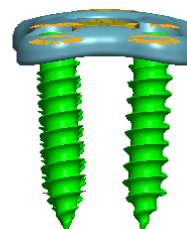
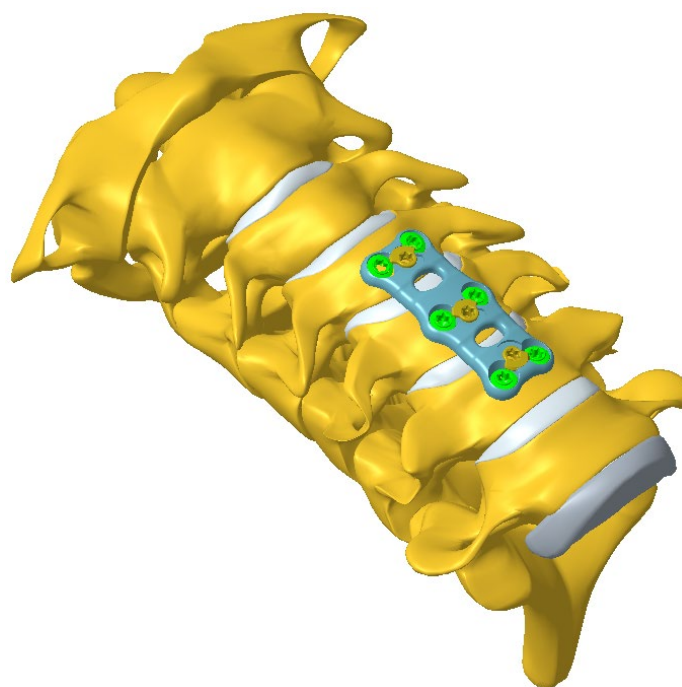
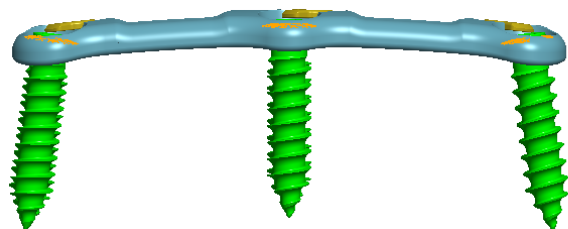
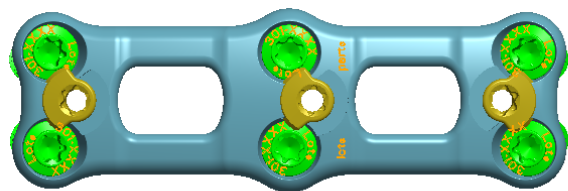
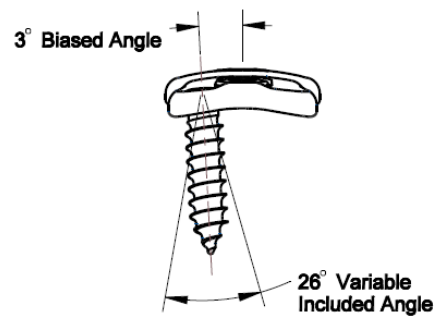
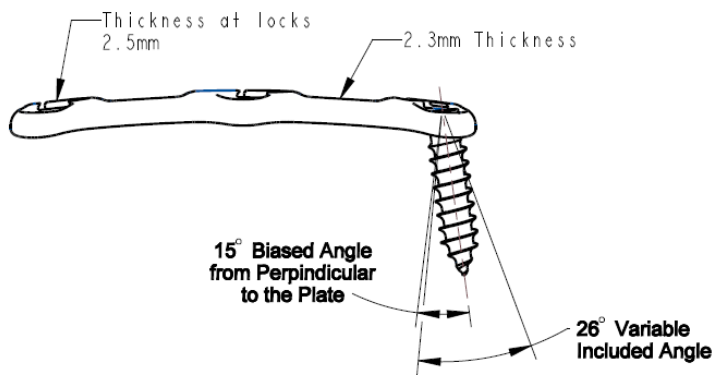
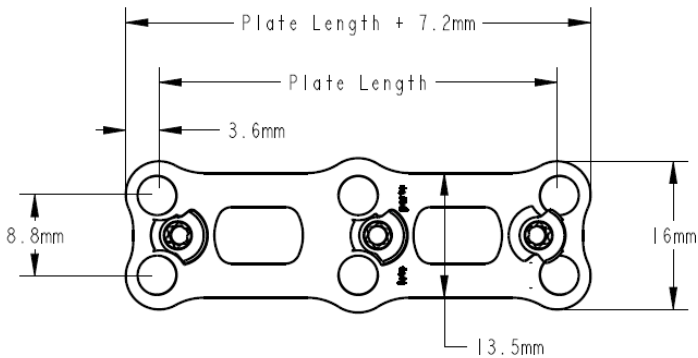


