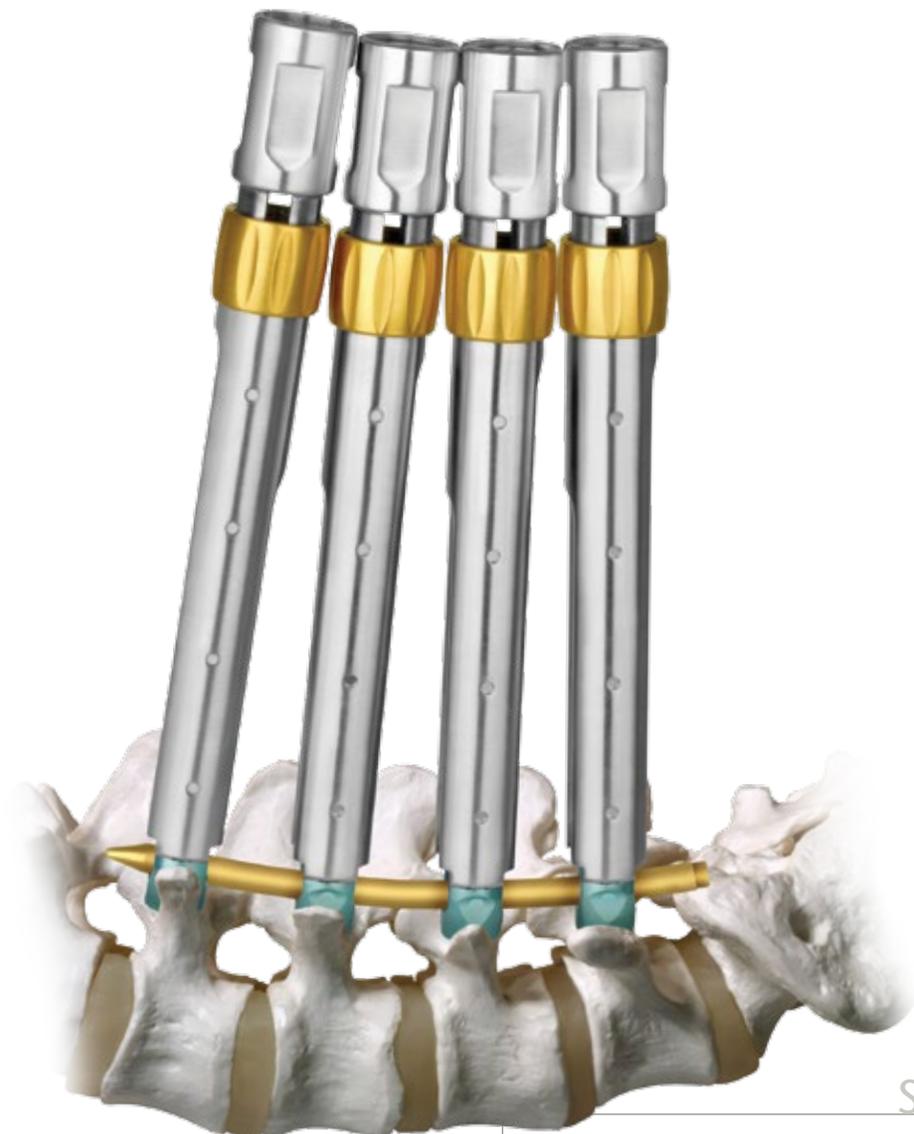
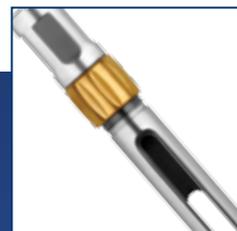
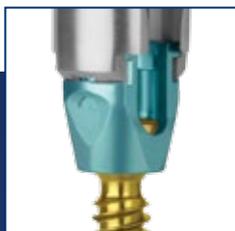


Life moves us 



SURGICAL TECHNIQUE



REVOLVE[®]

Stabilization System



Outside the US Only



Life moves us ➤

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve

the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.



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REVOLVE[®]

Stabilization System



REVOLVE[®] is a posterior stabilization system designed for minimally invasive surgery (MIS), in which virtually every step of the MIS procedure has been enhanced.

REVOLVE[®] instrumentation provides ease of use irrespective of patient anatomy, due to integrated, streamlined rod reduction and a strong screw-sleeve connection. This screw-sleeve connection facilitates powerful and controlled manipulation of instruments and anatomy. Non-threaded locking caps eliminate cross-threading. This system has multi-level capability for tumor, trauma and deformity applications.



REVOLVE®

STABILIZATION SYSTEM

■ REVOLVE® Locking Technology

Non-threaded locking caps eliminate cross-threading and keyed instrumentation ensures correct cap placement

■ Powerful Rod Reduction

Provides fixation irrespective of complexity, due to integrated, streamlined rod reduction and a strong screw-sleeve connection

■ Multi-Level Capability

System adapts to surgeon needs, with capabilities for trauma, tumor and deformity applications

■ Low-Profile Sleeves

Optional Low-Profile Reduction Sleeves reduce instrument bulk to accommodate varying patient anatomy

REVOLVE® Enhances Every Step of a MIS Procedure

Tap and awl in one step

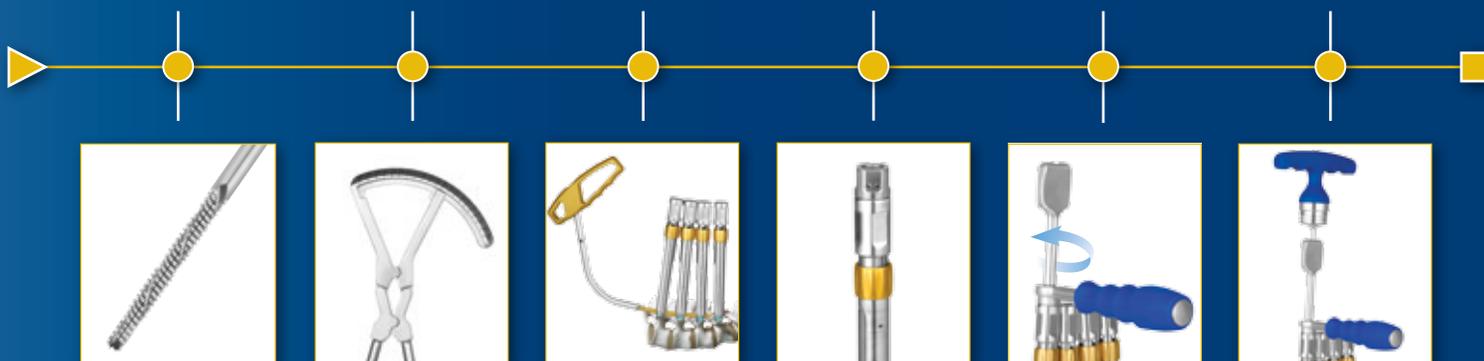
Precise rod measurement

Single handed rod manipulation

Built-in rod reduction

Simple locking cap mechanism requires only two finger 90° rotation

Final tightening



CONTENTS

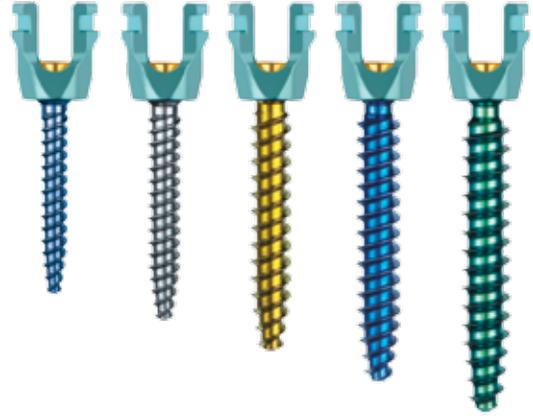
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The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

REVOLVE® Polyaxial Screw

- Cannulated Screws
- $\pm 30^\circ$ screw angulation (60° total) provides intraoperative versatility
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase
- Double lead thread for rapid insertion
- Screw diameters: 5.0, 5.5, 6.5, 7.5, 8.5mm
- Screw lengths: 25–90mm
- Additionally available: monoaxial, uniplanar, and uniplanar fracture screws



REVOLVE® Locking Cap

- Non-threaded locking cap
- Eliminates cross-threading
- 90° rotation captures rod
- Set screw secured in place to prevent displacement



