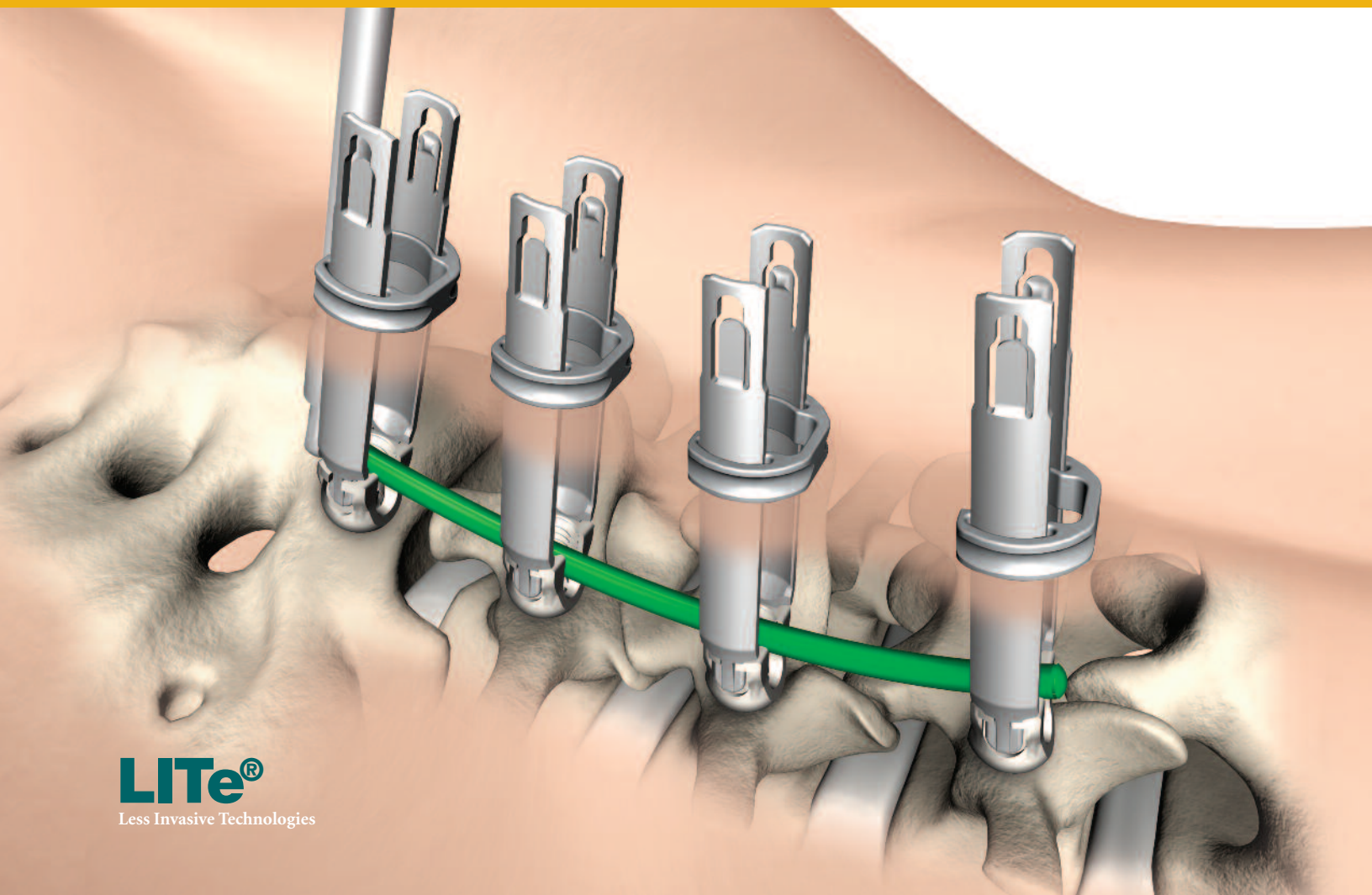
stryker

Spine

MANTIS® Spinal System
Surgical Technique



LITe®
Less Invasive Technologies

MANTIS
Surgical Technique

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Acknowledgments

Stryker Spine wishes to thank the MANTIS Surgeon Panel for their dedication to the development of the **MANTIS Spinal System**.

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Introduction

One primary objective of Stryker Spine 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 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.

Key Design Features

True percutaneous approach

- Stab incisions needed only for screw insertion

Supports multi-level procedures

- Scalable for degenerative and deformity applications

Direct Visualization

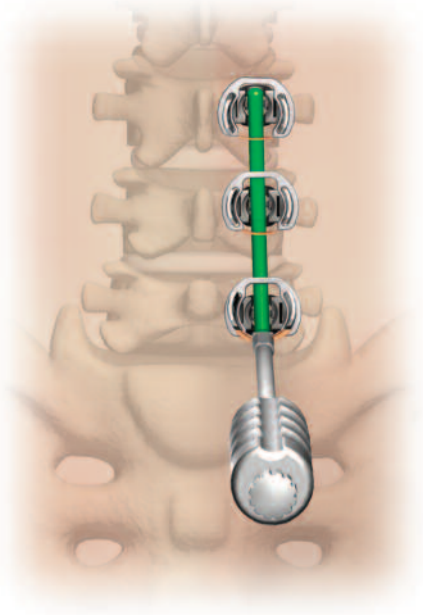
- Rod is seated under direct visualization

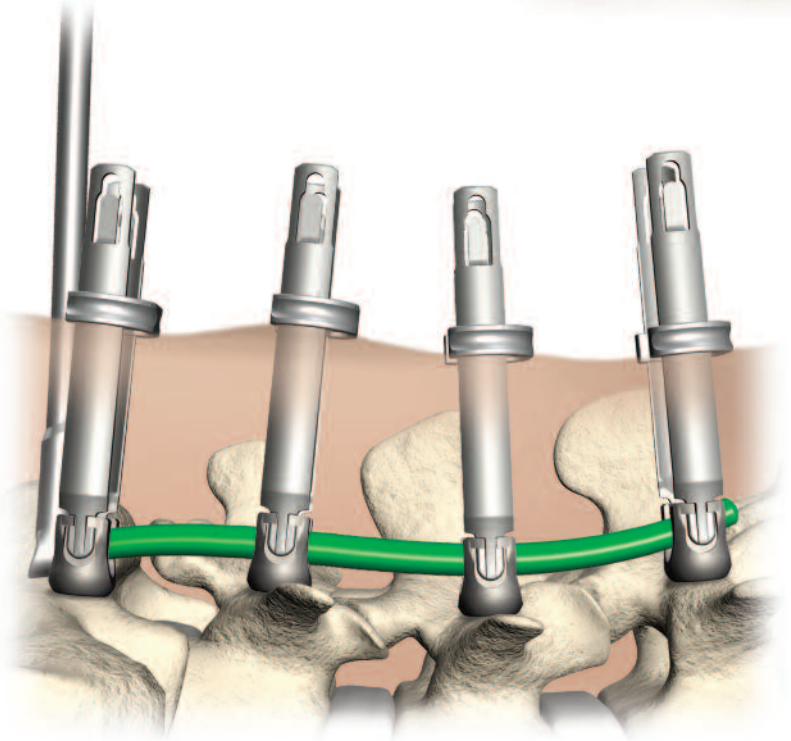
Precise rod contouring before rod insertion

- Allows rod bending to fit anatomy

Un-constrained rod insertion

- Rod insertion controlled by surgeon not system





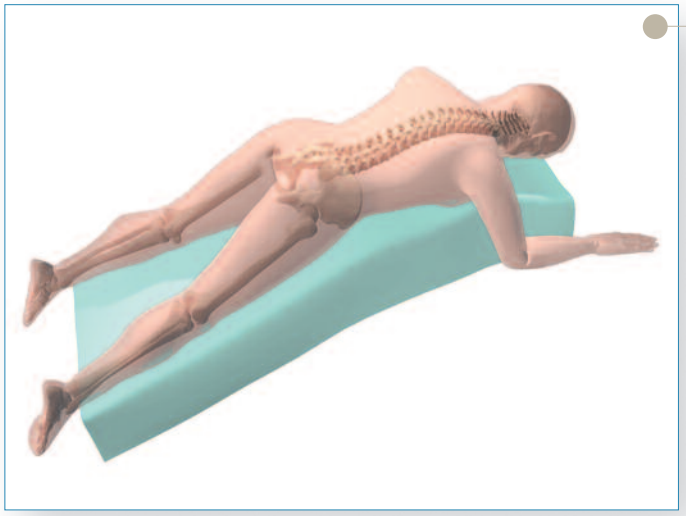


Figure 1

Patient Positioning

MANTIS 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.

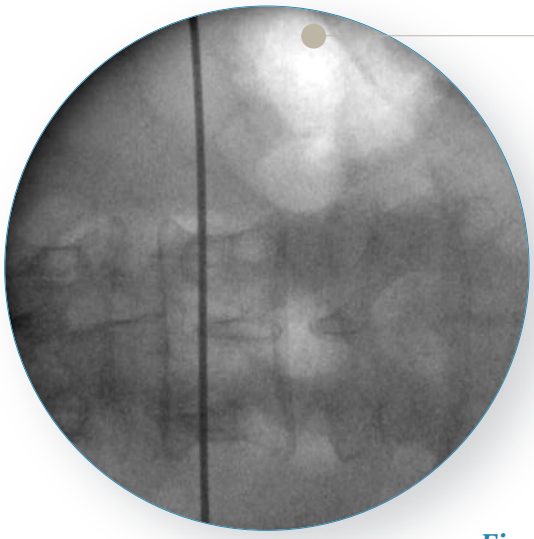
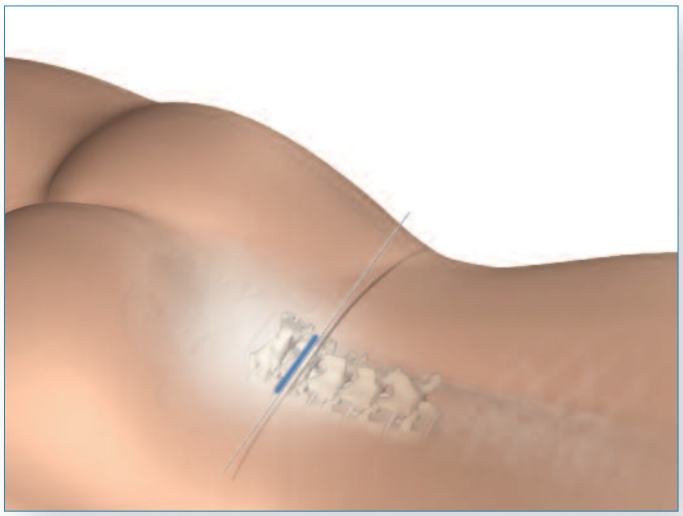


Figure 2

Markings

- Using A/P imaging, place the **K-Wire** (**Sharp - 48230230, Blunt - 48230231**) transversely across the mid-line of the cephalad pedicles.



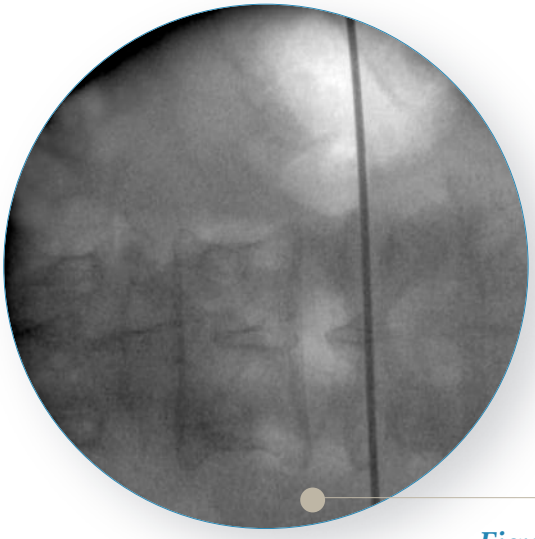


Figure 3

▶ Repeat for the caudal pedicles.

Instrument Bar

Sharp 48230230
Blunt 48230231
K-Wire

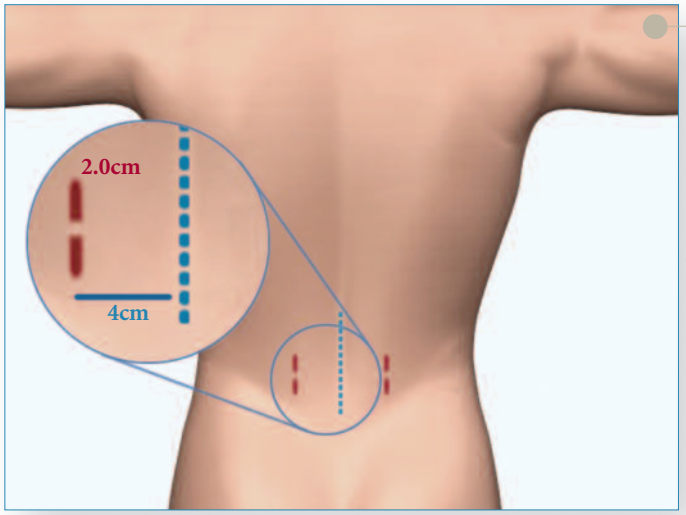


Figure 4

Carefully determine the appropriate entry point and trajectory for the **MANTIS Screw / Retractor Assembly**.

