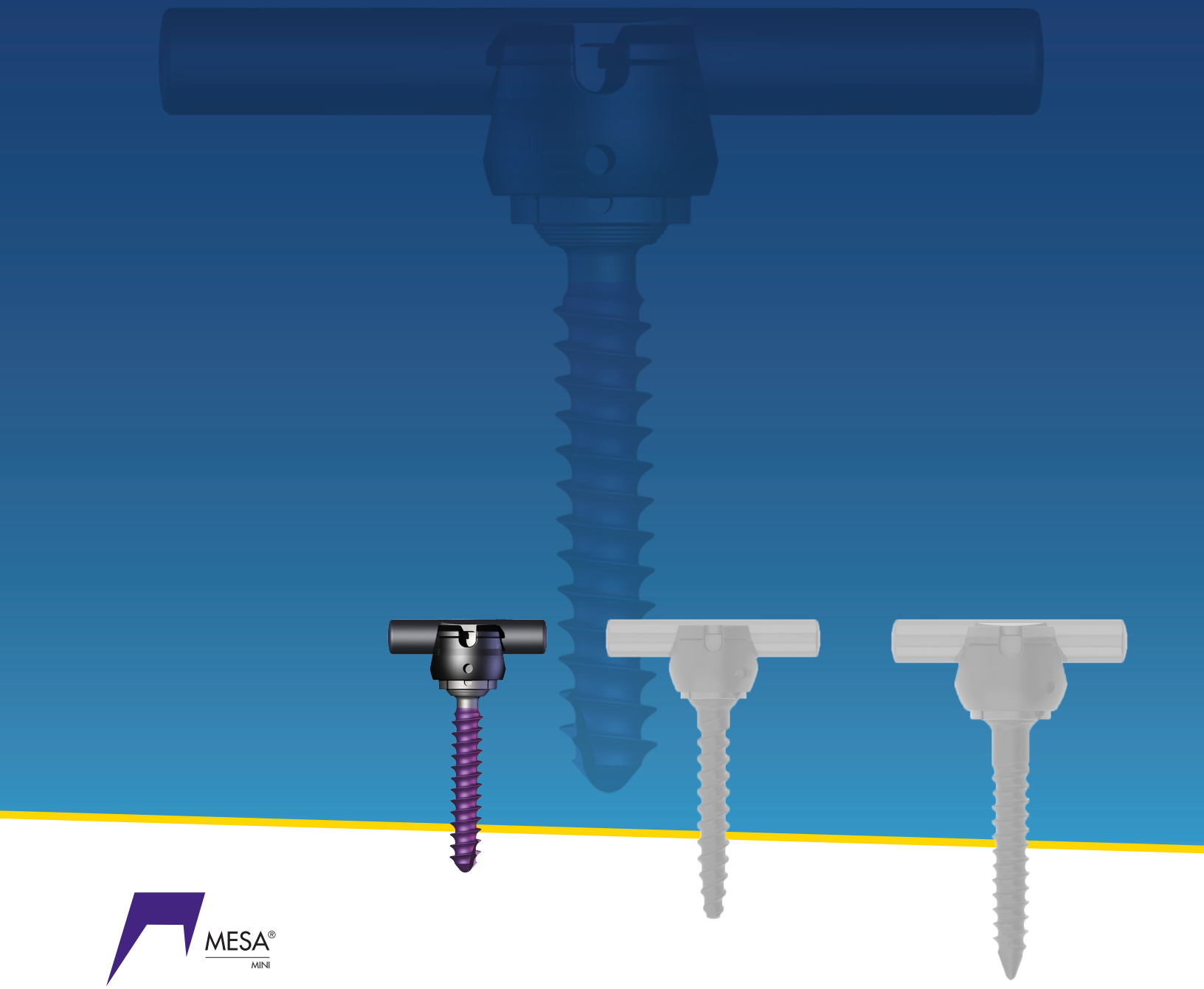
K2M

COMPLEX SPINE INNOVATIONS™

SURGICAL TECHNIQUE

MESA®

MINI SPINAL SYSTEM



MESA® MINI

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SURGICAL TECHNIQUE STEPS

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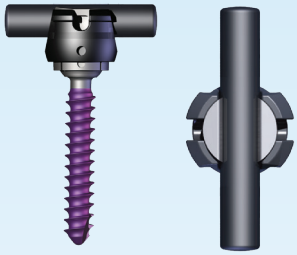
PRODUCT CATALOG

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FEATURES & BENEFITS

MESA® MINI SPINAL SYSTEM



- Zero-Torque Technology®
- No Profile Above the Rod
- One-step Final Locking
- Long Shank Screws Available (8 mm of Smooth Shaft)
- 90° Polyaxial Range of Motion
- Controlled Compression & Distraction

STEP 1

PREOPERATIVE PLANNING & EXPOSURE

The patient's position is always up to the discretion of the surgeon, but most commonly, patients will be positioned prone. The head and neck must be placed in proper alignment and held securely in position. Confirm proper alignment with images prior to draping.

Perform a standard midline exposure of the part of the cervical and/or thoracic spine to be fused. Place retractors to extend the exposure laterally, thus providing ample visualization.



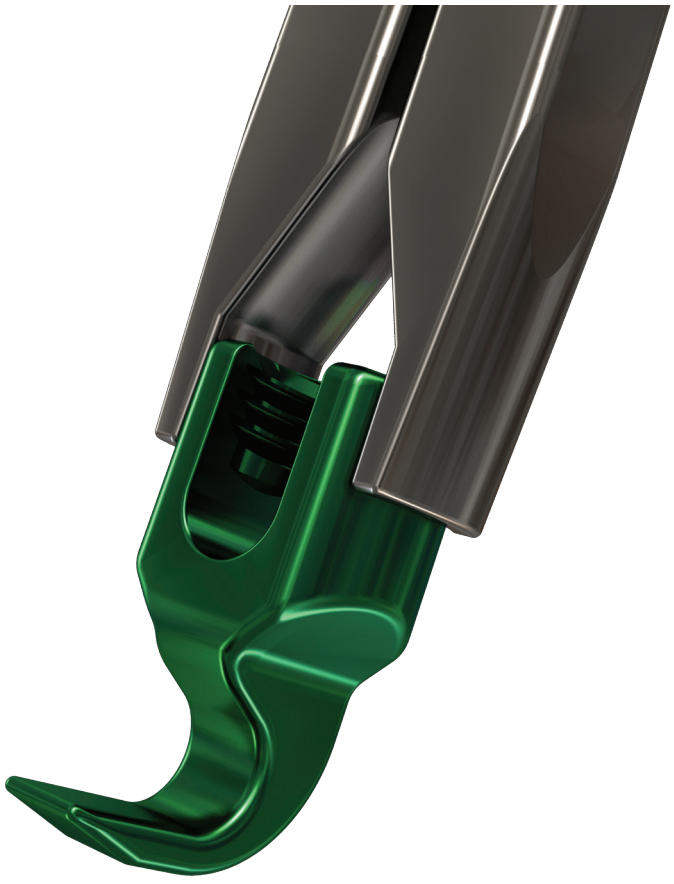
STEP 2

HOOK INSERTION

Hooks may be placed caudal or cranial and are inserted using the Hook Holder. Squeeze the Holder to engage the hook head, and then place the hook onto the lamina. Repeat until all hooks are placed.

For instructions on the implantation of the MESA Mini screws, continue to Step 3. If no pedicle screws will be placed, proceed by seating the rod into the hooks. For additional information on rod insertion, see Steps 5–8.

If significant rod reduction is necessary, the Firefly™ may be used to reduce the rod up to 10 mm. Place the distal tip of the Firefly over the hook head and squeeze gently to engage the hook head and reduce the rod. Optionally, turn the proximal knob clockwise for controlled, threaded reduction. Next, insert a Mini Set Screw into the hook. If using the Firefly, the instrument is cannulated, so a set screw can be passed through the center of the shaft of the instrument. Turn a quarter-turn to the left to seat the thread before provisionally tightening. To final tighten the set screws, use the Size 15 Torque Limiting Shaft attached to the gray Torque Limiting Handle. Keep the Firefly engaged or attach the Anti-Torque Alignment Tube to provide counter-torque. Turn the handle until it emits an audible click at 2 N-m (17.7 inch-pounds).



FIREFLY™



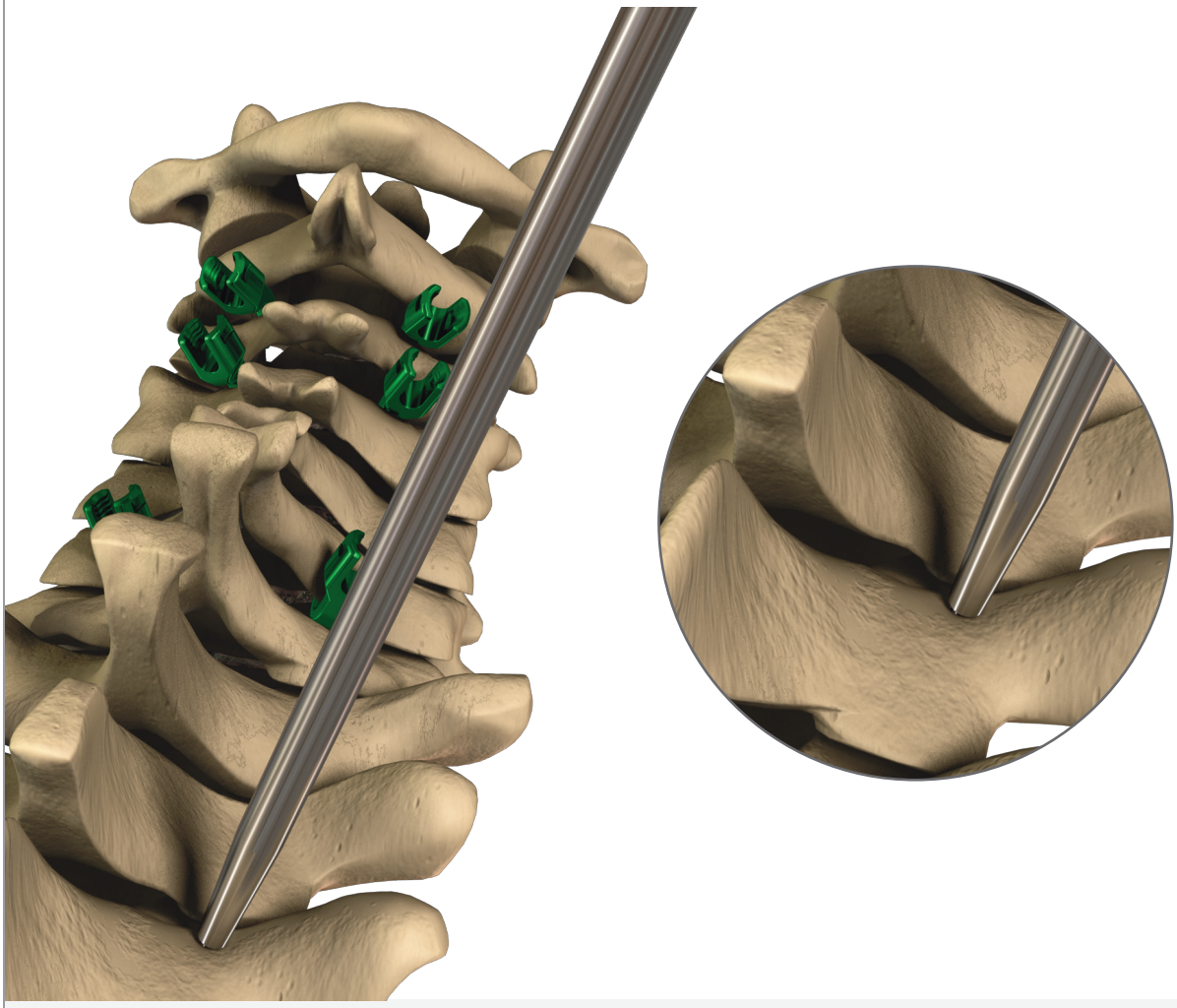
HOOK HOLDER



STEP 3

SCREW SITE PREPARATION

Choose the desired entry point of the pedicle and perforate the cortex with an Awl to expose the underlying cancellous bone. Use the Small Pedicle Probe to cannulate the entry point, and advance 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 Small Pedicle Probe is laser etched at 10 mm increments from 10–50 mm, indicating the depth to which the Probe has been inserted. These markings also help to identify proper Drill and screw lengths.



