MANTIS Redux
Surgical Technique

- True percutaneous screw and rod system
- Direct visualization
- Precise rod contouring allows multiple levels
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Introduction

One primary objective of Stryker Spine’s Less Invasive Technologies (LITe) is to replicate the clinical results of the corresponding open procedure.

At the moment there is insufficient data to show that minimally invasive spine surgery provides any short and long term benefit to patients when compared to traditional spine surgery.

Important

This Surgical Technique sets forth detailed, recommended procedures for using the MANTIS Redux Spinal System. It offers guidance that you should heed but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any Stryker implant or instrument.

Note: No acid or alkaline solvents should be used in the cleaning of anodized components.

Note: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.

Acknowledgments

Stryker Spine wishes to thank the following physicians for authoring this surgical technique.

Dan Cohen, MD

Nils Hansen-Algenstaedt, MD

Terrence Julien, MD

Reginald Knight, MD

Jeffrey Roh, MD
### Key Design Features

<table>
<thead>
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<th>Device</th>
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| **Titanium Polyaxial Reduction Screws** | 1) 4.5mm x 25-45mm  
2) 5.5mm x 30-55mm  
3) 6.5mm x 30-60mm |
| **Xia 3 Bone Screw** | Cannulated Xia 3 design offers a much more rigid connection to the screwdriver. |
| **Intraoperative Rod Options** | Accepts Titanium and Vitallium rods in 5.5mm and 6.0mm diameters. |
| **Low Profile** | The tulip is lower profile than the MANTIS screwhead when broken off. |
| **Spondy Reduction** | The surgeon should be able reduce a spondy with the implant. |
| **Guaranteed Rod Seating** | Provides for a larger margin of error when introducing the rod. The surgeon can use the implant to fully seat the rod every time. |
| **Reduction Tab Removal Instrument** | Self guiding instrument that can be used to break off and remove tabs percutaneously. |
Patient Positioning

MANTIS Redux can be used under local, epidural, spinal or general anesthesia. General anesthesia is commonly used since it is the most comfortable for the patient and allows immediate postoperative neurological assessment.

- The patient is prepped and draped in the usual sterile manner for posterior fusion with pedicle screw fixation.

Markings

- Using A/P imaging, place the **K-Wire** transversely across the mid-line of the cephalad pedicles.
Repeat for additional pedicles.
Carefully determine the appropriate entry point and trajectory for the **MANTIS Redux Screw**.

- For pedicle screws, the entry point is approximately 4cm off mid-line with a more lateral trajectory.
- Incise the skin. A fascial incision may be done to make tissue dilation easier.

Note: If tissue dilation is difficult, increase the fascial incision.

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**K-Wire Insertion**

- Insert the **Jam Shidi** through the skin incision to the intersection of the facet and transverse process.
- Confirm that the appropriate pedicle starting place has been determined using both A/P and lateral images.

**Note:** The diameter of the MANTIS K-Wire is 1.3mm.

**Note:** The Radius K-Wire is not compatible with the MANTIS Spinal System.

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- Use the Jam Shidi needle to gain access to the pedicle.
- After placing the Jam Shidi at the intersection of the facet and the transverse process, the needle may be advanced partially through the pedicle using the **Slap Hammer**.
As the pedicle is navigated with the Jam Shidi, it should approach the medial wall of the pedicle on the A/P view and should approach the base of the pedicle on the lateral view.

When the needle reaches the medial wall on the A/P view, verification needs to be performed in the lateral view to ensure that the needle is past the base of the pedicle.
Remove the inner trocar of the Jam Shidi.

The removal of the Jam Shidi inner trocar allows the K-Wire to be inserted into the pedicle.

Caution should be practiced with regard to the position of the K-Wire in order to avoid the advancement of the K-Wire.

Note: The K-Wire is a single use instrument.

Note: The Radius K-Wire is not compatible with MANTIS products.

Use the K-Wire Guide Tube to prevent the K-Wire from bending or moving during insertion.

Place the K-Wire Guide Tube over the K-Wire and dock on the Jam Shidi.

Use the Slap Hammer to impact the K-Wire.
Once the K-Wire is inserted, remove the outer shaft of the Jam Shidi.

Hold the K-Wire in position when removing the Jam Shidi.

