Ascential

ACP 1

Anterior Cervical Plating System

Surgical Technique

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System Overview

Ascential's ACP 1 anterior cervical plating system offers a simple backout prevention mechanism, a high degree of screw angulation and simplified instrumentation.

The primary screw locking mechanism is a locking screw, which is designed to lock over the bone screw heads. The Locking Screw locks the bone screws in place and allows for additional visual and tactile feedback that the bone screws are locked.

ACP 1 features both fixed and variable angle screws to accommodate both rigid and semi-constrained bone screw fixation philosophies. Variable angle screws offer up to 20° of screw angulation, and fixed screws are positioned at fixed trajectory of 11° cephalad/caudal. Both screws are designed with a square head to facilitate engagement with the instrumentation and to reduce the chance of stripping.

Instrument options further enhance surgical technique versatility by matching surgeon preference regarding approach and screw pathway preparation.

The ACP 1 plate is made of Titanium Alloy (Ti-6Al-4V) and is **2.5mm thick** and **18mm wide**.

The lordotic curve, or radius of curvature, in the sagittal plane is 190mm for one- and two-level plates, and 390mm for three- and four-level plates. The plate also features 25mm of curvature in the axial plane for matching of the patient's anatomy. The large graft-viewing windows allow for visualization of the endplates to aid in graft positioning.

ACP 1 Anterior Cervical Plating System

Screw Types

The ACP 1 system features both fixed and variable angle bone screws. **Fixed angle bone screws**, which are used if a rigid construct is desired, are inserted into the plate at a fixed trajectory, and they remain in this position under loading. The **variable angle bone screws** feature a spherical head allowing increased angulation against the plate.

Screws are offered as self-tapping, incorporating a cutting flute and less aggressive screw tip, and self-drilling, which have a cutting flute and a sharp tip.

Screw Sizes

ACP 1 screws are available in 4.0mm and 4.5mm diameters and are color-coded for easy identification.

Screw Angulation

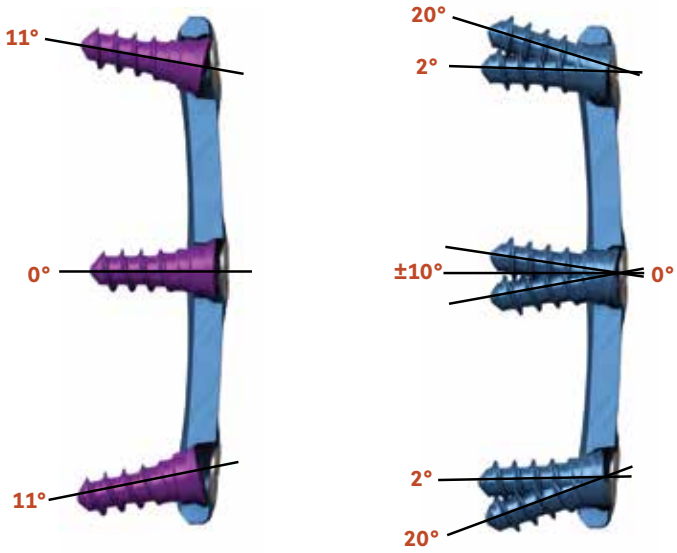
Cephalad/Caudal Angulation *In-situ*

Fixed Screws are positioned at fixed trajectory at the following angles:

Middle holes: **0°**
End holes: **11°**

Variable screws have a wide range of variability in their degree of cephalad/caudal orientation.

Middle holes: **0° neutral with +/- 10° of variability**
End holes: **+2° to +20°**



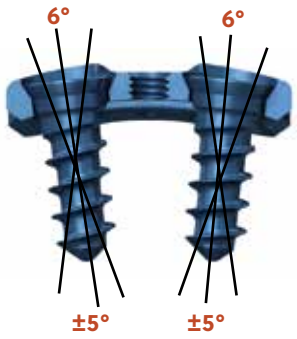
Medial/Lateral Convergence *In-situ*

Fixed screws are positioned in the plate with the following degrees of convergence beneath the plate:

Middle holes: **6°**
End holes: **6°**

Variable screws can have the following degrees of convergence beneath the plate:

Middle holes: **6° with +/- 5° of variability**
End holes: **6° with +/- 5° of variability**



AIM Packaging

The screws and plates that comprise the ACP 1 system are provided sterile in Ascential's proprietary Advanced Inventory Management (AIM) packaging.

Each AIM sterile plate package includes one plate in a sterile double blister.

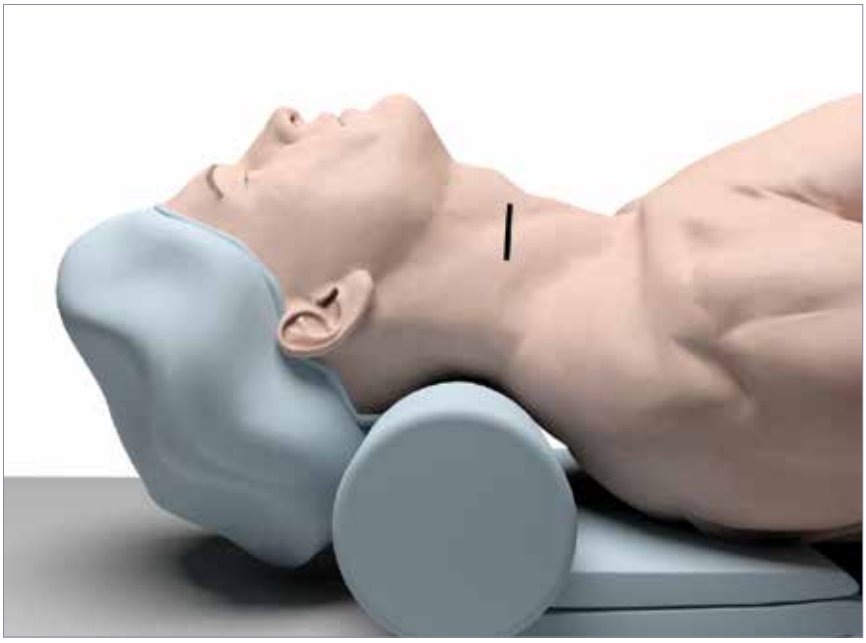
AIM sterile screw packages are comprised of a thermoplastic polyurethane (TPU) screw pouch contained in a sterile double blister. Each TPU screw pouch holds one locking screw and two bone screws of the same size and type. The TPU pouch enables implants to be presented and loaded onto their respective insertion instrumentation without direct human contact with the screws. Additional locking screws are also packaged individually should an extra be needed during surgery.

