

C³® *Control
Compression
Choice*

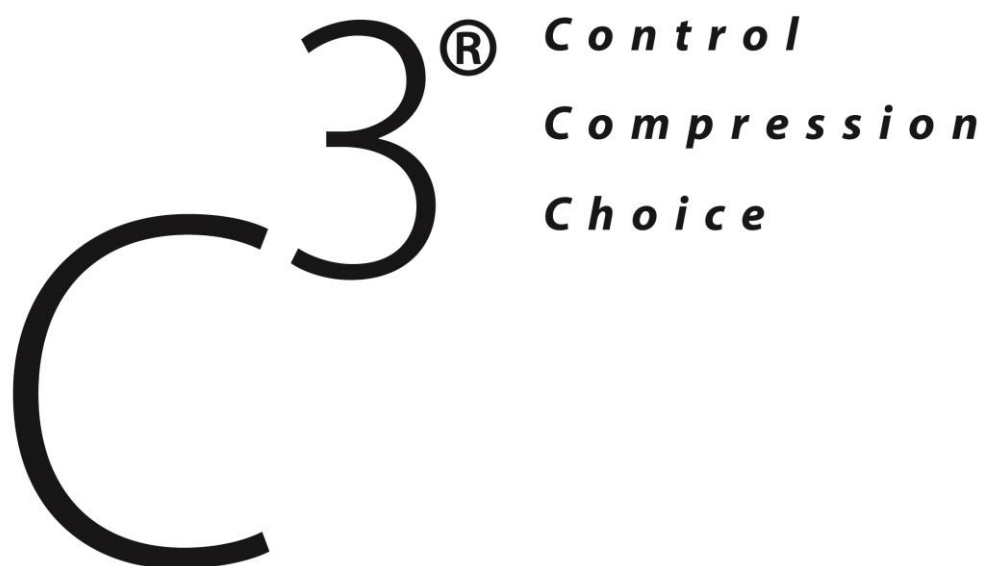
Anterior Cervical Plate System



Surgical Technique



SpineVision®
Innovation that matters



Anterior Cervical Plate System

Surgical Technique

English Version

Reference document: GC1-ST_04GB

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

Caution: The SpaceVision® ACIF cage system listed in this Surgical Technique is not yet cleared by FDA. These products are clearly marked with “**Not for Sale in the USA.**”



See package insert for labeling limitation



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General Description of the System

The C³® Anterior Cervical Plate System is intended to be used as a temporary internal fixation device for the correction and stabilization of the cervical spine.

The system is also intended to enhance the development of a solid fusion.


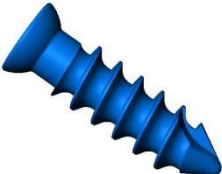
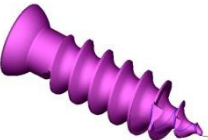
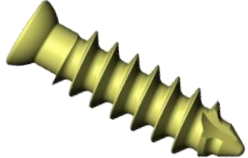
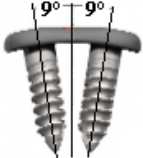
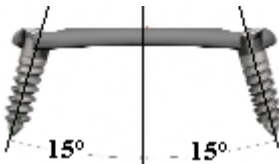
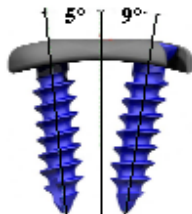

C³®ACPS provides the unique combination of:

- Per-operative compression of the graft
- Dynamic (2mm translation), hybrid (1mm translation) or fixed construct options
- Uni or bi cortical screws (self-tapping, self-drilling)
- Locking mechanism (Spring Locking System = SLS) to prevent backing out of screws
- Low profile system to avoid vascular injuries and dysphagia : The SLS covers the screw heads and gives a low and smooth plate profile (2,3 mm thickness)

Presentation of Implants

Screws

Depending on the type of construct Variable Angle Screws or Fixed Angle Screws can be used.

