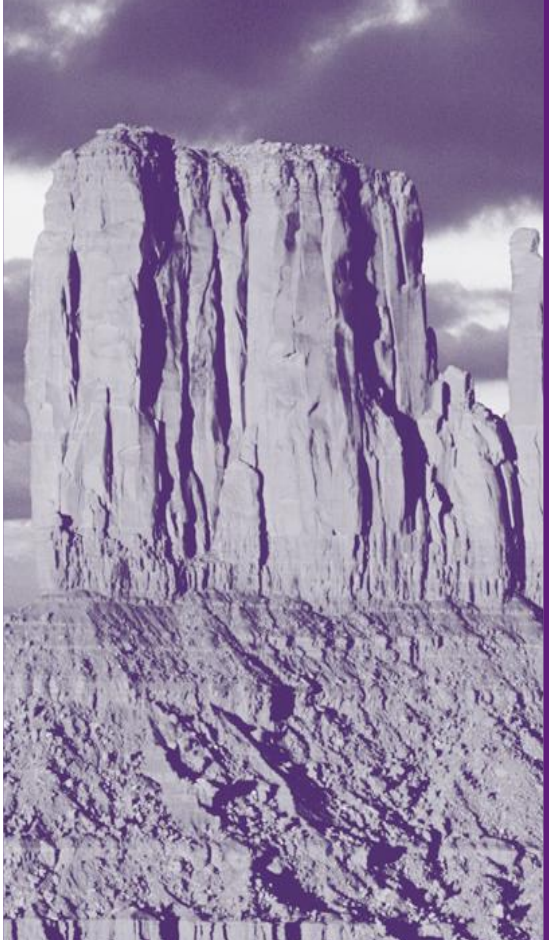


MESA
RAIL™ DEFORMITY

Surgical Technique

MESA Rail

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™

Surgical Technique Steps

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 Rail ™ Deformity System. This guide outlines a Single-Right Thoracic Curve using a Single MESA Rail Correction Technique.

Dear Colleagues,

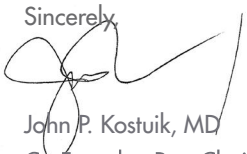
Welcome to K2M and the MESA Rail™ Deformity Spinal System. With this product, K2M strives to attain the highest level of excellence in the medical device industry. With the help of experts in both the orthopedic and neurosurgical communities, our Product Development team and I are extremely proud to provide surgeons with a breakthrough technology to address the most complex spinal deformities.

The MESA Rail Deformity System features a revolutionary "beam–like" implant, providing enhanced rigidity to aid in the restoration of sagittal balance while maintaining the low-profile characteristics of the MESA® Spinal System. Due to the beam-like implant design, reducing the Rail Crickets® over the MESA Rail will inherently result in rotation of the vertebral bodies as they are pulled up to the implant. The MESA Rail implant technology is state-of-the-art, with several features facilitating more efficient intra-operative use of the system. This technology also offers intra-operative variability of rod rigidity by offering different strength implants.

Great efforts have also been made in the instrument design to provide the surgeon with multiple options in one system during surgery. These designs include several new and innovative ideas for simplifying surgical application of the implants. The MESA Rail itself aids in correction by applying corrective forces during axial derotation.

The MESA Rail Deformity Spinal System is, in my opinion, a significant breakthrough in the correction of spinal deformities. The following manual clearly outlines the procedural details and options, and will offer a guide to help understand the many unique aspects of the MESA Rail Deformity Spinal System for use in treating our patients.

Sincerely,



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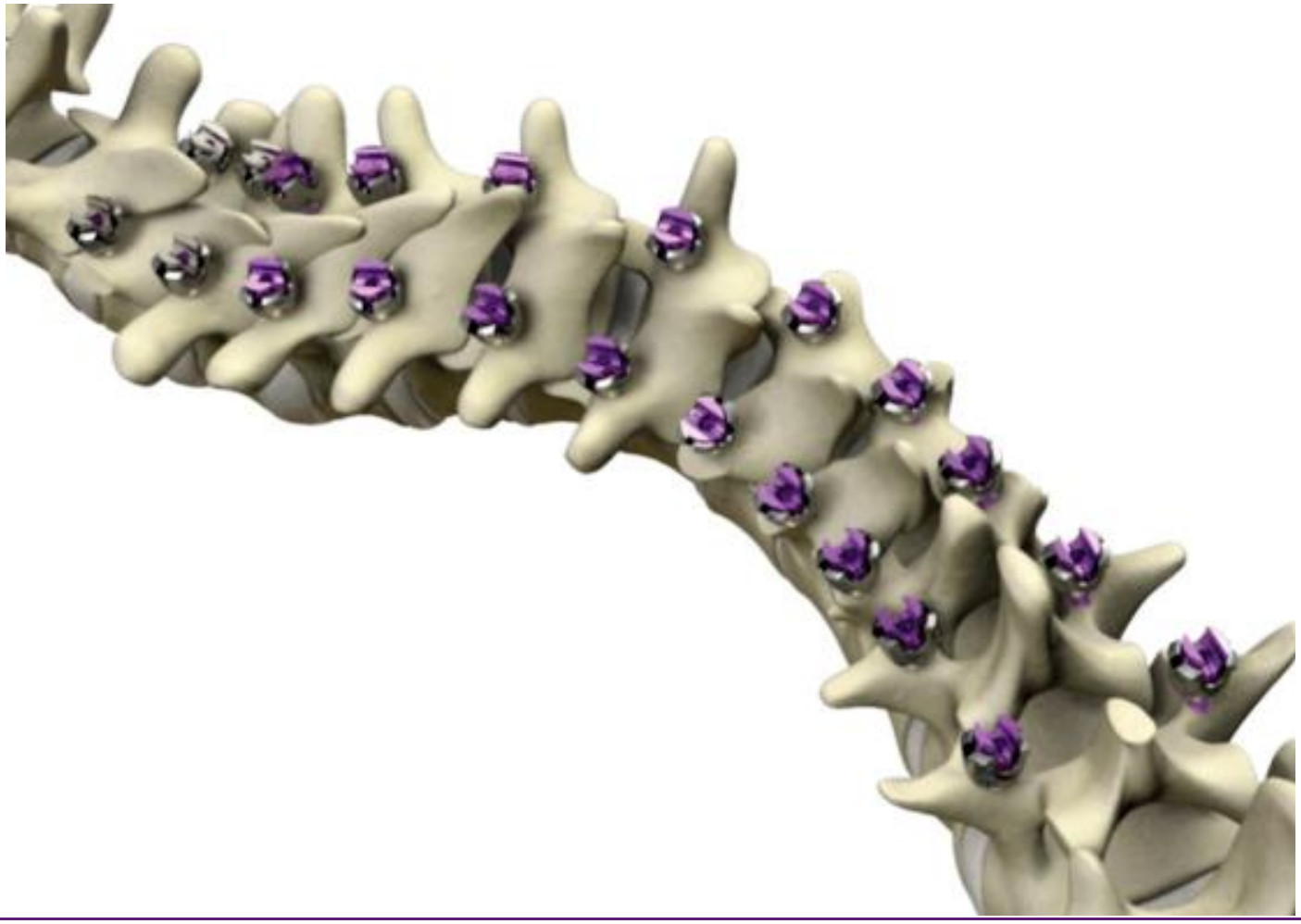
FEATURES & BENEFITS

Rail 4D™ Technology

- Uniquely Shaped to Provide Enhanced Rigidity, While Minimizing Implant Volume of Pedicle Screws
- Intra-operative Variability of Rod Rigidity With One Pedicle Screw
- Lower Profile Than Set Screw Based Systems
- Due to the Beam-like Design, Reducing the Rail Crickets® Will Inherently Result in Rotation of the Vertebral Bodies as They Are Pulled Up to the MESA Rail

MESA RAIL™ DEFORMITY SURGICAL TECHNIQUE

6



SCREW PLACEMENT

NOTE: For Steps 1 – 5, please refer to the MESA Deformity Surgical Technique.

MESA® Polyaxial Screws may be used at the most proximal levels (T4 and T5) for ease of MESA Rail™ attachment and establishment of the proximal foundation. Otherwise, use MESA Uni-Planar, Deformity Uni-Planar, or 360 Screws throughout the spine. MESA Foundation Screws are also available for those surgeons preferring to use them at the end of a construct for lumbosacral fixation. Confirm the screw heads are unlocked and all screws are at appropriate levels and aligned to accept the MESA Rail.

MESA RAIL PREPARATION

Once all screws have been inserted, the MESA Rail is selected and cut to the appropriate length, if necessary. The MESA Rail is available in both Colbalt Chrome and Titanium Alloy. To cut the MESA Rail, insert it into the appropriate hole of the Telescoping Rail Cutter and squeeze the handles together.

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

NOTE: Transition Rail-Rods are also available in Cobalt Chrome and Titanium Alloy.

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MESA RAIL PREPARATION (CONT.)

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

The Rail Telescoping Bender may be used to contour the MESA Rail to the desired amount of lordosis or kyphosis. By pulling out and rotating the dial, the MESA Rail may be bent to the desired curvature (Small, Medium, or Large).

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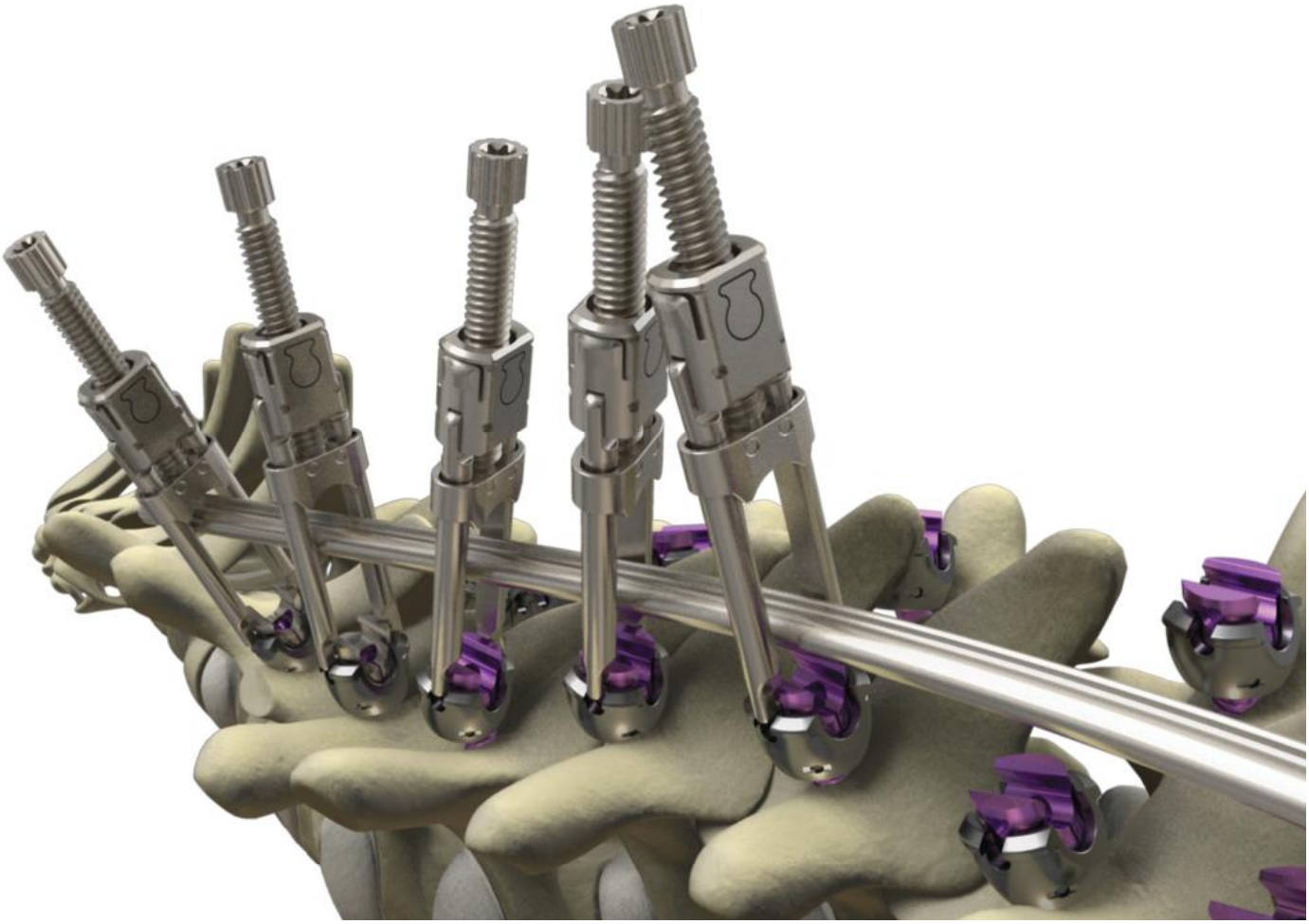
RAIL CRICKET®

