

Aviator®

Anterior Cervical Plating System

Surgical Technique

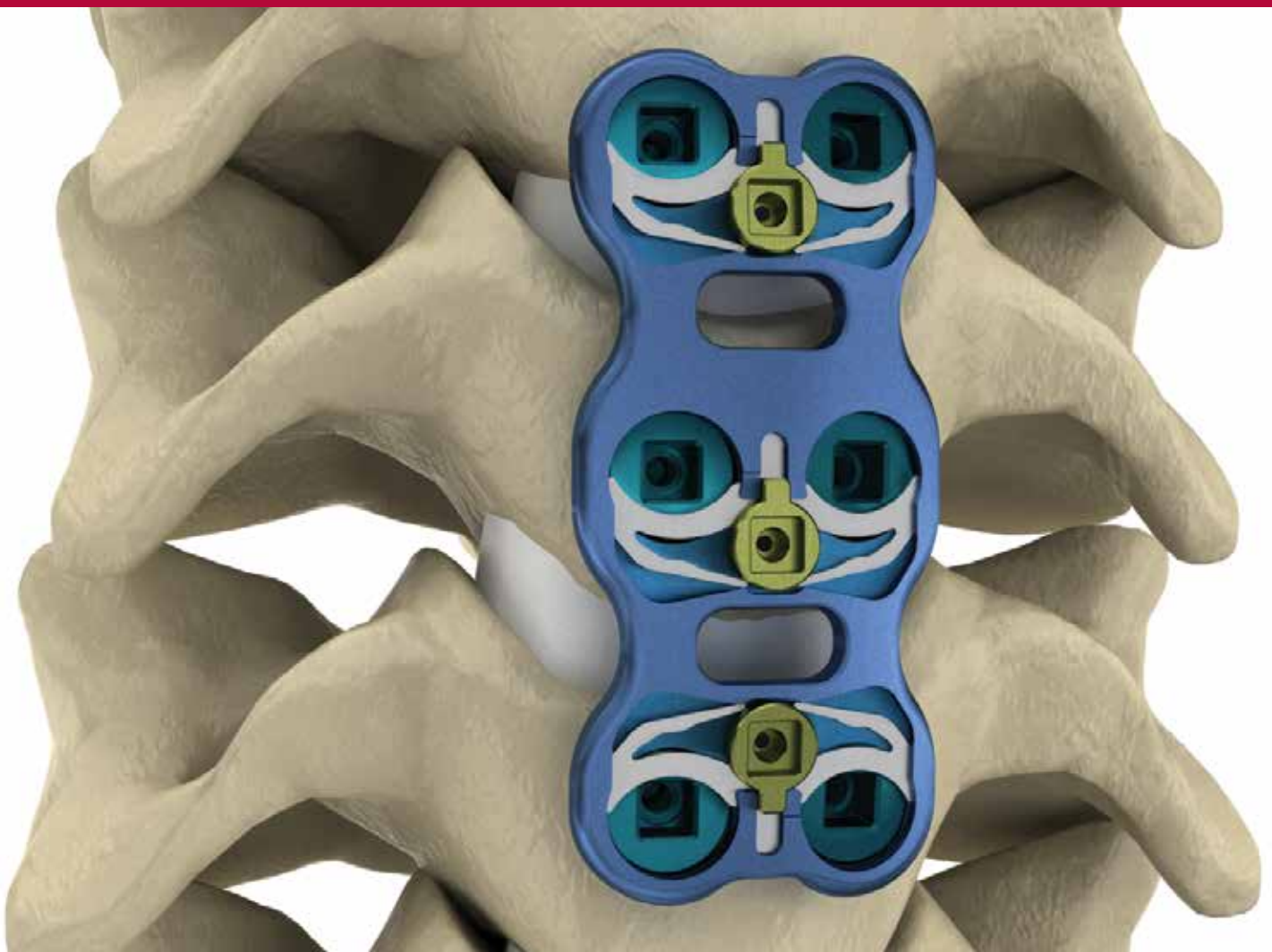


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System Overview

The Aviator anterior cervical plating system offers a unique double screw locking mechanism, a high degree of screw angulation and simplified instrumentation.

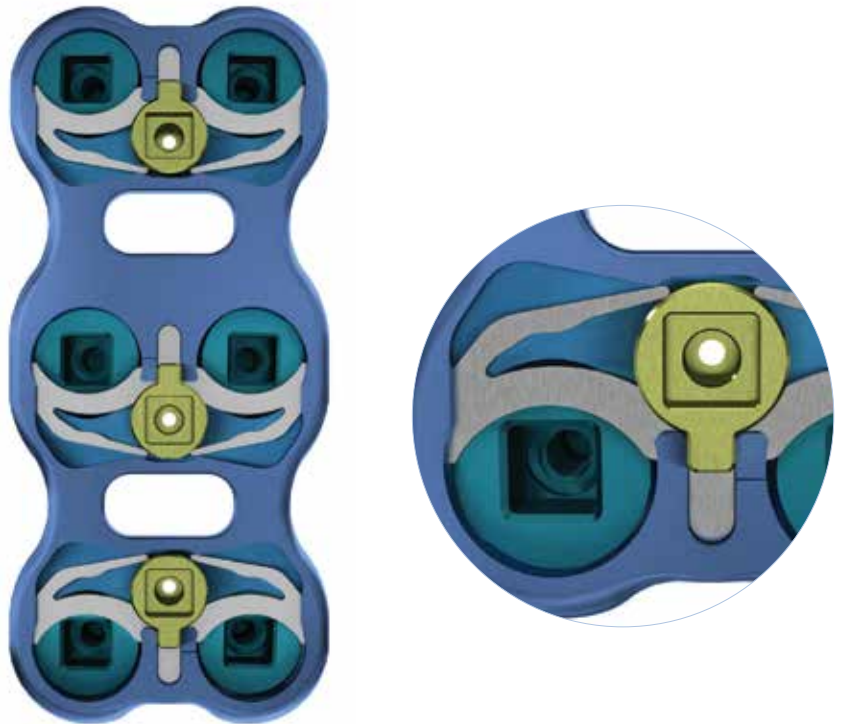
The primary screw locking mechanism is a spring-loaded bar, which is designed to automatically lock over the screw heads. Rotation of the blocker locks the spring bar in place and allows for additional visual and tactile feedback that the screws are locked.

