stryker

Mesa® 2

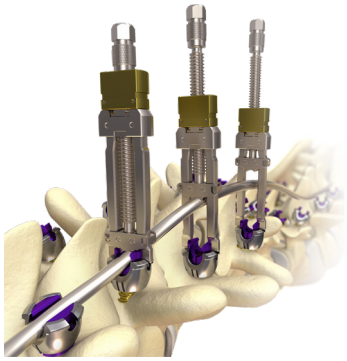
Deformity Spinal System

Surgical technique guide

Table of contents

This publication sets forth detailed recommended procedures for using the Mesa 2 Deformity Spinal System. If offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make adjustments when and as required.

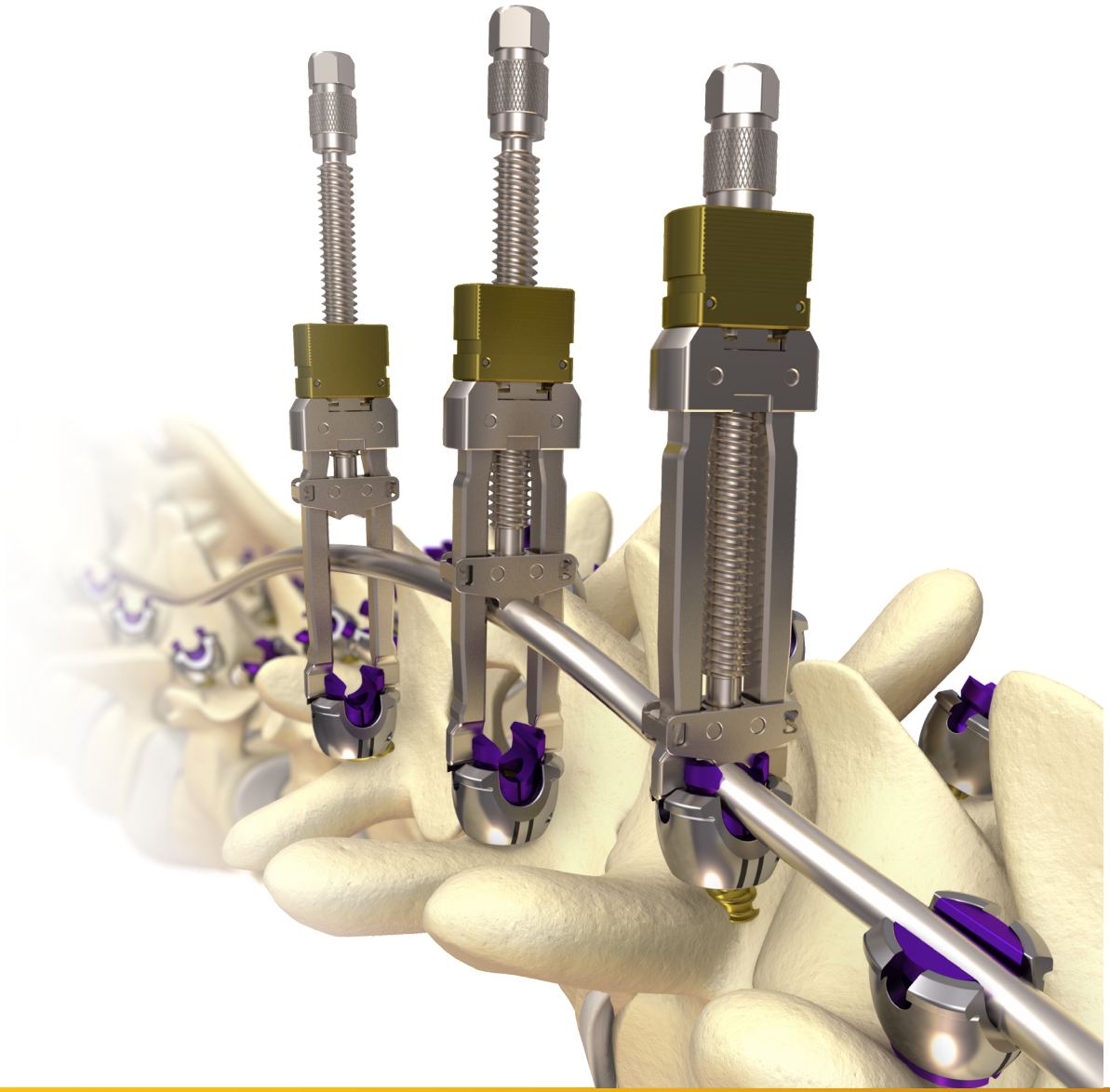
Features and potential benefits



Mesa 2 Deformity Spinal System[1]

- Dual-lead thread screw to allow for faster insertion
- Zero-torque technology
- No profile above the rod
- One-step final locking over Mesa 2 Crickets
- Revolutionary design of Crickets provides ability to accomplish correction maneuvers in all planes and allows for quick removal
- Streamlined instrumentation provides slow, controlled correction of spine, while distributing forces across entire construct
- Ability to segmentally derotate spine to help achieve axial plane correction

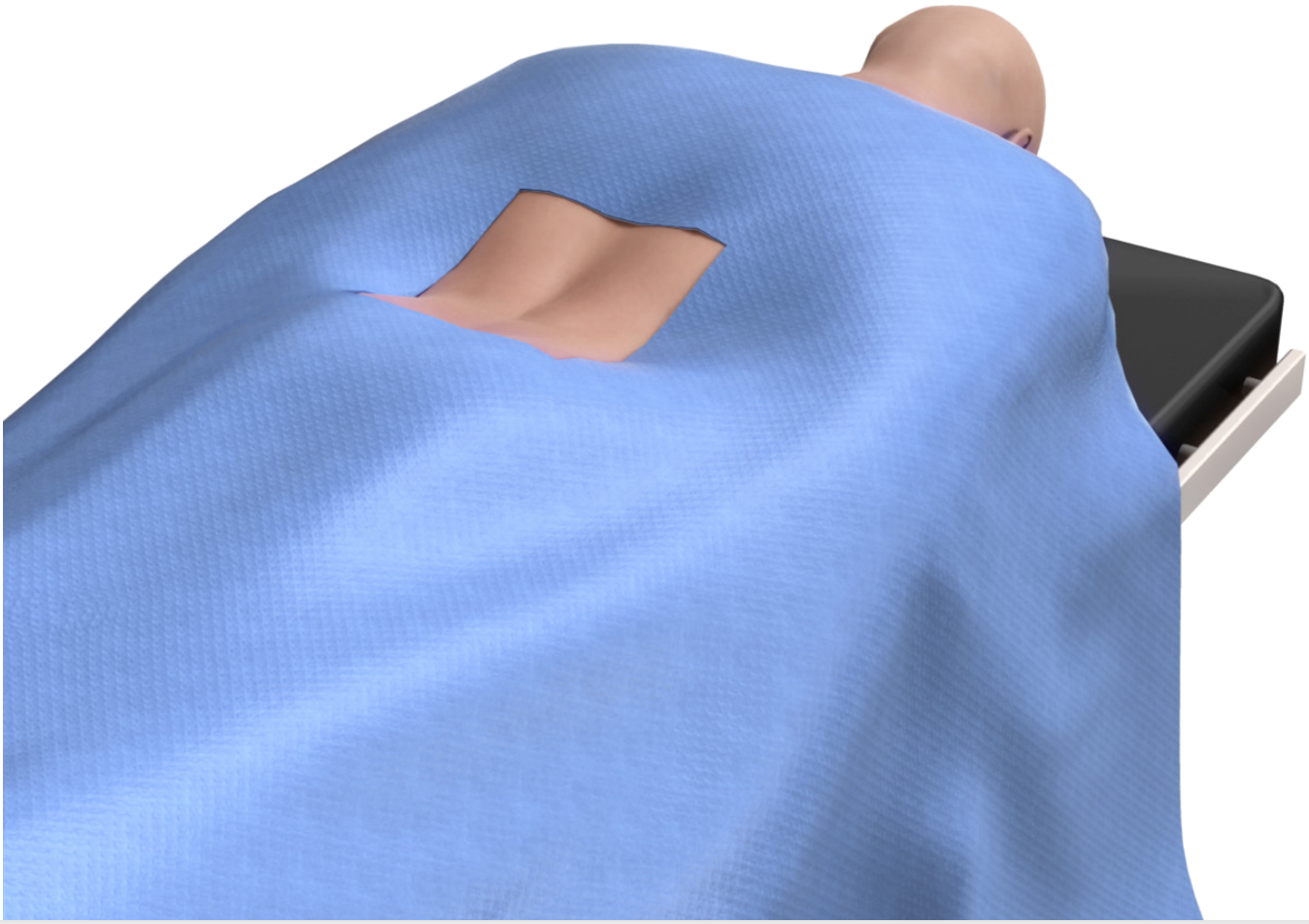
1. Mesa 2 Deformity Spinal System Product Flyer (MES2DF-SS-1_25369)



Surgical technique

Exposure and preparation

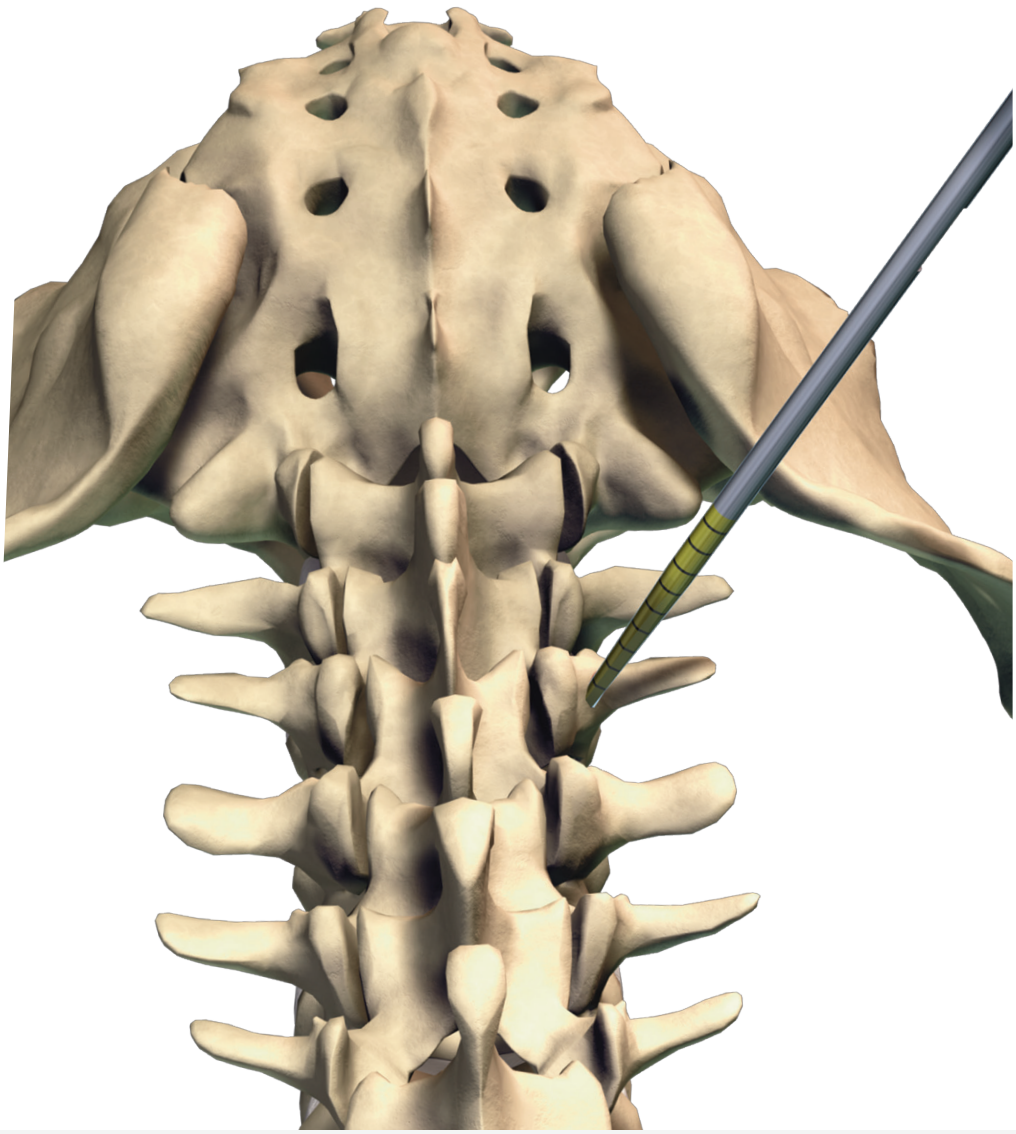
Perform facetectomies throughout.



