Genesys spine®

Surgical Technique

Binary® Anterior Buttress Plate

Table of Contents	Page

Binary® Anterior Buttress Plate Surgical Technique

The Genesys Spine Binary® Anterior Buttress Plate System is comprised of multiple sizes of plates and screws that are inserted into the anterior surface of adjacent lumbar vertebrae. The device is applied after discectomy and insertion of autograft or allograft in the interbody space, and acts to stabilize the spine during fusion.

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

Plate Selection

After exposing the lumbar 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. Select the appropriate plate length that will give adequate disc space coverage and placement of the bone screws.

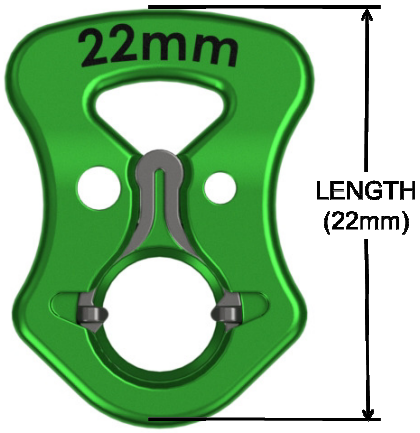


Plate Preparation and Application

Attach the selected Buttress Plate to the Plate Inserter by aligning the pin in the hole. Twist the thumb wheel clockwise to thread the post on the Plate Inserter into the threaded hole in the buttress plate.

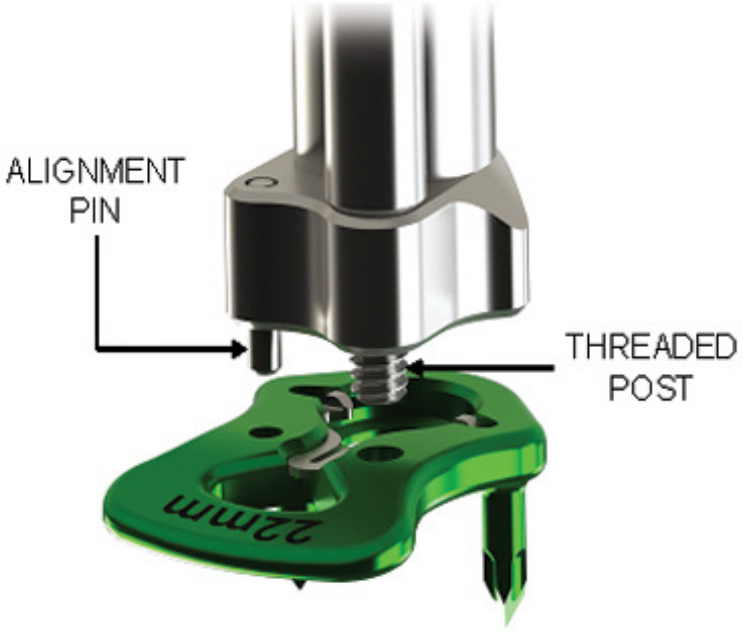
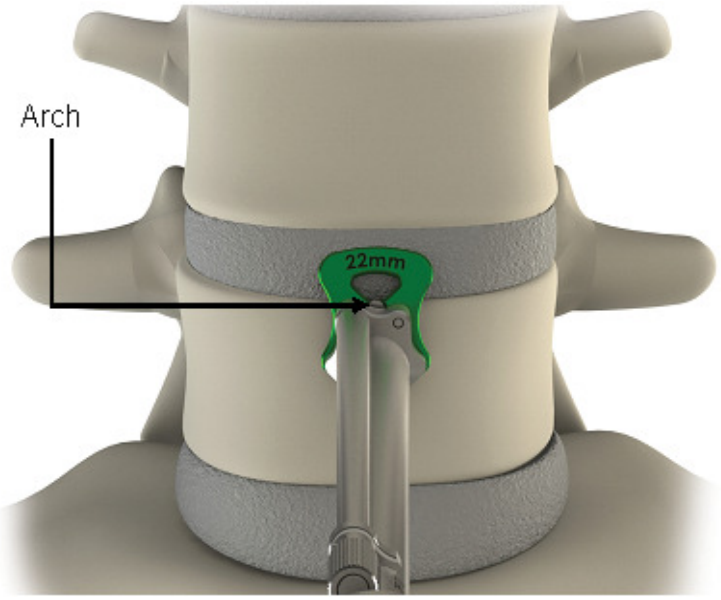


