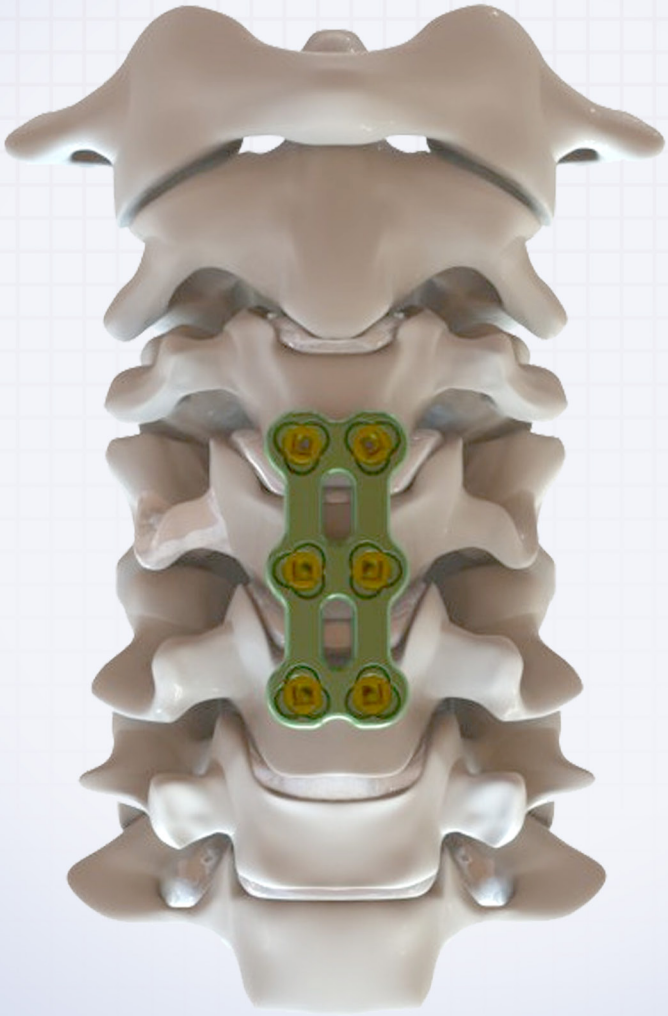
ASFORA ANTERIOR CERVICAL PLATE SYSTEM (AACP)

SURGICAL PROCEDURE MANUAL



MEDICAL DESIGNS L.L.C.

Surgical Instruments Designed by Medical Professionals

Contents:

Introduction

The Asfora Anterior Cervical Plate (AACP) System is designed to support the cervical spine and offers surgeons versatility and ease of use. The system is designed to allow the surgeon to tailor the construct to meet individual patient needs. The plates are pre-contoured to minimize additional bending in order to fit the contour of the patient anatomy. The pre-contoured plates are low-profile, have a narrow footprint, and have graft windows to provide optimal visualization. The plates are designed for application to the anterior aspect of the cervical spine (C2 to T1) and have integral locking mechanisms to reduce the potential for screws to back out of the vertebral body. Two locking screw configurations are included in the system providing the options of a constrained construct, semi-constrained construct, or unconstrained construct.

Indications

The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical spine fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Contraindications

The use of anterior cervical instrumentation is contraindicated in patients with:

- Open wounds
- Infection (systemic, in the spine, local)
- Osteoporosis or similar loss of bone density
- Certain metabolic disorders affecting osteogenesis
- Inflammatory conditions
- Certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period
- Sensitivity to Ti-6Al-4V (implant grade titanium alloy)
- Fever
- Morbid obesity
- Pregnancy
- Mental illness, alcoholism, or drug abuse
- Generally poor condition of the patient
- Inadequate patient compliance
- Cases not described in the Indications for Use

Cervical Plate Screws

Cervical Plate

Warnings

- This device is not intended for screw attachment or fixation to the posterior elements (pedicles of the cervical, thoracic or lumbar spine).
- The Asfora Anterior Cervical Plate System should only be used by surgeons who have been trained in the use of this device. Information on laboratory and clinical training may be obtained through Medical Designs, LLC.
- Mixing of dissimilar metals, such as stainless steel and titanium, in contact with each other can accelerate the corrosion process. There are many forms of corrosion damage and these can also occur on metals surgically implanted in humans. The presence of corrosion often accelerates fatigue fracture of implants. Thus, mixing implant components from other manufacturers is not recommended.
- Correct selection of the implant is extremely important. The potential for success is increased by selection of the proper size, shape and design. Implant selection should be based not only on the bone defect to be treated, but also the patient's height, weight, and physical activity level. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of the implants.
- Internal fixation appliances are load-sharing devices that are used to hold alignment until normal healing occurs. A relationship between device loading and device performance has been found in laboratory fatigue testing. This relationship makes patient selection factors and their adherence to weight bearing or load bearing instructions crucial to surgical success based on the load and number of cycles to which the implant is subjected.
- These devices are not designed to withstand activity levels and/or loads equal to those placed on normal healthy bone. Metallic internal fixation devices cannot withstand indefinitely the unsupported stress of full weight and/or load bearing.
- If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. To minimize stresses on the implant which may cause metal fatigue and consequent bending, loosening or breakage of the implant, care should be taken in patient selection, proper implant placement, and postoperative management.

