Addivation Medical Cervical Interbody System

Surgical Technique and Instructions for Use

Introduction:

The Addivation Medical Cervical Interbody System is a series of hollow titanium interbody fusion cages intended for use in the cervical spine. The cages feature open graft windows 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 Cervical Interbody System implants consist of a unique configuration of structures that are simultaneously built using the Electron Beam Melting (EBM) method of additive manufacturing. Addivation Medical Cervical Interbody System 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)
- 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 disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and imaging 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.

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 Steps:

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.

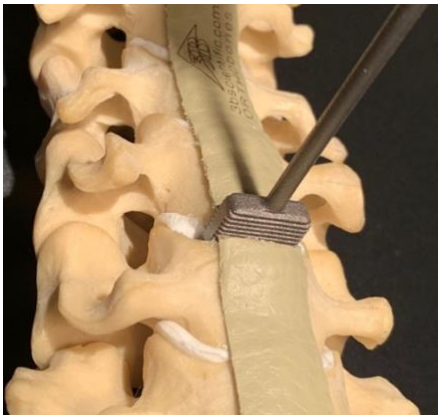
Discectomy and Endplate Preparation

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.

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.

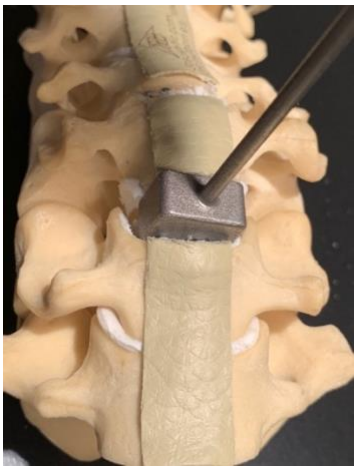


The Rasp instrument is used to symmetrically prepare the endplates

Sizing

Trial instruments are provided in a geometry that matches the implants to aid in determining the correct implant size.

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.

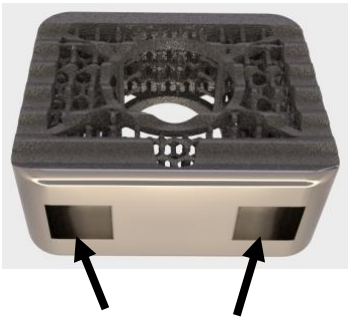


Trial instruments are used to determine the proper footprint size and implant height

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.



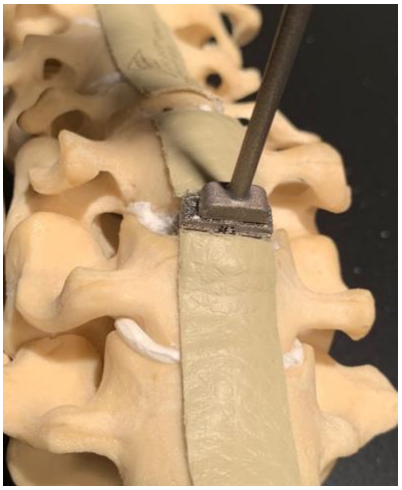
Attach the implant to the inserter by lining up the clutches of the inserter with the slots on the anterior side of the implant. Connect the implant to the inserter by rotating the knob clockwise with your thumb and index finger until the knob reaches the lock position. Note that there is a design feature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

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.

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



The tamp instrument is used to position the implant in its desired location

Supplemental Fixation:

After implantation of the interbody cage, 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.

Potential Adverse Effects

- Infection, deep and superficial
- Fracture of the implant
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Deep and superficial infections
- Allergies or other reactions to implant materials

- Loss of anatomic position with non-union or malunion with rotation or angulation
- Bone resorption or over-production
- Unknown histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Precautions

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- Surgical instruments and implants may only be used for surgeries, for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damages prior to each application i.e. use. In case of the implant or its packaging being damaged or deformed, it is not to be used.
- Only and exclusively Addivation Medical specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.
- Correct selection of the implant is extremely important. That patient's anatomy and indication will determine the size of the Addivation Medical Cervical Interbody implant to be used.
- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement of the fracture site and delay healing.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant or fracture or non-union. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.

