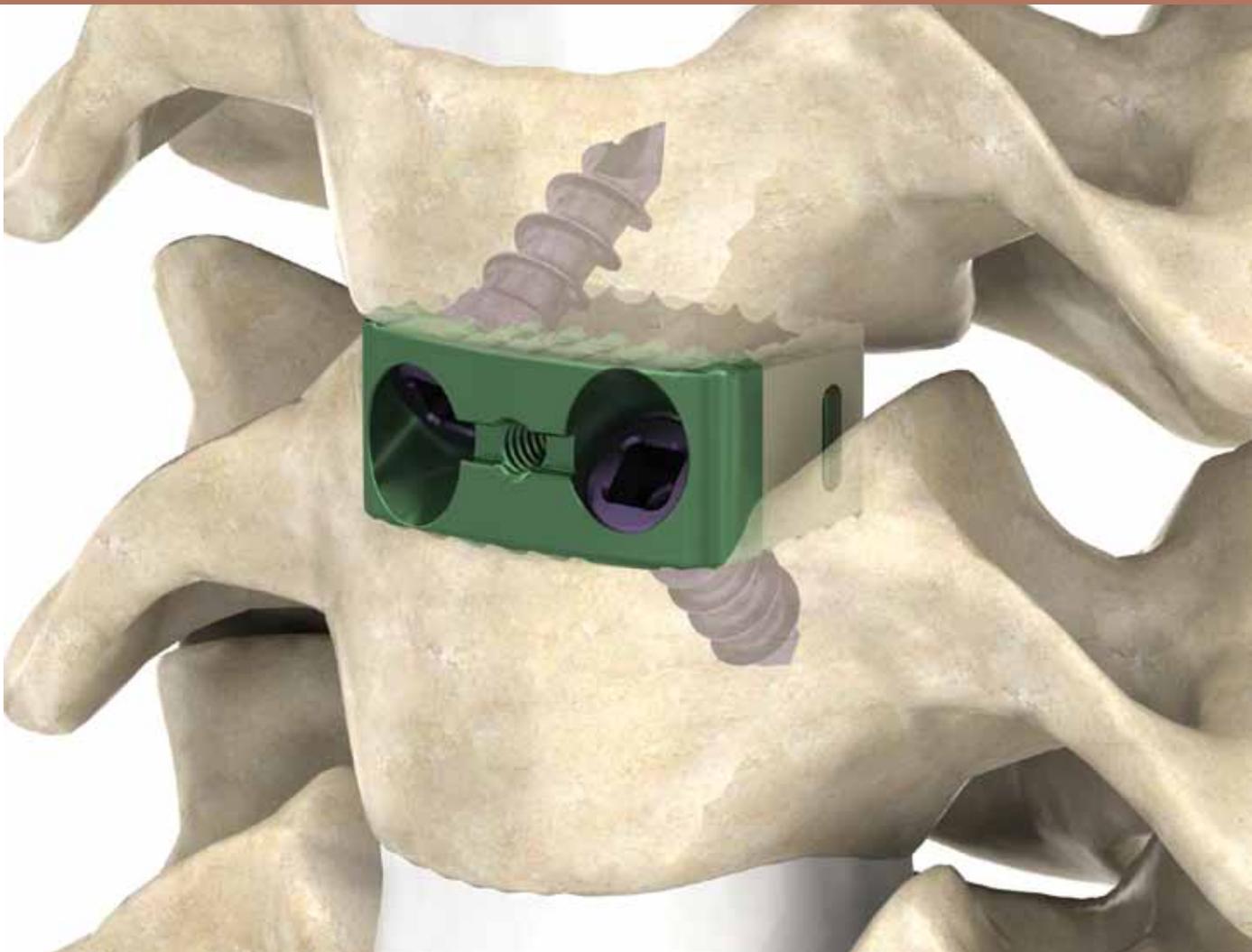


AVS Anchor®-C Cervical Cage System

Surgical Technique



AVS Anchor-C Cervical Cage System

Surgical Technique

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AVS Anchor-C Cervical Cage System

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System Overview

AVS Anchor-C is an interbody fusion device with internal screw fixation and is intended to be used in anterior cervical discectomy and fusion procedures.

This system integrates a hollow PEEK cage with a titanium screw locking mechanism and is designed to aid in cervical interbody fusion. A tantalum marker is embedded into the cage to help visually confirm the posterior position under fluoroscopy.

The integrated design allows for rigid screw fixation without any added anterior profile. AVS Anchor-C screws feature an outer clip which engages the titanium face plate on the cage. The interbody device is offered in a variety of lengths, heights and lordotic angles.



Cages

- **AVS Anchor-C cages** are available in 2 footprints, 3 lordosis options and 7 heights from 6mm - 12mm. The cage heights are measured anteriorly. The posterior cage heights are approximately 1mm shorter than the anterior height for every 4 degrees of lordosis.

Screw Types and Sizes

- **AVS Anchor-C screws** are available in fixed angle and are offered as self-tapping, featuring a cutting flute and a less aggressive screw tip, and self-drilling, designed with a sharp tip for insertion without prior drilling.

Self-Tapping



Diameter: 3.5mm
Length: 8-14mm



Diameter: 4.0mm
Length: 8-14mm

Self-Drilling



Diameter: 3.5mm
Length: 8-14mm

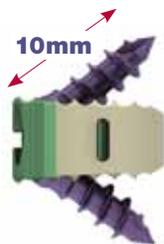


Diameter: 4.0mm
Length: 8-14mm

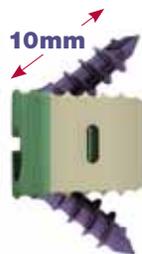
Note: The screw size indicates the amount of screw purchase in the bone. For example a 10mm screw has 10mm of purchase in bone along the 35° angle. Further, the amount of screw purchase in a given length screw is equivalent across all cage heights. For example, the screw purchase of a 10mm screw in a 6mm cage is equivalent to the screw purchase of a 10mm screw in a 9mm cage.

