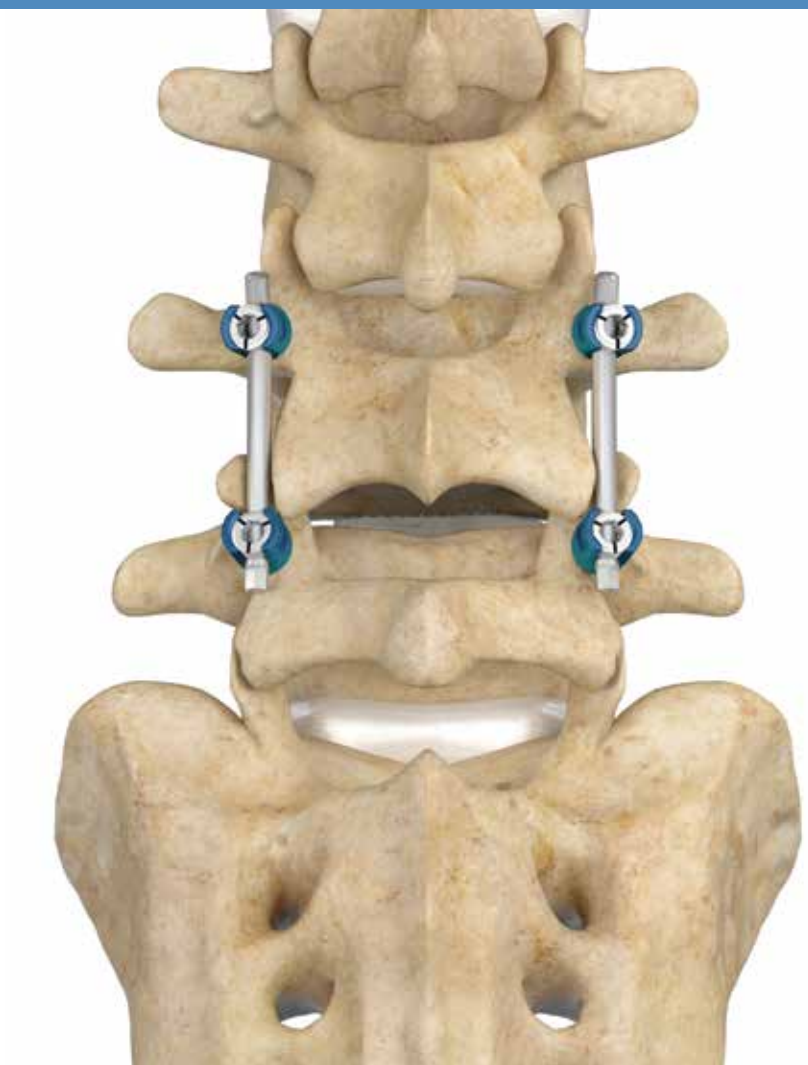
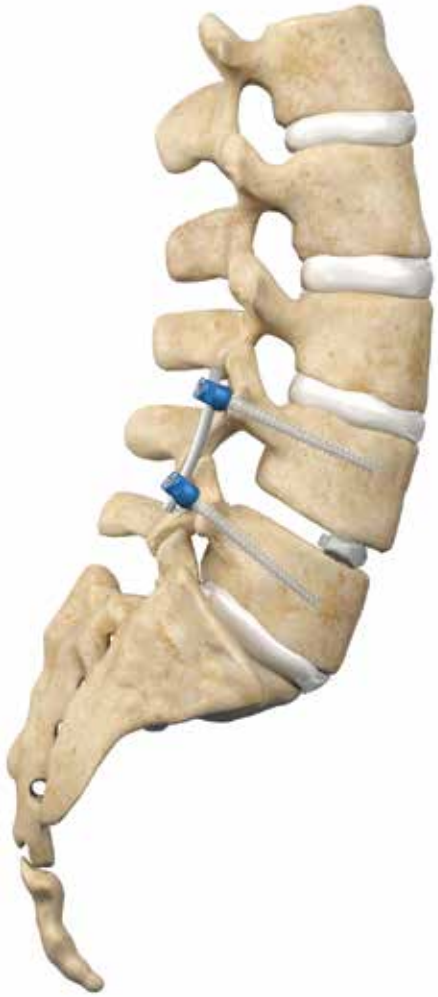
stryker

Spine

Xia® 4.5 Evolution
Surgical Technique





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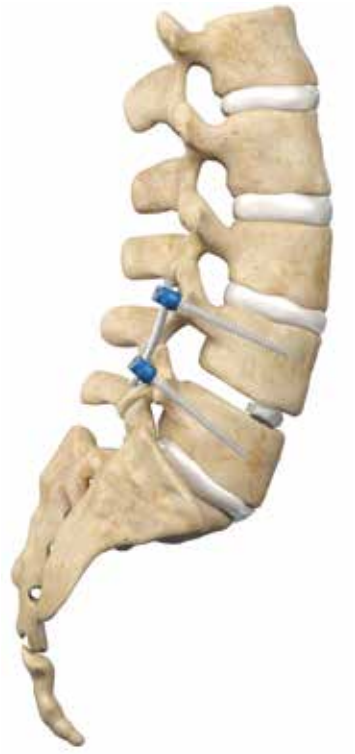
Introduction



Spine surgery is constantly evolving, and with it, the tools and technologies required by spine surgeons.

With approaches becoming less invasive and less disruptive every day, the need for lower profile implants has grown significantly in recent years.

Low profile implants:

- May allow surgeons more visibility in the surgical space
- May allow patients less post-operative implant prominence

Acknowledging these advantages, Stryker Spine is proud to introduce the **Xia 4.5 Evolution Spinal System**.

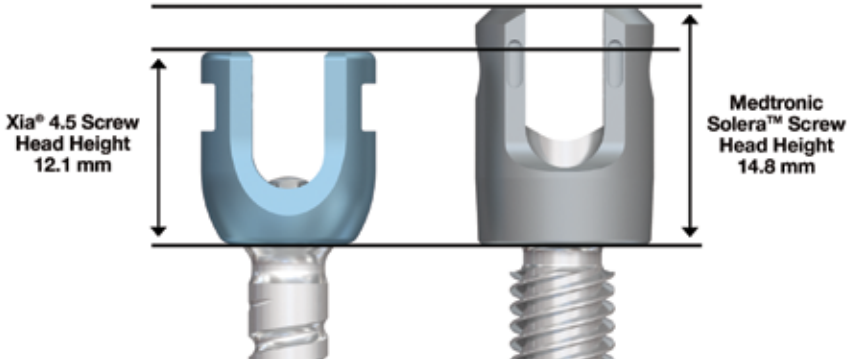
Long a leader in the low profile market for pedicle screws with the Xia 4.5 Spinal System, the Xia 4.5 Evolution Spinal System is the next generation of instruments and tools built to deliver the Xia 4.5 implant.

The following surgical technique demonstrates a procedural solution highlighting the Xia 4.5 Evolution Spinal System used with Stryker's full complement of spine implants and technologies.

For any questions or for a demonstration of the Xia 4.5 Evolution Spinal System, please reach out to your local Stryker Spine sales representative today.

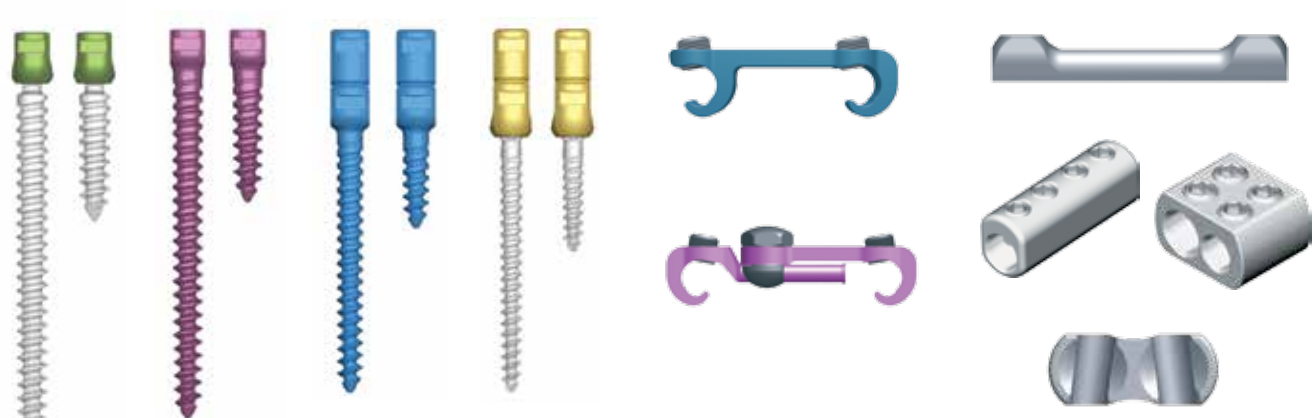
System Overview

The Xia 4.5 Evolution Spinal System was built on the same design rationale and philosophy that has made Xia one of the leading products on the market, and offers a user:



Extremely Low Profile Implant

Thread Pattern Optimized for Both Cortical and Cancellous Bone



Comprehensive Selection of Implant Sizes and Types

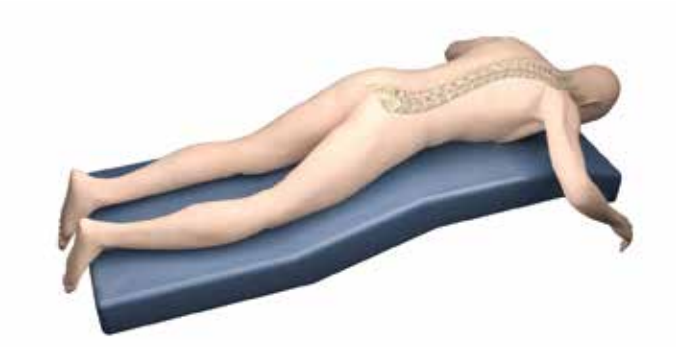
Ergonomic and Easy to Use Instrument Set

The ability to utilize Titanium or the increased stiffness and strength of the Vitallium Rod

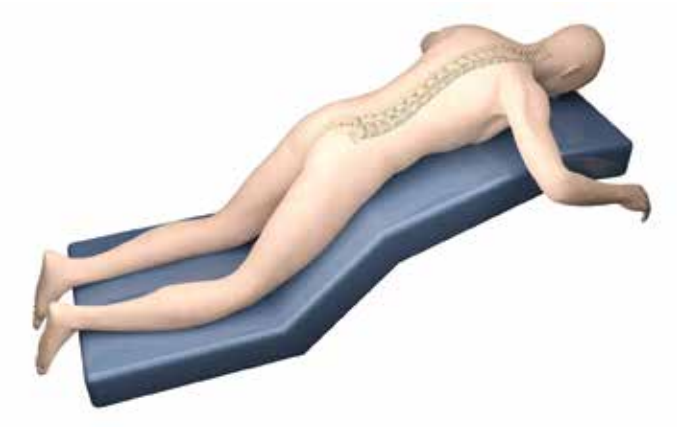
Surgical Technique

Patient Positioning

Diagnosis is based upon patient history, physical findings, and preoperative radiographic assessment.



