

Ant-Cer II[®]

Dynamic Anterior Cervical Plate System



Surgical Technique



Solutions by the people of Zimmer Spine.
zimmerspine.com

Segmented design. Dynamic results. From the people of Zimmer Spine.

The Ant-Cer II Dynamic Anterior Cervical Plate is the result of our engineering team providing an extraordinary solution to cervical spine fusion with the goal of improving patient results. The unique design features of Ant-Cer II System successfully leverage the principles of Wolff's Law to promote a quicker and stronger fusion while minimizing the risk of the implant impinging into the healthy disc space.

When employing Wolff's Law to cervical fusions, continual axial graft loading should be applied during discectomy fusions and corpectomy procedures, and Ant-Cer II System is designed to accommodate both. With its single-level and multi-level plate designs, Ant-Cer II System provides sustained axial load on the graft while maintaining intimate bone/plate fixation. Its effective, proprietary Controlled Ratcheting Technology and segmented design are examples of unique solutions brought to you by the people of Zimmer Spine.

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Description/Indications/Contraindications

Description

The Zimmer Spine *SC-AcuFix Ant-Cer II* Dynamic Anterior Cervical Plate System components are temporary implants that are used to stabilize the cervical spine during the development of a solid spinal fusion in patients with degenerative disease, trauma (including fractures), and tumor pathology.

The *SC-AcuFix Ant-Cer II* Dynamic Anterior Cervical Plate System consists of multi-segmented titanium bone plates of various sizes and lengths, titanium bone screws in various diameters and lengths, and associated instrumentation. Fixation is provided by the insertion of bone screws through the two openings at each end of a plate segment into the vertebral bodies of the cervical spine. Fixation of the screws to the plate is accomplished by seating into the SecureRing® screw retention mechanism. Screws may also be inserted into additional adjacent screw holes of multi-segment plates if needed.

Indications

The *SC-AcuFix Ant-Cer II* Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

Contraindications

1. Presence of overt infection and/or localized inflammation.
2. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
6. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
7. Use in displaced, non-reduced fractures with bone loss.
8. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
9. Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
10. The physical contact of the *SC-AcuFix Ant-Cer II* Dynamic Anterior Cervical System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F138) or MP35 N, or other dissimilar metal.
11. Situations with the absence or compromise of significant stabilizing elements.
12. Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.

Ant-Cer II System Implants



One-Level Plate (24 - 32mm)
1707-1024 to 1707-1032



Two-Level Plate (36 - 54mm)
1707-2036 to 1707-2054



Three-Level Plate (53 - 71mm)
1707-3053 to 1707-3071



Four-Level Plate (72 - 96mm)
1707-4072 to 1707-4096



Rescue Screw (12 - 15mm)
402-45112 to 402-45115



Self-Drilling Wide Root Screw (12 - 15mm)
402-47112 to 402-47115



Self-Tapping Wide Root Screw (12 - 15mm)
402-43112 to 402-43115

SC-AcuFix System Instruments



Temporary Fixation Pins
457-1

Provide additional plate stability before screw insertion.



Temporary Fixation Pin Inserter
497-1

Places Temporary Fixation Pins.



Modular Drill Guide Handle
462-1

Secures to Freehand Fixed Depth Drill Guides.



Modular AO Handle
561-2

Secures to Modular Hex Driver and 2.5mm Drills.



Reduced Length 2.5mm Long Drill
453-31

Drills holes for self-tapping screws in conjunction with Freehand Drill Guide.



Reduced Length Combo 2.5mm Drill/4.0mm Tap
489-31

Drills and taps holes for screws in conjunction with Freehand Drill Guide. **Power drilling is not recommended for use with this tap.**



Multi-Angle Fixed Depth Drill Guide
491-1

Allows for drilling, tapping and screw placement in intermediate screw holes.



Modular 2.5mm Hex Driver

450-2

Used with Modular AO Handle to implant 2.5mm self-tapping or self-drilling screws. **Do not use with Fixed Angle Guides. May cause screw misalignment.** Tapered, self-securing tip allows easy retrieval and insertion of screws.



Fixed Angle 2.5mm Stop Drill (12 - 14mm)

482-312 to 482-314

Used with the Fixed Angle Drill Guides to drill holes for screws. Available in lengths of 12, 13 and 14mm.



Fixed Angle Combo Stop 2.5mm Drill/

4.0mm Tap (12 - 14mm)

480-312 to 480-314

Used in conjunction with Fixed Angle Drill Guide in cases where surgeon identifies preference for tapping. Available in lengths of 12, 13 and 14mm. **Power drilling is not recommended for use with this tap.**



Fixed Angle 2.5mm Hex Driver

493-11

Implants *SC-AcuFix* Screws. When used with the Fixed Angled Drill Guide, it automatically disengages the implanted screw head 1 - 1.5mm proud of the *SecureRing*[®] Locking Mechanism, enabling easy removal and redirection of the screw, if necessary.



Rescue Driver

474-1

Used for screw removal and revision. Threaded Removal Driver may be substituted in cases of compromised bone purchase.



Threaded Removal Driver

479-1

Recommended for screw removal and revision in cases of compromised bone purchase. Central threaded post secures to the internal threads of bone screws.

Ant-Cer II One-Level System Instruments



Double Barrel Fixed Angle Drill Guide
1752-01

A single cannula for drilling and screw placement provides consistent screw angulation and screw-to-plate trajectory. A predetermined 6° medial, 6° cephalad/caudal bias guarantees placement within ROM. Registration pin-to-plate capture assures secure fit during usage.

Not compatible with multi-angle drill guides.



Freehand Fixed Depth Drill Guide (12 - 15mm)
1777-12 to 1777-15

Provides tactile feedback for screw placement within 15° ROM. Assembles with Modular System Handle.

Should not be used with the multi-level plates, as swivel damage may result.



Cortical Spring Punch*
447-13

Allows surgeon increased bone sparing during screw preparation and insertion. Instrument's hard stop prevents over-insertion.



Restrictor Plate Removal Driver
1755-01

Retention clips lock onto restrictor plate for secure restrictor plate removal.

Will not remove multi-level restrictor plates.



One-Level Sizing Templates (24 - 32mm)
1760-01 to 1760-05

Determine plate length, screw hole placement on affected vertebral bodies.

*Available by special order only.

Ant-Cer II Multi-Level System Instruments



Double Barrel Fixed Angle Drill Guide
1775-01

Single cannula for drilling, screw placement provides consistent screw angulation and screw-to-plate trajectory. Predetermined 6° medial, 6° cephalad/caudal bias guarantees placement within ROM. Hex geometry allows six-way rotation of handle for improved visualization.
Will not work with one-level plates.



Single Barrel Fixed Angle Drill Guide (Left)
1774-01

Single Barrel Fixed Angle Drill Guide (Right)
1774-02

Two cannulae for drilling, screw placement provides consistent screw angulation and screw-to-plate trajectory. Predetermined 6° medial, 6° cephalad/caudal bias guarantees placement within ROM. Hex geometry allows six-way rotation of handle for improved visualization.
Will not work with one-level plates.



Freehand Fixed Depth Drill Guide (12 - 15mm)
1765-12 to 1765-15

Provides greater visibility in drilling screw hole. Assembles with Modular System Handle (12 – 15mm).



Cortical Punch
1776-01

Allows surgeon increased bone sparing during screw preparation and insertion. Instrument's hard stop prevents over-insertion.



Restrictor Plate Removal Driver
1762-01

Retention clips lock onto restrictor plate for secure restrictor plate removal. Magenta handle differentiates multi-level from one-level removal driver.
Will not remove one-level restrictor plate.



Multi-Level Sizing Templates
1770-series

Determine plate length, screw hole placement on affected vertebral bodies. Trials have similar geometry to plates.

One-Level Surgical Technique

Patient Positioning

Step 1



Patient Positioning

Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination. Place the patient in a supine position. Support the posterior cervical spine to maintain normal lordosis and choose a right- or left-sided approach. Identify the symptomatic level and make a skin incision to the corresponding pathology.

