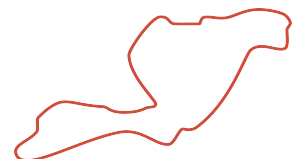
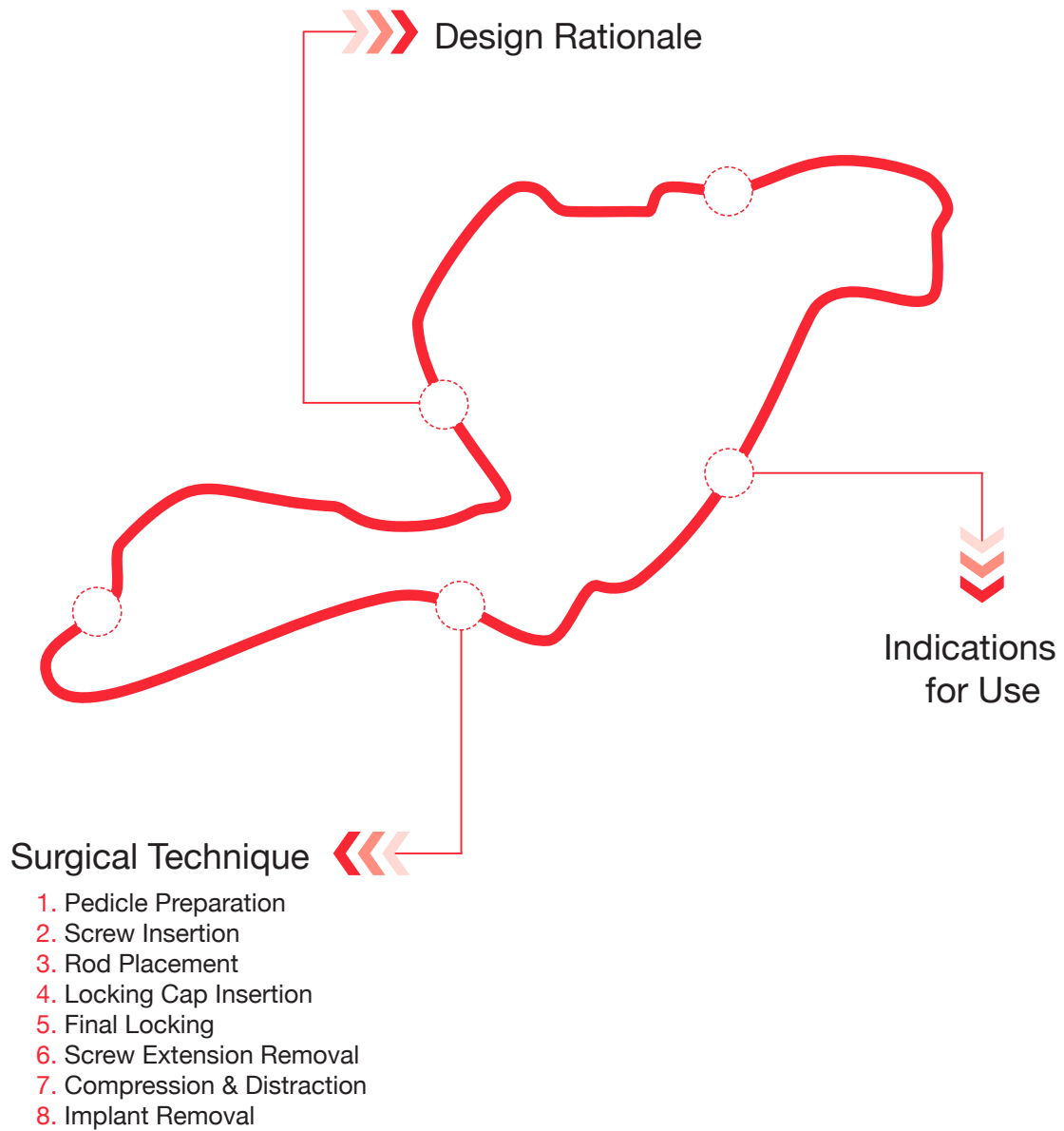




