As Described By:

John P. Konzak, MD
Co-Founder, President - K2M, Inc.
Professor Emeritus - Johns Hopkins University, Orthopaedics & Neurosurgery

MESA
Deformity Spinal System

Surgical Technique
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NOTE: Instrumented levels are based on surgeon preference and patient pathology. This surgical technique is intended to be used as a guideline for correction technique with the MESA® Deformity Spinal System.

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, the MESA 360 Screw, Cobalt Chrome and Titanium Rods, as well as Reduction Jigs (Cricket™).

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, providing a guide to help understand the many unique aspects of the system for use in treating our patients.

Sincerely,

John P. Kostuk, 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)
FEATURES & BENEFITS

MESA® Deformity Spinal System

- Zero-Torque Technology®
- No Profile Above the Rod
- One-step Final Locking
- Complete Offering of Polyaxial Screws, Uniplanar Screws, 360° Screws, Rod Connectors & Rod Options
- 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 Optimal Axial Plane Correction
**Surgical Technique Steps**

**STEP 1**

**EXPOSURE & PREPARATION**

Perform facetectomies throughout.

**STEP 2**

**SCREW SITE PREPARATION**

The small cortical crest of the pedicle is perforated with an Awl or removed with a Rongeur or Burr to expose the underlying cancellous bone. The entry point is cannulated with the Curved or Straight Thoracic Probe in the thoracic spine and the Curved or Straight Lumber 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 etched at 10 mm increments, from 30 to 60 mm, indicating the depth to which the Probe has been inserted. If the bone is sclerotic or hard, the appropriate size Tap may be used to prepare the pedicle screw canal. Each Tap is undersized a quarter of a millimeter (0.25 mm).

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

The prepared, probed pathway is sounded with the Ball Tip Feeler to verify the walls of the pedicle have not been breached and cancellous bone is felt through to the distal end of the prepared bony path.

4. **SCREW INSERTION**

After the pedicle pathway has been prepared and proper screw length and diameter have been determined, the appropriate implant is selected and loaded for screw insertion using the appropriate MESA Screw Inserter. The MESA Polyaxial Screws are inserted using the MESA Screw Inserter with the black sleeve. The MESA 360, Uniplanar, Deformity Uniplanar, and Foundation Screws are inserted using the MESA Screw Inserter with the green sleeve. It is important to grasp the implant by the screw shaft, while simultaneously applying an upward force to properly engage the screw. Inserters must be attached to a Handle before screw insertion. Ratcheting Handles are available in both Pear and T-Handle styles. The ratchet mechanism is selected by turning the metal portion of the Handle to the left or right to engage forward and reverse positions or in the neutral position to fix the ratchet.
**SCREW PLACEMENT**

MESA Polycocxial Screws may be used at the most proximal levels (T4 and T5) for ease of rod attachment and establishment of the proximal foundation. Otherwise, use MESA Uniplanar, Deformity Uniplanar, or 360 Screws throughout the spine. MESA Foundation Screws are also available to surgeons preferring to use them at the end of a construct for lumbosacral fixation.

**SCREW ADJUSTMENT**

Once the appropriate screw has been selected and inserted, the housing of the screw can be adjusted with the MESA Head Adjuster to accommodate the rod. Confirm the screw heads are unlocked and all screws are at appropriate levels and aligned to accept the rod when applied.
ROD PREPARATION

NOTE: A Rod Cutter does not come standard in the set and must be ordered separately.

Once all screws have been inserted, the rod is selected and cut to the appropriate length, if necessary. Both Cobalt Chrome and Titanium Alloy rods are available. The Rod Template may be used to help determine rod length. To cut the rod with the Open-Ended Telescoping Rod Cutter, insert it into the end of the Cutter and squeeze the handles together.

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

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

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

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

**CONCAVE ROD PLACEMENT**

Place Deformity Crickets on the concave side screws. These will later provide translation of the spine to the rod. Pre-bend the rods in the physiological sagittal plane. For ease of rod insertion, place Deformity Crickets on only the upper half 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 to pull the screws up to the rod.
CONCAVE ROD PLACEMENT (CONT.)
Rotate the rod into the sagittal plane. 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 25, and a Handle. Then, reduce the Deformity Crickets at least halfway at apical levels and tighten so they "kiss" the rod at all other levels.

COUNTERTORSION & AXIAL CORRECTION
If direct vertebral rotation is desired, apply Rotation Tubes on the Deformity Crickets at the apex of the curve on the concave side, and Manipulators to the convex apical screws to ease manipulation maneuvers during spinal vertebral derotation and translation. The Manipulators securely lock on the screws and place the screws into a partially locked state. Tubes and Manipulators should also be attached to the Lowest Instrumented Vertebra (LIV) to use as a counter-torque during derotation.

