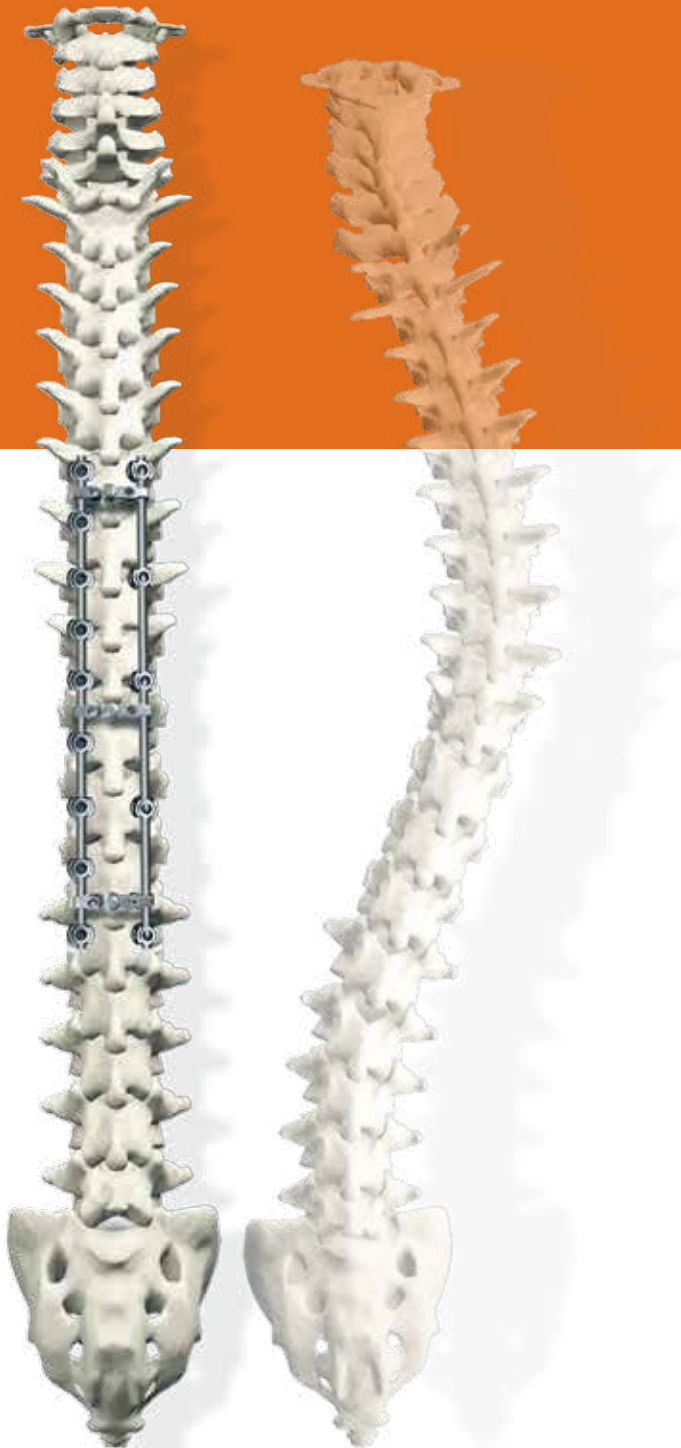


Xia® 3 Spinal System

Surgical Technique



Adolescent Idiopathic Scoliosis
Application

Introduction

Built on the successful foundation of Xia's history, Stryker Spine 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

Acknowledgements

Stryker Spine would like to extend their thanks to the following surgeons for their dedication and contributions:

- Tushar Patel, MD
- Alex Vaccaro, MD

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Key Design Features

Xia 3 Polyaxial Screw

- **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*



Diameter	4.0mm	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.0mm	7.5mm	8.5mm	9.5mm	10.5mm
Length	20mm-45mm	20mm-45mm	20mm-50mm	25mm-55mm	25mm-90mm	25mm-90mm	25mm-90mm	25mm-90mm	25mm-100mm	40mm-100mm	40mm-100mm

*See Xiapedia 2.0 for full listing of screw options including Closed Head Monoaxial and Polyaxial, Biased Angle, Medial Biased Angle, Uniplanar, and Reduction Uniplanar Screws.

Key Design Features



Polyaxial Freedom

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



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

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.

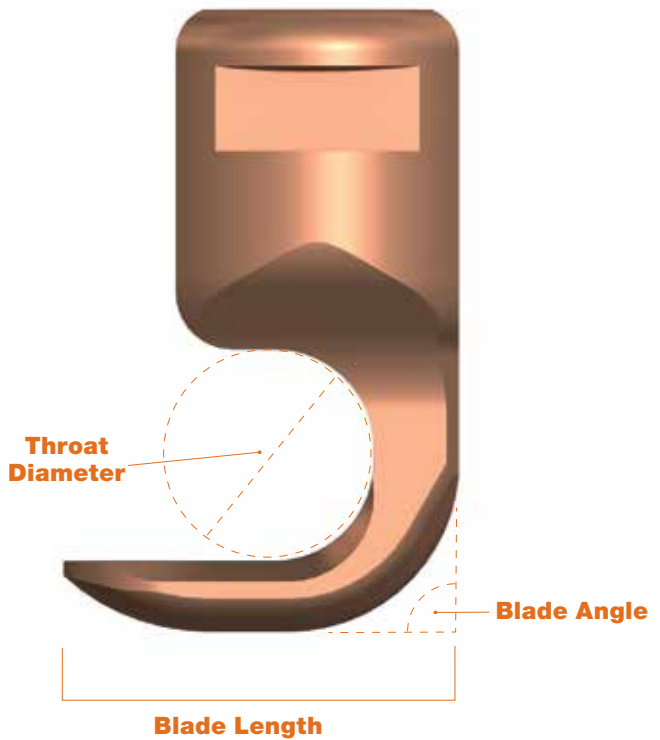
Surgeons may now choose from 3 different working lengths, standard or low profile, and standard or small handles for their screwdriver.

Ergonomic Handles

Stryker branded handles are designed to enhance comfort, function, and efficiency.

Key Design Features

Xia 3 Hooks



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.






Key Design Features

Xia 3 Hook Offering


Laminar

	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

Thoracic Laminar

	Reference Number	Description
	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 Small Thoracic Laminar Hook Narrow Blade
	48230217	Xia 3 Large Offset Hook, Right
	48230218	Xia 3 Large Offset Hook, Left




Transverse Process

	Reference Number	Description
	48230232	Xia 3 Transverse Process Hook, Right
	48230233	Xia 3 Transverse Process Hook, Left

Pedicle

	Reference Number	Description
	482302(20)-(22)	Xia 3 Small, Medium, Large Pedicle Hook

Hook Holders

	Reference Number	Description
	48231020	Standard Hook Holder
	48231040	Lateral Hook Holder
	48231170	Straight Hook Holder

NOTE: Reduction Hooks are available in the Xia II Spinal System.

Patient Positioning



Figure 1

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



Figure 2

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).

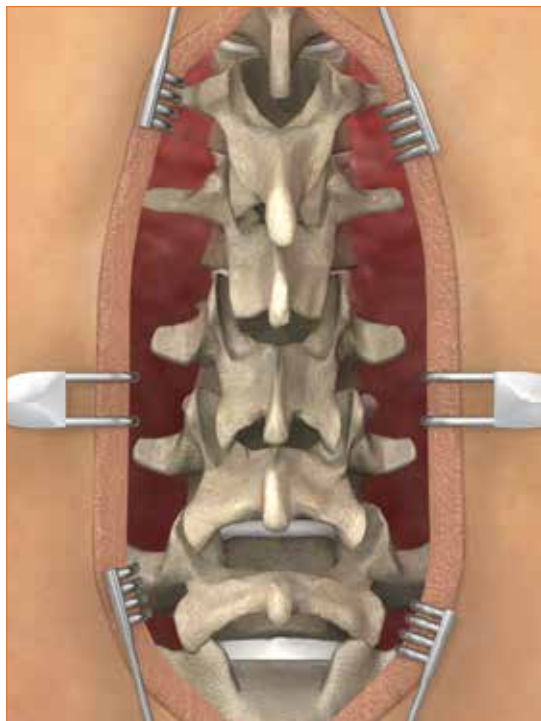
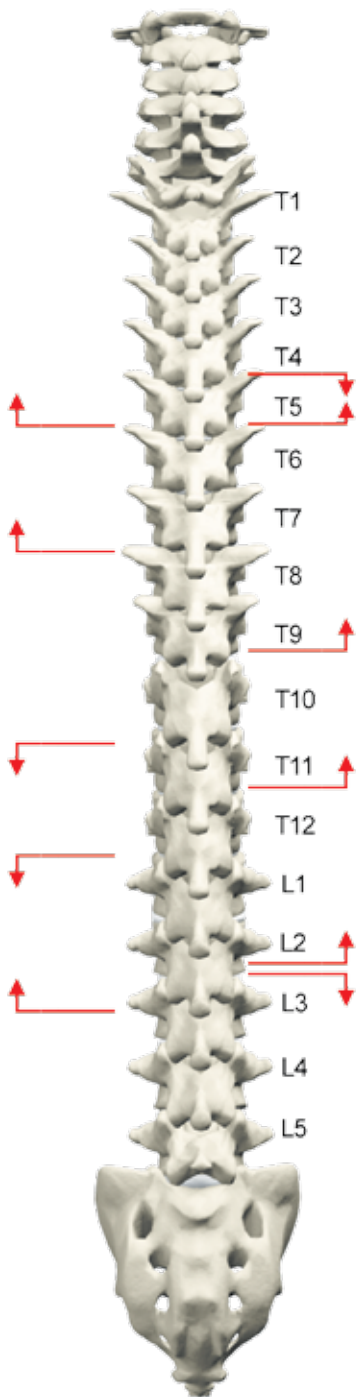


