



Medtronic

ATLANTIS TRANSLATIONAL™

Anterior Cervical Plate System

Surgical Technique

As described by:

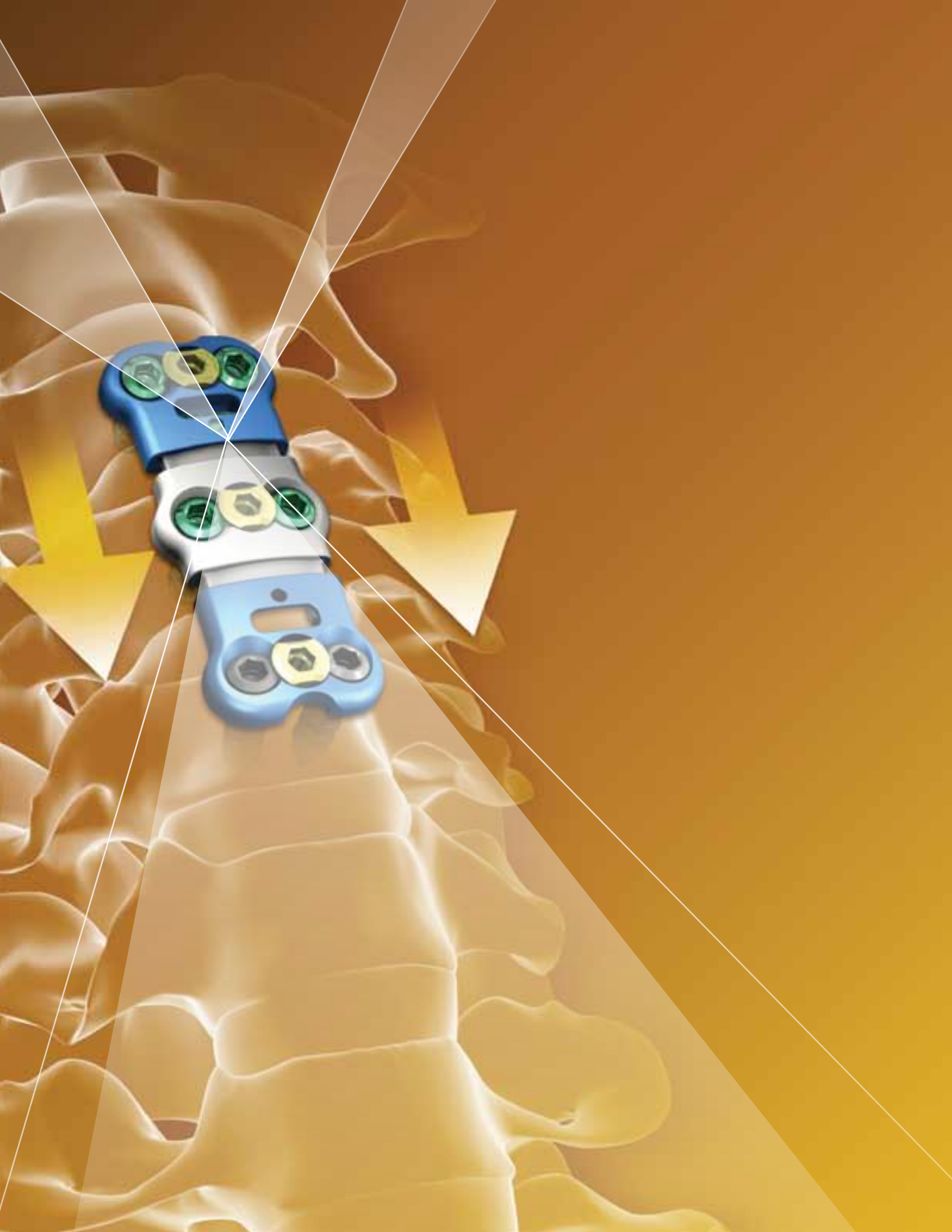
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Dear Colleagues,

A single-level anterior cervical discectomy and interbody arthrodesis with instrumentation is one of the most efficacious procedures that we perform. Unfortunately, this success is not as evident in multi-level discectomy and corpectomy procedures.

The advent of translation in devices such as the PREMIER™ Anterior Cervical Plate were intended to improve these outcomes. Many of these new plate designs allow for screws to rotate and translate, maintaining segmental graft compression, which we believe likely contributes to successful procedures. Despite these innovations, there were significant drawbacks including encroachment on adjacent level discs, and bulky high-profile mechanisms that limited visualization. In addition, the bidirectional loading and off-loading of the grafts was concerning, and was felt by many of us to limit the potential benefit of translational compression.

