ACP1 CERVICAL PLATE SPINAL SYSTEM

SURGICAL TECHNIQUE GUIDE

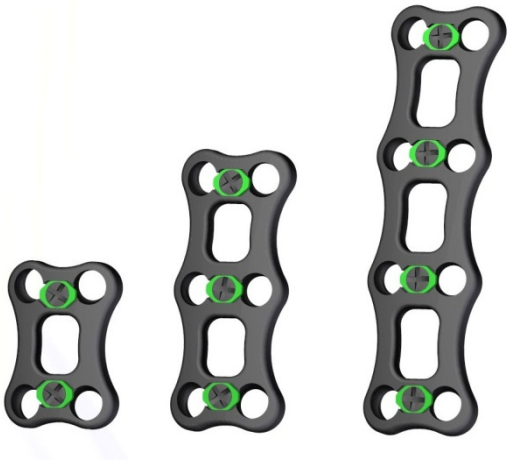
GOLD STANDARD ORTHOPAEDICS

I. Introduction

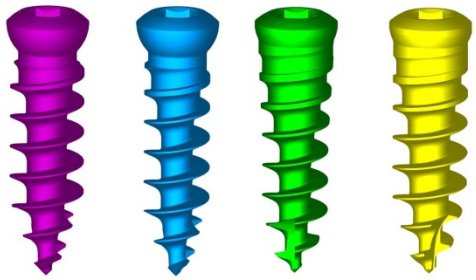
The Gold Standard Orthopaedics, LLC ACP1 Spinal System was designed with surgeons to incorporate strength, functionality, and ease of use into a Cervical Plate System.

The GS1 Spinal system is designed for the treatment of instability of the cervical spine (C2-C7). This is achieved through the use of the multiple available sizes of plates in conjunction with multiple available sizes of fixed and variable angle screws.

II. Implant Design and Features



- Available in 1, 2, 3, or 4 Level Versions
- Sizes Available from 20 to 100mm in Length
- All Plates are Pre-Curved to fit the Natural Lordotic Curve of the Spine
- Each pair of Screw Holes has its own Locking Mechanism



- Screws are available in Lengths from 10 to 20mm
- Screws are Color-Coded for easier recognition
  * 4.0mm Variable Angle – Magenta
  * 4.5mm Variable Angle – Light Blue
  * 4.0mm Fixed Angle – Green
  * 4.5mm Fixed Angle – Yellow
- Screws are self-drilling/self-tapping

