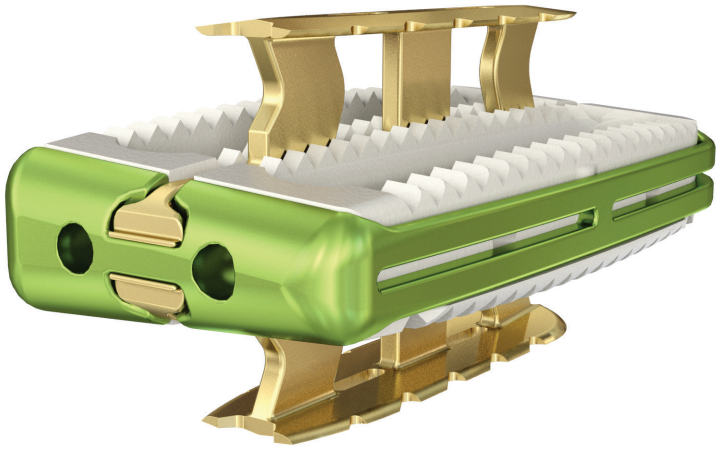
stryker

Aero®-LL

Lateral Lumbar Interbody and Fixation System



Surgical technique

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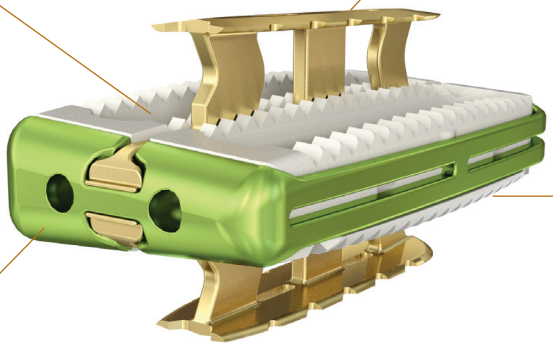
System overview

The Aero-LL lumbar interbody and fixation system is designed for use in lumbar interbody fusion procedures.

The system is comprised of:

A PEEK optima cage surrounded by a titanium jacket. The PEEK cage is available in a variety of sizes to allow the surgeon to customize to the patient's anatomy and pathology.

Titanium anchors, which are guided through the cage, engage with the proximal and distal aspects of the implant, and lock into the jacket to maximize segment stability and minimize micro-motion.



Instrumentation which is designed to facilitate ease of device insertion and to minimize exposure.

A titanium jacket that spans the entire height of the cage proximally and distally to show the overall height relative to the vertebral endplates, as well as, the implant-to-endplate proximity. The jacket and fixation anchors allow for fusion assessment through the device on radiographic images.

The Aero-LL lumbar interbody and fixation system may be used with or without the anchor fixation provided and must be used with additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine.

Implant overview

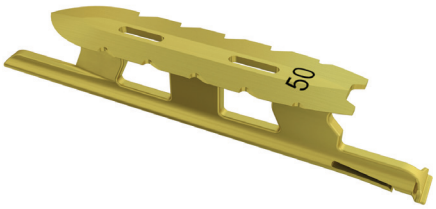
Aero-LL is available in a wide variety of footprints, heights and lordotic angles to allow the surgeon to choose which is best suited to the patient's anatomy and pathology.

	Aero-LL implants - 18mm width									
	Footprints	**18 x 40mm**		**18 x 45mm**		**18 x 50mm**		**18 x 55mm**		**18 x 60mm**	
	Lordosis	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**
Height	Blue	8mm	-	8mm	-	8mm	-	8mm	-	8mm	-
	Blue	-	10mm	-	10mm	-	10mm	-	10mm	-	10mm
	Green	-	12mm	-	12mm	-	12mm	-	12mm	-	12mm
	Magenta	-	14mm	-	14mm	-	14mm	-	14mm	-	14mm
	Aqua	-	-	-	16mm	-	-	-	-	-	-

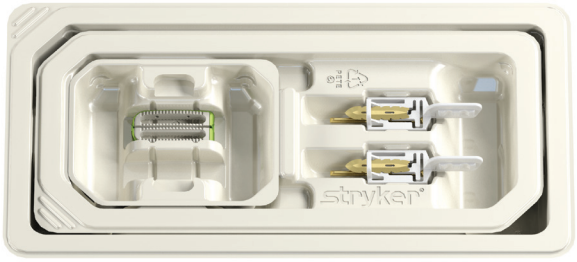
	Aero-LL implants - 22mm width									
	Footprints	**22 x 40mm**		**22 x 45mm**		**22 x 50mm**		**22 x 55mm**		**22 x 60mm**	
	Lordosis	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**	**0°**	**8°**
Height	Blue	-	-	8mm	-	8mm	-	8mm	-	-	-
	Blue	-	10mm	-	10mm	-	10mm	-	10mm	-	10mm
	Green	-	12mm	-	12mm	-	12mm	-	12mm	-	12mm
	Magenta	-	14mm	-	14mm	-	14mm	-	14mm	-	14mm
	Aqua	-	16mm	-	16mm	-	16mm	-	16mm	-	-

The PEEK cage and titanium jacket are pre-assembled. The titanium anchors provide fixation to the vertebral bodies. There are five different anchor lengths, each of which correspond to a specific implant footprint:

Anchor color	Anchor length	Cage length
Gold	40mm	40mm
	45mm	45mm
	50mm	50mm
	55mm	55mm
	60mm	60mm

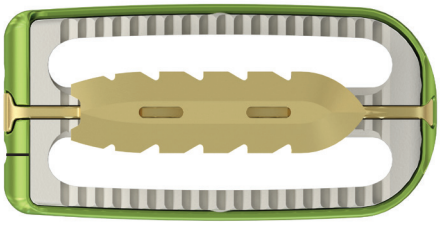


Aero-LL is provided sterile in a package. Each sterile package includes one cage and two anchors. The anchors are pre-loaded into plastic cartridges that are designed to facilitate anchor insertion and promote safe handling. Additional anchors are packaged individually should an anchor lose sterility during surgery.

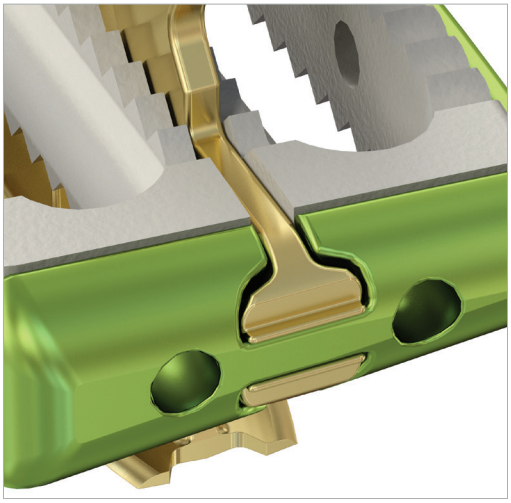


Aero-LL sterile package

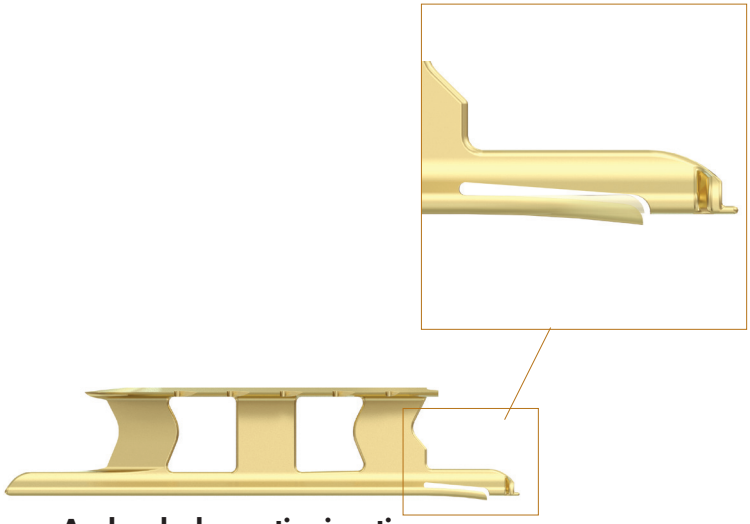
The anchors are designed to engage both the proximal and distal aspects of the jacket. This multi-point engagement is designed to promote circumferential motion resistance.



Anchor engagement – proximal and distal aspects of jacket



Anchor stop – distal anti-migration



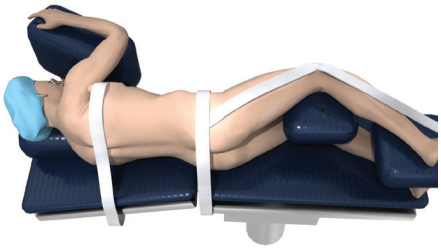
Anchor lock – anti-migration

The locking tab of the anchor engages the interior surface of the jacket to lock the anchor in place and to prevent migration (back-out) of the anchor. A positive stop engages the proximal surface of the jacket to ensure proper positioning of the anchor.

Surgical technique

Step 1. Patient positioning and exposure

The patient is placed on a flexible surgical table in a direct lateral decubitus (90°) position so that the iliac crest is directly over the table break. Alternatively, the patient may also be placed in a direct lateral decubitus position on a radiolucent jackson table with a wilson frame.



Note: In order to increase the working area, flex the surgical table to help increase the distance between the iliac crest and the rib cage.

Note: In certain cases the surgeon may opt to raise the kidney rest or to place a cushion under the patient's iliac crest, to help in opening the disc space.

Arm assembly

The **Arm Post** mounts to the hospital bed rail. Check compatibility of the arm post to the hospital bed prior to surgery. Mount the arm post to the bed rail on the opposite side of the surgeon near the patient's hip.

Rotate the arm post locking mechanism clockwise to secure it to the bed.

Once the arm post is secure, attach the **Snake Arm** to the arm post and lock into place.

The arm should be positioned to lie across the patient and wrapped in front of the surgeon.

Options are:
OSI retractor adapter PN 5888
OSI slide rail adapter PN 5855-830

Arm Post
48250240

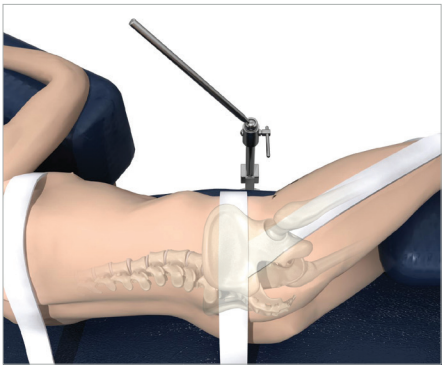
Snake Arm
48755400

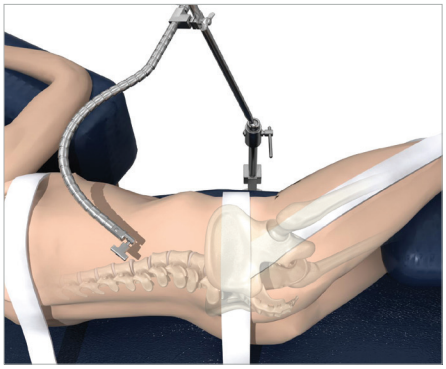
Note: Ensure to place the arm post out of the way of the anticipated direction of fluoroscopy.

Articulating Arm
48755452

Note: The snake arm should be properly reset and lubricated between uses. The articulating arm with table clamp may be used as an alternative.

Note: When using a jackson table, an OSI adapter is needed to mount the arm post to the table.





Lighting preparation

Attach the **Light Source** to the appropriate adapter.

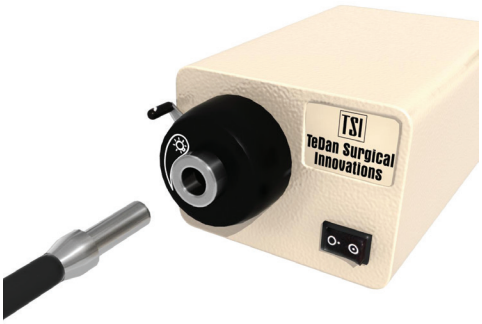
Insert the **Light Cable** into the light source.

Turn on the light source power to verify light output.

Note: The light cable is sold non-sterile and must be sterilized prior to use.

Note: The light source may need to be checked for electrical safety by the hospital before bringing it into the OR. Check local policy at least one day prior to surgery.

Note: If light output is low this instrument may need to be replaced.



Light Source
48252106

Light Cable
48758451

Establishing access

Localize the disc space of surgical interest by using A/P and lateral fluoroscopy.

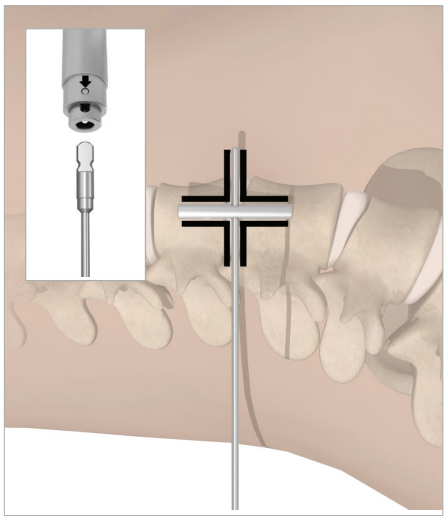
Insert the **Landmark Identifier Crosshair** into the **Quick Release Handle** by aligning the arrow on the tip of the quick release handle to the flat end of the landmark identifier crosshair.