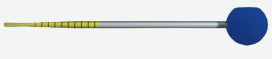
Step 2

Screw site preparation

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



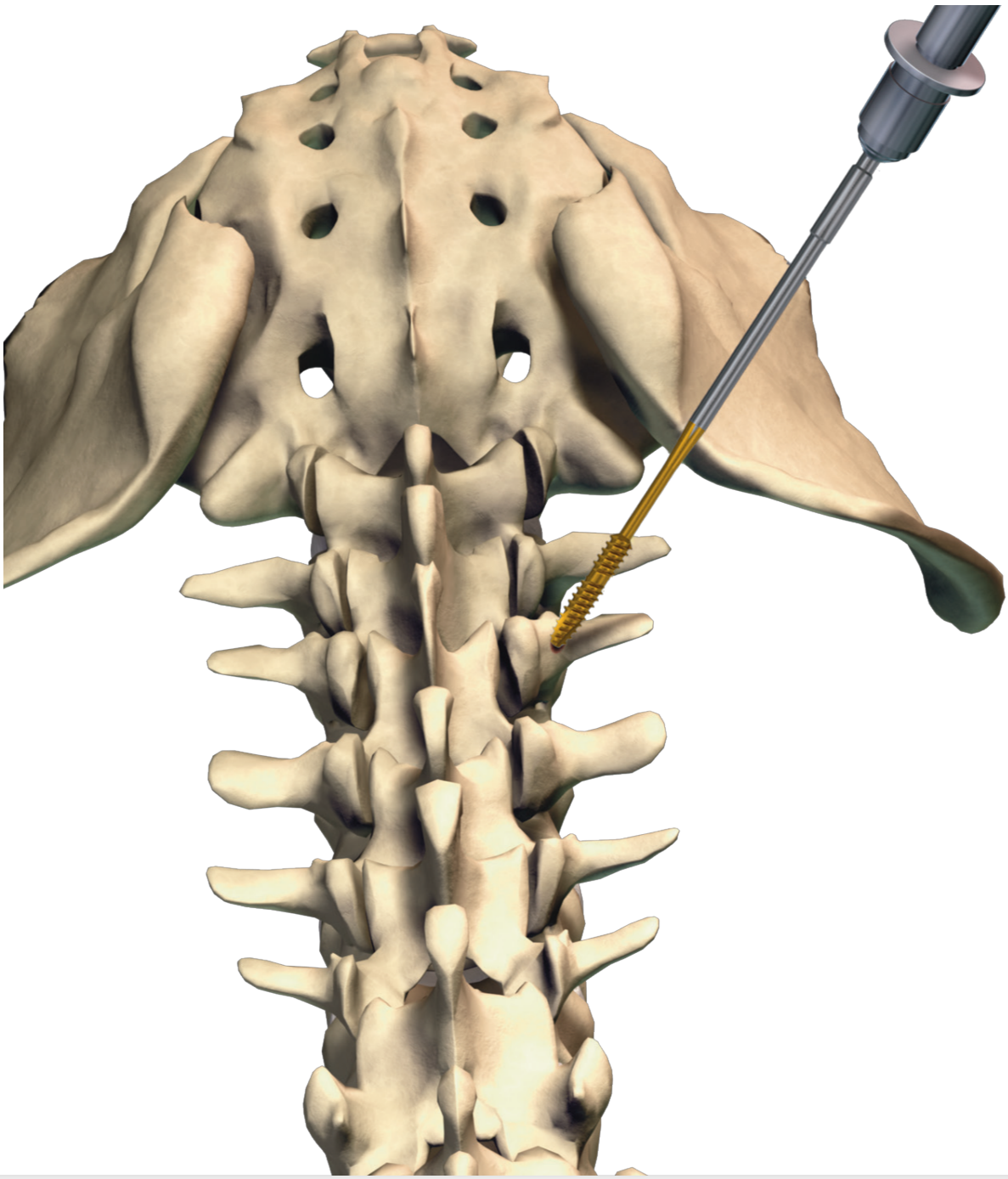
Straight Lumbar Probe



Curved Lumbar Probe

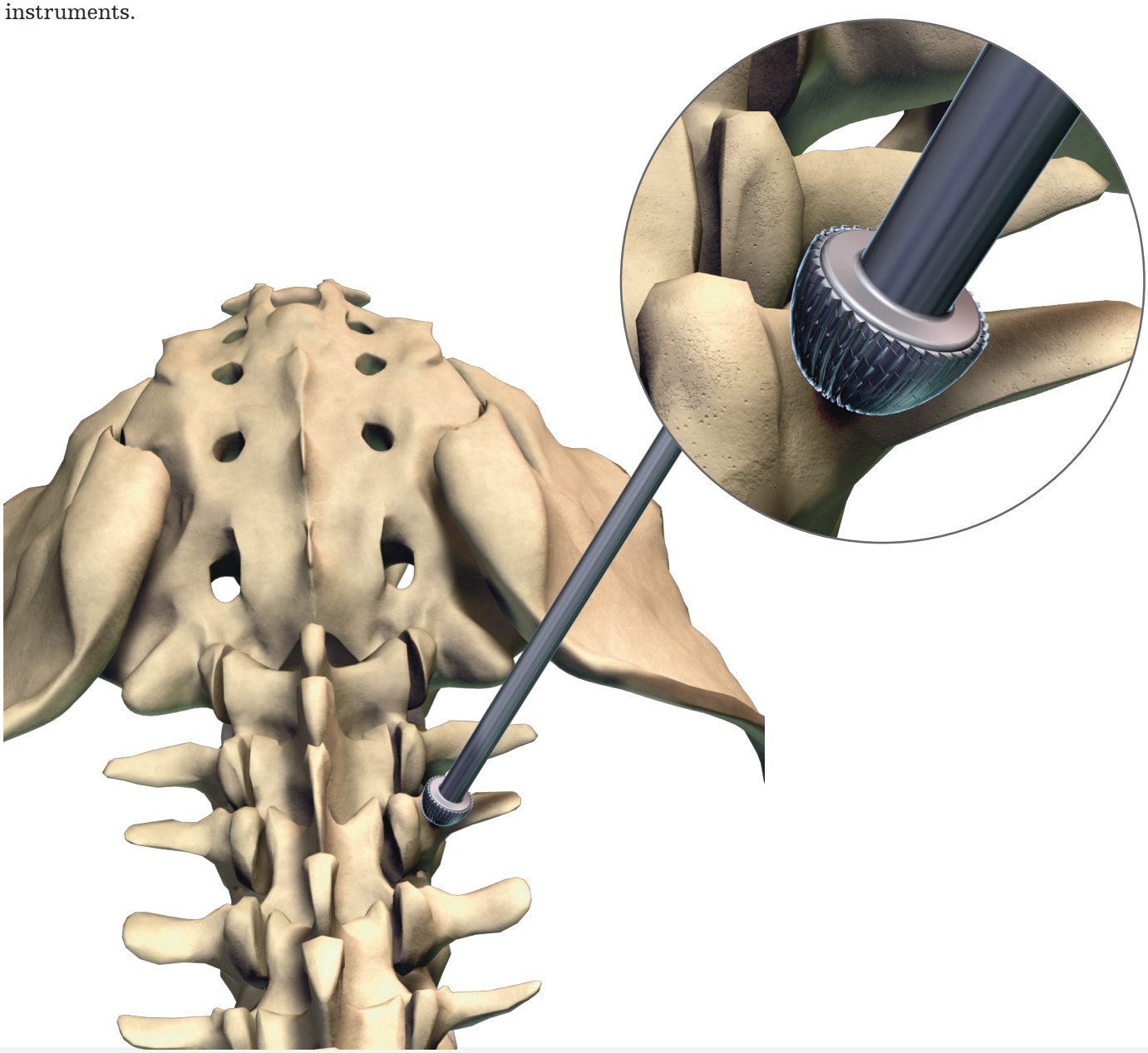
The correct insertion of the instrument will allow the tip of the Probe to follow a path of least resistance, reducing the potential of perforating the pedicle walls. The Probes are laser etched at 10mm increments, from 30-60mm, indicating the depth to which the probe has been inserted.*

If the bone is sclerotic or hard, the appropriate size Tap may be used to prepare the pedicle screw canal.



Screw site preparation (cont.)

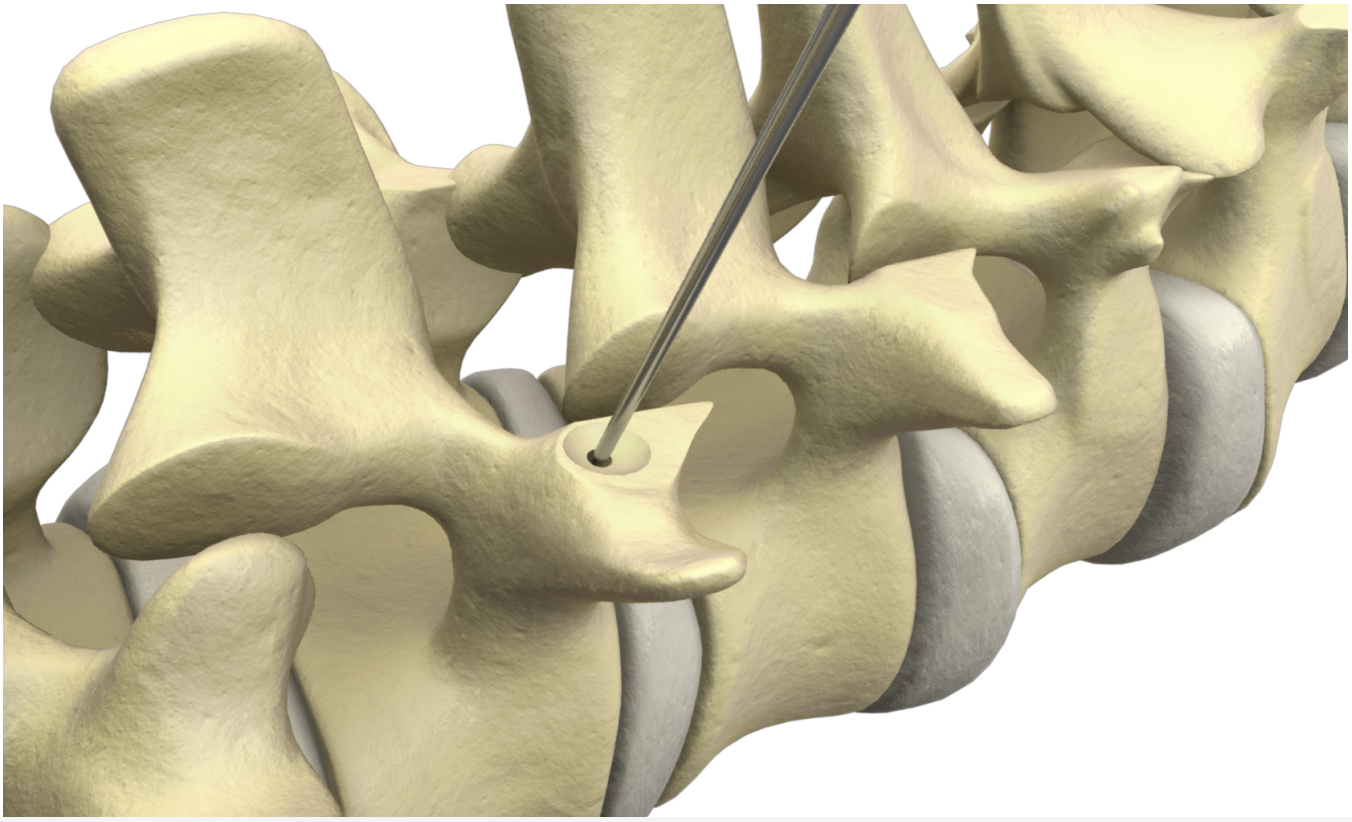
If desired, the Guiding Reamer may be used to remove bony anatomy. It can be useful when there are hypertrophic facets at the concavity in the thoratic spine. It can also assist in providing later decortications of the bony area surrounding the pedicle, creating the ability to countersink the screw, which allows for easier access for reduction instruments.



Guiding Reamer

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 though to the distal end of the prepared bony path. X-ray markers may be used for radiographic verification of the prepared path.



Ball Tip Feeler

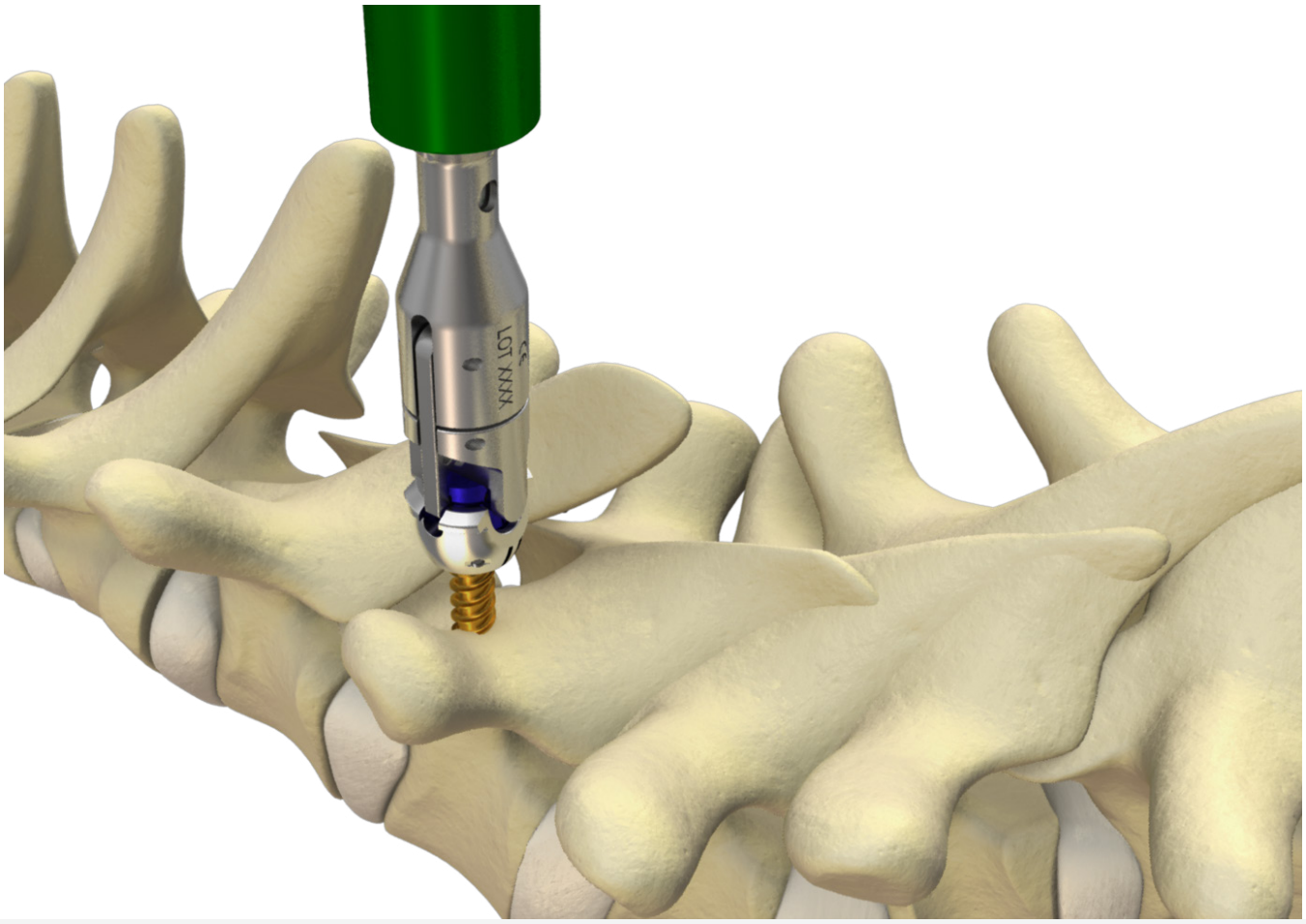
X-ray Markers

Step 4

Screw insertion

Mesa 2 Deformity Polyaxial and Mesa 2 Deformity Uniplanar screws are available to use as the surgeon finds appropriate. To insert the Mesa 2 screws, select a Handle and Inserter. Axial and T-Handles are available in both ratcheting and fixed positions. Positions are selected by turning the dial located at the bottom of the Handle. Attach the Inserter to a Handle.

After the pedicle screw pathway has been prepared and proper screw size has been determined, load the implant for screw insertion using the Mesa 2 Screw Inserter. It is important to grasp the implant by the screw shaft, while simultaneously applying a force between the Screw Inserter and implant to properly engage the screw onto the instrument.

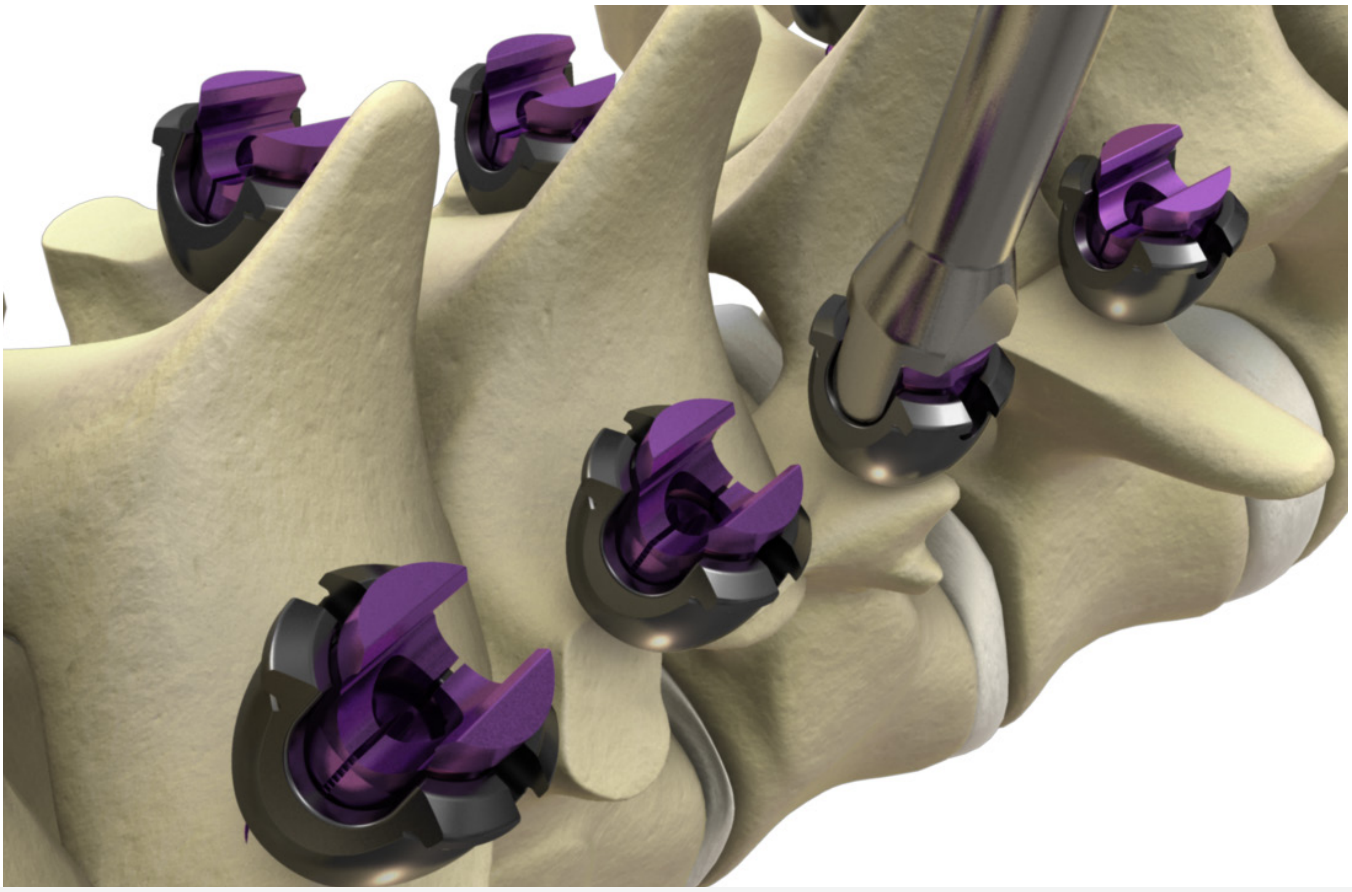


Short Deformity Inserter

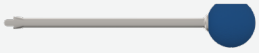
Deformity Screw Inserter

Screw adjustment

Once the appropriate screw has been selected and inserted, the head of the screw can be adjusted with the Mesa Head Adjuster to accommodate the rod. Confirm the screw heads are unlocked.