AIM Sterile Double Blister

AIM TPU Screw Pouch

Patient Positioning and Exposure

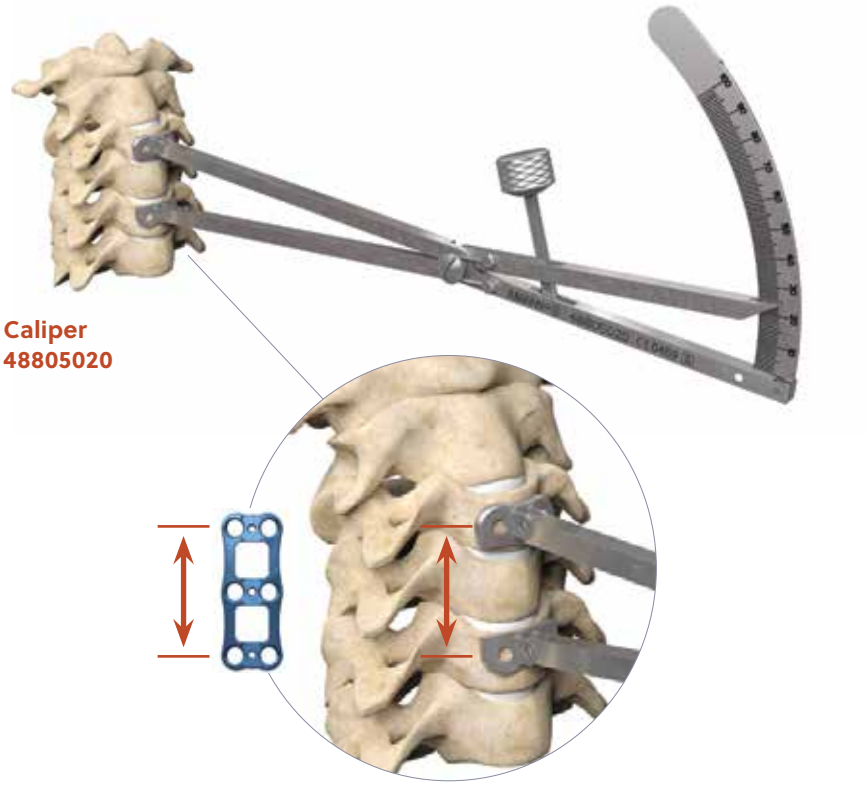
Patient is placed in a supine position with the head turned slightly away from the side of the approach. For one- or two-level procedures, a transverse incision parallel to the skin creases of the neck is recommended. For longer level procedures, one can choose to do a transverse or oblique incision placed along the anterior border of the sternocleidomastoid. The left side is preferred, as the more constant course of the recurrent laryngeal nerve on this side potentially minimizes the risk of its injury. After blunt dissection through the various tissue layers, the anterior cervical spine is gently exposed. The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/bone graft insertion.



Care should be taken to remove any bony anatomy or osteophytes which would inhibit the ACP 1 plate from sitting flat against the bone.

Implant Selection and Preparation

The correct **size of the ACP 1 plate** is determined by measuring from the center of the cephalad hole to the center of the caudal hole. The **Caliper's** feet each contain a pair of positioning holes that correspond to the end holes of the ACP 1 plate, which are designed to assist with plate sizing. Place the Caliper's positioning holes at the screw insertion points of the appropriate vertebrae, read the measurement and select the appropriate plate size. In cases in which the measured distance falls between two sizes, it is usually recommended that the smaller size be used. A plate that is too long may interfere with the adjacent disc space. Regardless of the plate size selected, the screws must be inserted with the correct amount of screw angulation. A **Universal Plate Holder** is available to hold the plate next to the vertebral column to confirm size selection.



Caliper
48805020

Hold the Universal Plate Holder by the outer ridged surface and attach it to the plate as shown in Figure 1 or Figure 2. Squeeze the Universal Plate Holder until it clicks one time, which locks the Universal Plate Holder to the plate. Squeeze the Universal Plate Holder a second time to release the plate from the Universal Plate Holder.

