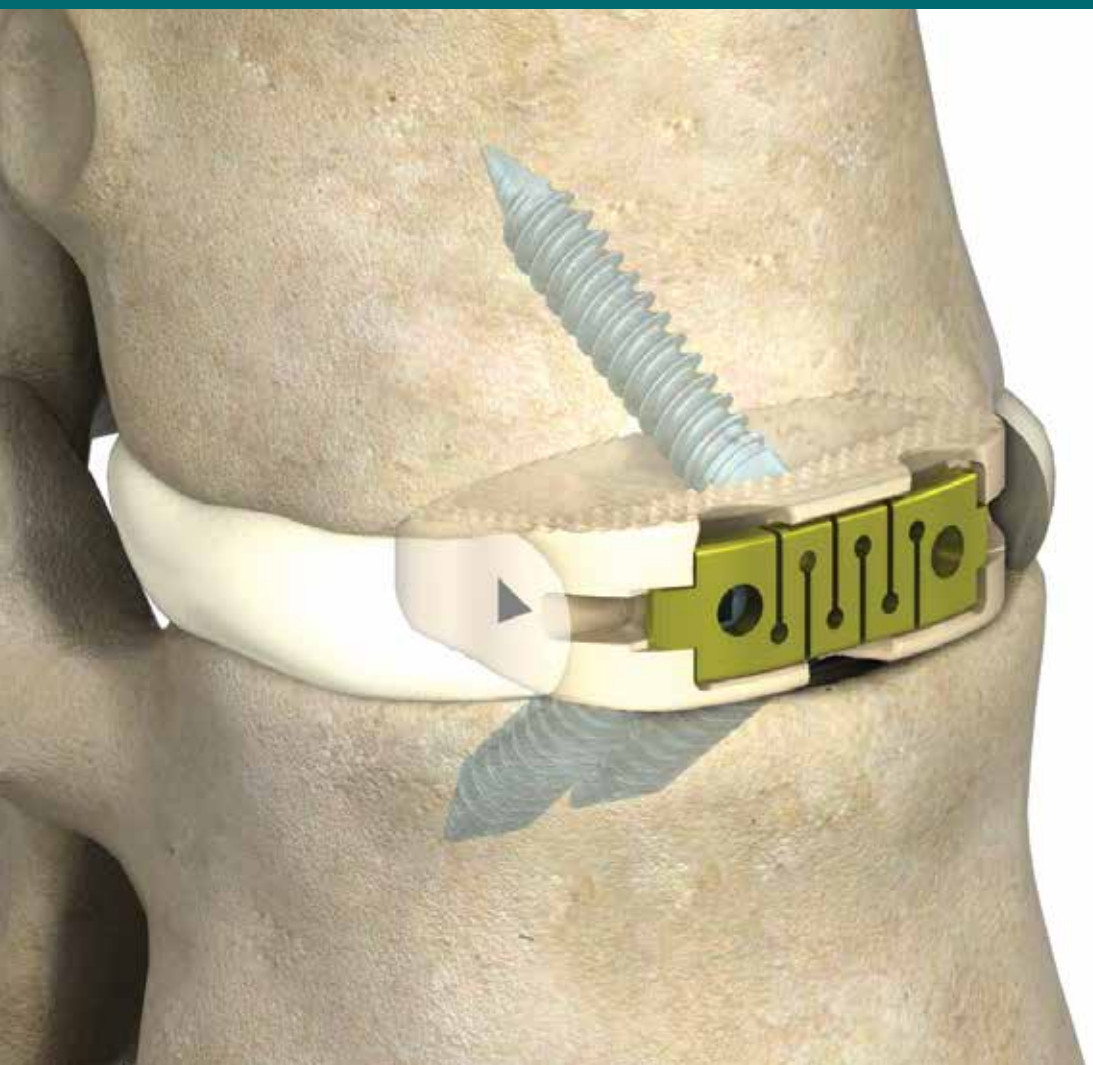
stryker

Spine

AVS Anchor®-L Lumbar Cage System

Surgical Technique



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Acknowledgments

Stryker Spine wishes to thank the following surgeons for their dedication and contributions to the development of the AVS Anchor-L Lumbar Cage System.

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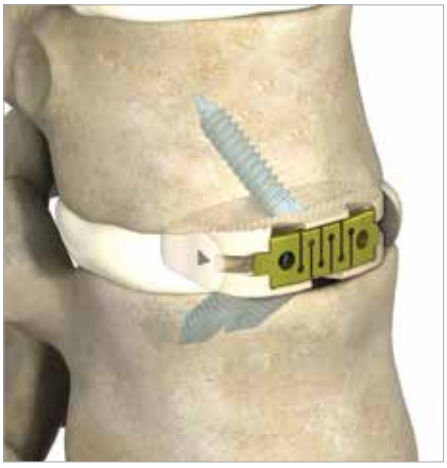
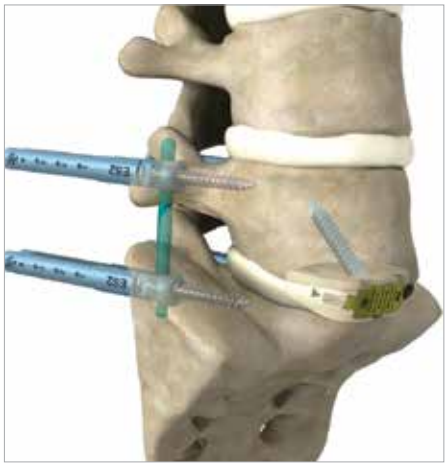
Introduction

The Stryker Spine AVS Anchor-L Lumbar Cage System includes a PEEK cage, three titanium bone screws, and a titanium locking plate that will be used together as an interbody fusion device for the lumbosacral spine (L2-S1). The PEEK cage incorporates three tantalum markers that aid in radiographic visualization. These markers are positioned on the posterior end and lateral aspects of the cage. The markers span the total height of the cage in order to show the overall height relative to the vertebral endplates as well as the cage-to-endplate proximity. The upper and lower aspects of the lumbar cage are open, and the superior and inferior surfaces have serrations that assist in positive anchorage and seating. The AVS Anchor-L PEEK cage and titanium bone screws are available in a variety of sizes in order to allow the surgeon to choose those that are best suited to the patient's anatomy and pathology.

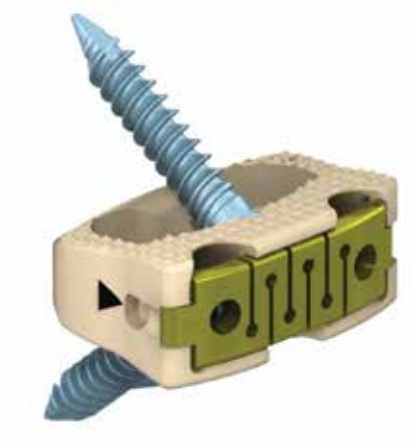
The AVS Anchor-L device is designed to be inserted via a transperitoneal or retroperitoneal surgical approach to the lumbosacral spine. After the cage is implanted, the bone screws should be inserted, and then the construct is locked with a titanium locking plate once it is determined that the construct is in its desired final position.

The AVS Anchor-L Lumbar Cage System may be used as an intervertebral device with integrated fixation or in conjunction with supplemental fixation. When used as a intervertebral device with integrated fixation, the AVS Anchor-L PEEK Cage must be used with three internal screws and plate fixation provided by AVS Anchor-L Fixation Screws and Locking Plate. If AVS Anchor-L is used with less than three or none of the provided screws, additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. The accompanying Locking Plate must be used anytime the device is used with any number of screws.





Preparation



Approach - Transperitoneal or Retroperitoneal

Determine surgical approach (transperitoneal or retroperitoneal). Surgeon preference, patient anatomy, and patient pathology should determine the approach used.

The 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 screws and locking plate. This technique details a retroperitoneal approach.

Cage Height Determination

Analyze preoperative imaging to determine height of the cage. The cage must be firmly seated with a secure fit in the disc space when the segment is distracted.

Step 1: Exposure

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 30mm – 40mm) **(Fig. 1)**.

