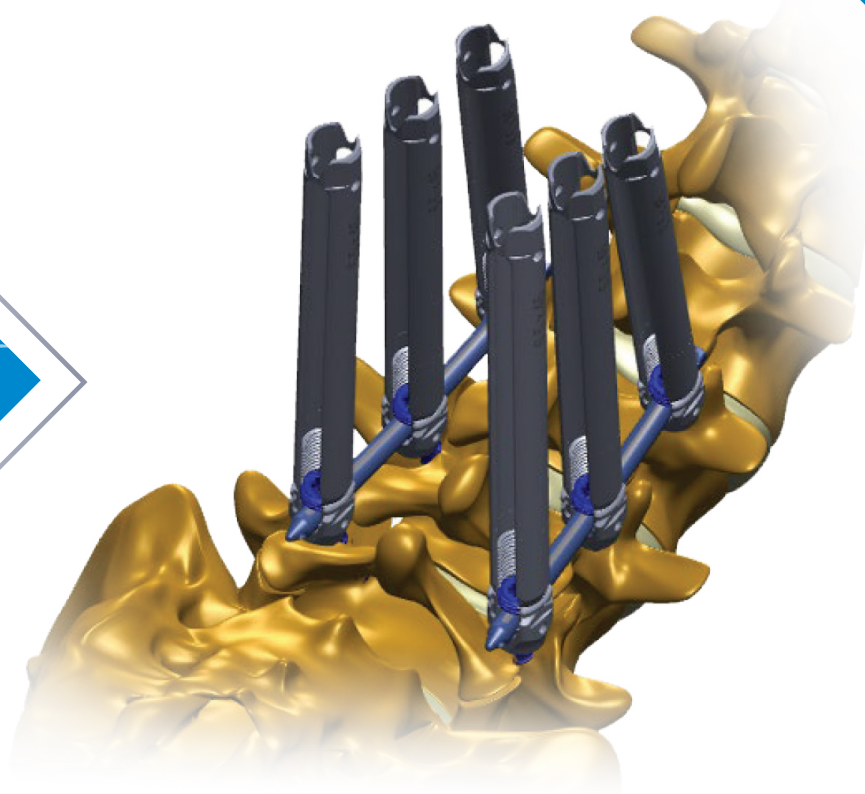


Cortera™ MIS

Posterior Fixation System



SURGICAL TECHNIQUE

DEVICE DESCRIPTION

The Cortera™ Spinal Fixation System (Cortera System) is a thoracolumbosacral pedicle screw system intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or the sacral spine. The Cortera System consists of screws, rod-to-rod connectors, lateral offset connectors, rods, locking set screws and associated reusable manual surgical instruments for an open or minimally invasive surgical approach. The screws, rod-to-rod connectors, lateral offset connectors, and set screws are manufactured from titanium alloy (Ti6Al4V per ASTM F136). The rods are available in titanium alloy or cobalt chromium alloy (Co-28Cr-6Mo per ASTM F1537). The implants are available in a variety of sizes to accommodate individual patient anatomy and are provided non-sterile. A variety of these implant configurations were previously covered in K221403. The Cortera System rods may be used in connection with Streamline Cross Connectors, cleared by FDA in K192800. The Streamline Cross Connectors accept various rod diameters and are appropriate for use with Cortera System 5.5 mm diameter rod-based systems. These cross connectors will keep their original cleared trade name.

INDICATIONS FOR USE

The Cortera™ Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Cortera™ Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Cortera™ Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach. The Cortera™ Spinal Fixation System is intended to be used with an autograft and/or allograft

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This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

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SURGICAL TECHNIQUE

Set-Up and Patient Positioning

Patient Positioning

Place the patient on the operating table in the prone position lying flat on a radiolucent table. Prepare and drape in a conventional manner. Ensure that unobstructed fluoroscopic images of the operative levels can be taken in both the A/P and lateral view. Clean and drape the operative site.

Step 1: Pedicle Targeting & Guidewire Placement

➤ Obtain an A/P image of the targeted vertebral body. Ensure that the endplates are parallel and that the spinous processes are centered on the image. Prepare for screw placement by aligning the first Guidewire in a cephalad/caudal orientation along the lateral borders of the pedicles. Transfer the Guidewire outline using a skin marker. Next, align a transverse Guidewire along the center of both pedicles. Transfer the outline of the second Guidewire using the skin marker. Intersect this line with the cephalad/caudal line. Repeat for each pedicle, progressing in a cephalad direction.

For placement of each percutaneous screw, make a longitudinal skin incision through the fascia approximately 2 cm long, located 1 to 2 cm lateral to the vertical line that marks the lateral border of the pedicle.

Insert the Jamshidi Needle (Figure 1) through the incision. Using A/P fluoroscopy, confirm the needle position at the lateral border of the pedicle. Using a mallet, advance the Jamshidi Needle slightly to dock it into the bone and stabilize. Reference a lateral fluoroscopic image to confirm that the cephalad/caudal trajectory matches the pedicular anatomy.

Continue advancing the Jamshidi Needle under A/P fluoroscopy. As the tip of the Jamshidi Needle approaches the middle of the pedicle cylinder, it should be approximately one third into the vertebral body when viewed on a lateral image. Advance the Jamshidi Needle to the desired depth, but no further than half the depth of the vertebral body.



Figure 1

SURGICAL TECHNIQUE

Remove the inner trocar of the Jamshidi Needle by turning the top handle 90° to the cannula handle. Carefully advance the Guidewire past the tip of the Jamshidi Needle and firmly into cancellous bone. Ideal placement of the Guidewire tip is approximately two-thirds of the depth of the vertebral body. Remove the Jamshidi Needle while maintaining the position of the Guidewire.

Repeat these steps for all pedicles that are intended for screw placement.

Caution: Do not bend the Guidewire. Bending the Guidewire could cause it to kink and/or break.

