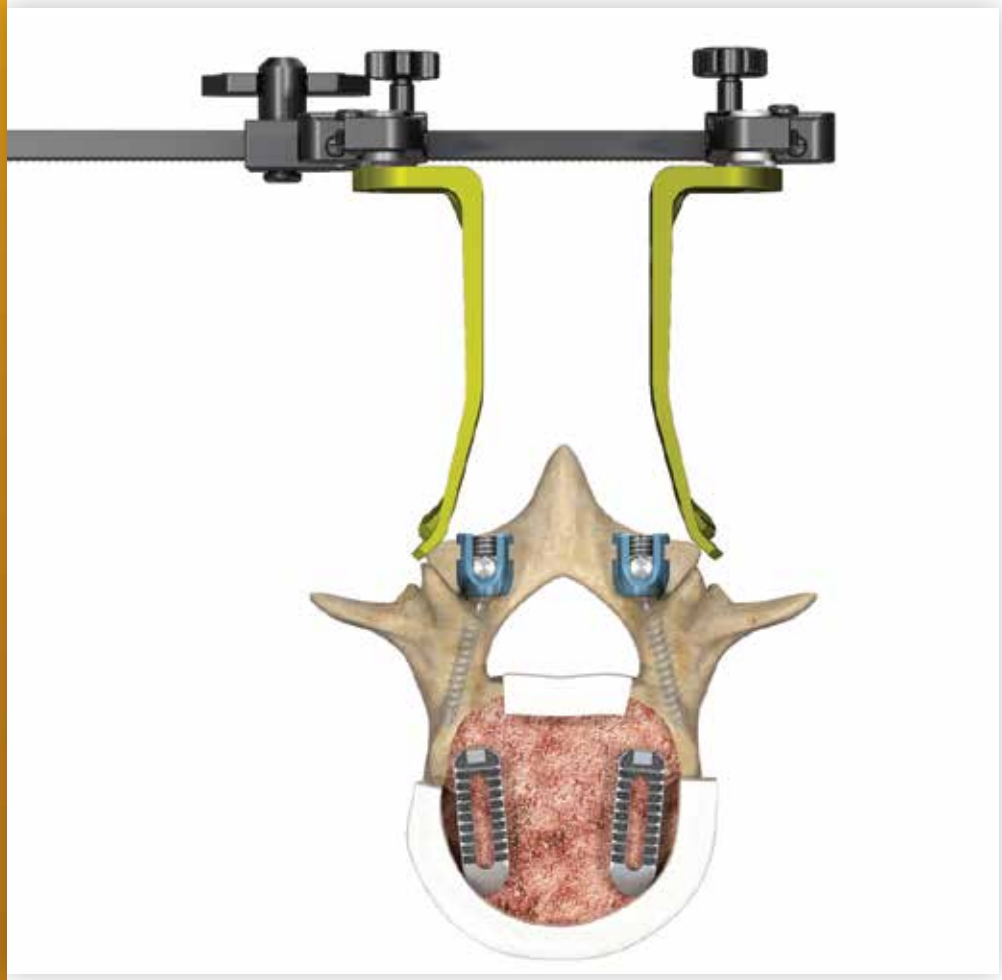
stryker

Xia® 4.5 Cortical Trajectory

LITe® LIF Procedure



Surgical technique

Table of contents

Case preparation

What to bring:
- **1 Xia CT Set**
- **1 Midline Retractor**
- **1 Xia 4.5 Evolution Set**

Note: Xia CT sets DO NOT include rods. Rods MUST be pulled from the Xia 4.5 Evolution set.

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

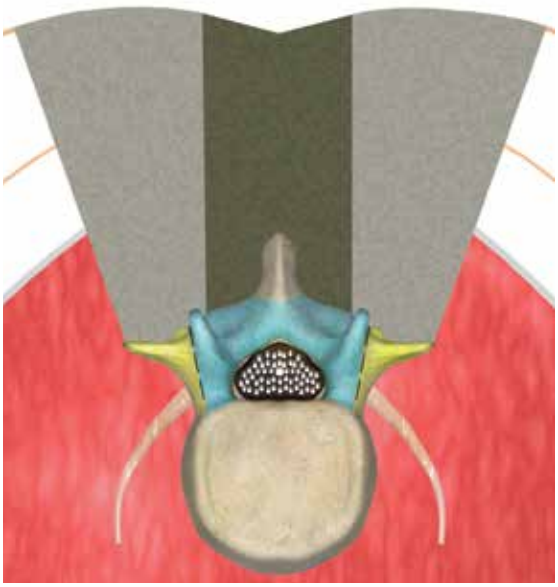
Anatomical considerations

The LITe LIF insertion points are encircled by cortical bone which allows for better purchase and strength during insertion. Upon screw insertion, screw trajectories must be directed in the opposite position of the neurovascular structures. The entrance points of the pedicle screw tend to be less obscure in degenerative conditions, which differentiates the LITe LIF procedure from traditional lateral to medial posterior approaches as the procedure is designed for the screw to reside in cortical bone.

Procedural considerations

Some procedural considerations during the LITe LIF approach include the cortical bone purchase, the amount of lateral retraction, exposure time, and closure time. Due to the limited amount of cortical bone available for this approach, smaller screws are generally used to prevent puncturing or breaching the lateral mass of the vertebral body.

Procedural exposure



LITe LIF procedure
Open TLIF
LITe LIF screw trajectory
Traditional screw trajectory

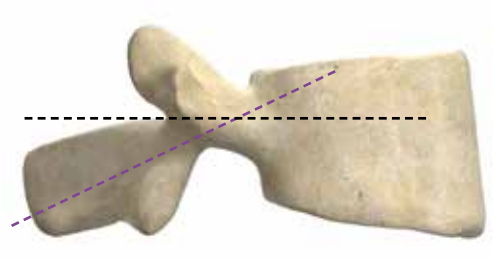
Screw trajectory and anatomy

During the LITe LIF procedure it's important to select a trajectory that allows the screw to be inserted medial to lateral and reside adjacent to the cortical wall of the vertebral body. Screw insertion and purchase may be more rigid and fixated when placed in the cortical space.

