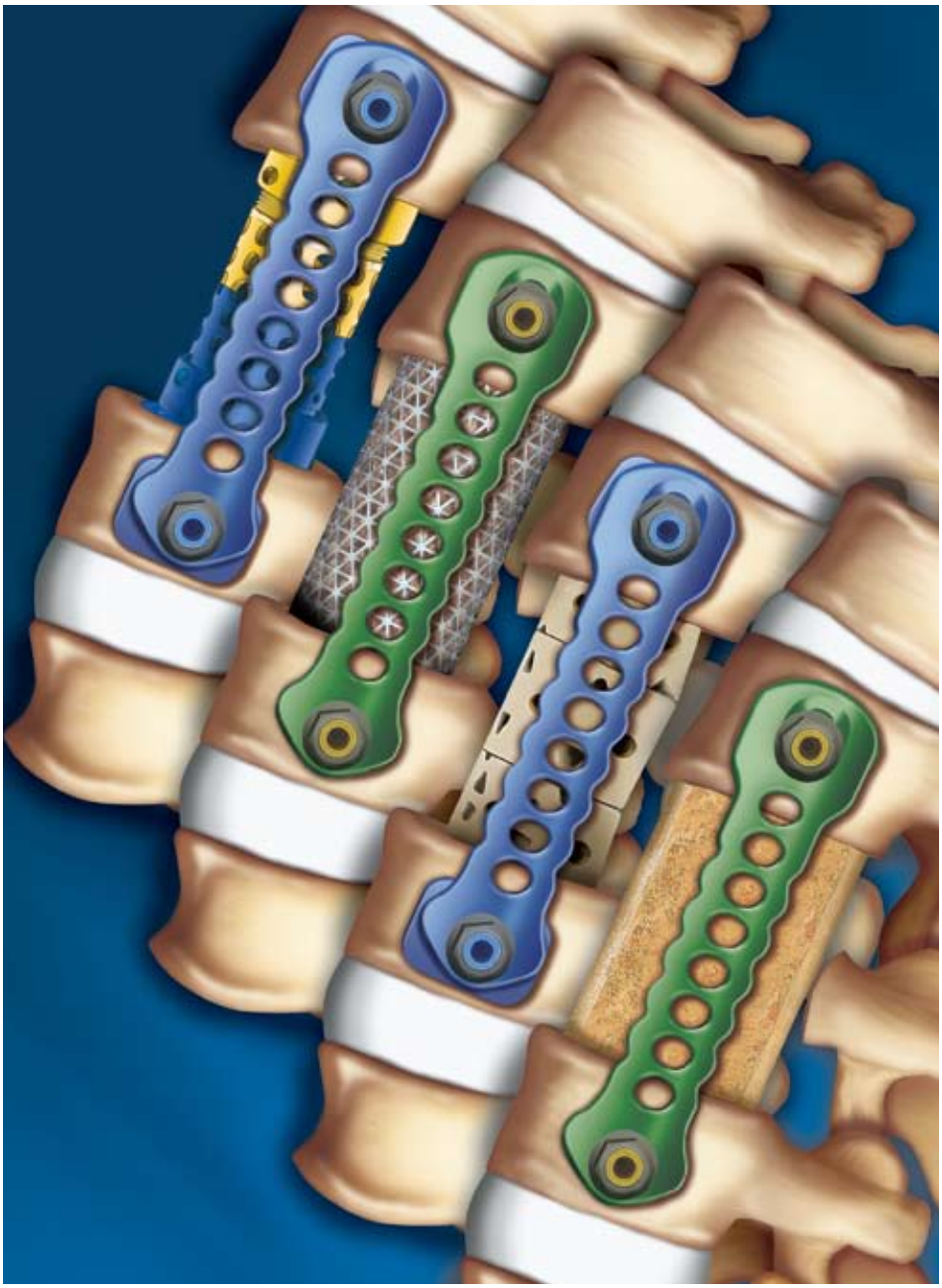
Medtronic

VANTAGE™ Anterior Fixation System

Surgical Technique



As described by:

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MICHELSON TECHNOLOGY AT WORK

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Implant Features and Benefits

Staples:

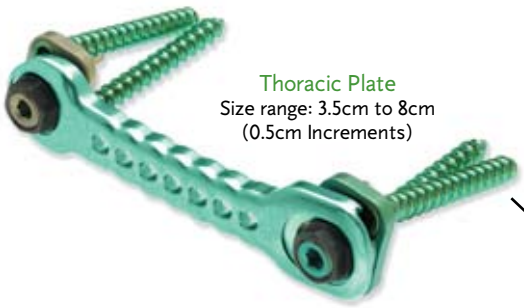
- Color-coded for anatomical placement
- Low profile
- Medial prongs
- Splines for rigid fixation to plate
- Interchangeable with plates (thoracic or lumbar)
- Allows for 10° of screw angulation

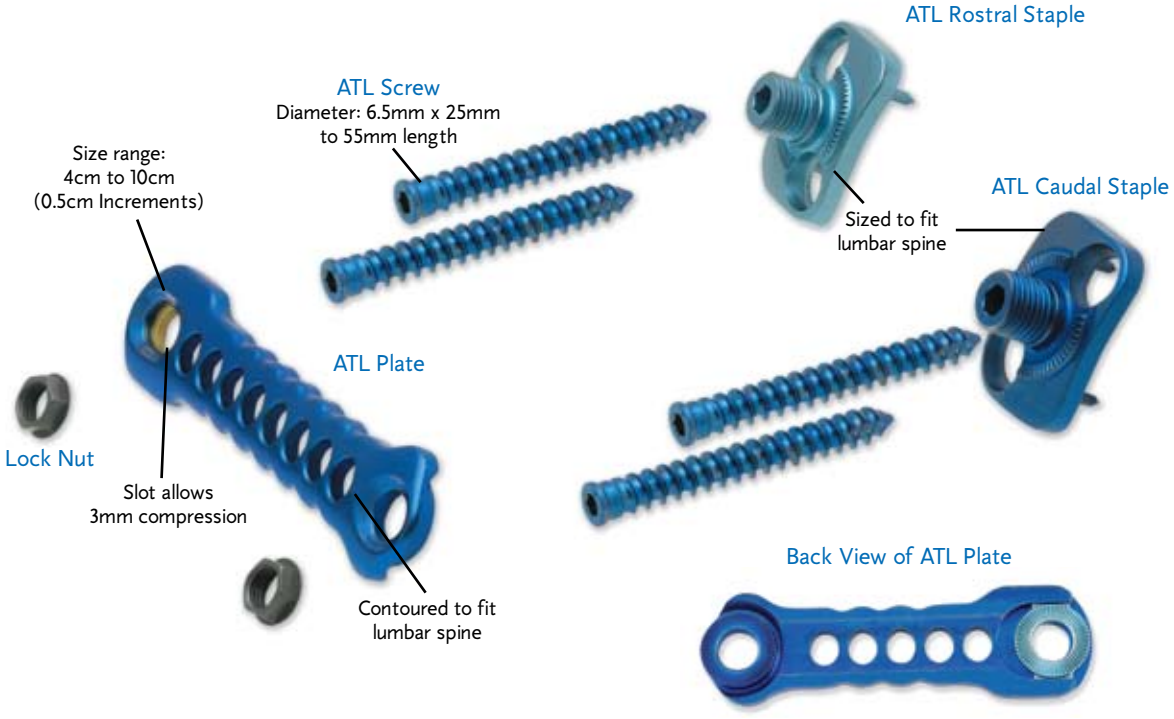
Screws:

- Self-tapping
- Cutting flute for easy insertion
- Color-coded for anatomical placement
- Internal hex for flush fitting
- Easy-to-start thread design
- Top-loading, top-tightening

Plates:

- Smooth surfaces
- Holes for visualization of graft
- Radial splines for rigid fixation to staple





Single Bolt:

This option is for use with the VANTAGE™ Anterior Fixation System

- Cannulated for endoscopic insertion
- Large diameter provides a versatile alternative to staples and screws
- Rigid fixation comparable, in rigidity, to a dual rod construct for corpectomy[1]
- Complements upper thoracic vertebrae when vertebral body size will not permit two staples and screws
- Can be used in the thoracic or lumbar spine
- Reduces the number of surgical steps compared to staple and screw constructs

