Zavation Varisync ALIF System

Device Description:

The Zavation Varisync ALIF System includes a spacer, plate, screws, and anchors. The spacer component is assembled to an interbody plate and implanted anteriorly. The spacer components are available in a variety of materials, depths, widths, and heights. The plate component includes three or four holes for inserting bone screws or anchors. The plate component also includes a lock at each hole. The bone screws are available in a variety of diameters and lengths. The anchors are available in a variety of lengths. The interbody plate components are available in a variety of heights.

Indications for Use:

The Zavation Varisync ALIF System is an anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation Varisync ALIF System is to be filled with autogenous bone graft material.

The Zavation Varisync ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar spine.

Materials:
The Zavation Varisync ALIF System components are manufactured from medical grade titanium alloy Ti-6Al-4V ELi (ASTM F136 and ASTM F3001), OR medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum (ASTM F560) alloy position markers. The PEEK implants are available with or without titanium plasma coating on the device. The plasma coating is made from commercially pure titanium per (ASTM F1580).

Contraindications:
-Instability
-Infection
-Severe Bleeding
-Known allergies to bone cement
-Pregnancy

Potential Adverse Events: Potential adverse events include, but are not limited to:

-Pseudarthrosis
-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:

-The Zavation Varisync ALIF System has not been evaluated for safety and compatibility in the MR environment. The Zavation Varisync ALIF System 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.

-Do not use if sterile package is opened or damaged.

-It is important to read the instructions for use, these precautions prior to device operation.

-Use the instrument kit prior to use by date noted on the package.

-Do not use damaged products. Before use, inspect the packaging to verify that no damage has occurred.

-Do not use this product if you have not been properly trained. Physicians using the device should be familiar with the physiology and pathology of the selected anatomy.

-The Zavation Varisync ALIF system should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.

-Do not reuse. The Zavation Varisync ALIF implants are for single use only. Reconditioning, refurbishing, or repair of the device to enable further use is expressly prohibited.

-Repacking or re-sterilization of sterile packed items is prohibited and must be returned to Zavation Medical for evaluation.

Other preoperative, intraoperative, and postoperative warnings are as followed:

Sterilization: The porous PEEK and porous Titanium spacers of the Zavation Varisync ALIF System will be received sterile. The solid PEEK and titanium coated PEEK spacers, all other implants and instruments will be received non-sterile.

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 peek 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

-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 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.
-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.

<table>
<tr><td colspan="2">Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.</td></tr>
<tr><td colspan="2">Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">2-Containment and transportation: Avoid damage and minimize time before cleaning</td></tr>
<tr><td colspan="2">3-Preparation for cleaning: Dis-assemble instruments as required. For the Zavation Varisync ALIF System, the only instruments requiring disassembly would be to remove the Universal Drive Sleeve from all Universal Instruments. The Universal Drive Sleeve is removed by sliding the sleeve over the square drive end of the Universal Instruments. (Note that these items are normally stored in the dedicated trays 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:
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 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 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</td><td>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 45°C 4 minutes does pump 4 (detergent) 5mL.
Wash 60°C 3 minutes
Rinse with unheated water 1 minute
Rinse 60°C 1 minute</td></tr>
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<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 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.
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.</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$3000
Dry 123°C air 14 minutes</td>
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<td colspan="2">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.</td>
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<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: The Zavation Varisync ALIF System instruments should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	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, 3670 Flowood Drive, 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 Drive, 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.