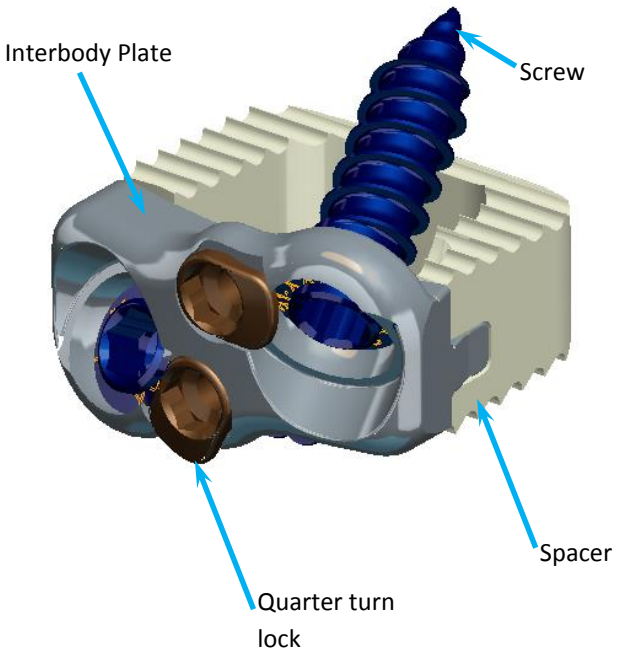
Zavation Z-Link Cervical



Interbody Plate:

- Quarter turn locks for each screw
- Locks use same driver as used for inserting screws
- 30° caudal and cephalad biased angles
- 15° midline biased angle
- ±10° Variable angle
- Plate Size
  - Width – 17.3mm
  - Heights – 6mm to 12mm
- Material: Titanium per ASTM F-136

Spacer:

- Bulleted insertion end
- Sizes
  - 0°, 6° 10° Lordotic
  - 6mm to 12mm height
  - Standard 12 x 15 and 15 x 17.5.
- Tantalum marker on distal end
- Material
  - Implantable PEEK Zeniva per ASTM F2026
- Markers –Tantalum per ASTM F560

Screws:

- Lengths: 12, 14, 16, 18, 20
- Angulation: Variable, Fixed
- Diameter:
  - 4.0mm – Self drilling or Blunt tip self tapping
  - 4.5mm – Self drilling or Blunt tip self tapping
- Material: Titanium per ASTM F-136

Surgical Technique for Zavation Z-Link Cervical

Step 1

Surgical approach to the disc

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

Step 2

Freshening of the endplate

Perform a standard discectomy used with an anterior cervical discectomy and fusion procedure. Use a curette or rasp to prepare the implant bed and the graft surfaces. Double ended rasps are provided with rasp ends that match the implant size.

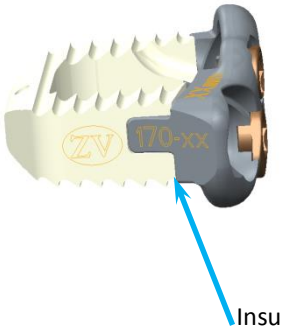
Step 3

Trial for implant size

Introduce the various sized trials into the intervertebral space to determine the height and degree of the implant. The available heights are 6mm, 7mm, 8mm, 9mm, 10mm, 11mm and 12mm. The available implant footprints are 12x15 and 15x17.5mm. The available lordotic angles are parallel(0°), 6 or 10 degree.

Step 4

Selection of the implant size



Choose the appropriate hieght titanium plate and PEEK spacer and assemble by pressing together until fully seated. There will be an audible click as the plate is seated. Visually confirm that the plate is flush to the spacer at the point indicated in the figure.

Attach to the inserter instrument. Load implant onto the inserter and clamp to the implant.

Step 5

Pack the implant with autograft

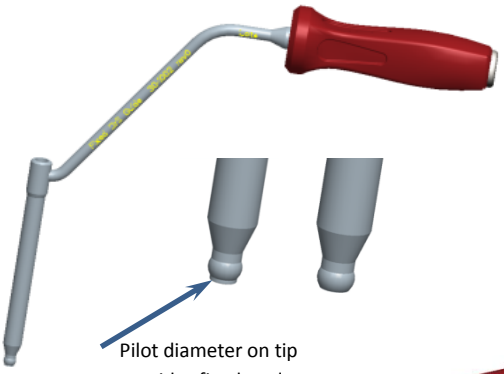
Use the graft loader and graft packer to facilitate loading of the autograft. With the selected implant attached to the insertion instrument, place the implant in the graft loader (note that two graft loaders are available to match implant footprint) fill the implant with autograft by loading autograft into the top of the graft loader and packing into the implant with the graft packer.

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.

A single midline x-ray marker in the PEEK spacer along with the titanium interbody plate enables intraoperative radiographic assessment of the implant position.