Plate Positioning

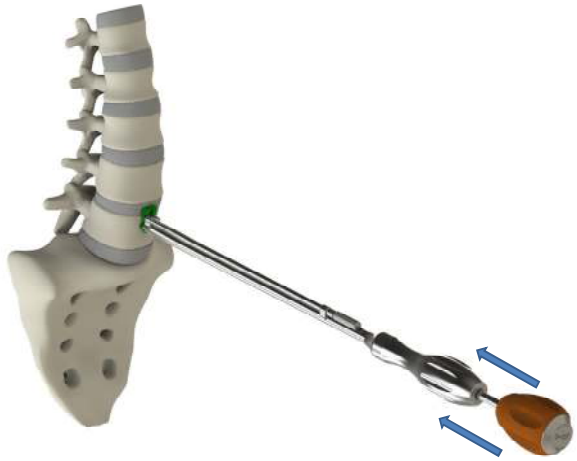
Position the buttress plate so that the Arch is aligned with the endplates and the fixation spikes and bone screw hole are located over the vertebral body.

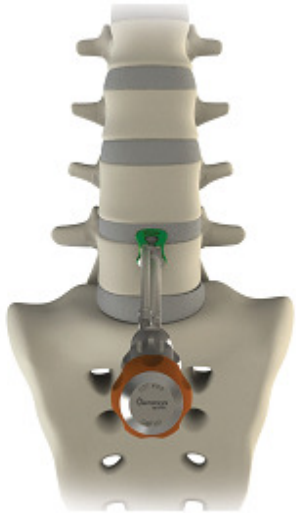


Temporarily attach the plate to the vertebral body by impacting the fixation spikes into the bone. This is accomplished by tapping on the top of the Plate Inserter with a mallet.

Hole Preparation

Insert the Awl through the cannulated shaft of the Plate Inserter. To create a pilot hole for the bone screw, advance the Awl down the shaft of the Plate Inserter until the T-handle of the Awl meets the handle of the Plate Inserter. Once the pilot hole has been created, remove the Awl from the Plate Inserter.

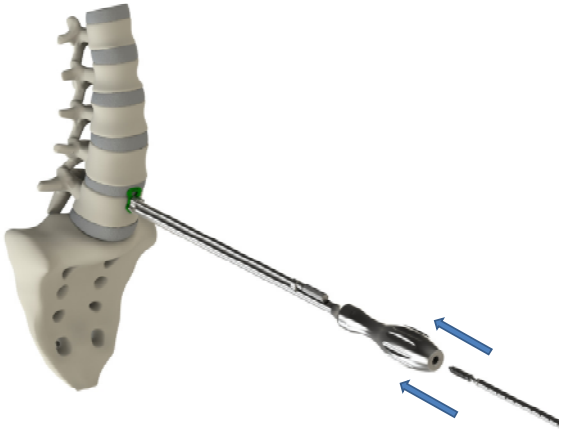




NOTE: A Drill & Tap are offered to prepare the hole as needed

Bone Screw Insertion

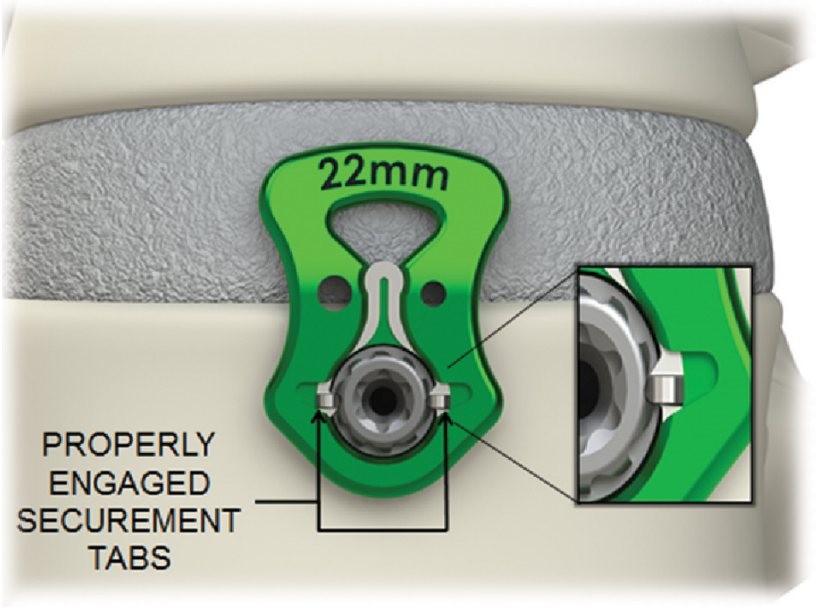
The standard bone screw diameter for the Single Screw Buttress plate is 5.5mm and the recovery bone screw diameter is 6.0mm. The standard bone screw diameter for the Dual Screw Buttress plate is 4.5mm and the recovery bone screw diameter is 5.0mm. These Bone Screws are available with self-starting tips in various lengths. Use the Buttress Screw Driver to pick up the desired screw from the tray by threading the tip of the driver into the screw.



