



SURGICAL TECHNIQUE

PRECISION SPINE
REFORM[®] Ti
TITANIUM PEDICLE SCREW SYSTEM

Standard • HA Coated • Modular • Cannulated



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REFORM® Ti PEDICLE SCREW SYSTEM OVERVIEW

Reform® Ti is a comprehensive pedicle screw system that is designed to meet the varying requirements of degenerative, trauma and deformity procedures. Reform Ti features a titanium tulip, a titanium triple lead, proximally tapered thread and titanium and cobalt chrome rods to deliver strength, stability and efficiency to all thoracolumbar constructs. Reduction and modular screw options, along with a full line of hooks, dominoes and offsets, complete the system to simplify the procedure and accommodate individual patient anatomy.

DEVICE DESCRIPTION

The Reform Ti Pedicle Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, locking cap screws, hooks, dominoes, and lateral offsets. All of the components are available in a variety of sizes to match more closely the patient's anatomy. All components are made from medical grade stainless steel, cobalt chromium alloys, titanium or titanium alloy described by such standards as ASTM F-138, ASTM F-1537, ISO 5832-12, ASTM F-136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

The Reform Ti HA Coated Pedicle Screws are supplied STERILE, are made from medical grade titanium or titanium alloy as described by such standards as ASTM F136 or ISO 5832-3 and feature Hydroxyapatite (HA) coating described by such standards as ISO 13779-2 and ASTM 1185-03.

INDICATIONS

The Reform Ti 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 Ti 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 Ti 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 Ti Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Ti 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) and (LBL-IFU-021; Reform Ti HA Coated Screws) for complete system description, indications and warnings.

REFORM[®] Ti IMPLANT FEATURES

Polyaxial & Modular Screws

- Provide 30° angulation in all planes
- T25 Hexalobe

Standard & Cannulated Options

- Provides Optimal Versatility

Triple Lead Thread

- Allows for efficient screw delivery

Low Profile Titanium Tulip

- 12.7mm Footprint x 14.4mm Height
- Decreases the risk of adjacent segment facet impingement

Aggressive Tip

- Provides Easy Starting

Polyaxial Screws, T25

Standard (39-TP-XXXX) & Cannulated (39-TC-XXXX)

4.5mm*	By request only
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm - 10.5 screws	By request only

HA Coated, Standard (39-HT-XXXX)

5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	By request only



Complete screw size offerings on pages 6 - 8

Modular Screws, T25

Standard (39-SB-XXXX) & Cannulated (39-SK-XXXX)

4.5mm*	By request only
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm, 9.5mm	By request only

HA Coated, Standard (39-HM-XXXX) & Cannulated (39-HMC-XXXX)

4.5mm*	By request only
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm, 9.5mm	By request only



Modular Tulips

- Standard Tulip (5.5mm)
- Reduction Tulip (5.5mm)



Complete screw size offerings on pages 6 - 8

*4.5mm screws are only offered in Standard configurations

Locking Cap, T25

Titanium Square Threaded Locking Cap

- Geometry Reduces the Risk of Cross-threading
- Reduces Risk of Head-Splay with DVR Maneuvers



T25 Hexalobe

- Reduces the Incidence of Toggle and Stripping

5.5mm Rods

Titanium and Cobalt Chrome Rods

Straight Rods

- 80mm - 150mm



Lordotic Rods

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



Straight Hex-End Rods

- 200 - 600mm



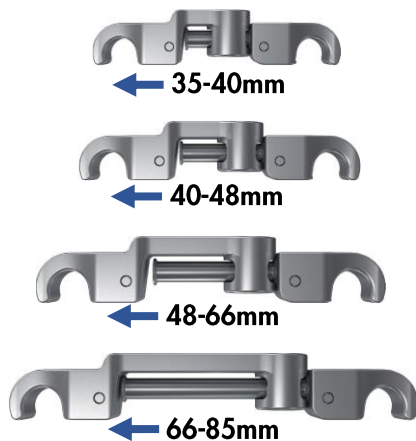
Complete rod size offerings on page 9

Cross Connectors, T20

Offset Cam Locking Mechanism

90° Locking Motion

3° of Freedom Linkage provides $\pm 25^\circ$ of Angulation



Dominoes, T20* or T25*

Parallel and Axial Options

Multiple Open-Closed Configurations

Wide and Narrow Widths



**Please see page 9 for specific set screw information*




Complete cross connector and domino size offerings and on page 9

REFORM® Ti





POLYAXIAL SCREWS

Set No.	Diameters	Rods
Standard, Polyaxial Screws (T25)		
39-BK-0701	5.5mm - 7.5mm	Titanium
39-BK-0705	5.5mm - 7.5mm	Cobalt Chrome

Set No.	Diameters	Rods
Cannulated, Polyaxial Screws (T25)		
39-BK-1701	5.5mm - 7.5mm	Titanium
39-BK-1705	5.5mm - 7.5mm	Cobalt Chrome

Screw Size (Ø x Length)	Part No.		Qty/Set	Screw Color
	Standard, Polyaxial	Cannulated, Polyaxial		
5.5mm x 30mm	39-TP-5530	39-TC-5530	6	
5.5mm x 35mm	39-TP-5535	39-TC-5535	6	
5.5mm x 40mm	39-TP-5540	39-TC-5540	8	
5.5mm x 45mm	39-TP-5545	39-TC-5545	8	
5.5mm x 50mm	39-TP-5550	39-TC-5550	6	
6.5mm x 30mm	39-TP-6530	39-TC-6530	6	
6.5mm x 35mm	39-TP-6535	39-TC-6535	6	
6.5mm x 40mm	39-TP-6540	39-TC-6540	10	
6.5mm x 45mm	39-TP-6545	39-TC-6545	10	
6.5mm x 50mm	39-TP-6550	39-TC-6550	8	
6.5mm x 55mm	39-TP-6555	39-TC-6555	8	
7.5mm x 35mm	39-TP-7535	39-TC-7535	6	
7.5mm x 40mm	39-TP-7540	39-TC-7540	8	
7.5mm x 45mm	39-TP-7545	39-TC-7545	8	
7.5mm x 50mm	39-TP-7550	39-TC-7550	6	
7.5mm x 55mm	39-TP-7555	39-TC-7555	6	

By Request Polyaxial Screws*

Screw Diameter	Standard, Polyaxial	Cannulated, Polyaxial	Screw Color
4.5mm	Please contact Customer Relations for complete screw length offerings and availability		Magenta 
8.5mm			Bronze 
9.5mm			Natural 
10.5mm			Purple 



4.5mm screws are only offered in Standard configuration




*Screw qty's vary per size

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MODULAR SCREWS

Set No.	Diameters	Rods
Standard, Modular Screws (T25)		
39-BK-0541	5.5mm - 7.5mm	Titanium
39-BK-0543	5.5mm - 7.5mm	Cobalt Chrome
Cannulated, Modular Screws (T25)		
39-BK-0545	5.5mm - 7.5mm	Titanium
39-BK-0547	5.5mm - 7.5mm	Cobalt Chrome

Modular Reform Ti Tulips	
Standard	Reduction
	
39-MT-0401 (24/set)	39-MT-0402 (10/set)

