



**FALCON™** Surgical Technique  
Anterior Cervical Plate System

## SYSTEM FEATURES

The FALCON™ Anterior Cervical Plate System simplifies anterior cervical spinal fusion with an improved semi-constrained system that offers fast, reproducible results. The Falcon cervical plate features a sleek, contemporary design for easy insertion and large graft windows for enhanced visual confirmation of the allograft. The instrumentation facilitates complete control by the surgeon during the procedure. The Falcon Cervical Plate is an effective plating system for degenerative disc disease or trauma application with:

- Low-profile design (1.9mm) and narrow silhouette for placement on the spinal column
- Large assortment of plate lengths to accommodate a variety of patient anatomies
- Large visual access area for maximum allograft viewing both through and around the scalloped sides of the plate
- Self-drilling and self-tapping, fixed and variable angle screws for maximum purchase
- Simple one-step locking clip to ensure that the screws are secure

## Step 1 Exposure

A 2-4 centimeter transverse incision is made in the neck, just off the midline. The cervical fascia is gently divided in a natural plane. Small retractors are used to allow the surgeon to visualize the anterior body and discs. An X-ray confirms that the appropriate spine level has been reached.

The decompression is performed. A rongeur is used to remove any arthritic, hypertrophic bone spurs from the endplates to create a smooth surface for the cervical plate to fit flush on the spinal column. The surrounding area is also checked for any loose disc fragments.

The size of the empty space is measured and the appropriate sized graft material is selected to restore the normal disc space height (Fig. 1).

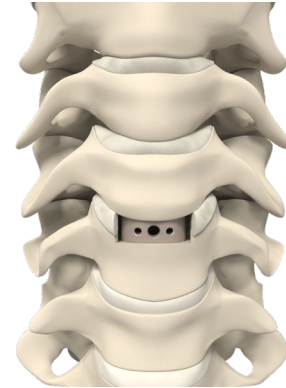


Fig. 1

## Step 2 Positioning the Plate

Select the appropriate sized Falcon Cervical Plate and affix it to the spinal column to ensure that the plate fits on the spinal column. After the plate is properly positioned, a temporary fixation pin may be inserted into the center fixation hole to facilitate alignment (Fig. 2).

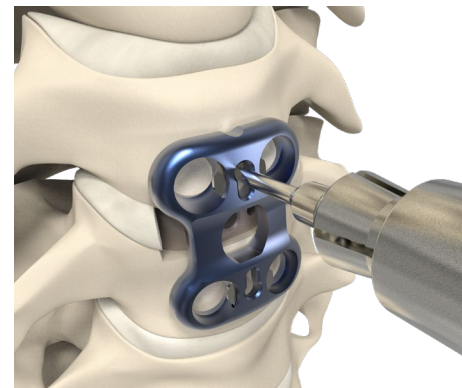


Fig. 2

The Falcon Cervical Plate is pre-contoured and can be bent so that the plate fits appropriately on the spine. To contour the plate: insert the plate into the plate bender and align the “bend zones” on the plate with the bending template. Use caution when bending and straightening the plate as too much bending will weaken the cervical plate (Fig. 3).