AWL



SMALL PEDICLE PROBE



Prior to drilling the pilot hole, select the Fixed Drill Guide or the Adjustable Drill Guide. Fixed Drills are available in both Ø2.3 and Ø2.8 mm with 12, 14, and 16 mm lengths. Adjustable Drills are available in Ø2.3 and Ø2.8 mm.

DRILL LENGTHS BY COLOR	
Size	**Color**
12 mm	
14 mm	
16 mm	



Ø2.3 mm SINGLE COLORED EPOXY RINGS



Ø2.8 mm DOUBLE COLORED EPOXY RINGS

FIXED DRILLS

Ø2.3 mm, Ø2.8 mm



ADJUSTABLE DRILLS

Ø2.3 mm, Ø2.8 mm



ADJUSTABLE DRILL GUIDE



FIXED DRILL GUIDE

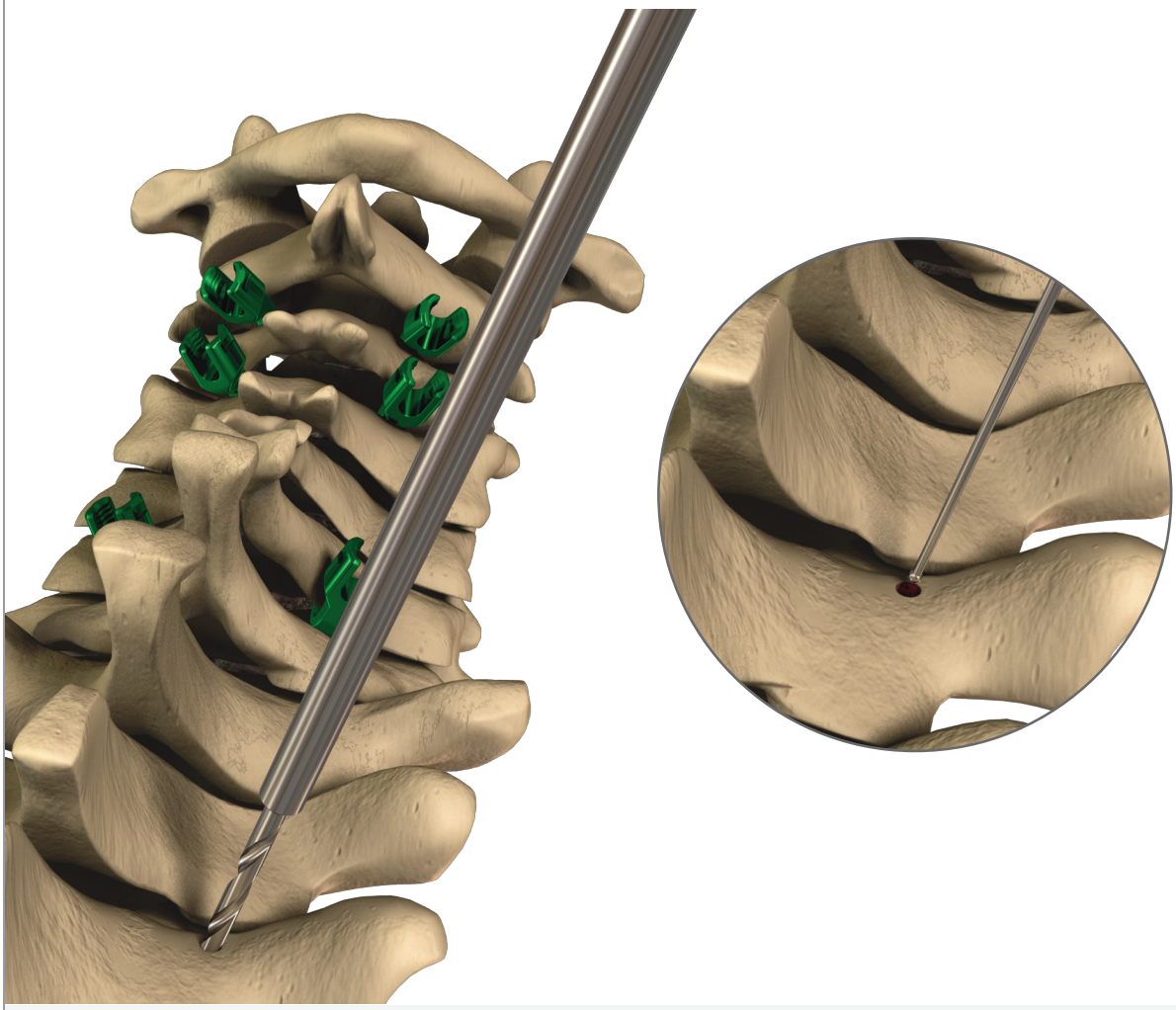


STEP 3

SCREW SITE PREPARATION (CONT.)

The Adjustable Drill Guide can vary the depth of the Drill from 6–50 mm. To set the desired depth, pull back on the lever above the handle, and slide the adjustable shaft. Once the desired Drill Guide and depth is determined, attach the Drill to either the Ratcheting Axial Handle or Fixed Axial Handle and begin drilling. Check the pedicle wall soundness with the Ball Tip Probe.

NOTE: All Drill Bits have an AO connection, which allows them to be used in conjunction with power drills, if preferred.



BALL TIP PROBE

RATCHETING AXIAL HANDLE



FIXED AXIAL HANDLE



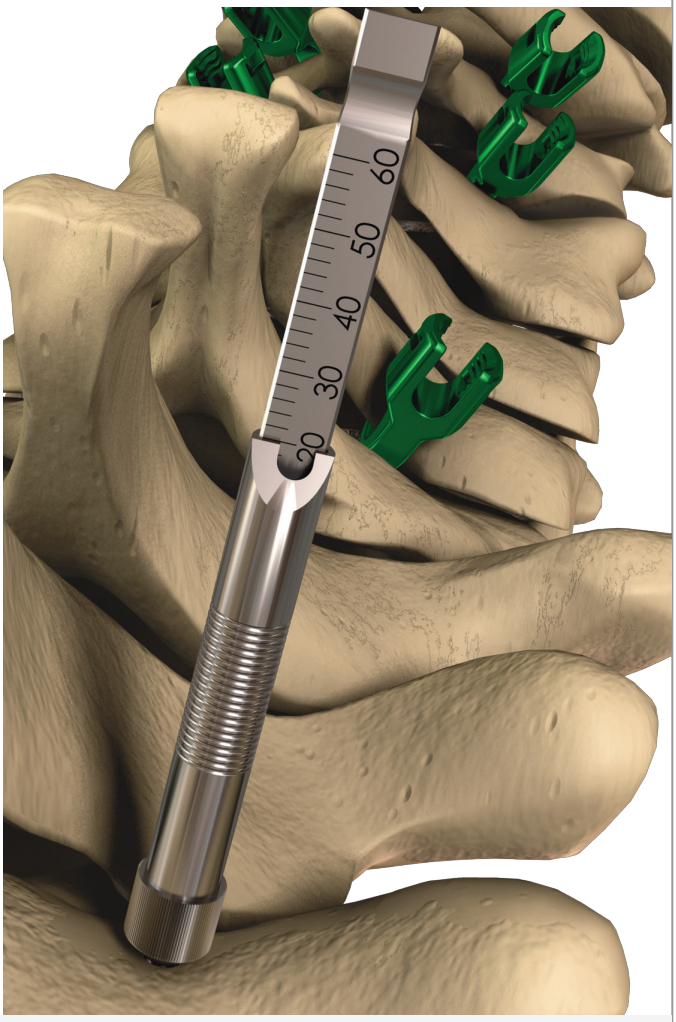
The 90° MESA Mini screws are self-tapping; however, Taps are available for the Ø3.5, Ø4.0, and Ø4.5 mm screws. Each Tap is undersized 0.5 mm relative to the major diameters of the screws.

To use the Tap, slide the Tap Sleeve, slit side first, over the threaded portion of the Tap until the distal end of the Tap Sleeve and the distal end of the Tap are flush.

As the Tap penetrates, the Tap Sleeve will begin to slide up the Tap. The Tap is etched with depth markings and the depth is determined by the position of the top of the Tap Sleeve relative to the markings. These markings also help assess proper screw length.

Use the Depth Gauge in the prepared space to determine the correlating screw length.





Ø3.5, 4.0, & 4.5 mm TAPS



60 mm DEPTH GAUGE



TAP SLEEVE



STEP 4

SCREW INSERTION

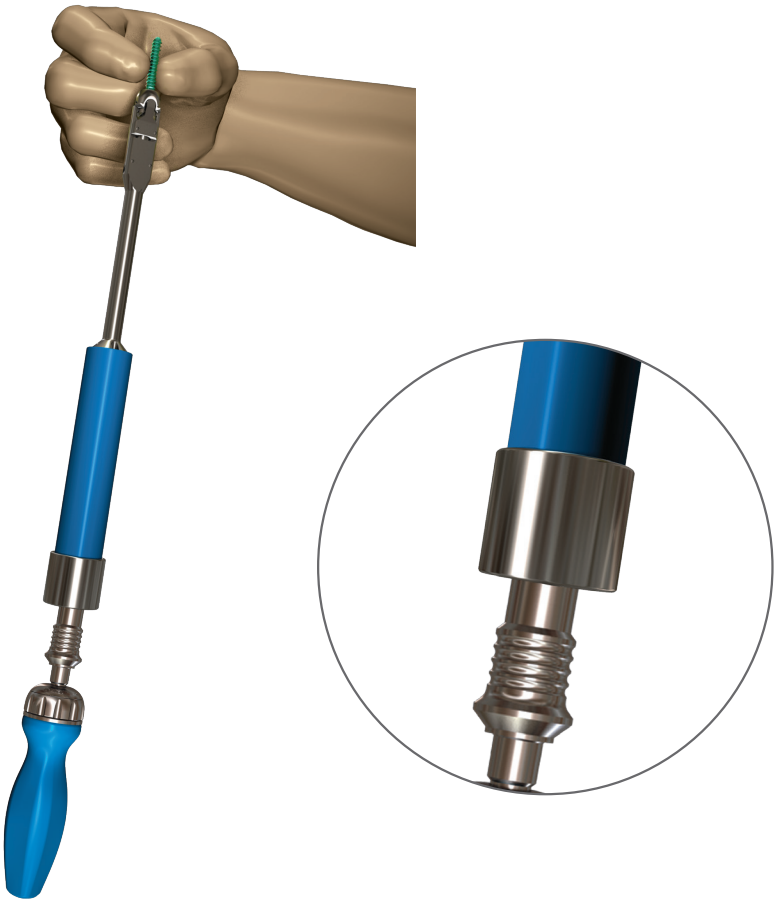
After the pedicle screw pathway has been prepared and proper screw size has been determined, load the implant for screw insertion onto the 90° MESA Mini Screw Inserter. The 90° MESA Mini Screw Inserter can be used with either the Ratcheting Axial Handle or the Fixed Axial Handle. Grasp the implant by the screw shaft and slightly rotate by hand while simultaneously applying a downward force to properly engage the screw. Once loaded, spin the knob located above the blue sleeve clockwise to lock the screw in place. Advance the screw into the pedicle until the desired depth is reached. Disengage the Screw Inserter by turning the knob above the sleeve counter-clockwise. Repeat until all screws are placed.