Screw Size (Ø x Length)	Part No.		Qty/Set	Screw Color
	Standard, Modular	Cannulated, Modular		
5.5mm x 30mm	39-SB-5530	39-SK-5530	6	
5.5mm x 35mm	39-SB-5535	39-SK-5535	6	
5.5mm x 40mm	39-SB-5540	39-SK-5540	8	
5.5mm x 45mm	39-SB-5545	39-SK-5545	8	
5.5mm x 50mm	39-SB-5550	39-SK-5550	6	
6.5mm x 30mm	39-SB-6530	39-SK-6530	6	
6.5mm x 35mm	39-SB-6535	39-SK-6535	6	
6.5mm x 40mm	39-SB-6540	39-SK-6540	10	
6.5mm x 45mm	39-SB-6545	39-SK-6545	10	
6.5mm x 50mm	39-SB-6550	39-SK-6550	8	
6.5mm x 55mm	39-SB-6555	39-SK-6555	8	
7.5mm x 35mm	39-SB-7535	39-SK-7535	6	
7.5mm x 40mm	39-SB-7540	39-SK-7540	8	
7.5mm x 45mm	39-SB-7545	39-SK-7545	8	
7.5mm x 50mm	39-SB-7550	39-SK-7550	6	
7.5mm x 55mm	39-SB-7555	39-SK-7555	6	

By Request Modular Screws*

Screw Diameter	Standard, Modular	Cannulated, Modular	Screw Color
4.5mm	Please contact Customer Relations for complete screw length offerings and availability		Magenta 
8.5mm			Bronze 
9.5mm			Natural 

4.5mm screws are only offered in Standard configurations

*Screw qty's vary per size

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HA COATED SCREWS

Set No.	Diameters
Standard, Polyaxial HA Coated Screws (T25)	
39-BK-0731	5.5mm - 7.5mm

Set No.	Diameters
Standard, Modular HA Coated Screws (T25)	
39-BK-0741	5.5mm - 7.5mm
Cannulated, Modular HA Coated Screws (T25)	
39-BK-0751	5.5mm - 7.5mm

Screw Size (Ø x Length)	Part No.		Qty/Set
	Standard, Polyaxial HA Coated	Standard, Modular HA Coated	
5.5mm x 30mm	39-HT-5530	39-HM-5530	6
5.5mm x 35mm	39-HT-5535	39-HM-5535	6
5.5mm x 40mm	39-HT-5540	39-HM-5540	6
5.5mm x 45mm	39-HT-5545	39-HM-5545	6
5.5mm x 50mm	39-HT-5550	39-HM-5550	6
6.5mm x 35mm	39-HT-6535	39-HM-6535	6
6.5mm x 40mm	39-HT-6540	39-HM-6540	10
6.5mm x 45mm	39-HT-6545	39-HM-6545	10
6.5mm x 50mm	39-HT-6550	39-HM-6550	8
6.5mm x 55mm	39-HT-6555	39-HM-6555	6
7.5mm x 35mm	39-HT-7535	39-HM-7535	6
7.5mm x 40mm	39-HT-7540	39-HM-7540	6
7.5mm x 45mm	39-HT-7545	39-HM-7545	6
7.5mm x 50mm	39-HT-7550	39-HM-7550	6
7.5mm x 55mm	39-HT-7555	39-HM-7555	6



By Request HA Coated Screws*

Screw Diameter	Standard, Polyaxial HA Coated	Standard, Modular HA Coated	Cannulated, Modular HA Coated
4.5mm	<p style="color: #ff0000; font-weight: bold;">Please contact Customer Relations for complete screw length offers and availability.</p>		
5.5mm			
6.5mm			
7.5mm			
8.5mm			
9.5mm			



Carrying Case

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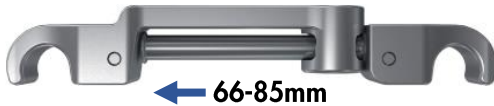
LOCK SCREW, CROSS CONNECTORS, RODS

Lock Screw, (T25)

Part No.	Qty/Set
39-LS-0100	24



Adjustable Cross Connectors, (T20)



Cross Connector Size (Adjustable Lengths)	Part No.	Qty/ Set
35mm (35mm - 40mm)	39-CC-0035	2
40mm (40mm - 48mm)	39-CC-0040	2
48mm (48mm - 66mm)	39-CC-0048	2
66mm (66mm - 85mm)	39-CC-0066	2
By Request Cross Connectors		
30mm (30mm - 32mm)	39-CC-0030	2
32mm (32mm - 35mm)	39-CC-0032	2

5.5mm Rods

Lordotic Rod Size (\emptyset x Length)	Part No.		Qty/ Set
	Titanium (Ti)	Cobalt Chrome (CoCr)	
Lordotic Rods			
5.5mm x 35mm	39-LT-5035	39-LC-5035	3
5.5mm x 40mm	39-LT-5040	39-LC-5040	3
5.5mm x 45mm	39-LT-5045	39-LC-5045	3
5.5mm x 50mm	39-LT-5050	39-LC-5050	3
5.5mm x 55mm	39-LT-5055	39-LC-5055	3
5.5mm x 60mm	39-LT-5060	39-LC-5060	3
5.5mm x 65mm	39-LT-5065	39-LC-5065	3
5.5mm x 70mm	39-LT-5070	39-LC-5070	3
5.5mm x 75mm	39-LT-5075	39-LC-5075	3
5.5mm x 80mm	39-LT-5080	39-LC-5080	3
5.5mm x 90mm	39-LT-5090	39-LC-5090	3
5.5mm x 100mm	39-LT-5100	39-LC-5100	3
5.5mm x 110mm	39-LT-5110	39-LC-5110	3
5.5mm x 120mm	39-LT-5120	39-LC-5120	3
Straight Rods			
5.5mm x 80mm	39-ST-5080	39-SC-5080	3
5.5mm x 100mm	39-ST-5100	39-SC-5100	3
5.5mm x 120mm	39-ST-5120	39-SC-5120	3
By Request Straight Rods			
5.5mm x 40mm	39-ST-5040	N/A	3
5.5mm x 60mm	39-ST-5060	N/A	3
5.5mm x 150mm	39-ST-5150	N/A	3
Straight Rods, Hex Ends			
5.5mm x 200mm	39-ST-5200	39-SC-5200	3
5.5mm x 400mm	39-ST-5400	39-SC-5400	3
By Request Straight Rods, Hex Ends			
5.5mm x 300mm	39-ST-5300	39-SC-5300	3
5.5mm x 500mm	39-ST-5500	39-SC-5500	3
5.5mm x 600mm	N/A	39-SC-5600	3

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DOMINOES *(By Request Only)*

Type	Part No.	Distance
5.5mm - 5.5mm Axial Domino, (T20)		
Closed-Closed	39-AA-0101	N/A
5.5mm - 5.5mm Parallel Domino, (T20)		
Closed-Closed, Wide	39-DA-0101	11mm
Closed-Closed, Narrow	39-DA-0102	9mm
Closed-Open, Wide	39-DA-0201	11mm
Closed-Open, Narrow	39-DA-0202	9mm
Open-Open, Wide	39-DA-0301	11mm
Open-Open, Narrow	39-DA-0302	9mm
Domino Set Screw, (T20)		
Domino Set Screw	39-LS-0200	N/A