The system 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 chance of stripping.

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

The Aviator plate is made of Titanium Alloy (Ti-6Al-4V) and is **2.5mm thick** and **17.4mm 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.



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Screw Types

The Aviator 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, which feature a cutting flute and a less aggressive screw tip, and self-drilling, which have been designed with a sharp tip for insertion without prior drilling.

Screw Sizes

Aviator screws are available in 4.0mm and 4.35mm 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



Fixed Angle Bone Screws

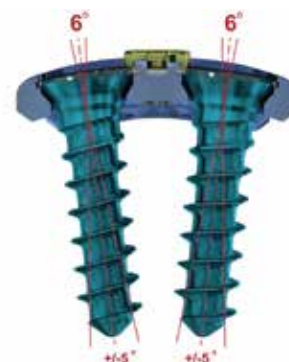
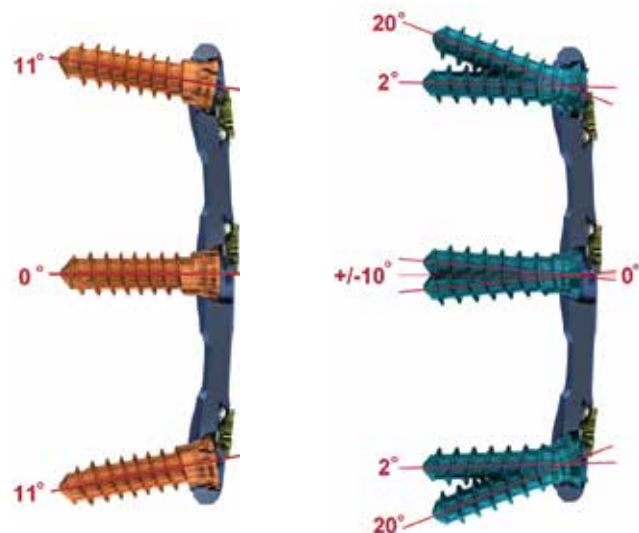


Self-tapping 4.0mm Self-drilling 4.0mm

Variable Angle Bone Screws



Self-tapping 4.0mm Self-drilling 4.0mm



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.

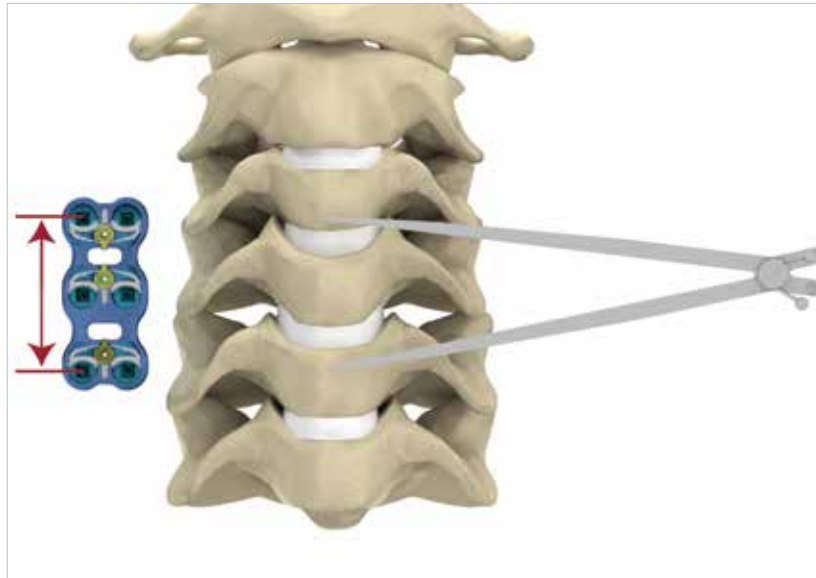
The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/bone graft insertion.

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



Implant Selection and Preparation

The **sizing of Aviator plates** is measured from the center of the cephalad hole to the center of the caudal hole. Using the **Caliper**, measure the distance between the center points of the appropriate vertebrae and select the corresponding plate. 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
48510100

Hold the Universal Plate Holder at the bend and attach to the narrow sides of the plate. Squeeze the Universal Plate Holder until it clicks one time to lock to the plate. Squeeze the Universal Plate Holder a second time to release the plate from the Universal Plate Holder.



Universal Plate Holder
48513010

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The Aviator plate has been designed with a slight sagittal and axial bend for matching of 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: Do not bend plates over the screw holes or the spring bar.

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.