Precautions

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- The Asfora Anterior Cervical Plate System implant components are not to be combined with the components from another manufacturer. Different metal types should not be used together.

Intraoperative:

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- If contouring of the implant with the Bender Instrument is necessary for optimal fit, the contouring should be gradual and care should be taken not to notch or scratch the implant surface.
- Plates must not be repeatedly or excessively bent. Repeated bending will cause the titanium plate to weaken. Alterations to the device may create notching and produce internal stress which may reduce the functional strength of the construct.
- Reverse bending will cause the titanium to weaken.
- Do not sharply bend the plate.
- Do not bend the plate more than +/- 7 degrees, including the pre-bend radius.
- Do not bend the smallest Level 1 and Level 2 plate with the Bender Instrument.
- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Prior to closing the soft tissues, all of the screws should be seated onto the plate in the locking tabs. Recheck the tightness of all screws after finishing making sure that none have loosened during the tightening of the other screws.

Caution: *Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.*

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

- To allow the maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions, and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion.

- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed union or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

Postoperative: (continued)

- The Asfora Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: 1) corrosion, with localized tissue reaction or pain, 2) migration of implant position possibly resulting in injury, 3) risk of additional injury from post-operative trauma, 4) bending, loosening and/or breakage, which could make removal impractical or difficult, 5) pain, discomfort, or abnormal sensations due to the presence of the device, 6) possible increased risk of infection, and 7) bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Asfora Anterior Cervical Plate System implant components should ever be reused under any circumstances.

Implant Overview

The Asfora Anterior Cervical Plate (AACP) System is manufactured in the United States of America from medical grade titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The system consists of bone plates and bone screws of varying lengths to accommodate surgical procedures from one to four levels. The plates are designed for application to the anterior aspect of the cervical spine and have integral locking mechanisms to reduce the potential for screws to back out of the vertebral body. All plate models are 17.5 mm wide and 2.3 mm thick and overall lengths range from 20 to 94 mm. The screws are provided in diameters of 4.0 mm (variable and fixed locking screw), and 4.4 mm (variable rescue screw) and lengths of 12 mm, 14 mm and 16 mm. The AACP plates, screws and instruments are provided non-sterile. Refer to the Asfora Anterior Cervical Plate System Package Insert for instructions on sterilization of the plates and screws and cleaning and sterilization of the instruments prior to use. The available plate and screw sizes are shown below.

LEVEL 1

Cervical Plate Model Number	Screw Holes	Hole Pair (mm)	Overall Plate (mm)
11-1106-FD1-20	4	12.0	20.0
11-1106-FD1-22	4	14.0	22.0
11-1106-FD1-24	4	16.0	24.0
11-1106-FD1-26	4	18.0	26.0
11-1106-FD1-28	4	20.0	28.0
11-1106-FD1-30	4	22.0	30.0
11-1106-FD1-32	4	24.0	32.0
11-1106-FD1-34	4	26.0	34.0

LEVEL 2

Cervical Plate Model Number	Screw Holes	Hole Pair (mm)	Overall Plate (mm)
11-1106-FD2-32	6	24.0	32.0
11-1106-FD2-35	6	27.0	35.0
11-1106-FD2-38	6	30.0	38.0
11-1106-FD2-41	6	33.0	41.0
11-1106-FD2-44	6	36.0	44.0
11-1106-FD2-47	6	39.0	47.0
11-1106-FD2-50	6	42.0	50.0

LEVEL 3

Cervical Plate Model Number	Screw Holes	Hole Pair (mm)	Overall Plate (mm)
11-1106-FD3-51	8	43.0	51.0
11-1106-FD3-54	8	46.0	54.0
11-1106-FD3-57	8	49.0	57.0
11-1106-FD3-60	8	52.0	60.0
11-1106-FD3-63	8	55.0	63.0
11-1106-FD3-66	8	58.0	66.0
11-1106-FD3-69	8	61.0	69.0
11-1106-FD3-72	8	64.0	72.0
11-1106-FD3-75	8	67.0	75.0

LEVEL 4

Cervical Plate Model Number	Screw Holes	Hole Pair (mm)	Overall Plate (mm)
11-1106-FD4-74	10	66.0	74.0
11-1106-FD4-78	10	70.0	78.0
11-1106-FD4-82	10	74.0	82.0
11-1106-FD4-86	10	78.0	86.0
11-1106-FD4-90	10	82.0	90.0
11-1106-FD4-94	10	86.0	94.0

Note: Hole Pair is measured Cephalad to Caudad.

