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Instructions for Use

Addivation Medical Cervical Interbody System

Description:

The Addivation Medical Cervical Interbody System (CIS) is a series of porous titanium interbody fusion cages intended for use in the cervical spine. The cage consists of an open window for bone graft containment and has serrations on the superior and inferior surfaces of the cage for fixation. The cage is 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 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) and Radel R5000
- Implant Trials- Surgical grade stainless steel (17-4 SS)
- Trial Handle – Surgical grade stainless steel (17-4-SS) and Silicone
- Tamp Instrument- Surgical grade stainless steel (17-4 SS)
- Rasp Instrument- Surgical grade stainless steel (17-4 SS)

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.

Contraindications:

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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.

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

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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 is 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.

Directions for Use

This outlines the basic procedure for device implantation and the use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of the products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. As the manufactures of this device, Addivation Medical does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. Please consult the Addivation Medical Cervical Interbody System Surgical Technique for a detailed surgical protocol.

1. Position the patient using standard positioning for anterior cervical fusion.
2. Expose the affected site using an anterior medial approach. Identify and confirm the affected disks.
3. Perform a standard cervical discectomy and decompression.
4. Remove the intervertebral disc out to the uncovertebral joints using general instrumentation such as Curettes or Rongeurs.
5. Distract the disc space using a Caspar style distractor.
6. Prepare the endplates by using rasps, standard curettes or burrs. Using the rasp, resect a minimal amount of the cartilaginous endplates to create a flat surface of bleeding bone.
7. Determine the implant size by measuring the disc space using the trials.
8. Select the desired implant size and fill the hole in the center of the implant with autogenous bone.
9. Position the anterior side of the device onto the clamp end of the Inserter. At the same time, turn the knob of the inserter clockwise to the “lock” position. Check to ensure the implant is now securely held by the inserter.
10. Place the implant in the prepared disc space using the inserter instrument. When the implant is in place, rotate the inserter knob counterclockwise to the “unlock” position to release the implant from the inserter.
11. Final placement of the implant should be slightly posterior to the anterior aspect of the vertebral bodies. Lateral and A/P radiographs may be taken to assure proper implant placement.

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12. After implantation, 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.
13. Should removal or revision of the device be determined necessary, an osteotome instrument can be used to break the interface between the bone and both superior and inferior faces of the implant. This effectively cuts the fused column of bone at the level of the boundaries of the implant. Once the fused column is completely cut, forceps or the inserter instrument can be used to remove the implant from the space.

How supplied
Implants 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 Spacer 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.

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

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Addivation Medical reusable surgical devices are intended for use in orthopaedic 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.

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STERILE EO

Rx only