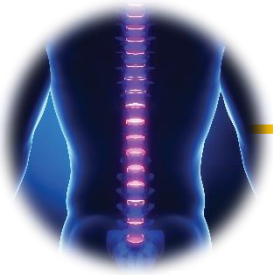
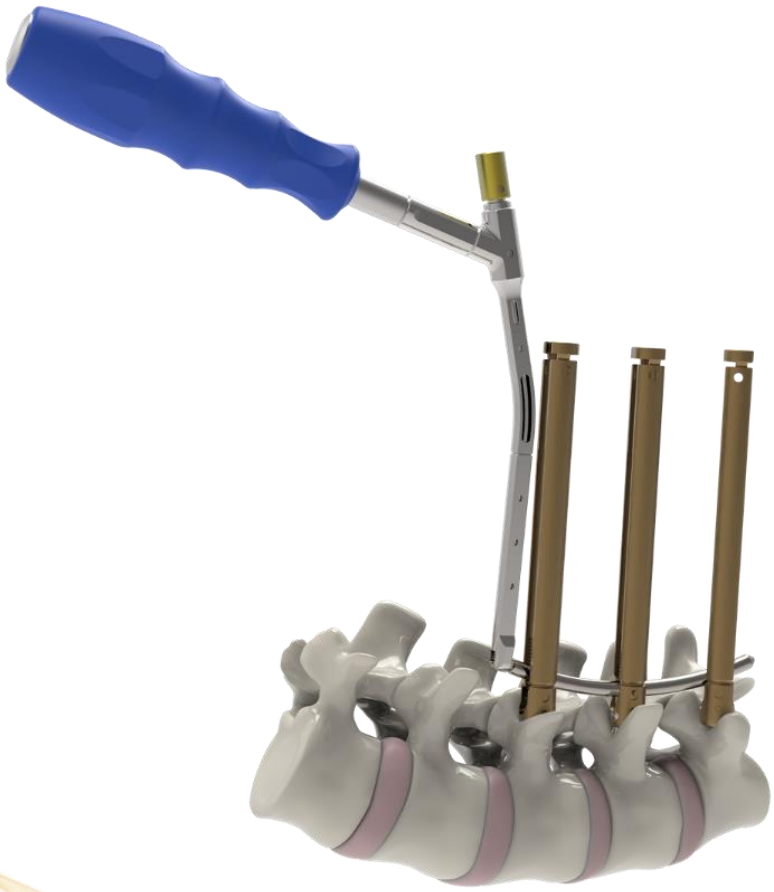


SURGICAL TECHNIQUE

PRECISION SPINE

REFORM® Ti MIS CT

MODULAR PERCUTANEOUS SCREW SYSTEM



PRECISION SPINE®

Discover the Difference

Made in the USA

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REFORM® Ti MIS CT MODULAR PERCUTANEOUS SCREW SYSTEM

OVERVIEW

Reform® Ti MIS CT Modular Percutaneous Screw System is a forward-thinking MIS system that is applicable for a variety of patient pathologies, anatomies, surgeons, and techniques. Modular extended tab tulips and bone screws offers increased flexibility and versatility to streamline the surgical process. All instrumentation was designed to be external to the skin or internal to the implants to avoid increasing the incision size.

INDICATIONS

The Reform Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Reform Pedicle Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation (T1-S1/ilium) for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to Instructions For Use (IFU) (LBL-IFU-011) for complete system description, indications and warnings.

REFORM® Ti MIS CT SYSTEM FEATURES

Modular Screw Platform

Cannulated Triple Lead Thread allows for efficient screw delivery and reduces fatigue

Minimally Tapered Thread increases bone screw interface, enhancing pull-out strength

Screw Diameters from 5.5 to 9.5mm provides intra-operative flexibility for diverse patient anatomy and pathology

Self Starting Aggressive Screw Tip allows for more immediate bone engagement

Enlarged T25 Drive Feature (30% larger) reduces the risk of screwdriver tip fatigue or fracture

REFORM® Ti MIS CT SYSTEM FEATURES

Modular Extended Tab Tulip

120mm Integrated Extension Tab features a low-profile outer diameter (12.7mm) allowing for a smaller incision to minimize tissue disruption

Audible Click and Consistent Engagement Force lets surgeon know modular tulip is permanently attached

¾ **Closed Extended Tab Tulip** provides stability during insertion and manipulation

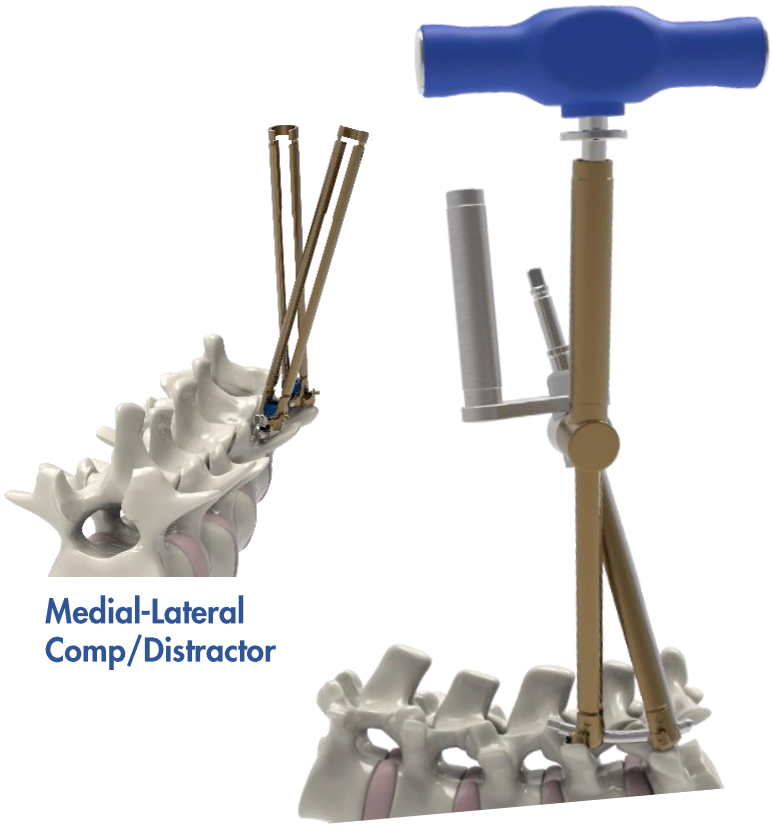
20mm of Internal Reduction Threads for controlled rod reduction. Additional 30mm achieved via internal instrumentation

Transitional Rod Slot design simplifies rod insertion

Visual Verification Markings provide confirmation and confidence

REFORM® Ti MIS CT SYSTEM FEATURES

Compressors and Distractors
Provide powerful and precise results directly at the screw-rod interface without increasing the skin incision



Medial-Lateral Comp/Distractor

Internal Rod Reduction
Allows for a total of 50mm of controlled rod reduction

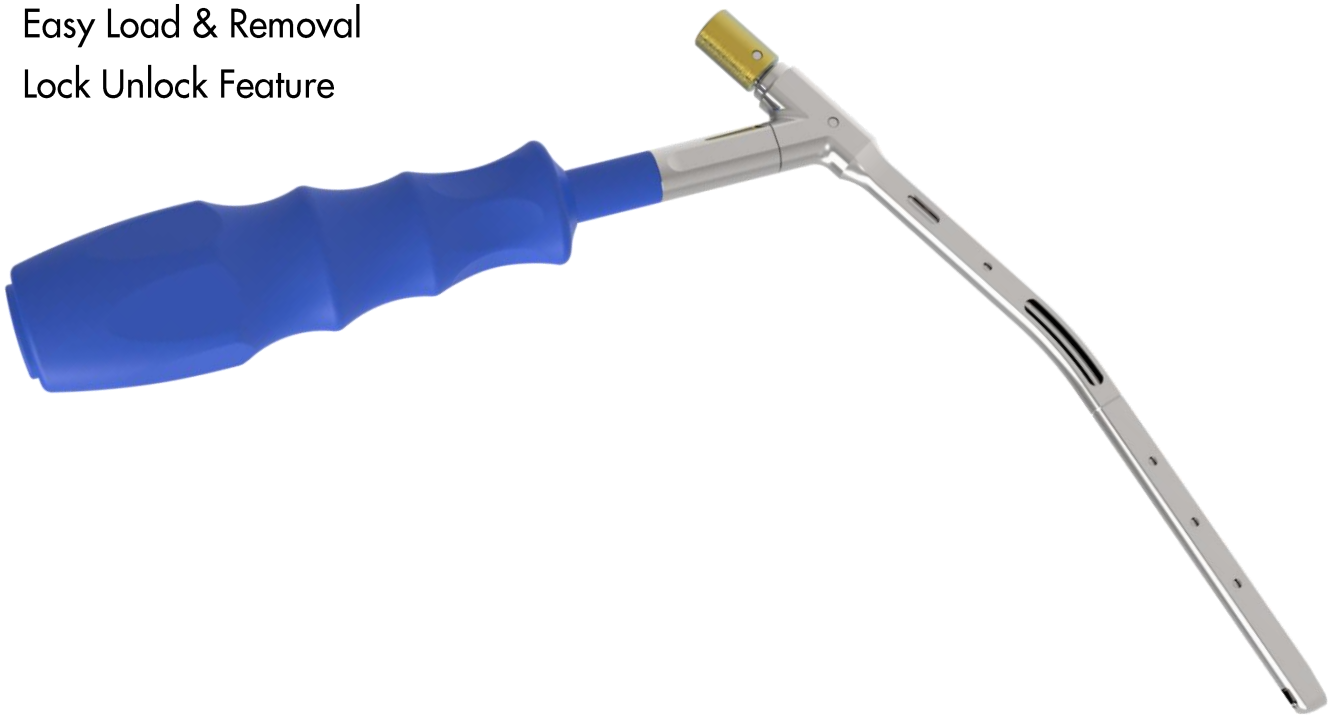
Parallel Comp/Distractor

Rescue Tower System
Provides an additional level of security and confidence. It can be used in place of the Extended Tab Tulip if Extended Tabs accidentally disengage from the base tulip or if the construct requires loosening and/or adjustment after lock screw insertion and tabs have already been broken off

REFORM® Ti MIS CT SYSTEM FEATURES

ROD INSERTER

- Center Load
- Easy Load & Removal
- Lock Unlock Feature



TWO ROD INSERTER OPTIONS

Non-Pass Thru Rod Inserter

64-RD-9050

Ensures that the hex end of the rod is correctly positioned outside of the tulip

Pass Thru Rod Inserter

64-RD-9010

Allows for technique versatility

REFORM® Ti MIS CT IMPLANT SIZING

Modular Screws, T25

Cannulated (39-SK-XXXX)

5.5mm	30-55mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-60mm (5mm)
8.5mm	35-60mm (5mm)
9.5mm	By request only

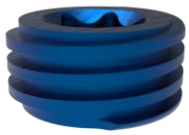
Complete screw size offerings on page 10

Modular Extended Tab Tulip

- 20mm Internal Reduction
- Overall Tab Height - 4.7" (120mm)
- Final Tulip - 12.7mm Width x 15.4mm Height

Lock Screw, T30

T30 Hexalobe



5.5mm Rods

Lordotic Rods

- 35mm-80mm (5mm increments)
- 90mm-120mm (10mm increments)

Straight Rod

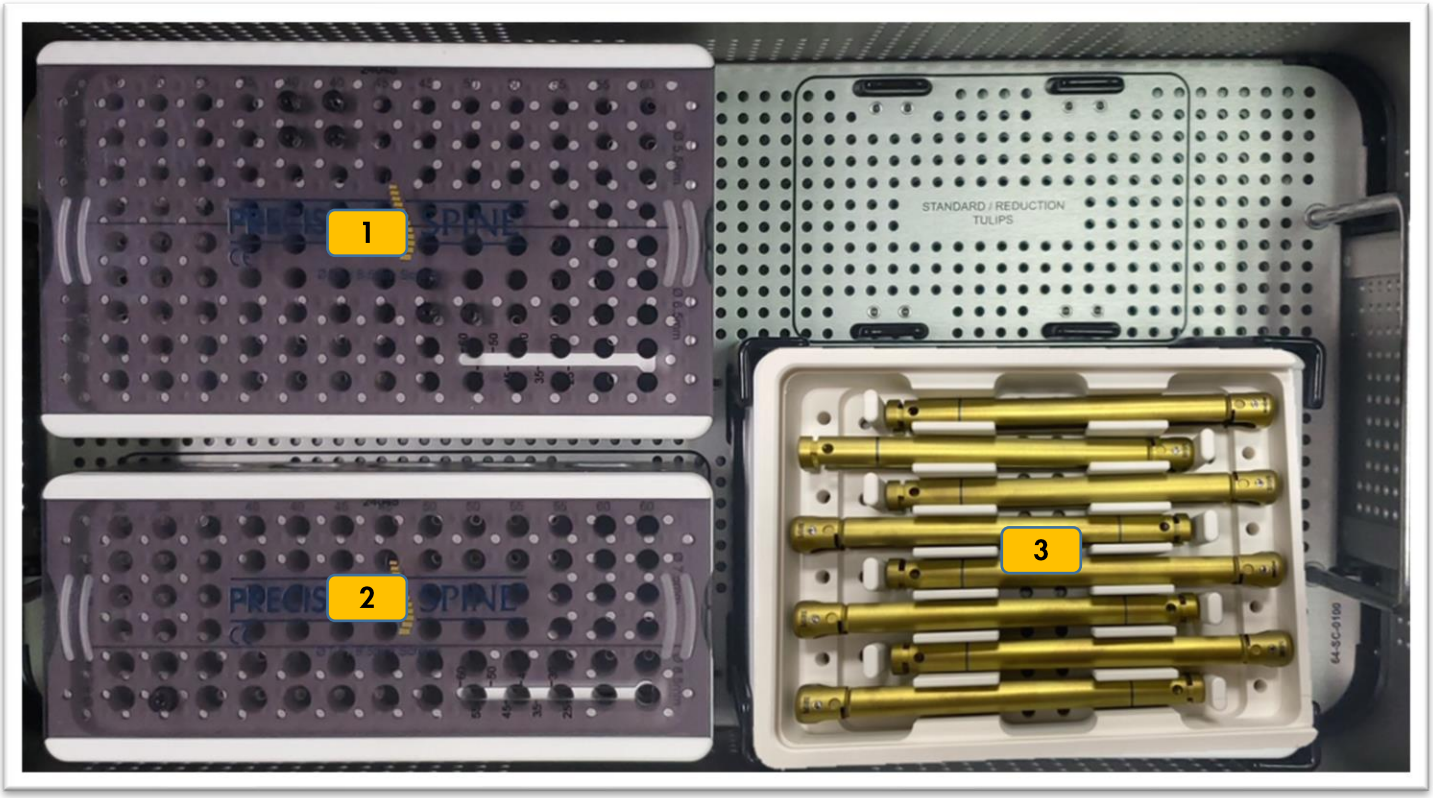
- 400mm

Complete rod size offerings on page 12

REFORM Ti MIS CT IMPLANT TRAY (5.5mm)