Screw Angulation

- Cephalad/caudal angulation of 35°
- Medial/lateral convergence of 10°



6mm cage with a 10mm screw Inserted



9mm cage with a 10mm screw Inserted

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Implantation Technique

Step 1. Patient Positioning and Exposure

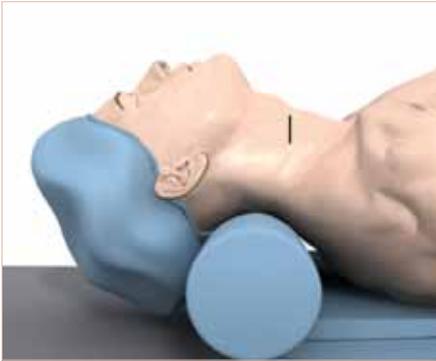


Figure 1

A direct anterior approach should be selected for the AVS Anchor-C Cervical Cage System. The patient is placed in a supine position with the head turned slightly away from the side of the approach (Fig. 1). A transverse or oblique incision parallel to the skin creases of the neck is recommended. Either a left side or right side approach can be used. After blunt dissection through the various layers, the anterior cervical spine is gently exposed. After exposing the vertebral bodies to be fused, prepare the fusion site following the appropriate technique for the given indication.

Care should be taken to remove any bony anatomy or osteophytes which might interfere with the instrumentation, as this is required to position the cage flush with the anterior aspect of the cervical spine.

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

Note: When previous instrumentation is present, pre-operative planning is strongly encouraged to help avoid implant contact.



Figure 2. Pin Guide Distractor
48328725

Step 2. Distraction Pin Placement

It is recommended to insert the Anchor-C cage under distraction. If distraction pins are used, it is recommended to use either the **Pin Guide Distractor** or an Inserter as a template when placing the distraction pins (Fig. 2). Due to the angulation and positioning of the Inserter's barrels, placing the distraction pins centrally into the vertebral bodies may result in the inability to insert the cage correctly.

As an alternative to the **Guide/Inserter Tip**, the **Anchor-C Low Profile Inserter** can be used for cage insertion, screw hole pathway creation, screw insertion and screw locking confirmation (Fig. 3).



Figure 3

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Figure 4a. Guide/Inserter Tip

Option 1: Use of Pin Guide Distractor

To place your distraction pins using the Pin Guide Distractor, a small window is cut into the anterior annulus to allow for insertion of the Pin Guide Distractor. When the Pin Guide Distractor is positioned correctly, distract the instrument such that the top of the paddles is in contact with the endplates. Insert the **Straight Awl** through each of the guides in the Pin Guide Distractor to create pilot holes for the distraction pins. Remove the Pin Guide Distractor from the disc space and insert distraction pins into the vertebral body using the **Pin Inserter** from the Reliance® C instrumentation set.

Note: The pins should be positioned slightly off from center to allow the Guide/Inserter Tip to be positioned correctly when inserting the cage (Fig. 4a, b).

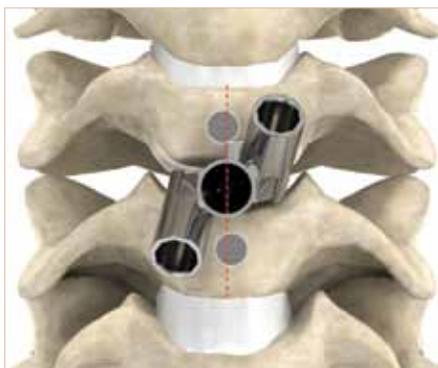


Figure 4b. Low Profile Inserter

Option 2: Use of Inserters as a Template

There are two inserter options: the Guide/Inserter Tip and the Low Profile Inserter (Fig. 5a, b). Either type of Inserter should be used for cage insertion, screw hole pathway creation, screw insertion, and screw locking confirmation.



Figure 5a. Guide/Inserter Tip



Figure 5b. Low Profile Inserter

To place your distraction pins using the Inserter as a template, lay the Inserter on top of the exposed vertebral bodies in the disc space. A cage can be threaded onto the Guide/Inserter Tip during this step to prevent the Guide/Inserter Tip from spinning. When the Inserter is positioned correctly, the remaining exposed portion of the vertebral bodies should reveal an area where the distraction pins can be placed.

Once the pins are inserted into the vertebral body, slide the Parallel Pin Distractor from the Reliance® C instrumentation set over the pins and distract the disc space (Fig. 6).



Figure 6

Step 3. Disc Removal and Endplate Preparation

Use preferred surgical approach and technique for the discectomy using curettes, rongeurs, rasps or high speed drills.

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Step 4. Cage Selection

To assist in determining the appropriate cage, several different **Cage Trials** are available in the set. These trials are designed to approximate the overall height, angulation, and endplate dimensions of the disc space. Each trial option has a matching cage (Fig. 7a, b).

Trial Options:

Height	6, 7, 8, 9, 10, 11, 12mm
Angulation	0°, 4°, 8°
Footprint	12 x 14mm, 14 x 16mm

Note: The trials measure line to line (e.g., a 6mm trial measures 6mm), but cage sizes are oversized because they do not include the implant teeth that are .5mm on each side (e.g., a 6mm cage measures 7mm including the teeth) (Fig. 7a, b).



Figure 7a. Cage Trial
See chart on page 22 for Trial part numbers



Figure 7b

Insert the appropriate trial into the **Quick Release Handle** (Fig. 8a) and carefully insert into the disc space (Fig. 8b). The trial should pass into the distracted disc space without excessive force. A mallet can be used to aid insertion or removal of the trial.



