Surgical Technique

Xultan 5.5

Pedicle Screw System

STG-1029-03 Rev A
11-15-2023

TABLE OF CONTENTS

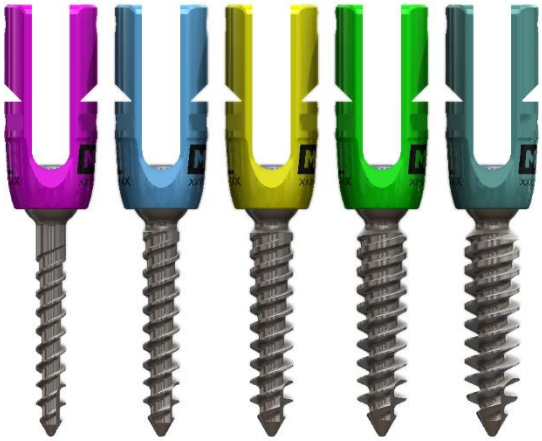
PRODUCT OVERVIEW

The Xultan 5.5 Pedicle Screw System is an implant device manufactured from titanium and silicone. The screws are available cannulated or non-cannulated in various diameters and lengths to accommodate various patient anatomies. The system includes straight rods, curved rods, crosslinks, and associated instrumentation.

POLYAXIAL SCREW FEATURES

- Polyaxial screws with 70° of conical angulation
- Tulip resists movement due to Silicone O-Ring Technology
- Reduction tulips available for simple rod reduction
- Sizes available for all surgical needs
  - 4.5 – 8.5mm Screw Diameters
  - 25 – 90mm Screw Lengths
  - Cannulated & Non-Cannulated Options

70° of Angulation



Reduction Polyaxial Screws

Standard Polyaxial Screws

ROD FEATURES

- Ø5.0 Straight Rods, available in 35 – 600mm lengths
- Ø5.0 Pre-bent Rods, available in 30 – 120mm lengths

CROSSLINK FEATURES

- Spans available from 28 – 60mm

INSTRUMENT OVERVIEW

30290323 Pedicle Feeler

30290321 Lenke Probe Straight

30290345 Lenke Probe Curved

30290302 8.5mm Tap

30290303 7.5mm Tap

30290304 6.5mm Tap

30290305 5.5mm Tap

30290306 4.5mm Tap

30290317 Non-Locking Driver

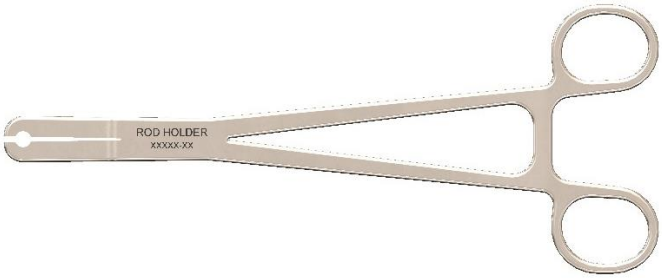
30290332 Non-Locking Reduction Driver

30290314 Ratcheting Driver

30290331 Ratcheting Reduction Driver

30290316 Tulip Orientation Tool

30290318 Rod Holder



30290319 French Bender

30290320 In-Situ Bender Left

30290344 In-Situ Bender Right

30290311 Counter Torque

30290349 Reduction Counter Torque

30290326 Tab Breaker

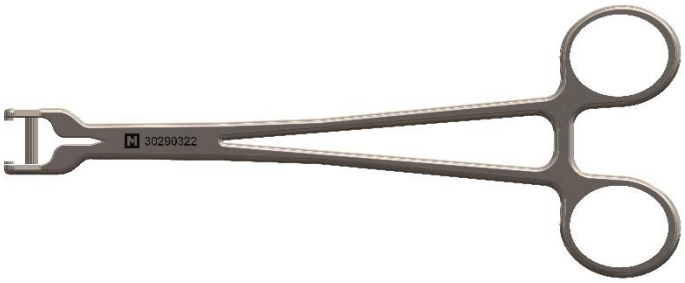
30290310 Stab Driver

30290316 Single Ended Driver

30290313 Double Ended Driver

30290329 Rod Pusher

30290322 Rod Rocker



30290312 Rod Reducer

30290343 Rod Reducer Handle

30290324 Compressor

30290325 Distractor

30290342 L Retractor

30290301 Final Driver

30290307 Crosslink Driver Handle

30290308 Crosslink Driver Threaded Shaft

30290309 Crosslink Driver

30290347 Crosslink Final Driver

30290348 Crosslink Removal Tool

30290326 Torque Limiting T-Handle

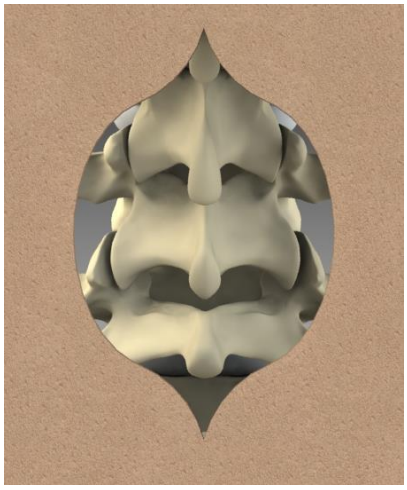
30290327 Inline Ratcheting Handle

30290328 Palm Ratcheting Handle

PATIENT POSITIONING AND SURGICAL EXPOSURE

Place the patient in the prone position on a lumbar support. Radiographic equipment can be used to confirm optimal positioning of relevant spine segment.

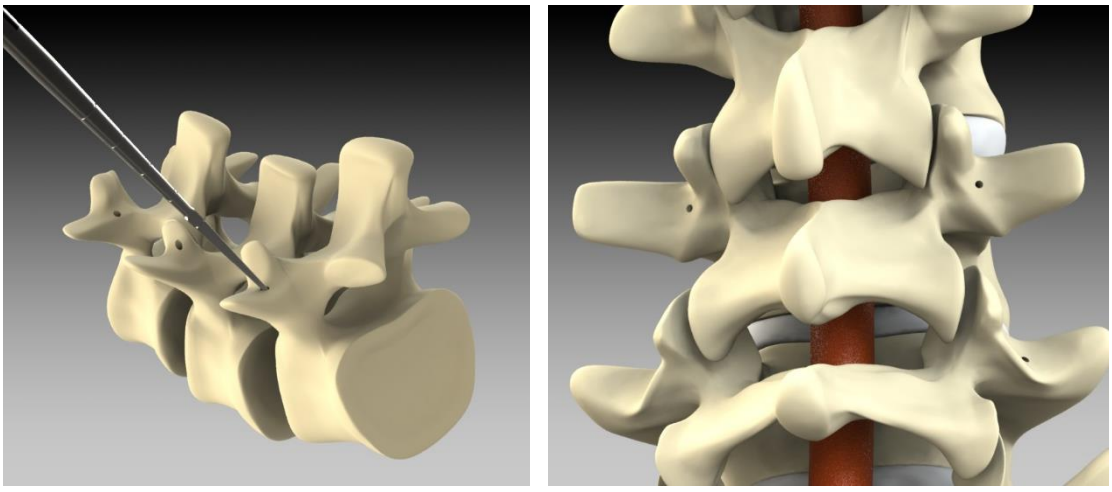
Incise and dissect laterally from the midline and locate the spinous processes, transverse processes, facets, lamina, dura and nerve roots.



Exposure

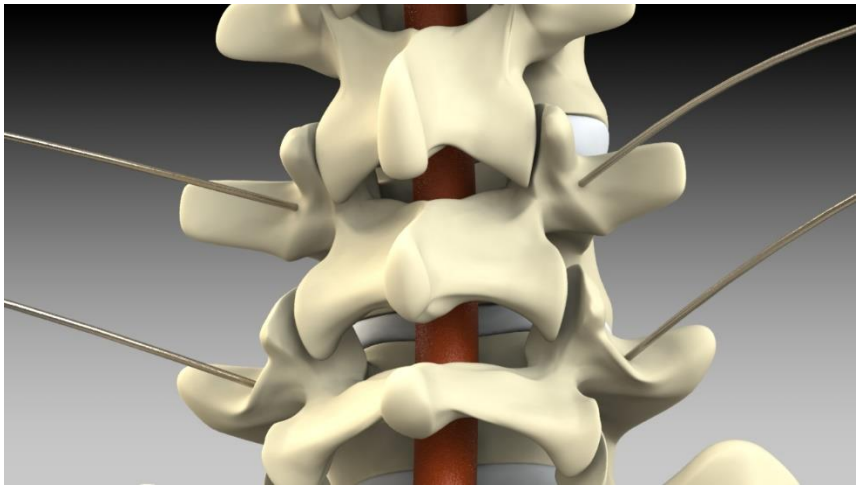
PEDICAL PREPERATION

Locate pedicles and use an awl to perforate the cortex. Employ the Lenke probe to open the pedicle canal. Confirm the pedicle location, depth and orientation using radiographic imaging and determine desired pedicle screw size.



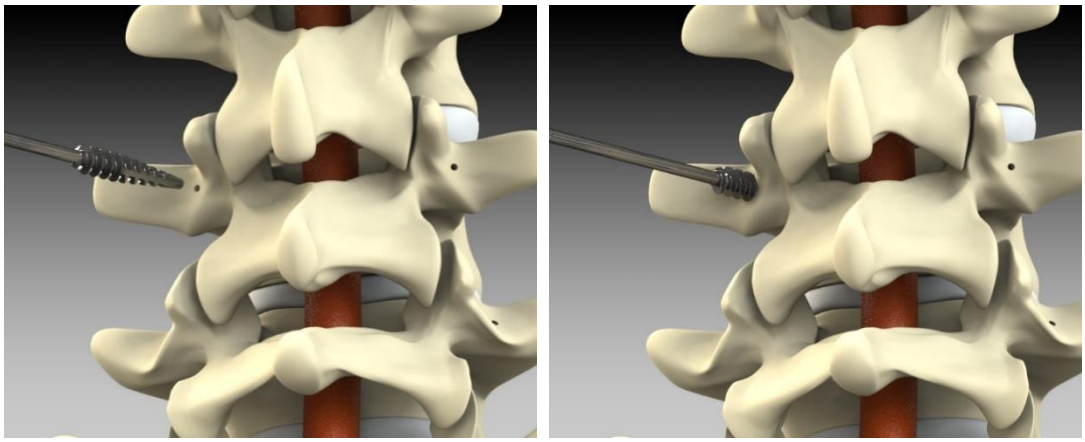
Use of Lenke probe and resulting pilot holes.

Alternately, k-wires may be placed using an approved guidance system.

