Package Insert

Z- CLAMP ISP System

Device Description: The Z-CLAMP ISP System is supplemental fixation device consisting of a variety of shapes and sizes of one-level lumbar and sacral plates and screws. The plates attach to the lumbar and lumbosacral spine (L1-S1). The implant components are made of titanium alloy per ASTM F-136 (Ti-6AL-4V ELi).

Indications: The Z-Clamp ISP System is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous process for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e. fracture or dislocation) and / or tumor. The Z-Clamp ISP System is not intended for standalone use.

Materials: The Z-CLAMP ISP System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Contraindications: Contraindications include, but not limited to: The Z-CLAMP ISP 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 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.

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:
-The Z-CLAMP ISP System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
-Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
-The safety and effectiveness of spinal plate systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

-Non-sterile, the Z-CLAMP ISP System implants and instruments are provided 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 Z-CLAMP ISP System components should not be used with components of any other system or manufacturer.
-The Z- CLAMP ISP System has not been evaluated for safety and compatibility in the MR environment. The Z- CLAMP ISP System has not been tested for heating or migration in the MR environment.

Precaution:
-The implantation of spinal plate systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal plate system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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. 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:
-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 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

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
-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 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: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap

<table>
<tr><td colspan="2">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).</td></tr>
<tr><td colspan="2">4 Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><td>Manual</td><td>Automated</td></tr>
<tr><td>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 (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</td><td>4.1 Pre-Cleaning-Automated:

• Soak in ultrasonic bath
• 15 minutes
• Use nonmetallic brush
• Rinse thoroughly with cold (>40°C) running tap water, 2 minutes</td></tr>
<tr><td>4.2 Cleaning-Manual:</td><td>4.2 Washer Disinfector:</td></tr>
</table>

• 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 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. • 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.	• 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, $A_0$3000 • 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
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 Z-CLAMP ISP 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

Instrument Maintenance: Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Follow lubricant manufacturer's instructions.

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, 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.

LBL-014 Rev 2