Genesys spine®

Surgical Technique

Binary® Anterior Cervical Plate System

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Binary® Anterior Cervical Plate System Surgical Technique

The Genesys Spine Binary® Anterior Cervical Plate System consists of multi-segmented titanium bone plates of various sizes and titanium bone screws in various diameters and lengths, which allow the surgeon the flexibility to individually tailor the construct to each patient's anatomy.

The narrow transverse width of the plate enhances visualization for precise placement of the *Binary* Anterior Cervical Plate while reducing the amount of traction necessary on the trachea and esophagus.

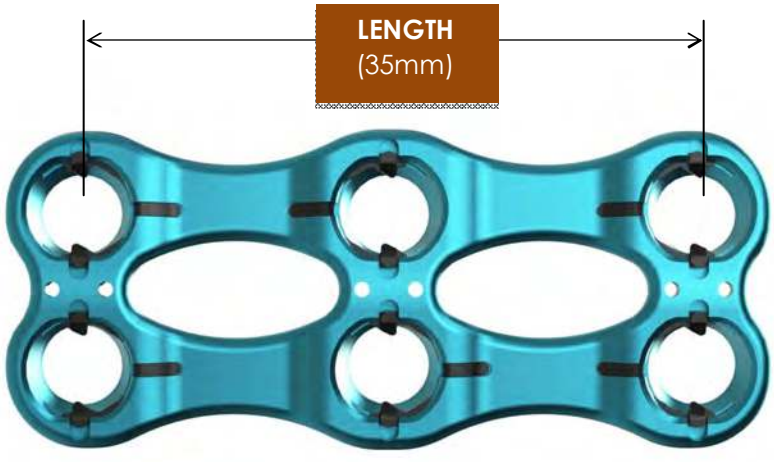
The straight forward instrumentation, self-tapping screws, and integrated one-step nitinol securement tabs simplify plate fixation and reduce operative time.

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 - Plate Selection

After exposing the cervical spine and placing either autograft or allograft material 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 determined according to the chosen screw length and angulation so that it does not interfere with the adjacent unfused disc spaces.



Surgical Technique - Plate Contouring

The *Binary* Anterior Cervical Plate has a precontoured lordotic curvature, anatomically appropriate for most 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 Zone (i.e. at the strut – away from the screw holes), which has a smooth undersurface and reduced cross-sectional thickness.

Note: Do not bend the plates repeatedly, excessively, or more than necessary

Increase Lordotic Bend

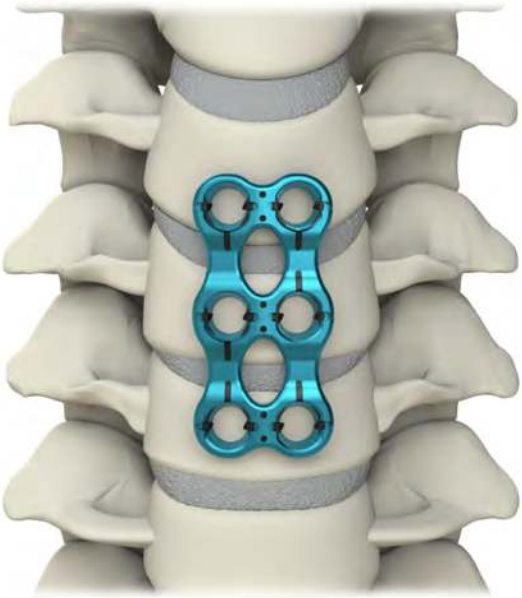
Decrease Lordotic Bend

Surgical Technique - 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 and not designed for long-term implantation.



Surgical Technique - Drilling

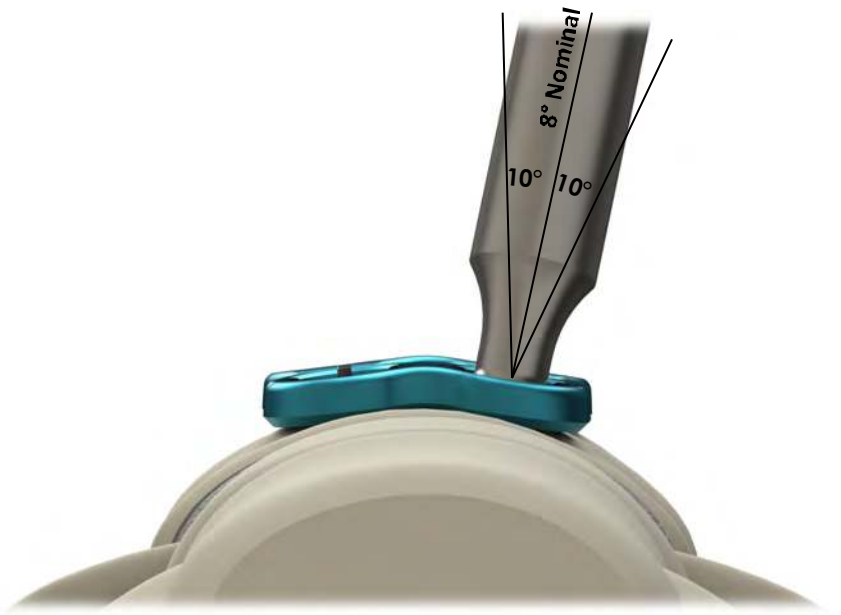
After confirming proper plate positioning, insert the distal tip of the Freehand Drill Guide into the screw cup of the *Binary* Anterior Cervical Plate. The orientation of the variable drill guide relative to the plate is not to exceed 10° medial/lateral from the 8° nominal angle, or 25° cephalad/caudad from the 0° nominal angle.

