

PRECISION SPINE
REFORM[®]
PEDICLE SCREW SYSTEM

Surgical Technique

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REFORM® PEDICLE SCREW SYSTEM OVERVIEW

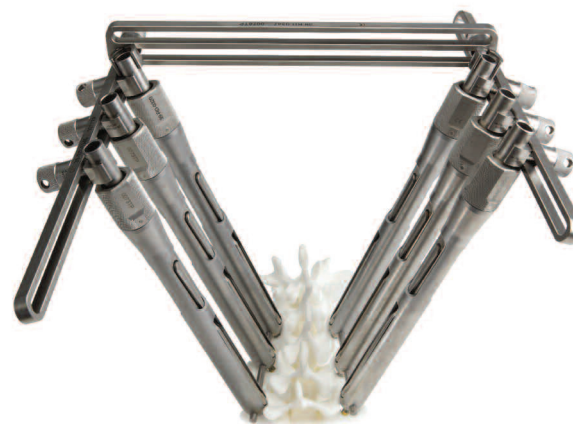
The Reform Pedicle Screw System is a top-loading, multiple component, posterior spinal fixation system with the versatility to accommodate complex spinal procedures. The system consists of pedicle screws, rods, cross-connectors, hooks, dominoes, lateral offsets and locking cap screws allowing adjustments to any construct. 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".

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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: 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. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion.

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



Reform Implants

Screws are available in Polyaxial, Uniplanar, Reduction and Modular offerings

Reform Polyaxial Screws Standard

4.5mm	25-45mm (5mm)
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-60mm (5mm), 70 & 80mm
9.5mm	60, 70 & 80mm
10.5mm*	

Reform Uniplanar Screws

4.5mm	25-45mm (5mm)
5.5mm	25-50mm (5mm)
6.5mm	30-50mm (5mm)
7.5mm	35-50mm (5mm)

Reform Reduction Screws

4.5mm*	
5.5mm	30-50mm (5mm)
6.5mm	30-50mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-55mm (5mm)
9.5mm*	
10.5mm*	

Reform Reduction Uniplanar Screws

5.5mm	25-50mm (5mm)
6.5mm	30-45mm (5mm)

Modular Tulips

Standard Tulip
Reduction Tulip

Modular Screws

4.5mm	25-45mm (5mm)
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-60mm (5mm), 70 & 80mm
9.5mm	60, 70 & 80mm

*Special Order

Additional sizes available by special order, see pages 31-33.



Rods

Straight Hex Ended Rods

- Available in lengths from 80mm, 100mm, 120mm, 150mm, 200mm, 300mm, 400mm, 500mm and 600mm

Lordotic Rods

- Available in lengths from 35mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 90mm, 100mm, 110mm and 120mm

**Straight & Lordotic Titanium and Cobalt Chrome
Rods in 5.5mm diameter offerings**

Cap

Locking Cap

- Universal for Polyaxial, Uniplanar and all Reduction Screws. The Hexalobular Screw Driver is a T-25 driver
- (P/N: 39LS-0100)



DEFORMITY ADD-ON SYSTEM IMPLANTS

Hooks

Various Hook options available to accommodate spine anatomy

Pedicle

- Small - Part Number: 39-TH-0101
- Medium - Part Number: 39-TH-0102
- Large - Part Number: 39-TH-0103

Straight Laminar

- Small - Narrow - Part Number: 39-TH-0201
- Small - Wide - Part Number: 39-TH-0202
- Medium - Narrow - Part Number: 39-TH-0203
- Medium - Wide - Part Number: 39-TH-0204
- Large - Narrow - Part Number: 39-TH-0205
- Large - Wide - Part Number: 39-TH-0206

Ext.-Body Laminar (+4mm)

- Medium - Part Number: 39-TH-0212
- Large - Part Number: 39-TH-0213

Ramped Laminar

- Small - Part Number: 39-TH-0221
- Medium - Part Number: 39-TH-0222

Down Angled Laminar

- Medium - Part Number: 39-TH-0232
- Large - Part Number: 39-TH-0233

Offset Angled Laminar

- Medium - Right - Part Number: 39-TH-0301
- Medium - Left - Part Number: 39-TH-0302

Angled Hook

- Medium - Right - Part Number: 39-TH-0401
- Medium - Left - Part Number: 39-TH-0402



Pedicle Hook



Wide



Narrow

Straight Laminar Hook



Ext.-Body Laminar (+4mm) Hook



Ramped Laminar Hook



Down Angled Laminar Hook



Left



Right

Offset Angled Laminar Hook



Angled Hook - Right

Reduction Hooks

Straight Laminar

- Medium - Part Number: 39-TH-0242

Ext.-Body Laminar (+4mm)

- Medium - Part Number: 39-TH-0252

Ramped Laminar

- Medium - Part Number: 39-TH-0262

Down Angled Laminar

- Medium - Part Number: 39-TH-0272

Offset Angled Laminar

- Medium - Right - Part Number: 39-TH-0351
- Medium - Left - Part Number: 39-TH-0352

Angled Hook

- Medium - Right - Part Number: 39-TH-0451
- Medium - Left - Part Number: 39-TH-0452

Lateral Offsets

Closed

- 20mm - Part Number: 39-LO-0120
- 30mm - Part Number: 39-LO-0130
- 40mm - Part Number: 39-LO-0140
- 50mm - Part Number: 39-LO-0150

Top-Loading

- 20mm - Part Number: 39-LO-0220
- 30mm - Part Number: 39-LO-0230
- 40mm - Part Number: 39-LO-0240
- 50mm - Part Number: 39-LO-0250



Straight Laminar Reduction Hook



Ext.-Body Laminar (+4mm) Reduction



Ramped Laminar Reduction Hook



Down Angled Laminar Reduction Hook



Offset Angled Laminar Reduction Hook - Right



Angled Reduction Hook - Right



Top Loading



Closed

Dominoes

Axial

- Closed-Closed - Part Number: 39-AA-0101

Parallel Domino

- Closed-Closed, Wide - Part Number: 39-DA-0101
- Closed-Closed, Narrow - Part Number: 39-DA-0102
- Closed-Open, Wide - Part Number: 39-DA-0201
- Closed-Open, Narrow - Part Number: 39-DA-0202
- Open-Open, Wide - Part Number: 39-DA-0301
- Open-Open, Narrow - Part Number: 39-DA-0302

Domino Set Screw

- Part Number: 39-LS-0200



Axial Domino Closed-Closed



Parallel Domino
Closed-Closed,



Parallel Domino
Closed-Closed,



Parallel Domino
Closed-Open,



Parallel Domino
Closed-Open,



Parallel Domino
Open-Open,



Parallel Domino
Open-Open,

Cross-Connectors

- Adjustable length and angulation make it possible to attach the Cross-Connector to constructs in a wide range of spinal anatomies
- 30mm (30-32mm) - Part Number: 39-CC-0030*
- 32mm (32-35mm) - Part Number: 39-CC-0032*
- 35mm (35-40mm) - Part Number: 39-CC-0035
- 40mm (40-48mm) - Part Number: 39-CC-0040
- 48mm (48-66mm) - Part Number: 39-CC-0048
- 66mm (66-85mm) - Part Number: 39-CC-0066

* Not Pictured



66mm



48mm



40mm



35mm

Reform Instrument Sets

Instrument Kit 1

- Part Number: 39-BK-0201

Instrument Kit 2

- Part Number: 39-BK-0202

Ratcheting T-Handle, 1/4" SQ

- T-Handle for Reamers, Drills, and Drivers
- Part Number: 39-CH-0003

Ratcheting In-line Handle, 1/4" SQ

- In-line Handle for Reamers, Drills, and Drivers
- Part Number: 39-CH-0004

Bone Awl

- Used to create a starter hole
- Part Number: 39-SP-0001

Curved Pedicle Probe

- Used to create access channels for pedicle screws prior to insertion of screws
- Part Number: 39-SP-0003

Duckbill Pedicle Probe

- Used to create access channels for pedicle screws prior to insertion of screws
- Part Number: 39-SP-0005

Straight Pedicle Probe

- Used to create access channels for pedicle screws prior to insertion of screws
- Part Number: 39-SP-0007



Ball-Tip Sounder

- Used to probe the wall prior to screw insertion
- Part Number: 39-SP-0011

Pedicle Screw Tap

- Designed to secure the thread pattern pathway for inserting the Pedicle Screw (Ø1/2mm undersized from screw)
- Available in diameters from 4.5 - 9.5mm, in 1mm increments
- Ø4.5mm - Part Number: 39-SP-0545
- Ø5.5mm - Part Number: 39-SP-0555
- Ø6.5mm - Part Number: 39-SP-0565
- Ø7.5mm - Part Number: 39-SP-0575
- Ø8.5mm - Part Number: 39-SP-0585
- Ø9.5mm - Part Number: 39-SP-0595

Retention Bone-Screw Driver

- Securely retains the Bone Screw for Insertion
- Part Number: 39-SP-0601

Polyaxial Driver

- Securely retains the Bone Screw for Insertion
- Part Number: 39-SP-0700

Tulip Manipulator

- Manipulates the head of the Screw in the proper alignment
- Part Number: 39-SP-0800

