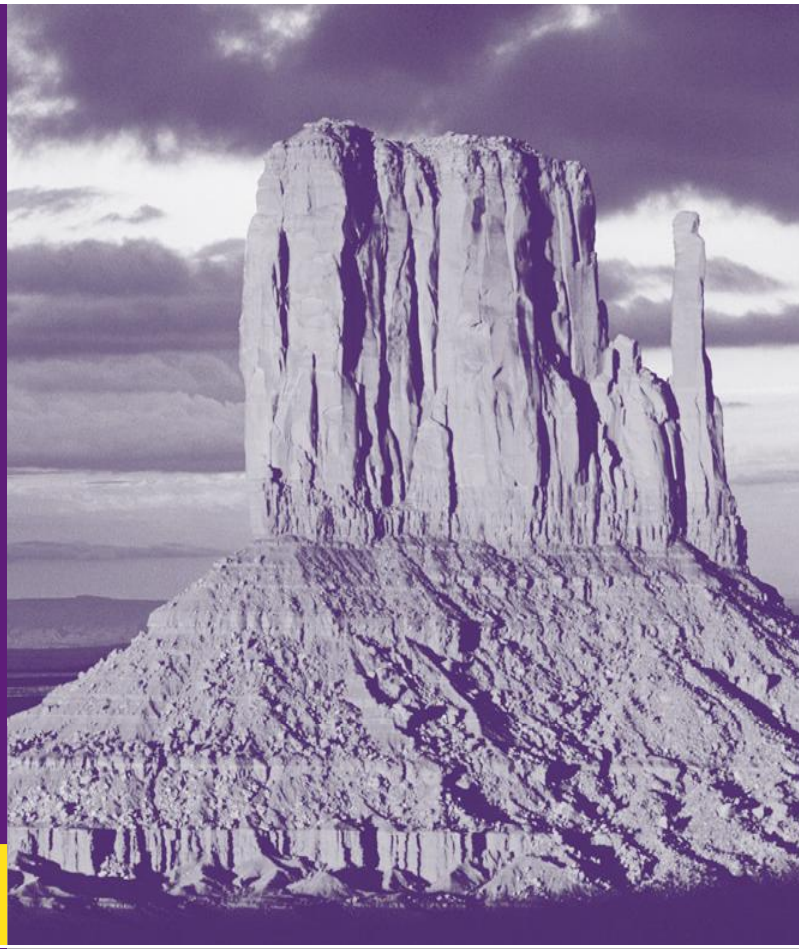

MESA®
DEFORMITY

Surgical Technique

mesa

Hooks

As Described By:

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

K2M
COMPLEX SPINE INNOVATIONS™

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Dear Colleagues,

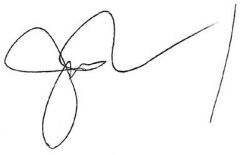
Welcome to K2M and the MESA® Deformity Spinal System! Our commitment to achieve the highest level of excellence in treating complex spinal pathologies continues with this comprehensive deformity system. MESA Deformity has been designed through an innovative collaborative approach, which includes spinal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

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

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

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

Sincerely,



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FEATURES & BENEFITS

MESA® Deformity Spinal System

– Zero-Torque Technology®

– No Profile Above the Rod

– One-Step Final Locking

– Complete Offering of Hooks: Transverse Process, Laminar, Pedicle

– Revolutionary Design of Deformity Reduction Jack (Cricket®) Provides Ability to Accomplish Correction Maneuvers in All Planes

– Unique Instrumentation Provides Slow, Controlled Correction of Spine, While Distributing Forces Across Entire Construct

