AURORA™

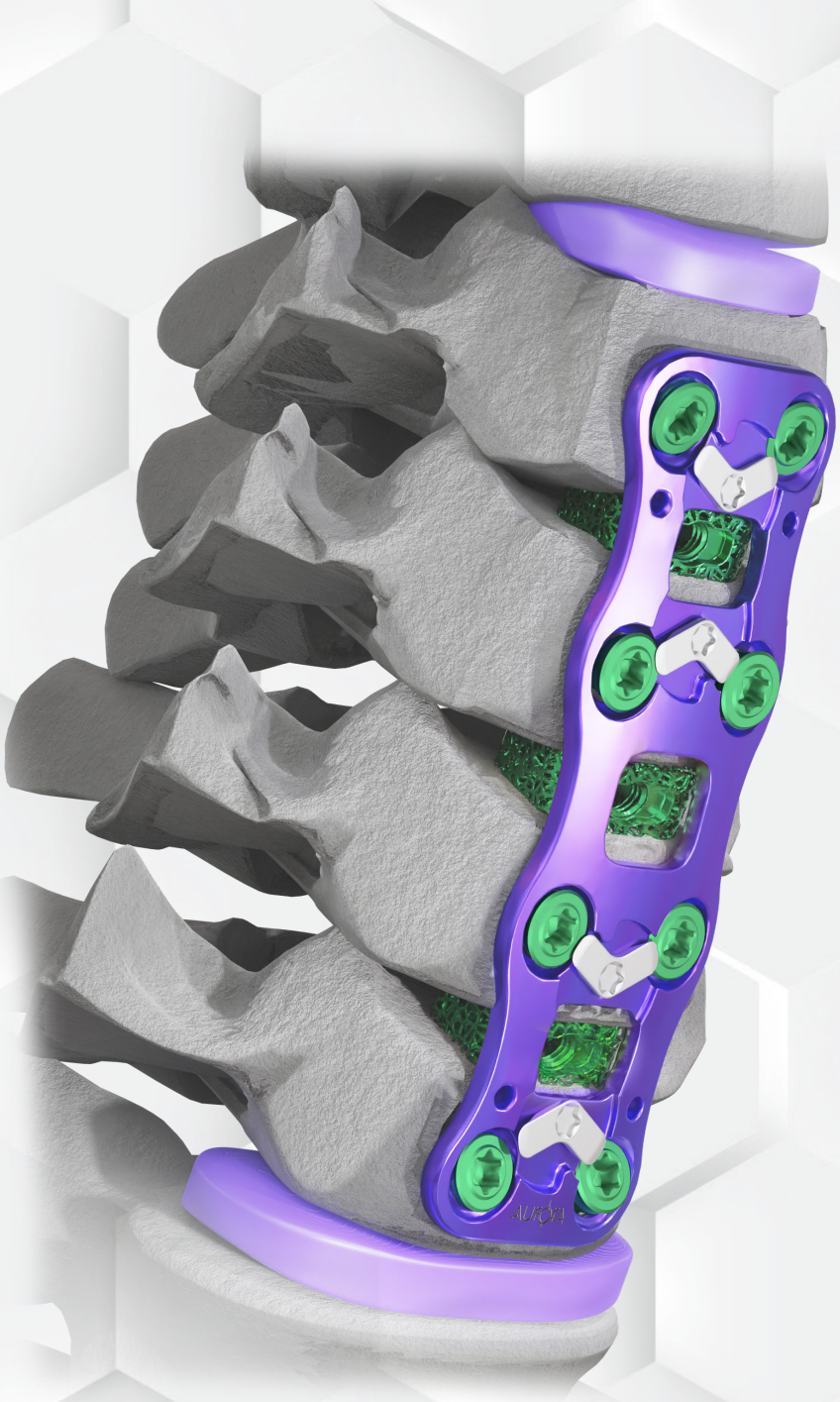
SIMPLIFYING THE COMPLEX

Anterior Cervical Plating System

apollo™

Surgical Technique Guide

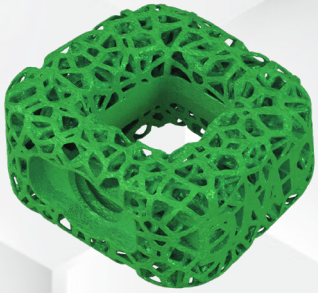
Revision: F280102-1_C



For this surgical technique guide, we used the DEXA-C™ technology. A cervical cage that adapts to the patient's bone density.

DEXA-C CERVICAL INTERBODY CAGE

"Bone Density Matched Implants"



Learn more about this product by visiting our website

aurora-spine.com

apollo™

Anterior Cervical Plating System

Table of Contents

Description

The apollo™ System is comprised of cervical plates and bone screws constructed of titanium alloy as described by ASTM F136. Plates are available in multiple levels and lengths, and screws are available in multiple diameters, lengths, and angulation configurations to accommodate variations in patient anatomy. The integrated screw locking mechanism is used to block the screw heads after the device construct has been attached to the anterior cervical spine.