Figure 3

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



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

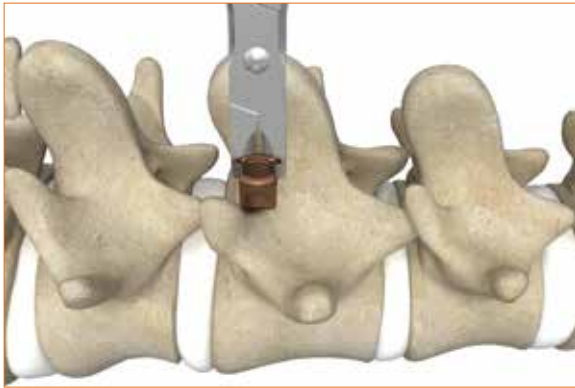


Figure 5



**Standard Lamina Hook Preparer
48237021**



**Narrow Lamina Hook Preparer
48230110**

Figure 6

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 Lamina 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 Lamina 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.

Hook Insertion



Figure 7

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.

Hook Insertion



Figure 8



Figure 9

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.

NOTE: To facilitate the introduction of the pedicle hook it may be necessary to remove the prominence of the caudal lamina below the hook.

Hook Insertion



Figure 10



Figure 11

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 Lamina 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

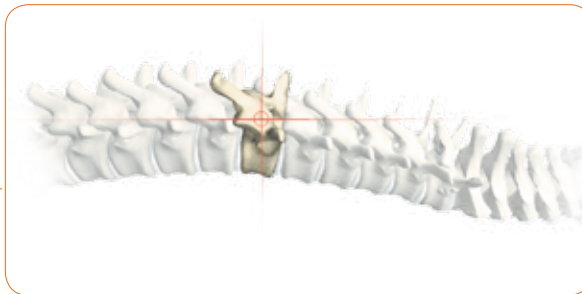
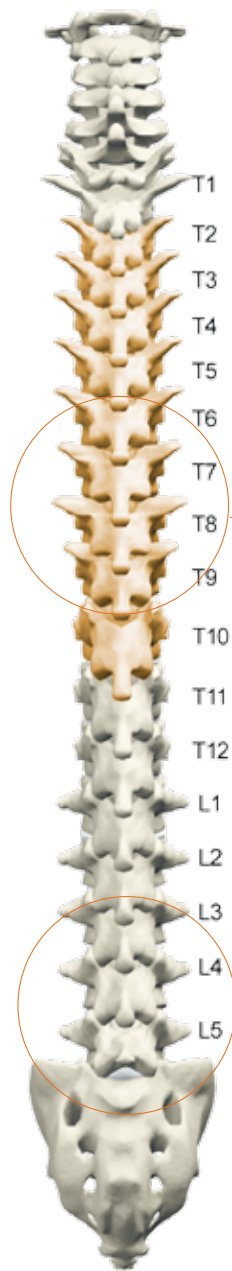


Figure 12

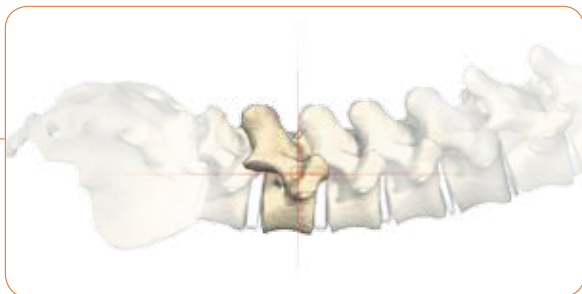
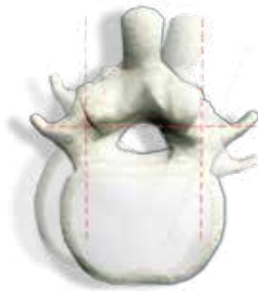


Figure 13

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.

Preparing the Pedicle



Figure 14



Awl 48237111

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

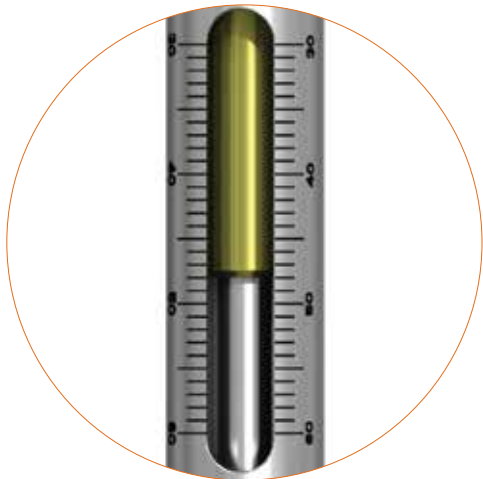


Figure 15



Sacral Awl 482397002

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

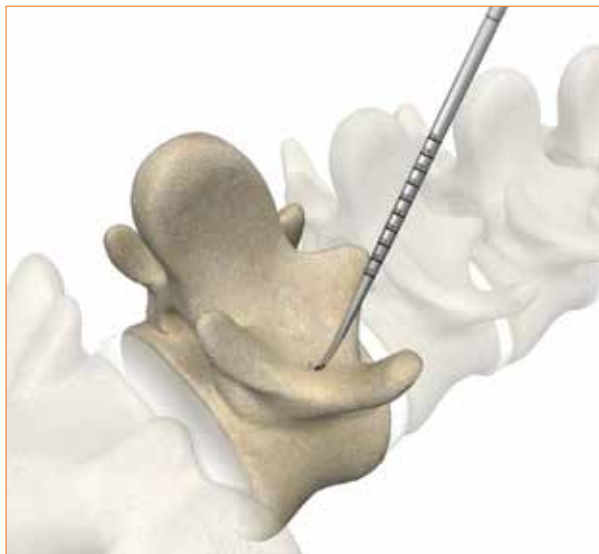
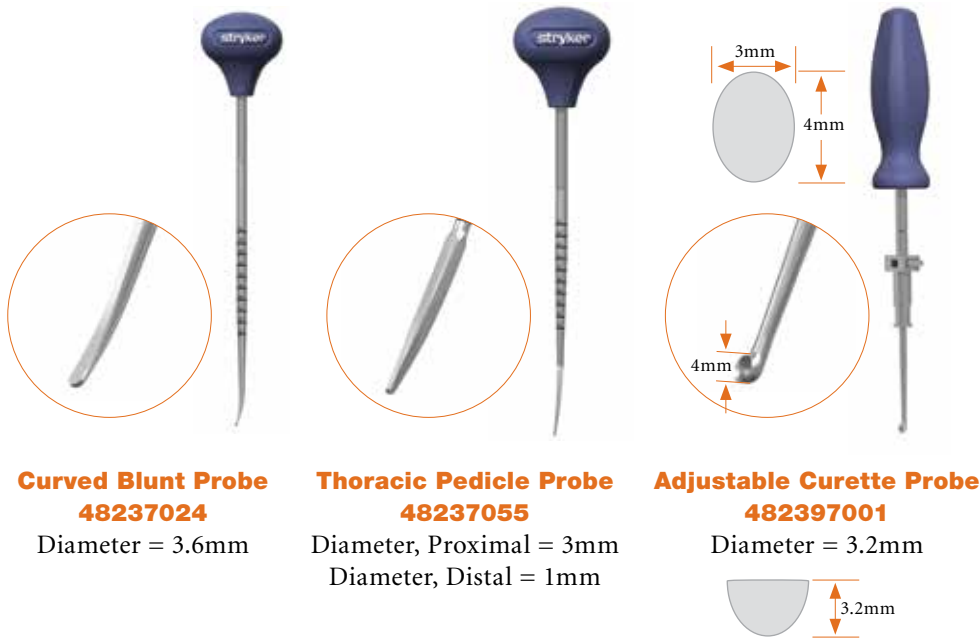


Figure 16

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.