Screw Head Adjuster



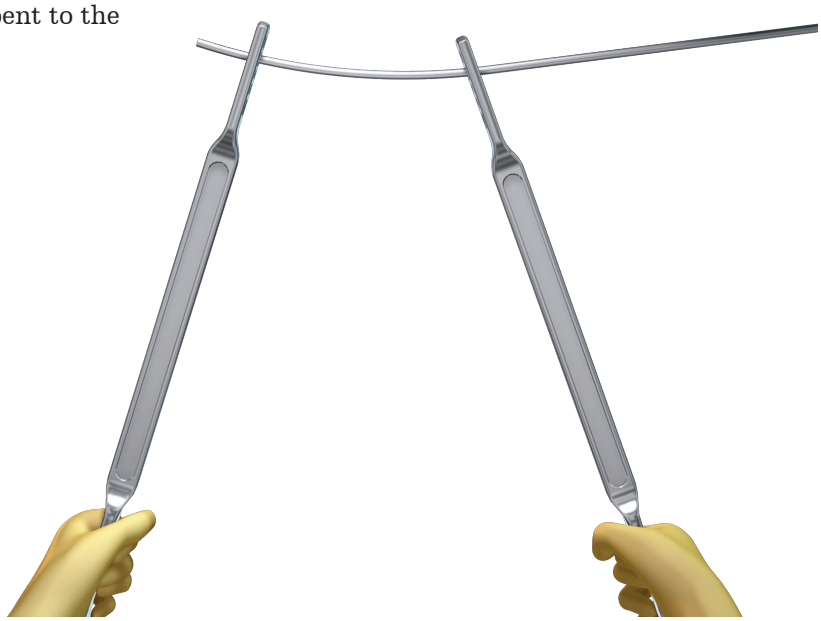
Step 6

Rod preparation

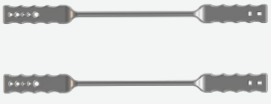
Note: A Rod Cutter does not come standard in the set and must be ordered separately. Once screws have been inserted, the rod is selected and cut to the appropriate length, if necessary. Both Cobalt Chrome and Titanium Alloy rods are available. The Rod Template may be used to help determine rod length. To extend the handles, pull the handle engagement towards the Cutter head and pull the handle in the opposite direction. To cut the rod, insert it into the end of the Cutter and squeeze the handles together.

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

The Deformity Rod Benders may 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 Deformity Rod Benders for optimal mechanical advantage. The rod is then bent to the desired contour as determined by the surgeon; if using the Dual Differential Correction (DDC) technique, it is recommended that the convex rod is under-bent and the concave rod is over-bent relative to the desired final kyphosis.



Deformity Rod Benders



Step 6

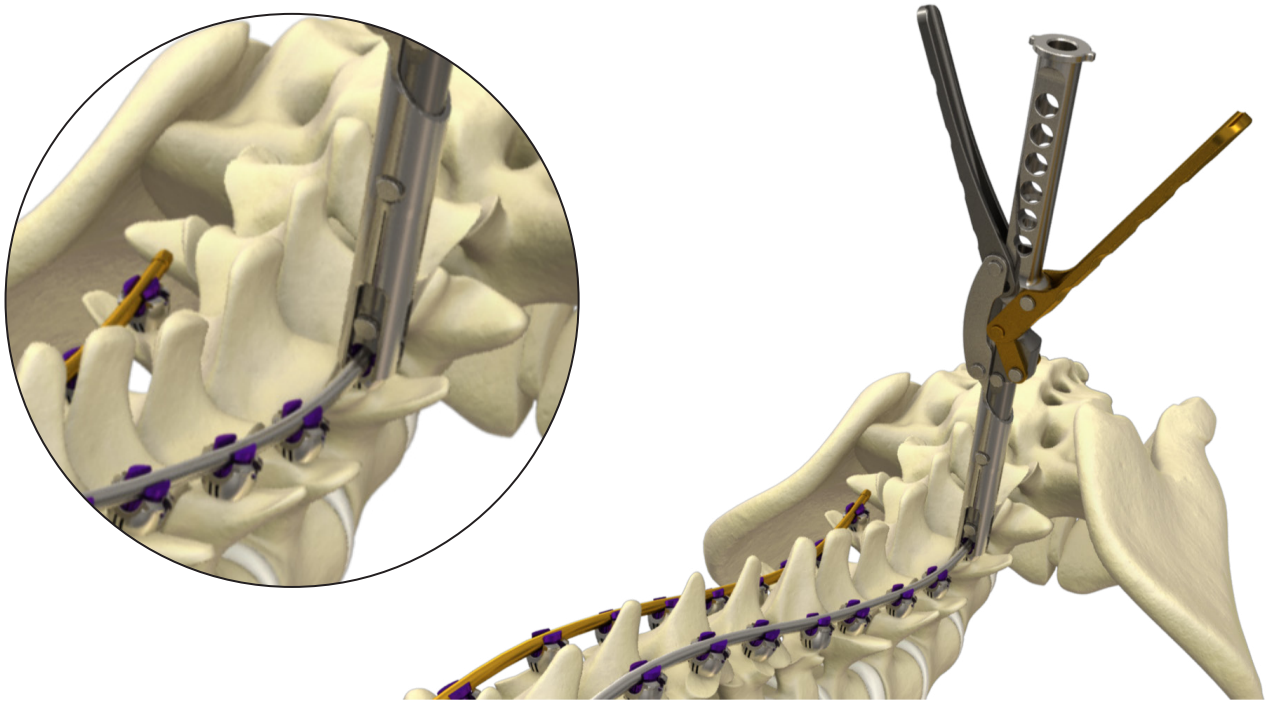
Rod preparation (cont.)

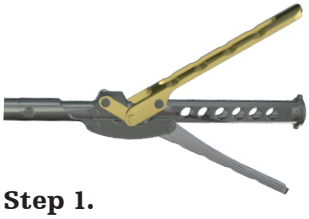
The French Rod Bender may be used to contour the rods to the desired amount of lordosis or kyphosis. By pulling out and rotating the dial, the rod may be bent to the desired curvature (small, medium, or large).

Rod reduction and partial locking

Once the rod is placed, for common reductions up to 15mm, the Dual Action Rod Reducer (Dragonfly) may be used. Ensure the instrument is fully open. When docking the Dragonfly, hold only the center shaft of the instrument to receive tactile feedback.

Once the instrument has been docked onto the screw housing, squeeze the gold lever first to reduce the rod. Next, squeeze the silver lever to achieve a partial lock.

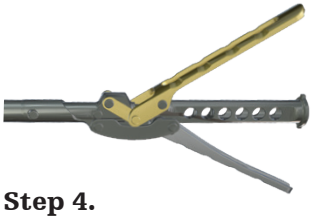




Step 1.
Instrument preparation and initial application

Step 2.
Reduction and seating

Step 3.
Partial locking



Step 4.
Instrument disengagement

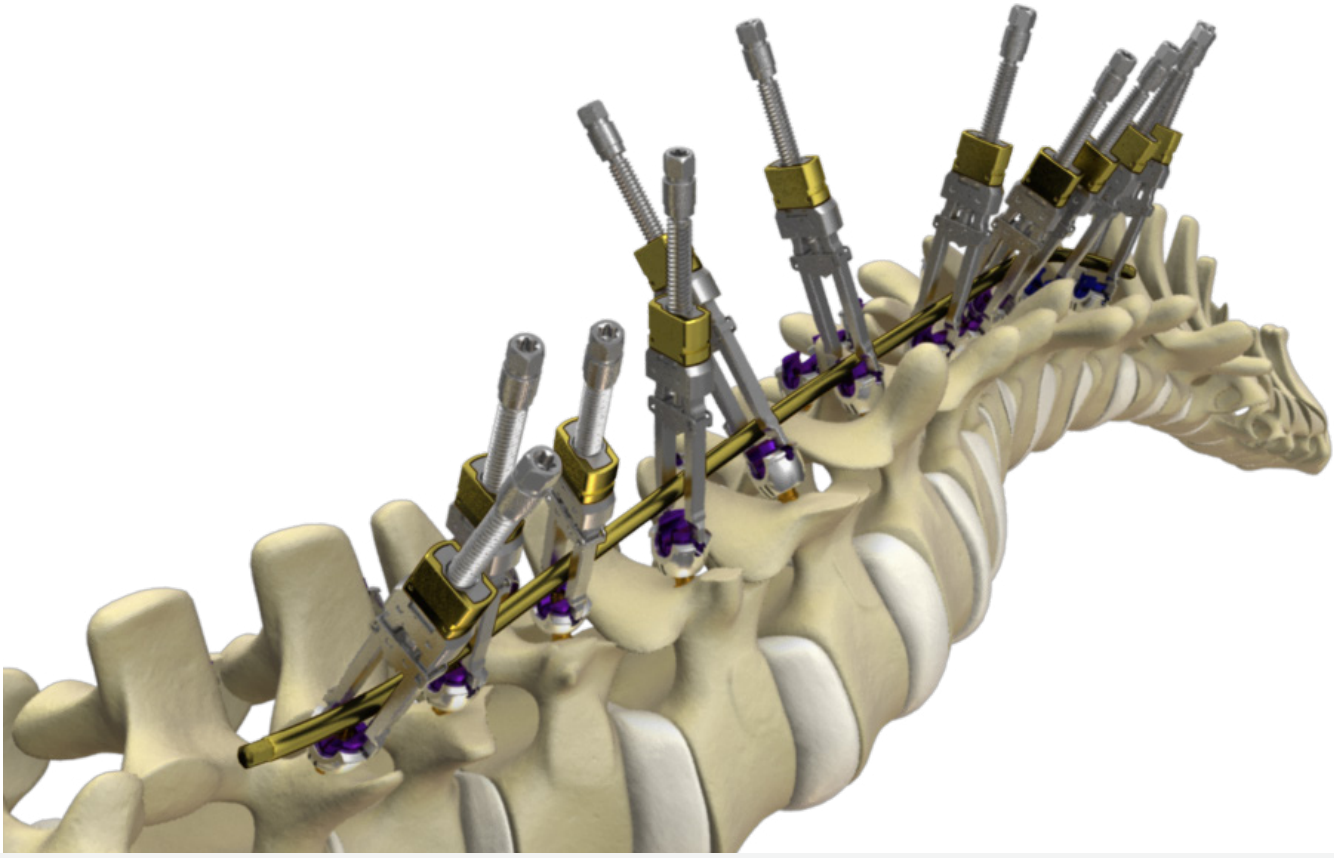
Dual Action Rod Reducer (Dragonfly)

Step 8

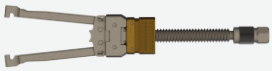
Convex rod placement

To achieve greater reduction up to 27mm, place Mesa 2 Crickets on the top half of the convex screws by threading approximately 5mm. These will later provide translation of the spine to the rod.

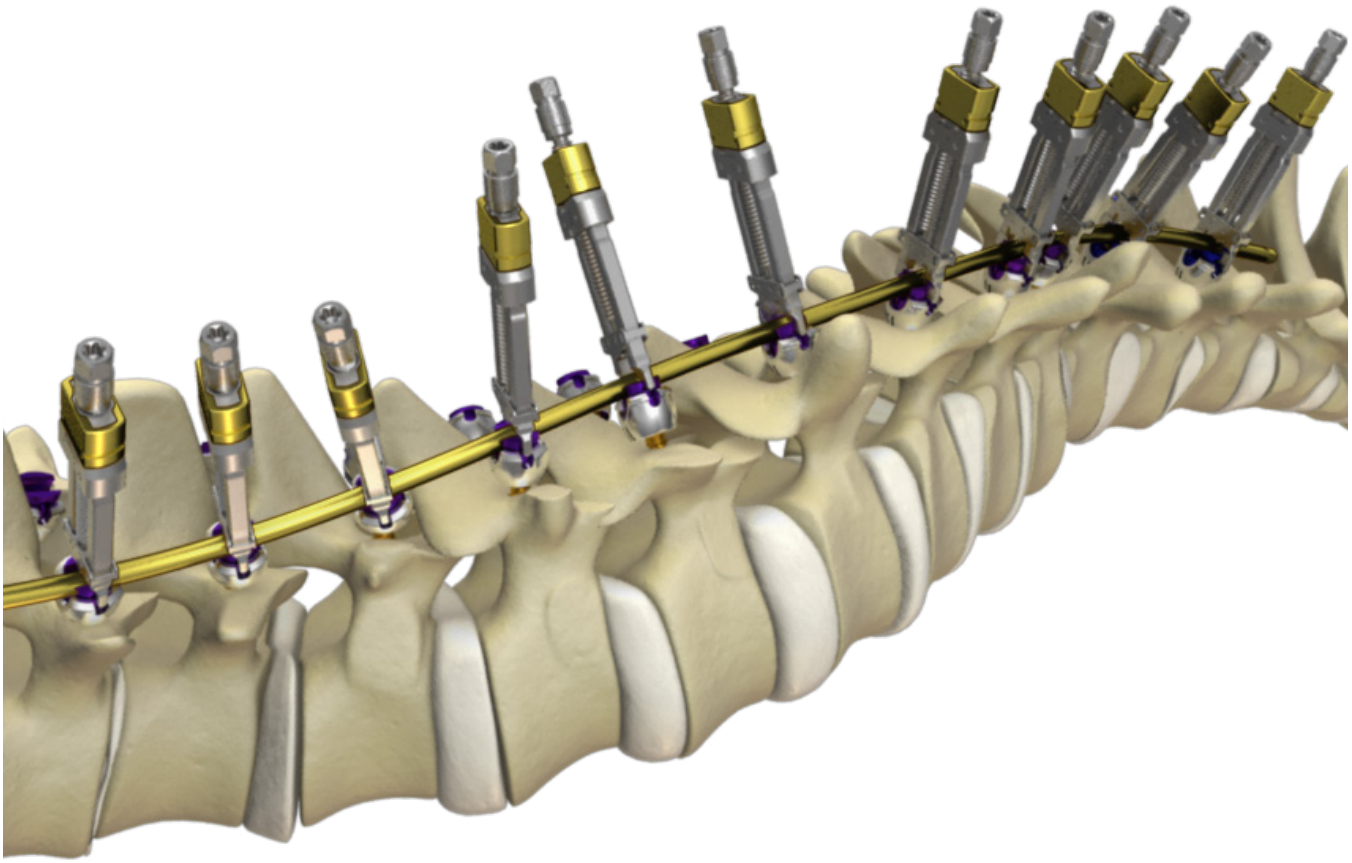
Introduce the convex rod and loosely place the remainder of the Mesa 2 Crickets over the lower half of the rod.



