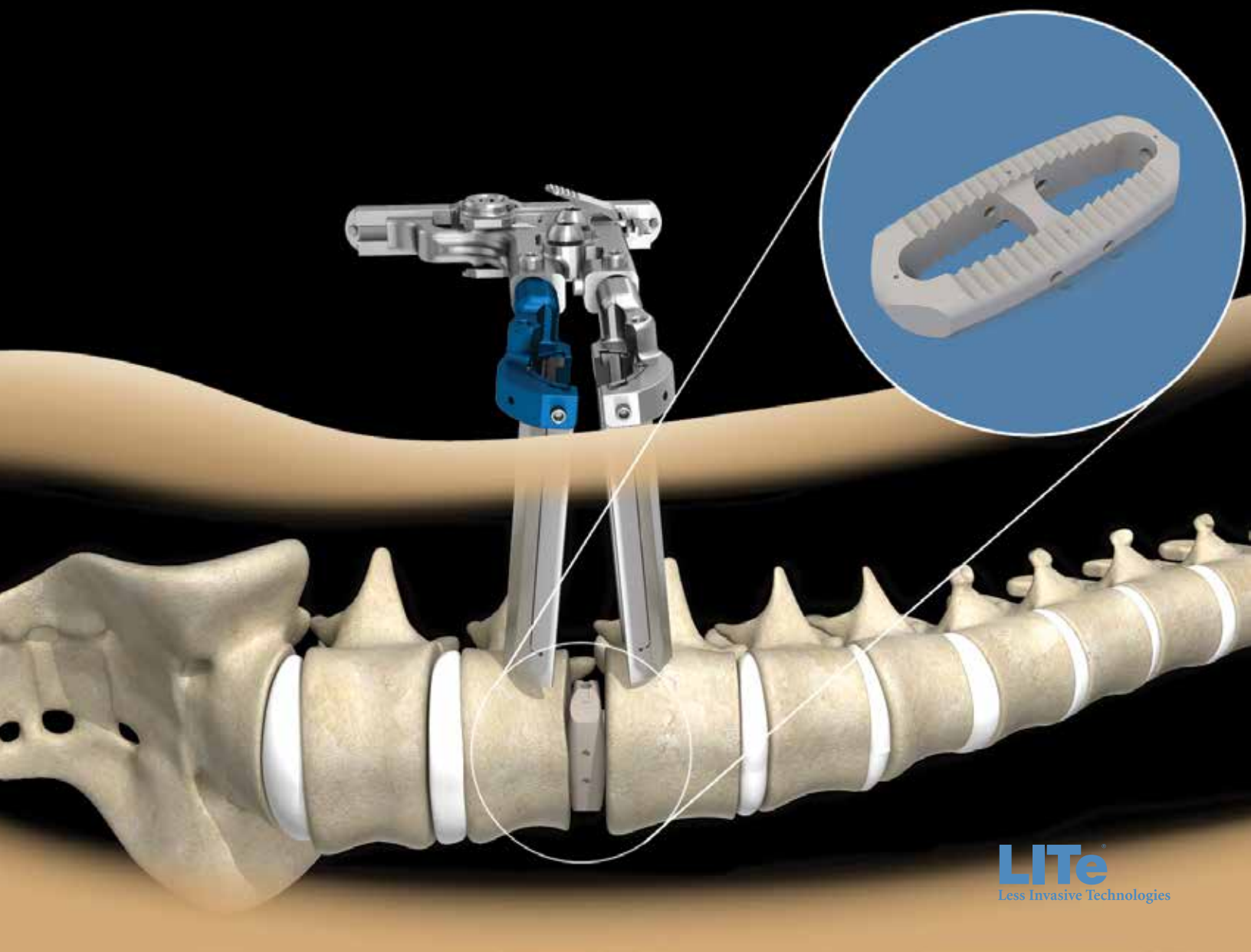
stryker

Spine

ARIA® Spinal System

Surgical Technique



LITe®
Less Invasive Technologies

ARIA Spinal System
Surgical Technique

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ARIA Spinal System
Surgical Technique

Acknowledgments

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Edward Dohring, MD
Spine Institute of Arizona
Scottsdale, AZ

Jeffrey Roh, MD
Seattle Minimally Invasive Spine Center
Orthopedics International
Seattle, WA

Introduction

One primary objective of Stryker Spine Less Invasive Technologies (LITe) is to replicate the clinical results of the corresponding open procedure. At the moment there is insufficient data to show that minimally invasive spine surgery provides any short and long term benefit to patients when compared to traditional spine surgery.

The **ARIA Spinal System**, part of the LITe platform, was designed to provide access and treatment to the lumbar spine via a lateral or anterolateral approach, including anterior retroperitoneal exposure through a small incision. This surgical technique allows the placement of an **AVS ARIA PEEK Spacer** across the disc space while avoiding the anterior vessels and posterior neural and bony elements.

Important

This Surgical Technique sets forth detailed, recommended procedures for using the **ARIA Spinal System**. It offers guidance that you should heed; however, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any Stryker implant or instrument.

Note: No acid or alkaline solvents should be used in the cleaning of anodized components.

Note: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.

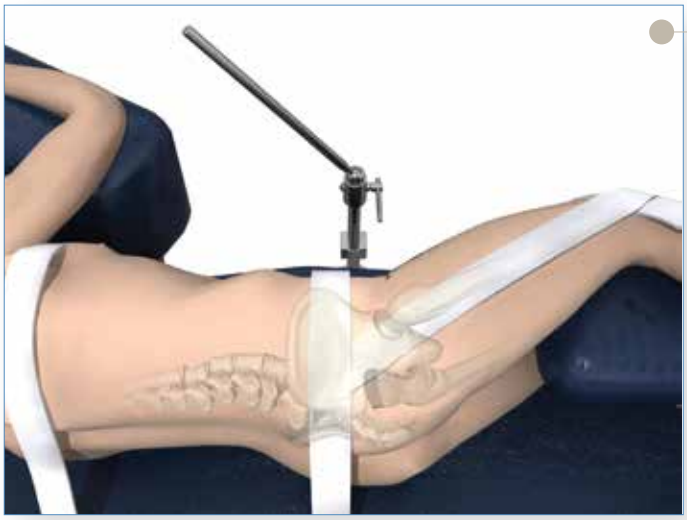
Note: Do not use if packaging or instrument is damaged. Check instrument before and after use.

Patient Positioning

- The patient is placed on a flexible surgical table in a direct lateral decubitus (90 degree) 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.



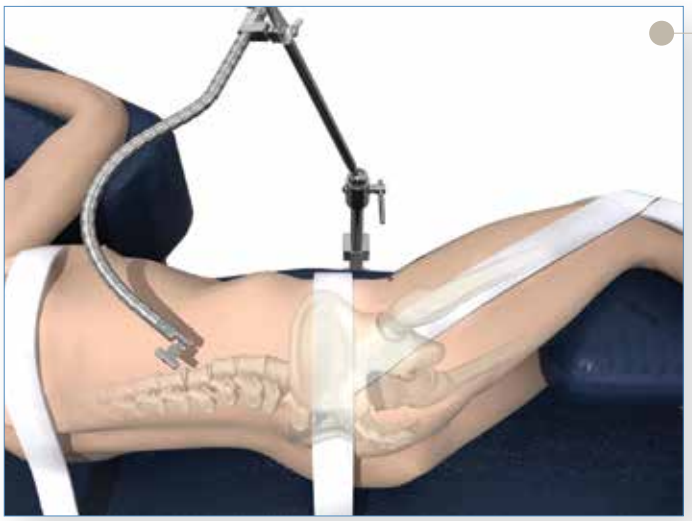
Arm Assembly

The **Arm Post** (**48250240**) 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.

Note: Make sure to place the **Arm Post** out of the way of the anticipated direction of fluoroscopy.

- Turn the **Arm Post** locking mechanism clockwise to secure it to the bed.



- Once the **Arm Post** is secure, attach the **Snake Arm** (**48755400**), to the **Arm Post** and lock into place.

Note: The **Snake Arm** should be properly reset and lubricated between uses.

Note: The **Articulating Arm** (**48758452**) with table clamp may be used as an alternative.

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

Note: When using a Jackson Table, an OSI Adapter is needed to mount the **Arm Post** to the table.

Options are:

OSI Retractor Adapter PN 5888
OSI Slide Rail Adapter PN 5855-830

Lighting Preparation

- Attach the **Light Source (48252106)** to the appropriate adapter.
- Insert the **Light Cable (48758451)** into the **Light Source**.

Note: The **Light Cable** is sold non-sterile and must be sterilized prior to use.

- Turn on the **Light Source** power to verify light output.

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.

Instrument Bar

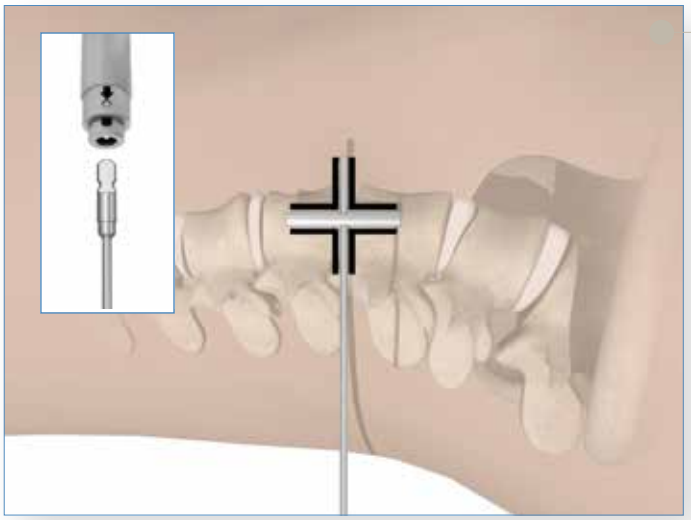
48250240
Arm Post

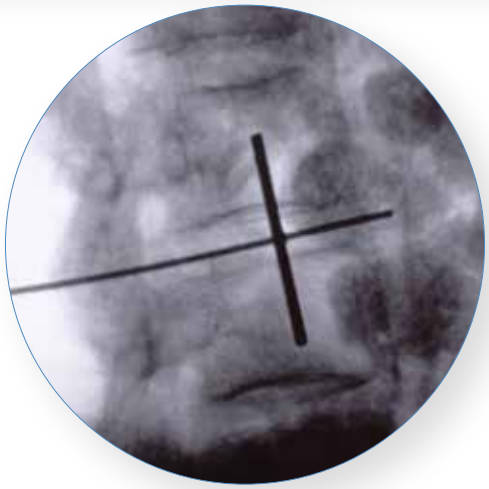
48755400
Snake Arm

48755452
Articulating Arm

48252106
Light Source

48758451
Light Cable

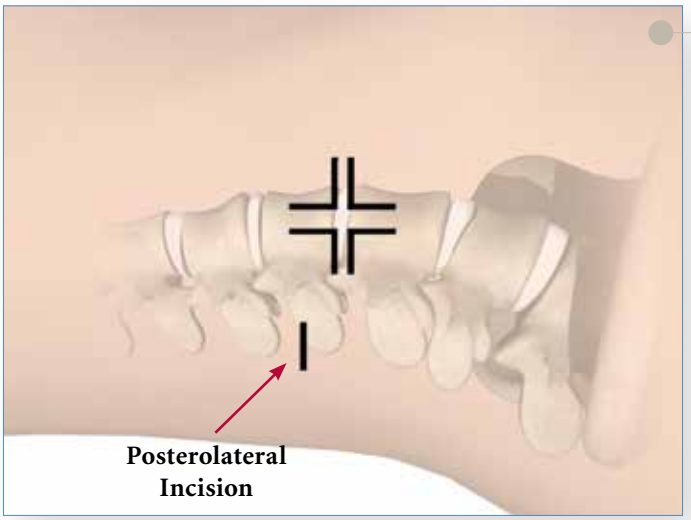




Establishing Access

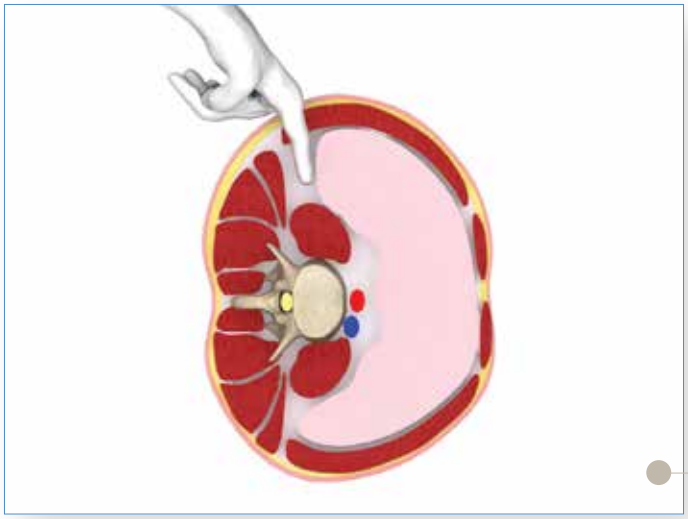
- Localize the disc space of surgical interest by using AP and lateral fluoroscopy.
- Insert the **Landmark Identifier Crosshair (48755720)** into the **Quick Release Handle (48755702)** by aligning the arrow on the tip of the **Quick Release Handle** to the flat end of the **Landmark Identifier Crosshair**.
- 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.

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.

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

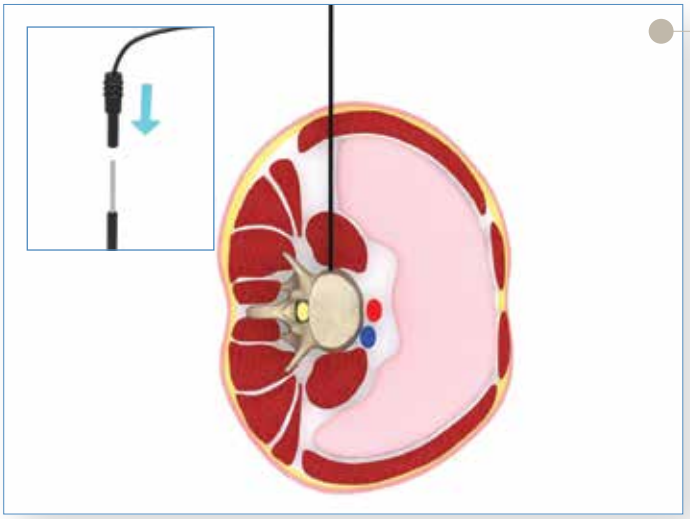
Note: Finger (or blunt clamp) dissection should be performed in line with the muscle fibers.

