



INSTRUCTIONS FOR USE

Pegasus® Anchored Cervical Interbody Fusion Device



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

Description:

The Pegasus Anchored Cervical Interbody Fusion Device (ACI) is a cervical implant with an integrated anchor. The device is to be used with supplemental fixation, i.e. an anterior cervical plate. The implant is titanium with a PEEK radiolucent spacer and has an anchor component. An insertion tool is used to implant the device and actuate the anchor members in one step. The anchor members pierce the vertebral superior and inferior endplates simultaneously. The implant has one large chamber for packing autogenous bone graft. The implant also includes radiopaque tantalum markers for implant visualization once implanted.

Indications

The Pegasus Anchored Cervical Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Pegasus Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Contraindications:

- spinal fractures
- spinal tumor
- osteoporosis
- infection

Materials:

The spacer is manufactured from PEEK-Optima® LT1 (ASTM F2026). The anchor and ramp components are manufactured from Ti-6AL-4V ELI (ASTM F136). The radiopaque markers consist of tantalum pins (ASTM 560) that are press-fit into small holes on the posterior portion of the PEEK spacer.

Packaging:

The implant and anchor are supplied separately in sterile double packaging. The packaging prevents product contamination in normal conditions of handling and transport. It is necessary to check the integrity of the packaging before use. The ACI instrumentation is supplied non-sterile. It must be cleaned and sterilized prior to use.

Instructions for Use:

- The instructions for using the ACI and associated instrumentation are described in the ACI Surgical Technique Guide. Before implanting the ACI, the site must be carefully prepared to avoid implant subsidence or implant migration.
- Components of this system should not be used with components of any other system or manufacturer, with the exception of the anterior cervical plate. Please refer to the Pegasus Anchored Cervical Interbody Device Surgical Technique Guide for recommendations on plate and screw sizing.
- The implant must be filled with autogenous bone graft in order to create a fusion across the motion segment.

Precautions:

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical

outcome. **Please read** the Surgical Technique Guide prior to implanting this device.

- Patients who smoke have been shown to have an increased risk of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting of significant loads, or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the device. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Visual inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
- Sale of this product is restricted to physicians.

Possible Adverse Effects:

- Possible adverse effects associated with general surgery include complications from anesthesia, infection, hematoma, and death.
- Possible adverse effects associated with the implantation of the ACI implant may include: fracture of another vertebrae during placement, device breakage, device migration, material sensitivity or allergic reaction, spinal cord impingement, bone resorption, loss of disc height, soft tissue damage, damage to large blood vessels, neurological complications, trauma to nerve root or dura, and pseudoarthrosis.
- The adverse effects listed above are possible adverse effects known to potentially occur for procedures that may involve this type of implant and surgical approach.

Warning:

- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- Potential risks associated with the use of this system, which may require additional surgery, include device component failure (bending, loosening or fracture), loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, or expulsion.
- The device can break if it is subjected to increased loading associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant.
- Care should be taken to avoid interference between the anchor blades and the screws used with the required anterior cervical plate. Please refer to the Pegasus Anchored Cervical Interbody (ACI) Surgical Technique Guide for recommendations on plate and screw sizing.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it or small defects may exist which may lead to fracture of the implant.
- The Pegasus Anchored Cervical Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. The

Pegasus ACI device has not been tested for heating or migration in the MR environment.

REPROCESSING OF REUSABLE INSTRUMENTS – Important information for all Pegasus Innovation Reusable Instruments

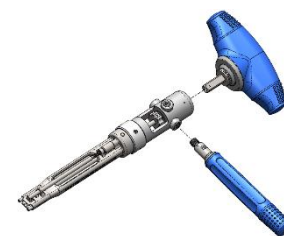
Note: Additional reprocessing instructions are required for the Pegasus Inserter, as defined below.

General Information (for all Instruments):

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated for this instrument and demonstrate that soil and contaminants have been effectively removed leaving the device free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, “Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008”.
- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 “Water for the reprocessing of medical devices, 2007” for example, RO, DI and/or distilled water.