Axial Domino
Closed-Closed



Distance



Parallel Domino
Closed-Closed, Wide



Parallel Domino
Closed-Closed, Narrow



Parallel Domino
Closed-Open, Wide



Parallel Domino
Closed-Open, Narrow



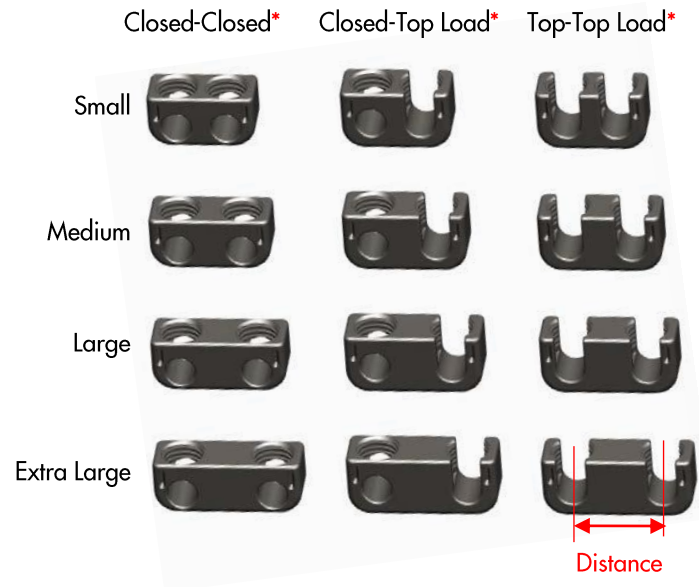
Parallel Domino
Open-Open, Wide



Parallel Domino
Open-Open, Narrow

Set # 39-BK-0526

Type	Part No.	Distance
5.5mm - 5.5mm Parallel, (T25)		
Closed-Closed, Small*	39-DA-1101	11mm
Closed-Closed, Medium*	39-DA-1102	14mm
Closed-Closed, Large*	39-DA-1103	17mm
Closed-Closed, Extra Large*	39-DA-1104	20mm
Closed-Top Load, Small*	39-DA-1201	11mm
Closed-Top Load, Medium*	39-DA-1202	14mm
Closed-Top Load, Large*	39-DA-1203	17mm
Closed-Top Load, Extra Large*	39-DA-1204	20mm
Top Load-Top Load, Small*	39-DA-1301	11mm
Top Load-Top Load, Medium*	39-DA-1302	14mm
Top Load-Top Load, Large*	39-DA-1303	17mm
Top Load-Top Load, Extra Large*	39-DA-1304	20mm
Set Screw, (T25)		
Lock Screw	39-LS-0100	N/A



*Utilizes Lock Screw 39-LS-0100 & Domino Counter Torque Wrench 39-RD-0066

REFORM® Ti INSTRUMENT TRAY

Top Level

Set No.	Instrument Sets
39-BK-0721	Standard Instrument Set
39-BK-1721	Cannulated Instrument Set
39-BK-0520	Standard Modular Instrument Set
39-BK-0525	Cannulated Modular Instrument Set



#	Part No.	Description	Qty
1	39-CH-0004	Ratcheting Straight Handle, 1/4" SQ	2
2	See table below	Taps	1
3	39-SP-0011	2mm Ball Tip Sounder Straight	2
4	39-SP-0007	Straight Pedicle Probe	1
5	39-SP-0005	Duckbill Pedicle Probe	1
6	39-SP-0003	Curved Pedicle Probe	1
7	39-SP-0001	Bone Awl, 3.6mm Ø x 15mm	1
8	39-CH-0003	Ratcheting T-Handle, 1/4" SQ	2

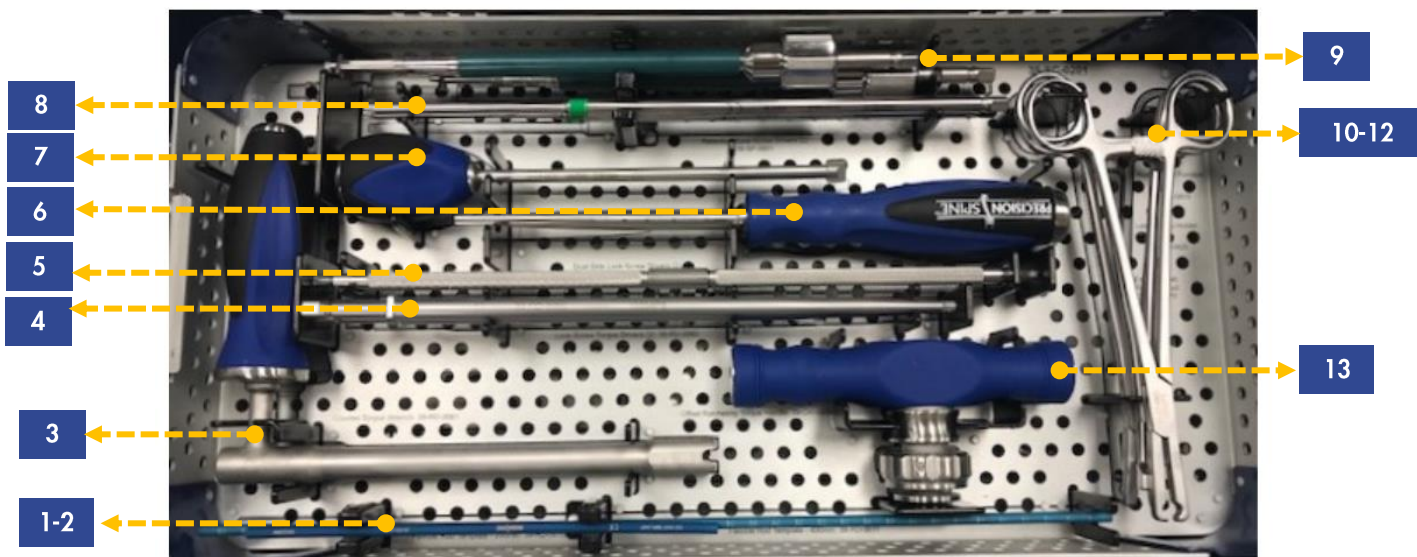
Standard Taps - All taps are undersized by 0.5mm		
Part No.	Description	Qty
39-SP-0545	4.5mm Standard Tap	1
39-SP-0555	5.5mm Standard Tap	1
39-SP-0565	6.5mm Standard Tap	1
39-SP-0575	7.5mm Standard Tap	1
39-SP-0585	8.5mm Standard Tap	1
39-SP-0595	9.5mm Standard Tap	1

Cannulated Taps - All taps are undersized by 0.5mm		
Part No.	Description	Qty
39-SP-1555	5.5mm Cannulated Tap	1
39-SP-1565	6.5mm Cannulated Tap	1
39-SP-1575	7.5mm Cannulated Tap	1
39-SP-1585	8.5mm Cannulated Tap	1
39-SP-1595	9.5mm Cannulated Tap	1