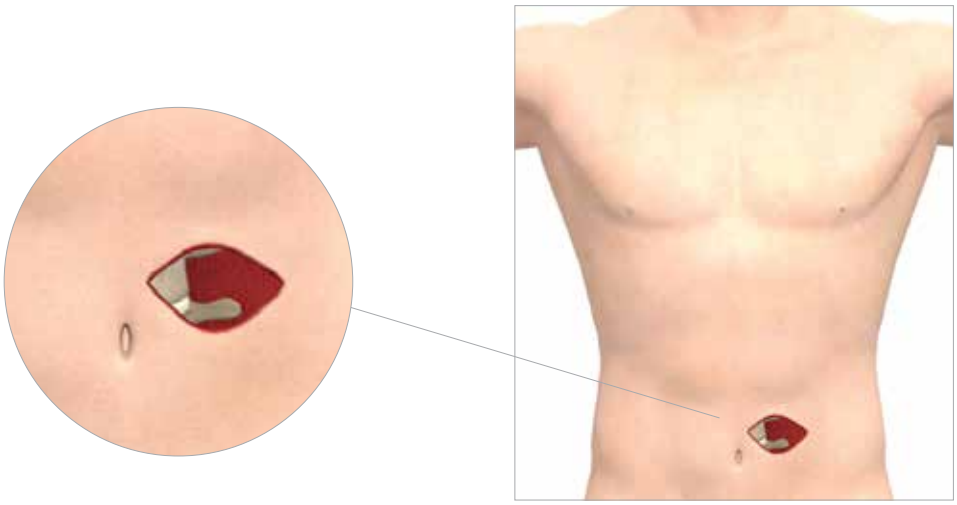


Figure 1

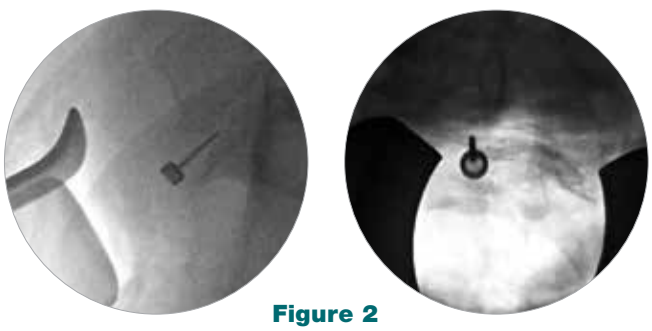


Figure 2

Consideration: Mark the midline of the disc/vertebral body under fluoroscopic guidance. This mark will assist in determining the annulotomy site width (Fig. 2).

Figure 3. Long Handle Knife

Figure 4. Cobb

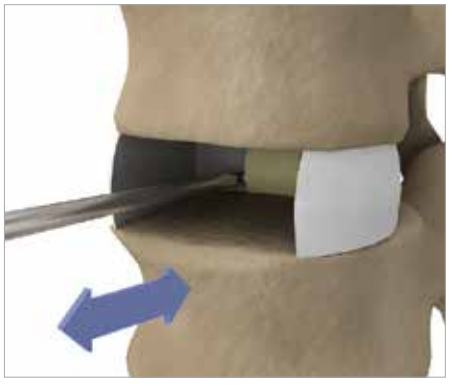


Figure 5. Posterior Longitudinal Ligament (PLL) Stripper
48361238

Step 2: Perform the Annulotomy & Discectomy

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 (**Fig. 3**).

Figure 3. Long Handle Knife
48361277

Warning: Care is required while performing the annulotomy with the Long Handle Knife as the blade can result in serious damage to the vascular elements. Blades for the Long Handle Knife are not included with the Reliance AL System.

A cobb can be used to separate the cartilaginous endplate from the bony vertebral endplate (**Fig. 4**).

Use a 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 pituitary rongeurs can also be used to remove disc material and cartilaginous tissue from the superior and inferior vertebral endplates.

A paddle distractor or a lordosed paddle distractor may be used to distract and allow room to work on the contralateral side.

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

Note: The Reliance AL Lumbar Fusion System includes instruments used during annulotomy, discectomy, bone removal, and endplate preparation. These instruments include cobbs, pituitary rongeurs, kerrisons, paddle distractors, curettes, and rasps. (See Reliance AL Surgical Technique for information regarding these instruments.)

Once the discectomy has been performed, the **Posterior Longitudinal Ligament (PLL) Stripper** may be used. The instrument may be 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. If the PLL Stripper is utilized, use caution to protect the neurological structures (**Fig. 5**).

Figure 6. Reliance AL Discectomy Distractor
48361150

Distraction of the discectomy site is important to restore lordosis, open the neural foramen, and stabilize the implant. The **Reliance AL Discectomy Distractor** can be used to provide distraction for the discectomy, endplate preparation, implant trialing, and implant insertion. The Modular Straight Tips or Offset Tips are recommended (**Fig. 6**).

Step 3: Prepare the Endplates

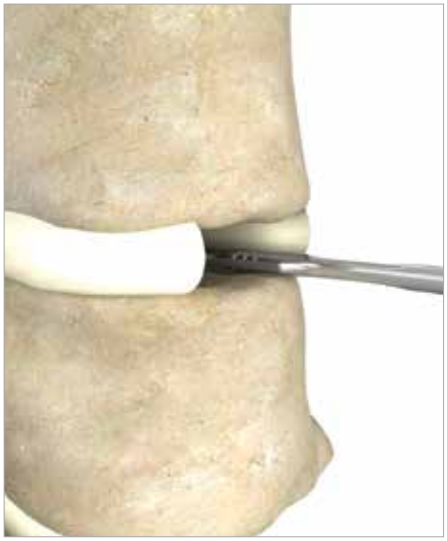


Figure 7

Adequate preparation of the endplates is important to enhance vascular supply to the fusion site. The AVS Anchor-L Lumbar Cage System includes **Single Side Rasps** in up, straight, and down facing orientations. It is recommended to move these 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 (**Fig. 7**).

48998200	6mm Single Side Straight Rasp
48998300	6mm Single Side Angled Rasp Up
48998400	6mm Single Side Angled Rasp Down

Caution: In patients with sclerosis of the endplates, more rigorous rasping may be useful to expose a bleeding surface. Care should be used to not remove the dense cancellous endplate.

Consideration: Additional rasps can be found in the Reliance AL set, and may also be used to help prepare the endplates.

Note: Depth notches indicate depth of rasp at 22mm, 25mm, and 28mm which represent the different trial footprint depth options.

Step 4: Determine Cage Size

Figure 8

Cage Sizes/Trial Sizes

AVS Anchor-L Lumbar Cage and Trial Sizes*			
Footprints	**22x30mm**	**25x35mm**	**28x40mm**
Heights	**10-20mm (2mm incr.)**	**10-20mm (2mm incr.)**	**10-20mm (2mm incr.)**
Lordosis	**4°, 8°, 12°, 16°**	**4°, 8°, 12°, 16°**	**4°, 8°, 12°, 16°**

Final cage size can be determined using the appropriate **Solid Trials.** Solid Trials range from 10mm-20mm matching the cage options in footprint, height, and lordosis (**Fig. 8**).

* The Standard AVS Anchor-L Lumbar Cage Set includes the following:
Footprints: 22x30mm and 25x35mm
Heights: 10-16mm
Lordosis: 4°, 8°, 12°

The 28x40mm footprint, the 18mm and 20mm heights, and the 16° cages are only available in the AVS Anchor-L Auxiliary Set (Loaners only).

Figure 9. Trial Handle
48361234

The **Trial Handle** can be used for trial insertion. The Trial Stop was designed to prevent the trial from being inserted too posteriorly which may inaccurately represent the position of the implant when placed with the **All-In-One Guide** (**AIOG**). Once the Trial Stop has been placed onto the Trial Handle, attach the trial by threading the distal end into the hole in the trial. Insert the trial into the disc space to confirm the appropriate size cage. Fluoroscopy can assist in confirming the proper fit (**Fig. 9**).

If the trial appears too small or too tight, the next larger or smaller size, respectively, should be chosen until the firmest fit is obtained. The Solid Trial can be removed from the Trial Handle by unthreading the trials from the handle.

Note: If using the AVS Anchor-L lumbar cage as an anterior lumbar cage with supplemental fixation, do not use the Trial Stop during trialing. Without the Trial Stop, the trials can be countersunk into the disc space to give an accurate representation of where the final implant will sit (Fig. 10).

Figure 10. Trial Stop
48991014

Consideration: Lateral imaging is recommended for confirming posterior trial-to-endplate contact. There should be no gaps between the endplates and the trial (Fig. 11).

Consideration: It is important to not oversize with the trial, as the overall implant height is 1mm taller than the trial when the height of the serrations (0.5mm per side) is included.

