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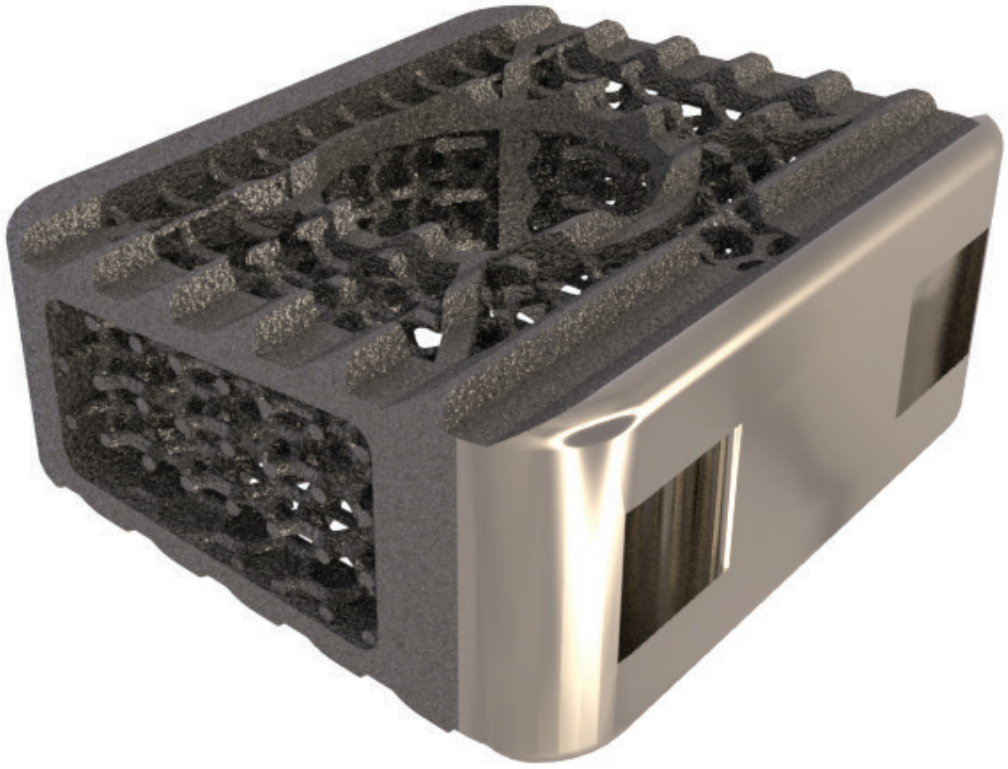

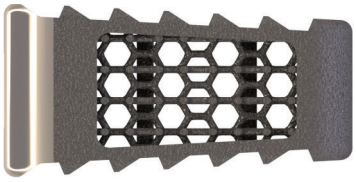

SURGICAL TECHNIQUE GUIDE

GAIA Cervical Interbody System

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Notice

Addivation Medical does not practice medicine. This technique guide is intended for experienced spine surgeons and is not intended for laypersons nor the novice surgeon. Surgeons that elect to utilize these implants must exercise independent judgment in the diagnosis and treatment of an individual patient, including indications for surgery, the intended surgical plan as well as the optimal surgical implant. This document does not replace the comprehensive training surgeons require (and have received). As with all surgical procedures, the specific technique used in each patient case will depend on the surgeon's clinical and medical judgment for the best treatment for each patient. In some cases, patients are not candidates for this product or procedure and indeed, the optimal implant for a specific patient may not be a GAIA spinal interbody device. Results will vary based upon patient factors (underlying severity of disease, other health issues, age, bone quality, weight, activity) as well as surgeon skill.

Technology Overview

The Addivation Medical Cervical Interbody System (CIS) is a series of porous titanium interbody fusion cages intended for use in the cervical spine. The cages feature a central space for bone graft containment with serrations on the superior and inferior surfaces for fixation. The cages are offered in a variety of footprints, heights, and lordotic angles to adapt to varying patient anatomies. The Addivation Medical CIS implants consist of a unique configuration of structures that are simultaneously built using the Electron Beam Melting (EBM) method of additive manufacturing. Addivation Medical CIS implants are provided sterile.