Caution: Do not advance or remove the Guidewire while placing instruments over the Guidewire during the procedure to prevent unintentional advancement of Guidewire.

Note: Do not advance the Jamshidi Needle cannula without the trocar.

Step 2: Tissue Dilation

➤ Assemble the Initial Dilator with the Tap Dilator and Screw Dilator (Figures 2 and 3). Slide the assembled Dilator over the Guidewire. Twist the assembled Dilator back and forth while advancing it down the Guidewire until it contacts the bone (Figure 4). Remove the Initial Dilator by pressing the release button located on the Tap Dilator and pulling the Initial Dilator out while leaving the Tap Dilator, Screw Dilator and Guidewire in place (Figure 5).

Caution: Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body in order to prevent damage to underlying structures.



Figure 2



Figure 3



Figure 4



Figure 5

SURGICAL TECHNIQUE

Step 3: Pedicle Preparation

➤ Attach the desired Tap to the preferred Ratcheting Handle and slide it over the Guidewire, through the Tap Dilator/Screw Dilator assembly to the bone (Figure 6). Advance the tap by turning the handle clockwise while applying firm downward pressure, cutting threads into the pedicle.

Caution: Select the proper sized Tap. Over-tapping can result in construct instability and screw loosening.

Caution: Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body to prevent damage to underlying structures.

Note: Taps are line-to-line (not undersized) and are available in standard sizes of 4.5, 5.5, 6.5 and 7.5mm.

Estimate the Tap depth by referencing the proximal end of the Tap Dilator to the depth marks on the Tap. These depth marks range from 30 to 60mm and are etched in 10mm increments. Figure 7 shows the Tap at a depth of 50mm. Tap sleeve can be used with the tap to max depth of 60mm.

The end of the Tap threads occurs at 30mm. (Figure 8).

Confirm position using lateral fluoroscopy and stop at the appropriate depth.

Remove the Tap by pressing the release button on the Tap Dilator while also keeping the Guidewire in place. Push the Screw Dilator down towards the bone to separate the Tap Dilator from the Screw Dilator. Remove the Tap Dilator, leaving the Screw Dilator and Guidewire in place.



Figure 6



Figure 7

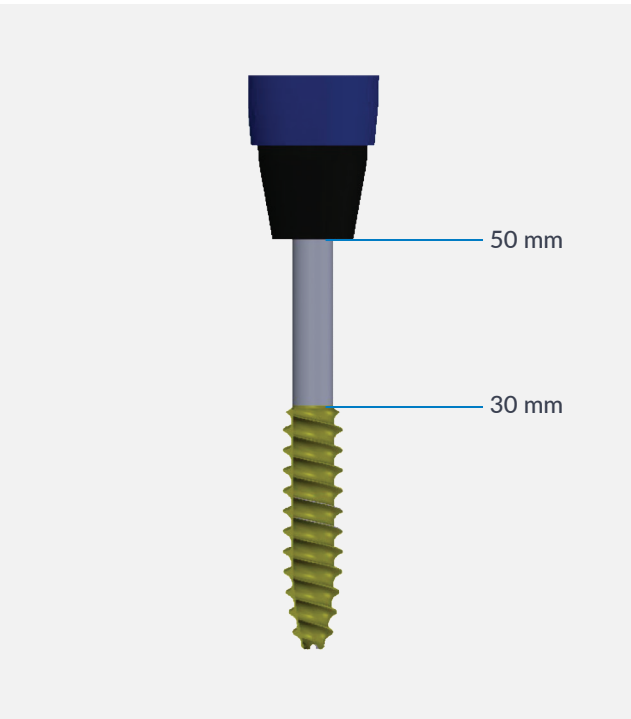


Figure 8

SURGICAL TECHNIQUE

Step 4: Pedicle Screw Placement

➤ Insert the Cannulated Driver Shaft into the Driver Body (Figure 9). Once the Cannulated Driver Shaft is fully seated into the Driver Body, push the clean button until it is flush within the Driver Body thumbwheel (Figures 10 and 11). Attach the Driver Shaft to the preferred Ratcheting Handle and insert the assembly through the screw extension and down into the head of the screw (Figure 12). Rotate the thumbwheel of the Driver Body clockwise into the tulip of the screw head until it is firmly in place and comes to a stop (Figure 13).

After loading a screw onto the Pedicle Screwdriver, place it over the Guidewire and slide it down through the Screw Sleeve to the bone (Figure 14). Rotate the handle of the Screwdriver clockwise to implant the screw into the pedicle. Continue rotating the handle of the Driver until the screw is implanted to the appropriate depth. Keep the screw and driver in line with the Guidewire during insertion. Use fluoroscopy to confirm the trajectory and depth of the screw. Remove the Guidewire after advancing the screw past the isthmus of the pedicle.

Caution: To maintain the polyaxial characteristics of the pedicle screw, avoid bottoming and/or impinging the tulip head against bony elements.

Caution: Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body in order to prevent damage to underlying structures.

Note: Do not hold the thumbwheel of the Driver Body while inserting the screw. This will cause the driver assembly to detach from the screw.

To disengage the driver from the screw, hold the screw extension while rotating the thumbwheel of the Driver Body counterclockwise until it disengages from the screw. Pull up on the attached handle and slide the driver out of the screw.

Repeat this step until all the screws are implanted.

Note: After Guidewire removal and driver disengagement, additional screw adjustments may be made with Shank Adjuster.



Figure 9

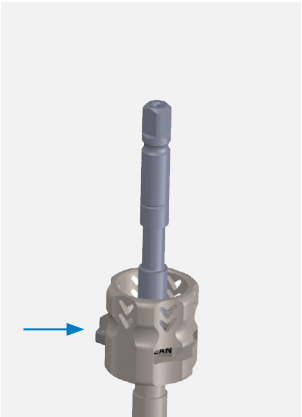


Figure 10



Figure 11



Figure 12



Figure 13



Figure 14

Rod Overview

Cortera™ MIS offers Pre-Bent Rods in 5.5 & 6.0mm diameter. The 5.5mm Pre-Bent Rod is blue in color and the 6.0mm Pre-Bent Rod is gold in color (Figure 15).

