stryker

Aero®-AL

Anterior Lumbar Interbody and Fixation System

Surgical technique

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Acknowledgments:

Stryker's Spine Division wishes to thank the following surgeons for their dedication and contributions to the development of the Aero-AL anterior lumbar interbody and fixation system.

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System overview

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

The system is comprised of:

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

Titanium anchors are guided through the cage, engaging with the posterior and anterior aspects of the implant, and lock into the jacket to maximize segment stability and minimize micro-motion.

Instrumentation designed to facilitate device insertion and to minimize exposure.

The titanium jacket spans the entire height of the cage anteriorly and posteriorly to show the overall height relative to the vertebral endplates, as well as, the implant-to-endplate proximity. The jacket and fixation anchors are open on the lateral aspects to allow for fusion assessment through the device on lateral radiographic images.

The Aero-AL anterior lumbar interbody and fixation system must be used with the anchor fixation provided and additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine.

Implant overview

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

	Aero-AL implants					
	Footprints (depth x width)	**22 x 28mm**		**26 x 32mm**		**30 x 38mm**	
	Lordosis	**4°**	**8°**	**8°**	**12°**	**8°**	**12°**
Height	Blue	11mm	11mm	11mm	-	11mm	-
	Green	13mm	13mm	13mm	13mm	13mm	13mm
	Magenta	15mm	15mm	15mm	15mm	15mm	15mm
	Aqua	17mm	17mm	17mm	17mm	17mm	17mm
	Purple	-	-	19mm	19mm	19mm	19mm

The PEEK cage and titanium jacket are pre-assembled. Four titanium anchors provide fixation to the vertebral bodies and all four anchors must be implanted during the procedure. There are three different anchor lengths, each of which correspond to a specific implant footprint:

Anchor color	Anchor length	Implant footprint
Silver	22mm anchor	22 x 28mm
Gold	26mm anchor	26 x 32mm
Light green	30mm anchor	30 x 38mm

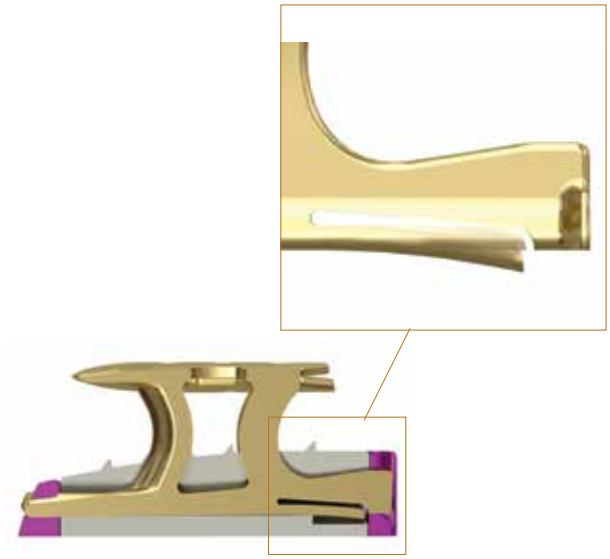
Aero-AL is provided sterile in a package. Each sterile package includes one implant and four anchors. The anchors are pre-loaded into plastic cartridges that are designed to facilitate anchor insertion and promote safe handling. The cartridges are color-coded to ensure proper placement of the anchors within the implant. Additional anchors are also packaged individually should an anchor lose sterility during surgery.

Anchor

Aero-AL sterile package

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

Anchor engagement – anterior and posterior aspects of jacket



Anchor lock – anterior anti-migration

Anchor stop – posterior anti-migration

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

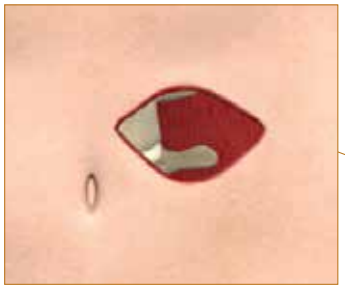
Surgical technique

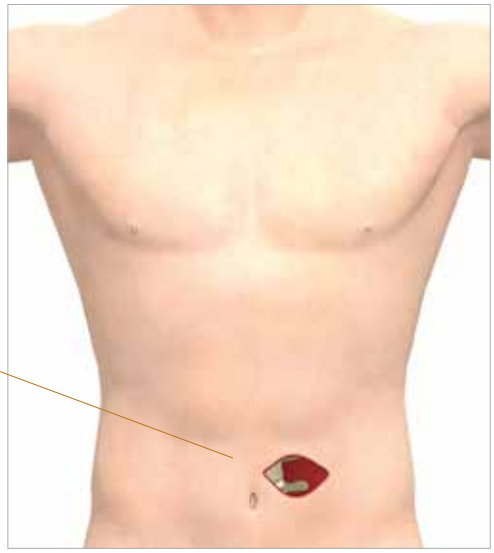
Step 1. Patient positioning and exposure

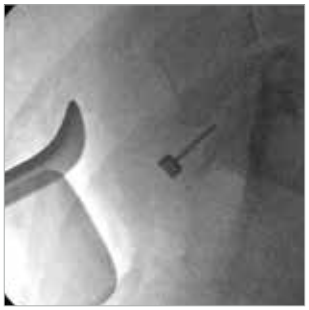
Determine surgical approach (transperitoneal or retroperitoneal). A direct anterior approach should be selected for Aero-AL implantation based on the design of the system.

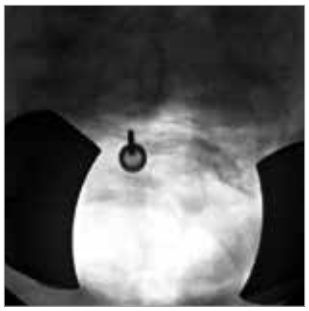
Stryker's Reliance AL instruments can be used in either a transperitoneal or retroperitoneal approach to the lumbosacral spine and may depend on which level of the spine is being treated. Anterior access is required for the insertion of the implant and anchors. This technique details a retroperitoneal approach.

Place the patient in the supine position. After blunt dissection through the various layers, expose the midline of the intervertebral disc. Take care to expose the segment with sufficient space on either side of the midline to allow for placement of the device (widths range from 28–38mm). Additionally, ensure there is sufficient exposure above and below the disc space to allow clearance for proper insertion of the anchor.









Consideration: Mark the midline of the disc/vertebral body under fluoroscopic guidance. This mark will assist in determining the annulotomy site width.

Note: Patient positioning should follow surgeon's standard technique for any anterior lumbar discectomy and fusion.

Step 2. Annulotomy, discectomy and endplate preparation

Using the **Long Handle Knife** (Reliance AL 48361277) cut a window in the annulus. It is important that the window is centered on the vertebral midline in order to prepare the position for the implant.

Long Handle Knife
48361277

Long handle knife

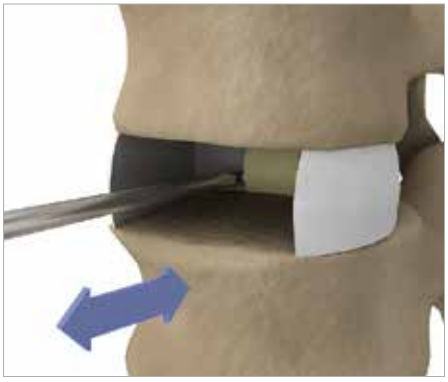
A cobb can be used to separate the cartilaginous endplate from the bony vertebral endplate. Osteophytes can be removed from the front of the vertebral bodies utilizing the **Double Action Ronguer** (48366240).

