PRODIGY™

PEDICLE SCREW SYSTEM

THORACOLUMBAR FIXATION

Surgical Technique Guide

CURITEVA®

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PRODIGY™
PEDICLE SCREW SYSTEM

Disclaimer

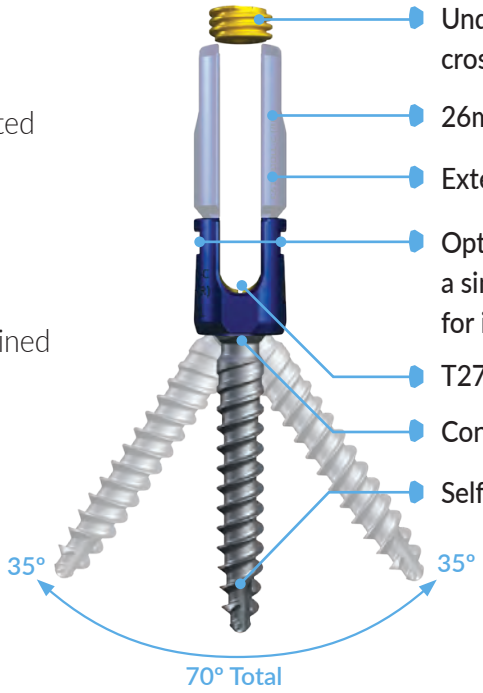
The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

PRODIGY™ Pedicle Screw System

The Prodigy Polyaxial Open Pedicle Screw System is a posterior spinal fixation system designed to enhance the surgical experience by providing surgeons with its comprehensive implant offering and ergonomically designed instrumentation. The Prodigy Pedicle Screw system was thoughtfully designed to handle correction maneuvers through the design of the friction fit tulip head and low profile. The Prodigy Pedicle Screw System is intended to address numerous pathologies for the thoracic and lumbar spine while facilitating biomechanical strength and surgical simplicity.

Polyaxial Screw

- Cannulated and non-cannulated options available
- Color coded tulip heads by bone screw diameter
- Comprehensive instrument package designed for streamlined use and efficiency



- Undercut square thread designed to prevent cross-threading and tulip head splaying
- 26mm of reduction threads
- Extended tulip height of 23.5mm
- Optimized instrument ports providing a simple and solid tulip engagement for implant manipulation
- T27 hexalobe drive feature
- Continuous friction to maintain tulip position
- Self-tapping double lead bone screw threads

Rod

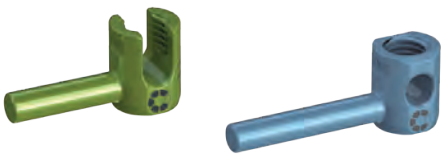
- Material: Ti 6AL-4V ELI
- 5.5mm Diameter
- Curved and straight options available

Variable Crosslink

- Versatile crosslink design with adjustable lengths and angle variability
- Center and lateral set screws feature the same T20 hexalobe drive

Offset Connectors

- 90° lateral offset Ø5.5mm rod
- Open and closed head options available
- Connects to a Ø5.5mm rod
- Accepts the same set screw as the pedicle screws



PRODIGY™ Pedicle Screw System

Non-Cannulated Polyaxial Pedicle Screws

Catalog Number	Description	Quantity
C504-4525	4.5 x 25mm PEDICLE SCREW	*
C504-4530	4.5 x 30mm PEDICLE SCREW	*
C504-4535	4.5 x 35mm PEDICLE SCREW	*
C504-4540	4.5 x 40mm PEDICLE SCREW	*
C504-4545	4.5 x 45mm PEDICLE SCREW	*
C504-4550	4.5 x 50mm PEDICLE SCREW	*
C504-4555	4.5 x 55mm PEDICLE SCREW	*
C504-5525	5.5 x 25mm PEDICLE SCREW	*
C504-5530	5.5 x 30mm PEDICLE SCREW	2
C504-5535	5.5 x 35mm PEDICLE SCREW	4
C504-5540	5.5 x 40mm PEDICLE SCREW	8
C504-5545	5.5 x 45mm PEDICLE SCREW	8
C504-5550	5.5 x 50mm PEDICLE SCREW	6
C504-5555	5.5 x 55mm PEDICLE SCREW	*
C504-6525	6.5 x 25mm PEDICLE SCREW	*
C504-6530	6.5 x 30mm PEDICLE SCREW	2

Catalog Number	Description	Quantity
C504-6535	6.5 x 35mm PEDICLE SCREW	4
C504-6540	6.5 x 40mm PEDICLE SCREW	8
C504-6545	6.5 x 45mm PEDICLE SCREW	8
C504-6550	6.5 x 50mm PEDICLE SCREW	8
C504-6555	6.5 x 55mm PEDICLE SCREW	4
C504-7525	7.5 x 25mm PEDICLE SCREW	*
C504-7530	7.5 x 30mm PEDICLE SCREW	*
C504-7535	7.5 x 35mm PEDICLE SCREW	4
C504-7540	7.5 x 40mm PEDICLE SCREW	8
C504-7545	7.5 x 45mm PEDICLE SCREW	8
C504-7550	7.5 x 50mm PEDICLE SCREW	6
C504-7555	7.5 x 55mm PEDICLE SCREW	4
C504-8540	8.5 x 40mm PEDICLE SCREW	*
C504-8545	8.5 x 45mm PEDICLE SCREW	*
C504-8550	8.5 x 50mm PEDICLE SCREW	*
C504-8555	8.5 x 55mm PEDICLE SCREW	*

**Available by request*

PRODIGY™ Pedicle Screw System

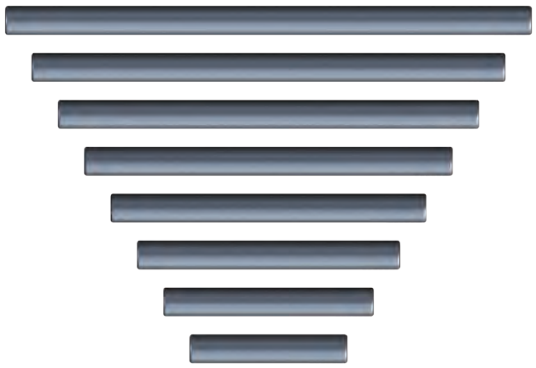
Cannulated Polyaxial Pedicle Screws		
Catalog Number	**Description**	**Quantity**
C504-5530-C	5.5 x 30mm CANNULATED PEDICLE SCREW	*
C504-5535-C	5.5 x 35mm CANNULATED PEDICLE SCREW	*
C504-5540-C	5.5 x 40mm CANNULATED PEDICLE SCREW	*
C504-5545-C	5.5 x 45mm CANNULATED PEDICLE SCREW	*
C504-5550-C	5.5 x 50mm CANNULATED PEDICLE SCREW	*
C504-5555-C	5.5 x 55mm CANNULATED PEDICLE SCREW	*
C504-6530-C	6.5 x 30mm CANNULATED PEDICLE SCREW	*
C504-6535-C	6.5 x 35mm CANNULATED PEDICLE SCREW	*
C504-6540-C	6.5 x 40mm CANNULATED PEDICLE SCREW	*
C504-6545-C	6.5 x 45mm CANNULATED PEDICLE SCREW	*
C504-6550-C	6.5 x 50mm CANNULATED PEDICLE SCREW	*
C504-6555-C	6.5 x 55mm CANNULATED PEDICLE SCREW	*
C504-7530-C	7.5 x 30mm CANNULATED PEDICLE SCREW	*
C504-7535-C	7.5 x 35mm CANNULATED PEDICLE SCREW	*
C504-7540-C	7.5 x 40mm CANNULATED PEDICLE SCREW	*
C504-7545-C	7.5 x 45mm CANNULATED PEDICLE SCREW	*
C504-7550-C	7.5 x 50mm CANNULATED PEDICLE SCREW	*
C504-7555-C	7.5 x 55mm CANNULATED PEDICLE SCREW	*

Reduction Polyaxial Pedicle Screws		
Catalog Number	**Description**	**Quantity**
C514-5525	5.5 x 25mm REDUCTION PEDICLE SCREW	*
C514-5530	5.5 x 30mm REDUCTION PEDICLE SCREW	*
C514-5535	5.5 x 35mm REDUCTION PEDICLE SCREW	*
C514-5540	5.5 x 40mm REDUCTION PEDICLE SCREW	*
C514-5545	5.5 x 45mm REDUCTION PEDICLE SCREW	*
C514-5550	5.5 x 50mm REDUCTION PEDICLE SCREW	*
C514-5555	5.5 x 55mm REDUCTION PEDICLE SCREW	*
C514-6525	6.5 x 25mm REDUCTION PEDICLE SCREW	*
C514-6530	6.5 x 30mm REDUCTION PEDICLE SCREW	*
C514-6535	6.5 x 35mm REDUCTION PEDICLE SCREW	*
C514-6540	6.5 x 40mm REDUCTION PEDICLE SCREW	*
C514-6545	6.5 x 45mm REDUCTION PEDICLE SCREW	*
C514-6550	6.5 x 50mm REDUCTION PEDICLE SCREW	*
C514-6555	6.5 x 55mm REDUCTION PEDICLE SCREW	*
C514-7525	7.5 x 25mm REDUCTION PEDICLE SCREW	*
C514-7530	7.5 x 30mm REDUCTION PEDICLE SCREW	*
C514-7535	7.5 x 35mm REDUCTION PEDICLE SCREW	*
C514-7540	7.5 x 40mm REDUCTION PEDICLE SCREW	*
C514-7545	7.5 x 45mm REDUCTION PEDICLE SCREW	*
C514-7550	7.5 x 50mm REDUCTION PEDICLE SCREW	*
C514-7555	7.5 x 55mm REDUCTION PEDICLE SCREW	*

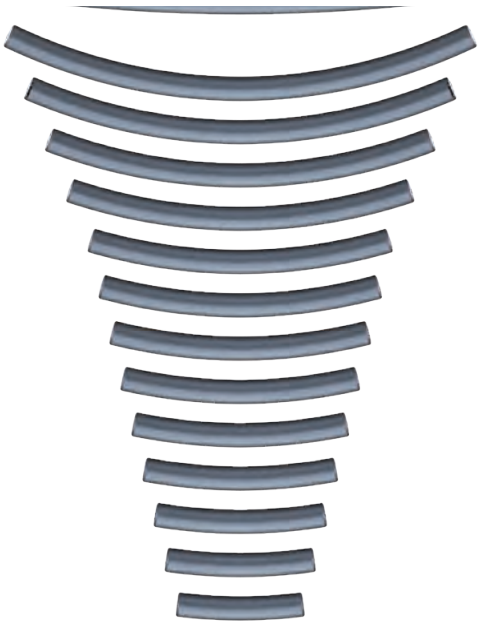
**Available by request*

PRODIGY™ Pedicle Screw System

Ø5.5mm Titanium Straight Rods		
Catalog Number	**Description**	**Quantity**
C504-R55-030	5.5 x 30mm STRAIGHT ROD	*
C504-R55-040	5.5 x 40mm STRAIGHT ROD	*
C504-R55-050	5.5 x 50mm STRAIGHT ROD	*
C504-R55-060	5.5 x 60mm STRAIGHT ROD	*
C504-R55-070	5.5 x 70mm STRAIGHT ROD	*
C504-R55-080	5.5 x 80mm STRAIGHT ROD	*
C504-R55-090	5.5 x 90mm STRAIGHT ROD	*
C504-R55-100	5.5 x 100mm STRAIGHT ROD	*
C504-R55-400	5.5 x 400mm STRAIGHT ROD	2



