the facet and penetrates the superior cortex of the pedicle (**FIG. 16**). Unthread the Tap and remove.

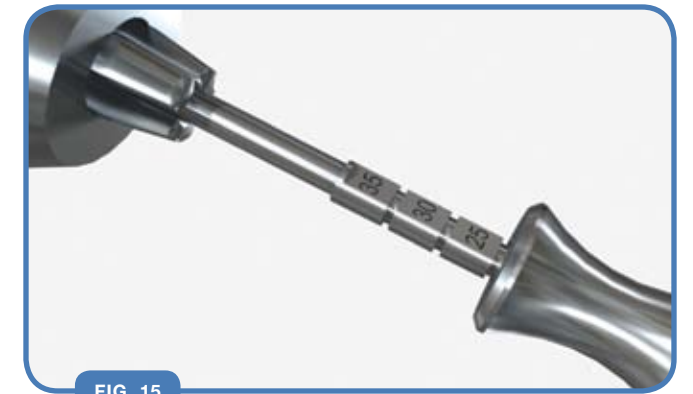


FIG. 15



FIG. 16



FIG. 17A



FIG. 17B

Implantation

Pass the Driver Shaft through the Driver Cannula until the distal end of the Driver Shaft is fully exposed beyond the distal end of the Driver Cannula (**FIGS. 17A & B**). Connect the assembly to the Palm Ratchet.

Place the distal tip of the Driver over the T-head of the desired screw (lag or fully threaded in appropriate length) and slide the Driver Cannula toward the screw to capture the screw (**FIGS. 18A & B**). Rotate the triangular jam nut until it abuts the Driver Cannula (**FIG. 19**).

Note: Screw length can be verified by placing the screw in the scale provided in the tray.

Pass the screw and Driver assembly over the Guide Pin, apply a small amount of downward pressure, and rotate the assembly clockwise to advance the screw (**FIG. 20**). When the tip of the screw enters the pedicle on AP x-ray, remove the Guide Pin (**FIG. 21**).

Revert to lateral x-ray and continue to advance the screw until the screw head contacts the facet and insertion resistance increases (**FIG. 22**).

To release the screw from the Driver, rotate the triangular jam nut counterclockwise until it stops. Retract the Driver

Cannula along the Driver Shaft. This releases the screw and allows the driver assembly to be removed (**FIG. 23**).

Repeat on the opposite side (**FIGS. 24 & 25**).

