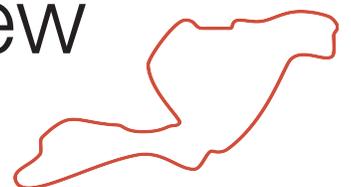


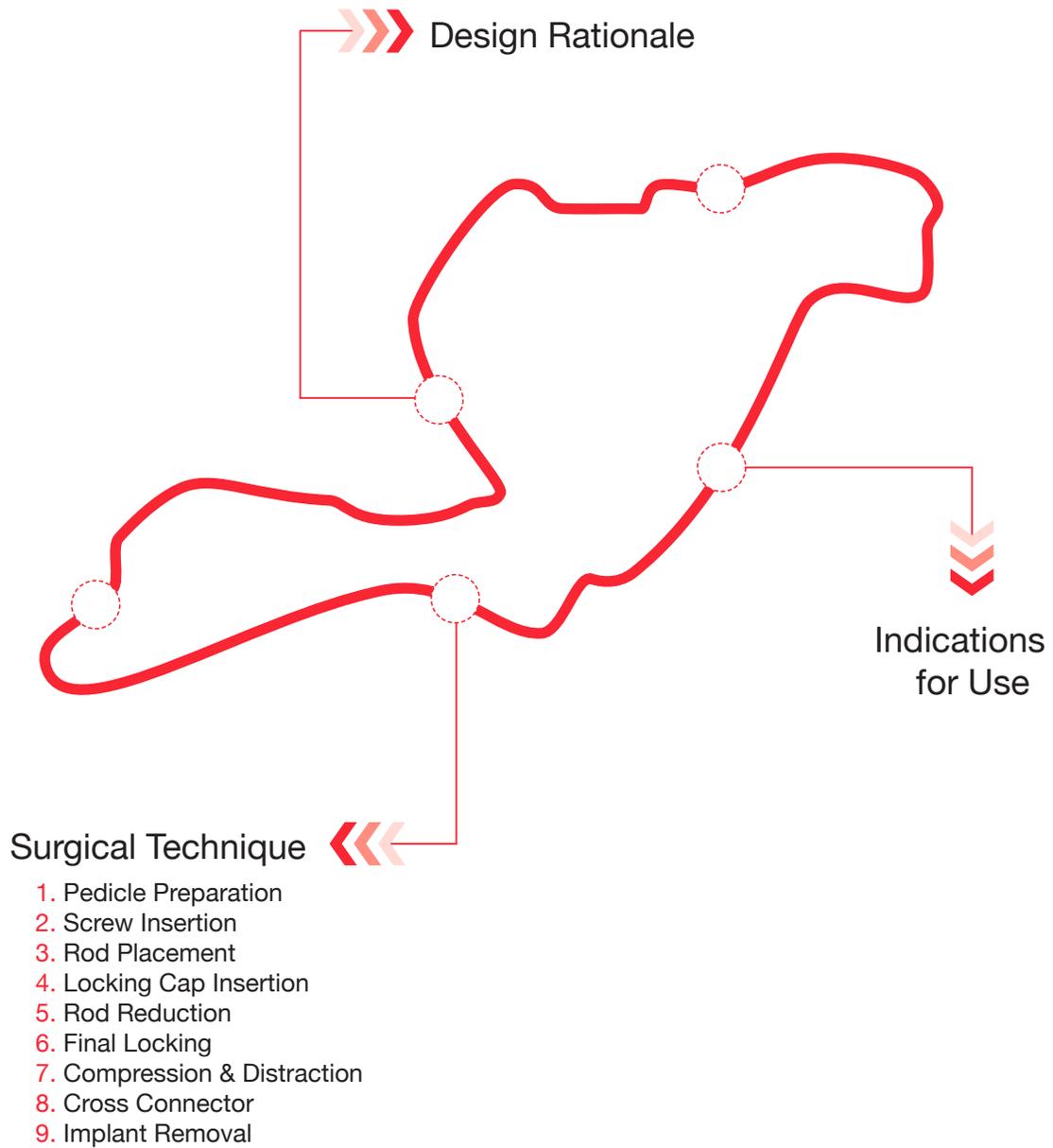
Valencia Pedicle Screw Surgical Technique



