

AQUILA[®] and BOREALIS[®] SPINE SYSTEM

Surgical Technique & Guide



One Modular Platform™

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One Modular System™, unprecedented versatility

With the patented Northpole Alignment and Guidance System, Prism Surgical introduces unprecedented implant technology – a versatile modular cervical spine fusion platform that expands surgical flexibility and leverages intraoperative experiences.

In conjunction with the Northpole Alignment and Guidance Instrumentation, the Aquila-Borealis System is the epitome of an innovative solution platform with technological advancements that leverages your surgical experiences and greatly increases clinical efficiency.

Based on the patented Northpole Alignment and Guidance Instrumentation, Aquila-Borealis facilitates surgeon choice and flexibility across patient types with a variety of implant options for treating multiple spinal pathologies with ONE system.

Features and Benefits

- * Intraoperative flexibility of integral screws or applying plate fixation through the use of one integrated modular platform— Northpole alignment and guidance instrumentation
- * Patented screw guidance and insertion system to ensure correct screw placement and angulation every time
- * Patented ‘hands free’ plate holding and alignment system to ensure stable temporary plate placement and accurate plate fixation every time
- * Integrated option may be used to facilitate fusion surgery adjacent to a previous fusion. Reduces the need to remove existing hardware from the previous surgery
- * Large internal graft space with lateral walls only 2mm thick
- * 7° lordosis | 2 footprints | 5 heights
- * 1-4 level | 12mm—88mm plates
- * One step integrated locking mechanism
- * Low plate profile of 1.8mm
- * Large central plate window for visualisation of cage placement
- * Constrained or semi-constrained screw options

Introduction

The Aquila-Borealis Spinal System is designed to stabilise and fuse the anterior cervical spine from C2-T2 with elegant and simple implants complemented by next generation instrumentation to simplify and maximize operative efficiency.

Pathology of the cervical spine, such as degenerative disc disease and stenosis are commonly treated by anterior discectomy and subsequent interbody fusion. A common surgical treatment method is the implantation of an interbody cage to restore patient specific height, lordosis and provide stabilisation of the segment/s until bony fusion occurs.

Intraoperative flexibility and functionality is seamlessly integrated into the systems with the introduction of the patented Northpole Alignment and Guidance Instrumentation system, allowing reproducible placement of either integral screws into the cage or plate fixation — every time!

Control is Key whether you prefer integral fixation or the rigidity of an anterior plate, the Aquila-Borealis System ensures all options are available in

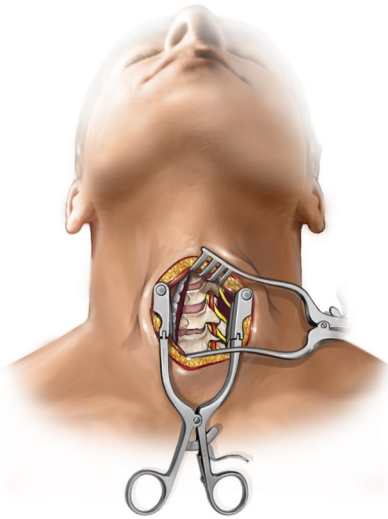
One Modular System™

Patient Positioning, Exposure and Discectomy

Using the standard anterior cervical surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate and preferred technique for the given indication.

PATIENT POSITIONING

Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittal neutral position and supported by a cushion or similar. When treating C6 – C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases, both vertebrae should be ideally visible.



ACCESS & DISCECTOMY

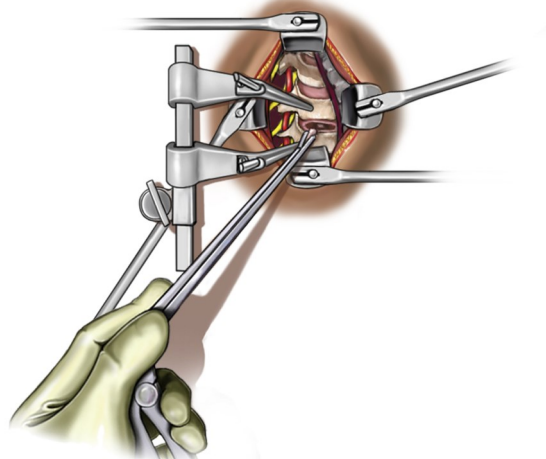
Locate the correct operative level under radiographic control and incise.

Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

Warning: Careful positioning of the Borealis IF Cervical Retractor is required to avoid soft tissue damage.

Prepare the fusion site by performing a thorough discectomy and decompression following the appropriate technique for the given indication. If required, perform segmental distraction using the Borealis IF distraction pins and cervical distractor.

Note: Distraction of the segment will aid in restoration of segmental disc height and provide good access to the intervertebral space.





Borealis® Cage Insertion

TRIALLING

Selection of the trial depends on the desired footprint and height of the intervertebral space, the preparation technique and the patient’s anatomy.

Choose a trial that reflects the best posterior height, depth and width of the patients anatomy.

Position the trial in the correct cranial/caudal alignment with the arrows facing cephalad and carefully insert the trial into the disc space.

Note: *The trials and implants are directional. They must be inserted in one orientation when the cage and integral screw option is utilised. Ensure the arrows on the lateral sides of the implant are orientated cephalad when implanted.*

Trial inserters are available with or without depth stops. If the trial is inserted using an inserter without a depth stop, a check x-ray is advised to ensure correct positioning.

Note: *The trial includes the pyramidal teeth of the implant and is exactly the same height as the actual implant.*

**The teeth add approximately 0.8mm to the total marked height of the implant.*

Warning: Choose the appropriate implant footprint and size to accommodate variations in patient anatomy; failure to do so may injure the patient.

Implant Height* (mm)	Width (mm)	Depth (mm)
5	16	14
6	16	14
7	16	14
8	16	14
5	19	17
6	19	17
7	19	17
8	19	17

***NOTE:** a 4mm non-integrated cage option is available.

Borealis® IF Insertion with Integral Fixation

There are two techniques available for inserting the cage with integral screw fixation. The first technique, and most preferred technique, is utilizing the Northpole Guidance and Alignment System. The second is freehand insertion of the cage and screws utilizing the standard inserter, awls and screwdrivers with sleeves.

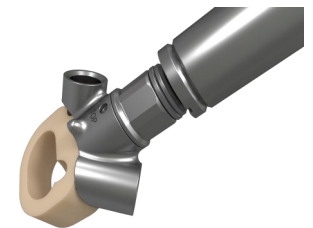
UTILIZING THE NORTHPOLE® GUIDANCE AND ALIGNMENT SYSTEM

Step 1. Insert the post into the selected size cage. Connect the post by tightening the nut at the top of the post. This can be done by hand or by using the 3.5mm driver. Excessive tightening is not required.



Step 1

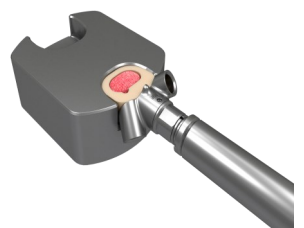
Step 2. Connect the corresponding sized guide block to the post using the 7.5mm driver. Attach the guide block body over the post and rotate the driver until firmly seated against the cage. Ensure the word TOP as marked on the guide block is correctly aligned with the directional arrows on the side of the cage.



Step 2-3

Note: Do not overtighten the guide block to the post/cage assembly. Overtightening will misalign the guide block screw holes to the cage screw holes.

Step 3. With the alignment assembly (post and guide block) connected to the cage, utilise the post inserter to re-engage the post until it bottoms out on the upper portion of the alignment assembly.



Step 4

Step 4. Place the assembled cage into the appropriate size of the graft packing block. Utilise the bone graft impactor to firmly pack preferred graft material into the cage cavity.

