



Medtronic

ATLANTIS VISION[®] ELITE

Anterior Cervical Plate System

Surgical Technique







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Anterior Cervical Plate System

Surgical Technique

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Instrument Set



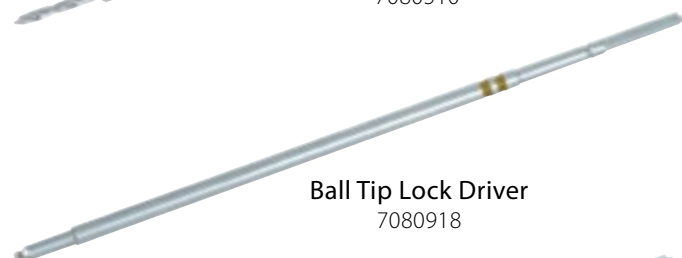
Universal Awl
7080906



Fixed Angle Awl
7080911



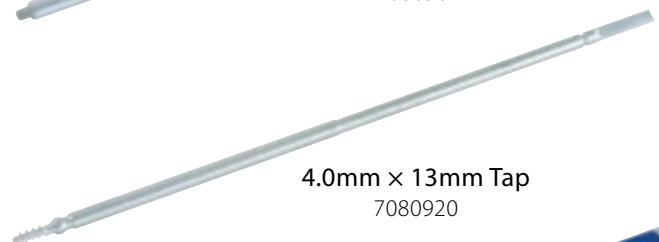
11mm Drill Bit, Sterile
7080510



Ball Tip Lock Driver
7080918



2.5mm Hex Screwdriver
7080907



4.0mm x 13mm Tap
7080920



Lock Screwdriver
7080930



Fixed Drill Guide
7080903



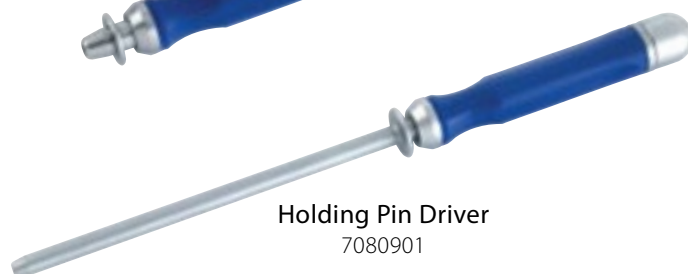
Variable Drill Guide
7080904



Plate Holding Pin
7080902



Universal Handle
6650250



Holding Pin Driver
7080901



Screw Removal Tool
7080919



Plate Holder
7080921D

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 left-sided or right-sided approach to the cervical vertebral column. After the approach is chosen, the head may be rotated to allow for adequate exposure of the upper cervical spine (**Figure 1**).

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



Figure 1

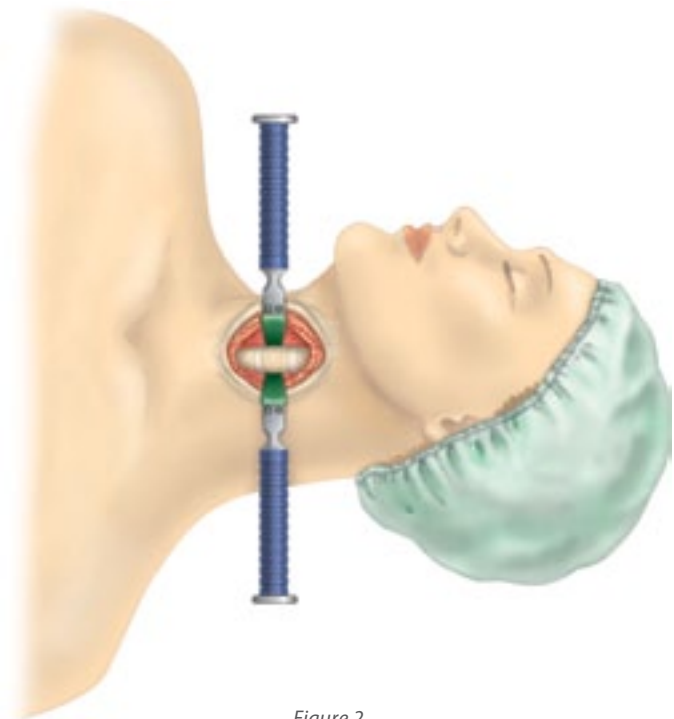


Figure 2

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**). The longitudinal self-retaining retractor is then placed to provide visualization (**Figure 4**).

A wide anterior discectomy to the uncovertebral joints can be performed to allow for an anterior release prior to the correction of a cervical kyphosis. 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.