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

Instrument Bar

48755720
Landmark Identifier Crosshair

48755702
Quick Release Handle



Neuromonitoring Probe Insertion

- Attach the **Neuromonitoring Cable (48755008)** to the **Neuromonitoring Probe (48755006)**.

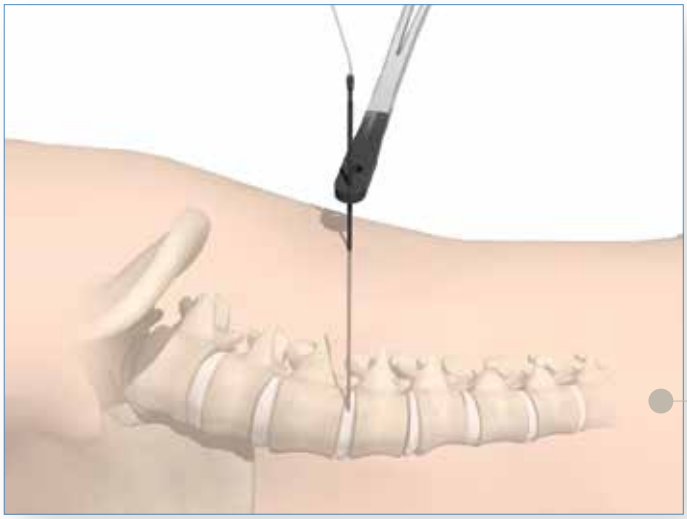
Note: The **Neuromonitoring Probe** is 2.1mm in diameter.

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.

- 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.

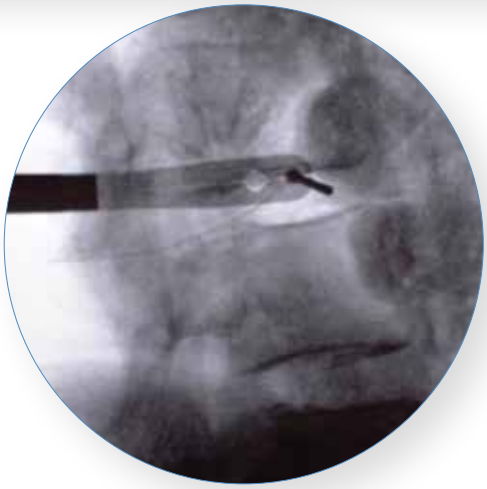


Note: For added safety, conduct free-running and triggered EMGs with the **Neuromonitoring Probe** while going through the psoas muscle.

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.

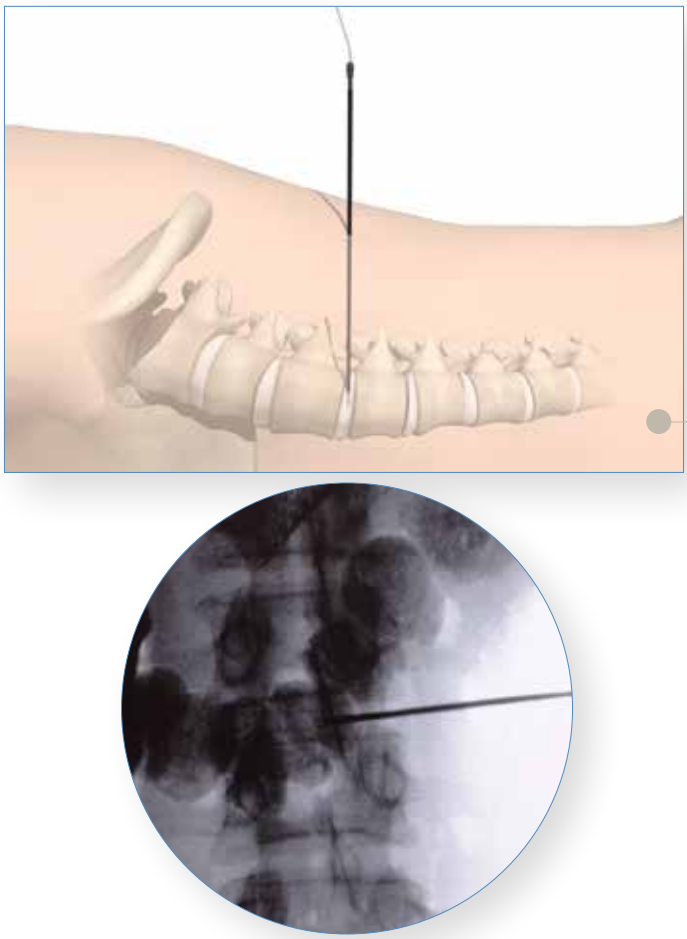
- Use fluoroscopic imaging to confirm proper alignment of the **Neuromonitoring Probe**.



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 (48755004)** 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.

Note: Use fluoroscopic imaging with the advancement of the **Neuromonitoring Probe**.

Note: If needed, clamp the probe and mallet the probe into the annulus.

Note: For collapsed discs or osteophytes, use a **Sharp Guide Wire (48755007)** with **Dilator 1 (48755001)**.

Note: The **Sharp Guide Wire** is a single use instrument.

▶ Use fluoroscopic imaging to confirm the final location of the **Neuromonitoring Probe**.

▶ Disconnect the **Neuromonitoring Cable** from the **Neuromonitoring Probe.**

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.

Instrument Bar

48755008
Neuromonitoring Cable (Disposable)

48755018
Lead Crocodile Clip

48755028
Lead Ext Blue

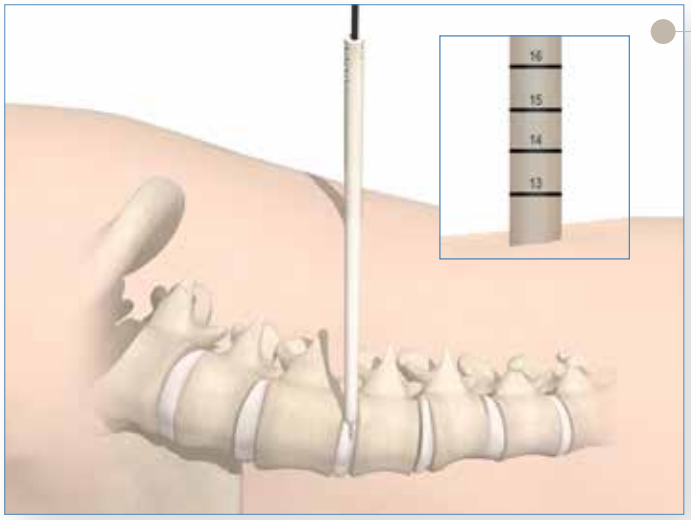
48755006
Neuromonitoring Probe (Disposable)

48755005
Guide Tissue Resector

48755004
Probe Holder

48755007
Sharp Guide Wire (Disposable)

48755001 – 6.4mm
Dilator 1 (Disposable)



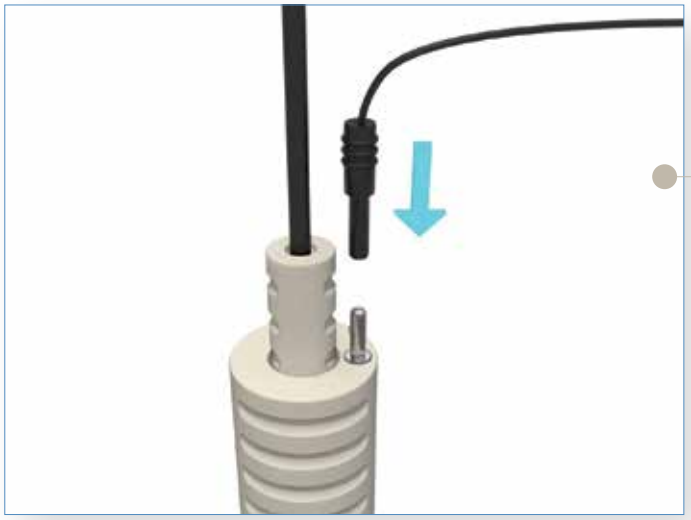
Sequential Dilation

- 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**.

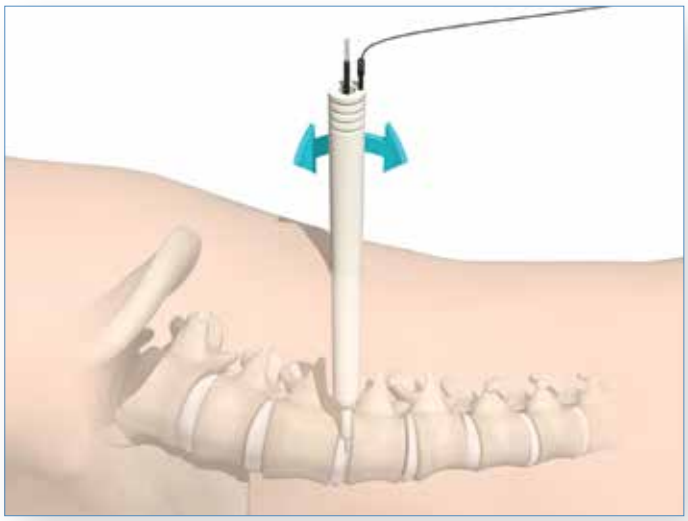
Note: Tactile feel, fluoroscopic imaging, anatomical knowledge of spinal elements, review of preoperative images, and direct partial visualization may all contribute towards desired accurate instrument placement.

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

The Dilators have depth markings (50-160mm) laser etched which correlate to the Retractor Blade lengths.



- Attach the end of the **Neuromonitoring Cable** to **Probe Dilator 2 (48755002)**.
- 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 (48755003)**.
- 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.

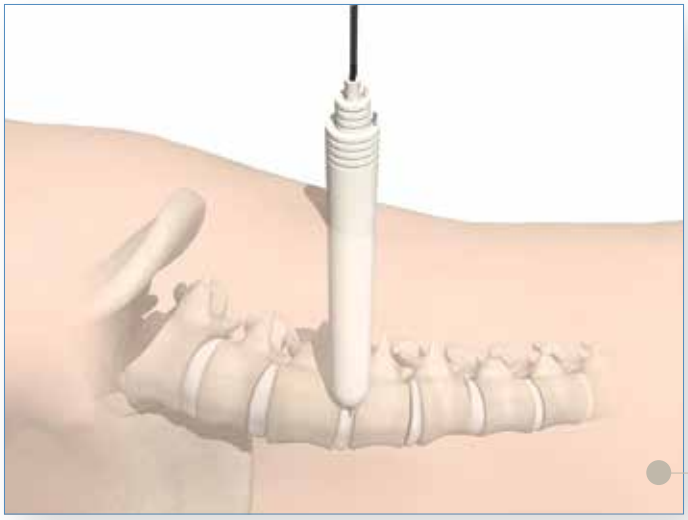


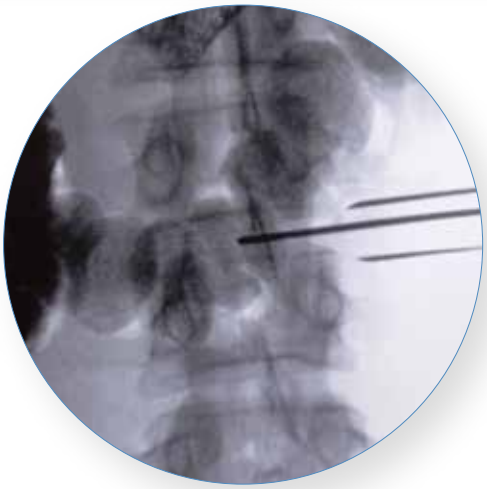
Note: Stimulation of the Dilators will help to avoid the neural elements through the psoas muscle.

Note: Make sure the line markings on the Dilators are flush to ensure that they are fully seated. Fluoroscopic imaging can also 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.

Note: The Dilators are single use instruments.





- 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.

Instrument Bar

48755001 – 6.4mm
Dilator 1 (Disposable)

48755006
Neuromonitoring Probe (Disposable)

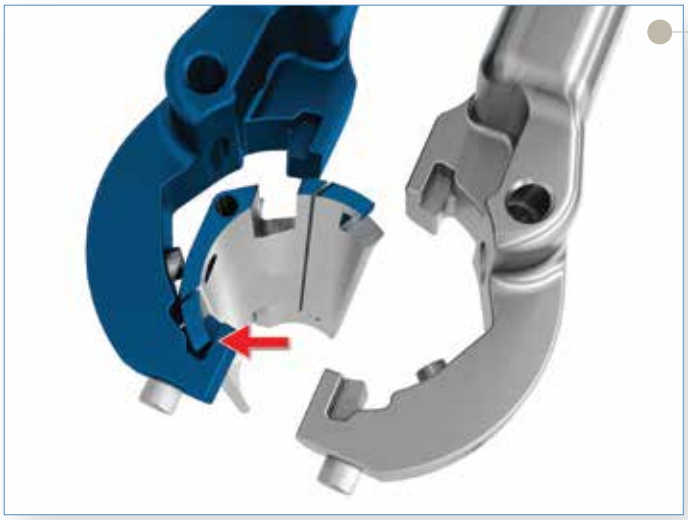
48755008
Neuromonitoring Cable (Disposable)

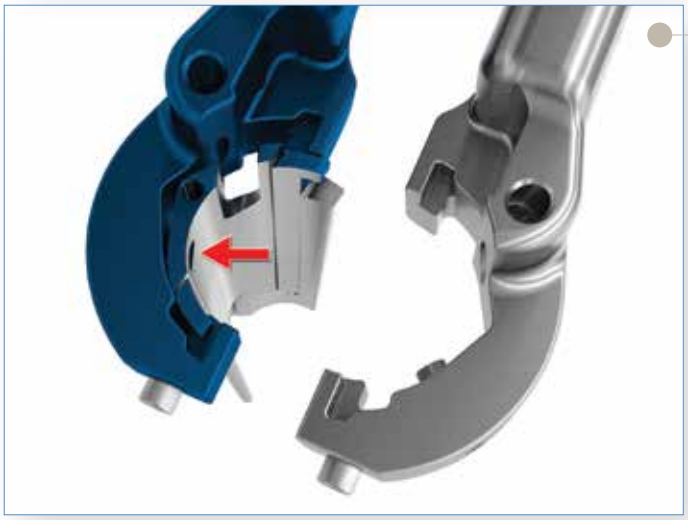
48755018
Lead Crocodile Clip

48755028
Lead Ext Blue

48755002 – 14.4mm
Probe Dilator 2 (Disposable)

48755003 – 22.5mm
Probe Dilator 3 (Disposable)





Retractor Assembly

Assemble each **Retractor "Blade" (48755 (050 – 090), (100 - 160))** into the **Retractor "Base" (48755000)**.