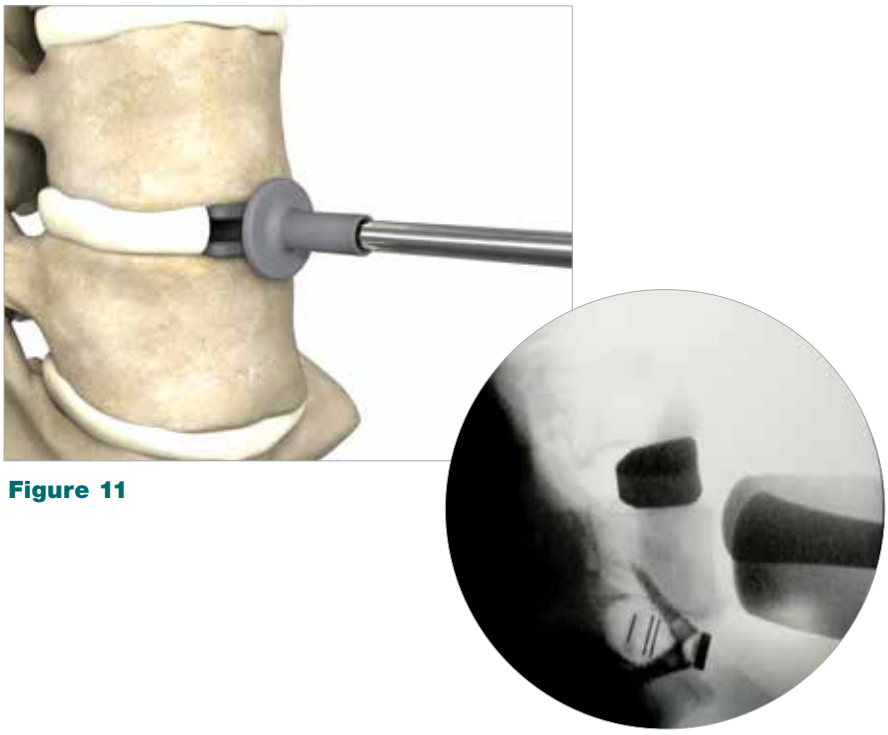


Figure 11

AVS Anchor-L Lumbar Cage System

Surgical Technique

Anchor-L Height Specifications

AVS Anchor-L Anterior vs. Posterior Height				
22mm x 30mm footprint				
Size	Ant height [mm]	Post height [mm]	Difference Ant/Post [mm]	Nose Height [mm]
10mm x 4°	10	8.9	1.1	6.8
10mm x 8°	10	7.8	2.2	5.5
10mm x 12°	10	6.7	3.3	4.1
12mm x 4°	12	10.9	1.1	8.8
12mm x 8°	12	9.8	2.2	7.5
12mm x 12°	12	8.7	3.3	6.1
12mm x 16°	12	7.6	4.5	4.7
14mm x 4°	14	12.9	1.1	10.8
14mm x 8°	14	11.8	2.2	9.5
14mm x 12°	14	10.7	3.3	8.1
14mm x 16°	14	9.6	4.5	6.7
16mm x 4°	16	14.9	1.1	12.8
16mm x 8°	16	13.8	2.2	11.5
16mm x 12°	16	12.7	3.3	10.1
16mm x 16°	16	11.6	4.5	8.7
18mm x 4°	18	16.9	1.1	14.8
18mm x 8°	18	15.8	2.2	13.5
18mm x 12°	18	14.7	3.3	12.1
18mm x 16°	18	13.6	4.5	10.7
20mm x 4°	20	18.9	1.1	16.8
20mm x 8°	20	17.8	2.2	15.5
20mm x 12°	20	16.7	3.3	14.1
20mm x 16°	20	15.6	4.5	12.7

AVS Anchor-L Anterior vs. Posterior Height				
25mm x 35mm footprint				
Size	Ant height [mm]	Post height [mm]	Difference Ant/Post [mm]	Nose Height [mm]
10mm x 4°	10	8.7	1.3	6.6
10mm x 8°	10	7.4	2.6	5.0
10mm x 12°	10	6.0	4.0	3.5
12mm x 4°	12	10.7	1.3	8.6
12mm x 8°	12	9.4	2.6	7.0
12mm x 12°	12	8.0	4.0	5.5
12mm x 16°	12	6.7	5.3	3.9
14mm x 4°	14	12.7	1.3	10.6
14mm x 8°	14	11.4	2.6	9.0
14mm x 12°	14	10.0	4.0	7.5
14mm x 16°	14	8.7	5.3	5.9
16mm x 4°	16	14.7	1.3	12.6
16mm x 8°	16	13.4	2.6	11.0
16mm x 12°	16	12.0	4.0	9.5
16mm x 16°	16	10.7	5.3	7.9
18mm x 4°	18	16.7	1.3	14.6
18mm x 8°	18	15.4	2.6	13.0
18mm x 12°	18	14.0	4.0	11.5
18mm x 16°	18	12.7	5.3	9.9
20mm x 4°	20	18.7	1.3	16.6
20mm x 8°	20	17.4	2.6	15.0
20mm x 12°	20	16.0	4.0	13.5
20mm x 16°	20	14.7	5.3	11.9

AVS Anchor-L Anterior vs. Posterior Height				
28mm x 40mm footprint				
Size	Ant height [mm]	Post height [mm]	Difference Ant/Post [mm]	Nose Height [mm]
10mm x 4°	10	8.5	1.5	6.4
10mm x 8°	10	6.9	3.1	4.6
10mm x 12°	10	5.4	4.6	2.8
12mm x 4°	12	10.5	1.5	8.4
12mm x 8°	12	8.9	3.1	6.6
12mm x 12°	12	7.4	4.6	4.8
12mm x 16°	12	5.9	6.1	3.0
14mm x 4°	14	12.5	1.5	10.4
14mm x 8°	14	10.9	3.1	8.6
14mm x 12°	14	9.4	4.6	6.8
14mm x 16°	14	7.9	6.1	5.0
16mm x 4°	16	14.5	1.5	12.4
16mm x 8°	16	12.9	3.1	10.6
16mm x 12°	16	11.4	4.6	8.8
16mm x 16°	16	9.9	6.1	7.0
18mm x 4°	18	16.5	1.5	14.4
18mm x 8°	18	14.9	3.1	12.6
18mm x 12°	18	13.4	4.6	10.8
18mm x 16°	18	11.9	6.1	9.0
20mm x 4°	20	18.5	1.5	16.4
20mm x 8°	20	16.9	3.1	14.6
20mm x 12°	20	15.4	4.6	12.8
20mm x 16°	20	13.9	6.1	11.0

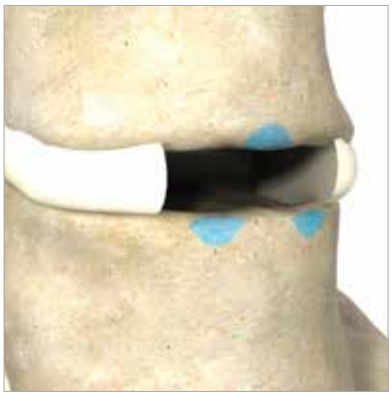


Figure 12

After trialing, if it is determined that a 10mm, 12mm, or 14mm cage will be implanted, a **Marking Guide** can be used to aid surgeons in identifying the areas of bone from the superior and inferior vertebral bodies that will need to be removed to allow for accurate screw insertion. Attach the appropriate Marking Guide (height and footprint matching the cage size determined by trialing) to the Trial Handle. Insert the Marking Guide into the disc space. Once the guide has marked the areas of bone needing to be removed, remove the guide (**Fig. 12**). Referencing the notches created by the Marking Guide, use a rongeur to remove any bone that may interfere with screw placement (**Fig. 13**).

Figure 12. Marking Guide

10x22x30° Marking Guide	**48999102**
10x25x35° Marking Guide	**48990102**
12x22x30° Marking Guide	**48999126**
14x22x30° Marking Guide	**48999146**
12x25x35° Marking Guide	**48990126**

14x25x35° Marking Guide	**48990146**
10x28x40° Marking Guide*	**48991102**
12x28x40° Marking Guide*	**48991126**
14x28x40° Marking Guide*	**48991146**

*Included in the Auxilary Instrument Set only.

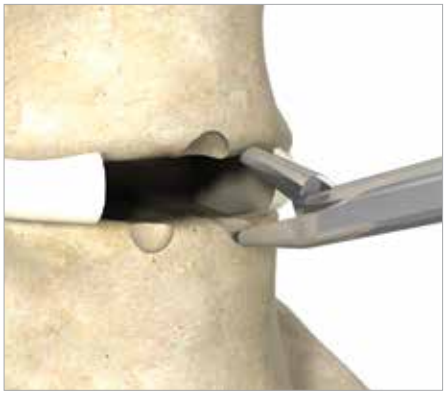


Figure 13

Note: It will be important to use the Marking Guides in the orientation that the screws will eventually be inserted.

Note: All Marking Guides have 16° of lordosis. The design intent is to avoid posteriorly over distracting a lordotic disc space.

Note: It is important to use the appropriate size Marking Guide relative to the implant height, as using a height that is shorter than the disc space could allow the guide to advance too far posteriorly.

Step 5: Load the Cage

Figure 14

Once the final cage size has been determined, select the corresponding AVS Anchor-L PEEK cage from the tray. Place the cage into the appropriate footprint on the **Graft Block** (**Fig. 15**), and use the **Graft Impactor** (**Fig. 16**) to pack autogenous bone graft into the open cavities of the cage (**Fig. 14**).

