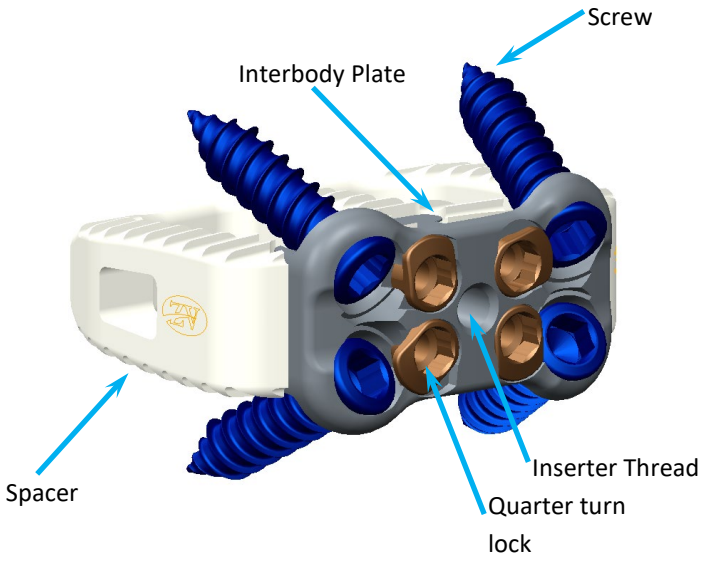
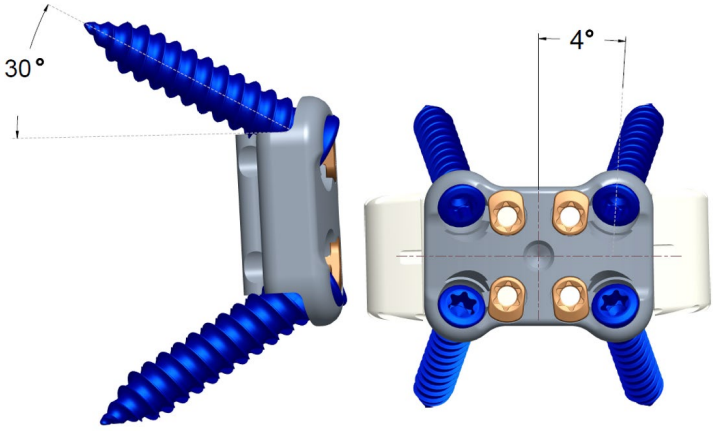
Zavation Z-Link® Lumbar





Interbody Plate:

- Quarter turn locks for each screw
- Locks use same driver as used for inserting screws
- 30° caudal and cephalad biased angles
- 4° medial lateral angle
- Plate Size
  - Width – 25mm
  - Heights – 11mm to 19mm
- Material: Titanium per ASTM F-136

Spacer:

- Bulleted insertion end
- Sizes
  - Lateral x AP
    - 33mm x 26mm
    - 38mm x 30mm
  - 8° and 15° Lordotic
  - Height:
    - 11mm to 19mm in 2mm increments. (Top of serrations)
- 2 Tantalum markers on distal end
- Material
  - Implantable PEEK per ASTM F2026
- Markers –Tantalum per ASTM F560

Screws:

- Lengths: 15, 20, 20, 25, 30mm
-
- Double lead thread
- Diameter:
  - 4.5mm – Self drilling or blunt tip self tapping, fixed
  - 4.0mm - Self drilling or blunt tip self tapping, variable
- Material: Titanium per ASTM F-136

Surgical Technique for Zavation Z-Link® Lumbar

Step 1

Surgical approach to the disc

Before performing the surgical approach, identify the involved level by radiologic control. Use a standard anterior approach for intervertebral disc exposure.