▶ Choose a **Blade** length based on where the top of the skin meets the laser markings on the Dilator.

Note: If the skin is between two laser markings on the Dilator choose the next longest **Blade**.

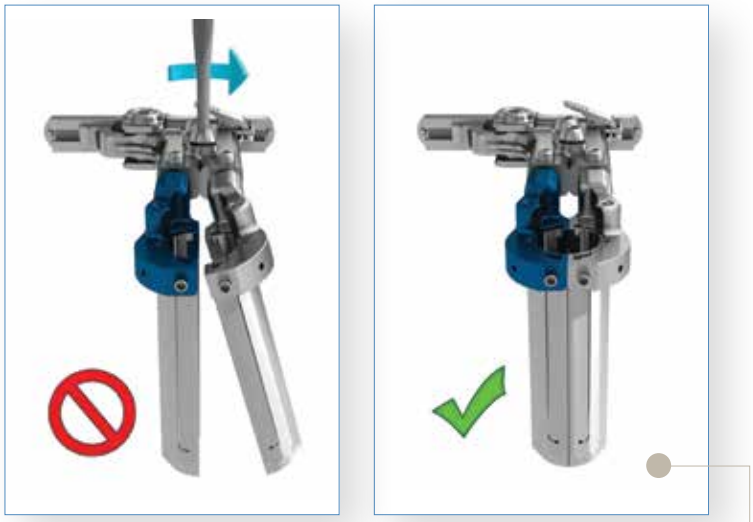
1. Insert the tab at the distal end of the **Blade** with the slot in the **Base**.
2. Locate the hole in the proximal end of the **Blade** with the pin in the **Base**.
3. Twist the **Blade** to snap in the other tab.
4. Release the **Blade** so that it engages the **Base**.
5. Repeat the process for 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 (see ARIA Retractor Lubrication Instructions, page 40).



▶ Visually ensure that the blade holders are aligned. If not, adjust the angulation screws by inserting the **Retractor Hex Driver** (**48250200**) and turning clockwise.

Use the **Anti Rotational Key** (**48755701**) to prevent the Retractor Blades from splaying or moving during insertion.

▶ Insert the **Anti Rotational Key** through the openings in the left and right blade holders.

Instrument Bar

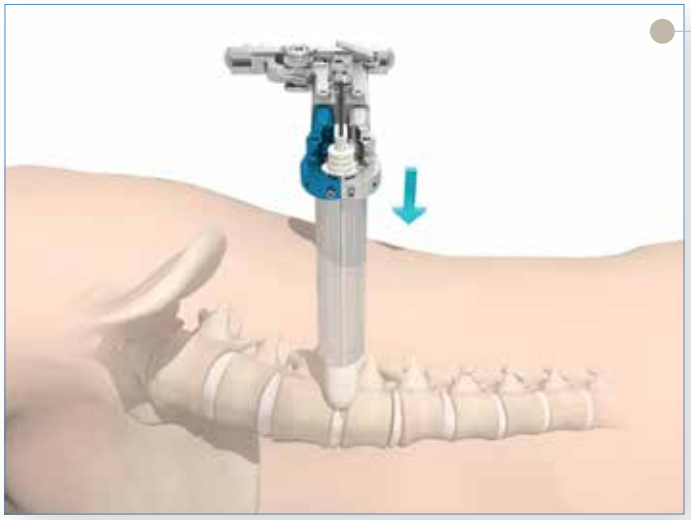
48755050 – 50mm
48755060 – 60mm
48755070 – 70mm
48755080 – 80mm
48755090 – 90mm
48755100 – 100mm
48755110 – 110mm
48755120 – 120mm
48755130 – 130mm
48755140 – 140mm
48755150 – 150mm
48755160 – 160mm

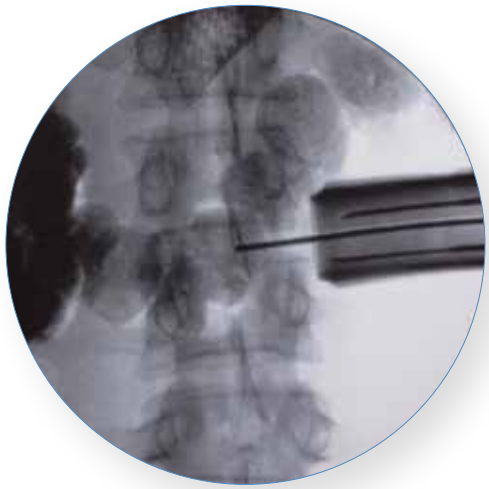
Retractor Blades

48755000
Retractor Base

48250200
Retractor Hex Driver

48755701
Anti Rotational Key



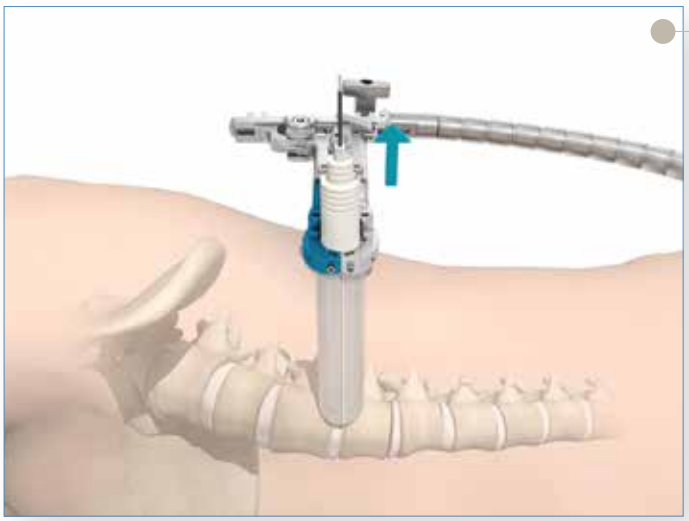


Retractor Insertion

- 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.

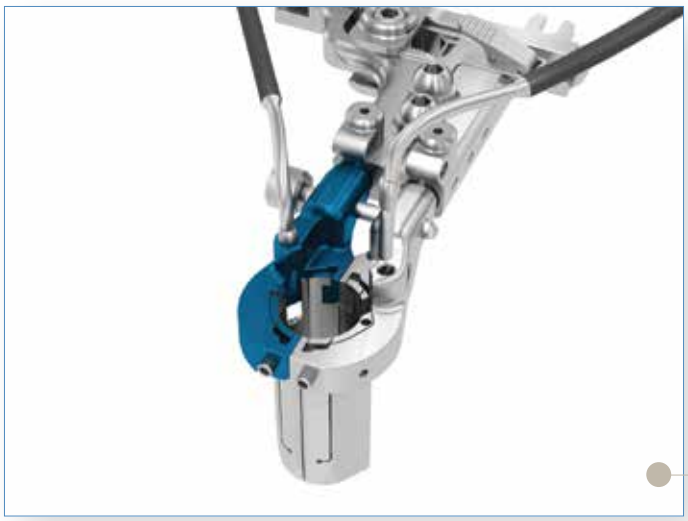


Arm Assembly Attachment

- 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.

Note: Hold the **Neuromonitoring Probe** in position when removing the Dilators.

- Use fluoroscopic imaging to confirm appropriate **Retractor** positioning.



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.

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.

- Stimulate the exposed area with the **Neuromonitoring Probe** to ensure the surgical field is free of neural elements.

Note: Before use, visually ensure the coating insulation at the tip of the **Neuromonitoring Probe** is not compromised.

Instrument Bar

48755006

Neuromonitoring Probe (Disposable)

48755008

Neuromonitoring Cable (Disposable)

48755018

Lead Crocodile Clip

48755028

Lead Ext Blue

48755400

Snake Arm

48755452

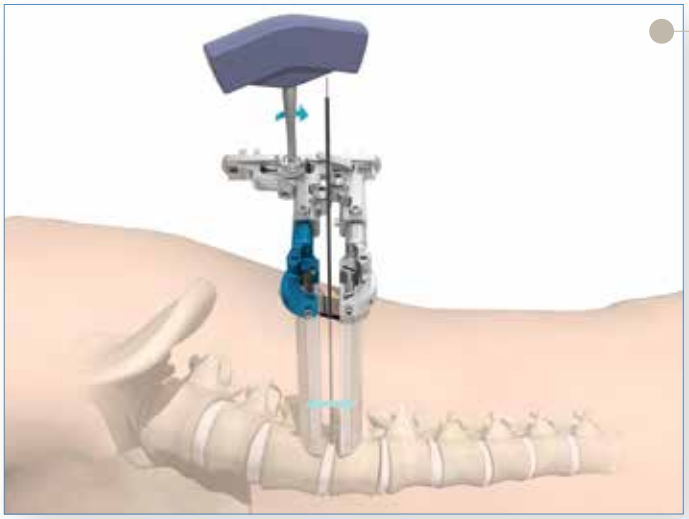
Articulating Arm

48755000

Retractor Base

48758451

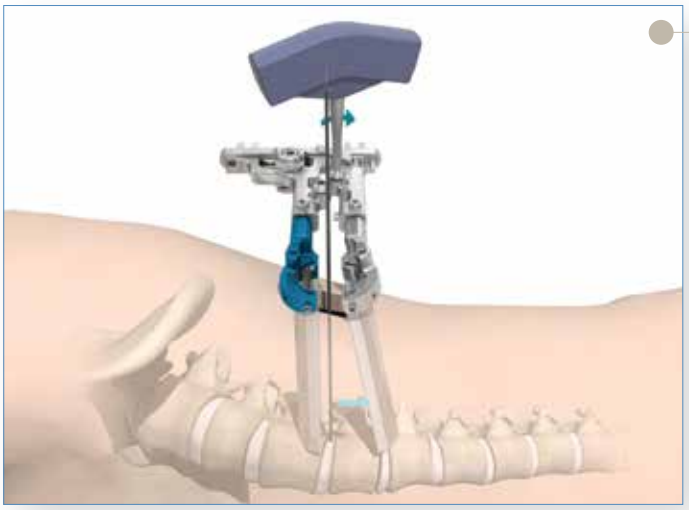
Light Cable



Retractor Opening/Closing Mechanism

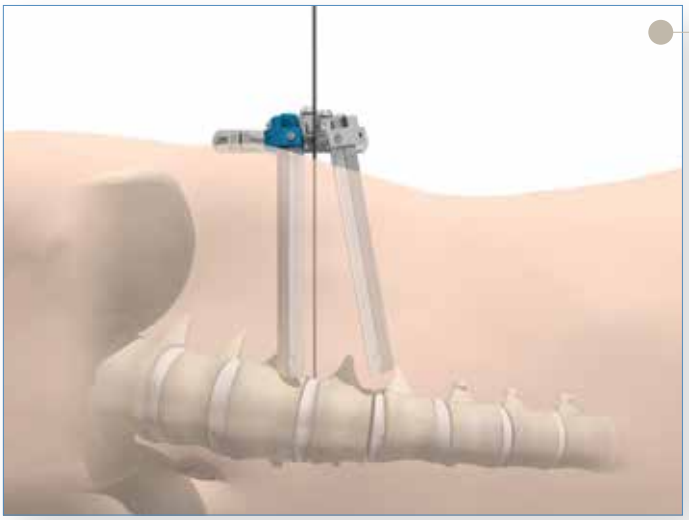
- Remove the **Anti Rotational Key** from the blade holders.
- Insert the **Retractor Hex Driver** into the translation screw of the **Retractor Base** and turn clockwise to expand the Retractor Blades open.

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

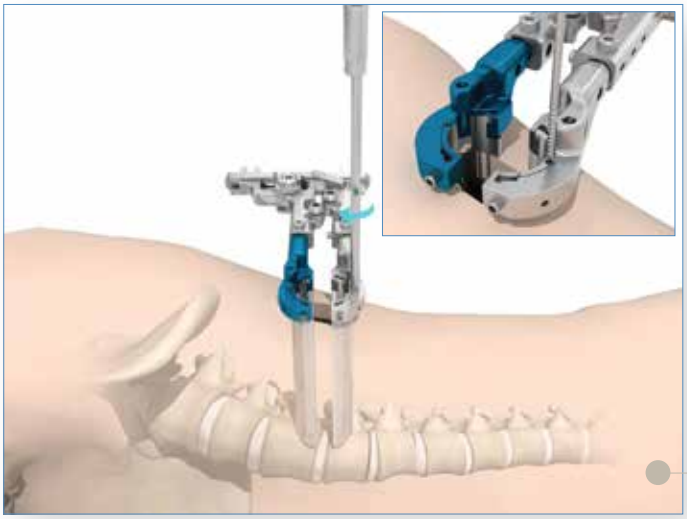


- Insert the **Retractor Hex Driver** into the angulation screws and turn clockwise to expand the distal end of the Retractor Blades.

Note: The angulation screws will angulate each of the Blades independently up to 15 degrees.



- 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** (**48755 (850 - 890), (900 - 960)**) into the vertebral body.

- Insert the **Anchoring Pin Driver** (**48755703**) 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.

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.

Note: The **Anchoring Pin** is a single use instrument.

- Remove the anchored **Neuromonitoring Probe**.

Instrument Bar

48755701
Anti Rotational Key

48250200
Retractor Hex Driver

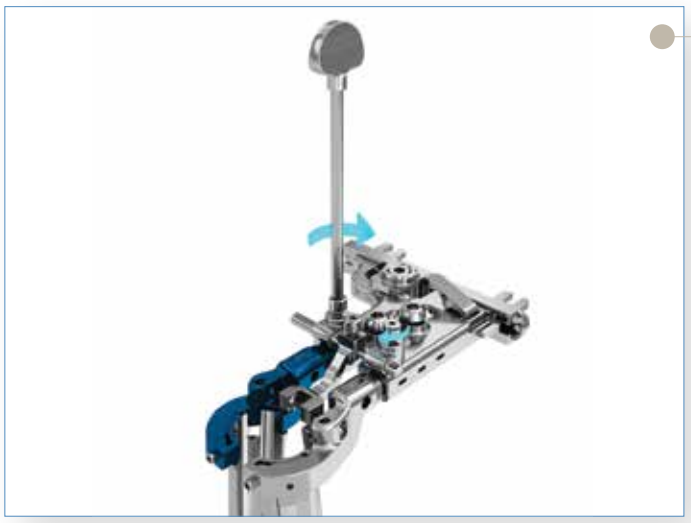
48755000
Retractor Base

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

48755703
Anchoring Pin Driver

48755702
Quick Release Handle

48755006
Neuromonitoring Probe (Disposable)



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

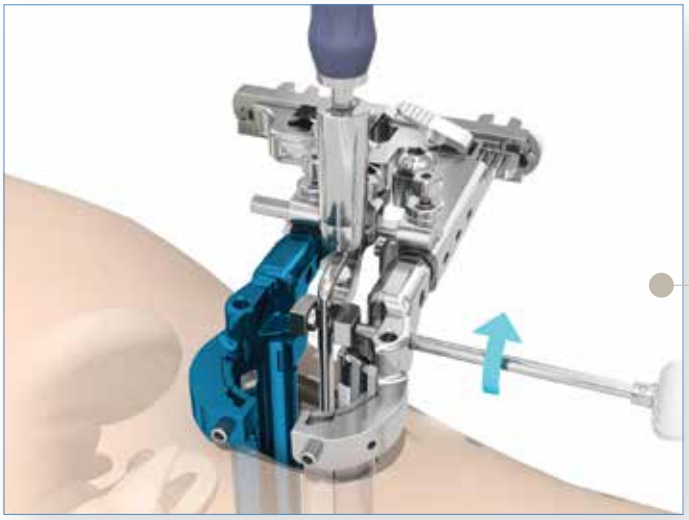
- Align the two holes on the **Posterior Frame (48759950)** with the two bosses on the **Retractor Base**.
- Secure the frame by finger tightening the two distal end thumb screws or by using the **AP Frame Driver (48755700)**.