Use the pituitary rongeur to remove disc material. To accommodate a range of needs, pituitary rongeurs are available in sizes of 4mm and 8mm, and in three different orientations; up, down and straight. The up and down biting pituitary rongeurs are especially effective in removing disc material posterolaterally. The pituitary rongeurs can also be used to remove disc material and cartilaginous tissue from the superior and inferior vertebral endplates.

Cobb

Curettes can also be used to remove disc material and cartilage from the superior and inferior vertebral endplates. Curettes are offered in straight, downward and upward bend orientations.

Once the discectomy has been performed, the **Posterior Longitudinal Ligament (PLL) Stripper** (Reliance AL 48361238) can be carefully inserted. Slowly advance the instrument to the posterior edge of the vertebral body. The instrument is used to release the PLL from the posterior edge of both the upper and lower vertebral bodies if deemed necessary by the surgeon. The value of releasing the PLL is to optimize parallel distraction and to permit maximum opening of the space for neural elements if required.



Posterior Longitudinal Ligament (PLL) Stripper
48361238

Distraction of the discectomy site is important to help restore lordosis and open the neural foramen. The **Reliance AL Discectomy Distractor** (Reliance AL 48361150) can be used to provide distraction for the discectomy, endplate preparation, implant trialing and implant insertion. The five pairs of unique modular tips for the discectomy distractor are used to facilitate each of these steps.

Reliance AL Discectomy Distractor
48361150

Note: Care is required while performing the annulotomy with the long handle knife as the blade can result in serious damage to the vascular elements.

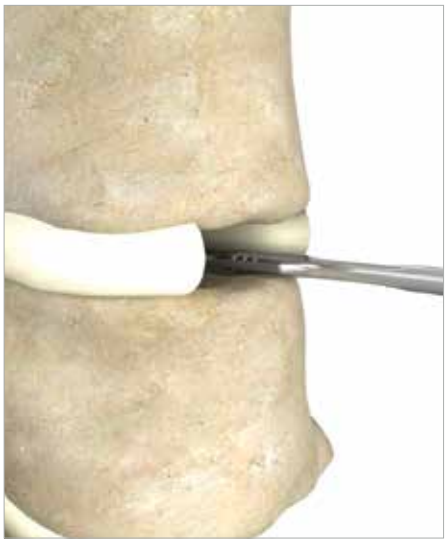
Note: Blades are not included with the Reliance AL system.

Endplate preparation

Adequate preparation of the endplates is important to enhance vascular supply to the fusion site. Prepare the endplates so as to ensure adequate surface contact between the superior and inferior surface of the implant with the endplates. Reliance AL curettes or rasps should be translated parallel to the endplates until sufficient decortication is achieved. The curettes can be used to "feel" the endplates ensuring that no soft tissue remains.

It is recommended to move the rasps in an anterior-posterior motion, and a medial-lateral motion to remove the superficial cartilaginous layers of the endplate and expose bleeding cancellous bone, being careful not to remove too much subchondral bone. This helps avoid subsidence and loss of segmental stability.

Care should be taken to remove any bony anatomy or osteophytes which might interfere with the instrumentation in order to position the implant flush with the anterior aspect of the lumbar spine. Based on the geometry of the implant, it is recommended to remove all osteophytes.



Inserter/Distractor
48921003

Note: The Aero-AL instrumentation includes an Inserter/Distractor for insertion that can be used in place of the Reliance AL discectomy distractor.

Note: In patients with sclerosis of the endplates, more rigorous rasping may be useful to expose a bleeding surface without compromise of the dense cortical endplate.

Consideration: Additional rasps can be found in the AVS Anchor-L set and may also be used to help prepare the endplates.

Step 3: Trialing and implant size determination

Final implant size can be determined using the appropriate color-coded trial. These trials match the implant options in footprint and lordosis.

	Aero-AL trial and implant sizing options					
	Footprints (depth x width)	**22 x 28mm**		**26 x 32mm**		**30 x 38mm**	
	Lordosis	**4°**	**8°**	**8°**	**12°**	**8°**	**12°**
Height	Blue	11mm	11mm	11mm	-	11mm	-
	Green	13mm	13mm	13mm	13mm	13mm	13mm
	Magenta	15mm	15mm	15mm	15mm	15mm	15mm
	Aqua	17mm	17mm	17mm	17mm	17mm	17mm
	Purple	-	-	19mm	19mm	19mm	19mm

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

Blue 11mm | **Green 13mm** | **Magenta 15mm** | **Aqua 17mm** | **Purple 19mm**

Note: The trials represent the height of only the body of the Aero-AL implant, not the teeth. Relative to the trial, the implant features an additional 1mm of "tooth height" (0.5mm on both the inferior and the superior aspects). The trials do not include the additional height, as the teeth are intended to fully engage with the endplates following implantation, and add no additional height than what is indicated by the implant's labeled size. For this reason, it is important to not oversize the trial as the overall implant height is 1mm taller than the trial.

Trials and Trial Handle

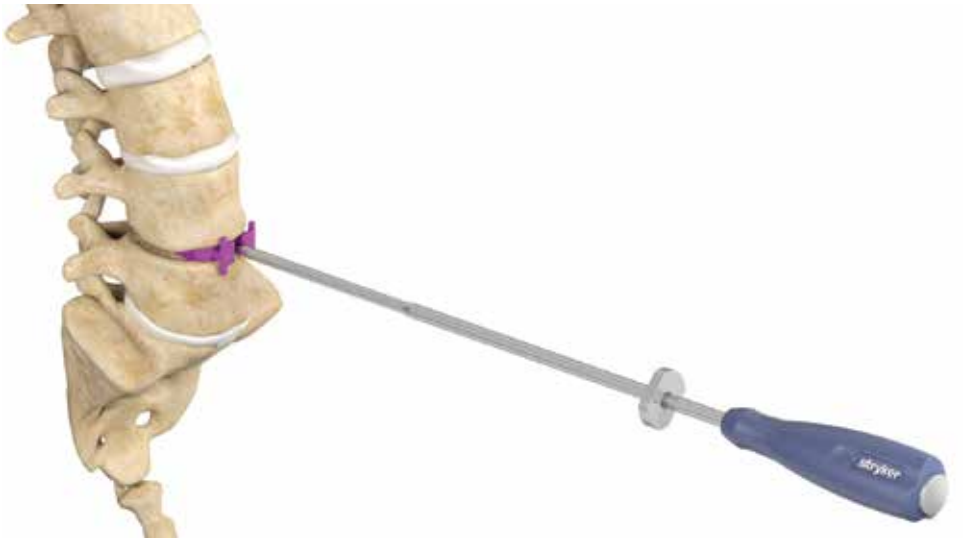
Attach the selected trial to the **Trial Handle** by threading the distal end of the shaft into the hole in the trial.

Trial Handle 48361234

Note: The trial handles are not compatible with the insertion hole on the implant. Attempting to thread the trial handle into the insertion hole on the implant may cause damage and should absolutely be avoided.