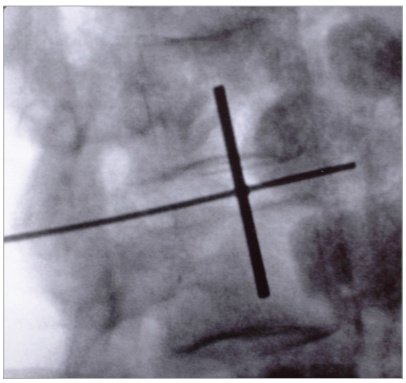
Place the landmark identifier crosshair over the surgical level, centered over the indicated disc space.

Mark the skin to serve as the location of the skin incision for the operative corridor.

Landmark Identifier Crosshair
48755720

Quick Release Handle
48755702





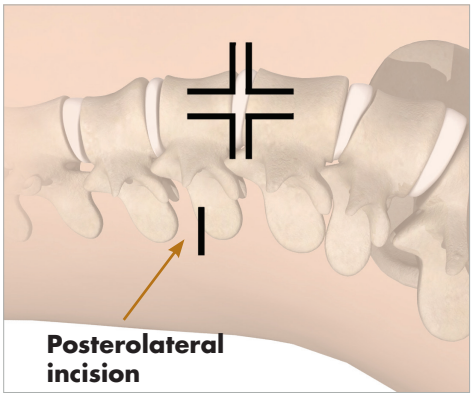
Note: **The landmark identifier crosshair crossbar is approximately 27.5mm in length, approximating a 1 inch skin incision.**

Optional: Posterolateral incision

A second mark is made posterior to the first mark at the lateral border of the erector spinae muscle.

A longitudinal incision at this location is made to accommodate finger dissection to the retroperitoneal space.

Once the psoas muscle is identified, the index finger is used to guide dilation through the access incision.



Approach

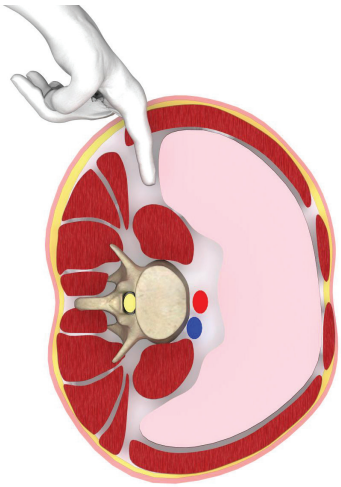
Through the incision, the subcutaneous tissues are dissected using finger dissection.

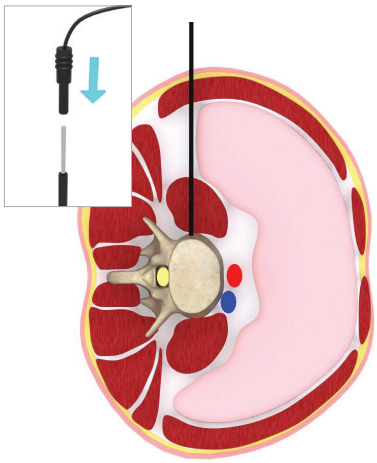
Once the superficial abdominal musculature is reached, use finger (or blunt clamp) dissection in order to separate the muscle fibers down to the retroperitoneal space.

Upon entering the retroperitoneal space, move the peritoneum anteriorly and continue finger dissection to palpate down to the lateral aspect of the psoas muscle.

Note: Great care must be taken to avoid penetration of the peritoneum.

Note: Finger (or blunt clamp) dissection should be performed in line with the muscle fibers.





Neuromonitoring probe insertion

Attach the **Neuromonitoring Cable** to the **Neuromonitoring Probe**.

Note: The neuromonitoring probe is 2.1mm in diameter.

Note: The neuromonitoring probe is compatible with any 1.5mm female DIN 42 802 touch proof connector cable. The neuromonitoring probe and the neuromonitoring cable are sold non-sterile and must be sterilized prior to use. Discard after use. Do not reuse.

Neuromonitoring Cable (disposable)
48755008

Neuromonitoring Probe (disposable)
48755006

Lead Crocodile Clip
48755018

Lead Ext Blue
48755028

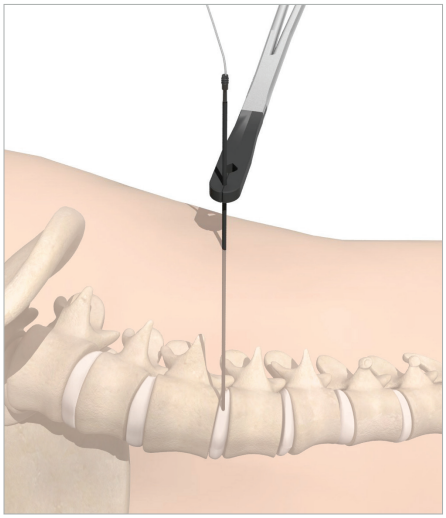
Note: The Lead Crocodile Clip can be used in place of the **Neuromonitoring Cable (48755008)**, to support the use of the **Neuromonitoring Probe (48755006), Probe Dilator 2 (48755002),** and **Probe Dilator 3 (48755003).**

Note: The Lead Ext Blue can be connected to the Lead Crocodile Clip to extend the length of the cable.

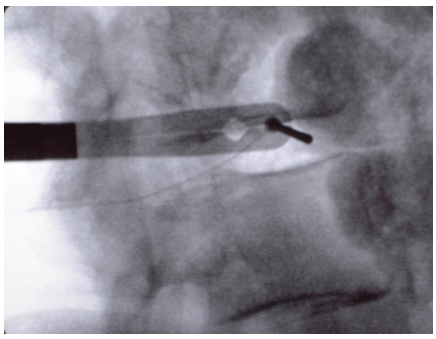
Pass the opposite end of the neuromonitoring cable to the neurophysiologist or neuromonitoring technician.

Guide the neuromonitoring probe through the incision to the retroperitoneal space.

Upon reaching the lateral aspect of the psoas muscle, map out a safe zone through the psoas muscle to the lateral aspect of the lumbar spine. Use fluoroscopic imaging to confirm proper alignment of the neuromonitoring probe.



Use fluoroscopic imaging to confirm proper alignment of the neuromonitoring probe.



Probe Holder
48755004

Note: For added safety, conduct free-running and triggered EMGs with the neuromonitoring probe while going through the psoas muscle.

Note: In order to obtain accurate neuromonitoring readings, sufficient stimulation time is necessary. This should be determined by a neuromonitoring technician, who is familiar with the neuromonitor being used.

Note: Caution should be heeded with regard to the position of the neuromonitoring probe in order to avoid aberrant advancement.

Note: The neuromonitoring probe should be placed approximately at the junction of the posterior two-thirds and anterior one-third of the disc as visualized on lateral fluoroscopy. When placement of the probe is performed with neurophysiologic monitoring, neural elements may be avoided.

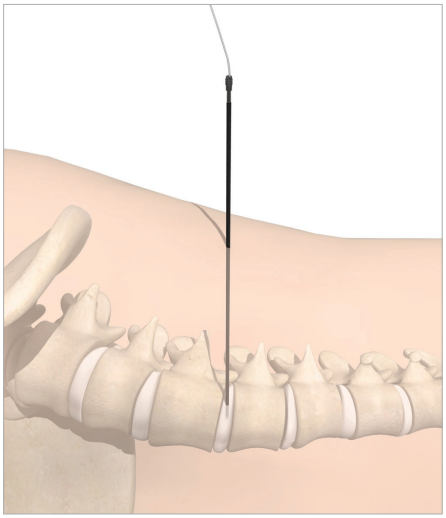
Note: The Probe Holder is radiolucent and can be used to maintain distance from the x-ray field while imaging. This is designed to hold the neuromonitoring probe, sharp guide wire, dilator 1, and probe dilator 2.

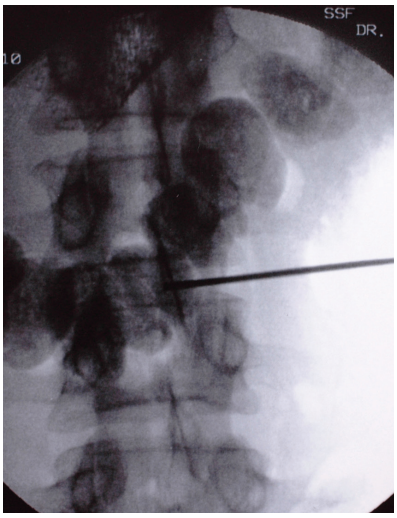
Warning: Do not mallet the probe holder while holding the neuromonitoring probe.

Place the neuromonitoring probe through the psoas muscle into the annulus of the disc space of interest.

Use fluoroscopic imaging to confirm the final location of the neuromonitoring probe.

Disconnect the neuromonitoring cable from the neuromonitoring probe.





Note: Use fluoroscopic imaging with the advancement of the neuromonitoring probe. If needed, clamp the probe and mallet the probe into the annulus.

Note: For collapsed discs or osteophytes, use a sharp guide wire with dilator 1.

Dilator 1 (disposable)
48755001 – 6.4mm

Sharp Guide Wire (disposable)
48755007

Note: The sharp guide wire is a single use instrument.

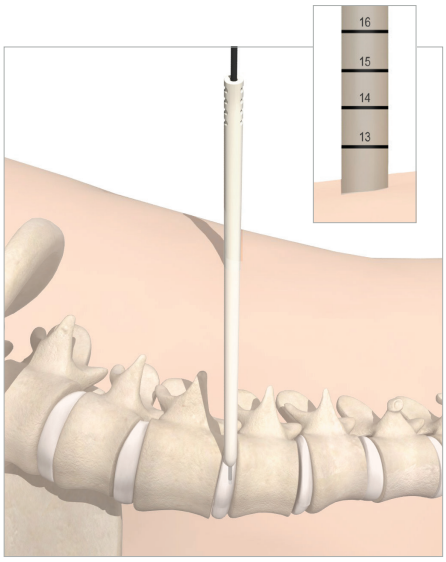
Sequential dilation

Place dilator 1 over the neuromonitoring probe.

Advance dilator 1 over the probe, rotating it through the psoas muscle while directing it toward the disc space.

Use fluoroscopic imaging to confirm the location of dilator 1.

The dilators have depth markings (50-160mm) laser etched which correlate to the retractor blade lengths.



Note: Tactile feel, fluoroscopic imaging, anatomical knowledge of spinal elements, review of preoperative images and direct partial visualization may all contribute towards desired accurate instrument placement.

Note: Notice the depth marking of dilator 1 in relation to the skin.

Attach the end of the neuromonitoring cable to **Probe Dilator 2**.

Stimulate probe dilator 2 while advancing through the psoas muscle. Rotate the dilator toward the posterior aspect in order to detect neural elements.

Disconnect the neuromonitoring cable from probe dilator 2 and connect the cable to **Probe Dilator 3**.

Slide probe dilator 3 over probe dilator 2 to penetrate and gently spread the psoas muscle down to the disc space. Stimulate probe dilator 3 and rotate it toward the posterior aspect in order to detect neural elements.

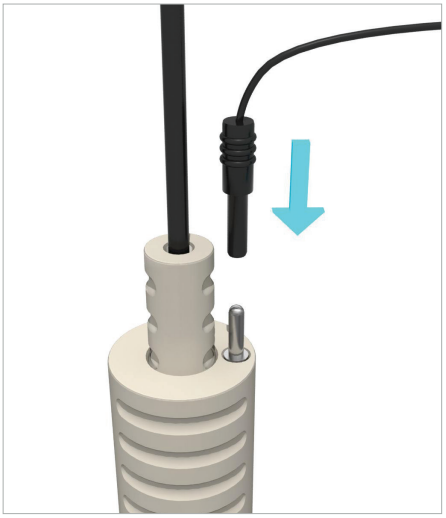
Note: Stimulation of the dilators will help to avoid the neural elements through the psoas muscle.

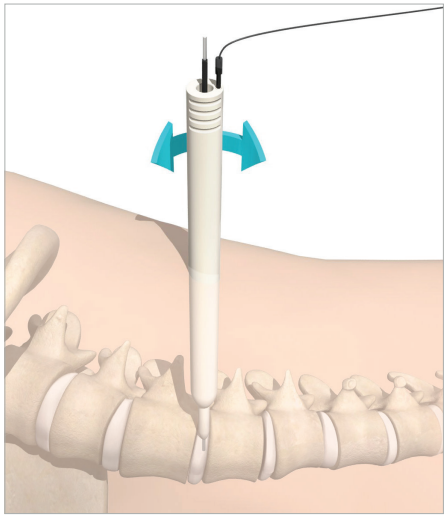
Note: Make sure the line markings on the dilators are flush to ensure that they are fully seated. Fluoroscopic imaging can be used to verify that the dilators are flush with the vertebral body.

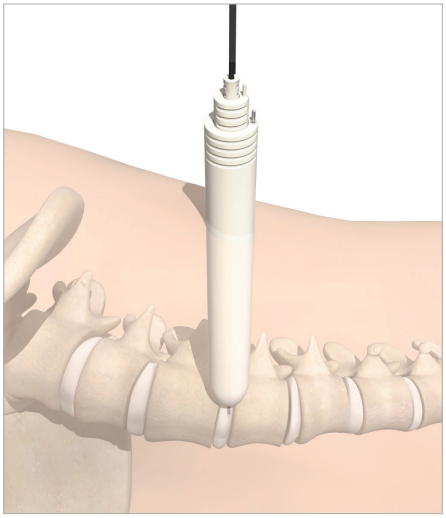
Note: After sterilization, make sure the dilators are cooled to room temperature before use. The dilators are single use instruments.