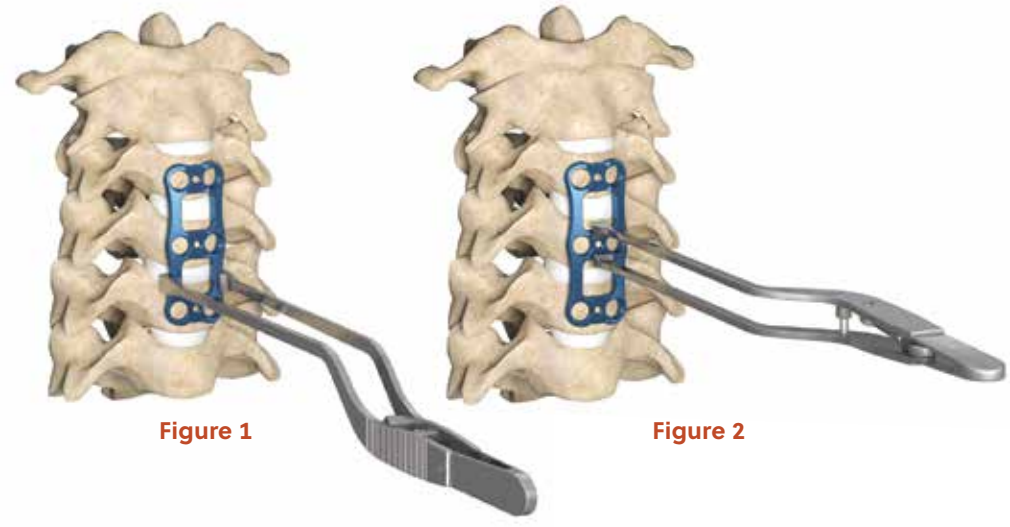


Figure 1

Figure 2

Universal Plate Holder
48513010

ACP 1 Anterior Cervical Plating System

The ACP 1 plate has been designed with a slight sagittal and axial bend to align to a patient's anatomy. If additional sagittal plate contouring is necessary, the **Plate Bender** may be used.

The Plate Bender has two sides: (+) which will increase lordosis and (-) which will decrease lordosis. Position the plate face-up to increase lordosis or face-down to decrease lordosis. Insert the plate on the appropriate side of the Plate Bender so that the axial curve of the plate matches the curve in the slot. The plate should fit between the two notches on either side of the slot, so that bending only occurs in the graft windows. Bend plates incrementally to help match patient anatomy.

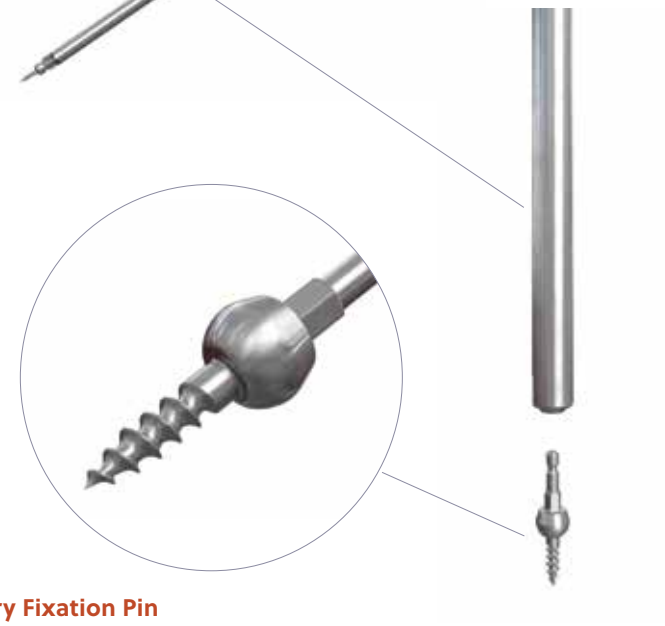
Note: Due to the notch sensitivity of titanium, the plate must never be unbent or reverted to its original shape once it has been contoured.

To remove the plate from the Plate Bender, hold the plate in one hand while releasing the handle with the other hand.

Plate Bender
48770200

Temporary Fixation Pins are available to hold the plate during screw hole preparation. Load the Temporary Fixation Pin onto the **Temporary Fixation Pin Inserter** by pulling up the sleeve of the inserter. Position the pin in the center of the screw hole. Apply slight downward pressure while threading the pin into the screw hole. When fully inserted, the pin can penetrate the bone up to 9.5mm. Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior vertebral column. Remove the Temporary Fixation Pins after the plate is sufficiently stabilized with screws.

Temporary Fixation Pin
Inserter
48510400



Temporary Fixation Pin
48770410

Note: Excessive pivoting or angulation on the Temporary Fixation Pin Inserter should be avoided, as it can cause fracturing of the Temporary Fixation Pins. Temporary Fixation Pins are recommended for single-use only.*

* The ACP 1 Temporary Fixation Pins are made of titanium alloy (Ti-6Al-4V) implantable-grade material

Screw Hole Preparation

One of the following screw hole preparation instruments, including the Fixed Drill Guide, Variable Drill Guide, or Punch Awl with Sleeve, is required to place the bone screws in the proper trajectory and help prevent damage to implants and difficulty securing the locking screw in its proper protective position.

If self-tapping screws are selected, use a Single Barrel Drill Guide to guide the appropriate Drill Bit. If self-drilling screws are used, use either the Punch Awl with Sleeve or a Drill Bit and Single Barrel Drill Guide to center and direct the pathway of the screw

Drilling Technique

ACP 1 Drill Bits, which are available in 2.5mm diameter and four sizes (10, 12, 14, 16mm), corresponding to the screw lengths, provide a positive stop for accurate drilling depth in combination with any of the guides.

A **Tap** is available in one pre-set depth (10mm). To create the screw thread pattern, rotate the Tap until it contacts the plate.

The Drill Bit and Tap can each be attached to the **Quick Release Handle**.