64-BK-0101

TOP LEVEL



	Part No.	Description	Qty
1.	Refer to page 10	5.5mm & 6.5mm Cannulated Modular Screws, T25	Refer to page 10
2.	Refer to page 10	7.5mm & 8.5mm Cannulated Modular Screws, T25	Refer to page 10
3.	64-MT-0403	Extended Tab Tulips	10

REFORM® Ti MIS CT

TULIP, SCREWS, LOCK SCREW

Modular Reform Ti MIS CT Extended Tab Tulips

64-MT-0403 (16/set)

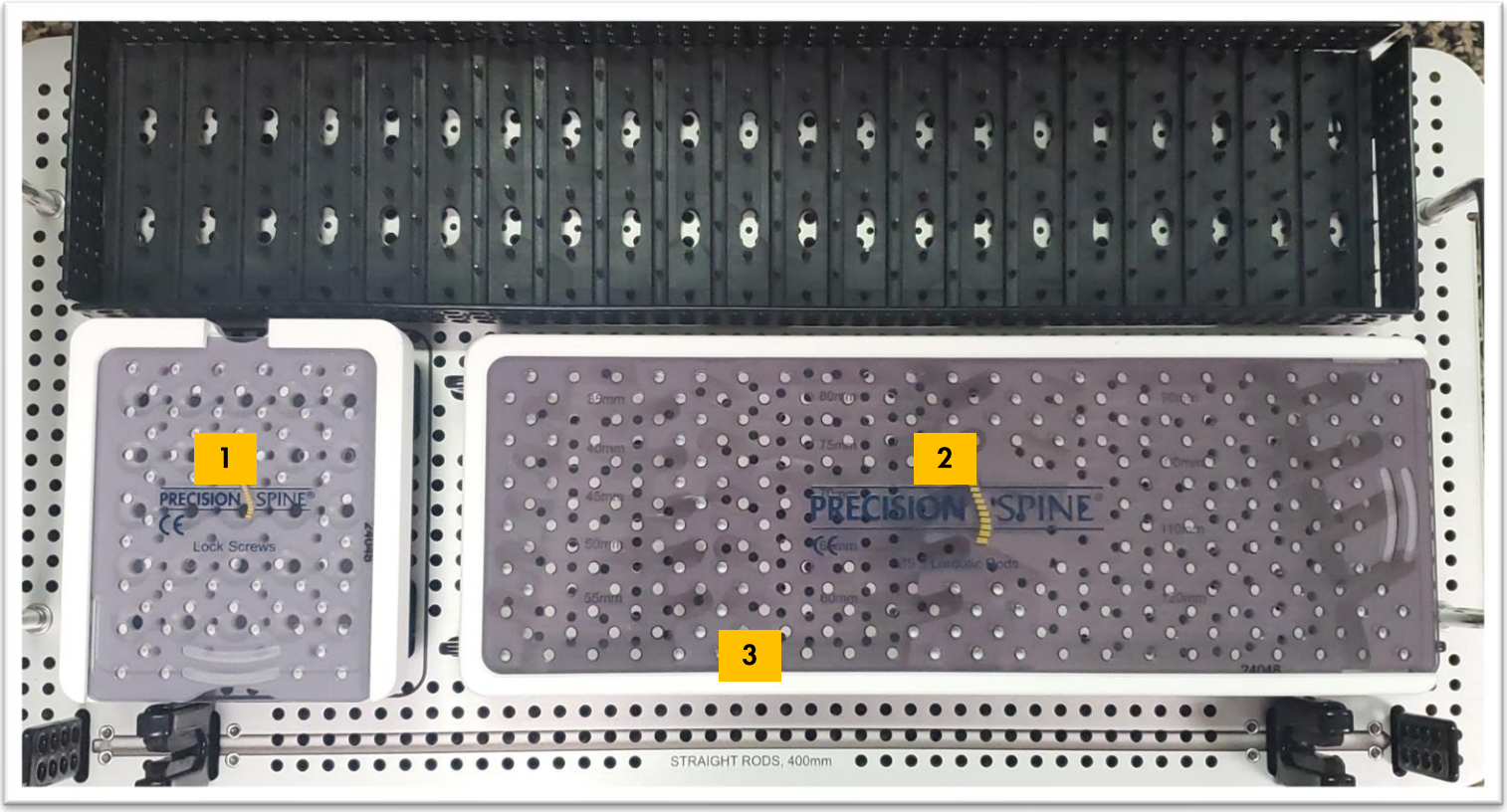
Locking Cap, T30

64-LS-0100 (25/set)

Screw Size* (Ø x Length), T25	Part No. Cannulated, Modular	Qty/Set	Screw Color
5.5mm x 30mm	39-SK-5530	6	
5.5mm x 35mm	39-SK-5535	6	
5.5mm x 40mm	39-SK-5540	8	
5.5mm x 45mm	39-SK-5545	8	
5.5mm x 50mm	39-SK-5550	6	
5.5mm x 55mm	39-SK-5555	6	
6.5mm x 30mm	39-SK-6530	6	
6.5mm x 35mm	39-SK-6535	6	
6.5mm x 40mm	39-SK-6540	10	
6.5mm x 45mm	39-SK-6545	10	
6.5mm x 50mm	39-SK-6550	8	
6.5mm x 55mm	39-SK-6555	8	
7.5mm x 35mm	39-SK-7535	6	
7.5mm x 40mm	39-SK-7540	8	
7.5mm x 45mm	39-SK-7545	8	
7.5mm x 50mm	39-SK-7550	6	
7.5mm x 55mm	39-SK-7555	6	
7.5mm x 60mm	39-SK-7560	6	
8.5mm x 35mm	39-SK-8535	4	
8.5mm x 40mm	39-SK-8540	4	
8.5mm x 45mm	39-SK-8545	4	
8.5mm x 50mm	39-SK-8550	2	
8.5mm x 55mm	39-SK-8555	2	
8.5mm x 60mm	39-SK-8560	2	

*By Request Only- 9.5mm Cannulated, Modular Screws. Please contact Customer Relations to order

REFORM Ti MIS CT IMPLANT TRAY (5.5mm)
64-BK-0101
BOTTOM LEVEL



	Part No.	Description	Qty
1.	64-LS-0100	Lock Screw, T30	25
2.	Refer to page 12	5.5mm Lordotic Rods, Titanium	3 per length
3.	63-ST-5400	5.5mm x 400mm Straight Rod, Titanium	3

REFORM® Ti MIS CT
RODS

5.5mm Rods

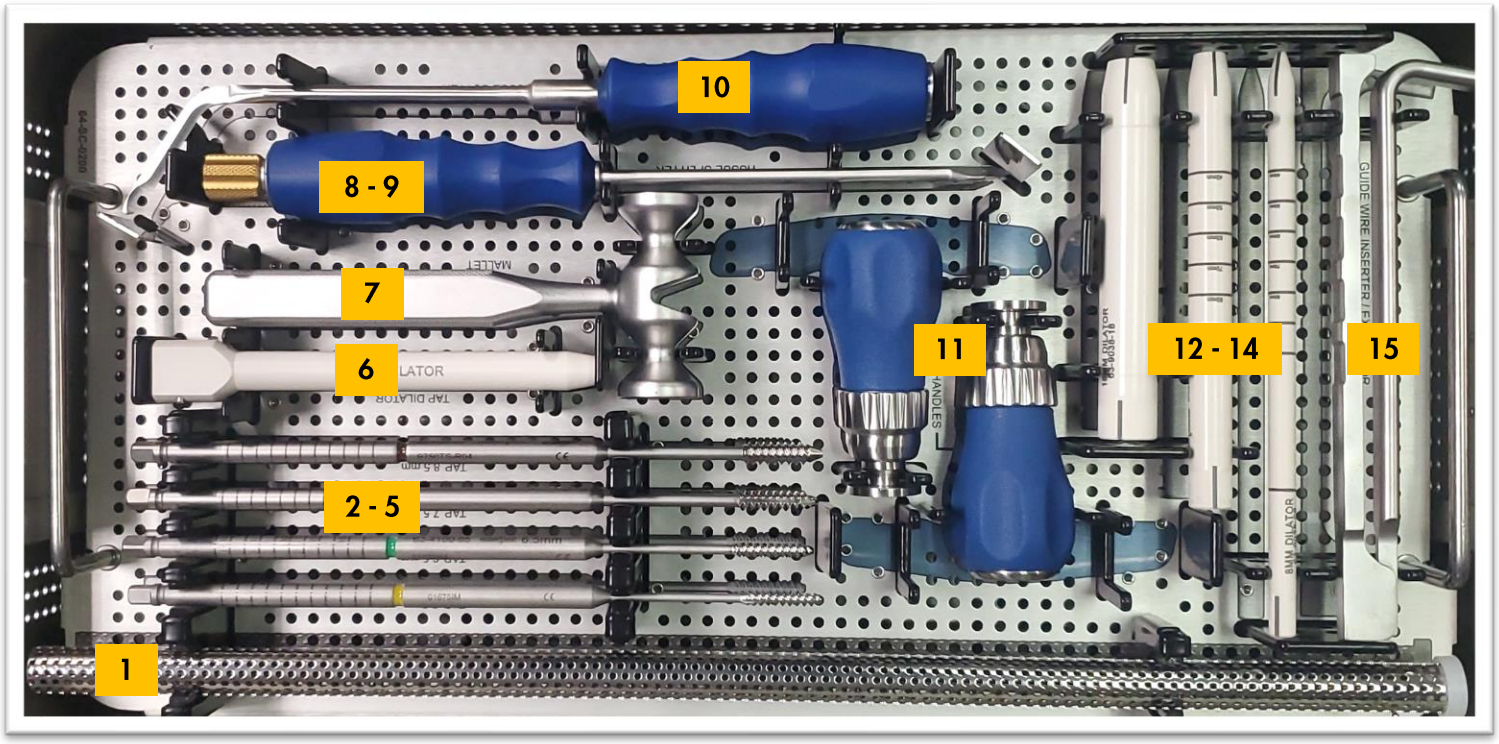
Rod Size (Ø x Length)	Part No. Titanium (Ti)	Qty/Set
Lordotic Rods 		
5.5mm x 35mm	63-LT-5035	3
5.5mm x 40mm	63-LT-5040	3
5.5mm x 45mm	63-LT-5045	3
5.5mm x 50mm	63-LT-5050	3
5.5mm x 55mm	63-LT-5055	3
5.5mm x 60mm	63-LT-5060	3
5.5mm x 65mm	63-LT-5065	3
5.5mm x 70mm	63-LT-5070	3
5.5mm x 75mm	63-LT-5075	3
5.5mm x 80mm	63-LT-5080	3
5.5mm x 90mm	63-LT-5090	3
5.5mm x 100mm	63-LT-5100	3
5.5mm x 110mm	63-LT-5110	3
5.5mm x 120mm	63-LT-5120	3
Straight Rods 		
5.5mm x 400m	63-ST-5400	3

5.5mm Rods*

Rod Size (Ø x Length)	Part No. Titanium (Ti)	Qty/Set
Lordotic Rods* 		
5.5mm x 130mm	63-LT-5130	3
5.5mm x 140mm	63-LT-5140	3
5.5mm x 150mm	63-LT-5150	3
Straight Rods* 		
5.5mm x 35mm	63-ST-5035	3
5.5mm x 40mm	63-ST-5040	3
5.5mm x 45mm	63-ST-5045	3
5.5mm x 50mm	63-ST-5050	3
5.5mm x 55mm	63-ST-5055	3
5.5mm x 60mm	63-ST-5060	3
5.5mm x 65mm	63-ST-5065	3
5.5mm x 70mm	63-ST-5070	3
5.5mm x 75mm	63-ST-5075	3
5.5mm x 80mm	63-ST-5080	3
5.5mm x 90mm	63-ST-5090	3
5.5mm x 100mm	63-ST-5100	3
5.5mm x 110mm	63-ST-5110	3
5.5mm x 120mm	63-ST-5120	3
5.5mm x 130mm	63-ST-5130	3
5.5mm x 140mm	63-ST-5140	3
5.5mm x 150mm	63-ST-5150	3
5.5mm x 200mm	63-ST-5200	3
5.5mm x 300mm	63-ST-5300	3
5.5mm x 500mm	63-ST-5500	3
5.5mm x 600mm	63-ST-5600	3

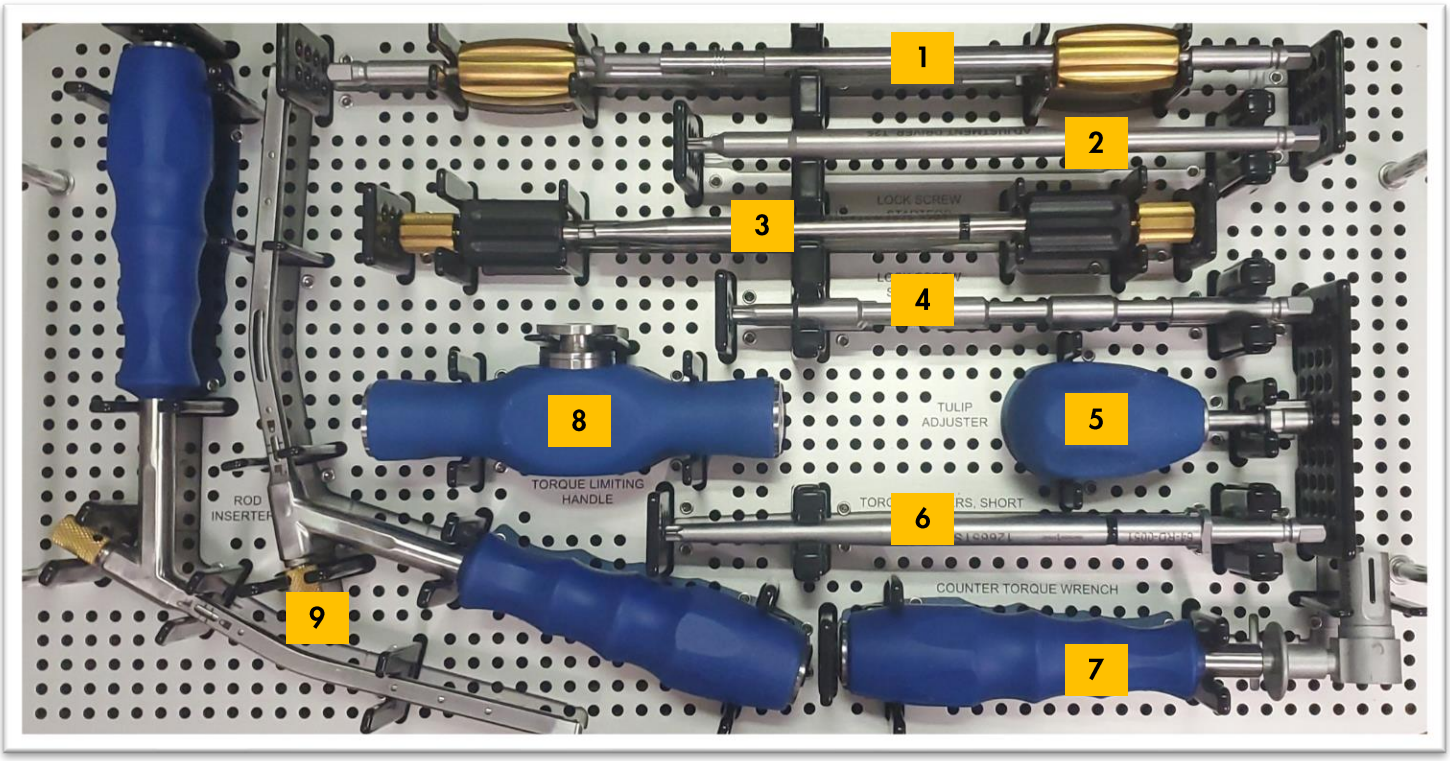
*By Request Only- Certain sizes of the 5.5mm Lordotic and Straight Rods. Please contact Customer Relations to order.

