



MESA® Small Stature

SURGICAL INFORMATION GUIDE





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Dear Colleagues,

Welcome to K2M and the MESA® Small Stature Spinal System. Our commitment to achieve the highest level of excellence in the treatment of spinal pathologies continues with this comprehensive system. With this product, K2M strives to better serve patients by building on our MESA technology platform.

The MESA Small Stature Spinal System has several offerings to facilitate a more efficient intra-operative experience. This Ø4.5 mm system features both polyaxial and deformity uniplanar screws. The polyaxial screws provide 65° range of motion and all screws are designed with an optimized dual lead thread to increase fixation in bone. These attributes are combined with the familiar flat geometry and Zero-Torque Technology® found in our other MESA systems.

The MESA Small Stature Spinal System has the potential to significantly impact the pedicle screw market. The following manual outlines the procedural details and options, providing a guide to help understand the many unique aspects of the system for use in treating our patients.

Sincerely,

A handwritten signature in black ink, appearing to read "John P. Kostuik".

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)

A handwritten signature in black ink, appearing to read "Oheneba Boachie-Adjei".

Oheneba Boachie-Adjei, MD

Chief Scoliosis Service; Hospital for Special Surgery, New York, New York



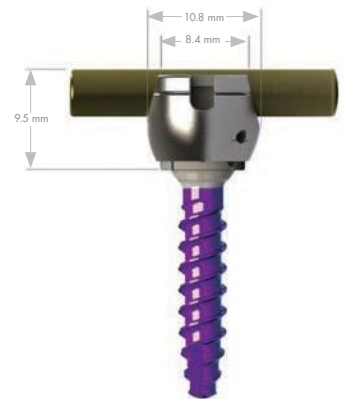
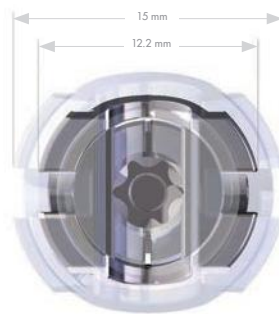
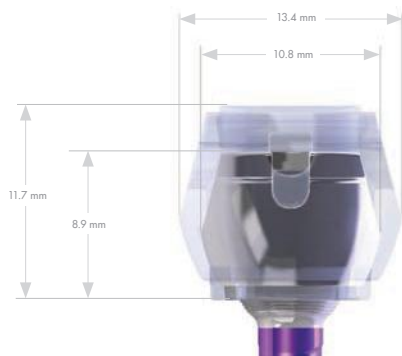
PRODUCT OVERVIEW



MESA® SMALL STATURE

SMALL JUST GOT SMALLER

The MESA® Small Stature Screw (Ø4.5 mm rod) offers an 18% reduction in screw head volume over a MESA Deformity Screw (Ø5.5 mm rod), and also offers the lowest profile in the industry.

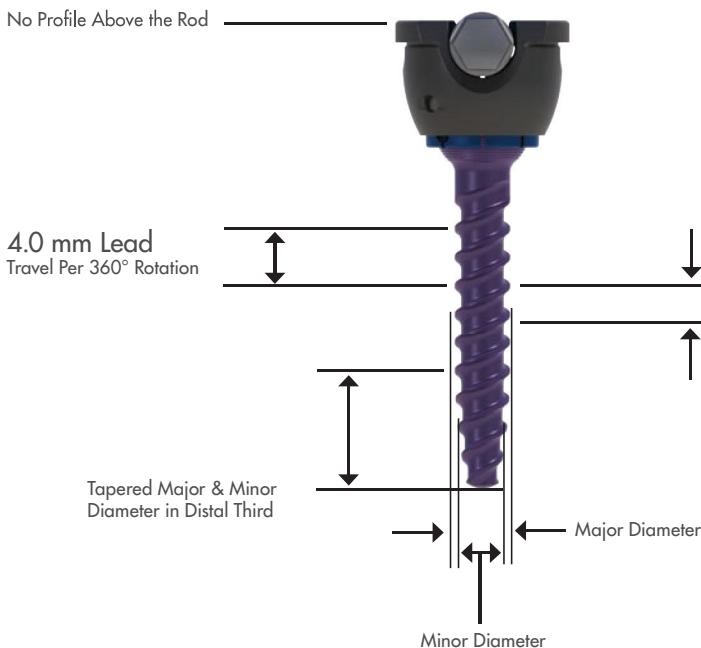


THREAD PATTERN

The thread pattern of the MESA Small Stature Screw is modeled after K2M's globally successful EVEREST® screw thread, to enhance pullout strength.

Design Rationale

- **Dual Lead Thread**
— 4.0 mm of insertion for every 360° rotation for faster insertion



- **Thread Pitch**
— Threads every 2.0 mm to further enhance pullout strength
- **Taper on Distal 3^d on Both Major & Minor Diameters**
— Provides wedging effect as the screw advances, resulting in higher pullout strength*
— Makes it easier to direct screw into the prepared hole
- **Threads Extend to the Tip**
— Screw gains purchase immediately upon engagement with bone
- **Self Tapping**
— Potentially reduces OR time by eliminating an operative step

Major Ø	4.0 mm	4.5 mm	5.0 mm	5.5 mm	6.5 mm	7.5 mm
Minor Ø	3.0 mm	3.5 mm	3.75 mm	4.0 mm	4.5 mm	5.0 mm
Pitch	2.0 mm	2.0 mm	2.0 mm	2.0 mm	2.0 mm	2.0 mm

*See Page 40 of the EVEREST® Degenerative Spinal System Surgical Technique for Supporting Data.

SET SCREW

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There is **NO** need for a set screw with MESA Technology.

ZERO-TORQUE TECHNOLOGY[®]

The MESA Spinal Systems are the only systems which apply no torsional load when locking the screw onto the rod. The forces are entirely axial and compressive.

- May decrease the potential for disrupting or fracturing the pedicles during final locking
- May benefit patients with poor bone quality
- Taper-Lock: Screw/rod locking mechanism is an interference fit

FLAT GEOMETRY

- No profile above the rod
- Flat geometry of inner & outer collet provides 100% visual confirmation the screw is final locked



INTRAOPERATIVE ROD

Surgery is dynamic. To accommodate varying patient needs, the surgeon has multiple rod options all using the MESA Small Stature Screws.



Titanium Alloy



Cobalt Chrome



Ø3.5 - Ø4.5 mm Transition - Titanium Alloy



Ø3.5 - Ø4.5 mm Transition - Cobalt Chrome

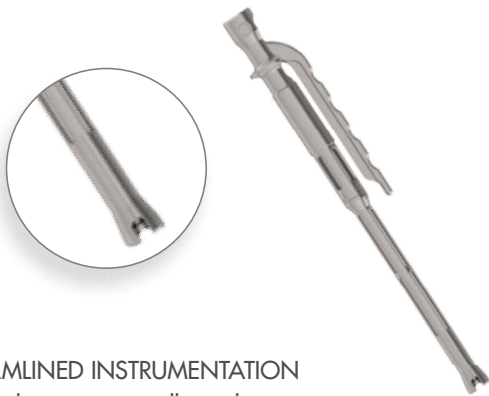


Ø4.5 - Ø5.5 mm Transition - Titanium Alloy



Ø4.5 - Ø5.5 mm Transition - Cobalt Chrome

FAMILIAR, UPGRADED INSTRUMENTS



STREAMLINED INSTRUMENTATION

- Reduction in overall weight
- Flushing ports designed for easy sterilization



AO HANDLE CONNECTIONS

- Ergonomic silicone design
- Allows for variable connection options



OVER CRICKET® LOCKER

- Silicone handles provide comfortable grip

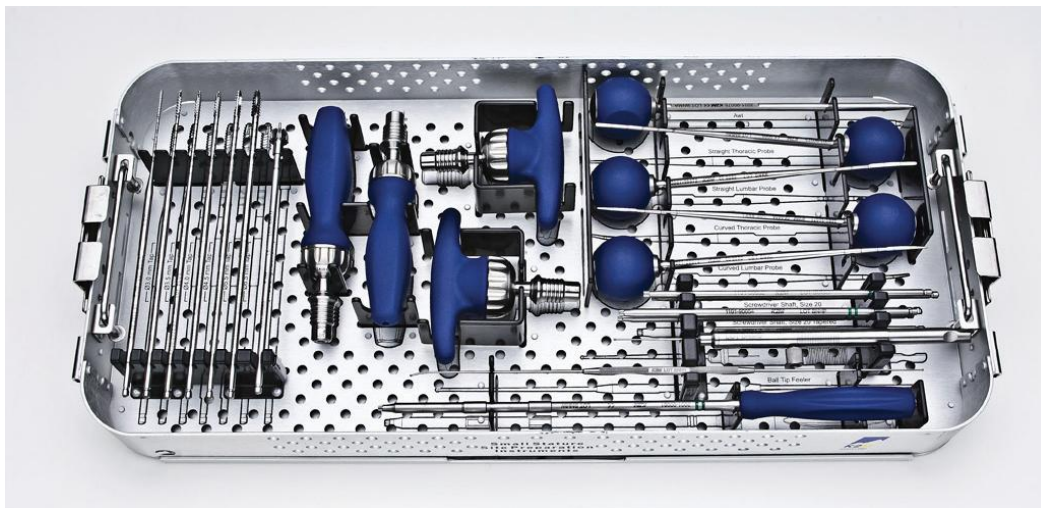


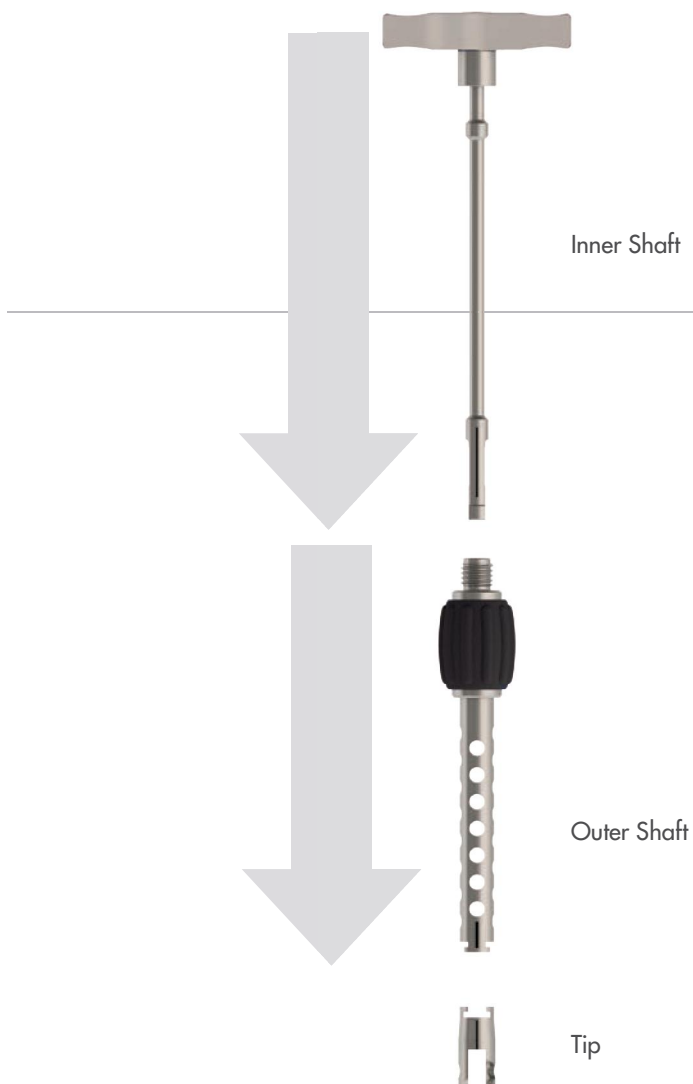
CRICKET® DESIGN

- Multiple Crickets® for segmental derotation of the Rod/ MESA Rail
- 30 mm of reduction
- Reduces inventory by eliminating need for reduction screws
- Allows for intra-operative flexibility

INSTRUMENT SET & TRAYS DESIGNED FOR EFFICIENCY & EASE OF USE

- Trays Arranged in Order of Use
- Modular Trays
 - Eliminating tubs for less hassle in the OR
 - Allows for customization of implants & instruments
- Lightweight Design
 - Trays double-stacked weigh less than 25 lbs
- Universal Screw Caddy
 - Stands upright to easily load screws
 - Removable & easily identifiable on the back table





ROD PULLER

To Assemble:

- Grasp the instrument tip & slide it into the distal end of the outer shaft, capturing the tip
- Use alignment markings to line up the inner shaft with the outer shaft
- Squeeze the tongs of the inner shaft to fit down the outer shaft
- Push the inner shaft into the instrument tip & an audible pop will confirm placement

To Disassemble:

- Hold the tip & the outer shaft together in one hand while disengaging the threads of the handle from the shaft
- To remove, pull back on the inner shaft while holding onto both the tip & outer shaft



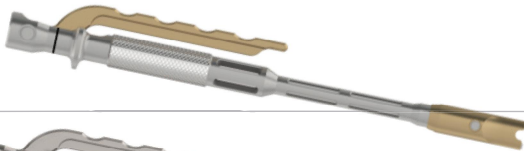
RATCHETING ROD CUTTER

- Alignment of the Cutter indicated with arrows
- Offers ergonomic silicone handles



TRANSVERSE COUPLER

- Connect to Rotation Tubes and/or Manipulators to triangulate forces
- Small, medium, & large sizes available



LOCKER/UNLOCKER

- Streamlined, ergonomic design
- Lightweight
- Flushing ports for irrigation



OVER CRICKET[®] LOCKER

- Locks screw head in one step over the Cricket
- Streamlined, ergonomic design
- Lightweight
- Flushing ports for irrigation



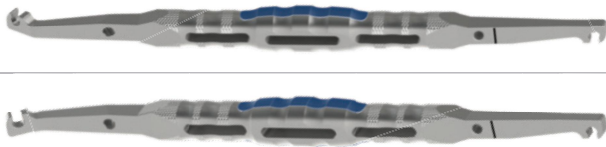
ROTATION TUBE

- Connect to top of Crickets
- Built-in drivers connect for easy Cricket reduction