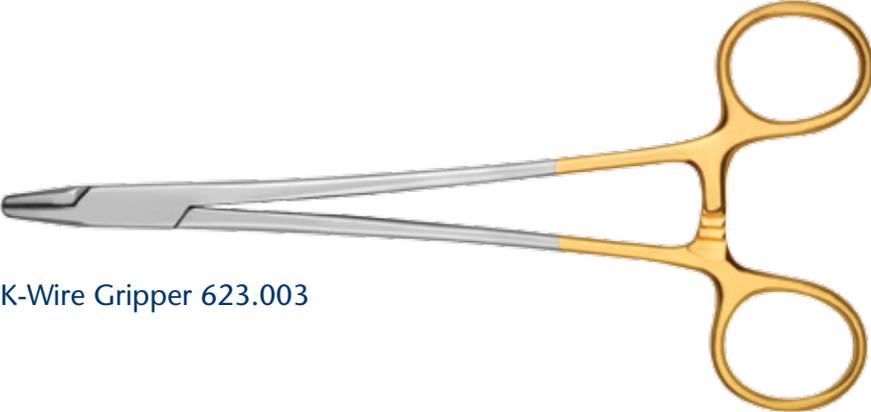
REVOLVE® Rods

- Distal end bullet-nosed to aid insertion
- Proximal end featured allows for manipulation
- 5.5mm diameter
- Straight and pre-lordosed rods (40–75mm)
- Rod Lengths:
 - 40–75mm, in 5mm increments
 - 80–240mm, in 10mm increments
 - 300–500mm, in 50mm increments



INSTRUMENT OVERVIEW

Preparation Instruments



K-Wire Gripper 623.003



Jamshidi Needle 685.022S



1.6mm K-Wire, 500mm, Blunt, Tip 685.005

1.6mm K-Wire, 500mm, Sharp, Tip 685.006



Cannulated Taps

5.5mm 685.055

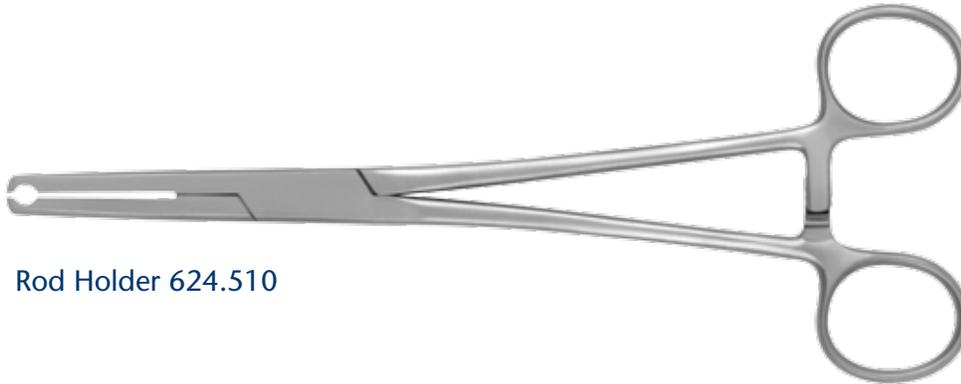
6.5mm 685.065

7.5mm 685.075

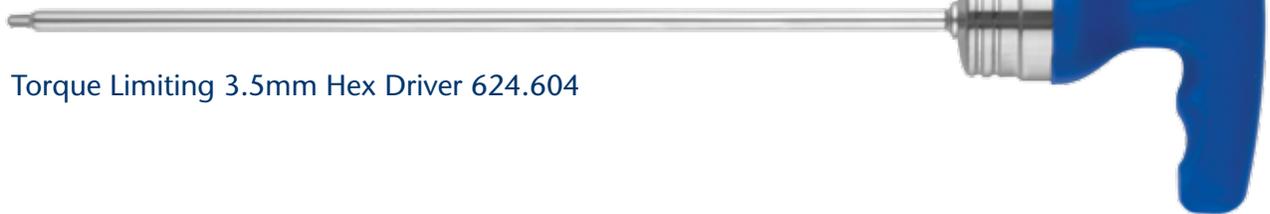


6.35 Quick Release Ratchet Handle, Straight 630.407

Rod Introduction Instruments



Rod Holder 624.510



Torque Limiting 3.5mm Hex Driver 624.604



Cannula A 685.100



Cannula B 685.101



Cannula C 685.102



Cannula Pusher 685.125



Screw Measuring Instrument 685.130

Rod Introduction Instruments (cont'd)



Reduction Sleeve 685.135



REVOLVE® Screwdriver 685.140



Locking Cap Guide 685.145



Fixed Dissector 685.150



10mm Hex Driver 685.155



Fixed Rod Holder 685.180

Rod Introduction Instruments (cont'd)



Locking Cap Driver 685.185



Threaded Reducer 685.190



Threaded Reducer Adaptor 685.195



Rod Indicator 685.205

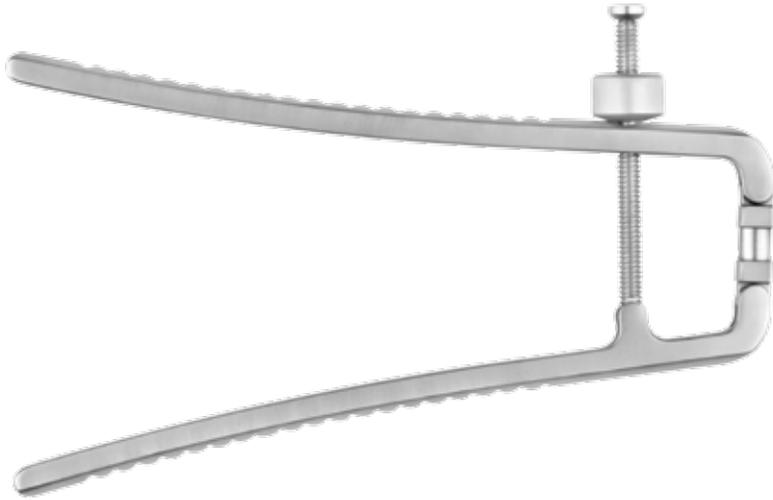


Rod Lever 685.215



Counter Torque 685.220

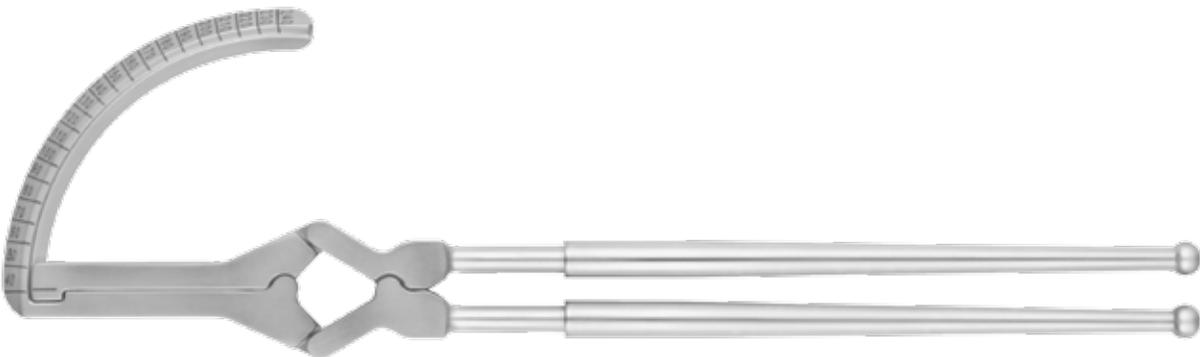
Rod Introduction Instruments (cont'd)



Compressor/Distractor 685.400



Fulcrum, Compressor/Distractor 685.410



Rod Calipers 685.420

Additionally Available Instruments



90° Rod Holder 685.430



Sleeve Positioner 685.435



5.5mm Ratcheting Reducer
685.450



Overhead Locking Cap Guide
685.451

Additionally Available

1.6mm K-Wire, 450mm, Blunt Tip 685.003	5.0mm Cannulated Tap 685.050
1.6mm K-Wire, 450mm, Sharp Tip 685.004	8.5mm Cannulated Tap 685.085
1.6mm K-Wire, 500mm, Sharp Tip 685.006	REVOLVE® Cannula A, PEEK 685.110
1.6mm Nitinol K-Wire, 500mm, Blunt Tip 685.007	REVOLVE® Cannula B, PEEK 685.111
1.6mm Nitinol K-Wire, 500mm, Sharp Tip 685.008	REVOLVE® Cannula C, PEEK 685.112
Jamshidi Needle, Single Trocar 685.023S	REVOLVE® Cannula D, PEEK 685.113

REVOLVE® SURGICAL TECHNIQUE

Step 1 Approach

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned. Lateral C-arm fluoroscopy or other radiographic methods are required throughout surgery to ensure correct screw placement. There are various techniques for pedicle screw and rod insertion. For the purposes of this surgical technique, a Wiltse paramedial approach and building of a 3 level construct is shown.

Refer to the specific product insert for additional information.

Step 2 Screw Insertion

Pedicle Access

Using C-arm fluoroscopy or other radiographic methods, access the pedicle with a **Jamshidi Needle**.

