AltusSpine

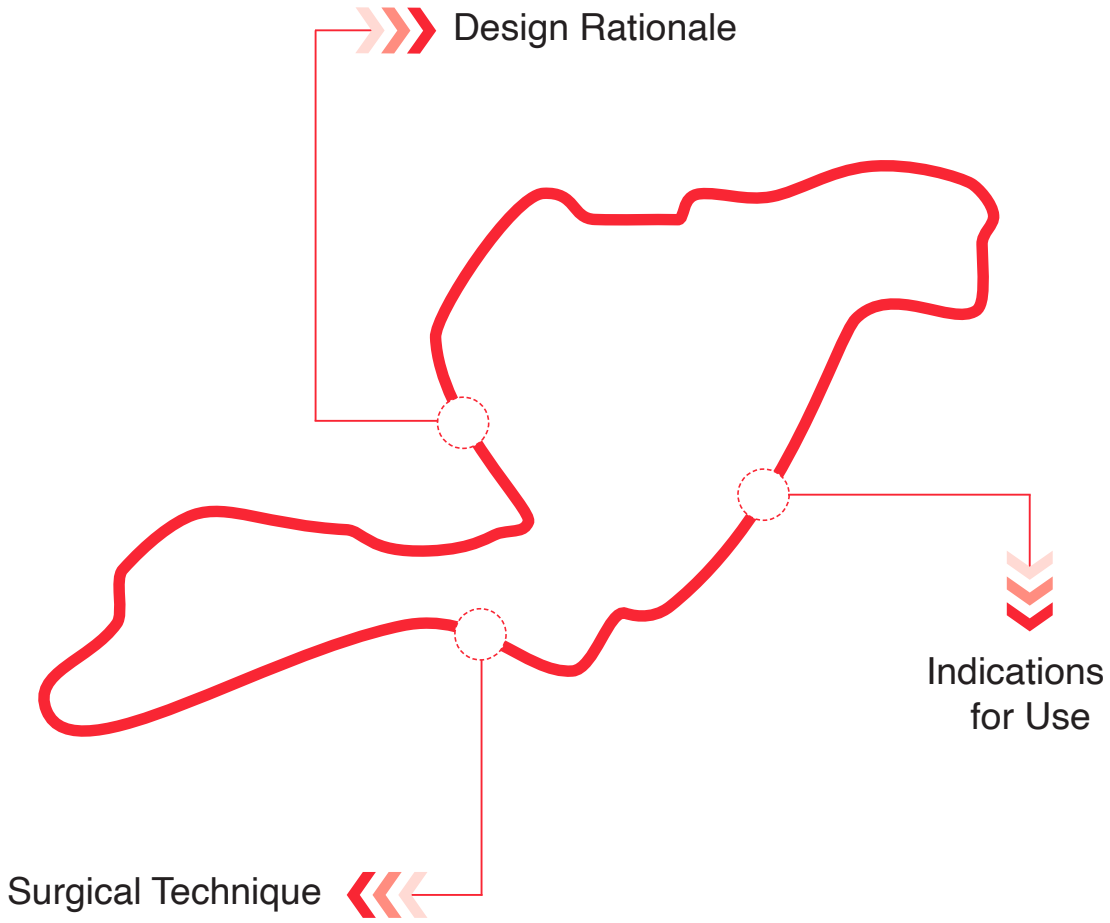


Valencia Pedicle Screw Surgical Technique



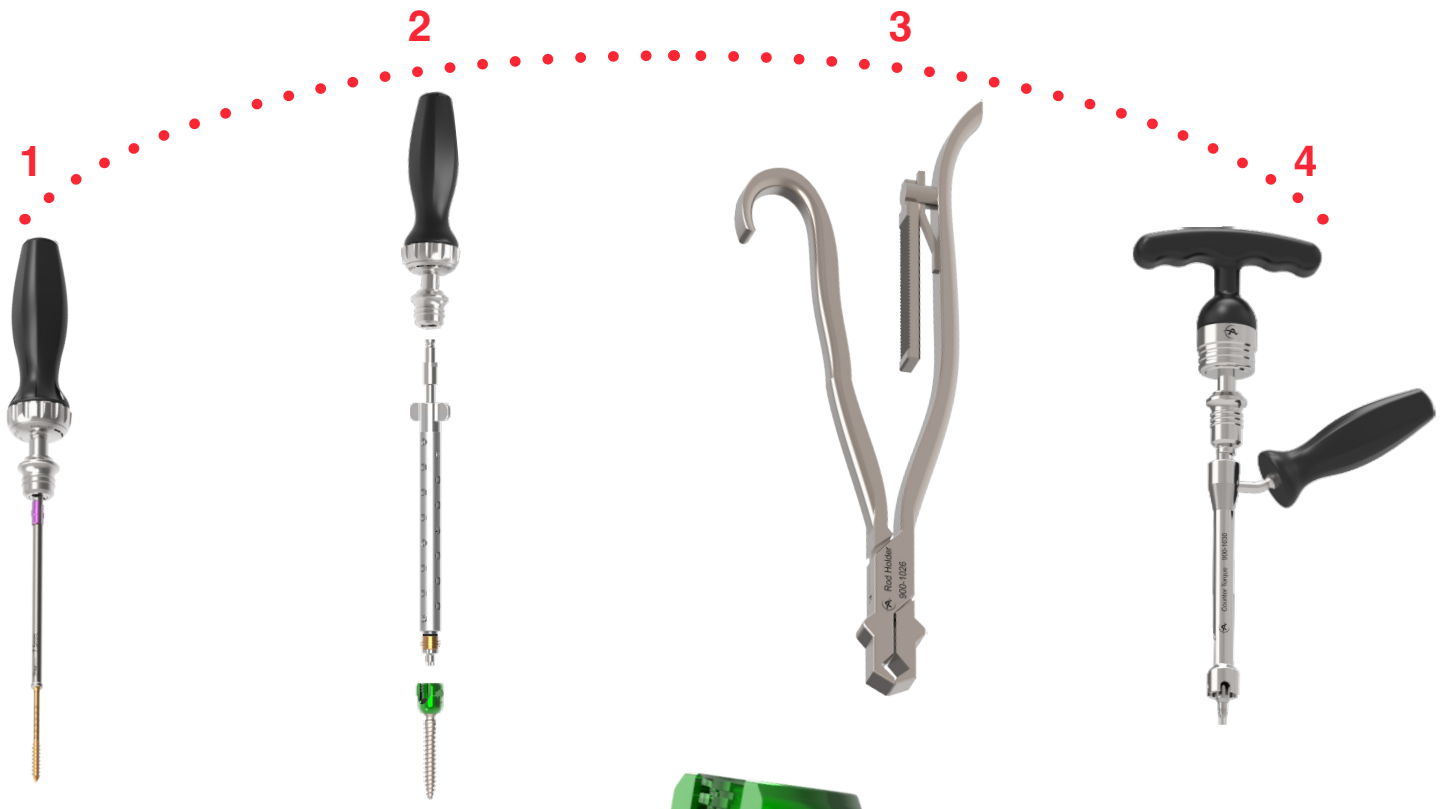
VALENCIA CIRCUIT

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DESIGN RATIONALE



Solid, cannulated and reduction head polyaxial screws

Low-torque hybrid square thread



T25 dual lead screw body

Up to 60° polyaxial angulation

4.5mm - 8.5mm screw diameters
25mm - 100mm screw lengths

INDICATIONS FOR USE

The Altus Spine Valencia Pedicle Screw System is intended to achieve immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The Altus Spine Pedicle Screw System is intended for noncervical pedicle fixation and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins 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 failed previous fusion is skeletally mature patients.

The Altus Spine Pedicle Screw System may be used for noncervical pedicle fixation via posterior percutaneous approach with MIS instrumentation for the indications listed above. When used as an anterolateral thoracic/lumbar system, the Altus Spine Pedicle Screw System may be used as an adjunct to fusion for the indications listed above.

