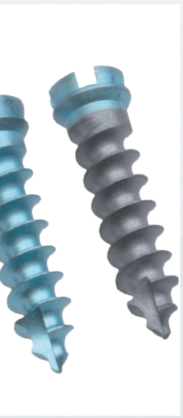
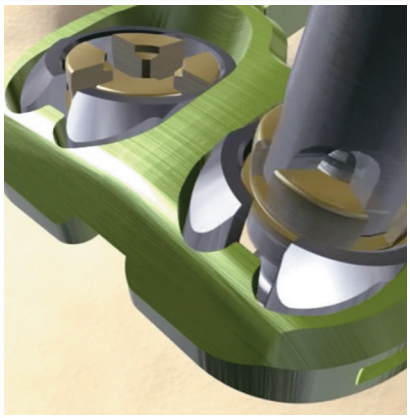
MaxAn®

Anterior Cervical Plate System

Surgical Technique Guide





MICHELSON TECHNOLOGY AT WORK

ZimVie

Designed to Help Minimize the Potential
for Adjacent Level Ossification

Table of Contents

ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

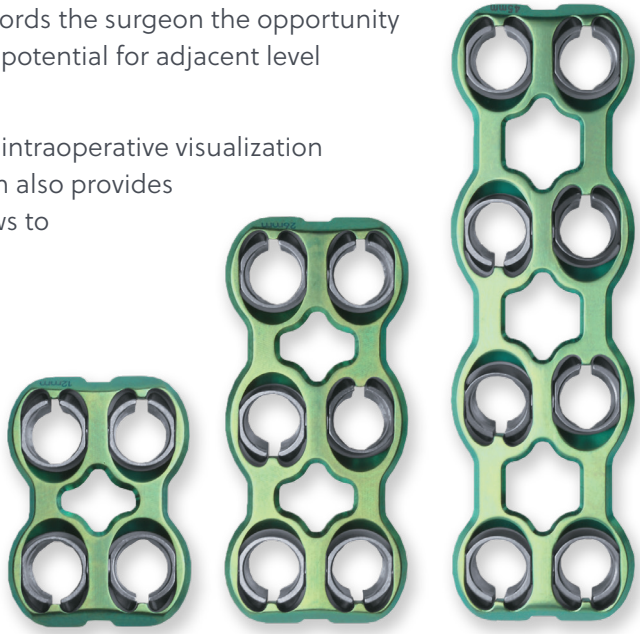
System Overview

The MaxAn Anterior Cervical Plate System provides a simple, efficient and innovative approach to anterior cervical plating. The system offers a decompression-based technique for cervical spine stabilization and introduces an innovative, one-level plate technique that provides a direct relationship between the bone graft/spacer size and the position of the plate holes.

The unique ability to obtain maximum screw angulation and place a fixed screw at any angle up to 30° cephalad on the superior end of the plate and up to 30° caudal on the inferior end of the plate allows for versatile screw placement close to the endplates. Note that the screws converge at 10° in the transverse plane and are not intended to have additional variability in that plane.

The significant cephalad-caudal angulation affords the surgeon the opportunity to choose a smaller plate to help minimize the potential for adjacent level degeneration.

The plate is low profile and allows for excellent intraoperative visualization of the vertebral end plate and graft. The system also provides a choice of fixed and variable self-drilling screws to provide the surgeon with multiple options.



One-Level Two-Level Three-Level

Fixed/Variable 12 mm

Fixed/Variable 14 mm

Fixed/Variable 16 mm

Design Features

The design rationale of the MaxAn System is based on a clinical paper that supports positioning an anterior cervical plate at least 5.0 mm away from the adjacent disc space as a means of avoiding the likelihood of moderate to severe adjacent level ossification.[1]

In order to achieve this, the MaxAn System offers one-level plate sizes that begin at 8.0 mm hole-to-hole and increase in size by 1.0 mm increments. In addition, the MaxAn System allows for screw angulation up to 30° cephalad on the superior end of the plate and up to 30° caudal on the inferior end of the plate. Combined with the ability to place fixed screws in the range mentioned above, the result is an accurate and reproducible cervical plate and screw placement that is as far away from the adjacent discs as possible.

The angulation of the rings on the MaxAn plate specifically allows for the maximum 30° angulation in the direction of the slot on the ring. This is what allows for the extreme angulation at the cephalad and caudal ends of the plate where it is most relevant and necessary. It is important to note that the angulation in the direction opposite the slot on the ring is limited to 10°. In addition, the middle holes of a multi-level plate follow the 30°/10° angulation, however the need for angulation at those locations is typically never more than 10° in either the cephalad or caudal direction.

The MaxAn System offers a one-step locking mechanism to insert and simultaneously capture the bone screws. This unique locking mechanism eliminates the need for additional locking components, and allows both the fixed and variable bone screws to be positioned at any angle within the sweep. The fixed screws are fixed in place via a friction lock. As the fixed screw seats into the locking ring in the plate, the screw head expands the ring causing a frictional lock between the screw, ring and plate.

System Components

The MaxAn Anterior Cervical Plate System is an anterior cervical spinal fixation device made from titanium alloy (Ti-6Al-4V). Pre-contoured plates that conform to the natural lordotic curvature of the spine are available in one, two, three, or four level configurations. These offerings also range from 8.0 mm to 72 mm in length when measured from screw hole to screw hole. The system also includes variable and fixed self-drilling bone screws, which are available in 4.0 mm and 4.5 mm diameters and several lengths.

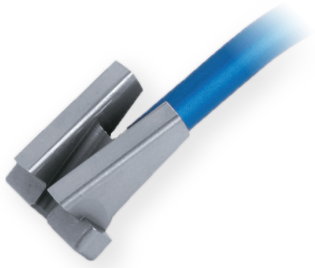
1 Park JB, Cho YS, Riew KD. Development of adjacent-level ossification in patients with an anterior cervical plate. J Bone Joint Surg Am. 2005;87:558–563.

Surgical Technique Options

The MaxAn Anterior Cervical Plate System offers three techniques for screw hole preparation and implant and graft placement. The techniques are summarized below and detailed in **(STEPS 3a–3c).**

MaxAn System Single-level Technique (STEP 3a)

- All four holes are prepared prior to screw placement
- Cephalad screws are angled at 20° and caudal screws at 10°
- Allows placement of hardware as far from adjacent levels as possible
- Simultaneous graft sizing and hole preparation
- Plate size is predetermined by graft size



MaxAn System Multi-level Technique (STEP 3b)

- Two most superior screw holes are prepared prior to plate placement using either the superior holes of a trial drill guide (20°) or using the endplate drill guide (15°)
- Allows placement of multi-level plates as far from adjacent superior level as possible
- Remaining screws can be placed at any angle using various drill guide options
- No need for fixation tacks to stabilize plate during screw hole preparation

MaxAn System Classic ACDF Technique (STEP 3c)

- Holes are prepared after plate placement
- Drill guide options include single- or double-barrel drill guides or a variable-angle punch awl

The table below summarizes all the guide options for the MaxAn Anterior Cervical Plate System.

