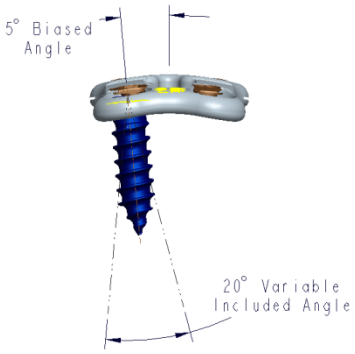
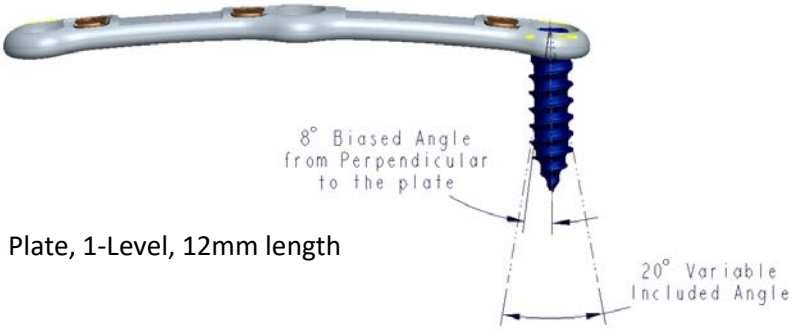
Zavation Cervical Plate System Surgical Technique

Cervical Plate

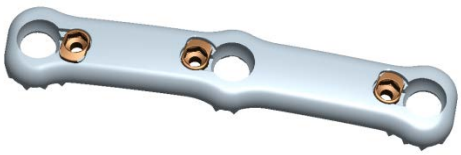
- Features
  - Quarter turn locks for each screw that use same driver as used for inserting screws
  - 8° caudal and cephalad biased angles
  - 5° midline biased angle
  - ±10° Variable angle



- Standard Cervical Plate
  - Size
    - Plate Lengths (end-hole to end-hole)
      - 1-Level: 12, 14, 16, 18, 20, 22, 24, 26
      - 2-Level: 24, 26, 28, 30, 32, 34, 37, 40, 43, 46
      - 3-Level: 39, 42, 45, 48, 51, 54, 57, 60, 63, 66, 69
      - 4-Level: 60, 64, 68, 72, 76, 80, 84
    - 16mm wide
    - 2mm thickness
  - Part Number
    - 30-XXYY
      - XX – levels
      - YY – length
      - i.e. 30-0112 Cervical Plate, 1-Level, 12mm length

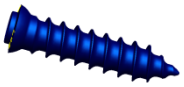


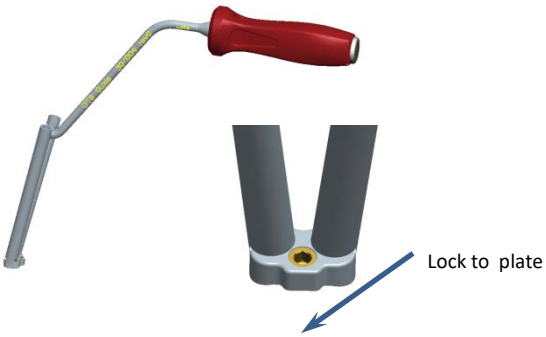
- Midline Cervical Plate
  - Size
    - Plate Lengths (end-hole to end-hole)
      - 1-Level: 12, 14, 16, 18, 20, 22, 24, 26
      - 2-Level: 24, 26, 28, 30, 32, 34, 37, 40, 43, 46
    - 10.5mm wide
    - 2.3mm thickness
  - Part Number
    - 150-XXYY
      - XX – levels
      - YY – length
      - i.e. 150-0112 Midline Cervical Plate, 1-Level, 12mm length