# **EZ Plate®**

## **Surgical Technique Guide**

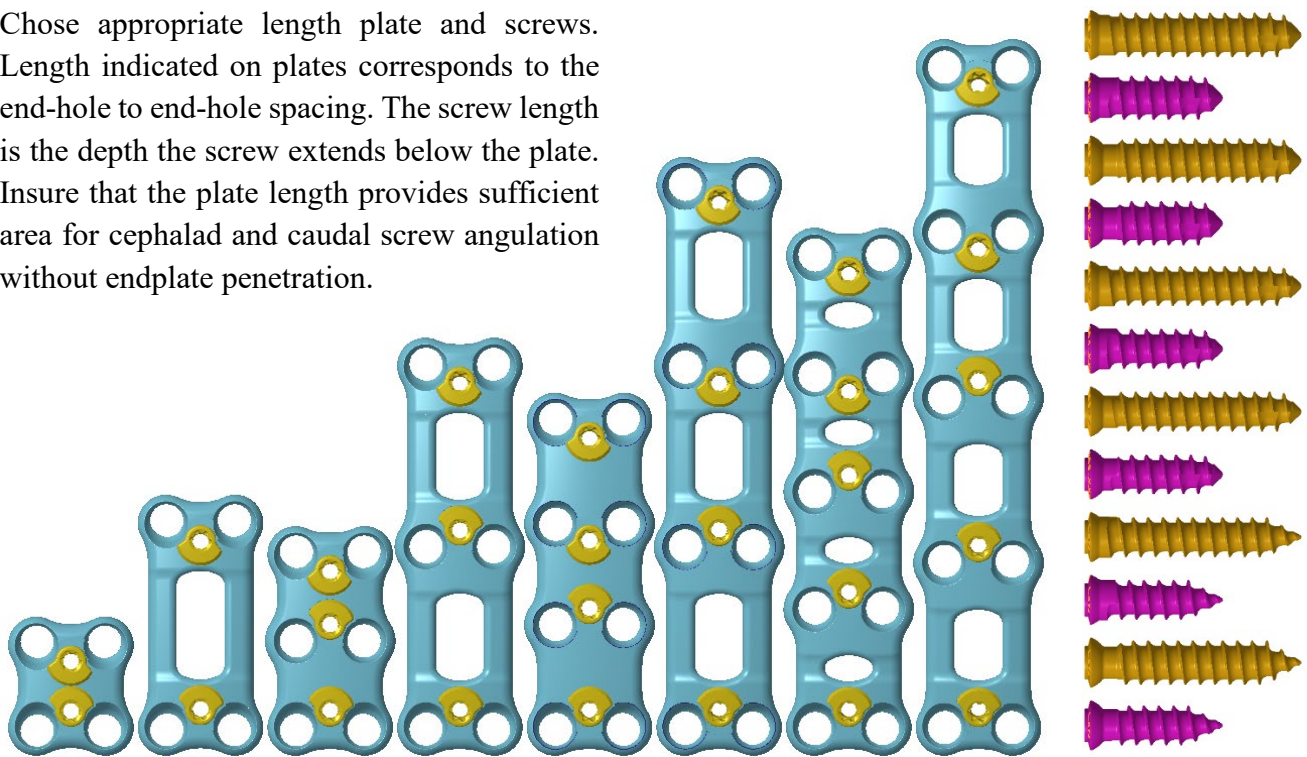


**EZ Plate® Dimensions and Screw Angulation**



## Step 1 – Implant Selection

Choose 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. Ensure that the plate length provides sufficient area for cephalad and caudal screw angulation without endplate penetration.



## Step 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.

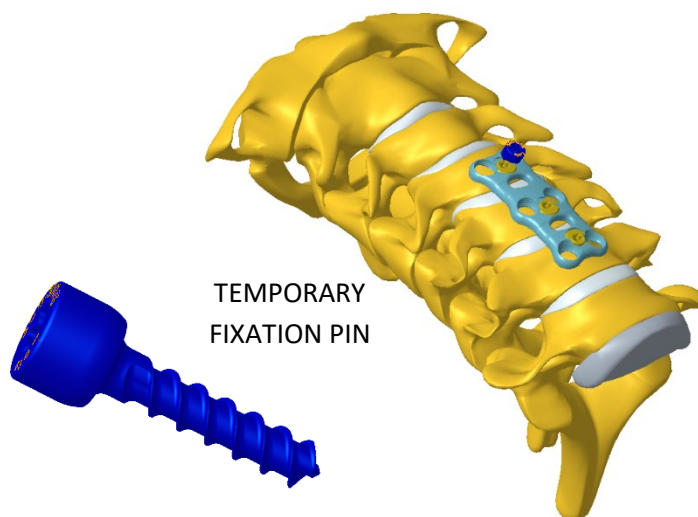


## Step 3 – Plate Placement

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

Option 2: Attach the plate to the DTS drill guide using the T-10 driver to turn the lock screw  $\frac{1}{4}$  turn. Place the plate into position. Ensure the plate is properly positioned with respect to the endplates.

Temporary fixation pins may be placed in any of the screw holes. The T-10 screw driver is used for insertion. Ensure that fixation pins are removed before completing case.