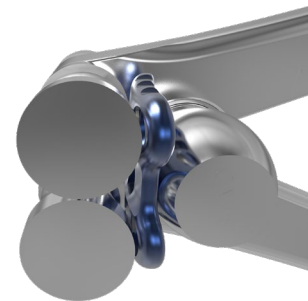
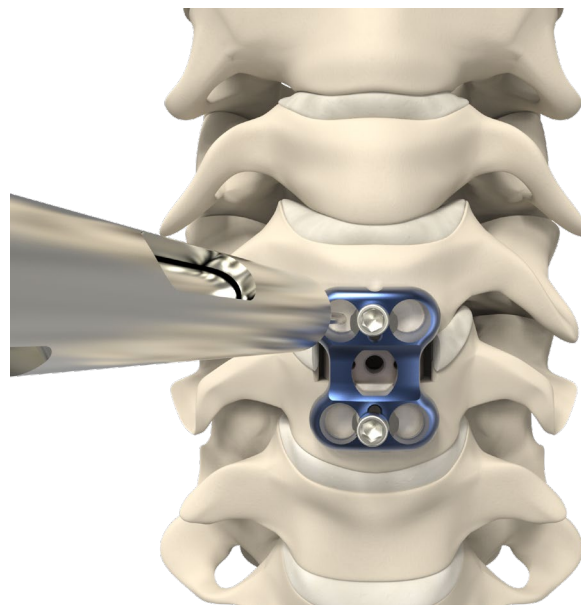
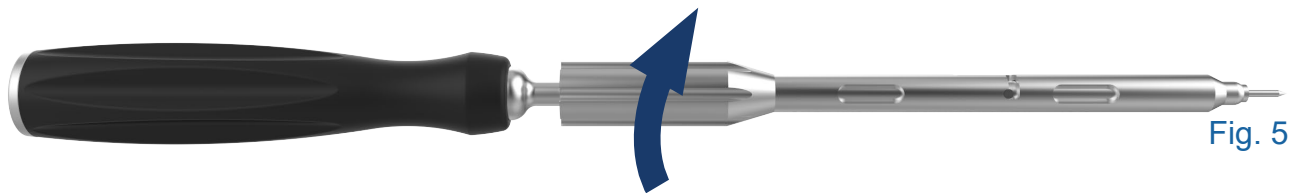
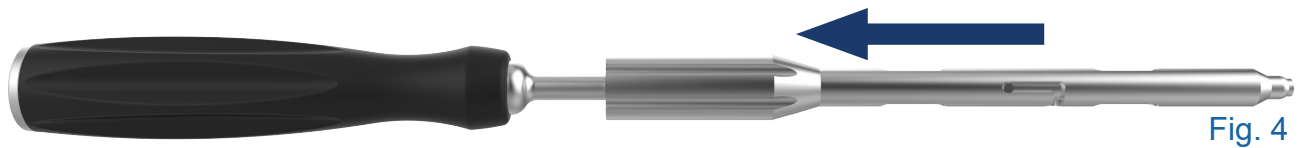


Fig. 3

## Step 3 Screw Hole Preparation

The awl tip can be locked out of the sleeve so that it works like a fixed awl. The awl tip at the top is in the unlocked position. The bottom awl tip is in the locked position (Fig. 4-5). Gently push down on this instrument to penetrate the cortex of the vertebral body to create a pilot hole for the screw. (Fig. 6)



## Step 3 Screw Hole Preparation (Cont.)

Determine if a fixed or variable screw is to be used and then select the appropriate drill length and guide to prepare a pathway for the screw. Place the selected drill guide into the desired screw hole, making sure it is properly seated. Then place the drill that is attached to the Quick Connect handle and rotate clockwise to drill to the desired length (Fig. 7). The drill will stop at the labeled length (Fig. 8)



Fig. 7

\* If desired, the tap is attached to the Quick Connect handle and can be used to prepare a pathway for the screw

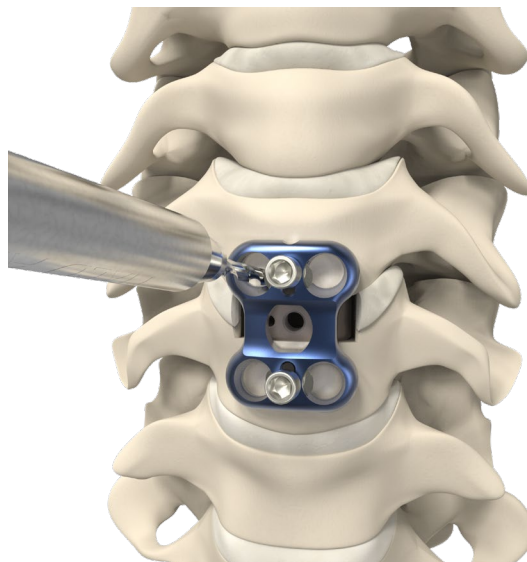


Fig. 8

## Step 4 Screw Placement



Fig. 9

Select the appropriate diameter and length screw and attach it to the screwdriver (Fig. 9). Advance the screw until it is fully seated in the plate and covered by the locking mechanism. Make sure to stay under the limits of screw angulation so that the locking mechanism can be engaged to cover a portion of the screw head (Fig. 10). The locking mechanism is engaged when it covers a portion of the screw head (Fig. 10). When used properly, the drill guide will allow the surgeon to angulate the screws in the proper orientation. Insert the remaining screws to secure the plate (Fig. 11). With multi-level procedures, the central screws are placed first. This anchors the plate and establishes the location for the upper and lower screws. After the second middle screw is fully seated, tighten both screws completely and observe the locking mechanism.