Instrumentation is provided to assist in the surgical implantation of the implants. It is important that the instruments and trial implants used are those specifically designed for this device to ensure accurate implantation.

System Components

- Interbody Devices- Implantable Ti-6Al-4V ELI
- Inserter Instrument- Surgical grade stainless steel (17-4 SS) and Radel R5000
- Implant Trials- Surgical grade stainless steel (17-4 SS)
- Tamp Instrument- Surgical grade stainless steel (17-4 SS)
- Rasp Instrument- Surgical grade stainless steel (17-4 SS)
- Trial Handle – Surgical grade stainless steel (17-4 SS) and Silicone

Indications for Use

The Addivation Medical Cervical Interbody System is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 discs.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The Addivation Medical Cervical Interbody System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft, and is to be implanted via an open, anterior approach.

The Addivation Medical Cervical Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

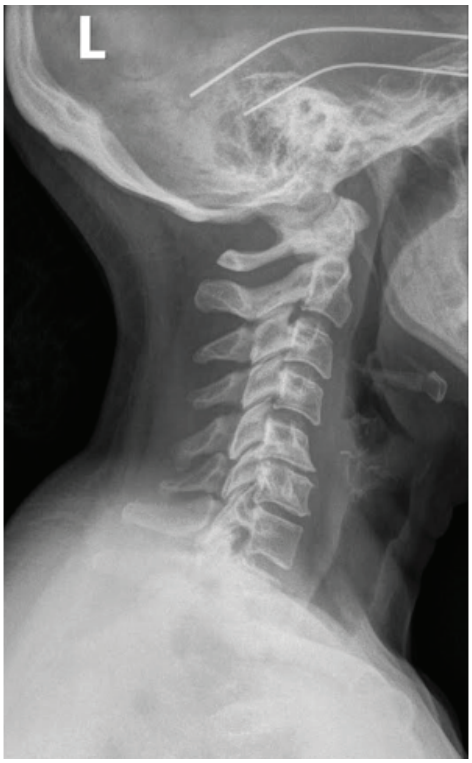

Fig #. Preoperative

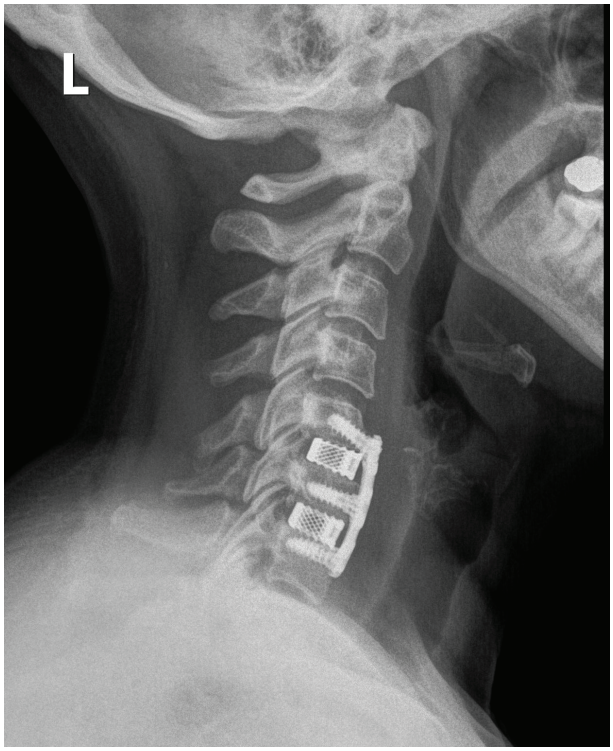

Fig #. 44 days post operative

Contraindications

The Addivation Medical Cervical Interbody System is not intended for posterior surgical implantation. Contraindications include, but are not limited to:

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to co-operate with postoperative instructions.
- Fever or leukocytosis.
- Infection, local to the operative site.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Signs of local inflammation.
- Suspected or documented metal allergy or intolerance.

These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

Surgical Technique

Patient Positioning

The patient is positioned using the standard positioning for anterior cervical fusion.

