Xia® 3 Spinal System

AIS surgical technique
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Introduction

Built on the successful foundation of Xia’s history, Stryker is proud to introduce Xia 3; a pedicle screw system designed to deliver “Simplicity with options.”

Xia 3 is a comprehensive system that is designed to treat degenerative, trauma and deformity applications including adolescent idiopathic scoliosis. Xia 3 is based upon the same design rationale and philosophy that has made Xia one of the leading spinal systems in the market.

• Ease of use
• Comprehensive system
• Proven core technology
• Successful clinical history
Key design features

**Xia 3 Titanium Polyaxial Screws**

- **Xia buttress thread blocker**
  With over a decade of consistent performance, the Xia buttress thread blocker helps to eliminate cross-threading, prevent screw head splaying and ensure secure closure.

- **Xia bone screw thread pattern**
  Based on patient anatomy, the Xia bone screw thread pattern is designed to increase performance and purchase in cortical and cancellous vertebral bone by featuring a constant outer and tapered inner diameter.

**Rod options**
Xia 3 screws can accommodate a variety of rod diameters and materials: 5.5mm and 6.0mm diameter in Commercially Pure Titanium, Titanium Alloy and Vitallium.

**Xia 3 Titanium Polyaxial and Monoaxial Self-Tapping Screws***

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*See Xiapedia 3.0 for full listing of screw options including closed head monoaxial and polyaxial, biased angle, medial biased angle, uniplanar and reduction uniplanar screws.
**Self-tapping screws**
Xia 3 screws have a cutting flute to allow a surgeon to eliminate the tapping step. The screws may be inserted immediately after preparing and probing the pedicle. However, in most cases, tapping is recommended. In addition, Xia 3 screws, like the entire Xia family, have a tip angle of 60°, which is designed to help ease insertion.

Xia 3 screws are fully anodized by screw diameter for easier identification in the OR.

**Screw to screwdriver interface**
The 6-point star screw head is designed:
- For faster and more intuitive engagement with the screwdriver
- To prevent screw head stripping
- For reengagement during screw adjustments

**Polyaxial freedom**
Xia 3 Polyaxial Screws are designed with 50° of conical angulation, or 25° in each direction.

**Xia 3 screwdriver options**

**Technology driven instruments**
With a continuing commitment to innovation, Xia 3 has introduced technologies to help improve function and efficiency in the OR.

Surgeons may now choose from three different working lengths, standard or low profile and standard or small handles for their screwdriver.

**Ergonomic handles**
Stryker branded handles are designed to enhance comfort, function and efficiency.
Hook vocabulary

**Supralaminar hook:** Directed caudally, the blade of these hooks fits within the epidural space. A narrow blade hook is recommended.

**Infralaminar hook:** Directed cephalad, the blade of these hooks fits between the anterior surface of the lamina and the ligamentum flavum. A wide blade hook is recommended.

**Pedicle hook:** Directed cephalad, the bifid blade of these hooks fits around the pedicle, directed slightly lateral of the midline through the superior facet of the caudal vertebra.

**Transverse process hook:** Directed cephalad or caudally, the blade of these hooks fits between either the superior or inferior anterior side of the transverse process and the rib head.
## Xia 3 hook offering

### Laminar

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<th>Reference number</th>
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<td>48230250</td>
<td>Xia 3 Medium Laminar Hook Standard Blade</td>
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### Transverse process

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### Pedicle

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### Hook holders

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<td>Lateral Hook Holder</td>
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<tr>
<td>48231170</td>
<td>Straight Hook Holder</td>
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**Note:** Reduction hooks are available in the Xia II Spinal System.
Patient positioning

Diagnosis is based upon patient history, physical findings and preoperative radiographic assessment (Fig. 1).

The patient can be positioned on the operating table in the prone position. Care should be taken to pad all bony prominences. To facilitate venous drainage, the abdomen should not be compressed (Fig. 2).

Surgical levels may be verified either clinically or radiographically. To help ensure adequate exposure, the incision is made to extend just beyond the length of the intended fusion (Fig. 3).

Presurgical planning defines the most appropriate implants in addition to the optimal location for insertion of implants.
Hook selection

Once appropriate dissection has been achieved and anatomic levels are confirmed by x-ray and anatomic landmarks, the hook sites are identified and prepared (Fig. 4). The appropriate hook is chosen according to a number of factors: patient anatomy, bone quality, correction technique and the forces applied. The surgeon has several options in choosing a hook pertaining to the blade width, throat length, body extension and hook shape. Hooks consist of three blade types. They are wide blade, narrow blade and bifid pedicle blade. The surgeon should choose the hooks that will allow the most successful outcome of the procedure.

Offset hooks are available in both wide and narrow blade widths. They may be inserted in thoracic or lumbar segments. Offset connectors can be helpful in lining up hook connections.

Figure 4
Hook insertion

**Supralaminar hooks**

Supralaminar hooks are directed caudally (Fig. 5). The blade of the hook sits within the epidural space. A narrow blade hook with a throat size that does not allow pistoning on the lamina is recommended. The ligamentum flavum is dissected from the lamina and a small laminotomy is made. The **Lamina Hook Preparer** may be used to estimate the appropriate hook size (Fig. 6). Care must be utilized in introducing hooks and instruments into the open spinal canal. The Laminar Hook Preparer comes in two blade widths to accurately match the patient’s anatomy (Fig. 6).

The appropriate hook is determined by the patient’s anatomy. Once the site is confirmed to be well prepared, the selected lamina hook is loaded onto a hook forceps.

Two options are possible for preparing the site and to insert the hook:

**Option 1:** A horizontal window is created by excising the ligamentum flavum combined with a limited osteotomy of the edge of the lamina.

The window is prepared large enough to accommodate the blade of the hook to be inserted. The blade is then turned down 90° and seated on the lamina.

This technique will assist in stabilization of the hook, which can help facilitate rod introduction.

**Option 2:** A more squared window is managed by opening the ligamentum flavum in conjunction with a limited laminotomy.

A Laminar Hook Preparer may be used with great care to dissect the ligamentum flavum.

Once the site is confirmed to be well prepared, the selected lamina hook is loaded on either the straight or lateral hook forceps. The hook is inserted in a downward rotational movement so that the tip of the blade hugs the anterior surface of the lamina at all times. A gentle burring of the lamina is sometimes necessary to ease the access to the canal.
**Infralaminar hooks**

Infralaminar hooks are directed cephalad (Fig. 7). The Laminar Hook Preparer is used to dissect the ligamentum flavum from the inferior lamina and prepare a path for the hook. The blade will seat between the anterior surface of the lamina and the ligamentum flavum and not interdural.