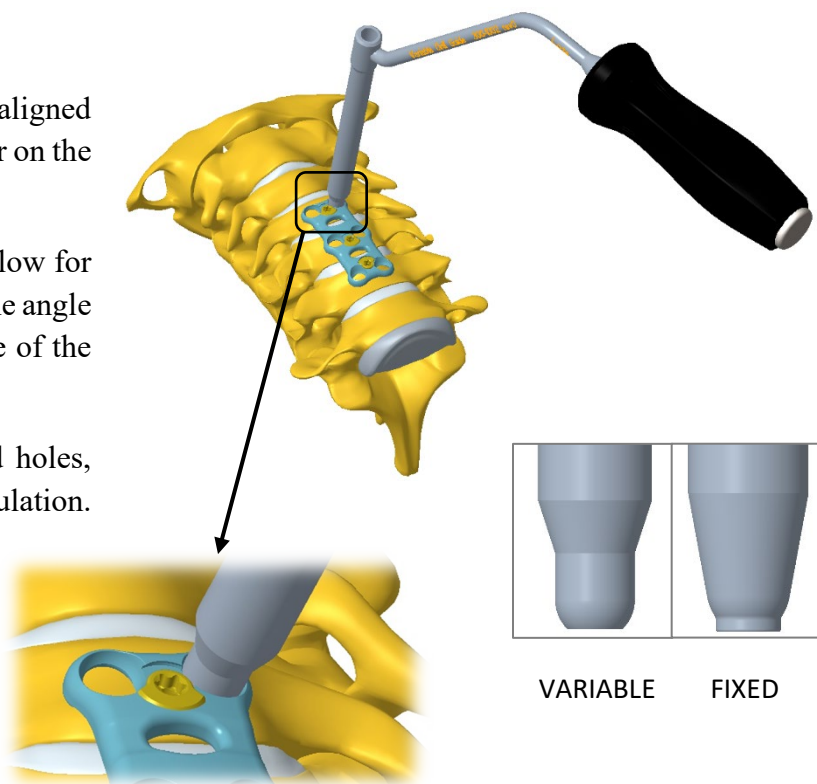


## Step 4 – Hole Preparation

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

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 13 degrees.

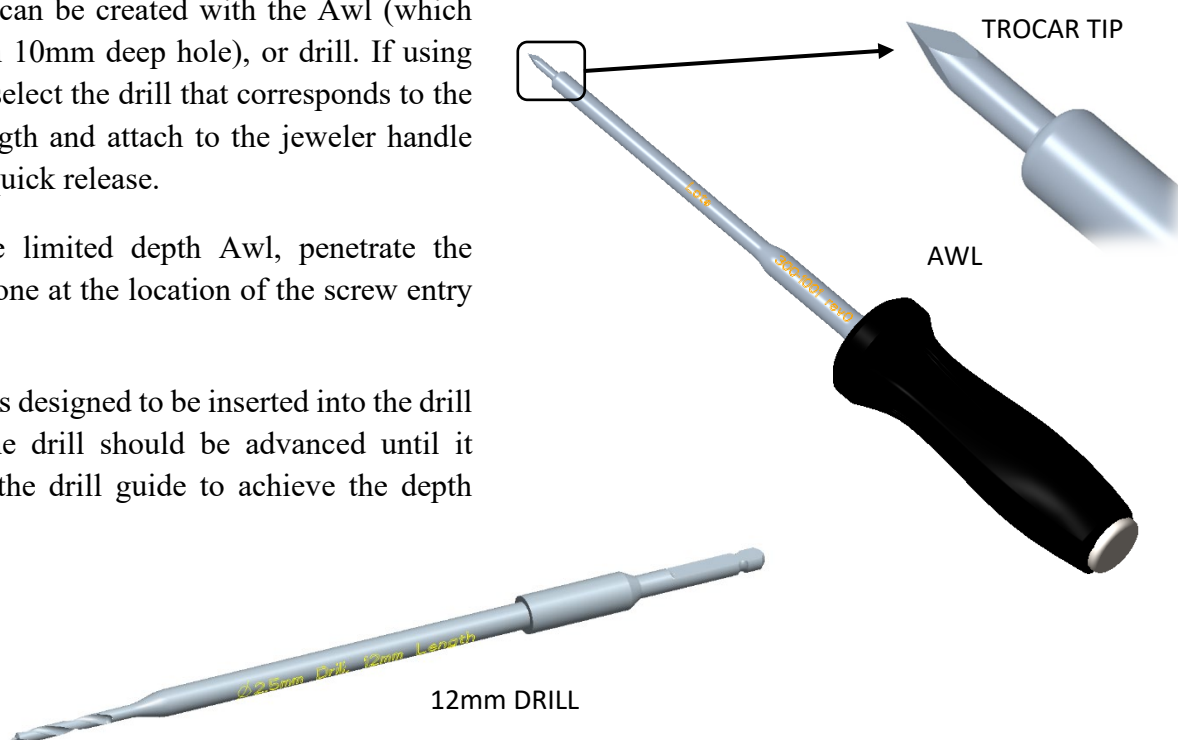
Option 3: For the caudal and cephalad holes, the DTS guide provides a 15° screw angulation.