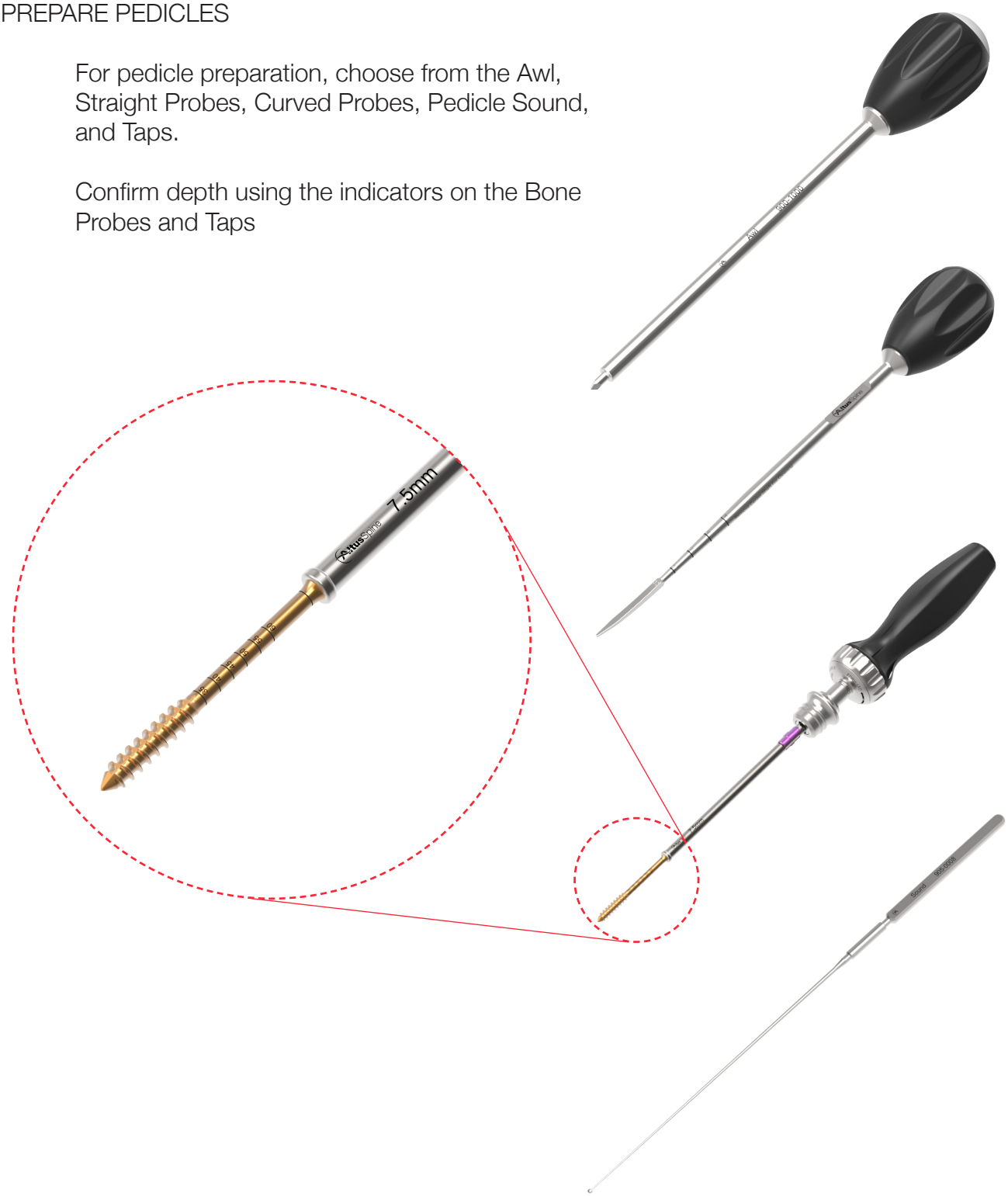
Reference product insert (PI-001) for complete system indications for use, description, warnings, and precautions

1. PEDICLE PREPARATION

PREPARE PEDICLES

For pedicle preparation, choose from the Awl, Straight Probes, Curved Probes, Pedicle Sound, and Taps.