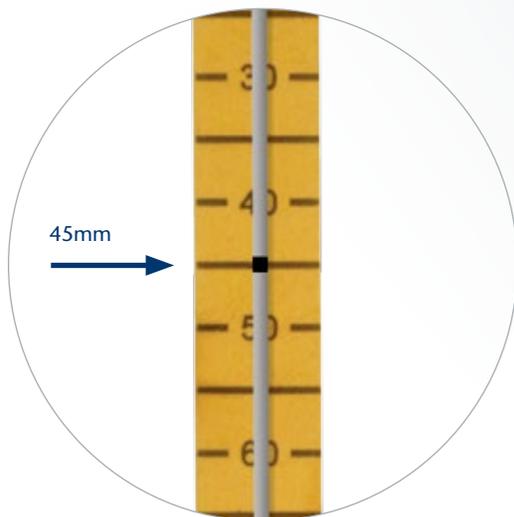
Remove the handle from the jamshidi needle and insert a K-Wire. The **K-Wire Gripper** can be used to aid K-Wire insertion. Verify K-Wire position with fluoroscopy.



Screw Insertion (cont'd)

Make an incision around the K-Wire. Dilate the incision by placing **Cannula A** over the K-Wire. Locate the **Screw Measuring Instrument** on the proximal end of the cannula to approximate the length of pedicle screw needed.

If using the 500mm K-Wire, the etched line corresponds to the length of the screw. If using the 450mm K-Wire, the proximal end of the K-Wire corresponds to the length of the screw.



Estimating screw length



Tissue Dilation

Remove the Screw Measuring Instrument and progressively dilate the incision using **Cannulas B and C**.

The **Cannula Pusher** can be used to introduce the cannulas into place.

Remove the cannulas ensuring that the K-Wire does not become displaced as the cannulas are removed.

Pedicle Preparation

REVOLVE® Pedicle Screws are self-tapping; however pedicles may be tapped if desired. Attach the **Cannulated Tap** of the desired diameter to the **6.35 Quick Release Ratchet Handle, Straight**. Tap the pedicle to the determined depth.

Note: Ensure that the K-Wire does not advance while tapping.



Dilating the incision

Screw Insertion (cont'd)

Assemble the **Reduction Sleeve** and **REVOLVE® Screwdriver** onto the REVOLVE® Polyaxial Pedicle Screw, as shown below.

Drive the sleeve/screw assembly over the K-Wire into the prepared pedicle. Use fluoroscopy to monitor screw insertion and placement. Do not allow advancement of the K-Wire.

Once the screw reaches the posterior aspect of the vertebral body, the K-Wire can be removed. Advance the screw to the desired position. Disconnect the screwdriver by rotating the knob counterclockwise until the thread disengages from the sleeve. Pull to release the screwdriver from the screw head. Repeat insertion steps for remaining pedicles.

Note: Ensure that the "ROD" etching on the Reduction Sleeve faces the direction of rod trajectory.

Reduction Sleeve/Screw Assembly

Insert the appropriate size screw into the Reduction Sleeve fixture located in the implant module.



Screw loaded into module

The sleeve is positioned above the screw. Ensure that the gold knob is fully loosened. The sleeve is then inserted into the screw and rotated 90°, as shown. Tighten the gold knob on the sleeve to secure the connection.



Attaching the sleeve

Attach the 6.35 Quick Release Ratchet Handle to the REVOLVE® Screwdriver. Insert the screwdriver into the sleeve/screw assembly. Locate the hex in the screw head, then tighten the knob on the screwdriver to secure the connection.



Insert screwdriver



Rotate knob



Pedicle screw insertion

Step

3

Rod Insertion

Rod Length Measurement

The **Calipers** are used to determine rod length. Insert the caliper into the Reduction Sleeves at either end of the construct, as shown below. This ensures the caliper is correctly seated in the screw head to give an accurate reading. The shoulder of the caliper must be flush with the top of the sleeve. The reading indicates the desired rod length. If the reading is between two numbers, the larger number should be used. Remove the calipers from the sleeves.



Rod Insertion (cont'd)

Rod Length Measurement (cont'd)

For long constructs, it may be necessary to determine rod length with two measurements: Start at one end of the construct, open the calipers as wide as possible and insert the caliper into the first Sleeve (A) at one end and the furthest possible sleeve (B) at the other. Make note of the reading (e.g. 95mm). Remove the Calipers from the sleeves. For the second reading, insert the caliper into sleeve (B) and the sleeve at the other extremity of the construct (C). Make note of the second reading (60mm). Add the two readings together and subtract 25mm from the total (Rod overhang of 12.5mm at each end = 25mm). This is the rod length needed for the construct (e.g. $95+60-25=130\text{mm}$).



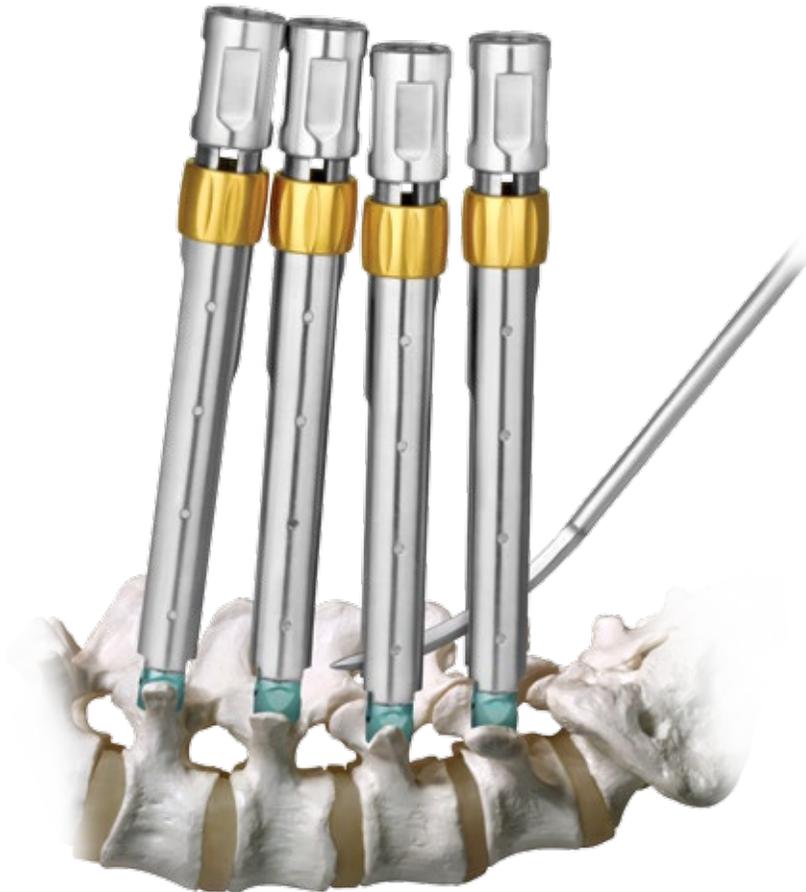
The appropriate rod length may also be determined by laying the rod template across the top of the sleeves.

Alternatively, hold the template against the skin, aligned with the screw. Take a lateral fluoroscopy image and contour the template accordingly. The rod can now be contoured using the template as a guide. Straight rods are available in a variety of lengths.

Note: To contour the rod, the Rod Bender from the REVERE® Instrument II Set is recommended.

Muscle Dissection

Use the **Fixed Dissector** to facilitate rod insertion between adjacent screw sleeves. Verify advancement of the dissector with frequent fluoroscopy. If needed, a scalpel may be used through the sleeve to separate the fascia.



Facilitating rod insertion

Rod Insertion (cont'd)

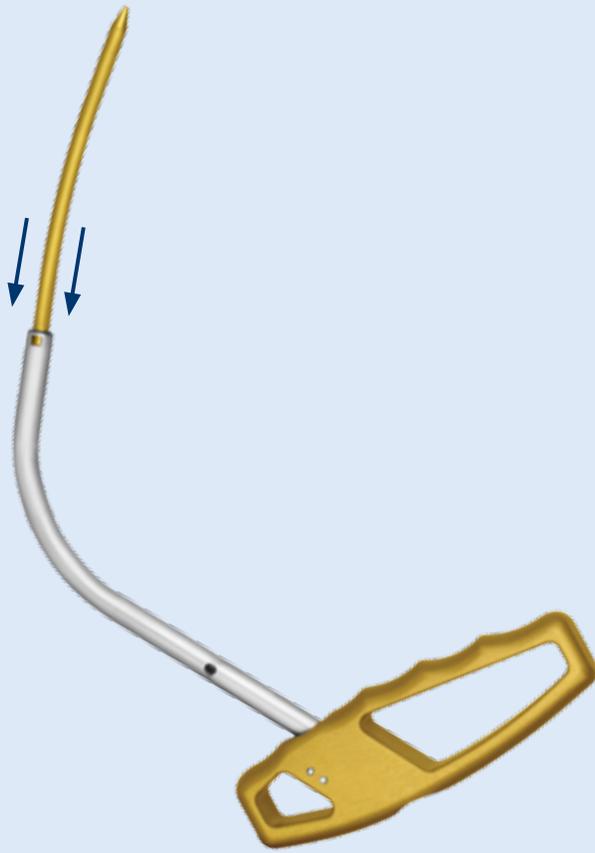
Rod Introduction

There are two options for rod insertion in the REVOLVE® system.