NOTE: Grasping the screw by the screw head during loading can partially lock the screw. Should this occur, manually pull down on the outer collet of the screw head or carefully engage the Unlocker to open the screw.

Standard Polyaxial Screws:
Diameters
- 3.5, 4.0, & 4.5 mm

Lengths (standard in the set)*
- 3.5 x 10–26 mm
- 4.0 x 10–32 mm
- 4.5 x 20–36 mm

*Lengths increase in 2 mm increments.



90° MESA MINI SCREW INSERTER



STEP 5

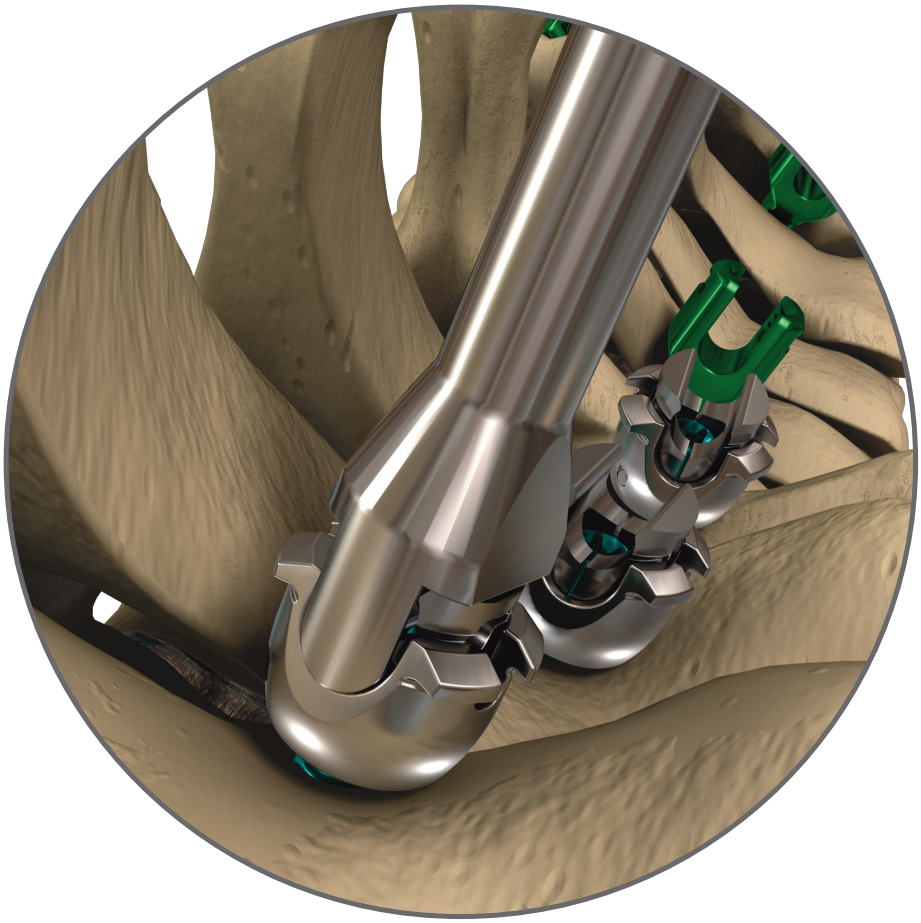
SCREW ADJUSTMENT

Polyaxial Long Shank Screws:
Diameters
- 3.5 & 4.0 mm

Lengths*
- 3.5 x 26–40 mm
- 4.0 x 26–40 mm

*Lengths increase in 2 mm increments.

Once the appropriate screw has been inserted, the housing of the screw can be adjusted with the MESA Mini Screw Head Adjuster. Should it be necessary to adjust the screw height, attach the Size 10 Screw Height Adjuster to a Fixed or Ratcheting Axial Handle and engage the hexalobe in the screw shaft. Proceed to rotate clockwise or counter-clockwise until the desired height is achieved.



SCREW HEIGHT ADJUSTER

MESA MINI HEAD ADJUSTER

STEP 6

ROD SELECTION

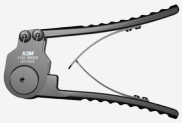
Ø3.5 mm rods are available in 80, 120, and 240 mm and may be cut to length with the Ratcheting Rod Cutter. To prep the Ratcheting Rod Cutter, align the two white lines on the wheel by turning the wheel counter-clockwise. Insert the rod into the Ratcheting Rod Cutter until the determined cut spot is lined up with the cut line. Continue to squeeze the handle, and then release, repeating until the rod is cut.

NOTE: Rod Templates*, available in 80 and 200 mm lengths, may be used to determine proper rod length and contour. Titanium Ø3.5 mm rods and Ø3.5–5.5 mm transition rods are standard in the set. Additionally, cobalt chrome Ø3.5 mm rods and cobalt chrome Ø3.5–5.5 mm and Ø3.5–4.5 mm transition rods are available by request.

*Single-use only



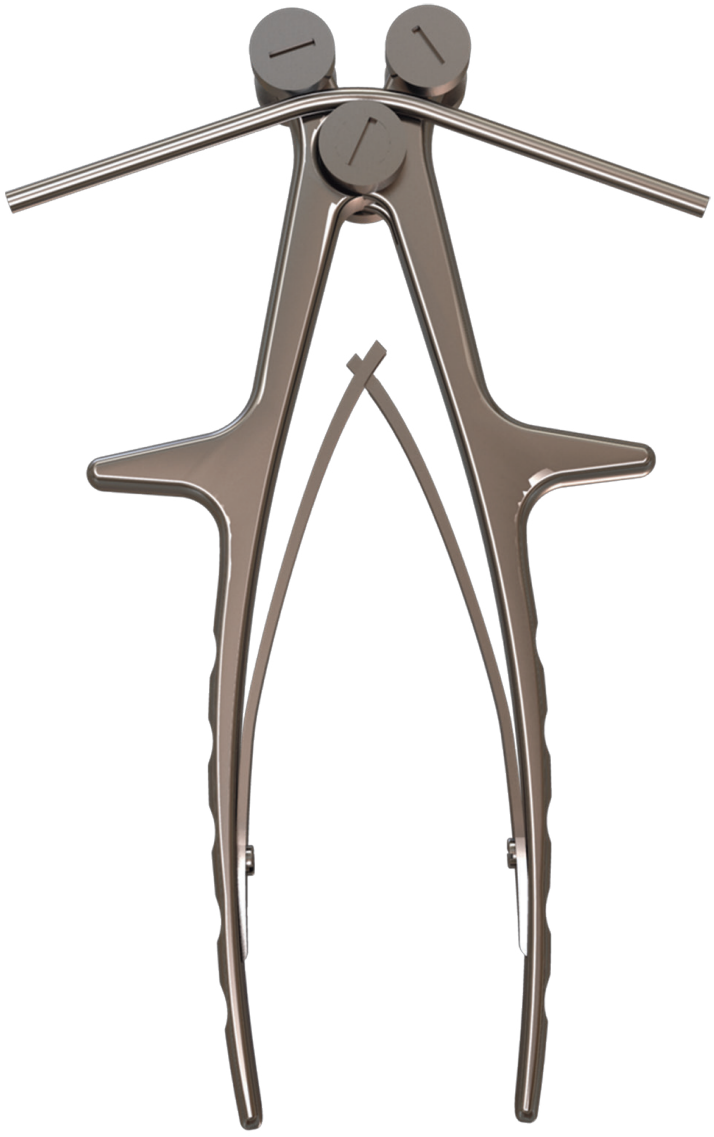
RATCHETING ROD CUTTER



ROD TEMPLATE, 80 mm

ROD TEMPLATE, 200 mm

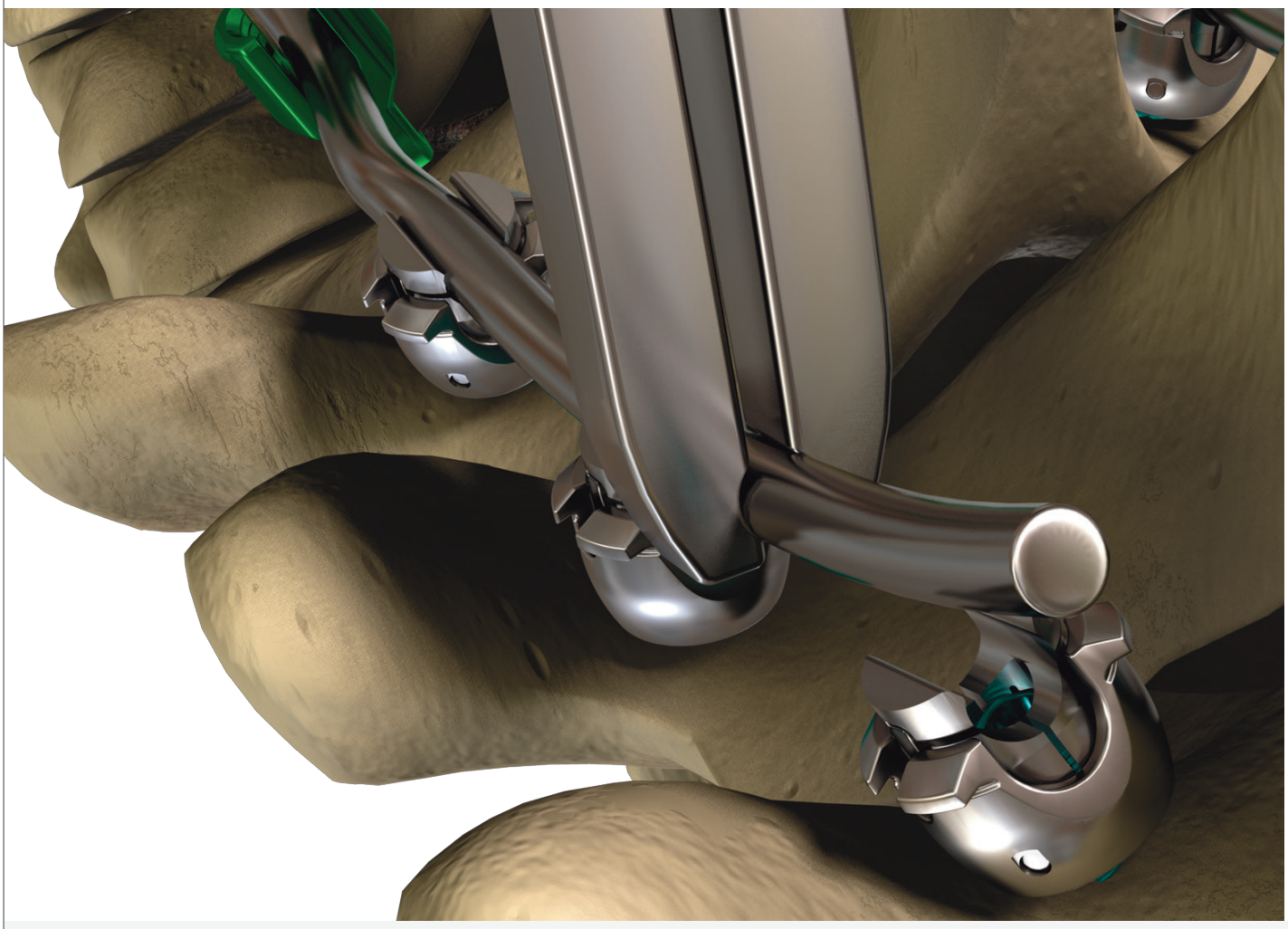
The Rod Bender may be used to contour the rods to the desired amount of lordosis or kyphosis.