Step 2

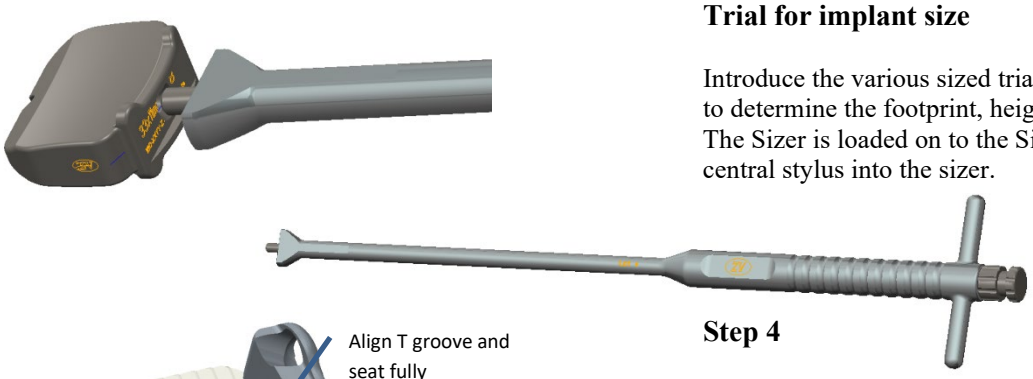
Freshening of the endplate

Perform a standard discectomy used with an anterior 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

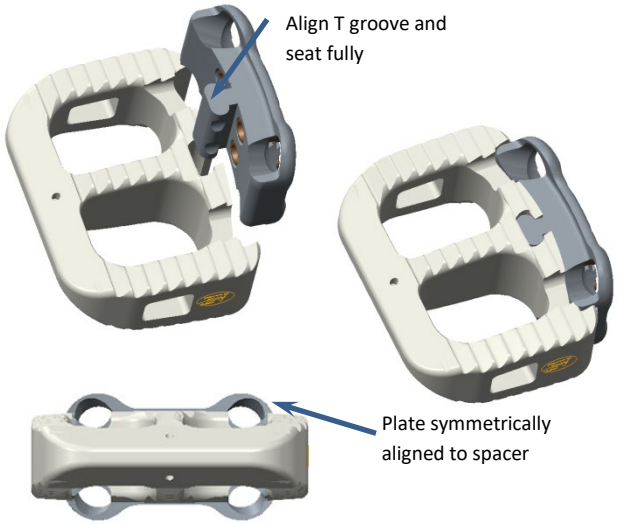
Introduce the various sized trials into the intervertebral space to determine the footprint, height, and degree of the implant. The Sizer is loaded on to the Sizer Inserter by threading the central stylus into the sizer.