Option A: Fixed Rod Holder

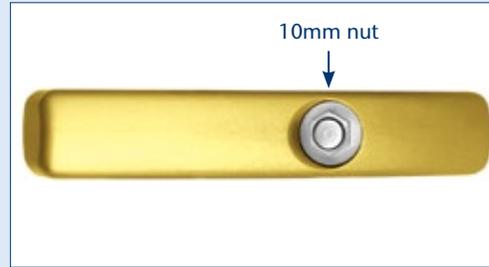
Load the appropriate rod onto the **Fixed Rod Holder**, as shown at right. Make a small stab incision approximately 4cm from the first Reduction Sleeve. Insert the rod through the incision, into the slots in the sleeves until the tip of the holder reaches the first sleeve. Verify rod position and advancement with fluoroscopy until fully seated.



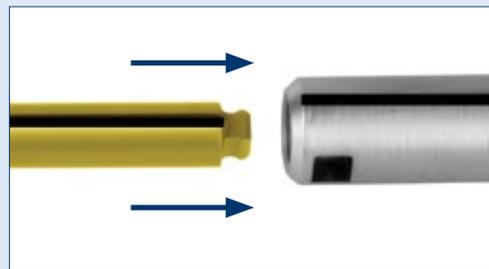


Loading Rod onto Fixed Rod Holder

Hold the Fixed Rod Holder so that the distal tip is facing straight up. Ensure that the 10mm nut on the gold handle is fully loosened.



Align etchings on the Fixed Rod Holder and the rod. Gently press together to engage.



Rod Tightening

Apply downward pressure on the rod while manually tightening the 10mm nut with the 10mm Hex Driver (two finger tight). Do not over-tighten.



While tightening the 10mm nut, look for visual indication that the rod is being loaded correctly onto the holder, as shown below.



Initial loading



Partially tightened



Fully tightened

Note: If resistance is met before the rod is fully tightened, loosen the nut, re-seat the rod on the holder, and tighten again.

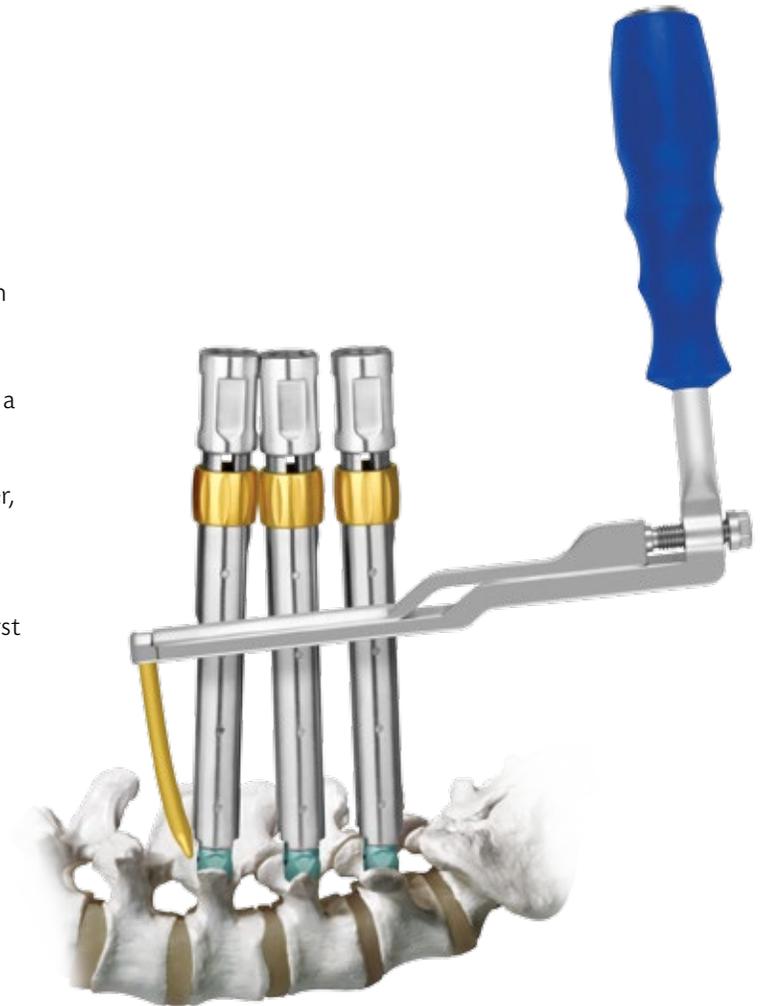
Rod Insertion (cont'd)

Option B: 90° Rod Holder

Alternatively, the **90° Rod Holder** may be used in place of the Fixed Rod Holder when dealing with a smaller, 1- to 2-level contract. Unlike the Fixed Rod Holder, the 90° Rod Holder may not require a separate stab incision to pass the rod.

Load the appropriate rod into the 90° Rod Holder, as shown on page 23.

Begin by orientating the rod parallel to the Reduction Sleeve with the tip of the rod in the first screw head.



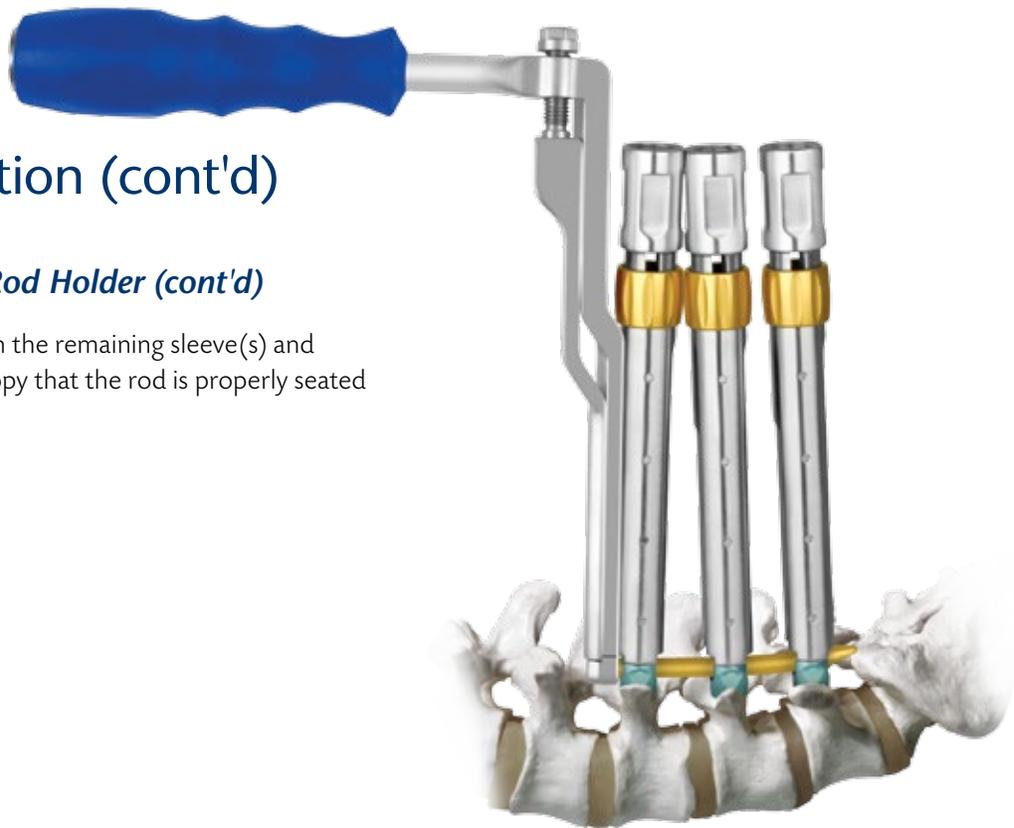
Rock the 90° holder back towards the handle to pass the rod into the second sleeve. Verify rod position and advancement with fluoroscopy until fully seated.

Note: The incision on the first sleeve may need to be extended to allow the 90° holder to pass under the skin during final positioning.

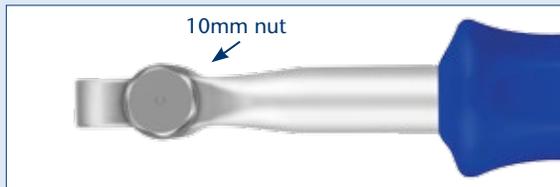
Rod Insertion (cont'd)

Option B: 90° Rod Holder (cont'd)

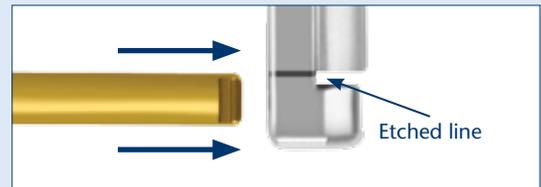
Pass the rod through the remaining sleeve(s) and verify with fluoroscopy that the rod is properly seated within the sleeves.



