as described by:
Curtis A. Dickman, M.D.
Barrow Neurological Associates
Phoenix, AZ

Rick C. Sasso, M.D.
Indiana Spine Group
Indianapolis, IN

Thomas A. Zdeblick, M.D.
University of Wisconsin
Madison, WI
### Surgical Technique

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**VANTAGE™**

Anterior Fixation System
Dear Colleague:

Anterior internal fixation of the thoracic and thoracolumbar spine is a growing trend in spinal surgery. In the thoracic and thoracolumbar spine, anterior fixation is indicated for burst fractures with significant canal compromise, vertebral body tumors, vertebral osteomyelitis, vertebral osteonecrosis or any other lesions that require corpectomy, and other indications requiring anterior stabilization. Primary advantages of anterior internal fixation include the ability to provide complete canal clearance and decompression of bony fragments and/or total resection of a tumor. Additionally, anterior thoracic and thoracolumbar surgery allows for fusion of a minimum number of motion segments, thus allowing for more normal spinal mechanics.

The specific goal in the development of the VANTAGE Anterior Thoracic and Lumbar Fixation System was to design a plating system that stabilizes thoracic, thoracolumbar, and lumbar burst fractures, tumors, and other unstable pathology while facilitating neural decompression and the restoration of vertebral height and lordosis. The VANTAGE Anterior Plating System allows for precise distraction outside the interbody space to aid visualization and decompression of the spinal canal. The plate permits anterior load sharing and is MRI compatible. The VANTAGE Anterior Fixation System consists of unique vertebral body staples, screws, and plates that are anatomically accommodating and low in profile.

Through extensive testing, design modifications, and continuous review, the design goals have been met and exceeded. The VANTAGE Anterior Fixation System incorporates a truly revolutionary design that allows for maximum surgical simplicity and intra-operative flexibility.

Sincerely,

Curtis A. Dickman, M.D.       Rick C. Sasso, M.D.       Thomas A. Zdeblick, M.D.
Surgical Technique

Implant Features and Benefits

**Staples:**
- Color-coded for Anatomical Placement
- Low Profile
- Easy-to-start Thread Design
- Medial Prongs for Preservation of Endplates
- Top-loading, Top-tightening
- Splines Ensure Rigid Fixation to Plate
- Interchangeable with Plates (Thoracic or Lumbar)
- Allows for 10° of Screw Angulation

**Plates:**
- Smooth Surfaces
- Holes for Visualization of Graft
- Radial Splines Ensure Rigid Fixation to Staple

**Screws:**
- Self-tapping
- Cutting Flute for Easy Insertion
- Color-coded for Anatomical Placement
- Internal Hex for Flush Fitting
Instruments

- Counter Torque Wrench 9339040
- Plate Pusher/Counter Torque 9339005
- 4.5mm Tap 8684500
- 5.5mm Tap 836-015
- Hex Driver 9339031
- Awl 9339096
- Torque Limiting Nut Driver 9339042
- Quick Connect Ratcheting Handle 9339082
- Screw Gauge 9339075
- Fixed Quick Connect Egg Handle 9339012
- Parallel Compressor 9339094

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## Instruments

- **Modular Drill Bit Handle**
  - 9339010
- **Fixed Drill Bit**
  - 9339021
- **Depth Gauge**
  - 870-501
- **Freehand Staple Impactor Shaft**
  - 9339002
- **ATL Freehand Drill Guide**
  - 9339003
- **Thoracic Freehand Drill Guide**
  - 9339004
- **Modular Distractor Rack**
  - 9339060
- **Modular Distractor Barrels**
  - 9339061
- **Caliper**
  - 9339095
- **Quick Load Distractor**
  - 9339085
Surgical Technique

When treating thoracic and thoracolumbar fractures or tumors with anterior instrumentation, 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.
Surgical Technique

Exposure

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 A/P 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 shown in the lower left-hand corner of 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 seen 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 in Figure 7.

**Corpectomy:**

1) The rib head and pedicle are removed to expose the spinal canal.
2) Discs are incised at margins of 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).
Surgical Technique

Staple Placement

The appropriate-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).
Surgical Technique

Staple Placement (Continued)

The Drill Guide is now 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 surgical set (Figure 14).
Surgical Technique

Screw Placement

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 to ensure bicortical fixation. Repeat the staple/screw insertion process for the next staple (Figure 16).
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 endplates. Remove the Distractor from the surgical site (Figure 19).
Surgical Technique

Reduction Option

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.
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 appropriate-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).
Surgical Technique

Nut Placement

Place the Counter Torque Wrench inside the T-Limiting Nut Driver and load the nut onto the Counter Torque Wrench (Figures 24 and 25). Use the T-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).
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 T-Limiting Nut Driver (Figure 28). Compress to the desired position and apply final tightening to the rostral nut. The T-Limiting Nut Driver is a limiting torque wrench driver that will click once it achieves 90 in.-lb. Do not exceed the recommended torque. Complete the process by tightening the caudal nut (Figure 29).
Surgical Technique

Closure/Postoperative Care/Explantation

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.