Figure 8a. Quick Release Handle
48328050



Figure 8b

Step 5. Cage Preparation and Insertion

Once the appropriate cage has been selected, bone graft can be packed into the cage.

There are two inserter options: the Guide/Inserter Tip and the Low Profile Inserter.



6mm Inserter Tip	48328006
7mm Inserter Tip	48328007
8mm Inserter Tip	48328008
9mm Inserter Tip	48328009
10mm Inserter Tip	48328010
11mm Inserter Tip	48328011
12mm Inserter Tip	48328012



6mm Low Profile Inserter	48327006
7mm Low Profile Inserter	48327007
8mm Low Profile Inserter	48327008
9mm Low Profile Inserter	48327009
10mm Low Profile Inserter	48327010
11mm Low Profile Inserter	48327011
12mm Low Profile Inserter	48327012
Low Profile Inserter Inner Draw Rod	48327000

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Figure 9. How to Hold Guide/Inserter Tip

The Guide/Inserter Tip has a size corresponding to each implant height. Select the appropriate Guide/Inserter Tip and insert into the Quick Release Handle. Check both the engraving and the laser-marking on the shaft of the Guide/Inserter Tip to ensure it is the intended size for the Guide/Inserter Tip. The cage can now be threaded onto the Guide/Inserter Tip by holding the cage between the thumb and forefinger of one hand and the shaft of the inserter in the other (Fig. 9). Continue turning the inserter shaft until it cannot be rotated any further.

Tip: When threading the cage onto the Guide/Inserter Tip, hold the instrument at the shaft/tip junction. This will keep the Guide/Inserter Tip from rotating during threading.

The Low Profile Inserter is comprised of an Outer Shaft and an Inner Draw Rod. The Outer Shaft has a size corresponding to each implant height. The Inner Draw Rod can be used with any size Outer Shaft.



Low Profile Inserter Outer Shaft



Low Profile Inserter Inner Draw Rod

48327000

Place the Inner Draw Rod inside the Inserter then attach the cage to the distal tip of the of the Inserter by turning the Inner Draw Rod knob. Fully thread the cage to the Low Profile Inserter. If some resistance is present while attaching the cage, verify that it is not cross-threaded (Fig. 10a, b).

Note: The shaft of the Inner Draw Rod features a threaded portion near the proximal end of the rod that is designed to prevent the draw rod from falling out of the Inserter if the Inserter is inverted.

Note: The cage should be fully threaded to the Inserter so that it is snug.

How to Attach Anchor-C Cage



Figure 10a. Guide/Inserter Tip



Figure 10b. Low Profile Inserter

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Figure 11a. Guide/Inserter Tip



Figure 11b. Low Profile Inserter

Note: Applying excessive cantilever force to the Inserter may cause damage to the instrument.

Once the cage is attached to the Inserter, the assembly should be carefully impacted into the disc space with a mallet. It is inadvisable to attempt to insert the cage using only the Low Profile Inserter Inner Draw Rod. The Inserters provide a positive stop to place the cage flush with the anterior profile of the vertebral bodies (Fig. 11a, b).

Note: The Low Profile Inserter features a positive stop on one side of the cage so that it can be positioned to avoid any adjacent-level instrumentation.

At this point, distraction should be removed from the disc space and removal of the distractor from the pins is recommended. Before proceeding to the next step, ensure the cage is still tight to the Inserter. If the Guide/Inserter Tip is used, the Quick Release Handle should be removed from the assembly, leaving the Guide/Inserter Tip in place.

Note: Excessive pivoting or angulation on the Inserter while attached to the cage should be avoided as it can damage the instrument.

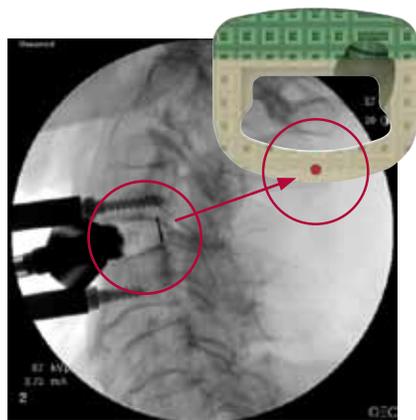


Figure 12. Tantalum Marker

A tantalum marker is embedded into the cage to help visually confirm the posterior position under fluoroscopy. The tantalum marker spans the entire height of the cage to indicate posterior contact with the vertebral endplates and is 1mm from the cage's posterior edge (Fig. 12).

Step 6. Screw Hole Preparation and Insertion

The Guide/Inserter Tip (without Quick Release Handle) or Low Profile Inserter should be left in place when preparing the screw hole. These Inserters can accommodate awls, drills and screwdrivers.

With self-drilling screws: Awl → Insert Screw

With self-tapping screws: Awl → Drill → Insert Screw

Note: Self-drilling screws do not need prior drilling. However, drilling is required with self-tapping screws.

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Figure 13a. Straight Awl
48328200



Figure 13b. Angled Awl
48328225



8mm Drill Bit	48328908
10mm Drill Bit	48328910
12mm Drill Bit	48328912



8mm Flexible Drill	48328808
10mm Flexible Drill	48328810
12mm Flexible Drill	48328812

Figure 14a, b

First, create a pilot hole in the vertebral body using the **Straight Awl** or **Angled Awl** through the Inserter for one of the screw holes (Fig. 13a, b).

Next, select the appropriate sized drill, attach the drill to the Quick Release Handle, and drill a hole into the vertebral body through the Inserter.

The Anchor-C screw hole preparation instrumentation features positive stops that limit the protrusion to 8mm into the bone for the Straight or Angled Awl and 8, 10, or 12mm for the Straight and Flexible Drill Bits (Fig. 14a, b).

Note: When using the Flexible Drill Bit, it is recommended that the shaft not be bent past the range indicated in the images below. This will help prevent damage to the shaft (Fig. 15a, b).