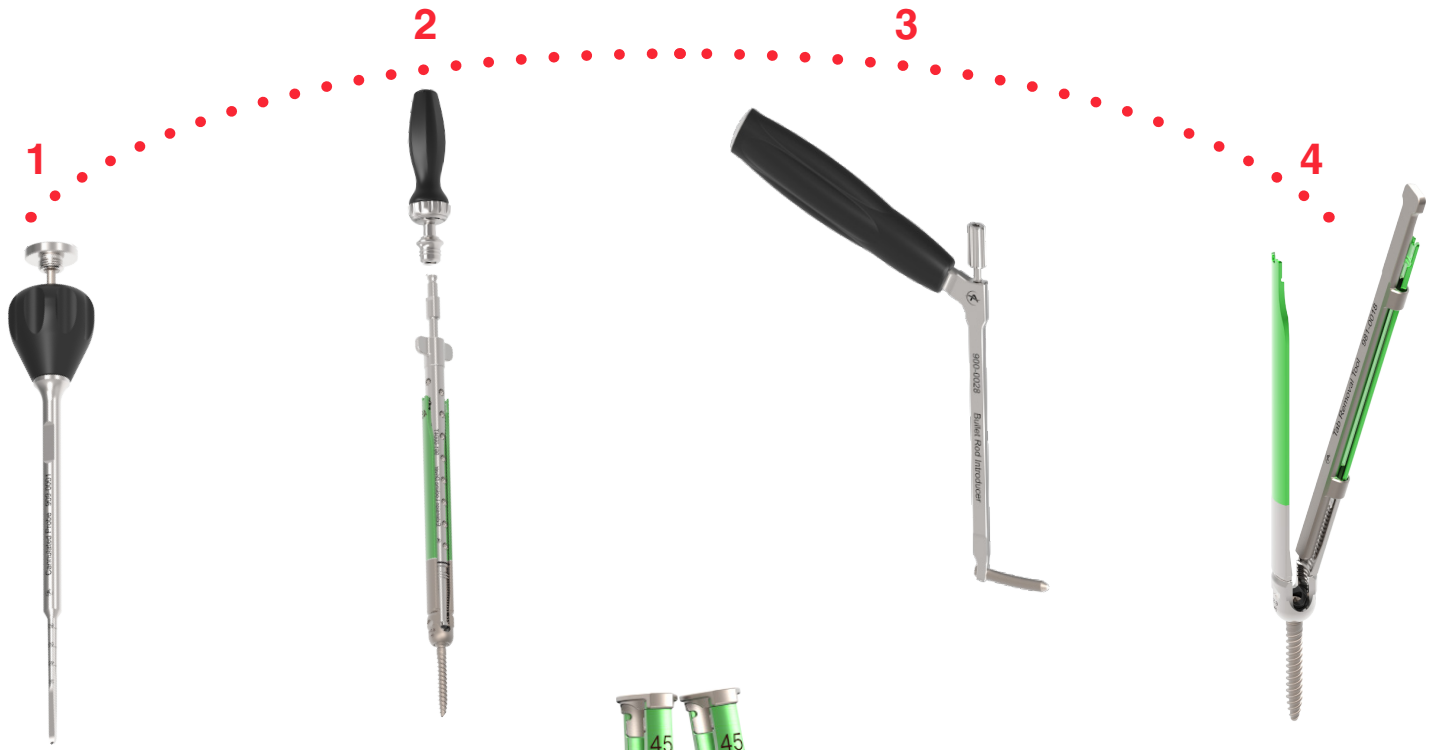
# Valencia MIS Pedicle Screw Surgical Technique