- For pedicle **Screws**, the entry point is approximately 4cm off mid-line with a more lateral trajectory.
- Incise the fascia to make tissue dilation easier.

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

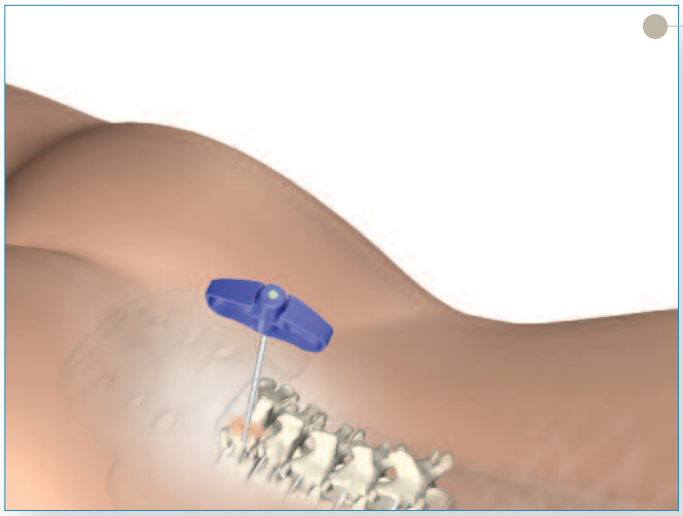


Figure 5

K-Wire Insertion

- Insert the **Jam Shidi 48237 (105), (110), (115), (135)** 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 Radius **K-Wire** is not compatible with the **MANTIS Spinal System**.

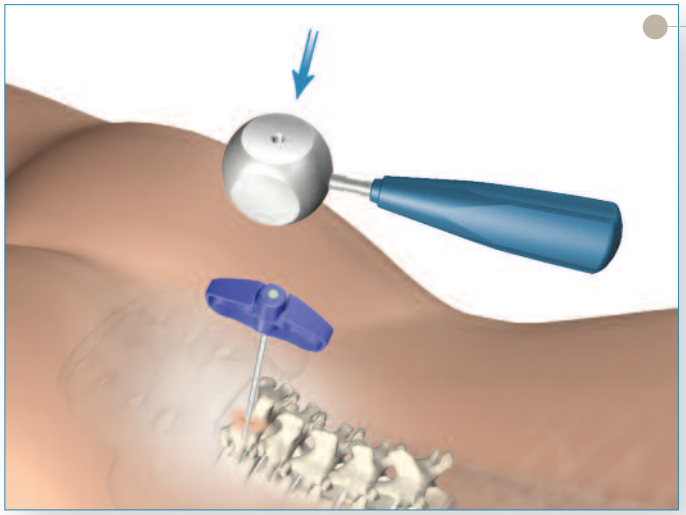


Figure 6

- 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 (48237120)**.

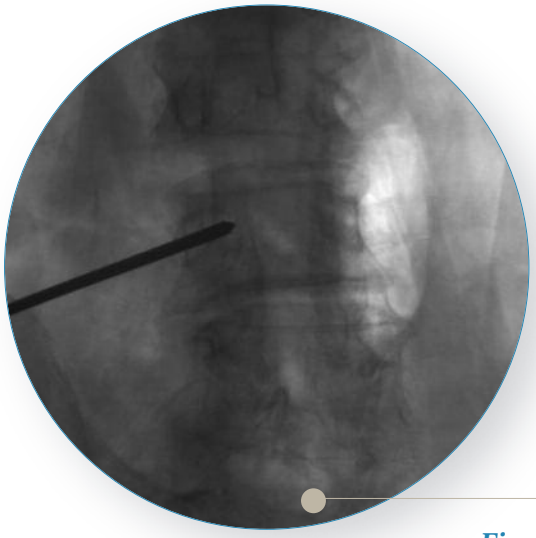


Figure 7

- 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.

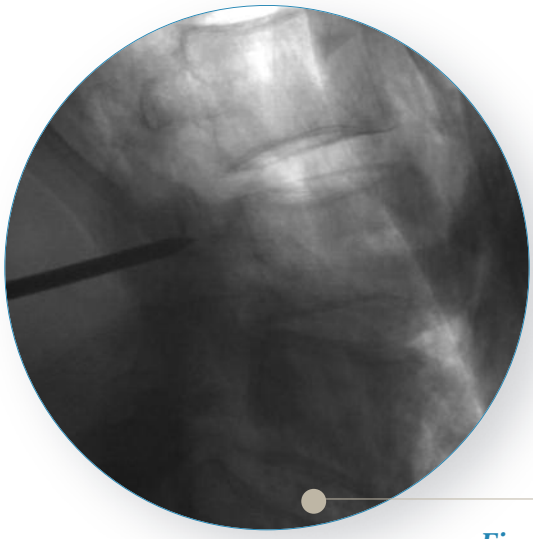


Figure 8

- When the needle reaches the medial wall on the A/P view, verification needs to be performed in the lateral view to ensure the needle is past the base of the pedicle.

Instrument Bar

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

Jam Shidi

48237120

Slap Hammer

Sharp 48230230
Blunt 48230231

K-Wire

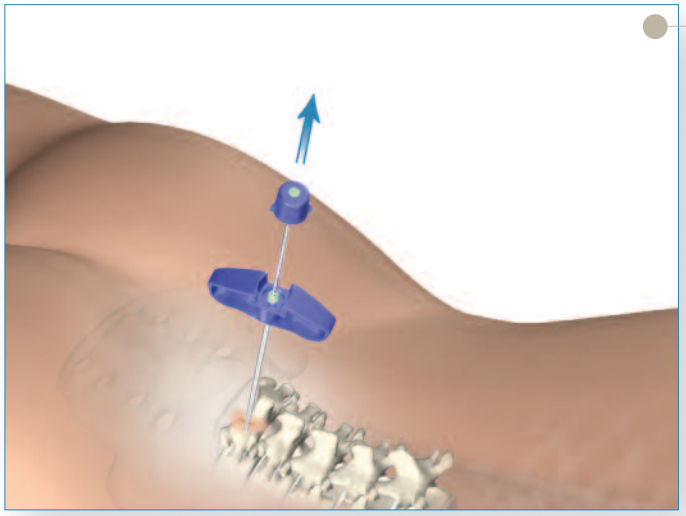


Figure 9

- Remove the inner trocar of the **Jam Shidi**.

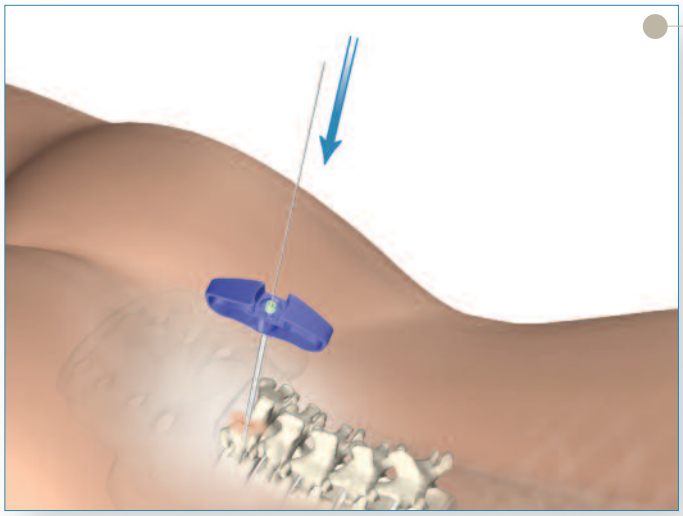


Figure 10

- 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 1.3mm in diameter.

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

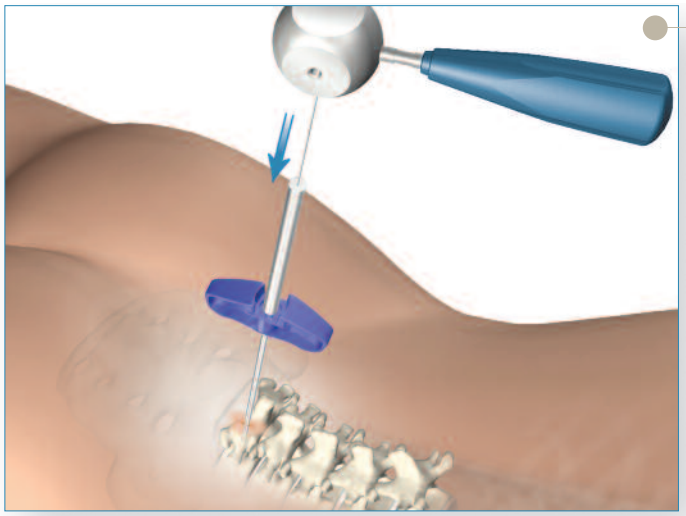


Figure 11

Use the **K-Wire Guide Tube** (**48230235**) 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**.

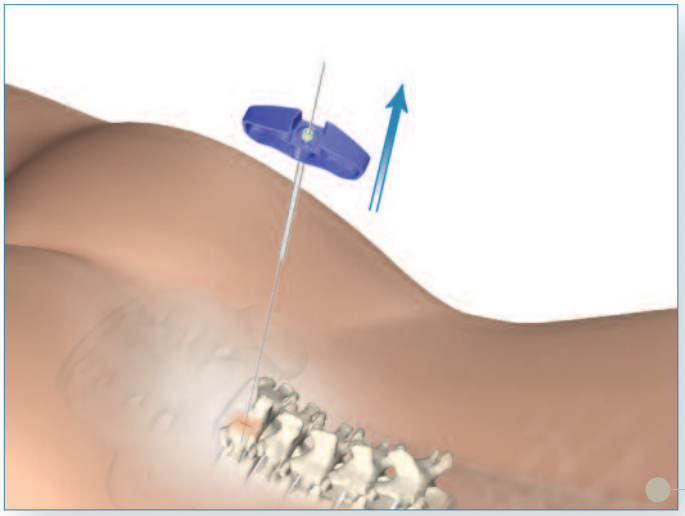


Figure 12

- 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

Sharp 48230230
Blunt 48230231
K-Wire

48230235
K-Wire Guide Tube

48237120
Slap Hammer

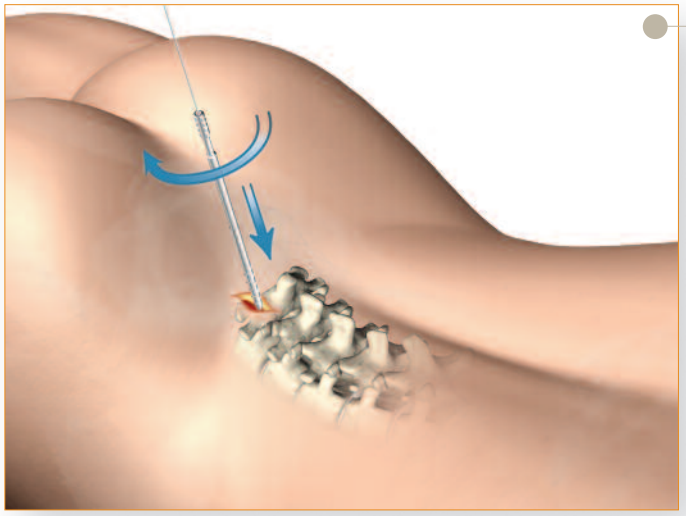


Figure 13

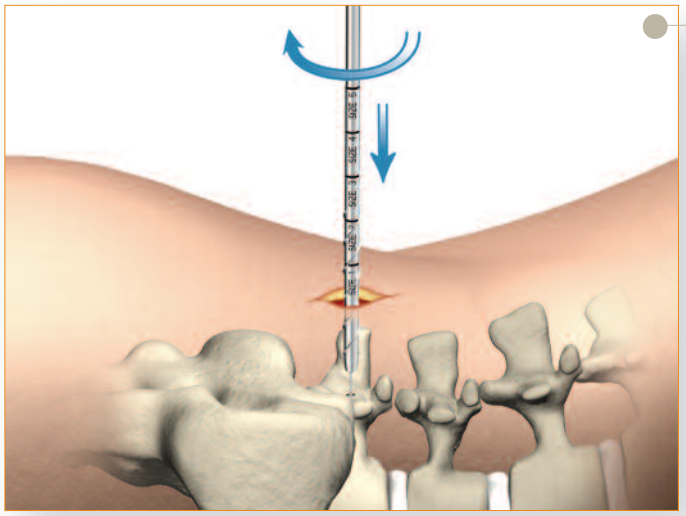


Figure 14

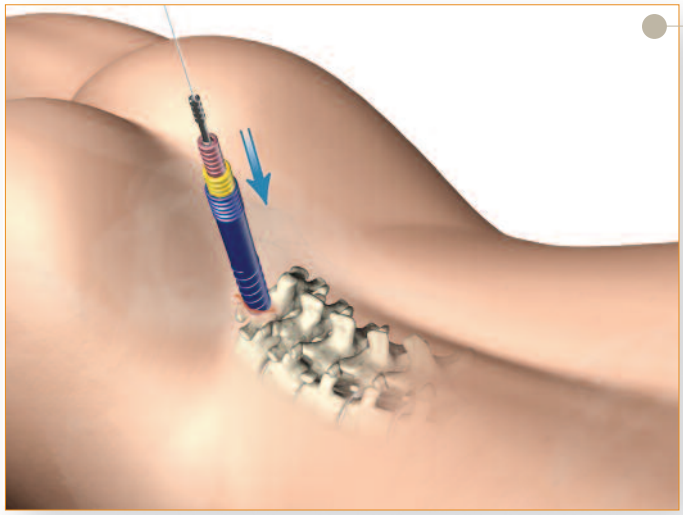


Figure 15

Dilation

- Place the **Slim Dilator (48280105)**, 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: Feel, fluoroscopy, anatomical knowledge, review of preoperative images, and partial visualization may all contribute towards desired instrument placement accuracy.

