



Anterior Cervical Plate

The Genesys Spine Anterior Cervical Plate System minimizes height and the narrow transverse width enhances visualization and plate manipulation for precise plate placement while reducing the amount of traction on the trachea and esophagus. The rotating drill guides, self-tapping screws and integrated securement tab simplify plate fixation and reduce operative time.

Finally, the flexibility of the Genesys Spine Anterior Cervical Plate System through multiple screw lengths and revision screws allows the surgeon to individually tailor the construct to each patient's anatomy.

Surgical Approach

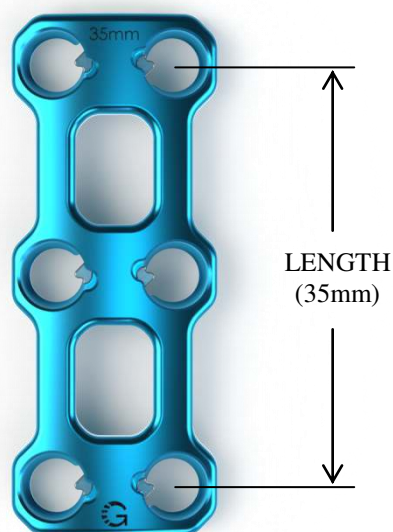
Position patient

The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis.

Surgical Technique

1. Plate Selection

After exposing the cervical spine and either an autograft or allograft material is positioned between the vertebrae, anterior osteophytes should be removed from the exposed vertebrae so that the plate may sit flush/evenly on the anterior cortex. The plate length should be defined according to the chosen screw length and angulation so that it does not interfere with the adjacent unfused disc spaces



2. Plate Contouring

The Genesys Spine Anterior Cervical Plate has a precontoured lordotic curvature, anatomically appropriate in the majority of procedures. If desired, the Plate Bender may be utilized to optimally contour the sagittal plane to ensure maximum bone/plate interface. It is critical to bend the plate in the specified Bending Zones (at the struts – away from the screw holes) which has a smooth undersurface and reduced cross-sectional thickness.

Do not bend the plates repeatedly, excessively, or any more than absolutely necessary.



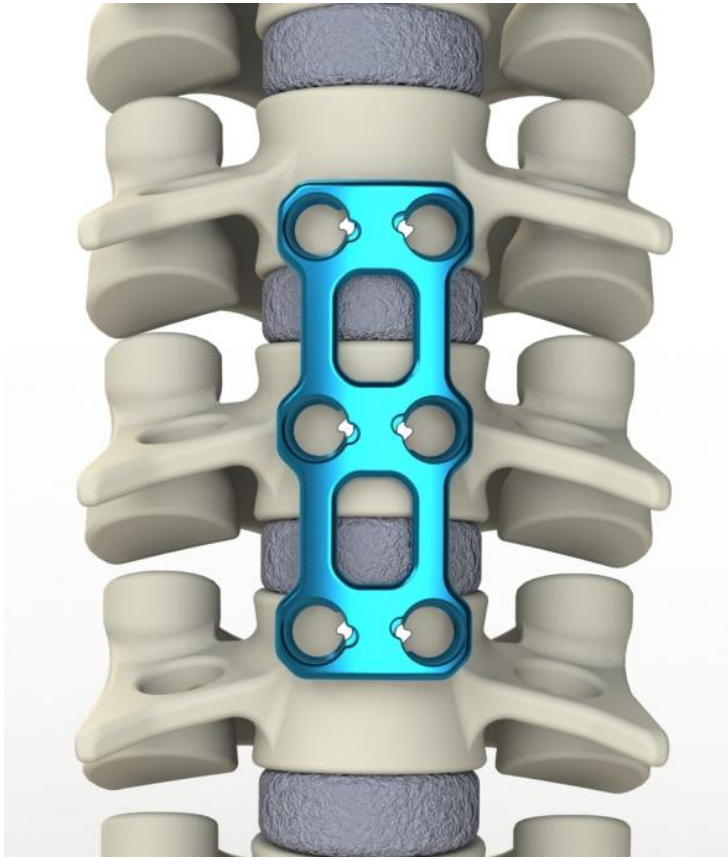
Increase Lordotic Bend



Decrease Lordotic Bend

3. Plate Positioning

Recommended placement is centered midline with the plate's screw holes as close as possible to the graft site without compromising the vertebral endplates.



