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CASSIOPEIA

Anterior Cervical
Plate System

SURGICAL TECHNIQUE GUIDE

GS Medical

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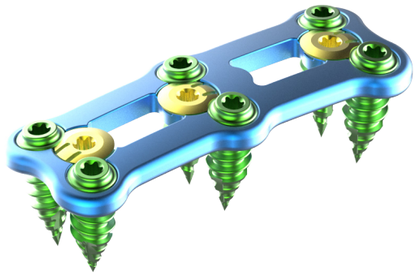


This is intended as a guide only. Please refer to the Instructions for Use insert for complete system description, indications, warnings, and accompanying instrumentation. There are multiple techniques for the insertion of a cervical implant and screw system and, as with any surgical procedure, GS Medical products should only be used after thorough surgeon training on the instrumentation and implants. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for each insert for complete system descriptions, indications and warning. Additional questions should be directed to GS Solutions, Inc., 949-380-6385, or GS Medical Co., Ltd., 82-43-237-7393.

Features and Benefits

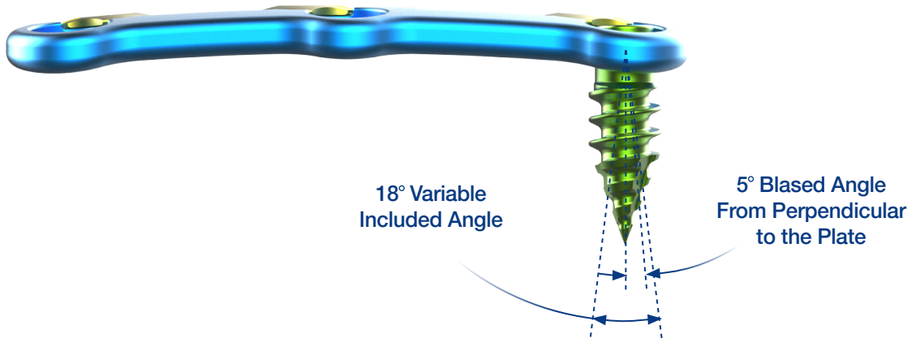
Welcome to GS Medical and the CASSIOPEIA Cervical Plate Implant System. Our goal at GS Medical is to offer cost-effective products with superior quality that provide innovative solutions for spine surgeons and their patients' needs.

The CASSIOPEIA Cervical Plate Implant System follows this principle and was developed to provide the surgeon with a comprehensive, state-of-the-art system for cervical fusion.

There are several key differentiating features and benefits one will find within this system including, but not limited to:

- A low profile that seamlessly integrates with existing patient anatomy the CASSIOPEIA Cervical Plate is 2.25mm thick
- The CASSIOPEIA Cervical Plate system offers Variable and fixed-angle screws available in self-drilling and self-tapping options in lengths from 12mm to 26mm, with diameters of 4.2mm (primary) or 4.6mm (rescue).
- A selection of 1-, 2-, 3-, 4- and 5-level plates in multiple lengths to conform to varying patient anatomies
- Large graft fenestrations to allow for a high volume of bone grafting material resulting in excel-lent bony in-growth
- Better visibility and graft accommodation through the large graft windows; and
- Unique and simple rotating locks with tactile feedback to prevent inadvertent screw back out.

All implants are made of Ti-6Al-4V ELI and are combined with biomechanical properties for advanced strength and stability.



Site Preparation

Expose the cervical spine via a standard anterior cervical approach. After the appropriate disc space levels are exposed, prepare the space by excising the disc and performing spinal decompression.
Insert the graft of choice at the desired level(s).

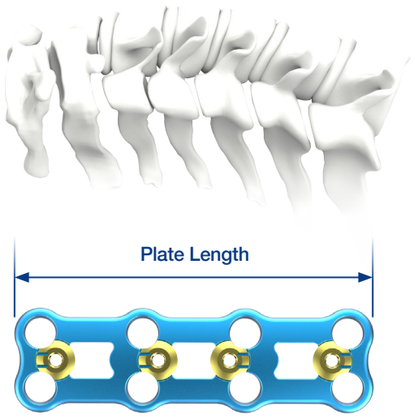
To ensure ideal bone-plate interface, the ventral cortical surface must be smooth in profile prior to plate placement.
To accomplish this, it may be necessary to remove all anterior osteophytes.
This can be accomplished by using a burr or rongeur.

Anterior Cervical Spine

Implant Size Selection

The CASSIOPEIA Cervical Plate is available in lengths from 1 to 5 levels, ranging from 19mm to 125mm.
Plate measurements are evaluated from the end of the plate to the end.

Measure the vertebral column and confirm proper implant length.
When the plate is appropriately sized, the superior screw holes align with the inferior third of the cephalad vertebral body, and the inferior screw holds align with the superior third of the caudal vertebral body.



