

Surgical Technique

MaxAn® Anterior Cervical Plate System

Designed to Help Minimize the Potential for Adjacent Level Ossification

- Allows for screw placement up to 30° cephalad on the superior end of the plate and up to 30° caudal on the inferior end of the plate
- Plate sizes that begin at 8.0mm hole-to-hole and increase in size by 1.0mm increments
- Intuitive instrumentation that places screw holes 1.5mm above and below the treated endplates



BIOMET®
SPINE

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Introduction

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 intra-operative 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.



Design Features

The Design Rationale of the MaxAn® System is based on a clinical paper that supports positioning an anterior cervical plate at least 5.0mm 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 8.0mm hole-to-hole and increase in size by 1.0mm 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.

¹ Park, et al., Development of Adjacent-Level Ossification in Patients with an Anterior Cervical Plate, JBJs, 2005; 87:558-563.



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 8.0mm to 72mm 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 4.0mm and 4.5mm diameters and several lengths.

Instruments



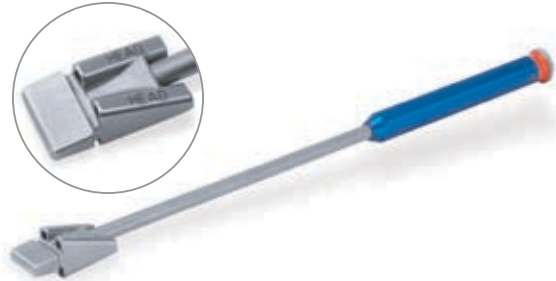
Distractor Pin Template



Pin/Tack Inserter



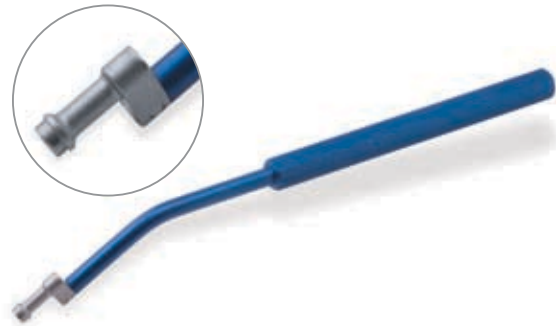
Pin Distractor



Trial Drill Guide



Endplate Drill Guide



Single Barrel Drill Guide



Double Barrel Drill Guide



Quick Connect Handle



Drills



Standard Awl



Punch Awl



Plate Holder

Instruments (Continued)



Screw Inserter



Green Handle Screw Remover



Gold Handle Screw Remover



Quick Adjustment Driver



Screw Remover Sleeve



Caliper



Bender



Tacks

Surgical Technique

The MaxAn® Anterior Cervical Plate System offers three techniques for screw hole preparation and implant and graft placement. The techniques are summarized in the chart below and detailed in Section 3.



**MaxAn® System Single Level Technique
(Section 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
(Section 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



**Classic ACDF Technique
(Section 3c)**

- Holes are prepared after plate placement
- Drill Guide options include Single or Double Barrel Drill Guides or a variable angle Punch Awl

Surgical Technique (Continued)

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

| | Technique | Angulation | # 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 |

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).

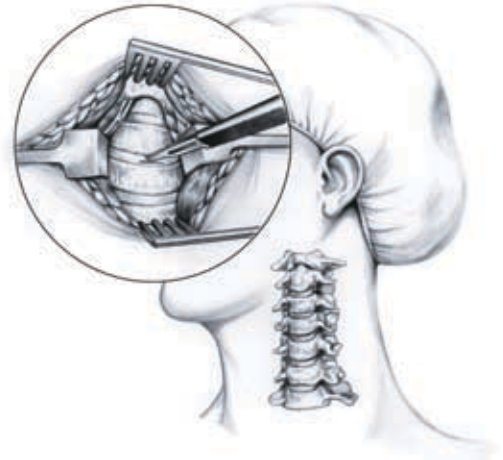


Figure 1

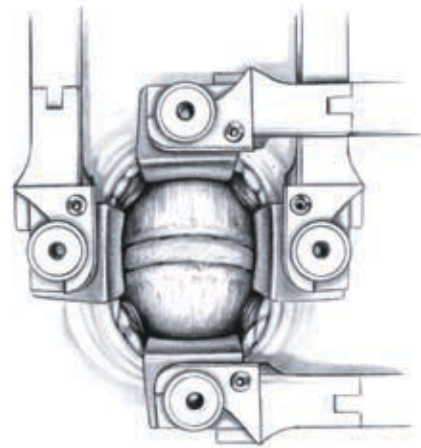


Figure 2

Surgical Technique (Continued)

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 endplate, relative to the disc space and the inferior endplate, 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.