A wide blade hook may be selected if the patient’s anatomy permits. This hook loaded onto a hook forceps and inserted into the path created by the Laminar Hook Preparer.

The hook pusher may be used in conjunction with the hook forceps to facilitate hook seating against the inferior lamina.
**Pedicle hooks**

The pedicle hook is always directed cephalad and is recommended for T10 and above (Fig. 8). A limited osteotomy (facetectomy) at the base of the facet opens the facet joint and exposes the underlying articular cartilage of the superior facet of the caudal vertebra. The **Pedicle Hook Preparer** is inserted into the facet joint with great care, aiming slightly lateral of the midline to identify the pedicle (Fig. 8). Once the pedicle is localized, the bifid on the pedicle preparer can be utilized to ensure that the fork is well applied onto the pedicle. The preparer, properly engaged on the pedicle, can be used to confirm a reliable fit on the vertebra by mobilizing the vertebra laterally. A prominent element indicates the appropriate location of the final osteotomy so that the hook will evenly seat onto the pedicle and on the facet.

Once the pedicle hook site is clearly identified, the pedicle hook is inserted.

The hook is firmly gripped by the hook forceps. The **Hook Impactor** is inserted into the hook (Fig. 9). The hook is slid into the desired position, and then gently tamped against the pedicle. The hook is then moved side to side to ensure the hook is around the pedicle.

This combination provides an optimal level of force and guidance to safely insert the hook.

**Alternate method:** The hook is temporarily secured to the Hook Impactor by tightening a closure screw. The screw may be removed once the hook has been placed.

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**Note:** To facilitate the introduction of the pedicle hook it may be necessary to remove the prominence of the caudal lamina below the hook.
Transverse process hooks
Based on the patient’s anatomy, a Xia 3 Transverse Process Hook or a standard lamina hook may be selected. The hook is loaded onto a hook forceps. The hook is then inserted into the space created with the Laminar Hook Preparer (Fig. 10).

The transverse process hook may be directed cephalad or caudal (Fig. 11).

Caudally directed transverse process hooks are often the top portion of the transverse pedicle claw configuration. The Xia 3 Transverse Process Hook is designed to closely line up with the inferior pedicle hook to help avial angulation and allow easy introduction of the closure screw.

Again, the Lamina Hook Preparer can be used to dissect around the superior and anterior surface of the transverse process to create room between the anterior aspect of the transverse process and the rib head.
Preparing the pedicle

**Thoracic pedicle entry**
Landmarks usually lie at the intersection of a vertical line through the middle of the convex part of each articular process and a horizontal line drawn across the middle to upper third of the base of the transverse process. This intersection is usually 2mm below the edge of the articular cartilage and just level with the small horizontal crest of bone (Fig. 12). The use of CT scans may be used to verify any anatomic variations.

**Note:** A pedicle, and the drilling direction, is usually globally perpendicular to the posterior plane of the vertebra (plane of the transverse process).
This is an important point to consider, especially when instrumenting the apical vertebrae, which are usually the most rotated ones.

**Lumbar pedicle entry**
Landmarks are at the intersection of a vertical line through the facet joint space and a horizontal line through the middle of the base of the transverse process (Fig. 13).

These two lines intersect at a small sharp crest of cortical bone which can be a reliable landmark since it is extra-articular and not affected by osteoarthritic deformities.
Once anatomical landmarks are identified, remove the cortical crest with a rongeur or power burr to expose the underlying cancellous bone.

Prepare the entry point with the Awl. The Awl is designed with a stop at 13mm to prevent overplunging (Fig. 14).

**Awl diameter = 2.9mm**

When placing sacral screws, the Sacral Awl can be used. Set the depth indicator on the Sacral Awl to the desired length; the Sacral Awl depth indicator can be set from 30mm to 60mm. The stop on the Sacral Awl is designed to prevent overplunging while breaching the anterior cortex (Fig. 15).

**Note:** The Sacral Awl must only be used for 6.5mm diameter screws and larger.

**Sacral Awl diameter = 4.1mm**

Using the Curved Blunt Probe, the Thoracic Pedicle Probe, or the Adjustable Curette Probe, create a pathway into the pedicle (Fig. 16). The correct rotational insertion of the instrument allows the probe to follow a path of least resistance without violating the pedicle walls. In the case that resistance is met, the entry point and trajectory should be reevaluated.
There are three probe options available with Xia 3. The primary differentiating feature between the Curved Blunt Probe, the Thoracic Pedicle Probe, and the Adjustable Curette Probe is the tip. The Curved Blunt Probe has a flat tip, while the Thoracic Pedicle Probe has a sharp tip designed to optimize its use in the thoracic region of the spine. The Adjustable Curette Probe has a curette tip as another blunt tip option (Fig. 17).

The Curved Blunt Probe and the Thoracic Pedicle Probe are laser marked in 5mm intervals to help indicate the depth to which the probe has been inserted. The Adjustable Curette Probe has an adjustable depth stop which allows the probe to be inserted to the indicated depth; the depth indicator can be set from 35mm to 50mm. These depth indicators on the probes are also helpful in determining the appropriate screw length.

**Note:** The Curved Blunt Probe and the Adjustable Curette Probe must not be used to prepare holes for 4.0mm diameter screws. The Thoracic Pedicle Probe is recommended for 4.0mm diameter screws.

Follow the prepared pathway with the Pedicle Feeler to confirm the walls of the pedicle have not been violated. Pedicle Feelers are available in Malleable, Medium and Stiff. Pedicle Feelers are laser marked in 10mm intervals. A Double Ended Pedicle Feeler is also available to feel the pedicle walls for any breaches (Fig. 18).
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For increased bone purchase, use the **Modular Taps** to prepare the pedicle canal. After attaching a Xia 3 handle, insert the Modular Tap into the pedicle and into the vertebral body (Fig. 19). The Modular Taps are laser marked with lines in 5mm increments and numbers in 10mm increments.

Taps are available in the following sizes:
- Ø3.0mm Modular Tap
- Ø3.5mm Modular Tap
- Ø4.0mm Modular Tap
- Ø4.5mm Modular Tap
- Ø5.0mm Modular Tap
- Ø5.5mm Modular Tap
- Ø6.5mm Modular Tap
- Ø7.5mm Modular Tap
- Ø8.5mm Modular Tap
- Ø9.5mm Modular Tap
- Ø10.5mm Modular Tap

**Note:** The nomenclature describing the taps represents the actual tap line to line diameter. This is different from previous versions of the Xia System.