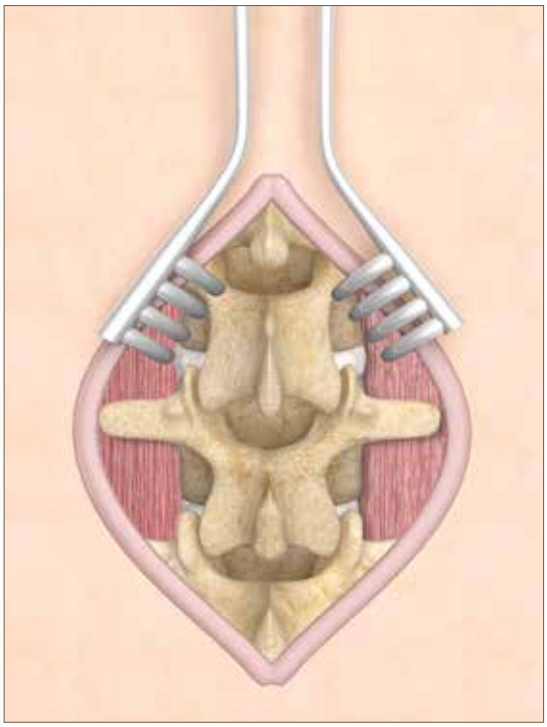
The patient can be positioned on the operating table in the prone position. Care should be taken to pad all bony prominences. To facilitate venous drainage, the abdomen should not be compressed.



Exposure

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.

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



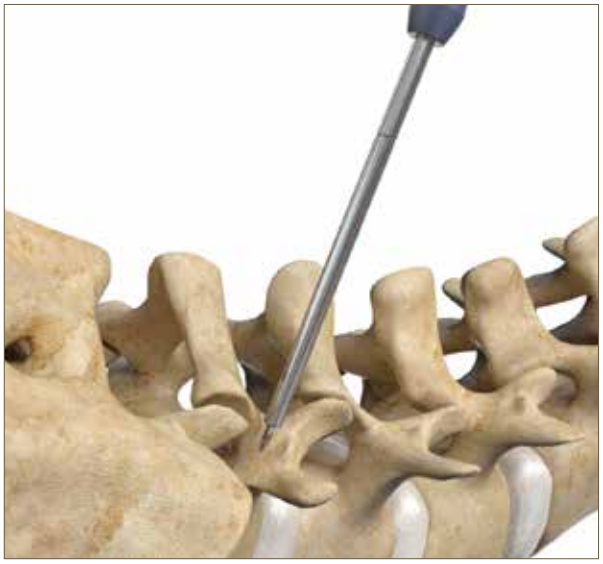
Surgical Technique

Preparing the Pedicle

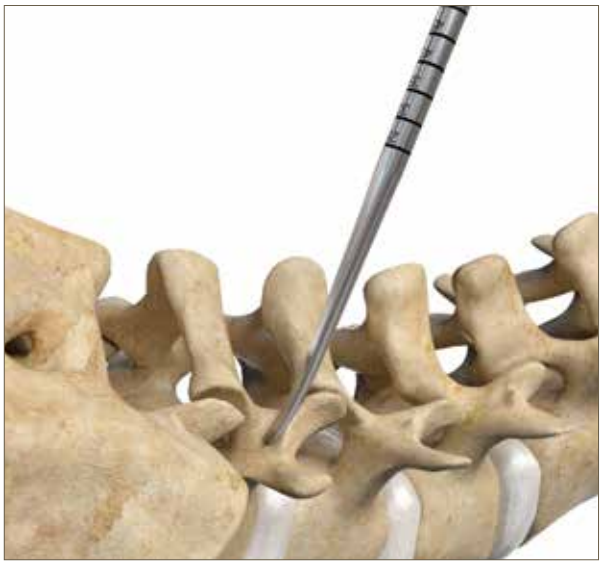
Once anatomical landmarks are identified, remove the cortical crest with a rongeur or power burr to expose the underlying cancellous bone. The Stryker Instruments CORE (Consolidated Operating Room Equipment) platform of products offers surgeons a wide range of handpiece and burr options to meet surgeon preferences.

Prepare the entry point with the **Awl**. The Awl is designed with a stop at 13mm to prevent overplunging.

Awl 48237111



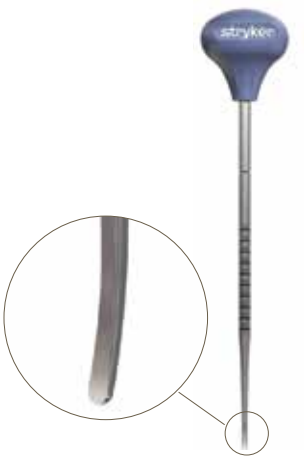
Use the **Curved Blunt Probe** or the **Thoracic Pedicle Probe** to create a pathway into the pedicle. The correct rotational insertion of the instrument allows the probe to follow a path of least resistance without violating the pedicle walls. In the case that resistance is met, the entry point and trajectory should be reevaluated.



There are two probe options available with Xia 4.5 Evolution. The primary differentiating feature of the Curved Blunt Probe and the Thoracic Pedicle Probe is the tip. The Curved Blunt Probe has a flat tip. The Thoracic Pedicle Probe has a sharp, pointy tip designed to optimize its use in the thoracic region of the spine.

The Curved Blunt Probe and the Thoracic Pedicle Probe are laser marked in 5mm intervals to help indicate the depth in which the probe has been inserted. These depth indicators on the probes are also helpful in determining the appropriate screw length.

NOTE: The Curved Blunt Probe must not be used to prepare holes for 4.0mm diameter screws. The Thoracic Pedicle Probe is recommended for 4.0mm diameter screws.



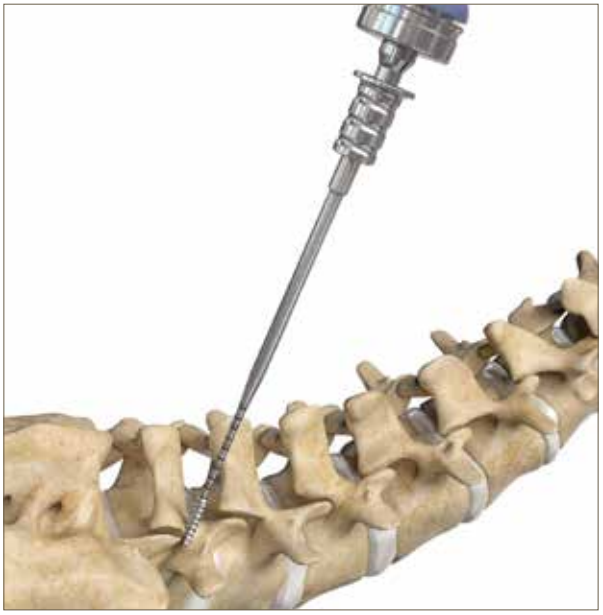
Curved Blunt Probe 48237024

Thoracic Pedicle Probe 48237055

Surgical Technique

Preparing the Pedicle

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 Ball Tip Probe** is also available to feel the pedicle walls for any breaches.



Malleable Pedicle Feeler
48237060

Medium Pedicle Feeler
48237059

Stiff Pedicle Feeler
48237003

Double-Ended Ball Tip Probe
48237061

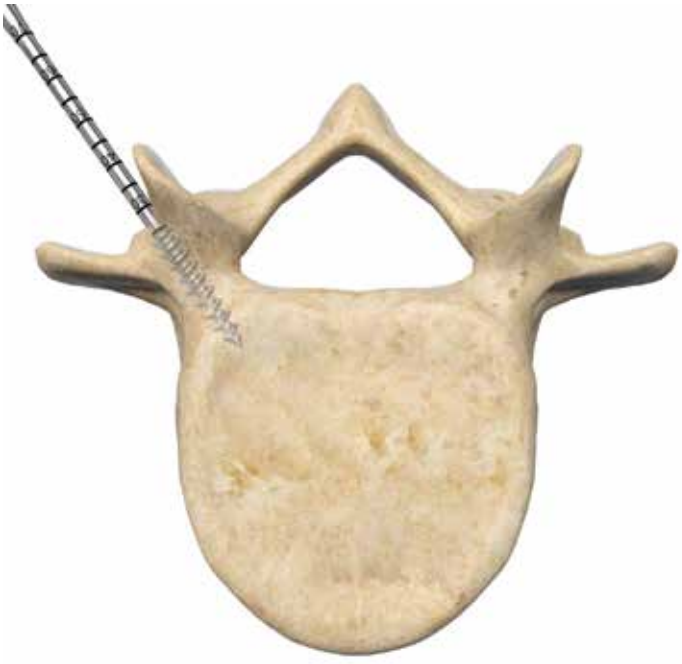
For increased bone purchase, use the **Modular Taps** to prepare the pedicle canal. After attaching a handle, insert the Modular Tap into the pedicle and the vertebral body. The Modular Taps are laser marked with lines in 5mm increments and numbers in 10mm increments.

