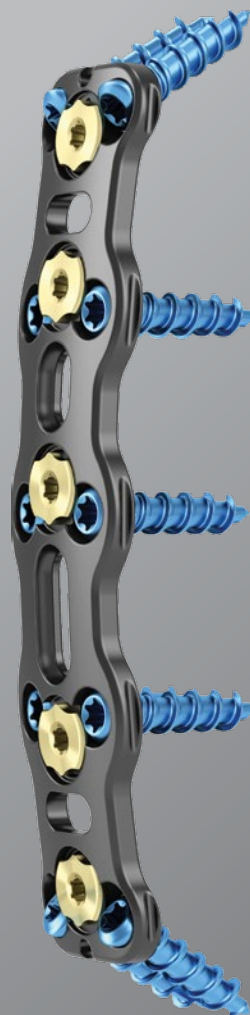


Zevo[®]

Anterior Cervical Plate System

Surgical Technique

VERSATILITY
MATTERS



Medtronic



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IMPLANT OVERVIEW

Plate Dimensions

Lengths:

- 1 level: 15 – 29mm
- 2 level: 27 – 51mm
- 3 level: 43 – 71mm
- 4 level: 65 – 89mm
- 5 level: 77 – 108mm

Thickness:

- 1, 2, and 3 level plates: 1.9mm
- 4 and 5 level plates: 2.1mm

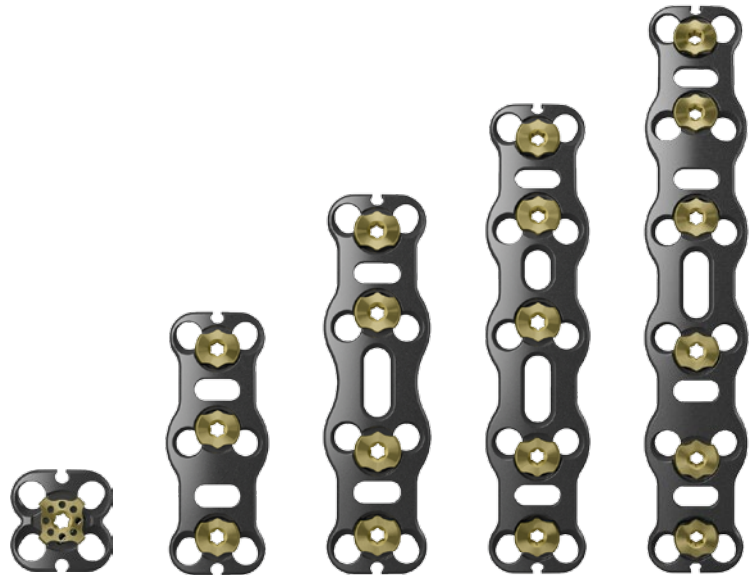
Width:

- Distal Screw Holes: 15mm
- Intermediate Screw Holes: 16mm
- Neck: 12mm

Lock: Visual, Tactile, Rotational

Visualization Windows
(*certain sizes excluded)

Central Screw Slots (3, 4, & 5 level plates)



Screw Dimensions

Diameters:

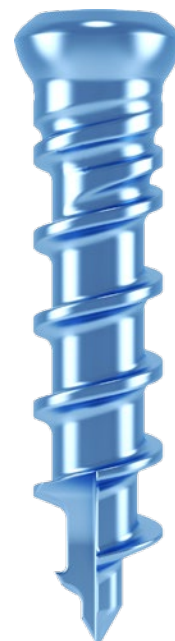
- Bone Screw: 3.5mm and 4.0mm
Lengths: 13mm, 15mm, and 17mm
(*other sizes available as extras)
- Slot Screw: 4.5mm
Lengths: 13mm and 15mm



Bone Screw



Slot Screw



Cortical Thread

Cancellous Thread

Self-Drilling & Self-Tapping

Dual Thread Design

INSTRUMENT OVERVIEW

Plate Holder



Plate insertion
2030006 Plate Holder

Pre-fixation



Versatile pre-fixation placement and offerings

3030002 Pin Holder

3030003 Pre-fixation Pin

3037000 Pre-fixation Staple (*available as extra)



Guides



Intradiscal drill guide option for pre-drilling screw holes

3031050 5mm Intradiscal Drill Guide

3031060 6mm Intradiscal Drill Guide

3031070 7mm Intradiscal Drill Guide



Single and double barrel variable drill guides

3030004 Single Barrel Variable Drill Guide

3030005 Double Barrel Variable Drill Guide



DTS Guides for 12°, 28°, or intermediate drill, tap, screw insertion

3032012 12° DTS Guide

3032028 28° DTS Guide

3032000 0° Intermediate DTS Guide

Drills, Awl, Screwdriver, Tap



G850000 Universal Handle



7080510 11mm Sterile Drill Bit



Proprietary dual hexalobe T8/T10 screwdriver design

3030007 T8/T10 Screwdriver



3030035 3.5mm Tap



7080906 Awl

POSITIONING, INCISION, EXPOSURE

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis (**Figure 1**). 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 (**Figure 2**).



Figure 1

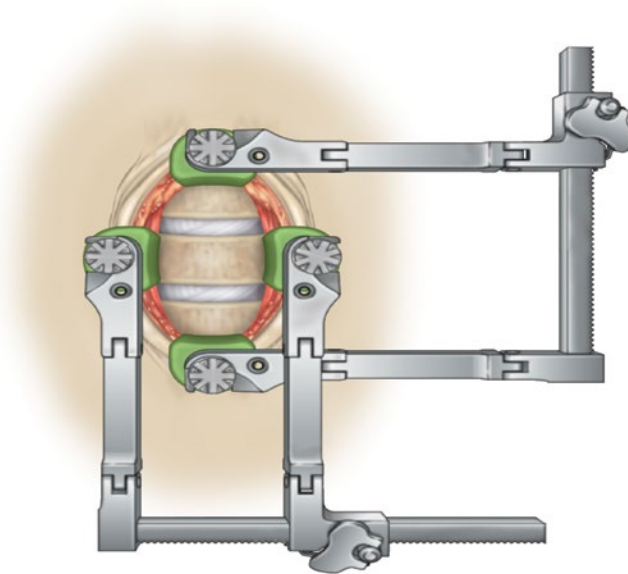


Figure 2

Use standard methods to distract the disc space as needed to complete the decompression.

Note

If the intradiscal drill guide will be used, be sure that appropriate clearance (minimum of 6.4mm) is provided during caspar pin placement to avoid interference between the distraction pins and the drill guide. (**Figure 3**).

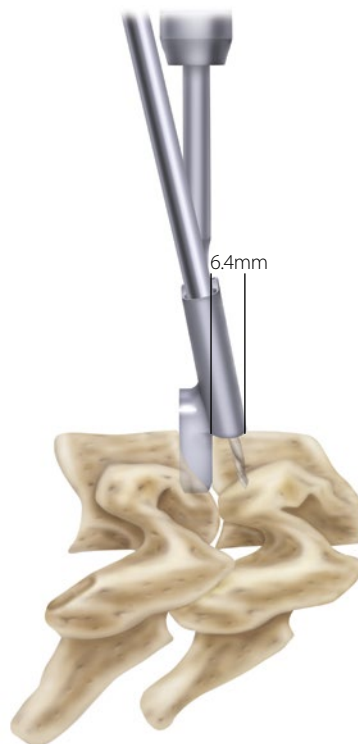


Figure 3

DISCECTOMY, CORPECTOMY AND GRAFT SITE PREPARATION, INTERBODY PLACEMENT

Discectomies are completed at each level. Perform disc excision and spinal decompression using standard surgical techniques (**Figures 4 and 5**).