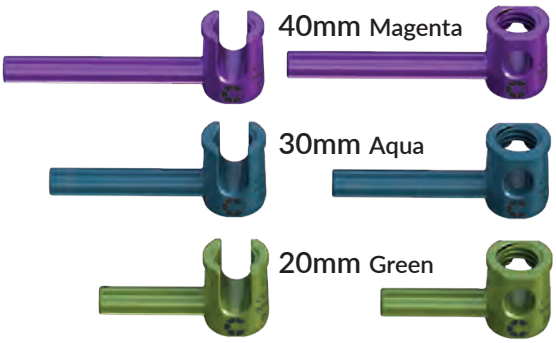
Ø5.5mm Titanium Curved Rods		
Catalog Number	**Description**	**Quantity**
C504-R55-030C	5.5 x 30mm CURVED ROD	3
C504-R55-035C	5.5 x 35mm CURVED ROD	2
C504-R55-040C	5.5 x 40mm CURVED ROD	3
C504-R55-045C	5.5 x 45mm CURVED ROD	2
C504-R55-050C	5.5 x 50mm CURVED ROD	3
C504-R55-055C	5.5 x 55mm CURVED ROD	2
C504-R55-060C	5.5 x 60mm CURVED ROD	3
C504-R55-065C	5.5 x 65mm CURVED ROD	2
C504-R55-070C	5.5 x 70mm CURVED ROD	3
C504-R55-080C	5.5 x 80mm CURVED ROD	2
C504-R55-090C	5.5 x 90mm CURVED ROD	2
C504-R55-100C	5.5 x 100mm CURVED ROD	2
C504-R55-110C	5.5 x 110mm CURVED ROD	2
C504-R55-120C	5.5 x 120mm CURVED ROD	*
C504-R55-130C	5.5 x 130mm CURVED ROD	*
C504-R55-150C	5.5 x 150mm CURVED ROD	*



**Available by request*

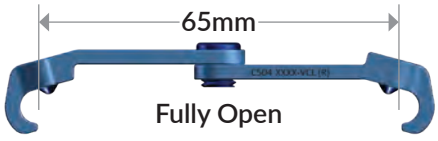
Set Screws		
Catalog Number	**Description**	**Quantity**
C504-001	SET SCREW	20

Offset Connectors		
Catalog Number	**Description**	**Quantity**
C554-5520-O	5.5 x 20mm OPEN OFFSET CONNECTOR	*
C554-5530-O	5.5 x 30mm OPEN OFFSET CONNECTOR	*
C554-5540-O	5.5 x 40mm OPEN OFFSET CONNECTOR	*
C554-5520-C	5.5 x 20mm CLOSED OFFSET CONNECTOR	*
C554-5530-C	5.5 x 30mm CLOSED OFFSET CONNECTOR	*
C554-5540-C	5.5 x 40mm CLOSED OFFSET CONNECTOR	*



Variable Crosslinks		
Catalog Number	**Description**	**Quantity**
C504-3445-VCL	VARIABLE CROSSLINK, 34 - 45mm	*
C504-4465-VCL	VARIABLE CROSSLINK, 44 - 65mm	*
C504-6485-VCL	VARIABLE CROSSLINK, 64 - 85mm	*

Dimensions from Rod to Rod centers.



**Available by request*

Instrument Guide

C505-100	Bone Awl

C505-110	Cannulated Bone Awl*

C505-200	Straight Pedicle Finder

C505-210	Curved Pedicle Finder

C505-300	Straight Sounder

C505-310	Curved Sounder

**Available by request*

Taps	
C505-400-45	4.5mm Tap*
C505-400-55	5.5mm Tap
C505-400-65	6.5mm Tap
C505-400-75	7.5mm Tap
C505-400-85	8.5mm Tap*
C505-410-55	5.5mm Cannulated Tap*
C505-410-65	6.5mm Cannulated Tap*
C505-410-75	7.5mm Cannulated Tap*

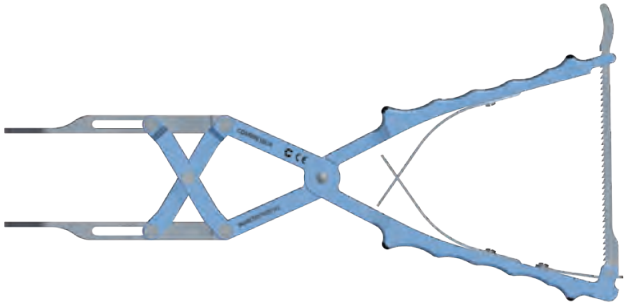
C505-501	Pedicle Screw Driver

C505-502	Extended Tab Pedicle Screw Driver*

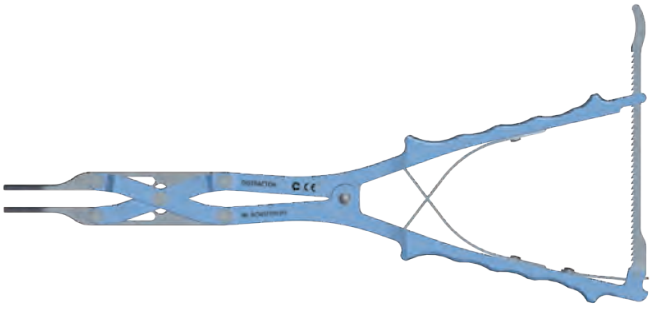
C505-510	Adjustment Driver

Instrument Guide

C505-600 Rod / Crosslink Holder



C505-700 Compressor



C505-710 Distractor

C505-800 5.5 x 400mm Rod Template

C505-900 Rod Bender

C505-1000 Tulip Positioner / Rod Pusher

C505-1100 Set Screw Starter

C505-1200 Axial Persuader

C505-1300 Counter Torque Handle

C505-1400 Pedicle Screw Sleeve

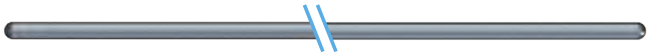
C505-1500 Final Locking Set Screw Driver

C505-1600 Crosslink Counter Torque

C505-1700 Final Locking Crosslink Driver

Instrument Guide

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

C505-2130 40 in-lbs Torque Limiting Axial Handle

C505-2200 Rod Rocker

C505-2300 Handle Extender

C505-2400 Rod Gripper*

C515-100 Reduction Tab Breaker*

**Available by request*

PRODIGY™
Surgical Technique

Disclaimer

Steps shown are for Non-Cannulated Polyaxial Screws.

Step 1: Pedicle Preparation

Use fluoroscopy to identify the appropriate level(s) and determine the pedicle entry point.

Use the **Bone Awl** at the pedicle entry point to penetrate the cortical bone and create a pilot hole. **(Figure 1a)**

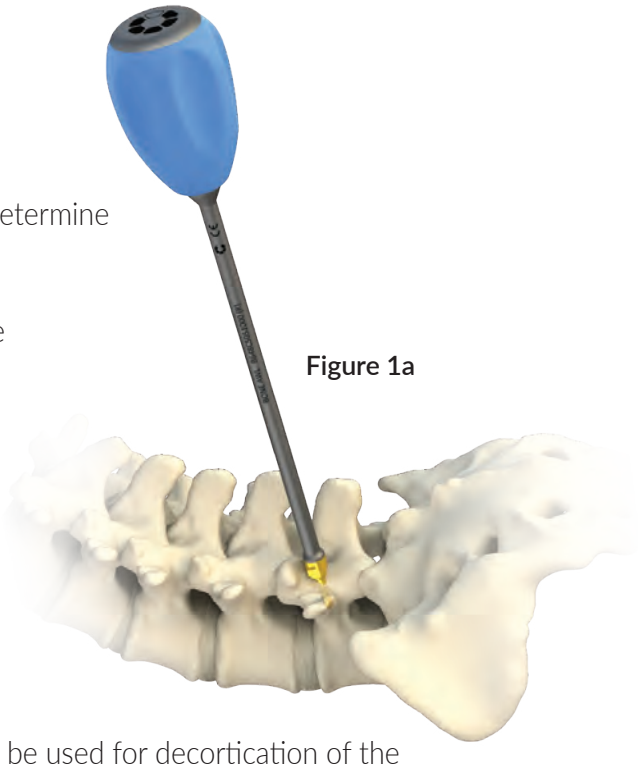


Figure 1a

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

Note: The **Bone Awl** tip diameter is 3.2mm and protrudes 15mm.

Create a pathway through the pedicle canal and into the vertebral body using either the **Straight or Curved Pedicle Finder**, being sure to stay within the pedicle walls. **(Figure 1b)**

Note: The Pedicle Finders feature depth markings on the shaft to aid in screw length selection.

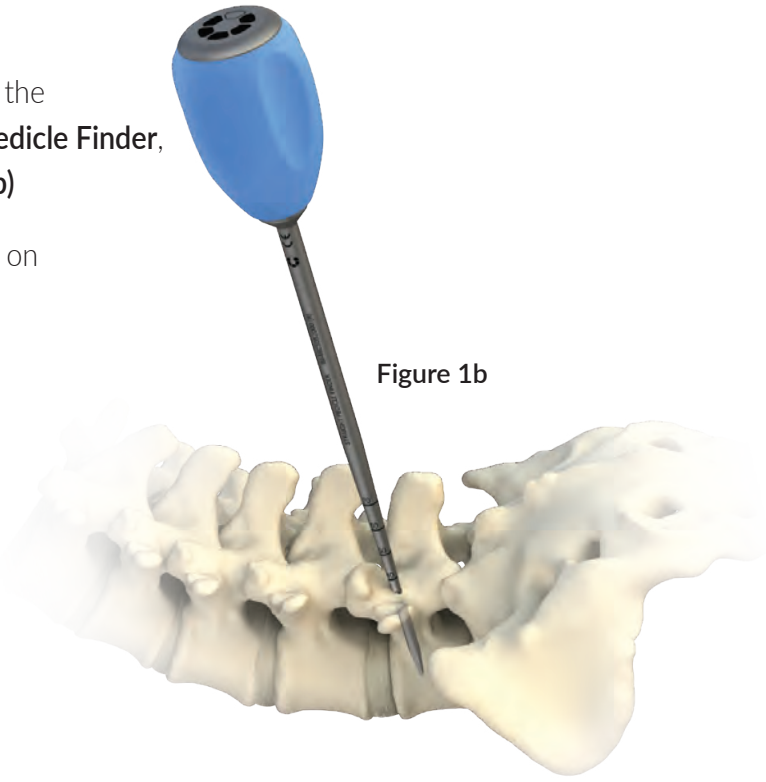


Figure 1b

Use either the **Straight or Curved Sounder** to internally palpate the pedicle walls to ensure its integrity. **(Figure 1c)**

Straight Sounder

Curved Sounder

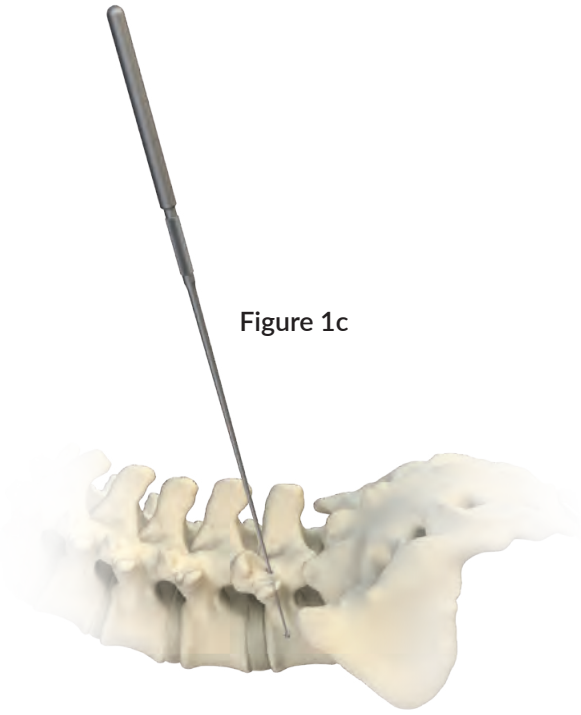


Figure 1c

Prodigy Pedicle Screws are self-tapping, but **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**. Tap to the desired depth. **(Figure 1d)**

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

Size	Color
4.5mm	Magenta
5.5mm	Green
6.5mm	Dark Blue
7.5mm	Teal
8.5mm	Sea Foam

Note: The Taps feature depth markings on the shaft to aid in screw length selection. All Taps have a thread length of 30mm.