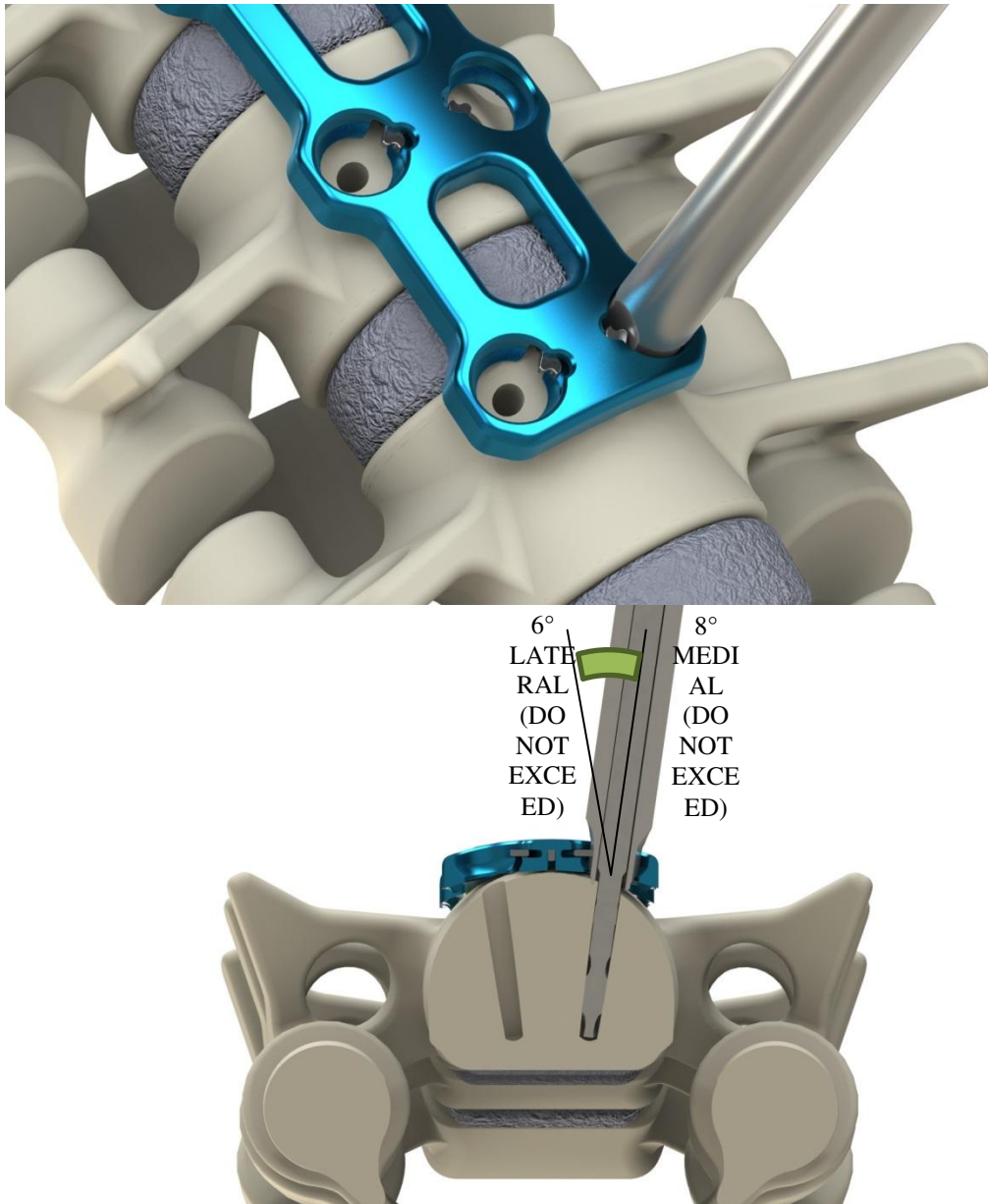
Note: Fixation Pins may be used as a means of temporary fixation during subsequent steps.

