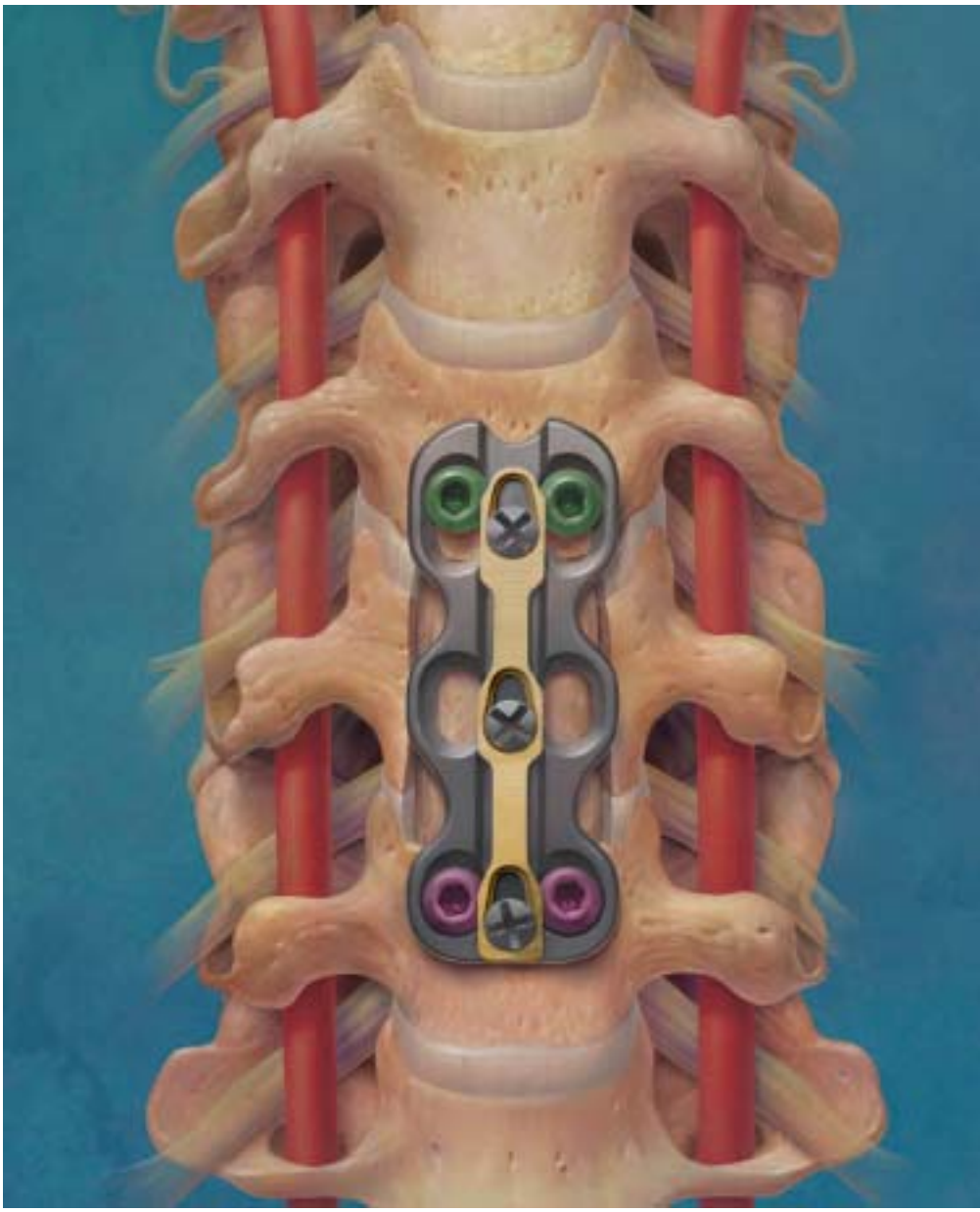
Medtronic
SOFAMOR DANEK

PREMIER® Anterior Cervical Plate System

Surgical Technique



as described by:

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MICHELSON TECHNOLOGY AT WORK

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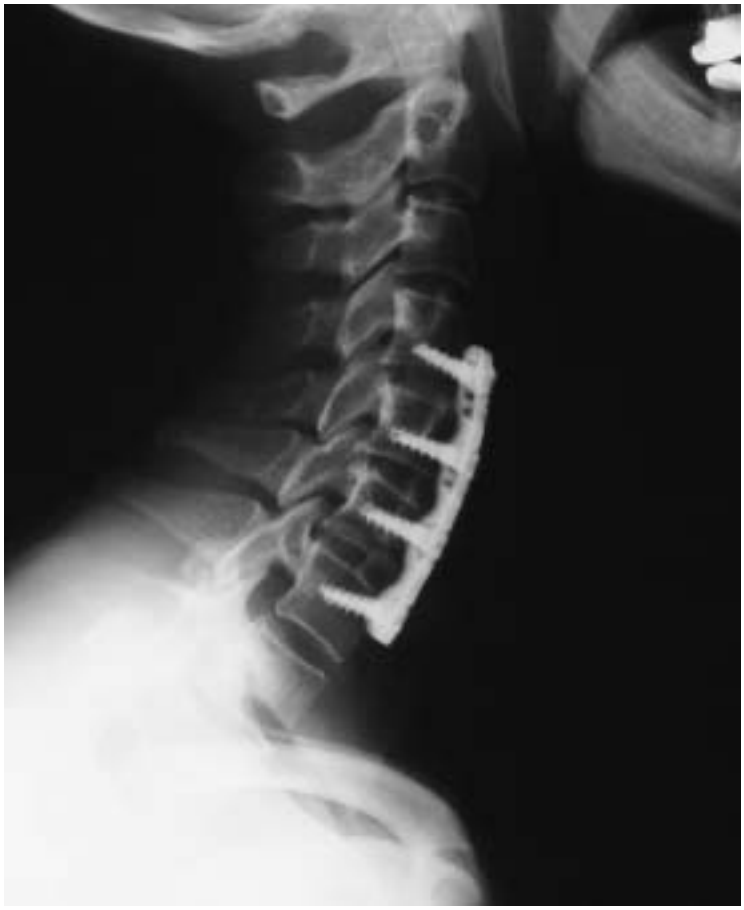
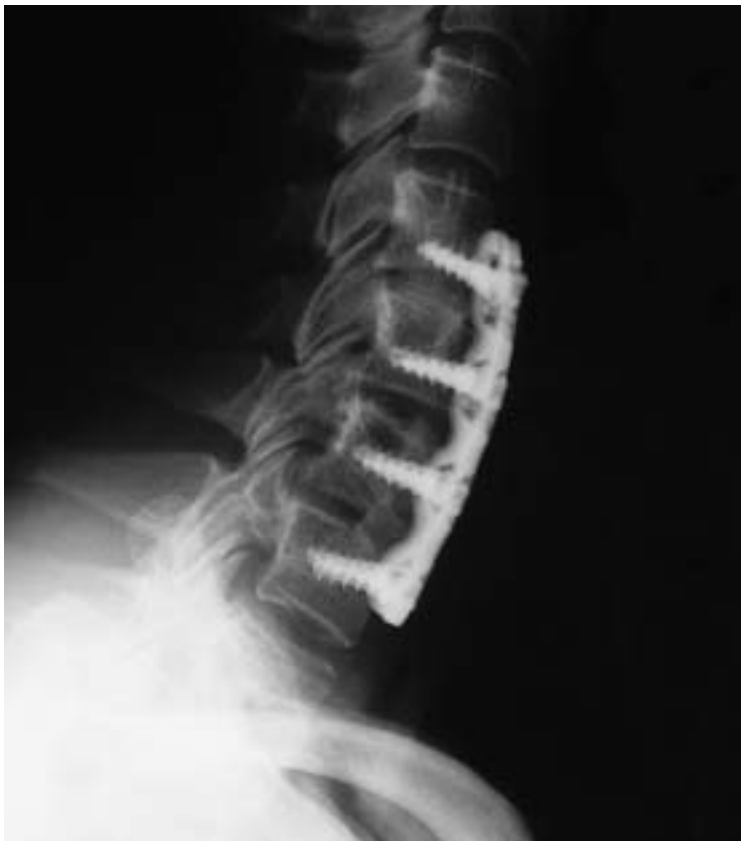


Multiple level ACDF (C4-C7)
Immediate post-op



Multiple level ACDF (C4-C7)
12 week follow-up

Axial Slots

Allow post-operative settling via axial screw translation.

Pre-Compression Techniques

Allow pre-compression of the graft construct to optimize fit and graft loading.

Attached Lock Mechanism

Sliding washer provides clearance for screw translation while providing a barrier to screw back out.

Superior Alignment Notch

Facilitates midline alignment of plate when utilized in conjunction with Compression Pin and Compression Sleeve.

Pre-Machined Lordotic Curve

Accommodates normal anterior cervical lordosis.

Bone Screw Diameters 4.0/4.5mm

Allow surgeon maximum bone purchase.

Cancellous Thread Form

Reverse thread pattern enhances screw purchase pullout resistance.

PREMIER® ANTERIOR CERVICAL PLATE SYSTEM

Dear Fellow Colleagues,

In recent years, semi-constrained plates have grown in popularity, due mainly to intraoperative flexibility in screw placement combined with the ability to allow for graft loading while incorporation progresses. The advantages of the PREMIER® Anterior Cervical Plate System are to provide for axial load sharing of the graft during incorporation, and that pre-compression of the graft may be obtained both externally and internally during implantation. In addition, a unique lock washer system allows quick and easy implantation.