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
- Ø6.0mm Modular Tap
- Ø6.5mm Modular Tap
- Ø7.0mm Modular Tap
- Ø7.5mm Modular Tap
- Ø8.5mm Modular Tap
- Ø9.5mm Modular Tap

NOTE: The nomenclature describing the taps represents the actual tap line to line diameter.

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**
Ø6.0mm Modular Tap	**481301311**
Ø6.5mm Modular Tap	**48230065**
Ø7.0mm Modular Tap	**481301312**
Ø7.5mm Modular Tap	**48230075**
Ø8.5mm Modular Tap	**48230085**
Ø9.5mm Modular Tap	**48230095**



Surgical Technique

Preparing the Pedicle

The Modular Taps can be attached to any one of the following Xia Handles:

- **T-Handle**
- **T-Handle, Ratchet**
- **Round Handle**
- **Round Handle, Ratchet**
- **Small Round Handle**
- **Small Round Handle, Ratchet**

T-Handle
48231201

T-Handle, Ratchet
48231202

Round Handle
48231301

Round Handle, Ratchet
48231302

Small Round Handle
482397006

Small Round Handle, Ratchet
482397005

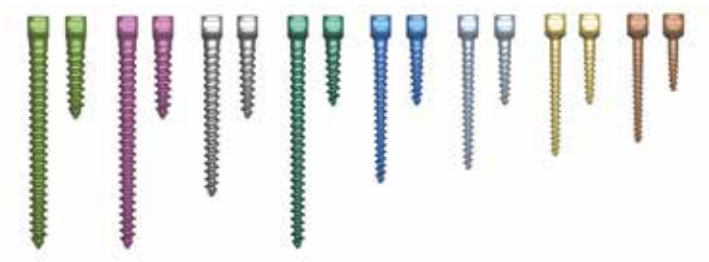
Surgical Technique

Screw Types

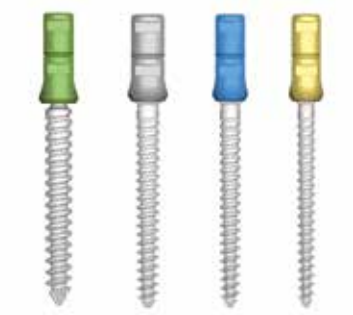
The Xia 4.5 Evolution Spinal System offers an extremely low profile implant that is available in a wide range of diameters and lengths and four different screw types:

Xia 4.5 Evolution Screw Types

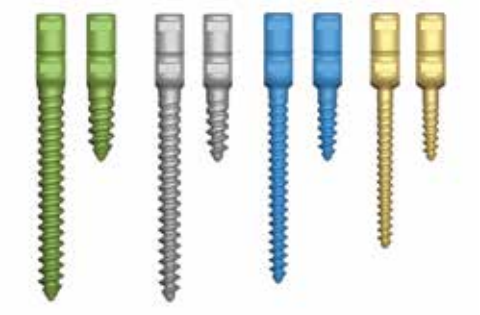
Polyaxial



Monoaxial



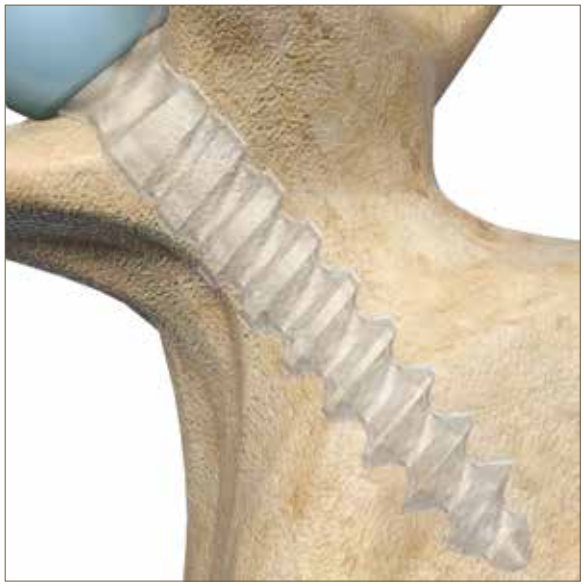
Polyaxial Reduction



Monoaxial Reduction

The Xia 4.5 thread pattern was designed for optimal purchase in both cortical and cancellous bone.

The Xia 4.5 thread pattern was designed to compress bone and create high performance pull out strength.

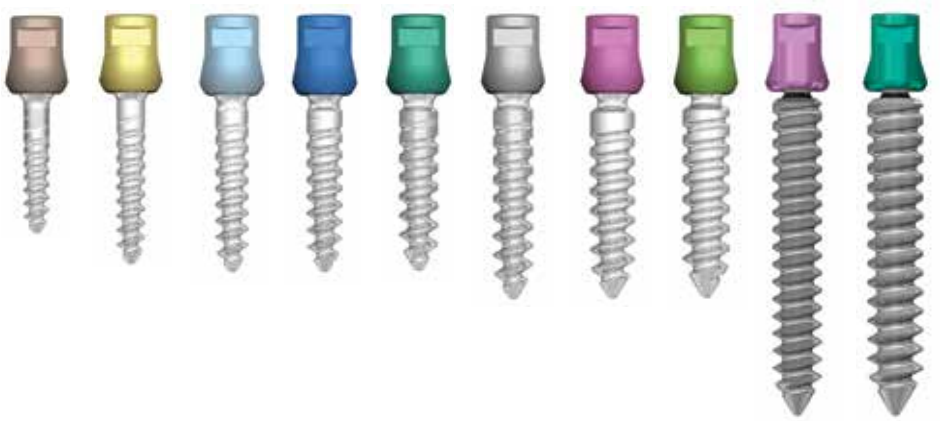


Surgical Technique

Screw Types

For easy identification in the OR, Xia 4.5 Evolution implant tulips are anodized a specific color. Each tulip head color corresponds to a screw diameter.

Xia 4.5 Evolution Screw Diameters



Diameter	4.0mm	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.0mm	7.5mm	8.5mm	9.5mm

Screw Insertion

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

The Xia 4.5 Evolution screw can be inserted either manually or using the Stryker Powered Screw Insertion Technique

Manual Screw Insertion

The **Polyaxial Screwdriver** and **Monoaxial Screwdriver** provide a rigid connection between the screw and the screwdriver.

The Polyaxial Screwdriver is compatible with both Polyaxial and Polyaxial Reduction Screws. The Monoaxial Screwdriver is compatible with both Monoaxial and Monoaxial Reduction Screws.

Polyaxial Screwdriver
48138010

Monoaxial Screwdriver
48138020

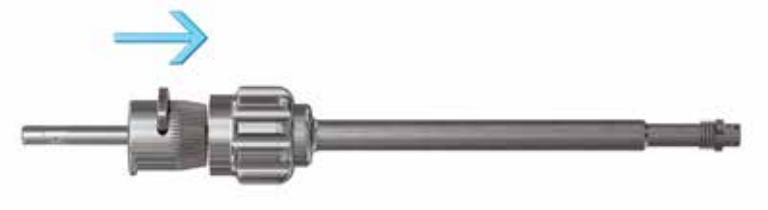
Surgical Technique

Manual Screw Insertion

To assemble the Polyaxial and Monoaxial Screwdrivers:

Step 1:
Insert the Inner Shaft up through the distal end of the Outer Sleeve.

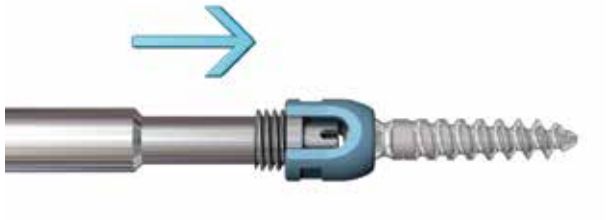
Step 2:
Slide the Locking Nut over the Inner Shaft with the serrated teeth facing downward.



Step 3:
Fully insert the Inner Shaft into the Quick Connect mechanism of the Handle.

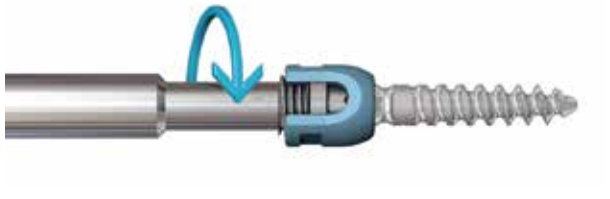
To load a screw onto the screwdriver:

Step 1:
Hold the screw by the threaded portion and engage the Inner Shaft into the saddle of the screw head.

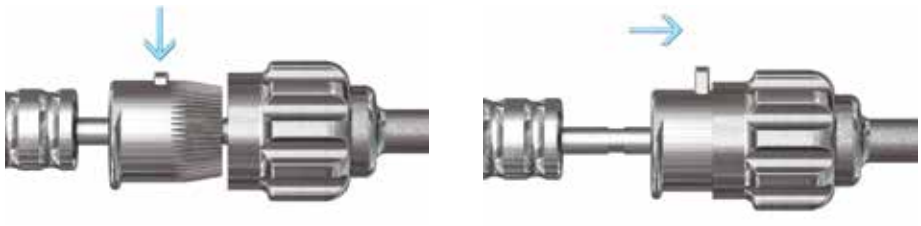


Step 2:
For a polyaxial screw, align the four prongs of the distal tip of the Inner Shaft with the four prongs on the head of the bone screw. For a monoaxial screw, align the "U"-shaped distal tip with the monoaxial tulip head.

Step 3:
Fully seat the Inner Shaft into the screw head. Turn the Outer Sleeve clockwise until the threads of the shaft are fully engaged with the threads of the screw head.