3. Screw Hole Preparation, Implant and Graft Placement

3a. MaxAn® System Single-Level Technique

i. Trial Drill Guides

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

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

Note that 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).

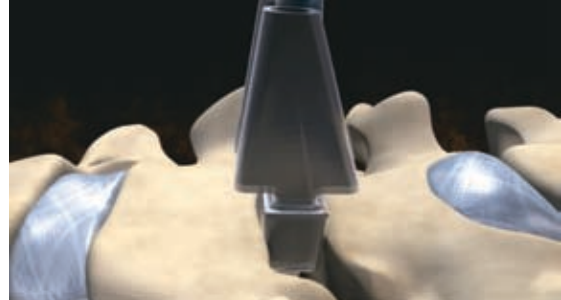


Figure 3

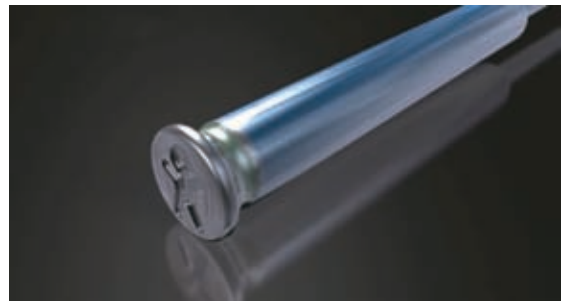


Figure 4



Figure 5

Surgical Technique (Continued)

ii. 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 4.0mm 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.



12mm
(Light Green)



14mm
(Gold)



16mm
(Light Blue)

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 4.0mm bone screw and to a depth of 10mm. The Trial Drill Guide may be removed once the holes have been prepared.

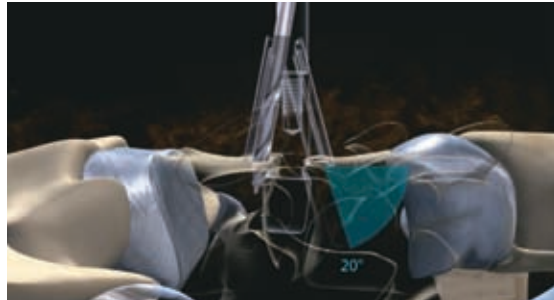


Figure 6

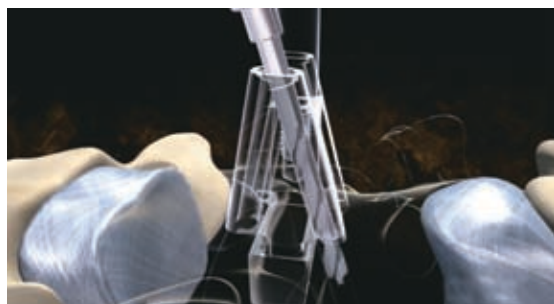


Figure 7

iii. 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 1.5mm from the vertebral endplates, the appropriate plate will always be 3.0mm greater than the height of the graft chosen. For example, if a 6.0mm graft is used, a 9.0mm single-level plate will be needed. The correct plate size for a given trial is identified on the handle of each Trial Drill Guide.

iv. 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 2.0mm.

v. 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.

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).



Figure 8

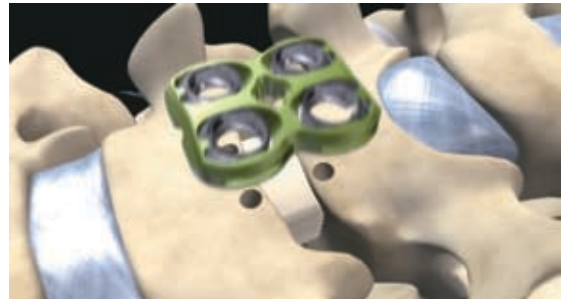


Figure 9



Figure 10



Figure 11

Surgical Technique (Continued)

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.