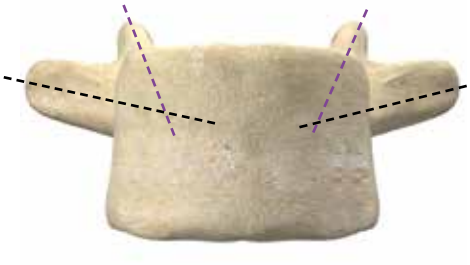
Traditional pedicle screw trajectory involves a lateral to medial approach through the pedicle, typically involving partial cortical and majority cancellous bone to achieve fixation and fusion, while the LITe LIF pedicle screw trajectory involves a medial to lateral approach through the pedicle typically involving majority cortical and partial cancellous bone. There is a distinct difference in trajectory between the LITe LIF procedure and standard TLIF or LIF open procedures.

---------- **Cortical screw trajectory**
---------- **Traditional pedicle screw technology**

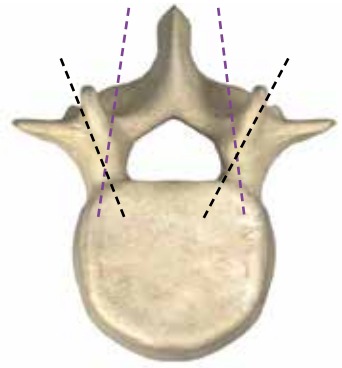
Lateral view



AP view

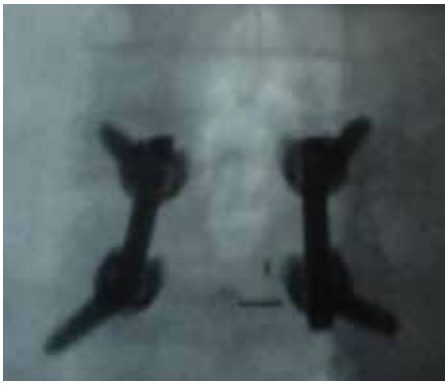


Axial view



Lateral view

AP view



System overview

The LITe LIF procedure using the Xia CT (Cortical Trajectory) implants and instruments with Stryker's vast interbody offering is a less invasive posterior lumbar interbody fusion procedure that facilitates a midline approach to help achieve decompression and fixation. The approach is comprised of a small midline exposure where the decompression and fusion will reside. Because lateral dissection is not necessary beyond the insertion point, there is potential for less lateral muscle retraction with this technique. The standard TLIF or LIF open procedure involves a lateral to medial trajectory and, therefore, increased lateral exposure.

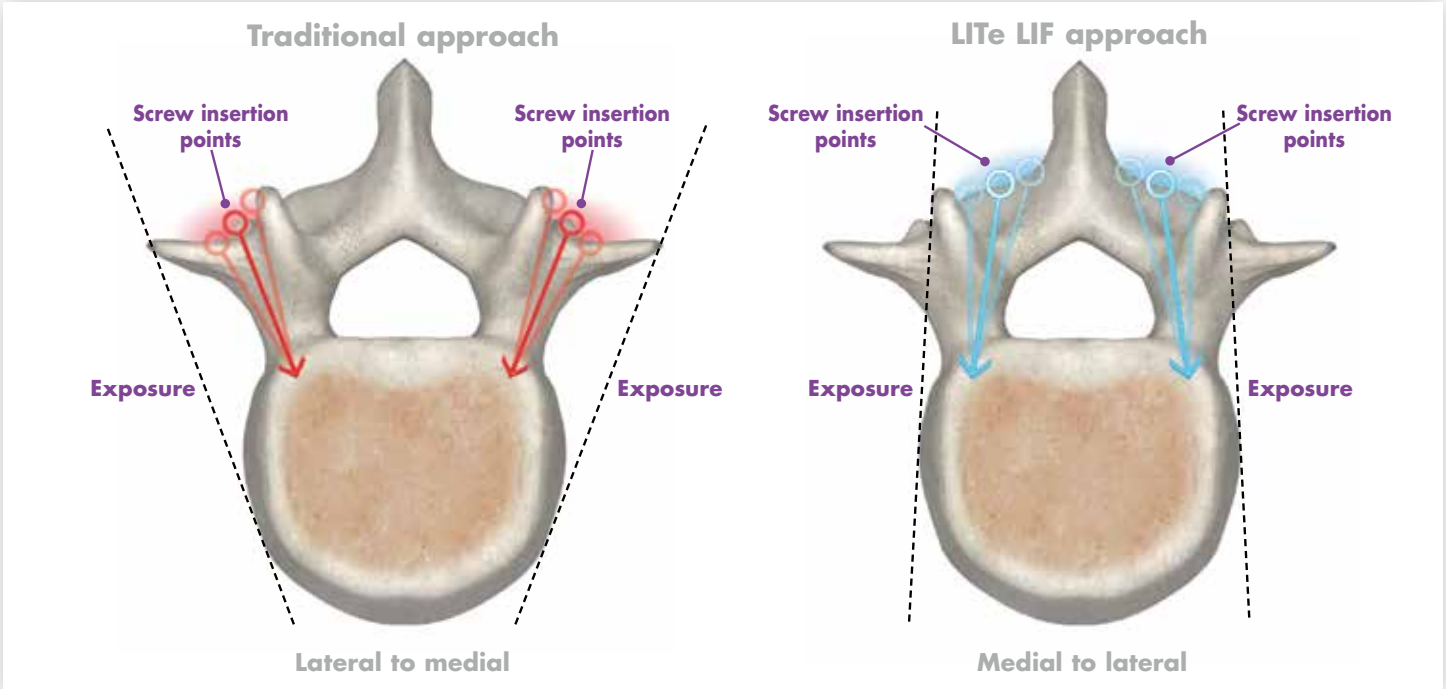
Stryker's Xia CT (Cortical Trajectory) implants and instruments are used to place screws in a cortical trajectory in the lumbar spine. The Xia CT implants and instruments utilize the low profile (12.1mm) tulip head of Stryker's Xia 4.5 implants. The Xia CT implants and instruments can be used with the LITe Midline Retractor that offers optimized visualization of the surgical site without the need for headlamps.

The Xia CT implants are offered in both cannulated and non-cannulated screw configurations. The cannulated screw offering and cannulated instruments allow for screw insertion over a guide wire with up to a 1.3mm diameter.

The Xia CT implants and instruments are compatible with existing Xia 4.5 implants and instrumentation.

Potential benefits of the cortical trajectory procedure are:

- A less invasive procedure through a small midline incision
- Decompression, fixation and fusion can be accomplished
- Intended to be more muscle sparing than a traditional open posterior procedure
- Exposure and closure time may be more efficient due to smaller incision



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.

Figure 1.

