Medtronic
SOFAMOR DANEK

CD Horizon® Eclipse™

Spinal System Surgical Technique

as described by:

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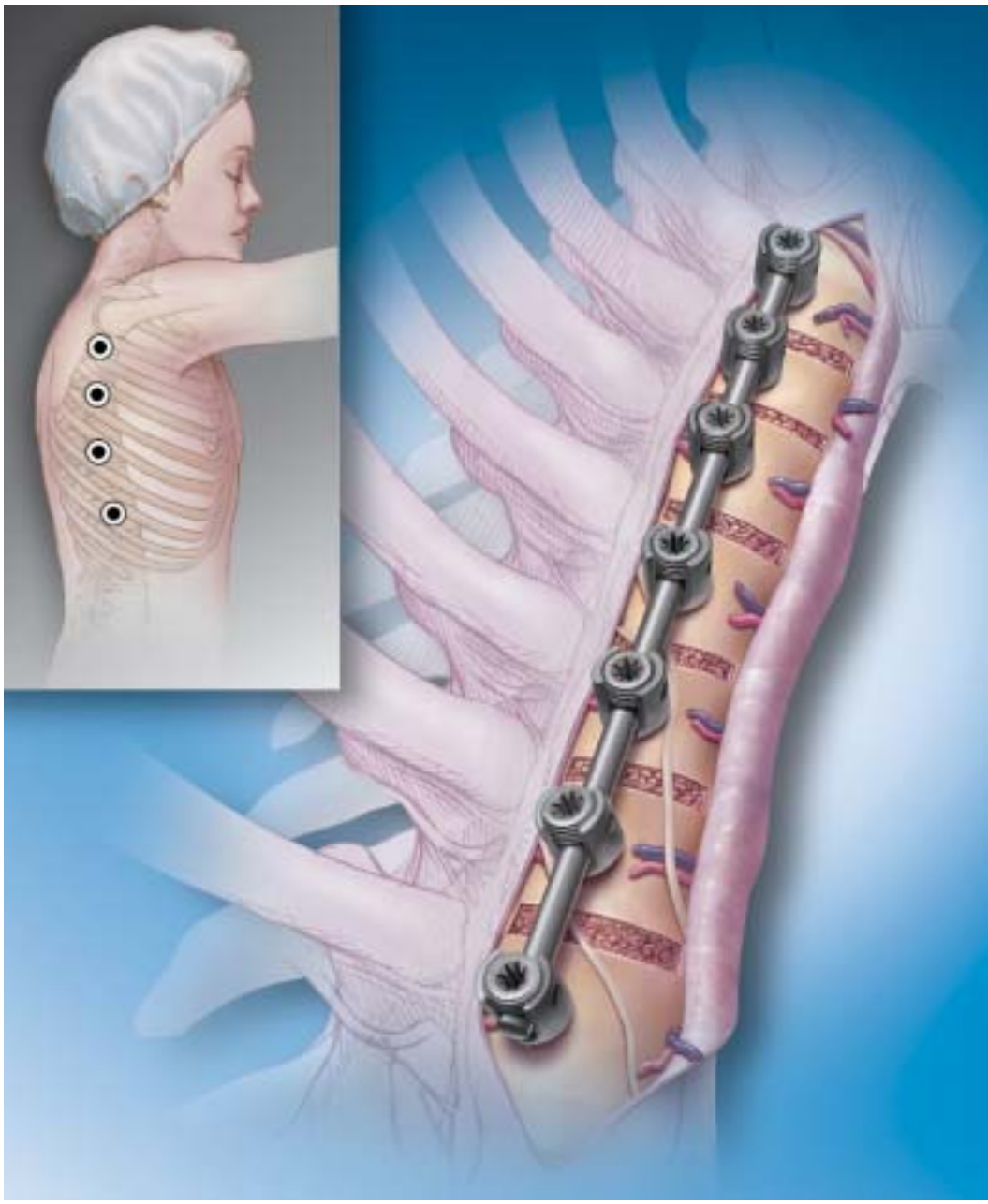

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HORIZON ECLIPSE™ SPINAL SYSTEM

HORIZON ECLIPSE™
SPINAL SYSTEM

FOR ANTERIOR CORRECTION OF IDIOPATHIC SCOLIOSIS

INTRODUCTION

The goals of scoliosis management are well recognized and include prevention of progression, maintenance of respiratory function with preservation of neurologic status and cosmesis. The advent of Harrington instrumentation in the late 50's and the subsequent improvement in instrumentation by Dwyer, Zielke, Cotrel and Dubousset, have led to marked improvement in the ability to deal with the complex problems of scoliosis management.