Next generation plate designs attempted to solve many of these problems. Strategies have included features that allow the plates themselves to telescope or slide, unidirectional mechanisms to prevent graft off-loading, wider apertures for improved graft visualization, and smaller profiles.

We are pleased to announce the release of the ATLANTIS TRANSLATIONAL™ Anterior Cervical Plate System, which integrates all of these features into one system. The ATLANTIS TRANSLATIONAL™ Anterior Cervical Plate System provides variable-angle screws for rotational settling, as well as a unidirectional translating mechanism that maintains segmental graft compression throughout the range of motion. Fixed and/or variable-angle screws can be used, at single and/or multiple levels, to create hybrid constructs. A one-step locking mechanism secures the screws even at off-axis angles. Finally, the option to use the device as a static plate in the fully collapsed configuration, positions the ATLANTIS TRANSLATIONAL™ Anterior Cervical Plate System as a solution for anterior cervical stabilization procedures.

It is our hope that the ATLANTIS TRANSLATIONAL™ Anterior Cervical Plate System provides you with useful features that will optimize your anterior cervical fusion procedures and results for your patients.

Sincerely,

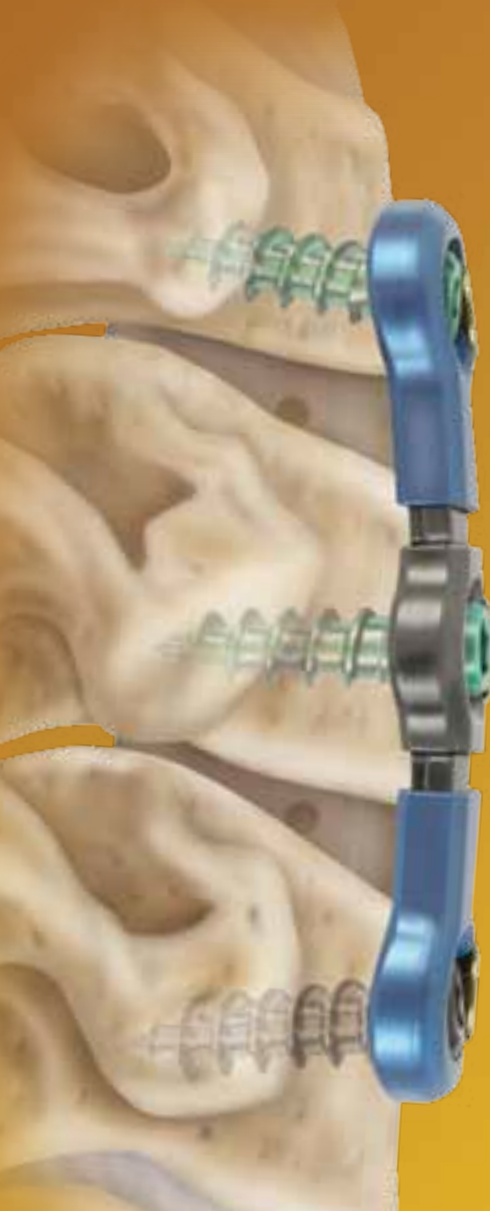
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Product Overview



Unidirectional Translation

- » Allows axial load-sharing between the graft and the vertebral body end plate.¹
- » Allows unidirectional translation up to 2mm per level in 1mm increments.
- » Unidirectional movement provides a continuous compressive load between the end plate and the bone graft based on in vitro testing.^{2,3}
- » Allows intraoperative precompression.
- » Adjustable plate allows flexibility of screw placement on vertebral body to fit pathology and patient anatomy (i.e., corpectomy, larger patients).
- » Sliding plate components minimize the possibility of adjacent-level disc impingement during postoperative settling.
- » Unidirectional mechanism allows the plate to function as a static plate when in the fully collapsed position.

Wolff's Law is a theory developed by German anatomist and surgeon Julius Wolff in the 19th century that states that bone in a healthy person will adapt to the load it is placed under. If loading on a particular bone increases, the bone will remodel itself over time to become stronger to resist that load. The converse should be considered as well, if the load on a bone decreases, the bone will adapt and become weaker.⁴

Integrated Locking Mechanism



Open Position



90° Turn



Locked Position

The locking mechanism is engaged with the same driver as the bone screws. A 90° clockwise turn securely locks both screws.