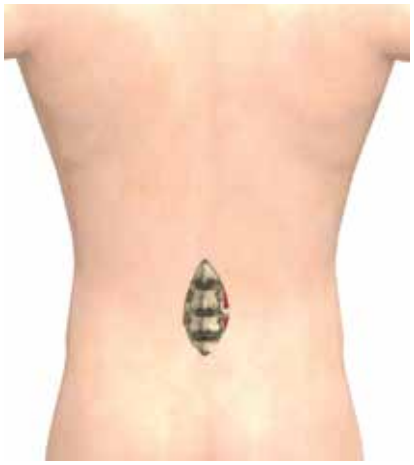


Figure 2.

Step 1: Exposure

Surgical levels may be verified either clinically or radiographically. After the surgeon has localized, marked and prepped the patient, a small midline incision will be made over the appropriate levels. Pre-surgical planning defines the most appropriate implants in addition to the optimal location for insertion of implants.

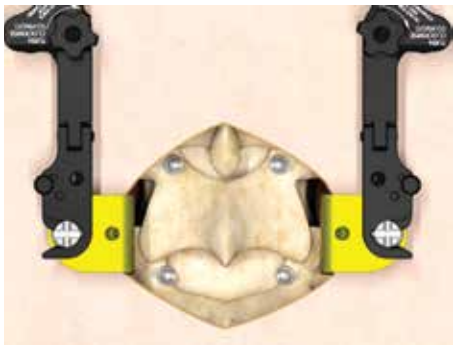


Figure 3.

Step 2: LITe Midline Retractor placement (optional)

The depth gauge may be utilized to identify length of the blades needed on the Midline Retractor. Manual retraction is used while placing the Midline Retractor onto the blades. Once the retractor is secure, connect the light source to illuminate the working area. Please refer to the **LITe Midline Retractor Sell Sheet PRTTL-SS-1**.

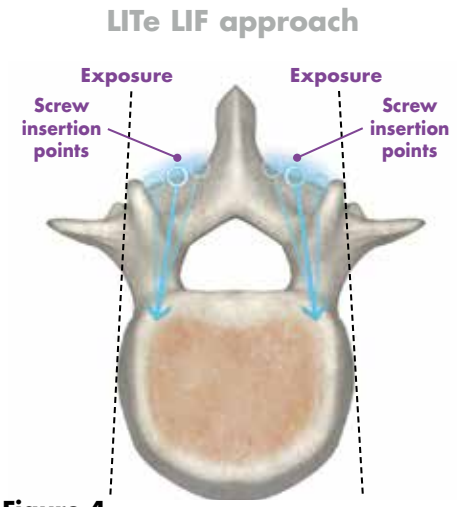


Figure 4.

Step 3: Starting point

Once the incision is made and the Midline Retractor is placed, fluoroscopy is used in an A/P orientation to identify the starting points. Penetrate the cortical bone with an awl, burr or drill to mark the screw entry point using anatomic, fluoroscopic or image-guided technique. Stryker's CORE (Consolidated Operating Room Equipment) platform of products offers surgeons a wide range of handpiece and burr options to perform this step of the surgical procedure/technique.

Step 4: Trajectory/screw preparation

Once the starting point is identified and marked, lateral fluoroscopy is used to identify the screw trajectory. In applicable anatomic areas, a pedicle probe – followed by a tap – can be used to prepare the screw pathway. In all other cases, the preparation of the screw hole should follow the steps below. Select the appropriate size drill bit and tap based on the desired screw diameter. The **Adjustable Drill Guide** assembled with the selected **Drill Bit** allows for variable depth drilling of the desired screw trajectory. To set the depth which corresponds to the final screw length, depress the locking button on the Drill Guide, and slide the inner sleeve to the desired depth according to the depth markings on the side of the inner sleeve.

Figure 7.

Once the inner sleeve is at the desired depth, release the locking button to engage the inner sleeve to the Drill Guide. The drilling depth can be adjusted while the Drill Bit is inserted in the Drill Guide.

Note: Do not adjust Drill Guide trajectory of depth stop while actively drilling.

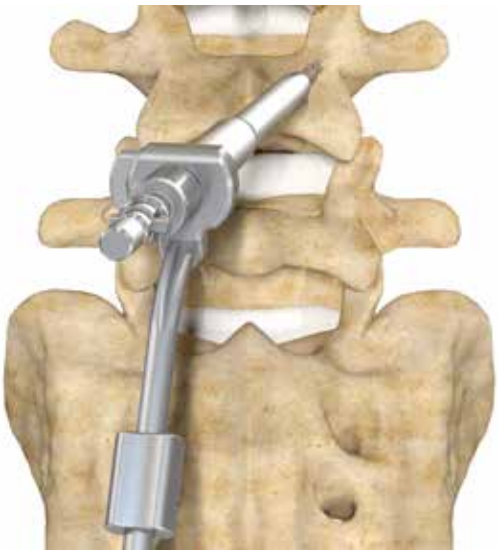


Figure 5.

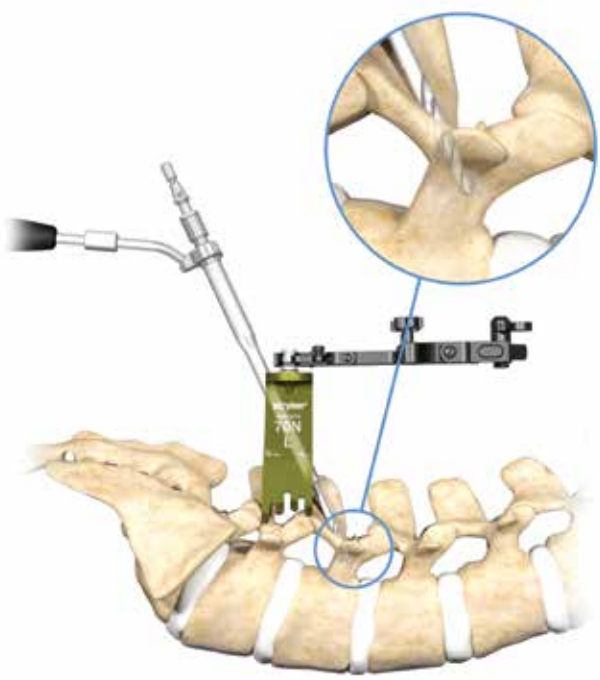


Figure 6.