	TECHNIQUE	ANGULATION	NUMBER OF HOLES	WHEN TO USE
TRIAL DRILL GUIDE	MaxAn System single-level and superior end of MaxAn System multi-level	20° Cephalad 10° Caudal	4	Before graft and plate
ENDPLATE DRILL GUIDE	MaxAn multi-level	15°	2	Before graft and plate
SINGLE-BARREL DRILL GUIDE	MaxAn multi-level, classic	Up to 30° cephalad on the superior end of plate, and up to 30° caudal on inferior end	1	After plate
DOUBLE-BARREL DRILL GUIDE	MaxAn multi-level, classic	Up to 30° cephalad on the superior end of plate, and up to 30° caudal on inferior end	2	After plate
PUNCH AWL	MaxAn multi-level, classic	Up to 30° cephalad on the superior end of plate, and up to 30° caudal on inferior end	1	After plate

Patient Positioning and Exposure

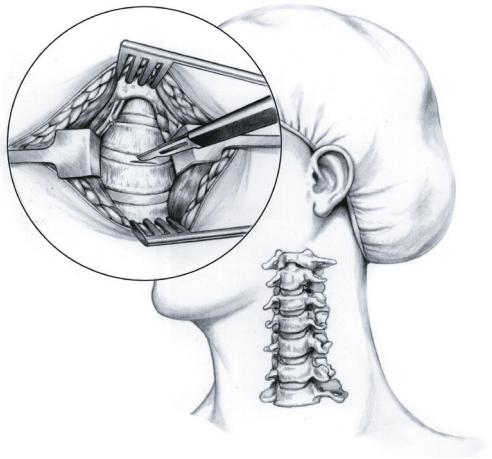


Figure 1
Surgical approach

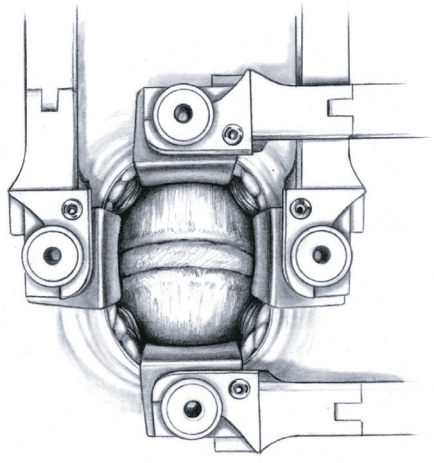


Figure 2
Exposure

STEP 1: Surgical Approach

- The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may be helpful. If fluoroscopy is used, it can be utilized at this point to confirm positioning and check that the desired vertebral levels can be adequately visualized **(Figure 1)**.
- A standard anterior approach to the mid and lower cervical spine is utilized. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for anterior interbody fusion is begun **(Figure 2)**.

Distractor Pin Template	PART NUMBER
	14-521078

Pin Distractor	PART NUMBER
Left	14-521080
Right	14-521081

STEP 2: Vertebral Body Distraction and Discectomy

- The MaxAn System provides sterile-packed distraction pins which can be used with the left or right pin distractor to distract the vertebral bodies. The distraction pins are loaded into the distraction pin/tack inserter by pulling back on the locking sleeve, sliding the pin into place and releasing the sleeve. The pins can then be inserted in the desired locations.
- The distraction pin template is available to provide assistance in the placement of the distraction pins so that they may be placed as far away from the adjacent segments as possible while ensuring that the Pins will not interfere with the trial drill guide used in the MaxAn System single-level technique. Preliminary discectomies are performed in order to seat the centering flange of the template against the superior and inferior endplates, relative to the disc space.
- Once the template is in place against the superior endplate, a distraction pin is placed through the hole and into the vertebral body. The distraction pin template is then repositioned for pin placement into the caudal vertebral body, so that the centering flange is placed against the inferior endplate. Care should be taken to ensure that the pins are placed directly opposite one another on the midline of the vertebral body. There is no need to perform any additional endplate preparation at this time. The template is then removed, leaving the two parallel distraction pins in place.
- The pin distractor is placed over the pins and opened as needed. The discectomy and resection of osteophytes is now completed, and further preparation of the interbody fusion bed or corpectomy space is performed as indicated.

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Single-level Technique

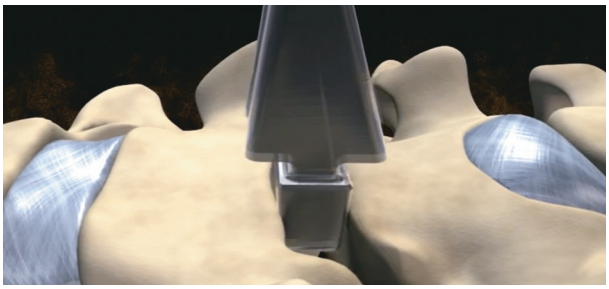


Figure 3
Trial drill guides

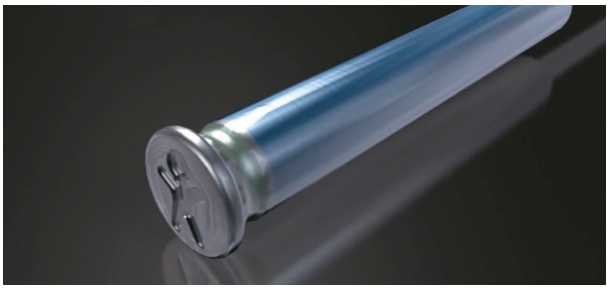


Figure 4
Stick figure notes directional orientation

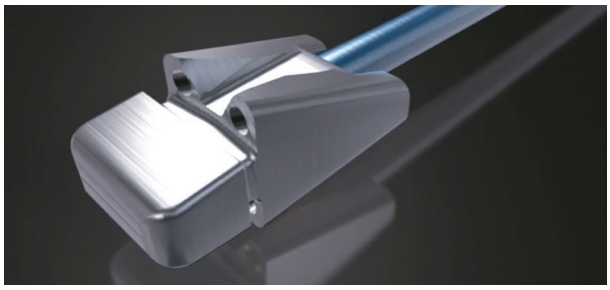


Figure 5
Trial drill guide

STEP 3a

- Using the trial drill guides, all four plate holes may be prepared prior to placing the plate on the vertebral bodies, while at the same time the graft size needed can be determined. This procedure allows the screw holes to be placed with excellent visualization and 1.5 mm above and below the endplates, keeping the plate away from the adjacent discs. The trial drill guide produces a cephalad screw hole angle of 20° and a caudal screw hole angle of 10°. The screws converge at 10° in the transverse plane.
- After performing a discectomy, a trial drill guide is placed in the disc space **(Figure 3)**.

Trial Drill Guide Size	Color Code	Corresponding MaxAn 1-level Plate
5.0 mm	Orange	8.0 mm
6.0 mm	Yellow	9.0 mm
7.0 mm	Green	10 mm
8.0 mm	Purple	11 mm
9.0 mm	Gray	12 mm
10 mm	Black	13 mm

- Trial drill guides are available in thicknesses of 5, 6, 7, 8, 9 and 10 mm. The various sizes are trialed in the disc space until the appropriate fit is achieved. Since the trial drill guide produces screw holes 1.5 mm above and 1.5 mm below the endplate, the corresponding plate to be implanted will always be 3.0 mm larger than the graft size chosen. The following chart may be used to reference the relationship between the trial drill guide and plate size.