Note: To ensure optimal contact with the vertebral end plates it is important to fill the implant until the graft material protrudes from the cage cavity.

Step 5. Ensuring the directional arrows marked on the cage and the word TOP on the guide block are in a cephalad direction, insert the cage assembly into the prepared disc space until the anterior stops on the guide block are positioned firmly against the vertebral rims of the adjacent vertebral bodies. This will ensure the cage is recessed within the prepared disc space and positioned optimally for integral screw insertion.

Note: *Light impaction with a mallet may be utilised for insertion. Do not use excessive force to insert the cage. If a high amount of resistance is felt on insertion, remove the cage and revisit the discectomy or review the amount of applied distraction.*

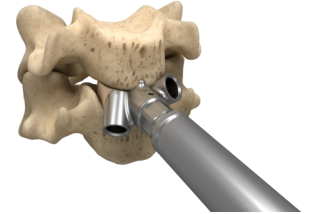
Note: *Check fluoroscopy is recommended at this stage to ensure optimal positioning. There are 3 radiopaque tantalum markers for fluoroscopic visualisation—1 in each anterior corner and 1 on the posterior wall in a midline position. NOTE: On a lateral view, the anterior markers are 3mm posterior of the most anterior aspect of the cage.*

Step 6. Disconnect the post driver, leaving the alignment assembly in situ.

Note: *The post driver can be left attached for manual control of the assembly in situ if required.*

Step 7. Insert the tip of the assembled self centring fixed awl into the first guide block screw hole and depress the fixed awl handle until it reaches the required depth.

Remove the awl. An angled awl may also be utilised to attain an optimal angle of 40° cephalad-caudal and 22° medial.

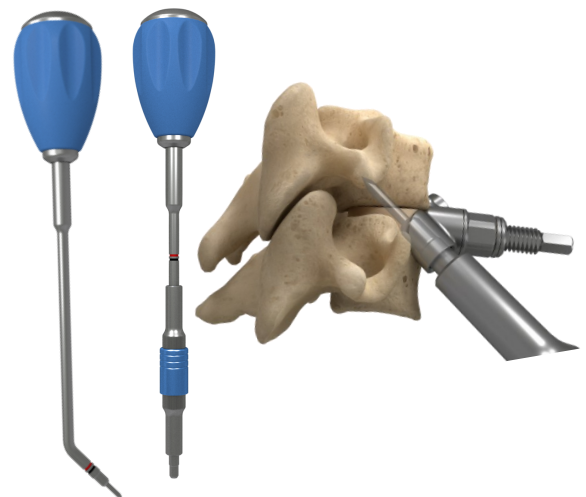


Step 5



Step 6

Awl Red indicator line = 10mm bone penetration
Awl Black indicator line = 8mm bone penetration.

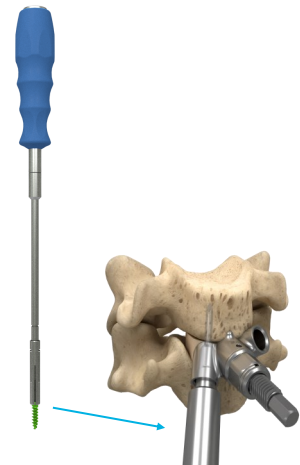


Step 7

Step 8. Load the selected sized screw onto the T10 screw inserter with assembled sleeve. Insert the screw into the guide block hole corresponding to the prepared bone hole. Do not release the driver sleeve. Insert the screw by turning the handle until the red indicator line is reached at the sleeve-shaft interface.

Once the red indicator line on the driver-sleeve interface is reached the screw is fully seated into the cage.

Note: Check fluoroscopy is recommended at this stage to ensure optimal positioning of the screw.