REFORM® Ti INSTRUMENT TRAY

Middle Level

Set No.	Instrument Sets
39-BK-0721	Standard Instrument Set
39-BK-1721	Cannulated Instrument Set
39-BK-0520	Standard Modular Instrument Set
39-BK-0525	Cannulated Modular Instrument Set



#	Part No.	Description	Qty
1	39-RD-0010	Flexible Rod Template - 200mm	1
2	39-RD-0011	Flexible Rod Template - 400mm	1
3	39-RD-0061	Counter-Torque Wrench	1
4	39-RD-0060	Lock-Screw Torque Driver, T25	2
5	39-SP-0603	Dual-Side Lock-Screw Driver, T25	2
6	39-SP-0815	Rod Pusher 5.5mm	1
7	39-SP-0800	Tulip Manipulator	1
8	See side table	Retention Bone Screw Drivers, T25	2
9	See side table	Polyaxial or Modular Screw Drivers, T25	2
10	39-SP-0805	Rod Inserter Forceps	1
11	39-SP-0825 or 39-MD-0825	Lateral Tulip Holder	1
12	39-RD-0070	Extended Tab Removal Tool	1
13	39-CH-0008	Offset Ratcheting Torque Handle, 106 in-lbs	2

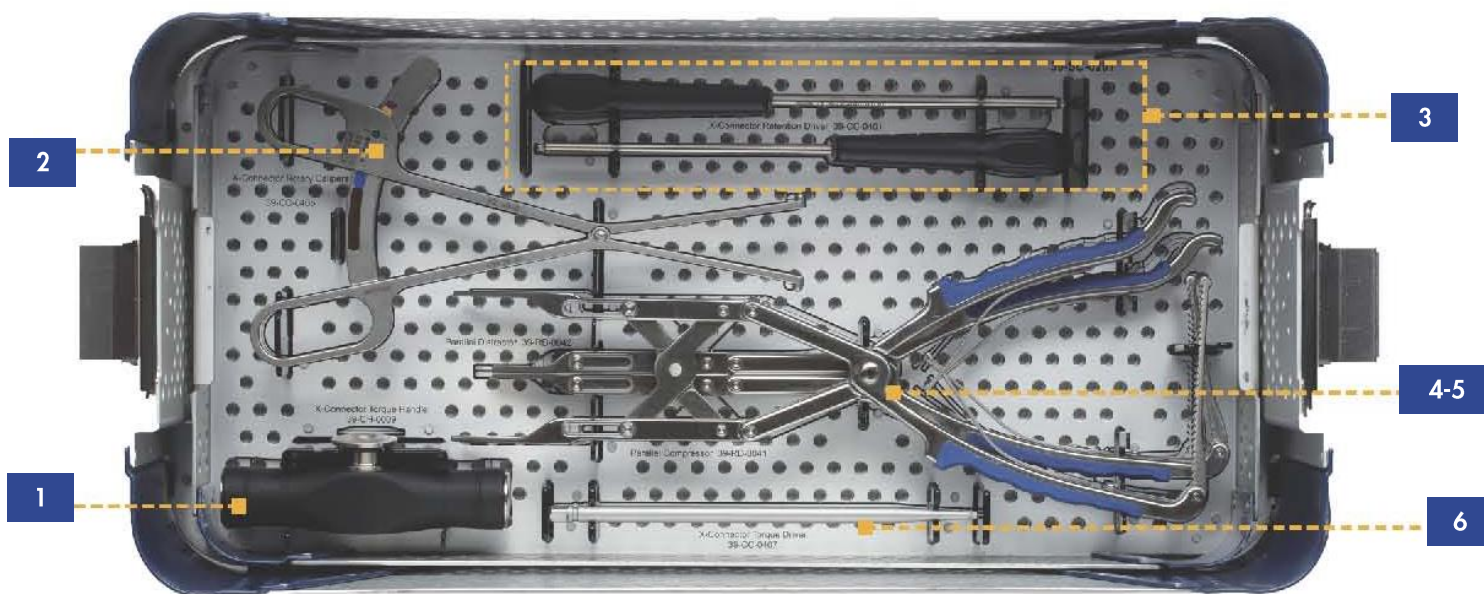
<i>Bone Screw Drivers</i>		
Part No.	Description	Qty
Standard Instrument Set		
59-SP-0601	Retention Bone Screw Driver, T25	2
39-SP-0720	Reform Ti Polyaxial Screw Driver, T25	2
Cannulated Instrument Set		
59-MS-0061	Cannulated Retention Bone Screw Driver, T25	2
39-SP-0750	Cannulated Reform Ti Polyaxial Screw Driver, T25	2
Standard, Modular Instrument Set		
59-SP-0700	Modular Bone Screw Driver, T25	2
59-SP-0601	Retention Bone Screw Driver, T25	2
39-SP-0720	Reform Ti Polyaxial Screw Driver, T25	1
Cannulated, Modular Instrument Set		
59-MS-0700	Cannulated Modular Bone Screw Driver, T25	2
59-MS-0061	Cannulated Retention Bone Screw Driver, T25	2
39-SP-0750	Cannulated Reform Ti Polyaxial Screw Driver, T25	1

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INSTRUMENT TRAY

Bottom Level

Set No.	Instrument Sets
39-BK-0721	Standard Instrument Set
39-BK-1721	Cannulated Instrument Set
39-BK-0520	Standard Modular Instrument Set
39-BK-0525	Cannulated Modular Instrument Set