Indications

The apollo™ System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (including fractures or dislocations)
- Tumors
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spinal stenosis

Contraindications

The contraindications of this system are comparable to other systems of similar design. Contraindications include, but are not limited to, the following conditions:

- Suspected or documented material allergy or intolerance.
- Patients with infection, inflammation, fever, leukocytosis, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcomes.
- Grossly distorted anatomy caused by congenital abnormalities.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any patient unwilling to follow postoperative instructions.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, fracture local to the operating site, the elevation of sedimentation rate unexplained by other diseases, the elevation of white blood count (WBC), or a marked shift in the WBC differential count.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.

Warnings, Precautions, and Potential Risks

Prescription Use - Caution: USA Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The surgeon should be aware of the following:

1. The correct selection of the implant is crucial. The potential for success is increased by selecting the implant's proper size, shape, and design. The size and shape of the human spine present limiting restrictions on the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight-bearing.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. They should be carefully unpacked and inspected for damage prior to use. The device must be handled and stored carefully, protected from damage and corrosive environments.

3. All instruments must be cleaned and sterilized prior to surgery.

4. As with all orthopedic implants, the Aurora Spine apollo™ System devices should never be re-used under any circumstances.

5. Possible risks associated with the re-use of any single-use Aurora Spine apollo™ System devices are infection, cross-infection, inability to clean and decontaminate the device, residues from chemical decontamination agents, material alteration, mechanical failure, reactions to endotoxins, the transmission of abnormal prion proteins, inflammation, migration/retropulsion or non-fusion.

6. The Aurora Spine apollo™ System devices should never be used with dissimilar materials.

7. Proper implant selection and patient compliance with postoperative precautions will significantly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

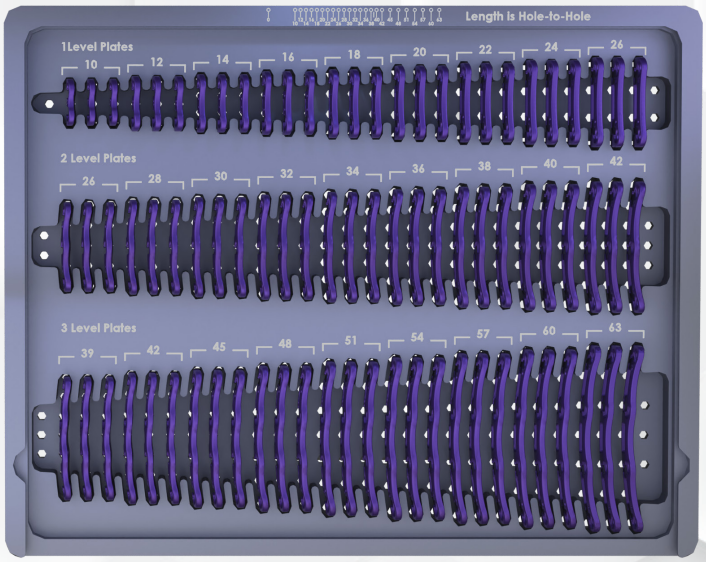
8. Postoperative care is essential. The patient should be instructed on the limitations of their implant and should be cautioned regarding weight-bearing and body stress on the appliance prior to secure bone healing.

9. This device is not intended for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Implant Tray Layout

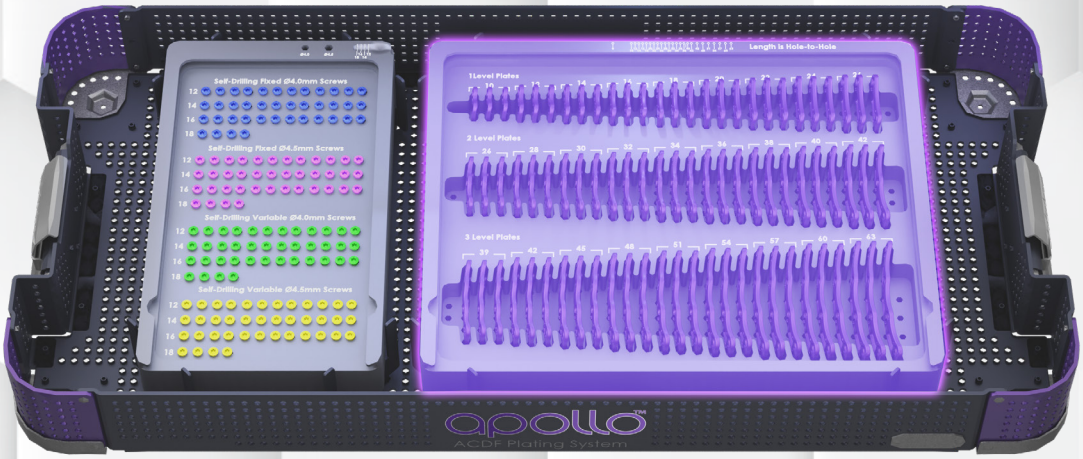
Plates

1-Level Plate	
REFERENCE	**HOLE TO HOLE LENGTH**
115-001-10	10mm
115-001-12	12mm
115-001-14	14mm
115-001-16	16mm
115-001-18	18mm
115-001-20	20mm
115-001-22	22mm
115-001-24	24mm
115-001-26	26mm



2-Level Plate	
REFERENCE	**HOLE TO HOLE LENGTH**
115-002-26	26mm
115-002-28	28mm
115-002-30	30mm
115-002-32	32mm
115-002-34	34mm
115-002-36	36mm
115-002-38	38mm
115-002-40	40mm
115-002-42	42mm

3-Level Plate	
REFERENCE	**HOLE TO HOLE LENGTH**
115-003-39	39mm
115-003-42	42mm
115-003-45	45mm
115-003-48	48mm
115-003-51	51mm
115-003-54	54mm
115-003-57	57mm
115-003-60	60mm
115-003-63	63mm

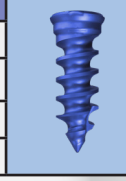


Images for reference only.
Actual tray configuration may vary from images shown.

