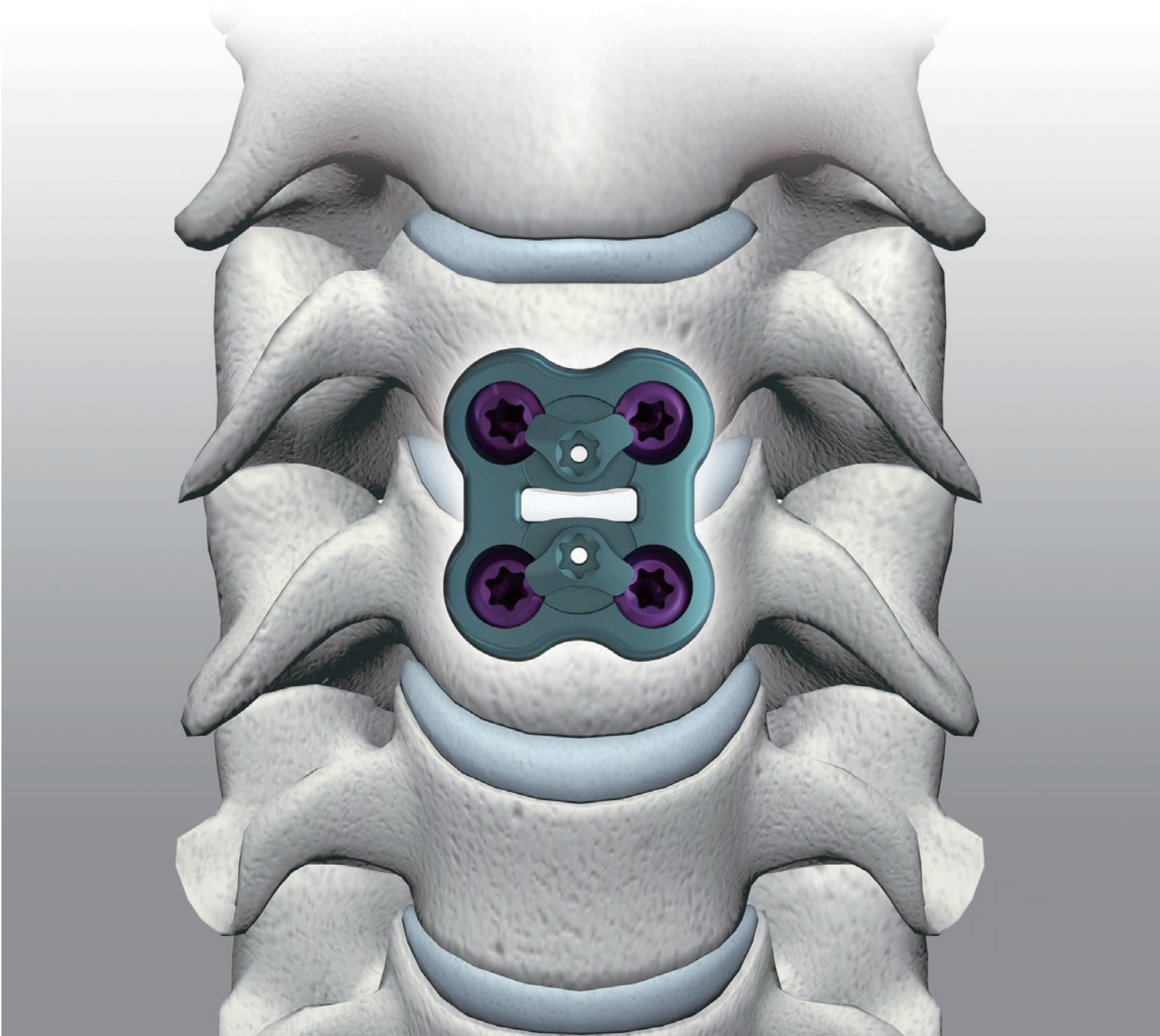
SOLCO.

