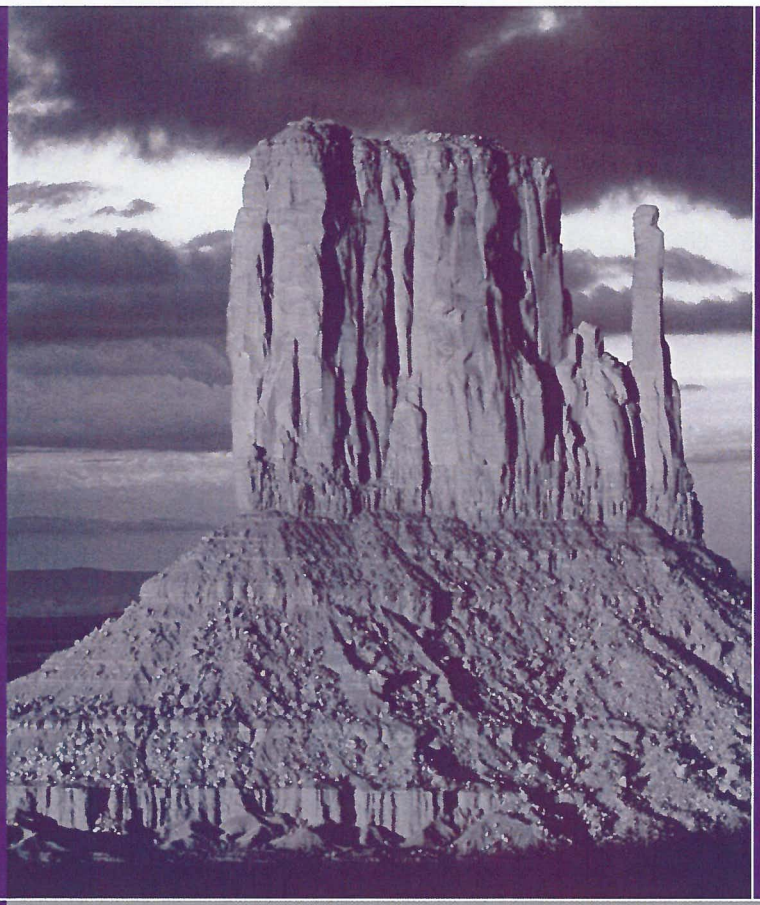


MESA®
DEFORMITY

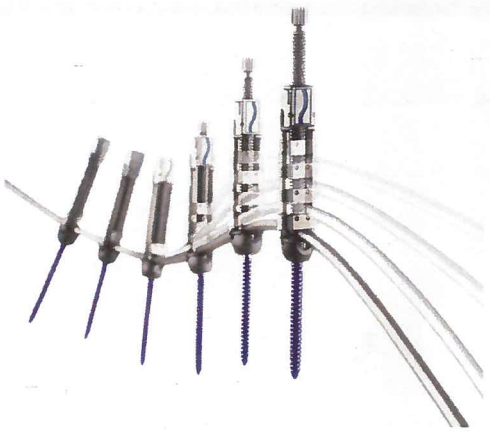
Surgical Technique

MESA

Deformity Spinal System

As Described By:

John P. Kostuik, MD
Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS)
& North American Spine Society (NASS)



K2M
COMPLEX SPINE INNOVATIONS™

TABLE OF CONTENTS

NOTE: Instrumented levels are based on surgeon preference and patient pathology. This surgical technique is intended to be used as a guideline for correction technique with the MESA® Deformity Spinal System.

Dear Colleagues,

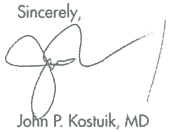
Welcome to K2M and the MESA® Deformity Spinal System! Our commitment to achieve the highest level of excellence in treating complex spinal pathologies continues with this comprehensive deformity system. MESA Deformity has been designed through an innovative collaborative approach, which includes spinal surgery opinion leaders, experienced biomechanical engineers, independent testing laboratories, and the K2M product development team.

The MESA Deformity Spinal System provides the surgeon with a wide range of implants and instruments necessary in the treatment of deformity, trauma, and tumor. The system is comprised of the MESA Foundation Screw, the MESA Deformity Uniplanar Screw, the MESA 360 Screw, Cobalt Chrome and Titanium Rods, as well as Reduction Jacks (Crickets®).

The implant and instrument technology is state-of-the-art with several innovative features to facilitate more efficient intra-operative use of the system. The implants incorporate a low-volume, uniquely shaped design and are color-coded for ease of identification during surgery. The system also features a variety of easy-to-use reduction instruments. The MESA Deformity Spinal System has many other benefits specific to the individual implants, such as MESA's Zero-Torque Technology®.

The MESA Deformity Spinal System has significantly impacted the complex spine market as we know it today. The following surgical technique outlines the procedural details and options, providing a guide to help understand the many unique aspects of the system for use in treating our patients.

Sincerely,



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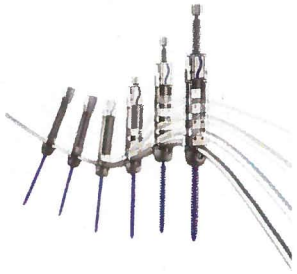
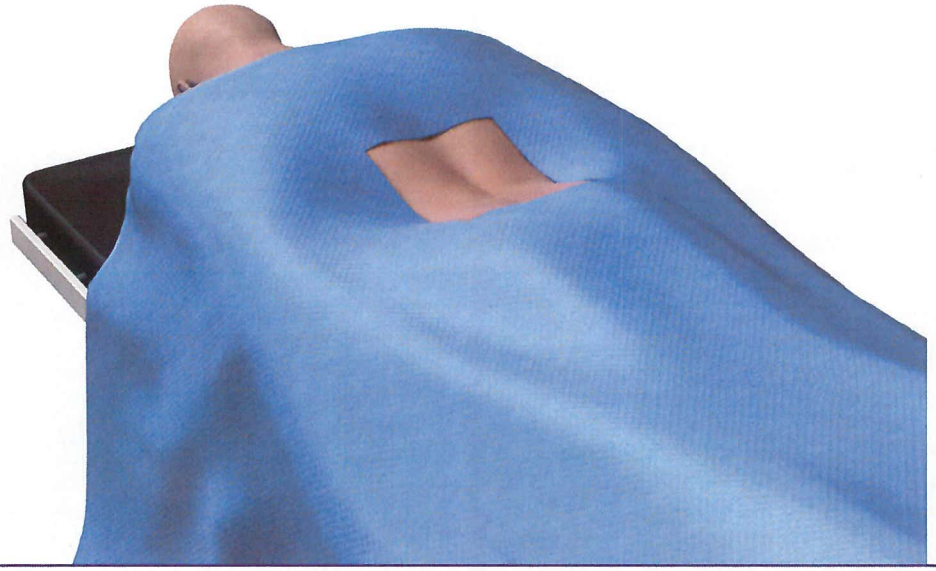
FEATURES & BENEFITS

MESA® Deformity Spinal System

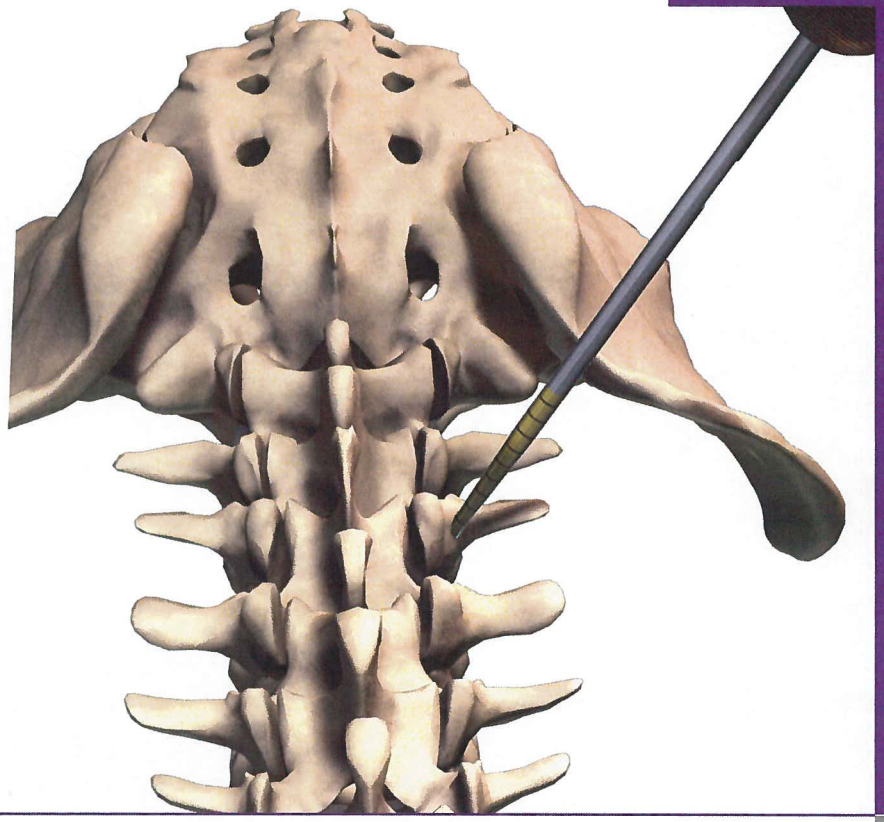


- Zero-Torque Technology®
- No Profile Above the Rod
- One-step Final Locking
- Complete Offering of Polyaxial Screws, Uniplanar Screws, 360° Screws, Rod Connectors & Rod Options
- Revolutionary Design of Deformity Reduction Jack (Cricket®) Provides Ability to Accomplish Correction Maneuvers in All Planes
- Unique Instrumentation Provides Slow, Controlled Correction of Spine, While Distributing Forces Across Entire Construct
- Ability to Segmentally or Globally Derotate Spine to Achieve Optimal Axial Plane Correction