Probe Dilator 2 (disposable)
48755002 – 14.4mm

Probe Dilator 3 (disposable)
48755003 – 22.5mm

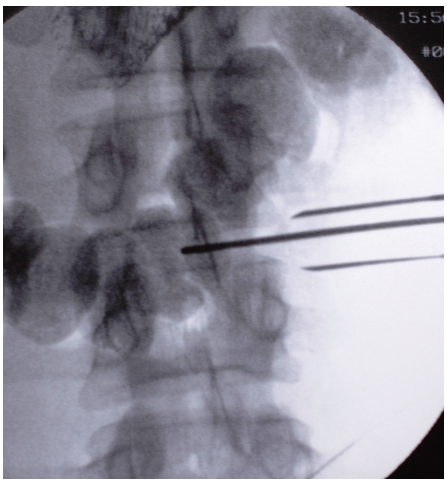






Disconnect the neuromonitoring cable from probe dilator 3.

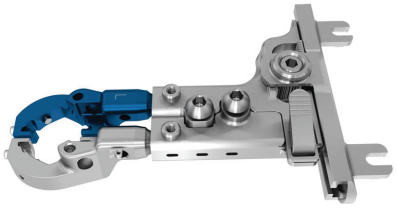
Confirm the final location of the dilators in relation to the center of the disc space by using fluoroscopic imaging.



Step 2. Retractot assembly

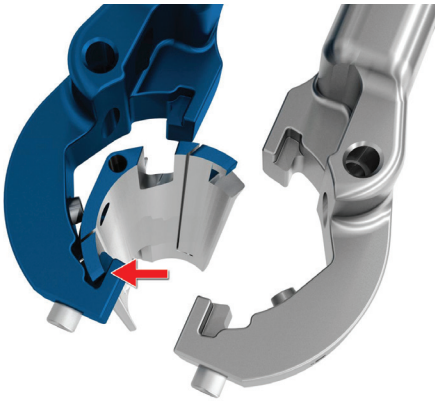
Assemble each **Retractor "Blade"** into the **Retractor "Base"**.
Choose a blade length based on where the top of the skin meets the laser markings on the dilator.

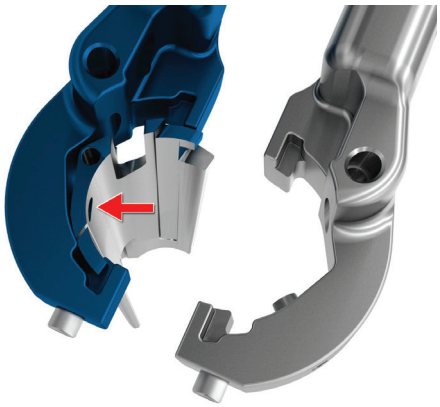
Retractor Blades	
48755050 – 50mm	48755110 – 110mm
48755060 – 60mm	48755120 – 120mm
48755070 – 70mm	48755130 – 130mm
48755080 – 80mm	48755140 – 140mm
48755090 – 90mm	48755150 – 150mm
48755100 – 100mm	48755160 – 160mm

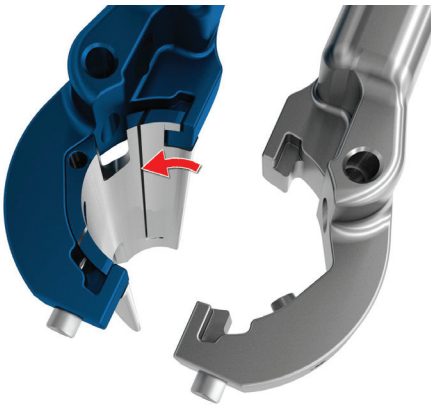


Retractor Base
48755000

Note: If the skin is between two laser markings on the dilator choose the next longest blade.







1. Insert the tab at the distal end of the blade with the slot in the base.
2. Locate the hole in the proximal end of the blade with the pin in the base.
3. Twist the blade to snap in the other tab.
4. Release the blade so that it engages the base.
5. Repeat the process for the second blade.

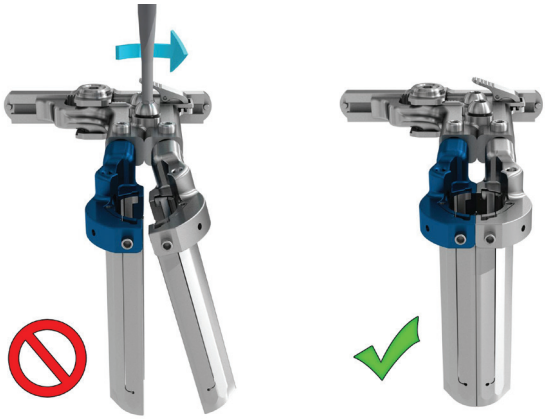
Note: The blades and blade holders are color coded and laser marked "L" and "R". Match the appropriate blade color or laser marking with the corresponding blade holder color or laser marking during assembly.

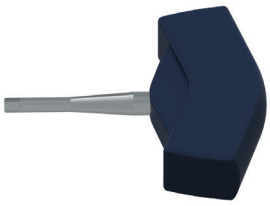
Note: For ease in blade insertion, open the retractor base. Close after blades are assembled.

Note: In cases where the retractor cannot be actuated due to docking on bone, using blades of different length is recommended.

Note: Lubricate the retractor base before use.

Visually ensure that the blade holders are aligned. If not, adjust the angulation screws by inserting the **Retractor Hex Driver** and turning clockwise.



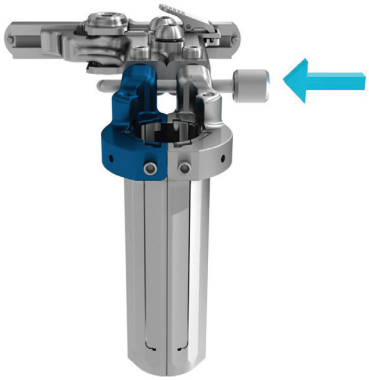


Retractor Hex Driver
48250200

Use the **Anti Rotational Key** to prevent the retractor blades from splaying or moving during insertion.

Anti Rotational Key
48755701

Insert the anti rotational key through the openings in the left and right blade holders.

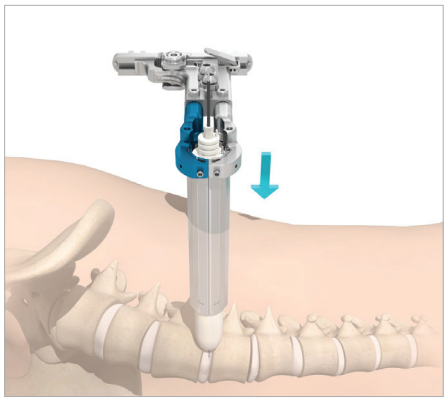


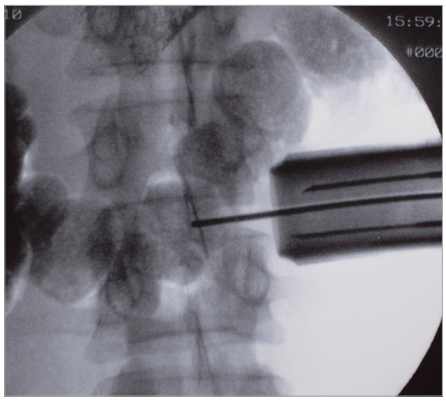
Step 3. Retractor insertion

Slide the closed retractor assembly over the dilators.

Push the retractor through the retroperitoneal space and the psoas muscle.

Dock the retractor on the disc and/or vertebral endplates, parallel to the disc space on a lateral fluoroscopic image.





Note: If avoidance of the neural elements proves to be difficult, the level of interest may be abandoned, or the incision and exposure may be expanded slightly, allowing for a mini-open approach to be utilized. Alternatively, the patient may be repositioned to the opposite lateral decubitus position, and the opposite approach may be attempted.

Note: Use the angulation capability of the retractor to maneuver the blades around osteophytes.

Arm assembly attachment

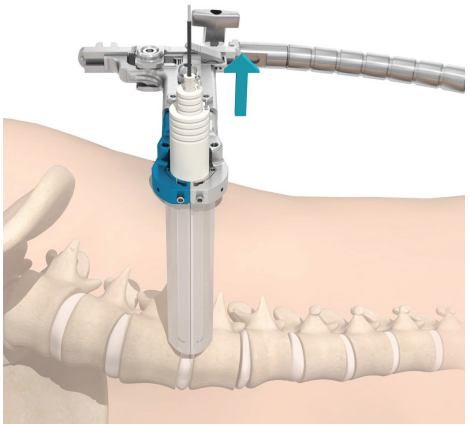
Attach the snake/articulating arm to the retractor base.

Lock the snake/articulating arm to the retractor base post by turning the knob clockwise.

Secure the arm assembly by tightening the knobs.

Remove the dilators, leaving the neuromonitoring probe anchored.

Use fluoroscopic imaging to confirm appropriate retractor positioning.

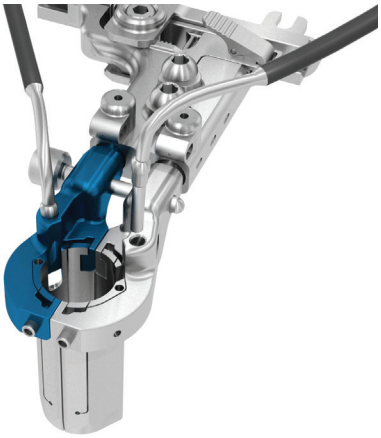


Note: Hold the neuromonitoring probe in position when removing the dilators.

Light source attachment

Insert the light cable into the retractor base. The light cable should be inserted into the light source holes on the blade holders.

Stimulate the exposed area with the neuromonitoring probe to ensure the surgical field is free of neural elements.



Note: The retractor will only accommodate the designated light cable and light source.

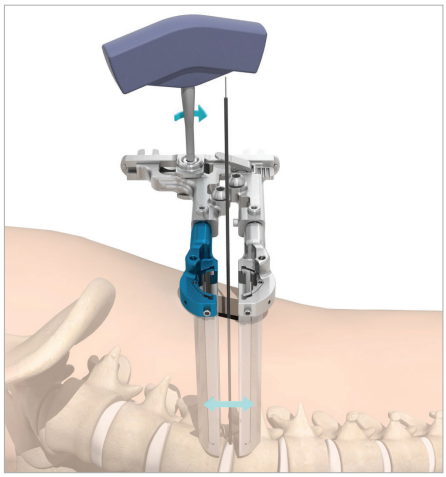
Note: During use, if the lighting component is obstructed by blood or bodily fluid, remove the light cable and wipe.

Note: Before use, visually ensure the coating insulation at the tip of the neuromonitoring probe is not compromised.

Retractor opening/closing mechanism

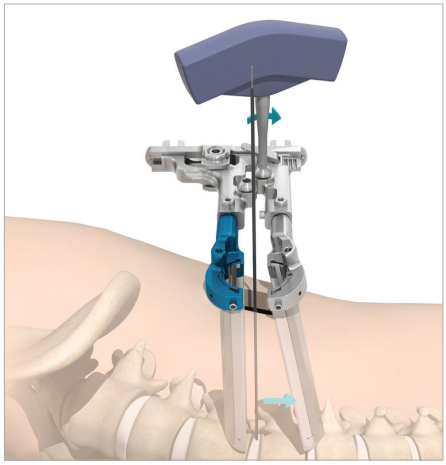
Remove the anti rotational key from the blade holders.

Insert the retractor hex driver into the translation screw of the retractor base and turn clockwise to expand the retractor blades open.

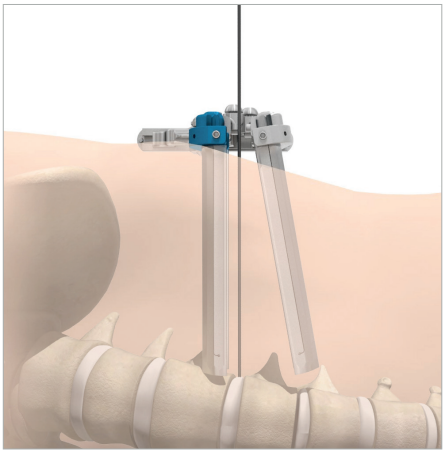


Note: The translation screw will expand both blades simultaneously up to 27.5mm.

Insert the retractor hex driver into the angulation screws and turn clockwise to expand the distal end of the retractor blades.



Note: The angulation screws will angulate each of the blades independently up to 15°.

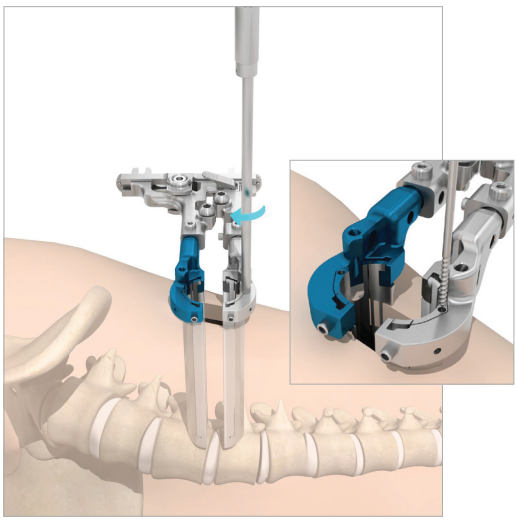


Retract and/or angulate the retractor to a desired position.

Confirm the final position of the retractor with fluoroscopic imaging.

Blade anchoring

For increased retractor stability, insert an **Anchoring Pin.**



Anchoring Pins (disposable)	
48755850 – 50mm	48755910 – 110mm
48755860 – 60mm	48755920 – 120mm
48755870 – 70mm	48755930 – 130mm
48755880 – 80mm	48755940 – 140mm
48755890 – 90mm	48755950 – 150mm
48755900 – 100mm	48755960 – 160mm

Insert the **Anchoring Pin Driver** into the quick release handle by aligning the arrow on the tip of the quick release handle to the flat end of the anchoring pin driver.

