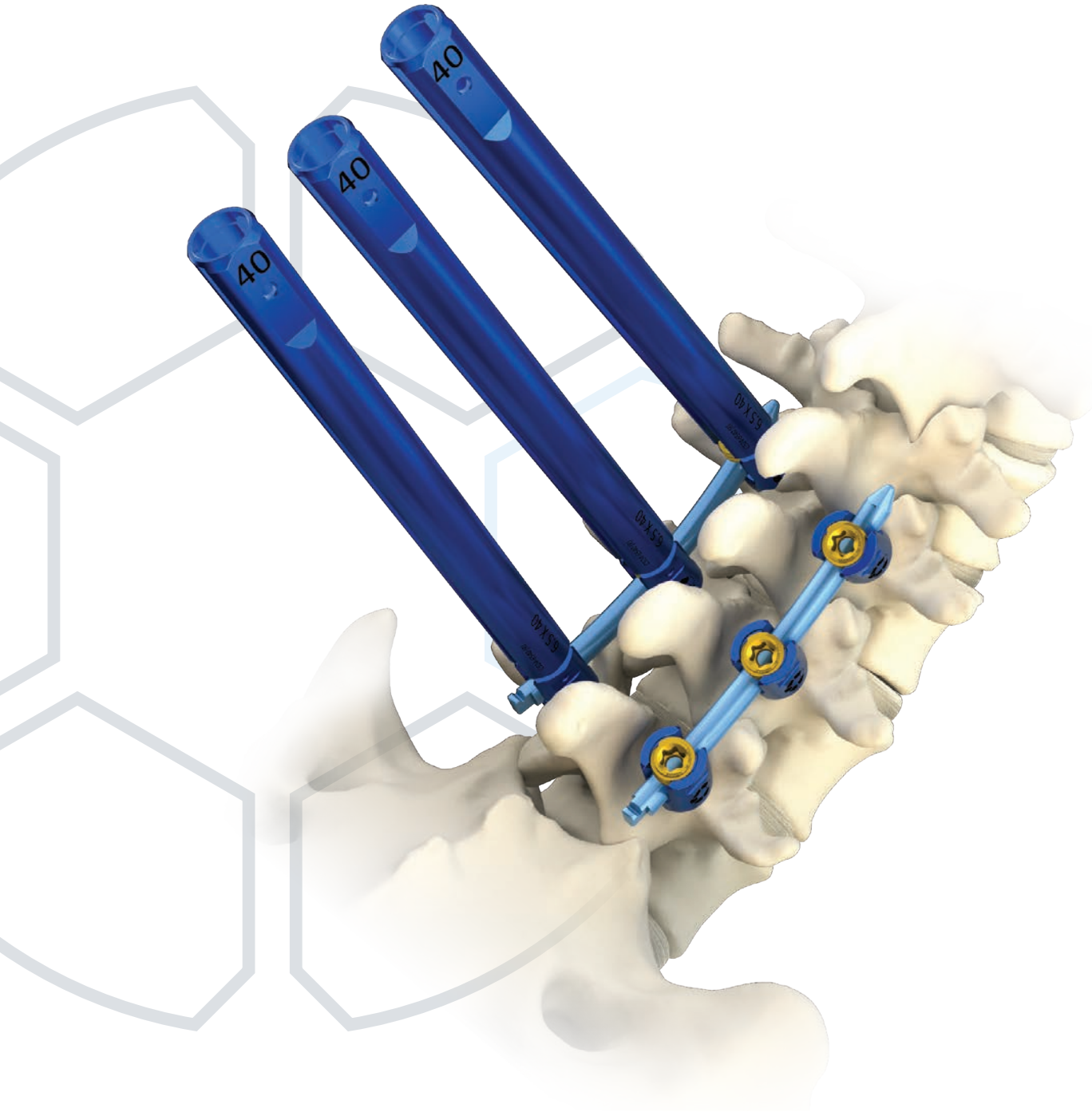
PRODIGY™

MIS PEDICLE SCREW SYSTEM



THORACOLUMBAR FIXATION

Surgical Technique Guide

CURITEVA®

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PRODIGY™
MIS PEDICLE SCREW SYSTEM

Disclaimer

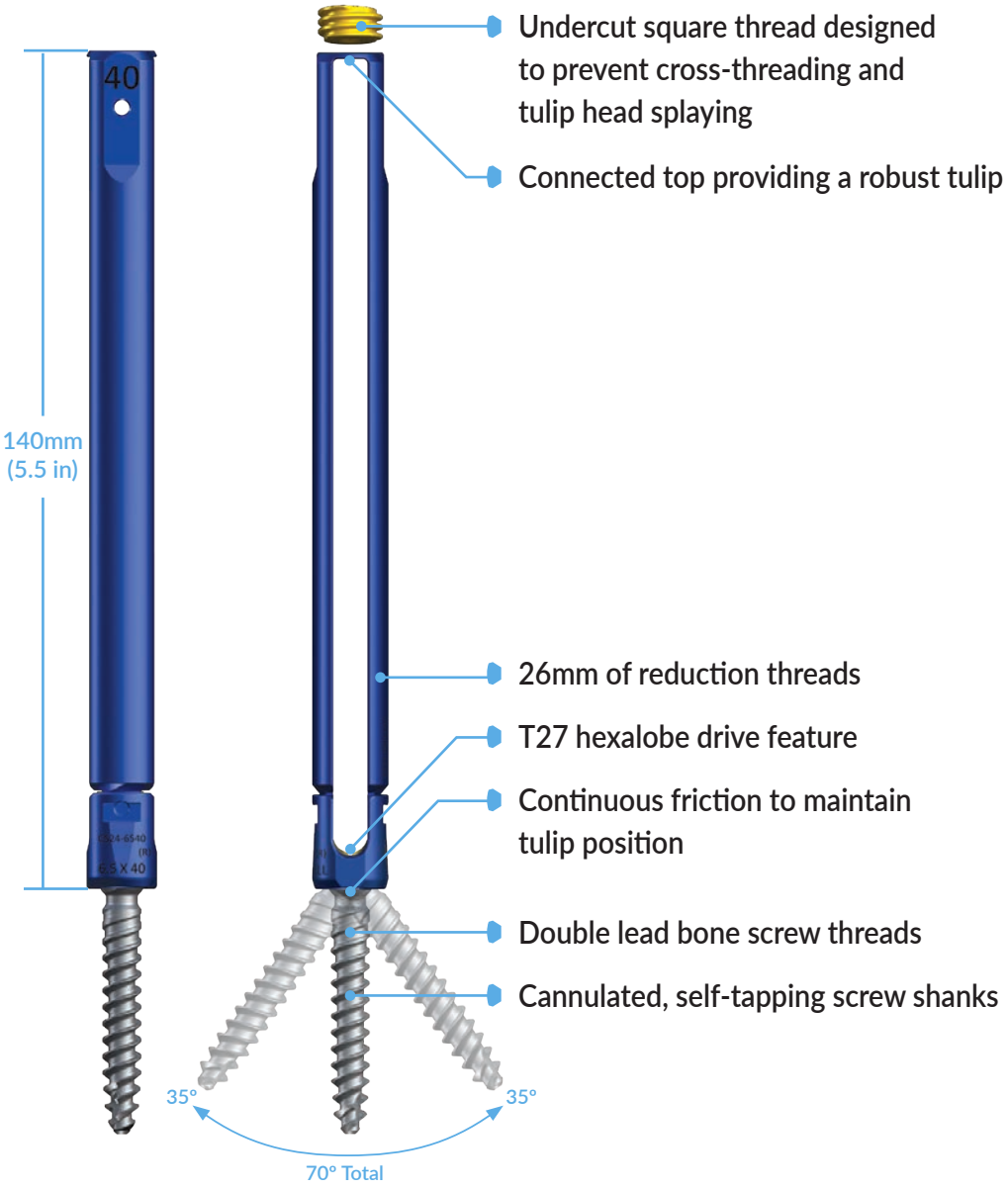
The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

PRODIGY™ MIS Pedicle Screw System

The Prodigy MIS Pedicle Screw system is designed to minimize the complexity of procedural steps while correcting and stabilizing the posterior thoracolumbar spine through a percutaneous approach. The streamline implant design and intuitive instrumentation minimize soft tissue disruption and reduce surgery time. The Prodigy MIS system provides reliable rod delivery and significant internal rod reduction capability while minimizing the incision size and tissue dissection.

MIS Polyaxial Screw

- Color coded tulip heads by bone screw diameter
- Easy tab removal leaving a low profile and clean break
- Simple and efficient instruments provide advanced manipulation techniques



Rod

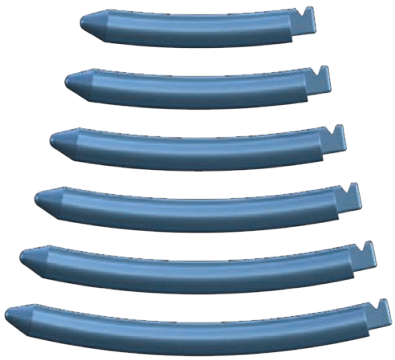
- Material: Ti 6AL-4V ELI
- 5.5mm Diameter
- Bulleted tip to facilitate placement
- Robust instrument engagement feature

PRODIGY™ MIS Pedicle Screw System

MIS Polyaxial Pedicle Screws		
Catalog Number	**Description**	**Quantity**
C524-5530	5.5 x 30mm MIS PEDICLE SCREW	2
C524-5535	5.5 x 35mm MIS PEDICLE SCREW	4
C524-5540	5.5 x 40mm MIS PEDICLE SCREW	4
C524-5545	5.5 x 45mm MIS PEDICLE SCREW	4
C524-5550	5.5 x 50mm MIS PEDICLE SCREW	4
C524-5555	5.5 x 55mm MIS PEDICLE SCREW	2
C524-6530	6.5 x 30mm MIS PEDICLE SCREW	2
C524-6535	6.5 x 35mm MIS PEDICLE SCREW	4
C524-6540	6.5 x 40mm MIS PEDICLE SCREW	4
C524-6545	6.5 x 45mm MIS PEDICLE SCREW	4
C524-6550	6.5 x 50mm MIS PEDICLE SCREW	4
C524-6555	6.5 x 55mm MIS PEDICLE SCREW	2
C524-7530	7.5 x 30mm MIS PEDICLE SCREW	2
C524-7535	7.5 x 35mm MIS PEDICLE SCREW	4
C524-7540	7.5 x 40mm MIS PEDICLE SCREW	4
C524-7545	7.5 x 45mm MIS PEDICLE SCREW	4
C524-7550	7.5 x 50mm MIS PEDICLE SCREW	4
C524-7555	7.5 x 55mm MIS PEDICLE SCREW	2