Step 5: Rod Measurement

➤ The Cortera MIS Instrument Set includes a Rod Caliper to provide guidance prior to rod length selection. Insert the posts of the Rod Caliper into the most cephalad and caudal screw extensions. Slide the posts down the screw extensions until the shelves of the posts are flush with and resting on top of the extensions. Read the value on either side of the scale at the top of the Rod Caliper, and the black line is buried in the screw extension (Figure 16). The value shown on the Rod Caliper represents the functional Pre-Bent Rod length. Any intended distraction or compression must also be considered as part of the rod length selection. An appropriately sized rod extends slightly beyond the cephalad and caudal ends of the screw head so that Set Screw locking occurs on the functional length of the rod. Determination of appropriate rod length is ultimately verified following rod insertion using A/P and lateral fluoroscopy.

Note: The screw extension may need to be adjusted in the sagittal plane to fully seat the Rod Caliper.

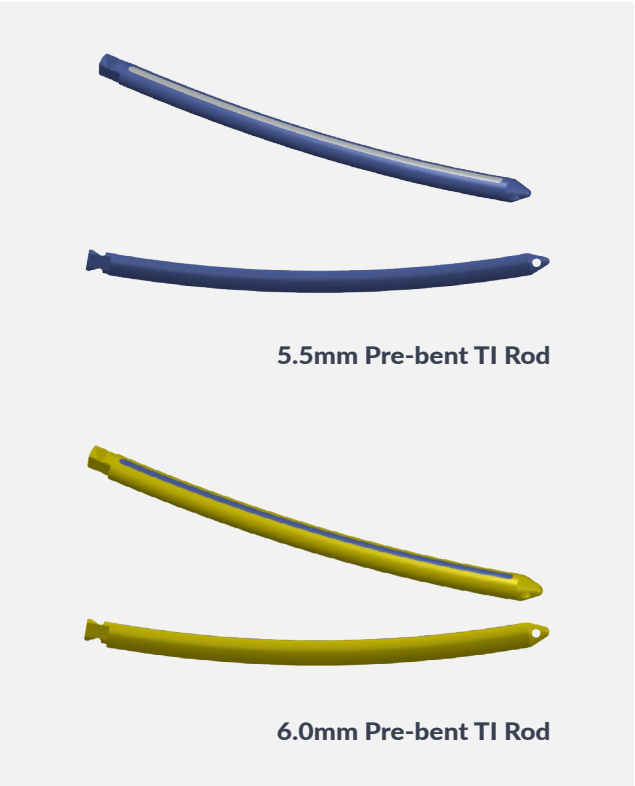


Figure 15



Figure 16

Step 6: Rod Contouring

➤ To make changes to the contour of the rod, select an appropriate bend radius on the French Rod Bender (Figure 17) and place the rod between the rollers of the French Rod Bender (Figure 18). There are three bend radius settings on the center roller. Compress the French Rod Bender until the desired contour is achieved.

Caution: Ensure proper rod orientation before bending the rod. Ensure the rod inserter engagement feature and bullet tip is fully cleared beyond the French Rod Bender roller.

Caution: Avoid creating a sharp bend or overbending the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction if the rod was already bent, as this may introduce micro fractures that compromise its strength.



Figure 17



Figure 18

SURGICAL TECHNIQUE

Step 7: Rod Insertion

➤ To insert a rod into the Rod Inserter, place the gold Rod Inserter Shaft (Figure 19) into the Rod Inserter Body (Figure 20). Rotate the gold actuator of the Rod Inserter Body clockwise until the Rod Inserter Shaft is seated within the Rod Inserter Body. With the rod properly oriented, place the connection end of the rod into the Rod Inserter. Tighten the Rod Inserter Shaft with the Rod Inserter Driver to secure the rod to the Rod Inserter (Figure 21).

Orient the handle of the Rod Inserter parallel to the patient's skin surface with the tip of the rod facing downward (Figure 22). Insert the tip of the rod into the incision of the screw extension with the Rod Inserter on the outside of the screw extension. Advance the tip of the rod downward through the screw extension toward the screw until it touches the screw head or as far as the tissue will allow. Ensure that the distal end of the rod is below the fascia. Begin to rotate the handle of the Rod Inserter up while keeping the shaft of the Rod Inserter as close to the screw extension as possible. Continue to rotate the handle up to a vertical position while guiding the distal tip of the Rod Inserter shelf to be flush with the top of the screw extension (Figure 23). Verify that the rod is in position using A/P and lateral fluoroscopy. Ensure that the rod extends slightly beyond the cephalad and caudal ends of the screw head and utilize the through hole on the bullet tip and the rod connection attachment feature for a visual indicator on lateral fluoroscopy.

Caution: Verify the superior and inferior rod overhang. Inadequate overhang may cause improper set screw placement resulting in an unstable construct.

Caution: Inability to identify the entirety of each MIS Rod through-hole with fluoroscopy may cause improper Set Screw placement or inadequate rod overhang, resulting in an unstable construct.

Note: In addition to the Rod Inserter Driver, any Cortera™ driver with a S27 driver feature can be used to engage the gold Rod Inserter Shaft.