Lateral Tulip Holder

- Holds the head of the screw in the proper position
- Part Number: 39-SP-0825



French Rod Bender - Ø5.50mm

- Allows for bending and contouring the Rod
- Part Number: 39-RD-0001

Flexible Rod Template

- Malleable Rod to size and template the Rod
- Available in 200mm (Part Number: 39-RD-0010) and 400mm (Part Number: 39-RD-0011)

Rod Holding Forceps - Ø5.50mm

- Holds the Rod to facilitate implantation
- Part Number: 39-SP-0805

Rod Pusher - Ø5.50mm

- Persuades the Rod into the head of the Screw
- Part Number: 39-SP-0815

Rod Rocker

- Persuades the Rod into the head of the Screw
- Part Number: 39-RD-0201

Tie Reduction Tower

- The most effective device to reduce the Rod into the Screw head
- Part Number: 39-RD-0310



INSTRUMENTS

Tie Tower Reducer

- Inner assembly for the Tower Reducer
- Outer housing to thread over the Tower Reducer
- Part Number: 39-RD-0320

T-Handle Reducer

- Used to apply additional leverage to the reduction tower
- Part Number: 39-RD-0315

Locking Cap Retention Driver

- Used to advance the Lock Screw into the Tulip Head
- Part Number: 39-SP-0602

Dual-Side Lock-Screw Driver

- Double-ended Tool used to advance the Lock Screw into the Tulip Head
- Part Number: 39-SP-0603

Parallel Compressor

- Device used to compress two bone screws closer together on the Rod
- Part Number: 39-RD-0041

Parallel Distractor

- Used to distract two bone screws farther apart on the Rod
- Part Number: 39-RD-0042



Rod Gripper - Ø5.50mm

- Designed to apply additional grip to the Rod during manipulation
- Part Number: 39-SP-0810

In-Situ Rod Bender - Ø5.50mm

- Allows for coronal adjustments to the Rod
- Left (Part Number: 39-RD-0020)
- Right (Part Number: 39-RD-0021)

Counter Torque Wrench

- Delivers appropriate torque with additional leverage for pedicle screws and lateral offsets with an offset ratcheting mechanism
- Part Number: 39-RD-0061

Offset Ratcheting Torque Handle

- Delivers appropriate torque with additional leverage for pedicle screws and lateral offsets with an offset ratcheting mechanism
- Part Number: 39-CH-0008

Locking Cap Torque Driver

- Attaches to the Lock-Screw for final tightening
- Part Number: 39-RD-0060

Extended Tab Removal Tool

- Removes the Extended Tab on Reduction Screws after reduction
- Part Number: 39-RD-0070



INSTRUMENTS

Torque Limiting Handle

- Delivers appropriate torque to Cross-Connectors and Dominoes
- Part Number: 39-CH-0009



Torque Limiting T20 Driver

- Attaches to the Lock-Screw for final tightening of Cross-Connectors and Dominoes
- Part Number: 39-CC-0407



Self-Retaining T20 Driver

- Attaches the Lock-Screw for definitive tightening of the Locking Cap to the construct
- Part Number: 39-CC-0401



Rotary Calipers

- Measures the distance between two points
- Part Number: 39-CC-0405



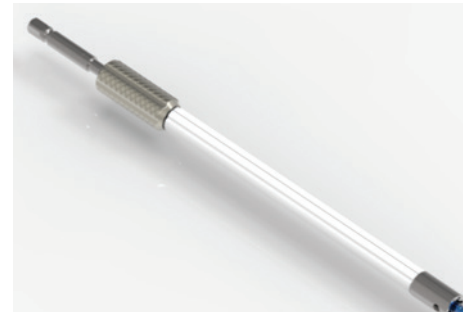
Rod Reducer

- Used to adjust rod
- Part Number: 39-RD-0100



Modular Screw Driver

- Securely holds the Modular Bone Screw for insertion
- Part Number: 39-MD-0700



Planar

- Decorticates the bone surrounding the Modular Bone Screw
- Part Number: 39-MD-0100



Angeled Lateral Tulip Clamp

- Used to attach the Modular Tulip to the Modular Bone Screw
- Part Number: 39-MD-0825



Deformity Add-on System Instrument Set

Instrument Kit

- Part Number: 39-BK-0203

Pedicle Elevator

- Part Number: 39-RD-0500

Laminar Elevators

- Small - Part Number: 39-RD-0502
- Medium - Part Number: 39-RD-0503

Hook Pusher

- Part Number: 39-RD-0560

Tie Reduction Tower

- The most effective device to reduce the Rod into the Screw head
- Part Number: 39-RD-0310

Tower Connector

- Part Number: 39-RD-0344

Tower Thumbscrew

- Part Number: 39-RD-0345

Tie Tower Reducer

- Inner assembly for the Tower Reducer
- Outer housing to thread over the Tower Reducer
- Part Number: 39-RD-0320

Tower Bridge

- Single - Part Number: 39-RD-0346
- Double - Part Number: 39-RD-0347



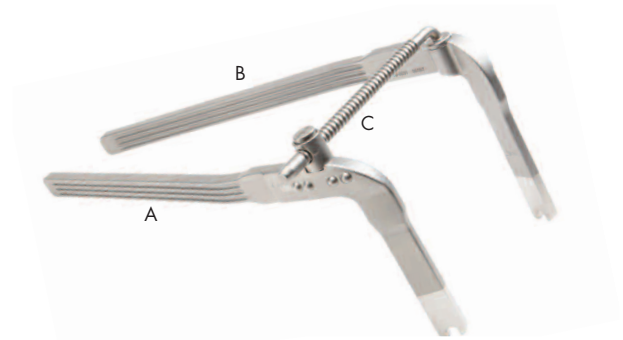
Tower Bridge Hex Wrench

- Part Number - 39-RD-0348



Coronal Rod Bender Assembly

- A Part Number - 39-RD-0030
- B Part Number - 39-RD-0031
- C Part Number - 39-RD-0032



Flexible Rod Template

- Available in 500mm
- Part Number - 39-RD-0012



Rod Gripper

- Designed to apply additional grip to the Rod during manipulation
- Part Number - 39-SP-0810



Domino Inserter

- Part Number - 39-RD-0570



Superior Hook Holder

- Part Number - 39-RD-0550



Counter Torque Wrench*

- Applies appropriate stabilization of the bone Screw and Rod interface
- Part Number - 39-RD-0061



Locking Cap Torque Driver*

- Part Number - 39-RD-0060



Offset Ratcheting Torque Handle*

- Applies appropriate stabilization of the bone Screw and Rod interface with an offset ratcheting mechanism
- Part Number - 39-CH-0008



Self-retaining T20 Driver*

- Part Number - 39-CC-0401



Torque-Limiting T20 Driver*

- Part Number - 39-CC-0407



Torque-Limiting Handle*

- Part Number - 39-CH-0009



* Located in Instrument Kit 1

Cross-Connector Instruments

Rotary Calipers

- Part Number: 39-CC-0405

Self-Retaining T20 Driver

- Utilized to place and definitively tighten Locking Cams
- Part Number: 39-CC-0401

Torque-Limiting T20 Driver

- Used for definitive tightening of the Locking Cap to the construct
- Part Number: 39-CC-0407

Torque-Limiting Handle

- Black, balanced T-Handle
- Part Number: 39-CH-0009

Special Request Instrumentation Available

Rod Gripper Vise Grip 5.5mm

- Part Number - 39-RD-0600

Rod Gripper Dual Action 5.5mm

- Part Number - 39-RD-0601



1. Preoperative Planning

The Surgeon should consider for surgery only those patients indicated for the use of the Reform® 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. The Surgeon should have 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 the entry point and trajectory should be re-evaluated. Laser etching on the Probe will indicate the depth of the Probe within the canal (30mm, 40mm, 50mm, 60mm, and 70mm depths).
- c. The prepared pathway can be explored with the Ball Tip Sounder (39-SP-0011) to confirm that integrity of the pedicle wall has not been violated (Figure 3).
- d. If tapping is preferred, the appropriate Tap may be used to prepare the pedicle for Screw insertion (Figure 4). The Tap sizes are undersized and correspond to the diameter of the Screw and are laser etched (40mm, 45mm, 50mm, 55mm, and 60mm). Taps can be utilized with the Ratcheting In-line Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003).
- e. Repeat the preparation procedure for each pedicle that has been identified for instrumentation.



