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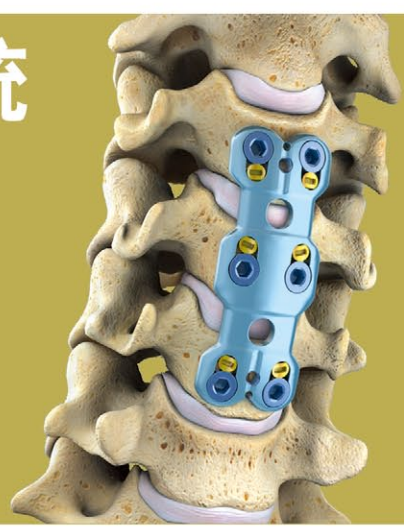
Surgical technique
操作手册

颈椎前路板系统
ACI System



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WASTON 华森医疗 操作手册 Surgical Guide

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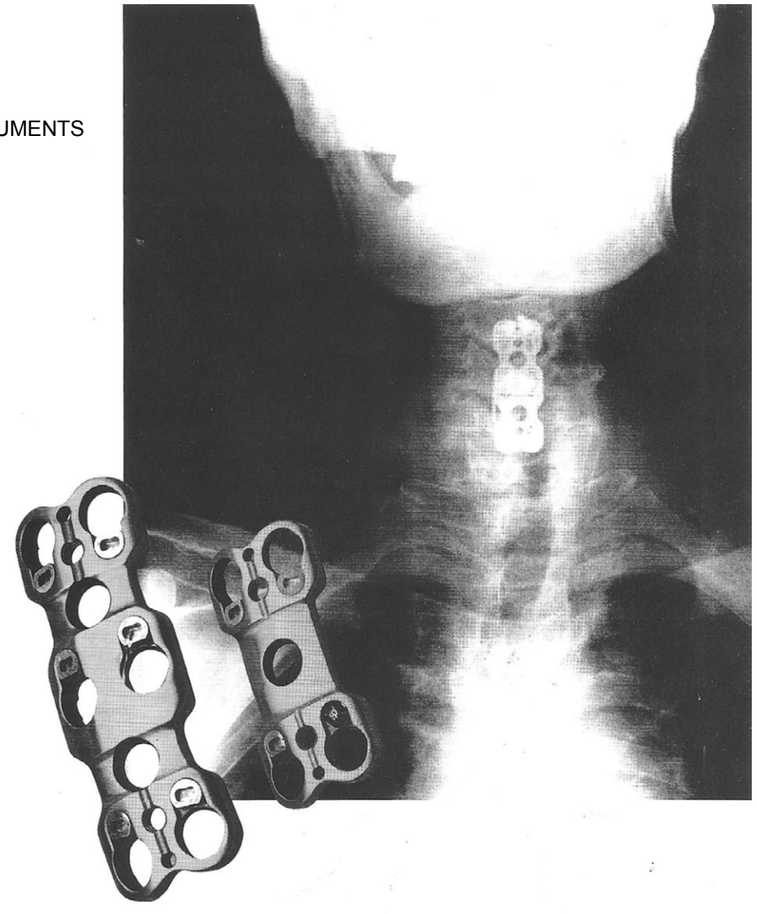
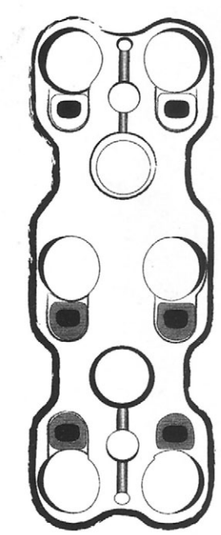


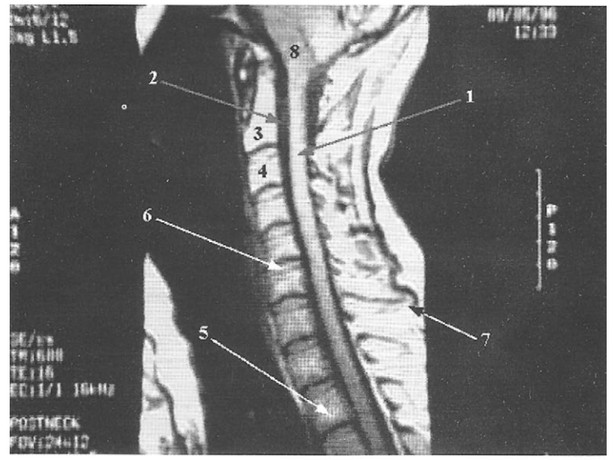
ACI 颈前路板是一种半限制（半坚强）固定系统，提供医生术中螺钉的多向选择，能达到与病人颈椎解剖的最佳匹配。“应力分担”设计理念，例纵向承载力导到植骨块，而不是由螺帽钉和板来完全承担。