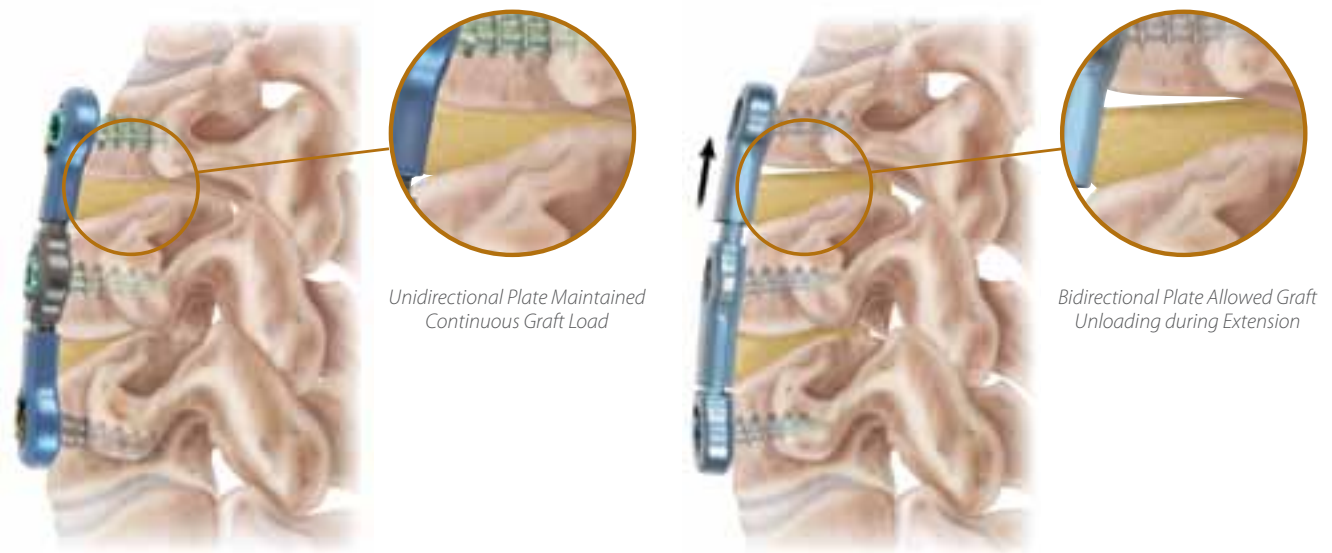
Testing Summary

Biomechanical Summary of Unidirectional Plate Design

Test results demonstrated that the unidirectional plate had less motion in flexion-extension and maintained a more consistent graft load when compared to the bidirectional design.

Further, the bidirectional design allowed a greater variance in graft loading during extension. Therefore, the ATLANTIS TRANSLATIONAL™ Anterior Cervical Plate System

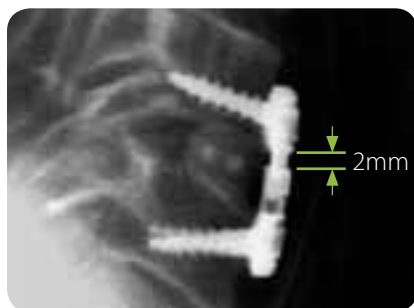
incorporates a unidirectional design to maintain consistent graft forces across multiple loading scenarios.^{2,3}



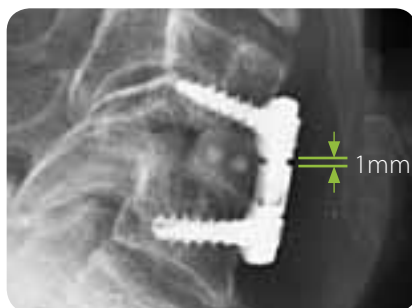
Compressive Load Translation

The ratchet mechanism of the unidirectional translation plate was also tested. The plate was able to translate under compressive load and

maintain its position under tension when ratcheted.^{2,3} Clinical results vary by patient.



Immediately Postoperative



One Week Postoperative



Four Weeks Postoperative

Instrument Overview

Ratchet Release Tool (7081914)

The Ratchet Release Tool may be used to open the plate in 1 mm increments when it is in the fully or partially closed position.



Plate Compressor (7080915)

The Plate Compressor is used to achieve *in situ* pre-compression and to adjust the plate length.



Drill, Tap, and Screw (DTS) Guide (7081912)

The DTS instrument guides the awl, drill bit, and bonescrews into the bone at 12° cephalad/caudal and 6° medially convergent angles.



