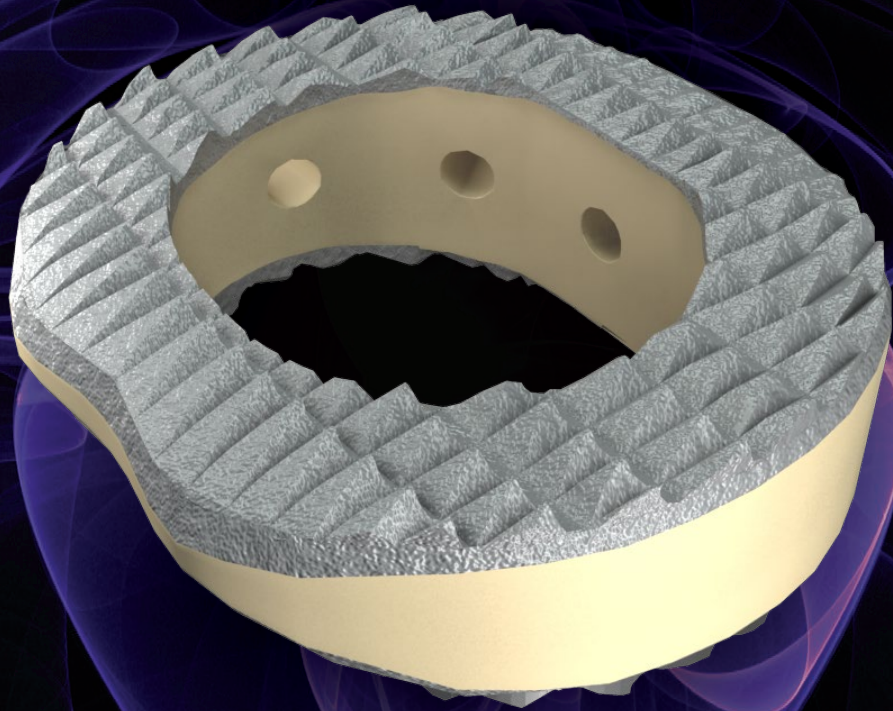


AURORA™



affinity™

Featuring

²²Ti NANO

MIS ALIF INTERBODY FUSION SYSTEM
SURGICAL TECHNIQUE GUIDE

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Content, clearances, approvals, specifications, descriptions and illustrative material in this literature are as accurate as known at the time of publication, but are subject to changes without notice. Visit aurora-spine.com for more information. Guides are revised from time to time and placed on the website. Look for updated guides on our website.

Product Descriptions

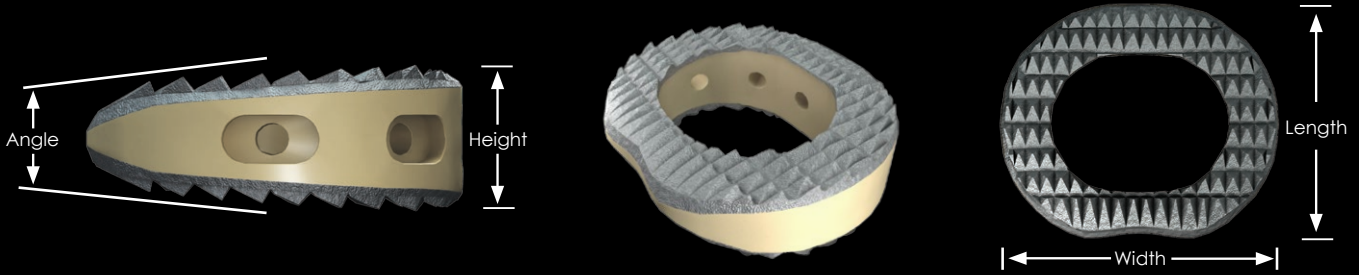
AFFINITY™ is Aurora Spine's modern, minimally invasive ALIF interbody fusion system. Manufactured out of PEEK, each cage is precision coated with TiNano®, Aurora Spine's titanium plasma spray coating. Aurora Spine cages feature a self-distracting nose, as well as teeth on the inferior and superior surfaces to help prevent retropulsion and migration. Graft windows have been designed to maximize the space for bone materials to help promote integration and fusion. Cages are available in various footprints and heights to accommodate variations in patient anatomy.