Set Screws		
Catalog Number	**Description**	**Quantity**
C504-001	SET SCREW	16

Ø5.5mm Titanium MIS Curved Rods		
Catalog Number	**Description**	**Quantity**
C524-R55-030C	5.5 x 30mm CURVED MIS ROD	2
C524-R55-035C	5.5 x 35mm CURVED MIS ROD	2
C524-R55-040C	5.5 x 40mm CURVED MIS ROD	2
C524-R55-045C	5.5 x 45mm CURVED MIS ROD	2
C524-R55-050C	5.5 x 50mm CURVED MIS ROD	2
C524-R55-055C	5.5 x 55mm CURVED MIS ROD	2
C524-R55-060C	5.5 x 60mm CURVED MIS ROD	2
C524-R55-065C	5.5 x 65mm CURVED MIS ROD	2
C524-R55-070C	5.5 x 70mm CURVED MIS ROD	2
C524-R55-080C	5.5 x 80mm CURVED MIS ROD	2
C524-R55-090C	5.5 x 90mm CURVED MIS ROD	2
C524-R55-100C	5.5 x 100mm CURVED MIS ROD	2
C524-R55-110C	5.5 x 110mm CURVED MIS ROD	*
C524-R55-130C	5.5 x 130mm CURVED MIS ROD	*
C524-R55-150C	5.5 x 150mm CURVED MIS ROD	*



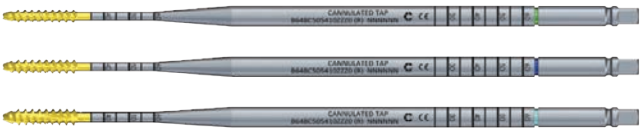
**Available by request*

PRODIGY™ MIS Pedicle Screw System

C525-100	Dilator # 1

C525-110	Dilator # 2

C525-120	Dilator # 3



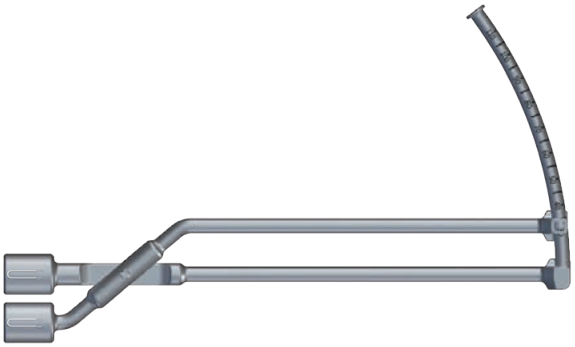
Taps	
C505-410-55	5.5mm Cannulated Tap
C505-410-65	6.5mm Cannulated Tap
C505-410-75	7.5mm Cannulated Tap

C505-502	Extended Tab Pedicle Screw Driver

C505-110	Cannulated Bone Awl*

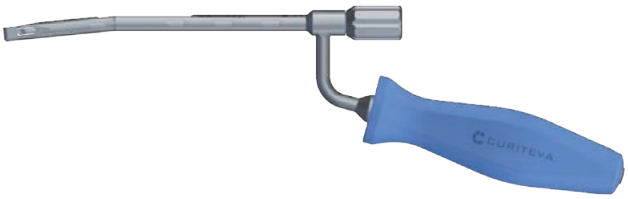
C505-510	Adjustment Driver

**Available by request*



C525-200 MIS Rod Caliper

C505-1300 Counter Torque Handle

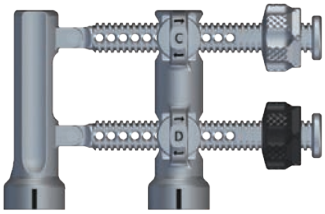


C525-300 MIS Rod Inserter

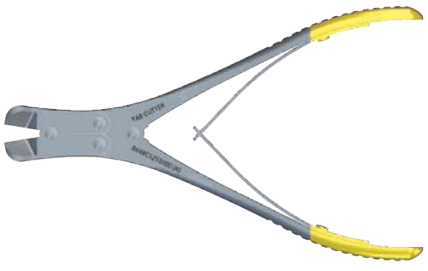
C505-1400 Pedicle Screw Sleeve

C505-1100 Set Screw Starter

C505-1500 Final Locking Set Screw Driver



C525-700 MIS Compressor / Distractor



C525-500 Tab Cutter

C525-800 T-Handle Jamshidi Needle 11Gx6in*

C525-801 Jamshidi Needle 11Gx6in*

* *The system requires the use of disposable Jamshidi Needles which are not included in the tray.*

C505-1800 1.4mm x 500mm Trocar K-Wire

C505-1801 1.4mm x 500mm Blunt K-Wire

C505-1900 Trocar K-Wire Holder

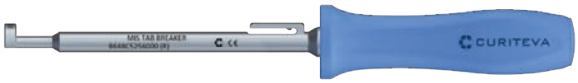
C505-1901 Blunt K-Wire Holder

C505-2000 Cannula Cleaner

C505-2100 Ratcheting T-Handle

C505-2110 Ratcheting Axial Handle

C505-2120 80 in-lbs Torque Limiting T-Handle



C525-600 MIS Tab Breaker

PRODIGY™

Minimally Invasive Surgical Technique

Step 1: Pedicle Targeting

- Use fluoroscopy to identify the appropriate level(s) and determine the pedicle entry point.
- Make an incision 1-3 cm lateral to the desired pedicle entry point depending on the depth of soft tissue and muscle.
- Advance the preferred **Jamshidi Needle** through the incision and dock at the pedicle entry point. **(Figure 1a)**

  Note: Both trocar and beveled tip options are available by request only.

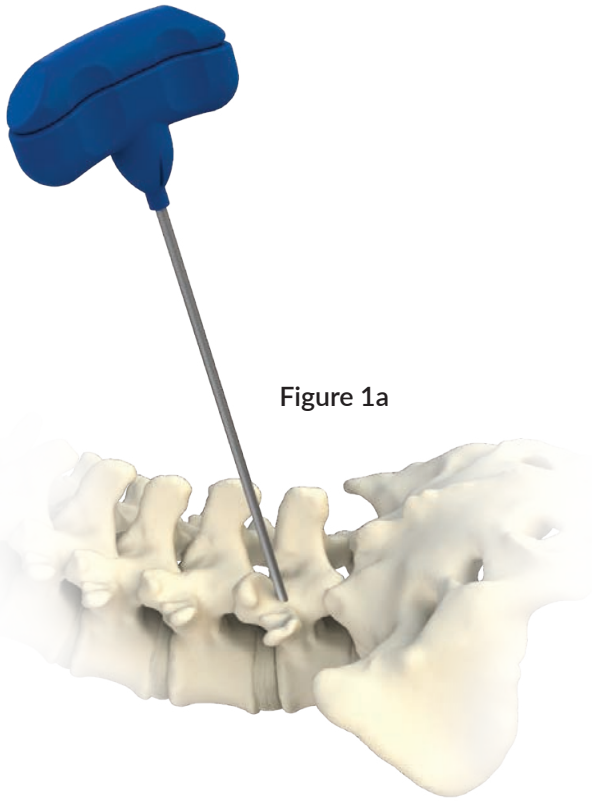
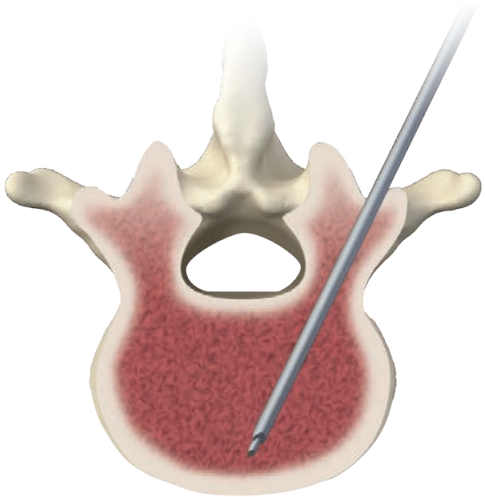


Figure 1a

Trocar Tip

Beveled Tip

- Using fluoroscopy to verify the proper trajectory, advance the Jamshidi Needle through the pedicle to the desired depth being sure to stay within the pedicle walls. In the A/P view, the Jamshidi Needle should begin at the lateral border of the pedicle and approach the medial border. In the lateral view, the Jamshidi Needle should remain centered in the pedicle and the tip should enter the vertebral body.



Step 2: K-Wire Insertion

- Remove the inner stylet from the **Jamshidi Needle**.
- Insert a **K-Wire** through the Jamshidi cannula. Using fluoroscopy, advance the K-Wire past the tip of the Jamshidi into the vertebral body, taking care to keep the tip of the K-Wire within the vertebral body. **(Figure 2)**

  Note: Use fluoroscopy to ensure the K-Wire is straight and in the proper position. Active K-Wire monitoring throughout the procedure is crucial to prevent unintended removal or advancement of the K-Wire, and to ensure passing of instruments does not kink or bend the K-Wire.

  Note: Both Trocar and Blunt K-Wire options are provided.

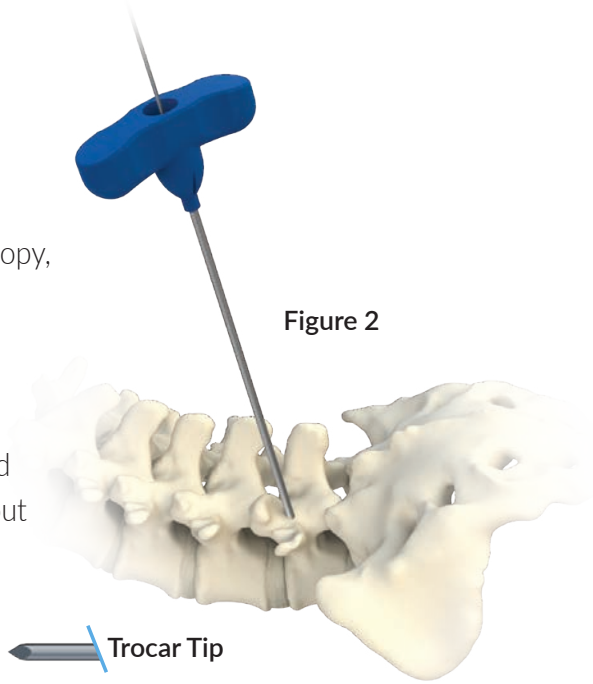


Figure 2

Trocar Tip

Blunt Tip

- Remove the Jamshidi cannula while holding the K-Wire in place.
- Repeat for all pedicles in the construct.