Drill Bits
10mm 48510610
12mm 48510612
14mm 48510614
16mm 48510616

Tap
48770700

Quick Release Handle
48805080

Drill Guides

Single Barrel Drill Guides, available in both Fixed and Variable designs, are one of the two options for preparing the screw pathway. Each Single Barrel Drill Guide design (Fixed or Variable) is designed to direct the Drill Bit along a screw trajectory within the effective working range of the system.

Note: Both the fixed and variable guides must be engaged securely to the plate prior to screw hole preparation. Additionally they will disengage from the plate if they are positioned outside the optimal range of angulation.

Fixed Single Barrel Drill Guide

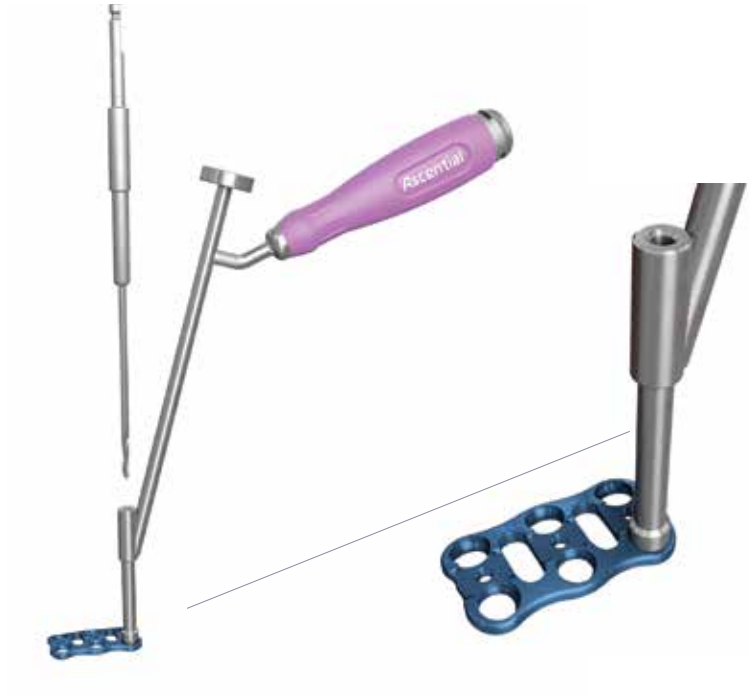
The **Fixed Single Barrel Drill Guide**, which can be identified by the fuchsia-colored handle, is rigidly attached to the plate at 11° of sagittal angulation in the end holes (neutral axis) and 0° of sagittal angulation in the middle holes. Outside of this position, the Fixed Drill Guide does not provide the optimal trajectory and may result in an inaccurate screw position. When properly seated in the screw hole, the Fixed Drill Guide will have limited range of angulation.

After preparing the screw pathway, remove the guide prior to tapping or screw insertion.

Caution: Do not apply cantilever loads while the drill is engaged in the bone.

Note: Use of either the Fixed Drill Guide or the Fixed Punch Awl Sleeve is required if fixed screws are desired. If fixed angle screws are not inserted at the correct trajectory, damage to the plate or bone screw could occur.

Single Barrel Drill Guide - Fixed
48805110



The Fixed Drill Guide features a thumb pad to help position the guide in the screw hole.

Variable Single Barrel Drill Guide

The **Variable Single Barrel Drill Guide**, which has a blue handle, features a spherical shape at the tip of the guide shaft, which allows the guide to angulate on the plate within the allowed range.

Position the bone screws within the recommended range of angulation to ensure secure locking of the screws within the plate.

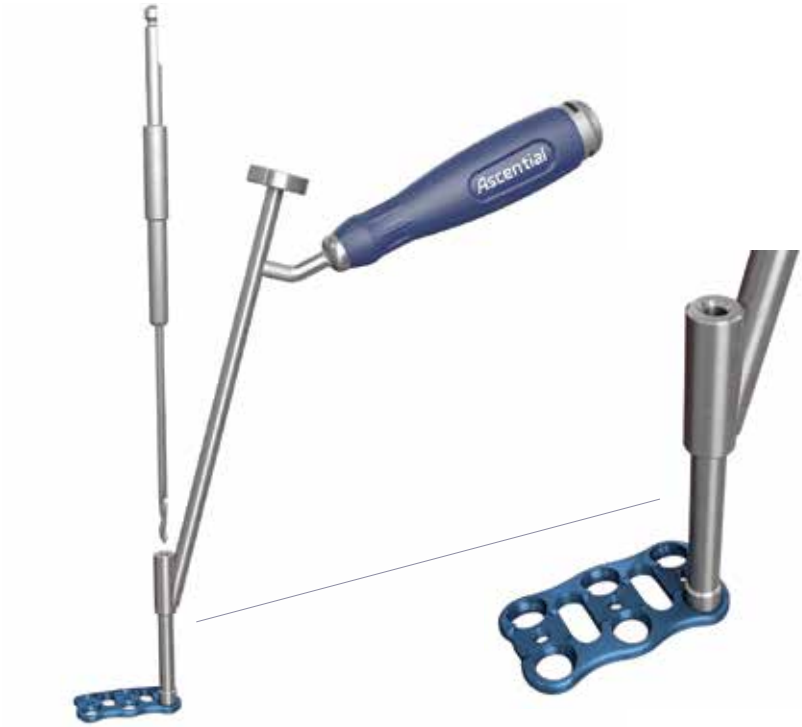
When properly seated in the screw hole, the Variable Drill Guide will have limited range of angulation. A slight downward pressure should be applied to the drill guide to keep it in the correct position during drilling.

The guide must be removed prior to tapping or screw insertion.