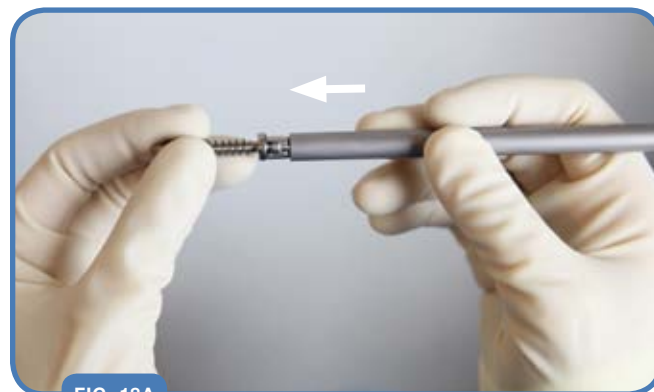


FIG. 18A

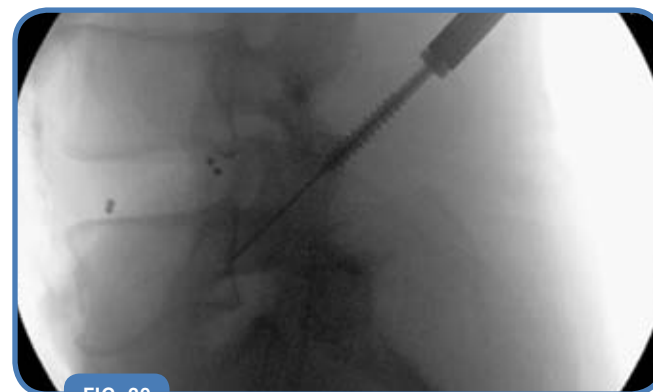


FIG. 20

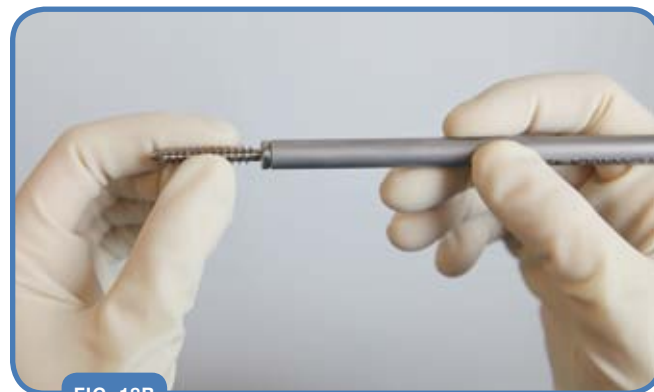


FIG. 18B



FIG. 21

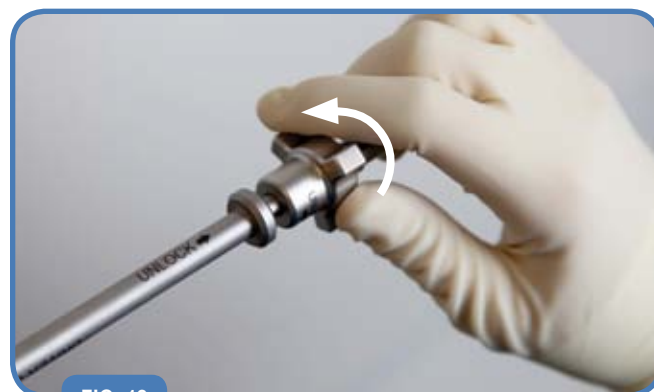


FIG. 19

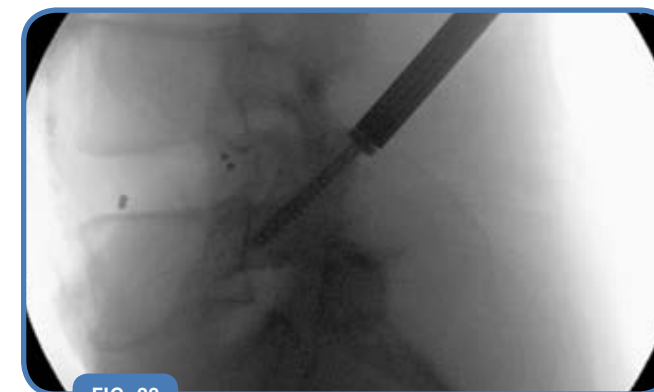


FIG. 22



FIG. 24

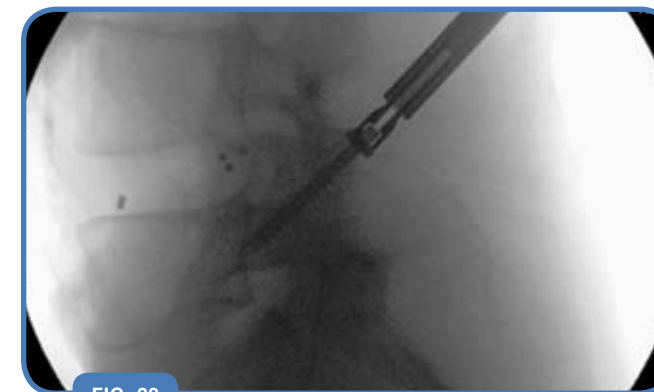


FIG. 23

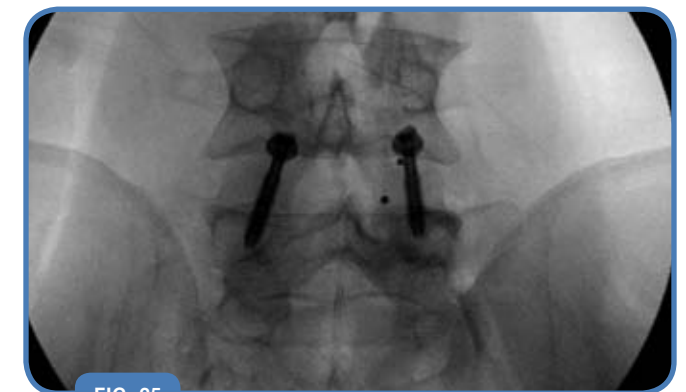


FIG. 25

Posterior Fusion Technique

Guide Pin Placement

Orient a C-arm to provide a true lateral image coplanar with the endplates of the level to be decorticated. Place the blunt end of the Guide Pin, midline, against the patient's skin and x-ray.

