

AURORA
Spine System

Surgical Technique

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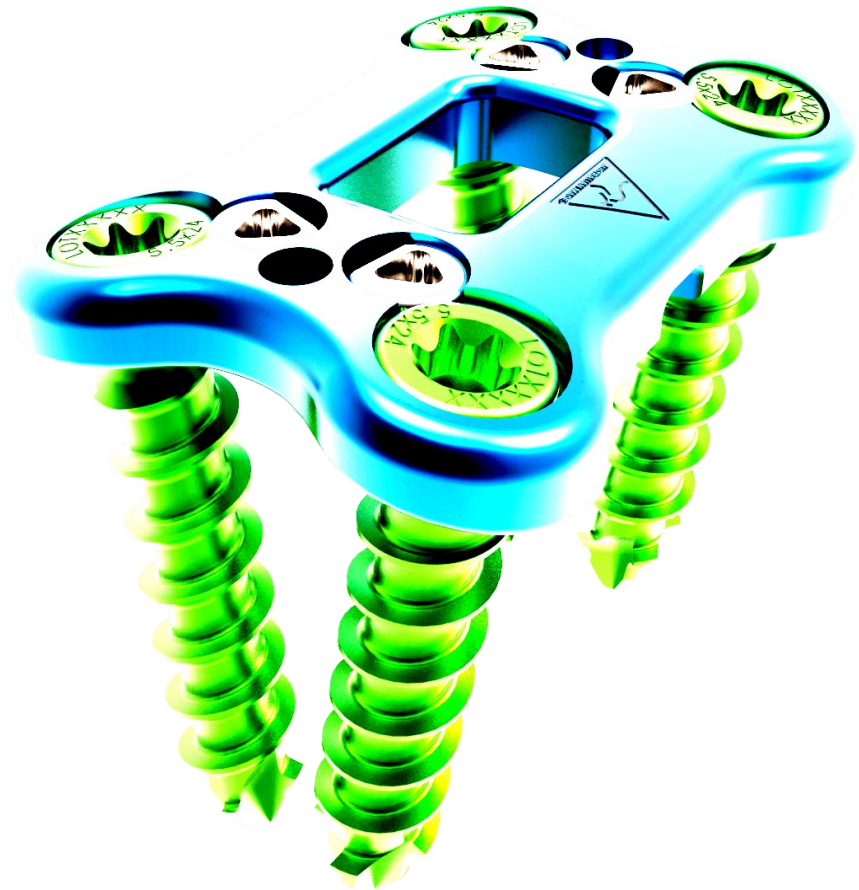
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System Features

The following are key features of the Aurora® ALIF Plate System;

- Low 4mm plate profile
- Indicated for L2-S1 anterior lumbar fixation
- Anterior, Lateral and Antero-lateral placement
- 30° cone of angulation for screw insertion
- Screws feature a progressive dual cortical to cancellous Smart-Thread® design.
- Midline window for visualisation of cage/graft
- Versatile articulating and fixed plate holder options
- 100% compatible with the Australis® ALIF Cage Spinal System for utilization of the patented SouthPole® Insertion & Alignment System.



Surgical Steps

General Considerations

The anterior lumbar and lumbosacral spine may be efficiently accessed through a retroperitoneal or transperitoneal approach. The supine position is preferred, especially for the lower lumbar segments for optimal restoration of lordosis and optimal visualization of anatomical structures. Co-ordination with a vascular surgeon as a spinal access surgeon is a recommended consideration.

Target Level Considerations and Preparation Determination of approach to the anterior lumbar spine is dependent on the level or levels to be fused. Evaluation of vasculature location & subsequent retraction, the superior iliac crest, lordotic angles, sacral inclination and anatomical variances/ pathology such as osteophytes or spondylolisthesis should all be considered when utilizing the Aurora ALIF Plate System. In general, taking into account patient variance, topographical landmarks for strategic incision include;

L3-4 - the level of the umbilicus

L4-5 - the level of the intercrestal line

L5-S1 - the level midway between the umbilicus and the symphysis pubis

For 2 level exposure the incision may be placed midway between the appropriate levels.

Patient Positioning Place the patient in a supine position on a radiolucent table. Position the patients upper limbs so that there is space for circumferential C-arm movement over and around the operative level. The arms should either be outstretched or folded across the chest.

Surgical Steps

STEP 1.1 Surgical Approach

The skin incision may be longitudinal or transverse based on surgeon preference. The fascial incision may also be longitudinal or transverse, however a longitudinal fascial incision allows greater flexibility in extending the exposure if necessary.

Retract the underlying subcutaneous tissue until the fascia is exposed. Divide longitudinally either in the midline or along the lateral rectus sheath using dissecting scissors.

Retract the left rectus muscle laterally with fingers or blunt retractors.

A left retroperitoneal approach is preferred.