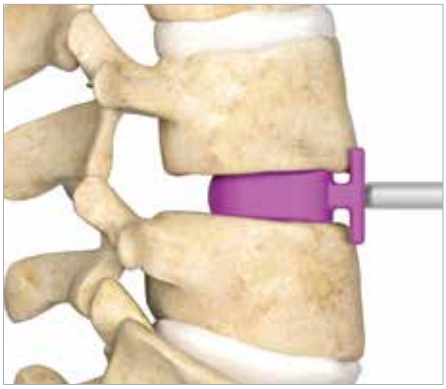
Insert the trial into the prepared disc space to confirm the appropriate implant size needed. Fluoroscopy can assist in confirming the proper fit. The trial should pass through the distracted disc space without excessive force.

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



Trial insertion

The trial features a built-in 4mm depth stop that is designed to control the depth that the trial can be inserted. This depth stop prevents the trial from inaccurately representing the final position of the implant when placed with the inserter guide.



As needed, tap the trial handle with the **Mallet** to facilitate insertion of the trial.

Mallet
48921009

The mallet can also be used to aid in trial removal. Engage the mallet prongs with the trial handle and tap in an upward motion until the trial is out of the disc space.

The trial can be removed from the trial handle by unthreading the trial from the handle.

Consideration: Lateral imaging is recommended for confirming posterior trial-to-endplate contact. There should be no gaps between the endplates and the trial.

Step 4. Implant insertion

Once the final implant size has been determined, select the corresponding Aero-AL implant and inserter guide. The jackets on the implant and rings on the inserter guide are color-coded by implant height.

Inserter Guide

Reference number	Description	Color
48921011	Inserter Guide, 11mm	Blue
48921013	Inserter Guide, 13mm	Green
48921015	Inserter Guide, 15mm	Magenta
48921017	Inserter Guide, 17mm	Aqua
48921019	Inserter Guide, 19mm	Purple

Inserter Guide Inner Shaft
48921100

Inserter guide assembly

Note: The inserter guides are used to implant both the cage and the anchors.

Assemble the **Inserter Guide** and **Inserter Guide Inner Shaft** by sliding the inner shaft through the body of the inserter guide. The inner shaft is slightly bent to aid in insertion and removal for cleaning and sterilization.

The implant can be loaded onto the inserter guide directly from the sterile package. Attach the implant to the appropriate inserter guide by rotating the knurled knob on the inner shaft clockwise until snug.

Loading implant with inserter guide

Inserter Guide Inner Shaft
48921100

Revision Guide Inner Shaft
48921050

Aero-AL implant height denoted by jacket color	
Color	**Height**
Blue	11mm
Green	13mm
Magenta	15mm
Aqua	17mm
Purple	19mm

Note: The inserter guide inner shaft is not the same as the revision guide inner shaft. When assembling the inserter guide, please be sure to use the inserter guide inner shaft.

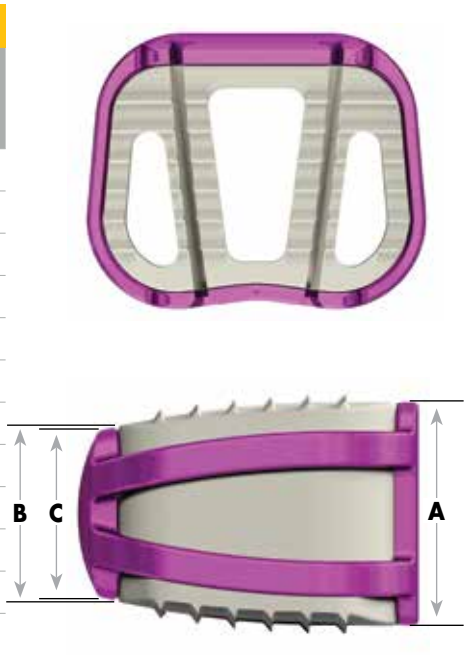
Note: When properly attached, the anterior face of the implant should be in direct contact with the inserter guide and firmly secured. A gap should not be present between the implant and the inserter guide.

With the implant attached to the inserter guide, remove from the sterile package, and load autogenous bone graft into the three open graft chambers of the cage. If desired, attach the **Impaction Handle** to the threaded end of the inserter guide. The impaction handle has a reverse thr Impaction handle ead to prevent loosening during impaction.

Impaction Handle
48921007

Aero-AL height specifications

Aero-AL height specifications					
Reference number	Description	Anterior height (A) (mm)	Posterior height (B) (mm)	Difference (mm)	Nose height (C)(mm)
48922214	22 x 28mm, 11mm, 4°	11.0	10.0	1.0	9.8
48922218	22 x 28mm, 11mm, 8°	11.0	9.0	2.0	8.5
48922234	22 x 28mm, 13mm, 4°	13.0	12.0	1.0	11.8
48922238	22 x 28mm, 13mm, 8°	13.0	11.0	2.0	10.6
48922254	22 x 28mm, 15mm, 4°	15.0	14.0	1.0	13.8
48922258	22 x 28mm, 15mm, 8°	15.0	13.1	1.9	12.7
48922274	22 x 28mm, 17mm, 4°	17.0	16.0	1.0	15.9
48922278	22 x 28mm, 17mm, 8°	17.0	15.0	2.0	14.7
48922618	26 x 32mm, 11mm, 8°	11.0	8.6	2.4	8.0
48922638	26 x 32mm, 13mm, 8°	13.0	10.6	2.4	10.1
48922632	26 x 32mm, 13mm, 12°	13.0	9.1	3.9	8.4
48922658	26 x 32mm, 15mm, 8°	15.0	12.6	2.4	12.2
48922652	26 x 32mm, 15mm, 12°	15.0	11.1	3.9	10.6
48922678	26 x 32mm, 17mm, 8°	17.0	14.6	2.4	14.2
48922672	26 x 32mm, 17mm, 12°	17.0	13.1	3.9	12.7
48922698	26 x 32mm, 19mm, 8°	19.0	16.6	2.4	16.3
48922692	26 x 32mm, 19mm, 12°	19.0	15.1	3.9	14.8
48923018	30 x 38mm, 11mm, 8°	11.0	8.0	3.0	7.3
48923038	30 x 38mm, 13mm, 8°	13.0	10.0	3.0	9.4
48923032	30 x 38mm, 13mm, 12°	13.0	8.3	4.7	7.5
48923058	30 x 38mm, 15mm, 8°	15.0	12.0	3.0	11.5
48923052	30 x 38mm, 15mm, 12°	15.0	10.3	4.7	9.7
48923078	30 x 38mm, 17mm, 8°	17.0	14.0	3.0	13.6
48923072	30 x 38mm, 17mm, 12°	17.0	12.3	4.7	11.8
48923098	30 x 38mm, 19mm, 8°	19.0	16.0	3.0	15.7
48923092	30 x 38mm, 19mm, 12°	19.0	14.3	4.7	13.9



Aero-AL implant graft volumes

Aero-AL implant graft volumes (cc)						
Implant height	22 x 28mm		26 x 32mm		30 x 38mm	
	4°	8°	8°	12°	8°	12°
11mm	1.4	1.3	2.3	–	4.3	–
13mm	1.6	1.6	2.7	2.6	5.1	4.8
15mm	1.8	1.8	3.2	3.1	5.9	5.6
17mm	2.1	2.1	3.6	3.5	6.7	6.5
19mm	–	–	4.0	3.9	7.5	7.3

After the implant has been packed with autogenous bone graft, insert it into the prepared disc space. Impact the proximal end of the impaction handle using the mallet to safely and gradually insert the implant.