Figure 1

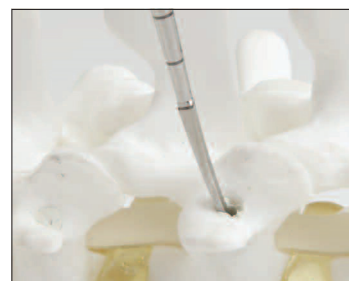


Figure 2

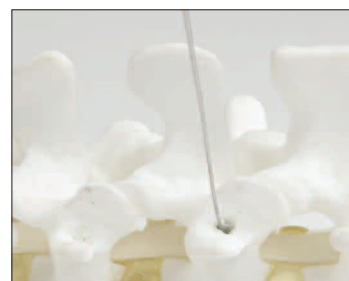


Figure 3

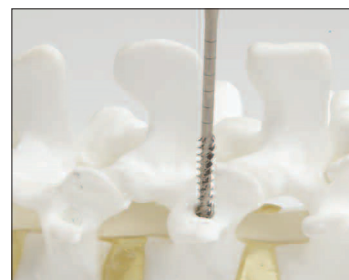


Figure 4

3. Polyaxial Screw Insertion

- a. With the pedicle pathway prepared and appropriate Screw length and diameter determined, the Polyaxial Screw is loaded for insertion on the preferred Screw Driver Assembly.
- b. The Polyaxial Driver (39-SP-0700) is attached to either the Ratcheting Inline Handle, (39-CH-0004) or Ratcheting T-Handle (39-CH-0003) (not shown).
 - i. Depress the silver collar on the Inline Handle or T-Handle and insert the Polyaxial Driver male end into the female end of the Handle. Confirm that the Driver is fully seated in the appropriate Handle and will not disengage.
- c. The Polyaxial Screw is now attached to the preferred Screw Driver Assembly.
 - i. Load the appropriate Screw chosen for length and diameter onto the hexalobe tip portion of the Polyaxial Driver. The Polyaxial Screw should be fully seated on the Driver assembly before the Screw Head Locking Sleeve of the Driver is engaged (Figure 5).
 - ii. With the Screw held firmly seated on the Driver, thread the Screw Head Locking Sleeve clockwise until fully engaged and flush with the convex portion of the Driver (Figure 6).
- d. The Polyaxial Screw is now inserted into the pedicle (Figures 7, 7a and 7b).
- e. Disengage the Polyaxial Driver by turning the shaft counterclockwise.
- f. Repeat the procedure for Polyaxial Screw insertion in each pedicle identified for instrumentation.

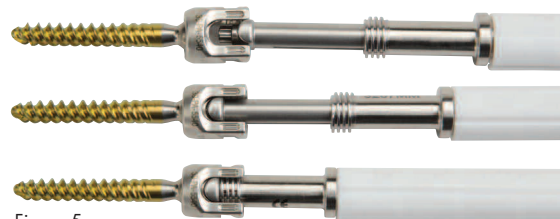


Figure 5



Figure 6



Figure 7



Figure 7a



Figure 7b

4. Modular Screw Insertion

- a. With the pedicle pathway prepared and Screw length and diameter determined, the appropriate Screw is loaded for insertion on the Screw Driver Assembly.
- b. The Modular Screw Driver (39-MD-0700) is attached to either the Ratcheting Inline Handle, (39-CH-0004) or Ratcheting T-Handle (39-CH-0003).
 - i. Depress the silver collate on the Inline Handle or T-Handle and insert the Modular Screw Driver male end into the female end of the Handle (Figure 7c). Confirm that the Driver is fully seated in the appropriate Handle and will not disengage.
- c. The Modular Screw is now attached to the Screw Driver Assembly.
 - i. Load the appropriate Modular Screw chosen for length and diameter by placing the head of the Screw into the collet of the Screw Driver's distal tip. Turn the knob clockwise until the sleeve completely surrounds the collet (Figure 7d).
- d. The Modular Screw is now inserted into the pedicle (Figures 7e).
- e. Disengage the Driver by turning the Screw Driver Knob counterclockwise.
- f. Repeat the procedure for Modular Screw insertion in each pedicle identified for instrumentation.



Figure 7c



Figure 7d



Figure 7e

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 7f).

6. Modular Tulip Attachment

Attach the appropriate Modular Tulip using either the Lateral Tulip Clamp (39-SP-0825) or the Angled Lateral Tulip Clamp (39-MD-0825) by aligning the Tulip Clamp with the tabs of the Modular Tulip. Slide the Tulip over the Bone Screw and apply an axial force until an audible click is heard (Figure 7g). Upward pressure of the attached Lateral Tulip Clamp can be applied to ensure that the Tulip is properly inserted.



Figure 7f

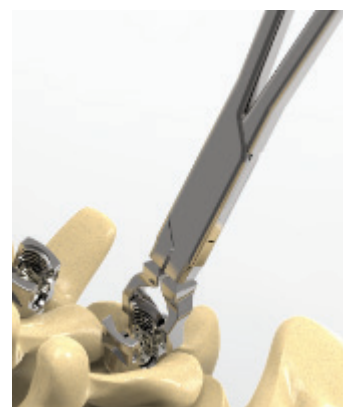


Figure 7g

7. Hook Surgical Procedure

There are four possible Hook placement sites in the spine: pedicle, transverse process, supra-lamina and infra-lamina.

The surgeon must choose the appropriate Hook based on the individual patient's anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants.

The first site is the pedicle. Pedicle Hooks (39-TH-010X) are placed in the thoracic spine via the facet joint (Figure 8). The direction for the Pedicle Hooks is always cephalad.

The facet of the appropriate level is identified and the capsule is removed. The cartilage on the inferior articular process of the next distal level should be visualized.

The facet is entered with the Pedicle Elevator (39-RD-0500).

The Pedicle Hook is inserted with the Superior Hook Holder (39-RD-0550) (Figure 9) and seated flush against the facet and the pedicle.

The second site is the transverse process. The Angled Hook (39-TH-040X) is recommended for this site.

An Elevator is used to dissect around the superior surface of the transverse process and then the Angled Hook is placed in the required position (Figure 10).



Figure 8



Figure 9



Figure 10

7. Hook Surgical Procedure (Continued)

The third possible site is the superior lamina. The Down Angled Laminar (39-TH-023X), Straight Laminar (39-TH-020X), Straight Laminar Ext. Body (+4mm) (39-TH-021X), Ramped Laminar (39-TH-022X) or Offset Angled Laminar (39-TH-030X) are recommended for this site. The direction is always caudal. These Hooks may be combined with other Hooks to produce a claw construct.

The ligamentum flavum is divided in the midline and excised. The amount of bone removed from the lamina may vary depending on the size of the Hook blade and throat angle chosen.

The inferior edge of the next proximal lamina is removed to permit the intracanal placement of the Hook.

The appropriate Lamina Hook is then placed by using the Hook Pusher (39-RD-0560) until well seated against the lamina.

The fourth possible site is the inferior lamina. The Down Angled Laminar, Straight Laminar, Ext.-Body Laminar (+4mm), Ramped Laminar or Offset Angled Laminar are recommended for this site in the lumbar spine. The direction is always cephalad.

Similar to the Supra-Lamina step, the ligamentum flavum is divided in the midline and excised.

The inferior edge of the selected lamina is removed to permit intra-canal placement of the Hook.

The appropriate Hook is then placed using the Hook Pusher until well seated against the lamina.



Pedicule Hook



Wide



Narrow



Ext.-Body Laminar
(+4mm) Hook



Ramped Laminar
Hook



Down Angled
Laminar Hook



Angled Hook - Right



Offset Angled
Laminar Hook

Left



Right



Straight Laminar
Reduction Hook



Ext.-Body Laminar
(+4mm) Reduction Hook



Ramped Laminar
Reduction Hook



Down Angled Laminar
Reduction Hook



Offset Angled Laminar
Reduction Hook - Right



Angled Reduction
Hook - Right

8. Reduction Hook Surgical Procedure

The Reform® Reduction Hooks are designed to further complement the innovative design of the existing Reform Hook range. These Hooks help to address, correct and also stabilize difficult anatomic variations. The Reduction Hooks are designed with removable tabs that allow the surgeon to approximate the spine to the desired sagittal or axial profile. They are provided in 6 styles similar to the standard Reform Hooks: Straight Laminar (39-TH-0242), Straight Laminar Ext. Body (+4mm) (39-TH-0252), Ramped Laminar (39-TH-0262), Down Angled Laminar (39-TH-0272), Offset Angled Laminar (39-TH-0351; 39-TH-0352) and Angled Laminar (39-TH-0451; 39-TH-0452).

Reduction Hooks are most commonly placed at the apex of the concavity. Contour the Rod to match the required spinal contours in the sagittal plane (Figure 11).

Utilize each Reduction Hook in the same way as the standard Reform Hooks. Place the contoured Rod into the spine anchors and fully seat. The extended tabs of the Reduction Hooks provide a means of capturing a Rod that may have crossed the midline and would otherwise be out of reach of the anchor (Figure 12).

Once the correction procedures have been carried out and the spine is in a satisfactory position, the definitive tightening of the Locking Cap (39-LS-0100) can be completed with the Offset Ratcheting Torque Handle (39-CH-0008), Counter-Torque Wrench (39-RD-0061), and Locking Cap Torque Driver (39-RD-0060). The extended tabs of the Reduction Hook can then be removed by using the Extended Tab Removal Tool (39-RD-0070) (Figure 13).



