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| Zavation | LABELING FOR ZAVATION TIGER® 2 SYSTEM | LBL-040 Rev 0 |
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Package Insert

Zavation Tiger® 2 System

Device Description: The Zavation Tiger® 2 System is comprised of polyaxial pedicle screws, rods and crosslinks. The Zavation Tiger® 2 System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications: The Zavation Tiger® 2 System is a pedicle screw system intended to provide Immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Zavation Tiger® 2 System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Zavation Tiger® 2 System when used as anterior thoracic/lumbar screw fixation systems, is indicated for degenerative disc disease (defined as discogenic back pain

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with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The Zavation Tiger® 2 System Fenestrated Screws are intended to be used with saline and radiopaque dye.

Materials: The Zavation Tiger® 2 System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 and cobalt chrome alloy (Co-28Cr-6Mo) as described by ASTM F1537.

Contraindications: Contraindications include, but not limited to: The Zavation Tiger® 2 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 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 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

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Note: Additional surgery may be necessary to correct some of these anticipated adverse events all of the components.

Warnings:

- The safety and effectiveness of pedicle screw spinal 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 screws, rods and instruments 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 Tiger® 2 System components should not be used with components of any other system or manufacturer.
- The Zavation Tiger® 2 System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Zavation Tiger® 2 System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
- The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). The device is intended only to be used with saline or radiopaque dye.

Precaution:

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

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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.
- The final operative procedure with the Zavation Tiger® 2 System must include tightening of all the set screws to the torque values indicated by the surgical technique with the instruments provided.

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.

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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 if the inspection criteria provided below are acceptable for the tray.

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| 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 by the surgical technique guide. | |
| 4 Thoroughly clean instruments per one of the following (Manual or Automated) | |
| Manual | Automated |
| 4.1 Pre-Cleaning-Manual: <ul style="list-style-type: none"> • Prepare a pH neutral, enzymatic detergent soak) 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. | 4.1 Pre-Cleaning-Automated: Automated washing shall be conducted in a validated washer-disinfector. An example of a validated cycle used for cleaning validation includes: <ul style="list-style-type: none"> • Wash 45°C 4 minutes dose pump 4 (detergent) 5mL • Wash 60°C 3 minutes • Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute. • Rinse 60°C 1 minute |

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| <p>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.</p> <ul style="list-style-type: none"> Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or 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>4.2 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 running critical water, such as reverse osmosis, distilled, and/or 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 alcohol to dry any lumens or crevices where water may become trapped. | <p>4.2 Washer Disinfectors: Automated washing shall be conducted in a validated washer-disinfectors.</p> <p>An example of a validated cycle used for cleaning validation includes:</p> <ul style="list-style-type: none"> Thermal Disinfection A₀ 93°C A₀ value: A₀3000 Dry 123°C air 14 minutes |
| Inspection: | |

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| <ul style="list-style-type: none"> • Visually inspect each disassembled 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 disassembled instruments with long slender features for distortion. • Inspect the disassembled 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 Tiger® 2 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 |
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| 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 Medical Products LLC, 3670 Flowood 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, 3670 Flowood Dr., 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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