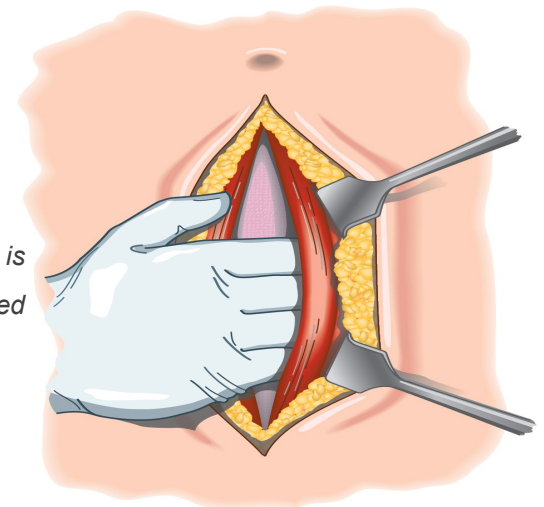
A 4-6cm incision is recommended.

Elevate the posterior rectus sheath and divide longitudinally with dissection scissors. Blunt retroperitoneal dissection is used to expose the psoas muscle and overlying great vessels.

Identify the psoas muscle, iliac artery and iliac vein.

Carefully apply an appropriate soft tissue retractor system.

A left retroperitoneal approach is preferred



Surgical Steps

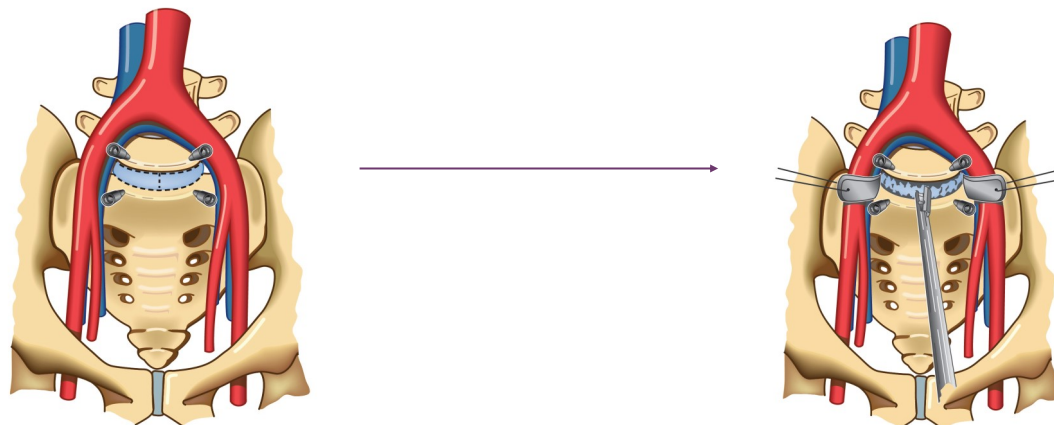
Approach of L5/S1

The further dissection of the tissue anterior to the inter-vertebral disc is performed using blunt dissection.

Do not use monopolar diathermy. Bipolar diathermy should be used sparingly. This will help lessen the risk of vessel and/or nerve injury. Dissection is carried to the left and right to achieve the maximum possible lateral exposure of the disc. Extreme care should be taken to protect the left and right common iliac vessels. To safely dissect the anterior surface of the lumbar bodies, knowledge of their spatial relationship to these blood vessels is important.

Bluntly mobilise the left common iliac vein and artery with peanut swabs and then the right common iliac artery together with the right common iliac vein that lies posterior. These vessels are retracted laterally and slightly superiorly to maximally expose the disc in the midline. Carefully apply an appropriate retraction system for the main vessels such as the AUS® retraction pins. Verification of the vertebral level can now be achieved with lateral fluoroscopy. Utilise a midline H-shaped annular incision to create two midline opening annular flaps. These flaps may be used to retract and protect the laterally displaced vessels via an attached stay suture.

L5-S1 approach and retraction of the anterior vessels utilizing AUS® retraction pins.



A complete discectomy will allow parallel distraction of the endplates allowing restoration of intervertebral height and sufficient opening of the neuroforamen.

Surgical Steps

Approach L4/5 and Above

For exposure of discs higher than L5/S1, it is necessary to mobilize the overlying aorta and inferior vena cava medially. Carefully apply an appropriate external soft tissue retractor system.

Mobilize the iliac vein, iliac artery, vena cava and aorta to the right. Verify the vertebral level by lateral fluoroscopy. Utilize a left-justified H shaped incision in the annulus as described above.

Note: It should be emphasized that venous anomalies are not infrequent, and therefore it is important to exercise caution when anatomic variants are encountered.

Note: When the L4-5 disc is being exposed special attention should be paid to the ilio-lumbar or ascending vein, a large venous branch overlying the L5 body and draining into the lateral left common iliac vein.

Surgical Steps

STEP 2.1 Anterior Decompression, Discectomy and Cage Insertion

Refer to the Australis® ALIF Cage Surgical Technique for further information.