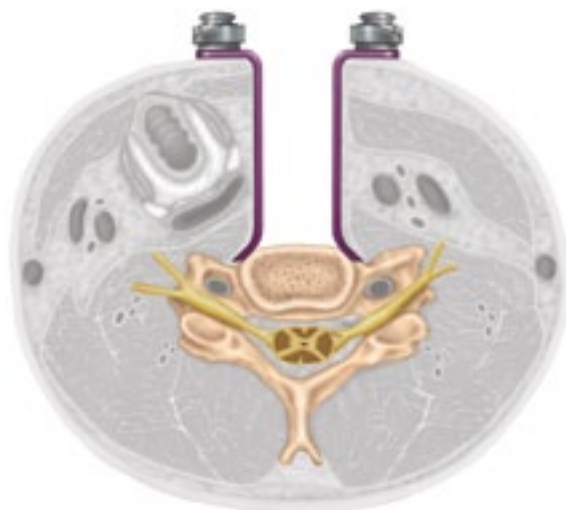


Figure 3

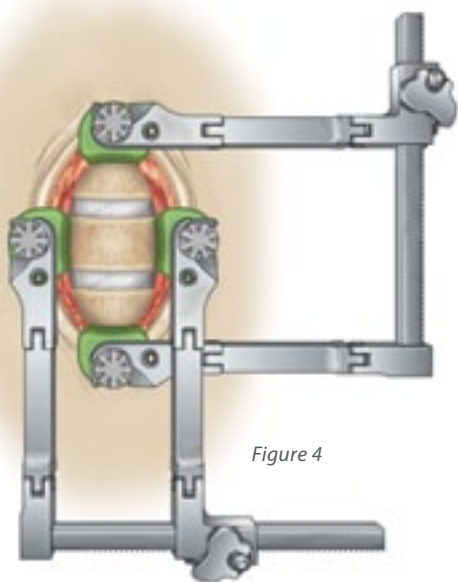


Figure 4

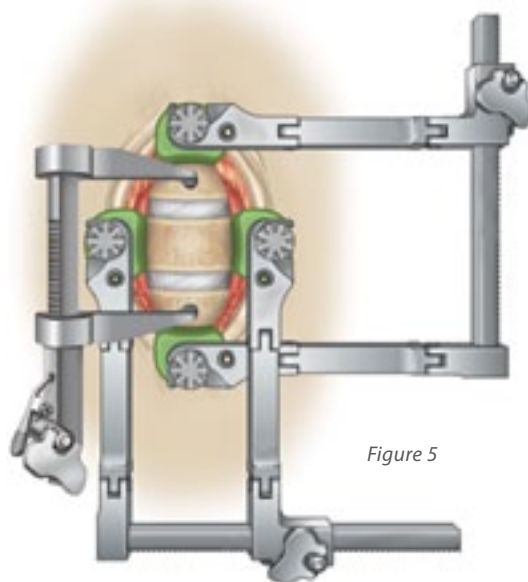


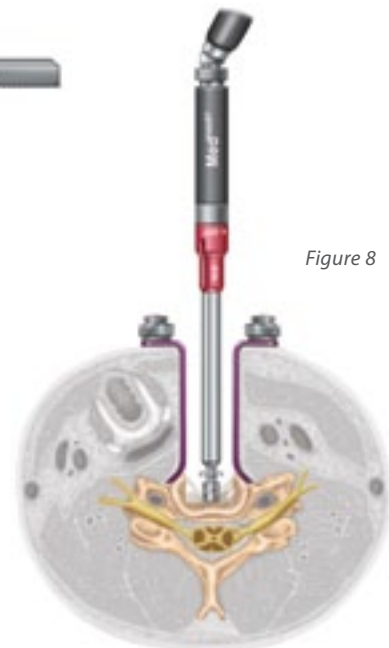
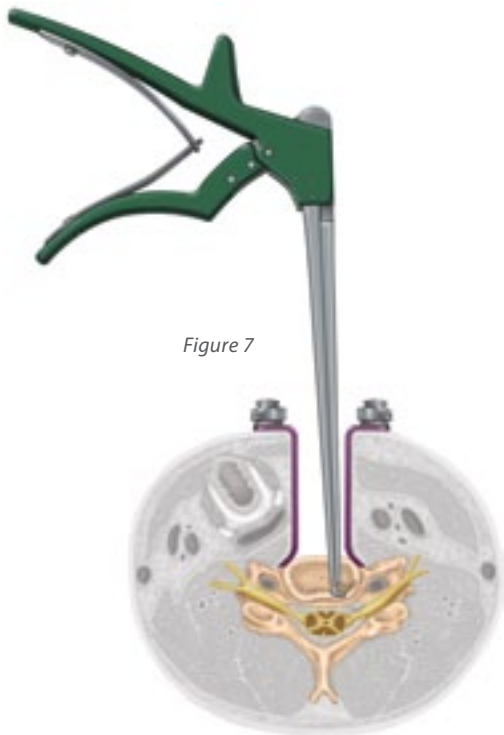
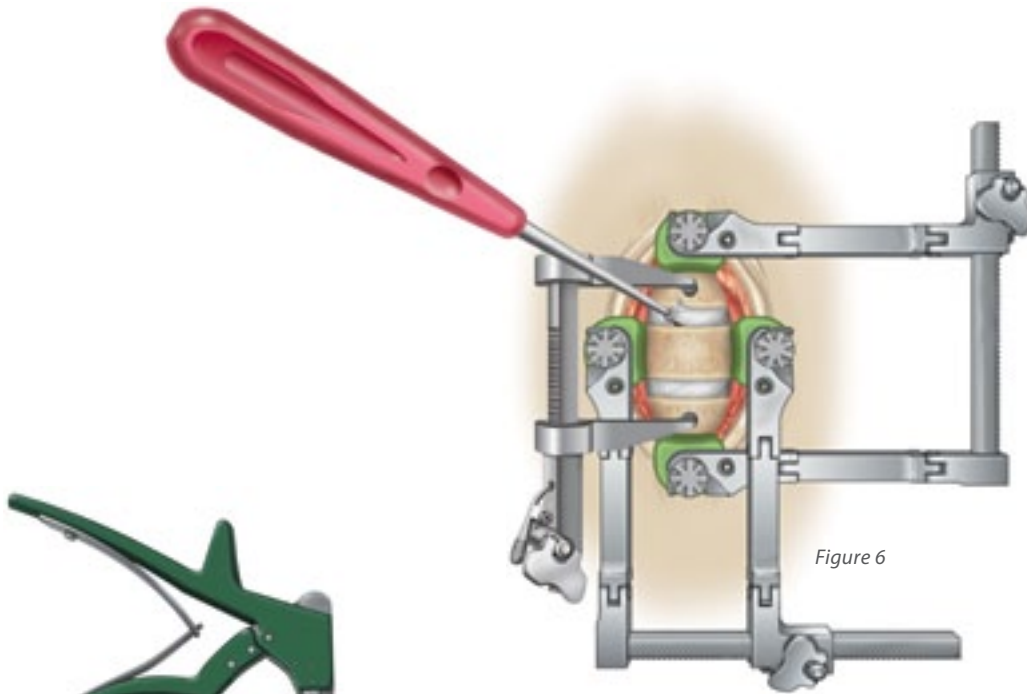
Figure 5