STEP 7

ROD PLACEMENT

Insert the rod into the hooks or screw heads using the Rod Holding Forceps. Ensure at least 4 mm of rod overhangs from the most proximal and distal screws. If preferred, the Unlocker may be used to introduce the rod up to 2 mm into the screw housing. See Step 14 for instructions for use of the Unlocker.



ROD HOLDING FORCEPS

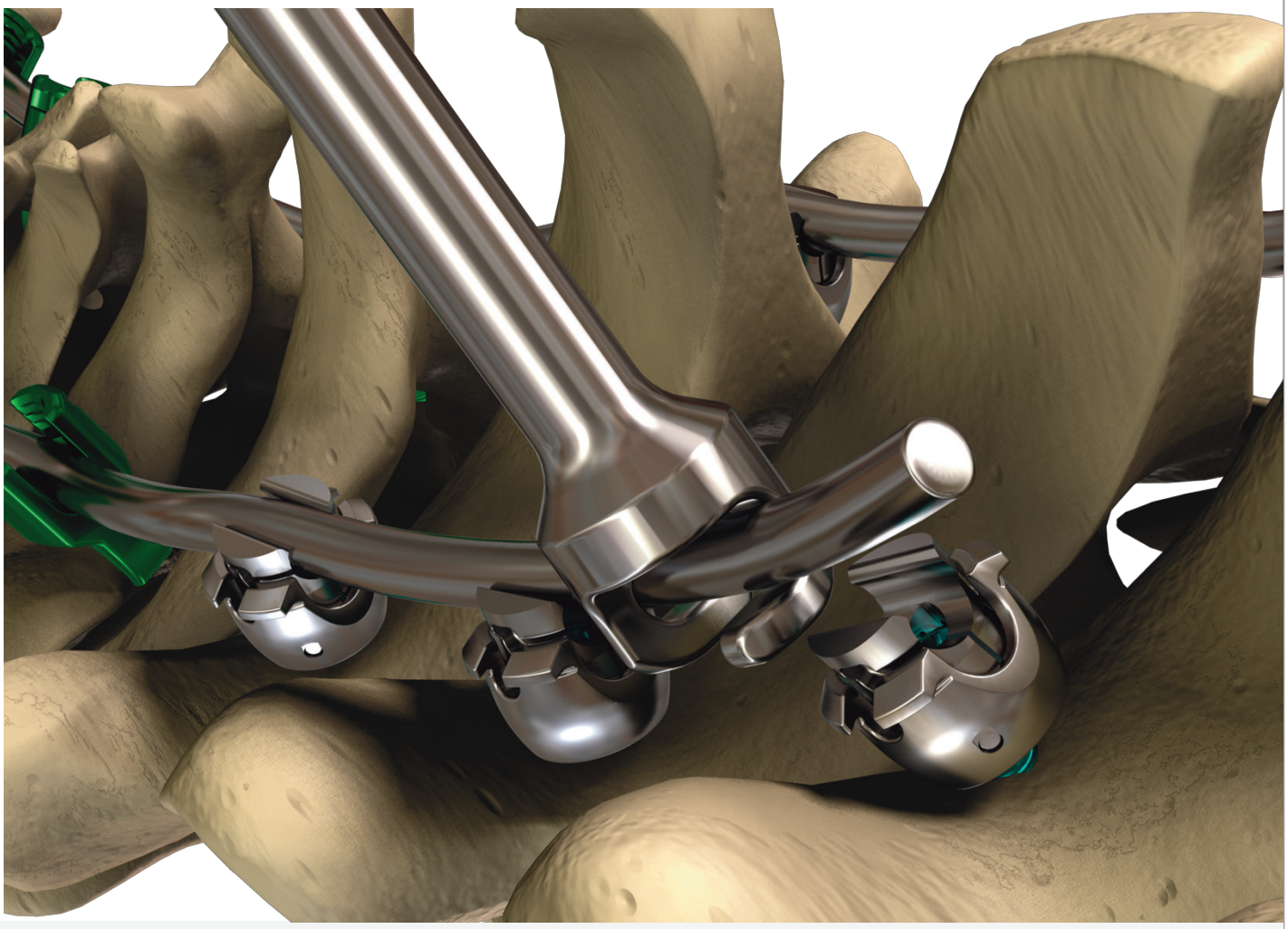


STEP 8

ROD REDUCTION & PARTIAL LOCKING

In instances where a translational or slight reduction force needs to be applied to the rod, the Torsional Rod Reducer (Right or Left) may be utilized. The Torsional Rod Reducer is introduced to the rod using the same procedure as traditional rod pushing instruments. A twisting motion is applied to capture the rod into the instrument.

NOTE: The Torsional Rod Reducer, Left has a partially gold shaft for identification.



TORSIONAL ROD REDUCER, RIGHT



TORSIONAL ROD REDUCER, LEFT



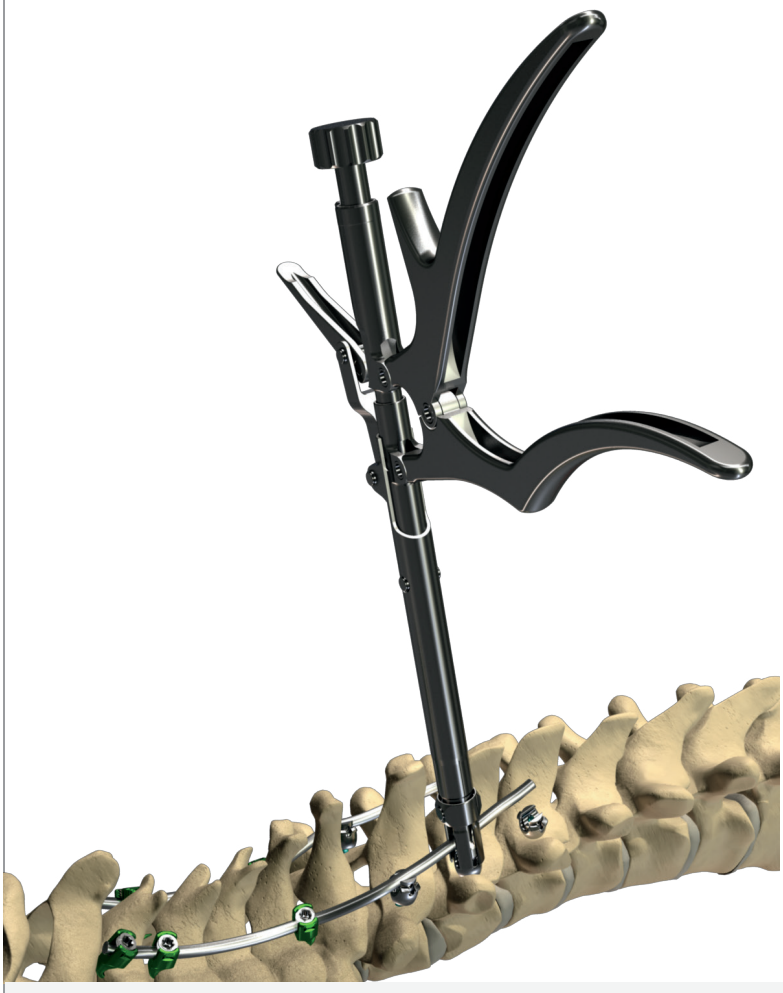
STEP 8

ROD REDUCTION & PARTIAL LOCKING (CONT.)

To reduce the rod up to 10 mm into the 90° MESA Mini screws, two instruments are available for use: the MESA Mini Dual Action Rod Reducer (Mini Dragonfly™) and the Reduction Jack (Mini Cricket®).

The Mini Dragonfly may be placed over the screw head collinear with the implant. Ensure both the lever on the side of the instrument and the handle are completely open to enable engagement of the screw.

Gently squeeze the handle for rapid reduction or turn the proximal knob clockwise for controlled, threaded rod reduction. When the rod is fully seated, close the lever on the side of the Mini Dragonfly to partial lock the MESA Mini screw. Fully open the lever, the handle, and the knob to disengage the instrument.





MINI DRAGONFLY™



MINI CRICKET® – 10 mm



The Reduction Jack, more commonly known as the Mini Cricket, engages the inner collet of the MESA Mini screws. Reduce the Mini Cricket by hand or with the Reduction Jack Shaft attached to either a Ratcheting Axial Handle or Fixed Axial Handle. When used at multiple levels, the Mini Crickets may be sequentially tightened. Next, the Partial Locker, better known as the Mini Superfly™, may be used over the Mini Crickets to partially lock the screws. The Mini Crickets must be fully reduced for the Mini Superfly to properly dock over the screw. Introduce the Mini Superfly over the Mini Cricket and squeeze the handle to the shaft of the instrument.





MINI SUPERFLY™

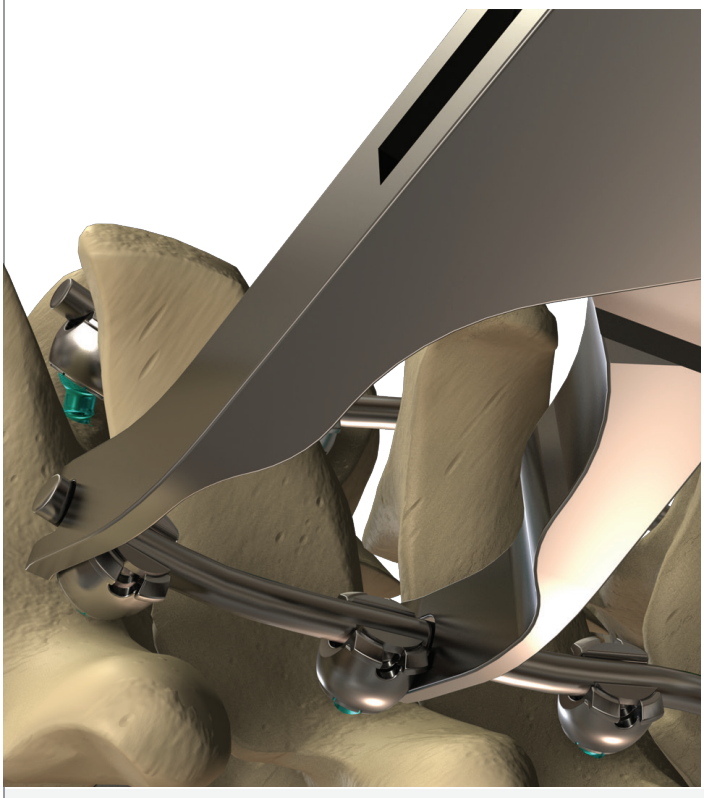


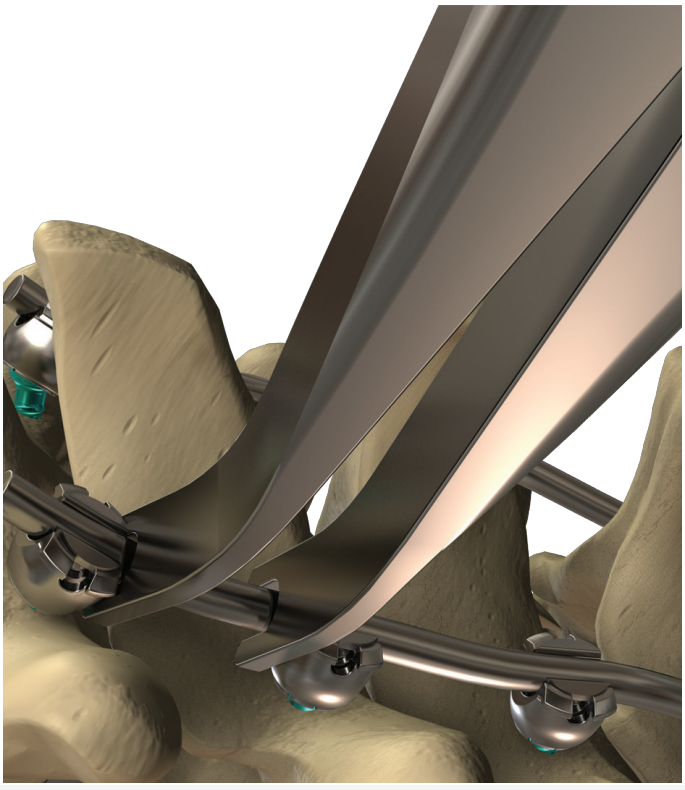
REDUCTION JACK SHAFT

STEP 9

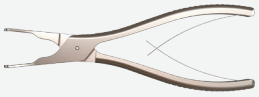
COMPRESSION & DISTRACTION

Compression and distraction may be performed with the 90° MESA Mini implants while the screws are partially locked.

