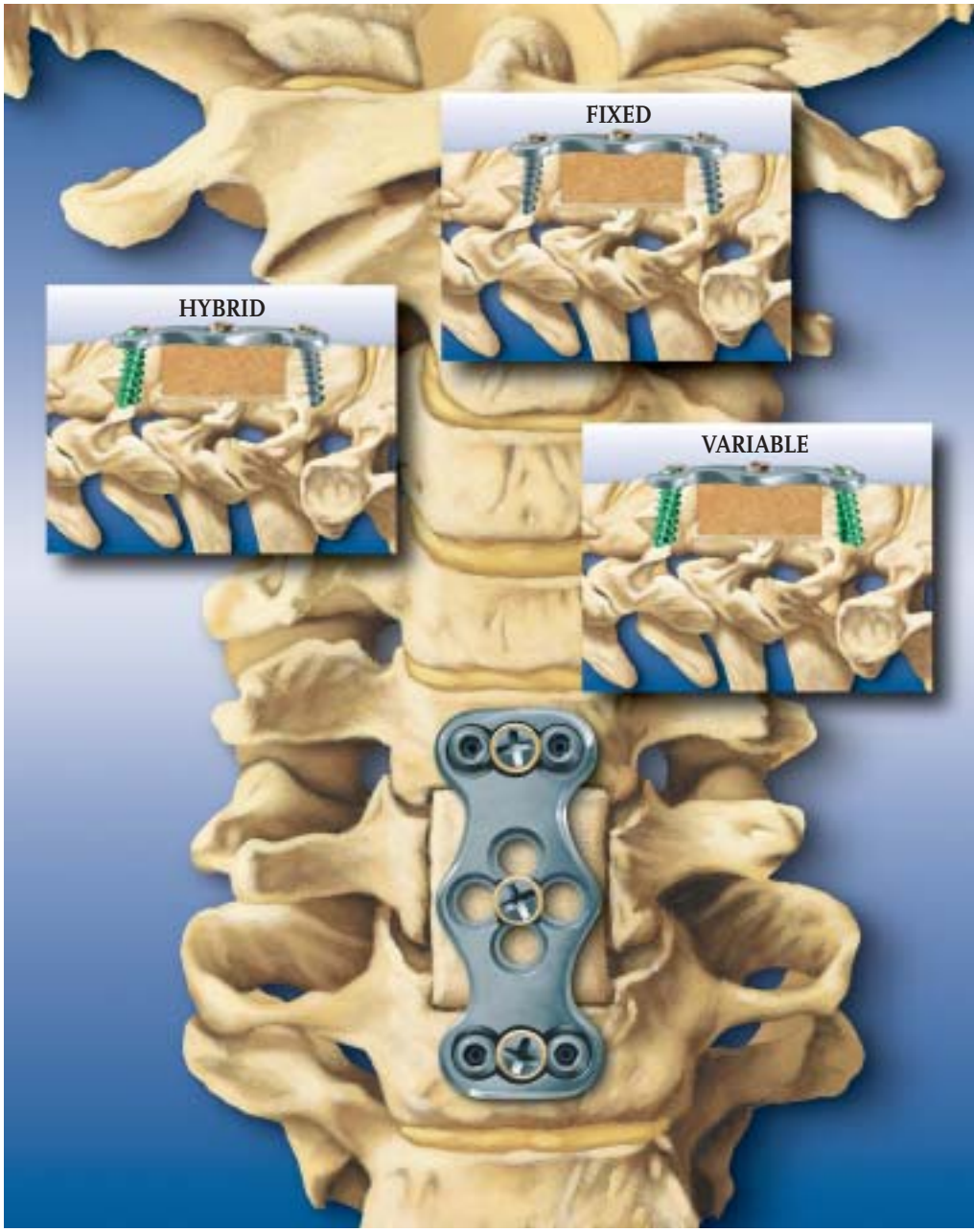
Medtronic
SOFAMOR DANEK

ATLANTIS™ Anterior Cervical Plate System
Surgical Technique



as described by:

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MICHELSON TECHNOLOGY AT WORK

ATLANTIS™

anterior cervical plate system

A system designed to meet the clinical challenges of anterior cervical surgery by offering an attached locking mechanism and the choice of fixed angle screws for standard cases or variable angle screws for ease of implantation in complex cases.

ATLANTIS™
anterior cervical plate system

Dear Fellow Colleagues

Anterior cervical internal fixation is increasingly utilized in spinal surgery. The application of an anterior cervical plate has become widely accepted when anterior spinal fusion is performed to stabilize the spine for tumor, trauma, deformity, degenerative disc disease and other forms of cervical instability. The addition of anterior plate fixation offers many benefits such as: resistance to graft displacement, a reduced incidence of pseudarthrosis related to micromotion at the graft-vertebral body interface, maintaining anterior cervical alignment when multi-level discectomies or corpectomies are performed, and a decreased reliance on prolonged external bracing.

From a clinical, biomechanical and biological perspective, we have looked at our surgical experiences over the past several years, in parallel with many changes in technology and anterior plate design. We have concluded that the ideal anterior cervical plate would allow: unicortical and/or bicortical bone screw purchase, constrained fixation for cases of significant spinal instability, and non-constrained fixation to facilitate a delayed remodeling at the fusion segment by allowing the transmission of physiological loading in more stable clinical scenarios. The specific design goals in the development of the ATLANTIS Anterior Cervical Plate System were to offer an implant that has an integral lock mechanism, is low profile, is CT/MRI compatible, is easy to use, offers the surgeon the versatility of creating either a constrained or non-constrained system, and allows for the placement of fixed, variable, or a combination of these two screw types within a single plate. Depending on the underlying etiology for instability, this system can be tailored to meet each patient's specific needs.

A constrained system can be created by using fixed screws in both ends of the plate. This type of construct is designed to offer maximum stability at the graft receptor site. We have found the constrained properties of this construct to be beneficial in tumor, trauma and some degenerative applications.

A hybrid system can be obtained by using a combination of fixed and variable screws within the end holes of the plate. This type of construct is designed to allow flexibility for a patient's aberrant anatomy or for sub-optimal screw positions or purchases. Consequently, the biomechanical stability of the implant can be optimized.

A non-constrained system can be achieved by using variable screws in both ends of the plate. This type of construct is designed to allow optimum physiologic loading of the pathology at the graft receptor site. We have found the non-constrained properties of this construct to be mostly beneficial in degenerative and multi-level applications.

The ATLANTIS™ Anterior Cervical Plate System was tested following ASTM testing standards and found to perform equal to or better than other systems. Prior to its introduction, the ATLANTIS plate was utilized by an international group of surgeons to help refine both implant and instrument designs. We believe the ATLANTIS Anterior Cervical Plate System offers the surgeon the versatility of tailoring the dynamics of the construct to meet individual patient needs and requirements when treating cervical instability.

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

Sincerely,

Volker K. H. Sonntag, M.D. Regis W. Haid, Jr., M.D. Stephen M. Papadopoulos, M.D.

Fixed Construct

Hybrid Construct

Variable Construct

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anterior cervical plate system

C6 corpectomy procedure: patient positioning and incision

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

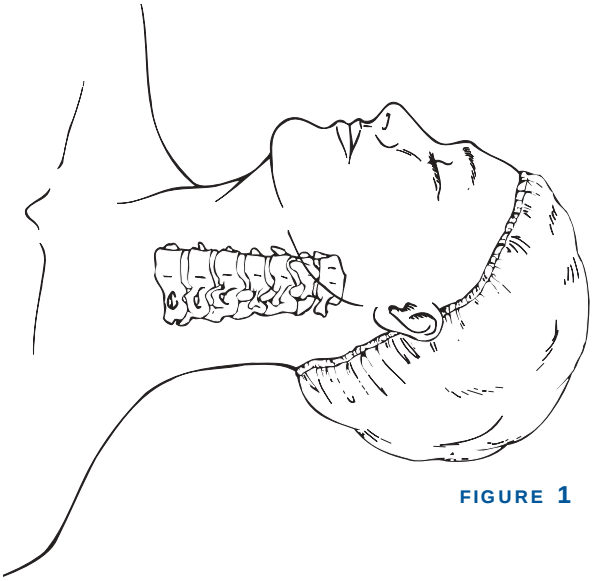


FIGURE 1

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

I prefer the left-sided approach due to the anatomic reliability of the recurrent laryngeal nerve. I typically use a transverse skin incision with a vertical, "muscle splitting" incision of the platysma. Adequate longitudinal exposure at this level is critical, particularly in multi-level procedures.

- S. Papadopoulos, M.D.

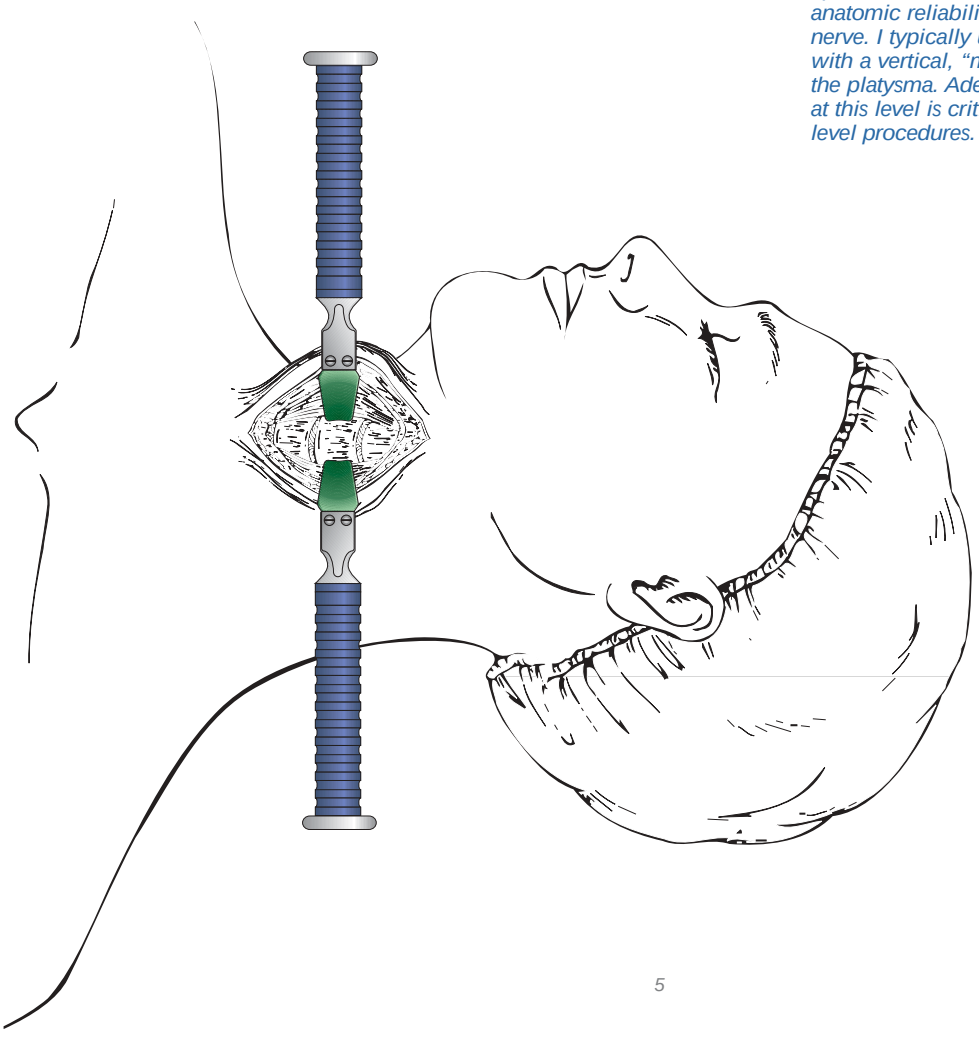


FIGURE 2

C6 corpectomy procedure: exposure

After the cervical vertebral column has been exposed, the longus colli muscles are elevated and the “slotted foot” medial/lateral self-retaining retractor blades are securely positioned *(Figure 3)*. Then the longitudinal self-retaining retractor is placed to provide optimal visualization *(Figure 4).*

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

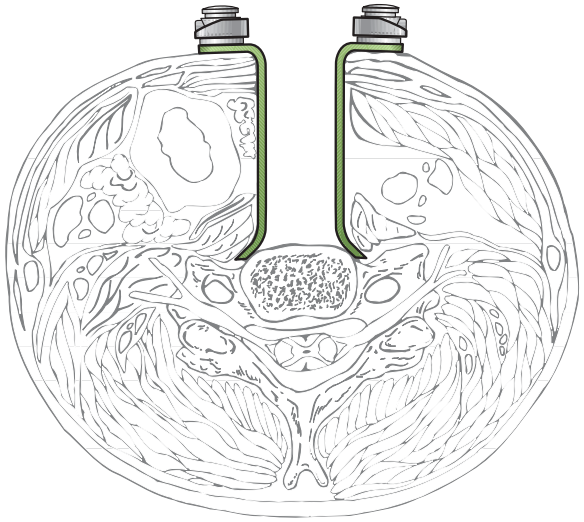


FIGURE 3

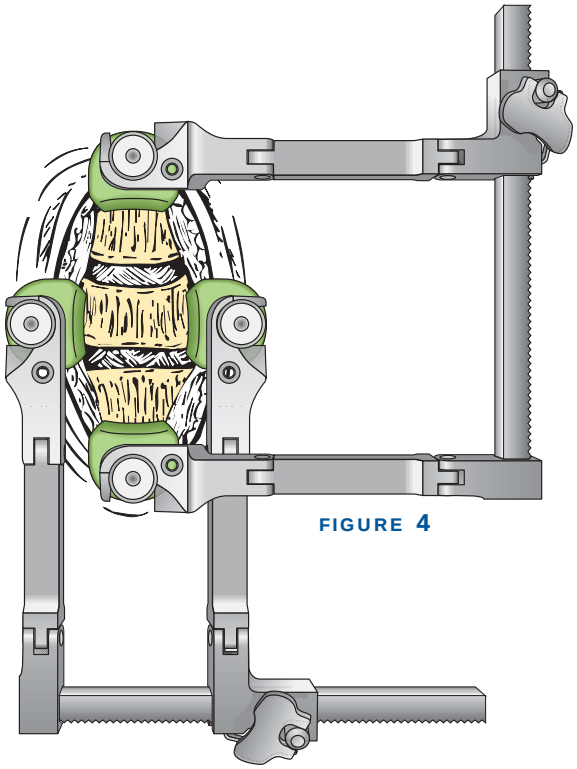


FIGURE 4

I usually perform an initial “anterior” discectomy, widely to the uncovertebral joints, to allow proper “anterior release” prior to placement of the distraction pins. This is particularly important for the correction of a cervical kyphosis.

- S. Papadopoulos, M.D.

Depending on the bone quality, I “pre-load” the graft by placing considerable force on the intervertebral body pins. This allows for optimal graft compression when the distraction pins are released.

- R. Haid, M.D.

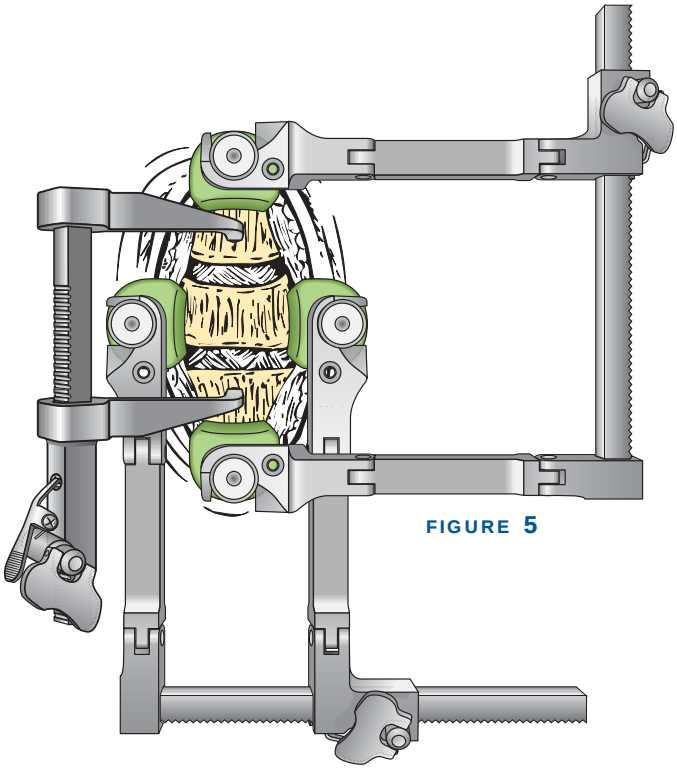


FIGURE 5

C6 corpectomy procedure: discectomy/corpectomy

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 6 and 7).*

After the discs 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 bur may be utilized to remove the remaining portion of the vertebrae *(Figure 8).* The posterior longitudinal ligament and osteophytes are then carefully removed.

