

Hallmark[®]

Anterior Cervical Plating (ACP) System



MICHELSON
TECHNOLOGY
AT WORK

Hallmark Operative Technique

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- 3 OPERATIVE**
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Orthofix Spinal Implants wishes to thank the following surgeon for his contribution to the development of this technique:

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INTRODUCTION

An anterior cervical discectomy and fusion is an operation that is commonly performed to treat herniated discs in the cervical spine, spinal stenosis, tumors, trauma, and infections.

Anterior cervical plating systems should:

- Align the spine in an anatomical position
- Maintain graft position
- Increase the likelihood of a fusion
- Allow patients to increase activity in a timely fashion

The Hallmark® Anterior Cervical Plating (ACP) System uses an intuitive top-locking mechanism. The screws are available either constrained or semi-constrained, and both have a thread design which is aggressive and secure even in soft bone. The plate shape is low profile, the trajectory for the screws is fairly narrow, so compression of the structures of the neck and access is relatively atraumatic.

The Hallmark ACP System is a reliable, adaptable system that can be used to suit surgeon preferences as they repair a wide spectrum of anterior spinal disorders.



1. PRE-OPERATIVE PLANNING AND PATIENT POSITIONING

As with any spine surgery, pre-operative planning is essential to reduce the risk of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device, cervical plate and bone screw sizes.

PATIENT POSITIONING

The patient is placed in a supine position with all bony prominences padded and the head in slight extension. The cervical spine is supported to maintain cervical lordosis.

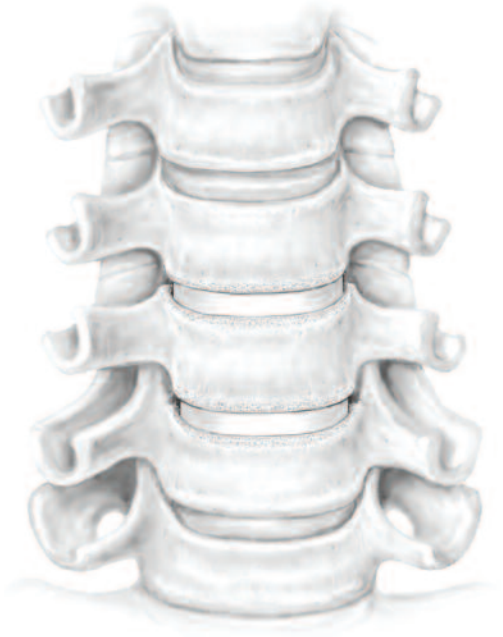


Fig. 2

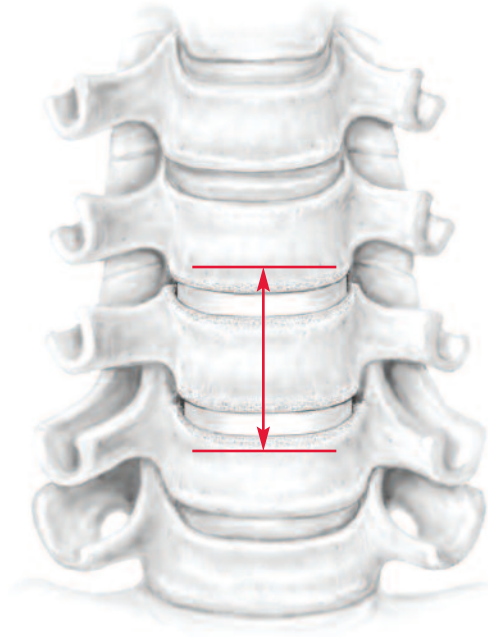


Fig. 3

2. EXPOSURE

Adequate visualization of the vertebrae and disc space is critical. Ventral soft tissue should be removed from the vertebral body to create a smooth surface for optimal surface exposure and plate placement.

Following decompression and anterior bone graft placement, osteophytes or irregularities should be removed from the anterior surface of the spine so the selected plate fits flush across the graft space.

3. PLATE LENGTH SELECTION

Measure the distance between the inferior endplate of the superior vertebral body to the superior endplate of the inferior vertebral body. This distance should be equal to or slightly smaller than the distance between the top locking screws on the plate.

The length of the plate should be selected so that the bone screws enter the respective superior and inferior vertebral body as close to the edge of the disc space as possible. The bone screw holes and plate should not abut the proximal or distal unfused disc spaces immediately adjacent to the plate.

Dr. Reichman Recommends:

“Optimal screw positioning always seems to be a bit higher than first visualized. If the plate looks slightly short, it is best to increase by one plate size. The goal is to position the screw 1mm - 2mm from the endplate at the cephalad and caudal vertebral body.”