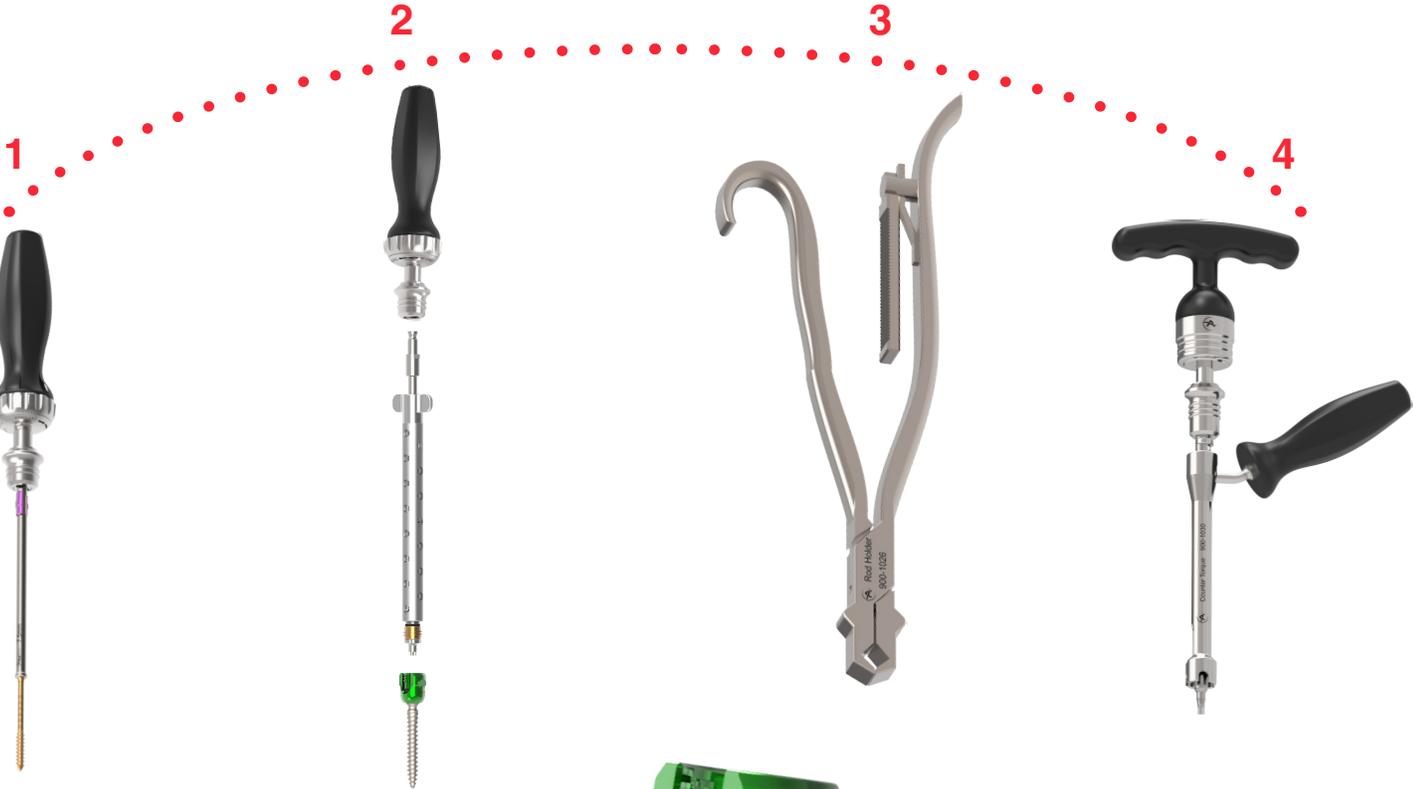


VALENCIA CIRCUIT

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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 provide 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.