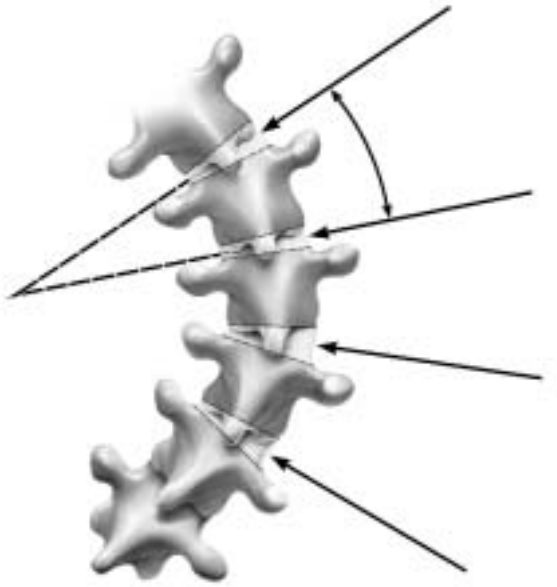


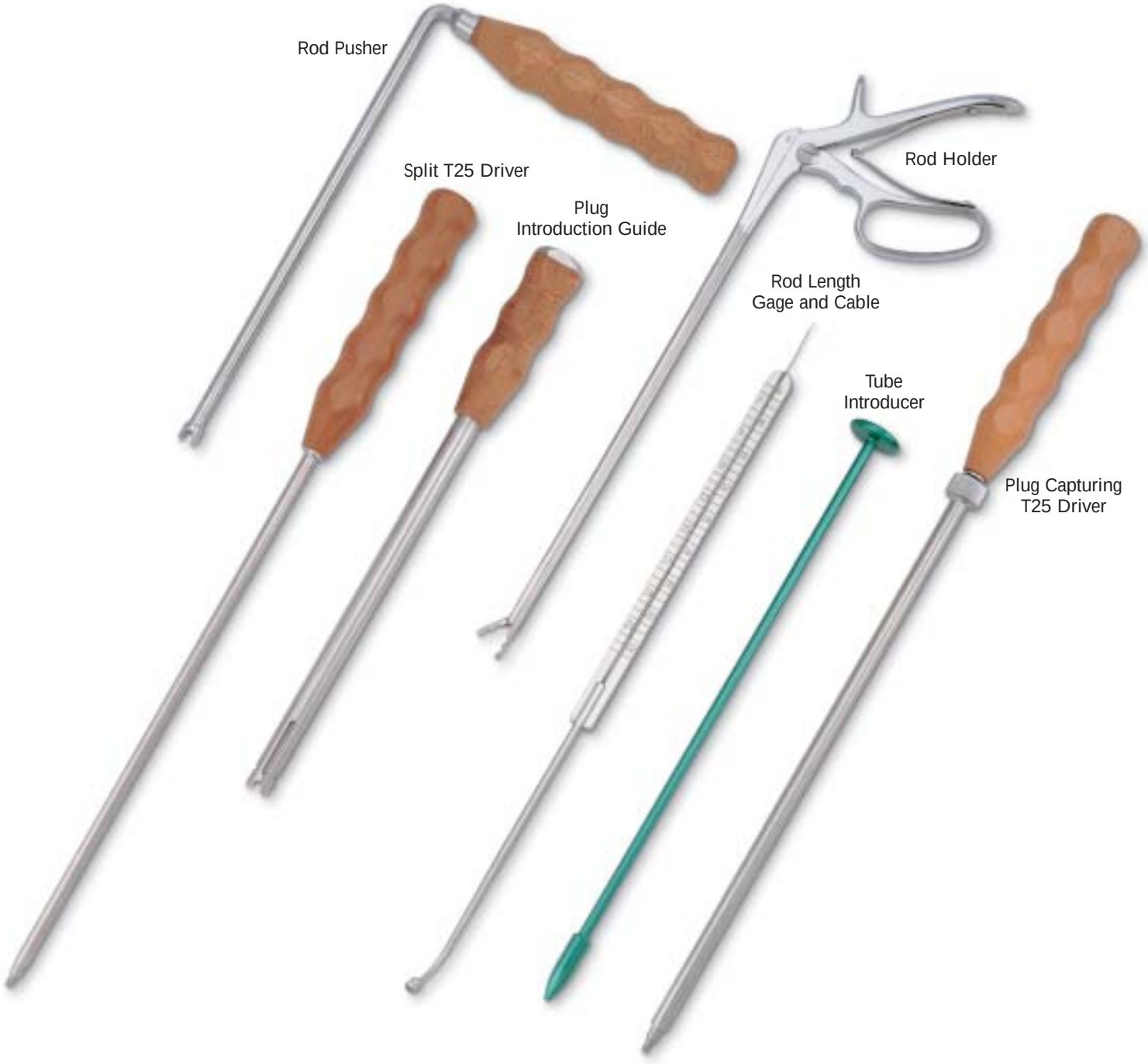
FIGURE 1

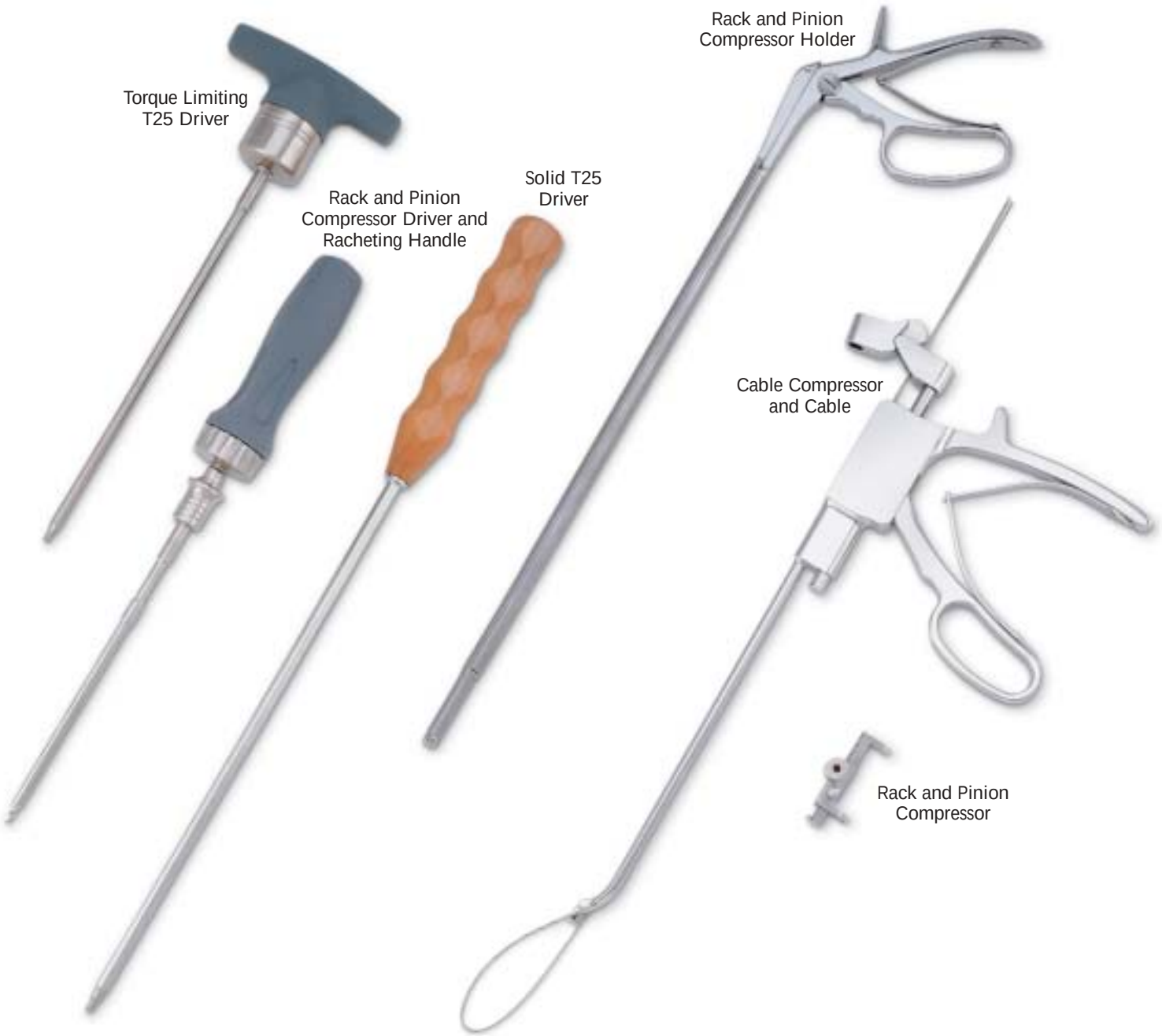
The anterior spinal approach has the advantage of improved mobilization of the spine, fusion of fewer segments and excision of the growth plates in young patients that may prevent the crankshaft phenomenon. As more surgeons gained experience with the anterior approach, it led to the development of a less invasive means of treatment with the goal of obtaining similar results. Video assisted thoracoscopic surgery has provided the spine surgeon with an endoscopic option in anteriorly approaching the thoracic and thoracolumbar spine. The endoscopic approach incorporates all the benefits of the open procedure. In addition, there is improved visualization of the spine, with enhanced access to the disc spaces especially at the ends of the curve (Figure 1), without the associated risks and poor cosmetic result from a thoracotomy incision. This allows for expedited patient rehabilitation and earlier discharge from the hospital with a greatly improved cosmetic result.


M-8 Non-breakoff
Set Screws
7.5, 6.5, 5.5mm
Diameter Screws
4.5mm Diameter Rod


Funnel
Fixed Egg Handle
Funnel Plunger
Rasp
Discectomy
Shaver
Guidewire
Wire Guide
Starting Awl
Eclipse
Screwdriver
Cannulated
Tap

INSTRUMENTS




Torque Limiting
T25 Driver
Rack and Pinion
Compressor Driver and
Racheting Handle
Solid T25
Driver
Rack and Pinion
Compressor Holder
Cable Compressor
and Cable
Rack and Pinion
Compressor

PRE-OPERATIVE PLANNING AND ANESTHESIA

Appropriate pre-operative x-rays and exam are performed. The fusion levels are determined by Cobb angles. General anesthesia is administered with a double lumen intubation technique in adults and children weighing more than 45kg. Children weighing less than 45kg may require selective intubation of the ventilated lung. Anesthesia has a major roll in the success of the procedure. **It is imperative to have the lung completely collapsed.** This depends on adequate one lung ventilation by an experienced anesthesiologist. The anesthesiologist must be well versed in fiberoptic intubation. General or thoracic surgeon assistance is recommended initially.

Once intubated, the patient is placed into the direct lateral decubitus position, with the arms at 90/90 and the concave side of the curve down. The hips and shoulders are taped to the operating table (Figure 2).

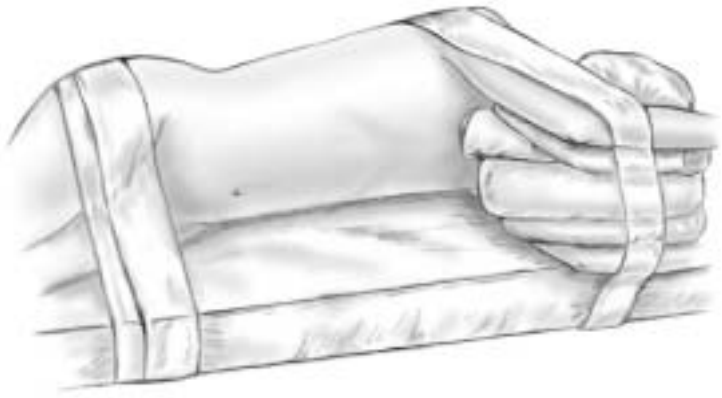


FIGURE 2

This will help ensure the patient is maintained in the correct position during the case. **On occasion when the patient has been positioned the O2 saturation will drop. This will occur if the endotrachial tube advances during the turning of the patient with subsequent occlusion of the upper lobe of the lung.** The anesthesiologist must readjust the tube, often fiberoptically.

PORTAL PLACEMENT

Proper portal placement is critical to the success of the procedure. A C-Arm and a straight metallic object, used as a marker, are utilized to identify the vertebral levels and portal sites. **The superior and inferior portals are the most critical since the vertebrae at these levels are at the greatest angle in relation to the apex of the curve.** The portal planes are visualized with a C-Arm in the P/A Plane being sure the endplates are parallel and well defined. **The C-Arm must be rotated until it is parallel to the vertebral body endplates, not perpendicular to the table (Figure 3).** The Marker is positioned posterior to the patient and aligned with every other vertebral body (Figure 4).

