

Surgical Technique

Aura cage

www.auxein.com

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements



Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Please NOTE that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

Warning:

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.



Organised by: Auxein

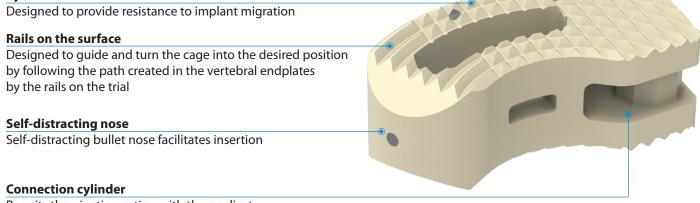




Articulating Implant

- Rails on top of the implant are designed to turn the cage into the desired position by guiding the cage along the pathway created in the vertebral endplates by the rails on the trial
- Three x-ray markers help to visualize the implant under radiographic control
- Cages available in three material types PEEK, Titanium & ProTi 360°™ Titanium Integrated Technology

Pyramidal teeth



Permits the pivoting action with the applicator

Two anterior radiographic marker pins

Enable visualization of the anterior implant position during imaging The PEEK Cages 1.4 mm diameter pins and ProTi 360° 1mm diameter pins are approximately 2 mm from the anterior edge of the implant.

Axial window

Accommodates autogenous bone graft or bone graft substitute

Implant materials

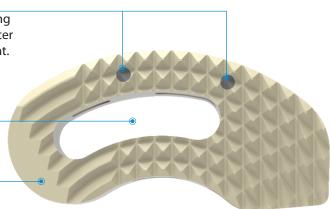
- TITANIUM
- PEEK

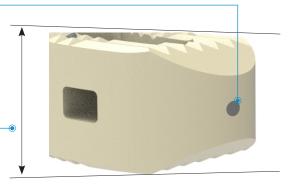
Radiographic marker pin

 Enable visualization of implant tip position during insertion The 1.4 mm diameter, pin is located in the middle of the cage and stops at the bullet nose tip of the cage. A 1 mm diameter, pin is represented in PEEK Aura Cage.

Lordotic angle

5° (except for the 7 mm height)



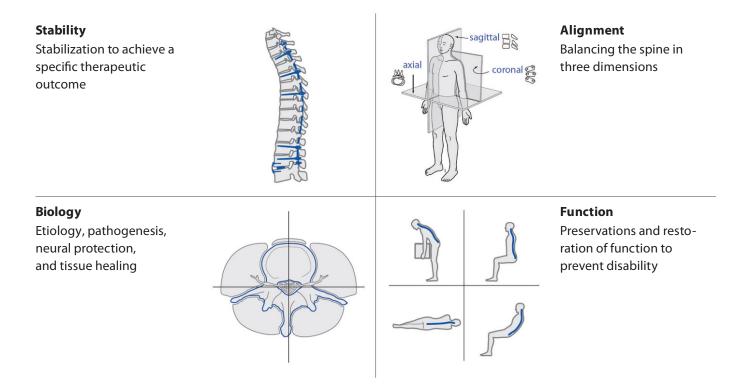




AO Spine Principles

Position the patient

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.1,2





Preoperative Planning and Preparation

Instruments:

7-009

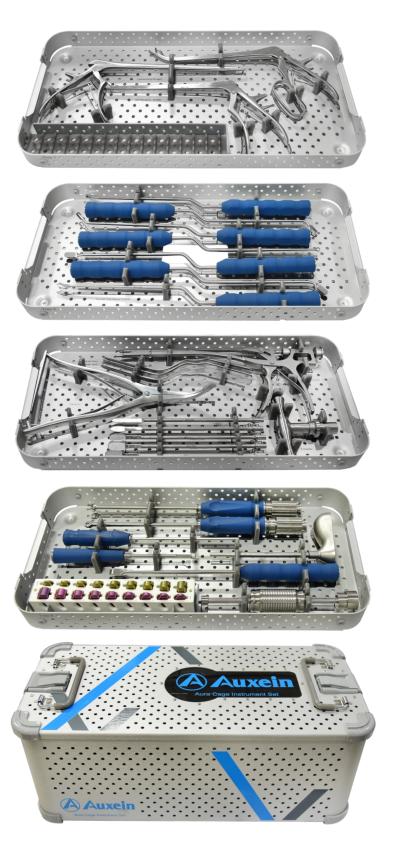
AURA Cage (TLIF) Instrument Set

Preparation

Have all necessary imaging studies readily available to plan implant placement and visualize individual patient anatomy.

Have all sets readily available prior to surgery.

Warning: Please see the Surgical Technique Guide .Addendum for information specific to the Aura Cage Advanced Applicator, including precautions, warnings, and other important information.





Patient Positioning

Position the patient

Position the patient in a restored physiological lordosis, avoiding abdominal restriction to reduce venous stasis.