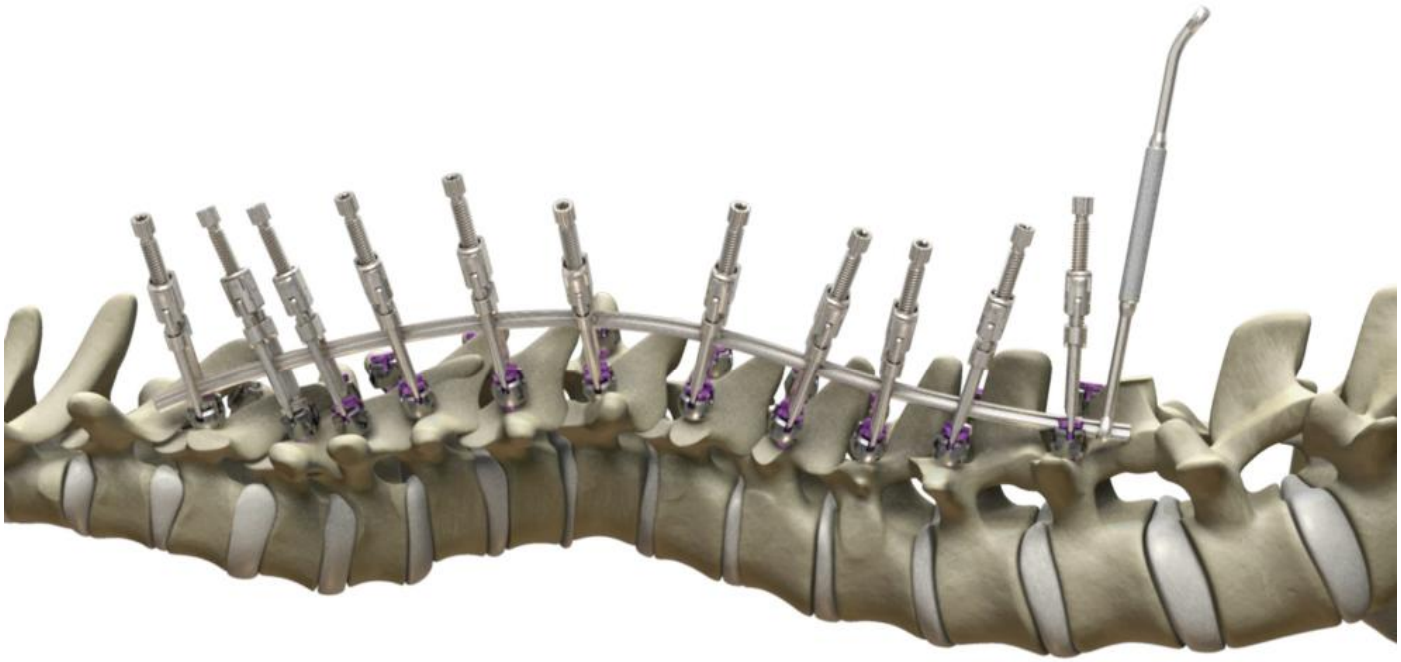


CONCAVE MESA RAIL PLACEMENT

After the MESA Rail has been bent into the physiological sagittal plane, place Rail Crickets® on the upper half of the concave screws. Then slide the pre-bent MESA Rail through the Crickets. After introducing the MESA Rail, place Rail Crickets over the lower half of the MESA Rail. Do not tighten the Rail Crickets, as they are only meant to ensure screw capture on the MESA Rail at this point. They will be used later for translation correction of the spine and reduction of the MESA Rail to the screws.

RAIL ROTATION WRENCH

RAIL VISE GRIP



Rotate the MESA Rail into the sagittal plane. This is preferably performed using the Rail Rotation Wrench and/or Rail Vise Grip(s). Seat the MESA Rail into the proximal fixation points T4 and T5 by tightening the Rail Crickets using the Screwdriver Shaft, Size 25, and a handle.

NOTE: The Rail Crickets have multiple potential uses in addition to reduction. They may be used for multi-axial correction or implant capturing in compression and distraction maneuvers where the partial locking feature is not desired.

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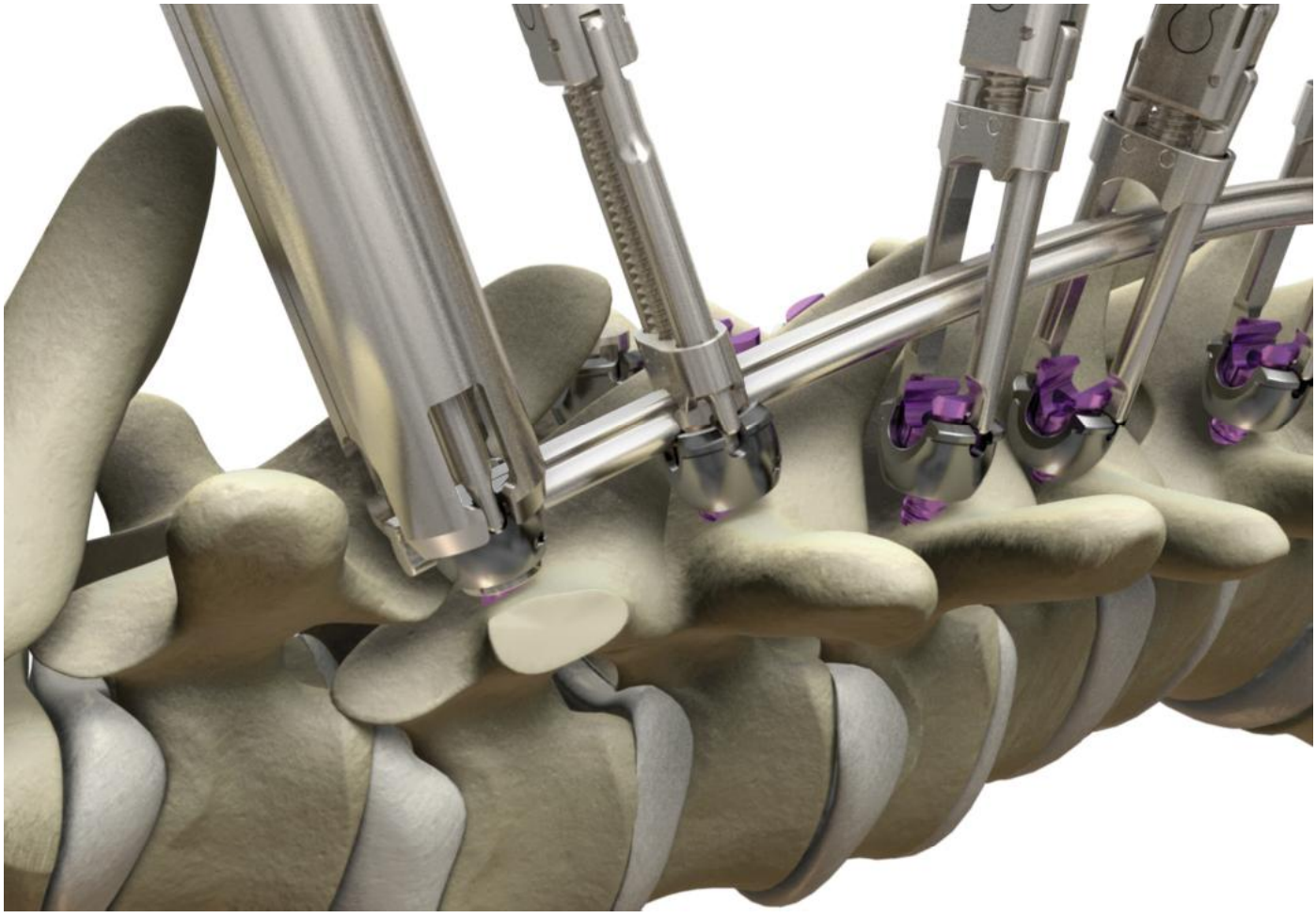
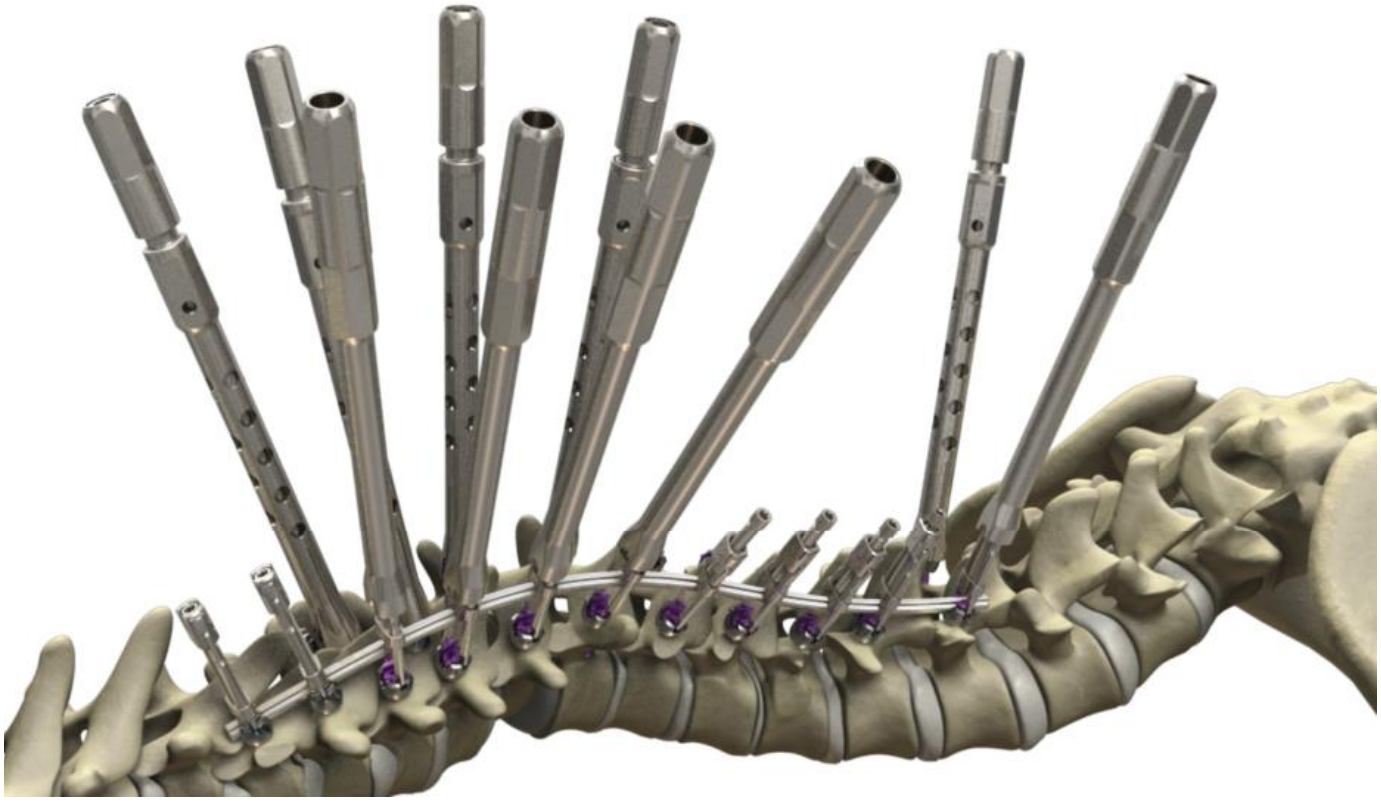
RAIL SUPERFLY™



CONCAVE MESA RAIL PLACEMENT (CONT.)