- Choose an appropriate option/length, **AP Retractor Blade, AP Blade, Narrow,** and **AP Blade, Wide**

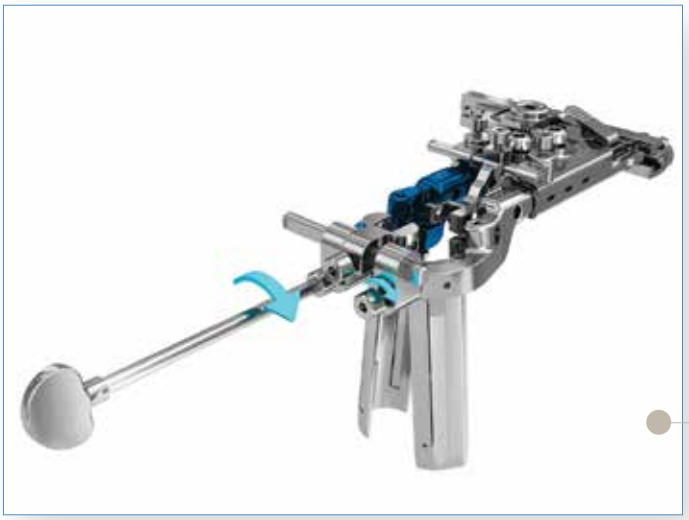
Note: The following table shows the sizing scheme as it correlates to the length of the Retractor Blades being used. The technique is the same for all AP Blades.

AP 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

AP Blade (narrow/wide)	Blade Lengths
80mm	70mm-80mm
100mm	90mm-100mm
120mm	110mm-120mm
140mm	130mm-140mm
160mm	150mm-160mm

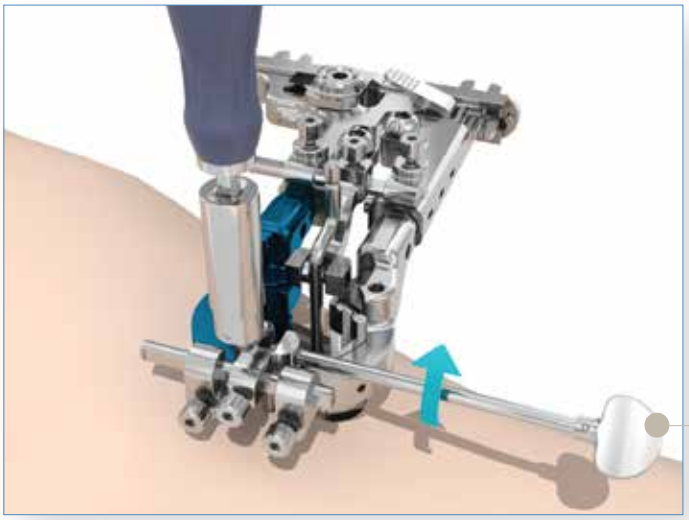


- Insert the **AP Retractor Blade** into the **Quick Release Handle** by pushing down on the quick release tip.
- Position the **AP Retractor Blade** into the **Posterior Frame**, ensuring the blade rests within the v-shaped feature.
- Once a desired position is achieved, lock the center arm by tightening the thumb screw.
- Lock the **Posterior Frame** by inserting the **AP 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 (48759900)** with the two bosses on the front of the **Retractor Base**.
- Secure the frame by tightening the two distal end thumb screws.



- Choose an appropriate length for the **AP Retractor Blade**.
- Position the **AP 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 **AP 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.

Instrument Bar

48759950
Posterior Frame

48755000
Retractor Base

48755700
AP Frame Driver

48755702
Quick Release Handle

48759900
Anterior Frame

48755708 – Short 4
48755710 – Medium 2
48755712 – Medium 4
48755716 – Long 4

AP Retractor Blades

48759908 – 80mm
48759910 – 100mm
48759912 – 120mm
48759914 – 140mm
48759916 – 160mm

AP Blade, Narrow

48759928 – 80mm
48759930 – 100mm
48759932 – 120mm
48759934 – 140mm
48759936 – 160mm

AP Blade, Wide

Disc Removal and Preparation

The ARIA Spinal System offers a comprehensive set of decompression instruments. This 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.


Penfield Elevators


Nerve Hooks


Nerve Retractors


Suction Tube


Osteotomes

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.
- Tips rounded 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.

Kerrison Rongeurs

Pituitary Rongeurs

Curettes

Rasps

Cobb Elevators

Disc Removal and Preparation

- Make an incision through the annulus using the **Long Handle Knife (48361277)** or the **Bayoneted Knife Holder (48759702)**.

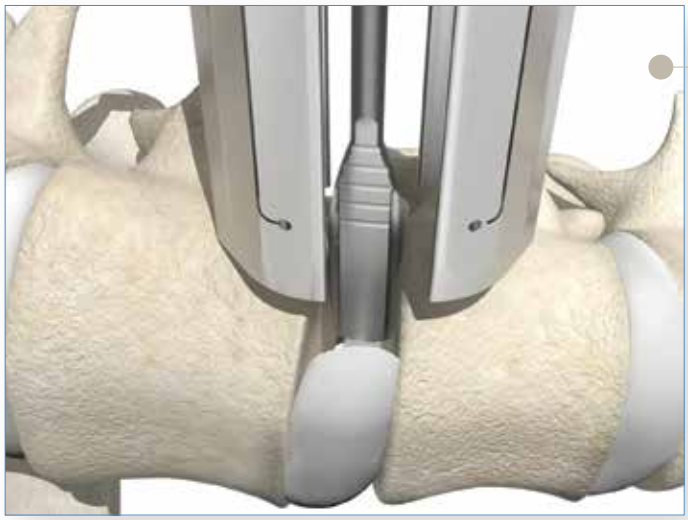
- Remove the disc by using any combination of curettes, cobb elevators, and rongeurs.

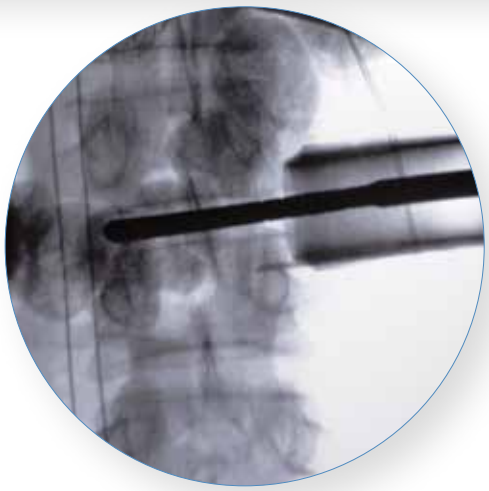
Note: If the disc is severely collapsed, an Osteotome may be utilized to create an initial opening into the disc.

Note: If the disc is severely collapsed, an **Osteotome (4875860 (0 - 1)** may be utilized as an initial distractor, followed by a combination of implant Trials and Reamer Distractors for further distraction.

- After the discectomy is completed, a **Cobb Elevator (4875800 (0 - 3))** may be used to release the contralateral annulus.

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





Option 1: Use of the Reamer Distractors

- Insert the **Reamer Distractor** into the **T-Handle (48061000)** by pulling up on the quick release tip.

- Insert the smallest **Reamer Distractor** into the disc space parallel to the disc space, while monitoring the insertion under fluoroscopic imaging.

Note: The widest side 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. These grooves can be visualized under fluoroscopic imaging and may be used as a guide to determine what length implant to select.

- Turn the **Reamer Distractor** 90 degrees to distract the disc space and to scrape the endplates. The endplates are scraped by rotating the **Reamer Distractor** clockwise or counterclockwise.

- After several turns, remove the **Reamer Distractor** without rotation.

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 soft and white (debris from the annulus fibrosus or cartilage), a larger **Reamer Distractor** can be used to reach the subchondral bone.

- Reamer Distractors of progressively increasing size are inserted sequentially, while monitoring the insertion under fluoroscopic imaging, thus widening the disc space until the optimal distraction is achieved.
- The final **Reamer Distractor** may temporarily be 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**.
- Remove the **Reamer Distractor** from the disc space.

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 Implant Trials and Reamer Distractors

- Insert the **Trial** into the **Trial Handle (48756500)** by pulling up on the quick release tip.
- Insert the smallest **Trial** parallel into the disc space.

Note: The implant Trials are smooth and rounded and are designed to reduce the risk of damage to the endplates during distraction of the disc space.

- Use controlled and light hammering on the **Trial Handle** to advance the **Trial** into the disc space, while monitoring the insertion under fluoroscopic imaging.
- Sequentially insert larger Trials to distract the disc space.
- The final **Trial** is temporarily left in position to maintain the disc space distraction.
- The same set of steps outlined previously (Option 1: Use of the Reamer Distractors) can be applied here for further endplate preparation and distraction.
- Remove the **Trial/Reamer Distractor** from the disc space.

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.

Instrument Bar

48759702
Bayoneted Knife Holder

48361277
Long Handle Knife

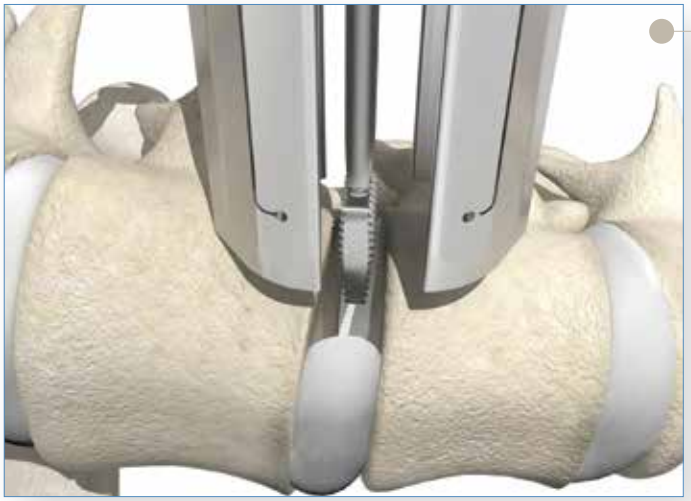
48758000 – 16mm Angled
48758001 – 16mm Straight
48758459 – 16mm Straight Teardrop
48758002 – 20mm Angled
48758003 – 20mm Straight
48758460 – 20mm Straight Teardrop
Cobb Elevators

48758600 – 10mm Straight
48758601 – Edge Cutting
Osteotomes

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

48061000
T-Handle

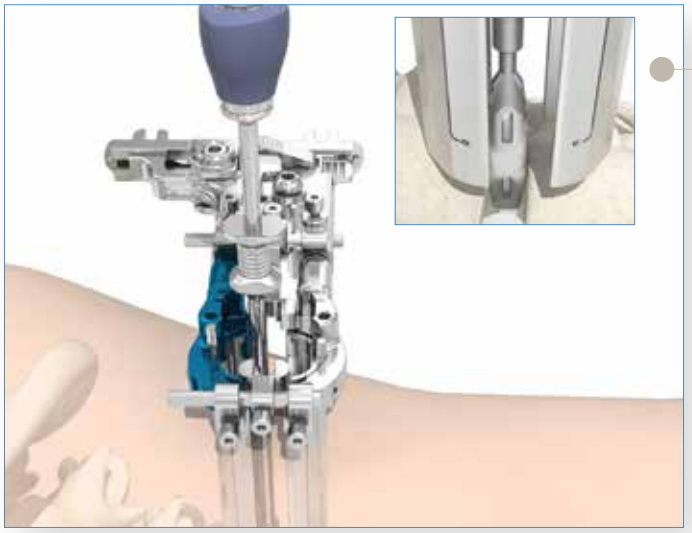
48756500
Trial Handle

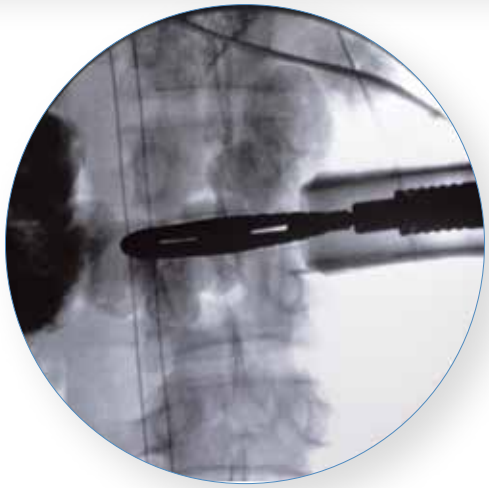


Option 3: Use of the Implant Trials, Reamer Distractors and Rasps

- The same set of steps outlined previously (Option 2: Use of the Implant Trials and Reamer Distractors) can be applied in conjunction with using the Rasps for endplate preparation and distraction.
- The **Dual-Sided Rasp** (**48758400**) and **Rasp Scraper** (**48758401**) 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.





Trialing and Preparation of the Implant (Trialing Option 1)

Once the endplates have been effectively prepared, the Trials may be used to help determine the appropriate height, width, and length of the implant.

- Insert the smallest **Trial** into the **Trial Handle** by pulling up on the quick release tip.
- Use controlled and light hammering on the **Trial Handle** to advance the **Trial** into the disc space, while monitoring the insertion under fluoroscopic imaging.
- Sequentially insert Trials into the disc space.