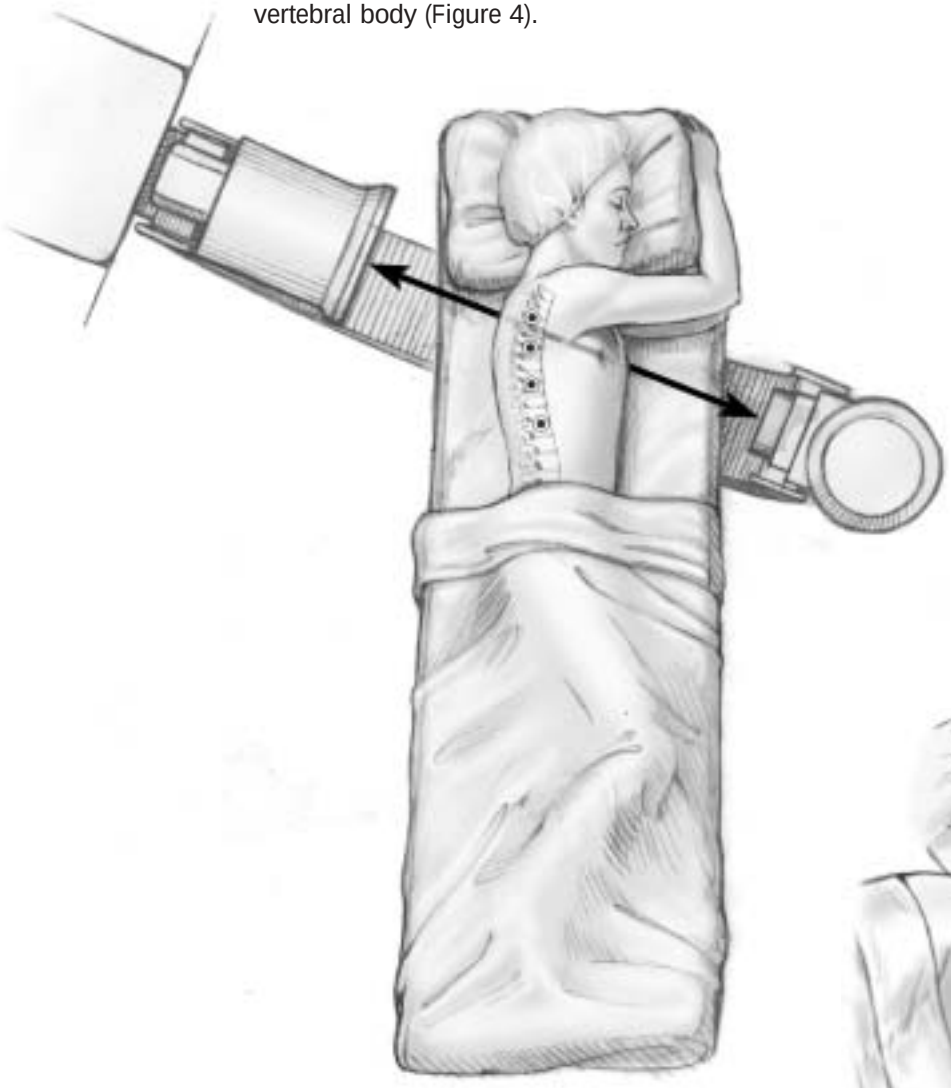


FIGURE 3

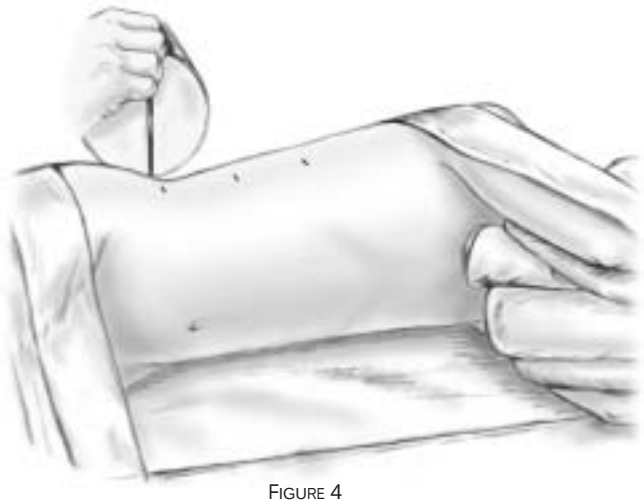


FIGURE 4

A C-Arm image is obtained at each level. Once the Marker is centered and parallel to the endplates (Figure 5), a line is made on the patient at each portal sight in line with the Marker. **Incisions should be placed two interspaces apart**, this allows for placing the portals above and below the rib at each level, enabling the surgeon to reach two levels through a single skin incision. Three to five incisions are used depending on the number of levels to be instrumented (Figure 6).

FIGURE 5

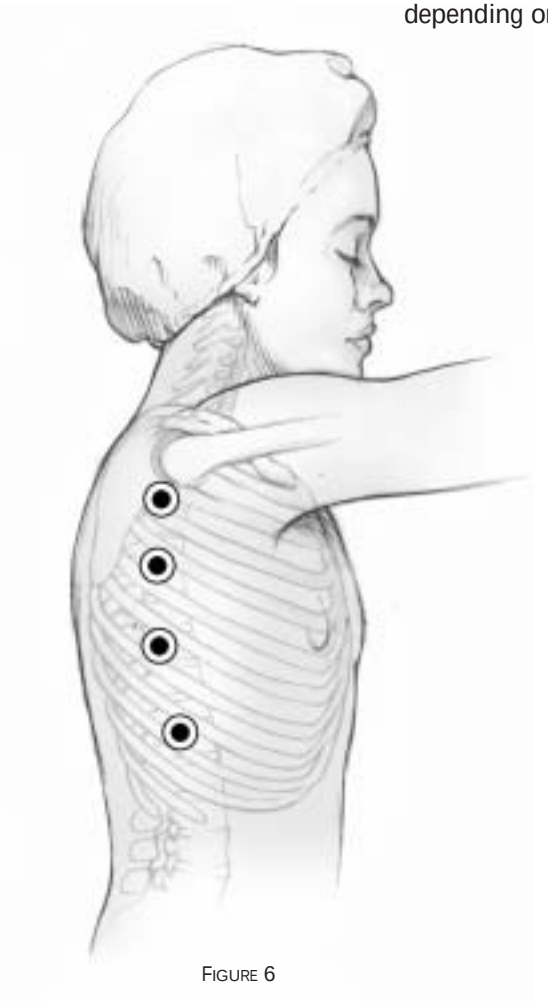


FIGURE 6

PORTAL PLACEMENT

Once these marks are made at all portal sights the C-Arm is rotated to the lateral position. The Marker end is placed on each line.

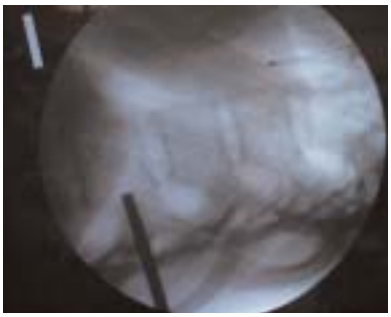


FIGURE 7

The Marker position is adjusted until the C-Arm image shows the end of the Marker at the level of the rib head on the vertebrae (Figure 7). A cross mark is then placed on the previous line (Figure 8). This is the location of the center of the portals. This will also show the degree of rotation of the spine.

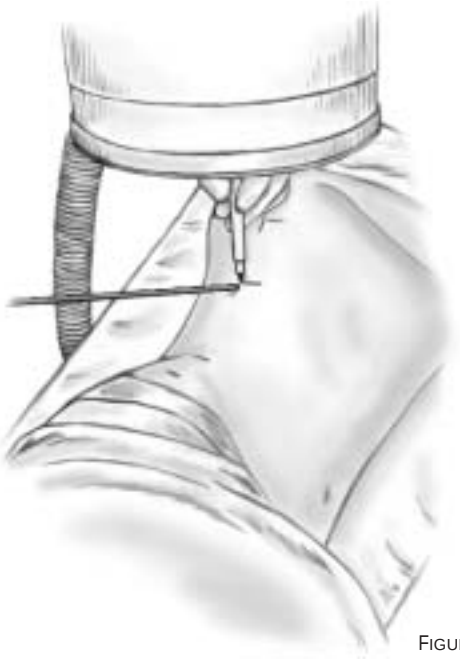


FIGURE 8

Two endoscopic monitors are utilized, one facing the patient as the spine surgeon positions himself or herself posterior to the patient. A second placed posterior to the patient and spine surgeon to allow visualization for the thoracic or assisting surgeon (Figure 9). **The spine surgeon's position at the patient's back allows all of the instruments to be directed away from the spinal cord.** Standing behind the patient will also assist the surgeon in his or her orientation to the external landmarks of the ribs and spine as seen through the scope without a mirror image on the screen. Depending on the video system the assistant's monitor may need to be flipped to give the correct image orientation. The fluoroscopy monitor is placed at the foot of the bed.

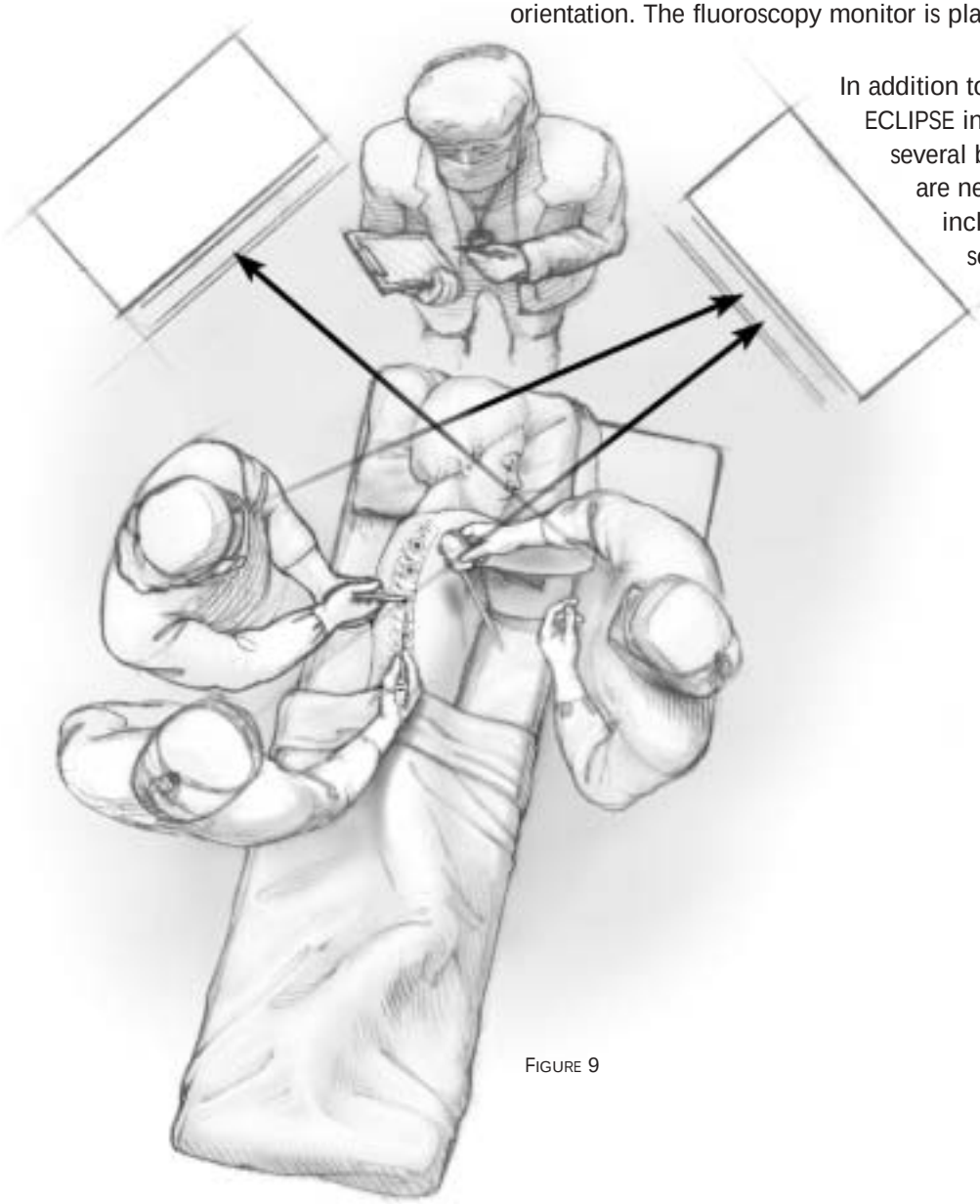


FIGURE 9

In addition to the standard CD HORIZON ECLIPSE instruments and implants, several basic endoscopic instruments are necessary. The instruments include a 30 degree 10mm scope with a three-chip camera, a selection of long curettes, pituitarys, kerrison rongeurs and some standard endoscopic instruments (kitners, bovie and hemostatic agents). For lung retraction the Expose™ fan is preferred.