Plate Preparation

Place the top locking plates and top locking screws in the open position. Top locking plates should slide freely to allow for bone screw placement.

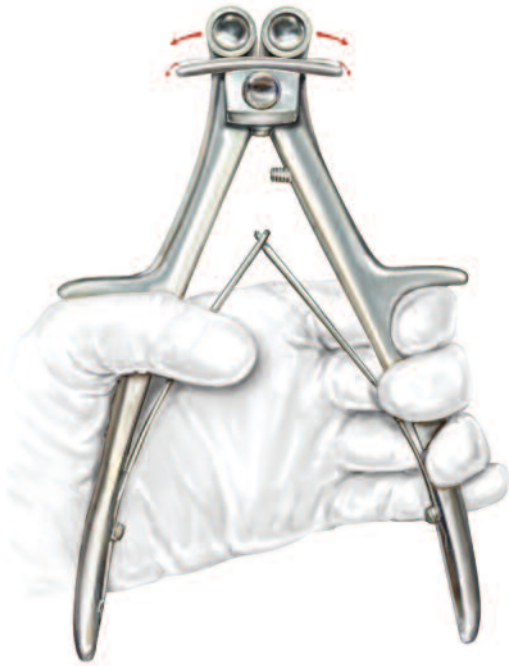


Fig. 4

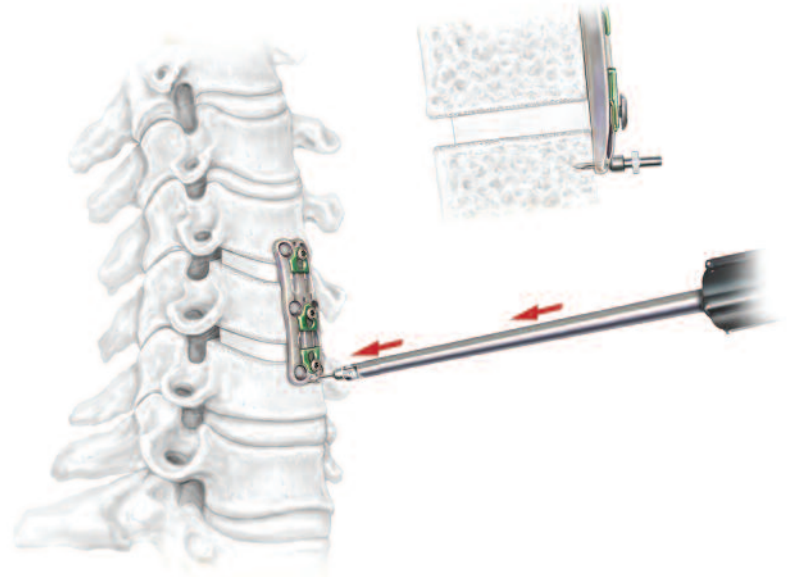


Fig. 5

4. CONTOURING THE PLATE

The Hallmark Anterior Cervical Plate is machined with an 8° lordosis. The plate can be contoured for additional lordosis by using the plate bender.

Caution: Due to titanium's notch sensitivity, Orthofix does not recommend decreasing the contour if the plate has been over bent.

- Ensure that the top locking plates are secure and in the open position.
- Insert the plate from the side into the plate bender. The plate is positioned with the top portion of the plate in contact with the two barrels of the plate bender. There is a track in the plate bender for the top locking screw.
- Apply moderate pressure to the handles. The plate should be bent only between the bone screw holes.
- It is recommended that the plate bender is used only to increase plate lordosis.

5. SECURING THE PLATE

After the plate is properly positioned, a temporary fixation tack may be inserted into either the cephalad or caudal temporary tack hole using the tack holder. The temporary tack will secure the plate to the cervical column to prevent plate slippage during the initial screw placement.

The distal tip of the tack holder has a bayonet style adapter. Ensure that the tack holder is in the open position prior to attaching the tack. The temporary tack is stabilized to the tack holder by "gently" turning the knurled knob clockwise on top of the handle. Ensure that the cervical tack is properly secured to the tack holder before proceeding to the next step.

The tack should be inserted perpendicular to the plate.

Remove the tack holder from the tack by turning the knurled knob counter clockwise on top of the handle.