Corpectomy Procedure: Discectomy and Corpectomy

Discectomies are completed at each level. Pituitaries, curettes, and Kerrison rongeurs 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 burr may be used to remove the remaining portion of the vertebrae (**Figure 8**). The posterior longitudinal ligament and osteophytes are then carefully removed. Bone removed from the corpectomy may be utilized as graft material placed into the implant and/or packed around the implant. This is often done with a rongeur after completing approximately three quarters of the discectomy.



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 an accurately matched mortise with the bone graft using a high-speed burr (**Figure 9**). A high-speed rectangular burr may also be used to create parallel end plates, leaving a posterior 'lip' of bone to prevent the bone graft from migrating into the spinal canal.

The dimensions of the corpectomy site are measured precisely and the bone graft is shaped appropriately. Depending on bone quality, you may attempt slight over-distraction against the vertebral body pins. This may allow the implant to be loaded in compression when releasing the distractor. The graft is held and tapped into place using a bone graft holder and mallet (**Figures 10 and 11**).



Figure 9



Figure 10



Figure 11

Plate Length Selection

Soft tissue and anterior osteophytes are removed from the adjacent vertebral bodies so the plate sits evenly on the anterior cortex. Position the plate so the superior and inferior screw holes are approximately at the mid-portion of the vertebral body (**Figure 12A**). This will allow for placement of Fixed Bone Screws or Variable Angle Bone Screws in the center of the vertebrae. The

edge of the plate should not interfere with the adjacent, unfused disc spaces (**Figure 12B**). Fluoroscopy may be used to determine the appropriate plate length and anticipated screw trajectories. The plate may be further contoured with the Plate Bender to match the lordotic curve of the anterior cervical spine.



Figure 12A



Figure 12B

Plate Contouring

The ATLANTIS VISION® ELITE Anterior Cervical Plate is provided with a premachined lordotic curve (**Figure 13A**). The pre-existing lordosis in the plates is appropriate in most cases and plate contouring is typically not required. If required, the plate may be contoured to increase the amount of lordotic curvature (**Figure 13B**) or decrease the amount of lordotic curvature

(**Figure 13C**) 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. Potential risks associated with the use of this device include, but are not limited to bending and/or breakage of any or all of the components.



Figure 13A



Figure 13B



Figure 13C

Attaching the Plate Holder

The Plate Holder may be attached to the plate in any of the screw holes. After determining the appropriate length plate, use the Plate Holder to place and position this plate. 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. To grasp the plate with the holder, push the button at the proximal end of the Plate Holder (**Figure 14**), and insert the Holder tip into any screw hole in the plate. Release the button to engage the plate, and place it on the anatomy centered medially/laterally on the spine.



Figure 14

Plate Positioning and Temporary Plate Fixation

Review landmarks to ensure the plate is centered medially and laterally on the spine. 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 plate can also be temporarily affixed to the vertebral bodies by inserting Plate Holding Pins in the midline of the plate through the locking cap (**Figure 15A**). Use **caution not to turn the locking cap when seating the Holding Pin**. This

could preclude the screws from being inserted.

These Pins are threaded for increased hold strength in the vertebral body. The instrument set includes a Plate Holding Pin Driver to facilitate pin insertion. Drive the sharp tip of the pin into the bone until the dorsal portion of the pin is flush with the plate (**Figure 15B**). To release a Plate Holding Pin from the Pin Driver, place upward pressure on the locking sleeve collar.

✓ Helpful Hint

Additional Plate Holding Pins may be used if desired.



