

Zavation	LABELING FOR THE Z-LINK_{PC} SYSTEM	LBL-010 Rev 2

Package Insert

Z-LINK_{PC} System

Device Description: The Z-LINK_{PC} System is a temporary, titanium alloy (Ti-6AL-4V ELI per ASTM F136), multiple component system comprised of a variety of non-sterile, single use implantable components. The system consist of polyaxial screws, hooks, rods, cross-connectors, rod connectors, offsets and cap screws. The components are available in a variety of lengths and sizes in order to accommodate patient anatomy.

Intended Use: The Z-LINK_{PC} System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Z-LINK_{PC} System may be connected to the Zavation Spinal System using rod connectors and tapered rods.

Materials: The Z-LINK_{PC} System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

Contraindications: Contraindications include, but not limited to: The Z-LINK_{PC} System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget’s disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

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Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- Infection
- Vertebral body fracture at, above, or below the level of surgery
- Loss of neurological function, including paralysis (complete or incomplete)
- Non-union, delayed union
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Hemorrhage
- Cessation of any potential growth of the operated portion of the spine
- Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:

- Single use only
- Non-sterile, the rods, polyaxial screws, hooks, locking screws, transverse bars and instruments are sold non-sterile, and therefore, must be sterilized before each use
- The polyaxial screws is not intended for attachment or fixation to the thoracic (T4-T12) or lumbar spine.
- Excessive torque applied to the screws when installing the screws may strip the threads in the bone
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
- Do not reuse implants; discard used, damaged, or otherwise suspect implants
- The Z-LINK_{PC} System components should not be used with dissimilar metals.
- The Z-LINK_{PC} System has not been evaluated for safety and compatibility in the MR environment.
- The Z-LINK_{PC} System has not been tested for heating or migration in the MR environment.
- Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would

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compromise the placement of lateral mass of pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

-Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

Implant Selection:

The selection of the implant for each patient is crucial to the success of the procedure. Metallic surgical 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 metal 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.

Preoperative:

- Carefully screen the patient, choosing only those that fit the indications described above
- Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
- An adequate inventory should be available at surgery than those expected to be used
- All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need

Intraoperative:

- Instructions should be carefully followed
- Extreme caution should be used around the spinal cord and nerve roots
- The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct
- Bone grafts must be placed in the area to be fused such that the grafts fits snugly against the upper and lower vertebral bodies
- Before closing soft tissue, check each screw to make sure that none have loosened

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Postoperative:

- Detailed instructions should be given to the patient regarding care and limitations, if any
- To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process
- The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred
- The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and should be removed

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):

For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays as long as the inspection criteria provide below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.	
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.	
1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.	
2-Containment and transportation: Avoid damage and minimize time before cleaning	
3-Preparation for cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills, taps and awl that are left in the drill guides. (note that these items are normally stored in their dedicated tray already disassembled).	
4 Thoroughly clean instruments per one of the following (Manual or Automated)	
Manual	Automated

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<p>4.1 Pre-Cleaning-Manual:</p> <ul style="list-style-type: none"> • Alcohol wipe • Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35- 40°C) per the instructions of the enzymatic solution manufacturer. • Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces. • Change the soak solution if the solution becomes visibly soiled. • While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen • Rinse instruments thoroughly with clean warm (35-40°C) deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear 	<p>4.1 Pre-Cleaning-Automated:</p> <ul style="list-style-type: none"> • Soak in ultrasonic bath • 15 minutes • Use nonmetallic brush • Rinse thoroughly with cold (>40°C) running tap water, 2 minutes
<p>4.2 Cleaning-Manual:</p> <ul style="list-style-type: none"> • Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under clean 	<p>4.2 Washer Disinfectors:</p> <ul style="list-style-type: none"> • Wash, 45°C, 4 minutes • Wash, 60°C, 3 minutes • Rinse, >40°C tap water, 1 minute • Rinse, 60°C tap water, 1 minute • Thermal rinse, ≥93°C tap water, A03000

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<p>warm (35-40°C) running deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear.</p> <ul style="list-style-type: none"> • Dry the exterior of the instruments with a clean soft cloth. Use clean compressed air or 70% isopropyl to dry any lumens or crevices where water may become trapped. 	<ul style="list-style-type: none"> • Rinse, 35-40°C deionized water, 1 minute • When unloading check cannulations, holes, etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning. • Dry, 123°C, air, 14 minutes
<p>Inspection:</p> <ul style="list-style-type: none"> • Visually inspect each device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Check instruments with long slender features for distortion • Inspect the devices for any cracking, pitting, or other signs of deterioration 	
<p>Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</p>	
<p>Sterilization: See sterilization procedure</p>	
<p>Storage: Control environment</p>	
<p>Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.</p>	
<p>Manufacturer contact: Contact local representative or call customer service at 601-919-1119</p>	

Sterilization: The Z-LINK_{PC} System should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

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Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation LLC, 400 Liberty Park Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products, LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119.

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

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