3b. MaxAn® System Multi-Level Technique

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 1.5mm 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.

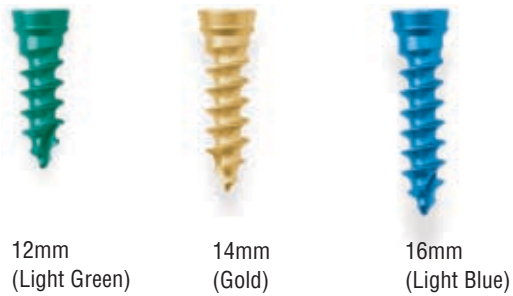
Option 2: Endplate Drill Guide

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 1.5mm 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 4.0mm 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.



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 4.0mm bone screw and to a depth of 10mm.

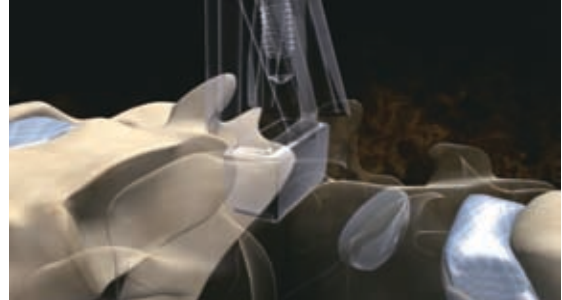


Figure 12

Surgical Technique (Continued)

i. Graft Placement

As 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.

ii. Plate Selection and Placement

A Caliper may be used to identify the appropriate plate length (Figure 13).

iii. 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 14). 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 15).

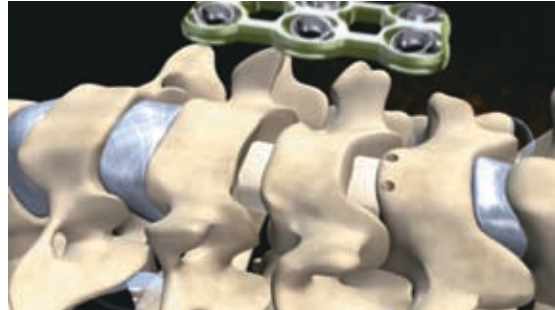


Figure 13



Figure 14



Figure 15

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.

Surgical Technique (Continued)

iv. 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 16). 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 17). 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 4.0mm bone screw and to a depth of 10mm.

v. Remaining Screw Insertion

Attach the appropriate bone screw to the Screw Inserter as detailed above and insert screws into the prepared holes (Figure 18).



Figure 16



Figure 17



Figure 18

3c. Classic ACDF Technique

i. Graft Placement

As 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.

ii. Plate Selection and Placement

A Caliper may be used to identify the appropriate plate length.

iii. (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.

The Temporary Fixation Tack is inserted by turning the Tack Inserter in a clockwise direction. Once the tack shoulder is fully seated into the screw hole, the Tack Inserter is removed by pulling back on the locking sleeve and releasing. Additional fixation tacks may be inserted, if desired.

iv. 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 4.0mm 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.



12mm
(Light Green)



14mm
(Gold)



16mm
(Light Blue)

Surgical Technique (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 4.0mm bone screw and to a depth of 10mm.

v. 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. 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 20). 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.



Figure 19



Figure 20

4. Closure and Post-Operative Care

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 and then by backing the screw out with the Green Handle Screw Remover.

Screw Remover Instrument

1. Seat the cruciate tip of the Screw Remover into the cruciate on the bone screw.
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. The Screw Remover is now fully engaged to the screw (Figure 21).
3. 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 22).
4. Hold the green handle of the Screw Remover still while turning the blue handle counter-clockwise (Figure 23).
5. 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.

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.



