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 compliance, and the correct replacement segment secondary to patient weight and activity level. Only patients that meet the criterion described in the indications should be selected. Patient conditions such as those addressed in the contraindications should be avoided.

An adequate inventory of supplies is available at the time of surgery, including the appropriate instrumentation and supplies necessary for the procedure. 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 procedure 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 these structures may not only cause functional loss but also may cause permanent neurologic deficit. To assure proper fusion before and around the location of the instrumentation, autogenous and/or allogeneic bone should be used. Autogenous and/or allogeneic bone must be fitted to the bony surface 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 device may appear narrow in the frontal projection. Periodic x-rays should be taken to detect evidence of positional changes, failures, and/or 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 non-steroidal anti-inflammatory activities, especially lifting and pulling motions and any type of sport participation. Patients should be advised of their inability to bend at the point of fusion and to avoid compression forces to the neck and extremities. The patient should be advised not to smoke or consume alcohol during the preoperative instructions.

If a non-unions develop or the components loosen, bend, and/or break, the device(s) should be removed and/or revised immediately before serious injuries occur. Failure to immediately a delayed or nonunion of bone will result in excessive and repetitive 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 implant materials in the Spinal System components should ever be reused under any circumstances.

Potential Complications and Adverse Effects:

Potential surgical and adverse effects include, 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 (allograft) reaction to the implants
4. Infection
5. Union (nonunion), delayed union, non-union
6. Failure of the fusion to occur, including paralysis (completely or incomplete), radiculopathy, dysphasia, hyperesthesia, anesthesiac, paraplegia, development or continuance of pain, numbness, paresthesia, weakness, spasticity, chronic disuse atrophy, dural rashes, neuropathy, neurological deficits (transient, permanent, or delayed), or other neurologic deterioration
7. Fatigue fracture, hemmorhage, seroma, serositis, edema, strikes, excessive bleeding, pleuritis, wound necrosis, or wound dehiscence
8. Malalignment of anatomical structures or loss of spinal mobility
9. Autogenous bone graft donor complications including pain, infection, wound healing problems
10. Atelectasis
11. Rupture of graft
12. Separation of any potential growth of the operated portion of the spine
13. Stenosis of the neck, including the esophagus, trachea, cardiac artery, bronchus, or larvalgym nerves
14. Early or late hoarseness, dysphagia, or dysphonia
15. Pulmonary, vascular, myocardial, or other major complications
16. Fracture, damage, degenerative changes or instability of any portion of the instrumentation
17. Bone loss due to resection or stress shielding
18. Death

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

How Supplied:

STERILE: The Ascendant PC Cervical Spinal System devices are supplied sterile. Sterile pack contains the device(s) with sterile bag. Keep intact and for single use only. Never re-sterilize 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 practice. The instrument and any damaged, soiled and contaminated devices, particularly instruments; these solutions should not be used. Also, certain instruments may require disinfecting before cleaning.

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

These devices are packaged in a convenient, autoclave. All devices must be carefully packaged in a manner that allows for easy access to and use of the appropriate methods below. Where applicable, instruments should be disassembled, washed, and disinfected before autoclaving. All devices must be placed back into the case and prior to steam sterilization.

Recommended Cleaning:

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

Automated Cleaning:

For instruments under cool running tap water (< 5 °C) to remove gross soil. Use a sterile syringe to flush water through and around cranks, crevices, and hard to reach areas.

Use a soft brush as needed to remove soil, paying close attention to threads, crevices, and hard to areas.

2. Transfer instrument(s) into a STERIS 444 washer with the following programmed settings and then run the instrument(s) to assist in drainage. Motor speed: High

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time (min)</th>
<th>Temperature</th>
<th>Detergent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash 1</td>
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<td>Hot Tap Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 1</td>
<td>3:00</td>
<td>Hot Tap Water</td>
<td>Enzol® at 1 oz per gal</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>0:00</td>
<td>Cold Tap Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Drying</td>
<td>10:00</td>
<td>115 °C</td>
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</tr>
</tbody>
</table>

3. Remove instrument(s) from washer and visually inspect for soil.

Mechanical Cleaning (Ultrasound):

7. Prepare the ultrasonic cleaner with an Enzol® solution of one ounce (1) per gallon of warm tap water (< 5 °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 ion-free deionized (RO/DI) water for at least one (1) minute

10. Dry instrument(s) using a clean, soft towel and filtered, warm air.

11. Visually inspect for soil. Repeat if necessary.

Maintenance 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 cranks, crevices, and hard to reach areas.

2. Prepare Enzol® solution of one ounce (1) per gallon of warm tap water (< 5 °C)

3. Fully immerse instrument(s) in the detergent for at least one (1) minute

4. Use a soft brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.

5. Use a sterile syringe to flush disinfectant through and around cranks, crevices, and hard to reach areas.

6. Remove instrument(s) from detergent and thoroughly rinse with reverse ion-free deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to flush water through and around cranks, crevices, and hard to reach areas.

7. Dry instrument(s) using a clean, soft towel and filtered, pressurized air

8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

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


Before using instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are disassembled, 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:** 132°C
**Duration:** 4 minutes
**Drying Time:** 40 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap (Kingsguard K500 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

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.

**Patient Education:**
It is essential to provide preoperative instructions to the patient. The patient must 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.

**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.

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

**Limitations and Restrictions:**
Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine 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 ChoiceSpine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

**Surgical Technique Manual:**

**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 any 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 choicepine.com for more information.
See choicepine.com/patents/ for patent information.

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

For additional product information please contact:
Choicepine, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919

Phone: 865-246-3333 or fax: 865-588-4045

**Symbol Legend:**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<td><img src="image.png" alt="Symbol" /></td>
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<td><img src="image.png" alt="Symbol" /></td>
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<td><img src="image.png" alt="Symbol" /></td>
<td>Use by</td>
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<tr>
<td><img src="image.png" alt="Symbol" /></td>
<td>Manufacturer</td>
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<tr>
<td><img src="image.png" alt="Symbol" /></td>
<td>Date of manufacture</td>
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<td>Federal law (USA) restricts this device to sale by or on the order of a physician</td>
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<td><img src="image.png" alt="Symbol" /></td>
<td>Non-Sterile</td>
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<td><img src="image.png" alt="Symbol" /></td>
<td>Authorized representative in the European Community</td>
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</tbody>
</table>

**Definitions:**
- **Non-Sterilized by irradiation**: The device is manufactured under clean conditions and may be contaminated. This device is not sterilized by irradiation.
- **Sterilized by irradiation**: The device is manufactured under clean conditions and may be contaminated. This device is sterilized by irradiation.