Mesa 2 Cricket



Hold the rod in the desired sagittal alignment using the Rod Rotation Wrench and/or a Vise Grip. Starting proximally, reduce the Mesa 2 Crickets by using the Size 25 Driver and a Handle until the rod is approximately 2mm above the screw heads. Do not seat the rod.



Rod Rotation Wrench

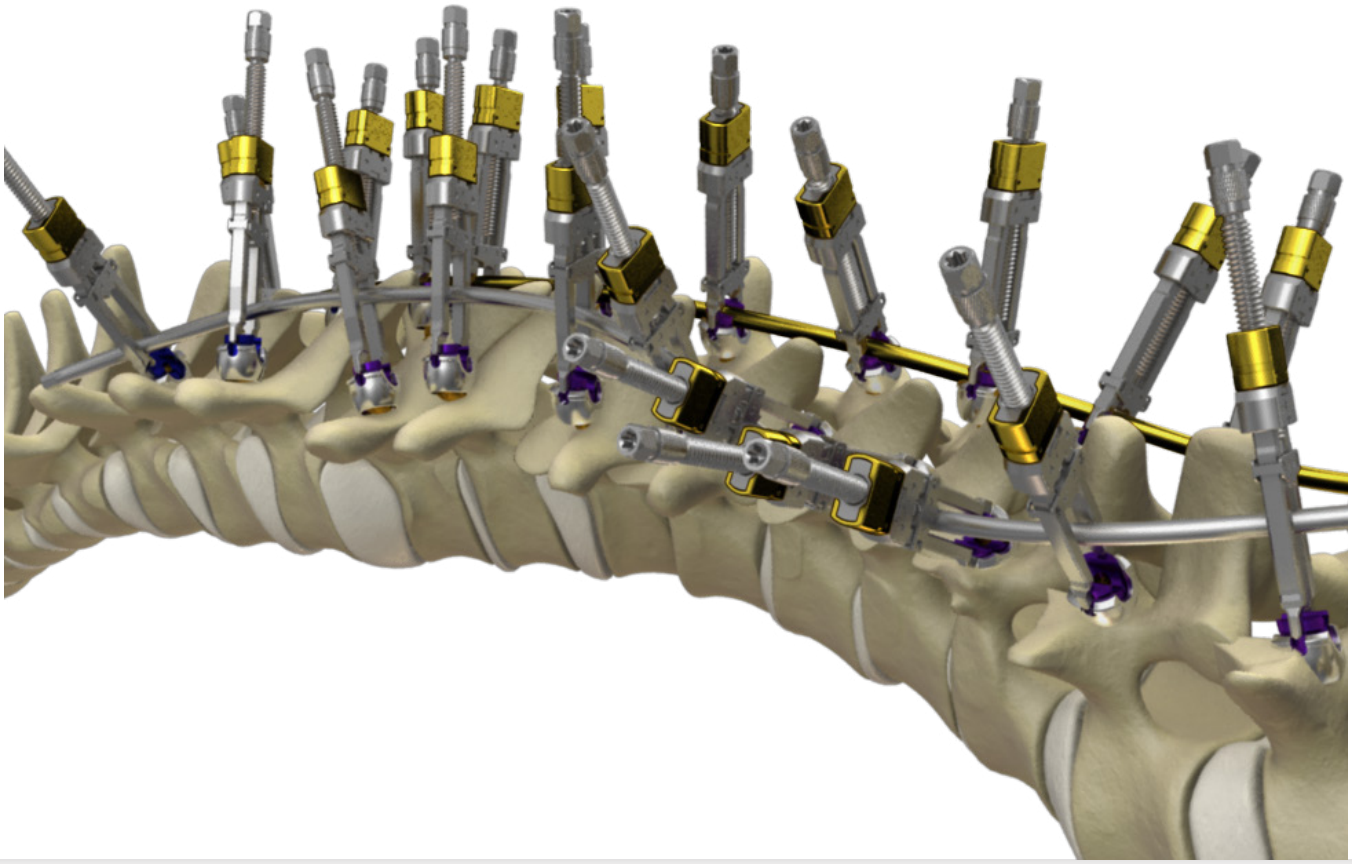
Size 25 Driver

Vise Grip

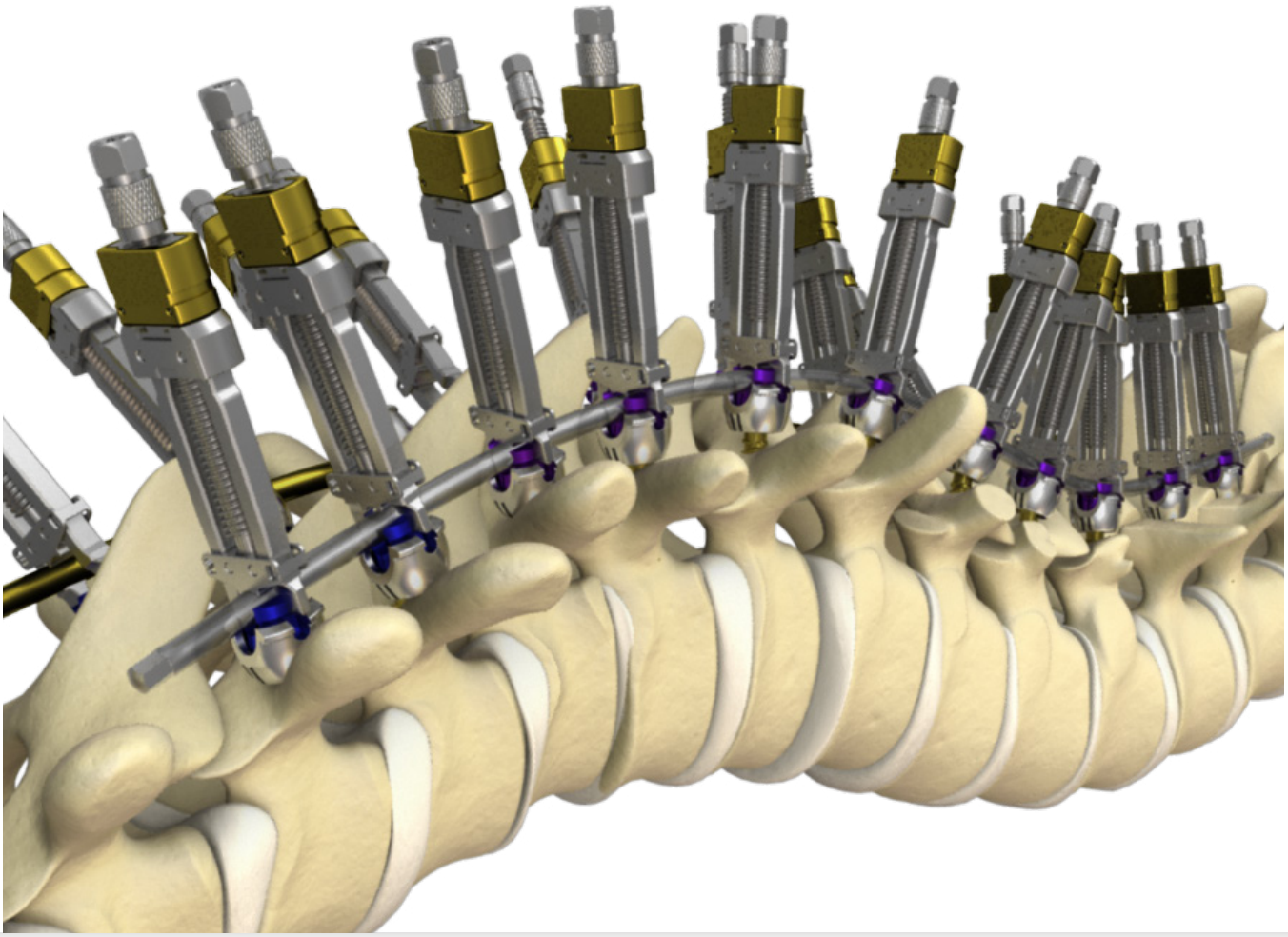
Step 9

Concave rod placement

Once the convex rod is placed and the Mesa 2 Crickets are reduced, place Mesa 2 Crickets on the proximal end of the concave side. Introduce the previously bent concave rod and place the remaining Mesa 2 Crickets over the top of the rod. Mesa 2 Crickets are only meant to capture the rod at this point.



Once Mesa 2 Crickets are applied, rotate the concave rod into the desired sagittal alignment. Reduce the Mesa 2 Crickets until they touch the rod. Slowly continue reducing from the distal end towards the apex of the curve. Once the Mesa 2 Crickets are fully reduced, the rod will be captured in the screw heads.

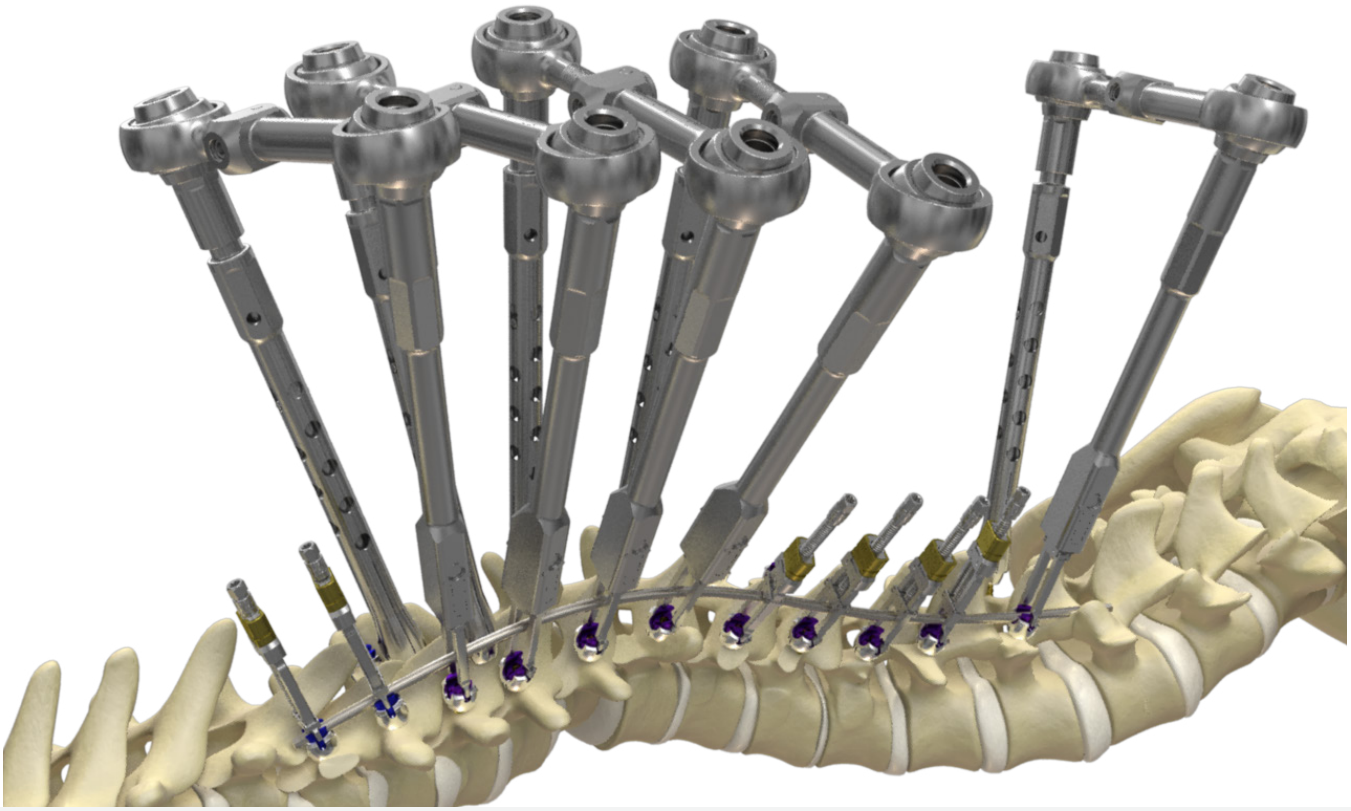


Step 10

Additional axial correction

If segmental direct vertebral rotation is desired, ensure the Mesa 2 Crickets are still loose. Apply Rotation Tubes bilaterally on the Mesa 2 Crickets at the apex of the curve on both the convex and concave sides. Tubes should also be attached to the Lowest Instrumented Vertebra (LIV) to use as a counter-torque. If there are no contralateral Mesa 2 Crickets, Manipulators can be applied directly to the screw heads and tightened down by using the Manipulator Wrench.

Apply Transverse Couplers by pressing them onto the Rotation Tubes to triangulate the pedicles at each vertebral level and evenly distribute the forces during segmental derotation. At each vertebral level, apply a downward and lateral force to convex instrumentation and a lateral force on the concave instrumentation to rotate the spine around the rods using the LIV as the foundation and counter-torque. Reduce Mesa 2 Crickets from the outside in towards the apex until the Mesa 2 Crickets are fully reduced.

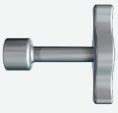


Transverse Coupler

Manipulator

Reduction Jack
Rotation Tube

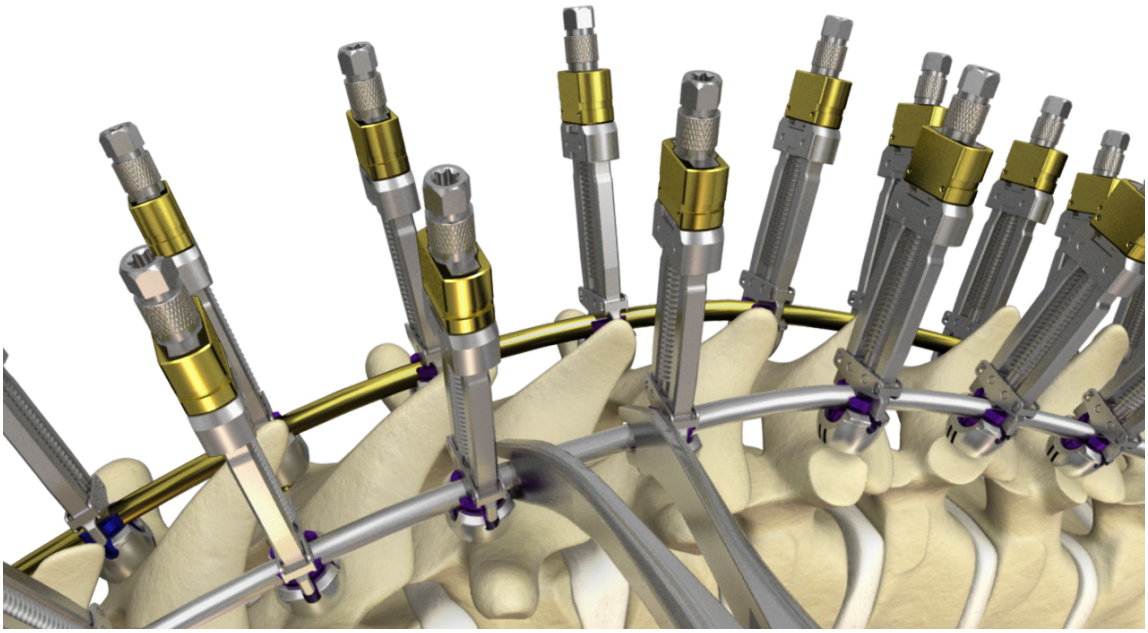
Manipulator Wrench

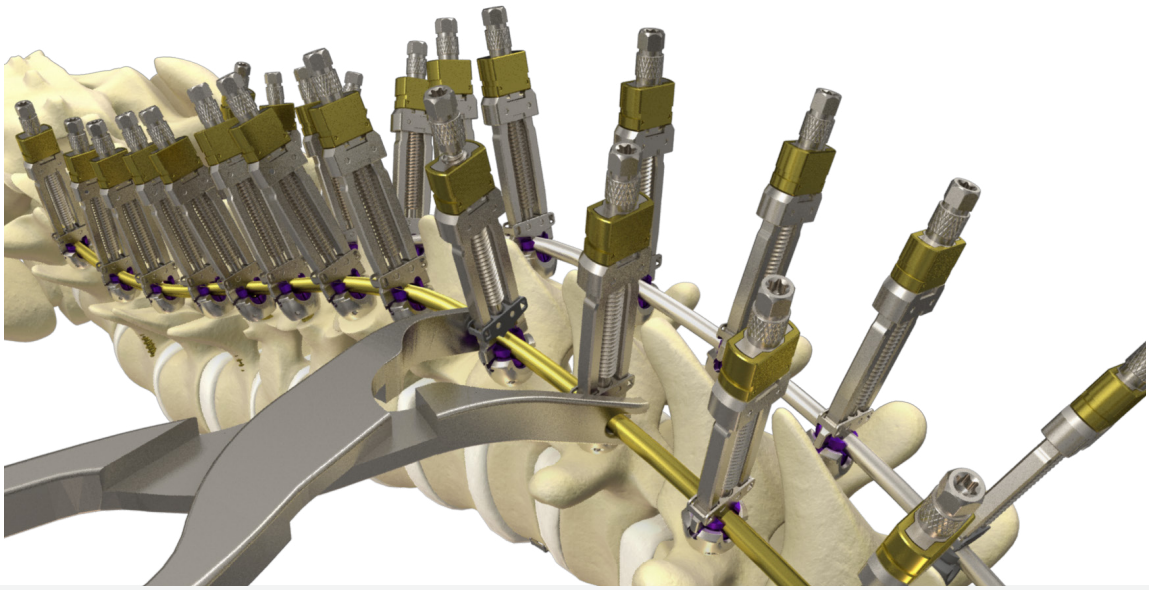


Compression/distraction

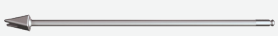
Additional correction can be performed using a variety of compression/distraction maneuvers. Begin proximal to the apex by releasing the Mesa 2 Cricket one to two turns. Compress or distract and retighten the Mesa 2 Cricket to maintain correction.
This method employs a similar technique to that of a standard set screw system.