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**Figure 19**

<table>
<thead>
<tr>
<th>Size</th>
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The Modular Taps can be attached to any one of the following Xia 3 handles (Fig. 20):
- T-Handle
- T-Handle, Ratchet
- Round Handle
- Round Handle, Ratchet
- Small Round Handle
- Small Round Handle, Ratchet

**Note:** The Jacobs Chuck Handle is another handle option for the Xia 3 System (Fig. 21). This handle can be hand tightened or the chuck key can be used to secure the handle. Ensure proper engagement between the handle teeth and the instrument shaft surface.
Screw insertion

With the pedicle pathway prepared, and the proper screw diameter and length determined, the screw can be inserted into the pedicle using the appropriate Xia 3 Screwdriver.

The Polyaxial Screwdriver and Monoaxial Screwdriver provide a more rigid connection between the screw and the screwdriver (Fig. 22).

The Polyaxial and Monoaxial Screwdrivers come in three different sizes (Fig. 23).
- Short Polyaxial Screwdriver
- Standard Polyaxial Screwdriver
- Long Polyaxial Screwdriver
- Short Monoaxial Screwdriver
- Standard Monoaxial Screwdriver
- Long Monoaxial Screwdriver

The Polyaxial and Monoaxial Screwdrivers can be connected to any of the Xia 3 handles.

A primary design goal of the Xia 3 System is to help improve the connection between the screw and the screwdriver. The Polyaxial and Monoaxial Screwdrivers were designed to help decrease toggle at two integral points of connection:
- Screwdriver to screw interface
- Screwdriver to shaft interface

The screwdriver locking feature is designed to provide tactile, visual and audible confirmation that the screwdriver is more securely locked.
To assemble and engage the Xia 3 Polyaxial and Monoaxial Screwdrivers:

**Step 1:**
Press the “UNLOCK” button on the outer shaft (Fig. 24).

**Step 2:**
Insert the **Polyaxial** or **Monoaxial Screwdriver Shaft** down the outer shaft (Fig. 25).

**Step 3:**
Slide the **Screwdriver Sleeve** up the inner shaft. Verify the sleeve for screwdriver is completely bottomed out (Fig. 26).

**Step 4:**
Align the tabs and fully insert the quick connect mechanism into the shaft (Fig. 27).
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**Step 5:**
Hold the screw by the threads and engage the tabs on the screwdriver inner shaft into the saddle of the screw head (Fig. 28).

**Step 6:**
Fully seat the inner shaft into the screw head. Turn the outer shaft clockwise using the “LOCK” button until the threads are fully engaged (Fig. 29).

**Step 7 (optional):**
If the ratchet sound is not present, confirm locking by pressing the “LOCK” button (Fig. 30).
To disengage and disassemble the Xia 3 Polyaxial and Monoaxial Screwdrivers:

Once the screw is placed, to disengage the screwdriver press and release the "UNLOCK" button. Rotate the outer shaft counterclockwise while firmly holding the handle (Fig. 31).

Release the quick connect handle from the sleeve and inner shaft. Remove the sleeve by sliding it down the inner shaft. Remove the inner shaft from the outer shaft.

Figure 31
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Xia 3 Low Profile Screwdriver

Note: The Xia 3 Low Profile Screwdriver provides an alternative locking mechanism to the standard Xia 3 Screwdriver while maintaining the 6-point star screw to screwdriver interface.

To assemble and engage the Xia 3 Low Profile Screwdriver:

Step 1:
Insert the Polyaxial Inner Shaft down the outer shaft (Fig. 32).

Step 2:
Slide the locking nut over the inner shaft with the serrated teeth positioned distally (Fig. 33).

Step 3:
Fully insert the handle quick connect mechanism onto the screwdriver shaft (Fig. 34).

Step 4:
Hold the screw by the threads and engage the tabs on the inner shaft into the saddle of the screw head.

Step 5:
Fully seat the inner shaft into the screw head. Turn the outer shaft clockwise until the threads are fully engaged.

Step 6:
Depress the button on the locking nut and slide the locking nut into the outer shaft to lock the screw to the screwdriver.

To disengage and disassemble the Xia 3 Low Profile Screwdriver:

Unlock the screwdriver from the screw by depressing the locking nut button and sliding it up out of the outer shaft.

While pulling upward, turn the outer shaft counterclockwise to disengage the threads from the screw head.

Release the quick connect handle from the screwdriver adapter and inner shaft.

Remove the locking nut by sliding it off the inner shaft.

Remove the inner shaft from the outer shaft.
Rod contouring

The Xia 3 screws are designed to accommodate both 5.5mm and 6.0mm diameter rods (Fig. 35). This versatility is designed to present various size and stiffness options to meet a spectrum of surgical needs. Pre-bent rad rods and max rad rods are also compatible with this system.*

**Note:** Straight rods 90mm and greater have hex ends.

Once all the screws are inserted, the appropriate length rod is determined. Use the Rod Template to more accurately determine the appropriate rod length (Fig. 36).

Use the appropriate pre-cut rods or cut a longer rod to the desired length using the **Table-Top Rod Cutter** and Stand (Fig. 37).

To fit the desired spinal contours, rod bending is performed. Bending can be performed with the **French Benders** or the **Tube Benders** (Fig. 38). To contour the rod, a series of small incremental adjustments will bend the rod gradually and help ensure even stress distribution on the rod.

**Note:** Do not repeatedly contour the rod. Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod. Do not contour a bent rod in the opposite direction; i.e. avoid bending and unbending the rod.

*For a full listing of 5.5mm and 6.0mm rods available, please reference Xiapedia 3.0.
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Once the rod is bent to the desired contour, the Rod Insertion Forceps or Rod Gripper can be used to help place the rod into the grooves of the implant (Fig. 39).

The In Situ Rod Benders and the Coronal Plane Benders can be used to achieve final incremental correction maneuvers (Fig. 40). Care should be taken to not make extreme bends in order to avoid stress concentration and notching of the rod.
Rod linkage

The Xia 3 Spinal System uses the Xia buttress thread blocker as its closure mechanism (Fig. 41). The titanium blocker is laser etched to more clearly differentiate it from other materials. The blocker is assembled onto the **Universal Tightener** for insertion. The Universal Tightener is available in three different options; standard, short and double-ended (Fig. 42).

**Note:** The Xia 3 Universal Tighteners are not to be used for final tightening.
Rod reduction

Xia 3 offers eight options for reducing the rod to the spine:

**Option 1: Inserter Tube and Universal Tightener**
The Inserter Tube helps align the Universal Tightener and the blocker with the implant (Fig. 43).

