

STERILE SPINE™

Anterior Cervical Plate System



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Introduction

Sterile Procedural Kits

The STERILE SPINE™ ACP System provides individually packaged sterile implants and single-use disposable ACD* instrument kits that are always ready to be used.



|| 1. ACP Drill - 10mm || 2. ACP Sizing Calipers || 3. ACP Single Barrel, VA, Drill Guide || 4. ACP Screw & Lock Driver -T15 ||

* ACD: Anterior Cervical Discectomy and Fusion

Note: All implants and instruments of the STERILE SPINE ACP system are sterile packaged, single-use, and disposable. Do not use if package is damaged. Do not reprocess/re-sterilize implants or instruments. Dispose of all unused items after surgery. For product information, including indications, contraindications, warnings, precautions and potential adverse effects, visit WishBone Medical's Instructions for Use page online: www.WishBoneMedical.com/IFU.

Implant Overview

Plate Dimensions

Lengths:

- » 1 level: 20 - 32mm (2mm increments)
- » 2 level: 34 - 52mm (3mm increments)

*Plate lengths measured "End to End"
Subtract 8mm for "Hole to Hole" length*

Thickness:

- » 1 & 2 level: 2.5mm

Other:

- » Screw angulation: up to 32° cephalad/caudal
- » Lock mechanism: Integrated, visual, one step
- » Pre-contoured, lordotic



- » Nominal convergence angle: 10°
- » Material - Ti6Al4V
- » **Sterile packaged, Qty. 1 per box**

Screw Dimensions

Diameters:

- » Ø4.0mm (standard)
- » Ø4.5mm (rescue)

Lengths:

- » 10, 12, 14, 16 & 18mm

Other:

- » Variable Angle (VA) & Fixed Angle (FA)
- » Self-Drilling and Self-Tapping
- » Material - Ti6Al4V



- » T15 Self-Retaining Interface
- » Fixed, Variable or Hybrid Constructs
- » **Sterile packaged, Qty. 2 per box**

Surgical Technique

Patient Positioning and Exposure

Position the patient on a radiolucent OR table in the supine position (**Figure 1**).

To obtain optimal visualization of the cervical spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP and lateral views.

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 osteophytes which would inhibit the anterior cervical plate from sitting flush against the vertebra.



Figure 1

Plate Selection

Using the ACP Sizing Calipers (Caliper) measure for the length of the plate required (**Figure 2**). Place the feet of the Caliper in the location of the desired screw locations. The length shown on the Caliper represents the approximate length of plate required.

The cephalad and caudal screws are started at the anterior end plate corners and angled away from the end plates to allow the use of the shortest possible plate and maximize the distance to the adjacent end plates (Figure 3). Lee et al.¹ suggest that this type of plating technique may reduce the incidence of Adjacent Level Ossification Development (ALOD)¹. (n=50/≤ 3 levels)

NOTE: The Caliper reading is a suggested plate length only. Each surgeon should consider their patient's indications and unique anatomy when determining a final plate length.

NOTE: Regardless of the plate size selected, the screws must be inserted with the correct amount of angulation.

NOTE: The combination of larger screw angles and short plate size options offer the surgeon the ability to minimize the potential encroachment of the plate to the adjacent level disc space



Figure 2

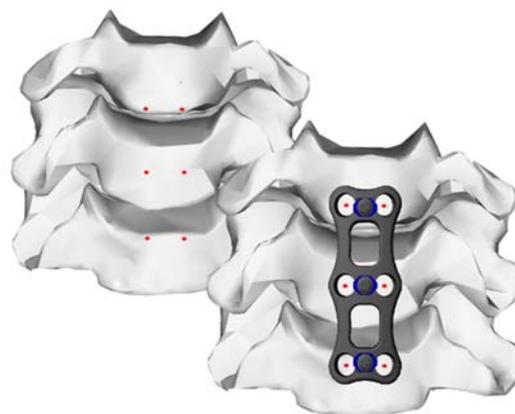


Figure 3

Plate lengths are labeled “End to End” (A). Subtract 8mm from labeled plate length to determine “Hole to Hole” (B) distance (**Figure 4**).

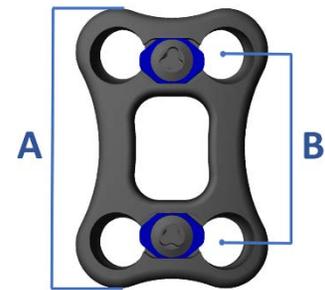


Figure 4

Plate Contouring (Optional)

The STERILE SPINE AC Plate has been designed with a slight longitudinal (lordotic) bend to match patient anatomy (**Figure 5**). The pre-existing lordosis in the plates is appropriate in most cases and plate contouring is typically not required.