If the screw heads are too close to engage the instruments, the Wedge Distractor may be used as initial distraction to separate the screw heads.





Wedge Distractor

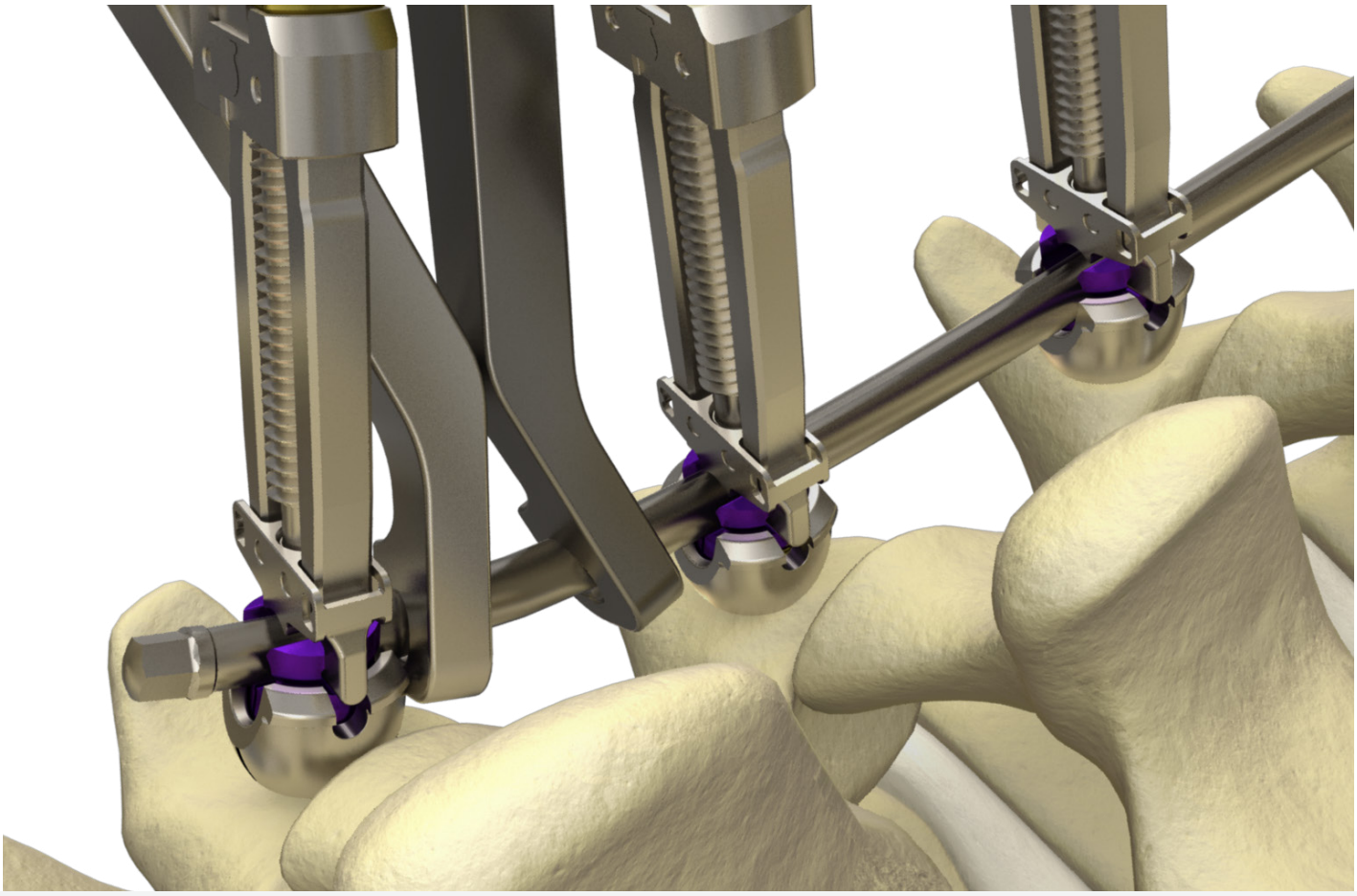


Step 12

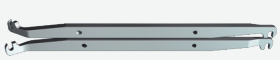
In-situ sagittal and coronal bending

The rod contour may also 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. Use a squeezing motion for coronal correction to ensure mechanical advantage. Do not pull instruments apart.



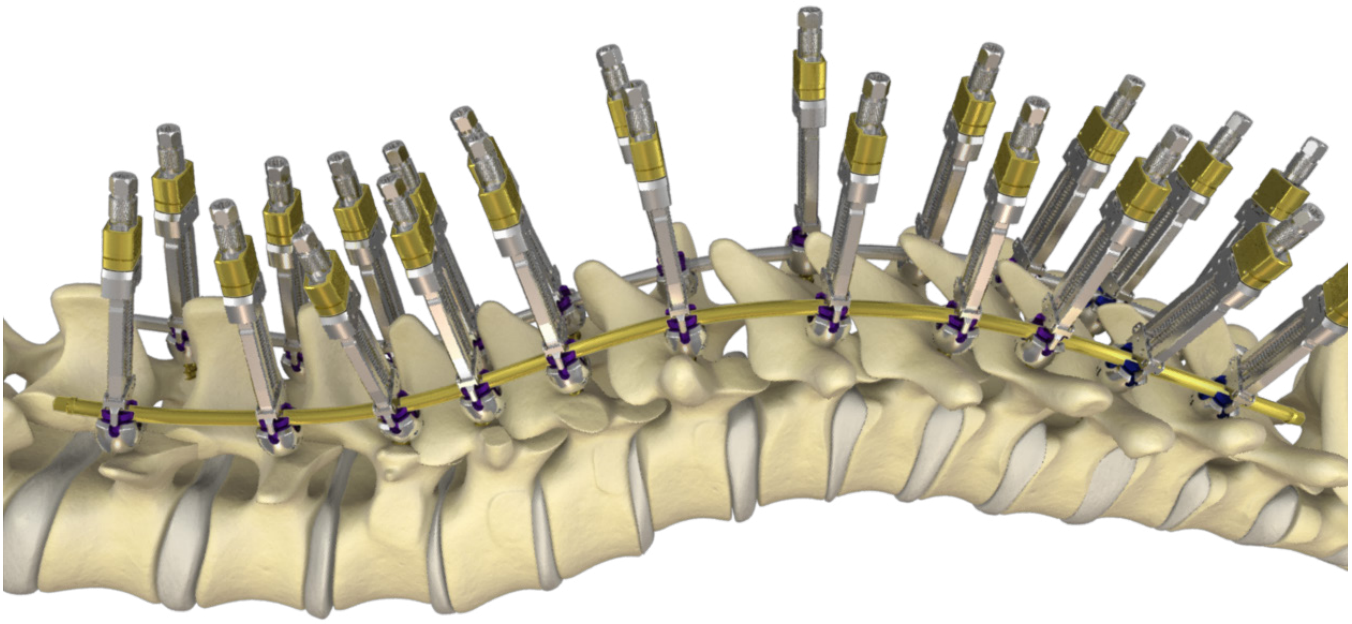
Sagittal Rod Benders



Coronal Rod Benders

Final convex rod fixation

To complete the construct, fully reduce the convex Mesa 2 Crickets working proximal to distal. Compression and distraction, as well as sagittal and coronal bending, can be performed on the convex rod as desired. Confirm at least 5mm of rod length extends beyond the most proximal and distal screws.

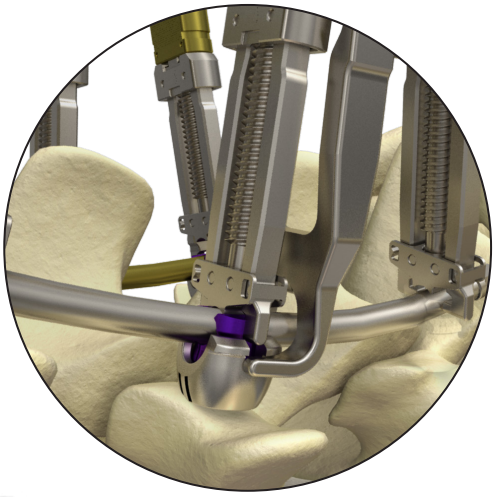


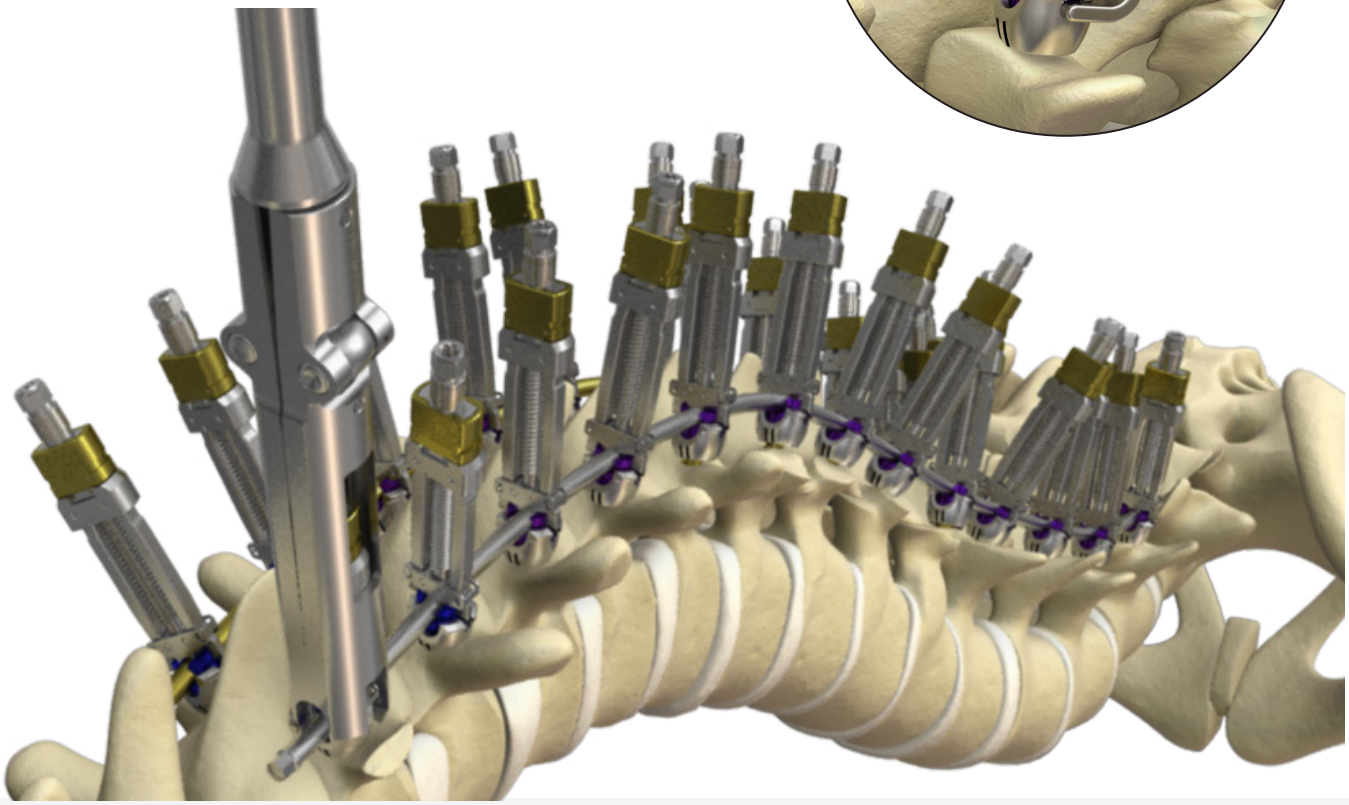
Step 14

Over Cricket final locking

Once the desired correction is obtained, a final lock can be achieved directly over the Mesa 2 Crickets using the Over Cricket Locker (OCL). Before engaging the OCL onto the Mesa 2 Cricket and the screw, ensure the Mesa 2 Cricket is fully reduced. If the OCL is hard to engage, the Dual-Ended Screw Head Elevator may be used to initially engage and pull up the outer collet. Fully squeeze the handle of the OCL to final lock the screws.

Remove the Mesa 2 Crickets by turning a Size 25 Driver counter-clockwise at least one half turn, and then pulling up on the Cricket housing and turning 90°. Alternatively, the Cricket can be removed manually by reversing the screw completely.