The two engraved lines on the Universal Tightener denote the following:

- When the lower line is aligned with the top of the Inserter Tube, the blocker is at the top of the implant (Fig. 44).

- When the upper line is aligned with the top of the Inserter Tube, the blocker is fully introduced into the implant (Fig. 45).

**Note:** The lower and upper indication lines reflect the above described positions of the blocker in relation to the implant when the Standard Universal Tightener is used with the Standard Inserter Tube, and when the Short Universal Tightener is used with the Short Inserter Tube. The Standard Universal Tightener can be used with the Short Inserter Tube, but the lower and upper indication lines will not denote the position of the blocker with respect to the implant. Do not use the Short Universal Tightener with the Standard Inserter Tube (Fig. 46).

**Note:** The Xia 3 Universal Tighteners are not to be used for final tightening.
Option 2: Rod Fork and Universal Tightener

When the rod is slightly proud with respect to the seat of the implant, the Rod Fork can be used (Fig. 47).

Slide the Rod Fork into the lateral grooves on the implant head and rotate backwards. This motion lever the rod into the head of the implant. When the rod is fully seated into the head of the implant, insert the blocker with the Universal Tightener.

Note: The Xia 3 Universal Tighteners are not to be used for final tightening.

Option 3: Persuader

Use the Persuader when additional force is needed to bring the rod to the implant. The Persuader is available in two sizes; standard and short (Fig. 48).

The Persuader has two windows at the top and two windows at the bottom of the instrument for visibility.

The Hex Drive T-Handle can be attached to the Persuader for additional leverage (Fig. 49).

There are three key indication lines on the Persuader:

• At “0”, the Persuader can be connected to the implant (Fig. 50).

• At “1”, the Persuader is locked to the implant (Fig. 50).

• At “2”, the rod is fully seated (Fig. 50).
Verify the indication line on the Persuader is in the “0” starting position.

Connect the Persuader to the head of the implant (Fig. 51). Rotate the handle of the Persuader clockwise until the indication line is in the “1” position. At this position the Persuader is locked to the implant and the rod can be pushed into the screw.

Rotate the handle of the Persuader clockwise until the indication line is in the “2” position. At this position, the rod is fully seated and the blocker can be inserted using the Universal Tightener.

To remove the Persuader, rotate the handle counterclockwise until the indication line is in the “0” starting position and twist the instrument to disengage from the implant (Fig. 52).

**Note:** Blockers can be inserted through the Persuader into the screw heads. The Short Universal Tightener will not work with the Standard Persuader.

**Note:** The Xia 3 Universal Tighteners are not to be used for final tightening.

**Note:** The Xia 3 Persuader is designed to provide up to 20mm of reduction.
Option 4: One Handed Persuader

The One Handed Persuader is designed to quickly and easily bring the rod to the implant (Fig. 53).

Connect the One Handed Persuader to the head of the implant with the handle in the open position (Fig. 54).

Squeeze the handle until it reaches the shaft of the instrument. As the handle is depressed, the rod is brought to the implant.

Designed with a natural stop, the One Handed Persuader offers tactile feedback and helps prevent over persuasion. In addition, the ratchet sound provides audible feedback to confirm the rod is fully seated. At this point, the blocker can be inserted with the Universal Tightener.

To remove the One Handed Persuader, slide the lock release and twist the instrument to disengage from the screw (Fig. 55).

Note: Blockers can be inserted through the One Handed Persuader into the screw heads. The Short Universal Tightener will not work with the One Handed Persuader.

Note: The Xia 3 Universal Tighteners are not to be used for final tightening.

Note: The One Handed Persuader is designed to provide up to 20mm of reduction.

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 helps 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 (Fig. 56).
Option 5: Lateral Persuader

The Lateral Persuader is designed to aid in medializing and reducing the rod when it is not centered over the tulip (Fig. 57).

Before use, ensure that the center tube is unthreaded to its desired height (Fig. 58).

Connect one of the distal ends of the Lateral Persuader to the head of the implant with the handle in the open position (Fig. 59). Squeeze the handle until the rod is medialized over the tulip. Rotate the center tube clockwise until the rod is fully seated in the tulip head (Fig. 60). A physical stop will indicate when the rod is in position.

If additional torque is needed to persuade the rod, a T-Handle (48237097) from the SUK DVR System can be connected to the proximal end of the tube for added leverage (Fig. 61).

**Note:** For instrument cleaning, unthread the center tube fully from the Lateral Persuader and clean the pieces separately.

**Note:** Blockers can be inserted through the Lateral Persuader into the screw heads with the Xia 3 Universal Tightener. The Short Universal Tightener will not work with the Lateral Persuader.

**Note:** The Xia 3 Universal Tighteners are not to be used for final tightening.

**Note:** The Lateral Persuader is designed to provide up to 10mm of medialization and up to 20mm of axial reduction.
Option 6: Reduction Clip
The Reduction Clip was designed to be a low profile reduction instrument (Fig. 62). The low profile of the Reduction Clip allows multiple clips to be used on adjacent segments.

To reduce the rod, attach the inner sleeve of the Reduction Clip to the notches on the tulip head of the screw (Fig. 63).

Rotate the outer sleeve clockwise until the rod is fully seated in the tulip head.

If additional torque is needed to persuade the rod, a T-Handle (48237097) from the SUK DVR System can be connected to the proximal end of the tube for additional leverage (Fig. 64).

**Note:** Blockers can be inserted through the Reduction Clip into the screw heads.

**NOTE:** The Xia 3 Universal Tighteners are not to be used for final tightening.

**NOTE:** Reduction Clips can also be used with SUK Derotator Clips to perform direct vertebral rotation.

**NOTE:** The Reduction Clips are designed to provide up to 10mm of axial reduction.
**Option 7: SUK Reduction Tube**

The **SUK Reduction Tube** was designed to function as both a reduction instrument and an instrument that can be used for direct vertebral rotation.

Attach the inner sleeve of the SUK Reduction Tube to the notches on the tulip head of the screw (Fig. 65).

Rotate the outer sleeve clockwise until the rod is fully seated in the tulip head (Fig. 66).

If additional torque is needed to persuade the rod, a T-Handle (48237097) from the SUK DVR System can be connected to the proximal end of the tube for additional leverage.

Once the outer sleeve has been fully threaded down and a secure connection ensured, the SUK Reduction Tube can now be used in direct vertebral rotation maneuvers.