Insert the Screwdriver through the cannulated shaft of the Plate Inserter. Once the screw is inserted into the body, remove both the Screwdriver and the Plate Inserter from the buttress plate. Confirm that the screw is flush with the plate.

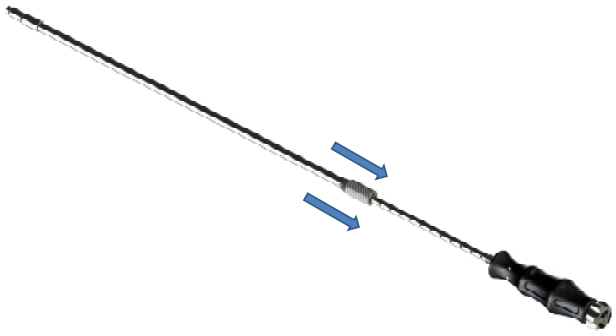
Securement Tab Locking

The Securement Tabs are assembled into the Genesys Spine Anterior Buttress Plate. By inserting the bone screw through the plate hole, 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).



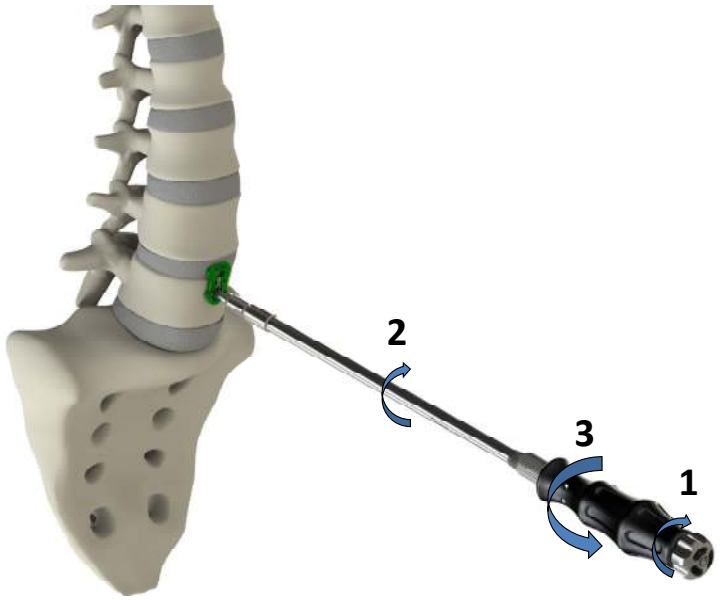
Revision/Removal

If Bone Screw unlocking and removal is needed, thread the Extraction Sleeve up to the handle of the Screw Driver. Insert the tip of the Screw Driver into the screw and tighten the knob on the back to lock the driver to the screw. Next rotate the Extraction Sleeve clock-wise to thread it toward the screw.



Revision/Removal Continued

Finally, 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 product information, list of Implants and Instruments, questions pertaining to sales and service, or to obtain a copy of the Instructions For Use (IFU), please contact your local sales representative or Genesys Spine customer service.

Indications/Contraindications/Warnings

Indications

The Genesys Spine Anterior Buttress Plate system in conjunction with traditional rigid fixation is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

Contraindications

The Genesys Spine Anterior Buttress 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 Buttress 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.

Precautions

1. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Do not over bend or alter any Genesys Spine Anterior Buttress Plate 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 refracture. 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 BUTTRESS PLATE SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The Genesys Spine Anterior Buttress Plate System is only a temporary implant used for the correction and stabilization of the lumbar 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 Buttress Plate System is used.
6. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Genesys Spine Anterior Buttress Plate System has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Anterior Buttress Plate has not been tested for heating or migration in the MR environment.

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.

Precautions and Possible Adverse Events

Precautions Continued

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 Buttress 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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