Package Insert

Zavation Ti3Z® Cervical Interbody System

Device

Description:

The Zavation Ti3Z® Cervical Interbody System implants are offered in two configurations: Ti3Z® cervical implants are additively manufactured entirely from medical grade Titanium Ti64ELI powder by way of laser sintering (ASTM F3001); Ti3Z®-PEEK cervical implants have an exterior that is manufactured from medical grade PEEK (polyetheretherketone) with tantalum beads or pins embedded in the implants to allow for radiographic visualization. Ti3Z®-PEEK implants also contain an interior titanium insert manufactured by way of laser sintering (ASTM F3001). The ends of the Ti3Z®-PEEK implants have machined teeth which are designed to engage with the vertebral body end plates. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

The Zavation Ti3Z® Cervical and Ti3Z®-PEEK Cervical Interbody implants are available in a range of heights, widths, and lengths as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. The internal body of both constructs have a porous structure while the external edges of the implants have a solid, roughened surface designed to engage with the vertebral body end plates. All implants will be provided sterile.

Indications for Use:

When used as a cervical intervertebral body fusion device, the Zavation Ti3Z® Cervical Interbody System implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The Ti3Z® cervical implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

For all the above indications the Zavation Ti3Z® Cervical Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Cervical Plate System.

Materials:

Ti3Z® Cervical devices are manufactured entirely from medical grade titanium (ASTM F3001-14).
Ti3Z®-PEEK Cervical devices have an exterior manufactured from medical grade PEEK with tantalaum markers or pins embedded into the implant and an interior manufactured from medical grade titanium (ASTM F3001-14).

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 Ti3Z® Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. The Zavation Ti3Z® Cervical Interbody 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 instruments should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
-Do not re-sterilize and/or reuse. The instruments are for single use only. Reconditioning, refurbishing, repair, or resterilization of the device to enable further use is expressly prohibited.

Sterilization: The Ti3Z® Cervical Interbody System implants will be received sterile in sealed sterile packaging. 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. Titanium 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 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 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 Zavation Ti3Z® Cervical Interbody System, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (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:	**4.1 Pre-Cleaning-Automated:**
• 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	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

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<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 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 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>
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<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>
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<td colspan="2">Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</td>
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<td colspan="2">Sterilization: See sterilization procedure</td>
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<td colspan="2">Storage: Control environment</td>
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<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>
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<td colspan="2">Manufacturer contact: Contact local representative or call customer service at 601-919-1119</td>
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Sterilization: The Zavation Ti3Z® Cervical Interbody 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 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.