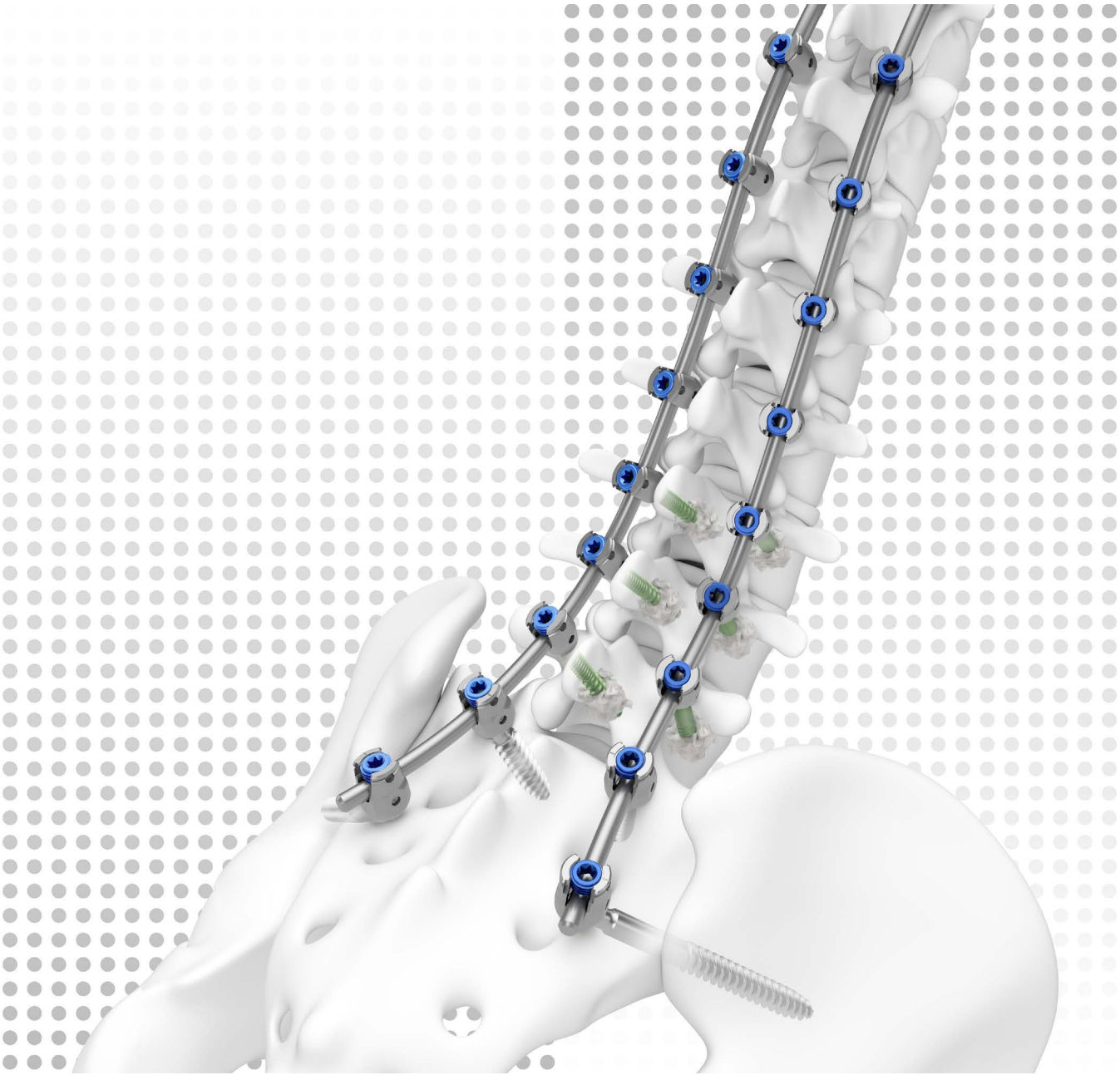
TriALTIS™

SPINE SYSTEM

Surgical Technique



DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

For more information, please refer to the full Instructions for Use (IFU):
TriALTIS IFU-0902-90-407

Additional IFUs are referenced on page 50.

■ Optional Notes
▲ Warnings and Precautions

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Product Descriptions

The TriALTIS™ Spine System is a streamlined offering to allow surgeons greater flexibility for their individual techniques while delivering consistent surgeon experience across the portfolio.

The system is comprised of a comprehensive set of implants and instruments for use in posterior spinal procedures.

The cases and trays include modularity for multiple pedicle screw, and rod configurations.
The instruments includes drills, taps, drivers, reducers, compressors and distractors, power, and cement delivery options.

Preoperative Preparations

Imaging

It is a prerequisite that, due to the anatomic variability of each patient, the surgeon has available the range of necessary images in order to plan the operation appropriately.

Use of cross-sectional imaging (i.e., CT and/or MRI) for posterior screw placement is recommended. The use of planar radiographs (or fluoroscopy) alone may not provide the necessary imaging to mitigate the risk of improper screw placement.

In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Patient Positioning

Patient positioning is critical for posterior fusion procedures. Place the patient on the operating table in the desired position.

Proper patient position should be confirmed via direct visualization and by radiographs prior to draping.

Approach

Expose the posterior bony elements sufficiently to allow placement of implants as well as preferred graft material in and around the decorticated posterior elements.

Pedicle Preparation

Instruments used in this step

5161-00-5000	Awl
5161-00-5003	Probe, Lumbar Straight
2997-04-125	Ball Tip Feeler Straight

Prepare the screw bed and locate the desired entry point.

A. Perforate the cortex using the **Awl** or **Burr**.

B. Cannulate the pedicle using the **Probe**. Markings on the probes indicate the approximate probe depth and can be used to inform screw length size selection.

Inspect the pedicle cannulation using the **Ball Tip Feeler**.

■ Note:
If tapping is preferred, select the desired tap and modular handle. Markings on the taps indicate the approximate tap depth and can be used to inform screw length size selection. Numbers on the probes and taps are shown on the device in centimeters to maximize legibility. A reading of “4” on a probe or tap indicates an approximate depth of 40 mm.

▲ Caution:
Examine the pedicle wall on all sides to verify integrity. Choose the preferred diameter screw and tap sized for the available bone. Refer to patient flouroscopic imaging for definitive depth, trajectory and size of planned implants.

■ Note:
The gold color extends 30 mm from the tip of the probe to visualize the depth of the pedicle (Fig. 1).

Fig. 1

Pedicle Preparation

Alternative Instruments

5161-00-5001	Probe, Thoracic Straight
5161-00-5002	Probe, Thoracic Curved
5161-00-5004	Probe, Lumbar Curved
2997-04-130	Ball Tip Feeler Curved
5161-00-0040	Tap, Long 4.0 mm
5161-00-0050	Tap, Long 5.0 mm
5161-00-0060	Tap, Long 6.0 mm
5161-00-0070	Tap, Long 7.0 mm
5161-00-0080	Tap, Long 8.0 mm
5161-00-0090	Tap, Long 9.0 mm
5161-00-0100	Tap, Long 10.0 mm
5161-00-0110	Tap, Long 11.0 mm
5161-00-0120	Tap, Long 12.0 mm
5161-00-5010	T-Handle, Ratcheting
5161-00-5011	Inline Handle, Ratcheting

Pedicle Preparation

Drilling / Tapping

Instruments used in this step

5161-00-5071	Drill Bit, 2.4 mm
05.001.261	Square Quick Coupling, Drill
2997-04-125	Ball Tip Feeler Straight
05.001.262	Square Quick Coupling, Tap/Screw

A. Connect the **Drill Square Quick Coupling** to the power handpiece.

B. Assemble the Drill Bit into the **Drill Square Quick Coupling**.

Proper connection is achieved when the line of the Drill Bit aligns with the distal face of the coupling (Fig. 2).

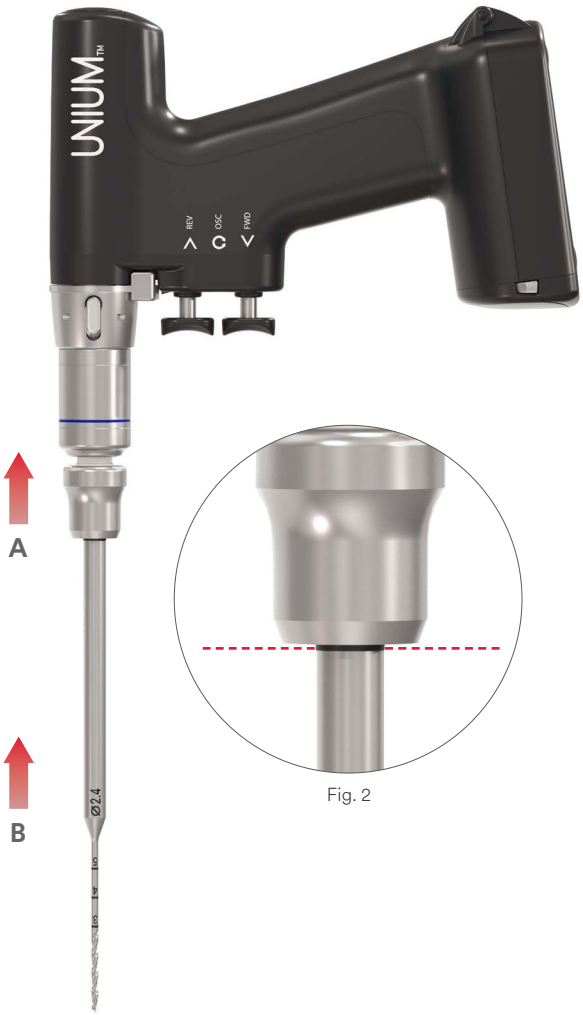


Fig. 2

Prepare the screw bed and locate the desired entry point. Use the Awl or Burr to perforate the cortex. Select appropriate drill bit based on patient anatomy and preferred screw diameter to cannulate the pedicle.

Inspect the pilot hole using a ball tip feeler by palpating the pedicle wall on all sides.

If tapping is preferred, select the desired tap and connect to the **Tap/Screw Square Quick Coupling**.

■ Note:
The TriALTIS™ Spine System utilizes a Quarter Inch Square Coupling that allows all modular instruments to work with the entire suite of handles as well as a **Square Quick Coupling** for the powered handpiece.

Alternative Instruments

5161-00-5072	Drill Bit, 3.2 mm

Screwdriver Assembly

Instruments used in this step

5161-00-5006	Screwdriver, T27 Long Cann
5161-00-5116	Retaining Sleeve, Long
5161-00-5070	Slip Sleeve, Long
5161-00-5010	T-Handle, Ratcheting

A. Slide the **Retaining Sleeve** onto the **T27 Screwdriver** until the button snaps over the shoulder.

■ Note:
The **T27 Screwdriver** has 2 shoulders. Use the distal shoulder when using Polyaxial and Favored Angle screws.

B. Slide the **Slip Sleeve** onto the **Retaining Sleeve** until the spring fingers snap over the shoulder on the **Retaining Sleeve**.

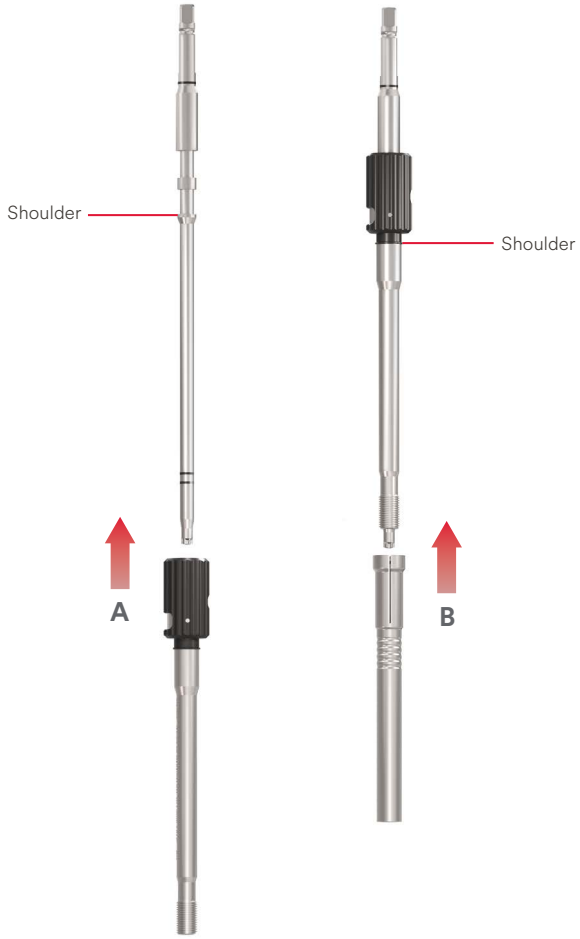
C. Connect the preferred handle to the screwdriver assembly.

Proper connection is achieved when the line of the **T27 Screwdriver** aligns with the distal face of the coupling (Fig. 3).

For ratcheting handles, rotate the ratchet selector clockwise for forward and counterclockwise for reverse.

The ratchet selector can also be placed into a locked position to turn off the ratchet function (Fig. 4).

■ Note:
Care should be taken to not constrain the spring fingers on the **Slip Sleeve** when assembling or disassembling it to or from the **Retaining Sleeve**.



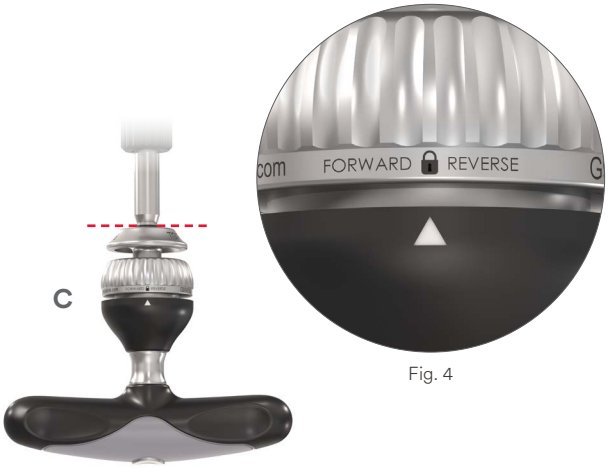


Fig. 4

Fig. 3

Screwdriver Assembly

Implant Loading

Instruments used in this step

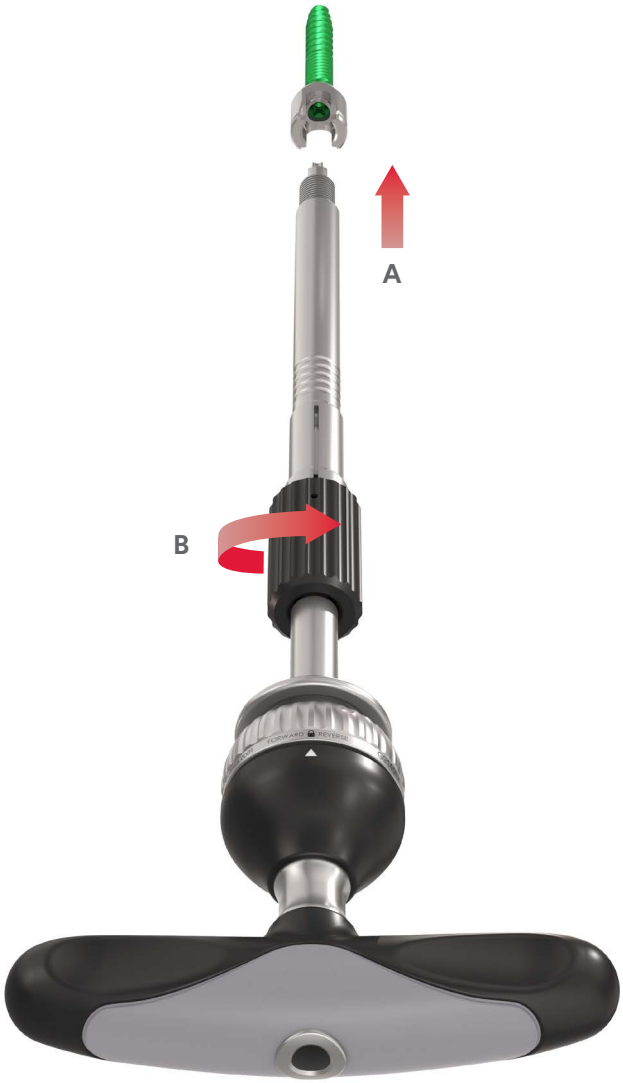
5161-00-5006	Screwdriver, T27 Long Cann
5161-00-5116	Retaining Sleeve, Long
5161-00-5070	Slip Sleeve, Long
5161-00-5010	T-Handle, Ratcheting

A. Place the Screwdriver tip securely into the **T27** recess of the pedicle screw.

■ Note:
Ensure the **Screwdriver** tip is fully engaged into the **T27** recess of the screw.