Instrument Set



Surgical Approach

Place the patient in the supine position with the head in slight extension (**Figure 1**). Support the posterior cervical spine to establish and maintain normal cervical lordosis. A right-sided or left-sided surgical approach may be used based on surgeon preference. After selecting the approach, rotate the head to allow for adequate exposure of the upper cervical spine.

Using a standard transverse incision, expose the vertebral bodies to be fused. To ensure proper plate positioning, care should be taken to ensure complete decompression of neural elements and removal of any anterior osteophytes.

✓ Note

"Drill down anterior osteophytes so there is a flat surface for the plate to lay flush with the vertebral bodies. This will allow the lordotic plate to conform to the ventral surface of the spine, reducing the need for additional plate contouring."

— Dean G. Karahalios, MD

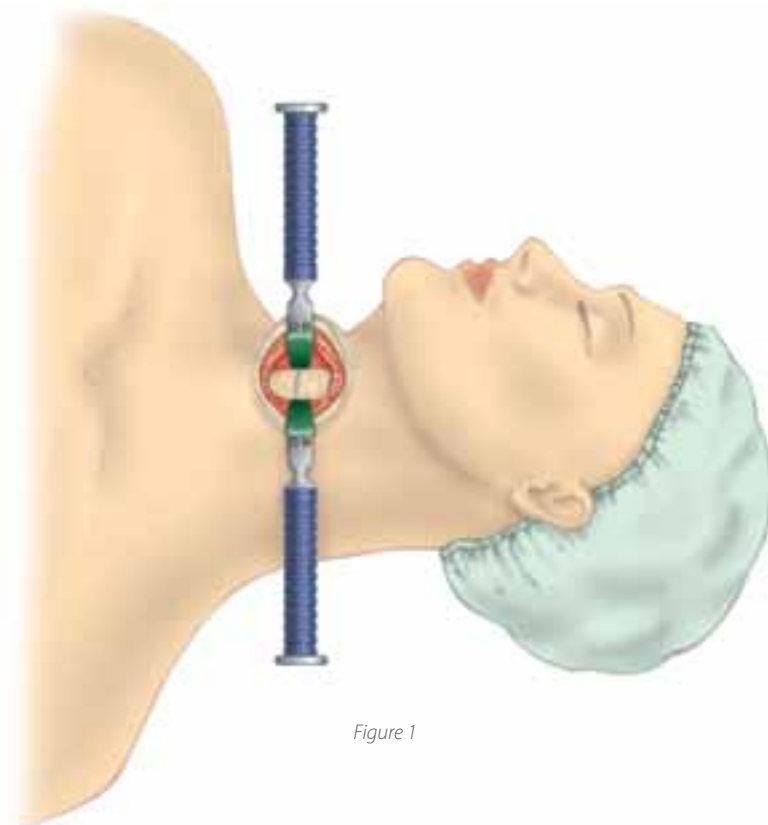


Figure 1

Plate Placement and Temporary Plate Fixation

The ATLANTIS TRANSLATIONAL™ Anterior Cervical Plates come in 19mm to 85mm lengths in 2.5mm increments. An appropriately sized plate spans the distance between the superior and inferior vertebral bodies to be fused.

After determining the appropriate length plate, use the Plate Holder to place and position this plate. To grasp the plate with the holder, push the button at the proximal end of the Plate Holder, 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.

The plate can be temporarily affixed to the vertebral bodies by inserting Plate Holding Pins in the midline of the plate through the locking cap. **Use caution not to turn the locking cap when seating the Holding Pin.** The Plate Holding Pins can also be placed in the bone screw holes.

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 (**Figure 2**). Drive the sharp tip of the pin into the bone until the dorsal portion of the pin is flush with the plate (**Figure 3**). To release a Plate Holding Pin from the Pin Driver, place upward pressure on the locking sleeve collar (**Figure 4**).

Note

Lift the collar to load and unload the Plate Holding Pin. Release the pressure to lock the pin to the instrument.



Figure 2



Figure 3



Figure 4

Bone Screw Options/Plate Configuration Options

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 to simplify hole preparation and insertion.
- » Tapered hex on the 2.5mm hex screwdriver allows a secure self-retaining fit between the screw and the driver.