If required, the plate may be contoured to increase or decrease the amount of lordotic curvature by using a Plate Bender.

Apply moderate pressure to the Plate Bender handles to increase or decrease the plate curvature. Bend plates incrementally to help match patient anatomy.

Avoid bending or contouring plate directly over top of Locking Mechanism (**Figure 6**).

Note: When bending the plates, avoid creating any abrupt changes, sharp bends, or reverse bends in curvature. Excessive bending of the plate or bending it back in the opposite direction will lead to weakened mechanical integrity and should be avoided.

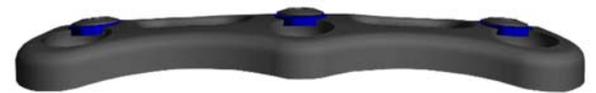


Figure 5



Figure 6

Plate Positioning

The undersurface of the STERILE SPINE AC Plate was designed to resist plate migration during positioning (**Figure 7**).

The plate can be introduced into the surgical wound with the use of forceps or by hand.

Position the plate so the cephalad and caudal screws can be started at the anterior end plate corners in order to use the shortest possible plate and maximize the distance to the adjacent disc spaces (**Figure 8**).

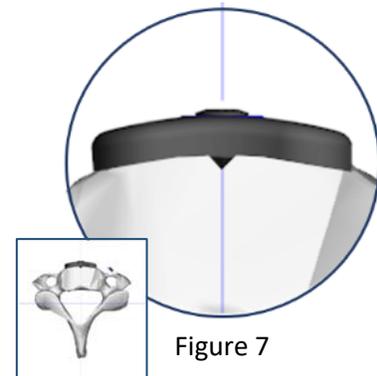


Figure 7

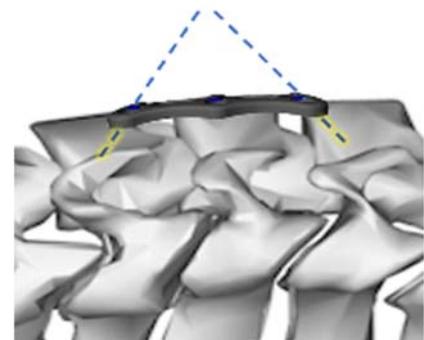


Figure 8

Screw Hole Preparation

The STERILE SPINE ACP Single Barrel, VA, Drill Guide (Drill Guide) directs the ACP Drill - 10mm (Drill) to prepare the pathway for the self-drilling screws. The Drill has a positive depth stop when utilized with the Drill Guide for accurate Drill depth and trajectory (**Figure 9**). Fluoroscopy should be used to confirm Drill trajectory and depth.

Insert the tip of the Drill Guide into the desired screw hole until the shoulder seats against the top surface of the plate.

The Drill Guide can be rotated along the sagittal plane to allow for variation in drilling angle.

Insert the Drill into the Drill Guide at the desired angle. The shoulder will stop the Drill against the Drill Guide at a 10mm depth.

NOTE: Once a screw hole is created, it is recommended to immediately place a screw in that position. This will ensure that the screw is centered within the screw hole.

The STERILE SPINE AC Plate design allows for a short-plate/hyper-angulated screw trajectory (**Figure 10**) up to 32° cephalad or caudal (at the ends of the plate).

The neutral or nominal convergent screw angle of the plate at every level is 10° medial (**Figure 11**).

Note: To avoid penetration of the adjacent endplate Fluoroscopy should be used to confirm screw depth and angular orientation, especially when using longer screws.

