SURGICAL TECHNIQUE

PRECISION SPINE

REFORM® MC

MIDLINE CORTICAL SCREW SYSTEM

PRECISION SPINE®

Discover the Difference

Made in the USA

TABLE OF CONTENTS

REFORM® *MC* (MIDLINE CORTICAL) SCREW SYSTEM

REFORM® *MC* SYSTEM OVERVIEW

DEVICE DESCRIPTION

The Reform *MC* (Midline Cortical) Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of cannulated pedicle screws, straight and lordotic rods, and locking cap screws. All components are available in a variety of sizes to more closely match the patient's anatomy. The Reform *MC* Posterior Screw System utilizes a minimally disruptive approach designed to reduce muscle retraction laterally past the facet joint. This approach requires a smaller incision while maintaining direct visualization and access to the disc space. Reform *MC's* medial to lateral trajectory combined with a cortical cancellous screw thread design achieves greater cortical bone purchase. Reform *MC* features a modular screw design to maximize visualization and a low-profile cobalt chrome, 4.75mm tulip to conserve space without compromising strength. All components are made from medical grade stainless steel, cobalt chrome alloys, titanium or titanium alloy, which comply with such standards as ASTM F-138, ASTM F-1537, ASTM F-136, ISO5832-12 or ISO5832-3. All components are supplied clean and "NON-STERILE".

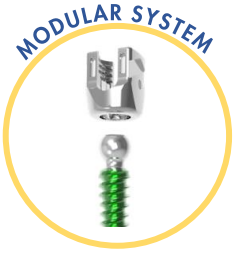
NOTE:
Reform *MC* HA Coated Pedicle Screws are supplied STERILE, are medical grade titanium or titanium alloy as described by such standards as ASTM F136 or ISO 5832-3 and feature Hydroxyapatite (HA) coating described by such standards as ISO 13779-2 and ASTM 1185-03.

INDICATIONS

The Reform *MC* 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 *MC* 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 *MC* 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 *MC* 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.



MODULAR
- Multiple Size Tulips
- Audible Attachment
- Consistent Insertion Force
- HA Coating

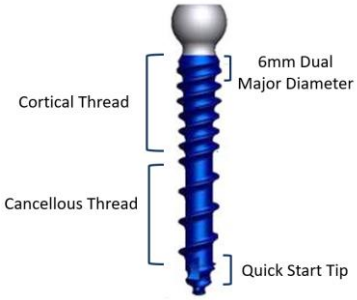
CORTICAL CANCELLOUS THREAD
- Dual Lead Thread
- Dual Major Diameter
- Stepped Minor Diameter

LOW PROFILE TULIP
- Cobalt Chrome
- 4.75 & 5.5mm Rod Options
- T25 Drive Feature

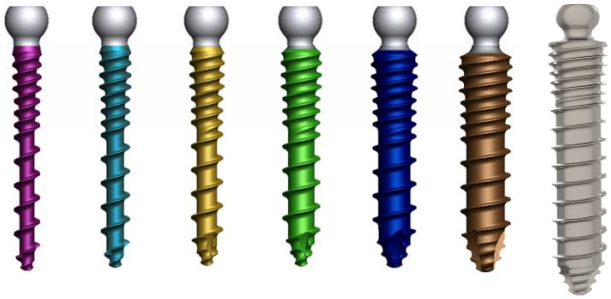
REFORM® *MC* SYSTEM OVERVIEW

4.75mm 5.5mm

- ***Modular System*** allows for complete visualization during decompression
- ***4.75 & 5.5mm Modular Tulips*** provide intraoperative flexibility
- ***Audible Click and Consistent Tactile Engagement Force*** confirms permanent attachment of tulips
- ***Reduced Tulip Axial Motion*** allows for locking screw to be started without pulling up on the tulip



- ***Dual Diameter Stepped Thread*** optimizes cortical bone purchase during final seating
- ***Dual Lead & Cortical Cancellous Thread*** provides compatible fixation options for PLIF & TPLIF applications
- ***Aggressive Distal Screw Tip*** optimizes initial bone engagement
- ***T25 Drive Feature*** provides greater stability during insertion
- **Quick Start Tip** efficiently engages cortical bone

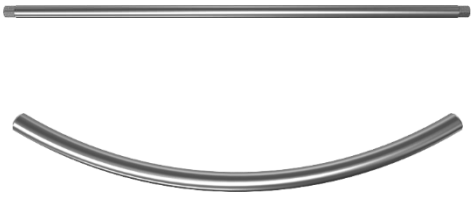


Midline Cortical Tray

Diameter	Length
4.5mm	25 - 45mm
5.0mm	25 – 45mm
5.5mm	25 – 55mm
6.5mm	25 – 60mm
7.5mm	30 – 80mm

Pedicular Approach (Hybrid) Tray

Diameter	Length
4.5mm	25 - 45mm
5.5mm	30 – 50mm
6.5mm	35 – 55mm
7.5mm	35 – 55mm
8.5mm	40 – 80mm
9.5mm	60 – 80mm



4.75mm – Cobalt Chrome

Lordotic
- 35 – 80mm (5mm inc.)
- 90 – 120mm (10mm inc.)

Straight
- 200 & 400mm

5.5mm – Cobalt Chrome & Ti

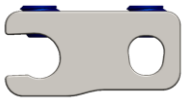
Lordotic
- 35 – 80mm (5mm inc.)
- 90 – 120mm (10mm inc.)

Straight
- 200 & 400mm

REFORM® *MC* SYSTEM OVERVIEW

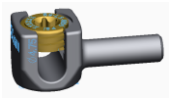
Cross Connectors
Sizes Offering
30 – 34mm
33 – 39mm
38 – 49mm
47 – 67mm

Narrow– 9mm Spacing

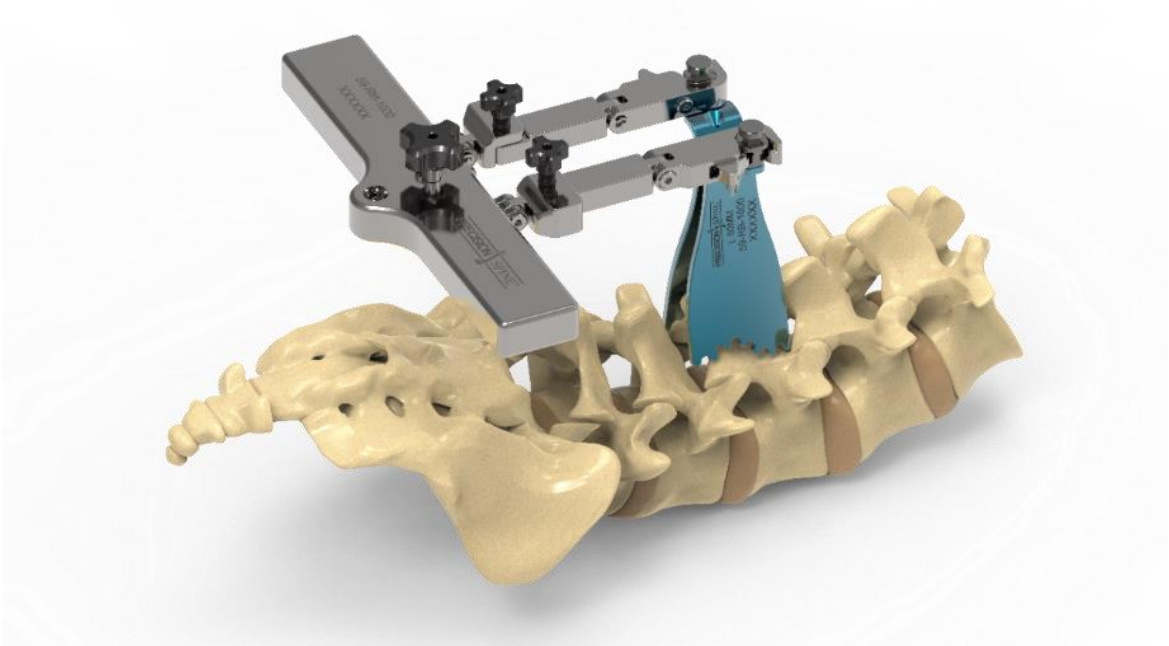


Wide – 15mm Spacing

Dominoes
Wide and Narrow
Closed-Open
Ø4.75mm→Ø5.5mm



Lateral Offsets
Open Offset
Top Loading
Opening: Ø5.5mm (39-LS-0100 Lock Cap)
Rod: Ø4.75mm
Lengths: 20, 30 & 40mm



Low Profile Retractor allows for a anatomy-conserving approach to minimize muscle disruption

- ***Symmetrical Ratcheting***
- ***30-Degree Articulating Blades***
- ***Anatomically Contoured Blades***
- ***40 – 110mm Blade Lengths (10mm)***
- ***Integrated Dual Fiber-Optics***

REFORM® *MC* SYSTEM OVERVIEW

SCREW SHANK DIMENSIONS

- Diameter (color) + (lengths)
  - 4.5mm (Magenta) (25-45mm)
  - 5.0mm (Light Blue) (25-45mm)
  - 5.5mm (Gold) (25-55mm)
  - 6.5mm (Green) (25-60mm)
- Diameters (color) + (lengths)
  - 7.5mm (Dark Blue) (30-80mm)
  - 8.5mm (Bronze) (40-80mm)
  - 9.5mm (Silver) (60-80mm)

NOTE: **All HA screws packaged pre-sterile without color**

TULIP DIMENSIONS

- 4.75mm – Cobalt Chrome
- 5.5mm – Cobalt Chrome

ROD DIMENSIONS

4.75mm – Cobalt Chrome

- Lordotic
  - 35 – 80mm (5mm increments), 90 – 120mm (10mm increments)
- Straight
  - 200 & 400mm

5.5mm – Cobalt Chrome & Titanium

- Lordotic
  - 35 – 80mm (5mm increments), 90 – 120mm (10mm increments)
- Straight
  - 80, 100, 120, 200 & 400mm

IMPLANT & INSTRUMENT SETS

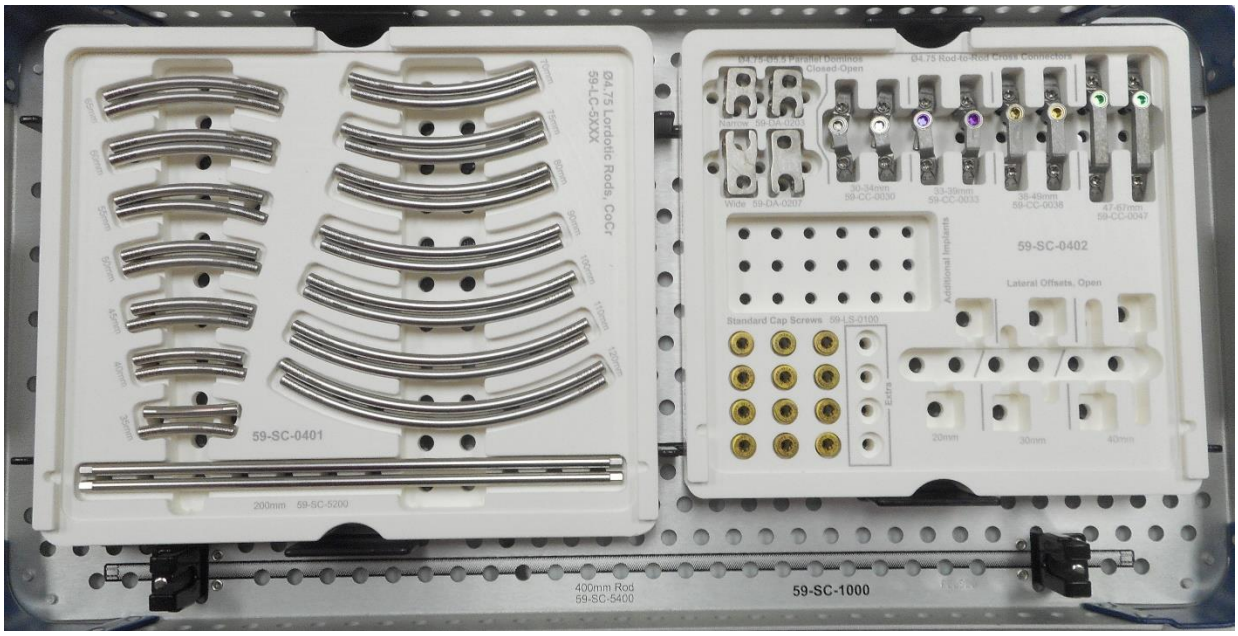
Standard 4.75mm Midline Cortical Approach

- 59-BK-1011 - Implants
  - 4.5, 5.0, 5.5 & 6.5mm Diameter Screws, 4.75mm Tulips, CoCR Rods, Cap Screws, Cross Connectors and Dominoes
- 59-BK-1012 - Implants
  - 4.5, 5.0, 5.5, 6.5 & **7.5mm Diameter Screws**, 4.75mm Tulips, CoCr Rods, Cap Screws, Cross Connectors and Dominoes
- 59-BK-2000
  - Instrument Set 1
- 59-BK-3000
  - Instrument Set 2
- 59-BK-0741
  - Midline Cortical (MC) HA Non-Cannulated Kit (Implants)
- 59-BK-0751
  - Midline Cortical (MC) HA Cannulated Kit (Implants)