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# DESIGN RATIONALE



Removable constraint collar provides extra control

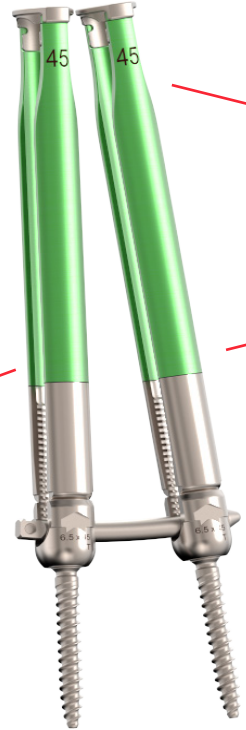
Common implant interfaces to reduce instrumentation

30mm integrated rod reduction capability

Visual guidance for rod delivery and construct locking

Reliable, over-the-skin rod length measurement

Robust hybrid square thread minimizes cross threading during rod reduction



## INDICATIONS FOR USE

The Altus Spine Valencia MIS Pedicle Screw System is intended to provide immobilization 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 TARGETING

Locate pedicle using standard intraoperative techniques under fluoroscopy

Insert the Cannulated Probe through incision and dock the tip on the bony anatomy of the desired level

Confirm position using A/P and lateral fluoroscopy

Advance the Cannulated Probe to desired depth while ensuring the probe does not breach the pedicle during placement

Remove the inner trocar of the Cannulated Probe by rotating the impaction cap counterclockwise

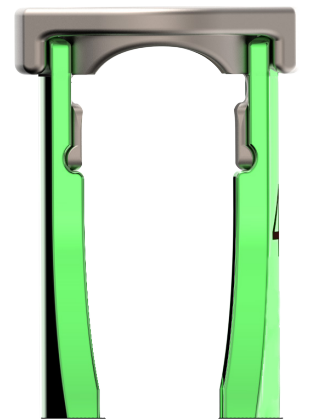
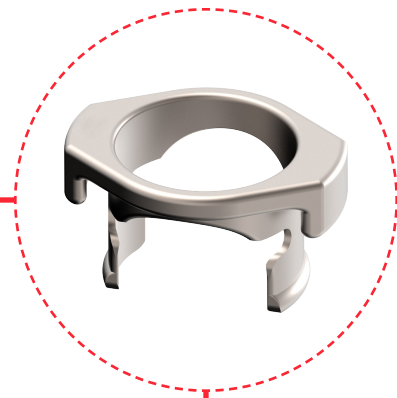
**Note:** Based on surgeon preference, a guide wire needle can also be used for targeting

## GUIDE WIRE PLACEMENT

Insert the guide wire through the Cannulated Probe and advance to desired depth

Confirm placement with A/P and lateral fluoroscopy, prior to removing the Cannulated Probe

**Note:** For multi-level constructs it is recommended to place all guide wires prior to inserting pedicle screws



# 1. PEDICLE PREPARATION (CONT.)

## TISSUE DILATION (OPTIONAL)

Place the Dilators over the guide wire from small to large to ensure each Dilator is flush with bone prior to placing the next dilator