**Instrument Bar**

10 Gauge, 9 inch 48237110
10 Gauge, 5 inch 48237105
11 Gauge, 5 inch 48237115
13 Gauge, 5 inch 48237135

Jam Shidi

<table>
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<tr>
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K-Wire

**48230235**

K-Wire Guide Tube

**48237120**

Slap Hammer
Dilation

- Place the Slim Dilator over the K-Wire, through the incision.

- Advance the Slim Dilator, over the K-Wire, through the tissue twisting clockwise while directing it toward the pedicle.

- The Slim Dilator is advanced through the lumbodorsal fascia.

- Location of the Slim Dilator is confirmed using imaging.

- Note the depth marking of the Slim Dilator in relation to the skin.

Note: Feel, fluoroscopy, anatomical knowledge, review of preoperative images and partial visualization may all contribute towards desired instrument placement accuracy.

Note: The dilators have depth markings laser-etched which correlate to the blade lengths.

- Choose a Redux Blade length based on where the top of the skin meets the Slim Dilator.

Note: If the skin is exactly on the marking on the Slim Dilator, choose the longer blade size.

- Sequentially slide Dilator 2, Dilator 3 and the Hollow Dilator over the Slim Dilator to sequentially penetrate and gently dissect soft tissue down to the pedicle.

- Twist the dilators clockwise during insertion to engage the thread features.
Remove the initial dilators after inserting the **Hollow Dilator**.

The Hollow Dilator remains in place as the working channel for pedicle preparation.
**Pedicle Preparation**

- With the Hollow Dilator still in place, prepare the pedicle by placing the **Cannulated Modular Awl** over the K-Wire and impact into the pedicle with a twisting motion.
- Hold the K-Wire in position when removing the awl.
- Use the cannulation of the Slap Hammer to impact the awl.

**Note:** The awl has a stop at 12mm.

- If the bone is too hard, the appropriate tap may be used to prepare the pedicle.
- The **Cannulated Modular Taps** are calibrated with the **Tap Sleeve** and laser etched with 5mm intervals to help indicate the depth at which the tap has been inserted. This is designed to help determine proper screw length.

**Note:** The length of the taps thread is 25mm.

**Note:** The Cannulated Modular Taps are calibrated with the MANTIS Tap Sleeve. This measurement technique will not work with the **Xia Precision Tap Sleeve**, as it is shorter.

- As an instrument advances into the pedicle, the proximal end of the instrument will move relative to the markings on the K-Wire. If this does not occur, the surgeon should stop and fluoroscopy should be used to verify the position of the K-Wire.

**Note:** 1cm interval markings on the K-Wire provide the cannulated instruments change in depth in the pedicle.
Check pedicle depth with either fluoroscopy or read the depth from the Tap Sleeve as it moves along the proximal edge of the tap. There are markings at 30mm, 40mm and 50mm.

**Note:** The Tap Sleeve is made of radiolucent Ultem Poly Ether Imide.

**Note:** Slide the Tap Sleeve proximal to the tap shaft to engage the friction fit. This prevents the Tap Sleeve from sliding off the tap.

Hold the K-Wire in position when removing the tap.

The Hollow Dilator can now be removed. Hold the K-Wire in position when removing the Hollow Dilator.

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<td>Tap Sleeve</td>
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Screw Insertion

With the pedicle pathways prepared and proper screw length and diameter selected, the screw is prepared for insertion.

Assemble each pair of Redux Blades into the Redux Screw.

- Orient the screw so that the tulip posts are pointing up.
- Insert the appropriate size blade into each side of the tulip posts and spread apart.

**Note:** Blade size is chosen from the measurement taken from the dilator.

- Orient the Sliding Ring with the flat side down.
- Insert the blades through the bottom of the Sliding Ring.
- Repeat this process for additional screws.

**Note:** If a lower profile is desired, the Slim Ring may be used as an alternative to the Sliding Ring.

**Note:** The MANTIS Redux Blades are not compatible with the MANTIS Persuader.
The MANTIS Redux Screws have 3 cutting flutes to allow a surgeon to eliminate the tapping step. The screws may be inserted immediately after the K-Wire is introduced. However, in most cases, tapping is recommended.

The 6 point star Screw head is designed:
- For faster and intuitive engagement with the Screwdriver.
- To prevent screwhead stripping.
- For reengagement for screw adjustments.