The PREMIER® Anterior Cervical Plate System provides for axial load sharing via vertical screw translation along slots in the plate, while maintaining constrained fixation at the distal end of the construct, where loading is highest. The use of external graft pre-compression helps to secure the graft in an optimal position for healing. The internal pre-compression component provides graft pre-load which we believe accelerates healing.

The wide range of plate lengths available in the PREMIER® Anterior Cervical Plate System accommodates the plating of single or multiple level anterior cervical fusions. Depending on the indication, internal and/or external pre-compression techniques may be applied to provide the same compression advantages to discectomy fusions as well as corpectomy struts. The unique attached bone screw locking mechanism ensures that screw back-out will not occur.

The PREMIER® Anterior Cervical Plate System provides versatile, straightforward instrumentation, and features which will make the surgeon's experience as stress free as possible while providing the optimal environment for bony healing. In our hands, this has led to excellent clinical results.

The following monograph introduces the PREMIER® Anterior Cervical Plate System, as well as many of our personal thoughts reflecting our current clinical practices and operative techniques.

Sincerely,

Thomas A. Zdeblick, M.D.
University of Wisconsin
Madison, Wisconsin

Harry N. Herkowitz, M.D.
William Beaumont Hospital
Royal Oak, Michigan

The patient is placed in the supine position with the head in slight extension. The posterior cervical spine may be supported to establish and maintain cervical lordosis. The surgeon must then choose a right- or left-sided approach. After this consideration, the head may be rotated to allow for adequate exposure of the cervical spine *(Figure 1)*.

Typically a transverse skin incision is made. An avascular dissection plane is developed between the esophagus/trachea, medially, and the sternocleidomastoid/carotid sheath, laterally. Hand-held retractors may be utilized to provide initial exposure of the anterior vertebral column and the adjacent longus coli muscles *(Figure 2)*.

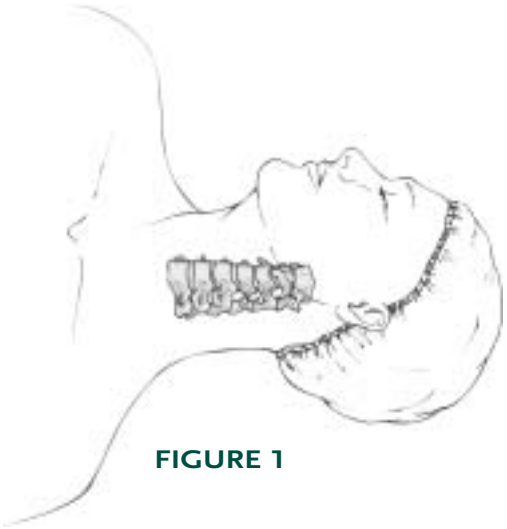


FIGURE 1

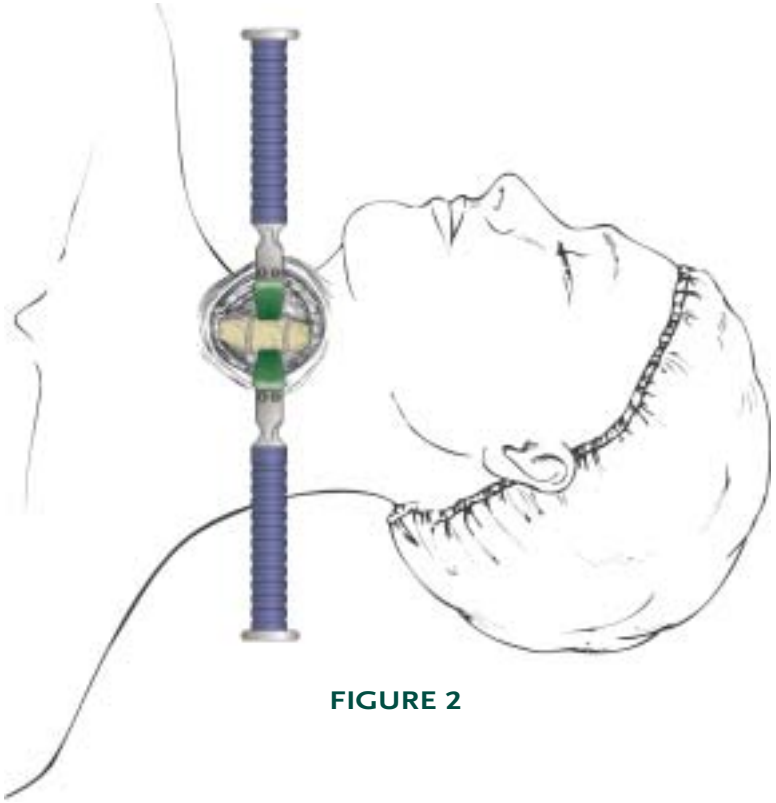


FIGURE 2

DISTRACTION ONLY

After the vertebral column has been exposed, the longus coli muscles are elevated and the "slotted foot" medial / lateral self-retaining retractor blades are securely positioned *(Figure 3)*. Longitudinal retractors may be used to maximize the exposure *(Figure 4)*.

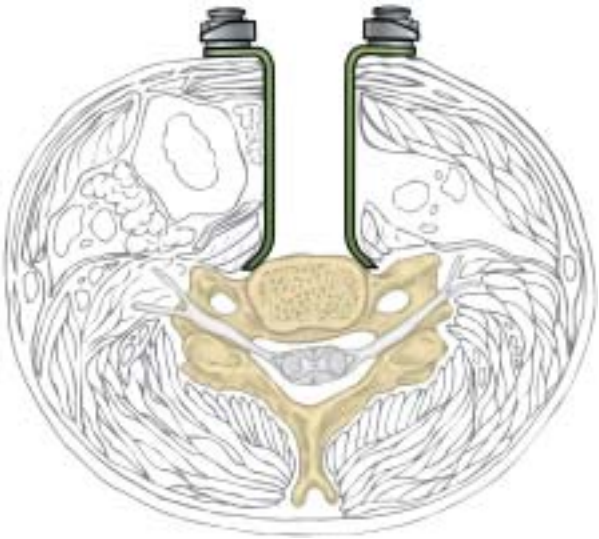


FIGURE 3

A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the level to be treated *(Figure 5)*. The distractor is placed over the pins and the appropriate amount of distraction is applied.

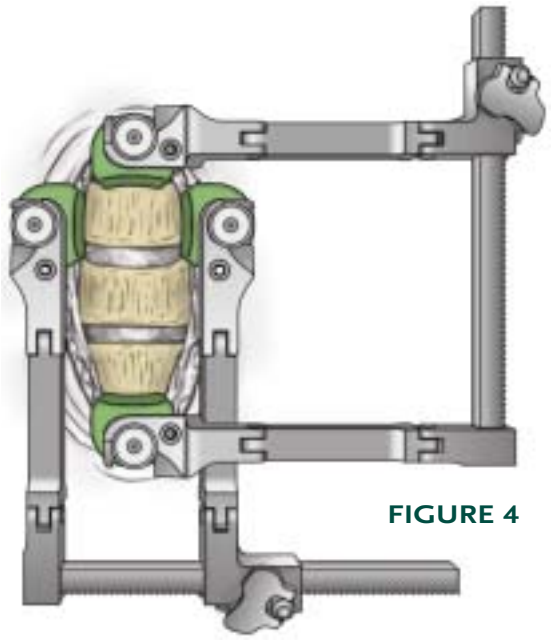


FIGURE 4

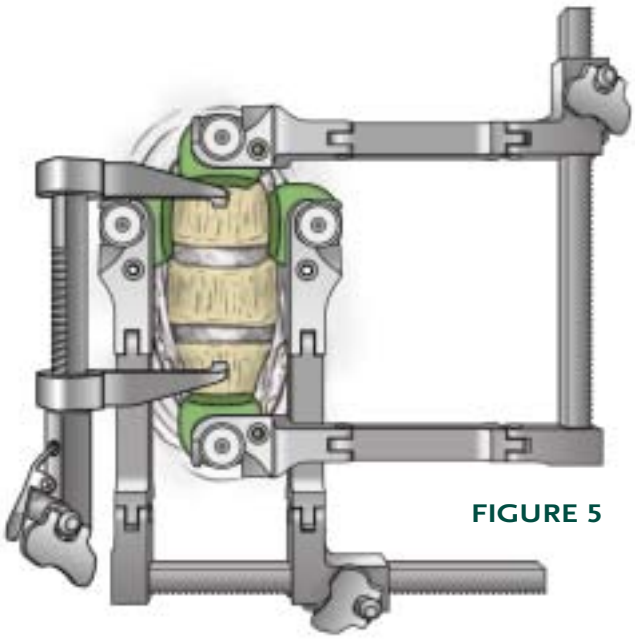


FIGURE 5

DISTRACTION WITH PLANNED EXTERNAL COMPRESSION

If the external compression technique is planned for later in the procedure, the Compression Pin Placement Template can be utilized. By placing the Compression Pin at this stage, it can be used as a distraction pin. This pin can be used in conjunction with a distraction pin for the distractor. Alternatively, two Compression Pins can be used for distraction. Use of the Template ensures proper location of the Compression Pin later in the procedure *(Figure 6)*.

"The short height on the Compression pin provides flexibility in maintaining a minimal exposure, particularly in corpectomy cases."

– T. Zdeblick, M.D.