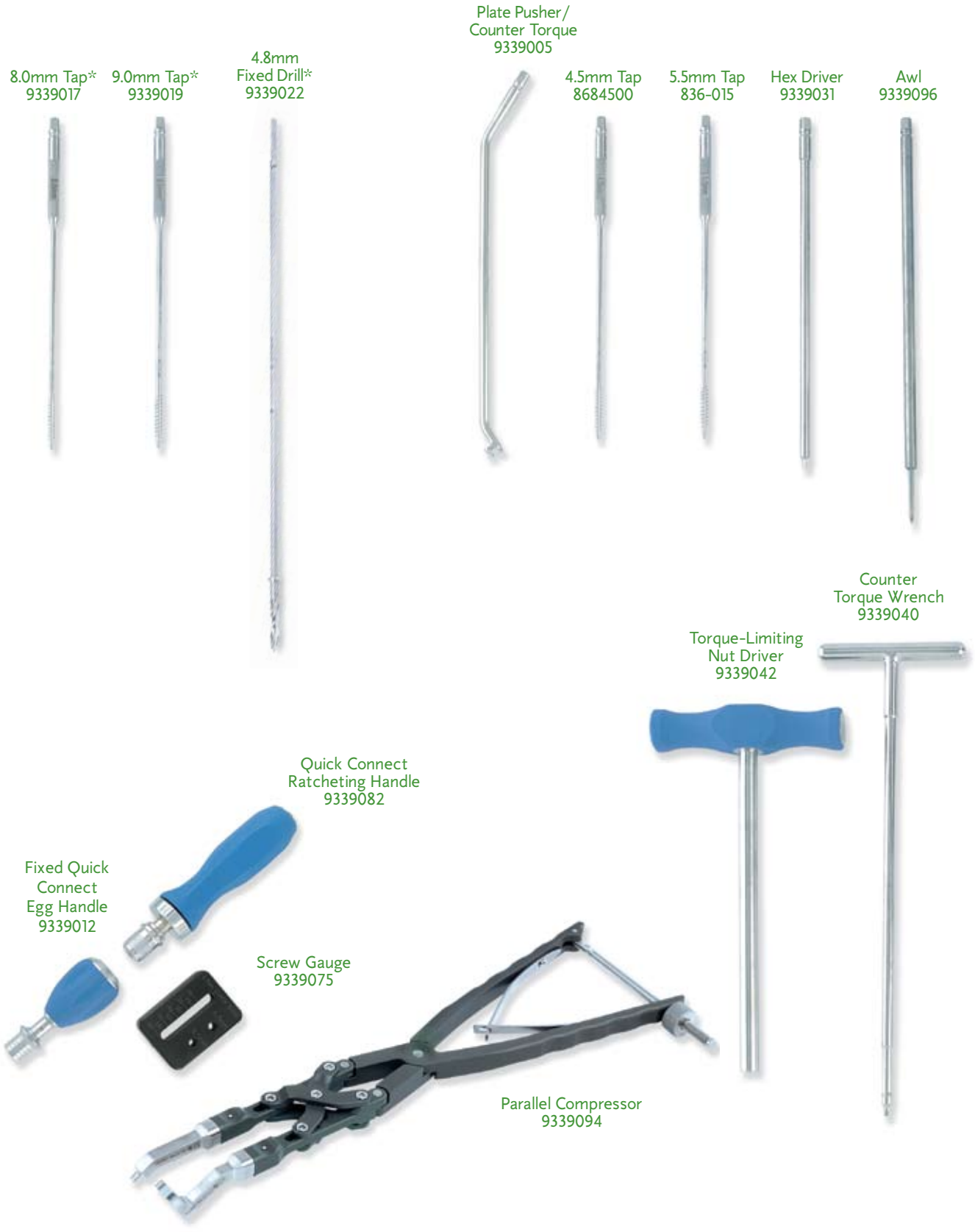
Bolts *

Diameter: 8.0mm and 9.0mm
Length: 20mm to 55mm

1 Chou D, Larios AE, Chamberlain RH, Fifield MS, Hartl R, Dickman CA, Sonntag VK, Crawford NR. A biomechanical comparison of three anterior thoracolumbar implants after corpectomy: are two screws better than one? *J Neurosurg Spine*. 2006 Mar;4(3):213-8.

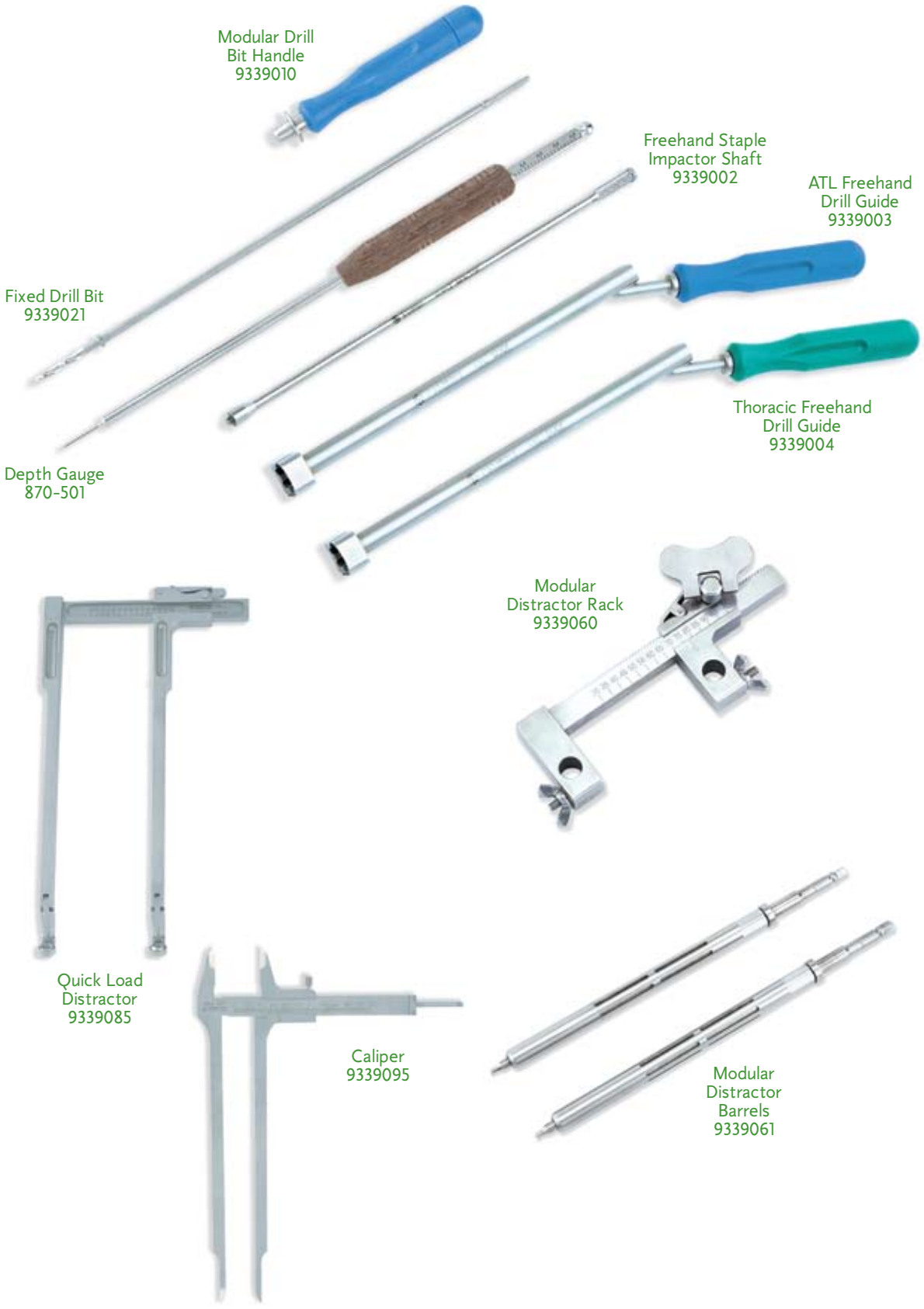
* Available in a separate set.

Instrument Set



*Available in a separate set.

Instrument Set (Continued)



VANTAGE™ Anterior Fixation System: Staple Option

When treating thoracic and thoracolumbar fractures or tumors with anterior instruments, it is important to ensure the patient is positioned in a true lateral position and that the position is maintained throughout the procedure (Figure 1). The approach can be made from the patient's left or right side. Occasionally, lateral deviation of the aorta will necessitate a right-sided approach. The preoperative axial MRI or CT should be evaluated to determine the position of the aorta relative to the spine (Figure 2). If neutral pathology essentially displaces the spinal cord toward one side, then the procedure should approach the side where the compression is greatest to avoid excessively manipulating the spinal cord.

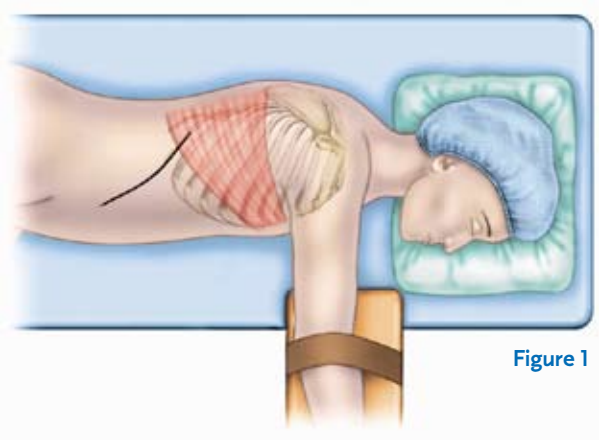


Figure 1

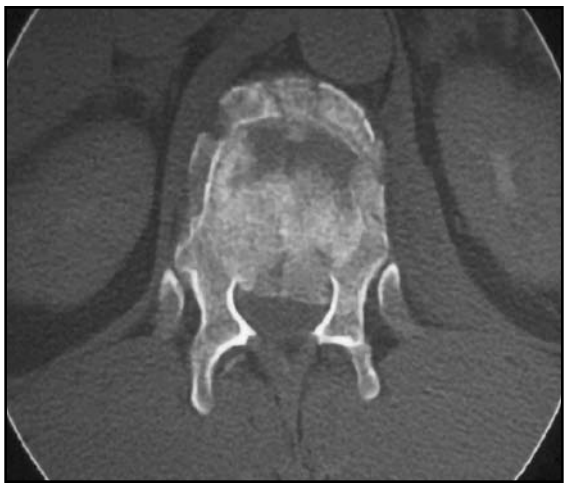


Figure 2

Surgical Approach and Exposure (Continued)

The incision depends on the level of the pathology. For thoracic segments, the rib is resected two levels above the lesion. At the thoracolumbar junction, the approach is through the bed of the tenth or eleventh rib. Checking an anterior-posterior radiograph may help determine which rib to use. Thoracolumbar lesions may require peripheral division of the diaphragm. Mid to low lumbar lesions are approached retroperitoneally.

Thoracolumbar Junction Exposure

Following a skin incision paralleling the tenth rib and transection of the latissimus dorsi muscle in line with the skin incision, the tenth rib is subperiosteally exposed, stripped, and removed. It is divided anteriorly near the costal cartilage and posteriorly back to its angle. The chest is then entered sharply and the pleura is incised (Figure 3).

Following the pleural opening, the lung is visualized and retracted. The diaphragm separates the pleural cavity from the peritoneal cavity. The entrance to the retroperitoneum is at the costal cartilage of the tenth rib (Figure 4).