Access and Exposure Open transforaminal approach

1. Retraction with an open transforaminial approach

Instruments:

7-009-23 Distractor for AURA Cage

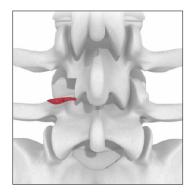
Make a standard open incision, retract the muscle layer to view the desired segment. Distract the segment if desired. Position the lamina spreader for Aura Cage at the base of the spinous processes. Distract carefully until required distraction is achieved. Distraction opens the posterior disc space and promotes exposure both for decompression and delivery of the implant.

2. Cut transforaminal window

Instruments:

7-009-02 Osteotome

Prepare a window for the transforaminal approach using the osteotome to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra. With the laminectomy punch, additional bone or osteophytes can be removed.



(1)



Discectomy

Instruments:

7-009-05	Raspatory, Curved
7-009-06	Curette, Ring
7-009-07	Curette Curved, Left
7-009-08	Curette Curved, Right
7-009-09	Bone Plugger for AURA Cage
7-009-10	Curette, Straight
7-009-11	Shaver, 7mm
7-009-12	Shaver, 9mm
7-009-13	Shaver, 11mm
7-009-14	Shaver, 13mm
7-009-15	Shaver, 15mm
7-009-16	T-Handle for AURA Cage
7-009-17	Retractor, 6mm
7-009-18	Retractor, 8mm
7-009-19	Retractor, 10mm
7-009-20	Intervertebral Disc (IVD) Rongeurs, Straight
7-009-21	Laminectomy Punche

Through an incision above the pedicle, access the foramen and remove disc material, using any of the following instruments: box and ring curettes, rongeurs as well as disc shavers.

Precaution: The annulus should be preserved as much as possible to provide additional support for the Aura Cage implant and prevent migration of bone graft and bone graft substitute into the spinal canal.

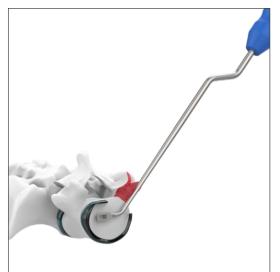
The shavers can initially be used to ream out disc material or for final removal of the disc material and cartilaginous tissue.

For removal of the tissue in the far lateral disc space, use the left/right angled curettes and the curved rongeur.

Warning: Provide enough lateral exposure to the disc to reduce dural retraction.









Disc Space Preparation

1. Prepare endplates

Instruments:

7-009-05	Raspatory, Curved
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When the discectomy is completed, use the rasp to remove the superficial cartilaginous layers of the endplates to expose the bleeding bone.

Warning: Excessive removal of the subchondral bone may weaken the vertebral endplate. The entire removal of the endplate may result in subsidence and a loss of segmental stability.



2. Pack disc space

Instruments:

7-009-09 Bone Plugger for Aura Cage

Before the Aura Cage cage is implanted, the anterior and far lateral disc space should be filled with bone graft or bone graft substitute.





TRIAL FOR IMPLANT SIZE

1. Assemble applicator and connect non detachable trial implant

Instruments:

7-009-03	Trial Holder
7-009-30	7 x 10 x 28
7-009-30	7 x 10 x 28
7-009-31	8 x 10 x 28
7-009-32	9 x 10 x 28
7-009-33	10 x 10 x 28
7-009-34	11 x 10 x 28
7-009-35	12 x 10 x 28
7-009-36	13 x 10 x 28
7-009-37	15 x 10 x 28
7-009-38	17 x 10 x 28

The applicator must be assembled before insertion of the trial.

Attach the applicator knob to the proximal end of the applicator outer shaft by turning the knob counterclockwise until it stops.

Select an appropriately sized trial implant. Insert the trial implant shaft into the applicator outer shaft making sure that the arrow on the outer shaft is aligned with the distal opening of the trial implant shaft. The trial implant shaft should now be trapped inside the applicator outer shaft.

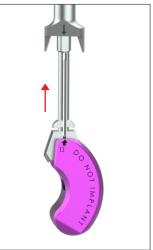
Turn the applicator knob clockwise to secure the trial implant. During this attaching procedure the security ring moves upwards, so that the green color band is visible. Continue to turn the knob until it is tightened.

Warning: Ensure the arrows on the end of the applicator align with those on the trial implant. The contact surfaces between the trial and the applicator should have no gap.

Note: For disassembly pull the security ring down, turn the applicator knob counterclockwise until it stops. Push the small button on the applicator knob and simultaneously pull the trial implant shaft out of the applicator outer shaft. Turn the applicator knob clockwise.











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2. Insert trial implant

Optional Instruments:

Recheck the firm connection of trial implant to applicator. Insert the trial implant into the disc space, ensuring that the orientation of the trial implant is correct. The trial implant tip should be orientated medially. Maintain $10-15^{\circ}$ between the applicator handle and the sagittal plane during trial implant insertiozn.

Controlled and light hammering on the applicator may be required to advance the trial implant into the intervertebral disc space. Use fluoroscopy to confirm position and fit of the trial implant. The tip should be positioned near the anterior edge of the adjacent vertebral bodies.

Notes:

- Firm connection of trial implant to applicator can be checked manually by applying pressure on the lateral side of the trial implant with the thumb. Trial implant should not pivot.
- Use soft tissue retractor

7-009-17	Retractor, 6mm
7-009-18	Retractor, 8mm
7-009-19	Retractor, 10mm to protect soft tissue.