Plate Placement

Step 2

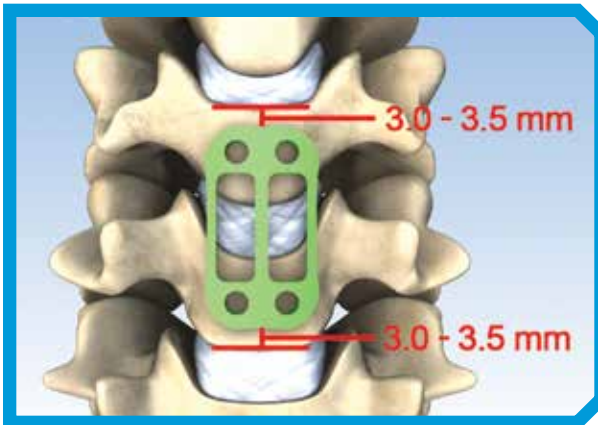


Plate Sizing

Use calipers or titanium templates to determine the appropriate plate size. The appropriately sized plate will not interfere with the adjacent unfused disc space.

If using calipers, take care with its sharp tips. If using templates, reference the holes in the trial to position its screw holes relative to the vertebral body's endplate. Do not drill holes or put screws in the template.

Step 3

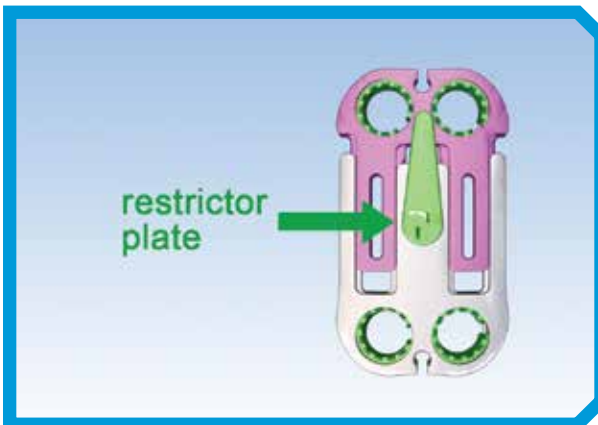


Plate Positioning

Confirm the presence of the implant's restrictor plates before removing it from the kit. Inspect the underside of the plate and ensure that the ratchet mechanism is engaged. On the anterior cervical spine, position the caudal and cephalad screw holes 3.0 - 3.5mm from edge of the vertebral body, or as close as possible to the graft site without compromising the vertebral endplate.

Do not remove the restrictor plate until the screws have been locked into the plate. Do not use the implant if the ratchet is not engaged or is otherwise compromised, bent or damaged.

Step 4



Temporary Fixation

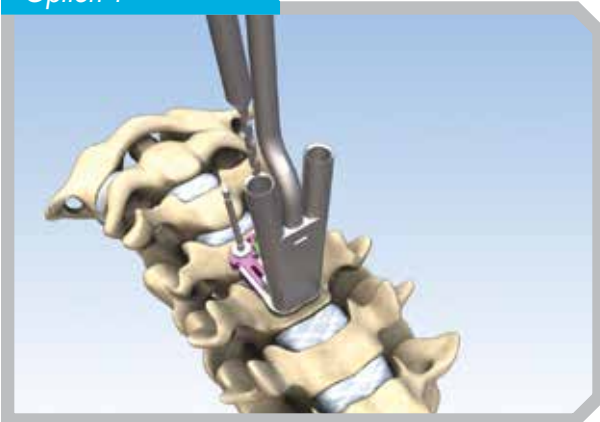
Pull back on the center ring of the Temporary Fixation Pin Inserter to hold the long shaft of the Temporary Fixation Pin. Position the pin's tip in the center of any screw hole at the same angle planned for the screw (ROM for screws is 15° for single-level plates). Take care to maintain its alignment and position.

Turn the pin clockwise until it is seated in the screw hole; remove the Temporary Fixation Pin Inserter from the driver by pulling up on its outer sleeve.

Note: Use of Temporary Fixation Pins may affect fixation of screws. Be sure to remove the Temporary Fixation Pins prior to inserting the screws and prior to closing the incision site.

Fixed Angle Drill Guide Option

Option 1

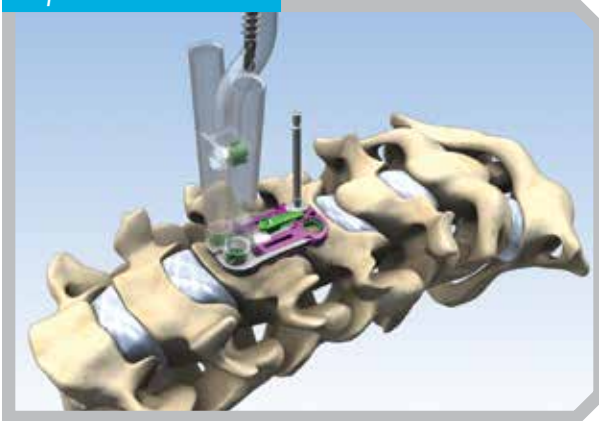


Option 1: 2.5mm Drill (Optional)

Securely engage the Fixed Angle Drill Guide (FADG) to the plate by sliding its pin into the hole at the end of the plate. Assemble the appropriate length 2.5mm Drill with the Modular AO Handle. Insert assembly into previously seated FADG. Rotate clockwise, advancing into bone until hard stop makes contact with top of the guide.

Note: Double-Barrel Drill Guide cannot be used with Temporary Fixation Pins in place. Remove pins prior to attaching guide.

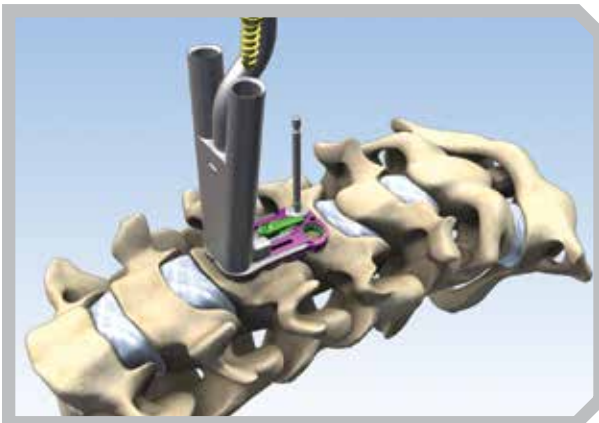
Option 2



Option 2: Combo 2.5mm Drill / 4.0mm Tap (Optional)

If using the Combo 2.5mm Drill/4.0mm Tap, observe the stop collar and stop rotation such that the drill/tap stops just short of seating with the top of the guide (to prevent stripping). The instrument will not come to a hard stop.

Note: Use of power is strongly discouraged with this tap. To remove from bone, turn drill or combo drill/tap counterclockwise while gently pulling up.



FADG Screw Placement

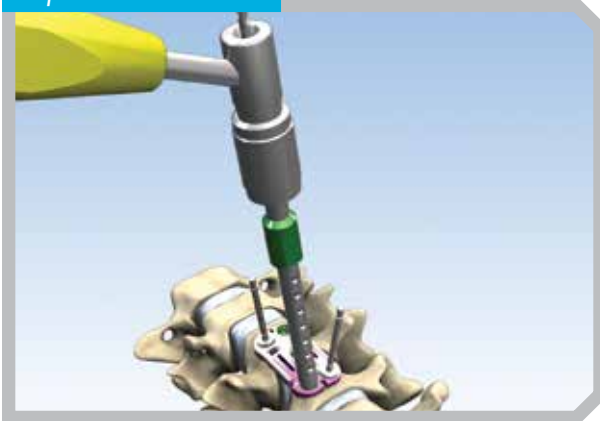
Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Select a screw length consistent with the drill size. Secure the screw to the driver and insert into the Drill Guide cannulae. Tighten screw into the plate until the Hex Driver's hard stop makes contact with the top of the guide. The guide will automatically disengage, leaving the top of the screw head 1 - 1.5mm proud of the top of the *SecureRing* Locking Mechanism. To prevent plate 'twisting' during screw insertion, insert the second screw contralateral to the first.

Note: Use of the Multi-Angle Drill Guide with the Modular Hex Driver is strongly discouraged. Use may increase risk of screw misalignment and/or alignment outside the ROM.