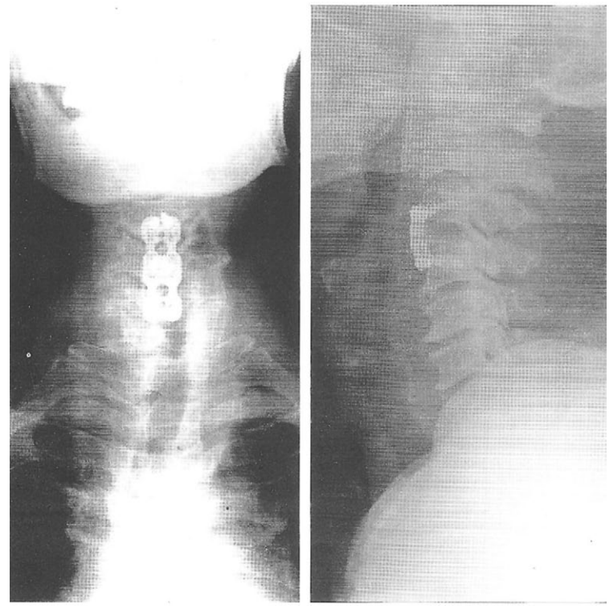
The ACI Anterior Cervical Plate is a semi-constrained (semi-rigid) system designed to offer the surgeon the possibiliry to choose intra-operatively the screw trajictory that beat fits the individual patient anatomy presented. The ‘load sharing’ design concept accommodates the safe transfer of axial load to the bone graft without putting strain on either the screws or the plate as can occur in more constrained (rigid) systems.



颈椎板的厚度是防止病人吞咽困难的重要考虑因素，切迹为 2.1mm 的 ACI 颈前路板是目前市场上最低切迹的产品之一。

Plate thickness is an important consideration in protecting the patient against risk of dysphagia. With a profile of 2.1mm, ACI is one of the lowest profile anterior cervical plates currently available today.



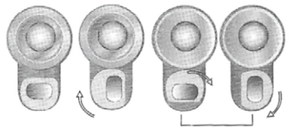


1．独特的凸轮锁定机制

Variable angle smei-rigid fixation system

ACI 独特的凸轮装置，确保每个拧入的螺钉都能可靠地固定钛板而不发生退钉。同时，该锁定装置采用预装设计，不干扰螺钉的拧入，也不增加钛板的厚度。

Design elements, such as the ACI Cam-lock mechanism, ensure that all implants screws hold the plate securely in place and are prevented from backing out. The cams do not interfere with screw placement and do not add to the profile of the plate.

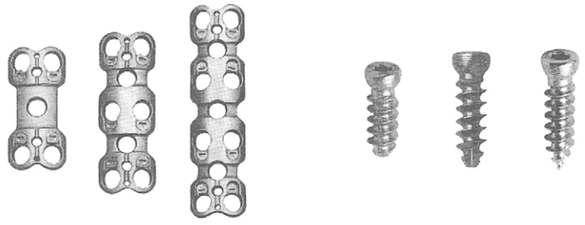


2．丰富的螺钉及板规格

Numerous screw and plate type for surgeon convenience

ACI 系统有 25 个规格的长度的钛板包括单节段板，双节段板和三节段板，螺钉有自攻和自钻 2 种类型，每种类型都有多种长度供医生手术时选择经。

The ACI system includes 25 types plates-one level, two level and three level plates. Self-drilling and Self-tapping screws both and included in multiple lengths. Every implant option is at the surgeon's fingertips during the procedure.

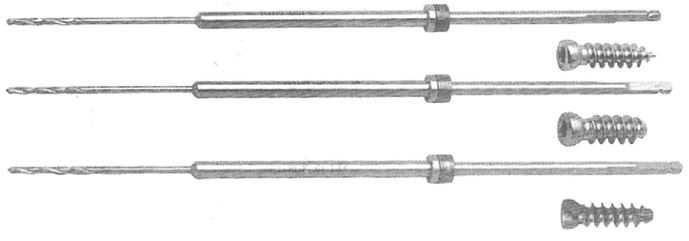


3．全新设计地操作工具

Compact and user-friendly instrumentation

ACI 工具经过优化设计，不仅单件器械符合人体工程学设计理念，而且每件工具都满足与整套系统相匹配的设计特点。比如 ACI 钻头工具颜色涂层与螺钉颜色涂层相匹配，整套工具操作简单方便。

In optimized designed instrumentation of ACI, Every element is not only designed with ergonomics ideology, but also designed to work in concert with the whole system. For example, color coding of he drill match the screws color. All the instruments make the procedures more simple and conveniences.



4．优化的形态设计

Optimized by size

钛板厚度 2.1mm，宽 16mm，外缘平滑设计，符合正常生理弧度。

The ACI plates have 2.1mm profile and 16mm width. The plates has contoured shape edges. The pre-curved design makes the cervical reconstruction as the normal curve.