• Use fluoroscopy during the insertion to confirm anterior positioning of the trial implant.

Warnings:

- The trial tip indicates approximate final anterior position of the trial implant.
- Maintain 10–15° between the applicator handle and the sagittal plane during trial implant insertion.





3. Position trial implant

Optional Instruments:

Turn the applicator knob counterclockwise until it stops

Precaution: Ensure applicator knob is turned counterclockwise until it stops to avoid deformation of the applicator outershaft.

Controlled and light hammering on the applicator may be required to pivot the trial implant into final position.

Use fluoroscopy during the pivoting procedure and confirm fit and position of the trial implant. Each trial has a medial/lateral and an anterior/posterior opening for position control. If the trial implant appears too small or too tight, try the next larger or smaller size height until the most secure fit is achieved.

Notes:

• Ensure that the trial implant is positioned where the implant will be placed.

Warnings:

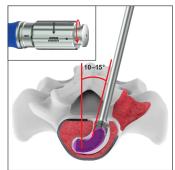
• Maintain 10–15° between the applicator handle and the sagittal plane during trial implant insertion.

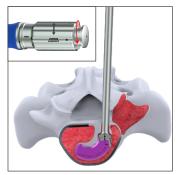
Optional: Position trial implant

If trial implant does not pivot automatically, turn the applicator handle medially to initiate pivoting upon impaction. After pivoting is initiated the applicator handle must be turned back to an angle of 10–15° from the sagittal plane to pivot the trial implant into final position.

Warning: Maintain 10–15° between the applicator handle and the sagittal plane for final trial implant insertion.









4. Remove non detachable trial implant

Instruments:

7-009-24	Sliding Hammer for AURA Cage
7-009-24	Sliding Hammer for AURA Cage

Warning: The applicator must be in the pivoting position to remove the trial implant. Slide the slide hammer onto the end of the applicator knob with quick coupling. While holding the handle with one hand, apply an upward force to the slide hammer with the other hand. Repeat this procedure until the trial implant is removed. Optionally the combination hammer may also be used to remove the trial implant. Remove the slide hammer from the handle by pushing on the end of the slide hammer.





To detach the trial implant from the applicator pull the security ring down and simultaneously turn the knob counterclockwise until it stops. Push the small button on the applicator knob and remove the trial implant.

Insert the applicator inner shaft into the applicator outer shaft making sure that the arrow on the outer shaft is aligned with the distal opening of the inner shaft. The applicator inner shaft should now be trapped inside the outer shaft. The applicator is now ready to accept the implant.

Note: If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.









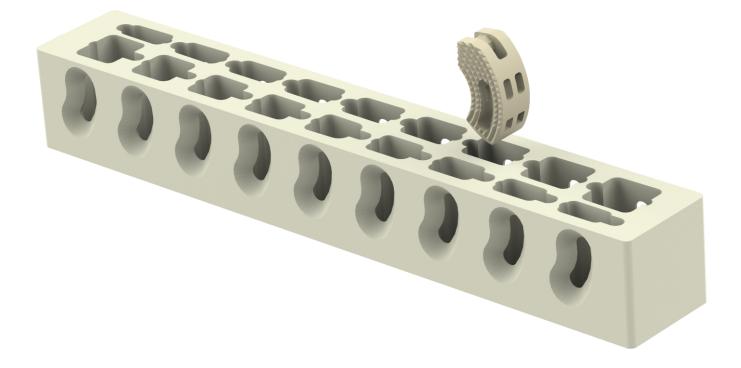
Implant Preparation

1. Select implant

Instruments:

7-009-27 Trial Case

Select the Aura Cage implant that corresponds to the height and size measured using the trial implant in the previous steps. Insert the selected implant into the appropriate packing block place. Note: Cages available in two material types PEEK, Titanium.



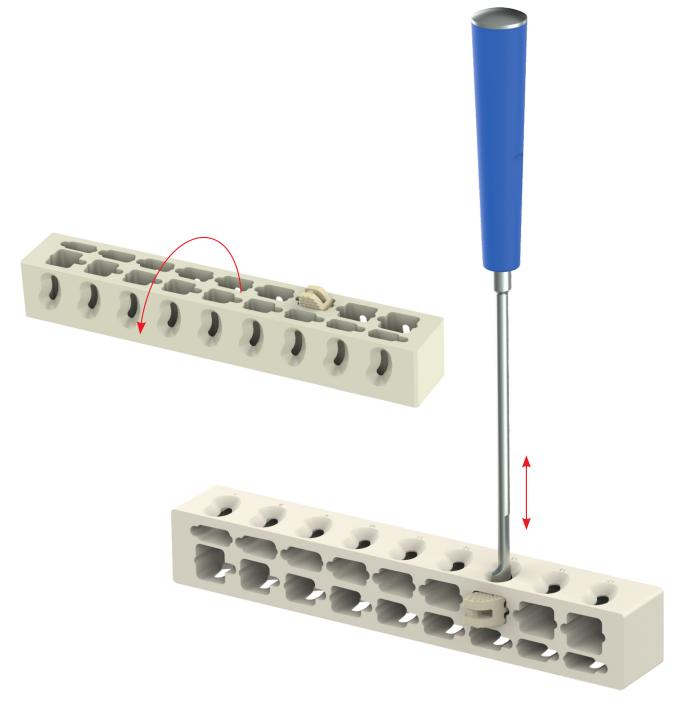


2. Pack implant

Instruments:

7-009-04 Graft Impactor

Turn the Use Trial case Instead of Packing block on its side and use graft impactor impactor to firmly pack the filling material into the implant cavities. Make sure the implant is well placed in the packing block to avoid implant damage while bone graft filling. It is important to fill the implant until the filling material protrudes from its perforations in order to ensure optimal contact with the vertebral endplates.





3. Connect implant to the applicator

Instruments:		
7-009-03	Trial Holder	

To connect the implant to the applicator turn the packing block upwards again. Pull the security ring down and simultaneously turn the knob at the proximal end of the applicator counterclockwise. The applicator jaws open. Place the jaws over the proximal end of the implant making sure to align the arrows on the end of the applicator with those on the implant.

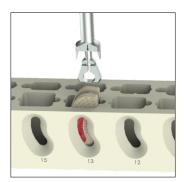
Turn the applicator knob clockwise to close the jaws. During this closing procedure the security ring moves upwards, so that the green color band is visible. Continue to turn the knob until it is tightened.

Note: When the applicator knob is tightened, the implant cannot pivot or detach.

Warning: Ensure the arrows on the end of the applicator align with those on the implant. The contact surfaces between the implant and the applicator should have no gap.









PEEK and TI Implant Insertation

1. Insert implant

Instruments:

7-009-24	Sliding Hammer for AURA Cage
7-009-17	Retractor, 6mm
7-009-18	Retractor, 8mm
7-009-19	Retractor, 10mm

Recheck the firm connection of implant to applicator. Insert the implant into the disc space, ensuring that the orientation of the implant is correct. The implant tip should be orientated medial. Maintain $10-15^{\circ}$ between the applicator handle and the sagittal plane during implant insertion.

Controlled and light hammering on the applicator may be required to advance the implant into the intervertebral disc space.

Use fluoroscopy to confirm position and fit of the implant. The tip should be positioned near the anterior edge of the adjacent vertebral bodies.

Notes:

- Firm connection of implant to applicator can be checked manually by applying pressure on the lateral side of the implant with the thumb. Implant should not pivot.
- Use fluoroscopy during the insertion to confirm anterior position of the implant.
- The anterior marker pins of the implant are located approximately 2 mm from the edge of the implant.

Warnings:

- The implant tip marker pin indicates approximate final anterior position of implant.
- Maintain 10–15° between the applicator handle and the sagittal plane during implant insertion.



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2. Position implant

Turn the applicator knob counterclockwise until it stops.

Precaution: Ensure applicator knob is turned counterclockwise until it stops to avoid trial or applicator outershaft deformation.

Controlled and light hammering on the applicator may be required to pivot the implant into final position.

Use fluoroscopy during the pivoting procedure and confirm fit and position of the implant.

With a medial/lateral fluoroscopic image of the cage in the final position, the two anterior pins of the implant should appear as one line.

In an anterior/posterior fluoroscopic image, the two anterior pins should be equidistant to the pedicles. The tip pin indicates the lateral edge of the implant.

Note: If bone graft or bone graft substitutes are placed into the disc space after trialing, the implant may not reach the same position as the trial.

Warning: Maintain 10–15° between the applicator handle and the sagittal plane during implant insertion.







3. Detach implant

To detach the implant, pull the security ring down and simultaneously turn the applicator knob counterclockwise until it stops. The applicator can now be removed from the implant.

Use fluoroscopy to verify final position of the implant. With a medial/lateral fluoroscopic image, the two anterior pins of the implant should appear as one line and the tip marker as a dot.

Notes:

- If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.
- If the applicator does not disengage from the implant move the applicator handle laterally to free the instrument.







Posterior Support

1. Pack disc space

Instrument

7-009-09	Bone Plunger for Aura Cage	

After the Aura Cage cage is implanted, fill the posterior disc space and the lateral disc space with bone graft or bone graft substitute to create desired conditions for fusion.



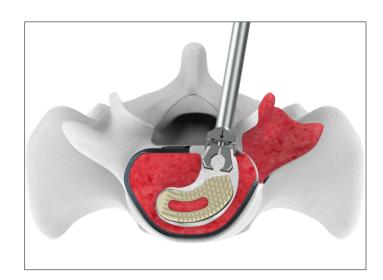
Implant Removal

Implant removal with the applicator

Ensure that the applicator is in the fully open position. Locate the implant and close the applicator by turning the knob clockwise until the security ring is moving upwards. There should be no gap between the applicator knob and the security ring. To ensure that the knob is in contact with the security ring, turn the knob counterclockwise until it stops, in this position the implant can pivot but not detach from the applicator. The implant can now be removed. The slap hammer may be required to facilitate removal.