Implant Tray Layout

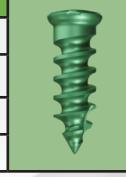
Screws

4.0mm Fixed Screws	
REFERENCE	LENGHT
115-006-SDFA-4012	Ø4.0mm x 12mm
115-006-SDFA-4014	Ø4.0mm x 14mm
115-006-SDFA-4016	Ø4.0mm x 16mm
115-006-SDFA-4018	Ø4.0mm x 18mm

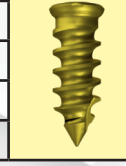


4.5mm Fixed Screws	
REFERENCE	LENGHT
115-006-SDFA-4512	Ø4.5mm x 12mm
115-006-SDFA-4514	Ø4.5mm x 14mm
115-006-SDFA-4516	Ø4.5mm x 16mm
115-006-SDFA-4518	Ø4.5mm x 18mm

4.0mm Variable Screws	
REFERENCE	LENGHT
115-006-SDVA-4012	Ø4.0mm x 12mm
115-006-SDVA-4014	Ø4.0mm x 14mm
115-006-SDVA-4016	Ø4.0mm x 16mm
115-006-SDVA-4018	Ø4.0mm x 18mm



4.5mm Variable Screws	
REFERENCE	LENGHT
115-006-SDVA-4512	Ø4.5mm x 12mm
115-006-SDVA-4514	Ø4.5mm x 14mm
115-006-SDVA-4516	Ø4.5mm x 16mm
115-006-SDVA-4518	Ø4.5mm x 18mm



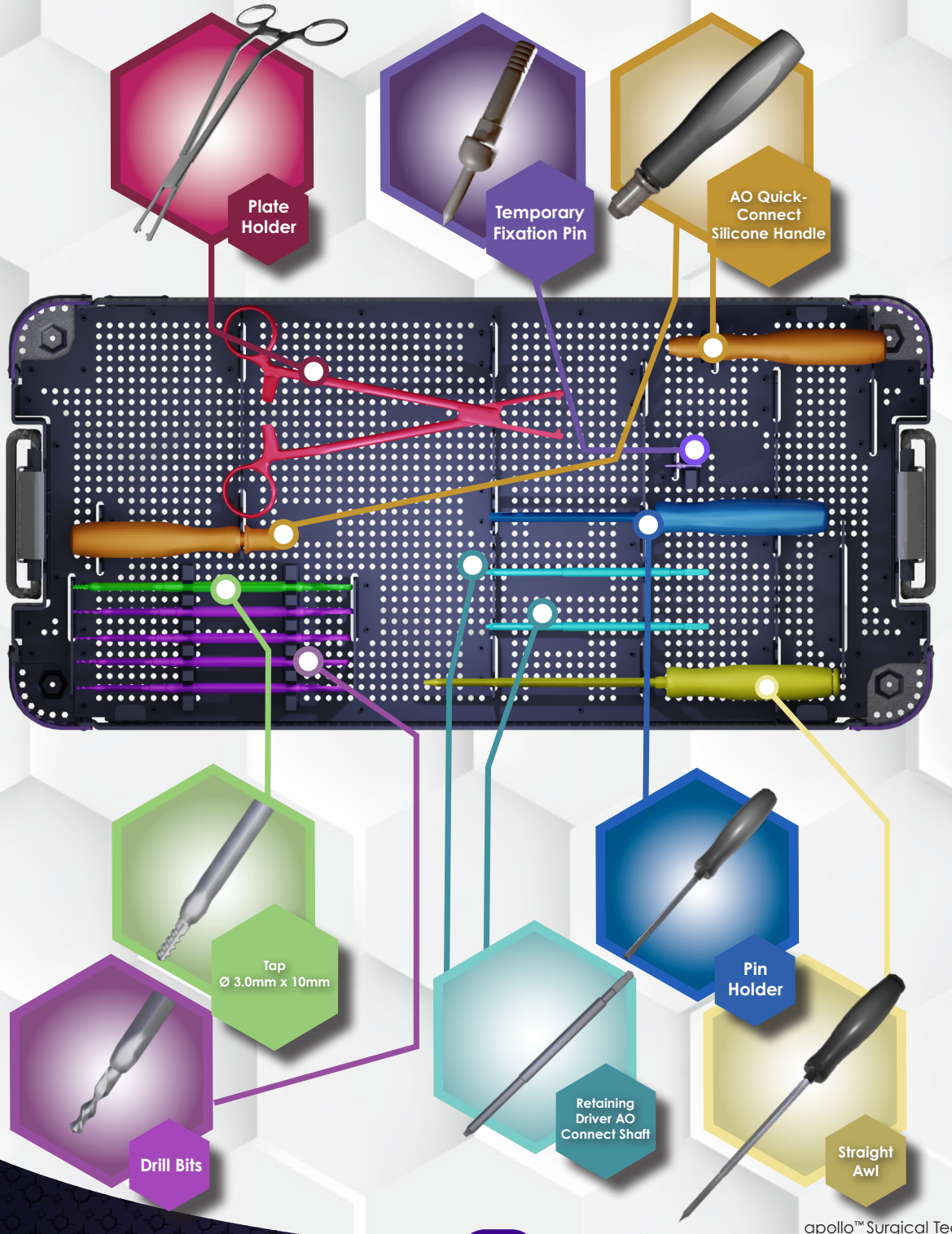
Images for reference only.
Actual tray configuration may vary from images shown.