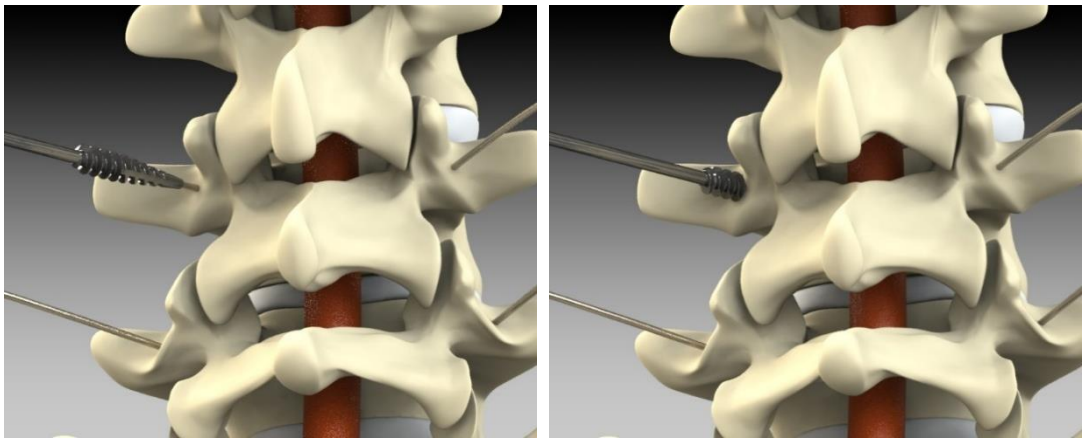


Example of k-wire placement

All Xultan 5.5. screws are self-tapping. If tapping is preferred by the surgeon, use the tap that matches the selected screw. The 5.5, 6.5, 7.5 and 8.5 taps are cannulated to allow use of k-wires.



Use of thread tap without guide wire



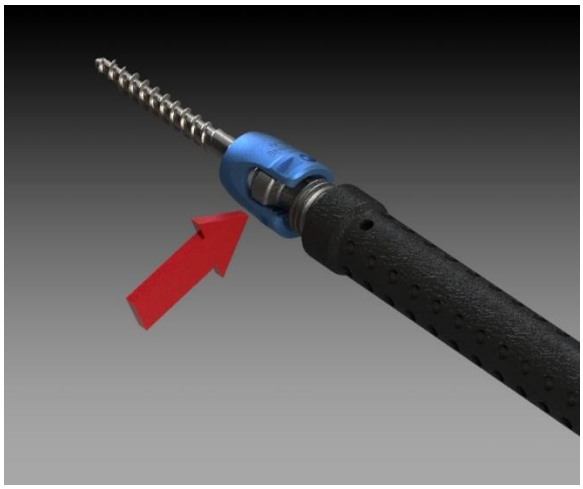
Use of thread tap guide wire

PEDICLE SCREW – ATTACH TO SCREWDRIVER

Take the pedicle screwdriver and ensure the ratchet sleeve is snapped into its forward position.

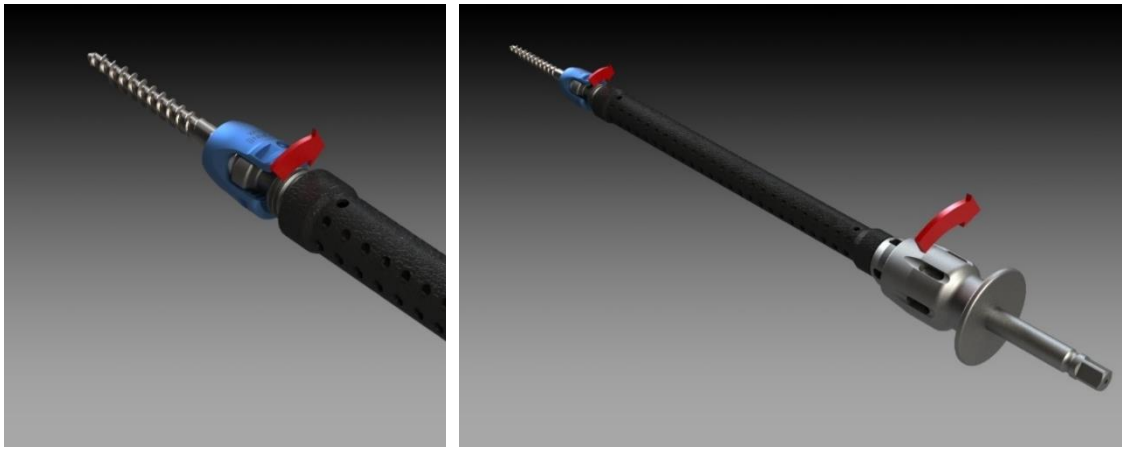
Slide ratchet sleeve into its forward (ratcheting) position

Select the desired pedicle screw and engage the drive feature of the screwdriver with that of the pedicle screw body. When this has been achieved, the t-bar on the screwdriver will be engaged near the bottom of the slot in the pedicle screw head. Ensure the t-bar is well seated prior to proceeding to the next step.



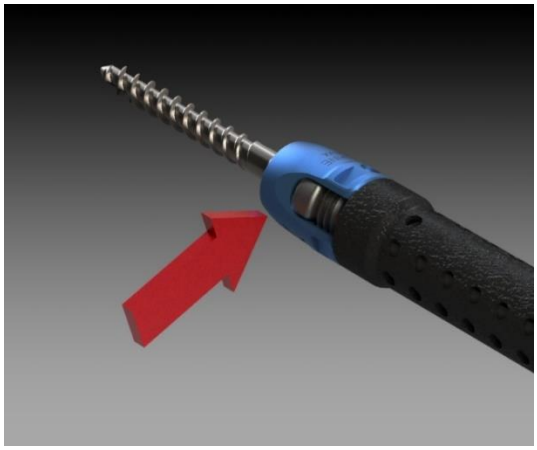
Ensure t-bar sits at the bottom of the screw head slot before engaging screw thread

While holding the screw head in stationary position, turn the sleeve in a clockwise direction to engage screwdriver sleeve thread with the pedicle screw thread. The ratchet in the driver should be audibly heard when turning the sleeve. If no ratcheting is heard, then slide the sleeve forward (as described in step 3a, above).



Engage thread by spinning sleeve in clockwise direction

Ensure that the screw has properly engaged by checking to see that the t-bar is still seated at the bottom of the screw head slot ***and*** that the screw thread is fully engaged (see figure below). If either of these is not evident, release the screw from the driver and reattempt engaging the screw to the driver.



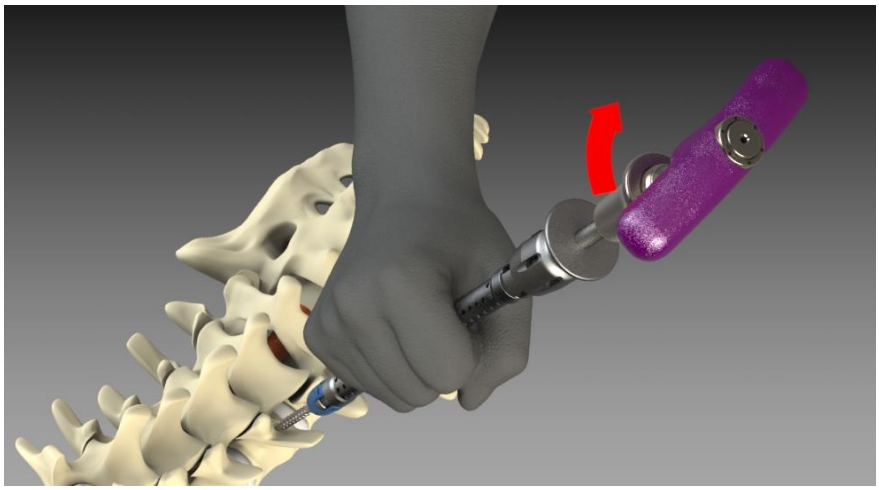
Fully engaged t-bar and screw thread
indicating a properly attached pedicle screw.

Pedicle screw attached to pedicle screwdriver

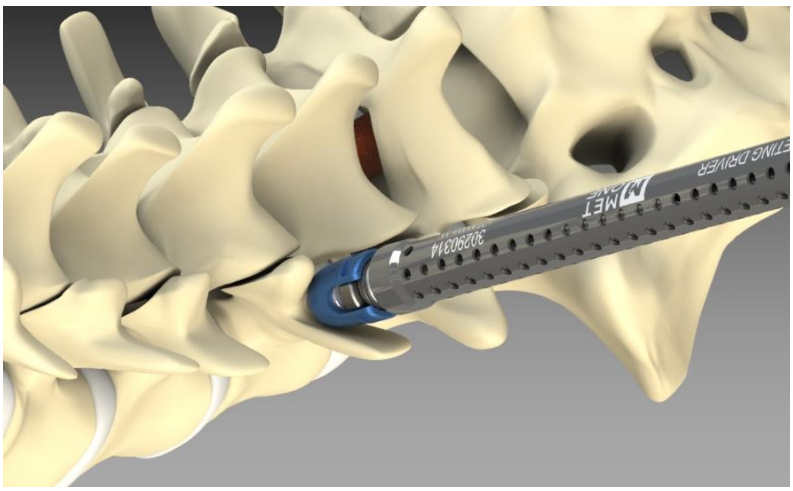
PEDICLE SCREW PLACEMENT

Connect a ratcheting handle to the screwdriver. Grasp the pedicle screwdriver by the black rotating sleeve and orient the screw along the desired trajectory into the pedicle. Alternately, the pedicle screw/screwdriver/handle assembly may be passed over the k-wires, if employed.

Screw the pedicle screw to the desire position by turning the driver handle in a clockwise direction (see figures below).



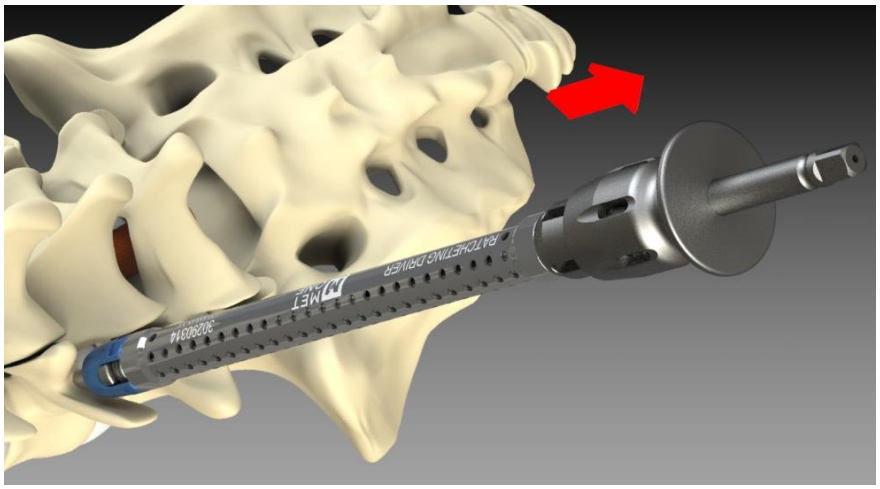
Driving the pedicle screw into place



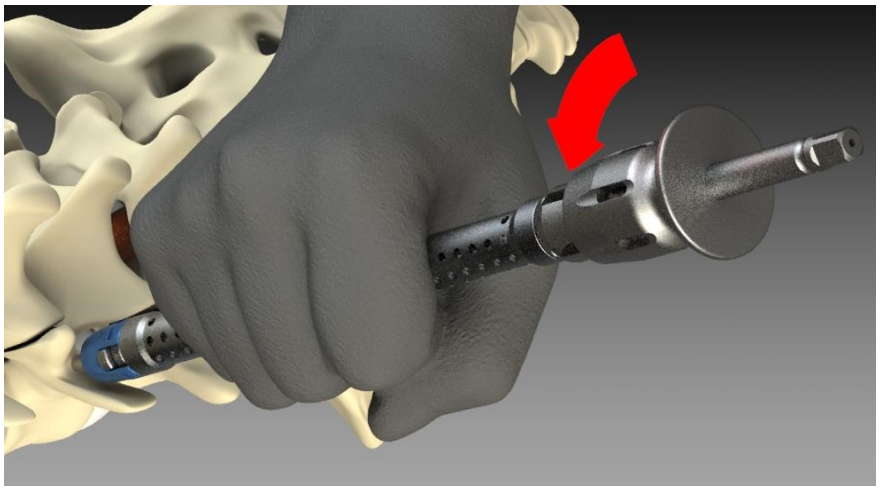
Typical placement of the pedicle screw

Once the pedicle screw placement had been confirmed as correct, remove the ratcheting driver handle from the screwdriver. Then slide the ratchet sleeve back until an audible click is heard. At this point, the driver ratchet has been disengaged.