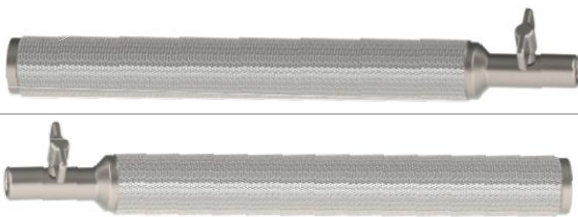
CORONAL BENDERS

- Ergonomic design & silicone grips



SAGITTAL BENDERS

- Ergonomic design/silicone grips
- Lightweight for in-situ manipulation



TUBE BENDER

- Acute bend & locking nut



HOOK INSERTERS

To Assemble:

- The inner stylet threads into the outer shaft
- The hook is loaded onto the tip of the instrument
- Continue threading & the tip of the instrument will flair out & securely capture the hook



OFFSET HOOK HOLDER

- Captures the hook & allows provisional set screw tightening & clearance for rod reduction



DRIVERS (Size 20)

- 1 Green Band – Non-Tapered Hexalobe, Size 20
- 2 Green Bands – Tapered Hexalobe, Size 20



MESA SMALL STATURE SCREW INSERTER

- Rounded distal end reduces the potential for anatomical interference
- Single Inserter accommodates all MESA screw options



HOOK & AXIAL CONNECTOR, PARALLEL CONNECTOR, LATERAL OFFSET CONNECTOR, & TORQUE LIMITING SHAFT & DRIVER

- Square Driver Connection
- Torque limit = 6 Nm
- Size 20 Driver



SINGLE ACTION ROD REDUCER

- 10 mm of controlled or fast-action reduction
- Offset, pistol-grip handle

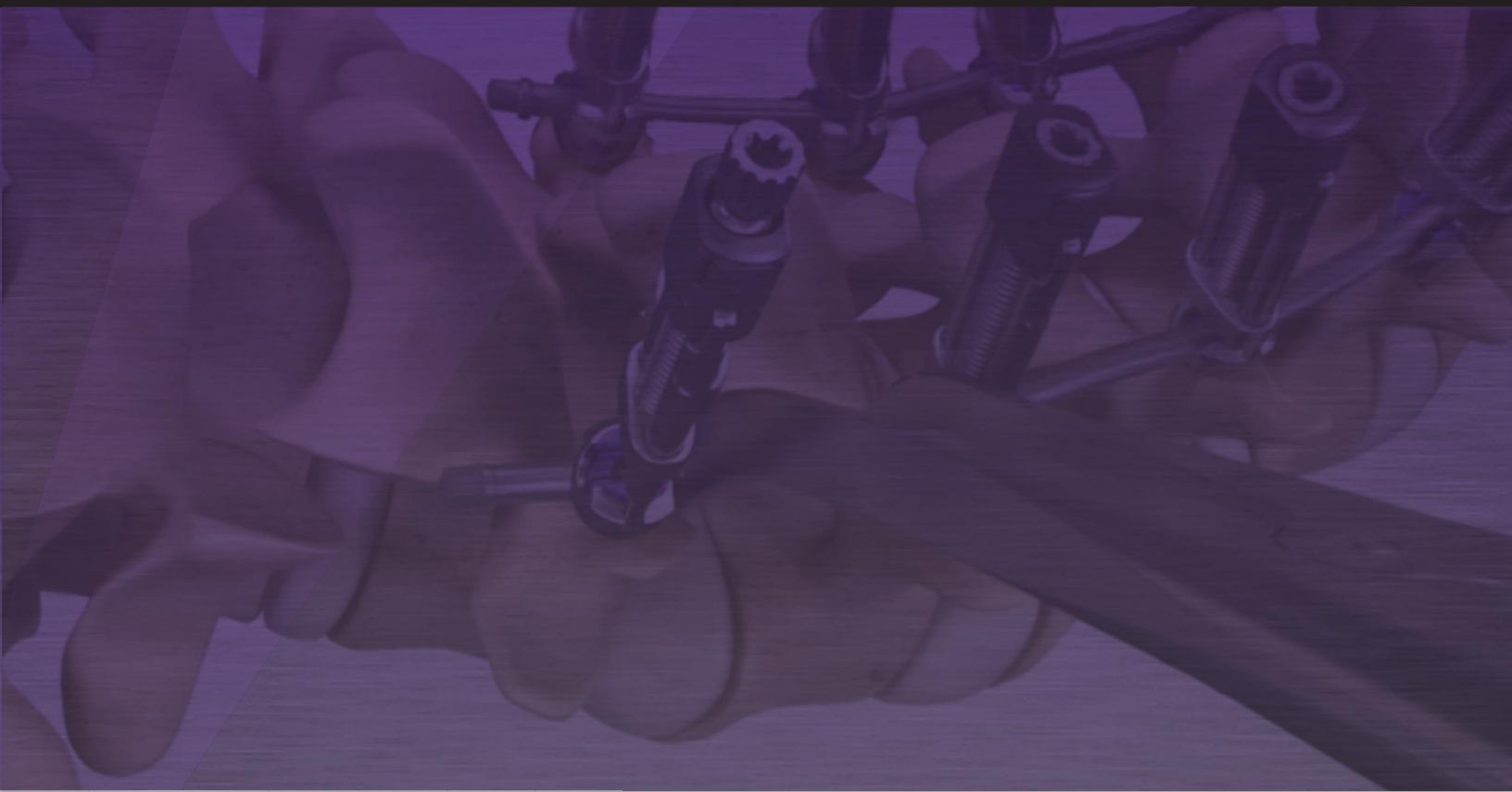


TRANSVERSE CONNECTOR TORQUE LIMITING SHAFT & DRIVER






























- Torque limit = 2 Nm
- Size 20 Driver
- For use with transverse connectors & Ø3.5 to Ø4.5 mm transition parallel connectors



PRODUCT CATALOG




MESA SMALL STATURE POLYAXIAL SCREWS


Catalog Number	Description	Color
3001-04020	MESA Small Stature Polyaxial Screw, 4.0 mm x 20 mm	
3001-040225	MESA Small Stature Polyaxial Screw, 4.0 mm x 22.5 mm	
3001-04025	MESA Small Stature Polyaxial Screw, 4.0 mm x 25 mm	
3001-040275	MESA Small Stature Polyaxial Screw, 4.0 mm x 27.5 mm	
3001-04030	MESA Small Stature Polyaxial Screw, 4.0 mm x 30 mm	
3001-04035	MESA Small Stature Polyaxial Screw, 4.0 mm x 35 mm	
3001-04040	MESA Small Stature Polyaxial Screw, 4.0 mm x 40 mm	
3001-04520	MESA Small Stature Polyaxial Screw, 4.5 mm x 20 mm	
3001-045225	MESA Small Stature Polyaxial Screw, 4.5 mm x 22.5 mm	
3001-04525	MESA Small Stature Polyaxial Screw, 4.5 mm x 25 mm	
3001-045275	MESA Small Stature Polyaxial Screw, 4.5 mm x 27.5 mm	
3001-04530	MESA Small Stature Polyaxial Screw, 4.5 mm x 30 mm	
3001-04535	MESA Small Stature Polyaxial Screw, 4.5 mm x 35 mm	
3001-04540	MESA Small Stature Polyaxial Screw, 4.5 mm x 40 mm	
3001-05025	MESA Small Stature Polyaxial Screw, 5.0 mm x 25 mm	
3001-05030	MESA Small Stature Polyaxial Screw, 5.0 mm x 30 mm	
3001-05035	MESA Small Stature Polyaxial Screw, 5.0 mm x 35 mm	
3001-05040	MESA Small Stature Polyaxial Screw, 5.0 mm x 40 mm	
3001-05045	MESA Small Stature Polyaxial Screw, 5.0 mm x 45 mm	
3001-05525	MESA Small Stature Polyaxial Screw, 5.5 mm x 25 mm	
3001-05530	MESA Small Stature Polyaxial Screw, 5.5 mm x 30 mm	
3001-05535	MESA Small Stature Polyaxial Screw, 5.5 mm x 35 mm	
3001-05540	MESA Small Stature Polyaxial Screw, 5.5 mm x 40 mm	
3001-05545	MESA Small Stature Polyaxial Screw, 5.5 mm x 45 mm	
3001-05550	MESA Small Stature Polyaxial Screw, 5.5 mm x 50 mm	
3001-06530	MESA Small Stature Polyaxial Screw, 6.5 mm x 30 mm	
3001-06535	MESA Small Stature Polyaxial Screw, 6.5 mm x 35 mm	
3001-06540	MESA Small Stature Polyaxial Screw, 6.5 mm x 40 mm	
3001-06545	MESA Small Stature Polyaxial Screw, 6.5 mm x 45 mm	













**3001-05020 / 3001-050225 / 3001-05520 / 3001-05555

also available by request.  = Can be used with the 4.5 mm MESA Rail™

MESA SMALL STATURE POLYAXIAL SCREWS (CONT.)

Catalog Number	Description	Color
3001-06550	MESA Small Stature Polyaxial Screw, 6.5 mm x 50 mm	
3001-06555	MESA Small Stature Polyaxial Screw, 6.5 mm x 55 mm	





MESA SMALL STATURE UNIPLANAR SCREWS

3001-34020	MESA Small Stature Uniplanar Screw, 4.0 mm x 20 mm	
3001-340225	MESA Small Stature Uniplanar Screw, 4.0 mm x 22.5 mm	
3001-34025	MESA Small Stature Uniplanar Screw, 4.0 mm x 25 mm	
3001-340275	MESA Small Stature Uniplanar Screw, 4.0 mm x 27.5 mm	
3001-34030	MESA Small Stature Uniplanar Screw, 4.0 mm x 30 mm	
3001-34035	MESA Small Stature Uniplanar Screw, 4.0 mm x 35 mm	
3001-34040	MESA Small Stature Uniplanar Screw, 4.0 mm x 40 mm	
3001-34520	MESA Small Stature Uniplanar Screw, 4.5 mm x 20 mm	
3001-345225	MESA Small Stature Uniplanar Screw, 4.5 mm x 22.5 mm	
3001-34525	MESA Small Stature Uniplanar Screw, 4.5 mm x 25 mm	
3001-345275	MESA Small Stature Uniplanar Screw, 4.5 mm x 27.5 mm	
3001-34530	MESA Small Stature Uniplanar Screw, 4.5 mm x 30 mm	
3001-34535	MESA Small Stature Uniplanar Screw, 4.5 mm x 35 mm	
3001-34540	MESA Small Stature Uniplanar Screw, 4.5 mm x 40 mm	
3001-35025	MESA Small Stature Uniplanar Screw, 5.0 mm x 25 mm	
3001-35030	MESA Small Stature Uniplanar Screw, 5.0 mm x 30 mm	
3001-35035	MESA Small Stature Uniplanar Screw, 5.0 mm x 35 mm	
3001-35040	MESA Small Stature Uniplanar Screw, 5.0 mm x 40 mm	
3001-35045	MESA Small Stature Uniplanar Screw, 5.0 mm x 45 mm	
3001-35530	MESA Small Stature Uniplanar Screw, 5.5 mm x 30 mm	
3001-35535	MESA Small Stature Uniplanar Screw, 5.5 mm x 35 mm	
3001-35540	MESA Small Stature Uniplanar Screw, 5.5 mm x 40 mm	
3001-35545	MESA Small Stature Uniplanar Screw, 5.5 mm x 45 mm	
3001-35550	MESA Small Stature Uniplanar Screw, 5.5 mm x 50 mm	
3001-36530	MESA Small Stature Uniplanar Screw, 6.5 mm x 30 mm	















**3001-35020 / 3001-350225 / 3001-35520 / 3001-35525 / 3001-36555 / 21
 3001-35555 also available by request.  = Can be used with the 4.5 mm MESA Rail™

MESA SMALL STATURE UNIPLANAR SCREWS (CONT.) 










Catalog Number	Description	Color
3001-36535	MESA Small Stature Uniplanar Screw, 6.5 mm x 35 mm	
3001-36540	MESA Small Stature Uniplanar Screw, 6.5 mm x 40 mm	
3001-36545	MESA Small Stature Uniplanar Screw, 6.5 mm x 45 mm	
3001-36550	MESA Small Stature Uniplanar Screw, 6.5 mm x 50 mm	

MESA SMALL STATURE POLYAXIAL SACROILIAC SCREWS 













3001-05560	MESA Small Stature Polyaxial Screw, 5.5 mm x 60 mm	
3001-05565	MESA Small Stature Polyaxial Screw, 5.5 mm x 65 mm	
3001-05575	MESA Small Stature Polyaxial Screw, 5.5 mm x 75 mm	
3001-05585	MESA Small Stature Polyaxial Screw, 5.5 mm x 85 mm	
3001-06560	MESA Small Stature Polyaxial Screw, 6.5 mm x 60 mm	
3001-06565	MESA Small Stature Polyaxial Screw, 6.5 mm x 65 mm	
3001-06575	MESA Small Stature Polyaxial Screw, 6.5 mm x 75 mm	
3001-06585	MESA Small Stature Polyaxial Screw, 6.5 mm x 85 mm	
3001-07560	MESA Small Stature Polyaxial Screw, 7.5 mm x 60 mm	
3001-07565	MESA Small Stature Polyaxial Screw, 7.5 mm x 65 mm	
3001-07575	MESA Small Stature Polyaxial Screw, 7.5 mm x 75 mm	
3001-07585	MESA Small Stature Polyaxial Screw, 7.5 mm x 85 mm	



MESA SMALL STATURE HOOK IMPLANTS





Catalog Number	Description		
3001-80400N	Infralaminar Hook, Narrow, 4 mm		<p>Multipurpose hook used in an upward or downward facing position on the laminae. Design incorporates a ramped base to minimize canal encroachment. Hooks have various sizes and blade volume to accommodate varying anatomy.</p>
3001-80600N	Infralaminar Hook, Narrow, 6 mm		
3001-80800N	Infralaminar Hook, Narrow 8 mm		
3001-80400	Infralaminar Hook, 4 mm		
3001-80600	Infralaminar Hook, 6 mm		
3001-80800	Infralaminar Hook, 8 mm		
3001-80401N	Thoracic Laminar Hook, Narrow, 4 mm		
3001-80601N	Thoracic Laminar Hook, Narrow, 6 mm		
3001-80801N	Thoracic Laminar Hook, Narrow, 8 mm		
3001-80401	Thoracic Laminar Hook, 4 mm		
3001-80601	Thoracic Laminar Hook, 6 mm		
3001-80801	Thoracic Laminar Hook, 8 mm		
3001-80402N	Lumbar Laminar Hook, Narrow, 4 mm		
3001-80602N	Lumbar Laminar Hook, Narrow, 6 mm		
3001-80802N	Lumbar Laminar Hook, Narrow, 8 mm		
3001-80402	Lumbar Laminar Hook, 4 mm		
3001-80602	Lumbar Laminar Hook, 6 mm		
3001-80802	Lumbar Laminar Hook, 8 mm		
3001-80403	Pedicle Hook, 4 mm		<p>Pedicle hook designed for use in the thoracic spine. Hook is inserted into the facet joint in an upgoing position with the notch of the hook resting on the inferior side of the pedicle. Partial resection of the inferior articular process may be required for best fit.</p>
3001-80603	Pedicle Hook, 6 mm		
3001-80803	Pedicle Hook, 8 mm		
3001-80404	Angled Left Hook, 5.5 x 4 mm		<p>Multipurpose angled hook placed lateral to the pedicle. Hooks come in various angles to accommodate varying anatomy.</p>
3001-80604	Angled Left Hook, 5.5 x 6 mm		
3001-80804	Angled Left Hook, 5.5 x 8 mm		
3001-80405	Angled Right Hook, 5.5 x 4 mm		
3001-80605	Angled Right Hook, 5.5 x 6 mm		
3001-80805	Angled Right Hook, 5.5 x 8 mm		