Loading the 90° Rod Holder



1. Loosen the 10mm nut until the bottom of the slide is aligned with the etched line on the side of the instrument.



2. Align the rod and insert into the bottom of the 90° holder.



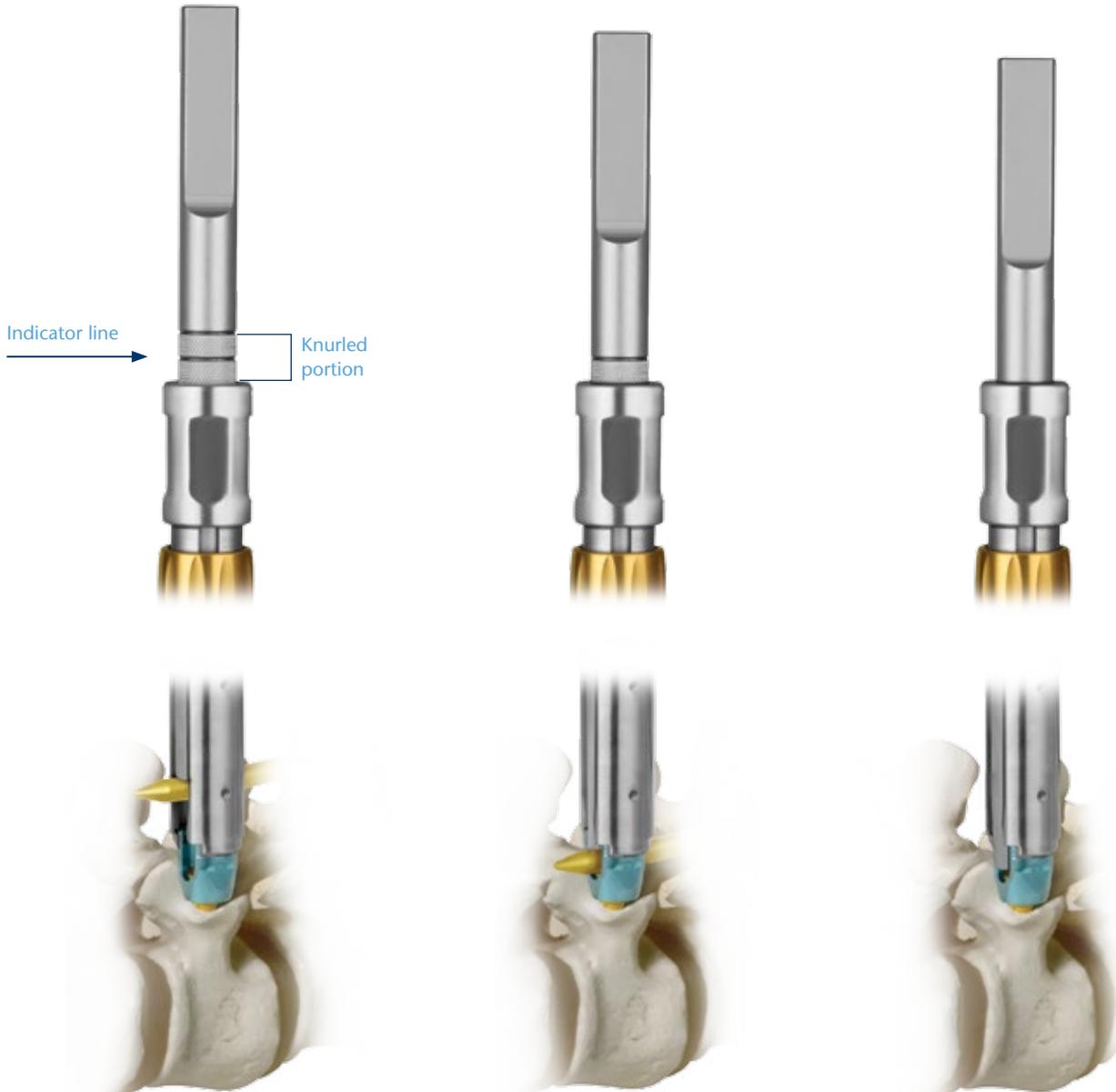
3. Maintain the rod connection while manually tightening the 10mm nut with the 10mm Hex Driver.



4. Assembled 90° Rod Holder

Step 4 Rod Verification

Use the **Rod Indicator** to verify rod location in the Reduction Sleeve. Introduce the indicator into each sleeve, sequentially. The indicator rests on the rod and acts as a gauge for rod location.



- ✓ Knurled portion visible
- ✓ Rod located in sleeve
- ✓ Rod reduction required

- ✓ Indicator line flush with sleeve
- ✓ Rod located in screw head
- ✓ Locking cap may be introduced

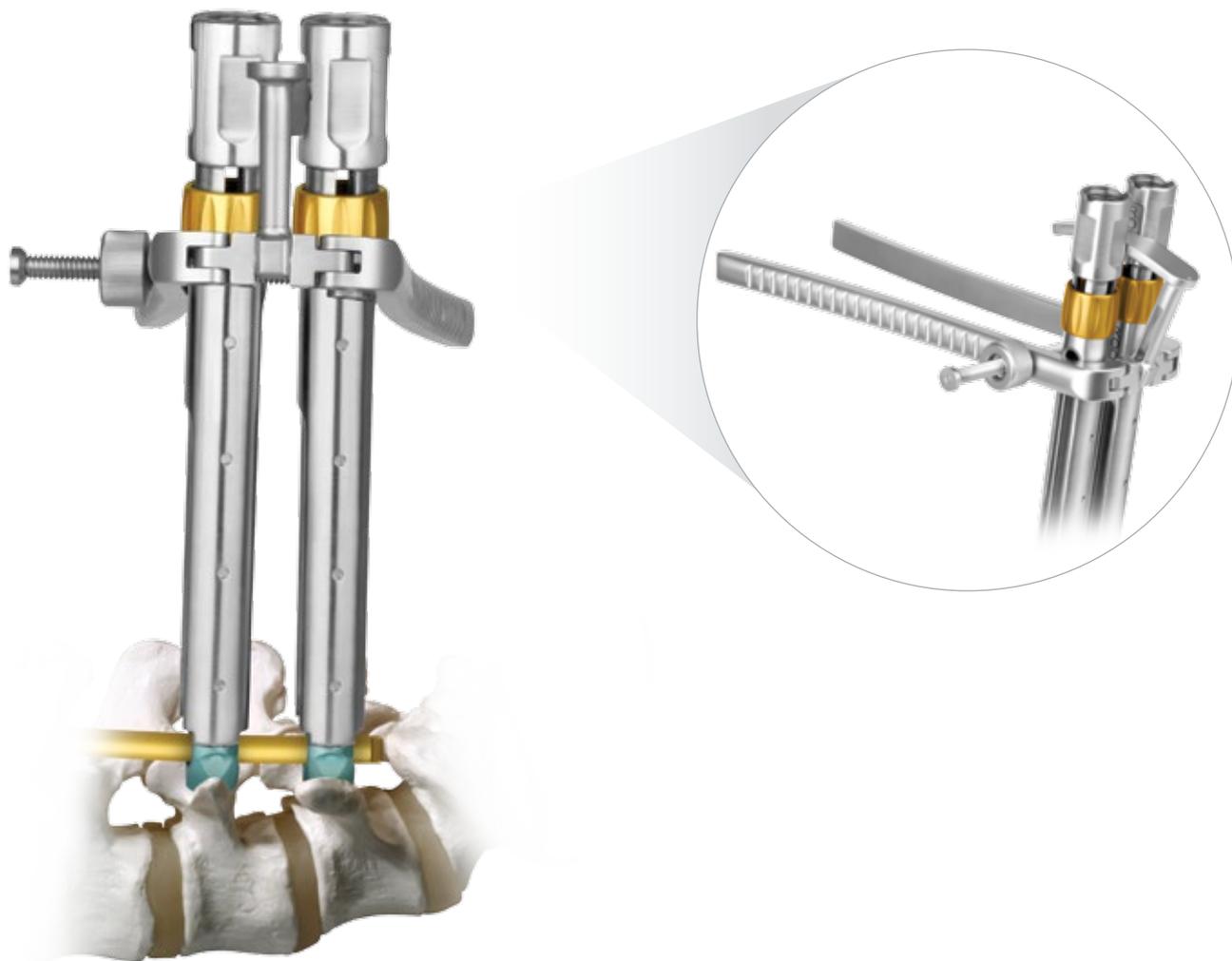
- ✗ No knurled portion visible
- ✗ Rod not located in sleeve
- ✗ Rod re-introduction required

Step

5

Compression or Distraction

If compression is required, place the **Compressor/Distractor** around the two Reduction Sleeves. Position the **Fulcrum, Compressor/Distractor** above the arms of the compressor, as shown below.