Partially lock the proximal fixation points using the Rail Reduction Jack Partial Locker, also known as the Rail Superfly™, over the Rail Crickets. It is important the Rail Crickets are fully reduced for the Rail Superfly to be properly docked. Introduce the Rail Superfly over the Rail Cricket and squeeze the handle to the shaft. Reduce the remaining Rail Crickets at least halfway at apical levels and tighten so they "kiss" the MESA Rail at all other levels.

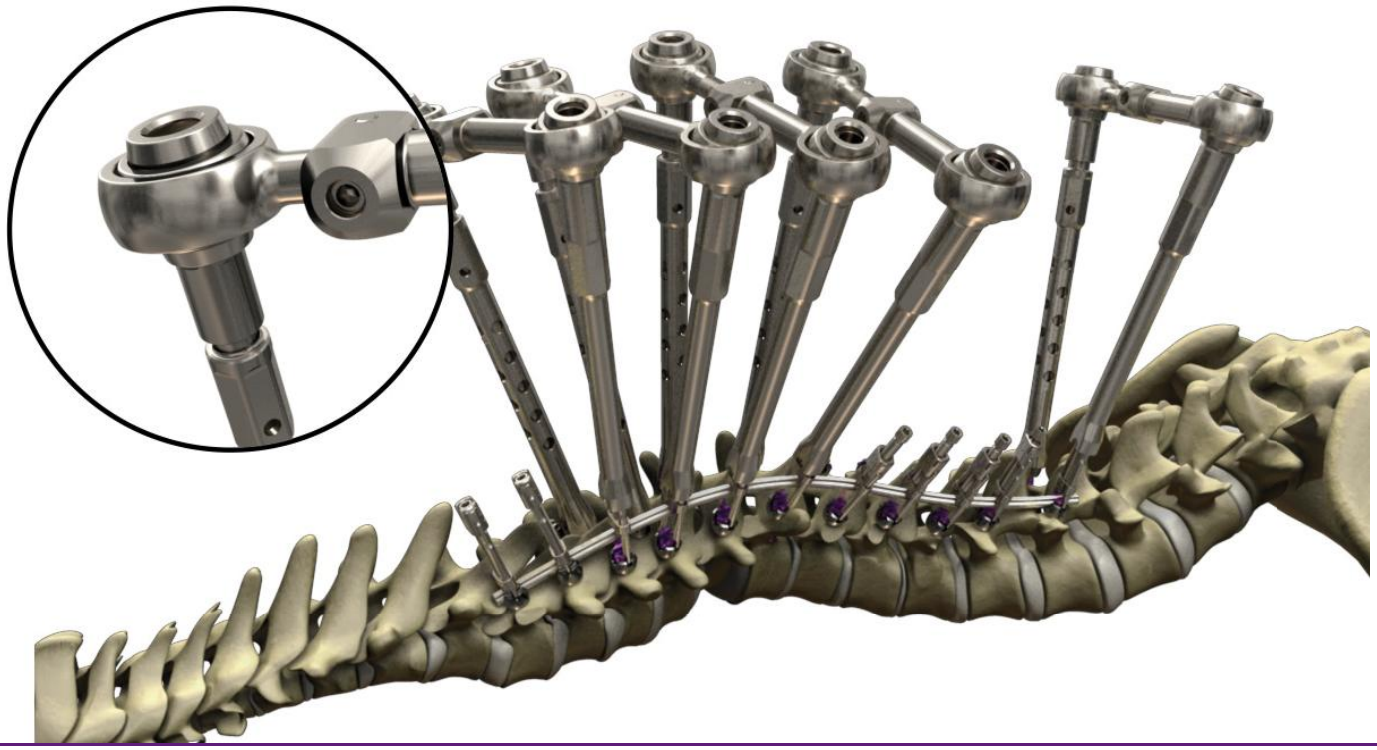
NOTE: Because of the unique geometry, the MESA Rail provides significant axial correction by simply tightening the Rail Deformity Crickets slowly along the construct. Be sure to distribute the forces along the entire construct to avoid point-loading the bone-screw interface.



COUNTERTORSION & AXIAL CORRECTION

If direct vertebral rotation is desired, apply Rotation Tubes at the apex 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.

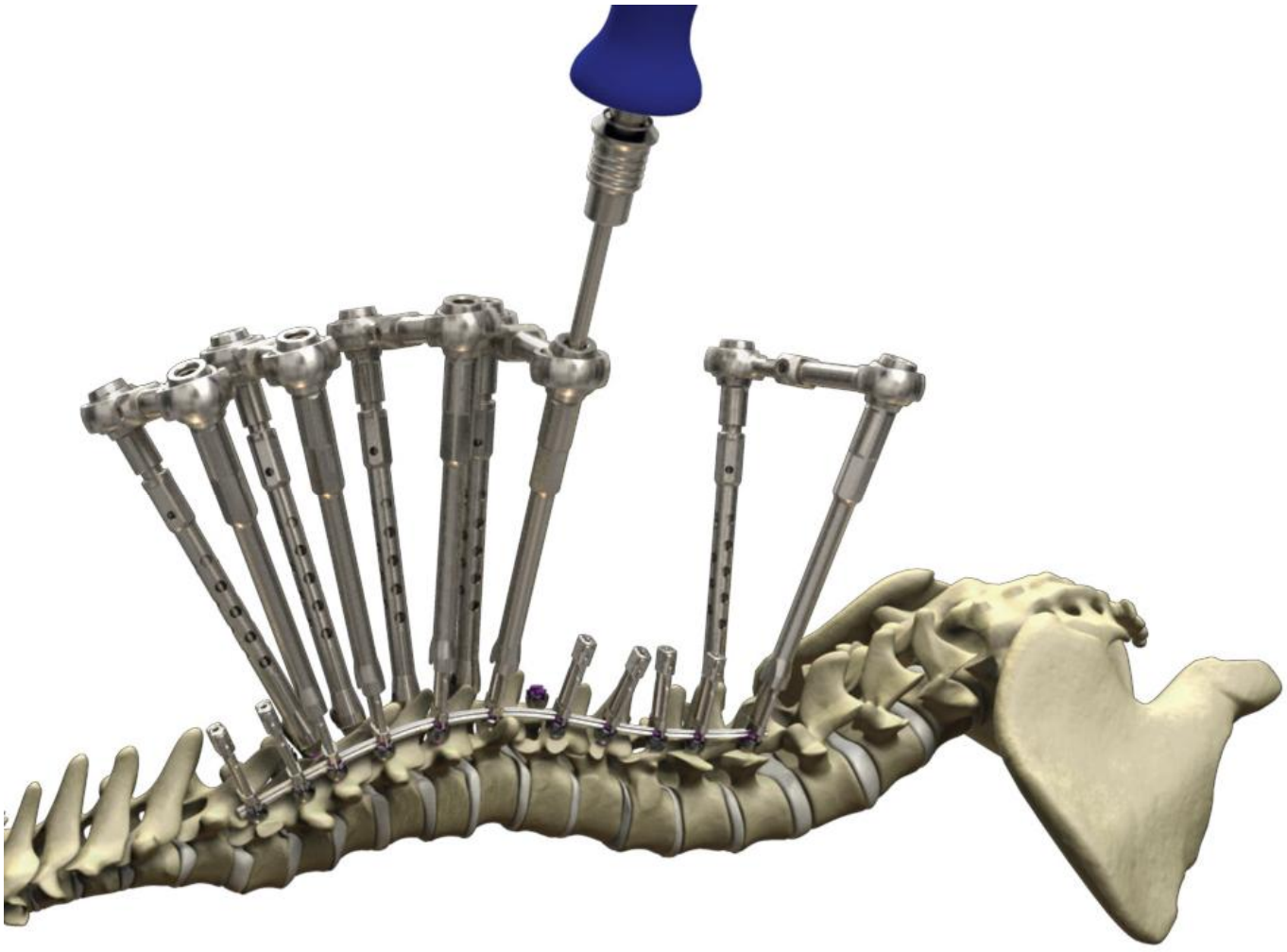
NOTE: The Manipulator Wrench can be used to help fully tighten the Manipulators.



COUNTERTORSION & AXIAL CORRECTION (CONT.)