Note: *The trial drill guide has a directional orientation due to different cephalad and caudal drill guide angulations. The proper directional orientation is identified by the stick figure at the top of the instrument and the "HEAD" and "FEET" markings on the drill guide tubes* ***(Figures 4 and 5).***

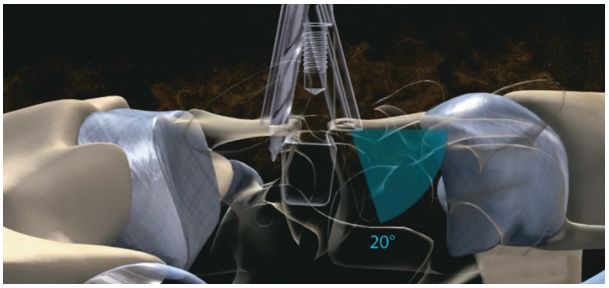


Figure 6
The trial drill guide prepares cephalad screw holes at 20 degrees angulation.

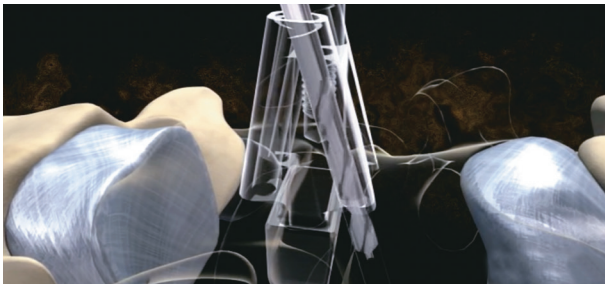


Figure 7
Trial drill guide allows for simultaneous graft sizing and hole preparation so that all four screw holes are prepared prior to plate insertion.

12 mm (Light Green) | 14 mm (Gold) | 16 mm (Light Blue)

Preparing the Screw Holes

- Once the correct spacer size is determined, the drill bit can be introduced through the guide barrels on the trial drill guide. The appropriate drill bit is attached to the handle with a quick-connect mechanism. The drill bit size is selected based on the corresponding bone screw size. The diameter is the same as the minor diameter of the 4.0 mm screws. Bone screw length is measured from the underside of the cervical plate and does not include the height of the screw head. The appropriate screw length can be verified using the screw gauge located on the screw caddy.

  Note: *The MaxAn System was designed to allow the screws to be placed up to 30° cephalad or caudal at those ends of the plate. Care should be taken to avoid penetration of the adjacent endplate, especially when using longer screws.*

  Note: *Drill bits and bone screws are color coded by length. Fixed screws are fully colored. Variable screws have silver shafts with colored heads.*

- All four holes are prepared prior to plate insertion **(Figures 6 and 7)**. After drilling the first hole, it is helpful to disengage the handle and leave the drill bit in place to stabilize the trial while the contralateral holes are drilled. After drilling the third hole, leave the drill bit in the place, remove the first drill bit and prepare the final hole.

- As an alternative to drilling through the drill guides, the standard awl may be placed through the drill guides to pierce the anterior cortex to the minor diameter of a 4.0 mm bone screw and to a depth of 10 mm. The trial drill guide may be removed once the holes have been prepared.

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Single-level Technique (continued)

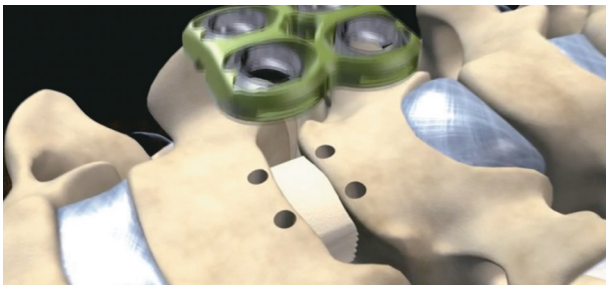


Figure 8

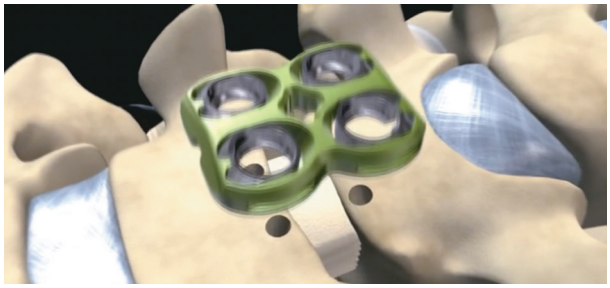


Figure 9

STEP 3a *(continued)*

Plate Selection

- The four holes prepared for the single-level plate have a predetermined location that corresponds to a specific cervical plate. Since the trial drill guides place the screw holes 1.5 mm from the vertebral endplates, the appropriate plate will always be 3.0 mm greater than the height of the graft chosen. For example, if a 6.0 mm graft is used, a 9.0 mm single-level plate will be needed. The correct plate size for a given trial is identified on the handle of each trial drill guide.

Graft Placement

- Per the appropriate technique, the graft or interbody spacer identified by the trial drill guide is inserted into the disc space. The trial portion of the trial drill guides assumes that the graft will be countersunk by 2.0 mm.

Plate and Screw Placement

- The plate is placed over the graft such that the screw holes are visible through the locking rings of the plate **(Figures 8 and 9)**. The appropriate bone screw is loaded on the screw inserter. Variable and fixed screws can be identified by their coloring and head geometry. Variable screws are colored on the head only, and the cruciate drive extends fully through the head of the screw. Fixed screws are fully colored and the cruciate drive does not cut through the head of the screw.

Figure 10

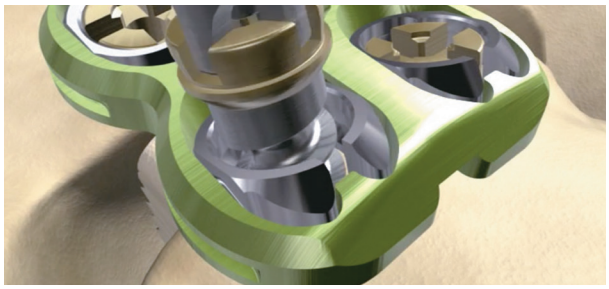


Figure 11

- Attach the appropriate size and style bone screw to the inserter by placing the distal tip of the inserter into the cruciate on the head of the screw. Turn the black knob at the top of the inserter clockwise until the screw is firmly attached to the inserter **(Figure 10)**. Insert the bone screw through the locking ring in the plate, taking care not to exceed 5° of medial-lateral angulation off of vertical **(Figure 11)**.
- Advance the screw until the lip on the screw head engages with the groove inside the locking ring. There is typically tactile feedback, and there may be audible feedback, once this capture has been achieved. At this point, the screw is captured to the plate but is not fully seated. It is recommended to partially insert at least two screws prior to fully seating either one. This will prevent the plate from turning as the screws are fully seated.
- Continue advancing the screws until the top of the screw is flush with the top of the locking ring. The fixed screw must be seated flush or below the top face of the locking ring in order to fully expand the locking ring and fix the screw in the desired trajectory. Similarly, the variable screws must be flush or below the top face of the locking ring to ensure that the plate is lagged down to the vertebral bodies.
- Remove the screw inserter from the bone screw by turning the black knob in a counterclockwise direction until the bone screw disengages. If adjustment to the screws is needed after the screw Inserter has been disengaged, the quick adjustment driver may be used.