Instrument Used	
Caliper	GS142-3600
Plate, 1 Level	3300-1019~1043
Plate, 2 Level	3300-2032~2054
Plate, 3 Level	3300-3047~3077
Plate, 4 Level	3300-4065~4101
Plate, 5 Level	3300-5080~5125

Plate Contouring

Plate Bender GS142-4100

The CASSIOPEIA Cervical Plate is pre-contoured with a standard lordotic curve. If additional contouring is needed to better match the anatomy, use only the provided Plate Bender to increase the lordotic curve.
The CASSIOPEIA Cervical Plate has specific bend zones and should not be bent across or near the locking mechanism. Doing so may result in a malfunction of the screw locking mechanism.

Once a plate is bent, do not reverse the bend as this may weaken the plate or cause premature fatigue fractures.

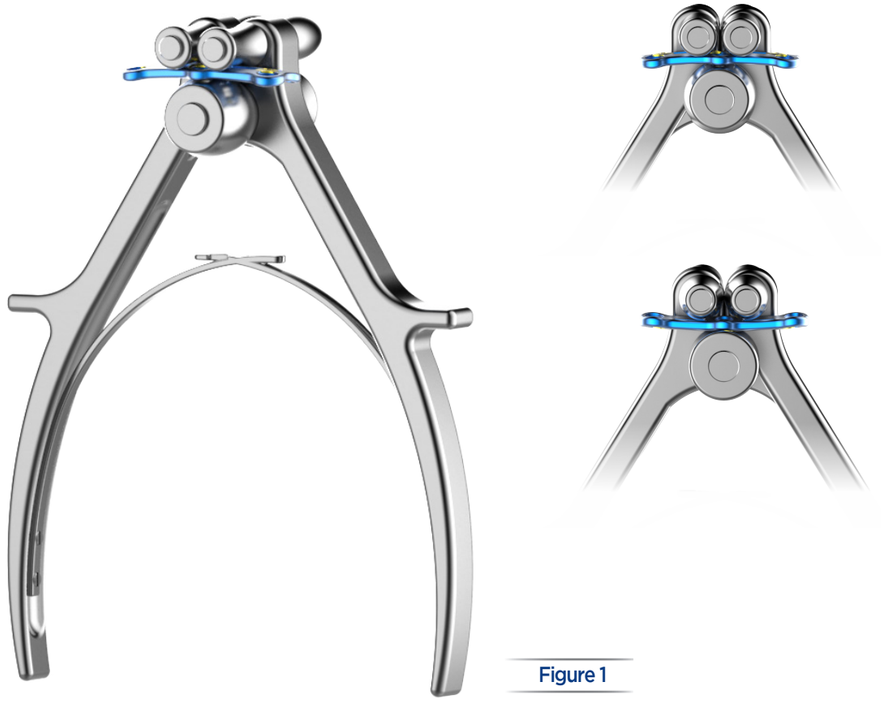


Figure 1

Plate Positioning and Placement of fixation Pins

GS142-4200 Simple Plate Holder
GS142-4201 Plate Holder

Using the provided Plate Holder, center the plate on the vertebral column. Using the Temporary Fixation Pin Driver, insert a Temporary Fixation Pin into one of the cephalad and one of the caudal fixation pin holes.
For 3-, 4- and 5-level plates, the Long Temporary Fixation Pins are recommended.
Confirm proper plate positioning and alignment using anatomical landmarks and/or fluoroscopy.

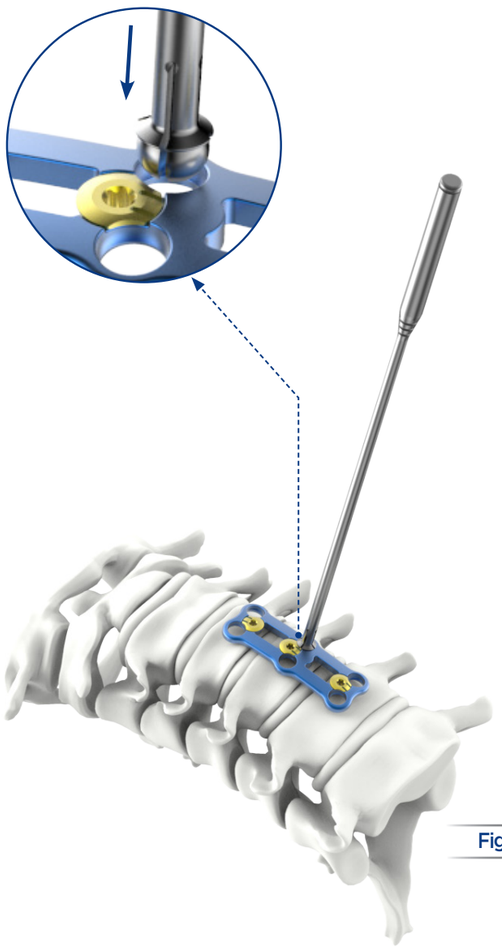
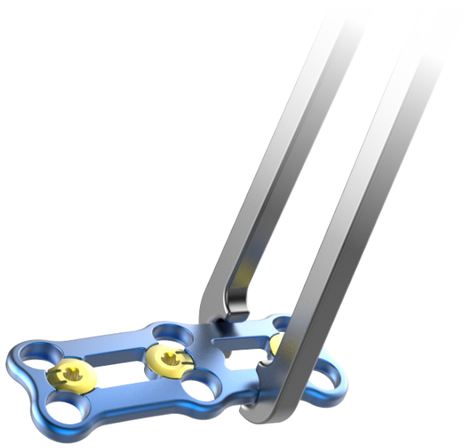