Figure 15A



Figure 15B

Construct Selection and Positioning

The ATLANTIS VISION® ELITE Anterior Cervical Plate System offers the surgeon the versatility of controlling the dynamics of the construct intraoperatively. Fixed, hybrid, or variable angle screw constructs may be configured using color coded Fixed or Variable Angle

Screws. Fixed and Variable Angle Screws can be identified by their distinctive color coding. Potential risks associated with the use of this device include pressure on the skin from component parts, possibly causing skin penetration, irritation, and/or pain.

Construct Options

The multiple screw options provide intraoperative flexibility. The ATLANTIS® Anterior Cervical Plate System was the first to offer surgeons the versatility to place their choice of either fixed- or variable-angle screws at any position on the plate. This feature allows surgeons to configure the following types of constructs:



Fixed Angle
(Constrained)



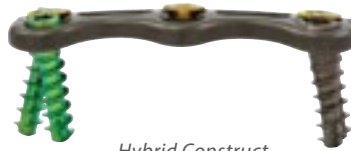
Variable Angle
(Semi-constrained)



Hybrid



Fixed Construct



Hybrid Construct



Variable Construct

Screw Options

- » Color-coded by screw type and diameter.
- » 4.0mm (standard) and 4.5mm (rescue) bone screw diameter.
- » 2.5mm hex screw head diameter.
- » 11 to 17mm bone screw lengths, in 1mm increments.
- » Incorporated self-drilling and self-tapping flute designs.
- » Tapered hex on the 2.5mm hex screwdriver.



GREEN
4.0mm Variable



MAGENTA
4.5mm Variable



GRAY
4.0mm Fixed



BLUE
4.5mm Fixed

Optional Bone Screw Hole Preparation

An awl can be used to break through the cortex of the vertebral body. The instrument set includes a Fixed Angle Awl (**Figure 16A**) and a Universal Awl to provide multiple options for screw hole preparation.

Fixed Angle Awl

- » Incorporates a silicone teardrop handle.
- » Allows for 10mm of bone penetration at a trajectory of 12° cephalad or 6° caudal.

Place the Fixed Angle Awl into a bone screw hole on the plate. Ensure that the awl is securely seated in the aperture of the screw hole. Place downward pressure on the Awl to puncture the cortex of the bone (**Figure 16B**).

Universal Awl

- » Uses the Variable or Fixed Drill Guide.
- » Allows for 8mm of bone penetration in the DTS guide and 10mm in the drill guides.
 - At a trajectory of 22° to -2° cephalad or caudal and 17° to 4° medially convergent with the Variable Drill Guide.
 - At a trajectory of 12° cephalad or 6° caudal and 4° medially convergent with the Fixed Drill Guide.

Snap the tri-flat end of the Universal Awl shaft into the Universal Handle. Ensure that the selected guide is securely seated in the aperture of the bone screw hole on the plate. Insert the Universal Awl into the guide. Place downward pressure on the awl to puncture the cortex of the bone (**Figure 16C**).



Figure 16A



Figure 16B



Figure 16C

Variable Angle Screw Positioning

Variable Drill Guide

The Variable Drill Guide handle is color coded to correspond with the color-coded Variable Angle Screws. Seat the Variable Drill Guide within the bone screw hole on the plate. Securely engage the guide into the plate by applying light downward pressure on the guide handle, making sure to align the guide at the required angle (**Figure 17A**). The Variable Drill Guide allows for a trajectory of 22° to -2° cephalad or caudal and 17° to 4° medially convergent (**Figures 17B and 17C**).

Snap the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the Variable Drill Guide sleeve by rotating the bit clockwise until reaching the stop collar located on the drill bit shaft. The bit shaft incorporates a stop collar that limits the depth of penetration to 11mm.



Figure 17A



Figure 17B

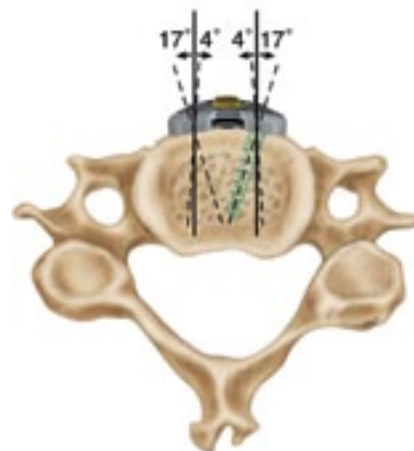


Figure 17C

Fixed Angle Screw Positioning

Fixed Drill Guide

The Fixed Drill Guide handle is color coded to correspond with the grey and blue Fixed Angle Screws. Seat the Fixed Drill Guide within the bone screw hole on the plate. Securely engage the guide into the plate by applying light downward pressure on the guide handle, making sure to align the guide at the required angle (**Figure 18A**). The Fixed Drill Guide allows for a trajectory of 12° cephalad or caudal and 6° medially convergent (**Figures 18B and 18C**).

Snap the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the Fixed Drill Guide sleeve by rotating the bit clockwise until reaching the stop collar located on the drill bit shaft. The bit shaft incorporates a stop collar that limits the depth of penetration to 11mm.