REFORM Ti MIS CT INSTRUMENT TRAY
64-BK-0201
TOP LEVEL



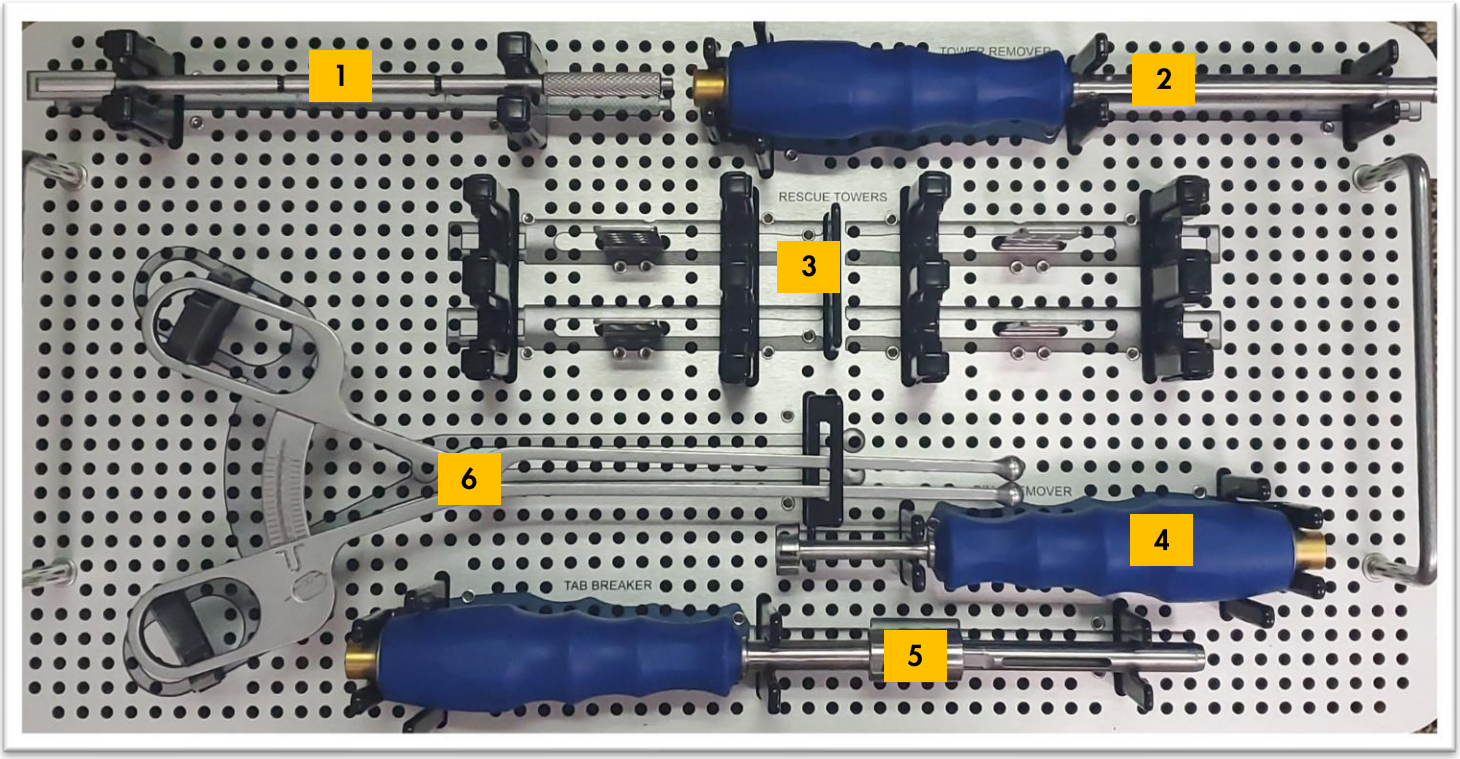
	Part No.	Description	Qty
1.	HXI-48-0003	18" x 1.6mm Guide Wire - Nitinol Blunt/Threaded	10
2.	63-4100-55	5.5mm Cannulated Tap (undersized by 0.5mm)	1
3.	63-4100-65	6.5mm Cannulated Tap (undersized by 0.5mm)	1
4.	63-4100-75	7.5mm Cannulated Tap (undersized by 0.5mm)	1
5.	63-4100-85	8.5mm Cannulated Tap (undersized by 0.5mm)	1
6.	63-4101	Tap Dilator	1
7.	09-9043	Mallet	1
8.	64-IN-0010	Tissue Splitter (compatible with Tissue Splitter Blade, 64-IN-0001)	1
9.	64-IN-0001	Tissue Splitter Blade, Disposable	1
10.	64-IN-0020	Tissue Cutter	1
11.	64-CH-0002	Ratcheting Palm Handle, ¼" SQ	2
12.	63-9038-08	8mm Dilator #1	1
13.	63-9038-13	13mm Dilator #2	1
14.	63-9038-18	18mm Dilator #3	1
15.	09-9027	Guide Wire Inserter/Extractor	1

REFORM Ti MIS CT INSTRUMENT TRAY
64-BK-0201
MIDDLE LEVEL



	Part No.	Description	Qty
1.	64-SP-1700	Cannulated Polyaxial Screw Driver, T25	2
2.	64-SP-0601	Adjustment Driver, ¼" SQ, T25	2
3.	64-SP-0652	Threaded Lock Screw Starter, T30	2
4.	64-SP-0602	Lock Screw Starter, ¼" S, T30	2
5.	64-RD-0800	Tulip Manipulator/Head Adjuster	1
6.	64-RD-0051	Torque Driver, Short, ¼" SQ, T30	2
7.	64-RD-0061	Counter Torque Wrench	1
8.	64-CH-0090	Torque Limiting Handle, 90 in-lbs	1
9.	64-RD-9010	5.5mm Rod Inserter	2

REFORM Ti MIS CT INSTRUMENT TRAY
64-BK-0201
BOTTOM LEVEL

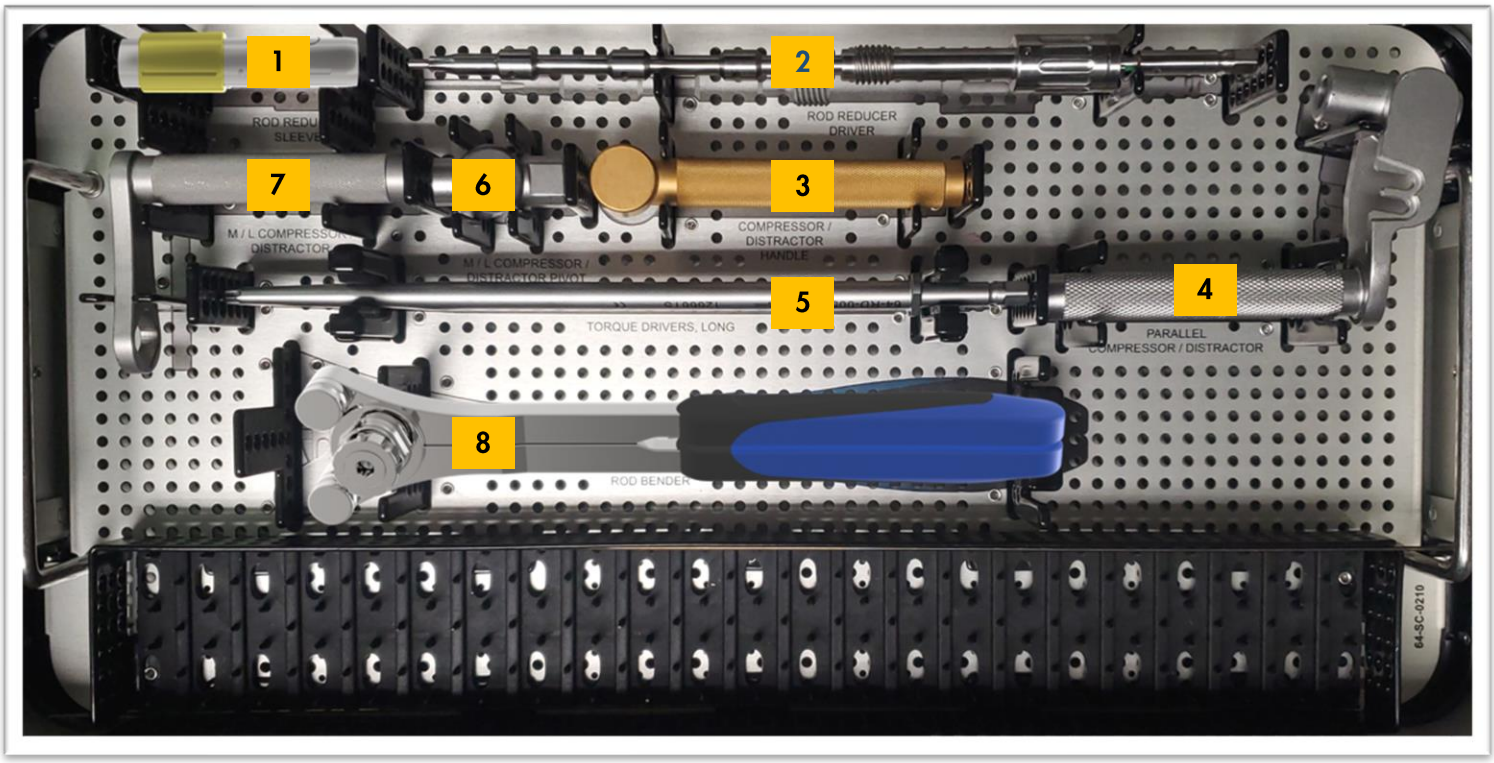


	Part No.	Description	Qty
1.	64-RD-0411	Rescue Tower Guide/Head Adjuster	1
2.	64-RD-0420	Rescue Tower Remover	1
3.	64-RD-0410	Rescue Towers	2
4.	64-RD-0940	Ring Remover	1
5.	64-RD-0900	Dual Tab Breaker	1
6.	64-CC-0440	Calipers	1

REFORM Ti MIS CT ADD-ON INSTRUMENT TRAY

64-BK-0210

MAIN LEVEL



	Part No.	Description	Qty
1.	64-RD-0450	Rod Reducer Sleeve	1
2.	64-RD-0453	Rod Reducer Driver	1
3.	64-RD-0040	Compressor/Distractor Handle	1
4.	64-RD-0044	Parallel Compressor/Distractor	1
5.	64-RD-0052	Torque Driver, Long, ¼" SQ, T30	2
6.	64-RD-0043	Medial/Lateral Compressor/Distractor Pivot	1
7.	64-RD-0042	Medial/Lateral Compressor/Distractor	1
8.	39-RD-0001	5.5mm Rod Bender	1

REFORM® Ti MIS CT

BY REQUEST *Please contact Customer Relations for product availability.*

DISPOSABLES

ACCESS NEEDLES

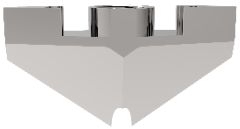
Part No.	Description
74174-01M	8 ga x 6in, Trocar and Bevel Tip Stylets
74066-15M	11 ga x 4.5in, Trocar Tip Stylet
74182-01M	13 ga x 4.5in, Trocar Tip Stylet
74182-02M	13 ga x 4.5in, Trocar and Bevel Tip Stylets

GUIDE WIRES

Part No.	Description
HXI-48-0002	18" x 1.6mm Guide Wire - Nitinol Trocar/Threaded
HXI-48-0004	18" x 1.6mm Guide Wire - Stainless Steel Trocar/Threaded
HXI-48-0005	18" x 1.6mm Guide Wire - Stainless Steel Blunt/Threaded

TISSUE SPLITTER BLADE

Part No.	Description
64-IN-0001	Tissue Splitter Blade (Used with 64-IN-0010 Tissue Splitter)



64-IN-0001

INSTRUMENTS

HANDLE

Part No.	Description
64-CH-0003	Ratcheting T-Handle, ¼" SQ

64-CH-0003

NAVIGATION INSTRUMENT SET*

Set No.	Description
70-BK-0109	Reform Ti CT Modular MIS Navigated Instrument Set
64-RD-0071	Full-Length Counter Torque Wrench

70-BK-0109

64-RD-0071

*Please refer to the Navigated Instrument System Instructions For Use (IFU) and Surgical Technique for complete system guide, descriptions, indications and warnings

SURGICAL TECHNIQUE

1 PATIENT POSITIONING

Place the patient in the prone position. Prepare and drape the patient in a conventional manner. Utilizing anterior/posterior and lateral fluoroscopic imaging and palpation of the patient's appropriate landmarks, locate and mark the targeted pedicles on the patient's skin (Figure 1).

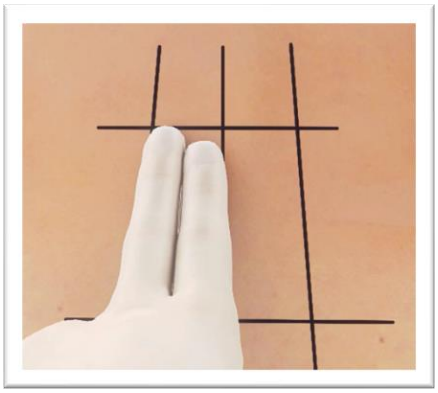


Figure 1

2 SKIN INCISION

With a knife blade at the location of the marks on the patient's skin, make a skin incision and fascia release slightly larger than the 18mm Dilator #3 (63-9038-18). Advance an Access Needle through the skin incision and dock onto the targeted pedicle (Figure 2 & 2a). Verify the placement of the Access Needle with fluoroscopic imaging.

