CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments single use only.

Description:
The Phenix™ Cervical Interbody is a cervical interbody fusion device that is implanted from the anterior approach. The device is designed to fit within the outer cortex of cervical spine vertebrae. It is to be packed with autogenous bone graft to facilitate fusion. It is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

Indications for Use:
The Phenix™ Cervical Interbody is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Phenix™ Cervical Interbody implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Contraindications include, but are not limited to:
- An active infection
- Suspected or documented allergy to polyetheretherketone or tantalum
- Severe osteoporosis
- Severe instability at the implanted level

Precautions:
A successful result is not always achieved in every surgical case. Surgeons should not implant the Phenix™ Cervical Interbody until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the Phenix™ Cervical Interbody Surgical Technique Manual for more information on proper implantation technique.

Possible Adverse Effects:
Possible adverse events or complications associated with the Phenix™ Cervical Interbody may include, but are not limited to:
- Implant breakage
- Implant migration
- Revision, removal or supplemental fixation of original implant
- Failure to relieve symptoms
- Dural tear
- Nerve damage leading to decrease or loss of sensory and/or motor function, or paralysis
- Dysphagia
- Pseudarthrosis
- Vocal paresis
- Vertebral body damage
- Degeneration at adjacent level
- Anesthesia or other drug reactions
- Incision related issues
- Bleeding, significant blood loss
- Pneumonia
- Thrombophlebitis
- Heart attack
- Nerve or soft tissue damage
- Death
Material Specification: The Phenix™ Cervical Interbody is manufactured from polyetheretherketone (PEEK) per ASTM F2026 and tantalum per ASTM F560. No warranties, expressed or implied, are made.

Packaging: Packages for each device should be intact and sterile upon receipt. Damaged packages or products should not be used and should be returned to SPINAL ELEMENTS.

Sterilization:
Products not clearly marked as sterile should be assumed non-sterile.

For Sterile Implants and Instruments:
Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by SPINAL ELEMENTS. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Implants supplied sterilized from SPINAL ELEMENTS must not be re-sterilized.

For Non-Sterile Implants and Instruments:
Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

Product Complaints: Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of SPINAL ELEMENTS or who has any complaints about SPINAL ELEMENTS products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the sales representative, distributor, or SPINAL ELEMENTS customer service. Further, if any of the devices, instruments or components ever malfunction, (i.e. do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately. If any SPINAL ELEMENTS product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Manufacturer: SPINAL ELEMENTS, 3115 Melrose Dr., Suite 200 Carlsbad, CA 92010 · U.S.A. · 760.607.0121
Recommended Sterilization Procedures for Phenix™ Cervical Interbody Instrumentation and Implants Provided Non-Sterile:

Manufacturer: SPINAL ELEMENTS

Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments

| CAUTIONS: | The Phenix™ Cervical Interbody system components provided NON-STERILE should be cleaned and sterilized before use. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used. Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents. |
**Phenix™ Cervical Interbody IMPLANTS** are single use. Therefore these guidelines are not intended for **USED** Phenix™ Cervical Interbody spinal implants or **DISPOSABLE**, single use instruments.

The Phenix™ Cervical Interbody has not been evaluated for safety and compatibility in the MR environment. The Phenix™ Cervical Interbody has not been tested for heating or migration in the MR environment.

**Limitations on Reprocessing:**
Repeated processing has limited effect on **REUSABLE** instruments.
End of life is normally determined by wear and damage due to use.

**INSTRUCTIONS**

**Point of use:**
Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.

**Preparation for decontamination:**
Disassemble all components to provide maximum exposure for cleaning.

**Cleaning - Automated**
Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.

**Cleaning - Manual**
1. Disassemble all components before cleaning.
2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush).
3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50kHz.
5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components.
6. Repeat the sonication and rinse steps above until all visible contamination has been removed.
7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

**Disinfection:**
Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

**Maintenance, inspection, and testing:**
Carefully inspect each device to ensure that all visible blood and soil have been removed.
Inspect lumens to confirm that all foreign material has been removed.
Visually inspect for damage and/or wear.
Note: If any damage or wear is noted that impairs the function of the instrument, contact your SPINAL ELEMENTS representative for a replacement.

<table>
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<th>Packaging:</th>
<th>This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.</th>
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| Sterilization: | Visually inspect all components for any remaining debris prior to sterilization.  

The Phenix™ Cervical Interbody system components provided **NON-STERILE** should be autoclave sterilized using the sterilizer manufacturer’s instructions and the institution’s procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.  

**Sterilize utilizing a pre-vacuum steam autoclave for a minimum of 10 minutes at 270°F (132°C.).**  

The 10 minute, 270° pre-vacuum steam sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature). |
| Drying: | A minimum drying time of 20 minutes, after sterilization, is recommended.  

Drying times may vary according to load size and should be increased for large loads.  
Dry, thoroughly and promptly, after both cleaning and sterilization. |
| Storage: | Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature. |

The instructions provided above have been validated by SPINAL ELEMENTS as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.