Preparing the Pedicle



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.

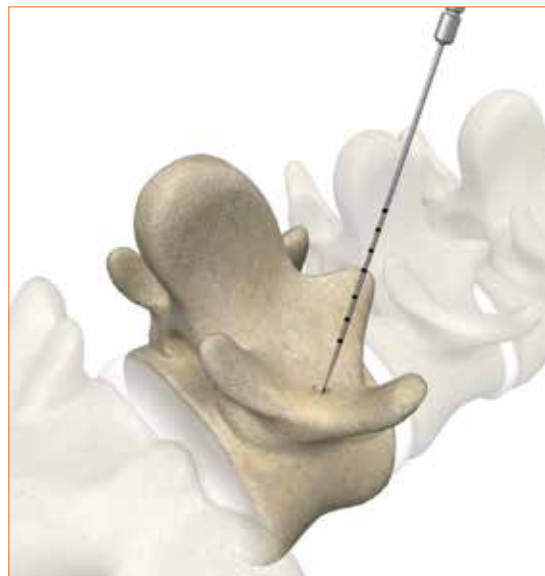


Figure 18

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).

Pedicle Feeler - Malleable 48237060

Tip Diameter = 1.5mm

Pedicle Feeler - Medium 48237059

Tip Diameter = 2mm

Pedicle Feeler - Stiff 48237003

Tip Diameter = 2mm

Double Ended Pedicle Feeler 48237061

Tip Diameter = 2mm

Preparing the Pedicle



Figure 19

Ø3.0mm Modular Tap	48230030
Ø3.5mm Modular Tap	48230035
Ø4.0mm Modular Tap	48230040
Ø4.5mm Modular Tap	48230045
Ø5.0mm Modular Tap	48230050
Ø5.5mm Modular Tap	48230055
Ø6.5mm Modular Tap	48230065
Ø7.5mm Modular Tap	48230075
Ø8.5mm Modular Tap	48230085
Ø9.5mm Modular Tap	48230095
Ø10.5mm Modular Tap	48230105



Figure 19



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.

Preparing the Pedicle



**T-Handle
48231201**



**T-Handle, Ratchet
48231202**



**Round Handle
48231301**



**Round Handle,
Ratchet
48231302**



**Small Round Handle
482397006**



**Small Round
Handle, Ratchet
482397005**

Figure 20



**Jacobs Chuck Handle
482397007**

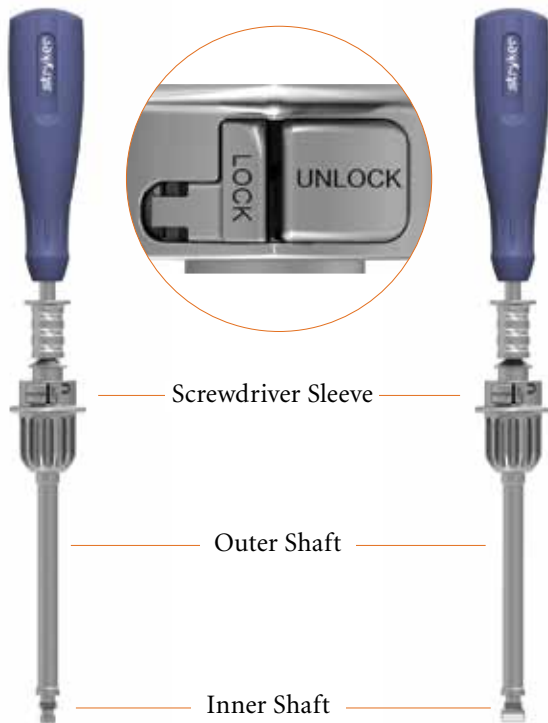
Figure 21

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.

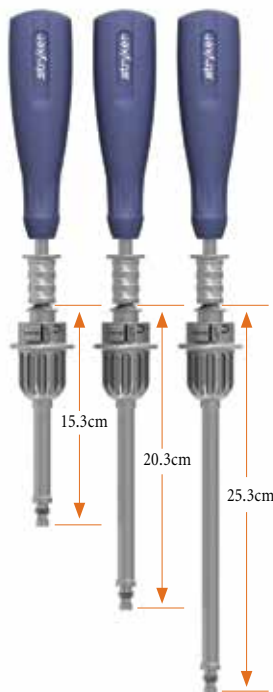
Screw Insertion



Xia 3 Polyaxial Screwdriver
Standard 48231330
Short 482391330S
Long 482391330L

Xia 3 Monoaxial Screwdriver
Standard 48231320
Short 482391320S
Long 482391320L

Figure 22



Screwdriver Length Options

Figure 23

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.

Screw Insertion



Figure 24

To assemble and engage the Xia 3 Polyaxial and Monoaxial Screwdrivers:

STEP 1:

Press the “UNLOCK” button on the Outer Shaft (Fig. 24).



Figure 25

STEP 2:

Insert the **Polyaxial** or **Monoaxial Inner Shaft** down the Outer Shaft (Fig. 25).



Screwdriver Sleeve 48231330S

Figure 26

STEP 3:

Slide the **Screwdriver Sleeve** up the Inner Shaft. Verify the Sleeve for Screwdriver is completely bottomed out (Fig. 26).



Figure 27

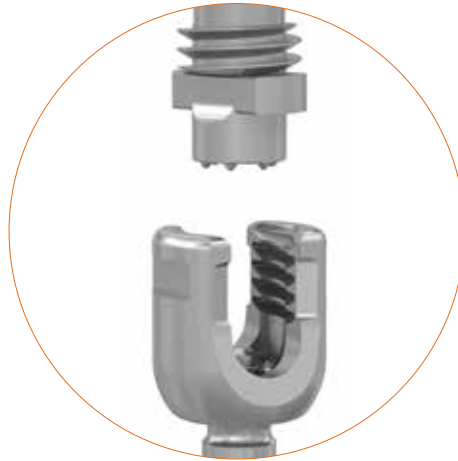
STEP 4:

Align the tabs and fully insert the quick connect mechanism into the shaft (Fig. 27).

Screw Insertion



Figure 28

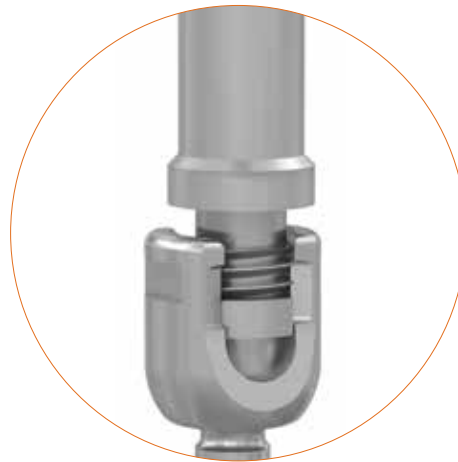


STEP 5:

Hold the screw by the threads and engage the tabs on the Screwdriver Inner Shaft into the saddle of the screw head (Fig. 28).



Figure 29



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).



Figure 30

STEP 7 (Optional):

If the ratchet sound is not present, confirm locking by pressing the “LOCK” button (Fig. 30).

Screw Insertion



Figure 31

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.

Xia 3 Low Profile Screwdriver



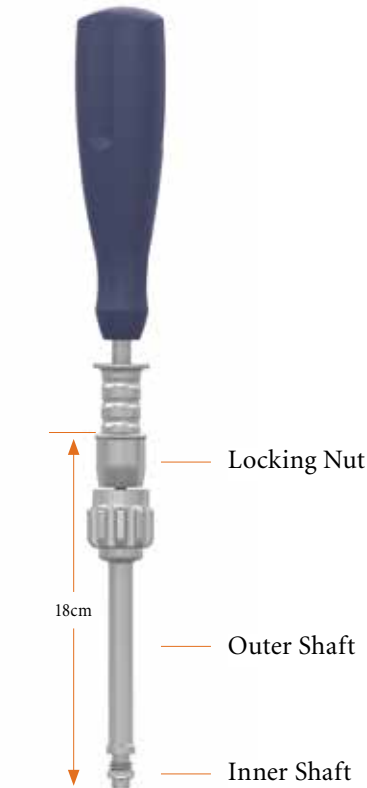
Figure 32



Figure 33



Figure 34



**Xia 3 Low Profile
Screwdriver
482397004**

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.