Freehand Drill Guide Option

Option 1



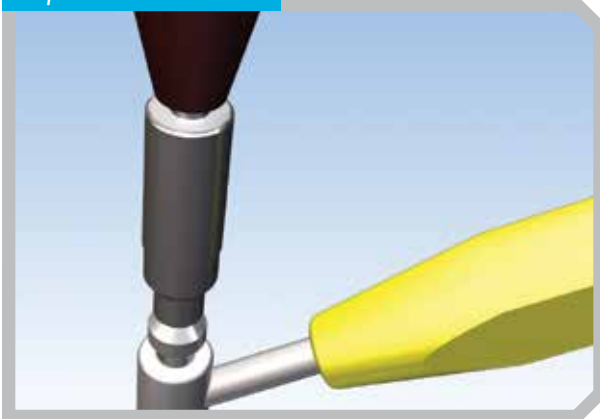
Freehand Fixed Depth Drill (Optional)

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Assemble the Reduced Length 2.5mm Drill/Mini AO Handle and appropriately sized Freehand Fixed Depth Drill Guides/Modular System Handle.

Prior to drilling, seat the tip of the Modular Tube assembly inside the *SecureRing* Mechanism swivel. Ensure that the Drill Guide is placed perpendicular to screw hole; then angle to its desired location, taking care not to exceed (15° for single-level) ROM. Place drill down the previously oriented Freehand Drill Guide assembly and rotate clockwise, advancing the drill into bone until its hard stop makes contact with the back of the guide. To remove it from the bone, turn counterclockwise while pulling up.

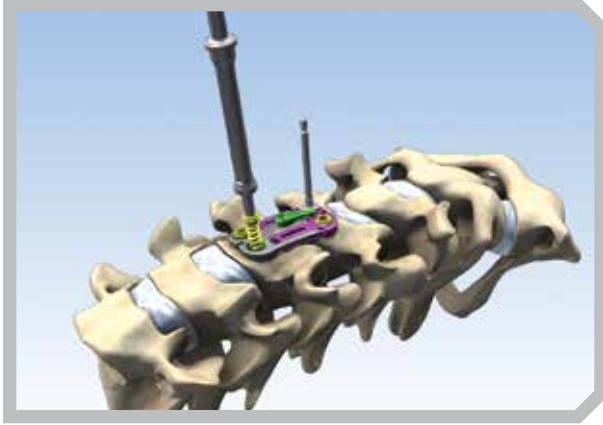
Option 2



Combo 2.5mm Drill / 4.0mm Tap (Optional)

If you prefer tapping, use the reduced length Combo 2.5mm Drill/4.0mm Tap and observe the distance of the stop collar on instrument and Drill Guide. Stop just short of seating the combo to prevent stripping; it will not come to a hard stop.

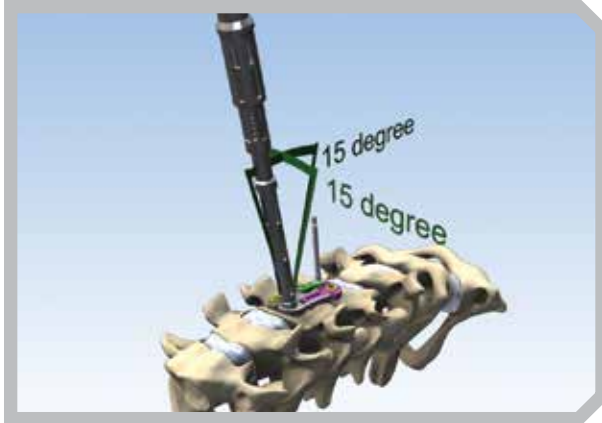
Note: Power is not recommended for use with this tap.



Screw Insertion

Select a screw length consistent with the size of the Modular Drill Tube. Secure the screw to the driver and insert into the plate until the screw is 1-2mm proud of the *SecureRing* Mechanism. For single-level plates, angle the screw toward its desired location. To prevent 'twisting' during screw insertion, insert the second screw contralateral to the first.

Cortical Punch Option

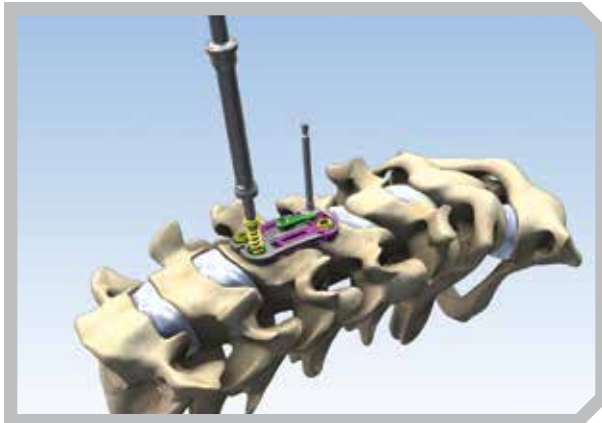


Cortical Punch (Optional)

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

If the Variable Depth Cortical Punch is used, adjust the depth of the punch (5 - 13mm) by turning its distal end until the gauge registers the desired depth. **Depth of punch is 5-13mm to prevent injury.**

Seat the Cortical Punch's tip inside the *SecureRing* Mechanism. Position the punch perpendicular to the screw hole. For single level plates, angle the punch to the desired location, taking care not to exceed 15° ROM. With hand pressure or a mallet, apply downward force to the handle, causing the trocar tip to extend from the punch's distal end. You may twist or turn the trocar tip to penetrate hard cortical bone prior to impacting the punch into the inner cancellous bone.

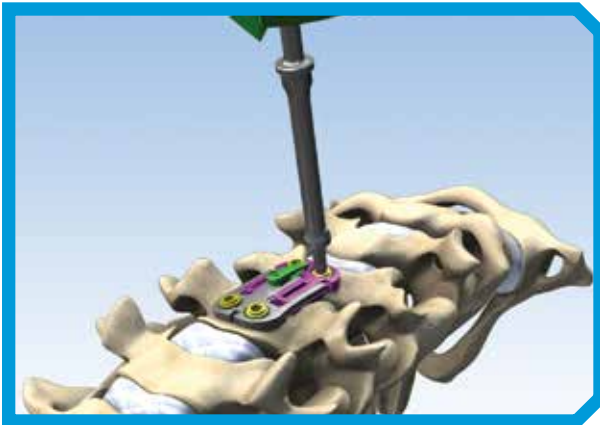


Screw Insertion

Assemble the modular 2.5mm Hex/Modular AO Handle. Select a screw length consistent with the depth of the punch. Secure the screw to the driver and insert into the plate until its head is 1-2mm proud of the *SecureRing* Mechanism. To prevent 'twisting' during screw insertion, insert the second screw contralateral to the first.

Final Placement

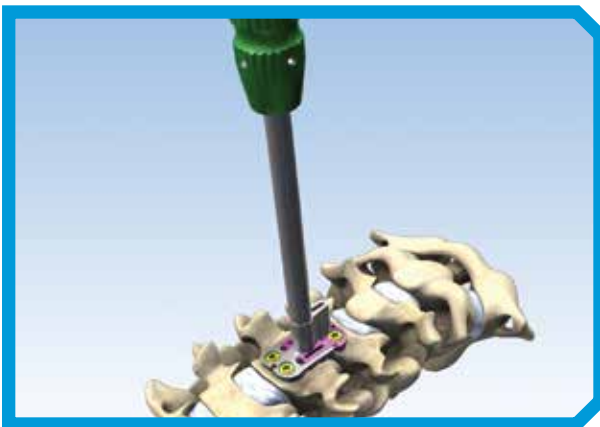
Step 5



Tighten Screws

Tighten all screws finger tight and position the plate flush to the anterior cortex of the cervical spine; screws should be locked in *SecureRing* Mechanism, flush or below the proximal surface of the plate. *SecureRing* “Fingers” should have slid over the screws’ heads. A lateral radiographic image taken before closing should confirm that all screw heads are flush or below the plate’s superior plane.

Step 6



Restrictor Plate Removal

The single-level restrictor plates can only be removed with the green-handled Restrictor Plate Removal Driver.

Position the Restrictor Plate Removal Driver over the restrictor plate, with its shaft located over the restrictor plate’s single screw. With gentle pressure, snap the driver’s retention clips onto the restrictor plate. Gently apply downward pressure, rotating the knob at the top of the driver counterclockwise (approximately six full rotations) and unscrewing the restrictor plate from the *Ant-Cer II* Plate.

Lift the driver from the wound. At the scrub table, remove the restrictor plate from the Removal Driver, confirming its full removal. **Discard the restrictor plate with other biohazardous material as determined by the facility; it cannot be reinstalled.**

Removal / Revision Option

The *SecureRing* Screw Locking Mechanism can be locked and unlocked up to three times without compromising strength. Use either the Rescue Driver or the Threaded Removal Driver.