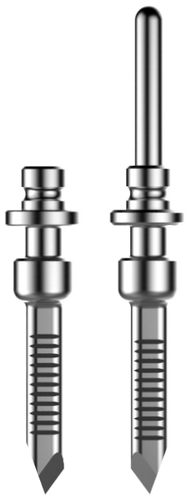
Figure 2



Option Instrument

Plate Positioning and Placement of fixation Pins

GS142-5200 Temporary Fixation Pin Driver
GS142-0700 Temporary Fixation Pin, Short
GS142-0701 Temporary Fixation Pin, Long



Short Long

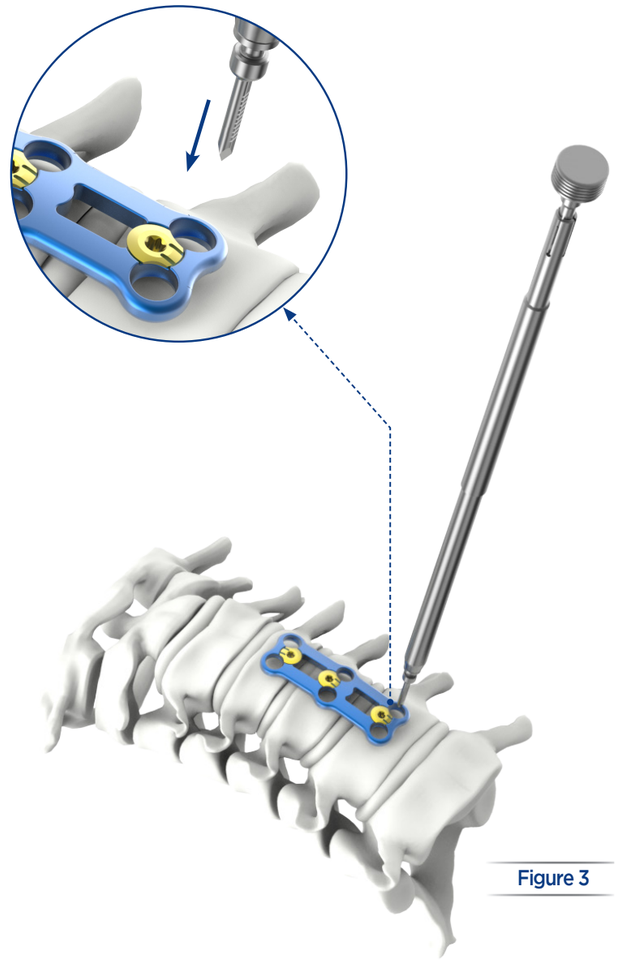
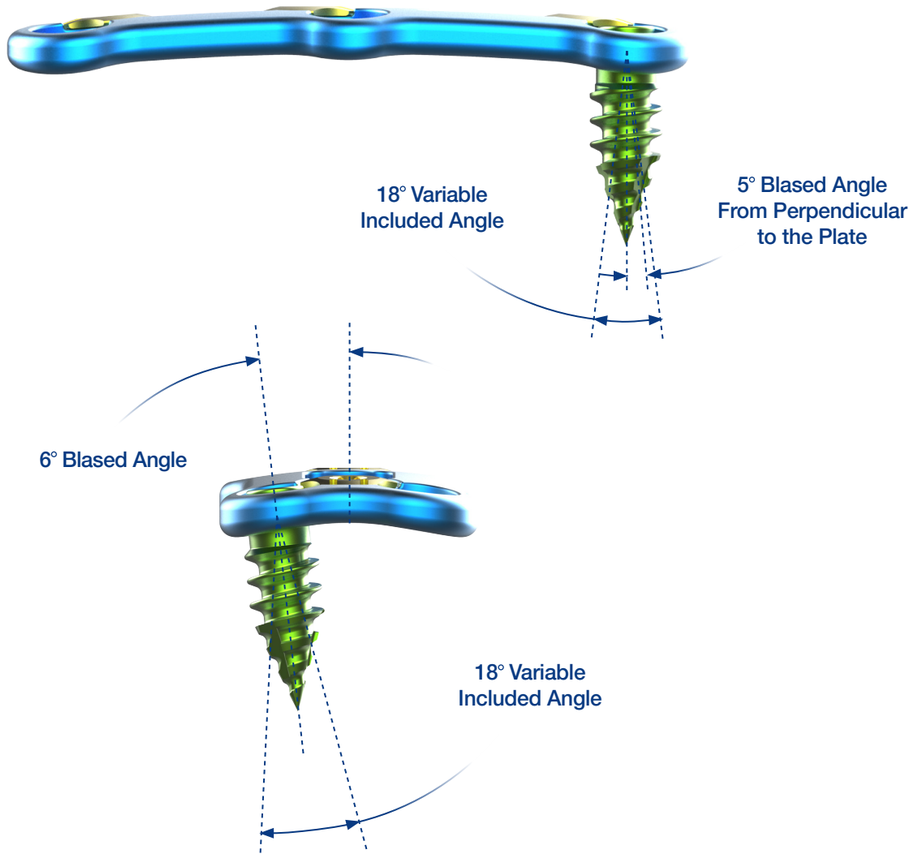