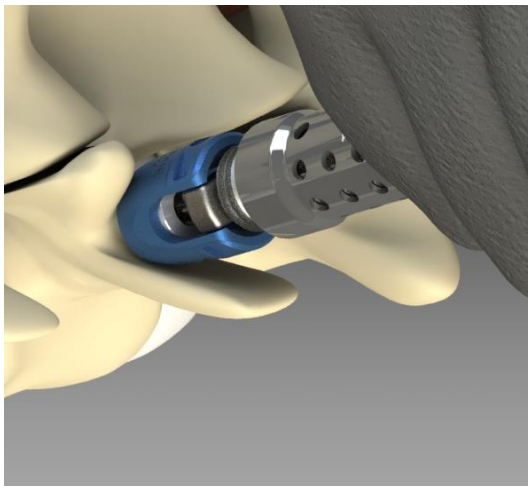
After grasping the black rotating sleeve, spin the ratchet sleeve in a counterclockwise direction until the screwdriver thread is disengaged from the pedicle screw tulip. Once the thread is disengaged, the screwdriver may be easily disengaged from the pedicle screw.



Slide ratchet sleeve to its rearward (non-ratcheting) position



Grasp the black rotating sleeve and turn the ratchet sleeve in a counterclockwise direction until the driver thread is disengaged



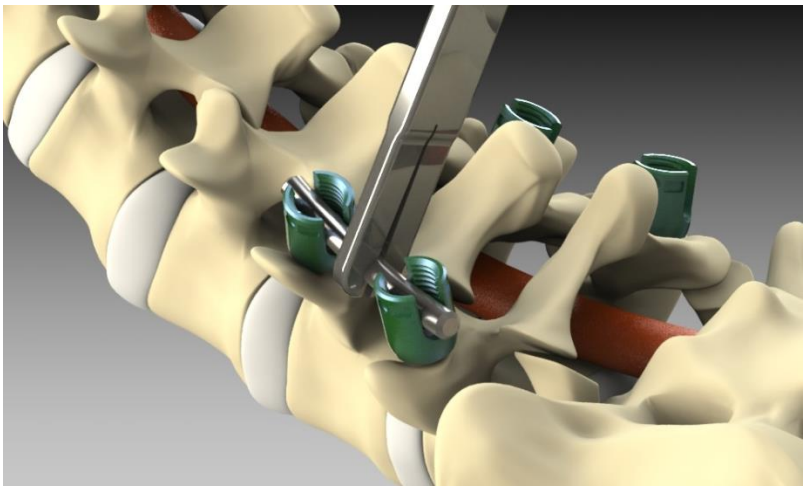
When thread is disengaged, the pedicle screwdriver may be removed

Repeat steps (a) and (b) for all pedicle screws being implanted.

ROD AND BLOCKER SCREW PLACEMENT

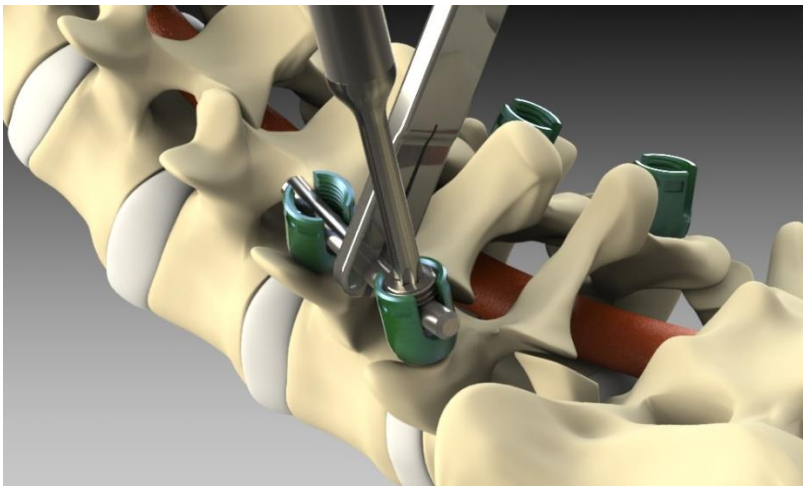
Employing the rod holder instrument, place the desired rod into place. If needed, the head turner instrument may be employed to better align the screw head slot with the rod.

Optional rod bending: Caution: Do not reverse bend rods. Reverse bending may produce internal stresses which may become the focal point for eventual breakage of the implant. Excessive rod contorting should be avoided.



Rod placement

Employing the single or double ended driver, place the blocker screws in all the pedicle screws in the construct. Employing a rod pushed may be required to get the rod to sit deeply enough to properly engage the blocker screw.



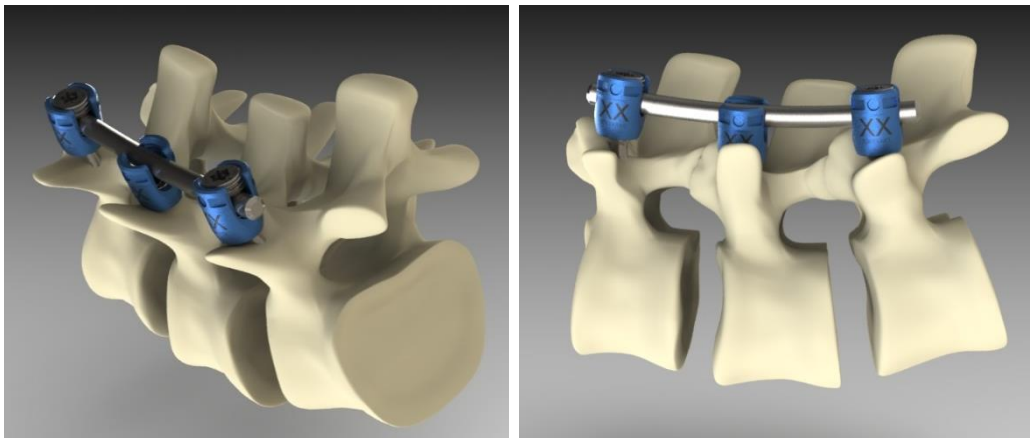
Placing blocker screws

Repeat steps (a) and (b) for the contralateral side.

BLOCKER SCREWS ARE NOW READY FOR FINAL TIGHTENING. REFER TO FINAL TIGHTENING OF BLOCKER SCREW SECTION FOR PROCEDURE DETAILS.

USE OF ROD REDUCER (OPTIONAL)

In certain cases (for example, where there is a significant degree of spondylolisthesis), a rod pusher may not be sufficient for engagement of the blocker screw in the screw head (an example is shown in the figure below). In this event, the rod reducer may be required to reduce the rod (and as a result, the vertebral body) into its desired position.



An example of a middle screw of being unable to engage a blocker in a screw head (see middle screw)

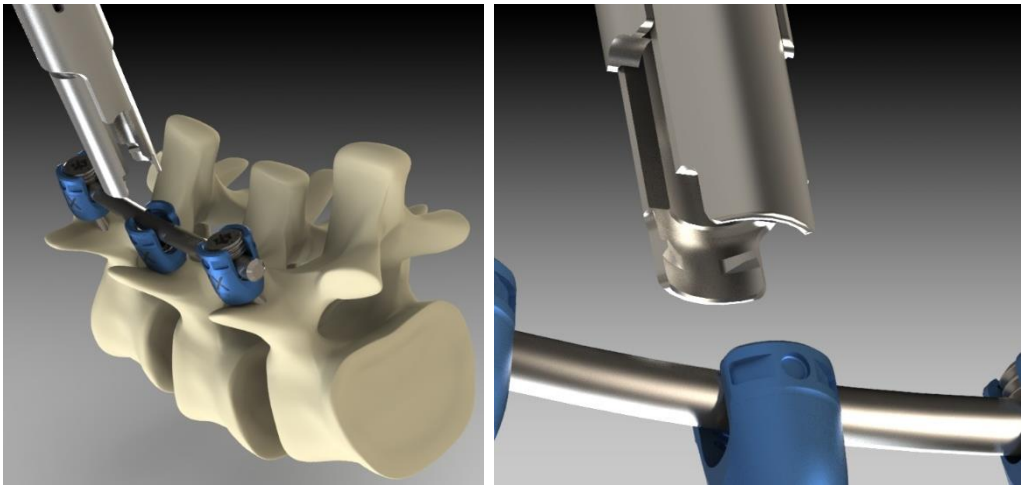
Rotating the drive end of the rod reducer in the clockwise direction will pull the inner locking sleeve into the instrument. Conversely, a counterclockwise rotation will result in the inner locking sleeve being pushed out of the instrument (see figure below).

Operation of the rod reducer

Note the window in the outer sleeve with position markers indicating the various operating positions of the instrument. Position the inner sleeve to the “SPRING” position, which will allow the inner sleeve to snap onto the pedicle screw head (see figure below).

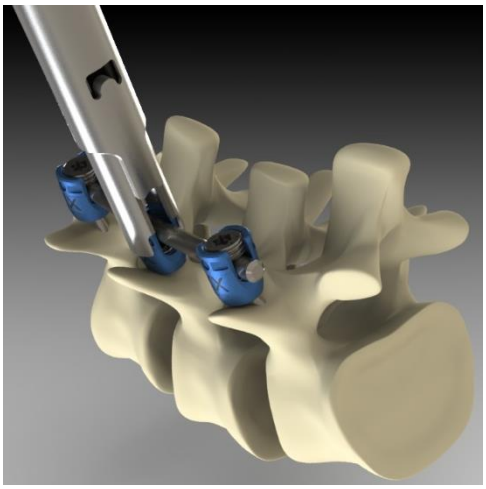
Rod reducer in the "SPRNG" position

Orient the red reducer over the pedicle screw head so that the rod being reduced in aligned with the slot in the inner locking sleeve.