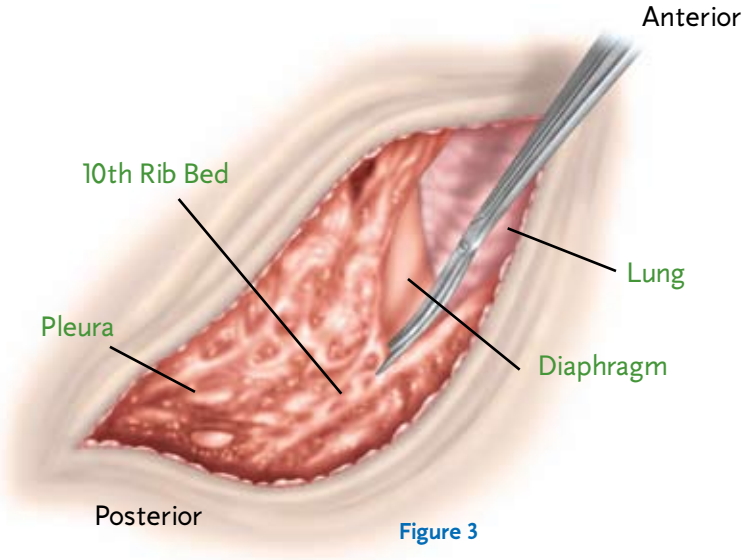


Figure 3

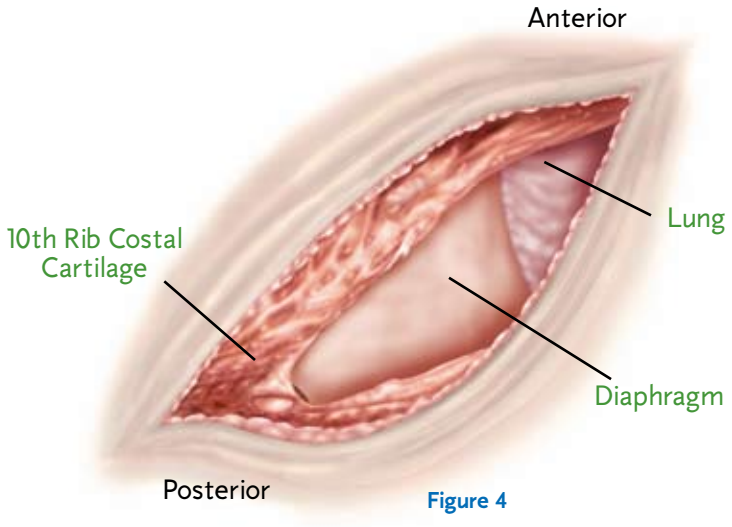


Figure 4

The peritoneum is swept off the undersurface of the diaphragm, which is mobilized to expose the spine. The diaphragm is radically incised, leaving a peripheral cuff attached to the chest wall. The edges of the diaphragm are tagged along the way for later closure (Figure 5). The diaphragm is incised down to the disc, which is then viewed between the distal edge of the pleura and the proximal portion of the psoas muscle.

Retroperitoneal contents are swept anteriorly off the proximal edge of the psoas muscle to expose the surface of the thoracic and lumbar spine (Figure 6).

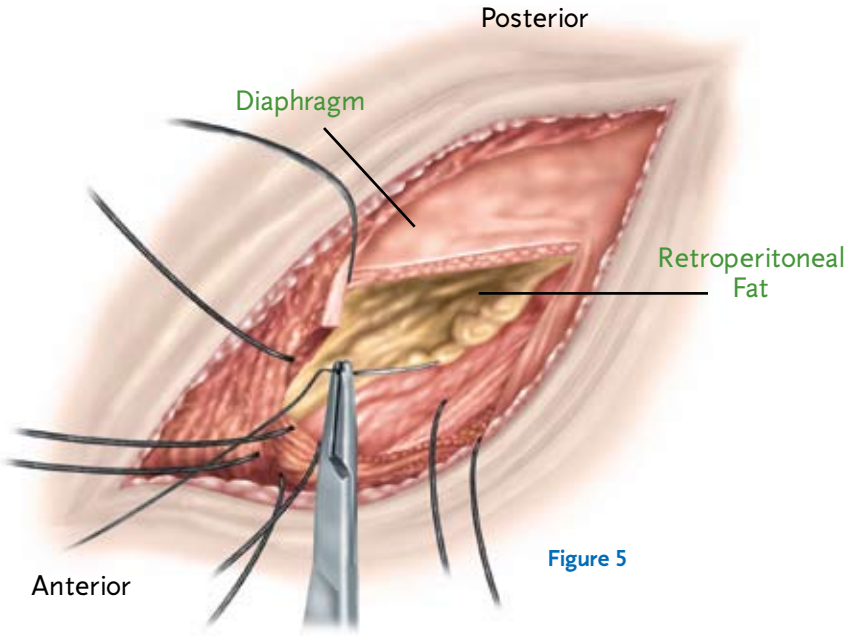


Figure 5

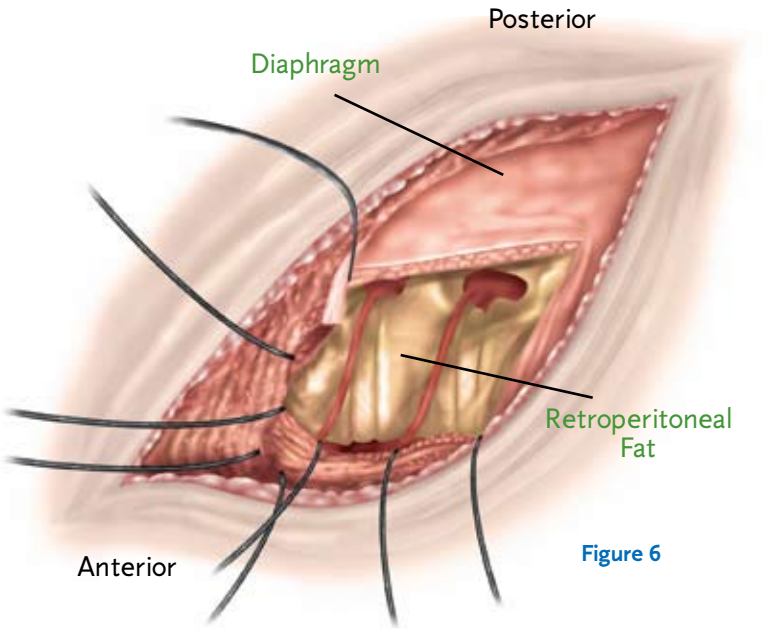


Figure 6

Following adequate confirmation of spinal levels, the segmental vessels are isolated, ligated, and divided at each vertebral body level to be included in the instrumentation and fusion. The intervertebral discs are then removed after incising the annulus.

A corpectomy is performed at the level(s) at which the spinal cord needs to be decompressed or at levels that pathology is present. This is accomplished by following the steps listed below, which are illustrated (Figure 7).

Corpectomy

1) The rib head and pedicle are removed to expose the spinal canal.
2) Discs are incised at margins of the body to be resected. The anterior and contralateral walls of the vertebral body are usually preserved in a routine corpectomy.
3) Vertebral bodies are removed with rongeurs, drills, and osteotomes.
4) The spinal cord is decompressed with microsurgical curettes to remove epidural compression.

Using a Depth/Screw Sizing Gauge, measure the coronal diameter of the vertebral body above and below the corpectomy. This distance is used to determine the length of the screws to be used. This measurement may also be performed by using the graduated scale on the preoperative MRI/CT films (Figure 8).

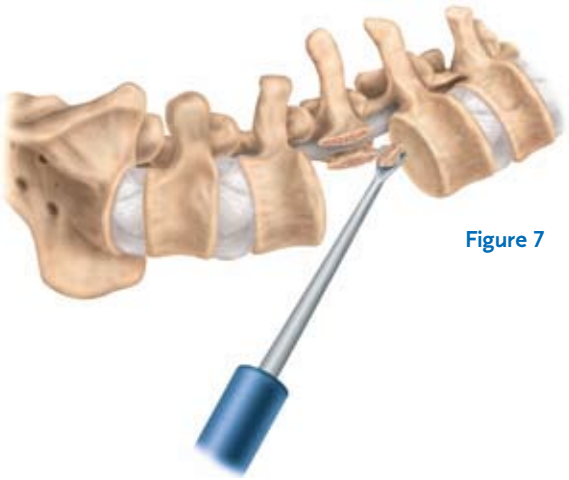
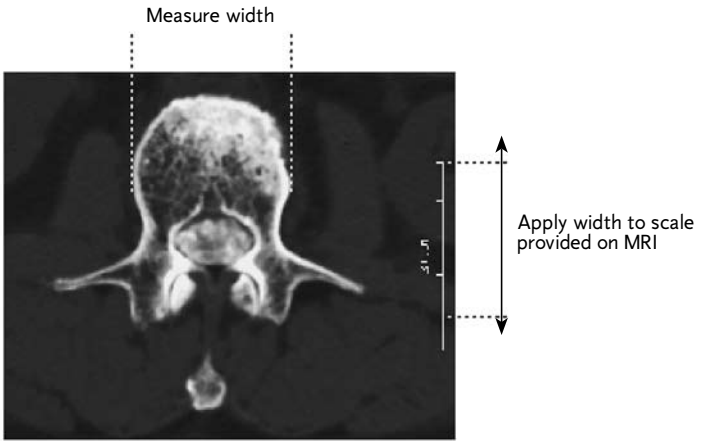


Figure 7



The screw length can also be determined by measuring the vertebral body width on a preoperative CT scan or MRI scan. Use the scale provided on the scan to accommodate magnification.

Figure 8

The appropriately sized Staple is selected, and the Staple Impactor Shaft is used to position it in place (Figure 9). Staples are available in thoracic and lumbar sizes. The colors of the Staples dictate the orientation of the Staples (dark green – caudal, light green – rostral, dark blue – caudal, and light blue – rostral). The Staples are mirror images of each other and interchangeable. Use the largest Staple that will fit within the confines of the vertebral body. The posterior margin of the Staple should be as near to the posterior edge of the vertebral body as possible (Figure 10). Impact the Staple in place using a mallet (Figure 11).

Figure 9

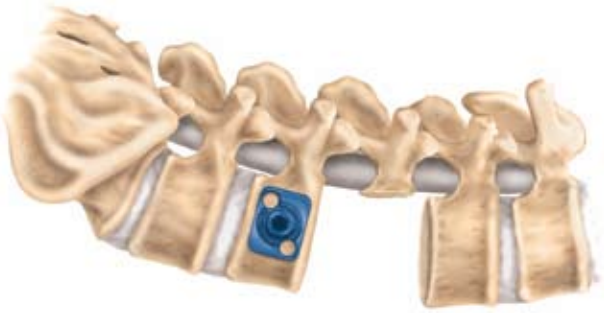


Figure 10

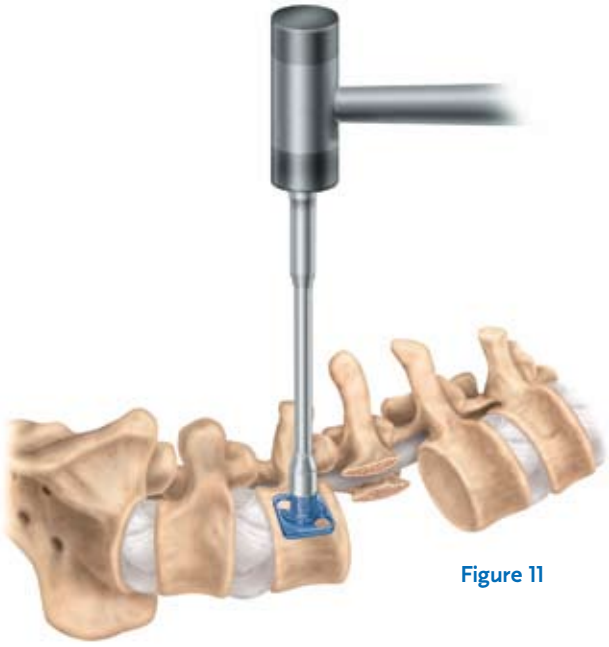


Figure 11

Staple Option—Staple Placement (Continued)

The Drill Guide is slipped over the Staple Impactor Shaft and held firmly against the Staple (Figure 12). The Staple should be flush against the vertebral body. If the Staple is not flush, removal of protruding bone with a burr may be necessary.