Surgical Approach

Prior to incision, the affected disc(s) should be confirmed and identified via imaging. The affected disks are accessed using a medial anterior surgical approach. The affected disc space is dissected per surgeon's standard operating procedure for anterior cervical discectomy and fusion.

Discectomy

Once the disc space is identified and exposed, Caspar pins or parallel pin distraction is placed to span that segment. Discectomy and decompression are performed as is necessary. Ventral osteophytes are also removed.

Precautions should be taken to preserve the adjacent discs. Preservation of subchondral bone is recommended. Preservation of the vertebral endplates will maintain distraction and minimize the risk of subsidence after interbody device insertion.

Fig #. Discectomy image

Endplate Preparation

Once surgical decompression is completed, preparation of the endplates is then performed. The goal should be to produce a flat, symmetrical surface to ensure maximum contact area of the implant. Preserving the integrity of the subchondral bone will reduce the risk of subsidence.

Assemble the rasp instrument to the modular handle using the quick connect feature. Using the rasp will aid to achieve proper endplate preparation. Remove the minimal amount of the cartilaginous endplates to produce a flat, symmetrical surface of bleeding bone. This will ensure maximum contact area of the implant and reduce the risk of subsidence.

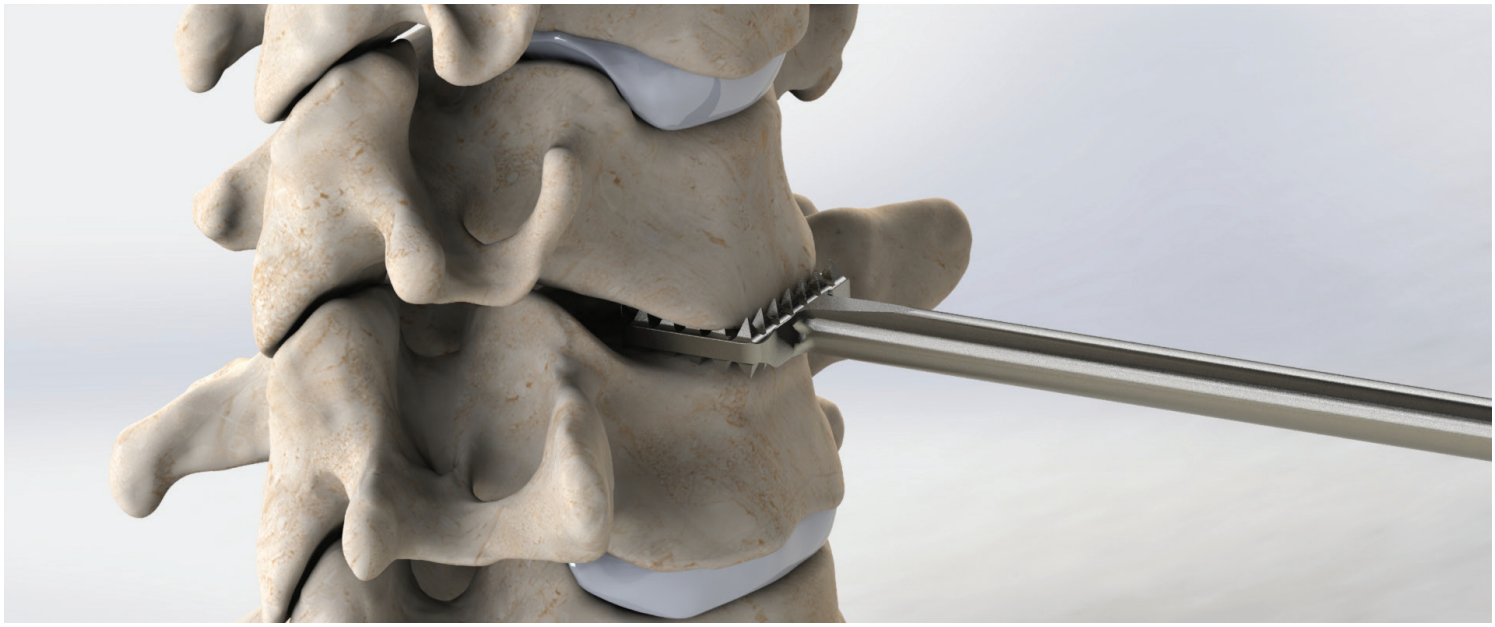

Fig #. Preparation of implant site with rasp.