Fixed angle	Variable angle		
Self-tapping (Ø 4mm, grey)	Self-tapping (Ø 4mm, blue)	Self-tapping, Self-drilling (Ø 4mm, purple)	Rescue (Ø 4.5mm, gold)
C1-C40xx	C1-S40xx	C1-SD40xx	C1-R45xx
			
Length(xx) = 12, 14, 16 mm	Length(xx) = 12, 14, 16 mm <i>[18,19,20mm for bi cortical fixation options]</i>	Length(xx) = 12, 14, 16 mm	Length(xx) = 12, 14, 16 mm
<p>9° convergent in the transverse plane</p>  <p>15° divergent in the sagittal plane</p> 	<p>5° to 9° convergent in the transverse plane</p>  <p>5° to 20° divergent in the sagittal plane.</p> 		

Plates

DESCRIPTION

- 2,3mm height including the Spring Locking System to prevent screw back-out
- Specific holes design to receive fixed angle or variable angle screws and allow graft maintenance during plate insertion and fixation
- All plates are pre-bent



Plate and its associated Spring Locking System

RANGE

Plate range: Plates are available from 21,5mm to 109mm length to fit the patient's needs.

1-Level plates

- Reference: **C1-P10xxx(N1)** ; 8 plates are available from 21.5 mm (Reference: C1-P10215) to 39 mm (C1-P10390) (2.5 mm increment)

2-Level plates

- Reference: **C1-P20xxx(N1)** ; 7 plates are available from 41.5 mm (Reference: C1-P20415) to 56.5 mm (C1-P20565) (2.5 mm increment)

3-Level plates

- Reference: **C1-P30xxx** ; 9 plates are available from 54 mm (Reference: C1-P30540) to 78 mm (C1-P30780) (3 mm increment)

4-Level plates


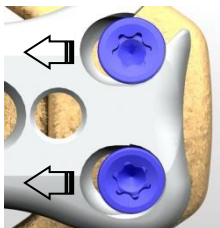
- Reference: **C1-P40xxx** ; 11 plates are available from 69 mm (Reference: C1-P40690) to 109 mm (C1-P41090) (4 mm increment)

Note : 4-Level plates are associated with 2 Spring Locking Systems



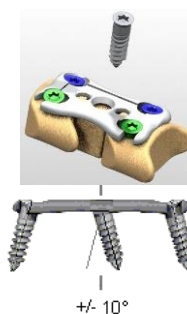
Example of 4-Level plate with its two SLS

CONSTRUCT OPTIONS

CONSTRUCT	SCREWS	TRANSLATION
Fixed	4 Fixed angle screws	No translation
Hybrid	2 Variable Angle Screws + 2 Fixed Angle Screws 	1mm translation 
Dynamic	4 Variable Angle Screws	2mm translation

Insertion of a bone graft or intermediate vertebral screw is also possible.

CAUTION: in this case, a fixed angle screw must be inserted in the sagittal plane (+/- 10°) in order to lay the SLS plate flush.



Presentation of Instruments

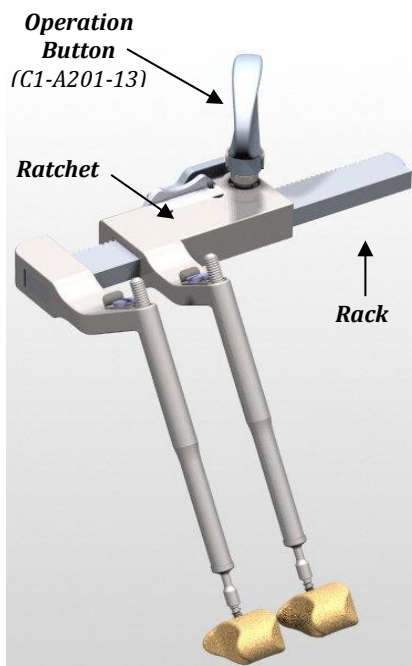
Pins & Distractor-Compressor

PRESENTATION

Distractor-Compressor (C1-A201) must be used with the pins (C1-A206N1) and their plugs (C1-A210).