Note: The depth marking of the **Slim Dilator** in relation to the skin.

The **Dilators** have depth markings (1, 2, 3, 4 and 5) laser etched which correlate to the **Retractor Blade** lengths.

Choose a **Retractor Blade** length **48281 (035), (057), (079), (911), (113)** based on where the top of the skin meets the **Dilator**.

Note: If the skin is on the marking on the **Dilator** choose the next longest Blade; (i.e., depth marking is exactly "2" on the **Dilator**, use # 3 **Retractor Blade**).

- Sequentially slide the **Dilator 2 (48280106), Dilator 3 (48280107) and the Hollow Dilator (48280102)** 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.

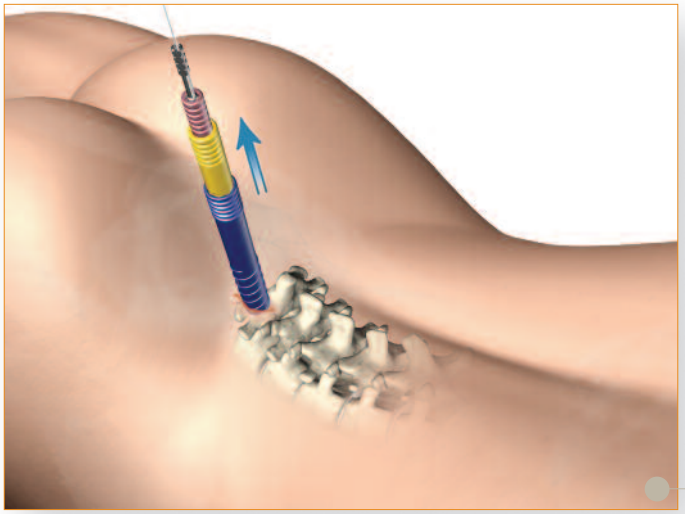


Figure 16

- Remove the initial Dilators after inserting the **Hollow Dilator**.
- The **Hollow Dilator** remains in place as the working channel for pedicle preparation.

Instrument Bar

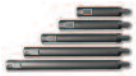
48280105

Slim Dilator

Sharp 48230230
Blunt 48230231

K-Wire

Size 1	**3-5cm**	**48281035**
Size 2	**5-7cm**	**48281057**
Size 3	**7-9cm**	**48281079**
Size 4	**9-11cm**	**48281911**
Size 5	**11-13cm**	**48281113**



Retractor Blade

48280106

Dilator 2

48280107

Dilator 3

48280102

Hollow Dilator

Figure 17

Pedicle Preparation

- With the **Hollow Dilator** still in place, prepare the pedicle by placing the **Cannulated Modular Awl (48281164)** 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 12.0mm.

Figure 18

- If the bone is too hard, the appropriate **Tap** may be used to prepare the pedicle **Screw** canal.
- The **Cannulated Modular Taps (4.5mm – 48281161, 5.5mm – 48281165, 6.5mm – 48281166, 7.5mm – 48281167)** are designed to be used with the **Tap Sleeve (48281315)** and laser etched with 5.0mm intervals to help indicate the depth at which the **Tap** has been inserted as well as to help determine proper **Screw** length.

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

Note: The **Cannulated Modular Taps** designed to be used with the **Tap Sleeve**, not the **Hollow Dilator**.

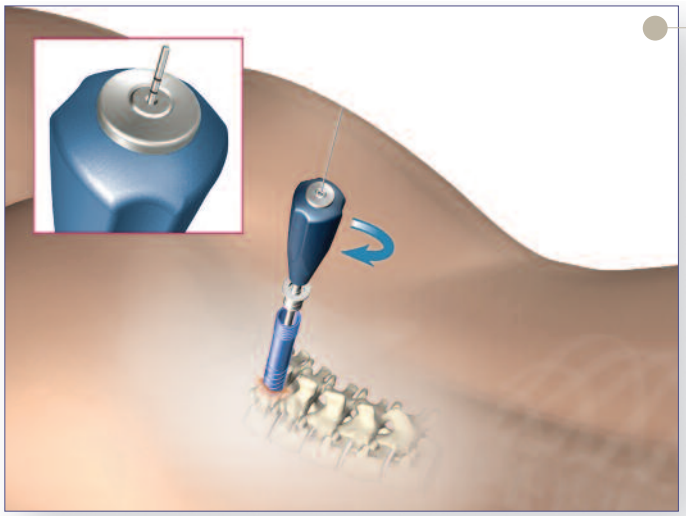


Figure 19

- 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 during insertion the procedure should be stopped and fluoroscopy should be used to verify the position of the **K-Wire** in relation to the **Cannulated Modular Awl** or **Cannulated Modular Tap**.

Note: 1.0cm interval markings on the **K-Wire** provide the cannulated instruments change in depth in the pedicle.

Note: Cantilevering the Awl and Taps while in the pedicle may damage the instrument.

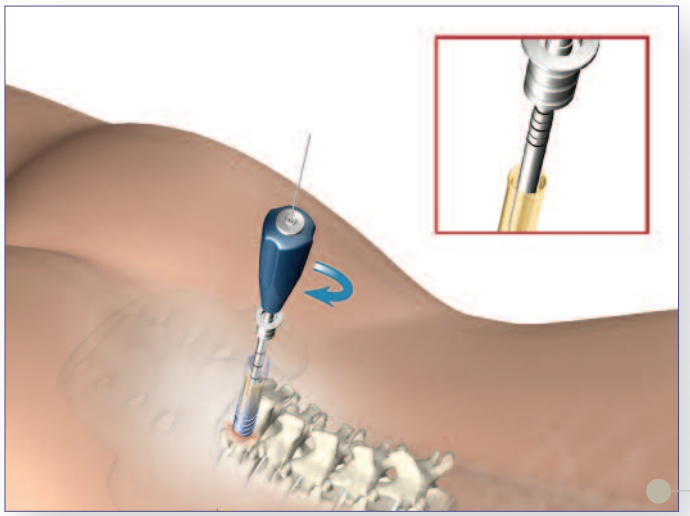


Figure 20

- Check pedicle depth with either fluoroscopy or read the depth from the **Tap Sleeve** as it moves along the proximal edge of the **Tap Sleeve**. There are markings at 30, 40 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 **Cannulated Modular Tap**.

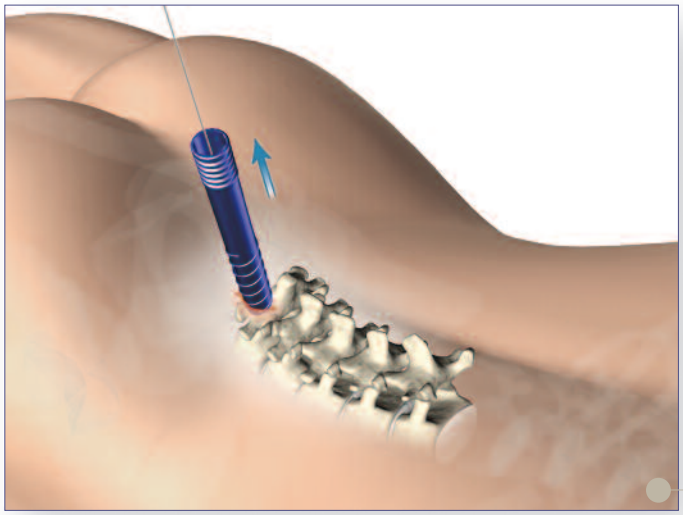


Figure 21

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

Instrument Bar

48280102
Hollow Dilator

48281164
Cannulated Modular Awl

Sharp 48230230
Blunt 48230231
K-Wire

48237120
Slap Hammer

4.5mm 48281161
5.5mm 48281165
6.5mm 48281166
7.5mm 48281167
Cannulated Modular Tap

48281315
Tap Sleeve

Figure 22

Screw / Retractor Assembly

Assemble each pair of **Retractor Blades** into the **MANTIS Screwhead**.

1. Orient the **Screw** so that the tulip posts are pointing up.
2. Insert the appropriate size **Retractor Blade** into each side of the tulip posts and spread apart.

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

Note: There are two types of Blades available. The Stainless Steel Reduction Blades and the Aluminum Retractor Blades. The Aluminum Blades are radiolucent and should be used as a single use instrument.

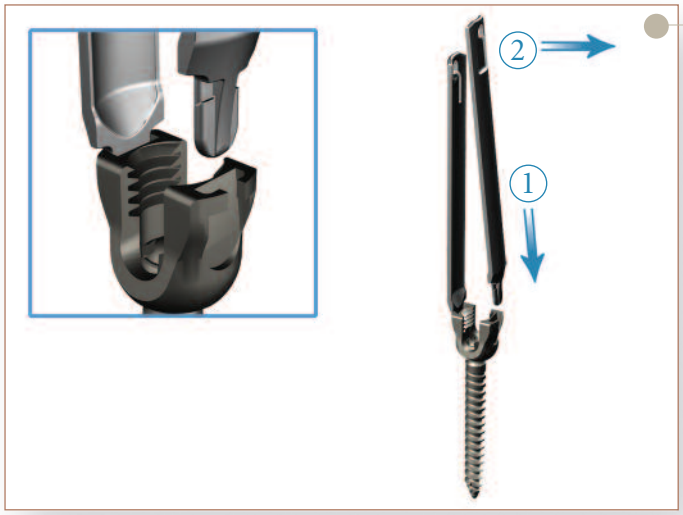


Figure 23

3. Orient the **Slim Ring (48281201)** with the flat side down. As an alternative, the **Sliding Ring (48281200)** may be used. The **Sliding Ring** is made from aluminum and is therefore radiolucent.

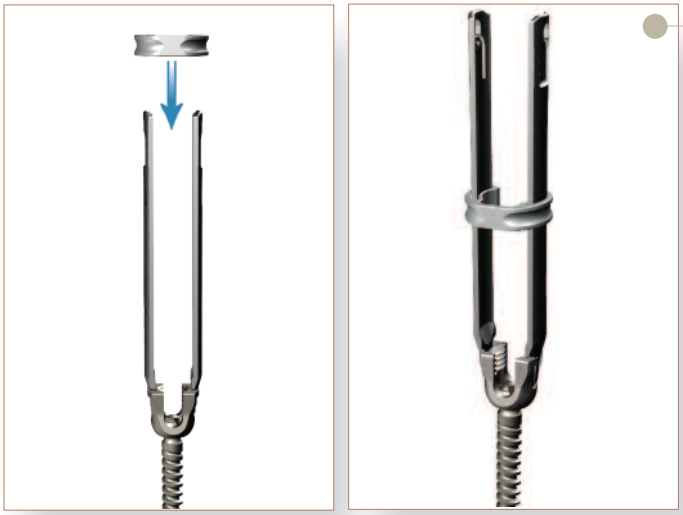


Figure 24

4. Insert the **Retractor Blades** through the bottom of the **Slim Ring**.
5. Slide the **Slim Ring** past the "stops" of the **Retractor Blades**.
6. Repeat this procedure for each **MANTIS Screw**.

Note: The **Retractor Blades** and **Sliding Ring** are reposable aluminum instruments and therefore may need to be replenished after a few uses. The **Slim Ring** is made of stainless steel.

Figure 25

Screw Insertion

With the pedicle pathways prepared and proper **Screw** length and diameter determined, the **MANTIS Screw** is prepared for insertion.

The **MANTIS Screwdriver** (**48281310**) provides a very rigid connection between the **MANTIS Screw** and **Screwdriver**. The **Screwdriver** can be attached to any of the cannulated modular handles (**T Ratchet - 48231200; Round Ratchet - 48231300; T Non-Ratchet - 48231205; Round Non-Ratchet - 48231305**) using the quick release mechanism.