Step 4:
Depress the button on the Locking Nut and slide the Locking Nut forward into the Outer Sleeve to lock the screw to the screwdriver.

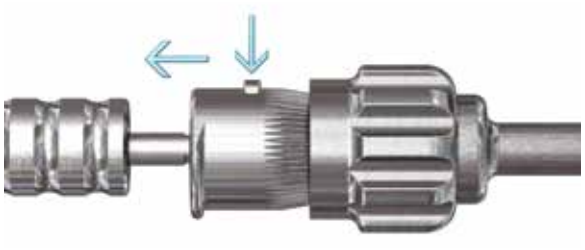


Surgical Technique

Manual Screw Insertion

To disengage the screwdriver from the screw:

Step 1:
Depress the button on the Locking Nut and slide the Locking Nut back up out of the Outer Sleeve along the Inner Shaft.



Step 2:
Turn the Outer Sleeve counterclockwise to disengage the threads of the shaft from the threads of the screw head.

Step 3:
Pull upward on the screwdriver.

To disassemble the screwdriver:

Step 1:
Release the quick connect handle from the Inner Shaft.

Step 2:
Remove the Locking Nut from the Inner Shaft.

Step 3:
Remove the Inner Shaft from the Outer Sleeve.

NOTE: After insertion, the screw positions may be adjusted as needed by attaching the appropriate Inner Shaft directly to a handle.

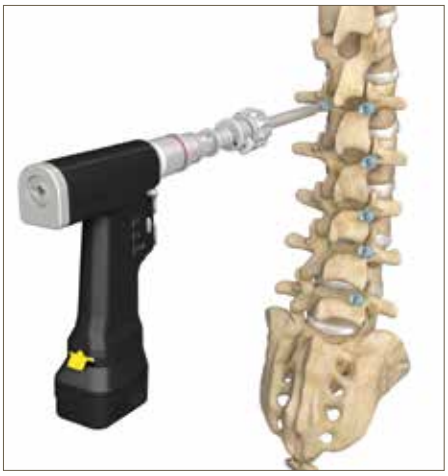
Surgical Technique

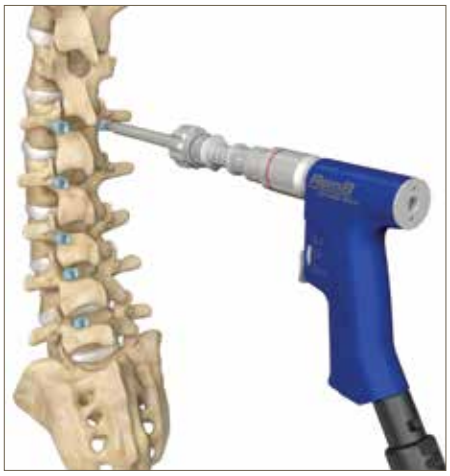
Powered Screw Insertion

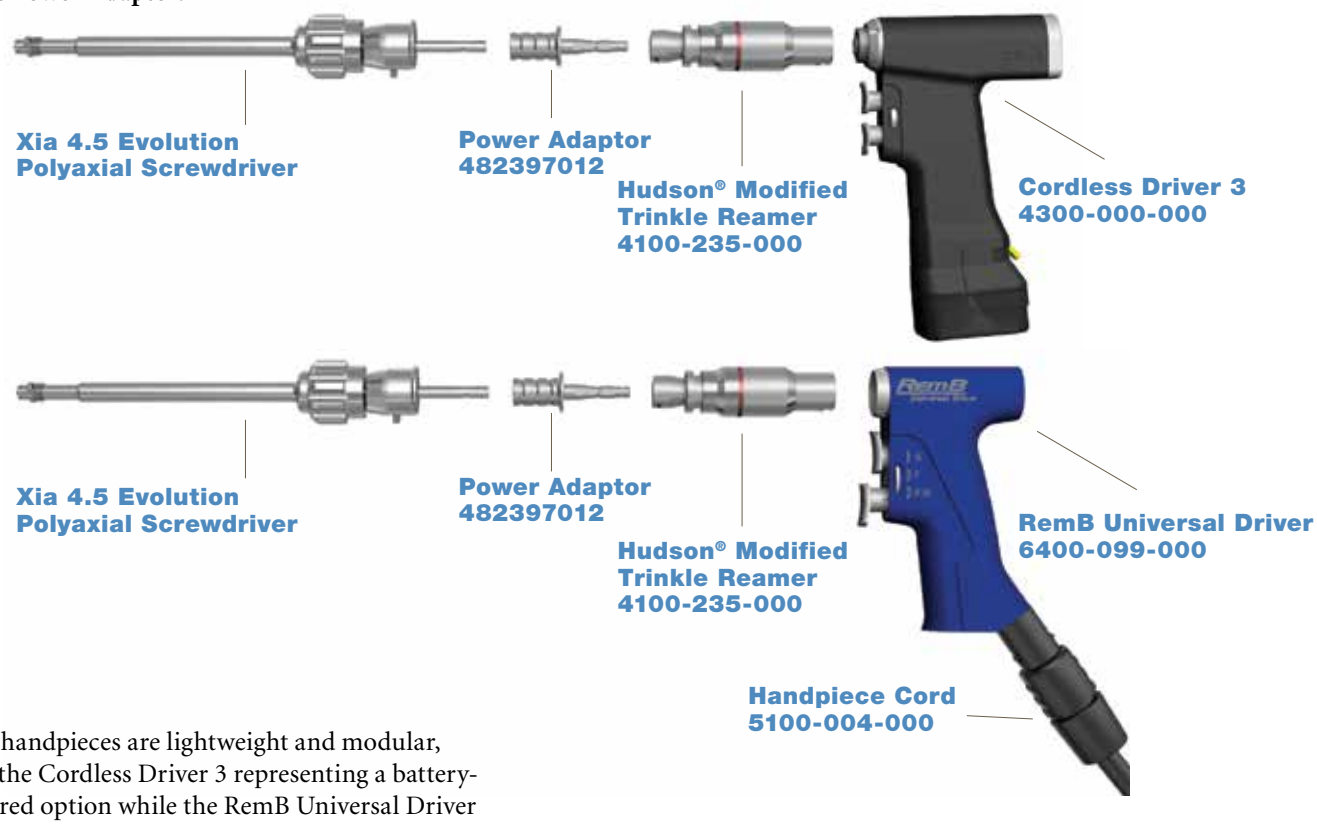
The Stryker Powered Screw Insertion technique can also be used to insert Xia 4.5 Evolution implants.

The Stryker Spine Powered Screw Insertion technique was developed with the goal of reducing the repetitive stress and fatigue spine surgeons encounter when inserting pedicle screws manually.

Depending on surgeon preference, the **Stryker Instruments Cordless Driver 3** or **RemB Universal Driver** can both be used to insert screws under power when combined with the Hudson Modified Trinkle Reamer attachment and **Stryker Spine Power Adaptor**.







Both handpieces are lightweight and modular, with the Cordless Driver 3 representing a battery-powered option while the RemB Universal Driver is powered by the CORE console.

The same screwdriver and steps for screw insertion as described above are followed, with the **Xia 4.5 Evolution Screwdriver** interfacing with the Power Adaptor instead of a Quick Connect handle.

Please refer to the **"Powered Screw Insertion Guide – Cordless Driver 3" (Literature Number: TLPOWBR1205)** or the **"Introducing Powered Screw Insertion"** document **(Literature Number: TLPOWSS110801)** for more details.

NAVIGATION USE: The Xia 4.5 Spinal System can be used with the Stryker Navigated Xia 4.5 Polyaxial Screwdriver to facilitate bone screw insertion. The Navigated Xia 4.5 Polyaxial Screwdriver is a Stryker Navigated Manual Surgical Instrument intended to be used as an accessory to the Stryker Spine Navigation System, when used with SpineMap 3D Navigation software. Please refer to the Stryker Navigated XIA 4.5 Polyaxial Screwdriver package insert, NOLISPINAVIN, and the Rotational Navigation Adapter Instructions for Use, provided with the Rotational Navigation Adapter, for the indications for use. For further details and instructions on using the Navigated Xia 4.5 instruments with the Xia 4.5 Spinal System refer also to the Stryker Navigated Spine Instruments Quick Guide provided with the Rotational Navigation Adapter.

Surgical Technique

Interbody Insertion (Optional)

If an interbody fusion is being performed in addition to a posterolateral fusion, Stryker offers a wide range of interbody options for posterior, anterior, and direct lateral interbody approaches.

Stryker Interbody Portfolio						
Product	**AVS UniLIF**	**AVS Navigator**	**AVS PL**	**AVS TL**	**AVS ARIA**	**AVS AL and ALign**
						
Approach	Posterior	Posterior	Posterior	Posterior	Direct Lateral	Anterior
Description	A PEEK interbody with a wedge nose to ease insertion and a large graft window	A steerable PEEK TLIF interbody designed to allow for optimal placement	A PEEK interbody with an adaptive size range and large graft windows	A PEEK TLIF interbody with a wedge nose to ease insertion	A PEEK interbody with a biconvex shape designed specifically for the lateral approach	A PEEK interbody available in a wide range of heights and lordosis options designed specifically for the anterior approach

Please refer to the **AVSapedia (Literature Number TLAVSRG12120_GLB)** for more details.

Using the Posted Compressor/Distractor

The **Posted Compressor/Distractor (PCD)** provides a unique non-rod based method to distract and compress during an interbody procedure.

The PCD consists of the **Compression/Distraction Posts** and **Compression/Distraction Rack**.