STEP ONE

The patient positioning is checked to confirm he/she has remained in the direct lateral decubitus position. This orientation provides the surgeon with a reference to gauge the A/P and lateral direction of the guide wires and the screws. The position will again be checked just prior to placement of the guide wires. The patient is prepped and draped, with the **prep extending into the axilla and including the scapula.**

Once the lung has been deflated, the initial portal is made in the 6th or 7th interspace using the alignment marks made previously. This ensures the portal is in line with the spine and positioned according to the amount of spinal rotation. Inserting the first portal at this level will avoid injury to the diaphragm, which normally is more caudal. Once the portal is made, **digital inspection of the portal is performed to assure the lung is deflated and there are no adhesions.** The camera is then inserted into the chest and additional portals are placed under direct visualization. Incisions are made at the predetermined positions as described above. The portals are 10.5 to 12mm in size. The ribs are counted to ensure the correct levels are identified based on pre-operative plans.

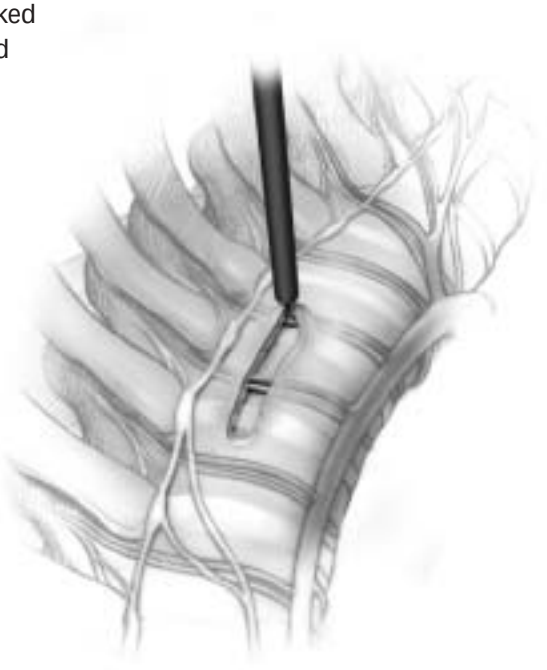


FIGURE 10

The pleura is incised longitudinally along the entire length of the spine to be instrumented. The hook bovie is placed on the pleura over a disc and an opening is made. The hook is then inserted under the pleura and the pleura is elevated and incised. With this technique the pleura can be incised along the entire length without injury to the segmental vessels (Figure 10). Suction is used to evacuate the smoke from the chest cavity. The pleura is then dissected off the vertebral bodies and discs, anteriorly off of the anterior longitudinal ligament and posteriorly off the rib heads using a peanut or endoscopic grasper (Figure 11).

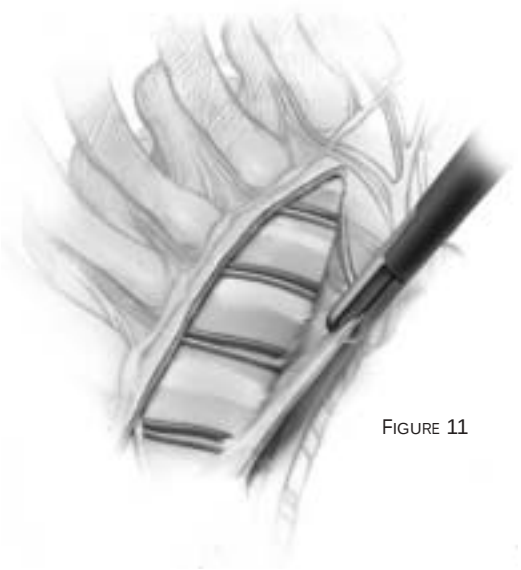


FIGURE 11

STEP ONE

A Guidewire is placed into the disc space and C-Arm images are used to confirm the level. The electrocautery is then used to incise the disc annulus (Figure 12).

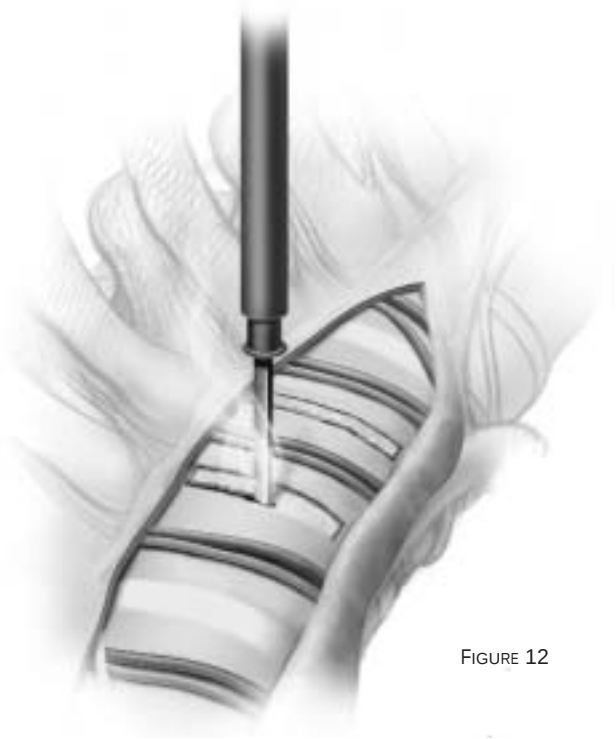


FIGURE 12

STEP ONE

The disc is removed in standard fashion, using various endoscopic curettes, pituitarys, cobbs, and kerrison rongeurs (Figures 13, 14A, 14B and 15). Discectomy Shavers and Rasps can also be used to assist in the discectomy. Once the disc is completely removed, the anterior longitudinal ligament is thinned from within the disc space with a pituitary. The ligament is thinned to a flexible remnant that is no longer structural, but will contain the bone graft. Posteriorly the disc and annulus are removed back to at least the rib head. A Kerrison Rongeur should be used to remove annulus posterior to the rib heads. **The rib head should be left intact, at this point, since it will be used to guide screw placement.**

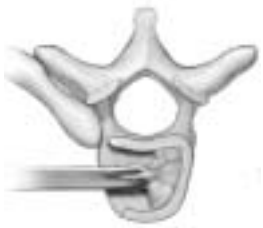


FIGURE 14A

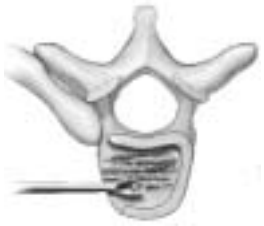


FIGURE 14B

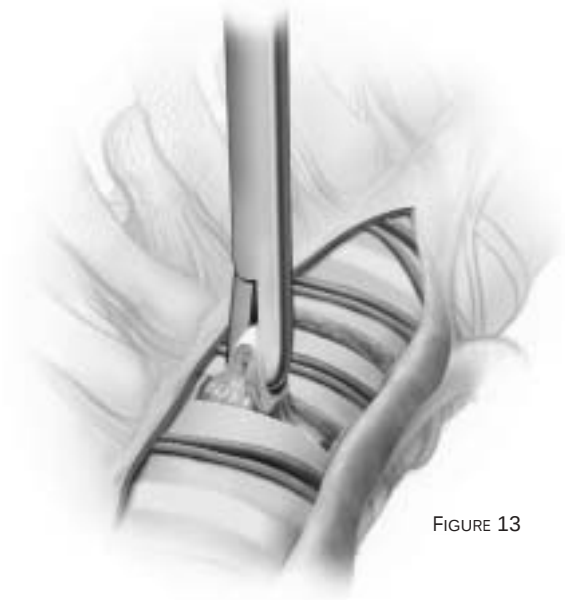


FIGURE 13

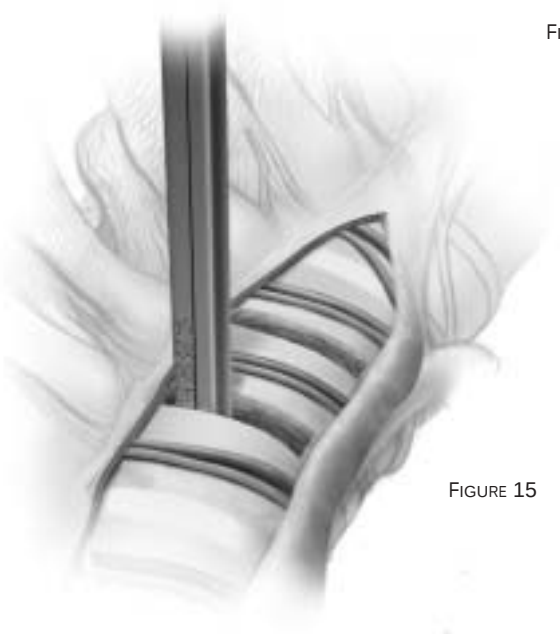


FIGURE 15

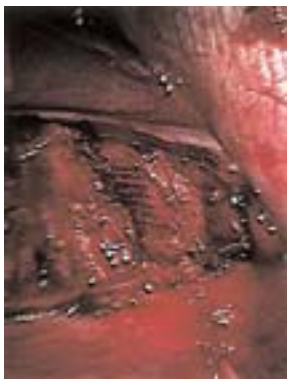


FIGURE 16

Once the disc has been evacuated, the endplate is then completely removed and the disc space can be inspected directly with the scope (Figure 16). The disc space is then packed with SurgicelI to control endplate bleeding.