MESA® DEFORMITY SURGICAL TECHNIQUE



CURVED PROBE

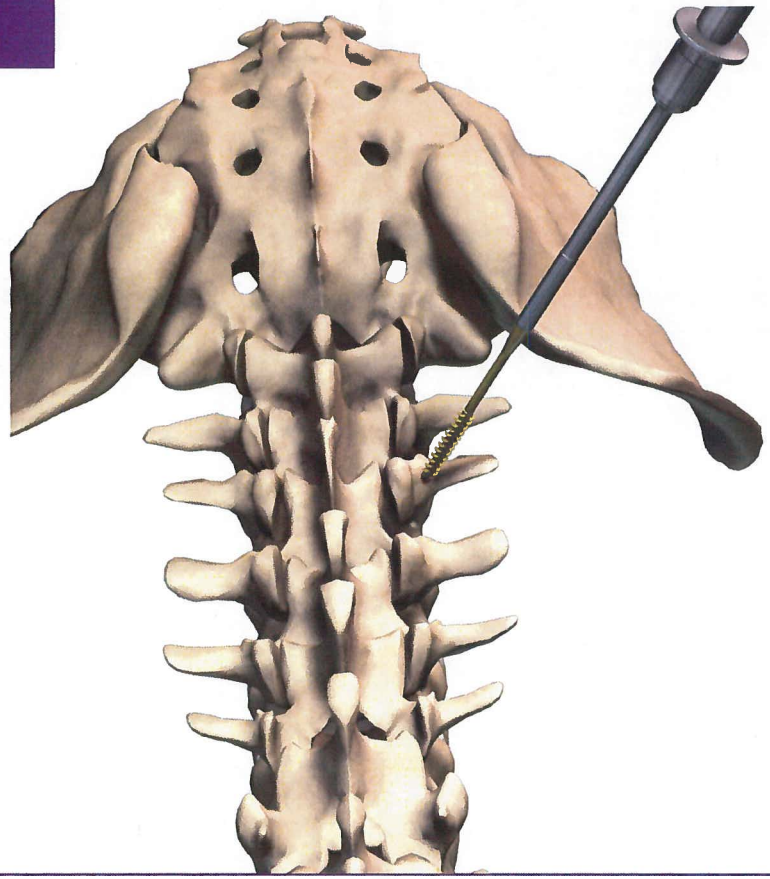


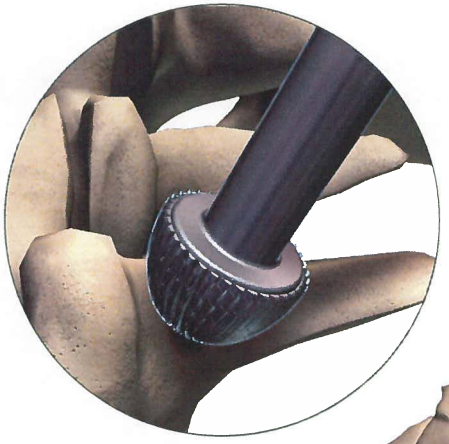
EXPOSURE & PREPARATION

Perform facetectomies throughout.

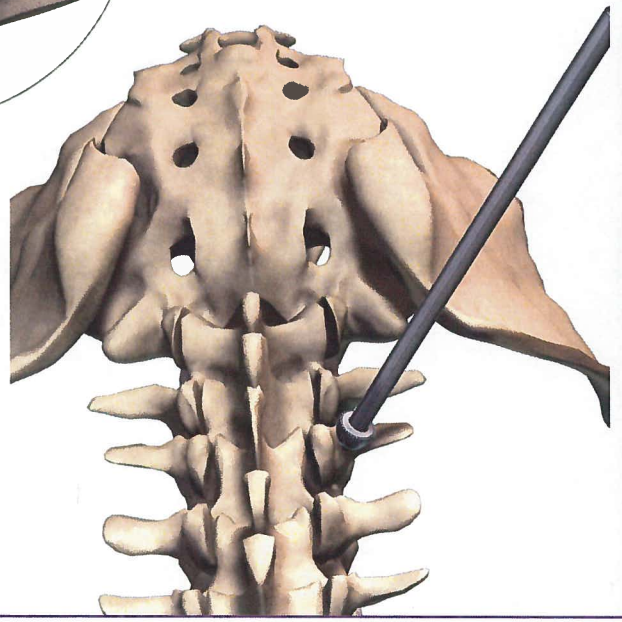
SCREW SITE PREPARATION

The small cortical crest of the pedicle is perforated with an Awl or removed with a Rongeur or Burr to expose the underlying cancellous bone. The entry point is cannulated with the Curved or Straight Thoracic Probe in the thoracic spine and the Curved or Straight Lumbar Probe in the lumbar spine. The Probe is advanced to the appropriate depth, as determined by the surgeon.





GUIDING REAMER



SCREW SITE PREPARATION (CONT.)

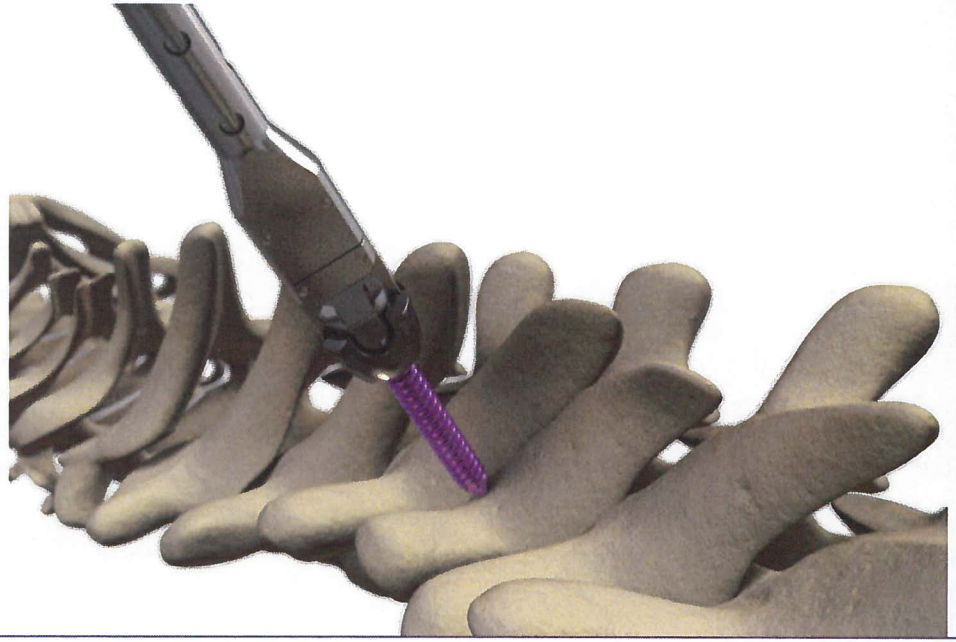
The correct insertion of the instrument will allow the tip of the Probe to follow a path of least resistance, reducing the potential of perforating the pedicle walls. The Probes are laser etched at 10 mm increments, from 30 to 60 mm, indicating the depth to which the Probe has been inserted. If the bone is sclerotic or hard, the appropriate size Tap may be used to prepare the pedicle screw canal. Each Tap is undersized a quarter of a millimeter (0.25 mm).

If desired, the Guiding Reamer may be used to remove bony anatomy. It can be beneficial when there are hypertrophic facets at the concavity in the thoracic spine. It can also assist in providing lateral decortications of the bony area surrounding the pedicle, thus providing the ability to countersink the screw and provide easier access for reduction instruments.

BALL TIP FEELER

POLYAXIAL SCREW INSERTER

DEFORMITY SCREW INSERTER

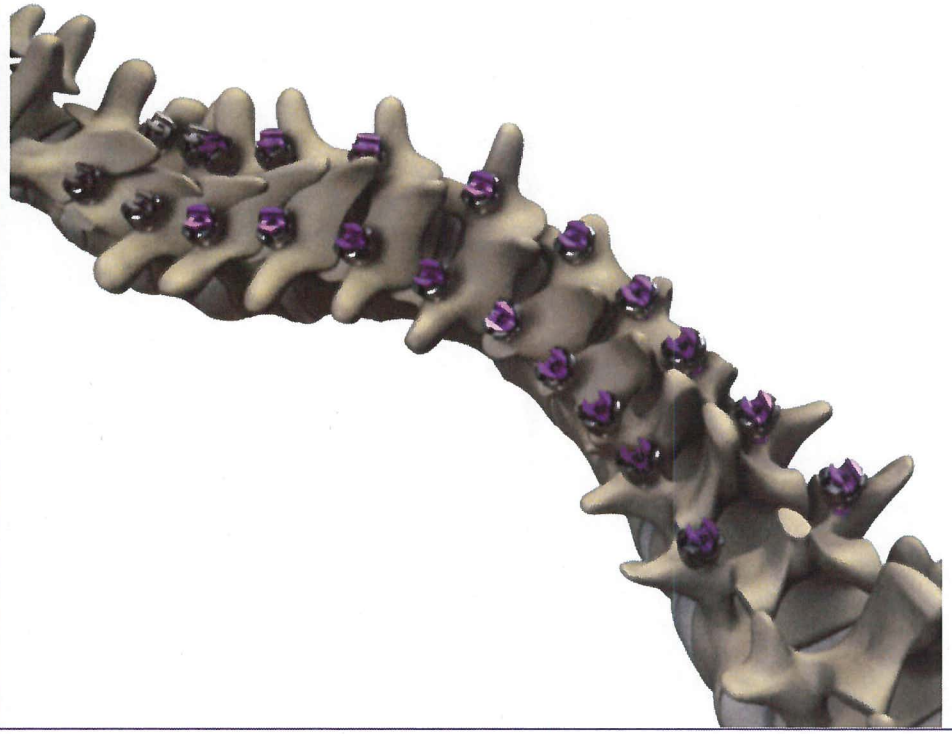


ANATOMICAL VERIFICATION

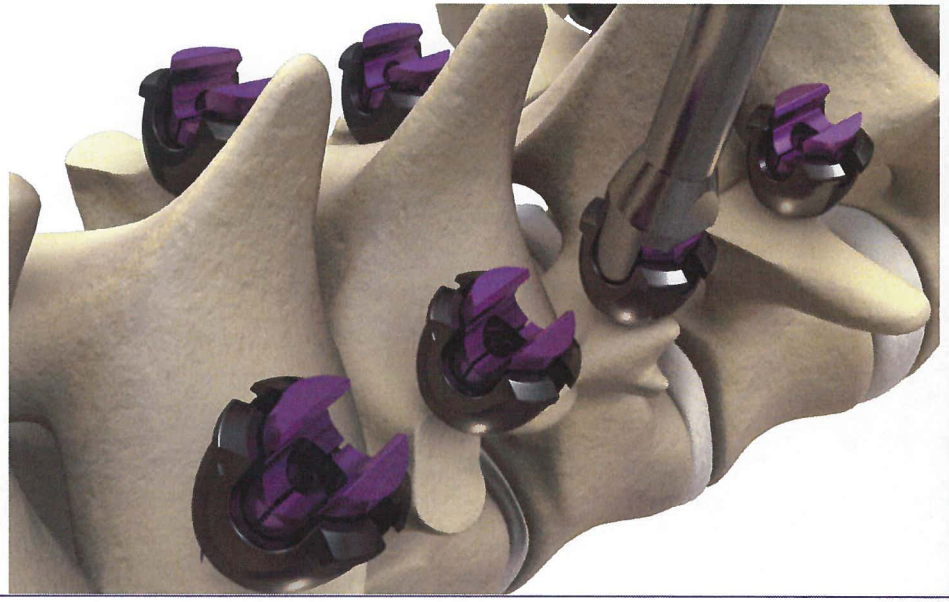
The prepared, probed pathway is sounded with the Ball Tip Feeler to verify the walls of the pedicle have not been breached and cancellous bone is felt through to the distal end of the prepared bony path.

