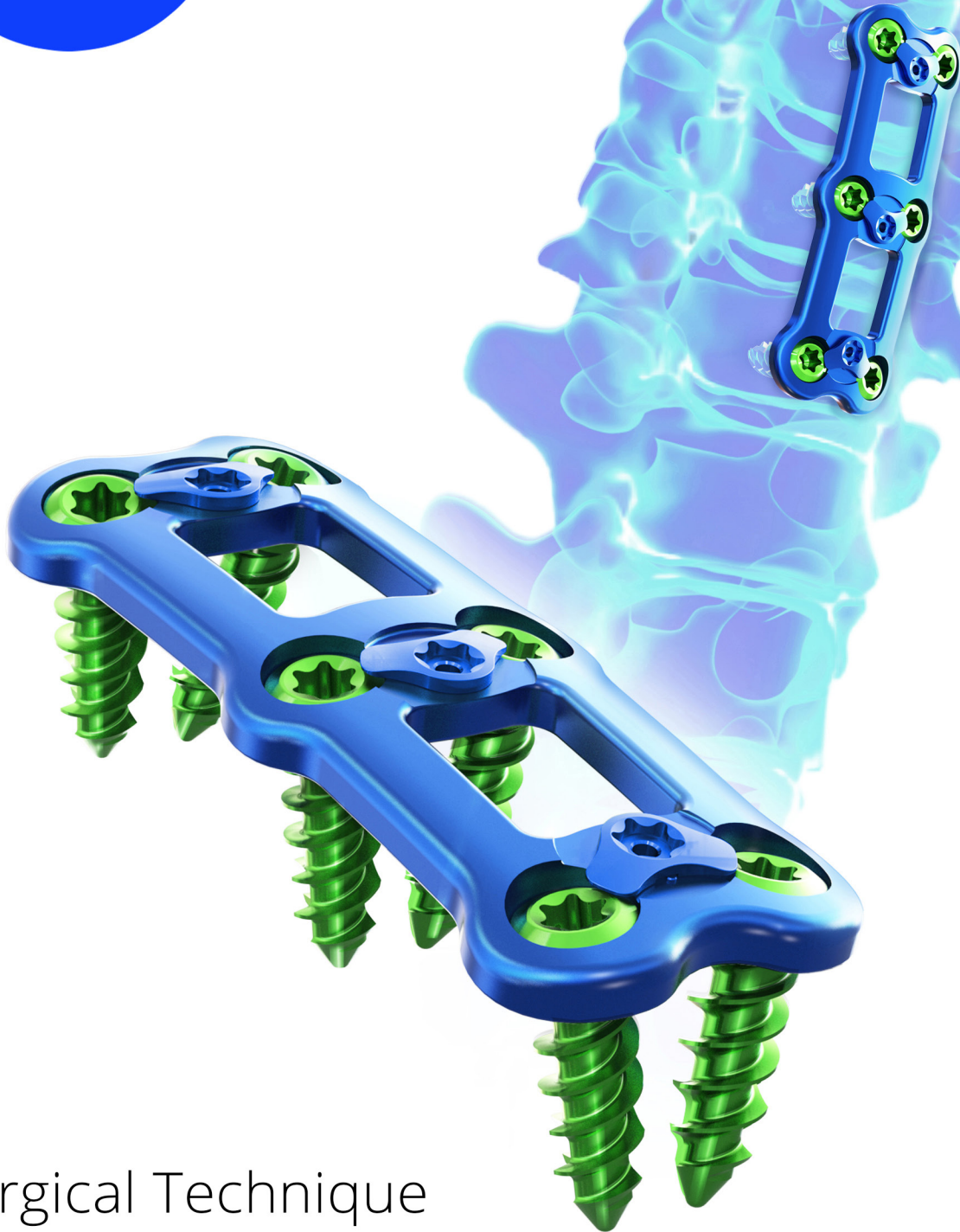


# **ACP**



Surgical Technique

SXT-S-003 Rev A

Anterior Cervical Plating System

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## INTRODUCTION

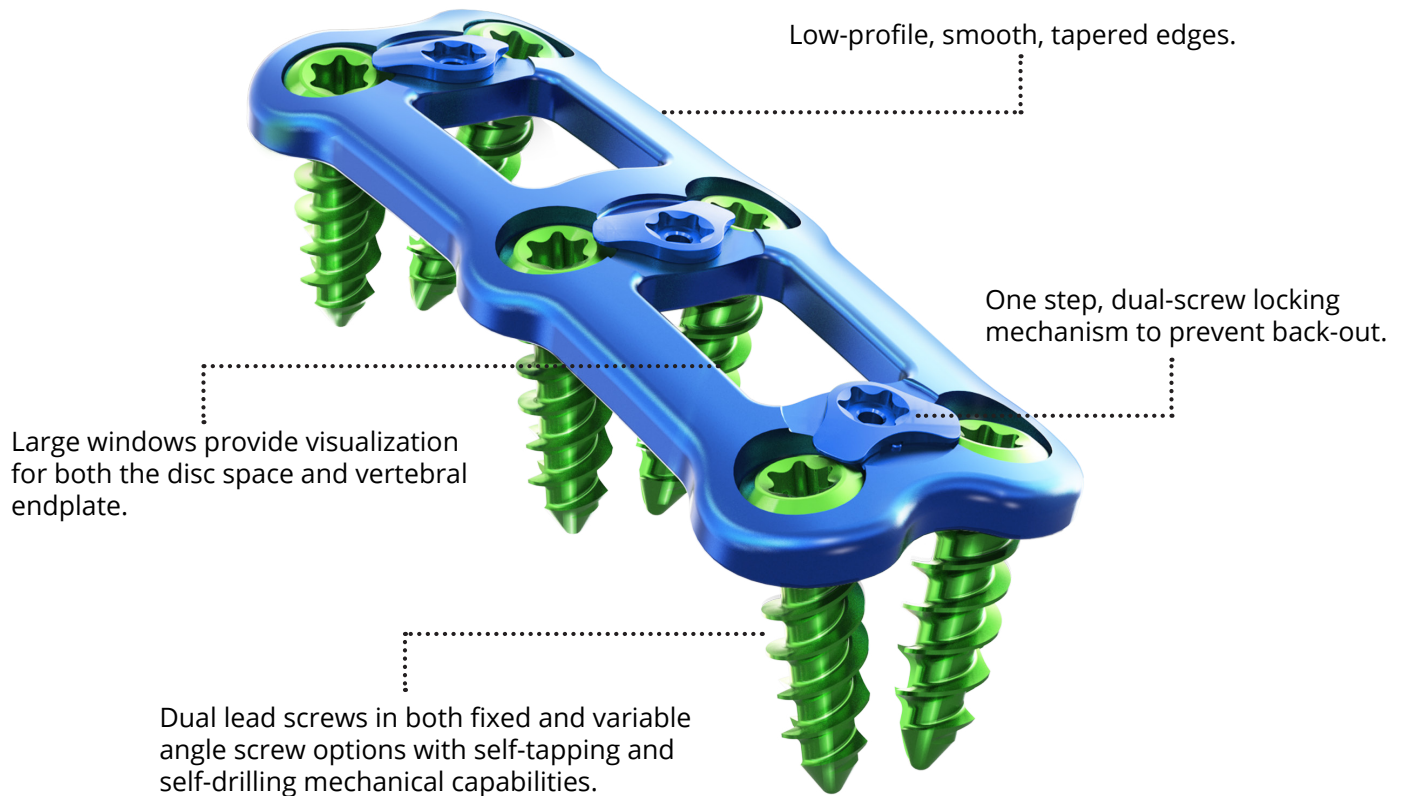
The FUSE ACP Anterior Cervical Plating System is designed for anterior cervical intervertebral body plate and screw fixation from C2 to T1 using an anterior approach.

The system consists of a wide range of anterior cervical plates for one to five level fusions, fixed/variable angle bone screw options and specialized instrumentation to suit individual pathology and anatomic conditions in the skeletally mature patient. System advantages include a low-profile plate height, smooth/tapered edges, large visualization windows, and a pre-assembled one-step, dual screw locking mechanism designed to reduce the potential for screw back-out and micromotion. FuseACP implants are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and must not be used with components from any other system or manufacturer.

## INDICATION

The FUSE ACP Anterior Cervical Plating System is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

- 1) Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- 2) Spondylolisthesis
- 3) Trauma (including fractures)
- 4) Spinal Stenosis
- 5) Tumors
- 6) Deformity (defined as kyphosis, lordosis, or scoliosis)
- 7) Pseudarthrosis
- 8) Failed previous fusions



## Plate Dimensions

### Lengths

1 Level: 08 - 26mm  
 2 Level: 22 - 46mm  
 3 Level: 36 - 69mm  
 4 Level: 46 - 78mm  
 5 Level: 71 - 91mm

### Width

Screw Holes: 16.5mm  
 Neck: 14mm

### Radius Curvature

Sagittal Plane  
 1 Level: 120mm  
 2-5 Levels: 200mm  
 Axial Plane: 25mm

### Thickness

Height: 2.0mm

## Screw Dimensions

### Diameters

4.0mm  
 4.35mm

### Lengths

10 - 22mm (2mm increments)

# OPERATIVE TECHNIQUE

## STEP 1: Site Preparation

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis. A standard incision is used to access the cervical spine and the longis colli muscles are elevated with medial/lateral retractor blades. Cranial/caudal retractor blades may also be used.