TiNano®

TiNano is Aurora Spine's titanium plasma spray coating on PEEK interbody cages. The TiNano surface is created by thermal spray technology depositing pure titanium onto PEEK surfaces. Interbody cages featuring TiNano are designed to have a friction fit. The TiNano coating will add approximately 0.25mm thickness to the overall height of the cage.

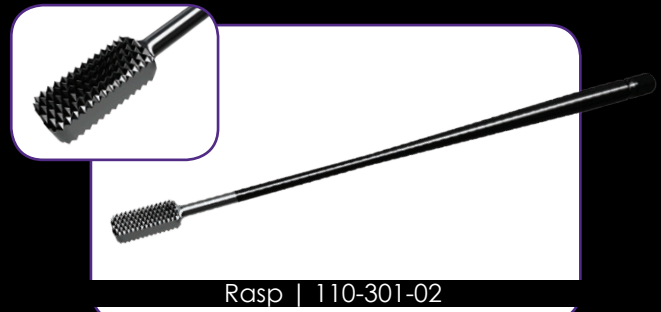
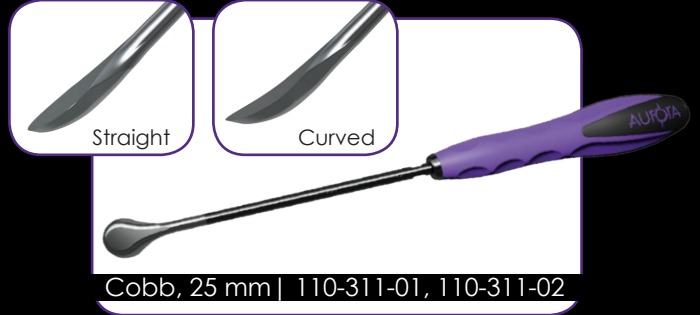
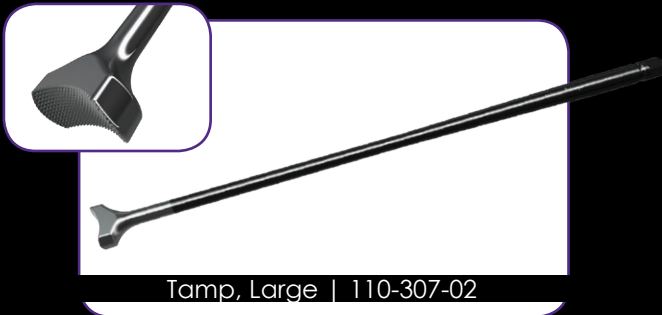
Indications

The Aurora Spine TiNano® Lumbar Interbody Fusion Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.



Catalog #	Description (L x W x A° x H)	Graft Volume
106-82430-0808	AFFINITY, 24mm x 30mm x 8° x 8mm	1.78cc
106-82430-0810	AFFINITY, 24mm x 30mm x 8° x 10mm	2.26cc
106-82430-0812	AFFINITY, 24mm x 30mm x 8° x 12mm	2.73cc
106-82430-0814	AFFINITY, 24mm x 30mm x 8° x 14mm	3.21cc
106-82430-0816	AFFINITY, 24mm x 30mm x 8° x 16mm	3.68cc
106-82634-0808	AFFINITY, 26mm x 34mm x 8° x 8mm	2.42cc
106-82634-0810	AFFINITY, 26mm x 34mm x 8° x 10mm	3.07cc
106-82634-0812	AFFINITY, 26mm x 34mm x 8° x 12mm	3.73cc
106-82634-0814	AFFINITY, 26mm x 34mm x 8° x 14mm	4.38cc
106-82634-0816	AFFINITY, 26mm x 34mm x 8° x 16mm	5.04cc
106-82838-0808	AFFINITY, 28mm x 38mm x 8° x 8mm	3.12cc
106-82838-0810	AFFINITY, 28mm x 38mm x 8° x 10mm	3.98cc
106-82838-0812	AFFINITY, 28mm x 38mm x 8° x 12mm	4.84cc
106-82838-0814	AFFINITY, 28mm x 38mm x 8° x 14mm	5.71cc
106-82838-0816	AFFINITY, 28mm x 38mm x 8° x 16mm	6.57cc