Note: The **Trial** footprint is available in all height and width offerings, including both lordotic and parallel configurations. However, it is only available in a medial/lateral length of 50mm and 60mm. Each groove is separated in 5mm increments starting from 40mm. These grooves can be visualized under fluoroscopic imaging and may be used as a guide to determine what length implant to select: 40, 45, 50, 55, or 60.

- To remove the **Trial**, use the slot on the **Slap Hammer** (**48061001**) in line with the **Trial Handle** shaft and apply an upward force.

Trialing and Preparation of the Implant (Trialing Option 2)

Threaded Engagement Trials.

- Attach the smallest **Trial** to the **Trial Shaft (48759700)** by threading the **Trial Shaft** clockwise until a positive stop is achieved.

- Attach the **Trial Handle (48759701)** onto the **Trial Shaft**, by pulling up on the quick release mechanism of the **Trial Handle**, followed by placing the **Trial Handle** onto the **Trial** and releasing the quick connect mechanism of the **Trial Handle.**

- Use controlled and light hammering on the **Trial Handle** to advance the **Trial** into the disc space, while monitoring insertion under fluoroscopic imaging.

Instrument Bar

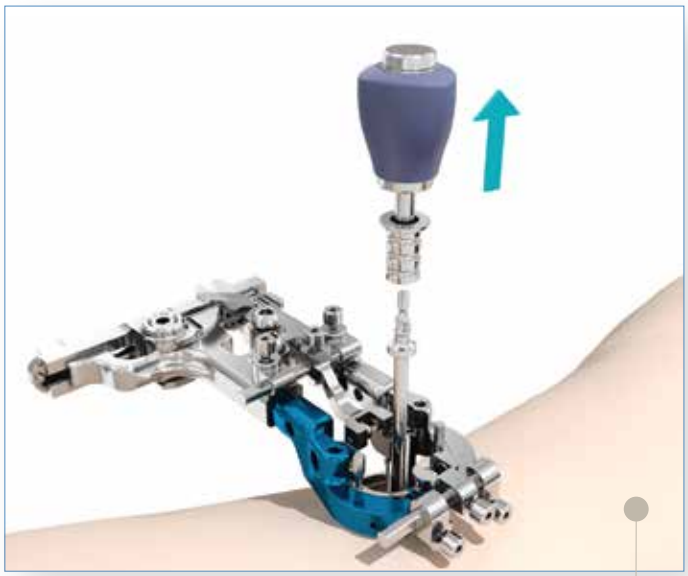
48759701
Trial Handle (Option 2)

48759700
Trial Shaft (Option 2)

48759600
Slap Hammer

48759108 – 60mm x 18mm x 8mm - 0°
48759110 – 60mm x 18mm x 10mm - 0°
48759112 – 60mm x 18mm x 12mm - 0°
48759114 – 60mm x 18mm x 14mm - 0°
48759116 – 60mm x 18mm x 16mm - 0°
48759118 – 60mm x 18mm x 18mm - 0°
48759208 – 60mm x 22mm x 8mm - 0°
48759210 – 60mm x 22mm x 10mm - 0°
48759212 – 60mm x 22mm x 12mm - 0°
48759214 – 60mm x 22mm x 14mm - 0°
48759216 – 60mm x 22mm x 16mm - 0°
48759218 – 60mm x 22mm x 18mm - 0°
48759308 – 60mm x 18mm x 8mm - 8°
48759310 – 60mm x 18mm x 10mm - 8°
48759312 – 60mm x 18mm x 12mm - 8°
48759314 – 60mm x 18mm x 14mm - 8°
48759316 – 60mm x 18mm x 16mm - 8°
48759318 – 60mm x 18mm x 18mm - 8°
48759408 – 60mm x 22mm x 8mm - 8°
48759410 – 60mm x 22mm x 10mm - 8°
48759412 – 60mm x 22mm x 12mm - 8°
48759414 – 60mm x 22mm x 14mm - 8°
48759416 – 60mm x 22mm x 16mm - 8°
48759418 – 60mm x 22mm x 18mm - 8°
Trial (Threaded Engagement)

Note: Selecting the appropriate height trial is important in order to avoid excessive distraction that may result in soft tissue damage.

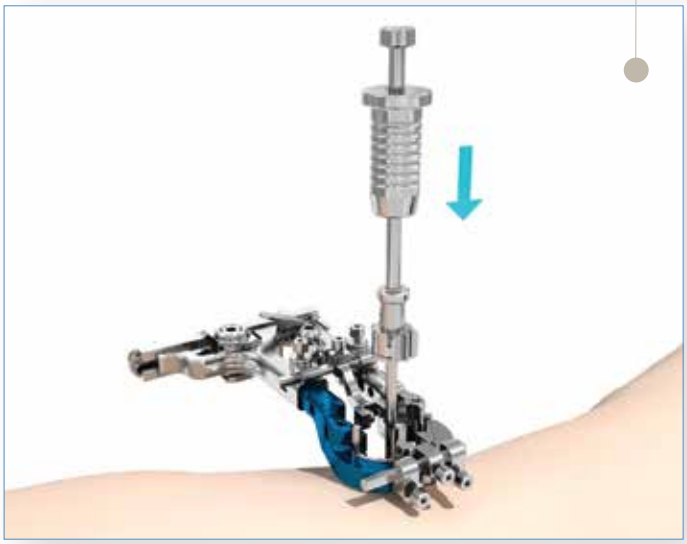


- Sequentially insert **Trials** into the disc space. The **Trial Shaft** can be removed once the **Trial** is impacted to provide better visualization of the **Trial** placement of a lateral fluoroscopic image. The **Trial Shaft** can then be re-engaged to remove the **Trial**.

Note: The **Trial** footprint is available in all height and width offerings, including lordotic and parallel configurations. The lordotic **Trials** feature a circular indentation to indicate the anterior side of the **Trial**.

Note: The **Trial** is only available in a medial/lateral length of 60mm. Each groove on the **Trial** is separated in 5mm increments, starting at 40mm. These grooves can be visualized under fluoroscopic imaging and may be used as a guide to determine what length implant to select: 40, 45, 50, 55, or 60.

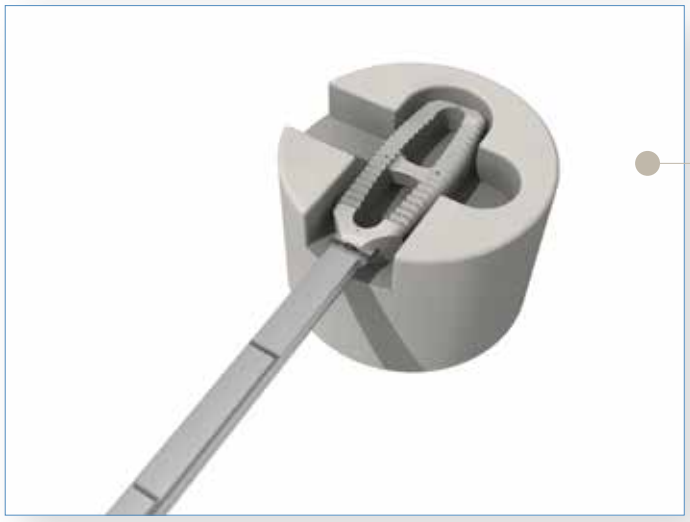
Warning: Avoid excessive cantilever and rotational force during trialing.



- To remove the **Trial**, remove the **Trial Handle** from the **Trial Shaft**. Prepare the **Slap Hammer (48759600)** by shifting it into the unlocked position. Place the **Slap Hammer** onto the **Trial Shaft** and move to the locked position. Use reverse hammer mechanism in an upwards fashion to remove the **Trial** from the disc space.

Unlocked

Locked



Select the appropriately sized **AVS ARIA** implant and attach it to the **Implant Inserter (48758500)** or **(48759500)**.

- **48758500**
  Fully back out the handle by turning the T-Handle counterclockwise until it bottoms out.

- Align the **Implant Inserter** tip with the side grooves located in the medial (back) side of the implant.

- While holding both the implant and the tip of the **Implant Inserter**, advance the inner shaft by turning the T-Handle clockwise until the handle bottoms out.

▶ **48759500**
Align implant with the **Implant Inserter**. Turn **Implant Inserter** knob clockwise to attach to the implant.

Note: When using the **Graft Protector** (**48759630**), first place the **Implant Inserter** (**48759500**) into the **Graft Protector**, then load the implant to the inserter. Autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone should be packed prior to attaching the implant to the inserter.

Note: Only **Implant Inserter** (**48759500**) is compatible with the **Graft Protector** (**48759630**).

▶ Place the implant in the **Graft Block** (**48758540**) and pack it with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

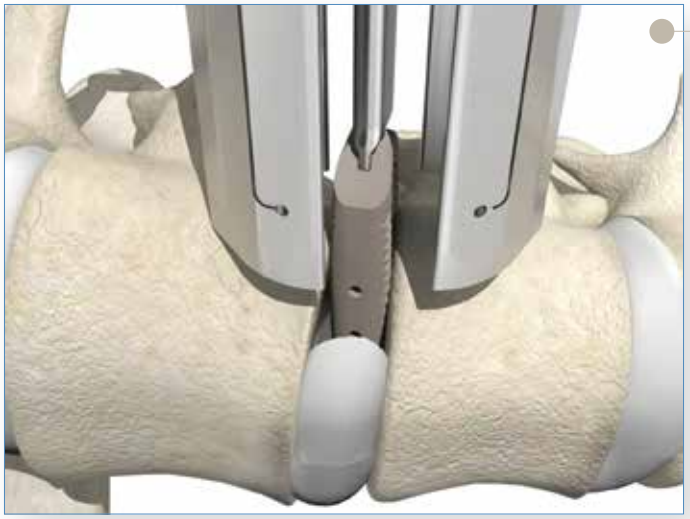
Note: The compacted graft should be flush with the upper and lower surfaces of the implant in order for it to be in contact with the endplates.

Instrument Bar

48758540
Graft Block

48759500
Implant Inserter

48759630
Graft Protector



Implant Insertion

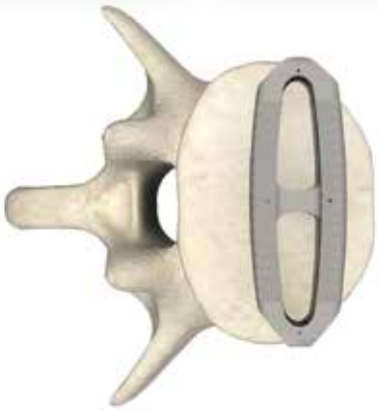
- Gently and progressively insert the **AVS ARIA** implant into the prepared disc space by applying controlled and light hammering on the **Implant Inserter (48758500)** handle, while monitoring the insertion under fluoroscopic imaging.

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

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

Note: Application of cantilever forces while using the Implant Inserter may result in breakage of the implant.

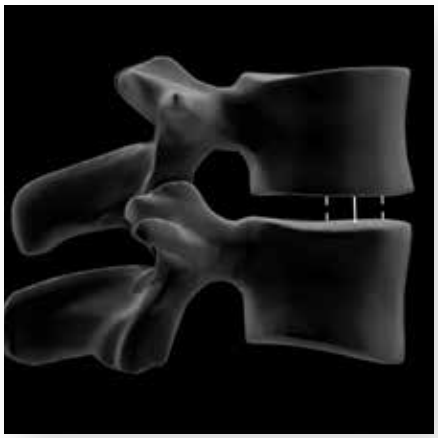
- When using the **Graft Protector** for insertion, insert the distal end of the **Graft Protector** into the disc space first. Ensure the notches are resting on the vertebral body. Then, progressively insert the **AVS ARIA** implant into the disc space.



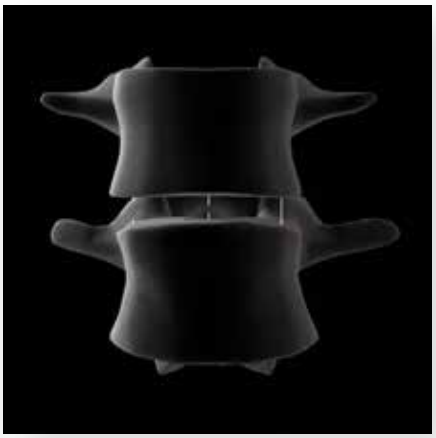
- Use fluoroscopic imaging to determine the final position of the implant.

Note: Proper placement of the implant is centered across the disc space on an AP fluoroscopic view, and between the anterior third and middle third of the disc space on a lateral fluoroscopic view.

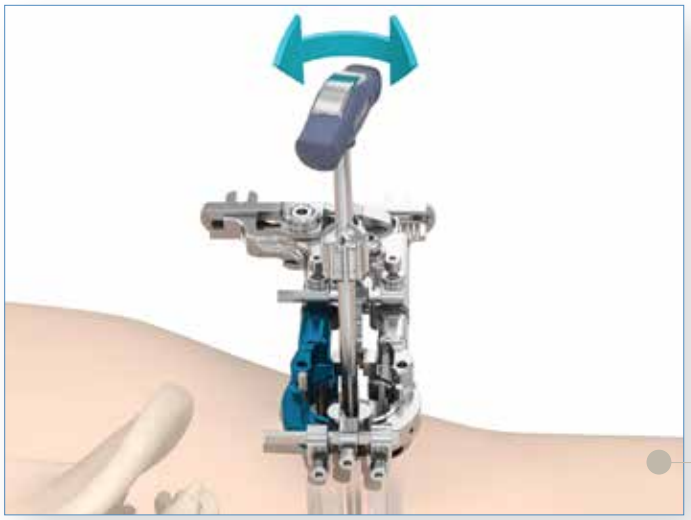
Note: There are seven tantalum markers embedded within the PEEK material of the **AVS ARIA** implants, which are designed to help visually confirm proper positioning and orientation of the implant in radiographic images.



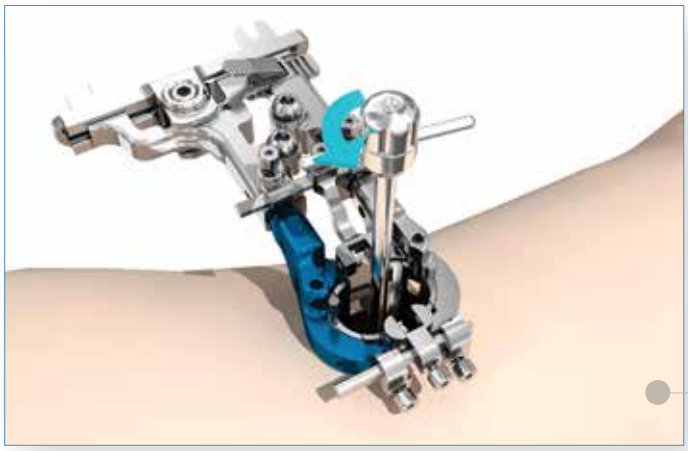
Lateral View



A/P View



▶ **48758500**
Remove the **Implant Inserter** by turning the T-Handle counterclockwise.