Figure 15. Graft Block
48999010

Figure 16. Graft Impactor
48999020

Anchor-L Graft Volumes

AVS Anchor-L Graft Volume				
22mm x 30mm footprint				
Size	4°	8°	12°	16°
10mm	1.6	1.5	1.4	-
12mm	2.1	2.0	1.9	1.7
14mm	2.5	2.4	2.2	2.2
16mm	2.9	2.8	2.7	2.6
18mm	3.3	3.2	3.1	3.0
20mm	3.8	3.6	3.5	3.4

AVS Anchor-L Graft Volume				
25mm x 35mm footprint				
Size	4°	8°	12°	16°
10mm	2.4	2.2	2.0	-
12mm	3.1	2.9	2.7	2.5
14mm	3.7	3.5	3.3	3.1
16mm	4.3	4.1	3.9	3.7
18mm	5.0	4.7	4.5	4.3
20mm	5.6	5.4	5.2	5.0

AVS Anchor-L Graft Volume				
28mm x 40mm footprint				
Size	4°	8°	12°	16°
10mm	3.4	3.0	2.7	-
12mm	4.4	4.1	3.7	3.4
14mm	5.3	4.9	4.6	4.3
16mm	6.2	5.8	5.5	5.1
18mm	7.1	6.7	6.4	6.0
20mm	7.9	7.6	7.3	6.9

Option 1: Interbody Technique

After the cage has been packed with bone graft, attach the cage to the Implant Holder by placing the distal end of the holder onto the front of the cage and then depressing the lever arm to tighten the arms into the lateral grooves on the cage (**Fig. 17**).

With the leading edge of the cage slightly between the vertebral endplates, gently impact the proximal end of the Implant Holder to safely and gradually insert the cage.

Reminder: If any screws are used, the Locking Plate must be inserted. If less than three screws are used, supplemental fixation that is cleared for use in the lumbosacral spine must be utilized.

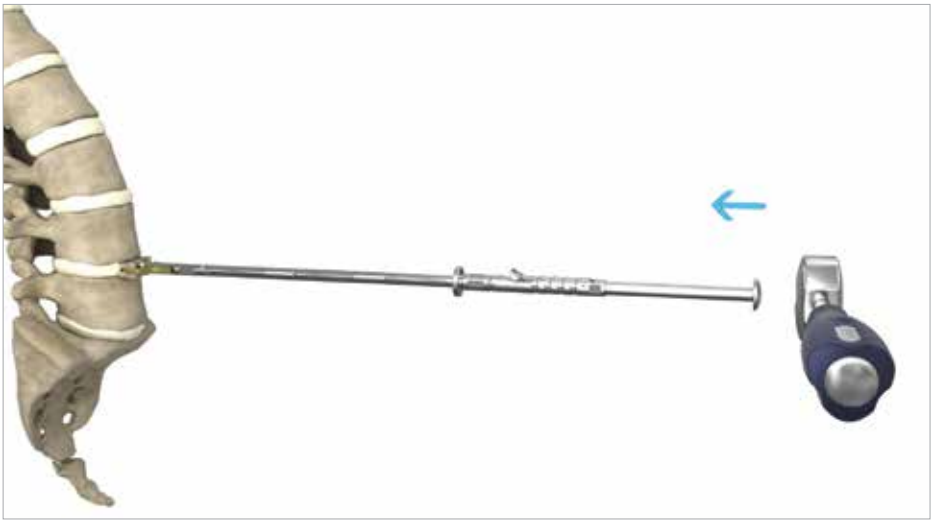


Figure 17. Implant Holder
48992001

Option 2: Stand Alone Technique

After the cage has been packed with bone graft, attach the appropriate height All-In-One Guide (AIOG) to the cage by aligning the laser marking on the AIOG arm with the corresponding laser marking on the side of the cage (**Fig. 18**). The AIOG is locked to the cage by using the **AIOG Small Locking Driver** (**Fig. 19**) to tighten the **AIOG Locking Screw**. (**Fig. 20**)

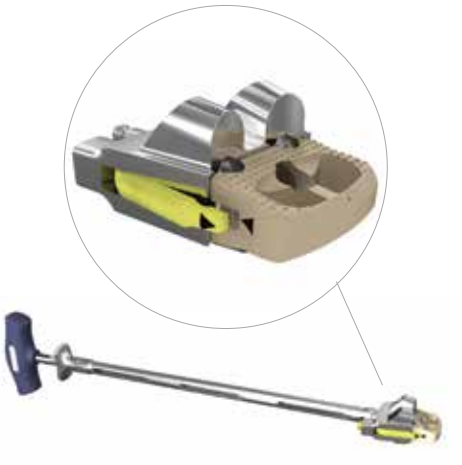


Figure 18

Figure 19. AIOG Small Locking Driver
48992115

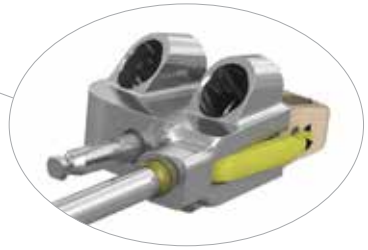


Figure 20. AIOG Locking Screw
48992110

Note: The AIOG's are cage height specific. There are six AIOG's. For example, if a 12mm cage is to be implanted, the 12mm AIOG must be used (Fig. 21).

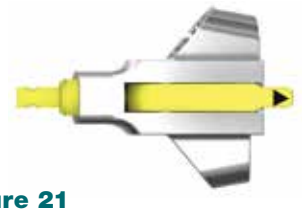


Figure 21

10mm All In One Guide	**48992010**
12mm All In One Guide	**48992012**
14mm All In One Guide	**48992014**

16mm All In One Guide	**48992016**
18mm All In One Guide*	**48992018**
20mm All In One Guide*	**48992020**

*Included in the Auxiliary Instrument Set only.

Note: Any screwdriver in the set, in addition to the Small Locking Driver, may be used to tighten or loosen the AIOG Locking Screw at any point during the procedure, as these screws also have a 3.5mm hex interface.

By fully tightening the AIOG Locking Screw, the AIOG is firmly attached to the cage. Be sure that the AIOG is flush with the anterior wall of the implant. Attach the **AIOG Holder** to the AIOG cage construct by using the quick release feature of the AIOG Holder.

Note: The AIOG Locking Screw is a separate piece, and may thread completely out. This allows for cleaning should tissue become lodged in the threads. If a Locking Screw (Fig. 22) is misplaced, simply use one of the extra Locking Screws in the set, or a Locking Screw from a different size AIOG.

Figure 22. AIOG Locking Screw
48992110

Tip: If the Locking Screw will not advance, back it up one turn, slightly depress the gold arm of the AIOG, and then advance the Locking Screw. The AIOG Locking Screw should not be over-tightened.

Figure 23. AIOG Holder
48992000

Note: The Implant Holder can be used instead of the AIOG to insert the cage if it is being used as an interbody fusion device with supplemental fixation in place of the internal bone screws and locking plate (Fig. 23).

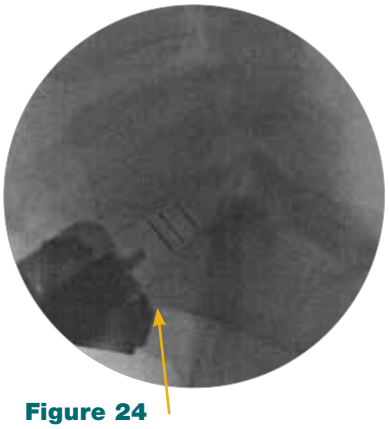
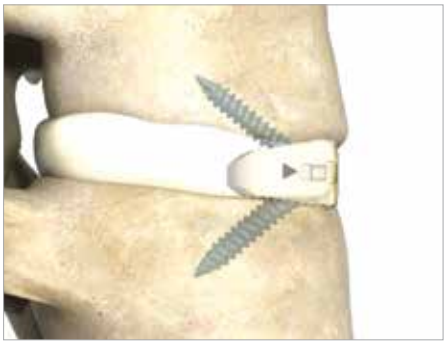
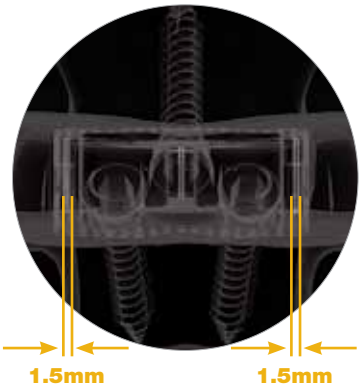


Figure 24

Note: The AIOG features a mechanical stop in order to 1) prevent the cage from being implanted too posteriorly, and 2) potentially maximize screw purchase by creating an entry point closer to the anterior vertebral wall (Fig. 24).