Figure 18A



Figure 18B

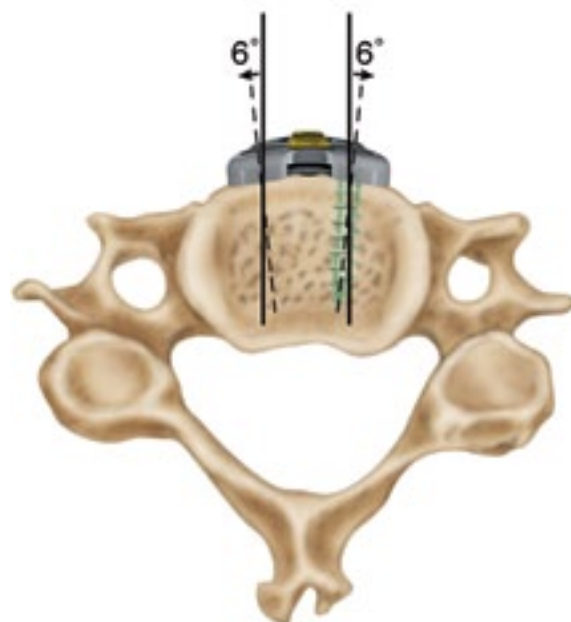


Figure 18C

Optional Bone Screw Hole Preparation

Drill, Tap, and Screw (DTS) Guide

The DTS Guide can only be used to drill pilot holes for the screw holes on the superior and inferior ends of the plate. The DTS Guide also functions as a plate holder, eliminating the need for Plate Holding Pins.

To place the guide clip in the open position, turn the DTS Guide knob counterclockwise (**Figure 19A**). To align and attach the DTS Guide to the plate, insert the guide tip into the superior/inferior locking cap.

Turn the DTS Guide knob clockwise, closing the guide and clamping the guide clip to the groove located on the dorsal side of the superior/inferior edge of the plate (**Figures 19B and 19C**). The DTS Guide allows for a trajectory of 12° cephalad or caudal and 6° medially convergent.



Figure 19A



Figure 19B



Figure 19C

Optional Bone Screw Hole Preparation *continued*

Snap the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the DTS Guide tube by rotating the bit clockwise until reaching the stop collar located on the drill bit shaft. The bit shaft incorporates a stop collar that limits the depth of penetration to 11mm (**Figure 20A**).

Remove the bit, and move the guide sleeve to the adjacent bone screw hole by lifting the sleeve slightly and rotating it 180° (**Figures 20B, 20C and 20D**).



Figure 20A



Figure 20B



Figure 20C



Figure 20D

Bone Screw Selection and Insertion

NOTE: If using the non-self-tapping bone screws, use the tap in the pilot holes at the same angulation before inserting the bone screws. When using Biocortical Screws, the outer cortex needs to be tapped to allow for easy initial engagement of the bone screw.

Select the appropriate length bone screw. Unicortical Screws may be used; however, bicortical purchase may be employed if clinically indicated. The appropriate length screw can be verified using the screw gauge. Snap the tri-flat end of the 2.5mm Hex Screwdriver shaft into the Universal Handle. The screwdriver incorporates a tapered hex that allows for a secure, self-retaining fit between the bone screw and screwdriver.

Using the driver to pick up the bone screw, insert the screw tip into the previously prepared bone screw hole. Applying moderate to light pressure, provisionally advance the bone screw by rotating the 2.5mm Hex Screwdriver clockwise until the screw head is seated in the plate.

After inserting all of the bone screws, final tightening is done, sequentially, so that the plate is evenly and firmly applied to the anterior surface of the vertebrae.

A Ball Tip Lock Driver is also included in the instrument set to allow the screws to be engaged from an angle (Figure 21).