SCREW INSERTION

After the pedicle pathway has been prepared and proper screw length and diameter have been determined, the appropriate implant is selected and loaded for screw insertion using the appropriate MESA Screw Inserter. The MESA Polyaxial Screws are inserted using the MESA Screw Inserter with the black sleeve. The MESA 360, Uniplanar, Deformity Uniplanar, and Foundation Screws are inserted using the MESA Screw Inserter with the green sleeve. It is important to grasp the implant by the screw shaft, while simultaneously applying an upward force to properly engage the screw. Inserters must be attached to a Handle before screw insertion. Ratcheting Handles are available in both Pear and T-Handle styles. The ratchet mechanism is selected by turning the metal portion of the Handle to the left or right to engage forward and reverse positions or in the neutral position to fix the ratchet.



HEAD ADJUSTER



SCREW PLACEMENT

MESA Polyaxial Screws may be used at the most proximal levels (T4 and T5) for ease of rod attachment and establishment of the proximal foundation. Otherwise, use MESA Uniplanar, Deformity Uniplanar, or 360 Screws throughout the spine. MESA Foundation Screws are also available to surgeons preferring to use them at the end of a construct for lumbosacral fixation.

SCREW ADJUSTMENT

Once the appropriate screw has been selected and inserted, the housing of the screw can be adjusted with the MESA Head Adjuster to accommodate the rod. Confirm the screw heads are unlocked and all screws are at appropriate levels and aligned to accept the rod when applied.

ROD PREPARATION

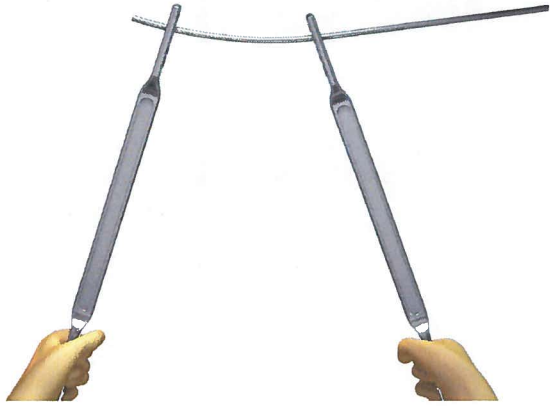
NOTE: A Rod Cutter does not come standard in the set and must be ordered separately.

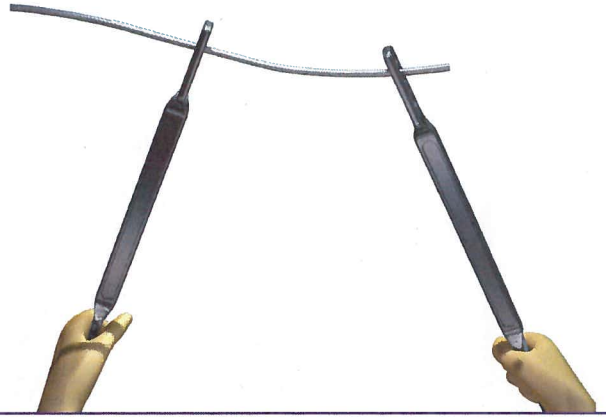
Once all screws have been inserted, the rod is selected and cut to the appropriate length, if necessary. Both Colbalt Chrome and Titanium Alloy rods are available. The Rod Template may be used to help determine rod length. To cut the rod with the Open-Ended Telescoping Rod Cutter, insert it into the end of the Cutter and squeeze the handles together.

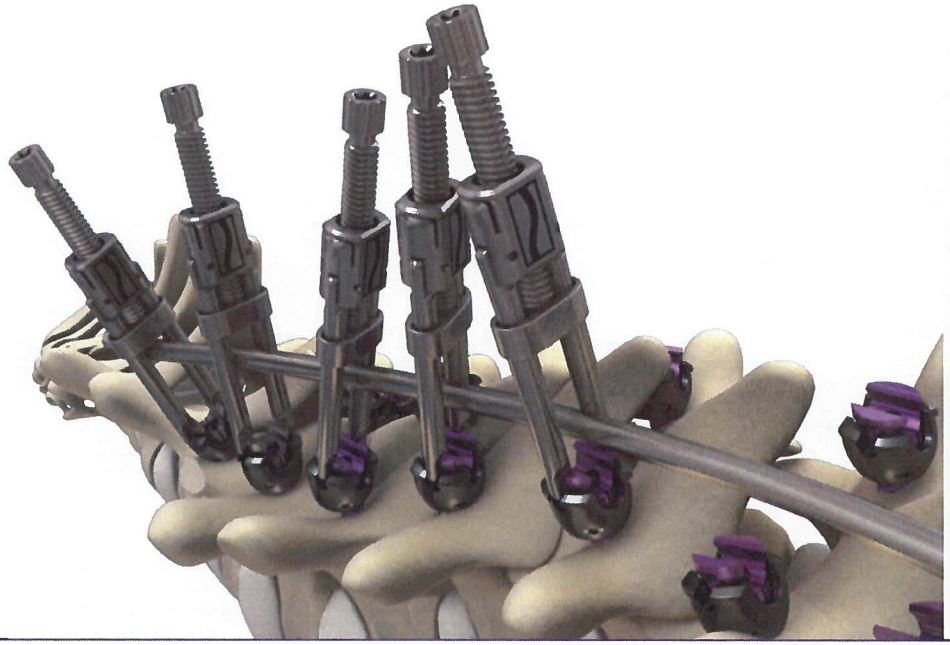
To extend the handles, pull the handle engagement towards the Cutter head and pull the handle in the opposite direction.

NOTE: Confirm at least 5 mm of rod length extends beyond the most proximal and distal screw.

The French Rod Bender may be used to contour the rods to the desired amount of lordosis or kyphosis. By pulling out and rotating the dial, the rod may be bent to the desired curvature (small, medium, or large).







ROD PREPARATION (CONT.)

The Deformity Rod Benders may also be used to contour the rod into the desired sagittal and/or coronal plane. Insert the rod into the appropriate hole. Support the inserted rod with the thumb by applying upward pressure, while inserting the rod into the opposite Bender. Place hands on the distal portion of the Bending Irons for optimal mechanical advantage. The rod is then bent to the desired contour as determined by the surgeon.

CONCAVE ROD PLACEMENT

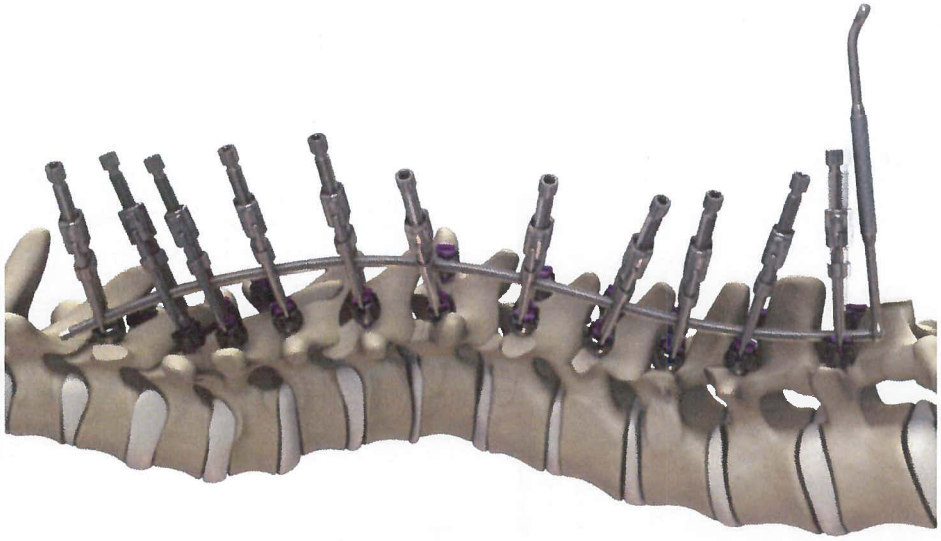
Place Deformity Crickets on the concave side screws. These will later provide translation of the spine to the rod. Pre-bend the rods in the physiological sagittal plane. For ease of rod insertion, place Deformity Crickets on only the upper half of the concave screws. After introducing the rod, place Deformity Crickets over the lower half of the rod. Do not tighten the Deformity Crickets, as they are only meant to ensure screw capture on the rod at this point. They will be used later for translation correction of the spine and to pull the screws up to the rod.