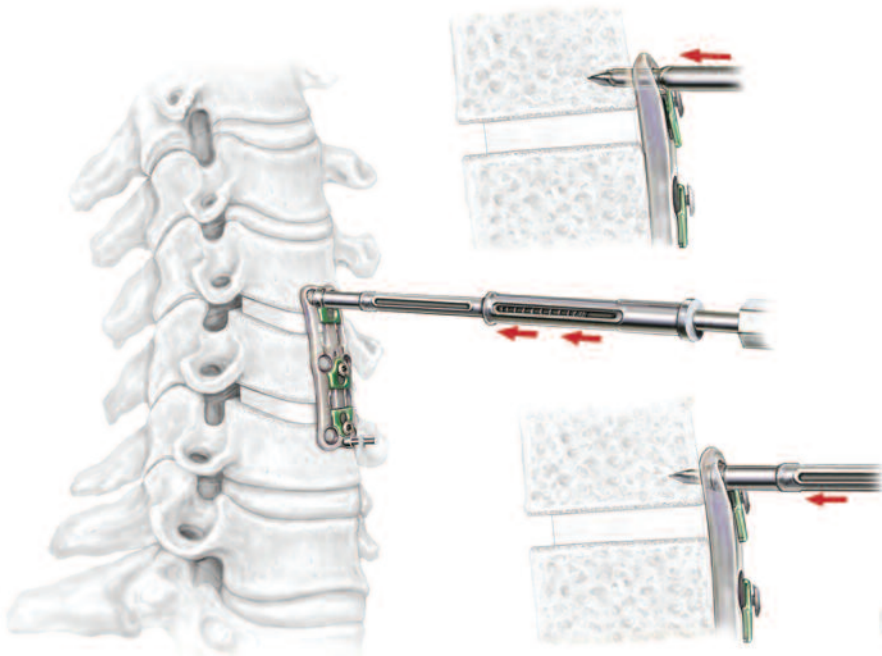


Fig. 6

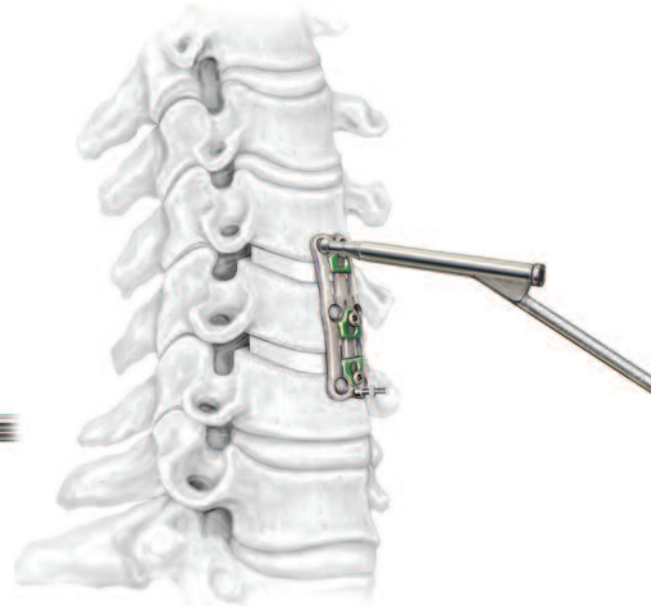


Fig. 7

6. PENETRATION OF THE CORTEX

The Hallmark Anterior Cervical Plating System provides the surgeon the option of using a bone awl.

Bone awls (standard and sleeved) are used in conjunction with the modular handle.

Standard Bone Awl

Insert the standard bone awl securely into the modular handle.

Position the freehand drill guide and standard bone awl in the desired bone screw hole. Angle the drill guide and bone awl as desired and apply gentle pressure to penetrate the underlying cortex.

Sleeved Bone Awl

The sleeved bone awl provides quick one step penetration of the cortex.

Insert the sleeved bone awl securely into the modular handle. Firmly seat and angle the sleeved bone awl (12° to -5° cephalad/caudal and 6° medial convergent angle) in the preferred bone screw hole. Apply pressure to the bone awl to penetrate the underlying cortex.

7. DRILL GUIDE

The freehand drill guide is used to protect the adjacent soft tissues and ensures proper drilling depth and orientation.

It is important to seat the drill guide securely within the hole prior to drilling.

Position the drill guide to the appropriate angle: 12° to -5° cephalad/caudal and 6° medial convergent angle.