Note: Fixation Pins are designed for single patient use.

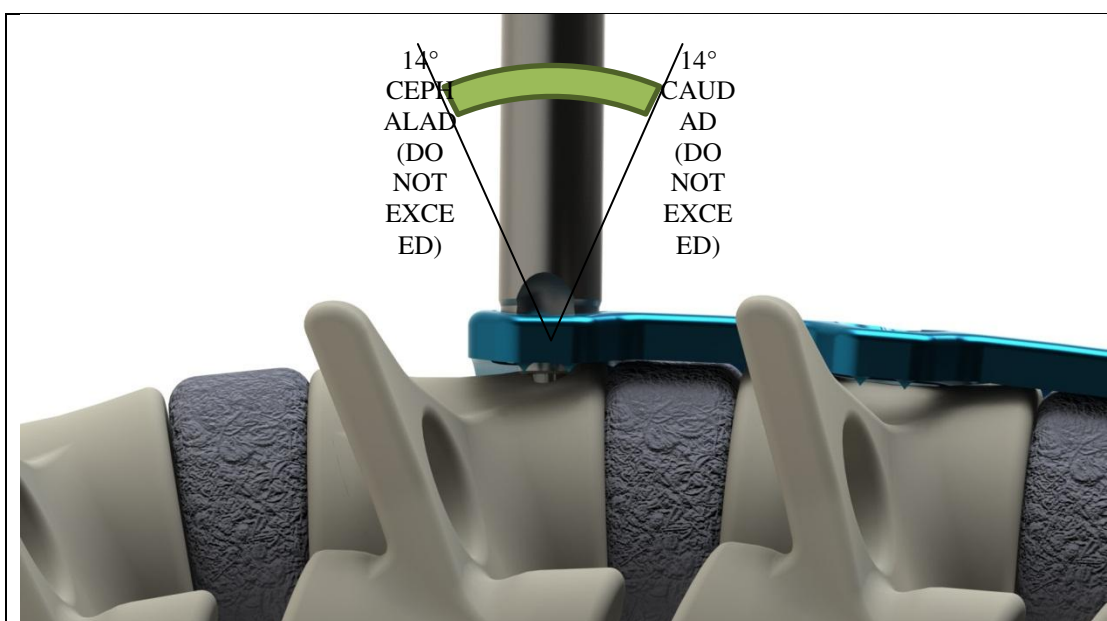
4. Drilling

After confirming proper plate positioning, align the cut-out on the distal tip of the Drill Guide over the Securement Tab on the plate. Press down on the proximal end of the drilling guide while inserting its distal tip into the plate's screw hole. The orientation of the drill relative to the Anterior Cervical Plate is not to exceed 8° medially, 6° laterally, or 14° in the cephalad / caudad direction. The drill guide will be approximately perpendicular to the curvature of the plate in the 8° medial position.

Note: Single-fixed, single-variable, and dual-fixed drill guides are available for use.



Step 4 continued on the next page...