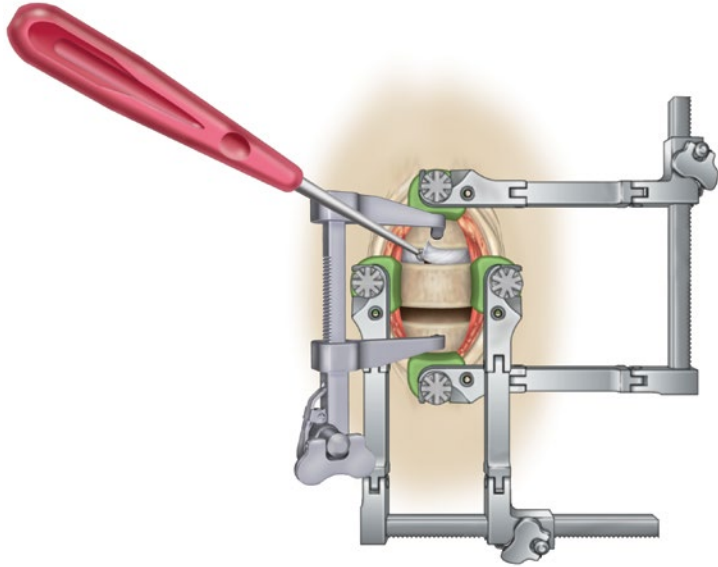


Figure 4

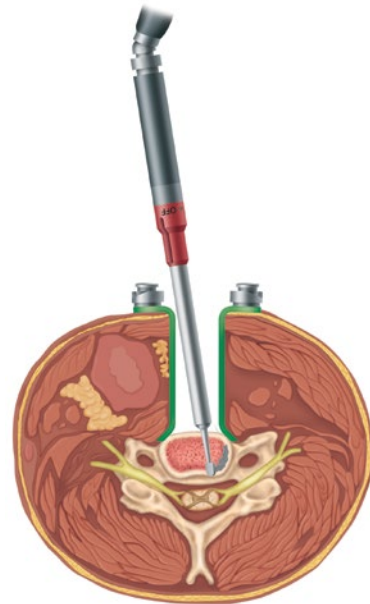


Figure 5

Care should be taken to perform appropriate soft-tissue dissection and to remove anterior osteophytes to provide an optimal bone-plate interface.

After the discs have been removed, trial for and Insert the appropriate interbody spacer.

If necessary, a corpectomy or partial corpectomy may be done to further decompress the spine.

Note

If utilizing the intradiscal drill guide, see next step prior to interbody trialing and placement.

OPTIONAL: INTRADISCAL DRILL GUIDE

Soft-tissue and anterior osteophytes are removed from the adjacent vertebral bodies so the guide sits evenly on the anterior cortex.

The intradiscal drill guide is designed to place bone screw pilot holes relative to the endplate surface at a 12° or 28° trajectory. The intent of this tool is to maximize the distance between the end of the plate and the adjacent disc space.

Once graft site preparation is complete, choose the size of the intradiscal drill guide that best matches that patient disc space (**Figure 6 and 7**). The intradiscal portion of the guide is used only for securing the guide in the disc space while drilling and is not meant to act as a trial for the interbody size. Trialing for the interbody size should be accomplished according to the surgical instructions supplied with the interbody of choice. Once the size has been chosen, select the desired screw angle and insert into the disc space. Finally, drill cranial (or caudal) bone screw holes.

Note

Only one vertebral body is drilled to accommodate final interbody and plate length combinations.



Figure 6



Figure 7

PLATE LENGTH SELECTION

Soft tissue and anterior osteophytes are removed from the adjacent vertebral bodies so the plate sits evenly on the anterior cortex (**Figure 8**). Fluoroscopy may be used to determine the appropriate plate length and anticipated screw trajectories. The plate may be further contoured with the Plate Bender to match the lordotic curve of the anterior cervical spine.

Note

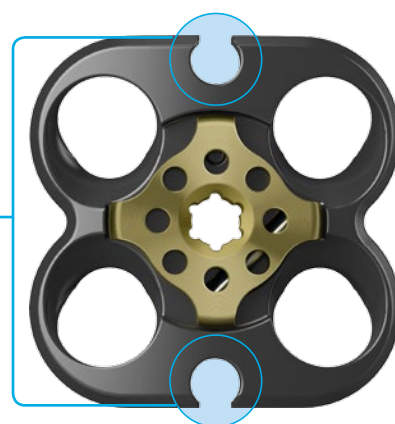
The combination of larger screw angles and short plate size options offer the surgeon the ability to minimize the potential encroachment of the plate to the adjacent level disc space.

Note

When using single level; plates, please note the the fixation pin feature denotes the cephalad/caudal orientation of the plate (**Figure 9**).



Figure 8



Fixation Pin
Feature

Figure 9

PLATE CONTOURING

The Zevo Anterior Cervical Plate is provided with a pre-machined lordotic curve (**Figure 10**). 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 the amount of lordotic curvature (**Figure 11**) or decrease the amount of lordotic curvature (**Figure 12**) by using

the Plate Bender. A gradual bend should be made and abrupt changes in curvature should be avoided. Bending of the plate in the region of the lock will weaken the plate or prevent proper actuation of the locking mechanism.



Figure 10

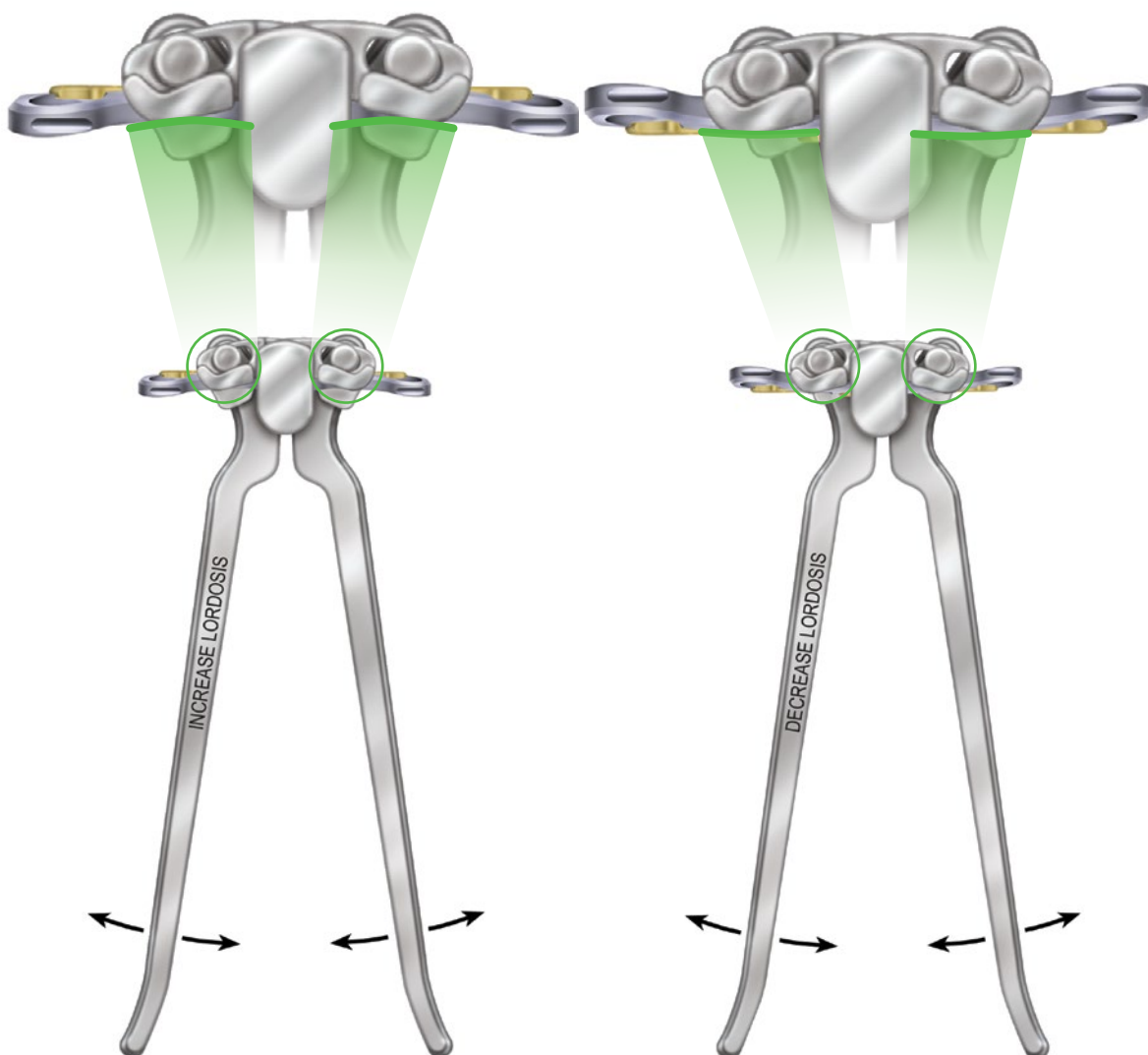


Figure 11

Figure 12

PLATE HOLDER

The Plate Holder can be used to grasp the plate on any edge. This instrument was designed with curved indentations that allow for variability in plate holding position (**Figure 13a and 13b**). After determining the appropriate length plate, use the Plate Holder to place and position the plate (**Figure 14**).