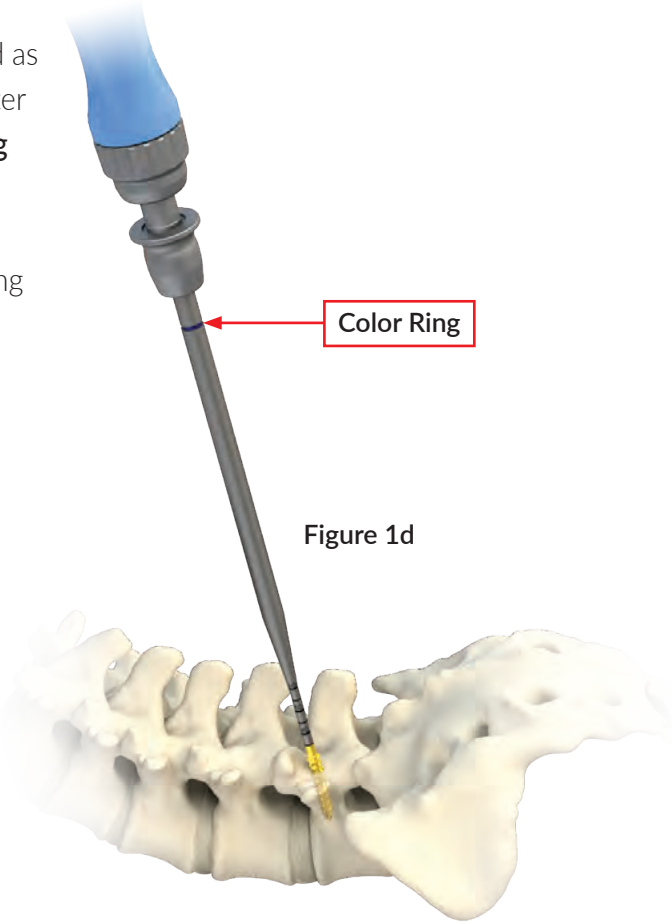


Figure 1d

Step 2: Screw Insertion

- Connect either the **Ratcheting Axial Handle** or **Ratcheting T-Handle** to the **Pedicle Screw Driver**. **(Figure 2a)**

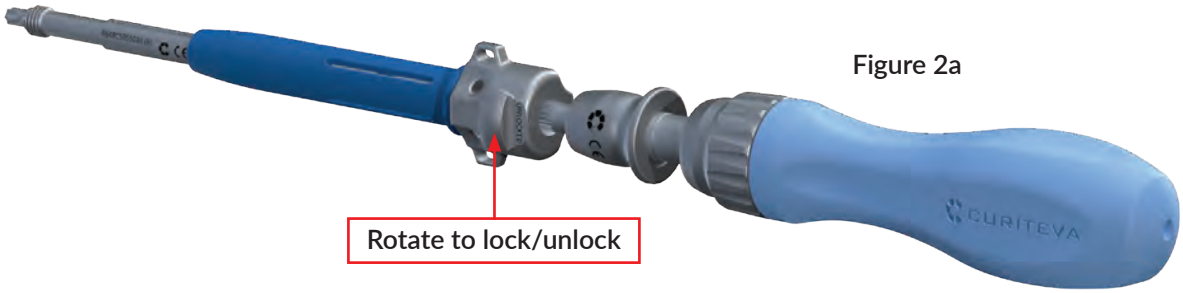


Figure 2a

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. 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 2b, 2c)**

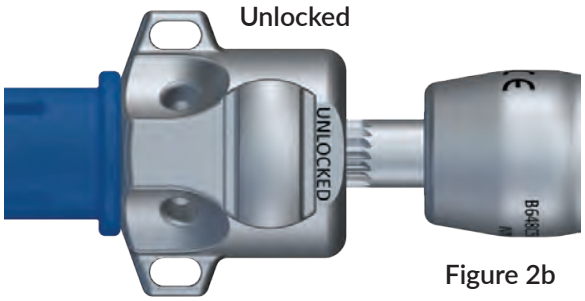


Figure 2b

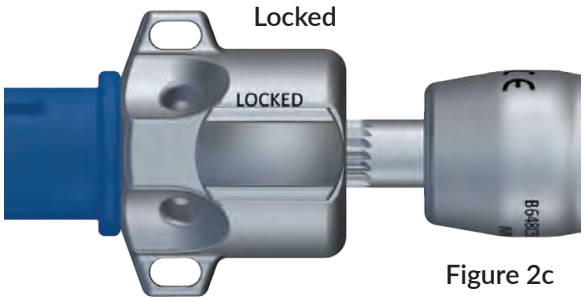


Figure 2c

- Select the desired Pedicle Screw diameter and length. Insert the distal tip of the Pedicle Screw Driver into the tulip, seating the hexalobe into the screw shank. **(Figure 2d)**
- With the 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. This step should be performed with the screw in the screw caddy or resting upon a sterile surface to avoid premature screw disengagement.

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

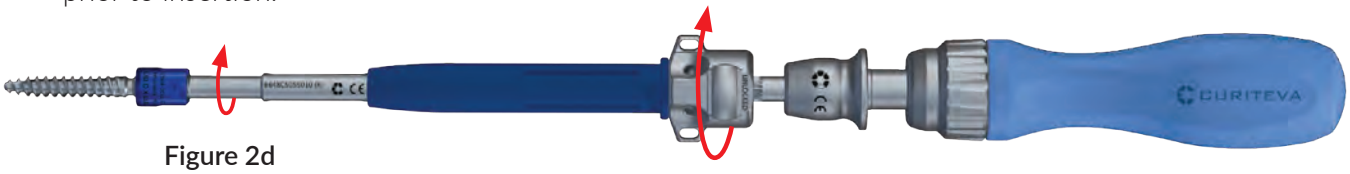


Figure 2d

- Ensure the chosen ratcheting handle is in the forward position and drive the Pedicle Screw into the prepared pedicle to the desired depth. **(Figure 2e)**
- To disengage the **Pedicle Screw Driver** from the Pedicle Screw, secure the ratcheting handle and 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 Pedicle Screw.

- Repeat for all pedicles supporting the construct.

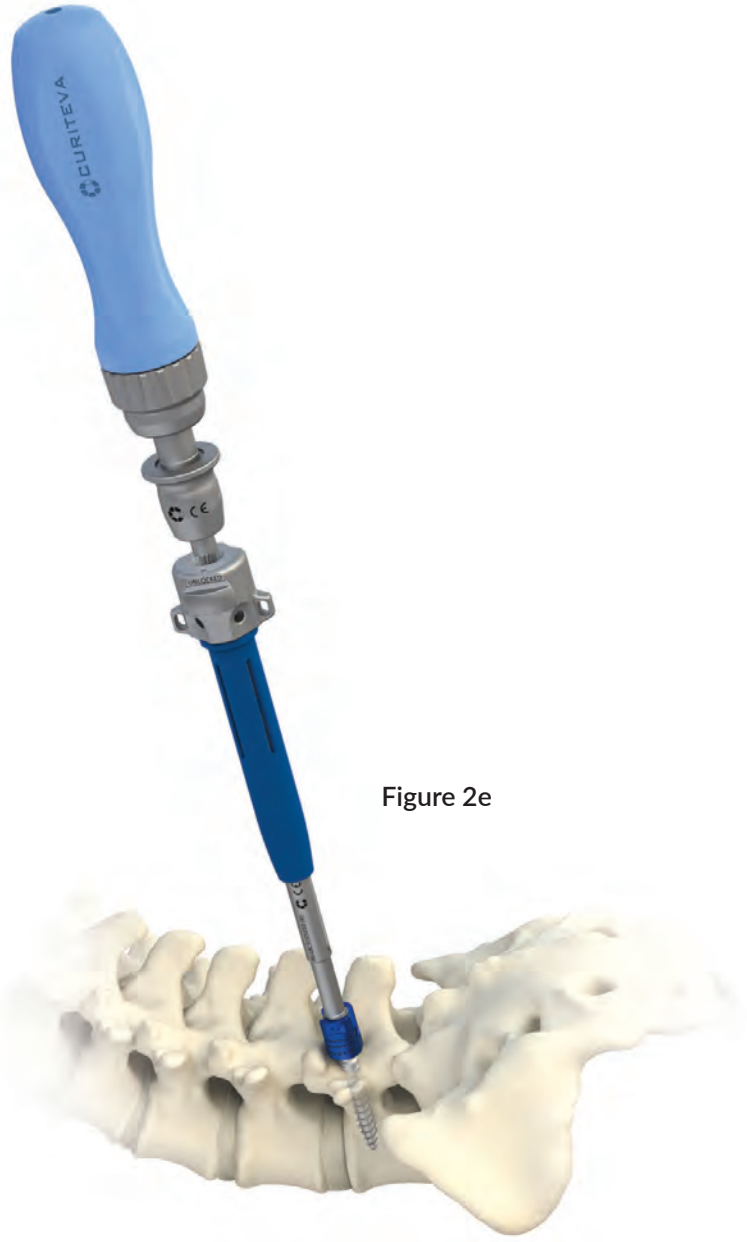
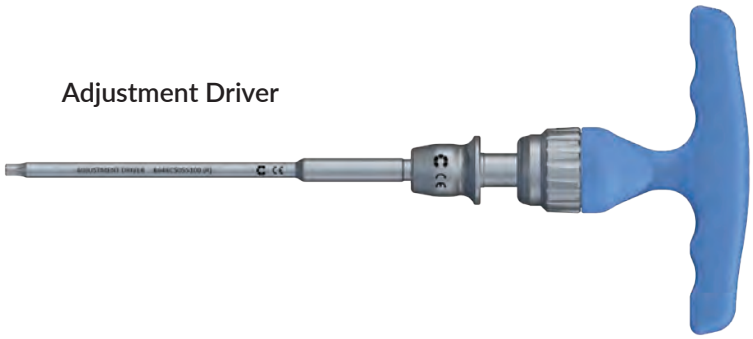