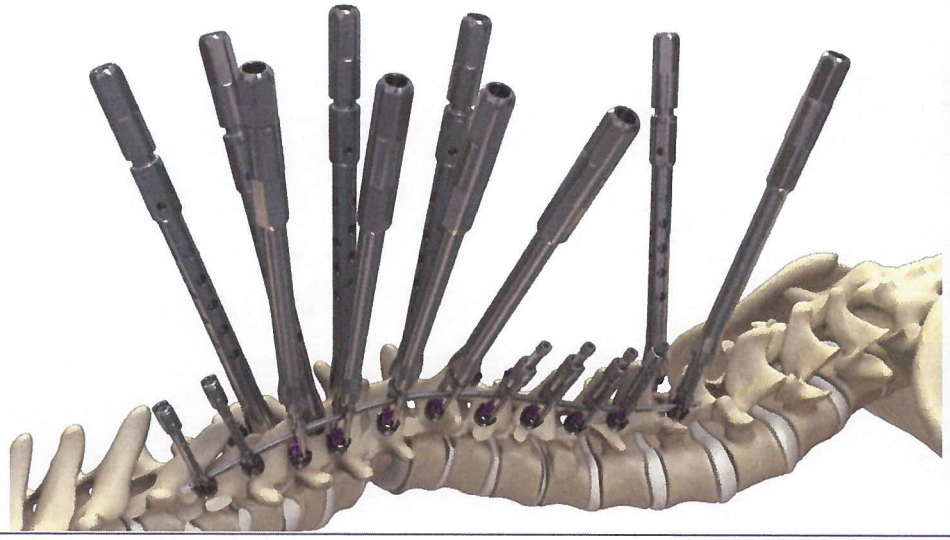
ROD ROTATION WRENCH

ROTATION TUBE

MESA MANIPULATOR

MANIPULATOR WRENCH





CONCAVE ROD PLACEMENT (CONT.)

Rotate the rod into the sagittal plane. This is preferably performed using the Rod Rotation Wrench and/or a Vise Grip. Seat the rod into the proximal fixation points by tightening the Deformity Crickets using the Screwdriver Shaft, Size 25, and a Handle. Then, reduce the Deformity Crickets at least halfway at apical levels and tighten so they "kiss" the rod at all other levels.

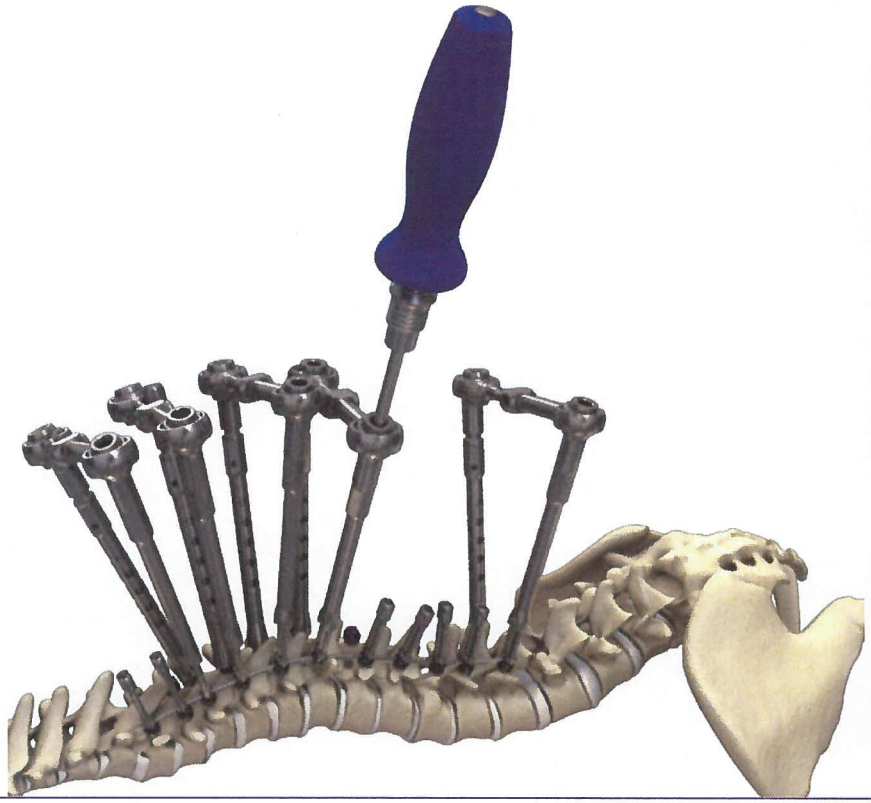
COUNTERTORSION & AXIAL CORRECTION

If direct vertebral rotation is desired, apply Rotation Tubes on the Deformity Crickets at the apex of the curve on the concave side, and Manipulators to the convex apical screws to ease manipulation maneuvers during spinal vertebral derotation and translation. The Manipulators securely lock on the screws and place the screws into a partially locked state. Tubes and Manipulators should also be attached to the Lowest Instrumented Vertebra (LIV) to use as a counter-torque during derotation.

NOTE: The Manipulator Wrench can be used to help fully tighten the Manipulators.

TRANSVERSE COUPLER

TORSIONAL ROD REDUCERS



COUNTERTORSION & AXIAL CORRECTION (CONT.)

Apply Transverse Couplers by pressing them onto the Rotation Tubes and Manipulators to triangulate the pedicles at each vertebral level and evenly distribute the forces during derotation. Apply a downward and lateral force to the convex instrumentation, including the rib hump, and a lateral force on the concave instrumentation to rotate the spine around the rod using the LIV as the foundation and counter-torque.

NOTE: Segmental or En Bloc Axial Correction can be achieved.

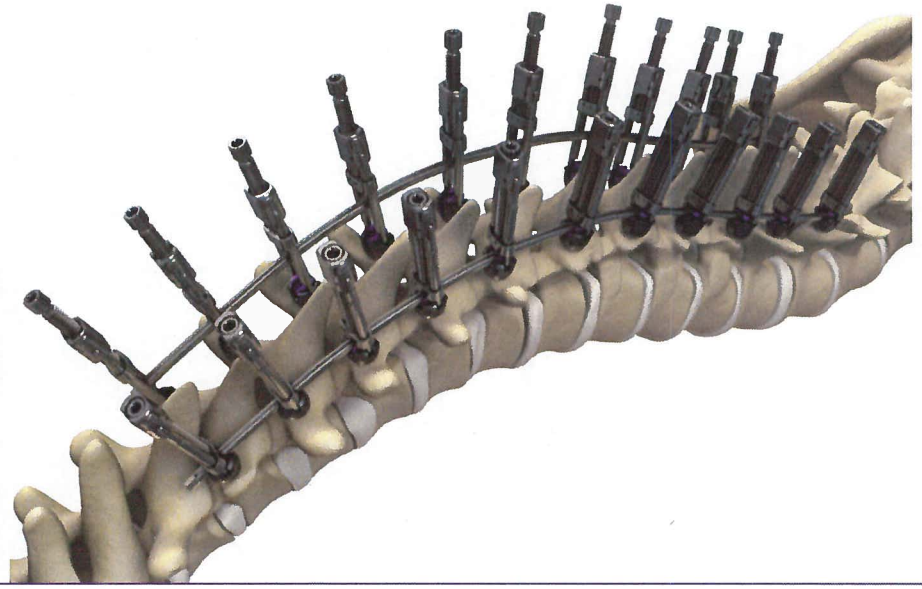
THORACIC CONCAVE TRANSLATION

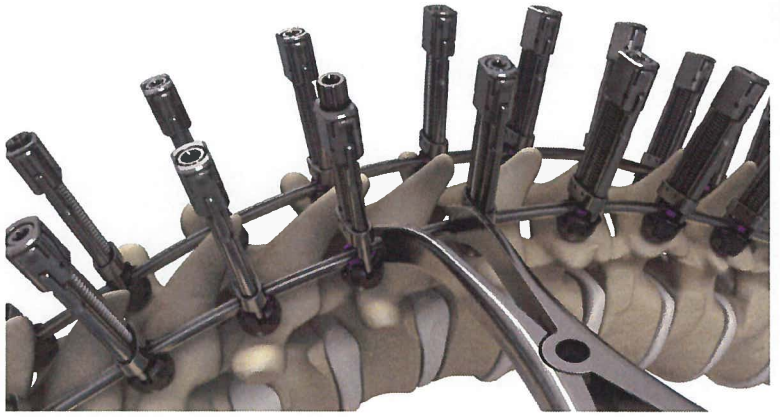
Translation of the concave thoracic apex to the rod is performed by gradually tightening the Deformity Crickets from the ends sequentially with progression across the apex of the deformity. By performing the translation simultaneously from the outside in with the Deformity Crickets, the forces are spread across the entire construct. Once all Deformity Crickets are maximally tightened, the rod will be captured in each of the screw heads.

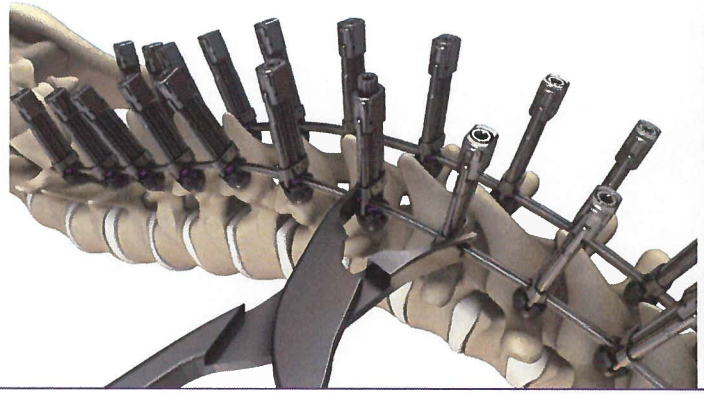
NOTE: Torsional Rod Reducers may be used during translational maneuvers.

UNLOCKER

ROD ROTATION WRENCH







CONVEX RIGHT ROD PLACEMENT

Remove the Rotation Tubes and Manipulators from the construct. Then, use the MESA Unlocker to unlock all convex apical screws where Manipulators have been applied. Place Deformity Crickets on the convex screws. The convex rod is introduced using the technique similar to the concave/corrective rod. Using the Rod Rotation Wrench or Vice Grip, hold the rod into the proper sagittal alignment. The top two Deformity Crickets are fully reduced. The remainder of the Deformity Crickets are then tightened sequentially to reduce the rod into the screws. If necessary, the rod contour may be adjusted using the Coronal or In-Situ Benders.