---

**Note:** Blockers can be inserted through the SUK Reduction Tube into the screw heads. The Short Universal Tightener will not work with the SUK Reduction Tube.

**Note:** The SUK Reduction Tubes are designed to provide up to 10mm of axial reduction.

**Note:** The Xia 3 Universal Tighteners are not to be used for final tightening.

**Note:** SUK Tube One-Piece (48237087) is also available and can be used over reduction screws.

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**Note:** Disassembly instructions for cleaning, please see page 41.
Option 8: Reduction screws
Xia 3 Reduction Uniplanar Screws* can also be used during a corrective procedure, and may be especially helpful at the concavity of the curve’s apex. The **Xia 3 Reduction Uniplanar Screwdriver** is used to insert the Xia 3 Reduction Uniplanar Screws into the pedicles (Fig. 67).

Uniplanar reduction screws are visibly distinguishable from standard Xia screws by the non-anodized bone screw, the extended tabs of the tulip heads and the two machined grooves on the extended tabs of the tulip head (Fig. 68).

The Xia 3 Reduction Uniplanar Screws are available in the following sizes:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>4.5mm</th>
<th>5.0mm</th>
<th>5.5mm</th>
<th>6.0mm</th>
<th>6.5mm</th>
<th>7.0mm</th>
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<td>Length</td>
<td>20mm-45mm</td>
<td>20mm-45mm</td>
<td>20mm-55mm</td>
<td>25mm-60mm</td>
<td>25mm-60mm</td>
<td>30mm-60mm</td>
<td>30mm-60mm</td>
</tr>
</tbody>
</table>

**Note:** The machined grooves will be on the extended tabs of the reduction uniplanar screws. Once the tabs are removed from the reduction uniplanar screws, the grooves will no longer be present. Use the edge of the break line on the tulip head of the reduction uniplanar screws to help distinguish the screws as reduction uniplanar screws.

Final tightening will take place once the blockers are inserted and the tabs are broken off.

When the Xia 3 Reduction Uniplanar Screws are used, the tabs are broken off when the reduction is complete.

A snap line allows a clean and easy break (Fig. 69).

The first tab is broken away using the **Reduction Screw Tab Remover** to grip the tab and bend it in a back and forth motion (Fig. 70).

The second tab is broken off in the same manner as the first (Fig. 71).

**Note:** The Xia 3 Reduction Uniplanar Screws are designed to provide up to 15mm of rod reduction into the screw’s tulip.

*Polyaxial Reduction Screws are available in the Xia II Spinal System or MANTIS System (Xia 3 Screw Design).
Correction procedures

Deformity correction
In working with our global panel of scoliosis specialists, the Xia 3 System was designed to offer solutions that accommodate various surgical philosophies.

Deformity correction may be obtained using one of five different reduction procedures:

1. Rod rotation
2. Translation
3. Distraction/compression
4. In Situ bending
5. Direct vertebral rotation

These maneuvers may be utilized independently or in any combination to facilitate optimal spinal deformity correction.

Option 1: Rod rotation
This technique begins by contouring the rod to the desired shape for the sagittal plane. The rod can then be inserted in the implants up to 90° out of phase to minimize the implant approximation necessary. The rod is then rotated, not to derotate the spine, but to place the implants in the proper alignment (Fig. 72). Final correction is then performed using distraction and compression techniques.

Option 2: Translation
Translation can be achieved by utilizing any of the persuader/reduction options on pages 27-34. Persuaders are typically placed at the distal and proximal ends of the curve apex (Fig. 73). As the spine is carefully translated at these points the closure screws are inserted and the implants secured. The persuaders are then moved toward the apex of the curve until translation is complete.
**Option 3: Distraction/compression**

Spinal deformities can be further corrected in the coronal plane by creating a distraction in the concavity of the deformity and compression on the convexity of the deformity (Fig. 74).

**Note:** Posterior distraction creates a kyphosis in the sagittal plane, compression creates a lordosis in the sagittal plane. Compression is achieved with the Compressor and distraction can be achieved with the Distractor. Once the construct is in the desired position, lock the closure screws with the Universal Tightener.

**Option 4: In Situ bending**

Great care must be taken during in situ bending not to overload the bone implant interface (Fig. 75). Also care must be used not to acutely notch the rod, which may weaken the implant.

Ensure that the closure screws are not completely tightened during rotation maneuvers or the compression/distraction process.
Xia 3 Spinal System
AIS surgical technique

Xia 3 Uniplanar screws

**Option 5: Direct vertebral rotation**
The Xia 3 Uniplanar Screws are designed to provide polyaxial freedom in the cephalad/caudal plane, but remain fixed in the medial/lateral plane (Fig. 76). The polyaxial movement in the cephalad/caudal plane facilitates easier rod seating. Prohibiting movement in the medial/lateral plane facilitates direct vertebral rotation, which helps achieve three dimensional correction of the spine.

Uniplanar screws are visibly distinguishable from standard Xia screws by the non-anodized bone screw as well as two machined grooves on the tulip. They are available in the following sizes:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>4.5mm</th>
<th>5.0mm</th>
<th>5.5mm</th>
<th>6.0mm</th>
<th>6.5mm</th>
<th>7.0mm</th>
<th>7.5mm</th>
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<tbody>
<tr>
<td>Length</td>
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<td>20mm-45mm</td>
<td>20mm-55mm</td>
<td>25mm-60mm</td>
<td>25mm-60mm</td>
<td>30mm-60mm</td>
<td>30mm-60mm</td>
</tr>
</tbody>
</table>

**Note:** The machined grooves will be visible on the tulips of the standard uniplanar screws.

To insert the uniplanar screws, follow the same screw insertion procedure thoroughly detailed in this surgical technique for the monoaxial and polyaxial screws.

**Note:** Uniplanar screws are compatible with all standard Xia 3 Instrumentation.

The **SUK DVR System** can be used in conjunction with uniplanar screws for vertebral body derotation maneuvers (Fig. 77).

The SUK DVR System can be arranged either unilaterally or bilaterally to correct the curvature of the spine by application of cantilever forces applied to the SUK tubes and clamps.

The T-Handle can be used in conjunction with the two-piece tubes to aid in tightening of the outer sleeve providing more rigid fixation between the tube and the Xia 3 Uniplanar Screw tulip head.

**Note:** During DVR maneuvers, it is recommended to translate the load evenly over multiple tubes.

**NOTE:** For more information on direct vertebral rotation maneuvers, see the Xia 3 SUK Direct Vertebral Rotation (DVR) System Surgical Technique.