Figure 11



Figure 12

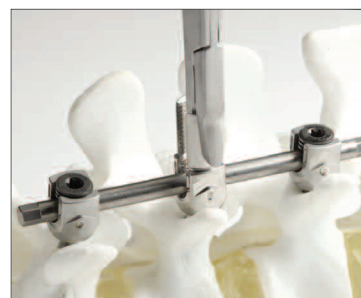


Figure 13

9. Rod Insertion

- a. Once all Screws and Hooks have been inserted, the appropriate Straight Rod or Curved Rod may be applied. A Flexible Rod Template (39-RD-0012) or Rotary Caliper (39-CC-0405) may be used to measure the appropriate length Rod. (Figure 14)
 - b. Use the appropriate pre-cut Rod or cut a longer Rod using a rod cutter (rod cutter not provided).
 - c. The Polyaxial Screw design will allow for some lateral Screw offset.
 - d. The Rod can be contoured if desired utilizing the French Rod Bender (39-RD-0001).
- Note: Repeated bending can weaken the Rod.
- e. Once the appropriate Rod has been selected, use the Rod Holding Forceps (39-SP-0805) to facilitate insertion into the Screw Head Tulip (Figure 15).
 - f. A Tulip Manipulator (39-SP-0800) may be used to align the Polyaxial Screws Head.

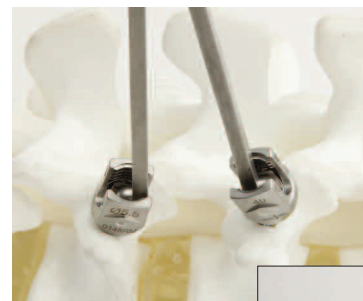


Figure 14



Figure 15

10. Rod Reduction

The Rod must be seated in the Reform® Screw head in order to engage the Locking Cap (39-LS-0100) for tightening. There are three alternative instruments used for this process.

Option 1

The Rod Pusher (39-SP-0815) can be used to seat the Rod. For constructs with two or more levels, begin with the central Screw. (Figure 16) Proceed to Step 11, Locking Cap Insertion.

Option 2

The Rod Rocker (39-RD-0201) can be utilized to seat the Rod within the Screw head (Figure 17). The Rod Rocker easily slides into the lateral slots on the side of the Screw head and is rotated backwards. This levers the Rod into the head of the implant. **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** (Figure 18). Proceed to Step 11, Locking Cap Insertion.

Option 3

The Tie Reduction Tower (39-RD-0310) is used when additional force is needed to seat the Rod into the Screw head. Engage the Tie Reduction Tower on the Screw head with the slots on the Tie Reduction Tower aligned with the rod slot on the Screw head (Figure 19). Place the Tower Reducer (39-RD-0320) over the Tie Reduction Tower and turn the capture sleeve clockwise to reduce the Rod into the Screw head. The T-Handle Reducer (39-RD-0315) can be used if additional force is required (Figure 20). Once the Rod is fully seated, the Locking Cap (39-LS-0100) can be seated using the Locking Cap Retention Driver (39-SP-0602) (Figure 21). Proceed to vertebral Body Derotation Procedure for advanced techniques.

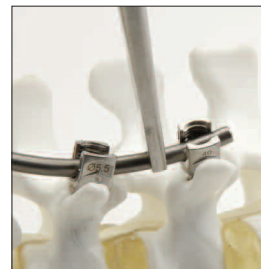


Figure 16



Figure 17

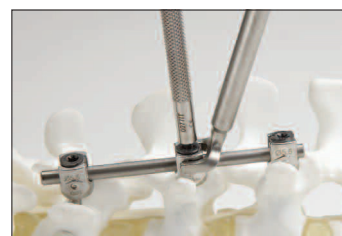


Figure 18

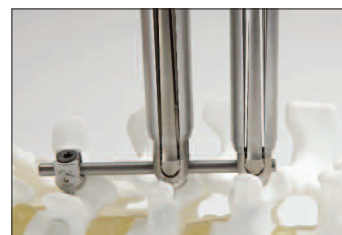


Figure 19



Figure 20



Figure 21

11. Locking Cap Insertion

For Options 1 & 2 – Once the Rod is fully seated, the Locking Cap (39-LS-0100) can be inserted into the Screw head with the Dual Sided Locking Cap Driver (39-SP-0603).

12. Final Tightening

Once the correction procedures have been carried out and the spine is in a satisfactory position, the final tightening of the Locking Cap can be commenced. Load the square end of the Locking Cap Torque Driver (39-RD-0060) into the Torque Wrench Handle. Place the Counter Torque Wrench (39-RD-0061) over the Reform Screw Head and apply downward pressure to stabilize the Screw Head and Rod. Turn the Torque Wrench Handle clockwise 90 degree and an audible click is heard (Figure 22).

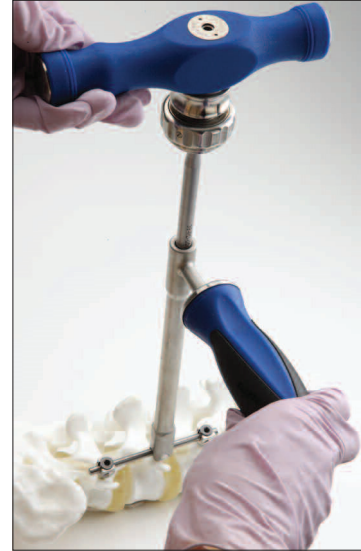


Figure 22

ADDITIONAL TECHNIQUES

1. Domino Surgical Procedure

Seven Domino Rod-to-Rod Connectors are offered in the Reform System (Figure 1). Two styles are available in the Closed-Closed Dominoes: a Wide style (39-DA-0101) and a Narrow style (39-DA-0102). Two styles are available in the Closed-Open Dominoes: a Wide style (39-DA-0201) and a Narrow style (39-DA-0202). Two styles are available in the Open-Open Dominoes: a Wide style (39-DA-0301) and a Narrow style (39-DA-0302). There is also an inline, axial connector in a Closed-Closed style (39-AA-0101).

The narrow style accommodates parallel Rods that are 8.5mm apart, the wide style accommodates parallel rods that are 11mm apart.

Place the appropriate style Domino onto the Longitudinal Rods utilizing the Domino Inserter (39-RD-0570) or the Self-retaining T20 Driver (39-CC-0401). The Self-retaining T20 Driver should be used for preliminary tightening of the preassembled Domino Set Screws (39-LS-0200). Once the desired position of the Domino on the Longitudinal Rods has been achieved, the Torque-Limiting T20 Driver (39-CC-0407) and the Torque-Limiting Handle (39-CH-0009) should be used for final tightening of the Set Screw to 66 in-lbs. The Domino Inserter (39-RD-0570) can be used as a counter-torque device to stabilize the construct during final tightening (Figure 2 and 2a).



Axial Domino Closed-Closed



Parallel Domino Closed-Closed,



Parallel Domino Closed-Closed,



Parallel Domino Closed-Open,



Parallel Domino Closed-Open, Narrow



Parallel Domino Open-Open,



Parallel Domino Open-Open,

Figure 1



Figure 2



Figure 2a

2. Lateral Offset Procedure

Eight Lateral Offset designs are offered in the Reform Application. Two styles are available in the Lateral Offsets: a Top Loading Offset connection (39-LO-02XX) and a Closed-Head connection (39-LO-01XX). Both styles come in lengths of 20, 30, 40, and 50mm.

All Lateral Offset Connectors will be perpendicular to the Rod when attached (Figure 3).

Preload the Lateral Offset onto the Longitudinal Rod. The post of the Lateral offset may be cut and contoured as deemed necessary. A Lateral Offset may also be used at points along the construct to connect to a screw that may be Lateral and out of line with the pedicle screw above and below this point.

When tightening the locking screws, first secure the locking screws along the Longitudinal Rod. Then secure each locking screw where it mates with the post of the Lateral Offset within the Lateral Screw. Finally, tighten each locking screw at the Lateral Offset/Longitudinal Rod interface using the Offset Ratcheting Torque Handle and Torque Driver (39-CH-008 & 39-RD-0060), and Counter Torque Wrench (39-RD-0061) (Figure 4). The locking torque for the Lateral Offset locking screw is 106in-lbs.

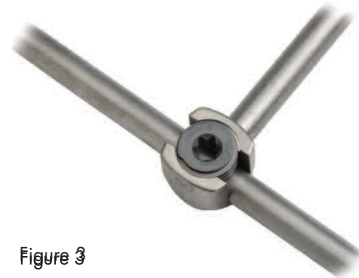


Figure 3



Figure 4

ADDITIONAL TECHNIQUES

3. Cross-Connector Surgical Procedure

Cross-Connectors can be added to increase the torsional stability of a construct. Long constructs may require Cross-Connectors to be placed at proximal and distal ends of the construct to increase rigidity. The Rotary Calipers can be used to determine the proper length of the Cross-Connector (Figure 5).

Two Self-Retaining T20 Drivers (39-CC-0401) are provided to engage and retain the Cross-Connector cams during placement (Figure 6). The midline screw should be loosened to allow for multi-axial flexibility when seating the Cross-Connector onto the constructs.