Figure 13a

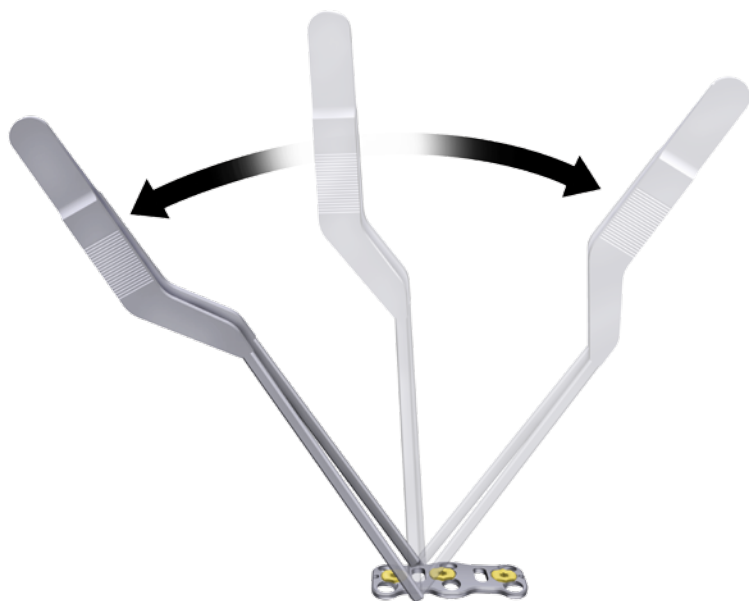
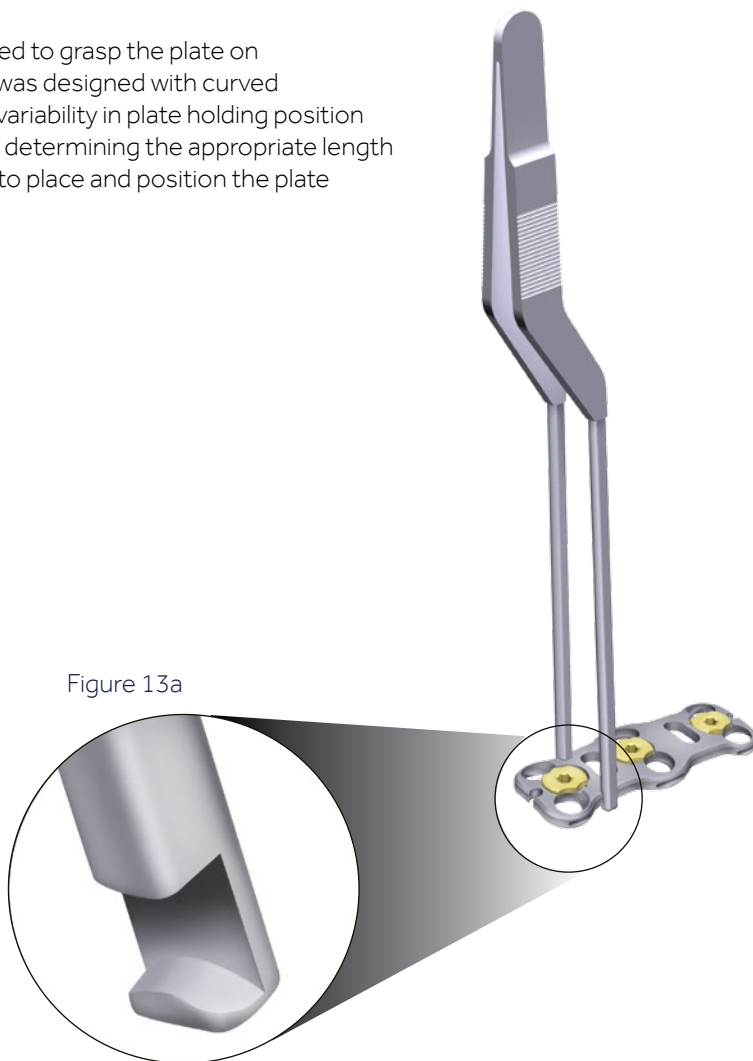


Figure 13b

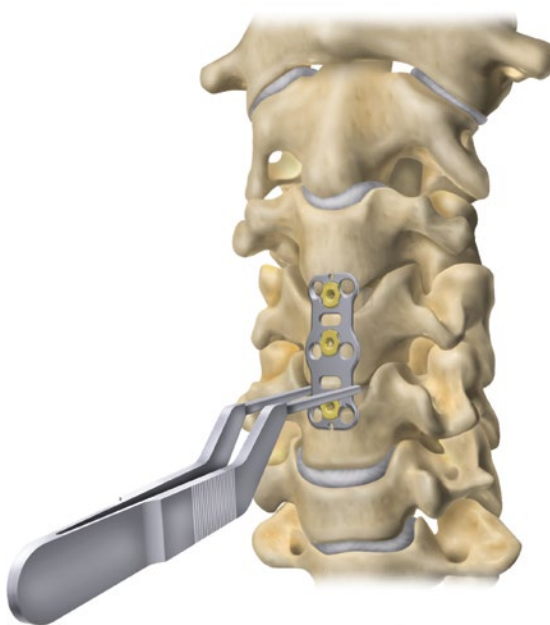


Figure 14

PLATE POSITIONING AND TEMPORARY PLATE FIXATION

Review anatomical landmarks to ensure the plate is centered laterally on the spine. After the plate length has been selected and placed on the anterior surface of the cervical spine, the threaded Plate Holding Pin can be placed into any of the bone screw holes, distal indentations, and/or the locking cap to provide temporary fixation while drilling and placing bone screws (**Figure 15**). Use caution not to turn the locking cap when seating the Holding Pin. This could preclude the screws from being inserted.

Drive the sharp tip of the pin into the bone until the dorsal portion of the pin is flush with the plate (**Figure 16**). Alternatively, the pre-fixation staple can be used as temporary fixation by inserting the staple into the adjacent screw holes at any level. The instrument set includes a plate holding pin driver to facilitate pin and staple insertion. To engage the pre-fixation options, pull the flange on the shaft of the driver toward the handle. Place over the pre-fixation pin and release the flange to engage the pin (**Figure 17**).

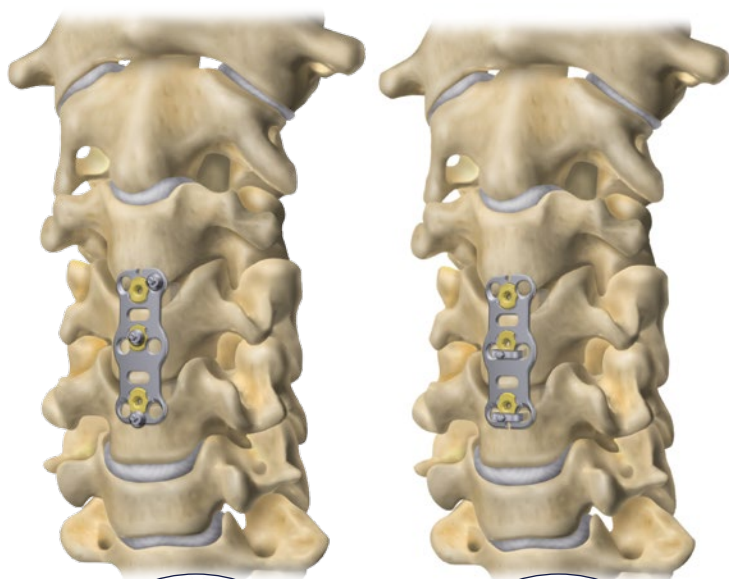


Figure 15

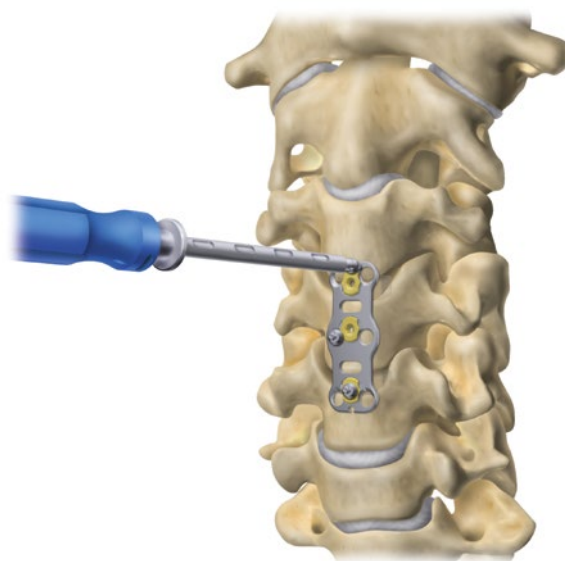


Figure 16

Note

The distal indentations are designed to fully capture the pre-fixation pins thus preventing translation of the plate on the vertebral body.