**Note:** Short, medium and long SUK clamps are compatible with standard one-piece SUK tubes, two-piece SUK tubes, reduction SUK tubes and reduction clips interchangeably.

**Note:** The SUK DVR Reduction Tube and the Reduction Clip are both designed to provide up to 10mm of reduction of the rod into the tulip head of the screw.
Final tightening

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, final tightening of the blockers can be performed. Use the **Anti-Torque Key** and the **Torque Wrench** or **Audible Torque Wrench**. The Anti-Torque Key and Torque Wrench come in two sizes; standard and short.

Place the Anti-Torque Key around the screw head. Place the Torque Wrench or Audible Torque Wrench through the Anti-Torque Key until it is guided into the blocker (Fig. 78).

The Torque Wrench indicates the optimal torque force that must be applied to the implant for final tightening. Line up the two arrows to achieve the final tightening torque of 12Nm. If using the Audible Torque Wrench, the blocker is completely tightened to 12Nm when the Audible Torque Wrench clicks once.

**Note:** Do not exceed 12Nm during final tightening.

**Note:** The Short Torque Wrench will not fit through the standard Anti-Torque Key.

**Note:** The ES2 Torque Wrench or the MANTIS Redux Torque Wrench may also be used as an alternative to the Xia 3 Torque Wrench to final tighten the Xia 3 blockers.

The Anti-Torque Key must be used for final tightening. The Anti-Torque Key performs two key functions (Fig. 80):
- Allows the Torque Wrench to align with the tightening axis.
- Helps to maximize the torque needed to lock the implant assembly.

**Note:** The ES2 Counter Torque Tube may also be used in conjunction with the Xia 3 Torque Wrench or Audible Torque Wrench.
Cross connectors
Cross connectors are recommended for increased rotational stability of the construct.

Once the final tightening of the construct is complete, choose the appropriate cross connector size by using the Cross Connector Measuring Device or the MAC Caliper (Fig. 80).

To allow for smooth and rapid insertion of the cross connector over the rods, ensure the spring tightened center nut is loose. This facilitates full range of motion and helps ensure the set screws are adequately backed out.

Use the CrossConnectorInserter to place the appropriate length connector on the rod (Fig. 81). Use the 3.5mm Hex Driver or the Double-Ended 3.5mm Set Screw Inserter to tighten one of the set screws onto the rod (Fig. 81).

Continue with the insertion of the cross connector by fully tightening the second set screw. Return to the first set screw for further tightening.

Confirm that the cross connector is correctly connected to the rods.

For final tightening, the 3.5mm Hex Driver must be used to tighten the set screws, and the 8mm Hex Driver must be used to final tighten the center nut (Fig. 81 and Fig. 82).
Revision procedures

**Rod to rod connection**

Rod to rod connection is occasionally necessary. There are several options available (Fig. 83):

1. Parallel connectors
2. Axial connectors
3. Open connectors
4. Angled, side loading and closed connectors
5. Offset connectors

For tightening those connectors use the 3.5mm Hexagonal Driver.

**Note:** For a full listing of the rod to rod, axial and offset connectors available in the Xia family, please reference the Xia 3 Ilios and Revision Surgical Technique or Xiapedia 3.0.

**Note:** The following connectors are compatible with a 6.0mm rod ONLY:

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03820101</td>
<td>Xia II Low Profile Closed Offset Connector</td>
</tr>
<tr>
<td>48230133</td>
<td>Xia 3 Low Profile Long Closed Offset Connector</td>
</tr>
<tr>
<td>03805001</td>
<td>Xia Rod-to-Rod Parallel Connector</td>
</tr>
<tr>
<td>03805002</td>
<td>Xia Rod-to-Rod Axial Connector</td>
</tr>
</tbody>
</table>
**Xia 3 Spinal System**

**AIS surgical technique**

**Instructions for cleaning**

**Step 1:**
Unthread the outside tube (1) from the inside tube (2) (Fig. 84).

**Step 2:**
Once the first level of threads is cleared, slide the outside sleeve (1) back until it reaches the stop threads (3) (Fig. 85).

**Step 3:**
Unthread the outside sleeve (1) until the stop threads (3) are cleared and continue to pull the outside sleeve off of the inside tube (2) (Fig. 86).

**Step 4:**
Further separate the outside sleeve (1) from the inside tube (2) (Fig. 87).
# Implants

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Sterile reference number*</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>48230000</td>
<td>48230000S</td>
<td>Xia 3 Blocker</td>
</tr>
<tr>
<td>4823040(20)-(45)</td>
<td>4823040(20)-(45)S</td>
<td>Xia 3 Ø4.0x 20-45mm Monoaxial Screw</td>
</tr>
<tr>
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<td>Xia 3 Ø4.5 x 20-45mm Monoaxial Screw</td>
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<tr>
<td>4823060(25)-(90)</td>
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<tr>
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<td>Xia 3 Ø7.5 x 30-60mm Uniplanar Screw</td>
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*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.
<table>
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<td>Xia 3 Ø7.5 x 30-60mm Uniplanar Reduction Screw</td>
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<tr>
<td>4823850(20) – (45)</td>
<td>N/A</td>
<td>Xia 3 Ø5.0 x 20-45mm Biased Angle Polyaxial Screw</td>
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<td>4823855(25) – (55)</td>
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<td>4823865(25) – (90)</td>
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<tr>
<td>4823875(25) – (90)</td>
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<td>Xia 3 Ø8.5 x 60-100mm Biased Angle Polyaxial Screw</td>
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<td>4823895(60) – (100)</td>
<td>N/A</td>
<td>Xia 3 Ø9.5 x 60-100mm Biased Angle Polyaxial Screw</td>
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</tbody>
</table>

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.
### Reference number | Description
--- | ---
48237140(20) – (45) | Xia 3 Ø4.0 x 20-45mm Medial Biased Angle Polyaxial Screw
48237145(20) – (45) | Xia 3 Ø4.5 x 20-45mm Medial Biased Angle Polyaxial Screw
48237150(20) – (45) | Xia 3 Ø5.0 x 20-45mm Medial Biased Angle Polyaxial Screw
48237155(25) – (55) | Xia 3 Ø5.5 x 25-55mm Medial Biased Angle Polyaxial Screw
48237165(25) – (90) | Xia 3 Ø6.5 x 25-90mm Medial Biased Angle Polyaxial Screw
48237175(25) – (90) | Xia 3 Ø7.5 x 25-90mm Medial Biased Angle Polyaxial Screw
48237185(60) – (90) | Xia 3 Ø8.5 x 60-90mm Medial Biased Angle Polyaxial Screw
48237195(60) – (90) | Xia 3 Ø9.5 x 60-90mm Medial Biased Angle Polyaxial Screw
4823765(30) – (00) | Xia 3 Ø6.5 x 30-100mm Closed Head Polyaxial Screw
4823775(30) – (00) | Xia 3 Ø7.5 x 30-100mm Closed Head Polyaxial Screw
4823785(30) – (00) | Xia 3 Ø8.5 x 30-100mm Closed Head Polyaxial Screw
4823795(30) – (00) | Xia 3 Ø9.5 x 30-100mm Closed Head Polyaxial Screw
48233500 | Set Screw for Xia 3 Closed Head Screw (M6 x 1)