Implant insertion with inserter guide and impaction handle

Alternatively, the inserter guide can be used with the inserter/distractor to place the implant while distracting the disc space.

Implant insertion with inserter guide and inserter/distractor

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

Leave the inserter guide in place for anchor insertion. If using the inserter/distractor, remove from the wound leaving the inserter guide in place.

Note: If using the inserter distractor to insert the implant, do not attach the impaction handle to the threaded end of the inserter guide.

Note: The depth stop is 4mm from the anterior face of the implant. This results in the implant being flush or slightly recessed within the disc space in its final position.

Note: For optimal anchor fixation, ensure a tight fit between the implant and the endplates so there is no gap.

Note: It is recommended that final implant positioning be confirmed using both A-P and lateral fluoroscopy prior to inserting the Anchors.

Step 5: Soft tissue guard (optional)

The **Soft Tissue Guard** may be used to protect surrounding vessels and soft tissue. This instrument is optional, but recommended, during the creation of the anchor channels and for anchor insertion.

To place the soft tissue guard, slide the inner tabs of the guard into the slots on the sides of the inserter guide. The soft tissue guard is radiopaque to allow visualization of its position. It is recommended that the soft tissue guard be seated flush against the vertebral bodies.

Soft Tissue Guard
48921008

Anchor - bone engagement (Vertical distance from anchor to implant)			
#	**Implant aspect**	**11mm**	**13-19mm**
1	Lateral anchor edge	5.2mm	4.2mm
2	Anchor midpoint	6.2mm	5.2mm
3	Medial anchor edge	7.1mm	6.1mm

Note: The anchors enter the vertebral body approximately 6-7mm from the top of the implant depending on implant height. Ensure all vessels and soft tissues are mobilized above the entry height of the anchors and are retracted by the soft tissue guard.

Soft tissue guard

Step 6. Anchor channel creation (optional)

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

Starting with the superior aspect of the implant, position the pilot cutter into one of the channels on the inserter guide. Slide the pilot cutter down until it rests against the superior vertebral body.

Using the mallet, tap the pilot cutter gently to penetrate the bone and create a channel. A built-in depth stop limits the depth of the pilot cutter insertion.

Remove the pilot cutter from the vertebral body by engaging the mallet prongs with the proximal end of the pilot cutter and gently tapping the cutter back out of the vertebral body.

With the pilot cut made, insert the anchor down the same channel on the inserter guide and into the vertebral body as shown in the anchor insertion step (page 17). Once the first anchor is placed and locked into the jacket, use the same methodology with the pilot cutter and inserter guide to create the remaining three channels and place the remaining three anchors.

Pilot cutter

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

Pilot Cutter
48921002

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

Note: Each anchor must be inserted immediately after channel creation. It is highly recommended to make the pilot cuts and place the anchors in a crosswise method. See the anchor insertion step (page 20) for proper anchor insertion and sequencing.

Step 7. Anchor insertion

If removal is required, the entire implant assembly must be removed as described on page 23. Once the implant assembly is removed, another Aero-AL implant cannot be inserted. An alternate method of fixation must be used. Stryker's anterior lumbar plate and peek interbody spacers or AVS Anchor-L lumbar cage system are recommended.

All four anchors required for implant fixation are sterile packaged with the implant. The anchors are color-coded to correspond with the appropriate implant footprint and are sized to match the appropriate implant depth. Only anchors that are designed for a specific footprint should be used with that implant. (For example, only 22mm anchors should be used with a 22 x 28mm implant).

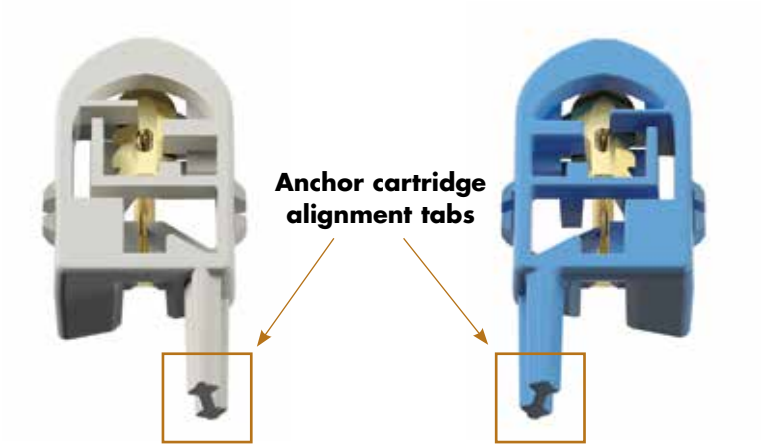
Aero-AL anchors		
Anchor color	**Anchor size**	**Implant footprint (depth x width)**
Silver	22mm	22 x 28mm
Gold	26mm	26 x 32mm
Light green	30mm	30 x 38mm

The anchors are provided in a plastic cartridge to protect the handler from the sharp edges, to indicate the correct orientation for insertion and to protect soft tissue as the anchor is introduced into the wound.

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

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

The plastic cartridges are color-coded, white and blue, and have an alignment tab to facilitate loading into the appropriate groove of the inserter guide. The alignment tab should always be aligned with the shaft of the inserter guide to ensure the anchor is inserted in the appropriate groove and locked into the implant.



Note: The white and blue colored cartridges have alignment tabs on opposite sides to accommodate the different diverging angle of the anchors.

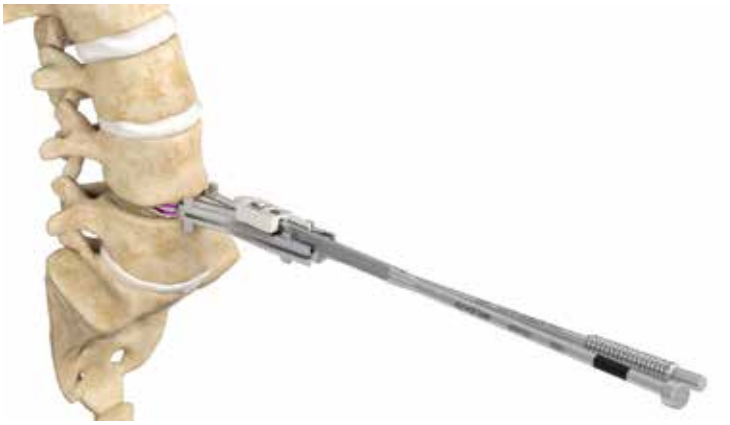
Starting with one of the superior anchors, slide the **Anchor Tamp** into the appropriate anchor cartridge within the sterile packaging. Alternatively, the anchor cartridge may be pulled from the tray and manually loaded onto the anchor tamp.

Anchor Tamp
48921001

Anchor cartridge loaded onto anchor tamp

The anchor should be facing toward the vertebral body and the alignment tab on the cartridge should be aligned with the inserter guide shaft. Slide the anchor tamp with the anchor cartridge assembly into the appropriate groove of the inserter guide.