Once all of the discs have been removed, the portals are removed and rib graft is harvested. An Army/Navy is utilized to stabilize the rib. The portal is retracted anteriorly as far as possible. The rib is then dissected subperiosteally. Dissection is then carried posteriorly as far as the portal can be retracted. Utilizing the endoscopic rib cutter, **two vertical cuts are made through the superior aspect of the rib.** The incisions are perpendicular to the rib and extend halfway across the rib. An osteotome is then used to connect the two previous incisions while using the retractor to support the rib. The rib section is removed and morsilized. Three to four other rib sections are removed in similar fashion until enough bone graft has been obtained (Figures 17 and 18). This technique will produce an adequate amount of graft and preserves the integrity of the rib, thus protecting the intercostal nerve and decreasing post-operative pain.

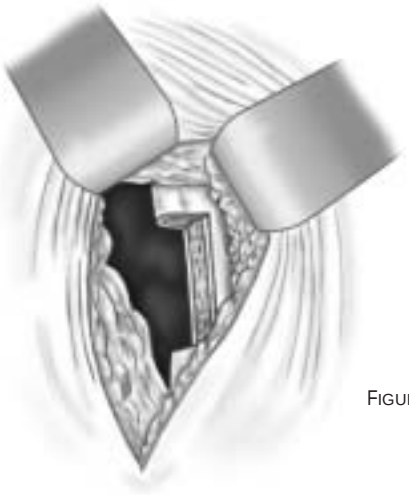


FIGURE 17

If the patient has a large chest wall deformity, thorascopic thoracoplasties can be performed and the rib sections can be utilized for graft. One should not remove the rib heads at this time, since they will function as landmarks for screw placement.

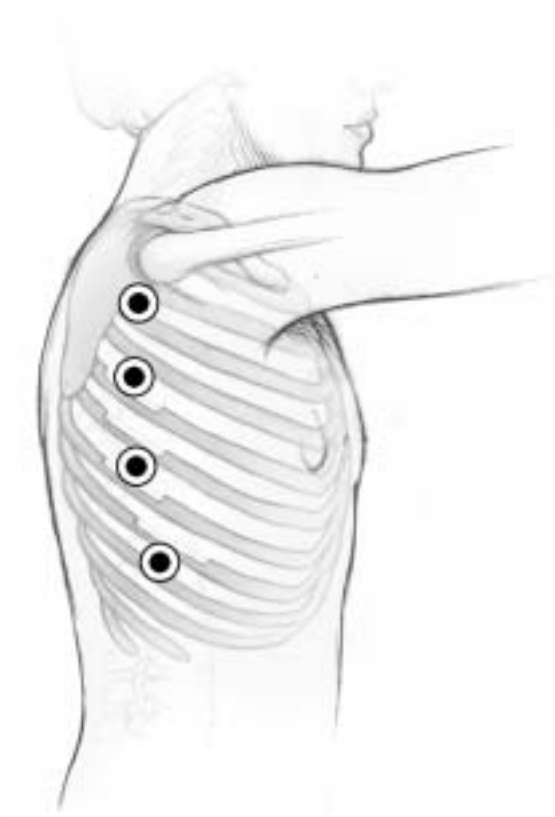


FIGURE 18

STEP THREE

The C-Arm is placed into the operating field and positioned at the superior most vertebral body to be instrumented. **It is imperative to have the C-Arm parallel to the spine to give an accurate image.**

The vessels are located in the valley or middle of the vertebral body and serve as an anatomical guide for screw placement. The segmental vessels are grasped and ligated at the mid-vertebral body level with the electrocautery (Figure 19). Larger segmental vessels and the Azygous system may be hemoclipped and cut if necessary. **The patient positioning is again checked to ensure they are still in the direct lateral decubitus position.**

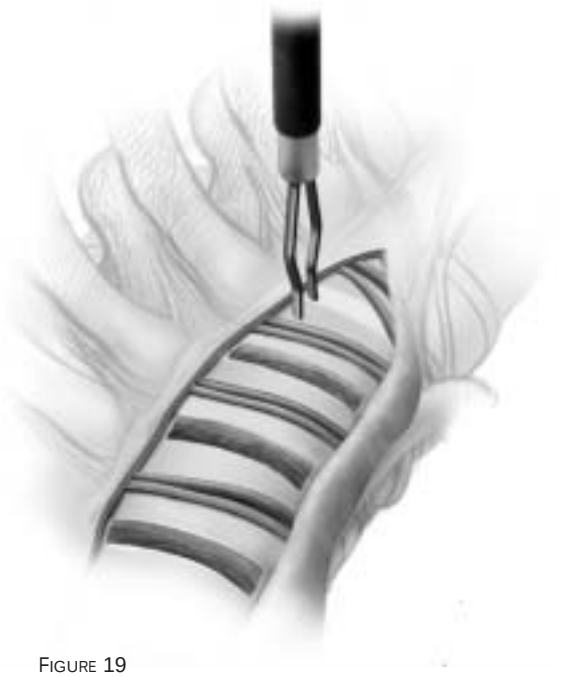


FIGURE 19

STEP THREE

The Wire Guide is placed onto the vertebral body just anterior to the rib head (Figure 20). The position is checked with the C-Arm to verify that the wire will be parallel to the endplates and in the center of the body. (Figure 21). The inclination of the guide is checked in the lateral plane by examining the chest wall and the rotation. The guide should be in a slight posterior to anterior inclination. This will direct the wire away from the canal. If there is any doubt or concern about the anterior inclination, a lateral C-Arm image should be obtained to verify position. Once the correct alignment of the guide has been attained, the Guidewire is inserted into the cannula of the Wire Guide that is positioned most centrally on the vertebral body (Figure 22). Drill the Guidewire to the opposite cortex, ensuring it is parallel to the vertebral body. The position is confirmed with the C-Arm as the wire is inserted. Care must be taken so the wire is not drilled through the opposite cortex. This can result in injury to the segmental vessels and the lung on the opposite side.

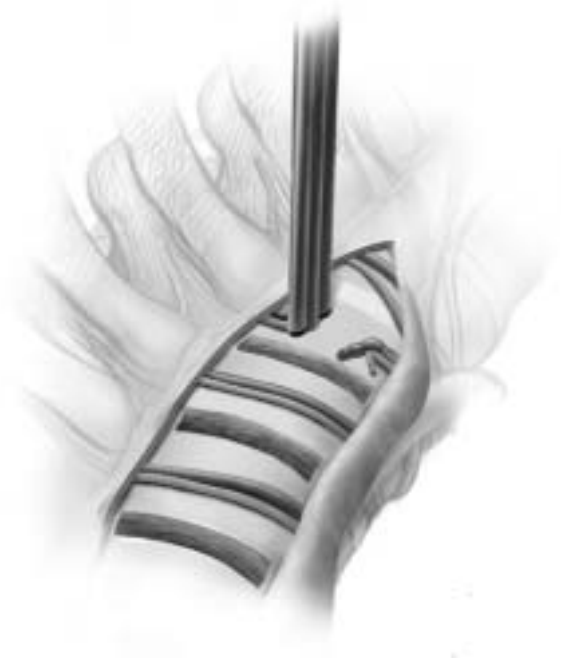


FIGURE 20

FIGURE 21

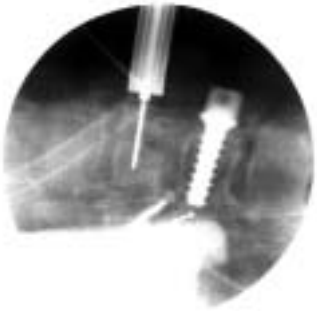


FIGURE 22

STEP THREE

The most superior mark on the Guidewire presents a length of 50mm and the etched lines are at 5mm increments. The length of the Guidewire in the vertebral body can be determined by these marks. Start at the 50mm mark and subtract 5mm for each additional mark that is showing. For example, if there are 4 marks, in addition to the 50mm mark, the length of Guidewire would be 30mm. The calculation for this would be 50-5-5-5-5. The 5mm subtractions are for the 4 marks showing (Figure 23).

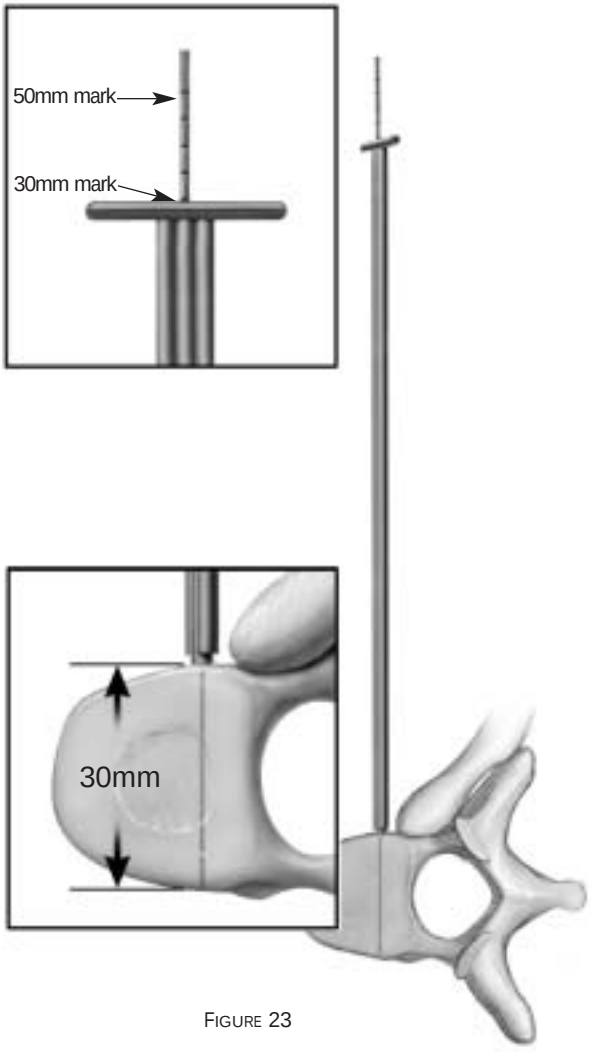


FIGURE 23

STEP THREE

The Wire Guide is removed and the starting awl is placed over the Guidewire. The awl is inserted through the proximal cortex. Upon removal of the awl, the tap is now placed over the Guidewire onto the vertebral body. The largest diameter tap that will fit in the vertebral bodies, based on the pre-operative x-rays, should be used to maximize fixation strength. The distal end of the Guidewire is grasped with a clamp (Figure 24) and held as the Awl and Tap are inserted so the wire will not advance. This is important in order to avoid a pneumothorax in the opposite chest cavity. Only the near cortex is tapped (Figure 25). The C-Arm should be used to monitor tap depth and Guidewire position.