Hybrid 5.5mm Pedicular Approach

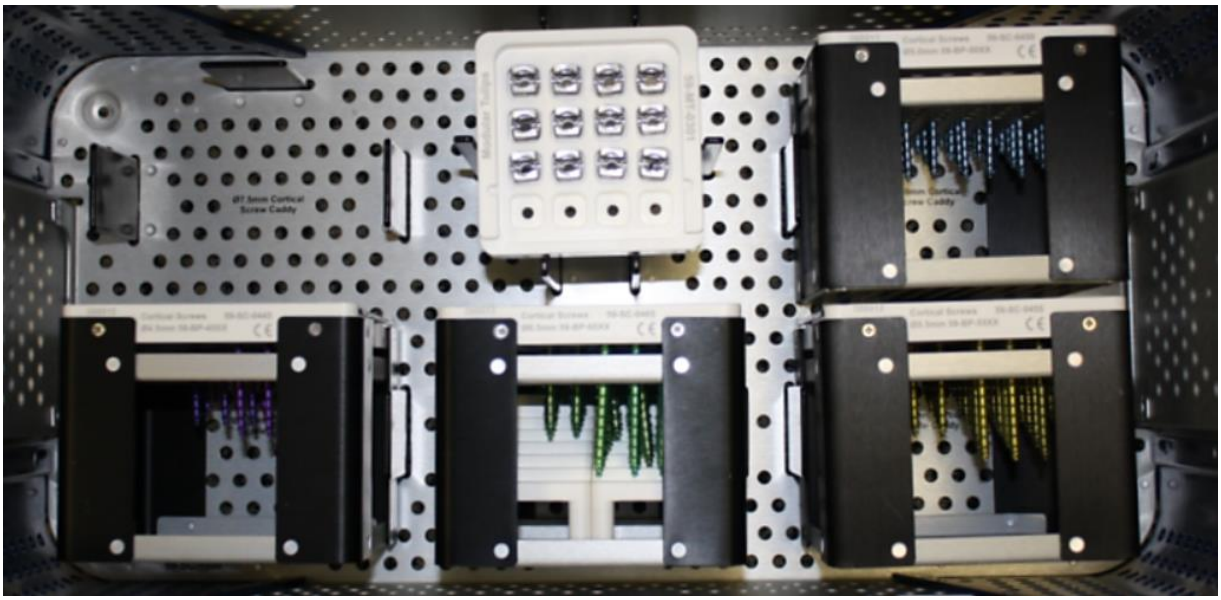
- 39-BK-0811 - Implants
  - 5.5, 6.5 & 7.5mm Diameter Screws, 5.5mm Tulips, **Ti Rods**, Cap Screws, Cross Connectors and Dominoes
- 39-BK-0812 - Implants
  - **4.5**, 5.5, 6.5, 7.5, **8.5 & 9.5mm** Diameter Screws, 5.5mm Tulips, **Ti Rods**, Cap Screws, Cross Connectors and Dominoes
- 39-BK-0813 - Implants
  - 5.5, 6.5 & 7.5mm Diameter Screws, 5.5mm Tulips, **CoCr Rods**, Cap Screws, Cross Connectors and Dominoes
- 39-BK-0814 - Implants
  - **4.5**, 5.5, 6.5, 7.5, **8.5 & 9.5mm** Diameter Screws, 5.5mm Tulips, **CoCr Rods**, Cap Screws, Cross Connectors and Dominoes
- 39-BK-0800
  - Instrument Set 1
- 59-BK-0502
  - Instrument Set 2

REFORM® *MC* IMPLANT TRAY (4.75mm)
59-BK-1011
Top Level



Part Number	Description	Qty
59-LC-5035	Ø4.75 x 35mm Lordotic Rod, CoCr	2
59-LC-5040	Ø4.75 x 40mm Lordotic Rod, CoCr	2
59-LC-5045	Ø4.75 x 45mm Lordotic Rod, CoCr	2
59-LC-5050	Ø4.75 x 50mm Lordotic Rod, CoCr	2
59-LC-5055	Ø4.75 x 55mm Lordotic Rod, CoCr	2
59-LC-5060	Ø4.75 x 60mm Lordotic Rod, CoCr	2
59-LC-5065	Ø4.75 x 65mm Lordotic Rod, CoCr	2
59-LC-5070	Ø4.75 x 70mm Lordotic Rod, CoCr	2
59-LC-5075	Ø4.75 x 75mm Lordotic Rod, CoCr	2
59-LC-5080	Ø4.75 x 80mm Lordotic Rod, CoCr	2
59-LC-5090	Ø4.75 x 90mm Lordotic Rod, CoCr	2
59-LC-5100	Ø4.75 x 100mm Lordotic Rod, CoCr	2
59-LC-5110	Ø4.75 x 110mm Lordotic Rod, CoCr	2
59-LC-5120	Ø4.75 x 120mm Lordotic Rod, CoCr	2
59-SC-5200	Ø4.75 x 200mm Lordotic Rod, CoCr	2
59-SC-5400	Ø4.75 x 400mm Lordotic Rod, CoCr	2
59-DA-0203	5.5-4.75mm Parallel Domino, Open-Closed, Narrow	2
59-DA-0207	5.5-4.75mm Parallel Domino, Open-Closed, Wide	2
59-CC-0030	4.75mm Rod-to-Rod Cross-Connector, 30-34mm	2
59-CC-0033	4.75mm Rod-to-Rod Cross-Connector, 33-39mm	2
59-CC-0038	4.75mm Rod-to-Rod Cross-Connector, 38-49mm	2
59-CC-0047	4.75mm Rod-to-Rod Cross-Connector, 47-67mm	2
59-LS-0100	4.75mm Lock Cap Gold (T25)	12

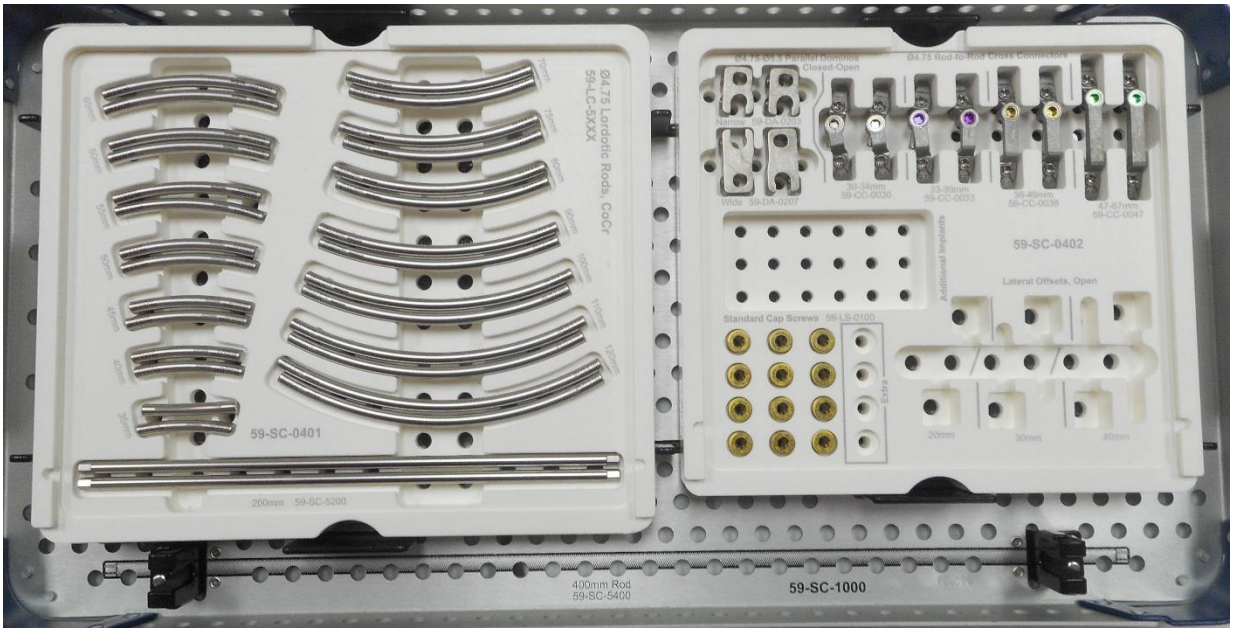
REFORM® *MC* IMPLANT TRAY (4.75mm)
59-BK-1011
Bottom Level



Part Number	Description	Qty
59-BP-4525	Ø4.5 x 25mm MC Bone Screw	4
59-BP-4530	Ø4.5 x 30mm MC Bone Screw	6
59-BP-4535	Ø4.5 x 35mm MC Bone Screw	6
59-BP-4540	Ø4.5 x 40mm MC Bone Screw	6
59-BP-4545	Ø4.5 x 45mm MC Bone Screw	4
59-BP-5025	Ø5.0 x 25mm MC Bone Screw	4
59-BP-5030	Ø5.0 x 30mm MC Bone Screw	6
59-BP-5035	Ø5.0 x 35mm MC Bone Screw	6
59-BP-5040	Ø5.0 x 40mm MC Bone Screw	6
59-BP-5045	Ø5.0 x 45mm MC Bone Screw	6
59-BP-5525	Ø5.5 x 25mm MC Bone Screw	4
59-BP-5530	Ø5.5 x 30mm MC Bone Screw	6
59-BP-5535	Ø5.5 x 35mm MC Bone Screw	6
59-BP-5540	Ø5.5 x 40mm MC Bone Screw	6
59-BP-5545	Ø5.5 x 45mm MC Bone Screw	6
59-BP-5550	Ø5.5 x 50mm MC Bone Screw	4
59-BP-5555	Ø5.5 x 55mm MC Bone Screw	4

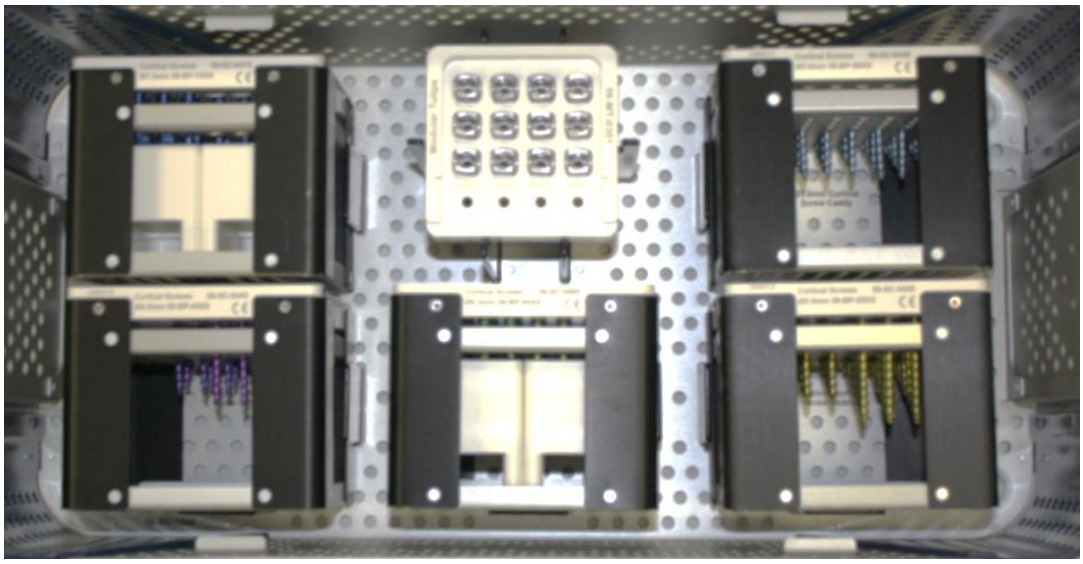
Part Number	Description	Qty
59-BP-5525	Ø5.5 x 25mm MC Bone Screw	4
59-BP-5530	Ø5.5 x 30mm MC Bone Screw	6
59-BP-5535	Ø5.5 x 35mm MC Bone Screw	6
59-BP-5540	Ø5.5 x 40mm MC Bone Screw	6
59-BP-5545	Ø5.5 x 45mm MC Bone Screw	6
59-BP-5550	Ø5.5 x 50mm MC Bone Screw	4
59-BP-5555	Ø5.5 x 55mm MC Bone Screw	4
59-BP-6525	Ø6.5 x 25mm MC Bone Screw	4
59-BP-6530	Ø6.5 x 30mm MC Bone Screw	6
59-BP-6535	Ø6.5 x 35mm MC Bone Screw	6
59-BP-6540	Ø6.5 x 40mm MC Bone Screw	6
59-BP-6545	Ø6.5 x 45mm MC Bone Screw	6
59-BP-6550	Ø6.5 x 50mm MC Bone Screw	4
59-BP-6555	Ø6.5 x 55mm MC Bone Screw	4
59-BP-6560	Ø6.5 x 60mm MC Bone Screw	4
59-MT-0301	4.75mm Standard Screw Tulip	12