Instruments



Instruments



Mallet | 110-314



Slap Hammer | 110-315



T Handle | 110-704



Single Handle | 110-702

AFFINITY Specific Instruments



AFFINITY Graft Station | 106-301



AFFINITY Inserter | 106-300



AFFINITY Trial Inserter | 106-302



AFFINITY MIS Inserter | 110-316



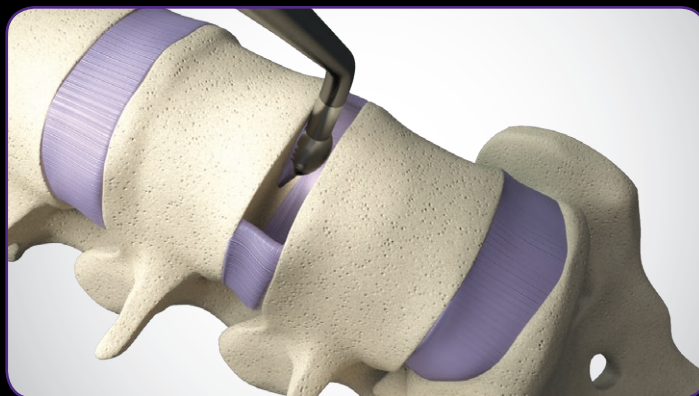
AFFINITY Trial | 106-3LLWW-AAHH

Surgical Technique

- 1. Approach:**
Patient should be placed in a supine position appropriate for an anterior approach. Identify the affected level using anterior and posterior fluoroscopic imaging. Determine surgical approach based on the surgeons preference. Mark and create the appropriate incisions. Dissect and retract soft tissues to reach the bony anatomy. For access to the target disc space, create an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus.
- 2. Preparing the Disc Space:**
Proceed with Discectomy. The Curettes and Rongeurs can be used to remove the affected disc while maintaining the integrity of the endplates.



The Rasp and Shavers can be connected to the Quick Connect Single Handle or the Quick Connect T-Handle and used to prepare the endplates by removing any remaining cartilage.



Surgical Technique

Quick Connect Handles



To Engage:

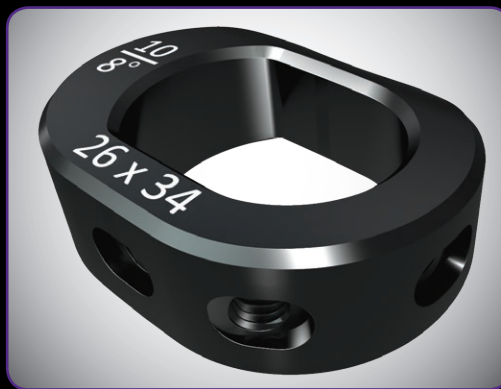
To engage the Quick Connect handles, insert the back end of any compatible instrument.



To Disengage:

To disengage Quick Connect handles, push down on the connector lock and remove the instrument.

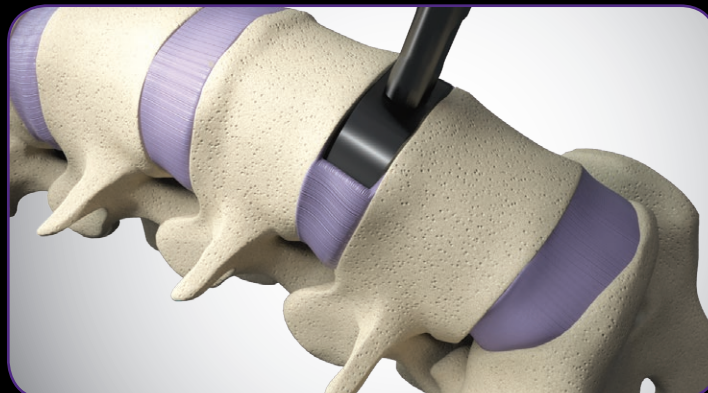
- Sizing:**
Select an appropriate sized Trial and attach to the Trial Inserter. Trial markings indicate footprint size, height, and angle of lordosis.