Align rod reducer with pedicle screw head and rod

Push the locking sleeve onto the screw head until the instrument snaps onto the screw head (tactile and audible feedback should indicate this has happened). A shoulder in the inner sleeve will bottom on the top of the screw head preventing the rod reducer from being driver too far over the screw head.



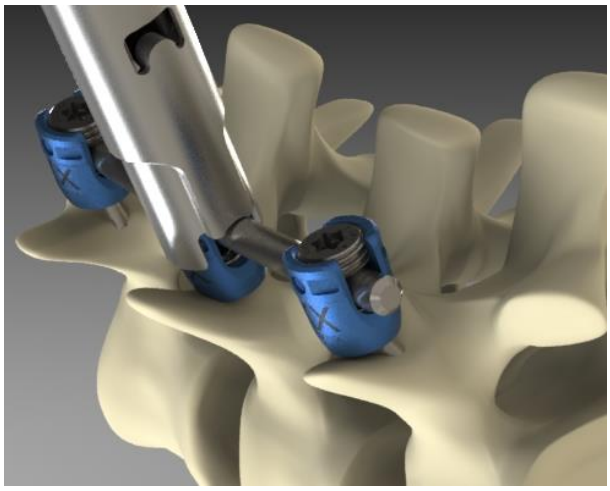
Rod reducer snapped onto screw head

Rotate the drive sleeve in the clockwise direction until the position indicator is at or beyond the "LOCK" position. At this point, the rod reducer should be locked onto the screw head, which may be checked by pulling the on rod reducer. In the unlikely event that the rod reducer comes loose, repeat steps (a) through (d) until the rod reducer is securely attached.

Rod reducer in the "LOCK" position

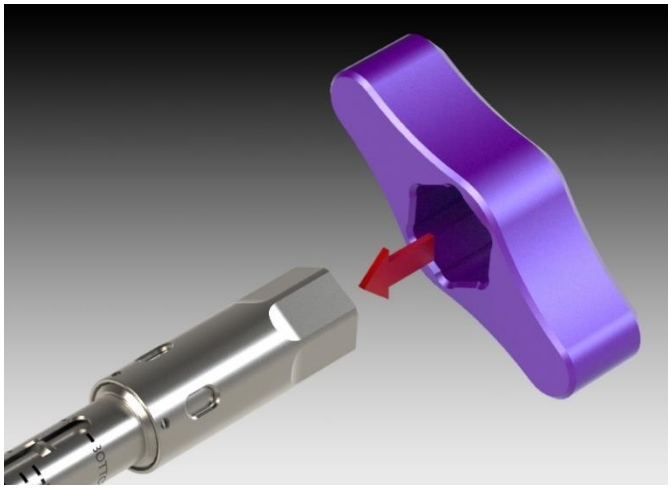
Continue to rotate the driver sleeve in the clockwise direction until the position indicator is at (or very near to) the "BOTTOM" position. At this point the outer sleeve should be located below the top of the screw head (see figure below).

Rod reducer in the "BOTTOM" position



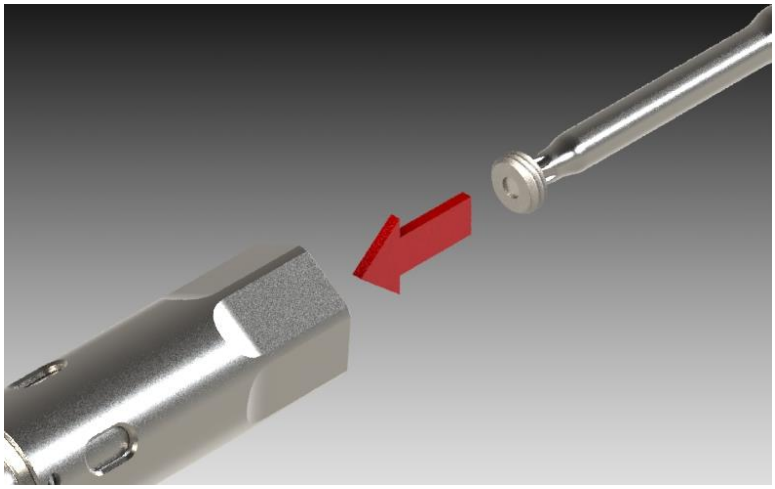
Rod reducer in the "BOTTOM" position

In the case where reducing loads are high, a driver handle is provided to engage the driver sleeve of the rod reducer.



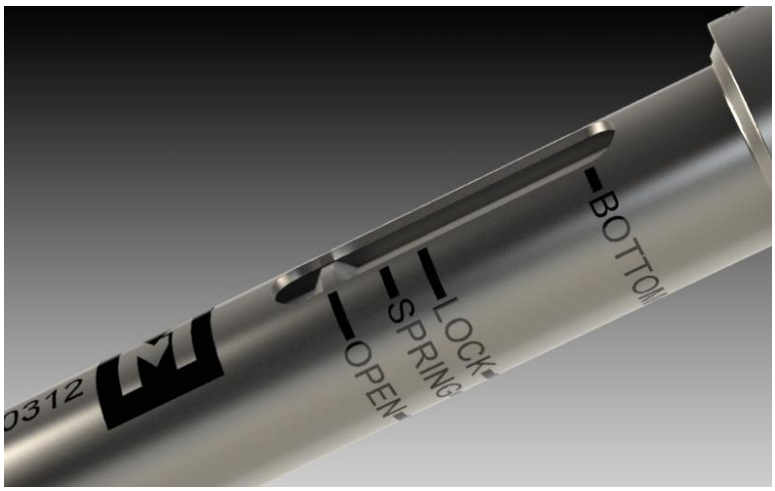
Rod reducer drive handle (if required)

Place a blocker screw on the end of the single ended driver and slide down the cannulation of the rod reducer. Engage the screw and turn until it a resistance is met, indicating that the blocker screw has encountered the rod. Remove the single ended driver from the rod reducer.



Inserting blocker screw with single ended blocker screwdriver

Turn the driver sleeve in the COUNTERCLOCKWISE direction to disengage the rod reducer from the pedicle screw head. When the position indicator is in the "OPEN" position, then the rod reducer may be easily removed from the screw head.

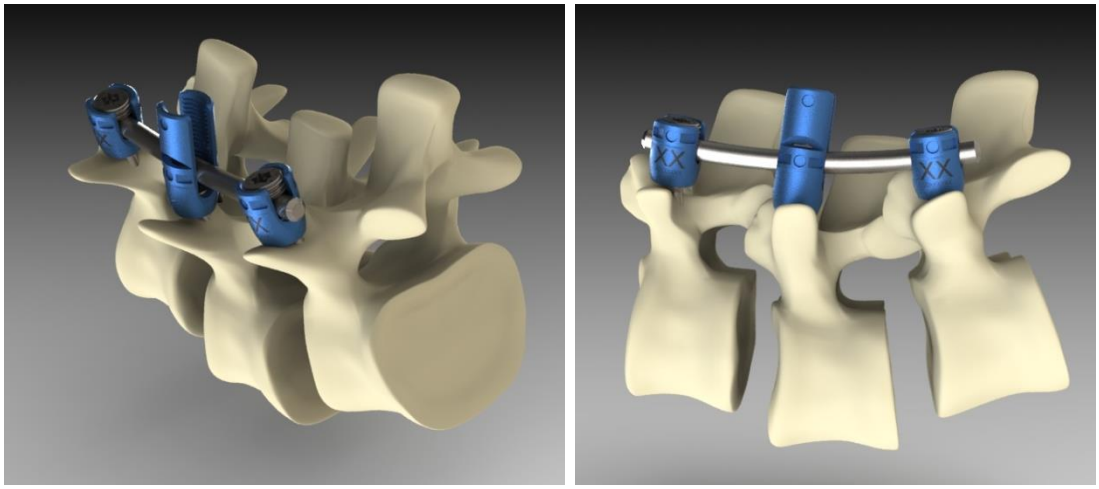


Rod reducer in the "OPEN" position

BLOCKER SCREWS ARE NOW READY FOR FINAL TIGHTENING. REFER TO FINAL TIGHTENING OF BLOCKER SCREW SECTION FOR PROCEDURE DETAILS.

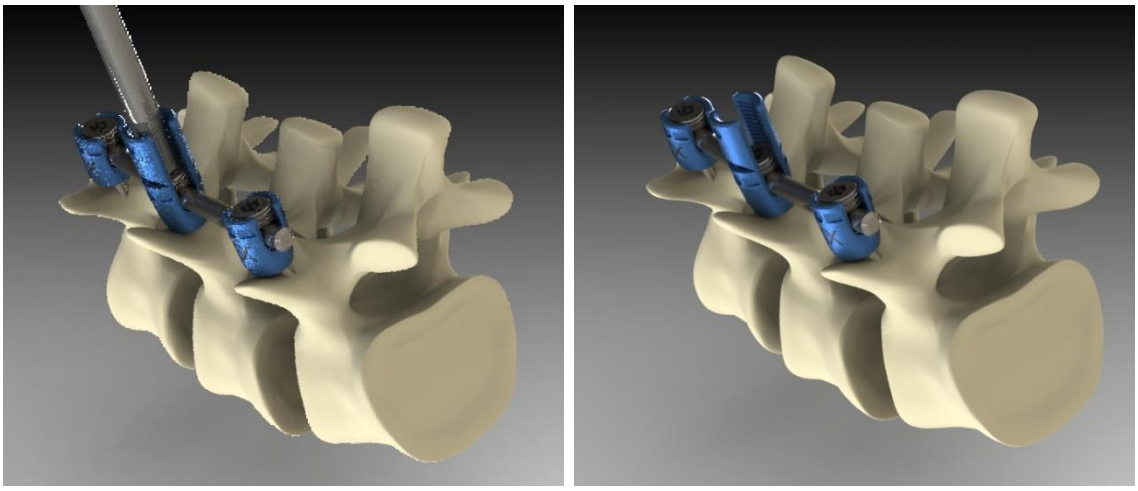
USE OF REDUCTION SCREWS (OPTIONAL)

In certain cases, it may be preferable to employ a reduction screw to reduce a rod into place. A possible case would be that shown in the figure below.