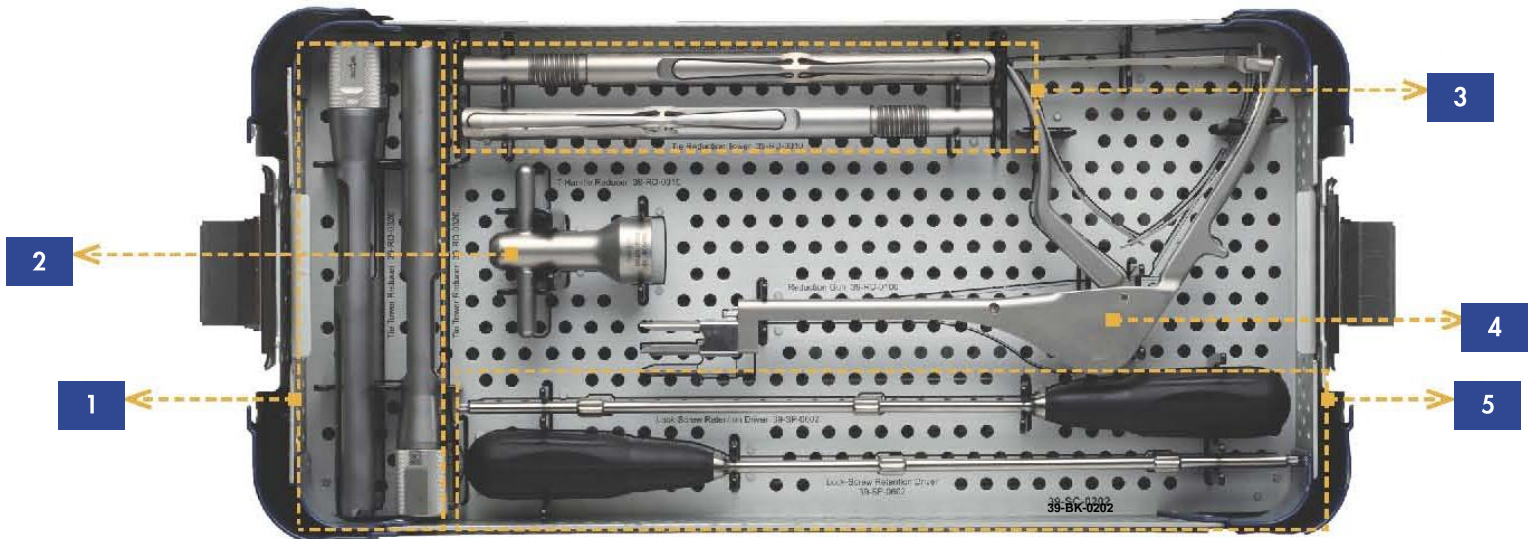


#	Part No.	Description	Qty
1	39-CH-0009	Cross Connector/Domino Torque Handle, 66 in-lbs	1
2	39-CC-0405	Calipers	1
3	39-CC-0401	Cross Connector/Domino Retention Driver, T20	2
4	39-RD-0041	Parallel Compressor	1
5	39-RD-0042	Parallel Distractor	1
6	39-CC-0407	Cross Connector/Domino Torque Driver, T20	1

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ADD-ON INSTRUMENT TRAY (39-BK-0202)

Top Level



#	Part No.	Description	Qty
1	39-RD-0320	Tie Tower Reducer, Outer Sleeve, (capable of 25mm reduction)	2
2	39-RD-0315	T-Handle (compatible with 39-RD-0320)	1
3	39-RD-0310	Tie Tower Reducer, Inner Shaft	2
4	39-RD-0100	Reduction Gun	1
5	39-RD-0602	Lock-Screw Retention Driver, T25	2

REFORM® Ti

ADD-ON INSTRUMENT TRAY (39-BK-0202)

Bottom Level



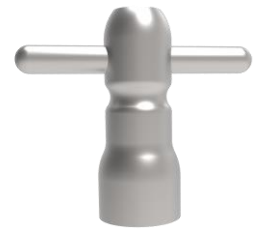
#	Part No.	Description	Qty
1	39-RD-0001	French Rod Bender	1
2	39-RD-0020	In Situ Rod Bender - (Left)	1
3	39-RD-0021	In Situ Rod Bender - (Right)	1
4	39-SP-0810	Rod Gripper	1
5	39-RD-0201	Rod Rocker	1
NOT PICTURED	39-MD-0100	Bone Planar (ONLY available in Modular Instrument Sets)	1

Reducers

Part No.	Description
39-RD-0415	T-Handle (compatible with 39-RD-0420)
39-RD-0420	Reduction Tower Assembly, (capable of 35mm reduction)



39-RD-0420



39-RD-0415

5.5mm Rod Grippers

Part No.	Description
39-RD-0600	Vise Grips
39-RD-0601	5.5mm Double Action Rod Gripper



39-RD-0600



39-RD-0601

Domino Inserter

Part No.	Description
39-RD-0570	Domino Inserter, T20

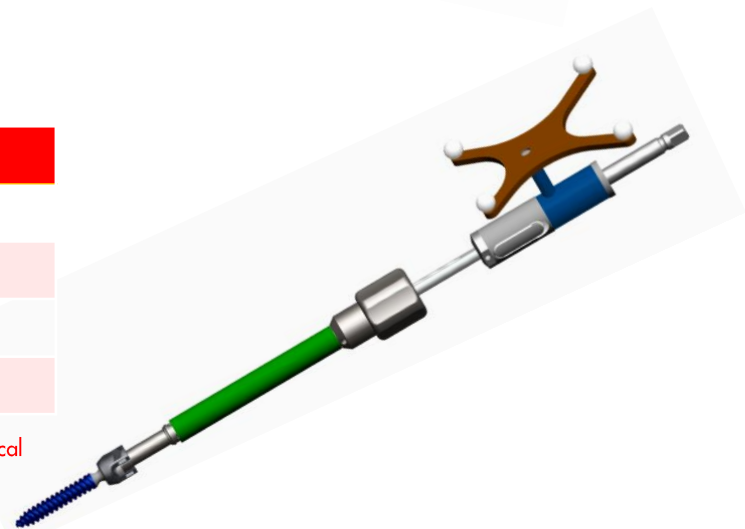


39-RD-0570

Reform Ti Navigation Instrument Sets*

Set No.	Description
70-BK-0103	Standard Navigated Instrument Set
70-BK-0104	Cannulated Navigated Instrument Set
70-BK-0105	Standard, Modular Navigated Instrument Set
70-BK-0106	Cannulated, Modular Navigated Instrument Set

*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

PREOPERATIVE PLANNING

The surgeon should consider for surgery only those patients indicated for the use of the Reform® Ti Pedicle Screw System. The surgeon should have a complete understanding of the surgical technique and of the system's design rationale, indications, contraindications and applications as well as a complete understanding of the function and limitations of each implant and instrument in the system.

2

PEDICLE PREPARATION

- a. Locate the desired entry point in the pedicle and perforate the cortex with the Awl (39-SP-0001) (Figure 1).
- b. Use a Straight (39-SP-0007), Curved (39-SP-0003), or Duckbill (39-SP-0005) Probe to open the pedicle canal (Figure 2). A pathway and trajectory through the pedicle can be established with a Probe allowing the instrument to follow the path of least resistance. The Probe should contact bone at all times. If resistance is felt while creating a pathway through the pedicle, trajectory should be re-evaluated. Etching on the Probe will indicate the depth of the Probe within the canal.
- c. Explore the prepared pathway with the Ball Tip Sounder (39-SP-0011) to confirm that integrity of the pedicle wall has not been violated (Figure 3).
- d. Select the appropriate Tap based on the pedicle screw diameter to prepare.
Note: The Taps are 0.5mm undersized. It is not recommended to under tap as it may result in pedicle fractures.
- e. Securely attach desired Tap to the Ratcheting Straight Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003). Confirm secure engagement to the Handle by gently pulling on the shaft of the Tap.
- f. Utilizing the depth measurements on the distal tip of the Tap as a guide, tap to the appropriate depth based on the pedicle screw length (Figure 4).