With the Drill Guide over the Staple, the Drill or Awl will create a trajectory for the posterior screw that is 10° anteriorly. Using the Guide for the anterior position will create a pilot hole 10° posteriorly. The screws will converge at 20° (Figure 13). After creating both pilot holes, the Drill Guide is removed. The Staple is held in place with the Staple Impactor until the Staple is secured with the Screws. The Screws are self-tapping, but if tapping is preferred, there are 4.5mm and 5.5mm Taps included in the instrument set (Figure 14).

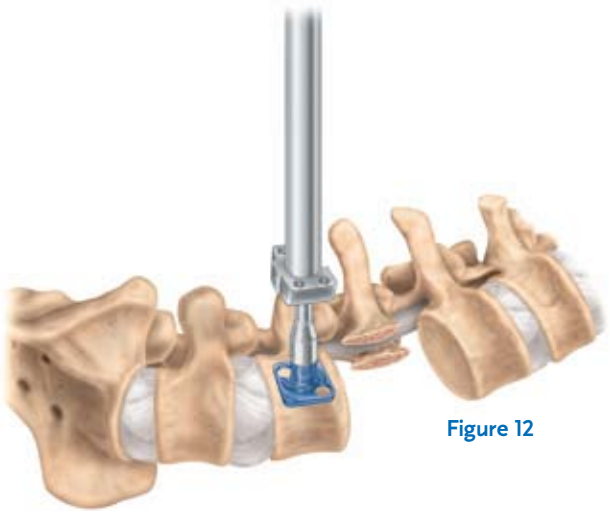


Figure 12

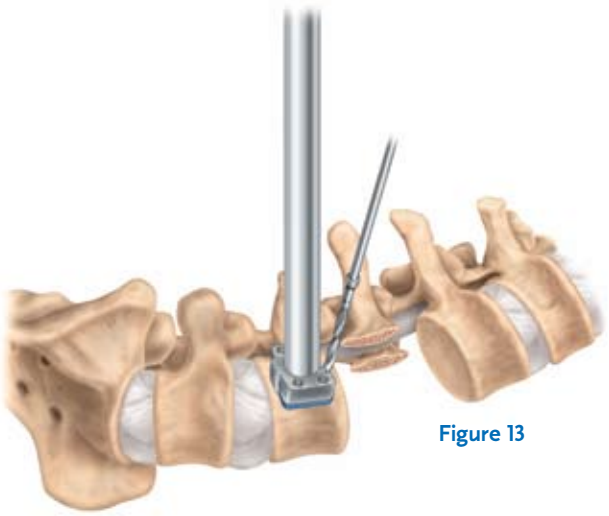


Figure 13

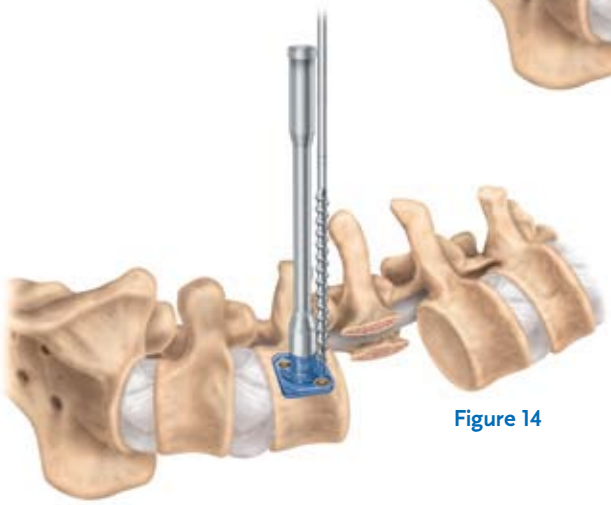


Figure 14

The Screws are then driven into the vertebral body until the head of each Screw tightens against the Staple (Figure 15). Each Screw should extend approximately one to two millimeters beyond the far cortex for bicortical fixation. Repeat the Staple and Screw insertion process for the next Staple (Figure 16).

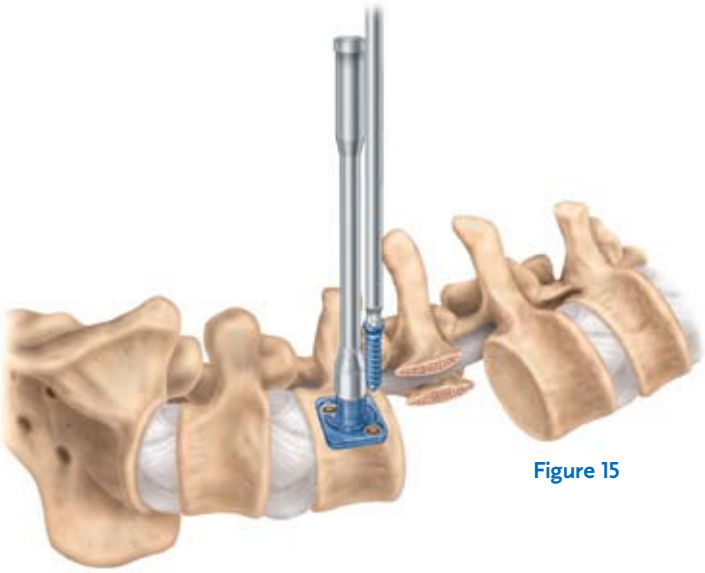


Figure 15

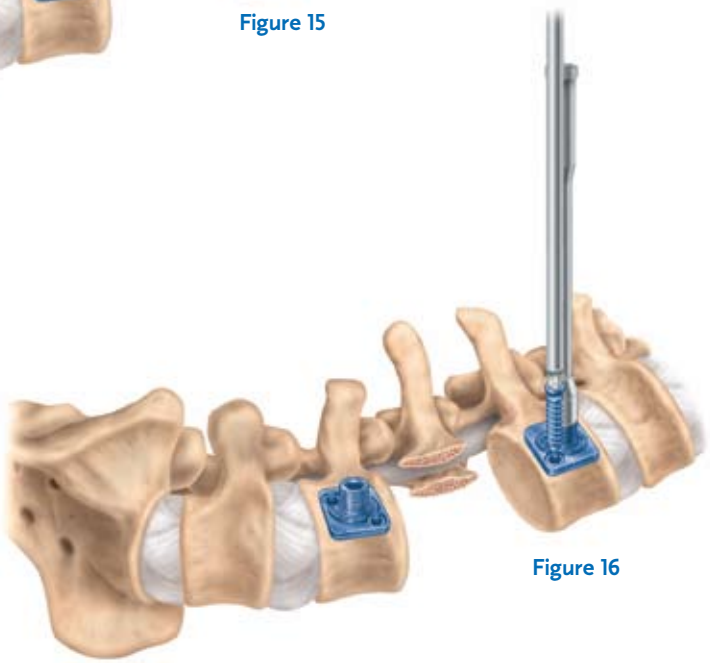


Figure 16

Staple Option—Reduction, Graft Measurement, and Placement

For simple or minimal reduction, the Quick Load Distractor may be used. Load the arm rings over the Staple posts of the rostral and caudal Staples (Figure 17). A distractive force is placed against the heads until the desired reduction is achieved. Once reduction has been achieved, the Measuring Caliper may be used to determine the required graft length (Figure 18).

After careful selection, measurement, and placement of the graft into the corpectomy site, distraction is released. Depress the ratchet lever on the Distractor until the graft comes into full contact with the superior and inferior end plates. Remove the Distractor from the surgical site (Figure 19).

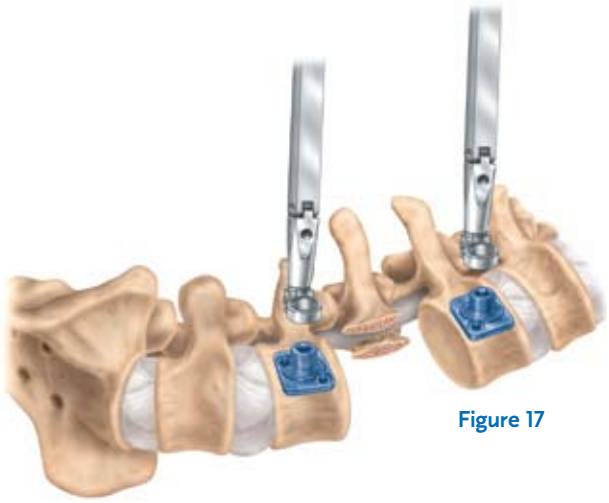


Figure 17

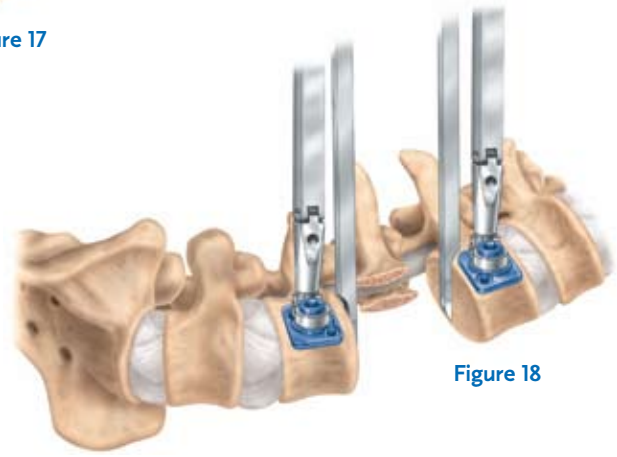


Figure 18

Figure 19

For more complex reduction, the Modular Reduction Distractor should be used. Thread the Modular Distractor Barrels onto the Staple posts (Figure 20). Apply the Modular Distractor Rack onto the Barrels (Figure 21) and attach the Quick Connect Ratcheting Handles. By applying torque to the handles, lordosis is restored. Lock this position in place using the wing nuts. Apply distraction and anterior-posterior rotation using the butterfly nut until reduction is satisfactory. Place the graft as previously described.