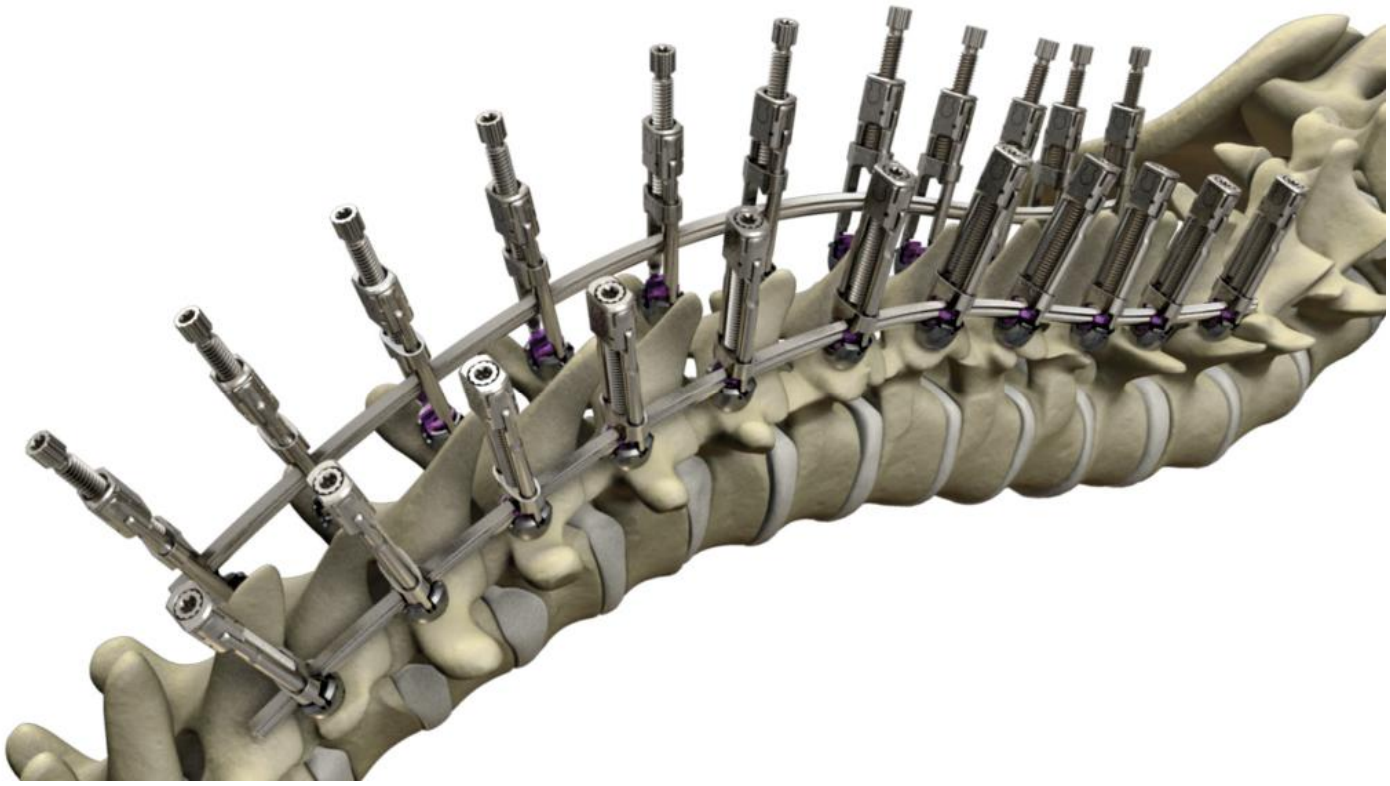
Apply Transverse Couplers by pressing them onto the Rotation Tubes and Manipulators to triangulate the pedicles at each vertebral level and evenly distribute the forces during derotation. Apply a downward and lateral force to the convex instrumentation, including the rib hump, and a medial force on the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

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



THORACIC CONCAVE TRANSLATION

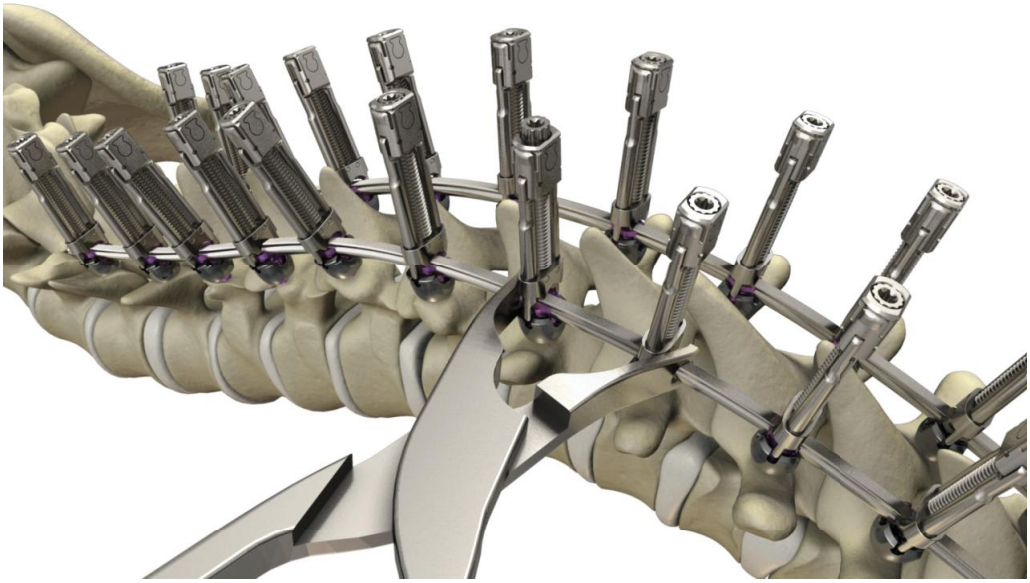
Translation of the concave thoracic apex to the MESA Rail is performed by gradually tightening the Rail Crickets from the ends sequentially with progression towards the apex of the deformity. By performing the translation simultaneously from the outside-in with the Rail Crickets, the forces are spread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

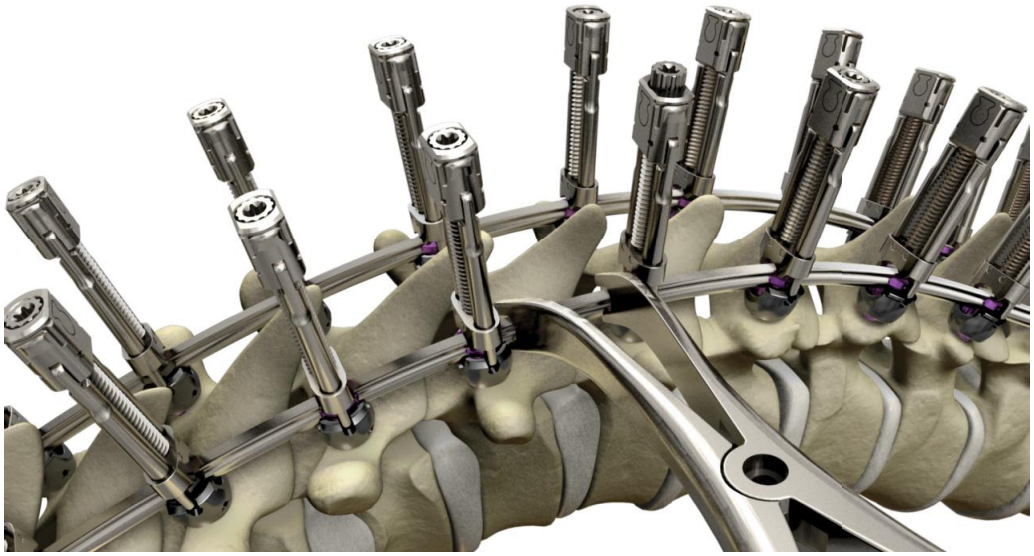


CONVEX MESA RAIL PLACEMENT

NOTE: Follow the remainder of this technique only if a MESA Rail is being used on the convex side. Otherwise, proceed with technique using MESA Deformity instrumentation.

With the Rail Unlocker, unlock the convex apical screws where Manipulators have been applied. Place Rail Crickets on the convex screws. The convex MESA Rail is introduced using the same technique as the concave/corrective MESA Rail. The proximal fixation points are partially locked using the Rail Superfly over the Rail Crickets and the MESA Rail is checked for proper sagittal plane alignment. The Rail Crickets are then tightened sequentially to reduce the MESA Rail into the screws.





COMPRESSION/ DISTRACTION

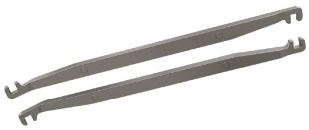
The final deformity correction is now performed using a variety of compression/distraction maneuvers. Begin proximal to the apex and release the Rail Cricket one to two turns. Then compress/distract and retighten the Rail Cricket to achieve correction. This method employs a technique similar to a standard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

NOTE: During compression/distraction maneuvers at apical levels, be sure to firmly grip the Rotation Tubes to maintain the axial correction, while releasing on the Rail Crickets to achieve necessary compression/distraction. Additional segmental Direct Vertebral Derotation can also be achieved at this time, if necessary.

RAIL SUPERFLY™

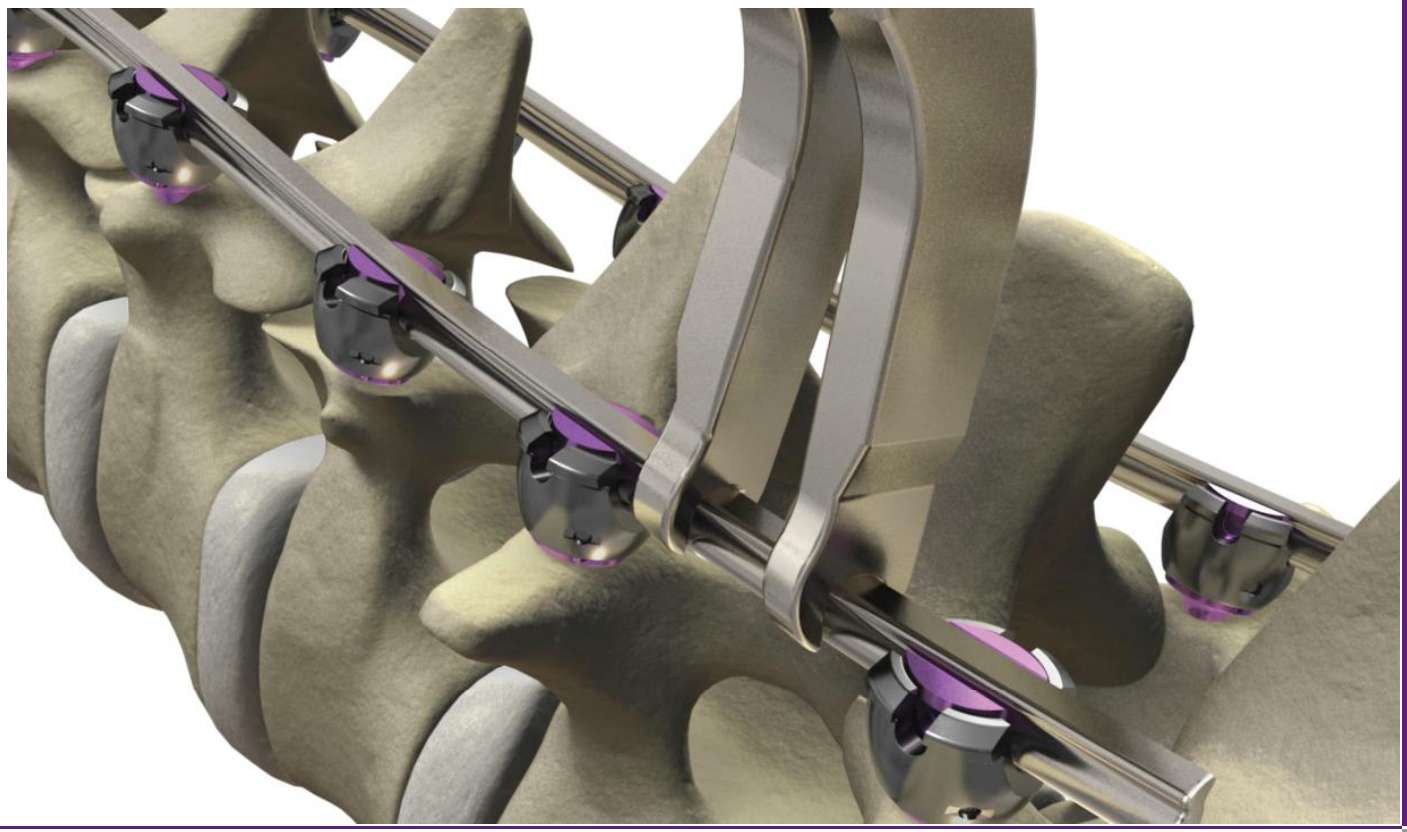
PARTIAL LOCKING

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



SAGITTAL BENDERS, LEFT & RIGHT

CORONAL BENDERS, LEFT & RIGHT



IN-SITU SAGITTAL & CORONAL BENDING

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

NOTE: When using the Rail Coronal 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.