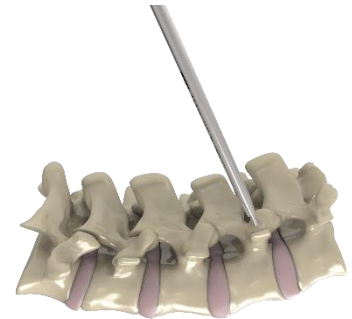


Figure 1

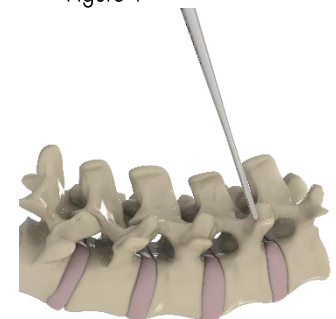


Figure 2

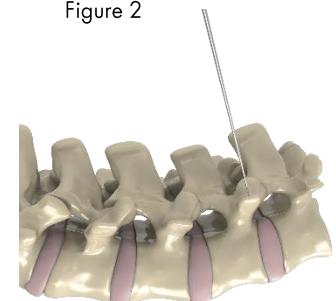


Figure 3

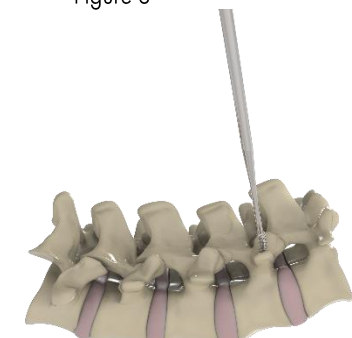


Figure 4

SURGICAL TECHNIQUE (continued)

3

SCREW DRIVER ATTACHMENT

- Securely attach either the Polyaxial Screw Driver (39-SP-0720/39-SP-0750) or the Modular Screw Driver (59-SP-0700/59-MS-0700) to the Ratcheting Straight Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003).
- Confirm secure engagement to the Handle by gently pulling on the shaft of the Screw Driver.

Polyaxial Screw Drivers (39-SP-0720/39-SP-0750)

- Insert the distal tip of the Polyaxial Screw Driver into the screw. The cross bar on the Polyaxial Screw Driver should be seated against the rod slot of the screw tulip (Figure 5).
- While holding the screw firmly on the Polyaxial Screw Driver, thread the knob clockwise until fully engaged and secure (Figure 6).
- To disengage the Polyaxial Screw Driver, turn the knob counterclockwise until the driver releases from the screw.

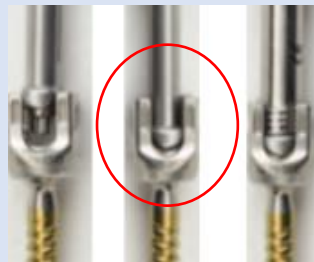


Figure 5

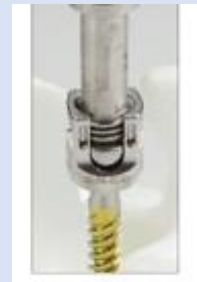


Figure 6

Modular Screw Drivers (59-SP-0700/59-MS-0700)

- Rotate the knob clockwise completely to fully open the collet of the Modular Screw Driver. (Figure 7a)
- Insert the distal tip of the Modular Screw Driver into the screw. (Figure 7b)
- While holding the screw firmly on the Modular Screw Driver, thread the knob counterclockwise until the collet and Driver sleeve completely surrounds and secures the screw. (Figure 7c)
- To disengage the Modular Screw Driver, turn the knob clockwise until the collet and driver release from the screw.

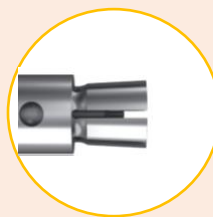


Figure 7a

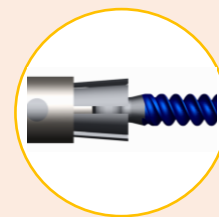


Figure 7b

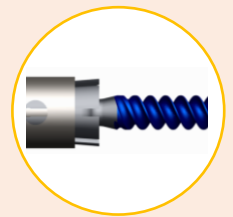


Figure 7c

Note: Ensure that the screw is fully engaged, securely rigid, and properly aligned with the Screw Driver. Improper engagement or misalignment can result in loosening of the driver from the screw and unintended screw trajectory.

SURGICAL TECHNIQUE (continued)

3

SCREW INSERTION

Polyaxial Screw Insertion

- a. While holding the sleeve of the Polyaxial Screw Driver, insert the screw into the prepared pedicle (Figure 8)

Note: Do not hold the knob of the Polyaxial Screw Driver during screw insertion as this may result in loosening of the driver from the screw and unintended screw trajectory.

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

- b. To disengage the Polyaxial Screw Driver, turn the proximal knob counterclockwise until the driver releases from the screw.



Figure 8

Modular Screw Insertion

- a. While holding the sleeve of the Modular Screw Driver, insert the screw into the prepared pedicle (Figure 9)

Note: Do not hold the knob of the Modular Screw Driver during screw insertion as this may result in loosening of the driver from the screw and unintended screw trajectory.

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

- a. To disengage the Modular Screw Driver, turn the proximal knob clockwise until the collet and driver release from the screw.

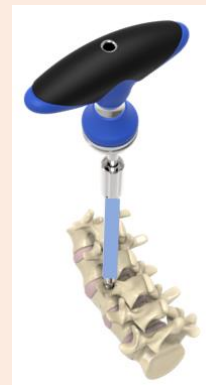


Figure 9

SURGICAL TECHNIQUE (continued)

5

DECORTICATION

Place the Bone Planar (39-MD-0100) over the head of the Modular Screw and rotate the Planar clockwise and counterclockwise to decorticate the bone and allow for optimal seating of the Modular Tulip (Figure 10).

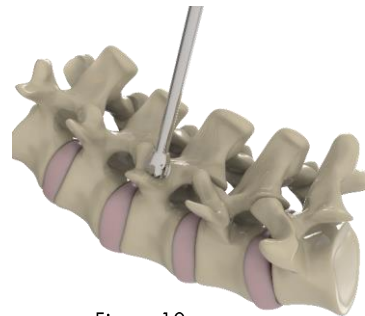


Figure 10

6

MODULAR TULIP ATTACHMENT

- Attach the Standard Modular Tulip (39-MT-0401) or the Reduction Modular Tulip (39-MT-0402) using the Angled Lateral Tulip Clamp (39-SP-0825/39-MD-0825).
- Align the inside tabs of the Tulip Clamp with the insets of the Modular Tulip (Figure 11).
- Slide the Tulip over the modular screw and apply an axial force until an audible click is heard (Figure 12).
- Upward pressure of the attached Lateral Tulip Clamp can be applied to ensure that the Tulip is properly inserted.

Note: Soft tissue between the Modular Screw and Tulip could prevent proper attachment.

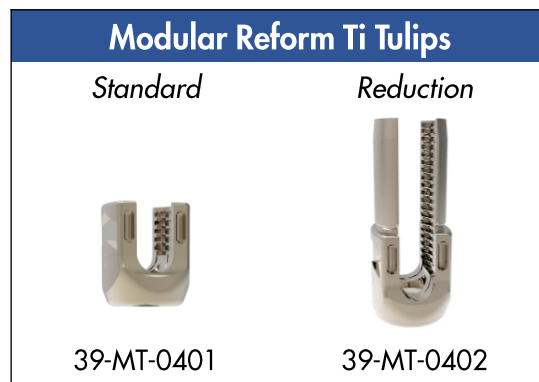


Figure 11

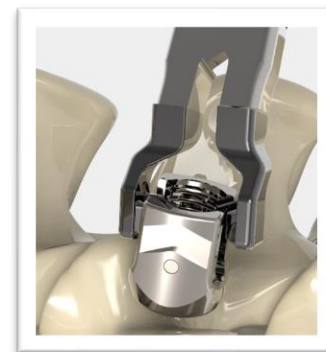


Figure 12

SURGICAL TECHNIQUE (continued)

7

SCREW ADJUSTMENT

Retention Bone Screw Drivers (59-SP-0601/59-MS-0061)

Use the Retention Bone Screw Driver to adjust the sagittal height of the screw prior to rod insertion or restoring range of motion of the tulip if screw has been inserted too deep.