Step 3: Pedicle Preparation

Dilator #1 and **Dilator #2** should be used for muscle dilation and soft tissue protection during pedicle preparation.

- Insert Dilator #1 over the K-Wire until the tip contacts the pedicle.
- Insert Dilator #2 over Dilator #1 **(Figure 3a)** until the tip contacts the pedicle. The laser marked line on Dilator #1 will align with the top of Dilator #2 when the tips are aligned.
- Remove Dilator #1 while holding the K-Wire in place. **(Figure 3b)**

  Note: Dilator #2 is radiolucent to allow for instrument visualization and neuromonitoring if desired.

Dilator #1

Dilator #2

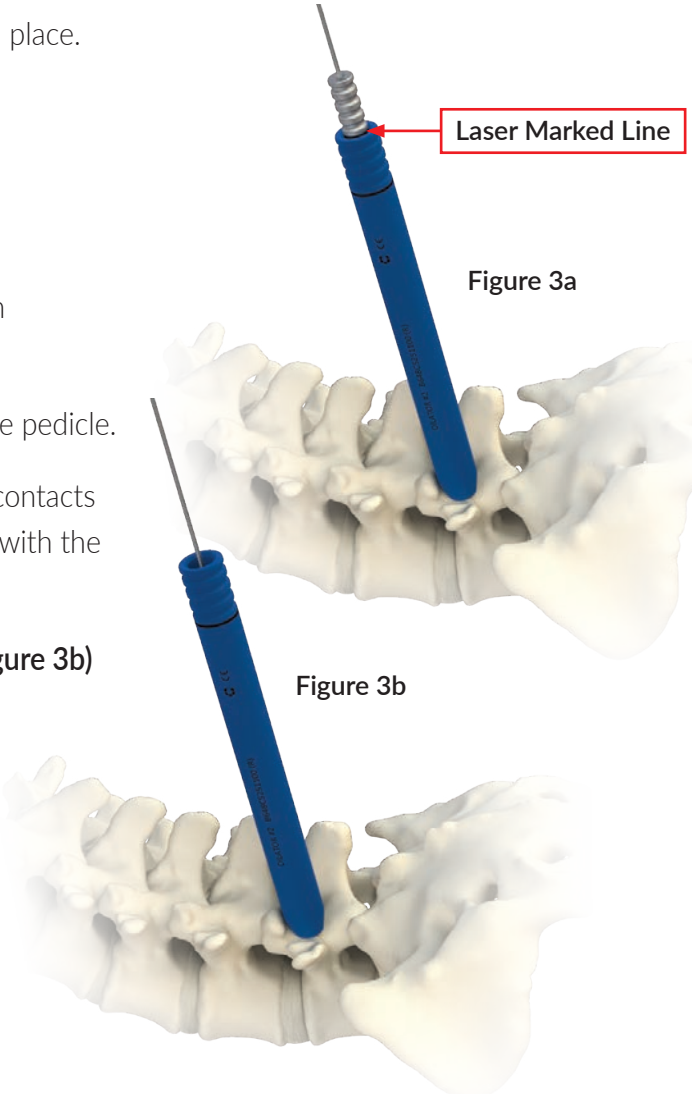


Figure 3a

Figure 3b

If desired, a **Cannulated Bone Awl** is available by request only to penetrate the cortical bone and create a pilot hole over the K-Wire. **(Figure 3c)**

Note: The flutes on the shoulder of the Cannulated Bone Awl can be used for decortication of the pedicle entry site by rotating clockwise once the tip is fully penetrated.

Note: The Cannulated Bone Awl tip diameter is 3.5mm and protrudes 15mm.

Cannulated Bone Awl

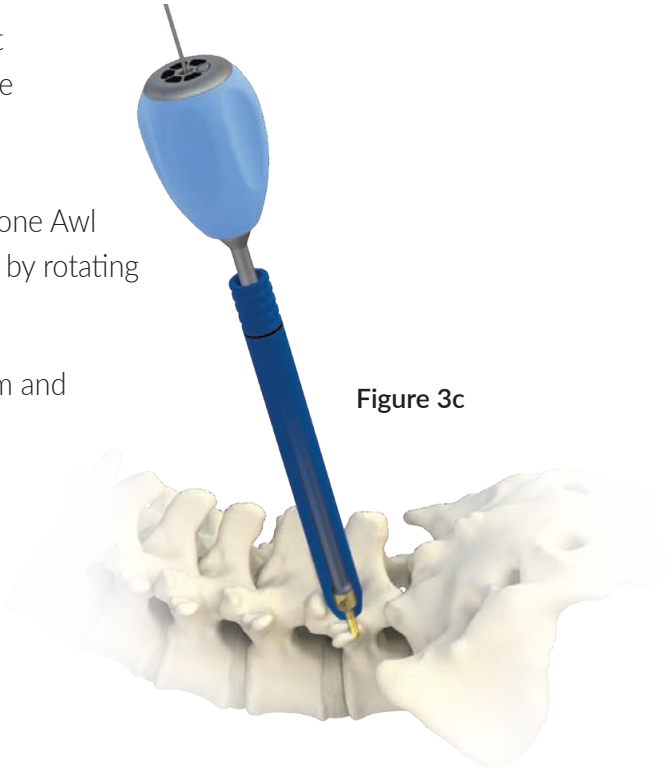


Figure 3c

Prodigy pedicle screws are self-tapping, but **Cannulated Taps** are provided as an option. If tapping is required, select the appropriate diameter and connect either the **Ratcheting Axial Handle** or **Ratcheting T-Handle**. Insert the Cannulated Tap over the K-Wire and tap to the desired depth. **(Figure 3d)**

Note: The Taps are color coded to match the corresponding screw diameter tulip color, see table below.

Size	Color
5.5mm	Green
6.5mm	Dark Blue
7.5mm	Teal

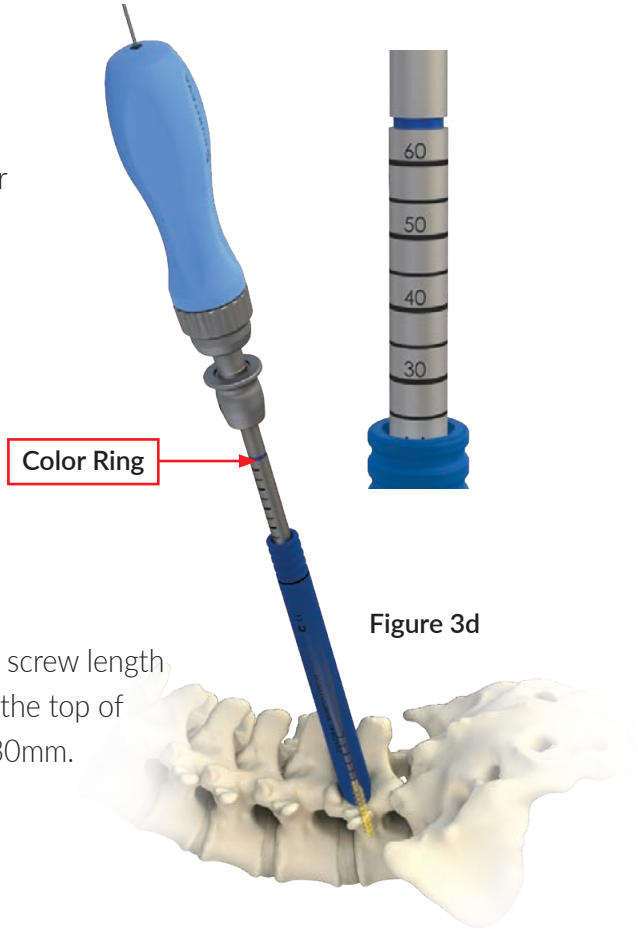


Figure 3d

Note: The Taps feature depth markings on the shaft to aid in screw length selection. The proximal depth markings should be read from the top of the Dilator #2. **(Figure 3d)** All Taps have a thread length of 30mm.

Step 4: Screw Insertion

Insert **Dilator #3** over **Dilator #2** until the tip contacts the pedicle. **(Figure 4a)** The laser marked line on Dilator #2 will align with the top of Dilator #3 when the tips are aligned. Remove Dilator #2.

Note: Dilator #3 is also radiolucent to allow for instrument visualization and neuromonitoring if desired.

Note: Dilator #3 features external helical fluting to assist in advancement of dilator.

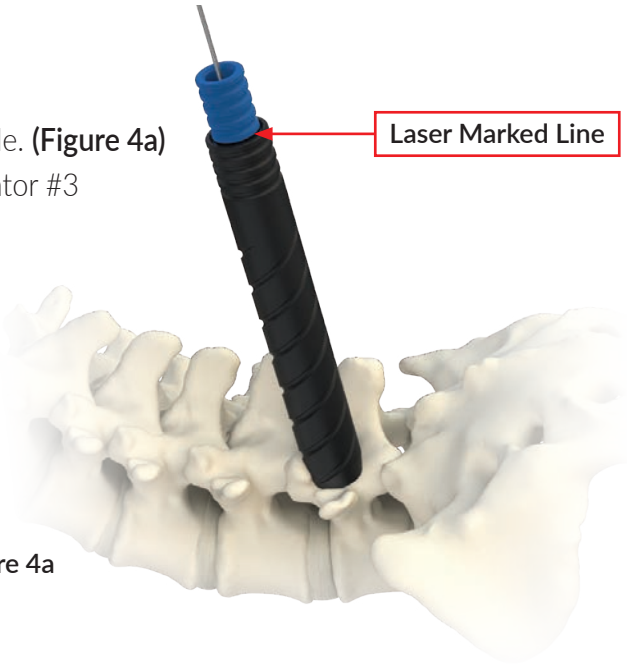


Figure 4a

- Connect either the **Ratcheting Axial Handle** or **Ratcheting T-Handle** to the **Extended Tab Pedicle Screw Driver**. **(Figure 4b)**