For optimal Aurora Plate application, anterior osteophytes impeding on adequate plate placement on the anterior surface of the vertebral bodies should carefully be removed. Aggressive osteophyte removal may weaken the integrity of the cortical bone and subsequent fixation of the smart-thread Aurora screws. Intact bony preservation of the cortical rims is important for optimal screw purchase and plate placement.

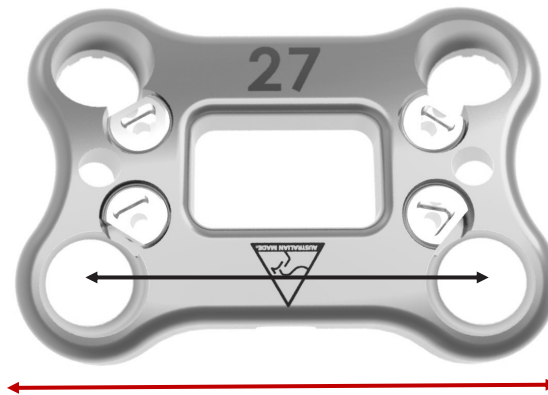
After the insertion of the Australis ALIF cage, ensure the cage is recessed within the disc space adequately.

Surgical Steps

STEP 3.1 Plate Selection

Aurora plates are available in lengths from 17mm to 27mm. This measurement is from the centre of the superior screw hole to the centre of the inferior screw hole. For the overall plate length add 10 mm.

Plate trials are recommended as the first step when utilising the SouthPole insertion and alignment instrumentation. Place the plate trial over the disc space with the central hole positioned directly over the insertion hole of the Australis ALIF cage. The plate screw holes should not extend too far past the cortical rims. An adequate size will reveal the screw hole 1/2-3/4 filled with cortical rim bone. Proper fitting will allow the smart-thread screw to purchase the hard cortical rim bone and reduce the profile of the plate over the disc space.



Surgical Steps

STEP 4.1 Plate Application

Selection of the rigid or articulating plate holder is dependent on anatomy and surgeon preference. The articulating plate holder is recommended at L5/S1 to accommodate the often steep sacral angle.

Anterior midline or antero-lateral positioning of the plate may be dictated by patient access and anatomy.

If utilizing the SouthPole alignment system, the plate will need to be positioned directly over the insertion hole of the Australis ALIF cage.

The plate may be secured in position with fixation pins, handheld in place using a plate holder or by utilizing the SouthPole system instrumentation — see Plate Application utilizing SouthPole pp14-16.



Surgical Steps

STEP 5.1 Screw Preparation

The Aurora Spinal System allows for fixed angle or variable angle screw placement.

The variable angle awl allows for screw hole preparation and insertion within an angulation cone of 30 degrees.

The fixed angle awl provides a guided trajectory of approximately 15 degrees in the sagittal plane and 10 degrees convergent in the axial plane. Both Awls have a maximum penetration depth of 20mm.

It is recommended to prepare and insert at least two screws diagonal in position to each other before releasing the plate holder or fixation pins.

A drilling option for screw preparation is available on request. **WARNING!** The 4.5mm Surgibit drill 192-11-0045 and Aurora Drill Guide 132-16-0135 MUST be utilized with a standard power drill AO connection ONLY. This is to ensure a maximum penetration drill depth of 20mm. DO NOT use other AO connections such as manual handles.

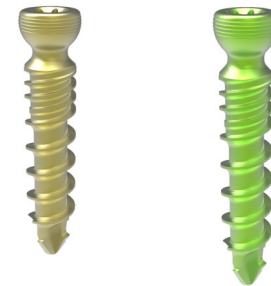


Surgical Steps

STEP 6.1 Screw Insertion

The Aurora Spine System offers 5.5mm primary screws and 6.0mm rescue screws in 24mm and 28mm lengths. The measurements of the screws correspond to the measure of bone engagement.

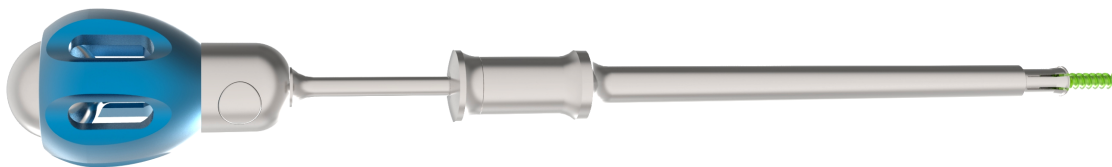
Note: 6.0mm rescue screws have a silver head and corresponding shaft colour.



24mm = GOLD 28mm = GREEN

Utilizing the Aurora driver sleeve and driver shaft, load the desired screw from the screw caddy by pressing the driver tip into the screw socket. Push the sleeve forward to lightly capture the screw head. The screw will be self-retained and can be removed from the caddy. Holding the screw firm with one hand, push the driver sleeve forward 1-2mm until a click is heard. The screw is now securely captured by the driver sleeve assembly.