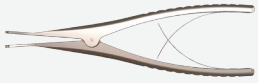




COMPRESSOR



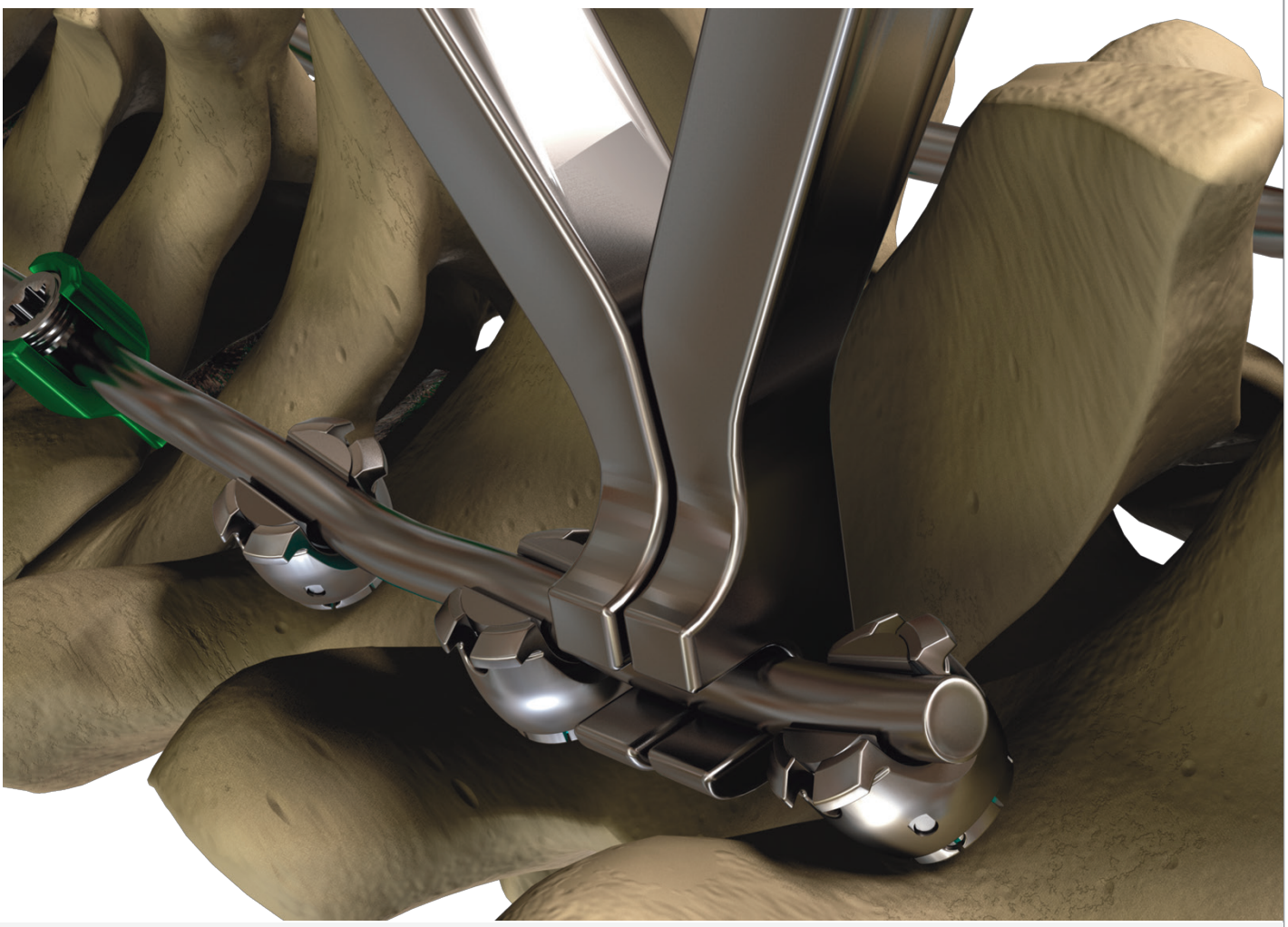
DISTRACTOR



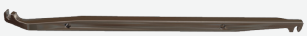
STEP 10

IN-SITU BENDING

Once the rod has been placed in the implants and partially locked, the rods may be contoured in-situ. To achieve additional correction in the sagittal plane, use the In-Situ Benders (Right and Left).



IN-SITU BENDER, RIGHT



IN-SITU BENDER, LEFT

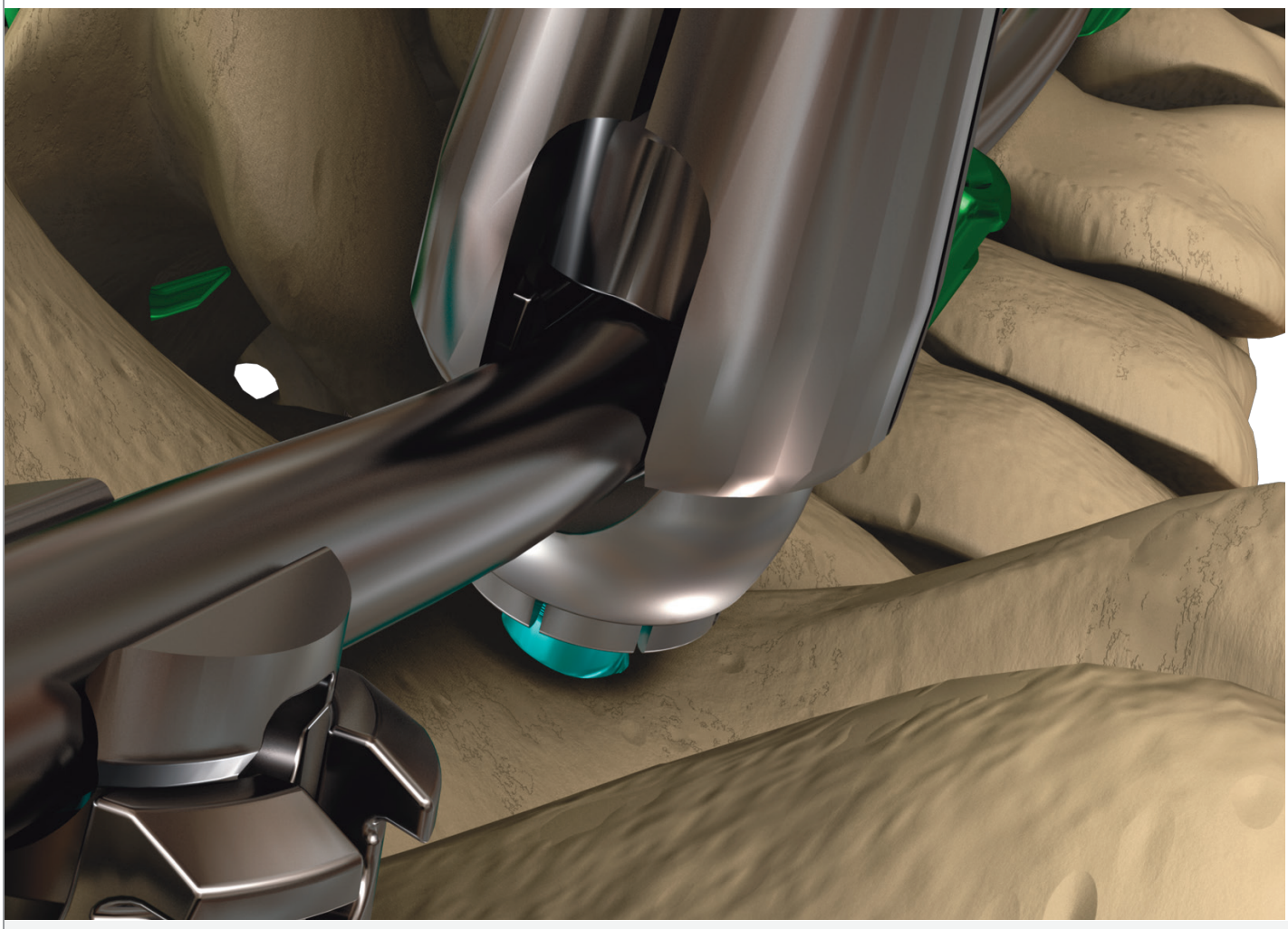


STEP 11

FINAL LOCKING

Dock the MESA Mini Locker onto the screw head. Ensure the shaft of the instrument is collinear with the implant. A gentle axial tug can then be performed to confirm docking. Squeeze the handle to fully lock the 90° MESA Mini screw.

Pull the instrument handle until it is fully opened, and remove the MESA Mini Locker from the surgical site.