5．背面防滑齿设计

Anti Skid Cleats

有效防止钛板安装过程中地滑动，同时不增加板地切迹。

Resists plate movement during the holes preparation and screws insertion. The Character adds zero profile to overall construct-cleats “dig in”

手术操作技术
SURGICAL TECHNIQUE

ACI 颈前路钛板固定系统介绍
INTRODUCTION

ACI 是一种半限制型钛板，适用于颈前路椎体间固定。它综合了目前临床所证实的各种设计，符合目前的市场需求。

The ACI Plate is semi-rigid system intenede for anterior cervical intervertebral body fixation. ACI is based on a comprehensive, clinically proven design, modified to incorporate current market technology.

适应症
INDICATIONS

ACI 系统最大限度的提供了植入物的多样性和器械的完整性，通过单皮质螺钉将钛板固定于颈椎体前面专用于 C2–C7 的前路稳定性治疗。包括以下病症：

The ACI System offers maximum implant versatility & integrated instrumentation. The ACI Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bobies. Specific clinical indications for anterior cervical plating include:

- 创伤
  Instability caused by trauma;
- 颈椎畸形矫正
  Instability associated with correction of cervical lordosis and kyphosis deformity;
- 先前颈椎手术融合失败，出现假关节
  Instability associated with pseudoarthosis as a result of previously failed cervical spine surgery;
- 颈椎椎体肿瘤切除术后固定
  Instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- 单节段或多节段的颈椎渐进性退变
  Instability associated with single or multiple level corpectomy in advanced degenerative disc dis ease, spinal canal stenosis and cervical myelopathy.

注意：本手册说的手术方法，只是许多方法中的一种，医生可以按照自己所熟悉的手术方法手术。

Note: The described technique presents only one of many approaches to the stabilization of the anterior cervical spine. The surgeon is encouraged to utilize the ACI Anterior Cervical Plating System with those techniques most familiar to the operating surgeon.

第一步：病人体位及入路
STEP 1: PATIENT POSITIONING AND APPROACH

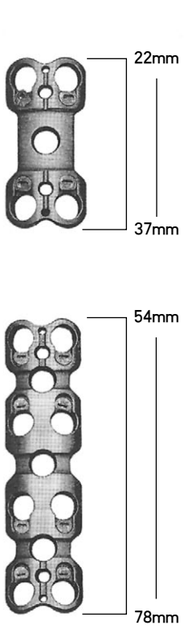
病人采用仰卧位，头颈轻微自然向后牵引。垫起颈后部，以确定和保持正常的颈的生理弯曲。可选择右侧或左侧入路。暴露出颈椎后，暴露出颈椎后，使用自动拉钩来获得最佳手术视野。还可以使用椎体器 15032–004 将撑开器的辅助撑开杆 15032–003 置于手术节段相邻的上、下椎体的中线上，在撑开杆上安装撑开器，适度用力撑开椎体。切除椎间盘，并根据需要进行必要的椎体切除，可用髓核钳、刮匙和咬骨钳等工具清理椎间盘和软骨组织直到暴露后纵韧带。根据需要选择使用植骨块或钛笼（Diamesh）进行椎体间融合。

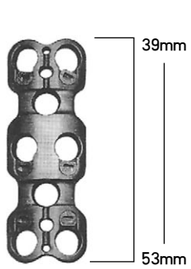
The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis. The surgeon must then choose a right-or left-sided approach to the cervical column After exposing the cervical spine, the self retaining retractor is placed to provide optimal visualization. Avertebral body distractor (15032-004) may be used. The distraction shafts (15032-003) are positioned midine in the vertebral bodies adjacent to the level to be treated. The distractor is placed over the shafts and the appropriate amount of distraction is applied. Discectomy are completed. Median corpectomy will be completed if required. Pituitary forceps, curettes, and kerissons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament.
Bone graft/substitute (Diamesh,e.g.) is then positioned between both vertebrae.

第二步 ：选择合适的钛板
STEP 2: CHOOSING PLATE SIZE

在椎体椎间处理结束并适当植骨后，用 (15032–005) 夹持 ACI 钛板，与椎体比较选择合适长度的板，放于椎体前面，ACI 颈前路板有 1–3 个节段的规格，长度从 22–78mm，持板时当不要刮伤表面，最佳长度的板为：跨过所需融合的全部节段，尽可能选取最短钛板，可以避免涉及到相邻的椎间隙。选板时用透视机观察帮助确定。

ACI Anterior Cervical Plates are available in 1-5level configuration with a length ranging from 22-78mm. When handling plates, use caution to avoid scratching or notching the plate surface. Following anterior bone graft placement, use the forceps (15032-005) to select the appropriate plate size and place it on the vertebral column. Confirm that the length is appropriate. The plate should span the entire fusion segment, preferably, using the shortest plate possible, therefore avoiding the adjacent disc space. Fluoroscopy may be utilized to optimize plate selection and screw placement.