Fixed screws can only be used after using the Fixed drill guide to drill holes. Attempting to use fixed screws without the Fixed drill guide may result in damage to the implants or system instruments.

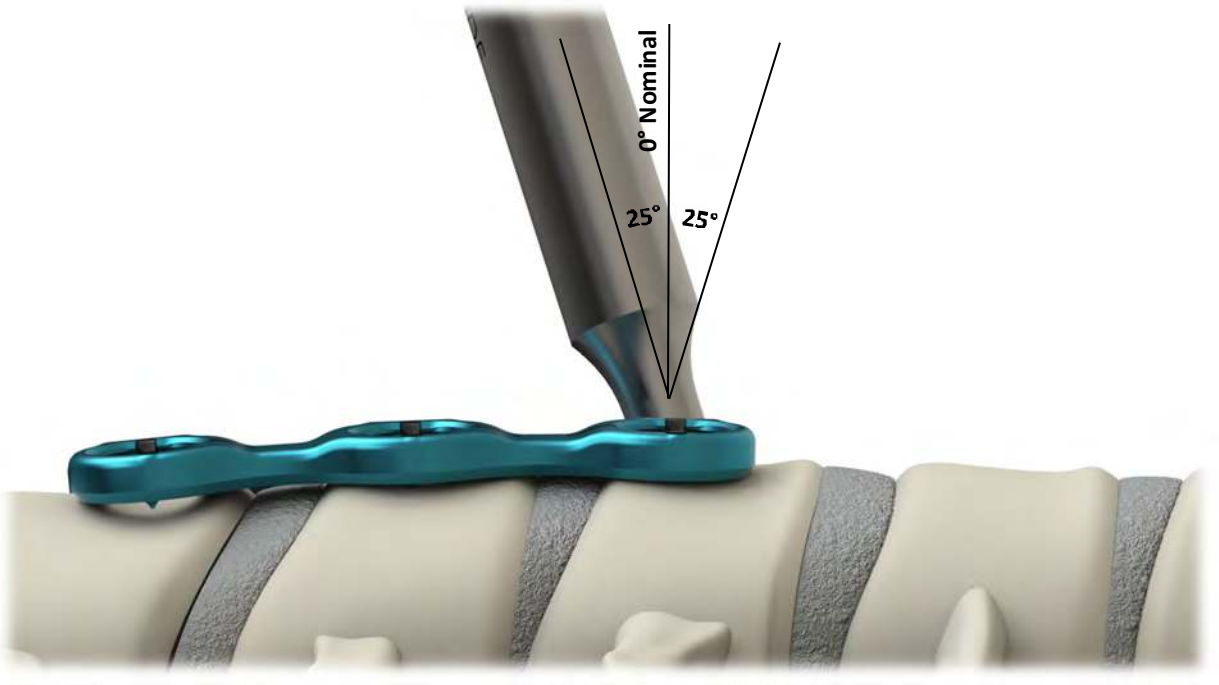
Note: Freehand (single barrel), Fixed (double barrel), and Angled (double barrel) drill guides are available for use.

Note: The Fixed and Angled Drill Guides will be aligned by inserting the two pins at the tip of the guide into the two holes between the screw cups.