Confirm depth using the indicators on the Bone Probes and Taps



1. PEDICLE PREPARATION (CONT.)

PEDICLE MARKING

Pedicle Markers can be used to determine the orientation and depth of pedicle cavities

Pedicle Markers with unique right and left geometries are supplied

Select the appropriate Pedicle Marker and load it into the Utility Driver

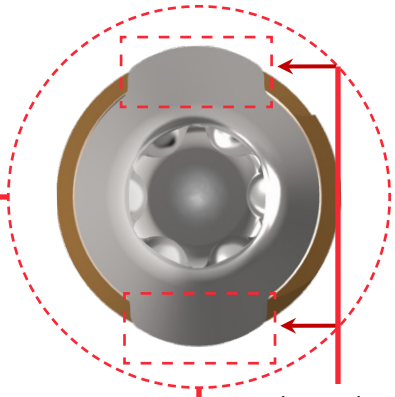
To load, pull back on the Utility Driver sleeve to the “unlock” position, insert the marker, and release the sleeve to lock the assembly

Place the Pedicle Marker into the prepared hole, unlock the sleeve, and remove the Utility Driver. Use fluoroscopy to confirm position





2. SCREW INSERTION

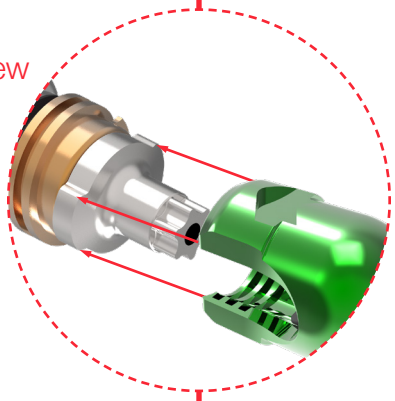


ASSEMBLE DRIVER, STANDARD LOCKING

Attach the Locking Driver to a Ratcheting Handle

Load the appropriate Pedicle Screw onto the Locking Driver by engaging the T25 tip of the driver into the drive feature of the screw body

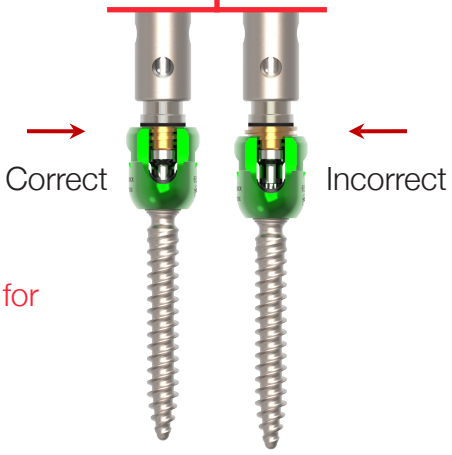
*Note: Assembly requires alignment of distal tip of driver with slots of screw head



Once the tip is properly seated in the screw, lower the sleeve of the driver into the threads of the screw

Rotate the thumb tab clockwise until the screw is firmly attached (as shown)

INSERT SCREW



Insert the screw until the tip of the screw reaches the pedicle entry point, and confirm desired trajectory

Advance the screw by rotating the Ratcheting Handle clockwise

*Note: Do not hold thumb tab while inserting screw as there is potential for locking sleeve to loosen during insertion

REMOVE THE DRIVER

Turn the thumb tab counterclockwise until it completely disengages the screw head

Repeat screw insertion steps until all screws are in place

*Caution: When making minor screw height adjustments, it is recommended that the Utility Driver with T25 Tip be used. Improper re-engagment of the Locking Driver can cause damage to the pedicle screw.



2. SCREW INSERTION (CONT.)



ASSEMBLE DRIVER, SUPER LOCKER

Attach the Locking Driver to a Ratcheting Handle

Unlock the driver by pulling the tightening knob in the direction of the arrow marked “Load”

Load the appropriate Pedicle Screw onto the Locking Driver by engaging the T25 tip of the driver into the drive feature of the screw body

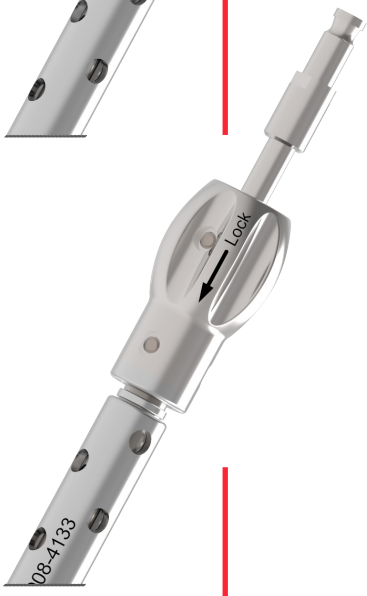


*Note: Assembly requires alignment of distal tip of driver with slots of screw head