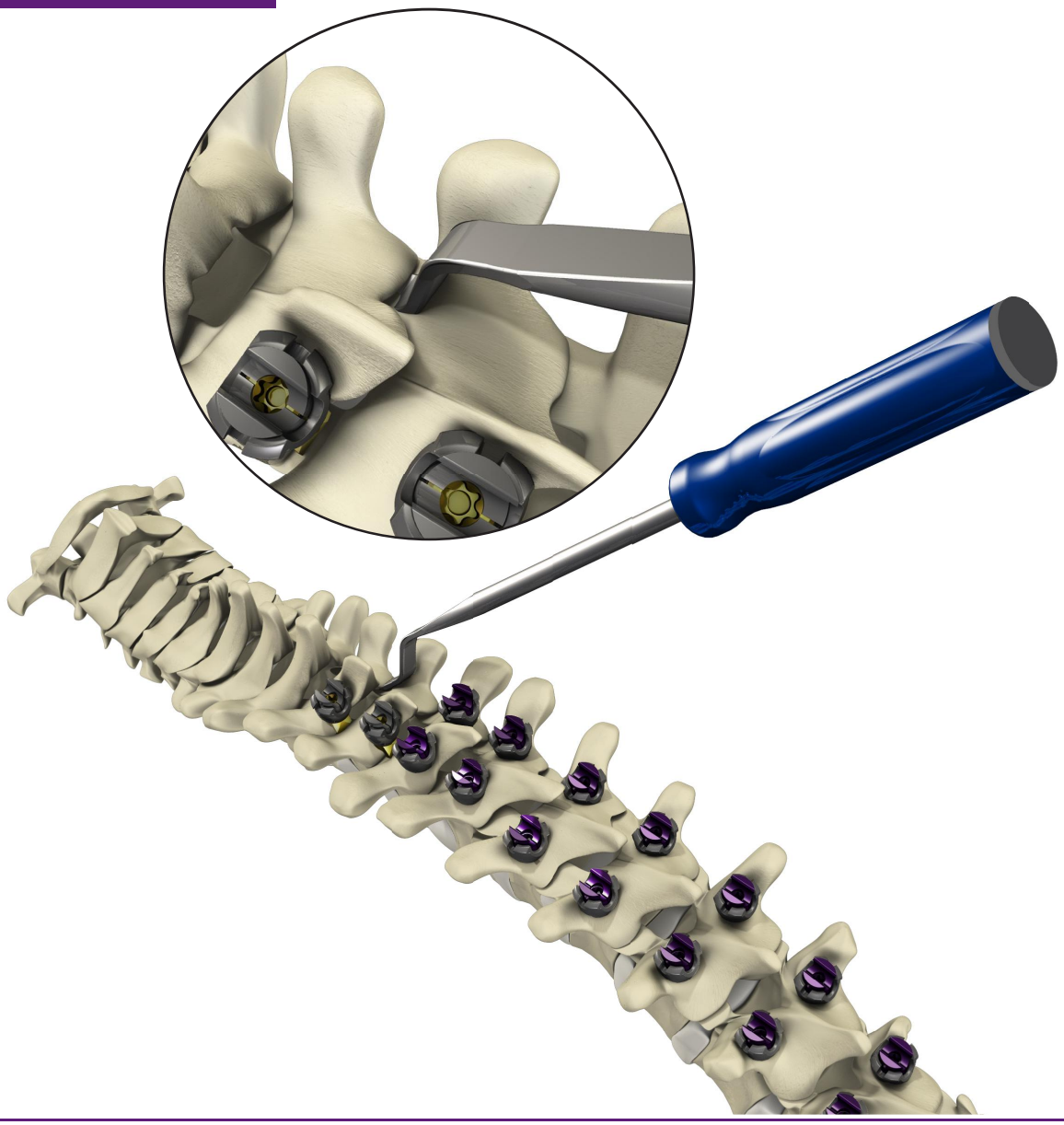
– Ability to Segmentally or Globally Derotate Spine to Achieve Axial Plane Correction