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:



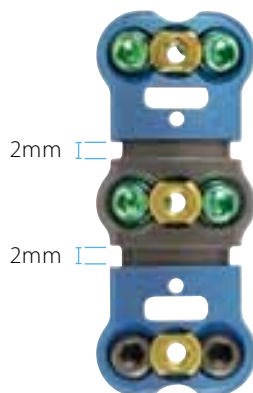
Fixed Angle
(Constrained)



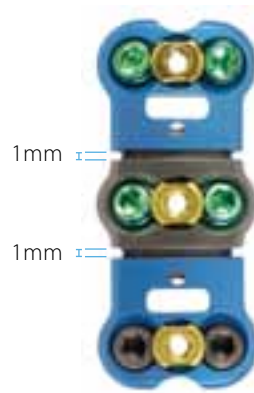
Variable Angle
(Semi-constrained)



Hybrid
(Allows Motion at the Plate-screw Interface on One End of the Construct but not the Other)



Open Position



Partially Closed Position



Closed Position
(Static Plate)

Bone Screw Hole Preparation *continued*

A drill bit can be used to drill pilot holes for the bone screws.

Drill

- » Uses the variable-angle, fixed-angle, or Drill, Tap, and Screw (DTS) guide.
- » Allows for 11 mm of bone penetration.

An awl can be used to break through the cortex of the vertebral body. The instrument set includes a Fixed Angle Awl (**Figure 5**) and a Universal Awl to provide multiple options for screw hole preparation.

Fixed Angle Awl

- » Incorporates a silicone teardrop handle that provides a comfortable fit in the palm of the hand.
- » Allows for 10 mm 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 6**).



Figure 5



Figure 6

Bone Screw Hole Preparation *continued*

Universal Awl

- » Uses the variable-angle, fixed-angle, or Drill, Tap, and Screw (DTS) 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-angle screw guide.
 - At a trajectory of 12° cephalad or 6° caudal and 4° medially convergent with the fixed-angle screw guide.
 - At a trajectory of 12° cephalad or 12° caudal and 6° medially convergent with the Drill, Tap, and Screw (DTS) 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 7**).



Figure 7

Bone Screw Hole Preparation *continued*

Variable-Angle Drill Guide

The Variable-Angle Drill Guide handle is color coded to correspond with the color-coded Variable-Angle Screws. Seat the Variable-Angle 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 8**). The Variable-Angle Drill Guide allows for a trajectory of 22° to -2° cephalad or caudal and 17° to 4° medially convergent (**Figures 9a and 9b**).

Snap the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the Variable-Angle 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 8



Figure 9a

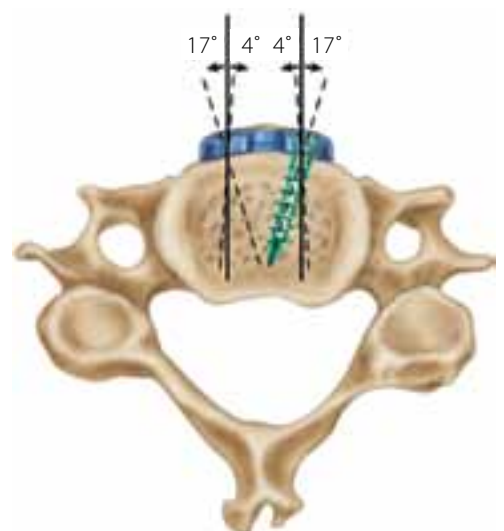


Figure 9b

Bone Screw Hole Preparation *continued*

Fixed-Angle Drill Guide

The Fixed-Angle Drill Guide handle is color coded to correspond with the grey and blue Fixed Angle Screws. Seat the Fixed-Angle 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 10**). The Fixed-Angle Drill Guide allows for a trajectory of 12° cephalad or caudal and 6° medially convergent (**Figures 11a and 11b**).

Snap the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the Fixed-Angle 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 11 mm.



Figure 10



Figure 11a

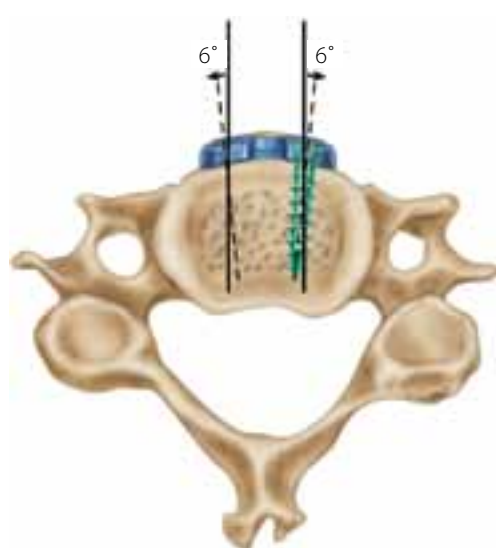


Figure 11b

Bone Screw Hole Preparation *continued*

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 12**). 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 13a and 13b**). The DTS Guide allows for a trajectory of 12° cephalad or caudal and 6° medially convergent.