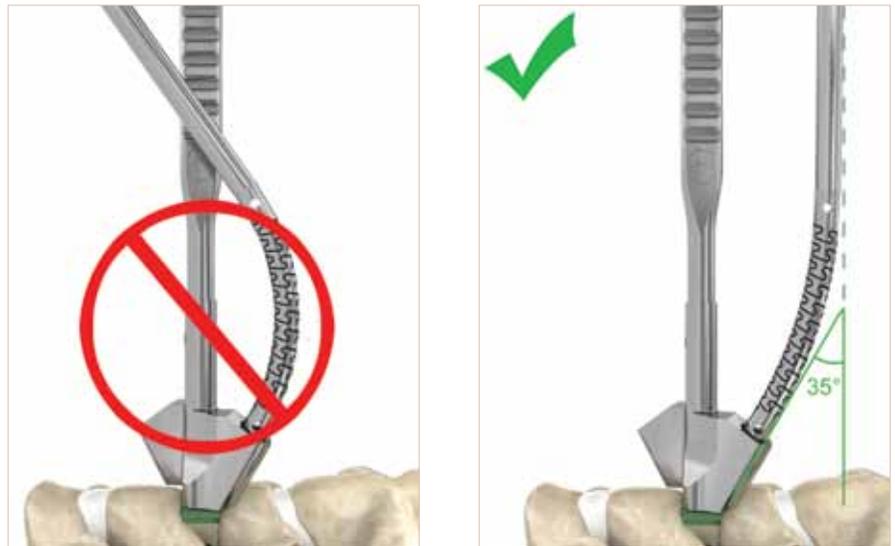


Figure 15a. Guide/Inserter Tip

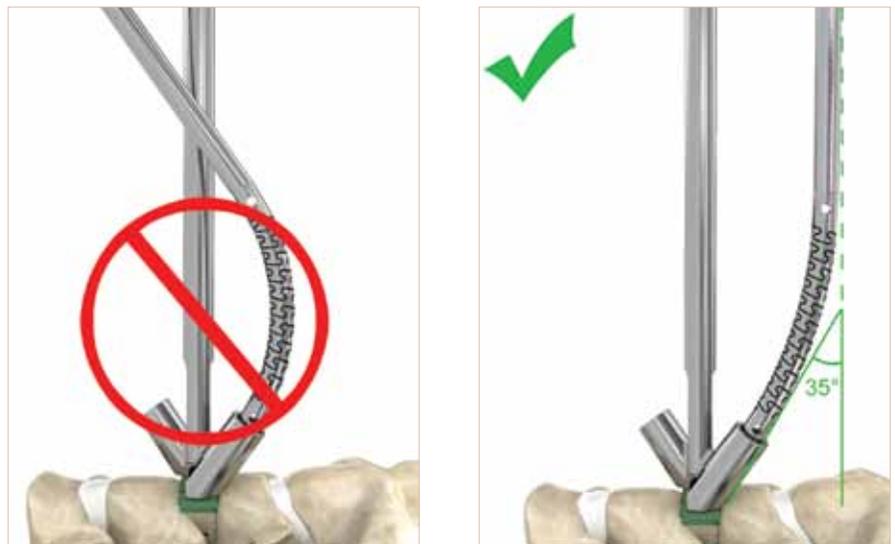


Figure 15b. Low Profile Inserter

Tip: Do not excessively bend Flexible Drill Bit back and forth; bending the shaft to the full limit repeatedly may result in fracture.

Select the appropriate screw and confirm the length using the screw length gauge in

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the screw caddy. The screw size indicates the actual amount of screw purchase in the bone (e.g., a 10mm screw protrudes 10mm into the bone, while the head of the screw is contained within the cage). The length of screw used should correspond to the length of drill used to prepare the hole.

Note: The 3.5mm screw should be used as the primary screw. The 4.0mm screw is provided as a rescue option and should not be used as the primary screw.

Due to the position of the screw holes in the cage, the amount of screw purchase in the bone is the same for all heights of implants. However, with different screw lengths and different cage footprints, the screws may protrude beyond the posterior end of the cage. For example, with a 12 x 14mm cage, the 8mm screw will be flush with the posterior end.

The picture and tables below detail screw positions with respect to the AVS Anchor-C cage (Fig. 16a, b):

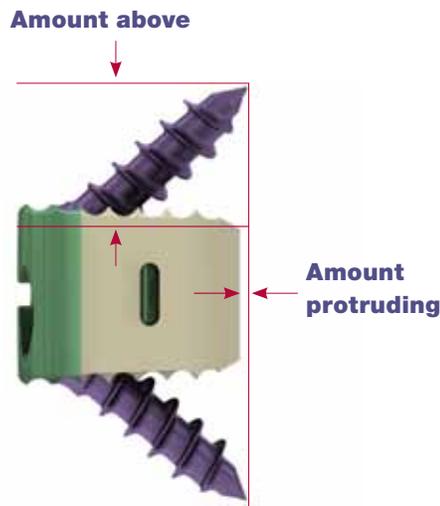


Figure 16a

Screw Length 12 x 14mm Cage

Screw Length	Amount of screw past post edge	Amount above 0° cage	Amount above 4° cage	Amount above 8° cage
8	Does not protrude	4.7	5.1	5.6
10	1.3	5.9	6.3	6.8
12	2.9	7.0	7.4	7.9
14	4.5	8.2	8.6	9.1

14 x 16mm Cage

Screw Length	Amount of screw past post edge	Amount above 0° cage	Amount above 4° cage	Amount above 8° cage
8	Does not protrude	4.7	5.2	5.7
10	Does not protrude	5.9	6.4	6.9
12	0.9	7.0	7.5	8.0
14	2.5	8.2	8.7	9.2

measurements in mm

Figure 16b

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Figure 17a. Straight Screwdriver
48328500



Figure 17b. Flexible Screwdriver
48328550



Figure 18

Screws may be inserted using either the **Straight Screwdriver** or **Flexible Screwdriver** (Fig. 17a, b, 18).