Instrument Tray Layout

Instrument Set Base

PART NUMBER	DESCRIPTION
115-302-01	Plate Holder
115-304-01	Temporary Fixation Pin
115-304-02	Pin Holder
115-305-02	Straight Awl
115-307-10	Drill Bit 10mm

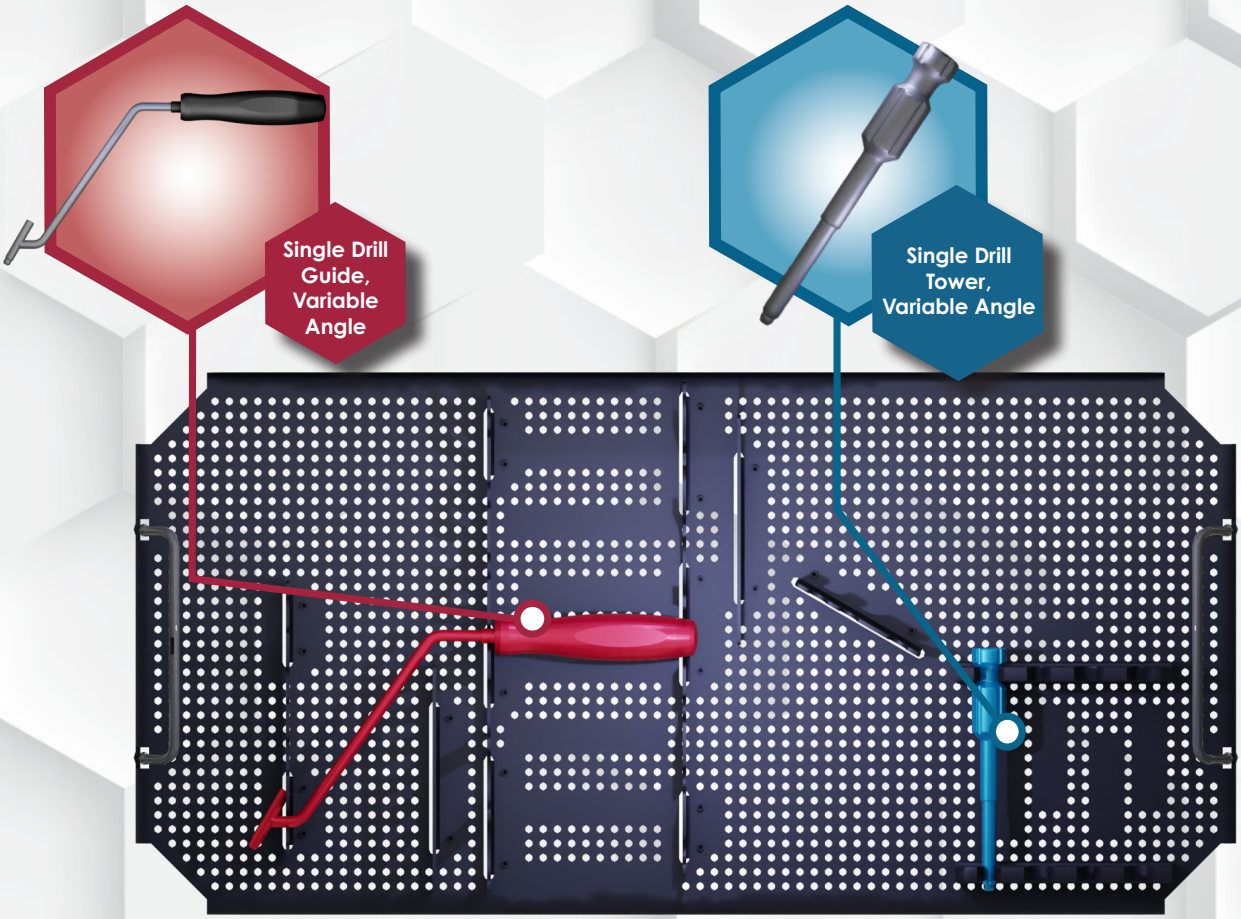
PART NUMBER	DESCRIPTION
115-307-12	Drill Bit 12mm
115-307-14	Drill Bit 14mm
115-307-16	Drill Bit 16mm
115-308-01	AO Quick-Connect Silicone Handle
115-309-3010	Tap Ø3.0mm x 10mm
115-312-01	Retaining Driver AO Connect Shaft



Instrument Tray Layout

Instrument Set Insert

PART NUMBER	DESCRIPTION
115-306-05	Single Drill Guide, Variable Angle
115-306-06	Single Drill Tower, Variable Angle



Surgical Technique

Discectomy & Interbody Fusion

Anterior discectomy and interbody fusion are performed prior to the start of the procedure.