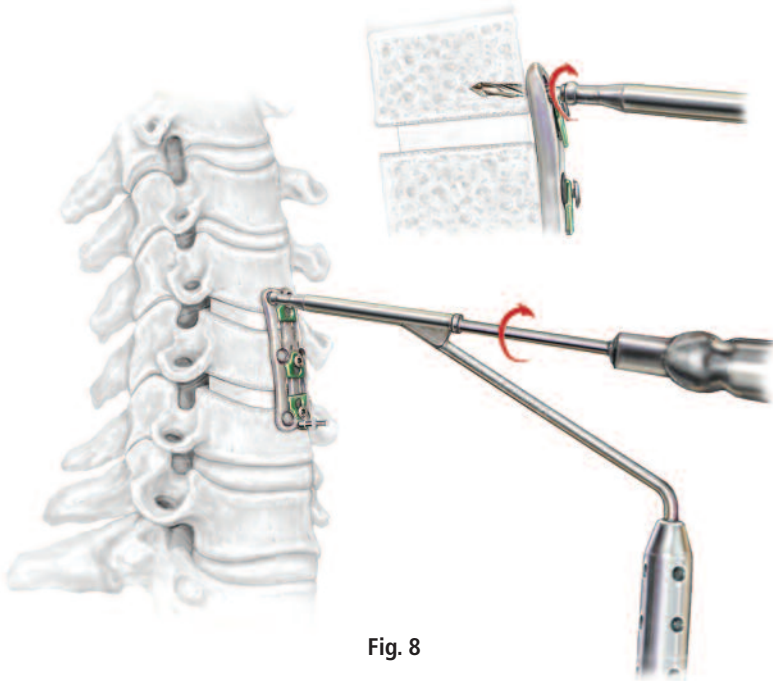


Fig. 8

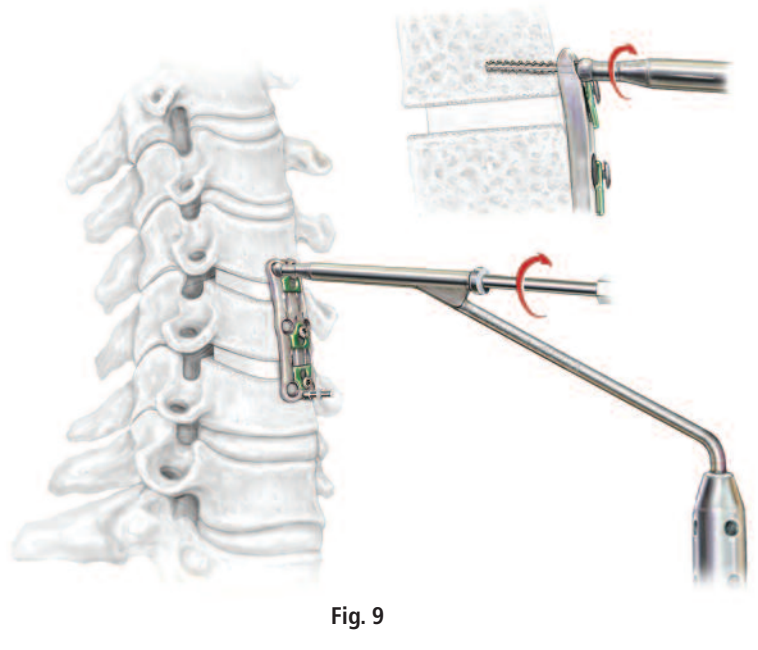


Fig. 9

8. DRILL

Drill bits are used in conjunction with the modular handle.

Insert the drill bit securely into the modular handle. The single-use, disposable drill bits are color coded for easy identification with their corresponding bone screw length. Screw and drill length are determined by the depth of bone screw purchase required.

Dr. Reichman recommends

“A 12mm drill is optimal for uniformity and consistency.”

Position the freehand drill guide securely in the desired bone screw hole. Insert the drill into the drill guide, position the drill guide and drill. Drill to the appropriate depth. When used in conjunction with the freehand drill guide, there is a positive stop on the drill bits to prevent over-drilling.

9. TAP (OPTIONAL)

After the bone screw hole is drilled, a tap is used to cut threads in the bone screw holes.

The 12mm tap is used in conjunction with the modular handle. Place the tap securely into the modular handle.

Position the freehand drill guide securely in the desired bone screw hole. Insert the tap into the drill guide, angle the drill guide and tap. Tap only to the desired length.

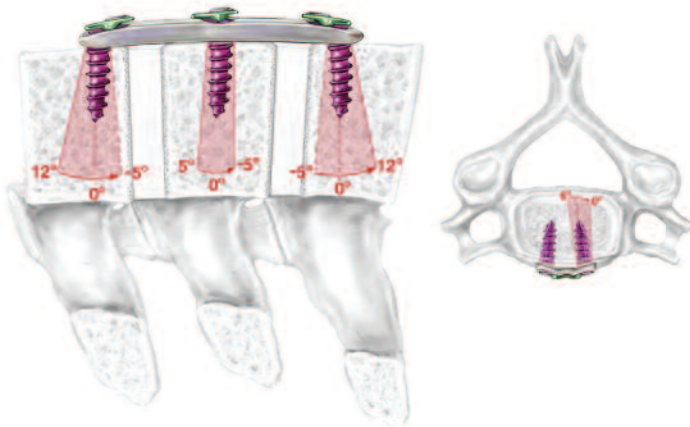


Fig. 10

10. SELF DRILLING/SELF TAPPING BONE SCREWS

Two types of bone screws are provided in the Hallmark ACP System, constrained bones screws and semi-constrained bone screws, to allow for construct configuration to meet the patient’s needs.