Select the Drill Bit (2.5mm, 3.0mm, 3.5mm, 4.0mm, or 5.0mm) that is appropriate for the size of the screw to be used. The Drill Bits are sized according to the minor diameter of the screw to be used (i.e., the 3.5mm Drill Bit should be used to prepare a pathway for a 5.0mm screw). The Drill Bits have a standard Xia 3 connection and can be used with any Xia 3 or ES2 quick connect handles. Slight positive downward pressure should be maintained during drilling to ensure the drill guide stays in contact with the entry point. Final depth can be confirmed by visual and tactile feedback. Visual confirmation of the final depth is achieved when the Drill Bit flange contacts the proximal end of the inner sleeve. Additionally, the surgeon will feel a tactile vibration when the Drill Bit flange makes contact with the proximal end of the inner sleeve. Once the pathway has been created with the Drill Bit, follow the prepared hole with the **Malleable Pedicle Feeler** to confirm the walls of cortical bone have not been violated. After use, the inner sleeve must be disassembled for cleaning purposes.

Figure 8.

Figure 9.

Adjustable Drill Guide
48856003

Drill Bits

48856440
48856445
48856450
48856455
48856465

Malleable Pedicle Feeler
48237060

Step 5: Tap/screw placement
For increased bone purchase, there are two line to line tap options within the Xia CT implants and instruments. The first tapping option is the non-cannulated **Modular Taps**, which have a standard Xia 3 connection to attach to the quick connect handles. After attaching a handle, insert the Modular Tap into the prepared hole of the vertebral body and pedicle. The Modular Taps are laser marked with depth marking lines in 5mm increments and numbers in 10mm increments. The threaded length of the modular taps is 25mm.

The second tapping option are the **Tap Markers**. These markers are available in cannulated and non-cannulated options. They attach to the distal end of the **Tap Marker Inserter** while an ES2 or Xia 3 quick handle is used to engage the proximal end of the Tap Marker Inserter. The Tap Markers are single use instruments that can be left in the wound during the procedure to allow the surgeon to perform a lumbar interbody fusion and/or decompression without having the tulip heads in the way.

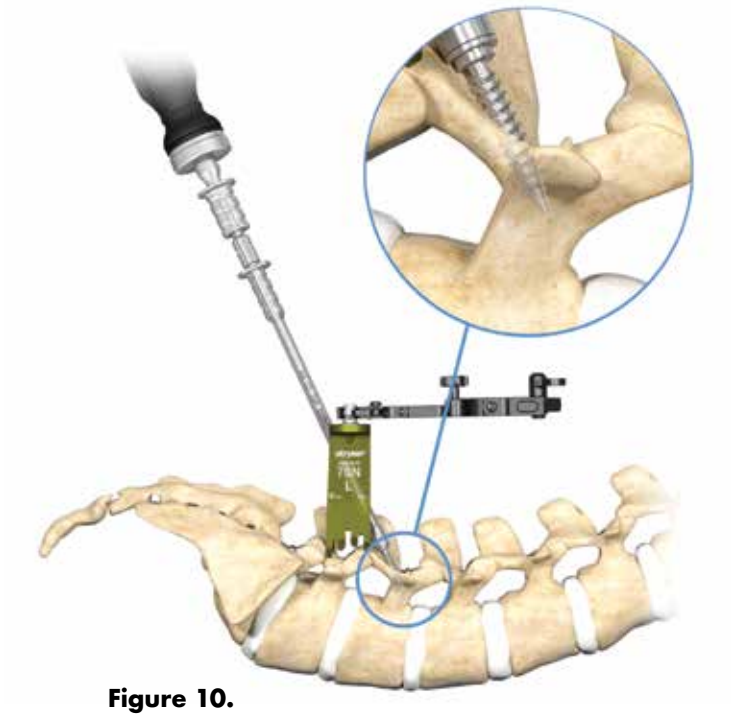


Figure 10.

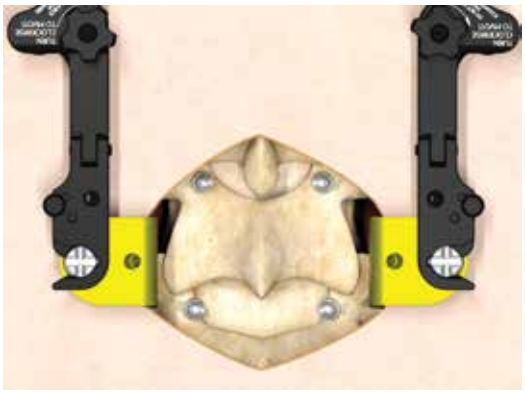


Figure 11.

Note: The pilot hole should be tapped lined-to-line to prevent fracture of the pathway during screw insertion. Under-tapping can result in fracture of the pars when the surgeon attempts to insert a large screw into an undersized cortical bone pathway.

Figure 12.

Note: An ES2 handle should be used when using the cannulated instruments and implants.

Note: The Tap Markers are to be removed prior to inserting screws.

Tap Marker Inserter
48856000

Note: Tap Markers and Drill Bits are single use, disposable instruments.

Modular Taps are available in the following sizes
(Available in non-cannulated only):

• Ø4.0mm Modular Tap	48856040
• Ø4.5mm Modular Tap	48856045
• Ø5.0mm Modular Tap	48856050
• Ø5.5mm Modular Tap	48856055
• Ø6.5mm Modular Tap	48856065
• Ø7.5mm Modular Tap	48856075

Tap Markers are available in the following sizes
(Available in cannulated and non-cannluated options):

- Ø4.0mmx20mm Tap Marker (non-cannulated only)
- Ø4.0mmx25mm Tap Marker (non-cannulated only)
- Ø4.0mmx30mm Tap Marker (non-cannulated only)
- Ø4.0mmx35mm Tap Marker (non-cannulated only)
- Ø4.5mmx20mm Tap Marker
- Ø4.5mmx25mm Tap Marker
- Ø4.5mmx30mm Tap Marker
- Ø4.5mmx35mm Tap Marker
- Ø5.0mmx20mm Tap Marker
- Ø5.0mmx25mm Tap Marker
- Ø5.0mmx30mm Tap Marker
- Ø5.0mmx35mm Tap Marker
- Ø5.5mmx20mm Tap Marker
- Ø5.5mmx25mm Tap Marker
- Ø5.5mmx30mm Tap Marker
- Ø5.5mmx35mm Tap Marker
- Ø6.5mmx20mm Tap Marker
- Ø6.5mmx25mm Tap Marker
- Ø6.5mmx30mm Tap Marker
- Ø6.5mmx35mm Tap Marker

Distraction (optional)
The Xia CT sets include a **Universal Distractor** that offers multiple adaptor options to accommodate a variety of distraction methodologies. The Universal Distractor gives surgeons the ability to distract off the spinous process, lamina, Tap Markers and screws. The Universal Distractor is composed of two pieces, the fixed arm and the mobile arm. To assemble, depress the button on the mobile arm while sliding along the rack of the fixed arm.