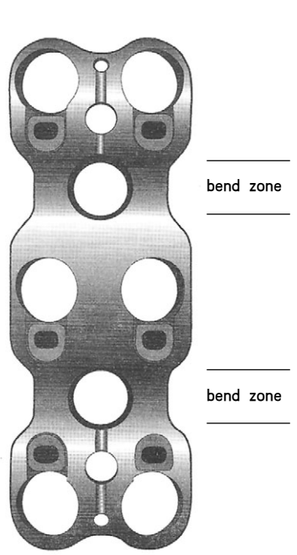




第三步：调节钛板的曲度
STEP 3: ADJUSTING PLATE CURVATURE

ACI 颈前路板出厂时已经作了前曲的预弯，符合大多数患者的解剖，如果需要，可用弯板器 (15032–013) 作钛板矢状面曲度的优化，以达到最大的板 – 骨接触面积。ACI 板有专门的折板区，该处的钛板窄而薄，易弯而不伤及螺钉锁定装置。

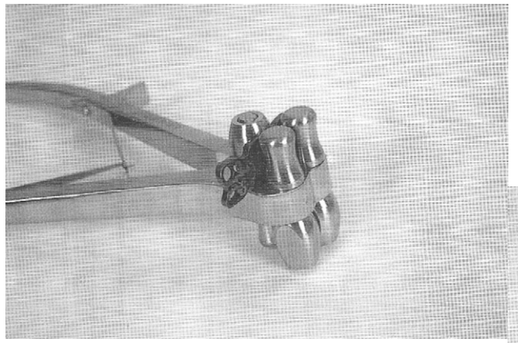
The ACI Plate has a precontoured lordotic curvature (13” Radius), anatomically appropriate in the majority of procedures. If desired, the Plate Bender (15032-013) may be utilized to optimally contour the sagittal plane to ensure maximum bone / plate interface. It is critical to bend the plate in the specified BEND ZONE(S), Which has a smooth undersurface and reduced cross-sectional thickness.



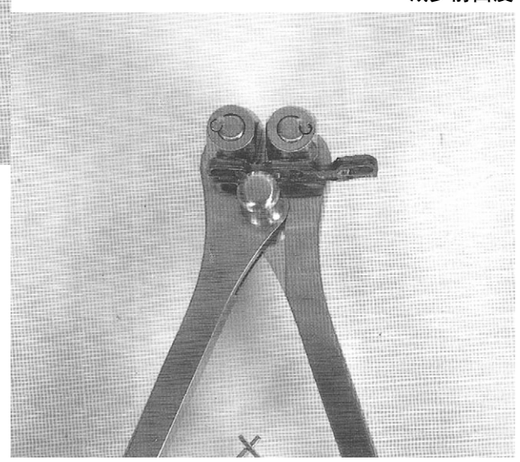
当需要加大前曲度时，将钛板的弯板区放在弯板器的弯板柱的中间，并正对着弯板器下方弯板柱中央，防滑齿面向下方。弯板要均匀分布在每个弯板区。如果要使板调直一点，要用弯板器的反面来折板，防滑齿面向上方。
弯板会使钛板的强度减弱，没有必要请不要弯板绝不可反复折板、一次过大折板。在向一面折板后，禁止再向另一面直接折板。

For additional lordosis, the desired plate BEND ZONE is placed between the lobes (cleats facing downward) of the Plate Bender. The BEND ZONE must be centrally located on the lower lobe of the plate Bender. Plate bending should be evenly distributed at the BEND ZONE along the length of the plate. For straightening of kyphotic bending. the opposite side of the Plate Bender is used. The BEND ZONE is placed between the lobes of the bender (cleats facing upward). Contouring titanium plates can weaken and compromise the mechanical integrity of the device. The fatigue life of the contoured implant in vivo cannot be precisely predicted. Do not bend the plates repeatedly, excessively, or any more than absolutely necessary. Once the sagittal contour has been altered by the Plate Bender, do not bend in the reverse direction.

加大前曲度



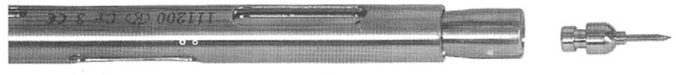
减少前曲度



第四步：放装临时固定针
STEP 4: PLACING TEMPORARY FIXATION PINS

选好合适的钛板后，用临时固定针 (15032–019) 固定于颈椎前面，保持手术钻孔和拧螺钉时的稳定。

After selecting the appropriate plate, use the Temporary Fixation Pins (15032-019)(TEPS) to hold the plate in plate in place while drilling and placing the screws.