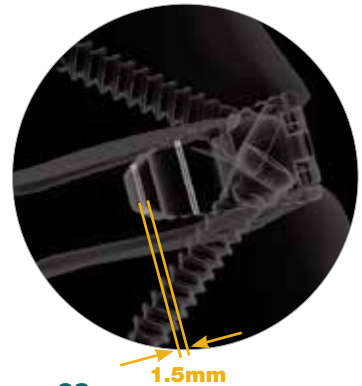


Figure 28

Step 6: Insert the Cage

AVS Anchor-L is designed with a beveled leading edge to assist in initial distraction during insertion. If additional distraction is needed, the Reliance AL Discectomy Distractor with Modular Straight or Offset Tips may be used. With the leading edge of the cage slightly between the vertebral endplates, gently impact the proximal end of the AIOG Holder to safely and gradually insert the cage (**Fig. 25**).

Figure 25. Insertion into the Disc Space

The AVS Anchor-L lumbar cage was designed to be implanted with either one cephalad screw and two caudal screws (**Fig. 26**), or one caudal screw and two cephalad screws (**Fig. 27**). This allows the surgeon the flexibility to choose screw orientation based on each patient's individual anatomy and pathology. This feature also decreases the chance of screw interference when used at two contiguous levels.

Note: The orientation of the cage and screws with one cephalad screw and two caudal screws is recommended especially at L5-S1 due to the difficult trajectory of the L5 screw and the location of the vessels.

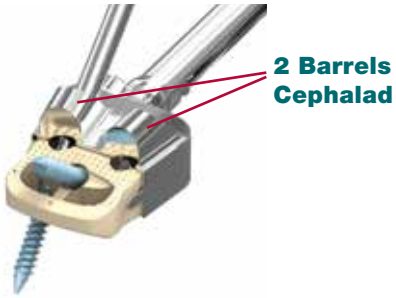


Figure 26. 2 Caudal / 1 Cephalad
(2 Barrels Cephalad / 1 Barrel Caudal)

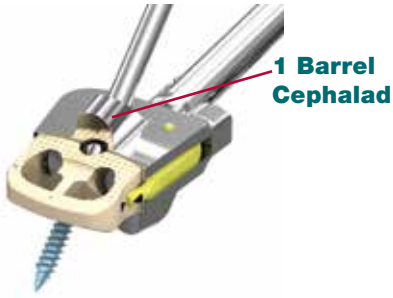


Figure 27. 1 Caudal / 2 Cephalad
(1 Barrel Cephalad / 2 Barrels Caudal)

Note: The sleeves of the AIOG are fully covered to help ensure that the awl, drill, tap, and screwdriver are properly guided into the vertebral endplate.

Final cage positioning can be verified with the help of fluoroscopy intraoperatively. Once the cage is in its desired position, release the AIOG Holder from the AIOG by using the quick release feature on the handle (**Fig. 28**).

Step 7: Prepare the Screw Pathway

Figure 29. Round Ratchet Handle
48231302

AVS Anchor-L is designed with three screw holes located at the anterior wall of the implant. The location of these holes relative to the superior and inferior aspects of the cage is consistent on every implant size in order to ensure a consistent vertebral wall entry point in every case. This entry point is designed to be the anterior most portion of the vertebral body, or the apophyseal ring, and may allow the surgeon to potentially achieve more optimal purchase in the bone.

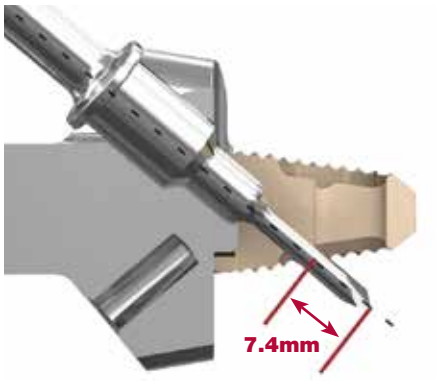


Figure 30

Connect the **Round Ratchet Handle (Fig. 29)** to the proximal end of either the **Modular Rigid** or **Flexible Awl**. Prepare the vertebral body for screw insertion by applying pressure on the handle of the Awl in conjunction with rotational motions until the Awl reaches a positive stop within the AIOG. The Awl length before the positive stop is 15mm. The depth awled will always be 7.4mm **(Fig. 30)**.

Awl Dimensions	
Overall Length	**15mm**
Depth in Bone	**7.4mm**
Diameter	**2.6mm**

Drill Dimensions	
Overall Length	**20mm**
Depth in Bone	**15mm**
Diameter	**2.6mm**

Note: The Round Ratchet Handle can be set to a non-ratcheting setting depending on surgeon preference. In addition, any Xia 3 handle may be used with the Anchor-L modular shaft instruments (Fig. 31).

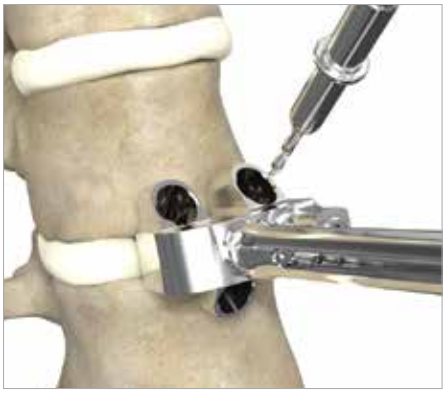


Figure 31

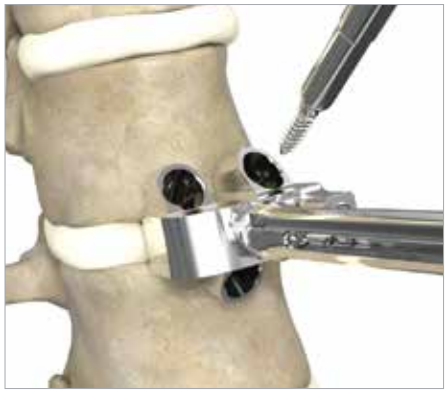


Figure 32

Modular Rigid Awl
48999110

Modular Rigid Drill
48999150

Modular Rigid Tap
48999250

Modular Flexible Awl
48994110

Modular Flexible Drill
48994150

Modular Flexible Tap
48994250

Tap Dimensions	
Overall Length	**20mm**
Depth in Bone	**15mm**
Diameter	**5mm**

Note: In cases where the anatomy requires additional preparation, the Modular Rigid or Flexible Drill and/or Tap may be used. The Drill tip features a positive stop. The diameter of the Drill is 2.6mm, and the total length before the positive stop is 20mm. The depth drilled will always be 15mm. The Tap tip features a black laser marking that will align with the AIOG when the Tap has been fully inserted. The positive stop on the Tap is located 2mm beyond the laser etched line as a safety precaution. It is recommended to tap only the laser etched line (depth of 15mm) to avoid potential stripping (Fig. 31 and Fig. 32).

Note: Should the screw hole get accidentally stripped, a 6.0mm screw may be utilized to increase purchase.

Step 8: Insert the Screws

Figure 33. Ø5.0mm

Figure 34. Ø6.0mm

The AVS Anchor-L Lumbar Cage System offers Ø5.0mm screws in lengths of 20mm, 25mm and 30mm (**Fig. 33**). In addition, Ø6.0mm screws in the same lengths are available should the surgeon need to revise a screw (**Fig. 34**).

AVS Anchor-L Fixation Screws

48665020	Bone Screw 5.0mm x 20mm	**48666020**	Bone Screw 6.0mm x 20mm
48665025	Bone Screw 5.0mm x 25mm	**48666025**	Bone Screw 6.0mm x 25mm
48665030	Bone Screw 5.0mm x 30mm	**48666030**	Bone Screw 6.0mm x 30mm

Figure 35

These screws feature a cortical/cancellous dual lead thread pattern and have a cutting flute at the tip to aid in insertion. This feature makes these screws self-drilling and self-tapping. Once the three screws have been placed, lateral fluoroscopy may be used to verify the final positioning of the screws (**Fig. 35**).

Note: There are several different screwdriver options available for placing the screws in order to meet surgeon preference and accommodate varying patient anatomy.