COMPRESSION/ DISTRACTION

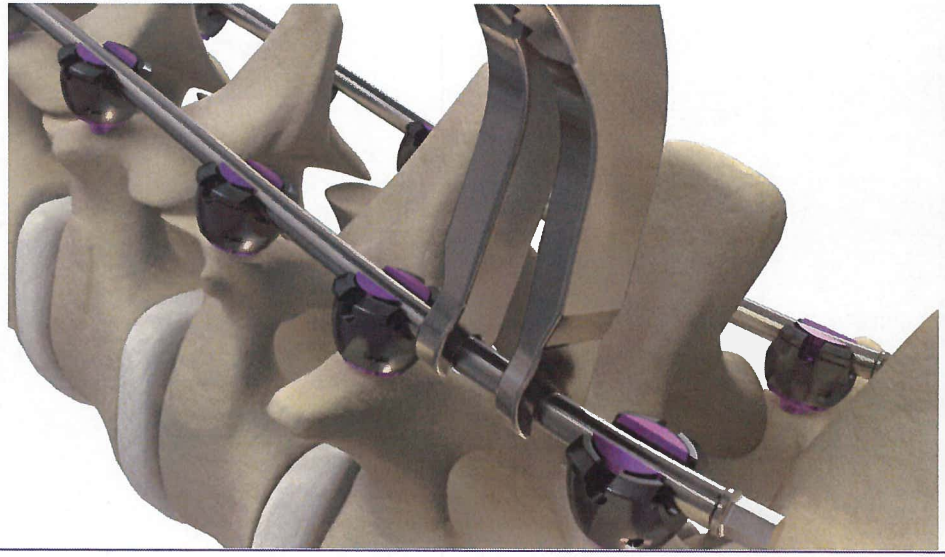
The final deformity correction is now performed using a variety of compression/distraction maneuvers. Begin proximal to the apex and compress/distract by releasing the Deformity Cricket one to two turns. Compress or distract and retighten the Cricket to achieve correction. This method employs a similar technique to that of a standard set screw system.

NOTE: Additional segmental Direct Vertebral Derotation can also be achieved at this time, if necessary.

PARTIAL LOCKER (SUPERFLY™)

IN-SITU ROD BENDERS

CORONAL ROD BENDERS



PARTIAL LOCKING

Partially lock all of the fixation points using the Superfly™ over the Deformity Crickets. The Deformity Crickets may now be removed from the screws.

IN-SITU SAGITTAL & CORONAL BENDING

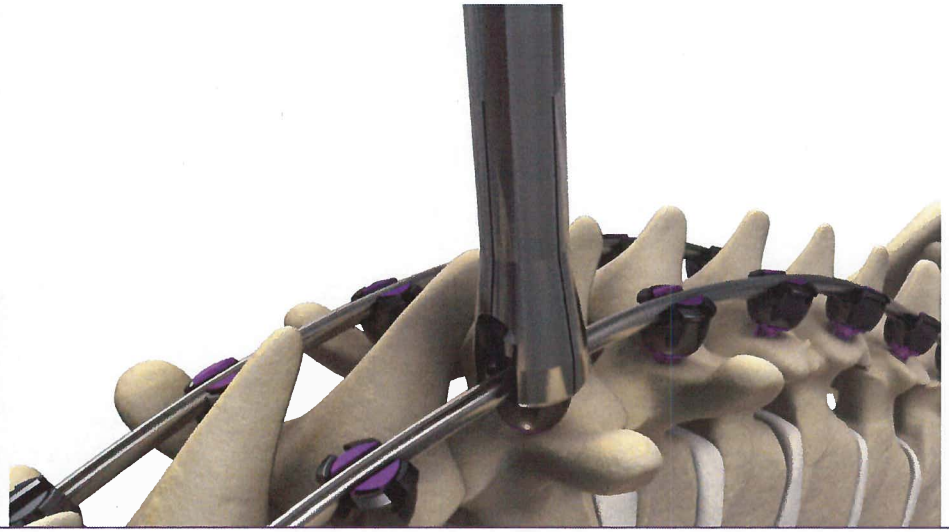
With the MESA Screws partially locked, the rod contour may be adjusted. For sagittal plane correction, use the left and right Sagittal Rod Benders. For coronal plane correction, use the left and right Coronal Rod Benders.

NOTE: When using the Coronal Rod Benders, arrange the parts to ensure the female and male parts of the instrument mate. Always use a squeezing motion for coronal correction to ensure mechanical advantage. Do not pull instruments apart.

15

Surgical Technique Steps

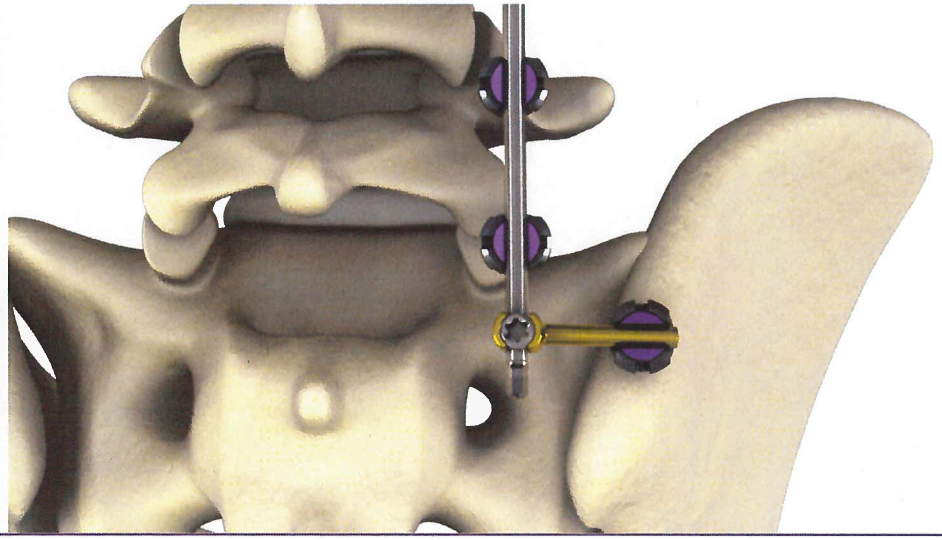
QUICK LOCKER

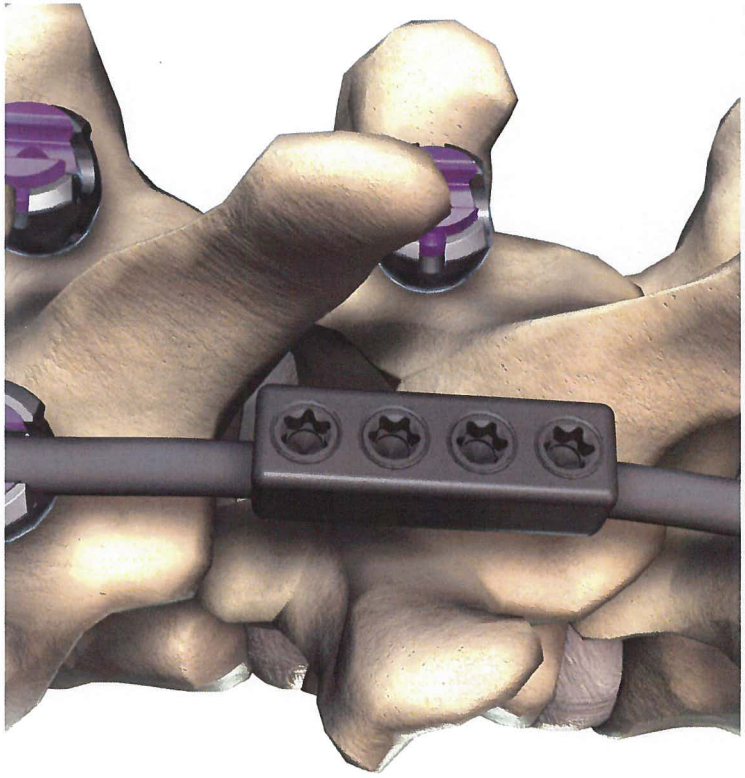


FINAL LOCKING

Fully lock each MESA Screw using the Quick Locker. Repeat final locking of each screw with the Quick Locker to confirm rigid fixation throughout. Confirm at least 5 mm of rod length extends beyond the most proximal and distal screws.

NOTE: The Quick Locker should be used to apply axial force only. It should not be used in compression, distraction, or rotational maneuvers.





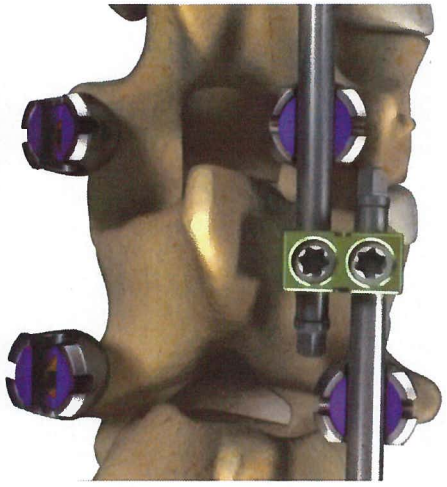
ROD CONNECTIONS
Lateral Offset Connectors
(Open & Closed; Variety of Angles)

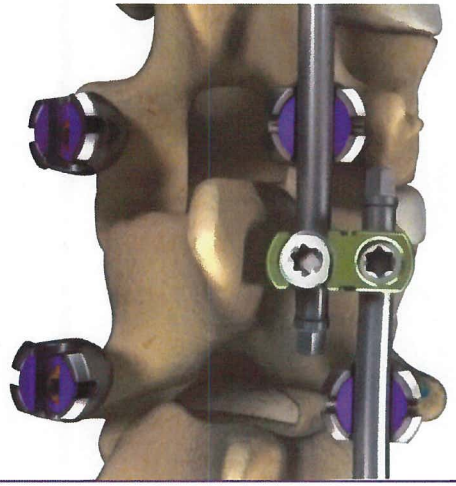
The Lateral Offset Connectors may be used to link a screw lateral to a rod. The rodded portion of the lateral offset connector is seated in the implant housing and the other end is attached to the rod with set screws and final tightened at 90 inch-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

NOTE: The lateral offset connectors are available in open and closed versions, and also come in variety of angles depending on surgeon preference.

