

Surgical Technique & Ordering Information



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INTRODUCTION/PHILOSOPHY

The EAGLE™ Plus Anterior Cervical Plate System features enhancements to the original EAGLE ACP System. The new system incorporates a dual sequential locking mechanism, improved screw purchase, and lagging capability. The EAGLE Plus ACP System continues to provide large windows and a single step polyaxial rigid screw locking mechanism.

Note: The described technique presents a few of many approaches to the stabilization of the anterior cervical spine. The surgeon is encouraged to utilize the EAGLE Plus Anterior Cervical Plate System with those techniques that accomplish the desired surgical result.

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EAGLE Plus System Description



- The EAGLE Plus Anterior Cervical Plate System is designed for anterior cervical applications where a rigid screw kinematic is desired.
- Bushings provide polyaxial screw angulation. The bushing/screw interface is self-locking with a dual sequential locking mechanism in the form of a ring at the base of the bushing.
- Large graft windows allow for enhanced graft and anatomical landmark visualization.
- Self-drilling and self-tapping screws are available to provide multiple fixation options.
- Rigid plates are pre-lordosed to a 180mm radius, reducing the need for plate contouring.

Note: The green plate color distinguishes the EAGLE Plus System from the blue plate of the original EAGLE System. Screw heads of the EAGLE Plus System have an etch mark to distinguish them from the original non-etched screws of the original EAGLE System. EAGLE Plus Plates should only be used with EAGLE Plus screws.

Reliability – Dual Sequential Lock
Flexibility – Polyaxial Screw Trajectory
Simplicity – One step Lag and Lock



EAGLE Plus Surgical Technique

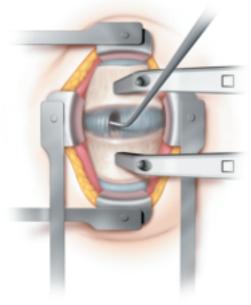


Figure 1

Step 1 - Site Preparation

Prepare the intervertebral space in the usual manner (Figure 1). Once appropriate disc excision and decompression have been achieved, insert appropriate graft such as VG2® Cervical Allograft. When satisfied with the graft position, remove all bone distraction instruments. Optimal bone-plate interface is achieved by removing anterior soft tissues and prominent osteophytes.



Figure 2

Step 2 - Plate Sizing

After graft has been inserted, determine plate size by placing the tips of the caliper arms on the vertebral bodies at the anticipated entry point for the screws. The appropriate plate is the size closest to indicated length for the number of levels being fused (Figure 2).

Figure 3

Step 3 - Plate Contouring

EAGLE plates are pre-lordosed to a 180mm radius. Additional contouring may be accomplished by inserting a plate into the rigid plate bender and squeezing the handles (Figure 3).

Note:

- Bend only in the bend zones.
- Do not bend across the screw holes.
- Plates should be bent in one direction, kyphosis or lordosis only. Never reverse the bend as this may create micro fractures that will weaken the plate.

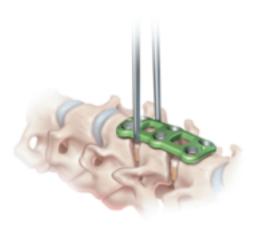


Figure 4

Step 4 - Plate Placement

Using the plate holder, position the plate on the vertebral bodies. When plate is properly sized and positioned (Figure 4):

• The superior screw holes should align with the inferior 1/3 of the superior vertebral body. Inferior screw holes should align with the superior 1/3 of the inferior vertebral body.

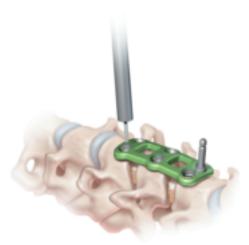


Figure 5

Step 5 - Temporary Fixation Pin (TFP) Insertion

Use the temporary fixation pin inserter to insert temporary fixation pins at the rostral and caudal ends of the plate (Figure 5). Pins are available in threaded (for screw hole) and non-threaded (for TFP hole) options.