B. Rotate the **Retaining Sleeve** black knob clockwise until firmly tight.

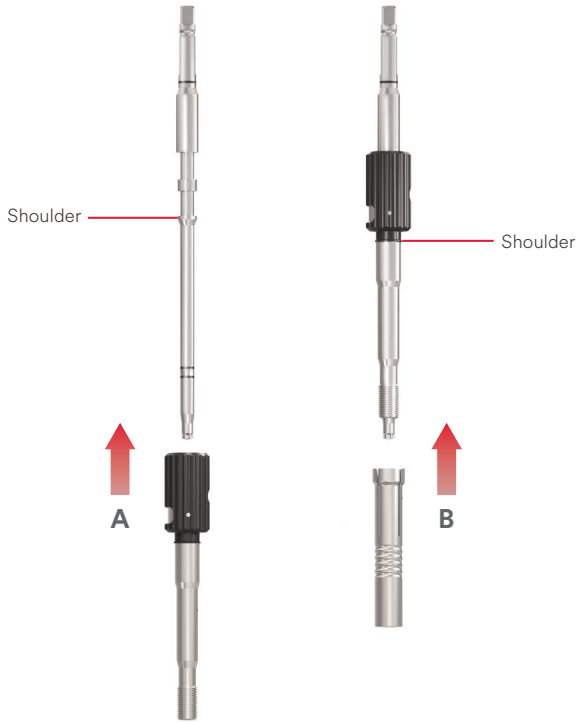
■ Note:
If a handle with a ratchet is used during implant engagement, the ratchet selector should be set to the Locked setting when tightening the **Retaining Sleeve** knob. For implant disengagement, the ratchet selector should be set to the Locked setting when loosening the **Retaining Sleeve** knob.



Powered Screwdriver Assembly

Instruments used in this step

5161-00-5074	Screwdriver, T27 Short Cann
5161-00-5117	Retaining Sleeve, Short
5161-00-5075	Slip Sleeve, Short
05.001.262	Square Quick Coupling, Tap/Screw



A. Slide the **Retaining Sleeve** onto the **T27 Screwdriver** until the button snaps over the shoulder.

■ Note:
The **T27 Screwdriver** has 2 shoulders. Use the distal shoulder when using **Polyaxial** and **Favored Angle** screws.

B. Slide the **Slip Sleeve** onto the **Retaining Sleeve** until the spring fingers snap over the shoulder on the **Retaining Sleeve**.

C. Connect the screwdriver assembly to the **Tap/ Screw Square Quick Coupling**. Proper connection is achieved when the line of the screwdriver aligns with the distal face of the coupling (Fig. 5).

■ Note:
Care should be taken to not constrain the spring fingers on the **Slip Sleeve** when assembling or disassembling it to or from the **Retaining Sleeve**.

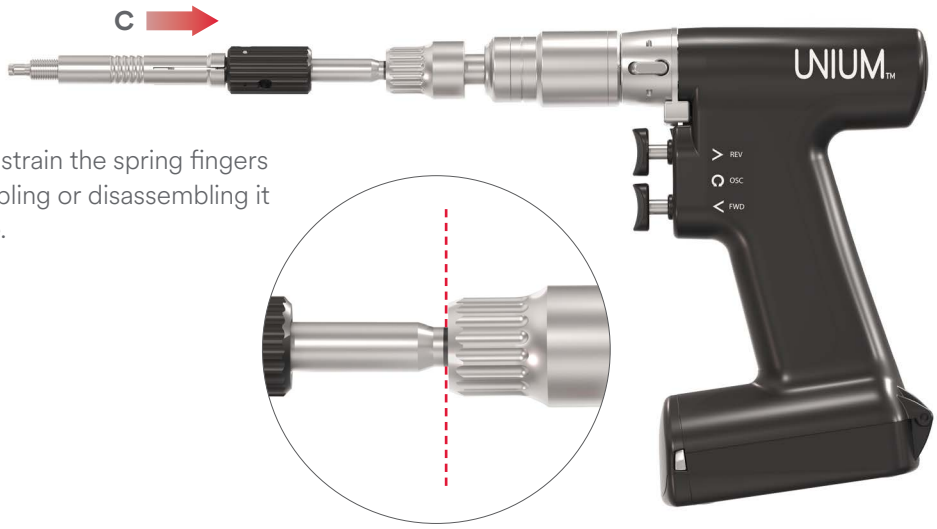


Fig. 5

Powered Screwdriver Assembly

Instruments used in this step

5161-00-5074	Screwdriver, T27 Short Cann
5161-00-5117	Retaining Sleeve, Short
5161-00-5075	Slip Sleeve, Short
5161-00-5097	Screwdriver, T27 Short Retain
05.001.262	Square Quick Coupling, Tap/Screw

A. Place the Screwdriver tip securely into the **T27** recess of the pedicle screw.

■ Note:
Ensure the Screwdriver tip is fully engaged into the **T27** recess of the screw.

B. Rotate the **Retaining Sleeve** black knob clockwise until firmly tight.

■ Note:
Ensure that the **Retaining Sleeve** is firmly tightened and that all instruments are correctly fitted into the power tool coupling.

Alternatively, use the **Retaining Screwdriver** to attach the pedicle screw.

C. Hold pedicle screw head firmly in hand.

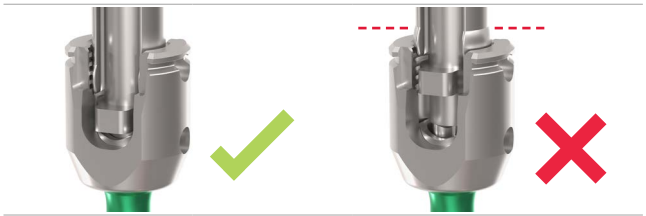
D. Align Retaining Screwdriver **T27** tip with screw shank **T27** recess and push firmly into screw head until fully engaged (Fig. 6). Refer to the table below for alternative instruments.

Fig. 6

Alternative Instruments

5161-00-5098	Screwdriver, T27 Long Retain

Retaining Screwdriver Implant Assembly



Pedicle Screw Insertion

Screw Insertion

Instruments used in this step

5161-00-5006	Screwdriver, T27 Long Cann
5161-00-5116	Retaining Sleeve, Long
5161-00-5070	Slip Sleeve, Long
5161-00-5010	T-Handle, Ratcheting
5161-00-5009	Head Adjuster 5.5-6.0
5161-00-5017	Mini Inline Handle

A. Introduce the screw into the prepared pedicle canal and advance clockwise until the desired depth is reached.

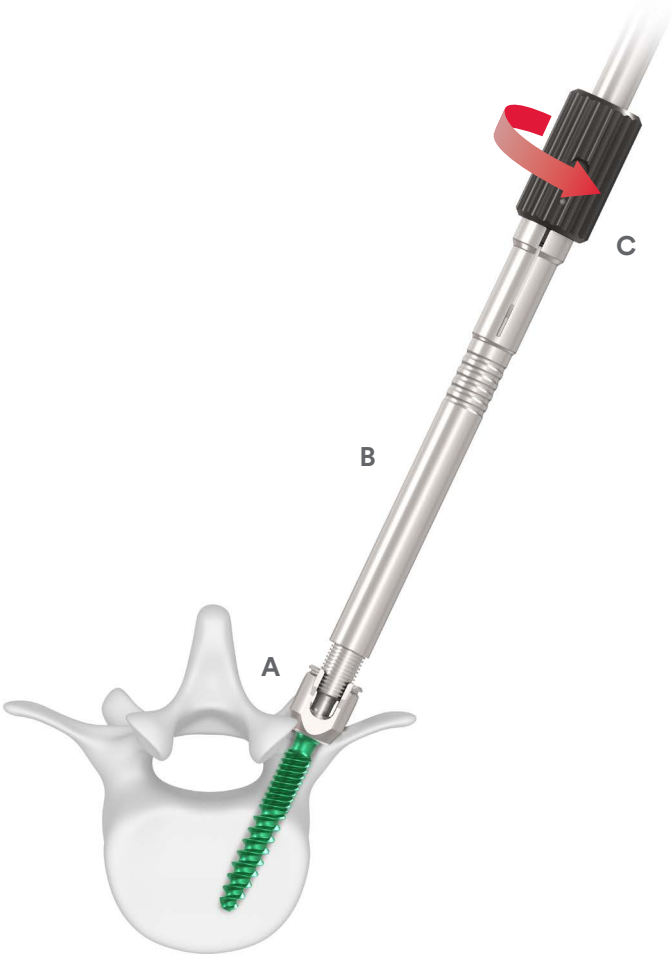
B. Stabilize the instrument by holding the **Slip Sleeve** throughout insertion.

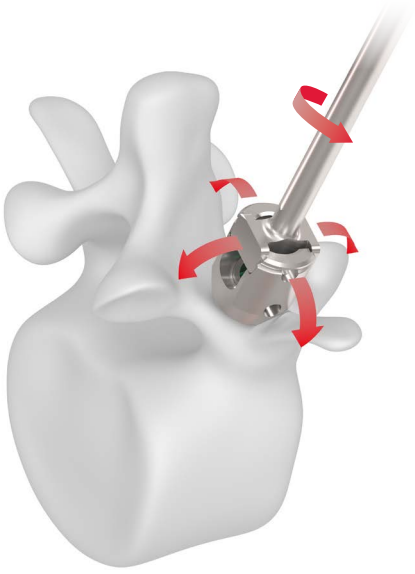
▲ Caution:
Excessive downward pressure on the **Slip Sleeve** will cause it to disengage from the **Retaining Sleeve**.

C. Rotate the **Retaining Sleeve** black knob counter-clockwise to disengage the instrument from the implant.

Prior to rod insertion, the **Head Adjuster 5.5-6.0** paired with a **Mini Inline Handle** may be used to adjust the orientation of the tulip.

▲ Caution:
Assess the mobility of the polyaxial heads. If the head does not pivot freely, prepare the surrounding tissue or adjust the screw depth to allow full mobility.





Cement Augmentation

Screwdriver Assembly - Cement

Instruments used in this step

5161-00-5058	Screwdriver, T27 Cement
5161-00-5059	Retaining Sleeve, Cement
5161-00-5075	Slip Sleeve, Short
5161-00-5060	Handle Adapter, Cement
5161-00-5011	Inline Handle, Ratcheting
2797-26-402	Plunger
2797-26-403	Alignment Device Cleaning Stylet
2797-26-511	Mini Cleaning Stylet

If enhanced fixation is desired, the **Fenestrated Screw** allows the delivery of cement through the fenestrated shank.

Refer to the surgical steps for pedicle preparation.

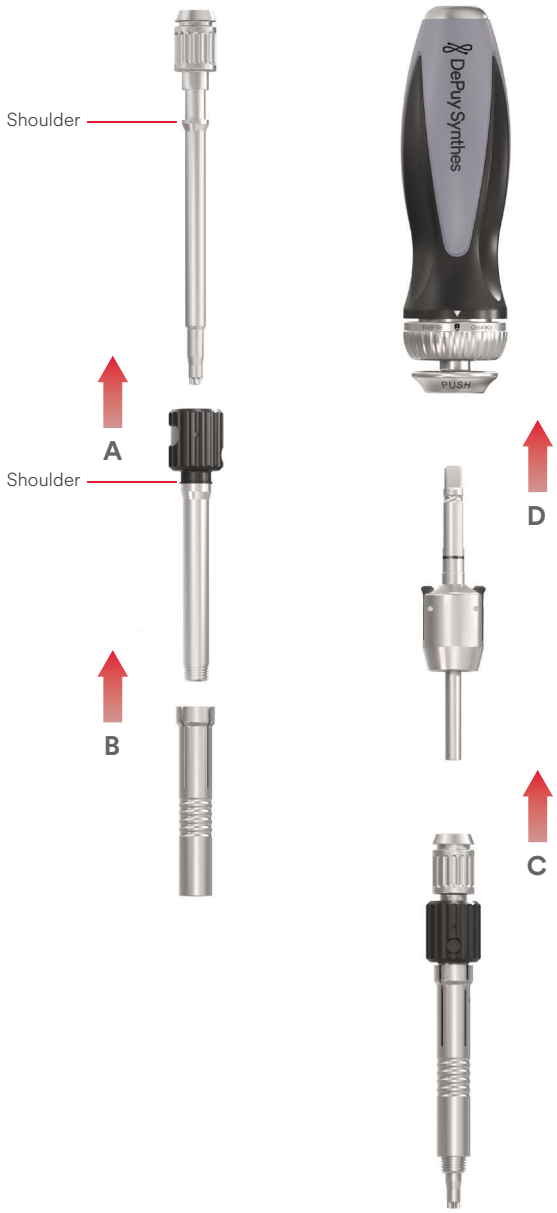
A. Slide the **Cement Retaining Sleeve** onto the **T27 Cement Screwdriver** until the button snaps over the shoulder.

B. Slide the **Short Slip Sleeve** onto the **Cement Retaining Sleeve** until the spring fingers snap over the shoulder on the **Cement Retaining Sleeve**.

C. Slide the Cement Screwdriver Assembly into the **Cement Handle Adapter** until the two black levers snap over the proximal end of the **T27 Cement Screwdriver**.

D. Connect the preferred handle to the **Cement Handle Adapter**.

■ Note:
Care should be taken to not constrain the spring fingers on the **Slip Sleeve** when assembling or disassembling it to or from the **Retaining Sleeve**.



Cement Augmentation

E. Place the **Screwdriver** tip securely into the **T27** recess of the pedicle screw.

F. Rotate the **Cement Retaining Sleeve** black knob clockwise until firmly tight.

Refer to previous steps on page 14 for screw insertion.

G. Disengage the **Cement Handle Adapter** by pinching the black levers to remove it from the **Cement Screwdriver Assembly**.

The **Cement Screwdriver Assembly** can also be assembled to **Fenestrated Screws** previously inserted using other screwdrivers (Fig. 7).