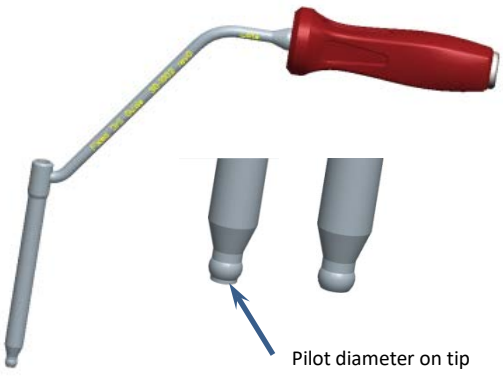


Screw

- Features
  - Variable and fixed angle options available
  - Self drilling and blunt tip self tapping available
- Sizes
  - 4.0mm, 4.5mm, or 5.0mm
  - Length: 12, 14, 16, 18, 20mm
- Part Number
  - 31-40XX Self Drilling Variable Screw, 4.0mm
  - 33-40XX Self Tapping Variable Screw, 4.0mm
  - 35-45XX Rescue Variable Screw, 4.5mm
  - 32-40XX Self Drilling Fixed Screw, 4.0mm
  - 34-40XX Self Tapping Fixed Screw, 4.0mm
  - 36-45XX Rescue Fixed Screw, 4.5mm
  - 151-45XX Self Drilling Variable Screw, 4.5mm
  - 152-45XX Self Drilling Fixed Screw, 4.5mm
  - 153-50XX Self Tapping Variable Screw, 5.0mm
  - 154-50XX Self Tapping Fixed Screw, 5.0mm
  - 155-50XX Self Drilling Variable Screw, 5.0mm
  - 156-50XX Self Drilling Fixed Screw, 5.0mm







Cervical Plate Surgical Technique

1. **Implant Selection**

   Chose appropriate length plate and screws. Length indicated on plates corresponds to the end-hole to end- hole spacing. The screw length is the depth the screw extends below the plate. Insure that the plate length provides sufficient area for cephalad and caudal screw angulation without endplate penetration.

2. **Plate Bending**

   Plates are pre-contoured with a lordotic curve. If forming is required to provide a better match for the anatomy, the plate benders may be used for contouring. Do not bend the plate in the proximity of the screw holes.

3. **Plate Placement**

   3.1. Option 1: Place the plate into position using the provided plate holder.

   3.2. Option 2(not available for Midline plate): Attach the plate to the DTS drill guide using the 2.5mm hex driver to turn the lock screw ¼ turn. Place the plate into position. Ensure the plate is properly positioned with respect to the endplates. (note that only variable angle screws can be used with this guide)

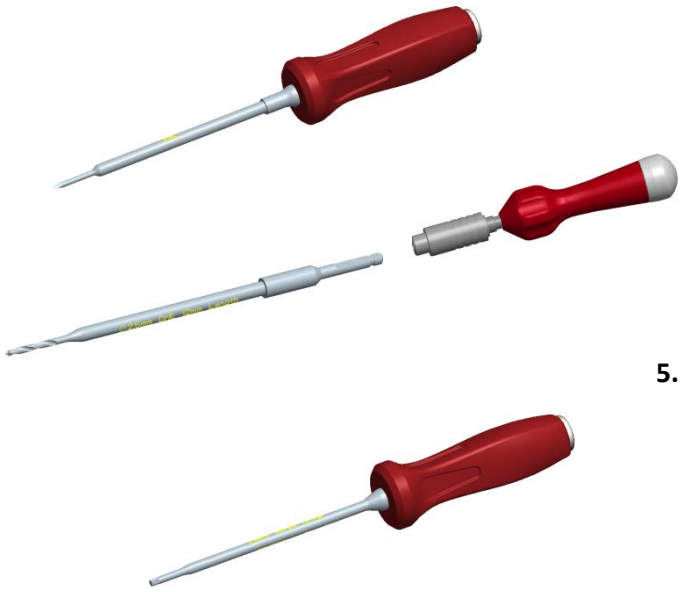
   3.3. Temporary fixation pins may be placed in any of the screw holes. The 2.5mm screw driver is used for insertion. Insure that fixation pins are removed before completing case.