MESA® HOOK SURGICAL TECHNIQUE

STEP 1

Surgical Technique Steps

PEDICLE OSTEOTOME



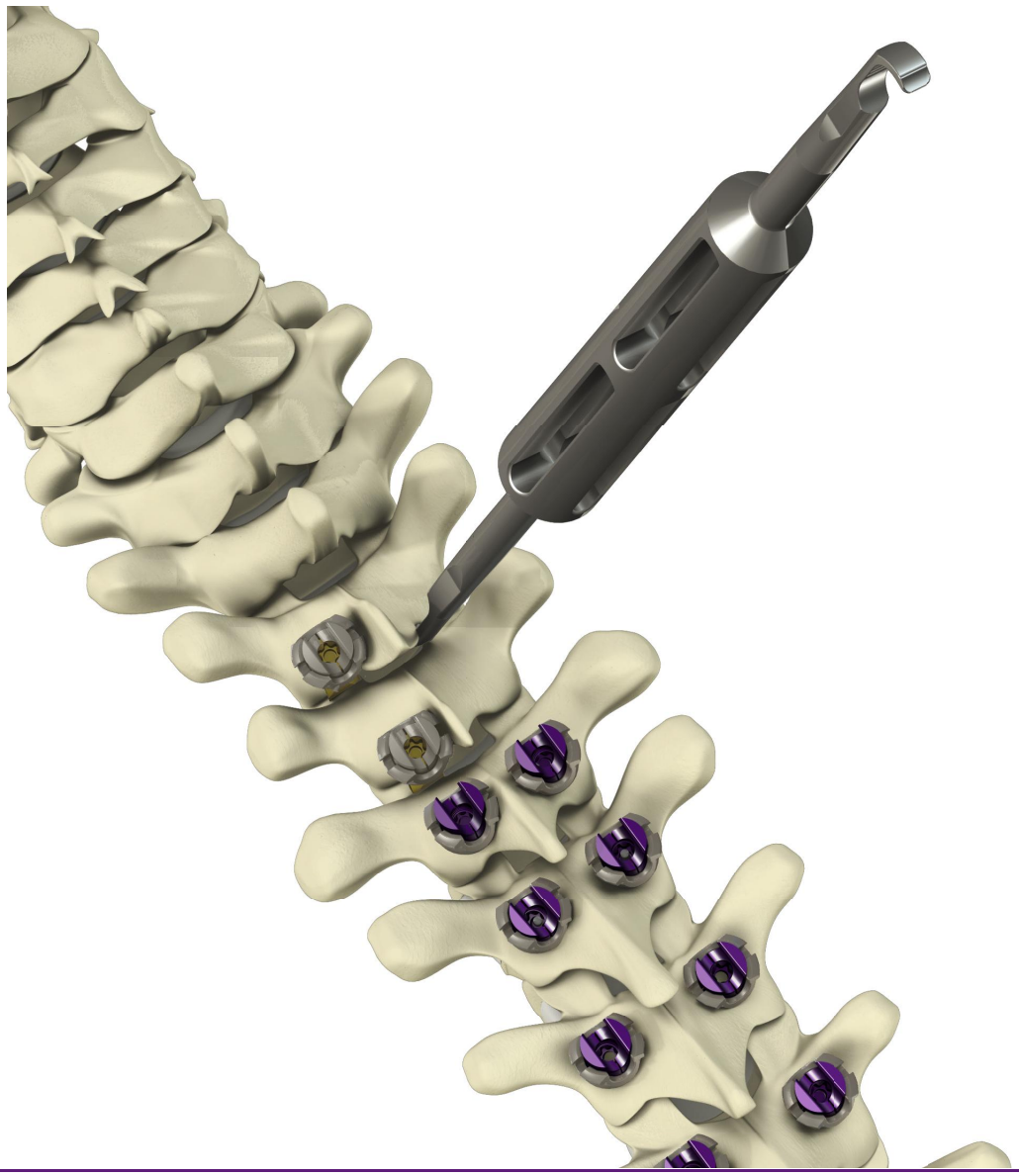
HOOK SITE PREPARATION: PEDICLE HOOKS

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 Osteotome is inserted into the facet joint pointing 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. A partial resection of the inferior articular process may be required for best fit.

HOOK ELEVATOR

HOOK STARTER



HOOK SITE PREPARATION: LAMINAR & TRANSVERSE PROCESS HOOKS

These multi-purpose hooks can be placed in an upward or downward facing position on the lamina or transverse process. 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. Additional hook site preparation may be performed using a Kerrison or the Hook Starter.

The Hook Elevator is used to access the anatomy between the laminar and peridural structures. Implants should be chosen to ensure best possible interface between the hook and bone.

STEP 3

Surgical Technique Steps

HOOK PUSHER

OFFSET HOOK HOLDER

LATERAL HOOK HOLDER

MESA HOOK INSERTION

The MESA Hooks may be inserted with a variety of instruments. The Lateral or Offset Hook Holders can be used with the MESA Hook.

The MESA Hooks can also be inserted using the MESA Deformity Screw Inserter. First, attach a Handle to the Inserter. To attach the hook, hold the blade and apply an upward force to properly engage the hook. Turn the Knurled Knob clockwise to attach.