The hole can be created with the Awl (which creates an 10mm 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.

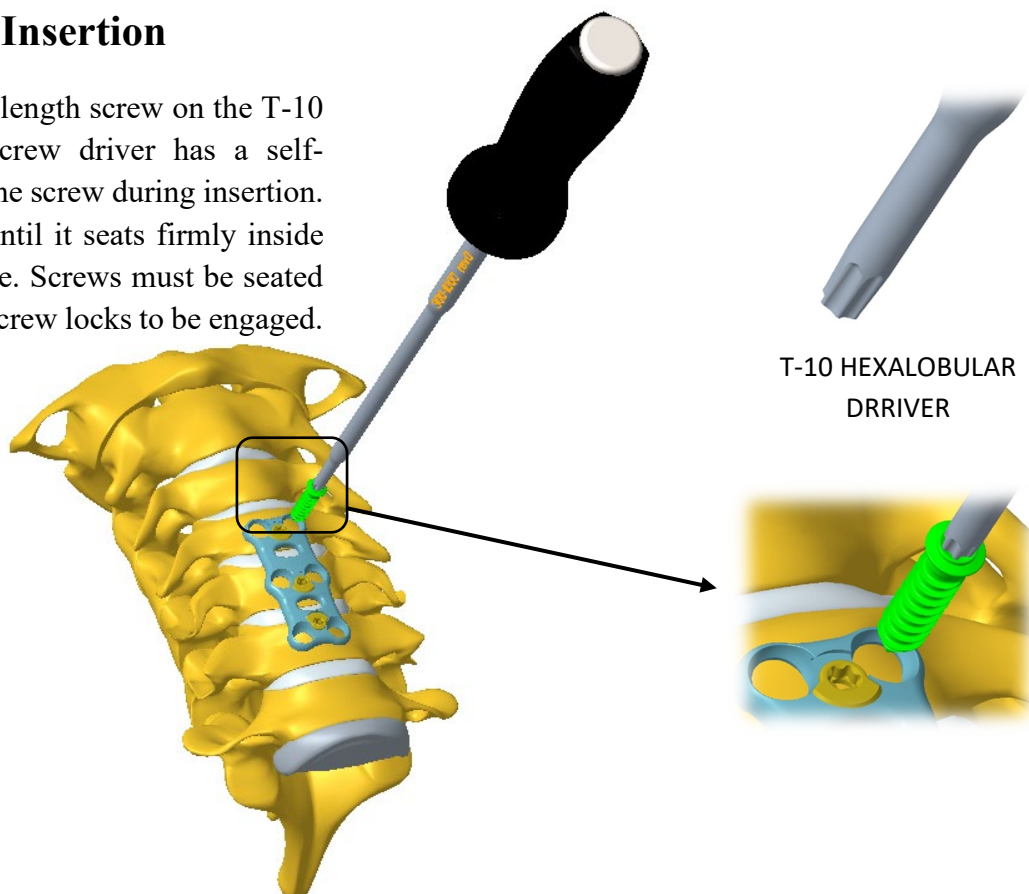
Using the limited depth Awl, penetrate the cortical bone at the location of the screw entry point.

The drill is designed to be inserted into the drill guide. The drill should be advanced until it stops on the drill guide to achieve the depth specified.



## Step 6 – Screw Insertion

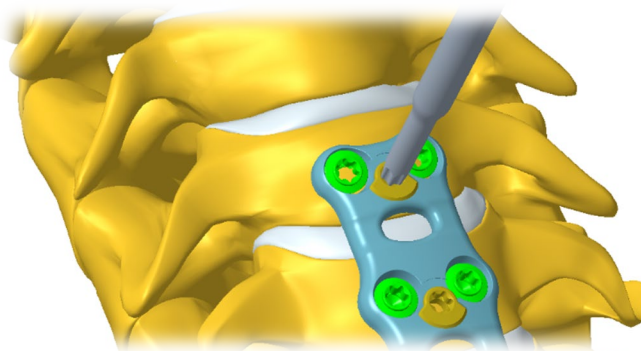
Load the appropriate length screw on the T-10 screw driver. The screw driver has a self-retaining tip to hold the screw during insertion. Advance the screw until it seats firmly inside the pocket in the plate. Screws must be seated completely to allow screw locks to be engaged.





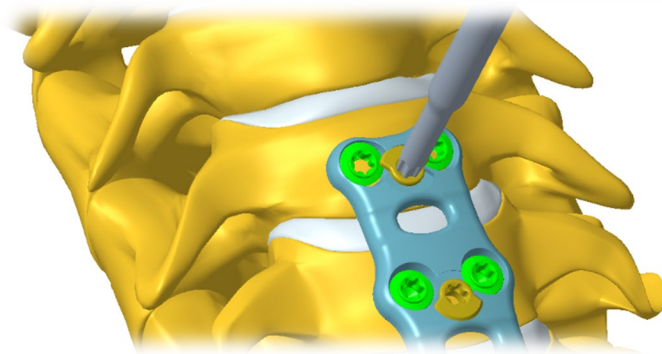
## Step 7 – Lock Screws

Each pair of screws is locked by rotating the screw lock ½ turn using the same driver that is used to insert the screws. It is recommended not to rotate from unlocked to locked more than 2 times.



