ZEUS® INTERVERTEBRAL BODY FUSION DEVICES (ZEUS A, C, D, L, P, O, T, V)

This package insert covers the Zeus Intervertebral Body Fusion Devices 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 Zeus® Intervertebral Body Fusion Devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various fixed heights and shapes for placement in the cervical or lumbar spine. There are different cages designed for specific regions of the spine and approaches to the spine. Each cage has a hollow center to allow placement of autograft inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion. These devices are made from either titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3, PEEK (polyetheretherketone) radiolucent material with embedded tantalum x-ray markers conforming to ASTM F2026 and ASTM F560.

Spinal Elements’ instruments are manufactured from various stainless steels, titanium, aluminums, and polymers. All materials used have a history of use in such instruments. All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

INDICATIONS
Zeus® Cervical (Zeus-C®)/ Zeus Cervical (Zeus-D) Intervertebral Body Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Zeus® Cervical (Zeus-C®)/ Zeus Cervical (Zeus-D) Intervertebral Body Fusion Devices are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone and supplemental fixation. Patients should have at least six (6) weeks of nonoperative treatment prior to treatment with an intervertebral cage.

The Zeus® Lumbar Intervertebral Body Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. The Zeus® (A, T, P, L, O) are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS:
1. Spondylolisthesis higher than grade I
2. Reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
3. Fractures
4. Tumors
5. Scoliosis
6. Active infection
7. Allergy to Titanium, tantalum or PEEK
8. Signs of local inflammation
9. Fever or leukocytosis
10. Morbid obesity
11. Pregnancy
12. Mental illness
13. Suspected or documented allergy or intolerance to composite materials.
14. Any case not needing a fusion.
15. Any case not described in the indications.
16. Any patient unwilling to cooperate with postoperative instructions.
17. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
18. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
19. Spondylolisthesis unable to be reduced to Grade 1.
20. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
21. Any case that requires the mixing of metals from two different components or systems.
22. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
23. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
24. Prior fusion at the level to be treated.
25. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.

Additional contraindications for the Zeus-L® Device include but are not limited to:

- Symptomatic level at L5-S1
- Lumbar deformities with more than 30° of rotation
- Retroperitoneal scarring on both left and right sides (e.g. due to abscess or prior surgery)
- Need for direct nerve decompression through the same approach.

**WARNING**

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.

MAGNETIC RESONANCE ENVIRONMENT
Zeus Intervertebral Body Fusion Devices System have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent CSF leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
13. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
14. Hemiated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Non-union (pseudo-arthrosis), delayed union, mal-union.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Inability to perform the activities of daily living.
19. Death.

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

PREOPERATIVE MANAGEMENT
1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device’s indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.
INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
5. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

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.

Implants that have directly come in contact with the patient or bio-contaminants should be discarded. Separate inserts for implants from the instrument tray prior to and during any processing.

CLEANING AND MAINTENANCE

All devices must be free of packaging material prior to reprocessing. All instruments must be free of bio-contaminants prior to reprocessing. 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.
### CAUTIONS:

The Zeus® Intervertebral Body Fusion systems 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.

All Zeus® Intervertebral Body Fusion IMPLANTS are single use. Therefore, these guidelines are not intended for USED Zeus® spinal implants or DISPOSABLE, single use instruments.

The Zeus® Intervertebral Body Fusion System has not been evaluated for safety and compatibility in the MR environment. The Zeus® Intervertebral Body Fusion System 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 ultrasonic 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.
<table>
<thead>
<tr>
<th><strong>Maintenance, inspection, and testing:</strong></th>
<th>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.</th>
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<tbody>
<tr>
<td><strong>Packaging:</strong></td>
<td>This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.</td>
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<tr>
<td><strong>Sterilization:</strong></td>
<td>Visually inspect all components for any remaining debris prior to sterilization. The Zeus® Intervertebral Body Fusion 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. Zeus-A® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) Zeus-C®/ Zeus-D system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) Zeus-T® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) Zeus-P® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) Zeus-V® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) Zeus-L® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 20 minutes</strong> at 270°F (132°C.) Zeus-O® system components should be sterilized utilizing a pre-vacuum steam autoclave for a <strong>minimum of 4 minutes</strong> at 270°F (132°C.) The 10-minute, 270°C 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).</td>
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<tr>
<td><strong>Drying:</strong></td>
<td>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.</td>
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<tr>
<td><strong>Storage:</strong></td>
<td>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.</td>
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</table>

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.
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Information

Catalog Number

Material

Batch Code

Packaged Quantity

Manufacturer

Date of Manufacture

Caution, Consult Accompanying Documents

Do Not Re-Use

Device Not Sterile

Instruction for Use are provided electronically at ifu.spinalelements.com

Rx Only

Prescription Only

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Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements’ devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

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