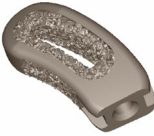


Surgical Technique for Zavation Ti3Z[®] Lumbar Interbody System (TLIF, T-PLIF and PLIF)

			
	TLIF	Parallel T-PLIF PLIF(23mm)	Lordotic T-PLIF-L PLIF-L(23mm)
Heights:	7mm-16mm	7mm-16mm	8mm-16mm
Widths:	10mm	9mm, 11mm	9mm, 11mm
Lengths:	25 and 30mm	27mm, 32mm	27mm, 32mm

PLIF & T-PLIF Lordotic Angles: Parallel (0°), 5°, and 12°

*23mm devices are to be used bi-laterally

Step 1

Surgical approach to the disc (posterior)

A midline incision provides exposure of the interlaminar space and facet joints at the indicated level. Pedicle screws of the surgeon's preference are inserted into the pedicles of the vertebrae adjacent to the disc space to be fused. Using a combination of surgical instruments (osteotomes, Kerrison rongeurs, curettes, etc.) appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy, is performed, along with the removal of the ligamentum flavum, to gain access to the disc space and identify neural and bony anatomy. Use a standard transforaminal approach for insertion of the TLIF and the 27mm and 32mm length T-PLIF devices. Use a standard bilateral posterior approach for insertion of the 23mm PLIF devices.

Step 2

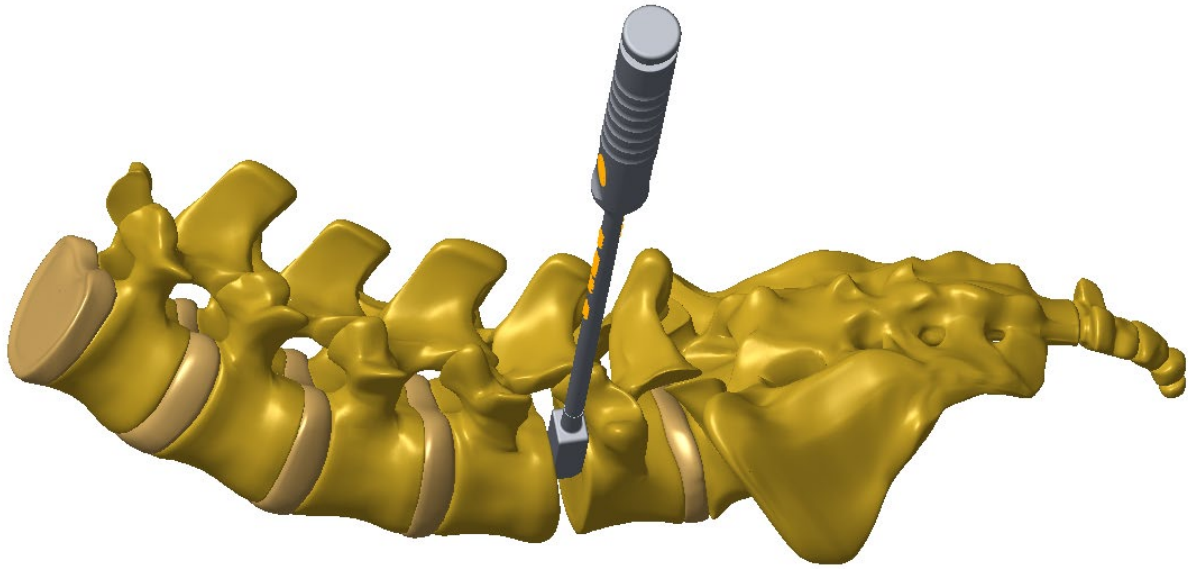
Freshening of the endplate



Perform a standard discectomy used with a posterior lumbar discectomy and fusion procedure. Use a curette or rasp to prepare the implant bed and the graft surfaces.