Figure 2e

Step 3: Screw Adjustment

The **Adjustment Driver** may be used to adjust the depth of the 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 3a)**

Adjustment Driver



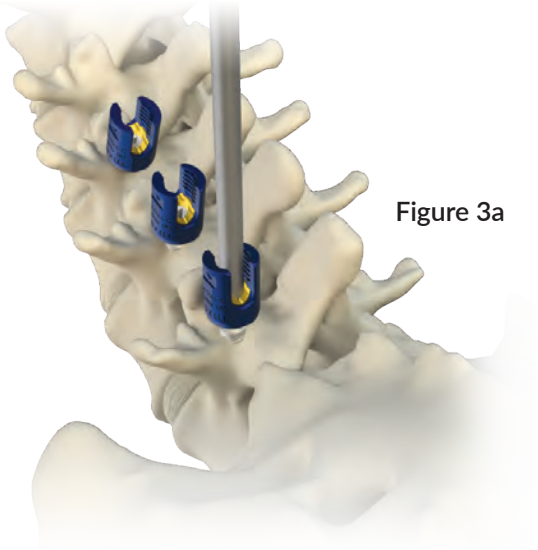
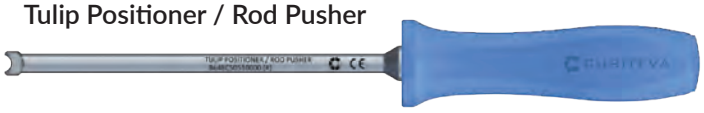


Figure 3a

The **Tulip Positioner / Rod Pusher** may be inserted into the tulip of the Pedicle Screw and rotated to adjust the position of the tulip before Rod placement. **(Figure 3b)**

Tulip Positioner / Rod Pusher



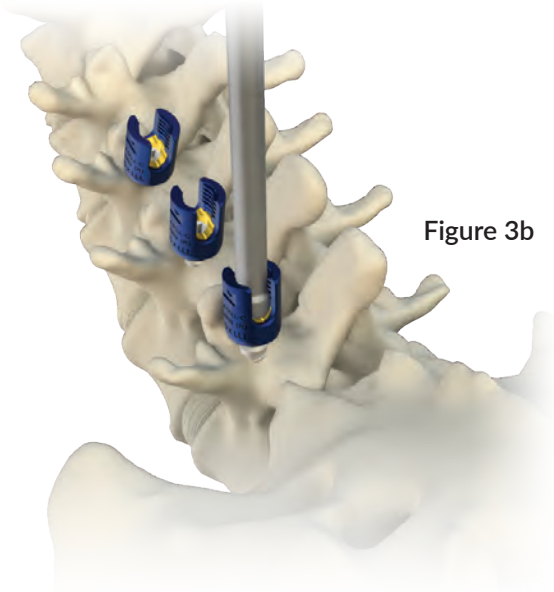


Figure 3b

Step 4: Rod Selection and Placement

Select the desired Rod and use the **Rod / Crosslink Holder** to place the Rod into the construct. **(Figure 4a)** The **Rod Bender** may be used to contour the Rod as needed. **(Figure 4b)** A **Rod Template** is available to determine the appropriate Rod contour and length.

Rod Template

Rod Bender

Rod / Crosslink Holder

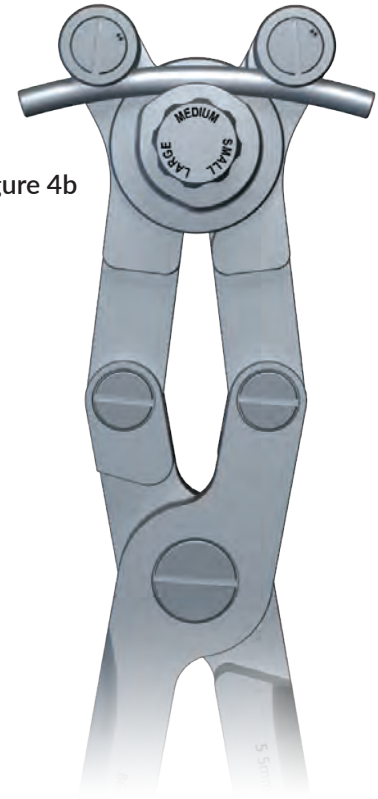


Figure 4b

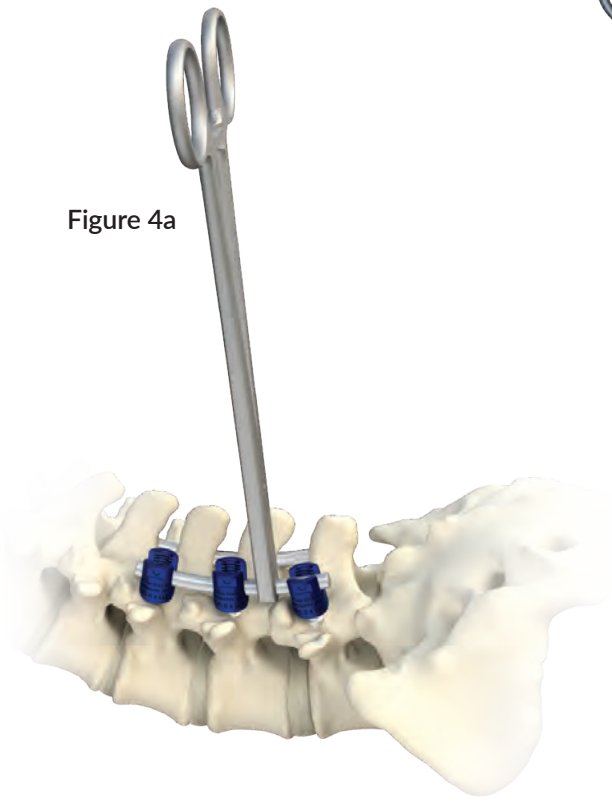
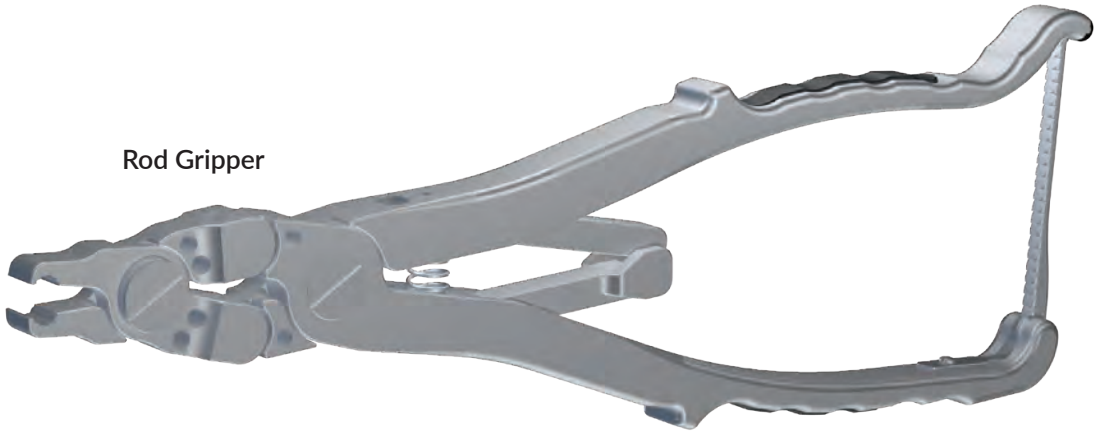


Figure 4a

Note: Curved Rods are available in the standard tray build. Straight Rods are available by request only.

Note: A **Rod Gripper** is available by request only to aid in Rod placement/adjustment, shown below.



Step 5: 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 **Rod / Crosslink Holder** or **Rod Gripper** still in place, insert the Set Screw into the tulips using the **Set Screw Starter**. Thread the Set Screw until it contacts the Rod. Repeat for each tulip. **(Figure 5)**

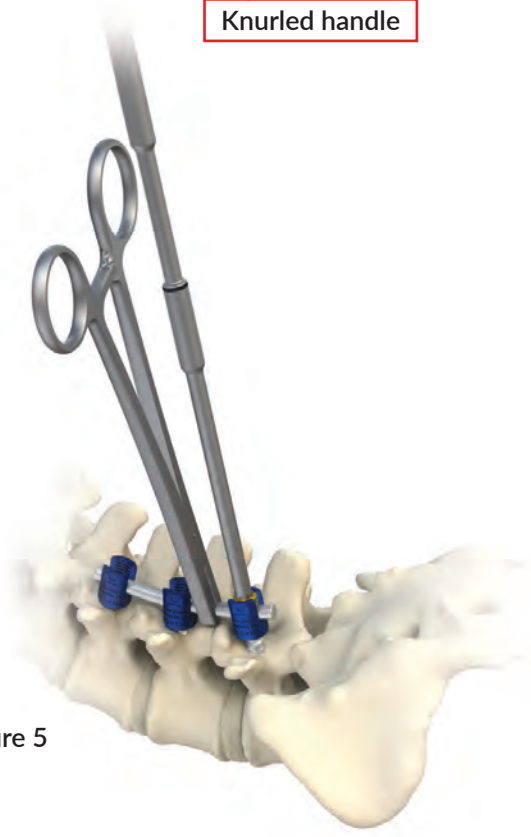


Figure 5

Step 6: Rod Reduction

The Prodigy Pedicle Screw System offers multiple methods to fully seat the Rod into the Pedicle Screw to allow proper installation of the Set Screw. The surgeon may utilize any of the following methods depending on the anatomy and the level of reduction required.

If minor Rod reduction with mild resistance is required, the **Tulip Positioner / Rod Pusher** may be used to seat the Rod into place. **(Figure 6a)**

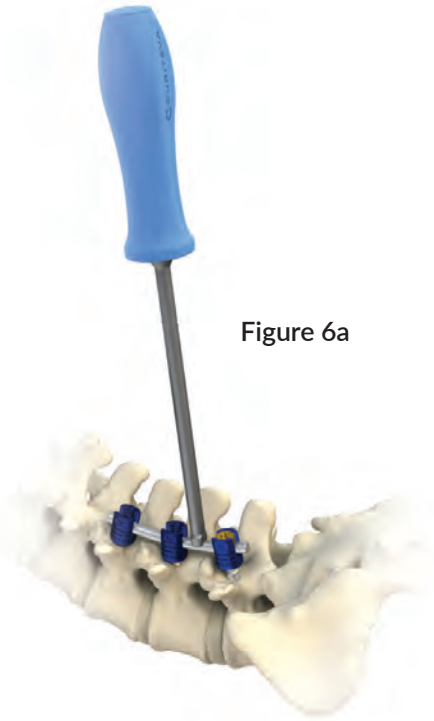


Figure 6a

The **Rod Rocker** may also be used to approximate the Rod into the tulip. Attach the Rod Rocker to the tulip by engaging the holes on both sides and lever the Rod until seated into the tulip. **(Figure 6b)**

> **Note:** The Rod Rocker achieves approximately 12mm of reduction.