Figure 21



Figure 22



Figure 23

Implant Removal – Primary Blue Plates

Removal of the MaxAn® Anterior Cervical Plate System is performed by disengaging the screw from the locking ring and then by backing the screw out with the Gold Handle Screw Remover.

Screw Remover Instrument

1. Seat the cruciate tip of the Screw Remover into the cruciate on the bone screw (Figure 24).
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 25). The Screw Remover is now fully engaged to the screw.
3. Spin the gold handle on the Screw Remover down until it makes contact with the ring (Figure 26). 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 27). 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.



Figure 24



Figure 25



Figure 26

Implant Removal – Blue Plates (Continued)

4. Hold the gold handle of the Screw Remover still while turning the blue handle counterclockwise (Figure 28).
5. 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 29).

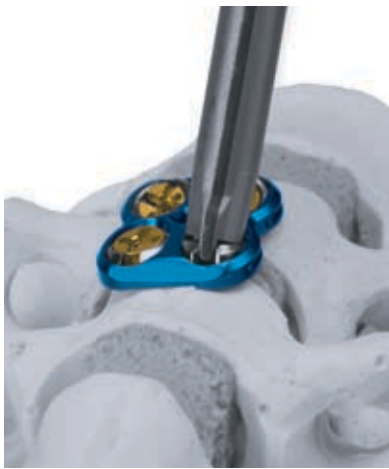


Figure 27



Figure 28



Figure 29

Implant Removal – Secondary

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.

1. Use the Quick Adjustment Driver to loosen or back out the screw to be removed approximately two turns.
2. Place the tip of the Remover Sleeve against the ring on the plate.
3. Using a mallet, softly tap the top of the Screw Remover Sleeve until the ring disengages from the screw head.
4. 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 pre-contoured 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 stresses and lead to early breakage.

Instrument Cleaning

For cleaning purposes, the Screw Inserter/Remover components may be disassembled by hand. Unthread the inner shaft counterclockwise until the inner shaft has exited the housing. The components must be sterilized according to sterilization recommendations.

Indications 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 – T-1.

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 attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The benefit of spinal fusions utilizing any screw fixation system has not been adequately established in patients with stable spines. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury. See the Warnings, Precautions, and Possible Adverse Effects sections of the package insert for a complete list of potential risks.

Sterilization Recommendations

The MaxAn® Anterior Cervical Plate System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle: High Vacuum

Temperature: 270°F (132°C)

Time: 8 minutes

Drying Time: 20 minutes

NOTE: Allow for Cooling

Ordering Information

Standard Implants

| Catalog # | Description | Qty |
|-----------|----------------------|-----|
| 14-522991 | Standard Implant Kit | |
| 14-522108 | 1-Level 8mm Plate | 2 |
| 14-522109 | 1-Level 9mm Plate | 2 |
| 14-522110 | 1-Level 10mm Plate | 2 |
| 14-522111 | 1-Level 11mm Plate | 2 |
| 14-522112 | 1-Level 12mm Plate | 2 |
| 14-522113 | 1-Level 13mm Plate | 2 |
| 14-522114 | 1-Level 14mm Plate | 2 |
| 14-522116 | 1-Level 16mm Plate | 2 |
| 14-522118 | 1-Level 18mm Plate | 2 |
| 14-522120 | 1-Level 20mm Plate | 2 |
| 14-522220 | 2-Level 20mm Plate | 2 |
| 14-522222 | 2-Level 22mm Plate | 2 |
| 14-522224 | 2-Level 24mm Plate | 2 |
| 14-522226 | 2-Level 26mm Plate | 2 |
| 14-522228 | 2-Level 28mm Plate | 2 |
| 14-522230 | 2-Level 30mm Plate | 2 |
| 14-522232 | 2-Level 32mm Plate | 2 |
| 14-522234 | 2-Level 34mm Plate | 2 |
| 14-522236 | 2-Level 36mm Plate | 2 |
| 14-522238 | 2-Level 38mm Plate | 2 |
| 14-522240 | 2-Level 40mm Plate | 2 |
| 14-522336 | 3-Level 36mm Plate | 1 |
| 14-522339 | 3-Level 39mm Plate | 1 |
| 14-522342 | 3-Level 42mm Plate | 1 |
| 14-522345 | 3-Level 45mm Plate | 1 |
| 14-522348 | 3-Level 48mm Plate | 1 |
| 14-522351 | 3-Level 51mm Plate | 1 |
| 14-522354 | 3-Level 54mm Plate | 1 |
| 14-522357 | 3-Level 57mm Plate | 1 |
| 14-522360 | 3-Level 60mm Plate | 1 |
| 14-522363 | 3-Level 63mm Plate | 1 |
| 14-522366 | 3-Level 66mm Plate | 1 |