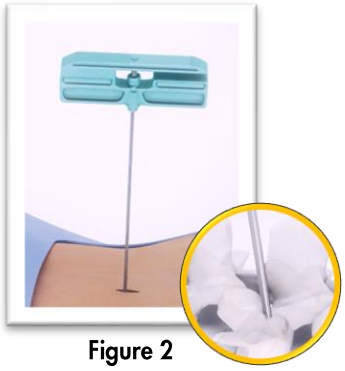


Figure 2

Figure 2a

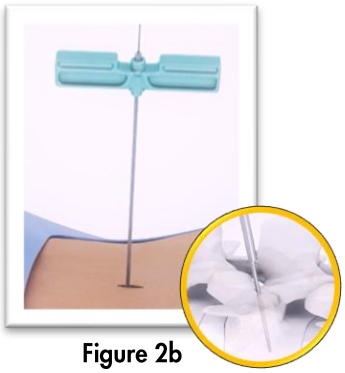


Figure 2b

Figure 2c

Once proper trajectory and docking of the Access Needle is confirmed, remove the inner trocar needle and replace with the Guide Wire (Figure 2b & 2c).

Securely attach the Tissue Splitter Blade (64-IN-0001) to the Tissue Splitter (64-IN-0010) by rotating the gold knob clockwise until fully tightened (Figure 2d).

Slide the Blade over the Guide Wire, through the fascia, until the Blade meets bone (Figure 2e).

Carefully remove the Tissue Splitter and Blade from the Guide Wire.

Rotate the gold knob counterclockwise to disengage the Blade and dispose of the sharp Blade properly.

Figure 2d

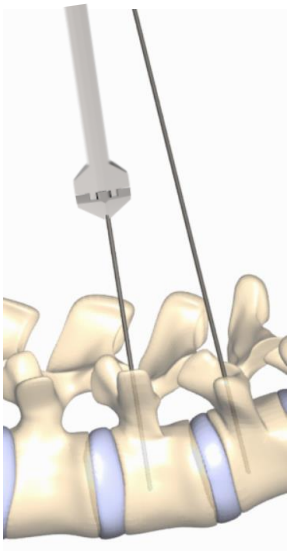


Figure 2e

SURGICAL TECHNIQUE

3 PEDICLE PREPARATION

Insert the 8mm Dilator #1 (63-9038-08) over the Guide Wire down to the bone (Figure 3 & 3a).

Slide the 13mm Dilator #2 (63-9038-13) over the 8mm Dilator to sequentially penetrate and gently dissect soft tissue down to the pedicle (Figure 3b).

Slide the 18mm Dilator #3 (63-9038-18) (Figure 3c) over the 13mm Dilator #2.

Figure 3

Figure 3a

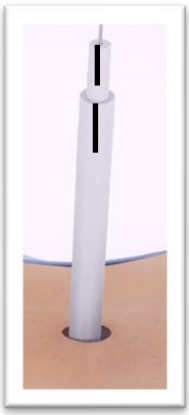


Figure 3b

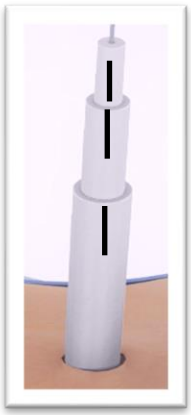


Figure 3c

Remove the 8mm Dilator #1 leaving the 13mm and 18mm Dilators over the Guide Wire. Select the appropriate diameter Tap (63-4100-XX) that corresponds to the selected Screw diameter.

Securely attach either the Ratcheting Palm Handle (64-CH-0002) or T-Handle (64-CH-0003) or PSST onto the Tap. Confirm proper engagement to the Handle by pulling on the shaft of the Tap.

Advance the tap over the guide wire, through the 13mm Dilator #2, and tap the pedicle (Figure 3d & 3e). Measurements on the Tap indicate the approximate tap depth in the bone (Figure 3f).

NOTE: Dilator #2 must be in contact with the bone surface to achieve an accurate measurement.

Carefully remove the Tap and the 13mm Dilator #2, leaving the Guide Wire and the 18mm Dilator #3 in place.

NOTE: Ensure that the Guide Wire does not advance further into the bone during tapping.

NOTE: The Taps are 0.5mm undersized. It is not recommended to under tap as it may result in pedicle fractures.

Figure 3d

Figure 3e

Figure 3f

SURGICAL TECHNIQUE

3 PEDICLE PREPARATION *(OPTIONAL)*

NOTE: Tap Dilator is NOT compatible with 18mm Dilator

Select the appropriate diameter Tap (63-4100-XX) that corresponds to the selected Screw diameter.

Securely attach the Ratcheting Palm Handle (64-CH-0002) or T-Handle (64-CH-0003) or PSST onto the Tap. Confirm engagement to the Handle by gently pulling on the shaft of the Tap.

Insert the Tap into the Tap Dilator (63-4101) while depressing the silver button (Figure 13g & Figure 3h).

Once the Tap is partially inserted into the Tap Dilator, take your thumb off the button and advance the Tap until it automatically stops at the zero position. Inspect the tip of the Tap to ensure that it is protruding from the Tap Dilator.

Place the Tap Dilator assembly over the Guide Wire and advance it through the tissue (Figure 3i). Once the Tap engages the pedicle, depress the button to advance the Tap into the pedicle (Figure 3j). Measurements on the Tap indicate the approximate tap depth in the bone.

NOTE: The Tap Dilator must be in contact with the bone surface to achieve an accurate measurement.

Remove the Tap and Tap Dilator leaving the Guide Wire in place.

NOTE: Ensure that the Guide Wire does not advance further into the bone during tapping.

NOTE: The Taps are 0.5mm undersized. It is not recommended to under tap as it may result in pedicle fractures.

Figure 3g

Figure 3h

Button compressed when advancing tap

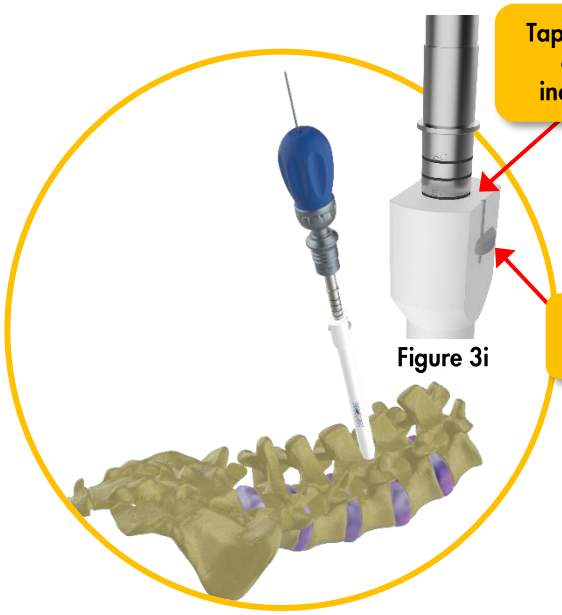


Figure 3i

Figure 3j

SURGICAL TECHNIQUE

4 EXTENDED TAB TULIP & SCREW ATTACHMENT

Remove the Modular Extended Tab Tulip (64-MT-0403) and the appropriate size Modular Screw Shank out of their caddies. Slide the Modular Extended Tab Tulip over the modular screw head and apply an axial force until an audible click is heard. (Figure 4)

Upward pressure of the attached Extended Tab Tulip can be applied to ensure that it is properly inserted.

Do not insert the Modular Extended Tab Tulip on the Modular Screw Shank while the shank is still in the caddy.

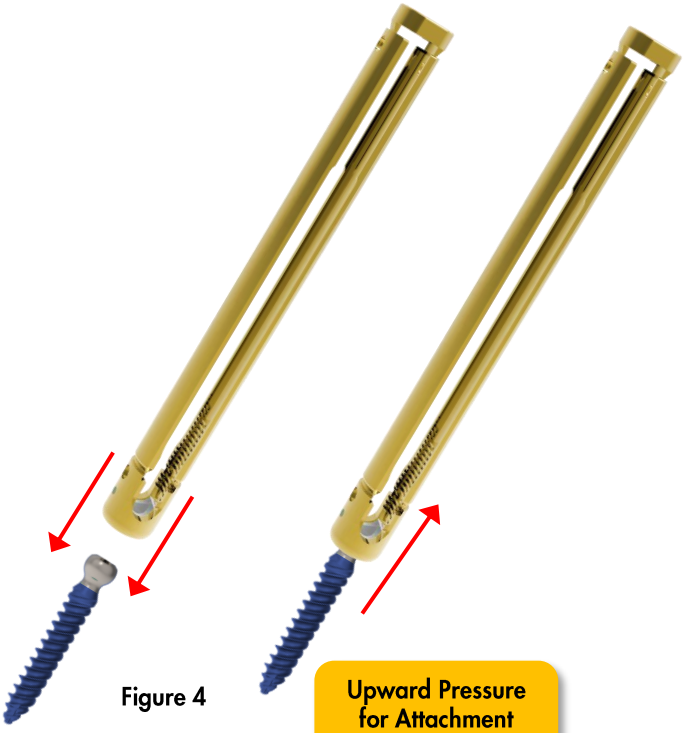


Figure 4

Upward Pressure for Attachment Confirmation

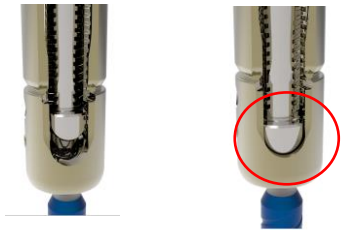
5 SCREW DRIVER ATTACHMENT

Securely attach the Cannulated Polyaxial Driver (64-SP-1700) to the Ratcheting Palm Handle (64-CH-0002) or T-Handle (64-CH-0003) or PSSRT. Confirm proper engagement to the Handle by pulling on the shaft of the Driver.

Insert the distal tip of the Driver fully into the Extended Tab Tulip and into the modular screw. Ensure that the Driver tip is firmly seated in the screw head (Figure 5).

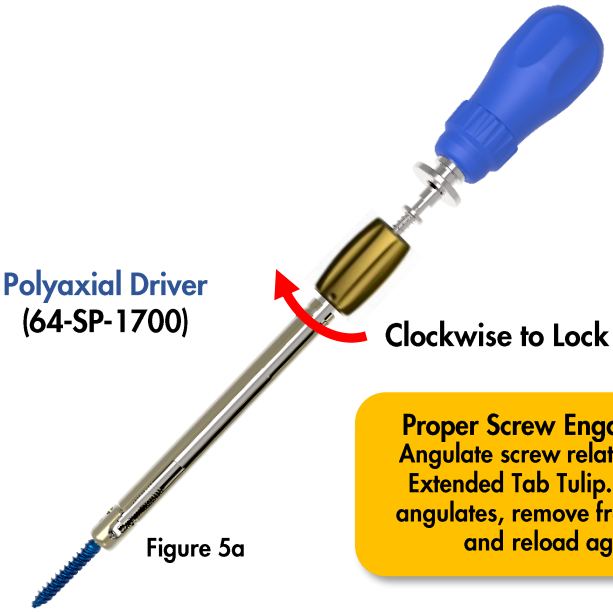
Once the screw is properly loaded onto the Driver, hold the screw firmly on the Driver with one hand and thread the knob clockwise until fully engaged and secure (Figure 5a).

Proper Driver Engagement
Cross bar is flush and against rod slot



Incorrect ***Correct***

Figure 5



Polyaxial Driver (64-SP-1700)

Clockwise to Lock

Figure 5a

Proper Screw Engagement
Angulate screw relative to the Extended Tab Tulip. If screw angulates, remove from driver and reload again

SURGICAL TECHNIQUE

6 SCREW INSERTION

While using fluoroscopic imaging, advance the screw over the Guide Wire, through the pedicle, and into the vertebral body (Figure 6).

To disengage the Driver, rotate the proximal knob counterclockwise until the driver releases from the screw.

Verify proper screw position, trajectory, and length via fluoroscopy.

NOTE: Do not hold the knob of the Driver during screw insertion as this may result in loosening of the driver from the screw.

NOTE: Do not angle or apply additional leverage to the Driver as this may result in unintended screw trajectory or pedicle fractures.

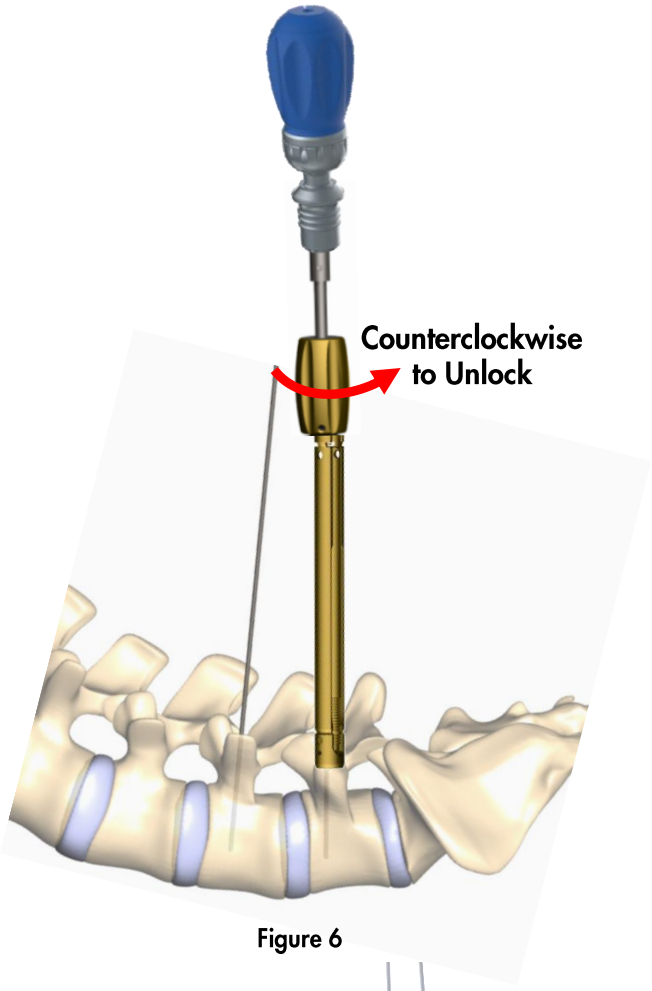


Figure 6

7 GUIDE WIRE REMOVAL

After confirming that the screws are in the proper position, remove the Guide Wire, Driver, and if applicable, Dilator #3 (Figure 7).

The Guide Wire Extractor (09-9027) and Mallet (09-9043) may be utilized in removing the Guide Wire.

NOTE: If the Guide Wire is deformed or damaged, it should not be re-used.

Figure 7

SURGICAL TECHNIQUE

8 SCREW ADJUSTMENT

Use the Adjustment Driver to adjust the sagittal height of the screw prior to rod insertion or restoring range of motion of the Extended Tab Tulip if screw has been inserted too deep.

Securely attach the Adjustment Driver to the Ratcheting Palm Handle (64-CH-0002) or T-Handle (64-CH-0003) or PSSRT. Confirm engagement to the Handle by gently pulling on the shaft of the Driver.

Fully seat the Adjustment Driver into the screw prior to applying any force (Figure 8).