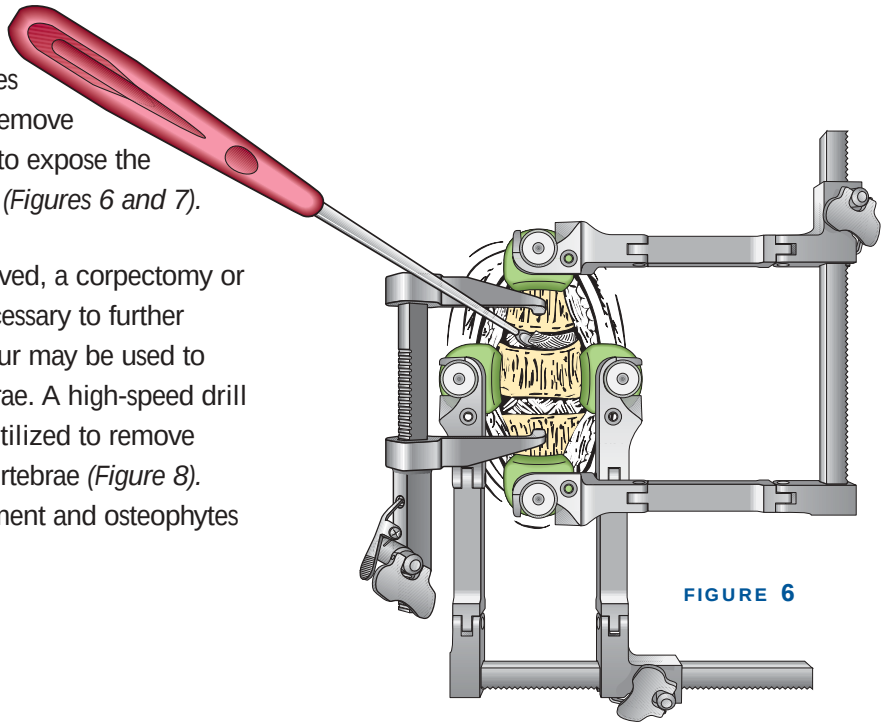


FIGURE 6

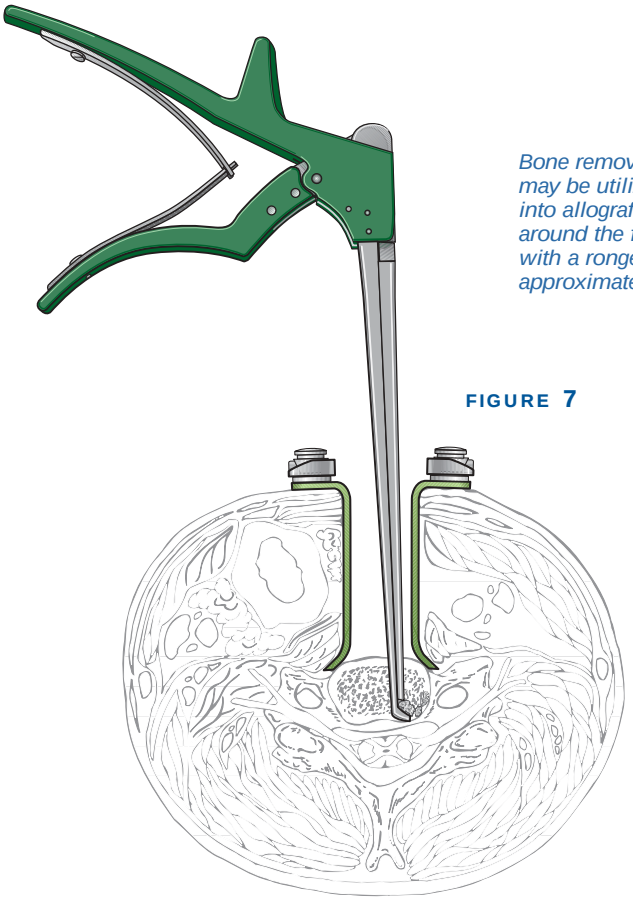


FIGURE 7

Bone removed from the corpectomy may be utilized as graft material placed into allograft fibula and/or packed around the fibula. This is often done with a rongeur after completing approximately 3/4 of the discectomy.
- R. Haid, M.D.

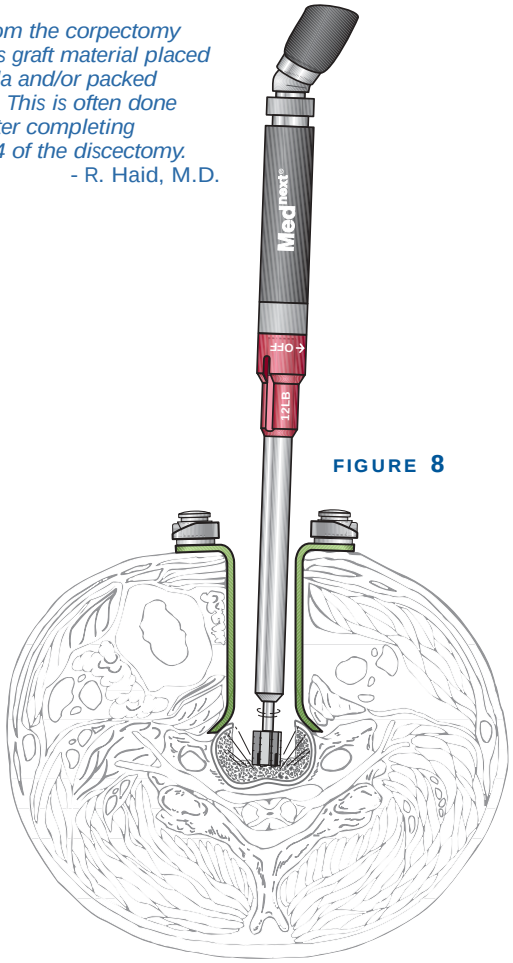


FIGURE 8

C6 corpectomy procedure: graft site preparation and placement

Once the decompression is completed, the bone graft receptor site is prepared. End plate preparation consists of creating a precisely matched mortise with the bone graft using a high-speed bur *(Figure 9)*.

The dimensions of the corpectomy site are measured precisely and the bone graft is shaped appropriately. Either autograft or allograft may be utilized. The graft is held and tapped into place using a bone graft holder and mallet *(Figures 10 and 11).*

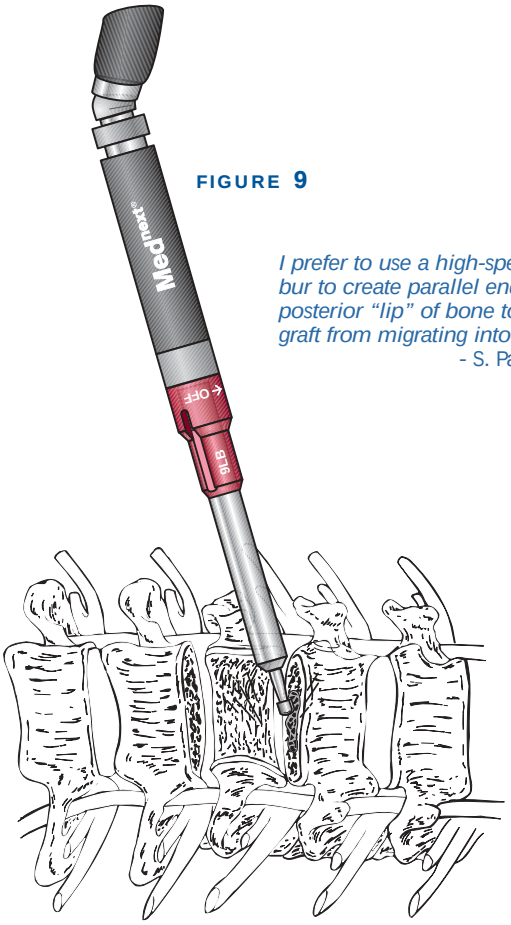


FIGURE 9

I prefer to use a high-speed rectangular bur to create parallel end plates, leaving a posterior "lip" of bone to prevent the bone graft from migrating into the spinal canal.
- S. Papadopoulos, M.D.

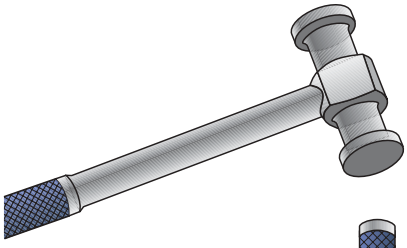
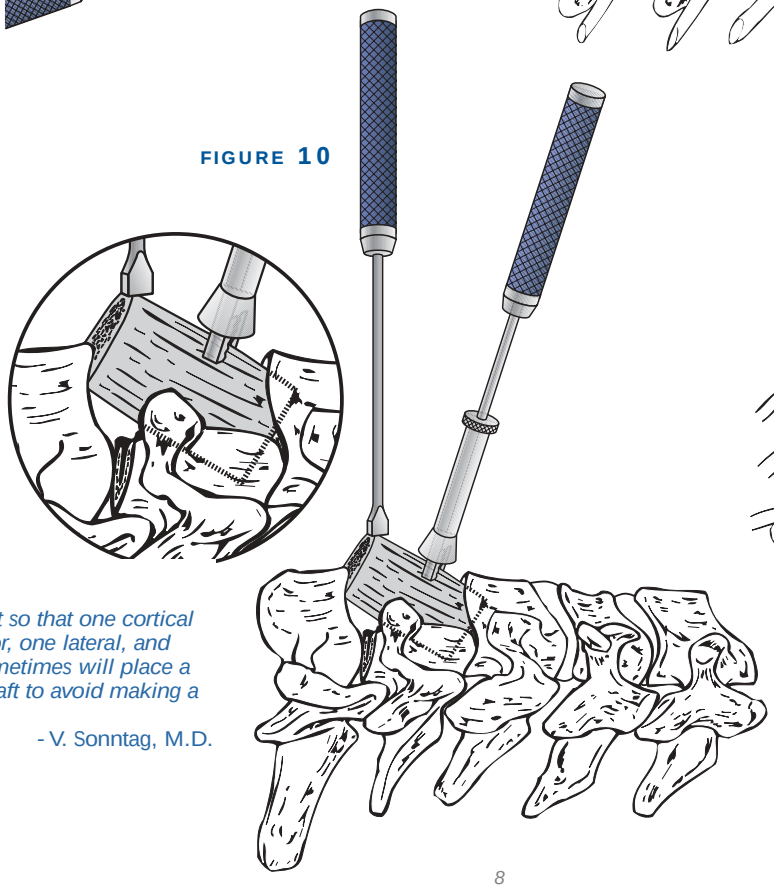


FIGURE 10



I position the graft so that one cortical surface is posterior, one lateral, and one anterior. I sometimes will place a screw into autograft to avoid making a posterior lip.
- V. Sonntag, M.D.

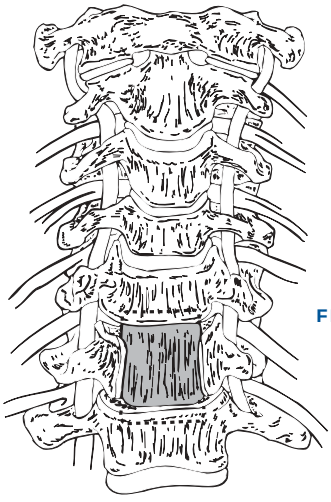


FIGURE 11

step 1 surgical technique: select appropriate plate length

Soft tissue and anterior osteophytes are removed from the adjacent vertebral bodies so the plate may sit evenly on the anterior cortex. Position the plate so the superior and inferior screw holes are at approximately the mid-portion of the vertebral body *(Figure 1A).* This will allow for placement of fixed bone screws or variable bone screws in the center of the vertebrae. The edge of the plate should not interfere with the adjacent unfused disc spaces *(Figure 1B).* The plate may be further contoured with the plate bender to precisely match the lordotic curvature of the anterior cervical spine.

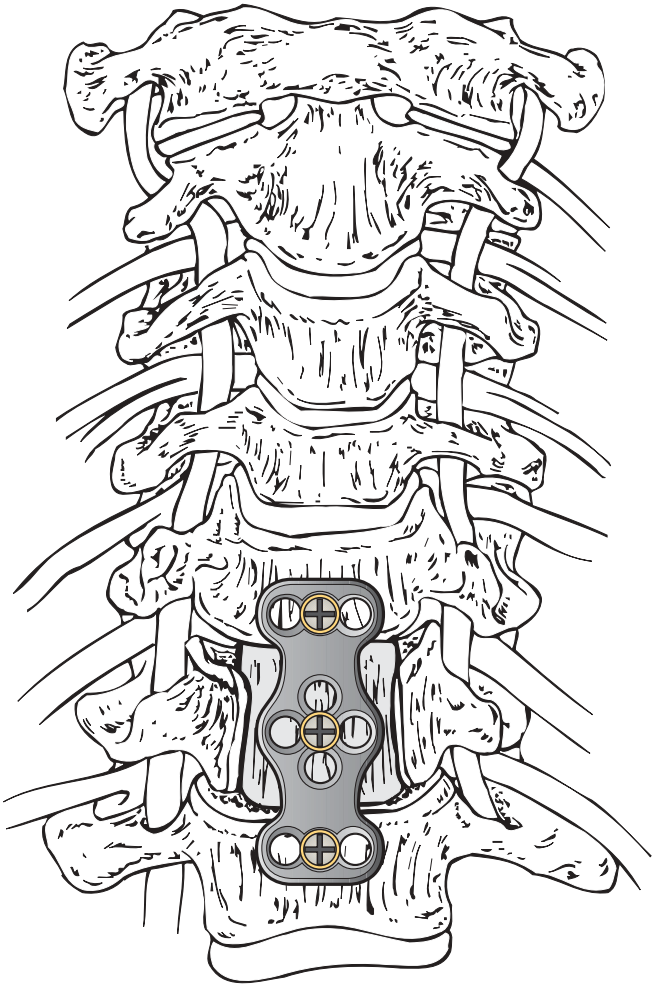


FIGURE 1A

Fluoroscopy may be used to determine the appropriate plate length and anticipated screw trajectories.
- V. Sonntag, M.D.

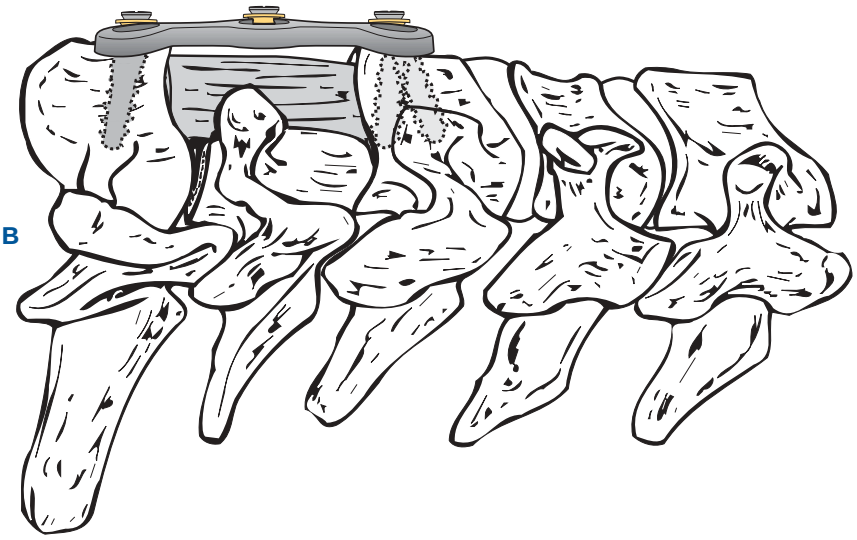


FIGURE 1B

step 2 surgical technique: plate contouring

The ATLANTIS™ Anterior Cervical Plate is provided with a pre-machined lordotic curve *(Figure 2A)*. If required, the plate may be contoured to increase the amount of lordotic curvature *(Figure 2B)* or decrease the amount of lordotic curvature *(Figure 2C)* 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.

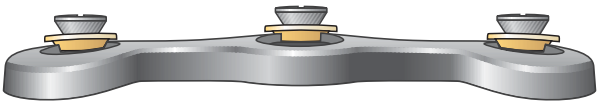


FIGURE 2A

The pre-existing lordosis in the plate is appropriate in most cases and plate contouring is typically not required. It is critical to contour the plate or "garden" the anterior spine to ensure optimal surface contact.

- R. Haid, M.D.