Compression/Distraction Rack
48138100

Compression/Distraction Posts
48138101

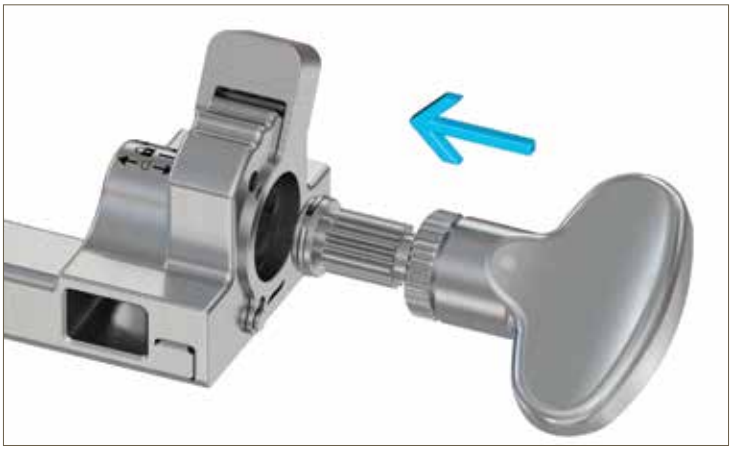
Surgical Technique

Using the Posted Compressor/Distractor

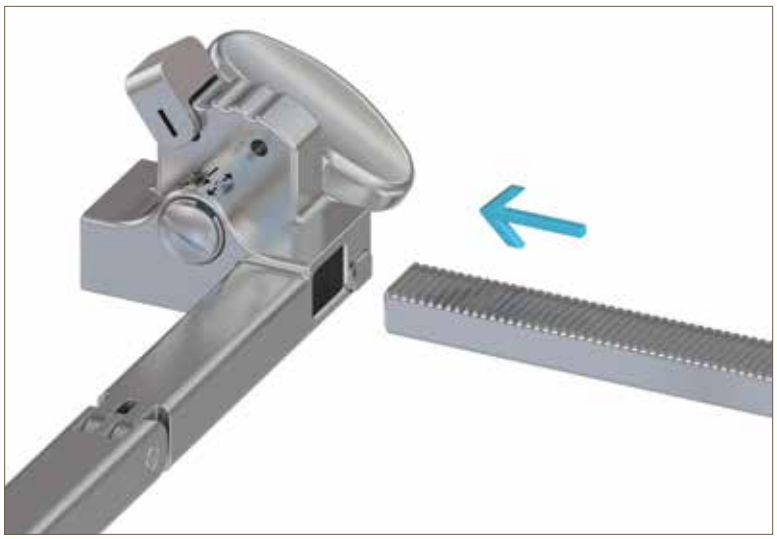
To Assemble the Compression/Distraction Rack:

Step 1:
Set the switch on the Ratchet Housing to "Unlock."

Step 2:
Insert the Key into the Ratchet Housing until it clicks.



Step 3:
Insert the distal tip of the Rack into the Ratchet Housing and advance.

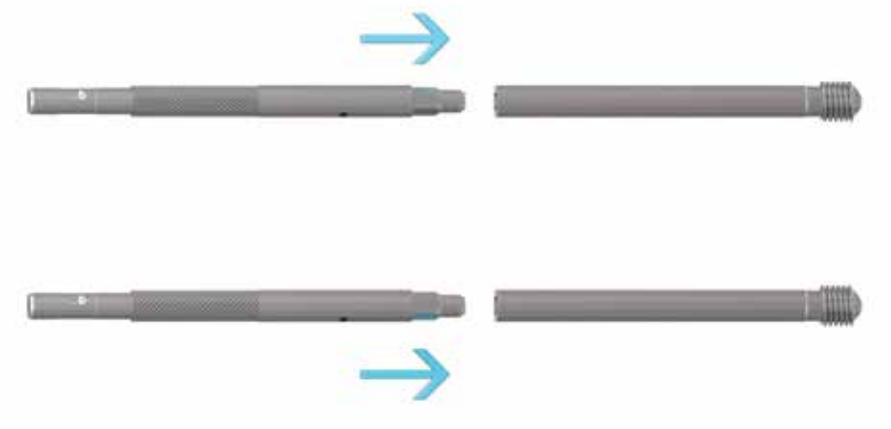


Surgical Technique

Using the Posted Compressor/Distractor

To Distract

Step 1:
Assemble the upper and lower half of the Posts.



Step 2:
After pedicle screws have been inserted, thread the Posts into tulip heads on adjacent levels and tighten until the screws become fixed.

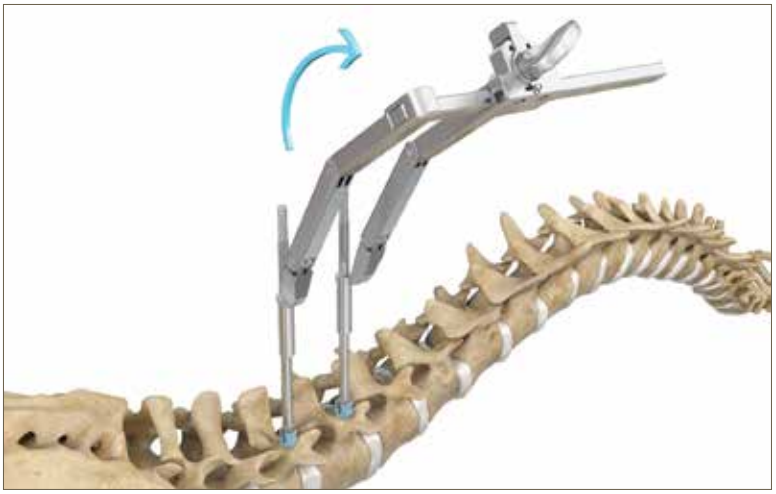
- **TIP:** Utilize the polyaxiality of the tulip head to help vertically align the Posts prior to fully tightening – this will make it easier to slide the tubes of the Rack over the Posts in future steps.
- **NOTE:** The Posts can be inserted by hand or attached to a Quick Connect handle.
- **NOTE:** Do not overtighten the Compression/Distraction Posts.
- **NOTE:** A rod fork may be used to stabilize the tulip head during post insertion.

Step 3:
Slide the tubes of the Rack over the Posts.

Surgical Technique

Using the Posted Compressor/Distractor

Step 4:
Fold the hinged legs of the Rack away from the surgical site.



Step 5:
Set the switch on the Ratchet Housing to the Distract (←D→) setting.

Step 6:
Turn the Key clockwise to distract.

(Optional) Step:
For optimized visualization of the surgical site, the upper half of the Posts can be removed.

The instrument can be left in place for decompression/disc space removal and interbody insertion.

NOTE: To prevent accidental turning of the Key, the switch on the Ratchet Housing can be set to "Lock."

Surgical Technique

Using the Posted Compressor/Distractor

To Compress

Step 1:
Once the interbody portion of the procedure is complete, set the switch on the Ratchet Housing to Compress (→C←).

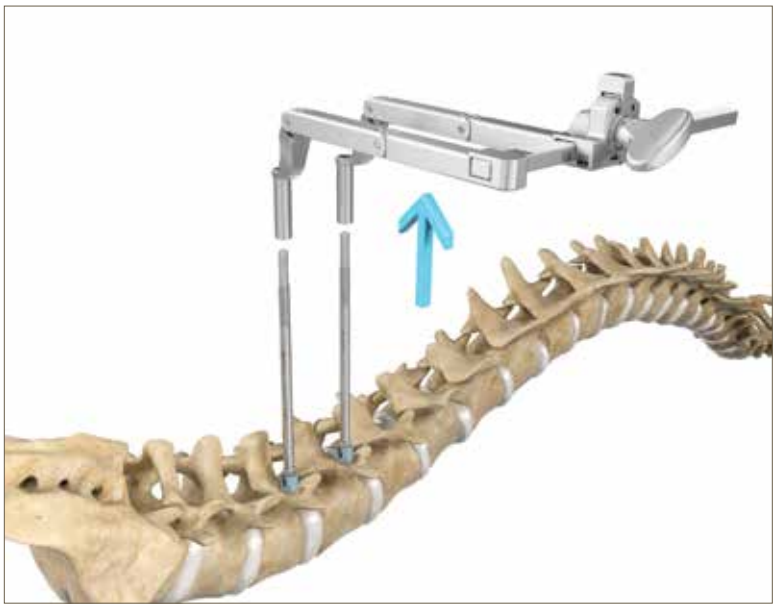
Step 2:
Compression is achieved by turning the Key counterclockwise.

To Remove the PCD

Step 1:
Slide the tubes up and over the Posts.

Step 2:
Re-insert the upper half of the Posts.

Step 3:
Remove the Posts by unthreading from the Tulip.



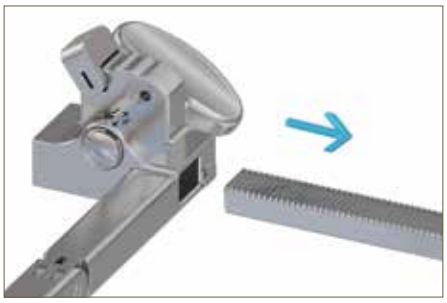
Surgical Technique

Using the Posted Compressor/Distractor

To Disassemble the PCD

Step 1:
Set the switch on the Ratchet Housing to "Unlock."

Step 2:
Rotate the Key until the Rack is removed from the Ratchet Housing.



Step 3:
Pull the Key out of the Ratchet Housing.

For surgeon users who prefer traditional compression/distraction instruments, please note that these are still available in the set.

Rod Insertion

The Xia 4.5 Evolution Spinal System offers both straight and Rad Rods in Titanium Alloy and Vitallium. This versatile rod offering is intended to present surgeons with various stiffness and strength options to meet a spectrum of surgical needs.

Once all the screws are inserted, the appropriate length rod is determined.

The Rod Template can be used to more accurately determine the appropriate rod length.