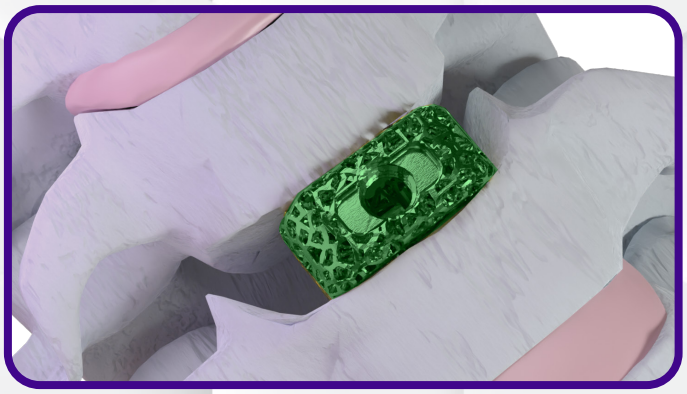
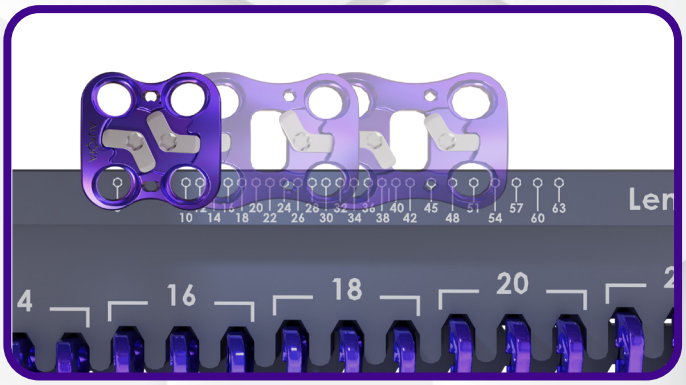
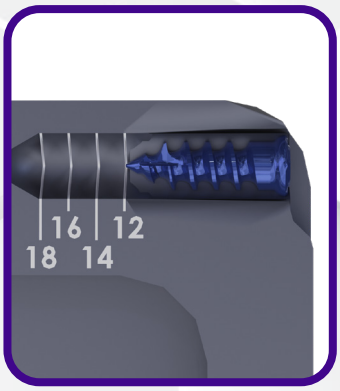
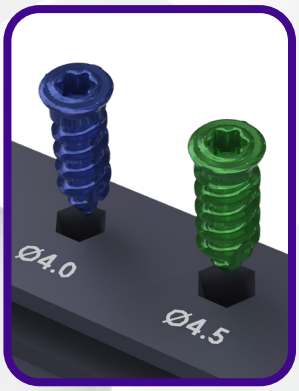


Plate & Screw Selection

Plate and screw sizes are determined intra-operatively.







Surgical Technique

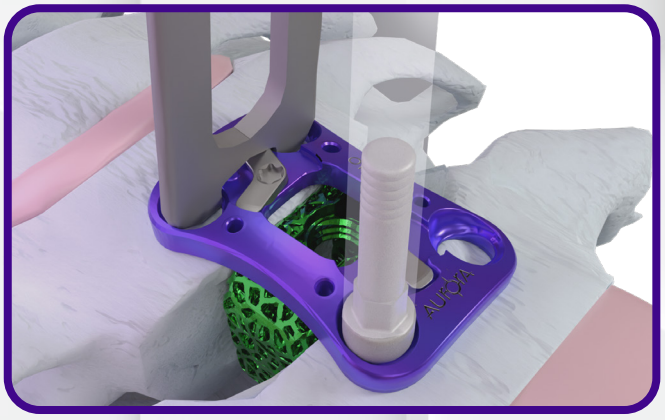
Plate Holding

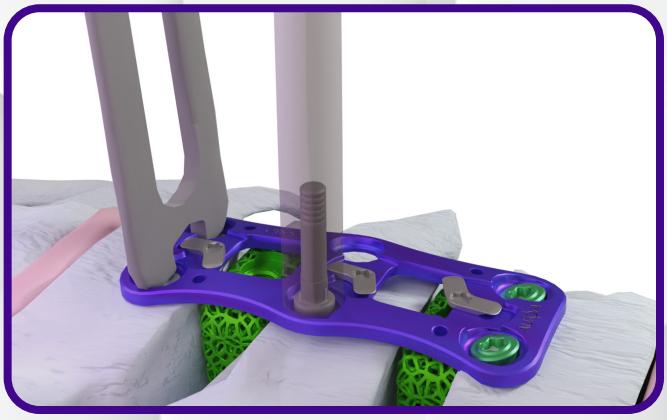
To hold the Plate, place the Plate Holder tips in the cephalad holes on the Plate.

Use the Plate Holder attached to the Plate to align the Plate over the segment(s) under AP fluoro.

Temporary Plate Fixation

The Pin Holder is used to drive the Temporary Fixation Pin through a Plate hole. Central or Caudal.