Proper tab alignment with inserter guide shaft

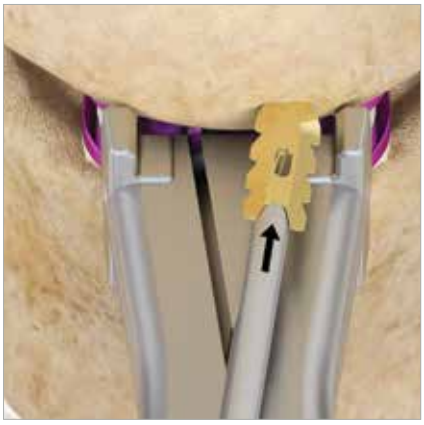


Anchor and anchor tamp insertion into inserter guide

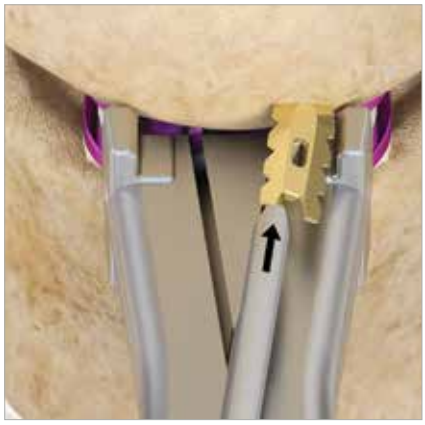
Note: The white and blue cartridges will be inserted in the opposite directions on the superior and inferior sides of the inserter guide. The alignment tab will always be aligned with the shaft of the inserter guide.

Using the mallet, tap the anchor tamp to push the anchor out of the cartridge, down the channel of the inserter guide and into the implant. The anchor will penetrate the anterior face of the vertebral body during insertion and engage into the jacket at both the anterior and posterior aspects of the implant.

Visually observe anchor during insertion process to verify proper alignment between anchor tamp and anchor. Anchor tamp should interface with notch on anchor during installation.



Correct alignment



Incorrect alignment

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

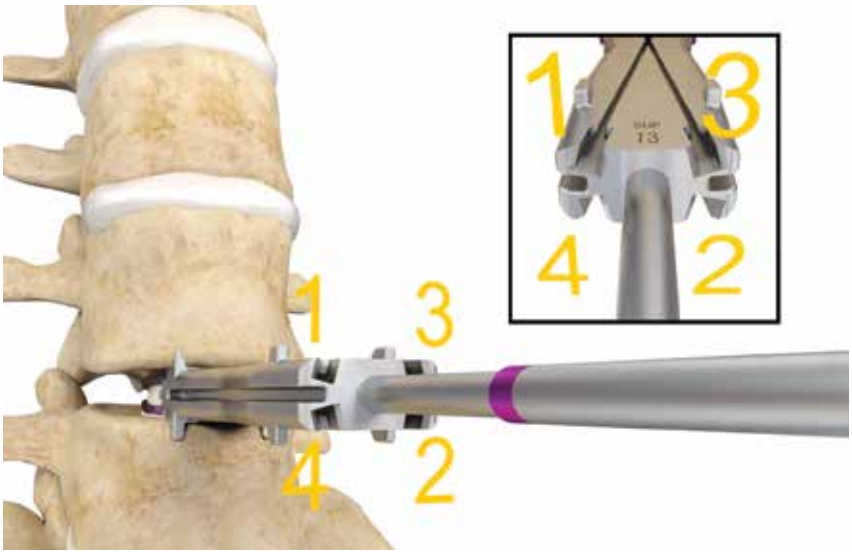
Caution: The anchors are exposed from the plastic cartridges as they travel down the channels of the inserter guide. Extreme care should be taken to ensure no vessels or soft tissues are within the 6-7mm space above the endplates of the vertebral bodies where the anchors will enter.

Anchor insertion into vertebral body

The mallet may be used to facilitate anchor tamp removal. The cartridge will remain on the anchor tamp during removal. Once the tamp is removed from the wound, slide the cartridge off of the anchor tamp and discard. These steps should be repeated for the remaining three anchors.

The anchors may be inserted into the implant in any order determined by the surgeon. However, it is highly recommended that the surgeon use a crosswise method of anchor insertion outlined in the image. This correlates to either a white-white-blue-blue (1-2-3-4) cartridge insertion order or a blue-blue-white-white (3-4-1-2) cartridge insertion order.

Note: The diagonal anchor insertion sequencing should be used to ensure strong anchor purchase into the vertebral body and proper implant fit within the disc space.



Crosswise anchor insertion order

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

Note: A built-in depth stop will automatically control the depth of anchor insertion and prevent the anchor tamp from entering the disc space or vertebral body. The depth stop on the anchor tamp will contact the inserter guide when the anchor is fully inserted providing visual, tactile and audible feedback.

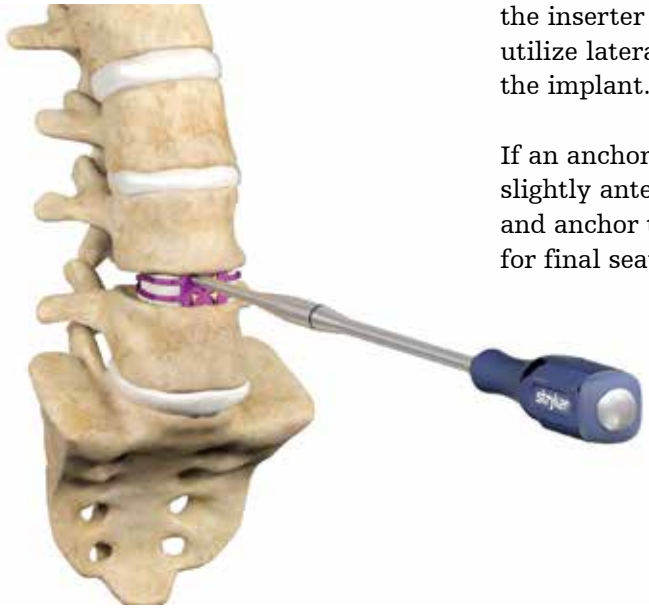
Anchor length

Note: If a replacement anchor is required, be sure to select the appropriate size anchor corresponding to the implant footprint (a 22, 26 or 30mm anchor) and the insertion orientation needed (either a white or blue cartridge). Use the size of the discarded anchor and plastic cartridge as a reference for the anchor size and orientation needed. Confirm the anchor size and color cartridge on the label of the sterile packaging.

Once all of the anchors are inserted and locked, release the implant from the inserter guide by unthreading the thumb screw. Visually confirm and utilize lateral fluoroscopic images to verify that the anchors are flush with the implant.

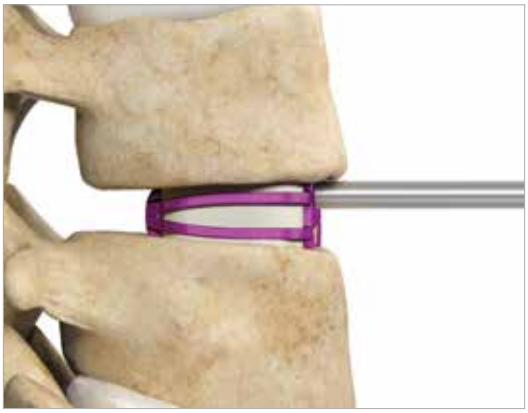
If an anchor is not locked, the distal end of the anchor will protrude slightly anteriorly from the implant. If after removing the inserter guide and anchor tamp, the anchor still appears proud, use the **Freehand Tamp** for final seating of the anchor.