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Multi-level Technique

12 mm (Light Green) | 14 mm (Gold) | 16 mm (Light Blue)

STEP 3b

There are two options listed here for preparing the cephalad holes in a multi-level construct using the MaxAn System multi-level technique.

Option 1: Trial Drill Guide

- The trial drill guide is also used for the preparation of the two most superior screw holes in multi-level plate placements. It provides a 20° screw angle and places two screw holes 1.5 mm from the vertebral endplates. If the trial drill guide is used, only the two most superior screw holes will be prepared prior to plate placement.

Option 2: Endplate Drill Guide

- The endplate drill guide is used for the preparation of the two most superior screw holes in multi-level plate placements. It provides a 15° screw angle. Similar to the trial drill guide, the endplate drill guide places two screw holes 1.5 mm from the vertebral endplates, thus allowing a smaller plate to be used.
- The drill bit is attached to the handle with a quick-connect mechanism. The drill bit size is selected based on the corresponding bone screw size. The diameter is the same as the minor diameter of the 4.0 mm screws. Bone screw length is measured from the underside of the cervical plate and does not include the height of the screw head. The appropriate screw length can be verified using the screw gauge located on the screw caddy.

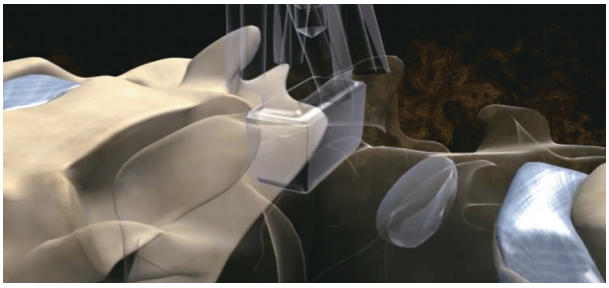


Figure 12

Note: *The MaxAn System was designed to allow the screws to be placed up to 30° cephalad or caudal at those ends of the plate, if so desired. Care should be taken to avoid penetration of the adjacent endplate, especially when using longer screws.*

Note: *Drill bits and bone screws are color coded by length. Fixed screws are fully colored. Variable screws have silver shafts with colored heads.*

- Place the trial drill guide or endplate drill guide against the vertebral endplate and introduce the appropriate drill bit through the guide barrels **(Figure 12)**. Advance the drill bit through the guide to the depth permitted by the stop. As an option, the standard awl may be used in place of the drill bit to pierce the anterior cortex to the minor diameter of a 4.0 mm bone screw and to a depth of 10 mm.

Graft Placement

- Per the appropriate technique, interbody grafts or a strut graft can now be sized and impacted into place. Any distraction previously applied can be released at this point to assess graft stability.

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Multi-level Technique (continued)

Figure 13
Firmly attach screw to inserter

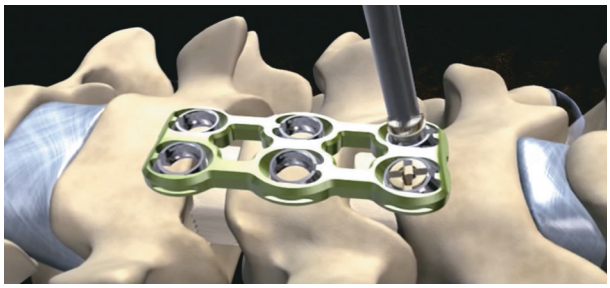


Figure 14

STEP 3b (continued)

Cephalad Screw Insertion

- Variable and fixed screws can be identified by their coloring and head geometry. Variable screws are colored on the head only, and the cruciate drive extends fully through the head of the screw. Fixed screws are fully colored, and the cruciate drive does not cut through the head of the screw.
- Attach the appropriate size and style bone screw to the inserter by placing the distal tip of the inserter into the cruciate on the head of the screw. Turn the black knob at the top of the inserter clockwise until the screw is firmly attached to the inserter **(Figure 13)**. Insert the bone screw through the locking ring in the plate, taking care not to exceed 5° of medial-lateral angulation off of vertical **(Figure 14)**.
- Advance the screw until the lip on the screw head engages with the groove inside the locking ring. There is typically tactile feedback, and there may be audible feedback, once this capture has been achieved. At this point, the screw is captured to the plate but is not fully seated. It is recommended to partially insert at least two screws prior to fully seating either one. This will prevent the plate from turning as the screws are fully seated.
- Continue advancing the screws until the top of the screw is flush with the top of the locking ring. The fixed screw must be seated flush or below the top face of the locking ring in order to fully expand the locking ring and fix the screw in the desired trajectory. Similarly, the variable screws must be flush or below the top face of the locking ring to ensure that the plate is lagged down to the vertebral bodies.

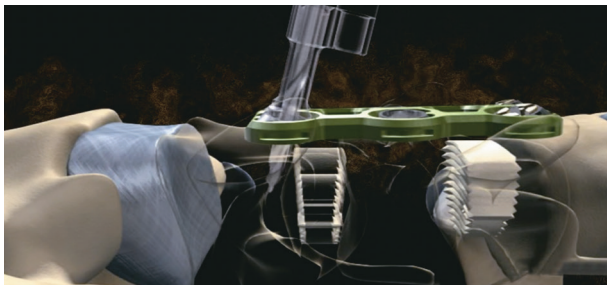


Figure 16
Preparing the remaining screw holes

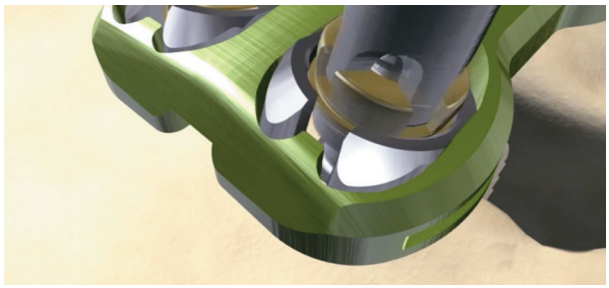


Figure 17
Remaining screw insertion

- Remove the screw inserter from the bone screw by turning the black knob in a counterclockwise direction until the bone screw disengages. If adjustment to the screws is needed after the screw Inserter has been disengaged, the quick adjustment driver may be used.