Once each hook portion of the Cross-Connector is fully seated on the Rod, the Self-Retaining T20 Drivers may each be rotated 90° clockwise to fully engage the Cross-Connector cam to the Rod.

Next, the midline nut is definitively tightened using the Torque-Limiting T20 Driver (39-CC-0407). An audible click from the Torque-Limiting T20 Driver will confirm that the midline nut is adequately tightened (Figure 7).

Cross-Connector Surgical Removal

If removal of a Cross-Connector is necessary, place the Torque-Limiting Screwdriver over the midline nut and turn counter-clockwise to loosen.

Place the Self-Retaining T20 Driver into each Cam and turn 90° counter-clockwise to loosen from the Rods.



Figure 5



Figure 6



Figure 7

ADVANCED TECHNIQUES

Vertebral Body Derotation Procedure

Reduction maneuvers can be performed to manipulate and stabilize deformities of the thoracolumbar spine through the use of segmental anchors and specialized instrumentation. Multiple anchors provide increased rigidity while allowing for safe and consistent correction.

Reduction can be achieved by bringing the spine to meet the Rod (as in the case of translation maneuvers) or by simply pushing the Rod to meet the spine to capture the Rod for fixation (cantilever maneuver). With flexible deformities, locking the proximal and distal ends of the construct (neutral levels) and segmentally reducing can result in translation of the spine. Anterior releases or osteotomies may be for correction of more rigid curves.

Multiple Level Spinal Derotation

In order to complete a multiple level derotation technique, the Tie Reduction Towers (39-RD-0310) are connected to apical screw heads on both concave and convex sides once the concave Rod is in place. If applicable the Tie Tower Reducers (39-RD-0320) may be attached to the Tie Reduction Towers to facilitate Rod reduction. The Tower Connector (39-RD-0344) can be attached to the proximal portion of the Tie Reduction Towers. The Tower Connectors can be aligned to the Tower Bridge, Single (39-RD-0346) or Tower Bridge, Double (39-RD-0347) to aid with rotation. The Tower Connectors are secured to the Tower Bridges via the Tower Thumbscrews (39-RD-0345) (Figure 1). At this point, the derotation maneuver can be performed to bring the spine into alignment (Figures 2 & 3). After reduction is completed, proceed to locking cap insertion.



Figure 1



Figure 2



Figure 3

ADVANCED TECHNIQUE (OPTIONAL)

Vertebral Body Derotation Procedure (Continued)

Individual level Spinal Derotation

Individual level spinal derotation can be done as the sole derotation maneuver or in addition to the multiple level maneuver described on the previous page. Implant both Rods and capture them with the Locking Caps. Most Locking Caps should be left loose since lengthening of the spine is expected at each level that will be segmentally derotated. Only the Set Screws in the distal neutral vertebra should be tightened. The Tie Reduction Towers are connected to the affected proximal vertebrae. If applicable, the Tie Tower Reducers (39-RD-0320) may be attached to the Tie Reduction Towers to facilitate rod reduction. The Tower Connector (39-RD-0344) can be attached to the proximal portion of the Tie Reduction Towers. The Tower Connectors can be aligned to the Tower Bridge, Single (39-RD-0346) or Tower Bridge, Double (39-RD-0347) to aid with derotation. The Tower Connectors are secured to the Tower Bridges via the Tower Thumbscrews (39-RD-0345). At this point, the derotation maneuver can be performed to bring the spine into alignment (Figure 4). Derotate each proximal vertebral body to achieve a neutral position in reference to the neutral distal vertebra. After derotation of each segment, the set screws are tightened. Repeat this process, moving along towards the apex.



Figure 4

Optional Surgical Procedures

Removal of the Reform® Pedicle Screw System components is performed by reversing the order of the implant procedure.

NOTE: The Counter-Torque Wrench (39-RD-0061) should be used when removing screws to prevent unintended screw pullout. The Counter-Torque Wrench may be used either directly on the screw to be removed, or on the adjacent screws, to hold the construct in place during removal.