Once the tip is properly seated in the screw, lower the sleeve of the driver into the threads of the screw

Rotate the knob clockwise until the screw is firmly attached

Lock the driver by pushing the knob in the direction of the arrow marked “Lock”



INSERT SCREW

Identical to standard driver, see prior section

REMOVE THE DRIVER

Unlock the driver by pulling the knob in the direction of the arrow marked “Load”

Turn the knob counterclockwise until it completely disengages the screw head

Repeat screw insertion steps until all screws are in place

*Caution: When making minor screw height adjustments, it is recommended that the Utility Driver with T25 Tip be used. Improper re-engagment of the Locking Driver can cause damage to the pedicle screw.

3. ROD PLACEMENT

SCREW HEAD ALIGNMENT

Use the Head Positioner to achieve desired alignment

Insert the Head Positioner into the head of the screw and rotate to desired position

To aid in Rod placement, utilize the Rod Holder

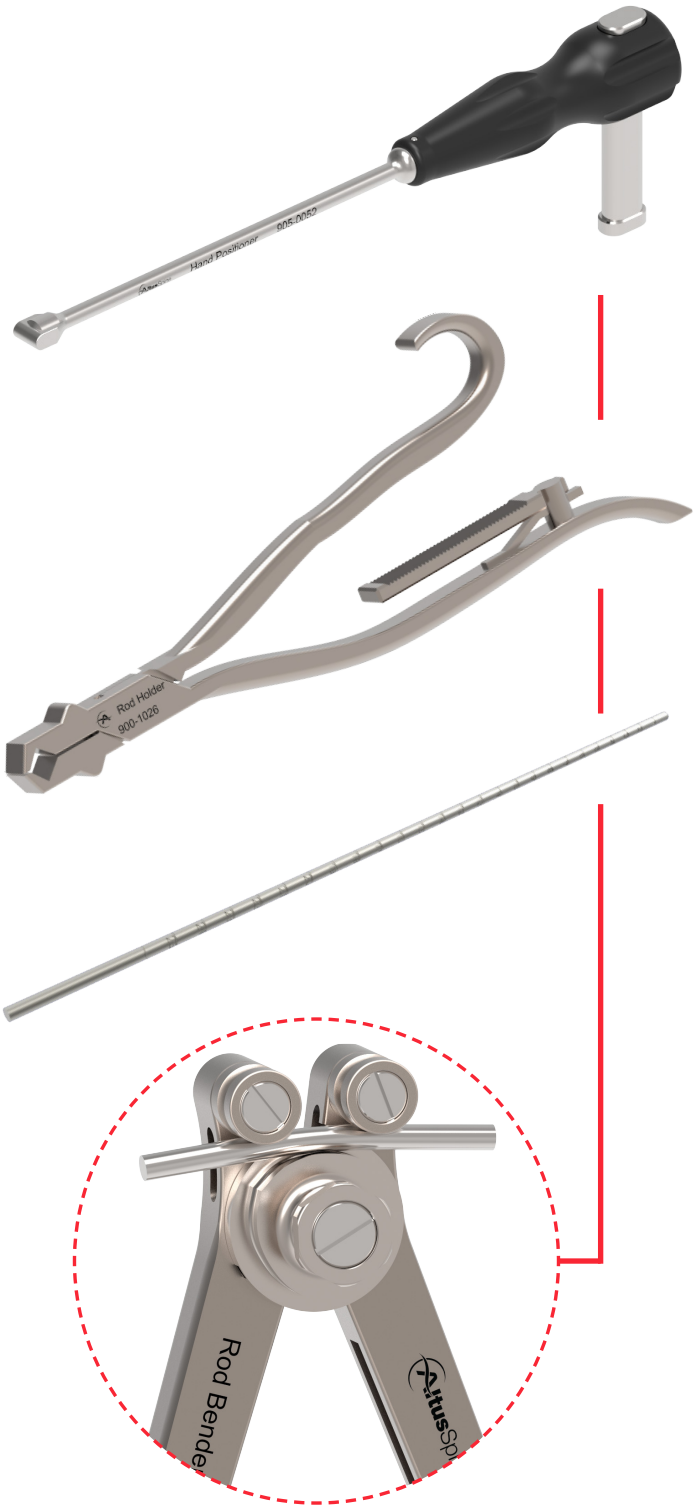
SELECT APPROPRIATE ROD

Determine Rod length by trial or using the Rod Template

ROD CONTOURING

Ensure the appropriate contour (small, medium, large) is set on the main cam prior to bending