III. Instrumentation

Driver/Inserter with Screw Holder

Locking Screw Driver

Caliper

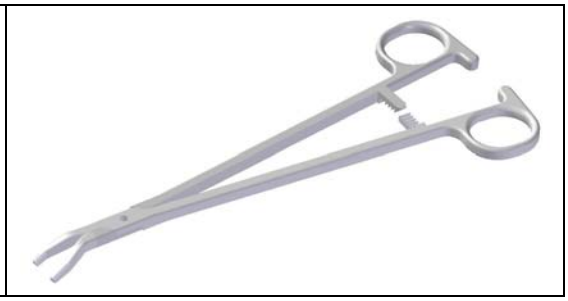


Plate Holder

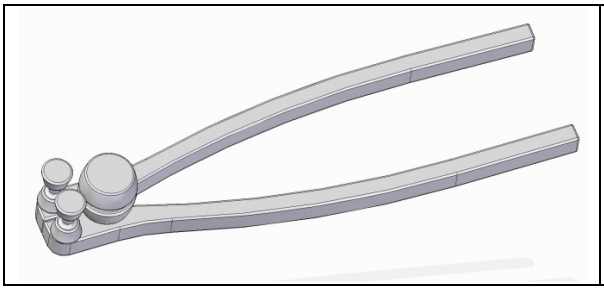


Plate Bender – Increase Lordosis

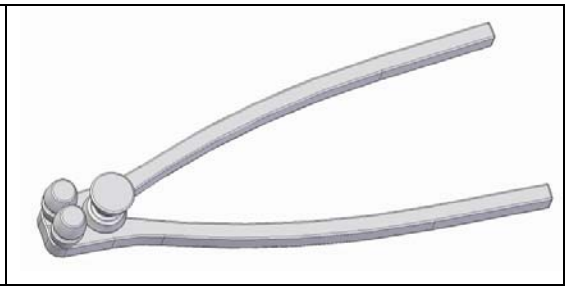
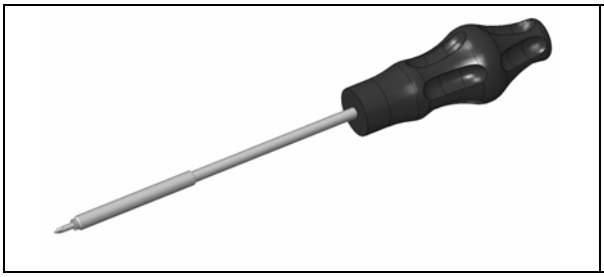
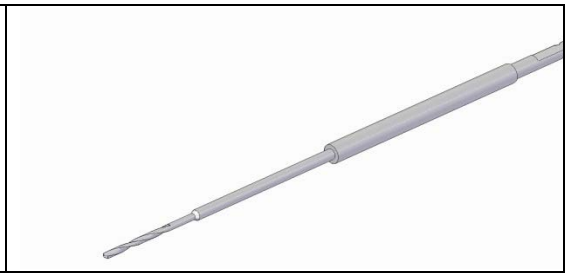


Plate Bender – Decrease Lordosis

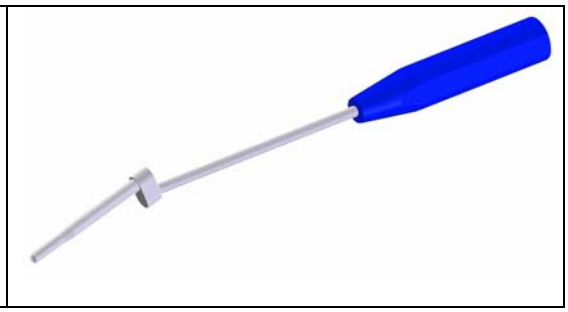


Bone Awl with Guide Sleeve



Drill Bit

Fixed Drill Guide



Variable Drill Guide

IV. Surgical Technique

A. Patient Positioning and Preparation

The patient is positioned supine on an operative table. The use of external rigging or positioners may be helpful to achieve proper patient positioning. Fluoroscopy may be used to confirm positioning and determine if the correct vertebral levels are accessible.

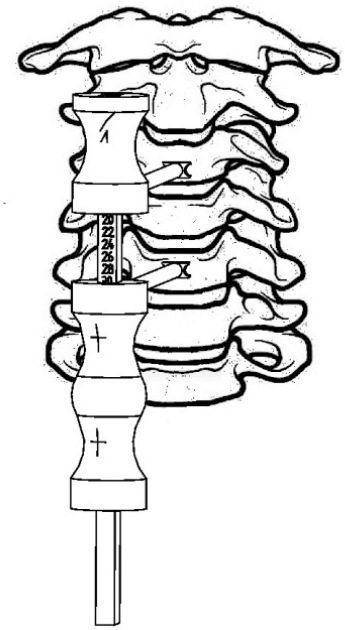
Using a standard anterior approach to the lower and mid cervical spine, make an incision with the exposure typically medial of the carotid sheath and lateral to the trachea and esophagus.

B. Site Preparation

Perform a discectomy and resection of the anterior osteophytes to allow for plate approximation to the spine. Additional preparation of the fusion site will be dictated as indicated for the particular circumstance.

Place interbody grafts or implants into the desired position. Release any distraction that may have been used. Assess graft stability and ensure proper placement. Repeat site preparation for each disc space to be included.