Figure 13.

Universal Distractor
48856010

Lamina Adaptor
48856010A

Spinous Process Adaptor, Left
48856010BL

Spinous Process Adaptor, Right
48856010BR

Ø4.0mm - 5.5mm Tap Marker Adaptor
48856010C

Ø5.5mm - 6.5mm Tap Marker Adaptor
48856010D

The arms of the Universal Distractor can be towed in or towed out by pulling back on the outer sleeve and rotating the arms as desired. The sleeve can then be pushed forward to lock the desired position of the arms of the Universal Distractor.

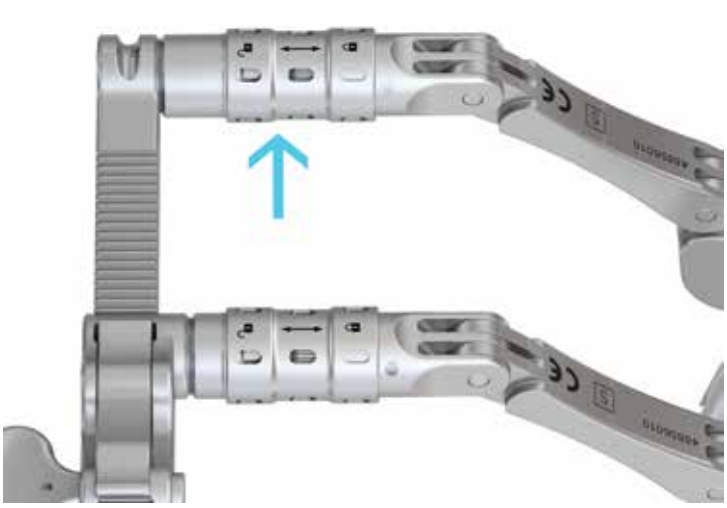


Figure 14.

Spinous Process and Lamina Adaptors

For spinous process or lamina distraction, the corresponding adaptors are attached by aligning the laser marked arrow on the adaptor to the arrow on the distractor tube at the distal end of the Universal Distractor arm. Then slide the split tip into the distractor tube until an audible click is heard. Gently pull on the adaptor to ensure it is secure in the tube.

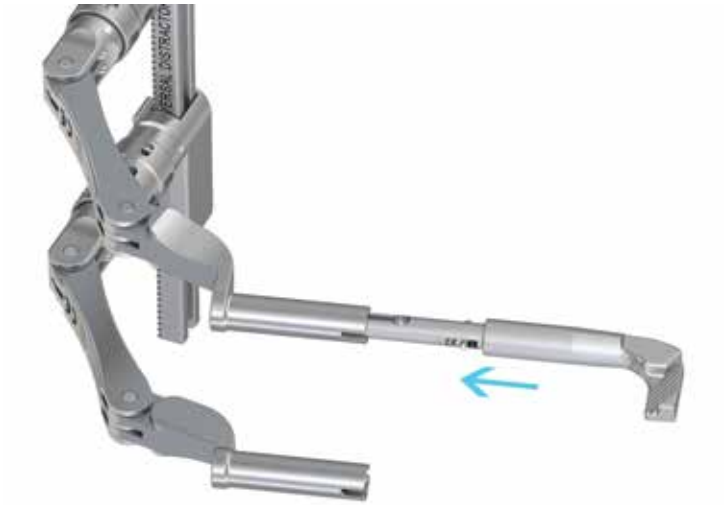


Figure 15.

Note: The Spinous Process Adaptors are sold separately as left and right. The Spinous Process Adaptors should be assembled to the Universal Distractor with the serrations on the distal feet positioned outward away from the affected disc in order to grip the spinous process.

Figure 16.

Tap Marker Adaptors

For distraction using Tap Markers, the **Tap Marker Adaptors** require assembly prior to Tap Marker placement.

Figure 17.

Once the Tap Markers are loaded onto the **Tap Marker Inserter**, slide the Tap Marker Adaptor over the threaded portion of the Tap Marker and hold in place during Tap Marker insertion.

Figure 18a.

Figure 18b.

Once the Tap Marker is inserted into bone, the Tap Marker Adaptors can be rotated about the Tap Markers to allow for better visualization. Once the Tap Marker Adaptors are properly seated, the Universal Distractor tubes can be placed over the posts of the Adaptors in preparation for distraction. Distraction can be achieved from both the ipsilateral and contralateral side of the surgeon based on preference. Care should be taken not to overdistract the disc space.

Figure 19.

Tap Marker Inserter
48856000

Tap Marker and Tap Marker Adaptor sizing chart

	Ø4.0mm Tap Marker	Ø4.5mm Tap Marker	Ø5.0mm Tap Marker	Ø5.5mm Tap Marker	Ø6.5mm Tap Marker
Tap Marker Adaptor for Ø4.0mm-Ø5.5mm **48856010C**	✔	✔	✔	✔	–
Tap Marker Adaptor for Ø5.5mm-Ø6.5mm **48856010D**	–	–	–	✔*	✔

*More polyaxiality with the Ø5.5mm Tap Marker can be achieved using the Tap Marker Adaptor for Ø5.5-Ø6.5mm.

When the Universal Distractor is properly positioned, distraction can be achieved by turning the knob on the mobile arm for incremental distraction.