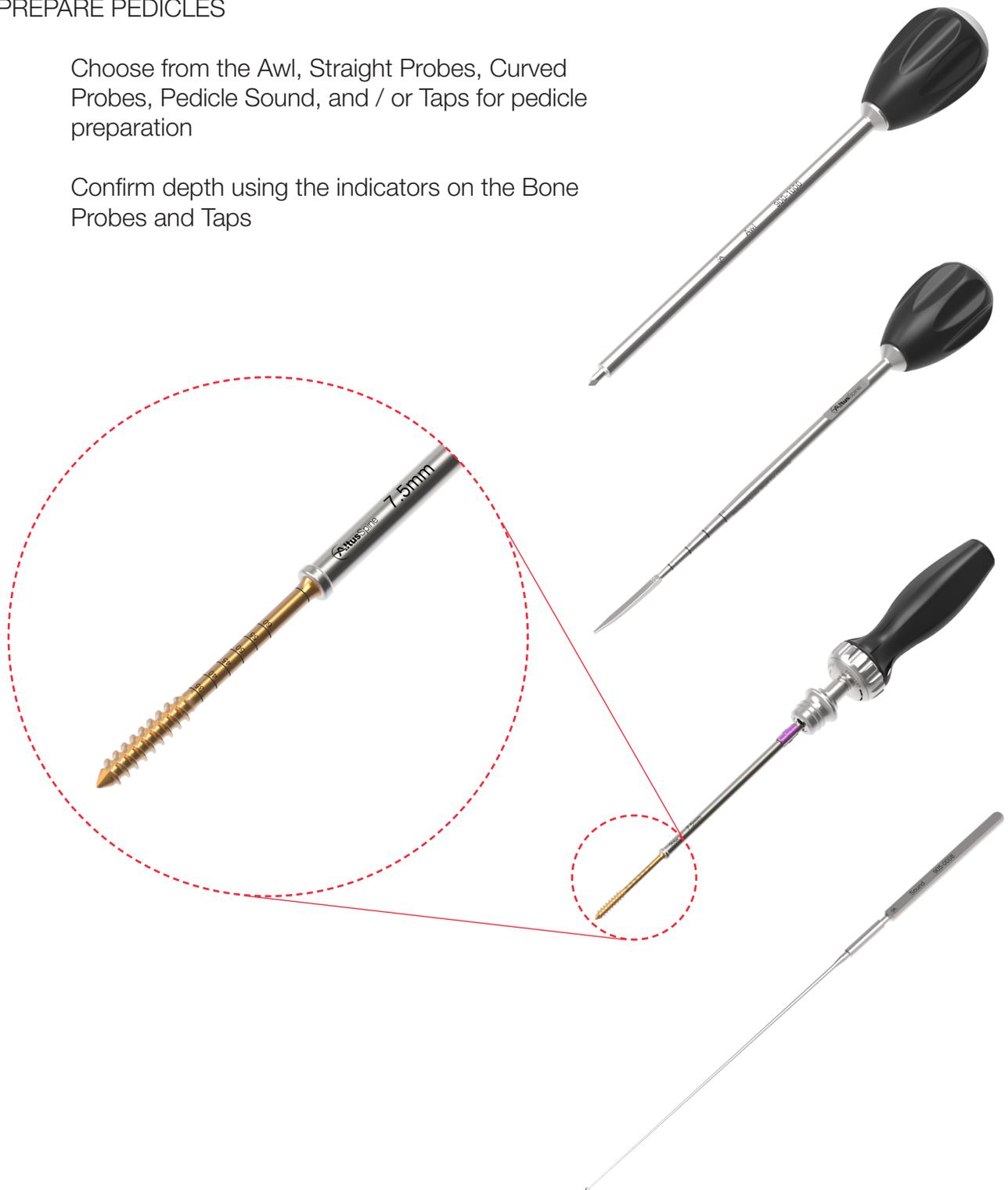
Reference product insert (PI-001) for complete system indications for use, description, warnings and precautions

1. PEDICLE PREPARATION

PREPARE PEDICLES

Choose from the Awl, Straight Probes, Curved Probes, Pedicle Sound, and / or Taps for pedicle preparation

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

Right and left specific Pedicle Markers are supplied

Select the appropriate Pedicle Marker and load into the Utility Driver

Pedicle Marker assembly: pull back on the 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

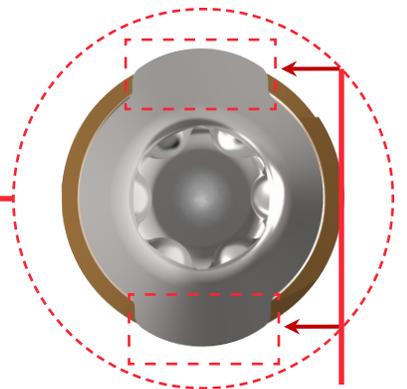
Note: Do not hold thumb tab while inserting screw as there is potential for locking sleeve to loosen during insertion