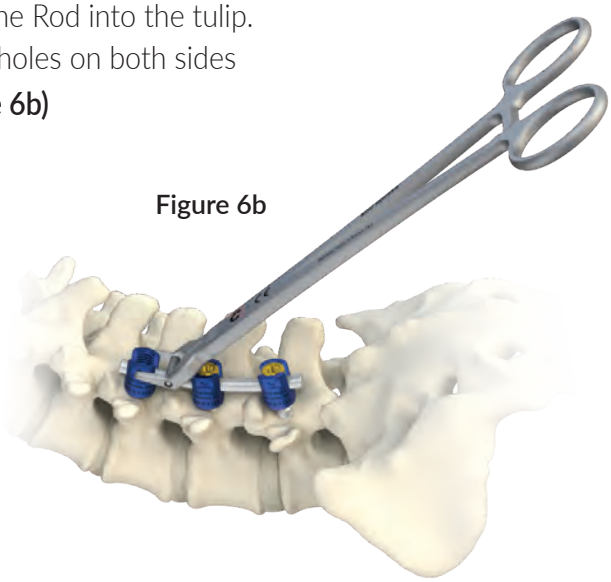


Figure 6b

Reduction Pedicle Screws are available as a substitute to the Standard Pedicle Screw, and feature 26mm of thread length for Rod reduction.

> **Note:** When using Reduction Pedicle Screws, the **Extended Tab Pedicle Screw Driver** should be used for quicker engagement, as shown below. The Extended Tab Pedicle Screw Driver is available by request only.

The **Axial Persuader** may be used to reduce the Rod. The Axial Persuader snaps onto the outer diameter of the tulip.

- Ensure the Axial Persuader inner shaft is positioned proximal by rotating the knob counterclockwise until stopped. **(Figure 6c)**
- Align the rod slot of the Axial Persuader with the rod slot of the tulip and press downward until the Axial Persuader release arms snap onto the side cutouts of the tulip. When properly seated, the inside shoulder of the Axial Persuader outer shaft will contact the top surface of the tulip. **(Figure 6d)** To ensure proper engagement, gently pull up on the Persuader confirming it is locked onto the screw.

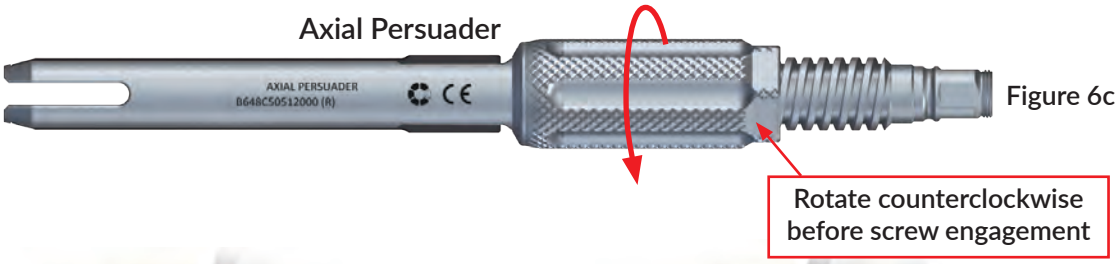


Figure 6c

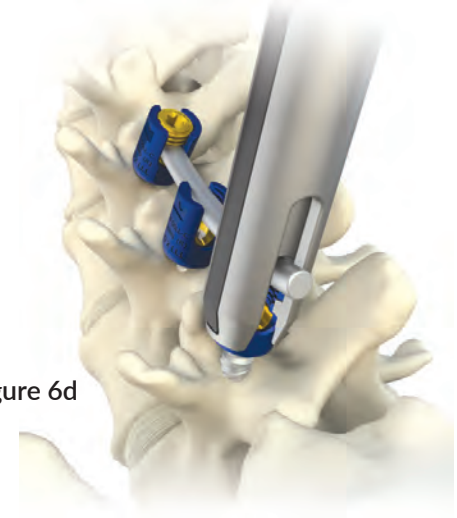


Figure 6d

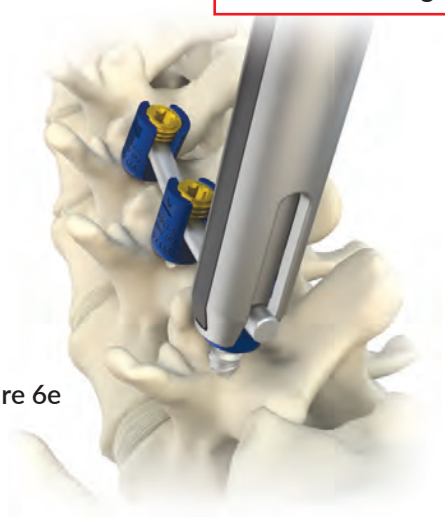


Figure 6e

- Reduce the Rod into the tulip by rotating the Axial Persuader knob clockwise. **(Figure 6e)**

Note: The Axial Persuader offers up to 30mm of rod reduction.

Note: If desired, the **Handle Extender** may be used to aid in rotating the Axial Persuader knob to reduce the Rod. **(Figure 6f)**

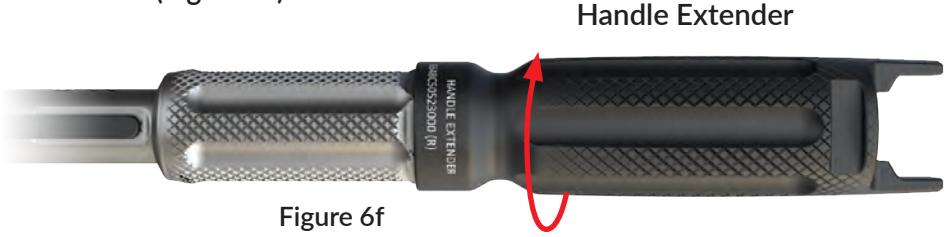


Figure 6f

- Once the rod is fully seated into the tulip, load the Set Screw onto the tip of the self-retaining Set Screw Starter and pass it through the Axial Persuader. Thread the Set Screw into the tulip until it contacts the Rod. **(Figure 6g)**
- Once fully reduced with the Set Screw installed, press on both sides to release.

Set Screw Starter

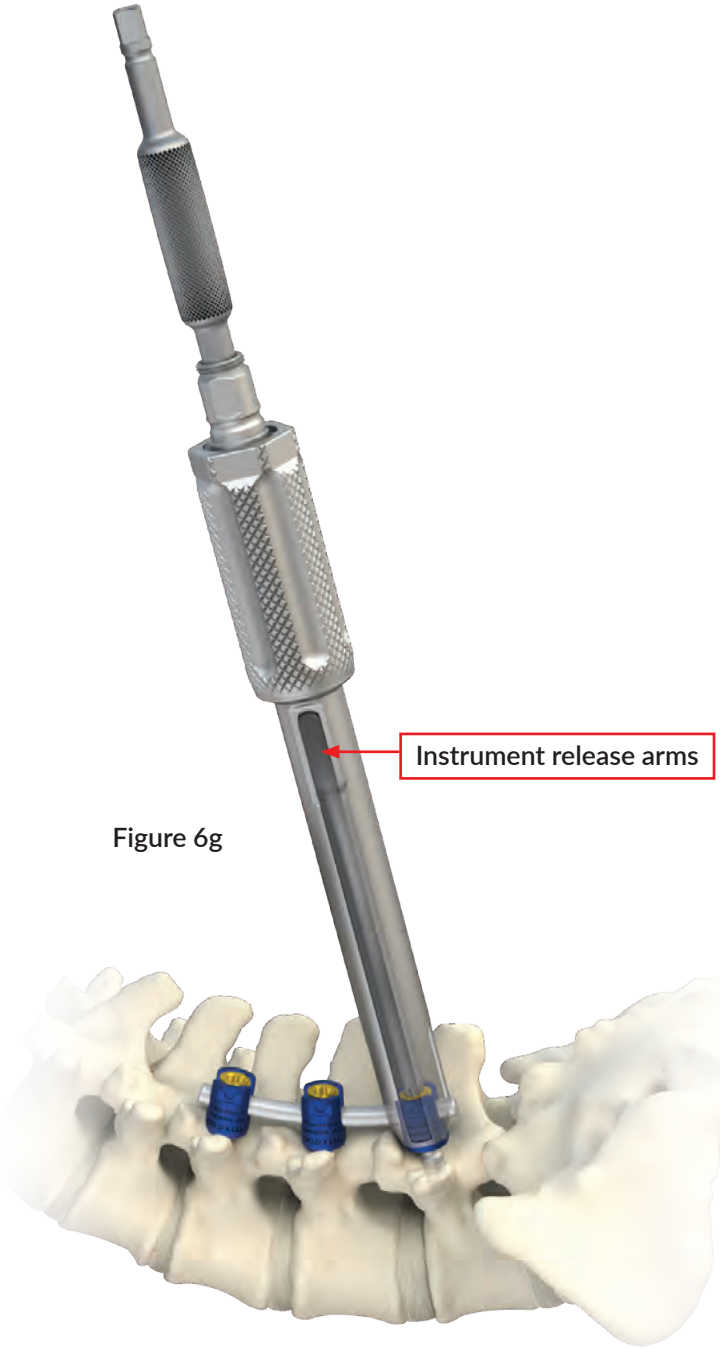


Figure 6g

- If desired, the Set Screw can be final tightened through the Axial Persuader. **(Figure 6h)**
  - Key the **Counter Torque Handle** to the back of the Axial Persuader inner shaft and press until it snaps into position. It is optional to thread the knurled knob of the Counter Torque Handle onto the Axial Persuader inner shaft for a more secure fit.

