

Phenix™ Cervical Interbody System PACKAGE INSERT

This package insert covers the Spartan® S3 Facet Screw System and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

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

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

- An active infection
- Suspected or documented allergy to polyetheretherketone or tantalum
- Severe osteoporosis
- Severe instability at the implanted level

WARNINGS

Implants and instruments are provided non-sterile. Instruments must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

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

SINGLE USE

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death. All implants are single use.

STERILITY

All devices provided sterile have been gamma irradiation sterilized and are for single use only. Do not re-sterilize sterile devices. All devices provided non-sterile must be sterilized prior to use. Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by Spinal Elements.

SHELF LIFE

The product expiration date is indicated by the hourglass symbol on the product label. Caution: Do not use sterile devices if the packaging providing the sterile barrier has been compromised. Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to Spinal Elements.

CLEANING AND MAINTENANCE**GENERAL INFORMATION**

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments. All devices provided non-sterile must be cleaned and sterilized prior to use. Do not clean devices provided sterile.

Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

Spring-Loaded Awls should be disassembled before cleaning by compressing the button and removing the external shaft from the handle. Follow the cleaning instructions listed in the Manual Surgical Instruments section of this insert. Pay special attention to the lumens of the external shafts of disassembled instruments and all guide sleeves.

An instrument lubricant should be applied to the engagement collar of AO Quick Release Handles after cleaning.

An instrument lubricant should be applied to all hinged instruments after cleaning.

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.

Disassemble all components to provide maximum exposure for cleaning.

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.

Caution: 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. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

INSTRUCTIONS

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

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.

STERILIZATION

Phenix™ Cervical Interbody system implants are supplied sterile using gamma irradiation.

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

INSTRUCTIONS

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.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	270°F (132°C)	10 minutes	20 minutes

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAM ST 79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10⁻⁶. The Pre-Vacuum, 270°F (132°C) 10-minute 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).

Information

-  REF Catalog Number
-  MAT Material
-  LOT Batch Code
-  QTY Packaged Quantity
-  Manufacturer
-  Date of Manufacture
-  Caution, Consult Accompanying Documents
-  Do Not Re-Use
-  STERILE R Sterilized using irradiation
-  Use-by date
-  NON-STERILE Device Not Sterile
-  Rx Only Prescription Only
-  Instruction for Use are provided electronically at ifu.spinalelements.com

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CAUTION: Federal law (USA) restricts these devices for sale by or on the order of a physician.