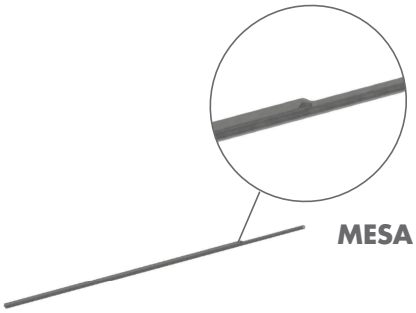
The Hook Pusher can be used by itself or in conjunction with other instruments. Using it in combination with a Hook Holder will allow for more control during insertion. The Pusher can also be used in combination with a Deformity Cricket®. Slide the Pusher into the Hook head and provisionally thread the Cricket to the Hook head. Fully reduce with a Size 25 Driver. Once the hook is inserted, back off the Cricket to remove the Hook Pusher.

TI ALLOY HEX END, 500 mm

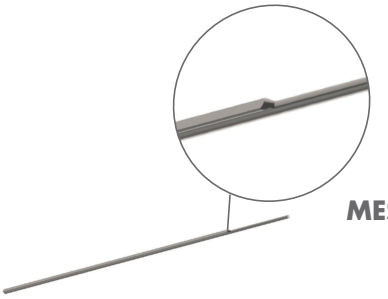
DUAL HEX COCR ROD, 500 mm

MESA RAIL STRAIGHT COBALT CHROME (COCR)

MESA RAIL STRAIGHT TITANIUM (TI)



MESA RAIL TRANSITION (COCR)



MESA RAIL TRANSITION (TI)

ROD/ MESA RAIL PLACEMENT

Once all of the hooks have been inserted, a rod or MESA Rail™ can be selected and cut to the appropriate length. Rods and MESA Rails are available in Ø5.5 mm in Titanium, as well as Cobalt Chrome. Confirm at least 5 mm of rod/MESA Rail extends beyond the most proximal and distal fixation points. For a more detailed description of rod preparation and cutting, please refer to the MESA Deformity Surgical Technique (K2-13-7053-01).