Place the tip of the screw into the prepared screw hole and rotate the handle clockwise to implant the screw. The driver sleeve may be firmly held for further stabilization of the driver during insertion. Note: Once the screw is 1/2-3/4 inserted into the bone, the driver sleeve may be retracted for improved visualization.



Surgical Steps

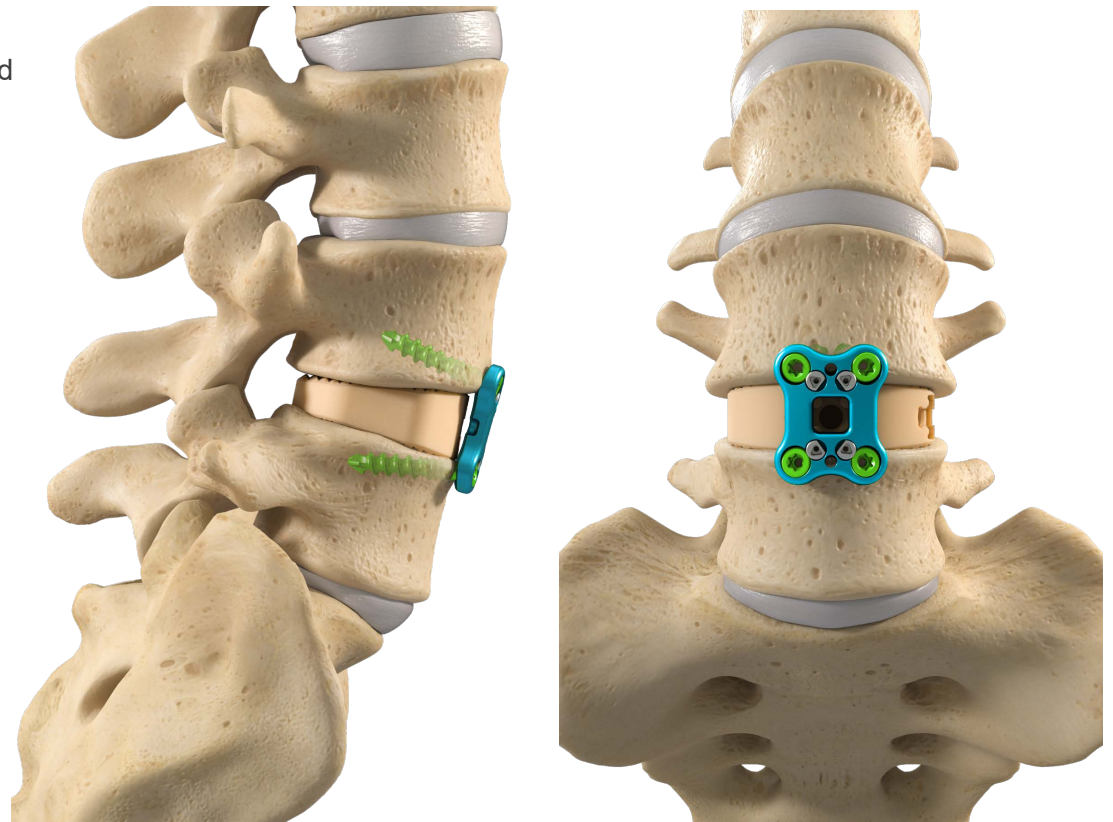
STEP 6.1 Screw Insertion

Once the screw is 1/2 to 3/4 inserted within the bone pull the driver sleeve backwards up the shaft to allow direct visualisation of the socket and driver interface and allow optimal seating within the plate.

It is recommended to not final tighten the screws until all four screws are inserted. This will allow a slight toggle of the plate during screw insertion allowing the plate to settle on both cortical rims adequately.

Final tightening of the screws and lagging of the plate will be achieved with the same driver.

Proper fitting will allow the plate to rest somewhat over the disc space decreasing the prominence of the plate. Proper fitting encourages stable plate/bone interface contact and promote optimal screw position and fixation.



Aurora® ALIF Plate implantation utilizing the SouthPole Technique

Complete STEPS 1.1—3.1 of the Aurora Spine System Surgical Technique.

Ensure the appropriate sized plate has been trialled before commencing the SouthPole steps.

STEP 1.2

Attach the SouthPole post to the SouthPole Inserter by inserting the 4.5mm nut end of the Southpole into the distal opening of the Inserter. Rotate the handle of the Inserter clockwise until firm. DO NOT OVERTIGHTEN. Insert the Inner 4.5mm driver into the SouthPole Inserter.