用持板器抓持钛板并放于颈椎正前方，然后用多功能把持器 (15032–006) 将临时固定针通过针孔固定钛板。

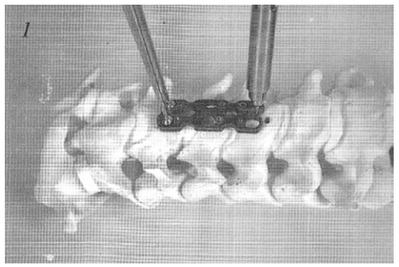
Using one of the plate holders mentioned in step 4, hold and lay the plate evenly on the anterior cervical spine. Place the Temporary Fixation Pin through the pinhole on the plate using the Temporary Fixation Pin Holder (15032-006).

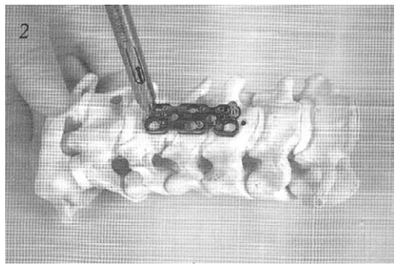
注意：临时固定针固定时不需要先用钻头钻孔。

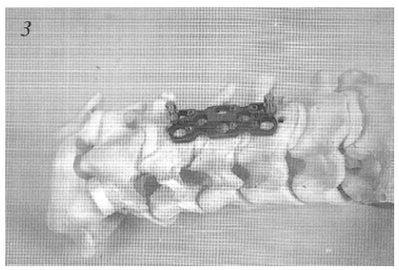
Note: Pre-drilling is not required for Temporary Fixation Pin insertion

固定好两枚临时固定针后，用透视机观察螺钉固定的位置和方向，以达到最佳效果。如果钛板固定位置不佳，可作调整，调整后应再透视检查。必要时，清除软组织和骨赘，可以使接骨板与骨面吻合。

After placing the two TFPs, fluoroscopy can be used to confirm optimal screw placement and trajectory. Any necessary adjustments may be done at this time and reconfirmed with fluoroscopy. Removing soft tissue and large osteophytes may improve bone-plate interface.



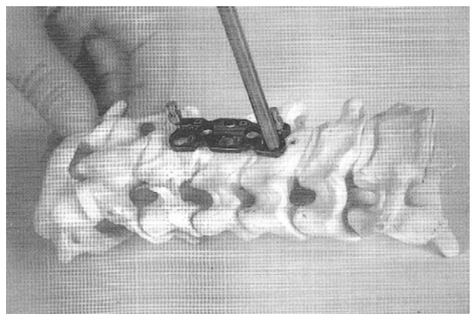




第五步：螺钉孔的准备
STEP5: PREPARING SCREW HOLE

钻孔前，可以用开口器（15032–001）准备螺钉孔道路将开口器头部对准螺钉孔，沿想要固定螺钉的角度用力挤压手柄，开口器将扎入到骨面。开口器手柄上有敲击平台，如果需要，可能轻轻锤击打人。

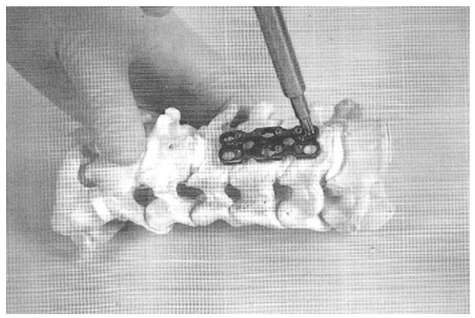
Before drilling ou may need to prepare your screw hole with an awl. To use the Ceres Awl, place the tip of the awl (15032-001)shaft against the screw hole on the plate and press it in the direction of the screw angle desired(Figure5a). The awl will protrude into the desired hole. The awl also has a striking plate on the handle should you need to strike it.



第六步：钻孔
STEP6: DRILLING HOLES

根据手术需要，选择固定螺钉（钻孔）的角度钻孔时要保持钛板稳定。持板钻孔导向器可扩张头部贴住需钻孔的螺钉孔处，顺时针持板导向器（15032–107）的尾端手轮 .

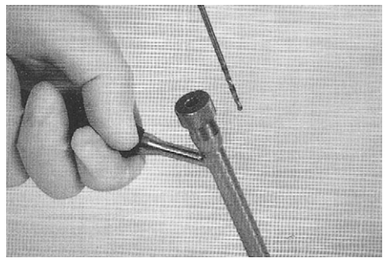
Screw angle may be selected and the plate stabilized during the drilling procedure. The Plate Holder / Drill Guide(15032-107) may be attached to the plate by placing the expandable end into a lateral screw hole and turnin the knurled knob clockwise.