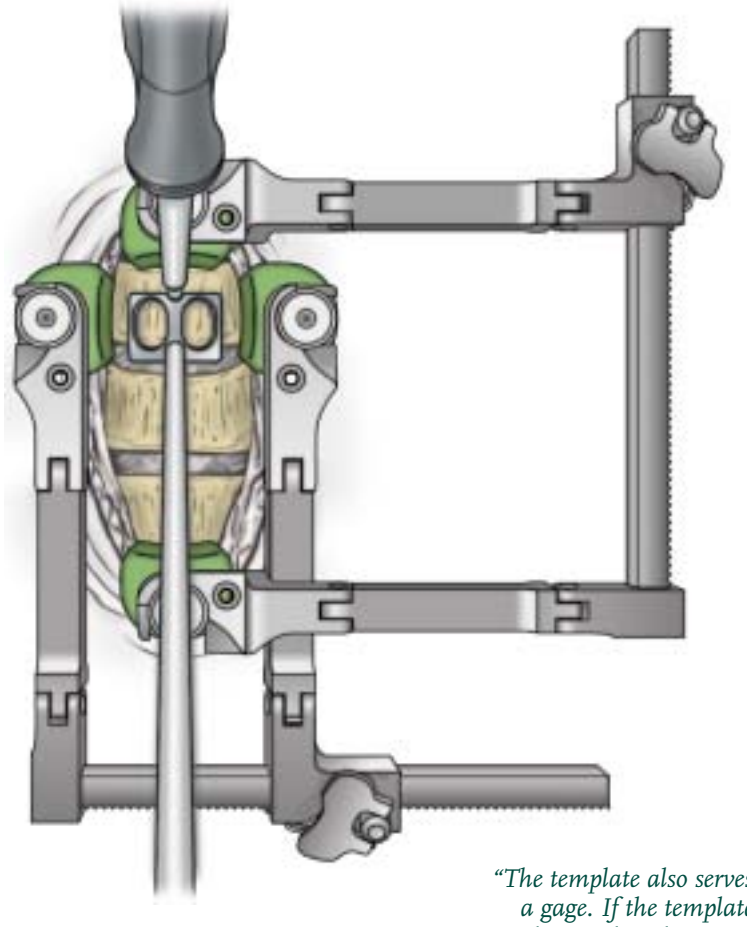


FIGURE 6

"It is helpful to remove any osteophytes from the endplate, and to smooth the superior endplate prior to using the template. The template references the edge of the endplate and subsequent tissue removal changes that reference."

– T. Zdeblick, M.D.

"The template also serves as a gage. If the template indicates that there is not adequate bone to place the pin, the anatomy is not suitable for external compression."

– H. Herkowitz, M.D.

Discectomies are completed at each level. Pituitaries, curettes, and kerrisons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament *(Figures 7 and 8)*.

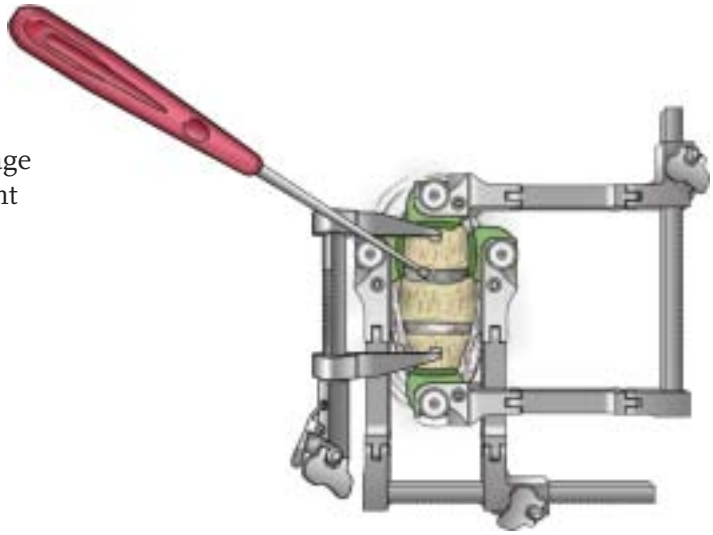


FIGURE 7

FIGURE 8

After the disc(s) have been removed, a corpectomy or partial corpectomy may be necessary to further decompress the spine. A rongeur may be used to remove a portion of the vertebrae. A high-speed drill with a large bore burr may be utilized to remove the remaining portion of the vertebrae *(Figure 9)*. A curette is then used to carefully elevate the remaining bone anteriorly away from the dura, and a kerrison is used to clear the remaining bone and soft tissue.

FIGURE 9

Once the decompression is completed, the bone graft receptor site is prepared. Endplate preparation consists of removing cartilage and a partial decortication, leaving a small posterior rim *(Figure 10)*.

The dimensions of the corpectomy are measured precisely and the bone graft is shaped appropriately. Either autograft or allograft may be utilized. The graft is held and placed using a bone graft holder and mallet *(Figures 11 and 12)*.

FIGURE 10

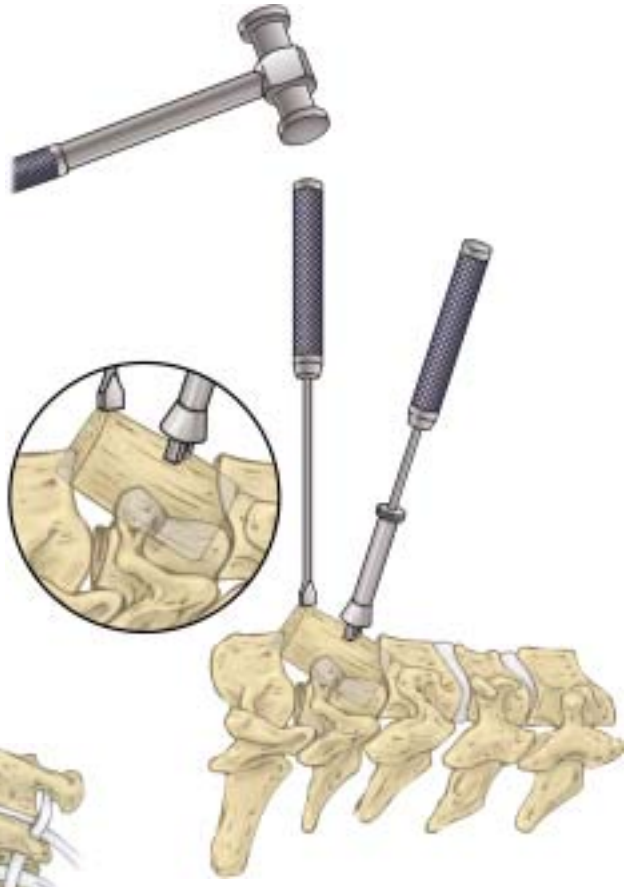


FIGURE 11

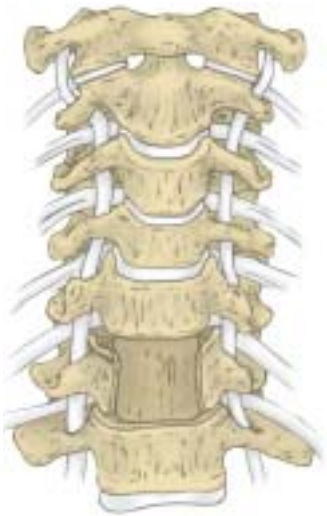


FIGURE 12

STEP 1

PLATE PLACEMENT ONLY (NO COMPRESSION)

Soft tissue and anterior osteophytes are removed from the adjacent vertebral bodies so that the plate may sit evenly on the anterior cortex. Position the plate so that the superior screw slots are close to the inferior endplate. This will ensure that as the settling occurs and the plate effectively shifts upwards, there is adequate vertebral body height to accommodate the shift *(Figure 13)*. The inferior screw holes should be placed close to the superior endplate, angled away from the bone graft. This ensures good screw purchase and will allow for placement of the fixed bone screws in the center of the vertebra. The edge of the plate should not interfere with the adjacent unfused disc spaces *(Figure 14)*.

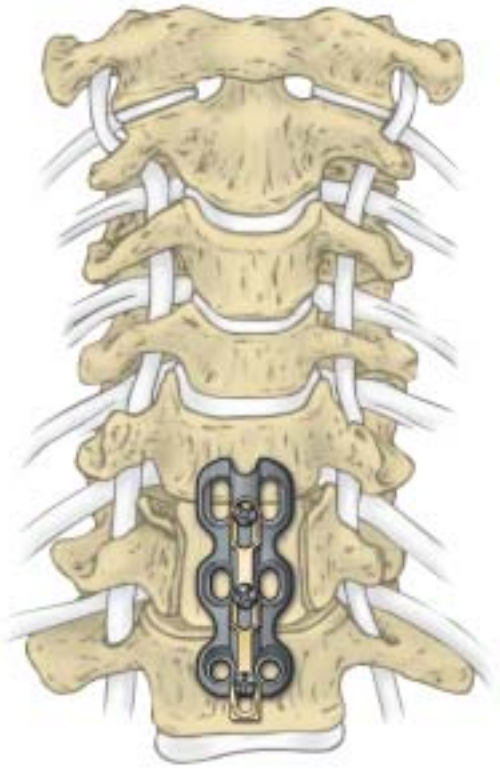


FIGURE 13

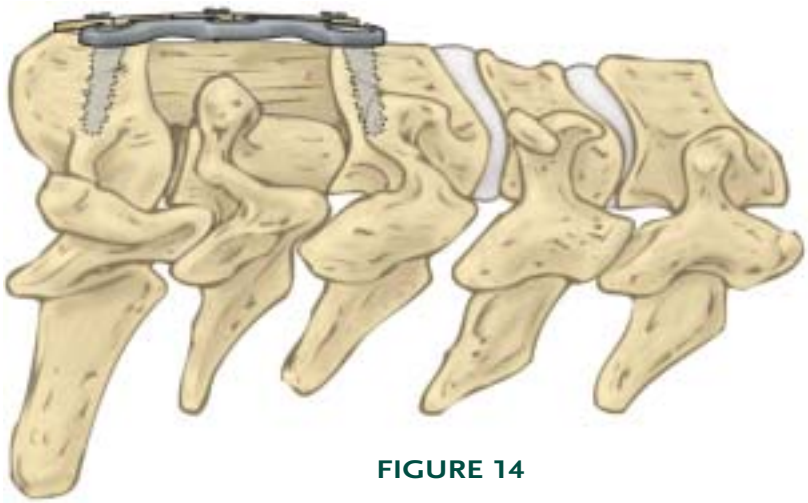


FIGURE 14

"By 'gardening' the spine; i.e. ensuring that anterior osteophytes or graft prominences are minimized, the lowest profile construct may be obtained."