4CIS® PINEHURST ANTERIOR CERVICAL PLATE SYSTEM

Surgical Technique



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4CIS® PINEHURST ANTERIOR CERVICAL PLATE SYSTEM

Surgical Technique

SYSTEM OVERVIEW

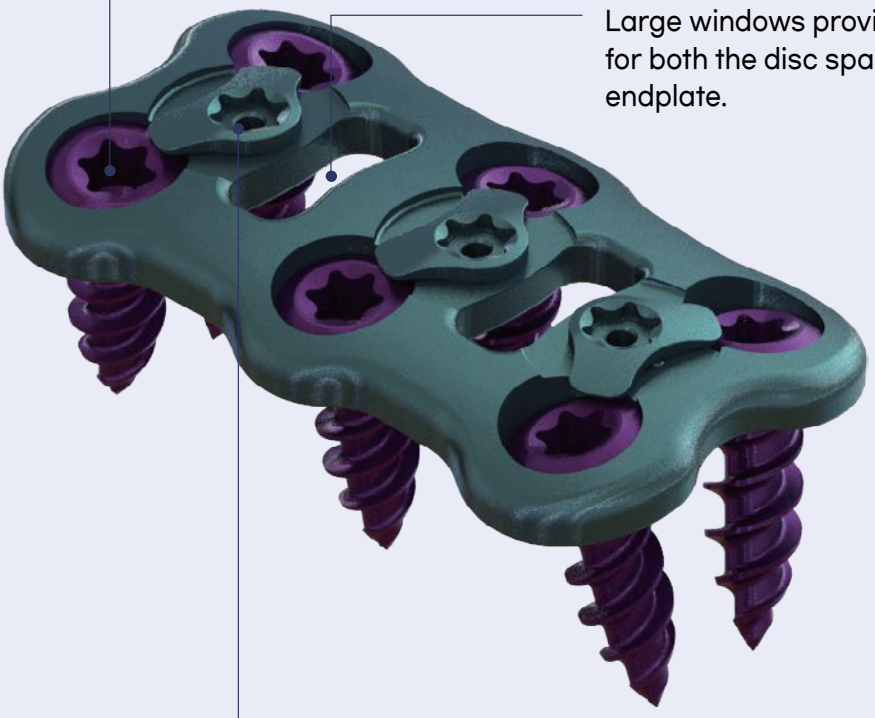
Introduction

The 4CIS® Pinehurst Anterior Cervical Plate system is intended for anterior cervical intervertebral body screw fixation from C2 to T1. Rigid fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.
Implant components consist of a variety of shapes and sizes of plates, bone screws and associated instruments. Locking caps are pre-assembled to the plates. They cover the heads of the bone screws to reduce the potential for screw back-out.
With this locking mechanism, implant components can be rigidly locked into many different configurations to suit the individual pathology and anatomical conditions of the mature patient.
They are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136.
Implants must not be used with the components from any other system or manufacturer in a construct.

Indication

The 4CIS® Pinehurst Anterior Cervical Plate system is intended for anterior interbody screw fixation from C2 to T1.
The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with:

1) Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2) Spondylolisthesis
3) Trauma (including fractures),
4) Spinal Stenosis
5) Tumors
6) Deformity (defined as kyphosis, lordosis, or scoliosis),
7) Pseudarthrosis, and/or 8) failed previous fusions.



The 4CIS® Pinehurst Anterior Cervical Plate system is an innovative cervical plate solution.
It offers direct visualization of implant placement and screw locking.
With its generous graft window, low profile, simple locking mechanism, narrow waist and aggressive self-drilling screws, This system provides a complete solution in one user-friendly implant.

OPERATIVE TECHNIQUE

STEP 1 : Site Preparation

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis.
A standard incision is used to access the cervical spine, and the longis colli muscles are elevated with medial/lateral retractor blades.
Cranial/caudal retractor blades may also be used.

STEP 2 : Plate Size Selection

The Pinehurst Anterior Cervical Plates from 1 to 5 levels ranging from 8 to 91mm (Hole-to-Hole).
Measurements are taken from the center hole of the cephalad level to the center hole of the caudad level.

- Using the plate holder, position the appropriate plate on the vertebral column to confirm its suitability (Figure 3). When the plate is properly sized and positioned, the superior screw holes should align with the inferior of the superior vertebral body.
  The inferior screw holes should align with the superior of the inferior vertebral body.

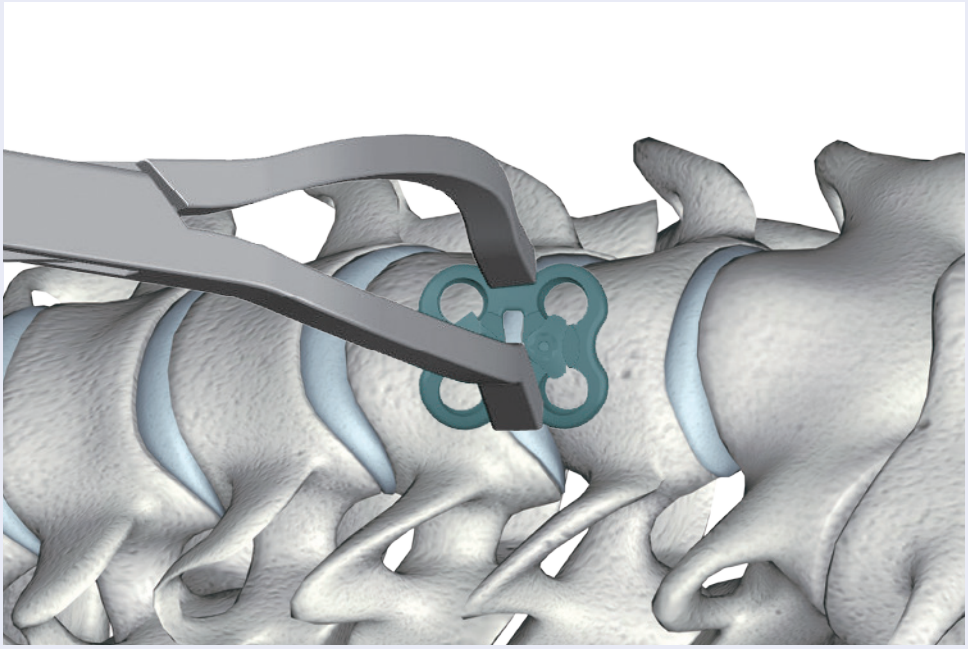


Figure 1

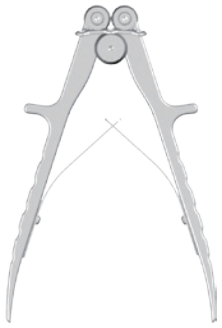
STEP 3 : Plate Contouring

The Pinehurst Anterior Cervical Plates are pre-bent When additional contouring is reguired, insert the plate into the plate bender (Figure 2, 3) and squeeze the handles.