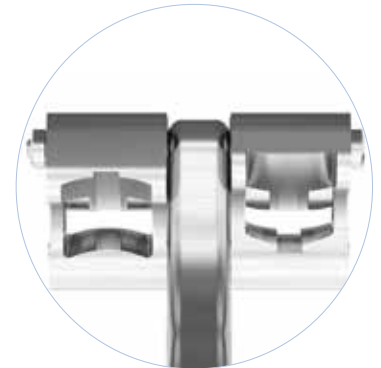
To remove the plate from the Plate Bender, hold the plate in one hand while releasing the handle with the other hand.

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.

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.*



Plate Bender
48770200



Temporary Fixation Pin Inserter
48510400



Temporary Fixation Pin
48770410

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

Screw Hole Preparation

Plate blockers should be in the unlocked position before attempting to prepare the screw hole.

Caution: Use of the Screw Hole Preparation Instruments including the Fixed or Variable Drill Guides, All-In-One Drill Guides or Punch Awl with Sleeves is required to place screws in the proper trajectory, help prevent damage to implants, difficulty locking the blocker, or locking mechanism malfunction.

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

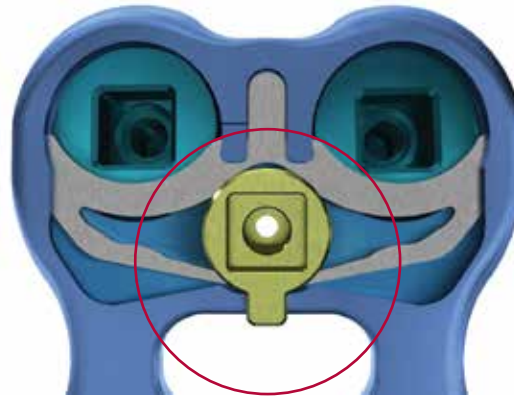
Drilling Technique

Aviator drill bits are available in two colors: silver and gold. Aesthetically, they are different but functionally they are identical. The gold color is available to better distinguish Aviator drill bits from Hybrid drill bits.

Note: Aviator drill bits are 10mm longer than the Reflex Hybrid drill bits and are not interchangeable. Using an Aviator drill bit in a Reflex Hybrid drill guide could lead to over-drilling by as much as 10mm. Prior to surgery check the drill bit length in each respective drill guide to ensure the correct length protrudes through the guide. Also check the part numbers: Reflex Hybrid part numbers start with "485," and Aviator part numbers start with "487."

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**.



Unlocked

Drill Bits
10mm 48770610
12mm 48770612
14mm 48770614
16mm 48770616



Drill Bits
10mm 48771610*1
12mm 48771612*2
14mm 48771614*3
16mm 48771616*4

Tap
48770700



Quick Release Handle
48770600

*1functional equivalent to 48770610 *2functional equivalent to 48770612
*3functional equivalent to 48770614 *4functional equivalent to 48770616

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Drill Guides

Single Barrel Drill Guides can be used to prepare the screw pathway. Single Barrel Drill Guides are available in Fixed and Variable designs and are described in detail in the following sections.

Fixed Single Barrel Drill Guide

Both the fixed and the variable angle drill guide instruments are designed to direct the screw trajectory within the effective working range of the system. This also helps ensure optimal functioning of the spring bar. The drill guides are used to guide the Drill Bit to prepare the screw pathway and must be engaged securely to the plate prior to screw hole preparation.

The **Fixed Single Barrel Drill Guide**, which can be identified by the fuchsia-colored handle, features a trigger which expands the tip of the guide into the screw hole to locate the fixed angle screw trajectory.

The fixed guides are 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.

To operate the Fixed Drill Guide, insert the tip completely into the screw hole. Depress the trigger fully to expand the tip of the guide so that it attaches firmly to the plate. After preparing the screw pathway, remove the guide prior to tapping or screw insertion. To disengage, fully release the trigger of the guide and gently remove from the plate.

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

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

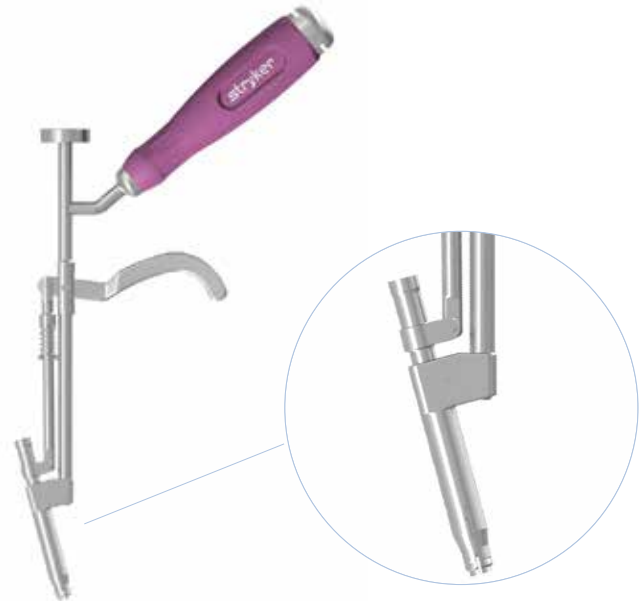
Note: Do not squeeze trigger until after drill guide is fully inserted into screw hole.

Note: The trigger must be fully depressed prior to and during drilling to ensure that the fixed angle trajectory and the desired depth are achieved.