REMOVE THE DRIVER

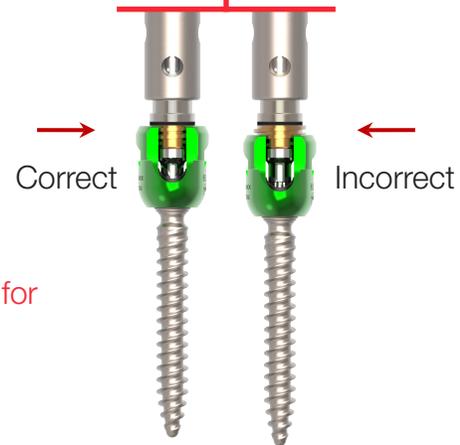
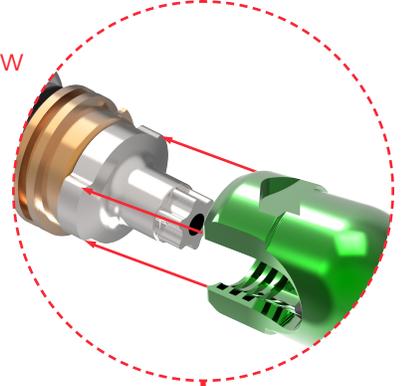
Turn the thumb tab counterclockwise until it completely disengages the screw head

Repeat screw insertion steps until all screws are in place

Use the Utility Driver with the T25 Tip to make minor height adjustments after all screws are inserted



Insertion Guides



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

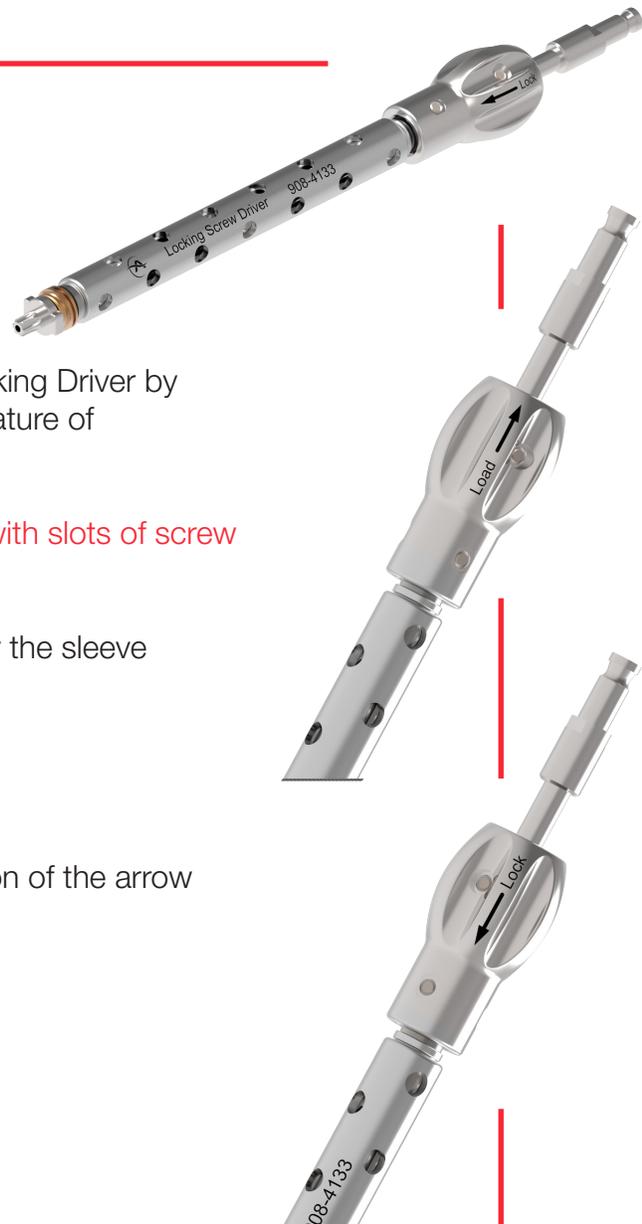
REMOVE THE DRIVER

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

Use the Utility Driver with the T25 Tip to make minor height adjustments after all screws are inserted