Pins are used in combination with the C1-A216 handle.



Distractor-Compressor
(C1-A201)
and pins (C1-A206N1)

The Distractor-Compressor has been developed to allow bone graft compression maintenance during plate placement.

List of components:

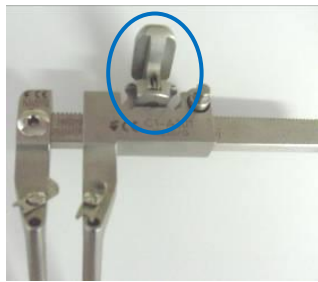
- C1-A201 : Distractor-Compressor
- C1-A201-13 : Operation Button
- C1-A201(C1-A219): 101mm (170mm) rack for Distractor-Compressor

Its rack can be changed according to the length of construct (C1-A201 or C1-A219) using a Hex 3.5mm Tip (C1-A214) for Distractor-Compressor assembly and disassembly (see CHANGE OF THE RACK SECTION for further information).

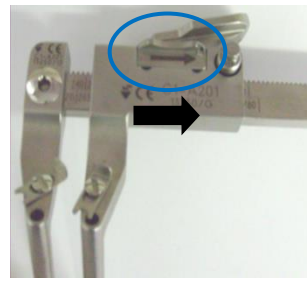


C1-A214

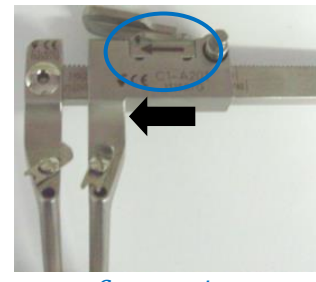
Function of the distractor-compressor can be changed by pulling, and turning the ratchet.



Neutral Position



Distraction

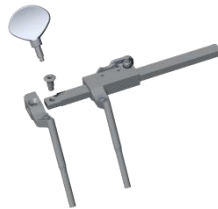
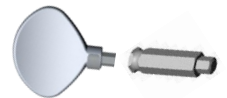


Compression

CHANGING THE RACK

In case the rack needs to be changed (3 & 4-Level constructs), use the Hex Tip (C1-A214) to disassemble the Distractor-Compressor.

- Remove the Operation Button (C1-A201-13), mount it in to the 3.5 Hex Tip (C1-A214)



- Untighten the screw of the Distractor-Compressor with the Hex Tip (C1-A214)
- Remove the rack
- Replace it by the 3&4 level scaled rack (C1-A219)

Follow the same procedure to disassemble the distractor-compressor for cleaning.

Drill guides

Stop drills (C1-A3xx) available in 12, 14, 16, 18, 19 and 20mm lengths have been designed to securely drill screw holes. Drill guides are to be used with the stop drills pre-assembled with the Snap-On handle (C1-A215(N1)).



C1-A215(N1) + C1-A316

Depending on the screw, drill guides can be used to facilitate hole drilling.



*Drill Guide for fixed angle screws
(C1-A202)*



*Drill guide for variable angle screw
(C1-A203)*

Note: The use of drill guides will enable good placement of the screws so that the SLS will be flush with the C3 plate.

Implant handling

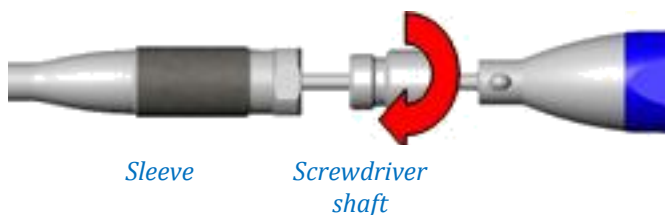
SCREW HANDLING

There are two screwdrivers options:

- C1-A204: T10 screwdriver with prehension



- C1-A234: C3 screwdriver



Screwdriver disassembly :