Step 7

Hole Preparation

Guided options:

Option 1: Fixed angle drill/awl guides are aligned to the holes with the small pilot diameter on the tip of the drill guide.

Option 2: Variable angle drill/awl guides allow for free hand angle selection. Ensure that the angle of the guide relative to the biased angle of the hole does not exceed 10 degrees.

The hole can be created with the awl (which creates an 11mm deep hole), or drill. If using the drill, select the drill that corresponds to the screw length and attach to the jeweler handle with the quick release. Both the drills and the awl should be advanced until they stop on the drill guide to achieve the depth specified.

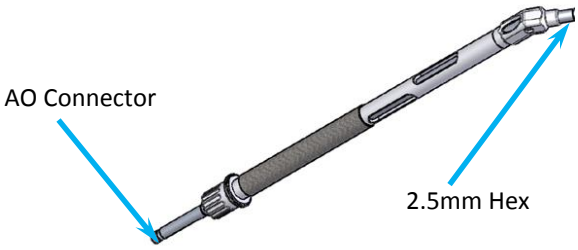
Angled awl:

The pilot hole can also be created with the angled awl. Advance the angled awl through the plate hole at the appropriate angle until the awl is seated in the screw hole of the plate.

Step 8

Screw Insertion

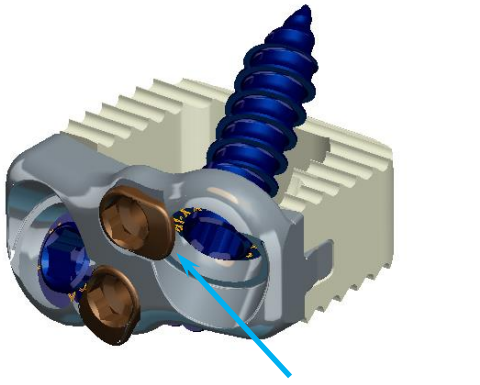
Load the appropriate length screw on the 2.5mm Driver or on the Angled Screw Driver. The screw driver has a self-retaining taper to hold the screw during insertion. Advance screw until it seats firmly inside the pocket in the interbody plate. Screws must be seated completely to allow screw locks to be engaged.



Step 9

Lock Screws

Each screw is locked by rotating the screw lock ¼ turn using the same 2.5mm Driver that is used to insert the screws. It is recommended not to rotate the lock more than 2 times.



Step 10

Implant removal

Unlock each screw lock by using the 2.5mm Driver. Remove each screw by using the 2.5mm Driver or the 2.5mm Angled 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	
30-1014	2.5mm Screw Driver
30-1001 30-1010	Awl
30-1002	Variable Drill Guide
30-1003	Fixed Drill Guide
30-1005-12	2.5x12mm Drill
30-1005-14	2.5x14mm Drill
30-1005-16	2.5x16mm Drill
30-1005-18	2.5x18mm Drill
30-1005-20	2.5x20mm Drill
170-2000-XX	Sizers
170-2001-XX	Rasps
170-2002	Impactor, ball
170-2003	Tamp
170-2004	Graft Packer
170-2005-X	Graft Loader
170-2006	Inserter
170-2008	Angled Awl
170-2009	Angled Screw Driver
Z-1004	Jeweler Handle
IMPLANTS	
Interbody Plate	
170-05	5mm Interbody Plate
170-06	6mm Interbody Plate
170-07	7mm Interbody Plate
170-08	8mm Interbody Plate
170-09	9mm Interbody Plate
170-10	10mm Interbody Plate
170-11	11mm Interbody Plate
170-12	12mm Interbody Plate
Spacer	
170-0006	Spacer 12x15, 0 deg, -06
170-0007	Spacer 12x15, 0 deg, -07
170-0008	Spacer 12x15, 0 deg, -08