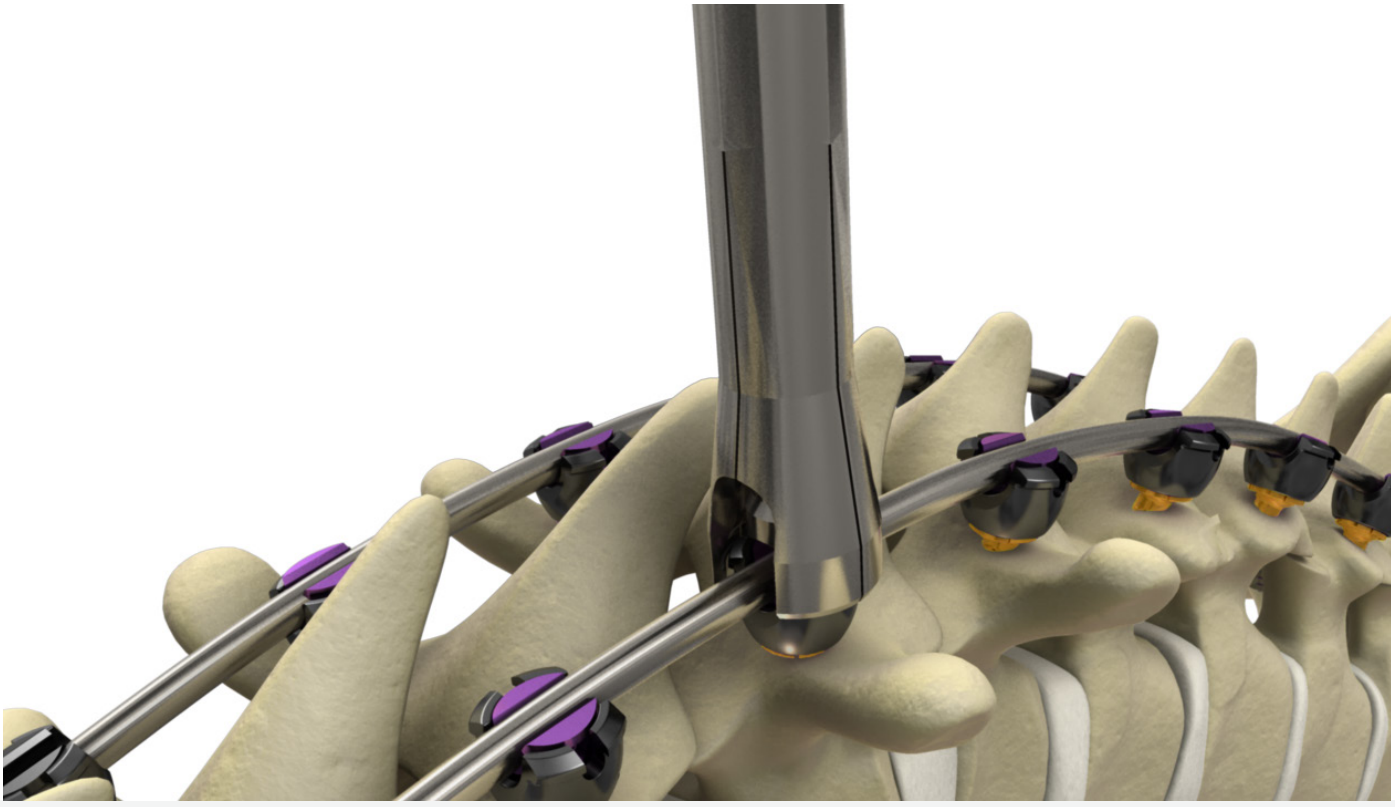
Over Cricket Locker (OCL)

Dual-Ended Screw Head Elevator

Partial locking and final locking

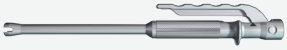
If desired, partially lock the fixation points using the Partial Locker over the Mesa 2 Crickets. Remove the Mesa 2 Crickets by turning a Size 25 Driver counter-clockwise at least one half turn then pulling up on the Cricket housing and turning 90°. Fully lock each Mesa 2 screw using the Quick Locker. Confirm at least 5mm of rod length extends beyond the most proximal and distal screws.

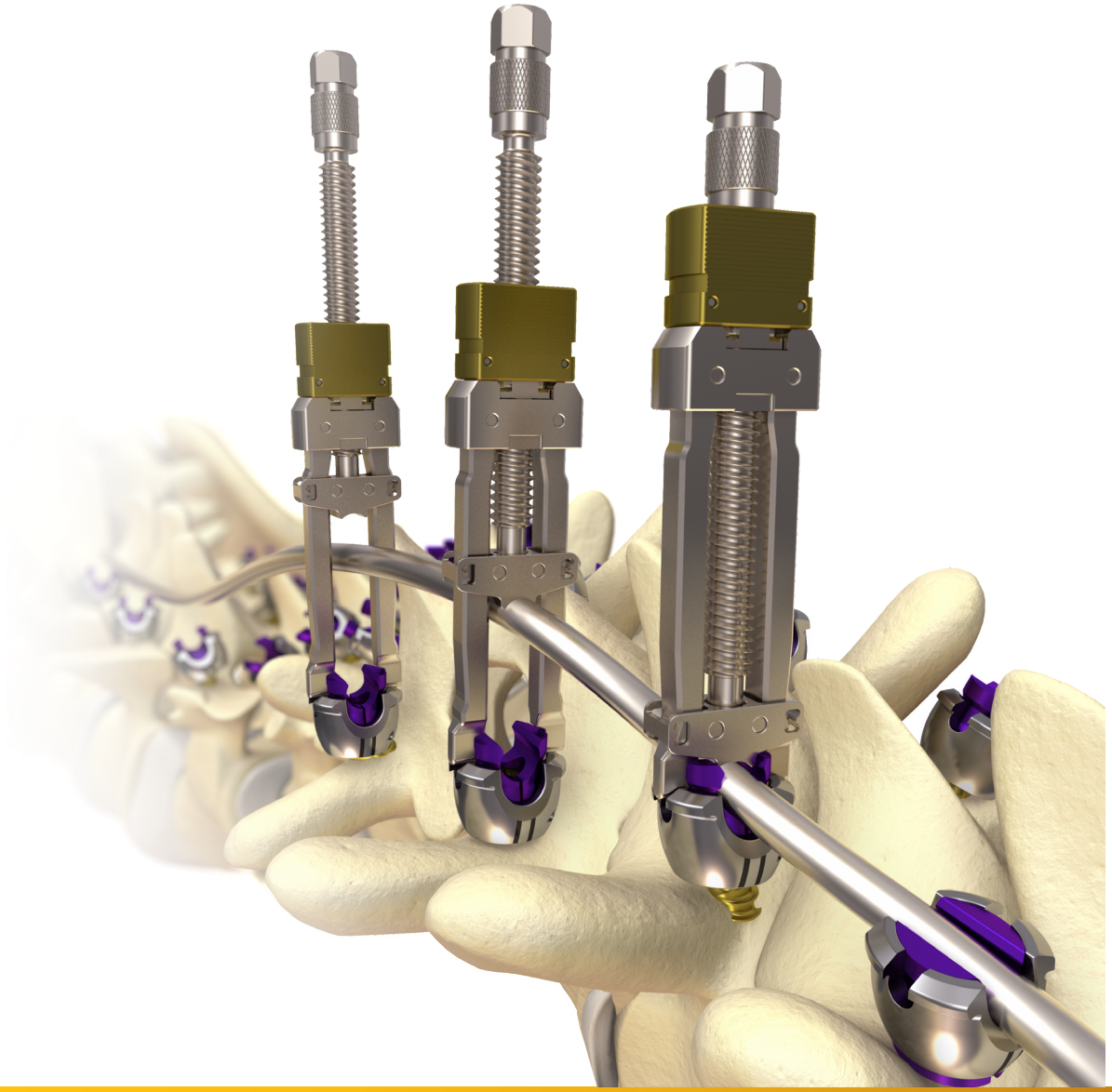
Note: The Locker should be used to apply axial force only. It should not be used in compression, distraction, or rotational maneuvers.



Partial Locker

Quick Locker



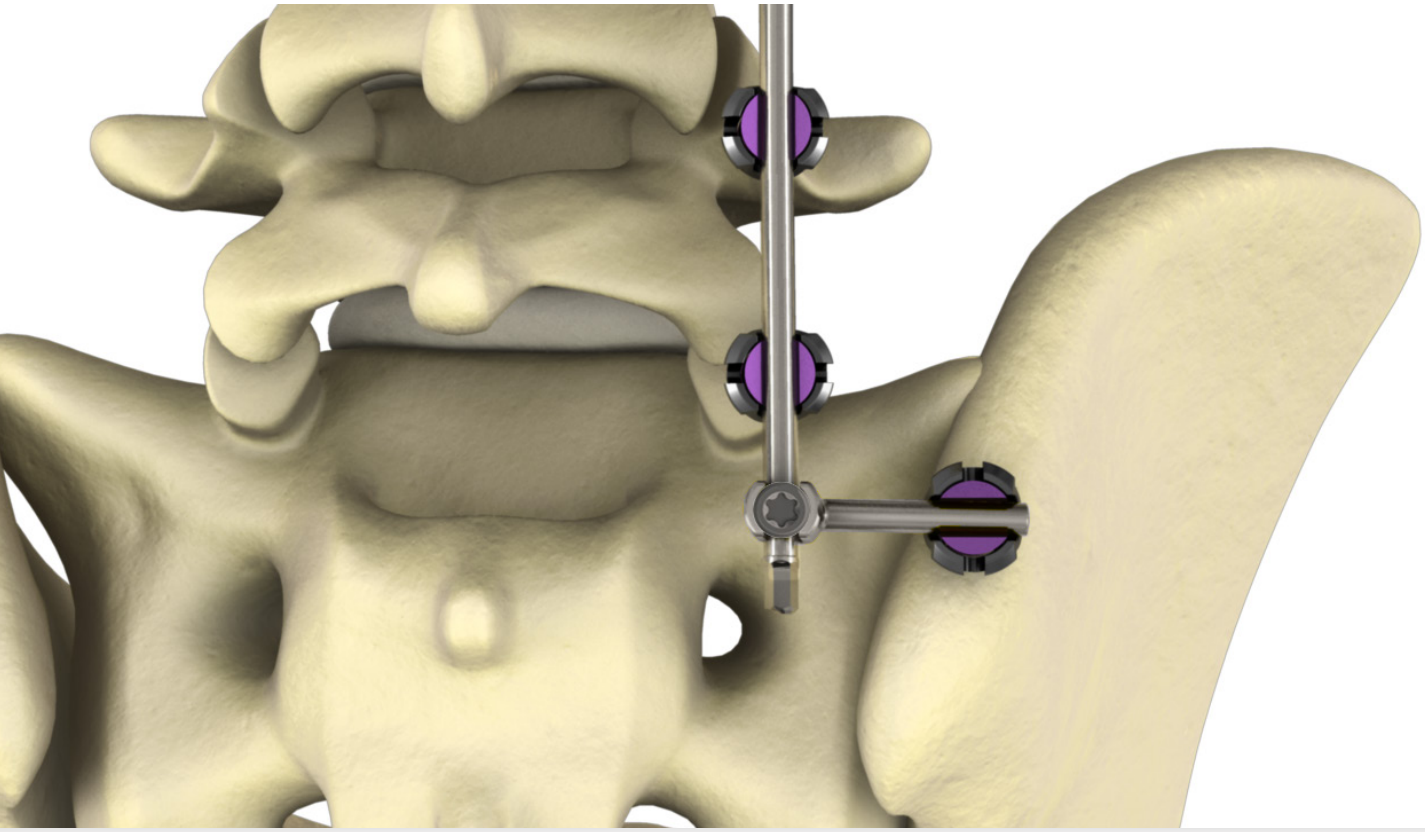


Connector surgical technique

Lateral offset connectors

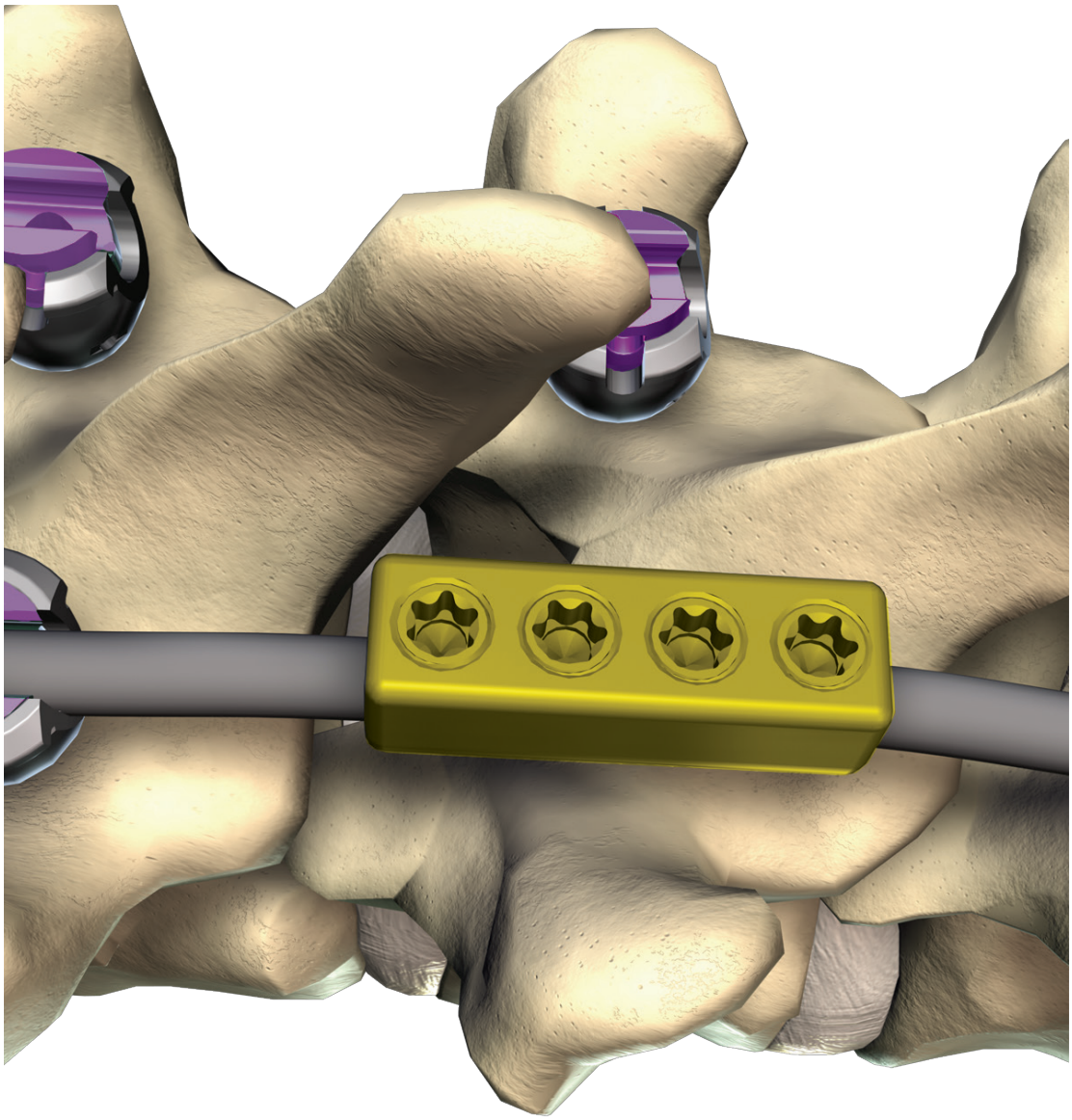
The lateral offset connectors may be used to link a screw lateral to a rod. The rod portion of the lateral offset connector is seated in the implant housing. The saddle end is attached to the rod with set screws and final tightened at 98 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

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



Axial connectors

Axial connectors may be used to join rods end to-end. The implant is final tightened at 98 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

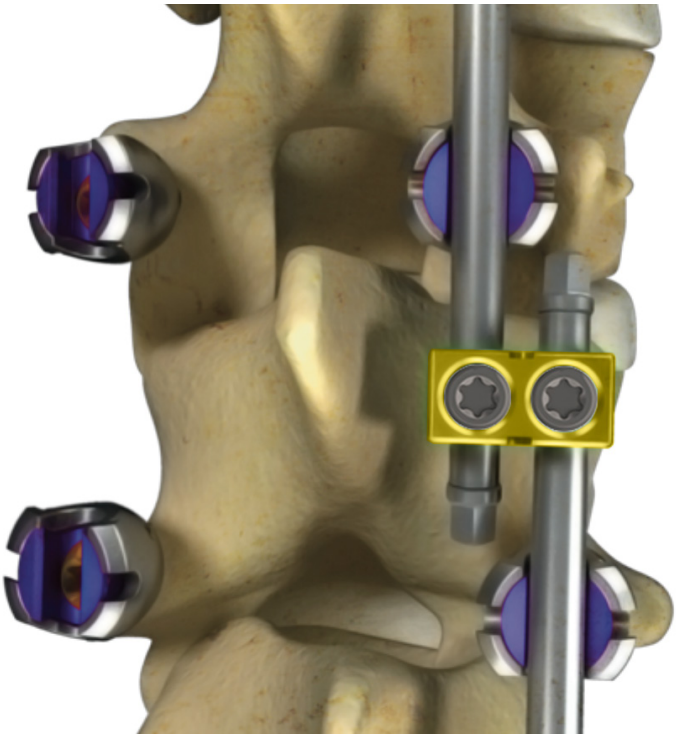


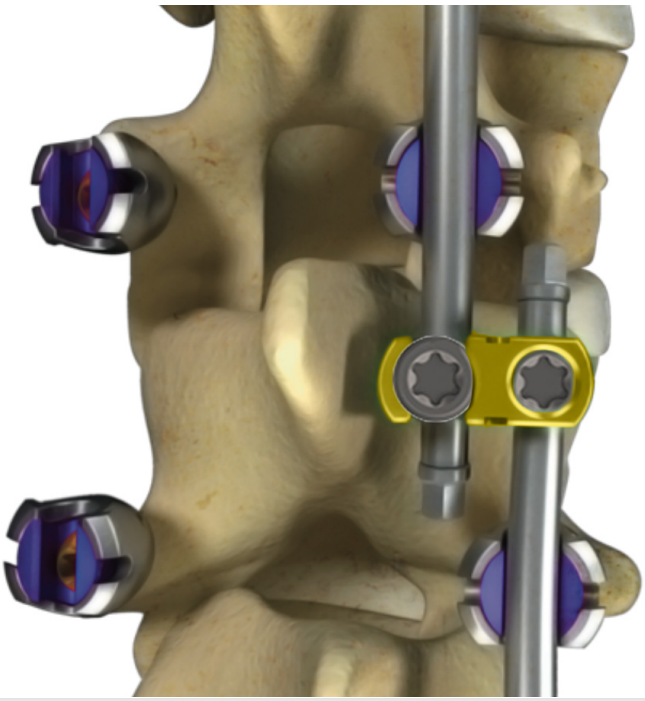
Torque Limiting Shaft

Torque Limiting Handle

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 98 in-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.