Step 3

Trial for implant size



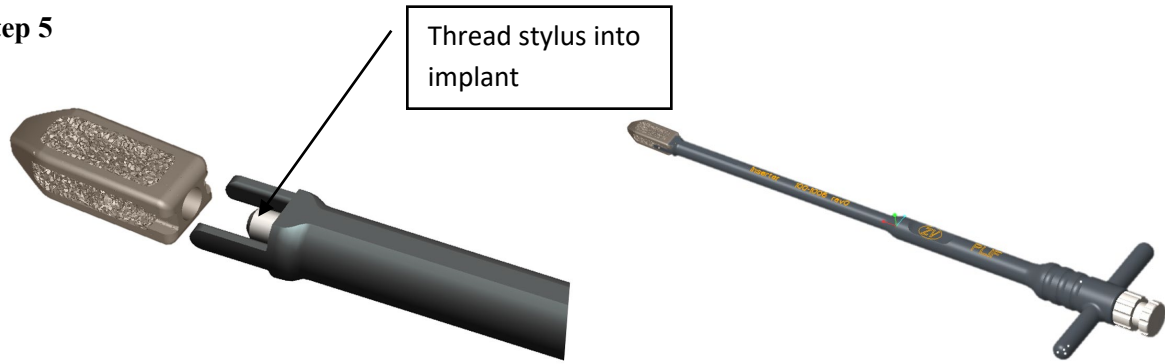
Introduce the various sized trials into the intervertebral space to determine the height, width and degree of the implant.

Step 4

Selection of the implant size

Select the appropriate implant and then attach to the inserter instrument. Load implant onto the inserter by aligning anti-rotation features, and threading central stylus into implant.

Step 5

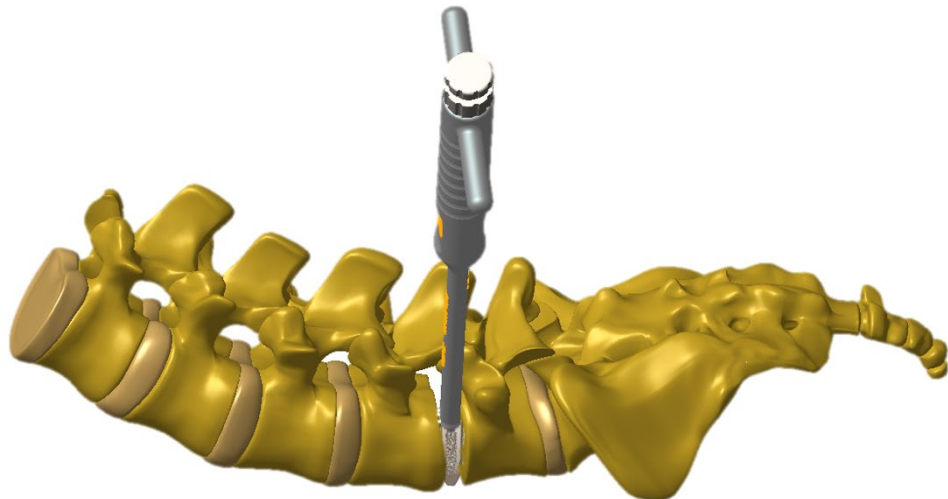


Filling implant with autograft

With the selected implant attached to the insertion instrument, fill the implant with autograft.

Step 6

Insert implant



Prior to inserting, if space allows pack graft in the anterior portion of the disc space.

The TLIF devices final position should be across the midline with the length of the device perpendicular to the midline. The 27mm and 32mm length T-PLIF devices' final position should be across the midline at a 30-to-45-degree angle from the midline. The 23mm PLIF devices should be placed bilaterally on each side of the midline.

Under fluoroscopy, with the implant mounted on the insertion instrument, gently insert into disc space towards its final position. A tamp is available for tamping the implant into final position.

For the rotatable series cages (T-PLIF-R and PLIF-R) the device is inserted into the disc space with the endplate contacting serrations perpendicular to the endplates. Gently insert into the disc space to its final position. Rotate the device 90 degrees clockwise so that the endplate contacting serrations are parallel with the endplates.

Step 7

X-ray verification

Remove the inserter instrument by unscrewing the knobs on the end of the inserter to allow X-ray or visual verification of the implant after implantation.

Step 8

After confirmation of implant position, pack additional graft material around the sides and posterior ends of the implant to fill any additional voids in the disc space.