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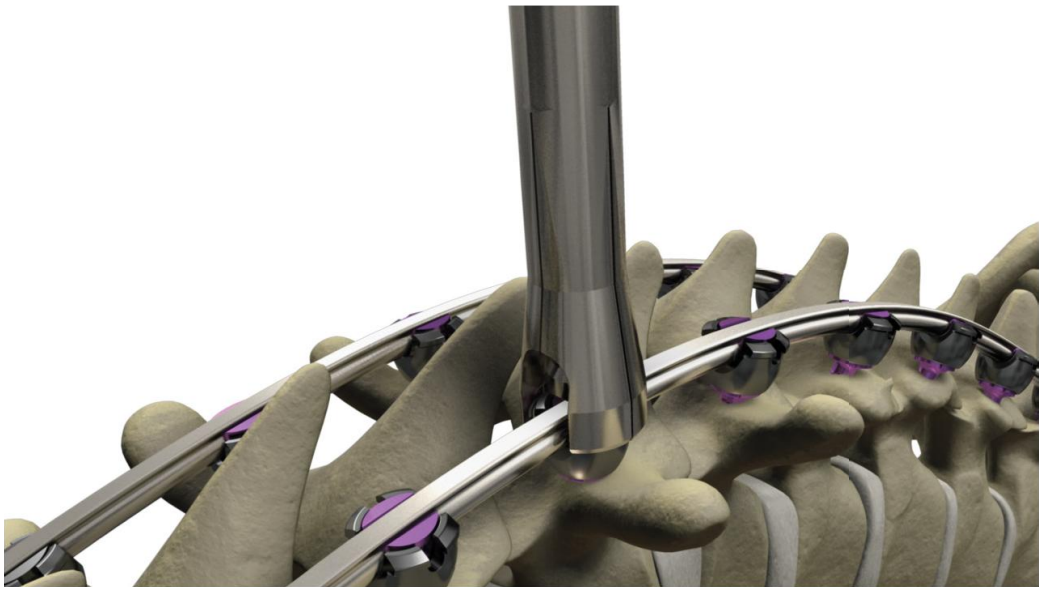
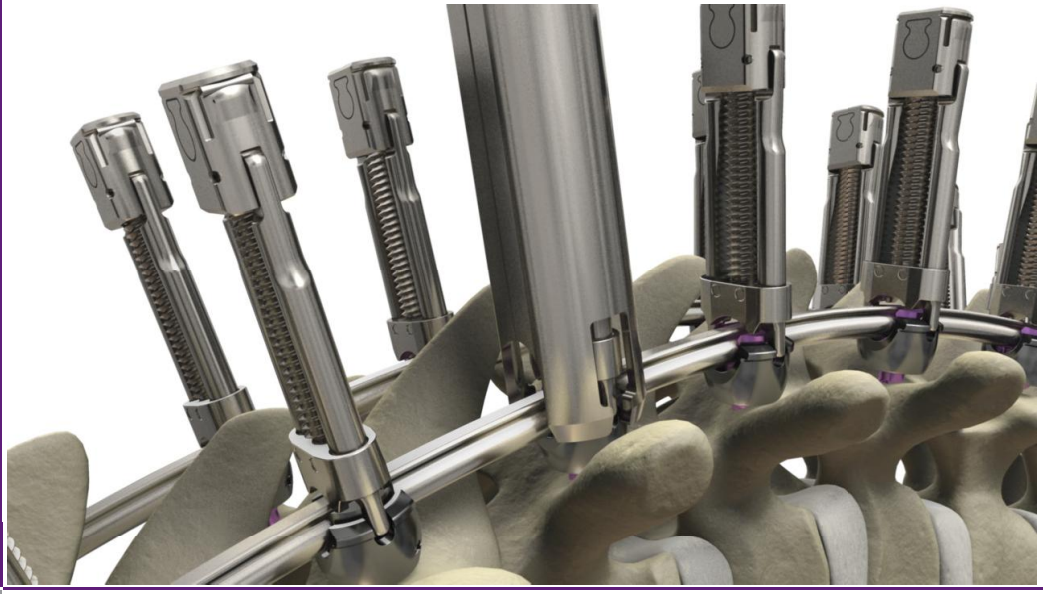
RAIL LOCKER

RAIL OVER CRICKET LOCKER



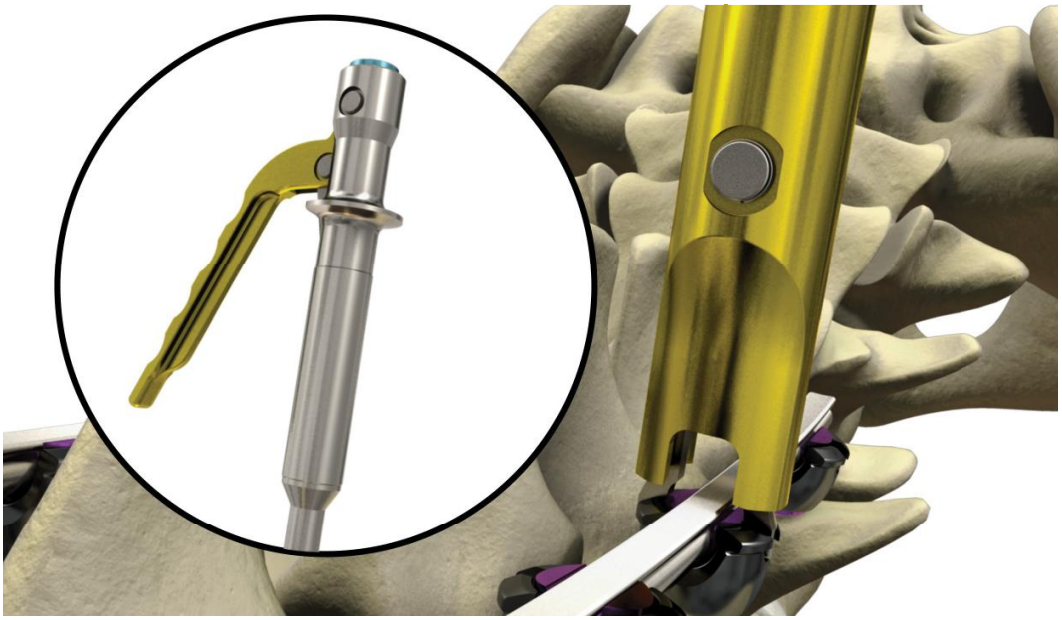


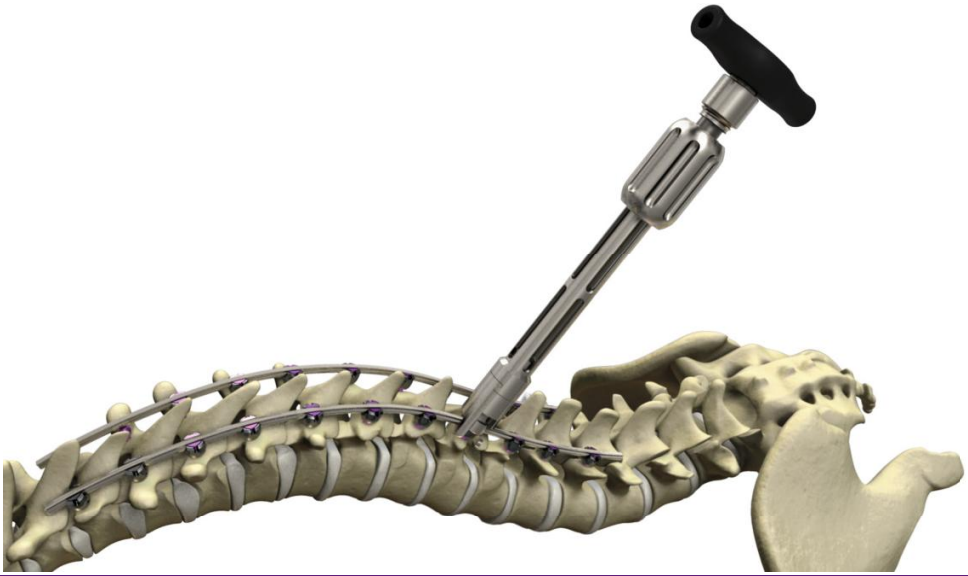
FINAL LOCKING

Confirm horizontal position of the Lowest Instrumented Vertebra (LIV) and fully lock these fixation points using the Rail Locker. Repeat final locking of each screw with the Rail Locker to confirm rigid fixation throughout. If preferred, the screws may also be final locked by using the Over Cricket Locker. Once each screw is locked, remove the Crickets. Confirm at least 5 mm of MESA Rail length extends beyond the most proximal and distal screws.

RAIL UNLOCKER

RAIL PULLER





UNLOCKING & REMOVAL

Should the surgeon decide to unlock a MESA screw from partial or full lock, the Rail Unlocker may be used. Fully open the Rail Unlocker 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 Rail Unlocker.

Once the MESA screw is in the unlocked position, the MESA Rail may be extracted from the implant housing using the Rail Puller. Apply the distal end of the Rail Puller over the MESA screw housing and rotate it in a clockwise direction until it securely engages the MESA Rail. Grab the handle and thread down in a controlled fashion in order to release the MESA Rail from the screw head.

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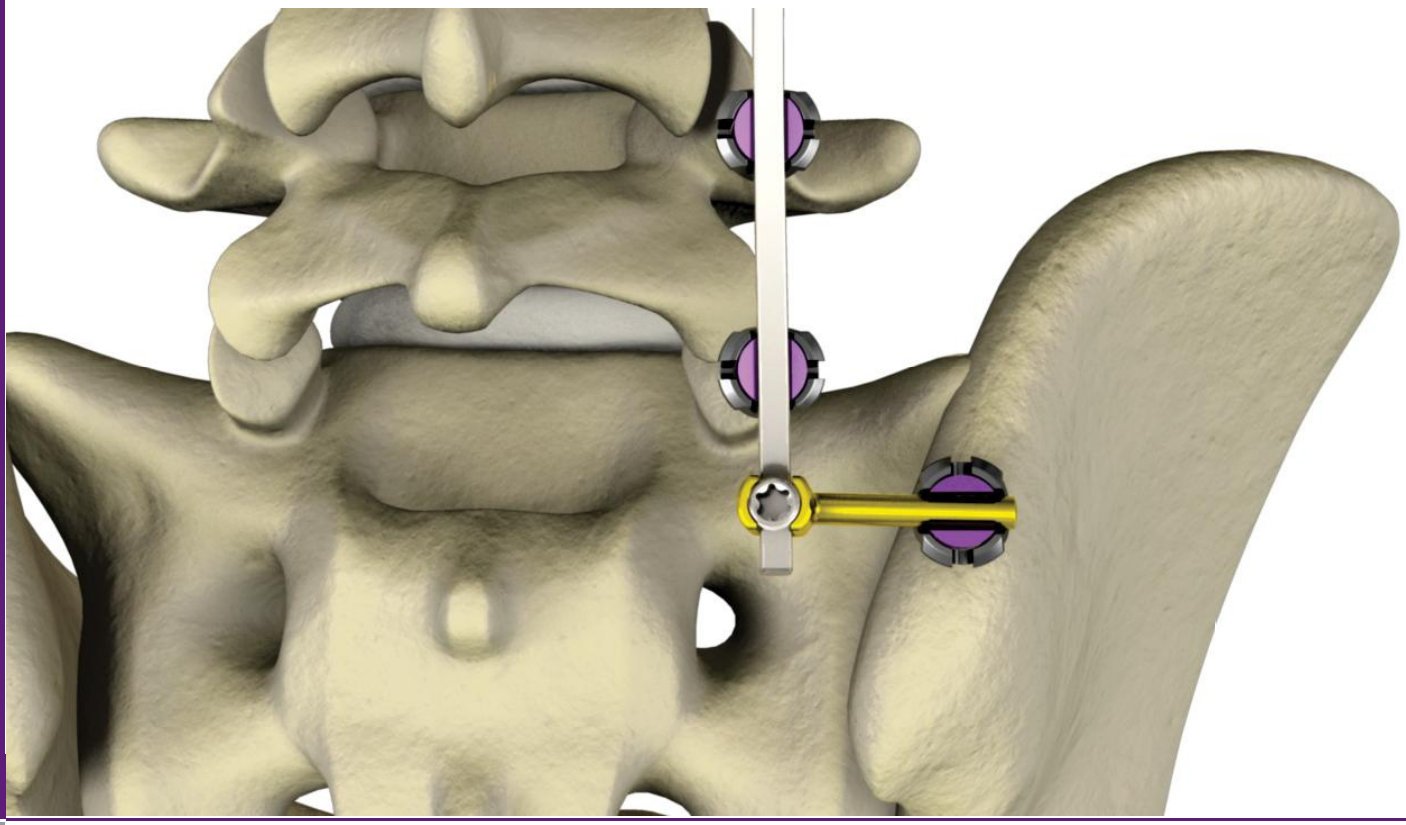
LATERAL OFFSET CONNECTOR, OPEN