Figure 3

Screw Selection

Fixed Angle Screw, Self-Drilling	**3310-0012~0026, 3312-0012~0026**
Fixed Angle Screw, Self-Tapping	**3311-0012~0026, 3313-0012~0026**
Variable Angle Screw, Self-Drilling	**3320-0012~0026, 3322-0012~0026**
Variable Angle Screw, Self-Drilling	**3321-0012~0026, 3323-0012~0026**

The CASSIOPEIA Cervical Plate system offers screws in lengths from 12mm to 26mm, with diameters of 4.2mm or 4.6mm. The screw length is the depth the screw extends beyond the plate, or screw engagement within the bone. Screws are available in variable angle self-drilling and self-tapping configurations, as well as fixed-angle self-drilling and self-tapping configurations. The variable-angle screws offer an 18° cone of angulation.



Screw Hole Preparation

GS142-0200	**Cervical Awl, with Sleeve**
GS142-0201	**Cervical Awl, for Drill Guide**
GS142-1000~1003	**Single Drill Guide**
GS142-1012~1026	**Drill Bit**
GS142-1032~1046	**Short Drill Bit**
GS142-0500	**Cervical Tap**
GS142-3601	**Cervical Depth Gauge**

Once the CASSIOPEIA Cervical Plate is properly positioned on the vertebral bodies, if the Surgeon prefers, use the provided Awl to penetrate the cortical bone via each screw socket to provide a starting point for screw insertion. If the cortical bone is particularly dense, use a mallet to gently strike the handle of the Awl.

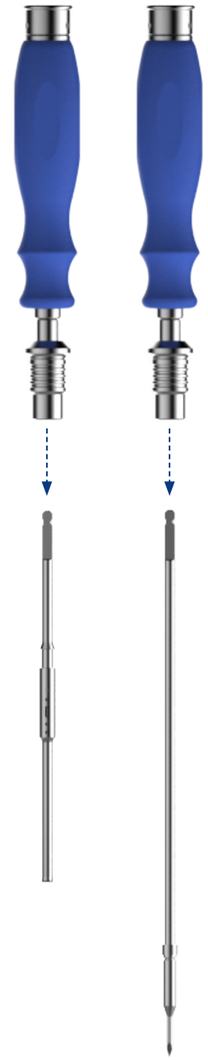
The GS system includes a variety of single drill guide options – fixed angle and variable angle with either a long or short barrel – that allow for proper screw insertion and correct angulation. Choose the appropriate Drill Guide for the selected screw type (e.g. a variable angle drill guide should be used with a variable angle screw).

Variable-Angle Self-Drilling or Self-Tapping Screws: Variable angle screws are typically placed at the end of the plate. When inserting a screw at the desired angle, use of the provided Variable Angle Drill Guide will enable correct angulation and proper screw insertion within the parameters of the plate design.

Fixed-Angle Self-Drilling or Self-Tapping Screws: Fixed-angle screws are typically placed in the middle of the plate. Use of the provided Fixed-Angle Drill Guide or Awl will ensure proper screw insertion.

If using a Drill Guide, insert the tip of the Drill Guide into the screw hole of the plate.
If using a Variable angle screw, align to the proper angle so as to avoid vascular and neural structures as well as other screw tips, which could interfere with proper screw insertion.

Attach the appropriate Drill Bit (either standard or short) to the power drill. The surgeon then advances the Drill Bit through the Drill Guide. Remove the Drill Guide and Drill Bit and confirm appropriate screw depth. If using a self-drilling screw, the CASSIOPEIA Cervical Plate system includes a Cervical Tap should tapping be necessary. If using a self-tapping screw, tapping is not required.



Screw Hole Preparation(Cont.)

Figure 4

Figure 5

Screw Hole Preparation(Cont.)

Figure 6

Screw Hole Preparation(Cont.)

Screw Insertion

GS142-0800 Screw Driver, Self-Retaining

Remove the previously selected screw from the screw caddy using the Self-Retaining Screw Driver. This Screw Driver is capable of holding the screw during insertion. Insert the screw into the screw hole and turn clockwise into the vertebral body. Use fluoroscopic imaging to confirm proper positioning of the plate and screws in the vertebral body prior to the final screw tightening and CAM locking.