Fluoroscopy may be considered to confirm alignment in both planes.

Figure 6a

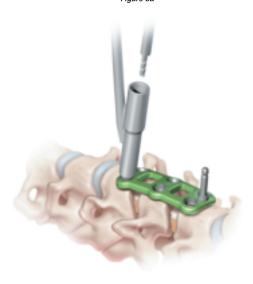


Figure 6b

Step 6 - Screw Hole Preparation

Multiple drill guide options are available with the EAGLE Plus System. Use of the single-barrel guide is detailed below. The insertion techniques for the double-barrel and four-barrel guides are detailed in the *Other Instruments* section.

Note: Self-drilling screws do not normally require pre-drilling; however, an awl should be used to perforate the cortex to provide a starting point for screw insertion. Always use a drill guide when using a drill or awl.

Single-Barrel Guide

The single-barrel guide allows adjustment of individual bushings/screws prior to screw insertion (Figure 6a).

Insert the awl or the 12, 14 or 16mm drill into the guide and advance fully to the positive stop. Remove drill or awl and guide (Figure 6b).

Notes:

- Use fluoroscopic imaging to assist with the appropriate and safe positioning of the screw.
- Use of the single-barrel guide is required when inserting the 4.4mm self-tapping screw as the primary screw in order to align the bushing with the trajectory of the screw.
- Care should be taken not to over drill screw holes. The drill length should not exceed the length of the screw to be inserted. The awl in conjunction with one of the drill guides should be used to prepare the hole of the 10mm screw, as the awl protrudes into the bone 7mm.

Step 7 - Screw Selection

Screws are available in three unicortical configurations:

		Screw Type	Length	Head Color	Cancellous Thread Color
		Self-Drilling (4.25mm)	10mm	Green	Silver
			12mm	Blue	Silver
8	8	<i>3 </i>	14mm	Gold	Silver
E.	E.	<i>E E E</i>	16mm	Magenta	Silver
7	子	7 7 7	18mm	Deep Purple	Silver
•	•				
		Self-Tapping (4.25mm)	10mm	Green	Green
6.0 0	5.00	<u> </u>	12mm	Blue	Blue
8	8	<i>3 </i>	14mm	Gold	Gold
#	E		16mm	Magenta	Magenta
T	T	· 李 · 李 · 李	18mm	Deep Purple	Deep Purple
		Self-Tapping (4.4mm)	10mm	Silver	Green
		<u> </u>	12mm	Silver	Blue
3	3	<i>를 를 를</i>	14mm	Silver	Gold
8	8	# # #	16mm	Silver	Magenta
7	7	₹ ₹ ₹	18mm	Silver	Deep Purple

Note: The green plate color distinguishes the EAGLE Plus System from the blue plate of the original EAGLE System. Screw heads of the EAGLE Plus System have an etch mark to distinguish them from the original non-etched screws of the original EAGLE System. EAGLE Plus Plates should only be used with EAGLE Plus screws.

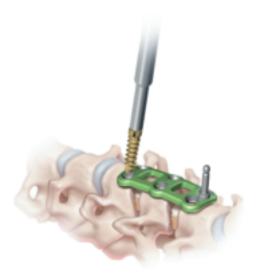


Figure 7a

Step 8 - Screw Insertion

Attach screw to a self-retaining screwdriver. Insert screw into selected screw hole and advance to a point before taper lock is engaged (Figure 7a). There will be a slight increase in resistance as the top screw thread moves past the bushing ring and then a drop in resistance (Figures 7b and 7c). Repeat for all screw holes.

Note: Use fluoroscopic imaging to assist with the appropriate and safe positioning of the screw.