- Unscrew the sleeve from the shaft.
- Remove the sleeve from the shaft of the screwdriver

PLATE HANDLING



Plate holder (C1-A200)

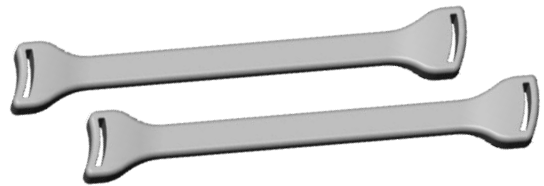
The plate can be manipulated by screwing the tip of the plate holder shaft (C1-A200) in the Spring Locking System screw hole of the C3 plate.

PLATE BENDING

All the plates are pre-bent; it is the choice of the surgeon to bend the plate more, if required, by using the 3-Point Plate Bender (C1-A205) or the benders (C1-A207).



C1-A205



C1-A207

SLS HANDLING



SLS screw holder
(C1-A209(N1))

- The SLS plate is already mounted with a SLS screw.
- Take the SLS plate from the plate rack using the SLS Screw Holder (C1-A209(N1))

Temporary fixation pins



Temporary Fixation
Pin (C1-A222N1)

In case the surgeon does not want to use the Distractor/Compressor, temporary fixation pins can be used to maintain the plate whilst screws are placed.

Temporary fixation pins can be removed from the screw rack and positioned using the C3 screwdriver (C1-A234)



Caution: This construct can be implanted solely using plates with additional holes as shown :



Temporary fixation pins are removed using the temporary fixation pin extractor (C1-A223)



Surgical steps

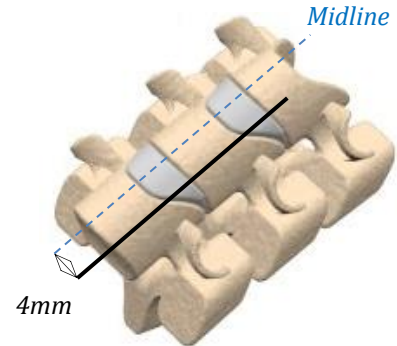
Exposure

Expose the intervertebral disc as a standard anterior approach to the cervical spine.

Pins & Distractor-Compressor placement

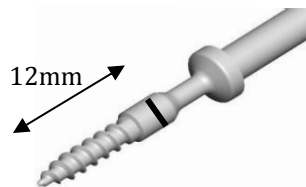
Selecting the right entry point for the Pins (C1-A206N1) for Distractor-Compressor (C1-A201) is essential for the final correct central positioning of the plate:

- Entry points must be placed 4mm lateral to the midline and at a safe distance from the intervertebral disc.
- Pins must be placed in a convergent direction so that their tips will be approximately at the center of the vertebral body.
- Distractor-Compressor shall be placed on the contralateral side for the surgeon

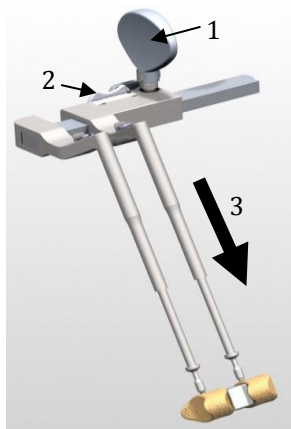


Pins (C1-A206N1) must be assembled with the C1-A216 handle.

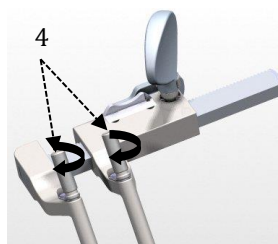
Insert the two Pins for distractor-compressor parallel in the sagittal plane into the entry points and screw them until the laser mark (12mm).



Note: The diameter of pins is 2.8mm (screw diameter: 4mm).