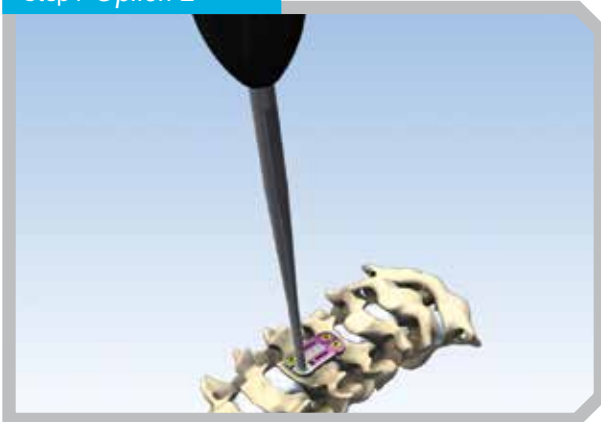
Step 7 Option 1



Option 1: Threaded Driver

Secure driver's threaded post into the central, internal thread of bone screws.

Step 7 Option 2



Option 2: Rescue Driver

Insert driver's tip into the screw, turning it 180° counterclockwise.

Rest either driver's handle in palm and rotate driver's head in a 2-inch circle, ensuring that its head stays seated within the screw. Remove the screw, maintaining downward pressure and rotating the driver's handle counterclockwise.

Multi-Level Surgical Technique

Patient Positioning

Step 1



Patient Positioning

Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination. Place the patient in a supine position. Support the posterior cervical spine to maintain normal lordosis and choose a right- or left-sided approach. Identify the symptomatic level and make a skin incision to the corresponding pathology.

Plate Placement

Step 2

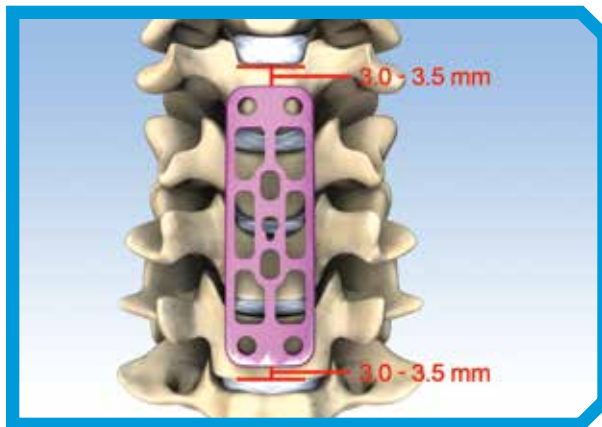


Plate Sizing

Ensure that the kit is clean and that the correct plates are present to address the pathology. An appropriately sized plate will not interfere with the adjacent unfused disc space. Use calipers or titanium templates to determine the plate size. If using calipers, be careful with their sharp tips. If using a template, reference its holes to position screw holes relative to the vertebral body's endplate. Do not drill holes or put screws in the template. Inspect the underside of the implant to ensure that the ratchet mechanism is engaged. Select an appropriately sized plate that will not interfere with the adjacent unfused disc space.

Step 3

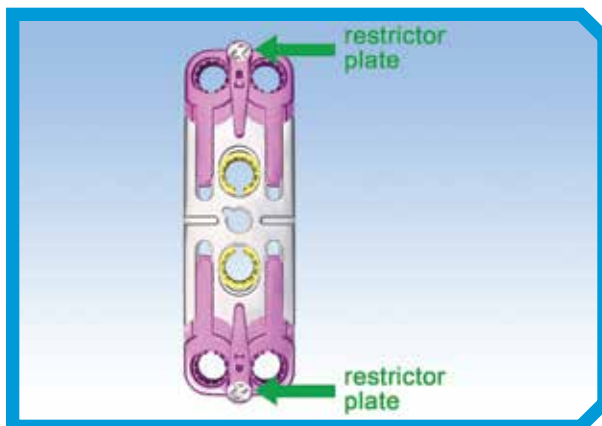
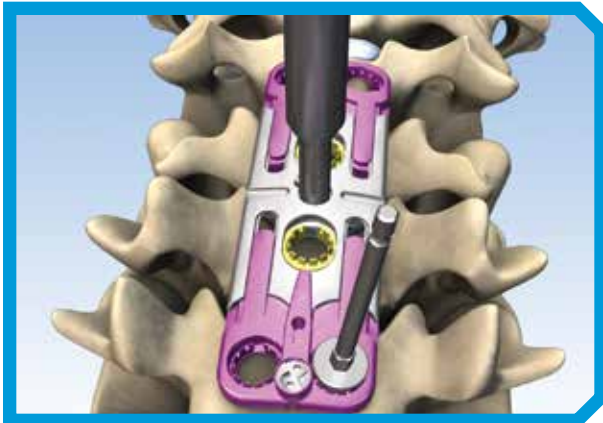


Plate Positioning

Confirm the presence of the implant's restrictor plates before removing it from the kit. Inspect the underside of the plate and ensure that the ratchet mechanism is engaged. On the anterior cervical spine, position the caudal and cephalad screw holes 3.0 - 3.5mm from the edge of the vertebral body, or as close as possible to the graft site without compromising the vertebral endplate.

Note: Do not remove the restrictor plate until the screws have been locked into the plate. Do not use the implant if the ratchet is not engaged or is otherwise compromised, bent or damaged.

Step 4



Temporary Fixation

Pull back on the center ring of the Temporary Fixation Pin Inserter to hold the long shaft of the Temporary Fixation Pin. Position the pin's tip in the center of any screw hole at the same angle planned for the screw (for multi-level plates, the ROM is constrained and screws can only be placed at an 8° caudal/cephalad and 6° medial angle). Take care to maintain plate alignment and position.

Turn the pin clockwise until seated in screw hole; remove the Temporary Fixation Pin Holder from the driver by pulling up on its outer sleeve.

Note: Use of Temporary Fixation Pins may affect the fixation of screws. Be sure to remove the Fixation Pin prior to inserting screw and prior to closing the incision site.

Two-level plates are not compatible with the plate holder. Use an alternate method (forceps, fingers) to place two-level plates on the anterior cervical spine. Be sure to remove the Fixation Pin prior to inserting screw and prior to closing the incision site.

Fixed Angle Drill Guide Option

Option 1

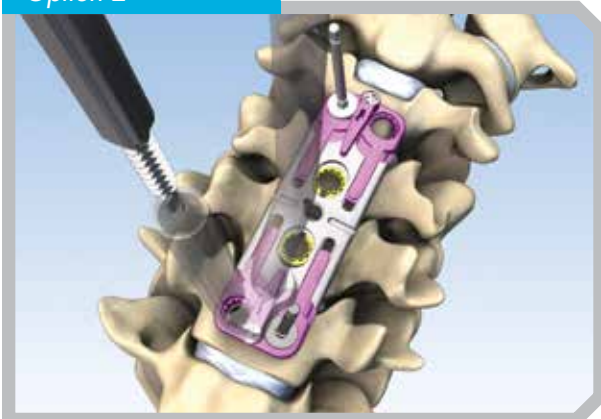


2.5mm Stop Drill (Optional)

At a minimum, prepare to place screws in all four cephalad/caudal holes. For cephalad and caudal holes, fit the multi-level FADG over the restrictor plate. Assemble the appropriate length Fixed Angle 2.5mm Stop Drill with the Modular AO Handle. Insert the assembly into the previously seated guide. Rotate clockwise, advancing into bone until hard stop makes contact with the top of guide.

Note: Double-Barrel Drill Guide cannot be used with Temporary Fixation Pins in place. Remove pins prior to attaching the guide.