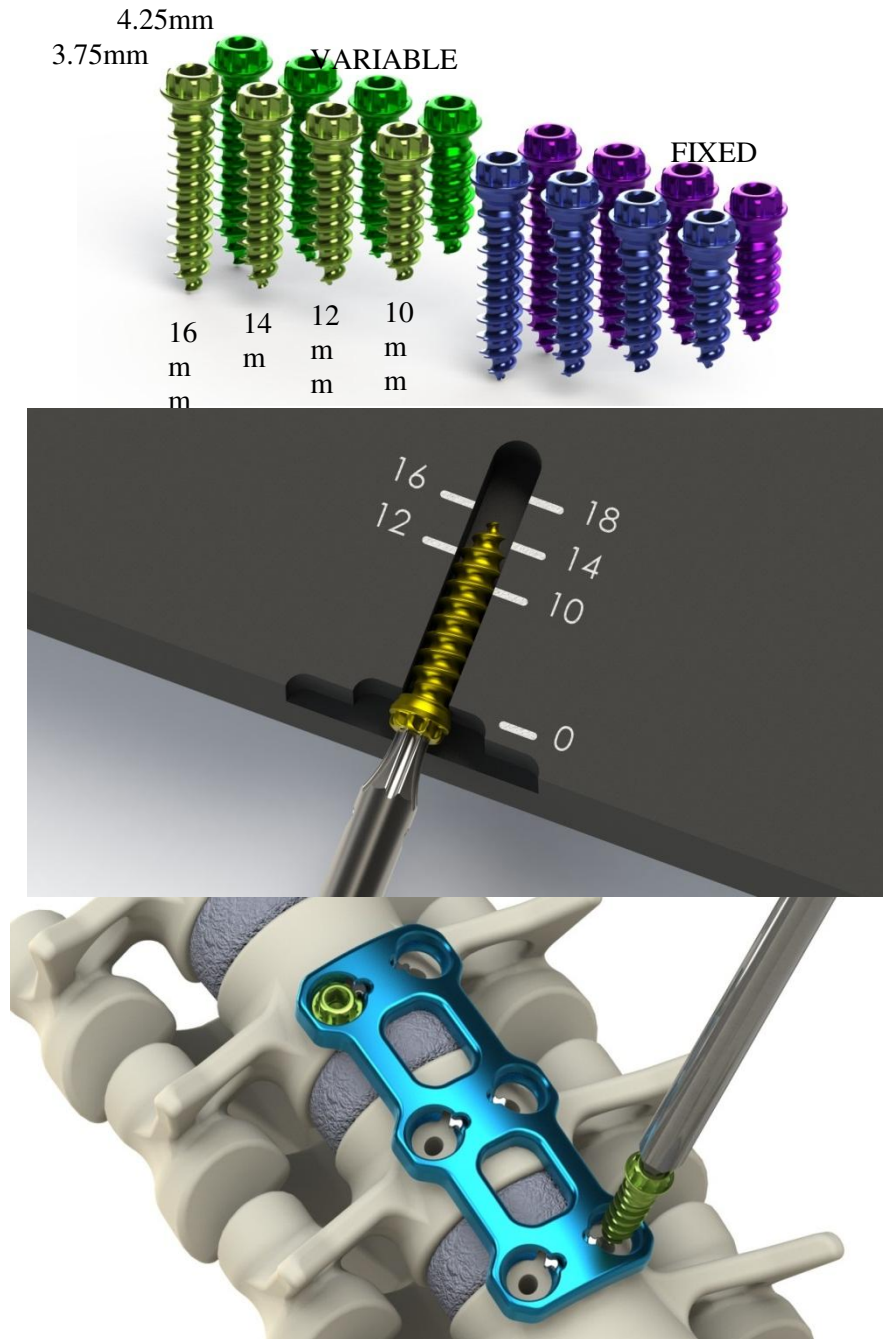


Use fluoroscopy to confirm drill bit penetration depth and angular orientation to assure that vulnerable vascular and neural tissues are not at risk. The tap may now be used to thread the holes. Depth of screw insertion and angular orientation of the screw must also be confirmed by fluoroscopy.

5. Bone Screw Selection

The standard bone screw diameter is 3.75mm and the recovery bone screw diameter is 4.25mm. These bone screws are self-tapping and come in 10, 12, 14, and 16mm lengths. Using the Cervical Friction Spring Driver, pick up the screw from the tray and verify the screw length using the length gauge built into the screw caddy (16mm screw depicted below).