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

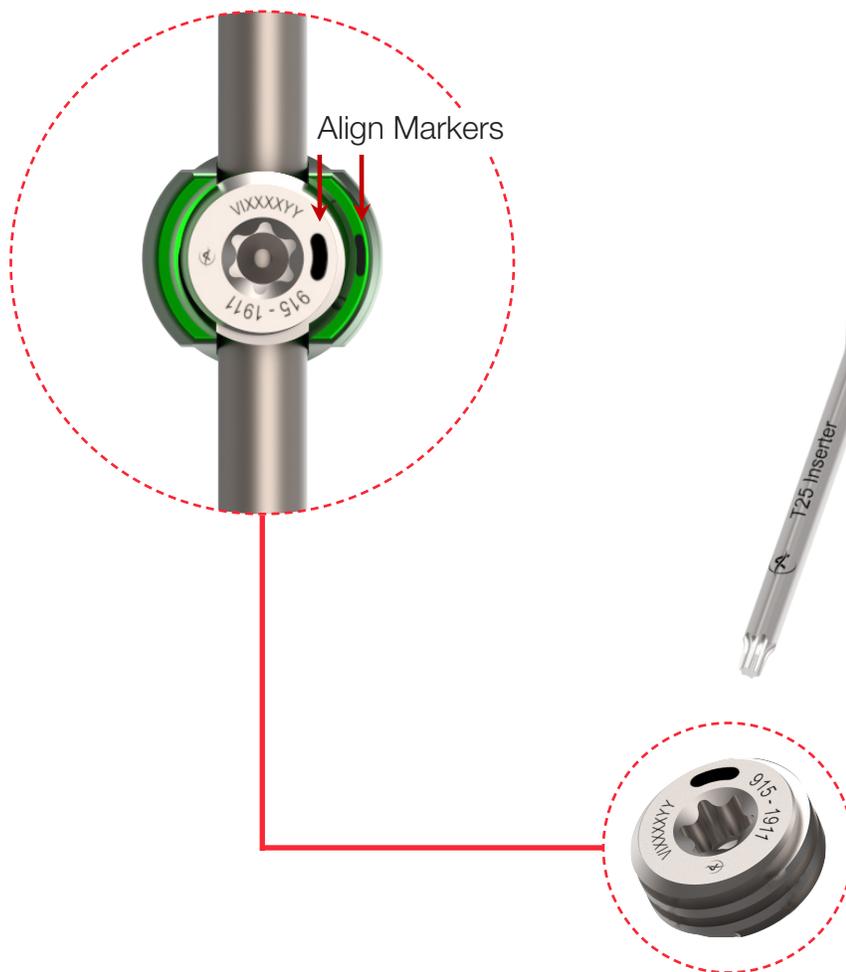
LOAD LOCKING CAPS

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

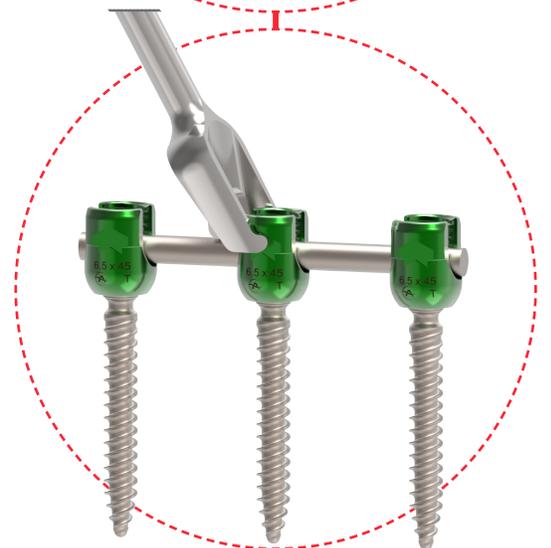


MAJOR REDUCTIONS

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

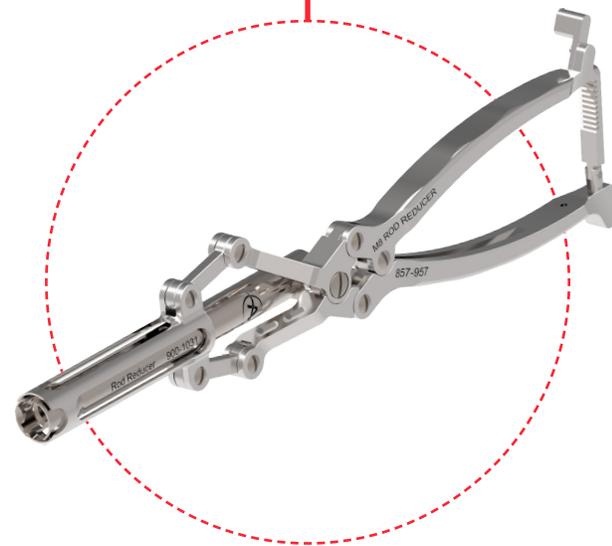
Note: If the Rod Persuader is not positioned correctly it may result in a jam. To release jam, hold the release knob down while using both hands to pull the handle levers apart

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 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 feedback 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 65 in-lb (7.3 N-m)



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



