Aspida™

Anterior Lumbar Plating System

ALIF | Surgical Technique Guide

FEATURES

- Multiple plate options to accommodate varying patient anatomies
- Consistent 3.5 mm thickness provides a low-profile design for reduced risk of vascular interference
- Anchor Max™ zero-step, hands free locking mechanism
- Dual-lead self-drilling and self-tapping screws for surgical efficiency

PREFACE

The Aspida™ Anterior Lumbar Plating System consists of specifically designed lumbar and lumbo-sacral anterior plates and dual-lead self-drilling and self-tapping screws for optimal fixation.

The intuitive instrument design, complemented by the AnchorMax™ locking mechanism may result in efficient as well as effective anterior plating procedures.

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PATIENT POSITIONING

Place the patient on a radiolucent operative table in the supine position with all bony prominences padded. Prepare and drape in the conventional manner. Fluoroscope should have adequate access to the surgical field for both lateral and A/P views. Placing a pillow beneath the knees to create a mild amount of hip flexion which aids in reducing tension across the iliopsoas muscle is recommended.

PERFORM DISCECTOMY/ INTERBODY FUSION

Alphatec Spine's Anterior Disc Prep System includes curettes, pituitary ronguers, and Kerrison rongeurs. Perform the discectomy at the indicated level. Disc material and cartilage shall be removed, as well as any osteophytes that may be present, to expose the posterior longitudinal ligament.

Place Novel® ALIF PEEK or IdentitTi™ ALIF Porous Titanium interbody spacer in the disc space by utilizing Alphatec Spine's Inserter/ Distractor instrument (shown at right), or other instruments indicated for insertion for each of the respective systems.

NOTE: Performing anterior lumbar interbody fusion with instrumentation at the L4 - L5 level or above has been shown to be associated with greater risks of thrombosis and injury due to vascular retraction. Hence, it's recommended that a pulse oximeter is placed onto the left great toe to access lower extremity oxygenation.

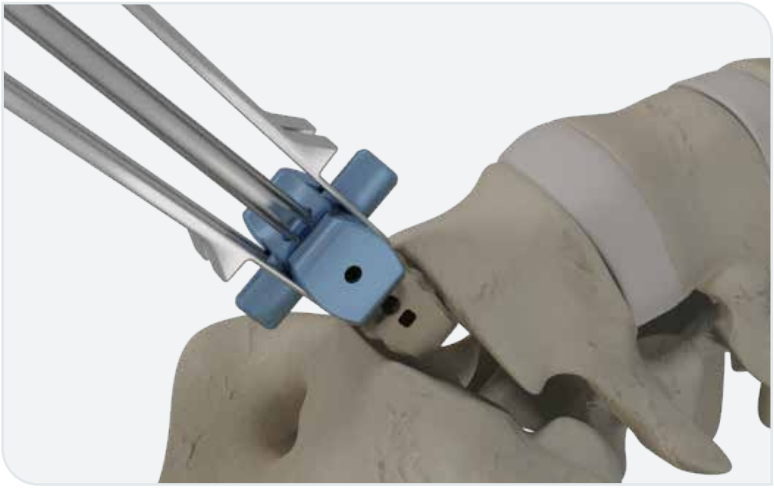


PLATE SIZING

NOTE: All plate sizing can be determined by referencing Alphatec Spine's ALIF Interbody System. Interbody implant heights correspond with the plate heights.

The appropriate plate size is determined by selecting the plate that satisfactorily spans the interbody disc space. Plate sizing can be confirmed with A/P fluoroscopy. The plates range from 8 – 24 mm heights in 2 mm increments, for both the lumbar and lumbo-sacral configurations.