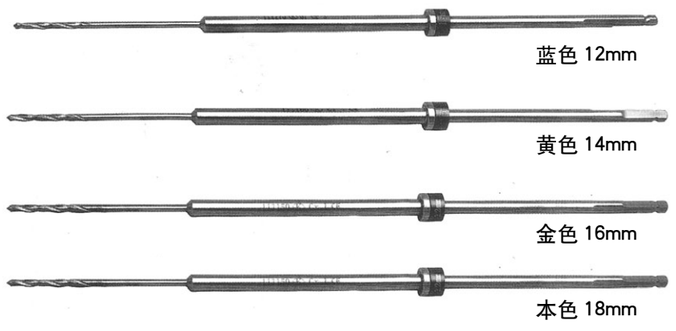


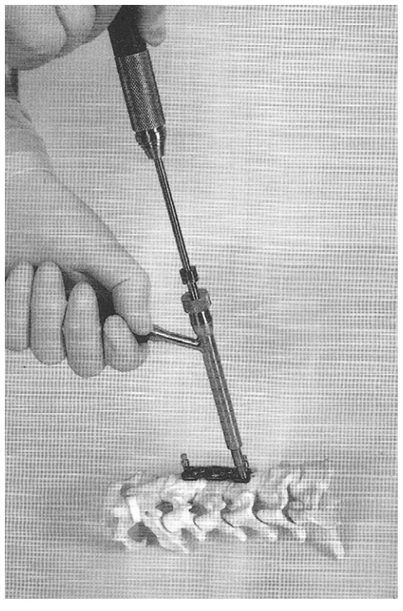
第七步：选择钻头
STEP 7: SELECTING AND USING DRILL BITS

ACI 颈椎板提供了螺钉旋转角度的多样性，以适应不同病人的解剖情况。某些角度可能朝向血管，所以在使用时要用透视机对外头的深度和角度进行检查，确保螺钉在安全的范围内。典型的螺钉固定：螺钉向内 5-10°，上部螺钉向头侧 7.5°，以避免伤及上下椎间盘。打入的螺钉不能大于 16°，会影响锁定装置的正常锁定。钻孔的深度与所固定的椎体大小相适应，要考虑到骨的大小，骨的密度，及不同的病类等因素。ACI 系统提供四种钻头，12mm（蓝色），14mm（金色），本色 18mm 和 16mm（玫瑰色），对应四种长度螺钉。

The ACI Anterior Cervical Plate System offers the ability to select various angles of screw placement to conform to individual platient anatomy. Certain angles maydirect the screws at vulnerable vascular and neural tissues. Use fluoroscopy to confirm drill bit penetration depth and angular orientation to assure that those strucures are not at risk. Depth of screw insertion and angular orientation of the acrew must also be confirmed by fluoroscopy. Typical screw placement is 5-10degrees medial angulation with the screw directed 7.5 degrees rostral & caudal to correspond with the superior and inferior disc space respectively. Avoid severe angulation of the superior screw (greater than 16 degrees) which may prevent optimal locking of the screw with th cam. The drill length should correspond to the depth of the bone purchase required,taking into consideration the size of the vertebra, the quality of the bone,diagnosis,etc. The ACI system is available with 12mm (blue), 14mm (gold), 18mm (white) and 16mm (rose) fixed length drill bits.These colors correspond to their respective screw size colors.







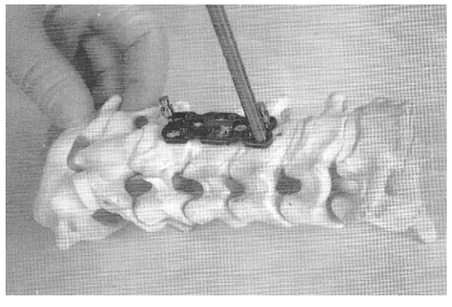
第八步：使用丝攻
SETP8: USING THE TAP

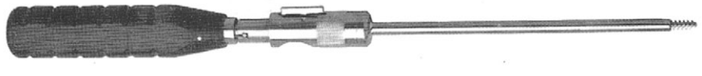
ACI 系统提供了自攻螺钉，所以不是所有螺钉孔都需要攻丝，在需要使用时，丝攻 (15032–012) 可调节与螺钉相应的深度丝攻头部可从软组织套筒中伸出，长度通过该套筒上的增粗部分来调节，并在其两个边的窗口上读取与伸出长度相对应的刻度。调节好所需的长度后，将套筒上的固定卡片固定丝攻长度。

The ACI System is provided with self-tapping screws. Hence, tapping is not always necessary. However, if tapping is required to prepate the passage of the screw, the Variable Depth Tap (15032-012) can be adjusted in 1mm increments to correspond to the drill depth setting. The length of the Tapthat will extend beyond the sofe tissue protection sleeve is set by turning the cylinder gauge mounted near the handle of the Tap in either direction. Please ensure that the release button is locked n place a the desired measure before using the Variable Dariable Depth Tap.

