ANTERIOR CERVICAL PLATE SYSTEM

SURGICAL TECHNIQUE







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WISHBONE MEDICAL ANTERIOR CERVICAL PLATE SYSTEM

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Single-Use. Sterile Packed.

SPINE

SPINE

The WishBone Medical STERILE SPINE[™] ACP System provides individually packaged sterile implants and single-use Anterior Cervical Discectomy and Fusion (ACDF) instrument kits.

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SYSTEM COMPONENTS

1 ACP Drill, 10mm

2 ACP Sizing Calipers

3 ACP Single Barrel, VA, Drill Guide

4 ACP Screw & Lock Driver - T15

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EVERYTHING YOU NEED, BRAND NEW EVERY TIME.

Single-use, sterile packed kits eliminate set processing and help avoid delays or cancellations attributed to missing components.

Readily available for immediate use, individual kits deliver pristine components, new for each procedure.

IMPLANT OVERVIEW

PLATE FEATURES & SPECIFICATIONS

» Screw Angulation: Up to 32° cephalad/caudal

» Lock Mechanism: Integrated, visual, one step

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.

» Sterile packaged, Qty. 1 per box

» Nominal Convergence Angle: 10°

» Pre-contoured, lordotic

» Material: Ti6Al4V



THICKNESS

1 & 2 Level: 2.5mm

Screw Dimensions

DIAMETERS

LENGTHS

» Ø4.0mm (standard) » Ø4.5mm (rescue) **10, 12, 14, 16, 18**mm

SCREW FEATURES & SPECIFICATIONS

- » Variable Angle (VA) and Fixed Angle (FA)
- » Self-Drilling and Self-Tapping
- » Material: Ti6Al4V
- » T-15 Self-Retaining Interface
- » Fixed, Variable or Hybrid Constructs
- » Sterile packaged, Qty. 2 per box



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SURGICAL TECHNIQUE

Patient Positioning and Exposure

Position the patient on a radiolucent OR table in the supine position (fig 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.

1 Plate Selection

Using the ACP Sizing Calipers (Caliper) measure for the length of the plate required (fig 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 (fig 3). Lee et al.¹ suggests that this type of plating technique may reduce the incidence of Adjacent Level Ossification Development (ALOD)¹ (n=50/ \leq 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.







fig. 3



1 Plate Selection (cont.)

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



fig. 4

2 Plate Contouring (Optional)

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

If needed, 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 the top of the Locking Mechanism (fig 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.



fig. 5





O Plate Positioning

The undersurface of the STERILE SPINE AC Plate was designed to resist plate migration during positioning (fig 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 (Fig 8).

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4 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 (fig 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 (fig 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 (fig 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.







fig. 10

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5 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 (fig 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.

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

Ø4.0mm	Ø4.0mm	Ø4.5mm	Ø4.5mm
Variable	Fixed	Variable	Fixed
Green	Magenta	Gold	Lt. Blue





STERILE SPINE

6 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 (fig 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 (fig 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.

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.







Partially Seated







D 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 (fig 16). Tightening the locking screw will automatically align the locking tab to block both screws (fig 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 dualhead tip before rotating the driver to tighten the locking screw may result in stripping or damage the locking mechanism.

8 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.

ORDER INFORMATION



STERILE SPINE ACP Instrument Kit (# KIT-ACP751)

KIT DESCRIPTION	QTY
ACP Drill, 10mm	1
ACP Sizing Calipers	1
ACP Single Barrel, VA, Drill Guide	1
ACP Screw & Lock Driver - T15	1

1 Level: Anterior Cervical Plates

(Individually Packed)

ITEM DESCRIPTION	ITEM #
STERILE SPINE AC Plate, 1 Level, 20mm	ACP75-1020
STERILE SPINE AC Plate, 1 Level, 22mm	ACP75-1022
STERILE SPINE AC Plate, 1 Level, 24mm	ACP75-1024
STERILE SPINE AC Plate, 1 Level, 26mm	ACP75-1026
STERILE SPINE AC Plate, 1 Level, 28mm	ACP75-1028
STERILE SPINE AC Plate, 1 Level, 30mm	ACP75-1030
STERILE SPINE AC Plate, 1 Level, 32mm	ACP75-1032

2 Level: Anterior Cervical Plates

(Individually Packed)

ITEM DESCRIPTION	ITEM #
STERILE SPINE AC Plate, 2 Level, 34mm	ACP75-2034
STERILE SPINE AC Plate, 2 Level, 37mm	ACP75-2037
STERILE SPINE AC Plate, 2 Level, 40mm	ACP75-2040
STERILE SPINE AC Plate, 2 Level, 43mm	ACP75-2043
STERILE SPINE AC Plate, 2 Level, 46mm	ACP75-2046
STERILE SPINE AC Plate, 2 Level, 49mm	ACP75-2049
STERILE SPINE AC Plate, 2 Level, 52mm	ACP75-2052

4.0mm Variable Angle Screws, Self-Drilling

ITEM DESCRIPTION	ITEM #
STERILE SPINE Screws, VA/SD, Ø4.0x10mm (Qty. 2)	ACP75-5140-010
STERILE SPINE Screws, VA/SD, Ø4.0x12mm (Qty. 2)	ACP75-5140-012
STERILE SPINE Screws, VA/SD, Ø4.0x14mm (Qty. 2)	ACP75-5140-014
STERILE SPINE Screws, VA/SD, Ø4.0x16mm (Qty. 2)	ACP75-5140-016
STERILE SPINE Screws, VA/SD, Ø4.0x18mm (Qty. 2)	ACP75-5140-018

4.0mm Fixed Angle Screws, Self-Drilling

ITEM DESCRIPTION	ITEM #
STERILE SPINE Screws, FA/SD, Ø4.0x10mm (Qty. 2)	ACP75-6140-010
STERILE SPINE Screws, FA/SD, Ø4.0x12mm (Qty. 2)	ACP75-6140-012
STERILE SPINE Screws, FA/SD, Ø4.0x14mm (Qty. 2)	ACP75-6140-014
STERILE SPINE Screws, FA/SD, Ø4.0x16mm (Qty. 2)	ACP75-6140-016
STERILE SPINE Screws, FA/SD, Ø4.0x18mm (Qty. 2)	ACP75-6140-018

4.5mm Variable Angle Screws, Self-Drilling

ITEM DESCRIPTION	ITEM #
STERILE SPINE Screws, VA/SD, Ø4.5x12mm (Qty. 2)	ACP75-5145-012
STERILE SPINE Screws, VA/SD, Ø4.5x14mm (Qty. 2)	ACP75-5145-014
STERILE SPINE Screws, VA/SD, Ø4.5x16mm (Qty. 2)	ACP75-5145-016
STERILE SPINE Screws, VA/SD, Ø4.5x18mm (Qty. 2)	ACP75-5145-018

4.5mm Fixed Angle Screws, Self-Drilling

ITEM DESCRIPTION	ITEM #
STERILE SPINE Screws, FA/SD, Ø4.5x12mm (Qty. 2)	ACP75-6145-012
STERILE SPINE Screws, FA/SD, Ø4.5x14mm (Qty. 2)	ACP75-6145-014
STERILE SPINE Screws, FA/SD, Ø4.5x16mm (Qty. 2)	ACP75-6145-016
STERILE SPINE Screws, FA/SD, Ø4.5x18mm (Qty. 2)	ACP75-6145-018

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REFERENCES

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.

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