REFORM® PEDICLE SCREW SYSTEM IMPLANTS

Item No. Description

39-LS-0100 Locking Cap

Polyaxial Screws

39-PA-4525 Ø4.5 x 25mm Polyaxial Screw

39-PA-4530 Ø4.5 x 30mm Polyaxial Screw

39-PA-4535 Ø4.5 x 35mm Polyaxial Screw

39-PA-4540 Ø4.5 x 40mm Polyaxial Screw

39-PA-4545 Ø4.5 x 45mm Polyaxial Screw

39-PA-5525 Ø5.5 x 25mm Polyaxial Screw

39-PA-5530 Ø5.5 x 30mm Polyaxial Screw

39-PA-5535 Ø5.5 x 35mm Polyaxial Screw

39-PA-5540 Ø5.5 x 40mm Polyaxial Screw

39-PA-5545 Ø5.5 x 45mm Polyaxial Screw

39-PA-5550 Ø5.5 x 50mm Polyaxial Screw

39-PA-5555 Ø5.5 x 55mm Polyaxial Screw

39-PA-5560 Ø5.5 x 60mm Polyaxial Screw

39-PA-6525 Ø6.5 x 25 mm Polyaxial Screw

39-PA-6530 Ø6.5 x 30mm Polyaxial Screw

39-PA-6535 Ø6.5 x 35mm Polyaxial Screw

39-PA-6540 Ø6.5 x 40mm Polyaxial Screw

39-PA-6545 Ø6.5 x 45mm Polyaxial Screw

39-PA-6550 Ø6.5 x 50mm Polyaxial Screw

39-PA-6555 Ø6.5 x 55mm Polyaxial Screw

39-PA-6560 Ø6.5 x 60mm Polyaxial Screw

39-PA-7530 Ø7.5 x 30mm Polyaxial Screw

39-PA-7535 Ø7.5 x 35mm Polyaxial Screw

39-PA-7540 Ø7.5 x 40mm Polyaxial Screw

39-PA-7545 Ø7.5 x 45mm Polyaxial Screw

39-PA-7550 Ø7.5 x 50mm Polyaxial Screw

39-PA-7555 Ø7.5 x 55mm Polyaxial Screw

39-PA-7560 Ø7.5 x 60mm Polyaxial Screw

39-PA-7570 Ø7.5 x 70mm Polyaxial Screw

39-PA-7580 Ø7.5 x 80mm Polyaxial Screw

Item No. Description

39-PA-8535 Ø8.5 x 35mm Polyaxial Screw

39-PA-8540 Ø8.5 x 40mm Polyaxial Screw

39-PA-8545 Ø8.5 x 45mm Polyaxial Screw

39-PA-8550 Ø8.5 x 50mm Polyaxial Screw

39-PA-8555 Ø8.5 x 55mm Polyaxial Screw

39-PA-8560 Ø8.5 x 60mm Polyaxial Screw

39-PA-8570 Ø8.5 x 70mm Polyaxial Screw

39-PA-8580 Ø8.5 x 80mm Polyaxial Screw

39-PA-8590 Ø8.5 x 90mm Polyaxial Screw

39-PA-8500 Ø8.5 x 100mm Polyaxial Screw

39-PA-8511 Ø8.5 x 110mm Polyaxial Screw

39-PA-8512 Ø8.5 x 120mm Polyaxial Screw

39-PA-9535 Ø9.5 x 35mm Polyaxial Screw

39-PA-9540 Ø9.5 x 40mm Polyaxial Screw

39-PA-9545 Ø9.5 x 45mm Polyaxial Screw

39-PA-9550 Ø9.5 x 50mm Polyaxial Screw

39-PA-9555 Ø9.5 x 55mm Polyaxial Screw

39-PA-9560 Ø9.5 x 60mm Polyaxial Screw

39-PA-9570 Ø9.5 x 70mm Polyaxial Screw

39-PA-9580 Ø9.5 x 80mm Polyaxial Screw

39-PA-9590 Ø9.5 x 90mm Polyaxial Screw

39-PA-9500 Ø9.5 x 100mm Polyaxial Screw

39-PA-9511 Ø9.5 x 110mm Polyaxial Screw

39-PA-9512 Ø9.5 x 120mm Polyaxial Screw

39-PA-1040 Ø10.5 x 40mm Polyaxial Screw *

39-PA-1045 Ø10.5 x 45mm Polyaxial Screw *

39-PA-1050 Ø10.5 x 50mm Polyaxial Screw *

39-PA-1055 Ø10.5 x 55mm Polyaxial Screw *

39-PA-1060 Ø10.5 x 60mm Polyaxial Screw *

39-PA-1070 Ø10.5 x 70mm Polyaxial Screw *

39-PA-1080 Ø10.5 x 80mm Polyaxial Screw *

39-PA-1090 Ø10.5 x 90mm Polyaxial Screw *

39-PA-1000 Ø10.5 x 100mm Polyaxial Screw *

39-PA-1011 Ø10.5 x 110mm Polyaxial Screw *

39-PA-1012 Ø10.5 x 120mm Polyaxial Screw *

* Special Order

REFORM® PEDICLE SCREW SYSTEM IMPLANTS

Item No.	Description
Reduction Polyaxial Screws	
39-RP-4525	Ø4.5 x 25mm Reduction Polyaxial Screw
39-RP-4530	Ø4.5 x 30mm Reduction Polyaxial Screw
39-RP-4535	Ø4.5 x 35mm Reduction Polyaxial Screw
39-RP-4540	Ø4.5 x 40mm Reduction Polyaxial Screw
39-RP-4545	Ø4.5 x 45mm Reduction Polyaxial Screw
39-RP-5525	Ø5.5 x 25mm Reduction Polyaxial Screw
39-RP-5530	Ø5.5 x 30mm Reduction Polyaxial Screw
39-RP-5535	Ø5.5 x 35mm Reduction Polyaxial Screw
39-RP-5540	Ø5.5 x 40mm Reduction Polyaxial Screw
39-RP-5545	Ø5.5 x 45mm Reduction Polyaxial Screw
39-RP-5550	Ø5.5 x 50mm Reduction Polyaxial Screw
39-RP-5555	Ø5.5 x 55mm Reduction Polyaxial Screw *
39-RP-5560	Ø5.5 x 60mm Reduction Polyaxial Screw *
39-RP-6525	Ø6.5 x 25mm Reduction Polyaxial Screw *
39-RP-6530	Ø6.5 x 30mm Reduction Polyaxial Screw
39-RP-6535	Ø6.5 x 35mm Reduction Polyaxial Screw
39-RP-6540	Ø6.5 x 40mm Reduction Polyaxial Screw
39-RP-6545	Ø6.5 x 45mm Reduction Polyaxial Screw
39-RP-6550	Ø6.5 x 50mm Reduction Polyaxial Screw
39-RP-6555	Ø6.5 x 55 mm Reduction Polyaxial Screw *
39-RP-6560	Ø6.5 x 60 mm Reduction Polyaxial Screw *
39-RP-7530	Ø7.5 x 30 mm Reduction Polyaxial Screw *
39-RP-7535	Ø7.5 x 35mm Reduction Polyaxial Screw
39-RP-7540	Ø7.5 x 40mm Reduction Polyaxial Screw
39-RP-7545	Ø7.5 x 45mm Reduction Polyaxial Screw
39-RP-7550	Ø7.5 x 50mm Reduction Polyaxial Screw
39-RP-7555	Ø7.5 x 55mm Reduction Polyaxial Screw
39-RP-7560	Ø7.5 x 60mm Reduction Polyaxial Screw *
39-RP-7570	Ø7.5 x 70mm Reduction Polyaxial Screw *
39-RP-7580	Ø7.5 x 80mm Reduction Polyaxial Screw *

Item No.	Description
39-RP-8535	Ø8.5 x 35mm Reduction Polyaxial Screw *
39-RP-8540	Ø8.5 x 40mm Reduction Polyaxial Screw *
39-RP-8545	Ø8.5 x 45mm Reduction Polyaxial Screw *
39-RP-8550	Ø8.5 x 50mm Reduction Polyaxial Screw *
39-RP-8555	Ø8.5 x 55mm Reduction Polyaxial Screw *
39-RP-8560	Ø8.5 x 60mm Reduction Polyaxial Screw *
39-RP-8570	Ø8.5 x 70mm Reduction Polyaxial Screw *
39-RP-8580	Ø8.5 x 80mm Reduction Polyaxial Screw *
39-RP-8590	Ø8.5 x 90mm Reduction Polyaxial Screw *
39-RP-8500	Ø8.5 x 100mm Reduction Polyaxial Screw *
39-RP-8511	Ø8.5 x 110mm Reduction Polyaxial Screw *
39-RP-8512	Ø8.5 x 120mm Reduction Polyaxial Screw *
39-RP-9540	Ø9.5 x 40mm Reduction Polyaxial Screw *
39-RP-9545	Ø9.5 x 45mm Reduction Polyaxial Screw *
39-RP-9550	Ø9.5 x 50mm Reduction Polyaxial Screw *
39-RP-9555	Ø9.5 x 55mm Reduction Polyaxial Screw *
39-RP-9560	Ø9.5 x 60mm Reduction Polyaxial Screw *
39-RP-9570	Ø9.5 x 70mm Reduction Polyaxial Screw *
39-RP-9580	Ø9.5 x 80mm Reduction Polyaxial Screw *
39-RP-9590	Ø9.5 x 90 mm Reduction Polyaxial Screw *
39-RP-9500	Ø9.5 x 100mm Reduction Polyaxial Screw *
39-RP-9511	Ø9.5 x 110mm Reduction Polyaxial Screw *
39-RP-9512	Ø9.5 x 120mm Reduction Polyaxial Screw *
39-RP-1040	Ø10.5 x 40mm Reduction Polyaxial Screw *
39-RP-1045	Ø10.5 x 45mm Reduction Polyaxial Screw *
39-RP-1050	Ø10.5 x 50mm Reduction Polyaxial Screw *
39-RP-1055	Ø10.5 x 55mm Reduction Polyaxial Screw *
39-RP-1060	Ø10.5 x 60mm Reduction Polyaxial Screw *
39-RP-1070	Ø10.5 x 70mm Reduction Polyaxial Screw *
39-RP-1080	Ø10.5 x 80mm Reduction Polyaxial Screw *
39-RP-1090	Ø10.5 x 90mm Reduction Polyaxial Screw *
39-RP-1000	Ø10.5 x 100mm Reduction Polyaxial Screw *
39-RP-1011	Ø10.5 x 110mm Reduction Polyaxial Screw *
39-RP-1012	Ø10.5 x 120mm Reduction Polyaxial Screw *

* Special Order

Item No.	Description
Uniplanar Screws	
39-UP-4525	Ø4.5 x 25mm Uniplanar Screw
39-UP-4530	Ø4.5 x 30mm Uniplanar Screw
39-UP-4535	Ø4.5 x 35mm Uniplanar Screw
39-UP-4540	Ø4.5 x 40mm Uniplanar Screw
39-UP-4545	Ø4.5 x 45mm Uniplanar Screw
39-UP-5525	Ø5.5 x 25mm Uniplanar Screw
39-UP-5530	Ø5.5 x 30mm Uniplanar Screw
39-UP-5535	Ø5.5 x 35mm Uniplanar Screw
39-UP-5540	Ø5.5 x 40mm Uniplanar Screw
39-UP-5545	Ø5.5 x 45mm Uniplanar Screw
39-UP-5550	Ø5.5 x 50mm Uniplanar Screw
39-UP-5555	Ø5.5 x 55mm Uniplanar Screw *
39-UP-5560	Ø5.5 x 60mm Uniplanar Screw *
39-UP-6525	Ø6.5 x 25mm Uniplanar Screw *
39-UP-6530	Ø6.5 x 30mm Uniplanar Screw
39-UP-6535	Ø6.5 x 35mm Uniplanar Screw
39-UP-6540	Ø6.5 x 40mm Uniplanar Screw
39-UP-6545	Ø6.5 x 45mm Uniplanar Screw
39-UP-6550	Ø6.5 x 50mm Uniplanar Screw
39-UP-6555	Ø6.5 x 55mm Uniplanar Screw *
39-UP-6560	Ø6.5 x 60mm Uniplanar Screw *
39-UP-7530	Ø7.5 x 30mm Uniplanar Screw *
39-UP-7535	Ø7.5 x 35mm Uniplanar Screw
39-UP-7540	Ø7.5 x 40mm Uniplanar Screw
39-UP-7545	Ø7.5 x 45mm Uniplanar Screw
39-UP-7550	Ø7.5 x 50mm Uniplanar Screw
39-UP-7555	Ø7.5 x 55mm Uniplanar Screw *
39-UP-7560	Ø7.5 x 60mm Uniplanar Screw *

Item No.	Description
Reduction Uniplanar Screws	
39-RU-4525	Ø4.5 x 25mm Reduction Uniplanar Screw
39-RU-4530	Ø4.5 x 30mm Reduction Uniplanar Screw
39-RU-4535	Ø4.5 x 35mm Reduction Uniplanar Screw
39-RU-4540	Ø4.5 x 40mm Reduction Uniplanar Screw
39-RU-4545	Ø4.5 x 45mm Reduction Uniplanar Screw
39-RU-5525	Ø5.5 x 25mm Reduction Uniplanar Screw
39-RU-5530	Ø5.5 x 30mm Reduction Uniplanar Screw
39-RU-5535	Ø5.5 x 35mm Reduction Uniplanar Screw
39-RU-5540	Ø5.5 x 40mm Reduction Uniplanar Screw
39-RU-5545	Ø5.5 x 45mm Reduction Uniplanar Screw
39-RU-5550	Ø5.5 x 50mm Reduction Uniplanar Screw
39-RU-5555	Ø5.5 x 55mm Reduction Uniplanar Screw
39-RU-5560	Ø5.5 x 60mm Reduction Uniplanar Screw
39-RU-6525	Ø6.5 x 25 mm Reduction Uniplanar Screw
39-RU-6530	Ø6.5 x 30mm Reduction Uniplanar Screw
39-RU-6535	Ø6.5 x 35mm Reduction Uniplanar Screw
39-RU-6540	Ø6.5 x 40mm Reduction Uniplanar Screw
39-RU-6545	Ø6.5 x 45mm Reduction Uniplanar Screw
39-RU-6550	Ø6.5 x 50mm Reduction Uniplanar Screw
39-RU-6555	Ø6.5 x 55mm Reduction Uniplanar Screw
39-RU-6560	Ø6.5 x 60mm Reduction Uniplanar Screw
39-RU-7530	Ø7.5 x 30mm Reduction Uniplanar Screw *
39-RU-7535	Ø7.5 x 35mm Reduction Uniplanar Screw *
39-RU-7540	Ø7.5 x 40mm Reduction Uniplanar Screw *
39-RU-7545	Ø7.5 x 45mm Reduction Uniplanar Screw *
39-RU-7550	Ø7.5 x 50mm Reduction Uniplanar Screw *
39-RU-7555	Ø7.5 x 55mm Reduction Uniplanar Screw *
39-RU-7560	Ø7.5 x 60mm Reduction Uniplanar Screw *