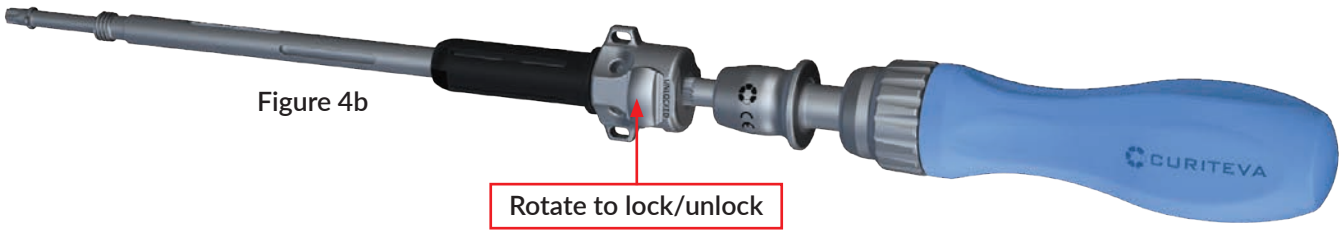


Figure 4b

Note: The cam on the side of the Pedicle Screw Driver knob can be rotated a quarter turn (90°) to engage the optional locking feature, and the "LOCKED" marking will be visible on the knob. **(Figure 4c)** This will prevent the Pedicle Screw Driver sleeve from rotating counter-clockwise, ensuring the sleeve does not prematurely unthread from the Pedicle Screw during insertion. If this feature is not desired, turn the cam so that the "UNLOCKED" marking is visible. **(Figure 4d)**

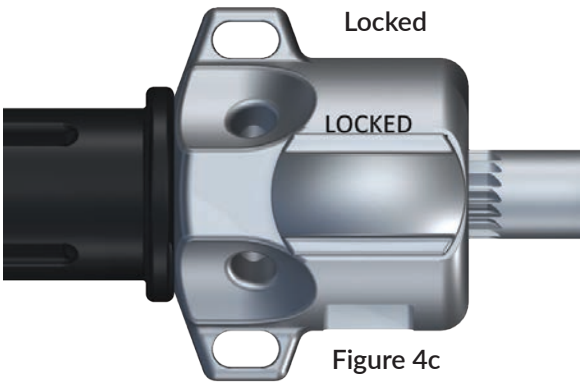


Figure 4c

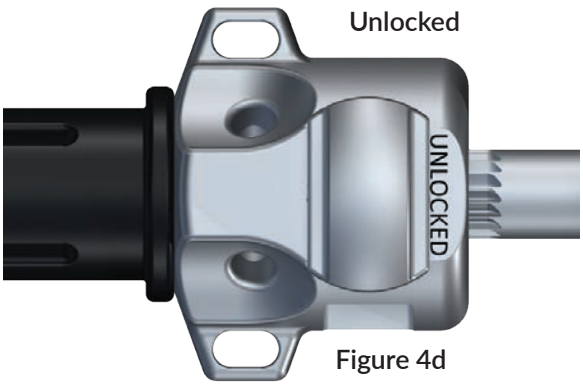


Figure 4d

- Select the desired MIS Pedicle Screw diameter and length. Insert the distal tip of the Extended Tab Pedicle Screw Driver into the tulip, seating the hexalobe driver into the screw shank.
- With the chosen ratcheting handle in the neutral non-ratcheting position, engage the internal threads of the tulip by rotating the Pedicle Screw Driver knob clockwise until tight. **(Figure 4e)** This step should be performed with the screw resting upon a sterile surface to avoid premature screw disengagement.

  Note: Ensure the MIS Pedicle Screw is fully threaded and fixed coaxial to the Pedicle Screw Driver shaft prior to insertion.

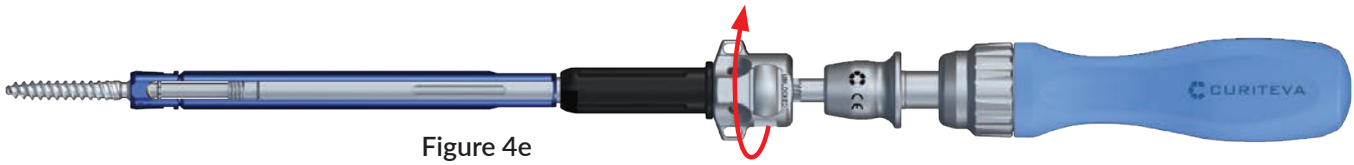


Figure 4e

- Ensure the chosen ratcheting handle is in the forward position and drive the MIS Pedicle Screw into the prepared pedicle over the K-Wire to the desired depth. **(Figure 4f)**

  Note: Take care not to advance the K-Wire during screw insertion.

- To disengage the **Extended Tab Pedicle Screw Driver** from the MIS Pedicle Screw, rotate the Pedicle Screw Driver knob counterclockwise until the Pedicle Screw Driver sleeve is fully unthreaded from the tulip.

  Note: If using the optional locking feature, the cam on the side of the Pedicle Screw Driver knob must be rotated a quarter turn (90°) so that the "UNLOCKED" marking is visible before disengaging the driver from the MIS Pedicle Screw.

- Repeat for all pedicles supporting the construct.
- Remove K-Wires and Dilator #3 after successful insertion of all MIS Pedicle Screws.

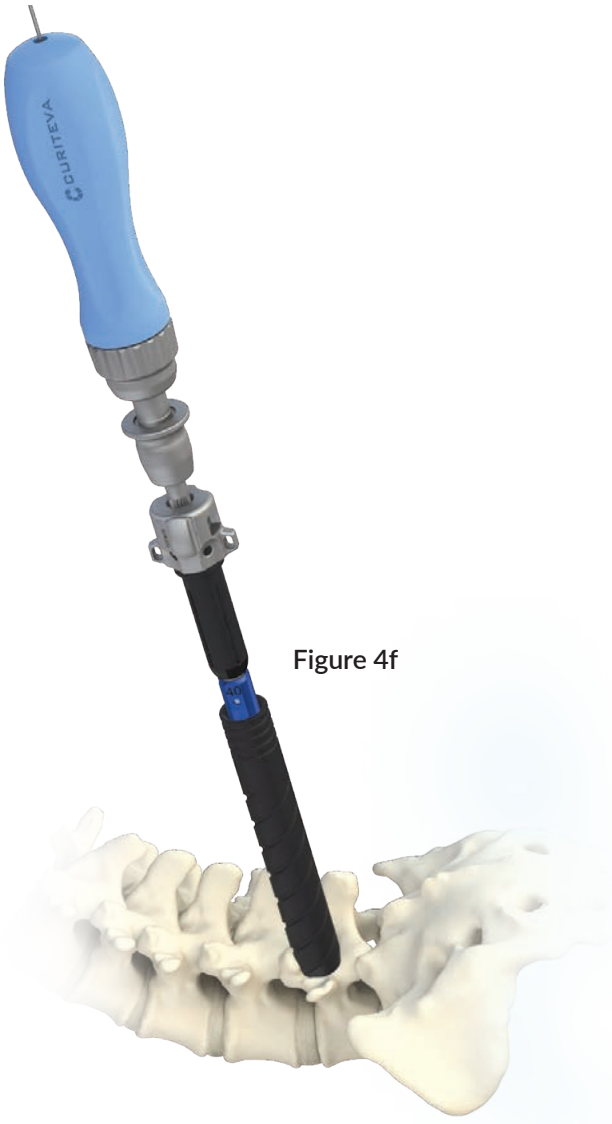


Figure 4f

Step 5: Screw Adjustment

The **Adjustment Driver** may be used to adjust the depth of the MIS Pedicle Screw by engaging the hexalobe feature of the screw shank. Either the **Ratcheting Axial Handle** or **Ratcheting T-Handle** can connect to the back of the Adjustment Driver. **(Figure 5a, 5b)**