Bone Screw Model Number	Configuration	Dimensions (mm)	
		Diameter	Length
11-1106-FD7-12	Variable Angle	4.0	12.0
11-1106-FD7-14	Variable Angle	4.0	14.0
11-1106-FD7-16	Variable Angle	4.0	16.0
11-1106-FD8-12	Fixed Angle	4.0	12.0
11-1106-FD8-14	Fixed Angle	4.0	14.0
11-1106-FD8-16	Fixed Angle	4.0	16.0
11-1106-FD9-12	Rescue (Variable)	4.4	12.0
11-1106-FD9-14	Rescue (Variable)	4.4	14.0
11-1106-FD9-16	Rescue (Variable)	4.4	16.0

Instruments Overview

Use of specialized instruments designed and provided by Medical Designs, LLC, assure accurate implantation of the device.

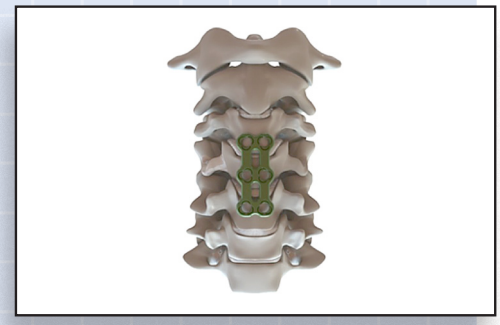
Each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instrumentation should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Medical Designs, LLC.

Instruments for implantation of the AACP include:

Instrument Model Number	Description
11-1106-FD12	2.5mm x 12mm Drill Bit (Single Use)
11-1106-FD14	2.5mm x 14mm Drill Bit (Single Use)
11-1106-FD16	2.5mm x 16mm Drill Bit (Single Use)
11-1106-FD27	Screw Extractor Set
11-1106-FD28	Screw Retention Driver
11-1106-FD29	Variable Angle Drill Guide
11-1106-FD35	Plate Bender
11-1106-FD36	Caliper
11-1106-FD41	Fixed Angle Drill Guide
11-1106-FD42	Axial Drill Bit Handle
11-1106-FD43	Axial Driver Handle

The AACP System Instruments used to implant the devices are provided non-sterile, and must be cleaned and sterilized in the Medical Designs' Sterilization Tray prior to each use, as described in the AACP Instructions for Use.

Note: All instruments, with the exception of the Drill Bits (11-1106-FD12, 11-1106-FD14, and 11-1106-FD16) are reusable. The Drill Bits are single use devices and should be discarded after use.

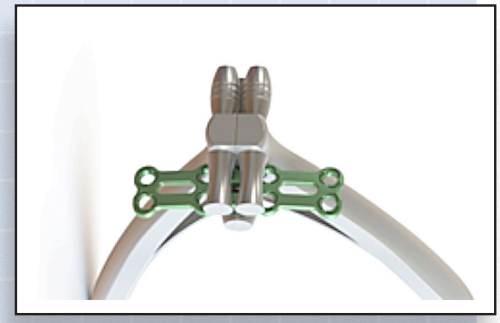


(Fig.1)

Step One: Anterior Cervical Discectomy and Fusion

The disc excision is performed using standard surgical technique. Following disc excision and prior to insertion of bone graft or cage of surgeon's preference, the surgeon needs to select the appropriate size screw to be used for the plate by placing it in the disc space. The superior aspect of the head of the screw should be flush with the anterior margin of the vertebrae to be fused. The tip of the screw should be short of the posterior longitudinal ligament. Following the placement of the bone graft, care should be taken to remove all anterior projecting osteophytes in order to create an even and smooth surface.

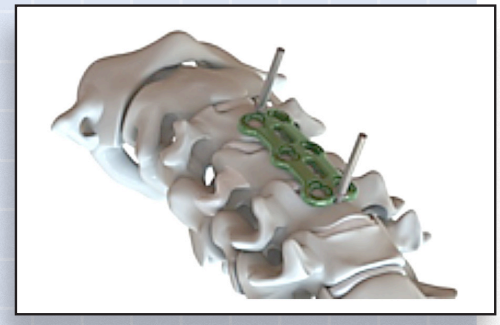
Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.