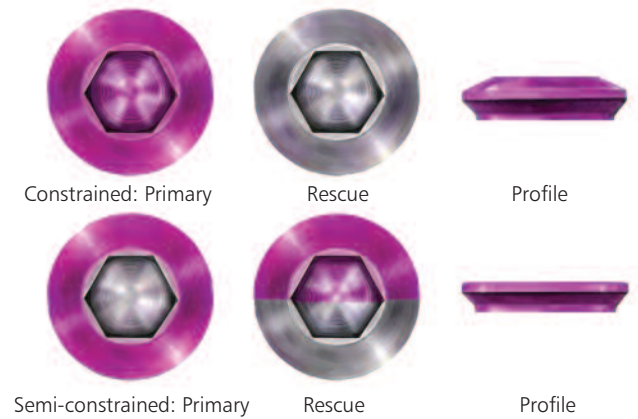


Fig.11

11. CONSTRAINED AND SEMI-CONSTRAINED BONE SCREWS

Constrained bone screws provide rigid fixation. Semi-constrained bone screws allow for screw toggle.

Primary and Rescue Bone Screws

Primary – 4.1mm diameter

Rescue – 4.5mm diameter

Rescue bone screws are used for revisions or when greater screw purchase is required.

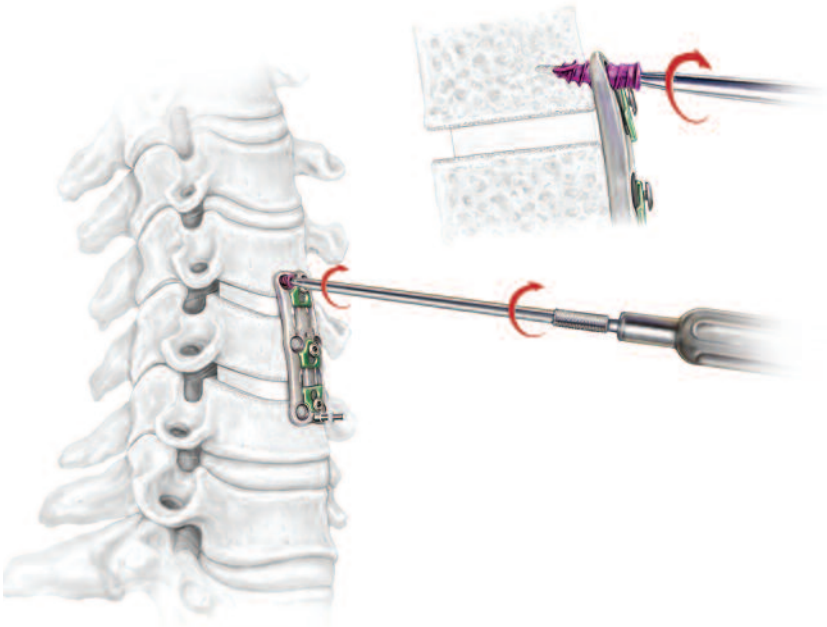


Fig. 12

12. BONE SCREW PLACEMENT

Place the bone screw driver securely into the modular handle.

The bone screw driver has an integral screw retention spring that ensures secure screw attachment to the screw driver.

Insert the appropriate length bone screw. The hex-tip on the screw driver must be completely seated into the hex-head of the bone screw during insertion to ensure proper placement.

Proper bone screw selection is dependent on bony structure and composition, surgeon preference, and intraoperative circumstances. Orthofix recommends the choice reflect optimal patient safety and minimal risk.

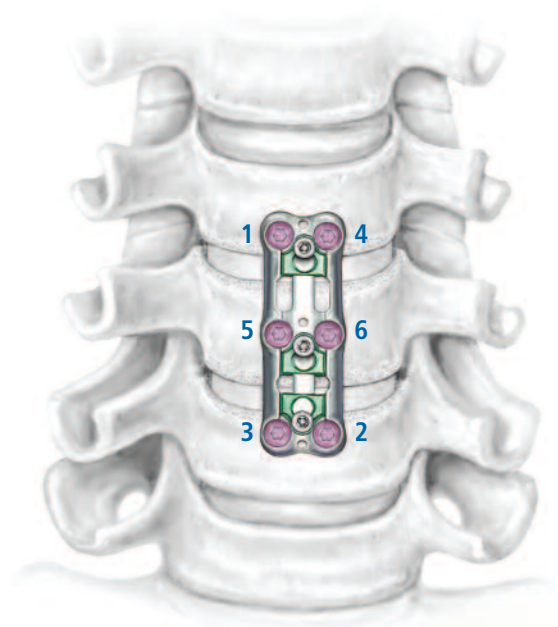


Fig. 13

13. PREFERRED METHOD OF BONE SCREW PLACEMENT

Drill, tap, and place one bone screw.