- The Pinehurst Anterior Cervical Plate is provided with CAP LOC mechanism should be bent across the bend zones (Figure 4).
- Plates should be bent in one direction, kyphosis or lordosis only.

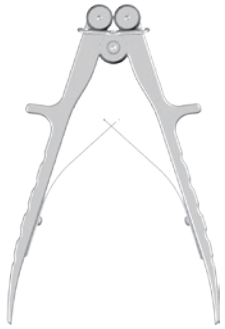
Never reverse the bend as this may create micro fractures that will weaken the plate.

- Short plates of each level do not have bend zones and therefore cannot be bent.



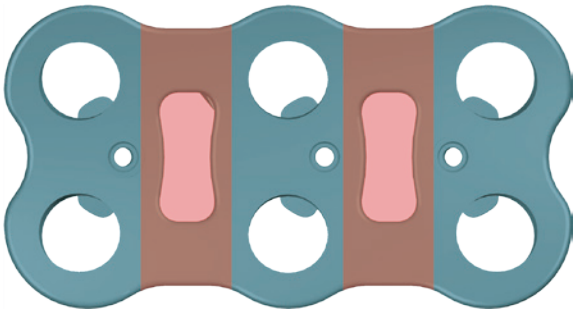
Increase lordotic curvature

Figure 2



Decrease lordotic curvature

Figure 3



Bend Zone Bend Zone

Figure 4

STEP 4 : Position Plate and Insert Temporary Fixation Pins

Using the Temporary Fixation Pin inserter, re-position the plate on the vertebral bodies. Insert a temporary fixation pin, available in threaded shaft options, into one of the cephalad and one of the caudad screw bores of the plate (Figure 5).

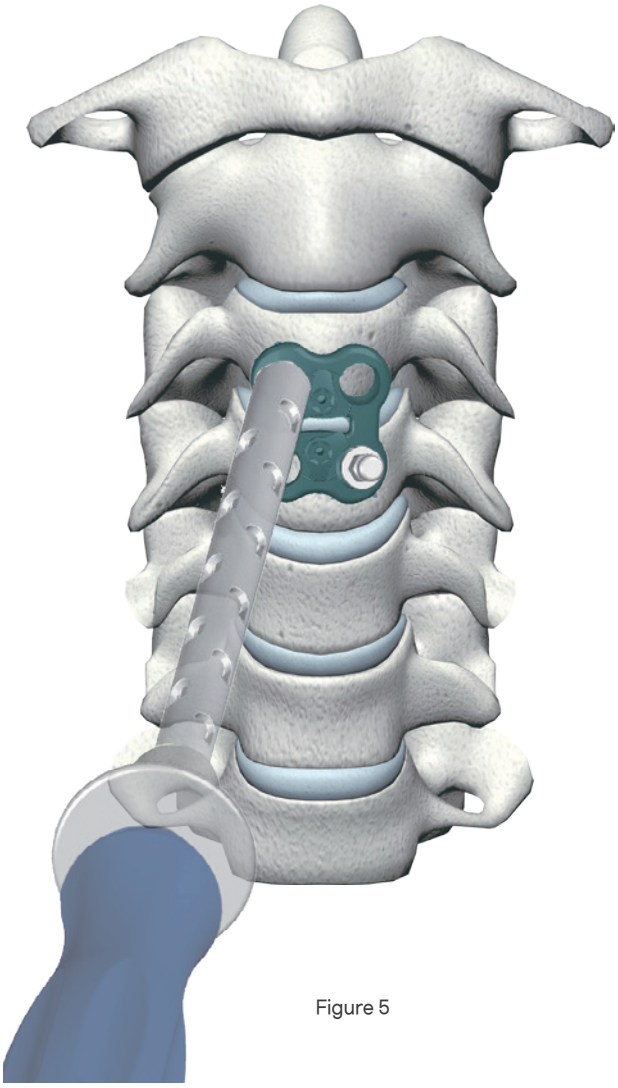


Figure 5

STEP 5 : Screw Selection

The Pinehurst Anterior Cervical Plate System offers surgeons the versatility to place their screws at additional angulations into the vertebral bodies. The system offers both self-tapping and self-drilling screws options. The system screw incorporates a dual thread screw pattern designed to maximize interface with cancellous bone.
Figure 6 below shows just a few options for screw placement.