PLATE POSITIONING

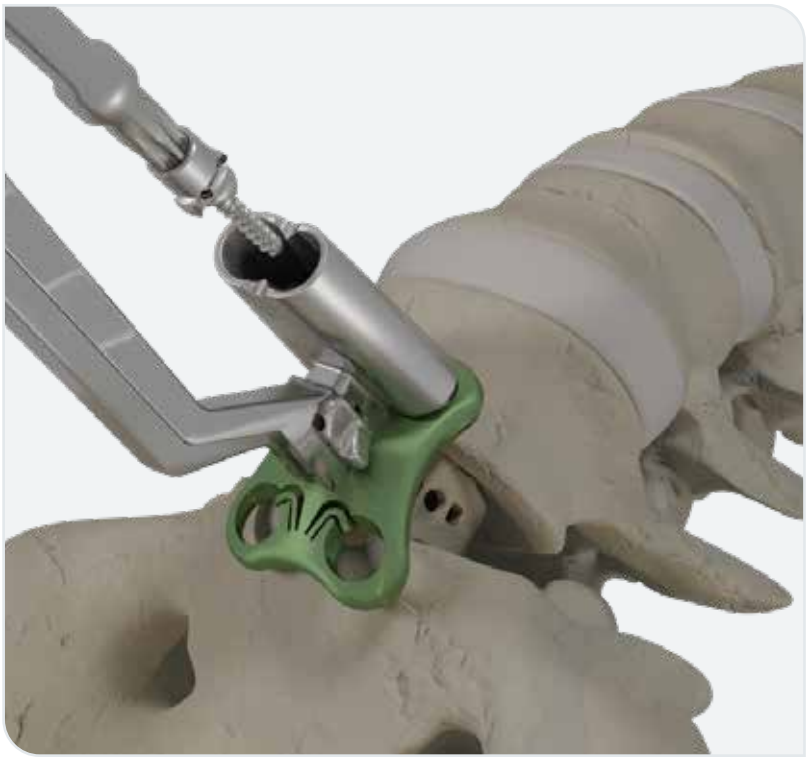
Select the appropriate sized plate, based on patient anatomy. Load plate on the Plate Holder and place into proper position to engage. The Plate Holder may be used to reposition the plate as well.

TEMPORARY FIXATION

Use Temporary Fixation Pins to provisionally hold plate in place for screw placement.

Insert the plate over the operative level with the screw holes positioned approximately 1-2 mm from the endplates of the cranial and caudal vertebral bodies.

Using the Self-Retaining Screwdriver, insert the Temporary Fixation Pin [PN 51910] into the screw hole until it's fully seated and the outer diameter is flush with the surface of the plate. Remove the Self-Retaining Screwdriver, and repeat this procedure to insert the remaining Temporary Fixation Pins as needed.



NOTE: For an alternative means of temporary fixation, plate part numbers PN 51101 – [08-24] and PN 51102 – [08-24] can be used with the Medial Temporary Fixation Pin, PN 51924.

PILOT HOLE PREPARATION/ SCREW INSERTION

The surgeon has the option of fixed angle screw insertion or variable angle screw insertion (see page 6).

FIXED ANGLE SCREW INSERTION

Confirm that the plate is properly aligned by using A/P fluoroscopy.

Choose appropriate DTS Guide corresponding to the plate size and type. Attach the DTS Guide to the distal end of the plate holder. The DTS Guide is available in sizes correlating to the Aspida Anterior Plates, ranging from 8 – 18 mm heights in 2 mm increments. DTS Guides are specific to either the Lumbar Plate, or the Sacral Plate. Please make sure to choose accordingly.

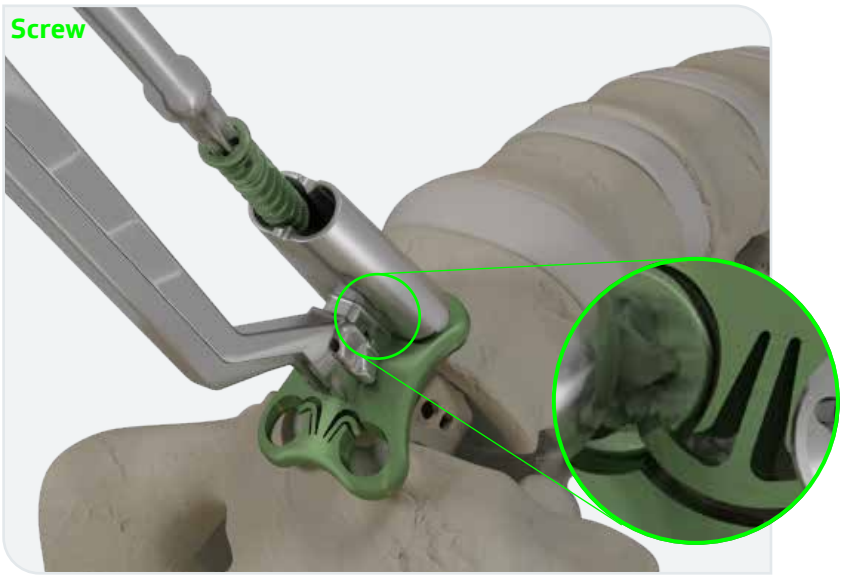
Drill: Attach the DTS Drill to the Ratcheting T-Handle. Place it through DTS Guide and advance through the cortical face of the vertebral body to create pilot hole.