MESA SMALL STATURE AUXILIARY CONNECTORS







Catalog Number	Description	
3001-84545	Ø4.5/Ø4.5 mm Parallel Connector, Closed/Closed	
3001-84545N	Ø4.5/Ø4.5 mm Parallel Connector, Closed/Closed, Narrow	
3001-84545B	Ø4.5/Ø4.5 mm Parallel Connector, Closed/Open	
3001-84545BN	Ø4.5/Ø4.5 mm Parallel Connector, Closed/Open, Narrow	
3001-74525	Lateral Offset Connector, 25 mm 	
3001-74550	Lateral Offset Connector, 50 mm 	
3001-74525C	Lateral Offset Connector, Closed, 25 mm 	
3001-74550C	Lateral Offset Connector, Closed, 50 mm 	

 = Can be used with the 4.5 mm MESA Rail™

MESA SMALL STATURE AUXILIARY CONNECTORS (CON'T)

Catalog Number	Description	
3001-84520D	Axial Connector, 20 mm	
3001-84540D	Axial Connector, 40 mm	
3001-84560D	Axial Connector, 60 mm	
3001-84580D	Axial Connector, 80 mm	
3001-70020A	Semi-Adjustable Transverse Connector, 20 mm	
3001-70023A	Semi-Adjustable Transverse Connector, 23 mm	
3001-70026A	Semi-Adjustable Transverse Connector, 26 mm	
3001-70029A	Semi-Adjustable Transverse Connector, 29 mm	
3001-70032A	Semi-Adjustable Transverse Connector, 32 mm	
3001-70035A	Semi-Adjustable Transverse Connector, 35 mm	
3001-73438	Adjustable Transverse Connector, Small	
3001-73743	Adjustable Transverse Connector, Medium	
3001-74250	Adjustable Transverse Connector, Large	
3001-74960	Adjustable Transverse Connector, Extra Large	
3001-10001	Set Screw	






MESA SMALL STATURE TRANSITION IMPLANTS








Catalog Number	Description	
3001-535300-45	Ø3.5/Ø4.5 mm Ti Alloy Transitional Rod, 300 mm	
3001-535500-45	Ø3.5/Ø4.5 mm Ti Alloy Transitional Rod, 500 mm	
3001-545500-55	Ø4.5/Ø5.5 mm Ti Alloy Transitional Rod, 500 mm	
3011-535300-45	Ø3.5/Ø4.5 mm CoCr Transitional Rod, 300 mm	
3011-535500-45	Ø3.5/Ø4.5 mm CoCr Transitional Rod, 500 mm	
3011-545500-55	Ø4.5/Ø5.5 mm CoCr Transitional Rod, 500 mm	
3001-83545	Ø3.5/Ø4.5 mm Parallel Connector, Closed/Closed	
3001-84555	Ø4.5/Ø5.5 mm Parallel Connector, Closed/Closed	
3001-83545N	Ø3.5/Ø4.5 mm Parallel Connector, Closed/Closed, Narrow	
3001-84555N	Ø4.5/Ø5.5 mm Parallel Connector, Closed/Closed, Narrow	

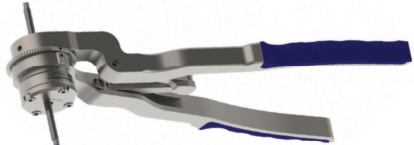

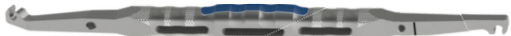
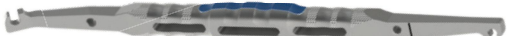




MESA SMALL STATURE RODS

Catalog Number	Description	
3001-B45150	Titanium Alloy Rod, 150 mm	
3001-B45300	Titanium Alloy Rod, 300 mm	
3001-B45500	Titanium Alloy Rod, 500 mm	
3011-B45150	CoCr Rod, 150 mm	
3011-B45300	CoCr Rod, 300 mm	
3011-B45500	CoCr Rod, 500 mm	

Catalog Number	Description	
3001-90001	SITE PREPARATION INSTRUMENTS	
2601-90023	T-Handle	
2601-90024	Axial Handle	
1101-90052	Non-Tapered Driver	
1101-90054	Screwdriver Shaft, Size 20 Tapered	
3001-90061	Screwdriver, Size 20 Tapered	




Catalog Number	Description	
3001-90001	SITE PREPARATION INSTRUMENTS (cont)	
3001-90062	Guiding Reamer	
3001-90063	Ball Tip Feeler	
3001-90064	Ø3.0 mm Tap	
3001-90065	Ø3.5 mm Tap	
3001-90066	Ø4.0 mm Tap	
3001-90067	Ø4.5 mm Tap	
3001-90068	Ø5.5 mm Tap	









Catalog Number	Description	
3001-90001	SITE PREPARATION INSTRUMENTS (cont)	
3001-90069	Ø6.5 mm Tap	
3001-90070	Curved Thoracic Probe	
3001-90071	Straight Thoracic Probe	
3001-90072	Curved Lumbar Probe	
3001-90073	Straight Lumbar Probe	
3001-90074	Depth Gauge	
3001-90075	Awl	








Catalog Number	Description	
3001-90002	ROD PREPARATION & IMPLANTS	
3001-90076	Ratcheting Rod Cutter	
3001-90077	French Rod Bender	
3001-90078	In-Situ Bender, Left	
3001-90079	In-Situ Bender, Right	
3001-90080	Tube Rod Bender	
3001-90081	Rod Locking Set Screw	
3001-90082	Wedge Distractor 	

 = Can be used with the 4.5 mm MESA Rai™






Catalog Number	Description	
3001-90002	ROD PREPARATION & IMPLANTS (cont)	
3001-90083	500 mm Rod Template	
3001-90084	Rod Rotation Wrench	
3001-90085	Torsional Rod Reducer, Left	
3001-90086	Torsional Rod Reducer, Right	
3001-90087	Rod Holding Forceps	







Catalog Number	Description	
3001-90002	ROD PREPARATION & IMPLANTS (cont)	
3001-90088	Medial/Lateral Rod Bender, Left	
3001-90089	Medial/Lateral Rod Bender, Right	
3001-90090	Vise Grip	






Catalog Number	Description	
3001-90004	COMPRESSION & DISTRACTION	
3001-90139	Compressor 	
3001-90092	Parallel Distractor, Wide 	
801-90028	Distractor 	
101-90284	Flat Iron Bender	
3001-90138	MESA Rail/Rod Distractor 	






Catalog Number	Description	
3001-90005	MESA® INSTRUMENTS	
3001-90094	Screw Inserter	
3001-90095	MESA Rail/Rod Puller, Outer Sleeve 	
3001-90096	MESA Rail/ Rod Puller, Inner Shaft 	
3001-90097	MESA Rail/ Rod Puller, Replaceable Tip 	
3001-90098	Screw Head Adjuster	
3001-90048	Dual Action Rod Reducer	







 = Can be used with the 4.5 mm MESA Rail™





Catalog Number	Description	
3001-90005	MESA® INSTRUMENTS (cont)	
3001-9099	Locker	
3001-90100	Unlocker	
3001-90101	AO Quick Knob	
3001-90102	Over Cricket Locker 	

Catalog Number	Description	
3001-90006	MESA® DEFORMITY INSTRUMENTS	
301-90103	Manipulator	
1101-90277	Manipulator Wrench	
1101-90273	Transverse Coupler, Small	
1101-90274	Transverse Coupler, Medium	
1101-90275	Transverse Coupler, Large	
3001-90104	T-Bar Screw Removal	
3001-90105	Reduction Jack Rotation Tube	
3001-90107	Cricket	

Catalog Number	Description	
3001-90007	HOOK IMPLANTS & INSTRUMENTS	
3001-90108	Offset Hook Holder	
3001-90109	Saddle Hook Holder	
3001-90110	Side Hook Holder	
3001-90111	Straight Hook Holder	
3001-90112	Rod Fork	

Catalog Number	Description	
3001-90008	HOOK INSTRUMENTS	
3001-90113	Hook Inserter, Outer Shaft	
3001-90114	Hook Inserter, Inner Shaft	
3001-90115	Hook Pusher	
3001-90116	Pedicule Hook Trial, Small	
3001-90117	Pedicule Hook Trial, Large	
301-90118	Hook Elevator	

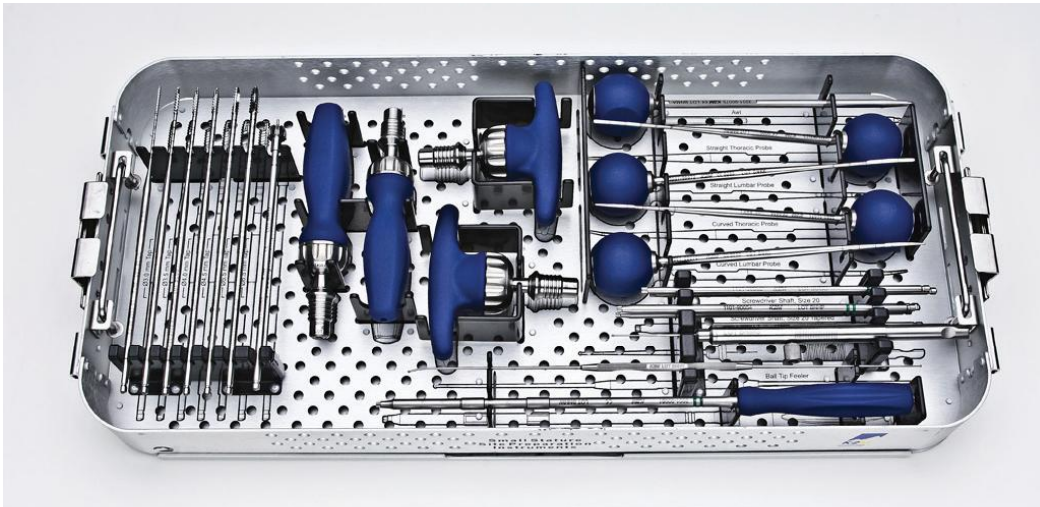
Catalog Number	Description	
3001-90009	AUXILIARY IMPLANTS & INSTRUMENTS	
101-90220	Rod Connector Holder	
2601-90010	Fixed T-Handle Square	
3001-90020	Torque Limiting Handle, 6 N-m	
3001-90119	Torque Limiting Shaft, Size 20	
3001-90120	Alignment Tube	
3001-90121	Single Action Rod Reducer	

Catalog Number	Description	
	NATURAL BRIDGE® Tray	
1101-90043	Torque Limiting Handle, 2 N-m	
101-90220	Transverse Connector Holder	
3001-90122	Transverse Connector Calipers	
1101-90052	Size 20 Driver Non-Tapered	