*Note: Do not reverse bend rods. Reverse bending may produce internal stresses which may become the focal point for eventual breakage of the implant



4. LOCKING CAP INSERTION

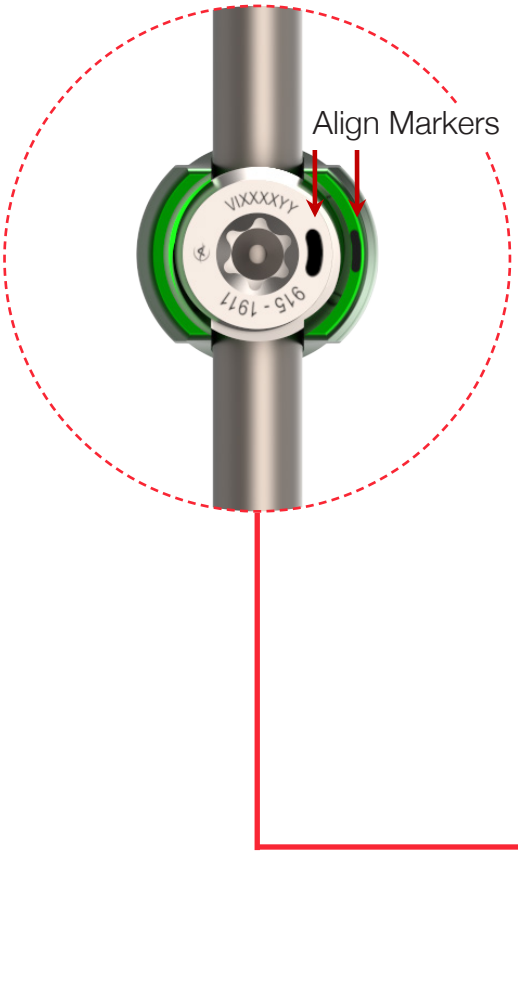
LOAD LOCKING CAPS

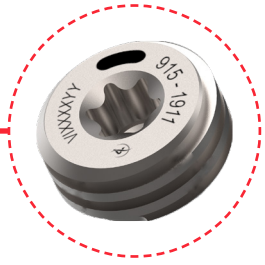
Load a T25 Locking Caps onto each and of the Double Sided Cap Inserter

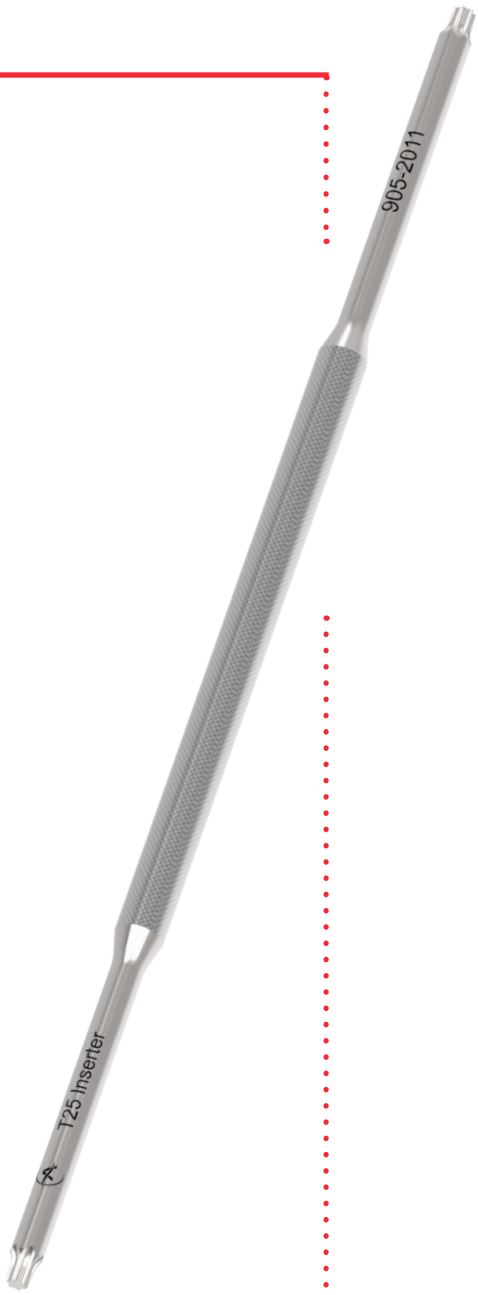
Introduce the tip of the inserter into the cap; a firm push will engage the cap properly