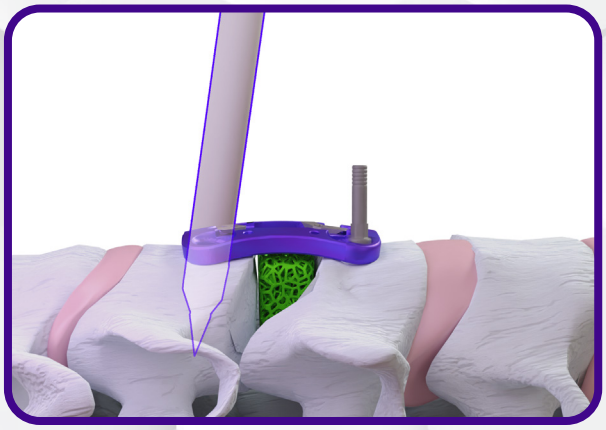




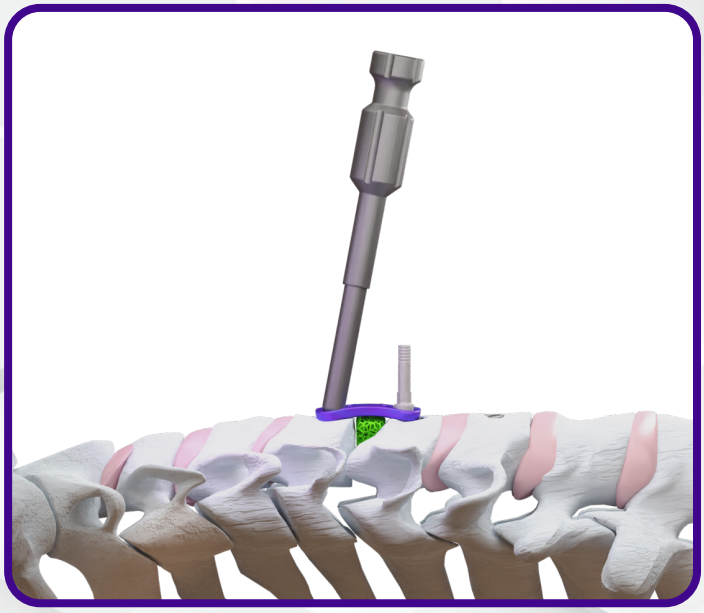
Surgical Technique

Screw Awling, Drilling & Tapping

Use the Straight Awl to punch through the cortical bone.
NOTE: The Awl and Tap may NOT be used with the Variable Angle Guide and Tower.



Remove the Plate Holder and place the Drill Guide or the Tower over Plate hole cephalad or caudal to the pin.



Surgical Technique

Using the Quick Connect Handle advance the 10mm, 12mm, 14mm or 16mm Drill through the Drill Guide while assessing depth under fluoro, or until positive stop.

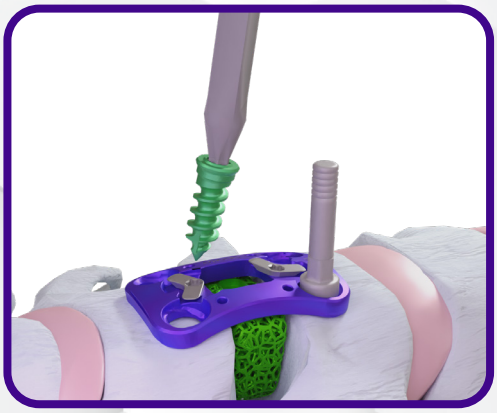
An optional Ø3.0mm x 10mm Tap is provided to be used with the Quick Connect Handle to ease the insertion of the screws into the harder bone.

Remove the Variable Angle Drill Guide or Tower before inserting the Tap.

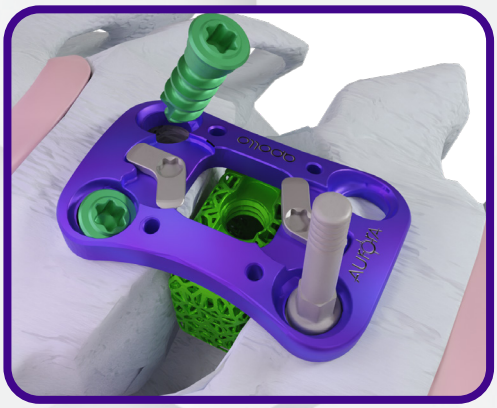
Surgical Technique

Screw Insertion

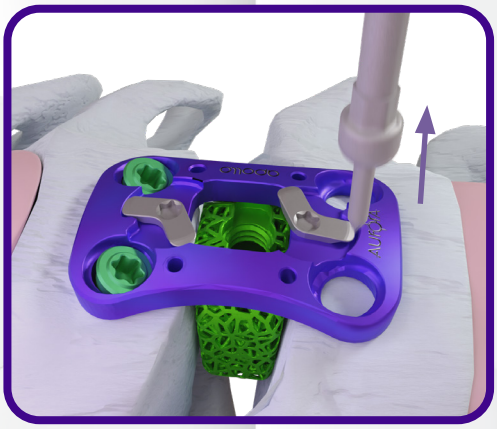
Insert the Screw with the Retaining Driver attached to a Quick Connect Handle and advance under lateral fluoro until the head of the Screw is seated in the Plate.



Awl, Drill/Tap, Screw adjacent hole.



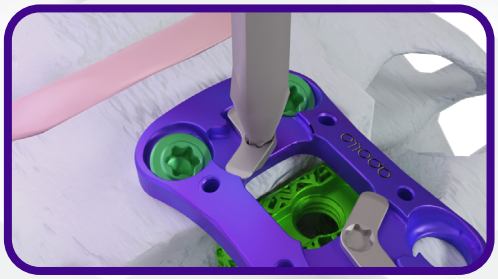
Remove the Temporary Fixation Pin once two Screws have been completely deployed through the Plate and into the vertebral body.