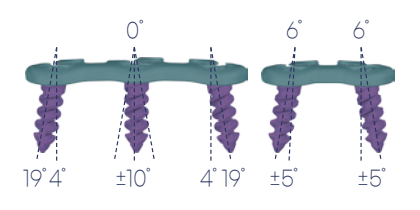


Figure 6

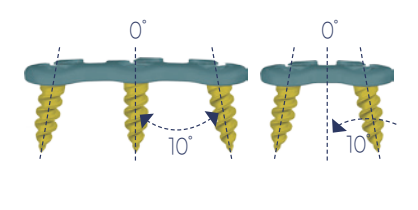


Figure 7

Figure 8

Using the Self-Constrained Awl

Once the plate is positioned and temporarily fixed to the vertebral bodies, place the tip of the Self-Constrained Awl in the screw bore and press it in the direction of the desired screw angle. The Self-Constrained Awl can protrude into the bone up to a depth of 8.5mm (Figure 9). To penetrate dense cortical bone, strike the handle of the Self-Constrained Awl with a mallet.

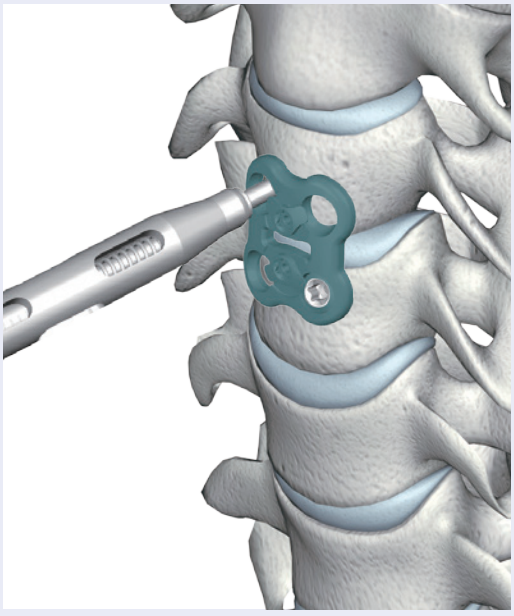


Figure 9

STEP 6 : Screw Positioning

- Attach the desired drill bit onto the AO I-Handle or power drill.

Advance the drill bit through the drill guide until the shelf of the drill contacts the guide (Figure 10).
The Pinehurst Anterior Cervical Plate System provides both self-drilling and self- tapping screws.

- A 10 mm tap is provided should tapping be required.

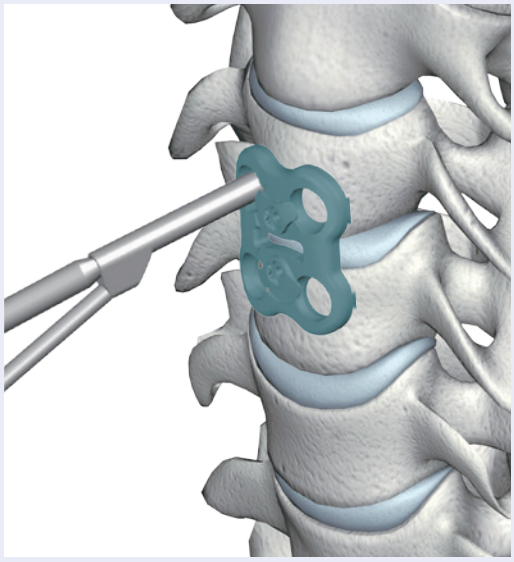


Figure 10

STEP 7 : Screw Insertion

- Use the screw driver to pick up the appropriate bone screw, insert the screw tip into the previously prepared bone screw hole.
- Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured with the CAP.

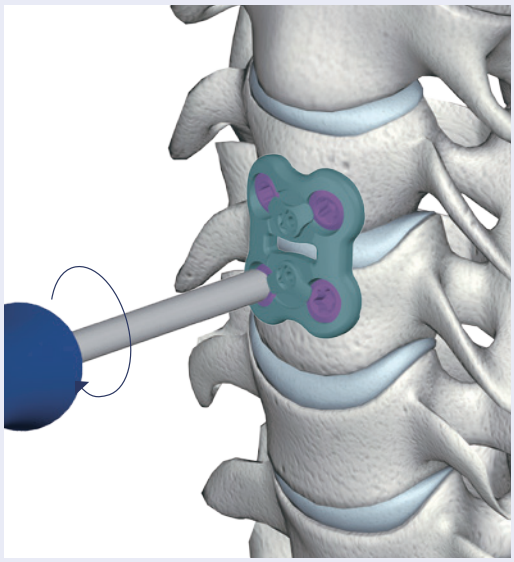


Figure 11

STEP 8 : Locking the Caps

The Pinehurst Anterior Cervical Plate System includes an attached locking CAP mechanism.

- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.
- Rotate the CAP clockwise until the CAP is parallel with the vertebral body (Figure 13) Be careful to ensure that the CAP is not over turned, as damage may occur.