Tap: Attach the DTS Tap to the Ratcheting T-Handle. Place it through the DTS Guide and tap hole to appropriate depth.

Screw: Load screw onto DTS Self-Retaining Screwdriver and place it through DTS Guide and advance until completely seated within the plate.

While advancing the screw, the self-locking mechanism will move medially. With the screw fully seated and the Self-Retaining Screwdriver removed, the locking mechanism will return to its closed position capturing the screw head securely within the plate. To remove or reposition screw, please refer to screw removal technique (see page 8).

⚠ **CAUTION!** Make sure screw is fully seated below the screw retention mechanism prior to inserting an adjacent screw. If a screw is left partially inserted, the screw retention mechanism could become damaged.



VARIABLE ANGLE SCREW INSERTION

The screw holes in the Aspida Anterior Lumbar Plate are designed to accommodate screw angle variability. Each lumbar bone screw can be placed divergent from 0° to 10° in the axial plane and 0° to 10° cephalad in the sagittal plane.

For the Lumbo-Sacral Plates (green), each cephalad sacral screw can be placed divergent from 0° to 10° in the axial plane and 0° to 10° caudal in the sagittal plane. Each caudal sacral bone screw can be placed convergent from -5° to 5° axial/medially and cephalad/caudal.

Pilot hole preparation for variable angle screws can be achieved by either using the Drill Guide or by using the Awl.

USING DRILL GUIDE

Use the Drill Guide to assure proper bone screw placement in a variety of anatomical situations. When drilling and tapping, soft tissue or vascular structure impingement may be avoided with the appropriate use of the Guide.

The Guide accommodates preparation of the bone screw hole in conjunction with the Drill and Tap.

Seat the Drill Guide completely into one of the screw holes on any plate.

Drill: Attach the Drill to the Ratcheting T-Handle. Insert the Drill into the Drill Guide and advance through the cortical face of the vertebral body to create a pilot hole.

Tap: Attach the Tap to the Ratcheting T-Handle. Insert the Tap into the Drill Guide and tap the hole to an appropriate depth.

Screw: Load the screw onto the Self Retaining Screwdriver and advance until completely seated within the screw hole.

As soon as the screw is seated fully within the plate, the self-locking mechanism will move medially. With the screw fully seated and the Self-Retaining Screwdriver removed, the locking mechanism will return to its closed state capturing the screw head within the plate. To remove or reposition screw, refer to screw removal technique (see page 8).

NOTE: The bone screws can not be implanted through the Drill Guide.

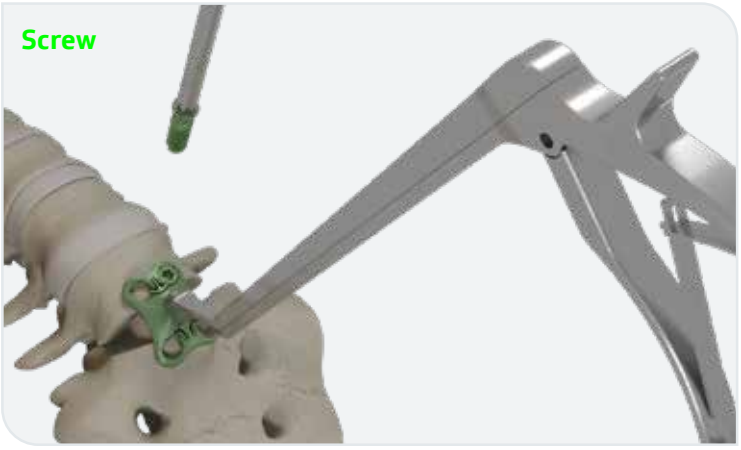
⚠ **CAUTION!** Take care to properly align both the Awl and Drill Guide relief notches to avoid damage to the screw retention mechanism.

⚠ **CAUTION!** Do not attempt to angle the bone screw in any plane beyond what the guide allows.

Drill

Tap

Screw



SELF-CENTERING AWL

⚠ **CAUTION!** Take care to properly align both the Awl and Drill Guide relief notches to avoid damage to the screw retention mechanism.

Instead of using the Drill and Tap to make a hole for the screw, a surgeon also has the option to use the Self-Centering Awl.

Pilot Hole Preparation: Confirm that the plate is properly aligned using A/P fluoroscopy. Place the Awl through desired screw hole and advance through the cortical face of the vertebral body to create a pilot hole.