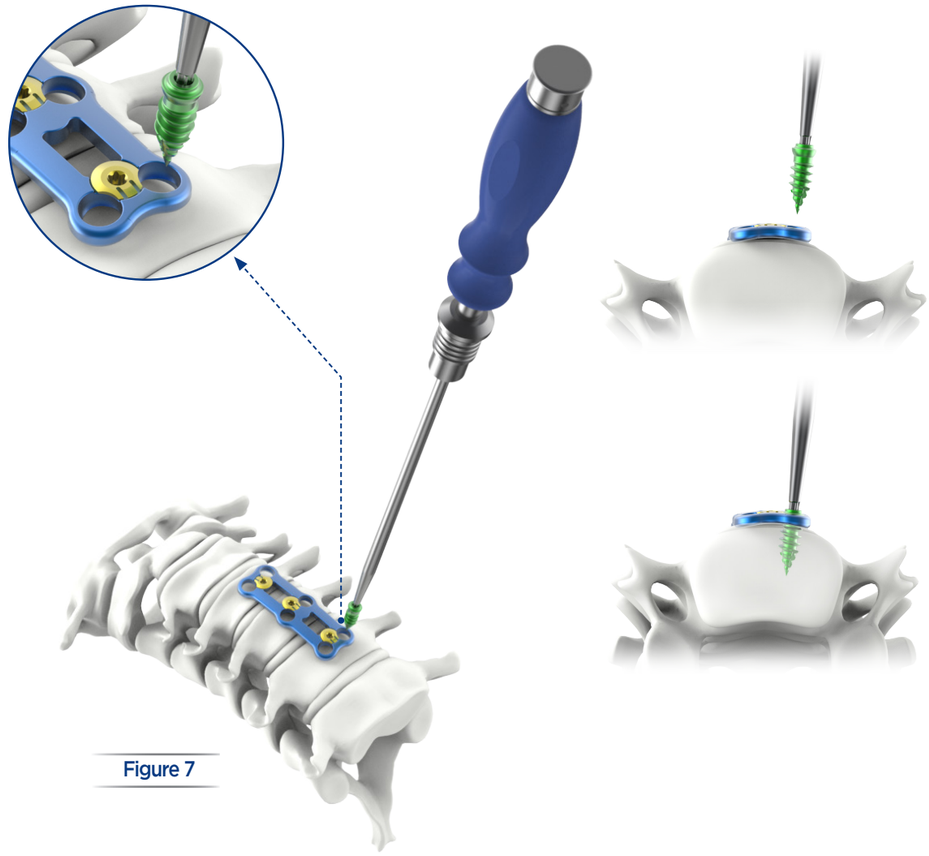


Figure 7

Screw Insertion(Cont.)

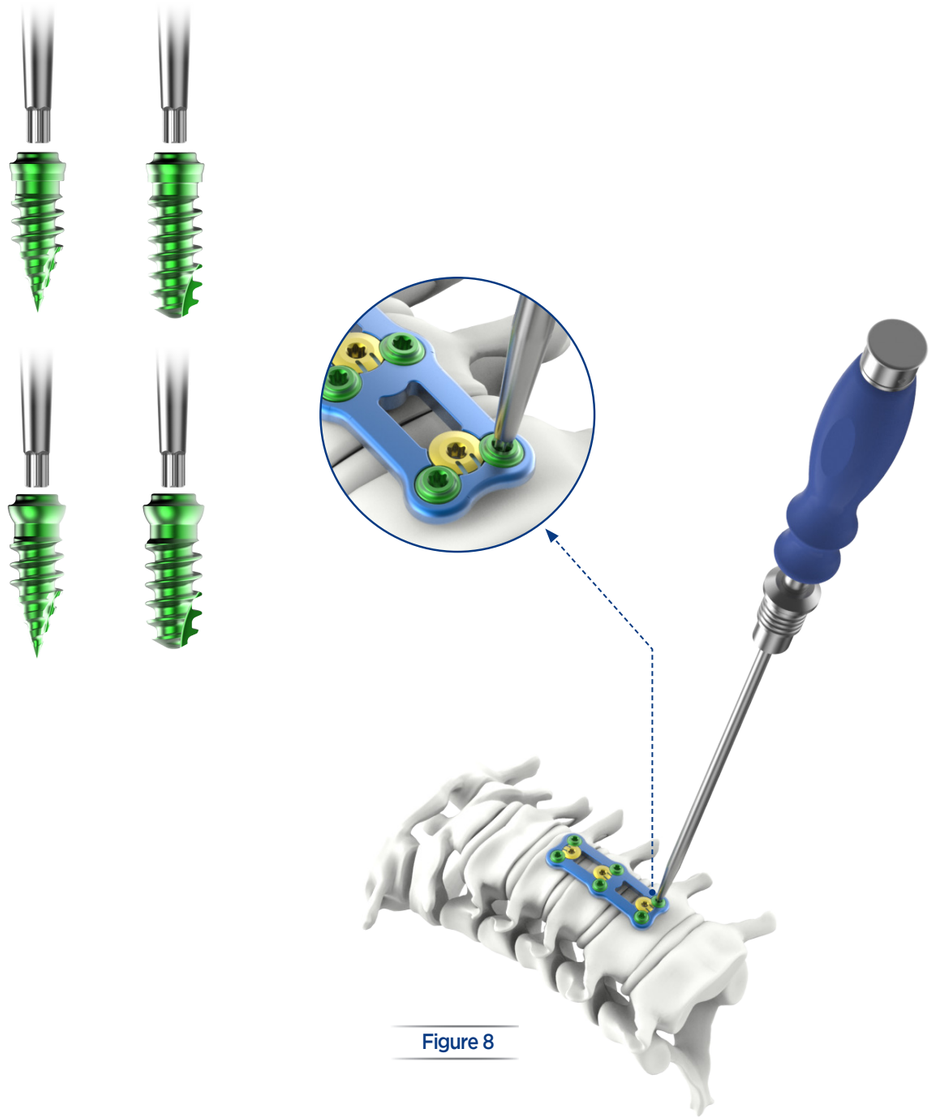


Figure 8

Locking the CAMs

GS142-0802 Screw Driver

Prior to beginning the CAM locking procedure, ensure all screws are secured to the vertebral bodies.
Assemble the Screw Driver and insert the tip of the Screw Driver into the CAM. The Driver should be fully seated within the CAM.