Fig. 10

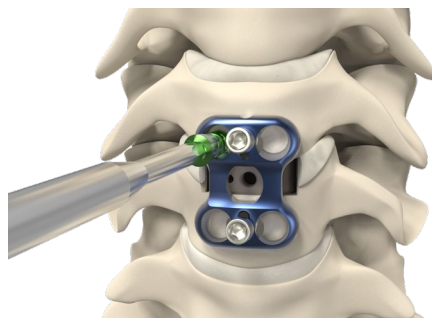
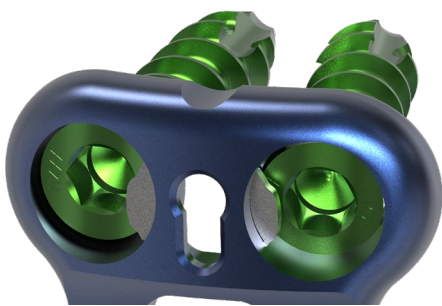


Fig. 11

### Variable Screw

Cranial-Caudal Screw Angulation

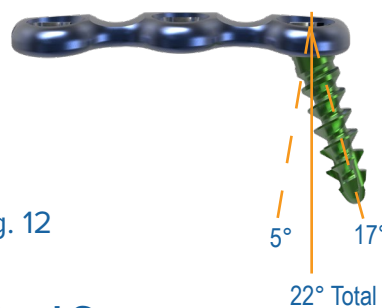
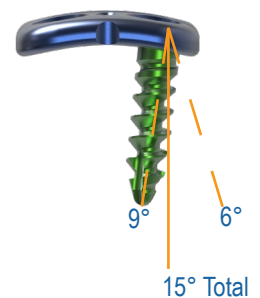


Fig. 12

Medial-Lateral Screw Angulation



### Fixed Screw

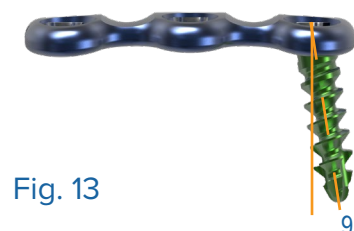
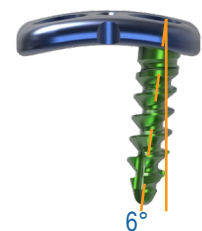


Fig. 13



## Step 5 Adjusting the Locking Mechanism to Secure Screw Placement

If the retention mechanism does not expand to cover a portion of the screw, then insert the clip expansion tool (Fig. 14) into the central fixation pin holes. Rotate it to assist the clip in moving lateral to cover over the screw head (Fig. 15-16). CARE MUST BE TAKEN NOT TO ANGLE THE SCREW BEYOND THE PRESCRIBED INSERTION ANGLES.



Fig. 14

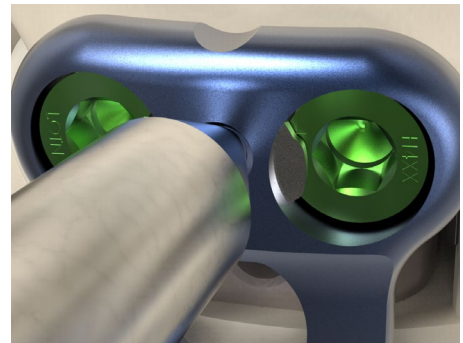


Fig. 15

Confirm proper placement and alignment with lateral and A/P X-ray. (Fig. 16)