Surgical Technique

Screw Locking Plate

The Driver is used to rotate the Locking Plate over the Screw heads. Rotate clockwise until the Locking Plate wings cover the Screws or until positive stop.



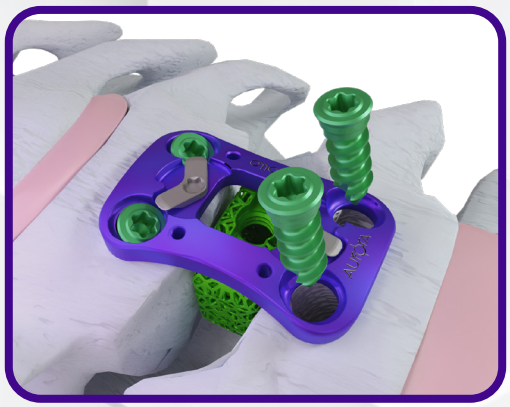
Confirm with direct visualization that the Locking Plate is directly over each Screw head.

Initial Position

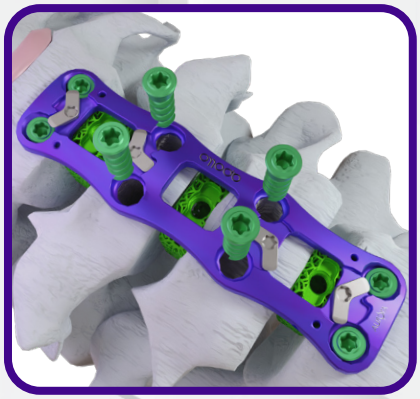
Final Position

Adjacent Screws

Move the Single Drill Guide to caudal vertebrae. Awl, Drill/Tap, Screw. Rotate Locking Plate. Remove retractors and close for single-level surgeries.



Awl, Drill/Tap and insert two center Screws for a two-level Plate. Awl, Drill/Tap and insert four center Screws for three-level Plates. Remove retractors and close.



Indications for Use

The operating surgeon draws up an operational plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite implant components are ready at hand.
- Operating conditions are highly aseptic.
- The implantation instruments are cleaned and sterilized prior to use according to the procedures outlined in this document.
- The implantation instruments, including the special Aurora Spine instruments, are complete and in working condition.
- The operating surgeon and team are aware of information concerning the operating technique, range of implants and associated instruments; this information is complete and ready.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the operated area.
- The intervention has been explained to the patient, whose consent concerning the following information has been documented:

    - In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
    - The lifespan of the implant depends on the patient's body weight.
    - Corrective surgery may become necessary if the implant loosens.
    - The patient must undergo regular check-ups of the implant components performed by a physician.

Implanting the Devices

- Select the appropriate implant size and shape according to the indication, preoperative planning, and intraoperatively bone situation.
- Correctly utilize the instruments for preparing the implantation site and implanting the device.
- To implant the apollo™ system devices, use only the specialized Aurora Spine instrumentation. Do not use implants or instruments from any other system or manufacturer.
- Apply appropriate care when inserting the device.

For complete instructions regarding the proper use and application of all apollo™ System devices and instruments, please refer to the Aurora Spine apollo™ System Surgical Technique Guide by contacting info@auroraspine.us.

Care & Handling

Aurora Spine instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing
Repeated processing has minimal effect on these implants and instruments. End of life is generally determined by wear and damage due to use.

Point of Use
The instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments before each use.

Containment and Transportation
Instruments are recommended to be reprocessed as soon as reasonably practical following use.

Preparation for Cleaning
Where instruments interface with other devices, disassemble prior to cleaning.

Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Decontamination
- Prepare a decontamination bath with enzymatic detergent (such as PROLYSTICA® 2x Concentrate Enzymatic Presoak and Cleaner solution at 1 - 4 mL/Liter) and warm water.
- Submerge the device in the decontamination bath for 5 minutes.
- Rinse thoroughly with warm water for 30 seconds while activating any moving parts. Use a syringe or water pistol to thoroughly flush the lumen and all difficult-to-reach areas.
- Place the device in a warm water enzymatic detergent bath (such as PROLYSTICA® 2x Concentrate Enzymatic Presoak and Cleaner solution at 1 - 4 mL/Liter) for 10 minutes with ultrasonic action.
- Rinse thoroughly with warm water for 30 seconds while activating any moving parts. Use a syringe or water pistol to thoroughly flush the lumen and all difficult-to-reach areas.

Cleaning (Automated)
- After decontamination, place the device in the automated washer, ensuring the samples do not touch each other. Load instruments in such a way that the parts can drain.
- Use a standard instrument cycle with the following recommended parameters (at a minimum):

Step	Time / Temperature	Cleaning Product
Prewash	Tap water 2 minutes (<45°C)	N/A
Wash	Tap water 5 minutes at 55°C	Prolystica® 2x Concentrate Enzymatic Presoak and Cleaner at 4mL / Liter
Neutralization	Tap water 2 minutes at 55°C	Prolystica® 2x Concentrate Neutral Detergent at 4mL / Liter
Rinse	Tap water 2 minutes (< 45°C)	N/A
Thermal Disinfection	Purified water 5 minutes at 93°C	N/A
Drying	22 minutes	N/A

Maintenance & Repair

Warning: Using damaged instruments may increase the risk of tissue trauma, infection, and length of operative procedures.