▶ **48759500**
Remove the **Implant Inserter** by turning the knob counterclockwise.

▶ Final adjustment of the implant can be performed using the **Implant Impactor** (**48758520**). Controlled and light hammering of the **Implant Impactor** will advance the implant in fine increments into its final position.

Intraoperative Rescue

If the implant needs to be realigned or removed, and is still engaged to the **Implant Inserter**, use the **Slap Hammer** to reverse impact the implant out of the disc space.

If the implant is disengaged from the **Implant Inserter**, the inserter should not be reattached to the implant for rescue. In this scenario, the **Implant Remover** (**48758530**) may be used to remove the implant. Align the tip of the **Implant Remover** to the threaded hole on the implant, and engage by turning the handle clockwise. The implant may then be removed by using the **Slap Hammer** to reverse impact the implant out of the disc space.

Instrument Bar

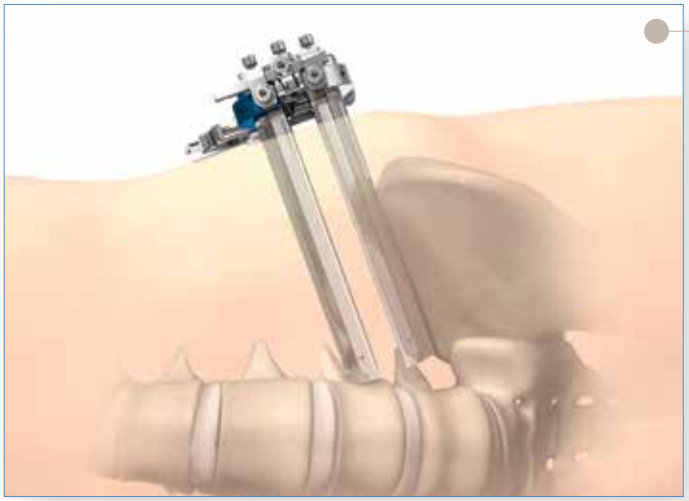
48758500
Implant Inserter

48758520
Implant Impactor

48061001
Slap Hammer

48758530
Implant Remover

48759500
Implant Inserter



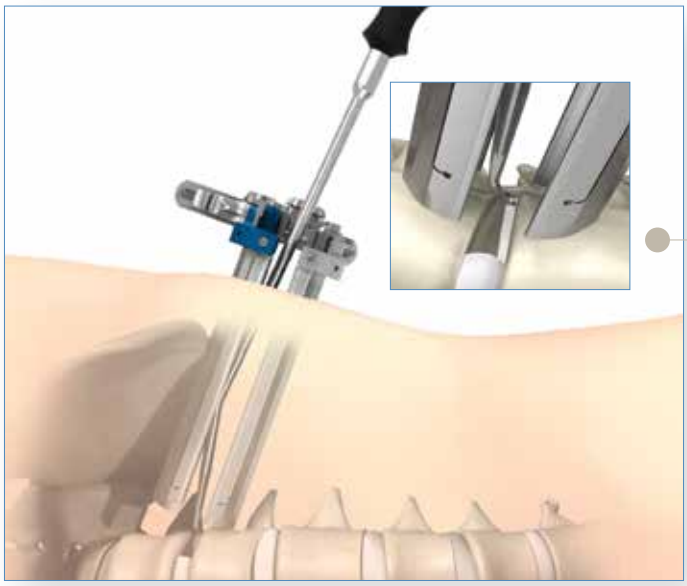
Angled Instruments

If patient anatomy causes the retractor to have an angled trajectory to the disc space, angled instruments can be utilized for disc preparation, trialing and implant insertion.

Disc Removal and Preparation

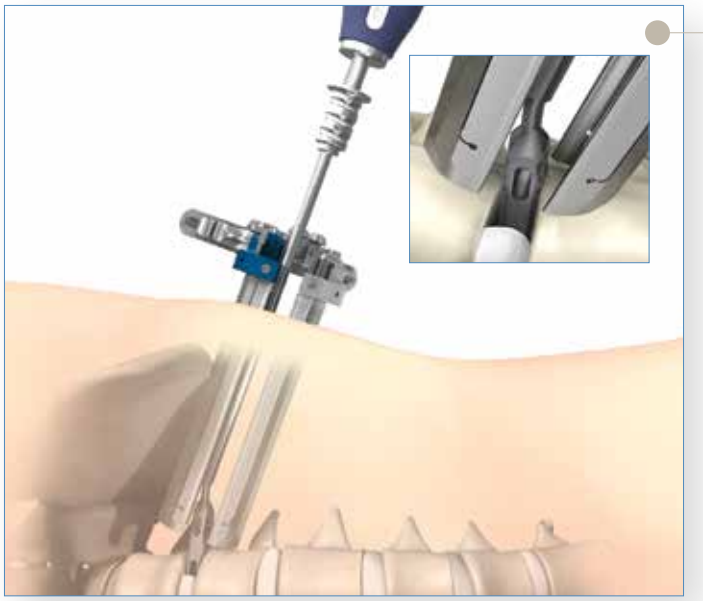
The angled disc preparation instrumentation is designed to perform the same function as the straight instrumentation described on pages 20 and 21:

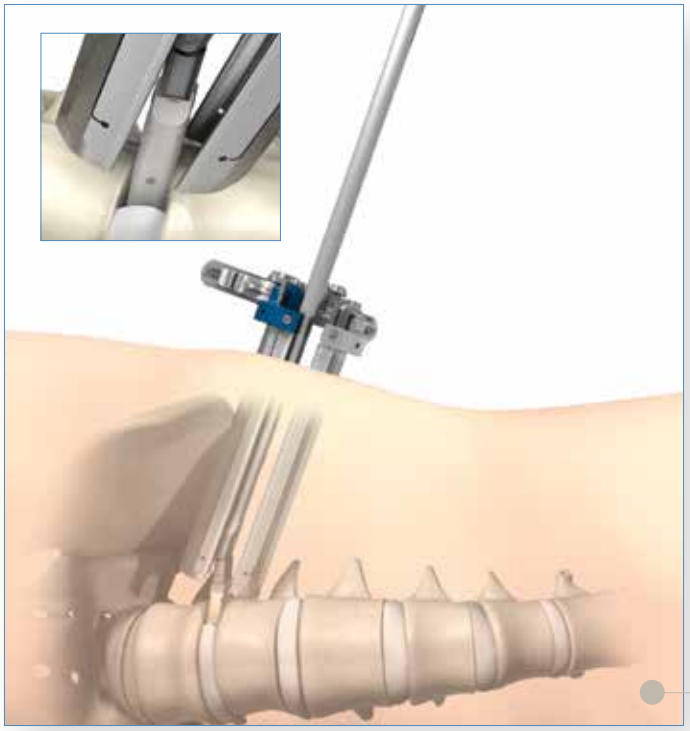
- Cobb Elevators: Loosen the disc material from the endplates.
- Pituitary Rongeurs: Remove the disc material from the disc space.
- Curettes: Remove any remaining disc material and cartilage from the disc space.
- Rasps: Remove any remaining disc material and cartilage from the disc space.



Trialing and Preparation of the Implant

The **Trial Handle (48759701)** and **Trial Shaft (48759700)** are utilized with both the straight and angled trials. To attach the **Angled Trial** to the **Trial Shaft**, thread the **Trial Shaft** clockwise until a positive stop is achieved and attach the **Trial Handle** onto the **Trial Shaft**.The trialing technique and **Slap Hammer** utilization is the same for the straight and angled trials. Refer to pages 25 - 26 for a full description.





Align the implant with the **Angled Implant Inserter** (**48759359**). Turn the **Angled Implant Inserter** knob clockwise to attach to the implant.

Gently and progressively insert the **AVS ARIA** implant into the prepared disc space by applying controlled and light hammering on the **Angled Implant Inserter**, while monitoring the insertion under fluoroscopic imaging.

Note: The distal end of the inserter is designed to flex, adjusting for the angle of the retractor during insertion. An arrow is laser marked on the handle and the word "TOP" is laser marked on the distal tip of the outer shaft to indicate the direction of the flexibility. The **Angled Implant Inserter** offers 15 degrees of flexibility.

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

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

Note: The **Graft Protector** (**48759630**) cannot be used with the **Angled Implant Inserter.**

Instrument Bar

48759359

Angled Implant Inserter

48759360

Angled Instrument Container

48759508 – 60mm x 18mm x 8mm - 0°
48759510 – 60mm x 18mm x 10mm - 0°
48759512 – 60mm x 18mm x 12mm - 0°
48759514 – 60mm x 18mm x 14mm - 0°
48759516 – 60mm x 18mm x 16mm - 0°
48759518 – 60mm x 18mm x 18mm - 0°
48759608 – 60mm x 22mm x 8mm - 0°
48759610 – 60mm x 22mm x 10mm - 0°
48759612 – 60mm x 22mm x 12mm - 0°
48759614 – 60mm x 22mm x 14mm - 0°
48759616 – 60mm x 22mm x 16mm - 0°
48759618 – 60mm x 22mm x 18mm - 0°

Angled Trial

48759701

Trial Handle

48759700

Trial Shaft

48759350

Cobb Elevator, 16mm, Upbiting Angled Access, Teardrop

48759351

Cobb Elevator, 16mm, Downbiting Angled Access, Teardrop

48759352 – Curved Right Angled Access
48759353 – Curved Left Angled Access

Pituitary Rongeur

48759354

Rasp, Dual Sided, Curved Angled Access

48759355 – 5.2mm
48759356 – Teardrop, 8mm

Ring Curette, Angled Access

48759357

Cup Curette, Curved Right Angled Access, Angled Tip, 5.2mm

48759358

Cup Curette, Curved Left Angled Access, Angled Tip, 5.2mm

Closure

- Examine the site for bleeding.
- Remove **Anchoring Pin** and **AP Retractor Blades** before closing the **Retractor**.
- Collapse the **Retractor** to its original position, using the **Retractor Hex Driver**, before withdrawing it from the incision.
- Close the outer layer of abdominal wall muscle fascia if desired. A subcuticular closure is recommended. Cover the skin edge with waterproof dressing.

The **AVS ARIA** implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine. Please refer to the surgical technique of any additional Stryker system before use.

ARIA Spinal System

Surgical Technique

AVS ARIA PEEK Spacer System

Standard Set Configuration

Reference	Description (height x length x lordosis - width)
Lordosis - 0°	
Width 18mm – Length 40mm	
48750008	8x40x0°-18
48750010	10x40x0°-18
48750012	12x40x0°-18
48750014	14x40x0°-18
48750016	16x40x0°-18
48750018	18x40x0°-18
Width 18mm – Length 45mm	
48750108	8x45x0°-18
48750110	10x45x0°-18
48750112	12x45x0°-18
48750114	14x45x0°-18
48750116	16x45x0°-18
48750118	18x45x0°-18
Width 18mm – Length 50mm	
48750208	8x50x0°-18
48750210	10x50x0°-18
48750212	12x50x0°-18
48750214	14x50x0°-18
48750216	16x50x0°-18
48750218	18x50x0°-18
Width 18mm – Length 55mm	
48750308	8x55x0°-18
48750310	10x55x0°-18
48750312	12x55x0°-18
48750314	14x55x0°-18
48750316	16x55x0°-18
48750318	18x55x0°-18
Width 18mm – Length 60mm	
48750408	8x60x0°-18
48750410	10x60x0°-18
48750412	12x60x0°-18
48750414	14x60x0°-18
48750416	16x60x0°-18
48750418	18x60x0°-18
Width 22mm – Length 40mm	
48752008	8x40x0°-22
48752010	10x40x0°-22
48752012	12x40x0°-22
48752014	14x40x0°-22
48752016	16x40x0°-22
48752018	18x40x0°-22
Width 22mm – Length 45mm	
48752108	8x45x0°-22
48752110	10x45x0°-22
48752112	12x45x0°-22
48752114	14x45x0°-22
48752116	16x45x0°-22
48752118	18x45x0°-22

Reference	Description (height x length x lordosis - width)
Width 22mm – Length 50mm	
48752208	8x50x0°-22
48752210	10x50x0°-22
48752212	12x50x0°-22
48752214	14x50x0°-22
48752216	16x50x0°-22
48752218	18x50x0°-22
Width 22mm – Length 55mm	
48752308	8x55x0°-22
48752310	10x55x0°-22
48752312	12x55x0°-22
48752314	14x55x0°-22
48752316	16x55x0°-22
48752318	18x55x0°-22
Width 22mm – Length 60mm	
48752408	8x60x0°-22
48752410	10x60x0°-22
48752412	12x60x0°-22
48752414	14x60x0°-22
48752416	16x60x0°-22
48752418	18x60x0°-22
Lordosis - 8°	
Width 18mm – Length 40mm	
48751008	8x40x8°-18
48751010	10x40x8°-18
48751012	12x40x8°-18
48751014	14x40x8°-18
48751016	16x40x8°-18
48751018	18x40x8°-18
Width 18mm – Length 45mm	
48751108	8x45x8°-18
48751110	10x45x8°-18
48751112	12x45x8°-18
48751114	14x45x8°-18
48751116	16x45x8°-18
48751118	18x45x8°-18
Width 18mm – Length 50mm	
48751208	8x50x8°-18
48751210	10x50x8°-18
48751212	12x50x8°-18
48751214	14x50x8°-18
48751216	16x50x8°-18
48751218	18x50x8°-18
Width 18mm – Length 55mm	
48751308	8x55x8°-18
48751310	10x55x8°-18
48751312	12x55x8°-18
48751314	14x55x8°-18
48751316	16x55x8°-18
48751318	18x55x8°-18