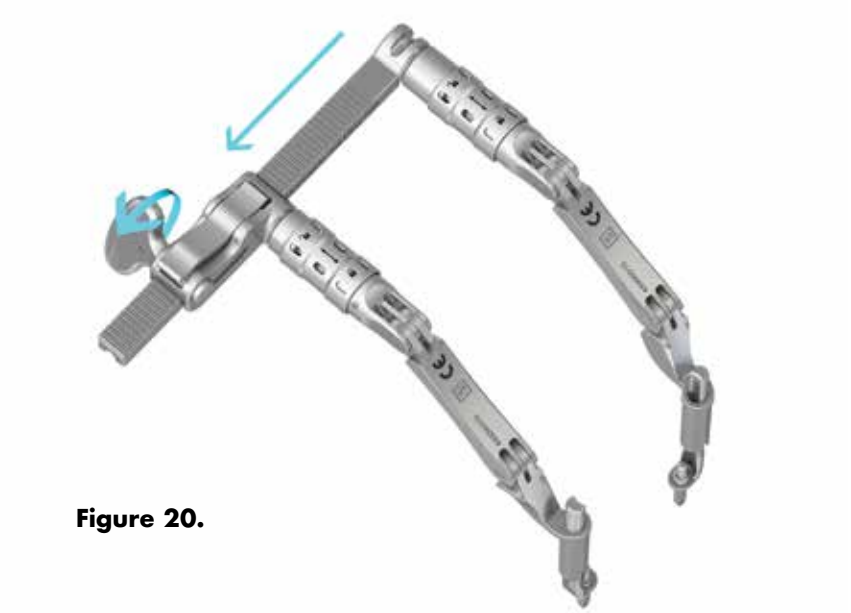


Figure 20.

Screw insertion

With the cortical pathway prepared, and the appropriate screw diameter and length determined, the screw can be inserted into the pedicle using the **Xia 4.5 Screwdriver assembled with the Xia CT Cannulated Screwdriver Shaft.** The Xia CT screw can be inserted either manually or using Stryker's powered screw insertion technique. 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.

Note: An ES2 handle should be used when using the cannulated instruments and implants.

Screwdriver Shaft, Cannulated
48856006

Screwdriver Outer Sleeve
48138012

Screwdriver Locking Nut
48138013

Manual screw insertion

The Xia CT Cannulated Screwdriver Shaft provides a rigid connection between the screw and the screwdriver. The Xia CT Cannulated Screwdriver Shaft is compatible with both Xia CT and Xia 4.5 polyaxial screws.

ES2 Handle, Round
48289300

To assemble the screwdriver:

Step 1:
Insert the Xia CT Cannulated Screwdriver Shaft up through the distal end of the **Screwdriver Outer Sleeve**.

Figure 21a.

Step 2:
Slide the **Locking Nut** over the Xia CT Cannulated Screwdriver Shaft with the serrated teeth facing downward.

Figure 21b.

Step 3:
Fully insert the Xia CT Cannulated Screwdriver Shaft into the quick connect mechanism of the **ES2 Handle, Round**.

Figure 21c.

To load a screw onto the screwdriver:

Step 1:
Hold the screw by the threaded portion and engage the Xia CT Cannulated Screwdriver Shaft into the saddle of the screw head.

Figure 22a.

Step 2:
For a polyaxial screw, align the four prongs of the distal tip of the Xia CT Cannulated Screwdriver Shaft with the four prongs on the head of the bone screw.

Figure 22b.

Step 3:
Fully seat the Xia CT Cannulated Screwdriver Shaft into the screw head. Turn the Screwdriver 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 Screwdriver Outer Sleeve to lock the screw to the screwdriver.

Figure 22c.

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 Screwdriver Outer Sleeve along the Xia CT Cannulated Screwdriver Shaft.

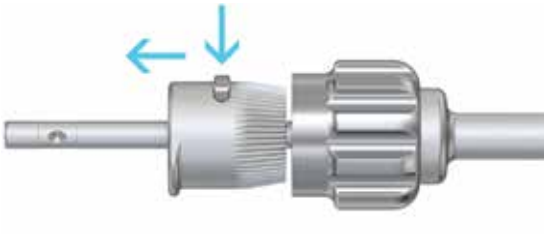


Figure 23a.

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

Figure 23b.

Step 3:
Pull upward on the Screwdriver Outer Sleeve.

Figure 23c.

To disassemble the screwdriver:

Step 1:
Release the quick connect handle from the Xia CT Cannulated Screwdriver Shaft.

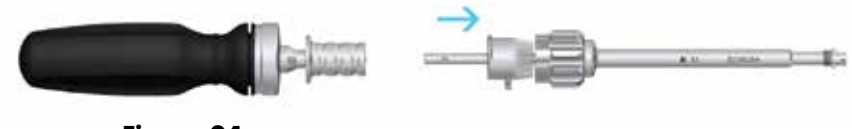


Figure 24a.

Step 2:
Remove the Locking Nut from the Xia CT Cannulated Screwdriver Shaft.

Figure 24b.

Step 3:
Remove the Xia CT Cannulated Screwdriver Shaft from the Screwdriver Outer Sleeve.

Figure 24c.

Note: After insertion, the screw positions may be adjusted as needed by attaching the appropriate Xia CT Cannulated Screwdriver Shaft directly to a handle.

Powered screw insertion
Stryker's powered screw insertion technique can be used to insert Xia 4.5 and Xia CT implants. Stryker's 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, Stryker's 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 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.

Step 6: 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.

Step 7: Rod insertion/final tightening

Use the appropriate pre-cut rods or cut a longer rod to the desired length using the Table-Top Rod Cutter 48238400 and Stand 48238400S (Not included in Xia CT set). To fit the desired spinal contours, rod bending can be performed with the French Bender 48237010 (Not included in Xia CT set). To contour the rod, a series of small incremental adjustments will bend the rod gradually and help ensure even stress distribution on the rod. Once the rod is to the desired shape, insert into the tulip heads of the screws. Refer to **Xia 4.5 Surgical Technique TLX45-ST-1** for instruments not included in Xia CT set.

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 by bending and unbending the rod.

The Xia CT implants use the **Xia Buttress Thread Blocker** as the closure mechanism. The titanium Blocker is laser etched to indicate the side to be inserted into the Blocker Inserter. Once the Blocker is assembled onto the Blocker Inserter, it is tightened by rotating clockwise.

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

Xia CT Blocker
48850000

Blocker Inserter
48856004

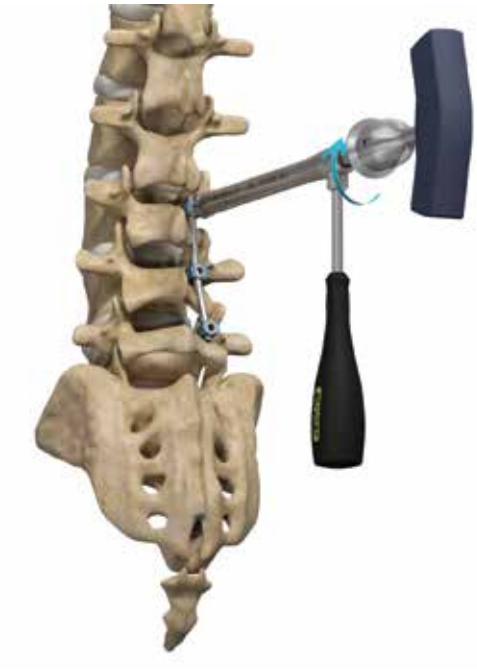
Final tightening

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the Xia CT Blockers is performed. To final tighten use the **Anti-Torque Key** and the **Torque Wrench** or **Audible Torque Wrench**:

Step 1:
Insert Torque Wrench or Audible Torque Wrench into Anti-Torque Key.