Implant Size Selection

Select a trial instrument size based on the suspected height, footprint, and lordotic angle of the intervertebral space. Assemble the trial instrument to the modular handle using the quick connect feature. Using the assembled instrument, insert the trial into the disk space and evaluate the fit by tactile feedback and if necessary, fluoroscopy.

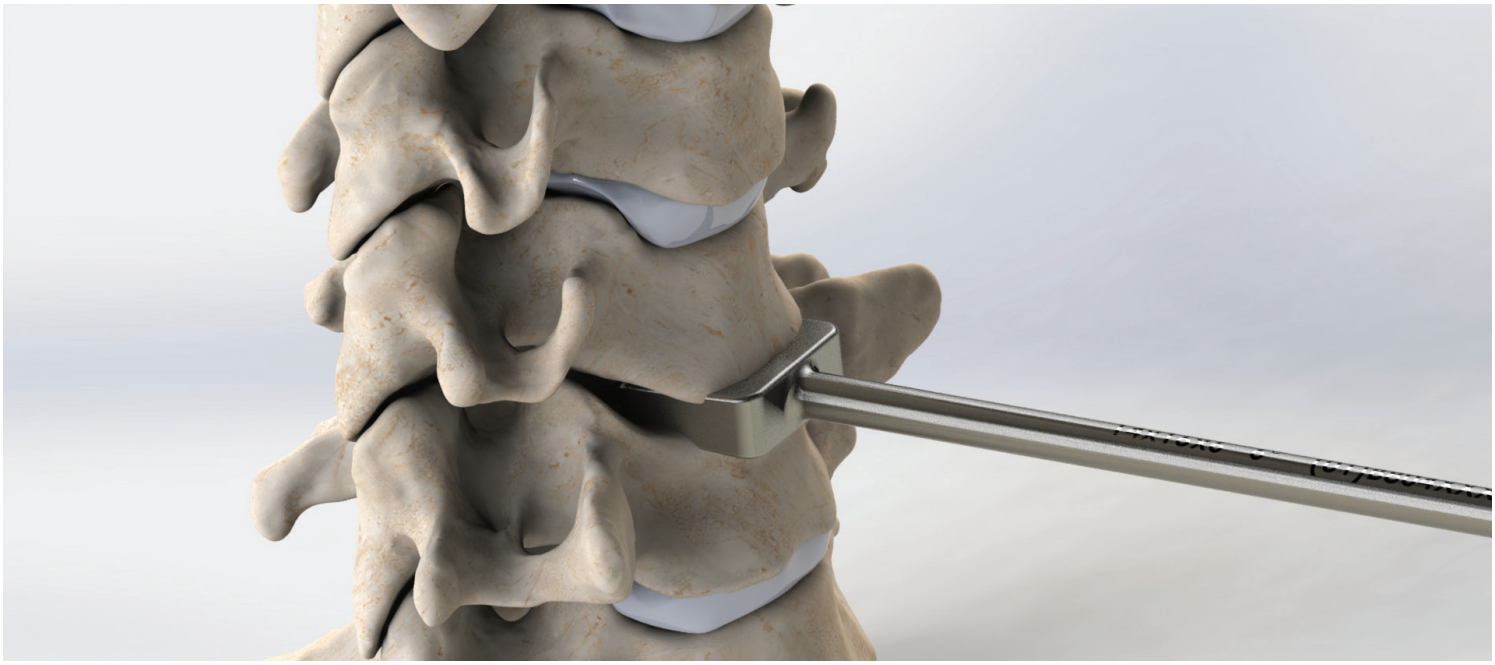

Fig #. Trial inserted into implant site

Caution: Trials do not have an interior stop feature so care must be taken not to over insert.

Fig #. 6mm trial instrument

Fig #. Inserter unlocked

Fig #. Inserter unlocked

Implant Placement

Note: Each implant is individually sterile packaged. Verify the proper implant is chosen prior to opening the package.

Open the sterile packaging of the implant size (height and footprint and lordosis) that was determined in sizing.