Figure 12



Figure 13a



Figure 13b

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 14**).

Remove the bit, and move the guide sleeve to the adjacent bone screw hole by lifting the sleeve slightly and rotating it 180° (**Figures 15a, 15b and 15c**).



Figure 14



Figure 15a



Figure 15b



Figure 15c

Bone Screw Selection and Insertion

Select the appropriate length bone screw. 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 (**Figure 16**).



Figure 16

✓ Note

*"By combining screw translation with rotation, the ATLANTIS TRANSLATIONAL™ Plate allows controlled lordotic graft subsidence and axial load sharing."
— Todd C. Bonvallet, MD*

Locking the Bone Screws

Locking Mechanism

The ATLANTIS TRANSLATIONAL™ 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 17**).

A Ball Tip Lock Driver is also included in the instrument set to allow the locking cap to be engaged from an angle (**Figure 18**). If the locking cap does not rotate and cover both screw heads check to make sure that the screws are fully seated.



Figure 17



Figure 18

Plate Compression

Preoperative and Intraoperative Precompression

The ATLANTIS TRANSLATIONAL™ Cervical Plate System allows for *in situ* compression. After locking the bone screws, insert the Compressor in the center and end locking cap (superior or inferior), and apply light to moderate pressure to engage the ratchet (**Figure 19**). The Compressor compresses the plate in 1mm increments for up to 2mm of compression per level (**Figures 20a and 20b**). The Compressor instrument can only be used when the interbody space allows for at least 1mm of compression.

✓ Note

"If a bone graft is inserted and determined to be too loose, an implanted plate may be collapsed in situ to create more compression or preload across the interspace."

— Eric A. Potts, MD



Figure 19



Figure 20a



Figure 20b

Plate Compression *continued*

Adjusting Compression or Plate Length

The Ratchet Release instrument may be used to adjust plate compression. The instrument opens the plate in 1mm increments. Align the Ratchet Release by inserting it into the section of the plate that matches the shape shown on the Ratchet Release handle. Press the instrument firmly against the plate to ensure the round tip of the instrument engages and compresses

the ratchet spring (**Figures 21a and 21b**). Turn the Ratchet Release handle 90° clockwise to open the plate (**Figure 22**). When the handle reaches 90°, the plate will open 1mm, and the Ratchet Release handle will spring back to its original position, perpendicular to the plate. Repeat this step to open the plate to its original length with a 2mm gap.

The tri-flat ends of the Ball Tip Lock Driver and screwdriver can be used as an alternative to open a partially closed or closed plate in 1mm increments. Place the detent into the small hole on the blue portion of the plate, immediately under the graft visualization window (**Figure 23**).