Surgical Technique Steps

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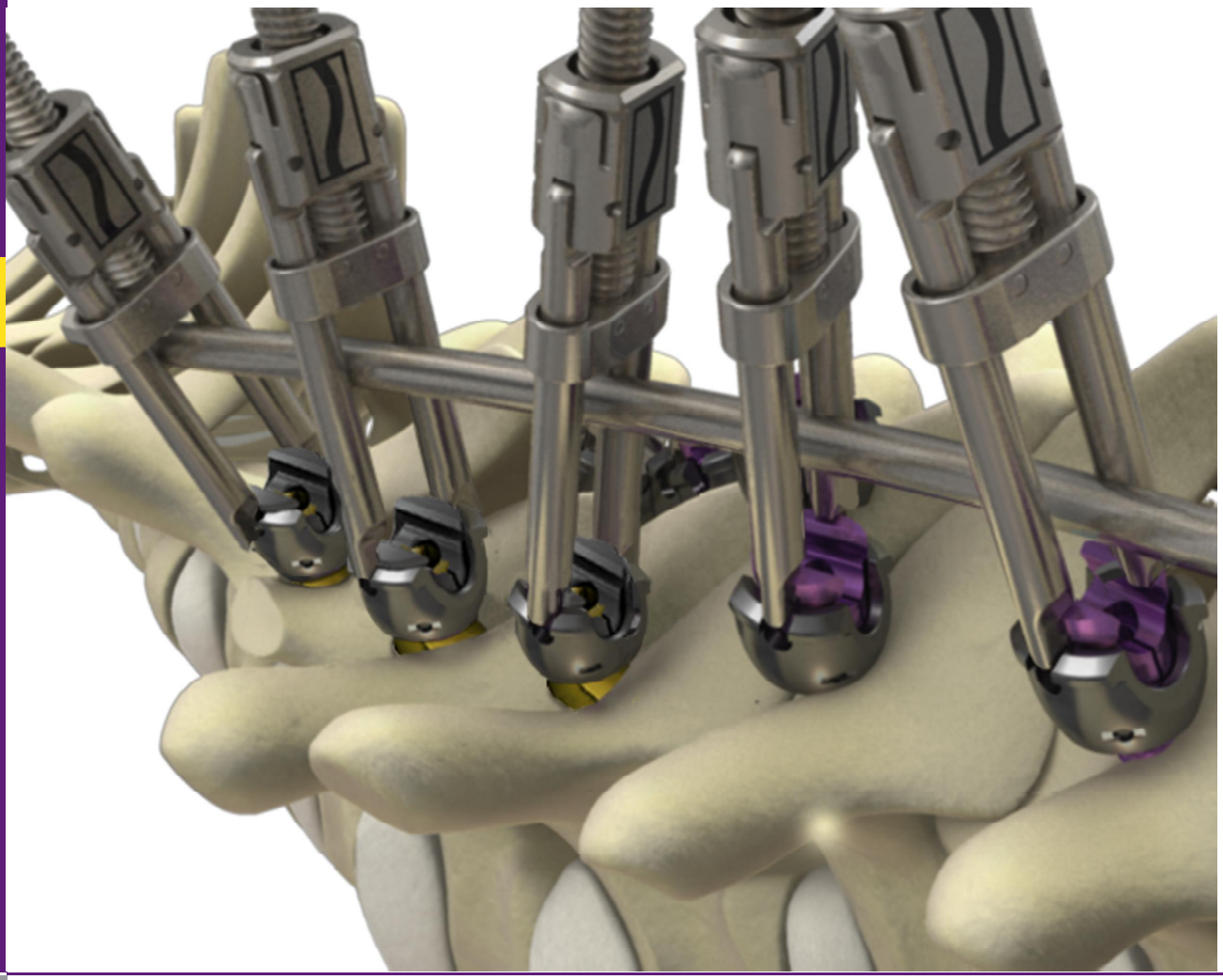
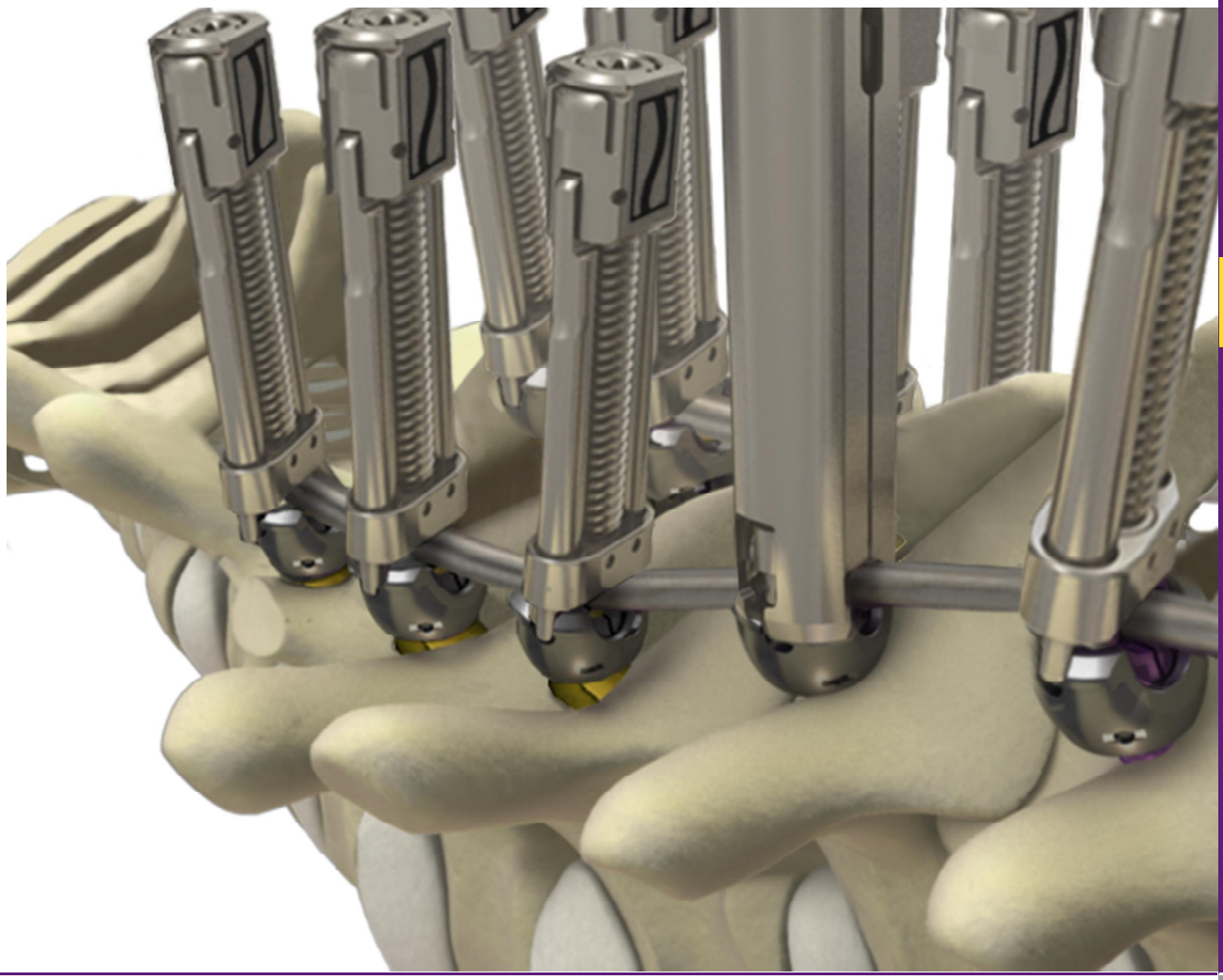
DEFORMITY CRICKET®