### Reference number | Description
--- | ---
48230250 | Xia 3 Medium Laminar Hook Standard Blade
48230201 | Xia 3 Medium Laminar Hook Narrow Blade
48230202 | Xia 3 Large Laminar Hook Standard Blade
48230203 | Xia 3 Large Laminar Hook Narrow Blade
48230204 | Xia 3 Laminar Hook Extended Body
48230205 | Xia 3 Small Laminar Hook Extended Body
48230206 | Xia 3 Laminar Hook Offset, Right
48230207 | Xia 3 Laminar Hook Offset, Left
48230208 | Xia 3 Large Laminar Hook Angled Blade
48230209 | Xia 3 Small Laminar Hook Angled Blade
48230210 | Xia 3 Thoracic Laminar Hook Standard Blade
48230211 | Xia 3 Thoracic Laminar Hook Narrow Blade
48230212 | Xia 3 Thoracic Laminar Hook Small Offset, Right
48230213 | Xia 3 Thoracic Laminar Hook Small Offset, Left
48230214 | Xia 3 Thoracic Laminar Hook Large Offset, Right
48230215 | Xia 3 Thoracic Laminar Hook Large Offset, Left
48230216 | Xia 3 Thoracic Laminar Hook Small Narrow Blade
48230217 | Xia 3 Large Offset Hook, Right
48230218 | Xia 3 Large Offset Hook, Left
482302(20)-(22) | Xia 3 Small, Medium, Large Pedicle Hook
48230232 | Xia 3 Transverse Process Hook, Right
48230233 | Xia 3 Transverse Process Hook, Left
48230240 | Xia 3 Small Laminar Hook Narrow Blade
48230241 | Xia 3 Small Laminar Hook Standard Blade

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These set screws come pre-packaged with these implants. This part need only be ordered as a replacement if lost or damaged.
### Xia 3 Spinal System

**AIS surgical technique**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Sterile reference number</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>48232(030)-(150)</td>
<td>48232(030)-(150)S</td>
<td>Xia 3 Ø6.0 x 30-150mm CP Ti Rod</td>
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<td>48232480</td>
<td>N/A</td>
<td>Xia 3 Ø6.0 x 480mm CP Ti Rod</td>
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<td>486613(110)-(600)</td>
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<td>Xia 3 Multi-Axial Cross Connector, 70mm-99mm</td>
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*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.*
### Xia 3 Spinal System
#### AIS surgical technique

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<td>Xia II 0° Large Rod-to-Rod Connector</td>
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<td>Xia 3 12mm Parallel Revision Connector Open-Closed</td>
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<td>48235008</td>
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<td>Xia 3 22mm Parallel Revision Connector Open-Closed</td>
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<td>Xia 3 Angled Loading Side Loading RRC</td>
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<td>Xia 3 Top Loading Side Loading RRC</td>
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<td>Xia 3 Long Offset Connector Open-Head</td>
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<td>Xia 3 Open Side-Loading Offset Connector</td>
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### Revision implants

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<td>Xia 3 Axial Revision RRC (D 6.5 - 9.5mm) (Length 40, 50, 60mm)</td>
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<tr>
<td>482365 (40)-(60)</td>
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<td>Xia 3 Revision Connector Screw 6.5mm x 40-60mm</td>
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<td>482375 (40)-(60)</td>
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<td>Xia 3 Revision Connector Screw 7.5mm x 40-60mm</td>
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<td>482385 (40)-(60)</td>
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<td>Xia 3 Revision Connector Screw 8.5mm x 40-60mm</td>
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<td>482395 (40)-(60)</td>
<td>N/A</td>
<td>Xia 3 Revision Connector Screw 9.5mm x 40-60mm</td>
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<td>48230260</td>
<td>N/A</td>
<td>Xia 3 Sacral Hook</td>
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<td>48230133</td>
<td>48230133S</td>
<td>Xia 3 Low Profile Long Closed Offset Connector</td>
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<tr>
<td>48233500</td>
<td>N/A</td>
<td>Set Screw for Xia 3 Small Offset Connector Closed Head (M6 x 1)</td>
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</table>

These set screws come pre-packaged with these implants. This part need only be ordered as a replacement if lost or damaged.

Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

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## Instruments

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<tbody>
<tr>
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<td>Awl</td>
<td>482391320S</td>
<td>Short Monoaxial Screwdriver*</td>
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<td>482397002</td>
<td>Sacral Awl</td>
<td>482391311S</td>
<td>Short Polyaxial Screwdriver</td>
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<td>48237024</td>
<td>Curved Blunt Probe</td>
<td>482391321S</td>
<td>Short Monoaxial Screwdriver</td>
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<tr>
<td>48237055</td>
<td>Thoracic Pedicle Probe</td>
<td>482391330L</td>
<td>Long Polyaxial Screwdriver*</td>
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<tr>
<td>482397001</td>
<td>Adjustable Curette Probe</td>
<td>482391320L</td>
<td>Long Monoaxial Screwdriver*</td>
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<td>48237060</td>
<td>Pedicle Feeler - Malleable</td>
<td>482391311L</td>
<td>Long Polyaxial Screwdriver</td>
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<tr>
<td>48237059</td>
<td>Pedicle Feeler - Medium</td>
<td>482391321L</td>
<td>Long Monoaxial Screwdriver</td>
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<tr>
<td>48237003</td>
<td>Pedicle Feeler - Stiff</td>
<td>482397004</td>
<td>Low Profile Screwdriver*</td>
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<tr>
<td>48237061</td>
<td>Double Ended Pedicle Feeler</td>
<td>482397009</td>
<td>Low Profile Screwdriver Shaft</td>
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<tr>
<td>48230(030)-(105)</td>
<td>Modular Tap, Ø3.0mm-Ø10.5mm</td>
<td>482391312S</td>
<td>Short Xia II Polyaxial Screwdriver Shaft</td>
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<td>48231201</td>
<td>T-Handle</td>
<td>482331330</td>
<td>Reduction Uniplanar Screwdriver</td>
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<td>48231202</td>
<td>T-Handle, Ratchet</td>
<td>48231326</td>
<td>Iliac Screwdriver - Two Piece</td>
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<td>48231301</td>
<td>Round Handle</td>
<td>482339110</td>
<td>Reduction Screw Tab Remover</td>
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<td>Round Handle, Ratchet</td>
<td>48237091</td>
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<td>482397006</td>
<td>Small Round Handle</td>
<td>48237033</td>
<td>Modular Polyadjustment Driver</td>
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<td>48231313</td>
<td>Self-Holding Polyaxial Screwdriver Shaft</td>
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<td>Xia 3 Monoaxial Screwdriver*</td>
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<td>Rod Rotation Key (Ø6.0mm)</td>
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<td>Xia 3 Polyaxial Screwdriver</td>
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<td>Xia II Rod Template</td>
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<td>Table-Top Rod Cutter Stand</td>
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<td>Screwdriver Sleeve</td>
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<td>Xia 3 Short Polyaxial Screwdriver*</td>
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<td>French Bender</td>
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*Everything but handle*
### Xia 3 Spinal System