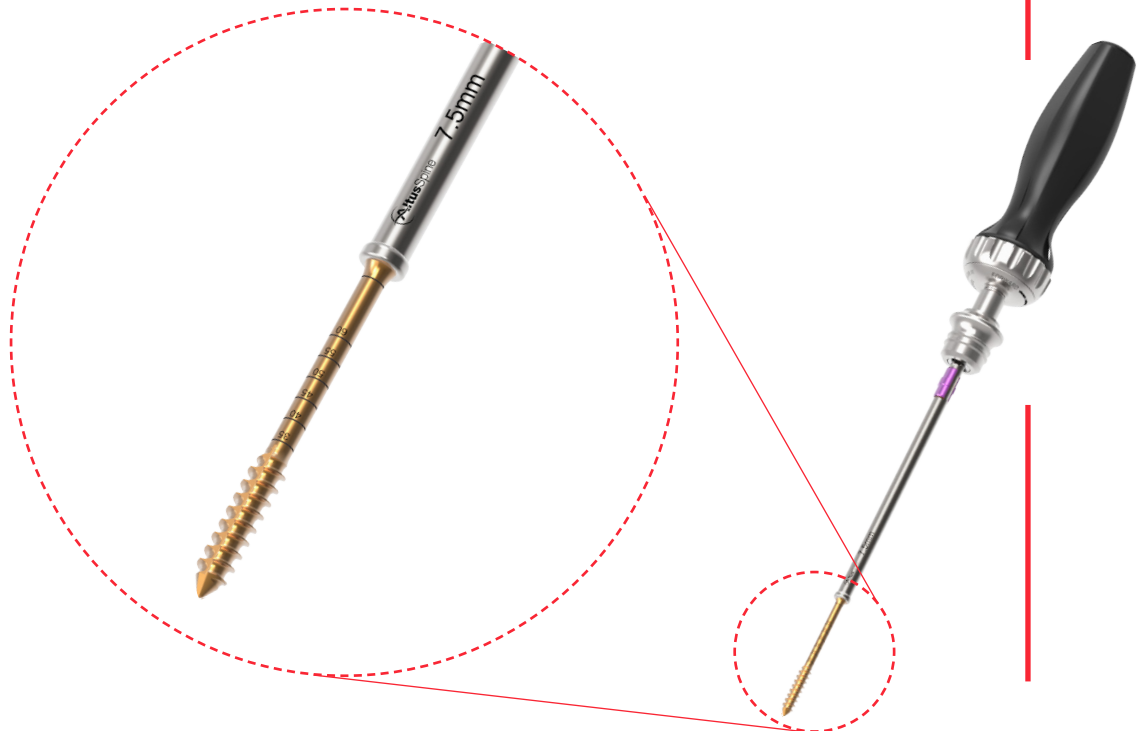
Confirm placement with fluoroscopy

Remove small and medium dilators, leaving the large dilator and guide wire; maintain control of the guide wire to prevent it from backing out

## TAP PEDICLE

Advance the appropriate size Cannulated Pedicle Tap over the guide wire and into the pedicle by turning the tap in a clockwise manner

Note: While tapping, care should be taken to avoid unintentional guide wire advancement



## 2. SCREW INSERTION

### ASSEMBLE DRIVER

Attach the Extension Locking Driver to the Ratcheting Handle

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

**Note:** Assembly requires alignment of distal driver with slots in 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)

**Note:** Optional collar may be used with the screws to constrain the tabs as desired

### INSERT SCREW

Pass the screw over the guide wire until the tip of the screw reaches the pedicle entry point. Confirm desired trajectory via fluoroscopy

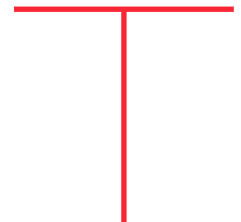
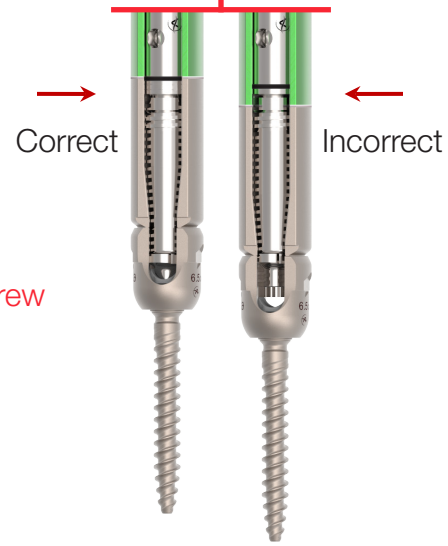
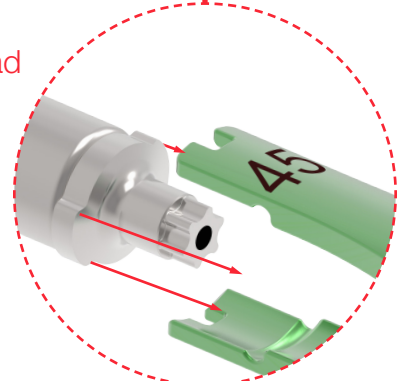
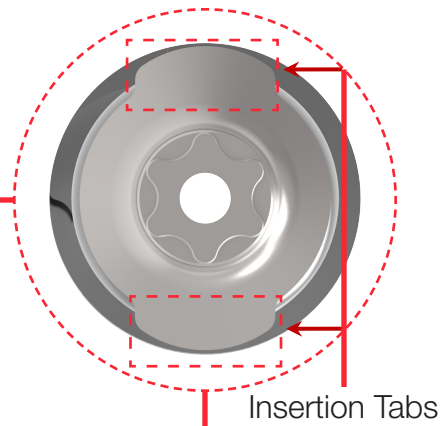
**Note:** Do not advance the screw into the pedicle until confirming the screw is aligned with the guide wire. Monitor the tip of the guide wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body