Caution: The Guide Pin has a sharp and blunt end. Exercise care to avoid injury to operating room personnel.

Alter the position of the Guide Pin on x-ray until it is parallel with the lamina and is directed towards the inferior aspect of the facet to be fused (**FIGS. 26A & B**). Incise.

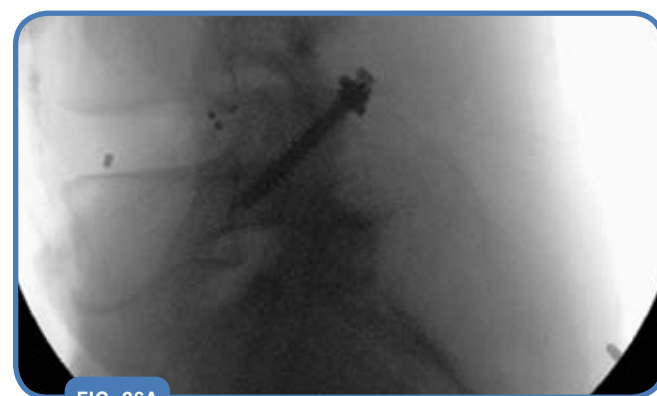


FIG. 26A



FIG. 26B

Note: A 2.4mm Guide Pin is used throughout the fusion technique.

Place the blunt end of the Guide Pin just inside the incision and alter the angle of the shaft to be coplanar with the previously noted trajectory.

Orient the C-arm to provide a true AP image coplanar with the endplates of the level to be decorticated. Adjust the Guide Pin trajectory to target the inferior articulating facet and laminar junction (**FIG. 27**). Continue the advancement of the Guide Pin. When bony contact is made, maintain

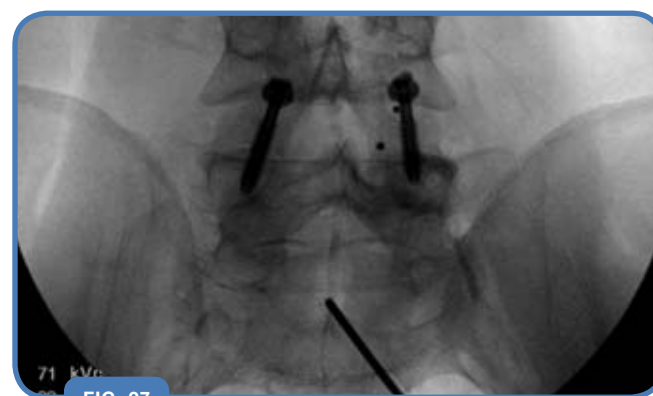


FIG. 27

the position of the guide pin by applying pressure to the proximal end of the Guide Pin (**FIG. 28**).

Revert to lateral x-ray and inspect the position of the Guide Pin (**FIG. 29**).

Note: Whenever alterations to the Guide Pin position and/or trajectory are made, re-inspect the Guide Pin with biplanar imaging to ensure good tip position and angle have been maintained in all planes.

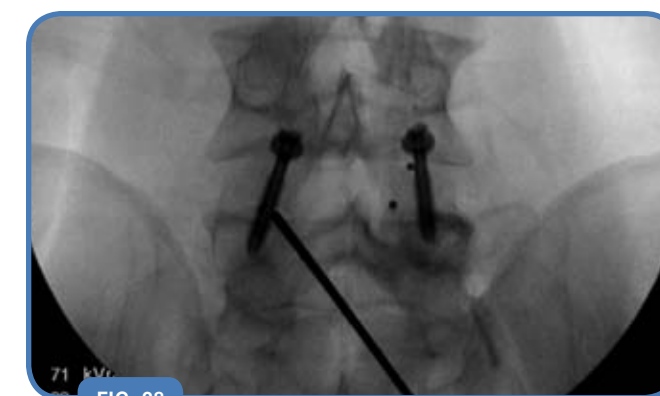


FIG. 28



FIG. 29

EMG Cannula Placement

Assemble the Dilator, Palm Ratchet, and EMG Cannula as previously described.