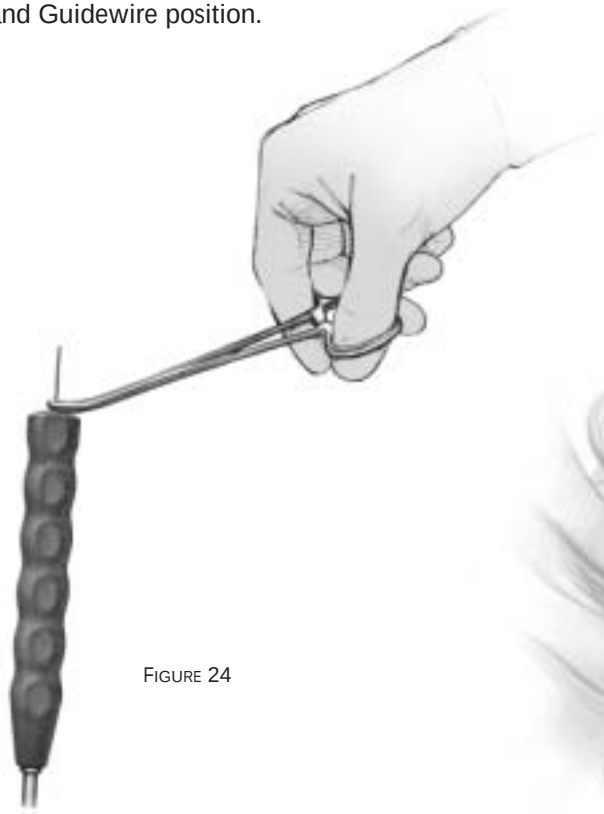


FIGURE 24

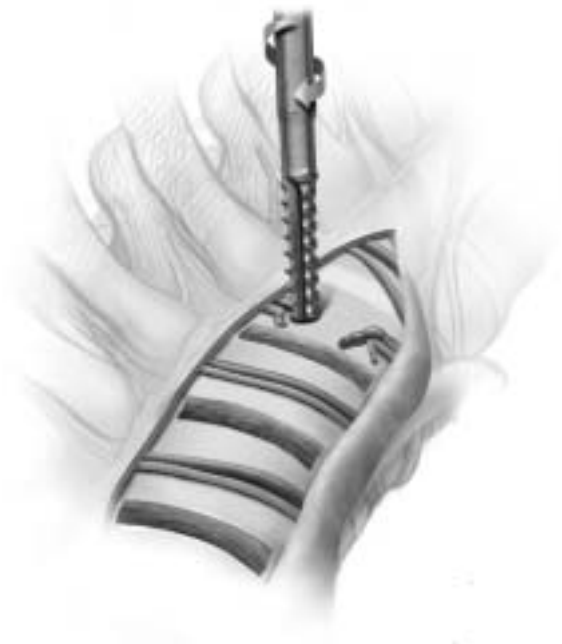


FIGURE 25

STEP THREE

The appropriate sized screw, based on the Guidewire measurement and tap diameter, is placed over the Guidewire with the Eclipse Screwdriver and advanced (Figure 26). One should select a screw that is 5mm longer than the width of the vertebral body, as measured with the Guidewire, to ensure bicortical fixation. The Guidewire is again grasped to avoid advancement while the screw is inserted. The Guidewire is removed when the screw is approximately 50% across the vertebral body. The screw direction is checked with C-Arm as it is advanced and seated against the vertebral body (Figure 27). The screw should penetrate the opposite cortex for bicortical fixation. All Cobb levels should be instrumented.

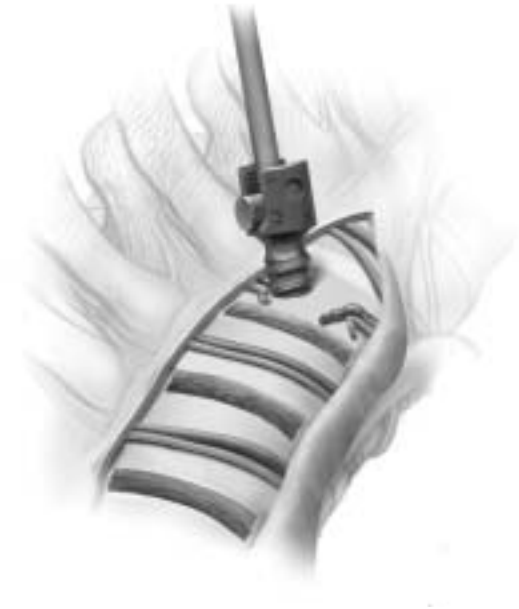


FIGURE 26

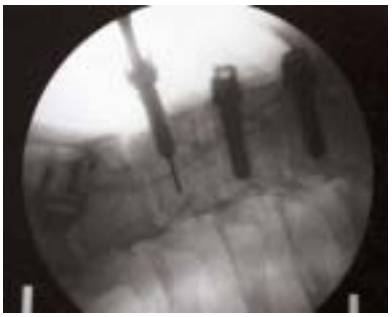


FIGURE 27

STEP THREE

Using each rib head as a reference for subsequent screw placements helps ensure the screws are in line and yield proper spinal rotation when the Rod is inserted. Properly aligned screws will have the screw heads aligned in an arc. This alignment can be verified with a lateral image (Figure 28).

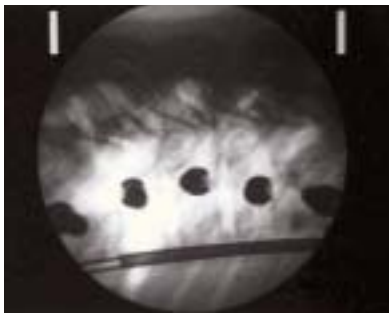


FIGURE 28

The side walls of the screws (saddles) are adjusted to be in line for receipt of the Rod (Figure 29). If a screw is sunk more than a few millimeters deeper than the rest of the screws, reduction of the Rod into the screw head may be difficult. The C-Arm image can clearly show this as the screws are being inserted.

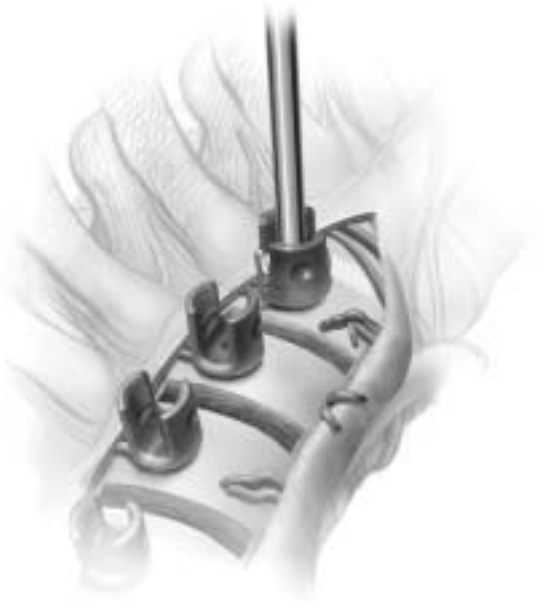


FIGURE 29

STEP THREE

Once all the screws have been placed the Surgicell is removed and the graft is inserted. The graft is delivered to the disc space using the Funnel and Plunger (Figures 30 and 31). The disc space should be filled all the way across to the opposite side.

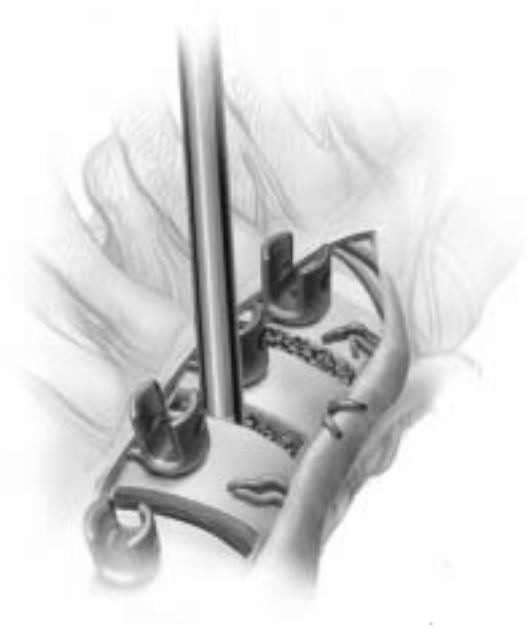


FIGURE 30

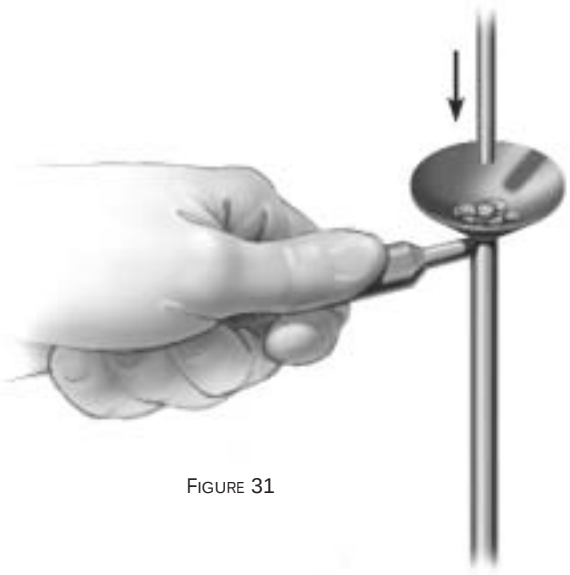


FIGURE 31

The Rod length is determined with the Length Gage. The fixed ball at the end of the measuring device is placed into the saddle of the inferior screw. The ball at the end of the cable is then guided through all of the screws with a pituitary to the superior most screw and inserted into the saddle (Figure 32). The cable is then pulled tight and a reading is taken from the scale (Figure 33). The scale is in centimeters.