ROD CONNECTIONS
Axial Connectors

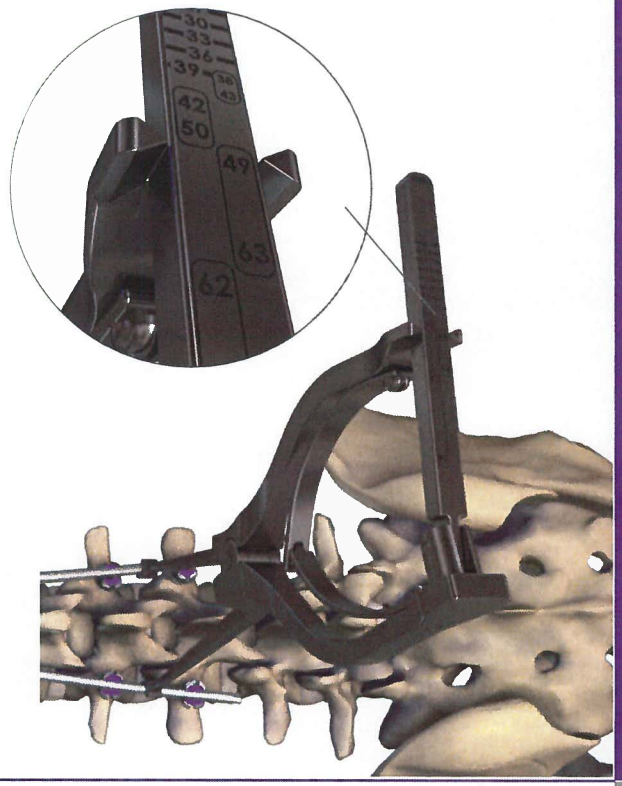
Axial Connectors may be used to join rods end-to-end. The implant is final tightened at 90 inch-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.





NATURAL BRIDGE® LP CALIPER

NATURAL BRIDGE® LP CONNECTOR HOLDER



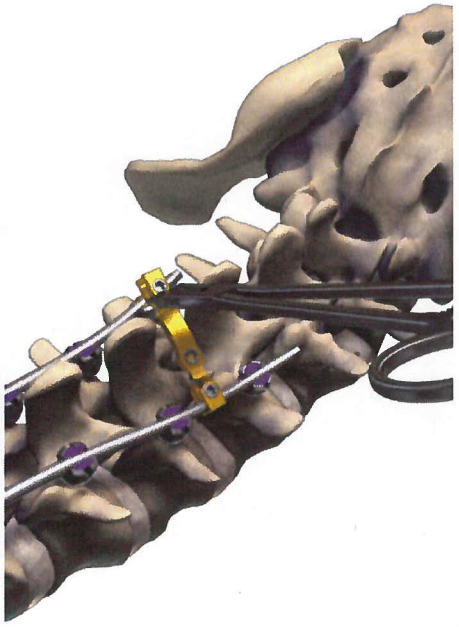
ROD CONNECTIONS
Parallel Connectors

Parallel connectors may be used to join rods parallel to one another. The implants come in closed-closed and closed-open styles. The closed-open style requires a set screw in the open portion. The implants are final tightened at 90 inch lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

TRANSVERSE CONNECTORS

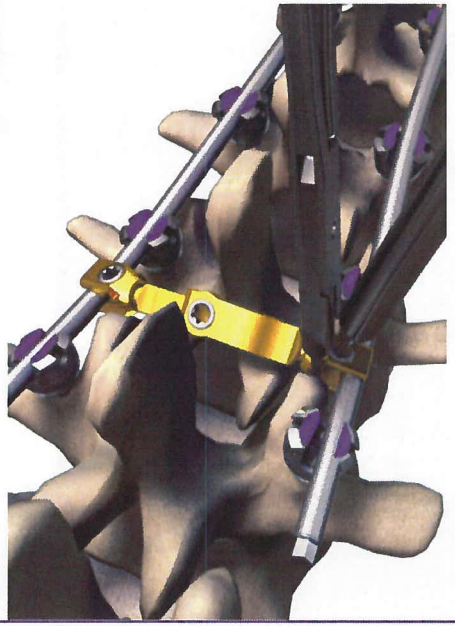
Use the NATURAL BRIDGE® LP Caliper to measure the appropriate length between the two rods, and choose the best fitting transverse connector. The connectors are available in both semi-adjustable and adjustable designs.

Grab onto the implant using the NATURAL BRIDGE LP Connector Holder. Ensure all connector set screws are adequately loosened to securely engage the rod. If using an adjustable connector, loosen the middle set screw. Utilizing the polyaxial head of the connector, snap one head onto the rod and provisionally tighten the set screw using the NATURAL BRIDGE LP Driver Shaft and Handle.



NATURAL BRIDGE LP DRIVER SHAFT

NATURAL BRIDGE LP DRIVER HANDLE



TRANSVERSE CONNECTORS (CONT.)

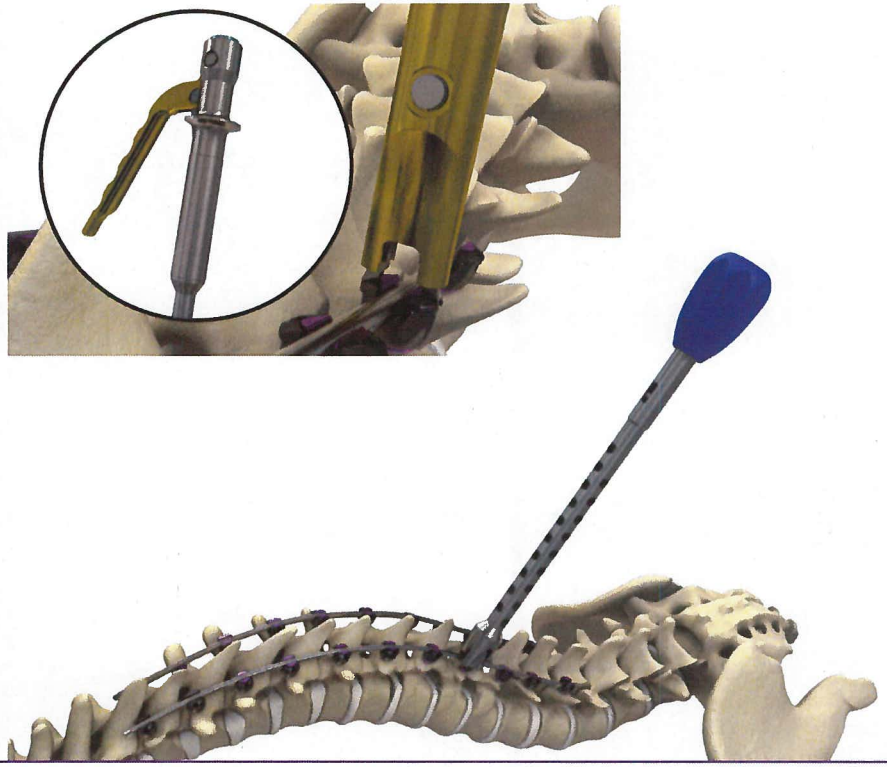
Stabilize the transverse connector to snap the other polyaxial head onto the opposite rod. Provisionally tighten both heads with the NATURAL BRIDGE LP Driver. If using an adjustable transverse connector, adjust the appropriate length and provisionally tighten to secure the transverse connector to the construct.

Ensuring the implant is in the desired position, lock down the implant by final tightening every set screw to optimal torque using the NATURAL BRIDGE LP Driver Shaft and Handle.

UNLOCKING & REMOVAL SURGICAL TECHNIQUE

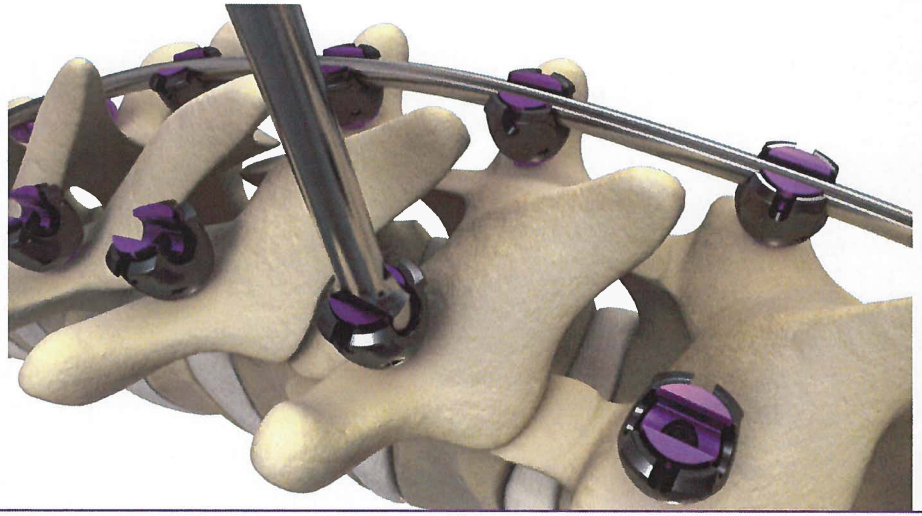
POWER PULLER

QUICK UNLOCKER



T-BAR SCREW REMOVER

T-HANDLE



UNLOCKING & REMOVAL

Should the surgeon decide to unlock the MESA screw from partial or full lock, the Quick Unlocker may be used. Fully open the instrument and engage the docking feet into the detents of the medial side of the screw housing. Gently move the instrument down laterally until the distal portion of the instrument has properly engaged both the medial and lateral side of the screw housing. Fully squeeze the lever of the Unlocker. Once the screw is in the unlocked position, the rod may be extracted from the implant housing using the Power Puller. Apply the distal end of the Power Puller over the screw housing and rotate it in a clockwise direction until it securely engages the rod. Grab the handle and thread down in a controlled fashion in order to release the rod from the screwhead.

