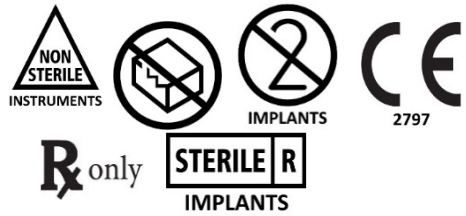
Ascendant® Cervical Spacer System
Instruction for Use



ChoiceSpine, LLC
400 Erin Drive, Knoxville, TN 37919
USA

General Description:
The Ascendant Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetherkeytone) implant cage with 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 and/or allogenic bone graft material. The Ascendant Cervical Spacer System is intended to be used with supplemental fixation (i.e., an anterior cervical plate).
Instruments used for insertion of the implants are made of 17-4 SS per ASTM A564/A564M or ASTM A693.

Indications for Use:
The Ascendant 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 Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous 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 levels may be treated with the device.

Contraindications:
Contraindications for the Ascendant 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 lifestyle may interfere with their ability to follow post-operative instructions
11. Any case not needing an autogenous and/or allogenic 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 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 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 and/or allogenic 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 and/or allogenic 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 Cervical Spacer System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system.

MR Magnetic Resonance Environment
MR Conditional: (implants only)
Non-clinical testing has demonstrated that the Ascendant Cervical Spacer System devices are MR conditional. A patient with these devices made of only PEEK and tantalum markers can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends radially up to 0.5cm and 0.7cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a gradient echo pulse sequence in a 3.0T MR 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.

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, autogenous and/or allogenic bone graft should be used. Autogenous and/or allogenic bone graft 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 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 ChoiceSpine 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 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.

Intended Clinical Benefit:

The intended benefit is to establish segment stability, directly addressing patient symptoms associated with spinal complications.

How Supplied:

STERILE R The Ascendant Cervical Spacer System implant devices are supplied "Sterile" (gamma radiation) with SAL of 10^{-6} and intended for single use only. The sterility can only be assured if the packaging is intact. Do not use this device if the sterile packaging has been opened or damaged. Contact your local sales representative or distributor for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse. Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours.

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.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected, and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

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 reach 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 & 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 & around cracks, crevices, & 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, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & 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 & around cracks, crevices, & 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, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & 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 & 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.

Sterilization:
ChoiceSpine 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.

Steam Sterilizer Type: Pre-vacuum
Temperature: 134°C
Duration: 3 minutes
Drying Time: 60 minutes

All devices are to be wrapped in two-layers of 1-ply polypropylene wrap (Kimguard KC400 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

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 ChoiceSpine. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging. Instrument and Implant disposal should follow local hospital disposal instructions, or the explanted implants may be returned to ChoiceSpine for disposal.

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.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the Ascendant® Cervical Spacer System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Manual:
The ChoiceSpine Ascendant Cervical Spacer System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

Product Lifetime:
The intention of the spinal implants included in this submission are to provide short-term stability while fusion occurs. The implant devices are mechanically tested in static and dynamic loading. Dynamic testing to 5,000,000 cycles is intended to represent the number of cycles experienced by a patient over a two-year period based on a moderate activity level. Within two-years of implantation, fusion is expected to occur which would alleviate the need for the implants to withstand loading. The minimum expected fusion expectancy would be one year therefore the lifetime range of our devices is one to two years. The device is intended to remain in the patient for the lifetime of the patient if fusion occurs.

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

Product Complaints:
Any dissatisfaction with the product quality, labeling, or performance should be reported to ChoiceSpine immediately by the customer or healthcare provider. Furthermore, ChoiceSpine 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.

Some components may not be currently available. Please contact your ChoiceSpine 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 ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.
Summary of Safety & Clinical Performance and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed
The Basic UDI for this system is 084099610350060GW.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located.

For product complaints please contact:
ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Telephone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:
ChoiceSpine, LLC
Sales Support
400 Erin Drive
Knoxville, TN 37919
Telephone: 865-246-3333 or fax: 865-588-4045
salessupport@choicespine.com

EC REP

Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
Netherlands

Symbol Legend:

Note: The symbol legend includes all symbols relative to ChoiceSpine portfolio. All the applicable symbols will either appear on the label or the IFU**.**

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
	MR Conditional
	Unique Device Identification
	Medical Device