

Aesculap® Implant Systems Arcadius^{XP} C Spinal System: Instructions for Use



Device Description

The Arcadius^{XP} C Spinal System is a stand alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy procedures. The system consists of PEEK cage and two bone screws. The PEEK cages are manufactured from a radiolucent material medical grade LT1 polyetheretherketone (PEEK) per ASTM F2026, with a titanium layer and a vacuum plasma spray coating (PlasmaporeXP). The Arcadius^{XP} C Spinal System implants are offered in various heights and geometrical options to fit the anatomical needs of a wide variety of patients. The Arcadius^{XP} C Spinal System implant is available in two footprints. The wide central opening holds optimal graft material. The screws are 4mm in diameter and offered in three lengths. The fixation screws and radiographic markers are manufactured of titanium alloy, (Ti6Al4V) according to ISO 5832/3.

Indications

The AIS Arcadius^{XP} C Spinal System is intended to be used as an intervertebral body fusion device as a standalone system used with the supplied bone screws and requires no additional supplementary fixation system. It is intended for spinal fusion procedures at one level in the cervical spine from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies) using autograft bone.

Patients should be skeletally mature and must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the AIS Arcadius^{XP} C Spinal System.

Materials

The materials used in the implant are listed on the packaging:

- The Arcadius^{XP} C cervical cages are made of PEEK-OPTIMA® LT1 in accordance with ASTM F2026, and coated with a pure titanium layer in accordance with ISO 5832-2 or ASTM F1580 and a vacuum plasma spray coating (PLASMAPORE^{XP}®). They contain marker pins made of titanium alloy to enable radiographic visualization for placement and follow-up evaluations.
- The bone screws and marker pins are made of surgical implant applications titanium alloy Ti6Al4V described in ISO standard 5832-3 or ASTM-F136.

The titanium bone screws are anodized with a colored oxide layer. Slight changes in coloration may occur, but do not affect the implant quality. PLASMAPORE® is a registered trademark of Aesculap AG, 78532 Tuttlingen / Germany. PEEK-OPTIMA® is a registered trademark of Invibio, Ltd Lancashire FY5 4QD / UK.

General Surgical Indications

Surgically installed implants serve to support normal healing processes. They should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.

Contraindications

Any medical or surgical condition that could preclude the potential success of the implantation. These include:

- Existing or risk of acute or chronic infections, fever/leukocytosis
- Progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation
- Severe defects of the bony structures of the spine which are a prerequisite for stable implantation of the cages
- Bone tumors in the region of the implant anchoring
- Proven or suspected allergy/foreign body reactions to implant materials
- Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities
- Systemic, metabolic and degenerative diseases
- Psychosocial problems; unwillingness or inability of the patient to follow the instructions for post-operative treatment
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Prior fusion at the level(s) to be treated
- All cases that are not listed under "Indications"

Risks

The surgical intervention involves the following potential risks:

- Neurological complications caused by overdistraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

Side-Effects and Adverse Interactions

In addition to surgery-related risks, potential complications in connection with intervertebral procedures can include, but are not limited to:

- Disassembly, bending and/or fracture of the implants or instruments
- Early or late loosening of the components
- Failure of the device to provide adequate mechanical stability
- Loss of fixation
- Implant migration/dislocation
- Malpositioning of the implant
- Subsidence of the device into vertebral body(ies)
- Foreign body reactions, allergy
- Nonunion or delayed union
- Infection

- Increase in biomechanical stress on adjacent levels
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, appearance or radiculopathy, and/or the development or continuation of pain, paralysis (complete or incomplete), pseudomeningocele, cerebral spinal fluid leakage, dysesthesia, hyperesthesia, anesthesia, paresthesia, numbness, neuroma, tingling sensation, sensory loss and/or spasms
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), reflex deficits, arachnoiditis, and/or muscle loss
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
- Spondylolisthesis, pseudoarthrosis, inadequate integration of the implant
- Changes in bone density, degenerative changes in the region of the adjacent vertebral bodies
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra)
- Hemorrhage of blood vessels, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise
- Wound necrosis or wound dehiscence
- Herniated nucleus pulposus, disc disruption or degeneration above/below the level of surgery
- Scar formation possibly causing neurological compromise around nerves and/or pain
- Bursitis
- Gastrointestinal complications
- Loss of bladder control or other types of urological system compromise
- Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
- Loss of spinal mobility or function
- Loss of intervertebral disk height due to removal of healthy bone material
- Changes of the normal spine lordosis
- Wound healing problems
- Pain or discomfort at the operative and/or bone graft donor site
- Meningitis
- Discomfort or abnormal sensations due to the presence of the device
- Limited performance
- Persistence of symptoms that were to be treated by the implantation
- Inability to resume activities of normal daily living
- Reoperation
- Death

Safety Notes

- Only patients that meet the criteria described in the indications should be selected.
- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present instructions for use.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be fully conversant with bone anatomy, including the pathways of nerves, blood vessels, muscles, and tendons.
- It is the operating surgeon's responsibility to ensure the correct combination of implant components and their implantation.
- Aesculap is not responsible for any complications arising from wrong indication, wrong choice of implant, incorrect combination of implant components and operating technique, the limitations of the treatment method, or inadequate asepsis.
- The instructions for use for individual Aesculap implant components must be followed.
- The implant components were tested and approved in combination with Aesculap components. If other combinations are used, the responsibility for such action lies with the operating surgeon.
- Do not, under any circumstances, combine implant components from different manufacturers.