Figure 20

Figure 21

Staple Option—Plate Measurement and Placement

Plate measurement can be taken from the scale located on the Distractor. Additionally, the Caliper can be used to measure for the Plate. The appropriate measurement for the Plate size can be achieved by measuring from the center of the rostral Staple post to the center of the caudal Staple post. This will determine the appropriate length of the Plate needed.

To assist in Plate placement, the Staple Impactor Shafts can be reattached. This will allow the Plate to be guided in place. Place the appropriately sized Plate over the post of the Staples with the slotted portion of the Plate oriented superiorly (Figure 22). To minimize impingement of the superior disc and allow appropriate compression, select the shortest length Plate possible (Figure 23).

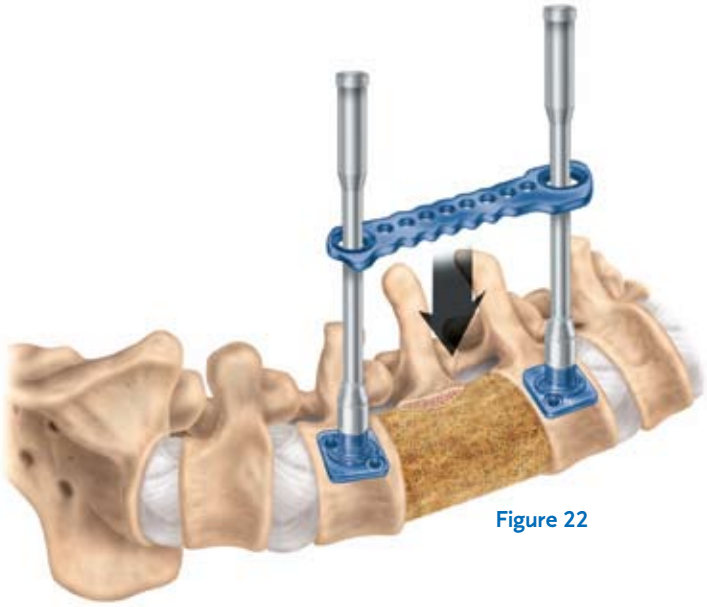


Figure 22

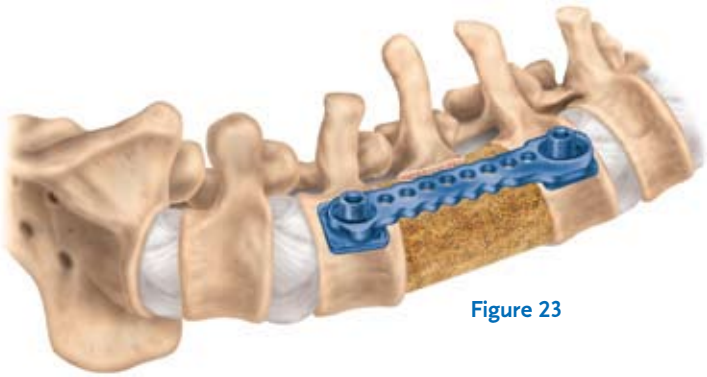


Figure 23

Place the Counter Torque Wrench inside the Torque-Limiting Nut Driver and load the Nut onto the Counter Torque Wrench (Figures 24 and 25). Use the Torque-Limiting Nut Driver to start the Nut on the fixed (caudal) end of the Plate (Figure 26). Do not completely tighten the Nut against the Plate. Repeat the process for the slot (rostral) end of the Plate (Figure 27).

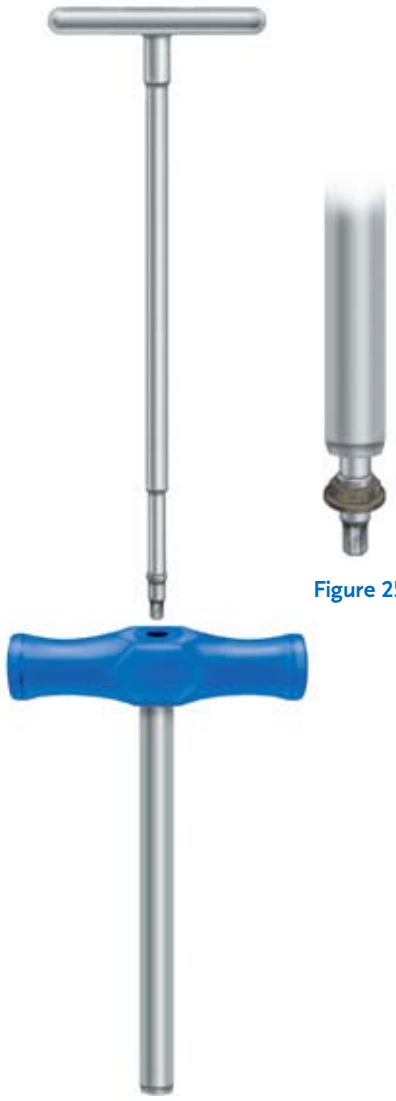


Figure 24

Figure 25

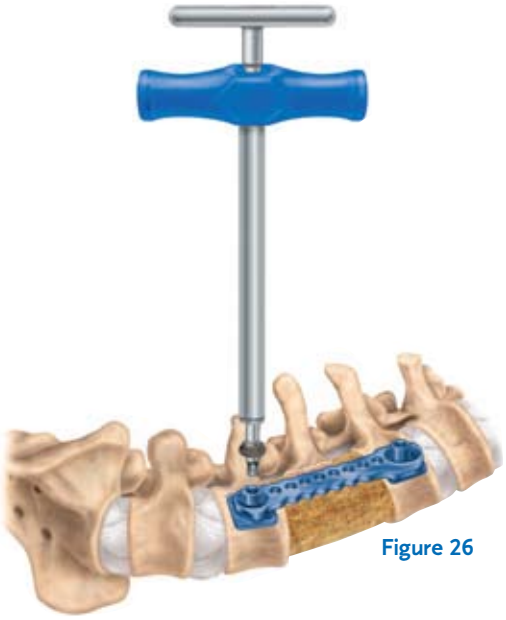


Figure 26

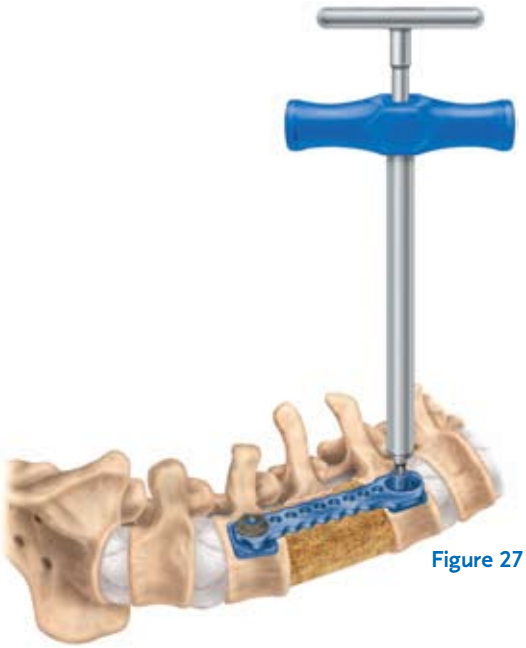


Figure 27

Staple Option—Compression and Final Tightening

Compression is optional and should be used with caution when osteoporosis is present. If compression is deemed appropriate, load the Parallel Compressor foot into one of the Plate holes and the other Compressor foot around the Torque-Limiting Nut Driver (Figure 28). Compress to the desired position and apply final tightening to the rostral Nut. The Torque-Limiting Nut Driver is a limiting torque wrench driver that will click when it achieves 90 in-lb. Do not exceed the recommended torque. Complete the process by tightening the caudal Nut (Figure 29).

Figure 28

Figure 29

Once instrumentation is complete (Figure 30), the construct should be checked radiographically. Closure is accomplished by first placing a chest tube and drain. The diaphragm is repaired using a running suture and stay sutures. Muscles are closed in a layered fashion, as is the chest wall. A rigid brace is recommended for eight weeks.

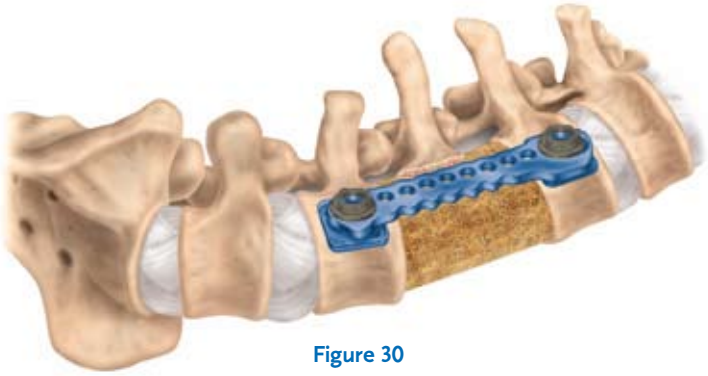
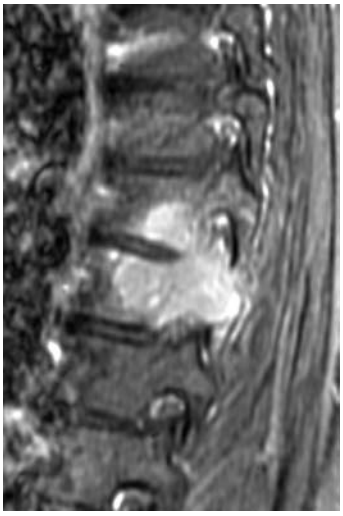
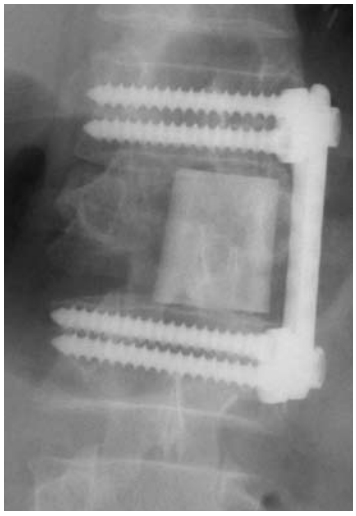