Step 2:
Place the Torque Wrench or Audible Torque Wrench tip into the Blocker.

Step 3:
Slide Anti-Torque Key distally over the tulip head to fully seat onto the screw/rod assembly. Line up the two arrows to achieve the final tightening torque of 8Nm. The Torque Wrench or Audible Torque Wrench indicates the optimal torque force that must be applied to the implant for final tightening. If using the Audible Torque Wrench, the blocker is completely tightened to 8Nm when the Audible Torque Wrench clicks once.



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

Anti-Torque Key
48856007

Torque Wrench
48137028

8Nm Audible Torque T-Handle (Standard)
G412162

4mm Hex Shaft (8Nm)
GC100185

Audible Torque Wrench

Note: The Audible Torque Wrench consists of the 8Nm Audible Torque T-Handle (Standard) connected to the 4mm Hex Shaft (8Nm).

Removal or revision of implants

Remove the Blocker(s) with the Torque Wrench from the appropriate screw head(s). Next, remove the rod with general surgical forceps. Lastly, remove the screws by using the Xia CT Cannulated Screwdriver Shaft for polyaxial screws.

Note: The same removal technique can be applied as necessary for revisions.

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

Included in Xia CT sets

Reference number	Description
48850000	Xia CT Blocker
488514020	Ø4.0mm x 20mm Polyaxial Cortical Screw
488514025	Ø4.0mm x 25mm Polyaxial Cortical Screw
488514030	Ø4.0mm x 30mm Polyaxial Cortical Screw
488514035	Ø4.0mm x 35mm Polyaxial Cortical Screw
488514040	Ø4.0mm x 40mm Polyaxial Cortical Screw
488514045	Ø4.0mm x 45mm Polyaxial Cortical Screw
488514520	Ø4.5mm x 20mm Polyaxial Cortical Screw
488514525	Ø4.5mm x 25mm Polyaxial Cortical Screw
488514530	Ø4.5mm x 30mm Polyaxial Cortical Screw
488514535	Ø4.5mm x 35mm Polyaxial Cortical Screw
488514540	Ø4.5mm x 40mm Polyaxial Cortical Screw
488514545	Ø4.5mm x 45mm Polyaxial Cortical Screw
488515020	Ø5.0mm x 20mm Polyaxial Cortical Screw
488515025	Ø5.0mm x 25mm Polyaxial Cortical Screw
488515030	Ø5.0mm x 30mm Polyaxial Cortical Screw
488515035	Ø5.0mm x 35mm Polyaxial Cortical Screw
488515040	Ø5.0mm x 40mm Polyaxial Cortical Screw
488515045	Ø5.0mm x 45mm Polyaxial Cortical Screw
488515520	Ø5.5mm x 20mm Polyaxial Cortical Screw
488515525	Ø5.5mm x 25mm Polyaxial Cortical Screw
488515530	Ø5.5mm x 30mm Polyaxial Cortical Screw
488515535	Ø5.5mm x 35mm Polyaxial Cortical Screw
488515540	Ø5.5mm x 40mm Polyaxial Cortical Screw
488515545	Ø5.5mm x 45mm Polyaxial Cortical Screw
488515550	Ø5.5mm x 50mm Polyaxial Cortical Screw
488515555	Ø5.5mm x 55mm Polyaxial Cortical Screw
488515560	Ø5.5mm x 60mm Polyaxial Cortical Screw
488515565	Ø5.5mm x 65mm Polyaxial Cortical Screw
488516520	Ø6.5mm x 20mm Polyaxial Cortical Screw
488516525	Ø6.5mm x 25mm Polyaxial Cortical Screw
488516530	Ø6.5mm x 30mm Polyaxial Cortical Screw
488516535	Ø6.5mm x 35mm Polyaxial Cortical Screw
488516540	Ø6.5mm x 40mm Polyaxial Cortical Screw
488516545	Ø6.5mm x 45mm Polyaxial Cortical Screw

Reference number	Description
488516550	Ø6.5mm x 50mm Polyaxial Cortical Screw
488516555	Ø6.5mm x 55mm Polyaxial Cortical Screw
488516560	Ø6.5mm x 60mm Polyaxial Cortical Screw
488516565	Ø6.5mm x 65mm Polyaxial Cortical Screw
488516570	Ø6.5mm x 70mm Polyaxial Cortical Screw
488517535	Ø7.5mm x 35mm Polyaxial Cortical Screw
488517540	Ø7.5mm x 40mm Polyaxial Cortical Screw
488517545	Ø7.5mm x 45mm Polyaxial Cortical Screw
488517550	Ø7.5mm x 50mm Polyaxial Cortical Screw
488517555	Ø7.5mm x 55mm Polyaxial Cortical Screw
488517560	Ø7.5mm x 60mm Polyaxial Cortical Screw
488517565	Ø7.5mm x 65mm Polyaxial Cortical Screw
488517570	Ø7.5mm x 70mm Polyaxial Cortical Screw
488524520	Ø4.5mm x 20mm Cannulated Polyaxial Cortical Screw
488524525	Ø4.5mm x 25mm Cannulated Polyaxial Cortical Screw
488524530	Ø4.5mm x 30mm Cannulated Polyaxial Cortical Screw
488524535	Ø4.5mm x 35mm Cannulated Polyaxial Cortical Screw
488524540	Ø4.5mm x 40mm Cannulated Polyaxial Cortical Screw
488524545	Ø4.5mm x 45mm Cannulated Polyaxial Cortical Screw
488525020	Ø5.0mm x 20mm Cannulated Polyaxial Cortical Screw
488525025	Ø5.0mm x 25mm Cannulated Polyaxial Cortical Screw
488525030	Ø5.0mm x 30mm Cannulated Polyaxial Cortical Screw
488525035	Ø5.0mm x 35mm Cannulated Polyaxial Cortical Screw
488525040	Ø5.0mm x 40mm Cannulated Polyaxial Cortical Screw
488525045	Ø5.0mm x 45mm Cannulated Polyaxial Cortical Screw
488525520	Ø5.5mm x 20mm Cannulated Polyaxial Cortical Screw
488525525	Ø5.5mm x 25mm Cannulated Polyaxial Cortical Screw
488525530	Ø5.5mm x 30mm Cannulated Polyaxial Cortical Screw
488525535	Ø5.5mm x 35mm Cannulated Polyaxial Cortical Screw
488525540	Ø5.5mm x 40mm Cannulated Polyaxial Cortical Screw
488525545	Ø5.5mm x 45mm Cannulated Polyaxial Cortical Screw
488526520	Ø6.5mm x 20mm Cannulated Polyaxial Cortical Screw
488526525	Ø6.5mm x 25mm Cannulated Polyaxial Cortical Screw
488526530	Ø6.5mm x 30mm Cannulated Polyaxial Cortical Screw
488526535	Ø6.5mm x 35mm Cannulated Polyaxial Cortical Screw
488526540	Ø6.5mm x 40mm Cannulated Polyaxial Cortical Screw
488526545	Ø6.5mm x 45mm Cannulated Polyaxial Cortical Screw