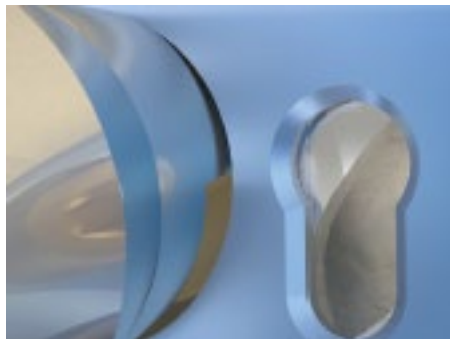


Fig. 16

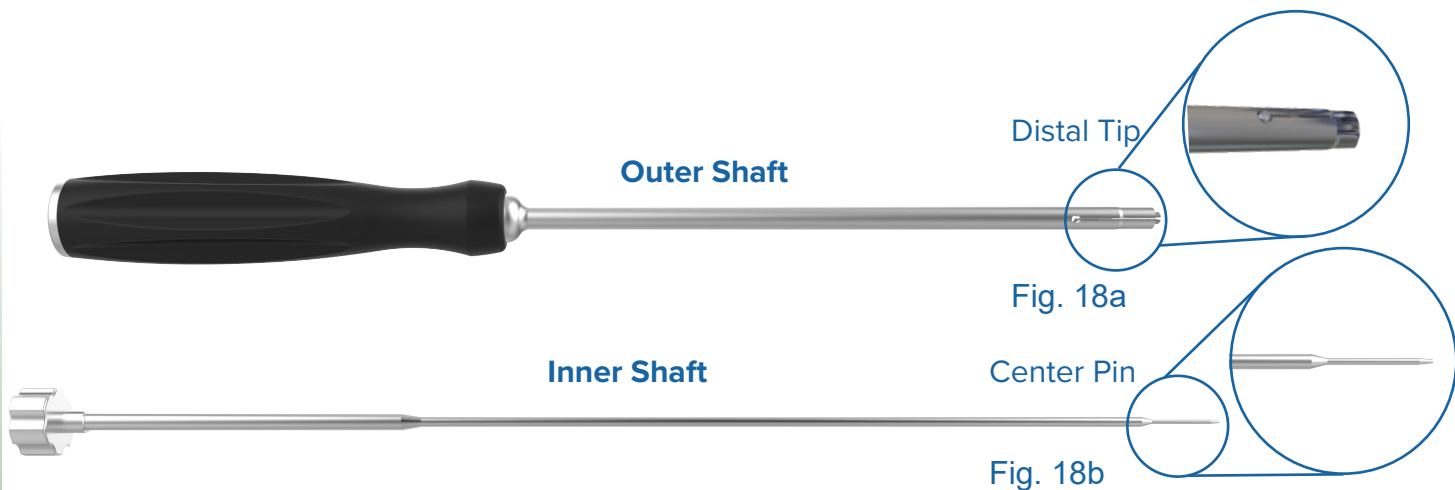


Fig. 17

## Step 6 Screw Removal

It may be necessary to reposition the screws in the Falcon Cervical Plate during the surgery. They can be removed and repositioned in the proper orientation. The Screw Removal Instrument is necessary to accomplish this.

- Disassemble the Screw Removal Instrument into its inner and outer shaft components: (Fig. 18a) (Fig. 18b)
- Make sure the flat face on the distal tip of the outer shaft faces medial so that the distal tip does not impinge on the locking clip.



Insert the outer shaft with distal tip into the head of the screw. Orient the instrument so it mimics the trajectory of the screw for a precise fit (Fig. 19).