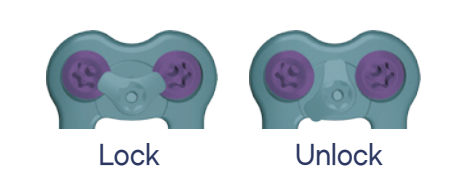


Figure 12

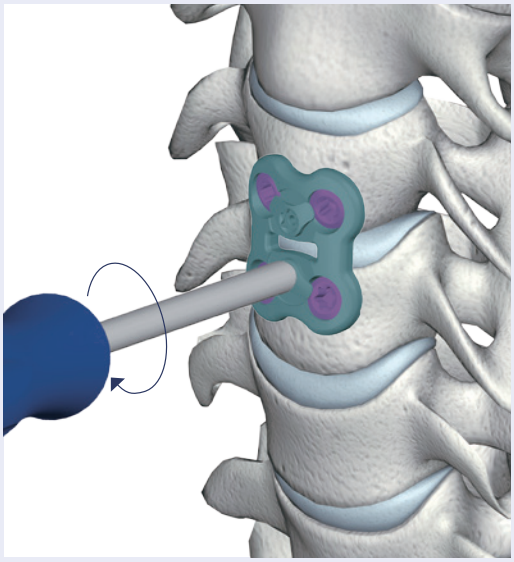


Figure 13

Optional Instrument : Double DTS

To attach the Double DTS Guide, begin with the guide off the distal end of the plate. Place one side of the guide in the side slot on the plate (Figure 14).
Next, twist the opposite side into position. Typically it is easier to attach the Double DTS Guide when downward pressure is maintained on the guide to keep contact between the guide and the plate.

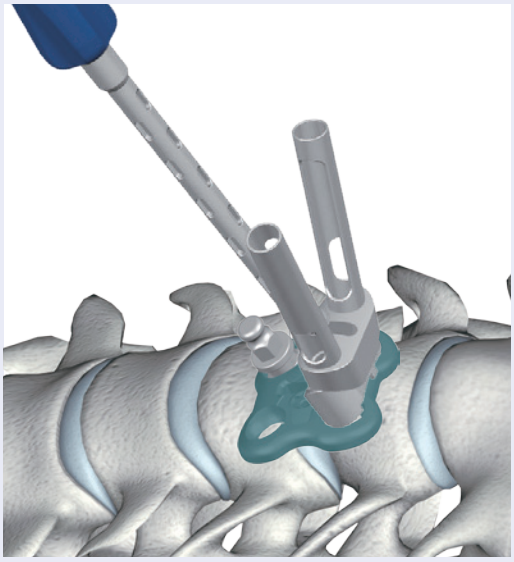


Figure 14

Removal Technique :

- Items needed : Screw driver, Hexlobe screw Removal tool.

- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.

- Rotate the CAP counter-clockwise until the CAP is parallel with the vertebral body (Figure 15). Be careful to ensure that the CAP is not over turned, as damage may occur.

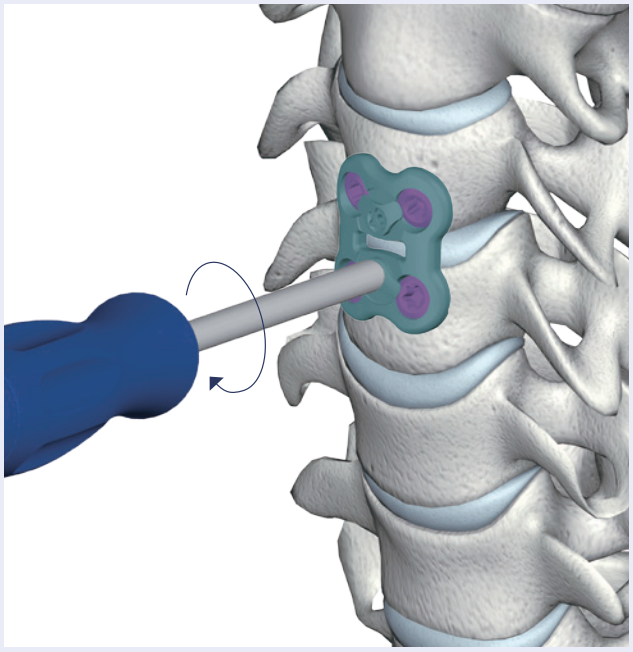


Figure 15

- Items needed : Screw driver, Hexlobe screw Removal tool.

- Insert the tip of the CAP tightener shaft into the CAP ensuring that the screw driver is fully seated within the CAP.

- Rotate the CAP counter-clockwise until the CAP is parallel with the vertebral body (Figure 16). Be careful to ensure that the CAP is not over turned, as damage may occur.