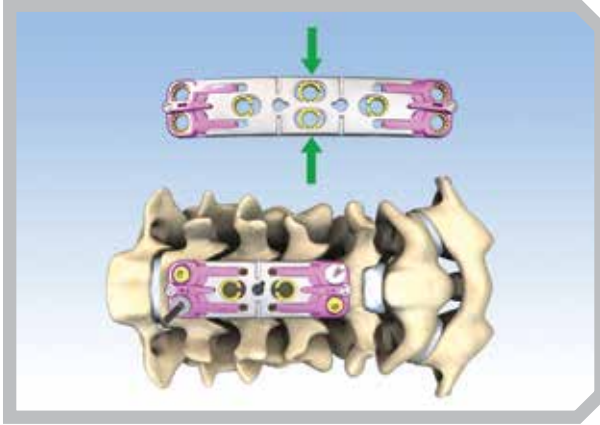
Option 2



2.5mm Drill / 4.0mm Tap (Optional)

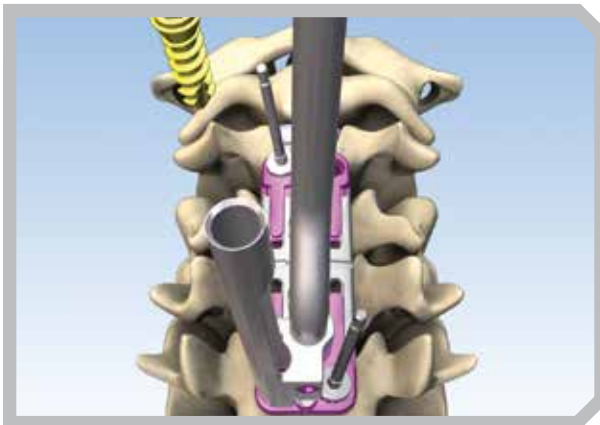
If using the combo 2.5mm drill/4.0mm tap, observe the stop collar and stop rotation such that the drill/tap stops just short of seating with the top of the guide to prevent stripping. The instrument will not come to a hard stop.

Note: Use of power is strongly discouraged with this tap. To remove from bone, turn the drill or Combo Drill/Tap counterclockwise while gently pulling up.



Drilling Intermediate Holes

Prior to drilling, move the gold *SecureRing* Locking Mechanism towards the nearest magenta plate end. For the four level plate, place the center-most *SecureRing* Mechanism in the middle of the slot. Drill intermediate holes identically as the cephalad/caudal holes, using either the 2.5mm Stop Drill or drill/tap combo.



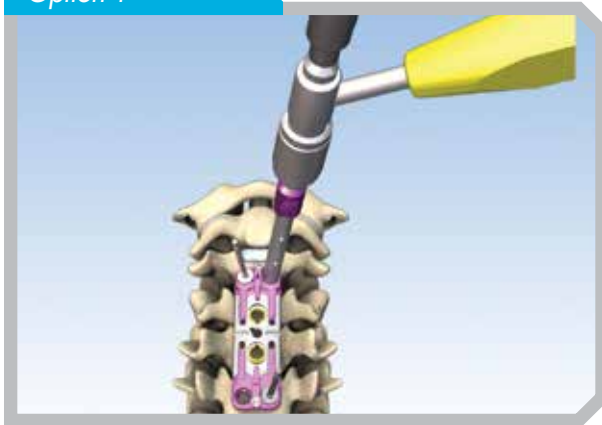
Screw Insertion

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes. Select a screw length consistent with the drill size. Secure screw to driver and insert into the Drill Guide cannulae. Tighten screw into the plate until Hex Driver's hard stop makes contact with the top of the guide. The guide will automatically disengage, leaving the top of the screw head 1 - 1.5mm proud of the *SecureRing* Mechanism. To prevent plate 'twisting' during screw insertion, insert the second screw contralateral to the first. Use of the Multi-Angle Drill Guide with the Modular Hex Driver is strongly discouraged.

Note: Use may increase risk of screw misalignment and/or alignment outside the ROM.

Freehand Fixed Depth Drill Option

Option 1



Reduced Length 2.5mm Long Drill (Optional)

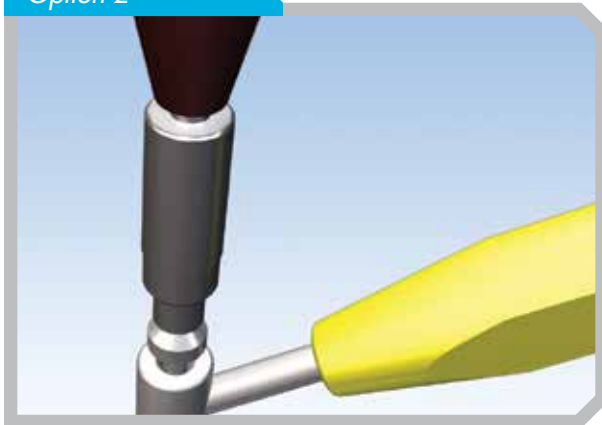
Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Assemble the Reduced Length 2.5mm Long Drill/Mini AO Handle and appropriately sized Freehand Fixed Depth Drill Guides/Modular System Handle.

Prior to drilling, seat the tip of the Modular Tube assembly inside the *SecureRing* Swivel. Ensure that the Drill Guide is placed perpendicular to screw hole; then angle to its desired location. Recall that the magenta swivel is constrained and screws can only be placed at a 8° cephalad/caudal and 6° medial angle. The gold (center) swivel has a 6° conical ROM.

Place the drill down the previously oriented Freehand Drill Guide assembly and rotate clockwise, advancing the drill into bone until its hard stop makes contact with the back of the guide. To remove from the bone, turn counterclockwise while pulling up.

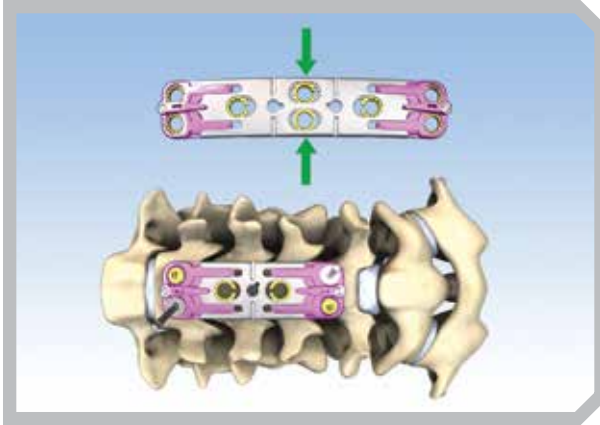
Option 2



Reduced Length 2.5mm Drill/4.0mm Tap (Optional)

If you prefer tapping, use Reduced Length Combo 2.5mm Drill/4.0mm Tap and observe the distance of the stop collar on the instrument and Drill Guide. Stop just short of seating combo to prevent stripping; it will not come to a hard stop.

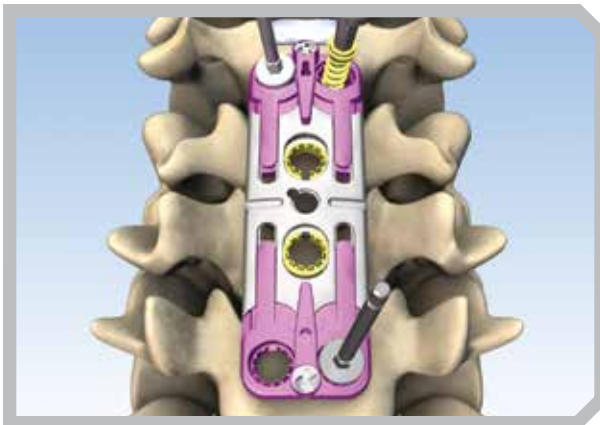
Note: Prior to drilling the intermediate holes, move the gold swivel towards the nearest magenta end of the plate.



Drilling Intermediate Holes

Place the center-most *SecureRing* Mechanisms in the middle of the slot. In creating the intermediate holes, use the Multi-Angle Fixed Depth Drill Guide with the 2.5mm Stop Drill or drill/tap combo to create the holes.

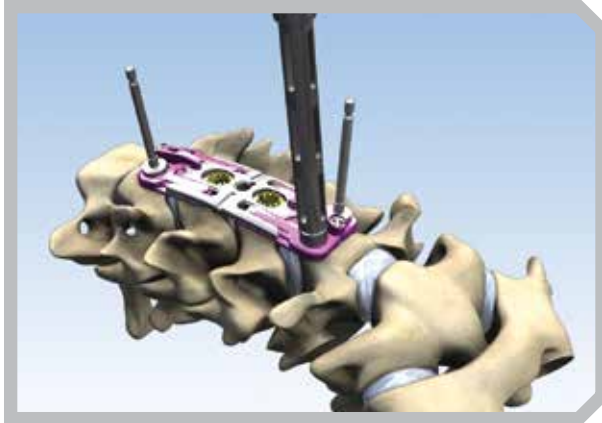
Note: Power is not recommended for use with this tap.