NOTE: The Manipulator Wrench can be used to help fully tighten the Manipulators.
COUNTERTORSION & AXIAL CORRECTION (CONT.)

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

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

THORACIC CONCAVE TRANSLATION

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

NOTE: Torsional Rod Reducers may be used during translational maneuvers.
CONVEX RIGHT ROD PLACEMENT

Remove the Rotation Tubes and Manipulators from the construct. Then, use the MESA Unlocker to unlock all convex apical screws where Manipulators have been applied. Place Deformity Crickets on the convex screws. The convex rod is introduced using the technique similar to the concave/corrective rod. Using the Rod Rotation Wrench or Vice Grip, hold the rod into the proper sagittal alignment. The top two Deformity Crickets are fully reduced. The remainder of the Deformity Crickets are then tightened sequentially to reduce the rod into the screws. If necessary, the rod contour may be adjusted using the Coronal or In-Situ Benders.

COMPRESSION/DISTRACTION

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

NOTE: Additional segmental Direct Vertebral Derotation can also be achieved at this time, if necessary.
**STEP 13**  
**PARTIAL LOCKER [SUPERFLY™]**

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

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**STEP 14**  
**IN-SITU ROD BENDERS**

**CORONAL ROD BENDERS**

**IN-SITU SAGITTAL & CORONAL BENDING**

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

**NOTE:** When using the Coronal Rod Benders, arrange the parts to ensure the female and male parts of the instrument mate. Always use a squeezing motion for coronal correction to ensure mechanical advantage. Do not pull instruments apart.
FINAL LOCKING

Fully lock each MESA Screw using the Quick Locker. Repeat final locking of each screw with the Quick Locker to confirm rigid fixation throughout. Confirm at least 5 mm of rod length extends beyond the most proximal and distal screws.

**NOTE:** The Quick Locker should be used to apply axial force only. It should not be used in compression, distraction, or rotational maneuvers.
Surgical Technique Steps

ROD CONNECTIONS
Lateral Offset Connectors
(Open & Closed; Variety of Angles)

The Lateral Offset Connectors may be used to link a screw lateral to a rod. The rodded portion of the lateral offset connector is seated in the implant housing and the other end is attached to the rod with set screws and final tightened at 90 inch-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

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

ROD CONNECTIONS
Axial Connectors

Axial Connectors may be used to join rods end-to-end. The implant is final tightened at 90 inch-lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.
Surgical Technique Steps

ROD CONNECTIONS
Parallel Connectors
Parallel connectors may be used to join rods parallel to one another. The implants come in closed-closed and closed-open styles. The closed-open style requires a set screw in the open portion. The implants are final tightened at 90 inch lbs using either the Torque Limiting Wrench or Torque Indicating Wrench.

TRANSVERSE CONNECTORS
Use the NATURAL BRIDGE® LP Caliper to measure the appropriate length between the two rods, and choose the best fitting transverse connector. The connectors are available in both semi-adjustable and adjustable designs. Grab onto the implant using the NATURAL BRIDGE LP Connector Holder. Ensure all connector set screws are adequately loosened to securely engage the rod. If using an adjustable connector, loosen the middle set screw. Utilizing the polyaxial head of the connector, snap one head onto the rod and provisionally tighten the set screw using the NATURAL BRIDGE LP Driver Shaft and Handle.
Surgical Technique Steps

TRANSVERSE CONNECTORS (CONT.)

Stabilize the transverse connector to snap the other polyaxial head onto the opposite rod. Provisionally tighten both heads with the NATURAL BRIDGE LP Driver. If using an adjustable transverse connector, adjust the appropriate length and provisionally tighten to secure the transverse connector to the construct.

Ensuring the implant is in the desired position, lock down the implant by final tightening every set screw to optimal torque using the NATURAL BRIDGE LP Driver Shaft and Handle.
Surgical Technique Steps

UNLOCKING & REMOVAL

Should the surgeon decide to unlock the MESA screw from partial or full lock, the Quick Unlocker may be used. Fully open the instrument and engage the docking feet into the detents of the medial side of the screw housing. Gently move the instrument down laterally until the distal portion of the instrument has properly engaged both the medical and lateral side of the screw housing. Fully squeeze the lever of the Unlocker. Once the screw is in the unlocked position, the rod may be extracted from the implant housing using the Power Puller. Apply the distal end of the Power Puller over the screw housing and rotate it in a clockwise direction until it securely engages the rod. Grab the handle and thread down in a controlled fashion in order to release the rod from the screw-head.