Step 8-10

Table 1 Borealis Screw Sizing	Colour Code	4.0mm Primary Self Drilling	4.4mm Rescue Self Tapping
12mm*	Gold	•	•
14mm*	Green	•	•
16mm*	Blue	•	•
18mm*	Magenta	•	•

*length in mm denotes bone engagement

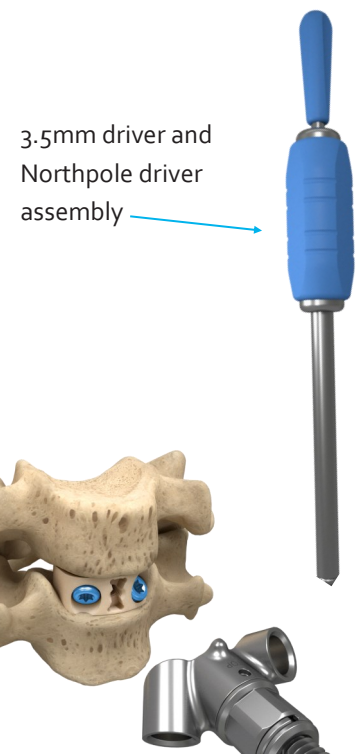
Step 9. Repeat Steps 7 – 8 for insertion of the second screw.

Step 10. With the T10 screw driver sleeve retracted or removed rotate the screw 1-2 final turns. This will ensure the locking mechanism is tightly compressed and 'locked'.

Step 11. To remove the alignment assembly, insert the 3.5mm driver down the cannulation of the post driver. Attach the dual driver assembly to the post by rotating the large handle of the post driver until it bottoms out on the guide block. Rotate the 3.5 inner driver anticlockwise to release the post from the cage. Pull upwards.

The alignment assembly will disconnect as one piece.

Note: Check fluoroscopy is recommended to ensure optimal Borealis IF cage and screw positioning.



Step 11

Borealis® IF Removal

If required, the cage can be removed by the following technique;

Remove the screws using the standard T10 screwdrivers.

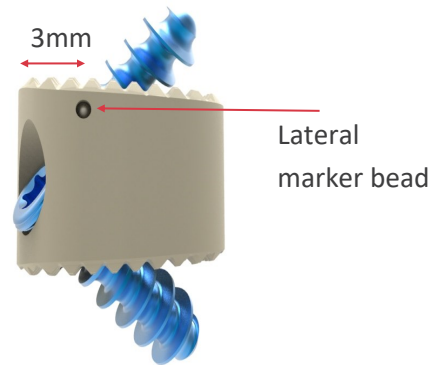
If after attempting to remove the screw, the screw continues to 'spin', utilisation of the rescue screwdriver is recommended.

Assemble the rescue screwdriver by inserting the inner stylet into the outer cannulated driver. Engage the hex portion of the outer shaft into the implanted screw for removal. Turn the inner stylet until engaged and firm. Rotate the assembled rescue screwdriver anti-clockwise whilst pulling up simultaneously. The screw will disengage from the cage.

Remove the cage by re-engaging the standard cage inserter and wiggle the cage outwards.

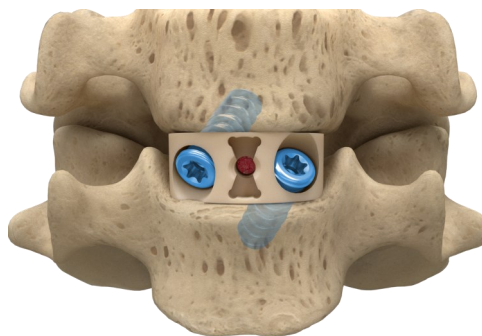
Note: If the cage is not easily removed, distraction may need to be re-applied to the disc space.

On a sagittal fluoroscopy image the lateral marker bead sits 3mm posterior of the anterior border of the cage.



*Refer to page 18 for fluoroscopy illustration of insitu marker beads.