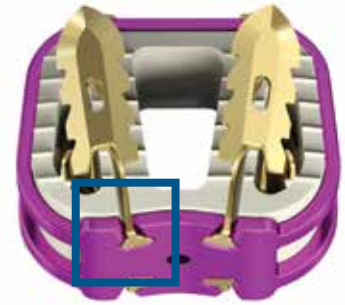
Place the distal end of freehand tamp against the dovetail of the proud anchor and tap with the mallet to ensure the anchor is fully seated. Repeat this step for any remaining proud anchors.



Freehand tamp

Freehand Tamp
48921006

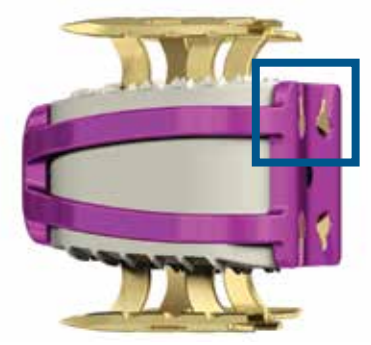




Correct alignment

A/P view

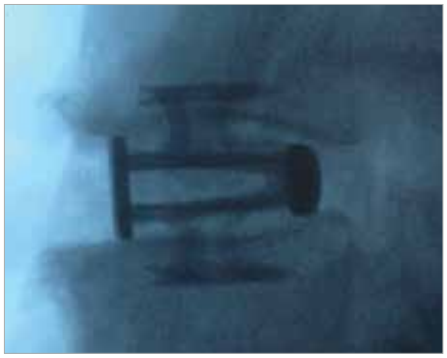
Incorrect alignment



Correct alignment

Lateral view

Incorrect alignment



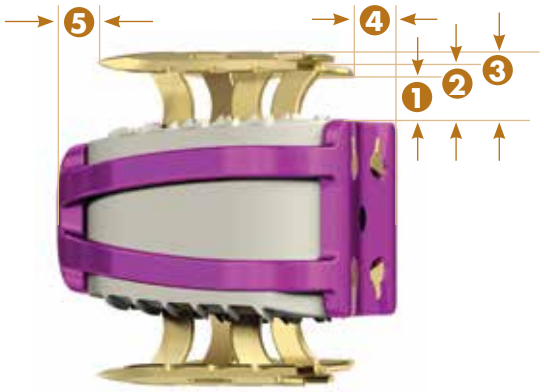
Aero-AL fully implanted

Step 8. Supplemental fixation

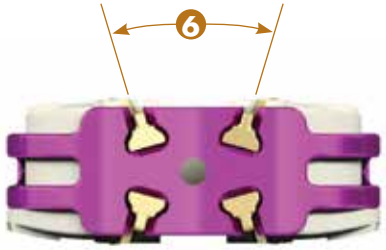
With all of the anchors inserted and locked in place, supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine (e.g. pedicle screws or, when performing a single-level fusion, an interspinous process plate) must be used to augment stability of the Aero-AL construct.

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

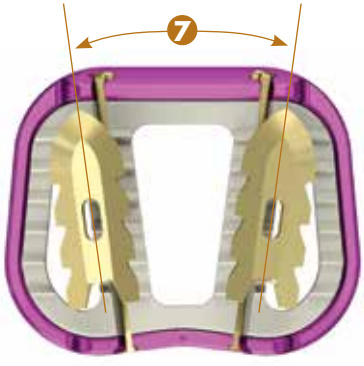
Anchor - bone engagement (Vertical distance from anchor to implant)			
#	Implant aspect	11mm	13-19mm
1	Lateral anchor edge	5.2mm	4.2mm
2	Anchor midpoint	6.2mm	5.2mm
3	Medial anchor edge	7.1mm	6.1mm



Distance of anchor from anterior and posterior edges of implant				
#	Implant aspect	22 x 28mm	26 x 32mm	30 x 38mm
4	Posterior edge	3.7mm	3.8mm	3.9mm
5	Anterior edge	4.1mm	4.2mm	4.4mm



Anchor angles			
#	Measurement	Total	Midline
6	Dovetail tilt	30°	15°
7	Anchor divergence	15°	7.5°



Implant removal

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

Should the Aero-AL implant need to be removed for any reason, utilize the **Revision Guide, Revision Guide Inner Shaft, Revision Housing and Revision Adapter** to remove the implant. The revision instruments are designed with a threaded persuader mechanism to allow removal of the implant without impaction, thus reducing unnecessary trauma to the patient.

Insert the revision guide inner shaft into the revision guide. Align the revision guide with the implant and rotate the shaft clockwise to engage the threaded hole in the implant.

Revision Guide
48921005

Revision Guide Inner Shaft
48921050

Revision Housing
48921004

Revision guide

Note: The revision guide inner shaft is not the same as the inserter guide inner shaft. When assembling the revision housing, be sure to use the revision guide inner shaft.

Revision Adapter

To assemble the revision guide and revision guide inner shaft, slide the inner shaft through the body of the revision guide. The revision guide inner shaft is slightly bent to aid in insertion and removal for cleaning and sterilization.

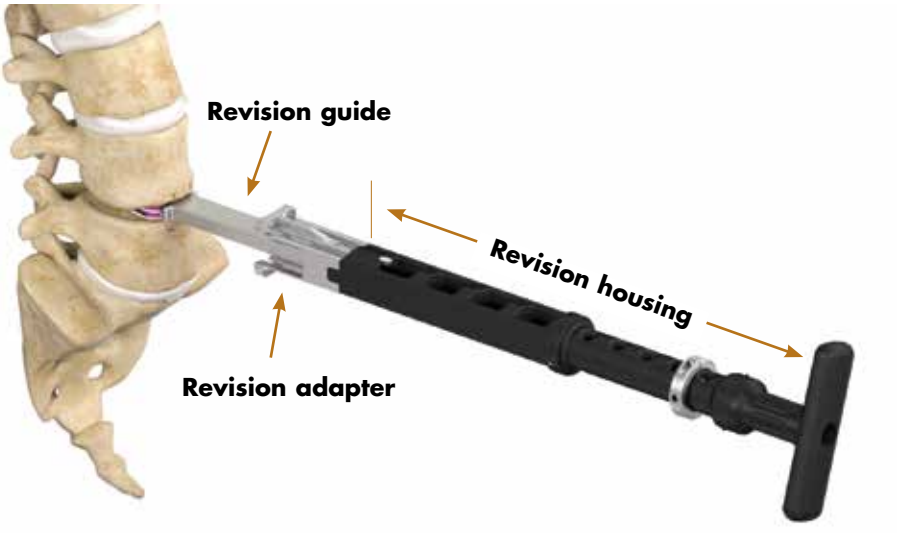
Reference number	Description
48926613	Revision Adapter, 11/13mm
48926615	Revision Adapter, 15mm
48926617	Revision Adapter, 17mm
48926619	Revision Adapter, 19mm

Select the appropriately sized revision adapter to match the size of the implant and assemble the revision adapter onto the revision housing by depressing and sliding the prongs toward the handle of the revision housing.