- Do not use instruments belonging to another system or made by another manufacturer.
- Do not, under any circumstances, use damaged or surgically removed components.
- Implants that have been used before must not be reused.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- Post-operatively, individual patient information, as well as mobility and muscle training, is of particular importance.
- Delayed healing can cause implant breakage due to material fatigue.
- The attending surgeon decides whether implant components should be explanted, taking into account the potential risk of another surgery and the difficulties involved in the removal of an implant.
- Damage to the load-bearing structures of the implant can lead to loosening of components, dislocation, migration, and other severe complications.
- In order to promote the earliest possible detection of any problems or complications, the operation results must be followed up at regular intervals with the aid of appropriate examination procedures. A precise diagnosis requires X-rays taken in the directions anterior-posterior and medial-lateral.

Care and Handling

The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

1. PRE-CLEANING

- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.
- Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.
- Disassemble components to expose all surfaces and clean separately. Disassemble the component parts for the implant inserter, trial inserter and any other instrument with component parts. Give special attention to joints and all parts to facilitate reassembly.

2. CLEANING

Cleaning Precautions

- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

a. Manual Cleaning

- Hand wash using a medical grade, low-sudsing, protein dissolving detergent. Follow the manufacturers' directions regarding concentration, temperature, contact time and reuse.
- Totally immerse instruments during cleaning to prevent aerosolization.
- Use a large syringe or pulsating water jet to thoroughly flush all channels and cavities with cleaning solution to remove debris.
- Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

b. Ultrasonic and Mechanical Cleaning

- For ultrasonic cleaning, follow manufacturer's specifications for water level, concentration levels of cleaning agent and temperature.
- When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other.
- Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal disinfection and cleaning.

c. Rinsing

Rinse all instruments thoroughly with tap water, de-ionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal cavities and ratchets are thoroughly rinsed.

3. DECONTAMINATION

Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the *STERILIZATION* section.

- Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent's recommended directions regarding concentration, temperature, contact time and solution re-use.
- Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury.
- Completely immerse instruments in the disinfecting solution. Force solution into all areas and cavities.
- Thoroughly rinse with distilled water to remove all traces of disinfecting solution. **USE STERILE WATER ON THE FINAL RINSE.**

4. DRYING

Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, lint-free, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

5. LUBRICATION / ASSEMBLY

- Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints and movable parts. Only lubricate dry instruments.
- Do not use mineral oil, petroleum, or silicone-based products. To lubricate joints, use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Instrument Oil, JG598.
- Reassemble instruments, as necessary, before assembly into baskets or trays. Inspect instrument components for mechanical damage, pits, cracks, misalignment and corrosion. Remove stained, discolored or damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly.

Sterility

Arcadius^{XP} C Spinal System cages:

- The Arcadius^{XP} C Spinal System cages come individually packed in protective packaging that is labeled according to its contents. The Arcadius^{XP} C Spinal System cages are provided gamma-sterilized.
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiration date or whose packaging is damaged.
- Damage to implants caused by processing and resterilization! Do not reprocess or resterilize the implants.

Arcadius^{XP} C Spinal System bone screws:

- The Arcadius^{XP} C Spinal System bone screws are supplied in an unsterile condition.
- The Arcadius^{XP} C Spinal System bone screws are packaged individually.
- Store the implant components in their original packaging and only remove them from their original and protective packaging immediately prior to processing.
- Use the implant system storage devices for processing, sterilization and sterile setup.
- Ensure that the implant components in their implant system storage devices do not come into contact with each other or with instruments.
- Ensure that the implant components are not damaged in any way.

Sterilization

The Arcadius^{XP} C Spinal System screws and instruments are provided non-sterile. Sterilization is accomplished by steam. To achieve a sterility assurance level of 10^{-6} , Aesculap Implant Systems recommends the following parameters:

Sterilization Method	EXPOSURE TIME		
	Temperature	Full Cycle Time	Minimum Dry Time
Pre-Vacuum	270° F (132°C)	4 minutes	20-30 minutes

The above parameters have been validated for sterility in an Aesculap STERILCONTAINER System. The cycle times for wrapped product are based on the recommendations of the AAMI Guidelines ST79 for steam sterilization.

Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle design, and packaging/ containerization. The manufacturer's instructions must be followed for each sterilization chamber.