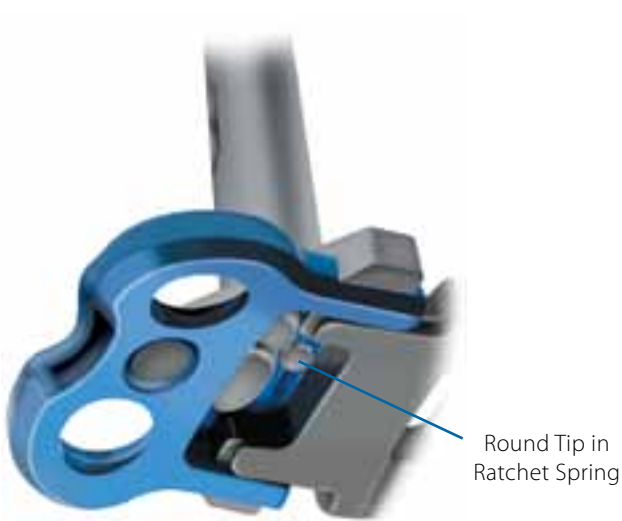


Figure 21a

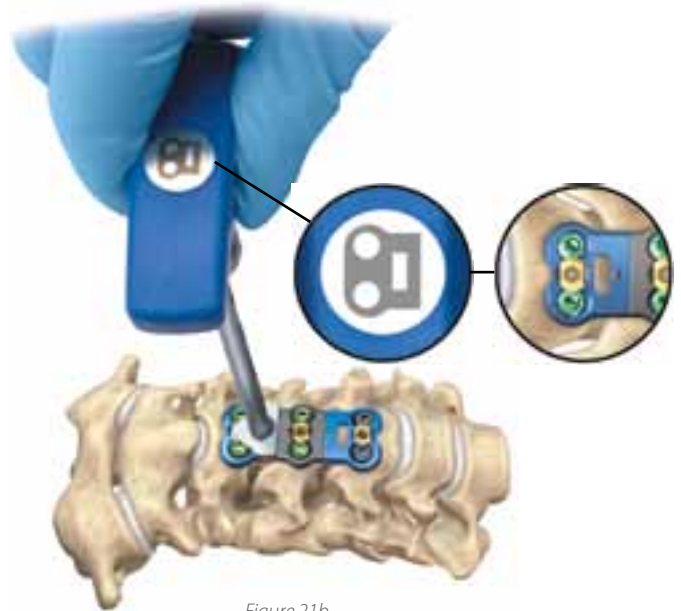


Figure 21b



Figure 22

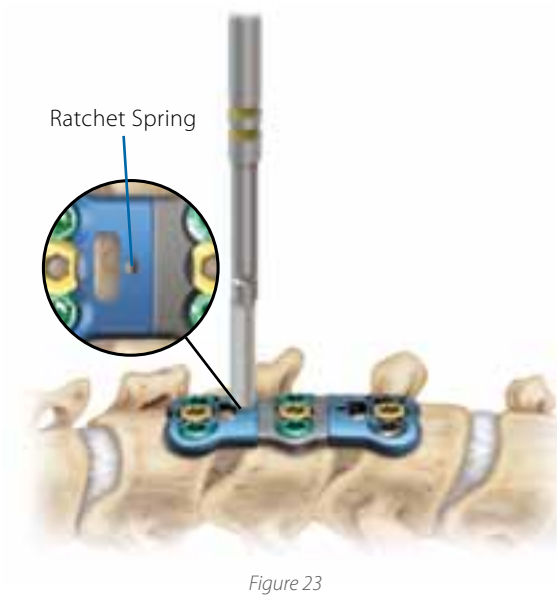


Figure 23

Procedural Pearls and Explantation

Procedural Pearls

- » Drill down or burr anterior osteophytes so there is a flat surface for the plate to lie flush with the vertebral bodies. This will allow the lordotic plate to conform to the ventral surface of the spine reducing the need for additional plate bending.
- » 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.
- » 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. Rotating the locking mechanism counterclockwise will begin to unthread the lock from the plate.
- » Use tri-flat end of standard screwdriver or the Ball Tip Lock Driver to open the plate if it collapses prior to insertion.
- » The Ratchet Release instrument **will not** open plate if the ratchet spring is not compressed. Use the laser mark on the handle to assist with correct orientation of the instrument with the implant. Locate the ratchet spring center hole prior to instrument engagement.
- » To confirm that the plate is in its fully open position, you should be able to see completely through the center hole of the plate for each segment. Reference photographs are on page 8.
- » The plate can be precollapsed either halfway (1mm), or completely (2mm) across each level to enable less compression, or to better tailor the length of the plate to a patient's anatomy. In addition, the unidirectional ratcheting mechanism allows the plate to function as a conventional static plate when implanted in the fully collapsed position.
- » If a bone graft is inserted and determined to be too loose, an implanted plate may be collapsed in situ to create more compression or preload across the interspace.
- » The Compressor instrument is designed to work only if the interbody gap allows for at least 1mm translation.
- » If the locking cap will not close over bone screws, ensure that the bone screws are fully seated and then lock the cap.
- » 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.

Explication

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.

Intraoperative and Postoperative Images*



Intraoperative



Immediately Postoperative



Four Weeks Postoperative

*Clinical results vary by patient.