Instrument Bar

4.5mm 482854(25)-(45)
5.5mm 482855(30)-(55)
6.5mm 482856(30)-(60)
7.5mm 482857(30)-(60)

MANTIS Cannulated Polyaxial Screw

48281201
Slim Ring

48281310
MANTIS Screwdriver

48231200
Xia Cannulated T-Handle Ratchet

48231205
Xia Cannulated T-Handle Non-Ratchet

48231300
Xia Cannulated Round Handle Ratchet

48231305
Xia Cannulated Round Handle Non-Ratchet

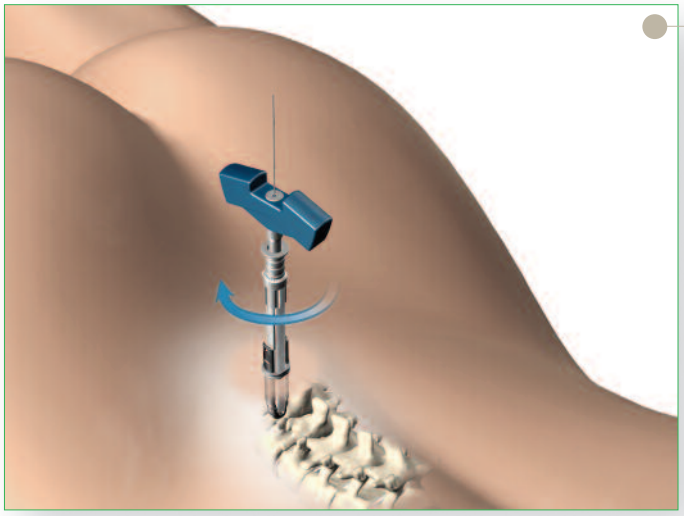


Figure 26

- Place a **MANTIS Screw** on the distal end of the **Screwdriver** and lock into place.
- Place the **MANTIS Screw** over the **K-Wire** and insert into the pedicle.

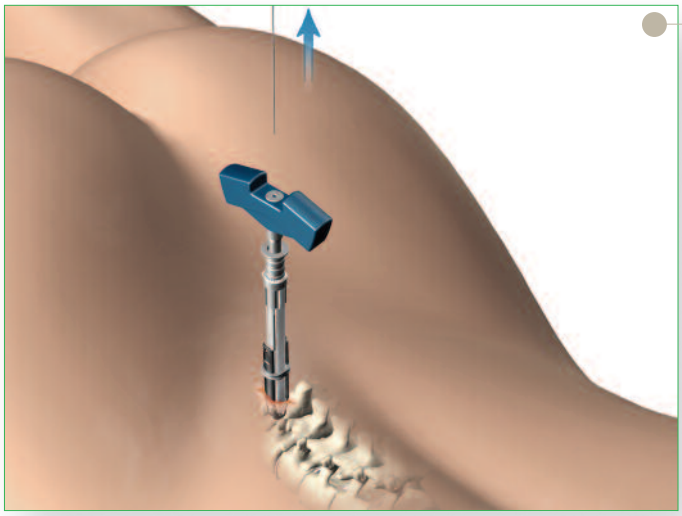


Figure 27

- After driving the **Screw Assembly** into the pedicle, remove the **K-Wire** to prevent it from advancing.

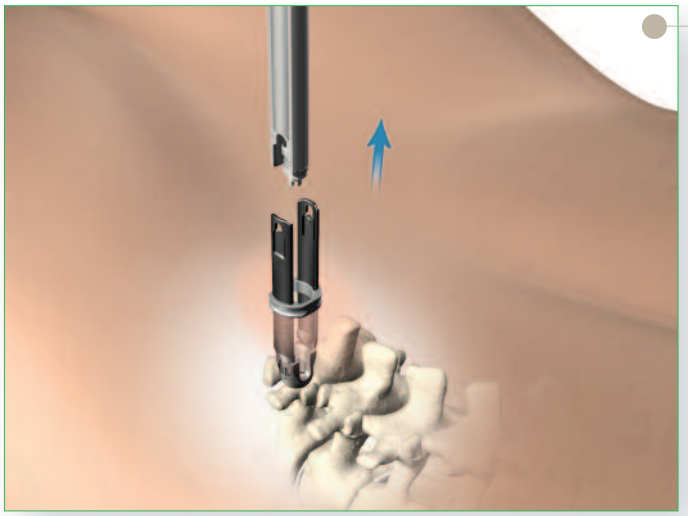


Figure 28

- Be certain that the **Screw Assembly** is not inserted too far. If the polyaxial head of the **MANTIS Screw** is driven too 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.

- Detach and remove **Screwdriver** from the **Screw**.

Note: The orientation of the **Slim Ring** can be changed after removal of the **Screwdriver**.

- Repeat the process for additional **Screws**.

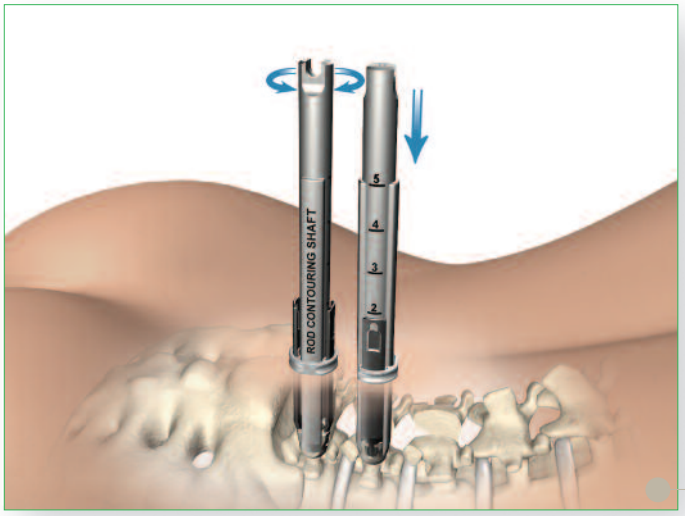


Figure 29

Screw Alignment

- Insert the **Rod Contouring Shafts** (**48284030**) into the **Screw / Retractor Assembly**. The **Rod Contouring Shafts** should be firmly seated into the **Screwheads**.

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

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

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

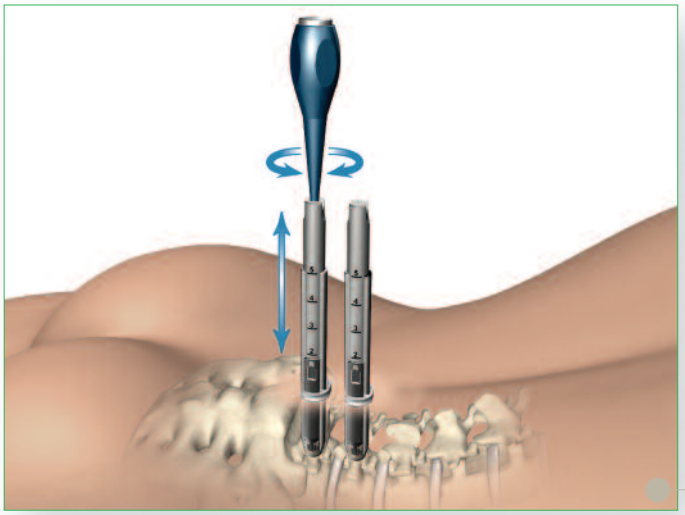


Figure 30

Screw Adjustment

- The **Screw** heights may be adjusted as needed using the **MANTIS Poly Adjustment Driver** (**48287033**). Use fluoroscopic images to confirm.
- The **Poly Adjustment Driver** can be inserted through the cannulas of the **Rod Contouring Shafts**.

Instrument Bar

48284030
Rod Contouring Shaft

48281201
Slim Ring

48281310
MANTIS Screwdriver

48231200
Xia Cannulated T-Handle Ratchet

48231205
Xia Cannulated T-Handle Non-Ratchet

48231300
Xia Cannulated Round Handle Ratchet

48231305
Xia Cannulated Round Handle Non-Ratchet

48287033
Poly Adjustment Driver

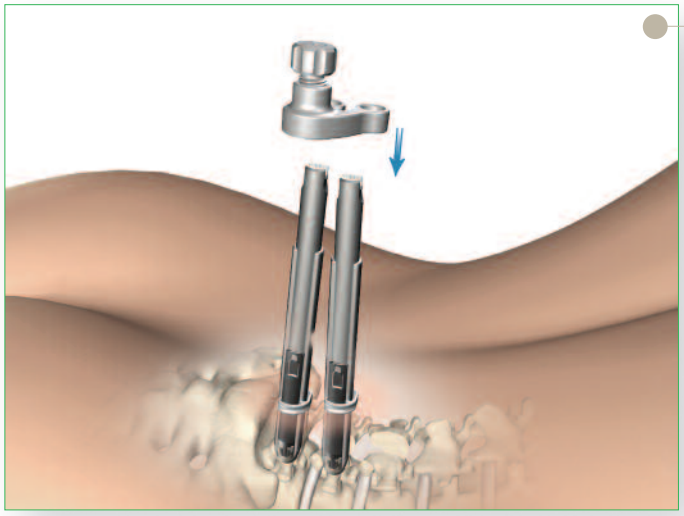


Figure 31

Rod Selection

- Align the **Rod Contouring Shafts** so that they are parallel.
- Attach the **Rod Contouring Linkage (48284035)** to the **Rod Contouring Shafts**. As needed, attach additional **Rod Contouring Linkages** to the remaining **Rod Contouring Shafts** alternating sides.

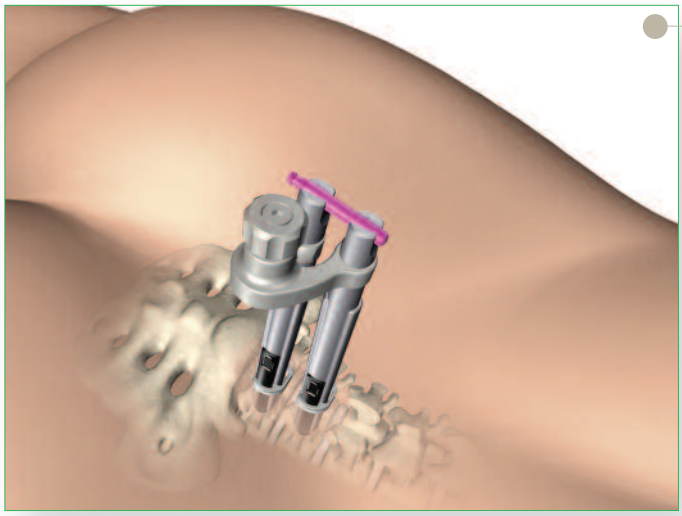


Figure 32

- 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 **Screwheads** above the skin.

Note: If the distance between **Rod Contouring Shafts** is too great, use the **Extended Rod Contouring Linkage (48284036)**.

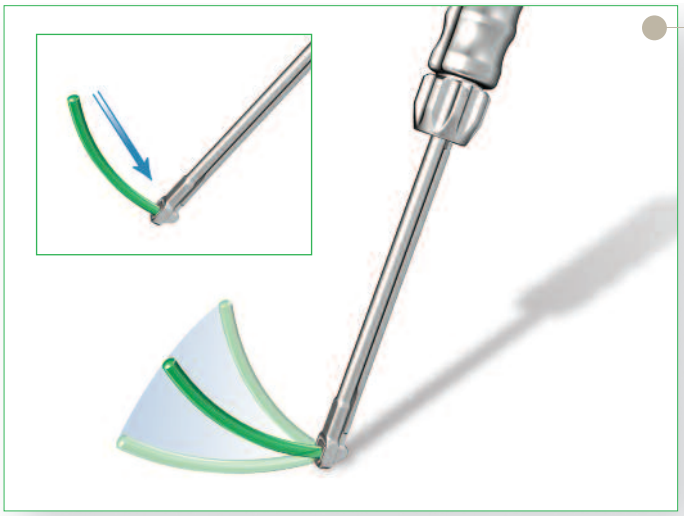
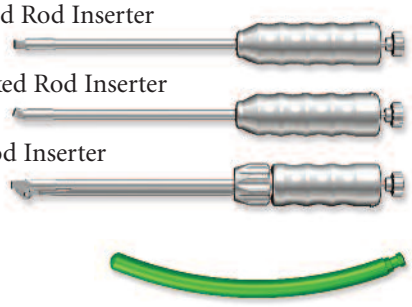


Figure 33

Rod Insertion

The MANTIS Spinal System offers a comprehensive selection of Rods and Rod Inserters. The MANTIS Hex End Rods provide a rigid connection between the Rod and Rod Inserter for easy insertion and manipulation. There are three types of Rod Inserters available:

- 90 degree fixed Rod Inserter
- 110 degree fixed Rod Inserter
- Adjustable Rod Inserter



- Choose the appropriate length Rod and desired **Rod Inserter.**
- Insert the **Rod Inserter Shaft** into the **Rod Inserter.**
- Attach the appropriate Rod to the **Rod Inserter**. The Rod should be attached from the side of the **Rod Inserter** that has a groove in the handle.

Note: The MANTIS Hex End Rods are laser marked with a dotted line to indicate their orientation. Ensure that the line is facing up when attached to the **Rod Inserter**.

- Lock the Rod into position by twisting the knob on the handle clockwise.

Figure 34

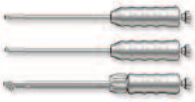
Note: When using the **Adjustable Rod Inserter**, attach the Rod in the "0" position. The angle of the Rod may be changed intraoperatively by turning the distal knob under the handle. The Rod can be angled up to 20 degrees.