Warnings

- This product may only be used with instruments from the respective Addivation Medical Cervical Interbody System.
- Application and use of other instruments or implants are not permitted (with exception to the ancillary plate and screw system).
- Cutting edges, blades, tips etc. can be very sensitive to false handling. Thus, these instruments must be handled with care.
- Do not re-sterilize the Addivation Medical Cervical Interbody System Implants. Re-sterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Please note that a single use device (SUD) which comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly

disposed.

- Do not reuse the Addivation Medical Cervical Interbody System implants. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- Plates and screws chosen to secure the fusion site could contact the implant. They should be manufactured from titanium to reduce the likelihood of galvanic corrosion.
- It is important that immobilization of the fusion site be maintained until healing is achieved.

MR Safety Information

The Addivation Medical Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Addivation Medical Cervical Interbody System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

How supplied

Implants are packaged sterile using EO sterilization. If either the implant or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the implant should not be used.

Instruments are non-sterile. To clean, disinfect and sterilize, follow the instructions below. Specifically follow the instructions for the Implant Trials, Handle, Tamp, Rasp, and Inserter. Only sterile implants and instruments should be used in surgery. Immediately re-sterilize all instruments removed from the sterile field before handling. To reprocess the instruments, make sure all instruments are cleaned, inspected and sterilized between uses. Always immediately clean and decontaminate all devices used in surgery. Reusable instruments can be reused if not damaged or worn and should be inspected before each use.

Recommendations for Cleaning, Disinfection and Sterilization of Instrumentations

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Addivation Medical manual surgical instruments. They are intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of reusable devices. The instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of instruments. Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR), may be directly involved in handling instruments. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

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Double wrap instruments in accordance with local procedures, using standard techniques such as those described in ANSI/AAMI ST46-1993. Be sure to sterilize in FDA approved sterilization wraps or pouches.

This information is NOT APPLICABLE to single use implants or instruments that are sold sterile and cannot be re-sterilized such as the Addivation Medical Cervical Interbody System implant.

1. DESCRIPTION AND INTENDED USE

Addivation Medical reusable surgical devices are intended for use in surgical procedures according to the Instructions for Use and Surgical techniques that accompany the implants. Reusable devices are to be cleaned, inspected, and sterilized between uses.

2. INSPECTION BEFORE USE

Reusable Devices can be used indefinitely if not damaged or worn. Device systems should be cleaned and then inspected between uses. DO NOT use broken or damaged devices. Contact Addivation Medical, LLC. for repair or replacement of damaged items. If damage or malfunction is detected, the device should not be used.

Disposable Devices should be disposed of according to hospital procedure and any applicable laws.

3. PREPARATION/GENERAL GUIDANCE FOR CLEANING

The cleaning protocol of Addivation Medical Cervical Interbody System has been validated to AAMI TIR12, AAMI TIR30 and FDA guidance documents. Verify that all instruments required for use are present in the case. For Manual Cleaning, devices should be grouped according to similar metals before subsequent processing in order to prevent galvanic corrosion. In addition, it is not recommended to use chloride containing cleaning solutions since its use has been linked to corrosion of metallic instruments, especially stainless steel.

Please also note the following:

- Disinfect and clean devices immediately after use in order to avoid device encrustations.
- Solutions used for cleaning must always be prepared in accordance with the manufacturer's instructions.
- Never use metal brushes or metal sponges for manual cleaning.
- Use a suitably sized non-metallic bristle brush for cleaning lumens, cannulations, blind holes, and cavities, making sure that every part of the inner surface can be properly accessed.
- Clean jointed instruments in closed as well as open positions.

- Disassemble instruments as far as possible before cleaning.
- Be sure to arrange the items so that the water can easily flow out of cannulations, blind holes, and cavities.
- For instruments with long or narrow lumens, standard processing should be used only if the disinfectant can flow easily through the lumens and safe rinsing is guaranteed.
- The cases/trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- After cleaning, check instruments for cleanliness (visible dirt). This especially applies to cannulated instruments or those with blind holes and crevices.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes, and other areas that are hard to access.
- Demineralized or distilled water should be used for the final rinse.