Note

The pre-fixation staple was designed to minimize rotation and migration of the plate. (Available as special order only)



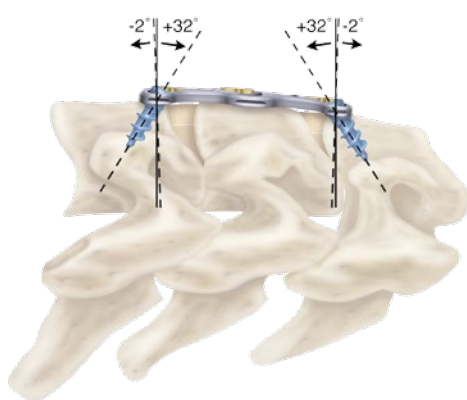
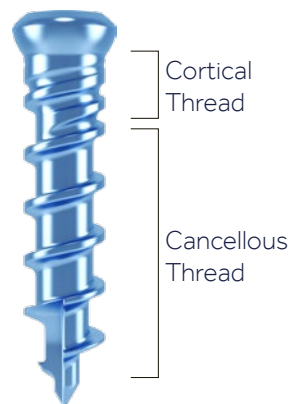
Figure 17

CONSTRUCT OPTIONS

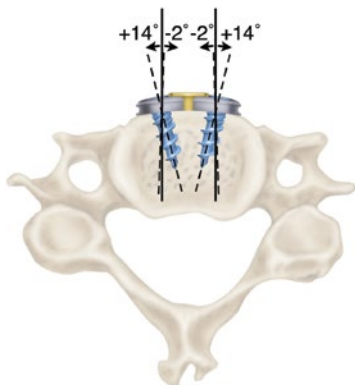
System Capabilities

The Zevo Anterior Cervical Plate System offers surgeons the versatility to place their screws at additional angulations into the vertebral bodies. The system offers both self-tapping and self-drilling screws options. The system screw incorporates a dual thread screw pattern designed to maximize interface with cortical and cancellous bone. A slot screw is also available for intermediate vertebral body or graft fixation through the central slots.

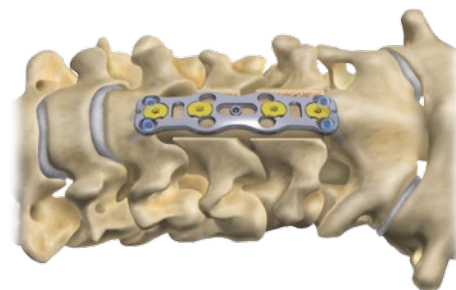
Figures below show just a few options for screw placement.



-2° to 32° Screw Angulations



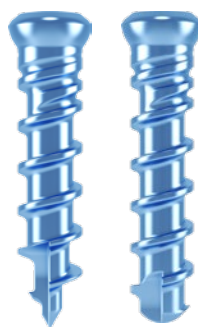
14° to -2° Screw Angulations



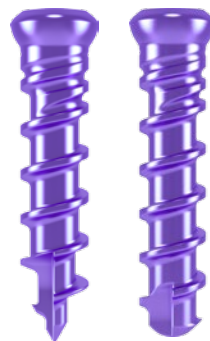
Slot Screw

Screw Options

- Color-coded by diameter.
- 3.5mm (standard) and 4.0mm (rescue) bone screw diameters.
- Cortical / cancellous dual thread pattern
- 4.5mm slot screw
- T8-T10 dual hexalobe screw head interface.
- 13 to 17mm bone screw lengths, in 2mm increments. (11mm available as extra)
- Self-drilling and self-tapping tip designs.



Light Blue
3.5mm Variable



MAGENTA
4.0mm Variable



GRAY
4.5mm Slot Screw

OPTIONAL BONE SCREW HOLE PREPARATION

An awl can be used to break through the cortex of the vertebral body. The instrument set includes an Awl for screw hole preparation.

- Can be used through the Variable or DTS guides
- Allows for 8mm of bone penetration when used with the guides.

Insert the tri-flat end of the Awl shaft into the Universal Handle. Ensure that the selected guide is securely seated and insert the Awl into the guide. Place downward pressure on the awl to puncture the cortex of the bone (**Figure 18**).

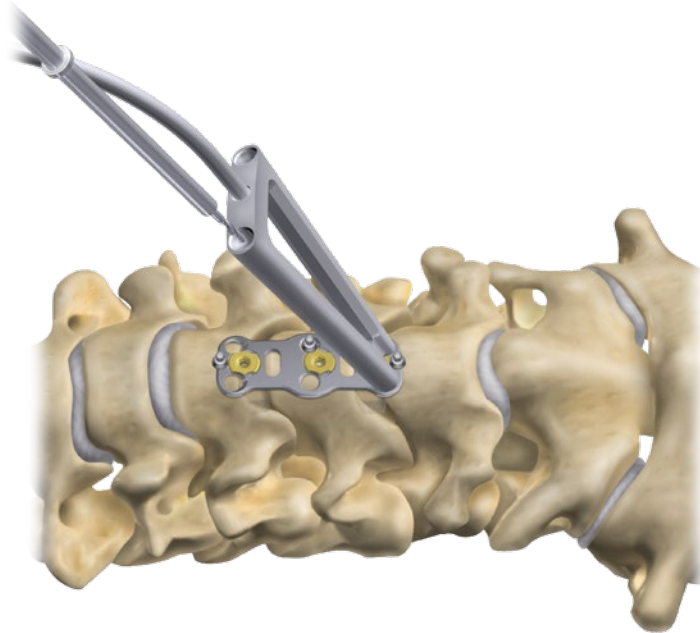


Figure 18

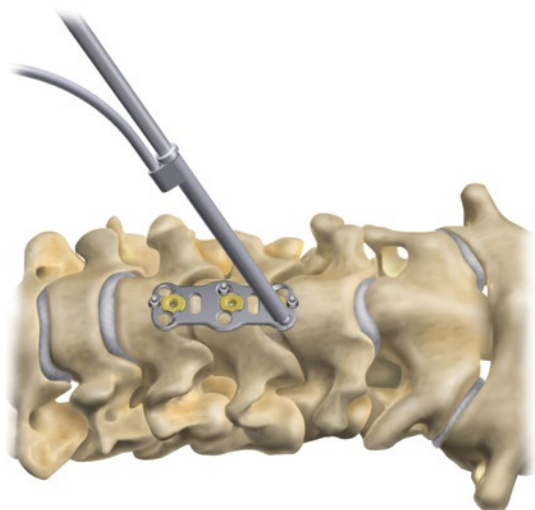
VARIABLE ANGLE SCREW POSITIONING

Variable Drill Guide

Seat the Double or Single Barrel Variable Drill Guide within the bone screw holes on the plate. Securely engage the guide into the plate by applying light downward pressure on the guide handle, aligning the guide at the desired angle within system capabilities (**Figures 19a and 19b**).

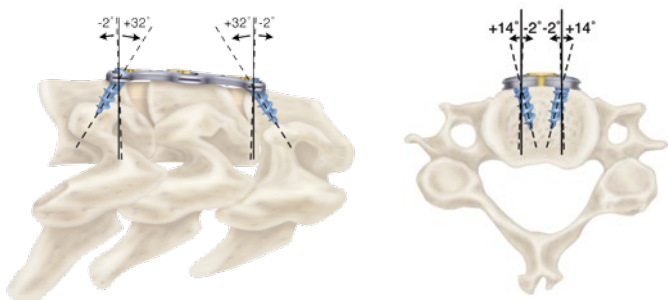
Insert the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the Variable Drill Guide sleeve by rotating the bit clockwise until reaching the stop collar located on the drill bit shaft. The stop collar limits the depth of penetration to 11mm, or 13mm based on the drill bit length selected.

Single Barrel

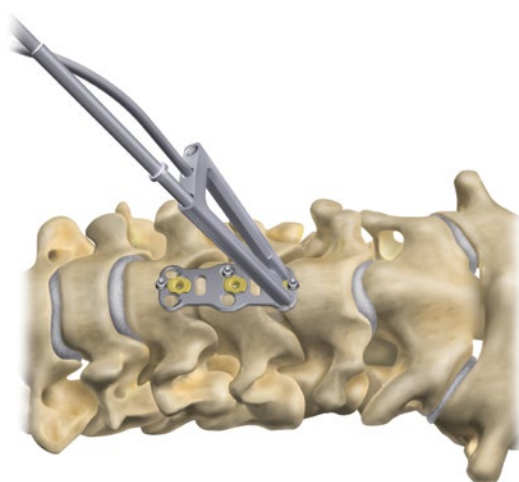


A trajectory of 32° to -2° cephalad or caudal and +14° to -2° medially convergent can be achieved with the single barrel drill guide.