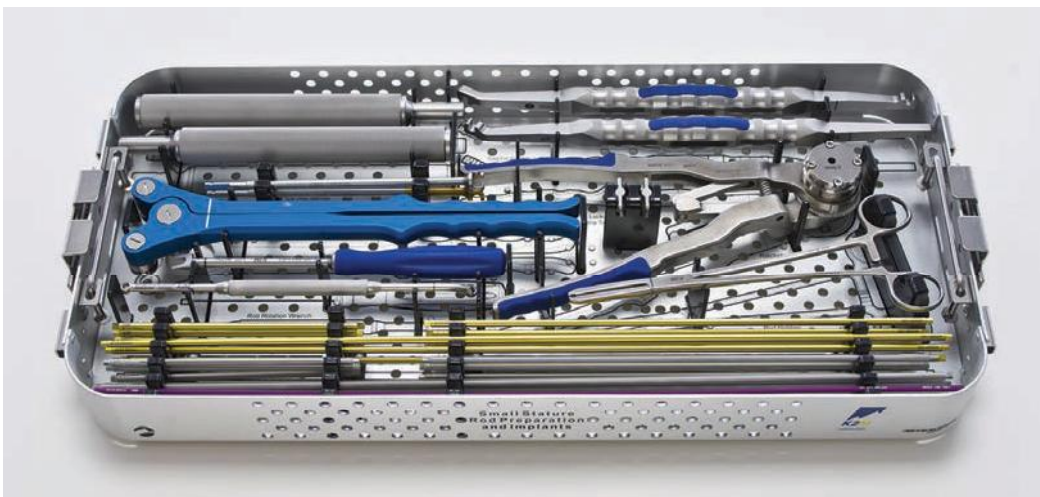
INSTRUMENT TRAYS



SITE PREPARATION INSTRUMENTS



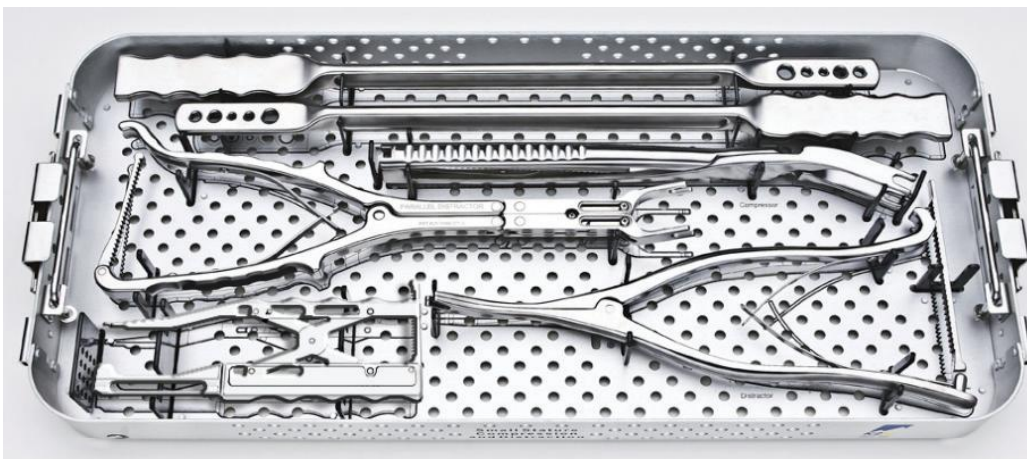
ROD PREPARATION & IMPLANTS



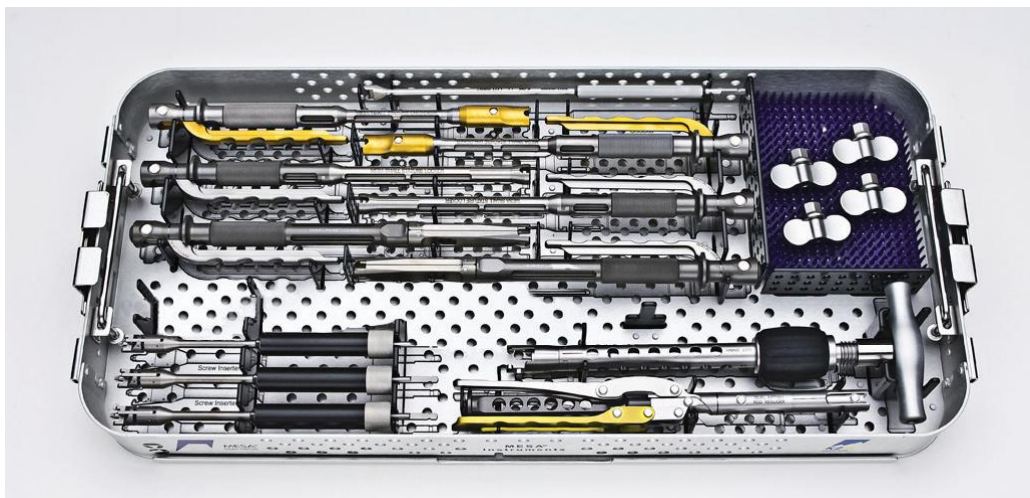
ROD PREPARATION INSTRUMENTS



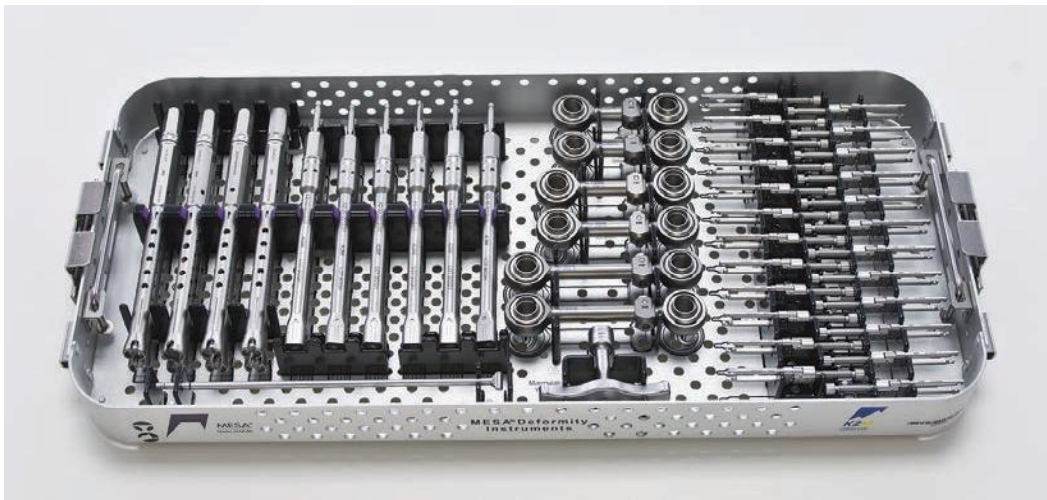
COMPRESSION & DISTRACTION



MESA INSTRUMENTS



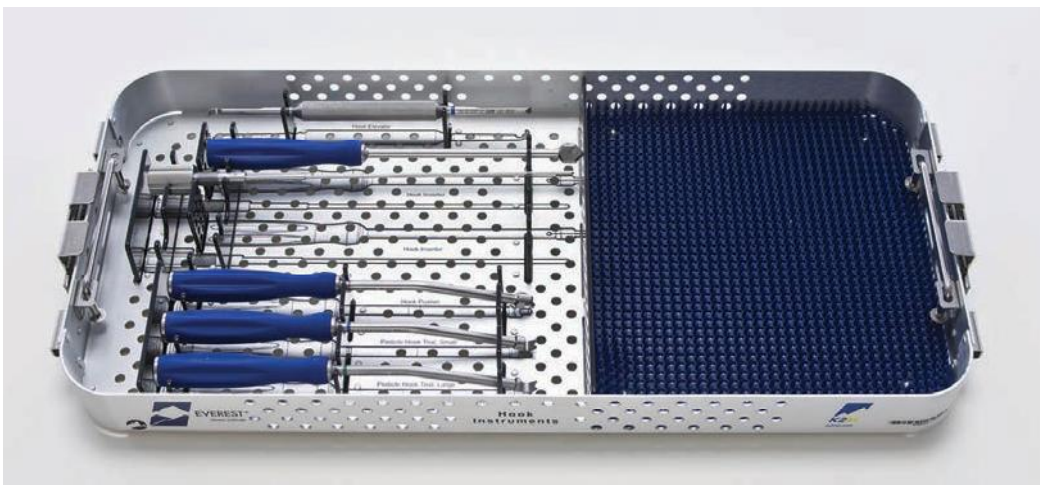
MESA DEFORMITY INSTRUMENTS



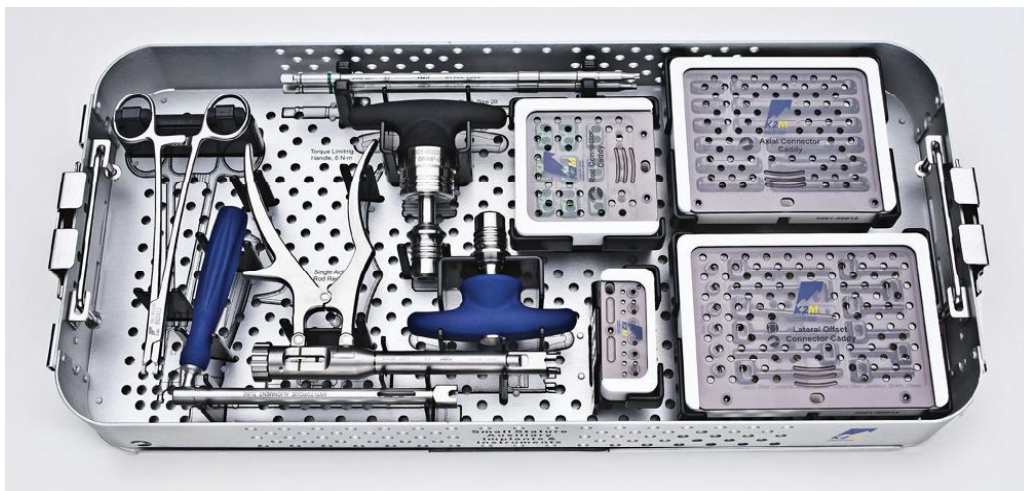
HOOKS IMPLANTS & INSTRUMENTS



HOOK INSTRUMENTS



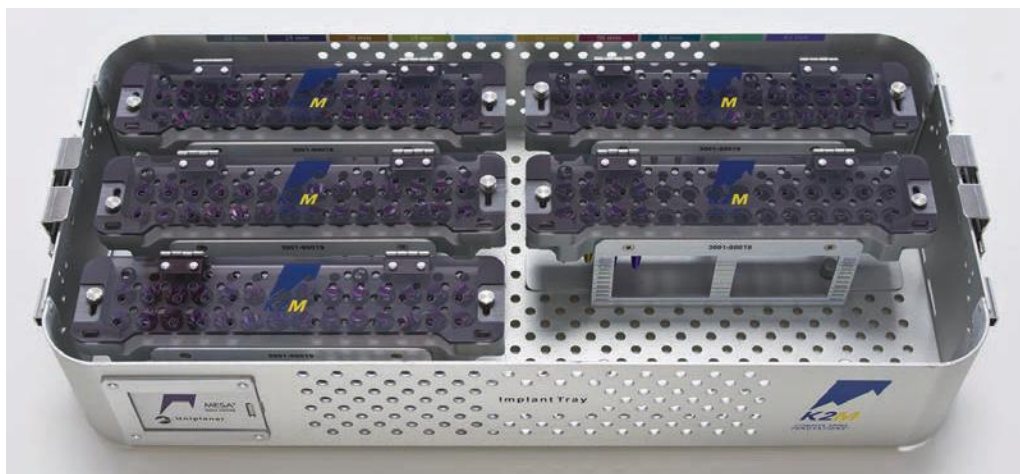
AUXILIARY IMPLANTS & INSTRUMENTS



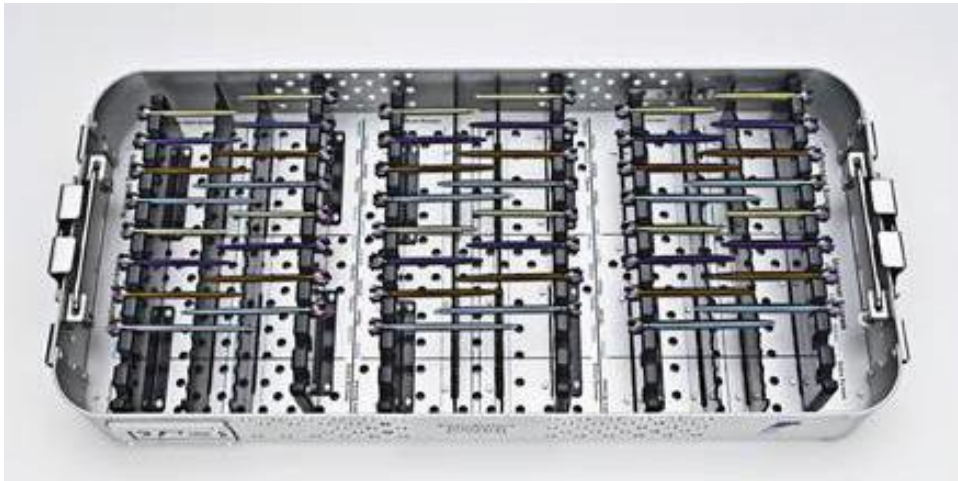
IMPLANT TRAY



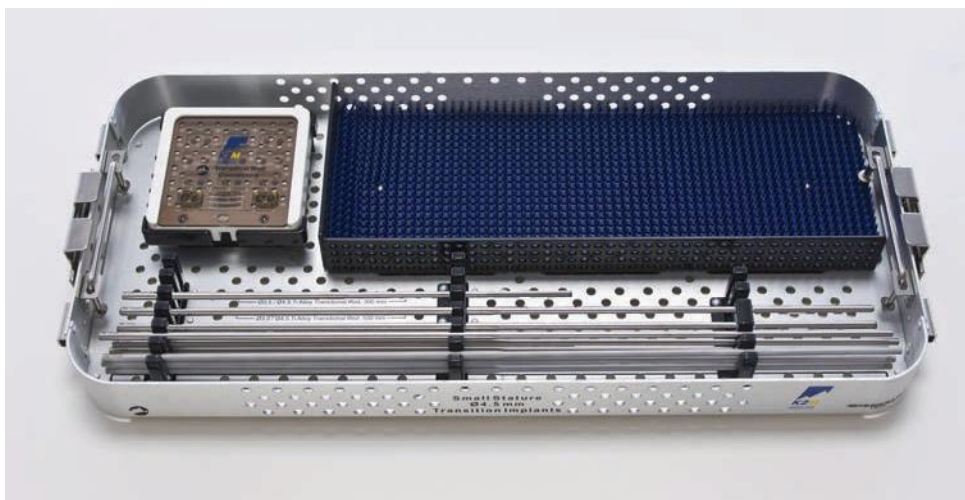
IMPLANT TRAY



SACROILIAC SCREW TRAY



TRANSITION TRAY



NATURAL BRIDGE[®] SMALL STATURE

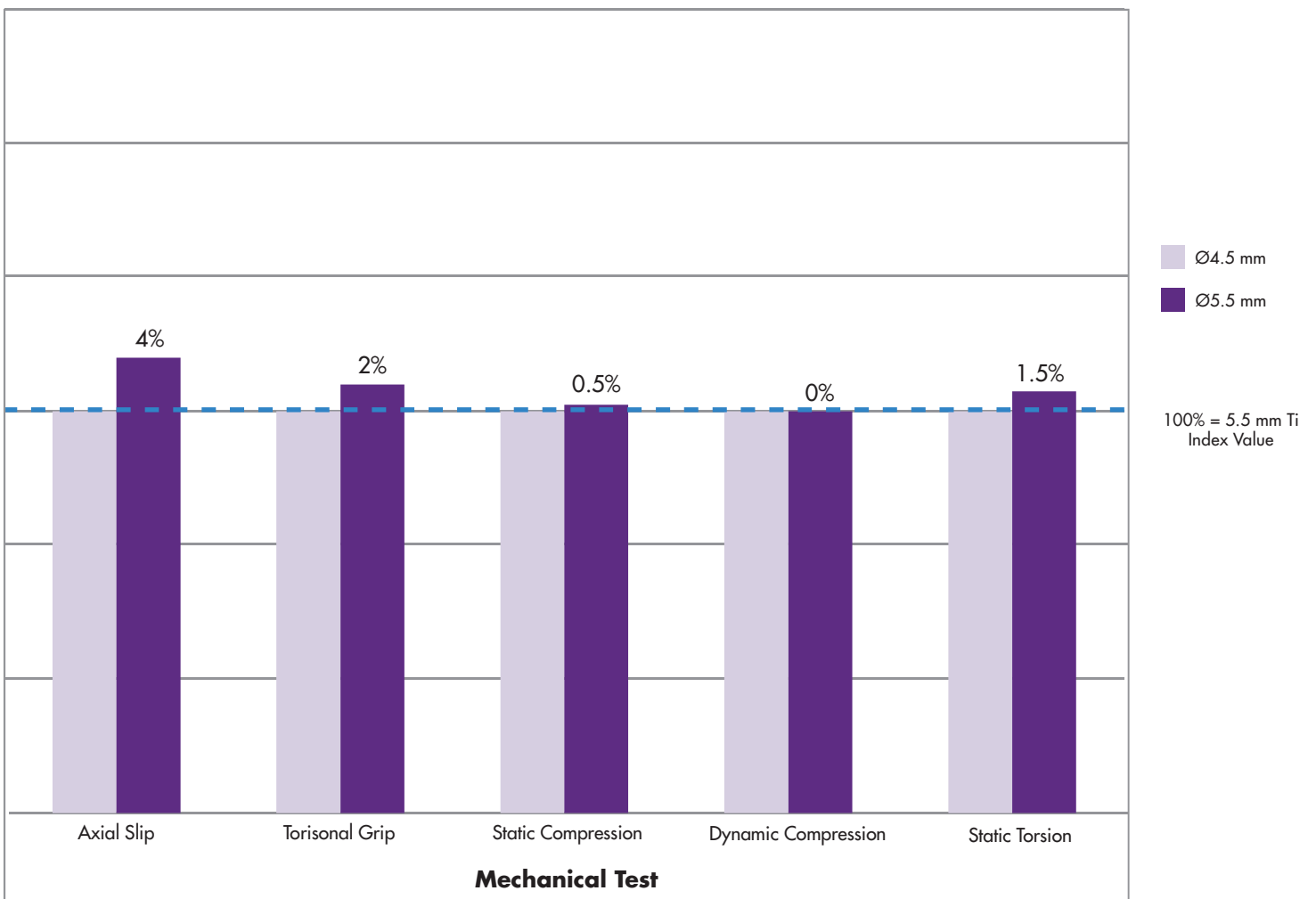




TESTING INFORMATION



Mechanical Testing
MESA® (Ø5.5 mm) vs. MESA® Small Stature (Ø4.5 mm)