The T-Bar Screw Remover may be used to remove the MESA screw after it has been implanted. It is especially beneficial where a fusion mass is present and it may be difficult to insert a Size 2S Driver into the internal hex of the MESA screw. Lock the MESA screw without a rod in the screw housing. Attach a Fixed T-Handle to the T-Bar Screw Remover and slide the distal end of the T-Bar Screw Remover into the locked saddle of the MESA screw. Turn the T-Bar Screw Remover counter-clockwise until the screw disengages from the bone.
<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Catalog Number</th>
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<tbody>
<tr>
<td>Quick Locker</td>
<td>801-90008</td>
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<tr>
<td>Partial Locker (Superfly™)</td>
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<td>Quick Unlocker</td>
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<td>Dual Action Rod Reducer (Dragonfly™)</td>
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<td>Polyaxial Screw Inserter</td>
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<td>Deformity Screw Inserter</td>
<td>801-90053</td>
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<tr>
<td>Deformity Reduction Jack (Crickey™)</td>
<td>801-90066</td>
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<tr>
<td>MESA Manipulator</td>
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<td>Manipulator Wrench</td>
<td>801-90069</td>
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<td>Reduction Jack Rotation Tube</td>
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<tr>
<td>Reduction Jack Driver</td>
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<tr>
<td>Screw Head Adjuster</td>
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### Instrument Description Table

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<thead>
<tr>
<th>Instrument Name</th>
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<tr>
<td>Coronal Rod Benders, Right</td>
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<td>Torsional Rod Reducer, Left</td>
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<tr>
<td>French Rod Bender</td>
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<td>Rod Rotation Wrench</td>
<td>101-900259</td>
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<tr>
<td>Telescoping Rod Cutter</td>
<td>101-900358</td>
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<td>Deformity Rod Benders</td>
<td>101-900284</td>
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<tr>
<td>Butress Rings</td>
<td>101-85500D</td>
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<td>Rod Holder</td>
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<td>Parallel Rod Connector Inserter</td>
<td>101-90222</td>
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<tr>
<td>Rod Holding Forceps</td>
<td>101-90039</td>
</tr>
<tr>
<td>Rod Holder</td>
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</tr>
</tbody>
</table>
**IMPLANTS**

- **LATERAL OFFSET CONNECTOR 25 mm**
- **CLOSED LATERAL OFFSET CONNECTOR 25 mm**
- **LATERAL OFFSET CONNECTOR 50 mm**
- **CLOSED LATERAL OFFSET CONNECTOR 50 mm**
- **LATERAL OFFSET CONNECTOR 100 mm**
- **CLOSED LATERAL OFFSET CONNECTOR 100 mm**
- **PARALLEL CONNECTOR, 5.5 TO 5.5 mm (CLOSED/CLOSED)**
- **PARALLEL CONNECTOR, 5.5 TO 5.5 mm (CLOSED/OPEN)**
- **TWO-PIECE PARALLEL ROD CONNECTOR**
- **AXIAL ROD CONNECTOR**
- **SET SCREW**
- **400 mm ROD TEMPLATE**
- **CP Ti GRADE 3, 500 mm**
- **CP Ti GRADE 4, 500 mm**
- **TI ALLOY HEX END, 500 mm**
- **DUAL HEX COC ROD, 500 mm**

**TRANSVERSE CONNECTORS**

Unique catalog numbers exist for each connector size. Please contact your local sales consultant with any questions you may have about ordering the NATURAL BRIDGE Spinal System or implants.

**NOTE:** All connectors come in sizes shown.

**DESCRIPTION**

- **Parallel Connector, 5.5 to 5.5 mm (Closed/Open)** 101-8555SF
- **Two-Piece Parallel Rod Connector** 101-8555SC
- **Axial Rod Connector** 101-8555SD
- **Set Screw** 101-10001
- **400 mm Rod Template** 101-90143
- **CP Ti Grade 3, 500 mm** 107-A55500
- **CP Ti Grade 4, 500 mm** 106-A55500
- **Ti Alloy Hex End, 500 mm** 101-A55500
- **Dual Hex CoCr Rod, 500 mm** 111-A55500

**CATALOG NUMBER**

**DESCRIPTION**

- **Torque Limiting Handle, 3.5 N·m** 801-90183
- **NATURAL BRIDGE LP Driver Shaft** 101-90278
- **NATURAL BRIDGE LP Caliper** 101-90281
- **NATURAL BRIDGE LP Connector Holder** 101-90220
SCREWS

DIAMETERS (mm): 4.5, 5.5, 6.5, 7.5, 8.5

**MESA 360°**

**MESA UNIPLANAR**

**MESA POLYAXIAL**

**MESA DEFORMITY UNIPLANAR**

**MESA FOUNDATION**

<table>
<thead>
<tr>
<th>SCREW COLORS BY LENGTH</th>
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<tr>
<td>Size</td>
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<td>40 mm</td>
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<tr>
<td>45 mm</td>
</tr>
<tr>
<td>50 mm</td>
</tr>
</tbody>
</table>