Possible reduction screw application

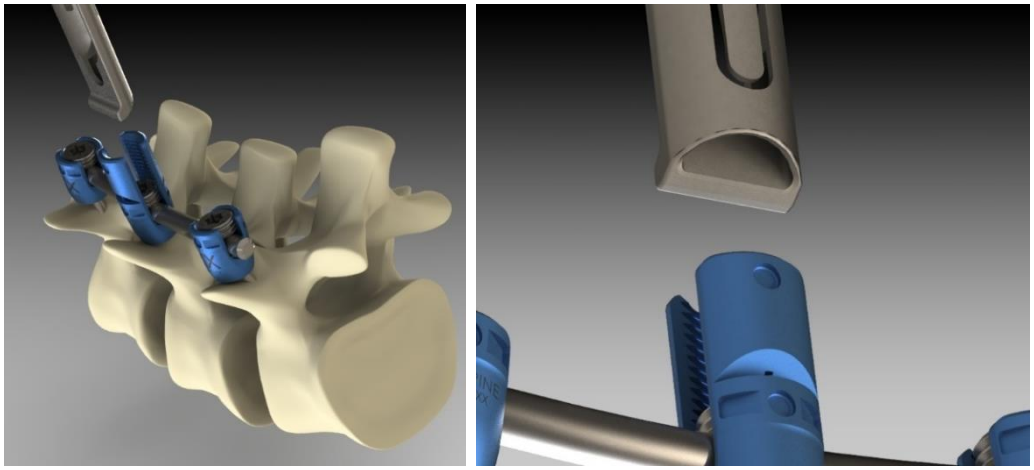
Using the double ended or single-ended driver, engage a blocker screw into the reduction screw head and screw down until the blocker screw contacts the rod. At this point employ the final driver to completely seat the rod into the screw head. When seated, the head of the screw should lie just below the breakaway point of the reduction screw head (as shown in the figures below). Remove the blocker screwdriver. NOTE THAT THE BLOCKER SCREWS WILL STILL REQUIRE FINAL TIGHTENING BEFORE THE CONSTRUCT IS CONSIDERED COMPLETE.



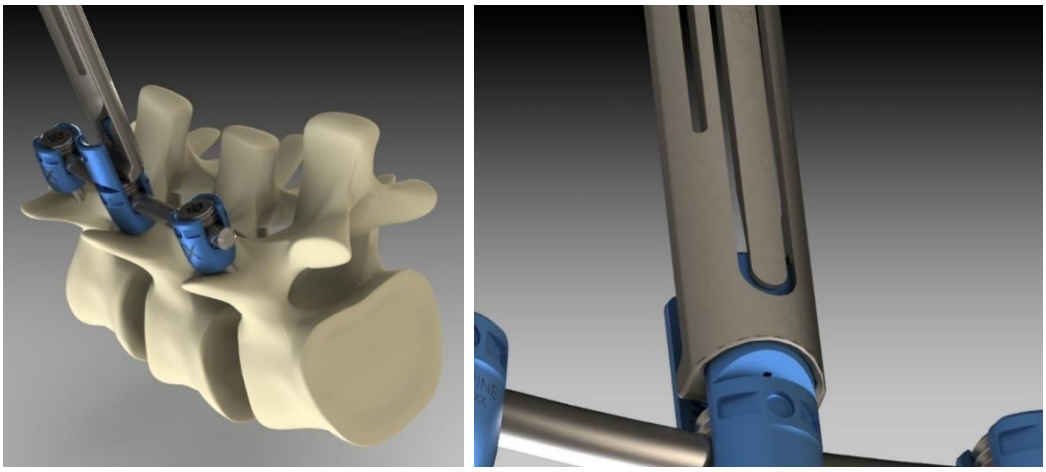
Inserting blocker screw into the reduction screw head

At this point the tabs may be removed from the reduction screw head by employing the tab breaker. Align the flat portion of the instrument to the inside (rod side) of the tab and slide over until fully engaged with the tab.

When Reduction Screws are used, the tabs are broken off when the reduction is complete.

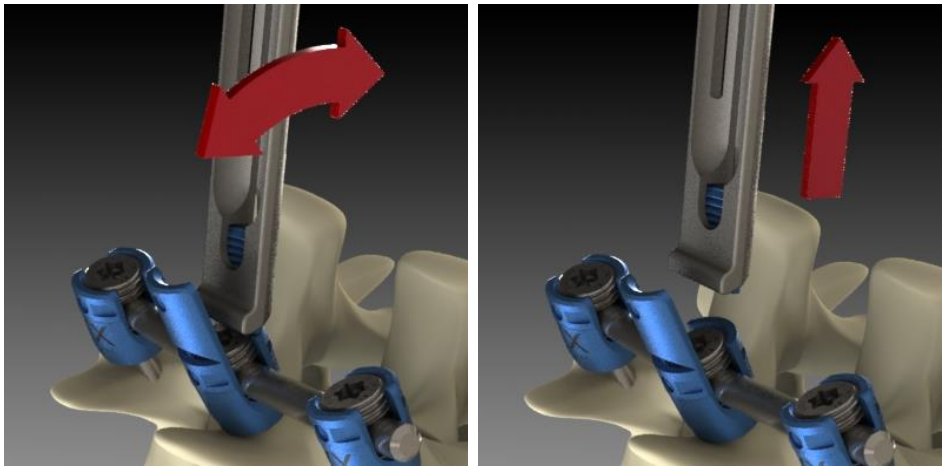


Aligning tab breaker with reduction pedicle screw tab



Breaker tab fully engaged

After the tab is fully engaged, bend the tab back and forth several times until the tab breaks. Remove the tab breaker, the broken tab should remain in the instrument. Repeat this procedure for any other tabs requiring removal.



Breaking and removing tab

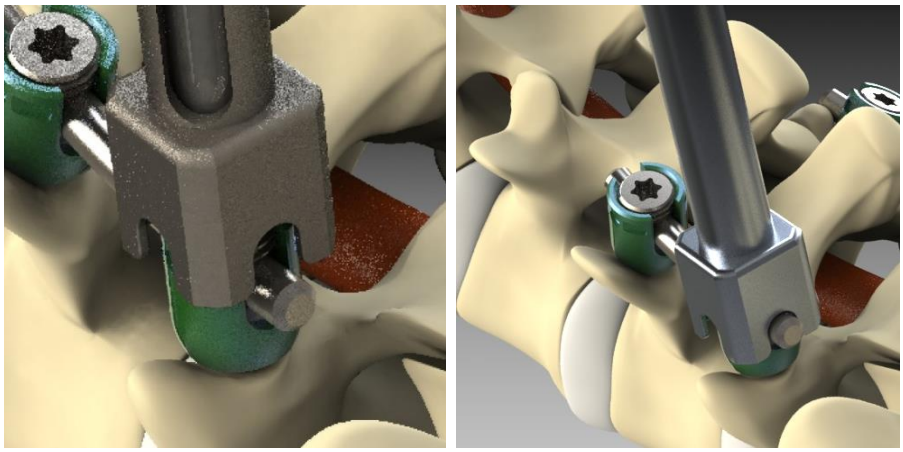
BLOCKER SCREWS ARE NOW READY FOR FINAL TIGHTENING. REFER TO FINAL TIGHTENING OF BLOCKER SCREW SECTION FOR PROCEDURE DETAILS.

FINAL TIGHTENING OF BLOCKER SCREWS

Final tightening of the blocker screws is achieved by using the counter torque tube, final driver and torque limiting handle.

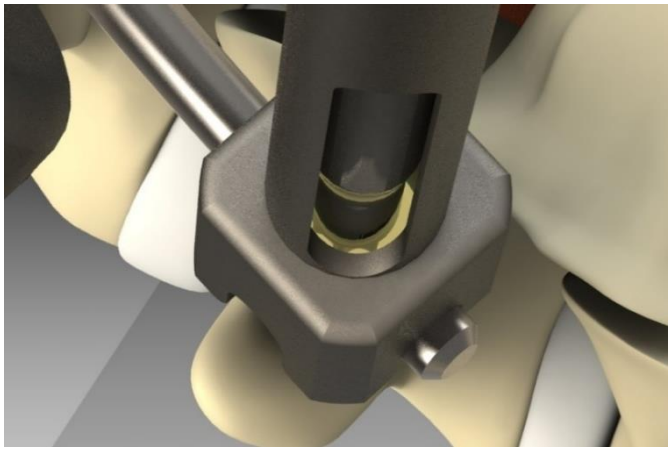
Align the counter torque tube with the pedicle screw head and slide down to engage the slots with the rod.

Note: The Counter Torque Tube must be used for final tightening. The Counter Torque Tube performs two important functions: 1. It allows the Torque Wrench to align with the tightening axis. 2. It allows one to apply the torque needed to lock the implant assembly without applying the torque to the rest of the construct.



Counter torque tube alignment and engagement with pedicle screw head

Attach the torque limiting handle to the final driver and slide the final drive down the counter torque tube. Use the aperture in the counter torque tube to ensure that the final driver is fully engaged with the blocker screw.



Checking for engagement between final driver and blocker screw

Tighten the blocker screw until the torque limiting handle snaps, indicating that a torque of 12N-m has been achieved. Snap the torque limiting handle one more time as a check that it has been properly tightened.

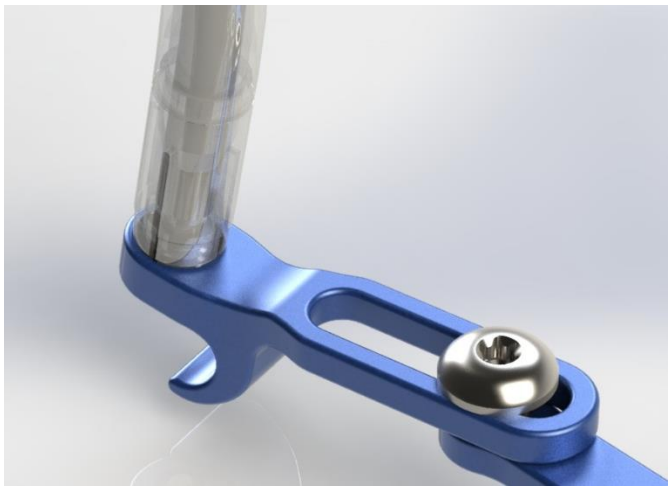
Warning: Final tightening of the blocker screw should only be performed with a calibrated, Met-One torque handle. Met-One screw implants achieve performance standard only when tightened to the required 12 Nm tightening torque. Refer to Met-One for calibration maintenance.

Final tightening of blocker screw

CROSSLINK PLACEMENT

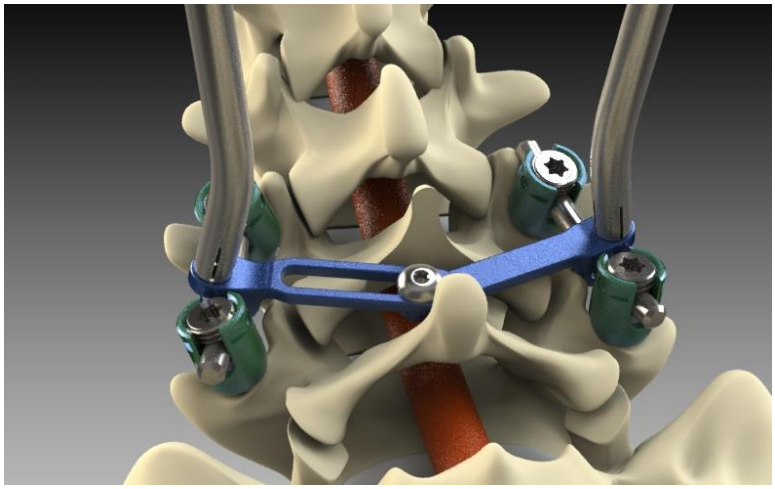
Determine an appropriately sized crosslink assembly. Ensure that the assembly can slide and rotate about the central screw as a check that the central screw has not been inadvertently tightened.

