Ascendant™ PC Cervical Spacer System
Instruction for Use

STERILE R Implants | Implants | Instruments | Rx only

Choice Spine
400 Erin Drive
Knoxville, TN 37919

General Description:

The Ascendant™ PC Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with CP titanium coating and tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous bone graft material.

Indications for Use:

The Ascendant PC Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (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 Ascendant PC Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Contraindications:

Contraindications for the Ascendant PC Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity
3. Pregnancy
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
8. Suspected or documented material allergy or intolerance
9. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
10. Patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
11. Any case not needing an autogenous bone graft and fusion
12. Any condition not described in the Indications for Use
13. Prior fusion at the level(s) to be treated

Warnings and Precautions:

The Ascendant PC Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

The Ascendant PC Cervical Spacer System is not intended to be the sole means of spinal support. This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. Autogenous bone grafting must be part of the spinal fusion procedure in which the Cervical Spacer System is used. Use of this product without an autogenous bone graft may not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. Based on fatigue testing results, when using the Ascendant PC Cervical Spacer System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Preoperative:

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Longevity of the implant depends on the weight and activity level of the patient, patient mortality, or need for component replacement secondary to patient weight and activity level.

Only patients that meet the criteria described in the indications should be selected. Patient conditions such as those addressed in the contraindications should be avoided.

An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should verify that all parts and necessary instruments are present before the surgery begins.

The Ascendant PC Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. The Ascendant PC Cervical Spacer System has not been tested for heating or migration in the MR environment.

Intraoperative:

The instructions in any available applicable surgical technique should be carefully followed.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and the graft material must extend from the upper to the lower vertebrae to be fused.

It is recommended to use an imaging system to verify that the implant is properly placed and correctly aligned within the disc space. Note that the convex version has a pronounced radial dome on the superior side. There is an arrow on the posterior end of the device to indicate which side is domed. The implant should be placed such that the arrow points to the superior side of the disc space (i.e., cephalad).

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Ascendant PC Cervical Spacer System must not be used with components from any other system or manufacturer

Postoperative:

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important. It is recommended that regular, long-term postoperative follow-up be undertaken to detect early signs of component wear and to consider the course of action to be taken if such events occur.

Periodic x-rays should be taken to detect evidence of positional changes, failed fusion, and/or device fracture. In such cases, patients should be closely monitored, and the benefits of revision surgery should be considered in order to avoid further deterioration.

All patients should be instructed on the limitations of the device and the possibility of subsequent surgery. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the autogenous bone graft healing process.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Ascendant PC Cervical Spacer System components should ever be reused under any circumstances.

Potential Complications and Adverse Effects:

Potential complications and adverse effects include, but are not limited to:

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Non-union (pseudarthrosis), delayed union, mal-union
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
8. Misalignment of anatomical structures or loss of spinal mobility
9. Autogenous bone graft donor complications including pain, fracture or wound healing problems
10. Atelectasis
11. Retropulsion of graft
12. Cessation of any potential growth of the operated portion of the spine
13. Injury to the neck, including the esophagus, trachea, carotid artery, larynx, or laryngeal nerves
14. Early or late hoarseness, dysphagia, or dysphonia
15. Vascular damage resulting in excessive bleeding
16. Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
17. Bone loss due to resorption or stress shielding
18. Death

Additional surgery may be necessary to correct some of these potential adverse effects.

How Supplied:

STERILE R The Ascendant™ PC Cervical Spacer System devices are supplied "Sterile" (gamma radiation) with SAL of 10^{-6} and intended for single use only. Never resterilize an implant. Resterilization may adversely affect implant materials and result in premature failure.

Cleaning and Decontamination:

All instruments are supplied to the health care facility clean but non-sterile. All instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Implants that have been implanted and then removed must be discarded. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, certain instruments may require dismantling before cleaning.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

Recommended Cleaning:

The terms "Steris 444", "Enzol® and Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz. per 1 gal. Water
Wash 1	2:00	60°C	Prolystica® 2x conc. Neutral at 1/8 oz. per 1 gal. water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer and visually inspect for soil. Repeat if necessary

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzo® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner and sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner and thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel and filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth and filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities. DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Inspection:

The implants should be inspected prior to implantation. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

Sterilization:

Choice Spine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used, but should be validated according to hospital practices and procedures):

Steam Sterilizer Type: Pre-vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use

only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used, but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Note: The inserter (05-099-01-2000) and inserter shaft (05-099-01-2006) are intended to be assembled during surgery and disassembled prior to cleaning and sterilization.

Figure 1 - Assembled Inserter and Inserter Shaft

Disassemble the assembly by pulling the knob of the inserter shaft and removing it from the inserter.

Figure 2 – Disassembled Inserter and Inserter Shaft

Storage and Handling:

Implants should be stored in their original, sealed packaging in clean, dry conditions. This packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for seal integrity. If the device has been opened, damaged or adulterated in any way, it must not be used and should be returned to Choice Spine. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Patient Education:

It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on Choice Spine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these Choice Spine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Device Retrieval Efforts:

Should it become necessary to remove any or all of the Ascendant™ PC Cervical Spacer System components, please call Choice Spine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Caution:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Information:

Some components may not be currently available. Please contact your Choice Spine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights, and pending and registered trademarks are property of Choice Spine. For more information on a specific product or trademark, please contact your local Choice Spine representative.

See www.choicespine.com/patents.html for patent information.

For product complaints please contact:
Choice Spine, LP
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:
Choice Spine, LP
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333 or fax: 865-588-4045

Product Complaints:

Any dissatisfaction with the product quality, labeling, or performance should be reported to Choice Spine immediately by the customer or health care provider. Furthermore, Choice Spine should be notified immediately of an implant malfunction by telephone, fax, or written correspondence. When filing a complaint, the name, part number, and lot number of the part should be provided along with the name and address of the person filing the complaint.

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European medical devices
	Authorized representative in the European Community