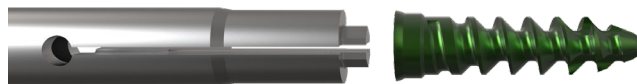
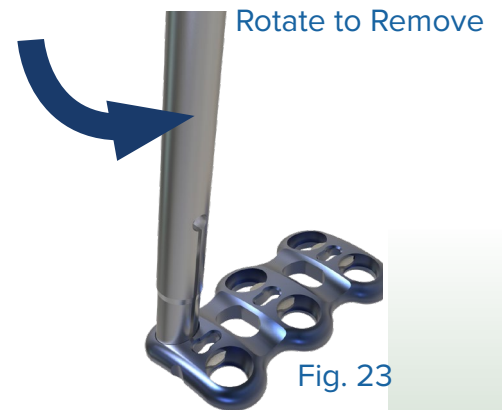
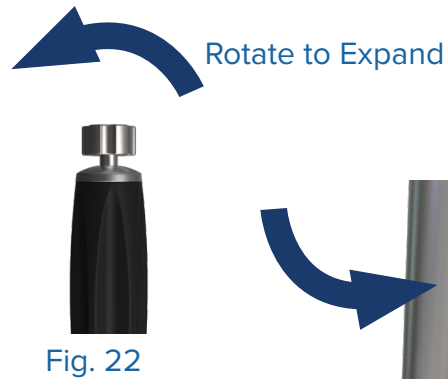
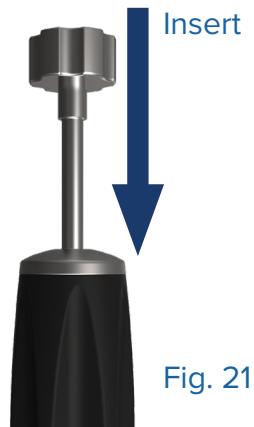
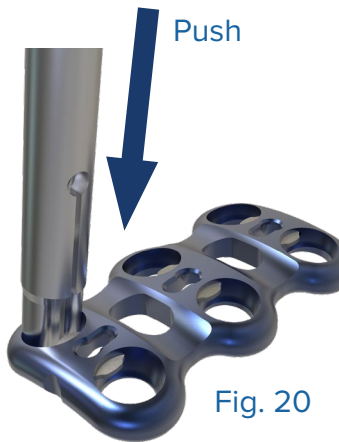


Fig. 19



## Step 6 Screw Removal (Cont.)

Apply constant downward pressure on the outer shaft while pushing into the screw (Fig. 20). Insert the inner shaft through the handle (Fig. 21) and rotate the inner shaft clockwise (Fig. 22) until it bottoms out. This action will advance the inner shaft and expand the distal tip, locking the instrument into the screw. Rotate the screw counterclockwise to remove it (Fig. 23).



## Step 6 Screw Removal (Cont.)

To remove the screw from the instrument, rotate the inner shaft counterclockwise until it can be extracted. The screw can then be removed from the distal tip (Fig. 24).



Fig. 24

If the screw does not back out, reattach the Screw Removal Instrument into the screw, paying close attention to the orientation of the instrument. Always keep pressure on the instrument while advancing the inner shaft.

**Item #**

FT10-BR410, FT10-BR412, FT10-BR414, FT10-BR416  
FT10-BP410, FT10-BP412, FT10-BP414, FT10-BP416  
FT10-BN410, FT10-BN412, FT10-BN414, FT10-BN416  
FT10-BL410, FT10-BL412, FT10-BL414, FT10-BL416  
FT10-BH410, FT10-BH412, FT10-BH414, FT10-BH416  
FT10-BF410, FT10-BF412, FT10-BF414, FT10-BF416  
FT10-BE412, FT10-BE414, FT10-BE416

**Implant Description**

4.0mm Fixed Angle Self Drilling Screws  
4.0mm Variable Angle Self Drilling Screws  
4.5mm Fixed Angle Self Tapping Screws  
4.5mm Variable Angle Self Tapping Screws  
4.0mm Fixed Angle Self Tapping Screws  
4.0mm Variable Angle Self Tapping Screws  
3.75mm Variable Angle Self Drilling Screws

**Available Lengths**

10mm, 12mm, 14mm, 16mm  
10mm, 12mm, 14mm, 16mm  
10mm, 12mm, 14mm, 16mm  
10mm, 12mm, 14mm, 16mm  
10mm, 12mm, 14mm, 16mm  
10mm, 12mm, 14mm, 16mm  
12mm, 14mm, 16mm



3.75mm Var. Angle Self Drilling Screws (Bronze)



4.0mm Fixed Angle Self Drilling Screws (Purple)