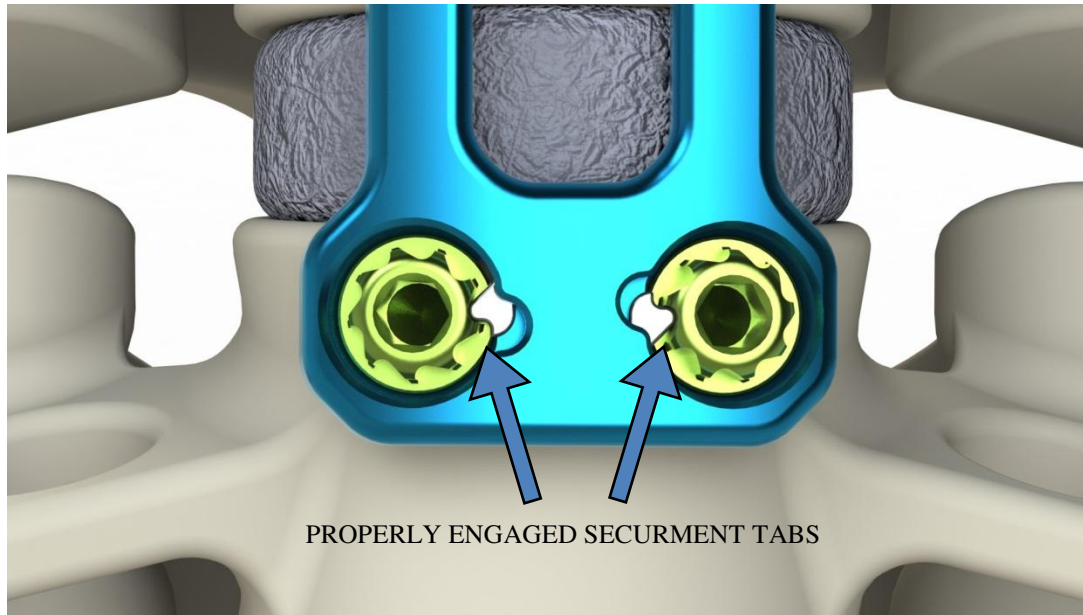
Align the Cervical Friction Spring Driver with the previously drilled holes and place screws in all screw holes beginning with the lateral hole that is opposite and diagonal to the first prepared hole. Perform final tightening of all screws using the Cervical Screw Driver.



Securement Tab Locking

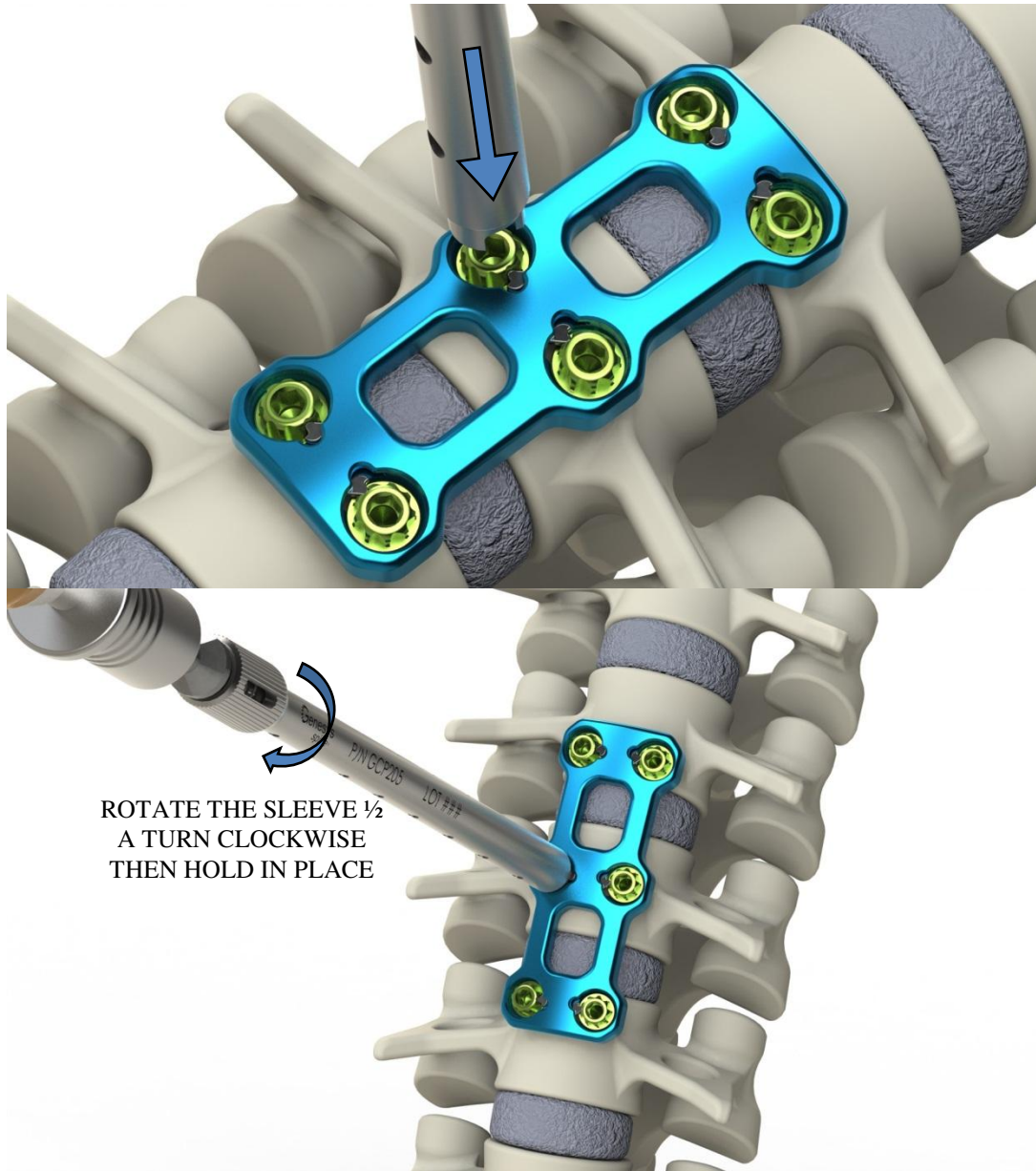
The Securement Tab is assembled into the Genesys Spine Anterior Cervical Plate. By inserting the bone screw through the plate holes with the proper orientation (refer to step 4), the Securement Tab will provide an audible and tactile “Click” once engaged. When properly advanced, the tips of the Securement Tab will partially cover the bone screw heads and seat in a groove of the Bone Screw ratchet (refer to the illustration below).