Preparing the Remaining Screw Holes

- The single- and double-barrel drill guides snap into the locking rings of the plate and can be angled up to 30° cephalad on the superior end of the plate and up to 30° caudal on the inferior end of the plate **(Figure 15)**. The single- and double-barrel drill guides snap into the locking rings of the plate and can be angled anywhere within the 40° sweep of each screw hole offered by the MaxAn plate **(Figure 16)**. Either a drill bit or the standard awl can be used through the single- and double-barrel guides.
- If a punch awl is preferred, snap it into the locking rings on the plate, angle it at the desired trajectory and depress the spring loaded punch through the bone. The punch awl and the standard awl will pierce the anterior cortex to the minor diameter of a 4.0 mm bone screw and to a depth of 10 mm.
- Attach the appropriate bone screw to the screw inserter as detailed above and insert screws into the prepared holes **(Figure 17)**.

Figure 15
Single- and double-barrel drill guides

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Classic ADCF Technique

Pin/Tack Inserter	PART NUMBER
	14-521070

STEP 3c (continued)

Graft Placement

- Per the appropriate technique, interbody graft(s) or a strut graft can now be sized and impacted into place. Any distraction previously applied can be released at this point to assess graft stability.

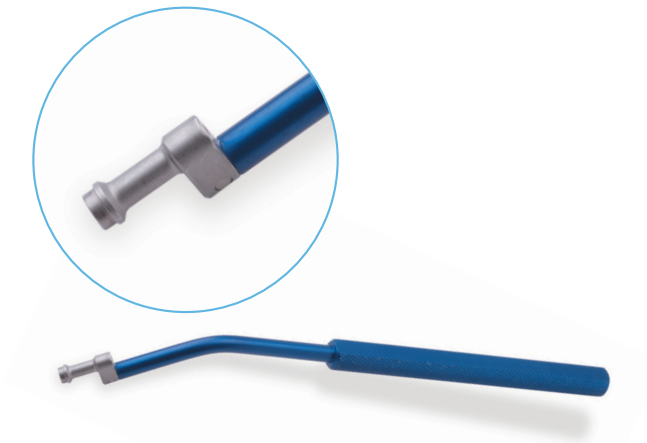
Plate Selection and Placement

- A caliper may be used to identify the appropriate plate length.

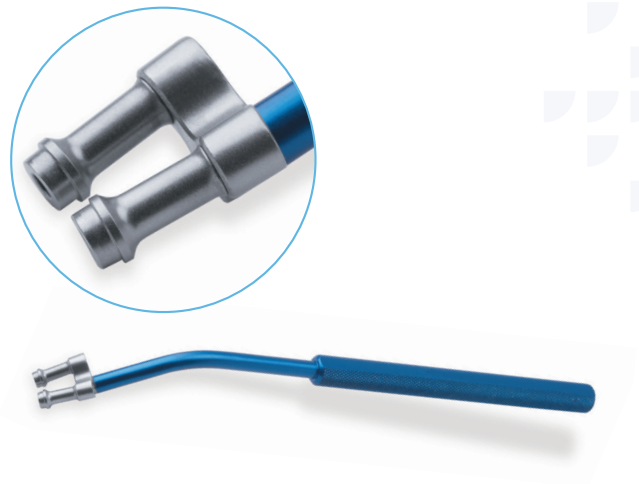
(Optional) Temporary Fixation

Tack Insertion

- After the plate has been positioned, a temporary fixation tack may be inserted to provide fixation while drilling holes and inserting bone screws.
- The temporary fixation tack is positioned utilizing the distraction pin/tack Inserter. The fixation tacks are loaded into the tack inserter by pulling back on the locking sleeve, sliding the tack into place and releasing the sleeve.



Single-barrel Drill Guide	PART NUMBER
	14-521030



Double-barrel Drill Guide	PART NUMBER
	14-521032

Establishing the Screw Holes

- The single- and double-barrel drill guides snap into the locking rings of the plate and can be angled up to 30° cephalad on the superior end of the plate and up to 30° caudal on the inferior end of the plate. The single- and double-barrel drill guides snap into the locking rings of the plate and can be angled anywhere within the 40° sweep of each screw hole offered by the MaxAn plate. Either a drill bit or the standard awl can be used through the single- and double-barrel guides. Advance the drill bit through the guide to the depth permitted by the stop.
- The appropriate drill bit is attached to the handle with a quick-connect mechanism. The drill bit size is selected based on the corresponding bone screw size. The diameter is the same as the minor diameter of the 4.0 mm screws. Bone screw length is measured from the underside of the cervical plate and does not include the height of the screw head. The appropriate screw length can be verified using the screw gauge located on the screw caddy.

  Note: *The MaxAn System was designed to allow the screws to be placed up to 30° cephalad or caudal at those ends of the plate, if so desired. Care should be taken to avoid penetration of the adjacent endplate, especially when using longer screws.*

  Note: *Drill bits and bone screws are color coded by length. Fixed screws are fully colored. Variable screws have silver shafts with colored heads.*

Screw Hole Preparation, Implant and Graft Placement

MaxAn System Classic ADCF Technique (continued)

Figure 18

STEP 3c (continued)

Establishing the Screw Holes (continued)

- If a punch awl is preferred, snap it into the locking rings on the plate, angle it at the desired trajectory and depress the spring-loaded punch through the bone. Both the punch awl and the standard awl will pierce the anterior cortex to the minor diameter of a 4.0 mm bone screw and to a depth of 10 mm.

Screw Insertion

- The appropriate bone screw is loaded on the screw inserter. Variable and fixed screws can be identified by their coloring and head geometry. Variable screws are colored on the head only, and the cruciate drive extends fully through the head of the screw. Fixed screws are fully colored, and the cruciate drive does not cut through the head of the screw.
- Attach the appropriate size and style bone screw to the inserter by placing the distal tip of the inserter into the cruciate on the head of the screw. Turn the black knob at the top of the inserter clockwise until the screw is firmly attached to the inserter **(Figure 18)**. Insert the bone screw through the locking ring in the plate, taking care not to exceed 5° of medial-lateral angulation off of vertical.
- Advance the screw until the lip on the screw head engages with the groove inside the locking ring. There is tactile feedback, and there may be audible feedback, once this capture has been achieved. At this point, the screw is captured to the plate, but is not fully seated. It is recommended to partially insert at least two screws prior to fully seating either one.

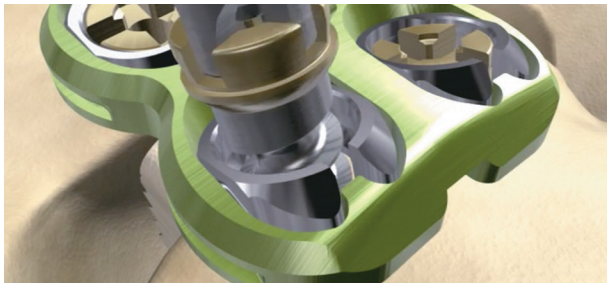


Figure 19

- Continue advancing the screws until the top of the screw is flush with the top of the locking ring. The fixed screw must be seated flush or below the top face of the locking ring in order to fully expand the locking ring and fix the screw in the desired trajectory **(Figure 19)**. Similarly, the variable screws must be flush, or below the top face of the locking ring, to ensure that the plate is lagged down to the vertebral bodies.
- Remove the screw inserter from the bone screw by turning the black knob in a counterclockwise direction until the bone screw disengages. If adjustment to the screws is needed after the screw inserter has been disengaged, the quick-adjustment driver may be used.