Both screwdrivers feature a square drive with a split tip to hold the screw head securely. Using the screw caddy to load the screws and the Straight Screwdriver or Flexible Screwdriver (in a “stab and grab” motion), attach the screw to the screwdriver.

Tip: The Inserter may separate slightly from the cage throughout the procedure. A gap between the cage and Inserter may result in improper seating of the screw. Prior to screw insertion, ensure the Inserter is flush to the cage (Fig. 19a, b).

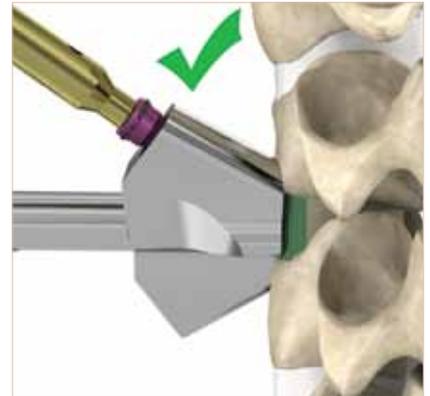
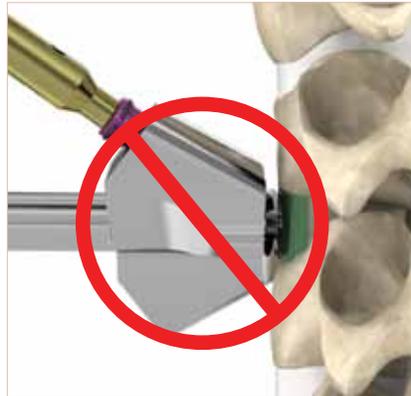


Figure 19a. Guide/Inserter Tip

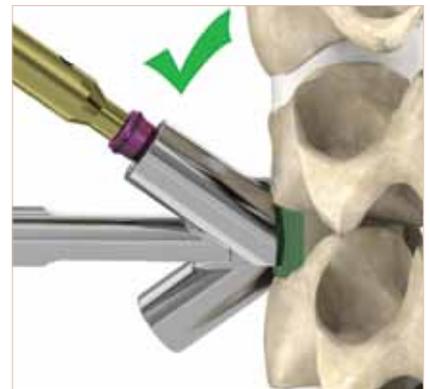
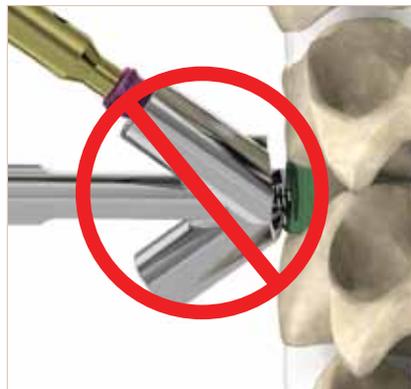


Figure 19b. Low Profile Inserter

Place the screw and screwdriver assembly through the Inserter and into the hole that has been previously prepared with the awl and/or drill (Fig. 20a, b).



Figure 20a. Guide/Inserter Tip



Figure 20b. Low Profile Inserter

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Note: When using the Flexible Screwdriver, it is recommended that the shaft not be bent past the range indicated in the images below. This will help prevent damage to the shaft (Fig. 21a, b).