See Catalog
Long Arm PA Screw

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<td>Size 5</td>
<td>11-13cm</td>
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Redux Blade

48281201
Slim Ring

Sharp 48230230
Blunt 48230231
K-Wire
The Polyaxial Screwdriver provides a rigid connection between the screws and the screwdriver.

A primary design goal of the MANTIS Redux system is to improve the connection between the screwdriver and screws. The screwdriver is improved to decrease toggle at 2 integral points of connection:

- Screwdriver to Screw Interface
- Screwdriver to Shaft Interface

The locking feature provides tactile, visual and audible confirmation that the screwdriver is securely locked.

The Polyaxial Screwdriver can be connected to the following Handles:

<table>
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<td>T-Handle Non-Ratchet</td>
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<tr>
<td>48289305</td>
<td>Round Handle Non-Ratchet</td>
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</table>
To assemble the Polyaxial Screwdriver:

**Step 1**
Press the “UNLOCK” button on the outer shaft.

**Step 2**
Insert the Shaft for Polyaxial Screwdriver down the outer shaft.

**Step 3**
Slide the sleeve for the screwdriver up the inner shaft. Verify the sleeve for screwdriver is completely bottomed out.
**Step 4**
Align the tabs and fully insert the quick connect mechanism into the shaft.

**Figure 29**

**Step 5**
Hold the screw by the threads and engage the tabs on the inner shaft onto the saddle of the screw head.

**Figure 30**

**Step 6**
Fully seat the inner shaft into the screwhead. Turn the outer shaft clockwise using the “LOCK” button until the threads are fully engaged.

**Figure 31**

**Step 7 (Optional)**
If the ratchet sound is not present, confirm locking by pressing the “LOCK” Button.

**Figure 32**
Place the screwdriver over the K-Wire and insert into the pedicle.

After driving the screw into the pedicle, remove the K-Wire to prevent it from advancing.
Be certain that the screw is not inserted too far. If the polyaxial head of the screw is driven to forcefully against bone, it will lose its polyaxial capabilities making it difficult to connect the assemblies during subsequent steps.

**Note:** Use imaging and monitoring, as preferred, for added information during bone screw insertion.

To disengage the screwdriver from the screw, press and release the “UNLOCK” button. Rotate outer shaft counter-clockwise while firmly holding the handle.

Repeat the process for additional screws.

---

**Screw Alignment**

- Insert the **Rod Contouring Shafts** into the screw head. The Rod Contouring Shafts should be firmly seated into the screw heads.

**Note:** The laser markings on the Rod Contouring Shafts correspond to the blades to indicate that the shafts are properly seated.

**Note:** It is recommended to use the Rod Contouring Shafts when manipulating the screw heads.

**Note:** The polyaxial bone screws may provisionally lock upon insertion. With the Rod Contouring Shafts in place, rotate the blades to unlock the heads before introducing the rod.

---

**Screw Adjustment**

The screw heights may be adjusted as needed using the **Poly Adjustment Driver**. Use fluoroscopic images to confirm.

The Poly Adjustment Driver can be inserted through the cannulas of the Rod Contouring Shafts.
Align the Rod Contouring Shafts so that they are parallel.

Attach the Rod Contouring Linkage to the Rod Contouring Shafts. As needed, attach additional Rod Contouring Linkages, alternating sides.

Lock the Rod Contouring Linkages into place by twisting the wing nut clockwise. The indicator should be flush on top.

Note: By locking the Rod Contouring Shafts in parallel, the top of the shafts reproduce the relative spacing of the screws above the skin.

Note: If the distance between screws is too great, use the Extended Rod Contouring Linkage.
Rod Insertion

- Attach the appropriate MANTIS Rod to the Rod Inserter. Lock the rod into position by twisting the knob clockwise.

**Note:** Match the laser mark on the rod with the slot on the Rod Inserter during assembly to ensure that the rod and Rod Inserter are aligned in the same plane.

**Warning:** Do not tighten the Rod Inserter without a rod in place. Tightening without a rod in place may damage the Rod Inserter.

**Note:** In order to insert a 5.5mm rod, the Rod Gripper should be used.

**Note:** The Rod Inserter is laser marked along the shaft to indicate when the rod is locked in place.

- Insert the rod percutaneously from either the cephalad or caudal side through the blades. Using direct visualization, guide the rod through each pair of blades.

**Note:** The rod is to be inserted from the open side of the Sliding Ring.
Note: The rod should overhang the screw by 4mm.