Cleaning Instructions (for all Instruments):

- Instruments must be cleaned prior to sterilization. Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Disconnect all handles prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- Visually inspect each instrument for deterioration such as corrosion and worn components.
- Ensure that the laser markings are legible and verify that all actuating parts move freely.
- Visual inspection must be performed at each cleaning to determine if the instrument is acceptable for use. If the instrument is not acceptable for use, return to the manufacturer.



CLEANING:

PEGASUS Implant Inserter (ratcheting type inserter) PN 22930:

- Ensure areas with tight clearances are flushed and clean from visible soil. Pay close attention to the lumens (shaft & tip), all retractable features, and textured surface finishes:

- Brush & flush areas with tight clearances.
- Flush areas where debris could become trapped between interfacing features: thumb wheels and flushing ports.
- Using the T-Handle, turn the black drive screw to move it through the full range of travel. Clean both extents of travel.
- Flush and turn the two thumb wheels of the ACI Inserter.
- Ensure the Depth Indicator rod does not block the distal end flush port.
- Thoroughly flush the open end of the instrument.

Visually inspect the instrument after each step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for all Instruments (Required):

Step 1	Rinse device in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as Prolystica 2X Enzymatic or equivalent, per manufacturer’s recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using a soft bristled brush and a pipe cleaner to brush the lumen for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for hard to reach areas and repeat 3 times. (For the Pegasus Inserter: See CLEANING of the PEGASUS Inserter section for details)
Step 4	Rinse devices in DI/RO water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as Prolystica® 2X Concentrate Alkaline, per manufacturer’s recommendations and submerge and actuate device in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse device with DI/RO water to remove all detergent residues.
Step 7	Dry device with a clean, lint free cloth or filtered compressed air.

IMPORTANT: Manual Cleaning Steps are required before performing the Automatic Washer Cleaning Steps.

Automatic Washer Cleaning Steps for all Instruments

Step 1	Follow steps 1 through 5 of the Manual Cleaning Steps for Instruments.
Step 2	PreWash, cold tap water, 2 minutes.
Step 3	Enzyme wash, hot tap water, 1 minute.
Step 4	Detergent wash, hot tap water (66°C/150°F), 2 minutes.
Step 5	Rinse 2 times, hot tap water, 15 seconds to remove chemical residues
Step 6	Hot air dry (115°C/239°F) for at least 10 minutes.

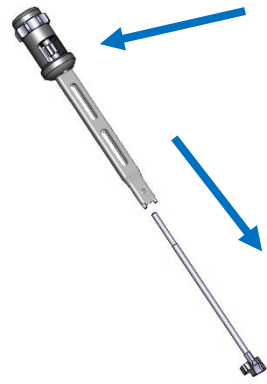
Cleaning Procedure for ACI Instrumentation

Implant Inserter (impaction type inserter) PN 22-93002:



- 1) Instruments should be cleaned initially directly after use to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- 2) The ACI Inserter must be disassembled for thorough cleaning. This is accomplished by:

- a) Turn Depth Stop Adjustment Knob continuously until Depth Stop Assembly can be removed from instrument and Remove Depth Stop Knob:



- b) Loosen and remove thumbscrew on the handle as shown below.



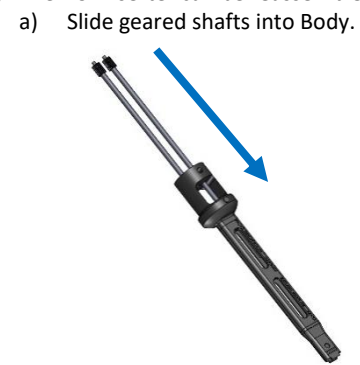
- c) Slide impactor cap and geared ring off instrument as shown below:



- d) Remove geared shafts from instrument.