Reference	Description (height x length x lordosis - width)
Width 18mm – Length 60mm	
48751408	8x60x8°-18
48751410	10x60x8°-18
48751412	12x60x8°-18
48751414	14x60x8°-18
48751416	16x60x8°-18
48751418	18x60x8°-18
Width 22mm – Length 40mm	
48753008	8x40x8°-22
48753010	10x40x8°-22
48753012	12x40x8°-22
48753014	14x40x8°-22
48753016	16x40x8°-22
48753018	18x40x8°-22
Width 22mm – Length 45mm	
48753108	8x45x8°-22
48753110	10x45x8°-22
48753112	12x45x8°-22
48753114	14x45x8°-22
48753116	16x45x8°-22
48753118	18x45x8°-22
Width 22mm – Length 50mm	
48753208	8x50x8°-22
48753210	10x50x8°-22
48753212	12x50x8°-22
48753214	14x50x8°-22
48753216	16x50x8°-22
48753218	18x50x8°-22
Width 22mm – Length 55mm	
48753308	8x55x8°-22
48753310	10x55x8°-22
48753312	12x55x8°-22
48753314	14x55x8°-22
48753316	16x55x8°-22
48753318	18x55x8°-22
Width 22mm – Length 60mm	
48753408	8x60x8°-22
48753410	10x60x8°-22
48753412	12x60x8°-22
48753414	14x60x8°-22
48753416	16x60x8°-22
48753418	18x60x8°-22

ARIA Spinal System
Surgical Technique

AVS ARIA PEEK Spacer Instrument
Standard Set Configuration








Reference	Description
48758500	Implant Inserter
48758520	Implant Impactor
48758530	Implant Remover
48758540	Graft Block
48759701	Trial Handle
48061000	T-Handle
48061001	Slap Hammer
48756408	50mm x 18mm x 8mm Trial, 0° Lordosis
48756410	50mm x 18mm x 10mm Trial, 0° Lordosis
48756412	50mm x 18mm x 12mm Trial, 0° Lordosis
48756414	50mm x 18mm x 14mm Trial, 0° Lordosis
48756416	50mm x 18mm x 16mm Trial, 0° Lordosis
48756418	50mm x 18mm x 18mm Trial, 0° Lordosis
48756008	60mm x 18mm x 8mm Trial, 0° Lordosis
48756010	60mm x 18mm x 10mm Trial, 0° Lordosis
48756012	60mm x 18mm x 12mm Trial, 0° Lordosis
48756014	60mm x 18mm x 14mm Trial, 0° Lordosis
48756016	60mm x 18mm x 16mm Trial, 0° Lordosis
48756018	60mm x 18mm x 18mm Trial, 0° Lordosis
48756508	50mm x 22mm x 8mm Trial, 0° Lordosis
48756510	50mm x 22mm x 10mm Trial, 0° Lordosis
48756512	50mm x 22mm x 12mm Trial, 0° Lordosis
48756514	50mm x 22mm x 14mm Trial, 0° Lordosis
48756516	50mm x 22mm x 16mm Trial, 0° Lordosis
48756518	50mm x 22mm x 18mm Trial, 0° Lordosis

AVS ARIA PEEK Spacer Instrument

Standard Set Configuration

Reference	Description
48756208	60mm x 22mm x 8mm Trial, 0° Lordosis
48756210	60mm x 22mm x 10mm Trial, 0° Lordosis
48756212	60mm x 22mm x 12mm Trial, 0° Lordosis
48756214	60mm x 22mm x 14mm Trial, 0° Lordosis
48756216	60mm x 22mm x 16mm Trial, 0° Lordosis
48756218	60mm x 22mm x 18mm Trial, 0° Lordosis
48756708	50mm x 18mm x 8mm Trial, 8° Lordosis
48756710	50mm x 18mm x 10mm Trial, 8° Lordosis
48756712	50mm x 18mm x 12mm Trial, 8° Lordosis
48756714	50mm x 18mm x 14mm Trial, 8° Lordosis
48756716	50mm x 18mm x 16mm Trial, 8° Lordosis
48756718	50mm x 18mm x 18mm Trial, 8° Lordosis
48756108	60mm x 18mm x 8mm Trial, 8° Lordosis
48756110	60mm x 18mm x 10mm Trial, 8° Lordosis
48756112	60mm x 18mm x 12mm Trial, 8° Lordosis
48756114	60mm x 18mm x 14mm Trial, 8° Lordosis
48756116	60mm x 18mm x 16mm Trial, 8° Lordosis
48756118	60mm x 18mm x 18mm Trial, 8° Lordosis
48756808	50mm x 22mm x 8mm Trial, 8° Lordosis
48756810	50mm x 22mm x 10mm Trial, 8° Lordosis
48756812	50mm x 22mm x 12mm Trial, 8° Lordosis
48756814	50mm x 22mm x 14mm Trial, 8° Lordosis
48756816	50mm x 22mm x 16mm Trial, 8° Lordosis
48756818	50mm x 22mm x 18mm Trial, 8° Lordosis
48756308	60mm x 22mm x 8mm Trial, 8° Lordosis
48756310	60mm x 22mm x 10mm Trial, 8° Lordosis
48756312	60mm x 22mm x 12mm Trial, 8° Lordosis
48756314	60mm x 22mm x 14mm Trial, 8° Lordosis
48756316	60mm x 22mm x 16mm Trial, 8° Lordosis
48756318	60mm x 22mm x 18mm Trial, 8° Lordosis
48758408	50mm x 8mm Reamer Distractor
48758410	50mm x 10mm Reamer Distractor
48758412	50mm x 12mm Reamer Distractor
48758414	50mm x 14mm Reamer Distractor
48758416	50mm x 16mm Reamer Distractor
48758418	50mm x 18mm Reamer Distractor
48758208	60mm x 8mm Reamer Distractor
48758210	60mm x 10mm Reamer Distractor
48758212	60mm x 12mm Reamer Distractor
48758214	60mm x 14mm Reamer Distractor
48758216	60mm x 16mm Reamer Distractor
48758218	60mm x 18mm Reamer Distractor

ARIA Spinal System
Surgical Technique

AVS ARIA PEEK Spacer Instrument
Standard Set Configuration

Reference	Description
48759040	AVS ARIA Implants and Instruments Tray
48759108	60mm x 18mm x 8mm Trial (Threaded), 0° Lordosis
48759110	60mm x 18mm x 10mm Trial (Threaded), 0° Lordosis
48759112	60mm x 18mm x 12mm Trial (Threaded), 0° Lordosis
48759114	60mm x 18mm x 14mm Trial (Threaded), 0° Lordosis
48759116	60mm x 18mm x 16mm Trial (Threaded), 0° Lordosis
48759118	60mm x 18mm x 18mm Trial (Threaded), 0° Lordosis
48759208	60mm x 22mm x 8mm Trial (Threaded), 0° Lordosis
48759210	60mm x 22mm x 10mm Trial (Threaded), 0° Lordosis
48759212	60mm x 22mm x 12mm Trial (Threaded), 0° Lordosis
48759214	60mm x 22mm x 14mm Trial (Threaded), 0° Lordosis
48759216	60mm x 22mm x 16mm Trial (Threaded), 0° Lordosis
48759218	60mm x 22mm x 16mm Trial (Threaded), 0° Lordosis
48759308	60mm x 18mm x 8mm Trial (Threaded), 8° Lordosis
48759310	60mm x 18mm x 10mm Trial (Threaded), 8° Lordosis
48759312	60mm x 18mm x 12mm Trial (Threaded), 8° Lordosis
48759314	60mm x 18mm x 14mm Trial (Threaded), 8° Lordosis
48759316	60mm x 18mm x 16mm Trial (Threaded), 8° Lordosis
48759318	60mm x 18mm x 16mm Trial (Threaded), 8° Lordosis
48759408	60mm x 22mm x 8mm Trial (Threaded), 8° Lordosis
48759410	60mm x 22mm x 10mm Trial (Threaded), 8° Lordosis
48759412	60mm x 22mm x 12mm Trial (Threaded), 8° Lordosis
48759414	60mm x 22mm x 14mm Trial (Threaded), 8° Lordosis
48759416	60mm x 22mm x 16mm Trial (Threaded), 8° Lordosis
48759418	60mm x 22mm x 18mm Trial (Threaded), 8° Lordosis
48759701	Trial Handle
48759700	Trial Shaft
48759600	Slap Hammer (Reverse)
48759660	Outlier Container
48759500	Implant Inserter
48759630	Graft Protector

Interbody-Prep Instrument

Standard Set Configuration

Reference	Description
48759702	Bayoneted Knife Holder
48758457	40°x2mm Kerrison Rongeur Bayonet
48759390	40°x4mm Kerrison Rongeur Bayonet
48758458	90°x2mm Kerrison Rongeur Bayonet
48759590	90°x4mm Kerrison Rongeur Bayonet
48758454	2x10mm Pituitary Rongeur Bayonet, Straight
48758455	3x10mm Pituitary Rongeur Bayonet, Straight
48758456	4x10mm Pituitary Rongeur Bayonet, Straight
48759190	5x10mm Pituitary Rongeur Bayonet, Straight
48759195	5x6mm Pituitary Rongeur Bayonet, Angled 30°
48758463	3.6mm Epstein Curette, Bayonet, Downbiting
48758478	5.2mm Epstein Curette, Bayonet, Downbiting
48757000	7mm Epstein Curette, Bayonet, Downbiting
48757001	7mm Epstein Curette, Bayonet, Upbiting
48757002	10mm Ring Curette, Bayonet, Angled
48757003	10mm Ring Curette, Straight, Angled
48758461	3.6mm Cup Curette, Bayonet, Forward Angled Tip
48758462	3.6mm Cup Curette, Bayonet, Forward Straight Tip
48758476	5.2mm Cup Curette, Bayonet, Forward Angled Tip
48758477	5.2mm Cup Curette, Bayonet, Forward Straight Tip
48757004	8mm Cup Curette, Bayonet, Angled Tip
48757005	8mm Cup Curette, Straight Shaft, Angled Tip

ARIA Spinal System
Surgical Technique

Interbody-Prep Instrument
Standard Set Configuration

Reference	Description
48758000	16mm Cobb Elevator, Angled Tip
48758001	16mm Cobb Elevator, Straight Tip
48758459	16mm Cobb Elevator, Straight Tip, Teardrop
48758002	20mm Cobb Elevator, Angled Tip
48758003	20mm Cobb Elevator, Straight Tip
48758460	20mm Cobb Elevator, Straight Tip, Teardrop
48758600	10mm Osteotome, Straight
48758601	Osteotome, Edge Cutting
48758400	Rasp, Dual Sided
48758401	Rasp / Scraper
48759000	Penfield, Pull
48759001	Nerve Root Retractor Bayonet 7x3mm
48759002	Nerve Hook with Ball Tip
48759015	Frazier Suction Tube, 10 French
48361277	Long Handle Knife
48759050	Interbody-Prep Instruments Tray

ARIA Spinal System
Surgical Technique

Rigid/Flexible Arms
Standard Set Configuration

Reference	Description
48250240	Arm Post
48758452	Articulating Arm
48755400	Snake Arm
48759030	Rigid/Flexible Arm Tray

Access Instrument
Standard Set Configuration

Reference	Description
48755720	Landmark Identifier Crosshair
48755007	Sharp Guide Wire (Disposable)
48755006	Neuromonitoring Probe (Disposable)
48755005	Guide Tissue Resector
48755004	Probe Holder
48755008	Neuromonitoring Cable (Disposable)
48755018	Lead Crocodile Clip
48755028	Lead Ext Blue

ARIA Spinal System
Surgical Technique

Access Instrument
Standard Set Configuration

Reference	Description
48755001	Dilator 1
48755002	Probe Dilator 2 (Disposable)
48755003	Probe Dilator 3 (Disposable)
48755000	Retractor Base
48755050	50mm Retractor Blades
48755060	60mm Retractor Blades
48755070	70mm Retractor Blades
48755080	80mm Retractor Blades
48755090	90mm Retractor Blades
48755100	100mm Retractor Blades
48755110	110mm Retractor Blades
48755120	120mm Retractor Blades
48755130	130mm Retractor Blades
48755140	140mm Retractor Blades
48755150	150mm Retractor Blades
48755160	160mm Retractor Blades
48759905	50mm AP Retractor Blade, Narrow
48759906	60mm AP Retractor Blade, Narrow
48759907	70mm AP Retractor Blade, Narrow
48759908	80mm AP Retractor Blade, Narrow
48759909	90mm AP Retractor Blade, Narrow
48759910	100mm AP Retractor Blade, Narrow
48759911	110mm AP Retractor Blade, Narrow
48759912	120mm AP Retractor Blade, Narrow
48759913	130mm AP Retractor Blade, Narrow
48759914	140mm AP Retractor Blade, Narrow
48759915	150mm AP Retractor Blade, Narrow
48759916	160mm AP Retractor Blade, Narrow

Access Instrument
Standard Set Configuration

Reference	Description
48759925	50mm AP Retractor Blade, Wide
48759926	60mm AP Retractor Blade, Wide
48759927	70mm AP Retractor Blade, Wide
48759928	80mm AP Retractor Blade, Wide
48759929	90mm AP Retractor Blade, Wide
48759930	100mm AP Retractor Blade, Wide
48759931	110mm AP Retractor Blade, Wide
48759932	120mm AP Retractor Blade, Wide
48759933	130mm AP Retractor Blade, Wide
48759934	140mm AP Retractor Blade, Wide
48759935	150mm AP Retractor Blade, Wide
48759936	160mm AP Retractor Blade, Wide

48755700	AP Frame Driver

48250200	Retractor Hex Driver

48755701	Anti Rotational Key

48755703	Anchoring Pin Driver

ARIA Spinal System
Surgical Technique

Access Instrument
Standard Set Configuration

Reference	Description
48755702	Quick Release Handle
48755850	50mm Anchoring Pin (Disposable)
48755860	60mm Anchoring Pin (Disposable)
48755870	70mm Anchoring Pin (Disposable)
48755880	80mm Anchoring Pin (Disposable)
48755890	90mm Anchoring Pin (Disposable)
48755900	100mm Anchoring Pin (Disposable)
48755910	110mm Anchoring Pin (Disposable)
48755920	120mm Anchoring Pin (Disposable)
48755930	130mm Anchoring Pin (Disposable)
48755940	140mm Anchoring Pin (Disposable)
48755950	150mm Anchoring Pin (Disposable)
48755960	160mm Anchoring Pin (Disposable)
48759900	Anterior Frame
48759950	Posterior Frame
48755708	80mm AP Retractor Blade, Short 4
48755710	100mm AP Retractor Blade, Medium 2
48755712	120mm AP Retractor Blade, Medium 4
48755716	160mm AP Retractor Blade, Long 4

Access Instrument
Standard Set Configuration

Reference	Description
48755700	AP Frame Driver
48252006	Light Source
48758451	Light Cable
48759020	Access Instruments Tray
48851313A	Disposable LITe Cable
48851313B	Universal LITe Cable Adaptor