REFORM® *MC* IMPLANT TRAY (4.75mm)
59-BK-1012
Top Level



Part Number	Description	Qty
59-LC-5035	Ø4.75 x 35mm Lordotic Rod, CoCr	2
59-LC-5040	Ø4.75 x 40mm Lordotic Rod, CoCr	2
59-LC-5045	Ø4.75 x 45mm Lordotic Rod, CoCr	2
59-LC-5050	Ø4.75 x 50mm Lordotic Rod, CoCr	2
59-LC-5055	Ø4.75 x 55mm Lordotic Rod, CoCr	2
59-LC-5060	Ø4.75 x 60mm Lordotic Rod, CoCr	2
59-LC-5065	Ø4.75 x 65mm Lordotic Rod, CoCr	2
59-LC-5070	Ø4.75 x 70mm Lordotic Rod, CoCr	2
59-LC-5075	Ø4.75 x 75mm Lordotic Rod, CoCr	2
59-LC-5080	Ø4.75 x 80mm Lordotic Rod, CoCr	2
59-LC-5090	Ø4.75 x 90mm Lordotic Rod, CoCr	2
59-LC-5100	Ø4.75 x 100mm Lordotic Rod, CoCr	2
59-LC-5110	Ø4.75 x 110mm Lordotic Rod, CoCr	2
59-LC-5120	Ø4.75 x 120mm Lordotic Rod, CoCr	2
59-SC-5200	Ø4.75 x 200mm Lordotic Rod, CoCr	2
59-SC-5400	Ø4.75 x 400mm Lordotic Rod, CoCr	2
59-DA-0203	5.5-4.75mm Parallel Domino, Open-Closed, Narrow	2
59-DA-0207	5.5-4.75mm Parallel Domino, Open-Closed, Wide	2
59-CC-0030	4.75mm Rod-to-Rod Cross-Connector, 30-34mm	2
59-CC-0033	4.75mm Rod-to-Rod Cross-Connector, 33-39mm	2
59-CC-0038	4.75mm Rod-to-Rod Cross-Connector, 38-49mm	2
59-CC-0047	4.75mm Rod-to-Rod Cross-Connector, 47-67mm	2
59-LS-0100	4.75mm Lock Cap Gold (T25)	12

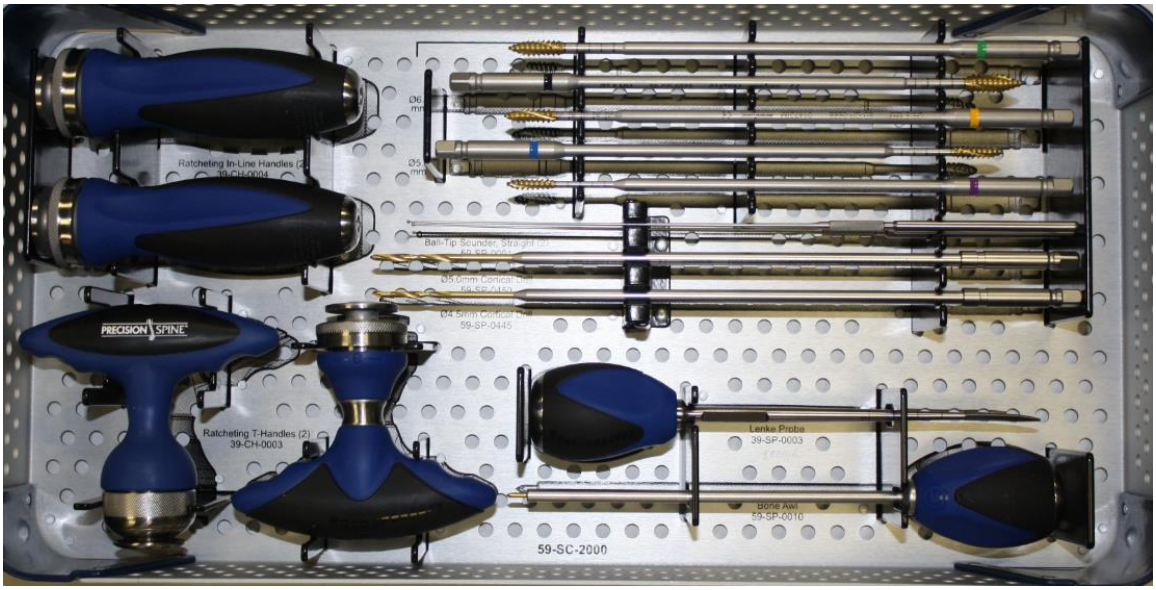
REFORM® *MC* IMPLANT TRAY (4.75mm)
59-BK-1012
Bottom Level



Part Number	Description	Qty
59-BP-4525	Ø4.5 x 25mm MC Bone Screw	4
59-BP-4530	Ø4.5 x 30mm MC Bone Screw	6
59-BP-4535	Ø4.5 x 35mm MC Bone Screw	6
59-BP-4540	Ø4.5 x 40mm MC Bone Screw	6
59-BP-4545	Ø4.5 x 45mm MC Bone Screw	4
59-BP-5025	Ø5.0 x 25mm MC Bone Screw	4
59-BP-5030	Ø5.0 x 30mm MC Bone Screw	6
59-BP-5035	Ø5.0 x 35mm MC Bone Screw	6
59-BP-5040	Ø5.0 x 40mm MC Bone Screw	6
59-BP-5045	Ø5.0 x 45mm MC Bone Screw	6
59-BP-5525	Ø5.5 x 25mm MC Bone Screw	4
59-BP-5530	Ø5.5 x 30mm MC Bone Screw	6
59-BP-5535	Ø5.5 x 35mm MC Bone Screw	6
59-BP-5540	Ø5.5 x 40mm MC Bone Screw	6
59-BP-5545	Ø5.5 x 45mm MC Bone Screw	6
59-BP-5550	Ø5.5 x 50mm MC Bone Screw	4
59-BP-5555	Ø5.5 x 55mm MC Bone Screw	4

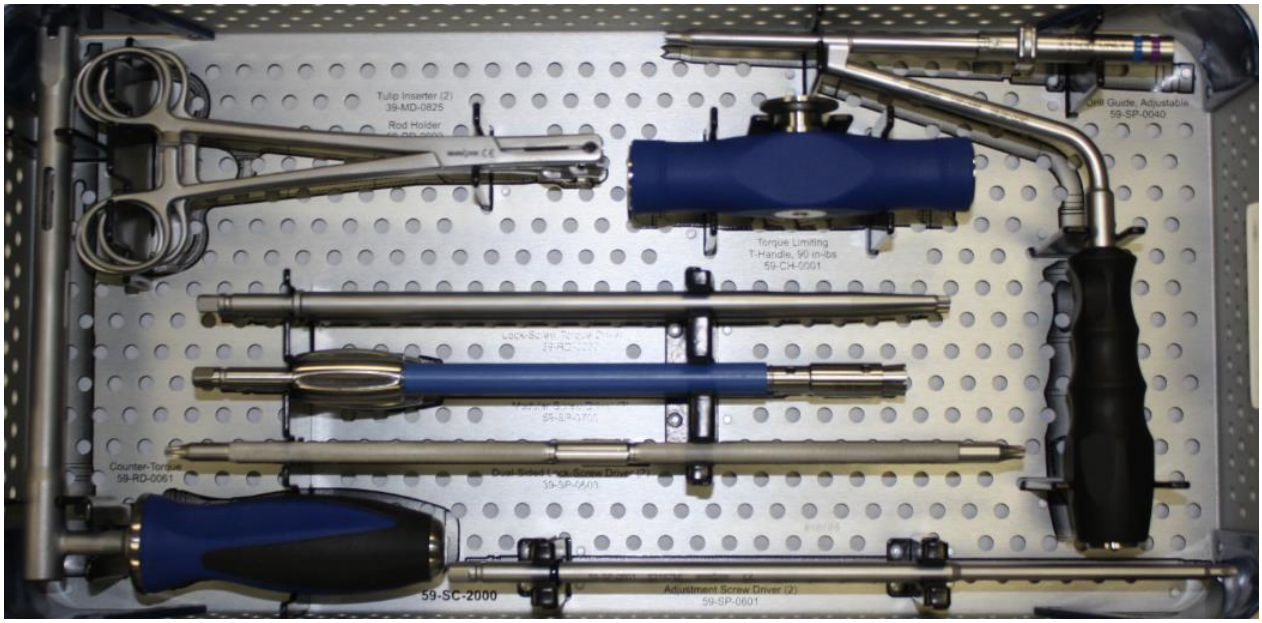
Part Number	Description	Qty
59-BP-6525	Ø6.5 x 25mm MC Bone Screw	4
59-BP-6530	Ø6.5 x 30mm MC Bone Screw	6
59-BP-6535	Ø6.5 x 35mm MC Bone Screw	6
59-BP-6540	Ø6.5 x 40mm MC Bone Screw	6
59-BP-6545	Ø6.5 x 45mm MC Bone Screw	6
59-BP-6550	Ø6.5 x 50mm MC Bone Screw	4
59-BP-6555	Ø6.5 x 55mm MC Bone Screw	4
59-BP-6560	Ø6.5 x 60mm MC Bone Screw	4
59-BP-7530	Ø7.5 x 30mm MC Bone Screw	4
59-BP-7535	Ø7.5 x 35mm MC Bone Screw	6
59-BP-7540	Ø7.5 x 40mm MC Bone Screw	6
59-BP-7545	Ø7.5 x 45mm MC Bone Screw	6
59-BP-7550	Ø7.5 x 50mm MC Bone Screw	6
59-BP-7555	Ø7.5 x 55mm MC Bone Screw	4
59-BP-7560	Ø7.5 x 60mm MC Bone Screw	4
59-BP-7570	Ø7.5 x 70mm MC Bone Screw	2
59-BP-7580	Ø7.5 x 80mm MC Bone Screw	2
59-MT-0301	Ø4.75mm Standard Tulips	12

REFORM® *MC* INSTRUMENT TRAY 1 (4.75mm)
59-BK-2000
Top Level



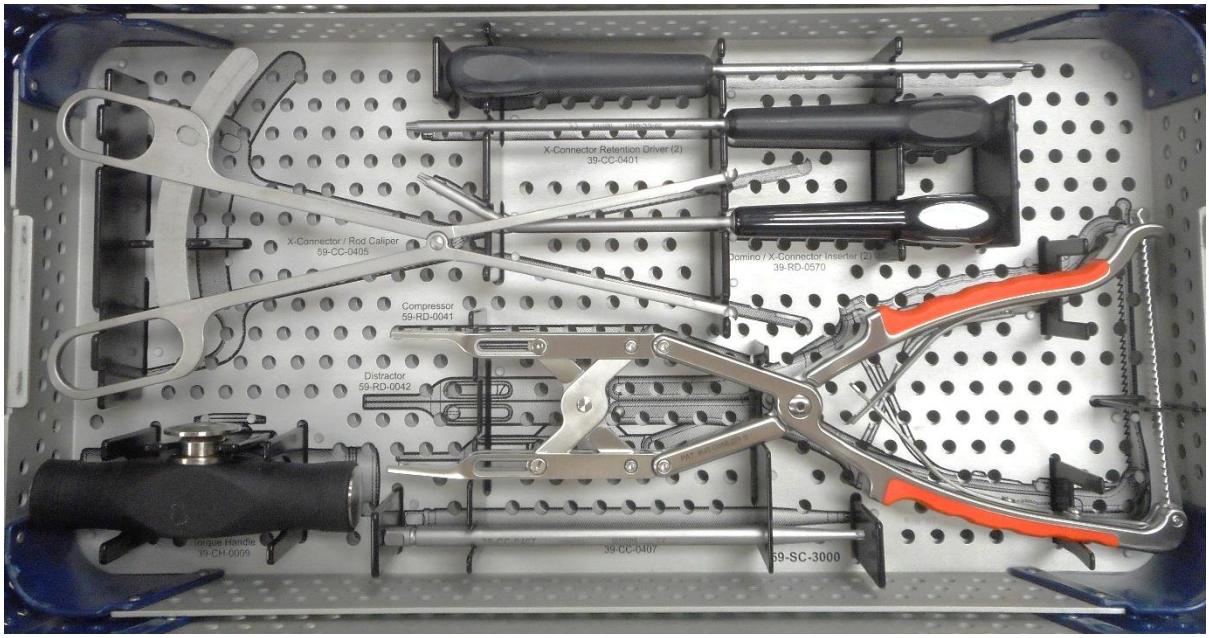
Part Number	Description	Qty
39-CH-0004	Ratcheting Inline-Handles	2
39-CH-0003	Ratcheting T-Handles	2
59-CP-0575	Ø7.5mm Cortical Screw Tap	1
59-CP-0565	Ø6.5mm Cortical Screw Tap	1
59-CP-0555	Ø5.5mm Cortical Screw Tap	1
59-CP-0550	Ø5.0mm Cortical Screw Tap	1
59-CP-0545	Ø4.5mm Cortical Screw Tap	1
59-SP-0001	Ball Tip Sounder, Straight	2
59-SP-0450	Ø5.0mm Cortical Drill	1
59-SP-0445	Ø4.5mm Cortical Drill	1
39-SP-0003	Lenke Probe	1
59-SP-0010	Bone Awl	1