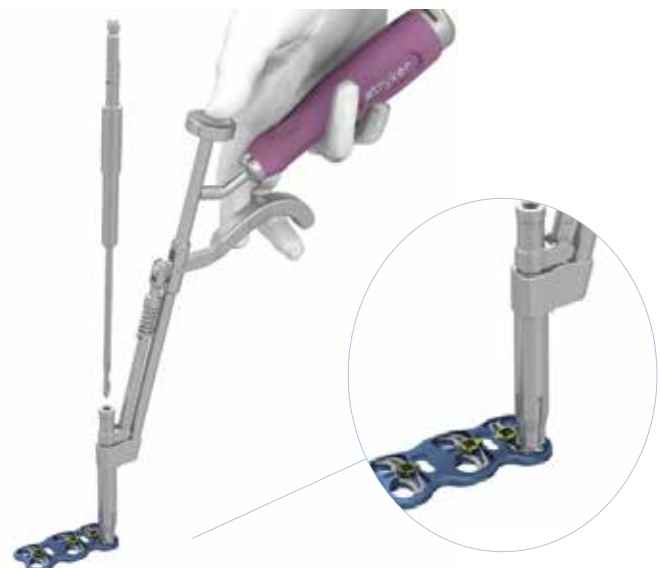
Note: The trigger must be released prior to removing the Fixed Drill Guide from the plate to avoid potential damage to the plate or spring bar.

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.

Caution: Do not cantilever the Guide during removal from plate as it can damage locking mechanism.



Single Barrel Drill Guide - Fixed
48770500



The Fixed Drill Guide features a trigger that expands the tip of the guide into the screw hole to locate the fixed angle screw trajectory.

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Variable Single Barrel Drill Guide

The **Variable Single Barrel Drill Guide**, which has a green handle, features a spherical shape which allows it 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.

The Variable Drill Guide provides a positive “snap” when inserted into the screw hole in the plate. 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. To disengage, rock the drill guide slightly while lifting the instrument from the plate. Forcing the drill guide straight into or out of the screw hole should be avoided.

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

Caution: Do not cantilever the Guide during removal from plate as it can damage locking mechanism.



**Single Barrel Drill Guide - Variable
48770505**



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

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All-In-One Drill Guides

All-In-One Drill Guides can be used to both prepare the screw pathway and guide screw insertion. All-In-One Drill Guides are available in Fixed and Variable designs as described in the following sections.

Note: A Drill Bushing must be added to all Aviator drill bits when using any of the All-In-One Drill Guides. Use a Drill Bushing to ensure the chosen drill fits securely in the All-In-One Drill Guide and measures accurate depth.

To attach a Drill Bushing to an Aviator drill, insert the drill bit through the bushing with the smaller diameter of the bushing facing the handle.



All-In-One Drill Guide Bushing
48770530



Fixed All-In-One Drill Guides

The Fixed All-In-One Drill Guides are single barrel guides that swivel to allow access to two screw holes at the same level without having to detach the instrument.

Two separate Fixed All-In-One Drill Guides are available, one for end holes (fixed at 11°) and one for center holes (fixed at 0°). The two Fixed All-In-One Drill Guides can be distinguished by the laser marked engraving on each instrument's barrel and handle or the number of posts on the tip of the guide. The end hole guide has two posts on its tip while the center hole guide has one.

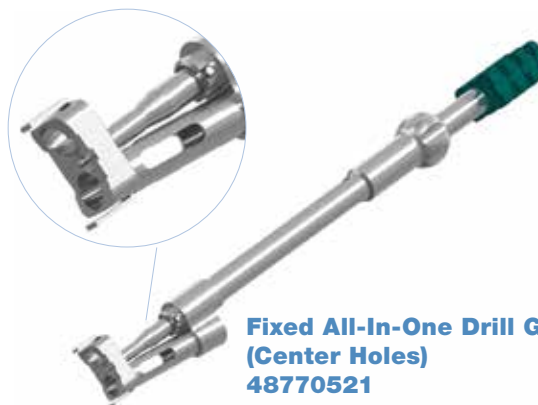
When using the Fixed All-In-One Drill Guides it is imperative that **the correct guide be used for end and center holes**. Use the correct guide to ensure all drills and taps are centered in the plate screw holes and screws are inserted at the appropriate angulation.

To facilitate alignment, an Aviator blocker shape has been added to the handle of each guide. When the blocker shape appropriately aligns with the position of an unlocked Aviator blocker, the guide is correctly positioned.

Note: Blockers must be unlocked prior to using All-In-One Drill Guides.



Fixed All-In-One Drill Guide
(End Holes)
48770520



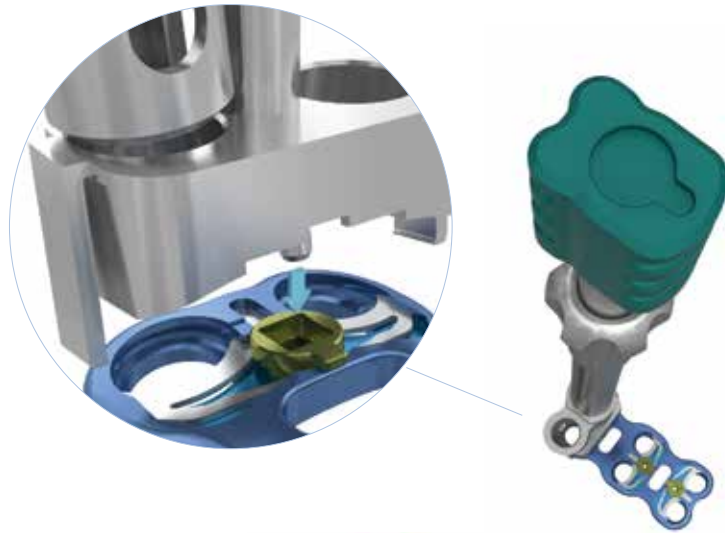
Fixed All-In-One Drill Guide
(Center Holes)
48770521



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Tip: To quickly attach any Fixed All-In-One Drill Guide, place the post on the tip of the guide into the Aviator blocker hole and gently rock back and forth applying downward pressure.