MESA MINI LOCKER

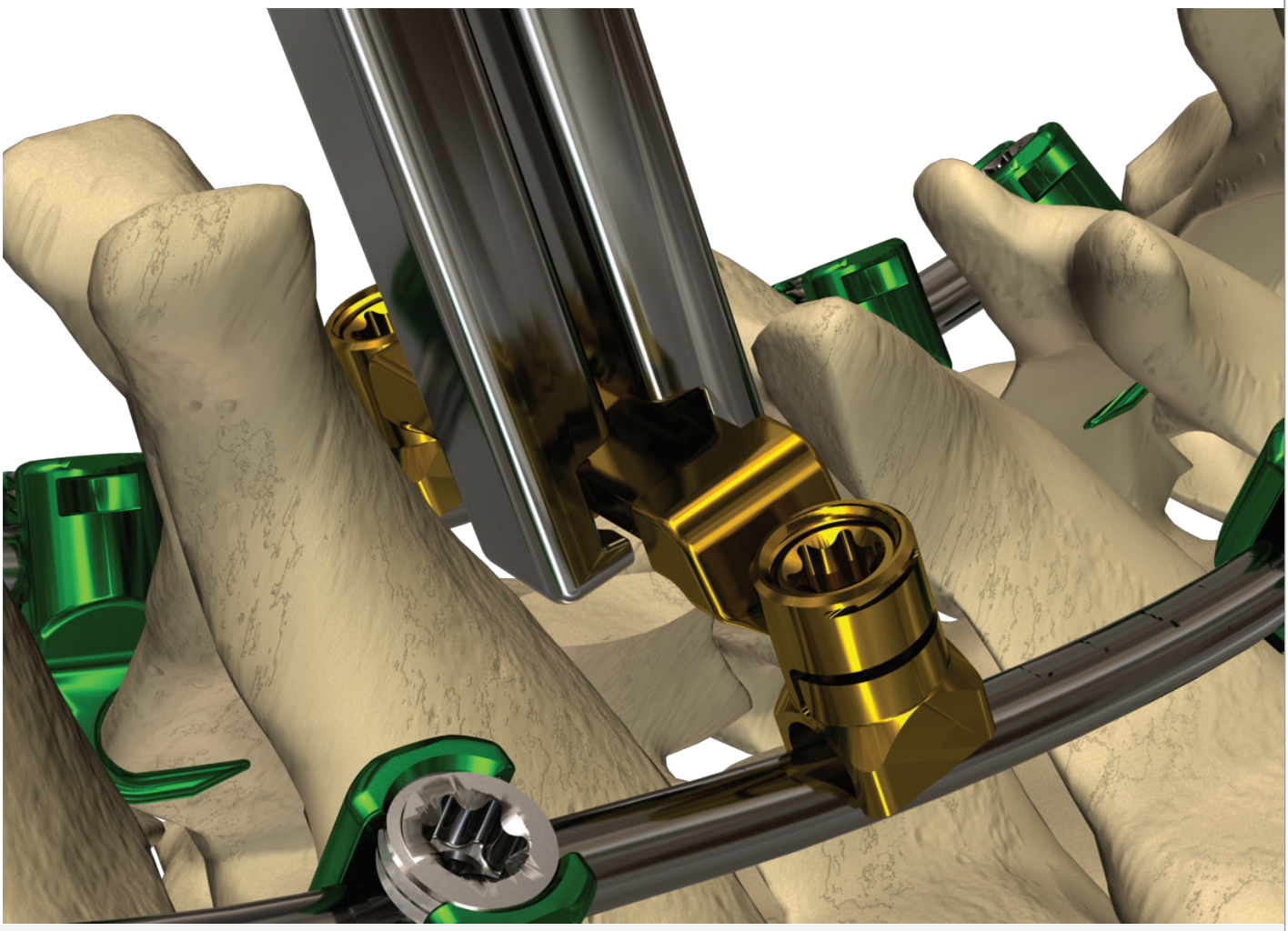


STEP 12

NATURAL BRIDGE® TRANSVERSE CONNECTORS

Should additional construct support be required, a NATURAL BRIDGE® Mini Transverse Connector may be used. Use the Transverse Connector Caliper to measure for the appropriately sized implant. Then, use the Transverse Connector Holder to grasp the head of the selected implant and rock cranial/caudal onto the rod. Repeat on the contralateral head.

NOTE: To remove the Connector, rock cranial/caudal. DO NOT pull up directly on the Transverse Connector head.



TRANSVERSE CONNECTOR HOLDER



TRANSVERSE CONNECTOR CALIPER

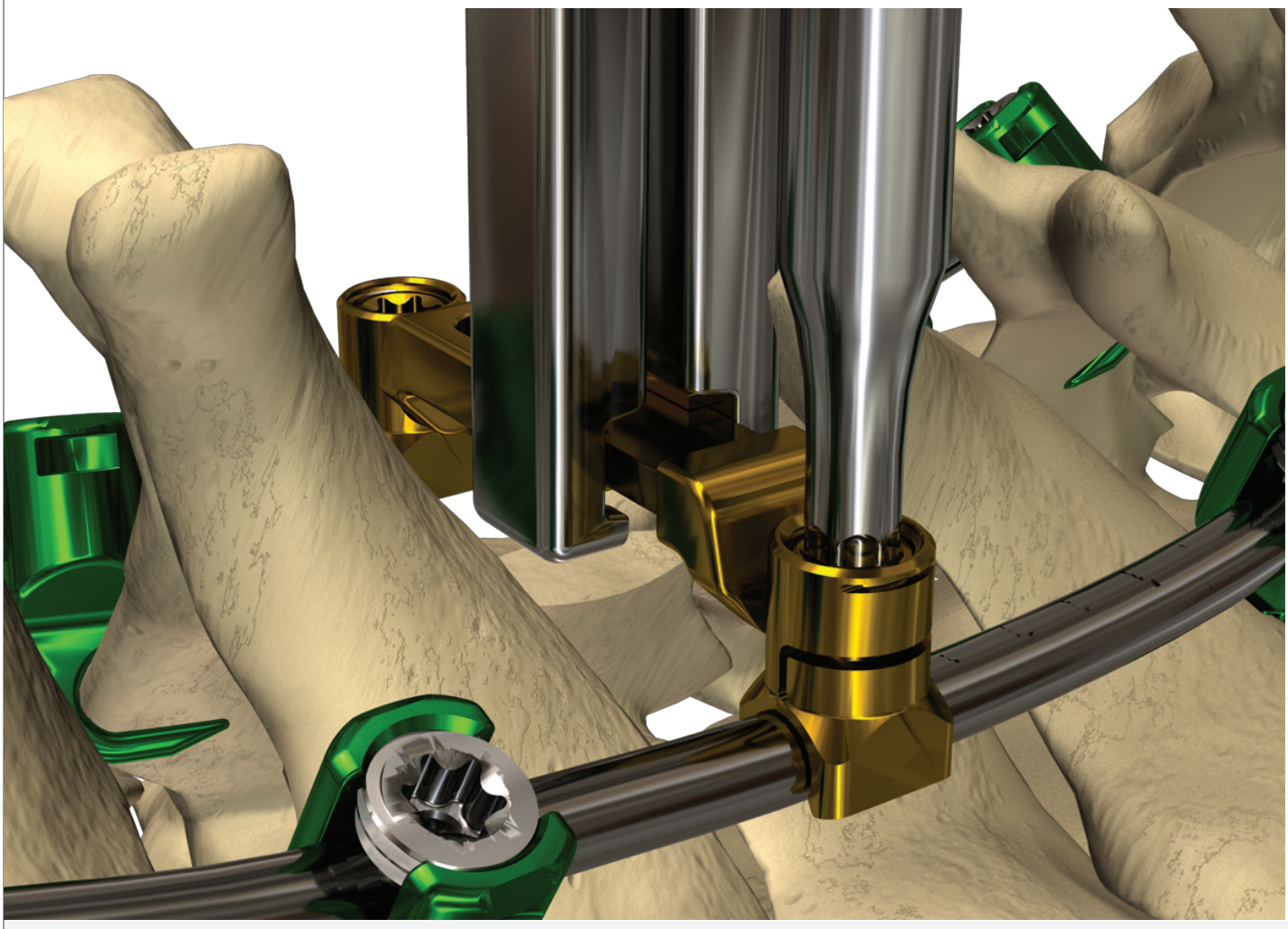


STEP 12

NATURAL BRIDGE® TRANSVERSE CONNECTORS (CONT.)

Utilize the black Torque Limiting Handle and Size 15 Torque Limiting Shaft to provisionally tighten both heads. Final tighten the heads and bridge. The Torque Limiting Handle will emit an audible click when it reaches 1.25 N-m.

NOTE: The black Torque Limiting Handle achieves 1.25 N-m (11.1 inch-pounds) of torque for final tightening. This handle should not be confused with the gray Torque Limiting Handle used to final tighten the cervical hooks to 2 N-m.



TORQUE LIMITING SHAFT

TORQUE LIMITING HANDLE (1.25 N-m)



STEP 13

ROD CONNECTION

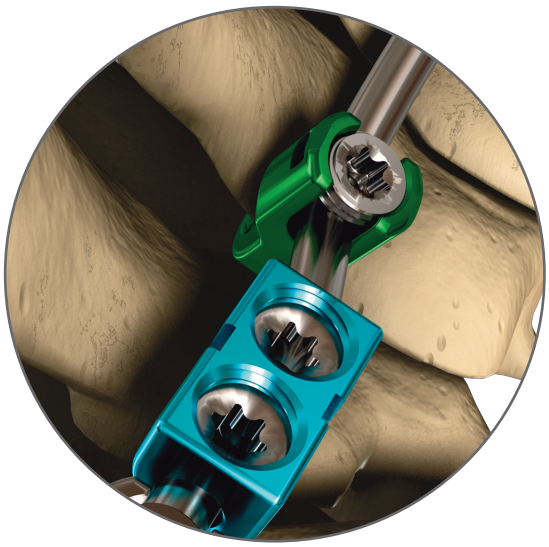
Axial and Parallel Connectors may be used to join two rods together that are end-to-end or side-by-side, respectively. Lateral Offset Connectors are also available to engage a screw lateral to the rod construct.

Axial and Parallel Connectors are pre-assembled with set screws, while Lateral Offset Connectors require placement of a set screw once the Lateral Offset Connector has engaged the rod. All implants are final tightened using the Size 15 Torque.

Limiting Shaft attached to the gray Torque Limiting Handle. The Handle will emit an audible click at 2 N-m (17.7 inch-pounds).

Parallel Connectors	3.5–3.5 mm & 3.5–5.5 mm	Standard in MESA Mini
Axial Connectors	3.5–3.5 mm & 3.5–5.5 mm	Standard in MESA Mini
Lateral Offset Connectors	10 mm	Standard in MESA Mini
Parallel Connectors	3.5–4.5 mm	Standard in MESA Small Stature