STEP 2.2

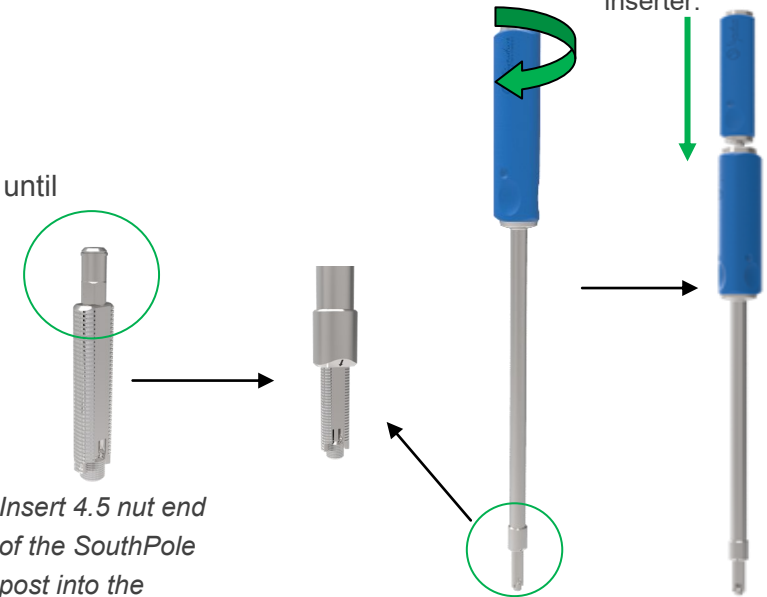
Firmly insert the SouthPole post into the Australis ALIF cage.

ENSURE THE POST IS IN THE MEDIAL-LATERAL HOLES OF THE INSERTION ATTACHMENT FEATURE OF THE CAGE.

Note: The arrows on the driver and the flats of the post MUST face cephalad-caudal.

STEP 1.2

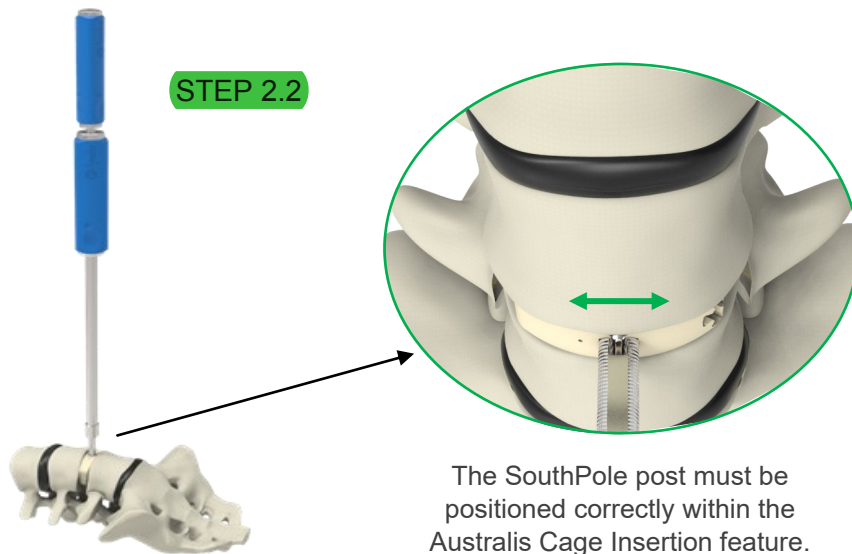
Insert 4.5mm Driver down the centre of the SouthPole inserter.



Insert 4.5 nut end of the SouthPole post into the SouthPole inserter.

Rotate handle clockwise to engage the post thread.

STEP 2.2

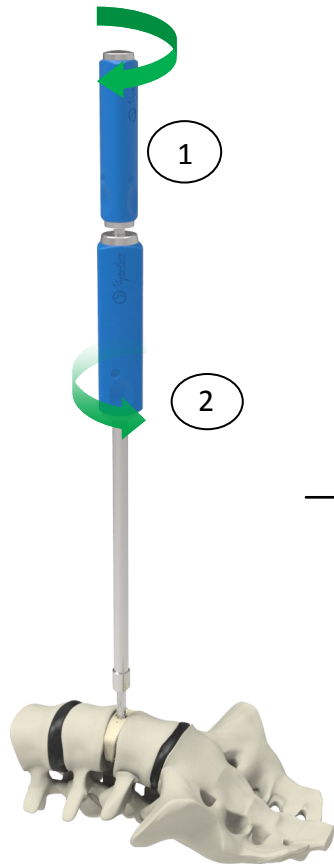


The SouthPole post must be positioned correctly within the Australis Cage Insertion feature.

Aurora® ALIF Plate implantation utilizing the SouthPole®Technique

STEP 3.2

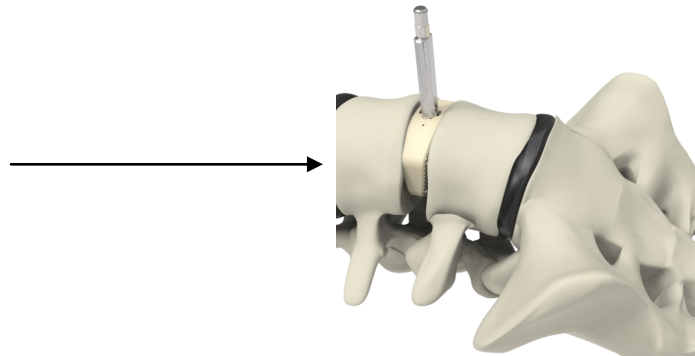
Rotate the inner 4.5mm driver clockwise to engage the 4.5mm nut until firm feedback indicating the thread has fully engaged the Australis insertion hole inner thread. This is approximately 8 half turns of the inner driver handle.