Trials and cages can attach at various angles (0°/45°/90°) for different approaches.

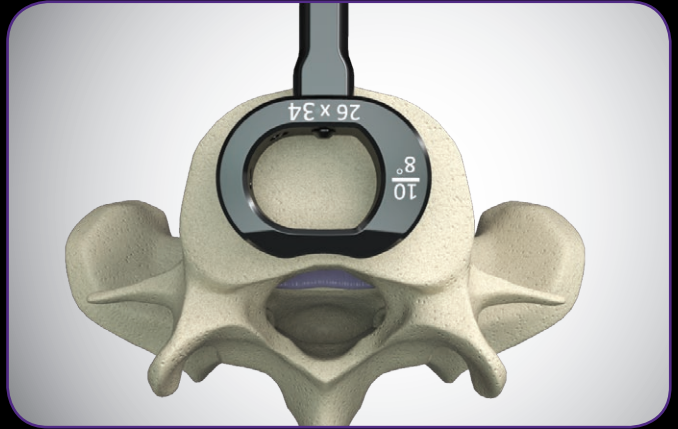


Insert the Trial into the annulotomy window. Check fit and positioning with anterior/posterior and lateral fluoroscopy. Repeat until the desired fit is achieved to identify the optimal Trial profile.



Surgical Technique

Use the Mallet to impact the Trial into the disc space.



The Slap Hammer or the Slotted Mallet can be used to help remove the Trial.



To Engage:

Slap Hammer secures onto the back end of the Single Quick Connect Handle.



To Use:

Apply a strong upward force to the slap hammer. Repeat until Trial is removed from the disc space.

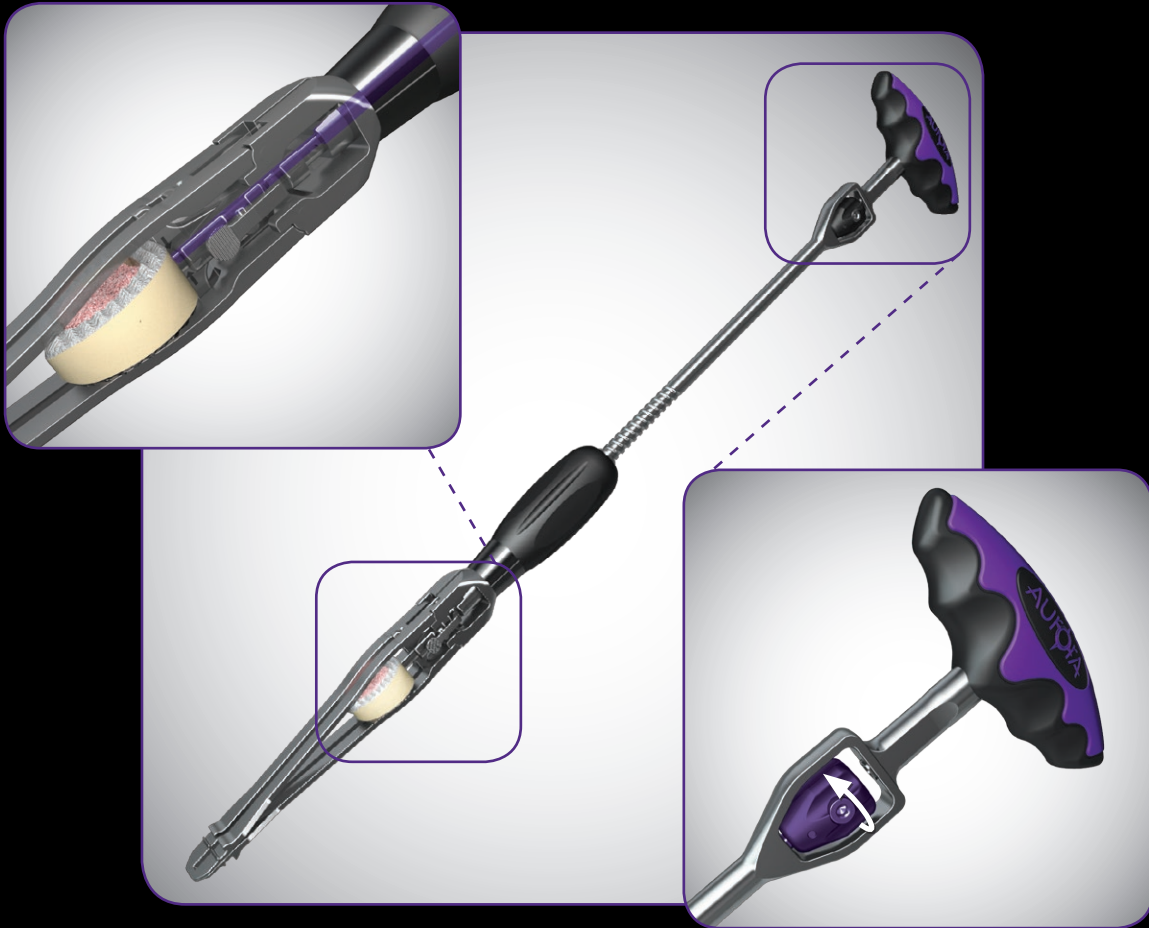
4. Preparing the Cage:

Select the cage profile that corresponds to the selected Trial. Lower the cage by hand into the corresponding space in the Graft Station. Fill the graft window with the desired graft material, and use the Tamp to secure the content in place.



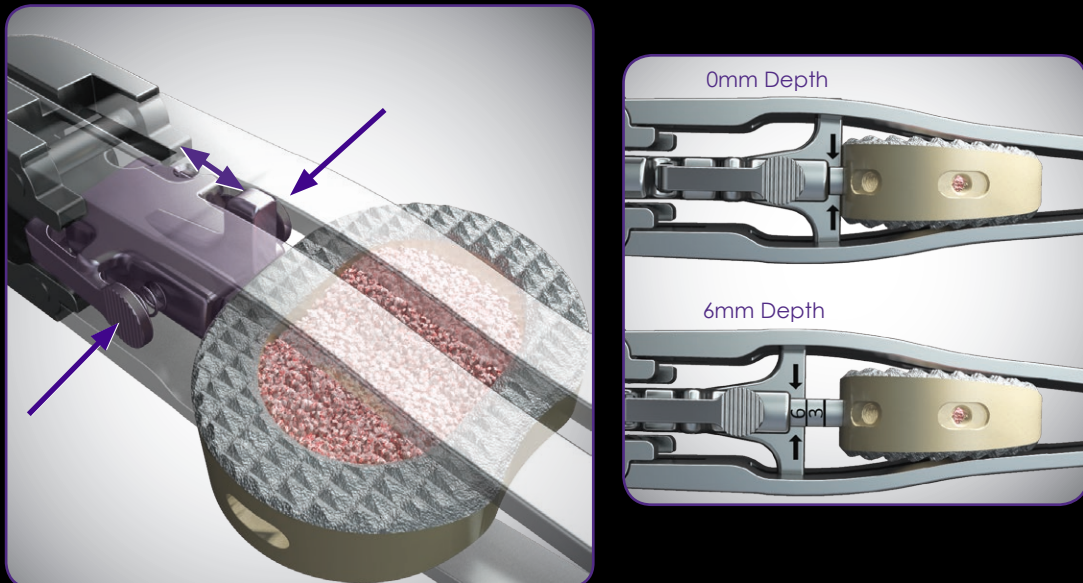
Surgical Technique

Take the cage from the Graft Station and guide it to the threaded prong of the Inserter. To secure the cage onto the Inserter, turn the tightening knob while holding the cage in place.