Note: The Rod Inserter should be disassembled before cleaning. To disassemble, press the button on the handle and rotate the knob counter-clockwise.

Important Notes:
Do Not excessively rotate the driving nut below 0° or above 20° as this could cause the Rod Inserter to malfunction.
Do Not hit on the Rod Inserter.
The Rod Inserter should be properly lubricated between uses.

Instrument Bar

48284030
Rod Contouring Shaft



48480001 Adjustable
48480111 110°
48480091 90°
Rod Inserter

48284035
Rod Contouring Linkage

48284036
Extended Rod Contouring Linkage

484860(30)-(80) (5mm increments)
48486(090)-(130) (10mm increments)
Hex Rad Rod 6.0 x 30-130mm

48487(030)-(080) (5mm increments)
48487(090)-(200) (10mm increments)
48487480 (480mm)
48487600 (600mm)
Hex Straight Rod 6.0 x 30-600mm

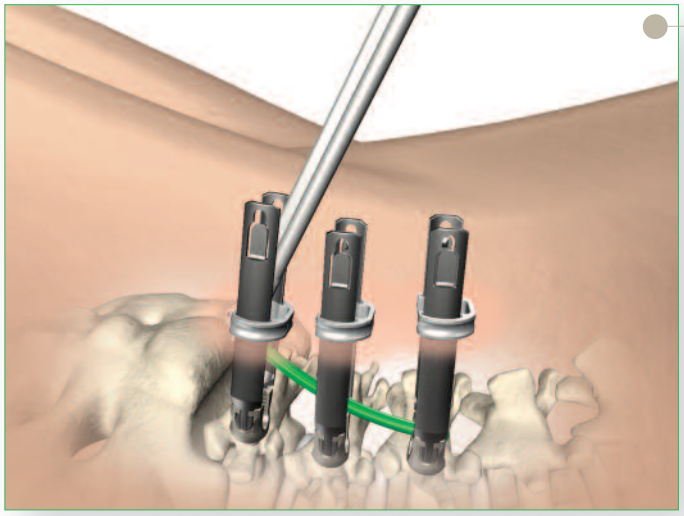


Figure 35

- Insert the **Rod** percutaneously from either the cephalad or caudal side through the **Retractor Blades**. Guide the **Rod** through each pair of **Retractor Blades**.

Note: The **Rod** is to be inserted from the open side of the **Slim Ring**.

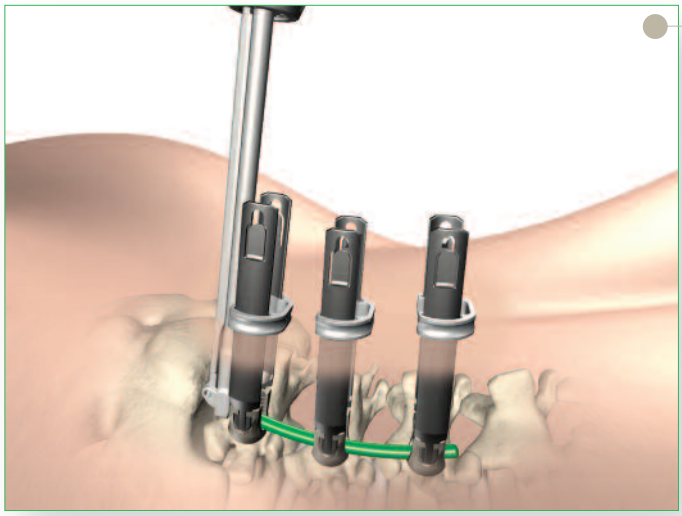


Figure 36

Note: Ensure that the **Rod** overhangs the distal screwhead.

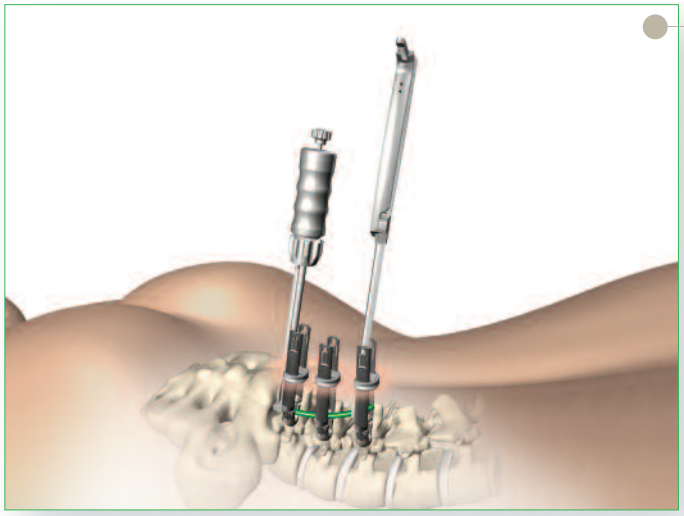


Figure 37

- The **Rod Gripper** (**48284055**) may be used for adjustment of the **Rod**.
- Insert the **Rod Gripper** down the **Retractor Blades**. Squeeze the handle to engage the **Rod**.
- Manipulate the **Rod** as needed.

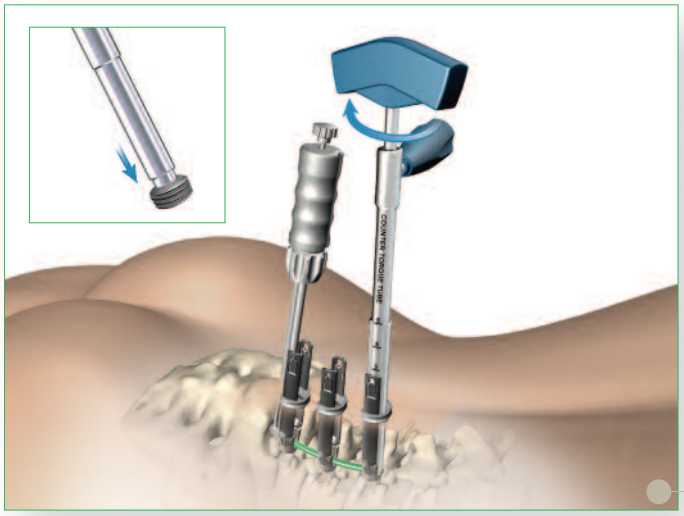


Figure 38

Blocker Insertion

- Insert the **Universal Tightener** (**03807008**) into the **Blocker** (**48289999**).
- Use the **Counter Torque Tube** (**48284080**) as an insertion tube to facilitate alignment of the Blocker with the tulip and to prevent cross-threading.

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

- Slide the **Universal Tightener** and **Blocker** through the **Screw / Retractor Assembly** and secure it in the tulip head of the **Screw**.

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 **Universal Tightener** is not intended to be used for final tightening.

Instrument Bar

48487(030)-(080) **(5mm increments)**
48487(090)-(200) **(10mm increments)**
48487480 **(480mm)**
48487600 **(600mm)**

Hex Straight Rod 6.0 x 30-600mm

48281201

Slim Ring

48284055

Rod Gripper

03807008

Xia Universal Tightener 5mm

48289999

LITe Blocker

48284080

Counter Torque Tube

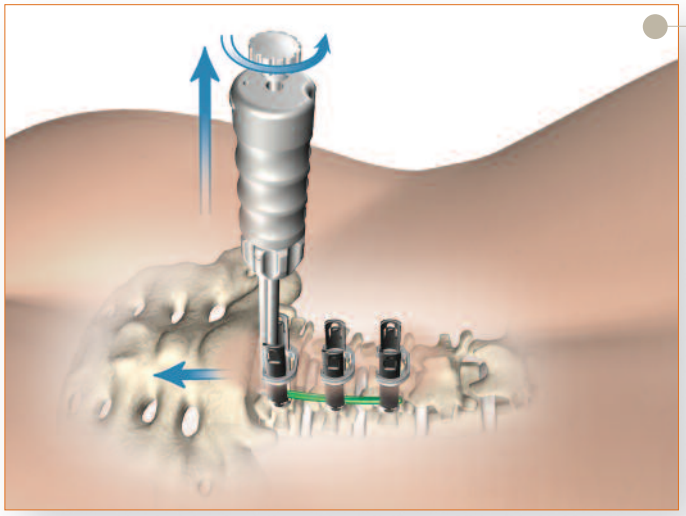


Figure 39

- Once the **Rod** is sufficiently captured in the **Screws**, detach the **Rod Inserter** from the **Rod** by turning the knob on the **Rod Inserter** in a counter clockwise direction.

Note: There is a mechanical stop to indicate that the **Rod Inserter** is fully disengaged.

Note: The **Adjustable Rod Inserter** should be lubricated between use.

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

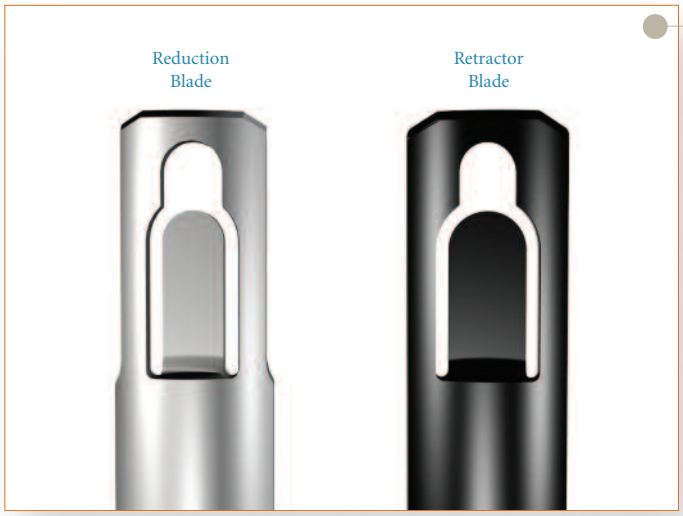


Figure 40

Rod Reduction

The **MANTIS Persuader** can be used when additional force is needed to bring the rod to the implant.

If Aluminum **Retractor Blades** are being used, they must be exchanged for **Reduction Blades** in order to use the persuader. The **MANTIS Persuader** is only compatible with the Stainless Steel **Reduction Blades**.

Figure 41

Exchanging Blades

The **Blade Exchanger** set can be used to change the blades at any time. There are two **Blade Exchanger Inserts, With (48280077) and Without (48280076) Rod**. For this technique it is assumed that there is a rod located in the screwhead.

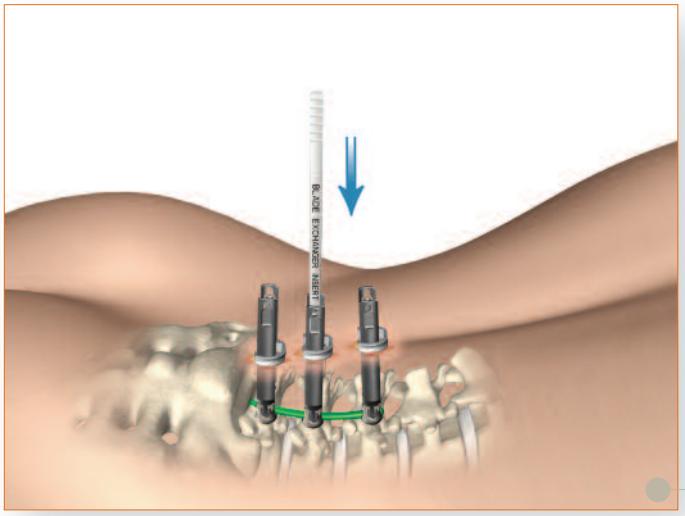


Figure 42

▶ Slide the **Blade Exchanger Insert** down the **Retractor Blades** and into the screw head. Ensure that the **Blade Exchanger Insert** is fully seated.

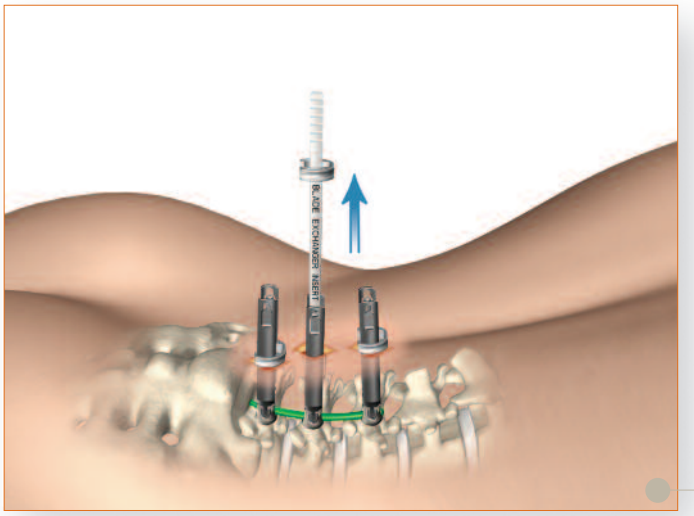
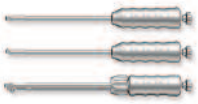


Figure 43

▶ With the **Blade Exchanger Insert** seated in the screwhead, remove the **Slim Ring**.