Place the cap into the screw head and turn clockwise

Use the “Thread Start” markings to aid in starting cap







5. ROD REDUCTION

MINOR REDUCTIONS

Utilize the Rod Pusher to gain the additional clearance needed to start threading the cap



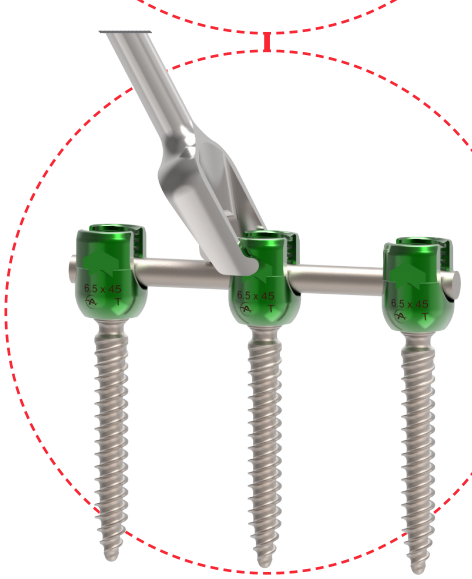
MAJOR REDUCTIONS

Engage the Rod Rocker to either side of the screw head

Rock the instrument against the rod to reduce

With the rod reduced, introduce the T25 Locking Cap





5. ROD REDUCTION (CONT.)

SIGNIFICANT REDUCTIONS

Place the distal end of the Rod Persuader down over the tulip head of the screw

The inside edge of the Rod Persuader must be lower than the “ledge” on the side of the screw head

Firmly squeeze the handles together to reduce the rod

*Note: If the Rod Persuader is not positioned correctly it may result in a jam. To release jam, hold the release knob down while using both hands to pull the handle levers apart

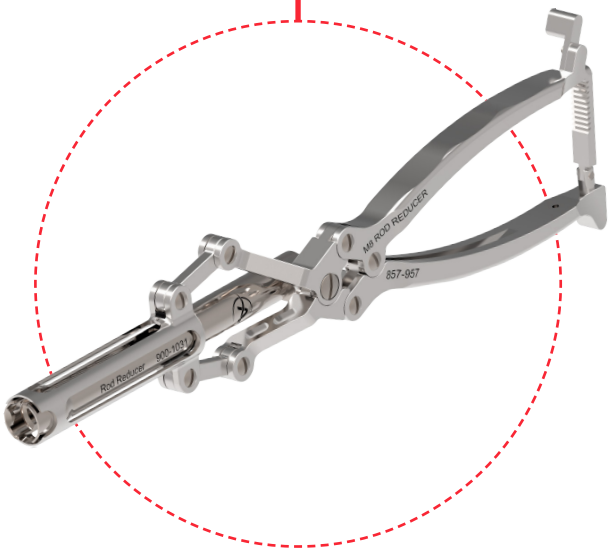


Once the rod is appropriately reduced, insert the T25 Inserter loaded with a cap

Turn the T25 Inserter clockwise, either manually or with a Ratcheting Handle, to insert the cap

After provisionally tightening the cap, remove the Inserter and the persuader

To remove the persuader, pull the release knob and allow the handles to retract



5. ROD REDUCTION (CONT.)

EXTENSIVE REDUCTIONS



Place the distal end of the Threaded Rod Persuader down over the tulip head of the screw

The inside edge of the Rod Persuader must be lower than the “ledge” on the side of the screw head

Twist the shaft handle clockwise to reduce the rod

Once the rod is appropriately reduced, insert the T25 Inserter loaded with a cap

Turn the T25 Inserter clockwise, either manually or with a Ratcheting Handle, to insert the cap

*Note: You may insert the T25 with loaded cap through the hollow shaft to reach screw if maintaining reduction is necessary for insertion

After provisionally tightening the cap, remove the Inserter and the reducer

To remove the reducer, turn shaft handle counterclockwise until tip comes free of the screw

6. FINAL LOCKING

ASSEMBLE T25 DRIVE SHAFT TO TORQUE LIMITING HANDLE

Pull back the plunger and insert the shaft until the “load line” is flush with the plunger, then release

Lower the Counter Torque over the head of the screw until seated against the rod

Insert the driver into the Counter Torque

*Note: It is important to ensure that the Counter Torque is properly seated, and the T25 Drive Shaft is properly engaged in the Locking Cap Prior to final locking. Failing to do so may result in a damaged construct or instrument.