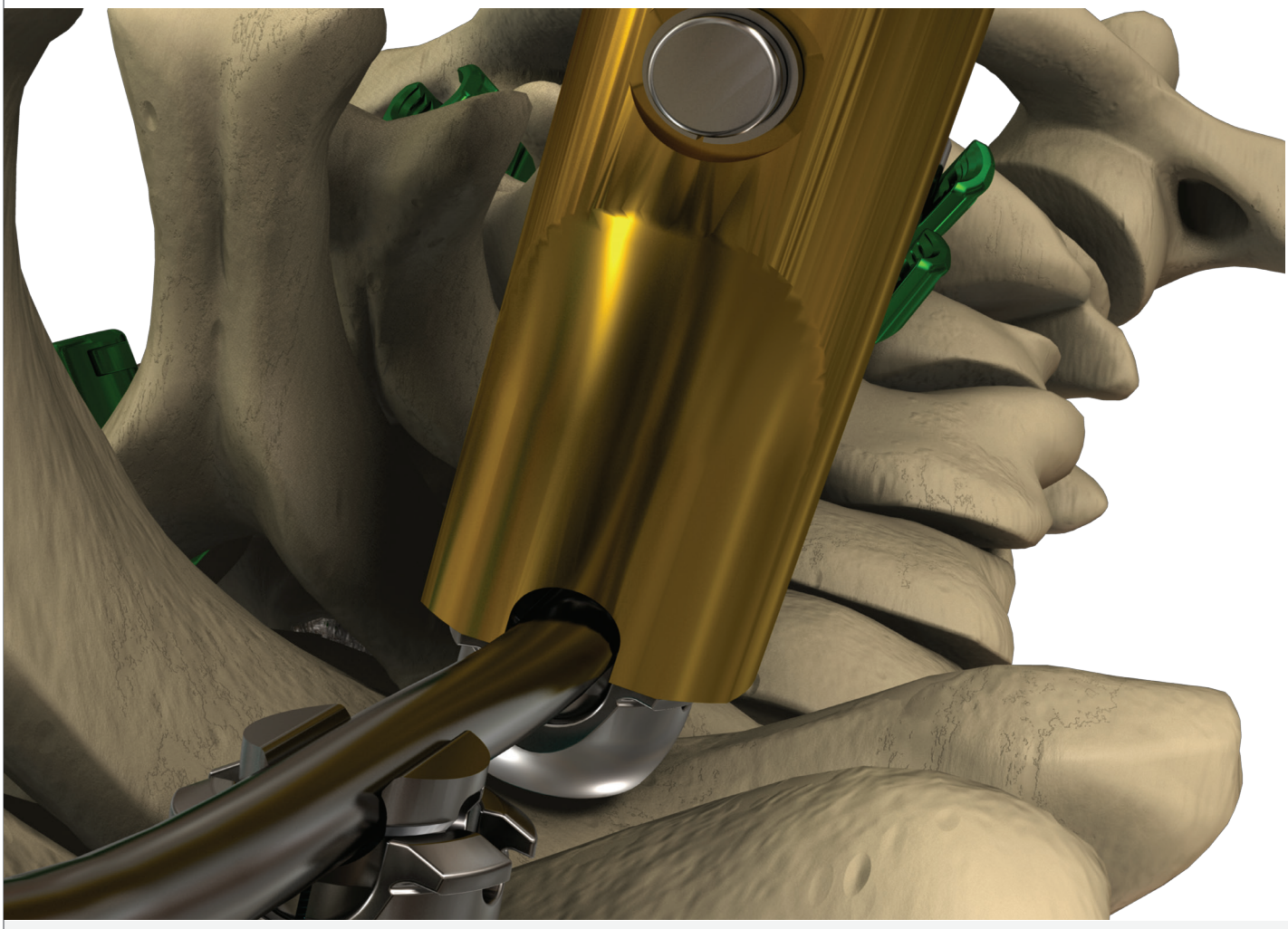




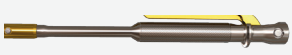
STEP 14

UNLOCKING & REMOVAL INSTRUMENTS

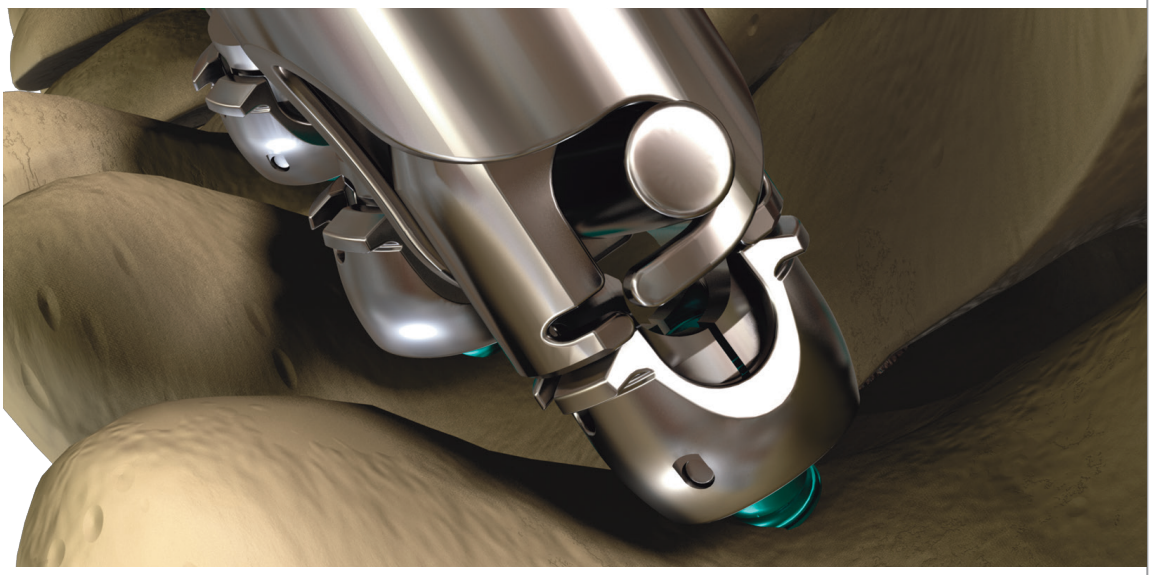
Should the surgeon decide to unlock the 90° MESA Mini screw from a partial or full lock, the MESA Mini Unlocker may be utilized. Fully open the instrument and engage the docking feet onto the detents of the medial side of the screw housing. Gently squeeze the handle and move the instrument down laterally 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 MESA Mini Unlocker.

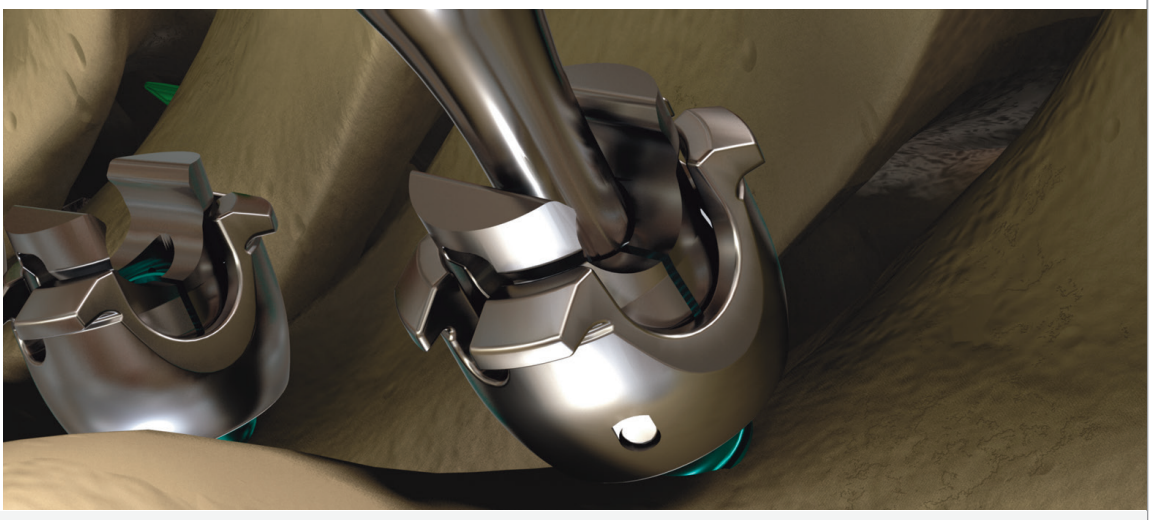


MESA MINI UNLOCKER



Once the 90° MESA Mini screw housing is in the unlocked position, the rod may be extracted from the implant housing using the Rod Puller Plus. Apply the distal end of the Rod Puller Plus over the MESA Mini screw housing and rotate clockwise until the rod is securely engaged. Grab the T-Handle and push down on the proximal end of the instrument in a syringe-like manner. To fully remove the screw from the vertebral body, use the Size 10 Screw Height Adjuster attached to a Fixed or Ratcheting Handle. With the screw head collinear to the screw shaft, engage the Screw Height Adjuster in the hexalobe within the screw head. Rotate counter-clockwise to remove the screw.





ROD PULLER PLUS





PRODUCT CATALOG

INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90021	MESA Mini Head Adjuster
1101-90026	MESA Mini Locker
1101-90027	MESA Mini Unlocker
1101-90186	90° MESA Mini Screw Inserter
1101-90018	Rod Puller Plus

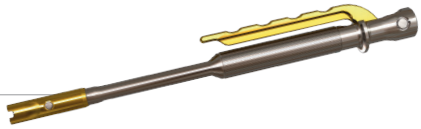
MESA MINI HEAD ADJUSTER



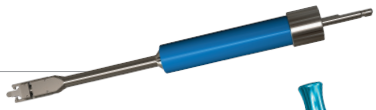
MESA MINI LOCKER



MESA MINI UNLOCKER



90° MESA MINI SCREW INSERTER



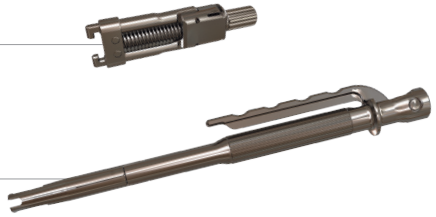
ROD PULLER PLUS



INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90156	Mini Cricket – 10 mm (Reduction Jack)
1101-90155	Mini Superfly (Partial Locker)
1101-90311	Mini Dragonfly (Dual Action Rod Reducer)
1101-90205	Firefly (Single Action Rod Reducer)

MINI CRICKET – 10 mm (REDUCTION JACK)



MINI SUPERFLY (PARTIAL LOCKER)

MINI DRAGONFLY (DUAL ACTION ROD REDUCER)



FIREFLY (SINGLE ACTION ROD REDUCER)

INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90003	Small Pedicle Probe
1101-90001	Awl
1101-90002	Ball Tip Probe
1101-90016	60 mm Depth Gauge
1101-90017	Reamer

SMALL PEDICLE PROBE



AWL



BALL TIP PROBE



60 mm DEPTH GAUGE



REAMER



INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90125	Ø2.3 x 12 mm Fixed Drill Bit
1101-90126	Ø2.3 x 14 mm Fixed Drill Bit
1101-90127	Ø2.3 x 16 mm Fixed Drill Bit
1101-90133	Ø2.8 x 12 mm Fixed Drill Bit
1101-90134	Ø2.8 x 14 mm Fixed Drill Bit
1101-90135	Ø2.8 x 16 mm Fixed Drill Bit

CATALOG #	DESCRIPTION
1101-90005	Ø2.3 mm Adjustable Drill Bit
1101-90006	Ø2.8 mm Adjustable Drill Bit
1101-90012	Ø3.5 mm Tap
1101-90013	Ø4.0 mm Tap
K2-11-2098-01	Ø4.5 mm Tap

FIXED DRILL BITS

DRILL LENGTHS BY COLOR	
Size	Color
12 mm	
14 mm	
16 mm	

Ø2.3 mm SINGLE COLOR RINGS



Ø2.3 mm DOUBLE COLOR RINGS



Ø2.3 mm ADJUSTABLE DRILL BITS



Ø2.8 mm ADJUSTABLE DRILL BITS



Ø3.5 mm TAP



Ø4.0 mm TAP



Ø4.5 mm TAP



INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90015	Ratcheting Axial Handle
1101-90014	Fixed Axial Handle
1101-90123	Torque Limiting Shaft, Size 15
1101-90116	Torque Limiting Handle, 2 N-m
1101-90246	Torque Limiting Handle, 1.25 N-m
1101-90045	Anti-Torque Alignment Tube
1101-90020	Screw Height Adjuster, Size 10
1101-90041	Reduction Jack Shaft, Size 15
1101-90042	Double-Ended Set Screw Driver, Size 15
1101-90122	Provisional Screwdriver, Size 15, Tapered

HEXALOBE SIZE	NON-TAPERED*	TAPERED**
Size 10	—	=
Size 15	—	=

*Non-tapered has 1 epoxy ring
**Tapered has 2 epoxy rings

RATCHETING AXIAL HANDLE

FIXED AXIAL HANDLE

TORQUE LIMITING SHAFT, SIZE 15

TORQUE LIMITING HANDLE, 2 N-m

TORQUE LIMITING HANDLE, 1.25 N-m

ANTI-TORQUE ALIGNMENT TUBE

SCREW HEIGHT ADJUSTER, SIZE 10

REDUCTION JACK SHAFT, SIZE 15

DOUBLE-ENDED SET SCREW DRIVER, SIZE 15

PROVISIONAL SCREWDRIVER, SIZE 15, TAPERED



INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90022	Rod Template, 80 mm
1101-90068	Rod Template, 200 mm
1101-90044	Rod Fork
1101-90256	Transverse Connector Holder
1101-90069	Hook Holder
101-90220	Connector Holder