## STEP 2: Plate Size Selection

The FuseACP Anterior Cervical Plate portfolio offers solutions for 1 to 5 level fusions. Hole-to-hole measurements are taken from the center hole of the cephalad level to the center hole of the caudad level (8 to 91mm range).

Using the plate holder, position the appropriate plate on the vertebral column to confirm its suitability (Figure 1). When the plate is properly sized and positioned, the superior screw holes should align with the inferior aspect of the superior vertebral body and the inferior screw holes should align with the superior of the inferior vertebral body.

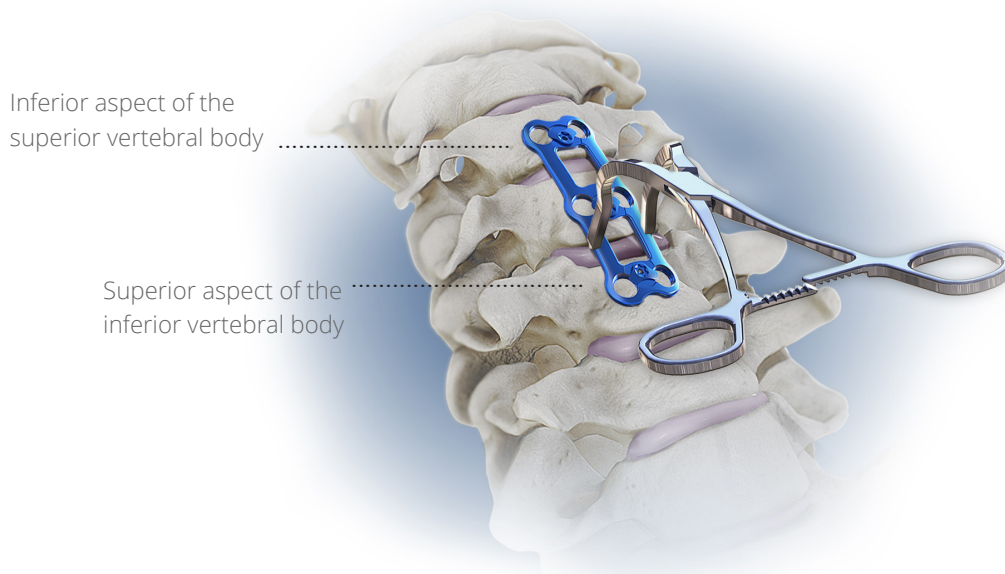


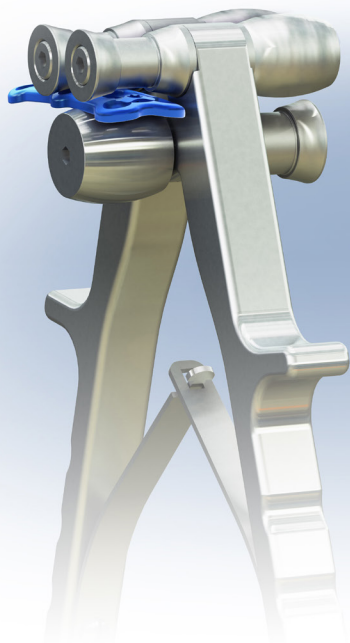
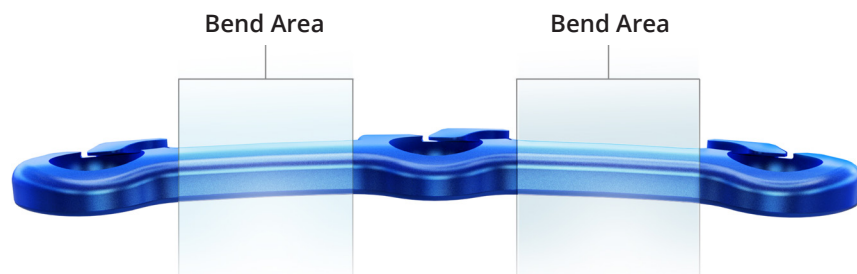
Figure 1



### STEP 3: Plate Contouring

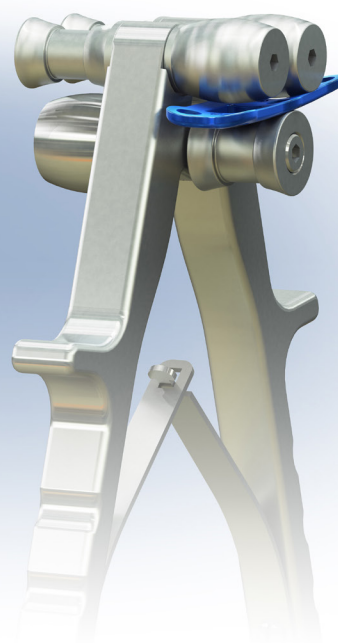
The FuseACP Anterior Cervical Plates are pre-bent. When additional contouring is required, insert the plate into the plate bender (Figure 2, 3) and squeeze the handles.