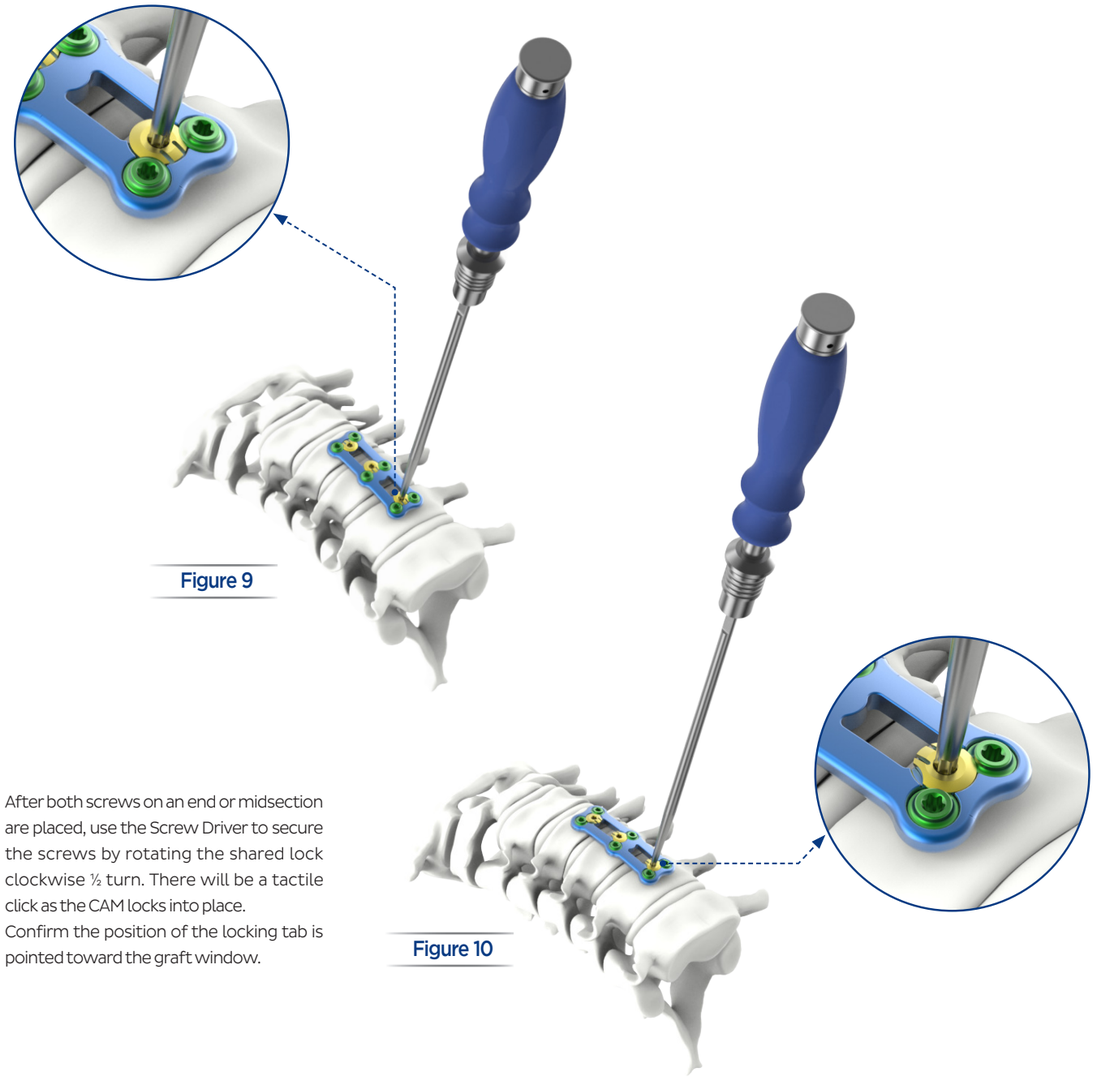


Figure 9

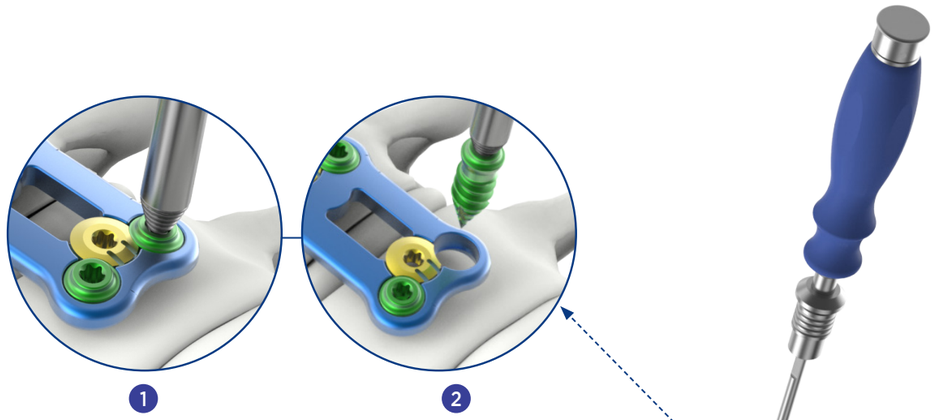
After both screws on an end or midsection are placed, use the Screw Driver to secure the screws by rotating the shared lock clockwise ½ turn. There will be a tactile click as the CAM locks into place.
Confirm the position of the locking tab is pointed toward the graft window.

Figure 10

Screw Removal

GS142-0800 Screw Driver
GS142-0803 Screw Extractor
GS142-4200 Simple Plate Holder
GS142-4201 Plate Holder

To unlock the screws, use the Screw Driver to rotate the shared lock counter-clockwise ½ turn.
The screws may be removed using the Screw Extractor or the Screw Driver.
After all screws are removed, the plate may be removed by the Simple Plate Holder or by hand.



Closure

Properly irrigate the surgical site, then close the fascia, subcutaneous layers and skin, and seal with skin adhesive.

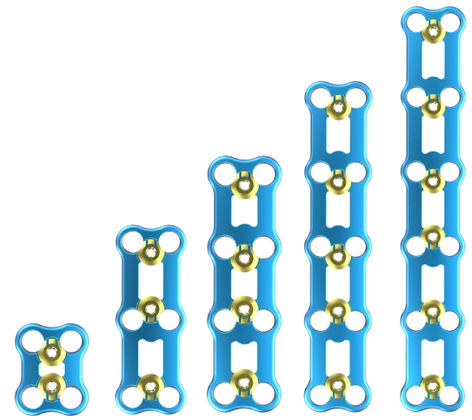
Figure 11

Product Specification

The CASSIOPEIA Cervical Plate system is available in lengths from 1 to 5 levels, ranging from 19mm to 125mm.

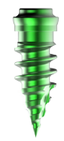
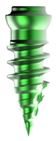
CASSIOPEIA Implants		
No.	**Code No.**	**Description**
1	3300-1019~1043	Plate, 1 Level, 19mm~43mm
2	3300-2032~2054	Plate, 2 Level, 32mm~54mm
3	3300-3047~3077	Plate, 3 Level, 47mm~77mm
4	3300-4065~4101	Plate, 4 Level, 65mm~101mm
5	3300-5080~5125	Plate, 5 Level, 80mm~125mm

* The plate length increases by 1mm.



The CASSIOPEIA Cervical Plate system offers screws in lengths from 12mm to 26mm, with diameters of 4.2mm (primary) or 4.6mm (rescue).

CASSIOPEIA Screws		