Step 9

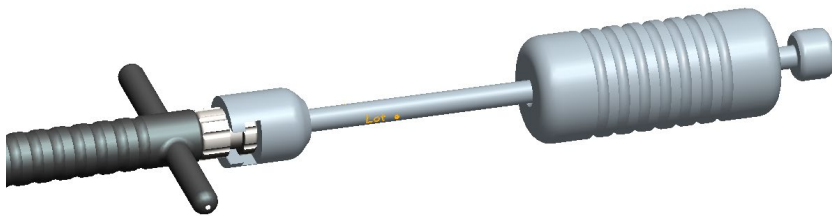
Supplemental fixation

Use of supplemental fixation is required with the TLIF, T-PLIF, or PLIF implant. Zavation Spinal System (pedicle screw system) may be used as supplemental fixation.

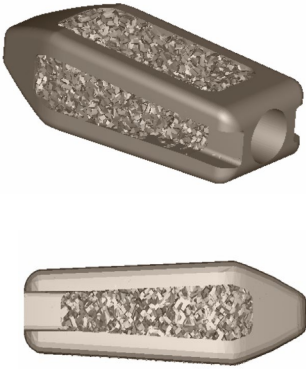
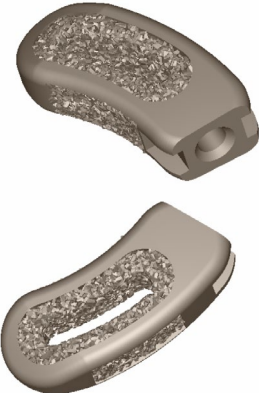
Step 10

Implant removal

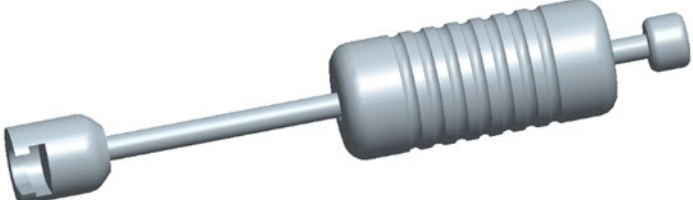
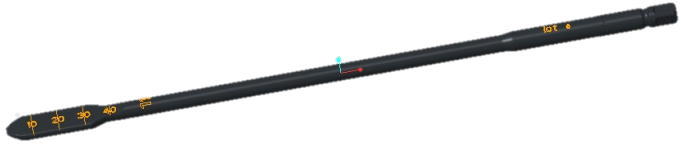
Attach inserter into implant posteriorly, thread inserter into threads of implant until tightened, gently remove implant from disc space. If the implant cannot be easily removed, a Cobb elevator, slap hammer or osteotome should be used to loosen the bone to implant interface.



Device View	Part #	Description
Implants		

	23X-XXXX-XX	Ti3Z® Posterior LIF (PLIF) • Widths ○ 9mm and 11mm • AP lengths ○ 23mm, 27mm, 32mm • Heights ○ 7mm to 16mm in 1mm increments • Three lordotic angle options ○ 0°, 5°, 12°
	340-XXXX-XX	Ti3Z® Transforaminal LIF (TLIF) • Widths ○ 10mm • Lengths ○ 25mm and 30mm • Heights ○ 7mm to 16mm in 1mm increments

Device View	Part #	Description
Instruments		

	100-1006 (PLIF) 100-1007(TLIF)	Cage Inserter • Threaded stylus • Anti-rotation features
	100-1002(PLIF) 101s-XXXX0XX(TLIF)	Cage Sizers • Sizer ends match implant shape and size
	100-1008	Slap Hammer • Mates with Cage Sizers • Slide on attachment
	100-1012/1013-XX	Paddle Distracter and Paddle Shaver • Distracting paddles for ease of insertion

System Bill of Materials

Ti3Z® Lumbar Interbody System (TLIF, T-PLIF, PLIF)