STANDARD SCREWDRIVERS

1. **The Modular Rigid (Fig. 36) and Flexible Screwdrivers (Fig. 37) and the U-Joint Driver (Fig. 38) each have a black laser marking that will align with the AIOG when the screw has been fully inserted.**

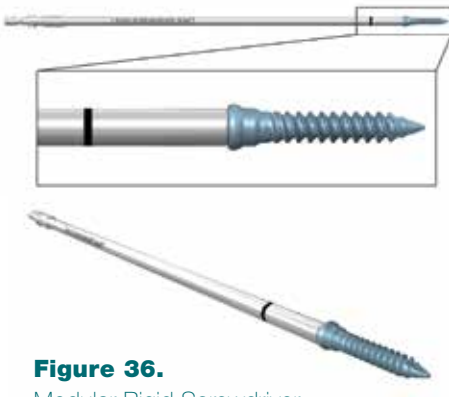


Figure 36.
Modular Rigid Screwdriver
48999000

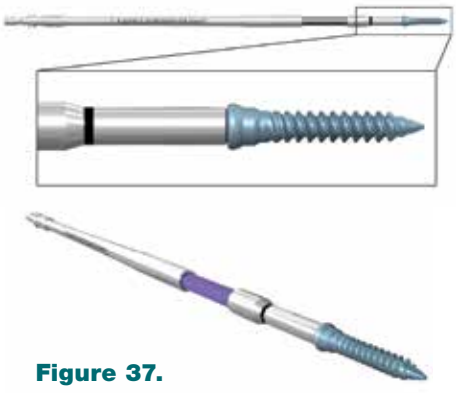


Figure 37.
Modular Flexible Screwdriver
48994000

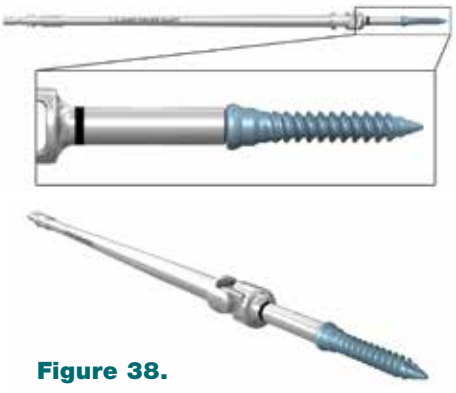


Figure 38.
Modular U-Joint Driver
48999002

SPECIAL ORDER SCREWDRIVERS

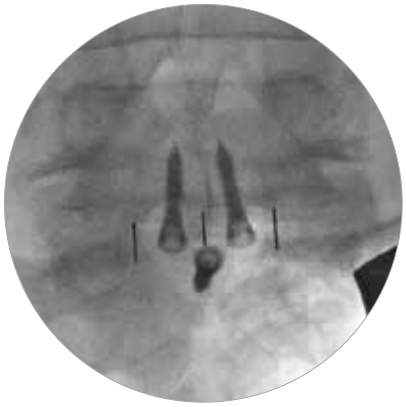
1. **The Rigid and Flexible 3.5mm Hex Round Tip Screwdrivers are compatible with the AIOG, but they do not have a black laser mark line to indicate when the screw is fully inserted. These screwdrivers are ideally used for screw adjustments if necessary after the AIOG is removed. The 3.5mm Hex Round Tip Drivers interface with the screw head up to 30° off axis, which may allow for easier access at challenging levels (Fig. 39 and Fig. 40).***
2. **The 90° Angled Screwdriver is not compatible with the AIOG and does not have a black laser mark to indicate screw positioning (Fig. 41).***

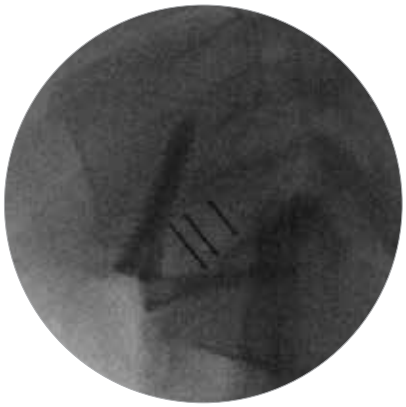
Figure 39. 3.5mm Modular Hex Round Tip Rigid Screwdriver*
48999003
*Special order only

Figure 40. 3.5mm Modular Hex Round Tip Flexible Screwdriver
48994003

Figure 41. 90° Angled Screwdriver*
48990005

Step 9: Remove the AIOG





Once the screws have been inserted, re-attach the AIOG Inserter to the shaft of the AIOG using the quick release feature. Any Screwdriver may be used to loosen the AIOG Locking Screw. With the AIOG Locking Screw loosened, carefully pull the AIOG out of the surgical site.

Caution: It is only necessary to loosen the AIOG locking screw 2-3 full rotations in order to detach it from the cage. Avoid over-loosening, as this could result in the gold arm releasing and potentially contacting surrounding soft tissue.

Note: If the AIOG does not easily remove from the cage after loosening the Locking Screw, apply a gentle rocking motion from side to side to detach from the cage (Fig. 42).

Figure 42. Loosening the Locking Screw Removing the All-in-One Guide

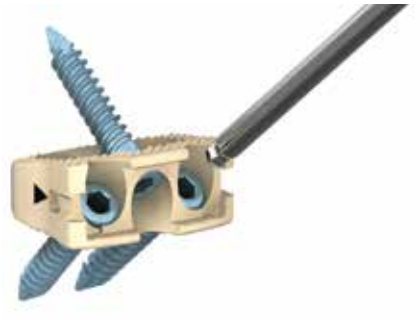
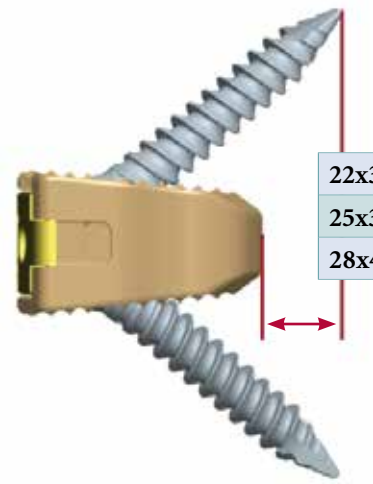


Figure 43

Note: **If any of the screws need additional turns for final positioning, the Rigid or Flexible 3.5mm Hex Round Tip Screwdrivers may be used. These drivers are designed to quickly and easily find the head of the screw and allow collinear force to continue to advance the screw in its initial insertion trajectory up to 30° off axis (Fig. 43).**

Figure 43. 3.5mm Hex Round Tip Rigid and Flexible Screwdrivers*

*Special order only



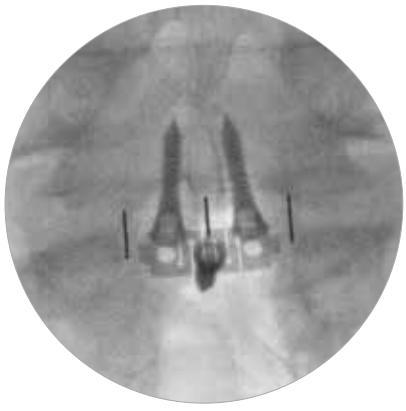
	Measurements of Screw Protruding from Cage								
	Screw oriented at 35°			Screw oriented at 40°			Screw oriented at 45°		
	20mm	25mm	30mm	20mm	25mm	30mm	20mm	25mm	30mm
22x30	4.7 mm	8.8 mm	13.0 mm	3.4 mm	7.2 mm	11.0 mm	1.8 mm	5.4 mm	8.9 mm
25x35	1.7 mm	5.8 mm	10.0 mm	0.3 mm	4.2 mm	8.0 mm	-1.2 mm	2.4 mm	5.9 mm
28x40	1.3 mm	2.8 mm	6.9 mm	-2.6 mm	1.2 mm	5.0 mm	-4.1 mm	-0.6 mm	2.9 mm

Note: **Some of the measurements have negative value. The screw is therefore not protruding from the cage in that particular case.**

Step 10: Insert the Locking Plate

Figure 44. Plate Inserter
48997010

The AVS Anchor-L locking plate was designed to be simple and easy to use. The plate is "one size fits all," and should be inserted after all three screws have been placed in their desired positions. Attach the **Plate Inserter** to the locking plate by placing the distal prongs inside the two holes on the plate, and depressing the lever arm. This action squeezes or pinches the plate to a width smaller than the locking tabs on the front of the cage (**Fig. 44**).



Caution: It is recommended to load the locking plate onto the Plate Inserter with the plate laying on a flat surface; either inside the tray or on a table in the sterile field. Because the plate pinches, there is the potential to catch a glove in the slots as they are compressed if the plate is held during loading.

Using caution to avoid damage to the vascular elements, place the locking plate firmly onto the front of the cage. With the locking plate contacting the cage, gently release the lever arm in order to allow the locking plate to regain its original shape underneath the PEEK locking tabs.