Choose the appropriate anchoring pin length based on the length of the retractor blades.

Insert the anchoring pin through the cannulation in the blade.

Attach the anchoring pin driver to the anchoring pin.

Drive the anchoring pin into the vertebral body by turning the quick release handle clockwise.

Remove the anchored neuromonitoring probe.

Anchoring Pin Driver
48755703

Note: Using the slotted window at the distal end of the blade, visually confirm that the anchoring pin avoids all critical anatomical elements.

Note: If angulation of the blades is needed, remove the anchoring pin before angulating. The anchoring pin is a single use instrument.

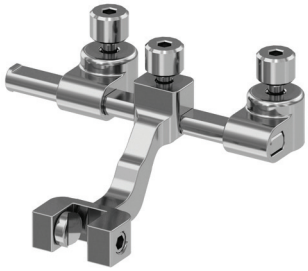
Anterior and posterior frame assembly

Anterior and posterior retractor blades can be used to prevent soft tissue creep in the working space. These blades can only be utilized after the retractor blades have been expanded two or more clicks.

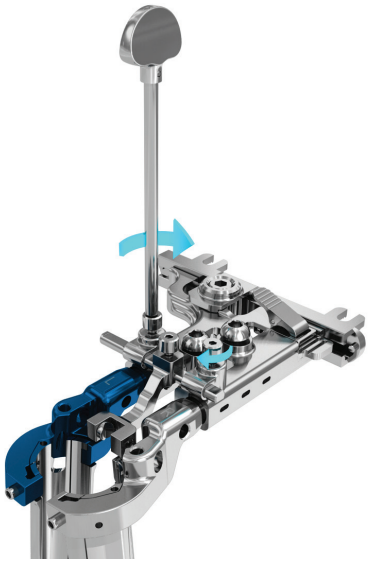
Posterior blade

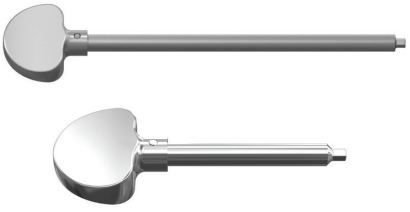
Align the two holes on the **Posterior Frame** with the two bosses on the retractor base.

Secure the frame by finger tightening the two distal end thumb screws or by using the **A/P Frame Driver**.



Posterior Frame
48759950





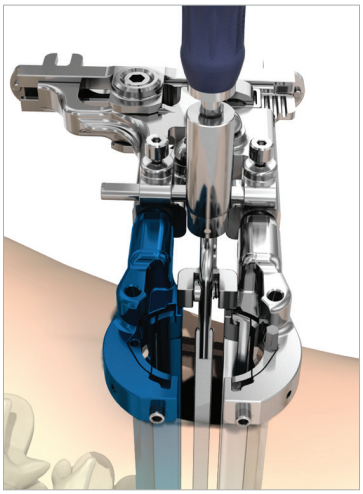
A/P Frame Driver
48755700

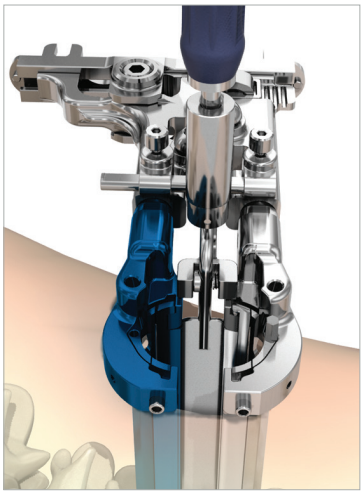
Choose an appropriate option/length, A/P retractor blade, A/P blade, narrow and A/P blade, wide.

A/P retractor blade	Retractor blade lengths
Short 4 (80mm)	50mm – 80mm
Medium 2 (100mm)	90mm – 100mm
Medium 4 (120mm)	110mm – 120mm
Long 4 (160mm)	130mm – 160mm

A/P blade (narrow/wide)	Blade lengths
80mm	70mm – 80mm
100mm	90mm – 100mm
120mm	110mm – 120mm
140mm	130mm – 140mm
160mm	150mm – 160mm

Note: The table on the left shows the sizing scheme as it correlates to the length of the retractor blades being used. The technique is the same for all A/P blades.





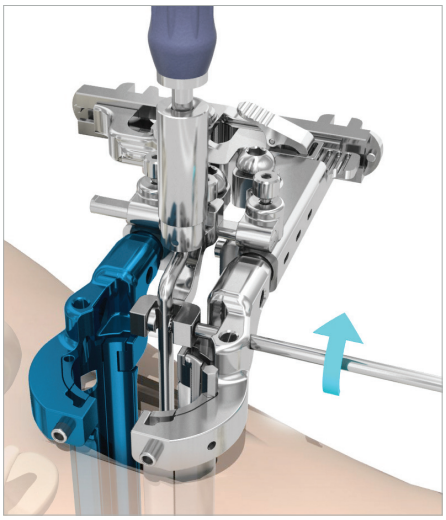
Insert the A/P retractor blade into the quick release handle by pushing down on the quick release tip.

Position the A/P retractor blade into the posterior frame, ensuring the blade rests within the v-shaped feature.

Once a desired position is achieved, lock the center arm by tightening the thumb screw.

Lock the posterior frame by inserting the A/P frame driver through the opening in the **right** blade holder and into the hole on the center arm, and turn clockwise.

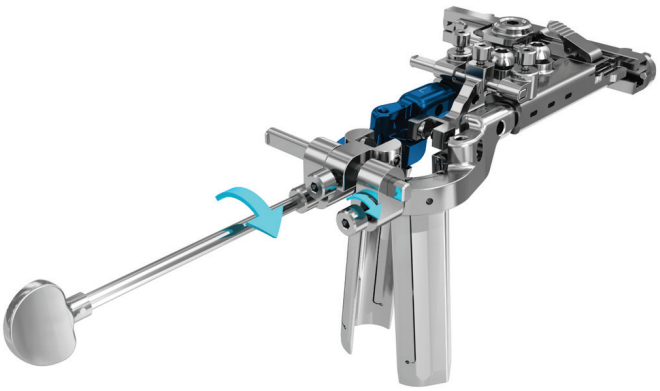
For better viewing, remove the quick release handle by pushing down on the quick release tip.

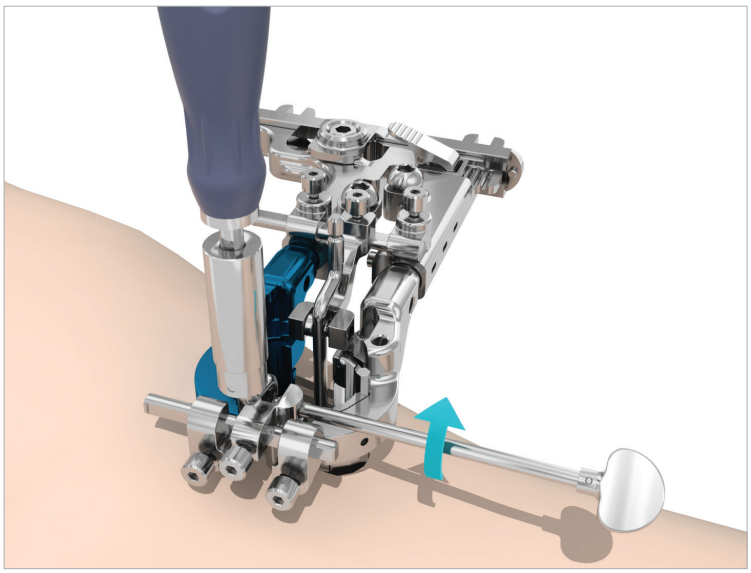


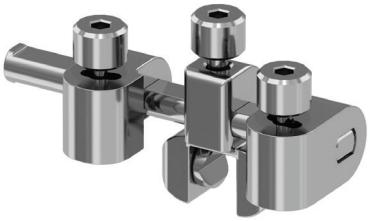
Anterior blade

Align the two holes on the **Anterior Frame** with the two bosses on the front of the retractor base.

Secure the frame by tightening the two distal end thumb screws.







Anterior Frame
48759900

A/P Retractor Blades
48755708 – Short 4
48755710 – Medium 2
48755712 – Medium 4
48755716 – Long 4

A/P Blade, Narrow
48759908 – 80mm
48759910 – 100mm
48759912 – 120mm
48759914 – 140mm
48759916 – 160mm

A/P Blade, Wide
48759928 – 80mm
48759930 – 100mm
48759932 – 120mm
48759934 – 140mm
48759936 – 160mm

Choose an appropriate length for the **A/P Retractor Blade**.

Position the A/P retractor blade in the anterior frame, ensuring the blade rests within the v-shaped feature.

Once a desired position is achieved, lock the center arm by tightening the thumb screw.

Lock the blade into the anterior frame by inserting the A/P frame driver into the hole on the right side of the center arm, and turn clockwise.

Note: Avoid over-torquing of the blade to the frame to prevent damage to the instruments.

Disc removal and preparation

Aero-LL is to be utilized in conjunction with the ARIA spinal system. The ARIA spinal system system consists of:

- **Penfield elevators:** inspection of the surgical site.
- **Nerve hooks:** inspection of the surgical site. Mobilize nerve during surgical procedure. Ball tip to help protect nerve.
- **Nerve retractors:** retract nerve root away from disc space.
- **Nerve probes:** inspection of the surgical site. The ball tip helps to prevent damage of the nerve.
- **Suction tubes:** provide suction capabilities to evacuate fluid and debris from surgical site.
- **Osteotomes:** remove any osteophytes or bone that prevent access to the disc space.
- **Kerrison rongeurs:** remove disc material, cartilage and hard connective tissue.
- **Pituitary rongeurs:** remove disc material from the disc space.
- **Curettes:** remove any remaining disc material and cartilage from the disc space.
- **Rasps:** remove any remaining disc material and cartilage from the disc space.
- **Cobb elevators:** loosen the disc material from the endplates.

These instruments are designed with:

- Bayoneted and straight working shafts to provide greater visibility while working through the retractor.
- Unique angles to provide access to difficult orientations.
- Non-reflective coating to further increase visibility by reducing glare, while working through the retractor.
- Handle profiles and shaft diameters minimized to provide greater visibility.
- Rounded tips for safety.

Note: Proper patient positioning and fluoroscopic visualization are critical to the procedure. Awareness of instrument angulation anteriorly or posteriorly is important to avoid risk to the patient.

Note: Leave sufficient annulus material on the anterior and posterior to reduce the potential of breaching the annulus and causing damage to vasculature or spinal cord.

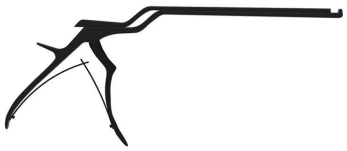
Penfield elevators

Nerve hooks

Nerve retractors

Suction tube

Osteotomes



Kerrison rongeurs

Pituitary rongeurs

Curettes

Rasps

Cobb elevators

Step 4. Annulotomy, discectomy and endplate preparation

Perform the annulotomy and discectomy

Reference number	Description
48759016	Annulotomy Knife
48759390	Kerrison Rongeur Bayonet, 40 deg Angled Tip, 4mm
48759590	Kerrison Rongeur Bayonet, 90 deg Angled Tip, 4mm
48759190	Pituitary (IVD) Rongeur Bayonet, Straight, 5x10mm Bite
48759395	Pituitary (IVD) Rongeur Bayonet, Angled 30 deg, 5x6mm Bite
48757000	Epstein Currette, Bayonet, Downbiting 90 deg, 7mm
48757001	Epstein Currette, Bayonet, Upbiting 40 deg, 7mm
48757002	Ring Currette, Bayonet, 10mm 25 deg Angle
48757003	Ring Currette, Straight, 10mm 25 deg Angle
48757004	Cup Currette, Bayonet, Angled Tip, 8mm 20 deg Angle
48757005	Cup Currette, Straight Shaft, Angled Tip, 8mm 20 deg Angle
48758000	Cobb Elevator, 18mm, Angled Tip 20 deg
48758001	Cobb Elevator, 18mm, Straight Tip
48758002	Cobb Elevator, 22mm, Angled Tip 20 deg
48758003	Cobb Elevator, 22mm, Straight Tip
48758600	Osteotome, Straight, 10mm
48758601	Osteotome, Edge Cutting w. Distraction Tips, NEW

Note: If the disc is severely collapsed, an osteotome may be utilized as an initial distractor, followed by a combination of implant trials and reamer distractors for further distraction.

Make an incision through the annulus using the **Long Handle Knife**, the **Bayoneted Knife Holder** or the **Annulotomy Knife**.

Remove the disc by using any combination of curettes, cobb elevators and rongeurs.

After the discectomy is completed, a cobb elevator may be used to release the contralateral annulus.

Long Handle Knife
48361277

Bayoneted Knife Holder
48759702

Annulotomy Knife
48759016

Note: Instruments to be inserted into the disc space through a minimally invasive approach should be inserted under fluoroscopic imaging.