Attach outer sleeve and driver shaft to each side of the crosslink being implanted.



Attach driver sleeve and driver to crosslink

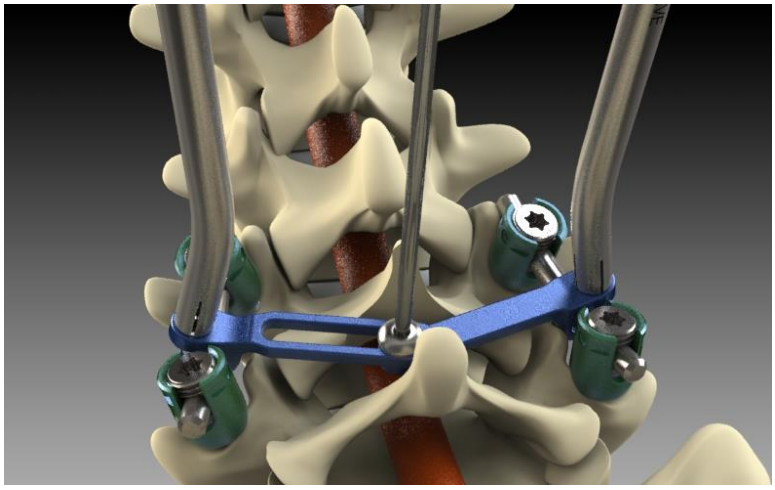
With the driver sleeve and driver attached to the crosslink, place the crosslink in the desired position. Ensure that the rod is fully seated against the crosslink and lockout the lateral screws against the rod by twisting the torque limiting handle provide until it snaps.



Fit crosslink to rods and lockout using torque limiting handle

Lockout the central screw by twisting the crosslink driver with a torque limiting handle until it snaps.

Warning: Final tightening of all crosslink screws should only be performed with a calibrated, Met-One torque handle. Met-One crosslink implants achieve performance standard only when tightened to the required 4.5 Nm tightening torque. Refer to Met-One for calibration maintenance

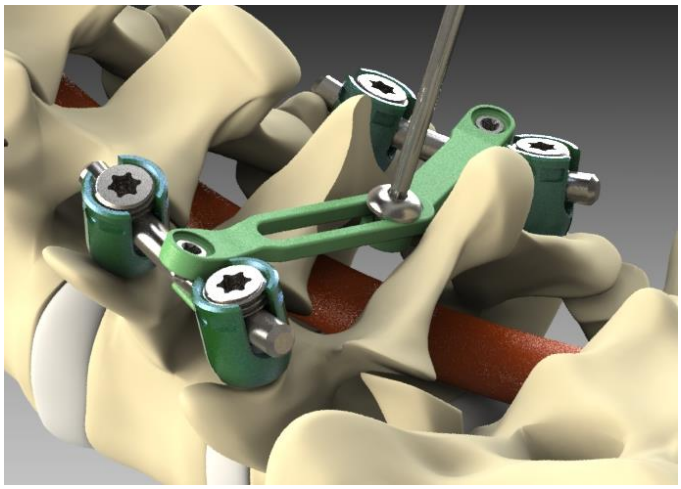


Lockout the central screw using torque limiting handle

Check that each of the three screws are correctly tightened by tightening each until the torque limiting handle snaps.

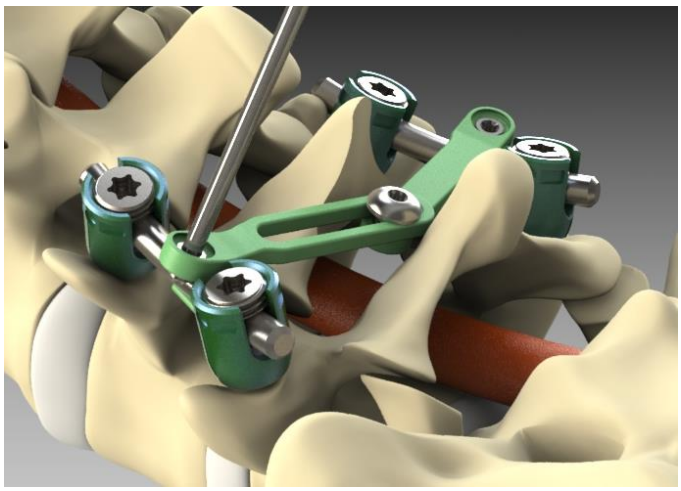
CROSSLINK REMOVAL

Using the crosslink driver, loosen the central screw by turning the driver in a counterclockwise direction until the screw is obviously loosened. Leave the screw in the construct.



Loosening the crosslink central screw.

Continuing to use the crosslink driver, loosen each of the lateral screws by turning the driver in the counterclockwise direction. Continue loosening until the cross link is released from the rod.



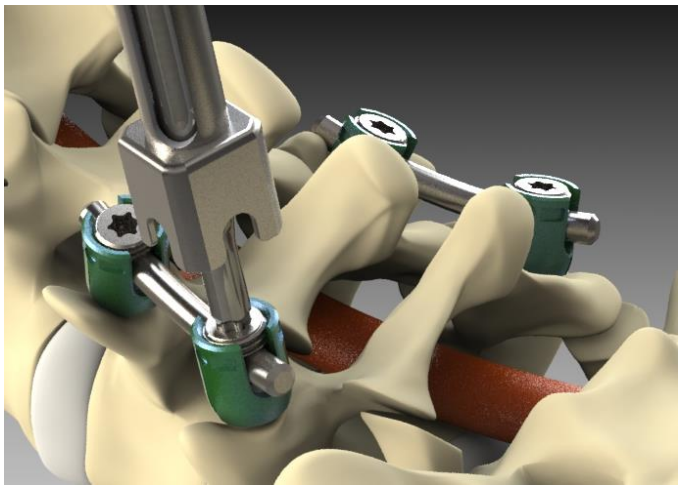
Loosening the crosslink lateral screws

Carefully remove the cross link from the surgical site and dispose. DO NOT REUSE A CROSS LINK THAT HAS BEEN REMOVED FROM A PATIENT.

PEDICLE SCREW REMOVAL

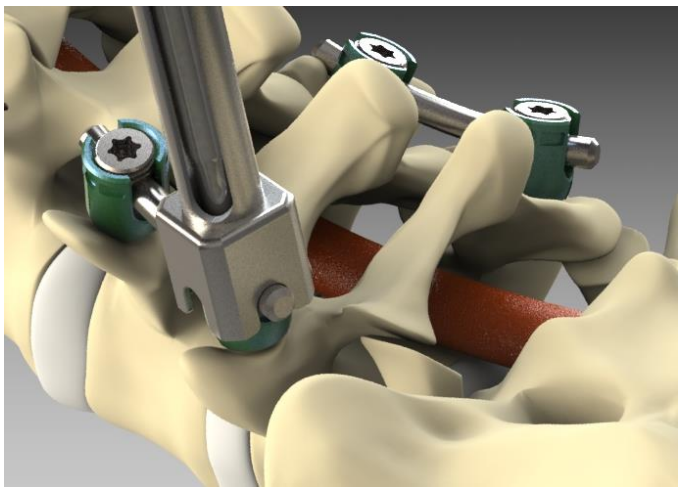
Remove any crosslink that are attached to the pedicle screw and rod construct.

Slide the blocker final tightening driver into the counter torque tube and be sure that the driver extends beyond the end of the counter torque tube. Engage the driver to the blocker screw to be removed.



Engaging driver with the blocker screw

Slide the counter torque tube down the driver shaft until it engages with the rod.

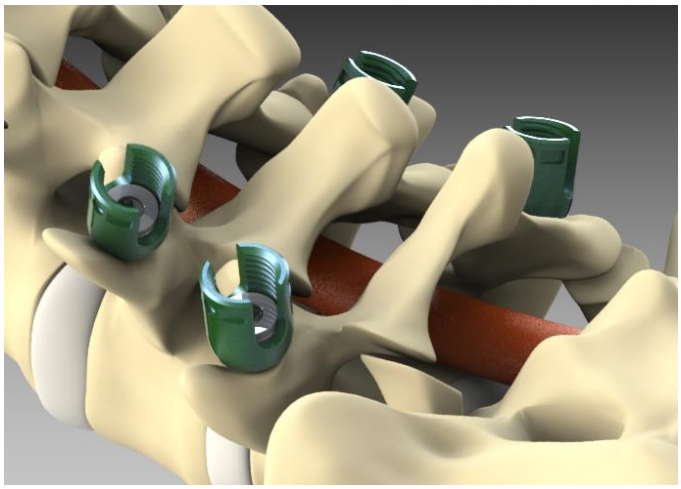


Engage the torque tube with rod

Turn the driver in a counterclockwise direction until the blocker screw is loose.

Remove the counter torque tube and driver and retrieve the loosened blocker screw. Discard the used blocker screw. DO NOT REUSE A BLOCKER SCREW THAT HAS BEEN RETRIEVED FROM A PATIENT.

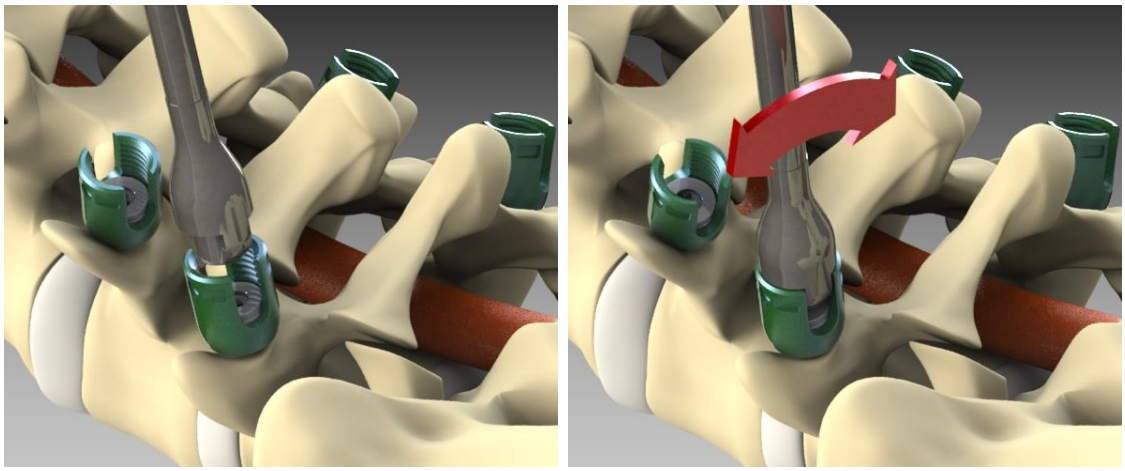
Repeat for all blocker screws in the pedicle screw/rod construct being removed.