(Fig.2)

Step Two: Selection and Bending of Plate

Selection of plate size may be performed by measuring the desired size with the caliper or by positioning different sized plates over the vertebral column to see which provides the best fit. Usually the smallest size plate that fits the construct should be used. The superior screw bores should usually align with the inferior one-third of the superior vertebral body and the inferior screw bores should align with the superior one-third of the inferior vertebral body (Fig. 1). The AACP Plate is precontoured with lordosis. If additional contouring is required, the plate can be contoured to the desired degree of lordosis utilizing the Plate Bender provided in the AACP System Sterilization Tray. Care should be taken not to damage the gripper tabs of the plate with the Plate Bender and the plate should only be contoured in-between the screw bores (Fig. 2). Repeat bending may weaken the plate. Do not bend the smallest Level 1 and Level 2 plate with the Bender Instrument.



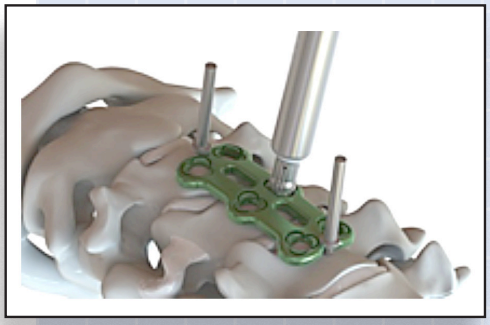
(Fig.3)

Step Three: Plate Fixation

Once the plate has been contoured to the desired shape for the in situ anatomy, temporary fixation of the plate may be done by using two pins from a distractor system (not provided in the AACP System). Secure the plate by placing a pin in the notches at each end of the plate to temporarily hold it in place (Fig. 3). Some surgeons may choose not to use temporary fixation and secure the plate directly with the Locking Screws.

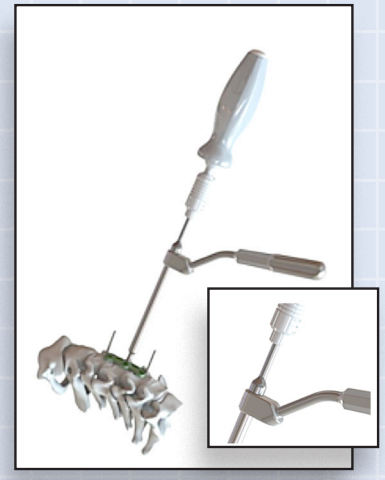
Step Four: Screw Placement

Although the screws are self-drilling and self-tapping, to better direct the screw, usually five degrees medially in the coronal plane and within 20 degrees cone of angulation in the sagittal plane, a Drill Guide and Drill Bit should be used. The depth to be drilled will depend on the size of the screw selected. Assemble the selected size Drill Bit into the Axial Drill Bit Handle and verify that the Drill Bit is secured. Insert the Drill Guide into a screw bore, ensuring that the spherical tip of the Drill Guide is captured inside the Cervical Plates' spherical cavity, and align the Drill Guide to the correct screw angle (Fig. 4). Create a pilot hole by inserting the Drill Bit assembly through the Drill Guide and rotating the Drill Bit clockwise while applying a downward force until the Drill Bit's stop collar makes contact with the tip of the Drill Guide (Fig. 5). Remove the Drill Bit and Drill Guide. Verify that the pilot hole appears concentric to the Cervical Plate's spherical cavity and that the plate did not move while removing the Drill Guide.



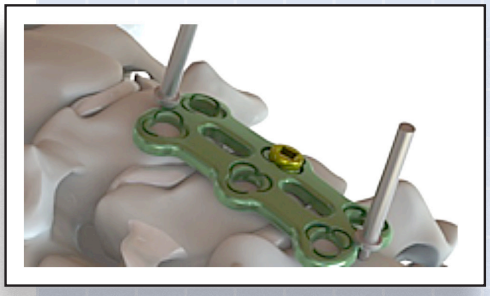
(Fig.4)

Assemble the Retention Driver onto the Axial Driver Handle and verify that the driver is secured. Use the Retention Driver to engage the selected size Locking Screw (selected screw size should be the same size as the selected Drill Bit). Insert the tip of the Locking Screw into the just-created pilot hole and align the Locking Screw to match the pilot hole angle. Begin driving in the Locking Screw by rotating the Retention Driver clockwise while applying a downward force. Continue driving in the Locking Screw until the screw head is just above the Cervical Plate's gripper tabs (Fig. 6). Ensure that the Locking Screw followed the pilot hole and that the screw head appears concentric to the Cervical Plate's spherical cavity. Remove the Retention Driver. The Cervical Plate should still be secure and not have shifted during placement of the Locking Screws.