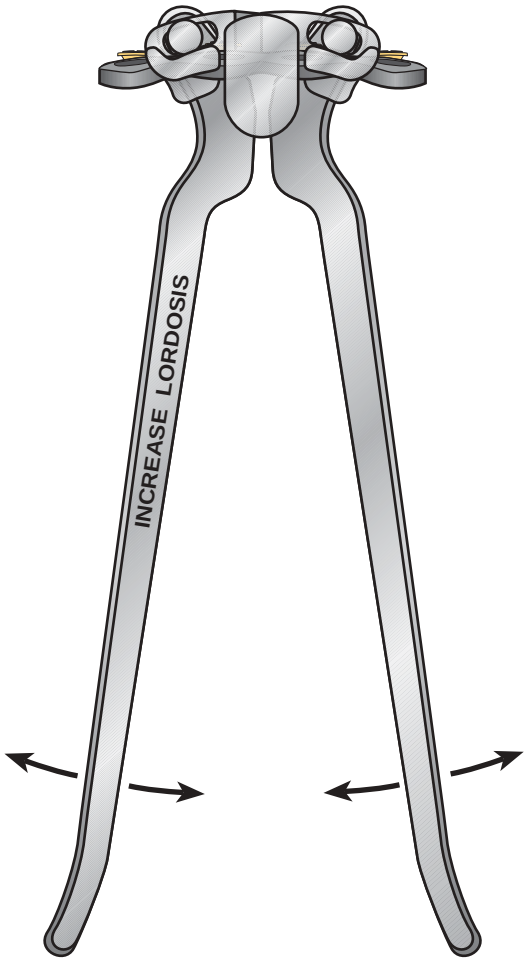


FIGURE 2B

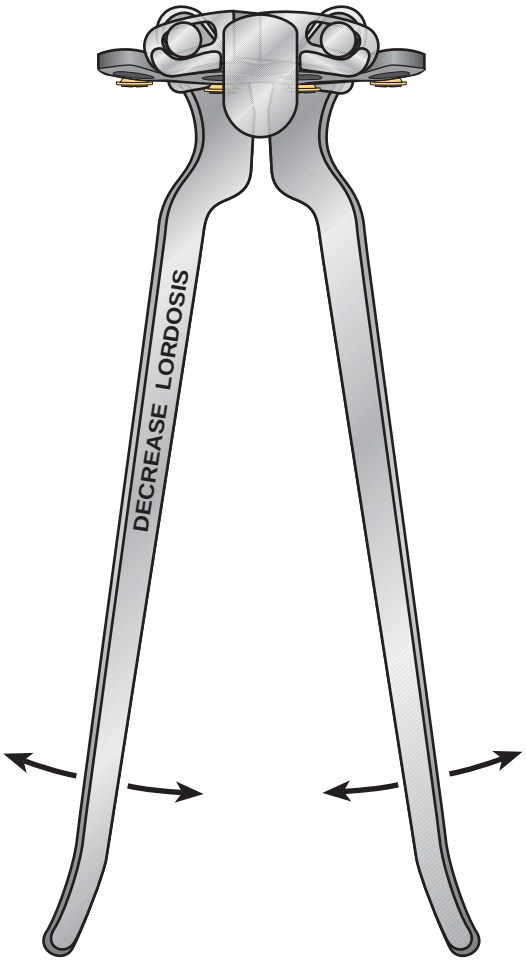


FIGURE 2C

step 3 surgical technique: attach the plate holder

The ATLANTIS™ System Plate Holder may be attached to the plate in any of the screw holes (the tip of the plate holder has a sharp tip to prevent plate migration while positioning). The tip of the plate holder collapses when pressure is applied to the locking sleeve cap *(Figure 3A)*. Insert the collapsed tip into the appropriate screw hole. Releasing pressure to the locking sleeve cap will allow the plate holder to securely engage the plate *(Figure 3B).*

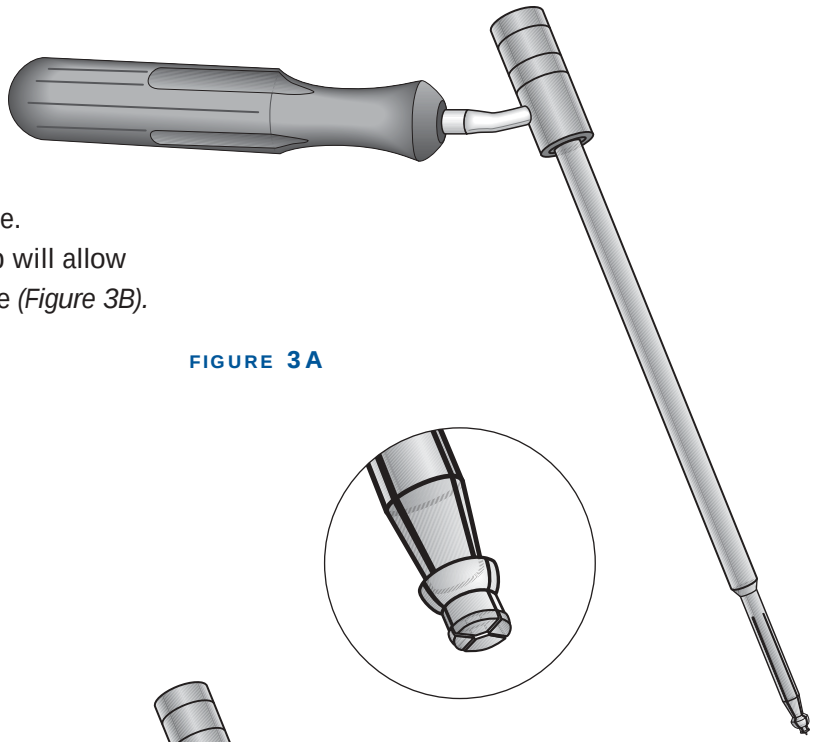


FIGURE 3A

The plate holder may be used as a "visual guide" when placing variable angle screws. The plate holder is directed 6˚ medially and 12˚ rostral/caudal. This serves as a frame of reference.

- R. Haid, M.D.

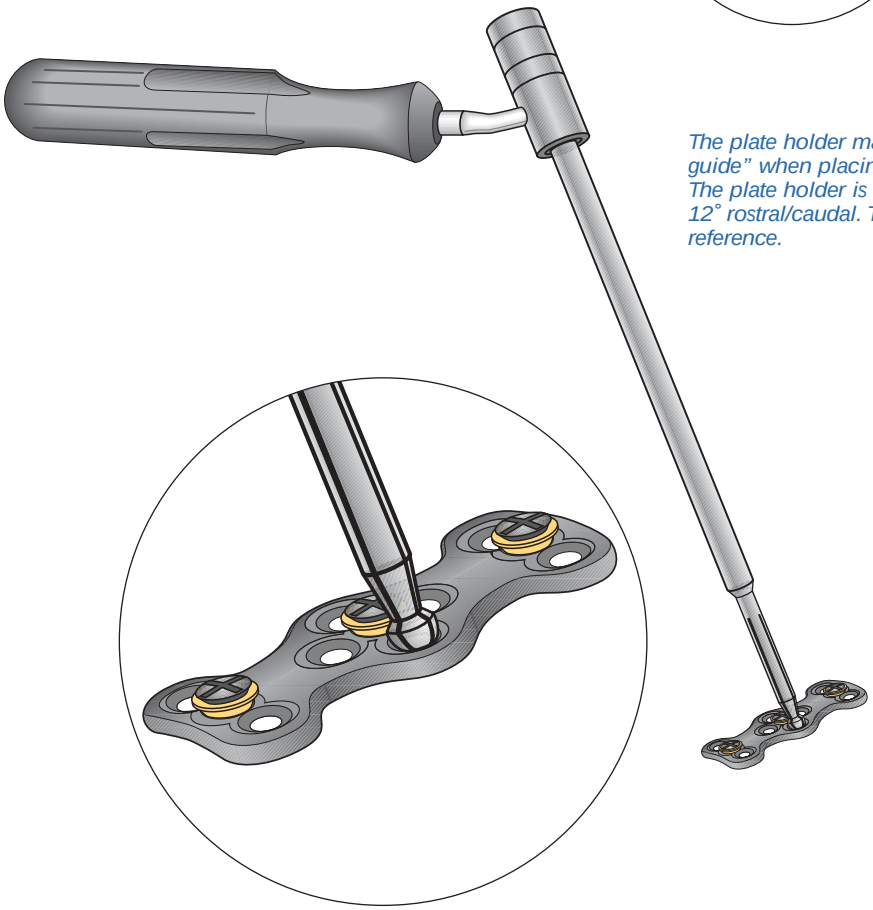


FIGURE 3B

step 4 surgical technique: position the atlantis™ system plate on the anterior surface of the spine

Review landmarks to ensure the plate is centered medially/laterally on the spine (Figure 4A). After the plate length has been selected and placed on the anterior surface of the cervical spine, a plate holding pin can be placed into any of the bone screw holes to provide temporary fixation while drilling and placing bone screws. The pins are engaged into the Plate Holding Pin Driver to allow easy insertion into the bone (Figure 4B). Once seated, the pin may be disengaged from the Plate Holding Pin Driver by applying upward pressure on the locking sleeve *(Figure 4C).*

NOTE: Additional plate holding pins may be used if desired.

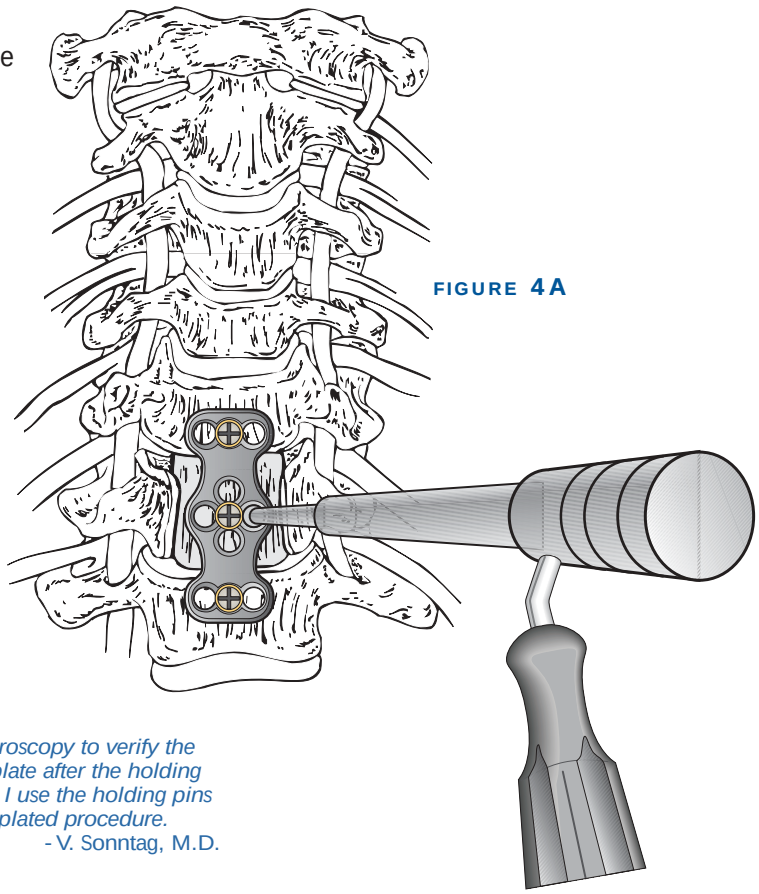


FIGURE 4A

I use lateral fluoroscopy to verify the position of the plate after the holding pins are placed. I use the holding pins in almost every plated procedure.
- V. Sonntag, M.D.

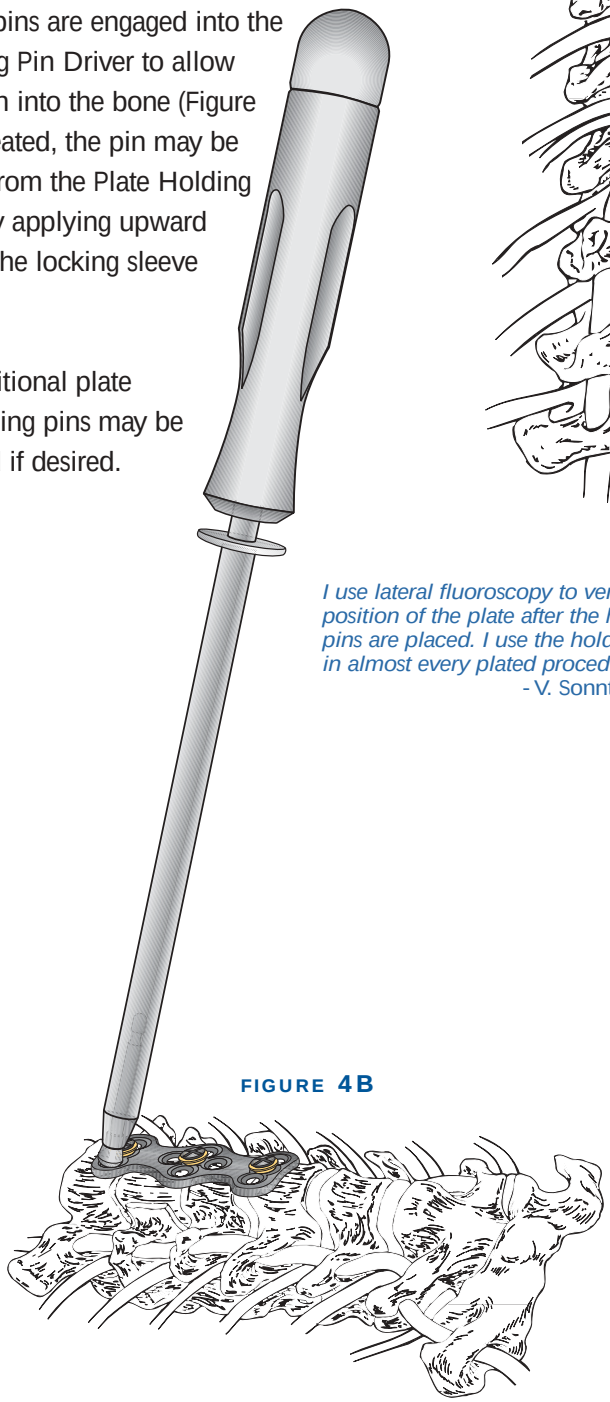


FIGURE 4B

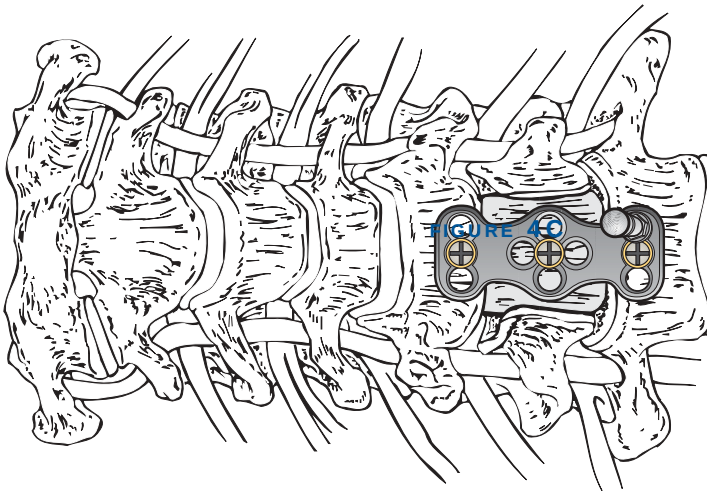


FIGURE 4C

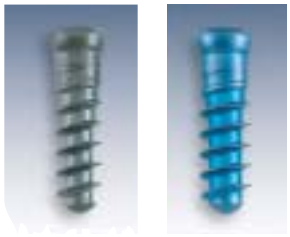
step 5 surgical technique: construct selection and positioning

The ATLANTIS™ System offers the surgeon the versatility of controlling the dynamics of the construct intraoperatively. Fixed, Hybrid or Variable angle constructs may be configured using fixed or variable angle color-coded bone screws.

Fixed and Variable Angle Bone Screws can be identified by their unique color coding.

Fixed Construct

Fixed Angle Bone Screw Options:
4.0mm Fixed Bone Screw (Gray)
4.5mm Fixed Bone Screw (Blue)



Hybrid Construct

Variable Angle Bone Screw Options:
4.0mm Variable Bone Screw (Green)
4.5mm Variable Bone Screw (Magenta)

Variable Construct

The following surgical steps outlined in this surgical technique are specific to the type of construct. Please choose the construct technique from the sections identified as Fixed, Hybrid or Variable.

step 6: fixed angle bone screw positioning

The Fixed Angle Drill Guide is selected and seated within the bone screw hole in the plate. The Fixed Drill Guide can then be securely engaged into the plate by applying light downward pressure on the handle *(Figure 6A)* making sure to align the Drill Guide in the correct 12˚cephalad or 12˚caudad and 6˚ medial convergent angle *(Figure 6B).*

NOTE: The Fixed Angle Drill Guide has a color band incorporated into the handle that corresponds to the appropriate type and diameter of color-coded screw.