Figure 19a

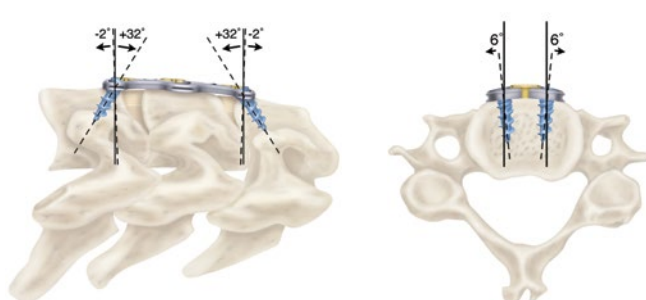


Double Barrel



A trajectory of 32° to -2° cephalad or caudal can be achieved with the variable double barrel drill guide. The medially convergent angles are set at 6°.

Figure 19b



OPTIONAL BONE SCREW HOLE PREPARATION

Drill, Tap, and Screw (DTS) Guides

There is a distal DTS guide for a 12° and 28° cephalad/caudal screw trajectory. The intermediate DTS guide will place the screws at a 0° cephalad/caudal screw trajectory. All of the DTS guides will place the screws at a 6° medially convergent angle.

The 12° and 28° DTS Guides can only be used on the superior and inferior ends of the plate. The Intermediate 0° DTS Guide is used on the intermediate screw holes of the plate.

To attach the DTS Guide, begin with the guide off the distal end of the plate. Place one side of the guide in the side slot on the plate (**Figures 20a and 20b**). Next, twist the opposite side into position. Typically it is easier to attach the DTS Guide when downward pressure is maintained on the guide to keep contact between the guide and the plate.

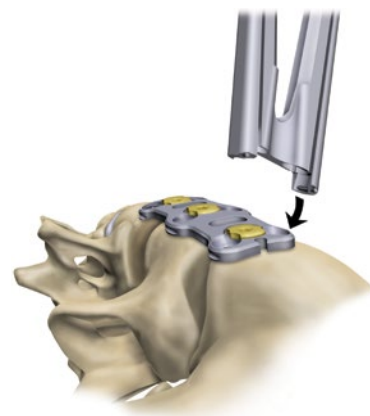


Figure 20a

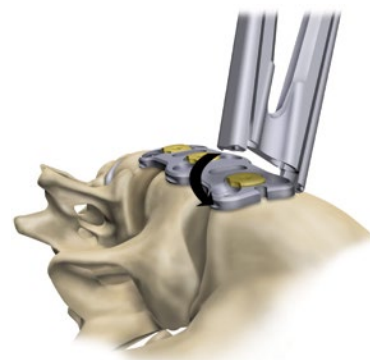
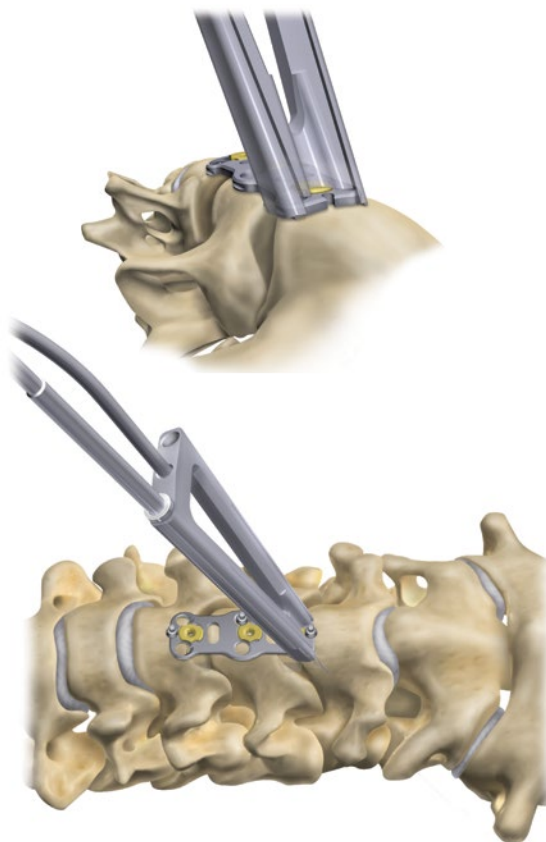


Figure 20b



Drill, Tap, and Screw (DTS) Guides Continued

Insert the tri-flat end of the Drill Bit shaft into the Universal Handle. Advance the bit through the DTS Guide tube by rotating the bit clockwise until reaching the stop collar located on the drill bit shaft.

To remove the DTS guide, a slight twist of the handle will release the plate. **See Figures 21, 22 and 23.**

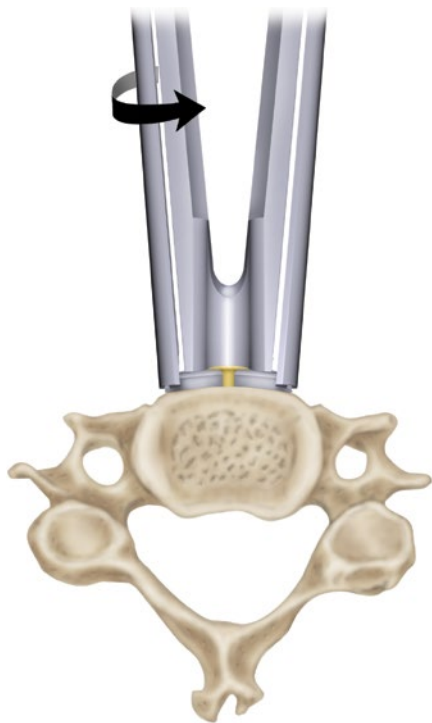


Figure 21

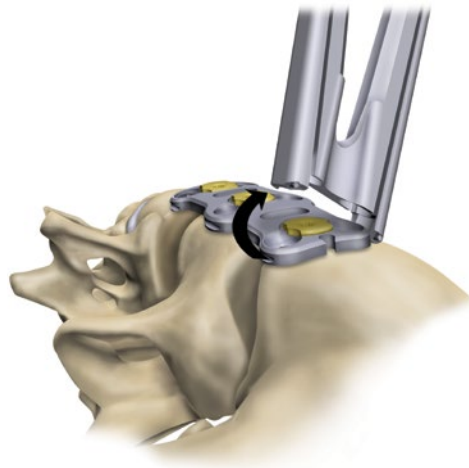


Figure 22

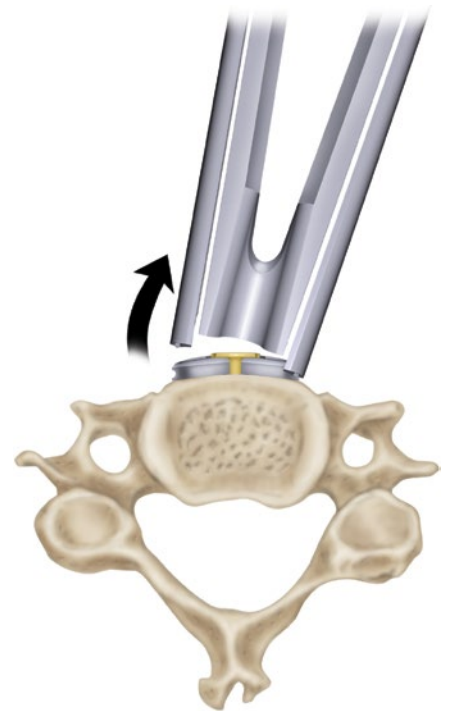


Figure 23

BONE SCREW SELECTION AND INSERTION

Select the appropriate length bone screw. The screw length can be verified using the screw gauge. Insert the tri-flat end of the Screwdriver shaft into the Universal Handle. The screwdriver incorporates a dual hexalobe design that allows for a secure, self-retaining fit between the bone screw and screwdriver (Figures 24a, 24b, 25 and 26).

Using the driver to pick up the bone screw, insert the screw tip into the previously prepared bone screw hole. Applying moderate to light pressure, provisionally advance the bone screw by rotating the Screwdriver clockwise until the screw head is loosely seated in the plate.

After inserting all of the bone screws, final tightening is done sequentially, so that the plate is evenly and firmly applied to the anterior surface of the vertebrae.

If additional fixation is necessary, the 3, 4 and 5 level plates have a central slot designed to be specifically used with the slot screw. Screw back-out prevention in this slot is accomplished by an interference between the screw and the side walls of the slots. Thus, it is recommended that the screws be placed roughly perpendicular to the plate for the best screw security (Figure 27).

Note

This system allows the screws to be placed up to 32° cephalad or caudad at the ends of the plate. Care should be taken to avoid penetration of the adjacent endplate, especially when using longer screws.

Note

Make sure the T8 and T10 tips of the Driver are fully seated inside the Bone Screw head before tightening. Failure to fully seat both the T8 tip and the T10 tip before rotating the Driver to advance the screw may result in stripping.