– T. Zdeblick, M.D.

STEP 1A

PLATE PLACEMENT WITH COMPRESSION OR ALIGNMENT

If the compression or alignment technique is desired, the Compression Pin should be placed with the Compression Pin Placement Template. If the Compression Pin was also used for distraction, it should remain in place for this step. Refer to the "Distraction with Planned External Compression" section on page 4.

The Compression Sleeve is placed over the Compression Pin to serve as a spacer *(Figure 15)*. The plate is then nestled against the Sleeve *(Figure 16)*. Care should be taken to ensure that the upper portion of the slot is positioned just superior to the graft/endplate interface.

As the plate is constrained by the Compression Sleeve, it also provides for alignment as the inferior portion of the plate is positioned.

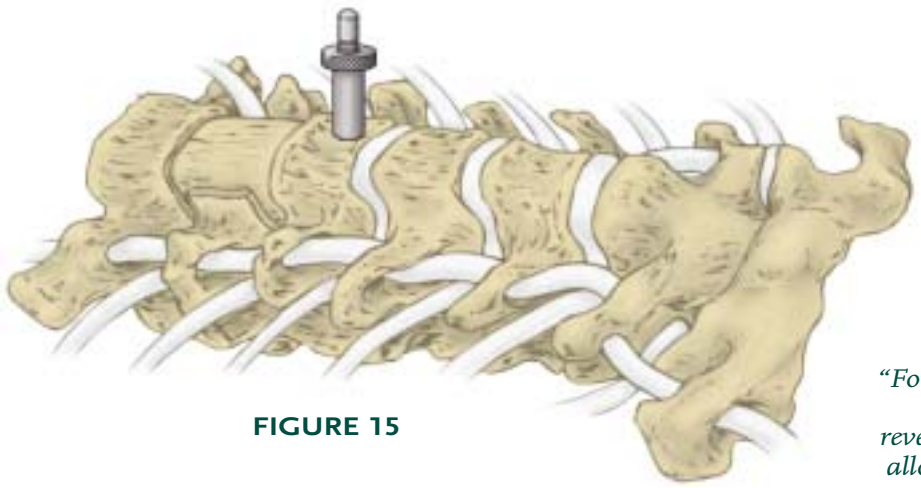


FIGURE 15

"Use of the compression pin for alignment is particularly helpful in multi level cases, when visualizing both ends of the plate simultaneously may be difficult."

– T. Zdeblick, M.D.

"For cases at the lower cervical or upper thoracic spine, the plate may be reversed, with the slot end inferior. This allows easier placement of the screws."

– T. Zdeblick, M.D.

"By placing the compression pin at the proximal end of the vertebra in the center, it ensures the plate is straight and there is sufficient room for the compression screws."

– H. Herkowitz, M.D.

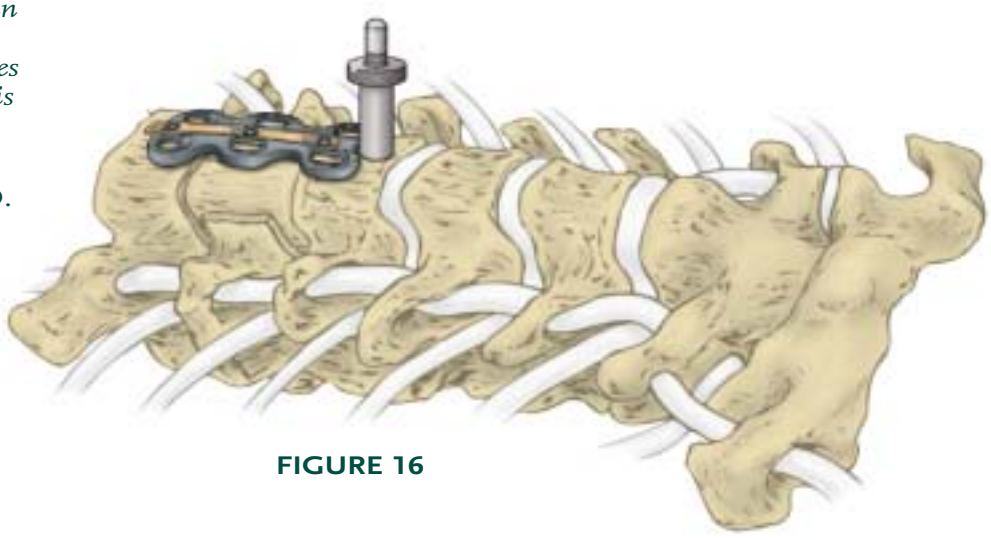


FIGURE 16

STEP 2

The PREMIER® Anterior Cervical Plate is provided with a pre-machined lordotic curve *(Figure 17)*. If required, the plate may be contoured to increase the amount of lordotic curvature (*Figure 18A*) or decrease the amount of lordotic curvature *(Figure 18B)* by using the Plate Bender. A gradual bend should be made over the entire length of the plate and abrupt changes in curvature should be avoided.

FIGURE 17

FIGURE 18A

FIGURE 18B

STEP **3**

The PREMIER® System Plate Holder may be attached to the plate in one of the slots. The tip of the Plate Holder collapses when pressure is applied to the locking sleeve cap *(Figure 19)*. Insert the collapsed tip into the slot. Releasing the pressure to the locking sleeve cap will allow the Plate Holder to securely engage the plate *(Figure 20)*.

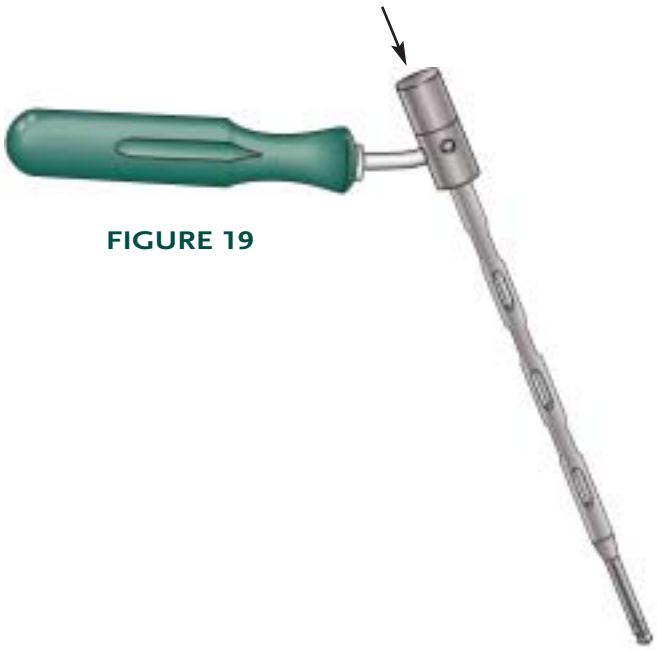


FIGURE 19

"Take care to align the plate vertically. By palpating the sternal notch, the inferior alignment can be verified."

– T. Zdeblick, M.D.

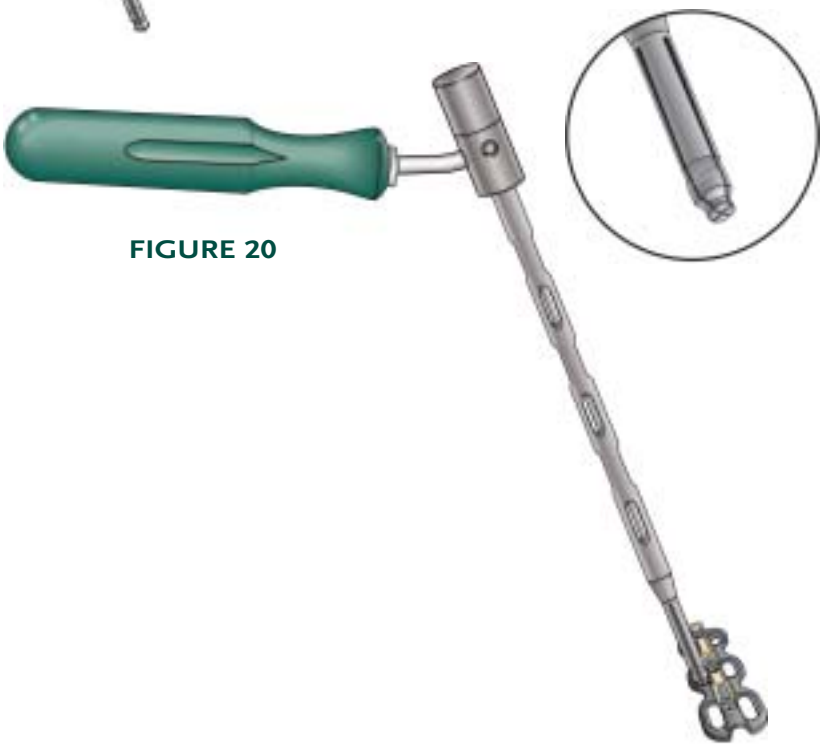


FIGURE 20

STEP **4**

After the plate length has been selected and placed on the anterior cervical spine, a Plate Holding Pin can be placed in the plate to provide temporary fixation while drilling and placing bone screws. The pins are engaged in a Plate Holding Pin Driver to allow easy insertion into the bone *(Figure 21A)*. Once seated, a Plate Holding Pin may be disengaged from the driver by applying upward pressure on the locking sleeve *(Figure 21B)*.