Pass the assembly over the Guide Pin and through the tissue until the Dilator tip contacts the facet (**FIG. 30**).

While maintaining downward pressure on the EMG Cannula, remove the Guide Pin, and re-insert with the sharp side down. Once bony contact is made with the Guide Pin, gently seat the Guide Pin into the bone (**FIG. 31**).

Caution: Use lateral imaging to ensure that the Guide Pin tip does not enter the foramen.

Grip the EMG Cannula below the slits, have an assistant maintain position of the Guide Pin, and remove the Dilator leaving the radiolucent EMG Cannula and Guide Pin in place.



FIG. 30



FIG. 31

Decortication

Place the Rasp over the Guide Pin and advance until in contact with bone.

Apply slight downward pressure to the Guide Pin and rotate the tip of the Rasp clockwise to decorticate the opposing surfaces of the inferior articulating facet and lamina (**FIGS. 32 & 33**).

When decortication is complete at this location, unseat the Guide Pin, alter the location of the instruments along the facet/lamina junction, reseat Guide Pin and repeat the decortication.

After completing the desired amount of decortication, remove the Guide Pin and Rasp, leaving the EMG Cannula in place.

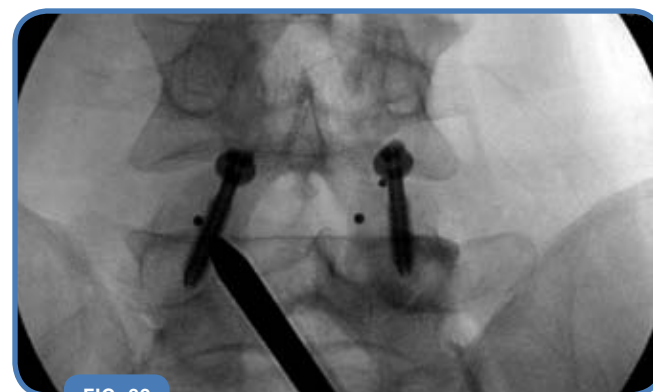


FIG. 32

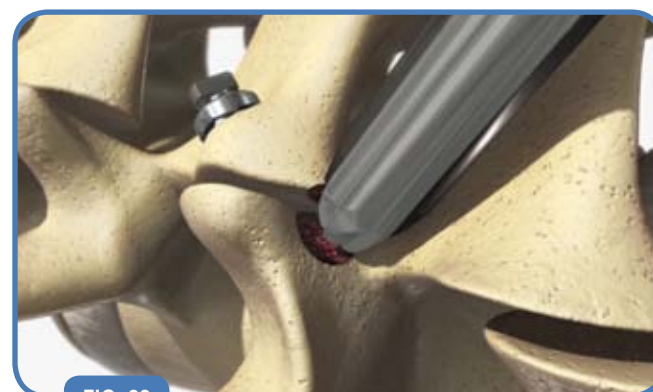


FIG. 33

Bone Graft Placement

Place the Graft Spacer into the EMG Cannula. Insert a straight bone tube into the Graft Spacer. Place the Push Rod in the end of the bone tube (**FIG. 34**). Tap on the Push Rod with a Mallet to deploy approximately 1/3 cc of bone graft to the desired location (**FIG. 35**).

Note: A straight bone tube contains 4 segments of bone. One segment is equal to one-third of a cc.

Once the deployment of bone graft is complete, remove the bone tube, Graft Spacer, and EMG Cannula from the incision site.

Repeat the decortication and bone graft placement on the opposite side.