PN	Description
2231-0161	Sterilization Tray Lid
100-9000	Instrument Tray
100-1001-092700-07	PLIF Sizer 07 mm
100-1001-092700-08	PLIF Sizer 08 mm
100-1001-092700-09	PLIF Sizer 09 mm
100-1001-092700-10	PLIF Sizer 10 mm
100-1001-092700-11	PLIF Sizer 11 mm
100-1001-092700-12	PLIF Sizer 12 mm
100-1001-092700-13	PLIF Sizer 13 mm
100-1001-092700-14	PLIF Sizer 14 mm
100-1001-092700-15	PLIF Sizer 15 mm
100-1001-092700-16	PLIF Sizer 16 mm
101s-3007	TLIF Sizer 07 mm
101s-3008	TLIF Sizer 08 mm
101s-3009	TLIF Sizer 09 mm
101s-3010	TLIF Sizer 10 mm
101s-3011	TLIF Sizer 11 mm
101s-3012	TLIF Sizer 12 mm
101s-3013	TLIF Sizer 13 mm
101s-3014	TLIF Sizer 14 mm
101s-3015	TLIF Sizer 15 mm
101s-3016	TLIF Sizer 16 mm
100-1006	Cage Inserter
100-1007	Cage Inserter (TLIF)
100-1008	Slap Hammer
100-1011	Distracting Inserter
100-1012-07	Paddle distractor 07 mm
100-1012-08	Paddle distractor 08 mm
100-1012-09	Paddle distractor 09 mm
100-1012-10	Paddle distractor 10 mm
100-1012-11	Paddle distractor 11 mm
100-1012-12	Paddle distractor 12 mm
100-1012-13	Paddle distractor 13 mm
100-1012-14	Paddle distractor 14 mm
100-1012-15	Paddle distractor 15 mm
100-1012-16	Paddle distractor 16 mm
100-1013-07	Paddle shaver 07 mm
100-1013-08	Paddle shaver 08 mm
100-1013-09	Paddle shaver 09 mm
100-1013-10	Paddle shaver 10 mm
100-1013-11	Paddle shaver 11 mm
100-1013-12	Paddle shaver 12 mm
100-1013-13	Paddle shaver 13 mm
100-1013-14	Paddle shaver 14 mm
100-1013-15	Paddle shaver 15 mm
100-1013-16	Paddle shaver 16 mm
Z-1009	T-Handle (2)
Sterile Packed Implants	
Ti3Z® PLIF	
230-0923-07	Ti3Z® PLIF 9mmx23mmx7mm -0deg
230-0923-08	Ti3Z® PLIF 9mmx23mmx8mm -0deg
230-0923-09	Ti3Z® PLIF 9mmx23mmx9mm -0deg
230-0923-10	Ti3Z® PLIF 9mmx23mmx10mm -0deg

230-0923-11	Ti3Z® PLIF 9mmx23mmx11mm -0deg
230-0923-12	Ti3Z® PLIF 9mmx23mmx12mm -0deg
230-0923-13	Ti3Z® PLIF 9mmx23mmx13mm -0deg
230-0923-14	Ti3Z® PLIF 9mmx23mmx14mm -0deg
230-0923-15	Ti3Z® PLIF 9mmx23mmx15mm -0deg
230-0923-16	Ti3Z® PLIF 9mmx23mmx16mm -0deg
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231-0923-08	Ti3Z® PLIF 9mmx23mmx8mm -5deg
231-0923-09	Ti3Z® PLIF 9mmx23mmx9mm -5deg
231-0923-10	Ti3Z® PLIF 9mmx23mmx10mm -5deg
231-0923-11	Ti3Z® PLIF 9mmx23mmx11mm -5deg
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231-0923-16	Ti3Z® PLIF 9mmx23mmx16mm -5deg
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230-0932-09	Ti3Z [®] PLIF 9mmx32mmx9mm -0deg
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231-1132-16	Ti3Z [®] PLIF 11mmx32mmx16mm -5deg
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233-1132-08	Ti3Z [®] PLIF 11mmx32mmx8mm -12deg
233-1132-09	Ti3Z [®] PLIF 11mmx32mmx9mm -12deg
233-1132-10	Ti3Z [®] PLIF 11mmx32mmx10mm -12deg
233-1132-11	Ti3Z [®] PLIF 11mmx32mmx11mm -12deg
233-1132-12	Ti3Z [®] PLIF 11mmx32mmx12mm -12deg