Once positioned, the instrument can be used as a guide for drilling (with Drill Bushing attached), tapping, or screw insertion.



To rotate the barrel of a Fixed All-In-One Drill Guide from one screw hole to the next, lift up on the spherical portion of the handle and twist the guide shaft in the direction of the desired screw hole. The guide handle should snap into place when the guide shaft is appropriately in position.

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



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Variable All-In-One Drill Guide

The **Variable All-In-One Drill Guide** is a double barrel design that allows for drilling, tapping, and screw insertion at both screw holes for a given level. The Variable All-In-One Drill Guide allows surgeons to achieve $+2^{\circ}$ to $+22^{\circ}$ of angulation at plate end holes and $\pm 10^{\circ}$ of angulation at plate center holes.

In contrast to the Fixed All-In-One Drill Guides, only one Variable All-In-One Drill Guide exists for both end and center screw holes in an Aviator plate.

Tip: The tip of the variable guide can be swiveled to adjust the position of the handle prior to inserting the guide into the wound or after the guide has been attached to an Aviator plate.

When using the Variable All-In-One Drill Guide, ensure the Aviator plate blocker is unlocked and place the post of the variable guide into the desired screw holes blocker. This action appropriately aligns the guide.

The Variable All-In-One Drill Guide can now be angled to the desired screw trajectory for plate end or center holes. Once positioned, drill guides can be used as a guide for drilling (with Drill Bushing attached), tapping, or screw insertion.

Note: The Variable All-In-One Drill Guide does not rigidly attach to the plate so the full range of angulation can be achieved at end and center screw holes.

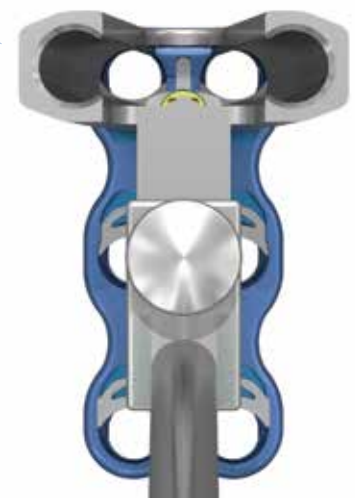
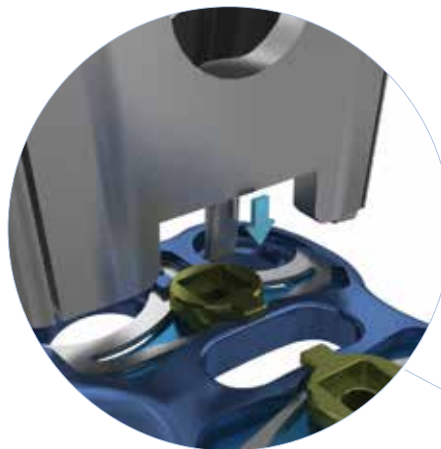
Note: Fixed screws must not be used with the Variable All-In-One Drill Guide. The use of fixed screws with the Variable All-In-One Drill Guide will cause damage to the screws, or the screw will not remain in the fixed position.

Note: Do not over-angulate or under-angulate any drill guide. Doing so can damage implants.

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



Variable All-In-One Drill Guide
48770525



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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. The Punch Awl must be used with either a Fixed or Variable Punch Awl Sleeve.

Both the Fixed and Variable Awl Sleeves are threaded onto the Punch Awl shaft and are designed to seat into the screw hole of the plate, and to provide the Punch Awl the correct range of angulation for the screw type selected.

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

The awl should be in the locked position so as to avoid prematurely engaging the awl tip into the bone. The button is positioned in the bottom key hole of the collar when in the locked position.

With the Variable Punch Awl Sleeve assembled to the Punch Awl shaft, the Punch Awl will snap 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 snaps into the plate hole.

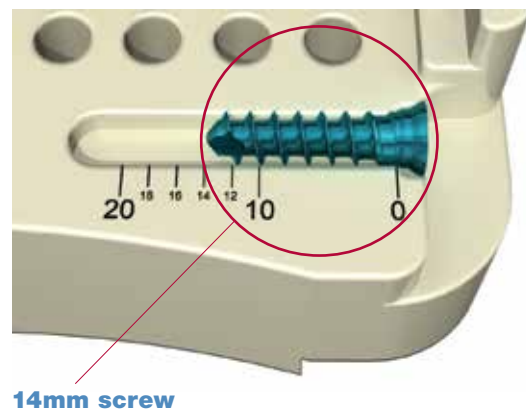
With either assembly, depress the button to unlock the tip, and then apply downward pressure to penetrate the bone. A slight rocking motion facilitates disassembly. Rotate the awl while applying upward force to remove.

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 and confirm its length using the **Screw Depth Gauge** in the screw tray. 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).



