Package Insert

Zavation Z-Link Cervical System

Device Description:
The Zavation Z-Link Cervical includes a PEEK spacer, titanium interbody plate and screws. The spacer component is assembled to an interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes two holes for inserting one bone screw in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights.

Indications for Use:
The Z-Link Cervical is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Z-Link Cervical should be packed with autogenous bone graft and implanted with an anterior approach.

Materials:
The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 or Superior Polymers Magnolia PEEK (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

Contraindications:
-The Zavation Z-Link Cervical is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice
-Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications

may be relative or absolute and must be carefully weighed against the patient's entire evaluation
-This device is not intended for use except as indicated
-Prior fusion at the level(s) to be treated

Potential Adverse Events: Potential adverse events include, but are not limited to:
-Pseudoarthrosis
-Early or late loosening of the components
-Bending, and/or breakage of the components
-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, straining, tumor formation, and/or auto-immune disease
-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:
-A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful
-Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion
-Non-sterile, the Zavation Z-Link Cervical implants are sold non-sterile, and therefore, must be sterilized before each use
-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
-Single use only

-The Zavation Z-Link Cervical components should not be used with components of any other system or manufacturer.
-The Zavation Z-Link Cervical has not been evaluated for safety and compatibility in the MR environment. The Zavation Z-Link Cervical has not been tested for heating or migration in the MR environment.
-Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Other preoperative, intraoperative and postoperative warnings are as followed:

Implant Selection:
The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Peek 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 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:
-Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
-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 of 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
-To assure proper fusion below and around the location of the fusion, autogenous bone graft should be used.
-Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the

components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

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 or 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
-Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible

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 provided 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: Dis-assemble instruments as required for the Zavation Z-Link Cervical System, (note that these items are normally stored in the dedicated trays already disassembled). Insure that the jeweler handle AO connection is removed from any drill or driver that it is connected to, and that the graft loader blocks are separated. Place these instruments in their dedicated locations in the sterilization trays after cleaning.

4 Thoroughly clean instruments per one of the following (Manual or Automated)	
Manual	**Automated**
4.1 Pre-Cleaning-Manual: • 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 the 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 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	**4.1 Pre-Cleaning-Automated:** • Soak in ultrasonic bath • 15 minutes • Use nonmetallic brush • Rinse thoroughly in running water
4.2 Cleaning-Manual: • 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	**4.2 Washer Disinfector:** • Wash • 93°C (200°F) minimum • 10 minutes • Rinses; when unloading check cannulations, holes, etc. for complete removal of visible soil.

running 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. • 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.	If necessary, repeat cycle or use manual cleaning. • Dry
Inspection: • 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	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Zavation Z-Link Cervical 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

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, 220 Lakeland Parkway, 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, 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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