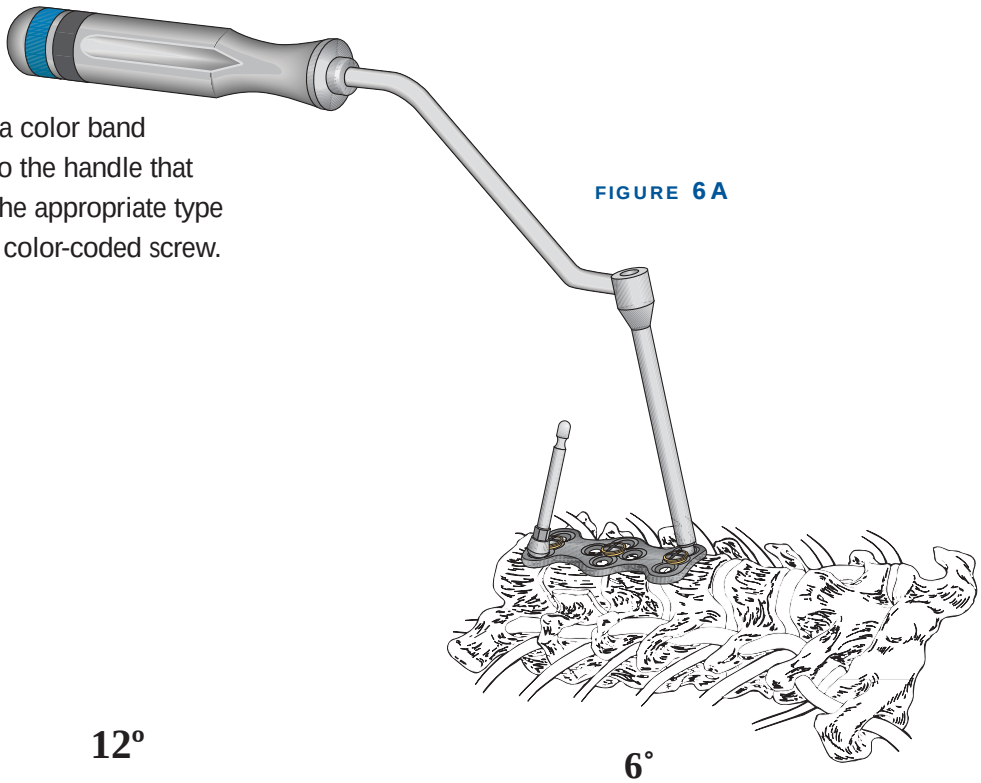


FIGURE 6A

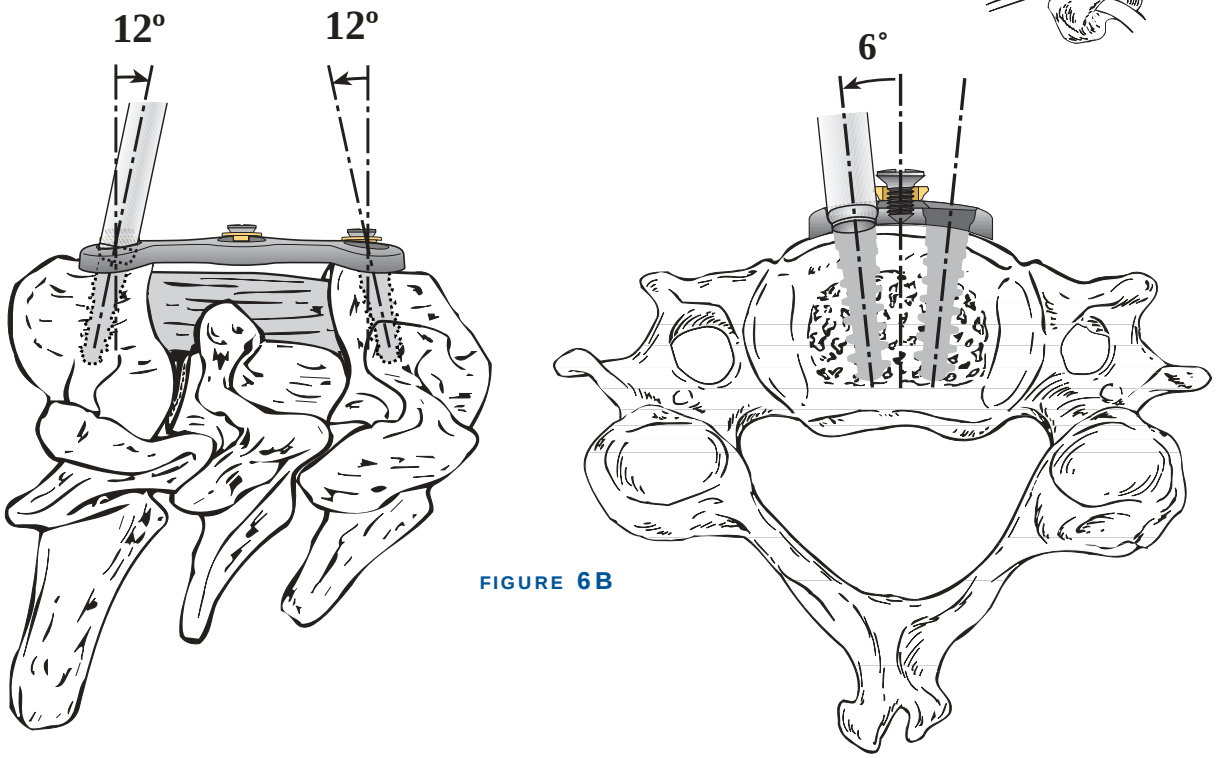
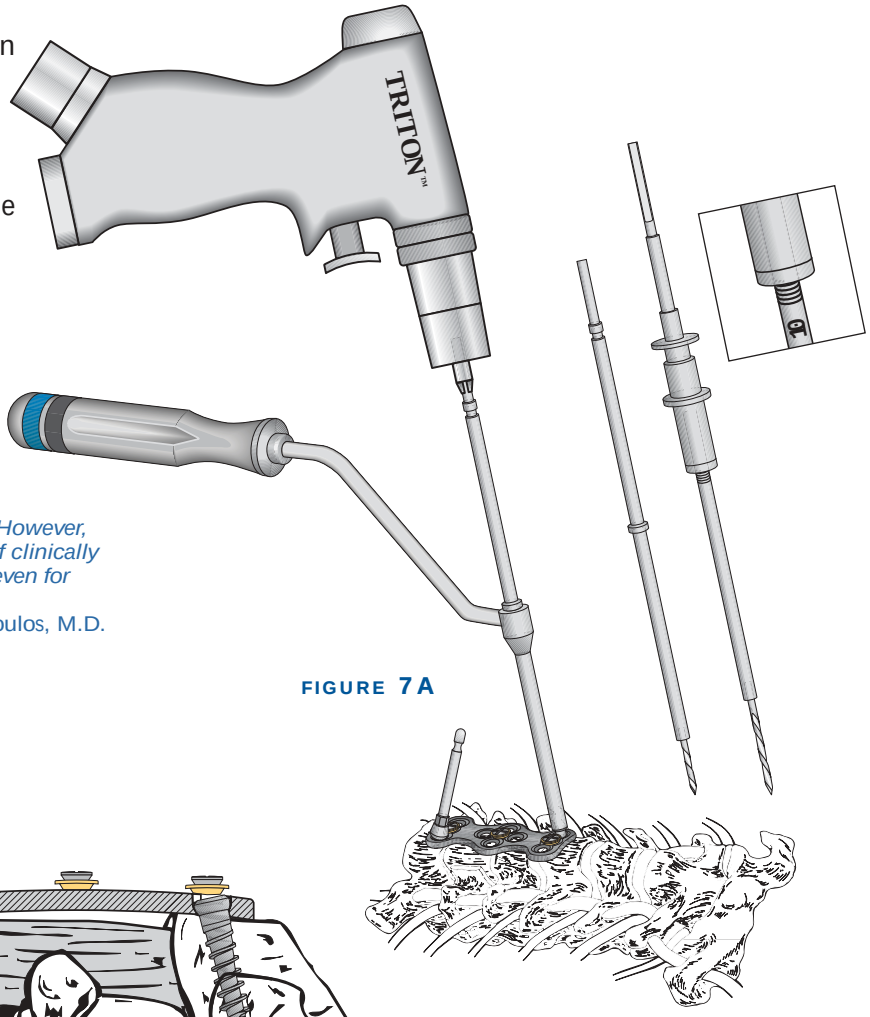


FIGURE 6B

step 7: drill holes

Insert the selected Drill Bit into the TRITON™ Mini Driver. Place the Drill Bit into the fixed angle Drill Guide. Drill the screw holes using either the 13mm Drill Bit or the Adjustable Drill Bit with Adjustable Drill Stop *(Figure 7A).* Screw length is determined by the depth of bone purchase required *(Figure 7B).*

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



Unicortical screws are routinely used. However, bicortical purchase may be employed if clinically indicated. I routinely use fluoroscopy, even for unicortical screw fixation.

- S. Papadopoulos, M.D.

FIGURE 7A

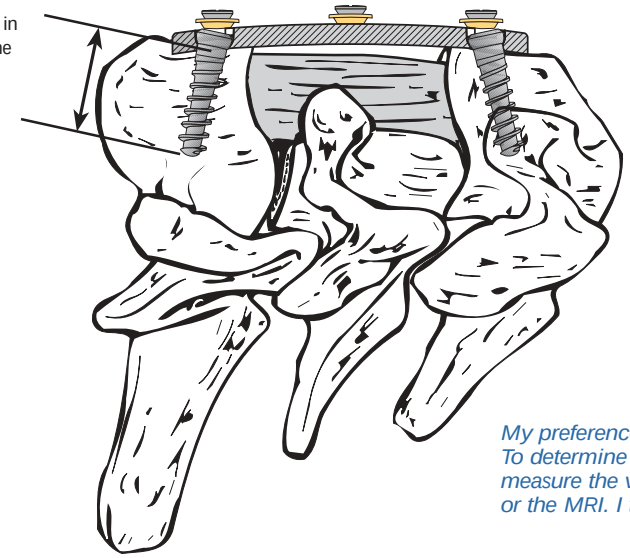


FIGURE 7B

My preference is for long unicortical screws. To determine the optimal length preoperatively, I measure the vertebral body on the axial CAT scan or the MRI. I typically do not use fluoroscopy.

- R. Haid, M.D.

step 8: tap the vertebral bodies

Insert the color-coded Tap into the pilot hole at the same angulation, and tap the vertebral bodies using the Tap which corresponds to the Drill Bit length determined in Step 7 *(Figure 8A).* Taps are available color coded in 4.0 and 4.5mm diameters with a 13mm length. A 4.0mm Adjustable Depth Tap is available for screw lengths 10-20mm.

The 4.0mm Adjustable Depth Tap is adjusted by depressing the lever on the adjustable sleeve and turning the handle to increase or decrease tap length *(Figure 8B).* The length can be visually measured on the tap shaft and can be confirmed by the screw gage in the fixed or variable angle bone screw block *(Figure 8C).*

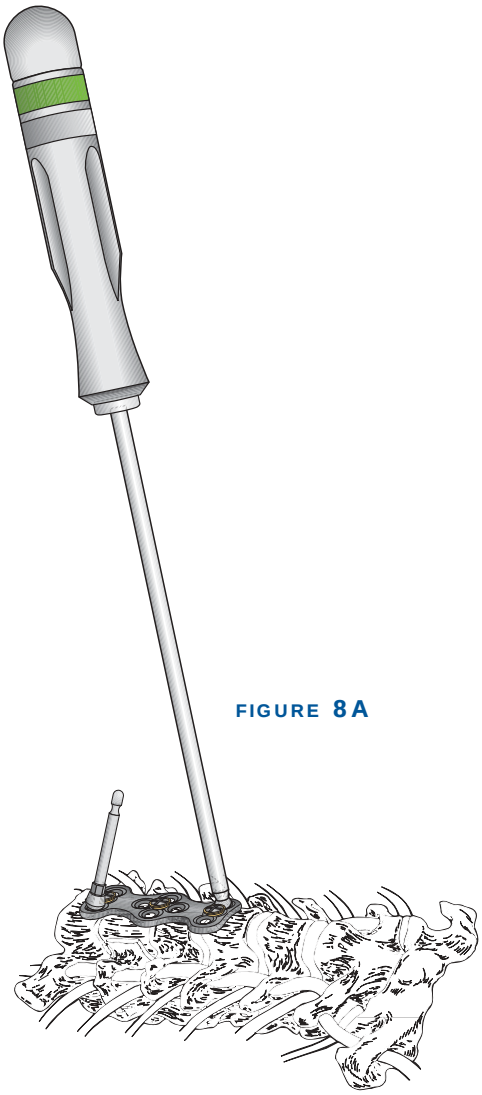


FIGURE 8A

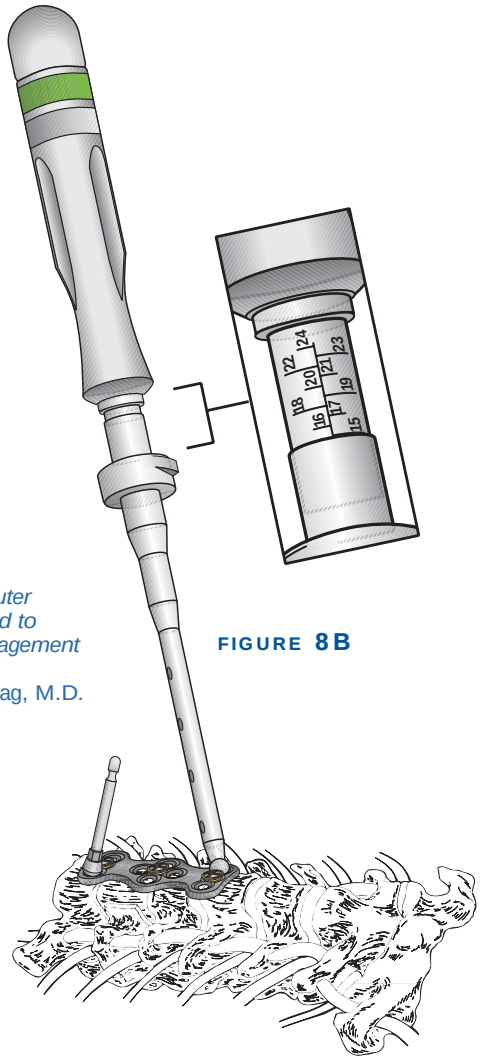


FIGURE 8B

In most cases only the outer cortex needs to be tapped to allow for easy initial engagement of the bone screw.
- V. Sonntag, M.D.

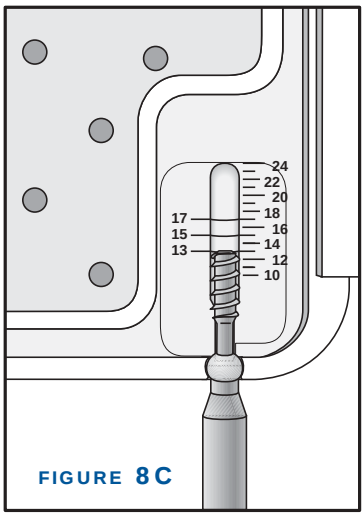


FIGURE 8C

step 9: implant bone screws

If required, a Depth Gage may be used to confirm depth of the pilot hole for proper screw length. The Depth Gage works either through the plate *(Figure 9A*) or directly against the bone.

The appropriate length screw can be verified using the Screw Gage located in the fixed or variable angle bone screw block *(Figure 9B).*

Insert the appropriate length bone screw through the plate, using the Screwdriver with tapered, self-holding tip and preliminarily tighten the bone screw (not final tightening).

NOTE: Place the initial screws deep enough so that the head of the screw "slips past" the gold washer. This allows the washer to move freely, thus providing space for the contralateral screw drilling.

The preferred method of screw insertion is as follows:

Drill, tap and place one bone screw securely through the plate (not final tightening).

Drill, tap and place the second bone screw securely on the opposite end of the plate, diagonally from the first screw position.

Remove Plate Holding Pin with Plate Holding Pin Driver if appropriate.

The remaining two bone screw implant sites are then drilled and tapped with the bone screws securely inserted.

Additional bone screws can be placed at this time in the central screw holes if appropriate (i.e., multi-level interbody fusions or long strut graft reconstructions/steps 6 through 9 should be repeated).

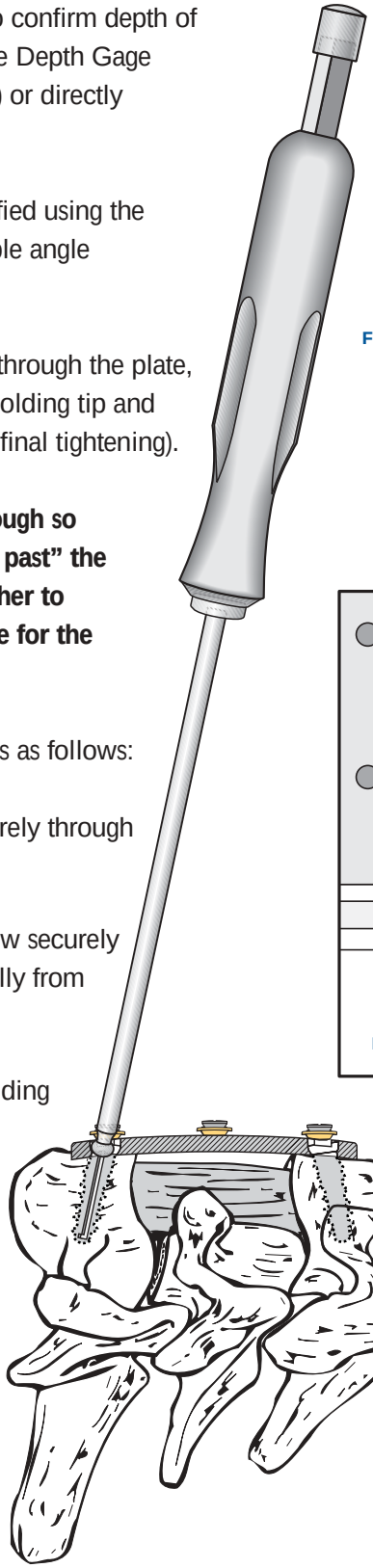


FIGURE 9A

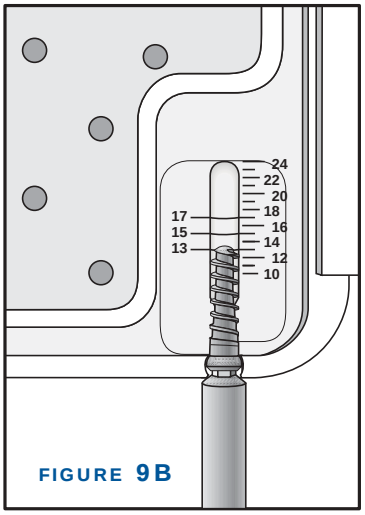


FIGURE 9B

step 10: final tightening of bone screws

Final tightening is done sequentially so that the plate is evenly and firmly applied to the anterior cortical surface of the spine *(Figure 10A)*.

FIGURE 10A

step 11: tightening of the attached lock mechanism

All of the ATLANTIS™ 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 Lockscrew Driver is engaged into each lockscrew and tightened *(Figure 11A)*. The lockscrew centers the washer and covers a portion of the bone screw head. The lock mechanism is now firmly secured.