NOTE: Use the Tulip Manipulator or the tab end of the Rescue Tower Guide to align the rod slot of the Extended Tab Tulips prior to rod insertion

Figure 8

Tulip Manipulator/Head Adjuster
(64-RD-0800)

Adjustment Driver, T25
(64-SP-0601)

Rescue Tower Guide/Head Adjuster
(64-RD-0411)

9 ROD MEASUREMENT

Place the distal ends of the Rod Caliper (64-CC-0440) arms into the Extended Tab Tulips until they contact the screw heads.

Select the appropriate rod length based on the measurement in the Caliper window (Figure 9).

Use the Rod Bender (39-RD-0001) to create the desired contour.

NOTE: Excessive or repeated bending can weaken the rod and may lead to failure of the device.

Rod Bender
(39-RD-0001)

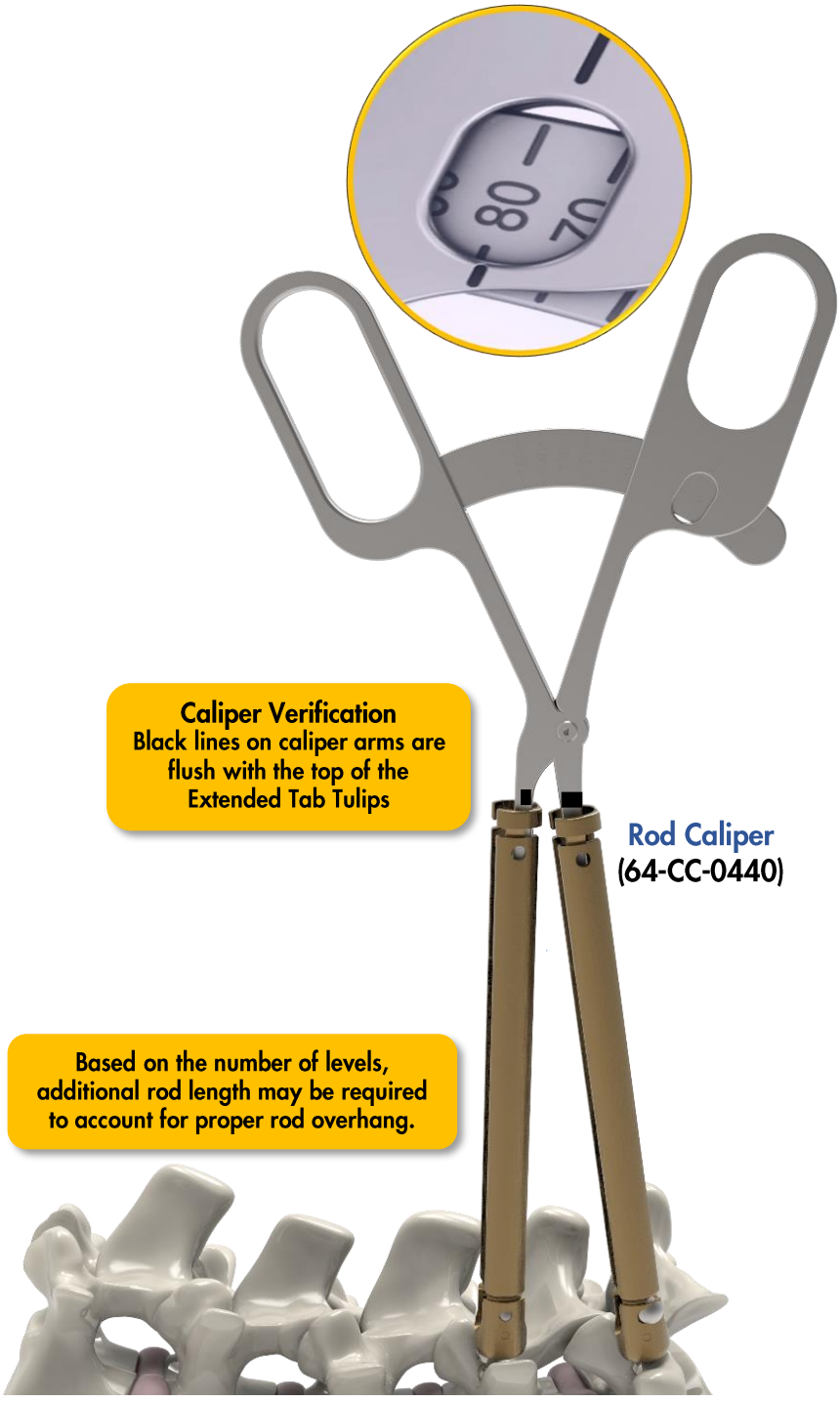


Figure 9

SURGICAL TECHNIQUE

10 ROD INSERTION

Rotate the gold knob on the Rod Inserter (64-RD-9010 or 64-RD-9050) counterclockwise to fully open the distal tip. Ensure that the black laser mark is in the UNLOCK position (Figure 10).

Insert the non-bullet, gold end of the selected rod into the distal opening of the Inserter.

While holding the rod in place, securely tighten the rod by turning the gold knob on the Inserter clockwise (Figure 10a).

NOTE: Ensure that the black laser mark is in the LOCK position prior to rod insertion (Figure 10).

The Adjustment Driver, 64-SP-0601, may be used for additional assistance in loosening the gold knob on the Rod Inserter.

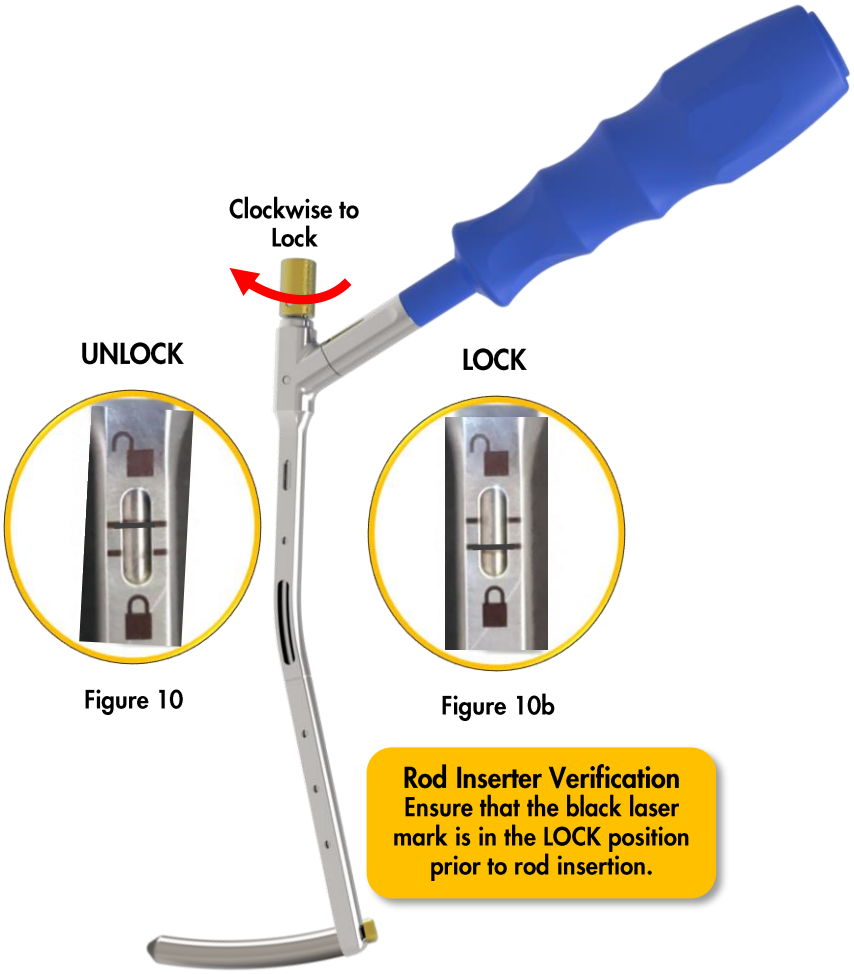


Figure 10

Figure 10b

Figure 10a

Rod Inserter Verification
Ensure that the black laser mark is in the LOCK position prior to rod insertion.

Pass Thru Rod Inserter 64-RD-9010

Pass Thru Inserter allows for technique versatility.

Non-Pass Thru Rod Inserter 64-RD-9050

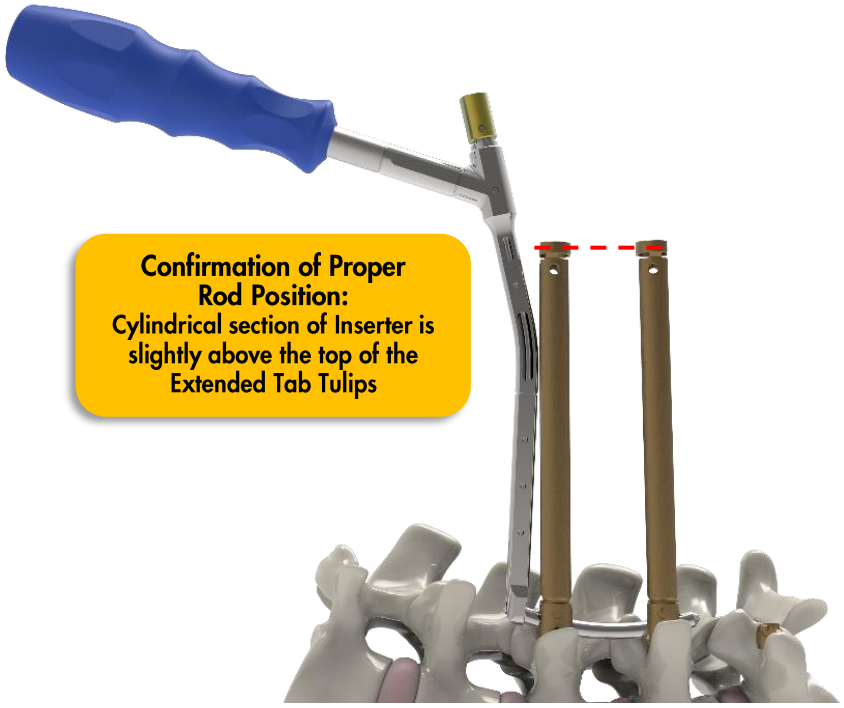
Non-Pass Thru Rod Inserter ensures that the hex end of the rod is correctly positioned outside of the tulip.

SURGICAL TECHNIQUE

10 ROD INSERTION

Place the Rod Inserter into the rod slot of the Extended Tab Tulips and advance the rod into the tulip (Figure 10c).

Confirm proper rod placement via instrumentation and intraoperative fluoroscopy.



Confirmation of Proper Rod Position:
Cylindrical section of Inserter is slightly above the top of the Extended Tab Tulips

Figure 10c

Verification of Rod Passage through Tulips:
Black line on the Rescue Tower Guide (64-RD-0411) should be positioned above the top of the Extended Tab Tulip.

Confirmation of Proper Rod Placement:
Complete bullet tip of the rod and the non-bullet, gold end of the rod (or rod inserter) should be positioned outside the tulip.

SURGICAL TECHNIQUE

11 LOCK SCREW INSERTION

To unlock the distal tip, rotate counterclockwise the gold knob on the Threaded Lock Screw Starter (64-SP-0652).

Firmly press a Locking Cap onto the distal tip of the Threaded Lock Screw Starter and rotate the gold knob clockwise to attach the Locking Screw (Figure 11).

Insert and thread the Lock Screw into the Extended Tab Tulip to secure the rod (Figure 11a). Provisionally tighten the Lock Screw.

Rotate the gold knob on the Threaded Lock Screw Starter counterclockwise to unlock from the Lock Screw and pull up to remove from the Extended Tab Tulip.

Repeat for remaining screws.

NOTE: The Threaded Lock Screw Starter should be used for Lock Screw Removal

Threaded Lock Screw Starter T30
64-SP-0652

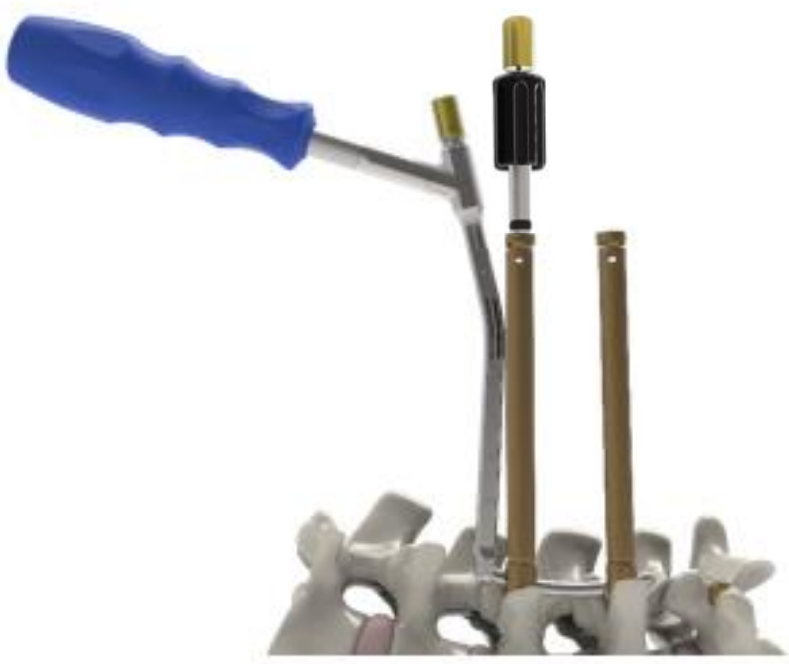


Figure 11a

Final Position of Threaded Lock Screw Starter: Black line should be positioned above the top of the Extended Tab Tulip.

Figure 11

11a LOCKING SCREW INSERTION *(OPTIONAL)*

Attach the Lock Screw Starter (64-RD-0602) to the Ratcheting Palm Handle (64-CH-0002) or optional Ratcheting T-Handle, ¼" SQ (64-CH-003).

Pull the shaft of the Lock Screw Starter, T30 to ensure secure attachment

Firmly press a Locking Cap onto the distal tip of the Lock Screw Starter.

To secure the rod, using a clockwise rotation on the Ratcheting Palm Handle (64-CH-0002) or optional Ratcheting T-Handle, ¼" SQ (64-CH-003) insert the Locking Cap until it reaches the threads of the Extended Tab Tulip (Figure 11b).