Preparation of insertion site

Reference number	Description
48061000	T-Handle
48756500	Trial T-Handle
48758400	Rasp, Dual Sided, Straight
48758401	Rasp-Scraper, Straight

(See appendix for Reamer Distractor and Trial reference numbers)

T-Handle
48061000

Once an effective discectomy is performed, the intervertebral disc space and endplates must be prepared for implant insertion. Since techniques vary depending upon surgeon preference, two different options of instrumentation are available for distraction:

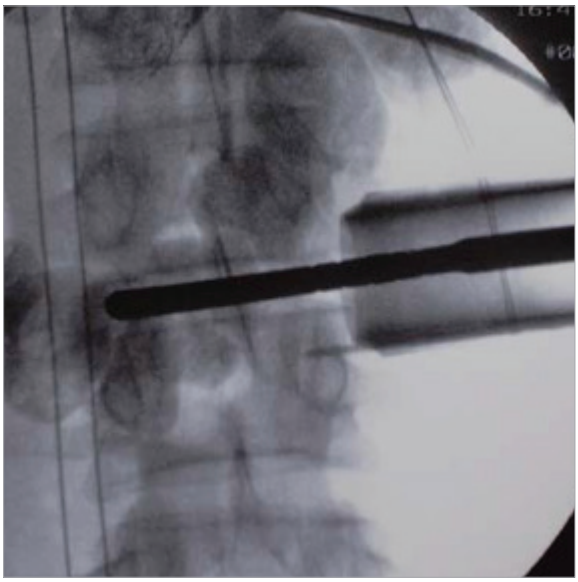
- Reamer distractors
- Reamer distractors and dual-sided rasp

Option 1: Use of the reamer distractors

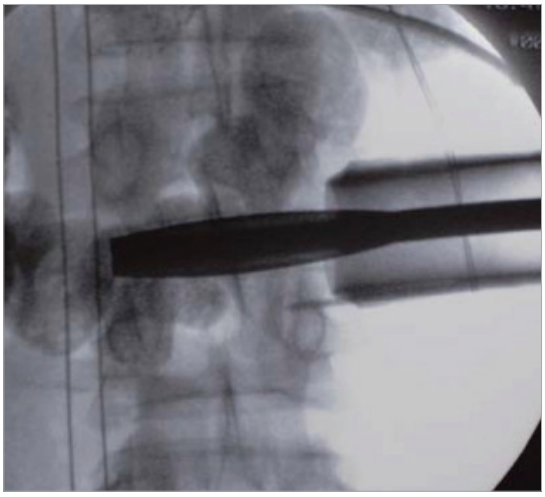
Insert the **Reamer Distractor** into the **T-Handle** by pulling up on the quick release tip.

Insert the smallest reamer distractor into the intervertebral disc space at a horizontal angle, while monitoring the insertion with fluoroscopy.

Reamer Distractor
48758408 – 8 x 50mm
48758410 – 10 x 50mm
48758412 – 12 x 50mm
48758414 – 14 x 50mm
48758416 – 16 x 50mm
48758418 – 18 x 50mm
48758208 – 8 x 60mm
48758210 – 10 x 60mm
48758212 – 12 x 60mm
48758214 – 14 x 60mm
48758216 – 16 x 60mm
48758218 – 18 x 60mm



Note: The widest part of the reamer distractor should be facing anterior/posterior and the thinnest part facing superior/inferior.



Note: The medial/lateral dimensions of the reamer distractors are 50mm and 60mm. Each groove is separated in 5mm increments starting from 40mm. The grooves can be visualized under fluoroscopic imaging and may be used as a guide to determine the desired implant length.

Turn the reamer distractor 90° to distract the intervertebral disc space and to scrape the endplates. The endplates are scraped by rotating the reamer distractor clockwise or counterclockwise.

After several turns, the reamer distractor is removed without rotation.

Reamer distractors of progressively increasing size are inserted sequentially, while monitoring the insertion with fluoroscopy, thus widening the intervertebral disc space until the optimal distraction is achieved.

The final reamer distractor is temporarily left in the vertical position on the contralateral side to maintain the disc space distraction.

Curettes may be used to complete the preparation of the parts of the endplates that are not accessible with the reamer distractor.

Note: Examination of the material removed with the reamer distractor helps to determine whether the endplates have been sufficiently prepared. If the material removed with the reamer distractor is the annulus fibrosus or cartilage, a larger reamer distractor can be used to reach the subchondral bone.

Note: Excessive removal of the subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.

Option 2: Use of the reamer distractors and rasps

The steps outlined previously in option 1 can be applied in conjunction with using the rasps for endplate preparation and distraction.

The dual-sided rasp and rasp-scraper can be used to remove cartilage from the endplates and to expose subchondral bone.

Note: Excessive removal of the subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.

Step 5. Determine the implant size by trialing

Reference number	Description
48942005	Mallet
48759701	Trial Handle
48759700	Threaded Trial Shaft

Once the endplates have been effectively prepared, the trials may be used to help determine the appropriate height, width and length of the implant. Final implant size can be determined using the appropriate color-coded trial. The trials match the implant options in footprint and lordosis.

The lordotic trials feature a boss on the anterior face to be clearly identified from the parallel trials.

Front view of parallel trial

Front view of lordotic trial

Attach the **Threaded Trial Shaft** into the **Trial Handle** by pulling up on the quick release tip.

Threaded Trial Shaft
48759700

Trial Handle
48759701

The trials are color-coded by height as indicated below:

8mm

10mm

12mm

14mm

16mm

Note: The trials represent the height of only the body of the Aero-LL implant, excluding the teeth. Relative to the trial, the implant features an additional 1mm of "teeth height." For this reason, it is important to not oversize the trial as the overall implant height is 1mm taller than the trial.

Attach the selected trial to the trial shaft by threading the distal end of the shaft over the threads of the trial.

Insert the trial into the prepared disc space to confirm the appropriate implant size. Fluoroscopy can assist in confirming the proper fit. The trial should pass through the distracted disc space without excessive force.

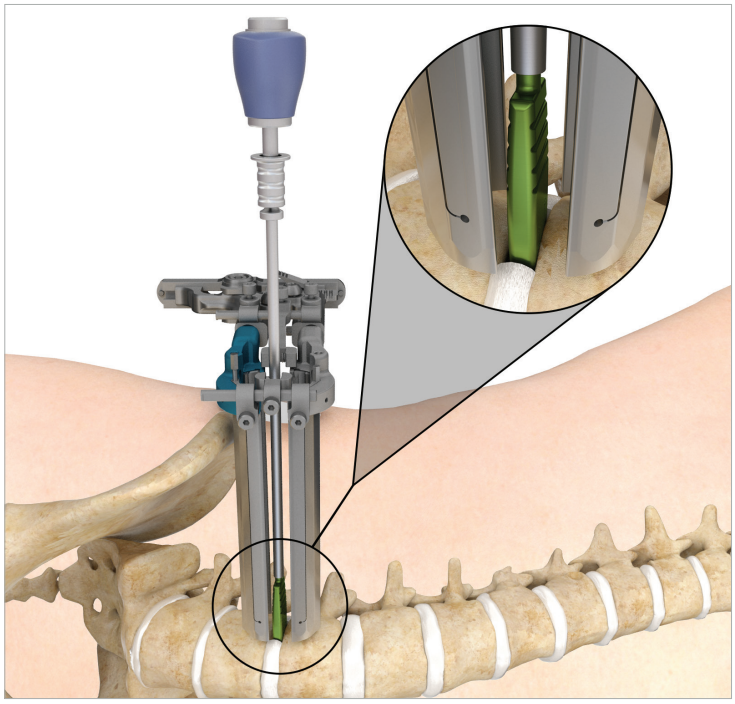
Note: The trials are smooth with rounded edges and are designed to reduce the risk of damage to the endplates during distraction of the intervertebral disc space.

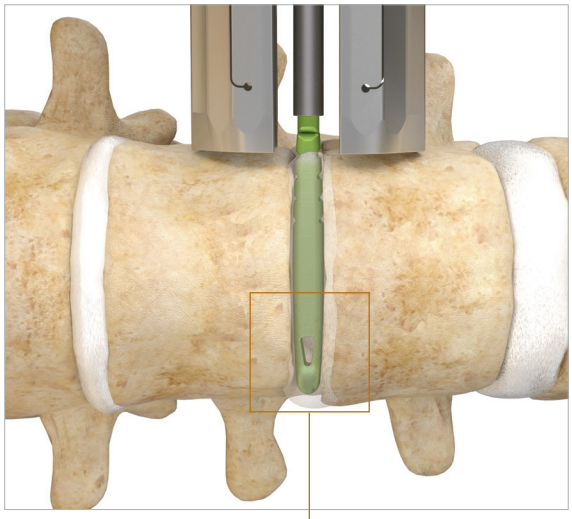
Note: The trial selected should have a tight fit between the endplates such that there is no gap. If the trial is too loose or too tight, the next larger or smaller size should be chosen until the best fit is obtained. The trial can be removed from the trial shaft by unthreading the trial from the trial shaft.

As needed, tap the trial handle with the mallet to facilitate insertion of the trial. The trial is temporarily left in position to maintain the disc space distraction.

Adjust insertion depth in order to determine the proper implant length. Each groove is separated by 5mm increments starting at 40mm. Utilize the triangular window to visually determine the position of the distal tip of the anchor.

Note: Excessive removal of the subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.





The distal tip of the triangular window indicates final distal positioning of the anchor

To remove the trials, attach the **Slap Hammer** to the trial shaft to apply an upward force.

Slap Hammer
48759600

Step 6. Implant insertion

Once the final implant size has been determined, select the corresponding Aero-LL implant and **Inserter Guide**. The jackets on the implants and the handle of the inserter guides are color-coded by implant height.

Inserter Guide

Reference number	Description	Color
48944810	Inserter Guide, 8mm/10mm	Blue
48944012	Inserter Guide, 12mm	Green
48944014	Inserter Guide, 14mm	Magenta
48944016	Inserter Guide, 16mm	Aqua

Note: For a lordotic implant, ensure that the orientation of the implant is correct. Each implant is lasermarked with anterior and posterior markings.

Note: The serrated sides of the implant should be positioned to face the endplates.

To load the implant onto the inserter guide, align the lasermarking on the implant with the lasermarking of the inserter guide. The implant is attached to the appropriate inserter guide by rotating the knurled knob clockwise until snug.

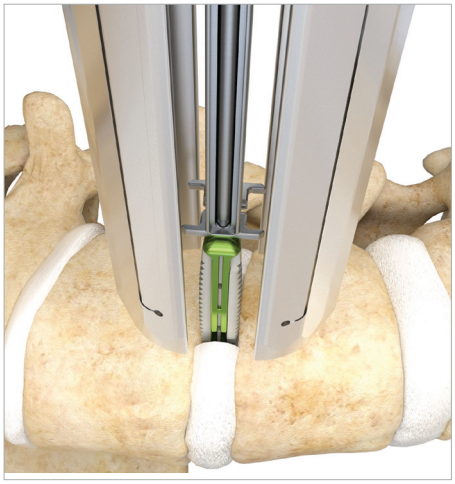
With the implant attached to the inserter guide, load autogenous bone graft into the open graft chambers.

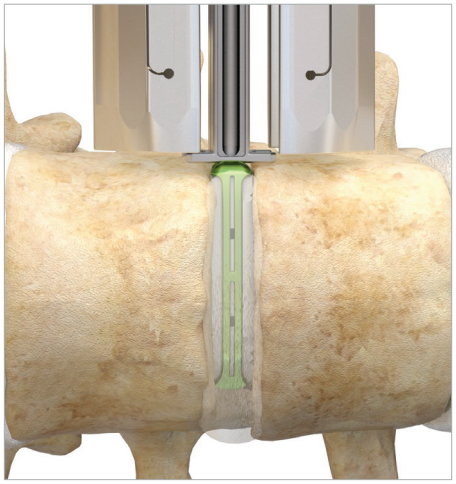
After the implant has been packed with autogenous bone graft, insert the implant into the prepared disc space and insert the leading edge gently between the vertebral endplates.

Impact the proximal end of the inserter guide using the mallet to safely and gradually insert the implant. Alternatively, the inserter guide can be used with the **Inserter/Distractor** to appropriately position the implant while distracting the disc space.

The implant is fully implanted when the depth stops on the inserter guide make contact with the lateral aspects of both the superior and inferior vertebral bodies.

Inserter/Distractor
48942004

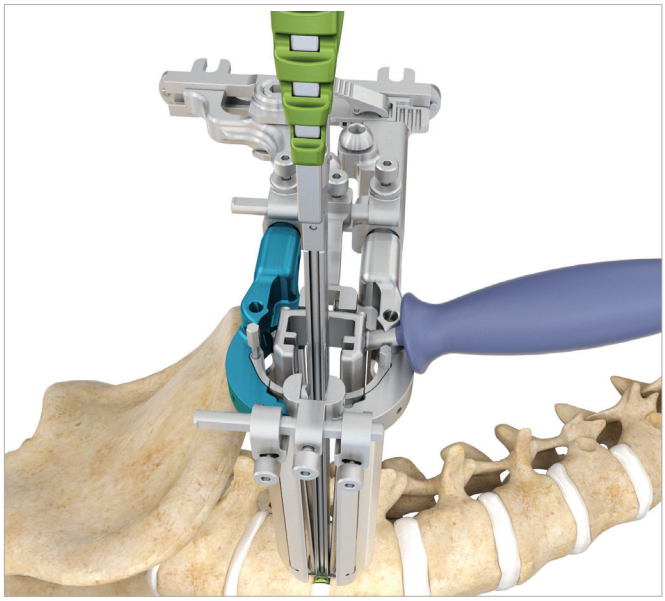




An alternate method of introducing the implant into the disc space is by using the inserter/distracter to simultaneously distract the vertebral bodies and position the implant.

If used, remove the inserter/distractor prior to anchor insertion.