Turn the Torque Limiting Handle clockwise until it “clicks”

The audible and tactile “click” confirms the construct is locked down to its proper specification

Remove Driver and Counter Torque from the screw

Repeat Section 6 steps for remainder of the construct

*Note: Final locking must be secured using a Torque Limiting Handle of 7.3 N-m (65 in-lb)



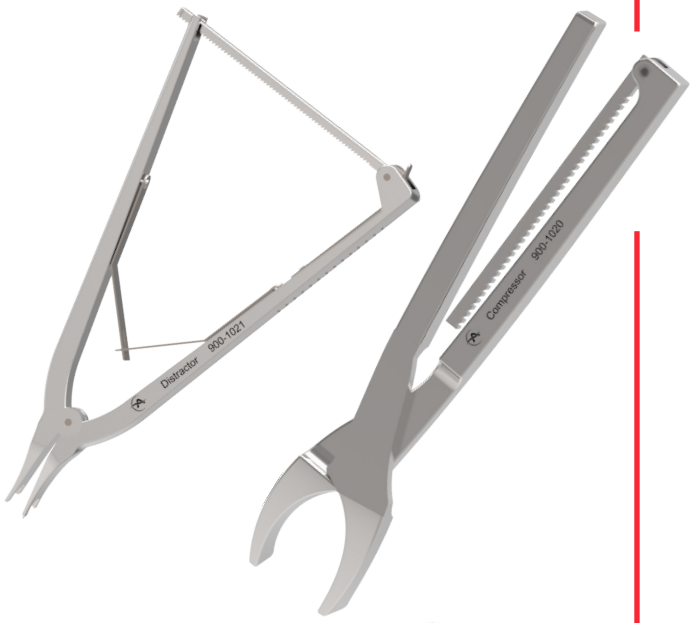
7. COMPRESSION & DISTRACTION (OPTIONAL)

Ensure that one locking cap has been through “Final Locking” (section 6). Keep the second cap is seated on the rod, but not locked

Position the Compressor or the Distractor such that the instrument straddles the rod, while still making contact with the screw heads

Squeeze the handles together until the desired amount of compression / distraction has been achieved

The instrument has a ratcheting lock at its proximal end if needed, or it can be folded inside the handle if it is not needed



8. CROSS CONNECTORS (OPTIONAL)

The Cross Connectors come in 4 different sizes, (small, medium, large, and extra-large) and automatically adjust length, rotation, and angulation to seat properly on each rod

Place each hook end of the Cross Connector over the rod, in the desired location

Connect the Cross Connector Cam Driver to the X/C Torque Limiter Handle and place the instrument over the hook slots. Turn clockwise until audible “click”

Connect the Cross Connector Nut Driver to the X/C Torque Limiter Handle and place the instrument over the center nut. Turn clockwise until audible “click”

Repeat this for each Cross Connector



9. IMPLANT REMOVAL (OPTIONAL)

CROSS CONNECTOR REMOVAL

Connect the Cross Connector Nut Driver to the X/C Torque Limiter

Place the instrument over the center nut and turn counterclockwise until loose

Connect the Cross Connector Cam Driver to the X/C Torque Limiter

Place the instrument into the cam socket and turn counterclockwise until loose and in the unlock position

PEDICLE SCREW REMOVAL

Engage the Counter Torque over the screw head

Insert the Screw Driver into the Counter Torque, turn counterclockwise

Repeat for each locking cap

Remove rods from construct

If necessary, use the Head Positioner to mobilize the polyaxial screw head of implant

Engage the Screw Driver T25 Tip into the screw body socket, turn counterclockwise and remove from the pedicle; repeat for each pedicle screw



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