Borealis IF Final Construct



WARNING: DO NOT REUSE IMPLANTS ONCE REMOVED AS LOCKING MECHANISM DAMAGE MAY NOT BE VISIBLE ON INSPECTION

Borealis® Cage with Aquila® Plate Fixation

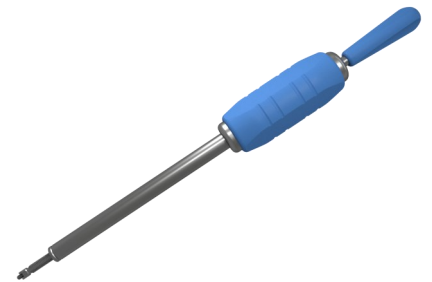
Expose and prepare the disc space and select trials as outlined on pages 4-5. Assemble the post assembly to the cage by following steps 1-5 outlined below;

Step 1 Assemble the post driver handle to the post. Thread the driver to the post, stopping approximately half way down the thread, leaving enough room for visualisation of the post tip.



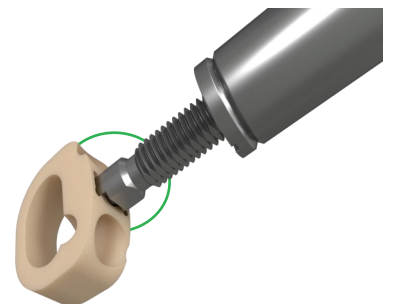
Step 1

Step 2 Insert the inner 3.5mm driver down the cannulation of the post driver.



Step 2

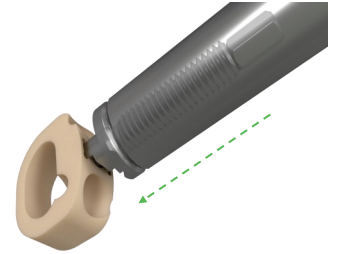
Step 3 Insert the distal tip of the post into the desired size cage insertion hole. Attach the post to the cage insertion hole by turning the inner 3.5mm driver clockwise until firm. Do not overtighten.



Step 3

Borealis® Cage with the Aquila® Plate Fixation cont..

Step 4 Turn the post driver clockwise until it bottoms out on the post and cage assembly. Remove the inner 3.5mm driver, leaving the post and driver attached to the Borealis cage ready for insertion.

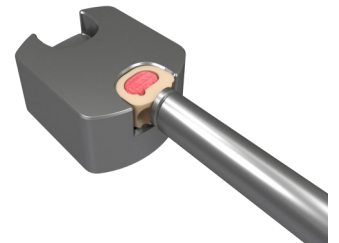


Step 4

Step 5 Utilise the graft packing block and the Borealis graft tamp to pack the cage with the desired grafting material.

Note: To ensure optimal contact with the vertebral end plates it is important to fill the implant until the graft material protrudes from the cage cavity.

Note: The directional arrows marked on the cage are not applicable if integral screws are not being inserted.



Step 5

Step 6 Insert the cage into the prepared disc space. Remove the post driver by rotating the handle counter-clockwise. The cage will be left in the desired position with the post attached.

A check x-ray is recommended to ensure optimal position of the Borealis cage.

Note: If the cage requires repositioning, reattach the post driver and reposition. As integral screws are not being utilised with plate fixation the cage may be recessed as far posteriorly as desired.



Step 6

Aquila® Plate Size Selection

Aquila plates are available in lengths from one to four levels ranging from 12mm to 88mm. Measurements are taken from the screw hole centre of the cephalad level to the screw hole centre of the caudal level.

Note: For total plate length, end to end, add 8.5mm.

Using the Kerrison plate holder, position the appropriate plate over the cage-post assembly onto the adjacent vertebral bodies to confirm suitability. The plate is appropriately sized and positioned when;

- The superior screw holes align with the inferior $\frac{1}{3}$ of the superior vertebral body
- The inferior screw holes align with the superior $\frac{1}{3}$ of the inferior vertebral body

Alternatively, callipers may be used to measure the required hole to hole distance. This measurement will correspond to the size marked on the plate.