Surgical Technique - Drilling Continued

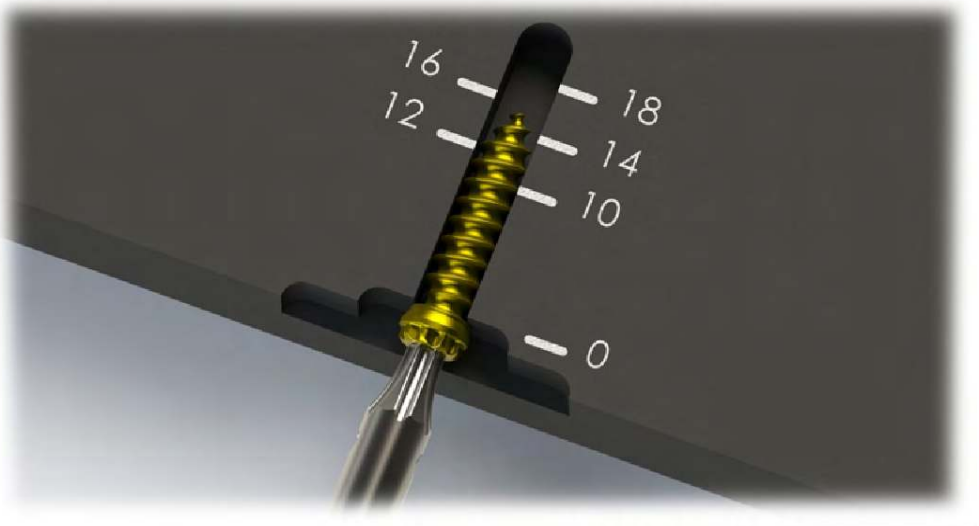


Use fluoroscopy to confirm drill bit penetration depth and angular orientation to assure that vulnerable vascular and neural tissues are not at risk. The tap may now be used to thread the holes. Depth of screw insertion and angular orientation of the screw must also be confirmed by fluoroscopy.



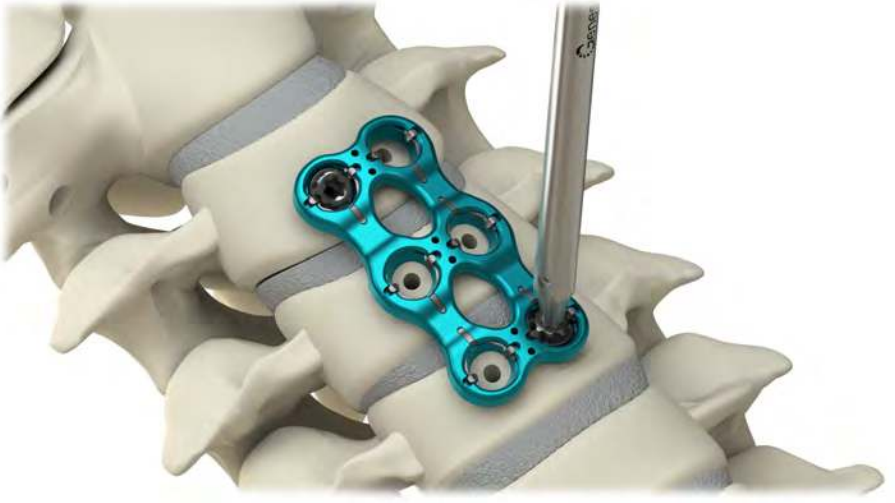
Surgical Technique - Bone Screw Selection

The standard bone screw diameter is 3.75mm and the recovery bone screw diameter is 4.25mm. These Bone Screws are available with self-starting and blunt tips in 10, 12, 14, 16 and 18mm lengths. Use the Cervical Friction Star Driver (GCP246) to pick up the screw from the tray by pressing driver into the screw. Verify the screw length using the length gauge built into the screw caddy (16mm screw depicted below).



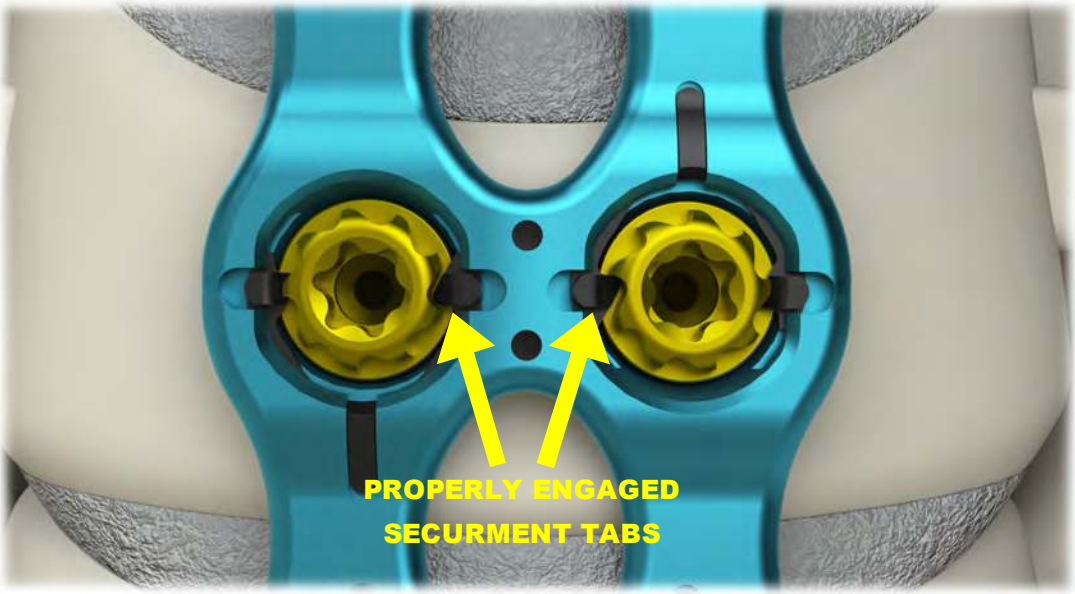
Surgical Technique - Bone Screw Selection Continued