Advance the screw by rotating the Ratcheting Handle clockwise

**Note:** Do not hold knob while inserting screw as there is potential for locking sleeve to loosen if the surgeon holds onto knob during screw insertion

Once the screw is aligned and established in the pedicle, remove the guide wire

Continue to advance screw with fluoroscopic guidance as needed



## 2. SCREW INSERTION (CONT.)

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### REMOVE THE DRIVER

Once the screw has reached the desired depth, remove the driver by turning the thumb tab counterclockwise until it completely disengages from the screw head

Repeat previous steps to until all screws are in place

Note: Minor height adjustments may be done after screw implantation by utilizing the Utility Driver with T25 Tip





### 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

#### SELECT APPROPRIATE ROD

Determine Rod length by using the Rod Length Template

Insert each shaft of the Rod Length Template into each of the Screw Extension Tabs until fully seated in the screw heads

Confirm placement under fluoroscopy

**Note:** The indication marks on the Rod Length Template directly estimate rod length required

#### ROD CONTOURING

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

Place rod into Rod Bender and squeeze handles to bend rod

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



### 3. ROD PLACEMENT (CONT.)

#### ASSEMBLE THE ROD TO THE ROD INTRODUCER

Insert the flats of the rod into the opening of the Rod Introducer; orient as shown

Lock the rod into position by twisting the knob on the proximal end of the Rod Introducer clockwise

Verify the rod is securely attached to the Rod Introducer prior to the insertion

**Note:** The notch of the connection end of the rod must face the handle of the Rod Introducer

#### ROD PLACEMENT

Using the Rod Introducer, insert the rounded tip of the rod into each extension

Slide the rod down the screw extensions until the rod is fully seated in the head of the screws

Utilize fluoroscopy to confirm rod placement and assess rod overhang at each end of the construct prior to removing the Rod Introducer

**Note:** Do not remove Rod Introducer until Locking Caps are placed and tightened

### 4. LOCKING CAP INSERTION

#### LOAD LOCKING CAPS

Load T25 Locking Caps onto the Single 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



## 5. 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 T25 Drive Shaft 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 5 steps for remainder of the construct

**Note:** Final locking must be secured using a Torque Limiting Handle of 90 in-lb (10.1 N-m)



## 6. SCREW EXTENSION REMOVAL

Slide the openings of the Tab Removal Tool over the screw extension and tilt towards the mating tab until the extension breaks away from the screw

Repeat for all screw extensions

## 7. COMPRESSION & DISTRACTION (OPTIONAL)

Using the steps in Section 5, ensure screw has gone through the final locking procedure, and the adjacent screw has the locking cap in place but has not yet been final locked

Slide one shaft of the Compressor/Distractor through the locked screw, and the other shaft through the loose screw

Place the Compressor Driver through the hollow of the shaft and fully engage the loose T25 Locking Cap

Squeeze the handles together until the desired amount of compression/distraction has been achieved. While holding Compression/Distractor load, final tighten the locking can

**Note: The Compressor/Distractor comes equipped with a ratcheting lock at its proximal end as needed**



## 8. IMPLANT REMOVAL (OPTIONAL)

### 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