- The FuseACP Anterior Cervical Plate should only be bent across the bend zones.
- Plates should be bent in one direction, kyphosis or lordosis only. Never reverse the bend as this may create micro-fractures that could weaken the plate.
- Short plates of each level do not have bend zones and therefore cannot be bent.



**Increase lordotic curvature**

Figure 2



**Decrease lordotic curvature**

Figure 3

## STEP 4: Position Plate and Insert Temporary Fixation Pins

Insert a temporary fixation pin into the distal tip of the Temporary Fixation Pin Inserter, position the plate on the vertebral bodies for final placement, then screw in one temporary fixation pin into opposing cephalad and caudal screw holes of the plate (Figure 4).

Pull back collar to release the temporary fixation pin from the Temporary Fixation Pin Inserter.

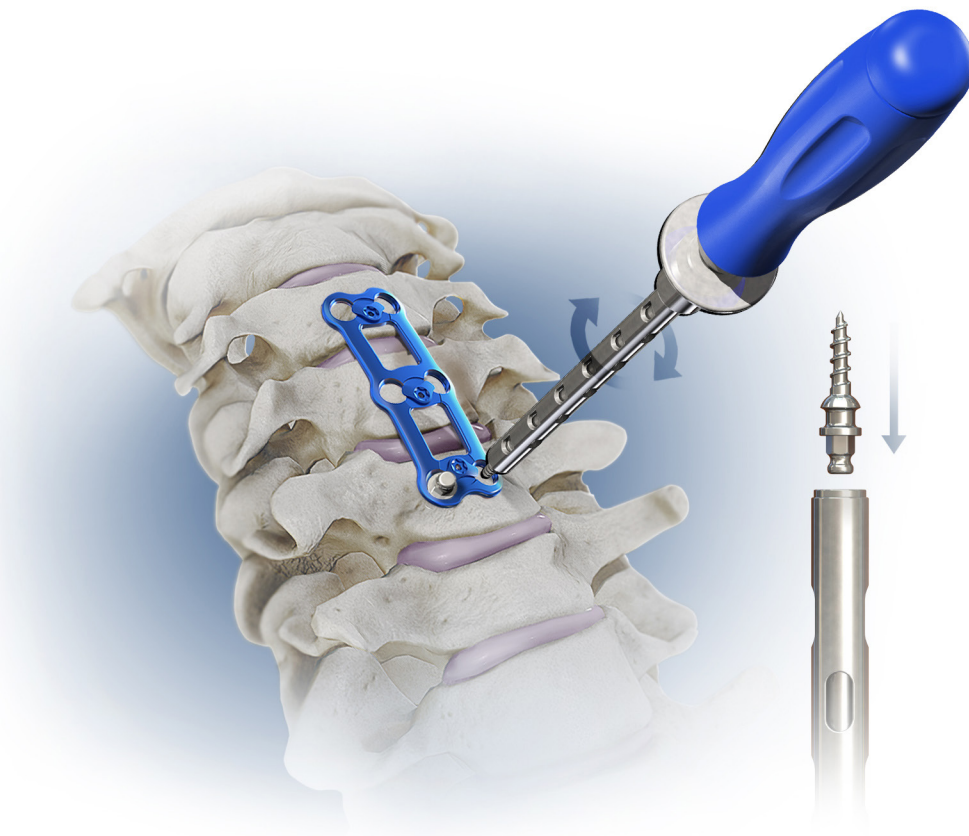
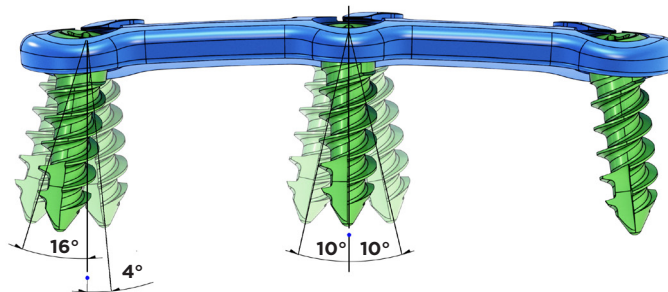


Figure 4

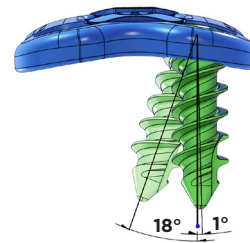
## STEP 5: Screw Selection

The FuseACP Anterior Cervical Plating System offers surgeons both fixed and variable angle screw options with self-tapping and self-drilling mechanical capabilities providing screw and plate placement versatility to achieve desired fusion angulation of the vertebral bodies.