The T-Bar Screw Remover may be used to remove the MESA screw after it has been implanted. It is especially beneficial where a fusion mass is present and it may be difficult to insert a Size 25 Driver into the internal hex of the MESA screw. Lock the MESA screw without a rod in the screw housing. Attach a Fixed T-Handle to the T-Bar Screw Remover and slide the distal end of the T-Bar Screw Remover into the locked saddle of the MESA screw. Turn the T-Bar Screw Remover counter-clockwise until the screw disengages from the bone.

INSTRUMENTS

GUIDING REAMER

BALL TIP FEELER

TAPS: 4.5 mm
5.5 mm
6.5 mm
7.5 mm
8.5 mm

STRAIGHT THORACIC PROBE

STRAIGHT LUMBAR PROBE

CURVED LUMBAR PROBE

CURVED THORACIC PROBE

AWL, SHORT

SILICONE PEAR HANDLE

SILICONE T-HANDLE

INSTRUMENTS

X-RAY MARKER, LEFT

X-RAY MARKER, RIGHT

VISE GRIPS

ADJUSTABLE AWL

PROVISIONAL SCREW DRIVER (LONG)

PROVISIONAL SCREW DRIVER (SHORT)

PROVISIONAL DRIVER HANDLES

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Guiding Reamer	801-90048
Ball Tip Feeler	101-90214
4.5 mm Tap	101-90224
5.5 mm Tap	101-90225
6.5 mm Tap	101-90226
7.5 mm Tap	101-90227
8.5 mm Tap	101-90228

DESCRIPTION	CATALOG NUMBER
Straight Thoracic Probe	101-90296
Straight Lumbar Probe	101-90294
Curved Lumbar Probe	101-90293
Curved Thoracic Probe	101-90295
Awl, Short	101-90001
Silicone Pear Handle	101-90276
Silicone T-Handle	101-90275

INSTRUMENTS

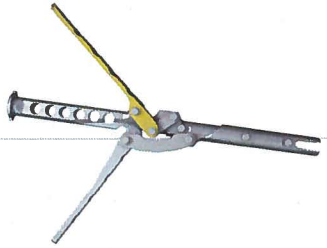
DESCRIPTION	CATALOG NUMBER
X-ray Marker, Left	101-90012
X-ray Marker, Right	101-90013
Vise Grips	101-90306
Adjustable Awl	101-90114
Provisional Screw Driver (Long)	101-90101
Provisional Screw Driver (Short)	101-90208
Provisional Driver Handle	101-90249

INSTRUMENTS

QUICK LOCKER

PARTIAL LOCKER (SUPERFLY™)

QUICK UNLOCKER



DUAL ACTION ROD REDUCER (DRAGONFLY™)

INSTRUMENTS

POLYAXIAL SCREW INSERTER

DEFORMITY SCREW INSERTER

DEFORMITY REDUCTION JACK (CRICKET®)

MESA MANIPULATOR

MANIPULATOR WRENCH

REDUCTION JACK ROTATION TUBE

REDUCTION JACK TORQUE LIMITING HANDLE

REDUCTION JACK DRIVER

SCREW HEAD ADJUSTER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Quick Locker	801-90008
Partial Locker (Superfly™)	801-90060
Quick Unlocker	801-90025
Dual Action Rod Reducer (Dragonfly™)	801-90038

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Polyaxial Screw Inserter	801-90029
Deformity Screw Inserter	801-90053
Deformity Reduction Jack (Cricket®)	801-90066
MESA Manipulator	801-90054
Manipulator Wrench	801-90069
Reduction Jack Rotation Tube	801-90073

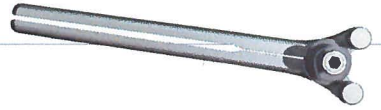
DESCRIPTION	CATALOG NUMBER
Reduction Jack Torque Limiting Handle	801-90067
Reduction Jack Driver	801-90068
Screw Head Adjuster	801-90031

INSTRUMENTS

CORONAL ROD BENDERS
RIGHT, LEFT

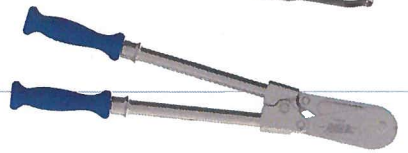
IN-SITU ROD BENDERS
RIGHT, LEFT

TORSIONAL ROD REDUCER
RIGHT, LEFT



FRENCH ROD BENDER

ROD ROTATION WRENCH

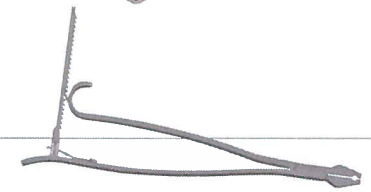


TELESCOPING ROD CUTTER

DEFORMITY ROD BENDERS

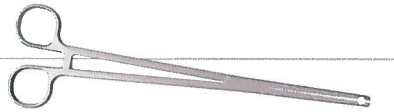
INSTRUMENTS

BUTTRESS RINGS

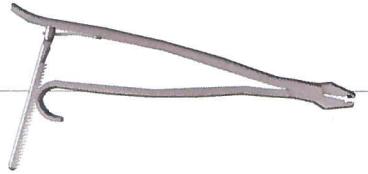


ROD HOLDER

PARALLEL ROD CONNECTOR
INSERTER



ROD HOLDING FORCEPS



ROD HOLDER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Coronal Rod Benders, Right	101-90312
Coronal Rod Benders, Left	101-90313
In-situ Rod Bender, Left	101-90217
In-situ Rod Bender, Right	101-90218
Torsional Rod Reducer, Right	101-90024
Torsional Rod Reducer, Left	101-90081

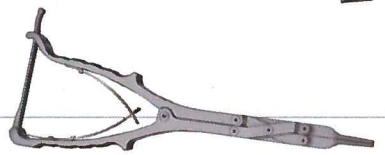
DESCRIPTION	CATALOG NUMBER
French Rod Bender	101-90031
Rod Rotation Wrench	101-90259
Telescoping Rod Cutter	101-90338
Deformity Rod Benders	101-90284

INSTRUMENTS

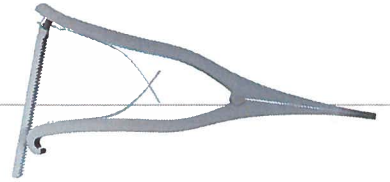
DESCRIPTION	CATALOG NUMBER
Buttress Rings	101-85500D
Rod Holder	101-90038
Parallel Rod Connector Inserter	101-90222
Rod Holding Forceps	101-90039
Rod Holder	101-90038

INSTRUMENTS

WEDGE DISTRACTOR



PARALLEL DISTRACTOR



DISTRACTOR

COMPRESSOR

INSTRUMENTS

POWER ROD PULLER

T-BAR SCREW REMOVER

SCREW REMOVER, FIXED HANDLE

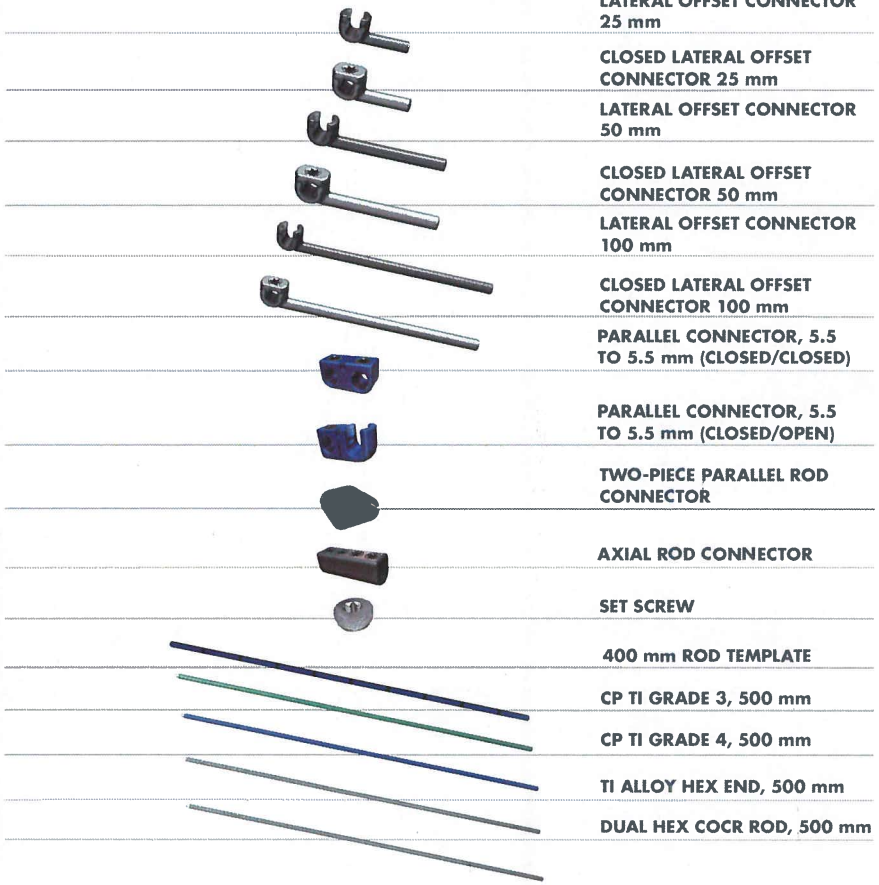
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Wedge Distractor	801-90026
Parallel Distractor	801-90051
Distractor	801-90028
Compressor	801-90027