* Special Order

Item No.	Description
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Modular Tulips

39-MT-0301	Reform Modular Tulip Assembly
39-MT-0302	Reform Modular Reduction Tulip Assembly

Modular Screws

39-MS-4525	Reform Ø4.5 x 25mm Modular PedicleScrew
39-MS-4530	Reform Ø4.5 x 30mm Modular Pedicle Screw
39-MS-4535	Reform Ø4.5 x 35mm Modular PedicleScrew
39-MS-4540	Reform Ø4.5 x 40mm Modular Pedicle Screw
39-MS-4545	Reform Ø4.5 x 45mm Modular PedicleScrew
39-MS-5530	Reform Ø5.5 x 30mm Modular Pedicle Screw
39-MS-5535	Reform Ø5.5 x 35mm Modular PedicleScrew
39-MS-5540	Reform Ø5.5 x 40mm Modular Pedicle Screw
39-MS-5545	Reform Ø5.5 x 45mm Modular PedicleScrew
39-MS-5550	Reform Ø5.5 x 50mm Modular Pedicle Screw
39-MS-6530	Reform Ø6.5 x 30mm Modular PedicleScrew
39-MS-6535	Reform Ø6.5 x 35mm Modular Pedicle Screw
39-MS-6540	Reform Ø6.5 x 40mm Modular PedicleScrew
39-MS-6545	Reform Ø6.5 x 45mm Modular Pedicle Screw
39-MS-6550	Reform Ø6.5 x 50mm Modular PedicleScrew
39-MS-6555	Reform Ø6.5 x 55mm Modular Pedicle Screw
39-MS-6560	Reform Ø6.5 x 60mm Modular PedicleScrew
39-MS-7535	Reform Ø7.5 x 35mm Modular Pedicle Screw
39-MS-7540	Reform Ø7.5 x 40mm Modular PedicleScrew
39-MS-7545	Reform Ø7.5 x 45mm Modular Pedicle Screw
39-MS-7550	Reform Ø7.5 x 50mm Modular PedicleScrew
39-MS-7555	Reform Ø7.5 x 55mm Modular Pedicle Screw
39-MS-8540	Reform Ø8.5 x 40mm Modular PedicleScrew
39-MS-8545	Reform Ø8.5 x 45mm Modular Pedicle Screw
39-MS-8550	Reform Ø8.5 x 50mm Modular PedicleScrew
39-MS-8555	Reform Ø8.5 x 55mm Modular Pedicle Screw
39-MS-8560	Reform Ø8.5 x 60mm Modular PedicleScrew
39-MS-8570	Reform Ø8.5 x 70mm Modular Pedicle Screw
39-MS-8580	Reform Ø8.5 x 80mm Modular PedicleScrew
39-MS-9560	Reform Ø9.5 x 60mm Modular Pedicle Screw
39-MS-9570	Reform Ø9.5 x 70mm Modular PedicleScrew
39-MS-9580	Reform Ø9.5 x 80mm Modular Pedicle Screw

REFORM® PEDICLE SCREW SYSTEM IMPLANTS

Item No. Description

Lordotic Rods (Ti)

39-LT-5035	Ø5.5 x 35mm Lordotic Rod (Ti)
39-LT-5040	Ø5.5 x 40mm Lordotic Rod (Ti)
39-LT-5045	Ø5.5 x 45mm Lordotic Rod (Ti)
39-LT-5050	Ø5.5 x 50mm Lordotic Rod (Ti)
39-LT-5055	Ø5.5 x 55mm Lordotic Rod (Ti)
39-LT-5060	Ø5.5 x 60mm Lordotic Rod (Ti)
39-LT-5065	Ø5.5 x 65mm Lordotic Rod (Ti)
39-LT-5070	Ø5.5 x 70mm Lordotic Rod (Ti)
39-LT-5075	Ø5.5 x 75mm Lordotic Rod (Ti)
39-LT-5080	Ø5.5 x 80mm Lordotic Rod (Ti)
39-LT-5090	Ø5.5 x 90mm Lordotic Rod (Ti)
39-LT-5100	Ø5.5 x 100mm Lordotic Rod (Ti)
39-LT-5110	Ø5.5 x 110mm Lordotic Rod (Ti)
39-LT-5120	Ø5.5 x 120mm Lordotic Rod (Ti)

Straight Rods (Ti)

39-ST-5080	Ø5.5 x 80mm Straight Rod (Ti)
39-ST-5100	Ø5.5 x 100mm Straight Rod (Ti)
39-ST-5120	Ø5.5 x 120mm Straight Rod (Ti)
39-ST-5150	Ø5.5 x 150mm Straight Rod (Ti) *
39-ST-5200	Ø5.5 x 200mm Hex-End Rod (Ti)
39-ST-5300	Ø5.5 x 300mm Hex-End Rod (Ti)
39-ST-5400	Ø5.5 x 400mm Hex-End Rod (Ti)
39-ST-5500	Ø5.5 x 500mm Hex-End Rod (Ti)
39-ST-5600	Ø5.5 x 600mm Hex-End Rod (Ti) *

Item No. Description

Lordotic Rods (CoCr)

39-LC-5035	Ø5.5 x 35mm Lordotic Rod (CoCr)
39-LC-5040	Ø5.5 x 40mm Lordotic Rod (CoCr)
39-LC-5045	Ø5.5 x 45mm Lordotic Rod (CoCr)
39-LC-5050	Ø5.5 x 50mm Lordotic Rod (CoCr)
39-LC-5055	Ø5.5 x 55mm Lordotic Rod (CoCr)
39-LC-5060	Ø5.5 x 60mm Lordotic Rod (CoCr)
39-LC-5065	Ø5.5 x 65mm Lordotic Rod (CoCr)
39-LC-5070	Ø5.5 x 70mm Lordotic Rod (CoCr)
39-LC-5075	Ø5.5 x 75mm Lordotic Rod (CoCr)
39-LC-5080	Ø5.5 x 80mm Lordotic Rod (CoCr)
39-LC-5090	Ø5.5 x 90mm Lordotic Rod (CoCr)
39-LC-5100	Ø5.5 x 100mm Lordotic Rod (CoCr)
39-LC-5110	Ø5.5 x 110mm Lordotic Rod (CoCr)
39-LC-5120	Ø5.5 x 120mm Lordotic Rod (CoCr)

Straight Rods (CoCr)

39-SC-5080	Ø5.5 x 80mm Straight Rod (CoCr)
39-SC-5100	Ø5.5 x 100mm Straight Rod (CoCr)
39-SC-5120	Ø5.5 x 120mm Straight Rod (CoCr)
39-SC-5150	Ø5.5 x 150mm Straight Rod (CoCr) *
39-SC-5200	Ø5.5 x 200mm Hex-End Rod (CoCr)
39-SC-5300	Ø5.5 x 300mm Hex-End Rod (CoCr)
39-SC-5400	Ø5.5 x 400mm Hex-End Rod (CoCr)
39-SC-5500	Ø5.5 x 500mm Hex-End Rod (CoCr)
39-SC-5600	Ø5.5 x 600mm Straight Rod (CoCr) *

* Special Order

Item No.	Description
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Pedicle Hooks

39-TH-0101	Pedicle Hook, SM
39-TH-0102	Pedicle Hook, MD
39-TH-0103	Pedicle Hook, LG

Laminar Hooks

39-TH-0201	Straight Lam. Hook, SM, Nar.
39-TH-0202	Straight Lam. Hook, SM, Wide
39-TH-0203	Straight Lam. Hook, MD, Nar.
39-TH-0204	Straight Lam. Hook, MD, Wide
39-TH-0205	Straight Lam. Hook, LG, Nar.
39-TH-0206	Straight Lam. Hook, LG, Wide
39-TH-0212	Ext-Body (+4mm) Lam. Hook, MD
39-TH-0213	Ext-Body (+4mm) Lam. Hook, LG
39-TH-0221	Ramped Lam. Hook, SM
39-TH-0222	Ramped Lam. Hook, MD
39-TH-0232	Down-Angled Lam. Hook, MD
39-TH-0233	Down-Angled Lam. Hook, LG