Plate trialing over Northpole post



Aquila® Plate Contouring and Positioning

The Aquila plate has an inbuilt 155° radius of curvature. Additional contouring may be accomplished by inserting the plate into the plate bender and squeezing the handle.

Note: Ensure the removable curvature plate of the plate bender is in the correct orientation for more or less bend.

Warning: Plates should only be bent in one direction. Never reverse the bend as this may create micro fractures that will weaken the plate.

Using the Kerrison or forcep plate holders, grasp the plate across the inferior or superior cam lock and squeeze the handles. Position the plate over the post onto the vertebral column in the optimal cephalad-caudal position.

Note: Once tightened, the alignment assembly will align the plate in a medial-lateral direction.

Load the alignment block onto the 7.5mm driver. Thread the alignment block onto the post-cage assembly and rotate clockwise until the assembly bottoms out on the plate.

The plate is now self-retained to the post-cage assembly and should be in an optimal position. If re-positioning is required, turn the 7.5mm driver counter-clockwise a few turns to loosen the plate position and reposition the plate as desired.

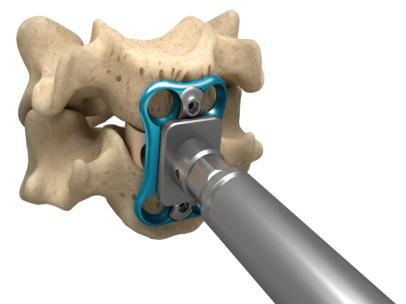
Fluoroscopy may be used to confirm alignment of the plate in both planes.

Pull up on the 7.5mm driver to release, leaving the plate, cage, and alignment assembly in situ.

Position the plate over Northpole post



Attach the Northpole alignment block





Aquila® Screw Selection

Two options for screw kinematics are available; constrained and semi-constrained. Constrained screws maintain a rigid sagittal and coronal plane when inserted in the nominal trajectory. Semi-constrained screws offer a 10° cone of angulation and allow for minor settling of the cage. 4.0mm screws are self tapping and colour coded. Rescue or 4.5mm screws are blunt tipped, colour coded and have a silver head for differentiation from primary screws. Screw length corresponds to bone engagement.

Note: Semi-constrained screws have a visible black indicator line located on the screw head.

		Colour Code	4.0mm Primary Self Tapping	4.5mm Rescue Blunt Tip
	12mm	Gold	•	•
	14mm	Green	•	•
	16mm	Blue	•	•
	18mm	Magenta	•	•
	20mm	Aqua	•	•

Note: length in mm denotes bone engagement.

14mm green coded
constrained screw loaded
onto the Aquila T15 driver



Aquila® Screw Insertion

The Aquila Spinal System offers multiple screw hole preparation options.

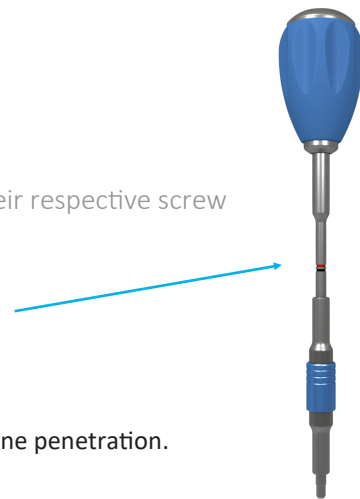
Pending surgeon preference and patient bone condition, the following screw hole preparation options may be utilised;

- Variable drill guide and fixed depth drill bit.
- Fixed drill guide and fixed depth drill bit.

Note: Drill bits are colour coded around the collar and correspond to their respective screw length colours.