All lockscrews within the plate must be fully engaged and tightened before the procedure is complete *(Figure 11B).*

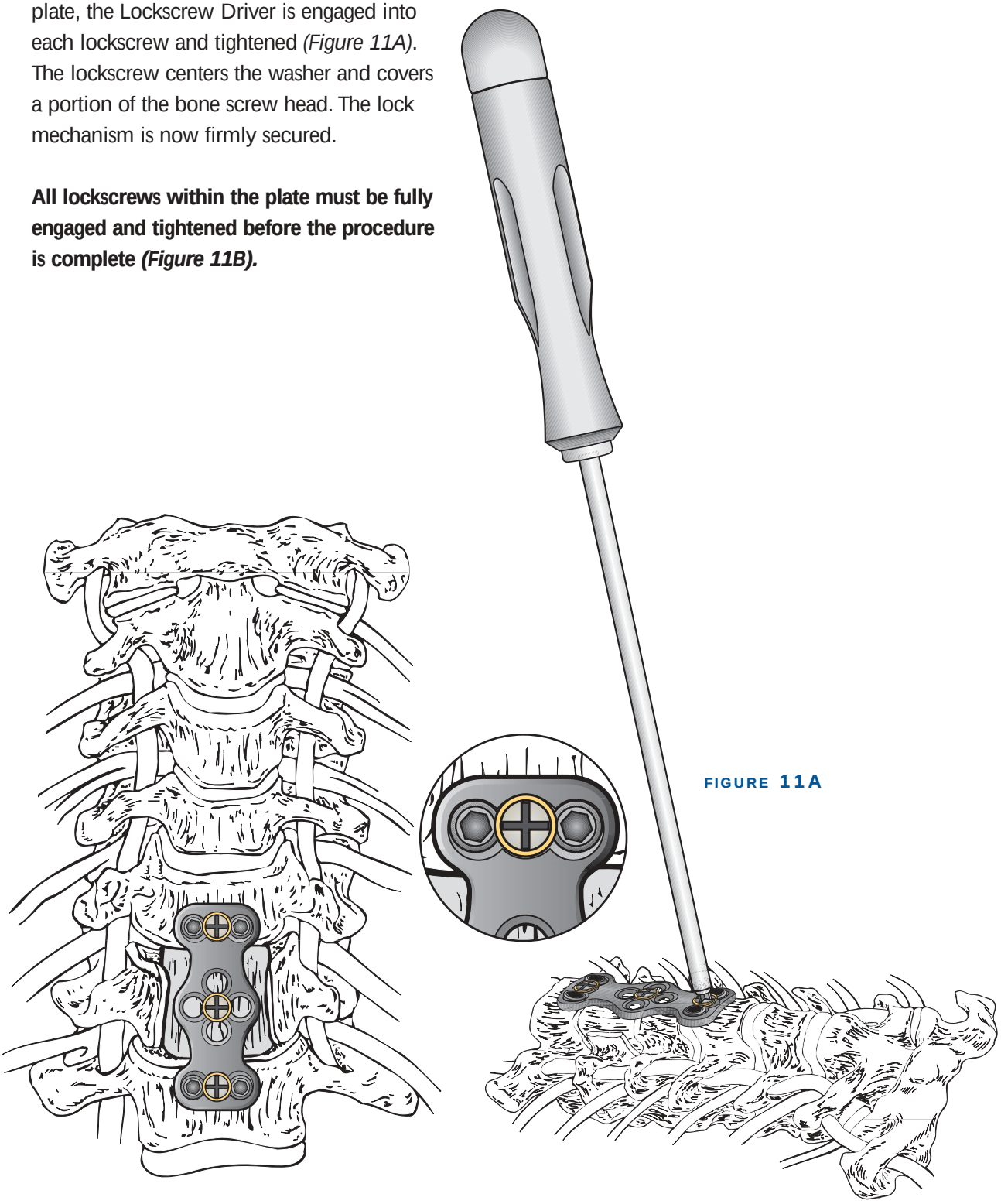


FIGURE 11A

FIGURE 11B

step 6: fixed and variable angle bone screw positioning

Select the Variable Angle or Fixed Angle Drill Guide. The Drill Guide is selected and seated within the bone screw hole in the plate. The Drill Guide can then be directed in the appropriate screw trajectory angle.

NOTE: The Drill Guide selected has a color band incorporated into the handle to aid in selecting type of color-coded screw.

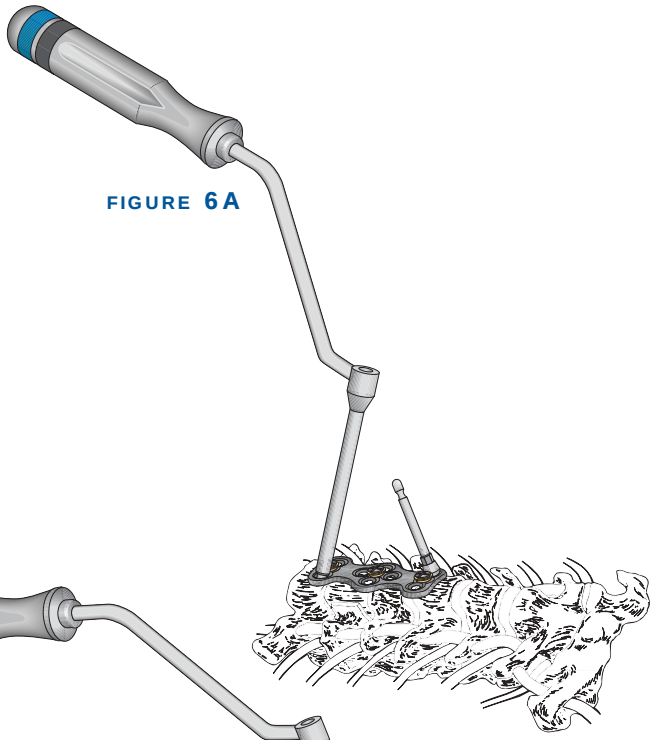


FIGURE 6A

Fixed Angle: The Fixed Angle Drill Guide *(Figure 6A)* can be securely engaged into the plate by applying light downward pressure on the handle, making sure to align the Drill Guide in the correct 12˚ cephalad or 12˚ caudad *(Figure 6C)* and 6˚ medial convergent angle *(Figure 6D).*

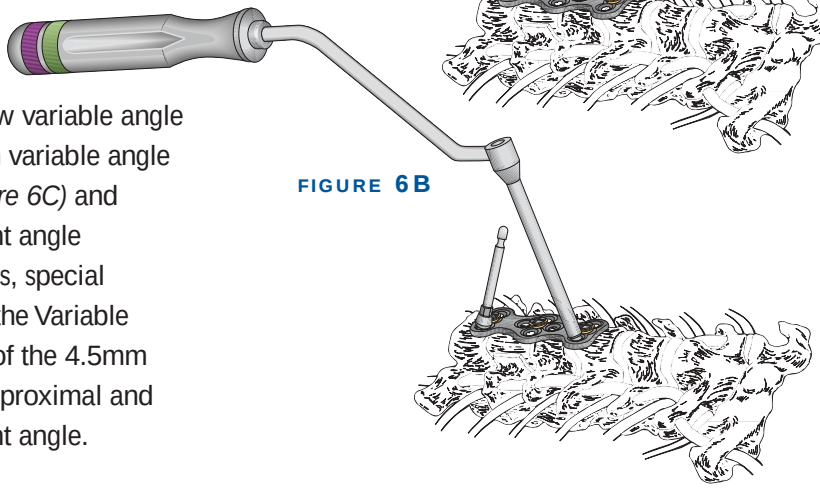


FIGURE 6B

Variable Angle: The Variable Angle Drill Guide *(Figure 6B)* is designed not to allow variable angle bone screw trajectory outside the 4.0mm variable angle bone screw: 22˚ distal/-2˚ proximal *(Figure 6C)* and 17˚ medial convergent/4˚ lateral divergent angle *(Figure 6E)*. When utilizing 4.5mm screws, special attention needs to be taken not to angle the Variable Angle Drill Guide outside the trajectory of the 4.5mm variable angle bone screw: 15˚ distal/-2˚ proximal and 17˚ medial convergent/1˚ lateral divergent angle.

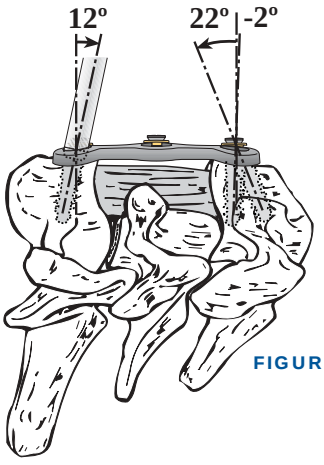


FIGURE 6C

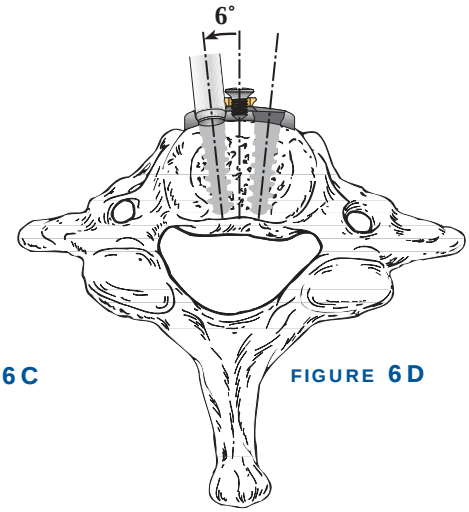


FIGURE 6D

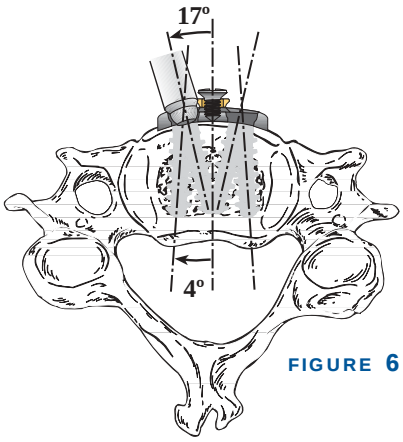


FIGURE 6E

step 7: drill holes

Insert the selected Drill Bit into the TRITON™ Mini Driver. Place the Drill Bit into the selected Drill Guide. Drill the screw holes using either the 13mm Drill Bit or the Adjustable Drill Bit with Adjustable Drill Stop *(Figure 7A).* Screw length is determined by the depth of bone purchase required *(Figure 7B).*

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

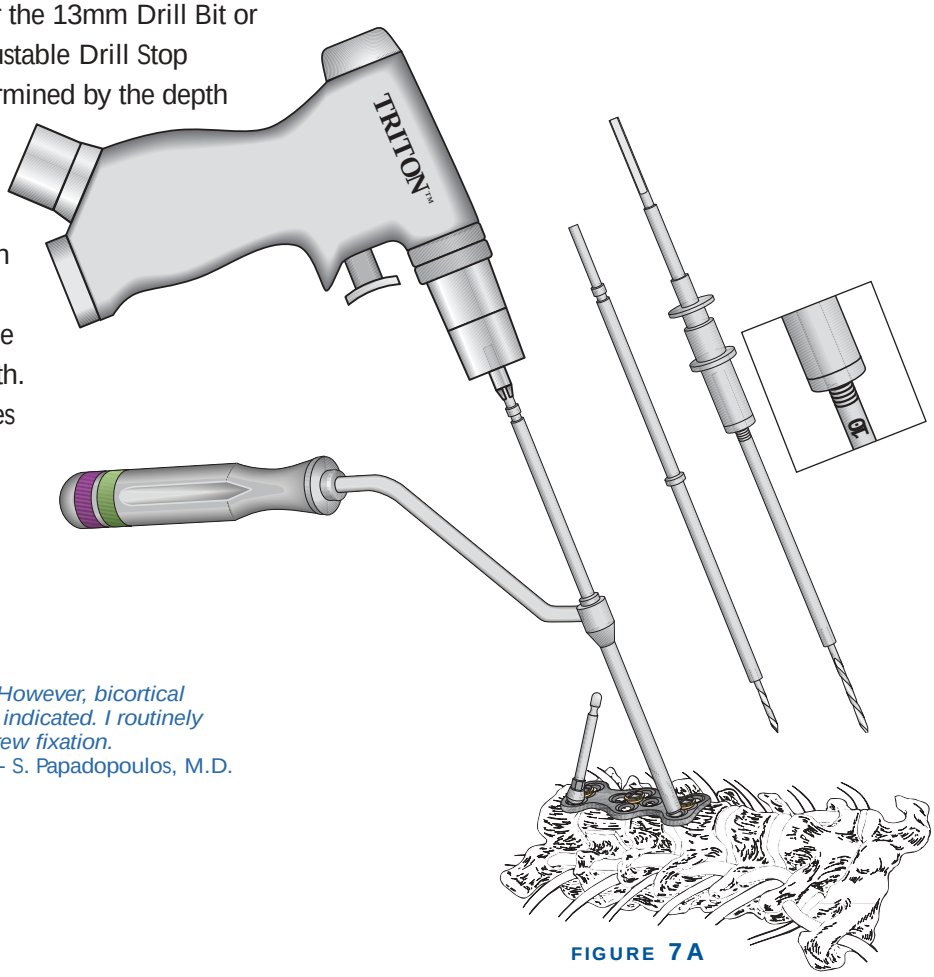


FIGURE 7A

Unicortical screws are routinely used. However, bicortical purchase may be employed if clinically indicated. I routinely use fluoroscopy, even for unicortical screw fixation.
- S. Papadopoulos, M.D.

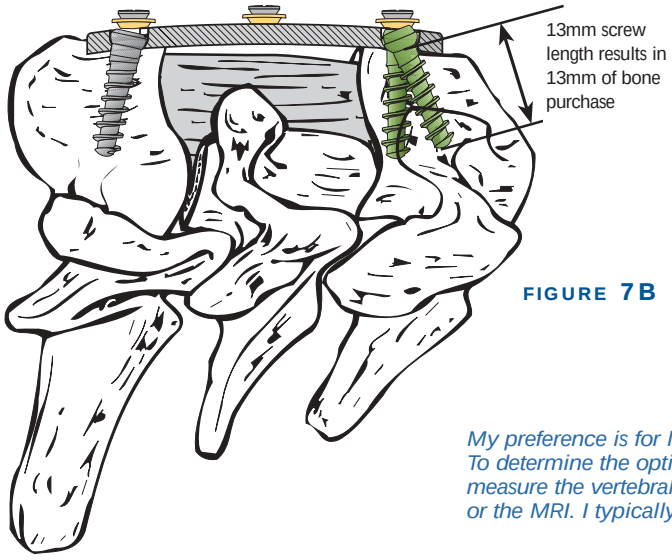


FIGURE 7B

My preference is for long unicortical screws. To determine the optimal length preoperatively, I measure the vertebral body on the axial CAT scan or the MRI. I typically do not use fluoroscopy.
- R. Haid, M.D.

step 8: tap the vertebral bodies

Insert the color-coded Tap into the pilot hole at the same angulation, and tap the vertebral bodies using the Tap which corresponds to the Drill Bit length determined in Step 7 *(Figure 8A).* Taps are available color coded in 4.0 and 4.5mm diameters with a 13mm length. A 4.0mm Adjustable Depth Tap is available for screw lengths 10-20mm.

The 4.0mm Adjustable Depth Tap is adjusted by depressing the lever on the adjustable sleeve and turning the handle to increase or decrease tap length *(Figure 8B).* The length can be visually measured on the tap shaft and can be confirmed by the screw gage in the fixed or variable angle bone screw block *(Figure 8C).*

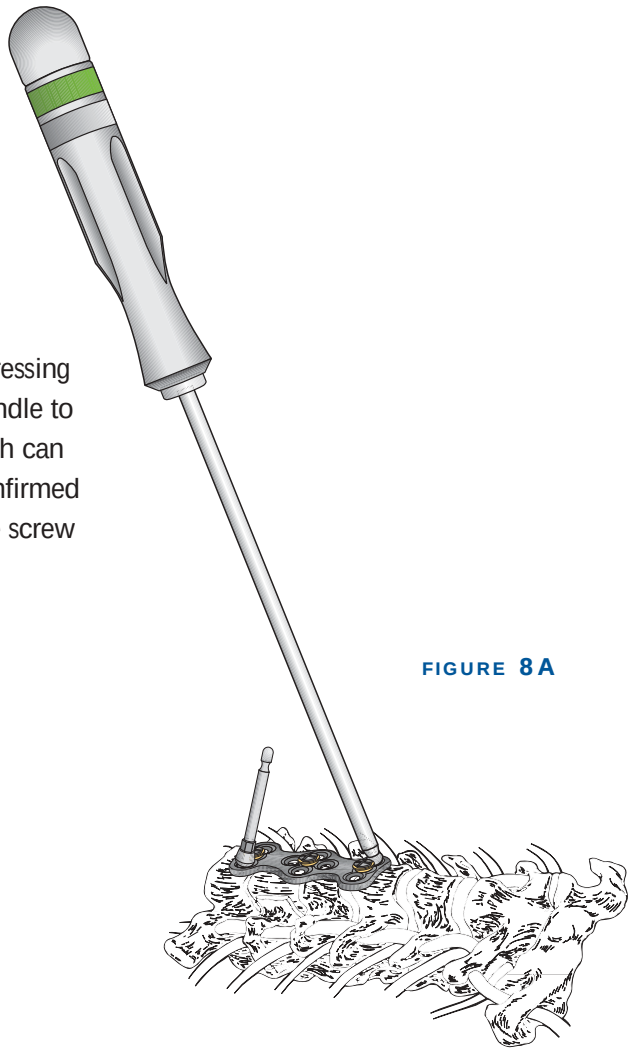


FIGURE 8A

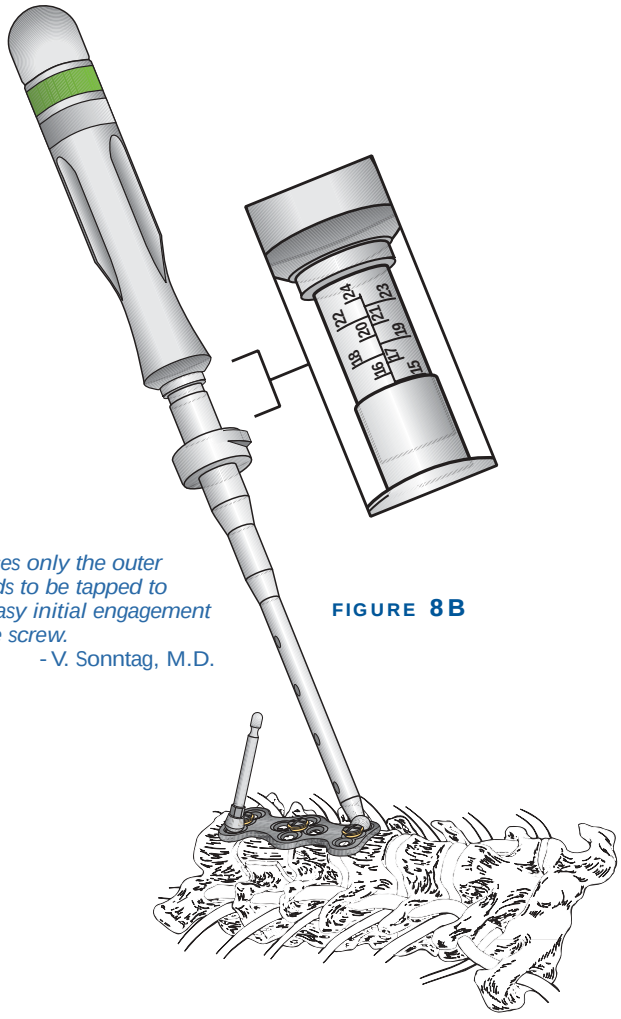


FIGURE 8B

In most cases only the outer cortex needs to be tapped to allow for easy initial engagement of the bone screw.
- V. Sonntag, M.D.