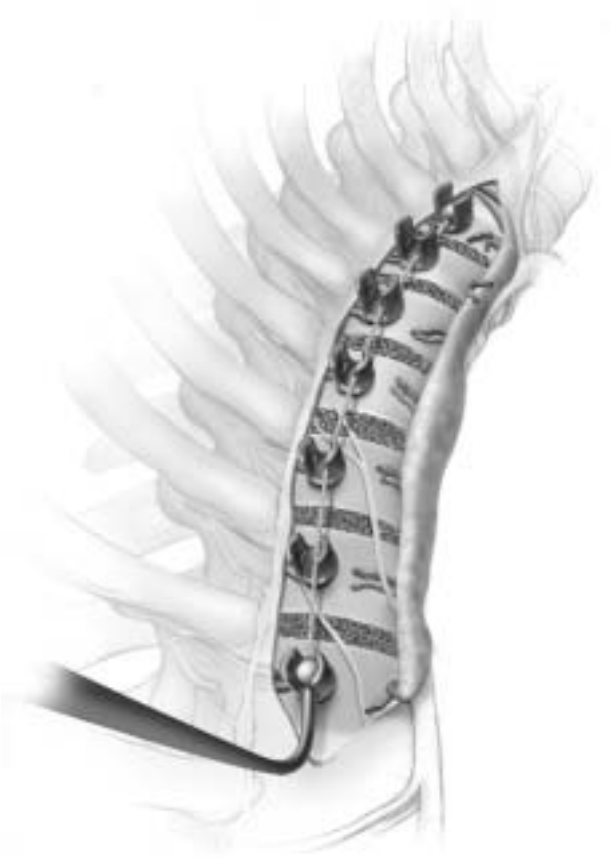


FIGURE 32

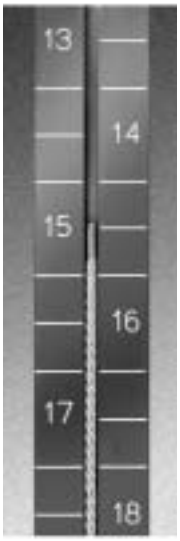


FIGURE 33

ROD MEASUREMENT AND PLACEMENT

STEP FOUR

The 4.5mm Rod is then cut to length and inserted into the chest cavity through the inferior most port. The Rod has a slight flexibility and is not bent prior to insertion. With the anterior compression, kyphosis is obtained in the thoracic spine. Do not cut Rod longer than measured since the total distance between the screws will be reduced with compression. The Rod is manipulated into the inferior screw with the Rod Holder (Figure 34). The end of the Rod should be flush with the saddle of the screw. This is done to prevent the Rod from protruding and irritating or puncturing the diaphragm. Once the Rod is in place, the portal is removed and the Plug Introduction Guide is placed over the screw to guide the plug and hold the Rod into position (Figure 35). The Tube Introducer can be placed in the Introduction Guide to assist in the insertion through the incision.

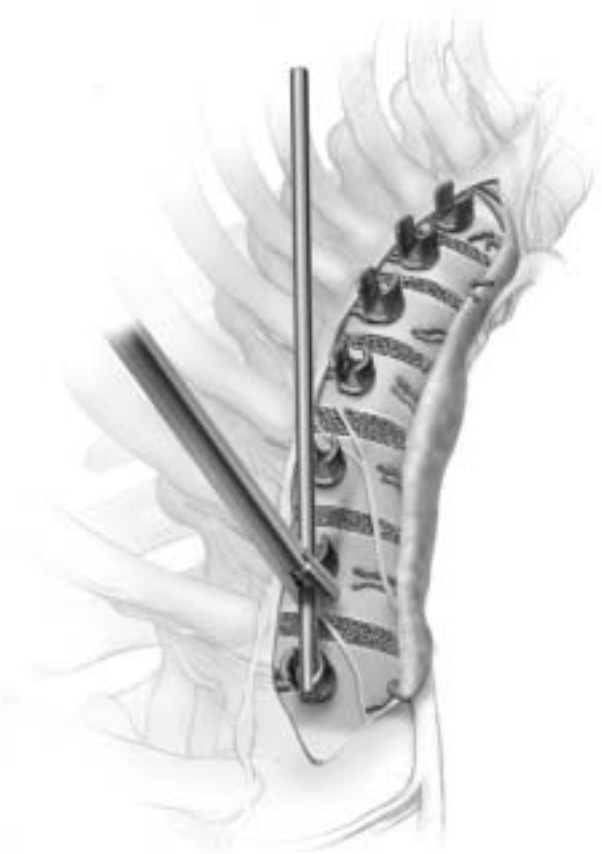


FIGURE 34

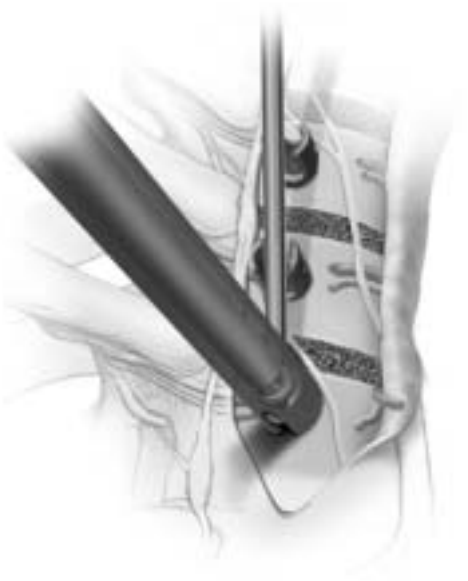


FIGURE 35

STEP FOUR

The plug is loaded onto the Plug Capturing T25 Driver (Figure 36). The plug must be inserted with the laser etched side facing the handle. Once the plug is placed on the driver turn the sleeve clockwise to engage the plug with the sleeve. The Plug Driver is then placed through the Plug Introduction Guide and inserted into the screw. The plug should not be placed without using the Introduction Guide and the Plug Driver. One turn counter clockwise before advancing the plug will assist in ensuring proper threading. Once the plug has been correctly started, hold the locking sleeve to prevent any further rotation. This will disengage the plug from the Driver as the plug is inserted into the screw (Figure 37). Remove the Driver and Introduction Guide and torque the screw with the Torque Limiting Driver. This is the only plug that is tightened completely at this time.

FIGURE 36

FIGURE 37

STEP FOUR

The Rod is then sequentially reduced into the remaining screws using the Rod Pushers (Figure 38). The Rod Pushers should be placed on the Rod several screws above the screw that the Rod is being reduced into. This will assist in Rod reduction. The plugs are applied through the Plug Introduction Guide as described previously. These plugs should not be fully tightened at this time in order to allow for compression.

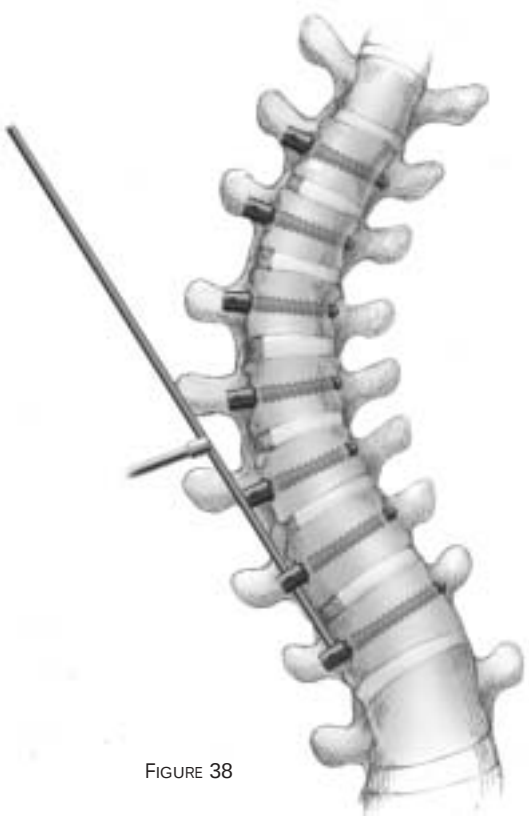


FIGURE 38

COMPRESSION

Once the Rod has been seated and all the plugs inserted into the screws, compression between the screws is performed. Compression of the construct must be performed. There are two styles of compressors.

COMPRESSION-RACK AND PINION

The Compressor is inserted through one of the portal sites with the portal removed. Once in the thoracic cavity, it can be manipulated by holding the ball shaped attachment with the Rack and Pinion Compressor Holder. The Rack and Pinion Compressor fits over two screw heads on the Rod and can be compressed by turning the Compressor Driver clockwise and compressing the two screws together (Figure 39). Compression is started at the inferior end of the construct with the most inferior screw's plug fully tightened. Once satisfactory compression has been performed on a level the superior plug is fully tightened using the Plug Driver through the Plug Introduction Guide. Compression is sequentially performed superiorly until all levels have been compressed. After all levels are compressed each plug is torqued to 75 in-lbs. with the Torque Limiting Driver. The construct is complete at this point (Figures 40A and 40B).