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

Revision adapter and revision housing assembly

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



Revision housing and revision guide assembly

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

Assembled revision housing and adapter with counter torque handle

Counter Torque Handle
48394006

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

Anchor Remover
48926600

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

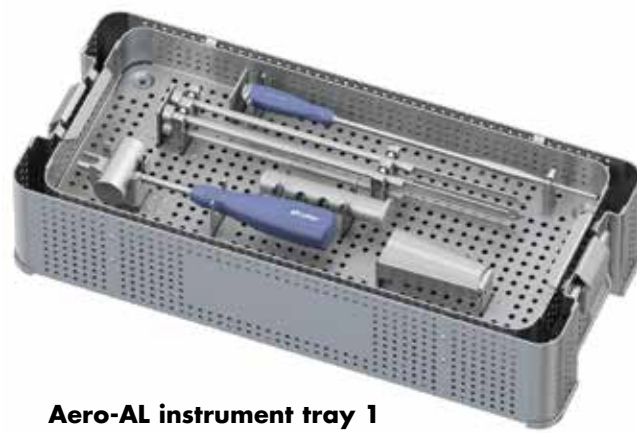
Once the implant is removed from the vertebral bodies, all revision instruments can be removed from the wound.

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

Note: Once an Aero-AL implant has been inserted and removed, another Aero-AL implant cannot be placed at that level. Alternative anterior lumbar instrumentation should be used.

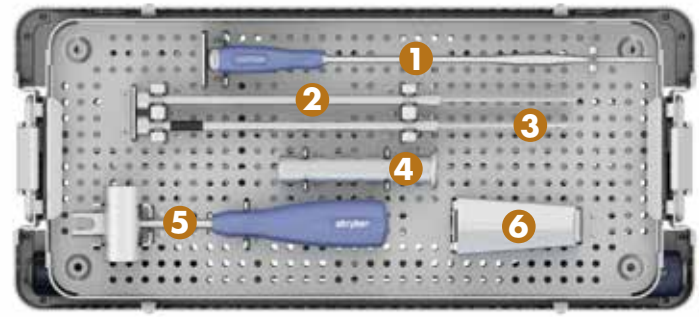
Note: Following implant removal, disassemble the revision housing, revision adapter and counter torque handle for cleaning and sterilization.

Tray overview

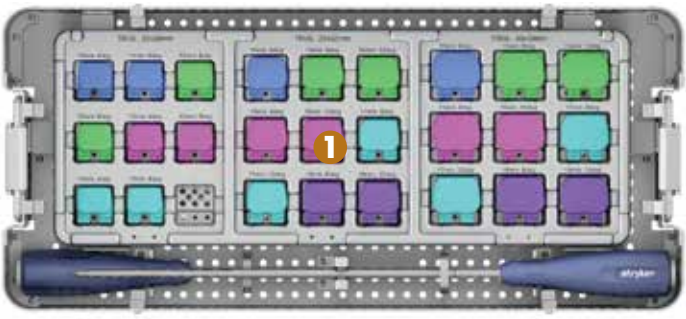


Aero-AL instrument tray 1
48922000

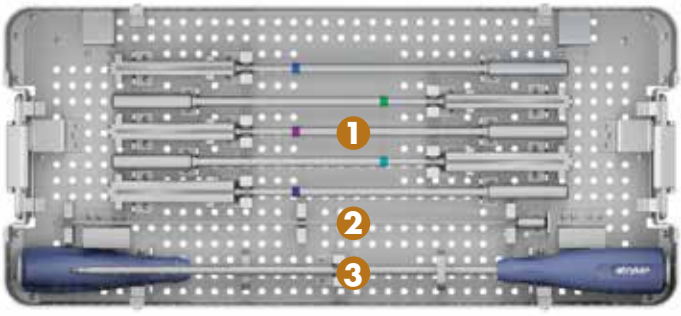
Top tray		
	Description	**Reference number**
1	Freehand Tamp	48921006
2	Pilot Cutter	48921002
3	Anchor Tamp	48921001
4	Impaction Handle	48921007
5	Mallet	48921009
6	Soft Tissue Guard	48921008

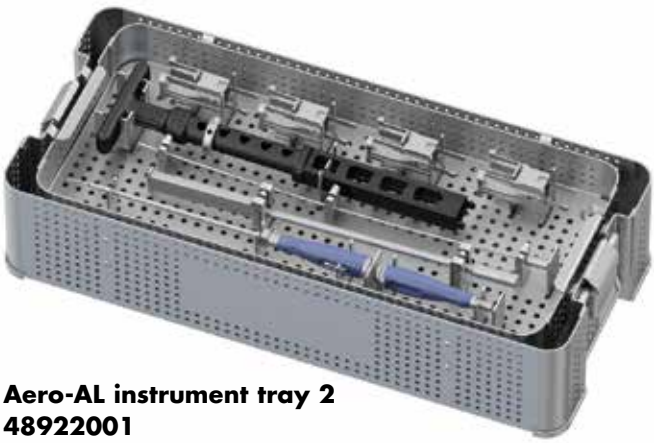


Middle tray		
	Description	**Reference number**
1	Trials	48924122 - 48922930



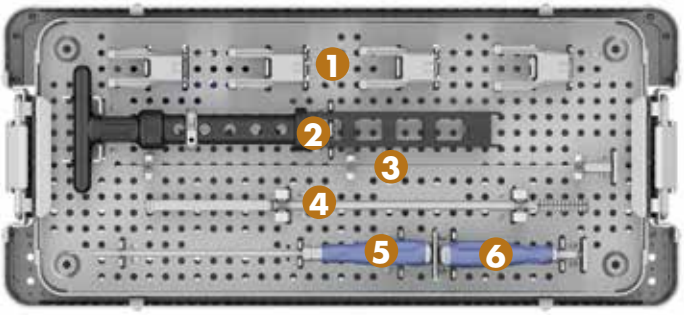
Bottom tray		
	Description	**Reference number**
1	Inserter Guides	48921011 - 48921019
2	Inserter Guide Inner Shaft	48921100
3	Trial Handles	48361234



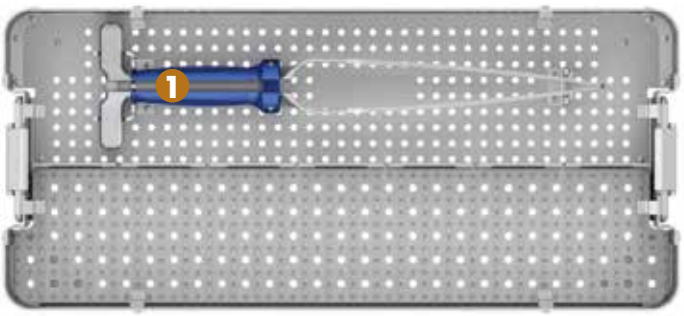


Aero-AL instrument tray 2
48922001

Top tray		
	Description	**Reference number**
1	Revision Adapters	48926613 - 48926619
2	Revision Housing	48921004
3	Revision Guide Inner Shaft	48921050
4	Revision Guide	48921005
5	Anchor Remover	48926600
6	Counter Torque Handle	48394006