Figure 19

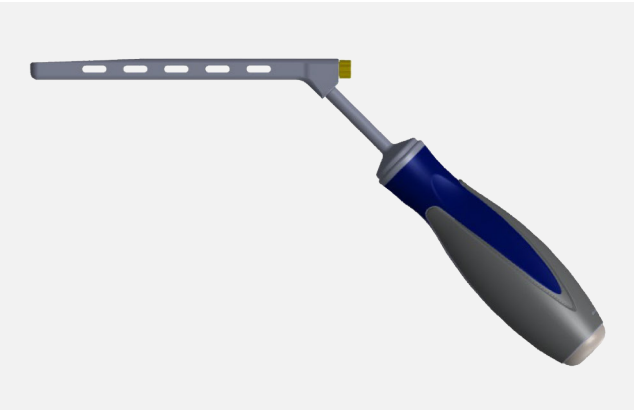


Figure 20



Figure 21

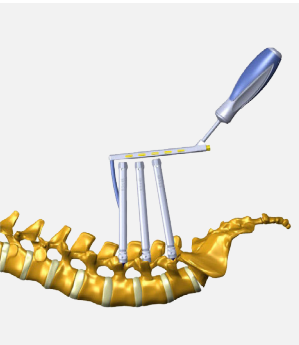


Figure 22

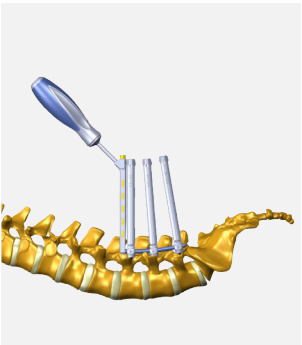


Figure 23

SURGICAL TECHNIQUE

Step 8: Set Screw Insertion

➤ Retaining Set Screw Starter

Place the Set Screw Starter (Figure 24) into a Set Screw in the set screw caddy, retaining it on the tip of the instrument. Insert the loaded Set Screw Starter into the screw extension and thread the Set Screw into the tulip of the screw by rotating clockwise until the Set Screw and rod are fully seated in the tulip of the screw. When the Set Screw is fully seated, pull up on the Set Screw Starter to disengage it from the Set Screw.

Repeat this step to insert Set Screws into the remaining pedicle screws.

➤ Expandable Set Screw Starter

If the Expandable Set Screw Starter is preferred, insert the gold Expandable Set Screw Starter Shaft into the Expandable Set Screw Starter Body (Figure 25). Turn the proximal knob of the gold shaft clockwise until the threads are engaged with the Body. Place the assembled Expandable Set Screw Starter into a Set Screw and rotate the proximal knob of the gold shaft clockwise until fully tightened (Figure 26). Insert the loaded Expandable Set Screw Starter into the screw extension (Figure 27) and thread the Set Screw into the tulip of the screw by rotating the handle clockwise until the Set Screw and rod are fully seated in the tulip of the screw (Figure 28). When the Set Screw is fully seated, rotate the proximal knob of the gold shaft counterclockwise until the Set Screw is disengaged.

Repeat this step to insert set screws into the remaining pedicle screws.

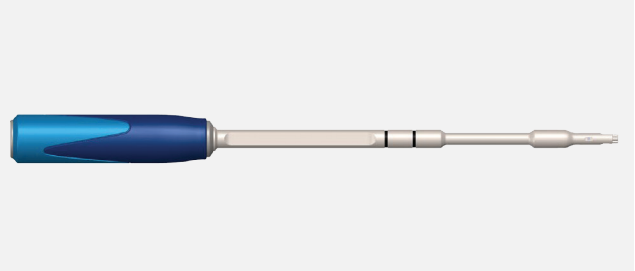


Figure 24

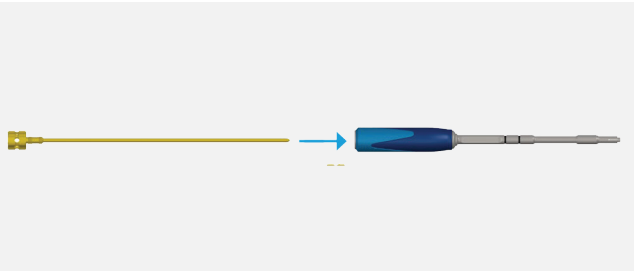


Figure 25



Figure 26

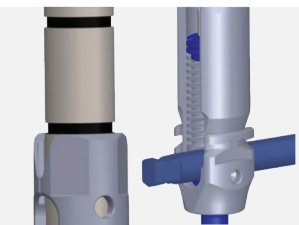


Figure 27

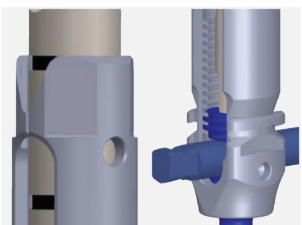


Figure 28

SURGICAL TECHNIQUE

Once the Set Screws have been provisionally tightened, insert the Rod Inserter Driver into the gold hex of the Rod Inserter and rotate counterclockwise to unlock and remove the Rod Inserter. Pull the Rod Inserter away from the rod to separate the connection. Lift the instrument up to remove it from the patient.

Note: The Set Screw Starter is intended for provisional locking only and should not be used for final locking.

Note: In order to reduce the incidence of cross-threading, slowly rotate the set screw counterclockwise until it drops and seats in the screw tulip. Turn clockwise until resistance is felt and construct is locked.

Note: Both the Retaining and Expandable Set Screw Starters have two black indicating bands towards the proximal portion of the Set Screw Starter shaft. When the distal band reaches the top of the extension sleeve, the Set Screw is at the reduction threads (Figure 27). When the top of the proximal band reaches the top of the extension sleeve, the set screw is fully seated (Figure 28).

Step 9: Additional Reduction (Optional)

MIS Threaded Reducer

1. Turn the gold reduction knob counterclockwise until the “Clean” button is visible on the reducer body. Depress the “Clean” button and insert the silver inner shaft until an audible click is heard. Pull back on inner shaft to confirm proper assembly (Figure 29).
2. To load Set Screw onto the MIS Threaded Reducer, place thumb on proximal end of the MIS Threaded Reducer and stab into Set Screw until the inner shaft driver hex is buried. Place the MIS Threaded Reducer with the Set Screw on a flat surface and remove thumb so that the bottom of the Set Screw is aligned with the reducer wing arms (Figure 30). Spin the gold reduction knob counterclockwise until the MIS Threaded Reducer is backed up all the way. The MIS Threaded Reducer is now ready for use (Figure 31).