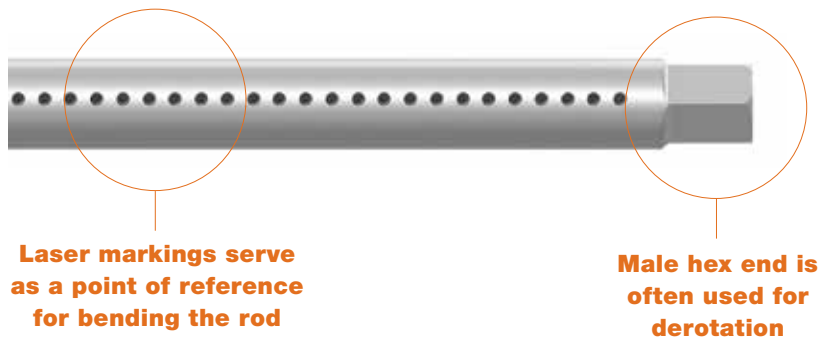
While pulling upward, turn the Outer Shaft counterclockwise to disengage the threads from the screw head.

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



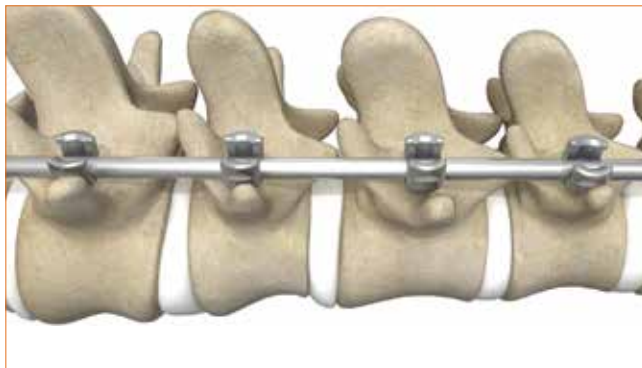
Laser markings serve as a point of reference for bending the rod

Male hex end is often used for derotation

Figure 35

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.



Rod Template 03710620
Figure 36

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).

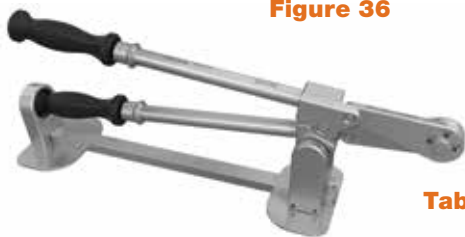
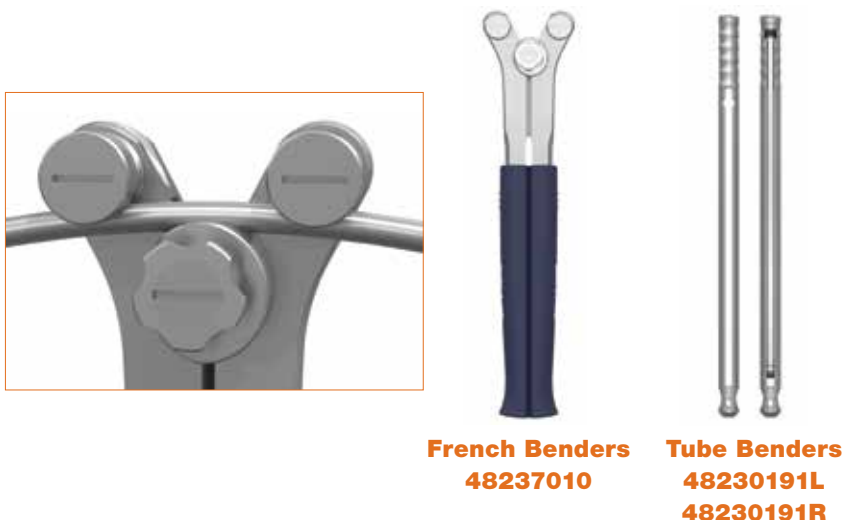


Table-Top Rod Cutter 48238400
and Stand 48238400S

Figure 37

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).



French Benders 48237010
Tube Benders 48230191L
48230191R

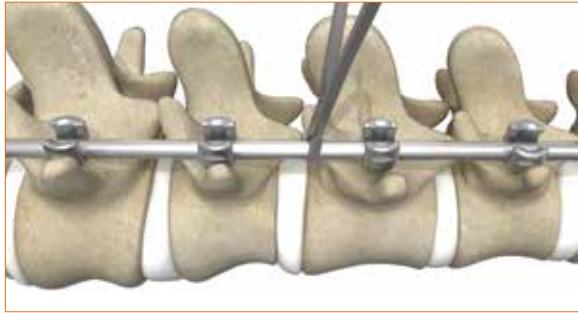
Figure 38

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 2.0.

Rod Contouring



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).



Rod Insertion Forceps
48230140



Rod Gripper
48231140



Figure 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.



Coronal Plane Benders
48230180, 48230190



Ball Joint
48230180S



In Situ Rod Benders
48237011L, 48237011R

Figure 40

Rod Linkage

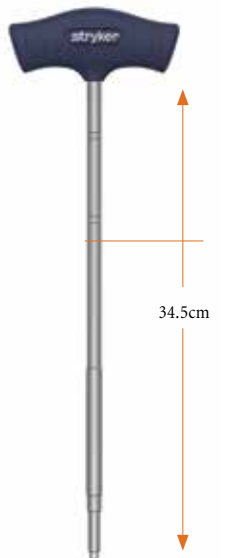


**Blocker
48230000**

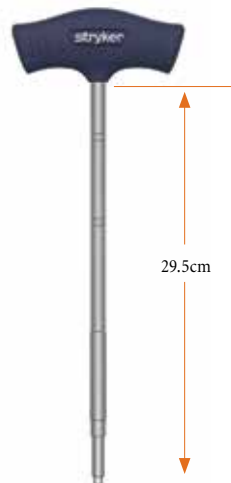
Figure 41

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.



**Universal Tightener
48237008**



**Short Universal
Tightener
482397008**



**Double-Ended
Universal Tightener
48237065**

Figure 42

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).

Inserter Tube
48237109

Length = 27.2cm

Short Inserter Tube
482397109

Length = 22cm

Figure 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).



Figure 44



Figure 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).



Split hex design for secure engagement to blocker

Figure 46

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

Rod Reduction

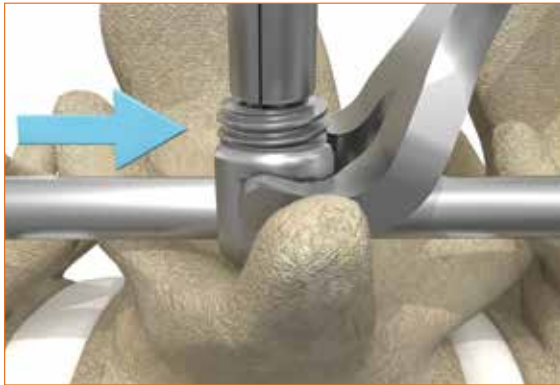


Figure 47



**Rod Fork
48237018**

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 levers 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:



Persuader 48237016
Length = 27cm

Short Persuader 482397016
Length = 22cm
Figure 48

Figure 50

- 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).

Rod Reduction

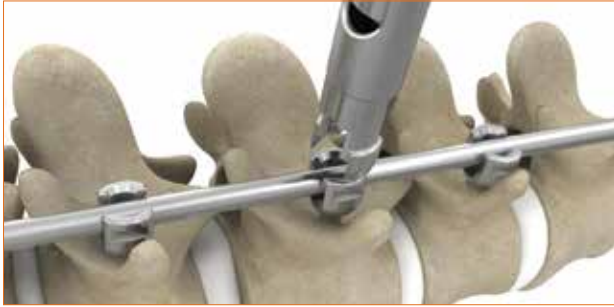


Figure 51



Figure 52

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.

Rod Reduction



One Handed Persuader
48237015
Figure 53



Figure 54



Figure 55

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).



Figure 56

Rod Reduction



Figure 57



Figure 58



Figure 59



Figure 60



T-Handle (48237097) from the SUK DVR System connected to the proximal end of the tube for added leverage.