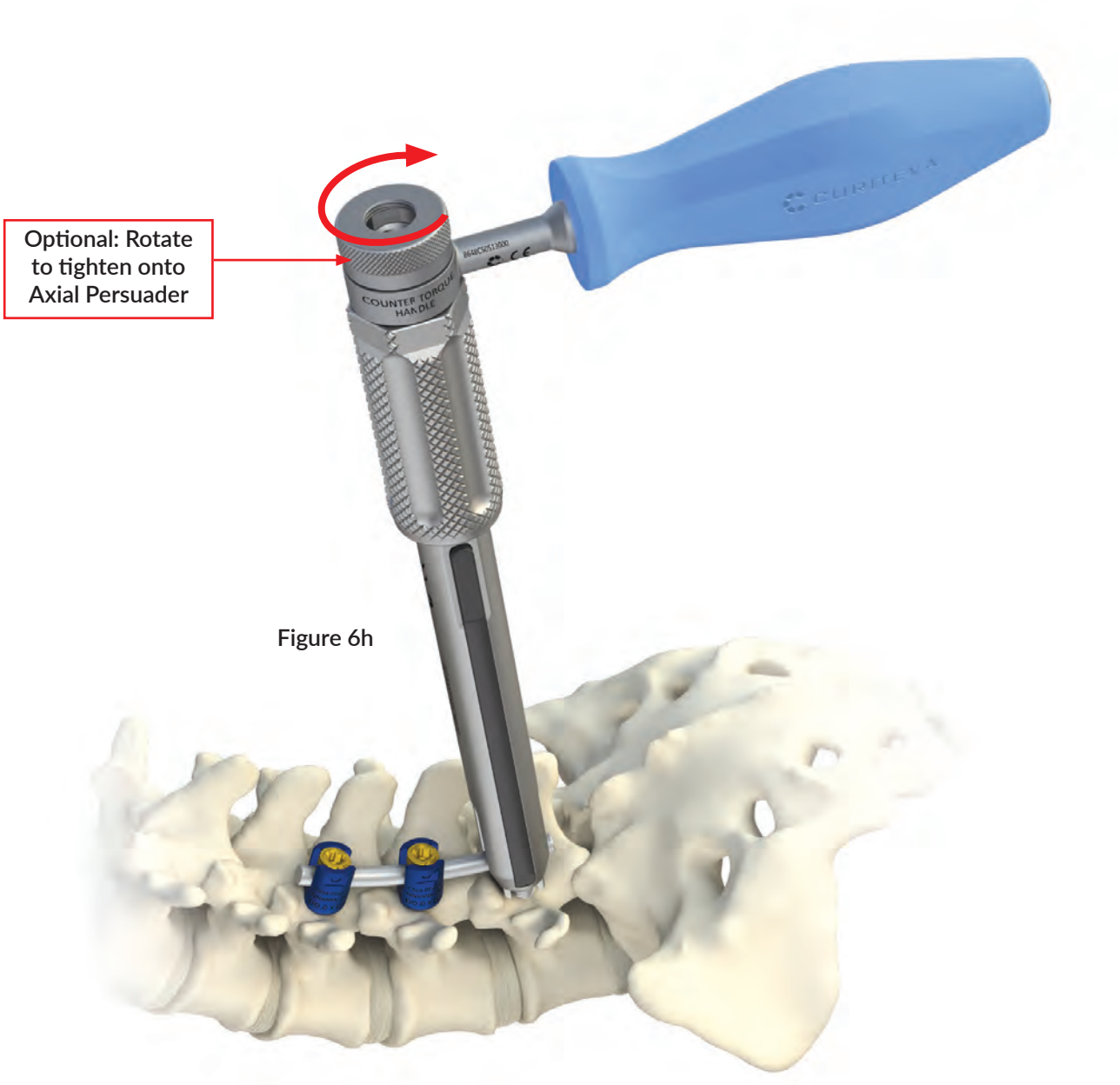


Figure 6h

- Attach the **80 in-lbs Torque Limiting T-Handle** to the back of the **Final Locking Set Screw Driver**.

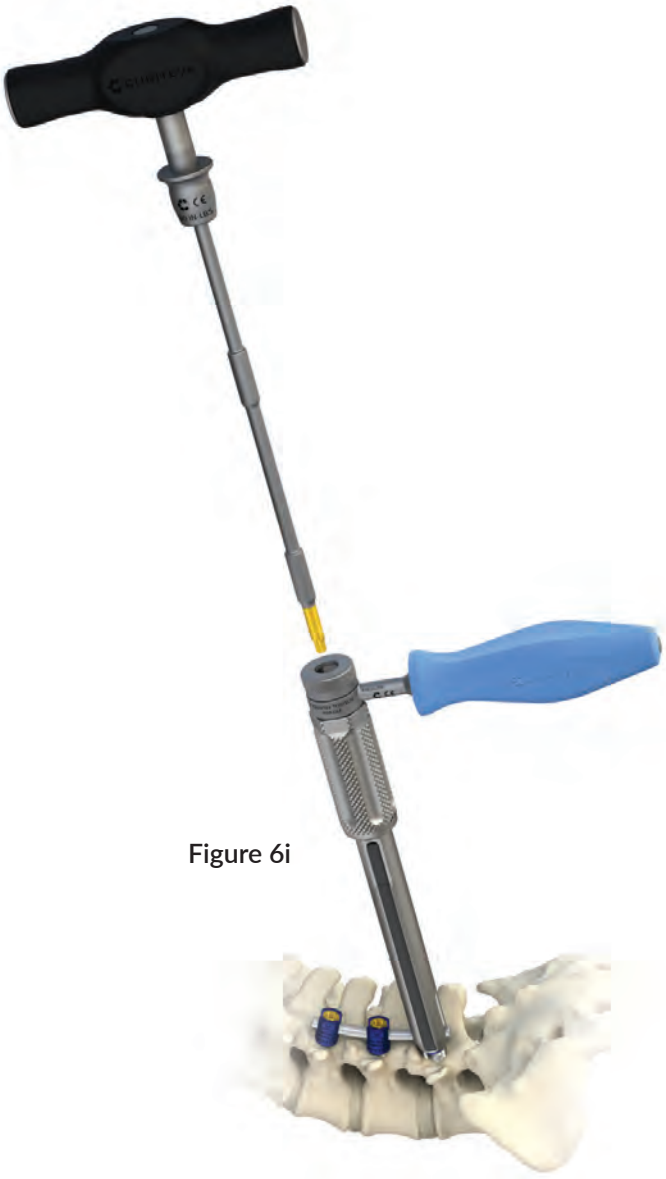


Figure 6i

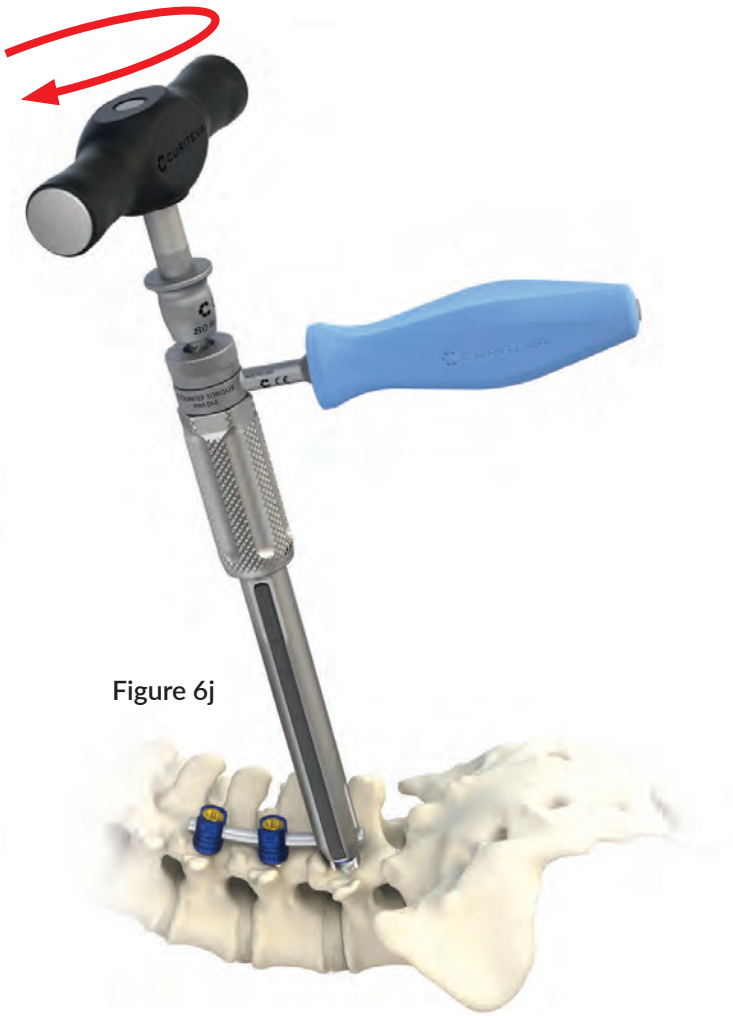


Figure 6j

- Insert the Final Locking Set Screw Driver through the Axial Persuader to engage the hexalobe feature of the Set Screw. **(Figure 6i)**
- Rotate the 80 in-lbs Torque Limiting T-Handle clockwise until the handle releases at the 80 in-lbs limit, confirmed with an audible "click". **(Figure 6j)**

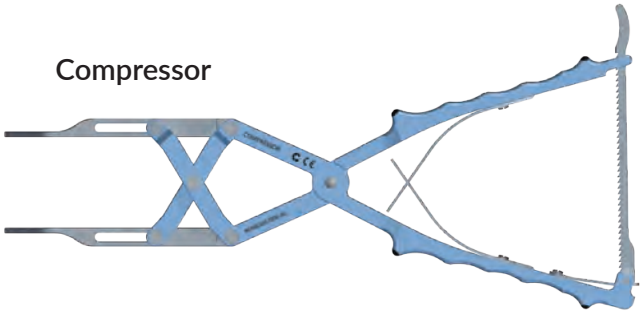
- Release the Axial Persuader from the tulip by pressing the release arms on the sides of the outer shaft.

  Note: The release arms cannot be actuated until the Axial Persuader is in the reduced position (knob fully rotated clockwise).

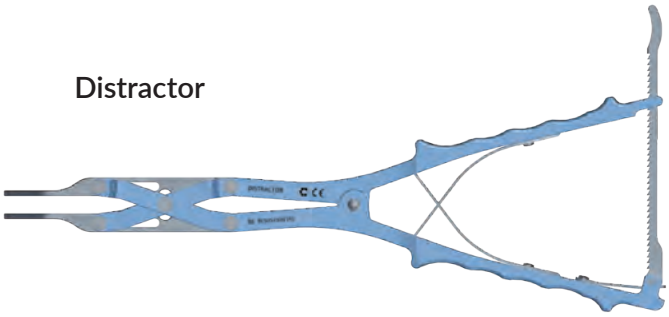
Step 7: Compression/Distraction

- Use the **Compressor** or **Distractor** to achieve the desired level of compression or distraction. **(Figure 7a, 7b)**

Compressor



Distractor



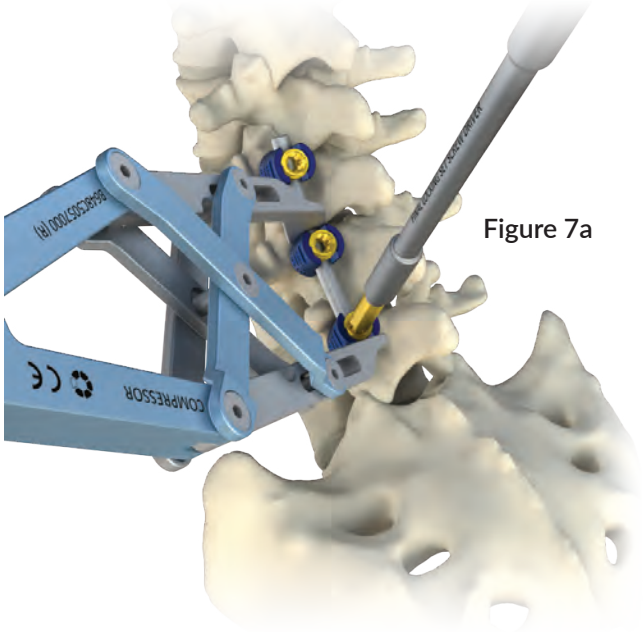


Figure 7a

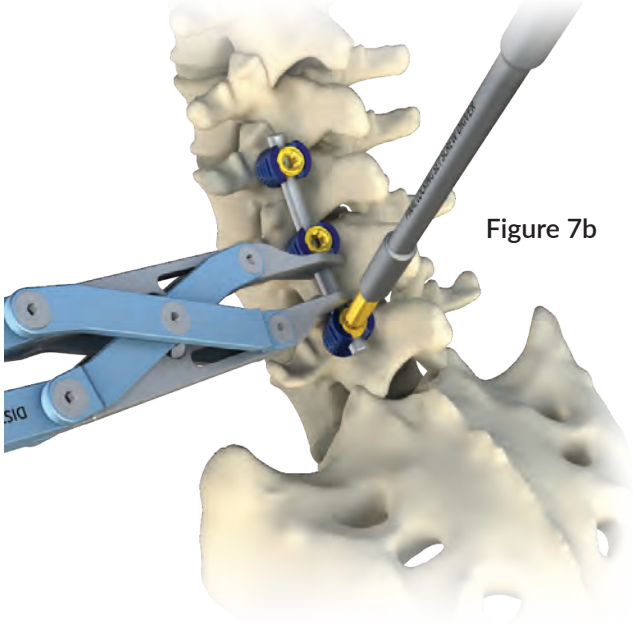


Figure 7b

- Final tighten the desired Set Screw and leave the adjacent Set Screw loose during compression or distraction to allow the loose Pedicle Screw to move along the Rod in the desired direction.
- Tighten the loose Set Screw once the desired compression or distraction is achieved.