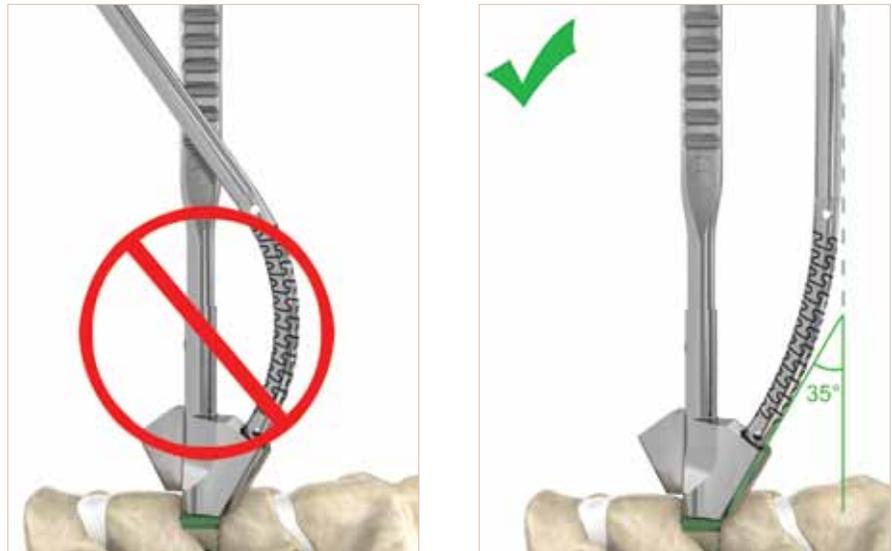


Figure 21a. Guide/Inserter Tip

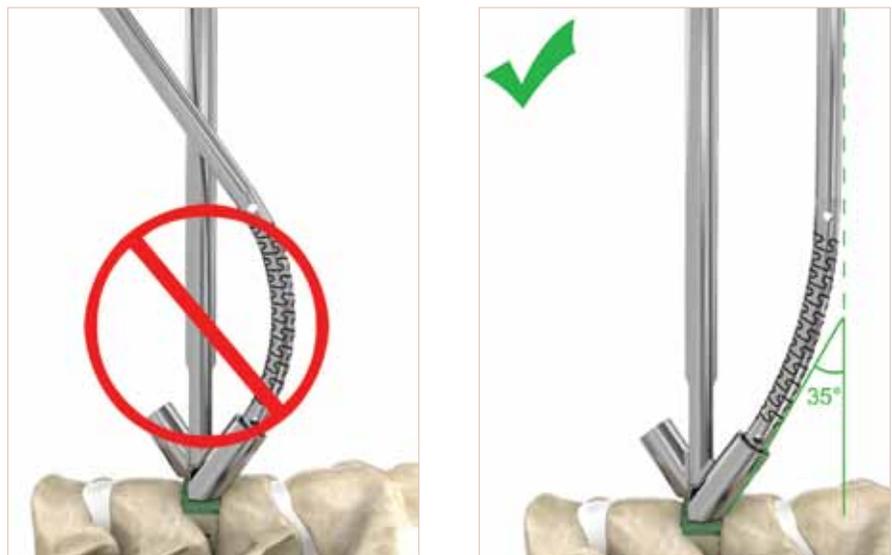


Figure 21b. Low Profile Inserter

Tip: Do not excessively bend Flexible Screwdriver back and forth; bending the shaft to the full limit repeatedly may result in fracture.



Figure 22

Turn until the gold tip and laser marking on the instrument disappear within the Inserter. This indicates that the clip on the screw is engaged with the implant and the screw is locked (Fig. 22).

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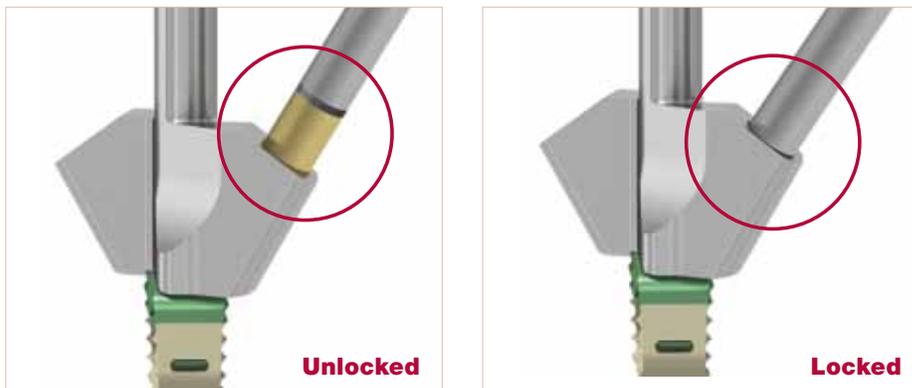


Figure 23a. Guide/Inserter Tip

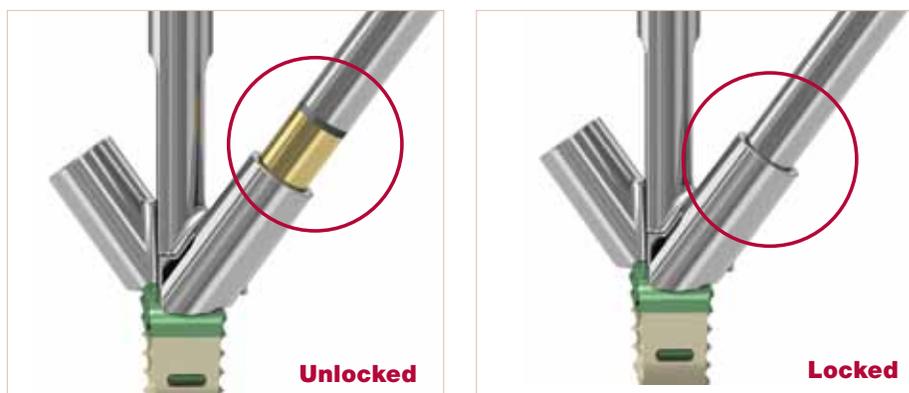
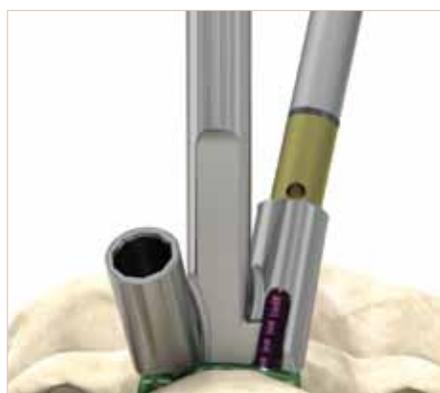


Figure 23b. Low Profile Inserter

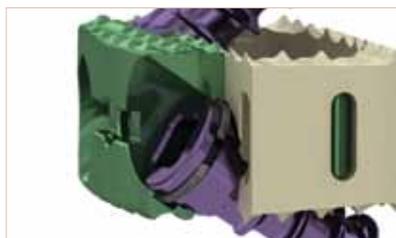


Figure 24

Screw is locked when the gold color and the black line are no longer visible (Fig. 23a, b, 24).

Repeat screw hole preparation and insertion technique for the other screw hole.

Note: To ensure proper depth and adequate locking when using the awl, drilling, or locking bone screws, use of a free hand technique is strongly discouraged. Use of the Guide/Inserter Tip or Low Profile Inserter is required.

Note: Excessive pivoting or angulation on the screwdriver while attached to the screw should be avoided as it can cause damage to the screwdriver and/or screw.

Caution: Driving the black line beyond the indicated area may lead to screw and/or cage deformation.



Figure 25

Remove the Inserter by fully unthreading the cage. To ensure the screw is locked into the cage, check to make sure the grey clip around the screw is not visible (Fig. 25).

Tip: After the Inserter has been removed, screws can be lagged to the bone by slowly turning each screw approximately one quarter turn.

Once the cage is in the correct position and the screws are locked, the wound is closed in the normal fashion.