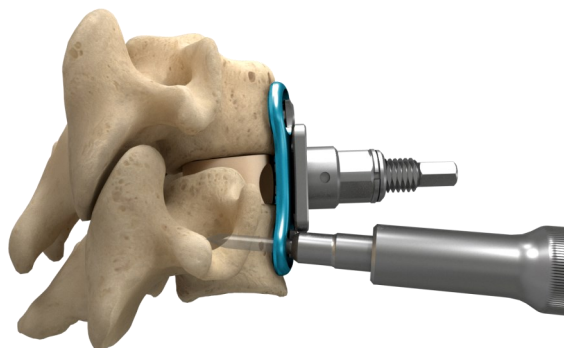
- Simple 8mm Awl
- Self Centring Awl; the awl depth is colour coded.

Red indicator line = 10mm bone penetration **Black indicator line** = 8mm bone penetration.



The neutral angle of the constrained screw is 0° in the sagittal plane and 6° in the coronal plane. The semi-constrained screw can pivot in all directions from the neutral angle within a 10° cone of angulation.

Insert the drill guide tip or the awl tip into the screw-hole of the plate. If using the self centring awl, press the awl handle in the desired direction into the screw hole. The self centring awl will bottom out at 10mm bone depth. To penetrate dense bone, lightly strike the handle of the awl with a mallet.



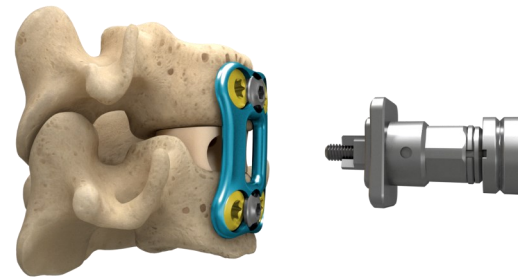
The self centering awl (with sleeve) will bottom out at 10mm bone penetration

Removal of the Northpole® Alignment Assembly

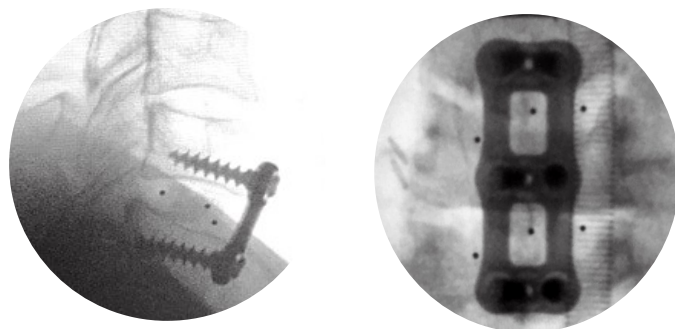
All screws should be secured to the vertebral bodies before removal of the alignment assembly.

To remove the alignment assembly, insert the inner 3.5mm driver into post driver. Attach the dual driver assembly to the post by rotating the large handle of the post driver until it bottoms out on the top of the plate alignment block. Once re-attached, rotate the 3.5mm inner driver anticlockwise. Pull upwards to release the assembly in one piece.

Final fluoroscopy is recommended to ensure optimal construct positioning.



The Northpole alignment assembly is removed as one piece.

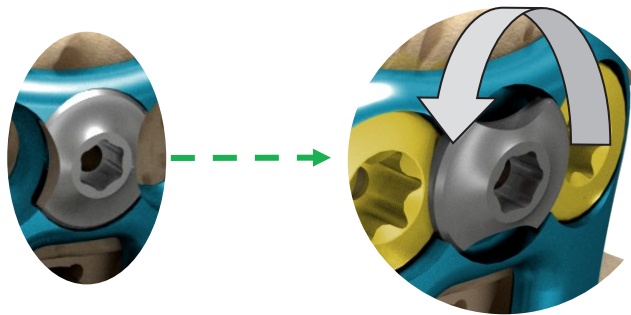


Final positioning of fluoroscopic positioning markers contained within the Borealis and Aquila implants.

NB: Borealis markers align centrally on either side of the Aquila plate in an AP plane when the Northpole® alignment assembly has been utilised.