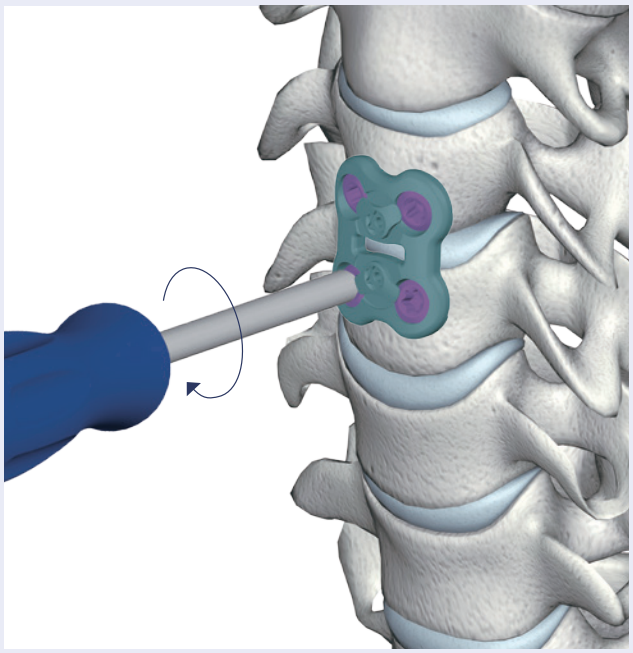
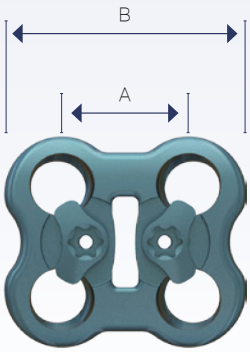


Figure 16

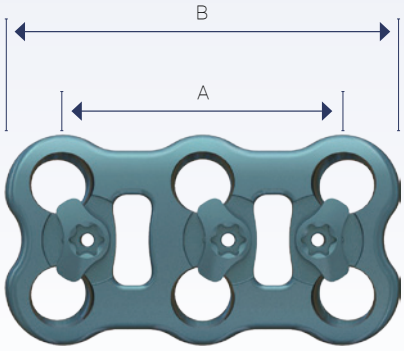
4CIS® PINEHURST ANTERIOR CERVICAL PLATE

One Level Plates



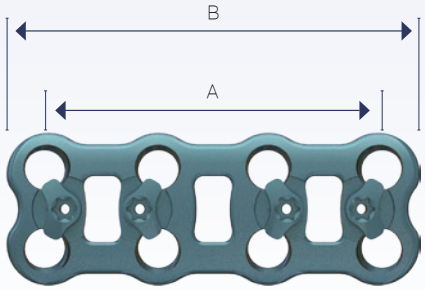
Catalog No.	Description	
	A (Hole-to-Hole)	B (End-to-End)
8013-0108	8mm	17mm
8013-0110	10mm	19mm
8013-0112	12mm	21mm
8013-0114	14mm	23mm
8013-0116	16mm	25mm
8013-0118	18mm	27mm
8013-0120	20mm	29mm
8013-0122	22mm	31mm
8013-0124	24mm	33mm
8013-0126	26mm	35mm

Two Level Plates



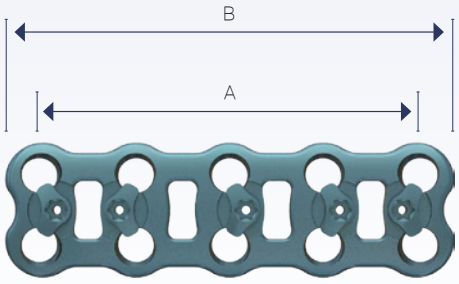
Catalog No.	Description	
	A (Hole-to-Hole)	B (End-to-End)
8013-0222	22mm	31mm
8013-0224	24mm	33mm
8013-0226	26mm	35mm
8013-0228	28mm	37mm
8013-0230	30mm	39mm
8013-0232	32mm	41mm
8013-0234	34mm	43mm
8013-0236	36mm	45mm
8013-0238	38mm	47mm
8013-0240	40mm	49mm
8013-0242	42mm	51mm
8013-0244	44mm	53mm
8013-0246	46mm	55mm

Three Level Plates



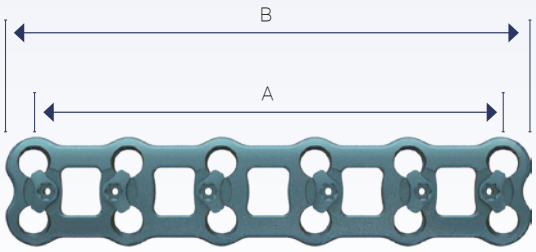
Catalog No.	Description	
	A (Hole-to-Hole)	B (End-to-End)
8013-0336	36mm	45mm
8013-0339	39mm	48mm
8013-0342	42mm	51mm
8013-0345	45mm	54mm
8013-0348	48mm	57mm
8013-0351	51mm	60mm
8013-0354	54mm	63mm
8013-0357	57mm	66mm
8013-0360	60mm	69mm
8013-0363	63mm	72mm
8013-0366	66mm	75mm
8013-0369	69mm	78mm

Four Level Plates



Catalog No.	Description	
	A (Hole-to-Hole)	B (End-to-End)
8013-0446	46mm	55mm
8013-0450	50mm	59mm
8013-0454	54mm	63mm
8013-0458	58mm	67mm
8013-0462	62mm	71mm
8013-0466	66mm	75mm
8013-0470	70mm	79mm
8013-0474	74mm	83mm
8013-0478	78mm	87mm

Five Level Plates



Catalog No.	Description	
	A (Hole-to-Hole)	B (End-to-End)
8013-0571	71mm	80mm
8013-0576	76mm	85mm
8013-0581	81mm	90mm
8013-0586	86mm	95mm
8013-0591	91mm	100mm