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. Using the screw tray to load the screws, depress the square screwdriver tip into the recessed square of the screw head.

Drive the bone screws until they are past the spring bar, which is designed to flex away from the screw as it progresses into the bone.

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.

Caution: Avoid reattaching the retaining driver to a screw after the screw is below the spring bar as this may result in damage to the locking mechanism. Instead, use the Solid Screwdriver Shaft if additional screw tightening is needed.

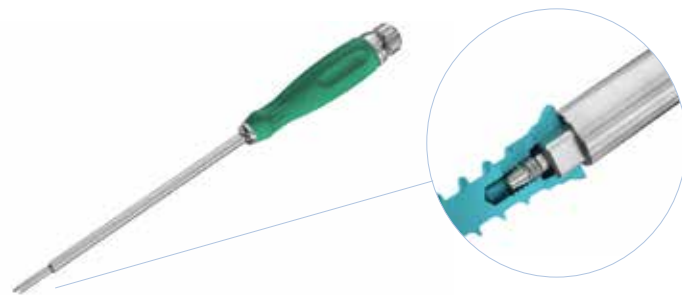
Screws are fully seated once the spring bar has returned to its original position and covers the screw head. Gently pull back on the screwdriver to release the screw after insertion.

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

To remove the Quick Turn Screwdriver, unthread the Draw Rod completely, and gently remove the screwdriver from the bone screw.



Retaining Screwdriver
48770800



Quick Turn Screwdriver
48770820



Draw Rod
48770905B

Note: The Draw Rod is used with both the Quick Turn Screwdriver and the Rescue Driver.



Locking the Screws

When screws are fully inserted within the allowed range of angulation, the spring bar can then expand over the screw head.

Once the spring bar is positioned over the screw heads, the blocker should be rotated to secure the spring bar over the screws. Using the **Solid Screwdriver Shaft**, rotate the blocker clockwise 180° until the blocker tab is facing between the screw heads. Tension will begin to be felt as the tab reaches the locked position. This must be done for each level of screws on the plate.

Note: As the blocker is rotated, the spring bar may advance further over the screw heads to its final position.

Locking is confirmed when the gold tab on the blocker is aligned with the groove located between the two screws.

Note: If excessive force is applied, the blocker can rotate past the groove. If this occurs, rotate the blocker counterclockwise so that it realigns with the groove.

Note: Be sure to confirm that both screws are below the spring bar before attempting to tighten a blocker.

Note: If the blocker cannot be rotated 180°, the bone screws have not been driven far enough below the spring bar and need to be driven further.



Solid Screwdriver Shaft
48770805

Tip: The Solid Screwdriver is optimized for rotating the blocker, but the Quick Turn Screwdriver can also be used.

Do not use the Retaining Screwdriver to rotate the blocker as it can strip the screw of the blocker and make rotation extremely difficult.



Blocker Unlocked

Blocker Locked

Blocker must be turned 180° to lock the plate



Screw must be below the spring bar before locking the blocker

Bone Screw Removal

The **Rescue Driver** allows for removal of bone screws in a previously locked plate. The square tip of the Rescue Driver allows for a rigid attachment to the screw, while the protruding foot deflects the spring bar away from the screw to facilitate removal.

The Draw Rod or inner shaft threads into the screw head providing a rigid attachment to the screw and ensuring that the Rescue Driver sits flat on the screw so that the foot can engage the spring bar.

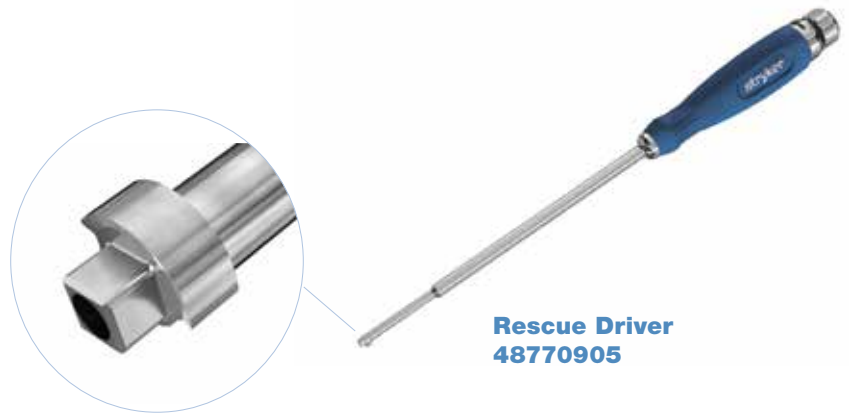
To begin removal of the screw, unlock the blocker using either the Solid Screwdriver Shaft or the square head of the Rescue Driver. Rotate the blocker 180° counterclockwise until you feel a positive stop. This will unlock the spring bar and allow it to move.

Note: The blockers must be unlocked before attempting to back out a screw which has been seated underneath a spring bar.

Insert the shaft of the Rescue Driver into the screw head with the protruding foot facing 180° away from the spring bar.