Figure 61

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.

Rod Reduction



**Reduction Clip
48237079**

Figure 62



Figure 63



Figure 64

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.

Rod Reduction



SUK Reduction Tube
48237078
Figure 65



Figure 66

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) are also available and can be used over Reduction Screws.

Rod Reduction



Figure 67

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:

Diameter	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.0mm	7.5mm
Length	20mm-45mm	20mm-45mm	20mm-55mm	25mm-60mm	25mm-60mm	30mm-60mm	30mm-60mm

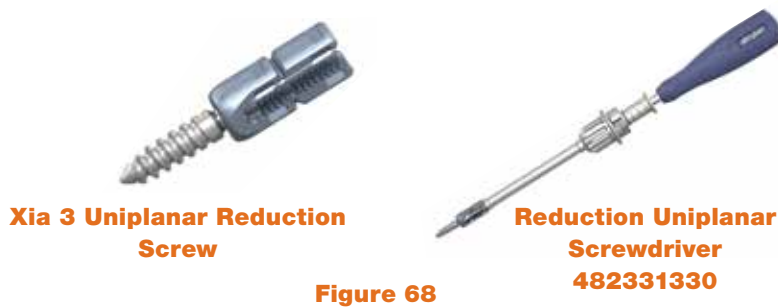


Figure 68

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.

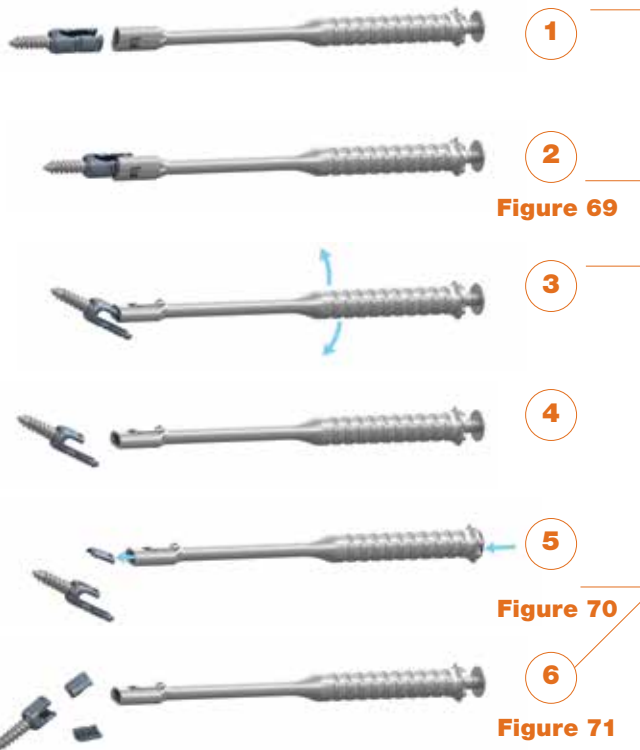


Figure 69

Figure 70

Figure 71

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.

Reduction Screw Tab Remover 482339110

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

Compression/Distraktion



Figure 72

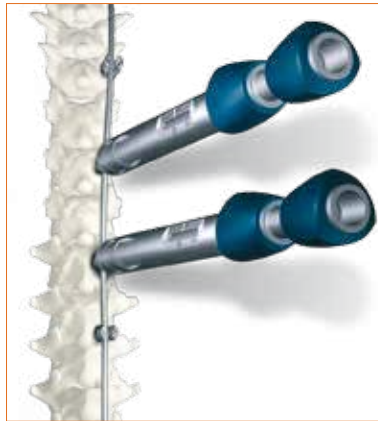


Figure 73

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 degrees 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

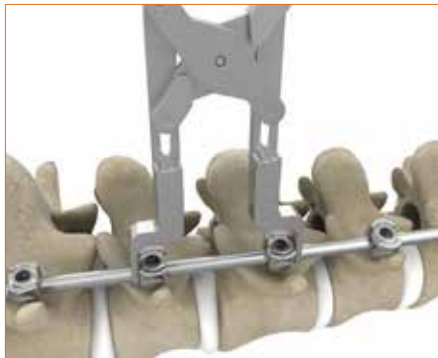
Translation can be achieved by utilizing any of the persuader/reduction options on pages 27-34. Persuaders are typically placed at the distal and proximal ends of the curve apex (Fig. 73). As the spine is carefully translated at these points the Closure Screws are inserted and the implants secured. The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

Correction Procedures

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.

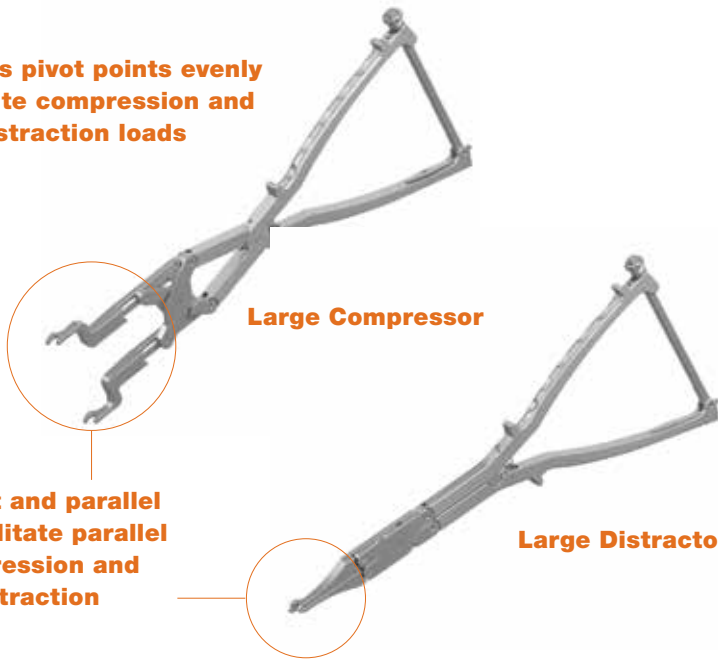


Small Compressor 48236100
Large Compressor 48236101



Small Distractor 48236000
Large Distractor 48236001

Dual axis pivot points evenly distribute compression and distraction loads



Large Compressor

Large Distractor

Straight and parallel tips facilitate parallel compression and distraction

Figure 74



Figure 75

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.

Correction Procedures

Xia 3 Uniplanar Screws



Figure 76

Xia 3 Titanium Uniplanar Screws:

Diameter	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.0mm	7.5mm
Length	20mm-45mm	20mm-45mm	20mm-55mm	25mm-60mm	25mm-60mm	30mm-60mm	30mm-60mm



Figure 77

- T-Handle, SUK Tube 48237097** (16cm)
- SUK Tube - One Piece 48237087** (27.2cm)
- SUK Tube - Two Piece 48237077** (26.8cm)
- SUK DVR Reduction Tube 48237078** (26.8cm)
- Reduction Clip 48237079** (12.7cm)
- Short SUK DVR Clamp 48237068** (11.8cm)
- SUK Derotator Clamp 48237067** (20.7cm)
- Long SUK DVR Clamp 48237069** (29.6cm)

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.

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:

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.

Final Tightening



Figure 78



Anti-Torque Key
48237026
 Length = 22cm

Short Anti-Torque Key
482397026
 Length = 17cm

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**. 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 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.

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 (Fig. 79).



Torque Wrench
48237028
 Length = 37.8cm

Short Torque Wrench
482397028
 Length = 32.8cm



ES2 Torque Wrench
48280081

Figure 79

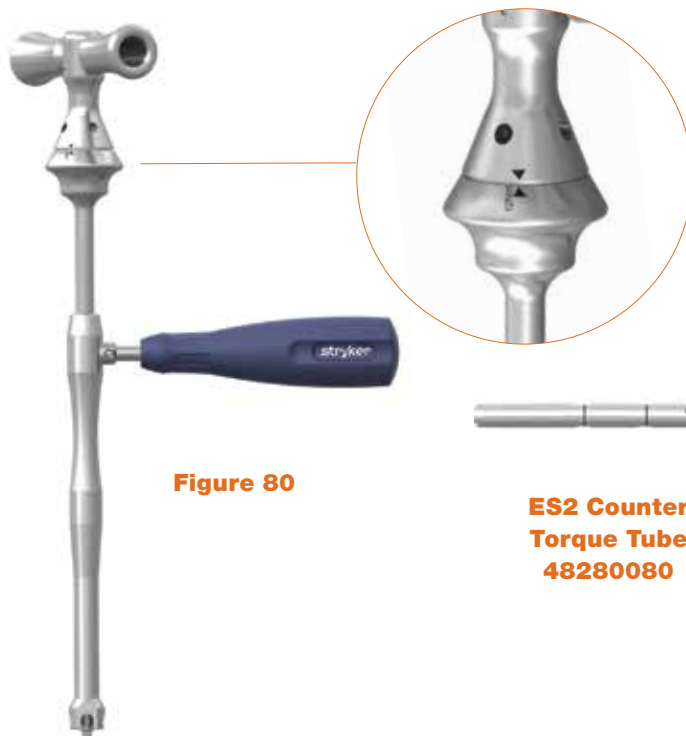


Figure 80

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.