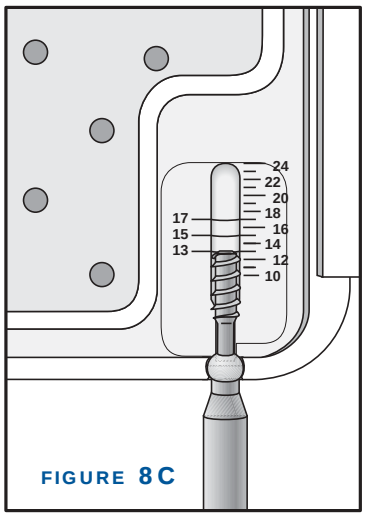


FIGURE 8C

step 9: implant bone screws

If required, a Depth Gage may be used to confirm depth of the pilot hole for proper screw length. The Depth Gage works either through the plate *(Figure 9A)* or directly against the bone.

The appropriate length screw can be verified using the Screw Gage located in the fixed or variable angle bone screw block *(Figure 9B).*

Insert the appropriate length bone screw through the plate, using the Screwdriver with tapered, self-holding tip and preliminarily tighten the bone screw (not final tightening).

NOTE: Place the initial screws deep enough so that the head of the screw "slips past" the gold washer. This allows the washer to move freely, thus providing space for the contralateral screw drilling.

The preferred method of screw insertion is as follows:

Drill, tap and place one bone screw securely through the plate (not final tightening).

Drill, tap and place the second bone screw securely on the opposite end of the plate, diagonally from the first screw position.

Remove Plate Holding Pin with Plate Holding Pin Driver if appropriate.

The remaining two bone screw implant sites are then drilled and tapped with the bone screws securely inserted.

Additional bone screws can be placed at this time in the central screw holes if appropriate (i.e., multi-level interbody fusions or long strut graft reconstructions/steps 6 through 9 should be repeated).

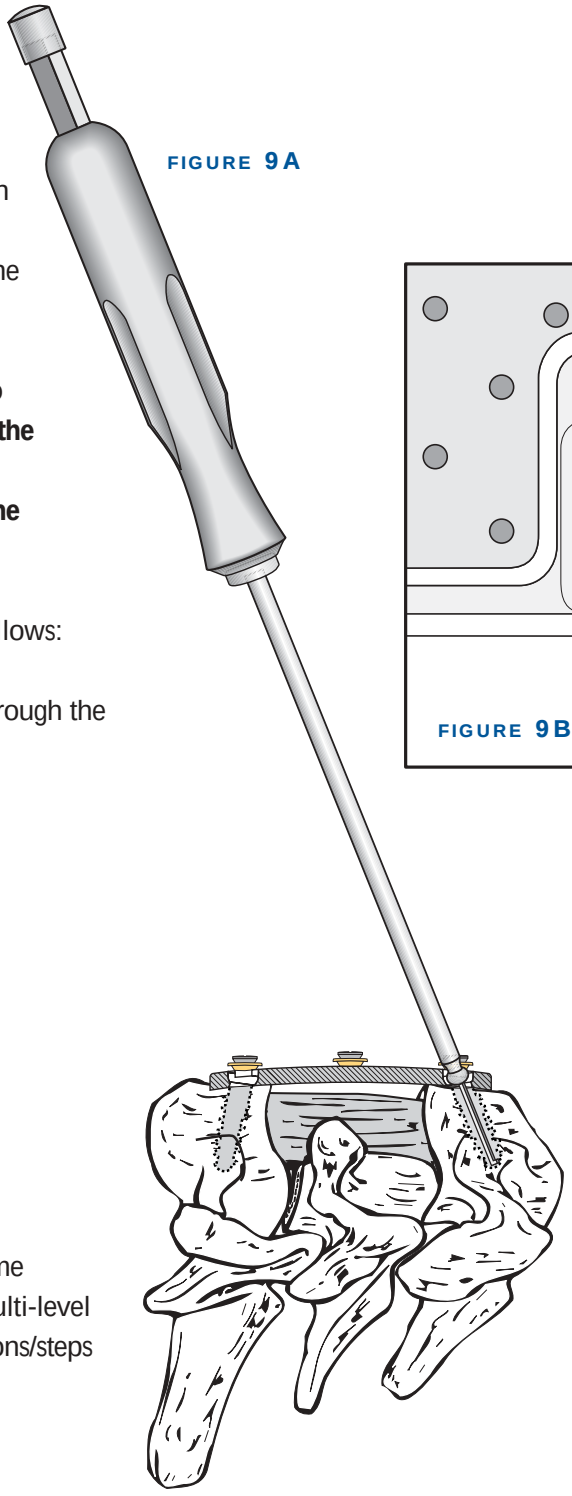


FIGURE 9A

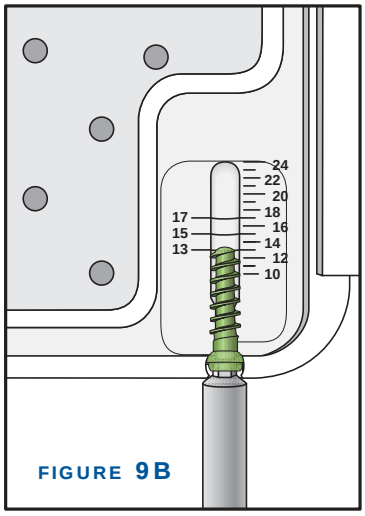


FIGURE 9B

step 10: final tightening of bone screws

Final tightening is done sequentially so that the plate is evenly and firmly applied to the anterior cortical surface of the spine *(Figure 10).*

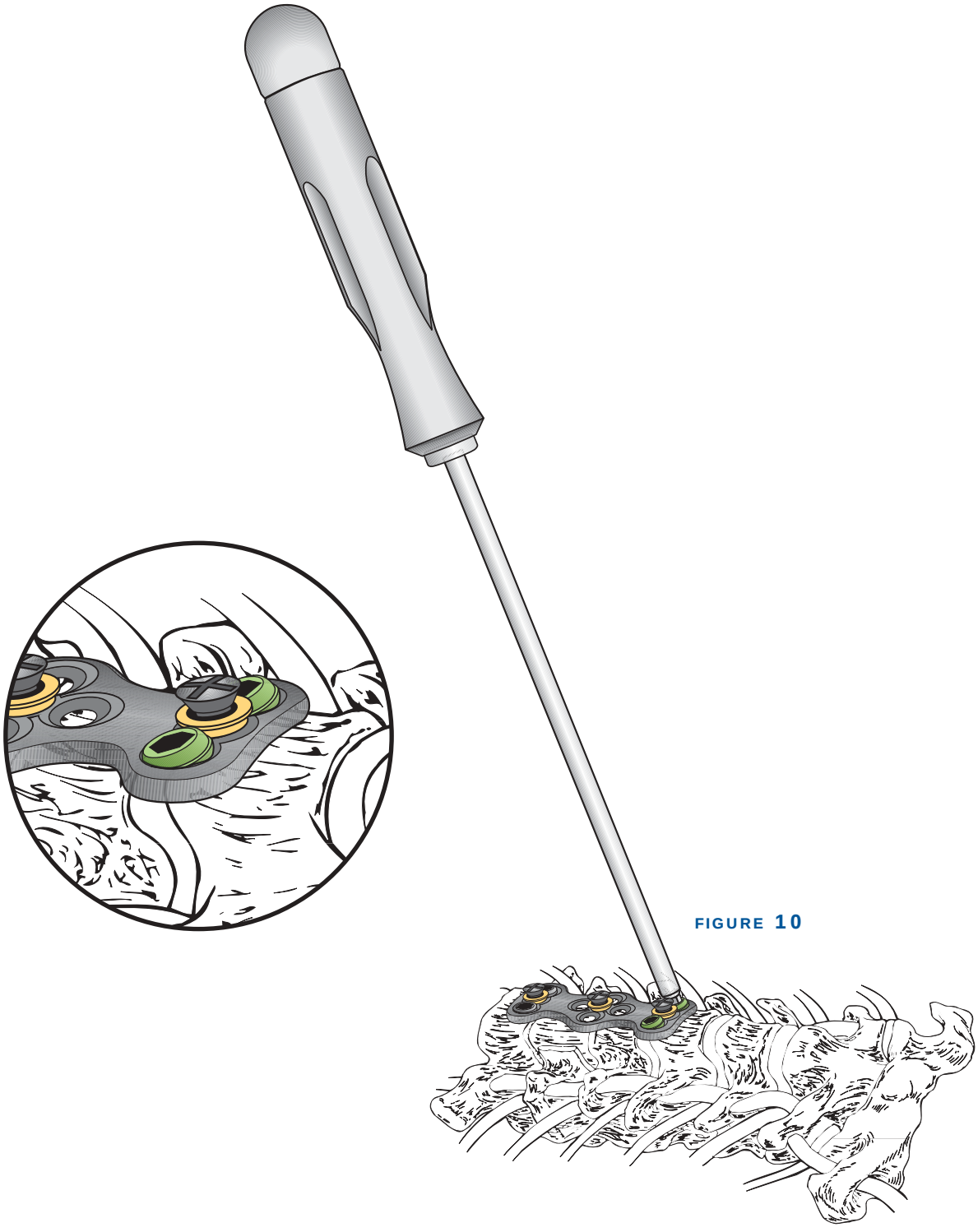


FIGURE 10

step 11: tightening of the attached lock mechanism

All of the ATLANTIS™ 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 Lockscrew Driver is engaged into each lockscrew and tightened *(Figure 11A).* The lockscrew centers the washer and covers a portion of the bone screw head. The lock mechanism is now firmly secured.

All lockscrews within the plate must be fully engaged and tightened before the procedure is complete *(Figure 11B).*

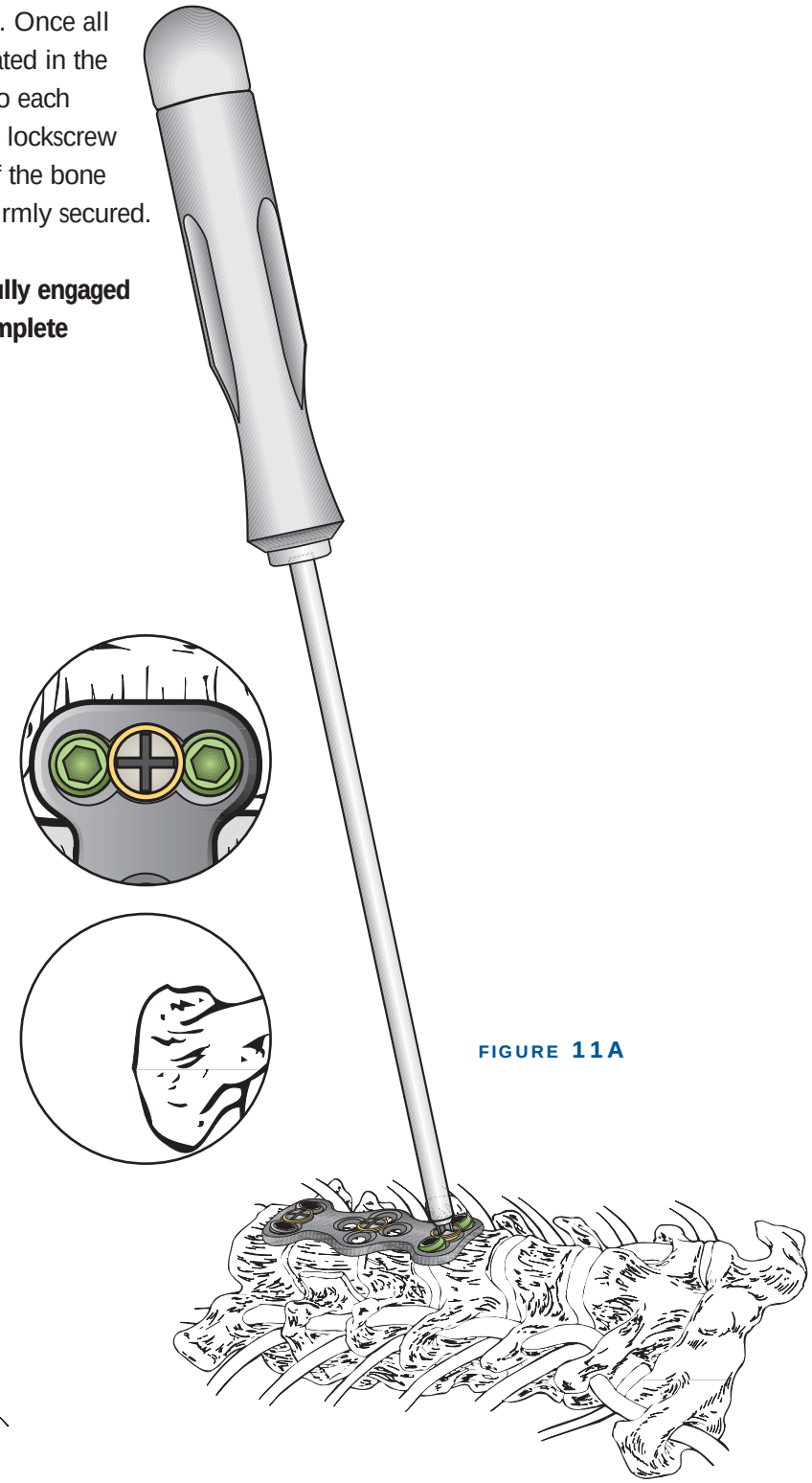


FIGURE 11A

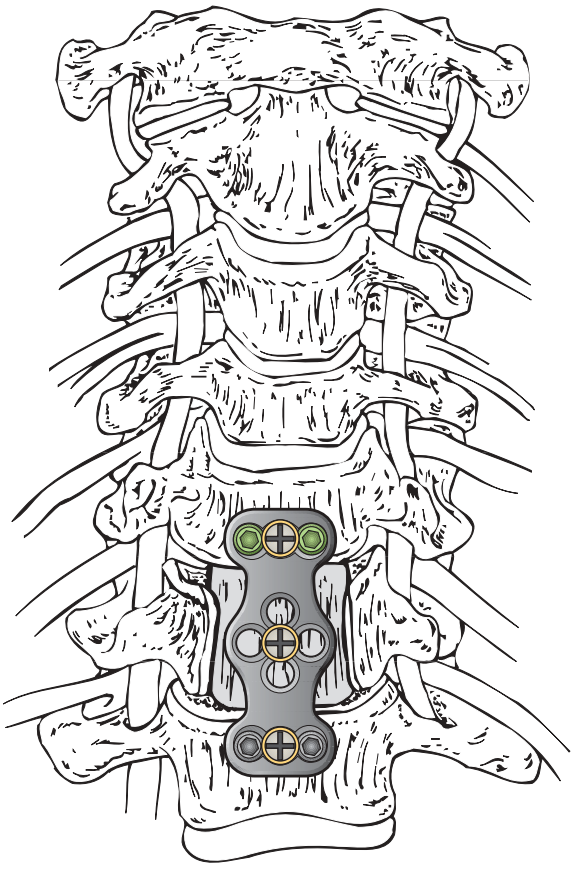


FIGURE 11B

step 6: variable angle bone screw positioning

The Variable Angle Drill Guide is selected and seated within the bone screw hole in the plate. The Variable Drill Guide is directed in the appropriate angle of screw trajectory *(Figure 6A).* When selecting a 4.0mm variable angle screw, the surgeon may choose any angle within a 22˚ distal/-2˚ proximal and 17˚ medial convergent/4˚ lateral divergent angle *(Figure 6B).*

NOTE: The Variable Angle Drill Guide has a color band incorporated into the handle to aid in choosing the appropriate type of color-coded screw.