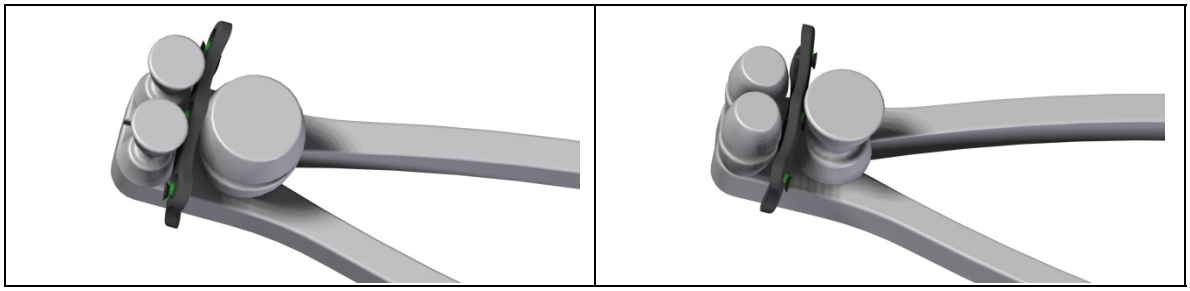
C. Plate Selection



The ACP1 Spinal System has plates available for one, two, three, and four level versions. Using the CALIPERS, measure the approximate length of the plate required. Place the arms of the CALIPERS in the location of the desired screw locations. Allow for the proper cephalad and caudal screw angles at each end of the plate. The length shown on the CALIPERS represents the approximate length of plate required. Select the proper plate by using the correct level version and approximate length measured.

D. Adjustment of Plate Curvature (optional)

The ACP1 Cervical Plate is designed with a predetermined amount of lordosis that is acceptable in the majority of cases. However, plate benders are available to change the standard curvature. When bending the plates, avoid creating any abrupt changes, sharp bends, or reverse bends in curvature. Select the proper plate bender for increasing or decreasing lordosis.

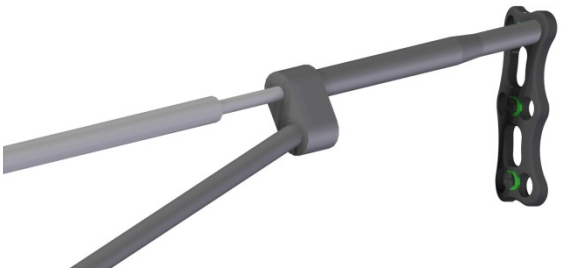


Increase Lordosis | Decrease Lordosis

E. Temporary Placement

ACP1 plates have spikes protruding from the underside of the plate at each screw level. These are designed to help hold the plate in its desired location during screw placement. A gentle tap at each locate with prevent the plate from moving during installation.

F. Drill Guide Selection and Use



Two types of drill guides are available. The fixed drill guide allows the drill hole to be on axis with the holes in the plate. This follows a 10° medial angle for all holes. The center holes are neutral in the cranial/caudal angle, while the end holes are 10° outward cranial/caudal angle. The variable angle drill guide allows the insertion angle to be varied slightly. After the style of drill guide is chosen, it is placed in the desired hole for the first screw. A drill is then used to create the hole. The depth is fixed and controlled by a firm shoulder stop on the drill.

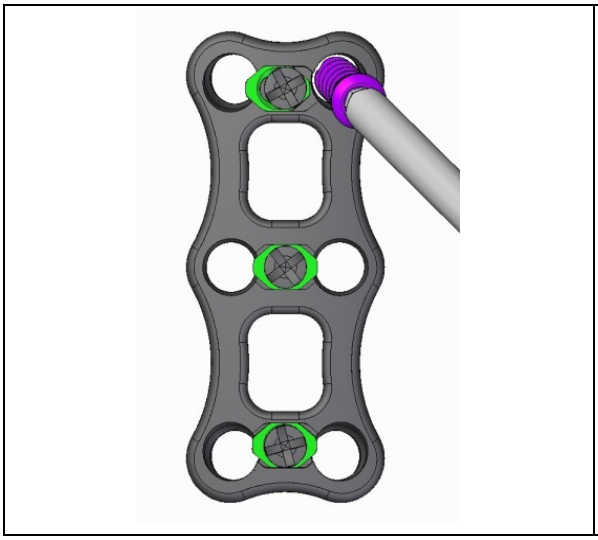
G. Screw Selection

Various methodologies exist for selecting the screw type. The choice of variable angle or fixed angle screws should be made by the surgeon based on each individual case. The 4.0mm diameter is typically used first with the 4.5mm diameter being available if needed. The length can be approximated from the available MRI or radiograph information. The length should be chosen to avoid the tip of the screw protruding on the posterior side.