REFORM® *MC* INSTRUMENT TRAY 1 (4.75mm)
59-BK-2000
Bottom Level



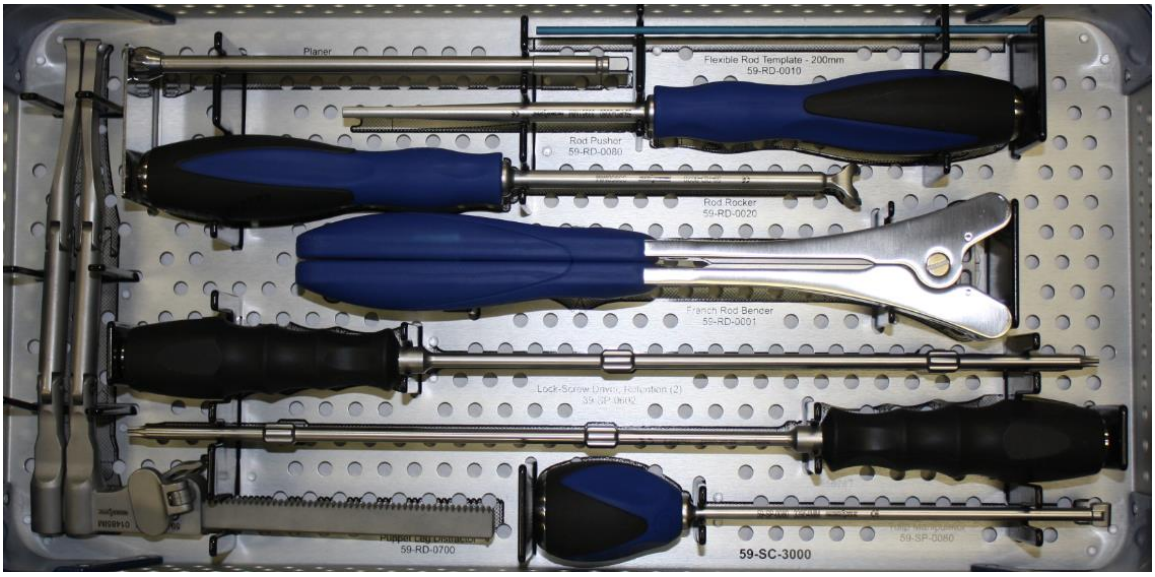
Part Number	Description	Qty
39-MD-0825	Angled Tulip Clamp	2
59-RD-0090	Rod Holder	1
39-RD-0060	Lock Cap Torque Driver (T25)	2
59-SP-0700	Modular Screw Driver (T25)	2
39-SP-0603	Dual-Sided Lock Cap Driver (T25)	2
59-RD-0061	Counter-Torque Wrench (T25)	1
59-SP-0040	Drill Guide, Adjustable	1
59-CH-0001	Torque Limiting T-Handle (90 in-lbs.)	1
59-SP-0601	Adjustment Screw Driver	2

REFORM® *MC* INSTRUMENT TRAY 2 (4.75mm)
59-BK-3000
Bottom Level



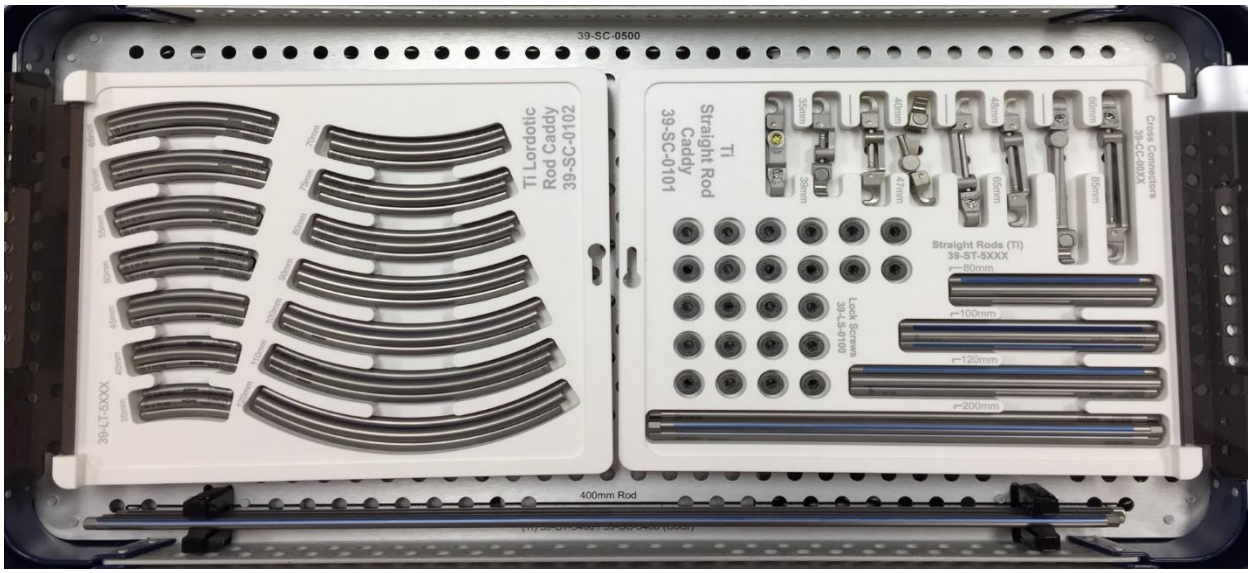
Part Number	Description	Qty.
59-CC-0405	X-Connector/Rod Caliper (T20)	1
39-CH-0009	Domino / X-Connector Torque Handle (66 in-lbs.)	1
39-CC-0401	Domino / X-Connector Retention Drivers (T20)	2
39-RD-0570	Domino / X-Connector Inserter (T20)	2
59-RD-0041	Parallel Compressor	1
39-CC-0407	Domino / X-Connector Torque Shaft	1

REFORM® *MC* INSTRUMENT TRAY 2 (4.75mm)
59-BK-3000
Top Level



Part Number	Description	Qty
59-RD-0010	Flexible Rod Template	1
39-MD-0100	Planer	1
59-RD-0080	Rod Pusher	1
59-RD-0020	Rod Rocker	1
59-RD-0001	French Rod Bender	1
39-SP-0602	Lock-Screw Driver, Retention (T25)	2
59-RD-0700	Puppet Leg Distractor	1
59-SP-0080	Tulip Manipulator	1

REFORM® *MC* IMPLANT TRAY (5.5mm)
39-BK-0811
Top Level



Part Number	Description	Qty
39-LT-5035	Lordotic Rod (Ti), Ø5.5 x 35mm	3
39-LT-5040	Lordotic Rod (Ti), Ø5.5 x 40mm	3
39-LT-5045	Lordotic Rod (Ti), Ø5.5 x 45mm	3
39-LT-5050	Lordotic Rod (Ti), Ø5.5 x 50mm	3
39-LT-5055	Lordotic Rod (Ti), Ø5.5 x 55mm	3
39-LT-5060	Lordotic Rod (Ti), Ø5.5 x 60mm	3
39-LT-5065	Lordotic Rod (Ti), Ø5.5 x 65mm	3
39-LT-5070	Lordotic Rod (Ti), Ø5.5 x 70mm	3
39-LT-5075	Lordotic Rod (Ti), Ø5.5 x 75mm	3
39-LT-5080	Lordotic Rod (Ti), Ø5.5 x 80mm	3
39-LT-5090	Lordotic Rod (Ti), Ø5.5 x 90mm	3
39-LT-5100	Lordotic Rod (Ti), Ø5.5 x 100mm	3
39-LT-5110	Lordotic Rod (Ti), Ø5.5 x 110mm	3
39-LT-5120	Lordotic Rod (Ti), Ø5.5 x 120mm	3

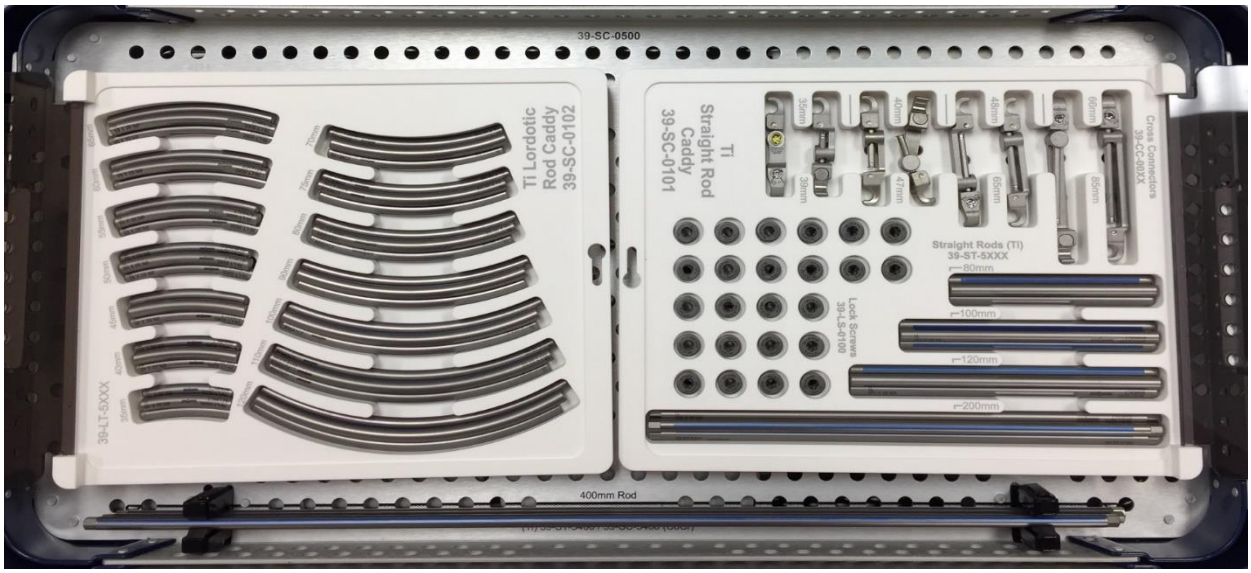
Part Number	Description	Qty
39-CC-0035	35mm Cross Connector	2
39-CC-0040	40mm Cross Connector	2
39-CC-0048	48mm Cross Connector	2
39-CC-0066	66mm Cross Connector	2
39-LS-0100	Lock Screw (T25)	24
39-ST-5080	Straight Rod (Ti), Ø5.5 x 80mm	3
39-ST-5100	Straight Rod (Ti), Ø5.5 x 100mm	3
39-ST-5120	Straight Rod (Ti), Ø5.5 x 120mm	3
39-ST-5200	Straight Rod (Ti), Ø5.5 x 200mm	3
39-ST-5400	Straight Rod (Ti), Ø5.5 x 400mm	3

REFORM® *MC* IMPLANT TRAY (5.5mm)
39-BK-0811
Bottom Level

Part Number	Description	Qty
59-BP-5530	Ø5.5 x 30mm MC Bone Screw	6
59-BP-5535	Ø5.5 x 35mm MC Bone Screw	6
59-BP-5540	Ø5.5 x 40mm MC Bone Screw	8
59-BP-5545	Ø5.5 x 45mm MC Bone Screw	8
59-BP-5550	Ø5.5 x 50mm MC Bone Screw	6
59-BP-6530	Ø6.5 x 30mm MC Bone Screw	6
59-BP-6535	Ø6.5 x 35mm MC Bone Screw	6
59-BP-6540	Ø6.5 x 40mm MC Bone Screw	10
59-BP-6545	Ø6.5 x 45mm MC Bone Screw	10
59-BP-6550	Ø6.5 x 50mm MC Bone Screw	8
59-BP-6555	Ø6.5 x 55mm MC Bone Screw	8

Part Number	Description	Qty
59-BP-7535	Ø7.5 x 35mm MC Bone Screw	6
59-BP-7540	Ø7.5 x 40mm MC Bone Screw	8
59-BP-7545	Ø7.5 x 45mm MC Bone Screw	8
59-BP-7550	Ø7.5 x 50mm MC Bone Screw	6
59-BP-7555	Ø7.5 x555mm MC Bone Screw	6
39-MT-0301	Standard Tulip	25
39-MT-0302	Reduction Tulip	10