STEP 4

Closure

- After implantation of the MaxAn Anterior Cervical Plate System is completed using one of the techniques described above, closure is performed in layers according to standard protocol. A soft collar may be used postoperatively for patient comfort. Postoperative radiographs should be taken.

Implant Removal – Primary Green Plates

Removal of the MaxAn Anterior Cervical Plate System is performed by disengaging the screw from the locking ring, then backing the screw out with the green-handle screw remover.

Figure 20
Screw remover instrument

Figure 21

STEP 1

Screw Remover Instrument

- Seat the cruciate tip of the screw remover into the cruciate on the bone screw.
- Turn the black knob at the top of the remover clockwise until the threads on the inner shaft engage with the threads in the bone screw. The screw remover is now fully engaged to the screw **(Figure 20)**.

STEP 2

- Spin the green handle of the remover until the sleeve makes contact with the ring. Continue to spin the green handle until the tactile resistance is increased. Avoid over-tightening the green handle, as this may result in stripping the bone **(Figure 21)**.

Figure 22

STEP 3

- Hold the green handle of the screw remover still while turning the blue handle counterclockwise **(Figure 22)**.

STEP 4

- The locking lip on the screw will disengage from the capture groove in the ring, and the screw can now be backed out past the ring. Once the screw is no longer captured to the plate, the green handle no longer needs to be held. Continue turning the blue handle counterclockwise to back the screw completely out of the bone.

  Note: *Do not reuse a screw that has been removed from the locking ring. Confirm that the slots on the rings are oriented in the cephalad-caudal direction once the screw has been removed. If they are not, discard the plate and use a new one.*

Implant Removal – Primary Blue Plates

Removal of the MaxAn Anterior Cervical Plate System is performed by disengaging the screw from the locking ring, then backing the screw out with the gold-handle screw remover.

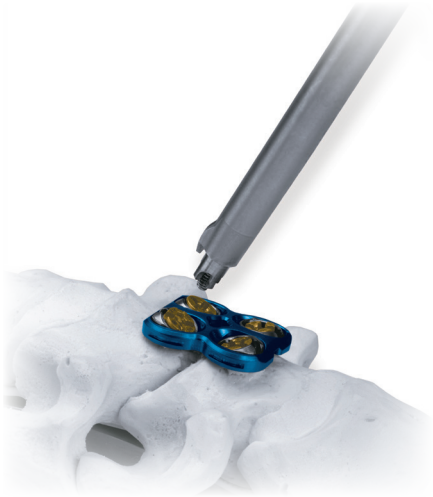


Figure 23

Figure 24

STEP 1

Screw Remover Instrument

- Seat the cruciate tip of the screw remover into the cruciate on the bone screw **(Figure 23)**.

STEP 2

- Turn the black knob at the top of the remover clockwise until the threads on the inner shaft engage with the threads in the bone screw **(Figure 24)**. The screw remover is now fully engaged to the screw.

Figure 25

Figure 26

STEP 3

- Spin the gold handle on the screw remover down until it makes contact with the ring **(Figure 25)**. Grasp the knurled portion of the shaft and turn it to seat the tine on the tip of the instrument into the slot in the ring. The shaft is spring-loaded to facilitate this process.
- There is a black line that runs down the length of the shaft to help locate the tine into the ring **(Figure 26)**. Once the tine at the tip of the instrument is fully seated into the slot of the ring, the gold handle on the screw remover should be advanced until the resistance begins to increase slightly. Advancing the gold handle allows the tine to slightly open the ring. Avoid over-tightening the sleeve, as this may result in stripping of the bone.

Implant Removal – Primary Blue Plates *(continued)*

Figure 27

Figure 28

STEP 4

- Hold the gold handle of the screw remover still while turning the blue handle counterclockwise **(Figure 27)**.

STEP 5

Screw Remover Instrument

- The locking lip on the screw will disengage from the capture groove in the ring, and the screw can now be backed out past the ring. Once the screw is no longer captured to the plate, the gold handle no longer needs to be held. Continue turning the blue handle counterclockwise to back the screw completely out of the bone **(Figure 28)**.

Bender	PART NUMBER
	14-521063

Screw Remover Sleeve

Use the screw remover sleeve to remove a MaxAn screw if the inner threads on the screw head have been stripped, preventing the screw remover instrument from engaging to the MaxAn screw.

- Use the quick-adjustment driver to loosen or back out the screw to be removed approximately two turns.
- Place the tip of the remover sleeve against the ring on the plate.
- Using a mallet, softly tap the top of the screw remover sleeve until the ring disengages from the screw head.
- Once the ring has disengaged from around the screw head, the MaxAn screw can be unscrewed with the quick adjustment driver.

Do not reuse a screw that has been removed from the locking ring. Confirm that the slots on the rings are oriented in the cephalad-caudal direction once the screw has been removed. If they are not, discard the plate and use a new one.

(Optional) Lordotic Curvature of Plate

The amount of precontoured lordosis in the MaxAn Anterior Cervical Plate is sufficient in the majority of cases. If desired, changes can be made to the standard lordotic curvature by using the plate bender. Seat the plate inside the plate bender and gradually depress the handles until the desired curvature has been achieved.

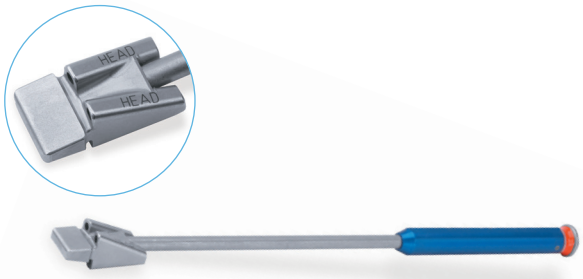
The bend should be applied in the area between the screw holes in order to avoid bending across the screw holes themselves. As with any titanium cervical plate, avoid sharp bends, reverse or repetitive bends and notching or scratching of the device, which could produce internal stress and lead to early breakage.