5. Insertion

The insertion depth can be controlled by squeezing the clips on either side of the cage mount and sliding the depth stop in or out. The markings on the side of the holder indicate insertion depth in millimeters.

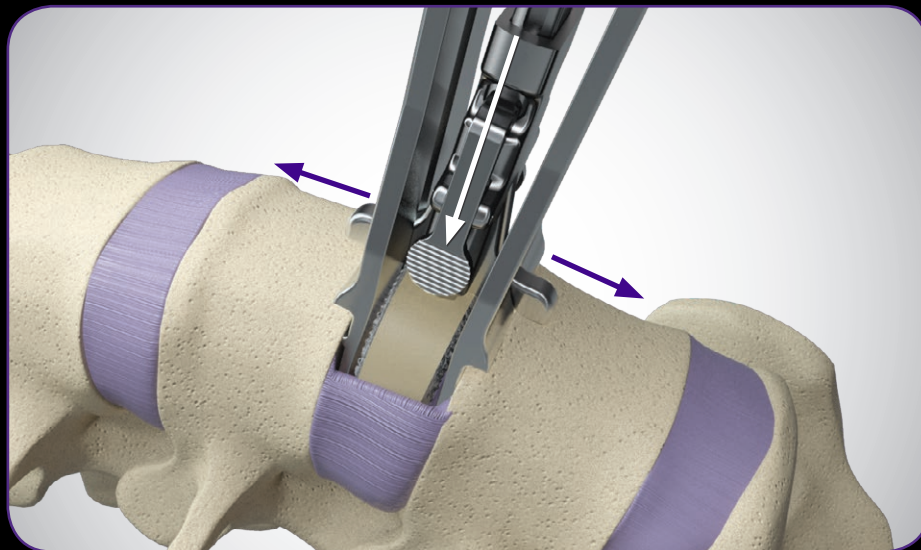


Surgical Technique

Guide the blades of the Inserter through the annulotomy window into the intervertebral space. Ensure the blades are seated flush against the vertebral bodies. Firmly grip the central handle and apply even counterpressure to keep the Inserter secure and stable during insertion. Gradually turn the Inserter T-handle clockwise to drive the cage forward, through the Inserter blades and into the intervertebral space. The blades will automatically distract the vertebrae to allow impact-free insertion.

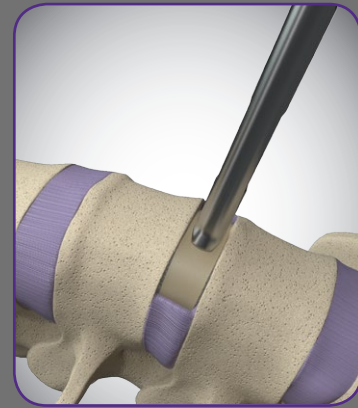


Turn the tightening knob of the inserter counter clockwise to release the cage, and remove the Inserter. Once cage has been inserted, confirm final positioning with anterior/posterior and lateral fluoroscopy.



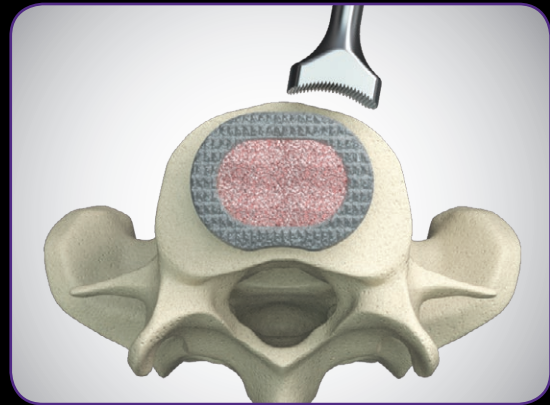
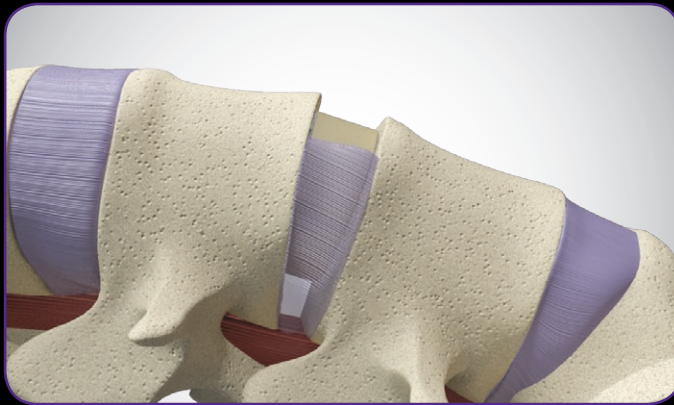
Optional