Attach the implant to the inserter by lining up the clutches of the inserter with the slots on the anterior side of the implant. Connect the implant to the inserter by rotating the knob clockwise with your thumb and index finger until the knob reaches the lock position. Note that there is a design feature in the inserter that prevents over-tightening.

Fill the graft window of the implant with autogenous or allogenic bone graft prior to implantation.

Using the inserter, gently insert the implant into the intervertebral disc space. The implant should be positioned approximately 1mm posterior to the anterior edge of the vertebra to allow for maximum contact to ensure the implant is adequately supported. In addition, confirm the optimal position of the implant with the correct medial to lateral and anterior/posterior position. Care must be taken that the posterior edge of the implant has a 2-3 mm separation from the dura. Detach the inserter from the implant by rotating the inserter knob counterclockwise until the implant is released.

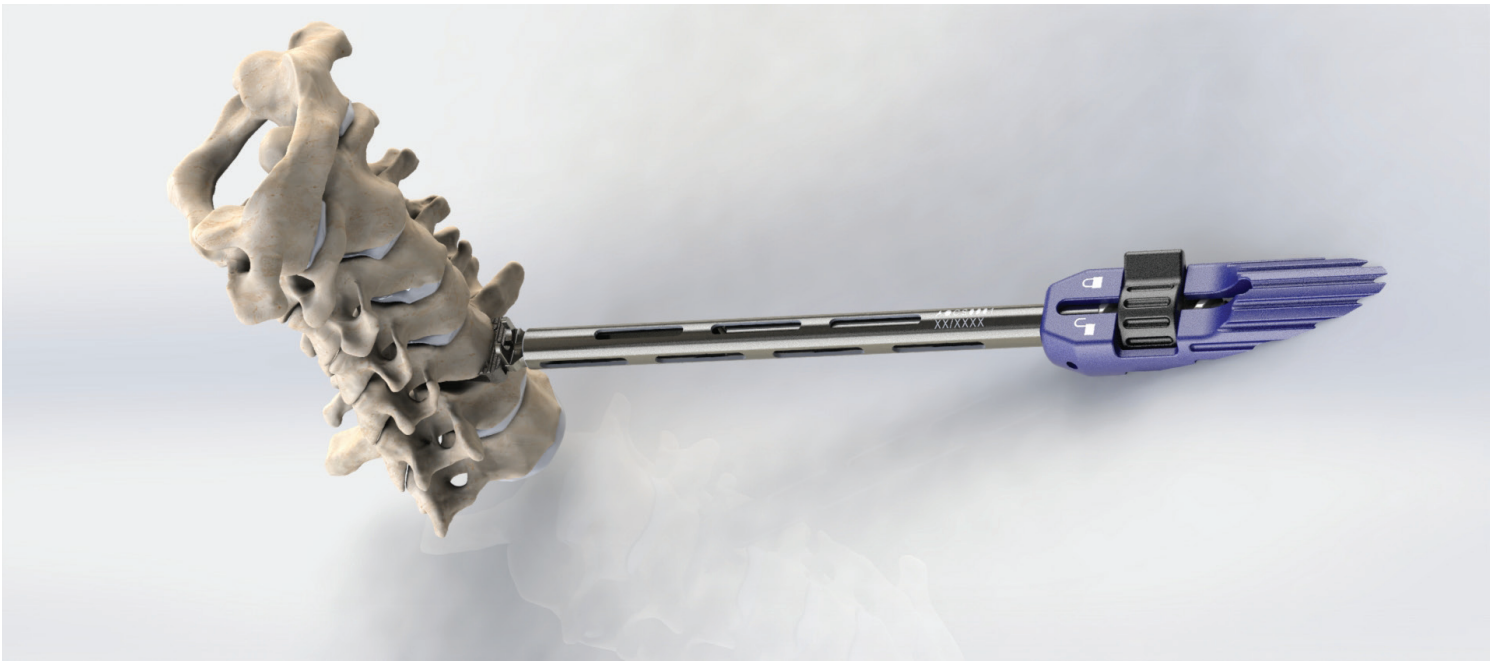

Fig #. Insertion of implant

Final position can be adjusted using the tamp instrument. To use the tamp, attach the instrument to the modular handle using the quick connect feature. When using the tamp, ensure that the teeth of the tamp are engaged with the anterior slots of the implant.