- 5) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes. Thoroughly flush lumens, holes and other difficult to reach areas. Actuate any moving parts while rinsing the device.
- 6) Ultrasonically clean the device components for ten (10) minutes in a neutral pH detergent (Neutral or acceptable alternative), preferably at 45-50 kHz. Prepare the detergent according to the manufacturer's recommendations.
- 7) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes until there is no sign of blood or soil in the rinse stream. If blood or soil are present rinse for an additional three minutes until is no sign of blood or soil in the rinse stream.
- 8) Repeat steps 4 and 5 with a freshly prepared detergent solution.
- 9) Dry the disassembled device components with a clean, absorbent, disposable, lint-free cloth.
- 10) Repeat this cleaning procedure if the devices appear to be soiled after initial cleaning.
- 11) The ACI Inserter can be reassembled using the following steps:



- b) Slide the geared ring and impactor cap into body. Secure with thumbscrew (not shown).



- c) Place the Depth Stop Assembly through the Guide and thread it into the Depth Stop Knob.



STERILIZATION (for all Instruments and Implants):

- The ACI implant and anchor are supplied sterile, having been irradiated by gamma radiation with a minimum dose of 25 kGy.
- The product is sterile for a period of 3 years provided that the packaging stays intact.
- The ACI implant and anchor are single use and should not be resterilized.
- All ACI surgical instruments are supplied NON-STERILE and in an instrument tray. The instruments should be steam sterilized in the ACI sterilization tray using the following validated cycle:

Table - 1 Sterilization Parameters for SET ID: PEGINT

Method:	Steam
Cycle:	Pre-vacuum
Temperature:	132°C (270°F)
Exposure Time:	4 min full cycle
Drying Time:	20 Minutes

Sterilization Notes:

- 1) The cycle conditions noted above were validated and are considered adequate to achieve an SAL of 10⁻⁶.
- 2) These parameters are consistent with ANSI/AAMI ST79:2010/A2:2011 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

FDA cleared wraps are recommended when sterilizing ACI instrumentation. Only sterile instruments should be used in surgery. Instruments should be properly cleaned and sterilized prior to use. Soiled instruments must be properly cleaned prior to sterilization to ensure the product is sterile.

STERILIZATION/RESTERILIZATION OF INSTRUMENTS IN ALPHATEC CASES AND TRAYS:

- All instruments are provided non-sterile and must be cleaned and sterilized before use. Instruments must be sterilized using the appropriate cycle parameters in the tables below.
- Alphatec perforated trays have been validated to achieve sterility assurance level (SAL) of 10⁻⁶ using FDA cleared sterilization accessories (container and filters). FDA cleared reusable or paper filters should be used to achieve and maintain sterility after processing.
- Alphatec perforated container/tray configurations have also been validated to achieve a sterility assurance level (SAL) of 10⁻⁶ using FDA cleared sterilization wrap. Perforated container/tray configurations must be double wrapped to allow steam to penetrate and make direct contact with all surfaces.
- Do not stack trays during sterilization.
- Instrument sets have been validated in standard configurations. **No additional items should be added to the set for sterilization.**

Table - 2 Sterilization Parameters for SET ID: PEG2INT

Method:	Steam
Cycle:	Pre-vacuum
Minimum Temperature:	132°C (270°F)
Minimum Exposure Time:	4 Minutes
Minimum Drying Time:	30 Minutes
Minimum Cool Down Time:	15 minutes

Sterilization Notes:

- These parameters are consistent with ANSI/AAMI ST79:2010/A2:2011 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."

Storage & Transport:

There are no special storage or transport conditions.

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INS-080, Revision E, 2022/12/09 (Based on LA-22-0004 rev. G)

- 3) Submerge the disassembled components and the anchor driver in an enzymatic detergent safe for use with metal devices. Prepare the detergent according to the manufacturer's recommendations. Soak the device(s) for twenty (20) minutes in the protein solubilizing detergent.
- 4) Thoroughly scrub the submerged device components with a soft bristled brush until all visible soil has been removed, for at least a period of one (1) minute. Agitate the device(s) in the solution while scrubbing and actuate any moving parts. Lumens or other hard to reach areas should be cleaned with a soft-bristled brush.