Screw Insertion

Select a screw length consistent with the size of the Modular Drill Tube. Secure the screw to the driver and insert into the plate until screw is 1-2mm proud of the *SecureRing* Mechanism. To prevent 'twisting' during screw insertion, insert a second screw contralateral to the first.

Cortical Punch Option



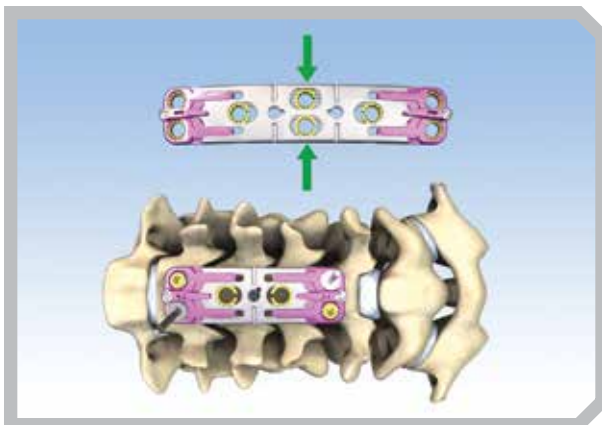
Cortical Punch (Optional)

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

If the Variable Depth Cortical Punch is used, adjust the depth of the punch (5 - 13mm) by turning the distal end of the punch until the gauge registers the desired depth.

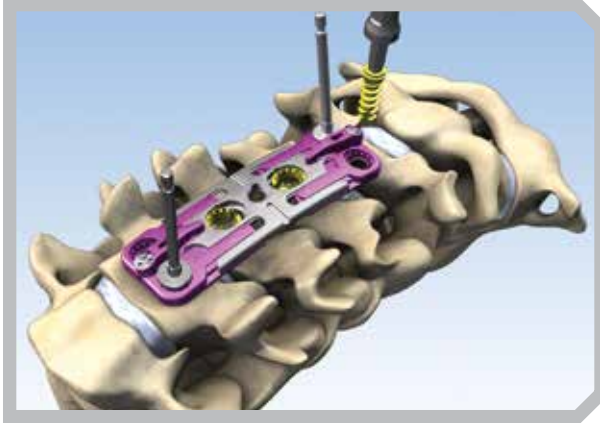
Depth of punch is 5-13mm to prevent injury.

Seat the Cortical Punch's tip inside the *SecureRing* Mechanism. Position punch perpendicular to screw hole, then angle to its desired trajectory. The magenta (constrained) *SecureRing* Mechanism will facilitate screw placement at a 8° caudal/cephalad and 6° medial angle. The gold *SecureRing* Mechanism has a 6° conical ROM with a 0° cephalad/caudal bias. Prior to punching the intermediate holes, move the gold ring towards the nearest magenta end of the plate.



Drilling Intermediate Holes

For the four-level plate, place the center-most *SecureRing* Mechanisms in the middle of the slot. With hand pressure or a mallet, apply downward force to handle, causing the trocar tip to extend from the punch's distal end. You may twist or turn the trocar tip to penetrate hard cortical bone prior to impacting the punch into the inner cancellous bone.



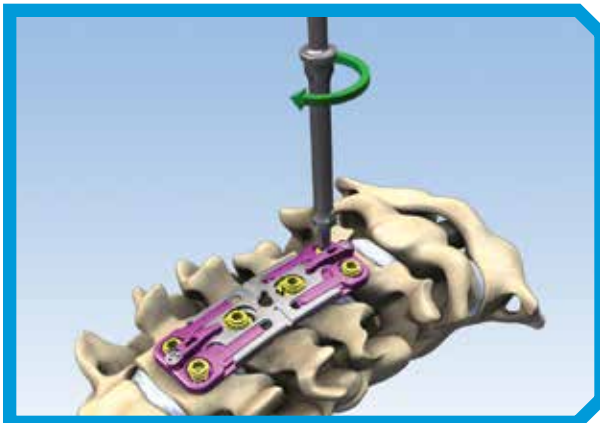
Screw Insertion

Assemble the modular 2.5mm Hex/Modular AO handle. Select a screw length consistent with the depth of the punch. Secure the screw to the driver and insert into plate until head is 1-2mm proud of the *SecureRing* Mechanism. To prevent 'twisting' during screw insertion, insert a second screw contralateral to the first.

Note: In order to obtain full subsidence on two-level plates, be sure to place screw such that the gold (center) *SecureRing* Mechanism is as far cephalad as possible.

Final Placement

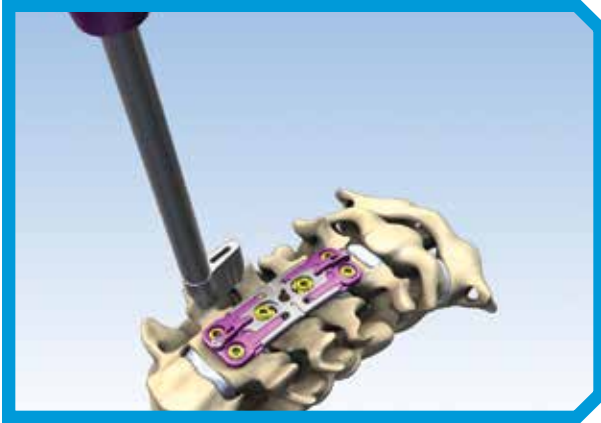
Step 5



Tighten Screws

Tighten all screws finger tight and position the plate flush to the anterior cortex of the cervical spine; screws should be locked in the *SecureRing* Mechanism, flush or below the proximal surface of the plate. *SecureRing* "Fingers" should have slid over the screws' heads. A lateral radiographic image taken before closing should confirm that all screw heads are flush or below the plate's superior plane.

Step 6



Restrictor Plate Removal

Multi-level restrictor plates can only be removed with the magenta-handled Restrictor Plate Removal Driver.

Position the Restrictor Plate Removal Driver over the restrictor plate, with shaft located over the restrictor plates's single screw. With gentle pressure, snap the driver's retention clips onto the restrictor plate. Gently apply downward pressure, rotating the knob at the top of the driver counterclockwise (approximately six full rotations), unscrewing the restrictor plate from the *Ant-Cer II* Plate.

Lift the driver from the wound. At the scrub table, remove the restrictor plate from the Removal Driver, confirming full removal.

Note: Discard restrictor plate with other biohazardous material as determined by the facility; it cannot be reinstalled.

Removal / Revision Option

The *SecureRing* Screw Locking Mechanism can be locked and unlocked up to three times without compromising strength. Use either the Rescue Driver or the Threaded Removal Driver.

Step 7 Option 1



Option 1: Threaded Driver

Secure the driver's threaded post into the central, internal thread of the bone screws.

Step 7 Option 2



Option 2: Rescue Driver

Insert the driver's tip into the screw, turning it 180° counterclockwise.

Rest either driver's handle in the palm and rotate its head in a 2-inch circle, ensuring that its head stays seated within the screw. Remove the screw, maintaining downward pressure and rotating the driver's handle counterclockwise.

Kit Contents

Module Number 400-0005-PL

SC-AcuFix System Core Instruments

Part Number	Description	Standard Kit Quantity
450-2	2.5mm Modular Hex Driver	2
451-2	Plate Bender	1
452-2	Plate Holder With Rotating Handle	1
462-1	Modular Drill Guide Handle	2
474-1	Hex Rescue Driver Assembly	1
479-1	Threaded Screw Removal Driver	1
481-1	Bone Compass	1
488-1	Plate Tamp	1
491-1	Multi-Angle Fixed Drill Guide	1
493-11	FA 2.5mm Hex Driver, Short	1
497-1	SC-AcuFix Temp Fixation Pin Insrter	1
561-2	D Cnct Finger Tip Handle AO Capture	2

Module Number 400-0008-PL

SC-AcuFix System Core Consumables

Part Number	Description	Standard Kit Quantity
453-31	2.5mm Reduced Length Long Drill	1
457-1	Screw Hole Temporary Fixation Pin	3
480-312	FA ShrtCmbo Stp 2.5mmDril/4mmTap 12	1
480-313	FA ShrtCmbo Stp 2.5mmDril/4mmTap 13	1
480-314	FA ShrtCmbo Stp 2.5mmDril/4mmTap 14	1
482-312	ACP FA 2.5mm Dia Shrt Stp Dril,12mm	1
482-313	ACP FA 2.5mm Dia Shrt Stp Dril,13mm	1
482-314	ACP FA 2.5mm Dia Shrt Stp Dril,14mm	1
489-31	Rdcd Lgth Combo 2.5mm Drill/4mm Tap	1