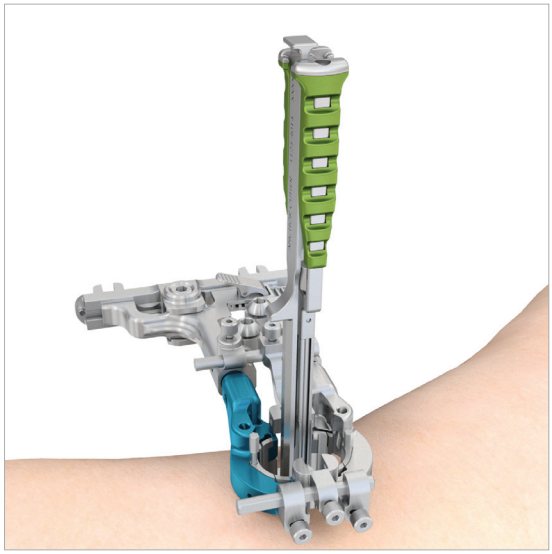
Note: The compacted graft should be flush with the upper and lower surfaces of the implant in order to be in contact with the endplates.



Step 7. Create anchor channels

Use the **Pilot Cutter** to perforate the cortex and create channels for the anchors.

Position the pilot cutter onto the arms of the inserter guide. Slide the pilot cutter down until it rests against the vertebral body.

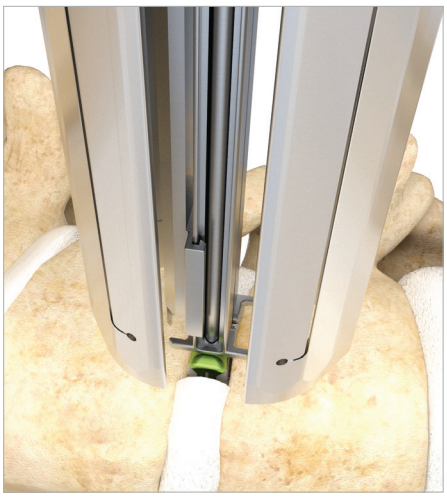


Attachment of pilot cutter onto inserter guide

Using the mallet, tap the pilot cutter gently to penetrate the cortex and create a channel. A built-in depth stop on the proximal end of the inserter guide limits the depth of the pilot cutter insertion.

Remove the pilot cutter from the vertebral body by gently tapping the cutter back out of the vertebral body.

With the pilot cut made, insert an anchor into the same channel on the inserter guide and into the vertebral body as shown in the anchor insertion step (page 29). Once the first anchor is placed and locked into the jacket of the cage, use the same methodology with the pilot cutter and inserter guide to create remaining channel and place the remaining anchors.



Pilot Cutter
48942003

Note: It is recommended that final implant positioning be confirmed using both A/P and lateral fluoroscopy prior to using the pilot cutter to create channels for the anchors.

Note: The Pilot Cutter may be used to create channels for the Anchors. This step is optional, but is recommended for patients with harder bone quality.

Note: When using the pilot cutter, hold onto the inserter guide shaft and apply downward pressure to help maintain the positioning of the implant within the disc space and to prevent any rotation of the inserter guide.

Note: If posterior fixation already exists, the pilot cutter can be utilized to visualize the final position of the anchor. This will ensure an unobstructed anchor insertion.

Note: Each anchor must be inserted immediately after channel creation.

Step 8. Anchor insertion

The two anchors required for implant fixation are sterile packaged with the implant. The anchors are sized to match the appropriate implant length. Only anchors that are designed for a specific implant length should be used with that implant. (For example, only 50mm anchors should be used with a 50mm long implant).

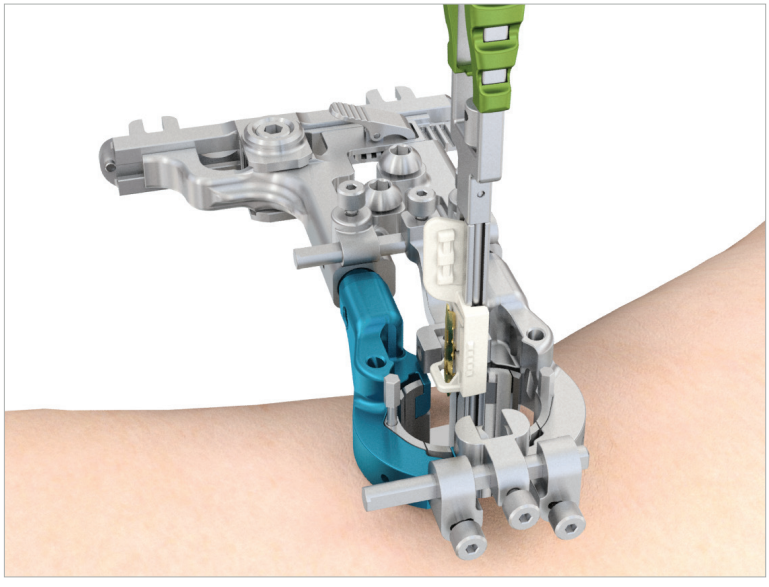
Aero-LL anchors	
Anchor size	**Implant length**
40mm	40mm
45mm	45mm
50mm	50mm
55mm	55mm
60mm	60mm

The anchors are packaged in a plastic cartridge to ensure safe handling.

Pull the anchor cartridge from the tray and manually load into the groove of the inserter guide. Downward pressure onto the anchor cartridge releases the anchor from the anchor cartridge.

Insert the **Anchor Tamp** into the groove of the inserter guide and slide downward until it interfaces with a notch on the anchor. Using the mallet, tap the anchor tamp to advance the anchor through the cortex of the vertebral body and engage into the jacket.

Anchor Tamp
48942001



Anchor cartridge being placed onto the inserter guide

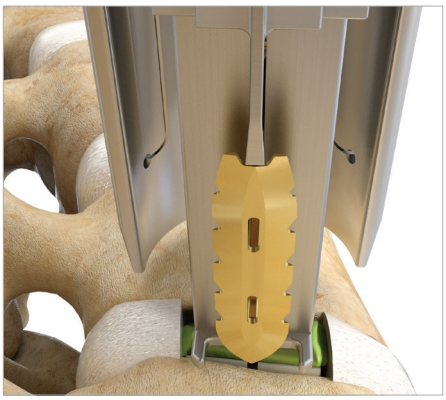
Note: For optimal anchor fixation, ensure a tight fit between the implant and the endplates so there is no gap. It is recommended that final implant positioning be confirmed using both A/P and lateral fluoroscopy prior to inserting the anchors.

Note: Use the pilot cutter to perforate the cortex and create channels for the anchors. This step is optional, but is recommended for patients with harder bone quality.

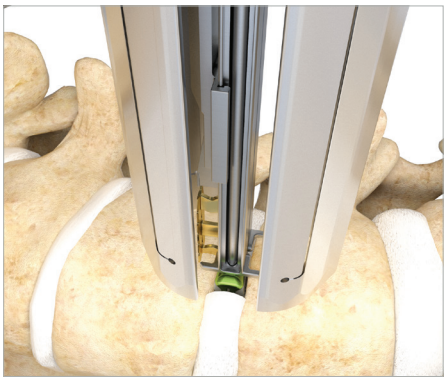
Note: When addressing a disc that is adjacent to a previously instrumented level, a radiograph should be utilized to asses the number of anchors that may be inserted.

Note: If a replacement anchor is required, be sure to select the appropriate size anchor corresponding to the implant length. Use the anchor's lasermarkings as a reference for the anchor size. Confirm the anchor size on the label of the sterile packaging.

Note: Confirm that the anchor size which is laser marked on the top of the anchor matches the length laser marked on the implant.



Once the first anchor is placed and locked into the jacket of the cage, use the same methodology with the optional pilot cutter and inserter guide to create remaining channel and place the remaining anchor.

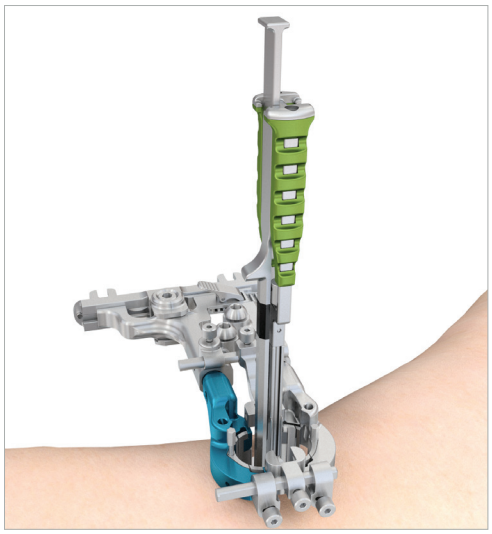


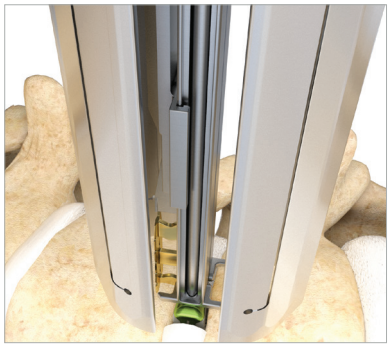
Note: When inserting the anchor, hold onto the inserter guide and apply downward pressure to help maintain the positioning of the implant within the disc space and to prevent any rotation of the inserter guide.

Caution: The anchors are exposed from the plastic cartridges as they travel down the channels of the inserter guide. Extreme care should be taken to ensure no vessels or soft tissues are within the 6-7mm space above the endplates of the vertebral bodies where the anchors will enter.

The mallet may be used to facilitate anchor tamp removal.

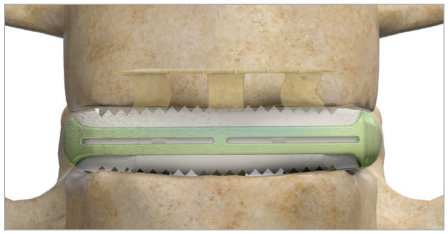
The anchor is locked in the cage when the anchor tamp is flush with the proximal end of the inserter guide.

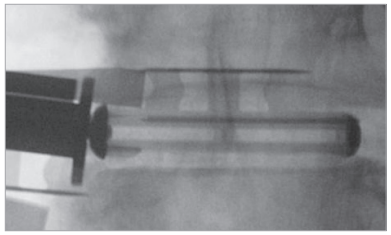




Note: A built-in depth stop on the proximal end of the inserter guide ensures proper anchor position and prevents the anchor tamp from entering the disc space. The depth stop on the anchor tamp will contact the inserter guide when the anchor is fully inserted providing both tactile and audible feedback.

Note: Once the anchors are locked into the jacket, they cannot be removed from the implant. It is recommended that implant positioning be confirmed using both A/P and lateral fluoroscopy prior to inserting the anchors.





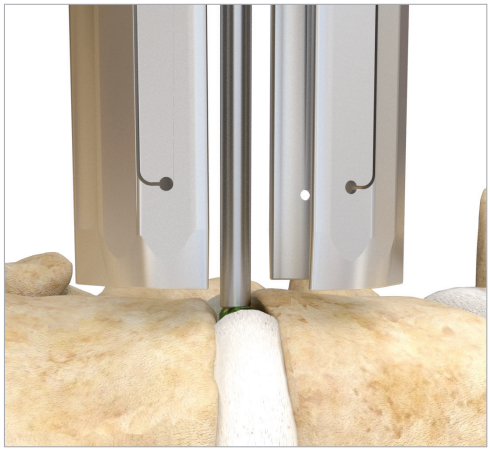
Repeat the optional anchor channel creation and anchor insertion as described above for the remaining anchor.

Once the anchors are inserted and locked, release the implant from the inserter guide by unthreading the knurled knob. Visually confirm and utilize A/P fluoroscopic images to verify that the anchors are flush with the implant.

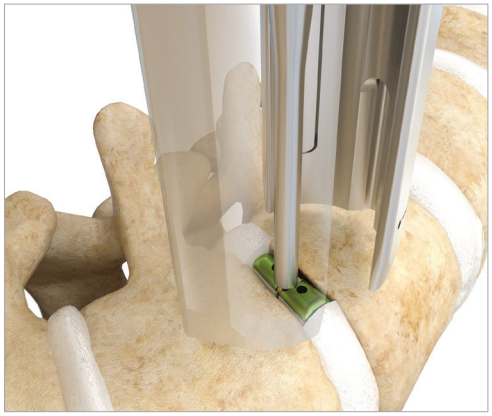
If an anchor is not locked, the distal end of the anchor will protrude slightly laterally from the implant. If after removing the inserter guide and anchor tamp, the anchor still appears proud, use the **Freehand Tamp** for final seating of the anchor.

Note: If a replacement anchor is required, be sure to select the appropriate size anchor corresponding to the implant length. Use the anchor's lasermarkings as a reference for the anchor size. Confirm the anchor size on the label of the sterile packaging.

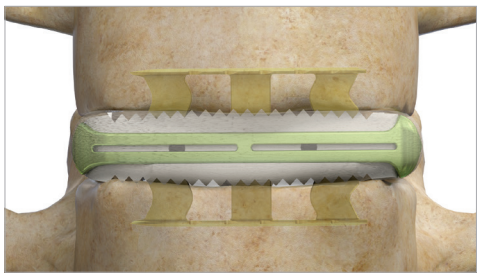
Freehand Tamp
48942002



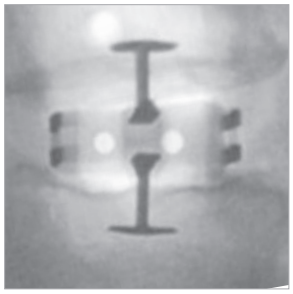
Place the distal end of freehand tamp against the notch of the proud anchor and tap with the mallet to ensure the anchor is fully seated.



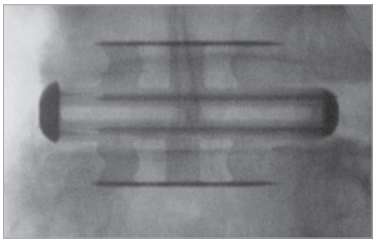
Use fluoroscopic imaging to determine the final position of the implant.