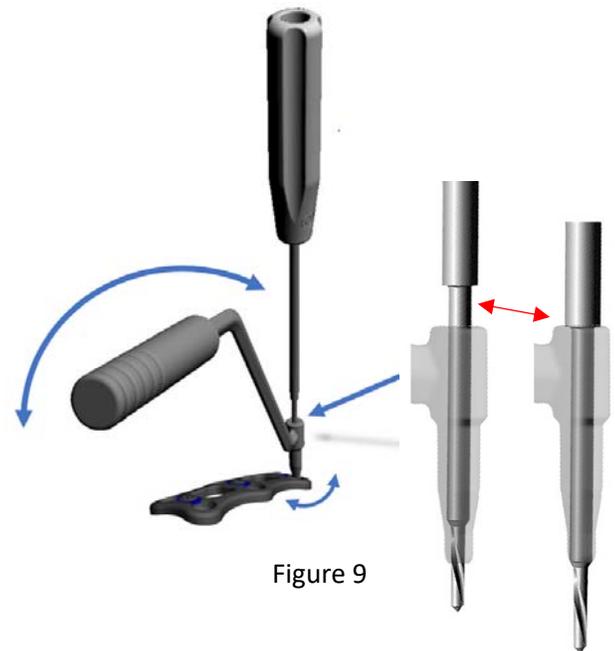


Figure 9



Figure 10

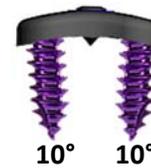


Figure 11

Screw Selection

The STERILE SPINE ACP system offers both fixed and variable self-drilling/self-tapping screws, allowing surgeons the versatility to create semi-constrained, rigid, or hybrid cervical plate constructs (**Figure 12**).

Fixed and variable screw (Hybrid) combinations allow the surgeon to customize biomechanical construct performance at each level based on unique patient needs.

Once locked, variable angle screws can pivot along the sagittal plane to allow for compression within intervertebral disc space and fixed angle screws cannot move, maintaining the intended screw trajectory.

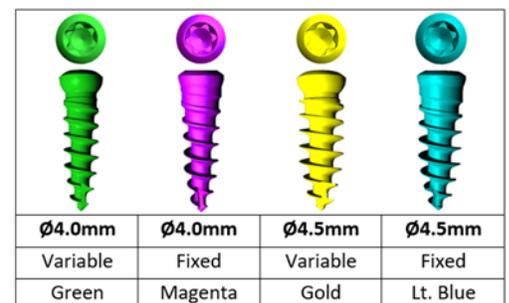


Figure 12

Labeled screw lengths are measured from the bottom of the screw head (underneath surface of plate) to the distal tip (Figure 13).

Self-drilling/self-tapping screws may eliminate the need for an awl or Drill to penetrate the cortex of the vertebral body.

Ø4.0mm screws are used as the primary screw diameter in most cases. Ø4.5mm screws may be used as an emergency screw in cases where the Ø4.0mm screw has stripped the bone and a larger screw thread is required, or in revision cases.

NOTE: Screw lengths can be approximated from pre-operative imaging studies when available.

NOTE: Ø4.5mm diameter screws should only be used when Ø4.0mm diameter screws do not provide enough purchase to the bone.

NOTE: It is not recommended to implant fixed and variable angle screws on the same vertebral level.

WARNING: The proper size screw should be chosen to avoid the tip of the screw protruding on the posterior side of the vertebral body.

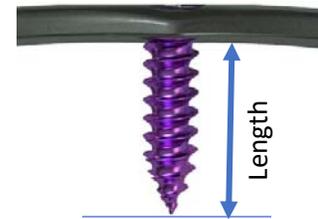


Figure 13

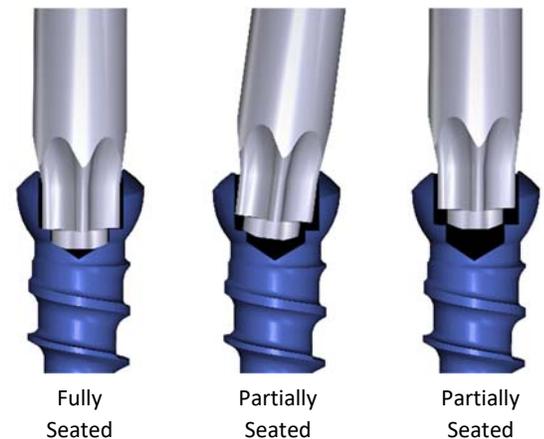


Figure 14

Screw Insertion

Load the appropriate length screw onto the ACP Screw & Lock Driver - T15 (Driver) by pressing the tip of the Driver firmly into the head of the screw until it is fully seated (Figure 14). The Driver is designed to provide a secure, self-retaining fit with the screw during implantation.

Applying moderate to light pressure, provisionally advance the screw by rotating the Driver clockwise until the screw head is loosely seated in the plate. The unlocked locking mechanism will translate contralaterally as the screw is inserted into the bone (Figure 15).

The first screw should be one of the most cephalad, the second screw should be placed diagonally from the first. The rest should be implanted in the order illustrated or symmetrically so that the plate is evenly and firmly applied to the surface of the bone.