Part#	Description
170-0009	Spacer 12x15, 0 deg, -09
170-0010	Spacer 12x15, 0 deg, -10
170-0011	Spacer 12x15, 0 deg, -11
170-0012	Spacer 12x15, 0 deg, -12
170-0506	Spacer 12x15, 5 deg, -06
170-0507	Spacer 12x15, 5 deg, -07
170-0508	Spacer 12x15, 5 deg, -08
170-0509	Spacer 12x15, 5 deg, -09
170-0510	Spacer 12x15, 5 deg, -10
170-0511	Spacer 12x15, 5 deg, -11
170-0512	Spacer 12x15, 5 deg, -12
170-0606	Spacer 12x15, 6 deg, -06
170-0607	Spacer 12x15, 6 deg, -07
170-0608	Spacer 12x15, 6 deg, -08
170-0609	Spacer 12x15, 6 deg, -09
170-0610	Spacer 12x15, 6 deg, -10
170-0611	Spacer 12x15, 6 deg, -11
170-0612	Spacer 12x15, 6 deg, -12
170-0706	Spacer 12x15, 7 deg, -06
170-0707	Spacer 12x15, 7 deg, -07
170-0708	Spacer 12x15, 7 deg, -08
170-0709	Spacer 12x15, 7 deg, -09
170-0710	Spacer 12x15, 7 deg, -10
170-0711	Spacer 12x15, 7 deg, -11
170-0712	Spacer 12x15, 7 deg, -12
170-0806	Spacer 12x15, 8 deg, -06
170-0807	Spacer 12x15, 8 deg, -07
170-0808	Spacer 12x15, 8 deg, -08
170-0809	Spacer 12x15, 8 deg, -09
170-0810	Spacer 12x15, 8 deg, -10
170-0811	Spacer 12x15, 8 deg, -11
170-0812	Spacer 12x15, 8 deg, -12
170-0906	Spacer 12x15, 9 deg, -06
170-0907	Spacer 12x15, 9 deg, -07
170-0908	Spacer 12x15, 9 deg, -08
170-0909	Spacer 12x15, 9 deg, -09
170-0910	Spacer 12x15, 9 deg, -10
170-0911	Spacer 12x15, 9 deg, -11

Part#	Description
170-0912	Spacer 12x15, 9 deg, -12
170-1006	Spacer 12x15, 10 deg, -06
170-1007	Spacer 12x15, 10 deg, -07
170-1008	Spacer 12x15, 10 deg, -08
170-1009	Spacer 12x15, 10 deg, -09
170-1010	Spacer 12x15, 10 deg, -10
170-1011	Spacer 12x15, 10 deg, -11
170-1012	Spacer 12x15, 10 deg, -12
171-0006	Spacer 15x17.5, 0 deg, -06
171-0007	Spacer 15x17.5, 0 deg, -07
171-0008	Spacer 15x17.5, 0 deg, -08
171-0009	Spacer 15x17.5, 0 deg, -09
171-0010	Spacer 15x17.5, 0 deg, -10
171-0011	Spacer 15x17.5, 0 deg, -11
171-0012	Spacer 15x17.5, 0 deg, -12
171-0506	Spacer 15x17.5, 5 deg, -06
171-0507	Spacer 15x17.5, 5 deg, -07
171-0508	Spacer 15x17.5, 5 deg, -08
171-0509	Spacer 15x17.5, 5 deg, -09
171-0510	Spacer 15x17.5, 5 deg, -10
171-0511	Spacer 15x17.5, 5 deg, -11
171-0512	Spacer 15x17.5, 5 deg, -12
171-0606	Spacer 15x17.5, 6 deg, -06
171-0607	Spacer 15x17.5, 6 deg, -07
171-0608	Spacer 15x17.5, 6 deg, -08
171-0609	Spacer 15x17.5, 6 deg, -09
171-0610	Spacer 15x17.5, 6 deg, -10
171-0611	Spacer 15x17.5, 6 deg, -11
171-0612	Spacer 15x17.5, 6 deg, -12
171-0706	Spacer 15x17.5, 7 deg, -06
171-0707	Spacer 15x17.5, 7 deg, -07
171-0708	Spacer 15x17.5, 7 deg, -08
171-0709	Spacer 15x17.5, 7 deg, -09
171-0710	Spacer 15x17.5, 7 deg, -10
171-0711	Spacer 15x17.5, 7 deg, -11
171-0712	Spacer 15x17.5, 7 deg, -12
171-0806	Spacer 15x17.5, 8 deg, -06
171-0807	Spacer 15x17.5, 8 deg, -07

Part#	Description
171-0808	Spacer 15x17.5, 8 deg, -08
171-0809	Spacer 15x17.5, 8 deg, -09
171-0810	Spacer 15x17.5, 8 deg, -10
171-0811	Spacer 15x17.5, 8 deg, -11
171-0812	Spacer 15x17.5, 8 deg, -12
171-0906	Spacer 15x17.5, 9 deg, -06
171-0907	Spacer 15x17.5, 9 deg, -07
171-0908	Spacer 15x17.5, 9 deg, -08
171-0909	Spacer 15x17.5, 9 deg, -09
171-0910	Spacer 15x17.5, 9 deg, -10
171-0911	Spacer 15x17.5, 9 deg, -11
171-0912	Spacer 15x17.5, 9 deg, -12
171-1006	Spacer 15x17.5, 10 deg, -06
171-1007	Spacer 15x17.5, 10 deg, -07
171-1008	Spacer 15x17.5, 10 deg, -08
171-1009	Spacer 15x17.5, 10 deg, -09
171-1010	Spacer 15x17.5, 10 deg, -10
171-1011	Spacer 15x17.5, 10 deg, -11
171-1012	Spacer 15x17.5, 10 deg, -12
Screws	
31-4012	Self Drilling Variable Screw, 4.0x12mm
31-4014	Self Drilling Variable Screw, 4.0x14mm
31-4016	Self Drilling Variable Screw, 4.0x16mm
31-4018	Self Drilling Variable Screw, 4.0x18mm
31-4020	Self Drilling Variable Screw, 4.0x20mm
33-4012	Self Tapping Variable Screw, 4.0x12mm
33-4014	Self Tapping Variable Screw, 4.0x14mm
33-4016	Self Tapping Variable Screw, 4.0x16mm
33-4018	Self Tapping Variable Screw, 4.0x18mm
33-4020	Self Tapping Variable Screw, 4.0x20mm
35-4512	Rescue Variable Screw, 4.5x12mm
35-4514	Rescue Variable Screw, 4.5x14mm
35-4516	Rescue Variable Screw, 4.5x16mm
35-4518	Rescue Variable Screw, 4.5x18mm
35-4520	Rescue Variable Screw, 4.5x20mm