Figure 7b

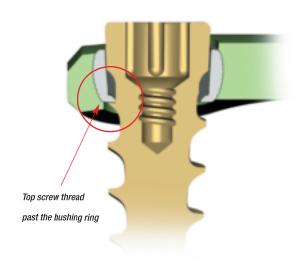


Figure 7c



Figure 8

Step 9 - Final Tightening

Inspect the plate/bone interfaces with a right angle nerve hook. There should be apposition between the plate, screws and vertebral body. Sequentially tighten all screws using the standard screwdriver until the plate has lagged down to the bone (Figure 8).

When the posterior surface of the plate is in contact with the vertebral body, screw lock is achieved by applying axial force and slowly turning the driver until the screw head engages the bushing taper.

Notes:

- Final screw tightening should be done slowly and care should be taken not to over tighten screws.
- Fluoroscopic imaging should be considered to confirm screw depth and orientation to insure important structures are not at risk.

Remove Temporary Fixation Pins.

Step 10 - Final Support

For patients with three- or four-level constructs, compromised bone quality or other complications, additional fixation options may need to be considered. Posterior or external reinforcement of long anterior constructs can be achieved with Bremer HALO® CROWN System and/or MOUNTAINEER™ OCT Spinal System.

EAGLE Plus Other Instruments

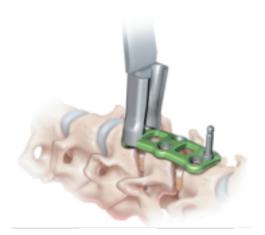
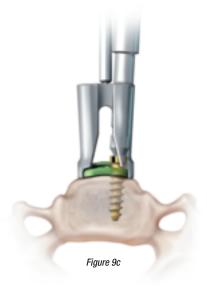


Figure 9a



Figure 9b



In order to provide enhanced versatility, the EAGLE Plus System was designed with additional instrumentation to facilitate a variety of surgical preferences and needs.

Double-Barrel and Retractor Drill Guides

The EAGLE Plus double-barrel guide will attach to, and hold the plate to facilitate use of awls, drills, and taps - as well as screw insertion - without needing to remove the guide from the plate. The retractor drill guide also acts as a soft tissue retractor when used on the ends of the plate.

The double-barrel guide will angle each screw 3° medially and allow for screw angulations in the sagittal plane.

Note: Use fluoroscopic imaging to assist with the appropriate and safe positioning of screws.

Place the double-barrel drill guide over the two screw holes. The flanges on the guide should grip the sides of the plate (Figures 9a and 9b).

Insert the awl or the 12, 14 or 16mm drill into the double-barrel drill guide and advance fully to the positive stop. Remove drill or awl. Keep the double-barrel drill guide attached for screw insertion.

Attach screw to a self-retaining screwdriver. Insert screw through the double-barrel drill guide into selected screw hole and advance to a point before taper lock is engaged (Figure 9c). There will be a slight increase in resistance as the top screw thread moves past the bushing ring and then a drop in resistance. Repeat for all screw holes.

Remove the double-barrel drill guide.

Four-Barrel Drill Guide

The four-barrel combination plate holder/drill guide will orient each screw 3° medially and 5° cephalad/caudad. The four-barrel drill guide is designed to facilitate use of awls, drills, taps and screw insertion without removing the guide from the plate. The four-barrel drill guide does not allow the use of temporary fixation pins.

- 1. Assemble the guide by inserting the guide ends into the handle (Figure 10a).
- 2. Adjust the guide to the approximate length of the plate by depressing the release button on the top of the plate.
- 3. Attach the plate to the guide by inserting the plate between the flanges on the drill guide (Figure 10b).
- 4. Tighten the drill guide/plate assembly by expanding the arms while attached to the plate.