NOTE: MESA Polyaxial Screw/ Ø5.5 mm Ti Rod as compared to a MESA Small Stature Polyaxial Screw/ Ø4.5 mm Ti Rod



MESA® Small Stature

SURGICAL TECHNIQUE



STEP 1

Surgical Technique

STEP 1: Exposure & Preparation

PERFORM FACETECTOMIES throughout.

Note: Instrumented levels are based on surgeon preference and patient pathology. This manual is intended to be used as a guideline for correction techniques with the MESA Small Stature Spinal System.



STEP 2

Surgical Technique

STEP 2: Screw Site Preparation

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

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 marked at 10 mm increments, from 10 mm to 50 mm, indicating the depth to which the Probe has been inserted. These markings also help the surgeon assess proper screw length.



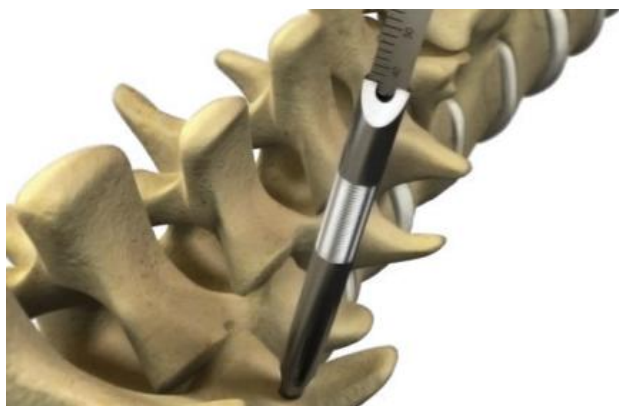
STEP 2

Surgical Technique

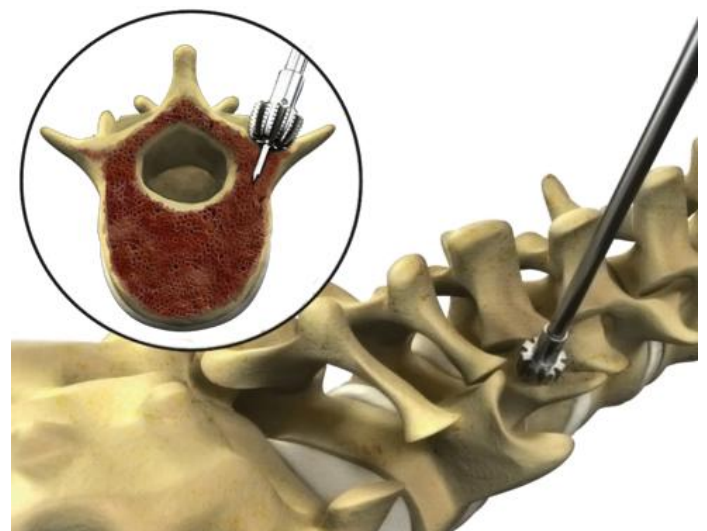
STEP 2: Screw Site Preparation (CON'T)

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

NOTE: A Depth Gauge may be used to determine screw length.



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



STEPS 3 & 4

Surgical Technique

STEP 3: Anatomical Verification

THE PREPARED, PROBED PATHWAY is sounded with the Ball Tip Feeler to verify the walls of the pedicle have not breached and cancellous bone is felt through to the distal end of the prepared bony path.



STEP 4: Screw Insertion — MESA[®] Implants

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 an Axial or T-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 Small Stature Screw Inserter. It is important to grasp the implant by the screw shaft, while simultaneously applying a force between the Screwdriver and implant to properly engage the screw onto the Inserter.



STEPS 5 & 6

Surgical Technique

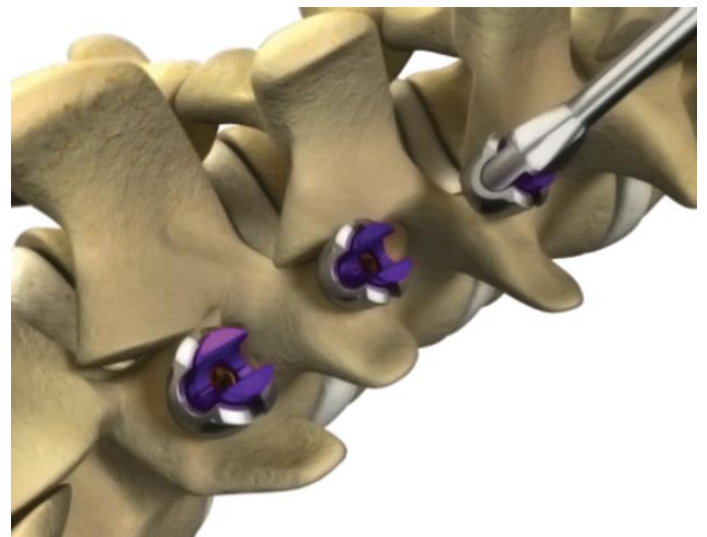
STEP 5: Screw Placement

MESA SMALL STATURE Polyaxial Screws can be used at the most proximal levels for ease of rod attachment and establishment of the proximal foundation. Otherwise, MESA Small Stature Uniplanar Screws can be used throughout the spine.



STEP 6: Screw Adjustment

ONCE THE APPROPRIATE SCREW has been selected and inserted, the housing of the screw can be adjusted with the MESA Small Stature Screw Head Adjuster. Confirm the screw heads are unlocked and all screws are at the appropriate levels and aligned to accept the rod.



STEP 7

Surgical Technique

STEP 7: Rod Preparation

ONCE ALL SCREWS HAVE been inserted, the rod is selected and cut to the appropriate length, if necessary. If preferred, length can be determined using the 500 mm Rod Template. To prep the Ratcheting Rod Cutter, make sure to align the two black arrows on the wheel by turning it counter-clockwise. To cut the rod, insert it into the Ratcheting Rod Cutter until determined cut spot is lined up with the cut line. Proceed to squeeze handle and then release, repeating until rod is cut.

NOTE: Both Cobalt Chrome and Titanium Alloy rods are available in $\text{\O}4.5$ mm, as well as Transition Rods from $\text{\O}3.5 - \text{\O}4.5$ mm and $\text{\O}4.5 - \text{\O}5.5$ mm. The Rod Template may be used with any type of rod to determine correct rod length.



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 ($\text{\O}4.5$ mm, $\text{\O}5.5$ mm, & $\text{\O}6.0$ mm).

NOTE: Flat Iron Benders are also available for contouring the rods to the desired amount of lordosis or kyphosis.

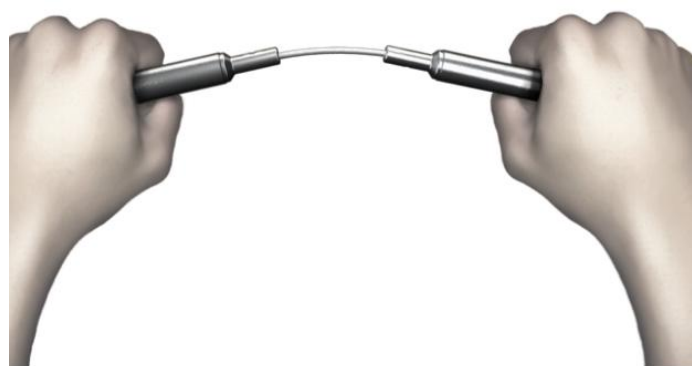


STEPS 7 & 8

Surgical Technique

STEP 7: Rod Preparation (CON'T)

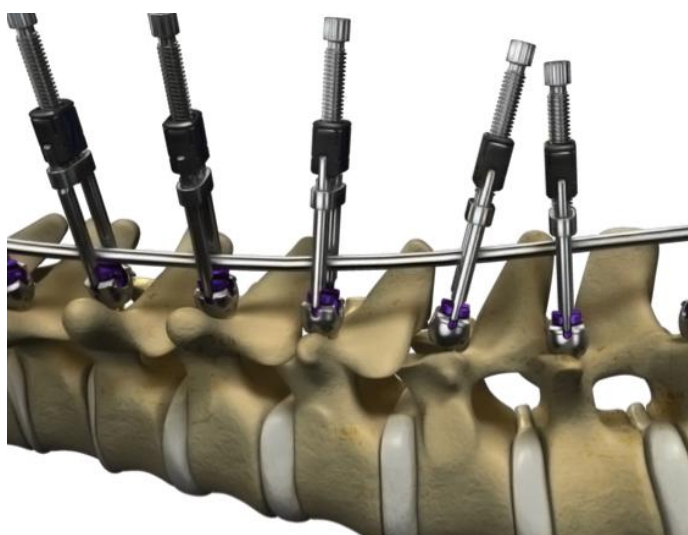
The Tube Rod Benders may also be used to contour the rod into the desired sagittal and/or coronal plane. Insert the rod into the end of the Tube Rod Bender and place hands at the distal portion of the Benders for optimal mechanical advantage. Rod locking set screws are provided for stabilization of the rod while bending. Bend the rod to the desired contour as determined by the surgeon.



STEP 8: Concave Left Rod Placement

PLACE DEFORMITY CRICKETS® ON the screws on the concave side. Pre-bend the rods in the physiological sagittal plane. For ease of rod insertion, place Deformity Reduction Jacks (Crickets®) on only the upper portion of the concave screws. After introducing the rod, place Deformity Crickets over the lower half of the rod. Do not tighten the Deformity Crickets, as they are only meant to ensure screw capture on the rod at this point. They will be used later for translation correction of the spine and reduction of the rods to the screws.

NOTE: Rod Holding Forceps are also available for rod introduction.



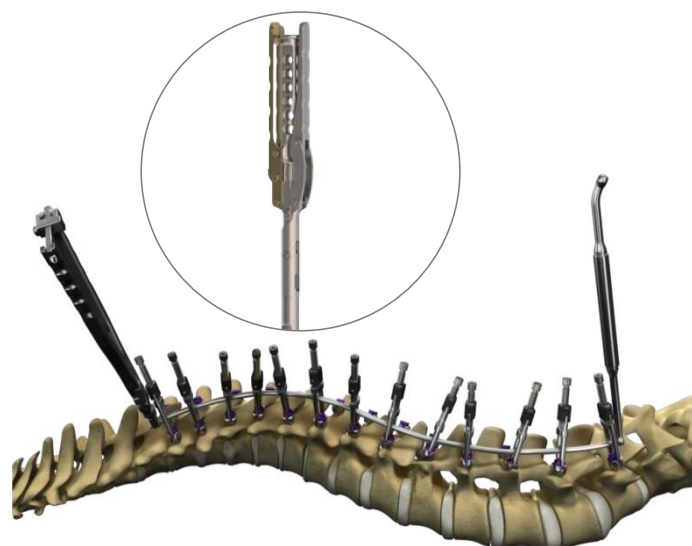
STEP 8

Surgical Technique

STEP 8: Concave Left Rod Placement (CON'T)

Rotate the rod into the desired sagittal alignment. This is preferably performed using the Rod Rotation Wrench and/or a Vise Grip. Seat the rod into the proximal fixation points by tightening the Deformity Crickets using the Screwdriver Shaft, Size 20, and a Handle.

NOTE: The Dual Action Rod Reducer (Dragonfly™) may be used to reduce the rod at the proximal levels or in instances where minimal reduction is required. When docking the Dragonfly, hold only the center shaft of the instrument to receive better 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. A Screwdriver Shaft, Size 20 Tapered may also be used in place of the Screwdriver Shaft, Size 20 with a Handle.



Holding the rod in the physiological sagittal plane with the Rod Rotation Wrench or a Vise Grip, reduce the Deformity Crickets at least halfway at the apical levels and tighten to “kiss” the rod at all other levels.