Module Number 1700-0018-PL

Ant-Cer II One-Level Plate Systems

Part Number	Description	Standard Kit Quantity
1707-1024	Dynamic ACP Plate, 1 Level, 24mm	2
1707-1026	Dynamic ACP Plate, 1 Level, 26mm	2
1707-1028	Dynamic ACP Plate, 1 Level, 28mm	2
1707-1030	Dynamic ACP Plate, 1 Level, 30mm	1
1707-1032	Dynamic ACP Plate, 1 Level, 32mm	1

Module Number 1700-0024-PL

Ant-Cer II One-Level Plates

Part Number	Description	Standard Kit Quantity
1707-1024	Dynamic ACP Plate, 1 Level, 24mm	2
1707-1026	Dynamic ACP Plate, 1 Level, 26mm	2
1707-1028	Dynamic ACP Plate, 1 Level, 28mm	2
1707-1030	Dynamic ACP Plate, 1 Level, 30mm	1
1707-1032	Dynamic ACP Plate, 1 Level, 32mm	1

Module Number 1700-0025-PL

Ant-Cer II One-Level Plates Instruments

Part Number	Description	Standard Kit Quantity
1760-01	Dyn ACP 24mm 1 Lvl Sizing Template	1
1760-02	Dyn ACP 26mm 1 Lvl Sizing Template	1
1760-03	Dyn ACP 28mm 1 Lvl Sizing Template	1
1760-04	Dyn ACP 30mm 1 Lvl Sizing Template	1
1760-05	Dyn ACP 32mm 1 Lvl Sizing Template	1

Module Number 1700-0019-PL

Ant-Cer II One-Level Instruments

Part Number	Description	Standard Kit Quantity
1752-01	Dyn ACP 1 Level Double Barrel FADG	1
1760-03	Dyn ACP 28mm 1 Lvl Sizing Template	1
1760-05	Dyn ACP 32mm 1 Lvl Sizing Template	1
1777-13	Dyn ACP Freehand FDDG 1 Lvl Only-13	1
1777-15	Dyn ACP Freehand FDDG 1 Lvl Only-15	1
1777-14	Dyn ACP Freehand FDDG 1 Lvl Only-14	1
1777-12	Dyn ACP Freehand FDDG 1 Lvl Only-12	1
1760-04	Dyn ACP 30mm 1 Lvl Sizing Template	1
1760-02	Dyn ACP 26mm 1 Lvl Sizing Template	1
1755-01	Dyn ACP 1 Level Stall Screw Driver	1
1760-01	Dyn ACP 24mm 1 Lvl Sizing Template	1
1094-021	Instrument Case (Metal) - 2" Base	1
1094-101	Instrument Case (Metal) - Base Lid	1
1795-1	Ant-Cer II Single Level System small tag	2
1795-2	Ant-Cer II Single Level System large tag	2
1790-27	Single Level Instrument Insert Tray	1

Module Number 1700-0027-PL

Ant-Cer II Two-Level Plates

Part Number	Description	Standard Kit Quantity
1707-2036	<i>Ant-Cer II 2 Level Plate Assy - 36mm</i>	0
1707-2038	<i>Ant-Cer II 2 Level Plate Assy - 38mm</i>	1
1707-2040	<i>Ant-Cer II 2 Level Plate Assy - 40mm</i>	1
1707-2042	<i>Ant-Cer II 2 Level Plate Assy - 42mm</i>	1
1707-2044	<i>Ant-Cer II 2 Level Plate Assy - 44mm</i>	1
1707-2046	<i>Ant-Cer II 2 Level Plate Assy - 46mm</i>	1
1707-2048	<i>Ant-Cer II 2 Level Plate Assy - 48mm</i>	1
1707-2050	<i>Ant-Cer II 2 Level Plate Assy - 50mm</i>	1
1707-2052	<i>Ant-Cer II 2 Level Plate Assy - 52mm</i>	0
1707-2054	<i>Ant-Cer II 2 Level Plate Assy - 54mm</i>	0

Module Number 1700-0028-PL

Ant-Cer II Two-Level Plates Instruments

Part Number	Description	Standard Kit Quantity
1770-2036	<i>Ant-Cer II 2 Level Plt Trial, 36mm</i>	0
1770-2038	<i>Ant-Cer II 2 Level Plt Trial, 38mm</i>	1
1770-2040	<i>Ant-Cer II 2 Level Plt Trial, 40mm</i>	1
1770-2042	<i>Ant-Cer II 2 Level Plt Trial, 42mm</i>	1
1770-2044	<i>Ant-Cer II 2 Level Plt Trial, 44mm</i>	1
1770-2046	<i>Ant-Cer II 2 Level Plt Trial, 46mm</i>	1
1770-2048	<i>Ant-Cer II 2 Level Plt Trial, 48mm</i>	1
1770-2050	<i>Ant-Cer II 2 Level Plt Trial, 50mm</i>	1
1770-2052	<i>Ant-Cer II 2 Level Plt Trial, 52mm</i>	0
1770-2054	<i>Ant-Cer II 2 Level Plt Trial, 54mm</i>	0

Module Number 1700-0030-PL

Ant-Cer II Three Level Plates

Part Number	Description	Standard Kit Quantity
1707-3053	<i>Ant-Cer II 3 Level Plate Assy - 53mm</i>	1
1707-3056	<i>Ant-Cer II 3 Level Plate Assy - 56mm</i>	1
1707-3059	<i>Ant-Cer II 3 Level Plate Assy - 59mm</i>	1
1707-3062	<i>Ant-Cer II 3 Level Plate Assy - 62mm</i>	1
1707-3065	<i>Ant-Cer II 3 Level Plate Assy - 65mm</i>	1
1707-3068	<i>Ant-Cer II 3 Level Plate Assy - 68mm</i>	1
1707-3071	<i>Ant-Cer II 3 Level Plate Assy - 71mm</i>	0

Module Number 1700-0031-PL

Ant-Cer II Three-Level Plates Instruments

Part Number	Description	Standard Kit Quantity
1770-3053	<i>Ant-Cer II 3 Level Plt Trial, 53mm</i>	1
1770-3056	<i>Ant-Cer II 3 Level Plt Trial, 56mm</i>	1
1770-3059	<i>Ant-Cer II 3 Level Plt Trial, 59mm</i>	1
1770-3062	<i>Ant-Cer II 3 Level Plt Trial, 62mm</i>	1
1770-3065	<i>Ant-Cer II 3 Level Plt Trial, 65mm</i>	1
1770-3068	<i>Ant-Cer II 3 Level Plt Trial, 68mm</i>	1
1770-3071	<i>Ant-Cer II 3 Level Plt Trial, 71mm</i>	0

Module Number 1700-0033-PL

Ant-Cer II Four-Level Plates

Part Number	Description	Standard Kit Quantity
1707-4072	<i>Ant-Cer II 4 Level Plate Assy - 72mm</i>	1
1707-4076	<i>Ant-Cer II 4 Level Plate Assy - 76mm</i>	1
1707-4080	<i>Ant-Cer II 4 Level Plate Assy - 80mm</i>	1
1707-4084	<i>Ant-Cer II 4 Level Plate Assy - 84mm</i>	1
1707-4088	<i>Ant-Cer II 4 Level Plate Assy - 88mm</i>	1
1707-4092	<i>Ant-Cer II 4 Level Plate Assy - 92mm</i>	1
1707-4096	<i>Ant-Cer II 4 Level Plate Assy - 96mm</i>	1

Module Number 1700-0034-PL

Ant-Cer II Four-Level Plates Instruments

Part Number	Description	Standard Kit Quantity
1770-4072	<i>Ant-Cer II 4 Level Plt Trial - 72mm</i>	1
1770-4076	<i>Ant-Cer II 4 Level Plt Trial - 76mm</i>	1
1770-4080	<i>Ant-Cer II 4 Level Plt Trial - 80mm</i>	1
1770-4084	<i>Ant-Cer II 4 Level Plt Trial - 84mm</i>	1
1770-4088	<i>Ant-Cer II 4 Level Plt Trial - 88mm</i>	1
1770-4092	<i>Ant-Cer II 4 Level Plt Trial - 92mm</i>	1
1770-4096	<i>Ant-Cer II 4 Level Plt Trial - 96mm</i>	1