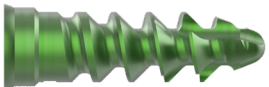
4.0mm Var. Angle Self Drilling Screws (Dark Purple)



4.5mm Fixed Angle Self Tapping Screws (Blue)



4.5mm Var. Angle Self Tapping Screws (Type II [Gray])



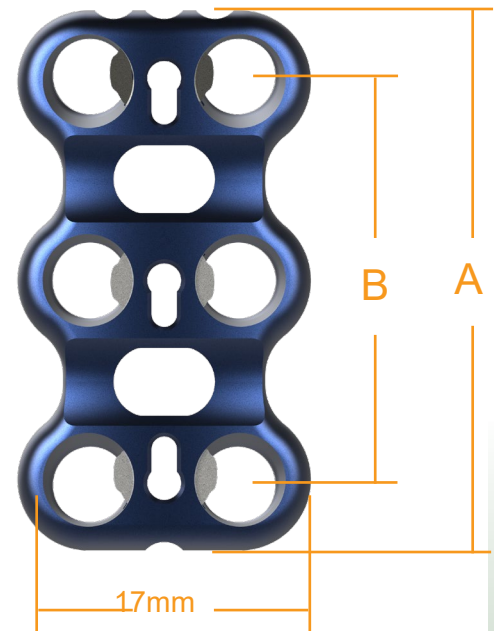
4.0mm Fixed Angle Self Tapping Screws (Green)


















4.0mm Var. Angle Self Tapping Screws (Gold)

## Cervical Plate Configurations

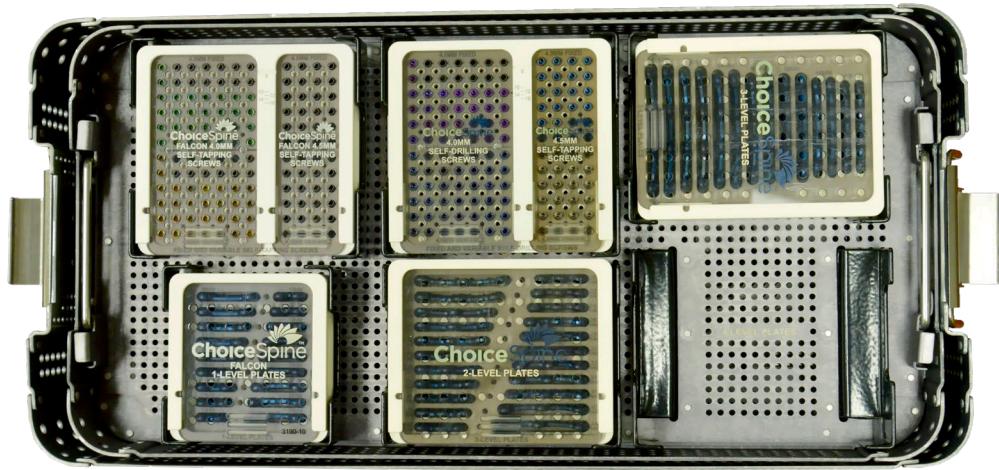
Level	Item #	Implant Description	A	B
1	AT10-1010	10mm 1-Level Anterior Cervical Plate	18	10
1	AT10-1012	12mm 1-Level Anterior Cervical Plate	20	12
1	AT10-1014	14mm 1-Level Anterior Cervical Plate	22	14
1	AT10-1016	16mm 1-Level Anterior Cervical Plate	24	16
1	AT10-1018	18mm 1-Level Anterior Cervical Plate	26	18
1	AT10-1020	20mm 1-Level Anterior Cervical Plate	28	20
1	AT10-1022	22mm 1-Level Anterior Cervical Plate	30	22
1	AT10-1024	24mm 1-Level Anterior Cervical Plate	32	24
1	AT10-1026	26mm 1-Level Anterior Cervical Plate	34	26
2	AT10-2020	20mm 2-Level Anterior Cervical Plate	28	20
2	AT10-2022	22mm 2-Level Anterior Cervical Plate	30	22
2	AT10-2024	24mm 2-Level Anterior Cervical Plate	32	24
2	AT10-2026	26mm 2-Level Anterior Cervical Plate	34	26
2	AT10-2028	28mm 2-Level Anterior Cervical Plate	36	28
2	AT10-2030	30mm 2-Level Anterior Cervical Plate	38	30
2	AT10-2032	32mm 2-Level Anterior Cervical Plate	40	32
2	AT10-2034	34mm 2-Level Anterior Cervical Plate	42	34
2	AT10-2036	36mm 2-Level Anterior Cervical Plate	44	36
2	AT10-2040	40mm 2-Level Anterior Cervical Plate	48	40
2	AT10-2044	44mm 2-Level Anterior Cervical Plate	52	44
3	AT10-3040	40mm 3-Level Anterior Cervical Plate	48	40
3	AT10-3044	44mm 3-Level Anterior Cervical Plate	52	44
3	AT10-3048	48mm 3-Level Anterior Cervical Plate	56	48
3	AT10-3050	50mm 3-Level Anterior Cervical Plate	58	50
3	AT10-3054	54mm 3-Level Anterior Cervical Plate	62	54
3	AT10-3058	58mm 3-Level Anterior Cervical Plate	66	58
3	AT10-3062	62mm 3-Level Anterior Cervical Plate	70	62
4	AT10-4060	60mm 4-Level Anterior Cervical Plate	68	60
4	AT10-4064	64mm 4-Level Anterior Cervical Plate	72	64
4	AT10-4068	68mm 4-Level Anterior Cervical Plate	76	68
4	AT10-4072	72mm 4-Level Anterior Cervical Plate	80	72
4	AT10-4076	76mm 4-Level Anterior Cervical Plate	84	76
4	AT10-4080	80mm 4-Level Anterior Cervical Plate	88	80
4	AT10-4084	84mm 4-Level Anterior Cervical Plate	92	84