LATERAL OFFSET CONNECTOR, CLOSED

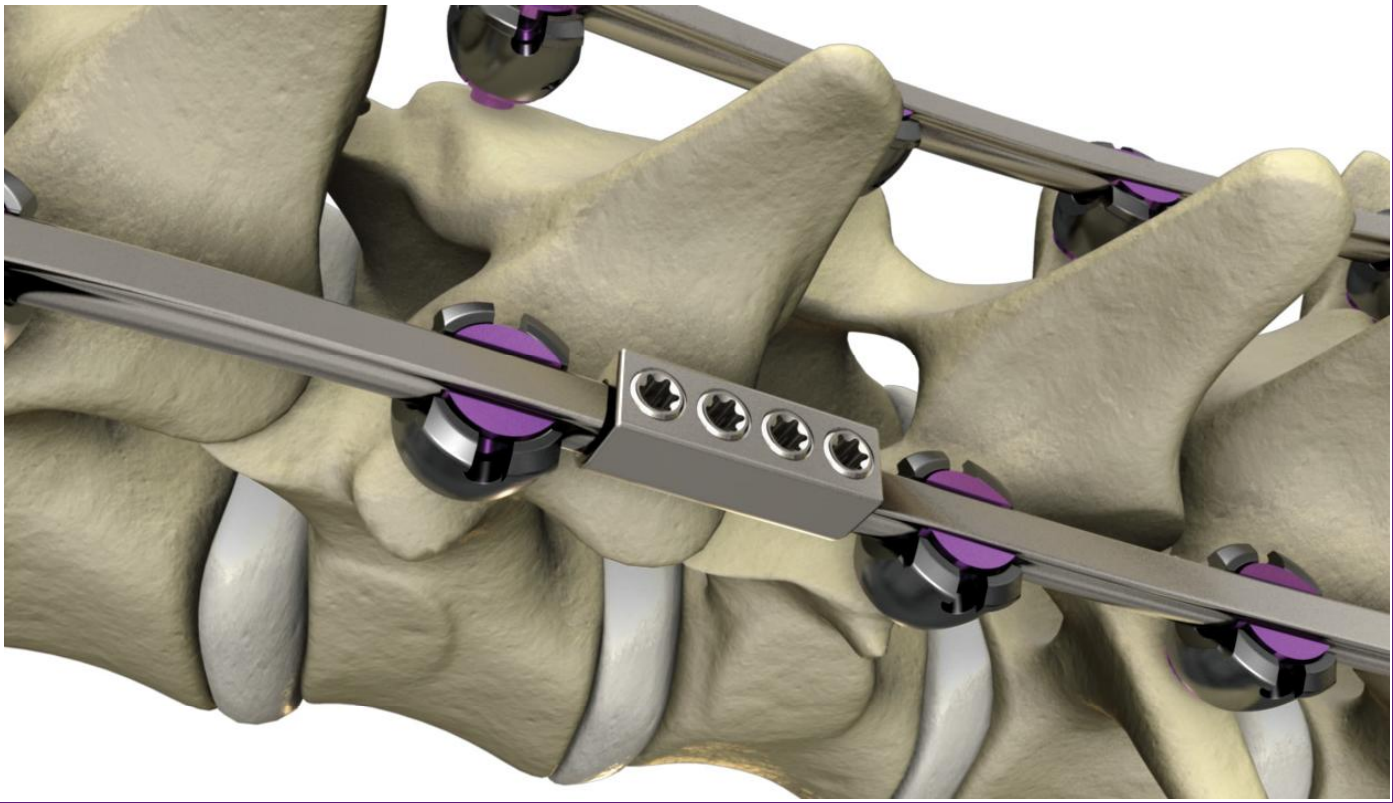


MESA RAIL CONNECTIONS: LATERAL OFFSET CONNECTOR (OPEN & CLOSED; VARIETY OF ANGLES)

The Lateral Offset Connectors may be used to link a screw that is lateral to a rod/MESA Rail. The rodded portion of the lateral offset connector is seated in the implant housing and the other end is attached to the MESA Rail with a set screw. Lateral offset connectors are available in open and closed versions, and also come in variety of angles.

Connectors are final tightened at 90 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

AXIAL CONNECTOR

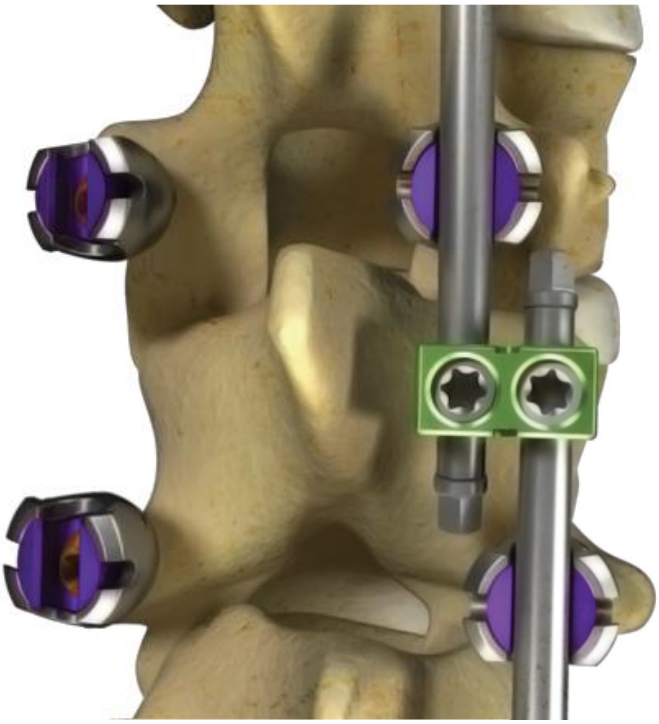


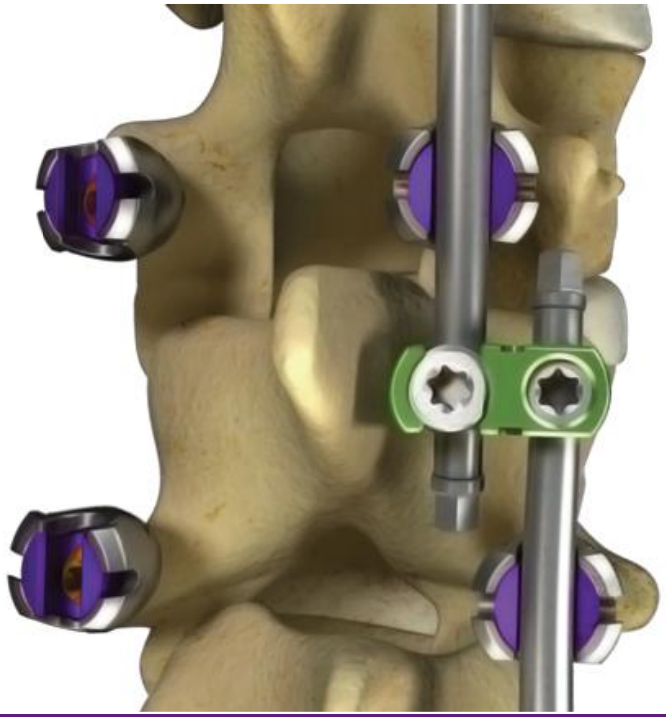
MESA RAIL CONNECTIONS: AXIAL CONNECTOR

The Axial Connector may be used to join MESA Rails and/or rods end-to end. The implant is final tightened at 90 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

PARALLEL CONNECTOR,
CLOSED/CLOSED

PARALLEL CONNECTOR,
CLOSED/OPEN

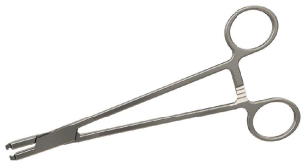




MESA RAIL CONNECTIONS: PARALLEL CONNECTOR

The parallel Rail connectors may be used to join MESA Rails and/or rods that are 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 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

NATURAL BRIDGE® CALIPER



RAIL CONNECTOR HOLDER

MESA RAIL CONNECTIONS: TRANSVERSE CONNECTORS

Use the NATURAL BRIDGE® Low Profile (LP) Caliper to measure the appropriate length between a MESA Rail and a MESA Rail/Rod and choose the best fitting transverse connector. The connectors come in Rail-rod and Rail-Rail styles, in both the semi-adjustable and adjustable designs.

Grab onto the desired implant using the Rail Connector Holder. Ensure all connector set screws are adequately loosened to securely engage the MESA Rail or rod. If using an adjustable transverse connector, loosen the middle set screw. Utilizing the polyaxial head of the connector, snap one head onto the MESA Rail or rod.