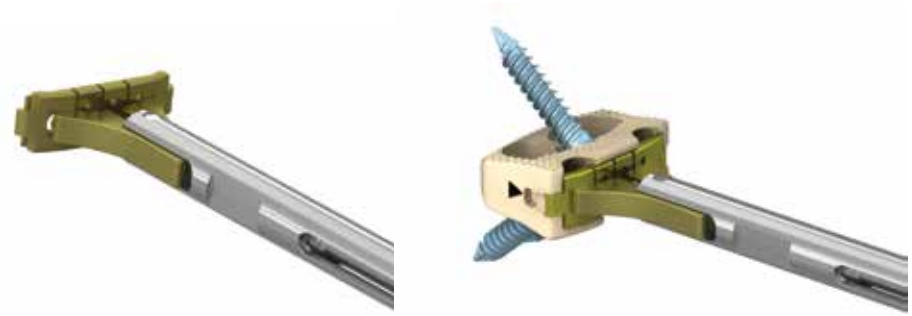


Figure 45

Tip: It is recommended to slip one side of the locking plate underneath the PEEK locking tabs, lower the contralateral side, then release the lever arm. This helps guide the plate more easily into its final locked position (**Fig. 45**).

Caution: Minimize the number of plate deformations as repetitive deformations may jeopardize the integrity of the plate.

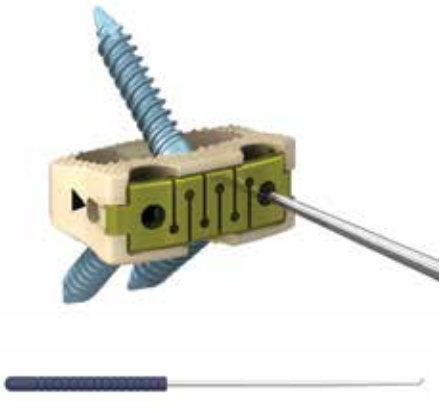


Figure 46. Plate Feeler
48997020

The locked position of the locking plate may be verified using the **Plate Feeler** (**Fig. 46**). Insert the prong of the Plate Feeler into the holes on the locking plate and exert gentle upward force to confirm that the plate is locked. Fluoroscopy may be used at this time to verify final positioning.

Note: It is recommended to check both holes on the locking plate in order to confirm the security of the plate.

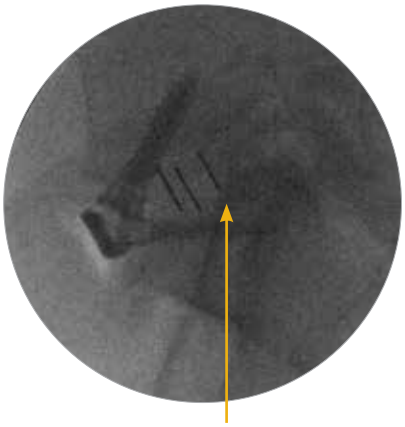


Figure 47. Posterior Tantalum Marker

Note: If a surgeon wishes to use the AVS Anchor-L lumbar cage with less than three or none of the screws provided, supplementary fixation that is cleared for use in the lumbosacral spine must be utilized. If using supplementary fixation with screws, care must be taken regarding the trajectory of the supplementary fixation and any AVS Anchor-L screws. Use the Implant Holder to insert the cage and then introduce supplementary fixation. If any screws are used, the locking plate must be inserted.

As a reminder, all tantalum markers are positioned 1.5mm from the edges of the cage. For example, there is an additional 1.5mm of PEEK extending beyond the posterior tantalum marker in the image to the left (**Fig. 47**).

Implant Removal

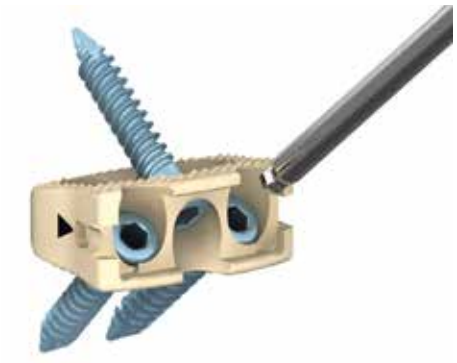


Figure 48

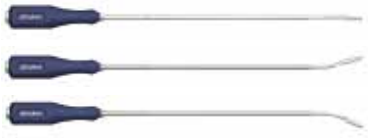
If the implant needs to be removed, first use the Plate Inserter to remove the locking plate. Engage the distal prongs into the holes on the plate, depress the lever arm to pinch the plate, and lift the plate off the cage.

Next, use the Rigid or Flexible 3.5mm Hex Tip Screwdriver to engage with the screw heads and back out the screws. Once the screw heads are more accessible, it is recommended to use the Rigid or Flexible Screwdrivers, as these are self-holding and will maintain control of the screw during removal (**Fig. 48**).

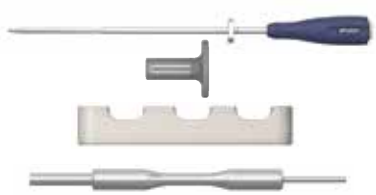
After all screws have been removed, use the Implant Holder to grasp the sides of the cage by depressing the handle and locking the instrument to the cage. Carefully remove the cage from the disc space. If necessary, use a mallet to back the cage out.

Set Definition

Standard Set Definition

Instruments	Reference #	Description
	48998200	6mm Single Side Straight Rasp
	48998300	6mm Single Side Angled Rasp Up
	48998400	6mm Single Side Angled Rasp Down
	48992104	10x22x30x4° Trial
	48992108	10x22x30x8° Trial
	48992102	10x22x30x12° Trial
	48992124	12x22x30x4° Trial
	48992128	12x22x30x8° Trial
	48992122	12x22x30x12° Trial
	48992144	14x22x30x4° Trial
	48992148	14x22x30x8° Trial
	48992142	14x22x30x12° Trial
	48992164	16x22x30x4° Trial
	48992168	16x22x30x8° Trial
	48992162	16x22x30x12° Trial
	48993104	10x25x35x4° Trial
	48993108	10x25x35x8° Trial
	48993102	10x25x35x12° Trial
	48993124	12x25x35x4° Trial
	48993128	12x25x35x8° Trial
	48993122	12x25x35x12° Trial
	48993144	14x25x35x4° Trial
	48993148	14x25x35x8° Trial
	48993142	14x25x35x12° Trial
	48993164	16x25x35x4° Trial
	48993168	16x25x35x8° Trial
	48993162	16x25x35x12° Trial

Standard Set Definition

Instruments	Reference #	Description
	48999102	10x22x30° Marking Guide
	48990102	10x25x35° Marking Guide
	48999126	12x22x30° Marking Guide
	48999146	14x22x30° Marking Guide
	48990126	12x25x35° Marking Guide
	48990146	14x25x35° Marking Guide
	48361234	Trial Handle
	48991014	Trial Stop
	48999010	Graft Block
	48999020	Graft Impactor
	48992010	10mm All In One Guide
	48992012	12mm All In One Guide
	48992014	14mm All In One Guide
	48992016	16mm All In One Guide
	48992110	AIOG Locking Screw
	48992000	AIOG Holder
	48992115	AIOG Screwdriver
	48992001	Implant Holder
	48999110	Modular Rigid Awl
	48999150	Ø5mm Modular Rigid Drill
	48999250	Ø5mm Modular Rigid Tap
	48994110	Modular Flexible Awl
	48994150	Ø5mm Modular Flexible Drill
	48994250	Ø5mm Modular Flexible Tap
	48999000	Modular Rigid Screwdriver
	48999002	Modular U-Joint Driver
	48994000	Modular Flexible Screwdriver
	48231301	Xia 3 Round Handle
	48231302	Xia 3 Ratchet Round Handle
	48997010	Plate Inserter
	48997020	Plate Feeler

Standard Set Definition

Instruments	Reference #	Description
	48993000	Implant Tray Lid
	48993002	Implant Tray Top Insert
	48993003	Implant Tray Bottom Insert
	48993001	Implant Tray Base
	48991000	Instrument Tray Lid
	48991002	Instrument Tray Top Insert
	48991003	Instrument Tray Bottom Insert
	48991001	Instrument Tray Base

Special Order Only - Instruments	Reference #	Description
	48990005	90° Angled Screwdriver
	48990006	90° Angled Screwdriver Gear Cover
	48999003	3.5mm Modular Hex Round Tip Rigid Screwdriver
	48994003	3.5mm Modular Hex Round Tip Flexible Screwdriver

