

<b>Zavation</b>	<b>LABELING FOR FACET SCREW SYSTEM</b>	LBL-021 Rev 0

## Package Insert

### Facet Screw System

#### Device Description:

The Zavation Facet Screw System is a permanent implant device made from Cobalt Chrome Alloy per ASTM 1537. It is to be implanted from the posterior approach. The device is provided in one diameter and multiple lengths to accommodate the various anatomy of the spine. The device is intended to provide mechanical support and stability to the implanted level until biologic fusion is achieved.

#### Indications

The Zavation Facet Screw System is indicated for the posterior surgical treatment at L1-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability. The system is intended for use with only autogenous bone graft material.

#### Materials:

The Zavation Facet Screw System is a permanent implant device made from Cobalt Chrome Alloy per ASTM 1537.

#### Contraindications:

1. Prior fusion at the level(s) to be treated.
2. Patients with probable intolerance to the materials used in the manufacture of this device.
3. Patients with infection, inflammation, fever, tumors, elevated white blood count, morbid obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
4. Patient resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
5. Use with components from other systems.
6. Grossly distorted anatomy caused by congenital abnormalities.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
8. Rapid joint disease, bone absorption, osteopenia, Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indications for use.
13. Reuse or multiple use.

#### Potential Adverse Events:

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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. Foreign body (allergic) reaction to implant.
4. Postoperative change in spine curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficit, paraplegia, reflex deficit, irritations, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro fracture, damage or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
13. Non-union (pseudo-arthritis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.
18. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.

**Warnings and Precautions:**

Implants and instruments are provided non-Sterile and must be cleaned and sterilized before each use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

This system is not to be used with bone cement. The safety and efficacy of using bone cement with this system has not been established.

The Zavation Facet Screw System has not been evaluated for safety and compatibility in the MR environment nor has it been tested for heating or migration in the MR environment.

A successful result is not always achieved in every surgical case. This is especially true in spine surgery where many extenuating circumstances may compromise the results.

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. Patients who smoke have been shown to have an increase 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 this device.

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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.

**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 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 devices indications, contraindications and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

**Intraoperative Management:**

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. 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 screws.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
6. 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 device.
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.

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

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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.

<b>Cautions:</b> Long, narrow cannulations and blind holes require particular attention during cleaning.	
<b>Limitations on reprocessing:</b> Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.	
<b>1-Point of use:</b> 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.	
<b>2-Containment and transportation:</b> Avoid damage and minimize time before cleaning	
<b>3-Preparation for cleaning:</b> Dis-assemble instruments as required.	
<b>4 Thoroughly clean instruments per one of the following (Manual or Automated)</b>	
<b>Manual</b>	<b>Automated</b>
<b>4.1 Pre-Cleaning-Manual:</b> <ul style="list-style-type: none"> <li>• Alcohol wipe</li> <li>• Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35- 40°C) per the instructions of the enzymatic solution manufacturer.</li> <li>• 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.</li> <li>• Change the soak solution if the solution becomes visibly soiled.</li> <li>• 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</li> <li>• 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</li> </ul>	<b>4.1 Pre-Cleaning-Automated:</b> <ul style="list-style-type: none"> <li>• Soak in ultrasonic bath</li> <li>• 15 minutes</li> <li>• Use nonmetallic brush</li> <li>• Rinse thoroughly in running water</li> </ul>

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<p>flush them completely until water runs clear</p> <p><b>4.2 Cleaning-Manual:</b></p> <ul style="list-style-type: none"> <li>• 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 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.</li> <li>• 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.</li> </ul>	<p><b>4.2 Washer Disinfectors:</b></p> <ul style="list-style-type: none"> <li>• Wash</li> <li>• 93°C (200°F) minimum</li> <li>• 10 minutes</li> <li>• Rinses; when unloading check cannulations, holes, etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning.</li> <li>• Dry</li> </ul>
<p><b>Inspection:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Check instruments with long slender features for distortion</li> <li>• Inspect the devices for any cracking, pitting, or other signs of deterioration</li> </ul>	
<p><b>Packaging:</b> Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</p>	
<p><b>Sterilization:</b> See sterilization procedure</p>	
<p><b>Storage:</b> Control environment</p>	
<p><b>Additional information:</b> When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.</p>	
<p><b>Manufacturer contact:</b> Contact local representative or call customer service at 601-919-1119</p>	

**Sterilization:** The Zavation Facet Screw 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 Medical Products 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.**

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