



F3D-Z Cervical Interbody System

The Zavation F3D-Z Cervical Interbody System implants are additively manufactured entirely from medical grade Titanium Ti64ELI powder by way of laser sintering (ASTM F3001).

The Zavation F3D-Z 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 has 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

When used as a cervical intervertebral body fusion device, the Zavation F3D-Z 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 F3D-Z 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 F3D-Z Cervical Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Cervical Plate System.

CONTRAINDICATIONS

- Instability
- Infection
- Severe Bleeding
- Pregnancy

POSSIBLE ADVERSE EFFECTS

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
- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

WARNINGS AND PRECAUTIONS

- The Zavation F3D-Z Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. The Zavation F3D-Z 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.
- The safety and effectiveness of Cervical Interbody Fusion Device System have been established only for spinal conditions with acute and chronic instabilities or deformities of the Cervical spine (C2-T1): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.
- Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-implant interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used, if pseudarthrosis develops, or if patients have severe or multiple preoperative curves.
- Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implant components and the development of the fusion mass about the implant components. Instruct the patient that implant components may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.
- This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness.
- Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.
- Altering an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the F3D-Z Ti3Z Cervical Series Interbody System surgical technique manual for descriptions of appropriate implant handling and insertion techniques.
- Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

In addition to the warnings and precautions discussed above, patients must be informed about general surgical risks prior to surgery.

The implantation of the F3D-Z Ti3Z Cervical Series of intervertebral body fusion devices is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from Zavation by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting in erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the F3D-Z Ti3Z Cervical Series Interbody System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

STERILIZATION

The F3D-Z Cervical Interbody System implants will be received sterile in sealed sterile packaging.

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 peak 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.
- The implants of the F3D-Z Ti3Z Cervical Series Interbody System are provided sterile. The surgical instruments provided with the F3D-Z Ti3Z Cervical Series Interbody System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use.
- Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization.
- Remove all packaging that individual instruments may be provided prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container.
- Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.
- Prior to use, instruments must be inspected for signs of wear, damage, and proper function. If an instrument is suspected to be damaged, please contact Zavation for a replacement.

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.

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 tables in sections 4.1 and 4.2.

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Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual instruments may be provided prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. If an instrument is suspected to be damaged, please contact Zavation for a replacement. 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.

Caution: 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.

- 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.
- The maximum recommended time between use and cleaning is 4 hours.
 - Instruments should not be exposed to elevated air temperatures (>100 °F).
 - Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.
- Containment and Transportation: Avoid damage and minimize time before cleaning.
- Preparation for cleaning: Dis-assemble instruments as required. For the Zavation F3D-Z 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).

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

5.1 Pre-Cleaning

5.1.1 Manual Pre-Cleaning

- 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.

5.1.2 Automated Pre-Cleaning

- Automated washing shall be conducted in a validated washer-disinfector.
- An example of a validated cycle used for cleaning validation includes:

Step	Description
1	Wash 45°C 4 minutes dose pump 4 (detergent) 5mL.
2	Wash 60°C 3 minutes.
3	Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute.
4	Rinse 60°C 1 minute.

5.2 Cleaning

5.2.1 Manual Cleaning

- 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.

5.2.2 Washer Disinfector Cleaning

- Automated washing shall be conducted in a validated washer-disinfector.
- An example of a validated cycle used for cleaning validation includes:

Step	Description
1	Thermal disinfection A ₀ 93°C
2	A ₀ Value: A ₀ 3000
3	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.
- 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: Controlled 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 F3D-Z Cervical Interbody System instruments should be sterilized by the hospital using the recommended cycle:

Do not stack trays in 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.