### 4.0mm Variable Angle Screw

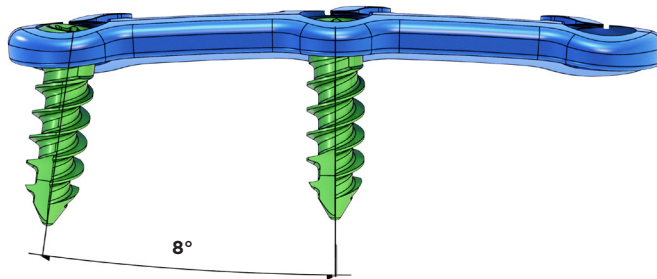


Cephalad / Caudal Angulation

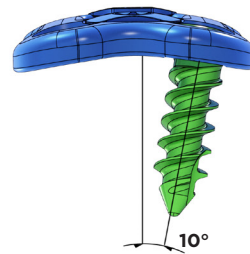


Medial / Lateral Angulation

### 4.0mm Fixed Angle Screw

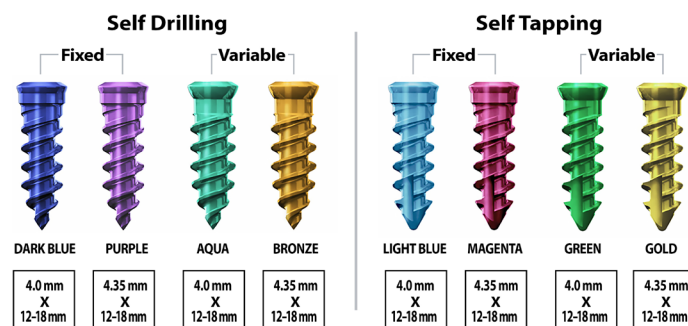


Cephalad / Caudal Angulation



Medial / Lateral Angulation

The FuseACP Anterior Cervical Plating System screw incorporates a dual-thread screw pattern designed to maximize interface with cancellous bone.



\*10, 20, and 22mm sizes available with special order request



## STEP 6: Screw Hole Preparation

### Using the Self-Constrained Awl

Once the plate is positioned and temporarily fixed to the vertebral bodies, place the tip of the Self Constrained Awl in the screw hole and press it in the direction of the desired screw angle. The Self Constrained Awl can protrude into the bone up to a depth of 8.5mm. To penetrate dense cortical bone, strike the handle of the Self Constrained Awl with a mallet.



### Drilling Technique

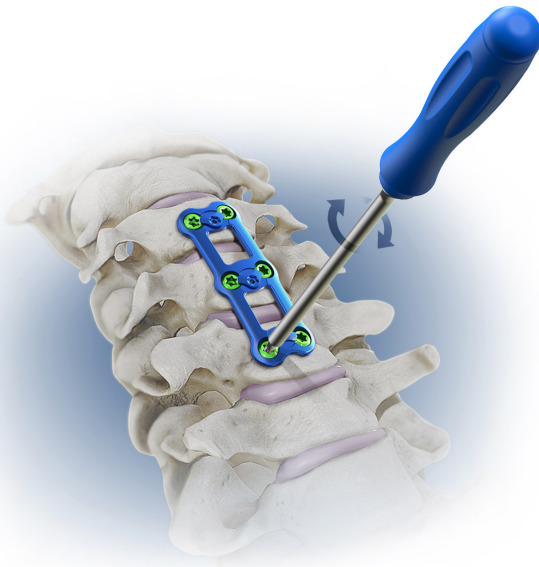
Select screw diameter size and attach the corresponding drill bit onto an AO I-Handle or power drill. Position corresponding drill guide (Fixed or Variable Angle) on the screw hole of choice and advance the drill bit to the desired depth under fluoroscopic imaging. A 10 mm tap is provided should tapping be required.



### Optional Instrument: Double DTS Drill Guide

To attach the Double DTS Guide, begin by placing the guide on the distal end of the plate. Place one side of the guide in the side slot on the plate. Next, twist the opposite side into position. Typically it is easier to attach the Double DTS Guide when downward pressure is maintained on the guide to keep contact between the guide and the plate.





## STEP 7: Screw Insertion

Use the screwdriver to pick up the appropriate bone screw, insert the screw tip into the prepared bone screw hole.