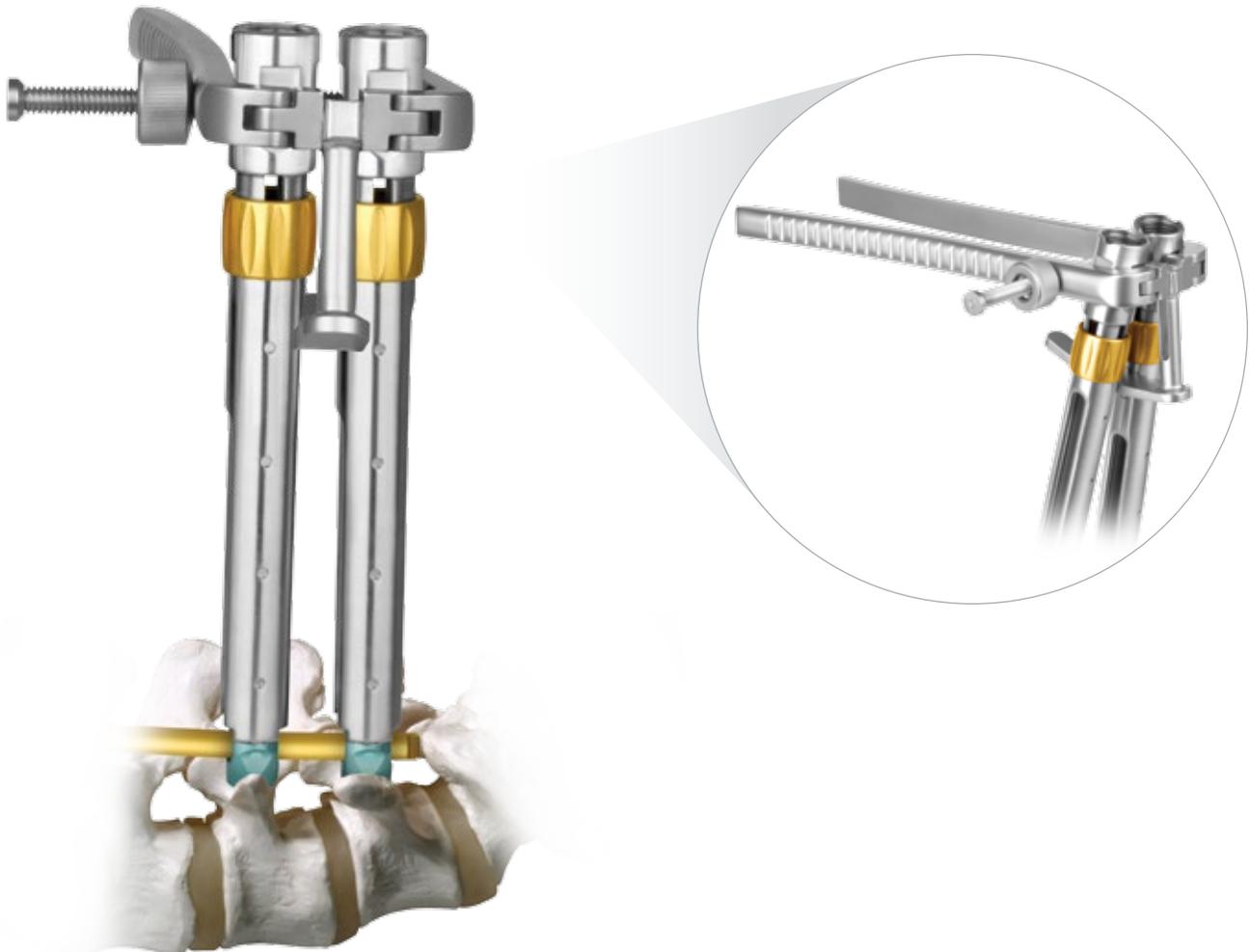


Compress the compressor arms until adequate compression is achieved. Secure the instrument in place by tightening the thumb lock on the side.

Note: Ensure that both components of the Compressor/Distractor are straddling the gold knobs on the Reduction Sleeves. Do not directly compress or distract on the gold knobs.

Compression or Distraction (cont'd)

To achieve distraction, place the distractor around the two sleeves and position the fulcrum below the arms of the instrument.



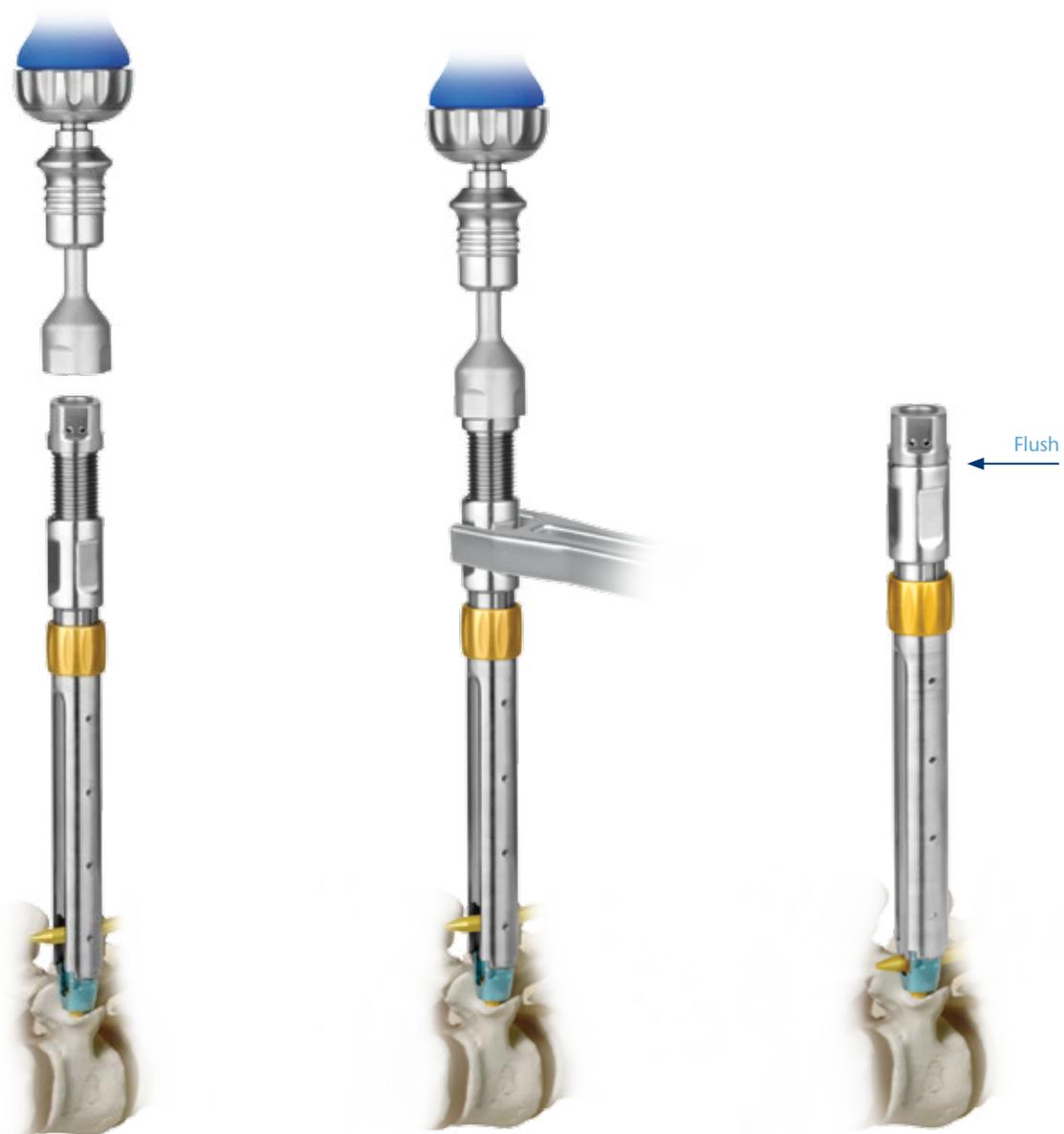
Compress the distractor arms until adequate distraction is achieved. Secure the instrument in place by tightening the thumb lock on the side.

Step 6 Rod Reduction

Rod reduction may be required prior to delivering the locking cap. Ensure that the rod is properly contoured prior to insertion and reduction.