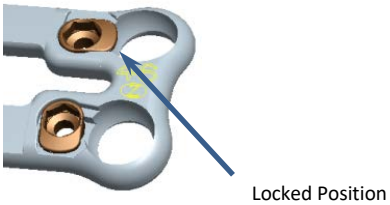
4. **Hole Preparation**

   4.1. Guide options

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

   4.1.2. Option 2: Variable angle drill 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.





Locked Position

4.1.3. Option 3(not available for Midline plate): For the caudal and cephalad holes, the DTS guide provides a 10 degree screw angulation. (note that only the variable angle screws can be used with this guide)

4.2. 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.

5. Screw Insertion

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

6. Lock Screws

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

7. Removal

7.1. Unlock screws: unlock the screw locks by rotating ¼ turn to uncover the screw pocket.

7.2. After screw locks have been rotated, each screw can be removed by using the 2.5mm screw driver.

Part#	Description
INSTRUMENTS	
30-1000	2.5mm Screw Driver
30-1001	Awl
30-1002	Variable Drill Guide
30-1003	Fixed Drill Guide
30-1004	DTS 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
30-1006	Plate Bender
30-1009	Plate Holder
Z-1004	Jeweler Handle
30-1008	Cervical Plate Temporary Screw
IMPLANTS	
Cervical Plate	
30-0112	1-Level, 12 mm Cervical Plate
30-0114	1-Level, 14 mm Cervical Plate
30-0116	1-Level, 16 mm Cervical Plate
30-0118	1-Level, 18 mm Cervical Plate
30-0120	1-Level, 20 mm Cervical Plate
30-0122	1-Level, 22 mm Cervical Plate
30-0124	1-Level, 24 mm Cervical Plate
30-0126	1-Level, 26 mm Cervical Plate
30-0224	2-Level, 24 mm Cervical Plate
30-0226	2-Level, 26 mm Cervical Plate
30-0228	2-Level, 28 mm Cervical Plate
30-0230	2-Level, 30 mm Cervical Plate
30-0232	2-Level, 32 mm Cervical Plate
30-0234	2-Level, 34 mm Cervical Plate
30-0237	2-Level, 37 mm Cervical Plate
30-0240	2-Level, 40 mm Cervical Plate
30-0243	2-Level, 43 mm Cervical Plate
30-0246	2-Level, 46 mm Cervical Plate
30-0339	3-Level, 39 mm Cervical Plate

Part#	Description
30-0342	3-Level, 42 mm Cervical Plate
30-0345	3-Level, 45 mm Cervical Plate
30-0348	3-Level, 48 mm Cervical Plate
30-0351	3-Level, 51 mm Cervical Plate
30-0354	3-Level, 54 mm Cervical Plate
30-0357	3-Level, 57 mm Cervical Plate
30-0360	3-Level, 60 mm Cervical Plate
30-0363	3-Level, 63 mm Cervical Plate
30-0366	3-Level, 66 mm Cervical Plate
30-0369	3-Level, 69 mm Cervical Plate
30-0460	4-Level, 60 mm Cervical Plate
30-0464	4-Level, 64 mm Cervical Plate
30-0468	4-Level, 68 mm Cervical Plate
30-0472	4-Level, 72 mm Cervical Plate
30-0476	4-Level, 76 mm Cervical Plate
30-0480	4-Level, 80 mm Cervical Plate
30-0484	4-Level, 84 mm Cervical Plate
Midline Cervical Plate	
150-0112	1-Level, 12 mm Midline Cervical Plate
150-0114	1-Level, 14 mm Midline Cervical Plate
150-0116	1-Level, 16 mm Midline Cervical Plate
150-0118	1-Level, 18 mm Midline Cervical Plate
150-0120	1-Level, 20 mm Midline Cervical Plate
150-0122	1-Level, 22 mm Midline Cervical Plate
150-0124	1-Level, 24 mm Midline Cervical Plate
150-0126	1-Level, 26 mm Midline Cervical Plate
150-0224	2-Level, 24 mm Midline Cervical Plate
150-0226	2-Level, 26 mm Midline Cervical Plate
150-0228	2-Level, 28 mm Midline Cervical Plate
150-0230	2-Level, 30 mm Midline Cervical Plate
150-0232	2-Level, 32 mm Midline Cervical Plate
150-0234	2-Level, 34 mm Midline Cervical Plate
150-0237	2-Level, 37 mm Midline Cervical Plate
150-0240	2-Level, 40 mm Midline Cervical Plate
150-0243	2-Level, 43 mm Midline Cervical Plate
150-0246	2-Level, 46 mm Midline Cervical Plate