STEP 4.2

Reverse the handle of the SouthPole Inserter to disengage the SouthPole leaving the post attached to the Australis cage and drop or slide the selected Aurora plate over the SouthPole post.

NB: the Aurora plate does not have to be aligned with the cortical rims as the system will centralize the plate over the disc space and the implanted Australis cage.

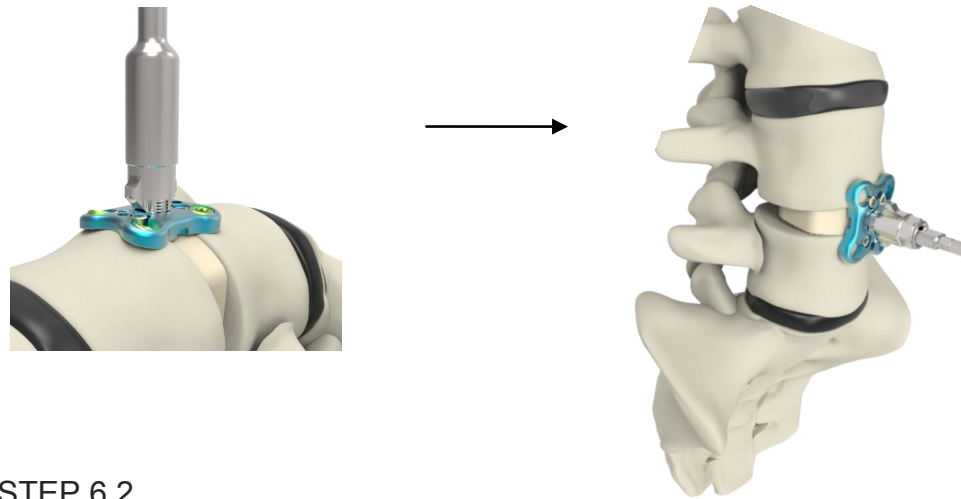


Remove both drivers from the SouthPole post leaving the post threaded into the Australis cage.

Aurora® ALIF Plate implantation utilizing the SouthPole®Technique

STEP 5.2

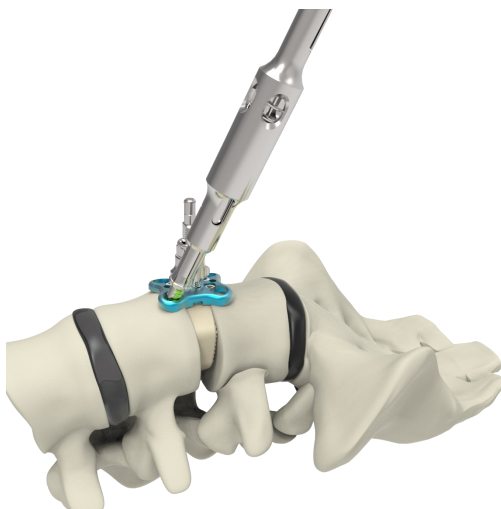
Load the arrowhead onto the Arrowhead driver. Insert the arrowhead over the post with the angled shoulders positioned cephalic-caudal and rotate the handle clockwise until firm. DO NOT OVERTIGHTEN. The plate is now secured to the Australis ALIF cage for screw preparation and screw insertion. Note: If the arrowhead is overtightened it may pull the cage anteriorly from the desired position. Visually monitor the Australis cage position closely when applying high force to the arrowhead driver to ensure anterior migration does not occur.



STEP 6.2

Continue with screw preparation, screw insertion and final tightening.

A check x-ray of screw and plate placement is recommended before removal of the SouthPole.