Insert the **Threaded Reducer** into the Reduction Sleeve. Attach the Quick Release Ratchet Handle to the **Reducer Adaptor** to advance the reducer. Use the **Counter Torque** to hold the flats of the sleeve while reducing the rod. Rod reduction is complete when the reducer is flush with the sleeve. Remove the ratchet handle and adaptor.

For multiple levels, reduction should be applied incrementally at each level. A loaded **Locking Cap Driver** may be introduced through the reducer.



Rod reduction

Use of counter torque

Rod fully reduced

Step

7

Locking Cap Insertion

Loading the Locking Cap Driver

Align the tabs on the Locking Cap Driver with the indentations on the locking cap within the implant module. Press the driver down over the locking cap until fully seated.

Note: Ensure that the locking cap is properly seated in the driver before insertion.



Locking Cap Driver



Load Locking Cap Driver



Aligning driver with the locking cap

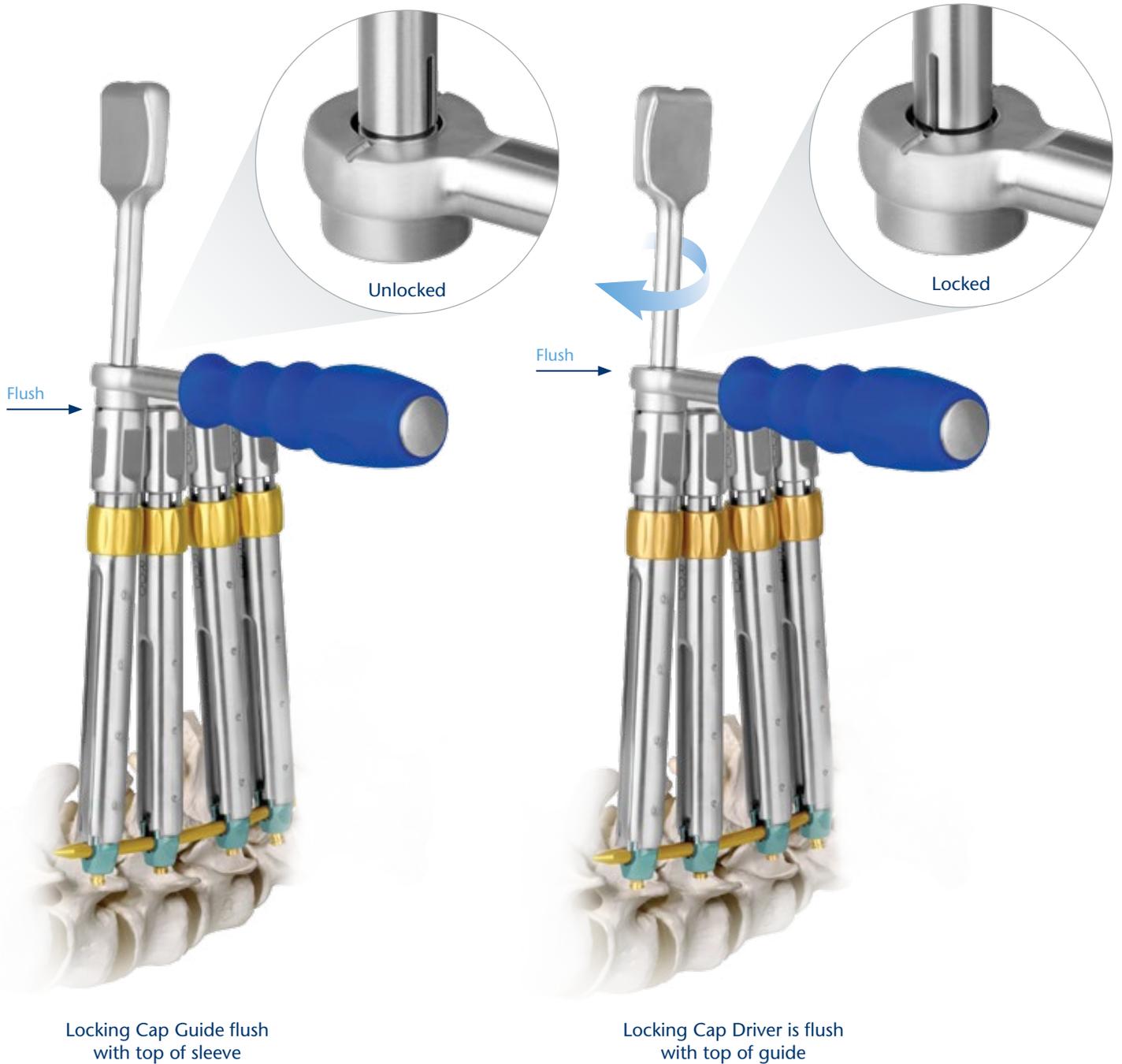


Driver loaded

Locking Cap Insertion

Introduce the **Locking Cap Guide** so that it is flush with the top of the sleeve. Insert the driver into the screw head with the handle perpendicular to the rod, and rotate clockwise 90° to capture the rod. In the locked position, the etched lines on the driver and guide are aligned.

Note: Locking cap insertion requires minimal effort. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction or rod re-contouring is required.



Step

8

Final Tightening

Final tightening of the set screw is necessary to secure the construct and is accomplished using the **Torque Limiting 3.5mm Hex Driver**.

Insert the hex driver through the Locking Cap Driver until it is engaged in the set screw. Rotate the hex driver until it reaches the torque limit (5.5Nm).



Step

9

Rod Holder Extraction

After final tightening all set screws, the Fixed Rod Holder may be released. Using the 10mm Hex Driver, loosen the nut on the handle of the holder. Gently retract the holder away from the sleeve to release the holder.

Note: Patient anatomy may require that the fixed rod holder be released earlier in the procedure.



Rod Holder Extraction (cont'd)

To release the 90° Rod Holder, use the 10mm Hex Driver to loosen the nut on top of the holder.

Gently retract the inserter away from the sleeve to release the holder.

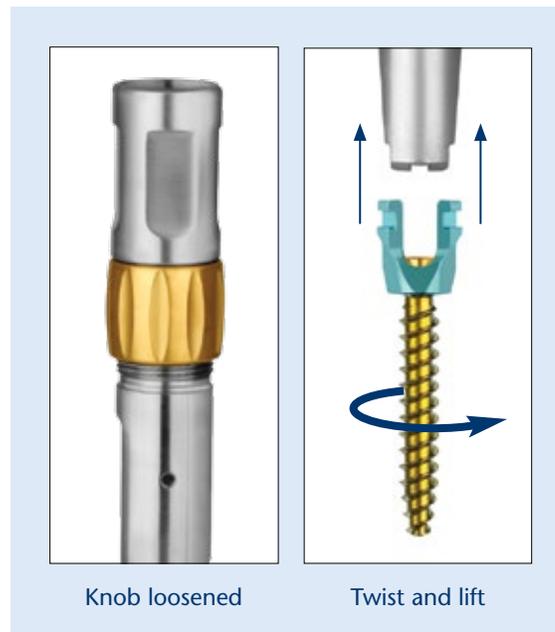


Step 10 Reduction Sleeve Extraction

Remove the Reduction Sleeves by loosening the gold knob and rotating the sleeve 90°.

If the Threaded Reducer was utilized, loosen the reducer with five rotations. Loosen the gold knob of the sleeve to remove the sleeve and the reducer together.

Note: The sleeves will only disengage if the set screw has been final tightened.



REVOLVE[®] IMPLANT SET



REVOLVE® Implant Set 985.901

REVOLVE® Pedicle Screws

Ø5.5mm	Length	Qty	Ø6.5mm	Length	Qty	Ø7.5mm	Length	Qty	Ø8.5mm	Length
185.452	30mm	0	185.462	30mm	0	185.472	30mm	0	185.482	30mm
185.453	35mm	2	185.463	35mm	6	185.473	35mm	4	185.483	35mm
185.454	40mm	2	185.464	40mm	8	185.474	40mm	6	185.484	40mm
185.455	45mm	2	185.465	45mm	8	185.475	45mm	6	185.485	45mm
185.456	50mm	2	185.466	50mm	4	185.476	50mm	4	185.486	50mm
185.457	55mm	0	185.467	55mm	2	185.477	55mm	2	185.487	55mm
			185.468	60mm	0	185.478	60mm	2	185.488	60mm
			185.469	65mm	0	185.479	65mm	0	185.489	65mm

5.5mm Straight Rods

Part No.	Description	Qty	Part No.	Description	Qty
185.280	5.5mm REVOLVE® Rod, Straight, 80mm	2	185.340	5.5mm REVOLVE® Rod, Straight, 140mm	2
185.290	5.5mm REVOLVE® Rod, Straight, 90mm	2	185.350	5.5mm REVOLVE® Rod, Straight, 150mm	2
185.300	5.5mm REVOLVE® Rod, Straight, 100mm	2	185.400	5.5mm REVOLVE® Rod, Straight, 200mm	2
185.310	5.5mm REVOLVE® Rod, Straight, 110mm	2	185.500	5.5mm REVOLVE® Rod, Straight, 300mm	2
185.320	5.5mm REVOLVE® Rod, Straight, 120mm	2	185.000	REVOLVE® Locking Caps	12
185.330	5.5mm REVOLVE® Rod, Straight, 130mm	2			