Figure 10a

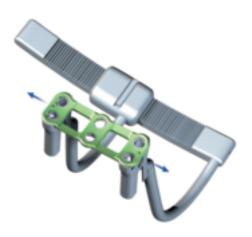


Figure 10b



Figure 10c



Figure 10d

- 5. Place plate as previously noted and insert drill or awl, advancing fully to the positive stop (Figure 10c).
- 6. Attach screws to the self-retaining driver and insert through the drill guide into the prepared screw site. Screw progress will be visible through the windows in the guide. Advance the screw until resistance is felt, do not tighten fully. Repeat awl or drill/screw insertion for the remaining screws, alternating between opposite corners of the plate (Figure 10d).
- 7. Remove the four-barrel drill guide by depressing the thumb-latch to loosen the tension. For three- and four-level plates the single- or double-barrel guides may be used on the remaining segments.
- 8. Tighten all screws. Proper tightening is achieved by applying axial force and slowly turning the driver until the screw head engages the bushing taper.

EAGLE Plus Plate Removal



Figure 11

Items Needed:

- EAGLE Plus/SWIFT Plus Instrument Set.
- The standard screwdriver should be used for revisions.

A screw removal tool is included for use in the event the screw does not disengage when using the standard screwdriver.

The screw removal tool tip should be in good condition. A worn out tip should be inspected and replaced prior to surgery.

Prepare Screw Head

Thoroughly clean out the inside of the screw head and bushing notch (Figure 11).

EAGLE Plus Screw Removal

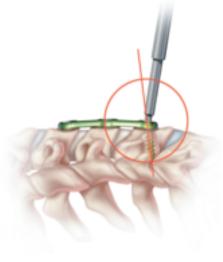


Figure 12a - Incorrect

Figure 12b - Correct

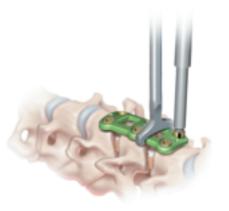


Figure 13

Screw Removal

Using Standard Screwdriver

- Insert the tip of the standard screwdriver and align into the head of the screw.
- The shaft of the standard screwdriver must be aligned with the screw shaft; see figures 12a and 12b for proper alignment.
 Turn the driver counter-clockwise until the screw is disengaged from the bushing.

Disengage the screw that is diagonal from the first loosened screw. Followed by all remaining screws. After all screws have been disengaged from the bushings, back each out slowly until removed.

Note: The anti-torque device may be used as shown to hold the plate in place during screw removal (Figure 13).



Screw Removal

Using the Screw Removal Tool

If the screw does not back out using the standard screwdriver, typically observed as the screw spinning without disengaging from the bushing, use the screw removal tool provided in the set.

Insert the tip of the screw removal tool into the drive feature of the screw until fully seated and the shaft of the screw removal tool is aligned with the axis of the screw (Figure 14a).

Turn the screw removal tool inner shaft clockwise until it fully engages the thread at the base of the hex lobe drive feature (Figure 14b).

Note: The screw removal tool consists of the threaded driver (2865-60-000) and the removal driver sheath (2865-60-200).





Screw removal tool assembly



Lower the screw removal tool outer sheath by turning it clockwise until it touches the plate (Figure 14c).

Hold the outer sheath while turning the screw removal tool handle counter-clockwise until the screw is successfully disengaged from the plate (Figure 14d).

To disengage the screw removal tool from the screw, turn the inner shaft counter-clockwise.



EAGLE Plus Ordering Information





Part Number	Description	Size
1836-50-010	Self-Drilling	10mm
1836-50-012	Self-Drilling	12mm
1836-50-014	Self-Drilling	14mm
1836-50-016	Self-Drilling	16mm
1836-50-018	Self-Drilling	18mm

Primary Self-Tapping Screw (4.25mm)



Part Number	Description	Size
1836-56-010	Self-Tapping	10mm
1836-56-012	Self-Tapping	12mm
1836-56-014	Self-Tapping	14mm
1836-56-016	Self-Tapping	16mm
1836-56-018	Self-Tapping	18mm

Large Diameter Self-Tapping Screw (4.4mm)