4CIS® PINEHURST SCREW

Variable Self Drilling Screw

Catalog No.	Description	Size (Thread Length)
8208-3510	Self-Drilling Ø3.5 Screw	10mm
8208-3511	Self-Drilling Ø3.5 Screw	11mm
8208-3512	Self-Drilling Ø3.5 Screw	12mm
8208-3513	Self-Drilling Ø3.5 Screw	13mm
8208-3514	Self-Drilling Ø3.5 Screw	14mm
8208-3515	Self-Drilling Ø3.5 Screw	15mm
8208-3516	Self-Drilling Ø3.5 Screw	16mm
8208-3517	Self-Drilling Ø3.5 Screw	17mm
8208-3518	Self-Drilling Ø3.5 Screw	18mm
8208-3519	Self-Drilling Ø3.5 Screw	19mm
8208-3520	Self-Drilling Ø3.5 Screw	20mm
8208-4010	Self-Drilling Ø4.0 Screw	10mm
8208-4011	Self-Drilling Ø4.0 Screw	11mm
8208-4012	Self-Drilling Ø4.0 Screw	12mm
8208-4013	Self-Drilling Ø4.0 Screw	13mm
8208-4014	Self-Drilling Ø4.0 Screw	14mm
8208-4015	Self-Drilling Ø4.0 Screw	15mm
8208-4016	Self-Drilling Ø4.0 Screw	16mm
8208-4017	Self-Drilling Ø4.0 Screw	17mm
8208-4018	Self-Drilling Ø4.0 Screw	18mm
8208-4019	Self-Drilling Ø4.0 Screw	19mm
8208-4020	Self-Drilling Ø4.0 Screw	20mm

Fixed Self Drilling Screw

Catalog No.	Description	Size (Thread Length)
8206-3510	Self-Drilling Ø3.5 Screw	10mm
8206-3511	Self-Drilling Ø3.5 Screw	11mm
8206-3512	Self-Drilling Ø3.5 Screw	12mm
8206-3513	Self-Drilling Ø3.5 Screw	13mm
8206-3514	Self-Drilling Ø3.5 Screw	14mm
8206-3515	Self-Drilling Ø3.5 Screw	15mm
8206-3516	Self-Drilling Ø3.5 Screw	16mm
8206-3517	Self-Drilling Ø3.5 Screw	17mm
8206-3518	Self-Drilling Ø3.5 Screw	18mm
8206-3519	Self-Drilling Ø3.5 Screw	19mm
8206-3520	Self-Drilling Ø3.5 Screw	20mm
8206-4010	Self-Drilling Ø4.0 Screw	10mm
8206-4011	Self-Drilling Ø4.0 Screw	11mm
8206-4012	Self-Drilling Ø4.0 Screw	12mm
8206-4013	Self-Drilling Ø4.0 Screw	13mm
8206-4014	Self-Drilling Ø4.0 Screw	14mm
8206-4015	Self-Drilling Ø4.0 Screw	15mm
8206-4016	Self-Drilling Ø4.0 Screw	16mm
8206-4017	Self-Drilling Ø4.0 Screw	17mm
8206-4018	Self-Drilling Ø4.0 Screw	18mm
8206-4019	Self-Drilling Ø4.0 Screw	19mm
8206-4020	Self-Drilling Ø4.0 Screw	20mm

Variable Self Tapping Screw

Catalog No.	Description	Size (Thread Length)
8209-3510	Self-Drilling Ø3.5 Screw	10mm
8209-3511	Self-Drilling Ø3.5 Screw	11mm
8209-3512	Self-Drilling Ø3.5 Screw	12mm
8209-3513	Self-Drilling Ø3.5 Screw	13mm
8209-3514	Self-Drilling Ø3.5 Screw	14mm
8209-3515	Self-Drilling Ø3.5 Screw	15mm
8209-3516	Self-Drilling Ø3.5 Screw	16mm
8209-3517	Self-Drilling Ø3.5 Screw	17mm
8209-3518	Self-Drilling Ø3.5 Screw	18mm
8209-3519	Self-Drilling Ø3.5 Screw	19mm
8209-3520	Self-Drilling Ø3.5 Screw	20mm
8209-4010	Self-Drilling Ø4.0 Screw	10mm
8209-4011	Self-Drilling Ø4.0 Screw	11mm
8209-4012	Self-Drilling Ø4.0 Screw	12mm
8209-4013	Self-Drilling Ø4.0 Screw	13mm
8209-4014	Self-Drilling Ø4.0 Screw	14mm
8209-4015	Self-Drilling Ø4.0 Screw	15mm
8209-4016	Self-Drilling Ø4.0 Screw	16mm
8209-4017	Self-Drilling Ø4.0 Screw	17mm
8209-4018	Self-Drilling Ø4.0 Screw	18mm
8209-4019	Self-Drilling Ø4.0 Screw	19mm
8209-4020	Self-Drilling Ø4.0 Screw	20mm