Tip: A slight rocking motion facilitates disassembly of the guide from the plate.

Caution: Do not apply cantilever loads while the drill is engaged in the bone.

Single Barrel Drill Guide - Variable
48805120



The Variable Drill Guide features a thumb pad to help position the guide in the screw hole.

Punch Awl Technique

As an alternative to the drill guide, the **Punch Awl** may be used to center and direct the pathway of the self-drilling screws. When fully deployed, the Punch Awl can penetrate up to 8mm of bone. Either a **Fixed** or **Variable Punch Awl Sleeve** must be threaded onto the Punch Awl before use.

The Fixed and Variable Punch Awl Sleeves are designed to seat in the plate's screw holes, and to provide the Punch Awl the correct range of angulation for the corresponding fixed or variable screw types.

Note: Do not use the Punch Awl without a Punch Awl Sleeve.

While initiating engagement of the Punch Awl Sleeve with the ACP 1 plate, the awl should be in the locked position so as to avoid prematurely engaging the bone with the awl tip. In the locked position, the button on the awl's collar is positioned in the key hole of the collar closest to the blue handle.

With the Variable Punch Awl Sleeve assembled to the Punch Awl shaft, the Punch Awl will seat into the screw hole in the same manner as the Variable Single Barrel Drill Guide. With the Fixed Punch Awl Sleeve, position the awl on the plate hole at the proper fixed trajectory, and then gently rock the instrument while applying downward pressure until the tip fully seats into the plate hole.

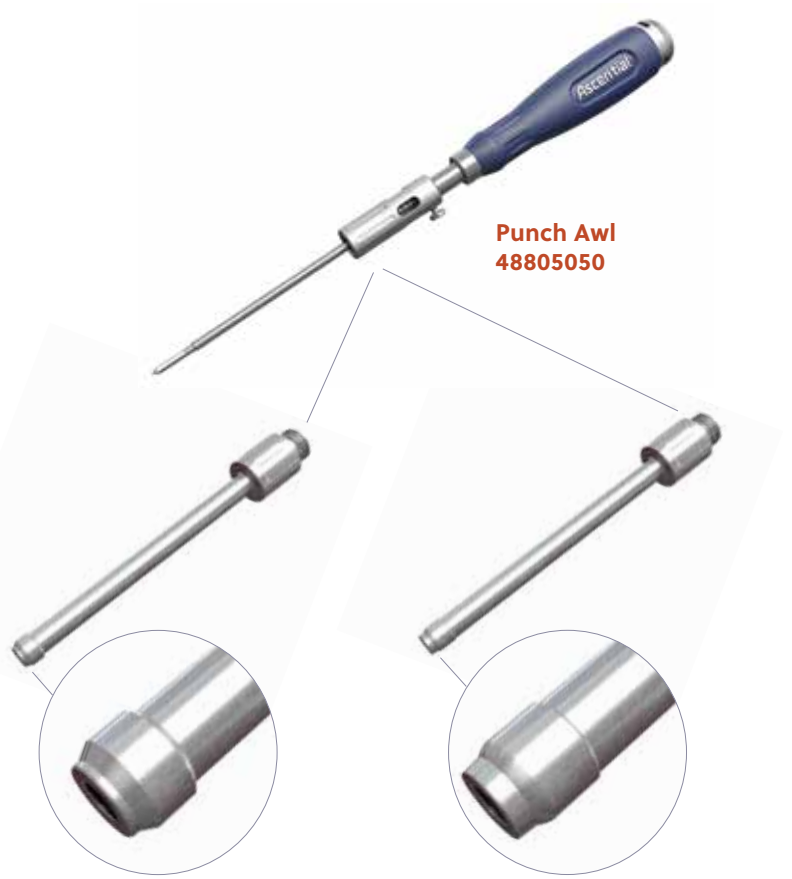
To initiate bone penetration with either assembly, depress the button to unlock the tip, and then apply downward pressure to penetrate the bone. Rotate the awl while applying upward force, to remove the awl from the site.

Caution: Do not apply cantilever loads while the Punch Awl is engaged in the bone.

Press the sleeve button again to return the awl sleeve to the locked position prior to engaging the awl into an additional screw hole.

Note: Using the Punch Awl is strongly recommended when self-drilling screws are used, as it helps to provide an optimal screw trajectory.

Following screw hole preparation, select the appropriate screw. The screw size indicates the actual amount of screw purchase in the bone below the bottom surface of the plate (i.e., a 14mm screw protrudes 14mm below the plate, while the screw head is contained within the screw hole).



Punch Awl
48805050

Punch Awl Sleeve, Fixed
48805050F

Punch Awl Sleeve, Variable
48805050V

Punch Awl in unlocked position.

Punch Awl in locked position.

Bone Screw Insertion

Screws may be placed using either the **Retaining Screwdriver** or the **Quick Turn Screwdriver**.

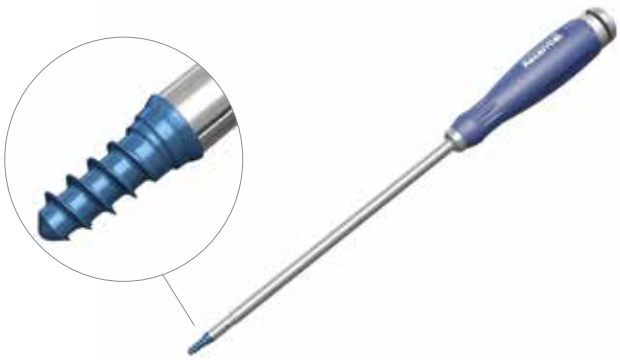
The Retaining Screwdriver features a square drive with a split tip to hold the screw head securely. To load the Retaining Screwdriver, open the TPU screw pouch and hold it in one hand. Using the other hand, depress the square tip of the screwdriver into the square recess of the screw head until the screw snaps onto the Retaining Screwdriver.