Lock Screw Starter
64-RD-0602

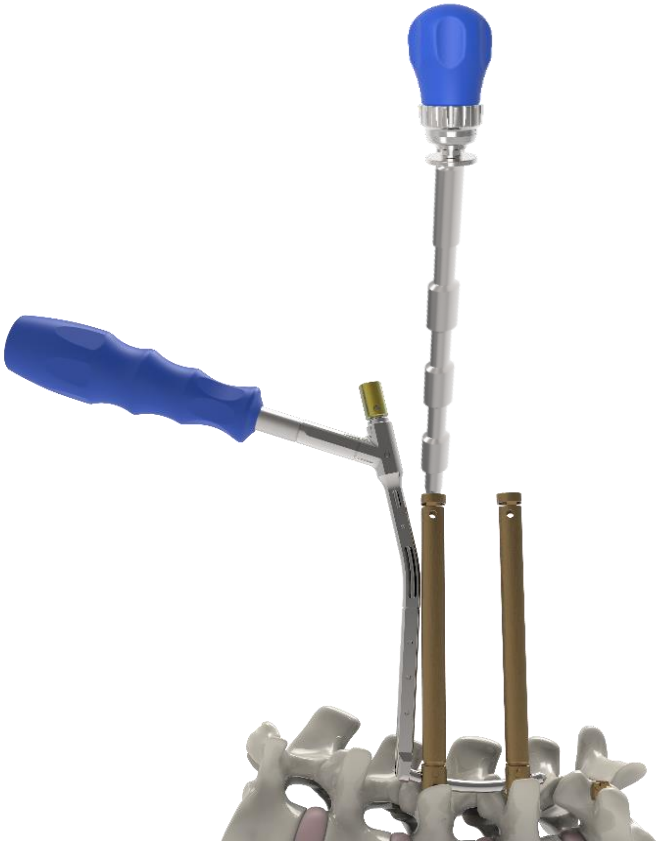
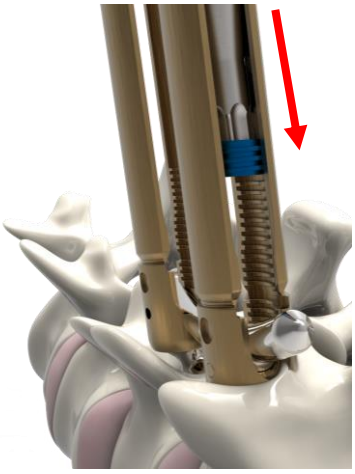


Figure 11b

Ratcheting T-Handle, ¼" SQ
(Optional – By Request)
(64-CH-0003)

Ratcheting Palm Handle
(64-CH-0002)



SURGICAL TECHNIQUE

12 FINAL TIGHTENING OF LOCK SCREW

With the black line on the Counter Torque Wrench facing the open portion of the Extended Tab Tulip, firmly seat the Counter Torque Wrench (64-RD-0061) over the Tulip (Figure 12) .

Pull the collar on the Counter Torque Wrench towards the handle and rotate handle to desired position (Figure 12a).

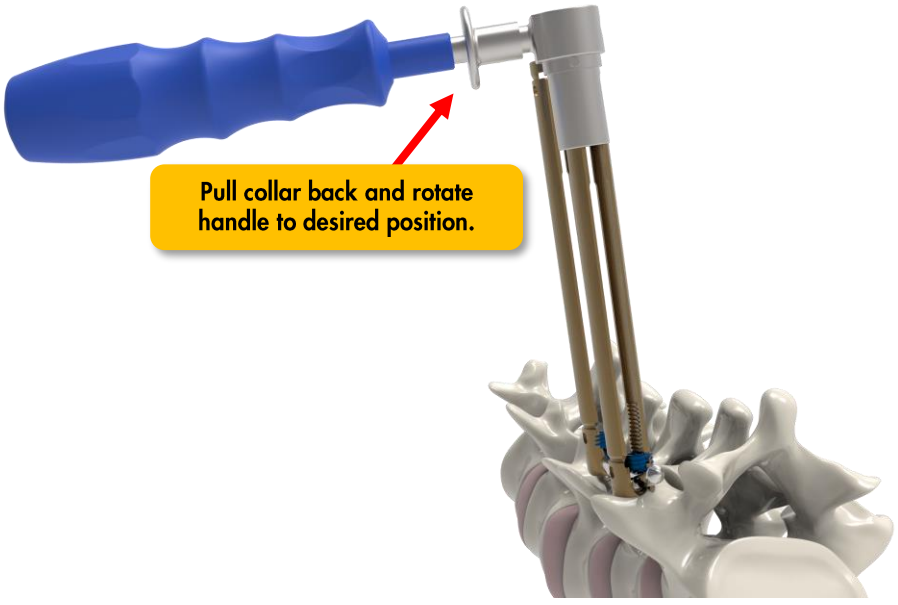


Figure 12a

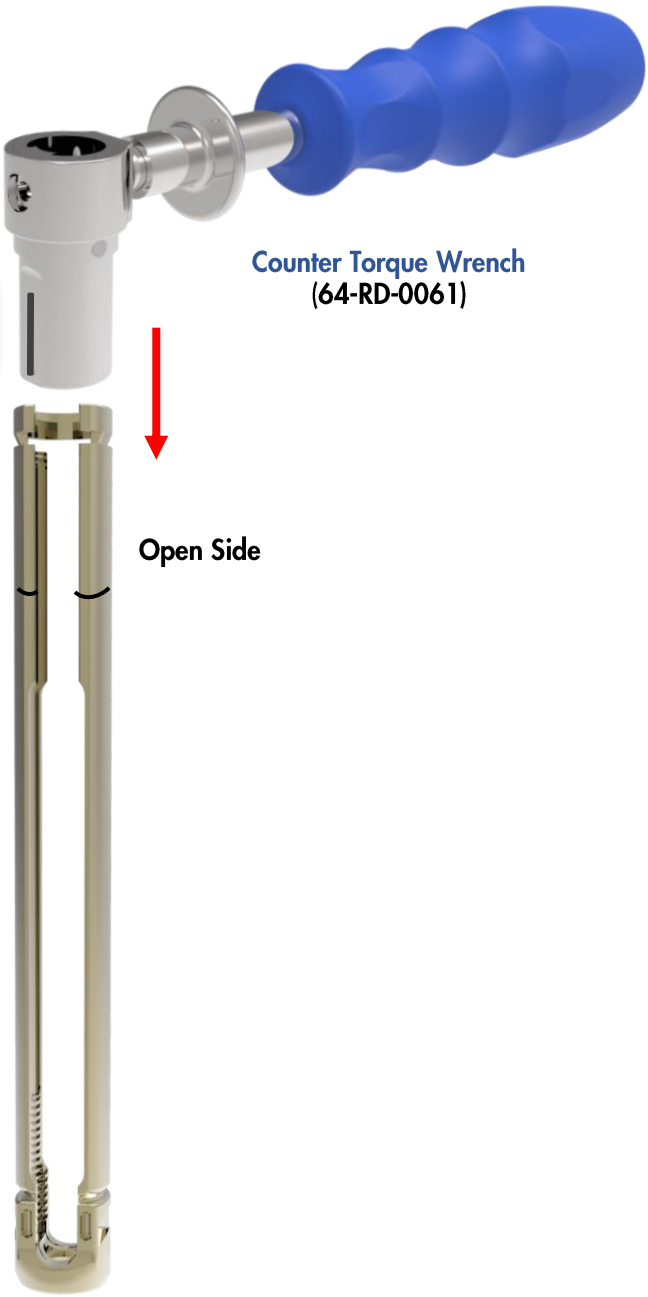


Figure 12

SURGICAL TECHNIQUE

12 FINAL TIGHTENING OF LOCK SCREW

Assemble the Torque Limiting Handle (64-CH-0090) to the Short Torque Driver (64-RD-0051). Confirm engagement to the handle by gently pulling on the shaft of the Torque Driver.

Insert the assembled Short Torque Driver and Torque Limiting Handle through the Extended Tab Tulip.

Ensure that the tip of the Torque Driver is seated into the Lock Screw.

Rotate the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 90 in-lbs (Figure 12b).

Repeat for the remaining screws.

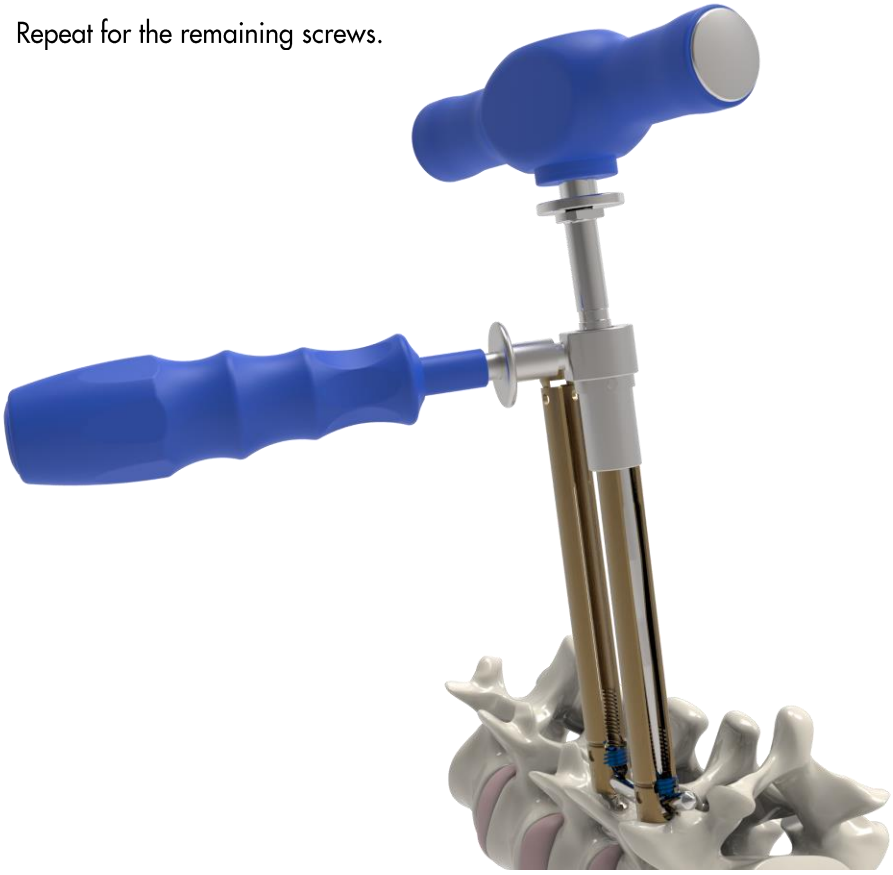


Figure 12b

SURGICAL TECHNIQUE

12a FINAL TIGHTENING OF LOCK SCREW *(OPTIONAL)*

Place the Full-Length Counter Torque Wrench (64-RD-0071) over the entire Extended Tab Tulip. The scallops on the distal end of the Counter Torque Wrench should seat firmly over the base of the tulip head and rod. (Figure 12c)

Full-Length Counter Torque Wrench
(Optional — By Request)
64-RD-0071

Figure 12c

SURGICAL TECHNIQUE

13 ROD REDUCTION (ADDITIONAL 30mm) *(OPTIONAL)*

Arrow corresponds to sleeve opening.

Rod Reducer Sleeve
64-RD-0450

Initial Set-Up

Additional 30mm of rod reduction, beyond the 20mm provided by the internal Extended Tab Tulip threads, can be achieved via the Rod Reducer Sleeve (64-RD-0450) and Rod Reducer Driver (64-RD-0453).

Pull up on the gold collar of the Rod Reducer Sleeve (64-RD-0450) to the unlock position (Figure 13).

Line up the black arrow on the Rod Reducer Sleeve with the open side of the Extended Tab Tulip (Figure 13a).

Insert the Sleeve over the Extended Tab Tulip until it snaps into place (Figure 13b).

Slide the gold collar down to the lock position (Figure 13c).

Unlocked | **Locked** | **Side View**

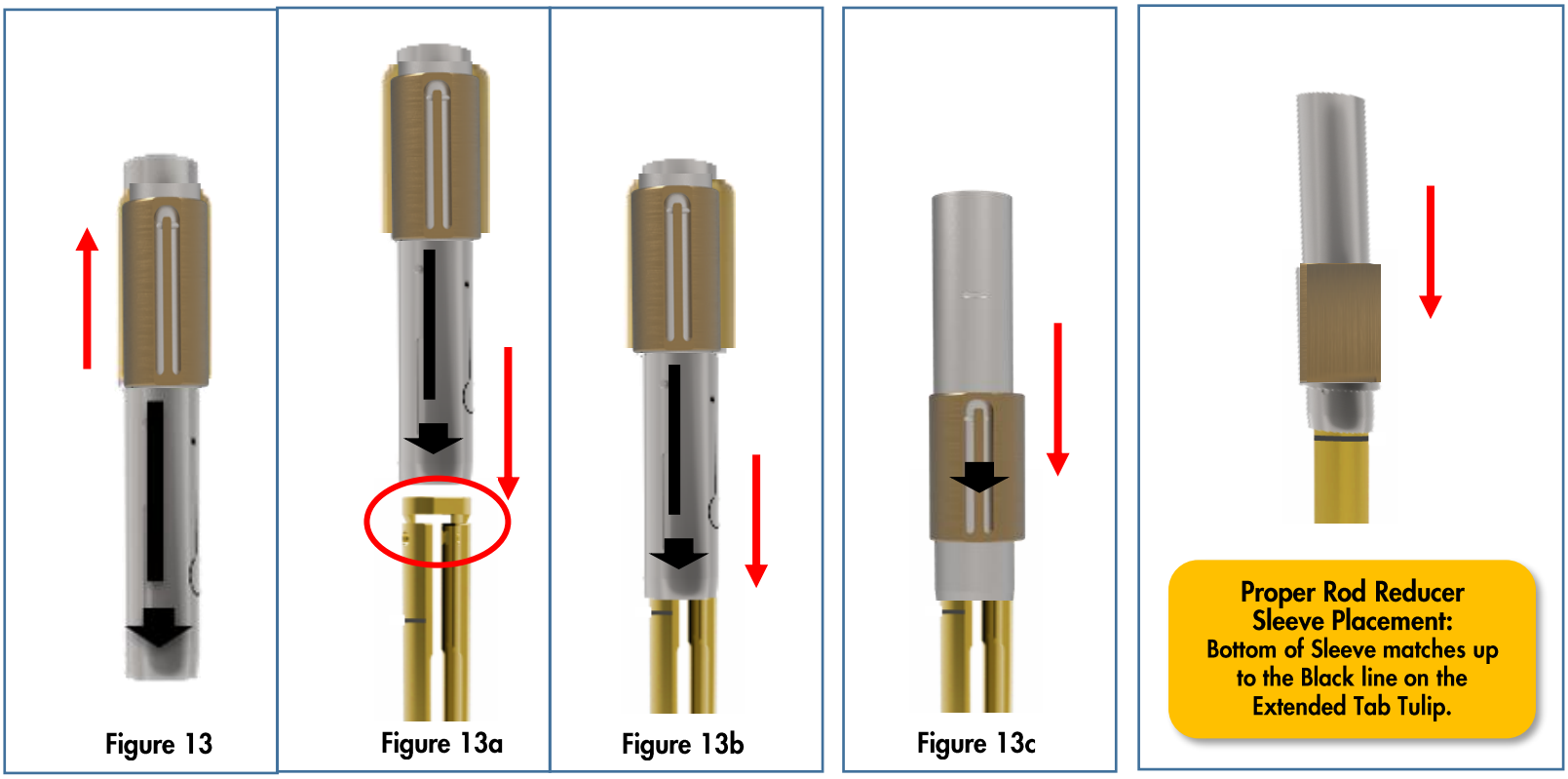


Figure 13 | Figure 13a | Figure 13b | Figure 13c

Proper Rod Reducer Sleeve Placement:
Bottom of Sleeve matches up to the Black line on the Extended Tab Tulip.