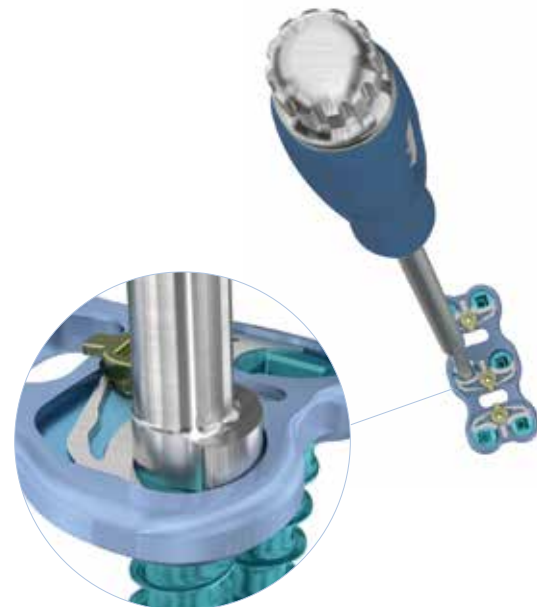
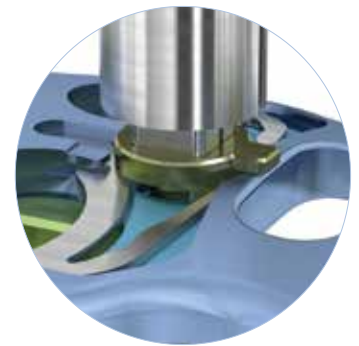


Tip: The groove along the shaft of the driver aligns with the rounded foot and can be used to assist in proper positioning of the Rescue Driver.



**Rescue Driver
48770905**

Step 1. Unlock the blocker.



Step 2. Fully seat the driver in the bone screw with the rounded foot 180° away from the spring bar.

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Align the Rescue Driver with the screw trajectory to seat the square head of the driver into the screw head. Ensure that the driver is fully seated into the screw head before inserting the draw rod. 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 Rescue Driver and reposition it so that the square head of the Rescue Driver is fully seated in the screw head.

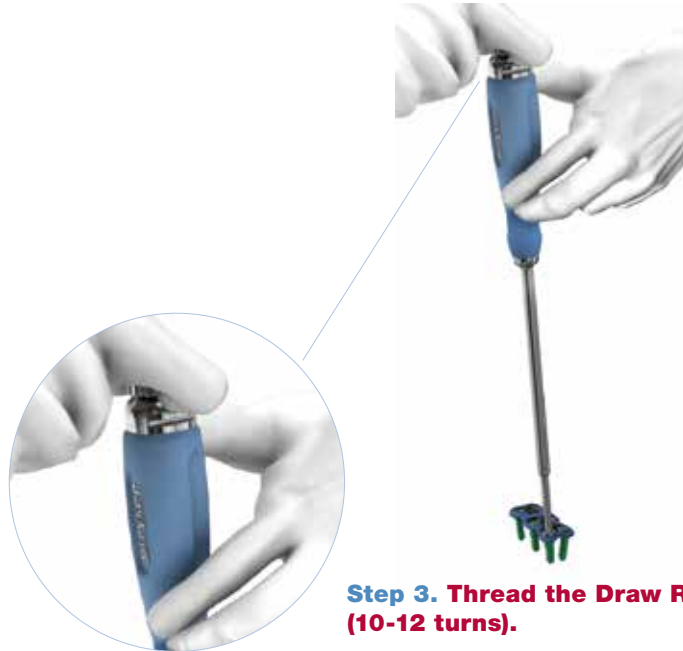
Caution: If the Rescue Driver is not properly seated while attempting to back out the screw, the spring bar may deform to allow the screw to pass.

Rotate the Rescue Driver counterclockwise so that the rounded foot deflects the spring bar away from the screw head, as the screw is simultaneously being backed out of the bone.

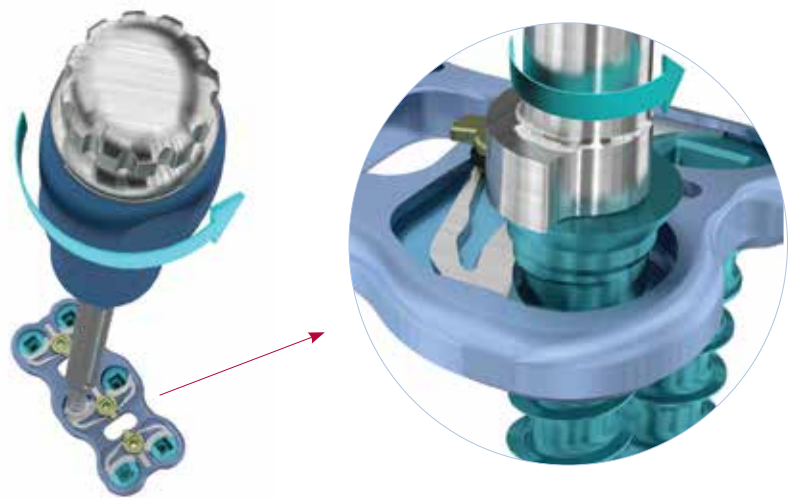
The locking mechanism of the Aviator system has been tested to ensure that a screw inserted into a previously used screw hole will be securely locked.* The spring bar can be locked and unlocked for the implantation of a rescue screw.

Caution: Repeated screw insertion through the plate should be avoided as its function may have been compromised. A maximum of two bone screw insertions is recommended for any level within a plate.

Note: If an implant is suspected damaged or defective, e.g. the spring bar is deformed, it must be replaced.



Step 3. Thread the Draw Rod (10-12 turns).



Step 4. Rotate the driver counterclockwise to push back the spring bar and remove the screw.

*Data on file at Stryker Spine (Ref. DHF0000015820).