Drive the bone screws until they are fully seated in the plate. Inserting the screws sequentially at opposite corners of the plate, working toward the center of the plate, helps keep the plate flat against the bone. Release the screw after insertion by gently applying an upward force on the Retaining Screwdriver.

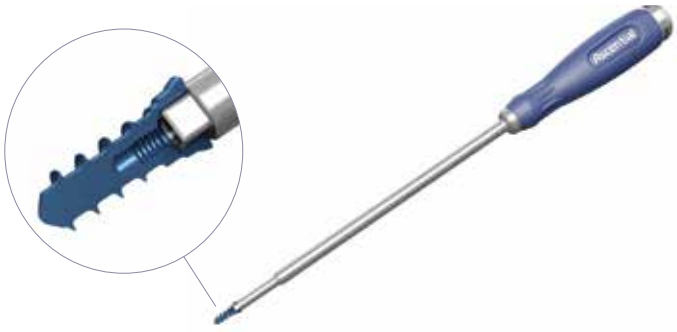
Screws may also be inserted using the Quick Turn Screwdriver. To load the screws, ensure the Quick Turn Screwdriver is fully seated in the square drive recess of the bone screws, and tighten the **Draw Rod** until resistance is felt. Draw Rod tightening is designed to require approximately five to seven turns. Do not over-tighten the Draw Rod.

After a bone screw is attached to the Quick Turn Screwdriver and the Draw Rod is appropriately engaged, drive the bone screws until they are fully seated in the plate. Inserting the screws sequentially at opposite corners of the plate, working toward the center of the plate, helps keep the plate flat against the bone.

To remove the Quick Turn Screwdriver, unthread the Draw Rod completely and gently apply an upward force on the screwdriver to remove it from the bone screw.

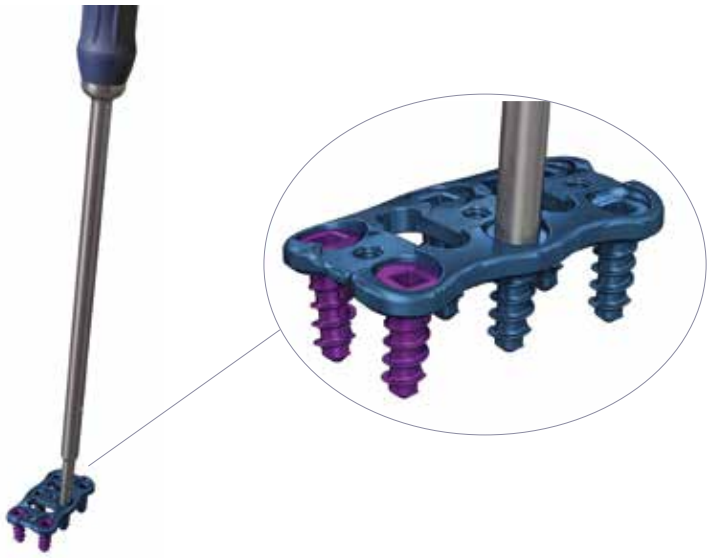


Retaining Screwdriver
48805100



Quick Turn Screwdriver
48805090

Draw Rod
48770905B



Locking the Screws

When all of the bone screws are fully inserted within the allowed range of angulation, Locking Screws can then be inserted to provide coverage over the bone screw heads.

To prepare the **Locking Screws** for attachment to the plate, open the TPU screw pouch and hold it in one hand. Using the other hand, slide the long unthreaded shaft of the Locking Screw into the hollow tip of the **Locking Screw Inserter**. Push the entire length of the Locking Screw's shaft into the Locking Screw Inserter until fully seated and then remove the Locking Screw from the TPU screw pouch.

Note: Confirm that both bone screw heads are positioned below the plane defining the top of the locking screw hole before attempting to insert and tighten the Locking Screw.

To attach the Locking Screw to the ACP 1 plate, align the tip of the Locking Screw with the appropriate screw hole and apply a gentle downward force while rotating the Locking Screw Inserter. The four protrusions at the tip of the Locking Screw Inserter will engage the holes in the head of the Locking Screw to affix the Locking Screw to the plate. Continue rotating the Locking Screw Inserter until the Locking Screw is firmly secured to the plate. Gently rock the inserter to separate the Locking Screw from its shaft.

After the Locking Screw Inserter has been removed from the surgical site. eject the inserted Locking Screw's shaft by holding the Locking Screw Inserter handle-side-up and depressing the button at the top of the instrument.

Step 1: Fully seat the Locking Screw's shaft in the Locking Screw Inserter.

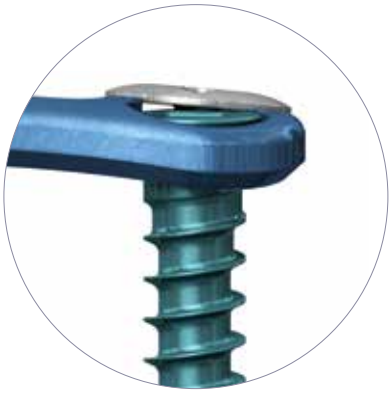
Step 2: Rotate the Locking Screw Inserter until the Locking Screw is firmly affixed to the plate.