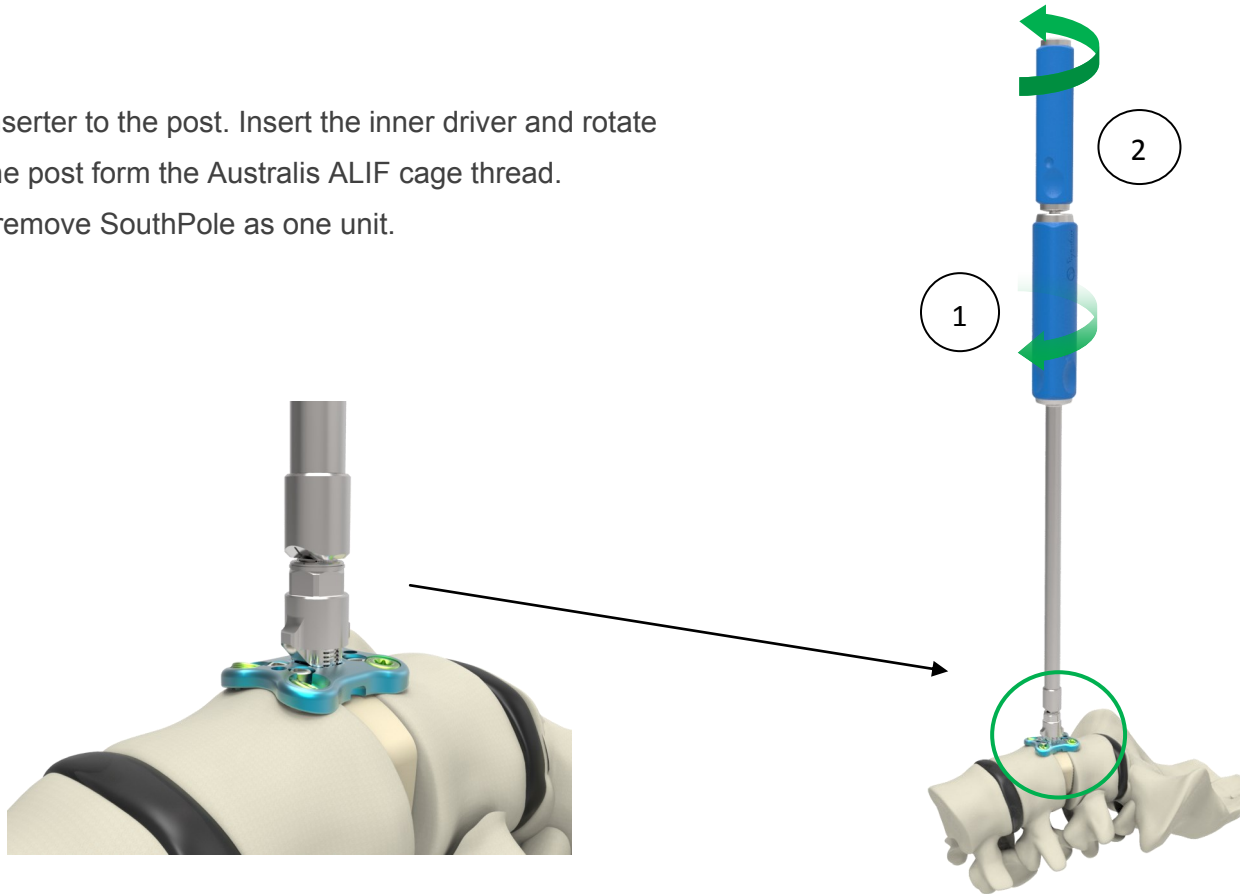


Aurora® ALIF Plate implantation utilizing the SouthPole®Technique

STEP 7.2

Reattach the SouthPole inserter to the post. Insert the inner driver and rotate anticlockwise to release the post from the Australis ALIF cage thread.

Pull up on both drivers to remove SouthPole as one unit.



Surgical Steps

STEP 7.1 Final Locking

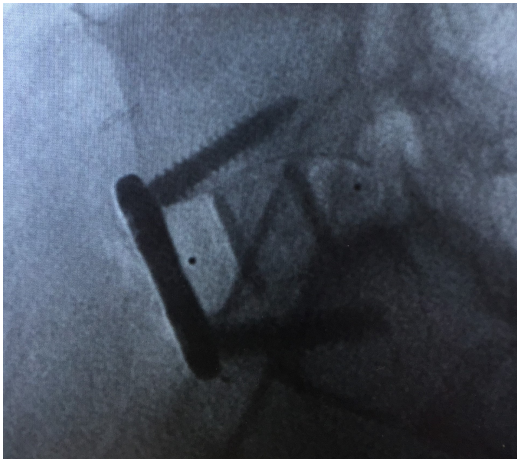
All screws should be secured within the plate before beginning the locking procedure.

It is strongly advised to obtain a check x-ray of screw placement before locking the plate.

Insert the tip of the tightener shaft into the locking drive and ensure the driver tip is fully seated. Rotate the torque driver clockwise until it releases with an audible click.

The torque driver will release when the resistance reaches 1.35-1.65Nm (nominal 1.5Nm).

Note: Exact position of the locking mechanism will vary depending on screw position and angulation.



Lateral fluoroscopy of final Aurora-Australis Spinal System plate and cage position at L5-S1.