Titanium Alloy Rad Rods

Vitallium Rad Rods

Titanium Alloy Straight Rod

Vitallium Straight Rod

Titanium Transition Rod

Vitallium Transition Rod

Rod Template
48130620

Surgical Technique

Rod Insertion

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

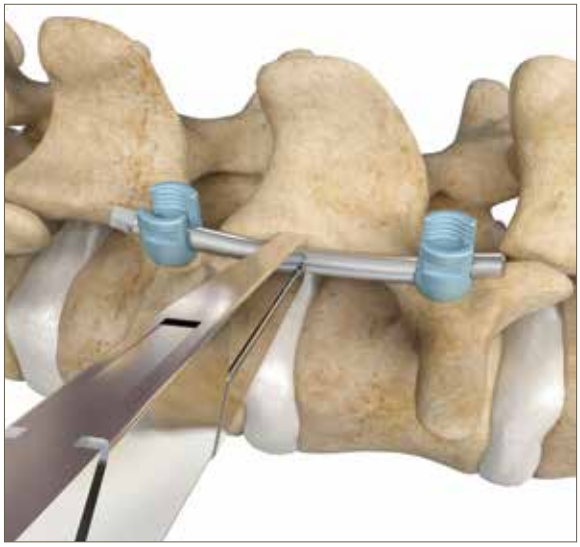
Table-Top Rod Cutter 48238400 and Stand 48238400S

To fit the desired spinal contours, rod bending can be performed with the **French Benders**. 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 not to make extreme bends, so as to avoid stress concentration and notching of the rod. Do not contour a bent rod in the opposite direction; bending and unbending the rod.

French Bender 48237010

Once the rod is bent to the desired contour, the **Rod Insertion Forceps** or **Rod Holder** can be used to help place the rod into the grooves of the implant.



Rod Insertion Forceps 48138140

Surgical Technique

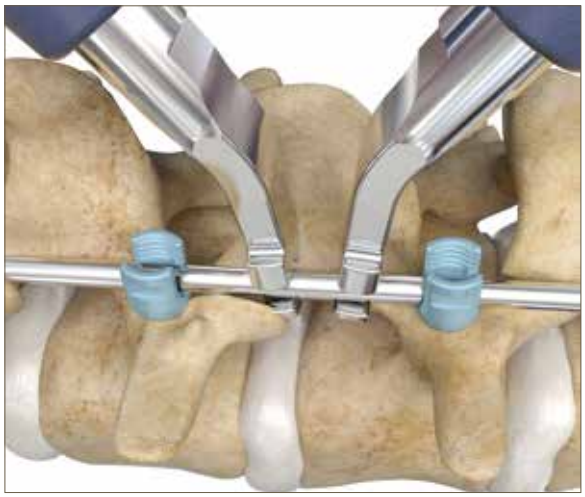
Rod Insertion

***In-Situ* Bender**
Right 48138011R
Left 48138011L

Coronal Bender
Right 48138190R
Left 48138190L

Ball Joint
48230180S

The ***In-Situ*** **Rod Benders** and the **Coronal Rod Benders** can be used to achieve final incremental correction maneuvers. Care should be taken not to make extreme bends as that can cause stress concentration and notching of the rod.



The Xia 4.5 Evolution Spinal System uses the Xia Buttress Thread **Blocker** as its closure mechanism. The titanium Blocker is laser etched to more clearly differentiate it from other materials.

The blocker is assembled onto the **Blocker Inserter** for insertion, and tightened by rotating clockwise.

NOTE: The Blocker Inserter is not to be used for final tightening.

Blocker
48130000

Blocker Inserter
48138008

Surgical Technique

Rod Linkage

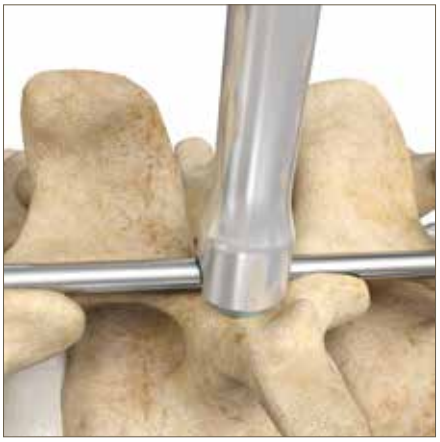
The Xia 4.5 Evolution System offers multiple ways to link the rod to the spine.

Option 1: Inserter Tube

Place the **Inserter Tube** over the rod and tulip. The Inserter Tube helps align the Blocker Inserter and the Blocker with the implant. Place the Blocker through the Inserter Tube and tighten.

Inserter Tube
48137009

Blocker Inserter
48138008



Option 2: Rod Fork

When the rod is slightly proud with respect to the seat of the implant, the **Rod Fork** can be used.

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 Blocker Inserter.

Rod Fork
48138018

Option 3: Persuader

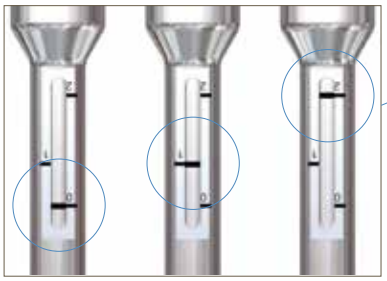
Use the **Persuader** when additional force is needed to bring the rod to the implant. The Persuader has two windows at the top and two windows at the bottom of the instrument for visibility.

The **Hex Drive T-Handle** can be attached to the Persuader for additional leverage.

Hex Drive T-Handle
48237017

There are three key indication lines on the Persuader:

- At **"0"**, the Persuader can be connected to the implant
- At **"1"**, the Persuader is locked to the implant
- At **"2"**, the rod is fully seated



Persuader 48138016

NOTE: Use of the Corkscrew Persuader with Reduction Screws is not recommended due to an increased risk of unintentional Reduction Tab breakage.

Surgical Technique

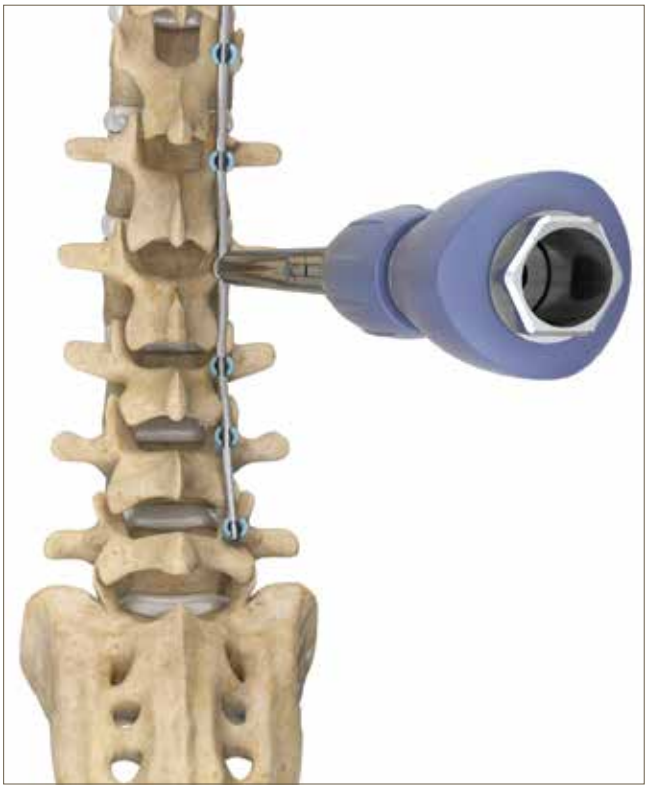
Rod Linkage

To Persuade

Step 1:
Verify the indication line on the Persuader is in the "2" starting position.

Step 2:
Connect the Persuader to the head of the implant. 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.

Step 3:
Rotate the handle of the Persuader clockwise until the indication line is in the "0" position. At this position, the rod is fully seated and the Blocker can be inserted using the Blocker Inserter.



To Remove the Persuader:

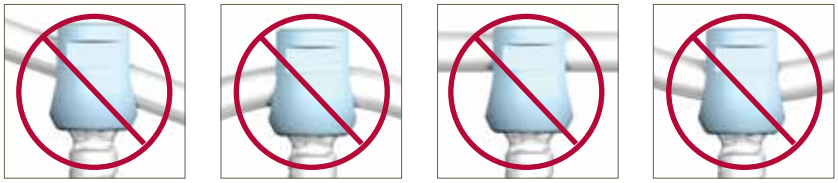
Step 1:
Rotate the handle counterclockwise until the indication line is in the "0" starting position.

Step 2:
Twist the instrument to disengage from the implant.

NOTE: Blockers can be inserted through the Persuader into the screw heads.

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.