Part Number	Description	Size
1836-51-010	Self-Tapping	10mm
1836-51-012	Self-Tapping	12mm
1836-51-014	Self-Tapping	14mm
1836-51-016	Self-Tapping	16mm
1836-51-018	Self-Tapping	18mm

EAGLE Plus Ordering Information



One-Level Plates

Part Number	Description	Size*
1836-11-012	One-Level	12mm
1836-11-014	One-Level	14mm
1836-11-016	One-Level	16mm
1836-11-018	One-Level	18mm
1836-11-020	One-Level	20mm
1836-11-022	One-Level	22mm
1836-11-024	One-Level	24mm
1836-11-026	One-Level	26mm



Two-Level Plates

Part Number	Description	Size*
1836-12-028	Two-Level	28mm
1836-12-030	Two-Level	30mm
1836-12-032	Two-Level	32mm
1836-12-034	Two-Level	34mm
1836-12-036	Two-Level	36mm
1836-12-038	Two-Level	38mm
1836-12-040	Two-Level	40mm
1836-12-042	Two-Level	42mm

^{*} Plates are measured hole-to-hole. For end-to-end plate measurement, add 8.2mm



Three-Level Plates

Part Number	Description	Size*
1836-13-042	Three-Level	42mm
1836-13-045	Three-Level	45mm
1836-13-048	Three-Level	48mm
1836-13-051	Three-Level	51mm
1836-13-054	Three-Level	54mm
1836-13-057	Three-Level	57mm
1836-13-060	Three-Level	60mm
1836-13-063	Three-Level	63mm

Four-Level Plates

Part Number	Description	Size*
1836-14-060	Four-Level	60mm
1836-14-064	Four-Level	64mm
1836-14-068	Four-Level	68mm
1836-14-072	Four-Level	72mm
1836-14-076	Four-Level	76mm
1836-14-080	Four-Level	80mm
1836-14-084	Four-Level	84mm

^{*} Plates are measured hole-to-hole. For end-to-end plate measurement, add 8.2mm

EAGLE Plus Instrument Ordering Information



Drill Guides

Part Number	Description	
2865-15-000	Double-Barrel Drill Guide	
2865-20-000	Four-Barrel Drill Guide	
2865-21-000	Single-Barrel Drill Guide	
2865-25-000	Retractor Drill Guide	



Part Number	Description
2865-01-000	Fixed Depth Awl
2865-19-000	Freehand Tap
2865-18-012	12mm Fixed Depth Drill (A0)
2865-18-014	14mm Fixed Depth Drill (A0)
2865-18-016	16mm Fixed Depth Drill (A0)
2865-18-112	12mm Fixed Depth Drill (Jacobs)
2865-18-114	14mm Fixed Depth Drill (Jacobs)
2865-18-116	16mm Fixed Depth Drill (Jacobs)
2865-22-000	Jeweler's Handle



Drivers

Part Number	Description
2865-09-000	Standard Screwdriver
2865-60-000	Threaded Driver (Contains Threaded Driver Inner Shaft)
2865-60-200	Removal Driver Sheath
2865-61-000	Threaded Driver Inner Shaft
2865-68-500	Spring Tip Pencil Grip Driver

Note: The screw removal tool consists of the threaded driver (2865-60-000) and the removal driver sheath (2865-60-200).



Temporary Fixation Pins (TFP)

Part Number	Description
2865-65-001	TFP Threaded
2865-65-000	TFP Straight
2868-50-000	TFP Inserter

Other

Part Number	Description
2865-04-000	Rigid Bender
2865-06-000	Plate Holder
2865-03-000	Caliper

Cases and Trays

Part Number	Description	
2865-70-001	EAGLE Plus Plate Caddy	
2865-70-604	Screw Caddy	
2865-70-000	Case & Trays (no caddies)	





Other DePuy Spine cervical brands:









INDICATIONS

The EAGLE Plus Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

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