Warning: Do not attempt to repair any Aurora Spine apollo™ System instrument.

If your Aurora Spine instrument requires repair or maintenance, return the instrument in the Aurora Spine's box or another sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:
Aurora Spine, Inc.
1930 Palomar Point Way, STE 103, Carlsbad, CA 92008 USA
Attn: Aurora Spine Customer Service

Note: Instruments returned to Aurora Spine must have a statement that testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Inspection & Function Testing

Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, and bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored, or damaged instruments.

Packaging
Instruments may be loaded into the specified Aurora Spine instrument trays or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization
Components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: Aurora Spine does not recommend the instruments be sterilized by Flash, EtO, or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10-6, Aurora Spine recommends the following parameters:

Sterilizer Type	Pre-Vacuum
Minimum Temperature	132 °C (270 F)
Exposure*	4 min
Dry Time	60 minutes

*Aurora Spine has verified the above sterilization cycles and has the validation data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665-1. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

Do not stack sterilization trays during the sterilization process.

Aurora Spine recommends following **ANSI/AAMI ST79, a comprehensive guide to steam sterilization and sterility assurance in healthcare facilities**, this includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Storage
Aurora Spine instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas that provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Retrieval and analysis of removed devices
The most important part of surgical retrieval of devices is preventing damage that would render scientific examination useless. Special care should be given to protect the device during handling and shipping. Follow internal hospital procedures for retrieving and analyzing devices removed during surgery. When handling removed devices, use precautions to prevent the spread of bloodborne pathogens. Please contact Aurora Spine Customer Service for the return of removed devices.

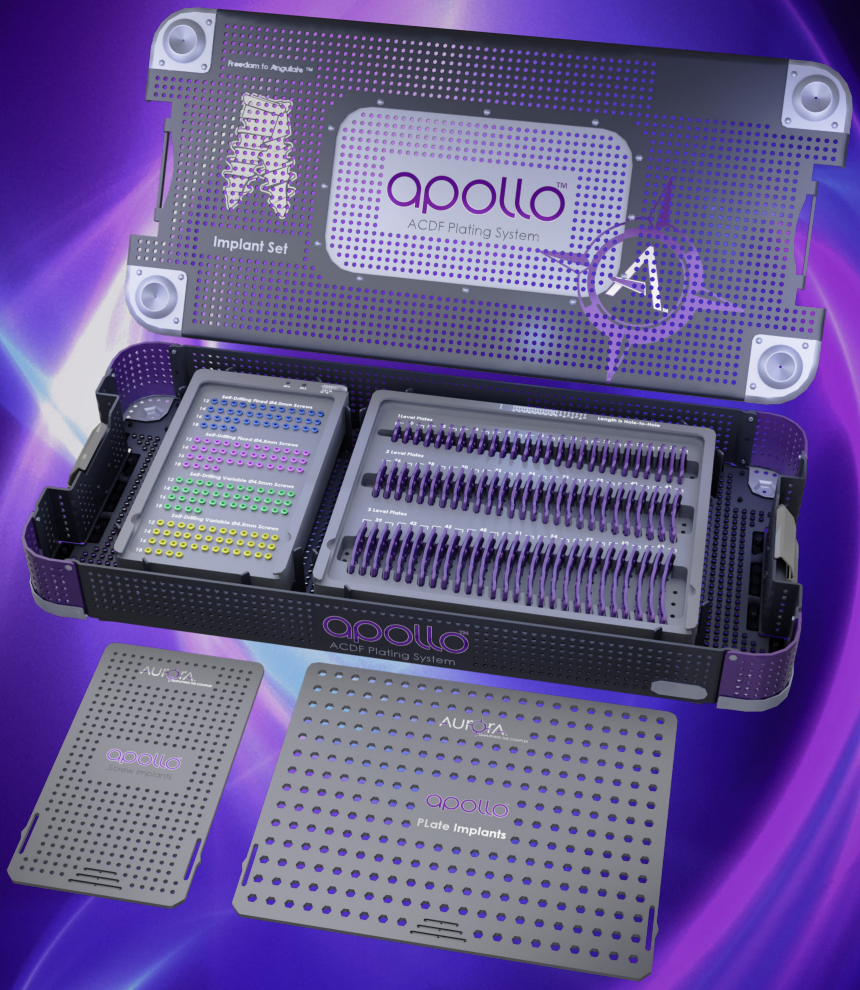
Customer Service

For further information regarding the Aurora Spine apollo™ System or Surgical Technique Guide, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

Description	Symbol
Manufacturer: Aurora Spine, Inc. 1930 Palomar Point Way, STE 103, Carlsbad, CA 92008, USA Telephone +1 (760) 424 2004	
Lot / Control Number	
Part Number	
Do NOT re-use / Single use Only	
Keep Dry	
Quantity	
Catalog Number / Identifier	
Expiration Date / Use By Date	
See Instructions For Use	
Do NOT use if package is damaged	
Prescription Use Caution: USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	

AURORA™

SIMPLIFYING THE COMPLEX



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Aurora is ISO 13485 certified. F280102-1_C

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Fax: 844.528.1794

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