Note: Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the applicator.

Warning: The applicator must be in the pivoting position to remove the implant.





Implant removal with the removal tool

Optional instrument

7-009-49	Remover for AURA Cage
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Ensure that the removal tool for Aura Cage is in the fully open position. Locate the implant and squeeze the handle firmly. Advance the speed nut to lock the handle. The implant can now be removed. The slide hammer may be required to facilitate removal.

Notes:

- When the removal tool handle is squeezed, the implant can pivot but not detach from the removal tool.
- Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the removal tool.





Applicator Instructions

Attach position

Pull the security ring down and simultaneously turn the knob counterclockwise. No gap between the handle, security ring and the applicator knob should be present.



Insertion position

Turn the applicator knob clockwise to close the jaws. During this closing procedure the security ring moves upwards, Continue to turn the knob until it is tightened.

In the insertion position; the implant or trial is fixed. The implant or trial cannot pivot or detach.







Pivoting position

Turn the applicator knob counterclockwise until it stops. The applicator knob and the security ring will now be in contact.

In this position the implant or trial can pivot 80°. Implant or trial cannot detach from applicator.





Detach position

Pull the security ring down and simultaneously turn the

knob counterclockwise. No gap between the handle, security ring and the Applicator knob should be present. The implant or trial can be detached.

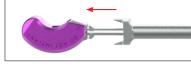
Note: If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.

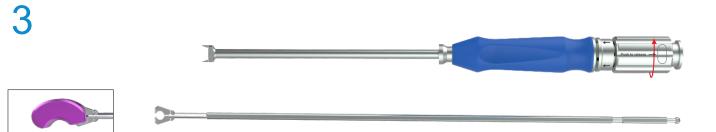












4





2



AURA Cage (TLIF)



TITANIUM



Code	Product Specification (mm)
SP-2807	7 x 10 x 28
SP-2808	8 x 10 x 28
SP-2809	9 x 10 x 28
SP-2810	10 x 10 x 28
SP-2811	11 x 10 x 28
SP-2812	12 x 10 x 28
SP-2813	13 x 10 x 28
SP-2815	15 x 10 x 28
SP-2817	17 x 10 x 28
SP-3107	7 x 12 x 31
SP-3108	8 x 12 x 31
SP-3109	9 x 12 x 31
SP-3110	10 x 12 x 31
SP-3111	11 x 12 x 31
SP-3112	12 x 12 x 31
SP-3113	13 x 12 x 31
SP-3115	15 x 12 x 31
SP-3117	17 x 12 x 31

AURA Cage (TLIF)



PEEK OPTIMA



Code	Product Specification (mm)
SP-2807P-NS	7 x 10 x 28
SP-2808P-NS	8 x 10 x 28
SP-2809P-NS	9 x 10 x 28
SP-2810P-NS	10 x 10 x 28
SP-2811P-NS	11 x 10 x 28
SP-2812P-NS	12 x 10 x 28
SP-2813P-NS	13 x 10 x 28
SP-2815P-NS	15 x 10 x 28
SP-2817P-NS	17 x 10 x 28
SP-3107P-NS	7 x 12 x 31
SP-3108P-NS	8 x 12 x 31
SP-3109P-NS	9 x 12 x 31
SP-3110P-NS	10 x 12 x 31
SP-3111P-NS	11 x 12 x 31
SP-3112P-NS	12 x 12 x 31
SP-3113P-NS	13 x 12 x 31
SP-3115P-NS	15 x 12 x 31
SP-3117P-NS	17 x 12 x 31



AURA Cage (TLIF)

STERILE

TITANIUM



Code	Product Specification (mm)		
SP-2807-S	7 x 10 x 28		
SP-2808-S	8 x 10 x 28		
SP-2809-S	9 x 10 x 28		
SP-2810-S	10 x 10 x 28		
SP-2811-S	11 x 10 x 28		
SP-2812-S	12 x 10 x 28		
SP-2813-S	13 x 10 x 28		
SP-2815-S	15 x 10 x 28		
SP-2817-S	17 x 10 x 28		
SP-3107-S	7 x 12 x 31		
SP-3108-S	8 x 12 x 31		
SP-3109-S	9 x 12 x 31		
SP-3110-S	10 x 12 x 31		
SP-3111-S	11 x 12 x 31		
SP-3112-S	12 x 12 x 31		
SP-3113-S	13 x 12 x 31		
SP-3115-S	15 x 12 x 31		
SP-3117-S	17 x 12 x 31		

AURA Cage (TLIF)