Part#	Description
32-4012	Self Drilling Fixed Screw, 4.0x12mm
32-4014	Self Drilling Fixed Screw, 4.0x14mm
32-4016	Self Drilling Fixed Screw, 4.0x16mm
32-4018	Self Drilling Fixed Screw, 4.0x18mm
32-4020	Self Drilling Fixed Screw, 4.0x20mm
34-4012	Self Tapping Fixed Screw, 4.0x12mm
34-4014	Self Tapping Fixed Screw, 4.0x14mm
34-4016	Self Tapping Fixed Screw, 4.0x16mm
34-4018	Self Tapping Fixed Screw, 4.0x18mm
34-4020	Self Tapping Fixed Screw, 4.0x20mm
36-4512	Rescue Fixed Screw, 4.5x12mm
36-4514	Rescue Fixed Screw, 4.5x14mm
36-4516	Rescue Fixed Screw, 4.5x16mm
36-4518	Rescue Fixed Screw, 4.5x18mm
36-4520	Rescue Fixed Screw, 4.5x20mm
151-4512	Self Drilling Variable Screw, 4.5x12mm
151-4514	Self Drilling Variable Screw, 4.5x14mm
151-4516	Self Drilling Variable Screw, 4.5x16mm
151-4518	Self Drilling Variable Screw, 4.5x18mm
151-4520	Self Drilling Variable Screw, 4.5x20mm
152-4512	Self Drilling Fixed Screw, 4.5x12mm
152-4514	Self Drilling Fixed Screw, 4.5x14mm
152-4516	Self Drilling Fixed Screw, 4.5x16mm
152-4518	Self Drilling Fixed Screw, 4.5x18mm
152-4520	Self Drilling Fixed Screw, 4.5x20mm

Zavation Z-Link Cervical

Device Description:
The Zavation Z-Link Cervical 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 two holes for inserting one bone screw 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.

Indications for Use:
The Z-Link Cervical is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Z-Link Cervical should be packed with autogenous bone graft and implanted with an anterior approach..

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 Cerivical 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 Cervical 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 Cerivical components should not be used with components of any other system or manufacturer.
-The Zavation Z-Link Cerivical has not been evaluated for safety and compatibility in the MR environment. The Zavation Z-Link Cerivical 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 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 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 as long as the inspection criteria provided below are acceptable for the tray.

<table>
<tr><td colspan="2">Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.</td></tr>
<tr><td colspan="2">Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">2-Containment and transportation: Avoid damage and minimize time before cleaning</td></tr>
<tr><td colspan="2">3-Preparation for cleaning: Dis-assemble instruments as required for the Zavation Z-Link Cervical System, (note that these items are normally stored in the dedicated trays already disassembled). Insure that the jeweler handle AO connection is removed from any drill or driver that it is connected to, and that the graft loader blocks are separated. Place these instruments in there dedicated locations in the sterilization trays after cleaning.</td></tr>
<tr><td colspan="2">4 Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><td>Manual</td><td>Automated</td></tr>
<tr><td>4.1 Pre-Cleaning-Manual:
Alcohol wipe
Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35-40°C) 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 clean warm 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</td><td>4.1 Pre-Cleaning-Automated:
Soak in ultrasonic bath
15 minutes
Use nonmetallic brush
Rinse thoroughly in running water</td></tr>
<tr><td>4.2 Cleaning-Manual:</td><td>4.2 Washer Disinfector:</td></tr>
</table>

• 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 clean running 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 70% isopropyl to dry any lumens or crevices where water may become trapped.	• Wash • 93°C (200°F) minimum • 10 minutes • Rinses; when unloading check cannulations, holes, etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning. • Dry
Inspection: • Visually inspect each 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 instruments with long slender features for distortion • Inspect the 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 Cerivical 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 LLC, 220 Lakeland Parkway Park 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 LLC, 220 Lakeland Parkway, 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.