No.	**Code No.**	**Description**
1	3310-0012~0026	Φ4.2mm Fixed Angle Screw, Self-Drilling, 12mm~26mm
2	3312-0012~0026	Φ4.6mm Fixed Angle Screw, Self-Drilling, 12mm~26mm
3	3311-0012~0026	Φ4.2mm Fixed Angle Screw, Self-Tapping, 12mm~26mm
4	3313-0012~0026	Φ4.6mm Fixed Angle Screw, Self-Tapping, 12mm~26mm
5	3320-0012~0026	Φ4.2mm Variable Angle Screw, Self-Drilling, 12mm~26mm
6	3322-0012~0026	Φ4.6mm Variable Angle Screw, Self-Drilling, 12mm~26mm
7	3321-0012~0026	Φ4.2mm Variable Angle Screw, Self-Drilling, 12mm~26mm
8	3323-0012~0026	Φ4.6mm Variable Angle Screw, Self-Tapping, 12mm~26mm

Φ4.2 / Φ4.6		
	Fixed Angle	**Variable Angle**
Self- Drilling		
Self- Tapping		

* The screw length increases by 2mm.
** The colors are displayed differently depending on the length.

CASSIOPEIA Instruments

GS142-0200	Cervical Awl, with Sleeve	
GS142-0201	Cervical Awl, For Drill Guide	
GS142-0500	Cervical Tap	
GS142-0700	Temporary Fixation Pin, Short	
GS142-0701	Temporary Fixation Pin, Long	
GS142-0702	Temporary Screw	
GS142-0800	Screw Driver, Self-Retaining	
GS142-0802	Screw Driver	
GS142-0803	Screw Extractor, 2.25 Hexalobe	

GS142-1000	Single Drill Guide, Variable Angle, Short Barrel	
GS142-1001	Single Drill Guide, Variable Angle, Long Barrel	
GS142-1002	Single Drill Guide, Fixed Angle, Short Barrel	
GS142-1003	Single Drill Guide, Fixed Angle, Long Barrel	
GS142-1004	Double DTS Guide Short Barrel	
GS142-1005	Double DTS Guide Long Barrel	

CASSIOPEIA Instruments

GS142-1012~1026	Drill Bit 12mm~26mm	
GS142-1032~1046	Short Drill Bit 12mm~26mm	

* The Drill length increases by 2mm. ** The colors are displayed differently depending on the length.