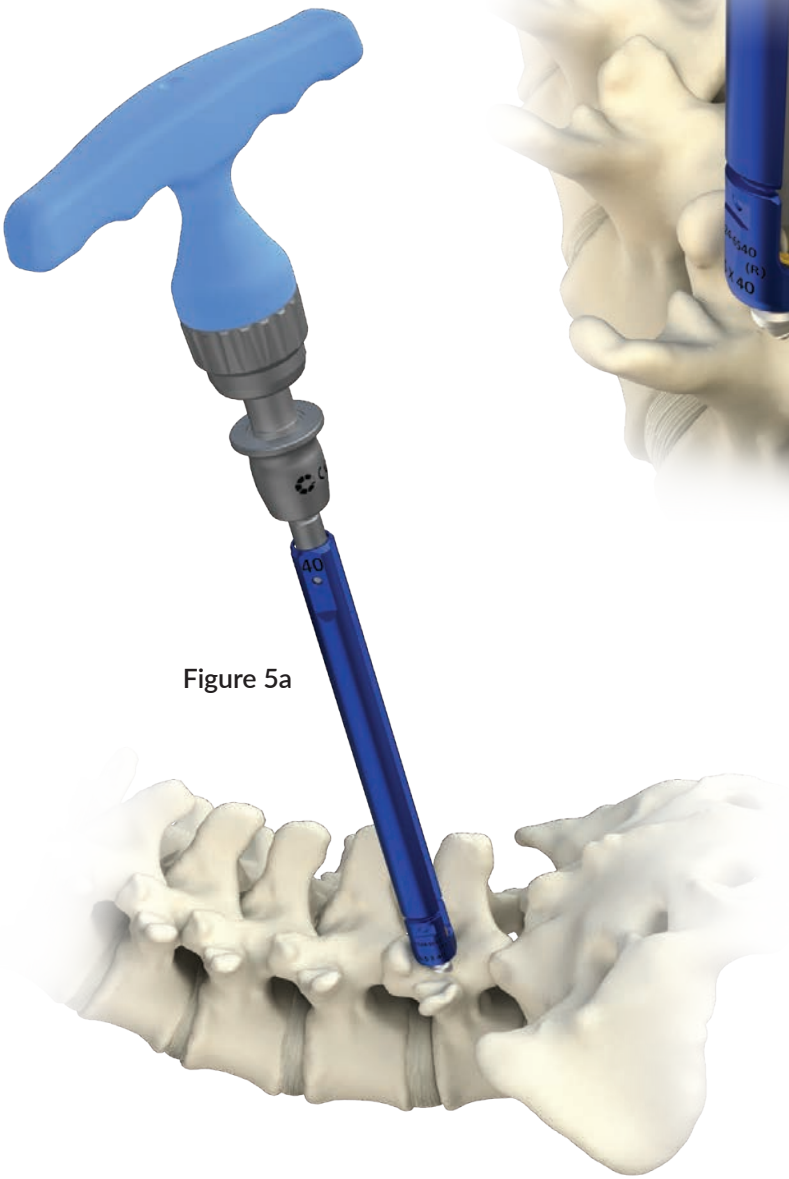


Figure 5a

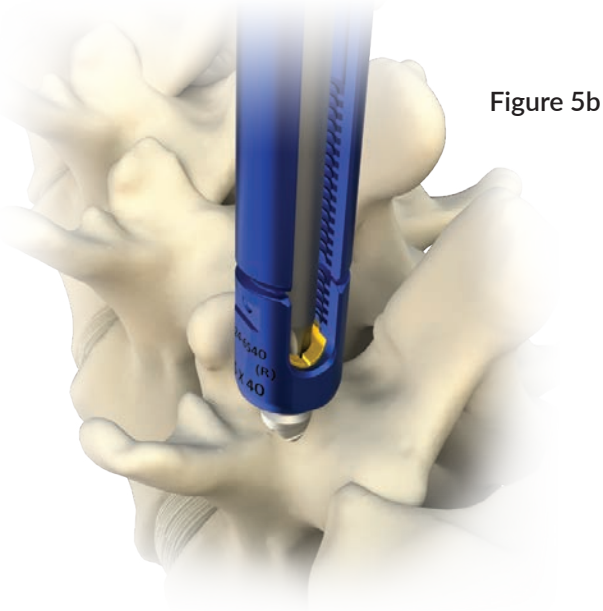


Figure 5b

Step 6: Rod Selection

To determine the appropriate **MIS Rod** length, attach the **MIS Rod Calipers** to the extended tabs of the MIS Pedicle Screws. Key the distal ends of the calipers over the tops of the extended tabs and press down until the springs of the calipers snap into the holes of the extended tabs on both sides. **(Figure 6a)**

Note: The MIS Rod Calipers should be used as a guide only, and the appropriate MIS Rod length should always be confirmed via fluoroscopy.

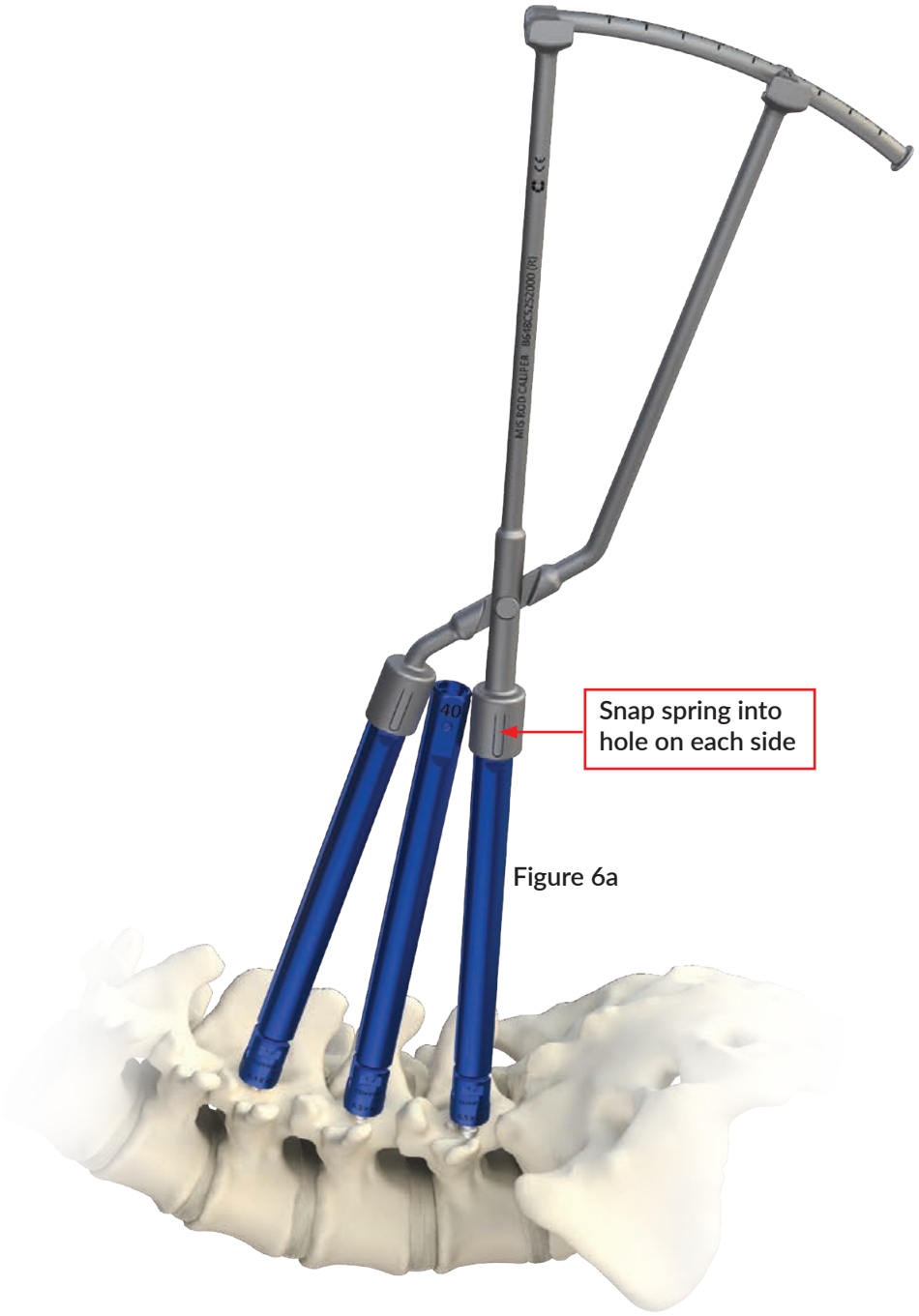


Figure 6a

The MIS Rod Calipers can be read from the top or through the side window. **(Figure 6b)**

Figure 6b

Appropriate MIS Rod length and overhang from the tulips can be confirmed by placing an MIS Rod in the saddles located at the top of the MIS Rod Calipers as illustrated. These saddles match the width of the MIS Pedicle Screw tulip head. **(Figure 6c)**

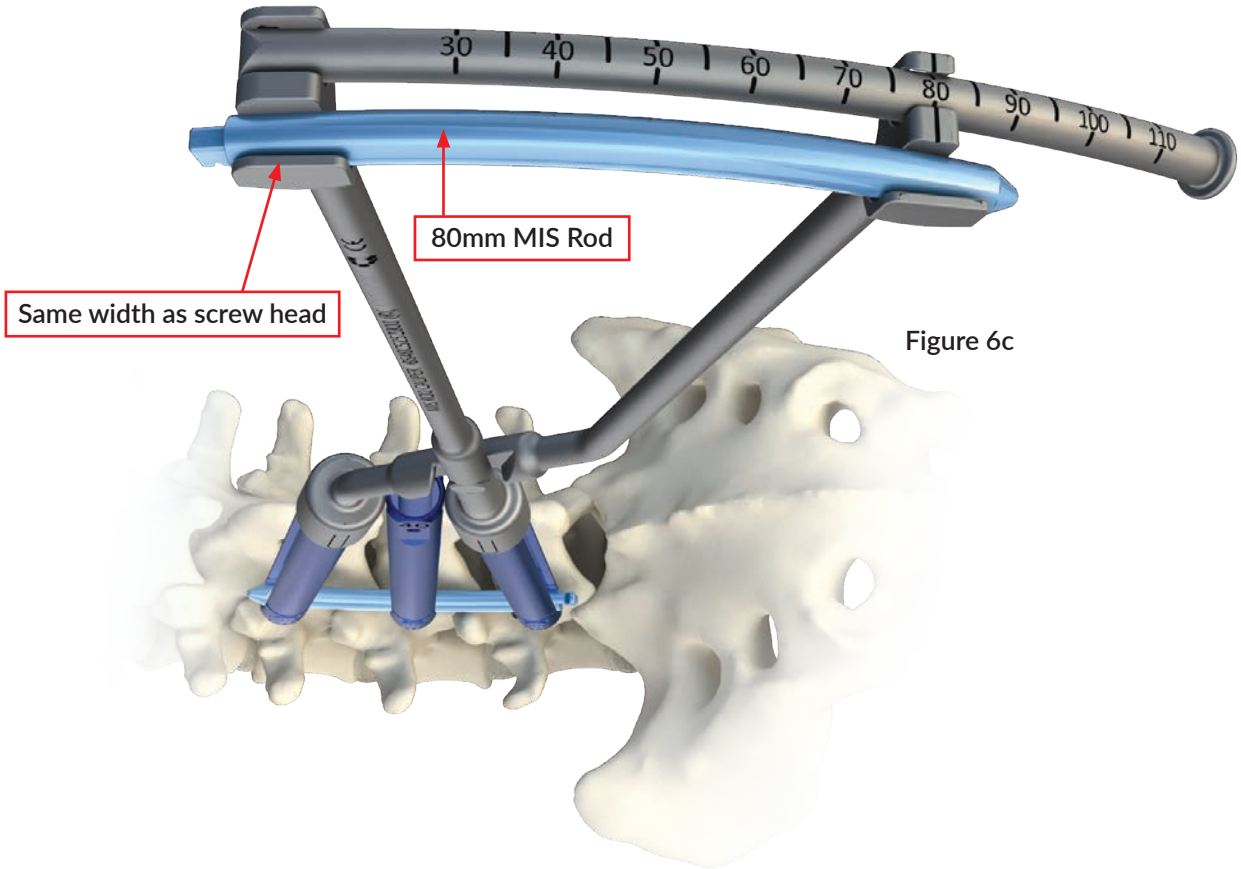
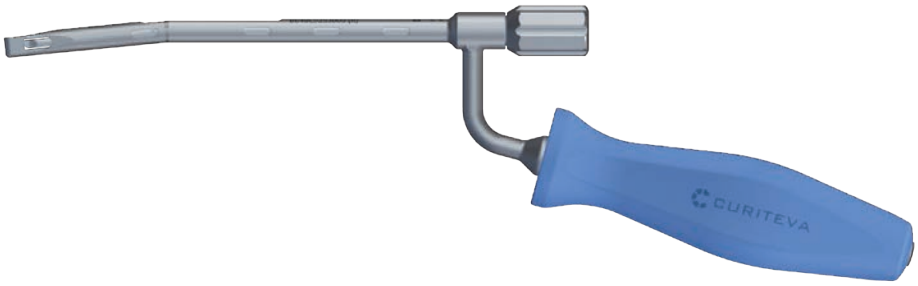


Figure 6c

Step 7: Rod Placement

- Align the open slots of the extended tabs of the MIS Pedicle Screws.
- Rotate the knob on the back of the **MIS Rod Inserter** counterclockwise to allow clearance for the MIS Rod in the distal pocket.

