Package Insert

Zavation Cervical Plate System

Device Description:
The Zavation Cervical Plate System consists of self-tapping/self-drilling screws and plates. Screws are available in a variety of diameter and length combinations. Plates are available in a variety of lengths. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications: The Zavation Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis, or scoliosis), tumor, pseudarthrosis or failed previous fusion.

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

Contraindications: Contraindications include, but not limited to: The Zavation Cervical Plate 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.

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 all the components
-Disassembly, bending, and/or breakage of any or all 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
-The Zavation Cervical Plate System is not approved for screw attachment or fixation to the (pedicles) of the cervical, thoracic, or lumbar spine
- Unless clearly marked as sterile and presented in an unopened sterile package, the plates, screws, and instruments should be assumed non-sterile, and therefore, must be sterilized before each use
-For implants marked as sterile, do not use if sterile package is opened or damaged.
-Always orient the plate along the midline of the spine
-To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated
-To facilitate fusion, enough autologous bone should be used
-Excessive torque applied to the screws when seating the plate 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 Zavation Cervical Plate System components should not be used with dissimilar metals or with components of any other system or manufacturer.
-The Zavation Cervical Plate System has not been evaluated for safety and compatibility in the MR environment.
-The Zavation Cervical Plate System has not been tested for heating or migration in the MR environment.
-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.

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:
-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
-Unless clearly marked as sterile and presented in an unopened sterile package, 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 fit snug against the upper and lower vertebral bodies
-Before closing soft tissue, check each screw to make sure that none have loosened

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 if 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 Cervical Plate System, the only instruments requiring disassembly would be Drills that are left assembled to the Jeweler Handle. (Note that these items are normally stored in the dedicated trays already disassembled).

4 Thoroughly clean instruments per one of the following (Manual or Automated)

Manual	Automated
4.1 Pre-Cleaning-Manual: • 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. 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 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 to direct the rinse flow into any lumens, crevices, grooves, or	**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: • Wash 45ºC 4 minutes dose pump 4 (detergent) 5mL • Wash 60ºC 3 minutes • Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute. • Rinse 60ºC 1 minute

<table>
<tr><td>slots and flush them completely until water runs clear</td><td></td></tr>
<tr><td>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 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 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.</td><td>4.2 Washer Disinfector:

Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Thermal Disinfection A_0 93ºC
A_0 value: $A_0$3000
Dry 123ºC air 14 minutes</td></tr>
<tr><td colspan="2">Inspection:
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</td></tr>
<tr><td colspan="2">Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</td></tr>
<tr><td colspan="2">Sterilization: See sterilization procedure</td></tr>
<tr><td colspan="2">Storage: Control environment</td></tr>
<tr><td colspan="2">Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded.</td></tr>
<tr><td colspan="2">Manufacturer contact: Contact local representative or call customer service at 601-919-1119</td></tr>
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Sterilization: Unless clearly marked as sterile and presented in an unopened sterile package, the implants and instruments of the Zavation Cervical Plate 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

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.