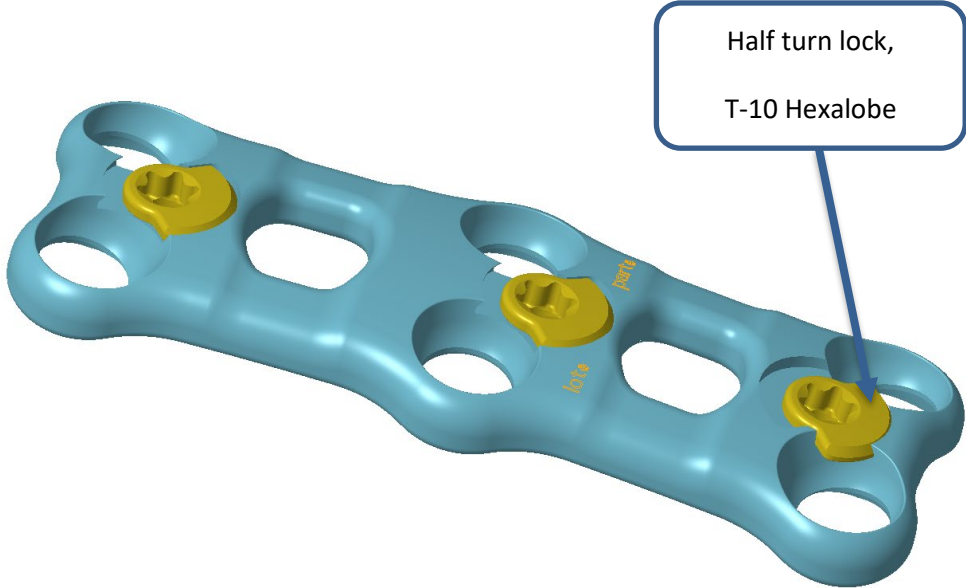
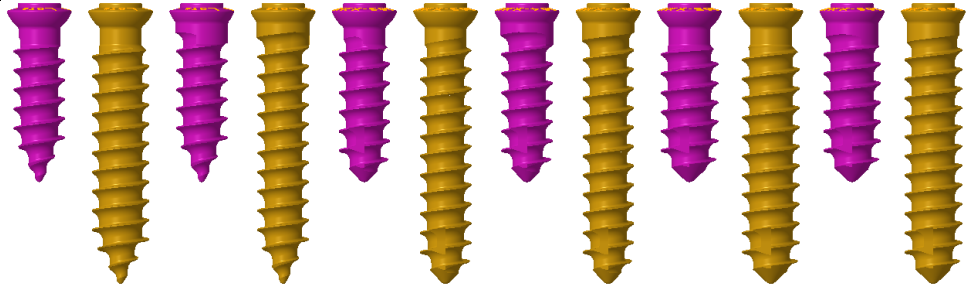
NOT LOCKED

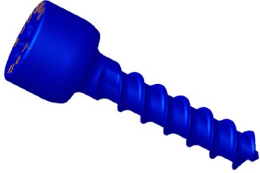
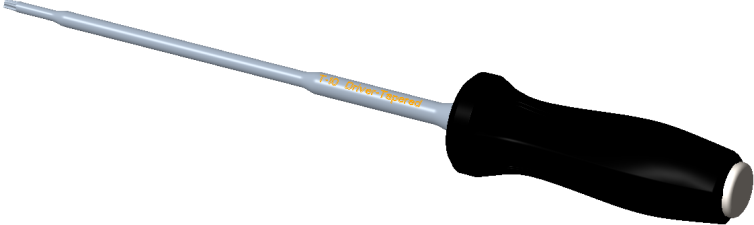
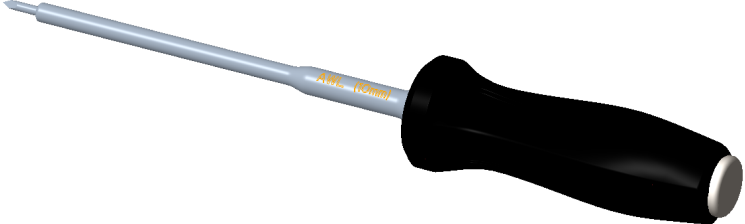
LOCKED