MIS Rod Inserter



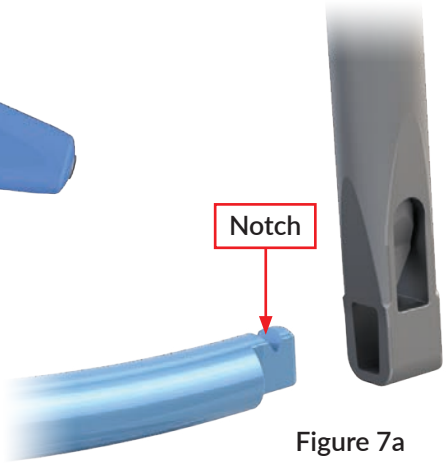


Figure 7a

- Key the MIS Rod into the distal pocket so that the notch is facing the handle of the MIS Rod Inserter. **(Figure 7a)**

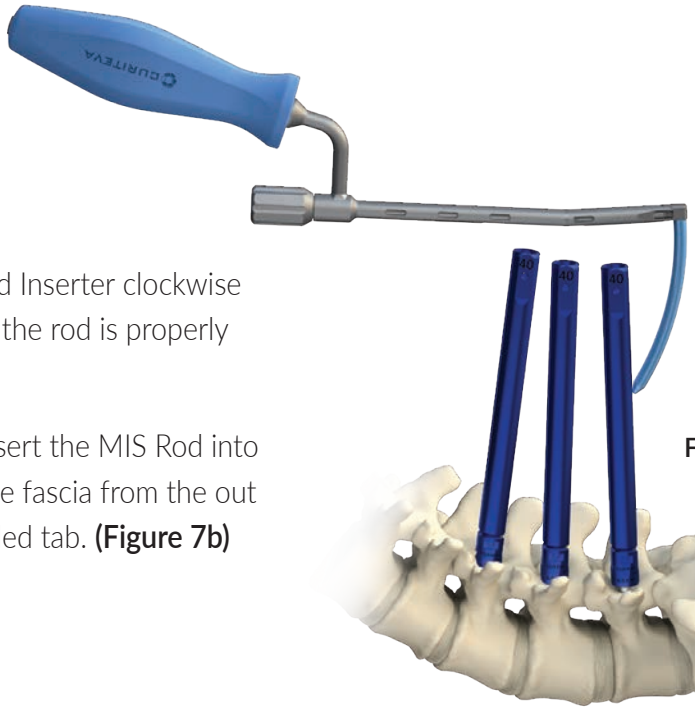


Figure 7b

- Rotate the knob of the MIS Rod Inserter clockwise to secure the MIS Rod. Ensure the rod is properly secured with no toggle.
- Use the MIS Rod Inserter to insert the MIS Rod into the extended tab and below the fascia from the out side slot opening of the extended tab. **(Figure 7b)**

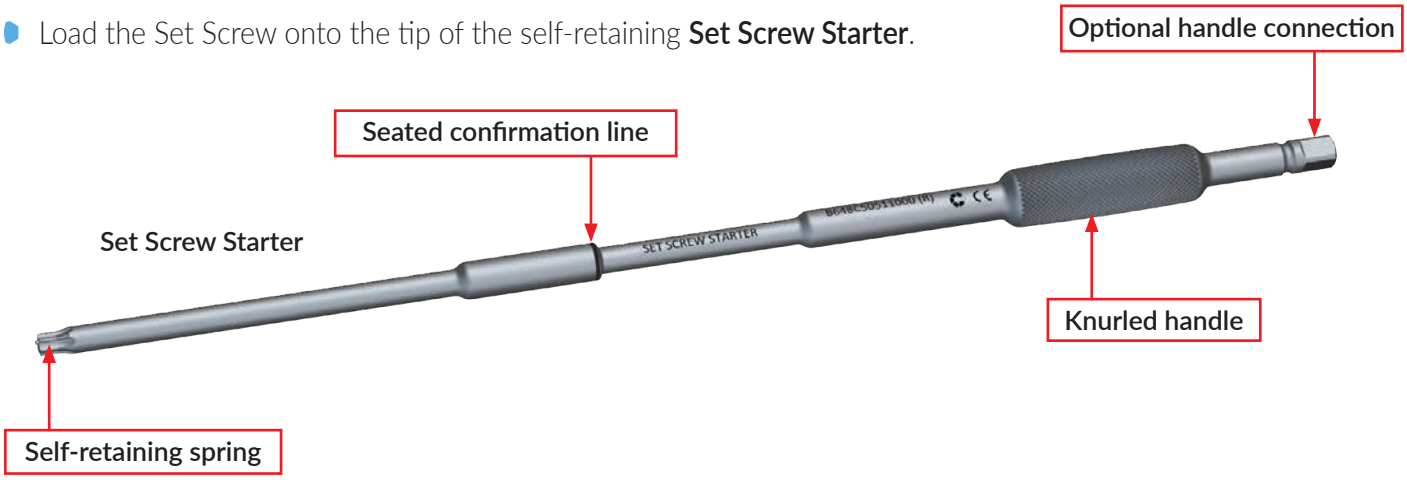
- Using fluoroscopy, pivot the MIS Rod Inserter and work the bullet tip of the MIS Rod through the slot of each MIS Pedicle Screw. Position the MIS Rod Inserter so that the MIS Rod seats into the Pedicle Screw saddles with proper overhang, and the shaft of the MIS Rod Inserter sits in line with the MIS Pedicle Screw extended tabs. **(Figure 7c)**

  Note: Do not release the MIS Rod from the MIS Rod Inserter until at least one Set Screw has been inserted and engages the MIS Rod.

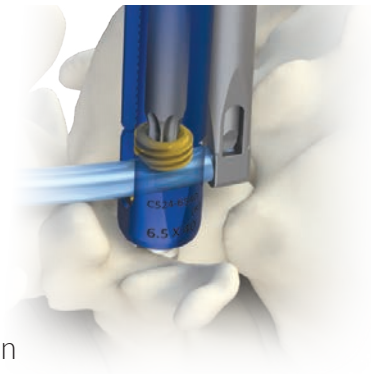
Figure 7c

Step 8: Set Screw Insertion

- Use fluoroscopy to confirm proper rod position prior to Set Screw insertion.
- Load the Set Screw onto the tip of the self-retaining **Set Screw Starter**.



Note: If desired, the **Ratcheting Axial Handle** or **Ratcheting T-Handle** can connect to the back of the **Set Screw Starter**.



- With the MIS Rod Inserter still in place, insert the Set Screw into the tulips using the Set Screw Starter. Thread the Set Screw until it contacts the MIS Rod and the MIS Rod is fully seated within the tulip. Repeat for each tulip.

Note: The Set Screw Starter features a laser marked seated confirmation line on the shaft that will approximately align with the top of the MIS Pedicle Screw when the Set Screw and Rod are fully seated. **(Figure 8)**

Figure 8

Note: The internal threads of the MIS Pedicle Screw are 26mm in length for rod reduction.

- Release the MIS Rod by rotating the knob on the back of the MIS Rod Inserter counterclockwise.

Step 9: Final Tightening

- Key the **Counter Torque Handle** to the back of the **Pedicle Screw Sleeve** and press until it snaps into position. It is optional to thread the knurled knob of the Counter Torque Handle onto the Pedicle Screw Sleeve for a more secure fit.

- After the MIS Rods and all Set Screws are secured within the tulips, place the Pedicle Screw Sleeve over the tulip and seat onto the Rod. **(Figure 10a)**

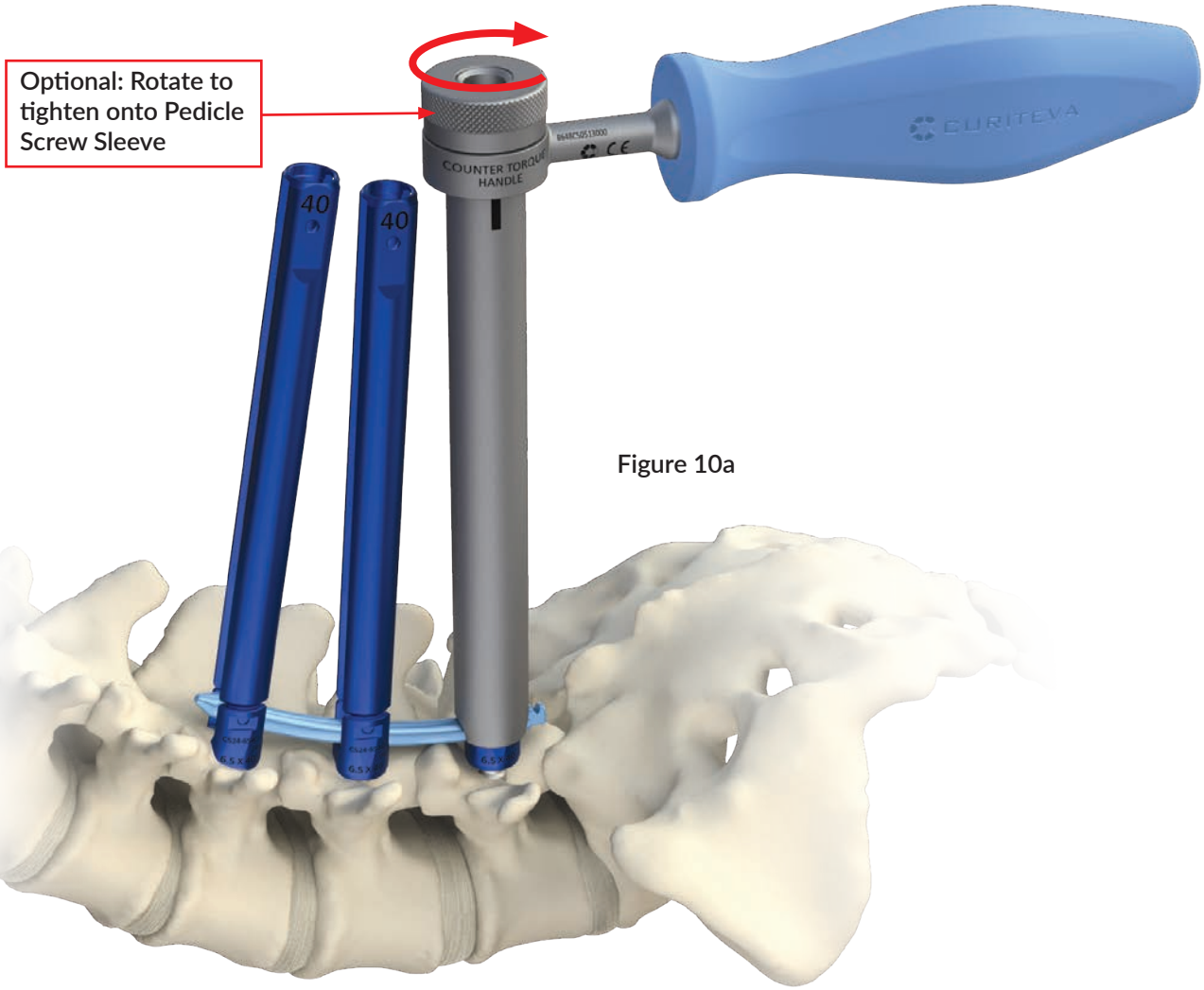


Figure 10a

- Attach the **80 in-lb Torque Limiting T-Handle** to the back of the **Final Locking Set Screw Driver**.
- Insert the Final Locking Set Screw Driver through the Pedicle Screw Sleeve to engage the hexalobe feature of the Set Screw. **(Figure 10b)**

Figure 10b

- Rotate the 80 in-lb Torque Limiting T-Handle clockwise until the handle releases at the 80 in-lb limit, confirmed with an audible "click".
- Repeat for all Set Screws in the construct.