Figure 30



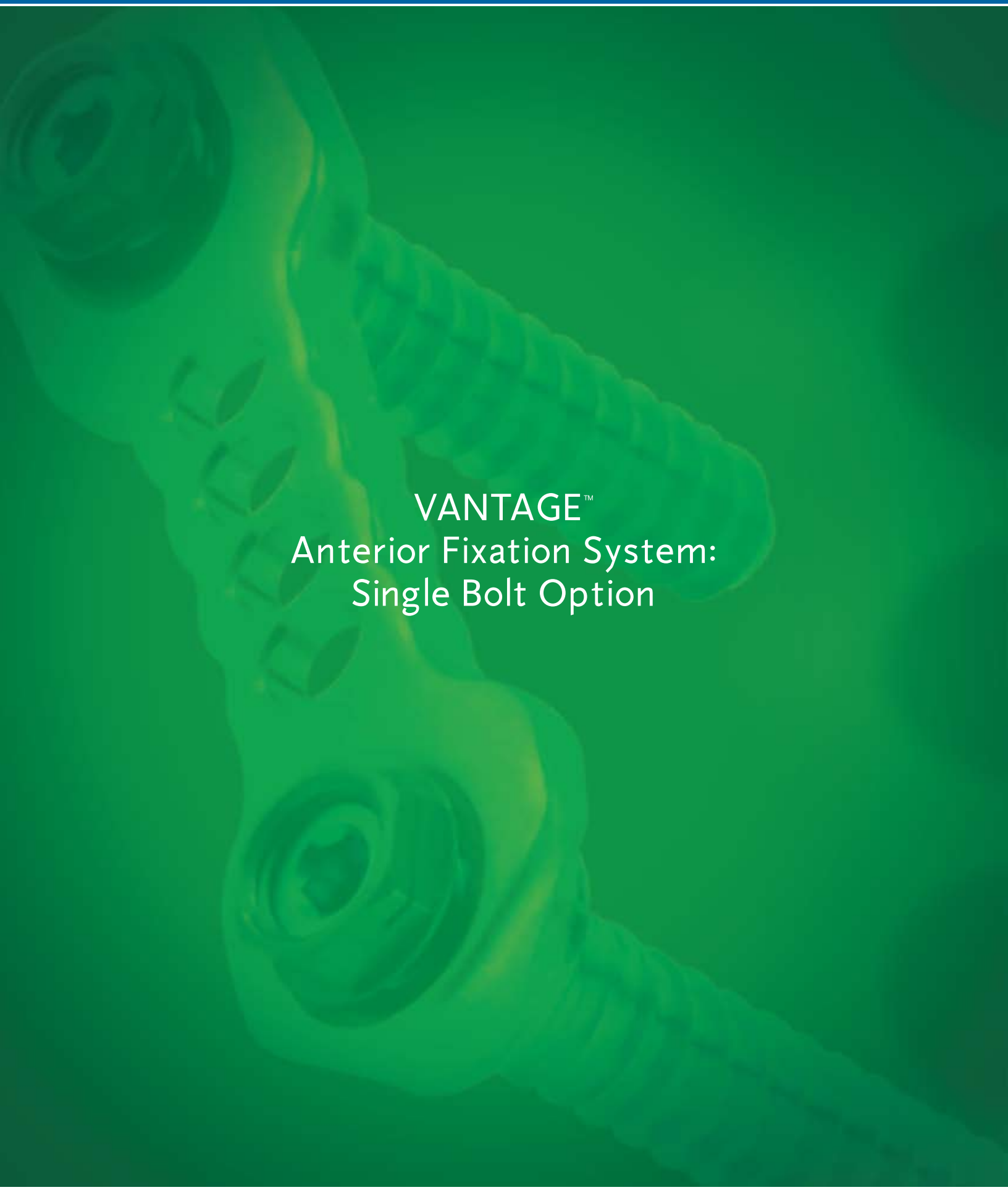
Preoperative lateral view MRI of tumor.



Postoperative anterior/posterior view of the VANTAGE™ Anterior Fixation System with corpectomy reconstruction.

Explantation

If removal of the VANTAGE™ Anterior Fixation System is necessary, insert the Counter Torque Wrench into the Torque-Limiting Nut Driver and remove the Lock Nuts. Remove the Plate using forceps. Next, load the Hex Driver shaft into the Quick Connect Ratcheting Handle and remove the Screws. Lastly, remove the Staples using forceps.



VANTAGE™
Anterior Fixation System:
Single Bolt Option

Refer to pages 7–10 for an explanation of the Exposure and Corpectomy techniques.

The Bolt is positioned in a coronal plane with bicortical fixation. A pilot hole is created with the Awl or Drill. The pilot hole is tapped before the Bolt is inserted until its flared portion nests against the lateral surface of the vertebral body (Figure 31). The Bolt is inserted in the center of the lateral surface of the vertebral body.

Note: If using a guidewire, use a Ratcheting Handle as well.

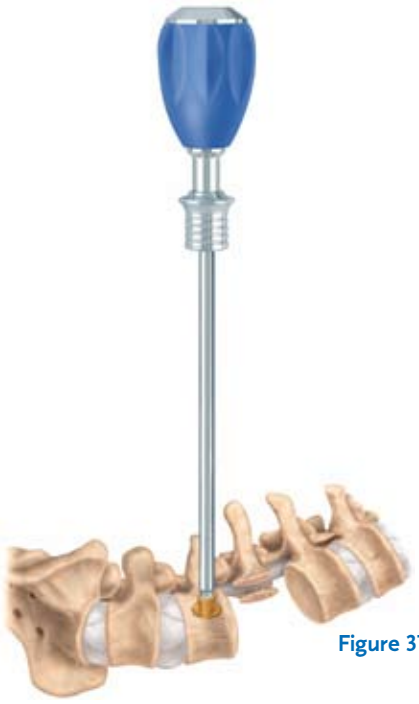
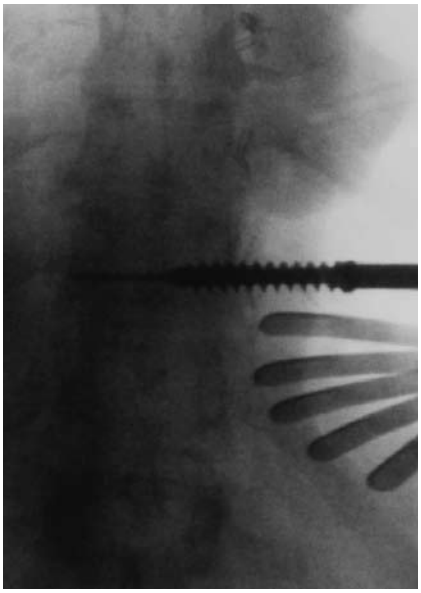
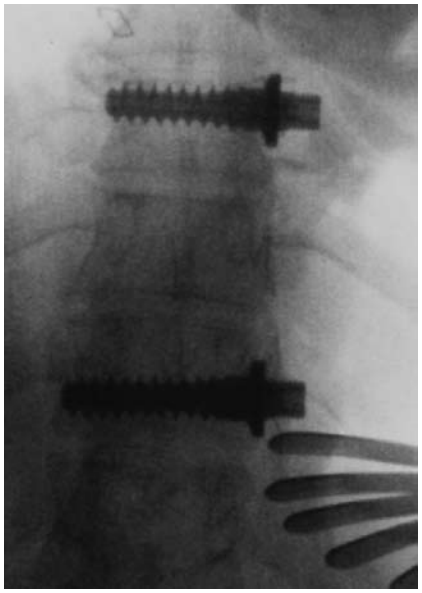


Figure 31

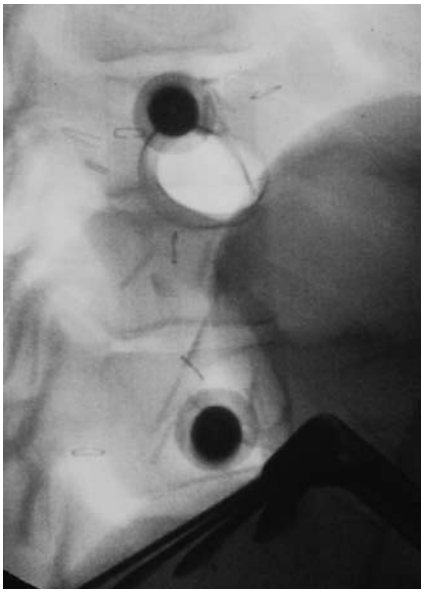
The Bolts must be oriented to allow the Plate to sit flush against the bone surfaces. When two Bolts are used to fixate the distal ends of a corpectomy, their trajectory must be parallel.



Tap



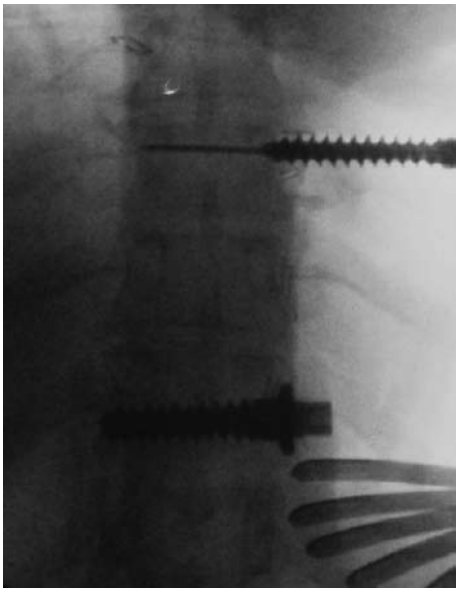
2 Bolts



Intraoperative Lateral View

Endoscopic Option

If desired, a Kirshner wire (K-wire) can be used to guide the Bolt for endoscopic insertion. The K-wire is drilled into the vertebral body using a K-wire Drill Guide. The trajectory and depth of the K-wire are monitored fluoroscopically. The K-wire is positioned in the intended Bolt trajectory. The proximal end of the K-wire must be anchored with a needle driver. The position of its tip is monitored with fluoroscopy so that it is not inadvertently advanced when the pilot hole is tapped and the Bolt is inserted. After the Bolt is inserted, the K-wire is removed.



K-wire

For simple or minimal reduction, the Quick Load Distractor may be used. Load the arm rings over the Bolt posts (Figure 32). A distractive force is placed against the Bolt posts until the desired reduction is achieved. Once reduction has been achieved, the Measuring Caliper may be used to determine the required graft length (Figure 33).

After careful selection, measurement, and placement of the graft into the corpectomy site, distraction is released. Depress the ratchet lever on the Distractor until the graft comes into full contact with the superior and inferior end plates. Remove the Distractor from the surgical site (Figure 34).