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Implant Removal

To remove the implant, first remove each of the bone screws using the **Screw Extractor**, and then use the Inserter to remove the cage (Fig. 26).



Figure 26. Screw Extractor
48328625

Bone Screw Removal:

The Screw Extractor allows for removal of a bone screw from the cage after the screw has been locked within the cage.

To begin removal of the screw, the outer sleeve of the Screw Extractor should be threaded up to the handle, to keep the sleeve from impeding visibility when seating the instrument within the screw (Fig. 26).



Figure 27

The Screw Extractor should then be fully seated within the screw. Ensure the instrument is aligned at the same 35° angle as the screw (Fig. 27). Insert the Draw Rod through the instrument and thread into the screw until the knob will no longer turn.



Figure 28a

Figure 28b

To remove the screw, unthread the outer sleeve towards the cage, ensuring that the angle on the tip mates with the face of the cage. Hold onto the outer sleeve and unthread the bone screw from the cage (Fig. 28a, b).

It is inadvisable to attempt to remove the screw from the cage using only the Draw Rod.

Note: Excessive pivoting or angulation on the Screw Extractor while attached to the screw should be avoided as it can cause damage to the Screw Extractor and/or screw.

Note: Once a screw is removed from the cage after it has been locked, the screw cannot be reused.

For cleaning, the outer sleeve should be completely unthreaded from the handle and the Draw Rod removed from within the handle. After the components have been cleaned the threaded handle should be dried prior to re-assembly to the outer threaded sleeve.

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Figure 29

Cage Removal:

To remove the cage, thread the cage to the Inserter, and gently remove the cage from the disc space (Fig. 29).

It is inadvisable to attempt to remove the cage using only the Low Profile Inserter Draw Rod.

Note: It is recommended that the Parallel Pin Distractor and Pins from the Reliance® C instrumentation set be used to distract the disc space before removing the cage.

If necessary, the entire construct (cage and screws) may be removed by using the Straight Screwdriver. If both screws are in the cage, alternate backing the screws out with the Straight Screwdriver and distracting the disc space until the construct is removed from the vertebral body.

If only one screw remains in the cage, distract the disc space and use the Straight Screwdriver to backout the screw with the cage attached.

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Implant Reference Numbers

AVS Anchor-C Cervical Cages



12 x 14mm Footprint

48321060	6 x 12 x 14 x 0°
48321070	7 x 12 x 14 x 0°
48321080	8 x 12 x 14 x 0°
48321090	9 x 12 x 14 x 0°
48321100	10 x 12 x 14 x 0°
48321110	11 x 12 x 14 x 0°
48321120	12 x 12 x 14 x 0°
48321064	6 x 12 x 14 x 4°
48321074	7 x 12 x 14 x 4°
48321084	8 x 12 x 14 x 4°
48321094	9 x 12 x 14 x 4°
48321104	10 x 12 x 14 x 4°
48321114	11 x 12 x 14 x 4°
48321124	12 x 12 x 14 x 4°
48321068	6 x 12 x 14 x 8°
48321078	7 x 12 x 14 x 8°
48321088	8 x 12 x 14 x 8°
48321098	9 x 12 x 14 x 8°
48321108	10 x 12 x 14 x 8°
48321118	11 x 12 x 14 x 8°
48321128	12 x 12 x 14 x 8°



14 x 16mm Footprint

Reference #	Description
48323060	6 x 14 x 16 x 0°
48323070	7 x 14 x 16 x 0°
48323080	8 x 14 x 16 x 0°
48323090	9 x 14 x 16 x 0°
48323100	10 x 14 x 16 x 0°
48323110	11 x 14 x 16 x 0°
48323120	12 x 14 x 16 x 0°
48323064	6 x 14 x 16 x 4°
48323074	7 x 14 x 16 x 4°
48323084	8 x 14 x 16 x 4°
48323094	9 x 14 x 16 x 4°
48323104	10 x 14 x 16 x 4°
48323114	11 x 14 x 16 x 4°
48323124	12 x 14 x 16 x 4°
48323068	6 x 14 x 16 x 8°
48323078	7 x 14 x 16 x 8°
48323088	8 x 14 x 16 x 8°
48323098	9 x 14 x 16 x 8°
48323108	10 x 14 x 16 x 8°
48323118	11 x 14 x 16 x 8°
48323128	12 x 14 x 16 x 8°

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Bone Screws

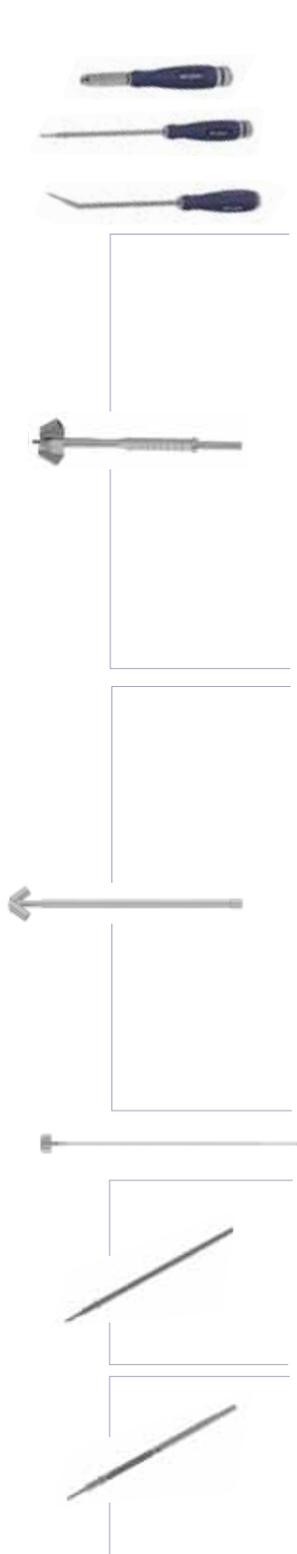
	Screw Type	Reference #	Size (Diameter x Length)
	3.5mm Self-Tapping	48325308	Ø3.5mm x 8mm
		48325310	Ø3.5mm x 10mm
		48325312	Ø3.5mm x 12mm
		48325314	Ø3.5mm x 14mm
	3.5mm Self-Drilling	48335308	Ø3.5mm x 8mm
		48335310	Ø3.5mm x 10mm
		48335312	Ø3.5mm x 12mm
		48335314	Ø3.5mm x 14mm
	4.0mm Self-Tapping	48325408	Ø4.0mm x 8mm
		48325410	Ø4.0mm x 10mm
		48325412	Ø4.0mm x 12mm
		48325414	Ø4.0mm x 14mm
	4.0mm Self-Drilling	48335408	Ø4.0mm x 8mm
		48335410	Ø4.0mm x 10mm
		48335412	Ø4.0mm x 12mm
		48335414	Ø4.0mm x 14mm