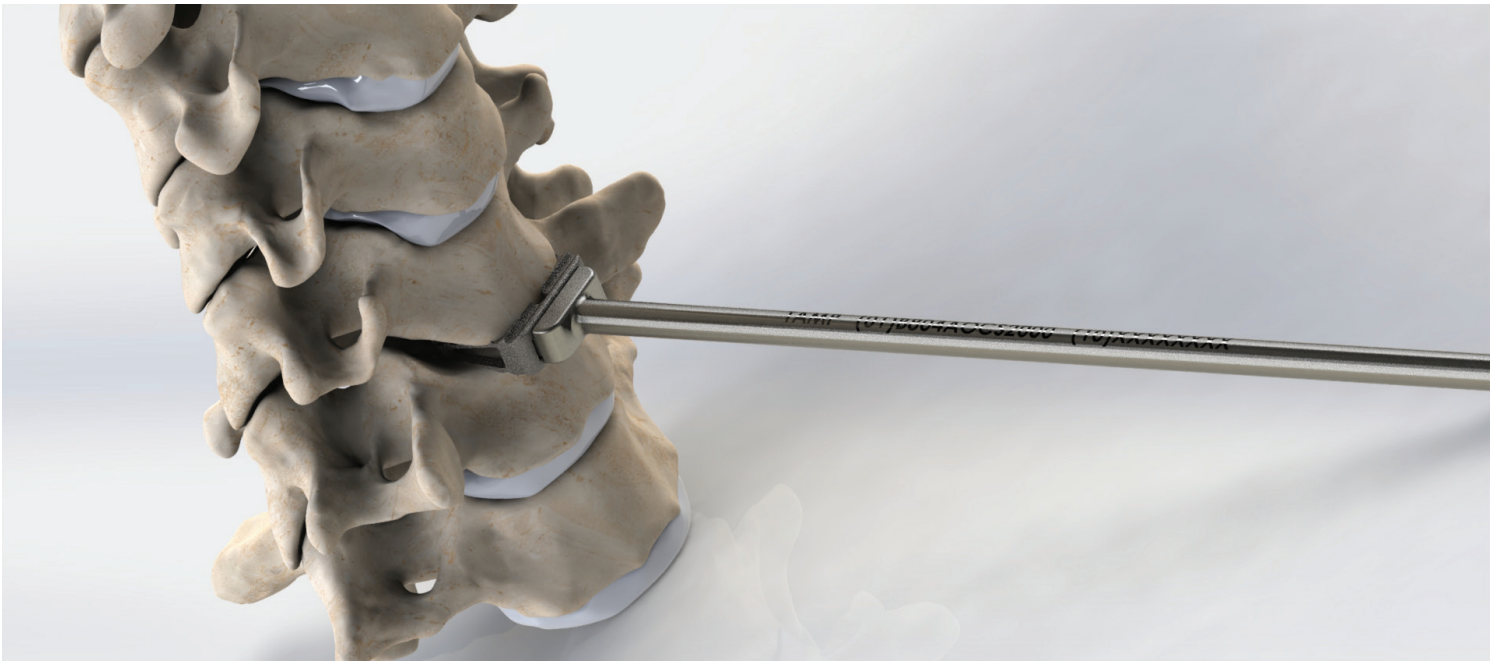

Fig #. Adjusting position of implant with tamp

Note: The use of fluoroscopy can be beneficial in the trial and insertion steps to ensure optimal positioning.

Supplemental Fixation:

After implantation of the interbody device, anterior or posterior supplemental fixation must be used. Only titanium alloy (ASTM F-136) systems should be used. Care must be taken to avoid using dissimilar metals in contact with one another as corrosion may occur.

Revision/Removal Steps

In cases where the implant needs to be removed, the implant site should be fully exposed. Remove any overlying osteophytes or overlying anterior bone formation. Discretion should be used to determine a method to break the bone/implant interfaces.

Once the interfaces are released, removal of the implant can be accomplished by using forceps or the inserter instrument. If the inserter is used, follow the steps in the Implant Placement section to attach the inserter to the implant prior to removal.