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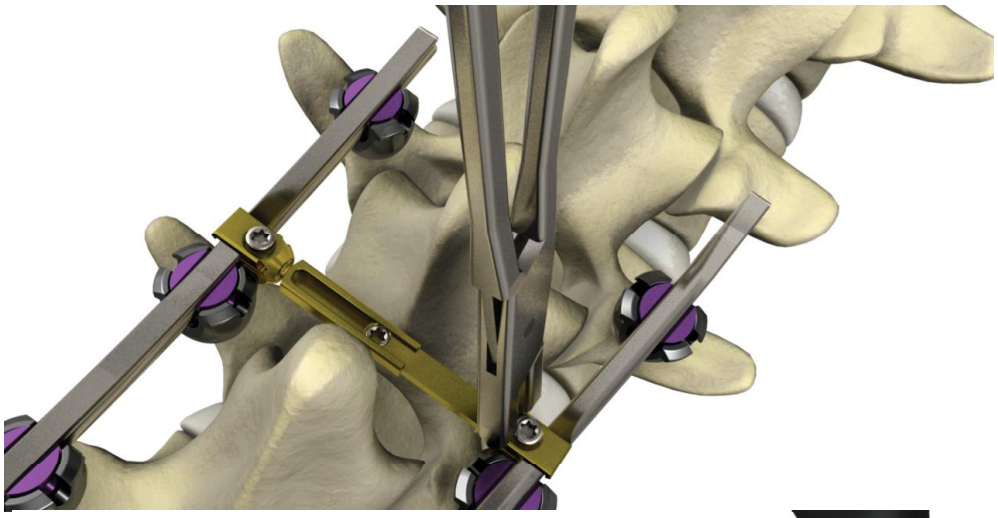
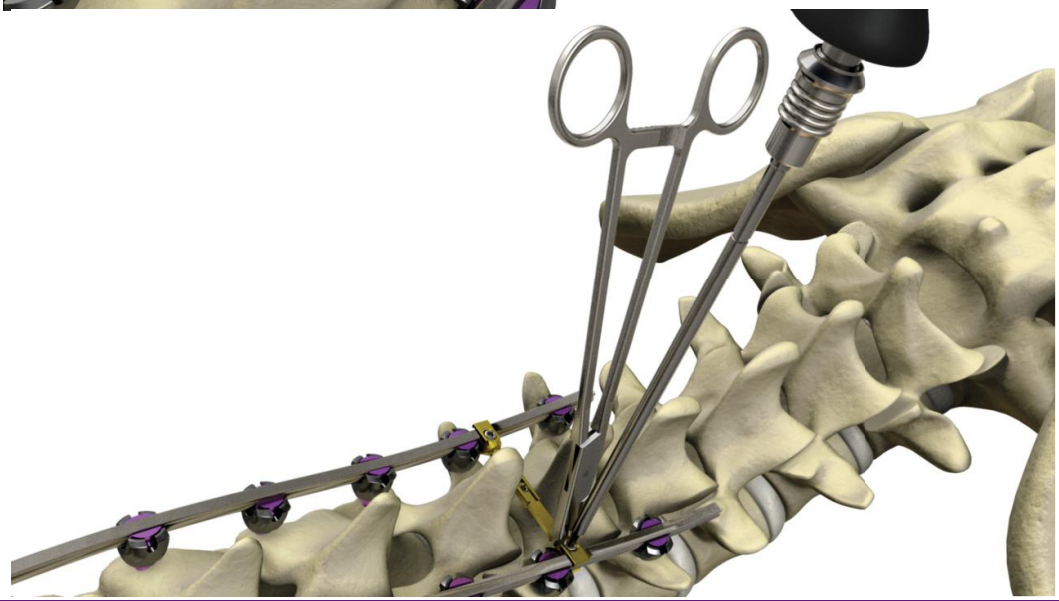
SIZE 15 CONNECTOR DRIVER

CONNECTOR HANDLE



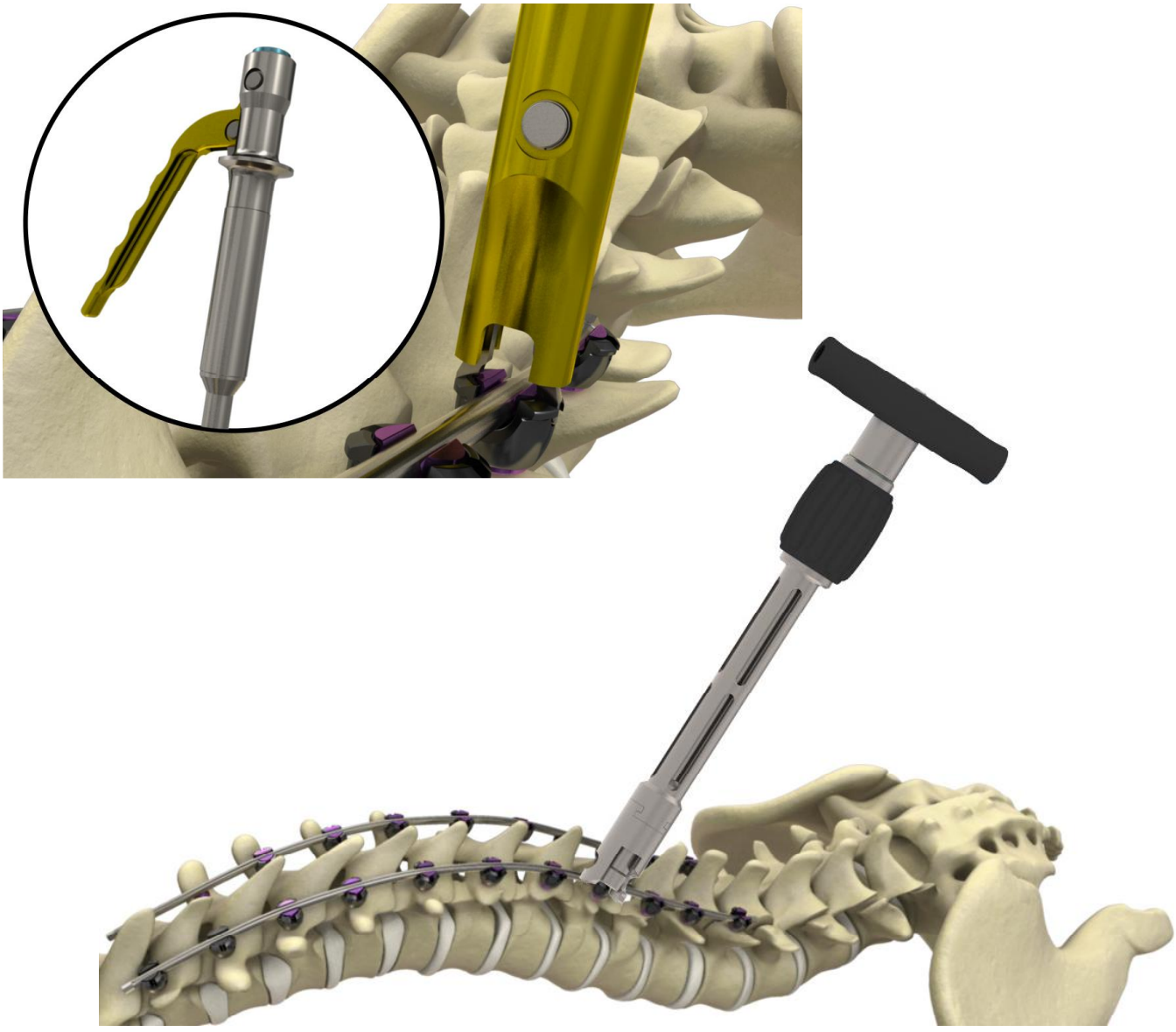


MESA RAIL CONNECTIONS: TRANSVERSE CONNECTORS (CONT.)

Stabilize the transverse connector and snap the other polyaxial head onto the opposite MESA Rail or rod. Provisionally tighten both heads with the Size 15 Connector Driver and Handle. If using an adjustable transverse connector, adjust to the appropriate length and provisionally tighten the middle set screw 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 Torque Limiting Driver, Size 15, and the Torque Limiting Handle, 30 in-lbs.

RAIL UNLOCKER

RAIL PULLER



UNLOCKING & REMOVAL

Should the surgeon decide to unlock the MESA screw from partial or full lock, the Rail 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 Rail Unlocker. Once the screw is in the unlocked position, the MESA Rail may be extracted from the implant housing using the Rail Puller. Apply the distal end of the Rail Puller over the screw housing and rotate it in a clockwise direction until it securely engages the MESA Rail. Grab the handle and thread down in a controlled fashion in order to release the MESA Rail from the screwhead.

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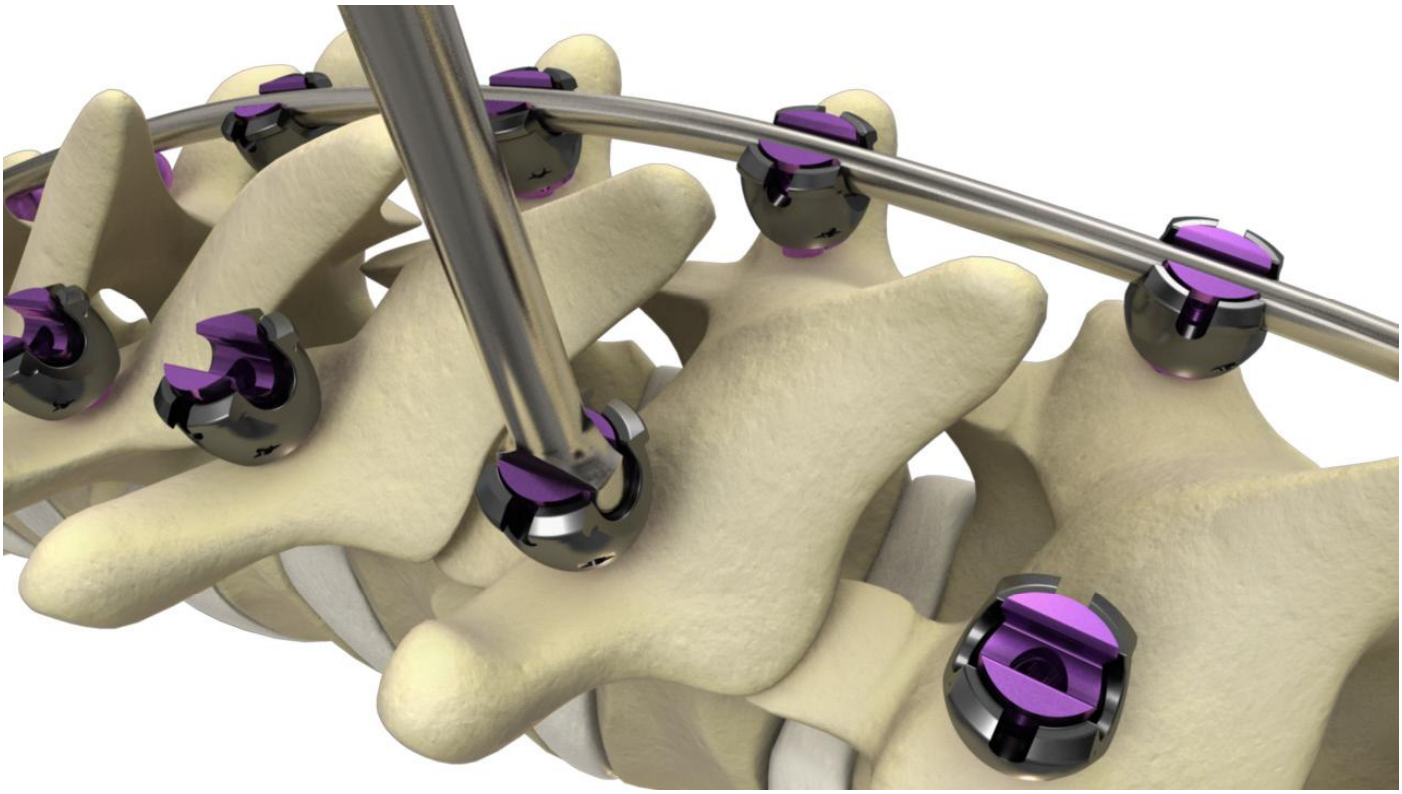
T-BAR SCREW REMOVER

T-HANDLE



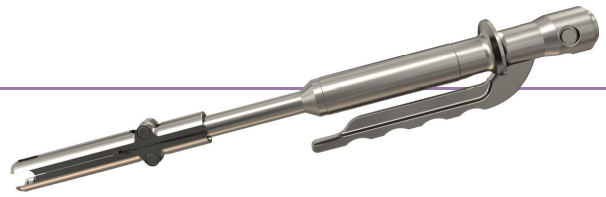
UNLOCKING & REMOVAL (CONT.)