ROD REDUCTION & PARTIAL LOCKING

For long reductions up to 27 mm, or multi-level reduction, the Deformity Crickets may be used. Engage the Cricket feet into the inner collet of the MESA Hook and reduce the threaded feature using a Driver, Size 25. Continue reducing until the rod is fully seated into the hook head and the Cricket is fully tightened.

PARTIAL LOCKER



Additional correction can be achieved with a variety of compression and distraction maneuvers. With the Crickets attached, use a driver to release a Cricket by one or two turns. Engage the Compressor or Distractor on the hook heads and retighten the Cricket to hold correction. Repeat on additional levels as needed. This method employs a similar technique to a standard set screw system.

Partially lock all fixation points over the Deformity Crickets using the Partial Locker (Superfly™). The Deformity Crickets may now be removed from the hooks.

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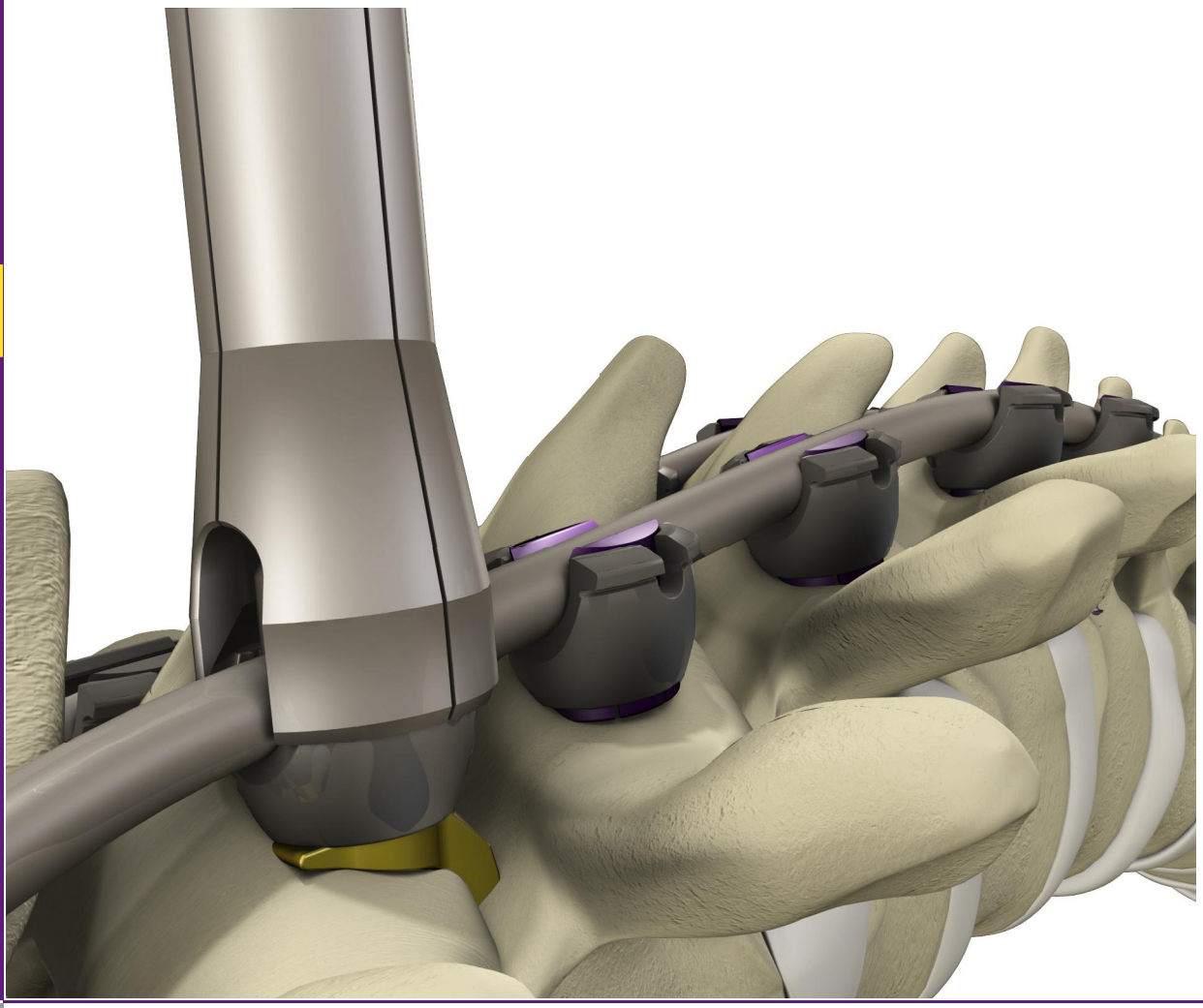
QUICK LOCKER