ES2 Counter Torque Tube
48280080

Cross Connectors



Figure 81

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. 81).

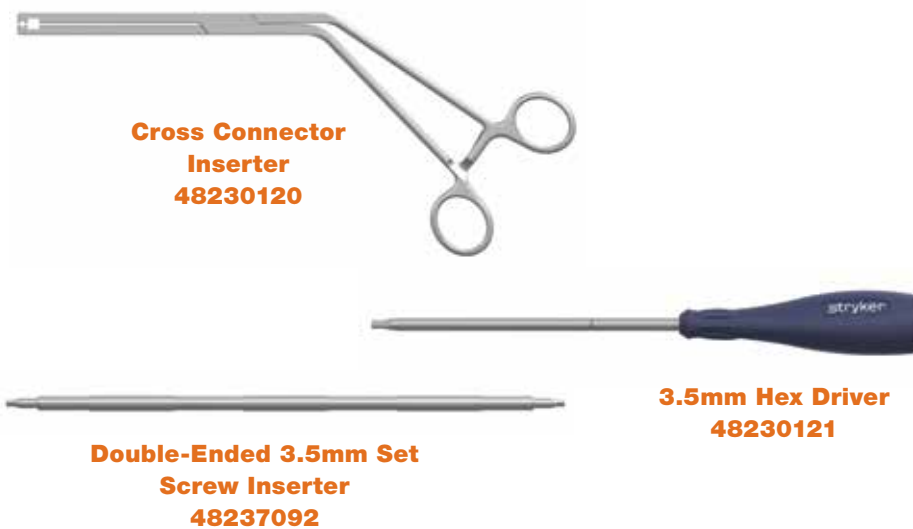


Figure 82

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 **Cross Connector Inserter** to place the appropriate length connector on the rod (Fig. 82). 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. 82).

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. 82 and Fig. 83).



Figure 83

Revision Procedures



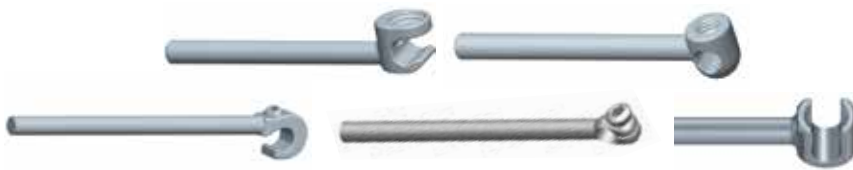
Parallel Rod to Rod Connectors



Axial Rod to Rod Connectors



Open Rod to Rod Connectors group



Offset Connectors group

Figure 84

Rod to Rod Connection





Rod to Rod connection is occasionally necessary. There are several options available (Fig. 84):

1. Parallel Connectors
2. Axial Connectors
3. Open Connectors
4. Angled, Side Loading and Closed Connectors
5. Offset Connectors

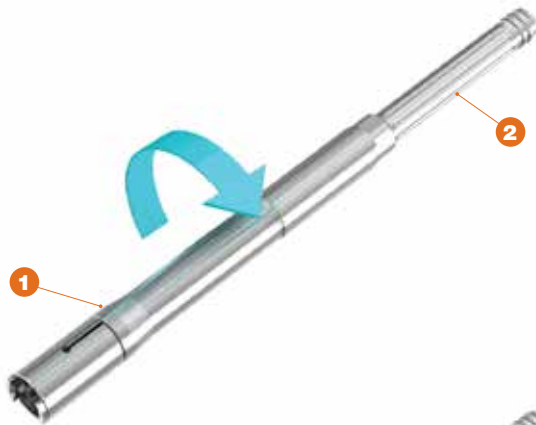
For tightening those connectors use the 3.5mm Hexagonal driver.

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 2.0.

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

	Reference	Description
	03820101	Xia II Low Profile Closed Offset Connector
	48230133	Xia 3 Low Profile Long Closed Offset Connector
	03805001	Xia Rod-to-Rod Parallel Connector
	03805002	Xia Rod-to-Rod Axial Connector

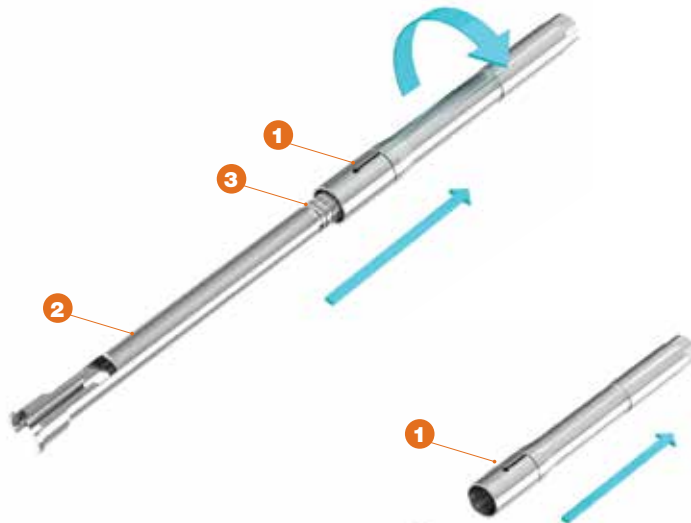
Xia 3 SUK Tubes Disassembly



STEP 1
Figure 85



STEP 2
Figure 86



STEP 3
Figure 87



STEP 4
Figure 88

Instructions for Cleaning



















STEP 1: Unthread the outside tube (1) from the inside tube (2) (Fig. 85).

STEP 2: Once the first level of threads is cleared, slide the outside sleeve (1) back until it reaches the stop threads (3) (Fig. 86).

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. 87).

STEP 4: Further separate the outside sleeve (1) from the inside tube (2) (Fig. 88).

Implants

	Reference Number	Sterile Reference Number*	Description
	48230000	48230000S	Xia 3 Blocker
	4823040(20)-(45)	4823040(20)-(45)S	Xia 3 Ø4.0x 20-45mm Monoaxial Screw
	4823045(20)-(45)	4823045(20)-(45)S	Xia 3 Ø4.5 x 20-45mm Monoaxial Screw
	4823050(20)-(50)	N/A	Xia 3 Ø5.0 x 20-50mm Monoaxial Screw
	4823055(25)-(55)	4823055(25)-(55)S	Xia 3 Ø5.5 x 25-55mm Monoaxial Screw
	4823060(25)-(90)	N/A	Xia 3 Ø6.0 x 25-90mm Monoaxial Screw
	4823065(25)-(90)	4823065(25)-(90)S	Xia 3 Ø6.5 x 25-90mm Monoaxial Screw
	4823070(25)-(90)	N/A	Xia 3 Ø7.0 x 25-90mm Monoaxial Screw
	4823075(25)-(90)	4823075(25)-(90)S	Xia 3 Ø7.5 x 25-90mm Monoaxial Screw
	4823140(20)-(45)	4823140(20)-(45)S	Xia 3 Ø4.0 x 20-45mm Polyaxial Screw
	4823145(20)-(45)	4823145(20)-(45)S	Xia 3 Ø4.5 x 20-45mm Polyaxial Screw
	4823150(20)-(50)	N/A	Xia 3 Ø5.0 x 20-50mm Polyaxial Screw
	4823155(25)-(55)	4823155(25)-(55)S	Xia 3 Ø5.5 x 25-55mm Polyaxial Screw
	4823160(25)-(90)	N/A	Xia 3 Ø6.0 x 25-90mm Polyaxial Screw
	4823165(25)-(90)	4823165(25)-(90)S	Xia 3 Ø6.5 x 25-90mm Polyaxial Screw
	4823170(25)-(90)	N/A	Xia 3 Ø7.0 x 25-90mm Polyaxial Screw
	4823175(25)-(90)	4823175(25)-(90)S	Xia 3 Ø7.5 x 25-90mm Polyaxial Screw
	482334(20)-(45)	482334(20)-(45)S	Xia 3 Ø4.5 x 20-45mm Uniplanar Screw
	4823350(20)-(45)	4823350(20)-(45)S	Xia 3 Ø5.0 x 20-45mm Uniplanar Screw
	482335(20)-(55)	482335(20)-(55)S	Xia 3 Ø5.5 x 20-55mm Uniplanar Screw
	4823360(25)-(60)	N/A	Xia 3 Ø6.0 x 25-60mm Uniplanar Screw
	482336(25)-(60)	482336(25)-(60)S	Xia 3 Ø6.5 x 25-60mm Uniplanar Screw
	4823370(30)-(60)	N/A	Xia 3 Ø7.0 x 30-60mm Uniplanar Screw
	482337(30)-(60)	482337(30)-(60)S	Xia 3 Ø7.5 x 30-60mm Uniplanar Screw