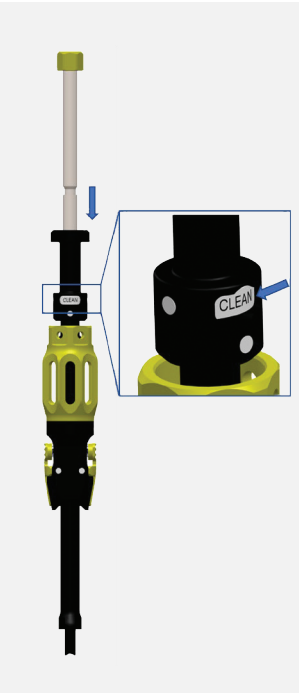


Figure 29



Figure 30

SURGICAL TECHNIQUE

3. Place distal tip of the MIS Threaded Reducer through the top of the screw extension and slide down until audible and tactile click occurs. Pull up on MIS Threaded Reducer to confirm proper engagement to screw extension (Figure 32).
4. Spin the gold reduction knob clockwise until the rod reaches the top of the screw’s built-in reduction threads. Full reduction is indicated when the distal black washer bottoms out on top of the gold reduction knob (remove dual-handed handle for visual confirmation) (Figure 33).
 - If additional torque is required during reduction, attach the MIS Threaded Reducer Handle to the MIS Threaded Reducer. Mate the reduction end of the MIS Threaded Reducer Handle to the proximal hex feature on the gold reduction knob and push until an audible and tactile click occurs to confirm engagement of the handle to the reduction knob (Figure 34 A).
5. To deliver the Set Screw, attach the Set Screw end of the MIS Threaded Reducer Handle to the proximal gold hex on the MIS Threaded Reducer and turn handle clockwise to deliver Set Screw (Figure 34 B). Continue to turn handle to reduce rod through the built-in reduction threads and into the screw tulip. Delivery of the Set Screw into the screw tulip can be visually confirmed when the proximal gold hex on the MIS Threaded Reducer is flush against the black washer (remove MIS Threaded Reducer Handle for visual confirmation) (Figure 35).
6. To remove the MIS Threaded Reducer, depress the lateral gold buttons on the reducer body and pull the Threaded Reducer out of the screw extension (Figure 36). Confirm the Set Screw is no longer attached to the reducer.

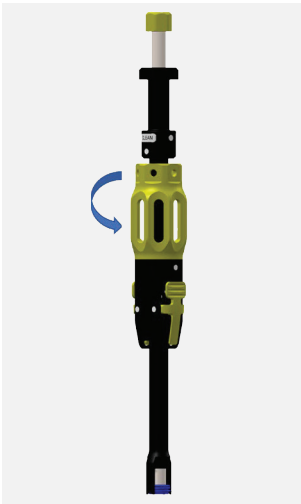


Figure 31



Figure 32



Figure 33

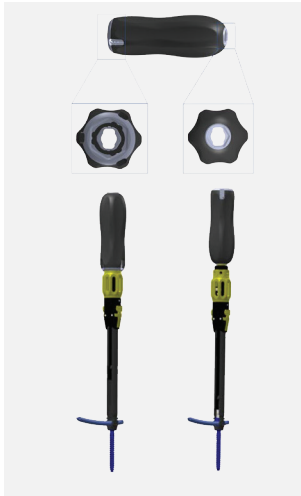


Figure 34 A Figure 34 B



Figure 35

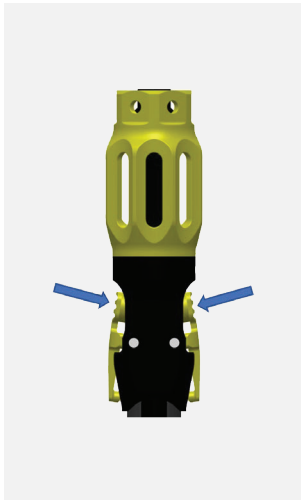


Figure 36

Step 10: Compression & Distraction

➤ Compression

1. To apply compression to one or more levels utilizing the Compressor, first provisionally lock one of the Set Screws of the level being compressed.
2. Insert the post of the Compressor into the extension tab of the provisionally locked screw (Figure 37) until the post of the Compressor bottoms out on the locked Set Screw (Figure 38).
3. Assemble the Provisional Driver to the Ratcheting Handle and insert this assembly through the Compressor's cannulation into the screw extension, and seat the driver tip into the unlocked Set Screw (Figure 39). Ensure Set Screw is loose enough to allow for motion along the rod.
4. While applying downward pressure on the Provisional Driver, squeeze the Compressor handles together to compress the level. Once adequate compression is achieved, turn the Provisional Driver clockwise until the Set Screw is tight on the rod (Figure 40). Do not attempt to apply full locking torque to the Set Screw with the Compressor in place. Remove the Compressor and Provisional Driver, then proceed to final Set Screw locking (Step 11).

Note: The Compressor must be removed prior to final Set Screw locking to ensure proper final tightening with Final Driver. Refer to Step 11 for proper final Set Screw locking instructions.