REFORM® *MC* IMPLANT TRAY (5.5mm)
39-BK-0812
Top Level



Part Number	Description	Qty
39-LT-5035	Lordotic Rod (Ti), Ø5.5 x 35mm	3
39-LT-5040	Lordotic Rod (Ti), Ø5.5 x 40mm	3
39-LT-5045	Lordotic Rod (Ti), Ø5.5 x 45mm	3
39-LT-5050	Lordotic Rod (Ti), Ø5.5 x 50mm	3
39-LT-5055	Lordotic Rod (Ti), Ø5.5 x 55mm	3
39-LT-5060	Lordotic Rod (Ti), Ø5.5 x 60mm	3
39-LT-5065	Lordotic Rod (Ti), Ø5.5 x 65mm	3
39-LT-5070	Lordotic Rod (Ti), Ø5.5 x 70mm	3
39-LT-5075	Lordotic Rod (Ti), Ø5.5 x 75mm	3
39-LT-5080	Lordotic Rod (Ti), Ø5.5 x 80mm	3
39-LT-5090	Lordotic Rod (Ti), Ø5.5 x 90mm	3
39-LT-5100	Lordotic Rod (Ti), Ø5.5 x 100mm	3
39-LT-5110	Lordotic Rod (Ti), Ø5.5 x 110mm	3
39-LT-5120	Lordotic Rod (Ti), Ø5.5 x 120mm	3

Part Number	Description	Qty
39-CC-0035	35mm Cross Connector	2
39-CC-0040	40mm Cross Connector	2
39-CC-0048	48mm Cross Connector	2
39-CC-0066	66mm Cross Connector	2
39-LS-0100	Lock Screw	24
39-ST-5080	Straight Rod (Ti), Ø5.5 x 80mm	3
39-ST-5100	Straight Rod (Ti), Ø5.5 x 100mm	3
39-ST-5120	Straight Rod (Ti), Ø5.5 x 120mm	3
39-ST-5200	Straight Rod (Ti), Ø5.5 x 200mm	3
39-ST-5400	Straight Rod (Ti), Ø5.5 x 400mm	3

REFORM® *MC* IMPLANT TRAY (5.5mm)
39-BK-0812
Bottom Level

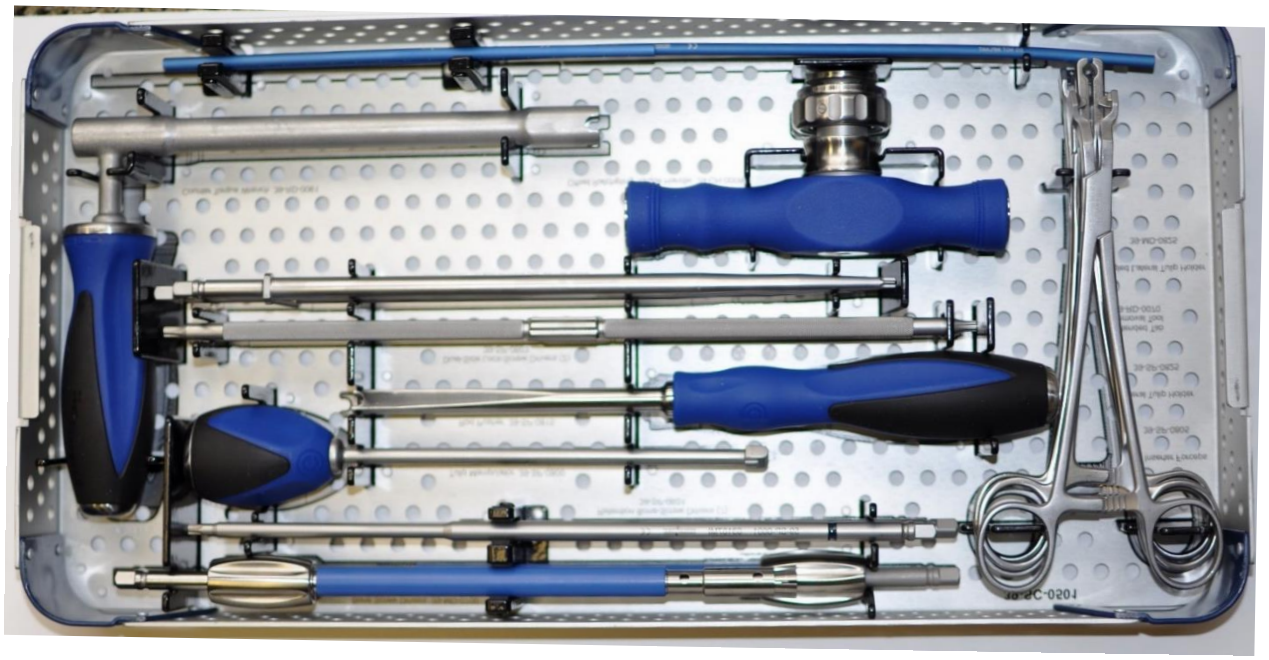
Part Number	Description	Qty
59-BP-5530	Ø5.5 x 30mm MC Bone Screw	6
59-BP-5535	Ø5.5 x 35mm MC Bone Screw	6
59-BP-5540	Ø5.5 x 40mm MC Bone Screw	6
59-BP-5545	Ø5.5 x 45mm MC Bone Screw	6
59-BP-5550	Ø6.5 x 30mm MC Bone Screw	6
59-BP-6530	Ø6.5 x 35mm MC Bone Screw	6
59-BP-6535	Ø6.5 x 35mm MC Bone Screw	6
59-BP-6540	Ø6.5 x 40mm MC Bone Screw	6
59-BP-6545	Ø6.5 x 45mm MC Bone Screw	6
59-BP-6550	Ø6.5 x 50mm MC Bone Screw	6
59-BP-6555	Ø6.5 x 55mm MC Bone Screw	6
59-BP-7535	Ø7.5 x 35mm MC Bone Screw	6
59-BP-7540	Ø7.5 x 40mm MC Bone Screw	6
59-BP-7545	Ø7.5 x 45mm MC Bone Screw	6
59-BP-7550	Ø7.5 x 50mm MC Bone Screw	6
59-BP-7555	Ø7.5 x 55mm MC Bone Screw	6
39-MT-0301	Standard Tulip	25
39-MT-0302	Reduction Tulip	10

Part Number	Description	Qty
59-BP-4525	Ø4.5 x 25mm MC Bone Screw	2
59-BP-4530	Ø4.5 x 30mm MC Bone Screw	2
59-BP-4535	Ø4.5 x 35mm MC Bone Screw	2
59-BP-4540	Ø4.5 x 40mm MC Bone Screw	4
59-BP-4545	Ø4.5 x 45mm MC Bone Screw	4
59-BP-8540	Ø8.5 x 40mm MC Bone Screw	4
59-BP-8545	Ø8.5 x 45mm MC Bone Screw	4
59-BP-8550	Ø8.5 x 50mm MC Bone Screw	2
59-BP-8555	Ø8.5 x 55mm MC Bone Screw	2
59-BP-8560	Ø8.5 x 60mm MC Bone Screw	2
59-BP-8570	Ø8.5 x 70mm MC Bone Screw	2
59-BP-8580	Ø8.5 x 80mm MC Bone Screw	2
59-BP-9560	Ø9.5 x 60mm MC Bone Screw	2
59-BP-9570	Ø9.5 x 70mm MC Bone Screw	2
59-BP-9580	Ø9.5 x 80mm MC Bone Screw	2

REFORM® *MC* INSTRUMENT TRAY (5.5mm)
39-BK-0800
Top Level

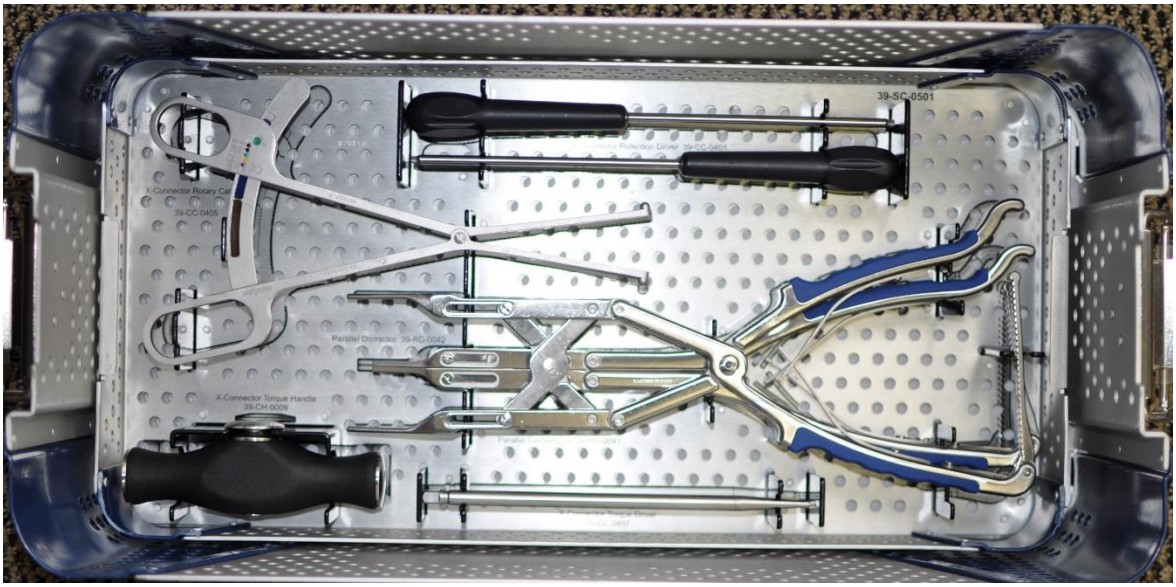
Part Number	Description	Qty
39-CH-0004	Ratcheting Inline-Handles	2
39-CH-0003	Ratcheting T-Handles	2
59-CP-0595	Ø9.5mm Cortical Screw Tap	1
59-CP-0585	Ø8.5mm Cortical Screw Tap	1
59-CP-0575	Ø7.5mm Cortical Screw Tap	1
59-CP-0565	Ø6.5mm Cortical Screw Tap	1
59-CP-0555	Ø5.5mm Cortical Screw Tap	1
59-CP-0545	Ø4.5mm Cortical Screw Tap	1
39-SP-0011	Ball Tip Sounder, Straight	2
39-SP-0007	Straight Pedicle Probe	1
39-SP-0005	Duckbill Pedicle Probe	1
39-SP-0003	Curved Pedicle Probe	1
39-SP-0001	Bone Awl	1

REFORM® *MC* INSTRUMENT TRAY (5.5mm)
39-BK-0800
Middle Level



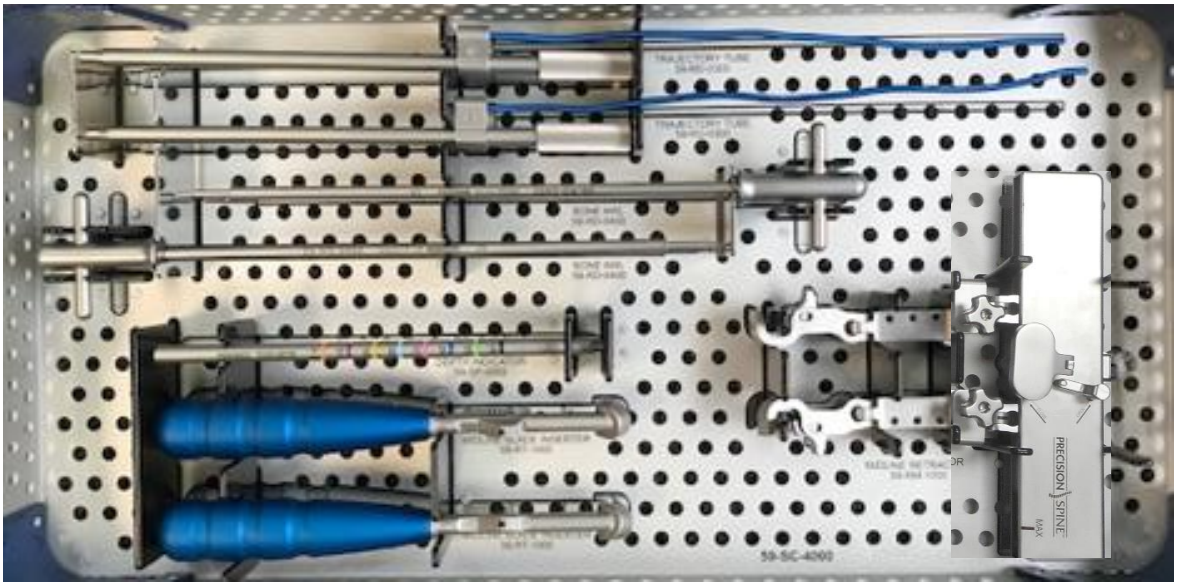
Part Number	Description	Qty
39-RD-0010	Flexible Rod Template-200mm	1
39-RD-0011	Flexible Rod Template - 400mm	1
39-RD-0061	Counter Torque Wrench	1
39-RD-0060	Lock-Screw Torque Driver (T25)	2
39-SP-0603	Dual-Side Lock-Screw Driver (T25)	2
39-SP-0815	Rod Pusher	1
39-SP-0800	Tulip Manipulator	1
59-SP-0601	Retention Bone Screw Driver (T25)	2
59-SP-0700	Screw Driver, Modular Screw (T25)	2
39-CH-0008	Ratcheting Torque Handle	1
39-MD-0825	Angled Tulip Clamp	2
39-SP-0805	Rod Insertor Forceps	1
39-RD-0070	Extended Tab Removal Tool	1