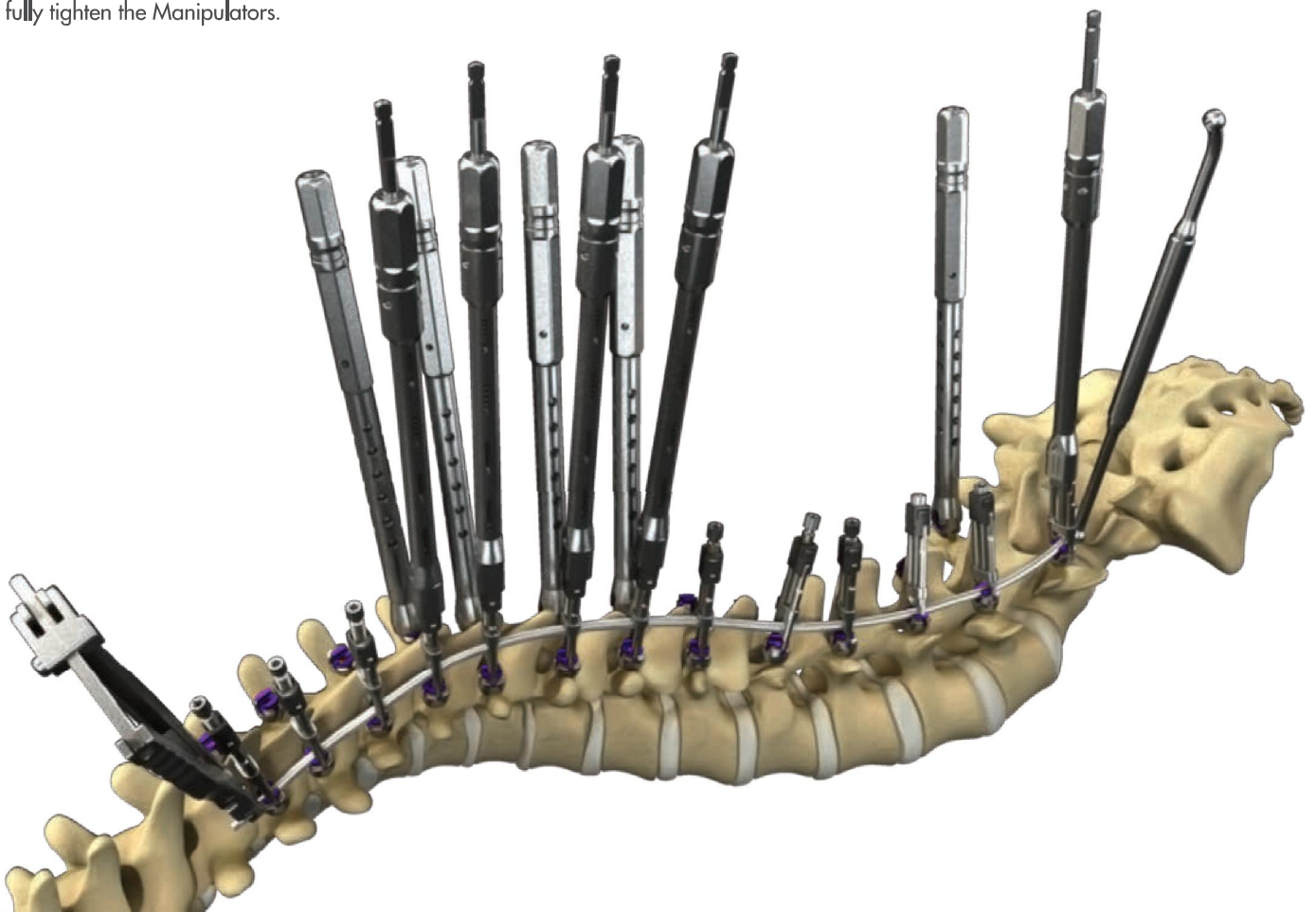


STEP 9

Surgical Technique

STEP 9: Axial Correction & Countertorsion

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 screw heads and place the screws into a partially locked state. The Manipulator Wrench can be used to help fully tighten the Manipulators.



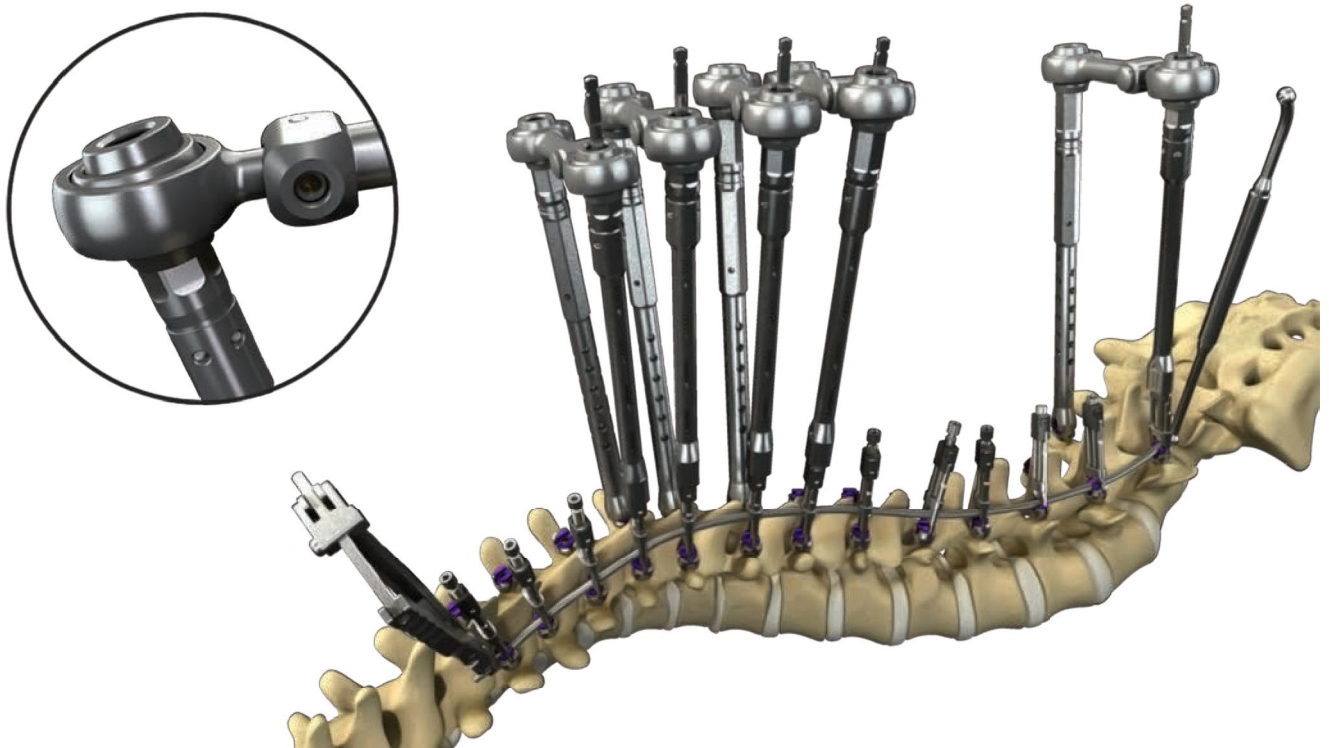
STEP 9

Surgical Technique

STEP 9: Axial Correction & Countertorsion (CON'T)

Apply Transverse Couplers by pressing them onto the Rotation Tubes and Manipulators to triangulate the pedicles at the vertebral level and evenly distribute the forces during derotation. Apply a downward and lateral force to the convex side and a lateral force on the concave side to rotate the spine around the rod, using the Lowest Instrumented Vertebra (LIV) as the foundation and countertorque.

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



STEPS 10 & 11

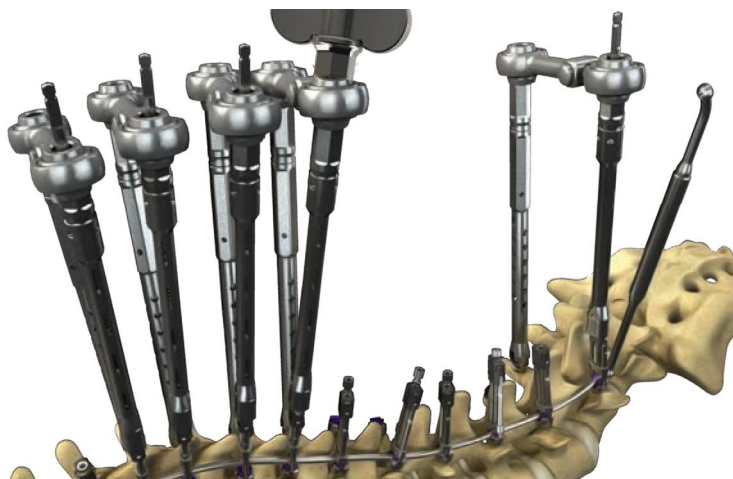
Surgical Technique

STEP 10: Thoracic Concave Translation

TRANSLATION OF THE CONCAVE thoracic apex to the rod is performed by gradually tightening the Deformity Crickets sequentially from the ends with progression toward the apex of the deformity. By performing the translation simultaneously from outside in with the Deformity Crickets, the forces are spread across the entire construct. The rod should be held in the physiological sagittal plane with the Rod Rotation Wrench or a Vise Grip. Once all Deformity Crickets are maximally tightened, the rod will be captured in each of the screw heads.

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

NOTE: A/O Quick Knob can be used to reduce Rotation Tube Drivers.



STEP 11: Convex Right Rod Placement

UNLOCK ALL CONVEX APICAL screws where Manipulators have been applied. Place Deformity Crickets on the convex screws. The convex rod is introduced using a technique similar to the concave/corrective rod. The Deformity Crickets on the proximal screws are fully reduced, the rod is checked for proper sagittal plane alignment, and the remainder of the Deformity Crickets are reduced.



STEP 12

Surgical Technique

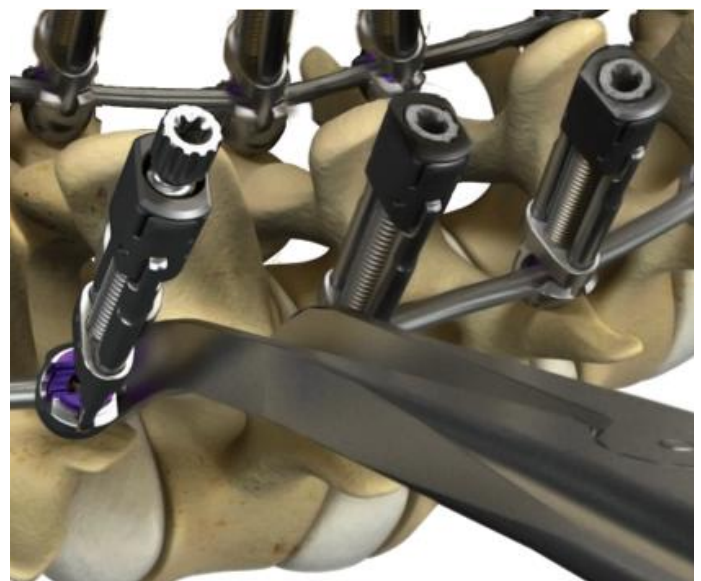
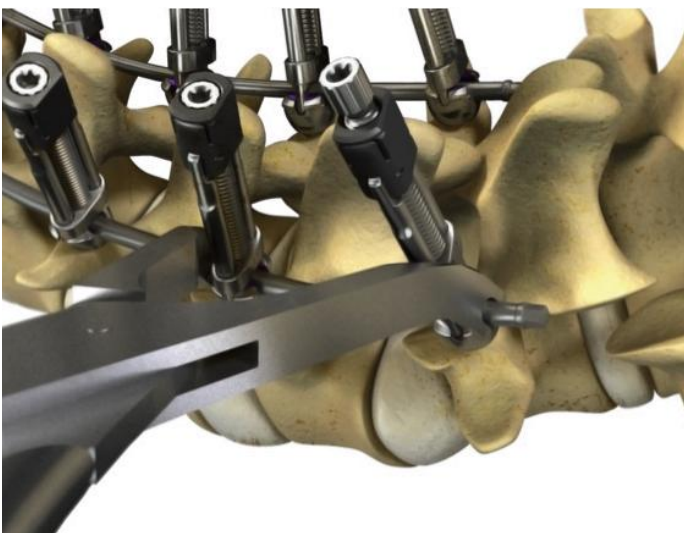
STEP 12: Compression/Distraction

THE FINAL DEFORMITY CORRECTION is now performed using the Compressor or Distractor. For compression/distraction, begin proximal to the apex. Compress or distract by releasing the Deformity Cricket one to two turns to achieve final deformity correction and retighten the Deformity Cricket. During compression/distraction maneuvers at apical levels, be sure to keep a firm grip on the Rotation Tubes to maintain axial correction while releasing the Deformity Crickets. This method employs a similar technique to that of a standard set screw system. Additional segmental vertebral derotation maneuvers can also be achieved at this time, if necessary.

NOTE: If any additional segmental Direct Vertebral Derotation (DVD) is needed, be sure to place Rotation Tubes on the Deformity Crickets and stabilize the adjacent level(s).

For instances with abutting screws, the Wedge Distractor may be used to separate the screws.

For distraction over multiple levels, use the Parallel Distractor, Wide.



STEPS 13 & 14

Surgical Technique

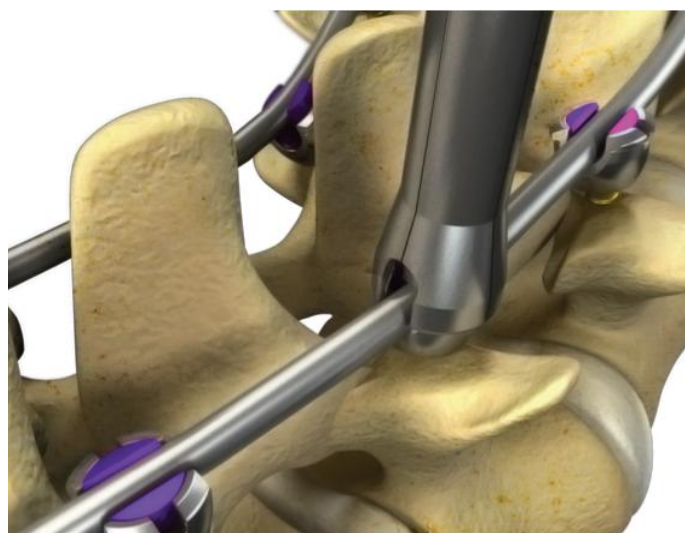
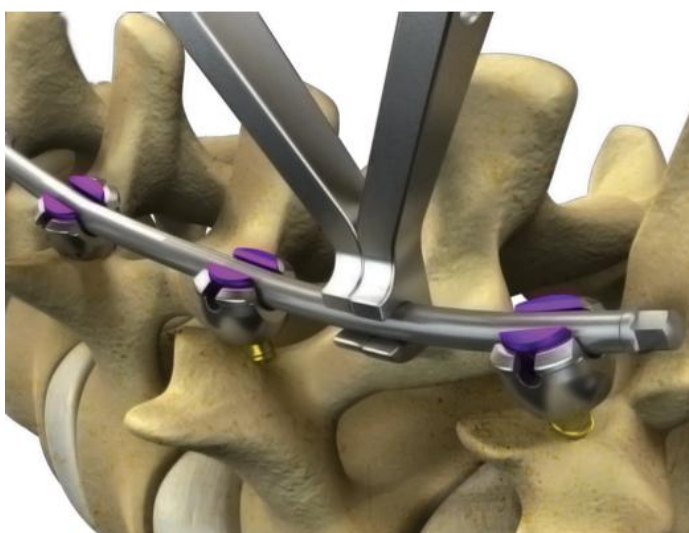
STEP 13: In-Situ Sagittal & Coronal Bending

ONCE THE ROD HAS been placed in the implants, the rods may be contoured in-situ. To achieve additional correction in the sagittal plane, use the In-Situ Benders (Right and Left). To achieve additional correction in the coronal plane, use the Medial/Lateral Benders (Right and Left).