Product Ordering Information



ITEM NUMBER	DESCRIPTION
Plates	
1-Level Plates	
6190019	19mm Plate
6190021	21mm Plate
6190025	25mm Plate
6190027	27.5mm Plate
6190030	30mm Plate
6190032	32.5mm Plate
2-Level Plates	
6190035	35mm Plate
6190037	37.5mm Plate
6190040	40mm Plate
6190042	42.5mm Plate
6190045	45mm Plate
6190047	47.5mm Plate
6190050	50mm Plate
3-Level Plates	
6190052	52.5mm Plate
6190055	55mm Plate
6190057	57.5mm Plate
6190060	60mm Plate
6190062	62.5mm Plate
6190065	65mm Plate
6190067	67.5mm Plate
6190070	70mm Plate
6190072	72.5mm Plate
4-Level Plates	
6190075	75mm Plate
6190077	77.5mm Plate
6190080	80mm Plate
6190082	82.5mm Plate
6190085	85mm Plate



ITEM NUMBER	DESCRIPTION
Self-Tapping Screws	
4.0mm Fixed Angle (Gray)	
3120211	4.0mm × 11mm
3120212	4.0mm × 12mm
3120213	4.0mm × 13mm
3120214	4.0mm × 14mm
3120215	4.0mm × 15mm
3120216	4.0mm × 16mm
3120217	4.0mm × 17mm
4.5mm Fixed Angle (Blue)	
3125211	4.5mm × 11mm
3125213	4.5mm × 13mm
3125215	4.5mm × 15mm
3125217	4.5mm × 17mm
4.0mm Variable Angle (Green)	
3120311	4.0mm × 11mm
3120312	4.0mm × 12mm
3120313	4.0mm × 13mm
3120314	4.0mm × 14mm
3120315	4.0mm × 15mm
3120316	4.0mm × 16mm
3120317	4.0mm × 17mm
4.5mm Variable Angle (Magenta)	
3125311	4.5mm × 11mm
3125313	4.5mm × 13mm
3125315	4.5mm × 15mm
3125317	4.5mm × 17mm

Product Ordering Information *continued*



ITEM NUMBER	DESCRIPTION
Self-Drilling Screws	
4.0mm Fixed Angle (Gray)	
3120411	4.0mm × 11mm
3120412	4.0mm × 12mm
3120413	4.0mm × 13mm
3120414	4.0mm × 14mm
3120415	4.0mm × 15mm
3120416	4.0mm × 16mm
3120417	4.0mm × 17mm
4.5mm Fixed Angle (Blue)	
3125411	4.5mm × 11mm
3125413	4.5mm × 13mm
3125415	4.5mm × 15mm
3125417	4.5mm × 17mm
4.0mm Variable Angle (Green)	
3120511	4.0mm × 11mm
3120512	4.0mm × 12mm
3120513	4.0mm × 13mm
3120514	4.0mm × 14mm
3120515	4.0mm × 15mm
3120516	4.0mm × 16mm
3120517	4.0mm × 17mm
4.5mm Variable Angle (Magenta)	
3125511	4.5mm × 11mm
3125513	4.5mm × 13mm
3125515	4.5mm × 15mm
3125517	4.5mm × 17mm

ITEM NUMBER	DESCRIPTION
General Instruments	
9790903	Pin Driver
7080903	Fixed Drill Guide
7080904	Variable Drill Guide
6650250	Universal Handle
7080906	Universal Awl
7080907	2.5mm Hex Screwdriver
7080610	11mm Drill Bit
7080920	4.0mm × 13mm Tap
7080918	Ball Tip Lock Driver
7080911	Fixed Angle Awl
7080919	Screw Removal Tool
7080921	Plate Holder
ATLANTIS TRANSLATIONAL™ Plate Instrument Set	
7081912	Drill, Tap, and Screw Guide
7080915	Plate Compressor
7081914	Ratchet Release Tool
Disposable Instruments	
7080510	11mm Drill Bit, Sterile
7080902	Plate Holding Pin

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), dysesthesia, 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.



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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References

1. Brodke DS, Gollojly S, Alexander Mohr R, Nguyen BK, Dailey AT, Bachus AK. Dynamic cervical plates: biomechanical evaluation of load sharing and stiffness. *Spine*. 2001 Jun 15;26(12):1324-1329.
2. DiAngelo DJ, Roberson J, Karahalios DG, Kelly BP, Bonvallet TC, Potts E, Vaccaro A. *Use of Compliant Interbody Load Cells to Compare Load Sharing Properties of Unidirectional and Bidirectional Multilevel Dynamic Translational Anterior Cervical Plates* [white paper]. Memphis, TN: Medtronic; 2008.
3. Cervical Spine Research Society 35th Annual Meeting: Nov. 29–Dec. 1, 2007; San Francisco, CA.
4. Steinmetz MP, Benzel EC, Apfelbaum RI. Axially dynamic implants for stabilization of the cervical spine. *Neurosurgery*. 2006 Oct;59(4 Suppl 2):ONS378-ONS388.

Notes

Notes

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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.