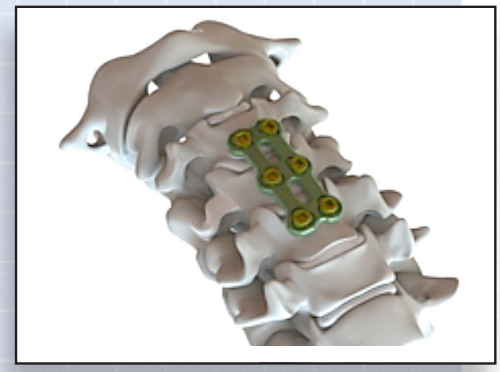
(Fig.5)

Repeat the process of preparing each screw hole and inserting the Locking Screws in each successive hole of the Cervical Plate. It is important to insert the screws immediately following pilot hole preparation. Care should be taken to not prepare multiple holes before inserting screws as plate location may still shift slightly, resulting in alignment difficulties between the Locking Screw and previously prepared pilot holes.

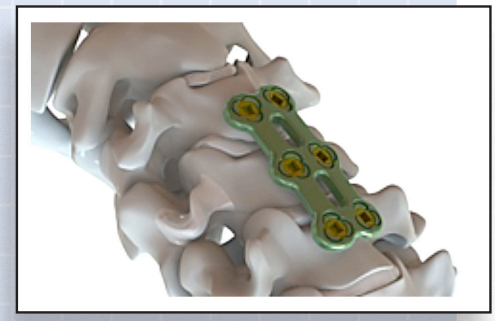


(Fig.6)

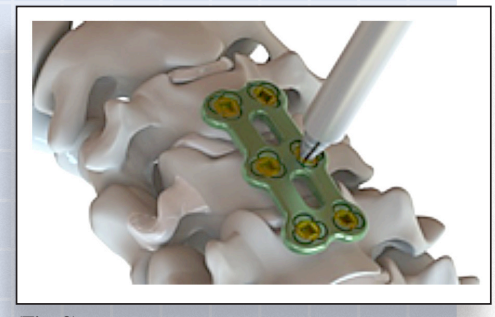
Step Four: Screw Placement (cont.)



(Fig. 7)



(Fig. 8)



(Fig. 9)

Once the Cervical Plate is fully populated with Locking Screws, remove the distractor pins and verify the Cervical Plate alignment to the cervical vertebrae (Fig. 7). Verify that the removal of the distractor pins did not deform the plate. Use the Retention Driver to torque the Locking Screws starting from the center position of the plate and moving outwards. Continue torqueing to overcome the resistance of the gripper tabs and seat the Locking Screw fully in the Cervical Plate. Proceed to securely lag the Cervical Plate to the vertebra until tactile feedback is observed and the head of the Locking Screw bottoms out within the Cervical Plate (Fig. 8), indicating that the screws have been properly positioned and are secure.

Verify that the gripper tabs do not appear deformed or broken by the installation of the Locking Screws and that the gripper tabs go over the Locking Screw head and that the screw has not stripped the cervical vertebrae. Verify that the Cervical Plate is secure and does not move.

At the completion of the procedure, re-check all screws to ensure that they are locked to the plate and tight. Screws are locked when they are securely seated flush within the plate. Failure to do so may result in screw loosening or backing out. Proceed with standard wound closure.

Extreme caution should be used around the spinal cord and nerve roots, especially when inserting screws. Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.

Reasons to remove a screw during plate implantation may include the need to replace the plate with a different size or the desire to change the trajectory of the screw due to incorrect screw placement where the screw trajectory angle is such that it will not allow the head of the screw to engage the gripper tabs. In these cases, remove the screw with the same Retention Driver or the Screw Extractor Set if the screw is locked, re-drill using the desired trajectory if needed, and use a Rescue Screw as it has a larger diameter and provides a better chance for the screw to remain tight.

If removal is necessary, and the screw has already been locked into the gripper tabs, the Screw Extraction Set is needed and a Rescue Screw will be inserted. Assemble the Extraction Set by threading the Extractor Driver through the Screw Extractor Sleeve until the tip of the driver protrudes past the end of the sleeve by approximately 5mm. Insert the Extraction Driver tip into the Locking Screw head that is to be removed. Insert the Wedge Lock through the center of the driver, align the rectangular slots on the mating parts and push the Wedge Lock into place to engage the Extraction Driver tip into the Locking Screw (Fig. 9-11). The Wedge Lock should bottom out on the Extractor Driver and the driver tip should engage the screw head and remain engaged after the Wedge Lock is installed. Attach the Axial Driver Handle onto the Screw Extractor Driver and verify that the handle is secured. Rotate the handle clockwise to lower the Extractor Sleeve down the Extractor Driver shaft until the driver makes contact with the Cervical Plate.