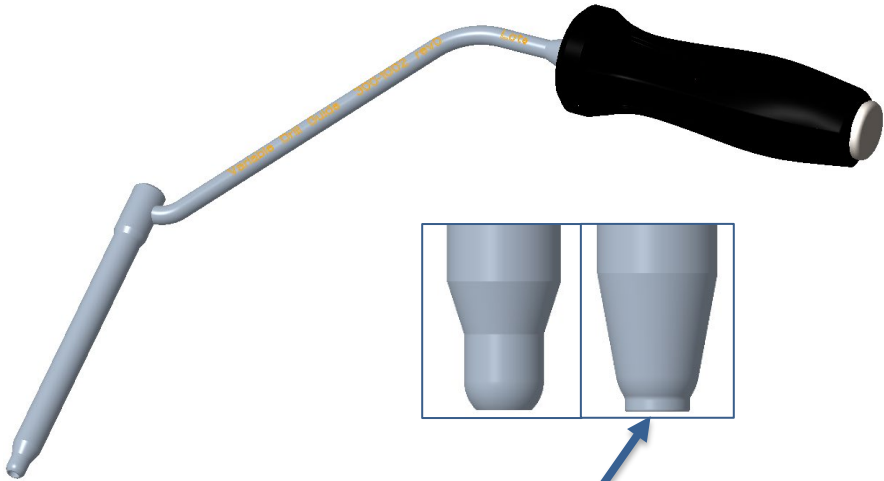
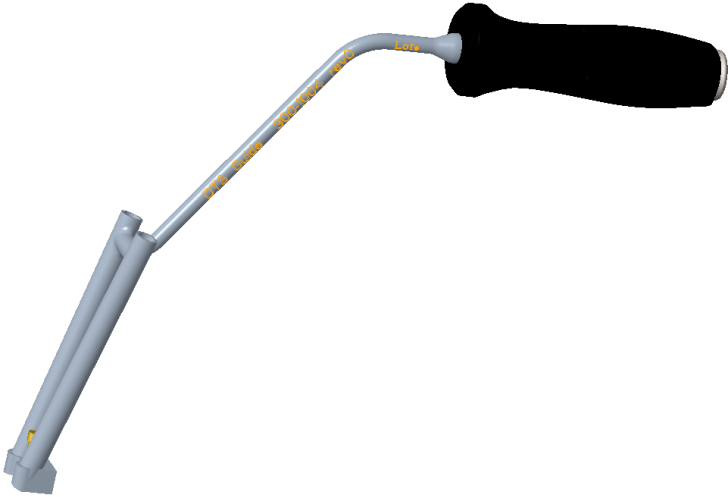
## Removal Process




The removal of the EZ Plate® cervical plate system is accomplished by reversing the order of the implant procedure steps 7 and 6.

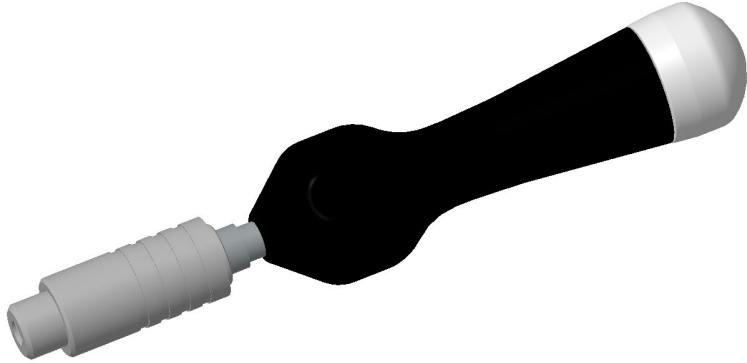
Device View	Part #	Description
Implants		
	300-XXXX	<b>Cervical Plate</b> <ul style="list-style-type: none"> <li>• Half turn locks for each pair of screws</li> <li>• Locks use same driver as used for inserting screws</li> <li>• 14.5° caudal and cephalad biased angles</li> <li>• 3° midline biased angle</li> <li>• ±13° Variable angle</li> <li>• Plate Lengths(end-hole to end-hole) <ul style="list-style-type: none"> <li>○ 1-Level: 10, 12, 14, 16, 18, 20, 22, 24, 26</li> <li>○ 2-Level: 24, 26, 28, 30, 32, 34, 37, 40, 43, 46</li> <li>○ 3-Level: 39, 42, 45, 48, 51, 54, 57, 60, 63, 66, 69</li> <li>○ 4-Level: 60, 64, 68, 72, 76, 80, 84</li> </ul> </li> <li>• 16mm wide</li> <li>• 2.5mm thickness</li> <li>• Material: Titanium per ASTM F-136</li> </ul>
	301-XXXX 302-XXXX 303-XXXX 304-XXXX 305-XXXX 306-XXXX	<b>Cervical Plate Screws:</b> <ul style="list-style-type: none"> <li>• Lengths: 12, 14, 16, 18, 20</li> <li>• Angulation: Variable, Fixed</li> <li>• Diameter: <ul style="list-style-type: none"> <li>○ 4.0mm – Self drilling or Blunt tip self tapping</li> <li>○ 4.5mm –Blunt tip self tapping</li> </ul> </li> <li>• Material: Titanium per ASTM F-136</li> </ul>
Instruments		