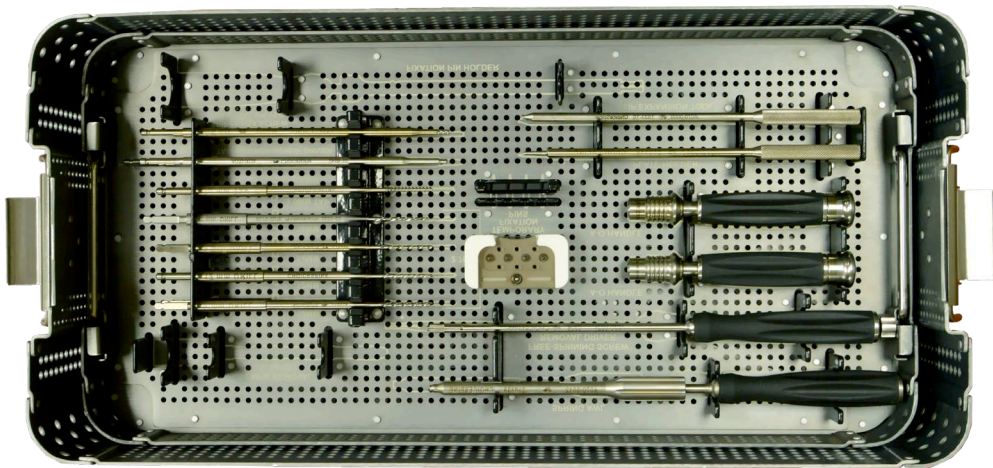
## Instruments

Item #	Instrument Description	Quantity	
A070-0002	Fixed Angle Drill Guide	1	
A070-0028	Temporary Fixation Pin	4	
A070-0006	Plate Bender	1	
A070-0008	Short W/Spin Cap Handle	2	
A070-0009	Clip Expansion Tool	1	
A070-0010	Plate Holder	1	
A070-0012	Awl	1	
A070-0015	Spiral Hex Removal Driver	1	
A070-0016	Variable Angle Drill Guide	1	
A070-0024	Driver, Screw Removal	1	
A070-0026	Driver, Split Tip	2	
A070-0D10	2.7 X 10mm Drill	2	
A070-0D12	2.7 X 12mm Drill	2	
A070-0D14	2.7 X 14mm Drill	2	
A070-0D16	2.7 X 16mm Drill	2	
A070-0T10	3.0 X 10mm Tap	1	