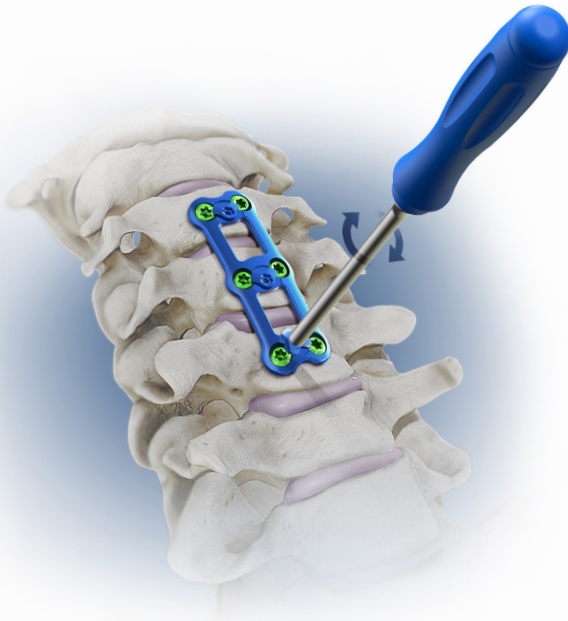
Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured with the locking mechanism.

## STEP 8: Engaging the Locking Mechanism

The FuseACP Anterior Cervical Plating System includes a built-in locking mechanism. Confirm all screws are fully seated prior to engaging the locking mechanism.

Insert the tip of the Screw Driver into the locking mechanism ensuring that the screwdriver is fully seated.

Rotate the locking mechanism clockwise until it is parallel with the window endplate. Be careful to ensure the locking mechanism is not overturned as damage may occur.



**Locked**



**Unlocked**



## REMOVAL TECHNIQUE:

Items needed

- Screwdriver

Insert the tip of the screwdriver into the locking mechanism ensuring that the screwdriver is fully seated.

Rotate the locking mechanism counter-clockwise until the locking mechanism is perpendicular to the window endplate. Be careful to ensure the locking mechanism is not overturned, as damage may occur (Figure 5).

To remove screws, insert screwdriver into the screw head and turn counter-clockwise until the screw is fully removed from the plate (Figure 6).