Step 3: Gently rock the Locking Screw Inserter to separate the Locking Screw from its shaft.

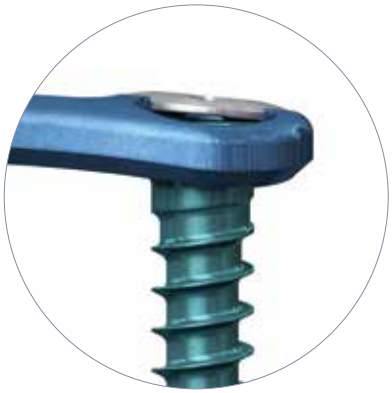
Step 4: Depress the Locking Screw Inserter's button to eject the Locking Screw's shaft.

Caution: When tightening the Locking Screw to the plate, do not overtighten as stripping can occur.

Note: If the bone screws prevent the Locking Screw from being fully seated, remove the Locking Screw and reposition the bone screws so that the bone screws are in the correct trajectory and the bone screw heads are flush or recessed relative to the plane defining the top of the Locking Screw hole.



Locking Screw Unseated



Locking Screw Seated

Bone Screw Removal

Before removing a bone screw, remove the associated Locking Screw from the plate. First, unthread the Locking Screw using the Locking Screw Inserter. Then, completely remove the Locking Screw from the surgical site with forceps.

Note: The Locking Screws must be removed before attempting to back out a bone screw from a properly implanted ACP 1 plate.

The Quick Turn Driver is used to remove implanted ACP 1 bone screws in an unlocked plate. This driver affixes to implanted screws via ACP 1 screws' internal threading. The Draw Rod or inner shaft threads into the screw head providing a rigid attachment to the screw and ensuring that the Quick Turn Driver sits flat on the screw.

To remove a bone screw, align the Quick Turn Driver with the screw trajectory and seat the square head of the driver into the square recess of the screw head. After ensuring the driver is fully seated in the screw head, insert the Draw Rod into the Quick Turn Driver. Maintaining alignment, thread the draw rod until it is finger tight (approximately 10-12 turns).

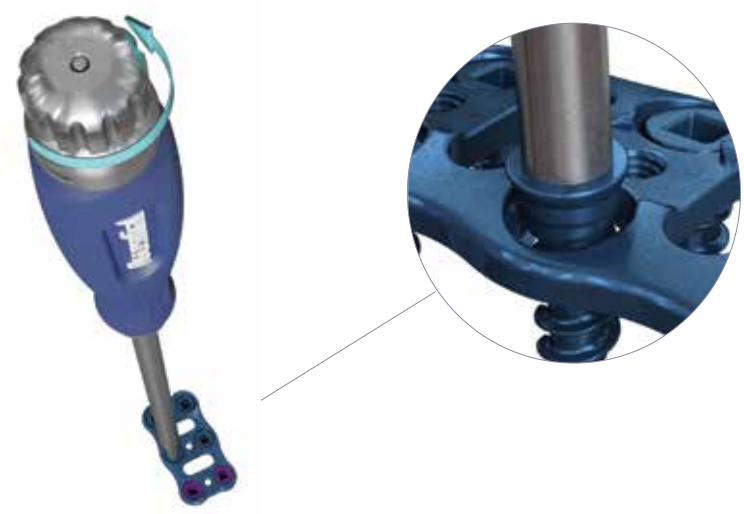
Note: The Draw Rod must be threaded completely before attempting to extract the screw. If you do not feel the Draw Rod tighten, remove the Quick Turn Driver and reposition it so that the square head of the Quick Turn Driver is fully seated in the screw head.

Rotate the Quick Turn Driver counterclockwise to back the bone screw out of the bone.

Note: If an implant is suspected damaged or defective, it must be replaced.

Step 1: Use the Locking Screw Inserter to unscrew the Locking Screw. Use forceps to remove the Locking Screw from the surgical site.

Step 2: Fully seat the Quick Turn Driver in the square recess of the bone screw head. Thread the Draw Rod into the Quick Turn Driver until it is finger tight (approximately 10-12 turns).



Step 3: Rotate the driver counterclockwise to remove the screw.

Implants

Reference #	Description
Fixed Angle Bone Screws, Self-Tapping	
48804210A	Ø 4.0 x 10mm
48804212A	Ø 4.0 x 12mm
48804214A	Ø 4.0 x 14mm
48804216A	Ø 4.0 x 16mm
48804218A	Ø 4.0 x 18mm
48804812A	Ø 4.5 x 12mm
48804814A	Ø 4.5 x 14mm
48804816A	Ø 4.5 x 16mm
48804818A	Ø 4.5 x 18mm
48804820A	Ø 4.5 x 20mm

Reference #	Description
Fixed Angle Bone Screws, Self-Drilling	
48804110A	Ø 4.0 x 10mm
48804112A	Ø 4.0 x 12mm
48804114A	Ø 4.0 x 14mm
48804116A	Ø 4.0 x 16mm
48804118A	Ø 4.0 x 18mm

Reference #	Description
Variable Angle Bone Screws, Self-Tapping	
48804410A	Ø 4.0 x 10mm
48804412A	Ø 4.0 x 12mm
48804414A	Ø 4.0 x 14mm
48804416A	Ø 4.0 x 16mm
48804418A	Ø 4.0 x 18mm
48804912A	Ø 4.5 x 12mm
48804914A	Ø 4.5 x 14mm
48804916A	Ø 4.5 x 16mm
48804918A	Ø 4.5 x 18mm
48804920A	Ø 4.5 x 20mm