FIGURE 21A

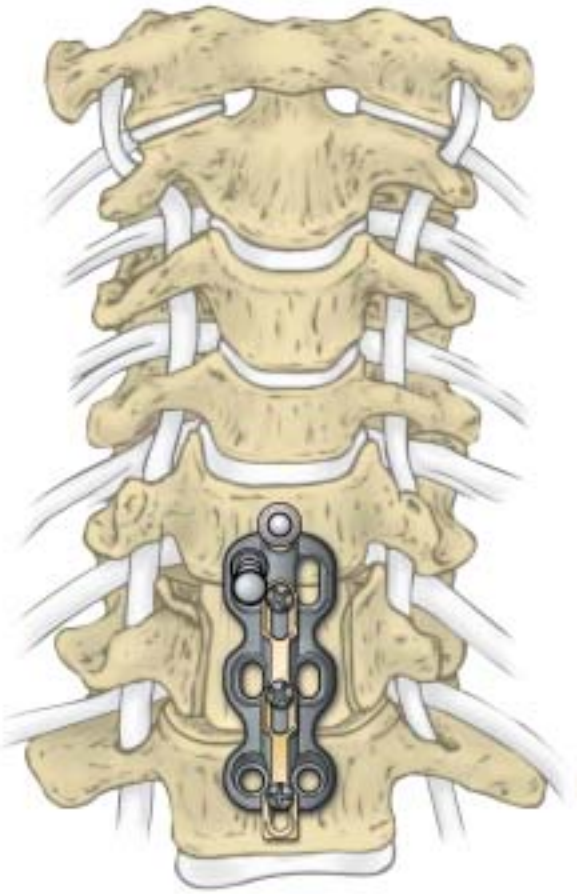


FIGURE 21B

STEP 5

The PREMIER® System offers the surgeon the versatility of color-coded bone screws in two diameters *(Figure 22)*.

The same bone screw can be utilized in the slots or the fixed holes. When the bone screws are placed in a slot, there is some intrinsic variability of placement longitudinally.

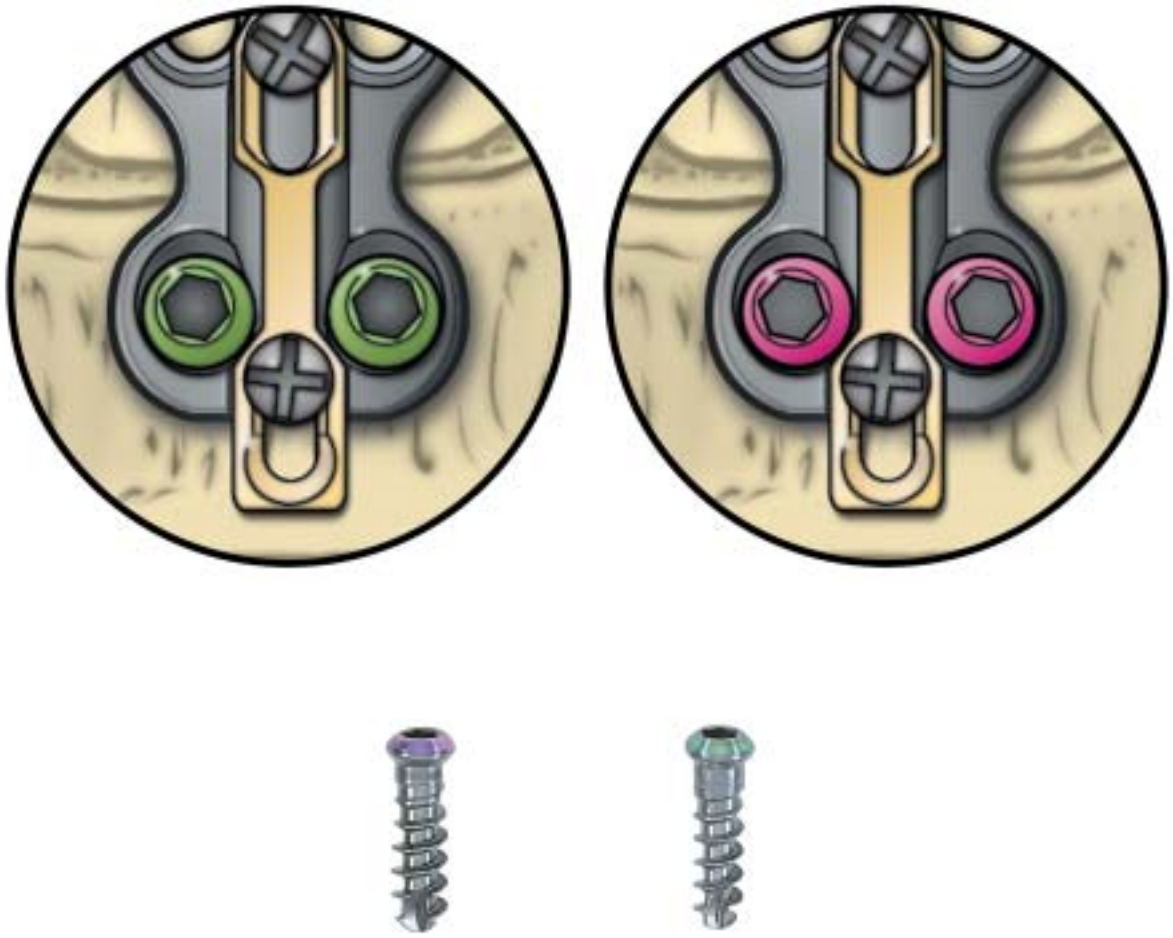


FIGURE 22

STEP **6**

The Drill Guide or the Dual Drill Guide is utilized to place the bone screws in the fixed holes of the PREMIER® plate. The Dual Drill Guide can be securely engaged in the plate by applying light downward pressure on the handle *(Figure 23)* making sure to align the drill guide in the correct 12° caudal angle *(Figure 24)*.

FIGURE 23

"Either the single or dual guide can be used for both the fixed holes and slots."

– H. Herkowitz, M.D.

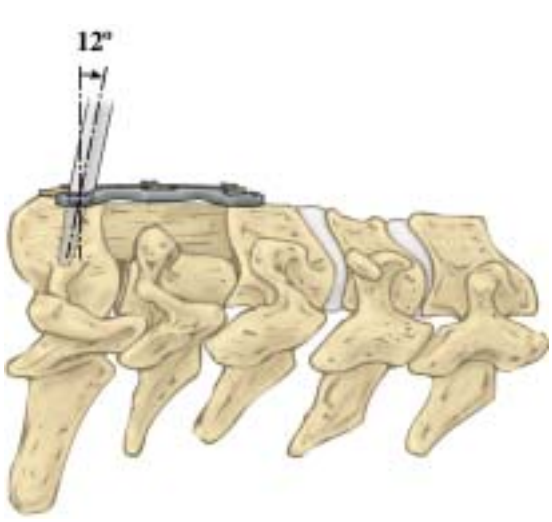
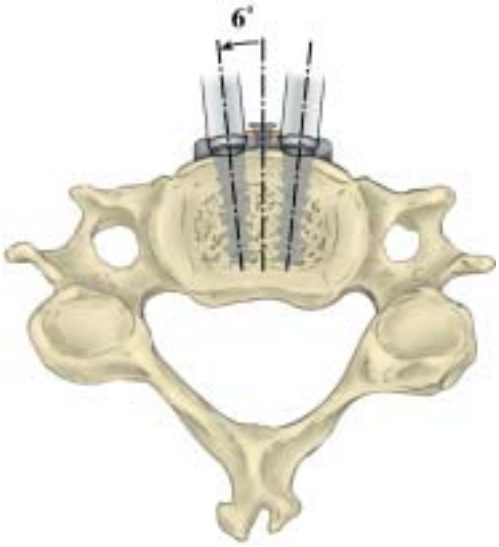


FIGURE 24



STEP **7**

Insert the selected Drill Bit into the manual Drill Bit Handle or a power drill. A Circular Drill Bit Adaptor is provided. Place the Drill Bit into the Dual Drill Guide. Drill the screw holes using either the 13mm Drill Bit or the Adjustable Drill Bit with Adjustable Drill Stop *(Figure 25)*. Screw length is determined by the depth of bone purchase required *(Figure 26)*.

If required, a controlled penetration of the posterior cortex may be achieved by setting the Adjustable Stop to the appropriate depth. The Adjustable Drill Stop provides settings in 1mm increments.