Device View	Part #	Description
	300-1005	<b>Cervical Plate Temporary Screw:</b> <ul style="list-style-type: none"> <li>• Inserted with T-10 driver</li> <li>• 2.5mm diameter</li> <li>• 10mm length</li> <li>• Double thread for quick insertion/removal</li> <li>• Material: Titanium</li> </ul>
	300-1000	<b>T-10 Hexalobe Screw Driver</b> <ul style="list-style-type: none"> <li>• Self retaining tip</li> <li>• Material: Stainless steel with silicon handle</li> </ul>
	300-1001	<b>Awl:</b> <ul style="list-style-type: none"> <li>• Trocar tip</li> <li>• 2.5mm diameter</li> <li>• Bottoms on plates to give 10mm depth</li> <li>• Material: Stainless steel with silicon handle</li> </ul>



Device View	Part #	Description
 <p>Pilot diameter on tip provides fixed angle</p>	<p>300-1002 300-1003</p>	<p><b>Drill Guides:</b></p> <ul style="list-style-type: none"> <li>• Variable guide(300-1002) – allows free-hand angulation up to 13°</li> <li>• Fixed guide(300-1003) –fixed angulation</li> <li>• Material: Stainless steel with silicon handle</li> </ul>
	<p>300-1004</p>	<p><b>Drill thru and Screw thru guide</b></p> <ul style="list-style-type: none"> <li>• Double Barrel</li> <li>• Locks to plate with same driver that is used for inserting screws</li> <li>• Material: Stainless steel with silicon handle</li> </ul>
	<p>30-1005-XX</p>	<p><b>Drill:</b></p> <ul style="list-style-type: none"> <li>• 2.5mm diameter</li> </ul>

Device View	Part #	Description
		<ul style="list-style-type: none"> <li>• Lengths (in depth below plate) – 12, 14, 16, 18</li> <li>• Material: Stainless steel</li> </ul>
	30-1009	<p><b>Plate holder:</b></p> <ul style="list-style-type: none"> <li>• Allows holding plate in multiple locations</li> <li>• Material: Stainless steel</li> </ul>
	30-1006	<p><b>Plate Bender:</b></p> <ul style="list-style-type: none"> <li>• Bends lordotic one side kyphosis on opposite</li> <li>• Material: Stainless steel</li> </ul>
	Z-1015	<p><b>Jeweler handle:</b></p> <ul style="list-style-type: none"> <li>• Quick release</li> <li>• Spinner cap</li> </ul>

Device View	Part #	Description
		<ul style="list-style-type: none"><li>Material: Stainless steel with silicon handle</li></ul>

IMPLANTS	
Part#	Description
1-Level Plate	
300-0110	1-Level, 10 mm Cervical Plate
300-0112	1-Level, 12 mm Cervical Plate
300-0114	1-Level, 14 mm Cervical Plate
300-0116	1-Level, 16 mm Cervical Plate
300-0118	1-Level, 18 mm Cervical Plate
300-0120	1-Level, 20 mm Cervical Plate
300-0122	1-Level, 22 mm Cervical Plate
300-0124	1-Level, 24 mm Cervical Plate
300-0126	1-Level, 26 mm Cervical Plate
2-Level Plate	
300-0224	2-Level, 24 mm Cervical Plate
300-0226	2-Level, 26 mm Cervical Plate
300-0228	2-Level, 28 mm Cervical Plate
300-0230	2-Level, 30 mm Cervical Plate
300-0232	2-Level, 32 mm Cervical Plate
300-0234	2-Level, 34 mm Cervical Plate
300-0237	2-Level, 37 mm Cervical Plate
300-0240	2-Level, 40 mm Cervical Plate
300-0243	2-Level, 43 mm Cervical Plate
300-0246	2-Level, 46 mm Cervical Plate
3-Level Plate	
300-0339	3-Level, 39 mm Cervical Plate
300-0342	3-Level, 42 mm Cervical Plate
300-0345	3-Level, 45 mm Cervical Plate
300-0348	3-Level, 48 mm Cervical Plate
300-0351	3-Level, 51 mm Cervical Plate
300-0354	3-Level, 54 mm Cervical Plate
300-0357	3-Level, 57 mm Cervical Plate

IMPLANTS	
Part#	Description
300-0360	3-Level, 60 mm Cervical Plate
300-0363	3-Level, 63 mm Cervical Plate
300-0366	3-Level, 66 mm Cervical Plate
300-0369	3-Level, 69 mm Cervical Plate
4-Level Plate	
300-0460	4-Level, 60 mm Cervical Plate
300-0464	4-Level, 64 mm Cervical Plate
300-0468	4-Level, 68 mm Cervical Plate
300-0472	4-Level, 72 mm Cervical Plate
300-0476	4-Level, 76 mm Cervical Plate
300-0480	4-Level, 80 mm Cervical Plate
300-0484	4-Level, 84 mm Cervical Plate
Variable Screws	
301-4012	Self Drilling Variable Screw, 4.0x12mm
301-4014	Self Drilling Variable Screw, 4.0x14mm
301-4016	Self Drilling Variable Screw, 4.0x16mm
301-4018	Self Drilling Variable Screw, 4.0x18mm
301-4020	Self Drilling Variable Screw, 4.0x20mm
301-4512	Self Drilling Variable Screw, 4.5x12mm
301-4514	Self Drilling Variable Screw, 4.5x14mm
301-4516	Self Drilling Variable Screw, 4.5x16mm
301-4518	Self Drilling Variable Screw, 4.5x18mm
301-4520	Self Drilling Variable Screw, 4.5x20mm
303-4012	Self Tapping Variable Screw, 4.0x12mm
303-4014	Self Tapping Variable Screw, 4.0x14mm
303-4016	Self Tapping Variable Screw, 4.0x16mm
303-4018	Self Tapping Variable Screw, 4.0x18mm

