Package Insert

Zavation VariSync™ System

Device Description:
The VariSync™ Plate is a non-sterile anterior, cervical fixation device available in various heights and widths to fit the anatomical needs of a wide variety of patients. The plates are made from titanium alloy, as specified in ASTM F136. The Screws for use with the VariSync™ Plates are non-sterile and manufactured from titanium alloy, as specified in ASTM F136. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

VariSync™ Spacers are non-sterile, anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and footprints to fit the anatomical needs of a wide variety of patients. These devices are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. The VariSync™ Spacers are manufactured from radiolucent PEEK polymer, with tantalum markers, as specified in ASTM F2026 and F560.

Indications for Use:
The VariSync™ Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The VariSync™ Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The VariSync™ Spacer is to be filled with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. These devices are intended to be used with supplemental fixation such as the Zavation VariSync™ Plate, Zavation Midline Plate, Zavation EZ Plate, or Zavation Cervical Plate Systems. When used with the VariSync™ Plate, the assembly takes on the indications of the VariSync™ Spacer, with the VariSync™ Plate acting as the supplemental fixation.

Materials:
The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 or Superior Polymers Magnolia PEEK (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

Contraindications:
-The Zavation Varisync™ System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
-Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
-This device is not intended for use except as indicated.
-Prior fusion at the level(s) to be treated.

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

-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
-Neurological injury, vascular or visceral injury.
-Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:
-A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful.
-Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
-Non-sterile, the Zavation Varisync™ System implants 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 Varisync™ System components should not be used with components of any other system or manufacturer.
-The Zavation Varisync™ System has not been evaluated for safety and compatibility in the MR environment. The Zavation Varisync™ 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.
-This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
-The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
-Do not use if package is opened or damaged or if expiration date has passed.

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

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 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 of 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 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 confirmed by visual inspection of each instrument.
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: Ensure that all instruments have been disassembled and placed in their dedicated locations in the sterilization tray after cleaning.
Remove central stylus from plate inserters and place in appropriate tray locations.
Disassemble removable handles that are left attached to the drill, awl and screw drivers.
(note that these items are normally stored in the dedicated trays already disassembled).

Plate inserters and removable handles should stay disassembled in appropriate tray locations after cleaning and sterilization until next use.

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 in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear	**4.1 Pre-Cleaning-Automated:** Automated washing shall be conducted in a validated washer-disinfector. Refer to labeling of automated washer for detailed instructions of use. An example of a validated cycle used for cleaning validation includes: • 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
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 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	**4.2 Washer Disinfector:** Automated washing shall be conducted in a validated washer-disinfector. Refer to labeling of automated washer for detailed instructions of use. An example of a validated cycle used for cleaning validation includes: • Thermal Disinfection A_0 93°C • A_0 value: $A_0$3000

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.	• Dry 123°C air 14 minutes
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. • Visually Check disassembled instruments with long slender features for distortion • Visually Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration • If distortion or any signs of deterioration are found, discontinue use, return device to Zavation, and request a replacement device from Zavation Medical Products, LLC.	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment Plate inserters and removable handles should stay disassembled in appropriate tray locations after cleaning and sterilization until next use.	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Before next use, to reassemble inserter, thread inserter stylus down central shaft of inserter until stop is reached. To reassemble removable handles, pull back outer metal sleeve on handle, place desired instrument (tap or drill) in open slot and slide outer sleeve back over to original position to lock instrument in place.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Zavation Varisync™ System 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 Medical Products 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.