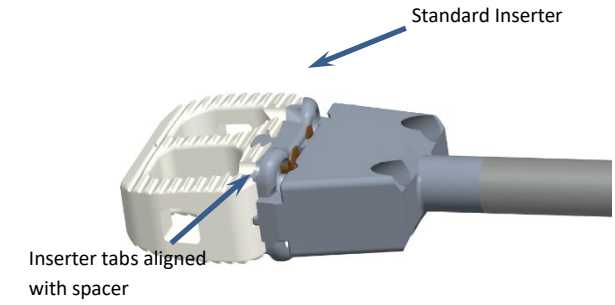
Step 4

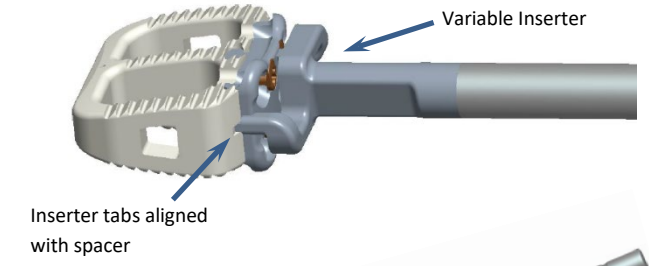
Selection of the implant size

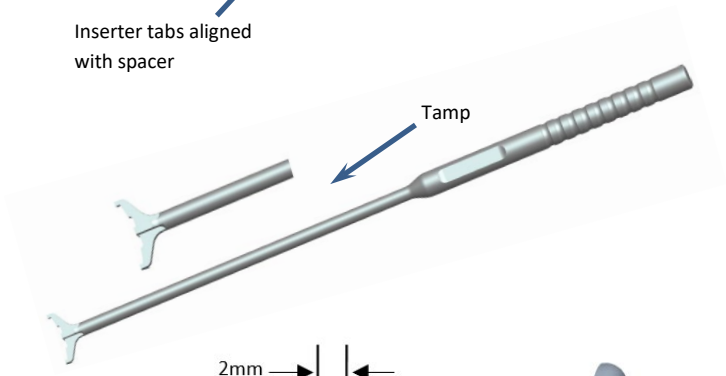
Choose the appropriate hieght titanium plate and PEEK spacer. Note that the plate height should match the spacer height. Assemble by pressing the “T” groove together until fully seated as shown.

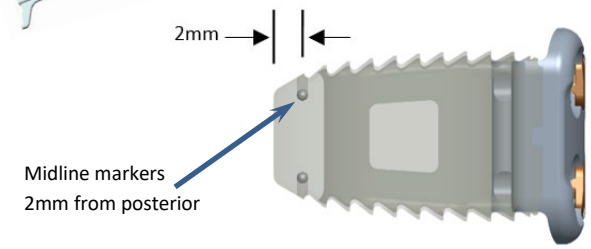


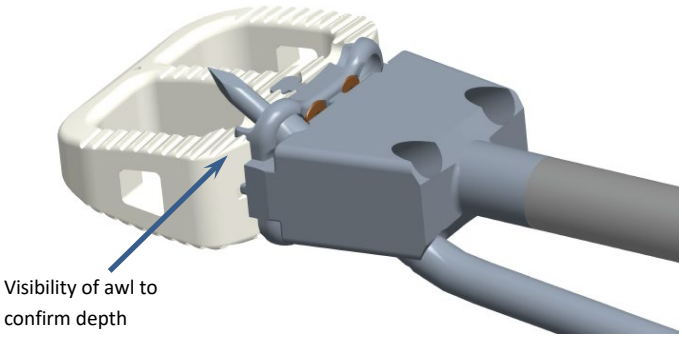
Correct assembly is confirmed visually as shown in the figure to the left. (minimal assembly friction prevents the spacer from sliding after it is postioned)











Attach to the inserter instrument. Load implant onto the inserter by threading the central stylus of the appropriate height inserter into the central thread of the plate.

Note: A standard inserter is available when applying fixed screws or a variable inserter can be used to implant variable screws.

Step 5

Pack the implant with autograft

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

Step 6

Insert implant

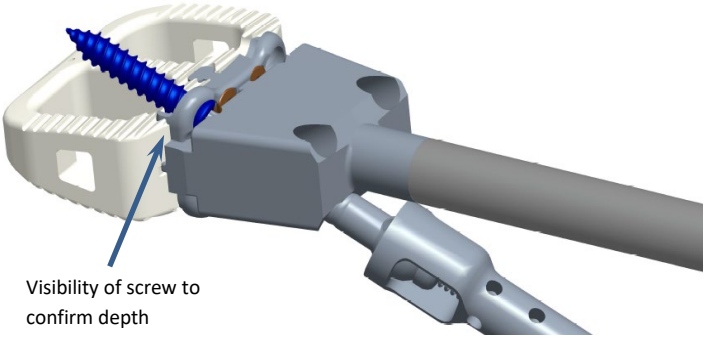
With the implant mounted on the insertion instrument, gently insert into the disc space towards its final position. A tamp is available for tamping the implant into final position. Verify the final implant position relative to the vertebral bodies.

Two midline x-ray markers 2mm from the posterior end in the PEEK spacer along with the titanium interbody plate enable intraoperative radiographic assessment of the implant position.

Step 7

Hole Preparation

The pilot hole can be created with the angled awl, universal drill, or the universal awl. Advance the awl through the guide hole in the inserter until fully seated. It is important that the 4 holes are prepared with screws inserted sequentially. Repeat steps 7 and 8 for each screw.