**AIS surgical technique**

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<thead>
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<th>Description</th>
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<td>Tube Bender Left</td>
<td>48237026</td>
<td>Anti-Torque Key*</td>
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<tr>
<td>48230191R</td>
<td>Tube Bender Right</td>
<td>482397026</td>
<td>Short Anti-Torque Key*</td>
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<tr>
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<td>Rod Insertion Forceps</td>
<td>48237028</td>
<td>Xia 3 Torque Wrench</td>
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<td>Rod Gripper</td>
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<td>Xia 3 Short Torque Wrench</td>
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<td>48237011L</td>
<td>In Situ Rod Bender Left</td>
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<td>ES2 Torque Wrench</td>
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<tr>
<td>48237011R</td>
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<td>ES2 Counter Torque Tube</td>
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<td>48230175</td>
<td>SUK Derotator Clamp</td>
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*Xia II Anti-Torque Keys can be used with Xia 3*
# Xia 3 Spinal System
## AIS surgical technique

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Xia 3 Spinal System

AIS surgical technique

Xia 3, Xia 4.5, and Xia Growth Rod Conversion Set

STRYKER SPINE Spinal Fixation Systems

NON-Sterile and Sterile Product

The STRYKER Spine Spinal Fixation Systems are made of devices for fixation of the non-cervical spine. They include smooth rods, screws, hooks, closure screws, connectors, and staples. The components are manufactured from either titanium material (Titanium alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy.

MATERIALS

Xia 3 Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, connectors and rods.
Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67: Rods
Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Xia 4.5 Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, connectors, rods, and staples.
Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Xia Growth Rod Conversion Set
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Growth Rod Connectors

Titanium and Stainless steel implants should not be mixed in a patient; otherwise corrosion may occur resulting in decreased mechanical resistance.

Cobalt-Chromium-Molybdenum Alloy and Stainless steel implants should not be mixed in a patient; otherwise corrosion may occur resulting in decreased mechanical resistance.

MATERIALS IDENTIFICATION

Titanium: symbol [T]
Stainless Steel: symbol [S]
Cobalt-Chromium-Molybdenum: symbol [C]

INDICATIONS

Xia 3 Spinal System
The Xia 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture of dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The 5.5 mm rods from the Stryker Spine Radius Spinal System and 6.0 mm Vitallium rods from the Xia Spinal System are intended to be used with the other components of the Xia 3 Spinal System.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondyloysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Xia 4.5 Spinal System
The Xia 4.5 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications:

- Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture of dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The Stryker Spine DIAPASON Spinal System, Opus Spinal System, and Xia 4.5 Spinal System can be linked to the Xia 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondyloysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Xia Growth Rod Conversion Set

The Xia Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia Growth Rod Conversion Set may be used with any cleared Xia 4.5 Spinal System rod construct. The Xia Growth Rod Conversion Set is not intended for use in conjunction with staples.

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.
- 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 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.

**ADDITIONAL CONTRAINDICATIONS FOR PEDIATRIC PATIENTS**

- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Patients having inadequate tissue coverage of the operative site or inadequate bone stock or quality.

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

**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 these devices. 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 these devices with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should 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 make aware of possible adverse effects. The surgeon must warn the patient that the devices cannot and do not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implants can break or become damaged as a result of strenuous activity or trauma, and that the devices 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 devices. 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.

**INSTRUMENTS**

Instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the devices. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery. Surgeons must verify that the instruments are in good condition and operating order prior to each use during surgery.

**REUSE**

Re-sterilization of implants provided sterile is strictly forbidden, regardless of the method that might be employed.

Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

**HANDLING**

Correct handling of the implant is extremely important. The operating surgeon should avoid nicking or scratching the device.

**ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES**

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.
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.

METAL COMPONENTS

Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer’s spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE 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 may 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.

The surgeon must warn the patient of these adverse effects as deemed necessary.

ADDITIONAL ADVERSE EFFECTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to limitations (pedicle dimensions and/or distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.
- Unintended fusion in Growth Rod patients.
- Increased risk of post-operative infection and wound-healing issues in Growth Rod patients.
- Increased risk of implant breakage in Growth Rod patients.
- Implant prominence (symptomatic or asymptomatic).
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)

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.

CAUTION

Stryker Spine has not validated and does not recommend Flash Sterilization. For Product being used in the US, a sterilization wrap that is FDA cleared for the cycle parameters noted is required.

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 risks 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.

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 Xia 3 Spinal System, Xia 4.5 Spinal System, and Xia Growth Rod Conversion Set have not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The safety and effectiveness of the Xia 3 Spinal System has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
Growth rod systems should only be used by surgeons who are experienced with pediatric posterior spine surgery procedures and have undergone hands-on training in both device implantation and adjustment. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with growth rod systems should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurologic complications.

Growth rod constructs typically require repeated planned-lengthening procedures until a determination is made that the patient is ready for a final fusion procedure. Growth rod patients are more susceptible to post-operative infections and wound-healing issues, as well as the potential for implant breakage requiring unplanned surgical procedures. The physician should discuss these and all other potential complications with the patient and the patient’s guardian.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter and length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device related injury because of their small stature.

PRECAUTIONS
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.

While the final decision on implant removal is up to the surgeon and the patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breaking which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.
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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TLXIA-ST-3_Rev-7_18185
SC/GS 08/18
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