Aero-LL fully implanted



Lateral x-ray



A/P x-ray

Note: Proper placement of the implant is centered across the disc space on an A/P fluoroscopic view, and between the anterior third and middle third of the disc space on a lateral fluoroscopic view. Utilize the jacket to help visually confirm proper positioning and orientation of the implant in radiographic images.

Step 9: Insertion of supplemental fixation

With the anchors inserted and locked in place, supplemental fixation that has been cleared by the FDA approved for use in the lumbosacral spine must be used to augment stability of the Aero-LL construct. Stryker's LITe plate system, posterior pedicle screws or interspinous process fusion plate are recommended.

Note: Take care to place the supplemental fixation so that it does not interfere with the anchors.

Implant removal

A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, or changes in device positioning. The surgeon user must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient's health, the nature of the problem and/or device failure, the patient's bone quality and the surgeon's expertise with other spinal treatments and instrumentation.

Should the Aero-LL implant need to be removed for any reason, removal can be achieved utilizing the two techniques described below.

Option 1:

Align the **Revision Guide** with the implant and thread the knurled barrel clockwise to engage the threaded hole in the cage.

Select the appropriately sized **Revision Adapter** to match the height of the implant and assemble the revision adapter onto the **Revision Housing** by depressing and sliding the prongs toward the handle of the revision housing.

Slide the revision housing with revision adapter over the shaft of the revision guide.

Once the revision housing is engaged with the revision guide, turn t-handle clockwise until the implant is extracted.

Once the implant is removed from the vertebral bodies, all revision instruments can be removed from the wound.

Revision Guide
48945001

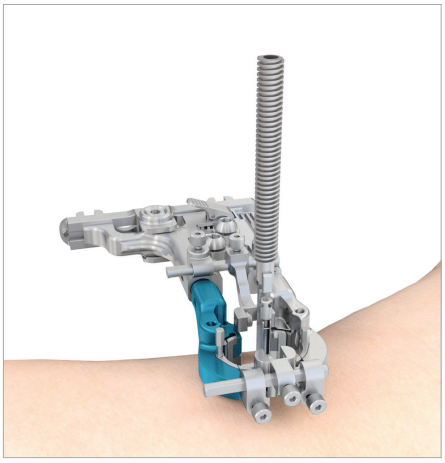
Revision Adapter
4895008 - 48945016

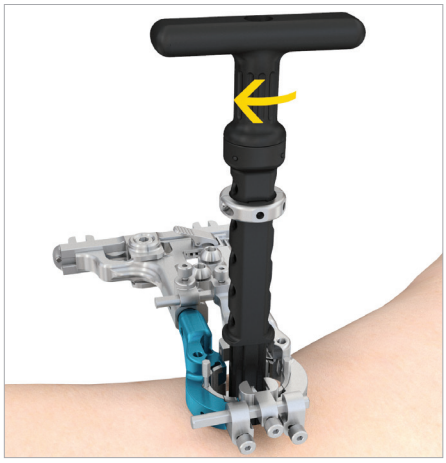
Revision Housing
48945000

Counter Torque Handle
48394006

Note: Use the color of the jacket to determine the height of the implant inserted and the proper revision adapter needed for removal.

Note: The Counter Torque Handle may be threaded onto the revision housing to aid in stabilizing the revision housing during removal.





Release the revision guide from the revision housing by rotating the t-handle counterclockwise until the thread is no longer engaged. Release the implant from the revision guide by rotating the thumb screw counterclockwise.

Anchor Remover
48926600

Note: If an anchor is not fully removed by the revision housing/ adapter, the Anchor Remover can be used to remove it from the vertebral body.

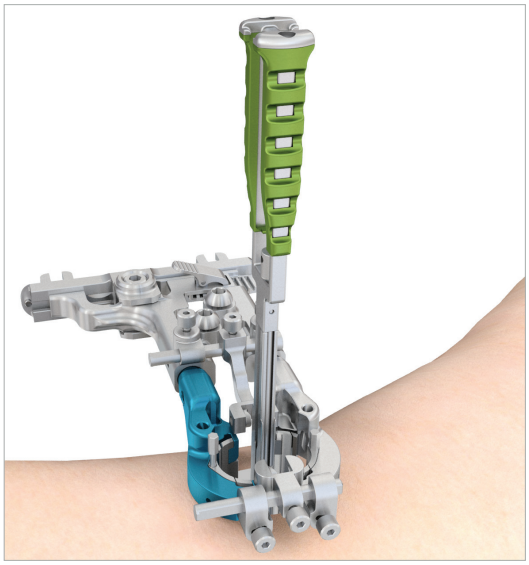
Note: Once an Aero-LL implant with fixation anchors has been inserted and removed, another Aero-LL implant with fixation anchors cannot be placed at that level.

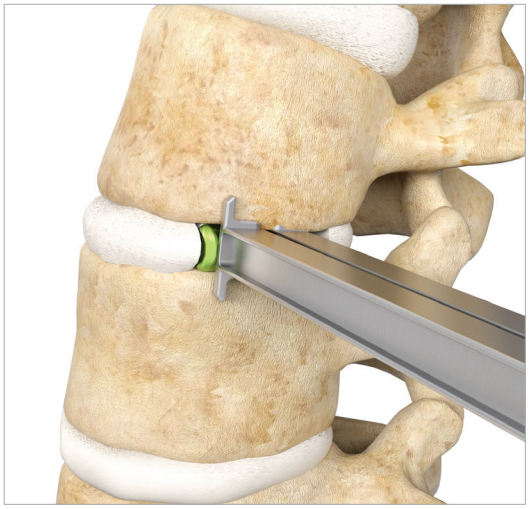
Note: Following implant removal, disassemble the revision housing, revision adapter and counter torque handle for cleaning and sterilization.

Option 2:

Reengage the corresponding inserter guide into the implant until snug. The jackets on the implants and the handle of the inserter guides are color-coded by implant height.

Utilize the slot on the distal end of the mallet to apply an upward force by tapping onto the inserter guide.



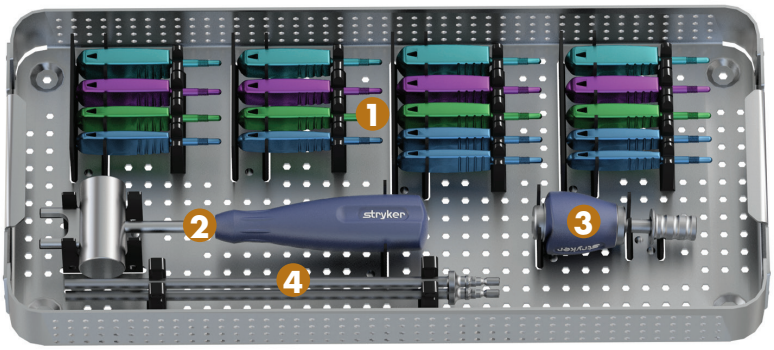


Note: Care should be taken to remove the implant in-line with the disc space.

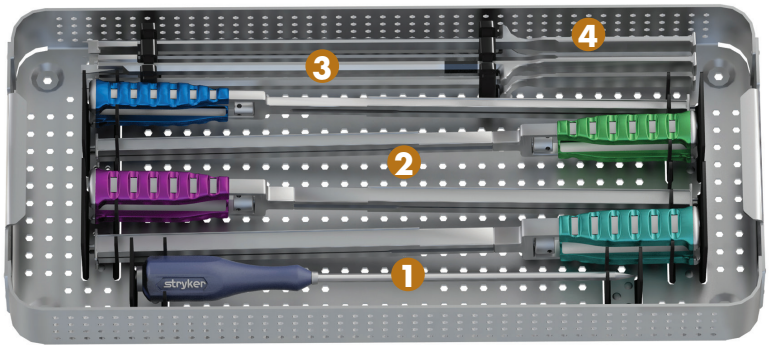
Mallet
48942005

Tray overview

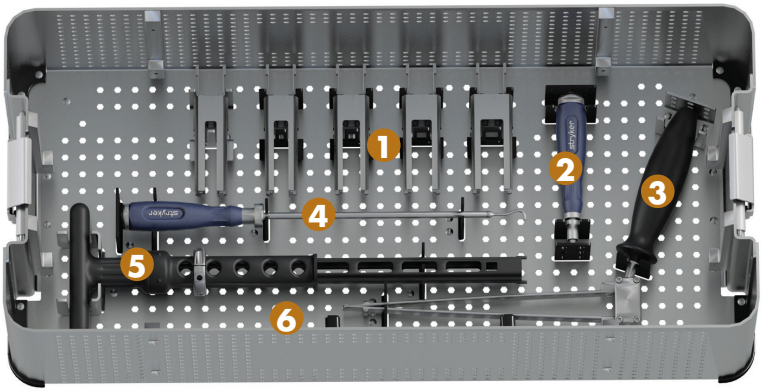
Top tray		
	Description	**Reference number**
1	Trials	48940818-48948622
2	Mallet	48942005
3	Trial Handle	48759701
4	Threaded Trial Shaft	48759700



Middle tray		
	Description	**Reference number**
1	Freehand Tamp	48942002
2	Inserter Guides	48944810-48944016
3	Anchor Tamp	48942001
4	Pilot Cutter	48942003



Bottom tray		
	Description	**Reference number**
1	Revision Adapters	48945008-48945016
2	Counter Torque Handle	48394006
3	Inserter/Distractor	48942004
4	Anchor Remover	48926600
5	Revision Housing	48945000
6	Revision Guide	48945001



Core implants

Reference number	Description (height x length x lordosis - width)
Lordosis - 0° width 18mm	
Length 45mm	
48940108	8 x 45mm x 0°-18
Length 50mm	
48940208	8 x 50mm x 0°-18
Length 55mm	
48940308	8 x 55mm x 0°-18

Reference number	Description (height x length x lordosis - width)
Lordosis - 0° width 22mm	
Length 45mm	
48942108	8 x 45mm x 0°-22
Length 50mm	
48942208	8 x 50mm x 0°-22
Length 55mm	
48942308	8 x 55mm x 0°-22

Reference number	Description (height x length x lordosis - width)
Lordosis - 8° width 18mm	
Length 45mm	
48941110	10 x 45mm x 8°-18
48941112	12 x 45mm x 8°-18
48941114	14 x 45mm x 8°-18
48941116	16 x 45mm x 8°-18
Length 50mm	
48941210	10 x 50mm x 8°-18
48941212	12 x 50mm x 8°-18
48941214	14 x 50mm x 8°-18
Length 55mm	
48941310	10 x 55mm x 8°-18
48941312	12 x 55mm x 8°-18
48941314	14 x 55mm x 8°-18

Reference number	Description (height x length x lordosis - width)
Lordosis - 8° width 22mm	
Length 45mm	
48943110	10 x 45mm x 8°-22
48943112	12 x 45mm x 8°-22
48943114	14 x 45mm x 8°-22
48943116	16 x 45mm x 8°-22
Length 50mm	
48943210	10 x 50mm x 8°-22
48943212	12 x 50mm x 8°-22
48943214	14 x 50mm x 8°-22
48943216	16 x 50mm x 8°-22
Length 55mm	
48943310	10 x 55mm x 8°-22
48943312	12 x 55mm x 8°-22
48943314	14 x 55mm x 8°-22
48943316	16 x 55mm x 8°-22

Reference number	Description
48940045	Aero-LL Fixation Anchor, 45mm
48940050	Aero-LL Fixation Anchor, 50mm
48940055	Aero-LL Fxiation Anchor, 55mm

Outlier implants

Reference number	Description (height x length x lordosis - width)
Lordosis - 0° width 18mm	
Length 40mm	
48940008	8 x 40mm x 0°-18
Length 60mm	
48940408	8 x 60mm x 0°-18

Reference number	Description (height x length x lordosis - width)
Lordosis - 8° width 18mm	
Length 40mm	
48941010	10 x 40mm x 8°-18
48941012	12 x 40mm x 8°-18
48941014	14 x 40mm x 8°-18
Length 60mm	
48941410	10 x 60mm x 8°-18
48941412	12 x 60mm x 8°-18
48941414	14 x 60mm x 8°-18

Reference number	Description
48940040	Aero-LL Fixation Anchor, 40mm
48940060	Aero-LL Fixation Anchor, 60mm

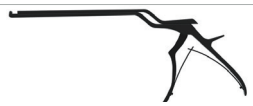
Reference number	Description (height x length x lordosis - width)
Lordosis - 8° width 22mm	
Length 40mm	
48943010	10 x 40mm x 8°-22
48943012	12 x 40mm x 8°-22
48943014	14 x 40mm x 8°-22
Length 60mm	
48943410	10 x 60mm x 8°-22
48943412	12 x 60mm x 8°-22
48943414	14 x 60mm x 8°-22

Aero-LL instruments

Reference number	Description
48940818	Trial, 8mm x 0°-18mm
48940018	Trial, 10mm x 0°-18mm
48940218	Trial, 12mm x 0°-18mm
48940418	Trial, 14mm x 0°-18mm
48940618	Trial, 16mm x 0°-18mm
48940822	Trial, 8mm x 0°-22mm
48940022	Trial, 10mm x 0°-22mm
48940222	Trial, 12mm x 0°-22mm
48940422	Trial, 14mm x 0°-22mm
48940622	Trial, 16mm x 0°-22mm
48948018	Trial, 10mm x 8°-18mm
48948218	Trial, 12mm x 8°-18mm
48948418	Trial, 14mm x 8°-18mm
48948618	Trial, 16mm x 8°-18mm
48948022	Trial, 10mm x 8°-22mm
48948222	Trial, 12mm x 8°-22mm
48948422	Trial, 14mm x 8°-22mm
48948622	Trial, 16mm x 8°-22mm
48944810	Inserter Guide, 8mm/10mm
48944012	Inserter Guide, 12mm
48944014	Inserter Guide, 14mm
48944016	Inserter Guide, 16mm
48942001	Anchor Tamp
48942002	Freehand Tamp
48942003	Pilot Cutter
48942004	Inserter/Distractor