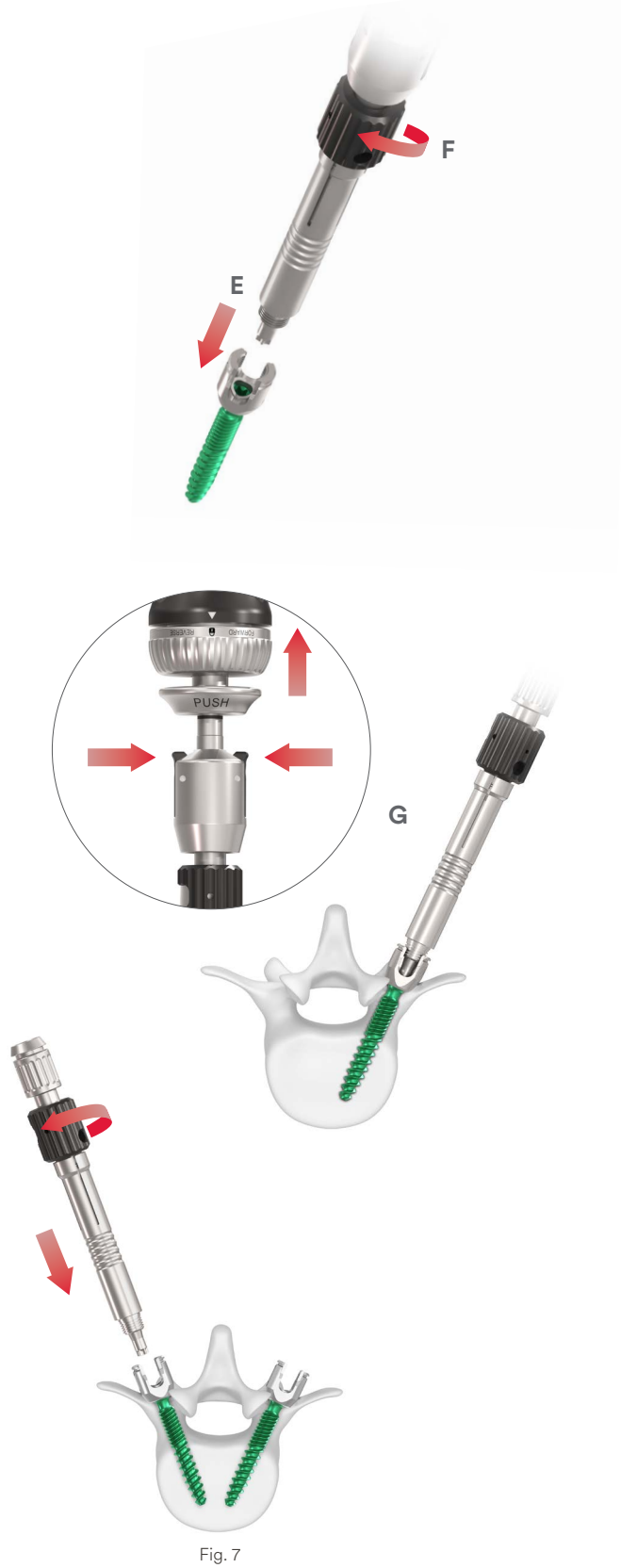


Fig. 7

Cement Augmentation

Cement Preparation

Once the **Fenestrated Screws** are in place and the Cement Screwdrivers are attached to those levels selected to be augmented, prepare the cement according to the manufacturer's published instructions.

When augmenting multiple screws/levels with cement, attention must be paid not to exceed the working time of the cement prior to the completion of cement delivery through the screw. When the cement working time is close to completion, a new cement, cement delivery system package, and cannula must be used for any remaining screws/levels.

Bone cement must be prepared as per the cement package insert or surgical technique manual. The Time/Temperature Graph provided in the package insert or surgical technique manual must be followed carefully.

Connection Of The Cannula To The Cement Reservoir

Thread the CONFIDENCE SPINAL CEMENT SYSTEM® reservoir onto the cannula (Fig. 8).

Fig. 8

Attachment of Cement Cannula to Cement Screwdriver Assembly

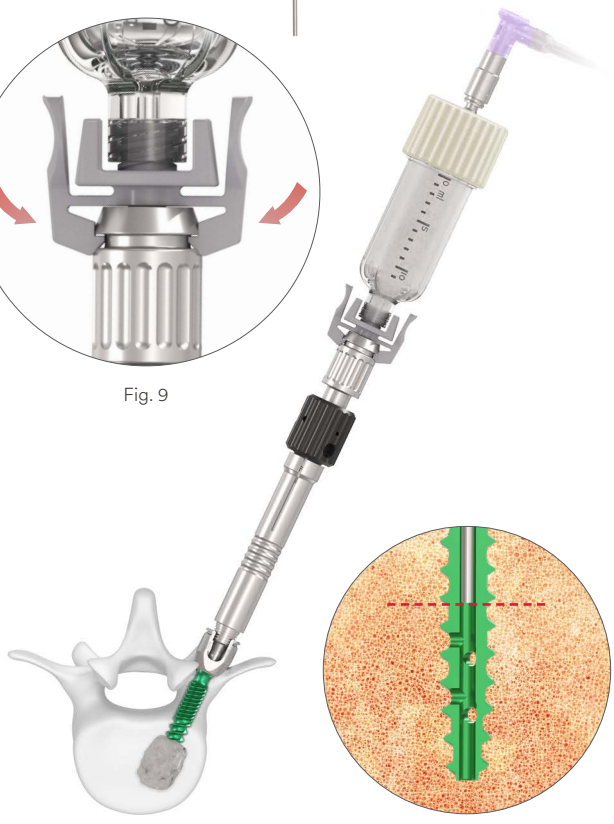
Place the cannula with cement reservoir through the cement screwdriver and into the screw shank. The cannula will click onto the cement screwdriver (Fig. 9).

Fig. 9

To ensure that the cannula is correctly positioned to deliver cement, the cannula **MUST** click into place before proceeding to the next step.

When the cannula is positioned in the screw shank, the tip will be just above the first fenestration.

If resistance is encountered while inserting the cannula into the screw shank, ensure that the cement screwdriver assembly is properly attached to the screw head.



Cement Augmentation

Cement Delivery

Follow the instructions from the respective bone cement and delivery system package inserts to introduce the cement through the delivery cannula.

Use fluoroscopy throughout the procedure to monitor cement flow as appropriate.

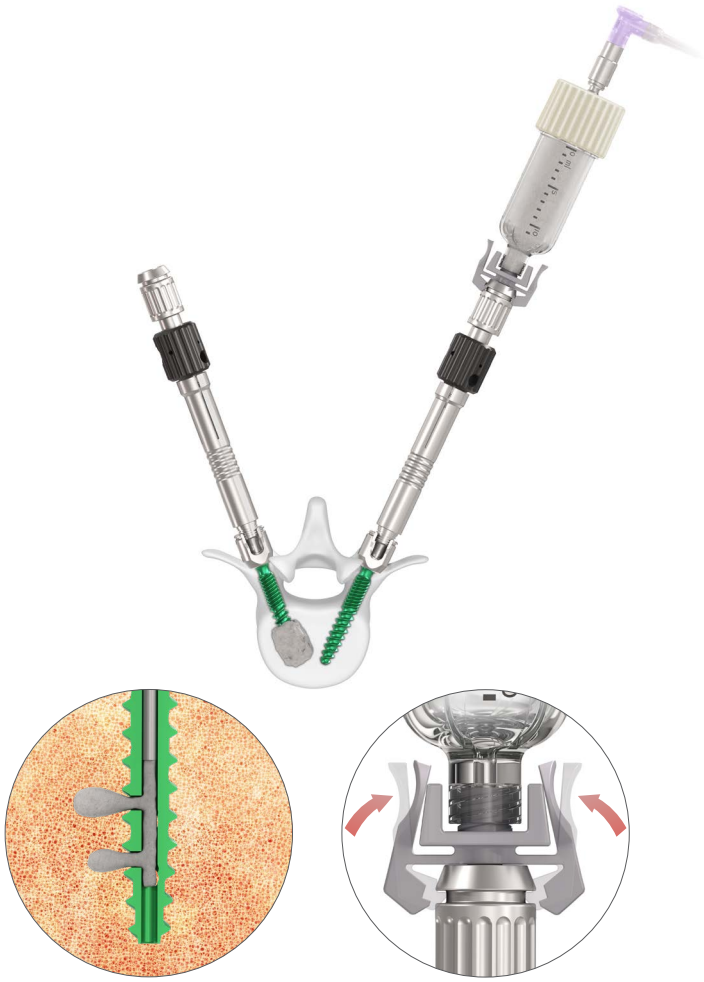
▲ Caution:
Controlled delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in cement leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.

Removal of Delivery Cannula

When the appropriate amount of cement has been introduced, stop cement introduction as indicated per the respective bone cement technique.

Disengage the cannula from the **Cement Screwdriver** by depressing the tabs on each side of the cannula and remove it from the screw as soon as cement injection is completed and flow has stopped through the cannula.

■ Note:
Confirm that cement flow has stopped before disengaging the cement delivery system from the screw head.



Cement Augmentation

Subsequent Level Augmentation

Place the existing cannula and cement reservoir into the next **Cement Screwdriver** and repeat the procedure described in the previous step.

Repeat for each desired vertebral level. Ensure cement flow has stopped between each level. If an additional cement package is needed, remove the existing cannula and attach a new cannula. If additional cement is needed beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for the remaining screws.

■ Note:
Optional: The **Plunger** can be used to pass the cement remaining in the cannula into the screw after the cement reservoir has been emptied. Detach the reservoir from the cannula and proceed with plunger insertion.

▲ Caution:
After cement injection, no torsional movement must be applied to the screw throughout the cement setting time outlined in the respective package insert. At the end of the case, any opened cannulas must be discarded.

Cement Augmentation

Removal of **Cement Screwdriver** assemblies:
After cement introduction and setting, the **Cement Screwdriver** assemblies can be removed from the screw head by turning the Cement Retaining Sleeve black knob counterclockwise while holding the proximal grooves of the **T27 Cement Screwdriver**.

■ Note:
If the black knob is too tight, reattach the **Cement Handle Adapter** with a T-Handle to use as a counter torque when loosening the **Cement Retaining Sleeve**.

Residual Cement Removal

After use, the **Cement Screwdriver** assemblies must be visually inspected for any cement. If cement remains in the **Cement Screwdriver**, insert the Stylet through the proximal end of the **Cement Screwdriver** and rotate to ensure any cement is removed.

Insert the Mini-Stylet into the tip of the **Cement Screwdriver** and rotate to ensure any cement is removed.

■ Note:
If cement remains in the device, repeat cleaning steps above or return it to DePuy Synthes.

Rod Selection and Preparation

Rod Selection

Instruments used in this step

5161-00-5016	Rod Length Gauge
2770-30-545	Rod Template
5161-00-5009	Head Adjuster 5.5-6.0

The TriALTIS™ Spine System offers multiple rod diameters and material choices as well as pre-lordosed and straight rod options.

The **Rod Length Gauge** may be used to approximate the rod size.

Select the appropriate rod based on patient need and surgeon preference.

A. In preparation for rod selection, rotate the screw head using the **Head Adjuster** paired with a **Mini Inline Handle**.

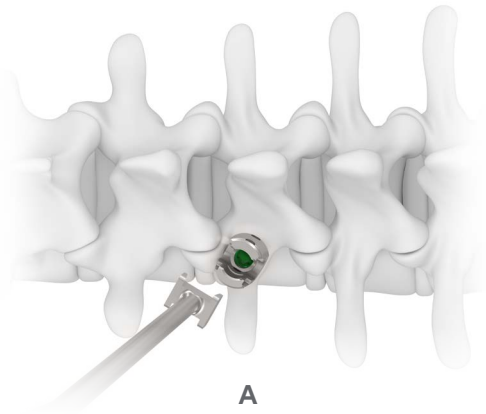
B. Insert the distal tips of the **Rod Length Gauge** into the cranial-most and caudal-most screw heads.

Select the rod that corresponds with the indicated rod length. If the measurement is between two lengths, it is recommended to select the longer rod. Adjust rod selection if additional compression or distraction or rod contouring is expected.

■ Note:
Favored Angle Screws reduce the rod overhang by 0.5 mm per each end they are used.

■ Note:
The measurement accuracy of the **Rod Length Gauge** can vary ±5.7% due to allowable manufacturing tolerances. Numbers on the **Rod Length Gauge** are shown on the device in centimeters to maximize legibility, even though rod length sizes for implants are in millimeters. A reading of 5 on the **Rod Length Gauge** indicates an approximate rod length size of 50 mm.

Alternatively, a **Rod Template** may be used to estimate rod length and contour, if preferred.



A

B

Marking Patterns for Rod Materials

	Titanium alloy (Ti)
	Cobalt Chromium alloy (CoCr)
	ALTALYNE™ Ultra Rods (CoNiCrMo)

Rod Selection and Preparation

Rod Contouring and Cutting

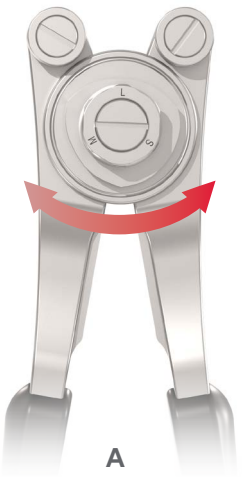
Instruments used in this step

5161-00-5029	French Rod Bender
5161-04-1701	Rod Cutter

Use the **Table Top Cutter** to cut the selected rod if necessary.

Open the cutter by lifting up the rod cutter handle. Insert the rod into the appropriate rod cutter slot and exert consistent downward pressure to cut the rod.

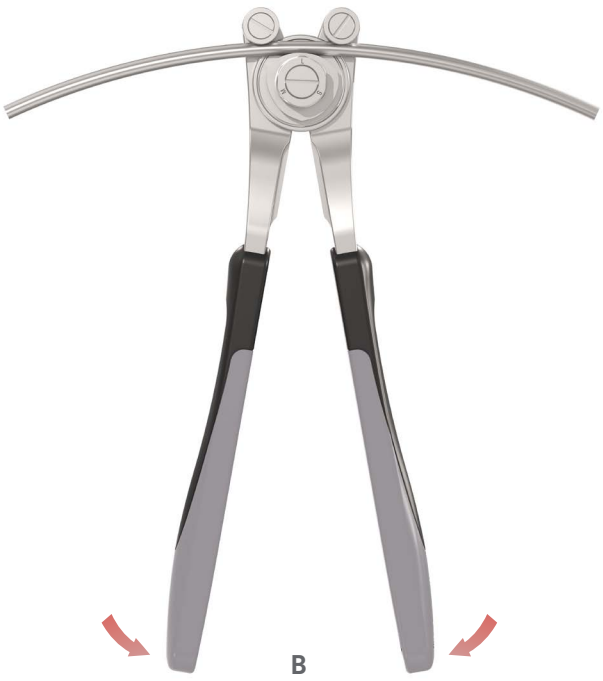
▲ Caution:
Care should be taken to secure and retain the cut ends during cutting to prevent injury.



Use the **French Rod Bender** to contour the rod if necessary.

A. Pull out and rotate the dial to select the desired bend radius.

B. Insert the rod into the **French Rod Bender** and apply force to form the rod to the desired curvature.



■ Note:
The **French Rod Bender** can be used with 5.5/6.0 mm Ti and CoCr rods.

The longitudinal lines on the rods serve as an alignment reference for rod contouring.

■ Note:
Refer to EXPEDIUM VERSE™ Spine System Surgical Technique Guide for details on handling ALTALYNE™ Ultra Rods (CoNiCrMo).