注意：可调丝攻可通过测量术前 X 线片（CT 或 MRI）来估算所需深度，也可以在术中测量暴露出的终板。使用透视检查，钻孔和丝攻会更精确。

Note: The setting for the Variable Depth Tap can be approximated by preoperative radiographic measurements (CT or MRI) or by interoperative measurement of the exposed vertebral endplates following decompression. The use of interoperative fluoroscopy while drilling and tapping, will further improve the accuracy of screw length selectin.





第九步：拧入螺钉
STEP9: INSERTIONG SCREWS

ACI 的螺钉有长度为 12–16mm，有自攻螺钉（直径 4.5mm），还有 4.8mm 直径的翻修螺钉，为了便于区分，不同长度的螺钉用不同的颜色区分。

The ACI screws are available as self-drilling (4.5mm major diameter)in lengths ranging from 12-16mm or self-tapping (4.5mm major diameter). Large-diameter screws (4.8mm major diameter) are available in 12, 14, and 16mm lengths. For identification prposes the screws are color coded for screw type.

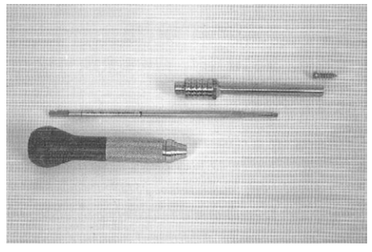
- 12mm 螺钉为蓝色
  12mm screws are blue colored;
- 14mm 螺钉为金色
  14mm serews are gold colored;
- 16mm 螺钉为玫瑰色
  16mm screws are rose colored.

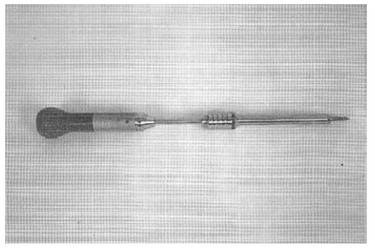
选取与外头相应长度的螺钉，用六角螺丝刀 15032–014 和螺钉（不要偏码）相配合从螺钉盒中取同螺钉。通过钛板的螺钉孔拧入螺钉，打第一个孔后，根据需要攻丝，拧入第一枚螺钉，但不要过紧，以便调整。

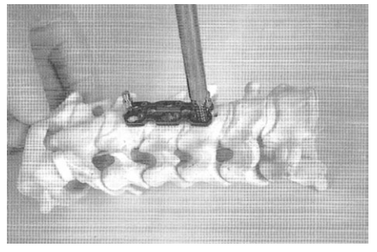
在证实钛板位置良好后，再将余下的螺钉孔 – 钻孔（必要时攻丝），拧入螺钉，最先拧入的是与第一枚螺钉呈对角的螺钉孔。

取出临时固定孔，按拧入的顺序最终拧紧螺钉。

Select the appropriate screw length corresponding to the hole drilled.Using the Hex Driver(15032-014),pick p the screw from the tray and disert it through the plate.Drill the first hole,tap if desired,and plae screw without tightening completely.
After confirming proper plate psitioning,drill,tap if desired and place screw in all remaining screw holes.Begin with the lateral hole that is opposite and diagonal to the first prepared hole.
Remove Temporary Fixation Pins and perform final tightening of all screws in the same sequence as mentioned above.







第十步：锁紧凸轮
STEP10: LOCKING THE CAMS

钛板固定的最后一步，是锁住钛板上的每一个螺钉，在锁紧凸轮前先确定所有螺钉都与预想的螺钉固定位置相符。螺钉锁紧时，凸轮锁紧器固定夹片起子 (15032–017) 头要完全垂直安放到凸轮的顶槽中，带动锁紧装置，要保证这个锁紧过程中锁紧器与凸轮顶面都相垂直，为了使锁紧器更好与凸轮有良好的对位对线关系，需要暂时增大暴露范围。

Locking all screws within the plate is the last step in the plating procedure. All screws should be secured to the vertebral bodies as previously described before beginning the cam locking procedure. To lock the screw, engage the CAM-LOC necgabusn (15032-017) by fully seating the Cam Tightener straigtht into the slot of the cam.It is important to maintain a relativel perpendicular orientation of the Cam Tightener to the cam solt during the entire locking procedure.Additional exposure may be temporarily reuired to properly align the Cam Tightener with the cam.