- Securely attach the Retention Bone Screw Driver (59-SP-0601/59-MS-0061) to the Ratcheting Straight Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003).
- Confirm secure engagement to the Handle by gently pulling on the shaft of the Driver.
- Fully seat the Retention Bone Screw Driver into the screw prior to applying any force.

8

ROD INSERTION

Tulip Manipulator (39-SP-0800)

Use the Tulip Manipulator to align the rod slot of the tulips prior to rod insertion.

- Once all screws and hooks have been implanted, insert the desired Straight Rod or Lordotic Rod.

A Flexible Rod Template (39-RD-0010/39-RD-0011) may be used to measure the appropriate length rod.

- Use the appropriate pre-cut rod or cut a longer rod using a rod cutter (rod cutter not provided).
- Using the line on the rod as a guide, create the desired contour utilizing the French Rod Bender (39-RD-0001).

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

- Utilize the Rod Inserter Forceps (39-SP-0805) to facilitate insertion into the screw tulip (Figure 13).

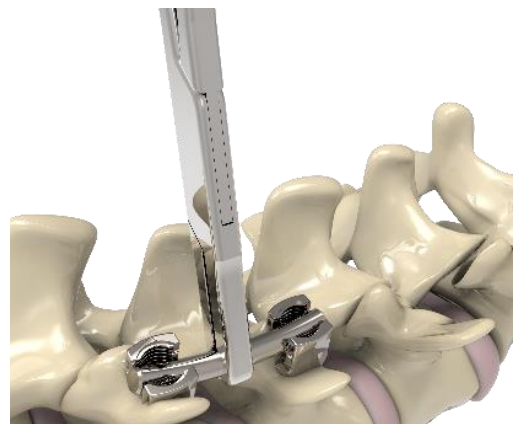


Figure 13

SURGICAL TECHNIQUE (continued)

9

ROD REDUCTION

Rod Pusher (39-SP-0815)

For constructs with two or more levels, begin with the central screw (Figure 14). Gently push the rod into the tulip and then insert lock screw to secure the rod. Rotate the lock screw clockwise until provisionally tightened.



Figure 14

Rod Rocker (39-RD-0201)

Slide the Rod Rocker into the lateral slots on tulip and lever the rod back until it is seated within the tulip (Figure 15). Insert lock screw to secure the rod. Rotate the lock screw clockwise until provisionally tightened.

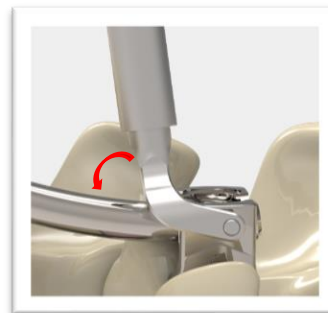


Figure 15

Note: Placing the Rod Rocker on the side where the rod is higher may be more effective at getting the rod seated evenly in the implant.

Tie Reduction Tower (39-RD-0310, 39-RD-0315, 39-RD-0320)

- Align the slots on the Tie Reduction Tower (39-RD-0310) with the rod slot on the tulip (Figures 16a) and engage the distal end of the Tie Reduction Tower to the lateral tulip slots (Figure 16b).
- Place the Tower Reducer (39-RD-0320) over the Tie Reduction Tower and turn the tower knob clockwise to reduce the rod into the tulip. The T-Handle Reducer (39-RD-0315) can be used if additional force is required (Figure 16c).
- Once the rod is fully seated, insert the Lock Screw (39-LS-0100) using the Lock Screw Retention Driver (39-SP-0602) to secure the rod. Rotate the lock screw clockwise until provisionally tightened.
- To release the Towers, gently squeeze the tabs on the Tie Reduction Tower to disengage from the tulip (Figure 16c).

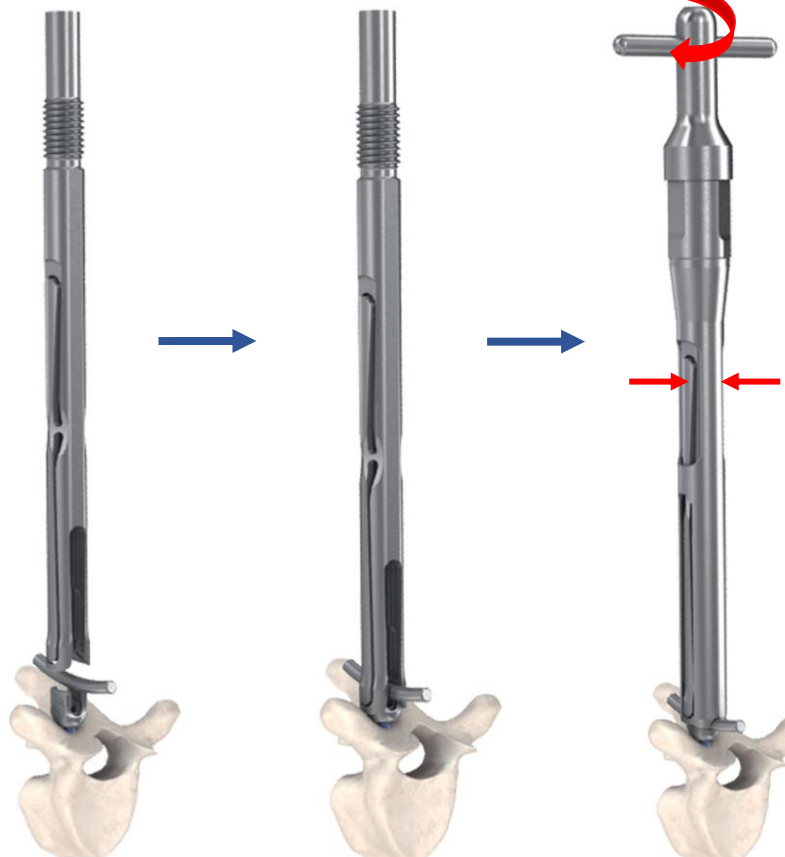


Figure 16a

Figure 16b

Figure 16c

Note: Applying excessive reduction force may result in screw pullout.