Alternative Instruments

2797-29-930	Table Top Rod Cutter

Rod Insertion

Instruments used in this step

5161-00-5019	Rod Clamp 6.0
2797-30-145	Rod Clamp 5.5
5161-00-5020	Rod Rotator Wrench, 5.5/6.0

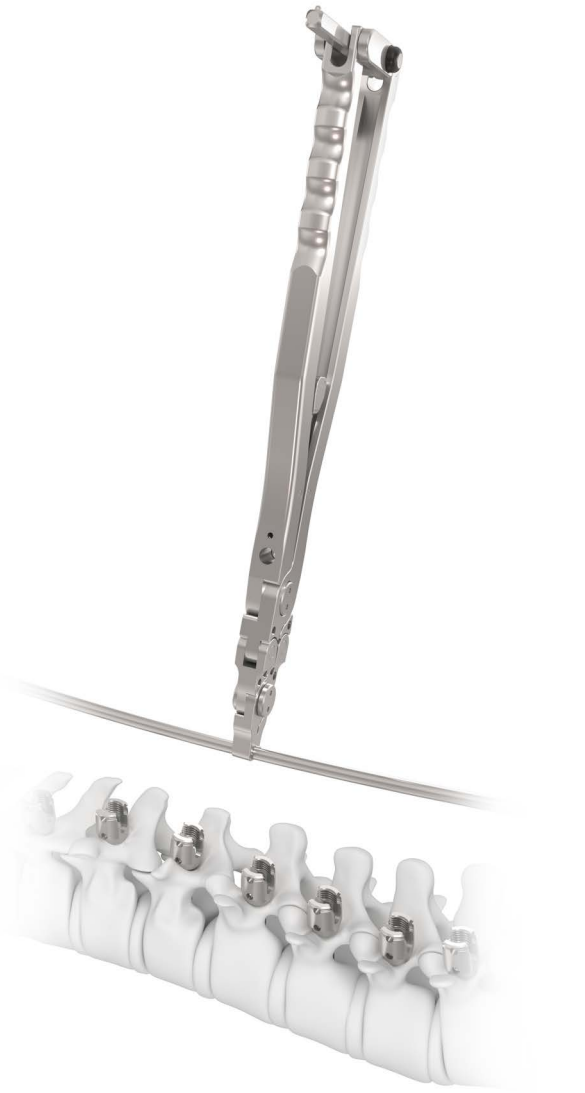
Use the **Rod Clamp** to hold and insert the rod into the openings of the screw heads.

■ Note:
Monitor the longitudinal axis of the rod to ensure it is placed in the desired alignment.

The **Rod Rotator Wrench** may be used to assist in orienting the rod during insertion of rods with hex end feature.

Alternative Instruments

2770-30-105	Forcep Rod Holder, Straight, 5.5



Set Screw Placement

Loading the Set Screw

Instruments used in this step

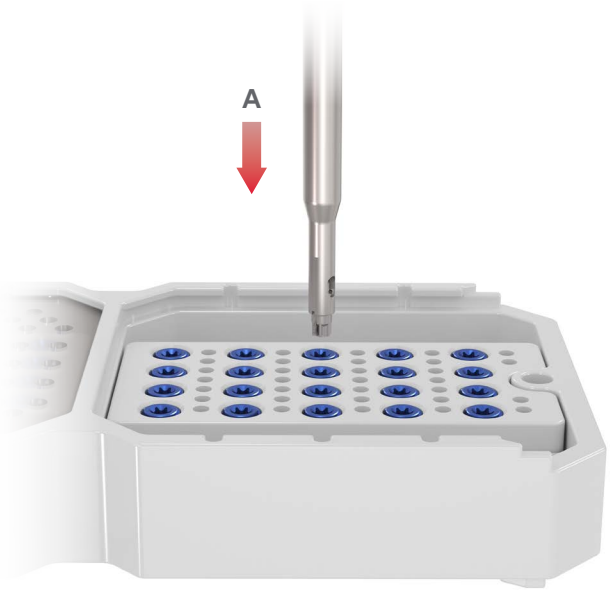
5161-00-5043	Set Screw Inserter, T27 Long
5161-00-0000	Set Screw Caddy

Load a **Set Screw** onto the **Set Screw Inserter** from the **Set Screw Caddy**.

If using sterile packaged set screws, transfer the implants into the sterile field.

The set screws may be placed into the **Set Screw Caddy** for loading.

A. Load the **Set Screw** fully onto the end of the **Set Screw Inserter** by aligning the **T27** drive tip with the **T27** recess in the **Set Screw** and applying light downward pressure.



Set Screw Placement

Insertion and Provisional Tightening

Instruments used in this step

5161-00-5043	Set Screw Inserter, T27 Long
5161-00-5042	Alignment Guide, Long Dbl End

The **Alignment Guide** may be used to assist in the placement of the set screws. Ensure optimal set screw contact by minimizing rod bends where it passes through the implant head.

A. Place **Double Ended Alignment Guide** over the head of the screw, aligning the distal rod slot with the rod and insert the loaded **Set Screw Inserter** through it. Refer to the compatibilty chart on the right.

B. Introduce the **Set Screw** into the head of the screw by turning clockwise (Fig. 10).

▲ Caution:
Do not cross thread set screws while engaging the implant head. Cross threaded set screws could lead to construct loosening.

C. Fully engage the **Set Screw** threads and apply a light torque to provisionally tighten it and maintain the desired rod position. Insert the remaining **Set Screws** and provisionally tighten as needed.

If desired, the set screws can be provisionally tightened using the **Set Screw Tightener** paired with a **Mini Inline Handle**.

▲ Caution:
Do not mallet on the proximal end of the **Alignment Guide** when seating it over a screw head. If the **Alignment Guide** does not fully seat onto the rod, prepare the surrounding tissue or bone to allow for

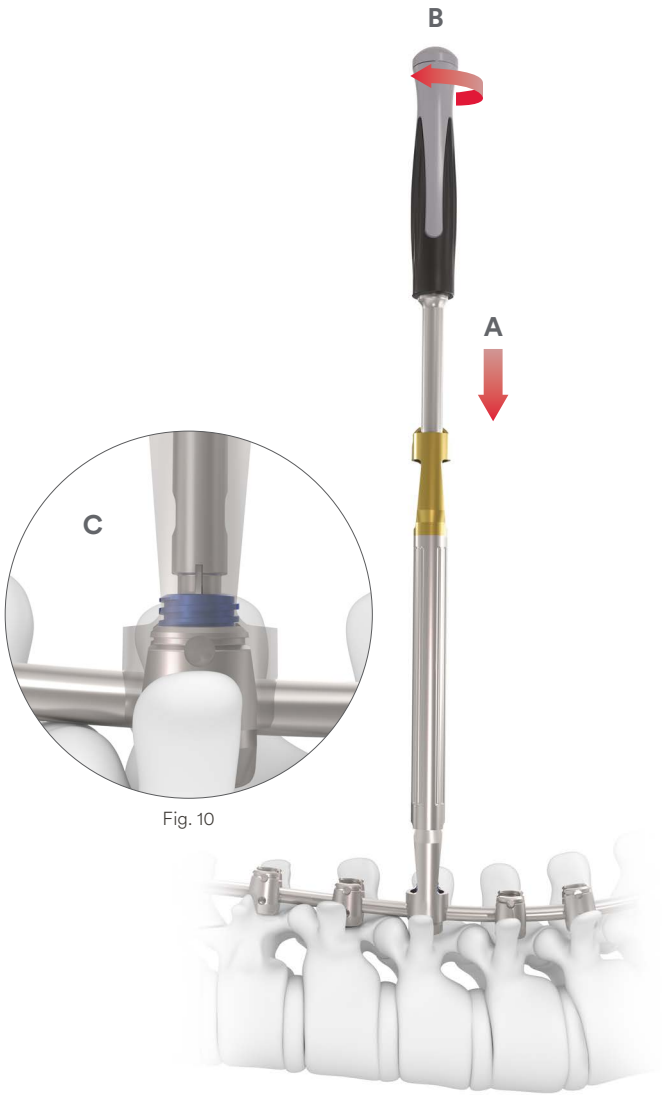


Fig. 10

Alignment Guide Compatibility Chart

Implant / Instrument End	TriALTIS Polyaxial Screws	TriALTIS Favored Angle Screws
Gold End	✓	✓
Silver End	✓	✗

Rod Reduction

Acute Reducer

Instruments used in this step

5161-00-5033	Acute Reducer 5.5-6.0
5161-00-5092	Set Screw Inserter, T27 X Long

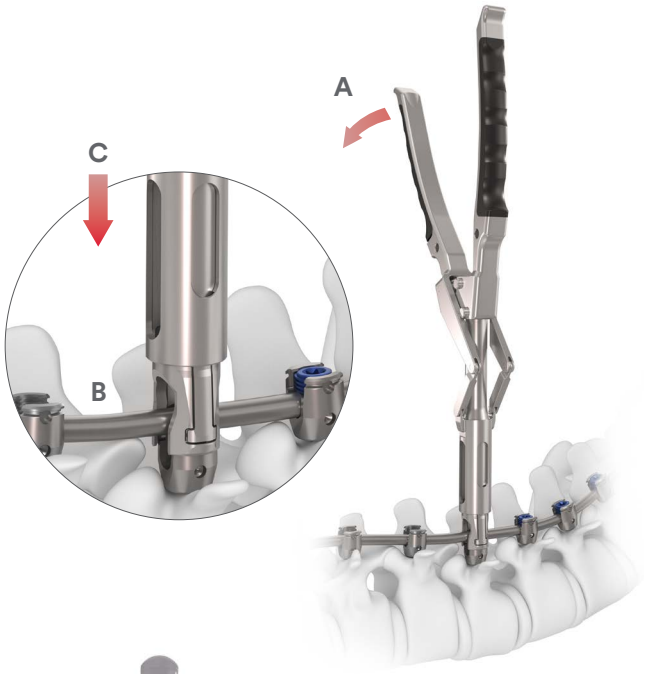
The **Acute Reducer** may be used to reduce the rod into a screw head, up to 13.0 mm.

A. Ensure the **Acute Reducer** handles are fully open.

B. Capture the rod within the distal end slot and align the distal tip of the **Acute Reducer** with the screw head.

C. Fully seat the distal end of the Acute Reducer onto the screw head.

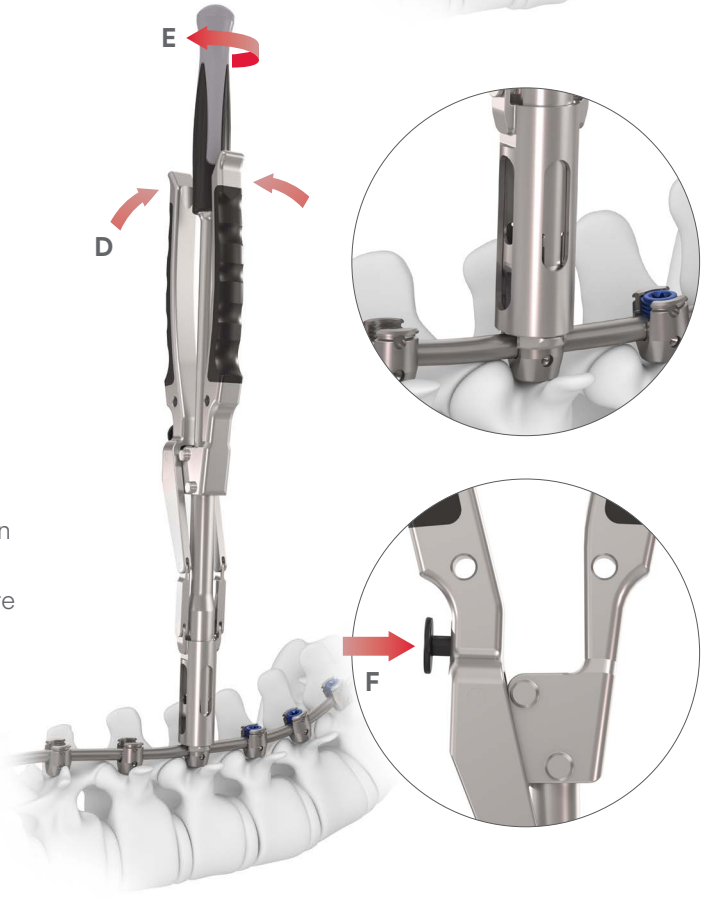
D. Fully close the handles until a tactile click is observed.



■ Note:
The tactile snap confirms that the rod has been sufficiently reduced to enable **Set Screw** insertion and the handles have been locked.

E. Load a **Set Screw** onto the **Extra Long Set Screw Inserter**. Insert the **Set Screw** through the **Acute Reducer** and provisionally tighten.

If required, the **Acute Reducer** handles can be squeezed to further seat the rod into the screw head, to facilitate provisional **Set Screw** tightening.



Removal

F. Slightly squeeze the handles to relieve tension within the device and press the black button to enable the handles to open. Allow the handles to fully open before removing the **Acute Reducer** from the implant.

■ Note:
If the distal end of the reducer is obstructed by rigid anatomy, loosen the set screw, reposition the screw head and provisionally tighten the **Set Screw**.

Rod Reduction

Sequential Reducer

Instruments used in this step

5161-00-5034	Sequential Reducer, Short Out
5161-00-5035	Sequential Reducer, Short In
5161-00-5065	Hex Handle
5161-00-5043	Set Screw Inserter, T27 Long
5161-00-5046	Set Screw Tightener, T27 Long
5161-00-5017	Mini Inline Handle

The **Sequential Reducer** may be used where large reduction (up to 40 mm) is necessary.

A. Assemble the **Sequential Reducer** by aligning the arrows on the inner sleeve with the arrows on the outer sleeve.

B. Insert the inner sleeve into the outer sleeve, and rotate the inner sleeve clockwise until the tip of the inner sleeve is visible in the rod slot of the outer sleeve window (Fig. 11).

C. Capture the rod within the distal slot and align the distal tip of the **Sequential Reducer** with the screw head.

D. Push down the **Sequential Reducer** to engage the screw head.

■ Note:
Do not depress the black levers during attachment of the instrument to the implant. An audible click or tactile snap suggests proper engagement with the implant. A light pull on the **Sequential Reducer** will confirm proper engagement.

■ Note:
If excessive resistance is encountered during reducer engagement, consider adjusting the position of the implant or minimize impingement of tissue at the implant/instrument interface.

Fig. 11

Rod Reduction

E. Seat the **Hex Handle** to the hex on the inner sleeve and turn handle clockwise to reduce the rod.

If large reduction forces are required, multiple **Sequential Reducers** should be used on nearby screws, to encourage load sharing across the implant construct.

■ Note:
Note the positive stop of the **Sequential Reducer** shown in the table below.

Set Screws can only be inserted after the inner sleeve reaches its positive stop (refer to table below).

Load a **Set Screw** onto the **Long Set Screw Inserter**. Insert the **Set Screw** through the **Hex Handle** and provisionally tighten.

If desired, **Set Screws** can be provisionally tightened using the **Tightener, T27 Long** paired with a **Mini Inline Handle**.

Removal

F. Disengage the **Sequential Reducer** by pinching the black buttons and pulling up to remove it from the implant.

■ Note:
If resistance is encountered when pinching the black buttons, unthread the inner sleeve by 1/4 turn to relieve tension and disengage the **Sequential Reducer**.

■ Note:
If the distal end of the reducer is obstructed by rigid anatomy, loosen the set screw, reposition the screw head and provisionally tighten the **Set Screw.**

Alternatively, the Short Set Screw Inserter may be used to insert a Set Screw through the Sequential Reducer after removing the Hex Handle.