The AFFINITY MIS ALIF Interbody fusion system includes an optional MIS Inserter. To use the MIS Inserter, attach the cage to the threaded prong and use the tightening knob to secure it in place.

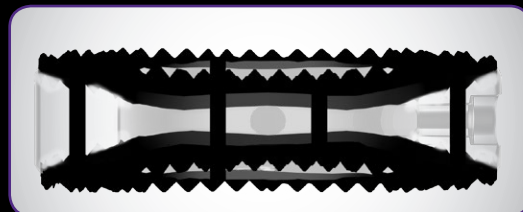
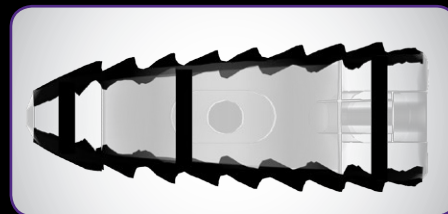
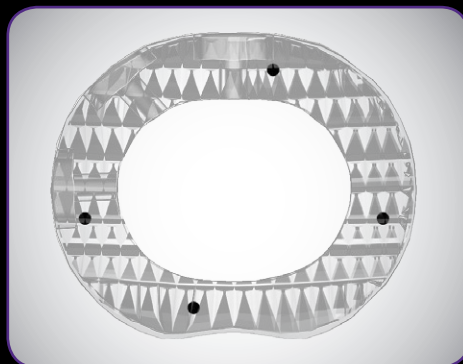


Insert the cage into the target disc space. Rotate the tightening knob counter-clockwise to release the cage and remove the inserter.

Fine adjustments to the cage positioning can be made using the Tamp. When using the Tamp, always use gentle force, and ensure that the cage surface is seated flush against the cage.



The tantalum wire markers in the Affinity cage can be used to verify proper positioning and orientation.



Instructions for Use

The Aurora Spine interbody devices are constructed of medical grade Polyetheretherketone (PEEK) as described by ASTM F2026 with a Titanium plasma spray as described by ASTM F1580.

- The teeth on the superior and inferior ends resist expulsion in all directions.
- The device is open in the transverse plane to allow insertion of bone graft material into the device prior to placement.
- The tantalum markers used for this product are made to the voluntary standard ASTM F560.
- The radiolucent PEEK material allows visualization of the defect site on radiograph to assess bone growth.
- For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbar spine (e.g., Interspinous fusion devices, posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems.)

The Aurora Spine interbody devices are supplied sterile. **STERILE R**


INDICATIONS FOR USE

The Aurora Spine Interbody Fusion Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

MATERIAL

The Aurora Spine interbody devices are constructed from implant grade Polyetheretherketone (PEEK) per ASTM F2026 and have a titanium plasma spray per ASTM F1580. Each implant contains Tantalum markers per ASTM F560. The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899).

HOW SUPPLIED

The Aurora Spine interbody devices are delivered sterile. All sterile implants are gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize. 

CONTRAINDICATIONS

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

Instructions for Use Continued

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of 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. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, the Aurora Spine interbody devices should never be reused under any circumstances. (2)
5. Possible risks associated with the re-use of any single use Aurora Spine interbody device are infection, cross-infection, inability to clean and decontaminate the device, residues from chemical decontamination agents, material alteration, mechanical failure, reactions to endotoxins, transmission of abnormal prion proteins, inflammation, migration/retropulsion or non-fusion.
6. The Aurora Spine interbody devices should never be used with dissimilar materials.
7. Proper implant selection and patient compliance to postoperative precautions will greatly 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 important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.