Figure 24a



Figure 24b
Axial Head of Screw

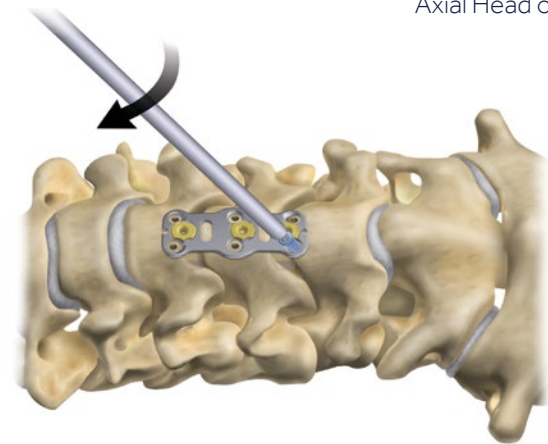


Figure 26

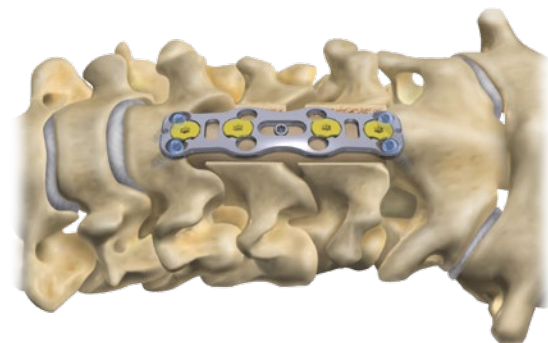


Figure 27

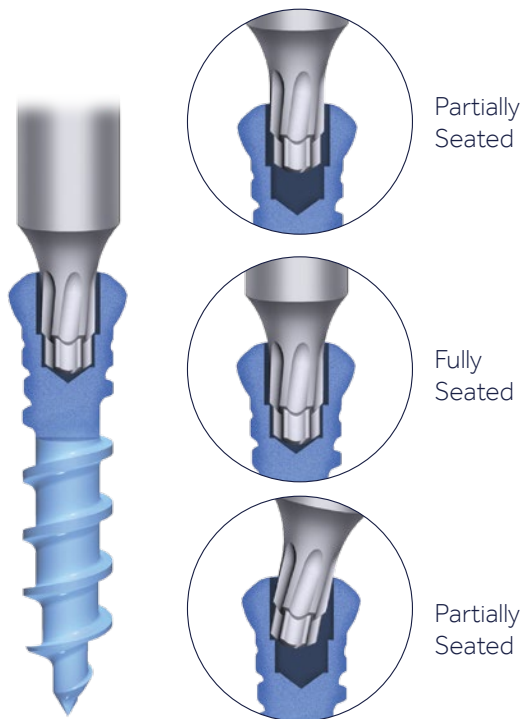


Figure 25

LOCKING THE BONE SCREWS

Locking Mechanism

The Zevo Anterior Cervical Plate System includes an attached locking cap mechanism. The lock detail has a visual and tactile confirmation that indicates the lock is rotated over the head of the screws. Avoid turning the locking cap counterclockwise as this can damage the locking mechanism.

The same screwdriver used for screw insertion can be used to engage the locking cap mechanism. Insert the tip portion of the screwdriver into the head of the locking cap and rotate until the cap covers both screw heads and a tactile confirmation is felt (Figure 28).

The locking cap should require minimal force to properly position.

If the locking cap does not easily rotate and cover both screw heads, check to make sure that the screws are fully seated.

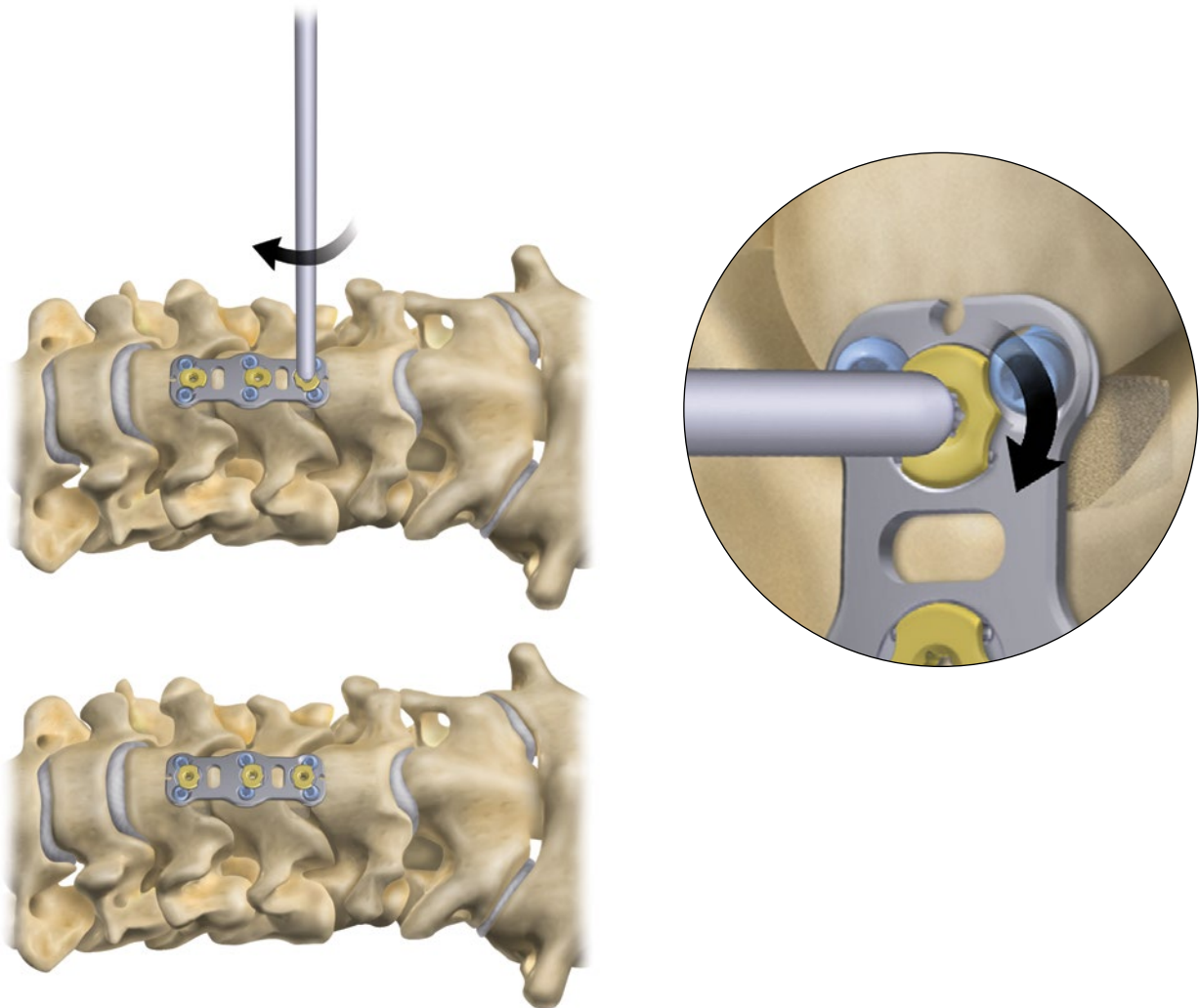


Figure 28

EXPLANTATION AND PROCEDURAL PEARLS

Explantation

Using the T8-T10 hexalobe screwdriver, rotate the locking caps counterclockwise to uncover the screw heads (**Figure 29**).

Using the same screwdriver, loosen and extract all the screws and then remove the plate.

A 2.0mm screw removal tool can be used to both disengage the lock and explant the screws if necessary. The tip of the screw removal tool is inserted into the head of the screw and rotated counter clockwise.

Slot Screw: a slot screw removal tool can be used to facilitate if necessary.