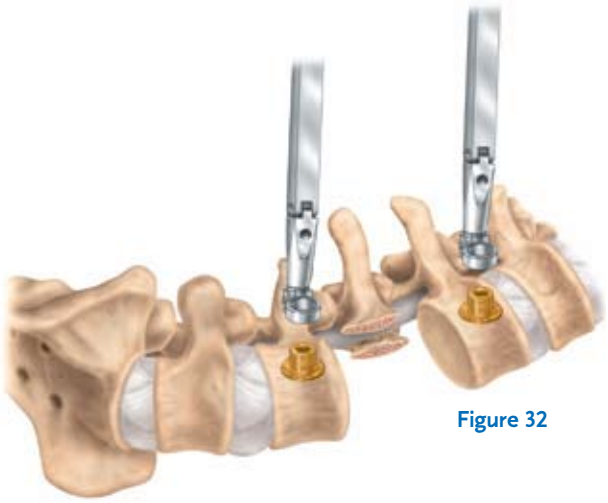


Figure 32

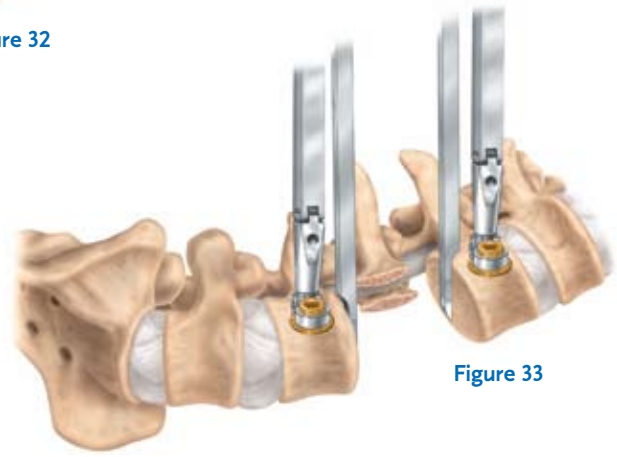


Figure 33

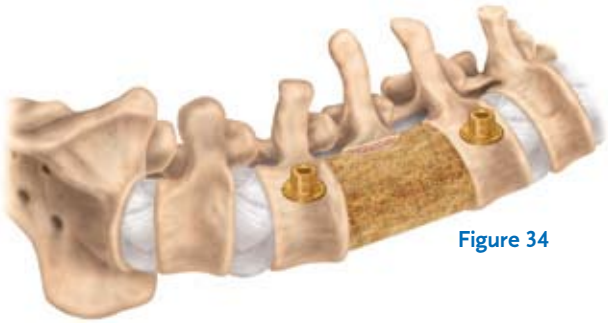


Figure 34

For more complex reduction, the Modular Reduction Distractor should be used. Thread the Modular Distractor Barrels onto the Bolt posts (Figure 35). Apply the Modular Distractor Rack onto the Barrels (Figure 36) and attach the Quick Connect Ratcheting Handles. By applying torque to the handles, lordosis is restored. Lock this position in place using the wing nuts. Apply distraction and anterior-posterior rotation using the butterfly nut until reduction is satisfactory. Place the graft as previously described.

Figure 35

Figure 36

Plate measurement can be taken from the scale located on the Distractor. Additionally, the Caliper can be used to measure for the Plate. The appropriate measurement for the Plate size can be achieved by measuring from the center of the rostral Bolt post to the center of the caudal Bolt post. This will determine the appropriate length of the Plate needed.

To assist in Plate placement, the Staple Impactor Shafts can be attached to the Bolt posts. This will allow the Plate to be guided in place. Place the appropriately sized Plate over the post of the Bolts with the slotted portion of the Plate oriented superiorly (Figure 37). To minimize impingement of the superior disc and allow appropriate compression, select the shortest length Plate possible (Figure 38).

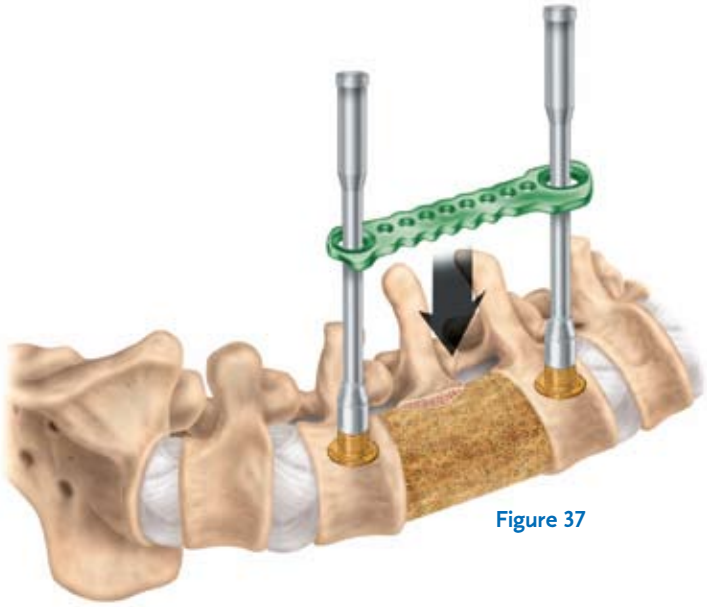


Figure 37

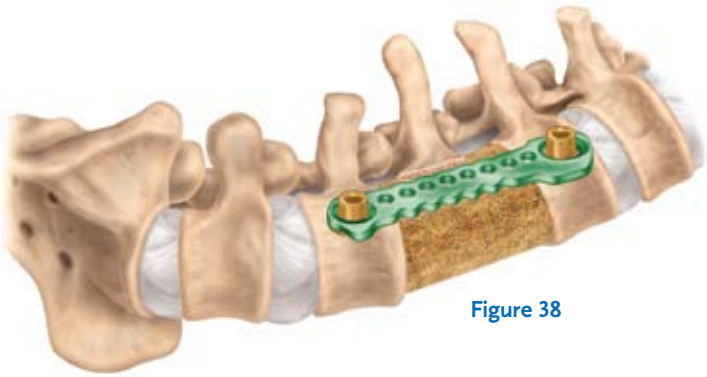


Figure 38

Single Bolt Option—Nut Placement

Place the Counter Torque Wrench inside the Torque-Limiting Nut Driver and load the Nut onto the Counter Torque Wrench (Figures 39 and 40). Use the Torque-Limiting Nut Driver to start the Nut on the fixed (caudal) end of the Plate (Figure 41). Do not completely tighten the Nut against the Plate. Repeat the process for the slot (rostral) end of the Plate (Figure 42).

Figure 39

Figure 40

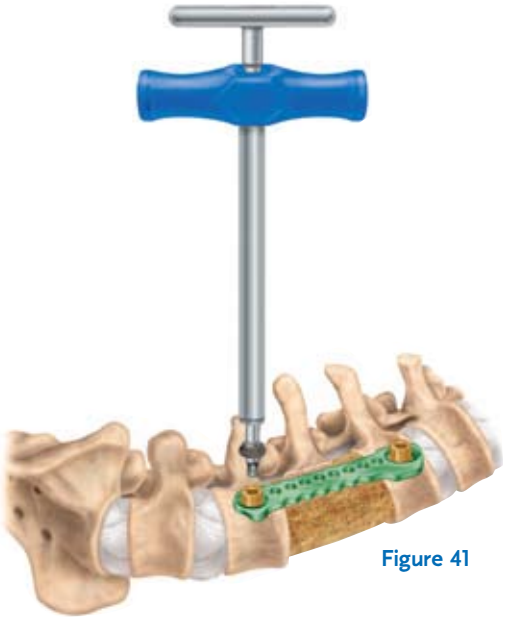


Figure 41

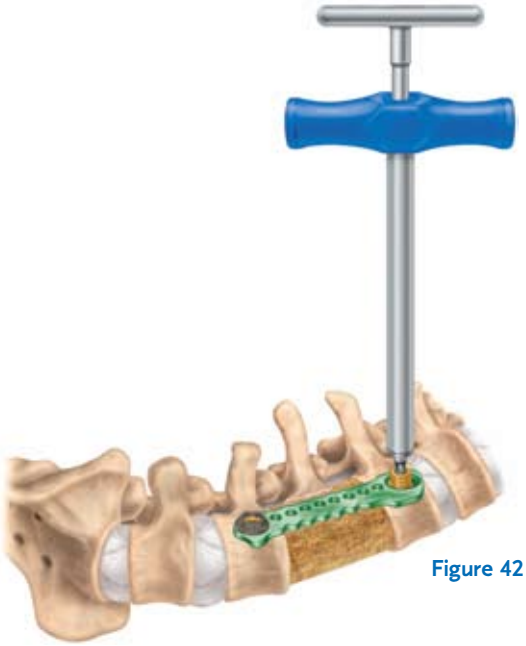


Figure 42

Compression is optional and should be used with caution when osteoporosis is present. If compression is deemed appropriate, load the Parallel Compressor foot into one of the Plate holes and the other Compressor foot around the Torque-Limiting Nut Driver (Figure 43). Compress to the desired position and apply final tightening to the rostral Nut. The Torque-Limiting Nut Driver is a limiting torque wrench driver that will click when it achieves 90 in-lb. Do not exceed the recommended torque. Complete the process by tightening the caudal Nut (Figure 44).

Figure 43

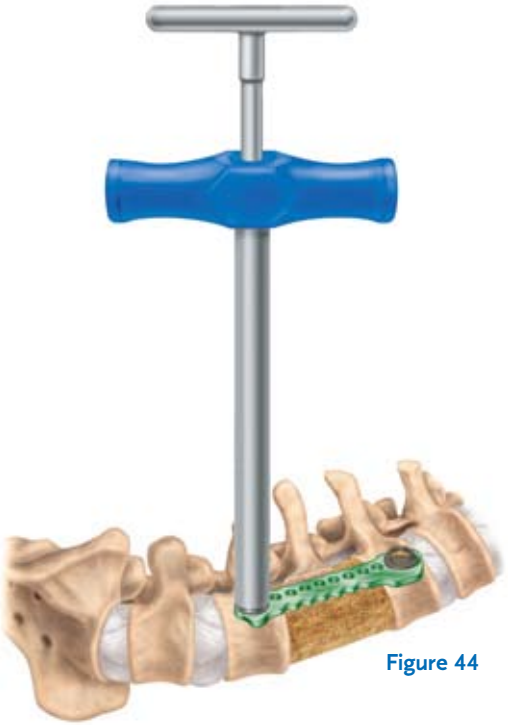


Figure 44

Once instrumentation is complete (Figure 45), the construct should be checked radiographically. Closure is accomplished by first placing a chest tube and drain. The diaphragm is repaired using a running suture and stay sutures. Muscles are closed in a layered fashion, as is the chest wall. A rigid brace is recommended for eight weeks.