Offset Angled Hooks

39-TH-0301	Offset Angled Hook, MD, Right
39-TH-0302	Offset Angled Hook, MD, Left

Angled Hooks

39-TH-0401	Angled Hook, MD, Right
39-TH-0402	Angled Hook, MD, Left

Reduction Hooks

39-TH-0242	Straight Lam. Red. Hook, MD
39-TH-0252	Ext-Body Lam. Red. Hook, MD
39-TH-0262	Ramped Lam. Red. Hook, MD
39-TH-0272	Down-Ang. Lam. Red. Hook, MD
39-TH-0351	Off. Ang. Red. Hook, MD, Right
39-TH-0352	Off. Ang. Red. Hook, MD, Left
39-TH-0451	Ang. Red. Hook, MD, Right
39-TH-0452	Ang. Red. Hook, MD, Left

Item No.	Description
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Dominoes

39-AA-0101	Axial Domino, Closed-Closed
39-DA-0101	Par. Domino, Closed-Closed, Wide
39-DA-0102	Par. Domino, Closed-Closed, Narrow
39-DA-0201	Par. Domino, Closed-Open, Wide
39-DA-0202	Par. Domino, Closed-Open, Narrow
39-DA-0301	Par. Domino, Open-Open, Wide
39-DA-0302	Par. Domino, Open-Open, Narrow
39-LS-0200	Domino Lock Screw

Lateral Offsets

39-LO-0120	Lat. Offset, Closed -20mm
39-LO-0130	Lat. Offset, Closed -30mm
39-LO-0140	Lat. Offset, Closed -40mm
39-LO-0150	Lat. Offset, Closed -50mm
39-LO-0220	Lat. Offset, Top-Loading -20mm
39-LO-0230	Lat. Offset, Top-Loading -30mm
39-LO-0240	Lat. Offset, Top-Loading -40mm
39-LO-0250	Lat. Offset, Top-Loading -50mm

Cross-Connectors

39-CC-0030	30mm Cross-Connector
39-CC-0032	32mm Cross-Connector
39-CC-0035	35mm Cross-Connector
39-CC-0040	40mm Cross-Connector
39-CC-0048	48mm Cross-Connector
39-CC-0066	66mm Cross-Connector

REFORM® PEDICLE SCREW SYSTEM INSTRUMENTS

Item No. Description

39-CH-0003	Ratcheting T-Handle, 1/4" SQ
39-CH-0004	Ratcheting In-line Handle, 1/4" SQ
39-SP-0001	Bone Awl
39-SP-0003	Curved Pedicle Probe
39-SP-0005	Duckbill Pedicle Probe
39-SP-0007	Straight Pedicle Probe
39-SP-0011	Ball-Tip Sounder
39-SP-0545	Pedicle Screw Tap - 4.5mm
39-SP-0555	Pedicle Screw Tap - 5.5mm
39-SP-0565	Pedicle Screw Tap - 6.5mm
39-SP-0575	Pedicle Screw Tap - 7.5mm
39-SP-0585	Pedicle Screw Tap - 8.5mm
39-SP-0595	Pedicle Screw Tap - 9.5mm
39-SP-0601	Retention Bone-Screw Driver
39-SP-0700	Polyaxial Driver
39-SP-0800	Tulip Manipulator
39-SP-0825	Lateral Tulip Holder
39-RD-0001	French Rod Bender - 5.50mm
39-RD-0010	Flexible Rod Template - 200mm
39-RD-0011	Flexible Rod Template - 400mm
39-SP-0805	Rod Holding Forceps - 5.50mm
39-SP-0815	Rod Pusher - 5.50mm
39-RD-0201	Rod Rocker
39-RD-0310	Tie Reduction Tower
39-RD-0320	Tie Tower Reducer
39-RD-0315	T-Handle Reducer

Item No. Description

39-SP-0602	Locking Cap Retention Driver
39-SP-0603	Dual-Side Lock-Screw Driver
39-RD-0041	Parallel Compressor
39-RD-0042	Parallel Distractor
39-SP-0810	Rod Gripper - 5.50mm
39-RD-0020	In-Situ Rod Bender Left- 5.50mm
39-RD-0021	In-Situ Rod Bender Right - 5.50mm
39-RD-0061	Counter Torque Wrench
39-CH-0008	Offset Ratcheting Torque Handle
39-RD-0060	Locking Cap Torque Driver
39-RD-0070	Extended Tab Removal Tool
39-SC-0100	Pedicle Screw Implant Case
39-SC-0101	Straight Rod Caddy - Titanium
39-SC-0102	Lordotic Rod Caddy - Titanium
39-SC-0103	Ø5.5mm Polyaxial Screw Caddy
39-SC-0104	Ø6.5mm Polyaxial Screw Caddy
39-SC-0105	Ø7.5mm Polyaxial Screw Caddy
39-SC-0106	Outlier Polyaxial Screw Caddy
39-SC-0108	Straight Rod Caddy - CoCr
39-SC-0109	Lordotic Rod Caddy - CoCr
39-SC-0201	Instrument Sterilization Case 1
39-SC-0202	Instrument Sterilization Case 2

Item No.	Description
Add-on Instruments	
39-RD-0600	Rod Gripper, Vice-grip 5.5mm
39-RD-0601	Rod Gripper, Dual Action 5.5mm
39-RD-0012	500mm Flexible Rod Template
39-RD-003X	Coronal Rod Bender Assembly
39-RD-0550	Superior Hook Holder
39-RD-0344	Tower Connector
39-RD-0345	Tower Thumbscrew
39-RD-0346	Tower Bridge, Single
39-RD-0347	Tower Bridge, Double
39-RD-0348	Tower Bridge Hex Wrench
39-RD-0050	Rod Derotation Hex Wrench
39-RD-0500	Pedicular Elevator
39-RD-0502	Laminar Elevator, Medium
39-RD-0503	Laminar Elevator, Small
39-RD-0560	Hook Pusher
39-RD-0570	Domino Inserter
39-CH-0009	Torque Limiting Handle
39-CC-0407	Torque Limiting T20 Driver
39-CC-0401	Self-Retaining T20 Driver
39-RD-0100	Rod Reducer
39-CC-0405	Rotary Calipers
39-SC-0203	Instrument Case
39-SC-0204	Instrument Caddy
39-SC-0300	Implant Case
39-SC-0301	Ø4.5mm/7.5mm Poly Screw Caddy
39-SC-0305	Hook Caddy
39-SC-0306	Reduction Hook Caddy
39-SC-0307	Lock-Screw & Cross-Connector Caddy
39-SC-0308	Domino Caddy
39-SC-0309	Lat. Offset Caddy
39-SC-0310	Lat. Offset Expansion Caddy
39-SC-0302	Ø5.5mm Polyaxial Screw Caddy
39-SC-0303	Ø6.5mm Polyaxial Screw Caddy
39-SC-0304	Ø4.5mm/7.5mm Poly Screw Caddy

Item No.	Description
Implant Kits	
39-BK-0101	Implant Kit: Std: Ø5.5-7.5 Poly (Ti)
39-BK-0102	Implant Kit: Std + Outlier 4.5, 8.5 & 9.5 Poly (Ti)
39-BK-0103	Implant Kit: Std + Red (Ti)
39-BK-0104	Implant Kit: Std + Outlier 4.5, 8.5 & 9.5 Poly + Red(Ti)
39-BK-0105	Implant Kit: Std: Ø5.5-7.5 Poly (Cr)
39-BK-0106	Implant Kit: Std + Outlier 4.5, 8.5 & 9.5 Poly (Cr)
39-BK-0107	Implant Kit: Std + Red(Cr)
39-BK-0108	Implant Kit: Std + Outlier 4.5, 8.5 & 9.5 Poly + Red (Cr)
Instrument Kits	
39-BK-0201	Instrument Kit 1
39-BK-0202	Instrument Kit 2
Add-on Implant Kits	
39-BK-0301	Implant Kit: Std: Poly
39-BK-0302	Implant Kit: Std: Poly + Hooks
39-BK-0303	Implant Kit: Std: Poly + Red
39-BK-0304	Implant Kit: Std: Poly, Red, + Hooks
39-BK-0305	Implant Kit: Uni
39-BK-0306	Implant Kit: Uni + Hooks
39-BK-0307	Implant Kit: Uni + Red
39-BK-0308	Implant Kit: Uni, Red, + Hooks
Add-on Instrument Kit	
39-BK-0203	Deformity Add-on Instrument Kit

INDICATIONS

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, 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 degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, hypnosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is 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 system 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.



Precision Spine, Inc.

2050 Executive Drive

Pearl, MS 39208

Customer Service: 1.888.241.4773

Phone: 601.420.4244

Toll Free: 877.780.4370

Fax: 601.420.5501

www.precisionspineinc.com



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