Top tray		
	Description	**Reference number**
1	Inserter/Distractor	48921003



Implants

Reference number	Description
48922214	Aero-AL, 22 x 28mm, 11mm, 4°
48922218	Aero-AL, 22 x 28mm, 11mm, 8°
48922234	Aero-AL, 22 x 28mm, 13mm, 4°
48922238	Aero-AL, 22 x 28mm, 13mm, 8°
48922254	Aero-AL, 22 x 28mm, 15mm, 4°
48922258	Aero-AL, 22 x 28mm, 15mm, 8°
48922274	Aero-AL, 22 x 28mm, 17mm, 4°
48922278	Aero-AL, 22 x 28mm, 17mm, 8°
48922618	Aero-AL, 26 x 32mm, 11mm, 8°
48922638	Aero-AL, 26 x 32mm, 13mm, 8°
48922632	Aero-AL, 26 x 32mm, 13mm, 12°
48922658	Aero-AL, 26 x 32mm, 15mm, 8°
48922652	Aero-AL, 26 x 32mm, 15mm, 12°
48922678	Aero-AL, 26 x 32mm, 17mm, 8°
48922672	Aero-AL, 26 x 32mm, 17mm, 12°
48922698	Aero-AL, 26 x 32mm, 19mm, 8°
48922692	Aero-AL, 26 x 32mm, 19mm, 12°
48923018	Aero-AL, 30 x 38mm, 11mm, 8°
48923038	Aero-AL, 30 x 38mm, 13mm, 8°
48923032	Aero-AL, 30 x 38mm, 13mm, 12°
48923058	Aero-AL, 30 x 38mm, 15mm, 8°
48923052	Aero-AL, 30 x 38mm, 15mm, 12°
48923078	Aero-AL, 30 x 38mm, 17mm, 8°
48923072	Aero-AL, 30 x 38mm, 17mm, 12°
48923098	Aero-AL, 30 x 38mm, 19mm, 8°
48923092	Aero-AL, 30 x 38mm, 19mm, 12°

48922200	Aero-AL, Anchor, 22mm, Blue Cartridge
48922600	Aero-AL, Anchor, 26mm, Blue Cartridge
48923000	Aero-AL, Anchor, 30mm, Blue Cartridge
48922201	Aero-AL, Anchor, 22mm, White Cartridge
48922601	Aero-AL, Anchor, 26mm, White Cartridge
48923001	Aero-AL, Anchor, 30mm, White Cartridge

Instruments

Reference number	Description
48924122	Aero-AL Trial, 22 x 28 mm, 11mm, 4°
48928122	Aero-AL Trial, 22 x 28 mm, 11mm, 8°
48924322	Aero-AL Trial, 22 x 28 mm, 13mm, 4°
48928322	Aero-AL Trial, 22 x 28 mm, 13mm, 8°
48924522	Aero-AL Trial, 22 x 28 mm, 15mm, 4°
48928522	Aero-AL Trial, 22 x 28 mm, 15mm, 8°
48924722	Aero-AL Trial, 22 x 28 mm, 17mm, 4°
48928722	Aero-AL Trial, 22 x 28 mm, 17mm, 8°
48928126	Aero-AL Trial, 26 x 32 mm, 11mm, 8°
48928326	Aero-AL Trial, 26 x 32 mm, 13mm, 8°
48922326	Aero-AL Trial, 26 x 32 mm, 13mm, 12°
48928526	Aero-AL Trial, 26 x 32 mm, 15mm, 8°
48922526	Aero-AL Trial, 26 x 32 mm, 15mm, 12°
48928726	Aero-AL Trial, 26 x 32 mm, 17mm, 8°
48922726	Aero-AL Trial, 26 x 32 mm, 17mm, 12°
48928926	Aero-AL Trial, 26 x 32 mm, 19mm, 8°
48922926	Aero-AL Trial, 26 x 32 mm, 19mm, 12°
48928130	Aero-AL Trial, 30 x 38 mm, 11mm, 8°
48928330	Aero-AL Trial, 30 x 38 mm, 13mm, 8°
48922330	Aero-AL Trial, 30 x 38 mm, 13mm, 12°
48928530	Aero-AL Trial, 30 x 38 mm, 15mm, 8°
48922530	Aero-AL Trial, 30 x 38 mm, 15mm, 12°
48928730	Aero-AL Trial, 30 x 38 mm, 17mm, 8°
48922730	Aero-AL Trial, 30 x 38 mm, 17mm, 12°
48928930	Aero-AL Trial, 30 x 38 mm, 19mm, 8°
48922930	Aero-AL Trial, 30 x 38 mm, 19mm, 12°

48926613	Revision Adapter, 11/13mm
48926615	Revision Adapter, 15mm
48926617	Revision Adapter, 17mm
48926619	Revision Adapter, 19mm

48926600	Anchor Remover

	Reference number	Description
	48921008	Soft Tissue Guard
	48921011	Inserter Guide, 11mm
	48921013	Inserter Guide, 13mm
	48921015	Inserter Guide, 15mm
	48921017	Inserter Guide, 17mm
	48921019	Inserter Guide, 19mm
	48921100	Inserter Guide Inner Shaft
	48361234	Trial Handle
	48921003	Inserter/Distractor
	48921001	Anchor Tamp
	48921004	Revision Housing
	48921005	Revision Guide
	48921050	Revision Guide Inner Shaft
	48921002	Pilot Cutter
	48921006	Freehand Tamp
	48921009	Mallet
	48394006	Counter Torque Handle
	48921007	Impaction Handle

IMPORTANT PRODUCT INFORMATION FOR AERO™-AL ANTERIOR LUMBAR CAGE AND FIXATION SYSTEM

STERILE PRODUCT

DESCRIPTION

The Aero™-AL Cage is a hollow, box-shaped PEEK cage surrounded by a titanium alloy jacket. The PEEK cage portion consists of three closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. The cage is designed to be used with the integrated fixation provided (Aero™-AL Fixation Anchors) in addition to supplemental fixation systems cleared for use in the lumbosacral spine. The Aero™-AL Fixation Anchors are constructed from titanium alloy and feature rails that mate with dovetail channels located within the Aero™-AL PEEK cage. Once fully seated into the channels, the anchors are designed to lock into the titanium jacket.

MATERIAL

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

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

INDICATIONS

USA and CANADA Indications:

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

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

The Aero™-AL Lumbar Cage System is to be implanted via an anterior approach.

The Aero™-AL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems) in addition to the included fixation anchors.

Indications outside USA and CANADA:

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

The Aero™-AL Lumbar Cage System is to be implanted via an anterior approach.

The Aero™-AL Lumbar Cage system may be used as a stand-alone device or in conjunction with supplemental fixation. The Aero™-AL Lumbar Cage must be used with the four fixation anchors provided.

GENERAL CONDITIONS OF USE

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

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

CAUTION

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

- Do not mix metals (e.g. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

INFECTION
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS
Instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, and disposal attention. Instruments must be examined for wear or damage prior to surgery.

REUSE
Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

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

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

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES
When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

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 Aero™-AL Lumbar Cage should not be implanted in patients with an active infection at the operative site.
- The Aero™-AL Lumbar Cage is not intended for use except as indicated.
- Marked local inflammation.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Pregnancy.
- Inadequate tissue coverage over the operative site.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Prior fusion at the levels to be treated.

These contra-indications 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 advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PRE-OPERATIVE PRECAUTIONS
The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected

with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue, fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INTRA-OPERATIVE PRECAUTIONS

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

PATIENT CARE FOLLOWING TREATMENT

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting may be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

Include but are not limited to:
- Late bone fusion or no visible fusion mass and pseudarthrosis;
- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials, although uncommon, can occur;
- Decrease in bone density due to stress shielding;
- Dural leak requiring surgical repair;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Cessation of growth of the fused portion of the spine;
- Loss of proper spinal curvature, correction, height and/or reduction;
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
- Neurological and spinal dura mater lesions from surgical trauma;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.
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 Aero™-AL is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

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Spine Division

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

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

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