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

Implants

	Reference Number	Sterile Reference Number*	Description
	4823645(20)-(45)	4823645(20)-(45)S	Xia 3 Ø4.5 x 20-45mm Uniplanar Reduction Screw
	4823650(20)-(45)	4823650(20)-(45)S	Xia 3 Ø5.0 x 20-45mm Uniplanar Reduction Screw
	4823655(20)-(55)	4823655(20)-(55)S	Xia 3 Ø5.5 x 20-55mm Uniplanar Reduction Screw
	4823660(25)-(60)	N/A	Xia 3 Ø6.0 x 25-60mm Uniplanar Reduction Screw
	4823665(25)-(60)	4823665(25)-(60)S	Xia 3 Ø6.5 x 25-60mm Uniplanar Reduction Screw
	4823670(30)-(60)	N/A	Xia 3 Ø7.0 x 30-60mm Uniplanar Reduction Screw
	4823675(30)-(60)	4823675(30)-(60)S	Xia 3 Ø7.5 x 30-60mm Uniplanar Reduction Screw
	4823965(60) – (00)	N/A	Xia 3 Ø6.5 x 60-100mm Biased Angle Monoaxial Screw
	4823975(60) – (00)	N/A	Xia 3 Ø7.5 x 60-100mm Biased Angle Monoaxial Screw
	4823985(60) – (00)	N/A	Xia 3 Ø8.5 x 60-100mm Biased Angle Monoaxial Screw
	4823995(60) – (00)	N/A	Xia 3 Ø9.5 x 60-100mm Biased Angle Monoaxial Screw
	4823840(20) – (45)	N/A	Xia 3 Ø4.0 x 20-45mm Biased Angle Polyaxial Screw
	4823845(20) – (45)	N/A	Xia 3 Ø4.5 x 20-45mm Biased Angle Polyaxial Screw
	4823850(20) – (45)	N/A	Xia 3 Ø5.0 x 20-45mm Biased Angle Polyaxial Screw
	4823855(25) – (55)	N/A	Xia 3 Ø5.5 x 25-55mm Biased Angle Polyaxial Screw
	4823865(25) – (90)	N/A	Xia 3 Ø6.5 x 25-90mm Biased Angle Polyaxial Screw
	4823875(25) – (90)	N/A	Xia 3 Ø7.5 x 25-90mm Biased Angle Polyaxial Screw
	4823885(60) – (100)	N/A	Xia 3 Ø8.5 x 60-100mm Biased Angle Polyaxial Screw
	4823895(60) – (100)	N/A	Xia 3 Ø9.5 x 60-100mm Biased Angle Polyaxial Screw
















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

Implants

Reference Number	Description	Reference Number	Description
48237140(20) – (45)	Xia 3 Ø4.0 x 20-45mm Medial Biased Angle Polyaxial Screw	 48230250	Xia 3 Medium Lamina Hook Standard Blade
48237145(20) – (45)	Xia 3 Ø4.5 x 20-45mm Medial Biased Angle Polyaxial Screw	 48230201	Xia 3 Medium Lamina Hook Narrow Blade
48237150(20) – (45)	Xia 3 Ø5.0 x 20-45mm Medial Biased Angle Polyaxial Screw	 48230202	Xia 3 Large Lamina Hook Standard Blade
48237155(25) – (55)	Xia 3 Ø5.5 x 25-55mm Medial Biased Angle Polyaxial Screw	 48230203	Xia 3 Large Lamina Hook Narrow Blade
48237165(25) – (90)	Xia 3 Ø6.5 x 25-90mm Medial Biased Angle Polyaxial Screw	 48230204	Xia 3 Lamina Hook Extended Body
48237175(25) – (90)	Xia 3 Ø7.5 x 25-90mm Medial Biased Angle Polyaxial Screw	 48230205	Xia 3 Small Lamina Hook Extended Body
48237185(60) – (90)	Xia 3 Ø8.5 x 60-90mm Medial Biased Angle Polyaxial Screw	 48230206	Xia 3 Lamina Hook Offset, Right
48237195(60) – (90)	Xia 3 Ø9.5 x 60-90mm Medial Biased Angle Polyaxial Screw	 48230207	Xia 3 Lamina Hook Offset, Left
4823265(30) – (00)	Xia 3 Ø6.5 x 30-100mm Closed Head Monoaxial Screw	 48230208	Xia 3 Large Lamina Hook Angled Blade
4823275(30) – (00)	Xia 3 Ø7.5 x 30-100mm Closed Head Monoaxial Screw	 48230209	Xia 3 Small Lamina Hook Angled Blade
4823285(30) – (00)	Xia 3 Ø8.5 x 30-100mm Closed Head Monoaxial Screw	 48230210	Xia 3 Thoracic Lamina Hook Standard Blade
4823295(30) – (00)	Xia 3 Ø9.5 x 30-100mm Closed Head Monoaxial Screw	 48230211	Xia 3 Thoracic Lamina Hook Narrow Blade
4823765(30) – (00)	Xia 3 Ø6.5 x 30-100mm Closed Head Polyaxial Screw	 48230212	Xia 3 Thoracic Lamina Hook Small Offset, Right
4823775(30) – (00)	Xia 3 Ø7.5 x 30-100mm Closed Head Polyaxial Screw	 48230213	Xia 3 Thoracic Lamina Hook Small Offset, Left
4823785(30) – (00)	Xia 3 Ø8.5 x 30-100mm Closed Head Polyaxial Screw	 48230214	Xia 3 Thoracic Lamina Hook Large Offset, Right
4823795(30) – (00)	Xia 3 Ø9.5 x 30-100mm Closed Head Polyaxial Screw	 48230215	Xia 3 Thoracic Lamina Hook Large Offset, Left
48233500	Set Screw for Xia 3 Closed Head Screw (M6 x 1)	 48230216	Xia 3 Thoracic Lamina 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 Lamina Hook Narrow Blade
		 48230241	Xia 3 Small Lamina Hook Standard Blade

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

Implants

	Reference Number	Sterile Reference Number*	Description
	48232(030)-(150)	48232(030)-(150)S	Xia 3 Ø6.0 x 30-150mm CP Ti Rod
	48232480	N/A	Xia 3 Ø6.0 x 480mm CP Ti Rod
	48232600	N/A	Xia 3 Ø6.0 x 600mm CP Ti Rod
	48233(030)-(150)	48233(030)-(150)S	Xia 3 Ø6.0 x 30-150mm Ti Alloy Rod
	48233480	N/A	Xia 3 Ø6.0 x 480mm Ti Alloy Rod
	48233600	N/A	Xia 3 Ø6.0 x 600mm Ti Alloy Rod
	03822601	N/A	Xia II Ø6.0 x 600mm Vitallium Rod
	48232601	N/A	Xia 3 Ø6.0 x 600mm Vitallium Rod, with hex
	48238(030)-(120)	48238(030)-(120)S	Xia 3 Ø6.0 x 30-120mm Ti Alloy Rad Rod
	48239(050)-(120)	48239(050)-(120)S	Xia 3 Ø6.0 x 50-120mm Ti Alloy Max Rad Rod
	4866130(03)-(20)	N/A	Radius Ø5.5 x 30-120mm Titanium Spinal Rod, without hex
	486613(110)-(600)	N/A	Radius Ø5.5 x 110-600mm Titanium Spinal Rod, with hex
	486613601	N/A	Radius 600mm Vitallium Spinal Rod
	4866150(30)-(20)	N/A	Radius Ø5.5 x 30-120mm Titanium Rad Rod
	4866152(80)-(20)	N/A	Radius Ø5.5 x 80-120mm Titanium Rad Rod, with hex
	4866155(50)-(20)	N/A	Radius Ø5.5 x 50-120mm Titanium Max Rad Rod
	482360(14)-(26)	482360(14)-(26)S	Xia 3 Monoblock Cross Connector
	48236028	48236028S	Xia 3 Multi-Axial Cross Connector, 28mm-31mm
	48236030	48236030S	Xia 3 Multi-Axial Cross Connector, 30mm-35mm
	48236035	48236035S	Xia 3 Multi-Axial Cross Connector, 35mm-44mm
	48236043	48236043S	Xia 3 Multi-Axial Cross Connector, 43mm-54mm
	48236053	48236053S	Xia 3 Multi-Axial Cross Connector, 53mm-73mm
	48236070	48236070 S	Xia 3 Multi-Axial Cross Connector, 70mm-99mm