Instruments

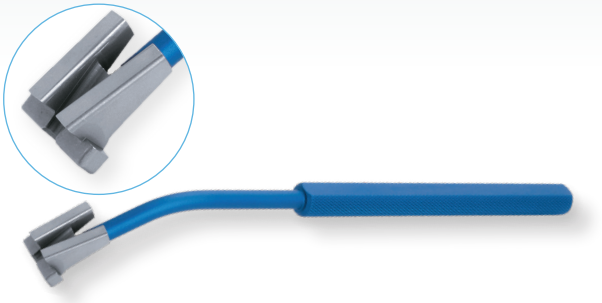
Distractor Pin Template	PART NUMBER
	14-521078

Pin/Tack Inserter	PART NUMBER
	14-521070

Pin Distractor	PART NUMBER
Left	14-521080
Right	14-521081

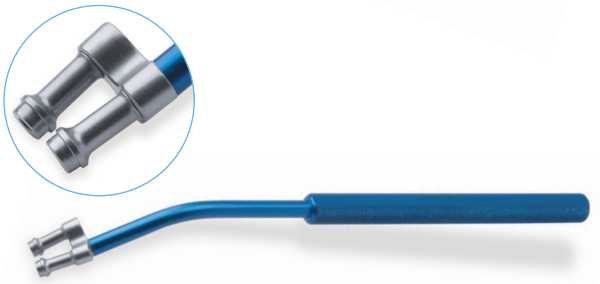


Trial Drill Guide	PART NUMBER
5.0 mm	14-521038
6.0 mm	14-521039
7.0 mm	14-521040
8.0 mm	14-521041
9.0 mm	14-521042
10 mm	14-521043



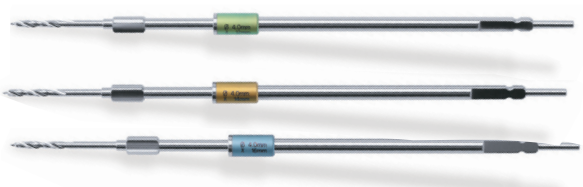
Endplate Drill Guide	PART NUMBER
	14-521035

Single-barrel Drill Guide	PART NUMBER
	14-521030



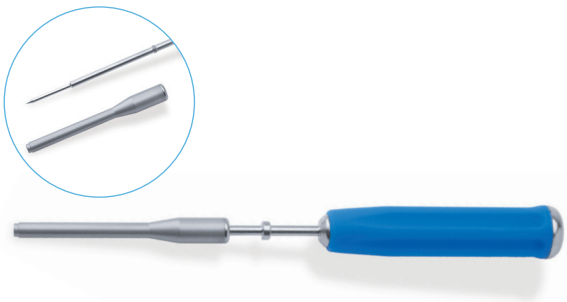
Double-barrel Drill Guide	PART NUMBER
	14-521032

Quick-connect Handle	PART NUMBER
	14-521004



Drills	PART NUMBER
4 mm × 12 mm	14-521012
4 mm × 14 mm	14-521014
4 mm × 16 mm	14-521016

Standard Awl — PART NUMBER 14-521060

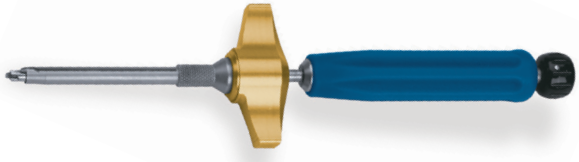


Punch Awl — PART NUMBER 14-521061

Plate Holder — PART NUMBER 14-521062

Screw Inserter — PART NUMBER 14-522000

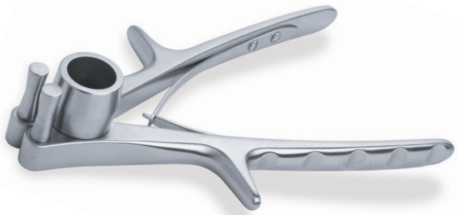
Green-handle Screw Remover — PART NUMBER 14-522001



Gold-handle Screw Remover — PART NUMBER 14-521091

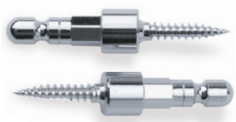
Quick-adjustment Driver — PART NUMBER 14-521002

Screw Remover Sleeve — PART NUMBER 14-521003



Bender — PART NUMBER 14-521063

Caliper — PART NUMBER 14-521064



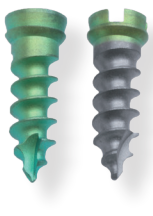
Tacks — PART NUMBER 14-521071

Kit Contents

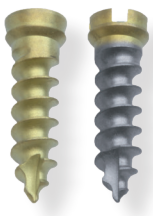
Standard Implant Kit (14-522991)

DESCRIPTION	QTY	PART NUMBER
1-level 8.0 mm Plate	2	14-522108
1-level 9.0 mm Plate	2	14-522109
1-level 10 mm Plate	2	14-522110
1-level 11 mm Plate	2	14-522111
1-level 12 mm Plate	2	14-522112
1-level 13 mm Plate	2	14-522113
1-level 14 mm Plate	2	14-522114
1-level 16 mm Plate	2	14-522116
1-level 18 mm Plate	2	14-522118
1-level 20 mm Plate	2	14-522120
2-level 20 mm Plate	2	14-522220
2-level 22 mm Plate	2	14-522222
2-level 24 mm Plate	2	14-522224
2-level 26 mm Plate	2	14-522226
2-level 28 mm Plate	2	14-522228
2-level 30 mm Plate	2	14-522230
2-level 32 mm Plate	2	14-522232
2-level 34 mm Plate	2	14-522234
2-level 36 mm Plate	2	14-522236
2-level 38 mm Plate	2	14-522238
2-level 40 mm Plate	2	14-522240
3-level 36 mm Plate	1	14-522336
3-level 39 mm Plate	1	14-522339
3-level 42 mm Plate	1	14-522342
3-level 45 mm Plate	1	14-522345
3-level 48 mm Plate	1	14-522348
3-level 51 mm Plate	1	14-522351
3-level 54 mm Plate	1	14-522354
3-level 57 mm Plate	1	14-522357
3-level 60 mm Plate	1	14-522360
3-level 63 mm Plate	1	14-522363
3-level 66 mm Plate	1	14-522366

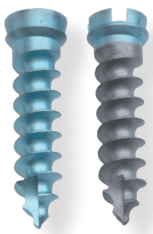
DESCRIPTION	QTY	PART NUMBER
ø4.0 mm × 12 mm Fixed Bone Screw	8	14-521512
ø4.0 mm × 14 mm Fixed Bone Screw	16	14-521514
ø4.0 mm × 16 mm Fixed Bone Screw	8	14-521516
ø4.5 mm × 12 mm Fixed Bone Screw	8	14-521542
ø4.5 mm × 14 mm Fixed Bone Screw	8	14-521544
ø4.5 mm × 16 mm Fixed Bone Screw	8	14-521546
ø4.0 mm × 12 mm Variable Bone Screw	8	14-521612
ø4.0 mm × 14 mm Variable Bone Screw	18	14-521614
ø4.0 mm × 16 mm Variable Bone Screw	8	14-521616
ø4.5 mm × 12 mm Variable Bone Screw	8	14-521642
ø4.5 mm × 14 mm Variable Bone Screw	8	14-521644
ø4.5 mm × 16 mm Variable Bone Screw	8	14-521646