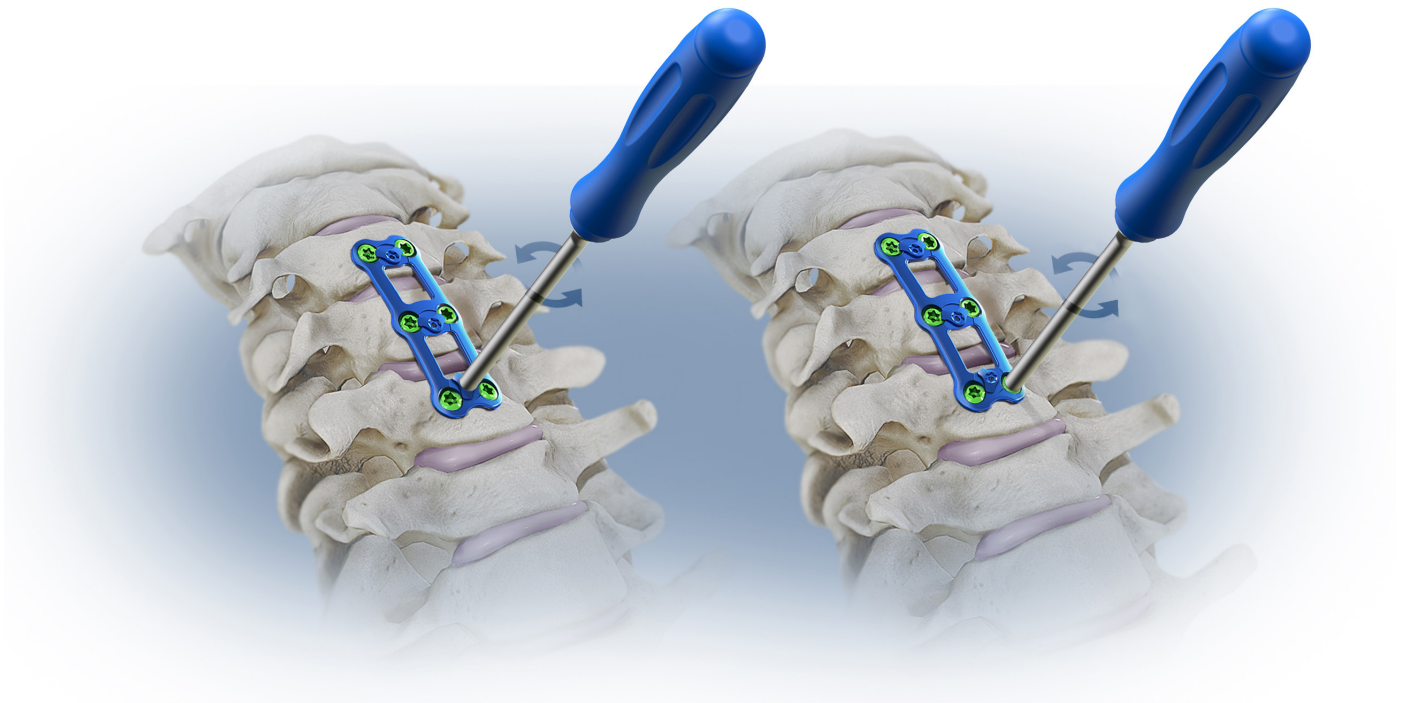


Figure 5

Figure 6

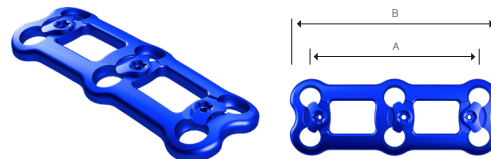
## FUSE ACP ANTERIOR CERVICAL PLATES

### One Level Plates



Catalog No.	Dimensions	
	A (Hole-to-Hole)	B (End-to-End)
F8014-0108	8mm	17mm *
F8014-0110	10mm	19mm
F8014-0112	12mm	21mm
F8014-0114	14mm	23mm
F8014-0116	16mm	25mm
F8014-0118	18mm	27mm
F8014-0120	20mm	29mm
F8014-0122	22mm	31mm
F8014-0124	24mm	33mm
F8014-0126	26mm	35mm

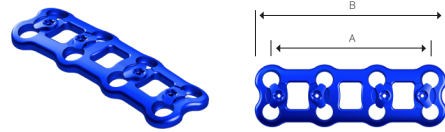
### Two Level Plates



Catalog No.	Dimensions	
	A (Hole-to-Hole)	B (End-to-End)
F8014-0222	22mm	31mm *
F8014-0224	24mm	33mm *
F8014-0226	26mm	35mm *
F8014-0228	28mm	37mm
F8014-0230	30mm	39mm
F8014-0232	32mm	41mm
F8014-0234	34mm	43mm
F8014-0236	36mm	45mm
F8014-0238	38mm	47mm
F8014-0240	40mm	49mm
F8014-0242	42mm	51mm
F8014-0244	44mm	53mm *
F8014-0246	46mm	55mm *

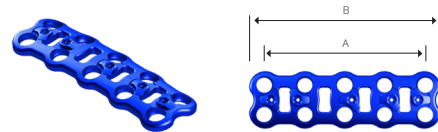
## FUSE ACP ANTERIOR CERVICAL PLATES

### Three Level Plates



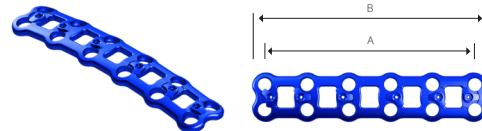
Catalog No.	Dimensions	
	A (Hole-to-Hole)	B (End-to-End)
F8014-0336	36mm	45mm *
F8014-0339	39mm	48mm *
F8014-0342	42mm	51mm *
F8014-0345	45mm	54mm
F8014-0348	48mm	57mm
F8014-0351	51mm	60mm
F8014-0354	54mm	63mm
F8014-0357	57mm	66mm
F8014-0360	60mm	69mm
F8014-0363	63mm	72mm
F8014-0366	66mm	75mm *
F8014-0369	69mm	78mm *

### Four Level Plates



Catalog No.	Dimensions	
	A (Hole-to-Hole)	B (End-to-End)
F8014-0446	46mm	55mm
F8014-0450	50mm	59mm
F8014-0454	54mm	63mm
F8014-0458	58mm	67mm
F8014-0462	62mm	71mm
F8014-0466	66mm	75mm
F8014-0470	70mm	79mm
F8014-0474	74mm	83mm
F8014-0478	78mm	87mm

### Five Level Plates



Catalog No.	Dimensions	
	A (Hole-to-Hole)	B (End-to-End)
F8014-0571	71mm	50mm
F8014-0576	76mm	85mm
F8014-0581	81mm	90mm
F8014-0586	86mm	95mm
F8014-0591	91mm	100mm

\*Indicates size is special order



## FUSE ACP SCREWS

### Fixed Self-Drilling Screw

Catalog No.	Dimensions	Color
	Diameter x Length	
F8224-4010	4.0 x 10mm	Dark Blue *
F8224-4012	4.0 x 12mm	Dark Blue
F8224-4014	4.0 x 14mm	Dark Blue
F8224-4016	4.0 x 16mm	Dark Blue
F8224-4018	4.0 x 18mm	Dark Blue
F8224-4020	4.0 x 20mm	Dark Blue *
F8224-4022	4.0 x 22mm	Dark Blue *
F8224-4310	4.35 x 10mm	Vector Purple *
F8224-4312	4.35 x 12mm	Vector Purple
F8224-4314	4.35 x 14mm	Vector Purple
F8224-4316	4.35 x 16mm	Vector Purple
F8224-4318	4.35 x 18mm	Vector Purple
F8224-4320	4.35 x 20mm	Vector Purple *
F8224-4322	4.35 x 22mm	Vector Purple *