Note: if the Securement Tab does not partially cover the screw head after full screw insertion, the screw must be backed out and retightened while attempting to align the screw with the plate.

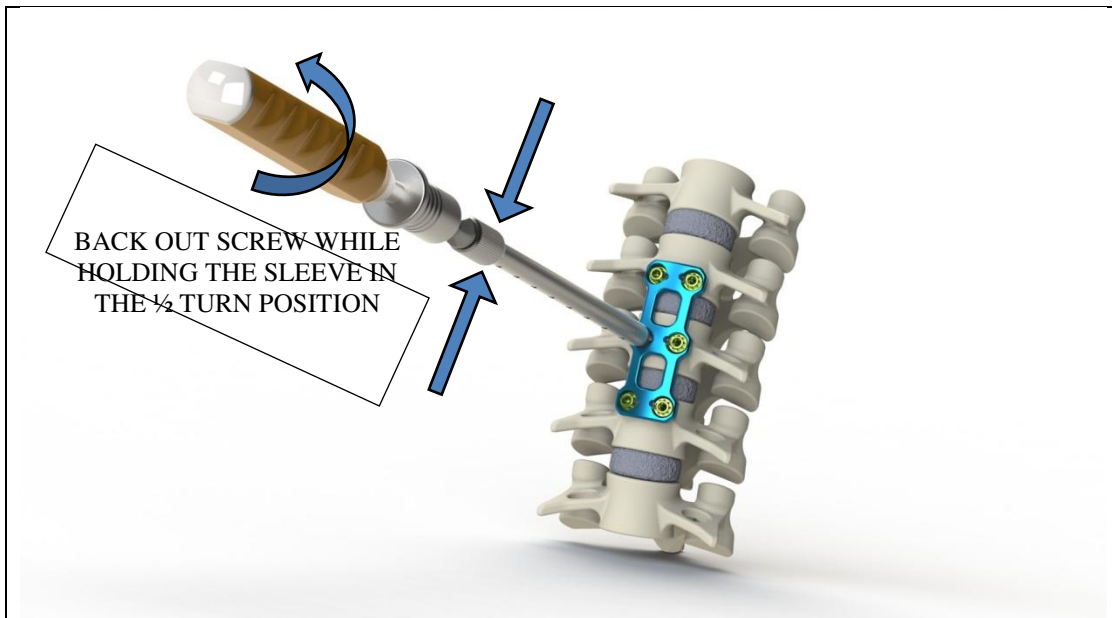


6. Revision / Removal Step

If unlocking and removal is needed, place the Removal tool over the Bone Screw and align the window on the tip of the tool over the Securement Tab. Rotate the outer sleeve of the Removal Tool half a turn in the clockwise direction to disengage the Securement Tab and back out the screw while holding the sleeve in place.



Step 7 continued on the next page...



7. Post-operative management step

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

Implants

Anterior Cervical Plates			
Part Number	Description	Part Number	Description
GCP10012	12mm 1 Level	GCP30046	46mm 3 Level
GCP10014	14mm 1 Level	GCP30049	49mm 3 Level
GCP10016	16mm 1 Level	GCP30052	52mm 3 Level
GCP10018	18mm 1 Level	GCP30055	55mm 3 Level
GCP10020	20mm 1 Level	GCP30058	58mm 3 Level
GCP10022	22mm 1 Level	GCP30061	61mm 3 Level
GCP10024	24mm 1 Level	GCP30064	64mm 3 Level
GCP10026	26mm 1 Level	GCP30067	67mm 3 Level
GCP20026	26mm 2 Level	GCP30070	70mm 3 Level
GCP20028	28mm 2 Level	GCP40060	60mm 4 Level
GCP20030	30mm 2 Level	GCP40064	64mm 4 Level
GCP20032	32mm 2 Level	GCP40068	68mm 4 Level
GCP20035	35mm 2 Level	GCP40072	72mm 4 Level
GCP20038	38mm 2 Level	GCP40076	76mm 4 Level
GCP20041	41mm 2 Level	GCP40080	80mm 4 Level
GCP20044	44mm 2 Level	GCP40084	84mm 4 Level
GCP20047	47mm 2 Level	GCP40088	88mm 4 Level
--	--	GCP40092	92mm 4 Level
Bone Screws			
Part Number	Description (mm)	Part Number	Description (mm)
GCSV37510	3.75 X 10 Variable	GCSF37510	3.75 X 10 Fixed
GCSV37512	3.75 X 12 Variable	GCSF37512	3.75 X 12 Fixed
GCSV37514	3.75 X 14 Variable	GCSF37514	3.75 X 14 Fixed
GCSV37516	3.75 X 16 Variable	GCSF37516	3.75 X 16 Fixed
GCSV37518	3.75 X 18 Variable	GCSF37518	3.75 X 18 Fixed
GCSV42510	4.25 X 10 Variable	GCSF42510	4.25 X 10 Fixed
GCSV42512	4.25 X 12 Variable	GCSF42512	4.25 X 12 Fixed
GCSV42514	4.25 X 14 Variable	GCSF42514	4.25 X 14 Fixed
GCSV42516	4.25 X 16 Variable	GCSF42516	4.25 X 16 Fixed
GCSV42518	4.25 X 18 Variable	GCSF42518	4.25 X 18 Fixed

Instruments

System Specific and Off-the-Shelf Instruments			
Part Number	Description	Part Number	Description
GCP100	Fixation Pin	GCP210	10mm Drill Bits
GCP200	Cervical Bone Awl-Punch	GCP212	12mm Drill Bits
GCP201	Cervical Tap	GCP214	14mm Drill Bits
GCP202	Cervical Screw Driver	GCP216	16mm Drill Bits
GCP202-F	Cervical Friction Spring Driver	GCP230	Angled Drill Guide
GCP204	Fixed Drill Guide	GCP231	Drill Bit Sleeve
GCP205	Cervical Screw Extraction Tool	GCP300	Plate Bender
GCP206	Variable Drill Guide	GCP400	Mini 4-Sided Fixed AO Connect Handle
GCP207	Plate Holder	GP704	Fixed AO Straight Handle

Indications

The Genesys Spine Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion 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 (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

Contraindications

The Genesys Spine Anterior Cervical Plate System is not designed or sold for any use except as indicated.