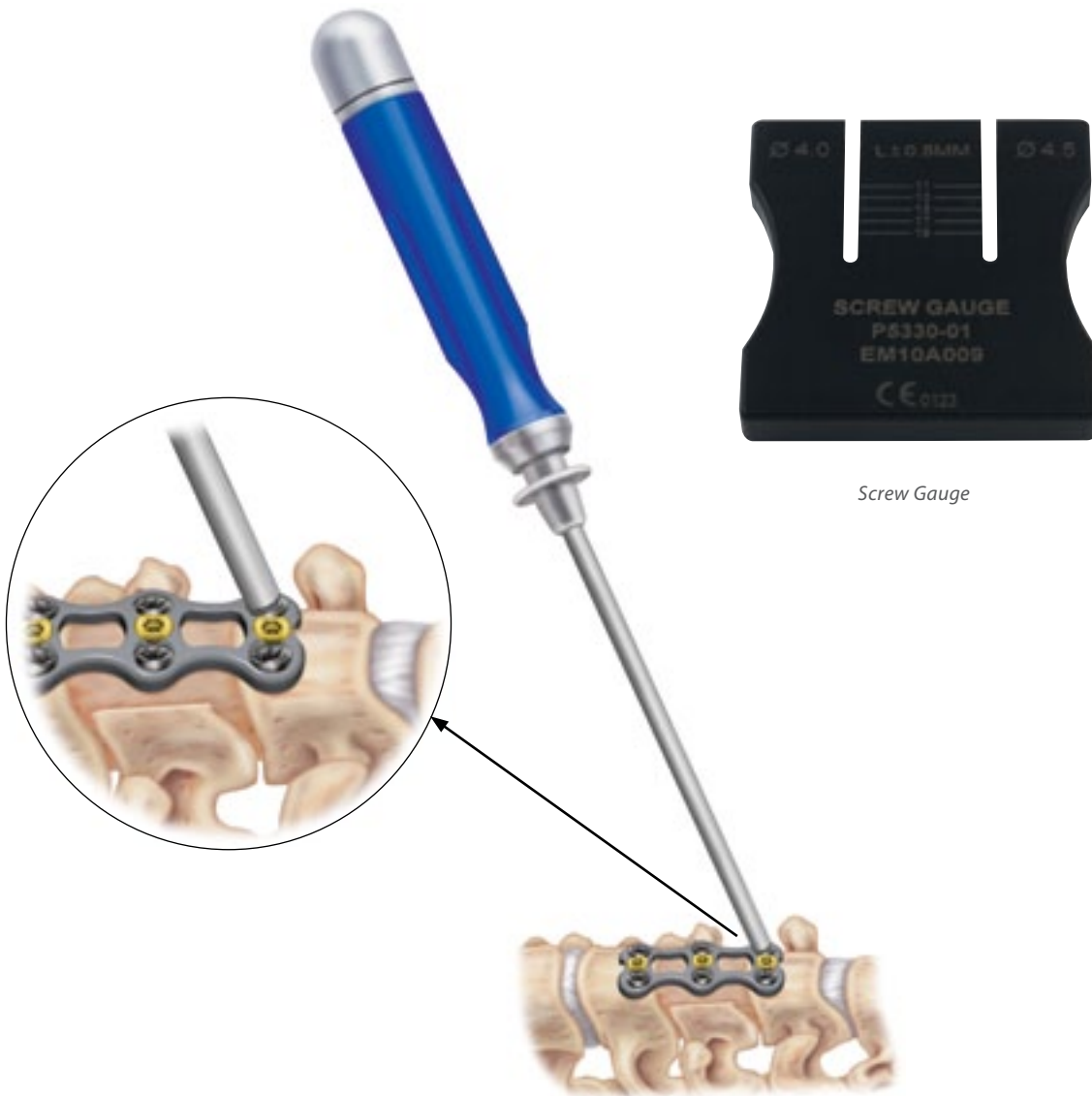


Figure 21

Locking the Bone Screws

Locking Mechanism

The ATLANTIS VISION® ELITE Anterior Cervical Plate System includes an attached locking cap mechanism. The lock detail has a positive stop that prevents the cap from turning more than 90° clockwise. Avoid turning the locking cap counterclockwise as this will detach the cap from the plate.

The same standard 2.5mm Hex Screwdriver used for screw insertion can be used to engage the locking cap mechanism. Insert the 2.5mm Hex Screwdriver into the head of the locking cap and rotate it 90° until the cap covers both screw heads and a positive stop is felt.

The stop provides tactile feedback that the cap is fully engaged and covering both screw heads (**Figure 22A**).

A Ball Tip Lock Driver is also included in the instrument set to allow the locking cap to be engaged from an angle (**Figure 22B**). If the locking cap does not rotate and cover both screw heads, check to make sure that the screws are fully seated. If bone screws are not fully seated and locked it could cause pressure on the skin from component parts in patients with inadequate tissue coverage over the implant, possibly causing skin penetration, irritation, and/or pain.