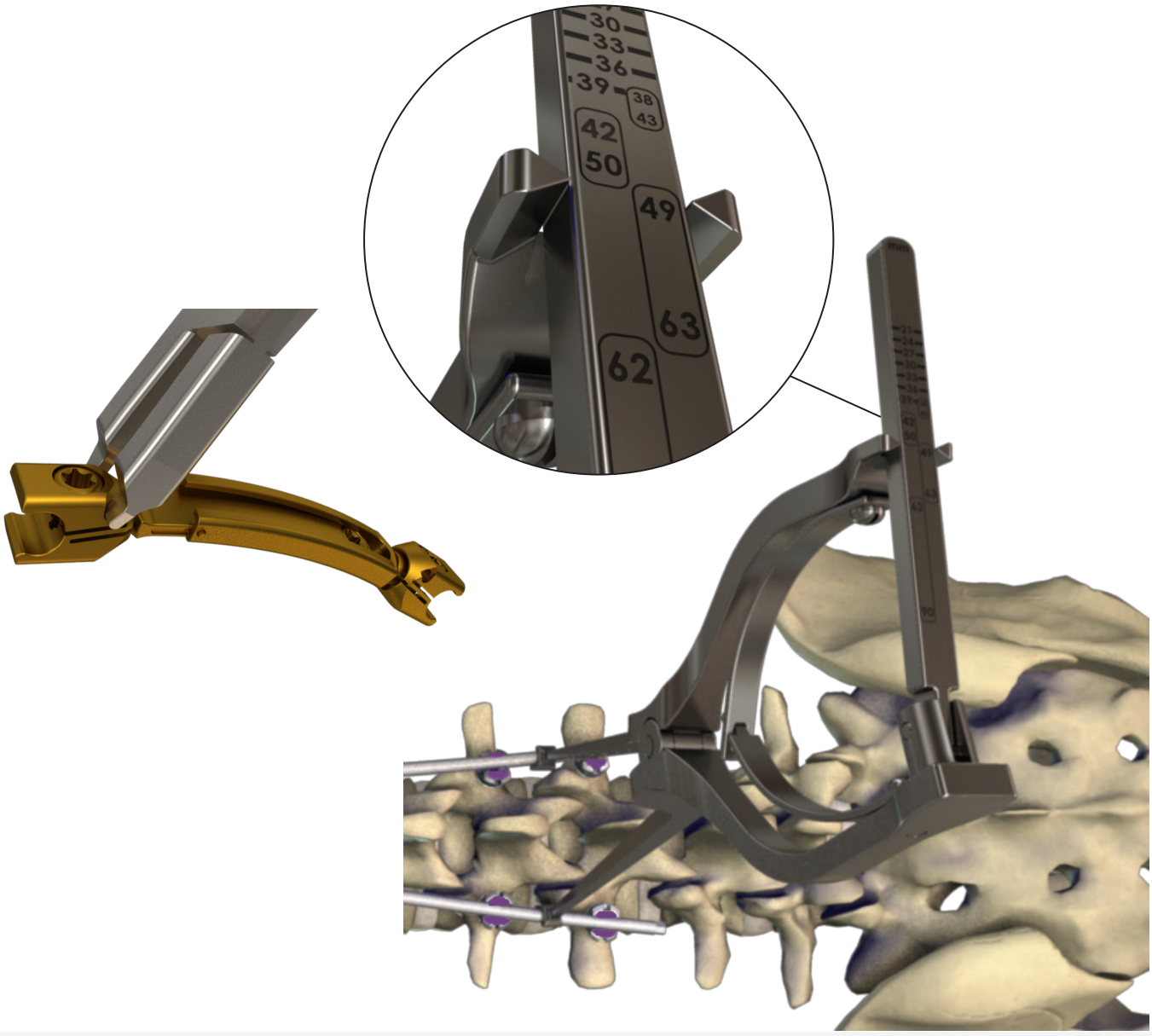


Rod connections

Transverse connectors

Use the Natural Bridge LP Caliper to measure the appropriate length between the two rods, and choose the 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 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.



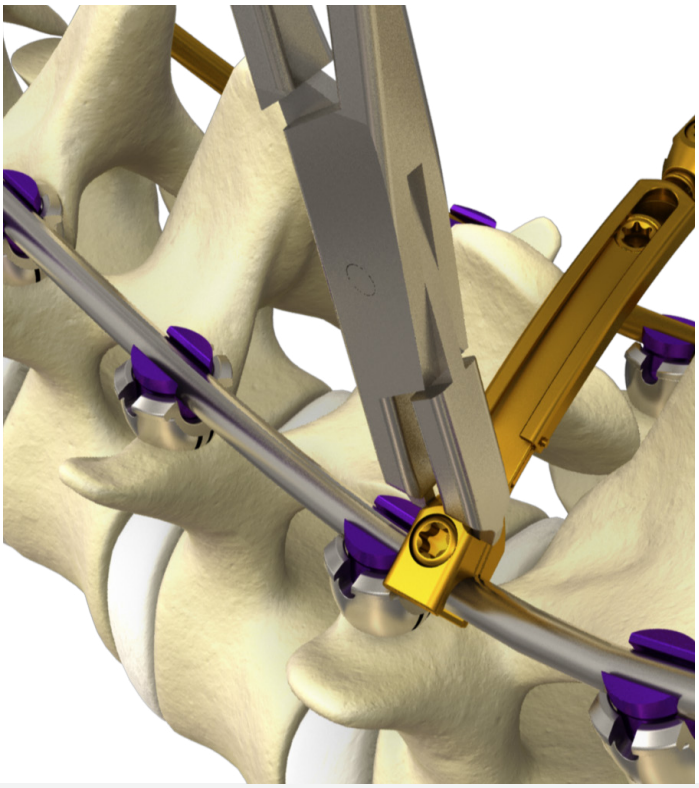
Natural Bridge LP Driver Shaft

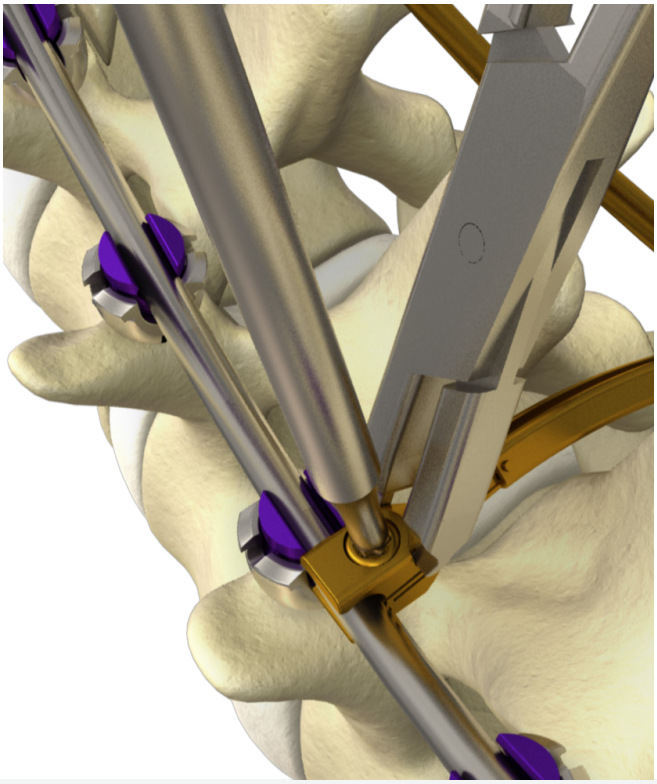
Natural Bridge LP Connector Holder

Natural Bridge LP Caliper

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 the set screw to optimal torque using the Natural Bridge LP Driver Shaft and Handle.





Natural Bridge LP Driver Shaft

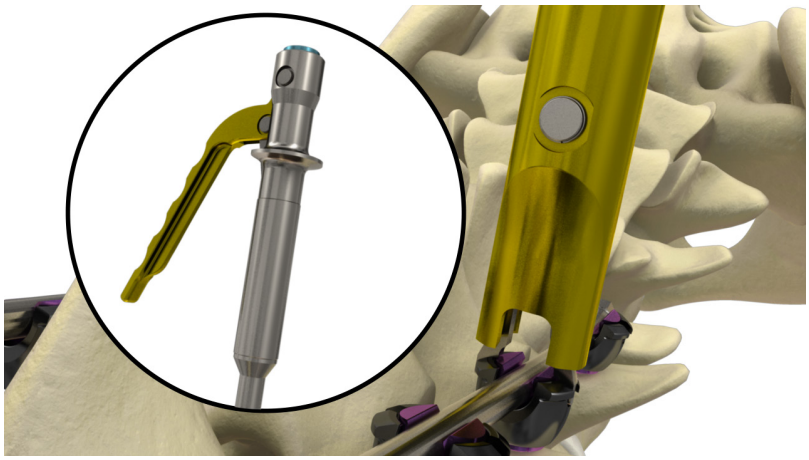
Natural Bridge LP Driver Handle

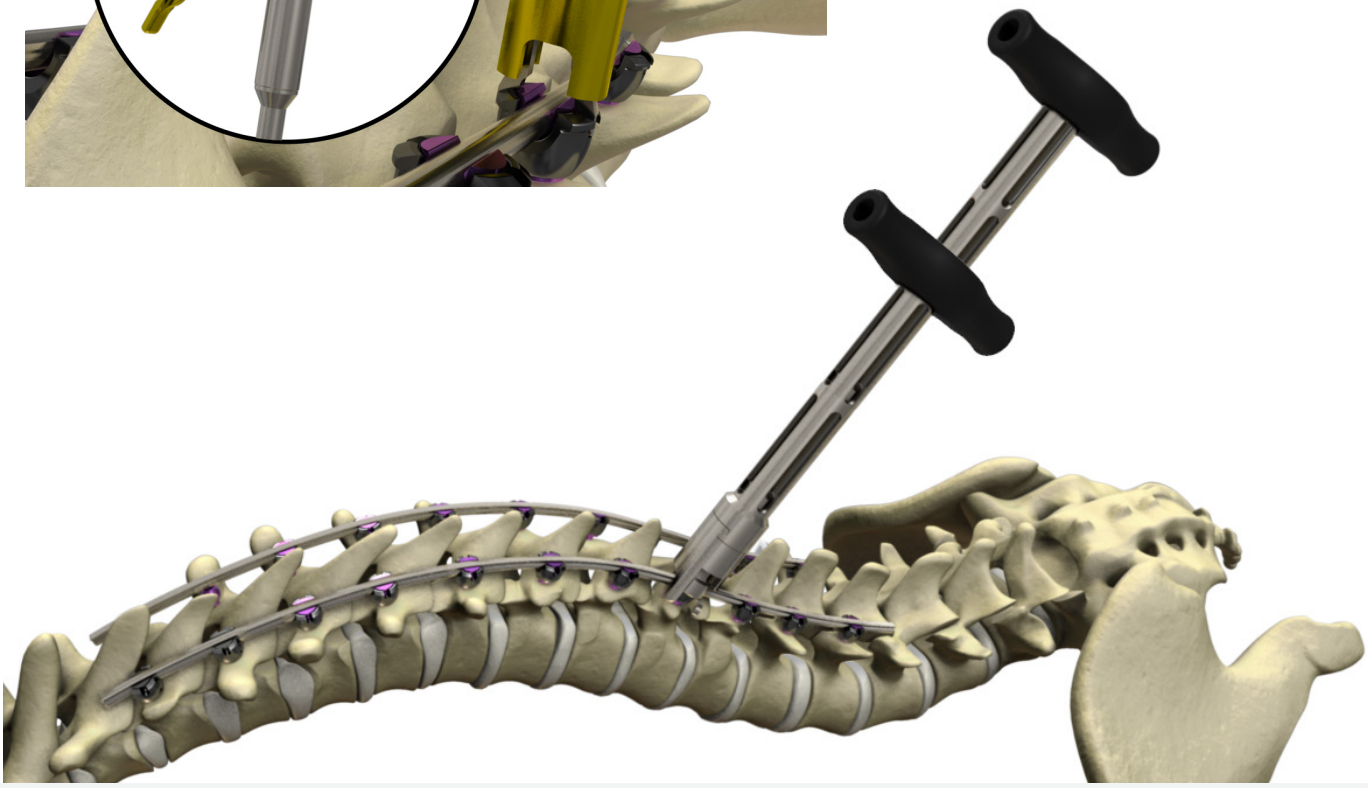
Unlocking and removal

Unlocking and removal

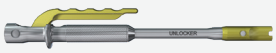
Should the surgeon decide to unlock the Mesa screw from partial or full lock, the Unlocker may be used. Fully open the instrument and engage the docking feet into the detents of the medial side of the screw housing. Gently move the instrument down laterally until the distal portion of the instrument 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 Mesa Rail/Rod Puller. Apply the distal end of the Mesa Rail/Rod Puller over the screw housing and rotate it in a clockwise direction until it securely engages the rod. Hold the distal handle while turning the proximal handle clockwise in order to release the rod from the screw head.