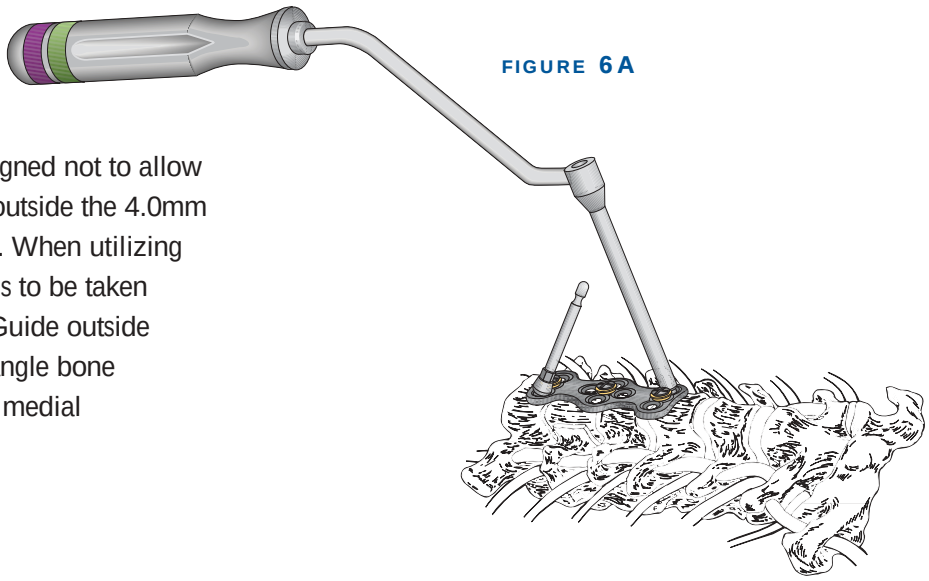


FIGURE 6A

The Variable Angle Drill Guide is designed not to allow variable angle bone screw trajectory outside the 4.0mm variable angle bone screw angulation. When utilizing 4.5mm screws, special attention needs to be taken not to angle the Variable Angle Drill Guide outside the trajectory of the 4.5mm variable angle bone screw 15˚ distal/-2˚ proximal and 17˚ medial convergent/1˚ lateral divergent angle.

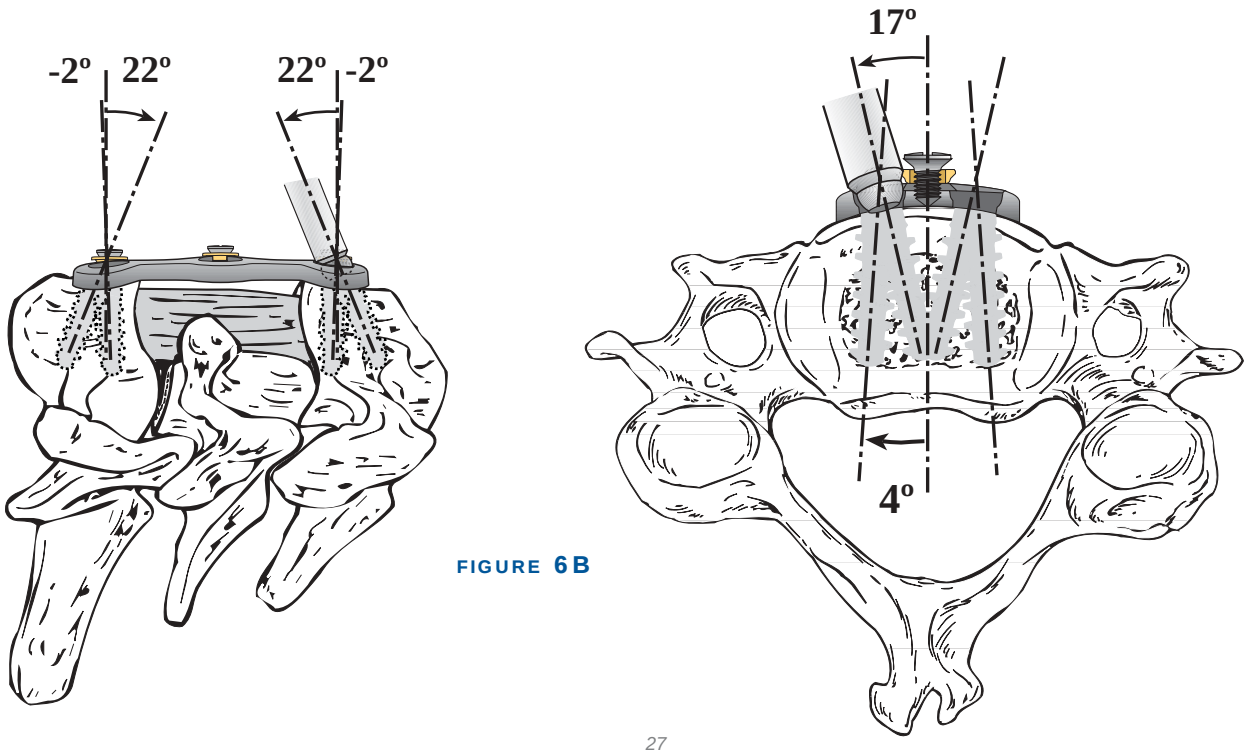


FIGURE 6B

step 7: drill holes

Insert the selected Drill Bit into the TRITON™ Mini Driver. Place the Drill Bit into the selected Drill Guide. Drill the screw holes using either the 13mm Drill Bit or the Adjustable Drill Bit with Adjustable Drill Stop *(Figure 7A).* Screw length is determined by the depth of bone purchase required *(Figure 7B).*

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

Unicortical screws are routinely used. However, bicortical purchase may be employed if clinically indicated. I routinely use fluoroscopy, even for unicortical screw fixation.
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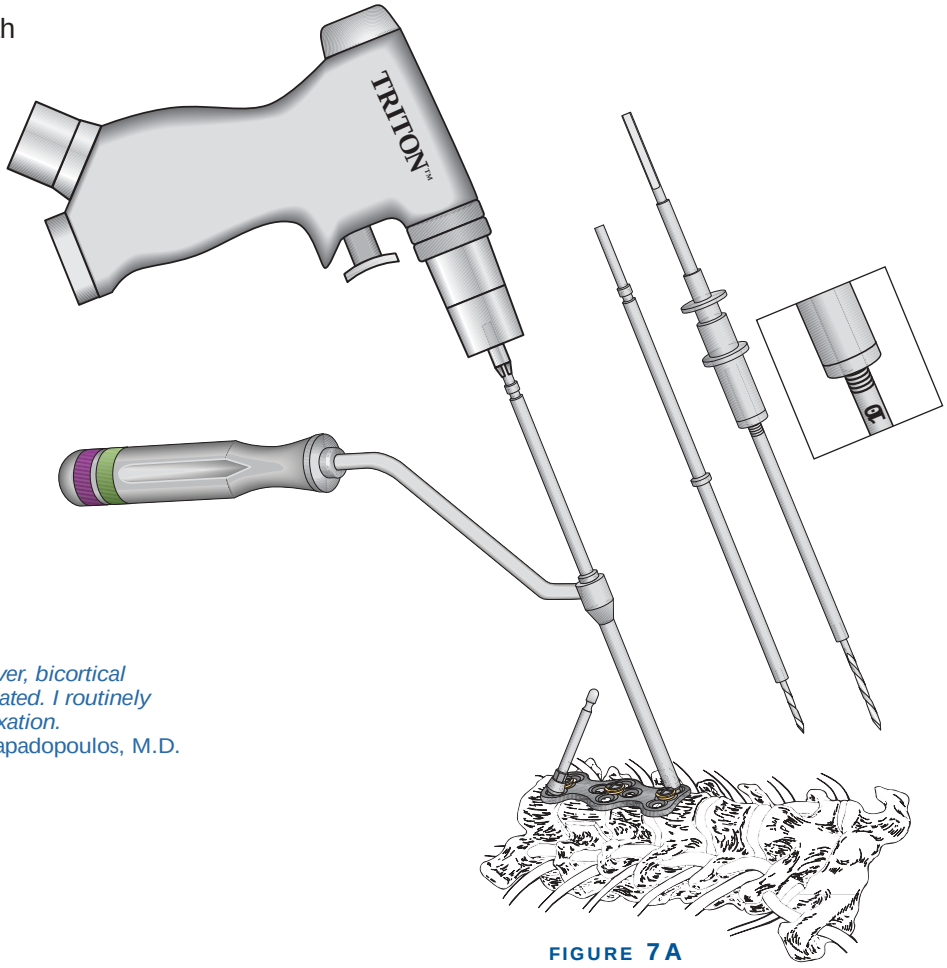

FIGURE 7A

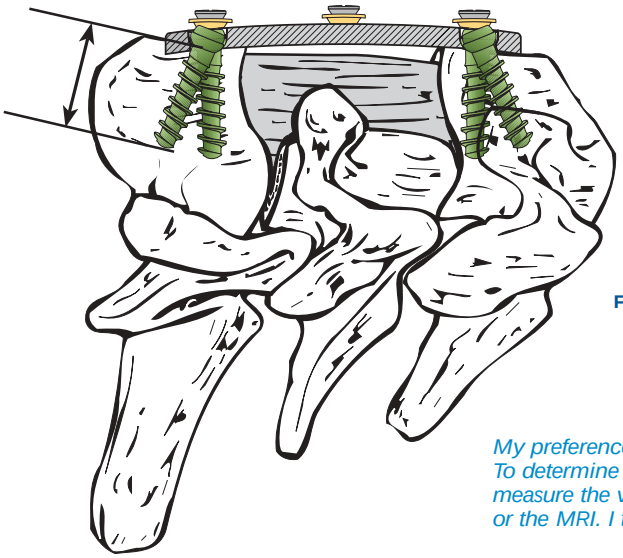

FIGURE 7B

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The 4.0mm Adjustable Depth Tap is adjusted by depressing the lever on the adjustable sleeve and turning the handle to increase or decrease tap length *(Figure 8B).* The length can be visually measured on the tap shaft and can be confirmed by the screw gage in the fixed or variable angle bone screw block *(Figure 8C).*

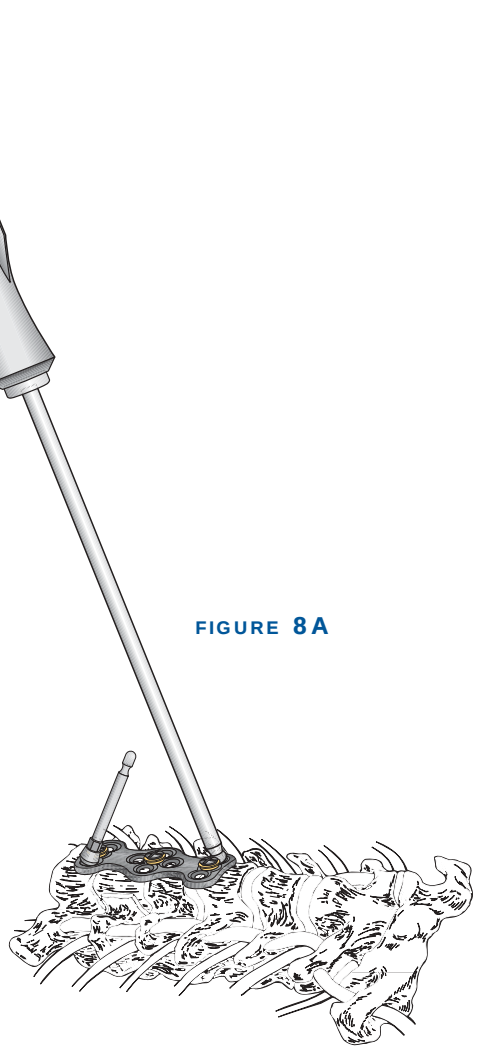

FIGURE 8A

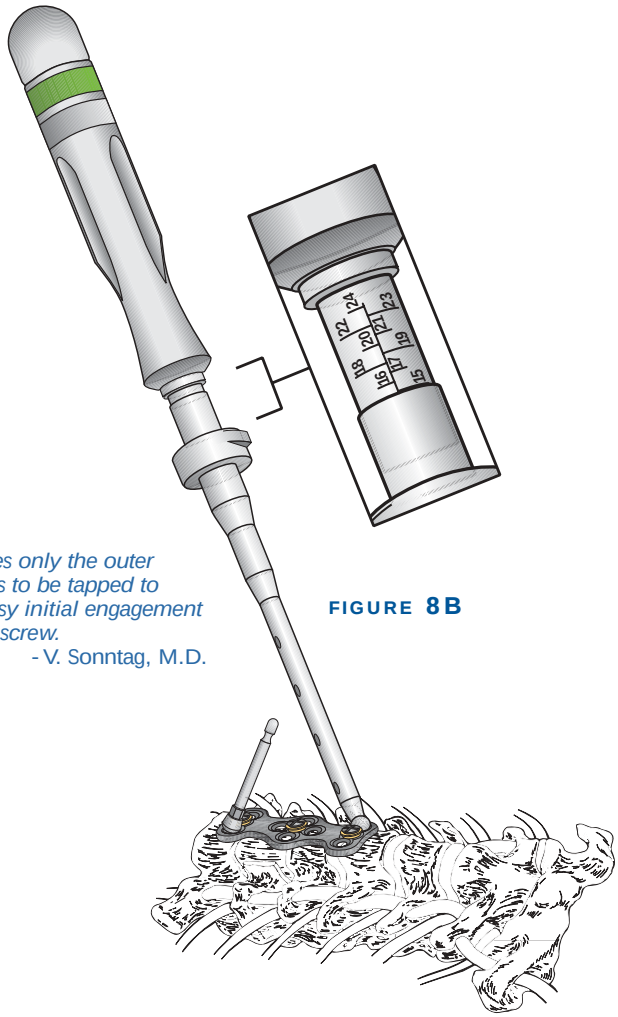

FIGURE 8B

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- V. Sonntag, M.D.

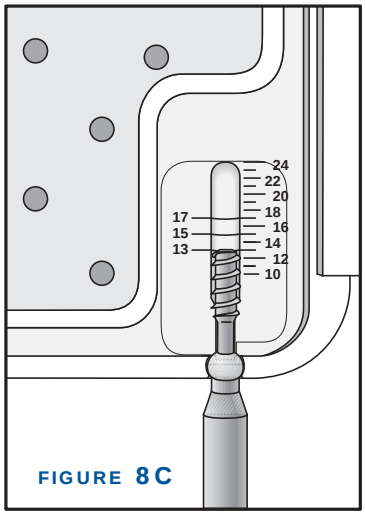

FIGURE 8C

step 9: implant bone screws

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The appropriate length screw can be verified using the Screw Gage located in the fixed or variable angle bone screw block *(Figure 9B).*

Insert the appropriate length bone screw through the plate, using the Screwdriver with tapered, self-holding tip and preliminarily tighten the bone screw (not final tightening).

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The preferred method of screw insertion is as follows:

Drill, tap and place one bone screw securely through the plate (not final tightening).

Drill, tap and place the second bone screw securely on the opposite end of the plate, diagonally from the first screw position.

Remove Plate Holding Pin with Plate Holding Pin Driver if appropriate.

The remaining two bone screw implant sites are then drilled and tapped with the bone screws securely inserted.

Additional bone screws can be placed at this time in the central screw holes if appropriate (i.e., multi-level interbody fusions or long strut graft reconstructions/steps 6 through 9 should be repeated).