Reference number	Description
48856003	Adjustable Drill Guide
48856440	Ø2.5mm Drill for Ø4.0mm Screw
48856445	Ø3.0mm Drill for Ø4.5mm Screw
48856450	Ø3.5mm Drill for Ø5.0mm Screw
48856455	Ø4.0mm Drill for Ø5.5mm Screw
48856465	Ø5.0mm Drill for Ø6.5mm Screw
48856040	Modular Tap Ø4.0mm
48856045	Modular Tap Ø4.5mm
48856050	Modular Tap Ø5.0mm
48856055	Modular Tap Ø5.5mm
48856065	Modular Tap Ø6.5mm
48856075	Modular Tap Ø7.5mm
48856004	Blocker Inserter
48856007	Anti-Torque Key
48856006	Screwdriver Shaft, Cannulated
48138012	Xia 4.5 Screwdriver Outer Sleeve
48138013	Xia 4.5 Screwdriver Locking Nut
48856000	Tap Marker Inserter
48137028	Xia 4.5 Torque Wrench
G412162	8Nm Audible Torque T-Handle (Standard)
GC100185	4mm Hex Shaft (8Nm)
48289300	ES2 Handle, Round
48237060	Malleable Pedicle Feeler
48856010	Universal Distractor

Reference number	Description
48856010A	Lamina Adaptor*
48856010BL	Spinous Process Adaptor, Left*
48856010BR	Spinous Process Adaptor, Right*
48856010C	Ø4.0mm - 5.5mm Tap Marker Adaptor*
48856010D	Ø5.5mm - 6.5mm Tap Marker Adaptor*
48859420	Tap Marker, Cannulated, Ø4.5mm x 20mm
48859425	Tap Marker, Cannulated, Ø4.5mm x 25mm
48859430	Tap Marker, Cannulated, Ø4.5mm x 30mm
48859435	Tap Marker, Cannulated, Ø4.5mm x 35mm
48850520	Tap Marker, Cannulated, Ø5.0mm x 20mm
48850525	Tap Marker, Cannulated, Ø5.0mm x 25mm
48850530	Tap Marker, Cannulated, Ø5.0mm x 30mm
48850535	Tap Marker, Cannulated, Ø5.0mm x 35mm
48859520	Tap Marker, Cannulated, Ø5.5mm x 20mm
48859525	Tap Marker, Cannulated, Ø5.5mm x 25mm
48859530	Tap Marker, Cannulated, Ø5.5mm x 30mm
48859535	Tap Marker, Cannulated, Ø5.5mm x 35mm
48859620	Tap Marker, Cannulated, Ø6.5mm x 20mm
48859625	Tap Marker, Cannulated, Ø6.5mm x 25mm
48859630	Tap Marker, Cannulated, Ø6.5mm x 30mm
48859635	Tap Marker, Cannulated, Ø6.5mm x 35mm
48857420	Tap Marker, Non-Cannulated, Ø4.0mm x 20mm
48857425	Tap Marker, Non-Cannulated, Ø4.0mm x 25mm
48857430	Tap Marker, Non-Cannulated, Ø4.0mm x 30mm
48857435	Tap Marker, Non-Cannulated, Ø4.0mm x 35mm
48858420	Tap Marker, Non-Cannulated, Ø4.5mm x 20mm
48858425	Tap Marker, Non-Cannulated, Ø4.5mm x 25mm
48858430	Tap Marker, Non-Cannulated, Ø4.5mm x 30mm
48858435	Tap Marker, Non-Cannulated, Ø4.5mm x 35mm
48857520	Tap Marker, Non-Cannulated, Ø5.0mm x 20mm
48857525	Tap Marker, Non-Cannulated, Ø5.0mm x 25mm
48857530	Tap Marker, Non-Cannulated, Ø5.0mm x 30mm
48857535	Tap Marker, Non-Cannulated, Ø5.0mm x 35mm

*For Universal Distractor Adaptors, each reference number yields a single adaptor.

Reference number	Description
48858520	Tap Marker, Non-Cannulated, Ø5.5mm x 20mm
48858525	Tap Marker, Non-Cannulated, Ø5.5mm x 25mm
48858530	Tap Marker, Non-Cannulated, Ø5.5mm x 30mm
48858535	Tap Marker, Non-Cannulated, Ø5.5mm x 35mm
48858620	Tap Marker, Non-Cannulated, Ø6.5mm x 20mm
48858625	Tap Marker, Non-Cannulated, Ø6.5mm x 25mm
48858630	Tap Marker, Non-Cannulated, Ø6.5mm x 30mm
48858635	Tap Marker, Non-Cannulated, Ø6.5mm x 35mm
48856111	Xia CT Instrument Container
48856112	Xia CT Implant Container
48856113	Xia CT LE Screw Caddy

Xia 4.5 spinal fixation system
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:

STRYKER SPINE
2 Pearl Court
Allendale, NJ 07401 USA
Tel. 201 749 8000
http://www.stryker.com

Spine Division

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

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

TLX45-ST-6_Rev-4_18189
SC/GS 08/18

Printed in USA

Stryker Spine
2 Pearl Court
Allendale, NJ 07401 USA
t: 201 749 8000

www.stryker.com