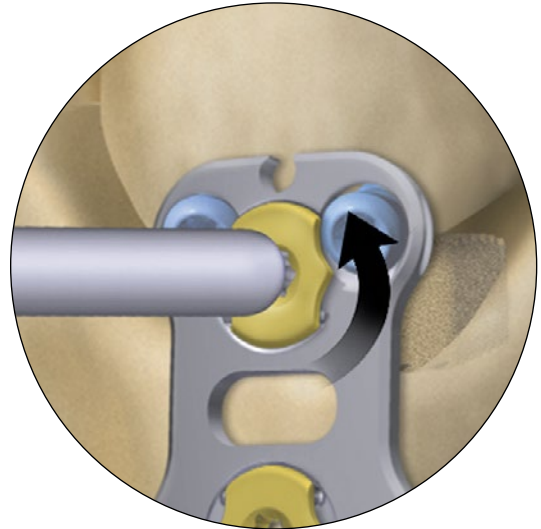


Figure 29

Procedural Pearls

- Use Plate Holding Pins through the cannulated locking cap to provide temporary midline fixation of the plate without interfering with bone screw insertion. Use caution not to turn the locking cap while seating the holding pin against the cap. This could preclude the screws from being inserted.
- Plate Holding Pins through the distal indentation to provide temporary midline fixation of the plate without interfering with bone screw insertion and preventing plate migration.
- Use pre-fixation staple to provide temporary fixation, thus preventing rotation and migration of the plate.
- When placing screws, partially advance one screw into the inferior end of the plate. Repeat with a second screw contralaterally in the superior end of the plate. Confirm plate placement and make any necessary adjustments. Once confirmed, partially insert remaining screws, alternating the advancement incrementally to avoid plate migration.
- Engage the locking mechanism with a clockwise motion using minimal force. Applying excessive torque or turning the lock counter-clockwise will damage the mechanism.
- If the locking cap will not close over bone screws, ensure that the bone screws are fully seated and then lock the cap.
- When using Ø4.0mm Rescue Screws, Ensure that proper drill guides are used to minimize insertion resistance.
- Make sure the T8 and T10 tips of the Driver are fully seated inside the Bone Screw head before tightening. Failure to fully seat both the T8 tip and the T10 tip before rotating the Driver to advance the screw may result in stripping.

PRODUCT ORDERING INFORMATION

Degenerative Self-Drilling - Set SPS02645

Category	CFN	Description	Qty in Set	Category	CFN	Description	Qty in Set
1 M Plates	3001015	PLATE 3001015 Zevo 15mm, 1 LVL	1	Screws	7713513	3.5 Self-Drilling Screw 13mm Variable	8
	3001017	PLATE 3001017 Zevo 17mm, 1 LVL	1		7713515	3.5 Self-Drilling Screw 15mm Variable	8
	3001019	PLATE 3001019 Zevo 19mm, 1 LVL	1		7713517	3.5 Self-Drilling Screw 17mm Variable	8
	3001021	PLATE 3001021 Zevo 21mm, 1 LVL	1		7714013	4.0 Self-Drilling Screw 13mm Variable	4
	3001023	PLATE 3001023 Zevo 23mm, 1 LVL	1		7714015	4.0 Self-Drilling Screw 15mm Variable	4
	3001025	PLATE 3001025 Zevo 25mm, 1 LVL	1		7714017	4.0 Self-Drilling Screw 17mm Variable	2
	3001027	PLATE 3001027 Zevo 27mm, 1 LVL	1		7710013	4.5 Slot Screw 13mm Variable	2
	3001029	PLATE 3001029 Zevo 29mm, 1 LVL	1		7710015	4.5 Slot Screw 15mm Variable	2
2 M Plates	3002027	PLATE 3002027 Zevo 27mm, 2 LVL	1	Instr.	7730913	Screw Gauge	1
	3002029	PLATE 3002029 Zevo 29mm, 2 LVL	1		G850000	Tri-Flat Quick Connect Fixed Inline Handle	2
	3002031	PLATE 3002031 Zevo 31mm, 2 LVL	1		3030003	Plate Holding Pin	3
	3002033	PLATE 3002033 Zevo 33mm, 2 LVL	1		3030002	Holding Pin Driver	1
	3002035	PLATE 3002035 Zevo 35mm, 2 LVL	1		7080906	Awl	1
	3002037	PLATE 3002037 Zevo 37mm, 2 LVL	1		3030007	Screw Driver	2
	3002039	PLATE 3002039 Zevo 39mm, 2 LVL	1		2030006	Plate Holder	1
	3002041	PLATE 3002041 Zevo 41mm, 2 LVL	1		3030004	Variable Single Barrel Drill Guide	1
	3002043	PLATE 3002043 Zevo 43mm, 2 LVL	1		3030005	Variable Double Barrel Drill Guide	1
	3002045	PLATE 3002045 Zevo 45mm, 2 LVL	1		3030008	Plate Bender	1
	3002048	PLATE 3002048 Zevo 48mm, 2 LVL	1		3031050	5mm Intradiscal Guide	1
	3002051	PLATE 3002051 Zevo 51mm, 2 LVL	1		3031060	6mm Intradiscal Guide	1
3 M Plates	3003043	PLATE 3003043 Zevo 43mm, 3 LVL	1		3031070	7mm Intradiscal Guide	1
	3003045	PLATE 3003045 Zevo 45mm, 3 LVL	1		3036024	Set Screw Removal Tool	1
	3003048	PLATE 3003048 Zevo 48mm, 3 LVL	1		3030035	3.5 Tap	1
	3003051	PLATE 3003051 Zevo 51mm, 3 LVL	1		3030010	Slot Screw Removal Tool	1
	3003053	PLATE 3003053 Zevo 53mm, 3 LVL	1	Case/Trays	3036015R	Self-Drilling Screw Caddy	1
	3003055	PLATE 3003055 Zevo 55mm, 3 LVL	1		3036016	Self-Drilling Screw Caddy Lid	1
	3003057	PLATE 3003057 Zevo 57mm, 3 LVL	1		1850079	Generic Lid	1
	3003059	PLATE 3003059 Zevo 59mm, 3 LVL	1		1850078	Generic Base	1
	3003061	PLATE 3003061 Zevo 61mm, 3 LVL	1		3036011	Label	2
	3003063	PLATE 3003063 Zevo 63mm, 3 LVL	1		3036012	Upper Tray	1
	3003065	PLATE 3003065 Zevo 65mm, 3 LVL	1		3036001	Lower Tray	1
	3003068	PLATE 3003068 Zevo 68mm, 3 LVL	1		3036004	Plate Holding Pin Caddy	1
	3003071	PLATE 3003071 Zevo 71mm, 3 LVL	1		3036005	Plate Holding Pin Caddy Lid	1
					3036013	Plate Caddy	1
					3036014	Plate Caddy Lid	1

Degenerative Self-Tapping - Set SPS02646

Category	CFN	Description	Qty in Set	Category	CFN	Description	Qty in Set
1 lvl Plates	3001015	PLATE 3001015 Zevo 15mm, 1 LVL	1	Screws	7713513	3.5 Self-Drilling Screw 13mm Variable	8
	3001017	PLATE 3001017 Zevo 17mm, 1 LVL	1		7713515	3.5 Self-Drilling Screw 15mm Variable	8
	3001019	PLATE 3001019 Zevo 19mm, 1 LVL	1		7713517	3.5 Self-Drilling Screw 17mm Variable	8
	3001021	PLATE 3001021 Zevo 21mm, 1 LVL	1		7714013	4.0 Self-Drilling Screw 13mm Variable	4
	3001023	PLATE 3001023 Zevo 23mm, 1 LVL	1		7714015	4.0 Self-Drilling Screw 15mm Variable	4
	3001025	PLATE 3001025 Zevo 25mm, 1 LVL	1		7714017	4.0 Self-Drilling Screw 17mm Variable	2
	3001027	PLATE 3001027 Zevo 27mm, 1 LVL	1		7710013	4.5 Slot Screw 13mm Variable	2
	3001029	PLATE 3001029 Zevo 29mm, 1 LVL	1		7710015	4.5 Slot Screw 15mm Variable	2
2 lvl Plates	3002027	PLATE 3002027 Zevo 27mm, 2 LVL	1	Instr.	7730913	Screw Gauge	1
	3002029	PLATE 3002029 Zevo 29mm, 2 LVL	1		G850000	Tri-Flat Quick Connect Fixed Inline Handle	2
	3002031	PLATE 3002031 Zevo 31mm, 2 LVL	1		3030003	Plate Holding Pin	3
	3002033	PLATE 3002033 Zevo 33mm, 2 LVL	1		3030002	Holding Pin Driver	1
	3002035	PLATE 3002035 Zevo 35mm, 2 LVL	1		7080906	Awl	1
	3002037	PLATE 3002037 Zevo 37mm, 2 LVL	1		3030007	Screw Driver	2
	3002039	PLATE 3002039 Zevo 39mm, 2 LVL	1		2030006	Plate Holder	1
	3002041	PLATE 3002041 Zevo 41mm, 2 LVL	1		3030004	Variable Single Barrel Drill Guide	1
	3002043	PLATE 3002043 Zevo 43mm, 2 LVL	1		3030005	Variable Double Barrel Drill Guide	1
	3002045	PLATE 3002045 Zevo 45mm, 2 LVL	1		3030008	Plate Bender	1
	3002048	PLATE 3002048 Zevo 48mm, 2 LVL	1		3031050	5mm Intradiscal Guide	1
	3002051	PLATE 3002051 Zevo 51mm, 2 LVL	1		3031060	6mm Intradiscal Guide	1
3 lvl Plates	3003043	PLATE 3003043 Zevo 43mm, 3 LVL	1		3031070	7mm Intradiscal Guide	1
	3003045	PLATE 3003045 Zevo 45mm, 3 LVL	1		3036024	Set Screw Removal Tool	1
	3003048	PLATE 3003048 Zevo 48mm, 3 LVL	1		3030035	3.5 Tap	1
	3003051	PLATE 3003051 Zevo 51mm, 3 LVL	1		3030010	Slot Screw Removal Tool	1
	3003053	PLATE 3003053 Zevo 53mm, 3 LVL	1	Case/Trays	3036017R	Self-Tapping Screw Caddy	1
	3003055	PLATE 3003055 Zevo 55mm, 3 LVL	1		3036018	Self-Tapping Screw Caddy Lid	1
	3003057	PLATE 3003057 Zevo 57mm, 3 LVL	1		1850079	Generic Lid	1
	3003059	PLATE 3003059 Zevo 59mm, 3 LVL	1		1850078	Generic Base	1
	3003061	PLATE 3003061 Zevo 61mm, 3 LVL	1		3036019	Label	2
	3003063	PLATE 3003063 Zevo 63mm, 3 LVL	1		3036012	Upper Tray	1
	3003065	PLATE 3003065 Zevo 65mm, 3 LVL	1		3036001	Lower Tray	1
	3003068	PLATE 3003068 Zevo 68mm, 3 LVL	1		3036004	Plate Holding Pin Caddy	1
	3003071	PLATE 3003071 Zevo 71mm, 3 LVL	1		3036005	Plate Holding Pin Caddy Lid	1
					3036013	Plate Caddy	1
					3036014	Plate Caddy Lid	1