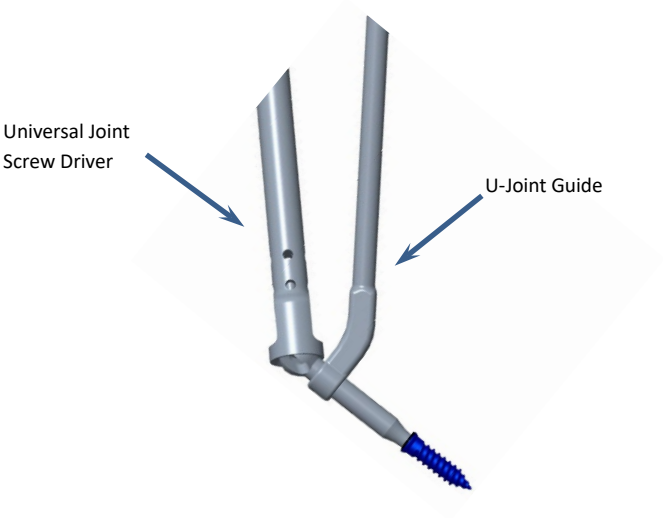
Step 8

Screw Insertion

Load the appropriate length screw on the Straight or Universal Joint Screwdriver. The screwdriver has a self-retaining taper to hold the screw during insertion. Advance the screw until it seats firmly inside the pocket in the interbody plate. Screws must be seated completely to allow screw locks to be engaged.

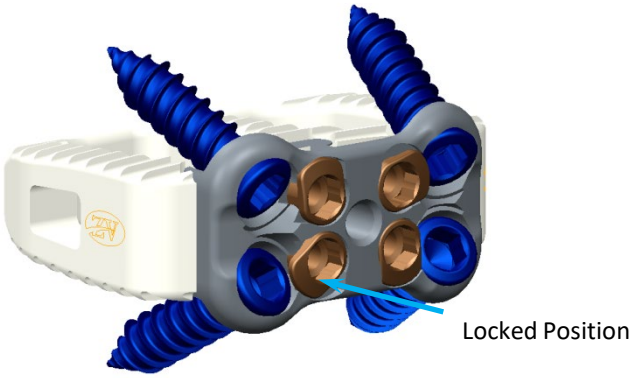
Note: A U-joint guide is available to assist the universal joint screwdriver during screw insertion.

After screws are inserted remove the inserter by unthreading the central stylus.



Note: Only two screws are inserted with the variable inserter attached. The final two screws are inserted after removing the variable inserter.

Note: The Zavation Z-Link® Lumbar is a stand-alone device and is intended to be used with the plate and screws provided and requires no additional supplementary fixation. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.



Step 9

Lock Screws

Each screw is locked by rotating the screw lock ¼ turn using the straight Driver that is used to insert the screws. It is recommended not to rotate the lock more than 2 times. The lock can be verified it is in the correct position visually, and it will also contact a stop in the locked position to provide a tactile indication.

Step 10

Implant removal

Unlock each screw lock by using the T15 Driver. Remove each screw by using the T15 Driver or the T15 Universal Joint Driver. Attach the inserter to the implant anteriorly, gentle remove the implant from disc space. If the implant cannot be easily removed, a cobb elevator or osteotome should be used to loosen the bone to implant interface.