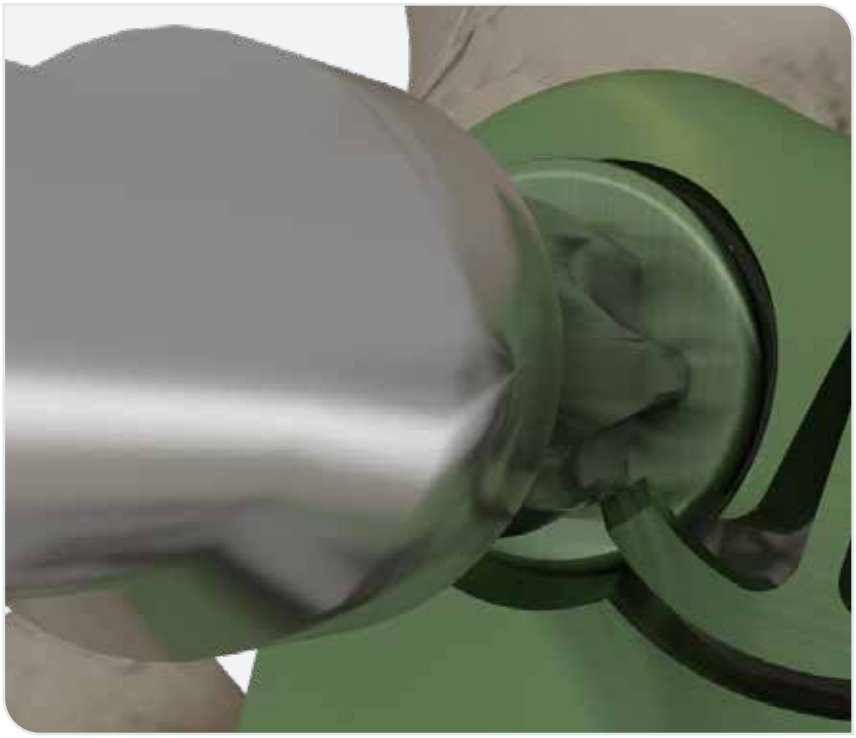
Screw: Select desired screw size. Load screw onto Self-Retaining Screwdriver and advance until completely seated within the screw hole.

While advancing the screw, the self-locking mechanism will move medially. With the screw fully seated and the Self-Retaining Screwdriver removed, the locking mechanism will return to its closed position capturing the screw head securely within the plate. To remove or reposition screw, please refer to screw removal technique (see page 8).

Verify Implant Alignment

Ensure that the screws are fully seated and the locking mechanism has captured screw heads within the plate.

Check final position of the plate and screws both visually and radiographically.



⚠ **CAUTION!** Make sure screw is fully seated below the screw retention mechanism prior to inserting an adjacent screw. If a screw is left partially inserted the screw retention mechanism could become damaged.

⚠ **CAUTION!** Bone screws should not be removed more than once to prevent damage to the screw retention mechanism. If necessary, screw removal should only be conducted with instrumentation provided.

SCREW REMOVAL

Insert the tip of the Removal Tool into the head of the desired screw.

NOTE: The opening on the distal tip of the Screw Removal Tool must be facing the anchor-lock mechanism, as illustrated, in order to unlock the self locking mechanism.

Ensure the hexalobe of the Removal Tool distal tip is fully seated within the screw head and thread the inner shaft into the screw's internal thread by pressing down on the proximal end and turning, the threads capturing the screw.

Rotate the Removal Tool counter-clockwise to disengage the anchor-lock mechanism to allow for screw extraction. Continue turning the Removal Tool counter-clockwise until the screw is removed from the plate.

Plate Holder
Part # 51904

DTS Guides

Lumbar
Part # 51921 [08-18]

Sacral
Part # 51922 [08-18]

Temporary Fixation Pin
Part # 51910

Self-centering Awl
Part # 51905

DTS Drill
Part # 51917

Medial Temporary Fixation Pin
Part # 51924

DTS Tap
Part # 51918

DTS Self Retaining Screwdriver
Part # 51911

Drill Guide
Part # 51906

Drill
Part # 51907

Tap
Part # 51908

Screw Removal Tool
Part # 51912

Aspida™ Anterior Lumbar Plating System

GENERAL INFORMATION:
The Aspida® Anterior Lumbar Plating System is a temporary device used to stabilize the lumbar spine during bone fusion development. Device implants include two styles of plate in a range of sizes and bone screws to provide the versatility required for the specific indications noted. Fixation is achieved by means of a rigid plate that is surgically attached to the spine with bone screws. Implant plates and bone screws are manufactured from surgical grade titanium alloy (ASTM F136). All device components are intended for fixation/attachment to the anterior lumbar spine only. It is intended that the implants be removed after successful fusion.