Drill, tap, and place second bone screw opposite and diagonal from the first screw position.

Remove temporary tack, if appropriate.

Drill, tap, and place bone screws in the remaining bone screw holes.

Final Tightening of Bone Screws

Final tightening of the bone screws is completed sequentially (in order of bone screw placement). Ensure that all bone screws are seated flush and within the bone screw holes.

Dr. Reichman recommends

"Tighten bone screws down 90% so plate is fairly secure. Once all bone screws are in position, final tightening of the screws can be completed. This will allow the plate to be flush with the spine after all the screws have been tightened."

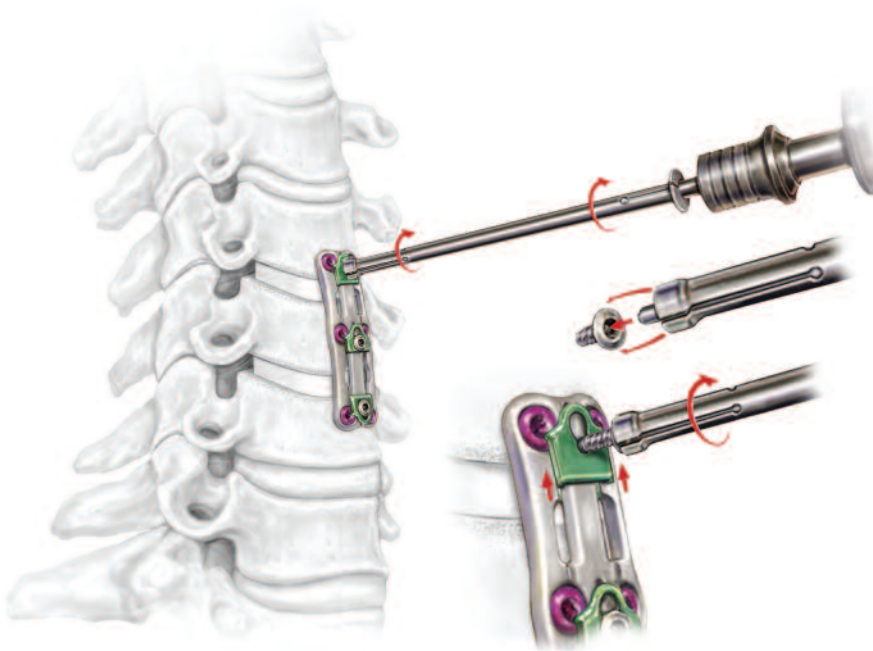


Fig. 14

14. TIGHTENING OF TOP LOCKING MECHANISM

The locking mechanism slides easily over both types of screws to prevent screw back-out.

Insert the top locking screw driver securely into the torque limiting handle.

Position the top locking plate over the bone screws making certain that the top locking screw and top locking plate are aligned to lock the system securely.

The top locking screw driver should be perpendicular to the cervical plate when tightening the top locking screw.

Turn the top locking screw driver clockwise to tighten the top locking screw and secure the top locking plate. Continue tightening the top locking screw until an audible click is heard. The click ensures that the top locking screw has been tightened to the required torque of 7 in/lbs.

If any pair of bone screw holes is not used, completely remove the top locking mechanism and top locking screw for proper plate performance.

Warning: When performing a corpectomy procedure using a Hallmark Anterior Cervical Plate, ensure that the top locking mechanisms are only used on the superior and inferior portions of the cervical plate prior to final tightening of the top locking plates to avoid potential plate performance deterioration.