Figure 22A

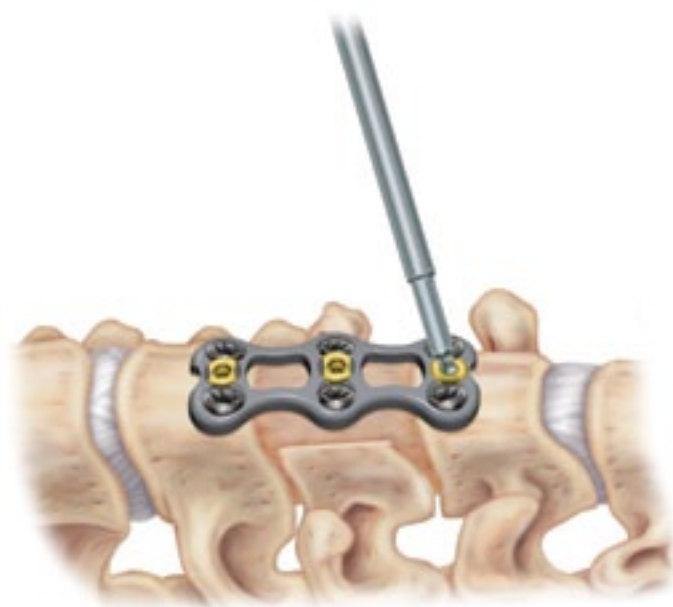


Figure 22B

Procedural Pearls and Explanation

Procedural Pearls

- » Use Plate Holding Pins through the cannulated locking cap to provide temporary midline fixation of the plate without interfering with bone screw insertion. Use caution not to turn the locking cap while seating the holding pin against the cap. This could preclude the screws from being inserted.
- » Use Ball Tip Lock Driver when trying to engage the locking mechanism from challenging angles. The driver facilitates conical angulations up to 20°.
- » Engage the locking mechanism with a clockwise motion. Do not rotate the locking mechanism counterclockwise. Rotating the locking mechanism counterclockwise will begin to unthread the lock from the plate.
- » If the locking cap will not close over bone screws, ensure that the bone screws are fully seated and then lock the cap. If bone screws are not fully seated and locked it could cause pressure on the skin from component parts in patients with inadequate tissue coverage over the implant, possibly causing skin penetration, irritation, and/or pain.
- » When using Ø4.5mm Rescue Screws, they must thread through the plate. Ensure that proper drill guides are used to minimize insertion resistance.
- » It is difficult to know when the screw is fully seated when using the DTS Guide because the tube is covering the screw. To verify the screw is seated, align the laser etching on the screwdriver shaft with the top of the DTS Guide tube. If the screw is not fully seated, it can lead to bending and/or breaking of any or all of the components.

Explanation

Using the 2.5mm Hex Screwdriver, rotate the locking caps counterclockwise 90° to uncover the screw heads. Using the same screwdriver, loosen and extract all the screws and then remove the plate.

ATLANTIS VISION® ELITE Product Ordering Information

ATLANTIS VISION® ELITE IMPLANT

Set Type: SPS02311

Plates



1-Level Plates

Part Number	Description	Quantity In Set	Quantity Used	Price
7200019	Plate 19mm	1		
7200021	Plate 21mm	2		
7200023	Plate 23mm	2		
7200025	Plate 25mm	2		
7200027	Plate 27.5mm	2		
7200030	Plate 30mm	2		
7200132	Plate 32.5mm	1		

2-Level Plates

Part Number	Description	Quantity In Set	Quantity Used	Price
7200127	Plate 27.5mm	1		
7200130	Plate 30mm	1		
7200032	Plate 32.5mm	1		
7200035	Plate 35mm	2		
7200037	Plate 37.5mm	2		
7200040	Plate 40mm	2		
7200042	Plate 42.5mm	2		
7200045	Plate 45mm	2		
7200047	Plate 47.5mm	1		
7200050	Plate 50mm	1		
7200152	Plate 52.5mm	1		
7200155	Plate 55mm	1		

3-Level Plates

Part Number	Description	Quantity In Set	Quantity Used	Price
7200145	Plate 45mm	1		
7200147	Plate 47.5mm	1		
7200150	Plate 50mm	1		
7200052	Plate 52.5mm	1		
7200055	Plate 55mm	1		
7200057	Plate 57.5mm	1		
7200060	Plate 60mm	1		
7200062	Plate 62.5mm	1		
7200065	Plate 65mm	1		
7200067	Plate 67.5mm	1		
7200070	Plate 70mm	1		
7200072	Plate 72.5mm	1		

4-Level Plates

Part Number	Description	Quantity In Set	Quantity Used	Price
7200167	Plate 67.5mm	1		
7200170	Plate 70mm	1		
7200172	Plate 72.5mm	1		
7200075	Plate 75mm	1		
7200077	Plate 77.5mm	1		
7200080	Plate 80mm	1		
7200082	Plate 82.5mm	1		
7200085	Plate 85mm	1		

ATLANTIS VISION® ELITE Product Ordering Information *continued*

5-Level Plates

Part Number	Description	Quantity In Set	Quantity Used	Price
7200180	Plate 80mm	1		
7200182	Plate 82.5mm	1		
7200185	Plate 85mm	1		
7200087	Plate 87.5mm	1		
7200090	Plate 90mm	1		
7200095	Plate 95mm	1		
7200100	Plate 100mm	1		
7200105	Plate 105mm	1		
7200110	Plate 110mm	1		

Self-Drilling Screws

4.0mm FIXED ANGLE (Grey)

Part Number	Description	Quantity In Set	Quantity Used	Price
3120411	4.0mm × 11mm	8		
3120412	4.0mm × 12mm	10		
3120413	4.0mm × 13mm	10		
3120414	4.0mm × 14mm	10		
3120415	4.0mm × 15mm	10		
3120416	4.0mm × 16mm	10		
3120417	4.0mm × 17mm	8		



4.5mm FIXED ANGLE (Blue)

Part Number	Description	Quantity In Set	Quantity Used	Price
3125411	4.5mm × 11mm	4		
3125413	4.5mm × 13mm	4		
3125415	4.5mm × 15mm	4		
3125417	4.5mm × 17mm	4		



4.0mm VARIABLE ANGLE (Green)

Part Number	Description	Quantity In Set	Quantity Used	Price
3120511	4.0mm × 11mm	8		
3120512	4.0mm × 12mm	10		
3120513	4.0mm × 13mm	10		
3120514	4.0mm × 14mm	10		
3120515	4.0mm × 15mm	10		
3120516	4.0mm × 16mm	10		
3120517	4.0mm × 17mm	8		



4.5mm VARIABLE ANGLE (Magenta)

Part Number	Description	Quantity In Set	Quantity Used	Price
3125511	4.5mm × 11mm	4		
3125513	4.5mm × 13mm	4		
3125515	4.5mm × 15mm	4		
3125517	4.5mm × 17mm	4		