- The Rod Gripper may be used for adjustment of the rod.
- Insert the Rod Gripper down the blades. Squeeze the handle to engage the rod.
- Manipulate the rod as needed.
Blocker Inserter

- Use the Counter Torque Tube as an insertion tube to facilitate alignment of the Blocker with the tulip.

**Note:** The laser markings on the Counter Torque Tube correspond to the blades to indicate that the instrument is properly seated.

- Slide the Blocker Inserter and Blocker through the Counter Torque Tube and into the screw head.

**Note:** It is recommended to insert the most distal Blocker first.

- Rotate the Blocker clockwise to seat the blocker.
- Repeat for other bone screws.

**Note:** The Blocker Inserter is not intended to be used for final tightening.

- Once the rod is sufficiently captured in the screws, detach the Rod Inserter from the rod by turning the knob on the Rod Inserter counter-clockwise.

**Note:** The Rod Inserter Inner Shaft is laser marked to indicate a locked and unlocked position.

**Note:** The Rod Inserter is to be removed along the axis of the rod.

Compression and Distraction

- To achieve compression and distraction, insert the Compression & Distraction Shaft and Compression & Distraction Hinge through the blades and into the screw heads.

- Note the laser marking on the shafts to ensure that the shafts are fully seated.

**Note:** The Compression & Distraction Shaft and Hinge are to be oriented so that the eyelets are located on the outside.
Mate the tops of the Compression & Distraction Shaft and Hinge using the connecting feature.

To distract, insert the Distractor into the eyelets of the Compression & Distraction Shaft and Hinge. Squeeze the Distractor to apply the appropriate distraction.
To compress, insert the **Compressor** into the eyelets of the Compression & Distraction Shaft and Hinge. Squeeze the Compressor to apply the appropriate distraction.

**Note:** The Compression & Distraction Shaft and Hinge are cannulated to allow for Blocker introduction.

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**Construct Tightening**

Once the correction procedures have been carried out and the spine is fixed in satisfactory position, the final tightening of the Blocker is done by utilizing the Counter Torque Tube and **Torque Wrench**.

- Dock the Counter Torque Tube on the screw.
- Note the depth markings on the Counter Torque Tube to ensure that it is fully engaged with the screw.
- Insert the Torque Wrench into the Counter Torque Tube to engage the Blocker.
- Line up the two arrows on the Torque Wrench to achieve the best possible torque of 12Nm for final tightening of the implants.

**Note:** The Counter Torque Tube must be used for final tightening. The Counter Torque Tube performs two important functions:

1. It allows the Torque Wrench to align with the axis of the tightening axis.
2. It allows one to apply the torque needed to lock the implant assembly without applying the torque to the rest of the construct.

**Note:** If the Counter Torque Tube cannot be easily removed from the implant head, the rod may not be fully seated.

**Note:** The Xia Torque Wrench is not compatible with MANTIS Redux.
Tab Removal

Once final tightening has taken place, the MANTIS Redux screw tabs are broken off. A snap line allows a clean and easy break.

- Remove the Sliding Ring from the blades by pulling up.

Slide the Tab Breaker over the blades and over the MANTIS Redux screw tabs.
The Tab Breaker is rocked in a back and forth motion to break the screw tab.

- The Tab Breaker will retain both the blades and the screw tab.

The Tab Breaker is removed from the incision.

- Remove the blade and screw tab from the Tab Breaker.

- Repeat for all other screws.

Note: The tab breaker has a large window to hold the blade during removal.
Closure

Examine the site for bleeding.

If accessible, close the fascia with one or two interrupted sutures. The subcutaneous tissue is closed in an inverted manner. A subcuticular closure is performed. Cover the skin edge with clear waterproof dressing.
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Indications

**MANTIS & MANTIS Redux Spinal Systems**
The MANTIS & MANTIS Redux Spinal Systems are intended for percutaneous, posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.
The Titanium & VITALLIUM rods from the Stryker Spine RADIUS Spinal System are intended to be used with the other components of MANTIS & MANTIS Redux Spinal Systems.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

Information for Patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is
involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

**Removal of Implants**

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

**Cautions and Warnings**

**Warning (U.S.A.)**

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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, 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.

**Precautions (U.S.A.)**

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. Based on the fatigue testing results, 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 the system.
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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Literature Number: TLMANST09111
MSGS XSm 11/09
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