| Catalog # | Description | Qty |
|-----------|----------------------------------|-----|
| 14-521512 | 4.0mm x 12mm Fixed Bone Screw | 8 |
| 14-521514 | 4.0mm x 14mm Fixed Bone Screw | 16 |
| 14-521516 | 4.0mm x 16mm Fixed Bone Screw | 8 |
| 14-521542 | 4.5mm x 12mm Fixed Bone Screw | 8 |
| 14-521544 | 4.5mm x 14mm Fixed Bone Screw | 8 |
| 14-521546 | 4.5mm x 16mm Fixed Bone Screw | 8 |
| 14-521612 | 4.0mm x 12mm Variable Bone Screw | 8 |
| 14-521614 | 4.0mm x 14mm Variable Bone Screw | 16 |
| 14-521616 | 4.0mm x 16mm Variable Bone Screw | 8 |
| 14-521642 | 4.5mm x 12mm Variable Bone Screw | 8 |
| 14-521644 | 4.5mm x 14mm Variable Bone Screw | 8 |
| 14-521646 | 4.5mm x 16mm Variable Bone Screw | 8 |



Ordering Information (Continued)

Standard Instruments

| Catalog # | Description | Qty |
|-----------|---|-----|
| 14-522992 | Instrument Kit | |
| 14-522000 | Screw Inserter | 2 |
| 14-522001 | Screw Remover | 1 |
| 14-521003 | Large Handle Screw Remover Sleeve | 1 |
| 14-521002 | Quick Adjustment Driver | 1 |
| 14-521004 | Quick Connect Handle | 2 |
| 14-521012 | 4.0mm x 12mm Drill | 2 |
| 14-521014 | 4.0mm x 14mm Drill | 2 |
| 14-521016 | 4.0mm x 16mm Drill | 2 |
| 14-521030 | Single Barrel Handheld Drill Guide | 1 |
| 14-521032 | Double Barrel Handheld Drill Guide | 1 |
| 14-521035 | Endplate Drill Guide | 1 |
| 14-521038 | 5.0mm Graft Trial Drill Guide | 1 |
| 14-521039 | 6.0mm Graft Trial Drill Guide | 1 |
| 14-521040 | 7.0mm Graft Trail Drill Guide | 1 |
| 14-521041 | 8.0mm Graft Trail Drill Guide | 1 |
| 14-521042 | 9.0mm Graft Trial Drill Guide | 1 |
| 14-521043 | 10mm Graft Trial Drill Guide | 1 |
| 14-521060 | Awl (10mm in Bone) | 1 |
| 14-521061 | Punch Awl (10mm in Bone) | 1 |
| 14-521062 | Plate Holder | 1 |
| 14-521063 | Plate Bender | 1 |
| 14-521070 | Distractor Pin / Tack Inserter | 1 |
| 14-521071 | Tack | 6 |
| 14-521072 | 12mm Distraction Pins (Qty. 2) | 2* |
| 14-521074 | 14mm Distraction Pins (Qty. 2) | 2* |
| 14-521076 | 16mm Distraction Pins (Qty. 2) | 2* |
| 14-521079 | Large Distraction Pin Template | 1 |
| 14-521080 | Pin Distractor (Left) | 1 |
| 14-521081 | Pin Distractor (Right) | 1 |
| 14-521091 | Screw Remover with Tine (Blue Plate Removal) | 1 |

*Not part of kit, to be ordered separately

Further Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

This brochure describes the surgical technique used by Alan S. Hilibrand, M.D., K. Daniel Riew, M.D. and Jeffrey C. Wang, M.D. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Biomet Spine
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