PRECAUTIONS

Caution: Federal law restricts this device to sale by or on the order of a physician.

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
3. Bone graft material may be placed in the area to be fused.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during post-operative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or

Instructions for Use Continued

consume alcohol during the healing process.

4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic devices, none of the Aurora Spine interbody device components should ever be reused under any circumstances. ⓧ

POSSIBLE ADVERSE EFFECTS

1. bending, loosening or fracture of the implants or instruments;
2. loss of fixation;
3. sensitivity to a metallic foreign body, including possible tumor formation;
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. nonunion or delayed union;
6. infection;
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. pain or discomfort;
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra);
11. hemorrhage of blood vessels and/or hematomas;
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. bursitis;
14. bone graft material donor site pain;
15. inability to resume activities of normal daily living;
16. reoperation;
17. death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The Aurora Spine interbody devices have not been evaluated for safety and compatibility in the MR environment. The Aurora Spine interbody devices have not been tested for heating or migration in the MR environment.

DIRECTIONS FOR USE

The operating surgeon draws up an operating 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.

Instructions for Use Continued

- The implantation instruments, including the special Aurora Spine instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready at hand.
- 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 area operated on.

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 life-span 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, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
- To implant the Aurora Spine interbody 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 implant.
- Check implant height and/or angle using the trial implants.

For complete instructions regarding the proper use and application of all Aurora Spine lumbar interbody devices and instruments, please refer to the Aurora Spine TiNano™ Lumbar Interbody Surgical Technique Manual (provided with the system).

CARE AND 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 implant and instruments. End of life is normally determined by wear and damage due to use.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation

It is recommended that instruments are 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.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent¹, and neutral pH detergent².

- Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.

Instructions for Use Continued

- After pre-cleaning, place in the automated washer, making sure the samples do not touch each other. Load instruments in such a way that the parts can drain.
- Use a standard instruments cycle with the following parameters (at a minimum):

Enzyme Wash	Hot (40 - 65° C) (104 - 149° F) for 3 minutes
Neutral pH Wash	60° C (140° F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90° C (194° F) for 1 minute
Dry	82° C (180° F) for 6 minutes

- Determine if the instruments are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning.

Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 w of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the instruments in cold water.
- Rinse the instruments in deionized water.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning.

Maintenance and Repair

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

Warning: Do not attempt to repair any Aurora Spine interbody instrument.

If your Aurora Spine instrument requires repair or maintenance, return the instrument in the Aurora Spine box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008 USA

Attn: Aurora Spine Customer Service

Note: Instruments returned to Aurora Spine must have a statement which 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.

Instructions for Use Continued

Inspection and Function Testing

All instruments: 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, 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

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Aurora Spine.

If not specifically labeled **STERILE**, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: Aurora Spine does not recommend that 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

Sterilizer Type	Pre-Vacuum	Gravity
Minimum Temperature	132° C (270° F)	132° C (270° F)
Exposure*	4 min	15 min
Dry Time	20 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.*

Aurora Spine recommends following **ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities**, which 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 which 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 the retrieval and analysis of devices removed during surgery. When handling removed devices, use precautions to prevent the spread of bloodborne pathogens. Please contact Aurora Spine Customer Service for return of removed devices.

Instructions for Use Continued

CUSTOMER SERVICE

For further information regarding the Aurora Spine TiNano® Lumbar Interbody Fusion System or Surgical Technique Manual, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

 Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008, USA
Telephone +1 760 424-2004
Fax +1 760 444-5002
aurora-spine.com

EC	REP	EMERGO Europe Molenstraat 15 2513 BH, The Hague The Netherlands
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These devices are supplied

STERILE	R
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CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

¹ ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

² Polystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

Aurora Spine

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Carlsbad, CA 92008, USA

US: 760.424.2004

International: 44.1423.876315

Fax: 760.444.5002



aurora-spine.com

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Aurora is ISO 13485 certified. F240138-1_B