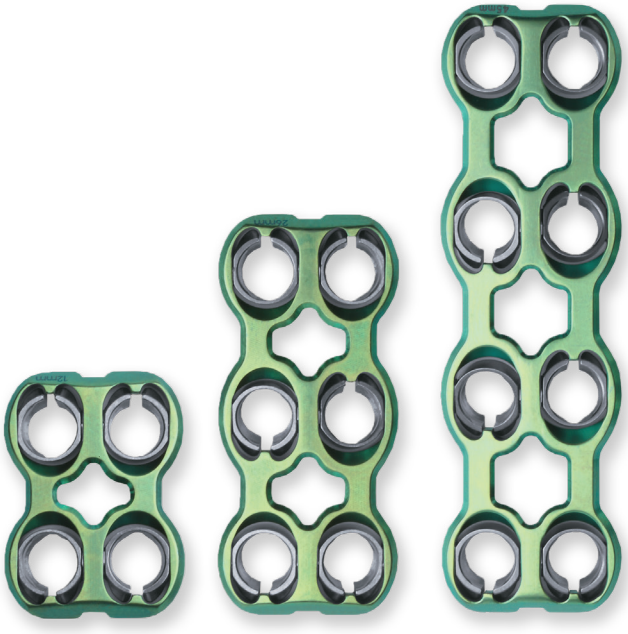
Fixed/Variable 12 mm



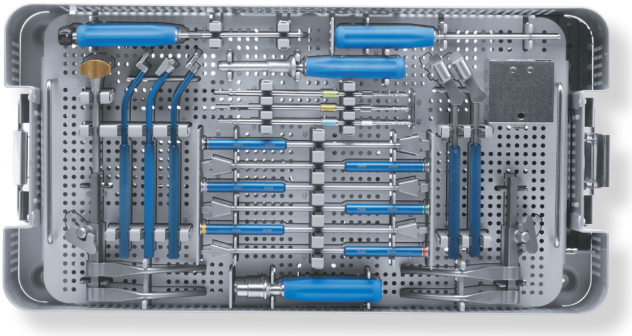
Fixed/Variable 14 mm

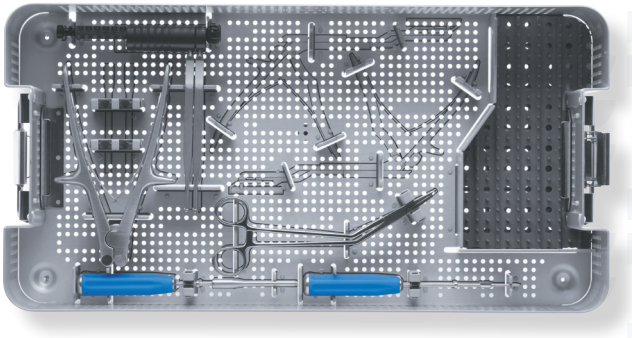


Fixed/Variable 16 mm



One-Level Two-Level Three-Level





Standard Instrument Kit (14-522992)

DESCRIPTION	QTY	PART NUMBER
Screw Inserter	2	14-522000
Screw Remover	1	14-522001
Large Handle Screw Remover Sleeve	1	14-521003
Quick Adjustment Driver	1	14-521002
Quick Connect Handle	2	14-521004
ø4.0 mm × 12 mm Drill	2	14-521012
ø4.0 mm × 14 mm Drill	2	14-521014
ø4.0 mm × 16 mm Drill	2	14-521016
Single-barrel Handheld Drill Guide	1	14-521030
Double-barrel Handheld Drill Guide	1	14-521032
Endplate Drill Guide	1	14-521035
5.0 mm Graft Trial Drill Guide	1	14-521038
6.0 mm Graft Trial Drill Guide	1	14-521039
7.0 mm Graft Trial Drill Guide	1	14-521040
8.0 mm Graft Trial Drill Guide	1	14-521041
9.0 mm Graft Trial Drill Guide	1	14-521042

DESCRIPTION	QTY	PART NUMBER
10 mm Graft Trial Drill Guide	1	14-521043
Awl (10 mm in Bone)	1	14-521060
Punch Awl (10 mm in Bone)	1	14-521061
Plate Holder	1	14-521062
Plate Bender	1	14-521063
Plate Caliper	1*	14-521064
Distractor Pin/Tack Inserter	1	14-521070
Tack	1	14-521071
Large Distraction Pin Template	1	14-521078
Pin Distractor (Left)	1	14-521080
Pin Distractor (Right)	1	14-521081
Screw Remover with Tine (Blue Plate Removal)	1	14-521091
12 mm Distraction Pins	2*	14-521072
14 mm Distraction Pins	2*	14-521074
16 mm Distraction Pins	2*	14-521076

*Not part of kit, to be ordered separately.

Important Information on the MaxAn® Anterior Cervical Plate System

Description

The MaxAn Anterior Cervical Plate System is a plate and screw system composed of titanium alloy (Ti-6Al-4V ELI). The system includes self-drilling bone screws, which are available in various diameters. The plates have an integral locking component that secures the bone screws into the plate. Various instruments are available to facilitate implantation of the device.

Indication for Use

The MaxAn Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disease of the cervical spine (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2–T1.

Contraindications

The MaxAn Anterior Cervical Plate System is contraindicated in patients with spinal infection or inflammation; morbid obesity; mental illness, alcoholism or drug abuse; pregnancy; metal sensitivity/foreign body sensitivity; inadequate tissue coverage over the operative site; open wounds local to the operative area, or rapid joint disease, bone absorption, osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication since the condition may limit the degree of obtainable correction, the amount of mechanical fixation and/or intolerance.

Warnings

- This device is not approved for screw attachments to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Selection of Implants: Selection of proper size, shape and design of the implant increase the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
- Implant strength and loading: These devices are not designed to withstand the unsupported stress of full weight bearing and/or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bones. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.
- Corrosion: Contact of dissimilar metals (e.g., titanium and stainless steel) accelerates the corrosion process, which could enhance fatigue fracture of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other.

Precautions

- Do not reuse: Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device. Do not treat patients with implants/devices that have been even momentarily placed in a different patient.
- Handling of implants: Titanium implants are to be handled with care. If contouring of the plate is required, avoid sharp bends and reverse or repetitive bends. Avoid notching or scratching of the device, which could produce internal stresses and lead to early breakage. Avoid bending across the screw holes.

Precautions (Continued)

- Implant removal after healing: After healing is complete, the implant may be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
- Adequate patient instructions: A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
- Surgical techniques: The device is recommended for use by surgeons thoroughly familiar with the relative current literature, surgical techniques, implantation technique for this device, and postoperative care of the patient.
- The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
- All instruments must be cleaned and sterilized prior to surgery.
- ZimVie Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.
- Based on fatigue testing results, when using the MaxAn Anterior Cervical Plate System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of this system.
- Non-clinical testing has demonstrated that the MaxAn plates are MR conditional. Patients with these plates may be scanned safely under the following conditions:

MRI Safety Information

Patients with the MaxAn Cervical Plate are not at added risk during MR imaging for scan sequence with a whole-body averaged SAR of less than 2 W/kg and in normal operating mode, as defined in IEC 60601-2-33. Edt. 3.1.

Non-clinical testing has demonstrated the MaxAn Cervical Plate is MR conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 Tesla (T)
- Spatial gradient field of 2500 Gauss/cm or less
- Quadrature transmit body coil
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (normal operating mode)

Under the scan conditions defined above, the MaxAn Cervical Plate is expected to produce a maximum temperature rise of 9°C after 15 minutes of continuous scanning. In image artifact tests performed in a GE Signa HDxt 3 T MR system according to ASTM F2119-07, the image artifact extended less than 10 mm from the implant for spin echo images and less than 22 mm for gradient images.

For more information, visit ZimVie.com

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