REFORM® *MC* INSTRUMENT TRAY (5.5mm)
39-BK-0800
Bottom Level



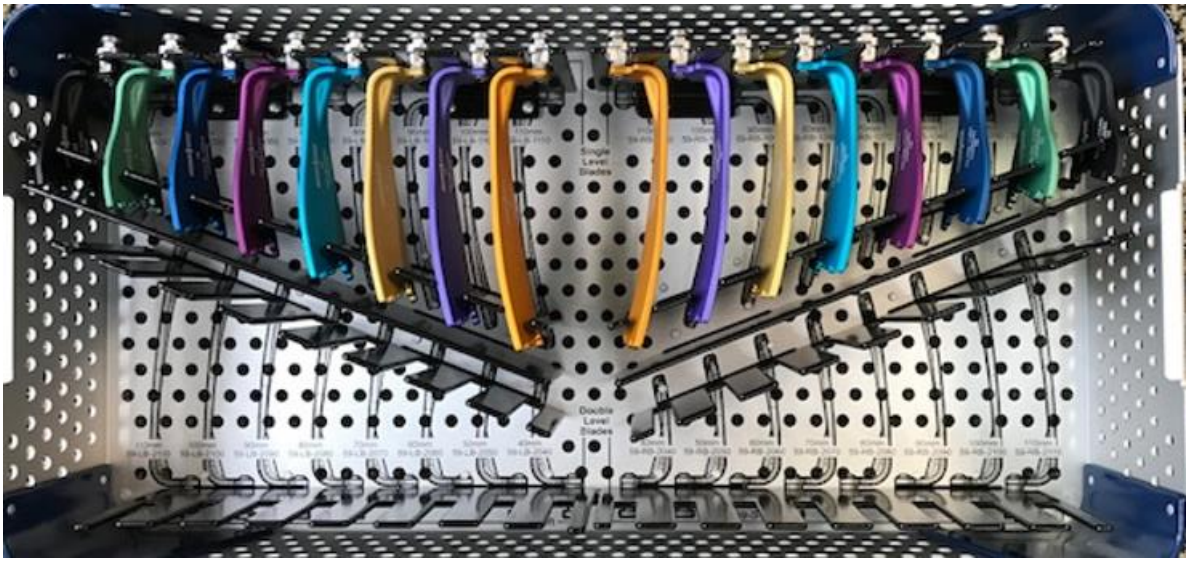
Part Number	Description	Qty
39-CC-0401	Domino / X-Connector Retention Driver (T20)	2
39-CC-0405	X-Connector Rotary Caliper	1
39-RD-0041	Parallel Compressor	1
39-RD-0042	Parallel Distractor	1
39-CH-0009	Domino / X-Connector Torque Handle (66 in-lbs.)	1
39-CC-0407	Domino / X-Connector Torque Driver (T20)	1

REFORM® *MC* RETRACTOR KIT
59-BK-4000
Middle Level



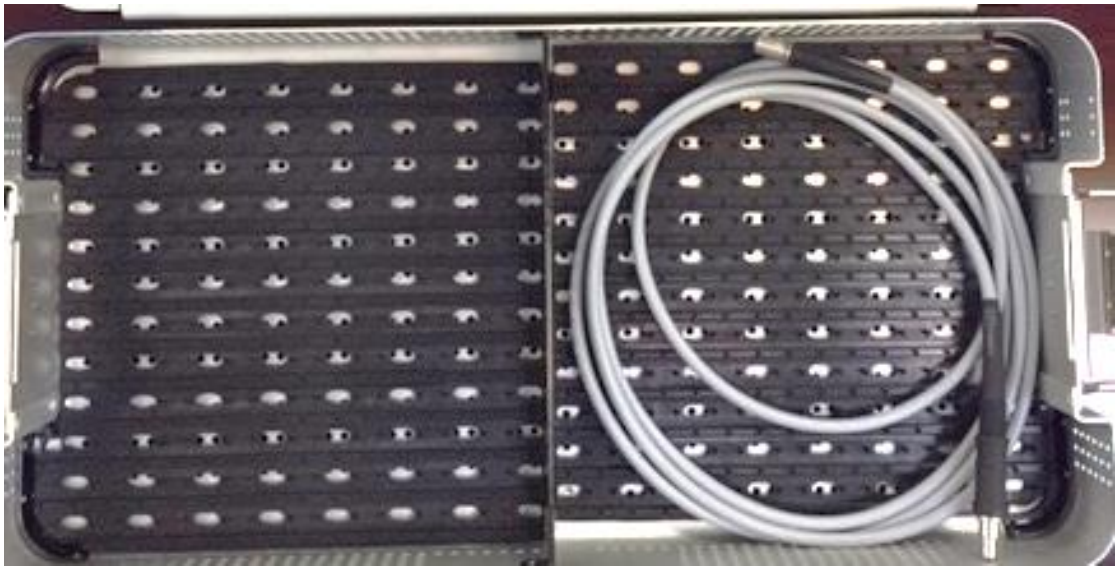
Part Number	Description	Qty
59-RD-0300	Trajectory Tube	2
59-RD-0400	Bone Awl	2
59-SP-0002	Depth Indicator	1
59-RT-1000	Midline Blade Inserter	2
59-RM-1000	Midline Retractor	1

REFORM® *MC* RETRACTOR KIT
59-BK-4000
Top Level



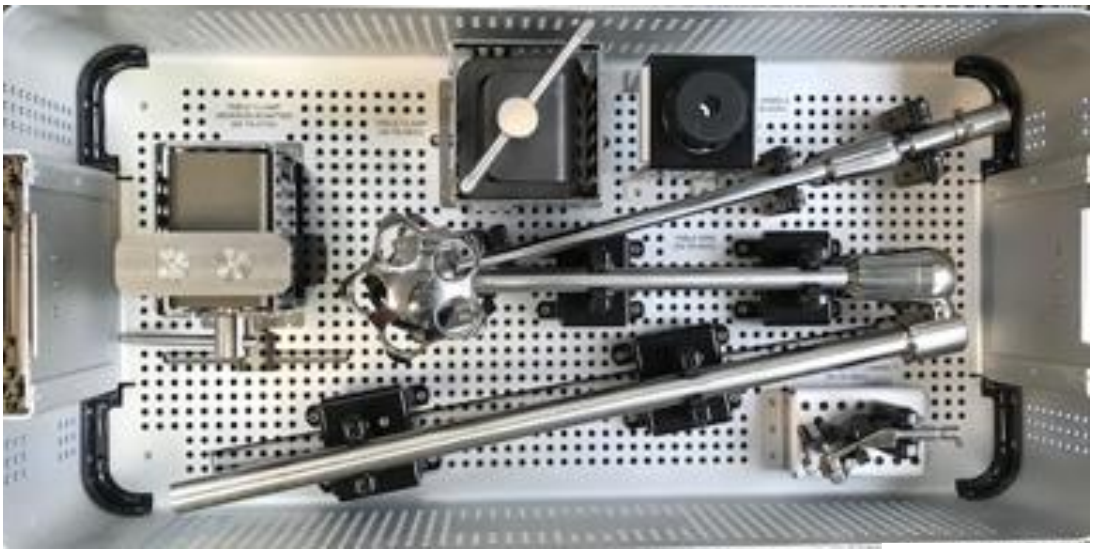
Part Number	Description	Qty
59-LB-1040	40mm Single Level Blade	1
59-LB-1050	50mm Single Level Blade	1
59-LB-1060	60mm Single Level Blade	1
59-LB-1070	70mm Single Level Blade	1
59-LB-1080	80mm Single Level Blade	1
59-LB-1090	90mm Single Level Blade	1
59-LB-1100	100mm Single Level Blade	1
59-LB-1110	110mm Single Level Blade	1
59-RB-1040	40mm Single Level Blade	1
59-RB-1050	50mm Single Level Blade	1
59-RB-1060	60mm Single Level Blade	1
59-RB-1070	70mm Single Level Blade	1
59-RB-1080	80mm Single Level Blade	1
59-RB-1090	90mm Single Level Blade	1
59-RB-1100	100mm Single Level Blade	1
59-RB-1110	110mm Single Level Blade	1

REFORM® *MC* RETRACTOR KIT
59-BK-4000
Bottom Level



Part Number	Description	Qty
59-LC-5100	Reusable Light Cable	1
59-LS-5000	Reform MC Surgical Illuminator (Sterile) Must be Ordered Separately	

REFORM® *MC* TABLE ARM TRAY
54-BK-2000



Part Number	Description	Qty
54-TA-0700	Jackson Adapter Clamp	1
54-TA-0600	Table Arm Clamp	1
54-RB-2000	Posterior Lobe Handle	1
54-TA-0500	Table Arm	1
54-TA-0800	Table Arm Quick Connect	1

PROCEDURE OVERVIEW

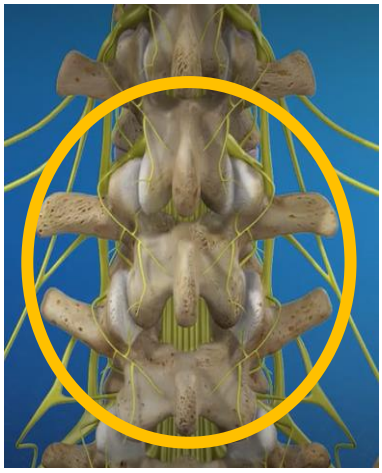
The Reform® MC System is designed to provide instrumentation and implants for a medial to lateral approach for spinal fixation.
This technique is commonly referred to as the midline cortical approach. This surgical technique guide may be used to illustrate the cortical approach and its differences compared to a traditional transpedicular surgical approach.

The Reform MC System is built off of the Reform Spinal Fixation Platform and features many of the same benefits, instruments, markings, color coding, and layout as the Reform Spinal Fixation System.

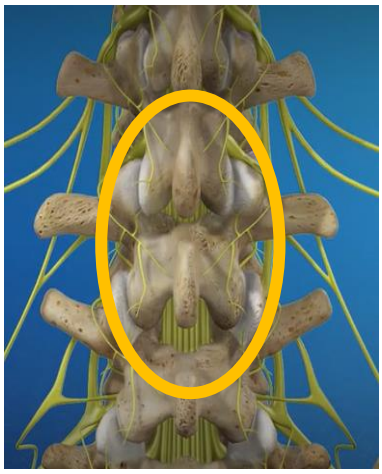
The midline cortical (MC) approach allows the surgeon to provide decompression, interbody fusion, and fixation through a laminectomy size incision. The starting point of the MC approach is medial to the superior articulating process, inferior to the transverse process, and approximately 3-5mm medial to the lateral border of the pars interarticularis.

Due to the size of the incision, the surgeon has two options relative to the timing of screw placement. Some surgeons may choose to place the screws prior to decompression and interbody placement to ensure the screw is placed properly. Others may choose to place the screws after the interbody cage(s) have been placed.

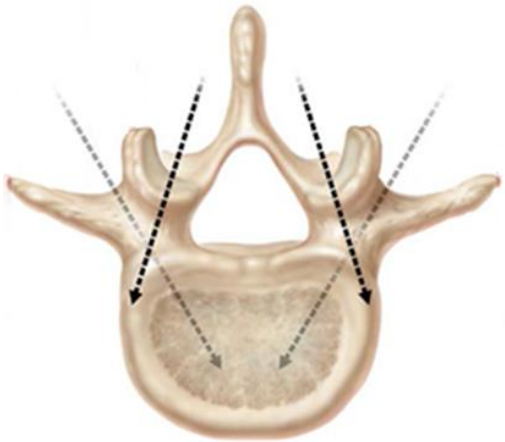
If surgeons chose the latter option, it is important to leave adequate bone near the pars interarticularis to place the screws. For purposes of this technique, instruction will be given for screw placement prior to decompression. The midline cortical pedicle screw trajectory follows a mediolateral and caudocranial path through the pedicle. This approach maximizes the screw's contact with cortical bone which enhances the thread purchase while minimizing soft tissue retraction.