SURGICAL TECHNIQUE (continued)

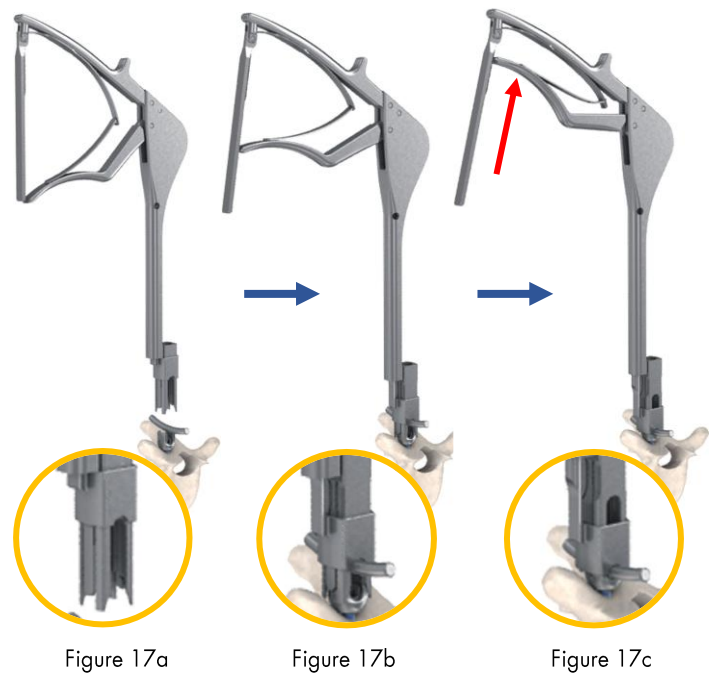
9

ROD REDUCTION (continued)

Reduction Gun (39-RD-0100)

- Align the slots on the Reduction Gun (39-RD-0100) with the rod slot on the tulip (Figures 17a) and engage the distal end of the Reduction Gun to the lateral tulip slots (Figures 17b).
- Squeeze the handle of the Reduction Gun to reduce the rod into the tulip (Figure 17c).
- Once the rod is fully seated, insert the Lock Screw (39-LS-0100) using the Lock Screw Retention Driver (39-SP-0602) to secure the rod. Rotate the lock screw clockwise until provisionally tightened.

Note: Applying excessive reduction force may result in screw pullout.



10

LOCK SCREW INSERTION

Once the rod is fully seated, insert the Lock Screw (39-LS-0100) using the Dual Sided Lock Screw Driver (39-SP-0603) or Lock Screw Retention Driver (39-SP-0602).

11

ROD MANIPULATION

In-Situ Rod Benders (39-RD-0020, 39-RD-0021)

Position the In-Situ Rod Benders on the rod and gently manipulate to create a bend in the sagittal plane and adjust rod lordosis.

Rod Gripper (39-RD-0810)

Attach Rod Gripper to rod and apply rotational force to adjust rod orientation.

Note: Applying excessive forces may result in screw pullout and/or pedicle fractures.

SURGICAL TECHNIQUE (continued)

12 COMPRESSION/ DISTRACTION

Provisionally tighten all lock screws and loosen the lock screw of the polyaxial screw to be adjusted. Compress or distractor across the screws and tighten the lock screw when desired compression or distraction has been achieved.

Note: Applying excessive force to screws may result in pedicle fracture.

13 FINAL TIGHTENING

- a. Securely attach Lock Screw Torque Driver (39-RD-0060) into the Offset Ratcheting Torque Handle (39-CH-0008).
- b. Confirm secure engagement to the Handle by gently pulling on the shaft of the Torque Driver.
- c. Place the Counter Torque Wrench (39-RD-0061) over the Reform Ti Screw Head and apply downward pressure to stabilize the tulip and rod.
- d. Rotate the Torque Handle clockwise until an audible click is heard at 106 in-lbs. (Figure 18).
- e. Repeat final tightening for all lock screws.

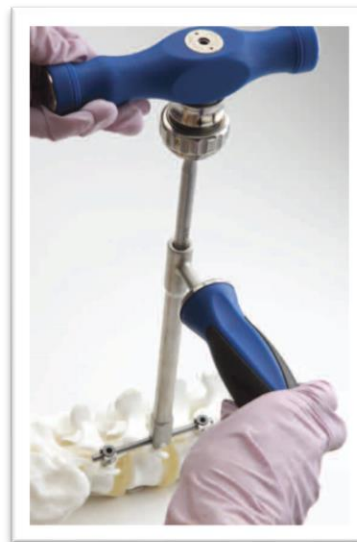


Figure 18

14 IMPLANT REMOVAL

- a. Attach the Lock Screw Torque Driver (39-RD-0060) 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) to back out the screws from the pedicles.

SURGICAL TECHNIQUE (continued)

15

CROSS CONNECTOR INSERTION

Cross Connectors can be added to increase the torsional stability of a construct. The Calipers (39-CC-0405) can be used to determine the proper length of the Cross-Connector (Figure 19).

Two T20 Cross Connector Retention Drivers (39-CC-0401) are provided to engage and retain the Cross Connector cams during placement.

- Loosen the midline screw to allow for multi-axial flexibility when seating the Cross Connector onto the constructs.
- Use the Retention Drivers to rotate both cams from "L" to "O" prior to positioning the Cross Connector on the rod.
- Once each hook portion of the Cross Connector is fully seated on the rod, seat the Retention Drivers into both Cross Connector cams and rotate 90° clockwise from "O" to "L" to fully engage the cams to the rod.
- Securely attach Cross Connector Torque Driver (39-CC-0407) into the Cross Connector Torque Handle (39-CH-0009).
- Confirm secure engagement to the Handle by gently pulling on the shaft of the Torque Driver.
- Place the Cross Connector Torque Driver securely into the midline nut of the Cross Connector and rotate the Cross Connector Torque Handle clockwise until an audible click is heard at 66 in-lbs. (Figure 20).

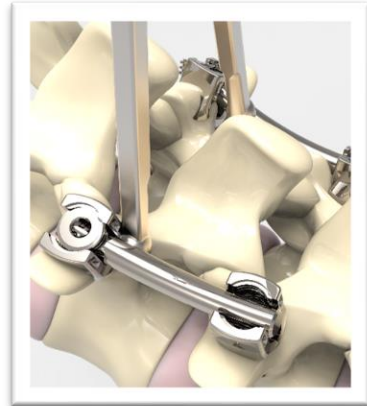


Figure 19



Figure 20

Cross Connector Removal

If removal of a Cross Connector is necessary, place the Cross Connector Torque Driver and Torque Handle assembly into the midline nut and turn the Torque Handle counter-clockwise to loosen.

Place the T20 Retention Driver into each Cam and turn 90° counterclockwise from "L" to "O" to loosen from the rods.

SURGICAL TECHNIQUE (continued)

16

DOMINO INSERTION

- a. Place the appropriate style Domino onto the rods utilizing the T20 Domino Retention Drivers (39-CC-0401) (Figure 21)
- b. Use the T20 Domino Retention Driver for preliminary tightening of the pre-assembled Domino Set Screws (39-LS-0200).
- c. Securely attach Domino Torque Driver (39-CC-0407) into the Domino Torque Handle (39-CH-0009).
- d. Confirm secure engagement to the Handle by gently pulling on the shaft of the Torque Driver.
- e. Once the desired position of the Domino on the rods has been achieved, place the Domino Torque Driver securely into the Domino set screw and rotate the Domino Torque Handle clockwise until an audible click is heard at 66 in-lbs.
- f. Optional: The T20 Domino Inserter (39-RD-0570) may be used as a counter torque to stabilize the construct during final tightening (Figure 22).
- g. Repeat final tightening for all Domino set screws.



Figure 21



Figure 22

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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