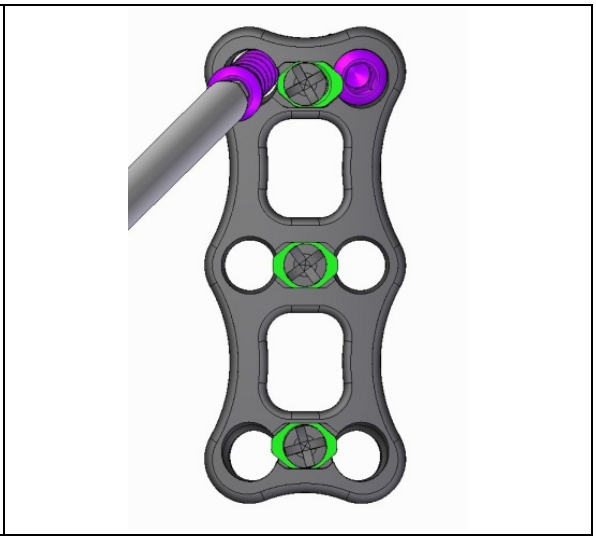
H. Insert Bone Screws

Load screw on driver and place in drill hole.

1) Load the screw on the driver by aligning the hex drive. The self-retaining feature of the driver holds the screw in place for insertion.

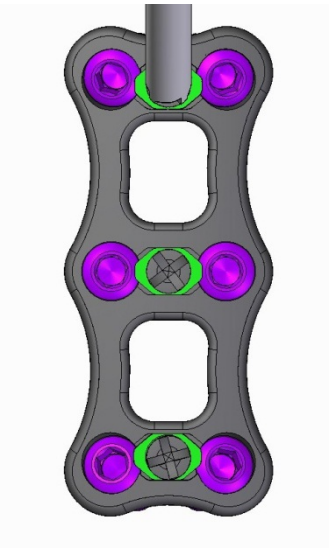


2) With the plate held in place and the holes prepared, insert the first screw.



3) The next screw can be inserted. Placing the second screw at the bottom set of holes on the adjacent side of the first may simplify the installation.

I. Tighten Locking Screws



Once all screws are properly installed, use the Locking Screw Driver to tighten the Locking Screw at each pair of screws. Advancing the locking screw will automatically align the locking tab into the central location allowing both screws at that level to be captured. Tighten this screw finger tight, taking care not to excessively tighten. Repeat this step for each level.

J. Screw Removal

For screw removal, loosen the Locking Screw in the center of each pair of screw holes. There is no need to remove this screw completely. Insert the driver into the bone screw(s) to be removed. The screw should urge the locking tab to the opposite side as it is being removed. If this does not occur, nudge the locking tab over manually to allow screw removal.

K. Closure

Perform closure in layers following standard protocol.

L. Implant Removal

Removal of the ACP1 Anterior Cervical Plate System is performed by reversing the order of the implant procedure. To unlock the screws use the Locking Screw Driver to unscrew the locking screw free the locking plate from the underlying screw heads. Then use the Driver Inserter to remove the bone screws and then the plate.

V. Indications for Use:

The GSO ACP1 Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions.

WARNING: This device system is intended for anterior cervical interbody fusions only. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

VI. Contraindications:

1. Infection local to the operative site
2. Signs of local inflammation or open wounds adjacent to the operative site
3. Fever or leukocytosis
4. Morbid obesity
5. Mental illness, alcoholism or drug abuse
6. Pregnancy
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal sensitivity, allergy, intolerance, or foreign body sensitivity
10. Patients with inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
11. Any case not described in the Indications for Use
12. Any patient unwilling to cooperate with the post-operative instructions

VII. Warnings:

1. This device system is intended for anterior cervical interbody fusions only.
2. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
4. Laboratory fatigue testing has shown a relationship between device loading and device performance which makes patient selection factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions and their effect on the load and number of cycles to which the implant is subjected crucial to surgical success.
5. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.
6. Contact of dissimilar metals accelerates the corrosion process, which could enhance fatigue fracture of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other. Stainless steel and titanium implant components must not be used together in a construct.

Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ACP1 Anterior Cervical Plate by the surgeon. A successful surgical result is not always achieved. This is especially true in spinal surgery where many extenuating circumstances may compromise the results. The ACP1 Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the ACP1 Anterior Cervical Plate System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

The proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

Postoperative care is extremely important. The patient should be warned that non-compliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the device.

VIII. PRECAUTIONS:

1. This implant system is intended for single use only. Never re-implant an explanted metal device, under any circumstances. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. Titanium implants are to be handled with care. If contouring of the plate is required, avoid sharp bends and reverse bends. Avoid notching or scratching of the device, which could produce internal stresses and lead to early breakage.
3. After healing is complete, the implant may be removed since it is no longer necessary. Implants which are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone; particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
4. Adequate patient instruction must include instructing the patient on the limitations of the metallic implant. The patient should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
5. This device is recommended for use by surgeons thoroughly familiar with the relative current literature, surgical techniques, implantation technique for this device, and postoperative care of the patient.

IX. Implant Listing

1 Level Plates

Part Number	Description
509120	20mm Plate
509122	22mm Plate
509124	24mm Plate
509126	26mm Plate
509128	28mm Plate
509130	30mm Plate
509132	32mm Plate

2 Level Plates

Part Number	Description
509234	34mm Plate
509237	37mm Plate
509240	40mm Plate
509243	43mm Plate
509246	46mm Plate
509249	49mm Plate
509252	52mm Plate

3 Level Plates

Part Number	Description
509353	53mm Plate
509356	56mm Plate
509359	59mm Plate
509362	62mm Plate
509365	65mm Plate
509368	68mm Plate
509371	71mm Plate
509374	74mm Plate
509377	77mm Plate

4 Level Plates

Part Number	Description
509468	68mm Plate
509472	72mm Plate
509476	76mm Plate
509480	80mm Plate
509484	84mm Plate
509488	88mm Plate
509492	92mm Plate
509496	96mm Plate
509499	100mm Plate

Fixed Angle Screws

Part Number	Description
509210	4.0 x 10mm
509212	4.0 x 12mm
509214	4.0 x 14mm
509216	4.0 x 16mm
509218	4.0 x 18mm
509220	4.0 x 20mm
509310	4.5 x 10mm
509312	4.5 x 12mm
509314	4.5 x 14mm
509316	4.5 x 16mm
509318	4.5 x 18mm
509320	4.5 x 20mm

Variable Angle Screws

Part Number	Description
509410	4.0 x 10mm
509412	4.0 x 12mm
509414	4.0 x 14mm
509416	4.0 x 16mm
509418	4.0 x 18mm
509420	4.0 x 20mm
509510	4.5 x 10mm
509512	4.5 x 12mm
509514	4.5 x 14mm
509516	4.5 x 16mm
509518	4.5 x 18mm
509520	4.5 x 20mm

X. Instrument Listing

Part Number	Description
509710	2.5mm Hex Driver
509714	Locking Screw Driver
509716	Caliper - Measuring Device
509719	Plate Bender - Increase
509720	Plate Bender - Decrease
509722	Awl
509723	Variable Drill Guide *
509724	Fixed Drill Guide *
509726	Soft Tissue Sleeve
509728	Plate Holder
509730	Drill Bit *

Instrumentation:

• This System is designed to be compatible with a combination of device specific* and common instruments currently available in an operation room equipped for Spine Surgery. These Items are listed to the left.

XI. Additional Information

A. Sterilization Recommendations

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be cleaned and sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified otherwise, these products are recommended to be steam sterilized by the hospital using the process parameters below:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	[1] Pre-Vacuum	270F (132C)	4 Minutes	30 Minutes

[1] Validated steam sterilization time required to achieve a 10^{-6} sterility assurance level (SAL).

Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility. Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment.

B. Surgical Technique Note

All surgical procedures and techniques are the responsibility of the medical professional. The surgeon based on personal medical training and experience must evaluate the procedure for appropriateness. No one technique is suitable for all patients.

Caution: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

INFORMATION: For further information, please contact your local GSO Distributor.

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