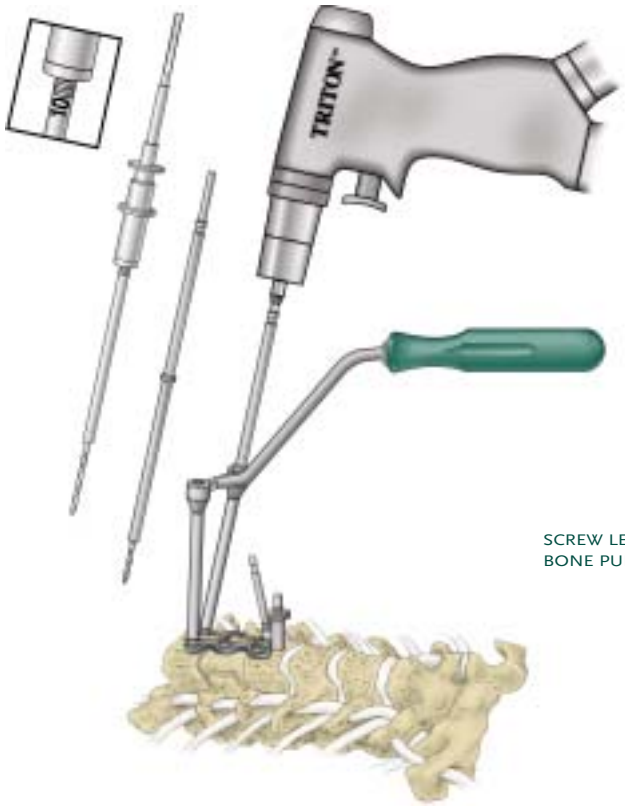


FIGURE 25

"I adjust the screw length depending on the size of the vertebra, the quality of the bone, and the diagnosis. For trauma cases, longer screws that come close to the posterior cortex are used. I use 15mm length most commonly for degenerative cases."

– T. Zdeblick, M.D.

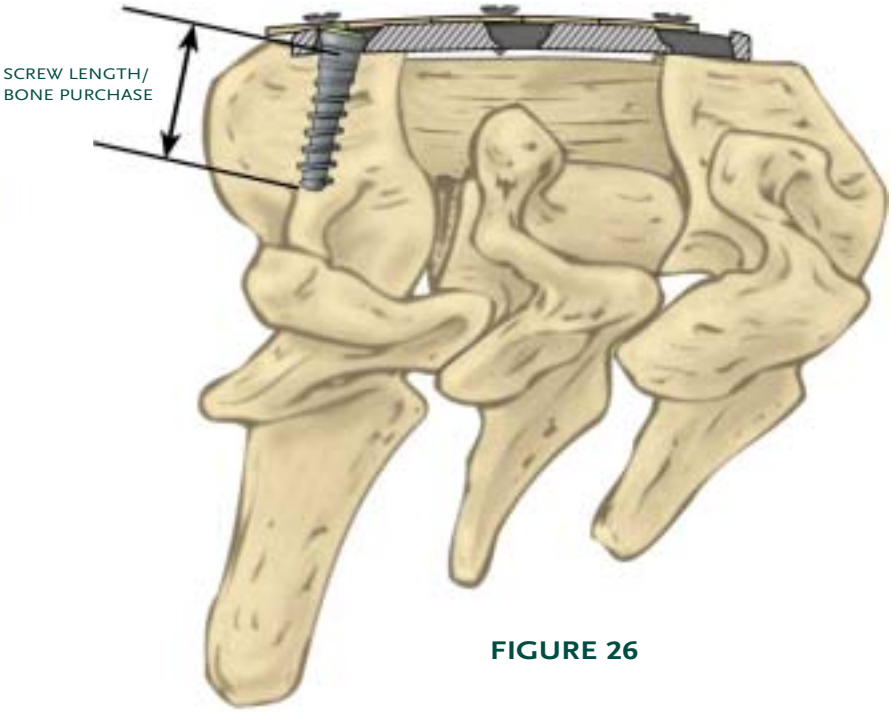


FIGURE 26

STEP 8

The PREMIER® System Bone Screws are provided self-tapping *(Figure 27)*. However, if desired, the Bone Screw Tap can be inserted into the pilot hole at the same angulation that was drilled to tap the vertebral bodies *(Figure 28)*.

4.0mm **4.5mm**

FIGURE 27

"I find it necessary to tap when extremely hard bone is encountered."

– H. Herkowitz, M.D.

FIGURE 28

STEP
9

If required, a Depth Gage may be used to confirm the depth of the pilot hole for proper screw length. The Depth Gage works through the plate *(Figure 29)*.

The appropriate screw can be verified using the Screw Gage located in the Bone Screw Block *(Figure 30)*.

Insert the appropriate length bone screw through the plate using the Screwdriver and preliminarily tighten the bone screw (not final tightening). The Screwdriver has a tapered, self-holding tip to provide for easy insertion of the screw.

The preferred method of bone screw insertion is as follows:

Drill both fixed holes with the Dual Drill Guide, tap if desired, place both bone screws and incrementally tighten. Remove Plate Holding Pin with Plate Holding Pin Driver if appropriate.

Applying the bone screws to the fixed portion of the plate provides an anchor point for the compression techniques that follow.

FIGURE 29

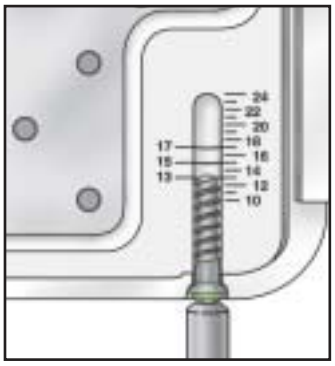


FIGURE 30

STEP
10

If desired, the external Compressor can be utilized after both fixed screws have been placed to anchor the plate. The Compressor can be utilized in the intermediate slot and with the Compression Pin to achieve up to 2mm of compression *(Figure 31)*. The Compression Pin should have been placed previously with the Compression Pin Placement Template during the initial stages for distraction or during plate placement. By removing the Compression Sleeve, a space is left between the notch in the plate and the Compression Pin *(Figures 32 and 33)*.

The Compressor has a ratchet to maintain the applied compression during the next step, drilling for the slot bone screws.

FIGURE 31

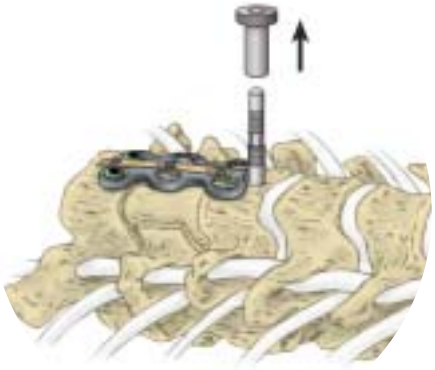


FIGURE 32

"For the majority of cases, the dynamic compression slot alone will provide adequate compression. I use the external compressor for multi level corpectomies or to correct a grafting deficit."

– T. Zdeblick, M.D.

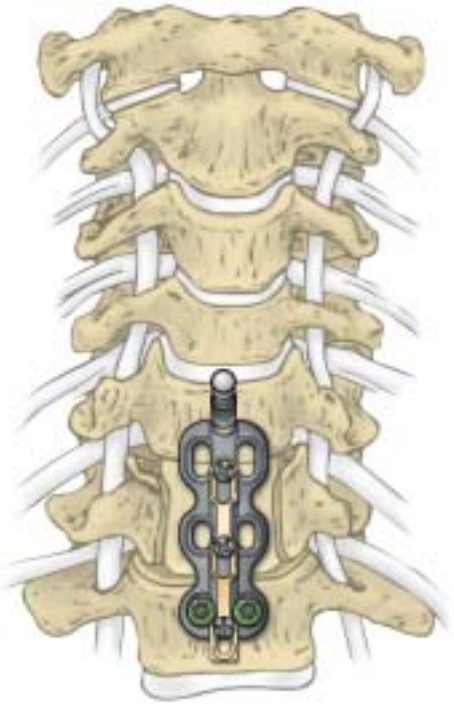


FIGURE 33

STEP 11

The PREMIER® System provides a Single or a Dual Dynamic Slot Drill Guide for placing bone screws in the superior slots that include the dynamic compression ramp. In order to utilize the compression ramp, the Drill Guide should be placed at the top of the slot with gentle pressure pushing the guide up to the top of the ramp. Placing the bone screw in this most superior position will ensure interference with the compression ramp as the bone screw is fully tightened.

The Dynamic Slot Guides do not lock in the plate like the fixed hole guides. The unique geometry of the Drill Guide helps to reference the slot and still provides some variability longitudinally in bone screw placement *(Figure 34)*.

The dynamic slot bone screw holes should both be drilled prior to placing bone screws to ensure parallel placement of the bone screws. As described previously, the pilot holes may be tapped if desired. The optimal angulation is 12° cephalad. However, when placed in a slot, the bone screw angulation may be varied up to ±20°. The medial/lateral angulation is 6° convergent.

The superior slot bone screw should be placed as described previously with the Screwdriver *(Figure 35)*. Once the bone screws are started, the external Compressor can be removed and the Compression Pin should be removed before engaging the dynamic compression ramp. The bone screws should be incrementally tightened alternating between the two as they engage the dynamic compression ramp to ensure gradual and equal compression.