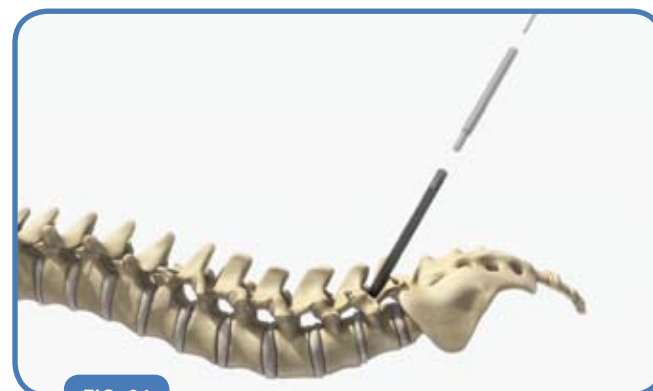


FIG. 34

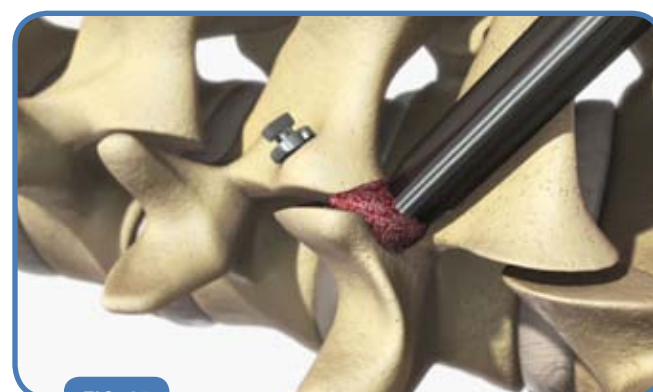
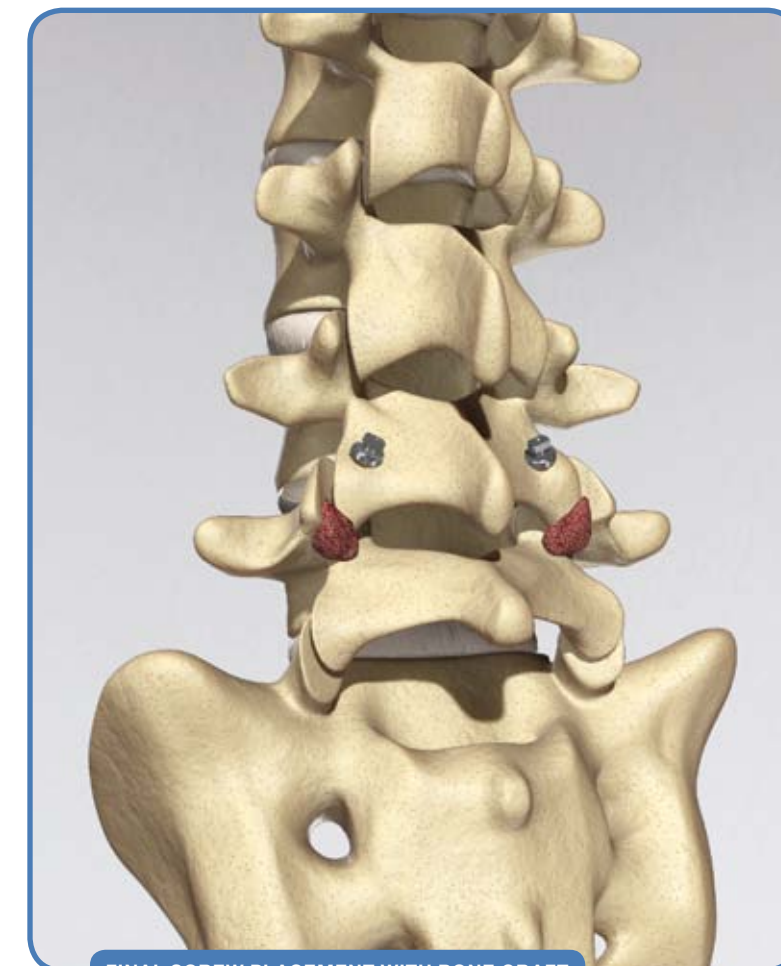


FIG. 35



FINAL SCREW PLACEMENT WITH BONE GRAFT

Capture™ implants and instruments for this procedure are patent pending.

Refer to package insert for labeling information.



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