Explantation

If removal of the VANTAGE Anterior Fixation System is necessary, insert the Counter Torque Wrench into the T-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.
# Surgical Technique

## Product Ordering Information

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<tr>
<th>ATL TITANIUM IMPLANTS</th>
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<tr>
<td>9330000 Lock Nut</td>
<td>9335515 5.5 x 15mm Screw, Thoracic</td>
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<tr>
<td>9330003 ATL Staple, Rostral, TI</td>
<td>9335520 5.5 x 20mm Screw, Thoracic</td>
</tr>
<tr>
<td>9330004 ATL Staple, Caudal, TI</td>
<td>9335525 5.5 x 25mm Screw, Thoracic</td>
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<td>9330040 4cm ATL Plate</td>
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<td>9330045 4.5cm ATL Plate</td>
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<tr>
<td>9330070 7cm ATL Plate</td>
<td>9339004 Thoracic Awl Guide</td>
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<td>9330075 7.5cm ATL Plate</td>
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<td>9330100 10cm ATL Plate</td>
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<td>9339003 ATL Awl Guide</td>
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| THORACIC TITANIUM IMPLANTS                                                           |                                                                      |
|--------------------------------------------------------------------------------------|                                                                      |
| 9330000 Lock Nut                                                                     | 9335515 5.5 x 15mm Screw, Thoracic                                  |
| 9330001 Thoracic Staple, Rostral, TI                                                | 9335520 5.5 x 20mm Screw, Thoracic                                  |
| 9330002 Thoracic Staple, Caudal, TI                                                 | 9335525 5.5 x 25mm Screw, Thoracic                                  |
| 931035 3.5cm Thoracic Plate                                                         | 9335530 5.5 x 30mm Screw, Thoracic                                  |
| 931040 4cm Thoracic Plate                                                           | 9335535 5.5 x 35mm Screw, Thoracic                                  |
| 931045 4.5cm Thoracic Plate                                                         | 9335540 5.5 x 40mm Screw, Thoracic                                  |
| 931050 5cm Thoracic Plate                                                           | 9335545 5.5 x 45mm Screw, Thoracic                                  |
| 931055 5.5cm Thoracic Plate                                                         | 9335550 5.5 x 50mm Screw, Thoracic                                  |
| 931060 6cm Thoracic Plate                                                           | 9339002 Staple Impactor Shaft                                       |
| 931065 6.5cm Thoracic Plate                                                         | 9339004 Thoracic Awl Guide                                          |
| 931070 7cm Thoracic Plate                                                           |                                                                      |
| 931075 7.5cm Thoracic Plate                                                         |                                                                      |
| 931080 8cm Thoracic Plate                                                           |                                                                      |

| GENERAL INSTRUMENTS                                                                  |                                                                      |
|--------------------------------------------------------------------------------------|                                                                      |
| 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                                                                         |                                                                      |
Important Information on the VANTAGE Anterior Fixation System

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 5833-1 or ISO 5833-9. Alternatively, the entire system may be made out of medical grade titanium alloy described by such standards as ASTM F136 or ISO 5833-3. Never use stainless steel and titanium implant components in the same construct.

Medtronic Sofamor Danek 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 Sofamor Danek Catalog for further information about warranties and limitations of liability.

To achieve best results and unless stated otherwise in another Medtronic Sofamor Danek 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) pseudarthrosis, (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, spinal 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.
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/or requiring fracture healing.
12. Curves originating superior to T-5 may be a relative contraindication since the exposure may be difficult, the vertebral bodies small, and the correction is minimal.
13. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
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 losening of any or all of the components.
2. Diassembly, 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. Burstitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative 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.
13. Cessation of any potential growth of the operated portion of the spine.

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

WARNING AND PRECAUTIONS:

WARNINGS: 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. 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. Ebene, 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.

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.
Important Information on the VANTAGE Anterior Fixation System

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 function 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.

PACKAGING:
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and 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. Resulting in the patient being advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal anti-inflammatory medications such as aspirin during the bone graft healing process.
4. The patient should be advised of the risk that the patient or 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 debridged or detemined. The patient should be warned to avoid falls or sudden jolts in spinal position.
5. 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-steroidal anti-inflammatory medications such as aspirin during the bone graft healing process.
6. The patient should be advised of the possibility to bend or rotate at the point of spinal fusion and to allow the maximum chances for a successful surgical result in body motion.
7. 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 stress 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.
8. 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 bone is fused, these devices serve no functional purpose and may be removed. 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 activity or the device is not removed following completion of its intended use, or 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 or 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.
9. 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 kits 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:
Unless just removed from an unopened Medtronic Sofamor Danek 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 Sofamor Danek. Cleaning and disinfecting of instruments can be performed with alcohol-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 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 10º Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below.

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 (i.e., 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 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 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, hospital name, patient’s name and identity, and 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 SOFAMOR DANEK USA, INC. Customer Service. If further information is needed or required, please contact:

IN EUROPE
MEDTRONIC SOFAMOR DANEK International**
13, rue de la Perle
92340 TREMBLAY EN FRANCE
FRANCE
*authorized EC representative
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For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek USA, Inc. products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

MEDTRONIC SOFAMOR DANEK USA, INC.
1800 Pyramid Place Memphis, TN 38132
(901) 396-3133 (800) 876-3133
Customer Service: (800) 933-2635

www.sofamordanek.com

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WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.