ATLANTIS VISION® ELITE Product Ordering Information *continued*

Self-Tapping Screws

4.0mm FIXED ANGLE (Grey)

Part Number	Description	Quantity In Set	Quantity Used	Price
3120211	4.0mm × 11mm	8		
3120212	4.0mm × 12mm	10		
3120213	4.0mm × 13mm	10		
3120214	4.0mm × 14mm	10		
3120215	4.0mm × 15mm	10		
3120216	4.0mm × 16mm	10		
3120217	4.0mm × 17mm	8		



4.5mm FIXED ANGLE (Blue)

Part Number	Description	Quantity In Set	Quantity Used	Price
3125211	4.5mm × 11mm	4		
3125213	4.5mm × 13mm	4		
3125215	4.5mm × 15mm	4		
3125217	4.5mm × 17mm	4		



4.0mm VARIABLE ANGLE (Green)

Part Number	Description	Quantity In Set	Quantity Used	Price
3120311	4.0mm × 11mm	8		
3120312	4.0mm × 12mm	10		
3120313	4.0mm × 13mm	10		
3120314	4.0mm × 14mm	10		
3120315	4.0mm × 15mm	10		
3120316	4.0mm × 16mm	10		
3120317	4.0mm × 17mm	8		



4.5mm VARIABLE ANGLE (Magenta)

Part Number	Description	Quantity In Set	Quantity Used	Price
3125311	4.5mm × 11mm	4		
3125313	4.5mm × 13mm	4		
3125315	4.5mm × 15mm	4		
3125317	4.5mm × 17mm	4		



Disposable Instruments

Part Number	Description	Quantity In Set	Quantity Used	Price
7080510	11mm Drill Bit (Sterile)	1		
7080513	13mm Drill Bit (Sterile)	1		
7080902	Plate Holding Pins	3		

ATLANTIS VISION® ELITE Product Ordering Information *continued*

Universal Instrument Set

Set Type: SPS02121

Instrument/Set

Part Number	Description	Quantity In Set
6650250	Universal Handle	3
7080902	Plate Holding Pin	3
7080903	Fixed Drill Guide	1
7080904	Variable Drill Guide	1
7080906	Universal Awl	1
7080907	2.5 Hex Screwdriver	2
7080911	Fixed Angle Awl	1
7080918	Ball Tip Driver	1
7080919	Screw Removal Tool	1
7080920	4.0mm x 13mm Tap	1
7080921D	Plate Holder	1
7080930	Lock Screwdriver	1
7080901	Holding Pin Driver	1

Cases and Trays

Part Number	Description	Quantity In Set
7081932	Instrument Outer Case	1
1850079	Generic Outer Lid	1
7082005	Instrument Tray Lower	1
7082105	Plate Holding Pin Caddy Lid	1

Important Product Information

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, with certain plates having subcomponents manufactured from shape memory alloys (Nitinol-NiTi). Stainless steel and titanium implant components must not be used together in a construct. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability. Do not use any of the ATLANTIS® Anterior Cervical Plate System components with the components from any other system or manufacturer.

INDICATIONS

Properly used, this system is intended for anterior interbody screw fixation from C2 to T1. 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:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- 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.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia
- Severe osteoporosis.

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:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- 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 and tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears.
- 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.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.

- Scar formation possibly causing neurological compromise around nerves and/or pain.
- 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.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- 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.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- 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 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. The implants are not prostheses.

This system was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

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.



FOR US AUDIENCES ONLY

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

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

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- 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.
- 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.
- 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.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

Important Product Information *continued*

- 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.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- 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.
- 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.
- 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 mechanism into place to cover the screw heads.

POSTOPERATIVE

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

- 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.
- 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.
- 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.
- 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 ensure cooperation until bony union is confirmed.
- 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.
- Any retrieved devices should be treated in

PACKAGING

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

CLEANING AND DECONTAMINATION

Unless just removed from an unopened sterile MEDTRONIC package, all instruments and implants must be unpackaged, disassembled (if applicable), and cleaned before sterilization, cleaned before introduction into a sterile surgical field, or if applicable, cleaned before being returned to MEDTRONIC. Remove all packaging materials prior to disassembly (if applicable) and cleaning. Cleaning instructions and associated disassembly instructions (if applicable) can be found at <http://manuals.medtronic.com>.

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

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

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes	30 Minutes
Steam	Pre-Vacuum	273°F (134°C)*	20 Minutes*	30 Minutes*
Steam	Gravity	273°F (134°C)*	20 Minutes*	30 Minutes*

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

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC 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 or not a written report from the distributor is requested.

MRI INFORMATION

The ATLANTIS® Anterior Cervical Plate System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

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.

LICENSED UNDER ONE OR MORE OF G. KARLIN MICHELSON, M.D., PATENT NOS.: 6,193,721; 6,398,783; 6,454,771; 6,527,776; 6,620,163.



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EXPLANATION OF SYMBOLS

	Authorized Representative in the European Community
	The device complies with European Directive MDD 93/42/EEC
	CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.
	Consult Instructions for Use
	Do Not Reuse
	Batch Code
	Manufacturer
	Catalog Number
	Non-sterile
	For US Audiences Only

Contact Customer Service or your Sales Representative for the most up to date revision of the package insert.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