While holding the Extractor Sleeve in place with one hand, rotate the Axial Driver Handle counter-clockwise to fully unthread the Locking Screw from the bone and extract it from the Cervical Plate (Fig. 12). The Extractor Driver should fully unthread from the Extractor Sleeve to ensure that the Locking Screw is free from the Cervical Plate. In order to release the Locking Screw from the Extractor Driver tip, remove the handle from the driver and then remove the Wedge Lock. Verify that the gripper tabs do not appear deformed or broken by the removal of the Locking Screw. The removed Locking Screw must be discarded and not reused.

To install the Rescue Screw, use the Retention Driver Assembly to engage a Rescue Screw of the same length as the just removed Locking Screw, and insert the tip of the Rescue Screw into the hole of the just-removed Locking Screw. Match the screw insertion angle to the hole angle and insert the Rescue Screw using the same method as used to install the removed Locking Screw. Verify that the gripper tabs go over the Rescue Screw head and that the screw has not stripped the cervical vertebrae. Remove the Retention Driver from the Rescue Screw. Verify that the plate is secure and does not move.

Caution: *Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.*

Step Five: Wound Closure

The wound should be closed in two layers utilizing standard surgical technique. It should be emphasized that there is a need to close the platysma muscle layer for better cosmetic results.

It is the surgeon's discretion as to whether a drain should be used or not.

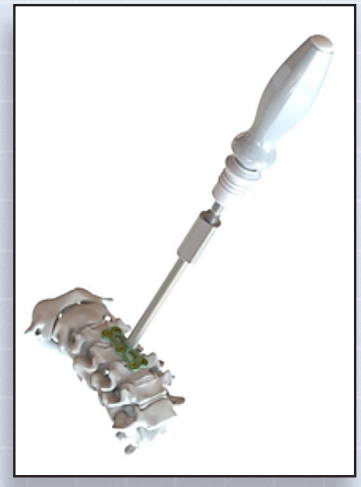
Postoperative Care

Standard postoperative care is carried out. The head of the bed should be kept elevated at approximately 30 degrees. Antibiotics are routinely used for 24 hours postoperatively. A cervical collar is recommended for three and four level fusions, and this should be worn for approximately three months. The patient's diet and activities are increased as tolerated. A drain, if present, should be removed when drainage is less than 5 cc in an 8 hour period.

Device Retrieval Efforts

If removal of the Cervical Plate is indicated, such as in cases of device migration or adjacent level surgery, extra care should be taken not to injure soft tissues of the neck during exposure of the spine and plate. Dissection is more difficult in redo cases due to the presence of scar from previous surgery. Once the plate is exposed, follow the instructions above to remove the Locking and/or Rescue Screws until all screws have been successfully removed, thus allowing the plate to be removed.

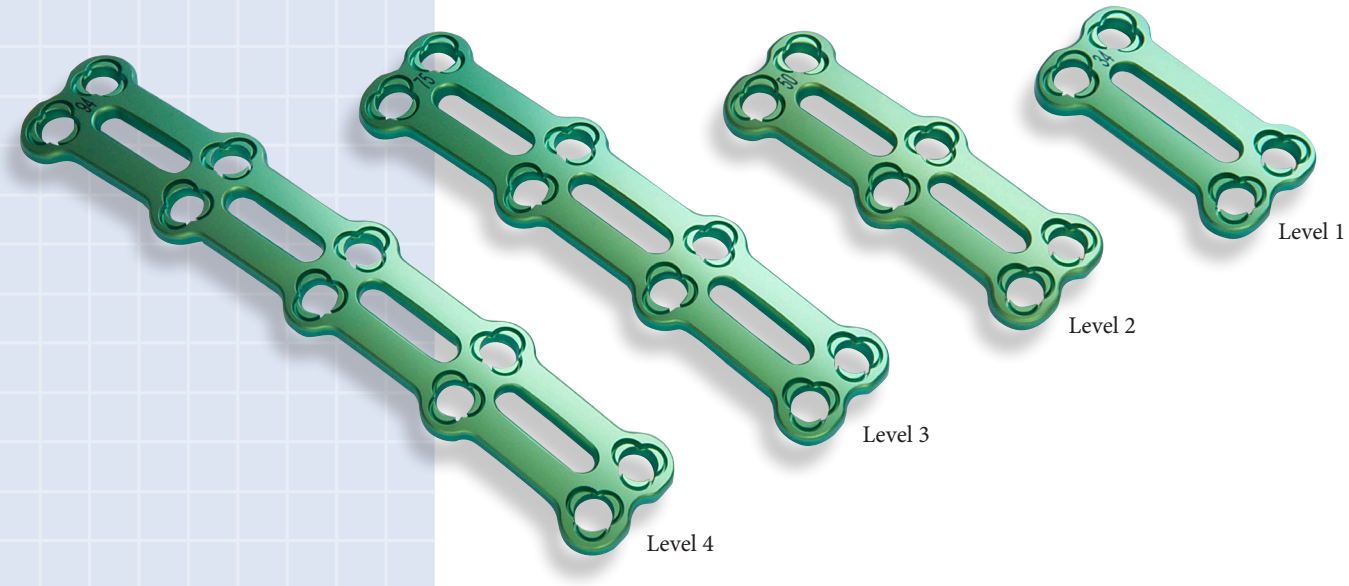
(Fig. 10)