Figure 37



Figure 38



Figure 39

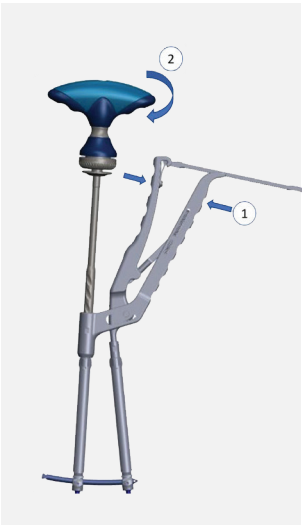


Figure 40

➤ Distraction

1. To apply distraction to one or more levels using the Distractor, first provisionally lock one of the Set Screws of the level being distracted (Figure 41).
2. Insert the post of the Distractor into the screw extension of the provisionally locked screw until the post of the Distractor bottoms out on the locked Set Screw (Figure 42).
3. Assemble the Provisional Driver to the Ratcheting Handle and insert this assembly through the Distractor's cannulation into the screw extension, and seat the driver tip into the unlocked Set Screw (Figure 43). Ensure Set Screw is loose enough to allow for motion along the rod.
4. While applying downward pressure on the Provisional Driver, squeeze the Distractor handles together to distract the level. Once adequate distraction is achieved, turn the Provisional Driver clockwise until the Set Screw is tight on the rod (Figure 44). Do not attempt to apply full locking torque to the Set Screw with the Distractor in place. Remove the Distractor and Provisional Driver, then proceed to final locking the Set Screw (Step 11).

Note: Do not over distract the rod. The rod should remain in the tulip of the screw during distraction.

Note: The Distractor must be removed prior to final Set Screw locking to ensure proper final tightening with Final Driver. Refer to Step 11 for proper final Set Screw locking instructions.



Figure 41



Figure 42



Figure 43



Figure 44

Step 10: Final Tightening

External Counter Torque

To final lock the Set Screw, attach the Final Driver to the Torque-Limiting Handle. Seat the tip of the External Counter-Torque over a screw and slide it down until it rests on top of the rod. The rod is held in the grooves of the External Counter-Torque when the top of the extension sleeve is flush with the opening of the Counter-Torque. Insert the assembled Final Driver through the screw extension and engage the Set Screw (Figure 45).

Holding the handle of the External Counter-Torque in place, rotate the Torque-Limiting Handle clockwise until it emits an audible and/or tangible “click.” Apply no more torque. Carefully remove the instruments and repeat this step for all screws.

Caution: The Final Driver must be used in combination with the Torque-Limiting Handle to complete final Set Screw locking.

Caution: Failure to tighten Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.

Proximal Counter Torque

In addition to the External Counter Torque, the Proximal Counter Torque can also be used for final Set Screw locking and offers both a closed ring and offset fork depending on surgeon preference. To final lock the Set Screw, attach the Final Driver to the Torque-Limiting Handle. If the closed ring is preferred, attach the closed ring of the Proximal Counter Torque to the top of the extended screw tab in the medial/lateral or superior/inferior orientations until it is fully seated (Figure 46). If the offset fork is preferred, place the Proximal Counter Torque offset fork over the top of the extended screw tab, aligning the flats of the offset fork with the flats of the extended screw tabs (Figure 47). While engaged, slide the Proximal Counter-Torque down as close as possible to the patient’s skin. Once fully seated, insert the assembled Final Driver through the screw extension and engage the Set Screw.

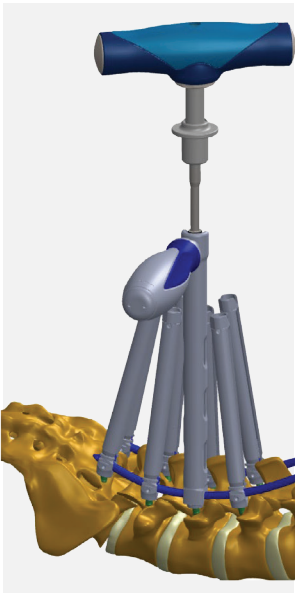


Figure 45



Figure 46



Figure 47

Holding the handle of the Proximal Counter Torque in place, rotate the Torque-Limiting Handle clockwise until it emits an audible and/or tangible “click.” Apply no more torque. Carefully remove the instruments and repeat this step for all screws.

Caution: The Final Driver must be used in combination with the Torque-Limiting Handle to complete final Set Screw locking.

Caution: Failure to tighten Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct

Step 12: Screw Extension Removal

Note: Ensure all Set Screws have been final locked prior to removing the screw extensions

MIS Tab Splitter

Orient the MIS Tab Splitter (Figure 48) so that the handles are perpendicular to the rod. Place the MIS Tab Splitter over the top of the screw extension so that the post of the instrument fits down into the collar of the screw extension (Figure 49). Once the MIS Tab Splitter is fully seated, squeeze the handle of the MIS Tab Splitter to split the proximal portion of the screw extension. Release the handle.

Tab Breaker

To remove the tower extension from the screw tulip, slide the Tab Breaker over the proximal end of one of the remaining extensions as shown in Figure 50. Gripping the Tab Breaker, rock back and forth (mediallateral) until the screw extension breaks away from screw tulip (Figure 51). Remove extension from Tab Breaker and repeat removal for the remaining MIS screw extension.

Remove all pieces of the screw extension and discard. Repeat for all implanted screws until all screw extensions are removed from the construct (Figure 52).

Note: Using A/P and lateral fluoroscopy, ensure that all pieces of the screw extension have been removed



Figure 48



Figure 49

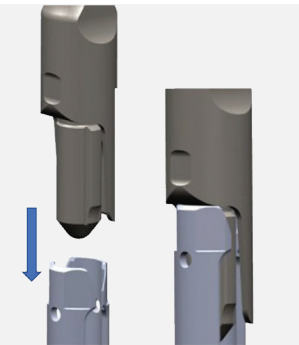


Figure 50



Figure 51

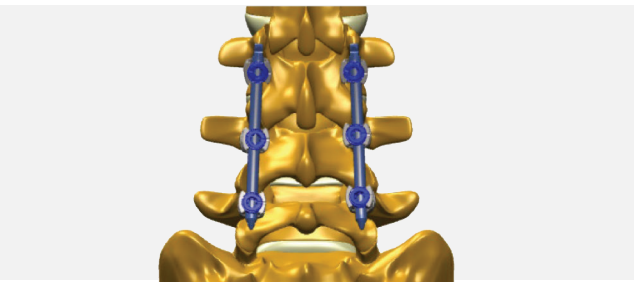


Figure 52

SURGICAL TECHNIQUE

Rescue System (if Necessary)

The Cortera™ MIS System comes with a Rescue Tower for the unlikely event that an MIS screw extension breaks in-situ prior to final locking.