SURGICAL TECHNIQUE

13 ROD REDUCTION (ADDITIONAL 30mm) *(OPTIONAL)*

Attach the Ratcheting Palm Handle (64-CH-0002) or Ratcheting T-Handle (64-CH-0003) to the Rod Reducer Driver. Confirm engagement to the Handle by pulling on the shaft of the Driver (Figure 13d)

Ratcheting T-Handle, ¼" SQ
(Optional – By Request)
(64-CH-0003)

Ratcheting Palm Handle
(64-CH-0002)

Rod Reducer Driver
(64-RD-0453)

Figure 13d

13 ROD REDUCTION (ADDITIONAL 30mm) *(OPTIONAL)*

Holding the palm handle, pull down and rotate clockwise the center knob of the Rod Reducer Driver so the driver pins seat into the slots with the black divots (Figure 13e).

Stab and grab a Lock Screw from the caddy using the distal end of the Rod Reducer Driver (Figure 13f).

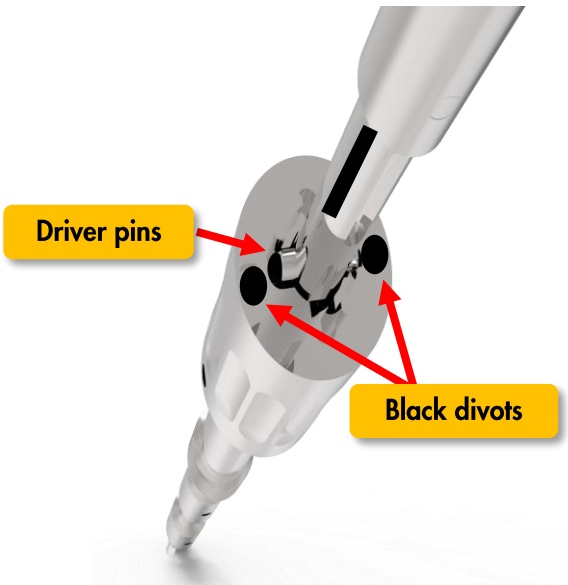


Figure 13e

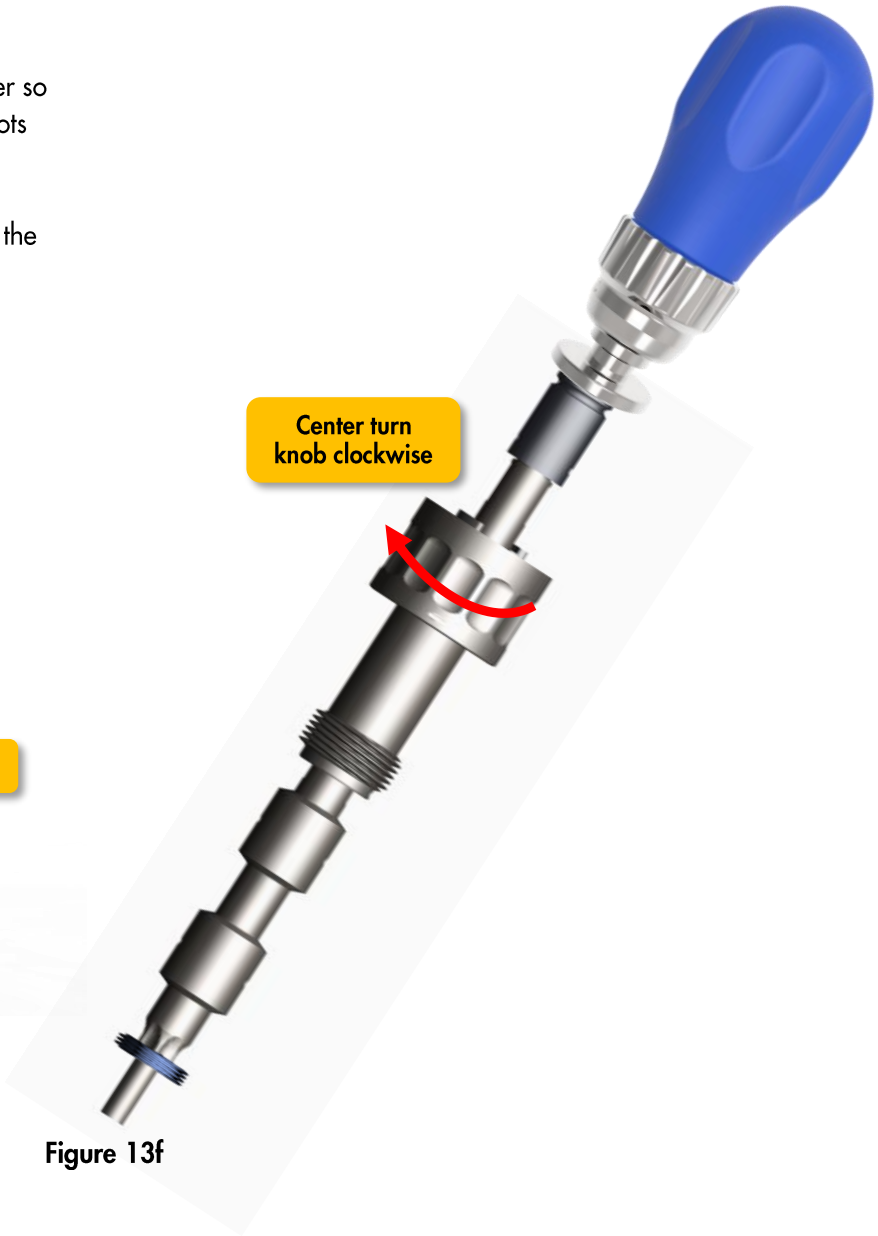


Figure 13f

SURGICAL TECHNIQUE

13 ROD REDUCTION (ADDITIONAL 30mm) *(OPTIONAL)*

Insert the Driver and Locking Screw into the Rod Reducer Sleeve and Extended Tab Tulip.

Rotate the Palm Handle clockwise until the Center Knob bottoms out completely against the Rod Reducer Sleeve. The rod is now completely reduced into the tulip. (Figure 13g)

The Lock Screw is in final position when the top of the black mark on the driver meets the top of the center knob. (Figure 13h)

ALL-IN-ONE REMOVAL

Carefully pull up on the gold collar of the Rod Reducer Sleeve to remove both the Sleeve and the Driver from the Extended Tab Tulip.

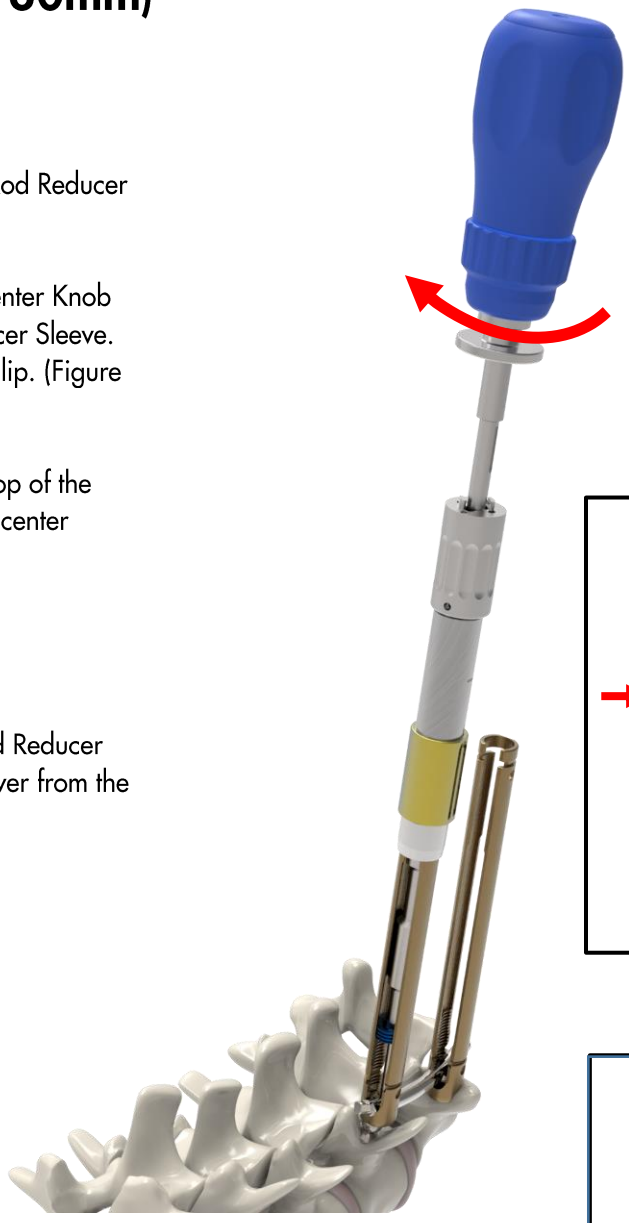
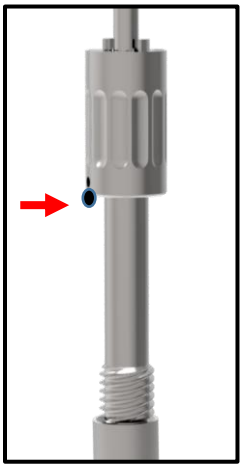
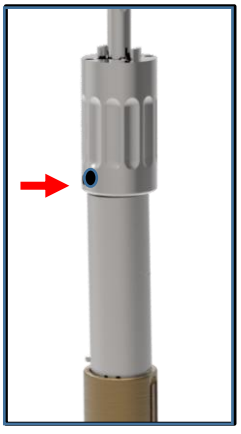


Figure 13g



Unseated

Figure 13h



Seated

SURGICAL TECHNIQUE

14 COMPRESSION/ DISTRACTION PARALLEL

Attach the Parallel Compressor/Distractor (64-RD-0044) over the final tightened Extended Tab Tulip (Figure 14).

NOTE: Ensure that the loosely tightened Extended Tab Tulip is seated within the Parallel Compressor/Distractor center opening.

Slide the Gold Compressor/Distractor Handle (64-RD-0040) over the loosely tightened Extended Tab Tulip and the handle knob fits into the connection slot. (Figure 14a).

Insert the Short Torque Driver (64-RD-0051) into the final tightened Extended Tab Tulip (Figure 14a).

Securely attach the Torque Limiting Handle (64-CH-0090) onto the Long Torque Driver (64-RD-0052).

Insert the Long Torque Driver through the Gold Compressor/Distractor Handle and into the loosely tightened Extended Tab Tulip (Figure 14b) and seated securely into the Lock Screw.

Compress/Distract to desired position.

Rotate the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 90 in-lbs.

Parallel Compressor Distractor (64-RD-0044)

Compressor Distractor Handle (64-RD-0040)

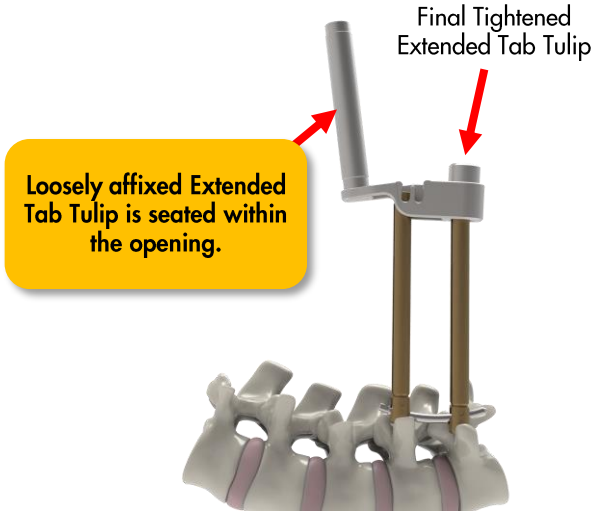


Figure 14

Figure 14a

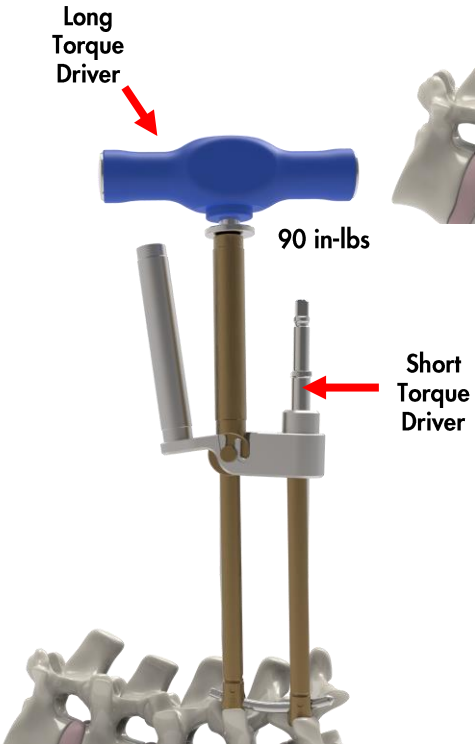


Figure 14b

15 COMPRESSION/DISTRACTION MEDIAL-LATERAL

Slide the Medial-Lateral Compressor/Distractor Pivot (64-RD-0043) over the final tightened Extended Tab Tulip. Orient the slot on the Pivot towards the loosely affixed Extended Tab Screw (Figure 35).

With the knob facing the Pivot slot, slide the Compressor/Distractor Handle (64-RD-0040) over the loosely tightened Extended Tab Tulip.

Connect the Handle knob to the Pivot slot (Figure 36).

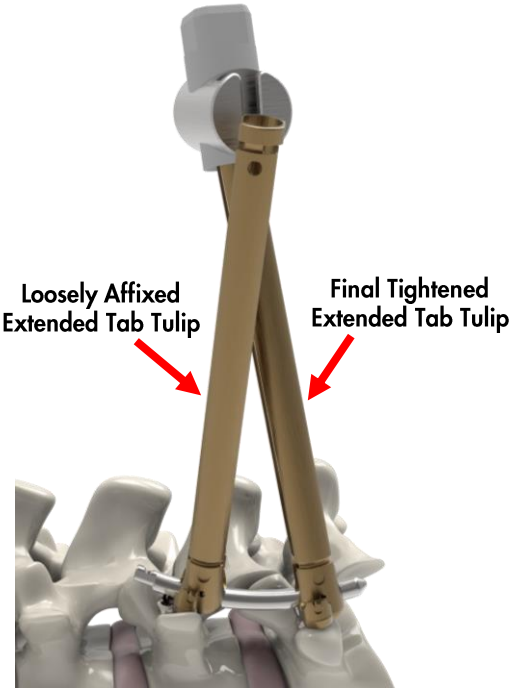


Figure 15

Compressor
Distractor Pivot
(64-RD-0043)

Compressor
Distractor Handle
(64-RD-0040)

Figure 15a

15 Compression/Distraction Medial-Lateral

Attach the Medial-Lateral Handle (64-RD-0042) to the Pivot so that the Handle is in the opposite direction of the Compressor/Distractor Handle.