Alternative Instruments

5161-00-5090	Set Screw Inserter, T27 Short

Sequential Reducer States

Not fully reduced

Fully reduced

Rod Reduction

Rocker Reducer

Instruments used in this step

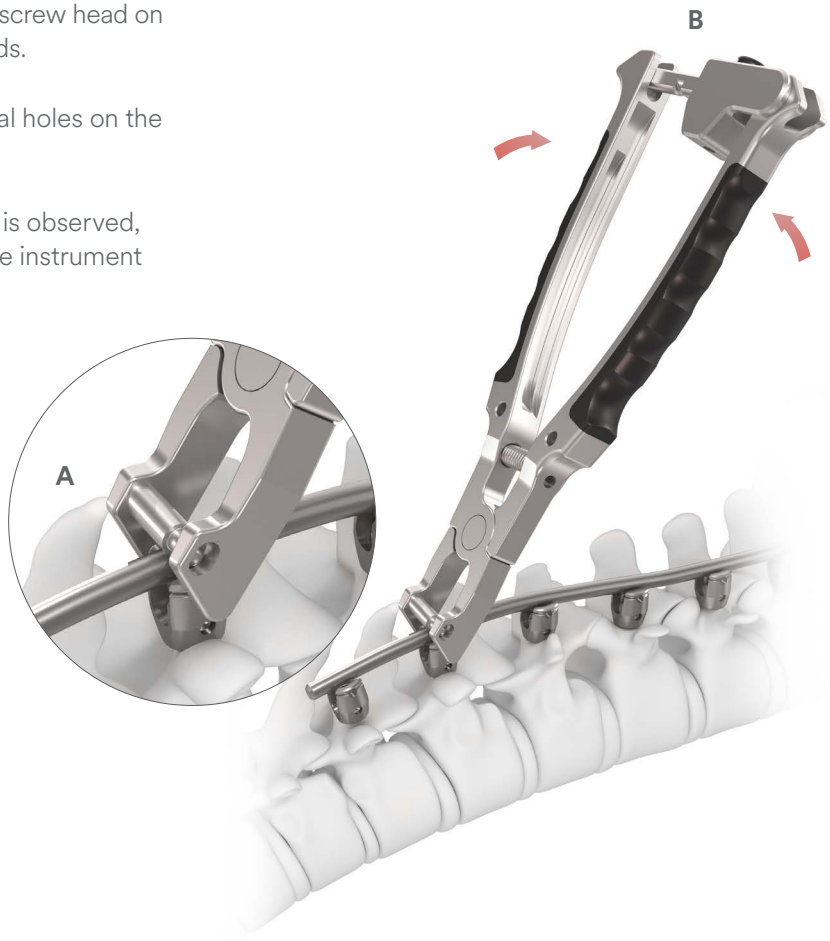
5161-00-5096	Rocker 5.5/6.0
5161-00-5043	Set Screw Inserter, T27 Long

The **Rocker** may be used to reduce the rod into the screw head up to 10.0 mm.

■ Note:
The **Rocker** requires a minimum of 5.5 mm of cylindrical rod length extending from the connected screw head on the side that the **Rocker** is reduced towards.

A. Align the **Rocker** pins with the proximal holes on the screw head.

B. Squeeze the handle until a tactile click is observed, indicating proper connection between the instrument and implant.



Rod Reduction

C. Lever the **Rocker** over the rod and fully seat it into the screw head.

D. Load a set screw onto the **Long Set Screw Inserter**. Fully engage the **Set Screw** and provisionally tighten.

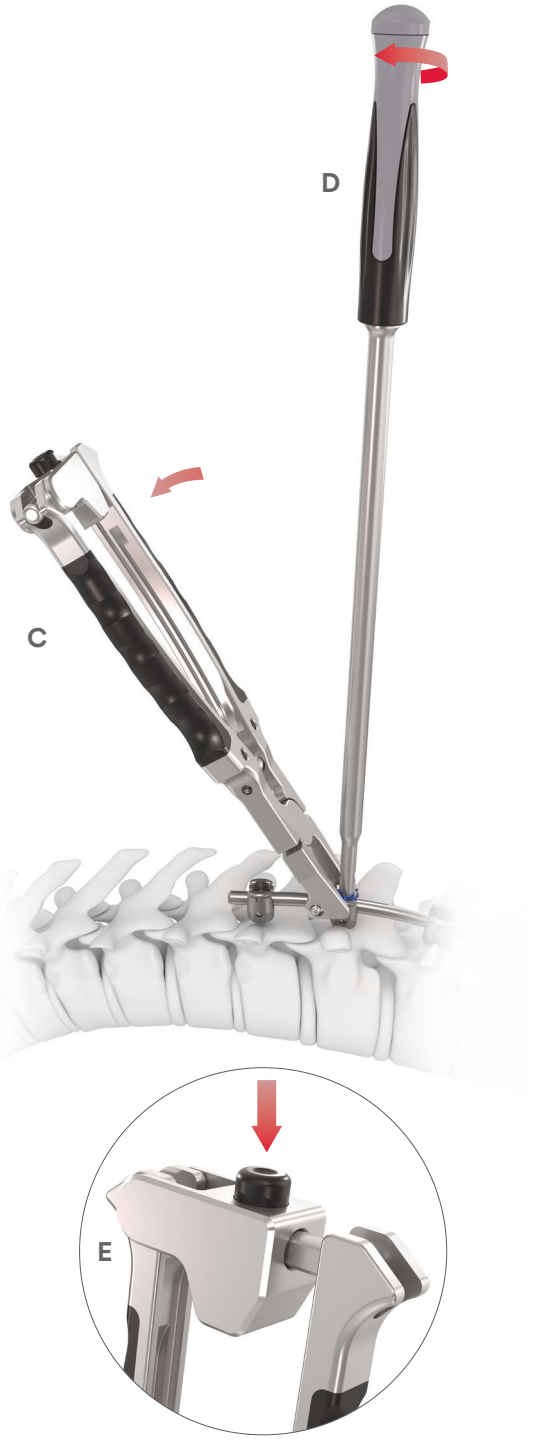
Removal

E. To remove the **Rocker**, slightly squeeze the handles to relieve tension within the instrument and press the black button on the top of the **Rocker** to enable the handles to open.

Alternatively, the **Rod Pusher** may be used to fully seat the rod prior to introduction of the **Set Screw**.

Alternative Instruments

5161-00-5030	Rod Pusher 5.5/6.0
5161-00-5015	Palm Handle
5161-00-5090	Set Screw Inserter, T27 Short



Final Tightening

Instruments used in this step

5161-00-5095	Counter Torque, Universal
5161-00-5048	Ratcheting Torque Limiter, 11.3Nm
5161-00-5046	Set Screw Tightener, T27 Long

Confirm that the rod slots in all implant heads are inline with the rod before final tightening.

■ Note:
Ensure all set screws are fully reduced and provisionally tightened prior to beginning final tightening steps. Failure to do so could potentially lead to misalignment of the rod with respect to the implant head during subsequent final tightening.

A. Attach the **Set Screw Tightener** to the **Ratcheting Torque Limiter**, ensuring full engagement of the shaft into the handle.

Proper connection is achieved when the line of the tightener aligns with the distal face of the coupling.

B. Place the **Universal Counter Torque** over the head of the screw, aligning the distal rod slot with the rod (Fig. 12). Refer to the compatibilty chart below.

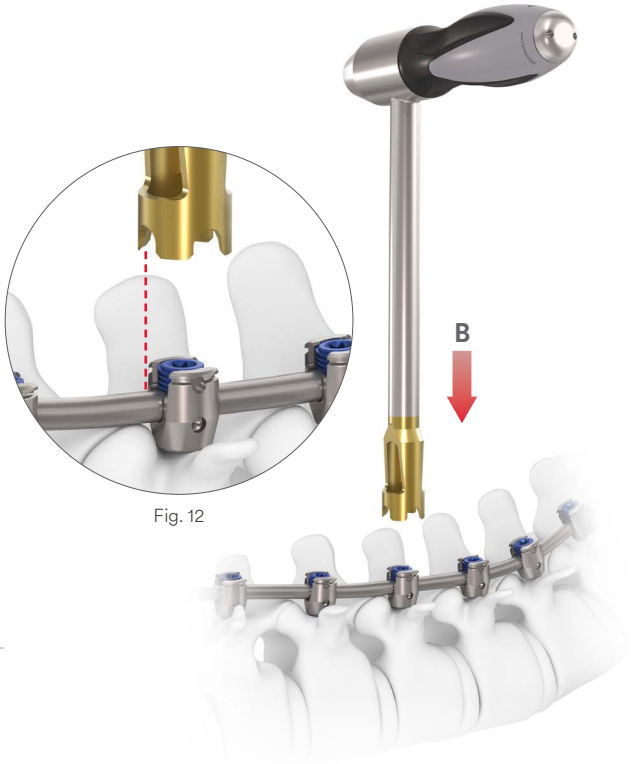


Fig. 12

▲ Caution:
Final tightening of **Set Screws** should only be performed with a calibrated 11.3Nm **Torque Limiter** and **Set Screw Tightener**. TriALTIS Implants achieve performance standards only when tightened with the specified 11.3Nm **Torque Limiter**. Refer to IFU for **Torque Limiter** (IFUN-006) for the recommended calibration maintenance.

Counter Torque Compatibility Chart

Implant / Instrument End	TriALTIS Polyaxial Screws	TriALTIS Favored Angle Screws
 Gold End	✓	✓
 Silver End	✓	✗

Final Tightening

C. Insert the assembled torque handle and shaft through the **Universal Counter Torque** cannula and into the T27 drive recess of the set screw.

■ Note:
Ensure that the **Set Screw Tightener** tip is fully seated in the **Set Screw T27** recess, and ensure that the **Counter Torque** is fully seated over the rod.

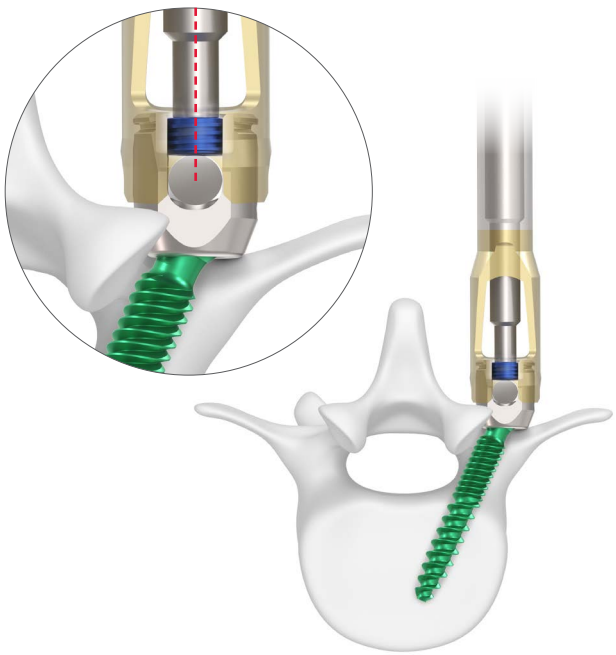
■ Note:
Care should be taken not to accidentally depress the release collar on the torque limiters during **Set Screw** tightening as this could cause the instrument shaft to disengage from the handle.

D. Apply torque in a clockwise motion until there is a tactile response. This indicates that the required 11.3Nm of torque has been applied.

Revisit **Set Screws** at every level.

Alternative Instruments

5161-00-5045	Counter Torque
5161-00-5047	Torque Limiter, 11.3Nm



In Situ Rod Bending

Instruments used in this step

5161-00-5025	Sagittal Bender 5.5, Left
5161-00-5026	Sagittal Bender 5.5, Right
5161-00-5027	Coronal Bender 5.5, Left
5161-00-5028	Coronal Bender 5.5, Right

Sagittal Correction

A. Slide either the angled or straight ends of the **Sagittal Benders** flush within the rod slot.

B. Compress the **Sagittal Benders** toward each other to achieve lordosis or pull away from each other to produce kyphosis.

■ Note:
Ensure that the open end of the **Sagittal Benders** rod slot faces medially to minimize the likelihood of tissue damage in the event of accidental slippage.

Coronal Correction

C. Slide the ends of the **Coronal Benders** over the rod until the slots sit flush.

D. Compress the arms of the **Coronal Benders** toward each other or pull away from each other depending on the desired contour.

■ Note:
The **Sagittal** and **Coronal 5.5 Benders** can be used with 5.5 Ti and CoCr Rods. The **Sagittal 6.0** and **Coronal 6.0 Benders** can be used with 6.0 Ti and CoCr Rods.

Refer to EXPEDIUM VERSE™ Spine System Surgical Technique Guide for details on handling CoNiCrMo.

Alternative Instruments with 6.0 Rods

5161-00-5023	Coronal Bender 6.0, Left
5161-00-5024	Coronal Bender 6.0, Right
5161-00-5021	Sagittal Bender 6.0, Left
5161-00-5022	Sagittal Bender 6.0, Right

Compression and Distraction

Instruments used in this step

5161-00-5054	Compressor 5.5/6.0, Hinged
5161-00-5055	Distractor 5.5/6.0, Hinged

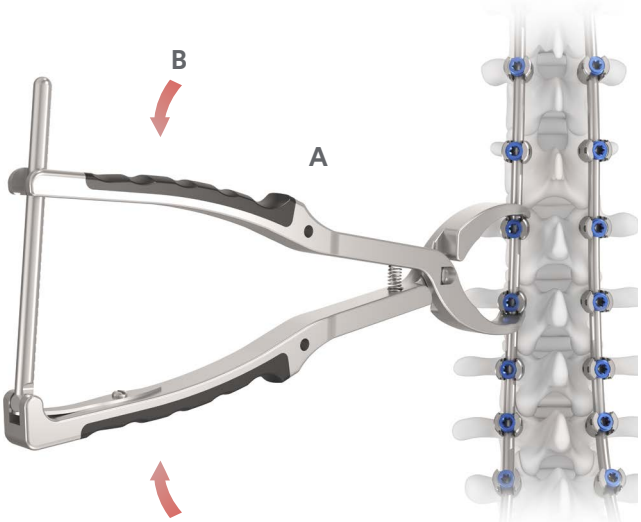
If compression or distraction is desired, perform final tightening on one **Set Screw** to create a fixed point and leave the adjacent **Set Screw** loose during compression and distraction maneuvers.

Compression

A. Place the **Hinged Compressor** jaws over either side of the locked and un-locked pedicle screws.

B. Compress the construct to the desired position and provisionally tighten the un-locked **Set Screw**.

Remove the **Hinged Compressor** and lock the **Set Screw** using the **Set Screw Tightener** and **Torque Limiter** (see Final Tightening step p.31).

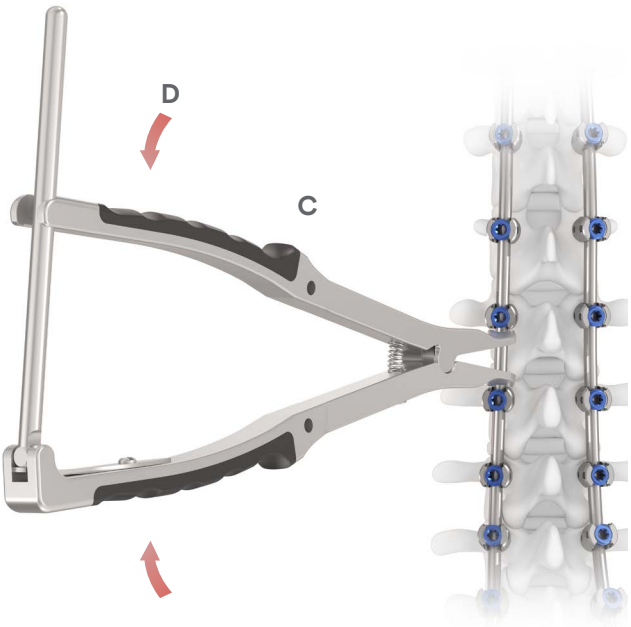


Distraction

C. Place the **Hinged Distractor** jaws on the rod between the locked and un-locked pedicle screws.

D. Distract the construct to the desired position and provisionally tighten the un-locked **Set Screw**.

Remove the **Hinged Distractor** and lock the **Set Screw** using the **Set Screw Tightener** and **Torque Limiter** (see Final Tightening step p.31).