4 Level Module SPS02647

Category	CFN	Description	Qty in Set
4 lvl Plates	3004065	PLATE 3004065 Zevo 65mm, 4 LVL	1
	3004067	PLATE 3004067 Zevo 67mm, 4 LVL	1
	3004069	PLATE 3004069 Zevo 69mm, 4 LVL	1
	3004071	PLATE 3004071 Zevo 71mm, 4 LVL	1
	3004073	PLATE 3004073 Zevo 73mm, 4 LVL	1
	3004075	PLATE 3004075 Zevo 75mm, 4 LVL	1
	3004078	PLATE 3004078 Zevo 78mm, 4 LVL	1
	3004081	PLATE 3004081 Zevo 81mm, 4 LVL	1
	3004083	PLATE 3004083 Zevo 83mm, 4 LVL	1
	3004086	PLATE 3004086 Zevo 86mm, 4 LVL	1
	3004089	PLATE 3004089 Zevo 89mm, 4 LVL	1
Screws	7713513	3.5 Self-Drilling Screw 13mm Variable	2
	7713515	3.5 Self-Drilling Screw 15mm Variable	2
	7723513	3.5 Self-Tapping Screw 13mm Variable	2
	7723515	3.5 Self-Tapping Screw 15mm Variable	2
Case/Trays	3036020	Caddy	1
	3036021	Caddy Lid	1

Complex 5 Level Module SPS02648

Category	CFN	Description	Qty in Set
5 lvl Plates	3005077	PLATE 3005077 Zevo 77mm, 5 LVL	1
	3005079	PLATE 3005079 Zevo 79mm, 5 LVL	1
	3005081	PLATE 3005081 Zevo 81mm, 5 LVL	1
	3005085	PLATE 3005085 Zevo 85mm, 5 LVL	1
	3005090	PLATE 3005090 Zevo 90mm, 5 LVL	1
	3005095	PLATE 3005095 Zevo 95mm, 5 LVL	1
	3005100	PLATE 3005100 Zevo 100mm, 5 LVL	1
	3005105	PLATE 3005105 Zevo 105mm, 5 LVL	1
	3005108	PLATE 3005108 Zevo 108mm, 5 LVL	1
Screws	7713513	3.5 Self-Drilling Screw 13mm Variable	4
	7713515	3.5 Self-Drilling Screw 15mm Variable	4
	7723513	3.5 Self-Tapping Screw 13mm Variable	4
	7723515	3.5 Self-Tapping Screw 15mm Variable	4
	7723515	3.5 Self-Tapping Screw 15mm Variable	4
Case/Trays	3036022	Caddy	1
	3036023	Caddy Lid	1

DTS Guides SPS02650

Category	CFN	Description	Qty in Set
Instr.	3032012	12° DTS Guide	1
	3032028	28° DTS Guide	1
	3032000	0° Intermediate DTS Guide	1
Case/Trays	3036010	Base	1
	1850094	Lid	1

Sterile Drill Bit SPS02139

Category	CFN	Description	Qty in Set
Instr.	7080510	Sterile Drill Bit, 11mm	1
Case/Trays	9790901	Generic lid Drill	1
	176-530	Generic Base Drill	1

Self-Drilling Screw Module SPS02773

Category	CFN	Description	Qty in Set
Screws	7713513	3.5 Self-Drilling Screw 13mm Variable	6
	7713515	3.5 Self-Drilling Screw 15mm Variable	6
	7713517	3.5 Self-Drilling Screw 17mm Variable	6
	7714013	4.0 Self-Drilling Screw 13mm Variable	2
	7714015	4.0 Self-Drilling Screw 15mm Variable	2
	7714017	4.0 Self-Drilling Screw 17mm Variable	2
Case / Trays	3036015	Caddy 1 Self- Drill	1
	3036016	Caddy 1 Self- Drill Lid	1

Self-Tapping Screw Module SPS02774

Category	CFN	Description	Qty in Set
Screws	7723513	3.5 Self-Tapping Screw 13mm Variable	6
	7723515	3.5 Self-Tapping Screw 15mm Variable	6
	7723517	3.5 Self-Tapping Screw 17mm Variable	6
	7724013	4.0 Self-Tapping Screw 13mm Variable	2
	7724015	4.0 Self-Tapping Screw 15mm Variable	2
	7724017	4.0 Self-Tapping Screw 17mm Variable	2
Case / Trays	3036017	Caddy 2 Self Tap	1
	3036018	Caddy 2 Self Tap lid	1

IMPORTANT PRODUCT INFORMATION

SUMMARY OF IMPORTANT INFORMATION ON THE ZEVO™ Anterior Cervical Plate System

PURPOSE

The ZEVO™ Anterior Cervical Plate System implant components are temporary implants intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the ZEVO™ Anterior Cervical Plate System is via an anterior surgical approach.

DESCRIPTION

The ZEVO™ Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The ZEVO™ Plates include anti-migration caps that cover the heads of the bone screws to reduce the potential for screw back-out. The anti-migration caps are shipped pre-assembled to the plate. The implants are supplied both sterile and non-sterile.

The ZEVO™ Anterior Cervical Plate System implant components are made from titanium alloy, with plates having subcomponents manufactured from Nitinol-NiTi. Stainless steel and titanium implant components must not be used together in a construct.

Do not use ZEVO™ Anterior Cervical Plate System components with components from any other system or manufacturer. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The ZEVO™ Anterior Cervical Plate 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) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

NOTA BENE: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CONTRAINDICATIONS

The ZEVO™ Anterior Cervical Plate System is not intended for posterior surgical implantation.

Contraindications include, but are not limited to:

- Any case needing to mix metals from different components.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case not described in the Indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Fever or leukocytosis.
- Infection local to the operative site.
- Morbid obesity.
- Mental illness.
- Pregnancy.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Signs of local inflammation.
- Suspected or documented metal allergy or intolerance.

Nota Bene: this device system is intended for anterior cervical intervertebral body fusions only. Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

- Atelectasis, ileus, gastritis, herniated nucleus pulposus, and/or retropulsed graft.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Bursitis and tissue damage caused by improper positioning and placement of implants or instruments.
- Cessation of any potential growth of the operated portion of the spine.

- Change in mental status.
- Death.
- Development of respiratory problems (e.g., pulmonary embolism, bronchitis, pneumonia, etc.).
- Disassembly, bending, and/or breakage of any or all of the components.
- Dural tears.
- Dysphagia.
- Early or late loosening of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Inability to perform the activities of daily living.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Infection.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Loss of spinal mobility or function.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Scar formation possibly causing neurological compromise around nerves and/or pain.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The ZEVO™ Anterior Cervical Plate 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 ZEVO™ Anterior Cervical Plate 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. Preoperative planning and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ZEVO™ Anterior Cervical Plate System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. The implants are not prostheses.

A device that has been implanted should never be reused, reprocessed, or resterilized under any circumstances. Implants which have come in contact with the patient are designed for single patient use only. Sterile packaged devices should also never be resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

!USA For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Please contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert for current indications, warnings, precautions and other important medical information.

NOTES

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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