Transpedicular Incision



Midline Cortical Incision



SURGICAL TECHNIQUE

1 EXPOSURE

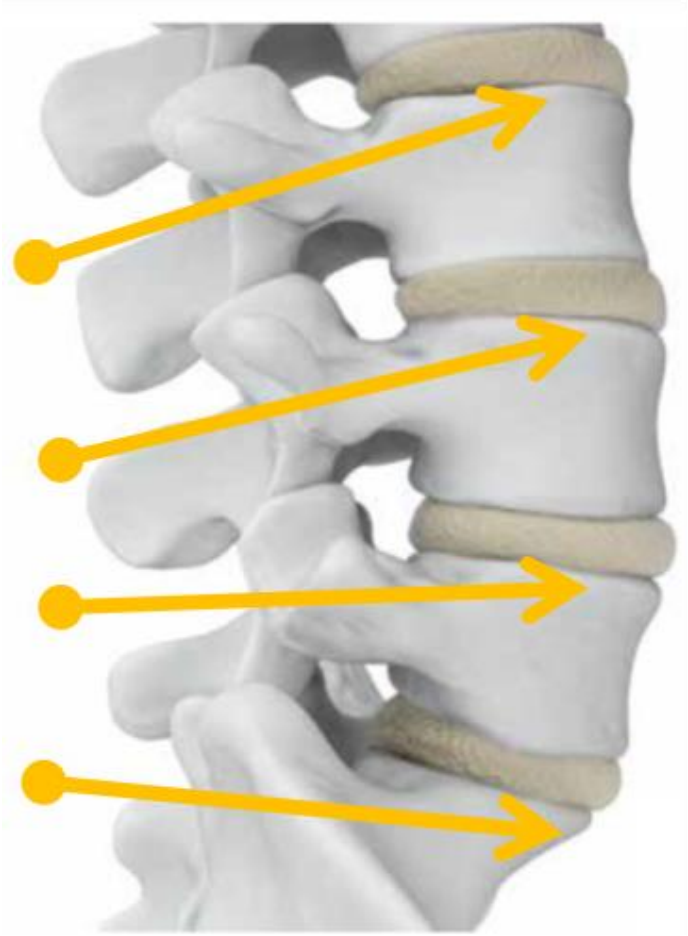
Under fluoroscopic guidance, obtain a true A/P and lateral image in order to identify the starting location. Create a midline skin incision over the spinous process that spans from the inferior 1/3 of the cranial spinous process to the center of the caudal spinous process. Elevate the muscles to the lateral edge of the pars and to the joint line. Expose to mid facet at the cephalad level and to mid lamina at the caudal level. Use a gelpi style retractor to maintain the exposure.

2 SCREW TRAJECTORY

The trajectory for the screw is approximately 20 degrees medial to lateral and 30 to 45 degrees caudal to cephalad. The trajectory should ensure that the screw shank remains within the pars.

The starting point should be 1-2mm medial of the lateral border of the pars and the inferior portion of the transverse process, inferior to the upper facet complex (Figure 1).

The distal tip of the screw should stop approximately at the intersection of the second 1/3 and last 1/3 of the vertebral body (Figures 2 and 3).



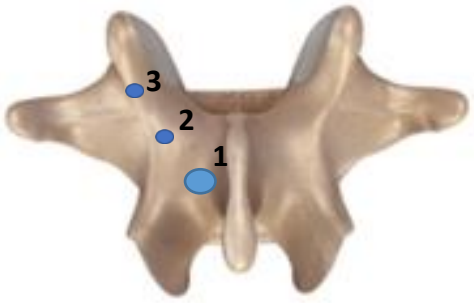


Figure 1

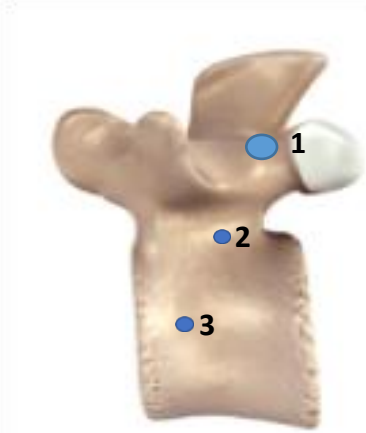


Figure 2

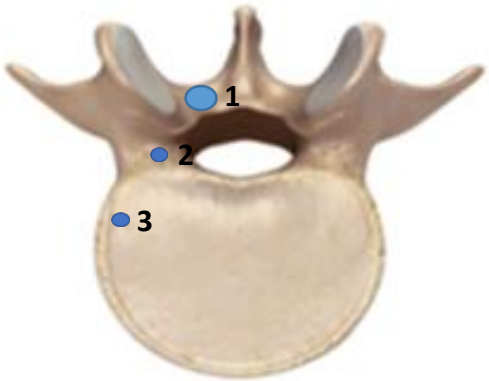


Figure 3

SURGICAL TECHNIQUE

3 SCREW HOLE PREPARATION

Create a 2 -3mm pilot hole by penetrating the cortical bone through the pars interarticularis using the Bone Awl (59-SP-0010) (Figure 3a)

Once the trajectory has been determined, place the distal tip of the Adjustable Drill Guide (59-SP-0040) over the starting point (Figure 3b). Load either the 4.5mm (59-SP-0445) or 5.0mm (59-SP-0450) drill on either the Ratcheting Inline Handle (39-CH-0004) or the Ratcheting T Handle (39-CH-0003).

Place the drill into the Drill Guide and advance into the pedicle. Depth can be set using the optional Depth Stop on the Drill Guide and should always be confirmed with fluoroscopy.

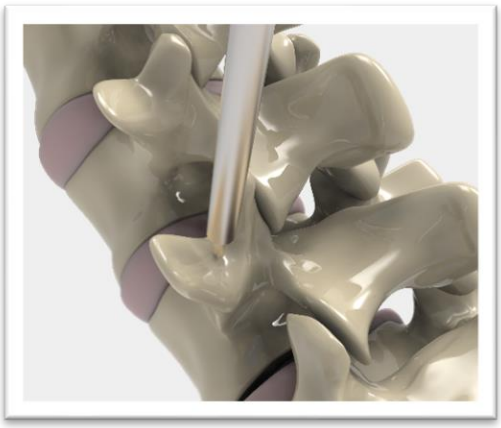


Figure 3a

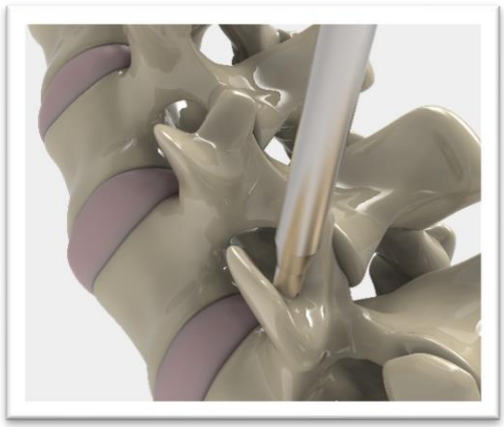


Figure 3b

3 SCREW HOLE PREPARATION (continued)

A pathway can be further established through the cortex with the Lenke probe (39-SP-0003) (Figure 3c). Aim for the posterior 1/3 or mid portion of the superior endplate in the sagittal plane while aiming 20 degrees medial to lateral.

The prepared pathway can be explored with the Ball Tip Sounder (59-SP-0001) (Figure 3d) to confirm the existence of bone along the walls of the screw trajectory.

Figure 3c

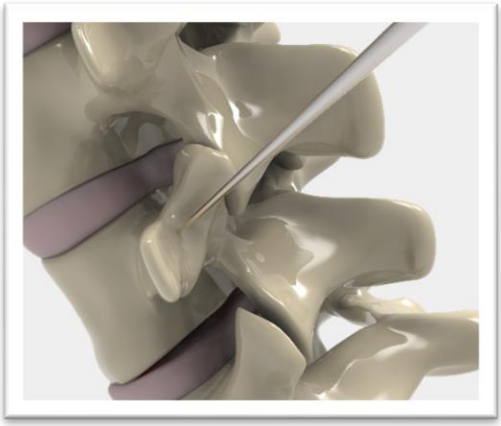


Figure 3d

3 SCREW HOLE PREPARATION (continued)

Under lateral fluoro, tap the pilot hole with the same diameter tap as the bone screw diameter selected. Due to the hardness of the bone, only tap to the depth of the gold coating.

Taps can be utilized with the Ratcheting In-line Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003). Repeat the preparation procedure for each pedicle that has been identified for instrumentation.

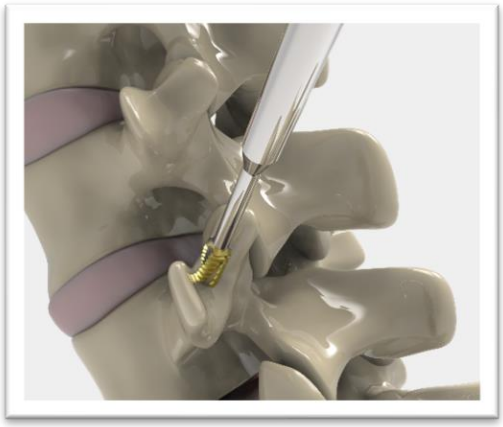


Figure 3e

4.5mm Tap
5.0mm Tap
5.5mm Tap
6.5mm Tap
7.5mm Tap

SURGICAL TECHNIQUE

4 SCREW INSERTION

With the pathway prepared and screw length and diameter determined, the appropriate Screw is loaded for insertion on the Screw Driver Assembly.

The Modular Screw Driver (59-SP-0700) is attached to either the Ratcheting Inline Handle (39-CH-0004) or Ratcheting T-Handle (39-CH-0003).

Depress the silver collet on the Inline Handle or T-Handle and insert the Modular Screw 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.

The Modular Screw is now attached to the Screw Driver Assembly. 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 Driver Handle to the "Forward" position. Hold onto the scalloped knob of the Modular Driver and turn the Driver Handle counterclockwise until the screw is fully tightened and the driver sleeve completely surrounds the collet.

5 SCREW INSERTION (continued)

Insert the screw so that it is positioned at the posterior 1/3 of the superior endplate (Figure 5a). Ensure that the screw head is above the pars to avoid damage to the facet capsule.

To disengage the Driver from the screw, move the Driver Handle to the "Reverse" position (Figure 5b), hold the Modular Driver's scalloped knob and turn Ratcheting Handle clockwise.

Repeat the procedure for Modular Screw Insertion in each pedicle identified for instrumentation.

Figure 5a

Figure 5b

6 BONE DECORTICATION

Place the bone Planar (39-MD-0100) over the head of the Modular Screw (Figure 6) and rotate the Planar clockwise and counterclockwise to decorticate the bone and allow for optimal seating of the Modular Tulip.

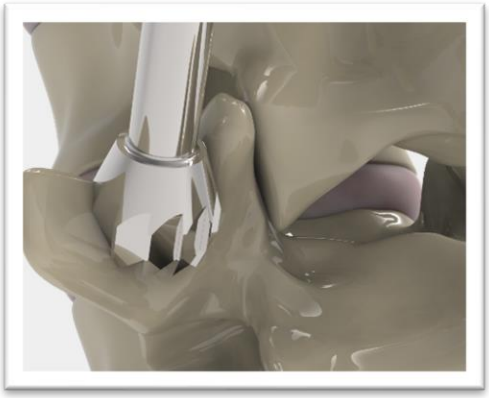


Figure 6

SURGICAL TECHNIQUE

7 DISTRACTION

To distract off of the bone screws, align the distal tips of the Puppet Leg Distractor (59-RD-0700) (Figure 7a) arms with the head of the bone screws. Once the arms are seated (Figure 7b), distraction can be achieved. Care should be taken not to over distract the disc space.

Figure 7a

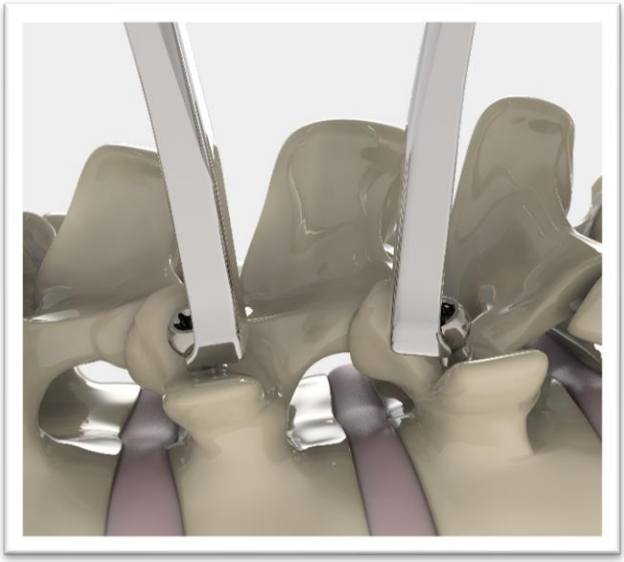


Figure 7b

8 TULIP INSERTION

Attach the appropriate Modular Tulip to the Angled Lateral Tulip Clamp (39-MD-0825) by aligning the inside tabs of the Tulip Clamp with the insets of the Modular Tulip (Figure 8a).

Slide the Tulip over the Bone Screw and apply an axial force until an audible click is heard (Figure 8b).

Upward pressure of the attached Angled Tulip Clamp can be applied to ensure that the Tulip is properly inserted (Figure 8c).

Figure 8a

Figure 8b

Figure 8c

9 ROD INSERTION

Once all screws have been inserted, the appropriate rod should be selected such that it fully fits into each of the tulips bilaterally (Figure 9a).

A Flexible Rod Template (59-RD-0010) or Rotary Caliper (59-CC-0405) (Figure 9b) may be used to measure the appropriate length Rod including rod overhang.

Use the appropriate pre-cut rod or cut a longer rod using a rod cutter (rod cutter not provided). Place the rod using the Rod Holder (Figure 9c).