Step 8: 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. **(Figure 8a)**
- After the Rods and all Set Screws are secured within the tulips, place the Pedicle Screw Sleeve over the tulip and seat onto the Rod.

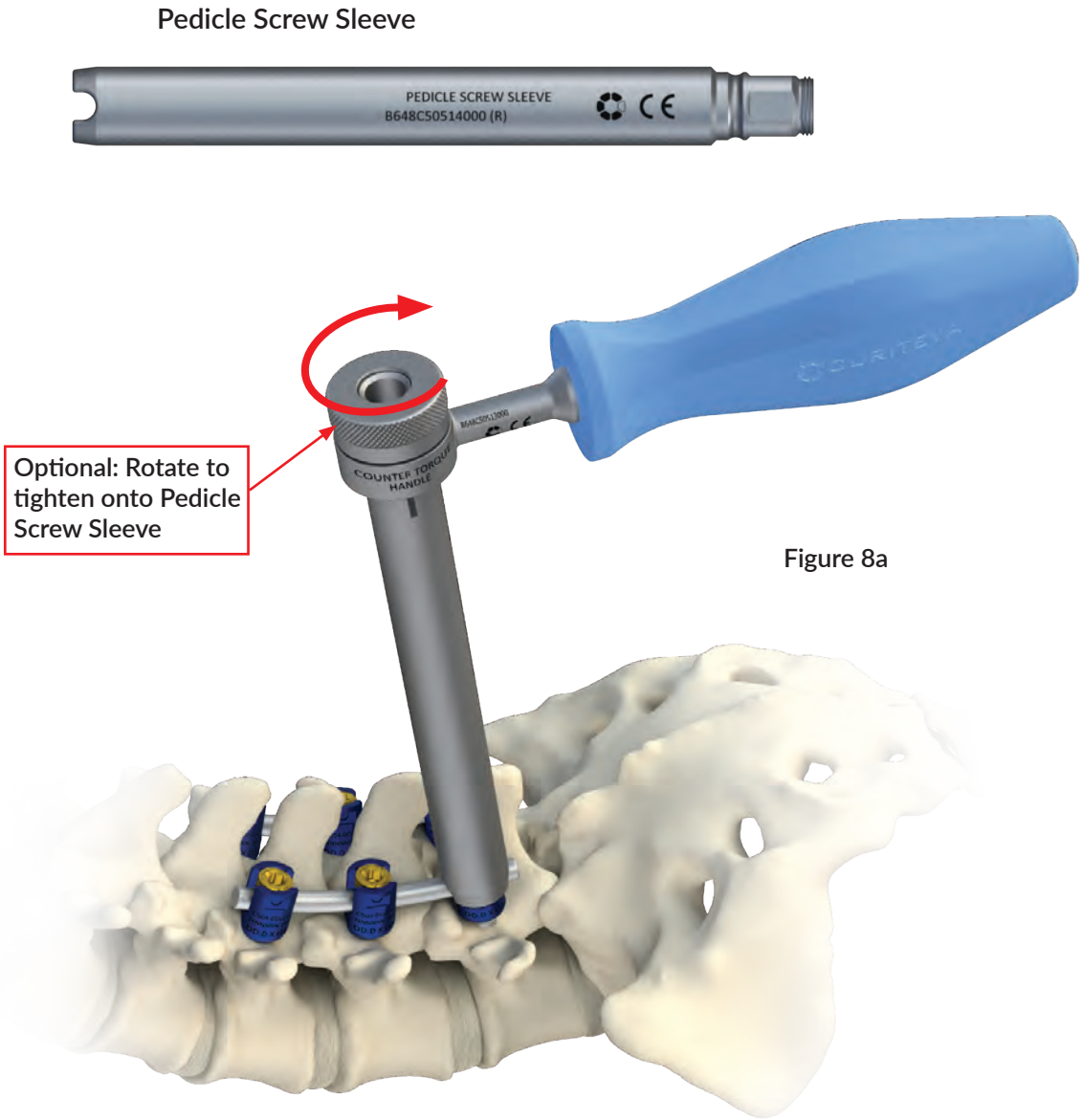


Figure 8a

- Attach the **80 in-lbs 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 8b)**

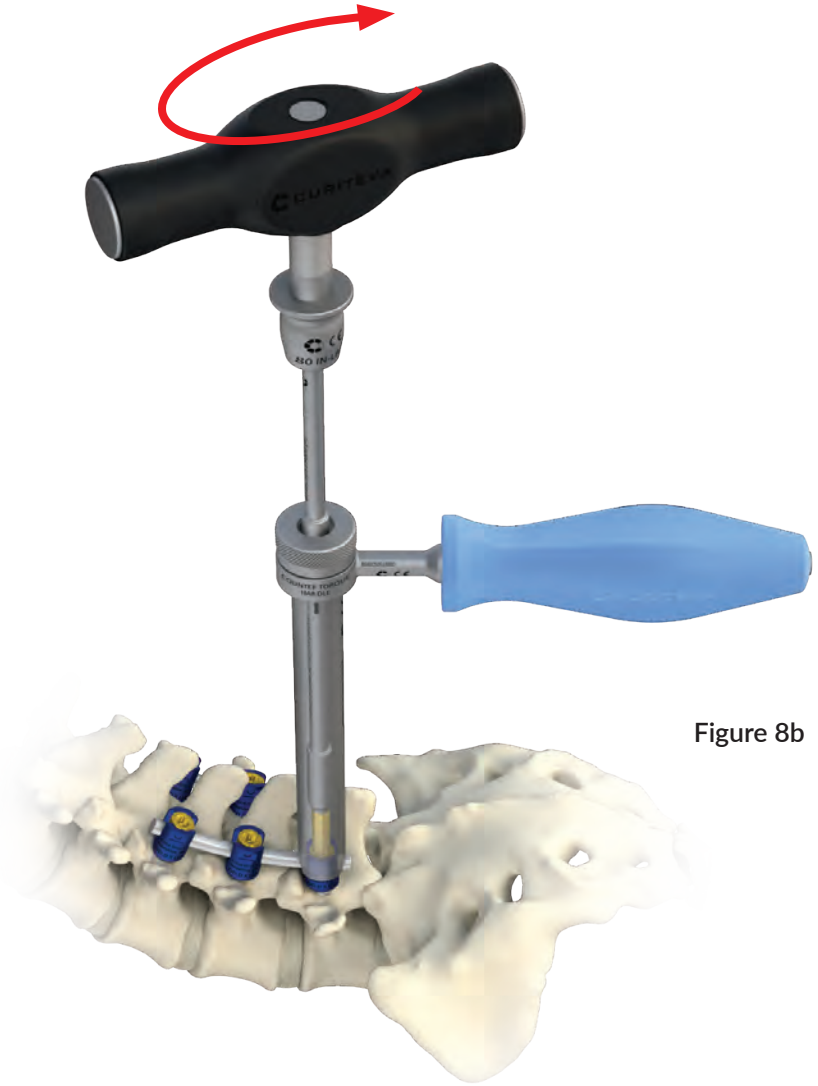


Figure 8b

Final Locking Set Screw Driver

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

Step 9: Tab Removal (optional)

- If Reduction Pedicle Screws were used, use the **Reduction Tab Breaker** to remove the extended tabs after final tightening is complete.
- Slide the Reduction Tab Breaker over one extended tab at a time so that the "INSIDE" marking is positioned inside the tulip and the "OUTSIDE" marking is positioned outside the tulip. Ensure the Reduction Tab Breaker is fully seated prior to breaking the tab. **(Figure 9a)**

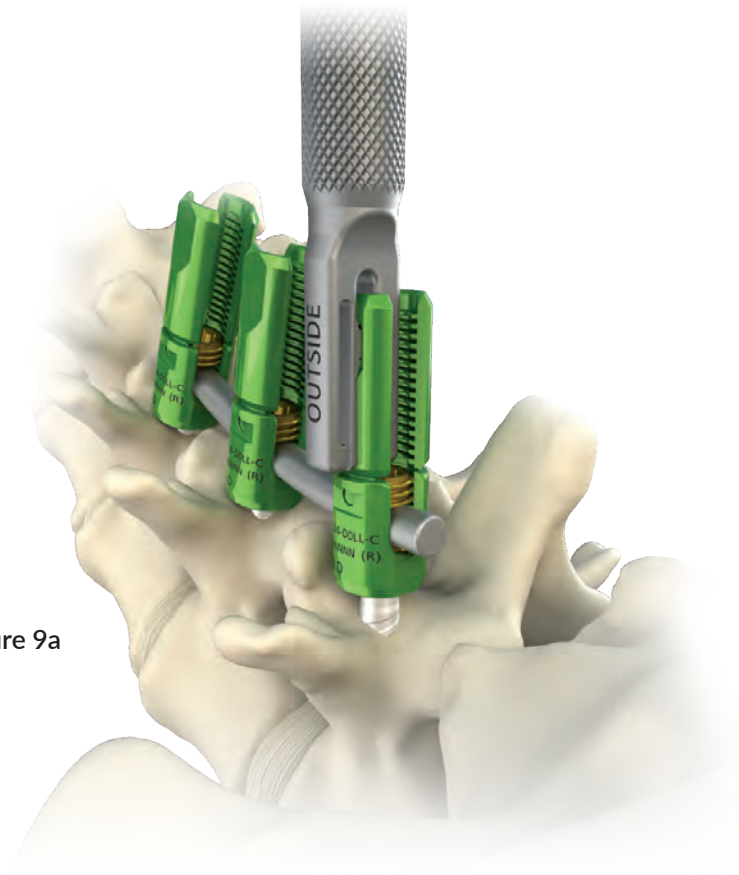


Figure 9a

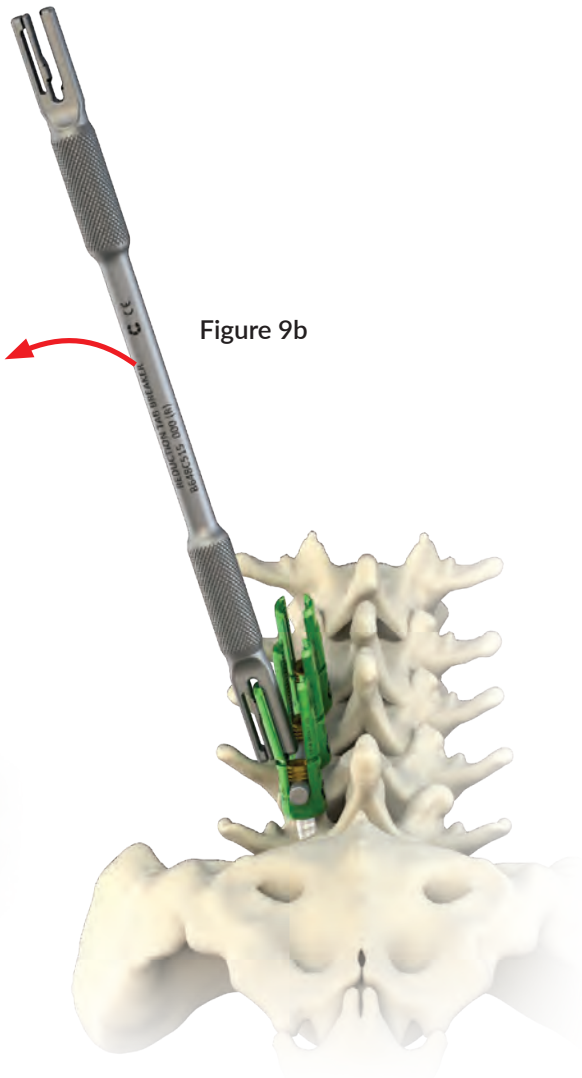


Figure 9b

- With one side of the tulip engaged, rock the Reduction Tab Breaker away from the screw medial/lateral to snap off the tab and remove. The Reduction Tab Breaker will retain the tab after it's broken away, and may be flipped to use the opposite end for the other tab. **(Figure 9b)**
- Repeat for all remaining Reduction Pedicle Screws.