Implants

Part # Description

Fixed Angle Bone Screws, Self-Tapping

48834010	Ø 4.0 x 10mm
48834012	Ø 4.0 x 12mm
48834014	Ø 4.0 x 14mm
48834016	Ø 4.0 x 16mm
48834018	Ø 4.0 x 18mm



48834512	Ø 4.35 x 12mm
48834514	Ø 4.35 x 14mm
48834516	Ø 4.35 x 16mm
48834518	Ø 4.35 x 18mm
48834520	Ø 4.35 x 20mm



Fixed Angle Bone Screws, Self-Drilling

48844010	Ø 4.0 x 10mm
48844012	Ø 4.0 x 12mm
48844014	Ø 4.0 x 14mm
48844016	Ø 4.0 x 16mm
48844018	Ø 4.0 x 18mm



Variable Angle Bone Screws, Self-Tapping

48814010	Ø 4.0 x 10mm
48814012	Ø 4.0 x 12mm
48814014	Ø 4.0 x 14mm
48814016	Ø 4.0 x 16mm
48814018	Ø 4.0 x 18mm



48814512	Ø 4.35 x 12mm
48814514	Ø 4.35 x 14mm
48814516	Ø 4.35 x 16mm
48814518	Ø 4.35 x 18mm
48814520	Ø 4.35 x 20mm



Variable Angle Bone Screws, Self-Drilling

48824010	Ø 4.0 x 10mm
48824012	Ø 4.0 x 12mm
48824014	Ø 4.0 x 14mm
48824016	Ø 4.0 x 16mm
48824018	Ø 4.0 x 18mm



Part # Description

One-Level Aviator Anterior Cervical Plate

48811112	One-Level, 12mm
48811114	One-Level, 14mm
48811116	One-Level, 16mm
48811118	One-Level, 18mm
48811120	One-Level, 20mm
48811122	One-Level, 22mm



Two-Level Aviator Anterior Cervical Plate

48811224	Two-Level, 24mm
48811226	Two-Level, 26mm
48811228	Two-Level, 28mm
48811230	Two-Level, 30mm
48811232	Two-Level, 32mm
48811234	Two-Level, 34mm
48811237	Two-Level, 37mm
48811240	Two-Level, 40mm
48811243	Two-Level, 43mm
48811246	Two-Level, 46mm



Three-Level Aviator Anterior Cervical Plate

48811339	Three-Level, 39mm
48811342	Three-Level, 42mm
48811345	Three-Level, 45mm
48811348	Three-Level, 48mm
48811351	Three-Level, 51mm
48811354	Three-Level, 54mm
48811357	Three-Level, 57mm
48811360	Three-Level, 60mm
48811363	Three-Level, 63mm
48811366	Three-Level, 66mm
48811369	Three-Level, 69mm



Four-Level Aviator Anterior Cervical Plate

48811456	Four-Level, 56mm
48811460	Four-Level, 60mm
48811464	Four-Level, 64mm
48811468	Four-Level, 68mm
48811472	Four-Level, 72mm
48811476	Four-Level, 76mm
48811480	Four-Level, 80mm
48811484	Four-Level, 84mm
48811488	Four-Level, 88mm
48811492	Four-Level, 92mm
48811496	Four-Level, 96mm



Instruments

Part #	Description
48510100	Caliper
48513010	Universal Plate Holder
48770200	Plate Bender
48770410	Temporary Fixation Pin
48510400	Temporary Fixation Pin Inserter
48770500	Single Barrel Guide - Fixed
48770505	Single Barrel Guide - Variable
48770530	All-In-One Guide Bushing
48770520	Fixed All-In-One Drill Guide (End Holes)
48770521	Fixed All-In-One Drill Guide (Center Holes)
48770525	Variable All-In-One Drill Guide
48770610	Drill, 10mm
48770612	Drill, 12mm
48770614	Drill, 14mm
48770616	Drill, 16mm



Instruments from other Stryker systems are not intended to be used with Aviator.

Aviator Anterior Cervical Plating System

Part #	Description
48771610* ¹	Drill, 10mm
48771612* ²	Drill, 12mm
48771614* ³	Drill, 14mm
48771616* ⁴	Drill, 16mm
48770655	Punch Awl
48770655F	Punch Awl Sleeve, Fixed
48770655V	Punch Awl Sleeve, Variable
48770700	Tap
48770600	Quick Release Handle
48770800	Retaining Screwdriver
48770820	Quick Turn Screwdriver
48770905B	Draw Rod
48770805	Solid Screwdriver Shaft
48770905	Rescue Driver
48771000	System Container



Instruments from other Stryker systems are not intended to be used with Aviator.

*¹functional equivalent to 48770610
 **²functional equivalent to 48770612
 *³functional equivalent to 48770614
 **⁴functional equivalent to 48770616

IMPORTANT PRODUCT INFORMATION FOR STRYKER SPINE AVIATOR ANTERIOR CERVICAL PLATING SYSTEM NON STERILE PRODUCT

DESCRIPTION

The Stryker Spine Aviator Anterior Cervical Plating (ACP) 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 Aviator plates are intended to be used with the Aviator bone screws. The Aviator ACP System is intended for unilateral fixation.

MATERIAL

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

INDICATIONS

The Aviator Anterior Cervical Plating 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

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

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.

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 component of the Aviator ACP System. Any such use will negate the responsibility of Stryker Spine 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.

Aviator Anterior Cervical Plating System

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.
- Stryker Spine 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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