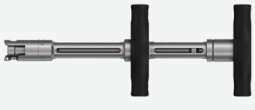




Unlocker



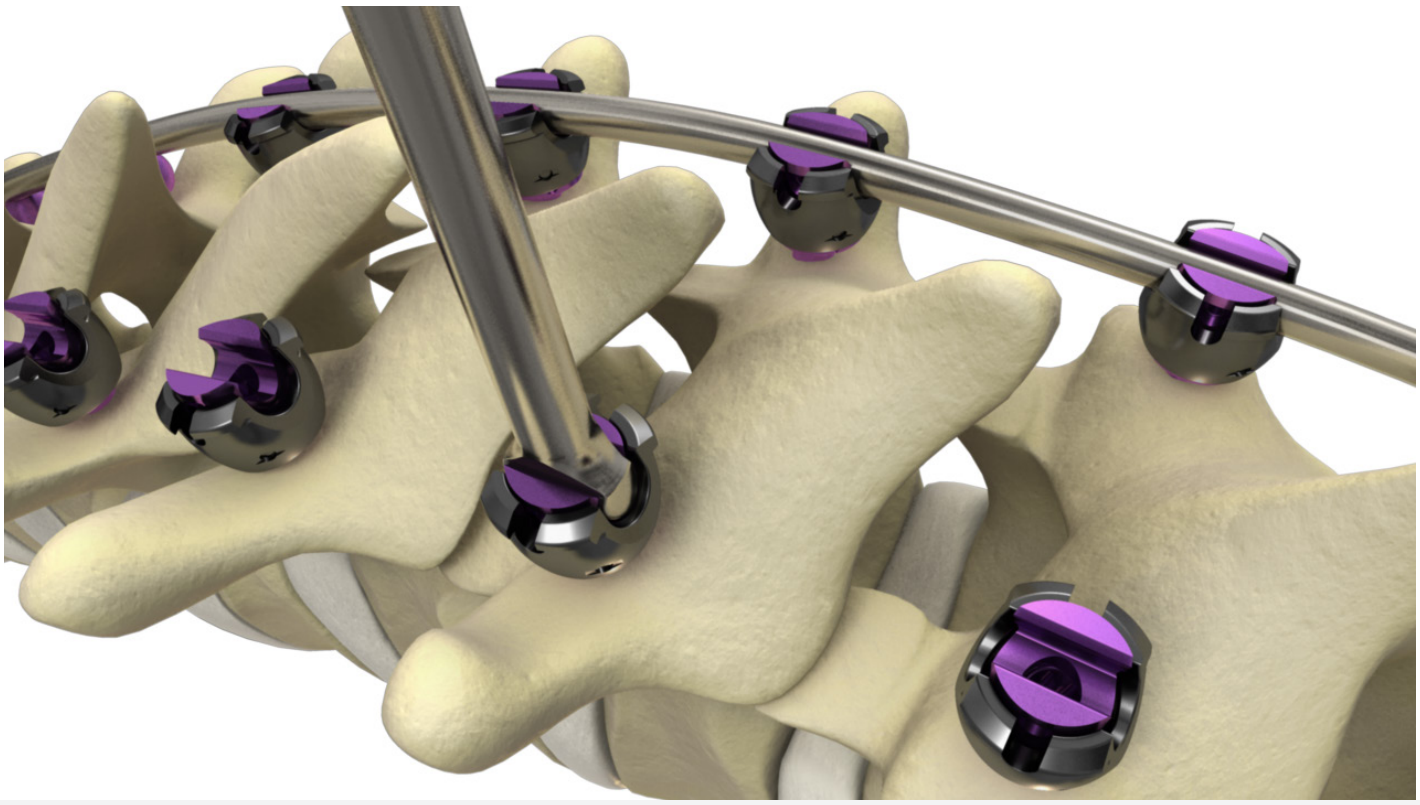
Mesa Rail/Rod Puller



Unlocking and removal (cont.)

The T-Bar Screw Remover may be used to remove the Mesa screw after it has been implanted. It is especially useful 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 ratcheting 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.



T-Handle

T-Bar Screw Remover

Product catalog

Implants

Catalog #	Description
3001-90083	Rod Template
107-A55500	CP TI Grade 3 Rod, 500mm
106-A55500	CP TI Grade 4 Rod, 500mm
101-A55500	TI Alloy Hex End Rod, 500mm
111-B55500	Dual Hex CoCr Rod, 500mm
801-70021A	Natural Bridge LP Semi-Adjustable, 21mm
801-70024A	Natural Bridge LP Semi-Adjustable, 24mm
801-70027A	Natural Bridge LP Semi-Adjustable, 27mm
801-70030A	Natural Bridge LP Semi-Adjustable, 30mm

Catalog #	Description
801-70033A	Natural Bridge LP Semi-Adjustable, 33mm
801-70036A	Natural Bridge LP Semi-Adjustable, 36mm
801-70039A	Natural Bridge LP Semi-Adjustable, 39mm
801-73040	Natural Bridge LP Adjustable, Small
801-74050	Natural Bridge LP Adjustable, Medium
801-75060	Natural Bridge LP Adjustable, Large
801-76070	Natural Bridge LP Adjustable, Extra Large

Rod Template

CP TI Grade 3 Rod, 500mm

CP TI Grade 4 Rod, 500mm

TI Alloy Hex End Rod, 500mm

Dual Hex CoCr Rod, 500mm

Natural Bridge LP Semi-Adjustable

Natural Bridge LP Adjustable

Small, Medium, Large, and Extra Large

Catalog #	Description
101-85555C	Two Piece Parallel Rod Connectors
101-85555D	Axial Rod Connectors
101-85555E	Parallel Rod Connector Closed/Closed
101-85555F	Parallel Rod Connector Closed/Open
101-755100	Lateral Offset Connector, 100mm
101-755100G	Closed Lateral Offset Connector, 100mm
101-75550	Lateral Offset Connector, 50mm
101-75550G	Closed Lateral Offset Connector, 50mm

Catalog #	Description
101-75525	Lateral Offset Connector, 25mm
101-75525G	Closed Lateral Offset Connector,25mm
101-10001	ATR Set Screw

Two Piece Parallel Rod Connectors

Axial Rod Connectors

Parallel Rod Connector Closed/Closed

Parallel Rod Connector Closed/Open

Lateral Offset Connector, 100mm

Closed Lateral Offset Connector, 100mm

Lateral Offset Connector, 50mm

Closed Lateral Offset Connector, 50mm

Lateral Offset Connector, 25mm

Closed Lateral Offset Connector, 25mm

ATR Set Screw

Instruments

Catalog #	Description
101-90275	Silicone T-Handle
101-90276	Silicone Pear Handle
2901-90071	X-ray Marker, Left
2901-90072	X-ray Marker, Right
801-90048	Guiding Reamer
801-90207	Over Screw Reamer
101-90214	Ball Tip Feeler, 9in
2801-90000	Ball Tip Feeler, 11in

Catalog #	Description
6201-90010	Ø3.5mm Tap
6201-90012	Ø4.5mm Tap
6201-90014	Ø5.5mm Tap
6201-90016	Ø6.5mm Tap
6201-90017	Ø7.5mm Tap
6201-90018	Ø8.5mm Tap

Silicone T-Handle

Silicone Pear Handle

X-ray Marker, Left

X-ray Marker, Right

Guiding Reamer

Over Screw Reamer

Ball Tip Feeler, 9in

Ball Tip Feeler, 11in

Taps

Ø3.5, 4.5, 5.5, 6.5, 7.5, and 8.5mm

Catalog #	Description
6201-90051	Curved Lumbar Probe
6201-90052	Straight Lumbar Probe
6201-90053	Curved Thoracic Probe
6201-90054	Straight Thoracic Probe
101-90310	Awl, Short

Catalog #	Description
801-90053	Deformity Screw Inserter
6201-90001	Short Deformity Screw Inserter
1001-90065	Cannulated Power Adapter

Curved Lumbar Probe

Straight Lumbar Probe

Curved Thoracic Probe

Straight Thoracic Probe

Awl, Short

Deformity Screw Inserter

Short Deformity Screw Inserter

Cannulated Power Adapter

Instruments

Catalog #	Description
6201-90002	Screw Head Adjuster
101-90259	Rod Rotation Wrench
101-90306	Vise Grip
6201-90049	Deformity Rod Benders
101-90031	French Rod Bender
101-90217	In-Situ Rod Bender, Left

Catalog #	Description
101-90218	In-Situ Rod Bender, Right
101-90313	Coronal Rod Bender, Left
101-90312	Coronal Rod Bender, Right

Screw Head Adjusters

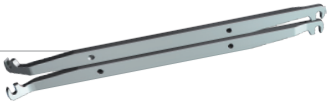
Rod Rotation Wrench

Vise Grips

Deformity Rod Benders

French Rod Benders

In-Situ Rod Bender, Left/Right



Coronal Rod Bender, Left/Right

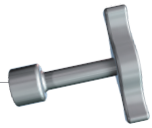
Catalog #	Description
6201-90080	Dual-Ended Screw Head Elevator
801-90038	Dual Action Rod Reducer (Dragonfly)
801-90054	Manipulator
801-90069	Manipulator Wrench
6201-90088	Reduction Jack Rotation Tube
6201-90084	Mesa 2 Cricket

Dual-Ended Screw Head Elevator

Dual Action Rod Reducer (Dragonfly)

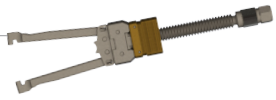
Manipulator

Manipulator Wrench



Reduction Jack Rotation Tube

Mesa 2 Cricket

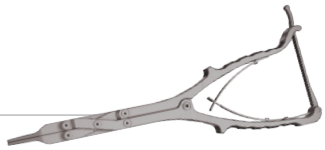


Instruments

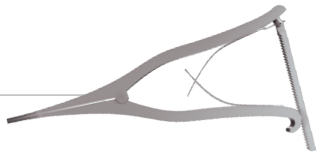
Catalog #	Description
801-90026	Wedge Distractor
801-90051	Parallel Distractor
801-90119	Distractor
801-90208	Compressor

Wedge Distractor

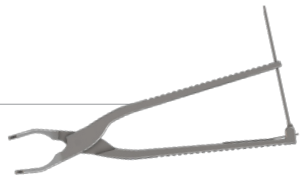
Parallel Distractor



Distractor



Compressor



Catalog #	Description
6201-90050	Mesa Rail/Rod Puller
101-90338	Telescoping Rod Cutter
801-90008	Quick Locker
801-90025	Unlocker
6201-90055	Partial Locker
6201-90079	Over Cricket Locker

Mesa Rail/Rod Puller

Telescoping Rod Cutter

Quick Locker

Unlocker

Partial Locker

Over Cricket Locker

Instruments

Catalog #	Description
101-90288	Size 25 Driver with Handle
101-90101	Torque-Limiting Shaft
101-90249	Provisional Handle
801-90068	Size 25 Driver
801-90067	Reduction Jack Torque Limiting Handle
801-90004	T-Bar Screw Remover

Catalog #	Description
101-90222	Parallel Rod Connector Inserter
101-90289	Alignment Tube Rod Seater

Size 25 Driver with Handle

Torque-Limiting Shaft

Provisional Handle

Size 25 Driver

Reduction Jack Torque Limiting Handle

T-Bar Screw Remover

Parallel Rod Connector Inserter

Alignment Tube Rod Seater

Catalog #	Description
101-90208	Torque Limiting Shaft, Size 25
101-90353	Torque Limiting Handle
101-90023	Single Action Anti-Torque Rod Reducer
101-90051	Anti-Torque Handle
101-90281	Natural Bridge LP Caliper
101-90220	Natural Bridge Connector Holder

Catalog #	Description
101-90278	Natural Bridge LP Driver Shaft
801-90183	Natural Bridge LP Handle

Torque Limiting Shaft, Size 25

Torque Limiting Handle

Single Action Anti-Torque Rod Reducer

Anti-Torque Handle

Natural Bridge LP Caliper

Natural Bridge Connector Holder

Natural Bridge LP Driver Shaft

Natural Bridge LP Handle

Screws

Catalog #	Description
*See note	Mesa 2 Deformity Polyaxial
*See Note	Mesa 2 Deformity Uniplanar

*Custom catalog numbers exist for each screw length in each diameter. Please contact your local sales consultant with any questions you may have about ordering Mesa 2 Deformity Spinal System implants.

Mesa 2 Deformity Polyaxial

Diameters (mm): Ø4.0, 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, 9.5

Mesa 2 Deformity Uniplanar

Diameters (mm): Ø4.0, 4.5, 5.0, 5.5, 6.5, 7.5

Screw colors by length

Size	Color	Size	Color
20mm		55mm	
25mm		60mm	
30mm		70mm	
35mm		80mm	
40mm		90mm	
45mm		100mm	
50mm		110mm	

Torque specification

Catalog #	Description	Torque values and accuracy
801-90067	Torque Limiting Handle, 30 in-lbs (3.4 N-m)	3.4 ± 0.17 Nm (5%)
801-90183	Torque Limiting Handle, 3.5 N-m	3.5 ± 0.21 Nm (6%)
101-90353	Torque Limiting Handle, 98 in-lbs (11.1 N-m)	11.1 ± 0.90 Nm (8%)

Instructions for use

Pedicle Screw Systems
IFU Reference Number: PI005-2EN-04 Rev 00

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175
USA
Toll Free: 1-866-526-4171
Fax: 1-703-777-4338

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 and Denali) Spinal Systems are 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.

Indications
The MESA and DENALI Spinal Systems (including ARI Staples) and the EVEREST Spinal System are cleared for the following indications:

Posterior 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; pseudoarthosis; 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 MESA, DENALI and EVEREST Spinal Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The MESA, DENALI and EVEREST 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.

Materials
The implants are manufactured from Titanium alloy, CP Titanium and Cobalt Chrome, per ASTM (F67, F1472, F136, F1537) and ISO standards.

Cleaning/Processing
K2M reusable devices are supplied non-sterile must be thoroughly cleaned prior to sterilization. The following instructions are recommended for Manual or Automated cleaning. Thermal disinfection may be also be performed to render the devices safe for handling however sterilization must be performed as a final step in reprocessing.

Point of use
Contaminated instruments should be wiped clean of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device. Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris on the inside.

Manual Cleaning Steps
1. PREPARE low foaming pH neutral enzymatic detergent per manufacturer's recommendation. Presoak the instruments for the specified time or a minimum of 5 minutes, whichever is longer.
2. MANUALLY clean instruments using a soft-bristled brush and/or soft lint-free cloth.
3. PAY ATTENTION to instruments with crevices, interfaces, cannulations and moving parts. Actuate device (if applicable) and use an appropriately sized lumen brush to clean all cannulas.
4. RINSE parts under warm running tap water for 1 minute.
5. REPEAT the process until no visible debris remains.
6. PREPARE pH neutral detergent for ultrasonic cleaning per manufacturer's recommendations. Immerse the articles into the prepared detergent solution and allow the articles to sonicate for 10 minutes.
7. REMOVE the instruments from the sonicator and rinse under warm tap water for a minimum of 1 minute.
8. RINSE the instruments under running reverse osmosis/deionized (RO/DI) water for a minimum of 1 minute.
9. VISUALLY inspect each instruments for visible soil. If visible soil is noticed contact the sponsor.
10. DRY using a clean, soft, lint-free single use cloth.

Automated Cleaning Steps
PERFORM steps 1-5 of Manual Cleaning steps.

6. PROCESS in washer-disinfector using the following cycle parameters.

Phase	Recirculation Time (min)	Temp	Detergent Type
Pre-Wash	2 Minutes	Cold tap water	N/A
Enzyme Wash	4 Minutes	Hot Tap water	Neutral pH
Detergent Wash	2 Minutes	65.5˚C	Neutral pH
Rinse	15 Seconds	Hot tap water	N/A
Drying	6 Minutes	98.8˚C	N/A
Thermal Disinfection* (optional)	2 Minutes, 30 Seconds	93˚C	N/A

7. VISUALLY inspect each test article for visible soil. If visible soil is noticed contact your local K2M sales representative.
8. DRY using a clean, soft, lint-free single use cloth.

Instructions for use

*Note: Sterilization must also be performed following thermal disinfection.

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.

US
Autoclave Cycle: Prevacuum
Temperature: 270°F (132°C)
Time: 4 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).

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. Store at ambient temperature.

Instructions for use
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

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 effects
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 effects for pediatric patients
1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
2. Pedicle screw malpositioning, with or without neurological or vascular 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 systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (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. 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.
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.

Additional potential adverse effects 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.

MRI safety information

Non-clinical testing and in-vivo electromagnetic simulations demonstrated that the K2M Pedicle Screw System is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the K2M Pedicle Screw System is expected to produce a maximum temperature rise of 3.92 ˚C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the K2M Pedicle Screw System extends approximately 40mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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.
7. Check expiration date and integrity of sterile packaging.

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.

Notes

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Spine division

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

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