## FUSE ACP SCREWS

### Fixed Self-Tapping Screw

Catalog No.	Dimensions	Color
	Diameter x Length	
F8225-4010	4.0 x 10mm	Sanding *
F8225-4012	4.0 x 12mm	Sanding
F8225-4014	4.0 x 14mm	Sanding
F8225-4016	4.0 x 16mm	Sanding
F8225-4018	4.0 x 18mm	Sanding
F8225-4020	4.0 x 20mm	Sanding *
F8225-4022	4.0 x 22mm	Sanding *
F8225-4310	4.35 x 10mm	Magenta *
F8225-4312	4.35 x 12mm	Magenta
F8225-4314	4.35 x 14mm	Magenta
F8225-4316	4.35 x 16mm	Magenta
F8225-4318	4.35 x 18mm	Magenta
F8225-4320	4.35 x 20mm	Magenta *
F8225-4322	4.35 x 22mm	Magenta *



## FUSE ACP SCREWS

### Variable Self-Drilling Screw

Catalog No.	Dimensions	Color
	Diameter x Length	
F8226-4010	4.0 x 10mm	Aqua *
F8226-4012	4.0 x 12mm	Aqua
F8226-4014	4.0 x 14mm	Aqua
F8226-4016	4.0 x 16mm	Aqua
F8226-4018	4.0 x 18mm	Aqua
F8226-4020	4.0 x 20mm	Aqua *
F8226-4022	4.0 x 22mm	Aqua *
F8226-4310	4.35 x 10mm	Bronze *
F8226-4312	4.35 x 12mm	Bronze
F8226-4314	4.35 x 14mm	Bronze
F8226-4316	4.35 x 16mm	Bronze
F8226-4318	4.35 x 18mm	Bronze
F8226-4320	4.35 x 20mm	Bronze *
F8226-4322	4.35 x 22mm	Bronze *



## FUSE ACP SCREWS

### Variable Self-Tapping Screw

Catalog No.	Dimensions	Color
	Diameter x Length	
F8227-4010	4.0 x 10mm	Green *
F8227-4012	4.0 x 12mm	Green
F8227-4014	4.0 x 14mm	Green
F8227-4016	4.0 x 16mm	Green
F8227-4018	4.0 x 18mm	Green
F8227-4020	4.0 x 20mm	Green *
F8227-4022	4.0 x 22mm	Green *
F8227-4310	4.35 x 10mm	Gold *
F8227-4312	4.35 x 12mm	Gold
F8227-4314	4.35 x 14mm	Gold
F8227-4316	4.35 x 16mm	Gold
F8227-4318	4.35 x 18mm	Gold
F8227-4320	4.35 x 20mm	Gold *
F8227-4322	4.35 x 22mm	Gold *



\*Indicates size is special order

## FUSE ACP INSTRUMENTS

<p><b>F5932-1138</b> Fuse ACP Plate Holder</p> 	<p><b>F5932-1143</b> Fuse ACP AO I-Handle</p> 
<p><b>F5932-1127</b> Fuse ACP Plate Bender</p> 	<p><b>F5932-1129</b> FUSE ACP Drill Guide-Drill Guide-Variable</p> 
<p><b>F5932-1139</b> Fuse ACP Temporary Fixation Pin</p> 	<p><b>F5932-1128</b> FUSE ACP Drill Guide-Fixed</p> 
<p><b>F5932-1140</b> Fuse ACP Temporary Fixation Pin Inserter</p> 	<p><b>F5932-1126</b> Fuse ACP Tap 10mm</p> 
<p><b>F5932-1141</b> Fuse ACP Self Constrained Awl</p> 	<p><b>F5932-1136</b> Fuse ACP Double DTS</p> 
<p> <b>F5932-1130</b> Fuse ACP Drill 10mm  <b>F5932-1131</b> Fuse ACP Drill 12mm  <b>F5932-1132</b> Fuse ACP Drill 14mm         </p> 	<p><b>F5932-1142</b> FUSE ACP Screw Driver</p> 

## WARNINGS & CAUTIONS

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### Warning

1. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.
2. Do not use this product other than its indication. Fuse ACP Anterior Cervical Plating System is indicated for cervical vertebral fusion. Do not use the product outside of its indication.
3. The FUSE ACP Anterior Cervical Plating System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the FUSE ACP Anterior Cervical Plating System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.
4. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.
5. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. (While the device may appear to be undamaged, it may have small defects or internal stress patterns as a result of the prior implantation or removal that could lead to fatigue failure.) Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for implants which have been reused.
6. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.



**Fuse Medical, Inc.**

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Richardson, TX 75080  
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Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

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