Instrument Bar

48480001 Adjustable
48480111 110°
48480091 90°



Rod Inserter

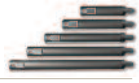
48480112

Rod Inserter Inner Shaft

48284065

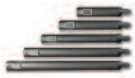
Persuader

Size 1 3-5cm 48281035
Size 2 5-7cm 48281057
Size 3 7-9cm 48281079
Size 4 9-11cm 48281911
Size 5 11-13cm 48281113



Retractor Blade

Size 1 3-5cm 48282035
Size 2 5-7cm 48282057
Size 3 7-9cm 48282079
Size 4 9-11cm 48282911
Size 5 11-13cm 48282113



Reduction Blade

48280076

Blade Exchanger Insert

48280077

Blade Exchanger Insert with Rod

48281201

Slim Ring

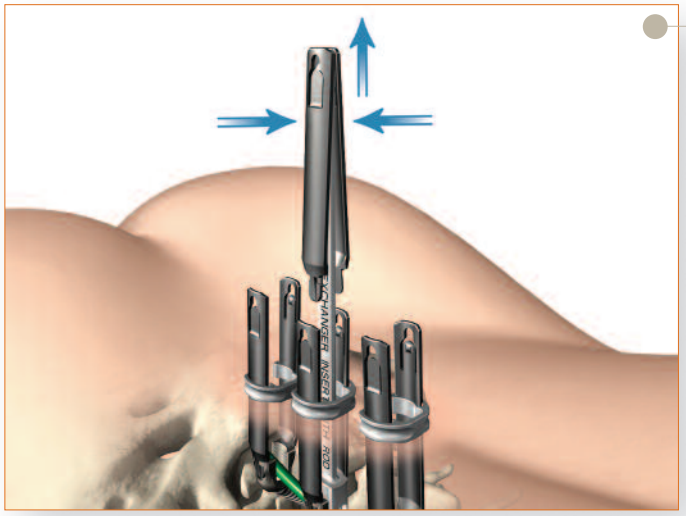


Figure 44

▶ With the **Slim Ring** removed, pinch the **Retractor Blades** together and lift up to remove.

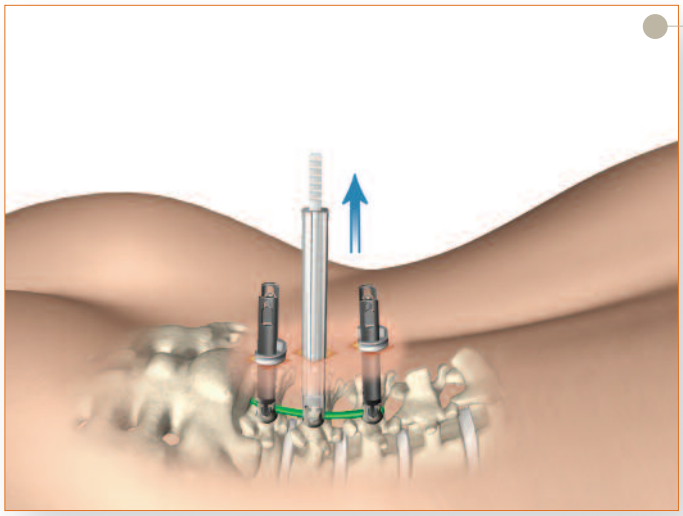


Figure 45

▶ With the **Blades** removed and the **Blade Exchanger Insert** seated, slide the **Blade Exchanger (48280075)** over the **Blade Exchanger Insert**. Ensure that the **Blade Exchanger** is fully seated.

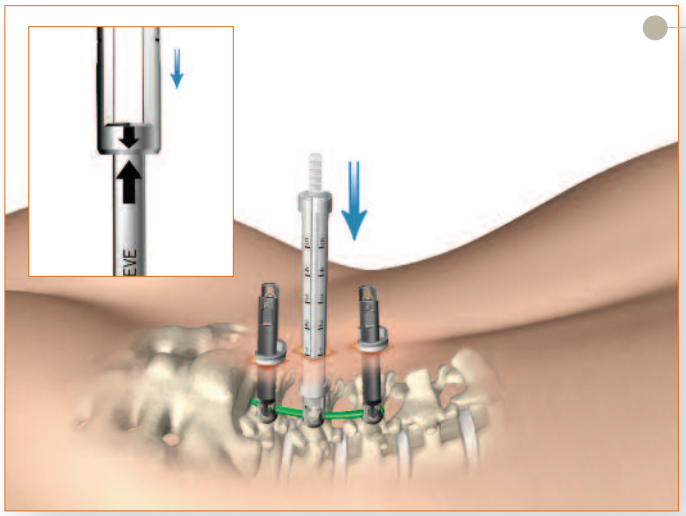


Figure 46

▶ Slide the **Blade Exchanger Guide (48282078)** over the **Blade Exchanger**. Ensure that the correct side is up.

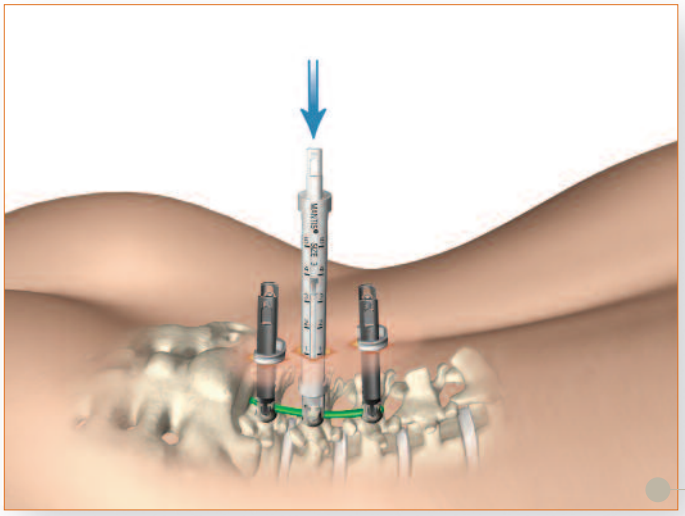


Figure 47

▶ Insert the **Reduction Blades** into the slits on the side of the **Blade Exchanger Guide**.

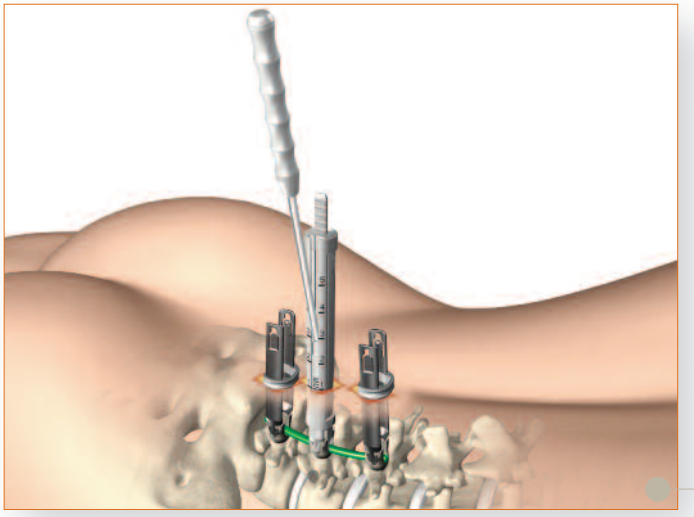


Figure 48

▶ Use the **Blade Pusher** (**48280079**) to slide the blades down the guide until they clip into place.

Instrument Bar

48281201
Slim Ring

48280076
Blade Exchanger Insert

48280075
Blade Exchanger

48280078
Blade Exchanger Guide

48280079
Blade Pusher

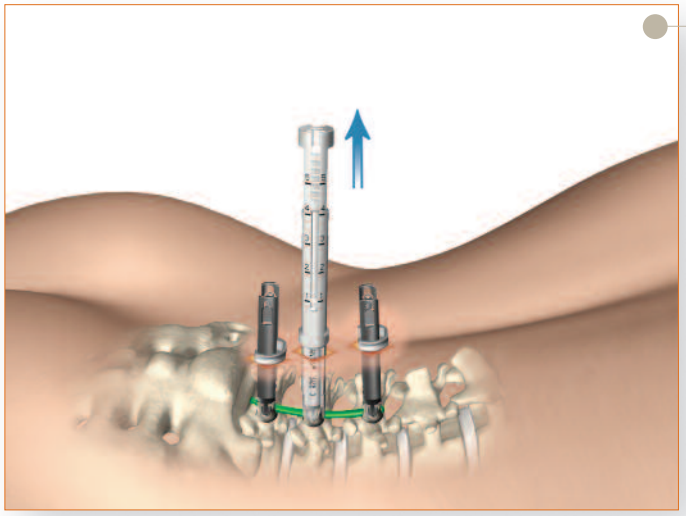


Figure 49

▶ Remove the **Blade Exchanger Guide**. Care should be taken not to remove the **Blade Exchanger** or **Reduction Blades**.

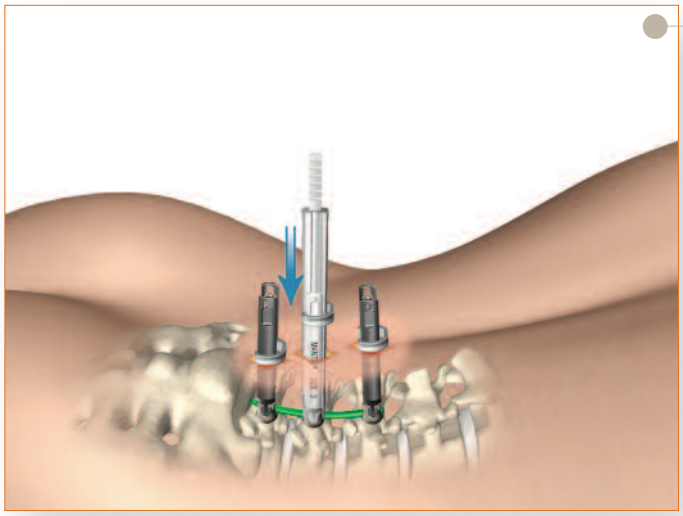


Figure 50

▶ Use the **Blade Exchanger** as a guide to reattach the **Slim Ring**.

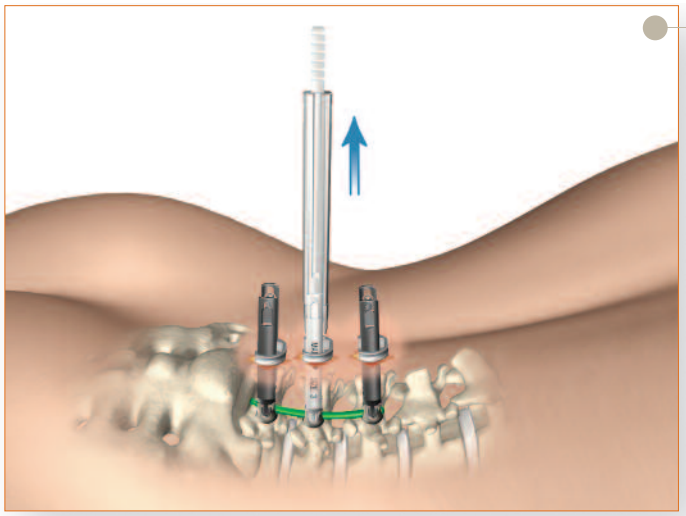


Figure 51

▶ Remove the **Blade Exchanger**.

Figure 52

Persuader

The **MANTIS Persuader** can be used when additional force is needed to bring the rod to the implant.

The **MANTIS Persuader** set has three components:

- **Persuader (48284065)**
- **Persuader Shaft (48284066)**
- **Blocker Inserter (48287008)**

▶ To assemble the **MANTIS Persuader**, insert the **Persuader Shaft** into the **Persuader**.

▶ Depress the gold button to slide the **Persuader Shaft** into place.

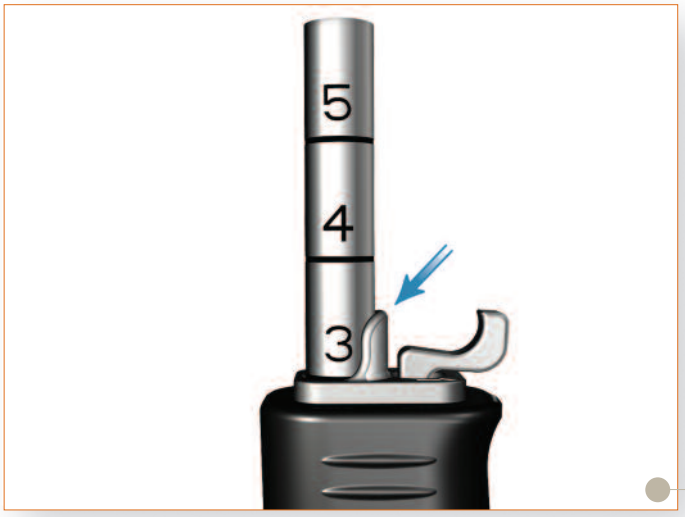


Figure 53

▶ Slide the **Persuader Shaft** to the appropriate **Retractor Blade** length.