FIGURE 34

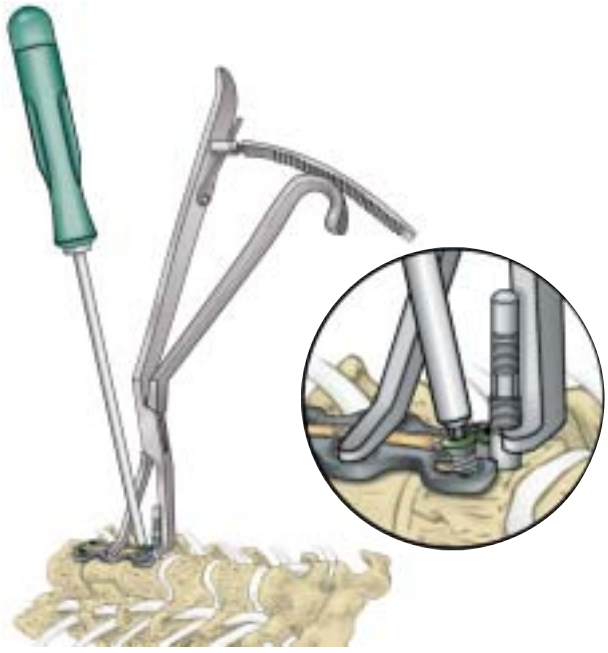


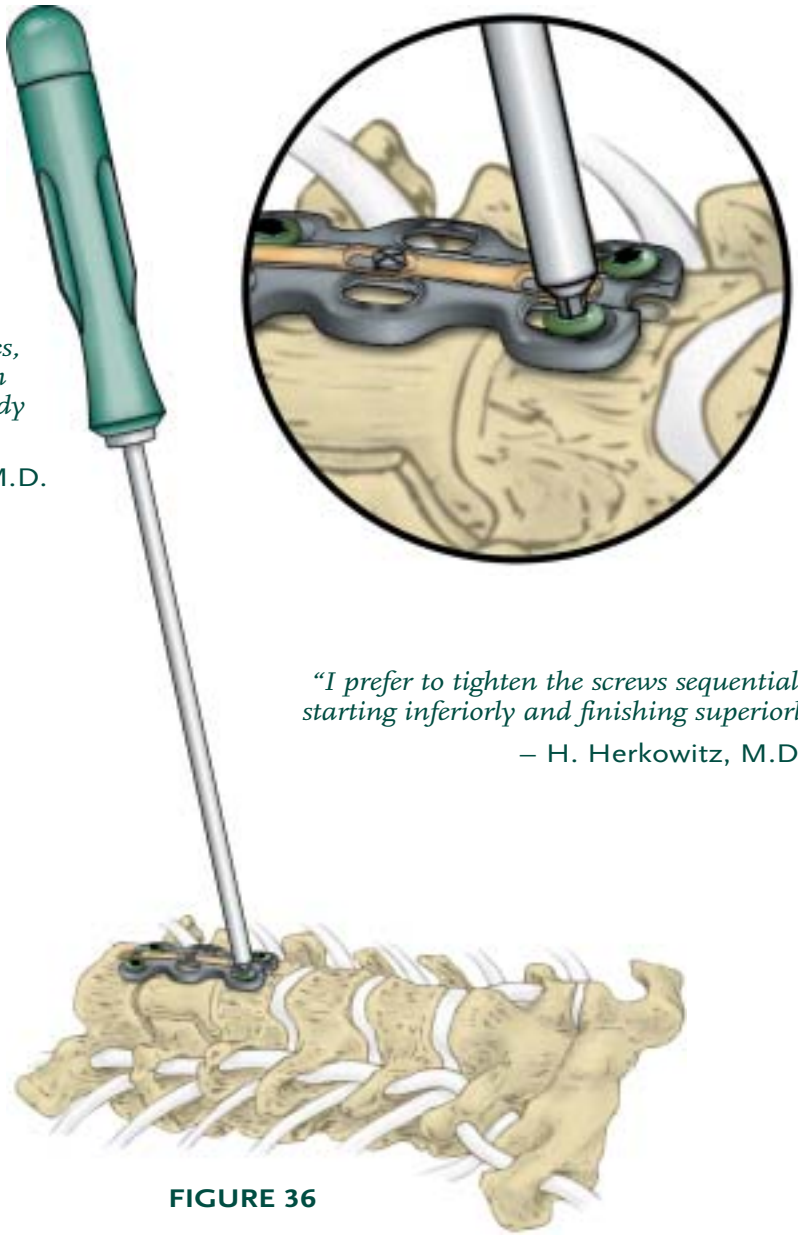
FIGURE 35

STEP 12

Final tightening of all screws is done sequentially so that the plate is evenly applied to the anterior cortical surface of the spine *(Figure 36)*.

"For multiple level discectomies, I typically place two screws in each intermediate vertebral body for additional fixation."

– T. Zdeblick, M.D.



"I prefer to tighten the screws sequentially, starting inferiorly and finishing superiorly."

– H. Herkowitz, M.D.

FIGURE 36

STEP 13

All of the PREMIER® System Lockscrews are attached to the plate in the unlocked or up position. Once all of the bone screws have been securely seated in the plate, the Lock Washer should be translated into the locked position *(Figure 37)*. Once the washer is in the locked position covering the bone screw heads, the Lockscrew Driver is engaged into each Lockscrew and tightened *(Figure 38)*. The lockscrew mechanism is now firmly secured.
Note: Tighten the Lockscrews starting at the inferior (fixed screw) end of the plate.

All Lockscrews within the plate must be fully engaged and tightened before the procedure is complete *(Figure 39)*.

UNLOCKED LOCKED

FIGURE 37

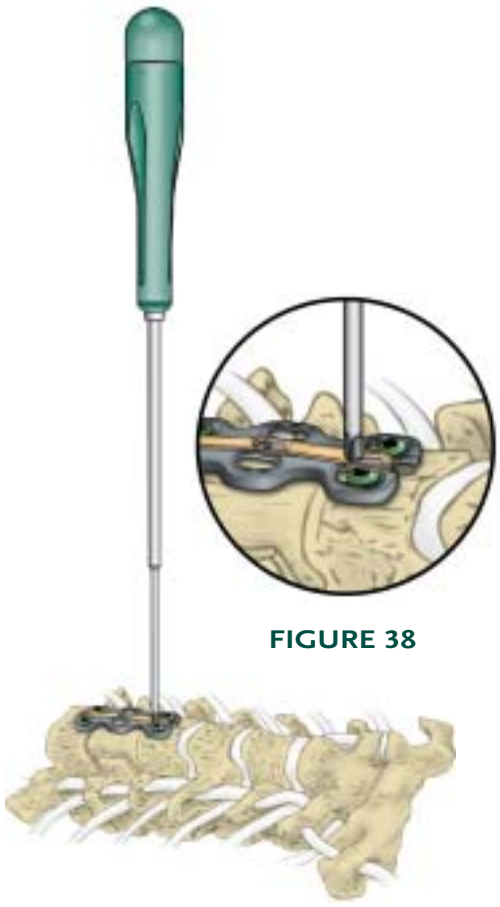


FIGURE 38

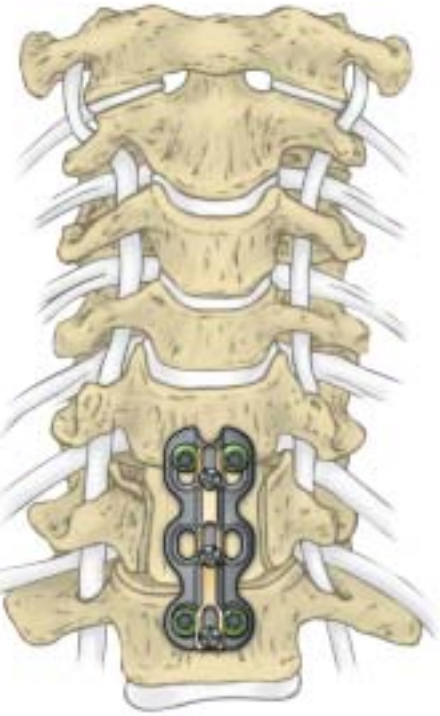


FIGURE 39

"The PREMIER® System has improved my fusion rates on interbody as well as strut graft fusions. It has also shortened my patients' rehabilitation time, brace use and gotten my patients back to normal activities much sooner."

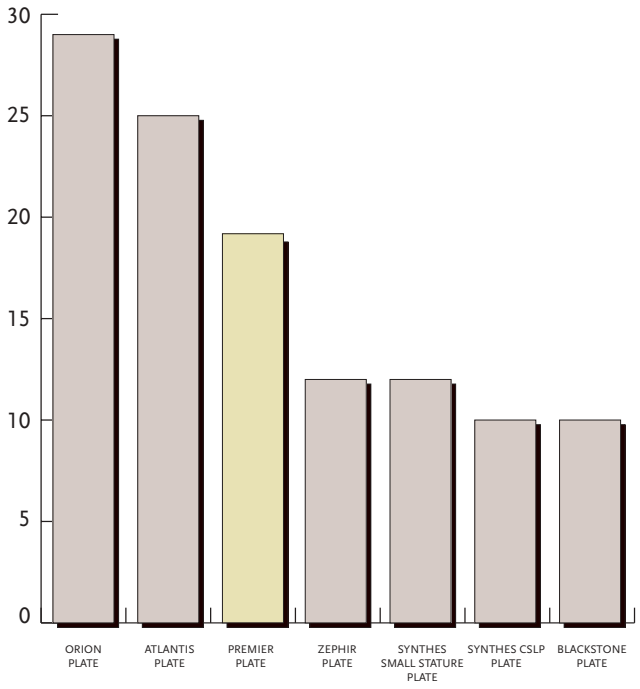
– H. Herkowitz, M.D.