The polyaxial screw design will allow for some lateral screw offset.

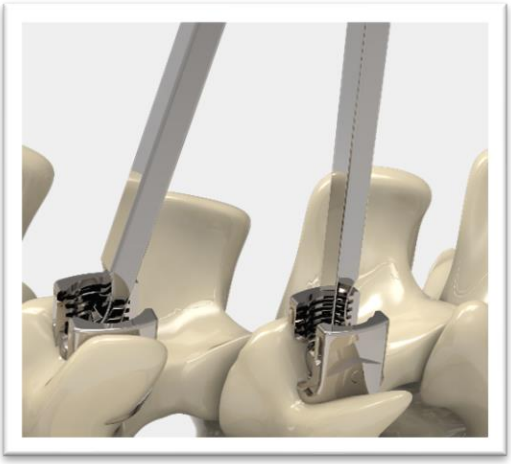


Figure 9a

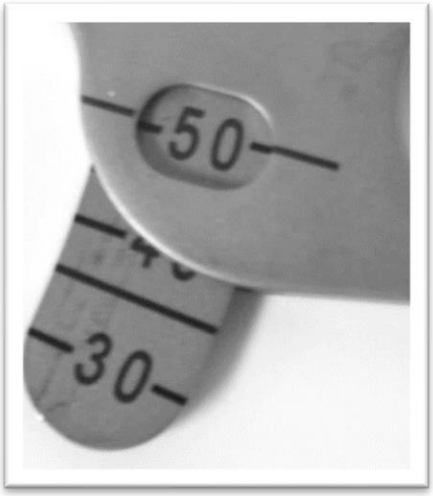


Figure 9b

Figure 9c

9 ROD INSERTION (continued)

The rod must be seated in the Reform® *MC* screw head in order to engage the Gold Lock Cap (59-LS-0100) for tightening. There are two alternative instruments used for this process.

OPTION 1

The Rod Pusher (59-RD-0080) can be used to seat the rod (Figure 9d). For constructs with two or more levels, begin with the central screw.

OPTION 2

The Rod Rocker (59-RD-0200) (Figure 9e) can be utilized to seat the rod within the screw tulip. The Rod Rocker easily slides into the lateral slots on the side of the tulip and is rotated backwards. This levers the rod into the tulip.

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 tulip.

Once the rod is properly in place, load the Gold Lock Cap from the caddy using the Dual Sided Lock Cap Driver (39-SP-0603) or the Bone Screw Retention Driver (39-SP-0602). Place the Lock Cap into the tulip and rotate clockwise until provisionally tightened. (Figure 9f)

Figure 9d

Figure 9e

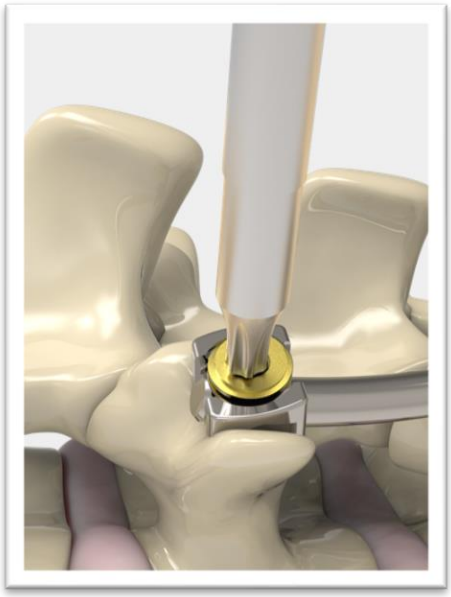


Figure 9f

10 FINAL TIGHTENING

Final tightening of the construct should be performed when all screws and rods are in their final positions.

Connect the Torque Limiting T-Handle (59-CH-0001) to the Lock Cap Torque Driver (39-RD-0060).

Insert the Torque Driver Assembly through the cannula of the Anti-Torque Wrench (59-RD-0061) and engage the tip of the Torque Driver into the Lock Cap. (Figure 10a)

Slide the Anti-Torque down until the instrument is fully seated over the rod and tulip. (Figure 10b) Turn T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks at 90 in-lbs.

Figure 10a

Figure 10b

11 CROSS-CONNECTOR INSERTION

Cross-Connectors can be added to increase the torsional stability of a construct. The Caliper (59-CC-0405) can be used to determine the proper length of the Cross-Connector. (Figures 11a & 11b)

Two Self-Retaining T20 Retention Drivers (39-CC-0401) are provided to engage and retain the Cross-Connector cams during placement. 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 retention 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 11c)

CROSS-CONNECTOR 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 T20 Retention Driver into each Cam and turn 90° counterclockwise to loosen from the rods.

Figure 11a

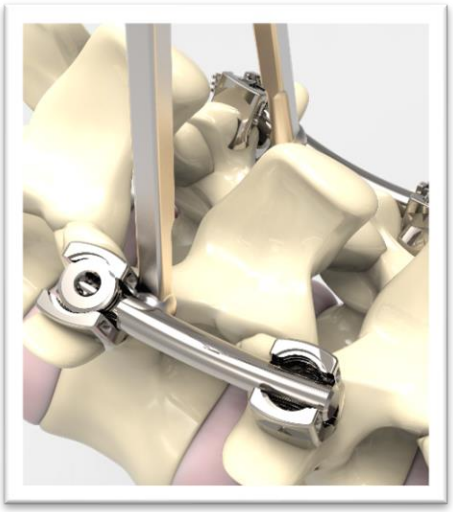


Figure 11b

Figure 11c

SURGICAL TECHNIQUE

12 REFORM® *MC* RETRACTOR

Once the incision has been made, Position the Depth Indicator (59-SP-0002) into the incision and advance it carefully while controlling the position under fluoroscopy. (Figure 12a)

Select the appropriate retractor blade length by noting the markings on the Depth Indicator (Figure 12b). Choose one right (59-RB-1XXX) and one left blade (59-LB-1XXX) (Figure 12c). Use the shortest allowable blades to access the posterior bony structures.

Attach the Blade to the Midline Blade Inserter (59-RT-1000) by pushing up the knurled thumb knob and placing the Inserter onto the Blade Fitting. (Figure 12d)

Figure 12a

Figure 12b

Left Blade Right Blade

Figure 12c

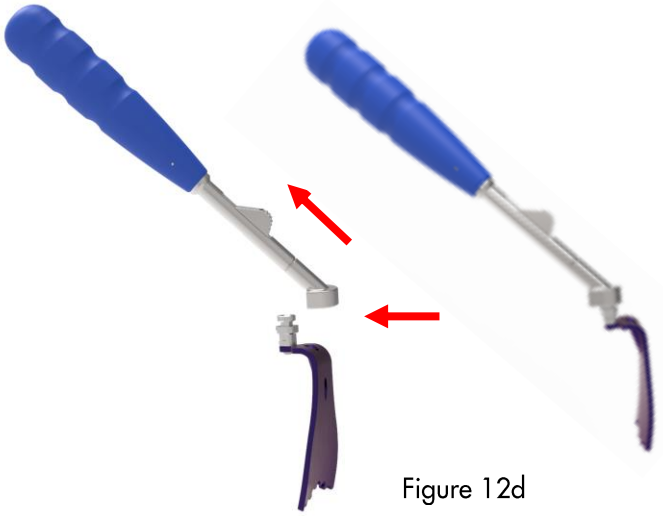


Figure 12d

12 REFORM® *MC* RETRACTOR (continued)

Place the Right and Left Blade Inserter Assembly into the incision (Figure 12e). Place the Reform MC Midline Retractor (59-RM-1000) Switch to the "OPEN" position (Figure 12f).

Align the Retractor Arms with the Blades, depress the Retractor Arm Lever and engage the Retractor Arms to the Retractor Blade (Figures 12g & 12h). Turn the Retractor Knob (Clockwise) to expand the Retractor Arms if necessary.

Figure 12e

Figure12f

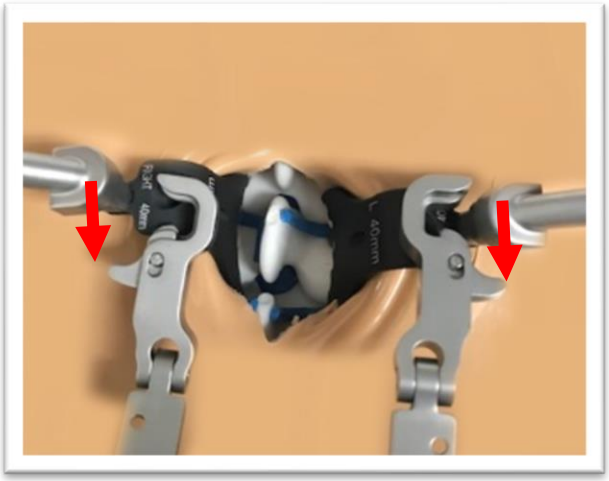


Figure 12g

Figure 12h

12 REFORM® *MC* RETRACTOR (continued)

When the retractor is connected, ensure that the Retractor Switch remains in the "Open" position (Figure 12i).

In this position the ratcheting mechanism is engaged and the retractor cannot be closed.

A Table Arm can be connected to the Midline Retractor if necessary. (Figure 12j)

Figure 12i

Figure 12j

12 REFORM® *MC* RETRACTOR (continued)

Open the Retractor to the appropriate position by turning the Retractor Knob clockwise. The Blades can be towed out by turning the Knob on the Retractor Arms (Figure 12k).

To enhance visualization, Attach the Reform MC Bifurcated Illuminator (59-LS-5000) to the Reusable Light Cable (54-LC-5100).

Slide the illuminators down the slot in the Right & Left Blades (Figure 12l). Turn on the Light Source and adjust the light intensity as needed.

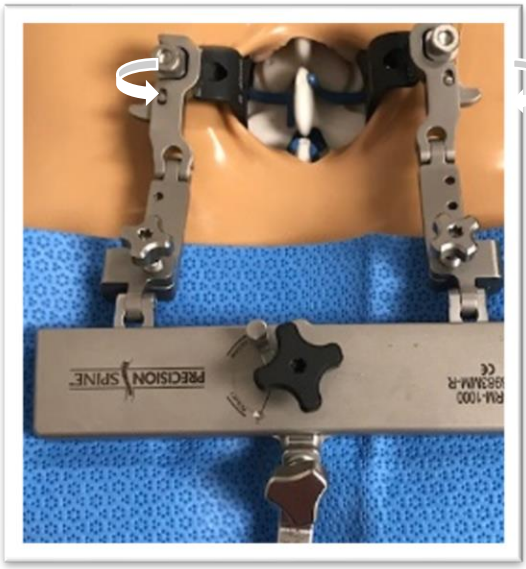


Figure 12k

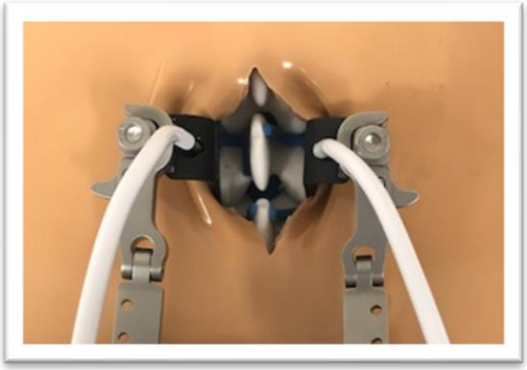


Figure 12l

12 REFORM® *MC* RETRACTOR (continued)

To aid in screw hole preparation, the Trajectory Tubes (59-RD-0300) may be utilized. The Tubes have been designed to position the Taps & Drills without holding them with your hands during fluoroscopy.

Place the Trajectory Tube in the appropriate position on the cortical bone. Bend the Trajectory Tube Wire and place it into one of the three slots on the contralateral side of the Retractor Arm (Figure 12m) while maintaining the position of the Trajectory Tube.

Place the Bone Awl (59-RD-0400) through the Trajectory Tube's cannula and pierce the cortical bone (Figures 12n & 12o).

Figure 12m

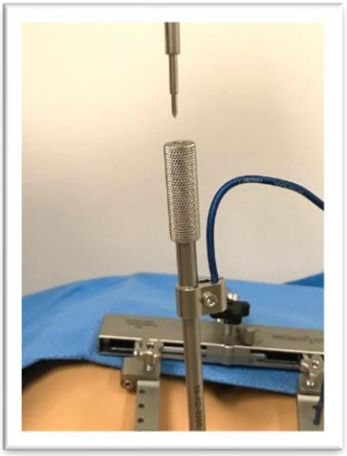


Figure 12n

Figure 12n

INDICATIONS

APPROVED INDICATIONS

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

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

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

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

CONTRAINDICATIONS

The Reform MC System contraindications include, but are not limited to the following:

1. Morbid obesity
2. Mental illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal insensitivity/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 the following:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late stage loosening of any or all components
6. Loss of fixation
7. Device component failure
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 components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage of 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 or increase in spinal mobility or function
18. Death

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

INDICATIONS (continued)

WARNINGS

The following list contains 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.

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