Instrument Bar

48280078
Blade Exchanger Guide

48280075
Blade Exchanger

48281201
Slim Ring

48284065
Persuader

48284066
Persuader Shaft

48287008
Blocker Inserter

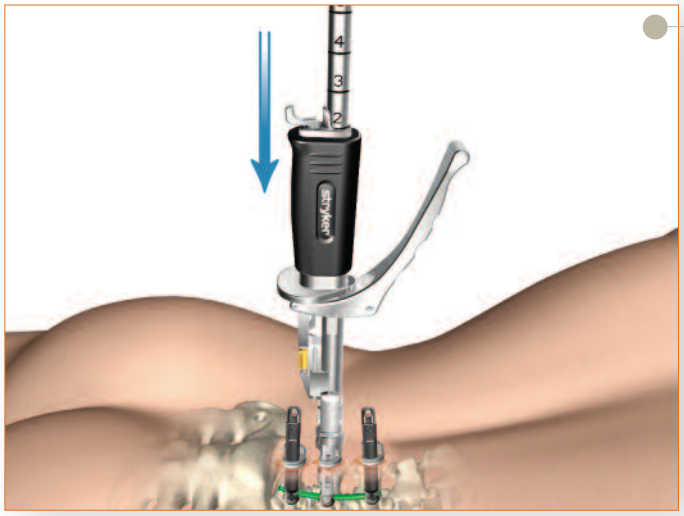


Figure 54

▶ The **Persuader** is then pressed onto the **Reduction Blades** of the appropriate screw and snapped into place.

Note: Only Stainless Steel **Reduction Blades** can be used with the **Persuader**.

Important Note:
The MANTIS Persuader is not intended to be used offset while reducing the rod into the tulip head. The Persuader should stay in line with the tulip head. Excessive force in an offset manner may result in blade disengagement, tulip head deformation or breakage.

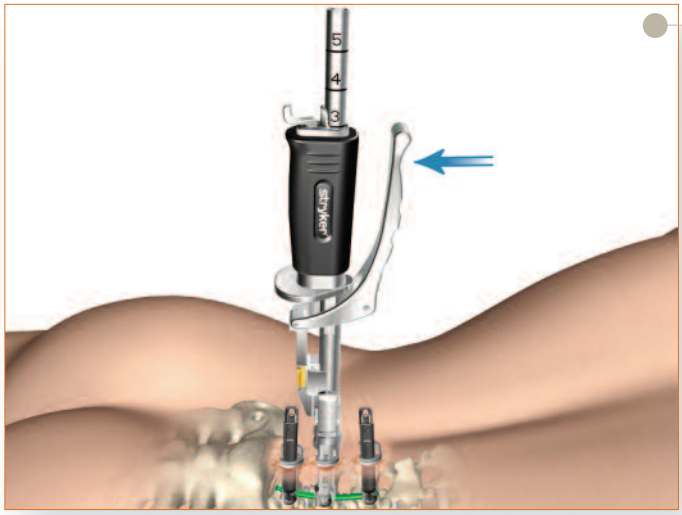


Figure 55

▶ Squeeze the lever to perform the desired reduction maneuver.

Note: The **MANTIS Persuader** offers 20mm of reduction capability.

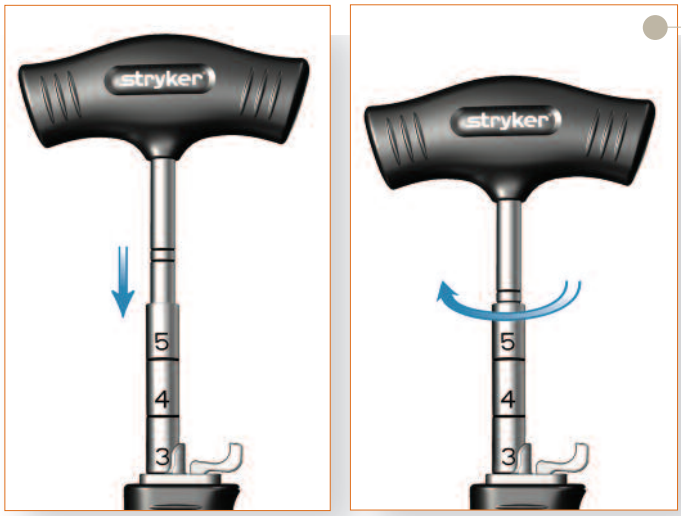


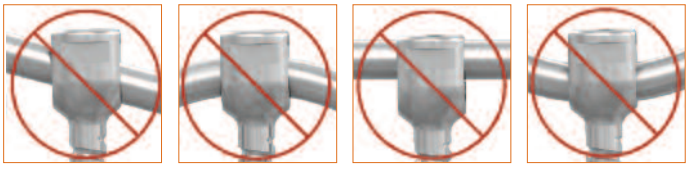
Figure 56

▶ Insert the **Blocker** using the **MANTIS Blocker Inserter**.

Note: The **Xia Universal Tightener** is too short to be used with the **MANTIS Persuader**.

Note: In the event the rod is forced down while tightening the blocker, be sure that the blocker is fully engaged into the screw head. This will help resist the high reactive forces generated by the final tightening maneuvers.

CAUTION: Extra caution is advised in the following cases:
- The rod is not horizontally placed into the screw head.
- The rod is high in the screw head.
- An acute convex or concave bend is contoured into the rod.



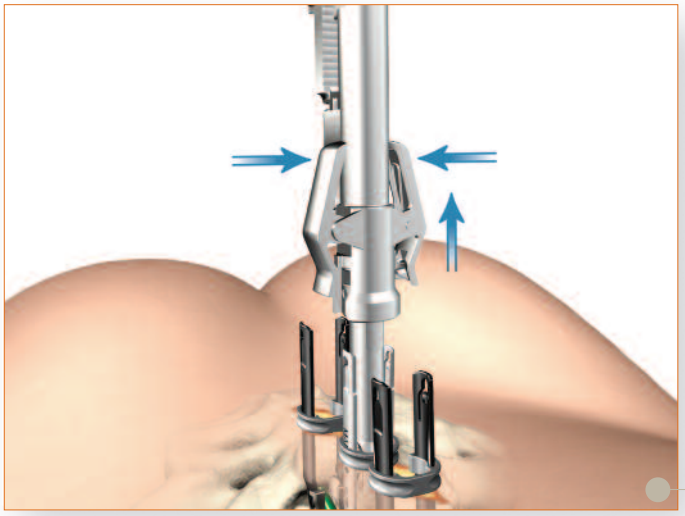


Figure 57

- To remove, squeeze the flanges on the **Persuader** and lift.

Figure 58

- Press the button on the handle to return the **Persuader** to the neutral position.
- Ensure that the inner shaft is removed from the persuader and cleaned separately.
- This instrument should be properly lubricated between use.

Instrument Bar

48284065
Persuader

48287008
Blocker Inserter

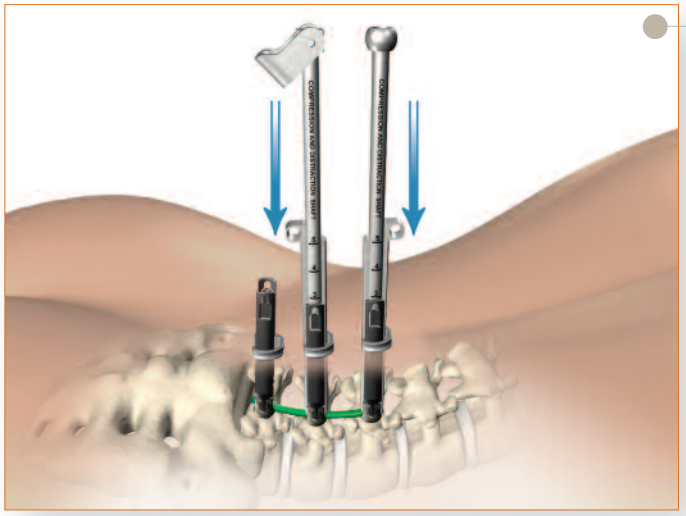


Figure 59

Compression and Distraction

- To achieve compression and distraction, insert the **Compression & Distraction Shaft** (**48284077**) and **Compression & Distraction Hinge** (**48284078**) through the **Screw/Retractor Assembly** and secure them into the tulip head of the **Screws**.
- 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.

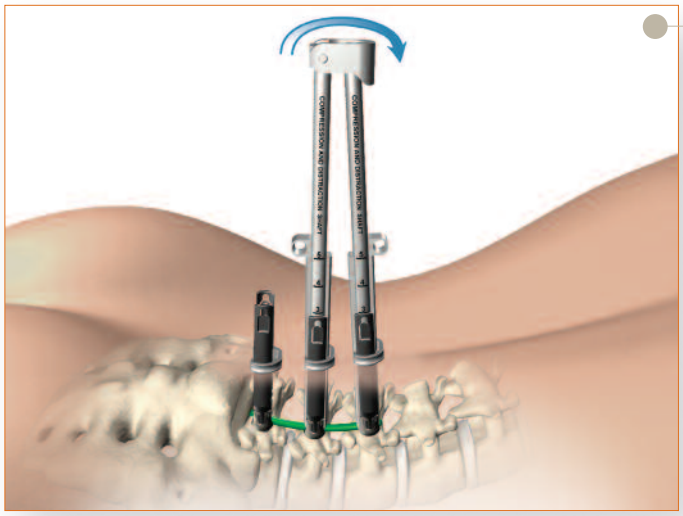


Figure 60

- Mate the tops of the **Compression & Distraction Shaft and Hinge** using the connecting feature.

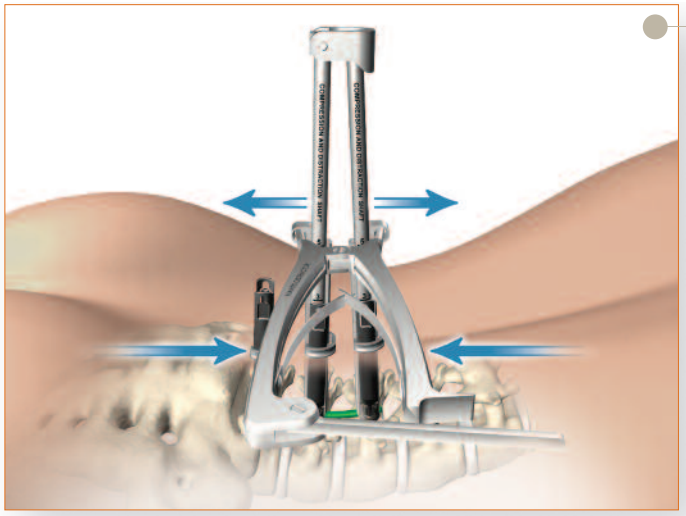


Figure 61

- To distract, insert the **Distractor** (**48284070**) into the eyelets of the **Compression & Distraction Shaft** and **Hinge**. **Squeeze** the **Distractor** to apply the appropriate distraction.

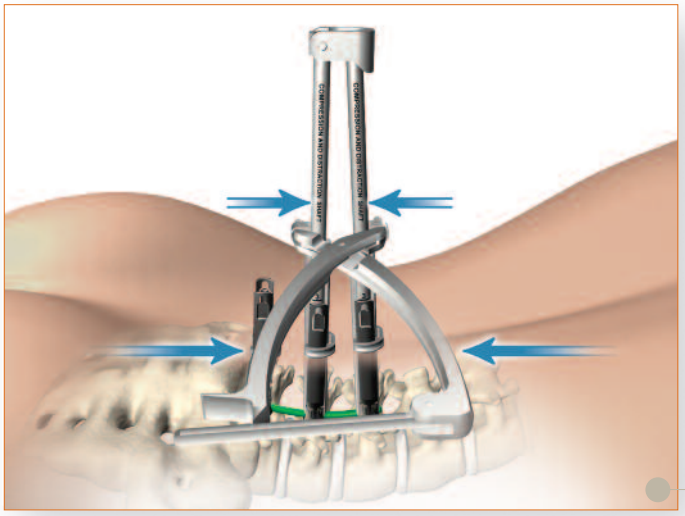


Figure 62

- To compress, insert the **Compressor** (**48284075**) into the eyelets of the **Compression & Distraction Shaft and Hinge**. Squeeze the **Compressor** to apply the appropriate compression.

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

Note: The **Compression & Distraction Shaft and Hinge** are not designed to be used with the **Torque Wrench** for Final Tightening. Please refer to page 32 for acceptable counter torque options to be used in conjunction with the **Torque Wrench**.