Alternative Instruments

5161-00-5051	Compressor 5.5/6.0, Parallel
5161-00-5052	Distractor 5.5/6.0, Parallel

SAI Technique

Instruments used in this step

5161-00-5063	Probe, SAI Straight
5161-00-5015	Palm Handle
2997-04-130	Ball Tip Feeler Curved
5161-00-4090	Tap, Long Cann 9.0 mm
5161-00-5011	Inline Handle, Ratcheting
5161-00-5006	Screwdriver, T27 Long Cann
5161-00-5116	Retaining Sleeve, Long
5161-00-5070	Slip Sleeve, Long
5161-00-5010	T-Handle, Ratcheting
2867-05-220	Viper 2 Guidewire

Starting Point - Use the **SAI Probe**.

Stand on the contralateral side of the patient to identify the starting point. The anatomical landmarks are the S1 and S2 dorsal foramina. Find the midpoint between the S1 and S2 dorsal foramina and the lateral border of the foramen. The starting point is where these two lines intersect (Fig. 13).

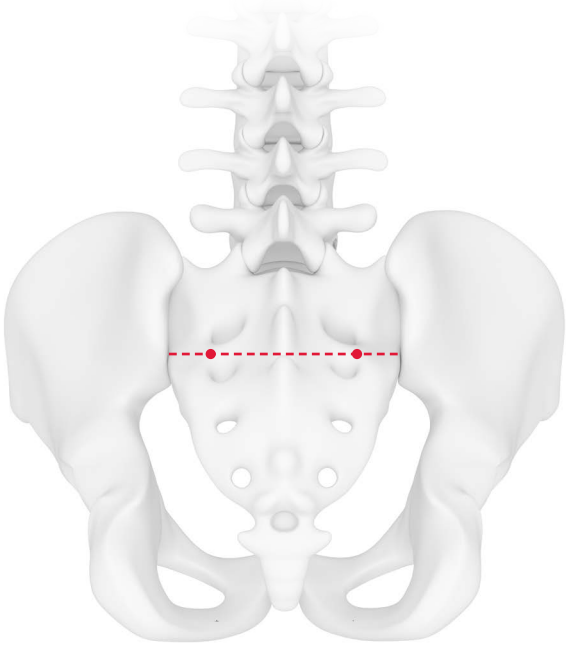


Fig. 13

The following are key points for proper use of the SAI technique:

- Major Alar Projection (forms upper part of ilio-pectineal line)
- 20-30 degrees caudal – guided by posterior surface of sacrum (Fig. 15)
- 40-50 degrees from the vertical axis perpendicular to horizontal plane (Fig. 16)
- Aim for anterior inferior iliac spine, which can be found by palpating the top of the greater trochanter (Fig. 14)
- Pathway passes immediately above the sciatic notch

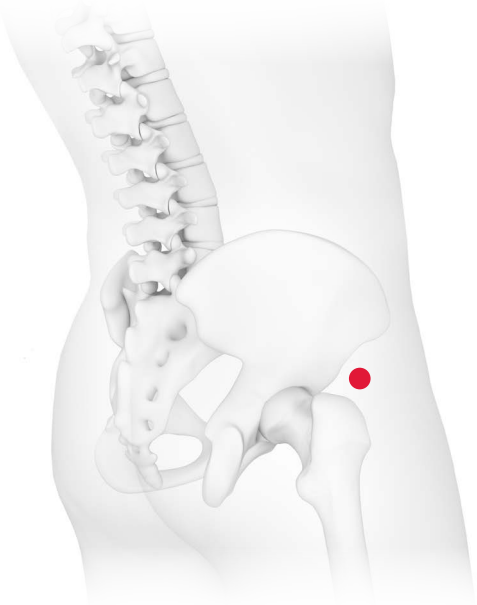
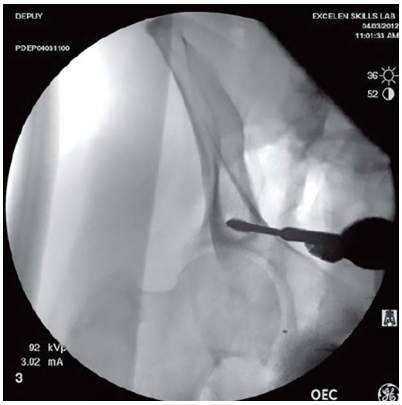


Fig. 14

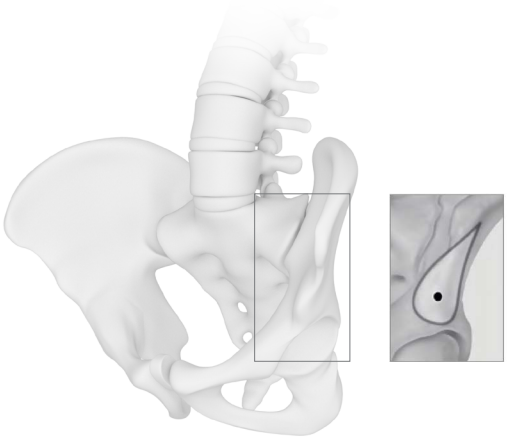
SAI Technique

Fluoroscopy can be helpful identifying the appropriate trajectory.



■ Note:
The **C-Arm** should be oriented in the intended trajectory of the implant. Position the **C-Arm** above the starting point.

■ Note:
The **C-Arm** angle can vary substantially depending on patient anatomy. Image guidance are 20-30 degrees caudal and 40-50 degrees to the vertical plane, aiming for the anterior inferior iliac spine (AIIS).



Confirm that the iliac teardrop is visible on your AP fluoroscopic image.

Once the trajectory is confirmed, cannulate the trajectory using the **SAI Probe**.

Alternatively use a **3.2 mm Ilium Drill Bit** with **Drill Square Quick Coupling** and powered handpiece to create the pilot hole.

Alternative Instruments

5161-00-5073	Drill Bit, 3.2 mm Ilium
05.001.261	Square Quick Coupling, Drill

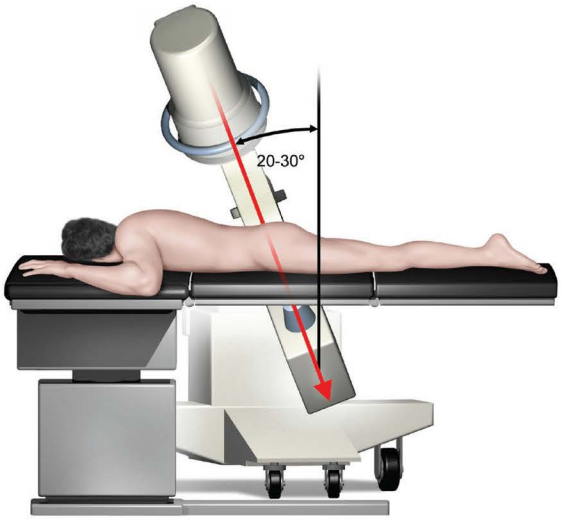


Fig. 15

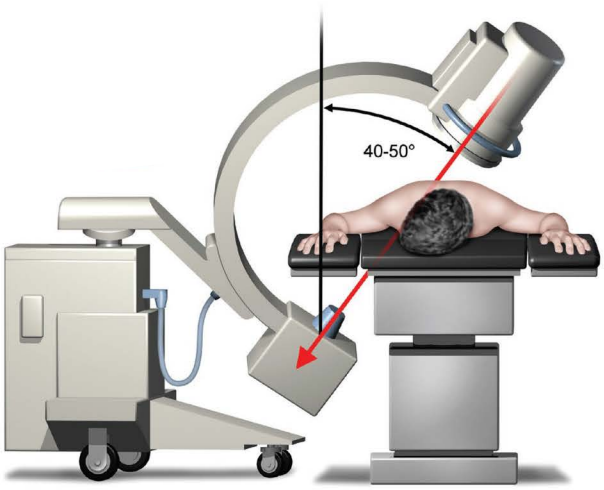


Fig. 16

SAI Technique

Guidewire Insertion and Tapping

A. Place the guidewire in the probed screw path under AP fluoroscopic view.

B. Determine the appropriate tap size.

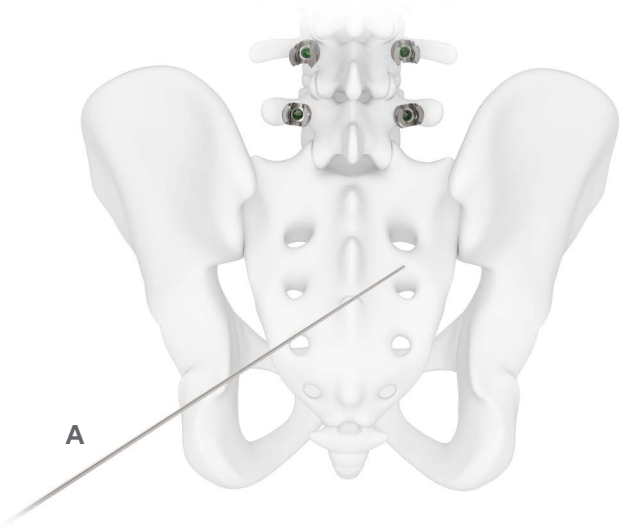
C. Connect desired cannulated tap to **Ratcheting Inline Handle** and tap the full length of the screw.

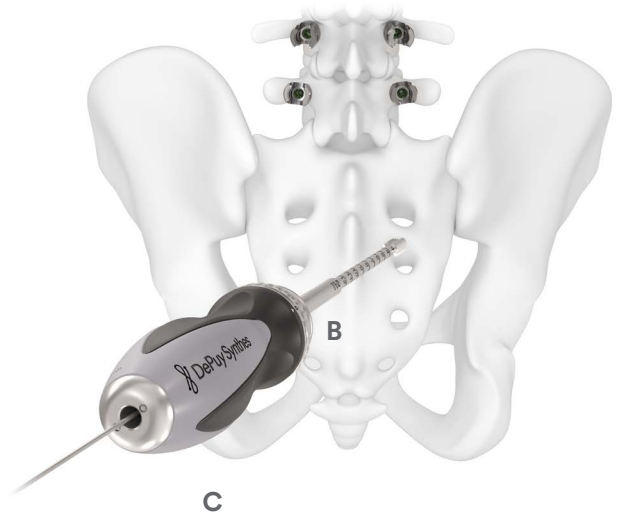
■ Note:
While advancing the tap, ensure that the guidewire does not advance.

■ Note:
When using a powered handpiece to perform tapping and screw insertion over a guidewire, the **Long Nitinol Guidewire** should be used.

■ Note:
When inserting TriALTIS Favored Angle screws, first tap the probed screw path for the full intended length of the screw with a 7.0 mm tap first, then sequentially increase by one tap diameter size and re-tap the full probed pathway again, repeating this process until reaching the desired screw diameter.

▲ Caution:
Do not under-tap the probed screw pathway prior to screw insertion when using TriALTIS Favored Angle screws as this can lead to excessive insertion torque required to implant the screws which could lead to instrument and/or implant failure during insertion.





Screw Placement

Refer to previous steps for Screwdriver assembly and implant loading.

Insert screw over the guidewire and advance the screw.

▲ Caution:
Be sure to remove the guidewire before the screw is fully placed to reduce the possibility of kinking or breakage.

Alternative Instruments

05.001.262	Square Quick Coupling, Tap/Screw
2867-05-340	Nitinol Guidewire, Long

Pelvic Fixation

Instruments used in this step

5161-00-5005	Probe, Iliac Straight
5161-00-5015	Palm Handle
2997-04-125	Ball Tip Feeler Straight

If iliac screw fixation is desired, expose the posterior superior iliac spine and decorticate the entry point using a Burr or Rongeur.

Prepare the screw bed and locate desired entry point.

A. Assemble the **Iliac Probe** with the **Palm Handle**.

B. Create a pilot hole using the **Iliac Probe**.

Palpate the cannulated hole on all sides using a **Ball Tip Feeler**. Probes and Taps are marked to estimate penetration depth.

Alternatively use a **3.2 mm Ilium Drill Bit** with **Drill Square Quick Coupling** and powered handpiece to create the pilot hole.

Alternative Instruments

5161-00-5073	Drill Bit, 3.2 mm Ilium
05.001.261	Square Quick Coupling, Drill

Pelvic Fixation

Instruments used in this step

5161-00-5074	Screwdriver, T27 Short Cann
5161-00-5117	Retaining Sleeve, Short
5161-00-5075	Slip Sleeve, Short
05.001.262	Square Quick Coupling, Tap/Screw

Select the desired Tap and connect to the **Tap/Screw Square Quick Coupling** or desired handle.

Markings on the Taps indicate the approximate tap depth and can be used to inform screw length size selection.

■ Note:
Numbers on the **Probes** and **Taps** are shown on the device in centimeters to maximize legibility.

■ Note:
When inserting TriALTIS Favored Angle screws, first tap the probed screw path for the full intended length of the screw with a 7.0 mm Tap first, then sequentially increase by one tap diameter size and re-tap the full probed pathway again, repeating this process until reaching the desired screw diameter.

▲ Caution:
Do not under-tap the probed screw pathway prior to screw insertion when using TriALTIS Favored Angle screws as this can lead to excessive insertion torque required to implant the screws which could lead to instrument and/or implant failure during insertion.

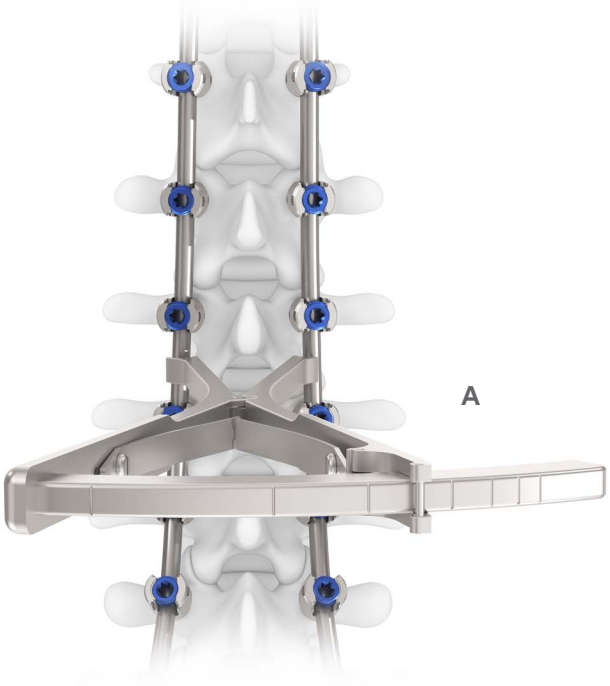
Select the desired TriALTIS Favored Angle Screw and insert into the prepared pathway. Refer to previous steps for screwdriver assembly and screw insertion.