Note: If compression / distraction is required, see Step 10 prior to final tightening.

Step 10: Compression/Distraction

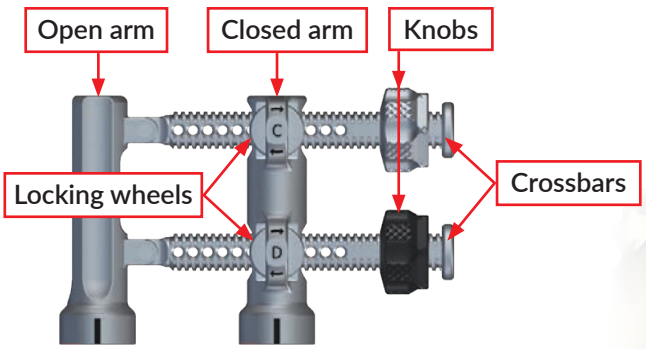
- Final tighten the desired Set Screw and leave the adjacent Set Screw(s) loose during compression or distraction to allow the loose MIS Pedicle Screw(s) to move along the MIS Rod in the desired direction.
- Slide a **Pedicle Screw Sleeve** over the desired MIS Pedicle Screws to compress or distract and seat onto the MIS Rod.
- Attach each arm of the MIS Compressor / Distractor by keying onto the Pedicle Screw Sleeve until it snaps into position and is secured, ensuring the closed arm of the MIS Compressor / Distractor is on the MIS Pedicle Screw with the tightened Set Screw.

  Note: Ensure the **MIS Compressor / Distractor** locking wheels are rotated counterclockwise to allow free motion of the closed arm along the crossbars.

  Note: The laser marked lines on the Pedicle Screw Sleeves should align with the laser marked lines on the MIS Compressor / Distractor arms. **(Figure 9a)**

  Note: The knobs of the MIS Compressor / Distractor may need to be rotated counterclockwise to allow for the MIS Compressor / Distractor arms to span the required length.

- For compression, rotate the upper locking wheel until the stop is reached. Rotate the black knob on the bottom crossbar clockwise to contact the closed arm and continue to rotate to compress the MIS Pedicle Screws. **(Figure 9a)**



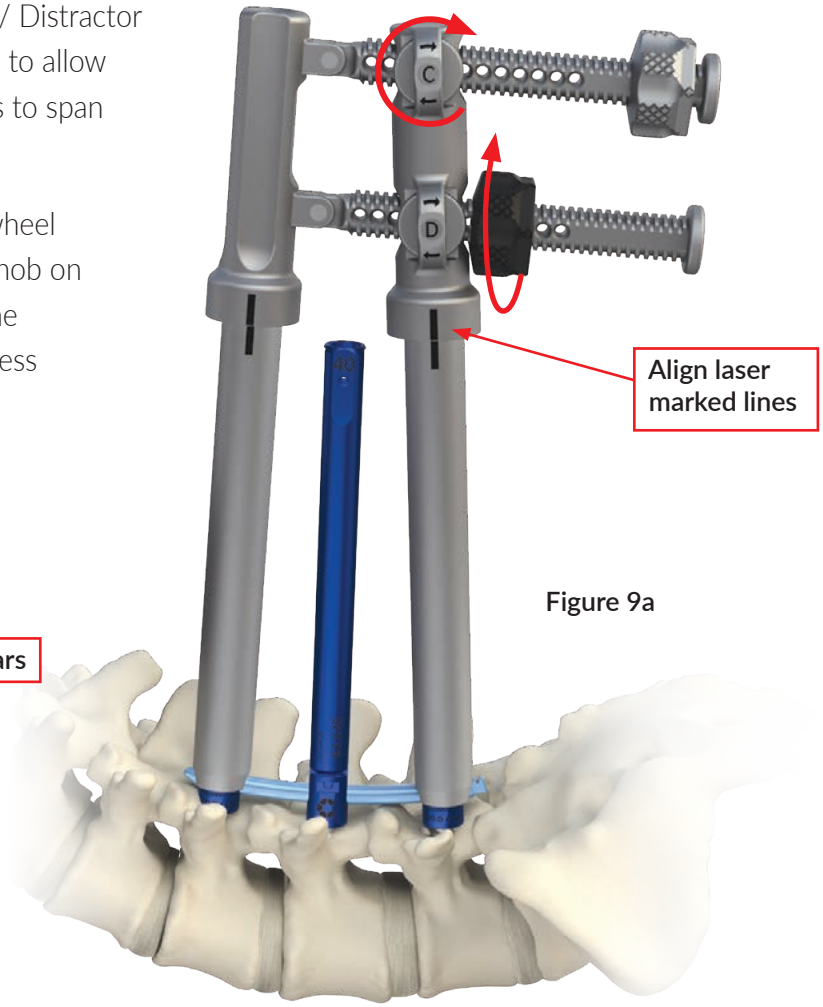


Figure 9a

- For distraction, rotate the lower locking wheel until the stop is reached. Rotate the silver knob on the top crossbar clockwise to contact the closed arm and continue to rotate to distract the MIS Pedicle Screws. **(Figure 9b)**

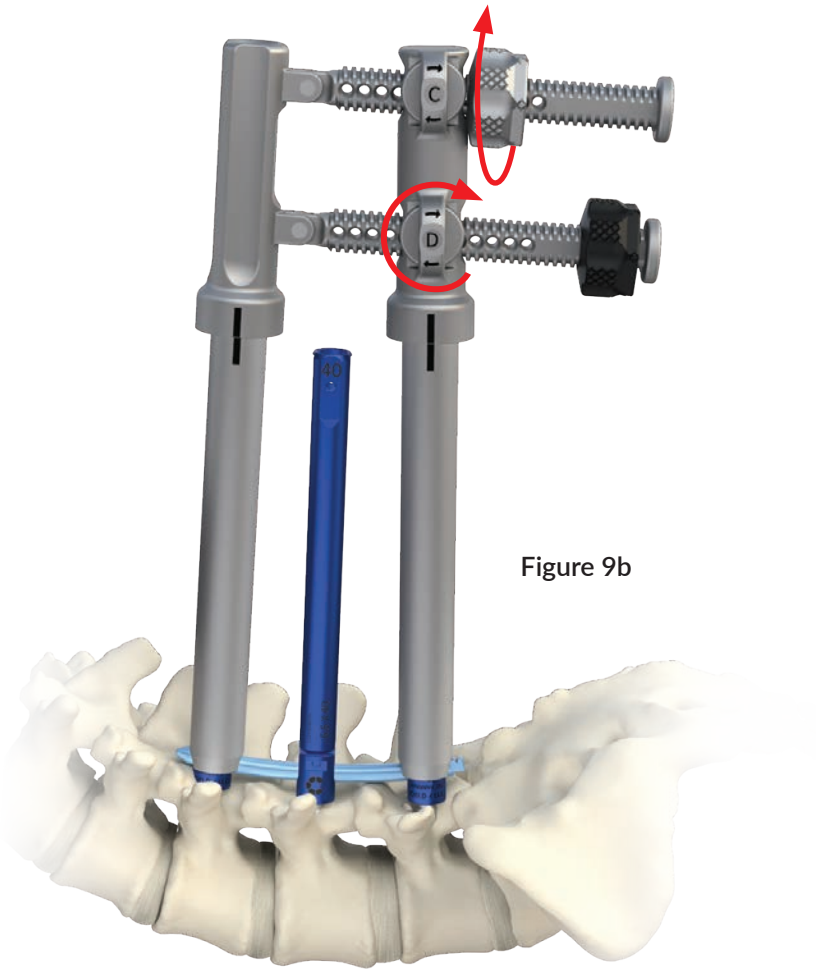
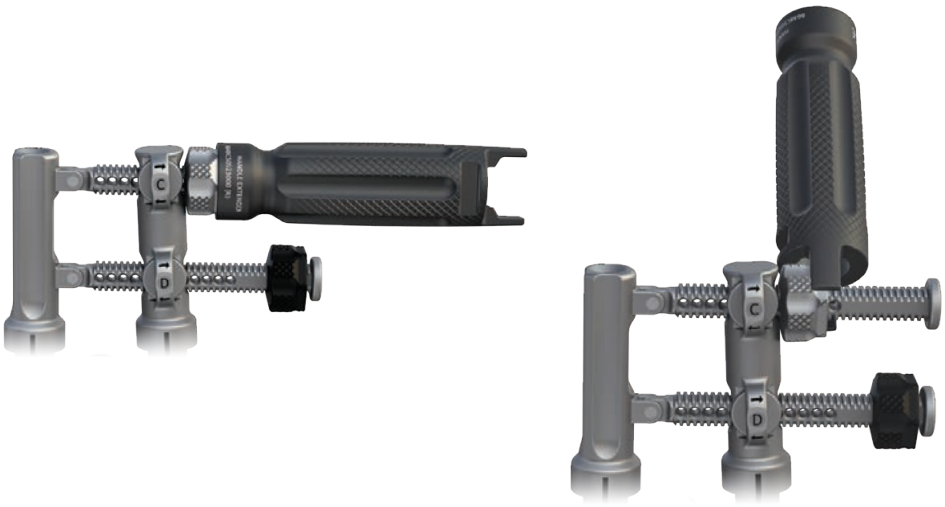


Figure 9b

Note: If desired, the **Handle Extender** may be used to aid in rotating the MIS Compressor / Distractor knobs to compress or distract. Either end of the Handle Extender can be used to drive the knobs.