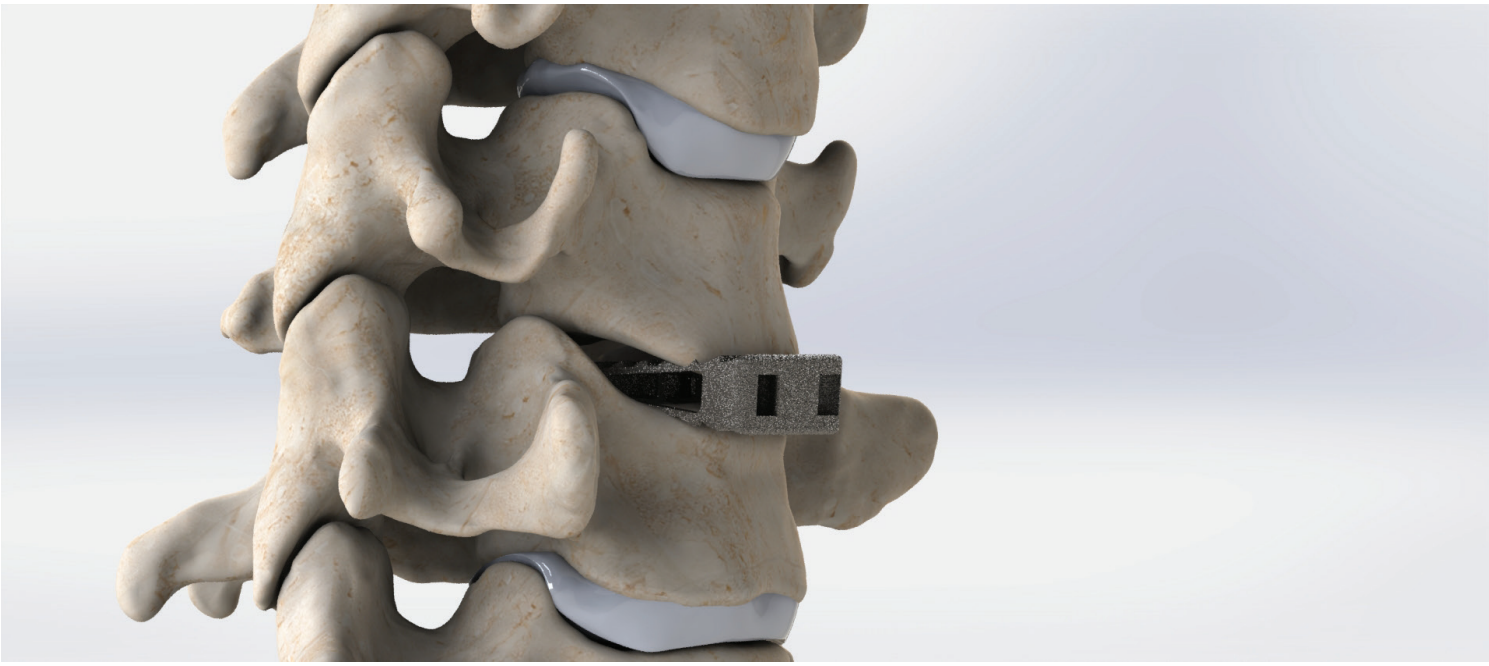

Fig #. Final position of implant

Instrument Set

Description	Part No.	GTIN
Inserter	AOCS0001	
Tamp	AOCS2000	
Rasp	AOCS3000	
Quick Connect Handle	AOCS4000	
12x14x5mm 6° Trial	AOCS0652	
12x14x6mm 6° Trial	AOCS0662	
12x14x7mm 6° Trial	AOCS0672	
12x14x8mm 6° Trial	AOCS0682	
12x14x9mm 6° Trial	AOCS0692	
12x14x10mm 6° Trial	AOCS0602	
12x14x11mm 6° Trial	AOCS0612	
12x14x12mm 6° Trial	AOCS0622	
14x16x5mm 6° Trial	AOCS0654	
14x16x6mm 6° Trial	AOCS0664	
14x16x7mm 6° Trial	AOCS0674	
14x16x8mm 6° Trial	AOCS0684	
14x16x9mm 6° Trial	AOCS0694	
14x16x10mm 6° Trial	AOCS0604	
14x16x11mm 6° Trial	AOCS0614	
14x16x12mm 6° Trial	AOCS0624	
12x14x5mm 0° Trial	AOCS0052	
12x14x6mm 0° Trial	AOCS0062	
12x14x7mm 0° Trial	AOCS0072	
12x14x8mm 0° Trial	AOCS0082	
12x14x9mm 0° Trial	AOCS0092	
12x14x10mm 0° Trial	AOCS0002	
12x14x11mm 0° Trial	AOCS0012	
12x14x12mm 0° Trial	AOCS0022	
14x16x5mm 0° Trial	AOCS0054	
14x16x6mm 0° Trial	AOCS0064	
14x16x7mm 0° Trial	AOCS0074	
14x16x8mm 0° Trial	AOCS0084	
14x16x9mm 0° Trial	AOCS0094	
14x16x10mm 0° Trial	AOCS0004	
14x16x11mm 0° Trial	AOCS0014	
14x16x12mm 0° Trial	AOCS0024	

Implants

Description	Part No.	GTIN	Depth	Width	Height	Lordosis
12x14x5mm 6°	AOCS6125		12mm	14mm	5mm	6˚
12x14x6mm 6°	AOCS6126		12mm	14mm	6mm	6˚
12x14x7mm 6°	AOCS6127		12mm	14mm	7mm	6˚
12x14x8mm 6°	AOCS6128		12mm	14mm	8mm	6˚