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

Implants

	Reference Number	Sterile Reference Number*	Description
	03820134	N/A	Xia II 0° Small Rod-to-Rod Connector
	03820135	N/A	Xia II 30° Small Rod-to-Rod Connector
	03820136	N/A	Xia II 0° Large Rod-to-Rod Connector
	03820137	N/A	Xia II 10° Large Rod-to-Rod Connector
	48235007	48235007S	Xia 3 12mm Parallel Revision Connector Open-Closed
	48235008	48235008S	Xia 3 22mm Parallel Revision Connector Open-Closed
	48235010	48235010S	Xia 3 Angled Loading Side Loading RRC
	48235011	48235011S	Xia 3 Top Loading Side Loading RRC
	48230141	N/A	Xia 3 7mm Closed Parallel RRC
	48235009	48235009S	Xia 3 11mm Closed Parallel RRC
	03820130	N/A	Xia II 75° Offset Connector Bend
	03820131	N/A	Xia II Offset Connector Neutral
	03820132	N/A	Xia II 105° Offset Connector Bend
	03820133	N/A	Xia II Long Offset Connector Neutral
	48230138	48230138S	Xia 3 Small Closed Offset Connector
	48230139	48230139S	Xia 3 Long Offset Connector Open-Head
	48230143	48230143S	Xia 3 J Hook Offset Connector
	48230144	48230144S	Xia 3 Open Side-Loading Offset Connector

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Revision Implants















































	Reference Number	Sterile Reference Number*	Description
	48235012	48235012S	Xia 3 Axial Revision RRC (D 6.5 - 9.5mm) (Length 40, 50, 60mm)
	482365 (40)-(60)	N/A	Xia 3 Revision Connector Screw 6.5mm x 40-60mm
	482375 (40)-(60)	N/A	Xia 3 Revision Connector Screw 7.5mm x 40-60mm)
	482385 (40)-(60)	N/A	Xia 3 Revision Connector Screw 8.5mm x 40-60mm
	482395 (40)-(60)	N/A	Xia 3 Revision Connector Screw 9.5mm x 40-60mm
		48230260	N/A
	48230133	48230133S	Xia 3 Low Profile Long Closed Offset Connector
	48233500	N/A	Set Screw for Xia 3 Small Offset Connector Closed Head (M6 x 1)

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.




































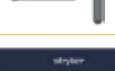








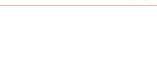
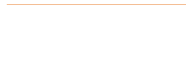
*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.

Instruments

	Reference Number	Description		Reference Number	Description
	48237111	Awl		482391320S	Short Monoaxial Screwdriver*
	482397002	Sacral Awl		482391311S	Short Polyaxial Screwdriver Shaft
	48237024	Curved Blunt Probe		482391321S	Short Monoaxial Screwdriver Shaft
	48237055	Thoracic Pedicle Probe		482391330L	Long Polyaxial Screwdriver*
	482397001	Adjustable Curette Probe		482391320L	Long Monoaxial Screwdriver*
	48237060	Pedicle Feeler - Malleable		482391311L	Long Polyaxial Screwdriver Shaft
	48237059	Pedicle Feeler - Medium		482391321L	Long Monoaxial Screwdriver Shaft
	48237003	Pedicle Feeler - Stiff		482397004	Low Profile Screwdriver*
	48237061	Double Ended Pedicle Feeler		482397009	Low Profile Screwdriver Shaft
	48230(030)-(105)	Modular Tap, Ø3.0mm-Ø10.5mm		482391312S	Short Xia II Polyaxial Screwdriver Shaft
	48231201	T-Handle		482331330	Reduction Uniplanar Screwdriver
	48231202	T-Handle, Ratchet		48231326	Iliac Screwdriver - Two Piece
	48231301	Round Handle		482339110	Reduction Screw Tab Remover
	48231302	Round Handle, Ratchet		48237091	Modular Monodriver Shaft
	482397006	Small Round Handle		48237033	Modular Polyadjustment Driver
	482397005	Small Round Handle, Ratchet		48237032	Monodriver
	482397007	Jacobs Chuck Handle		482397032	Short Monodriver
	48231330	Xia 3 Polyaxial Screwdriver*		48231313	Self-Holding Polyaxial Screwdriver Shaft
	48231320	Xia 3 Monoaxial Screwdriver*		48237056	Rod Rotation Key (Ø6.0mm)
	48231311	Xia 3 Polyaxial Screwdriver Shaft		03710620	Xia II Rod Template
	48231321	Xia 3 Monoaxial Screwdriver Shaft		48238400S	Table-Top Rod Cutter Stand
	48231330S	Screwdriver Sleeve		48238400	Table-Top Rod Cutter
	482391330S	Xia 3 Short Polyaxial Screwdriver*		48237010	French Bender


*(Everything but handle)

Instruments

	Reference Number	Description		Reference Number	Description
	48230191L	Tube Bender Left		48237026	Anti-Torque Key*
	48230191R	Tube Bender Right		482397026	Short Anti-Torque Key*
	48230140	Rod Insertion Forceps		48237028	Xia 3 Torque Wrench
	48231140	Rod Gripper		482397028	Xia 3 Short Torque Wrench
	48237011L	In Situ Rod Bender Left		48280081	ES2 Torque Wrench
	48237011R	In Situ Rod Bender Right		48287028	MANTIS Redux Torque Wrench
	48230180	Coronal Plane Bender Left		48280080	ES2 Counter Torque Tube
	48230190	Coronal Plane Bender Right		48230123	Cross Connector Measuring Device
	48230180S	Ball Joint		675024	Xia II MAC Caliper
	48237008	Universal Tightener		48230120	Cross Connector Inserter
	482397008	Short Universal Tightener		48230121	3.5mm Hex Driver
	48237065	Double-Ended Universal Tightener		48237092	Double-Ended 3.5mm Set Screw Inserter
	48237109	Inserter Tube		48230122	8mm Hex Driver
	482397109	Short Inserter Tube		48237087	SUK Tube - One Piece
	48237018	Rod Fork		48237077	SUK Tube - Two Piece
	48237016	Persuader		48237078	SUK DVR Reduction Tube
	482397016	Short Persuader		48237079	Reduction Clip
	48237015	One Handed Persuader		48237097	T-Handle, SUK Tube
	48235001	Lateral Persuader		48237067	SUK Derotator Clamp
	48236100	Small Compressor		48237068	Short SUK DVR Clamp
	48236101	Large Compressor		48237069	Long SUK DVR Clamp
	48236000	Small Distractor		48237021	Standard Lamina Hook Preparer
	48236001	Large Distractor		48230110	Narrow Lamina Hook Preparer

*Xia II Anti-Torque Keys can be used with Xia 3

Instruments

	Reference Number	Description
	48231020	Standard Hook Holder
	48231040	Lateral Hook Holder
	48231170	Straight Hook Holder
	48237029	Hook Impactor
	48237025	Pedicule Hook Preparer
	48230100	Vise Grip
	48237019	Rod Pusher
	486619160	4.5mm Combination Wrench (Ø5.5mm)
	48237080	Pedicule Marker Inserter
	48237081	Pedicule Markers (Set of 6)
	48237093	Soft Tissue Retractor
	48230001	Degenerative Implant Tray
	48230002	Degenerative Instrument Tray
	48230003	Complex Spine Implant Tray
	48230004	Complex Spine Instrument Tray
	48230005	Complex Spine Hooks and Instrument Tray
	48230006	Complex Spine Rod and Cross Connector Tray
	48230011	Degenerative Implant Tray Version B (SS)
	48230012	Degenerative Instrument Tray Version B (SS)
	48230013	Uniplanar Tray
	48230015	SUK Tray
	48230020	Outlier Implant Tray
	48230010	Outlier Instrument Tray

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/spondylolysis, 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/

spondylolysis, 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 notching 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.

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