(Fig.11)

(Fig.12)

AACP System (Implants)



Description	Hole Pair (Cephalad to Caudad)	Plate Length	Model Number	Size (Appears on plate)
Level 1, 20.0mm	12.0mm	20.0mm	11-1106-FD1-20	20mm
Level 1, 22.0mm	14.0mm	22.0mm	11-1106-FD1-22	22mm
Level 1, 24.0mm	16.0mm	24.0mm	11-1106-FD1-24	24mm
Level 1, 26.0mm	18.0mm	26.0mm	11-1106-FD1-26	26mm
Level 1, 28.0mm	20.0mm	28.0mm	11-1106-FD1-28	28mm
Level 1, 30.0mm	22.0mm	30.0mm	11-1106-FD1-30	30mm
Level 1, 32.0mm	24.0mm	32.0mm	11-1106-FD1-32	32mm
Level 1, 34.0mm	26.0mm	34.0mm	11-1106-FD1-34	34mm
Level 2, 32.0mm	24.0mm	32.0mm	11-1106-FD2-32	32mm
Level 2, 35.0mm	27.0mm	35.0mm	11-1106-FD2-35	35mm
Level 2, 38.0mm	30.0mm	38.0mm	11-1106-FD2-38	38mm
Level 2, 41.0mm	33.0mm	41.0mm	11-1106-FD2-41	41mm
Level 2, 44.0mm	36.0mm	44.0mm	11-1106-FD2-44	44mm
Level 2, 47.0mm	39.0mm	47.0mm	11-1106-FD2-47	47mm
Level 2, 50.0mm	42.0mm	50.0mm	11-1106-FD2-50	50mm
Level 3, 51.0mm	43.0mm	51.0mm	11-1106-FD3-51	51mm
Level 3, 54.0mm	46.0mm	54.0mm	11-1106-FD3-54	54mm
Level 3, 57.0mm	49.0mm	57.0mm	11-1106-FD3-57	57mm
Level 3, 60.0mm	52.0mm	60.0mm	11-1106-FD3-60	60mm
Level 3, 63.0mm	55.0mm	63.0mm	11-1106-FD3-63	63mm
Level 3, 66.0mm	58.0mm	66.0mm	11-1106-FD3-66	66mm
Level 3, 69.0mm	61.0mm	69.0mm	11-1106-FD3-69	69mm
Level 3, 72.0mm	64.0mm	72.0mm	11-1106-FD3-72	72mm
Level 3, 75.0mm	67.0mm	75.0mm	11-1106-FD3-75	75mm
Level 4, 74.0mm	66.0mm	74.0mm	11-1106-FD4-74	74mm
Level 4, 78.0mm	70.0mm	78.0mm	11-1106-FD4-78	78mm
Level 4, 82.0mm	74.0mm	82.0mm	11-1106-FD4-82	82mm
Level 4, 86.0mm	78.0mm	86.0mm	11-1106-FD4-86	86mm
Level 4, 90.0mm	82.0mm	90.0mm	11-1106-FD4-90	90mm
Level 4, 94.0mm	86.0mm	94.0mm	11-1106-FD4-94	94mm

AACP System (Screws and Drill Bits)

Variable Angle Locking Screws Description	Instrument Model Number
4.0mm x 12mm Variable Angle Locking Screw	11-1106-FD7-12
4.0mm x 14mm Variable Angle Locking Screw	11-1106-FD7-14
4.0mm x 16mm Variable Angle Locking Screw	11-1106-FD7-16