- Tighten the loose Set Screw through the MIS Compressor / Distractor open arm once the desired compression or distraction is achieved. **(Figure 9c)**

Figure 9c

- Remove the MIS Compressor / Distractor, including the attached Pedicle Screw Sleeves, from the construct.

Step 11: Tab Removal

- Use the **Tab Cutters** to snip both sides of the top ring of the extended tabs. Repeat for all MIS Pedicle Screws in the construct. **(Figure 11a)**

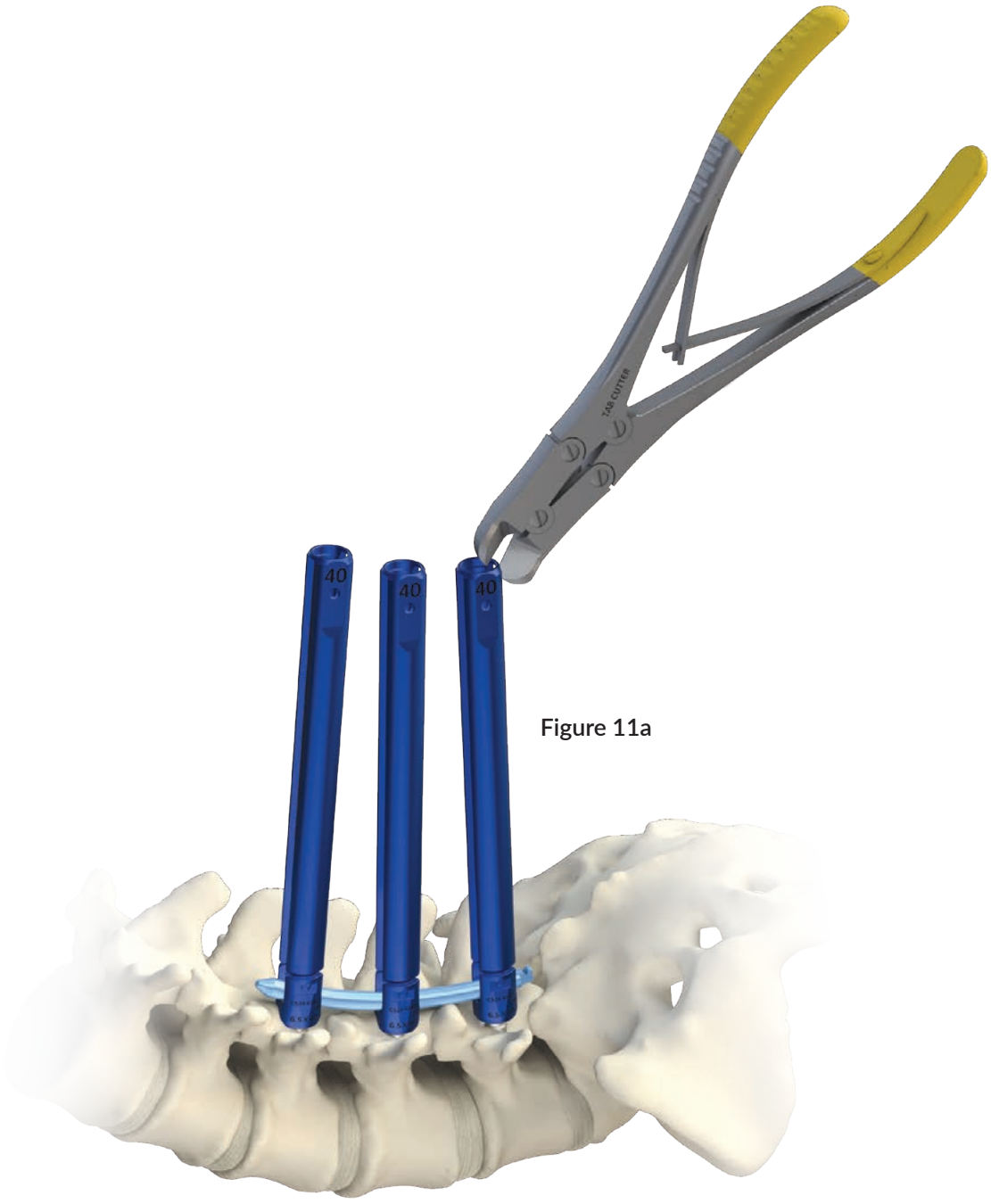


Figure 11a

- Slide the ring of the **MIS Tab Breaker** over one of the snipped extended tabs so that the "INSIDE" marking is positioned inside the tulip and the "OUTSIDE" marking is positioned outside the tulip, aligning the clip on the MIS Tab Breaker with one of the extended tabs. Press down until the MIS Tab Breaker clip engages the extended tab. **(Figure 11b)**

  Note: The top ring of the extended tabs must be snipped by the Tab Cutters prior to using the MIS Tab Breaker.

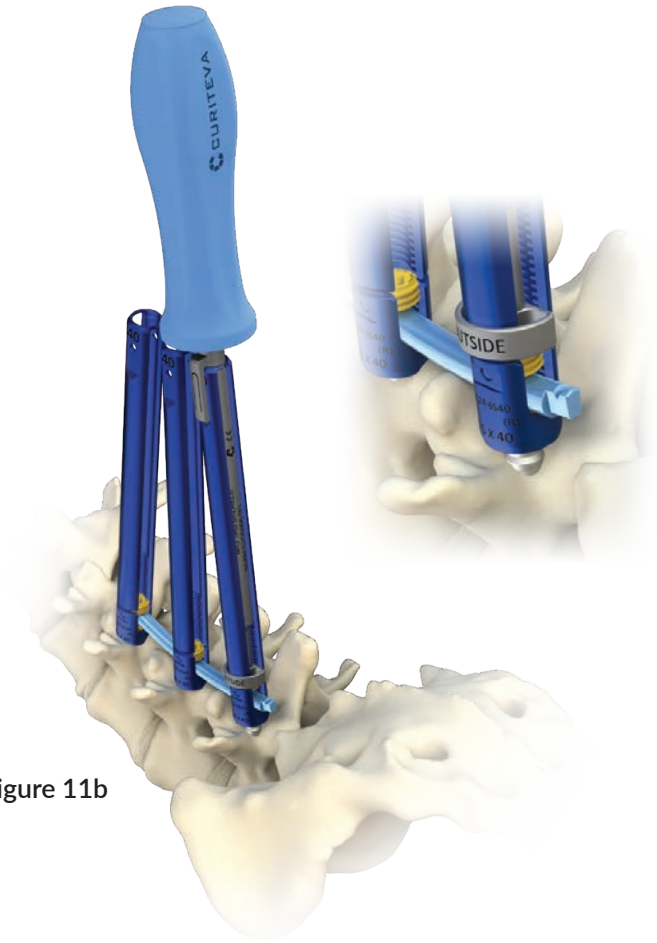


Figure 11b

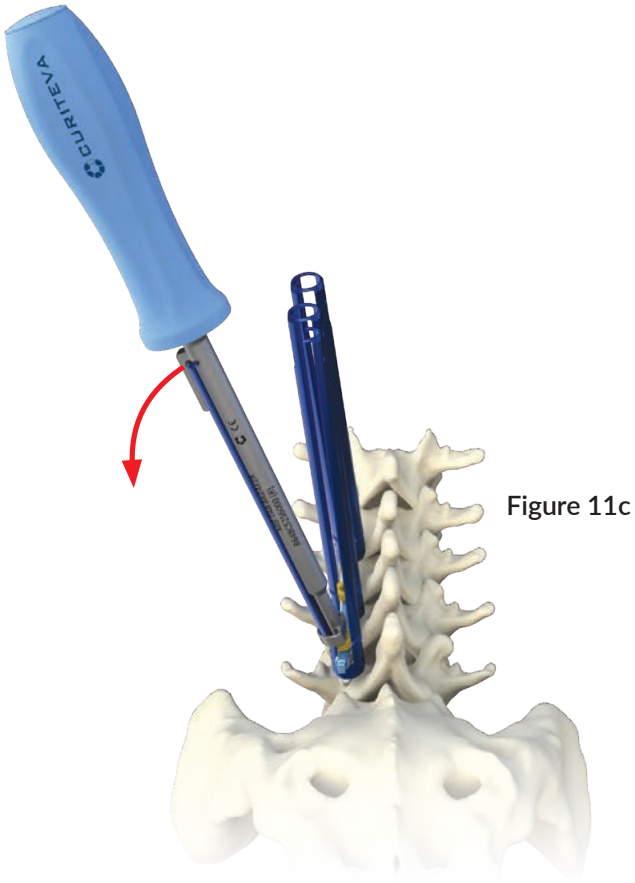


Figure 11c

- Rock the MIS Tab Breaker away from the screw medial/lateral to snap off the extended tab and remove. The MIS Tab Breaker clip will retain the extended tab after it's broken away. Repeat for the other side of the tulip. **(Figure 11c)**

- Repeat for all remaining MIS Pedicle Screws.

Step 12: Implant Removal (optional)

If revision is necessary, Set Screws and MIS Pedicle Screws can be removed using the Adjustment Driver. Engage the drive feature of the Set Screws with the Adjustment Driver and rotate counterclockwise until fully unthreaded. Grasp and remove the rod. Engage the drive feature of the Pedicle Screw shank with the Adjustment Driver and rotate counterclockwise until the screw is removed.

Indications for Use:

The PRODIGY Pedicle Screw System is intended for posterior, non-cervical pedicle screw fixation (T1-S2/ilium) and hook fixation (T1-L5) in skeletally mature patients as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis and/or failed previous fusion. The PRODIGY Pedicle Screw System is intended to be used with autograft and/or allograft.

Contraindications:

Contraindications for the PRODIGY Pedicle Screw System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, substance abuse, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing process.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

Cautions, Precautions and Warnings:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Do NOT use titanium and/or cobalt chromium with stainless steel in the same implant construct.

Do not use components of the PRODIGY Pedicle Screw System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects.

Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the PRODIGY Pedicle Screw System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The PRODIGY Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the PRODIGY Pedicle Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

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. The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

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