FIGURE 40

A mechanical testing standard exists to provide a basis of comparison between spinal implant assemblies. The current accepted standard of comparison is outlined in ASTM F1717 – Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy Model. The protocol for anterior cervical plates provides for a corpectomy model without a graft or spacer, and a 35mm spacing between inferior and superior bone screws. Plates and bone screws are assembled in the configuration shown *(Figure 40)*. In order to determine the endurance limit of a system, constructs are tested at various loads to the number of cycles that it can sustain prior to failure. The endurance limit of a construct for this protocol is the maximum load that is endured for at least 5,000,000 cycles without a failure. The PREMIER® and other systems were subjected to the standard corpectomy compression fatigue test. All testing was performed at an independent test laboratory *(Figure 41)* and complied with the protocol previously mentioned.

RUNOUT AT 5,000,000 CYCLES IN COMPRESSIVE FATIGUE (ASTM F1717)

FIGURE 41



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Premier®
ANTERIOR CERVICAL PLATE SYSTEM

ANTERIOR CERVICAL PLATES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860123	23mm Plate	6860162	62.5mm Plate
6860125	25mm Plate	6860165	65mm Plate
6860127	27.5mm Plate	6860167	67.5mm Plate
6860130	30mm Plate	6860170	70mm Plate
6860132	32.5mm Plate	6860172	72.5mm Plate
6860135	35mm Plate	6860175	75mm Plate
6860137	37.5mm Plate	6860177	77.5mm Plate
6860140	40mm Plate	6860180	80mm Plate
6860142	42.5mm Plate	6860182	82.5mm Plate
6860145	45mm Plate	6860185	85mm Plate
6860147	47.5mm Plate	6860187	87.5mm Plate
6860150	50mm Plate	6860190	90mm Plate
6860152	52.5mm Plate	6860195	95mm Plate
6860155	55mm Plate	6860200	100mm Plate
6860157	57.5mm Plate	6860205	105mm Plate
6860160	60mm Plate	6860210	110mm Plate

SELF-TAPPING CANCELLOUS SCREWS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860010	4.0 x 10mm Self-tapping Cancellous Screw	6860016	4.0 x 16mm Self-tapping Cancellous Screw
6860011	4.0 x 11mm Self-tapping Cancellous Screw	6860017	4.0 x 17mm Self-tapping Cancellous Screw
6860012	4.0 x 12mm Self-tapping Cancellous Screw	6860018	4.0 x 18mm Self-tapping Cancellous Screw
6860013	4.0 x 13mm Self-tapping Cancellous Screw	6860019	4.0 x 19mm Self-tapping Cancellous Screw
6860014	4.0 x 14mm Self-tapping Cancellous Screw	6860020	4.0 x 20mm Self-tapping Cancellous Screw
6860015	4.0 x 15mm Self-tapping Cancellous Screw		
6860053	4.5 x 13mm Self-tapping Cancellous Screw	6860057	4.5 x 17mm Self-tapping Cancellous Screw
6860055	4.5 x 15mm Self-tapping Cancellous Screw		

INSTRUMENTS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860402	Plate Bender	6860455	Adjustable Drill Bit, Tri-Flat
6860404	Plate Holding Pin	6860460	Adjustable Drill Stop
6860406	Plate Holding Pin Driver	6860465	Circular Bit Drill Adaptor
6860408	Plate Holder	6860468	Depth Gage
6860410	Drill Guide	6860470	Drill Bit Handle
6860412	Dual Drill Guide	6860472	4.0 x 13mm Tap
6860415	Dynamic Slot Drill Guide	6860482	Bone Screw Driver
6860417	Dual Dynamic Slot Drill Guide	6860484	Lockscrew Driver
6860420	Dual Guide Temporary Pin	6860500	Implant/Instrument Case
6860443	13mm Drill Bit, Tri-Flat		

COMPRESSION INSTRUMENTS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860510	Compressor	6860525	Compression Pin Placement Template
6860516	Compression Pin	6860531	Compression Pin Driver
6860521	Compression Sleeve	6860550	Compression/Auxiliary Instrument Case

TRIMLINE® ACDF

INSTRUMENT SET

STANDARD DISTRACTOR SET

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-080	Vertebral Body Distractor (Right)	875-089	16mm Distractor Pins, (10/Pkg) Sterile
875-081	Vertebral Body Distractor (Left)	875-090	Distractor Screwdriver
875-087	12mm Distractor Pins, (10/Pkg) Sterile	Note: Distractor pins are packaged sterile.	
875-088	14mm Distractor Pins, (10/Pkg) Sterile		

STANDARD DISTRACTOR SET – AUXILIARY ITEMS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-084	Drill Guide (R)	875-086	Twist Drill
875-085	Drill Guide (L)	875-950	Distractor Case

KERRISONS

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-251	1mm Kerrison	875-252	2mm Kerrison	875-253	3mm Kerrison

HAND-HELD RETRACTORS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-050	Hand-Held Retractor, Straight, 18mm	875-052	Hand-Held Retractor, Back Lip, 20mm
875-051	Small Hand-Held Retractor, Straight, 18mm	875-053	Hand-Held Retractor, Curved, 23mm

SELF-RETAINING RETRACTORS AND BLADES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-110	Transverse Self-Retaining Retractor Frame	875-156	23x60mm Discectomy Blade
875-115	Longitudinal Self-Retaining Retractor Frame	875-158	23x70mm Discectomy Blade
875-148	Retractor Blade Handle, Fixed	875-160	20x30mm Longitudinal Blade
875-149	Retractor Blade Handle, Swivel	875-162	20x40mm Longitudinal Blade
875-150	23x30mm Discectomy Blade	875-164	20x50mm Longitudinal Blade
875-152	23x40mm Discectomy Blade	875-166	20x60mm Longitudinal Blade
875-154	23x50mm Discectomy Blade	875-168	20x70mm Longitudinal Blade

CURETTES

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-300	Curette Straight 6-0	875-305	Curette Straight 1-0	875-313	Curette Angled 3-0
875-302	Curette Straight 4-0	875-307	Curette Straight 2-0	875-314	Curette Angled 2-0
875-303	Curette Straight 3-0	875-310	Curette Angled 6-0	875-315	Curette Angled 1-0
875-304	Curette Straight 2-0	875-312	Curette Angled 4-0		

MICRO CURETTES

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-370	Micro Curette Straight 6-0	875-374	Micro Curette Straight 2-0	875-383	Micro Curette Angled 3-00
875-372	Micro Curette Straight 4-0	875-380	Micro Curette Angled 6-0	875-384	Micro Curette Angled 2-0
875-373	Micro Curette Straight 3-0	875-382	Micro Curette Angled 4-0		

IMPORTANT INFORMATION ON THE PREMIER® ANTERIOR CERVICAL PLATE SYSTEM

PURPOSE:

The PREMIER® Anterior Cervical Plate System implant components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the PREMIER® Anterior Cervical Plate System is via an anterior surgical approach.

DESCRIPTION:

The PREMIER® Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The PREMIER® Anterior Cervical Plate System features a sliding washer that covers the heads of the bone screws to prevent screw back-out. The sliding washer is fixed into place with a set screw. The sliding washer and set screw come pre-assembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The PREMIER® Anterior Cervical Plate System implant components are made from titanium alloy such as described by ASTM F136 or ISO 5832-3. This material is not compatible with other metal alloys. Do not use any of the PREMIER® Anterior Cervical Plate System components with the components from any other system or manufacturer. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from 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.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:

Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

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

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EVENTS:

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible 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, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue 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. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
19. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
21. Development of respiratory problems, e.g., pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status
23. Death.

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

WARNINGS AND PRECAUTIONS:

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 PREMIER® Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended 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. Bone grafting must be part of the spinal fusion procedure in which the PREMIER® Anterior Cervical Plate System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot 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 planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the PREMIER® Anterior Cervical Plate 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

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.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

Other preoperative, intraoperative, and postoperative warnings 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.

DEVICE FIXATION:

The PREMIER® Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The PREMIER® Anterior Cervical Plate System features a sliding washer that covers the heads of the bone screws to prevent screw back-out. After the bone screws have been inserted through the plate, the sliding washer should be positioned over the heads of the bone screws. The washer is then locked into place by tightening the set screws. The sliding washer and set screws come pre-assembled to the plate. Associated instruments are available to facilitate the implantation of the device.

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 components. The 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 beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those 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 PREMIER® Anterior Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not 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. Any available instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at 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. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since 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, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Also make sure the sliding washer is positioned over the heads of the bone screws and secured tightly to the plate with the set-screws. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

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 or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive 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, demented or otherwise unable to use crutches or other such weight supporting devices. 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 device should not be exposed to mechanical vibrations 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 or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend 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 spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. The PREMIER® Anterior Cervical Plate 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. 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 post-operative trauma, (4) Bending, loosening and/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, and (7) Bone loss due to stress shielding.
6. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the PREMIER® Anterior Cervical Plate System components should ever 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 should be carefully checked for lack of 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 disinfecting of instruments can be performed with alkali aldehyde-free solvents at higher temperatures. Cleaning and decontamination can 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, 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 noted otherwise on the package labeling, the PREMIER® Anterior Cervical Plate System components are provided non-sterile. I**f the product described in this document is sterilized by the hospital in a tray or case, it should be sterilized in a tray or case provided by Medtronic Sofamor Danek.** These products need to be steam sterilized by the hospital using one of the following methods:

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)	20 Minutes
Steam	Pre-Vacuum	270° F (132° C)	5 Minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize before handling or (if applicable) return to MEDTRONIC SOFAMOR DANEK.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted PREMIER® Anterior Cervical Plate 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 and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medtronic Sofamor Danek:

IN THE USA

Customer Service Division
MEDTRONIC SOFAMOR DANEK USA, INC.
1800 Pyramid Place
Memphis, Tennessee 38132 USA
Telephone: 800-876-3133
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