Variable Angle Locking Screws

Fixed Angle Locking Screws Description	Instrument Model Number
4.0mm x 12mm Fixed Angle Locking Screw	11-1106-FD8-12
4.0mm x 14mm Fixed Angle Locking Screw	11-1106-FD8-14
4.0mm x 16mm Fixed Angle Locking Screw	11-1106-FD8-16

Fixed Angle Locking Screws

Variable Angle Rescue Screws Description	Instrument Model Number
4.4mm x 12mm Variable Angle Rescue Screw	11-1106-FD9-12
4.4mm x 14mm Variable Angle Rescue Screw	11-1106-FD9-14
4.4mm x 16mm Variable Angle Rescue Screw	11-1106-FD9-16

Variable Angle Rescue Screws

Disposable Instruments (shown below) Description	Instrument Model Number
2.5mm x 12mm Drill Bit (single use)	11-1106-FD12
2.5mm x 14mm Drill Bit (single use)	11-1106-FD14
2.5mm x 16mm Drill Bit (single use)	11-1106-FD16

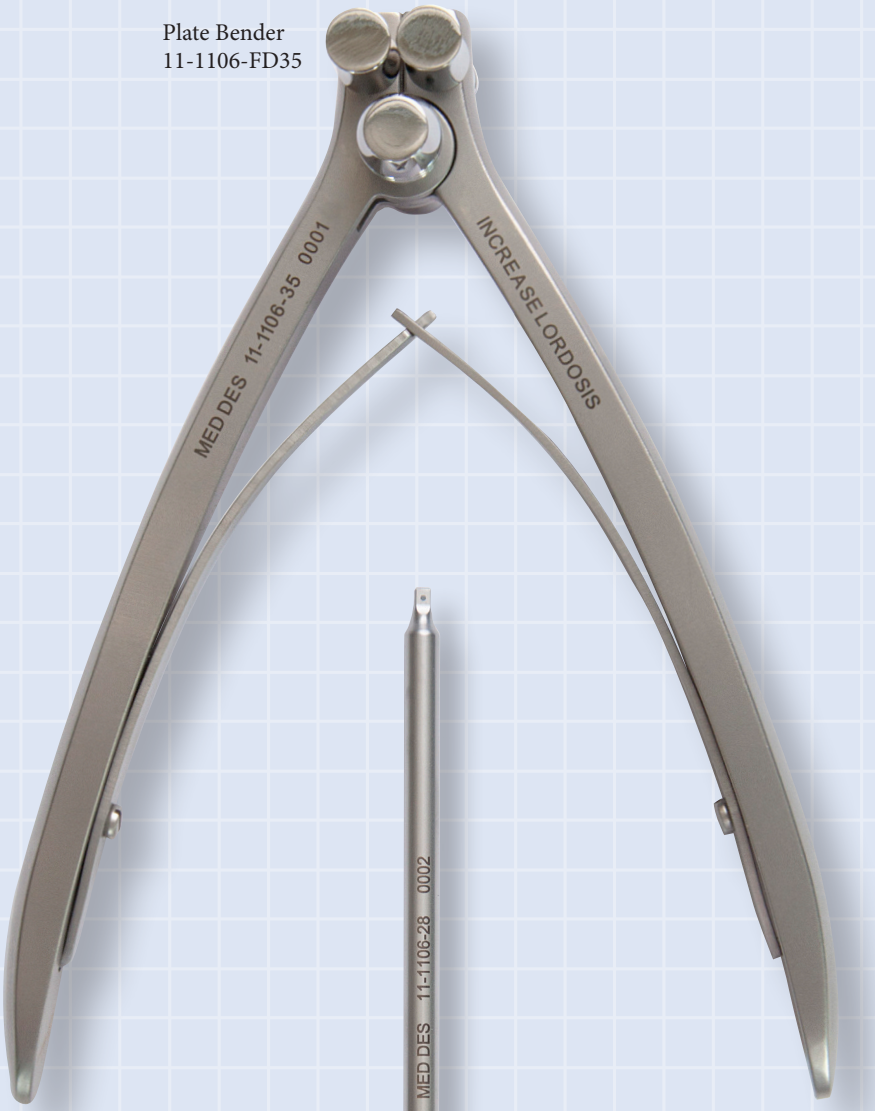
Drill Bit (12mm)
11-1106-FD12

Drill Bit (14mm)
11-1106-FD14

Drill Bit (16mm)
11-1106-FD16

AACP System (Instruments)

Plate Bender
11-1106-FD35



Screw Extractor Set
11-1106-FD27

Screw Retention Driver
11-1106-FD28

ASFORA ANTERIOR CERVICAL PLATE SYSTEM STERILIZATION CASE

Model Number: 11-1106-FD37 (pictured with instruments)

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