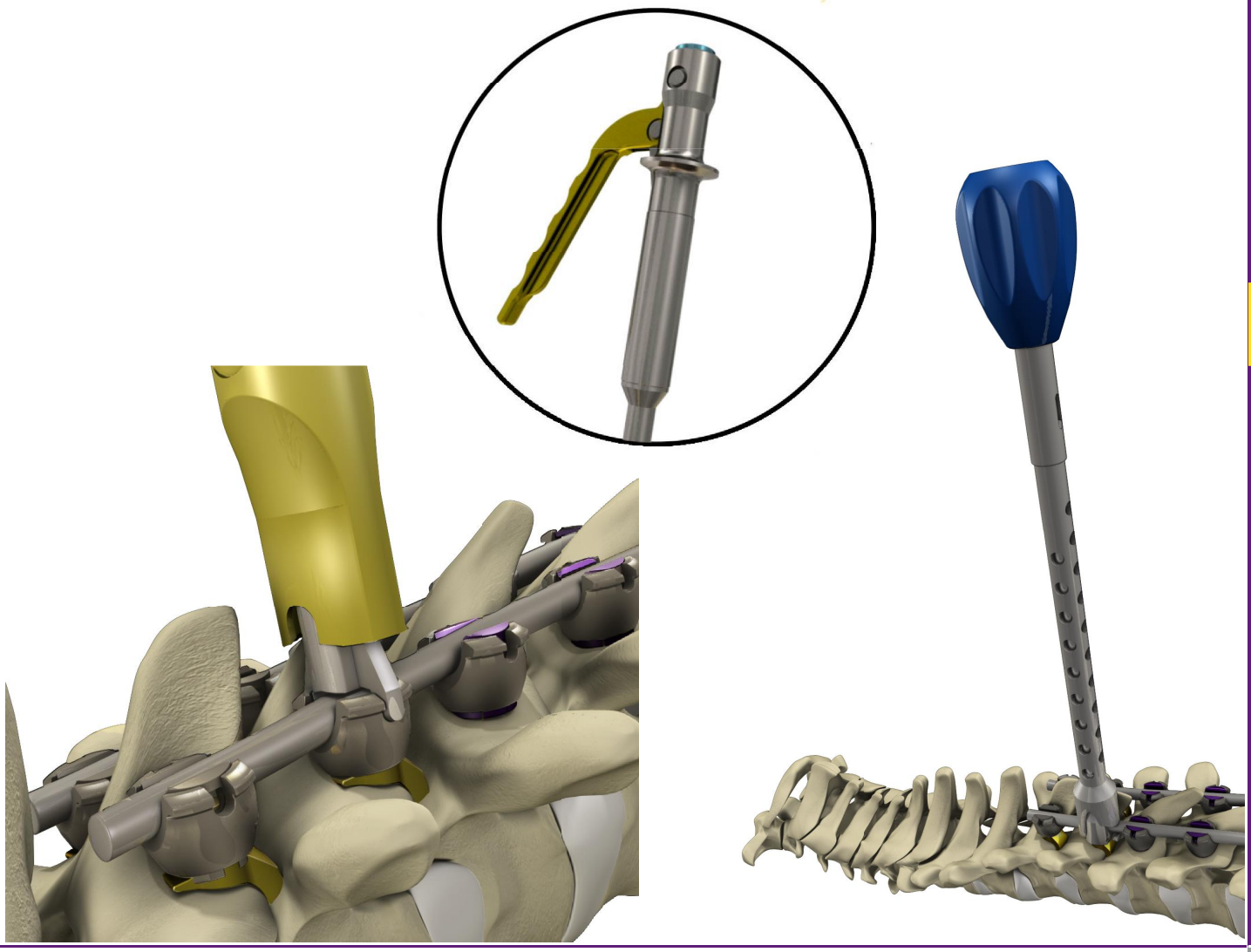
FINAL LOCKING

Fully lock each MESA Hook using the Quick Locker to confirm rigid fixation throughout. This will complete the construct.

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

QUICK UNLOCKER

POWER PULLER



UNLOCKING & REMOVAL

Should the surgeon decide to unlock the MESA Hook from a partial or full lock, the Unlocker may be used. Fully open the instrument and engage the docking feet into the detents on 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 hook housing. Fully squeeze the lever of the Unlocker. Once the hook is unlocked, the rod may be extracted from the implant housing using the Power Puller. Apply the distal end of the Power Puller over the hook housing and rotate it clockwise until it securely engages the rod. Grab the handle and thread down in a controlled fashion in order to release the rod from the hook head.

Product Catalog

IMAGE	HOOK TYPE	CATALOG NUMBER	DESCRIPTION	BLADE WIDTH	THROAT	COLOR
	Transverse Process Hook	801-80601H	Transverse Process Hook, 6 mm	5 mm	6 mm	
		801-80801H	Transverse Process Hook, 8 mm	6 mm	8 mm	
		801-81001H	Transverse Process Hook, 10 mm	7 mm	10 mm	
		801-80804H	Transverse Process Angled, Left	7 mm	8 mm	
		801-80805H	Transverse Process Angled, Right	7 mm	8 mm	
	Laminar Hook	801-80602HN	Laminar Hook, 6 mm / Narrow	5 mm	6 mm	
		801-80802HN	Laminar Hook, 8 mm / Narrow	5 mm	8 mm	
		801-81002HN	Laminar Hook, 10 mm / Narrow	5 mm	10 mm	
		801-80602H	Laminar Hook, 6 mm	7 mm	6 mm	
		801-80802H	Laminar Hook, 8 mm	7 mm	8 mm	
		801-81002H	Laminar Hook, 10 mm	8 mm	10 mm	
		801-80806H	Laminar Offset, Left	7 mm	8 mm	
		801-80807H	Laminar Offset, Right	7 mm	8 mm	
	Pedicle Hook	801-80603H	Pedicle Hook, 6 mm	7 mm	6 mm	
		801-80803H	Pedicle Hook, 8 mm	8 mm	8 mm	
		801-81003H	Pedicle Hook, 10 mm	9 mm	10 mm	

OFFSET HOOK HOLDER

LATERAL HOOK HOLDER

HOOK PUSHER

PEDICLE HOOK OSTEOTOME

LUMBAR HOOK ELEVATOR

HOOK STARTER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Offset Hook Holder	801-90196
Lateral Hook Holder	801-90197
Hook Pusher	801-90195
Pedicle Hook Osteotome	5601-90006
Lumbar Hook Elevator (Dual Ended)	5601-90007
Hook Starter	5601-90008

Notes

Product Insert

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the DENALI®, DENALI Deformity, MESA®, and RANGE® Spinal Systems. It is not a reference for surgical techniques.

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

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

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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

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

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

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

For Single Level Trays:

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

For Stacked Trays:
Autoclave Cycle: Prevacuum
Temperature: 270°F (132°C)
Time: 35 minutes
Drying Time: 30 minutes

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

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

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

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

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

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

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

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

NOTE: Taps are sized smaller than the actual diameter of the screw to allow better screw fixation. Cut the rod to the proper length. Bend the rod as needed due to anatomical variations. Drop the rod into the top of the screw. Complete final locking of the assembly as described in the appropriate surgical technique. Once the surgeon is satisfied the device has been properly implanted, the surgical site is closed in the usual manner.

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

POSTOPERATIVE

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

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www.K2M.com

K2-56-7000-01 Rev. 0
Actual device color may vary.
Consult product catalog for details.
This product is not available for sale or distribution in the United States.

CE 0086