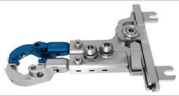
	Reference number	Description
	48945000	Revision Housing
	48945001	Revision Guide
	48945008	Revision Adapter, 8mm
	48945010	Revision Adapter, 10mm
	48945012	Revision Adapter, 12mm
	48945014	Revision Adapter, 14mm
	48945016	Revision Adapter, 16mm
	48926600	Anchor Remover
	48942005	Mallet
	48394006	Counter Torque Handle
	48759701	Trial Handle
	48759700	Threaded Trial Shaft
	48940000	Aero-LL Instrument Tray

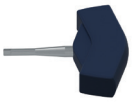
Endplate prep instruments

	Reference number	Description
	48758408	Reamer Distractor 8x50
	48758410	Reamer Distractor 10x50
	48758412	Reamer Distractor 12x50
	48758414	Reamer Distractor 14x50
	48758416	Reamer Distractor 16x50
	48758418	Reamer Distractor 18x50
	48758208	Reamer Distractor 8x60
	48758210	Reamer Distractor 10x60
	48758212	Reamer Distractor 12x60
	48758214	Reamer Distractor 14x60
	48758216	Reamer Distractor 16x60
	48758218	Reamer Distractor 18x60
	48759016	Annulotomy Knife
	48759390	Kerrison Rongeur Bayonet, 40 deg Angled Tip, 4mm
	48759590	Kerrison Rongeur Bayonet, 90 deg Angled Tip, 4mm
	48759190	Pituitary (IVD) Rongeur Bayonet, Straight, 5x10mm Bite
	48759395	Pituitary (IVD) Rongeur Bayonet, Angled 30 deg, 5x6mm Bite
	48757000	Epstein Currette, Bayonet, Downbiting 90 deg, 7mm
	48757001	Epstein Currette, Bayonet, Upbiting 40 deg, 7mm
	48757002	Ring Currette, Bayonet, 10mm 25 deg Angle
	48757003	Ring Currette, Straight, 10mm 25 deg Angle
	48757004	Cup Currette, Bayonet, Angled Tip, 8mm 20 deg Angle
	48757005	Cup Currette, Straight Shaft, Angled Tip, 8mm 20 deg Angle

	Reference number	Description
	48758000	Cobb Elevator, 18mm, Angled Tip 20 deg
	48758001	Cobb Elevator, 18mm, Straight Tip
	48758002	Cobb Elevator, 22mm, Angled Tip 20 deg
	48758003	Cobb Elevator, 22mm, Straight Tip
	48758600	Osteotome, Straight, 10mm
	48758601	Osteotome, Edge Cutting w. Distraction Tips, NEW
	48758400	Rasp, Dual Sided, Straight
	48758401	Rasp-Scraper, Straight
	48759000	Penfield, Pull w. Small Silicon Handle
	48759001	Nerve Root Retractor Bayonet 7x3 w. Sm. Silicon Handle, New
	48759002	Nerve Hook w. Ball Tip w. Small Silicon Handle
	48759015	Frazier Suction tube, 10Fr
	48061001	Slap Hammer
	48061000	T-Handle

Access instruments

	Reference number	Description
	48250230	Arm Post
	48755400	Snake Arm
	48755450	Rigid Arm
	48755720	Landmark Identifier
	48755007	Sharp Guide Wire
	48755006	NM Probe/Guide Wire (Disposable)
	48755004	Guide Wire/Dilator Radiolucent Holder
	48755008	Neuromonitoring Cable (Disposable)
	48755018	Lead Crocodile Clip
	48755028	Lead Ext Blue
	48755001	Dilator 1 – 6.5mm (Disposable)
	48755002	Dilator 2, NM – 14.5mm (Disposable)
	48755003	Dilator 3, NM – 22.5mm (Disposable)
	48755000	Retractor Base
	48755050	Blade 50mm Assy
	48755060	Blade 60mm Assy
	48755070	Blade 70mm Assy
	48755080	Blade 80mm Assy
	48755090	Blade 90mm Assy
	48755100	Blade 100mm Assy
	48755110	Blade 110mm Assy
	48755120	Blade 120mm Assy
	48755130	Blade 130mm Assy
	48755140	Blade 140mm Assy
	48755150	Blade 150mm Assy
	48755160	Blade 160mm Assy

	Reference number	Description
	48250200	Retractor Hex Driver
	48755701	Anti Rotational Key
	48755703	Anchoring Pin Driver
	48755702	Quick Release Handle
	48755850	Anchoring Pin 50mm
	48755860	Anchoring Pin 60mm
	48755870	Anchoring Pin 70mm
	48755880	Anchoring Pin 80mm
	48755890	Anchoring Pin 90mm
	48755900	Anchoring Pin 100mm
	48755910	Anchoring Pin 110mm
	48755920	Anchoring Pin120mm
	48755930	Anchoring Pin 130mm
	48755940	Anchoring Pin140mm
	48755950	Anchoring Pin 150mm
	48755960	Anchoring Pin 160mm
	48755600	Posterior Frame
	48755708	A/P Retractor Blade, Short (80mm)
	48755710	A/P Retractor Blade, Medium 1 (100mm)
	48755712	A/P Retractor Blade, Medium 2 (120mm)
	48755716	A/P Retractor Blade, Long (160mm)
	48755700	A/P Frame Driver
	48755500	Anterior Frame
	48252006	Light Source
	48758450	Light Cable, Disposable

	Reference number	Description
	48758451	Light Cable, Reusable
	48759050	Tray 1
	48759060	Tray 2
	48759070	Tray 3
	48759080	Tray 4

Important product information for Aero-LL

Sterile product

Description

The Aero-LL Cage is a hollow, bullet-shaped PEEK Optima cage surrounded by a titanium alloy (Ti-6Al-4V) jacket. The PEEK Optima cage portion consists of two closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used either with or without the internal supplemental fixation provided (Aero-LL Fixation Anchors) in addition to supplemental fixation systems cleared for use in the lumbosacral spine. The Aero-LL Fixation Anchors are constructed from titanium alloy (Ti 6Al-4V) and feature rails that mate with dovetail channels located within the Aero-LL PEEK cage. Once fully seated into the channels, the anchors are designed to lock into the titanium jacket.

Material

All components of the system are manufactured out of the following materials:

- Cage: Polyetheretherketone (PEEK Optima LT1) (ASTM F2026), and Titanium Alloy Ti6Al4V (ISO 5832-3, ASTM F136)
- Fixation Anchors: Titanium Alloy Ti6Al4V (ISO 5832-3, ASTM F136)

Indications

USA indications

The Stryker Spine Aero-LL is an intervertebral body fusion device indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero-LL Lumbar Cage System is to be implanted via a lateral approach.

The Aero-LL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems). In addition, the device may be used with or without the included fixation anchors.

Indications outside USA

The Stryker Spine Aero-LL is an intervertebral body fusion device indicated for the treatment of spondylolisthesis, degenerative spine disorders, and discal and vertebral instability, and may also be used in cases of spine revision surgery. Packing bone graft material within the implant is recommended.

The Aero-LL Lumbar Cage System is to be implanted via a lateral approach.

The Aero-LL Lumbar Cage system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Aero-LL Lumbar Cage must be used with the two fixation anchors provided.

General conditions of use

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

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

Caution

- Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.
- This device is not intended for posterior surgical implantation.
- Once an Aero-LL implant with Fixation Anchors has been inserted and removed, another Aero-LL implant with Fixation Anchors cannot be placed at that level.
- This device is provided STERILE. Do not use if package is opened or damaged or after the "Use by" date on the label has expired.
- The Aero-LL Lumbar Cages have not been evaluated for safety and compatibility in the MR environment. Aero-LL Lumbar Cages have not been tested for heating or migration in the MR environment.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the intervertebral body fusion device.
- The implantation of the intervertebral body fusion device must be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or visceral injury.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.
- Do not mix metals (e.g. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

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 may be 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 device. 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, and disposal attention. Instruments must be examined for wear or damage prior to surgery.

Reuse
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.

Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

Handling
Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

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

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:
- The Aero-LL Lumbar Cage should not be implanted in patients with an active infection at the operative site.
- The Aero-LL Lumbar Cage is not intended for use except as indicated.
- Marked local inflammation.
- 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.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Pregnancy.
- Inadequate tissue coverage over the operative site.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- 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 must 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.
- Prior fusion at the levels to be treated.

These contra-indications may be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

Information for patients
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and make them aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Pre-operative precautions
the surgical indication and the choice of implants must take into account certain important criteria such as:
- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

The choice of implants

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 implant 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 must 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 fatigue, 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.

Intra-operative precautions

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by STRYKER Spine.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

Patient care following treatment

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 must closely monitor the patient if a change at the site has been detected.

Adverse effects

Include but are not limited to:

- Late bone fusion or no visible fusion mass and pseudarthrosis;
- 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;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials, although uncommon, can occur;
- Decrease in bone density due to stress shielding;
- Dural leak requiring surgical repair;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Cessation of growth of the fused portion of the spine;
- 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) must be revised or removed immediately before serious injury occurs;
- Neurological and spinal dura mater lesions from surgical trauma;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur 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.
- 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.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

Removal

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the Aero-LL is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- 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.

Stryker Spine AVS ARIA neuromonitoring probe and probe dilators instructions

Non sterile product

Description / material composition

Surgical instruments supplied by Stryker Spine are manual medical tools designed solely for use in the fitting of Stryker Spine implants. They are made of different materials including stainless steel, aluminum, titanium and plastics (silicone, acetal, etc) that comply with the standards applicable to their specific material composition. However these materials are not implantable. Stryker Spine instruments do not contain natural rubber (such as: natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation).

Device reference number	Device name	Reusable / single use	Provided
48755006	Neuromonitoring Probe	Single Use	Non-Sterile
48755001	Dilator 1 – 6.5mm	Single Use	Non-Sterile
48755002	Probe Dilator 2, NM – 14.5mm	Single Use	Non-Sterile
48755003	Probe Dilator 3, NM – 22.5mm	Single Use	Non-Sterile

Indications for use

The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are indicated for use during surgery of the spine and are intended to deliver an electrical stimulus to the tissues and nerves at the operative site to assist in locating those nerves at risk during the surgical procedure.

The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are designed for use in conjunction with common Neuro Monitors and other Stryker Spine devices to assist in gaining controlled access to, and visualization of, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal approach, where anatomical restrictions safely permit.

Use

Stryker Spine instruments must be used in the manner described in the Surgical Techniques brochures provided by Stryker Spine. Prior to using the instruments, the surgeon shall have given careful consideration to all aspects of the surgical intervention as well as to the limits of the instrumentation.

Recommendations for use are provided in the Surgical Technique brochures available from Stryker Spine representatives.

Reuse

These instruments are labeled as single use and must not be reused or resterilized. While a single-use instrument may appear undamaged, the instrument may have acquired contaminants that compromise sterility and/or blemishes, nicks or latent compromise of its integrity.

Pre-operative precautions

Anyone using Stryker Spine products can obtain a Surgical Technique 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 request an updated version.

Stryker Spine devices may only be used by doctors who are fully familiar with the surgical technique required. 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 causes 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.

Any electrosurgical devices have the potential for providing an ignition source. Do not use in the presence of flammable substances.

Caution

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

Potential adverse effects

Incorrect maintenance, cleaning or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff.

Below is a list, albeit not exhaustive, of potential complications:

- Neurological lesion, paralysis, pain, lesion of the soft tissues, the visceral organs or the joints, in the event of incorrect use or breakage of the instruments.
- Infection, if the instruments are not properly cleaned and sterilized.
- Dural leaks, compression of vessels, damage to nerves or nearby organs as a result of slippage or poor positioning of a faulty instrument.
- Damage caused by the involuntary releasing of the springs of certain instruments.
- Damage caused by the instruments used to bend or cut in-situ due to excessive forces occurring when they are used.
- Cutting the gloves or the skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to dissemble the instruments during surgery.
- Crack, fracture or involuntary perforation of the bone.

As a result of the mechanical features required, most of the instruments are made of non implantable materials. In the event an instrument breaks, no fragment must remain in the patient as this could cause post-operative complications such as allergies, infections, or complications of a biological nature associated with the release of metal components, possibly requiring further intervention.

Packaging
- Stryker Spine ARIA Neuromonitoring instruments are sold non-sterile and are available in instrument containers or individual packaging. The containers and the packaging of the instruments must be intact when received. The packaging materials must be removed prior to sterilization.

Examination Prior to Use
For instruments designed for single use (sold non-sterile):
- It is recommended to verify the integrity of the instrument and original package before use.
- Instruments should be visually examined for damage by doctors and staff in operating centers prior to surgery.
- Stryker Spine and its representatives are available to help carry out proper instrument inspections.
- Stryker Spine shall not be responsible in the event of the use of instruments that are damaged, incomplete, or that have been repaired or sharpened outside the control of Stryker Spine. Any faulty instruments must be replaced prior to any intervention.

Sterilization
For safety reasons, non-sterile devices must be sterilized prior to use. Once this device has been sterilized, DO NOT RESTERILIZE. Discard the device using standard hospital procedures.

Storage
The instruments are packaged in individual packages or in containers. After they are used they must be stored in a clean, dry and temperate place.

Complaints
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, 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 detailed 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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Tel +1-201-749-8000

stryker

Spine Division

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