233-1132-13	Ti3Z® PLIF 11mmx32mmx13mm -12deg
233-1132-14	Ti3Z® PLIF 11mmx32mmx14mm -12deg
233-1132-15	Ti3Z® PLIF 11mmx32mmx15mm -12deg
233-1132-16	Ti3Z® PLIF 11mmx32mmx16mm -12deg
Ti3Z® TLIF	
340-2506-07	Ti3Z® TLIF 25 mm 6deg -07 mm
340-2506-08	Ti3Z® TLIF 25 mm 6deg -08 mm
340-2506-09	Ti3Z® TLIF 25 mm 6deg -09 mm
340-2506-10	Ti3Z® TLIF 25 mm 6deg -10 mm
340-2506-11	Ti3Z® TLIF 25 mm 6deg -11 mm
340-2506-12	Ti3Z® TLIF 25 mm 6deg -12 mm
340-2506-13	Ti3Z® TLIF 25 mm 6deg -13 mm
340-2506-14	Ti3Z® TLIF 25 mm 6deg -14 mm
340-2506-15	Ti3Z® TLIF 25 mm 6deg -15 mm
340-2506-16	Ti3Z® TLIF 25 mm 6deg -16 mm
340-3006-07	Ti3Z® TLIF 30 mm 6deg -07 mm
340-3006-08	Ti3Z® TLIF 30 mm 6deg -08 mm
340-3006-09	Ti3Z® TLIF 30 mm 6deg -09 mm
340-3006-10	Ti3Z® TLIF 30 mm 6deg -10 mm
340-3006-11	Ti3Z® TLIF 30 mm 6deg -11 mm
340-3006-12	Ti3Z® TLIF 30 mm 6deg -12 mm
340-3006-13	Ti3Z® TLIF 30 mm 6deg -13 mm
340-3006-14	Ti3Z® TLIF 30 mm 6deg -14 mm
340-3006-15	Ti3Z® TLIF 30 mm 6deg -15 mm
340-3006-16	Ti3Z® TLIF 30 mm 6deg -16 mm
340-2512-07	Ti3Z® TLIF 25 mm 12deg -07 mm
340-2512-08	Ti3Z® TLIF 25 mm 12deg -08 mm
340-2512-09	Ti3Z® TLIF 25 mm 12deg -09 mm
340-2512-10	Ti3Z® TLIF 25 mm 12deg -10 mm
340-2512-11	Ti3Z® TLIF 25 mm 12deg -11 mm
340-2512-12	Ti3Z® TLIF 25 mm 12deg -12 mm
340-2512-13	Ti3Z® TLIF 25 mm 12deg -13 mm
340-2512-14	Ti3Z® TLIF 25 mm 12deg -14 mm
340-2512-15	Ti3Z® TLIF 25 mm 12deg -15 mm
340-2512-16	Ti3Z® TLIF 25 mm 12deg -16 mm
340-3012-07	Ti3Z® TLIF 30 mm 12deg -07 mm
340-3012-08	Ti3Z® TLIF 30 mm 12deg -08 mm
340-3012-09	Ti3Z® TLIF 30 mm 12deg -09 mm
340-3012-10	Ti3Z® TLIF 30 mm 12deg -10 mm
340-3012-11	Ti3Z® TLIF 30 mm 12deg -11 mm
340-3012-12	Ti3Z® TLIF 30 mm 12deg -12 mm
340-3012-13	Ti3Z® TLIF 30 mm 12deg -13 mm
340-3012-14	Ti3Z® TLIF 30 mm 12deg -14 mm
340-3012-15	Ti3Z® TLIF 30 mm 12deg -15 mm
340-3012-16	Ti3Z® TLIF 30 mm 12deg -16 mm

Zavation Ti3Z® Lumbar Interbody System

Device Description:

The Zavation Ti3Z® Lumbar Interbody System implants are offered in five main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF with the choice of two different material options, allowing for multiple surgical technique options. Ti3Z® Lumbar implants are additively manufactured entirely from medical grade titanium Ti64ELI powder by way of laser sintering (ASTM F3001); Ti3Z® -PEEK lumbar 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® Lumbar 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 the implants 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 lumbar intervertebral body fusion device, the Zavation Ti3Z® Lumbar Interbody implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The Ti3Z® Lumbar Interbody implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

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

Materials:

Ti3Z® Lumbar devices are manufactured entirely from medical grade titanium (ASTM F3001-14).

Ti3Z®-PEEK Lumbar devices have an exterior manufactured from medical grade PEEK with tantalum 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® Lumbar Interbody System has not been evaluated for safety and compatibility in the MR environment. The Zavation Ti3Z® Lumbar 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® Lumbar Interbody System implants will be received sterile. 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 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 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® Lumbar 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: • 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 slots and flush them completely until water runs clear	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 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 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.	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 A₀3000 • 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: Control 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 Ti3Z® Lumbar 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 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.

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