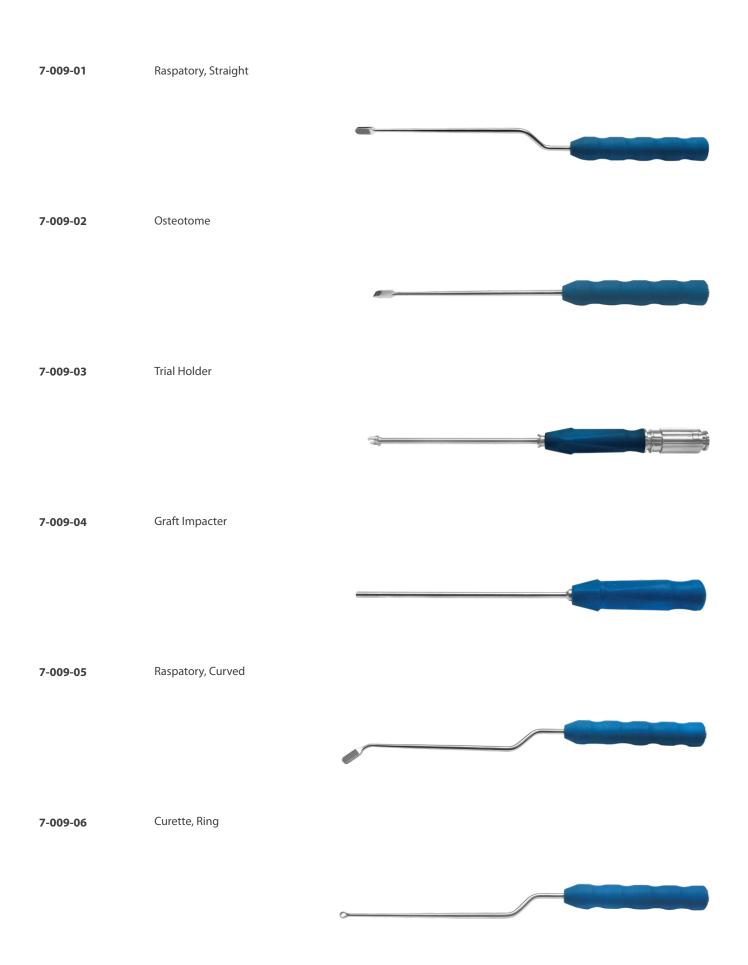


PEEK OPTIMA

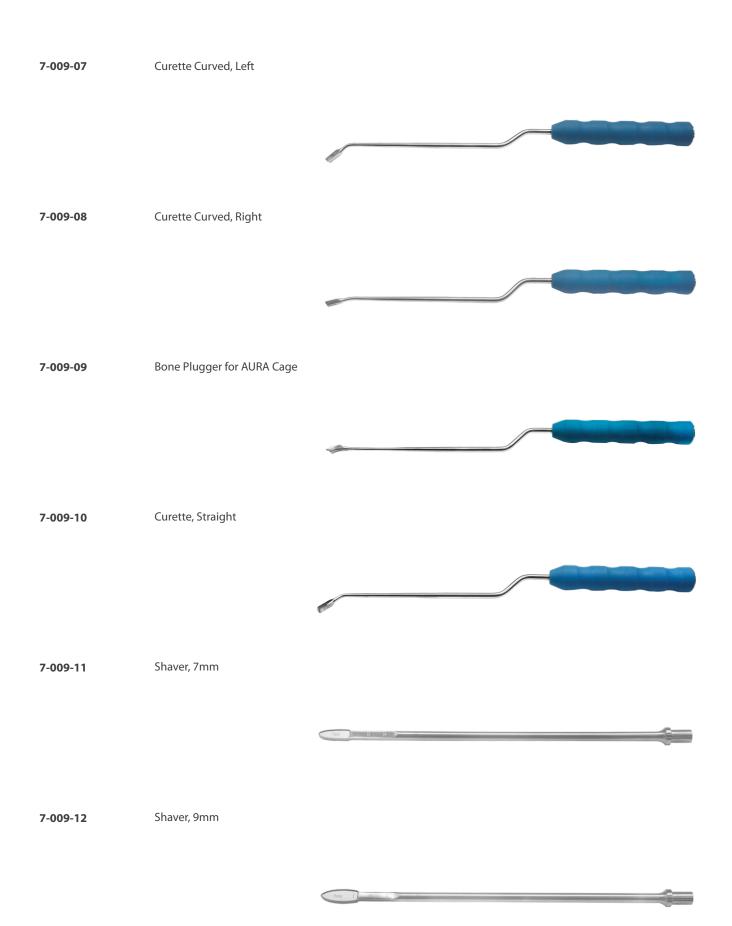


Code	Product Specification (mm)
SP-2807P	7 x 10 x 28
SP-2808P	8 x 10 x 28
SP-2809P	9 x 10 x 28
SP-2810P	10 x 10 x 28
SP-2811P	11 x 10 x 28
SP-2812P	12 x 10 x 28
SP-2813P	13 x 10 x 28
SP-2815P	15 x 10 x 28
SP-2817P	17 x 10 x 28
SP-3107P	7 x 12 x 31
SP-3108P	8 x 12 x 31
SP-3109P	9 x 12 x 31
SP-3110P	10 x 12 x 31
SP-3111P	11 x 12 x 31
SP-3112P	12 x 12 x 31
SP-3113P	13 x 12 x 31
SP-3115P	15 x 12 x 31
SP-3117P	17 x 12 x 31