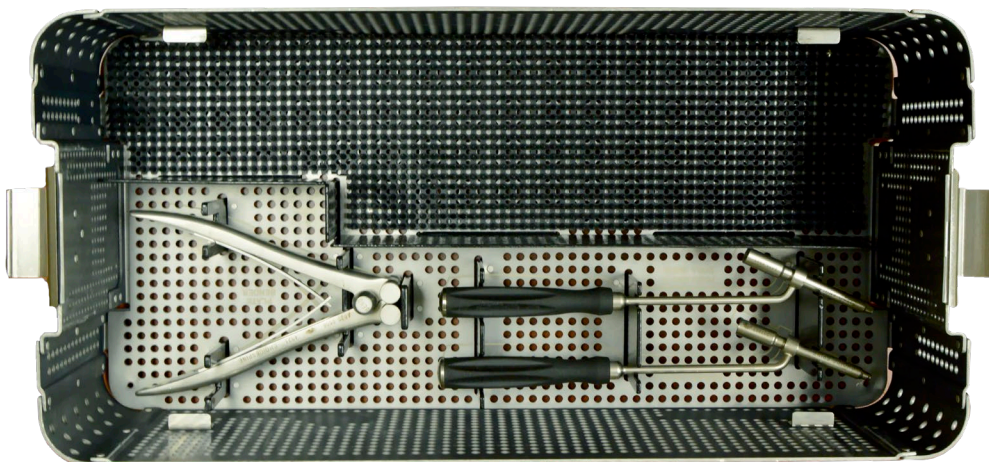
# Top



# Middle



# Bottom





## Description

The ChoiceSpine Falcon™ Anterior Cervical Plate System is an anterior cervical spinal fixation system consisting of plates and screws, manufactured from titanium alloy (Ti6Al4V ELI; ASTM F136). The plates are available in multiple lengths, suitable to 1-, 2-, 3-, and 4-level surgeries, in order to accommodate different anatomies. The plates incorporate a screw- retention mechanism, or clip, made of Nitinol alloy (NiTi; ASTM F2063) to prevent screw back-out. The screws, which serve as fixation devices of the plates, are available in diameters of 4.0mm and 4.5mm in either a fixed- or variable-angle design that has a self-tapping feature. A self- drilling version of the 4.0mm diameter screw is also available. A complete instrument set has been specifically designed to implant the Falcon™ Anterior Cervical Plate System components. It is essential that only these instruments be used with this system.

## Indication

The ChoiceSpine Falcon™ Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (levels C2 to C7) and is designed to provide stabilization as an adjunct to spinal fusion at these levels. Indications for the use of this device includes: failed previous fusion, pseudoarthrosis, tumor, deformity, spinal stenosis, trauma, spondylolisthesis, or degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

**WARNING:** The ChoiceSpine FALCON™ ACP System is not intended for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.

## Contraindications

Use of any implant system and spinal fixation surgery are contraindicated in the presence of existing or recent active infection near or at the proposed implantation site.

Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to:

- Cancer
- Fever
- Mental illness
- Alcoholism or drug abuse
- Osteoporosis or osteopenia
- Neurotrophic disease
- Obesity
- Pregnancy and foreign body sensitivity

In addition, patients who smoke have been shown

to have an increased incidence of pseudoarthrosis. Based upon the fatigue testing results, the physician/ surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system. See also the WARNING, POTENTIAL ADVERSE AFFECTS, and PRECAUTION section of this insert. The following are specific warnings, precautions and adverse events that should be understood by the surgeon and explained to the patient. They are specific metallic internal fixation devices. General surgical risk should be explained to the patient before surgery.

## WARNING

The ChoiceSpine FALCON™ Anterior Cervical Plate (ACP) System Implants have not been tested for safety and compatibility in the MR environment. ChoiceSpine FALCON™ Anterior Cervical Plate (ACP) System Implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of the ChoiceSpine FALCON™ Anterior Cervical Plate (ACP) System Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## Notes

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LIT# Falcon STG | REV07 | 9/19