ROD TEMPLATE, 80 mm



ROD TEMPLATE, 200 mm



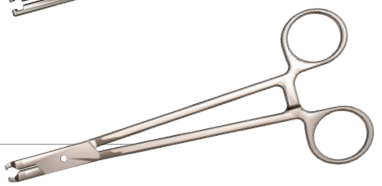
ROD FORK



TRANSVERSE CONNECTOR HOLDER



HOOK HOLDER



CONNECTOR HOLDER

INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90064	Transverse Connector Caliper
1101-90037	Tap Sleeve
1101-90007	Adjustable Drill Guide
1101-90008	Fixed Drill Guide
1101-90034	In-Situ Bender, Right
1101-90033	In-Situ Bender, Left
1101-90030	Torsional Rod Reducer, Right
1101-90029	Torsional Rod Reducer, Left
1101-90023	Ø3.5 mm Rod Bender

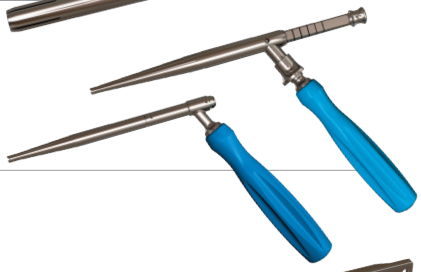
TRANSVERSE CONNECTOR CALIPER



TAP SLEEVE



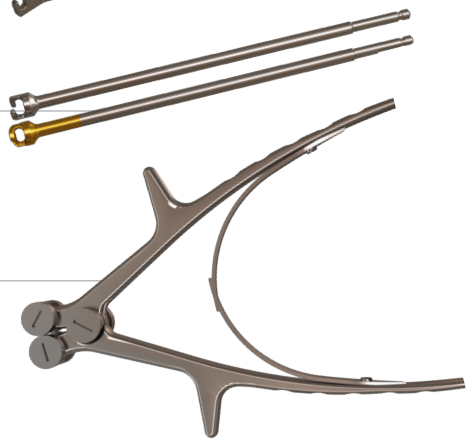
DRILL GUIDE, FIXED, ADJUSTABLE



IN-SITU BENDER – RIGHT, LEFT



TORSIONAL ROD REDUCER – RIGHT, LEFT

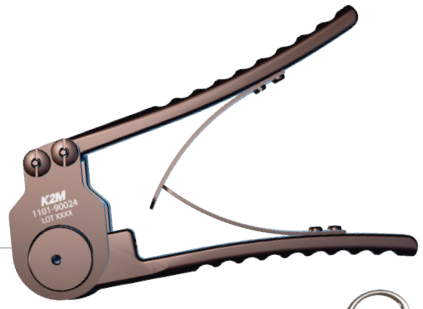


Ø3.5 mm ROD BENDER

INSTRUMENTS

CATALOG #	DESCRIPTION
1101-90024	Ø3.5 mm Ratcheting Rod Cutter
1101-90025	Rod Holding Forceps
1101-90032	Distractor
1101-90031	Compressor

Ø3.5 mm RATCHETING ROD CUTTER



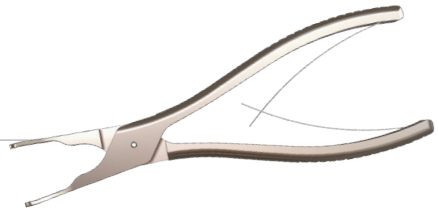
ROD HOLDING FORCEPS



DISTRACTOR



COMPRESSOR



IMPLANTS

CATALOG #	DESCRIPTION
1101-53580	Ø3.5 x 80 mm
1101-535120	Ø3.5 x 120 mm
1101-353240	Ø3.5 x 240 mm
3001-535300-45	Ø3.5–4.5 mm Transitional Rod x 300 mm
3001-535500-45	Ø3.5–4.5 mm Transitional Rod x 500 mm
1101-535300-55	Ø3.5–5.5 mm Transitional Rod x 300 mm
1101-535500-55	Ø3.5–5.5 mm Transitional Rod x 500 mm

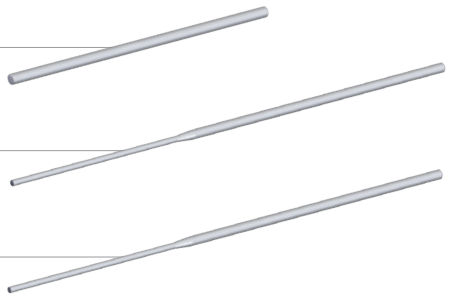
CATALOG #	DESCRIPTION
1111-B35300	Ø3.5 x 300 mm CoCr Rod
1111-B35400	Ø3.5 x 400 mm CoCr Rod
3011-535300-45	Ø3.5–4.5 mm CoCr Transitional Rod x 300 mm
3011-535500-45	Ø3.5–4.5 mm CoCr Transitional Rod x 500 mm
1111-535300-55	Ø3.5–5.5 mm CoCr Transitional Rod x 300 mm
1111-535500-55	Ø3.5–5.5 mm CoCr Transitional Rod x 500 mm

TITANIUM RODS

Ø3.5 mm x 80, 120, 240 mm

Ø3.5–4.5 mm x 300, 500 mm Transition

Ø3.5–5.5 mm x 300, 500 mm Transition

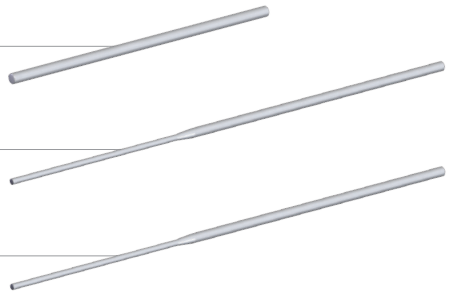


CoCr RODS

Ø3.5 mm x 300, 400 mm

Ø3.5–4.5 mm x 300, 500 mm Transition

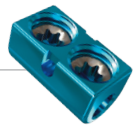
Ø3.5–5.5 mm x 300, 500 mm Transition



IMPLANTS

CATALOG #	DESCRIPTION
1101-83535D	Ø3.5–3.5 mm Axial Connector
1101-83555D	Ø3.5–5.5 mm Axial Connector
1101-83535	Ø3.5–3.5 mm Parallel Connector
3001-83545	Ø3.5–4.5 mm Parallel Connector
3001-83545N	Ø3.5–4.5 mm Parallel Connector Narrow
1101-83555	Ø3.5–5.5 mm Parallel Connector
1101-73510	Lateral Offset Connector – Open 10 mm
1101-10001	Mini Set Screw

AXIAL CONNECTOR



PARALLEL CONNECTOR



LATERAL OFFSET CONNECTOR – OPEN 10 mm



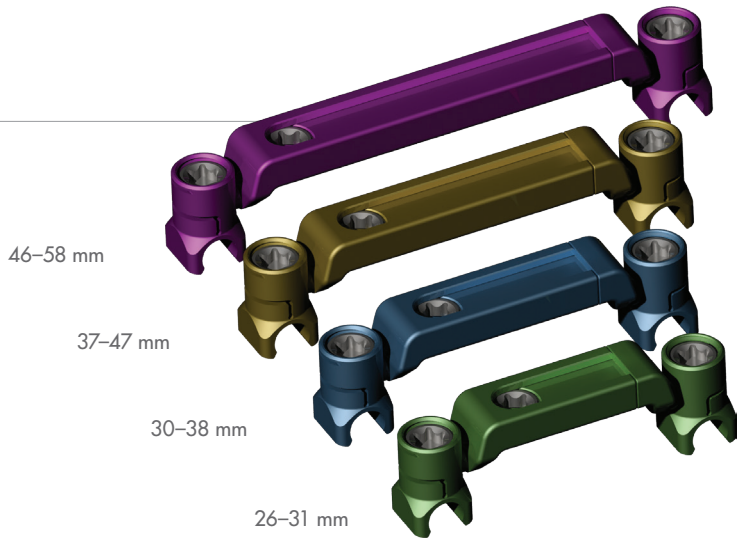
MINI SET SCREW



IMPLANTS

CATALOG #	DESCRIPTION
1101-72631M	Small 26–31 mm
1101-73038M	Medium 30–38 mm
1101-73747M	Large 37–47 mm
1101-74658M	X-Large 46–58 mm

NATURAL BRIDGE MINI



SCREWS

DESCRIPTION

MESA Mini Polyaxial

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

90° MESA MINI POLYAXIAL

Ø3.5, Ø4.0, & Ø4.5 mm

STANDARD POLYAXIAL SCREWS	
Diameter	**Lengths**
3.5 mm	10–26 mm (2 mm increments)
4.0 mm	10–32 mm (2 mm increments)
4.5 mm	20–36 mm (2 mm increments)



Ø3.5 mm Ø4.0 mm Ø4.5 mm

90° MESA MINI LONG SHANK

Ø3.5 & Ø4.0 mm

POLYAXIAL LONG SHANK SCREWS	
Diameter	**Lengths**
3.5 mm	26–40 mm (2 mm increments)
4.0 mm	26–40 mm (2 mm increments)



Ø3.5 mm Ø4.0 mm

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

IMPORTANT
This booklet is designed to assist in using the CASPIAN® OCT / MESA Mini / DENALI® Mini 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 CASPIAN OCT / MESA Mini / DENALI Mini Spinal Systems is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput–T3) when used with autograft or allograft and is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/dislocation, revision of previous cervical spine surgery, tumors, atlantoaxial fracture with instability, occipitocervical dislocation. The occipital bone screws are limited to occipital fixation only. The rod and hook components are intended for use in the cervical/upper thoracic (C1–T3) spine. The pedicle screws are limited to placement in T1–T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine. The CASPIAN OCT / MESA Mini / DENALI Mini Spinal Systems can also be linked to the RANGE® Spinal System using the rod connectors or transitional rods.

MATERIALS
All implant components are manufactured from Titanium and Cobalt Chrome per ASTM 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
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 are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

AUTOCLAVE CYCLES:
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.

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

Cut the rod to the proper length. Bend the rod as needed due to anatomical variations. Drop the rod into the top of the screw. Complete final locking of the assembly as described in the appropriate surgical technique. Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

For Hook Use
Prepare the hook site with the appropriate lamina finders to provide a good fit with the hooks. Assemble the proper hook onto the hook holder. Insert hook using the hook holder. Remove the hook holder. Cut the rod to the proper length. Bend the rod as needed due to anatomical variations. Drop the rod into the top of the hook. Insert the set screw. Use distraction or compression provided by the distractor or compressor as required. Thread the set screw completely down across the rod the assembly. Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

For Plate Insertion
Holding the plate with the plate holder, position it over the occiput. Bend the plate as needed due to anatomical variations.

NOTE: Excessive reverse bending of the plate can cause metal stressing resulting in a lower fatigue life for the plate. Use the drill guide, awl, drills and taps to prepare the screw site. Select the proper size screw. Insert with the screwdriver. Attach plate to the rod and secure with set screw. Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

CONTRAINDICATIONS
1. The CASPIAN OCT / MESA Mini / DENALI Mini Spinal Systems is 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
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. 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 in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
6. The K2M spinal implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
7. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.
8. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

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

OPERATIVE
1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Rods and plates 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.

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.

PI017-0A11-01 Rev 0
K2M, Inc. | 600 Hope Parkway SE | Leesburg, VA | 571.919.2000

MESA®

MINI SPINAL SYSTEM

The MESA® Mini Spinal System is a Ø3.5 mm rod system offering a differentiated solution for rigid posterior fixation of the cervico-thoracic regions of the spine. Based on K2M's revolutionary MESA Zero-Torque Technology®, this comprehensive system features a low-profile 90° range of motion cervico-thoracic screw, multiple hook and rod options, and a full complement of easy-to-use instrumentation.

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The MESA Mini System is cleared with and is part of the CASPIAN Occipito-Cervico-Thoracic (OCT) System. FDA 510(k) clearance letters for CASPIAN may be accessed at: http://www.fda.gov.

CE 0086

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