GS142-1900	Quick Connect Handle	
GS142-4100	Plate Bender	
GS142-4200	Simple Plate Holder	
GS142-4201	Plate Holder	
GS142-5200	Temporary Fixation Pin Drive	

Instructions for Use

General Information about CASSIOPEIA Cervical Plate System

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly li-censed practitioner) that has appropriate training or experience.

DEVICE DESCRIPTION

The CASSIOPEIA Cervical Plate System consists of a variety of sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

Plates and screws are available in a variety of sizes to suit the individual pathology and anatomic condition of the patient.

All implantable components are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136. Components from this system should not be used in conjunction with components from other systems.

Products
- CASSIOPEIA Cervical Plate System

INDICATIONS

The CASSIOPEIA Cervical Plate System is intended for anterior cervical fixation (C2-C7) in skeletally mature patients as an adjunct to fusion for the following indications:
- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (kyphosis, lordosis, or scoliosis)
- Tumors
- Pseudoarthrosis
- Failed previous fusion

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Suspected or documented metal allergy or intolerance.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any case requiring the mixing of metals form different components.
- Any case not described in the indications for use.

POSSIBLE ADVERSE EFFECTS

- 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.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, persistent CSF leakage, meningitis.
- Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
- Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
- Loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (pseudo-arthrosis), delayed union, mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Death.

Instructions for Use

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

WARNINGS

THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THROACIC, OR LUBMAR SPINE.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. CASSIOPEIA Cervical Plate System components are temporary implants used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can with-stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Preoperative 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 this device by the surgeon. Further, 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-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. The use of allograft material may not give as good a result as pure autograft.

Note: For use on or by the order of a physician only.
Federal Law (USA) restricts these devices to sale by or on the order of a physician.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
4. Device components should be received and accepted only in packages that have not been dam-aged or tampered with. Damaged implants and/or instruments should not be used. All implants and instruments should be inspected prior to use. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
5. The type of implant to be used for the case should be determined prior to beginning the surgery.
6. All parts should be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
4. Implants should not be reused under any circumstances.
5. Forming or bending of the plates should be kept to a minimum. Bending of the plate near the screw holes should be avoided. Distortion of the screw holes may prevent proper locking of the screw. If bending of the plate is performed, only benders supplied with the system should be used for such bending. Notching of the plate may reduce its fatigue life. Care should be taken to avoid bending the plate multiple times in the same location.
6. A drill guide should be used to limit the angle of drilling and subsequent insertion of screws. Insertion angles greater than what the drill guides allow may prevent adequate locking of the screw.
7. If the surgeon experiences difficulty in inserting screws (hard bone, etc.), drilling and/or tapping prior to screw insertion is recommended.
8. To help prevent screws from disassociating from the plate postoperatively, the screw locking mechanism of each screw should be engaged.
9. Caution should be taken not to over-tighten threaded components, including instruments, im-plants, and interfaces between implants and instruments.
10. Before the closing of the soft tissues, all screws should be secured to the plate by activating the locking mechanism as described.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:
1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Anterior cervical plate implant components are for temporary internal fixation during the formation of a spinal fusion. Implants are not meant to support a load for an indefinite period. After the formation of a fusion, the device may be removed.

PACKING AND STORAGE

1. The implants are delivered in packages; these must be intact at the time of receipt.
2. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
3. They must be stored in a clean, dry and temperate place.

Instructions for Use

STERILIZATION PROCEDURE RECOMMENDED FOR NON-STERILE MEDICAL DEVICES INCLUDING IMPLANTS

These are non-sterile implants. They must be sterilized before use. Use the storage trays for sterilization and intra-operative storage. The following recommendations should be followed when autodaving; Only Sterile products should be placed in the operative field. For a 10^{-6} Sterility.
Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the two sets of process parameters below:

Method	Cycle	Steriization Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270℉ (132℃)	4minutes	30 minutes
Steam	Gravity	270℉ (132℃)	15minutes	30 minutes

In case of sterilization boxes with paper filters the integrity of the filters must be checked before auto-claving. The user assumes responsibility for any other type of sterilization and relieves GS Medical of any liability. The user should contact GS Medical for full details.

For further information or complaints, please contact:

Manufacturer

90, Osongsaengmyeong 4-ro,
Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea
Tel : 82-43-237-7393 **Fax** : 82-43-237-7403
Home Page : www.gsmedi.com

US Distribution

GS Solutions, Inc., DBA GS Medical
23263 Madero, Suite C
Mission Viejo, CA 92691
Tel : 949-380-6385 **Fax** : 886-600-9712

CASSIOPEIA

ANTERIOR CERVICAL PLATE SYSTEM

GS Medical

90, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161 , Korea
Tel : 82-43-237-7393 Fax : 82-43-237-7404
Products Inquiries : productcontact@gsmedi.com

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