- 1. Remove remaining tower extensions using the Tab Breaker, as described in Step 12.
- 2. Determine if a rod is present within the screw or not. Select proper end of Alignment Tool to utilize on the screw:
 - If no rod is present in the screw, use the tulip end of the Alignment Tool (Figure 53).
 - If rod is present in screw use the rod end of the Alignment Tool (Figure 54).

Note: The below technique assumes a rod is in the screw tulip.

- 3. Place the Alignment Tool through the incision to locate the rod in the targeted screw tulip (Figure 54). Fluoroscopy may be used to confirm Alignment Tool is seated on the rod inside screw tulip.
- 4. Slide the Rescue Tower over the Alignment Tool until it clips onto screw tulip (Figure 55). If needed, use the Proximal Counter Torque to apply downward pressure when attaching the Rescue Tower to the screw tulip. Remove Alignment Tool by pulling it straight out.

Rescue Tower Removal:

- 1. Insert Removal Tool into the rescue tower until fully seated on the rod (Figure 56).
- 2. Twist Removal Tool counterclockwise (as indicated by the arrows on the top of the Removal Tool handle) to align the visual markers. Remove the Rescue Tower and Removal Tool from screw tulip (Figure 57).

Removal (if Necessary)

If screw removal is required, apply counterclockwise rotation to loosen its components and remove them in the opposite order in which the construct was built.



Figure 53

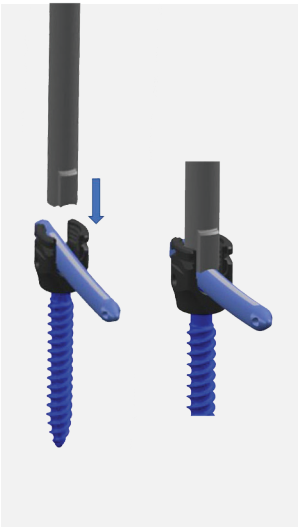


Figure 54



Figure 55



Figure 56



Figure 57

SURGICAL TECHNIQUE

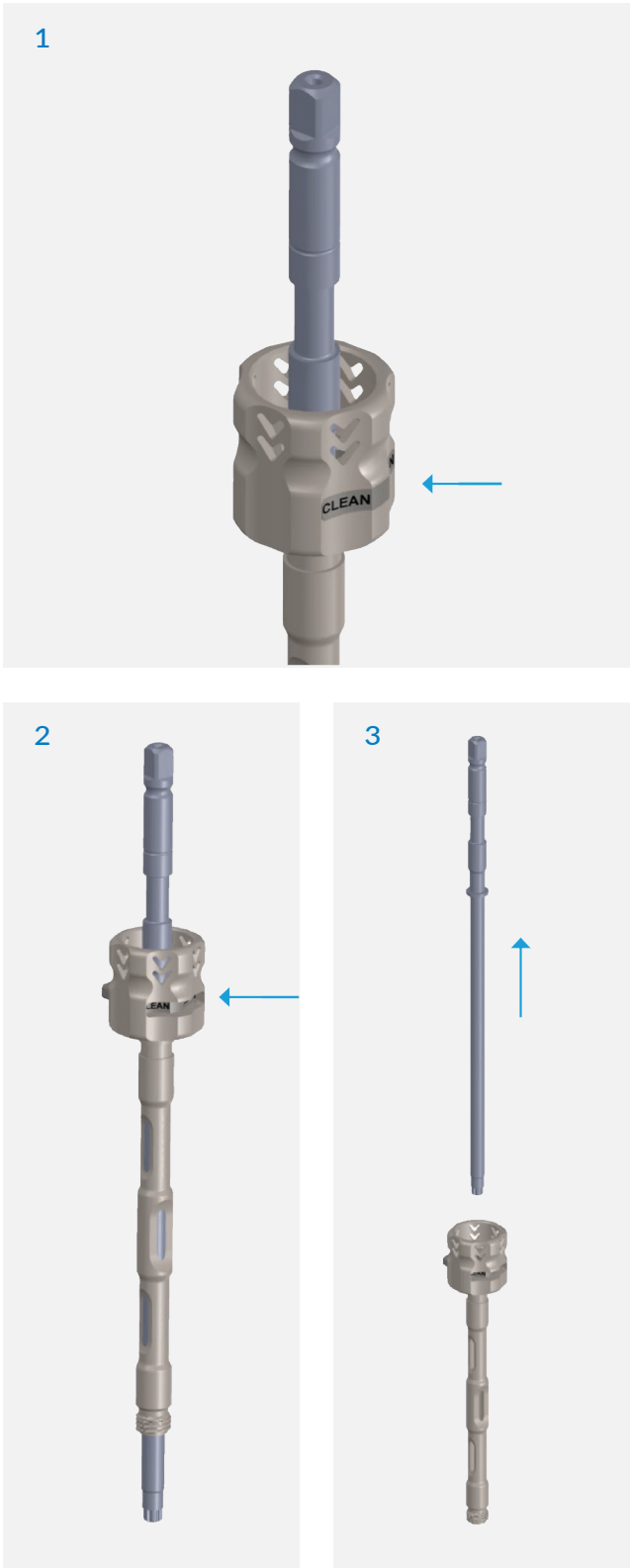
Disassembly Instructions:

Expandable Set Screw Starter



SURGICAL TECHNIQUE

Cannulated Pedicle Screwdriver



SURGICAL TECHNIQUE

Rod Inserter

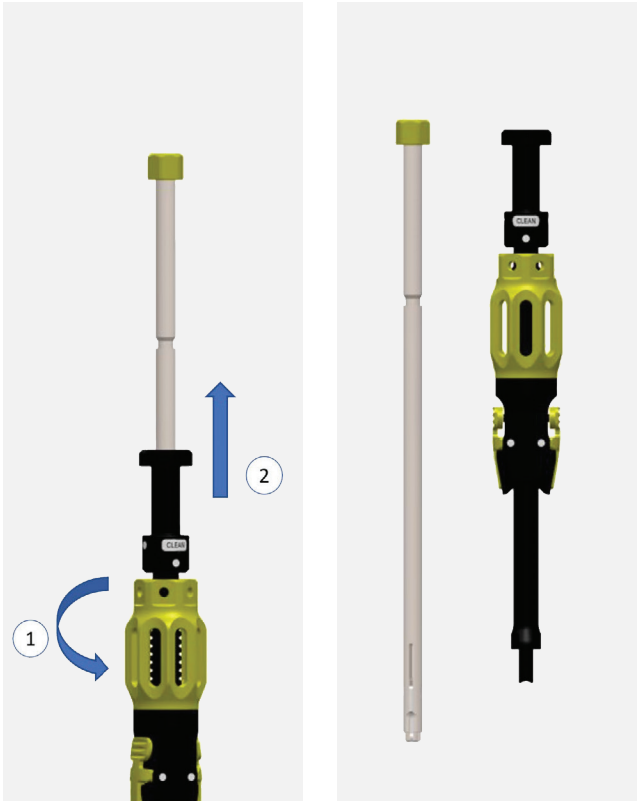


SURGICAL TECHNIQUE

MIS Threaded Reducer

Spin gold reduction knob counterclockwise to expose the “Clean” button on the reducer body.

Depress the “Clean” button and pull out the inner shaft.



ORDERING GUIDE

CORTERA™ MIS IMPLANT TRAY, ALPHA (CORMISIMPAL-R00P)

TOP TRAY IMPLANTS

Part Number	Description	Diameter	Length	Quantity
150150-55030	MIS Polyaxial Screw	5.5	30	4
150150-55035	MIS Polyaxial Screw	5.5	35	6
150150-55040	MIS Polyaxial Screw	5.5	40	8
150150-55045	MIS Polyaxial Screw	5.5	45	8
150150-55050	MIS Polyaxial Screw	5.5	50	8
150150-55055	MIS Polyaxial Screw	5.5	55	6
150150-55060	MIS Polyaxial Screw	5.5	60	2
150150-65030	MIS Polyaxial Screw	6.5	30	4
150150-65035	MIS Polyaxial Screw	6.5	35	6
150150-65040	MIS Polyaxial Screw	6.5	40	8
150150-65045	MIS Polyaxial Screw	6.5	45	10
150150-65050	MIS Polyaxial Screw	6.5	50	10
150150-65055	MIS Polyaxial Screw	6.5	55	6
150150-65060	MIS Polyaxial Screw	6.5	60	2
150150-75030	MIS Polyaxial Screw	7.5	30	4
150150-75035	MIS Polyaxial Screw	7.5	35	4
150150-75040	MIS Polyaxial Screw	7.5	40	8
150150-75045	MIS Polyaxial Screw	7.5	45	8
150150-75050	MIS Polyaxial Screw	7.5	50	8
150150-75055	MIS Polyaxial Screw	7.5	55	6
150150-75060	MIS Polyaxial Screw	7.5	60	2

CORTERA™ MIS IMPLANT TRAY, ALPHA (CORMISIMPAL-R00P)

BOTTOM TRAY IMPLANTS

Part Number	Description	Diameter	Length	Quantity
150203-55030	Prebent Rod, MIS, Ti	5.5	30	3
150203-55035	Prebent Rod, MIS, Ti	5.5	35	3
150203-55040	Prebent Rod, MIS, Ti	5.5	40	3
150203-55045	Prebent Rod, MIS, Ti	5.5	45	3
150203-55050	Prebent Rod, MIS, Ti	5.5	50	3
150203-55055	Prebent Rod, MIS, Ti	5.5	55	3
150203-55060	Prebent Rod, MIS, Ti	5.5	60	3
150203-55065	Prebent Rod, MIS, Ti	5.5	65	3
150203-55070	Prebent Rod, MIS, Ti	5.5	70	3
150203-55075	Prebent Rod, MIS, Ti	5.5	75	3
150203-55080	Prebent Rod, MIS, Ti	5.5	80	3
150203-55085	Prebent Rod, MIS, Ti	5.5	85	3
150203-55090	Prebent Rod, MIS, Ti	5.5	90	3
150203-55095	Prebent Rod, MIS, Ti	5.5	95	3
150203-55100	Prebent Rod, MIS, Ti	5.5	100	3
150203-55105	Prebent Rod, MIS, Ti	5.5	105	3
150203-55110	Prebent Rod, MIS, Ti	5.5	110	3
150203-55115	Prebent Rod, MIS, Ti	5.5	115	3
150203-55120	Prebent Rod, MIS, Ti	5.5	120	3
150203-55125	Prebent Rod, MIS, Ti	5.5	125	3
150203-55130	Prebent Rod, MIS, Ti	5.5	130	3
150203-55135	Prebent Rod, MIS, Ti	5.5	135	3
150203-55140	Prebent Rod, MIS, Ti	5.5	140	3
150203-55145	Prebent Rod, MIS, Ti	5.5	145	3
150203-55150	Prebent Rod, MIS, Ti	5.5	150	3
150000-00001	Set Screw			30

CLEANING AND STERILIZATION

Implants are not sterile packed

Reusable instruments are provided non-sterile.

For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device or contact Xtant Medical. See back page for contact information..



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INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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