Removal-Revision

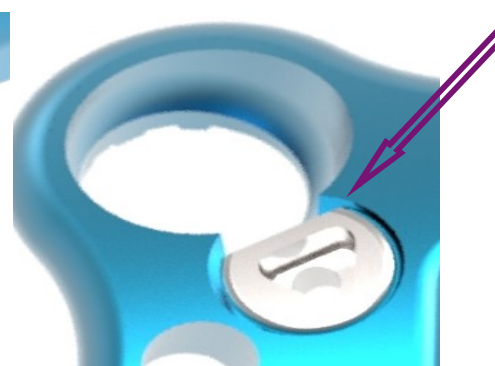
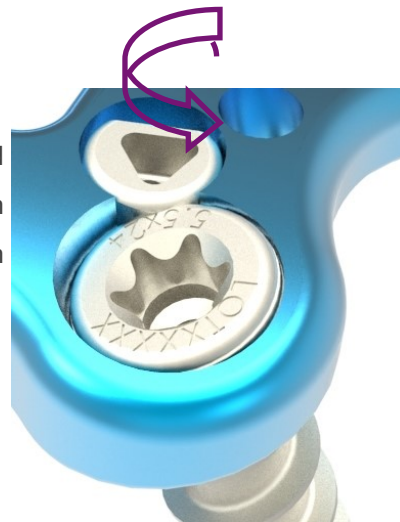
The plate and screws can be removed with the same instrumentation that was used to implant them.

Utilise the locking cam driver to reverse the locking cam back to the neutral position.

The screwdriver may then be used to rotate the screw in a counter-clockwise fashion until the screw is disengaged and removed from the plate screw hole. Repeat this process for all four screw holes. Remove the plate from the surgical site with forceps.

Note: If the screws are loose however continue to rotate freely in the screw-hole, it is recommended to utilise the rescue screwdriver. Assemble the inner stylet into the outer driver handle. Seat the driver into the screw head firmly, ensuring the driver is seated into the screw head. Rotate the inner stylet clockwise until firm. The rescue driver is now attached to the screw. Rotate the driver counter-clockwise whilst simultaneously pulling upwards. The screw will release from the screw hole. It is recommended all four screws are loosened prior to utilising the rescue screwdriver.

When the cam is in a locked position (as shown) rotate cam anti-clockwise to return the cam to the neutral position.



Cam in neutral position

Indications for Use

The Prism Surgical Aurora® Spinal System is an anterior spinal fusion device designed to promote arthrodesis and stabilization at one motion segment and is intended for use in the lumbar spine (L2-S1). The Aurora® Spinal System is designed to restore stability and increase spinal rigidity after total discectomy of the intervertebral disc and placement of an interbody fusion device (with graft material) to achieve a solid arthrodesis via an anterior or anterolateral surgical approach. The Aurora® Spinal System is indicated for use with both open and minimally invasive surgical techniques (MIS).

Indications

Arthrodesis required at any paired vertebral bodies in the lumbosacral spine
Degenerative disc disease confirmed by history and radiographic studies*
Spinal deformities or curvatures (ie, scoliosis, kyphosis and/or lordosis)
Spondylolisthesis
Previous failed fusion
Trauma (i.e. fracture or dislocation)
Tumour
Pseudoarthrosis

**DDD for non-cervical systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.*

Contraindications

Osteoporosis.
Active systemic infection or infection localized to the site of proposed implantation.
Any entity or condition that totally precludes the possibility of fusion.
Extensive calcification of the great vessels
Retroperitoneal fibrosis
High grade spondylolisthesis
Tumour or Trauma necessitating multiple vertebral segment stabilisation
Condition that may place excessive stresses on bone and implants, such as obesity and pregnancy. The decision to use these devices in such conditions must be made by the physician.

Ordering Information

Product Code Description

Implants

131-05-0117	17mm Aurora Plate	131-05-1724	5.5mm x 24mm Aurora Screw
131-05-0119	19mm Aurora Plate	131-05-1728	5.5mm x 28mm Aurora Screw
131-05-0121	21mm Aurora Plate	131-05-1624	6.0mm x 24mm Aurora Screw
131-05-0123	23mm Aurora Plate	131-05-1628	6.0mm x 28mm Aurora Screw
131-05-0125	25mm Aurora Plate		
131-05-0127	27mm Aurora Plate		

Instruments

132-16-0110	Aurora Trial Plate 17mm	132-16-0014	Cam Lock Shaft
132-16-0111	Aurora Trial Plate 19mm	132-16-0008	Hexalobe Driver Shaft
132-16-0112	Aurora Trial Plate 21mm	132-16-0010	Variable Awl
132-16-0113	Aurora Trial Plate 23mm	132-16-0057	Fixed Awl
132-16-0114	Aurora Trial Plate 25mm	132-16-0001	Rescue Screwdriver (Part 1 of 2)
132-16-0115	Aurora Trial Plate 27mm	132-16-0002	Rescue Screwdriver Lock (Part 2 of 2)
132-16-0089	Fixation Pins	132-16-0095	Southpole Inserter
132-112-007	Modular Bulb Handle	132-16-0071	Southpole Driver 4.5
132-16-0016	Plate Holder	132-16-0076	South Drive 10
132-16-0077	5-1 Plate Holder	132-16-0066	Arrow Head
132-16-0009	Screw Holding Sleeve	132-16-0060	Southpole Post
G132010	Mini Handle Torque 1.5Nm		

For further information refer to the Instructions for Use (IFU)

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