Blocker screws and rods removed

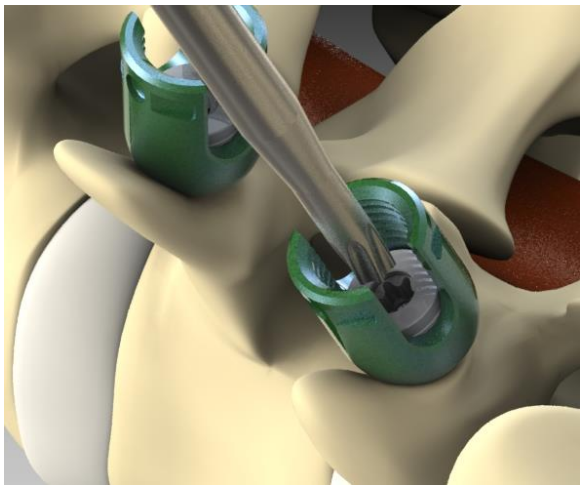
At this point, all screw heads will be in a locked position relative to the screw body. Prior to removing the pedicle screw, the screw heads must be unlocked from the screw head. Employing the head turner instrument, align and engage each screw head and toggle each screw head (as shown below) until it unlocks from the screw body.

Repeat for all pedicle screws in the pedicle screw/rod construct being removed.



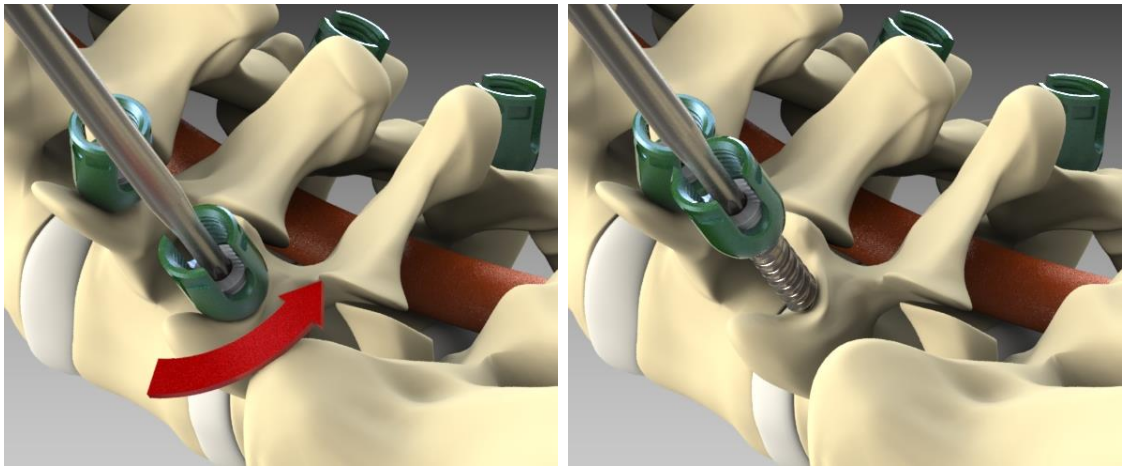
Insert head turner and toggle screw head to unlock head

After aligning (approximately) the pedicle screw head with the axis of the pedicle screw body, engage the taper driver with the pedicle screw body.



Engage taper driver with pedicle screw body

Turn the taper driver in a counterclockwise direction until the screw is completely free of the vertebral body and dispose. DO NOT REUSE ANY SCREW THAT HAS BEEN REMOVED FROM A PATIENT.



Turn taper driver in a counterclockwise direction and remove screw

Repeat this process for all pedicle screws being removed. DO NOT REUSE ANY PEDICLE SCREWS, BLOCKER SCREWS OR RODS THAT HAVE BEEN REMOVED FROM A PATIENT.

XULTAN 5.5 PEDICLE SCREWS

IMPLANT	CATALOG #
Ø4.5 x 25mm	50452500
Ø4.5 x 30mm	50453000
Ø4.5 x 35mm	50453500
Ø4.5 x 40mm	50454000
Ø4.5 x 45mm	50454500
Ø4.5 x 50mm	50455000
Ø4.5 x 55mm	50455500
Ø4.5 x 60mm	50456000
Ø4.5 x 65mm	50456500
Ø4.5 x 70mm	50457000

IMPLANT	CATALOG #
Ø5.5 x 30mm	50553000
Ø5.5 x 35mm	50553500
Ø5.5 x 40mm	50554000
Ø5.5 x 45mm	50554500
Ø5.5 x 50mm	50555000
Ø5.5 x 55mm	50555500
Ø5.5 x 60mm	50556000
Ø5.5 x 65mm	50556500
Ø5.5 x 70mm	50557000

IMPLANT	CATALOG #
Ø5.5 x 30mm, Cannulated	50553001
Ø5.5 x 35mm, Cannulated	50553501
Ø5.5 x 40mm, Cannulated	50554001
Ø5.5 x 45mm, Cannulated	50554501
Ø5.5 x 50mm, Cannulated	50555001
Ø5.5 x 55mm, Cannulated	50555501
Ø5.5 x 60mm, Cannulated	50556001
Ø5.5 x 65mm, Cannulated	50556501
Ø5.5 x 70mm, Cannulated	50557001

IMPLANT	CATALOG #
Ø6.5 x 30mm	50653000
Ø6.5 x 35mm	50653500
Ø6.5 x 40mm	50654000
Ø6.5 x 45mm	50654500
Ø6.5 x 50mm	50655000
Ø6.5 x 65mm	50656500
Ø6.5 x 60mm	50656000
Ø6.5 x 65mm	50656500
Ø6.5 x 70mm	50657000
Ø6.5 x 75mm	50657500
Ø6.5 x 80mm	50658000
Ø6.5 x 85mm	50658500
Ø6.5 x 90mm	50659000

IMPLANT	CATALOG #
Ø6.5 x 30mm, Cannulated	50653001
Ø6.5 x 35mm, Cannulated	50653501
Ø6.5 x 40mm, Cannulated	50654001
Ø6.5 x 45mm, Cannulated	50654501
Ø6.5 x 50mm, Cannulated	50655001
Ø6.5 x 65mm, Cannulated	50656501
Ø6.5 x 60mm, Cannulated	50656001
Ø6.5 x 65mm, Cannulated	50656501
Ø6.5 x 70mm, Cannulated	50657001
Ø6.5 x 75mm, Cannulated	50657501
Ø6.5 x 80mm, Cannulated	50658001
Ø6.5 x 85mm, Cannulated	50658501
Ø6.5 x 90mm, Cannulated	50659001

IMPLANT	CATALOG #
Ø7.5 x 30mm	50753000
Ø7.5 x 35mm	50753500
Ø7.5 x 40mm	50754000
Ø7.5 x 45mm	50754500
Ø7.5 x 50mm	50755000
Ø7.5 x 75mm	50757500

IMPLANT	CATALOG #
Ø7.5 x 30mm, Cannulated	50753001
Ø7.5 x 35mm, Cannulated	50753501
Ø7.5 x 40mm, Cannulated	50754001
Ø7.5 x 45mm, Cannulated	50754501
Ø7.5 x 50mm, Cannulated	50755001
Ø7.5 x 75mm, Cannulated	50757501

Ø7.5 x 60mm	50756000
Ø7.5 x 75mm	50757500
Ø7.5 x 70mm	50757000
Ø7.5 x 75mm	50757500
Ø7.5 x 80mm	50758000
Ø7.5 x 85mm	50758500
Ø7.5 x 90mm	50759000

Ø7.5 x 60mm, Cannulated	50756001
Ø7.5 x 75mm, Cannulated	50757501
Ø7.5 x 70mm, Cannulated	50757001
Ø7.5 x 75mm, Cannulated	50757501
Ø7.5 x 80mm, Cannulated	50758001
Ø7.5 x 85mm, Cannulated	50758501
Ø7.5 x 90mm, Cannulated	50759001

IMPLANT	CATALOG #
Ø8.5 x 30mm	50853000
Ø8.5 x 35mm	50853500
Ø8.5 x 40mm	50854000
Ø8.5 x 45mm	50854500
Ø8.5 x 50mm	50855000
Ø8.5 x 85mm	50858500
Ø8.5 x 60mm	50856000
Ø8.5 x 85mm	50858500
Ø8.5 x 70mm	50857000
Ø8.5 x 85mm	50858500
Ø8.5 x 80mm	50858000
Ø8.5 x 85mm	50858500
Ø8.5 x 90mm	50859000

IMPLANT	CATALOG #
Ø8.5 x 30mm, Cannulated	50853001
Ø8.5 x 35mm, Cannulated	50853501
Ø8.5 x 40mm, Cannulated	50854001
Ø8.5 x 45mm, Cannulated	50854501
Ø8.5 x 50mm, Cannulated	50855001
Ø8.5 x 85mm, Cannulated	50858501
Ø8.5 x 60mm, Cannulated	50856001
Ø8.5 x 85mm, Cannulated	50858501
Ø8.5 x 70mm, Cannulated	50857001
Ø8.5 x 85mm, Cannulated	50858501
Ø8.5 x 80mm, Cannulated	50858001
Ø8.5 x 85mm, Cannulated	50858501
Ø8.5 x 90mm, Cannulated	50859001

XULTAN 5.5 REDUCTION PEDICLE SCREWS

IMPLANT	CATALOG #
Reduction Ø4.5 x 25mm	51452500
Reduction Ø4.5 x 30mm	51453000
Reduction Ø4.5 x 35mm	51453500
Reduction Ø4.5 x 40mm	51454000
Reduction Ø4.5 x 45mm	51454500
Reduction Ø4.5 x 50mm	51455000
Reduction Ø4.5 x 55mm	51455500
Reduction Ø4.5 x 60mm	51456000
Reduction Ø4.5 x 65mm	51456500
Reduction Ø4.5 x 70mm	51457000

IMPLANT	CATALOG #
Reduction Ø5.5 x 30mm	51553000
Reduction Ø5.5 x 35mm	51553500
Reduction Ø5.5 x 40mm	51554000
Reduction Ø5.5 x 45mm	51554500
Reduction Ø5.5 x 50mm	51555000
Reduction Ø5.5 x 55mm	51555500
Reduction Ø5.5 x 60mm	51556000
Reduction Ø5.5 x 65mm	51556500
Reduction Ø5.5 x 70mm	51557000

IMPLANT	CATALOG #
Reduction Ø5.5 x 30mm, Cannulated	51553001
Reduction Ø5.5 x 35mm, Cannulated	51553501
Reduction Ø5.5 x 40mm, Cannulated	51554001
Reduction Ø5.5 x 45mm, Cannulated	51554501
Reduction Ø5.5 x 50mm, Cannulated	51555001
Reduction Ø5.5 x 55mm, Cannulated	51555501
Reduction Ø5.5 x 60mm, Cannulated	51556001
Reduction Ø5.5 x 65mm, Cannulated	51556501
Reduction Ø5.5 x 70mm, Cannulated	51557001