INSTRUMENTS

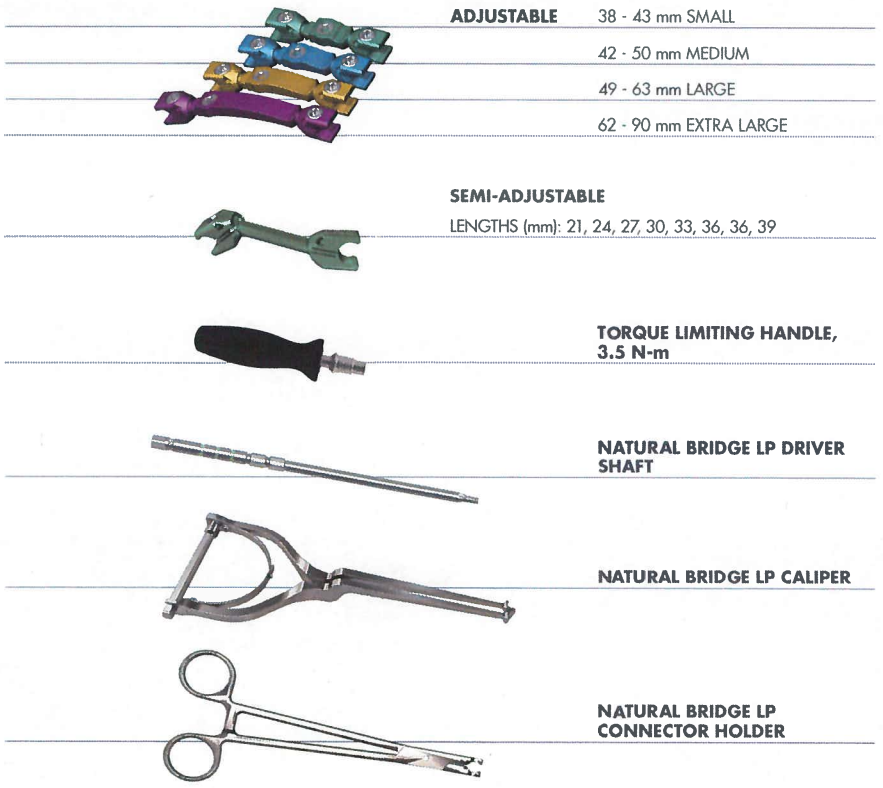
DESCRIPTION	CATALOG NUMBER
Power Rod Puller	801-90097
T-Bar Screw Remover	801-90004
Screw Remover, Fixed Handle	801-90052

Product Catalog



IMPLANTS

- LATERAL OFFSET CONNECTOR 25 mm
- CLOSED LATERAL OFFSET CONNECTOR 25 mm
- LATERAL OFFSET CONNECTOR 50 mm
- CLOSED LATERAL OFFSET CONNECTOR 50 mm
- LATERAL OFFSET CONNECTOR 100 mm
- CLOSED LATERAL OFFSET CONNECTOR 100 mm
- PARALLEL CONNECTOR, 5.5 TO 5.5 mm (CLOSED/CLOSED)
- PARALLEL CONNECTOR, 5.5 TO 5.5 mm (CLOSED/OPEN)
- TWO-PIECE PARALLEL ROD CONNECTOR
- AXIAL ROD CONNECTOR
- SET SCREW
- 400 mm ROD TEMPLATE
- CP TI GRADE 3, 500 mm
- CP TI GRADE 4, 500 mm
- TI ALLOY HEX END, 500 mm
- DUAL HEX COCR ROD, 500 mm



NATURAL BRIDGE LP TRANSVERSE CONNECTORS

ADJUSTABLE
- 38 - 43 mm SMALL
- 42 - 50 mm MEDIUM
- 49 - 63 mm LARGE
- 62 - 90 mm EXTRA LARGE

SEMI-ADJUSTABLE

LENGTHS (mm): 21, 24, 27, 30, 33, 36, 36, 39

- TORQUE LIMITING HANDLE, 3.5 N-m
- NATURAL BRIDGE LP DRIVER SHAFT
- NATURAL BRIDGE LP CALIPER
- NATURAL BRIDGE LP CONNECTOR HOLDER

IMPLANTS

DESCRIPTION	CATALOG NUMBER
Lateral Offset Connector, 25 mm	101-75525
Closed Lateral Offset Connector, 25 mm	101-75525G
Lateral Offset Connector, 50 mm	101-75550
Closed Lateral Offset Connector, 50 mm	101-75550G
Lateral Offset Connector, 100 mm	101-755100
Closed Lateral Offset Connector, 100 mm	101-755100G
Parallel Connector, 5.5 to 5.5 mm (Closed/Closed)	101-85555E
Parallel Connector, 5.5 to 5.5 mm (Closed/Open)	101-85555F
Two-Piece Parallel Rod Connector	101-85555C
Axial Rod Connector	101-85555D
Set Screw	101-10001
400 mm Rod Template	101-90143
CP TI Grade 3, 500 mm	107-A55500
CP TI Grade 4, 500 mm	106-A55500
TI Alloy Hex End, 500 mm	101-A55500
Dual Hex CoCr Rod, 500 mm	111-B55500

TRANSVERSE CONNECTORS

Unique catalog numbers exist for each connector size. Please contact your local sales consultant with any questions you may have about ordering the NATURAL BRIDGE Spinal System or implants.

NOTE: All connectors come in sizes shown.

DESCRIPTION	CATALOG NUMBER
Torque Limiting Handle, 3.5 N-m	801-90183
NATURAL BRIDGE LP Driver Shaft	101-90278
NATURAL BRIDGE LP Caliper	101-90281
NATURAL BRIDGE LP Connector Holder	101-90220

SCREWS

DIAMETERS (mm): 4.5, 5.5, 6.5, 7.5, 8.5

MESA 360°

MESA UNIPLANAR

MESA POLYAXIAL

MESA DEFORMITY UNIPLANAR

MESA FOUNDATION

SCREW COLORS BY LENGTH			
Size	**Color**	**Size**	**Color**
20 mm		55 mm	
25 mm		60 mm	
30 mm		65 mm	
35 mm		70 mm	
40 mm		75 mm	
45 mm		80 mm	
50 mm		85 mm	

SCREWS

DESCRIPTION	
MESA 360° (not standard)	*See note
MESA Uniplanar (not standard)	*See note
MESA Polyaxial	*See note
MESA Deformity Uniplanar	*See note
MESA Foundation (not standard)	*See note
ATR Set Screw	101-10001

*Unique catalog numbers exist for each screw length in each diameter. Please contact your local sales consultant with any questions you may have about ordering the MESA® Deformity Spinal System implants.

⚠ **BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION**

IMPORTANT
This booklet is designed to assist in using the RANGE®/DENALI®/ and MESA® Spinal Systems and the ARI® Anterior Vertebral Body Staples. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DESCRIPTION

The RANGE/MESA/DENALI Spinal System is a top-loading, multiple component, posterior (thoracic/lumbar/sacral) spinal fixation system which consists of pedicle screws, rods, hooks and rod connectors and anterior staple components. The implants are manufactured from Titanium alloy, CP Titanium and Cobalt Chrome, per ASTM (F67, F1472, F136, F1537) and ISO standards.

INDICATIONS

RANGE/DENALI/MESA and small stature and ARI are cleared for the following indications: Non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the RANGE Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the RANGE Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The RANGE Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
Unless specifically labeled as STERILE, K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Non-Sterile Devices
Packaged components are packaged individually in sealed poly bags. **Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use.** Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles were validated to an SAL of 10^{-6} using the biological indicator (BI) overkill method however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes
Outside USA	Prevacuum	273°F (134°C)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

Sterile Devices
Components labeled as STERILE were sterilized either by gamma radiation or ethylene oxide gas.

CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.

CAUTION: The implants are intended for single use only. Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE

Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin. Recommended storage temperatures are between 50-100°F (10-38°C).

INSTRUCTIONS FOR USE
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

The patient is placed in the position desired by the surgeon to allow a standard approach to the appropriate portion of the patient's anatomy for the procedure.

Following a standard approach to the patient's spine the appropriate implants are used for either screw fixation or hook fixation.

NOTE: Excessive reverse bending of Titanium Rods can cause metal stressing resulting in a lower fatigue life for the rod.

Screw Fixation
For screw fixation use the probe, reamer and tap to prepare the screw site. Select the proper size screw. Insert with the screw inserter.

NOTE: Taps are sized smaller than the actual diameter of the screw to allow better screw fixation.

Cut the rod to the proper length. Bend the rod as needed due to anatomical variations. Drop the rod into the top of the screw.

Complete final locking of the assembly as described in the appropriate surgical technique.

Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

For Hook Use
Prepare the hook site with the appropriate lamina finders to provide a good fit with the hooks. Assemble the proper hook onto the hook holder. Insert hook using the hook holder. Remove the hook holder.

Cut the rod to the proper length. Bend the rod as needed due to anatomical variations. Drop the rod into the top of the hook.

Insert the set screw. Use distraction or compression provided by the distractor or compressor as required. Thread the set screw completely down across the rod the assembly.

Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

For Anterolateral Use
The dual hole staples are designed to be used for anterolateral fixation with Range System screws (4.5 to 8.5 mm in diameter) and 5.5 mm diameter rods. The dual hole staples are intended for placement at both ends of a construct. The single hole staples and washers are intended to be used in multi-level fusions to provide additional support to the intermediate levels of the construct.

CONTRAINDICATIONS
1. K2M spinal systems are contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

ADDITIONAL POTENTIAL ADVERSE EVENTS FOR PEDIATRIC PATIENTS
1. Inability to use pedicle screw fixation due to anatomic limitation (pedicle dimensions, distorted anatomy)
2. Pedicle screw malpositioning, with or without neurological or vacular injury
3. Proximal or distal junctional kyphosis
4. Pancreatitis

WARNINGS AND PRECAUTIONS
Pedicle Screw Spinal Systems
WARNING: The safety and effectiveness of pedicle screw spinal syste 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 (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The implants are for single use only and are not designed to be combined with devices from other manufacturers. ⊗

PRECAUTION: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon should refer to the product labeling for details on use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.

Temporary Metallic Internal Fixation Devices
1. Patience selection and compliance is extremely important. Based on fatigue testing results, the K2M Range Spinal System has been determined to be substantially equivalent to predicate devices however, 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 this system. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
2. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
3. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
4. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
5. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals (e.g. titanium and stainless steel) in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
6. The K2M spinal implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
7. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS AND PRECAUTIONS FOR PEDIATRIC PATIENTS
1. 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.
2. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

   Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.
3. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

   Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

   The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

PREOPERATIVE
1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Rods may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The use of two rods and crosslinking the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.
6. Use of bone cement will make removal of the implants difficult and should be avoided.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY


Caution: Consult Accompanying Documentation


Consult Instructions For Use


Do Not Reuse

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Actual device color may vary.
Consult product catalog for details.