IMPLANTS	
Part#	Description
303-4020	Self Tapping Variable Screw, 4.0x20mm
305-4512	Self Tapping Variable Screw, 4.5x12mm
305-4514	Self Tapping Variable Screw, 4.5x14mm
305-4516	Self Tapping Variable Screw, 4.5x16mm
305-4518	Self Tapping Variable Screw, 4.5x18mm
305-4520	Self Tapping Variable Screw, 4.5x20mm
Fixed Screws	
302-4012	Self Drilling Fixed Screw, 4.0x12mm
302-4014	Self Drilling Fixed Screw, 4.0x14mm
302-4016	Self Drilling Fixed Screw, 4.0x16mm
302-4018	Self Drilling Fixed Screw, 4.0x18mm
302-4020	Self Drilling Fixed Screw, 4.0x20mm
304-4012	Self Tapping Fixed Screw, 4.0x12mm
304-4014	Self Tapping Fixed Screw, 4.0x14mm
304-4016	Self Tapping Fixed Screw, 4.0x16mm
304-4018	Self Tapping Fixed Screw, 4.0x18mm
304-4020	Self Tapping Fixed Screw, 4.0x20mm
306-4512	Self Tapping Fixed Screw, 4.5x12mm
306-4514	Self Tapping Fixed Screw, 4.5x14mm
306-4516	Self Tapping Fixed Screw, 4.5x16mm
306-4518	Self Tapping Fixed Screw, 4.5x18mm
306-4520	Self Tapping Fixed Screw, 4.5x20mm

## INSTRUMENTS

Part#	Description
300-1000	T-10 Driver
300-1001	Cervical Awl with Stop
300-1002	Variable Drill Guide
300-1003	Fixed Drill Guide
300-1004	DTS Guide
300-1005	Cervical Plate Temporary Screw
300-1006	Double Barrel Drill Guide
30-1005-12	12mm Cervical Drill
30-1005-14	14mm Cervical Drill
30-1005-16	16mm Cervical Drill
30-1005-18	18mm Cervical Drill
30-1006	Plate Bender
30-1009	Plate Holder
Z-1015	Jeweler Handle w/ AO Adapter and

## **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. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

**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 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
- 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.

<b>Cautions:</b> Long, narrow cannulations and blind holes require particular attention during cleaning.	
<b>Limitations on reprocessing:</b> Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.	
<b>1-Point of use:</b> 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.	
<b>2-Containment and transportation:</b> Avoid damage and minimize time before cleaning	
<b>3-Preparation for cleaning:</b> 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).	
<b>4 Thoroughly clean instruments per one of the following (Manual or Automated)</b>	
Manual	Automated
<b>4.1 Pre-Cleaning-Manual:</b> <ul style="list-style-type: none"><li>• Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer.</li><li>• 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.</li><li>• Change the soak solution if the solution becomes visibly soiled.</li><li>• 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</li><li>• 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</li></ul>	<b>4.1 Pre-Cleaning-Automated:</b> <p>Automated washing shall be conducted in a validated washer-disinfector.</p> <p>An example of a validated cycle used for cleaning validation includes:</p> <ul style="list-style-type: none"><li>• Wash 45°C 4 minutes dose pump 4 (detergent) 5mL</li><li>• Wash 60°C 3 minutes</li><li>• Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute.</li><li>• Rinse 60°C 1 minute</li></ul>

<p><b>4.2 Cleaning-Manual:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>	<p><b>4.2 Washer Disinfect:</b></p> <p>Automated washing shall be conducted in a validated washer-disinfect.</p> <p>An example of a validated cycle used for cleaning validation includes:</p> <ul style="list-style-type: none"> <li>• Thermal Disinfection A<sub>0</sub> 93°C</li> <li>• A<sub>0</sub> value: A<sub>0</sub>3000</li> <li>• Dry 123°C air 14 minutes</li> </ul>
<p><b>Inspection:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Check disassembled instruments with long slender features for distortion.</li> <li>• Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration</li> </ul>	
<p><b>Packaging:</b> Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</p>	
<p><b>Sterilization:</b> See sterilization procedure</p>	
<p><b>Storage:</b> Control environment</p>	
<p><b>Additional information:</b> When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.</p>	
<p><b>Manufacturer contact:</b> Contact local representative or call customer service at 601-919-1119</p>	

**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 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.