Application

The operating surgeon shall devise an operation plan that specifies and accurately documents the following:

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

The following conditions must be fulfilled prior to application:

- All requisite implant components are ready to hand.
- Operating conditions are highly aseptic.
- All requisite implantation instruments must be available and in working order, including specialized Aesculap implantation systems.
- All instruments must be cleaned and sterilized prior to surgery.
- The operating surgeon and operating room team are thoroughly familiar with the operating technique and with the available range of implants and instruments; information materials on these subjects must be complete and ready to hand.
- The operating surgeon is fully familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific articles 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 patient has been informed of the procedure, taking into account the information provided in the sections on indications, contraindications, side effects and interactions, and has documented his/her understanding and consent regarding the following points:

- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads and material fatigue.
- The implants can come loose or break under increased load. Factors such as the patient's body weight, their level of activity and their compliance with instructions concerning their bearing of weight or loads can influence the durability of the implant.
- 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. Physical activities must be limited and restricted, especially lifting, twisting motions and any type of sport participation.
- Corrective surgery may become necessary if the implant loosens.

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Smokers present an increased risk of bone fusion failure.
- The patient must undergo medical check-ups of the implant components at regular intervals.
- The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

Implanting the Arcadius^{XP} C Spinal System devices

The correct selection, placement and fixation of the Arcadius^{XP} C Spinal System components 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. Implantation of the Arcadius^{XP} C Spinal System requires the following steps:

- Only use Arcadius^{XP} C Spinal System instruments provided by Aesculap.
- Follow the instructions for use of the Arcadius^{XP} C Spinal System instruments and the O.R. manual.
- Select the appropriate Arcadius^{XP} C Spinal System cage size and shape according to the individual indication and preoperative planning.
- Prior to use: Unpack the Arcadius^{XP} C implants and inspect them for damage.
- Ensure that the implants are protected from being marred, nicked, scratched or notched as a result of contact with metal or abrasive objects. Alterations will result in defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Apply the preparation and implantation instruments correctly.
- Check spacer height and/or angle using the trial implants.
- Prior to inserting the cage it is recommended to fill it with bone or bone substitute
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- Confirm the anatomically suitable position and orientation of the Arcadius^{XP} C Spinal System cage.
- Select the appropriate length of bone screws.
- Insert the bone screws under X-ray control.
- Insert the bone screws until they reach the final seated position, ensuring full engagement of the two locking mechanisms.
- If a fully seated bone screw is removed from the implant, a small piece of PEEK debris from the locking rim in the locking mechanism may be present.
- Further information on Aesculap implant systems is always available from B. Braun/Aesculap or the appropriate B. Braun/Aesculap office.

WARNING

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization may occur!

WARNING

Increased risk of migration and subsidence due to over-preparation of the vertebral body endplates! Ensure that the base and cover plates of the adjacent vertebral bodies are not weakened.

WARNINGS

Inaccurate markings of the midline may result in incorrect position of the implant. Always mark the midline under X-Ray visualization. Determine the center of the vertebral disc using a midline marker under X-ray visualization.

WARNING

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, lost of fixation, pseudarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

WARNING

The coated surfaces of the Arcadius^{XP} C Spinal System cage may be damaged by improper handling! Avoid direct contact with the coated surfaces. Handle implants carefully.

WARNING

Excessive insertion forces may cause damage to the implant

WARNING

Risk of insufficient stability or implant failure due to using fewer than the two internal screw fixations provided! Apply both screws or use an additional supplemental spinal fixation system that has been cleared for use in the cervical spine, such as cervical plating systems.

WARNING

Backing out and loosening of the bone screw occurs when the screw is not fully inserted into the cage! Insert the bone screw until it is fully engaged.

WARNING

If a bone screw does not seat properly and needs to be removed, the physician should remove the cage and replace with a new cage and screw.

CAUTION

Damage to the PLASMAPORE^{XP}® cages through the use of high frequency or electrocautery surgical devices!

- Avoid using high frequency surgical devices in proximity to the implant.
- If the implant is damaged: Remove and replace the implant.

CAUTION

Based upon dynamic testing results, the physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the intervertebral body fusion device.

PRECAUTION

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

MRI SAFETY INFORMATION

The Arcadius^{XP} C Spinal 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 the Arcadius^{XP} C Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTION

Mixing unalloyed titanium, titanium alloy, stainless steel, and other cobalt alloy implants should be avoided for implants that are in contact with each other.

PRECAUTION

Components of the Arcadius^{XP} C Spinal System should not be used with components of any other system or manufacturer.

Additional Information

Please refer to the system's surgical technique for detailed implantation explanation information. To obtain a surgical technique guide, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.

MAINTENANCE AND REPAIR

If any Arcadius^{XP} C Spinal System instrument or its components require repair or maintenance, return the entire instrument set in a sturdy box with adequate foam, bubble wrap or other packaging material to protect it. Send the packaged instrument to:

Aesculap Technical Services
615 Lambert Point
Hazelwood, St. Louis, MO 63042

Instruments returned to Aesculap Implant Systems for repair 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.

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

Distributed in the U.S. by:

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