Refer to pages 51-53 for details on compatible Expedium 5.5 lateral connectors. Select the desired connector and place the connector rod into the screw head. Insert a set screw into the screw head and provisionally tighten. Reference the previous surgical steps for set screw insertion and tightening.

Transverse Connectors

Instruments used in this step

03.632.053	Length Indicator, Transverse Connectors, Snap-On For Matrix
03.632.204	Torque Limiting Handle, 3Nm
03.632.052	Screwdriver Stardrive T15, Short, For Matrix
03.632.050	Retaining Sleeve For Transverse Connectors, Snap-On For Matrix



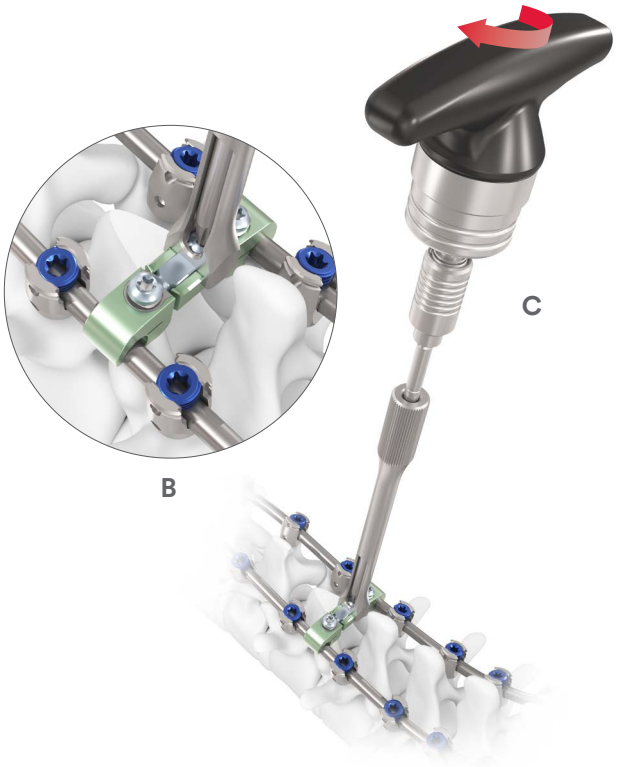
A. Use the length indicator for transverse connectors to estimate the distance between the two rods. Note the size of the appropriate transverse connector [1-8], on the crossbar of the length indicator.

Select the appropriate transverse connector.

B. Attach the ends of the transverse connectors to the rod, at the desired location.

C. Secure the connectors using the **T15 Screwdriver** and **3Nm Torque Limiting Handle**.

Use the **Retaining Sleeve for Transverse Connectors** when tightening the set screw.



▲ Caution:
The **MATRIX Transverse Connector** contains Nitinol components. Implants that contain Nitinol should not be used in patients with nickel sensitivities or allergies.

■ Note:
Refer to MATRIX™ Spine System Surgical Technique Guide for details on transverse connectors.

Distraction for Posterior Interbody Fusion

Instruments used in this step

5161-00-5056	TLIF Distractor 5.5/6.0
5161-00-5043	Set Screw Inserter, T27 Long

A. Depress the black lever and slide the **Distractor Arm** into the **Distractor Rack**.

B. Depress the black lever and insert both distal feet into the screw heads. Then release the black lever to set the foot distance position.

C. Insert **Set Screws** into both screw heads and provisionally tighten using the **Set Screw Inserter**, **T27**.

D. Rotate the black knob to achieve the desired distraction.

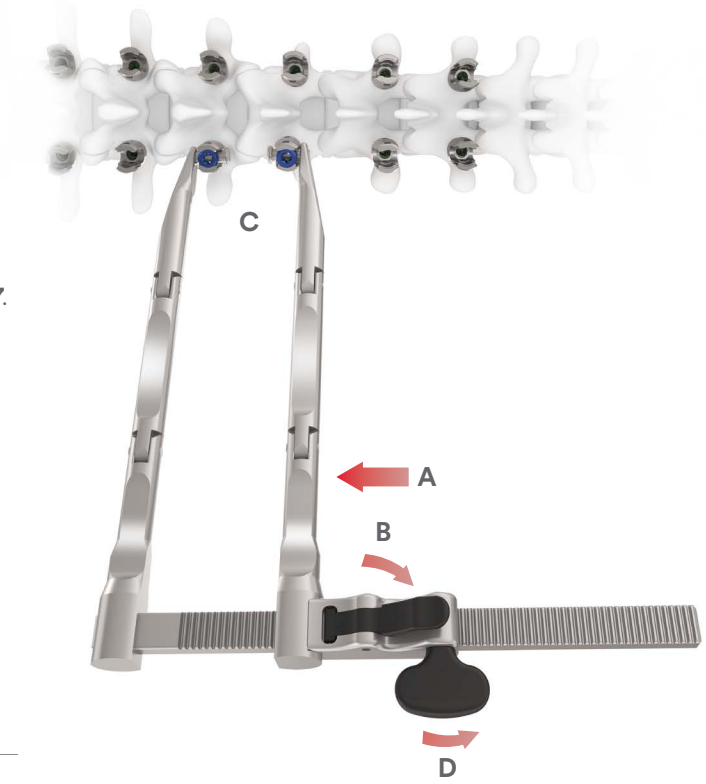
Perform discectomy and interbody fusion as needed.

Device removal is a reverse of the assembly steps.

■ Note:
Discard the used **Set Screws**.

Alternative Instruments

5161-00-5090	Set Screw Inserter, T27 Short



Implant Removal

If a decision is made to remove the implants after solid fusion occurs, the following steps should be taken, after the implant is exposed.

Remove any debris/tissue from set screws.

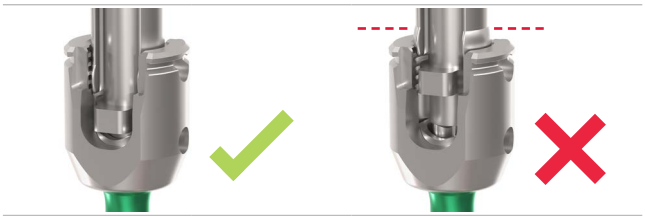
Connect the **T-Handle** to the **T27 Set Screw Tightener**. Insert the **Universal Counter Torque** over the targeted screw and engage the tightener. Turn the handle counterclockwise to loosen the set screw while also applying counter torque.

Once the set screws are loosened, completely unthread and remove them using the **T27 Long Set Screw Inserter**. Remove the rod.

Use the **Head Adjuster** paired with the **Mini Inline Handle** to ensure that the screw heads are polyaxial and facilitate subsequent screw removal.

Insert the **T27 Screwdriver Shaft** into the screw and turn counterclockwise to remove the screw. Ensure the screwdriver tip is fully seated in the screw shank prior to turning. If using the **Retaining Screwdriver**, refer to image on right for correct screwdriver-implant assembly.

Retaining Screwdriver Implant Assembly



Disassembly Instructions

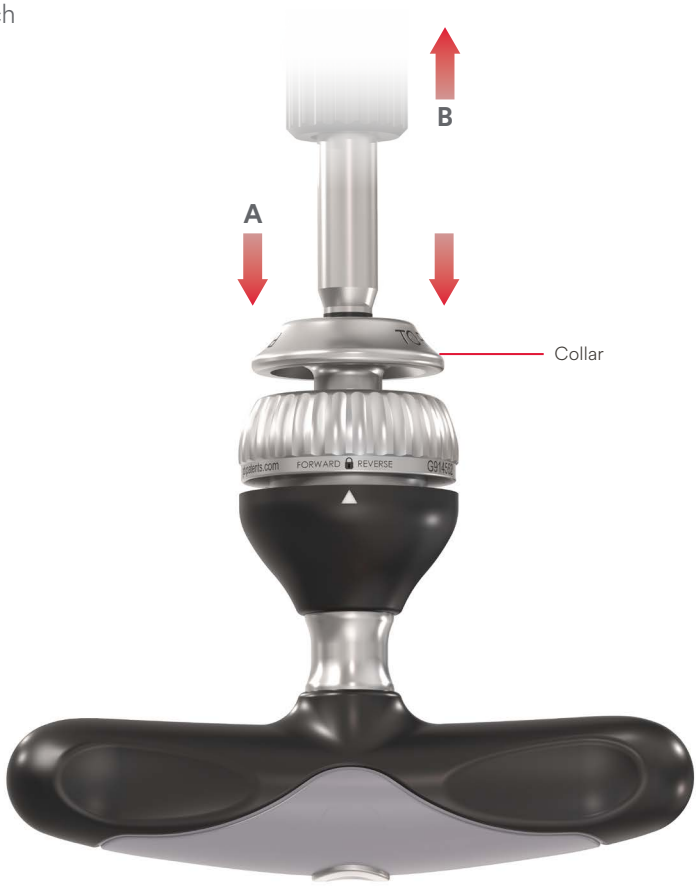
Modular Handles

Once the surgical technique is complete or if an instrument needs to be exchanged, disassemble the modular instruments from the **Modular Handle** as follows:

A. Firmly hold the instrument in one hand and depress the release collar of the **Modular Handle**.

B. Remove the instrument from the handle.

The same instructions apply to all instruments which connect to modular handles and torque limiting handles.



Disassembly Instructions

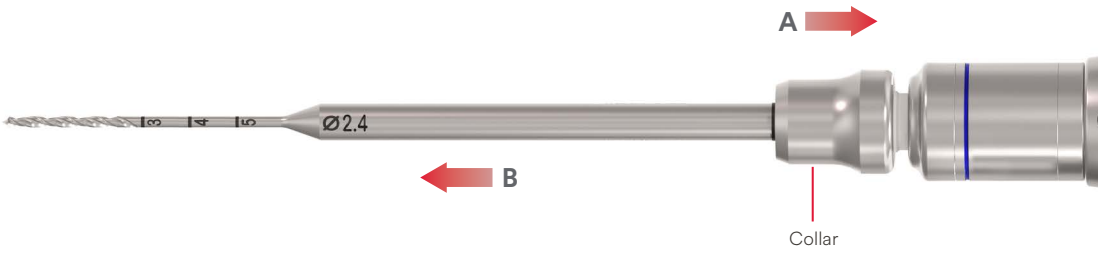
Power Couplings

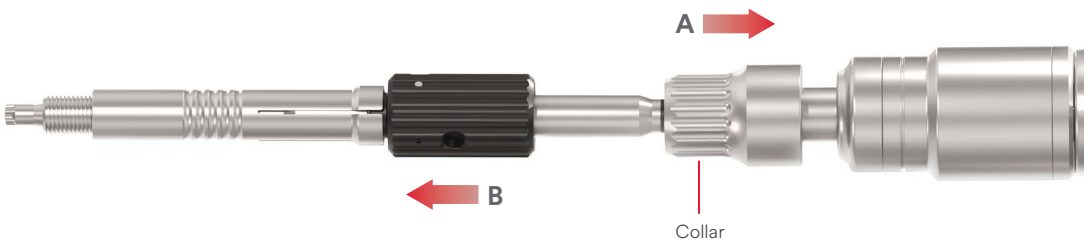
Once the surgical technique is complete or if an instrument needs to be exchanged, disassemble the modular instrument(s) from the **Square Quick Coupling** as follows:

A. Firmly hold the instrument in one hand and pull back the release collar of the **Square Quick Coupling**.

B. Remove the instrument from the coupling.

These instructions are applicable to all instruments which connect to the **Square Quick Coupling, Drill** or the **Square Quick Coupling, Tap/Screw**.





Disassembly Instructions

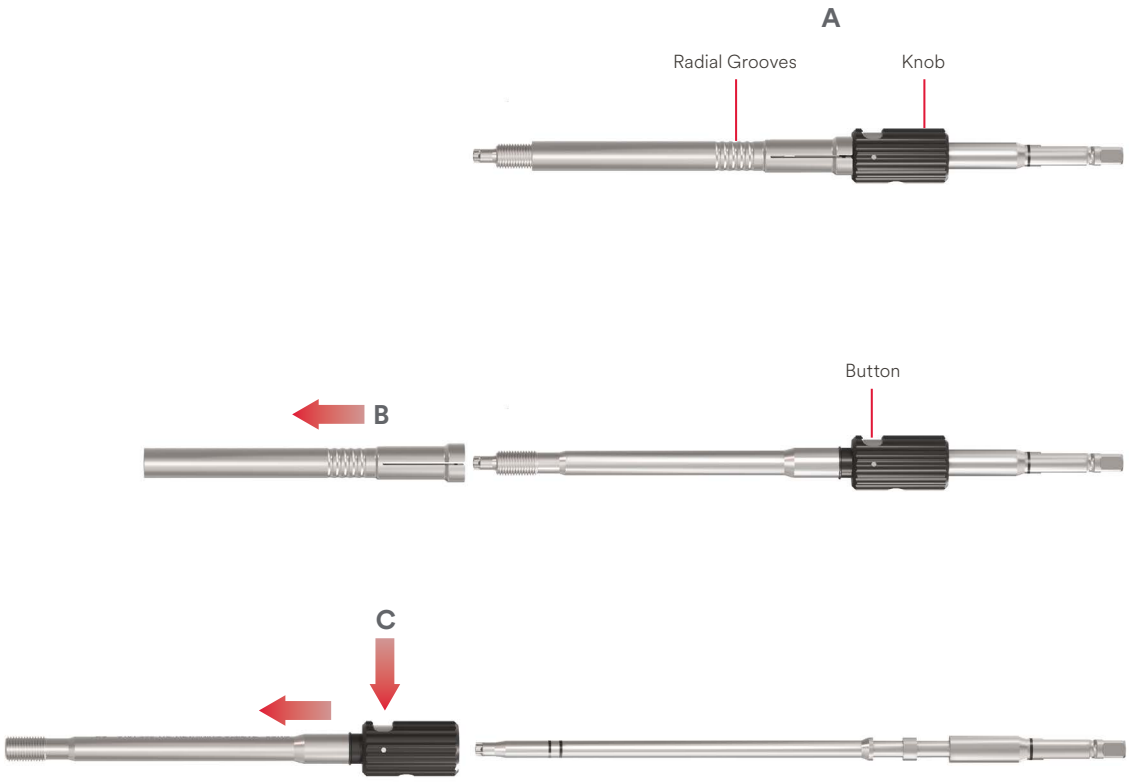
Screwdriver Assemblies

Follow the instructions below for disassembly of the **T27 Screwdriver** assemblies. These instructions are applicable for the Long, Short, and Cement Screwdriver assemblies.

A. Firmly hold the black knob of the **Retaining Sleeve** in one hand and grasp the radial grooves of the **Slip Sleeve** in the other hand.

B. Remove the **Slip Sleeve** by pulling it away from the retaining sleeve.

C. Holding the proximal end of the **T27 Screwdriver Shaft** in one hand, press the release button within the knob of the **Retaining Sleeve** and slide it away off of the shaft.