Locking the Aquila® Plate

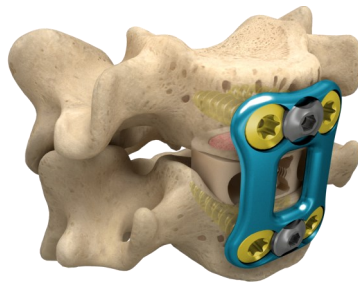
Using the T10 screwdriver rotate the central locking cam 90°. Locking is obtained when the cam cut out of the locking mechanism is in an inferior-superior direction.



Rotate the locking cam in a clockwise direction 90° from the neutral zone to cover the screw heads and prevent screw back-out.

Note: Final fluoroscopy images are recommended.

Final Aquila-Borealis Construct



Aquila® Plate Removal

To remove the plate reverse the locking cam to the neutral position with the T10 screwdriver.

Using the T15 screwdriver, reverse the screws out of the plate. If the screw does not back out and spins, the rescue screwdriver may be utilised by inserting the inner stylet of the assembled driver into the M2 thread of the screw until firm. Rotate the screwdriver assembly anticlockwise, whilst simultaneously pulling upwards.

Note: If the screws continue to spin, 2 or more screws may need to be loosened for the screws to adequately back out of the plate.



The Aquila and Borealis Spinal System is intended for use following anterior cervical discectomy for stabilisation and fusion of the cervical spine (C2-T1).

Indications

- Degenerative disc disease (DDD)
- Spondylolisthesis
- Spinal stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e., kyphosis, lordosis, and/or scoliosis)
- Fractures/dislocations
- Partial or complete spondylectomy

Contraindications

Infection

Severe Osteoporosis and indications not listed above

Any indication where fusion is not required.



Considerations for Borealis® IF Use Adjacent to a Prior Fusion

When implanting Borealis with integral fixation (IF) adjacent to a prior fusion, take care to avoid placing the cage and screws in direct contact with previously implanted hardware. As necessary, remove adjacent-level hardware that prevents the cage and screws from being implanted using the correct technique.

Precautions: Placement of Borealis IF adjacent to a previous, multi-level fusion could result in increased loading. Supplemental fixation should be considered in cases where the cage with integral screws is placed adjacent to a previous, multi-level fusion.

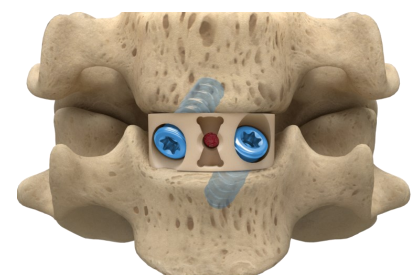
Do not place Borealis IF adjacent to previously implanted hardware if the adjacent level cannot be confirmed to be fused or where fusion has not occurred.

Warnings: Use radiographic imaging to verify final implant position relative to the vertebral bodies in the AP and lateral direction and remaining implanted hardware associated with the previously fused level.

If adjacent hardware prevents both screws from being implanted, a different device should be used, as increased loading may be placed on a single screw leading to potential post-operative device failure and potentially increased harm to the patient. If two screws cannot be inserted correctly, an Aquila plate should be utilised for alternative or secondary fixation.

If any integral screws cannot be inserted into the cage at the correct trajectory or seated into the cage according to recommended techniques as described in this technique, alternative fixation, such as the Aquila plate, should be used to avoid the potential risk of integrated screw back-out or screw failure.

Confirm that the Borealis IF construct is not placed in direct contact with implanted hardware associated with the previously fused level. If the Borealis IF implant remains in direct contact with hardware associated with the previously fused level, increased loading may be placed on the implant leading to potential post-operative device failure and potential harm to the patient.



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Please refer to the Instructions for Use or other labelling associated with the devices identified in this surgical technique for additional information.

WARNING: Not for Sale in the USA. FOR USE BY PHYSICIANS ONLY.

Not all products may currently be available in all markets.



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Note: For recognised legal manufacturer, refer to the product label.

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