12x14x9mm 6°	AOCS6129		12mm	14mm	9mm	6˚
12x14x10mm 6°	AOCS6120		12mm	14mm	10mm	6˚
12x14x11mm 6°	AOCS6121		12mm	14mm	11mm	6˚
12x14x12mm 6°	AOCS6122		12mm	14mm	12mm	6˚
14x16x5mm 6°	AOCS6145		14mm	16mm	5mm	6˚
14x16x6mm 6°	AOCS6146		14mm	16mm	6mm	6˚
14x16x7mm 6°	AOCS6147		14mm	16mm	7mm	6˚
14x16x8mm 6°	AOCS6148		14mm	16mm	8mm	6˚
14x16x9mm 6°	AOCS6149		14mm	16mm	9mm	6˚
14x16x10mm 6°	AOCS6140		14mm	16mm	10mm	6˚
14x16x11mm 6°	AOCS6141		14mm	16mm	11mm	6˚
14x16x12mm 6°	AOCS6142		14mm	16mm	12mm	6˚
12x14x5mm 0°	AOCS0125		12mm	14mm	5mm	0˚
12x14x6mm 0°	AOCS0126		12mm	14mm	6mm	0˚
12x14x7mm 0°	AOCS0127		12mm	14mm	7mm	0˚
12x14x8mm 0°	AOCS0128		12mm	14mm	8mm	0˚
12x14x9mm 0°	AOCS0129		12mm	14mm	9mm	0˚
12x14x10mm 0°	AOCS0120		12mm	14mm	10mm	0˚
12x14x11mm 0°	AOCS0121		12mm	14mm	11mm	0˚
12x14x12mm 0°	AOCS0122		12mm	14mm	12mm	0˚
14x16x5mm 0°	AOCS0145		14mm	16mm	5mm	0˚
14x16x6mm 0°	AOCS0146		14mm	16mm	6mm	0˚
14x16x7mm 0°	AOCS0147		14mm	16mm	7mm	0˚
14x16x8mm 0°	AOCS0148		14mm	16mm	8mm	0˚
14x16x9mm 0°	AOCS0149		14mm	16mm	9mm	0˚
14x16x10mm 0°	AOCS0140		14mm	16mm	10mm	0˚
14x16x11mm 0°	AOCS0141		14mm	16mm	11mm	0˚
14x16x12mm 0°	AOCS0142		14mm	16mm	12mm	0˚

Note: The surgical instruments are part of the Addivation Medical Instrument Kit. Only use the instruments applicable to the GAIA CIS.

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