INDICATIONS FOR USE:
The Aspida Anterior Lumbar Plating System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved.
The Aspida Anterior Lumbar Plating System is intended for anterior lumbar spine (L1-S1) fixation for the following indications:
1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies)
2. Pseudoarthrosis
3. Spondylolysis
4. Spondylolisthesis
5. Trauma (i.e., fracture or dislocation)
6. Spinal stenosis
7. Unsuccessful previous fusion surgery
8. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
9. Tumor

CONTRAINDICATIONS:
The Aspida Anterior Lumbar Plating System is contraindicated for:
1. Patients with osteopenia, osteoporosis, bone absorption or rapid joint disease.
2. Patients with infection in or adjacent to the spine or spinal structures, fever, leukocytosis.
3. Patients with probable titanium and/or titanium alloy intolerance.
4. Patients with deficient soft tissue at the wound site or inadequate bone stock or quality.
5. Patients with morbid obesity or gross distorted anatomy due to congenital abnormalities.
6. Pregnant patients or patients with mental illness or other medical conditions which would prohibit beneficial surgical outcome.
7. Patients resistant to following post-operative restrictions on movement.
8. Use with components from other systems.
9. Use with bone cement.
10. Reuse or multiple uses.

WARNINGS/CAUTIONS:
1. The Aspida Anterior Lumbar Plating System is an implant device used only to provide temporary internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with this device.
2. Without solid bone fusion, this device cannot be expected to support the lumbar spine indefinitely and may fail due to bone-metal interface or bone failure.
3. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system.
4. This product is a single use device. Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.
5. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, and necrosis of bone, neurological injury and vascular or visceral injury.
6. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
7. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
8. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
9. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

PRECAUTIONS:
1. Implantation should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
3. Based on dynamic testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system
4. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
5. Take care to properly align both the Awl and Drill Guide relief notches to avoid damage to the screw retention mechanism.
6. Take great care to properly position bone screw holes when using the proper drill guide and the self-centering awl. Excessive over angulation may prohibit proper seating of the bone screws.
7. Make sure screw is fully seated below the screw retention mechanism prior to inserting an adjacent screw. If a screw is left partially inserted the screw retention mechanism could become damaged.
8. Bone screws should not be removed more than once to prevent damage to the screw retention mechanism. If necessary, screw removal should only be conducted with instrumentation provided.

MRI SAFETY INFORMATION:
The Aspida Anterior Lumbar Plating System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Aspida Anterior Lumbar Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:
The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon should be discussed with the patient preoperatively.
1. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
2. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components.
3. Bone graft fracture, vertebral body fracture or discontinued growth of fused bone at, above and/or below the surgery level
4. Non-union or pseudoarthrosis.
5. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
6. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
7. Neurological disorder including paralysis, appearance of radiculopathy and/or abnormal pain development.
8. Displacement of a screw due to incorrect positioning or implant size.
9. Hemorrhaging.
10. Infection.
11. Revision surgery.
12. Death.

PREOPERATIVE MANAGEMENT:
1. Only patients meeting the criteria listed in the indications for the use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include implantation strategy and a verification of required inventory for the case.
4. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
5. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT:
1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
2. Proper sizing and positioning of bone graft is essential to obtain successful spinal fusion. The bone graft must extend from the upper to the lower vertebrae to be fused.

POSTOPERATIVE MANAGEMENT:
Postoperative management by the surgeon, including instruction and warning 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. The surgeon should instruct the patient on how to compensate for any loss in range of spinal motion due to bone fusion.

2. Additional or revision surgery may be necessary to correct an adverse effect.
3. Instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and /or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts or other movements preventing proper healing and/or fusion development.
4. In the case of delayed union or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by surgeon.
6. Implant devices should be revised or removed immediately, if appropriate, upon a case of a non-union, pseudoarthrosis or if the devices have been bent, dislocated or broken.
7. The Aspida Anterior Lumbar Plating System implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
8. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

Refer to INS-102 for additional information

Caution: Federal law (USA) restricts these instruments to sale by or on the order of a physician.

SYMBOLS:
For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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