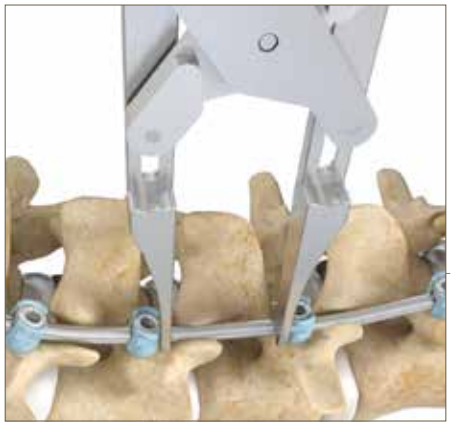
Surgical Technique

Compression/Distraction

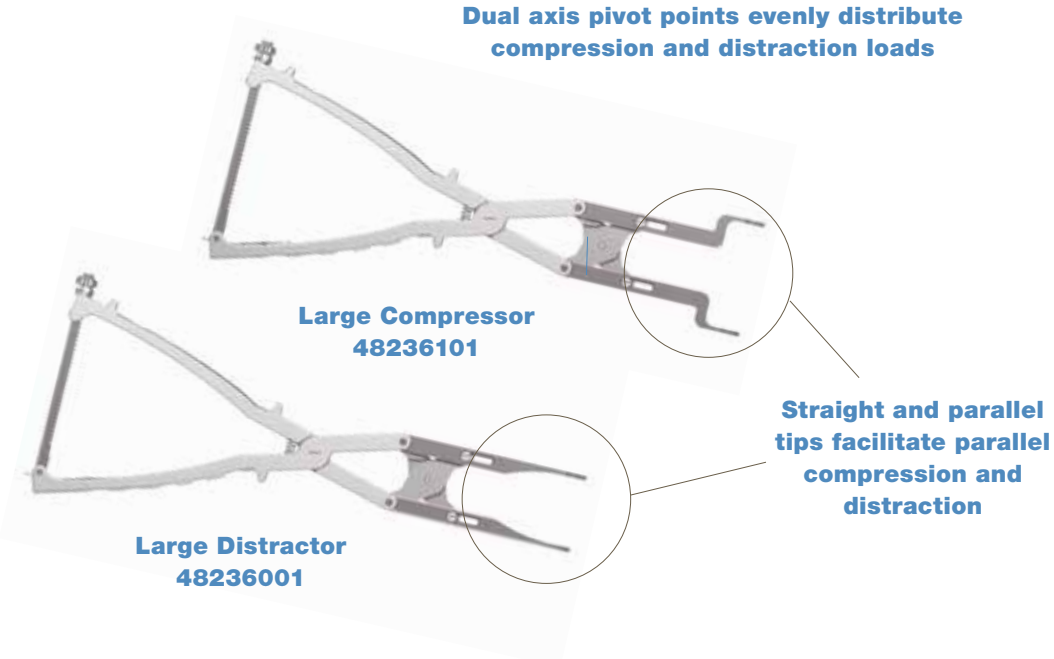
Compressors and **Distractors** are available for both distracting and compressing the disc space as well as correcting spinal deformities. Spinal deformities can be affected by creating a distraction on the concavity of the deformity and compression on the convexity of the deformity. The compression or distraction maneuvers should be performed once all of the blockers are inserted but not final tightened.

To accommodate a range of correction needs, small and large Compressors and Distractors are available.

Small Compressor 48236100



Small Distractor 48236000



Surgical Technique

Final Tightening

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the blockers is performed.

To final tighten; use the **Anti-Torque Key** and the **Torque Wrench**:

Step 1:
Place the Anti-Torque Key over the screw head.

Step 2:
Place the Torque Wrench through the Anti-Torque Key until it is guided into the blocker.

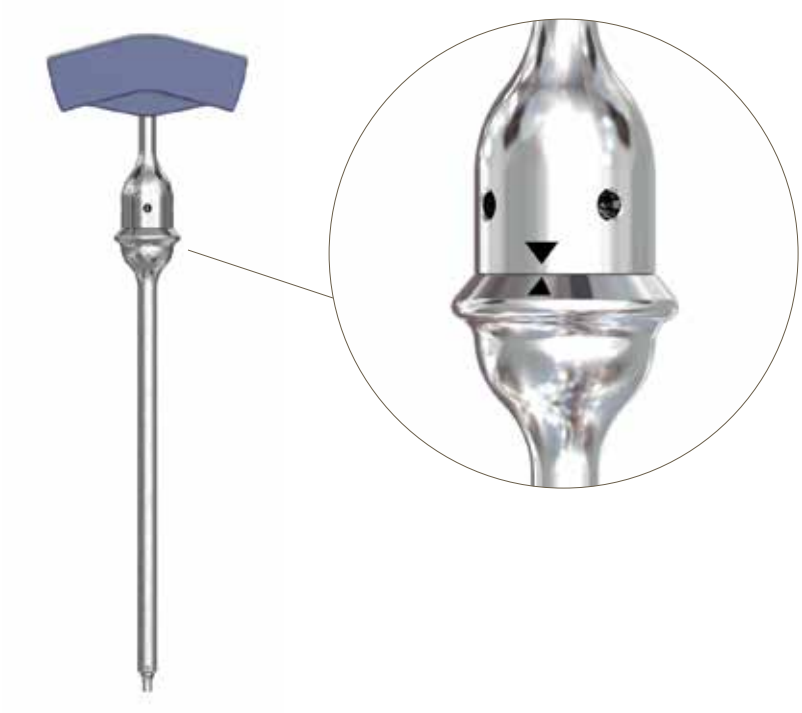
Step 3:
Line up the two arrows to achieve the final tightening torque of 8Nm. The Torque Wrench indicates the optimal torque force that must be applied to the implant for final tightening.

Anti-Torque Key
48138026

NOTE: Do not exceed 8Nm during final tightening.

The Anti-Torque Key must be used for final tightening. The Anti-Torque Key performs two key functions:

- Allows the Torque Wrench to align with the tightening axis
- Helps to maximize the torque needed to lock the implant assembly



Torque Wrench
48137028

Surgical Technique

Cross Connector Insertion

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 **Caliper**.

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.

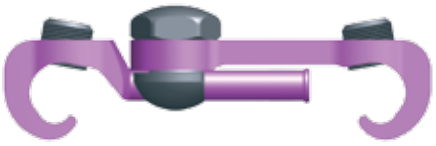
Use the **Cross Connector Holder** to place the appropriate length connector on the rod. Use the **3mm Hex Driver** to tighten one of the set screws onto the rod.

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 3mm Hex Driver must be used to tighten the set screws, and the **8mm Hex Driver** must be used to final tighten the center nut.

Monobloc Connector



Polyaxial Cross Connector

Caliper
48130130

Cross Connector Holder
48130120

3mm Hex Driver
48137057

8mm Hex Driver
48230122

Surgical Technique

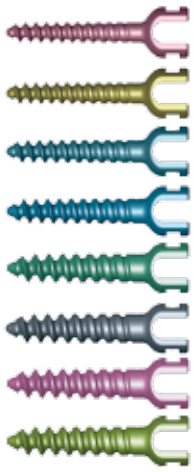
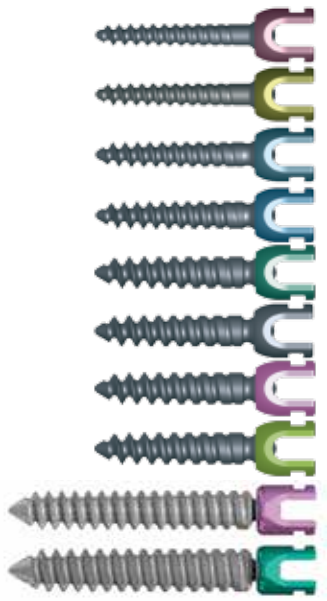
Use of Biologics

Autologous bone graft, synthetic bone graft, or allograft can be placed in the posterolateral space once final tightening has occurred. The Vitoss Bone Graft Substitute family of products, BIO DBM putty, boats, and shapes or BIO Chips may be used in the posterolateral spine to aid in fusion.

Please refer to the **Stryker Biologics Catalog** (**BIGENBR12011**) for a full description of Vitoss Bone Graft Substitute, BIO DBM and allograft product offerings.

Surgical Technique

Implants

	Reference Number	Description		
	48130000	Xia 4.5 Blocker		
	48134020-4040	Monoaxial Screw	Ø4.0mm	20mm-40mm
	48134520-4545	Monoaxial Screw	Ø4.5mm	20mm–45mm
	48135020-5080	Monoaxial Screw	Ø5.0mm	20mm–80mm
	48135520-5580	Monoaxial Screw	Ø5.5mm	20mm–80mm
	48136025-6080	Monoaxial Screw	Ø6.0mm	25mm–80mm
	48136530 - 6580	Monoaxial Screw	Ø6.5mm	30mm–80mm
	48137030 - 7080	Monoaxial Screw	Ø7.0mm	30mm–80mm
	48137530 - 7580	Monoaxial Screw	Ø7.5mm	30mm–80mm
	48144020-4040	Polyaxial Screw	Ø4.0mm	20mm-40mm
	48144520-4570	Polyaxial Screw	Ø4.5mm	20mm-70mm
	48145020-5080	Polyaxial Screw	Ø5.0mm	20mm-80mm
	48145520-5580	Polyaxial Screw	Ø5.5mm	20mm-80mm
	48146025-6080	Polyaxial Screw	Ø6.0mm	25mm-80mm
	48146530-6580	Polyaxial Screw	Ø6.5mm	30mm-80mm
	48147030-7080	Polyaxial Screw	Ø7.0mm	30mm-80mm
	48147530-7580	Polyaxial Screw	Ø7.5mm	30mm-80mm
	48148540-8500	Polyaxial Screw	Ø8.5mm	40mm-100mm
	48149540-9500	Polyaxial Screw	Ø9.5mm	40mm-100mm
	481304520-4545	Monoaxial Reduction Screw	Ø4.5mm	20mm–45mm
	481305520-5555	Monoaxial Reduction Screw	Ø5.5mm	20mm–55mm
	481306530-6560	Monoaxial Reduction Screw	Ø6.5mm	30mm–60mm
	481307530-7560	Monoaxial Reduction Screw	Ø7.5mm	30mm–60mm
	481404520-4545	Polyaxial Reduction Screw	Ø4.5mm	20mm–45mm
	481405520-5555	Polyaxial Reduction Screw	Ø5.5mm	20mm–55mm
	481406530-6560	Polyaxial Reduction Screw	Ø6.5mm	30mm–60mm
	481407530-7560	Polyaxial Reduction Screw	Ø7.5mm	30mm–60mm