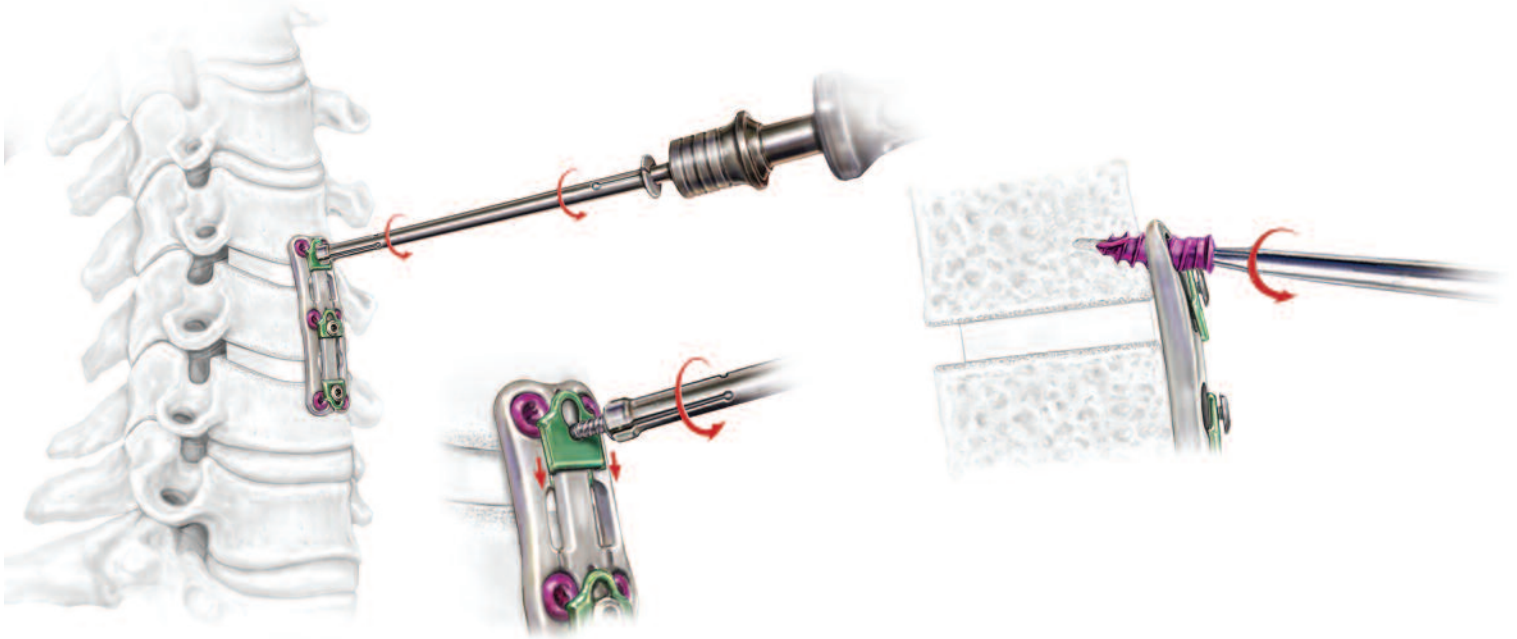


Fig. 15

Fig. 16

15. TOP LOCKING SCREW REMOVAL

To remove the top locking screw:

- Insert the top locking screw driver securely into the torque limiting handle.
- Insert the top locking screw retainer onto the top locking screw driver.
- Seat completely the top locking screw driver and top locking screw retainer in the tri-lobe of the top locking screw.
- Turn the top locking screw driver counter clockwise until the top locking screw and top locking plate can be removed.

16. BONE SCREW REMOVAL

To remove the bone screws:

- Place the bone screw driver securely into the modular handle.
- Seat completely the hex-tip on the bone screw driver into the hex-head of the bone screw.
- Turn the bone screw driver counter clockwise to remove the bone screws.

INSTRUMENTS

62-0031	Modular Drill, 10mm	60-0025	Modular Handle	62-0060	Top Locking Plate Screw Driver
62-0032	Modular Drill, 12mm	60-0050	Bone Screw Driver	62-0061	Torque Limiting Handle
62-0034	Modular Drill, 14mm	62-0010	Freehand Drill Guide	62-0062	Top Locking Screw Retainer
62-0036	Modular Drill, 16mm	62-0020	Tack Holder	62-0070	Plate Bender
62-0038	Modular Drill, 18mm	62-0033	Modular Bone Awl	62-0090	System Case
62-0044	Modular Tap, 10mm	62-0035	Sleeved Bone Awl	62-0021	Cervical Tack

1 LEVEL CERVICAL PLATES

62-6200	20mm One Level Cervical Plate Assembly, Hallmark ACPS	62-6300	30mm One Level Cervical Plate Assembly, Hallmark ACPS
62-6220	22mm One Level Cervical Plate Assembly, Hallmark ACPS	62-6320	32mm One Level Cervical Plate Assembly, Hallmark ACPS
62-6240	24mm One Level Cervical Plate Assembly, Hallmark ACPS	62-6340	34mm One Level Cervical Plate Assembly, Hallmark ACPS
62-6260	26mm One Level Cervical Plate Assembly, Hallmark ACPS	62-6360	36mm One Level Cervical Plate Assembly, Hallmark ACPS
62-6280	28mm One Level Cervical Plate Assembly, Hallmark ACPS		