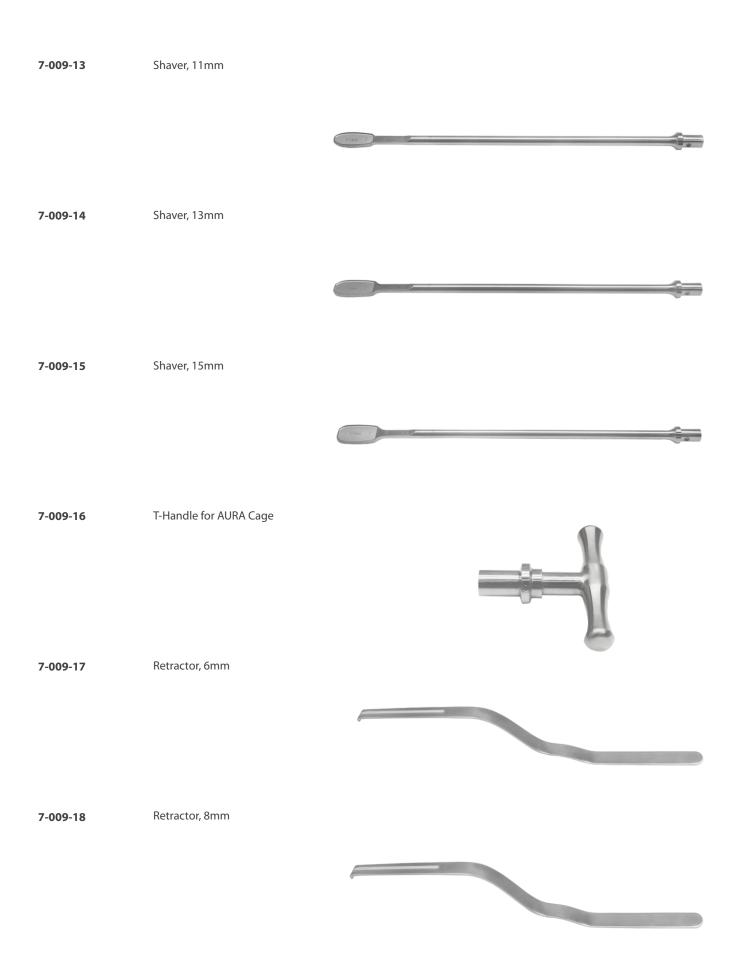




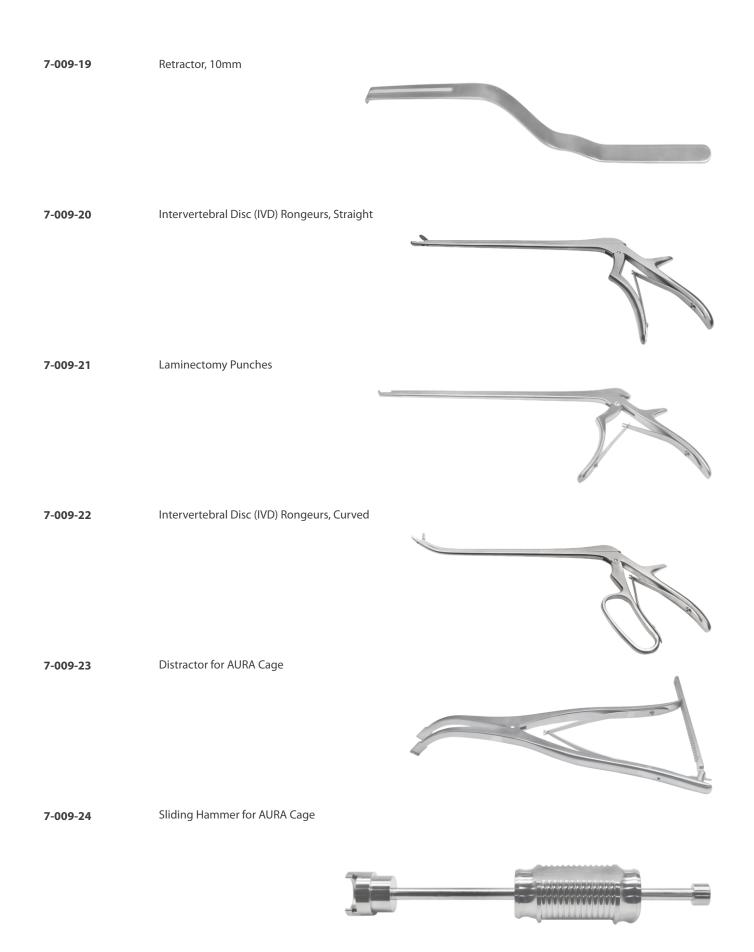
















TRIALS

Code	Product Specification (mm)
7-009-30	7 x 10 x 28
7-009-31	8 x 10 x 28
7-009-32	9 x 10 x 28
7-009-33	10 x 10 x 28
7-009-34	11 x 10 x 28
7-009-35	12 x 10 x 28
7-009-36	13 x 10 x 28
7-009-37	15 x 10 x 28
7-009-38	17 x 10 x 28