4. MANUAL CLEANING INSTRUCTIONS

The following steps should be completed in sequence. Depending upon the detergent selection, minimum processing times and temperature settings may need to be adjusted for optimal processing:

a) Prepare a neutral pH enzymatic detergent as per the manufacturer's recommendation (e.g. Enzol® prepared at 1 oz. per gallon of lukewarm deionized water complying with AAMI TIR 34).

b) Disassemble instruments to lowest level.

c) Rinse instruments under lukewarm running water to remove all gross soil. Use a soft bristled brush to aid in the brushing. Agitate the instruments under the running water. Agitation includes actuating all movable parts such as opening and closing hinges and moving the instruments around under the running water. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of instruments. Use a syringe to flush any lumens.

d) Fully immerse each device in the pre- pared detergent and allow it to soak for a minimum of two minutes.

e) After soaking the devices, scrub them using a soft bristle brush and circular strokes to remove any visible soil. Pay particular attention to all the areas where the soil could be imbedded (i.e. grooves, crevices, lumens, blind holes). Use a syringe to flush lumens and a pipe cleaner to clean lumens and holes. Perform cleaning under the surface of the prepared detergent solution to limit aerosolization of the cleaning fluid and soil, as well as for worker and environmental safety.

f) Rinse devices in lukewarm water for a minimum of one and a half (1.5) minutes to remove any detergent residuals. In accordance with Step C, agitate the instruments under the running water, being sure to actuate all movable parts, and using a sot bristled brush for internal and exterior device surfaces.

g) Prepare a neutral pH enzymatic detergent (eg. Enzol) in a sonicator, as per the manufacturer's recommendation using lukewarm water. Temperature should be 68-104 Degrees F. Fully immerse the devices in the detergent and soak for 20 minutes. Repeat as required and clean thoroughly. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the ridges are effectively cleaned. Use a small diameter brush, a syringe, or a pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.

h) After sonication, rinse the devices with running lukewarm water (use the highest grade of water available, distilled or deionized water is recommended) for three (3) minutes. Agitate the instruments under the running water, being sure to actuate all movable parts, and using a clean soft bristled brush for internal and exterior device surfaces and flush all lumens with a syringe.

i) Place units in an ultrasonic cleaner (neutral pH) neutral making sure devices are fully submerged for 10 minutes (68-104 Deg. F).

j) Rinse thoroughly for 3 minutes in warm, as delivered, hot water tap.

i) Dry the devices using a clean lint free cloth and visually examine to determine if all adherent visible soil has been removed. Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe.

j) Repeat the above cleaning procedure, if visible debris is detected.

6. INSPECTION AFTER CLEANING

Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. All movable parts, working tips and blades (scissors) should be inspected with particular care.

Packaging:

- Replace instruments in an instrument tray to contain the instruments.
- If biological or chemical indicators (BIs or Cis) are used for monitoring the performance of sterilization processes, they should be placed in the middle racks within wrapped trays.
- Double wrap instruments in accordance with local procedures, using standard techniques such as those described in ANSI/AAMI ST46-1993. Be sure to sterilize in FDA approved sterilization wraps or pouches.
- Label the contents of the wrapped tray using indelible marker or other sterilization compatible label system.

7. STERILIZATION

The validation protocols were performed in accordance with AAMI ST79:2QQ6 Steam Sterilization and Sterility Assurance in Health Care and AAMI ST77-2006 Containment Devices for Reusable Medical Device Sterilization. Be sure to sterilize in FDA approved sterilization wraps or pouches.

In accordance with our validation results, the following cycles are recommended for wrapped goods:

- Use a validated, properly maintained and calibrated steam sterilizer following the manufactures recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following cycles:
- Dynamic Air Removal Steam Exposure Temperature
    - 132C (270F) Exposure Time- 4 minutes
    - Minimal drying time- 30 minutes, Minimal cooling time- 30 minutes
- Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

* Dry time data for the shared cells is based upon the highlighted sterilization challenge set for the device set family grouping (#3).

Storage and Handling
Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

Packaging and Labeling
- Addivation Medical devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact customer service if the package has been opened or altered.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. These products are covered by one or more U.S. and international patents pending.
Printed in the USA

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