ARIA Spinal System
Surgical Technique

Angled Instruments
Standard Set Configuration

Reference	Description
48759359	Angled Implant Inserter
48759360	Angled Instrument Container
48759508	60mm x 18mm x 8mm Angled Trial, 0° Lordosis
48759510	60mm x 18mm x 10mm Angled Trial, 0° Lordosis
48759512	60mm x 18mm x 12mm Angled Trial, 0° Lordosis
48759514	60mm x 18mm x 14mm Angled Trial, 0° Lordosis
48759516	60mm x 18mm x 16mm Angled Trial, 0° Lordosis
48759518	60mm x 18mm x 18mm Angled Trial, 0° Lordosis
48759608	60mm x 22mm x 8mm Angled Trial, 0° Lordosis
48759610	60mm x 22mm x 10mm Angled Trial, 0° Lordosis
48759612	60mm x 22mm x 12mm Angled Trial, 0° Lordosis
48759614	60mm x 22mm x 14mm Angled Trial, 0° Lordosis
48759616	60mm x 22mm x 16mm Angled Trial, 0° Lordosis
48759618	60mm x 22mm x 18mm Angled Trial, 0° Lordosis
48759350	16mm Cobb Elevator, Upbiting Angled Access, Teardrop
48759351	16mm Cobb Elevator, Downbiting Angled Access, Teardrop
48759352	4x10mm Pituitary Rongeur, Curved Right Angled Access
48759353	4x10mm Pituitary Rongeur, Curved Left Angled Access
48759354	Rasp, Dual Sided, Curved Angled Access

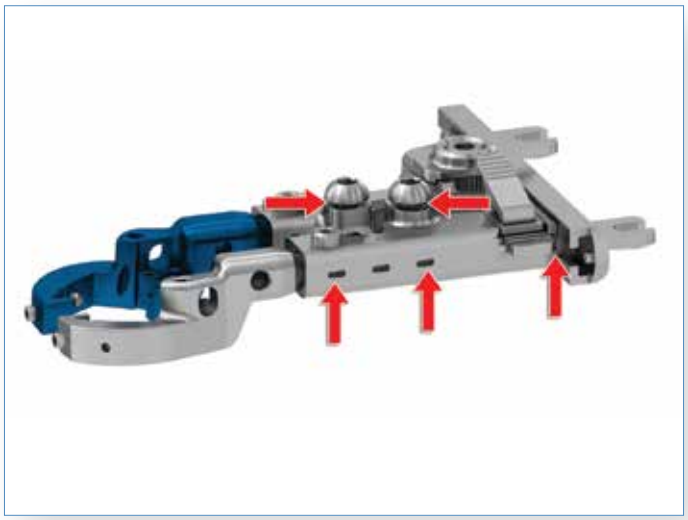
Angled Instruments

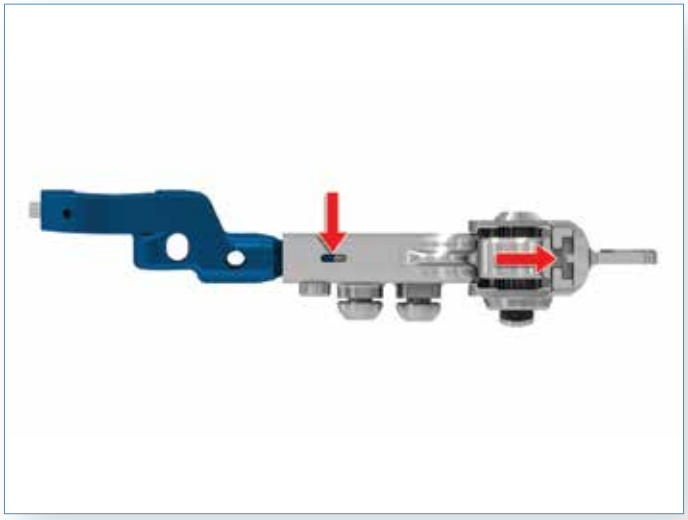
Standard Set Configuration

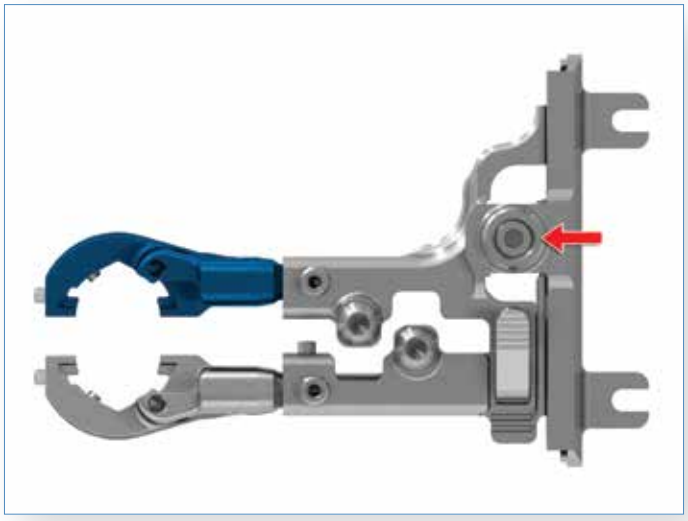
Reference	Description
48759355	5.2mm Ring Curette, Angled Access
48759356	8mm Ring Curette, Angled Access, Teardrop
48759357	5.2mm Cup Curette, Curved Right Angled Access, Angled Tip
48759358	5.2mm Cup Curette, Curved Left Angled Access, Angled Tip

ARIA Retractor Lubrication Instructions

Lubricate the Retractor Base before use. See below for lubrication locations.







ARIA Implant Inserter Lubrication Instructions

Lubricate the Implant Inserter before use. See below for the lubrication location.

Lubricate internal thread regularly. Rotate thread back and forth during lubrication.

ARIA Spinal System
Surgical Technique

IMPORTANT PRODUCT INFORMATION FOR STRYKER SPINE AVS® ARIA PEEK SPACERS

DESCRIPTION
The AVS® ARIA PEEK Spacers are intended for use as interbody fusion devices. They are offered in a variety of lengths, heights and lordotic angles. The hollow, oblong-shaped implant has serrations on the top and bottom for fixation.

MATERIAL
All components of all AVS® PEEK Spacer systems are manufactured out of the following materials:
- Implant: Polyetheretherketone (PEEK) (ASTM F2026)
- Radiopaque markers: Tantalum (ASTM F560)

INDICATIONS
The Stryker Spine AVS® ARIA PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion 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.

Additionally, the AVS® ARIA PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

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 (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) with appropriate training or experience.
- 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 on 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.
- Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the intervertebral body fusion 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. Instruments for implantation of the AVS® PEEK Spacers are provided non-sterile and must be sterilized prior to use.
- 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.
- The AVS® PEEK Spacers have not been evaluated for safety and compatibility in the MR environment. The AVS® PEEK Spacers have not been tested for heating or migration in the MR environment.

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, 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.

CONTRA-INDICATIONS
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 AVS® PEEK Spacers should not be implanted in patients with an active infection at the operative site.
- The AVS® PEEK Spacers are 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. Obesity is defined according to the W.H.O. standards.
- 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 can 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 advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of nonunions. Such patients should be advised of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. 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 nonunions. 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 add additional stresses and strains on the device which can lead to 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 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.

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

REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the AVS® PEEK Spacers are 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

PACKAGING

- The implants are single use devices, provided non-sterile, and delivered in individual packages. The typical packaging used is clear plastic tubes and polyethylene bags. The packages must be intact at the time of receipt.
- Implants must be removed entirely from their packaging prior to sterilization.
- The implants may also be supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes

FURTHER INFORMATION

A surgical technique brochure is available on request through your STRYKER representative or directly from STRYKER Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

COMPLAINTS

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

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

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

For further information regarding services, please contact:

STRYKER Spine
2 Pearl Court, Allendale, NJ 07401-1677 USA
Tel: +1-201-749-8000

STRYKER SPINE INSTRUMENTATION
ARIA NEUROMONITORING PROBE AND ARIA PROBE DILATORS INSTRUCTIONS

NON-STERILE PRODUCT

Description / Material Composition
The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are used as instruments to deliver electrical stimulation to tissue during intraoperative neurological monitoring. AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are available in monopolar configuration and are made from stainless steel insulated with polytetrafluoroethylene (PTFE).

The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators 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. The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators 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 #	Device Name	Reusable / Single Use	Provided
48755006	Neuromonitoring Probe	Single Use	Non-Sterile
48755001	Dilator 1 – 6.4mm	Single Use	Non-Sterile
48755002	Probe Dilator 2, NM – 14.4mm	Single Use	Non-Sterile
48755003	Probe Dilator 3, NM – 22.5mm	Single Use	Non-Sterile

Indications for Use
The ARIA Neuromonitoring Probe and ARIA Probe Dilators are indicated for use during surgery of the spine 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.

PRE-OPERATIVE PRECAUTIONS
Anyone using the AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators 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.

The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators may only be used by doctors who are fully familiar with the surgical technique required. The doctor operating must take care not to use these 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 these 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.

Use
The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators must be used in the manner described in the Surgical Techniques brochures provided by STRYKER Spine. Prior to using these 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
The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators 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.

Potential Adverse Effects
Incorrect cleaning or handling may render these 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, these 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.

The surgeon must warn the patient of the surgical risks and make them aware of possible adverse effects.

ARIA Spinal System
Surgical Technique

Packaging
STRYKER Spine AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are provided non-sterile. These devices are available in instrument containers with other ARIA System devices, or in individual packaging. The containers and the packaging of the AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators must be intact when received. The packaging materials must be removed prior to sterilization.

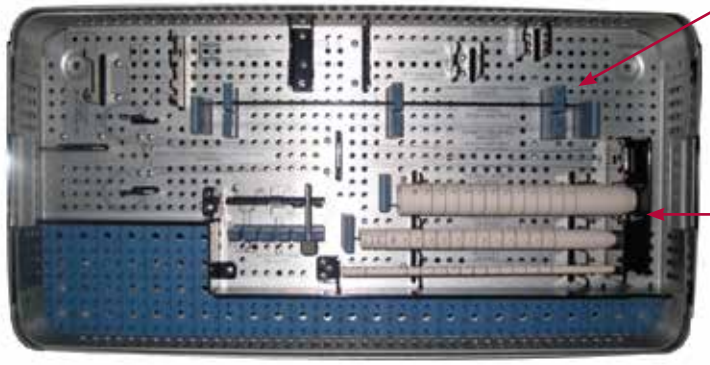
Examination Prior to Use
The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are designed for single use (sold non-sterile):
- The integrity of the instrument and original package must be verified before use.
- Instruments must be visually examined for damage by doctors and staff in operating 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.
- Inspect the packaging for any visible damage or breaches prior to use. **Any device that is damaged or the packaging is compromised must not be used and should be returned to STRYKER Spine or discarded**.

STERILIZATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE
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.

Sterilization procedure recommended for non-sterile medical devices.

DO NOT CLEAN OR RINSE THE AVS ARIA PROBE OR AVS ARIA DILATORS PRIOR TO LOADING IN THE ARIA ACCESS TRAY.

The subject devices must be sterilized in their individual slots located in the top tray of the Stryker Spine ARIA Access Instruments Container. Trays within the container must be stacked in order of instrumentation use during the surgical procedure (i.e., top tray contains instruments used during initial steps of surgery and bottom tray contains instruments used during final steps of surgery).



Place AVS ARIA Probe in the designated top tray position as indicated by the silkscreen image.

Place AVS ARIA Dilators in the designated top tray positions as indicated by the silkscreen image.

CAUTION: For product being used in the United States, two layers of a non-woven (54”x54”) sterilization wrap, FDA-cleared for the cycle parameters, must be used. All sterilization accessories must also be FDA-cleared for the cycle parameters selected.

Sterilization must be performed with water vapor in an autoclave in accordance with standard hospital procedures. The recommended sterilization methods have been validated according to the AAMI ST 79 in order to obtain a Sterility Assurance Level (SAL) of 10^{-6}.

CAUTION: Stryker Spine has not validated and Does Not recommend Flash Sterilization nor Immediate Use Sterilization for the AVS ARIA Probe or AVS ARIA Probe Dilators.

CAUTION: The end user is responsible for validating any revised sterilization protocol before deviating from the recommended parameters contained in this document.

The following parameters have been validated on containers double wrapped with non-woven 54”x54” sterilization wrap in fully-loaded hospital-sized autoclave chambers:

STERILIZATION CONDITIONS:
Prevacuum (Porous Load) steam sterilization autoclave:
- Temperature: 132°C (270°F)
- Exposure Time: 4 Minutes
- Dry Time: 20 Minutes

Gravity Displacement steam sterilization autoclave:
- Temperature: 132°C (270°F)
- Exposure Time: 15 Minutes
- Dry time: 30 Minutes

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.

Cleaning Instructions for Caldwell Lead
Crocodile Clip (48755018) and Lead Ext Blue (48755028)

⚠ **Prepare**
Disconnect items from equipment prior to cleaning or disinfection.

⚠ **After each use**
Clean with soft brush, water and mild detergent.
Disinfect with quaternary ammonium or alcohol solution such as Envirocide of Lysol I.C.

⚠ **Caution**
Inspect before use for damage and excessive wear.
Discard using appropriate procedure. Follow your facility’s approved infection control procedures.

⚠ **Disclaimer**
Caldwell is not responsible for injury, infection, or other damage resulting from improper storage, preparation, use, or disposal of electrodes.

Sterilize product in STERRAD® unit and follow all manufacturer’s (Advanced Sterilization Products) requirements as stated in the applicable user guide.

Storage
The AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators are packaged in individual packages. Unused devices must be stored in a clean, dry and temperate place. After use the AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators must be discarded.

Complaints
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators, its identity, durability, reliability, safety, effectiveness and / or 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:

STRYKER SPINE
ZI de Marticot, 33610 CESTAS – France
Tel. (33) (0)5.57.97.06.30
Fax. (33) (0)5.57.97.06.45 (Customer Service)
Fax. (33) (0)5.57.97.06.31 (Quality Assurance)
http://www.stryker.com

Stryker Spine
2 Pearl Court,
Allendale, NJ07401-1677 USA
Tel +1-201-760-8000

Notes

Notes

stryker

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Computer Assisted Surgery

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Beds, Stretchers & EMS

Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial

Interventional Spine

Neurosurgical, Spine & ENT

Neurovascular

Spinal Implants

Stryker Spine
2 Pearl Court
Allendale, NJ 07401-1677 USA
t: 201-749-8000
www.stryker.com

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

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

Lead Crocodile Clip (48755018) and Lead Ext Blue (48755028) manufactured by Cadwell Safe Electrodes, Kennewick, WA

Not intended for promotional or marketing use outside the United States.

MIARI-ST-1_Rev-5_11837
SC/GS 09/16