Align the Cervical Screw with the hole drilled into the vertebral body and thread the screw into place. Repeat the process for the remaining holes.



Surgical Technique – Securement Tab Locking

The Securement Tabs are assembled into the *Binary* Anterior Cervical Plate by inserting the bone screw through the plate holes with the proper orientation (refer to Drilling Step). The Securement Tabs 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.

Revision/Removal Process

If Bone Screw unlocking and removal is needed, thread the Extraction Sleeve over the shaft of the Binary A-O [Removal] Screw Driver (GCP237) as shown below. Once the Extraction Sleeve is threaded all the way onto the GCP237 removal driver it is ready for use.

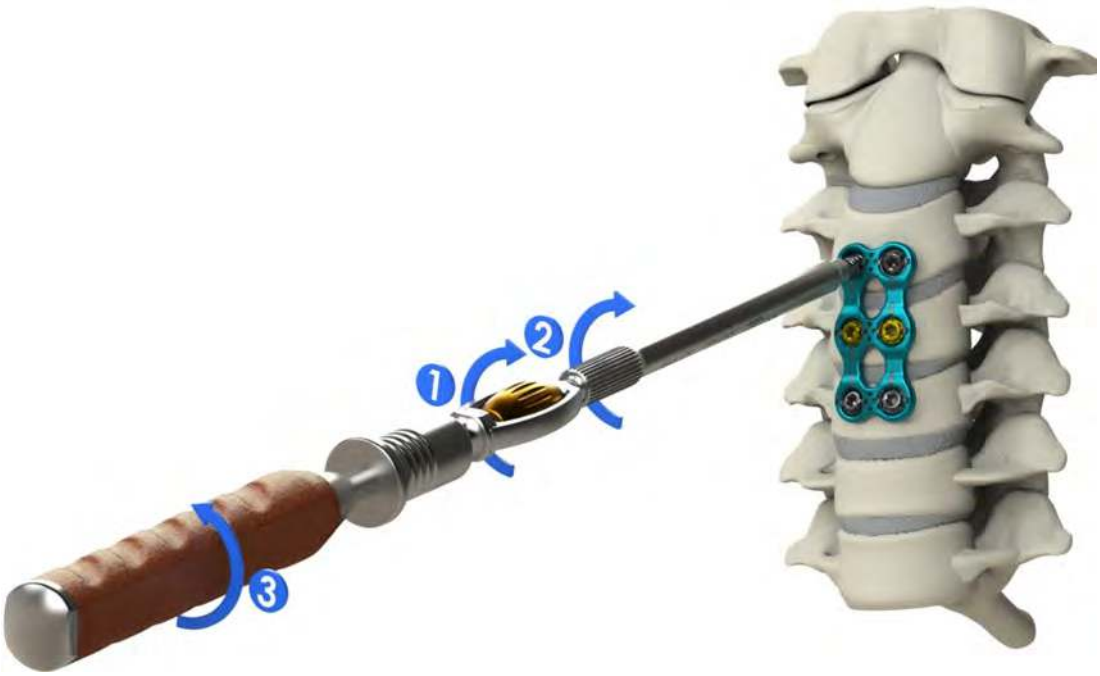
Place the removal driver with the removal sleeve into the screw head.

Revision/Removal Process Continued

First, Thread the tip of the Screw Driver into the screw by turning the orange wheel clockwise on the GCP237.

Second, rotate the Extraction Sleeve clock-wise to thread it down and towards the screw.

Third, with the Extraction Sleeve bottomed out, the Bone Screw is unlocked and can be unthreaded from the plate.



Post-Operative Management

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.

For list of Implants and Instruments, contact Genesys Spine.

Indications/Contraindications/Warnings

Indications

The Genesys Spine *Binary* 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 *Binary* 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 *Binary* 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. MIXING METALS CAN CAUSE CORROSION. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
6. 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 Plate II System. 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 II SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The Genesys Spine Anterior Cervical Plate II 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 II System is used.
6. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Genesys Spine Anterior Cervical Plate II System has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Anterior Cervical Plate II 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 II 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.

Precautions Continued and Possible Adverse Events

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 *Binary* 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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