Insert the Short Torque Driver into the final tightened Extended Tab Tulip.

Through the Compressor/Distractor Handle and into the loosely tightened Extended Tab Tulip, insert the Long Torque Driver (64-RD-0052) connected to the Torque Limiting Handle (64-CH-0090) (Figure 15b).

Ensure that the tip of the Long Torque Driver is seated firmly and securely into the Lock Screw. Compress/distract to desired position.

Rotate the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 90 in-lbs.

Medial Lateral Handle
(64-RD-0042)

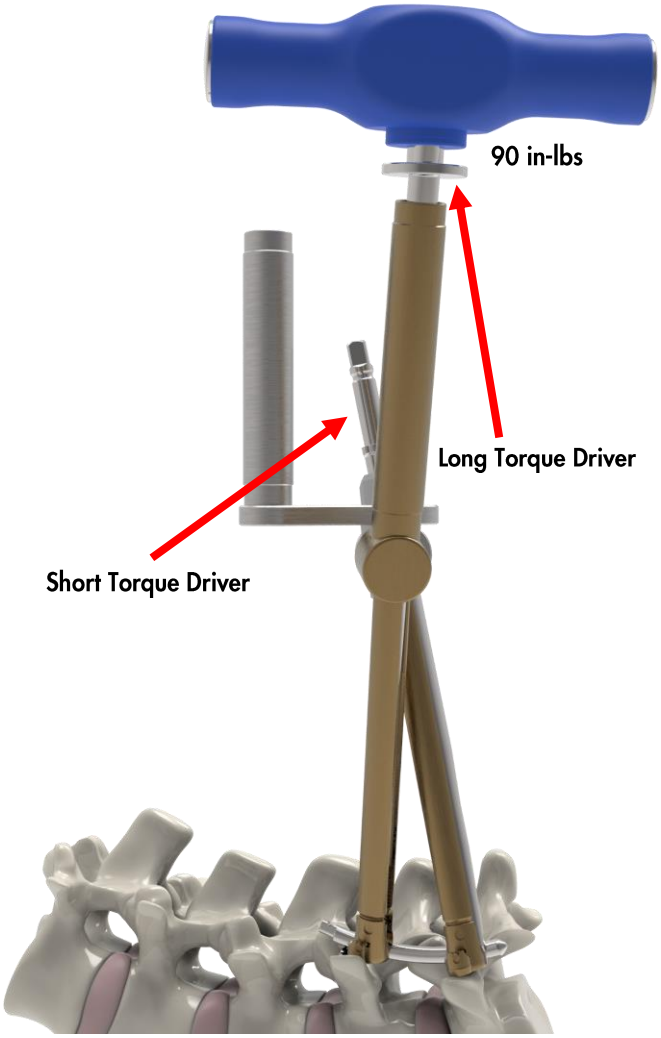


Figure 15b

SURGICAL TECHNIQUE

16 EXTENDED TAB REMOVAL

Perform a final verification of the screw and rod construct positioning using intraoperative fluoroscopy.

Securely insert the Ring Remover (64-RD-0940) into the Extended Tab Tulip.

Rock the Remover towards the closed ring until the ring has been broken (Figure 16).

Press the button to automatically remove the broken ring from the instrument.

Discard or recycle all broken rings.

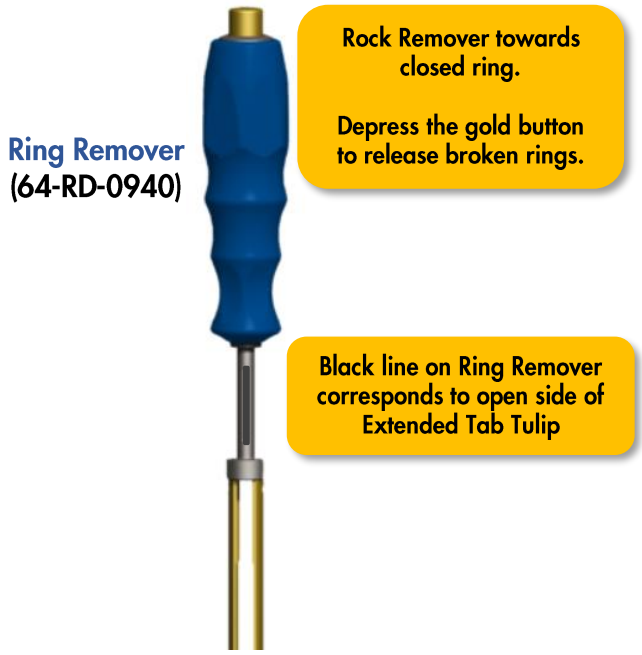


Figure 16

Securely insert the Dual Tab Breaker into and over the Extended Tab Tulip.

Rock the Dual Tab Breaker medial/lateral until both tabs break (Figure 16a). Repeat for remaining Extended Tab Tulips.

Discard or recycle all broken tabs.

Confirm that all tabs have been removed using intraoperative fluoroscopy.

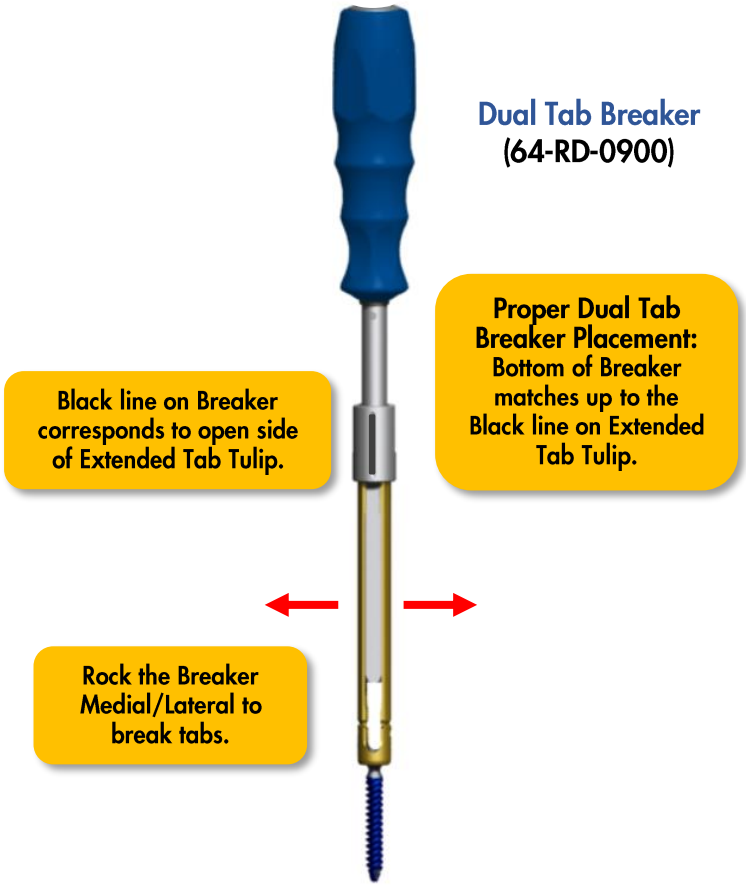


Figure 16a

SURGICAL TECHNIQUE

17 RESCUE TOWER

The Rescue Tower (64-RD-0410) can be used in place of the Extended Tab Tulip if:

1. Extended Tabs accidently disengage from the base tulip
2. Construct requires loosening and/or adjustment after lock screw insertion and tabs have already been broken off

Sequentially dilate with Dilators #1 through #3 to provide a path down to the tulip.

Remove Dilators #1 and #2 leaving Dilator #3 in position.

Insert and fully seat the tab end or post end (if Lock Screw is present) of the Rescue Tower Guide (64-RD-0411) into the tulip (Figure 17).

Remove Dilator #3 and slide the Rescue Tower (64-RD-0410) over the Rescue Tower Guide until it securely engages the tulip (Figure 17a).

Pull up on the Rescue Tower to ensure that is properly engaged with the tulip. If the Rescue Tower disengages from tulip, rotate the Tower 180° and reattach to the Tulip following previous steps.

Once the Rescue Tower is properly attached to the Tulip, all system instruments are compatible with the Tower (Figure 17b).

Tab End
No Rod Present

Rescue Tower Guide
(64-RD-0411)

Post End
Lock Screw Present

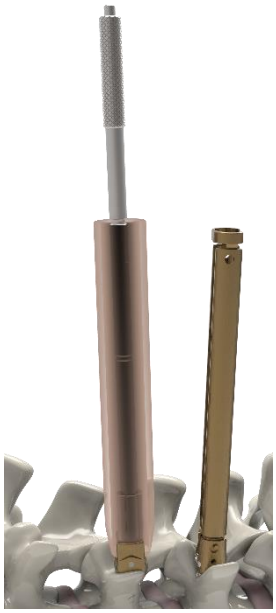


Figure 17

Rescue Tower
(64-RD-0410)

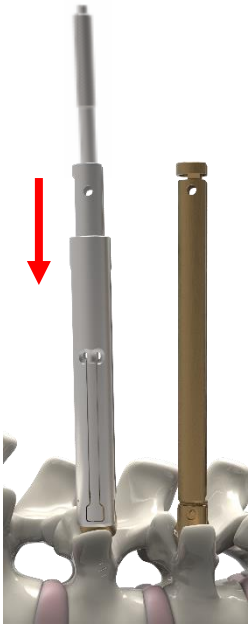


Figure 17a

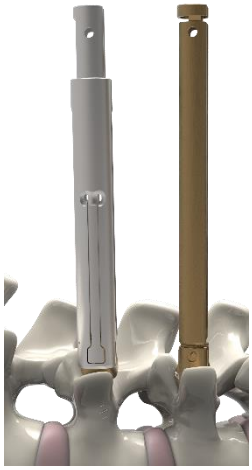


Figure 17b

17 RESCUE TOWER

To remove the Rescue Tower:

Insert the Rescue Tower Remover (64-RD-0420) into the Rescue Tower.

Press the proximal gold button on the Remover so it securely engages the Rescue Tower.

While depressing the button, gently pull up on the Remover to remove the Rescue Tower (Figure 17c).

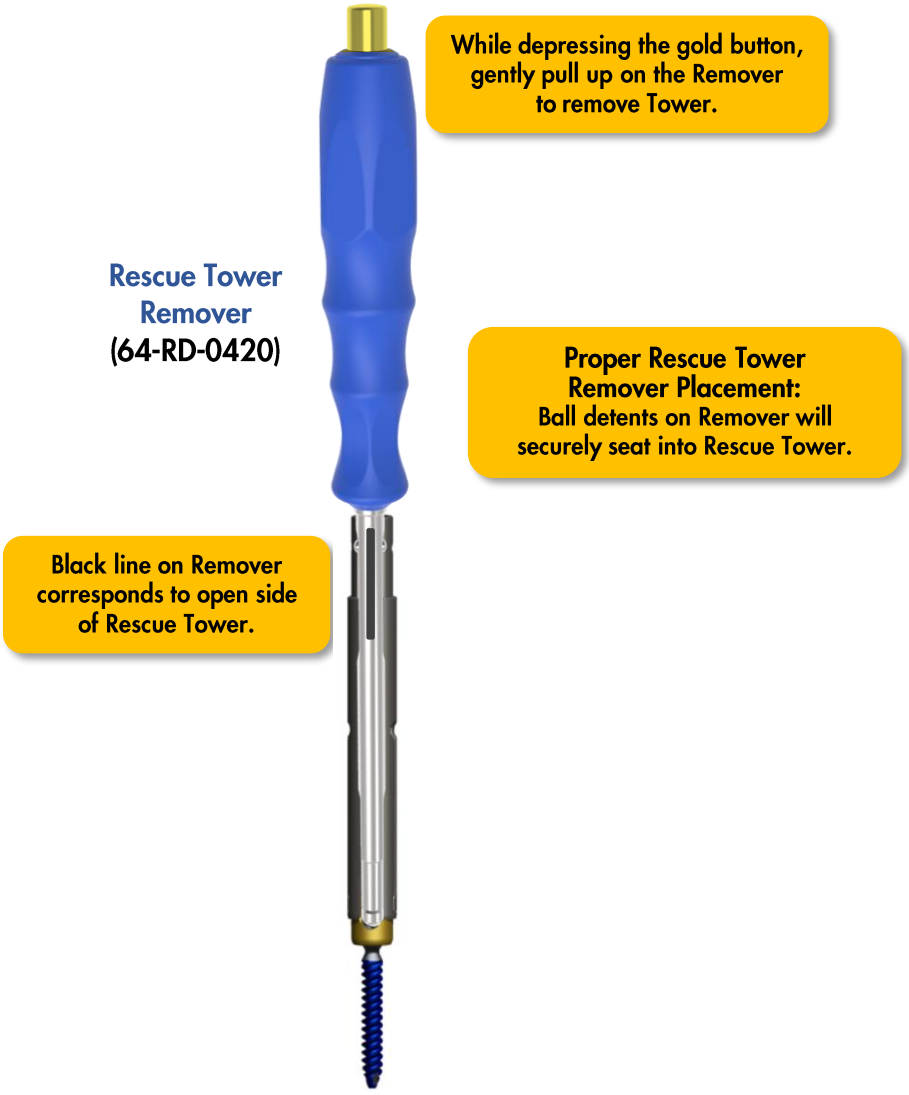


Figure 17c

SURGICAL TECHNIQUE

18 IMPLANT REMOVAL

a. Attach the Long Torque Driver (T30) (64-RD-0052) to the Offset Ratcheting Torque Handle (39-CH-0008).

b. Place the Counter Torque Wrench (39-RD-0061) over the Screw Tulip.

c. Insert the Torque Driver Assembly through the Counter Torque Wrench and rotate the Torque Handle counterclockwise to loosen the Lock Screw.

d. Remove rods and use the Retention Bone Screw Driver (59-SP-0601/59-MS-0061) or the Adjustment Driver (64-SP-0601) to back out the screws from the pedicles.

Indications, Contraindications, Warnings, and Precautions

INDICATIONS:
The **Reform** Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The **Reform** Pedicle Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation (T1-S1/ilium) for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

PRECAUTIONS:
The **Reform** Pedicle Screw System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.
All system implants are single-use only. Reuse of the device may result in the following:
1. Infection
2. Loosening
3. Fracture / mechanical failure of the device
4. Inability to properly engage surgical instrumentation
5. Pyrogenic reaction

CONTRAINDICATIONS:
The **Reform** Pedicle Screw System contraindications include, but are not limited to:
1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device

POTENTIAL ADVERSE EFFECTS:
All possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:
1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any, or all, of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase in spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS:
The following are warnings for this device.
1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only. AN IMPLANT SHOULD NEVER BE RE-USED. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. Titanium components should not be used with stainless steel components within the same system.
14. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
15. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

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