STEP 14: Final Locking

CONFIRM HORIZONTAL POSITION OF the Lowest Instrumented Vertebra (LIV) and fully lock these fixation points using the Quick Locker. Repeat final locking of each screw with the Locker to confirm rigid fixation throughout. The Locker should only be used to apply axial locking force to the screw head. It should not be used in compression, distraction, or rotational maneuvers.

NOTE: The Over Cricket Locker may be used to both partially or fully lock the screws while the Deformity Crickets are in place. Before engaging the Over Cricket Locker onto the Cricket and the screw, ensure the Cricket is fully reduced and the threaded head of the Cricket is sitting flush. Squeeze the handle to line up the laser marked line for partial lock. Squeeze the handle fully for final locking.



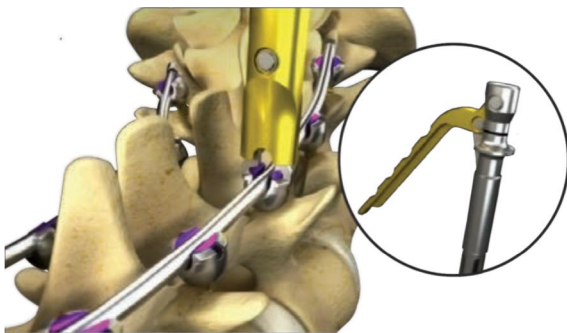
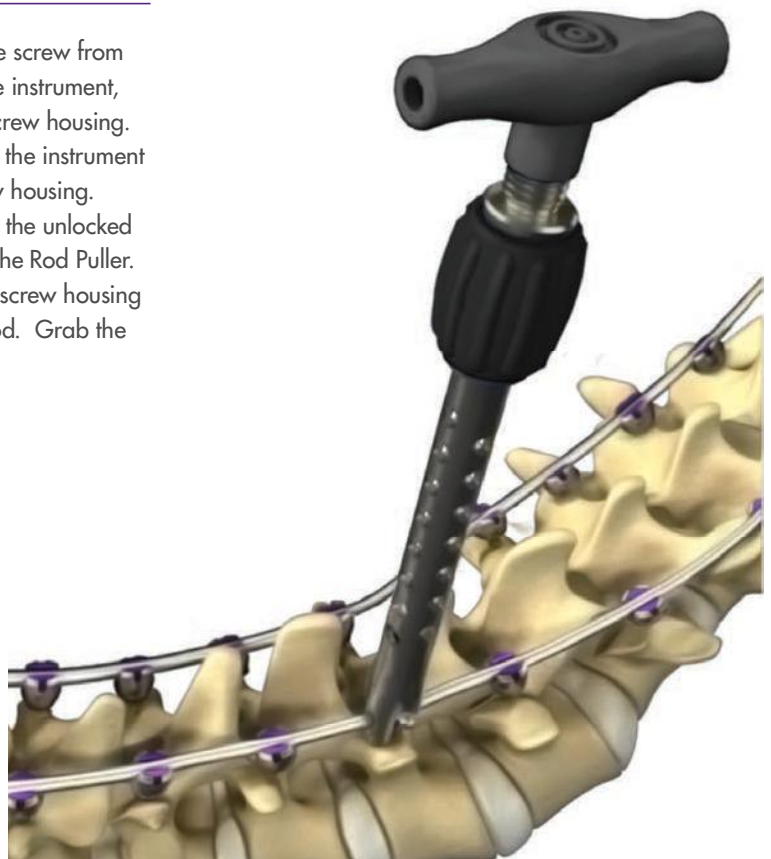
STEP 15

Surgical Technique

STEP 15: Unlocking & Removal - MESA Instruments

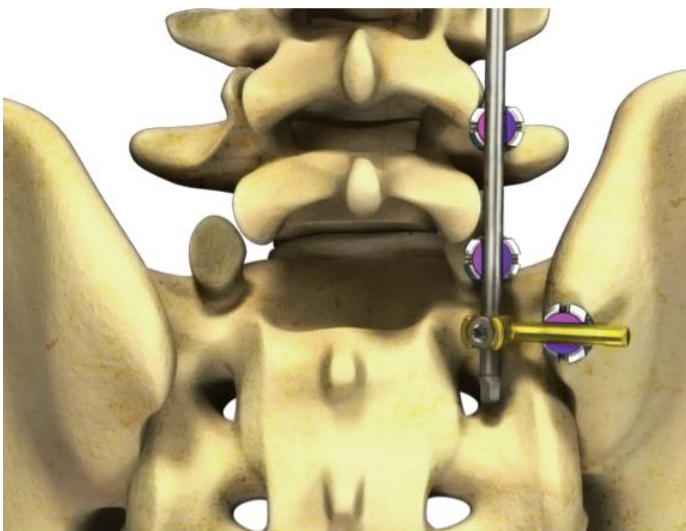
SHOULD THE SURGEON DECIDE to unlock the MESA Small Stature screw from partial or full lock, the Quick Unlocker may be used. Fully open the instrument, engage the docking feet into the detents of the medial side of the screw housing. Gently move the instrument down laterally until the distal portion of the instrument has properly engaged both the medial and lateral side of the screw housing. Fully squeeze the lever of the Unlocker. Once the MESA screw is in the unlocked position, the rod may be extracted from the implant housing using the Rod Puller. Apply the distal end of the Rod Puller over the MESA Small Stature screw housing and rotate it in a clockwise direction until it securely engages the rod. Grab the T-Handle and spin to pull the rod out of the screw.

NOTE: The T-Bar Screw Remover may be used to remove the MESA screw after it has been implanted. Lock the MESA screw without a rod in the screw housing. Attach the T-Bar Screw Remover to a T-Handle. Slide the distal end of the T-Bar Screw Remover into the locked saddle of the MESA screw. Remove the screw by turning the handle in the counterclockwise direction.



Lateral Offset Connectors

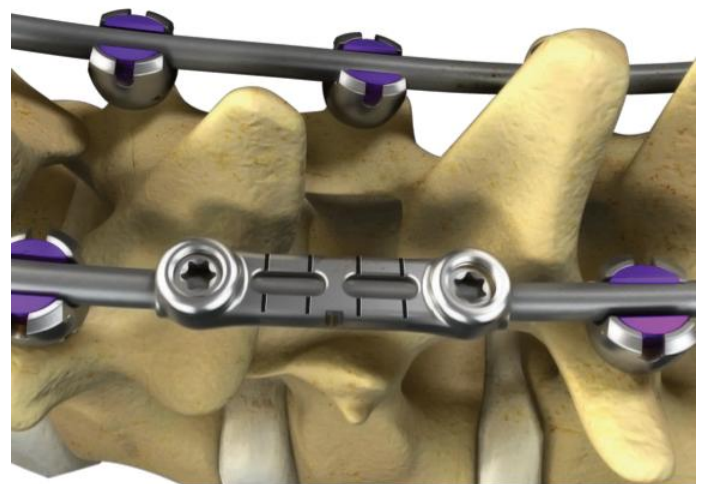
THE LATERAL OFFSET CONNECTORS may be used to link a screw lateral to the rod. The rodded portion of the Lateral Offset Connector is seated in the lateral implant housing, and the other end is attached to the primary rod with a set screw. The implant is final tightened using the Torque Limiting Shaft, Size 20, and Torque Limiting Handle, 6 Nm.



Axial Connectors

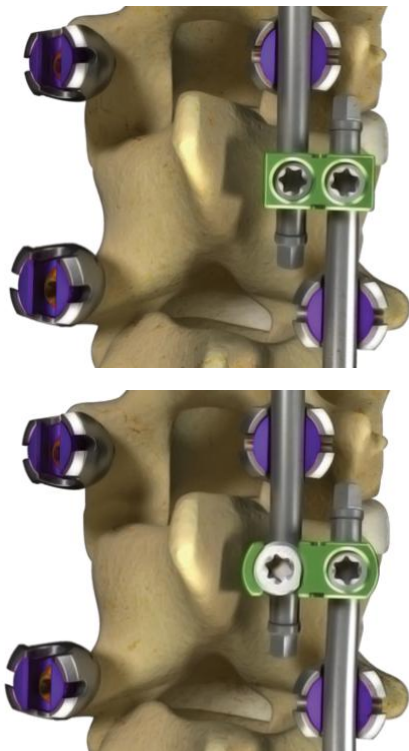
THE AXIAL CONNECTORS MAY be used to join two rods end-to-end. Implants are available in 20, 40, 60, and 80 mm sizes. The implant is final tightened using the Torque Limiting Shaft, Size 20, and Torque Limiting Handle, 6 Nm.

NOTE: Rods do not fit flush in the axial connector. There is a gap of 1 cm at the internal spacer. To adjust the implant on the rod, the MESA Rail/Rod Distractor can be positioned on the implant over the set screw and behind the rod. Squeeze the handles together to adjust the implant on the rod.



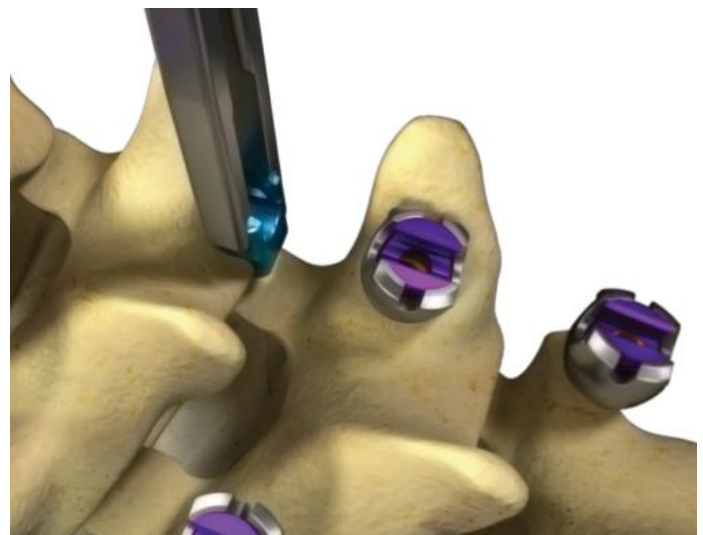
Parallel Rod Connectors

THE PARALLEL ROD CONNECTORS may be used to join two rods parallel to one another. Rod Connectors come in sizes $\text{Ø}3.5 - \text{Ø}4.5$ mm, $\text{Ø}4.5 - \text{Ø}4.5$ mm, and $\text{Ø}4.5 - \text{Ø}5.5$ mm. They also come in open/closed and closed/closed styles, as well as in narrow and wide options. The open/closed style requires a separate set screw. The implants are inserted using the Rod Connector Holder. $\text{Ø}4.5 - \text{Ø}4.5$ mm and $\text{Ø}4.5 - \text{Ø}5.5$ mm implants are final tightened using the Torque Limiting Shaft, Size 20, and Torque Limiting Handle, 6 Nm. $\text{Ø}3.5 - \text{Ø}4.5$ mm implants are final tightened using the Torque Limiting Shaft, Size 20, and the Torque Limiting Handle, 2 Nm.



Hook Site Preparation & Insertion: Pedicle Hooks

PEDICLE HOOKS ARE ALWAYS placed in an upgoing (cranial) position. They are typically used anywhere from T1 to T10. A limited facetectomy is typically performed using a straight quarter inch osteotome before hook insertion. The Pedicle Hook Trial (Large or Small) is inserted into the facet joint pointing somewhat lateral of the midline to locate the pedicle. A mallet is used to help seat the bifid end of the instrument into the base of the pedicle. The pedicle hooks may be inserted utilizing the following instruments: Hook Inserter, Straight Hook Holder, Offset Hook Holder, Lateral Hook Holder, Saddle Hook Holder, and Hook Pusher. Upon insertion, the notch of the hook should rest on the inferior side of the pedicle. A partial resection of the inferior articular process may be required for best fit.



Hook Reduction: Pedicle Hooks

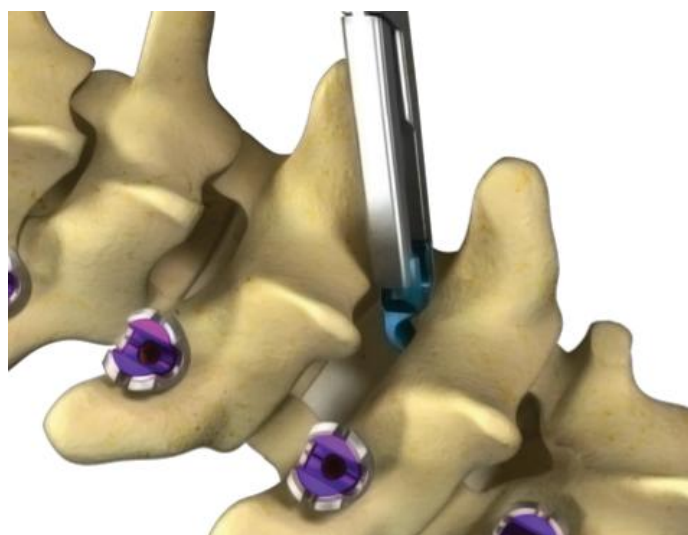
FOR COMMON HOOK REDUCTIONS, UP to 10 mm, the Single Action Anti-Torque Rod Reducer (Firefly™) can be used. It is necessary for the surgeon to grasp the center shaft of the instrument to ensure the instrument is properly docked onto the detents of the implant housing. Once the instrument is docked, squeeze the silver lever. This action reduces the rod into the implant housing. If a more controlled reduction is desired, reduce by spinning the metal knob. Insert a set screw and provisional tighten to hold the hook in place using the Screwdriver, Size 20, Tapered. To disengage the instrument, open the silver lever and release from the implant housing detent.