AVS Anchor-L Lumbar Cage System

Surgical Technique

Standard Set Definition

Implants	Reference #	Description
	48665020	Ø5.0mm x 20mm Bone Screw
	48665025	Ø5.0mm x 25mm Bone Screw
	48665030	Ø5.0mm x 30mm Bone Screw
	48666020	Ø6.0mm x 20mm Bone Screw
	48666025	Ø6.0mm x 25mm Bone Screw
	48666030	Ø6.0mm x 30mm Bone Screw
	48667000	Locking Plate
	48662104	10mm x 22x30mm x 4° Vertebral Spacer
	48662108	10mm x 22x30mm x 8° Vertebral Spacer
	48662102	10mm x 22x30mm x 12° Vertebral Spacer
	48662124	12mm x 22x30mm x 4° Vertebral Spacer
	48662128	12mm x 22x30mm x 8° Vertebral Spacer
	48662122	12mm x 22x30mm x 12° Vertebral Spacer
	48662144	14mm x 22x30mm x 4° Vertebral Spacer
	48662148	14mm x 22x30mm x 8° Vertebral Spacer
	48662142	14mm x 22x30mm x 12° Vertebral Spacer
	48662164	16mm x 22x30mm x 4° Vertebral Spacer
	48662168	16mm x 22x30mm x 8° Vertebral Spacer
	48662162	16mm x 22x30mm x 12° Vertebral Spacer
	48663104	10mm x 25x35mm x 4° Vertebral Spacer
	48663108	10mm x 25x35mm x 8° Vertebral Spacer
	48663102	10mm x 25x35mm x 12° Vertebral Spacer
	48663124	12mm x 25x35mm x 4° Vertebral Spacer
	48663128	12mm x 25x35mm x 8° Vertebral Spacer
	48663122	12mm x 25x35mm x 12° Vertebral Spacer
	48663144	14mm x 25x35mm x 4° Vertebral Spacer
	48663148	14mm x 25x35mm x 8° Vertebral Spacer
	48663142	14mm x 25x35mm x 12° Vertebral Spacer
	48663164	16mm x 25x35mm x 4° Vertebral Spacer
	48663168	16mm x 25x35mm x 8° Vertebral Spacer
	48663162	16mm x 25x35mm x 12° Vertebral Spacer

Auxiliary Set Definition

Instruments	Reference #	Description
	48992018	18mm All In One Guide
	48992020	20mm All In One Guide
	48992126	12x22x30x16° Trial
	48992146	14x22x30x16° Trial
	48992166	16x22x30x16° Trial
	48992184	18x22x30x4° Trial
	48992188	18x22x30x8° Trial
	48992182	18x22x30x12° Trial
	48992186	18x22x30x16° Trial
	48992204	20x22x30x4° Trial
	48992208	20x22x30x8° Trial
	48992202	20x22x30x12° Trial
	48992206	20x22x30x16° Trial
	48993126	12x25x35x16° Trial
	48993146	14x25x35x16° Trial
	48993166	16x25x35x16° Trial
	48993184	18x25x35x4° Trial
	48993188	18x25x35x8° Trial
	48993182	18x25x35x12° Trial
	48993186	18x25x35x16° Trial
	48993204	20x25x35x4° Trial
	48993208	20x25x35x8° Trial
	48993202	20x25x35x12° Trial
	48993206	20x25x35x16° Trial
	48998104	10x28x40x4° Trial
	48998108	10x28x40x8° Trial
	48998102	10x28x40x12° Trial
	48998124	12x28x40x4° Trial
	48998128	12x28x40x8° Trial
	48998122	12x28x40x12° Trial

Auxiliary Set Definition

Instruments	Reference #	Description
	48998126	12x28x40x16° Trial
	48998144	14x28x40x4° Trial
	48998148	14x28x40x8° Trial
	48998142	14x28x40x12° Trial
	48998146	14x28x40x16° Trial
	48998164	16x28x40x4° Trial
	48998168	16x28x40x8° Trial
	48998162	16x28x40x12° Trial
	48998166	16x28x40x16° Trial
	48998184	18x28x40x4° Trial
	48998188	18x28x40x8° Trial
	48998182	18x28x40x12° Trial
	48998186	18x28x40x16° Trial
	48998204	20x28x40x4° Trial
	48998208	20x28x40x8° Trial
	48998202	20x28x40x12° Trial
	48998206	20x28x40x16° Trial
	48991102	10x28x40° Marking Guide
	48991126	12x28x40° Marking Guide
	48991146	14x28x40° Marking Guide
	48995000	Auxiliary Tray Lid
	48995002	Auxiliary Tray Top Insert
	48995003	Auxiliary Tray Middle Insert
	48995001	Auxiliary Tray Base

Auxiliary Set Definition

Implants	Reference #	Description
	48662126	12mm x 22x30mm x 16° Vertebral Spacer
	48662146	14mm x 22x30mm x 16° Vertebral Spacer
	48662166	16mm x 22x30mm x 16° Vertebral Spacer
	48662184	18mm x 22x30mm x 4° Vertebral Spacer
	48662188	18mm x 22x30mm x 8° Vertebral Spacer
	48662182	18mm x 22x30mm x 12° Vertebral Spacer
	48662186	18mm x 22x30mm x 16° Vertebral Spacer
	48662204	20mm x 22x30mm x 4° Vertebral Spacer
	48662208	20mm x 22x30mm x 8° Vertebral Spacer
	48662202	20mm x 22x30mm x 12° Vertebral Spacer
	48662206	20mm x 22x30mm x 16° Vertebral Spacer
	48663126	12mm x 25x35mm x 16° Vertebral Spacer
	48663146	14mm x 25x35mm x 16° Vertebral Spacer
	48663166	16mm x 25x35mm x 16° Vertebral Spacer
	48663184	18mm x 25x35mm x 4° Vertebral Spacer
	48663188	18mm x 25x35mm x 8° Vertebral Spacer
	48663182	18mm x 25x35mm x 12° Vertebral Spacer
	48663186	18mm x 25x35mm x 16° Vertebral Spacer
	48663204	20mm x 25x35mm x 4° Vertebral Spacer
	48663208	20mm x 25x35mm x 8° Vertebral Spacer
	48663202	20mm x 25x35mm x 12° Vertebral Spacer
	48663206	20mm x 25x35mm x 16° Vertebral Spacer
	48668104	10mm x 28x40mm x 4° Vertebral Spacer
	48668108	10mm x 28x40mm x 8° Vertebral Spacer
	48668102	10mm x 28x40mm x 12° Vertebral Spacer
	48668124	12mm x 28x40mm x 4° Vertebral Spacer
	48668128	12mm x 28x40mm x 8° Vertebral Spacer
	48668122	12mm x 28x40mm x 12° Vertebral Spacer
	48668126	12mm x 28x40mm x 16° Vertebral Spacer
	48668144	14mm x 28x40mm x 4° Vertebral Spacer
	48668148	14mm x 28x40mm x 8° Vertebral Spacer

Auxiliary Set Definition

Implants	Reference #	Description
	48668142	14mm x 28x40mm x 12° Vertebral Spacer
	48668146	14mm x 28x40mm x 16° Vertebral Spacer
	48668164	16mm x 28x40mm x 4° Vertebral Spacer
	48668168	16mm x 28x40mm x 8° Vertebral Spacer
	48668162	16mm x 28x40mm x 12° Vertebral Spacer
	48668166	16mm x 28x40mm x 16° Vertebral Spacer
	48668184	18mm x 28x40mm x 4° Vertebral Spacer
	48668188	18mm x 28x40mm x 8° Vertebral Spacer
	48668182	18mm x 28x40mm x 12° Vertebral Spacer
	48668186	18mm x 28x40mm x 16° Vertebral Spacer
	48668204	20mm x 28x40mm x 4° Vertebral Spacer
	48668208	20mm x 28x40mm x 8° Vertebral Spacer
	48668202	20mm x 28x40mm x 12° Vertebral Spacer
	48668206	20mm x 28x40mm x 16° Vertebral Spacer

IMPORTANT PRODUCT INFORMATION FOR AVS Anchor-L LUMBAR CAGE SYSTEM

NON-STERILE PRODUCT

DESCRIPTION

The AVS Anchor-L Lumbar Cage System consists of a hollow, rectangular-shaped PEEK cage, bone screws, and locking plate. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to adapt to varying patient anatomies. The AVS Anchor-L cage consists of one closed pocket for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used exclusively with the internal supplemental fixation provided.

INDICATIONS

The Stryker Spine AVS Anchor-L 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. 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 AVS Anchor-L Lumbar Cage system is to be implanted via an open, anterior approach.

The AVS Anchor-L Lumbar Cage system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the AVS Anchor-L Lumbar Cage must be used with the internal screw and plate fixation provided by AVS Anchor-L Fixation Screws and Locking Plate. If AVS Anchor-L is used with less than three or none of the provided screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine must be used to augment stability. The accompanying Locking Plate must be used anytime the device is used with any number of screws.

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.
- The AVS Anchor-L Lumbar Cages have not been evaluated for safety and compatibility in the MR environment. AVS Anchor-L 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.
- Consider the impact of screw length and diameter on screw interference during preoperative planning when implanting the AVS Anchor-L Lumbar Cage in two contiguous levels.

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.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

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

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- The AVS Anchor-L Lumbar Cage should not be implanted in patients with an active infection at the operative site.
- The AVS Anchor-L 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 AVS Anchor-L 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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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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