Reference #	Description
Variable Angle Bone Screws, Self-Drilling	
48804310A	Ø 4.0 x 10mm
48804312A	Ø 4.0 x 12mm
48804314A	Ø 4.0 x 14mm
48804316A	Ø 4.0 x 16mm
48804318A	Ø 4.0 x 18mm

Reference #	Description
Locking Screw	
48805000A	Locking Screw

Reference #	Description
One-Level ACP 1 Anterior Cervical Plate	
48803110A	One-Level, 10mm
48803112A	One-Level, 12mm
48803114A	One-Level, 14mm
48803116A	One-Level, 16mm
48803118A	One-Level, 18mm
48803120A	One-Level, 20mm
48803122A	One-Level, 22mm

Reference #	Description
Two-Level ACP 1 Anterior Cervical Plate	
48803224A	Two-Level, 24mm
48803226A	Two-Level, 26mm
48803228A	Two-Level, 28mm
48803230A	Two-Level, 30mm
48803232A	Two-Level, 32mm
48803234A	Two-Level, 34mm
48803237A	Two-Level, 37mm
48803240A	Two-Level, 40mm
48803243A	Two-Level, 43mm
48803246A	Two-Level, 46mm

Reference #	Description
Three-Level ACP 1 Anterior Cervical Plate	
48803339A	Three-Level, 39mm
48803342A	Three-Level, 42mm
48803345A	Three-Level, 45mm
48803348A	Three-Level, 48mm
48803351A	Three-Level, 51mm
48803354A	Three-Level, 54mm
48803357A	Three-Level, 57mm
48803360A	Three-Level, 60mm
48803363A	Three-Level, 63mm
48803366A	Three-Level, 66mm
48803369A	Three-Level, 69mm

Reference #	Description
Four-Level ACP 1 Anterior Cervical Plate	
48803456A	Four-Level, 56mm
48803460A	Four-Level, 60mm
48803464A	Four-Level, 64mm
48803468A	Four-Level, 68mm
48803472A	Four-Level, 72mm
48803476A	Four-Level, 76mm
48803480A	Four-Level, 80mm
48803484A	Four-Level, 84mm
48803488A	Four-Level, 88mm
48803492A	Four-Level, 92mm
48803496A	Four-Level, 96mm

Instruments

Reference #	Description
48805020	Caliper
48513010	Universal Plate Holder
48770200	Plate Bender
48770410	Temporary Fixation Pin
48510400	Temporary Fixation Pin Inserter
48805110	Single Barrel Guide - Fixed
48805120	Single Barrel Guide - Variable
48510610	Drill, 10mm
48510612	Drill, 12mm
48510614	Drill, 14mm
48510616	Drill, 16mm
48805050	Punch Awl
48805050F	Punch Awl Sleeve, Fixed
48805050V	Punch Awl Sleeve, Variable
48770700	Tap

ACP 1 Anterior Cervical Plating System

Reference #	Description	
48805080	Quick Release Handle*1	
48805100	Retaining Screwdriver*2	
48805090	Quick Turn Screwdriver*3	
48770905B	Draw Rod	
48805005	Locking Screw Inserter	
48805200	System Container	

*1 Functionally equivalent to 48770600
*2 Functionally equivalent to 48770800
*3 Functionally equivalent to 48770820

IMPORTANT PRODUCT INFORMATION FOR ASCENTIAL ACP 1 ANTERIOR CERVICAL PLATING SYSTEM

DESCRIPTION

The Ascential ACP 1 anterior cervical plating system consists of bone plates that are available in a variety of sizes in order to help accommodate individual patient physiology and pathology and to help facilitate anterior stabilization of the cervical spine. The ACP 1 plates are intended to be used with the ACP 1 bone screws. The ACP 1 system is intended for unilateral fixation.

MATERIAL

The components of the ACP 1 system are manufactured out of Titanium alloy as defined in the ISO 5832-3 and ASTM F136 standards.

INDICATIONS

The ACP 1 Anterior Cervical Plating System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The ACP 1 system is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

CAUTION

Based on the fatigue testing results, the physician/ surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

WARNING

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

GENERAL CONDITIONS OF USE

Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure and limitations of the spinal device. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Consult the medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with spinal fixation surgery.

Do not substitute another manufacturer's device for any components of the ACP 1 system. Any such use will negate the responsibility of Ascential for the performance of the resulting mixed component implant.

Do not mix metals (i.e. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

CONTRAINDICATIONS

- Marked local inflammation.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Bony abnormalities preventing safe screw fixation.
- Open wounds.
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia are relative contraindications, since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Metal sensitivity, documented or suspected.
- Pregnancy.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Inadequate tissue coverage over the operative site.

Other medical or surgical conditions which would preclude the potential benefit of surgery, such as congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his/her decision. The above list is not exhaustive.

PRE-OPERATIVE PRECAUTIONS

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and surgeons should counsel patient to not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

INTRA-OPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.
- Discard all damaged or mishandled implants.
- Ascential implants must not be reshaped, unless otherwise indicated in the surgical technique instructions. When implants need to be bent, the bending must be carried out gradually using the appropriate instruments, provided by Stryker Spine. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating of the implant may result in implant failure.
- Never reuse an implant, even though it may appear undamaged.

Do not mix metals.

POST-OPERATIVE PRECAUTIONS

Physician instructions regarding full weight-bearing activities must be complied with until maturation of the fusion mass is confirmed. Failure to comply with physician instructions may result in failure of the implant, the fusion, or both.

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

For further information or complaints, please contact:

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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ACP1-ST-1_Rev-1
SC/GS 03/16

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