2 LEVEL CERVICAL PLATES

62-6380	38mm Two Level Cervical Plate Assembly, Hallmark ACPS	62-6480	48mm Two Level Cervical Plate Assembly, Hallmark ACPS
62-6400	40mm Two Level Cervical Plate Assembly, Hallmark ACPS	62-6500	50mm Two Level Cervical Plate Assembly, Hallmark ACPS
62-6420	42mm Two Level Cervical Plate Assembly, Hallmark ACPS	62-6520	52mm Two Level Cervical Plate Assembly, Hallmark ACPS
62-6440	44mm Two Level Cervical Plate Assembly, Hallmark ACPS	62-6540	54mm Two Level Cervical Plate Assembly, Hallmark ACPS
62-6460	46mm Two Level Cervical Plate Assembly, Hallmark ACPS		

3 LEVEL CERVICAL PLATES

62-6543	54mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6680	68mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6560	56mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6700	70mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6580	58mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6740	74mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6600	60mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6780	78mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6620	62mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6820	82mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6640	64mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6860	86mm Three Level Cervical Plate Assembly, Hallmark ACPS
62-6660	66mm Three Level Cervical Plate Assembly, Hallmark ACPS	62-6900	90mm Three Level Cervical Plate Assembly, Hallmark ACPS

SELF-DRILLING/SELF-TAPPING CONSTRAINED PRIMARY BONE SCREWS

62-1100	4.1mm x 10mm	62-1140	4.1mm x 14mm	62-1180	4.1mm x 18mm
62-1120	4.1mm x 12mm	62-1160	4.1mm x 16mm		

SELF-DRILLING/SELF-TAPPING CONSTRAINED RESCUE BONE SCREWS

62-2100	4.5mm x 10mm	62-2140	4.5mm x 14mm	62-2180	4.5mm x 18mm
62-2120	4.5mm x 12mm	62-2160	4.5mm x 16mm		

SELF-DRILLING/SELF-TAPPING SEMI-CONSTRAINED PRIMARY BONE SCREWS

62-3100	4.1mm x 10mm	62-3140	4.1mm x 14mm	62-3180	4.1mm x 18mm
62-3120	4.1mm x 12mm	62-3160	4.1mm x 16mm		

SELF-DRILLING/SELF-TAPPING SEMI-CONSTRAINED RESCUE BONE SCREWS

62-4100	4.5mm x 10mm	62-4140	4.5mm x 14mm	62-4180	4.5mm x 18mm
62-4120	4.5mm x 12mm	62-4160	4.5mm x 16mm		

INSTRUMENTATION

62-3000	Top Locking Screw	62-3010	Top Locking Screw, Short
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Description: The Hallmark Anterior Cervical Plate System consists of an assortment of implantable titanium alloy plates, and bone screws, that are provided nonsterile.

Indications: The Hallmark Anterior Cervical Plate System is a temporary implant, intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

- a) degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies)
- b) spondylolisthesis
- c) fracture
- d) spinal stenosis
- e) deformities (i.e. scoliosis, kyphosis, and/or lordosis)
- f) tumor
- g) pseudoarthrosis
- h) revision of previous surgery

Contraindications: The Hallmark Anterior Cervical Plate System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- 1) Early or late loosening of any or all of the components
- 2) Disassembly, bending, and/or breakage of any or all of the components
- 3) Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or autoimmune disease.
- 4) Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- 5) Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- 6) Infection
- 7) Vertebral body fracture at, above, or below the level of surgery
- 8) Loss of neurological function, including paralysis (complete or incomplete)
- 9) Non-union, delayed union
- 10) Pain, discomfort, or abnormal sensations due to the presence of the device
- 11) Hemorrhage
- 12) Cessation of any potential growth of the operated portion of the spine
- 13) Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:

- 1) Single use only
- 2) The Hallmark Anterior Cervical Plate System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine
- 3) Nonsterile; the plates, bone screws and instruments are sold nonsterile, and therefore, must be sterilized before each use
- 4) Always orient the plate along the midline of the spine
- 5) When performing a corpectomy procedure using a Hallmark Anterior Cervical Plate, ensure that the top locking mechanisms are only used on the superior and inferior portions of the cervical plate prior to final tightening the top locking plates to avoid potential plate performance deterioration.
- 6) To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated
- 7) To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used
- 8) Excessive torque applied to the screws when seating the plate may strip the threads in the bone
- 9) Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
- 10) Do not reuse implants; discard used, damaged, or otherwise suspect implants
- 11) Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not re-sterilize single-use implants that come in contact with body fluids.

Instructions for Use: See actual package insert for Instructions for Use.

 Orthofix Inc.
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Lewisville, Texas 75056 U.S.A.

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

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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