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Instrument Reference Numbers

AVS Anchor-C General Instruments



Reference #	Description
48328050	Quick Release Handle
48328200	Straight Awl
48328225	Angled Awl
48328006	6mm Inserter Tip
48328007	7mm Inserter Tip
48328008	8mm Inserter Tip
48328009	9mm Inserter Tip
48328010	10mm Inserter Tip
48328011	11mm Inserter Tip
48328012	12mm Inserter Tip
48327006	6mm Low Profile Inserter Outer Shaft
48327007	7mm Low Profile Inserter Outer Shaft
48327008	8mm Low Profile Inserter Outer Shaft
48327009	9mm Low Profile Inserter Outer Shaft
48327010	10mm Low Profile Inserter Outer Shaft
48327011	11mm Low Profile Inserter Outer Shaft
48327012	12mm Low Profile Inserter Outer Shaft
48327000	Low Profile Inserter Inner Draw Rod
48328908	8mm Drill Bit
48328910	10mm Drill Bit
48328912	12mm Drill Bit
48328808	8mm Flexible Drill
48328810	10mm Flexible Drill
48328812	12mm Flexible Drill

AVS Anchor-C Cervical Cage System

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Instrument Reference Numbers

AVS Anchor-C General Instruments

	Reference #	Description
	48328500	Straight Screwdriver
	48328550	Flexible Screwdriver
	4832862SAR	Replacement Screw Extractor Draw Rod
	48328625	Screw Extractor
	48328725	Pin Guide Distractor
	48328001	Screw Caddy
	48328002	Implant Caddy
	48328000C	Top Tray Insert
	48328000	Container

AVS Anchor-C Trials



Height	12 x 14mm Footprint (depth x width)			14 x 16mm Footprint (depth x width)		
	Parallel (0°)	Lordotic (4°)	Lordotic (8°)	Parallel (0°)	Lordotic (4°)	Lordotic (8°)
6mm	48328760	48328764	48328768	48328660	48328664	48328668
7mm	48328770	48328774	48328778	48328670	48328674	48328678
8mm	48328780	48328784	48328788	48328680	48328684	48328688
9mm	48328790	48328794	48328798	48328690	48328694	48328698
10mm	48328700	48328704	48328708	48328600	48328604	48328608
11mm	48328710	48328714	48328718	48328610	48328614	48328618
12mm	48328720	48328724	48328728	48328620	48328624	48328628

AVS Anchor-C Cervical Cage System

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IMPORTANT PRODUCT INFORMATION FOR STRYKER SPINE AVS ANCHOR-C CERVICAL CAGE SYSTEM NON STERILE PRODUCT

Description

The AVS Anchor-C Cervical Cage is a hollow, rectangular-shaped PEEK Optima® LT1 (per ASTM F2026) cage assembled to a titanium alloy (per ASTM F136 and ISO 5832-3) plate and has one tantalum marker (per ASTM F560). 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 PEEK Optima® LT1 cage portion 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 (AVS Anchor-C Fixation Screws). The AVS Anchor-C Fixation Screws are constructed from titanium alloy and possess clips that mate with internal features located within the AVS Anchor-C Cervical Cage. Once fully seated into the holes, the screws are designed to lock into the titanium plate.

Materials

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

- Cage: Polyetheretherketone (PEEK Optima® LT1) (ASTM F2026), Titanium Alloy Ti6Al4V (ISO 5832-3, ASTM F136) with a tantalum marker (ASTM F560)
- Fixation Screws: Titanium Alloy Ti6Al4V (ISO 5832-3, ASTM F136)

Indications

The Stryker Spine AVS Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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 to be used without the AVS Anchor-C fixation screws provided. Should removal of the AVS Anchor-C Fixation Screws be necessary during the surgery, the AVS Anchor-C cage should NOT be implanted alone, without the support of the AVS Anchor-C fixation screws.
- Instruments designed for use with implantation of the AVS Anchor-C Cervical Cage System are provided non-sterile and must be sterilized prior to use.
- This device is not intended for posterior surgical implantation.
- The AVS Anchor-C Cervical Cages have not been evaluated for safety and compatibility in the MR environment. AVS Anchor-C Cervical 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 reimplant 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.

AVS Anchor-C Cervical Cage System

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Handling

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

Allergy and Hypersensitivity to Foreign Bodies

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

Contraindications

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

- The AVS Anchor-C Cervical Cage should not be implanted in patients with an active infection at the operative site.
- The AVS Anchor-C Cervical 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. Obesity is defined according to the W.H.O. standards.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of

white blood cell count (WBC), or marked left shift in the WBC differential count.

- Prior fusion at the levels to be treated

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

Information for Patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weightbearing, 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.

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- 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-C 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.

Packaging

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

Complaints

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

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

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

For further information or complaints, please contact:

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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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