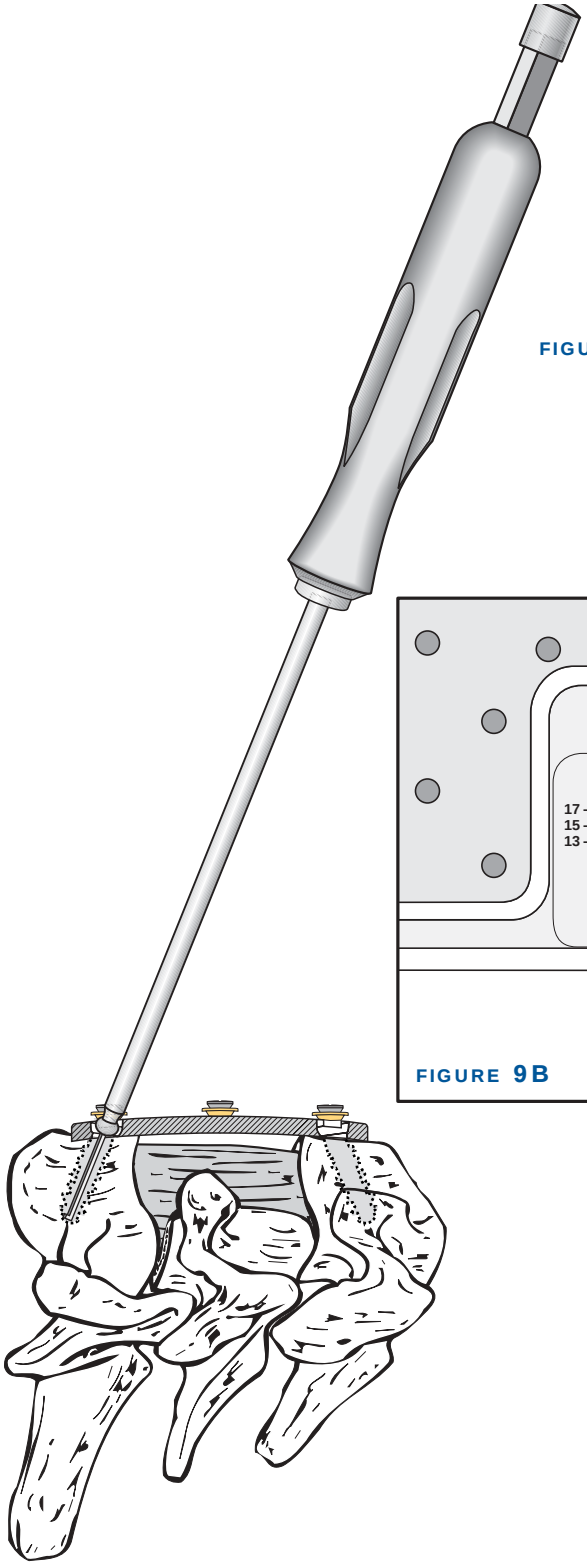

FIGURE 9A

FIGURE 9B

step 10: final tightening of bone screws

Final tightening is done sequentially so that the plate is evenly and firmly applied to the anterior cortical surface of the spine *(Figure 10).*

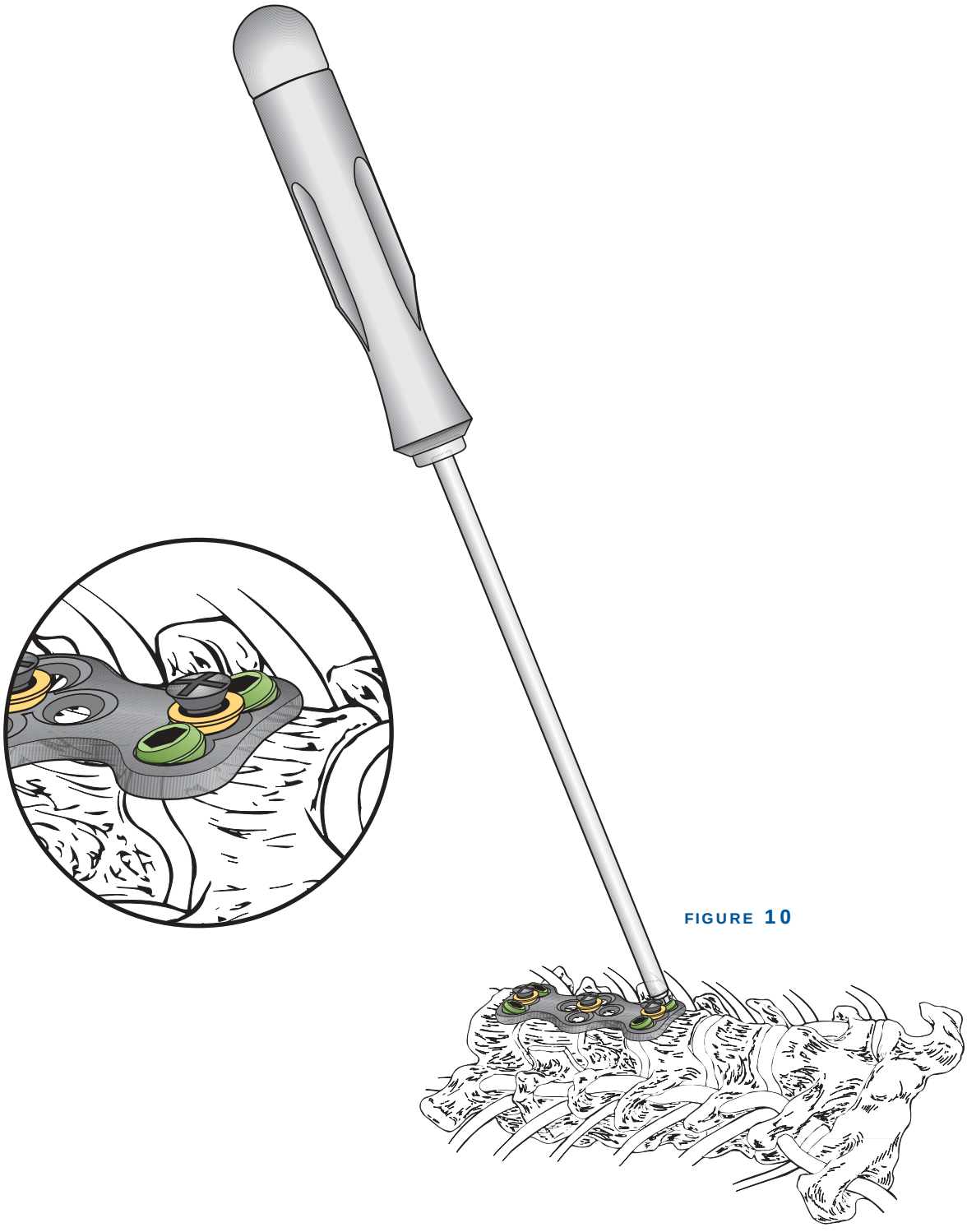

FIGURE 10

step 11: tightening of the attached lock mechanism

All of the ATLANTIS™ 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 Lockscrew Driver is engaged into each lockscrew and tightened *(Figure 11A).* The lockscrew centers the washer and covers a portion of the bone screw head. The lock mechanism is now firmly secured.

All lockscrews within the plate must be fully engaged and tightened before the procedure is complete *(Figure 11B).*

FIGURE 11A

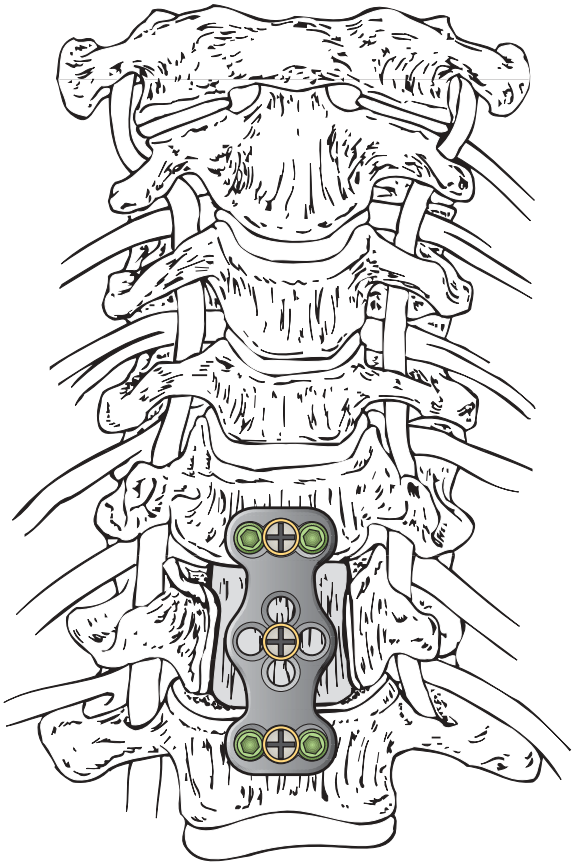

FIGURE 11B

ATLANTIS™†
anterior cervical plate system

PRODUCT INFORMATION

ANTERIOR CERVICAL PLATES

Catalog #	*Size*	*Catalog #*	*Size*	*Catalog #*	*Size*	*Catalog #*	*Size*
876-119	19mm plate	876-140	40mm plate	876-162	62.5mm plate	876-185	85mm plate
876-121	21mm plate	876-142	42.5mm plate	876-165	65mm plate	876-187	87.5mm plate
876-123	23mm plate	876-145	45mm plate	876-167	67.5mm plate	876-190	90mm plate
876-125	25mm plate	876-147	47.5mm plate	876-170	70mm plate	876-195	95mm plate
876-127	27.5mm plate	876-150	50mm plate	876-172	72.5mm plate	876-200	100mm plate
876-130	30mm plate	876-152	52.5mm plate	876-175	75mm plate	876-205	105mm plate
876-132	32.5mm plate	876-155	55mm plate	876-177	77.5mm plate	876-210	110mm plate
876-135	35mm plate	876-157	57.5mm plate	876-180	80mm plate		
876-137	37.5mm plate	876-160	60mm plate	876-182	82.5mm plate		

FIXED ANGLE CANCELLOUS BONE SCREWS

Catalog #	*Size*	*Catalog #*	*Size*	*Catalog #*	*Size*
876-010	▲ 4.0x10mm screw	876-015	▲ 4.0x15mm screw	876-020	▲ 4.0x20mm screw
876-011	▲ 4.0x11mm screw	876-016	▲ 4.0x16mm screw		
876-012	▲ 4.0x12mm screw	876-017	▲ 4.0x17mm screw	876-053	▲ 4.5x13mm screw
876-013	▲ 4.0x13mm screw	876-018	▲ 4.0x18mm screw	876-055	▲ 4.5x15mm screw
876-014	▲ 4.0x14mm screw	876-019	▲ 4.0x19mm screw	876-057	▲ 4.5x17mm screw

FIXED ANGLE SELF-TAPPING CANCELLOUS BONE SCREWS

Catalog #	*Size*	*Catalog #*	*Size*	*Catalog #*	*Size*
876-710	▲ 4.0x10mm self-tapping screw	876-715	▲ 4.0x15mm self-tapping screw	876-753	▲ 4.5x13mm self-tapping screw
876-711	▲ 4.0x11mm self-tapping screw	876-716	▲ 4.0x16mm self-tapping screw	876-755	▲ 4.5x15mm self-tapping screw
876-712	▲ 4.0x12mm self-tapping screw	876-717	▲ 4.0x17mm self-tapping screw	876-757	▲ 4.5x17mm self-tapping screw
876-713	▲ 4.0x13mm self-tapping screw	876-718	▲ 4.0x18mm self-tapping screw		
876-714	▲ 4.0x14mm self-tapping screw				

†Patent Pending

ATLANTIS™†
anterior cervical plate system

PRODUCT INFORMATION

VARIABLE ANGLE CANCELLOUS BONE SCREWS

Catalog #	Size	Catalog #	Size	Catalog #	Size
876-310	4.0x10mm screw	876-315	4.0x15mm screw	876-320	4.0x20mm screw
876-311	4.0x11mm screw	876-316	4.0x16mm screw		
876-312	4.0x12mm screw	876-317	4.0x17mm screw	876-353	4.5x13mm screw
876-313	4.0x13mm screw	876-318	4.0x18mm screw	876-355	4.5x15mm screw
876-314	4.0x14mm screw	876-319	4.0x19mm screw	876-357	4.5x17mm screw

VARIABLE ANGLE SELF-TAPPING CANCELLOUS BONE SCREWS

Catalog #	Size	Catalog #	Size	Catalog #	Size
876-810	4.0x10mm self-tapping screw	876-815	4.0x15mm self-tapping screw	876-853	4.5x13mm self-tapping screw
876-811	4.0x11mm self-tapping screw	876-816	4.0x16mm self-tapping screw	876-855	4.5x15mm self-tapping screw
876-812	4.0x12mm self-tapping screw	876-817	4.0x17mm self-tapping screw	876-857	4.5x17mm self-tapping screw
876-813	4.0x13mm self-tapping screw	876-818	4.0x18mm self-tapping screw		
876-814	4.0x14mm self-tapping screw				

INSTRUMENTS

Catalog #	Description	Catalog #	Description	Catalog #	Description
876-402	Plate Bender	876-455	Adjustable Drill Bit, Tri-flat	876-478	4.5 X 13mm Tap
876-404	Plate Holding Pin	876-460	Adjustable Drill Stop	876-482	Screw Driver
876-406	Plate Holding Pin Driver	876-465	Circular Drill Bit Adapter	876-484	Lockscrew Driver
876-408	Plate Holder	876-468	Depth Gage	876-501	Implant/Instrument Case Non-Self-Tapping
876-410	Fixed Angle Drill Guide	876-470	Drill Bit Handle		
876-415	Variable Angle Drill Guide	876-472	4.0 X 13mm Tap	876-502	Implant/Instrument Case Self-Tapping
876-443	13mm Drill Bit, Tri-flat	876-474	Adjustable Depth Tap 4.0 Canc.		

† Patent Pending

TrimLine™

ANTERIOR CERVICAL DISCECTOMY & FUSION INSTRUMENT SET

PRODUCT INFORMATION

HAND-HELD RETRACTORS

Catalog #	Description
875-050	Hand-Held Retractor, Straight, 18mm
875-051	Small Hand-Held Retractor, Straight, 18mm
875-052	Hand-Held Retractor, Back Lip, 20mm
875-053	Hand-Held Retractor, Curved, 23mm

SELF-RETAINING RETRACTORS AND BLADES

Catalog #	Description
875-110	Transverse Self-Retaining Retractor Frame
875-115	Longitudinal Self-Retaining Retractor Frame
875-149	Retractor Blade Handle

Catalog #	Description
875-150	23x30mm Discectomy Blade
875-152	23x40mm Discectomy Blade
875-154	23x50mm Discectomy Blade
875-156	23x60mm Discectomy Blade
875-158	23x70mm Discectomy Blade

Catalog #	Description
875-160	20x30mm Longitudinal Blade
875-162	20x40mm Longitudinal Blade
875-164	20x50mm Longitudinal Blade
875-166	20x60mm Longitudinal Blade
875-168	20x70mm Longitudinal Blade

CURETTES

Catalog #	Description
875-300	Curette Straight 6-0
875-302	Curette Straight 4-0
875-303	Curette Straight 3-0
875-304	Curette Straight 2-0
875-305	Curette Straight 1-0
875-307	Curette Straight 2-0

Catalog #	Description
875-310	Curette Angled 6-0
875-312	Curette Angled 4-0
875-313	Curette Angled 3-0
875-314	Curette Angled 2-0
875-315	Curette Angled 1-0

MICRO CURETTES

Catalog #	Description
875-370	Micro Curette Straight 6-0
875-372	Micro Curette Straight 4-0
875-373	Micro Curette Straight 3-0
875-374	Micro Curette Straight 2-0

Catalog #	Description
875-380	Micro Curette Angled 6-0
875-382	Micro Curette Angled 4-0
875-383	Micro Curette Angled 3-0
875-384	Micro Curette Angled 2-0

KERRISONS

Catalog #	Size
875-251	1mm Kerrison
875-252	2mm Kerrison
875-253	3mm Kerrison

GRAFT HARVEST/PLACEMENT INSTRUMENTS

Catalog #	Description
875-701	Graft Holder/Introducer
875-708	8mm Tapper
875-712	6x12mm Tapper
875-715	Mallet, 8”

Mednext® High Speed Bone Dissecting System

PRODUCT INFORMATION

SUGGESTED MEDNEXT BURS FOR 9LB, 9cm STRAIGHT DRILL ATTACHMENT

Catalog #	*Description*
23B9LB	3mm Ball
24.5B9LB	4.5mm Ball
26B9LB	6mm Ball
23.0M9LB	3mm Matchhead
25X9LB	5mm Coarse Diamond

SUGGESTED BURS FOR 12LB, 12cm STRAIGHT DRILL ATTACHMENT

Catalog #	*Description*
23B12LB	3mm Ball
24.5B12LB	4.5mm Ball
26B12LB	6mm Ball
23.0M12LB	3mm Matchhead
25X12LB	5mm Coarse Diamond

SUGGESTED MEDNEXT BURS FOR 9AN, 9cm ANGLED DRILL ATTACHMENT

Catalog #	*Description*
23B9ST	3mm Ball
24B9ST	4mm Ball
25B9ST	5mm Ball
26B9ST	6mm Ball
23.0M9ST	3mm Matchhead
23X9ST	3mm Coarse Diamond
24X9ST	4mm Coarse Diamond
25X9ST	5mm Coarse Diamond
26X9ST	6mm Coarse Diamond

TRITON™ POWER SURGICAL INSTRUMENT SYSTEM

PRODUCT INFORMATION

SUGGESTED SAWBLADES FOR TRITON SAGITTAL SAW ATTACHMENT

Catalog #	*Description*
201R1SS	Single Blade, 14.0mm (w) x 41.0mm (d)
202R1SS	Single Blade, 9.5mm (w) x 25.5mm (d)
235GH1SS	Graft Harvesting Blade, 5mm
236GH1SS	Graft Harvesting Blade, 6mm
237GH1SS	Graft Harvesting Blade, 7mm
238GH1SS	Graft Harvesting Blade, 8mm
239GH1SS	Graft Harvesting Blade, 9mm
230GH1SS	Graft Harvesting Blade, 10mm

TRITON JACOBS CHUCK ATTACHMENTS FOR ATLANTIS™ DRILL BITS

Catalog #	*Description*
720201	1/8” Keyless Chuck
720203	5/32” Jacobs Chuck - Keyed

Important Information on the ATLANTIS™ Anterior Cervical Plate System

PURPOSE:

The ATLANTIS™ Anterior Cervical Plate System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

DESCRIPTION:

The ATLANTIS™ Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates (set screws and washers are pre-assembled to the plates), screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

The ATLANTIS™ Anterior Cervical Plate System implant components are made from titanium alloy described by ASTM F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from the foregoing material specification. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Do not use any of the ATLANTIS™ Anterior Cervical Plate System components with the components from any other system or manufacturer.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EFFECTS.

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.

POSSIBLE 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.
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.

WARNING 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 ATLANTIS™ 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 ATLANTIS™ 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 ATLANTIS™ 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: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

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

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.

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 ATLANTIS™ 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 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 secure the locking screw into place to cover the portion of the screw heads which are located at the ends of the plate. 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 ATLANTIS™ 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 should 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.
   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.
6. 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 ATLANTIS™ 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:

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 aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should <u>not</u> be used. Also, many instruments require disassembly before cleaning.

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

STERILIZATION:

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

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

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and validate the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any 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 ATLANTIS™ 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

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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.

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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.

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