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 MESA Rail 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.

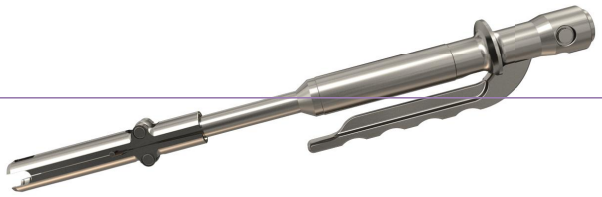
MESA RAIL™
PRODUCT CATALOG

MESA RAIL INSTRUMENTS

MESA RAIL REDUCTION JACK (CRICKET)

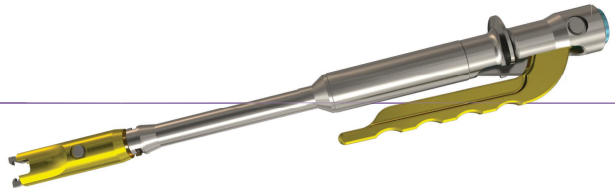


MESA RAIL OVER CRICKET LOCKER



MESA RAIL PARTIAL LOCKER

MESA RAIL LOCKER

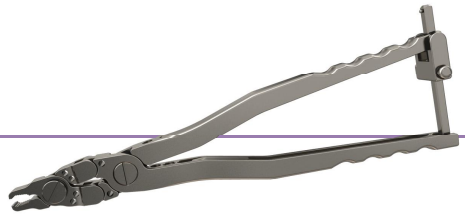


MESA RAIL UNLOCKER

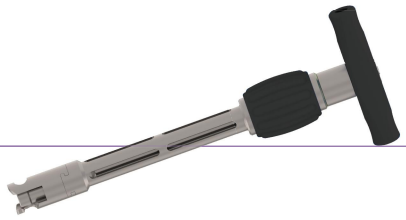
MESA RAIL INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
MESA Rail Reduction Jack (Cricket)	801-90147
MESA Rail Over Cricket Locker	801-90164
MESA Rail Partial Locker	801-90153
MESA Rail Locker	801-90129
MESA Rail Unlocker	801-90128

MESA RAIL INSTRUMENTS

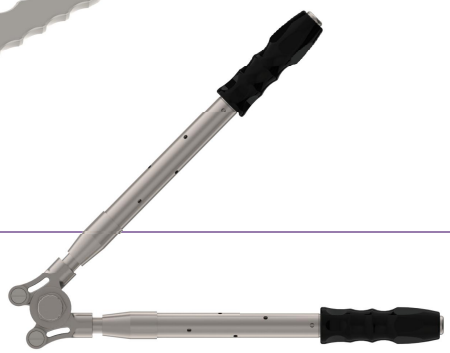


MESA RAIL VISE GRIP

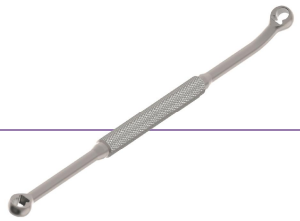


MESA RAIL PULLER

MESA RAIL FLAT BENDER



MESA RAIL TELESCOPING BENDER

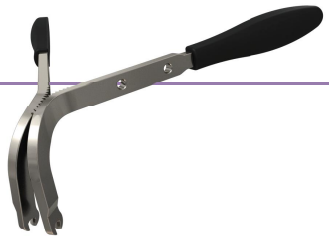


MESA RAIL ROTATION WRENCH

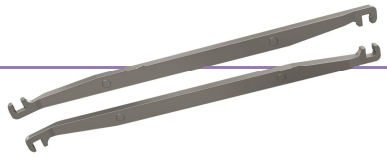
MESA RAIL INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
MESA Rail Vise Grip	801-90141
MESA Rail Puller	801-90143
MESA Rail Flat Bender	801-90145
MESA Rail Telescoping Bender	801-90152
MESA Rail Rotation Wrench	801-90142

MESA RAIL INSTRUMENTS



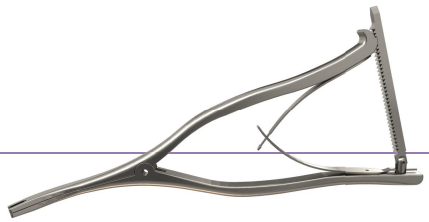
MESA RAIL CORONAL BENDERS (LEFT, RIGHT)



MESA RAIL IN-SITU BENDERS (LEFT, RIGHT)

MESA RAIL COMPRESSOR

MESA RAIL COMPRESSOR, ANGLED



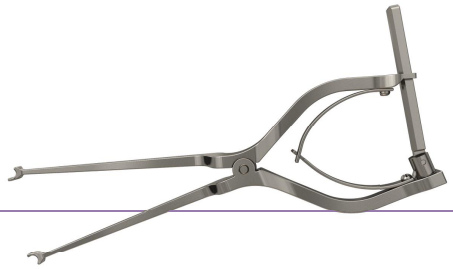
MESA RAIL DISTRACTOR

MESA RAIL INSTRUMENTS

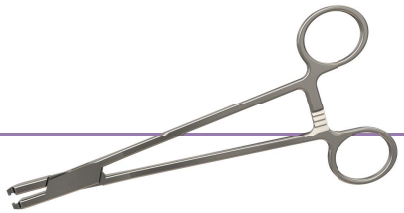
DESCRIPTION	CATALOG NUMBER
MESA Rail Coronal, Left	801-90122
MESA Rail Coronal, Right	801-90123
MESA Rail In-Situ, Left	801-90120
MESA Rail In-Situ, Right	801-90121
MESA Rail Compressor	801-90118

DESCRIPTION	CATALOG NUMBER
MESA Rail Compressor, Angled	801-90146
MESA Rail Distractor	801-90119

MESA RAIL INSTRUMENTS



NATURAL BRIDGE LP CONNECTOR CALIPER



MESA RAIL CONNECTOR HOLDER

TORQUE HANDLE (30 in-lbs)

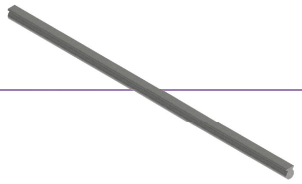
TORQUE LIMITING DRIVER (SIZE 15)

MESA RAIL CUTTER

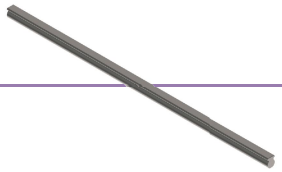
MESA RAIL INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
NATURAL BRIDGE LP Connector Caliper	101-90281
MESA Rail Connector Holder	801-90144
Torque Handle (30 in-lbs)	801-90067
Torque Limiting Driver (Size 15)	1101-90123
MESA Rail Cutter	801-90132

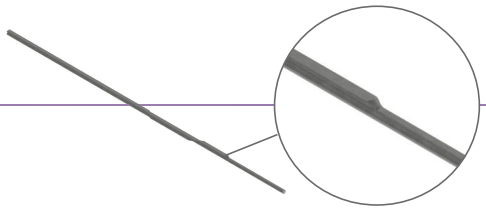
MESA RAIL IMPLANTS



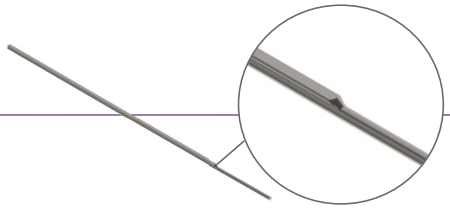
MESA RAIL STRAIGHT COBALT CHROME (COCR)



MESA RAIL STRAIGHT TITANIUM (TI)



MESA RAIL TRANSITION (COCR)



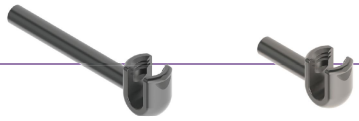
MESA RAIL TRANSITION (TI)

MESA RAIL IMPLANTS

DESCRIPTION	CATALOG NUMBER
MESA Rail Straight Cobalt Chrome (CoCr)	811-H55495
MESA Rail Straight Titanium (Ti)	801-H55495
MESA Rail Transition (CoCr)	811-H55495T
MESA Rail Transition (Ti)	801-H55495T

MESA RAIL IMPLANTS

LATERAL OFFSET CONNECTOR, CLOSED (25 mm, 50 mm)



LATERAL OFFSET CONNECTOR (25 mm, 50 mm)

AXIAL CONNECTOR

PARALLEL CONNECTOR, CLOSED/CLOSED

PARALLEL CONNECTOR, OPEN/CLOSED

MESA RAIL IMPLANTS

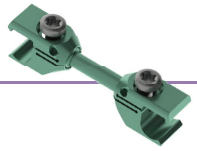
DESCRIPTION	CATALOG NUMBER
Lateral Offset Connector, Closed	801-755XXHG*
Lateral Offset Connector	801-755XXH*
Axial Connector	801-85555HD
Parallel Connector, Closed/Closed	801-85555HE
Parallel Connector, Open/Closed	801-85555HF

*Unique catalog numbers exist for each implant size. Please contact your local sales consultant with any questions you may have about ordering the MESA Rail Deformity Spinal System implants.

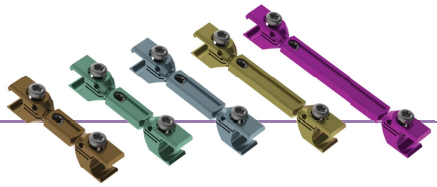
MESA RAIL IMPLANTS

MESA RAIL-ROD SEMI-ADJUSTABLE TRANSVERSE CONNECTORS

MESA RAIL-ROD ADJUSTABLE TRANSVERSE CONNECTORS



MESA RAIL-RAIL SEMI-ADJUSTABLE TRANSVERSE CONNECTORS



MESA RAIL-RAIL ADJUSTABLE TRANSVERSE CONNECTORS

MESA RAIL IMPLANTS

DESCRIPTION	CATALOG NUMBER
MESA Rail-Rod Semi-Adjustable Transverse Connectors*	801-700XXH*
MESA Rail-Rod Adjustable Transverse Connectors*	801-7XXXXH*
MESA Rail-Rail Semi-Adjustable Transverse Connectors*	801-700XXHH*
MESA Rail-Rail Adjustable Transverse Connectors*	801-7XXXXHH*

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

Product Insert

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the DENALI®, DENALI Deformity, MESA®, and RANGE® Spinal Systems. 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.

INDICATIONS
The RANGE Spinal System is comprised of the DENALI, DENALI Deformity, and MESA Spinal Systems and the ARI® Staple System, all of which are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications:

Trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated 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.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (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 failed previous fusion.

MATERIALS
All implant components are manufactured from Titanium alloy, CP Titanium and Cobalt Chrome, per ASTM (F67, F1472, F136, F1537) and ISO standards.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
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
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.

For Single Level Trays:

	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

For Stacked Trays:
Autoclave Cycle: Prevacuum
Temperature: 270°F (132°C)
Time: 35 minutes
Drying Time: 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).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

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.
3. This device is not intended for use except as indicated.

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.

WARNINGS AND PRECAUTIONS

1. The K2M Pedicle Screw and Hook Systems are intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use the surgeon should be specifically trained in the 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.
3. Patient 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.
4. 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.
5. 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.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. 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.
8. 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.
9. 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.

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.

PI005-0A11-00 Rev. 0
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K2-08-7053-02 Rev. 1
Actual device color may vary.
Consult product catalog for details.

CE 0086