Part#	Description
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
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

Part#	Description
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
153-5012	Self Tapping Variable Screw, 5.0x12mm
153-5014	Self Tapping Variable Screw, 5.0x14mm
153-5016	Self Tapping Variable Screw, 5.0x16mm
153-5018	Self Tapping Variable Screw, 5.0x18mm
153-5020	Self Tapping Variable Screw, 5.0x20mm
154-5012	Self Tapping Fixed Screw, 5.0x12mm
154-5014	Self Tapping Fixed Screw, 5.0x14mm
154-5016	Self Tapping Fixed Screw, 5.0x16mm
154-5018	Self Tapping Fixed Screw, 5.0x18mm
154-5020	Self Tapping Fixed Screw, 5.0x20mm
155-5012	Self Drilling Variable Screw, 5.0x12mm
155-5014	Self Drilling Variable Screw, 5.0x14mm
155-5016	Self Drilling Variable Screw, 5.0x16mm
155-5018	Self Drilling Variable Screw, 5.0x18mm
155-5020	Self Drilling Variable Screw, 5.0x20mm
156-5012	Self Drilling Fixed Screw, 5.0x12mm
156-5014	Self Drilling Fixed Screw, 5.0x14mm
156-5016	Self Drilling Fixed Screw, 5.0x16mm
156-5018	Self Drilling Fixed Screw, 5.0x18mm
156-5020	Self Drilling Fixed Screw, 5.0x20mm

Zavation Cervical Plate System

Device Description:
The Zavation Cervical Plate System consists of self-tapping/self-drilling screws and plates. Screws are available in a variety of diameter and length combinations. Plates are available in a variety of lengths.

Indications: The Zavation Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Materials: The Zavation Cervical Plate System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Contraindications: Contraindications include, but not limited to: The Zavation Cervical Plate System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:
-Early or late loosening of any or all of the components

-Disassembly, bending, and/or breakage of any or all of the components

-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease

-Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain

-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:

-Single use only

-The Zavation Cervical Plate System is not approved for screw attachment or fixation to the (pedicles) of the cervical, thoracic, or lumbar spine

-Non-sterile, the plates, screws and instruments are sold non-sterile, and therefore, must be sterilized before each use

-Always orient the plate along the midline of the spine

-To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated

-To facilitate fusion, a sufficient quantity of autologous bone should be used

-Excessive torque applied to the screws when seating the plate may strip the threads in the bone

-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

-The Zavation Cervical Plate System components should not be used with dissimilar metals or with components of any other system or manufacturer.

-The Zavation Cervical Plate System has not been evaluated for safety and compatibility in the MR environment.

-The Zavation Cervical Plate System has not been tested for heating or migration in the MR environment.

-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.

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. Metallic 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 metal 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:

-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

-Bone grafts must be placed in the area to be fused such that the grafts fits snugly against the upper and lower vertebral bodies

-Before closing soft tissue, check each screw to make sure that none have loosened

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

-The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and should be removed

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 provide 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 Cervical Plate System, the only instruments requiring disassembly would be Drills that are left assembled to the Jeweler Handle. (note that these items are normally stored in the dedicated trays already disassembled).</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>
</table>

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	**4.1 Pre-Cleaning-Automated:** • Soak in ultrasonic bath • 15 minutes • Use nonmetallic brush • Rinse thoroughly in running water
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 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	**4.2 Washer Disinfector:** • 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

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.	
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 Cervical Plate System 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, 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.