Fixed Self Tapping Screw

Catalog No.	Description	Size (Thread Length)
8207-3510	Self-Drilling Ø3.5 Screw	10mm
8207-3511	Self-Drilling Ø3.5 Screw	11mm
8207-3512	Self-Drilling Ø3.5 Screw	12mm
8207-3513	Self-Drilling Ø3.5 Screw	13mm
8207-3514	Self-Drilling Ø3.5 Screw	14mm
8207-3515	Self-Drilling Ø3.5 Screw	15mm
8207-3516	Self-Drilling Ø3.5 Screw	16mm
8207-3517	Self-Drilling Ø3.5 Screw	17mm
8207-3518	Self-Drilling Ø3.5 Screw	18mm
8207-3519	Self-Drilling Ø3.5 Screw	19mm
8207-3520	Self-Drilling Ø3.5 Screw	20mm
8207-4010	Self-Drilling Ø4.0 Screw	10mm
8207-4011	Self-Drilling Ø4.0 Screw	11mm
8207-4012	Self-Drilling Ø4.0 Screw	12mm
8207-4013	Self-Drilling Ø4.0 Screw	13mm
8207-4014	Self-Drilling Ø4.0 Screw	14mm
8207-4015	Self-Drilling Ø4.0 Screw	15mm
8207-4016	Self-Drilling Ø4.0 Screw	16mm
8207-4017	Self-Drilling Ø4.0 Screw	17mm
8207-4018	Self-Drilling Ø4.0 Screw	18mm
8207-4019	Self-Drilling Ø4.0 Screw	19mm
8207-4020	Self-Drilling Ø4.0 Screw	20mm

INSTRUMENT

5932-1106	4CIS® Pinehurst Drill 10mm
5932-1107	4CIS® Pinehurst Drill 12mm
5932-1108	4CIS® Pinehurst Drill 14mm
5932-1109	4CIS® Pinehurst Drill 16mm
5932-1211	4CIS® Pinehurst Drill 18mm

5932-1121 4CIS® Pinehurst Drill Guide-Fixed

5932-1122 4CIS® Pinehurst Drill Guide-Variable

5932-1113 4CIS® Pinehurst Tap 10mm

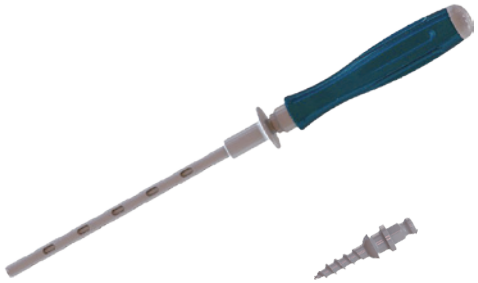
5932-1114 4CIS® Pinehurst Plate Holder

5932-1115 4CIS® Pinehurst Plate Bender

5932-1123 4CIS® Pinehurst Screw Driver

5932-1124 AO I-Handle

5932-1118 4CIS® Pinehurst Temporary Fixation Pin Inserter
5932-1117 4CIS® Pinehurst Temporary Fixation Pin



5932-1119 4CIS® Pinehurst Self Constrained Awl

5932-1111 4CIS® Pinehurst Double DTS
5932-1112 4CIS® Pinehurst Single DTS

5932-1116 4CIS® Pinehurst Hexlobe Screw Removal Tool

WARNING AND CAUTIONS

Warning

01. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.

02. Do not use this product other than its indication. Cannot be inserted other than indicated area and cervical vertebrae is not allowed.

03. The 4CIS® Pinehurst Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Pinehurst Anterior cervical Plate System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. in this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

04. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.

05. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. 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 implants which have been reused.

06. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.

07. All instruments are delivered non-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.

08. A wrong choice of implant size may cause damage to the product and may become the reason of unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, area of vertebral checked by X-ray, levels of implantation, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. Please refer to "the choice of implant".

09. It cannot be used with other product without validation regarding safety and effectiveness. If it is used with other product, Solco Biomedical Co., Ltd do not take any responsibility.

10. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.

11. It is important for surgeon and medical staff to be well-informed of the following information and give it to patient before the procedure, in order to be warned of the potential consequences and ensure success of the surgical implantation:
    - Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished, alcoholic, obese, or patients with drug abuse, muscle weakness or nerve paralysis.
    - To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
    - The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
    - Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations
    - These implants do not present any known risk of interference with other medical equipment.
    - Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting

12. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.

13. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Caution

01. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
02. The benefit of spinal fusions utilizing any intervertebral body fusion device has not been adequately established in patients with stable spines.
03. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
04. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are pre-requisites.
05. Physician note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
06. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Also, patients who smoke or abuse alcohol are poor candidates for spinal fusion as someone who should be advised and warned of the consequences of the fact that an increased incidence of non-union has been reported with such patients.
07. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions or many extenuating circumstances may compromise the results.
08. Non-Sterilized implants must be placed on sterilization for use.
09. Never reuse the implant under any circumstances. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.
10. The compatibility needs to be verified before use with other product.
11. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product maybe damaged from loads due to scratches not visible with naked eyes.
12. The use of implants may interfere with the anatomical structure or physiological performance of the patient. It should be reviewed carefully about radiological diagnosis and its side effects before the procedure.
13. 4CIS® Pinehurst Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of 4CIS® Pinehurst Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
14. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal or bone failure.
15. Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician

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