Do not use the implants in the presence of any contraindication.

Contraindications include, but are not limited to:

- Presence of overt infection and/ or localized inflammation.
- Rapid joint disease, bone absorption, osteopenia, and/ or osteoporosis.
- Suspected or documented metal allergy or intolerance.
- Any patient having inadequate tissue coverage over the operative site.
- Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
- Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
- Use in displaced, non-reduced fractures with bone loss.
- The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
- Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
- The physical contact of the Genesys Spine Anterior Cervical Plate System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F138) or MP35 N, or other dissimilar metal.
- Situations with the absence or compromise of significant stabilizing elements.
- Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.
- Use with components from any other system or company.

Warnings

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Corpectomy procedures should not be performed in the absence of posterior fixation.
4. Potential risks identified with the use of this device system, which may require additional surgery, include:
 - a) Device component fracture.
 - b) Loss of fixation.
 - c) Non-union.
 - d) Fracture of the vertebra.
 - e) Neurological injury.
 - f) Vascular or visceral injury
5. REUSE OF IMPLANTS. The risk of reusing implants includes infection and tissue irritation. In addition, exposure to the chemicals used for cleaning can induce physical changes to the materials; the result can be sudden mechanical failure or device malfunction. Genesys Spine accepts no responsibility for a re-used implant

Precautions

1. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Do not over bend or alter any Genesys Spine Anterior Cervical Plates. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
2. VERIFY SECUREMENT TAB ENGAGEMENT. Surgeon should visually inspect the plate to verify that the tab is properly engaged (refer to the surgical technique).
3. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, and possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the post-operative care regimen as instructed by his or her physician.
5. DO NOT ALTER OR MODIFY ANY GENESYS SPINE ANTERIOR CERVICAL PLATE SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The Genesys Spine Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the cervical spine. A successful result is not achieved in every surgical case. Bone grafting must be part of the spinal fusion procedure in which the Genesys Spine Anterior Cervical Plate System is used.

6. The Genesys Spine Anterior Cervical Plate has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Anterior Cervical Plate has not been tested for heating or migration in the MR environment.
7. FIXATION PINS ARE INSTRUMENTS AND MUST BE REMOVED PRIOR TO COMPLETING THE PROCEDURE. The Fixation Pins are for temporary stabilization of the Anterior Cervical Plate and not for implantation.
8. Instruments should not be used in any capacity other than their intended use

Reoperation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.

These complications may include but not be limited to:

1. Device Corrosion with localized tissue reaction and pain.
2. Device migration, which may result in injury to soft tissue, visceral organs or joints.
3. Loosening or disassembly of implants resulting in additional injury.
4. Bending, loosening or breaking of the implant making removal difficult, impractical or impossible.
5. Abnormal sensations discomfort or pain.
6. Increased risk of infection.
7. Bone loss due to stress shielding.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Genesys Spine Anterior Cervical Plate System.

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. Patients with poor bone quality are also poor candidates for surgery.

Possible Adverse Events

Occurrence of any adverse effects may require re-operation and removal of the implant. Adverse effects may include but not be limited to:

1. Early or late loosening of the components
2. Disassembly, fretting, loosening, bending, breakage and/ or migration of any component or component portion.
3. Foreign body reaction to the implants.
4. Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation.
5. Early or late infection.
6. Vertebral body fracture at, above, or below the level of surgery.
7. Implants cutting through bone, especially soft osteoporotic, osteopenic, or Cancellous bone.
8. Bone forming around the implant, making removal difficult or impossible.
9. Non-union (pseudarthrosis) or bone fracture.
10. Post-operative change in spinal curvature, loss of correction, height, and/ or reduction.
11. Neurovascular compromise including radiculopathy, paralysis, or other types of serious injury causing pain and disability.
12. Hemorrhage of blood vessels.
13. Cessation of growth of the operated portion of the bone.

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For product information, questions pertaining to sales and service, or to obtain a copy of the Instructions for Use, please contact your local sales representative or Genesys Spine customer service.
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