Ant-Cer II Multi-Level Plates

Part Number	Description	Standard Kit Quantity
1707-2036	<i>Ant-Cer II 2 Level Plate Assy - 36mm</i>	0
1707-2038	<i>Ant-Cer II 2 Level Plate Assy - 38mm</i>	1
1707-2040	<i>Ant-Cer II 2 Level Plate Assy - 40mm</i>	1
1707-2042	<i>Ant-Cer II 2 Level Plate Assy - 42mm</i>	1
1707-2044	<i>Ant-Cer II 2 Level Plate Assy - 44mm</i>	1
1707-2046	<i>Ant-Cer II 2 Level Plate Assy - 46mm</i>	1
1707-2048	<i>Ant-Cer II 2 Level Plate Assy - 48mm</i>	1
1707-2050	<i>Ant-Cer II 2 Level Plate Assy - 50mm</i>	1
1707-2052	<i>Ant-Cer II 2 Level Plate Assy - 52mm</i>	0
1707-2054	<i>Ant-Cer II 2 Level Plate Assy - 54mm</i>	0
1707-3053	<i>Ant-Cer II 3 Level Plate Assy - 53mm</i>	1
1707-3056	<i>Ant-Cer II 3 Level Plate Assy - 56mm</i>	1
1707-3059	<i>Ant-Cer II 3 Level Plate Assy - 59mm</i>	1
1707-3062	<i>Ant-Cer II 3 Level Plate Assy - 62mm</i>	1
1707-3065	<i>Ant-Cer II 3 Level Plate Assy - 65mm</i>	1
1707-3068	<i>Ant-Cer II 3 Level Plate Assy - 68mm</i>	1
1707-3071	<i>Ant-Cer II 3 Level Plate Assy - 71mm</i>	0

Ant-Cer II Multi-Level Instruments

Part Number	Description	Standard Kit Quantity
1762-01	Multi-Level Restrictor Plate Removal Driver	1
1765-12	Restricted Angle Drill Tube-Mod-12	1
1765-13	Restricted Angle Drill Tube-Mod-13	1
1765-14	Restricted Angle Drill Tube-Mod-14	1
1765-15	Restricted Angle Drill Tube-Mod-15	0
1770-2036	<i>Ant-Cer II</i> 2 Level Plt Trial, 36mm	0
1770-2038	<i>Ant-Cer II</i> 2 Level Plt Trial, 38mm	1
1770-2040	<i>Ant-Cer II</i> 2 Level Plt Trial, 40mm	1
1770-2042	<i>Ant-Cer II</i> 2 Level Plt Trial, 42mm	1
1770-2044	<i>Ant-Cer II</i> 2 Level Plt Trial, 44mm	1
1770-2046	<i>Ant-Cer II</i> 2 Level Plt Trial, 46mm	1
1770-2048	<i>Ant-Cer II</i> 2 Level Plt Trial, 48mm	1
1770-2050	<i>Ant-Cer II</i> 2 Level Plt Trial, 50mm	1
1770-2052	<i>Ant-Cer II</i> 2 Level Plt Trial, 52mm	0
1770-2054	<i>Ant-Cer II</i> 2 Level Plt Trial, 54mm	0
1770-3053	<i>Ant-Cer II</i> 3 Level Plt Trial, 53mm	1
1770-3056	<i>Ant-Cer II</i> 3 Level Plt Trial, 56mm	1
1770-3059	<i>Ant-Cer II</i> 3 Level Plt Trial, 59mm	1
1770-3062	<i>Ant-Cer II</i> 3 Level Plt Trial, 62mm	1
1770-3065	<i>Ant-Cer II</i> 3 Level Plt Trial, 65mm	1
1770-3068	<i>Ant-Cer II</i> 3 Level Plt Trial, 68mm	1
1770-3071	<i>Ant-Cer II</i> 3 Level Plt Trial, 71mm	0
1774-01	<i>Ant-Cer II</i> Single Barrel FADG - Left	1
1774-02	<i>Ant-Cer II</i> Single Barrel FADG - Right	1
1775-01	<i>Ant-Cer II</i> Double Barrel FADG, 6/8	1
1776-01	<i>Ant-Cer II</i> Multi-Level Cortical Punch	1

Module Number 430-0011-PL

SlimLine® Anterior Cervical Plate Self Drilling Screws

Part Number	Description	Standard Kit Quantity
402-45112	4.5mm Rescue Screw Int Thread 12mm	6
402-45113	4.5mm Rescue Screw Int Thread 13mm	6
402-45114	4.5mm Rescue Screw Int Thread 14mm	6
402-45115	4.5mm Rescue Screw Int Thread 15mm	6
402-47112	Slf Drill 4 Wd Rt Scrw IntThrd 12	10
402-47113	Slf Drill 4 Wd Rt Scrw IntThrd 13	10
402-47114	Slf Drill 4 Wd Rt Scrw IntThrd 14	10
402-47115	Slf Drill 4 Wd Rt Scrw IntThrd 15	10

Module Number 430-0014-PL

SlimLine Screws Top Level Module

Part Number	Description	Standard Kit Quantity
402-43112	Self Tap 4mm WideRt Scrw IntThrd 12	10
402-43113	Self Tap 4mm WideRt Scrw IntThrd 13	10
402-43114	Self Tap 4mm WideRt Scrw IntThrd 14	10
402-43115	Self Tap 4mm WideRt Scrw IntThrd 15	10
402-45112	4.5mm Rescue Screw Int Thread 12mm	6
402-45113	4.5mm Rescue Screw Int Thread 13mm	6
402-45114	4.5mm Rescue Screw Int Thread 14mm	6
402-45115	4.5mm Rescue Screw Int Thread 15mm	6

Warnings and Precautions

Warnings

Following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects, which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Corpectomy procedures should not be performed in the absence of posterior fixation.
4. Potential risks identified with the use of this device system, which may require additional surgery, include:
 - a) Device component fracture.
 - b) Loss of fixation.
 - c) Non-union.
 - d) Fracture of the vertebra.
 - e) Neurological injury.
 - f) Vascular or visceral injury.

Precautions

1. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Do not bend or alter any *SC-AcuFix Ant-Cer II* Implants. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
2. VERIFY RESTRICTOR PLATE. Surgeon should visually inspect the plate to verify that the restrictor plate is present and fully seated prior to implantation.
3. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, and possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the post-operative care regimen as instructed by his or her physician.

5. DO NOT ALTER OR MODIFY ANY *SC-ACUFIX ANT-CER II* DYNAMIC SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The *SC-AcuFix Ant-Cer II* Dynamic System is only a temporary implant used for the correction and stabilization of the cervical spine. A successful result is not achieved in every surgical case. Bone grafting must be part of the spinal fusion procedure in which the *SC-AcuFix Ant-Cer II* System is used.

6. All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is single use only. Single use devices should not be re-used. Possible risks associated with re-use of single-use devices include:

- Mechanical malfunction
- Transmission of infectious agents

Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur. These complications may include but not be limited to:

1. Device corrosion with localized tissue reaction and pain.
2. Device migration, which may result in injury to soft tissue, visceral organs or joints.
3. Loosening or disassembly of implants resulting in additional injury.
4. Bending, loosening or breaking of the implant making removal difficult, impractical or impossible.
5. Abnormal sensations discomfort or pain.
6. Increased risk of infection.
7. Bone loss due to stress shielding.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the *SC-AcuFix Ant-Cer II* System by the surgeon. Proper patient selection and the patient's ability to comply with physician instructions and follow prescribed treatment regimen will greatly affect the results.

It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindication or is predisposed to any contraindication, DO NOT USE the *SC-AcuFix Ant-Cer II* System. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Patients with poor bone quality are also poor candidates for surgery.

Solutions by the people of Zimmer Spine.

You are devoted to helping your patients reduce their pain and improve their lives. And the people of Zimmer Spine are devoted to you. We are dedicated to supporting you with best-in-class tools, instruments and implants. We are driven by the opportunity to share our unrivaled education and training. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. And we can be counted on always to act with integrity as ethical partners who are worthy of your trust. We are the people of Zimmer Spine.

Disclaimer:

This documentation is intended exclusively for physicians and is not intended for laypersons.

Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.



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