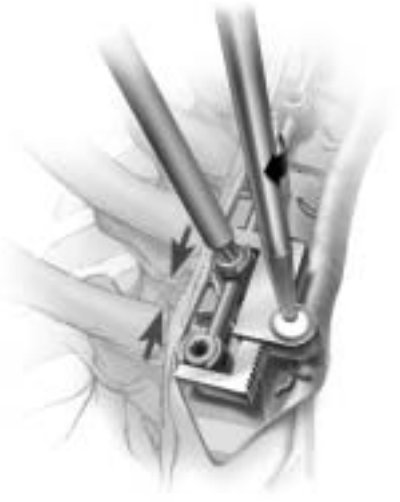


FIGURE 39

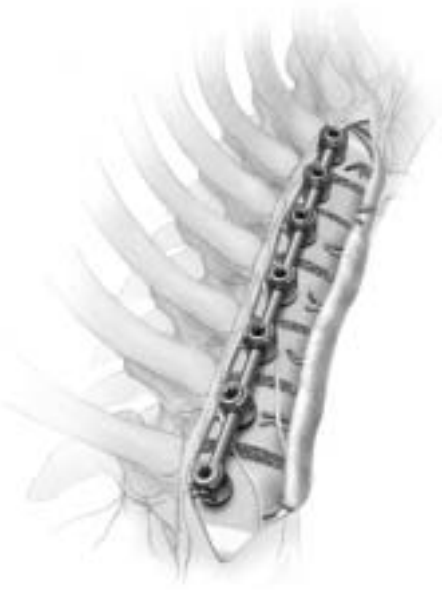


FIGURE 40A

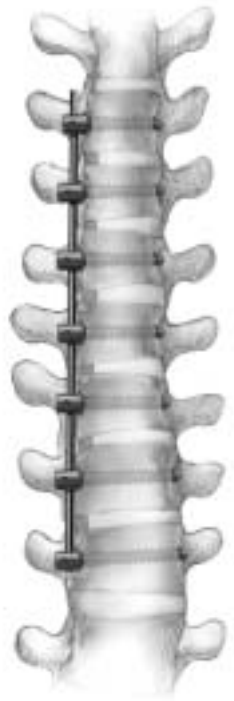


FIGURE 40B

STEP FIVE B

ASSEMBLY

The cable is inserted through the two distal holes in the guide. The Actuator (Figure 41 A) should be in the position closest to the compressor body (Figure 41). A three inch long loop should be formed at the end of the Compressor (Figure 41 B). The two cable ends should pass through the actuator body. The lever arm is then engaged using one of the Plug Drivers through the cam mechanism (Figure 42).

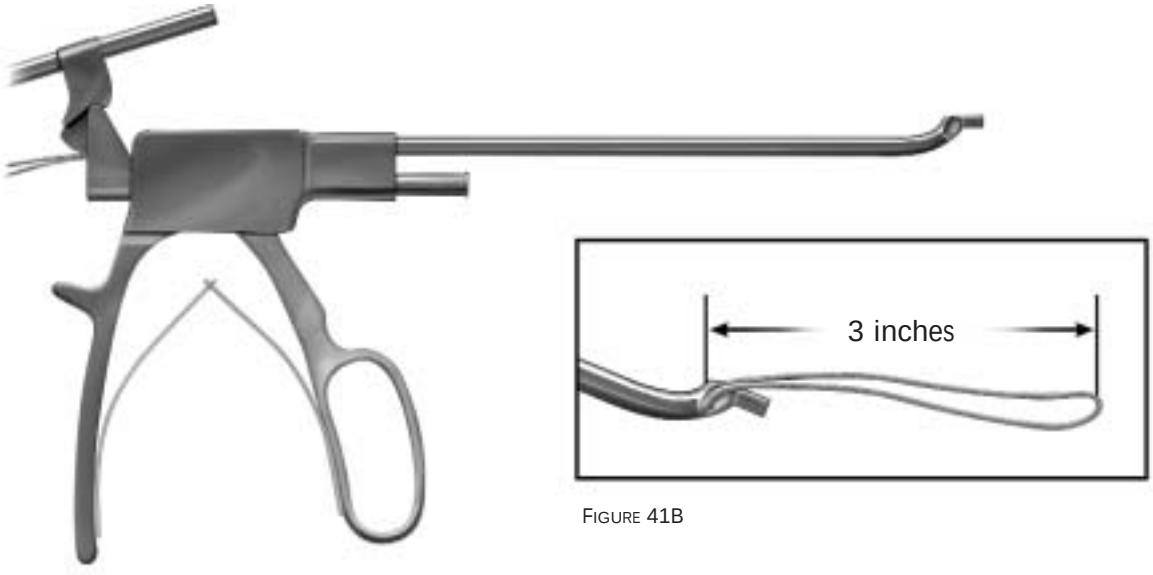


FIGURE 41B

FIGURE 41

FIGURE 41A

FIGURE 42

COMPRESSION

The end of the Cable Compressor is placed through the distal portal. A Plug Introduction Guide is placed through the adjacent incision, with the portal removed, through the loop and over the next screw to be compressed. The foot of the Compressor is then placed over the Rod and against the inferior side of the end screw (Figure 43). The plug in the end screw should be fully tightened. The handle of the Compressor is then squeezed several times to compress. Once satisfactory compression has been performed on a level the superior plug is fully tightened using the Plug Driver through the Plug Introduction Guide.

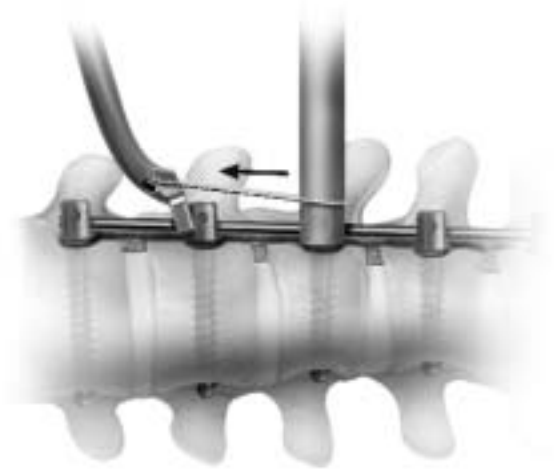


FIGURE 43

STEP FIVE B

COMPRESSION

To disengage the Cable Compressor tilt it towards the superior screw until the foot disengages from the inferior screw. Turn the actuator mechanism 90 degrees to disengage the Actuator (Figure 44). With the cable loop still around the Plug Introduction Guide that is on the superior screw, pull the Cable Compressor until the Actuator is next to the compressor body. The steps described above are then repeated on subsequent screws. Compression is sequentially performed superiorly until all levels have been compressed. After all levels are compressed each plug is torqued to 75 in-lbs. with the Torque Limiting Driver. The construct is complete at this point.

FIGURE 44

A #20 French chest tube is placed through the inferior portal and the incisions closed. A/P and lateral x-rays are obtained and the patient transferred to the recovery room.

POST-OPERATIVE REGIMENT

Chest tube is left in until drainage is less than 100 cc's/8hrs. Patients can be ambulated post-operative day one and are discharged the day after the chest tube is removed.

Patients should be braced for 3 months.

IMPORTANT INFORMATION

IMPORTANT INFORMATION ON THE CD HORIZON® SPINAL SYSTEM

PURPOSE:

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION:

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other MEDTRONIC SOFAMOR DANEK spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other MEDTRONIC SOFAMOR DANEK spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers, GDLH, rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS™ bolts. Please note that certain components are specifically designed to connect to Ø 4.5mm, Ø 5.5mm, or Ø 6.35mm rods, while other components can connect to both Ø 5.5mm rods and Ø 6.35 mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE™ rods and screws are intended for anterior use only.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. **Never use stainless steel and titanium implant components in the same construct.**

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium implants only. Do not use with stainless steel.

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another MEDTRONIC SOFAMOR DANEK document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS: When used in a percutaneous posterior approach with the SEXTANT instrumentation, the CD HORIZON® CANNULATED M8 MULTI-AXIAL SCREW components are intended for the following indications:

When used as a posterior spine thoracic/lumbar system, the CD HORIZON® CANNULATED M8 MULTI-AXIAL SCREW components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., degenerative scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CD HORIZON® CANNULATED M8 MULTI-AXIAL SCREW components are also indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

The CD HORIZON® ECLIPSE™ components are intended for the following indications:

When used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® system is also intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immuno-compromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.
17. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without in-strumentation are possible. With instrumentation, a list-ing of potential adverse events includes, but is not limited to:

1. Early or late loosen-ing of any or all of the compo-nents.
2. Disassembly, bend-ing, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor forma-tion, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tis-sue cov-erage over the implant possibly causing skin pene-tration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal cur-vature, loss of cor-rection, height, and/or reduc-tion.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthe-sias, hyperesthesia, anesthesia, paresthesia, appear-ance of radiculopa-thy, and/or the de-velopment or con-tinuation of pain, numb-ness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or be-low the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseud-arthrosis). Delayed union. Mal-union.
15. Cessation of any poten-tial growth of the operated por-tion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shield-ing.
19. Graft donor site compli-cations including pain, fracture, or wound heal-ing problems.
20. Ileus, gastri-tis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleed-ing, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of con-sortium, and sexual dysfunction.
23. Development of respira-tory problems, e.g. pul-monary embolism, atelectasis, bron-chitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown.

PRECAUTION: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect

IMPORTANT INFORMATION

the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Implant Selection :

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length neededf the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.
6. **Caution:** Do not overtap or use a screw/bolt that is either too long or too large. Overtapping or using an incorrectly sized screw/bolt may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
9. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
10. Before closing the soft tissues, all of the nuts or screws should be tightened firmly. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Also, certain instruments may require dismantling before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such, the CD HORIZON® Spinal System components, as well as those implants from other MEDTRONIC SOFAMOR DANEK spinal systems specifically indicated for use with the CD HORIZON® Spinal System, described in this insert are provided non-sterile and must be sterilized prior to use. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

NOTE: The following note applies to the process parameter identified with the ** below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	250° F (121° C)	30 Minutes
**Steam	Gravity	273*F (134*C)	18 Minutes
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted CD HORIZON, Spinal System component(s) ever "malfunctions". (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

In case of complaint , or for supplementary information, or further directions for use of this system, please see the address page on this information sheet.

NOTES

For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA Customer Service toll free: 800-933-2635.

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See package insert for labeling limitations.

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