NOTE: The Screwdriver Shaft, Size 20 Tapered, and a handle may also be used to provisional tighten to hold the hook in place.



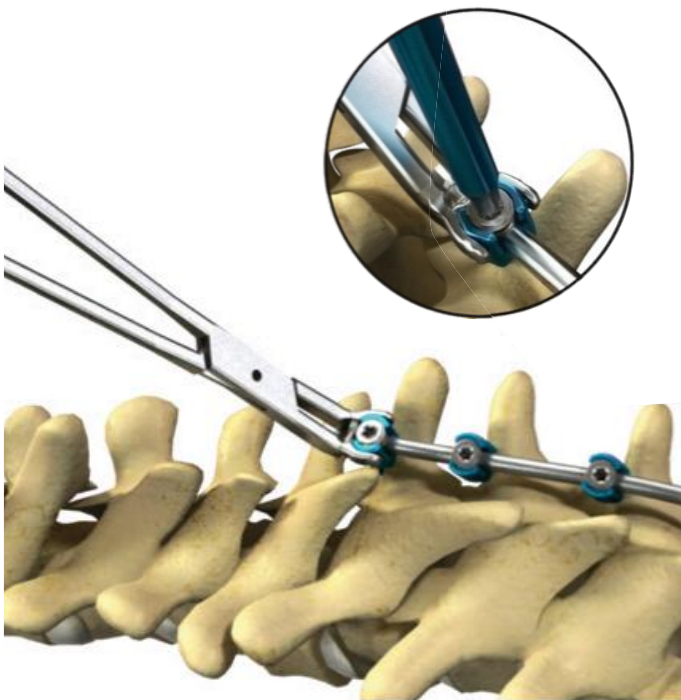
Hook Site Preparation & Insertion: Thoracic Laminar / Infralaminar / Angled Hooks

THESE MULTI-PURPOSE hooks can be placed in an upward or downward facing position on the lamina. A division or removal of the ligamentum flavum and/or laminotomies are performed with Currettes and Kerrisons on the superior lamina in order to prepare the hook site. The color-coded Hook Elevator is typically used as well. Additional hook site preparation may be performed using a Kerrison. The Hook Elevator may be used to access the anatomical fitting between the laminar and peridural structures. Implants can be chosen based on throat size and geometry to ensure best possible interface between the hook and bone. The implant may be inserted with the Hook Inserter, Straight Hook Holder, Offset Hook Holder, Lateral Hook Holder, or Saddle Hook Holder.



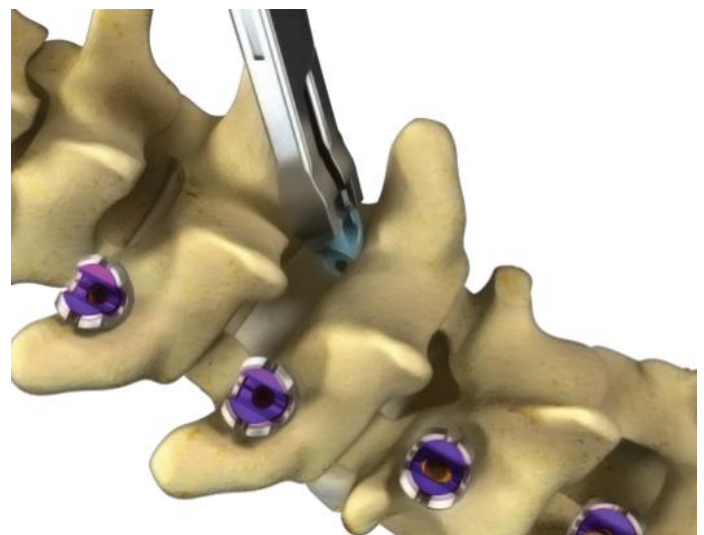
Hook Reduction: Thoracic Laminar / Infralaminar / Angled Hooks

FOR MINIMAL REDUCTIONS using hooks, the Rod Fork can be used. Ensure the ringed handle is in the open position, and attach the distal portion of the instrument into the detents of the implant housing. Once it has been secured onto the implant by closing the handle, gently rock the instrument back to seat the rod. Insert a set screw and provisionally tighten to hold the hook in place using the Screwdriver, Size 20, Tapered.



Hook Site Preparation & Insertion: Lumbar Laminar Hooks

LUMBAR LAMINAR HOOKS MAY be used down-going or up-going. The color-coded Elevator is used to separate the ligamentum flavum from the inferior surface of the lamina. Care must be taken not to direct the Hook Elevator into the canal. The implants may be inserted with the Hook Inserter.



Final Tightening: Hooks

FINAL TIGHTENING IS ACHIEVED utilizing the Anti-Torque Alignment Tube or Firefly™ and the Torque Limiting Shaft, Size 20, with the Torque Limiting Handle, 6 Nm.

Unlocking & Removal: Hooks

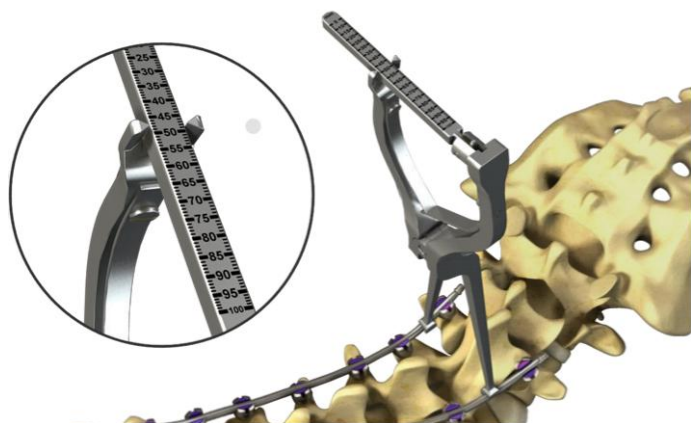
ONCE A HOOK IS LOCKED, the set screw can be removed by using the Anti-Torque Alignment Tube or Firefly and the Torque Limiting Shaft, Size 20, with the Fixed T-Handle.



Transverse Connectors

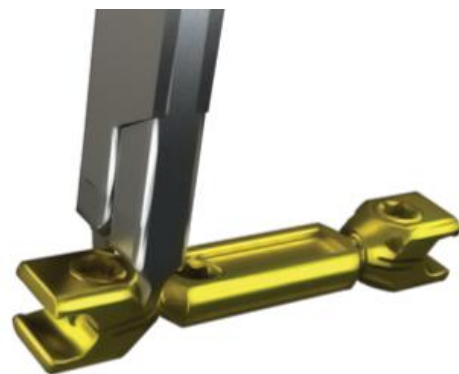
Implant Selection

USE THE TRANSVERSE CONNECTOR Caliper to measure the appropriate length between the two rods and choose the best fitting transverse connector in either the semi-adjustable or adjustable design.



Select Implant

GRAB ONTO THE SELECTED implant head using the Transverse Connector Holder.

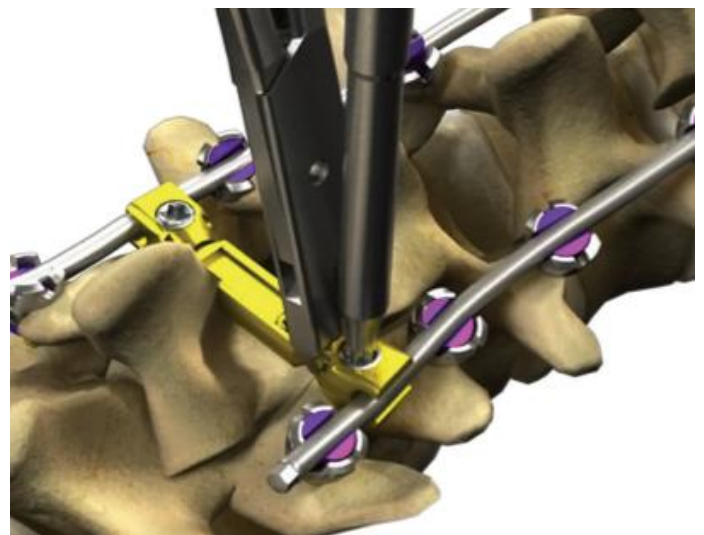
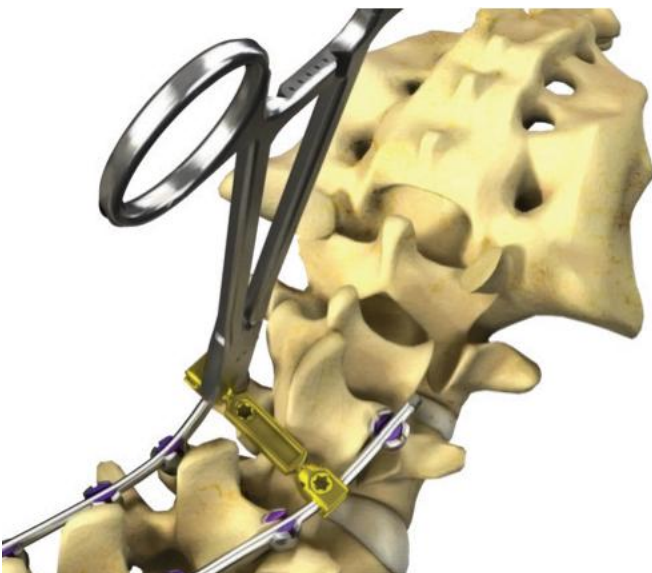


Transverse Connectors

Insert Implant

ENSURE THE CONNECTOR bolts on both feet are adequately loosened to accept the rod (not to exceed one full turn). If using an adjustable connector, ensure the bridge translates before insertion. Using the Transverse Connector Holder, snap one polyaxial head of the connector onto the rod.

Using the Transverse Connect Holder to stabilize the transverse connector, snap the opposite polyaxial head onto the opposite rod. Provisionally tighten both polyaxial heads with the Screwdriver Shaft, Size 20, and handle.

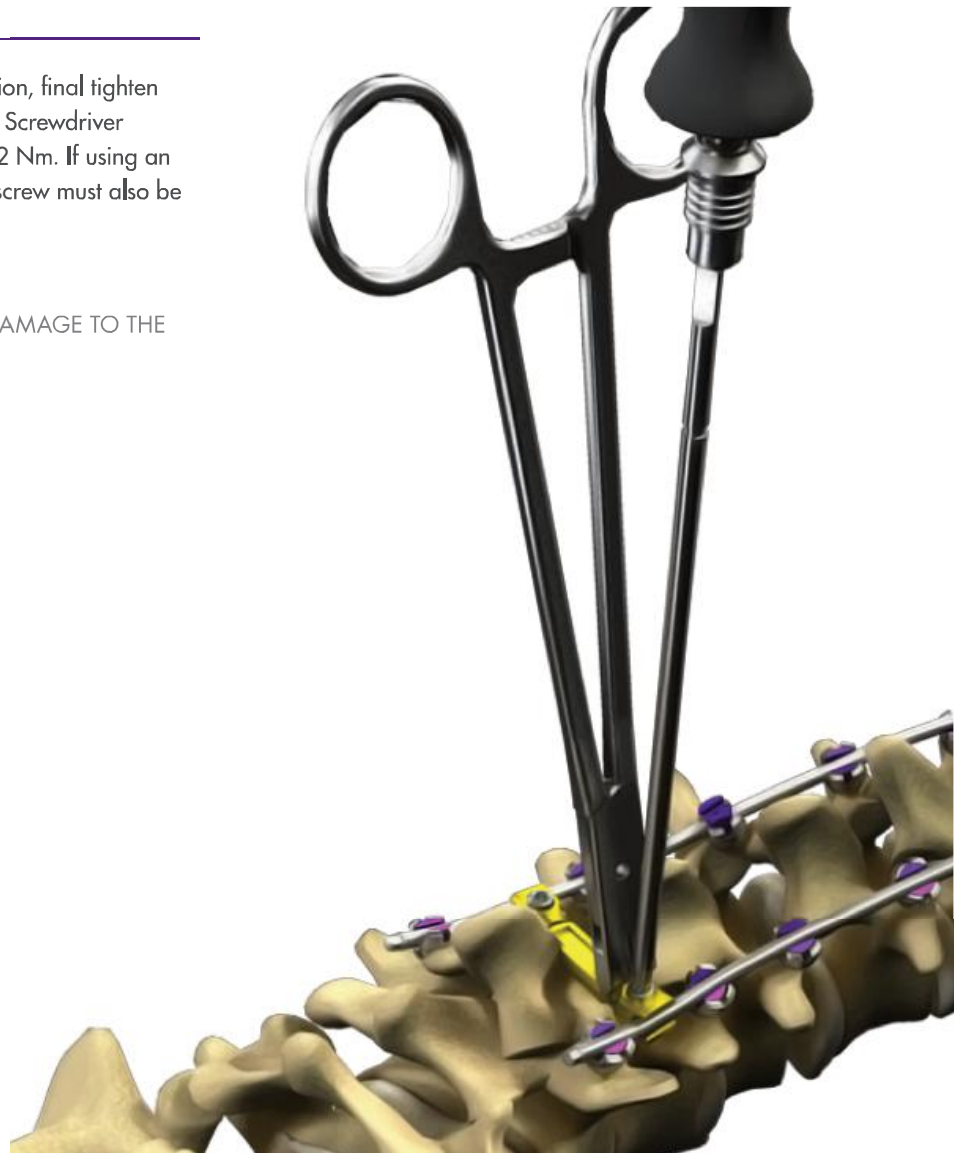


Transverse Connectors

Final Tightening

ENSURING THE IMPLANT is in the desired position, final tighten each polyaxial head to optimal torque using the Screwdriver Shaft, Size 20, and the Torque Limiting Handle, 2 Nm. If using an Adjustable Transverse Connector, the center set screw must also be final tightened.

Note: Do not exceed recommended torque or DAMAGE TO THE INSTRUMENT OR IMPLANT MAY RESULT.





BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

Product Insert

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™ Anterior Vertebral Body Staples. The RANGE 4.5mm Small Stature Rod System is indicated for the following:

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 in skeletally mature patients.

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.

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).

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.

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 8.5mm in diameter) and 5.5mm 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 arthrodesis 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.

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MESA® Small Stature SURGICAL INFORMATION GUIDE



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K2-30-7010-01 Rev. 1
Actual device color may vary.
Consult product catalog for details.



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