Instrument Bar

48284077
Compression & Distraction Shaft

48284078
Compression & Distraction Hinge

48284070
Distractor

48284075
Compressor

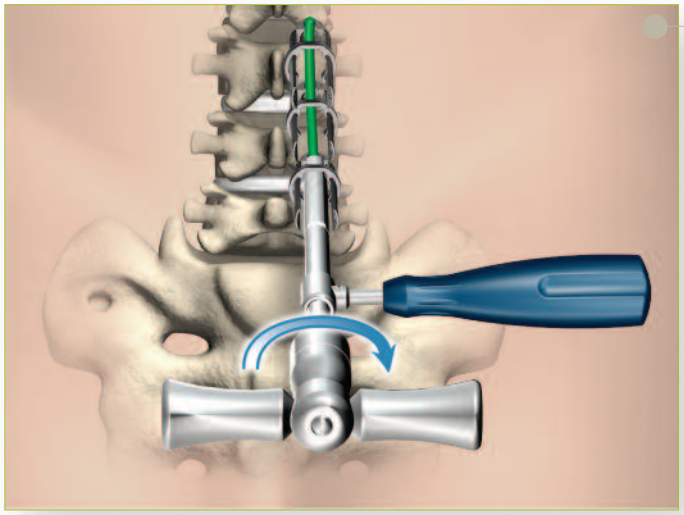


Figure 63

Construct Tightening

- Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the **Blocker** is done by utilizing the **Counter Torque Tube** (**48284080**) and the **Torque Wrench** (**03807028**).
- Dock the **Counter Torque Tube** on the **Screw**.

Note: 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 **ES2 Torque Wrench** may also be used as an alternative to the MANTIS Torque Wrench to final tighten the blockers.

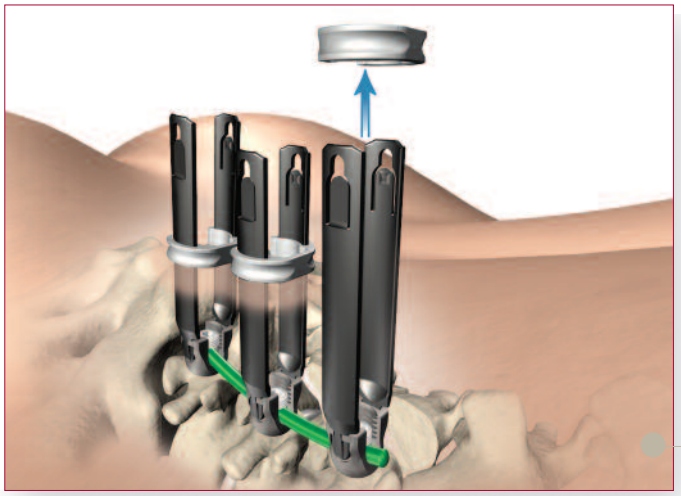


Figure 64

Retractor Blade Removal

▶ Remove the **Slim Ring** from the **Retractor Blade** by pulling up.

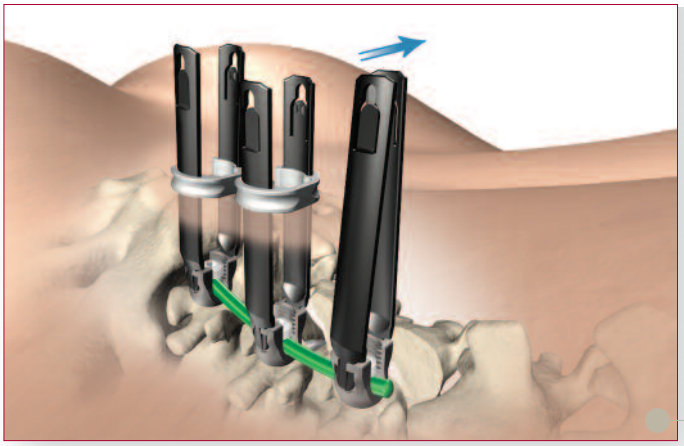


Figure 65

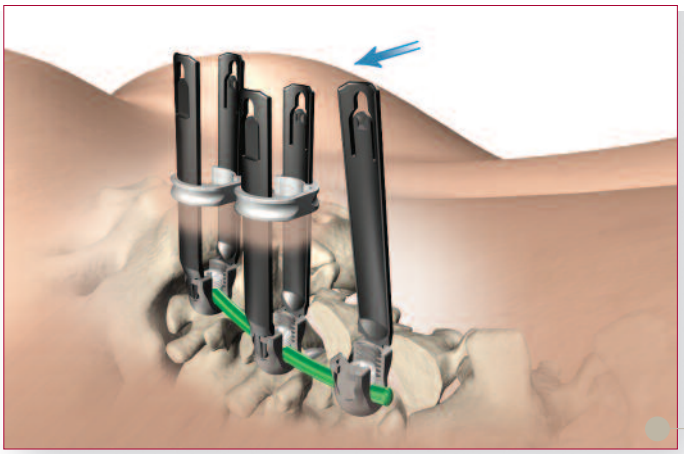


Figure 66

▶ Pinch one **Retractor Blade** over to the other and remove it by pulling up.

Instrument Bar

48284080
Counter Torque Tube

03807028
Xia Torque Wrench

48280081
ES2 Torque Wrench

48281201
Slim Ring

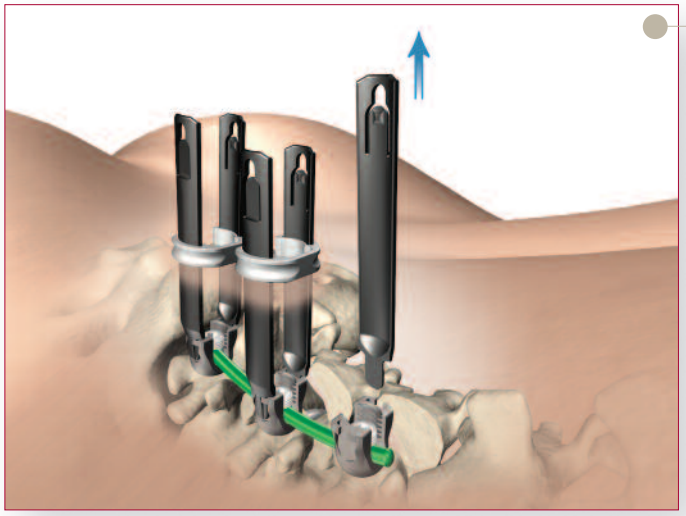


Figure 67

- Remove the other **Retractor Blade** by tilting it to the other side and pulling up.

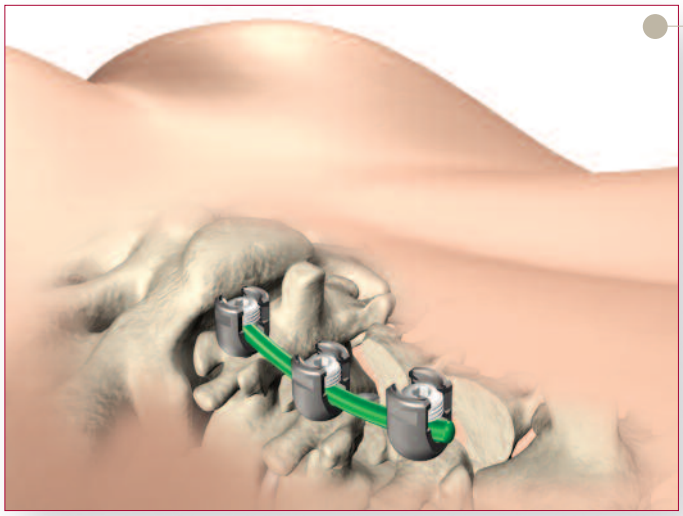


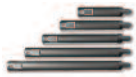
Figure 68

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.

Instrument Bar

Size 1	**3-5cm**	**48281035**
Size 2	**5-7cm**	**48281057**
Size 3	**7-9cm**	**48281079**
Size 4	**9-11cm**	**48281911**
Size 5	**11-13cm**	**48281113**



Retractor Blade

Reference #	Description
Instruments	
48280001	MANTIS Screw Insertion Tray
48280001A	Screw Insertion Base
48280001B	Screw Insert
48280001C	Retractor Blade Insert
48280001D	Dilator Insert
48280001E	Screw Insertion Lid
48280001F	Slim Dilator Tray
48280002	MANTIS Fixation Tray
48280002A	Fixation Base
48280002E	Fixation Middle Insert
48280002F	Fixation Top Insert
48280002D	Fixation Lid
48280004	MANTIS Auxiliary Tray
48237005	K-Wire Container
48237110	Jam Shidi 10 Gauge 9 Inch
48237105	Jam Shidi 10 Gauge 5 Inch
48237115	Jam Shidi 11 Gauge 5 Inch
48237135	Jam Shidi 13 Gauge 5 Inch
48230230	K-Wire Sharp
48230231	K-Wire Blunt
48230235	K-Wire Guide Tube
48237120	Slap Hammer
48280101	Blunt Dilator
48280102	Hollow Dilator
48280105	Slim Dilator
48280106	Dilator 2
48280107	Dilator 3

Reference #	Description

Instruments

48280104	Hollow Cannula
48281164	Cannulated Modular Awl
48281161	Cannulated Modular Tap 4.5mm
48281165	Cannulated Modular Tap 5.5mm
48281166	Cannulated Modular Tap 6.5mm
48281167	Cannulated Modular Tap 7.5mm
48281315	Tap Sleeve
48281035 **48282035**	Retractor Blade Size 1 (3 - 5cm) Reduction Blade Size 1 (3 - 5cm)
48281057 **48282057**	Retractor Blade Size 2 (5 - 7cm) Reduction Blade Size 2 (5 - 7cm)
48281079 **48282079**	Retractor Blade Size 3 (7 - 9cm) Reduction Blade Size 3 (7 - 9cm)
48281911 **48282911**	Retractor Blade Size 4 (9 - 11cm) Reduction Blade Size 4 (9 - 11cm)
48281113 **48282113**	Retractor Blade Size 5 (11 - 13cm) Reduction Blade Size 5 (11 - 13cm)





Continued

	Reference #	Description
Instruments		
	**48281200**	Sliding Ring
	**48281201**	Slim Ring
	**48281310**	MANTIS Screwdriver
	**48231200**	Xia Cannulated T-Handle Ratchet
	**48231300**	Xia Cannulated Round Handle Ratchet
	**48231205**	Xia Cannulated T-Handle Non-Ratchet
	**48231305**	Xia Cannulated Round Handle Non-Ratchet
	**48287033**	MANTIS Poly Adjustment Driver
	**48284010**	Fascia Scissors
	**48284057**	Tissue Wand
	48284030	Rod Contouring Shaft
	**48284035**	Rod Contouring Linkage
	**48284036**	Extended Rod Contouring Linkage
	**48284055**	Rod Gripper
	**03807010**	Xia French Bender

Reference #	Description	
Instruments		
48480001	Adjustable Rod Inserter	
48480111	110° Rod Inserter	
48480091	90° Rod Inserter	
48480112	Rod Inserter Inner Shaft	
48284080	Counter Torque Tube	
03807028	Xia Torque Wrench	
48280081	ES2 Torque Wrench	
48284077	Compression & Distraction Shaft	
48284078	Compression & Distraction Hinge	
48280075	Blade Exchanger	
48280076	Blade Exchanger Insert	
48280077	Blade Exchanger Insert with Rod	
48280078	Blade Exchanger Guide	
48280079	Blade Pusher	
48287008	Blocker Inserter	
48284066	Persuader Shaft	
48284065	Persuader	
48284070	Distractor	
48284075	Compressor	

	Reference #	Sterile* Reference #	Description
	Implants		
	**482854(25) – (45)**	**482854(25) – (45)S**	MANTIS Cannulated Polyaxial Screw 4.5 x 25 - 45mm
	**482855(30) – (55)**	**482855(30) – (55)S**	MANTIS Cannulated Polyaxial Screw 5.5 x 30 - 55mm
	**482856(30) – (60)**	**482856(30) – (60)S**	MANTIS Cannulated Polyaxial Screw 6.5 x 30 - 60mm
	**482857(30) – (60)**	**482857(30) – (60)S**	MANTIS Cannulated Polyaxial Screw 7.5 x 30 - 60mm
	**48289999**	**48289999S**	LITe Blocker
	**484860(30) – (80)**	**484860(30) – (80)S**	Hex Rad Rod 6.0 x 30-80mm (5mm increments)
	48486(090) – (130)	**48486(090) – (130)S**	Hex Rad Rod 6.0 x 90-130mm (10mm increments)
	**48487(030) – (080)**	**48487(030) – (080)S**	Hex Straight Rod 6.0 x 30-80mm (5mm increments)
	48487(090) – (200)	**48487(090) – (200)S**	Hex Straight Rod 6.0 x 90-200mm (10mm increments)
	48487480	**48487480S**	Hex Straight Rod 6.0 x 480mm
	48487600	**48487600S**	Hex Straight Rod 6.0 x 600mm

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.

Indications and Contraindications

Indications

MANTIS Spinal System

The **MANTIS Spinal System** is intended for percutaneous posterior, noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion 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 Ø5.5mm Titanium and VITALLIUM rods from the Stryker Spine Radius Spinal System are also intended to be used with the other components of MANTIS Spinal System and MANTIS Redux Spinal System.

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 unusually heavy load 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.
- 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 conditions 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.
- Surgeons should warn patients of the above listed potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant.

General Conditions of Use

The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

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.

Infection

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it is advisable to use antibiotic prophylaxis before and after such procedures.

Implant Selection and Use

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These

repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Post-Operative Care

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

Adverse Effects

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of

union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.

- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

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.

Pre-operative Precautions

Anyone using Stryker Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

Stryker Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risk of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Caution

Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

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.

The Mantis Spinal System has not been tested for heating or migration in the MR environment.

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.

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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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