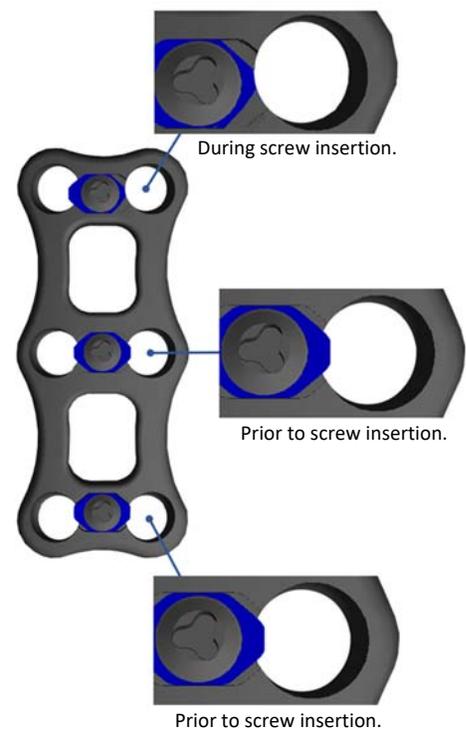


Figure 15

WARNING: Make sure the dual head tip design of the Driver is fully seated inside the screw head before tightening. Failure to fully seat the dual head tip before rotating the driver to advance the screw may result in stripping.

WARNING: Final screw tightening should be done slowly and care should be taken not to over-tighten screws. Use visual cues and tactile feedback to determine when the screw is fully seated.

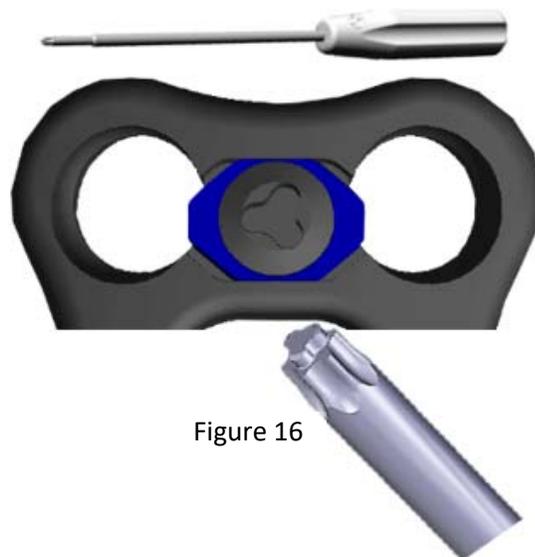


Figure 16

Locking the Screws

The STERILE SPINE ACP integrated tri-lobe locking mechanism provides visual and tactile confirmation of screw blockage. The locking mechanism is preinstalled and positioned on the plate to allow insertion of the screws.

Once all screws have been inserted, use the Driver to "finger tighten" (clockwise), locking screws located on the midline of the plate at every level (**Figure 16**). Tightening the locking screw will automatically align the locking tab to block both screws (**Figure 17**).

Visually confirm final locking tab position for occlusion of screw holes at each level.

NOTE: If the locking tab does not cover both screw heads, check to make sure that the screws are fully seated.

Warning: Tighten the locking screw with a clockwise motion using minimal force. Applying excessive torque or turning the locking screw counter-clockwise will damage the locking mechanism.

Warning: Make sure the dual head tip design of the Driver is fully seated inside the head of the locking screw before tightening. Failure to fully seat the dual head tip before rotating the driver to tighten the locking screw may result in stripping or damage the locking mechanism.



Figure 17

Closure

Wound closure is performed in the customary manner.

Implant Removal

The Driver can be used to both disengage the lock and explant the screws.

For screw removal, rotate the locking screw in the center of each pair of screw holes counterclockwise. There is no need to remove locking screw completely.

Using the same driver, loosen and extract all the screws and then remove the plate. The screw should translate the locking tab to the opposite side as it is being removed. If this does not occur, “nudge” the locking tab over manually to allow screw removal.

References

1. Lee DH, Lee JS, Yi JS, Cho W, Zebala LP, Riew KD. Anterior cervical plating technique to prevent adjacent-level ossification development. Spine J. 2013 Jul;13(7):823-9.

The aforementioned paper did not utilize the STERILE SPINE ACP System and findings are not necessarily indicative of results with the STERILE SPINE Anterior Cervical Plate System.

Manufactured For:



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