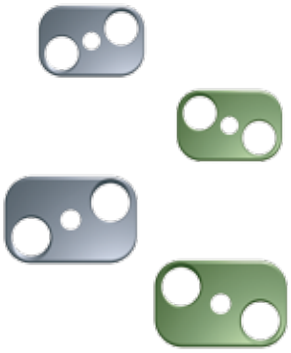
Surgical Technique

Implants

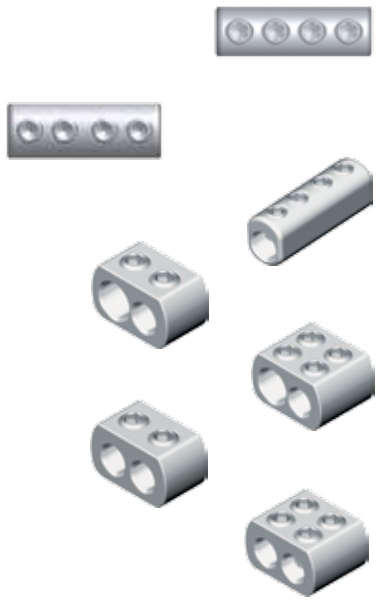
	Reference Number	Description
	481321(030 - 120)	Titanium Alloy Rad Rod
	481322(030 - 120)	Vitallium Rad Rod
	48133(030 - 120)	Titanium Alloy Straight Rod with Hex
	481313035, 481313045	Titanium Alloy Straight Rod with Hex
	48132(030 - 120)	Vitallium Straight Rod with Hex
	48133200	Titanium Long Rod Ø4.5mm 200mm
	48133480	Titanium Long Rod Ø4.5mm 480mm
	48132601	Vitallium Rod Ø4.5mm 600mm
	48143600	Titanium Transition Rod Ø4.5mm-Ø5.5mm 600mm
	48143602	Titanium Transition Rod Ø4.5mm-Ø6.0mm 600mm
	48143604	Vitallium Transition Rod Ø4.5mm-Ø5.5mm 600mm
	48143606	Vitallium Transition Rod Ø4.5mm-Ø6.0mm 600mm
	48130220	Pedicle Hook Small
	48130221	Pedicle Hook Large
	48130201	Laminar Hook Small
	48130202	Laminar Hook Medium
	48130203	Laminar Hook Large
	48130208	Laminar Hook Angled Blade
	48130210	Thoracic Laminar Hook Ramped

Implants

Reference Number	Description
48130204	Extended Body Laminar Hook
48130230	Transverse Process Hook, Right
48130231	Transverse Process Hook, Left
48130212	Thoracic Hook Offset, Right
48130213	Thoracic Hook Offset, Left
48130214	Supralaminar Thoracic Hook, Right
48130215	Supralaminar Thoracic Hook, Left



48130110	Dual Hole Staple Small, Caudal
48130111	Dual Hole Staple Small, Rostral
48130112	Dual Hole Staple Large, Caudal
48130113	Dual Hole Staple Large, Rostral



48135000	Ø4.5mm- Ø4.5mm Axial Rod to Rod Connector
48135001	Ø4.5mm- Ø6.0mm Axial Rod to Rod Connector
48135004	Ø4.5mm- Ø5.5/Ø6.0mm Axial Rod to Rod Connector
48135008	Ø4.5mm- Ø5.5/Ø6.0mm Parallel Rod to Rod Connector (Large)
48135003	Ø4.5mm- Ø5.5/Ø6.0mm Parallel Rod to Rod Connector (Small)
48135005	Ø4.5mm- Ø4.5mm Parallel Rod to Rod Connector (Small)
48135006	Ø4.5mm- Ø4.5mm Parallel Rod to Rod Connector (Large)

Surgical Technique

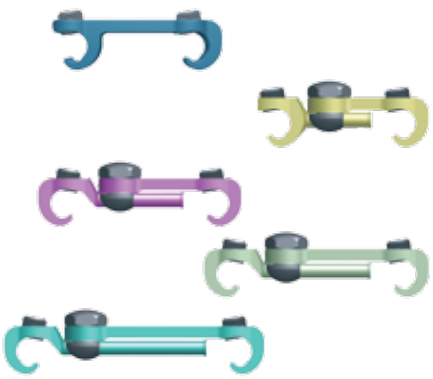
Implants

Reference Number	Description	
48145010	Ø4.5mm-Ø5.5/6.0mm Side Loading Top Loading Connector	
48145011	Ø4.5mm-Ø5.5/6.0mm Angled Side Loading Side Loading Connector	
48140134	Ø4.5mm-Ø5.5/6.0mm 0° Rod to Rod Connector (Small)	
48140135	Ø4.5mm-Ø5.5/6.0mm 30° Rod to Rod Connector (Small)	
48140136	Ø4.5mm-Ø5.5/6.0mm 0° Rod to Rod Connector (Large)	
48140137	Ø4.5mm-Ø5.5/6.0mm 10° Rod to Rod Connector (Large)	

48135101	30mm Offset Connector	
48135102	70mm Offset Connector	

48135103	Extended Connector Small	
48135104	Extended Connector Large	

48135105	Parallel Connector	
48135106	15 degree Iliac Connector	
48135107	25 degree Iliac Connector	
48135108	35 degree Iliac Connector	
48135109	45 degree Iliac Connector	



48133012-3024	Monobloc Cross Connector	12mm-24mm
48133224	Polyaxial Cross Connector Small	24mm-30mm
48133230	Polyaxial Cross Connector Medium	30mm-36mm
48133236	Polyaxial Cross Connector Large	36mm-45mm
48133245	Polyaxial Cross Connector Extra Large	45mm-60mm

Surgical Technique

Instruments

	Reference Number	Description
	48237111	Awl
	48237060	Malleable Pedicle Feeler
	48237059	Medium Pedicle Feeler
	48237003	Stiff Pedicle Feeler
	48237061	Double-Ended Ball Tip Probe
	48237024	Curved Blunt Probe
	48237055	Thoracic Pedicle Probe
	48230030	Modular 3.0 Tap
	48230035	Modular 3.5 Tap
	48230040	Modular 4.0 Tap
	48230045	Modular 4.5 Tap
	48230055	Modular 5.5 Tap
	481301311	Modular 6.0 Tap
	48230065	Modular 6.5 Tap
	481301312	Modular 7.0 Tap
	48230075	Modular 7.5 Tap
	48230085	Modular 8.5 Tap
	48230095	Modular 9.5 Tap
	48138010	Polyaxial Screwdriver (Assembly)
	48138020	Monoaxial Screwdriver (Assembly)
	48138012	Screwdriver Outer Sleeve
	48138013	Screwdriver Locking Nut
	48138011	Polyaxial Screwdriver Shaft

Surgical Technique

Instruments

	Reference Number	Description
	48138021	Monoaxial Screwdriver Shaft
	48130320	Modular Monodriver (Head Turner)
	48130310	Polyadjustment Driver
	48231201	T-Handle
	48231202	T-Handle, Ratchet
	48231301	Round Handle
	48231302	Round Handle, Ratchet
	482397006	Small Round Handle
	482397005	Small Round Handle, Ratchet
	48139110	Tab Remover
	48138140	Rod Insertion Forceps
	48138100	Posted Compression/Distraction Rack
	48138101	Posted Compression/Distraction Shaft
	48236100	Small Compressor
	48236000	Small Distractor
	48236101	Large Compressor
	48236001	Large Distractor
	48130620	Rod Template
	48138011R	*In-Situ* Bender Right

Surgical Technique

Instruments

	Reference Number	Description
	48138011L	*In-Situ* Bender Left
	48237010	French Bender
	48138190R	Coronal Bender Right
	48138190L	Coronal Bender Left
	48230180S	Ball-Joint
	48130140	Rod Holder
	48130100	Rod Rotation Forceps
	48137056	Rod Rotation Key
	48137019	Rod Pusher
	48138018	Rod Fork
	48138016	Corkscrew Persuader
	48237017	Hex Drive T-Handle
	48130130	Caliper
	48137057	3 mm Hex Driver
	48230122	8 mm Hex Driver
	48137009	Inserter Tube
	48138008	Blocker Inserter
	48138026	Anti-Torque Key
	48137028	Torque Wrench

Surgical Technique

Instruments

Reference Number	Description
481301321	Forcep Hook Holders
48137027	Hook Holder
48131040	Lateral Hook Holder
48137025	Pedicle Preparer
48137021	Lamina Preparer
48137029	Hook Impactor
48130241	Dual Staple Holder / Impactor
48130120	Cross Connector Holder
48238400S	Table-Top Rod Cutter, Stand
48238400	Table-Top Rod Cutter
48138001	Standard Implant Tray
48138002	Standard Instrument Tray
48138003	Deformity Tray
48138004	Auxiliary Tray
48850600	Transition Rod Tray (400 - 600mm)
48138001A	Standard Implant Tray Lid
48138001B	Standard Implant Tray Top Insert
48138001C	Standard Implant Tray Middle Insert
48138001D	Standard Implant Tray Base
48138001E	Standard Implant Tray Screw Caddy I (25 - 35mm)
48138001F	Standard Implant Tray Screw Caddy II (40 - 50mm)

Instruments

Reference Number	Description
48138001G	Blocker Caddy
48138001H	Standard Implant Tray Cross Connector Caddy
48138001I	Titanium Rad Rod Caddy
48138001J	Vitallium Rad Rod Caddy
48138001K	Large Diameter Screw Caddy
48138002A	Standard Instrument Tray Lid
48138002B	Standard Instrument Tray Top Insert
48138002C	Standard Instrument Tray Middle Insert
48138002D	Standard Instrument Tray Base
48138003A	Deformity Tray Lid
48138003B	Deformity Tray Top Insert
48138003C	Deformity Tray Middle Insert
48138003D	Deformity Tray Base
48138003E	Deformity Tray Screw Caddy I (20 - 35mm)
48138003F	Deformity Tray Screw Caddy II (40-60+mm)
48138003G	Deformity Tray Hook Caddy
48138003H	Deformity Tray Connector Caddy
48138004A	Auxiliary Tray Lid
48138004B	Auxiliary Tray Insert
48138004C	Auxiliary Tray Base
48138004D	Auxiliary Tray Implant Caddy
48138004E	Auxiliary Tray Connector Caddy
48138005	Deformity Screw Tray
48138005A	Deformity Screw Tray Lid
48138005B	Deformity Screw Tray Screw Rack
48138005C	Deformity Screw Tray Pin Mat
48138005D	Deformity Screw Tray Base

Xia 4.5 Spinal Fixation Systems
NON-STERILE AND STERILE PRODUCT

INDICATIONS

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.

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.

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.

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.

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 4.5 Spinal System has 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.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a complete description of the event to help STRYKER Spine understand the causes of the complaint.

For further information or complaints, please contact:

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