**SCREWS**

**DESCRIPTION**

MESA 360° (not standard)
MESA Uniplanar (not standard)
MESA PolyaXial
MESA Deformity Uniplanar
MESA Foundation (not standard)
ATR Set Screw

*See note

*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® Deformity Spinal System implants.
MESA: Deformity Spinal System

5. Implanting metals and alloys in the body subjects them to a constantly changing environment of salts, acids and alkaline media which can cause corrosion. This can cause the device to fail or be destroyed. The device must be in contact with each other can accelerate the corrosion process which in turn can cause the implant to fail. To prevent this effort should be made to use compatible metals and alloys. Fretting or wear on the metal to metal interface can cause the metal component to rotate and allow the corrosive agents to be released. This can cause the corrosion process and may lead to the generation of wear debris which can then be associated with inflammatory responses.

6. The KCM spinal implants are intended to provide temporary stabilization. If an implant remains in situ long after complete healing it can actually increase the risk of fracture in an already injured spine. 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 MRI environment. This device has not been tested for heating or migration in the MRI environment.

ADDITIONAL WARNINGS AND PRECAUTIONS FOR PEDIATRIC PATIENTS:

1. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

2. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletal immaturity. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screws malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may present specific challenges. A small pedicle diameter, or may be at risk for rotational spinal deformity (the "corkscrew" phenomenon) due to continued developmental growth of the anterior spine. Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or may also occur in pediatric patients and pediatric patients may be at increased risk for injury due to their smaller stature.

3. The use of the KCM Spinal System in pediatric patients should be performed only by experienced spine surgeons with specific training in the use of this pedicle screw system because this is technically a demanding and high risk procedure. The surgeon should refer to the product labeling for details on use of this spinal system and its instrumentarium 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 Fixation

1. Patience selection and compliance is extremely important. Based on following the manufacturer's instructions and using correct size and orientation of the device insertion tool the surgeon will be able to safely and effectively implant the device into the spinal canal. It is recommended to be substantially equivalent to predicates devices however, the physician/surgeon should consider the levels of implantation, patient weight, and the anatomic features of the patient. The implant may remain in the bone for up to 15 days of use. This is unrestricted for hours in the bone with possible neurologic damage, usually attributable to permanent neurologic injury. This may also cause mild to severe pain and discomfort, and more prolonged healing and fusion time. Painful or discomfort and pain may also cause extensive damage to the bone and surrounding tissues. In some cases the patient may or may not be aware of the pain or discomfort. Prolonged pain and discomfort may lead to a delay in achieving fusion. The patient should be informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure.

2. The risk of potential adverse events associated with the use of this device system which may include severe pain, discomfort, or pain. The patient may or may not be aware of the pain or discomfort. Prolonged pain and discomfort may lead to a delay in achieving fusion. The patient should be informed of the potential risks and adverse effects before undergoing the procedure.

3. The surgeon should ensure that the patient is informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously ad- vised in Contraindications and Warnings and Precautions should be avoided.

2. Preoperative testing (simple and where necessary, retreat testing) should be performed to assess the patient for any possibility of surgical planning or concomitant medication. This includes a thorough medical history and physical examination, and a complete review of systems. The procedure may be altered or contraindicated in the presence of certain conditions, as determined by the surgeon.

3. Care should be taken to ensure that the patient is in an appropriate condition for the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure. The patient should be informed of the potential risks and adverse effects before undergoing the procedure.

4. Adequate inventory of implant sizes should be available at the time of the surgical procedure.

5. All components should be cleaned and sterilized before use.

6. Prior to implantation, each component should be inspected visually for any evidence of damage, obstruction, or contamination before use. Each component should be tested and sterilized as necessary.
PRODUCT CATALOG

OPERATIVE
1. The primary goal of this surgery is to orthotropically correct vascular problems. Adequate exposure, bone preparation and grafting are essential to achieving this goal.
2. Rods may be prone to the degree of correction determined by preoperative testing. However, reverse bends should be avoided.
3. The use of two rods and crossovering the rods will provide a more rigid construct.
4. The placement of the 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 shielding bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of re-fracture 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 re-fracture.
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 possibility 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.

SYMBOL KEY

�单 Caution: Consult Accompanying Documentation

卄 Consult Instructions For Use

卑 Do Not Reuse

PD05-2EN-00 Rev. 0
K2M Inc. 701 Miller St. SE
Leesburg, VA 20175
1.571.919.2000