TRIALS

Code	Product Specification (mm)
7-009-39	7 x 12 x 31
7-009-40	8 x 12 x 31
7-009-41	9 x 12 x 31
7-009-42	10 x 12 x 31
7-009-43	11 x 12 x 31
7-009-44	12 x 12 x 31
7-009-45	13 x 12 x 31
7-009-46	15 x 12 x 31
7-009-47	17 x 12 x 31



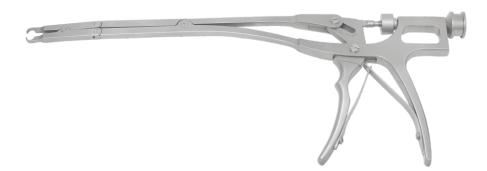
Specification: Length 28mm



Specification: Length 31mm



7-009-49 Remover for AURA Cage



7-009-48

Instrument Trays for AURA Cage (TLIF) Instrument Set



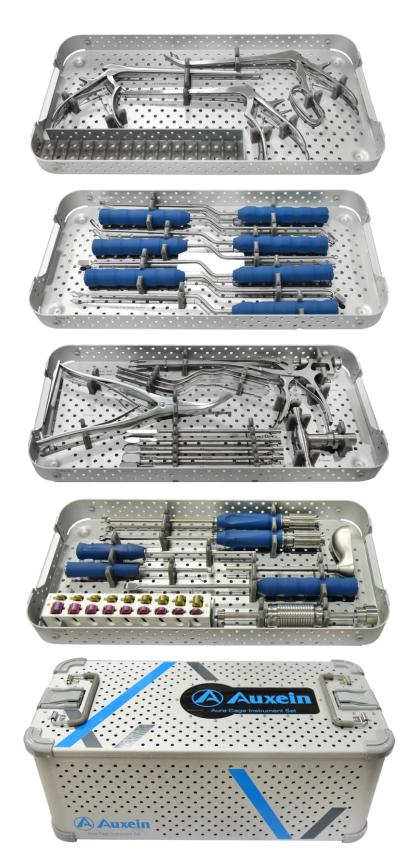
7-009-29

Container for AURA Cage (TLIF) Instrument Set











7-009 AURA Cage (TLIF) Instrument Set

Code	Set Consisting of	Qty.
7-009-01	Raspatory, Straight	1
7-009-02	Osteotome	1
7-009-03	Trial Holder	2
7-009-04	Graft Impacter	1
7-009-05	Raspatory, Curved	1
7-009-06	Curette, Ring	1
7-009-07	Curette Curved, Left	1
7-009-08	Curette Curved, Right	1
7-009-09	Bone Plugger for AURA Cage	1
7-009-10	Curette, Straight	1
7-009-11	Shaver, 7mm	1
7-009-12	Shaver, 9mm	1
7-009-13	Shaver, 11mm	1
7-009-14	Shaver, 13mm	1
7-009-15	Shaver, 15mm	1
7-009-16	T-Handle for AURA Cage	1
7-009-17	Retractor, 6mm	1
7-009-18	Retractor, 8mm	1
7-009-19	Retractor, 10mm	1
7-009-20	Intervertebral Disc (IVD) Rongeurs, Straight	1
7-009-21	Laminectomy Punches	1
7-009-22	Intervertebral Disc (IVD) Rongeurs, Curved	1
7-009-23	Distractor for AURA Cage	1
7-009-24	Sliding Hammer for AURA Cage	1
7-009-25	Curved Trial Pusher	1
7-009-26	Graft Impactor Funnel	1
7-009-27	Trial Case	1
7-009-30	Trial, 7mm x 10mm x 28mm	1
7-009-31	Trial, 8mm x 10mm x 28mm	1
7-009-32	Trial, 9mm x 10mm x 28mm	1
7-009-33	Trial, 10mm x 10mm x 28mm	1



Code	Set Consisting of	Qty.
7-009-34	Trial, 11mm x 10mm x 28mm	1
7-009-35	Trial, 12mm x 10mm x 28mm	1
7-009-36	Trial, 13mm x 10mm x 28mm	1
7-009-37	Trial, 15mm x 10mm x 28mm	1
7-009-38	Trial, 17mm x 10mm x 28mm	1
7-009-39	Trial, 7mm x 12mm x 31mm	1
7-009-40	Trial, 8mm x 12mm x 31mm	1
7-009-41	Trial, 9mm x 12mm x 31mm	1
7-009-42	Trial, 10mm x 12mm x 31mm	1
7-009-43	Trial, 11mm x 12mm x 31mm	1
7-009-44	Trial, 12mm x 12mm x 31mm	1
7-009-45	Trial, 13mm x 12mm x 31mm	1
7-009-46	Trial, 15mm x 12mm x 31mm	1
7-009-47	Trial, 17mm x 12mm x 31mm	1
7-009-49	Remover for AURA Cage	1
7-009-48	Instrument Trays for AURA Cage (TLIF) Instrument Set	4
7-009-29	Container for AURA Cage (TLIF) Instrument Set	1



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