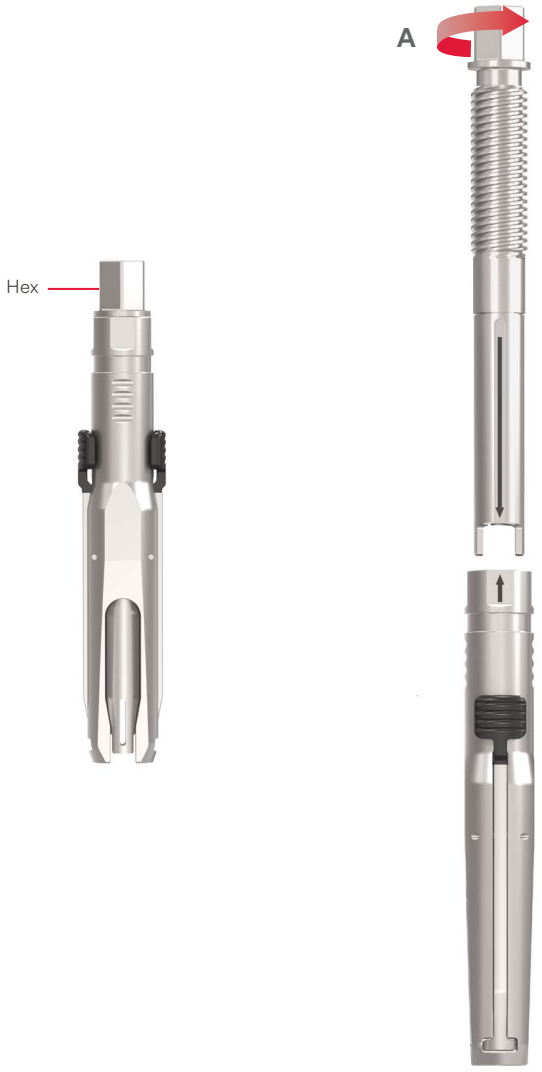


Disassembly Instructions

Sequential Reducer

Follow the instructions below for disassembly of the **Sequential Reducer** assembly.

A. Holding the **Sequential Reducer Outer Sleeve**, grasp the proximal hex feature of the **Sequential Reducer Inner Sleeve** and rotate counter-clockwise until the inner sleeve is fully unthreaded.



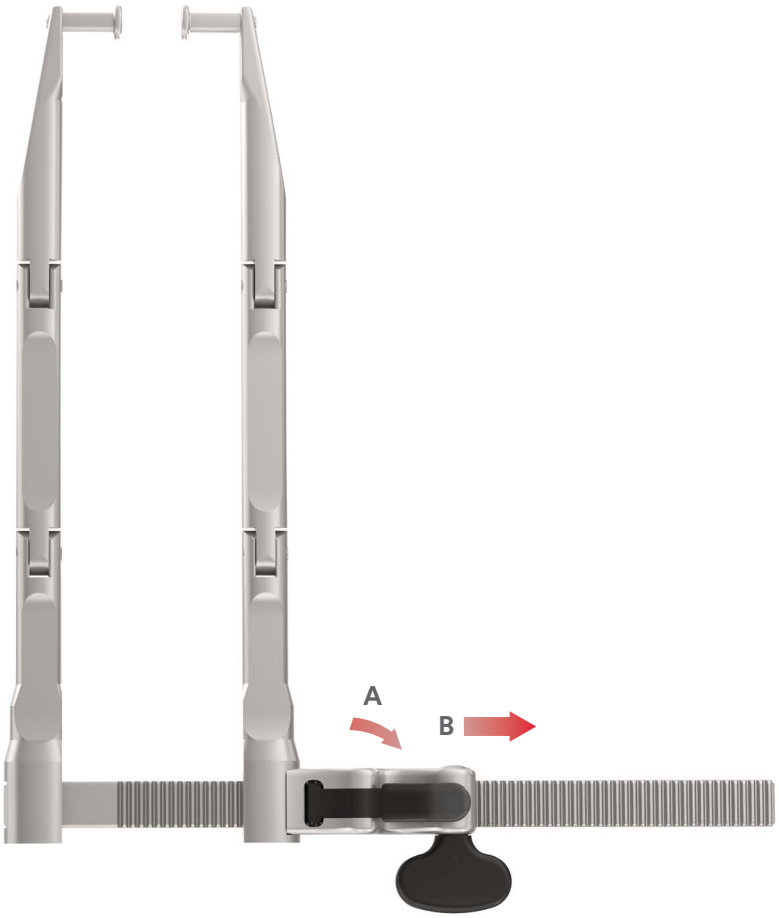
Disassembly Instructions

TLIF Distractor

Follow the instructions below for disassembly of the **TLIF Distractor** as follows:

A. Depress the black lever of the **Distractor Arm**.

B. Slide the **Distractor Arm** off of the **Distractor Rack**.



Indications and Contraindications

Indications for Use

The TriALTIS™ Spine 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.

The TriALTIS™ Spine System is intended for pedicle fixation of the thoracic, lumbar, and sacral spine (T1-S2) and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior pedicle screw fixation of the thoracic, lumbar, and sacral spine (T1-S2) and nonpedicle fixation in pediatric patients, the TriALTIS™ Spine System is indicated as an adjunct to fusion to treat spinal deformities (i.e, scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the TriALTIS™ Spine System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.

The TriALTIS™ Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When the TriALTIS™ Spine System Fenestrated Screws are used in conjunction with CONFIDENCE™ High Viscosity Spinal Cement, the TriALTIS™ Spine System is intended to stabilize the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The TriALTIS Fenestrated Screws augmented with the CONFIDENCE™ High Viscosity Spinal Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

Indications and Contraindications

Contraindications for Use

The TriALTIS™ Spine System is contraindicated in patients presenting any of the following conditions:

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include severe obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

The use of the Fenestrated Screws in conjunction with CONFIDENCE™ High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices
- Disruption of the posterior cortex
- Anatomical damage of the vertebra that prevents safe screw implantation
- Active or incompletely treated infection
- Coagulation disorders, or severe cardiopulmonary disease
- Spinal stenosis > 20% caused by retropulsed fragments
- Vertebral body collapse to less than 1/3 (33%) original height
- Coagulopathy or inability to reverse anticoagulant therapy (both during and approximately 24 hours post-procedure)
- Allergic reaction to any of the components of the cement or metal used
- Relative contraindications include severe obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure

See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this IFU.

Instructions for Use

For more information, please refer to the following IFUs:

DePuy Synthes	IFU-0902-90-406
Gauthier	IFUN-006
Intech	IFU-012 IFU-013 IFU-014 IFU-002

Connectors, Hooks, and Compatible Systems

The TriALTIS™ Spine System is compatible with the MATRIX™ Spine System cross-connectors.

The TriALTIS™ Spine System may be connected to the SYMPHONY™ OCT System using SYMPHONY OCT connectors and dual diameter rods (tapered rods).

The TriALTIS 5.5 mm diameter rods are compatible with the 5.5 mm diameter screws in EXPEDIUM VERSE, VIPER, VIPER 2, VIPER PRIME. Additionally, TriALTIS 5.5 mm diameter rods are compatible with 5.5 mm diameter EXPEDIUM™ Spine System titanium alloy screws, connectors and hooks. Both TriALTIS 5.5 mm and 6.0 mm diameter rods are compatible with EXPEDIUM 5.5-6.35 variable connectors. TriALTIS 6.0 mm diameter rods are only compatible with the variable connection portion of the variable connectors. Do not use the 6.35 mm connector portion of the variable connectors on a TriALTIS rod.

▲ Caution:
TriALTIS 6.0 mm diameter rods are only compatible with the variable connection portion of the variable connectors. Do not use the 6.35 mm connector portion of the variable connectors on a TriALTIS rod. Do not use EXPEDIUM connectors other than the ones indicated in this document as compatible with the TriALTIS™ Spine System rods.

Connectors, Hooks, and Compatible Systems

Compatible EXPEDIUM™ Spine System Titanium Alloy Connectors and Hooks for 5.5 mm TriALTIS Rods	
1799-74-555	Variable Open/Closed Pivoting Connector 6.35 x 5.5-6.35 mm
1797-74-555	Variable Open/Closed Pivoting Connector 5.5 x 5.5-6.35 mm
1797-76-555	Single Inline Rodded Connector, 5.5 x 5.5-6.35 x 200 mm
1799-76-555	Single Inline Rodded Connector, 6.35 x 5.5-6.35 x 200 mm
1797-98-020	Closed Polyaxial Lateral Connector Ø5.5 x 20 mm Ti
1797-98-040	Closed Polyaxial Lateral Connector Ø5.5 x 40 mm Ti
1797-98-060	Closed Polyaxial Lateral Connector Ø5.5 x 60 mm Ti
1797-98-100	Closed Polyaxial Lateral Connector Ø5.5 x 100 mm Ti
1797-98-200	Closed Polyaxial Lateral Connector Ø5.5 x 200 mm Ti
1797-97-020	Open Polyaxial Lateral Connector Ø5.5 x 20 mm Ti
1797-97-040	Open Polyaxial Lateral Connector Ø5.5 x 40 mm Ti
1797-97-060	Open Polyaxial Lateral Connector Ø5.5 x 60 mm Ti
1797-97-100	Open Polyaxial Lateral Connector Ø5.5 x 100 mm Ti
1797-97-200	Open Polyaxial Lateral Connector Ø5.5 x 200 mm Ti
1797-93-020	Open Lateral Connector Ø5.5 x 20 mm Ti
1797-93-050	Open Lateral Connector Ø5.5 x 50 mm Ti
1797-93-150	Open Lateral Connector Ø5.5 x 150 mm Ti
1797-40-040	Closed Lateral Connector Ø5.5 x 40 mm Ti
1797-40-060	Closed Lateral Connector Ø5.5 x 60 mm Ti
1797-40-125	Closed Lateral Connector Ø5.5 x 125 mm Ti
1774-92-020	Side-By-Side Connector 5.50 x 5.50 mm Ti
1774-92-060	End-To-End 5.50 x 5.50 mm Ti
1797-77-555	End-To-End Double Set-Screw Connector 5.50/5.50 mm Ti
1797-55-155	Conn Open/Closed 5.50 x 5.50 mm Ti

Connectors, Hooks, and Compatible Systems

Compatible EXPEDIUM™ Spine System Titanium Alloy Connectors and Hooks for 5.5 mm TriALTIS Rods	
1797-52-045	Wide Blade Hook 5.0 mm
1797-52-046	Wide Blade Hook 6.5 mm
1797-52-048	Wide Blade Hook 8.0 mm
1797-52-040	Wide Blade Hook 10.0 mm
1797-52-042	Wide Blade Hook 12.0 mm
1797-52-016	Reduced Distance Hook 6.5 mm
1797-52-018	Reduced Distance Hook 8.0 mm
1797-52-010	Reduced Distance Hook 10.0 mm
1797-52-012	Reduced Distance Hook 12.0 mm
1797-52-026	Angled Blade Hook 6.5 mm
1797-52-028	Angled Blade Hook 8.0 mm
1797-52-029	Angled Blade Hook 10.0 mm
1797-52-020	Angled Blade Hook 12.0 mm
1797-52-036	Narrow Blade Hook 6.5 mm

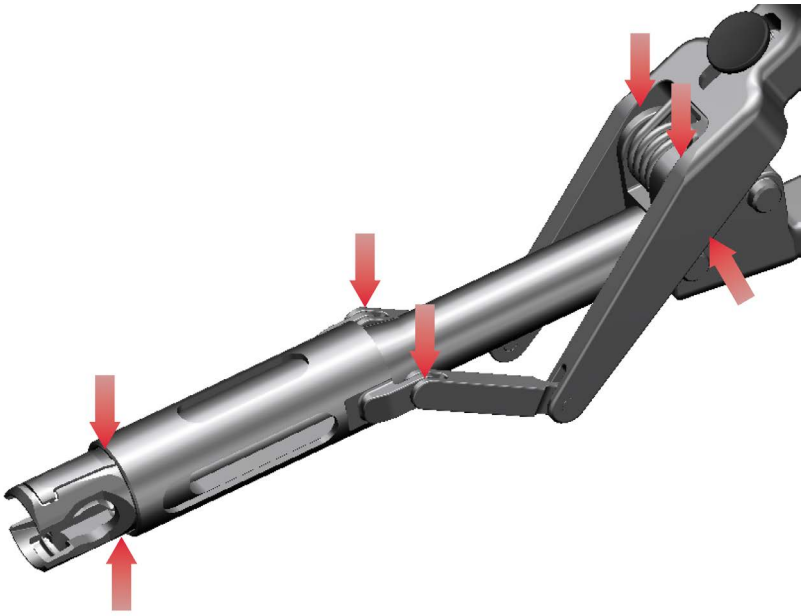
Connectors, Hooks, and Compatible Systems

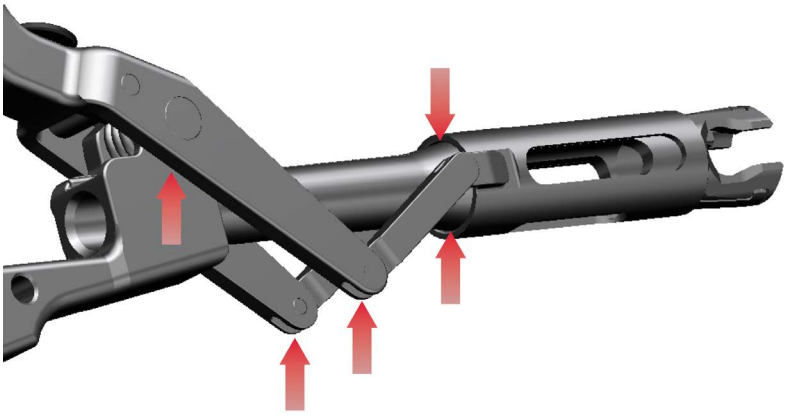
SYMPHONY™ OCT SYSTEM Compatible Devices	
1020-15-083	PARALL CON 3.5-4 TO 5.5-6.35 S
1020-15-083S	PARALL CON 3.5-4 TO 5.5-6.35 S
1020-15-113	PARALL CON 3.5-4 TO 5.5-6.35 L
1020-15-113S	PARALL CON 3.5-4 TO 5.5-6.35 L
1020-16-003	REDUCTION CON 3.5-4.0 TO 5.5
1020-16-003S	REDUCTION CON 3.5-4.0 TO 5.5
1020-19-004	AXIAL CON 3.5-4 TO 5.5-6.35
1020-19-004S	AXIAL CON 3.5-4 TO 5.5-6.35
1020-20-550	TOP LOADING ROD CON 5.5
1020-20-550S	TOP LOADING ROD CON 5.5
1020-31-506	TI 3.5-5.5X420 DD OFFST ROD S
1020-31-506S	TI 3.5-5.5X420 DD OFFST ROD S
1020-31-510	TI 3.5-5.5X420 DD OFFST ROD L
1020-31-510S	TI 3.5-5.5X420 DD OFFST ROD L
1020-41-506	TI 4.0-5.5X420 DD OFFST ROD S
1020-41-506S	TI 4.0-5.5X420 DD OFFST ROD S
1020-41-510	TI 4.0-5.5X420 DD OFFST ROD L
1020-41-510S	TI 4.0-5.5X420 DD OFFST ROD L
1020-84-420	TI 4.0-5.5X420 DD ROD
1020-84-420S	TI 4.0-5.5X420 DD ROD
1020-84-600	TI 4.0-5.5X600 DD ROD
1020-84-600S	TI 4.0-5.5X600 DD ROD
1020-85-420	TI 3.5-5.5X420 DD ROD

Reprocessing, Care, and Maintenance

Reusable, non-sterile surgical instruments are required to be cleaned, maintained and sterilized prior to surgical use.

Inspect the Acute Reducer 5.5/6.0 for proper function, including movement of hinges/joints and movable features. As required, lubricate the Acute Reducer 5.5/6.0 in the locations indicated by red arrows using a watersoluble surgical instrument lubricant. The lubricant should be approved for use on medical devices and provided with data to ensure biocompatibility with steam sterilization.





Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

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