Part#	Description
INSTRUMENTS	
180-1001-XX	Inserter
180-1002	Universal Awl
180-1004	Straight Driver
180-1005	Sizer Inserter
180-1006	Tamp
180-1007	Angled Awl
180-1009	Variable Inserter
180-1010	U-Joint Guide
180-1011	Universal Driver
180-1012	Driver Sleeve
180S-XXYY-ZZ	Sizer
100-1008	Slap Hammer
Z-1003	Ratcheting straight handle
IMPLANTS	
Interbody Plate	
180-11	11mm Z-Link® Lumbar Plate
180-13	13mm Z-Link® Lumbar Plate
180-15	15mm Z-Link® Lumbar Plate
180-17	17mm Z-Link® Lumbar Plate
180-19	19mm Z-Link® Lumbar Plate
Spacer	
180-0833-11	Z-Link® Lumbar Spacer Cage 8deg 33mmx11
180-0833-13	Z-Link® Lumbar Spacer Cage 8deg 33mmx13
180-0833-15	Z-Link® Lumbar Spacer Cage 8deg 33mmx15
180-0833-17	Z-Link® Lumbar Spacer Cage 8deg 33mmx17
180-0833-19	Z-Link® Lumbar Spacer Cage 8deg 33mmx19
180-0838-11	Z-Link® Lumbar Spacer Cage 8deg 38mmx11
180-0838-13	Z-Link® Lumbar Spacer Cage 8deg 38mmx13
180-0838-15	Z-Link® Lumbar Spacer Cage 8deg 38mmx15
180-0838-17	Z-Link® Lumbar Spacer Cage 8deg 38mmx17
180-0838-19	Z-Link® Lumbar Spacer Cage 8deg 38mmx19
180-1533-11	Z-Link® Lumbar Spacer Cage 15deg 33mmx11
180-1533-13	Z-Link® Lumbar Spacer Cage 15deg 33mmx13
180-1533-15	Z-Link® Lumbar Spacer Cage 15deg 33mmx15
180-1533-17	Z-Link® Lumbar Spacer Cage 15deg 33mmx17
180-1533-19	Z-Link® Lumbar Spacer Cage 15deg 33mmx19
180-1538-11	Z-Link® Lumbar Spacer Cage 15deg 38mmx11
180-1538-13	Z-Link® Lumbar Spacer Cage 15deg 38mmx13
180-1538-15	Z-Link® Lumbar Spacer Cage 15deg 38mmx15

Part#	Description
180-1538-17	Z-Link® Lumbar Spacer Cage 15deg 38mmx17
180-1538-19	Z-Link® Lumbar Spacer Cage 15deg 38mmx19
Screws	
181-4515	Self Drilling Fixed Screw, 4.5mmx15
181-4520	Self Drilling Fixed Screw, 4.5mmx20
181-4525	Self Drilling Fixed Screw, 4.5mmx25
181-4530	Self Drilling Fixed Screw, 4.5mmx30
182-4515	Self Tapping Fixed Screw, 4.5mmx15
182-4520	Self Tapping Fixed Screw, 4.5mmx20
182-4525	Self Tapping Fixed Screw, 4.5mmx25
182-4530	Self Tapping Fixed Screw, 4.5mmx30
183-4015	Self Drilling Variable Screw, 4.0mmx15
183-4020	Self Drilling Variable Screw, 4.0mmx20
183-4025	Self Drilling Variable Screw, 4.0mmx25
183-4030	Self Drilling Variable Screw, 4.0mmx30
184-4015	Self Tapping Variable Screw, 4.0mmx15
184-4020	Self Tapping Variable Screw, 4.0mmx20
184-4025	Self Tapping Variable Screw, 4.0mmx25
184-4030	Self Tapping Variable Screw, 4.0mmx30

Zavation Z-Link® Lumbar

Device Description:
The Zavation Z-Link® Lumbar includes a PEEK spacer, titanium interbody plate and screws. The spacer component is assembled to an interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes four holes for inserting two bone screws in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications for Use:
The Zavation Z-Link® Lumbar is a stand-alone 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 Z-Link® Lumbar is to be filled with autogenous bone graft material.

Materials:

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

Contraindications:
-The Zavation Z-Link® Lumbar 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
-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 Z-Link® Lumbar 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 Z-Link® Lumbar components should not be used with components of any other system or manufacturer.
-The Zavation Z-Link® Lumbar has not been evaluated for safety and compatibility in the MR environment. The Zavation Z-Link® Lumbar 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.

Other preoperative, intraoperative and postoperative warnings are as follows:

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 or 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. If wear and damage that renders the instrument inoperable is noted, the company should be contacted for a replacement.

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 Z-Link® Lumbar System, (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 the 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. 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
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 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	**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

70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.	
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 Z-Link® Lumbar should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum 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.