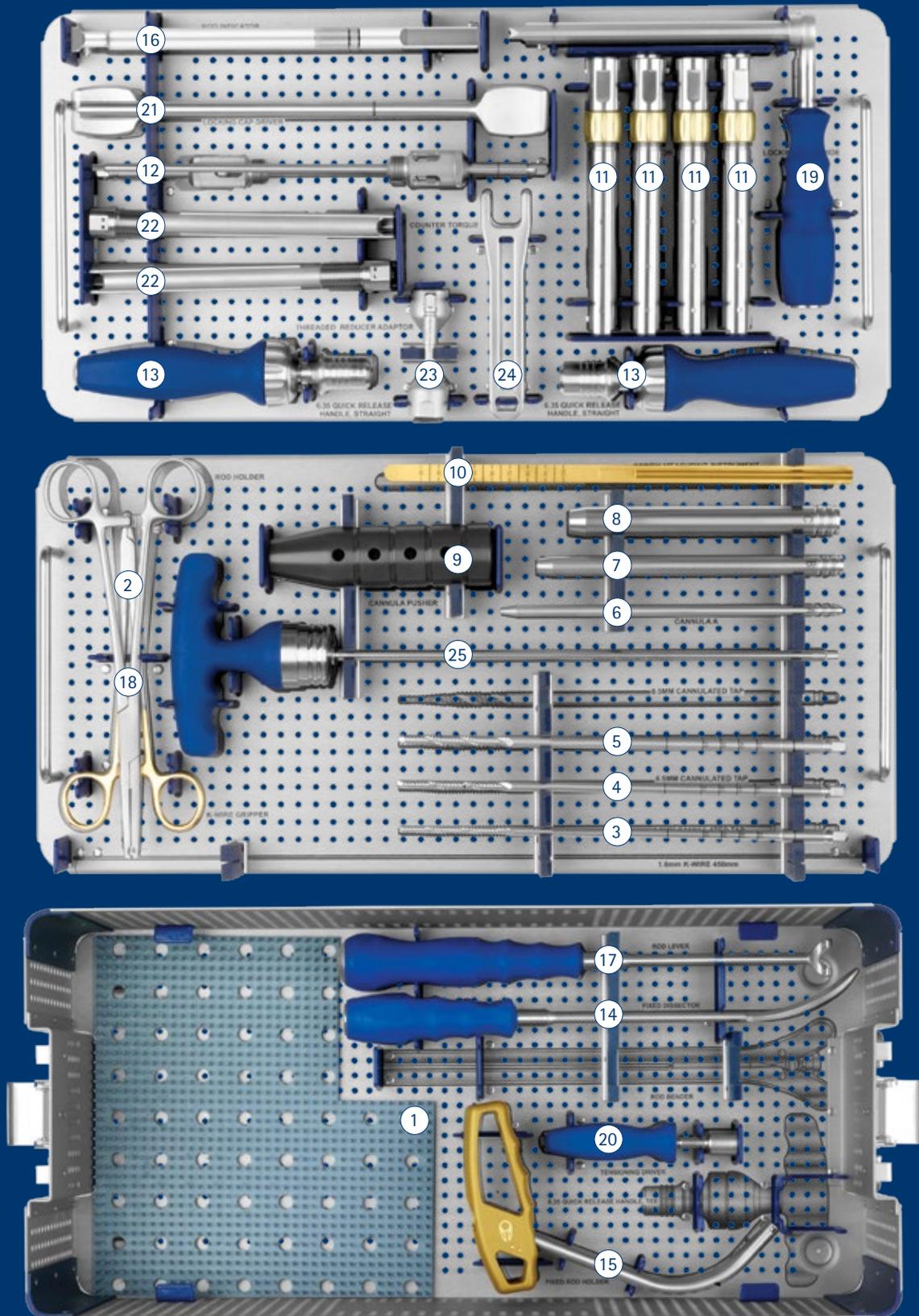
Additionally Available

Part No.	Description	Part No.	Description
185.240	5.5mm REVOLVE® Rod, Straight, 40mm	185.410	5.5mm REVOLVE® Rod, Straight, 210mm
185.245	5.5mm REVOLVE® Rod, Straight, 45mm	185.420	5.5mm REVOLVE® Rod, Straight, 220mm
185.250	5.5mm REVOLVE® Rod, Straight, 50mm	185.430	5.5mm REVOLVE® Rod, Straight, 230mm
185.255	5.5mm REVOLVE® Rod, Straight, 55mm	185.440	5.5mm REVOLVE® Rod, Straight, 240mm
185.260	5.5mm REVOLVE® Rod, Straight, 60mm	185.441	5.0mm REVOLVE® Polyaxial Pedicle Screw, 25mm
185.265	5.5mm REVOLVE® Rod, Straight, 65mm	185.442	5.0mm REVOLVE® Polyaxial Pedicle Screw, 30mm
185.670	5.5mm REVOLVE® Rod, Straight, 70mm	185.443	5.0mm REVOLVE® Polyaxial Pedicle Screw, 35mm
185.675	5.5mm REVOLVE® Rod, Straight, 75mm	185.444	5.0mm REVOLVE® Polyaxial Pedicle Screw, 40mm
185.360	5.5mm REVOLVE® Rod, Straight, 160mm	185.445	5.0mm REVOLVE® Polyaxial Pedicle Screw, 45mm
185.370	5.5mm REVOLVE® Rod, Straight, 170mm	185.446	5.0mm REVOLVE® Polyaxial Pedicle Screw, 50mm
185.380	5.5mm REVOLVE® Rod, Straight, 180mm	185.447	5.0mm REVOLVE® Polyaxial Pedicle Screw, 55mm
185.390	5.5mm REVOLVE® Rod, Straight, 190mm		

Items highlighted in gray are additionally available.

NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.

REVOLVE® INSTRUMENT SET



REVOLVE® Instrument Set 985.902

Pedicle Access		Qty	Additionally Available
①	685.005 1.6mm K-Wire, 500mm, Blunt Tip	12	623.050 Reamer
②	623.003 K-Wire Gripper	1	630.401 6.35 Quick Release Ratchet Handle, Tee
	685.022S Jamshidi Needle	6	685.003 1.6mm K-Wire, 450mm, Blunt, Threaded Tip
③	685.055 5.5mm Cannulated Tap	1	685.004 1.6mm K-Wire, 450mm, Sharp, Threaded Tip
④	685.065 6.5mm Cannulated Tap	1	685.006 1.6mm K-Wire, 500mm, Sharp, Threaded Tip
⑤	685.075 7.5mm Cannulated Tap	1	685.007 1.6mm Nitinol K-wire, 500mm, Blunt Tip
⑥	685.100 Cannula A	1	685.008 1.6mm Nitinol K-wire, 500mm, Sharp Tip
⑦	685.101 Cannula B	1	685.023S Jamshidi Needle, Single Trocar
⑧	685.102 Cannula C	1	685.050 5.0mm Cannulated Tap
⑨	685.125 Cannula Pusher	1	685.085 8.5mm Cannulated Tap
			685.110 Cannula A, PEEK
			685.111 Cannula B, PEEK
			685.112 Cannula C, PEEK
			685.113 Cannula D, PEEK
			685.430 90° Rod Holder
			685.435 Sleeve Positioner
			685.450 5.5mm Ratcheting Reducer
			685.451 Overhead Locking Cap Guide
Screw Insertion			
⑩	685.130 Screw Measuring Instrument	1	
⑪	685.135 Reduction Sleeve	8	
⑫	685.140 REVOLVE® Screwdriver	2	
	685.400 Compressor/Distractor	1	
⑬	630.407 6.35 Quick Release Ratchet Handle, Straight	2	
	685.410 Fulcrum, Compressor/Distractor	1	
Rod Introduction			
⑭	685.150 Fixed Dissector	1	
⑮	685.180 Fixed Rod Holder	2	
⑯	685.205 Rod Indicator	1	
⑰	685.215 Rod Lever	1	
	685.420 Rod Calipers	1	
⑱	624.510 Rod Holder	1	
Cap Insertion			
⑲	685.145 Locking Cap Guide	1	
⑳	685.155 10mm Hex Driver	1	
㉑	685.185 Locking Cap Driver	2	
㉒	685.190 Threaded Reducer	2	
㉓	685.195 Threaded Reducer Adaptor	2	
㉔	685.220 Counter Torque	1	
㉕	624.604 Torque Limiting 3.5mm Hex Driver	1	

NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.



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