顺时针旋转凸轮锁紧器，当凸轮接触到螺钉尾时，会感受到一定的阻力，确定不要旋转超过 270°，对线不良将导致凸轮顶槽地磨损滑口。

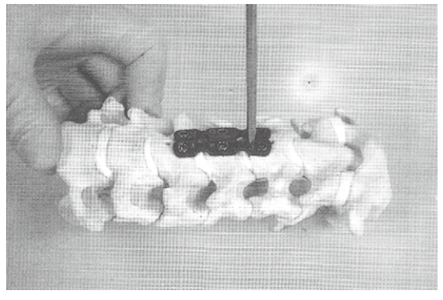
Rotate the Cam Tightener cockwise, resistance will be felt as the cam contacts the head of the screw. Ensure you do not rotate cam beyund 270 degrees (vertical slot). Failure to maintain proper alignment of the Cam Tightener my result in a stripped cam.Figure9b

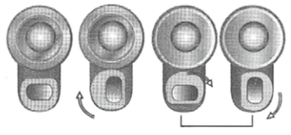
当螺钉与板成角超过 16° 时，凸轮会碰不到螺钉尾，在这种情况下，凸轮应放在锁定区域以提供一定的阻力防止螺钉退出。

For rostral and caudal screw trajectories more than 16degrees,the cam may not interfere with the screw hand and therefore the torque limiter will not release.In this case,the cam should be positioned within the locking zone to provied screw backout resistance.

注意：凸轮安放的准确位置，是根据许多因素决定的，在锁定区域可放在不同的角度，但严禁超过 270° 。

Note:Exact position of a locked cam is dependent on a number of factors and may vary within the typical locking zone.Do not turn cam past 270° .

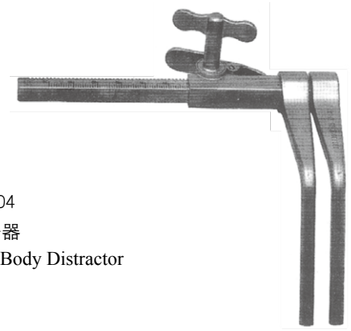




工具
INSTRUMENTS

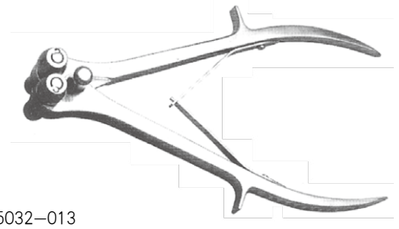
15032–001
开口器
Awl

15032–005
镊状持板器
Forceps Plate Holder

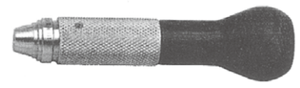


15032–004
颈椎撑开器
Vertebral Body Distractor

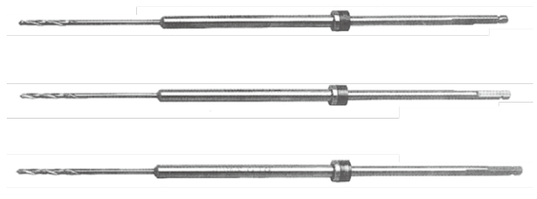
15032–107
钻孔导向器 / 持板器
Plate Holder / Drill Guide



15032–013
弯板器
Plate Bender



15032–011
快换手柄
Quick Couple Handle For use with Fixed and Variable Depth Drills



15032–010 钻头，12 毫米
12mm fixed depth drill assembly

15032–009 钻头，14 毫米
14mm fixed depth drill assembly

15032–008 钻头，16 毫米
16mm fixed depth drill assembly

工具
INSTRUMENTS

15032–012
可调深度丝攻
Variable Depth Tap

15032–006
定位钉植入器
Temporary Fixation Pin
Inserter / Removal Device

15032–003
撑开杆
Distraction shaft

15032–019
定位针
Temporary Fixation Pin

15032–016
六角螺钉拧入杆
Hex Driver

15032–014
固定六角螺钉起子
Screw Driver (Hex) & Screw Holding Guide

15032–017
压片起子杆
Cam Tightener Shaft

15032–015
固定压片起子
Screw Driver

15032–002
撑钉起子
Screw Driver

15032–007
钳式持板／钻孔导向器
Plate Holding & Guide for Drilling

产品信息
PRODUCT ORDERING INFORMATION

工具 INSTRUMENTS

器械编号 Product No.	器械名称	Product Name	数量 Qty
15032–001	开路锥	Awl	1
15032–002	撑钉起子	Screw Driver	1
15032–003	撑开钉	Position Pin	2
15032–004	撑开器	Distractor	1
15032–005	持板镊	Plate Holding Clamp	1
15032–006	定位钉植入器	Position Pin Holder	1
15032–007	钳式持板／钻孔导向器	Plate Holding & Guide for Drilling	1
15032–008	限位钻头 (I)	Drill Bit & Slide Limited Device (I)	1
15032–009	限位钻头 (II)	Drill Bit & Stide Limited Device (II)	1
15032–010	限位钻头 (III)	Drill Bit & Stide Limited Device (III)	1
15032–011	快换手柄	Quick Coupling Handle	2
15032–012	丝锥	Tap	1
15032–013	弯板钳	Bending Pliers	1
15032–014	六角起子 & 持钉套	Screw Driver (Hex) & Screw Holding Guide	1
15032–015	压片起子	Screw Driver	2
15032–000	器械盒	Instrument Case	1

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