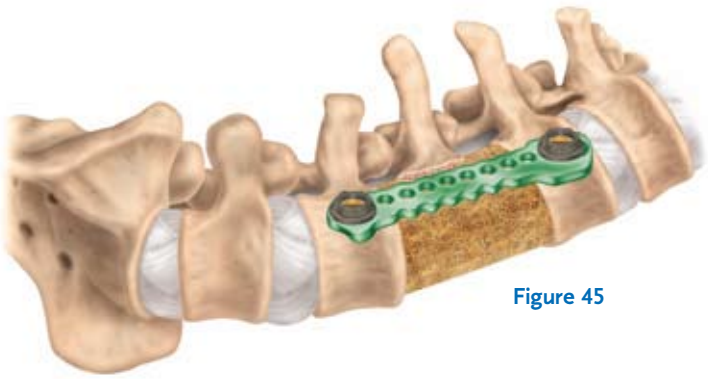
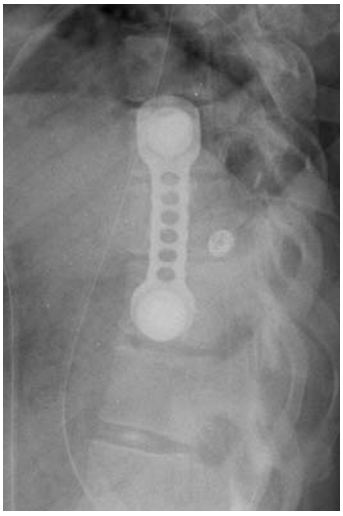
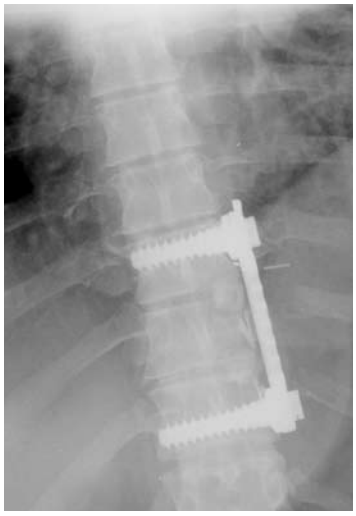


Figure 45



Postoperative Lateral View



Postoperative Anterior/ Posterior View

Explantation

If removal of the VANTAGE™ Anterior Fixation System is necessary, insert the Counter Torque Wrench into the Torque-Limiting Nut Driver and remove the Lock Nuts. Remove the Plate using forceps. Next, load the Hex Driver shaft into the Quick Connect Ratcheting Handle and remove the Bolts.

VANTAGE™ Anterior Fixation System

	ATL Titanium Implants
9330000	Lock Nut
9330003	ATL Staple, Rostral, Titanium
9330004	ATL Staple, Caudal, Titanium
9330040	4cm ATL Plate
9330045	4.5cm ATL Plate
9330050	5cm ATL Plate
9330055	5.5cm ATL Plate
9330060	6cm ATL Plate
9330065	6.5cm ATL Plate
9330070	7cm ATL Plate
9330075	7.5cm ATL Plate
9330080	8cm ATL Plate
9330085	8.5cm ATL Plate
9330090	9cm ATL Plate
9330095	9.5cm ATL Plate
9330100	10cm ATL Plate
9336530	6.5mm x 30mm Screw, ATL
9336535	6.5mm x 35mm Screw, ATL
9336540	6.5mm x 40mm Screw, ATL
9336545	6.5mm x 45mm Screw, ATL
9336550	6.5mm x 50mm Screw, ATL
9336555	6.5mm x 55mm Screw, ATL
9339002	Staple Impactor Shaft
9339003	ATL Awl Guide

	Thoracic Titanium Implants
9330000	Lock Nut
9330001	Thoracic Staple, Rostral, Titanium
9330002	Thoracic Staple, Caudal, Titanium
9331035	3.5cm Thoracic Plate
9331040	4cm Thoracic Plate
9331045	4.5cm Thoracic Plate
9331050	5cm Thoracic Plate
9331055	5.5cm Thoracic Plate
9331060	6cm Thoracic Plate
9331065	6.5cm Thoracic Plate
9331070	7cm Thoracic Plate
9331075	7.5cm Thoracic Plate
9331080	8cm Thoracic Plate
9335515	5.5mm x 15mm Screw, Thoracic
9335520	5.5mm x 20mm Screw, Thoracic
9335525	5.5mm x 25mm Screw, Thoracic
9335530	5.5mm x 30mm Screw, Thoracic
9335535	5.5mm x 35mm Screw, Thoracic
9335540	5.5mm x 40mm Screw, Thoracic
9335545	5.5mm x 45mm Screw, Thoracic
9335550	5.5mm x 50mm Screw, Thoracic
9339002	Staple Impactor Shaft
9339004	Thoracic Awl Guide

	General Instrument Set
836-015	5.5mm Tap
870-501	Depth Gauge
8684500	4.5mm Tap
9339002	Freehand Staple Impactor Shaft
9339003	ATL Freehand Drill Guide
9339004	Thoracic Freehand Drill Guide
9339005	Plate Pusher/Counter Torque
9339010	Modular Drill Bit Handle
9339012	Fixed Quick Connect Egg Handle
9339021	Fixed Drill Bit
9339031	9/64" Hex Driver
9339040	Counter Torque Wrench
9339042	Torque-Limiting Nut Driver
9339060	Modular Distractor Rack
9339061	Modular Distractor Barrel
9339075	Screw Gauge
9339082	Quick Connect Ratcheting Handle
9339085	Quick Load Distractor
9339094	Parallel Compressor
9339095	Caliper
9339096	Awl

	Cases
9337001	Instrument Tray 1
9337002	Base
9337007	Instrument Tray 2
9337008	Implant Tray
9337010	Implant Lid
9337015	Lid

	Single Bolt Implants and Instrument Set
9330000	Lock Nut, Titanium
9338020	8.0mm x 20mm Bolt, Titanium
9338025	8.0mm x 25mm Bolt, Titanium
9338030	8.0mm x 30mm Bolt, Titanium
9338035	8.0mm x 35mm Bolt, Titanium
9338040	8.0mm x 40mm Bolt, Titanium
*9338045	8.0mm x 45mm Bolt, Titanium
*9338050	8.0mm x 50mm Bolt, Titanium
*9338055	8.0mm x 55mm Bolt, Titanium
9338920	9.0mm x 20mm Bolt, Titanium
9338925	9.0mm x 25mm Bolt, Titanium
9338930	9.0mm x 30mm Bolt, Titanium
9338935	9.0mm x 35mm Bolt, Titanium
9338940	9.0mm x 40mm Bolt, Titanium
*9338945	9.0mm x 45mm Bolt, Titanium
*9338950	9.0mm x 50mm Bolt, Titanium
*9338955	9.0mm x 55mm Bolt, Titanium
9339017	8.0mm Tap
9339019	9.0mm Tap
9339022	4.8mm Fixed Drill

*Available separately.

Important Product Information

PURPOSE:

The VANTAGE™ Anterior Fixation 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 VANTAGE™ Anterior Fixation System consists of a variety of shapes and sizes of plates, screws, nuts, spacers and staples as well as ancillary products and instrument sets. VANTAGE™ Anterior Fixation System components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The VANTAGE™ Anterior Fixation 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 alloy described by such standards as ASTM F136 or ISO 5832-3. **Ne stainless steel and titanium implant components in the same construct.**

Medtronic expressly warrants that these devices are fabricated from one or more 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. See the Medtronic Catalog for further information about warranties and limitations of liability.

To achieve best results and unless stated otherwise in another Medtronic document, do not use any of the VANTAGE™ Anterior Fixation System components with the components from any other system.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:

Properly used, the VANTAGE™ Anterior Fixation System is intended to provide stabilization during the development of a solid spinal fusion. The specific indications are: (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) pseudoarthrosis, (3) spondylolysis, (4) spinal deformation such as kyphosis and lordosis, (5) fracture, (6) unsuccessful previous attempts at spinal surgery, (7) tumor resection, (8) correction of severe instability and/or deformity when used in addition to a posterior spinal instrumentation system, (9) neoplastic disease, and/or (10) deformity associated with deficient posterior elements, such as laminectomy, spina bifida, or myelomeningocele.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Fever or leukocytosis.
3. Morbid obesity.
4. Pregnancy.
5. Mental illness.
6. Any 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.
7. 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.
8. Suspected or documented metal allergy or intolerance.
9. Any case needing to mix metals from two different components or systems.
10. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
11. Any case not needing a bone graft and fusion or requiring fracture healing.
12. Curves originating superior to T5 may be a relative contraindication since the exposure may be difficult, the vertebral bodies are small, and the correction is minimal.
13. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Any patient unwilling to follow postoperative instructions.
16. Any case not described in the indications.

Contraindications of this device are consistent with those of other anterior spinal instrumentation systems. This spinal implant system is not designed, intended, or sold for uses other than those intended.

POSSIBLE ADVERSE EVENTS:

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

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, 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 formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Vertebral body fracture at, above or below the level of surgery.
8. Non-union or pseudoarthrosis.
9. Loss of neurological function, appearance of radiculopathy, and/or the development of pain.
10. Neurovascular compromise including paralysis or other types of serious injury that may cause pain.
11. Gastrointestinal and/or reproductive system compromise, including sterility.
12. Hemorrhage of blood vessels.
13. Cessation of any potential growth of the operated portion of the spine.
14. Death.

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

WARNINGS AND PRECAUTIONS:

WARNINGS:

The VANTAGE™ Anterior Fixation System components are only temporary implants used for the correction and stabilization of the spine. This system is also to be used to augment the development of a spinal fusion by providing temporary stabilization. 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 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 poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA For US Audiences Only

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

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 predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant component. Implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to the beginning of surgery.
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 VANTAGE™ Anterior Fixation System components are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. Unless sterile packaged all parts and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and that great care be used to avoid scratching the surface of the device(s). The components should not be excessively bent in the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used.
6. 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.
7. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. 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. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. 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 eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the fracture or surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient should be adequately warned of these hazards and closely supervised to insure cooperation until bony union is achieved.
5. The VANTAGE™ Anterior Fixation 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 case 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.
6. 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 VANTAGE™ Anterior Fixation 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.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. For a 10^{-6} Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes
Steam	Gravity	250° F (121° C)	30 Minutes
Steam*	Gravity*	273° F (134° C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment. *For 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 into contact with the central nervous system.

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. Further, if any of the implanted VANTAGE™ Anterior Fixation 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 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:

If further directions for use of this system are needed, please check with Medtronic Customer Service. If further information is needed or required, please contact Medtronic.

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901 396 3133
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Please contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

Notes

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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