Step 10: Crosslink (optional)

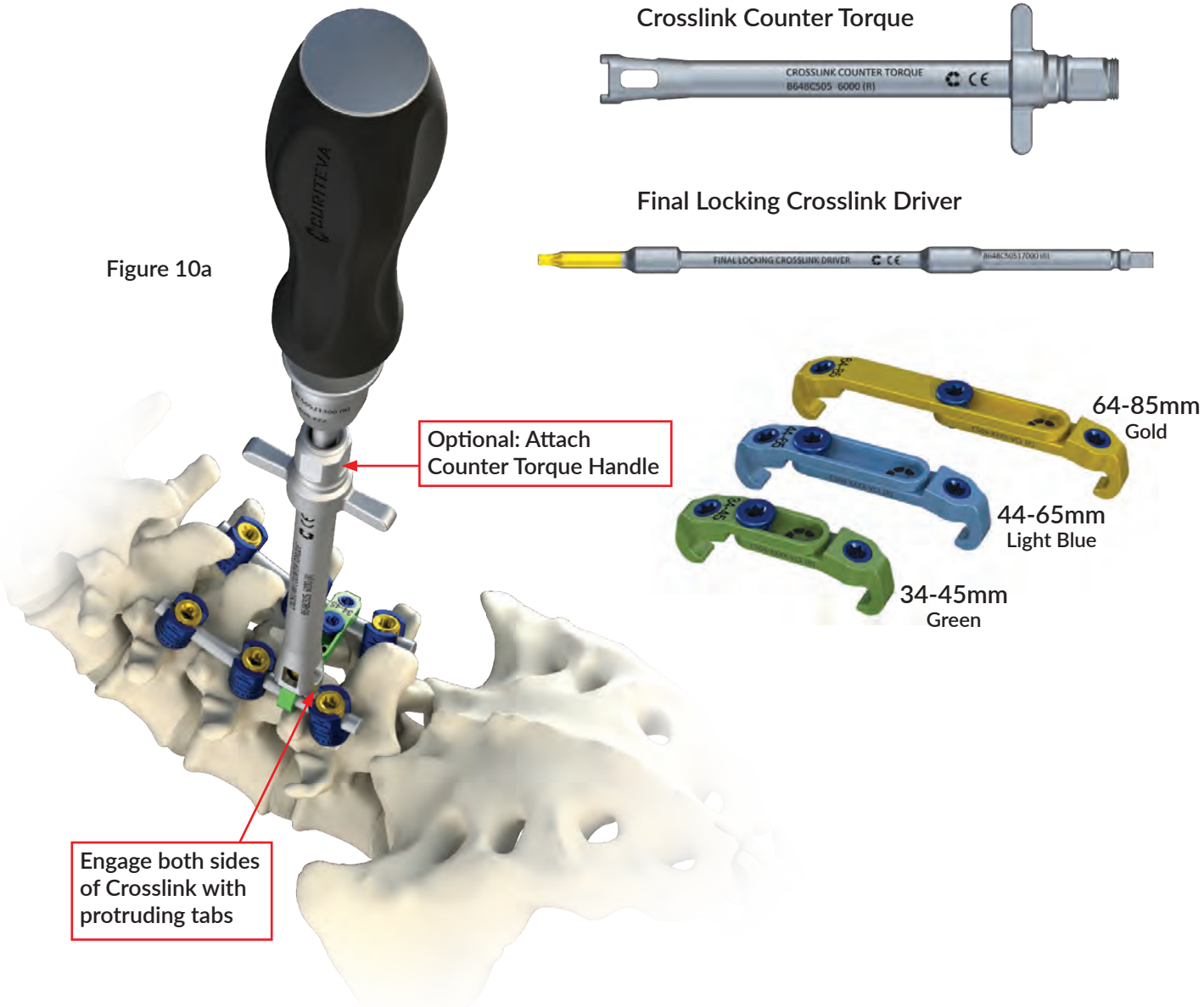
Variable length rod to rod Crosslinks are available for additional torsional rigidity.

- Use the **Rod / Crosslink Holder** to grip the appropriate length Crosslink and position it onto the Rods.
- Ensure both arms of the Crosslink are fully seated on the Rods. It is recommended to tighten the lateral set screws of the Crosslink before the center set screw.
- Place the **Crosslink Counter Torque** over the lateral set screw of the Crosslink so that the protruding tabs rest on the sides of the crosslink arm.

Note: If desired, the Counter Torque Handle can be attached to the back of the Crosslink Counter Torque.

- Attach the **40 in-lbs Torque Limiting Axial Handle** to the back of the **Final Locking Crosslink Driver**.
- Insert the Final Locking Crosslink Driver through the Crosslink Counter Torque to engage the hexalobe feature of the set screw. **(Figure 10a)**

Figure 10a



- Rotate the 40 in-lbs Torque Limiting Axial Handle clockwise until the handle releases at the 40 in-lbs limit, confirmed with an audible “click”.
- Repeat for the lateral set screw on the other arm of the Crosslink.
- Repeat for the center set screw of the Crosslink. **(Figure 10b)**

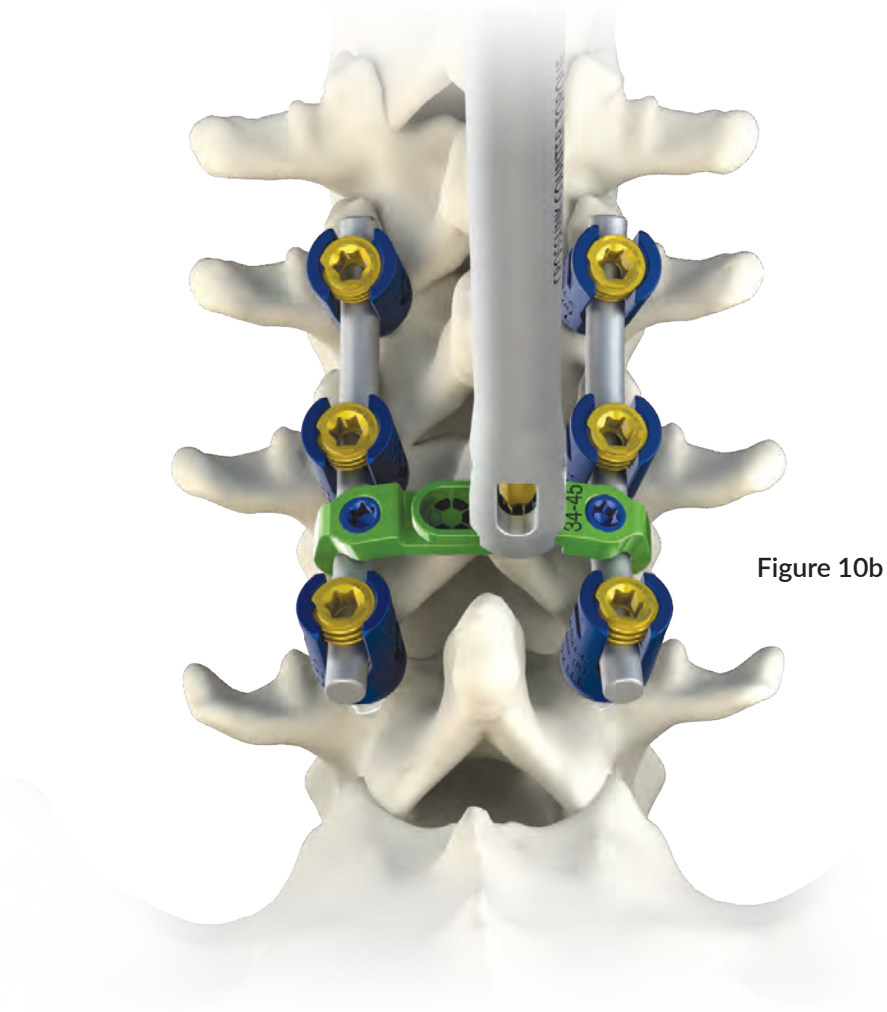
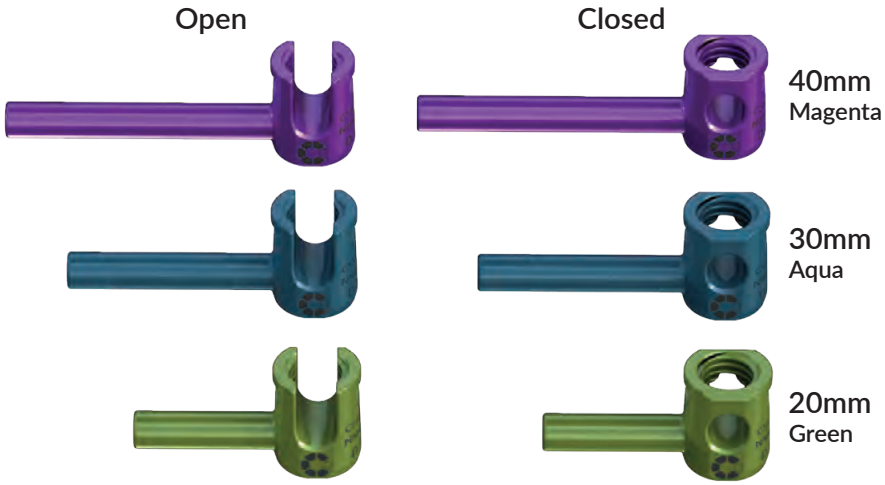


Figure 10b

Step 11: Offset Connectors (optional)

Open and Closed Offset Connectors are available by request only in 20, 30, and 40mm offset lengths. The offset rod is Ø5.5mm.

- Position the desired size Offset Connector to the Rod and adjacent Pedicle Screw tulip.
- Load a Set Screw onto the **Set Screw Starter**, and thread the Set Screw into the adjacent Pedicle Screw to secure the offset rod of the Offset Connector.
- Use the Set Screw Starter to insert a Set Screw into the Offset Connector, securing the connector to the Rod.
- Final tighten the Set Screws to 80 in-lbs using the same method as the Pedicle Screws. **(see step 8)**



Step 12: Implant Removal (optional)

If revision is necessary, Set Screws and 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 un-threaded. 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. The Crosslinks can be removed by loosening the lateral and center set screws using the Final Locking Crosslink Driver.

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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