IMPLANT	CATALOG #
Reduction Ø6.5 x 30mm	51653000
Reduction Ø6.5 x 35mm	51653500
Reduction Ø6.5 x 40mm	51654000
Reduction Ø6.5 x 45mm	51654500
Reduction Ø6.5 x 50mm	51655000
Reduction Ø6.5 x 65mm	51656500
Reduction Ø6.5 x 60mm	51656000
Reduction Ø6.5 x 65mm	51656500
Reduction Ø6.5 x 70mm	51657000
Reduction Ø6.5 x 75mm	51657500
Reduction Ø6.5 x 80mm	51658000
Reduction Ø6.5 x 85mm	51658500
Reduction Ø6.5 x 90mm	51659000

IMPLANT	CATALOG #
Reduction Ø6.5 x 30mm, Cannulated	51653001
Reduction Ø6.5 x 35mm, Cannulated	51653501
Reduction Ø6.5 x 40mm, Cannulated	51654001
Reduction Ø6.5 x 45mm, Cannulated	51654501
Reduction Ø6.5 x 50mm, Cannulated	51655001
Reduction Ø6.5 x 65mm, Cannulated	51656501
Reduction Ø6.5 x 60mm, Cannulated	51656001
Reduction Ø6.5 x 65mm, Cannulated	51656501
Reduction Ø6.5 x 70mm, Cannulated	51657001
Reduction Ø6.5 x 75mm, Cannulated	51657501
Reduction Ø6.5 x 80mm, Cannulated	51658001
Reduction Ø6.5 x 85mm, Cannulated	51658501
Reduction Ø6.5 x 90mm, Cannulated	51659001

IMPLANT	CATALOG #
Reduction Ø7.5 x 30mm	51753000
Reduction Ø7.5 x 35mm	51753500
Reduction Ø7.5 x 40mm	51754000
Reduction Ø7.5 x 45mm	51754500
Reduction Ø7.5 x 50mm	51755000
Reduction Ø7.5 x 75mm	51757500
Reduction Ø7.5 x 60mm	51756000
Reduction Ø7.5 x 75mm	51757500
Reduction Ø7.5 x 70mm	51757000
Reduction Ø7.5 x 75mm	51757500
Reduction Ø7.5 x 80mm	51758000
Reduction Ø7.5 x 85mm	51758500
Reduction Ø7.5 x 90mm	51759000

IMPLANT	CATALOG #
Reduction Ø7.5 x 30mm, Cannulated	51753001
Reduction Ø7.5 x 35mm, Cannulated	51753501
Reduction Ø7.5 x 40mm, Cannulated	51754001
Reduction Ø7.5 x 45mm, Cannulated	51754501
Reduction Ø7.5 x 50mm, Cannulated	51755001
Reduction Ø7.5 x 75mm, Cannulated	51757501
Reduction Ø7.5 x 60mm, Cannulated	51756001
Reduction Ø7.5 x 75mm, Cannulated	51757501
Reduction Ø7.5 x 70mm, Cannulated	51757001
Reduction Ø7.5 x 75mm, Cannulated	51757501
Reduction Ø7.5 x 80mm, Cannulated	51758001
Reduction Ø7.5 x 85mm, Cannulated	51758501
Reduction Ø7.5 x 90mm, Cannulated	51759001

IMPLANT	CATALOG #
Reduction Ø8.5 x 30mm	51853000
Reduction Ø8.5 x 35mm	51853500
Reduction Ø8.5 x 40mm	51854000
Reduction Ø8.5 x 45mm	51854500
Reduction Ø8.5 x 50mm	51855000
Reduction Ø8.5 x 85mm	51858500
Reduction Ø8.5 x 60mm	51856000
Reduction Ø8.5 x 85mm	51858500
Reduction Ø8.5 x 70mm	51857000
Reduction Ø8.5 x 85mm	51858500
Reduction Ø8.5 x 80mm	51858000
Reduction Ø8.5 x 85mm	51858500
Reduction Ø8.5 x 90mm	50859000

IMPLANT	CATALOG #
Reduction Ø8.5 x 30mm, Cannulated	51853001
Reduction Ø8.5 x 35mm, Cannulated	51853501
Reduction Ø8.5 x 40mm, Cannulated	51854001
Reduction Ø8.5 x 45mm, Cannulated	51854501
Reduction Ø8.5 x 50mm, Cannulated	51855001
Reduction Ø8.5 x 85mm, Cannulated	51858501
Reduction Ø8.5 x 60mm, Cannulated	51856001
Reduction Ø8.5 x 85mm, Cannulated	51858501
Reduction Ø8.5 x 70mm, Cannulated	51857001
Reduction Ø8.5 x 85mm, Cannulated	51858501
Reduction Ø8.5 x 80mm, Cannulated	51858001
Reduction Ø8.5 x 85mm, Cannulated	51858501
Reduction Ø8.5 x 90mm, Cannulated	50859001

XULTAN 5.5 RODS

IMPLANT	CATALOG #
35mm Straight	52035010
40mm Straight	52040010
45mm Straight	52045010
50mm Straight	52050010
55mm Straight	52055010
60mm Straight	52060010
65mm Straight	52065010
70mm Straight	52070010
75mm Straight	52075010
80mm Straight	52080010
85mm Straight	52085010
90mm Straight	52090010
95mm Straight	52095010
100mm Straight	52100010
200mm Straight	52200010
300mm Straight	52300010
400mm Straight	52400010
500mm Straight	52500010
600mm Straight	52600010

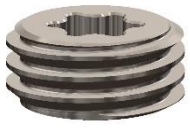
IMPLANT	CATALOG #
30mm Bent	52030020
35mm Bent	52035020
40mm Bent	52040020
45mm Bent	52045020
50mm Bent	52050020
55mm Bent	52055020
60mm Bent	52060020
65mm Bent	52065020
70mm Bent	52070020
75mm Bent	52075020
80mm Bent	52080020
85mm Bent	52085020
90mm Bent	52090020
95mm Bent	52095020
100mm Bent	52200020
200mm Bent	52200020
300mm Bent	52300020
400mm Bent	52400020
500mm Bent	52500020
600mm Bent	52600020

XULTAN 5.5 CROSSLINKS

IMPLANT	CATALOG #
28-30mm Crosslink	53283000
30-34mm Crosslink	53303400
34-40mm Crosslink	53344000
40-50mm Crosslink	53405000
50-60mm Crosslink	53506000

XULTAN 5.5 BLOCKER SCREWS

IMPLANT	CATALOG #
Standard Blocker	54000001
Reduction Blocker	54000002



EXCEPTIONAL SERVICE. SUPERIOR PRODUCTS. INNOVATIVE MINDS.

The physicians we work with are Renaissance thinkers. Their mastery, scientific insight and innovative minds inspire our product development. Met One puts advanced technology to work for physicians who artfully transform patients' lives.

INDICATIONS FOR USE

The XULTAN 5.5 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The XULTAN 5.5 Pedicle Screw System is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine (T1-S2/ilium): degenerative disc disease (DDD) (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; curvature (i.e. scoliosis, kyphosis and/or lordosis); tumor; and failed previous fusion (i.e. pseudoarthrosis).

For additional product information including warnings, precautions and adverse effects concerning spinal fixation implants refer to the product insert.

CONTRAINDICATIONS

The XULTAN 5.5 Pedicle Screw System is contraindicated for use in patients:

1. Active infectious process or significant risk of infection (immunocompromised).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Gross distorted anatomy caused by congenital abnormalities.
7. Suspected or documented metal allergy or intolerance.
8. Prior fusion at the level being treated.
9. Any case not described in the indications.

WARNINGS

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include:

- Device component fracture, bending, loosening or disassembly
- Loss of fixation
- Pseudoarthrosis or delayed pseudoarthrosis (i.e., non-union),
- Fracture of the vertebra
- Neurological injury or loss of function, including paralysis, radiculopathy, dysesthesia, hyperesthesia, paresthesia, development, or continuation of pain
- Vascular or visceral injury
- Sensitivity to a metallic foreign body, including possible tumor formation
- Infection
- Death

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Mixing of dissimilar metals in an implant construct may result in accelerated corrosion. Titanium and stainless-steel implant must NEVER be used together in an implant construct. NEVER use components from any other system or manufacturer with the XULTAN 5.5 pedicle screw system.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Never reuse an internal fixation device under any circumstances.

Only surgeons trained and experienced in spinal fusion and bone grafting techniques should use the XULTAN 5.5 Pedicle Screw System. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.

Do not reuse implants. Discard used, damaged, or otherwise suspect implants. AN IMPLANT SHOULD NEVER BE REUSED. Any implant, once used, should be discarded.

Minimize rotation and/or articulation of the screw prior to implantation to minimize the probability of damage to the O-ring.

PRECAUTIONS

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the XULTAN 5.5 Pedicle Screw System.

The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Magnetic Resonance (MR) Safety: the XULTAN 5.5 Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The XULTAN 5.5 Pedicle Screw System has not been tested for heating or migration in the MR environment.

Accepted medical practices, in addition to any local or national requirement, should be employed in the handling and disposal of all contaminated implants.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

CLEANING

Implants are provided clean but not sterile. ISO 8828 or ACORN recommended practices for in-hospital sterilization should be followed for all components.

Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used. PLEASE DISCARD ALL CONTAMINATED IMPLANTS.

1. Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions.
2. Immediately after the procedure, soak and manually agitate the soiled instruments in the solution for the minimum recommended time specified by the solution manufacturer or 10 minutes, whichever is longer.
3. Using a soft bristle scrub brush, scrub instruments to remove all traces of blood and debris from the instrument surfaces. Employ a soft bristle brush or pipe cleaner to reach the entire length of all instrument lumens.
4. Rinse instruments with warm 85°F-104°F (36°C-46°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
5. Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions.
6. Rinse instruments with warm 85°F-104°F (36°C-46°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
7. Dry the instruments immediately after final rinse with a clean towel or clean, dry compressed air until visibly dry.

INSPECTION

1. Carefully inspect all instruments before sterilization to ensure all visible blood and soil have been removed from surfaces, lumens, holes and moveable parts.
2. If damage or biological residue is observed on an implant, the implant must be discarded.

STERILIZATION

The XULTAN 5.5 Pedicle Screw System implants are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below. The ANSI/AAMI ST79 half-cycle method it utilized to validate the prescribed sterilization method to a sterility assurance level (SAL) of 10^{-6}. Implants are single-use devices, thus do no clean or resterilize an implant that has been in contact with or contaminated by blood or other infectious substances. Only FDA-cleared sterilization wraps should be used. The manufacturer and distributor assume no responsibility for cleaning and re-sterilization of implants, components, or reusable instruments performed by the individual or hospital.

Table 1: Recommended sterilization parameters

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes

LIMITED WARRANTY

Met One Technologies products are sold with a limited warranty to the original purchaser against defects in the workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Met One Technologies for current information.

MANUFACTURED BY

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El Paso, TX, 79922