1. Assemble the Distractor-Compressor by mounting the Operation Button (C1-A201-13)
2. Put the ratchet lock in the free position.
3. Slide the arms of the Distractor/Compressor over the Pins inserted into the vertebral bodies.



4. Lock the pins on the distractor by screwing on the Plugs for Pins (C1-A210).

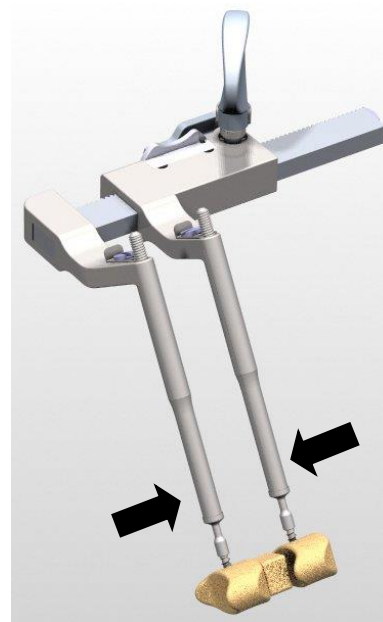
Discectomy & Graft Insertion



Distraction



Discectomy



Compression

Perform a complete discectomy as usual.

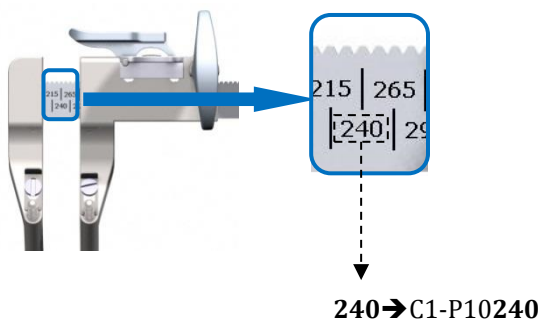
Once the distractor-compressor is in place, apply the desired distraction by turning the Operation Button clockwise.

Insert the bone graft as per standard surgical techniques. The SpaceVision® ACIF cage can be advantageously used to perform the interbody fusion.

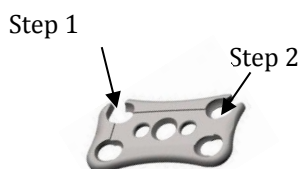
Reverse the ratchet lock to the compressing position. The intervertebral bone graft can then be maintained whilst the plate is placed.

Caution: SpaceVision® ACIF cage system is Not for Sale in the U.S.A.

Plate selection and insertion on pins



Read the length of the required plate on the Distractor-Compressor rack's scale.



Pick up the appropriate plate by screwing the Plate Holder (C1-A200) onto one of the small intermediate holes on the plate.

Start with the hole which opens onto the corner of the plate first (Step1) and then rotate the plate to slide it onto the second pin (Step2).

Slide the plate over the Pins for Distractor/Compressor via open holes.

If necessary, the plate curvature can be changed using the plate benders (C1-A205 / C1-A207).



C1-A205



C1-A207

CAUTION: Bend the plate carefully to avoid any damage to the plate holes. Otherwise the screws, especially the Fixed Angle Screws, may not fit properly.

Plate fixation

DRILLING

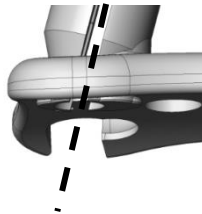


Choose the appropriate Stop Drill (C1-A3xx) and mount it on to the Snap-On handle (C1-A215N1).

Position the fixed angle drill guide (C1-A202) or the variable angle drill guide (C1-A203) on to the screw hole of the plate on the side opposite to the distractor-compressor.

Note: The fixed angle drill guide can also be used for variable screws.

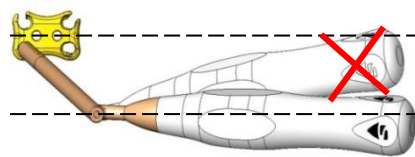
Perform the drilling by inserting the Stop Drill (C1-A3xx) into the guide



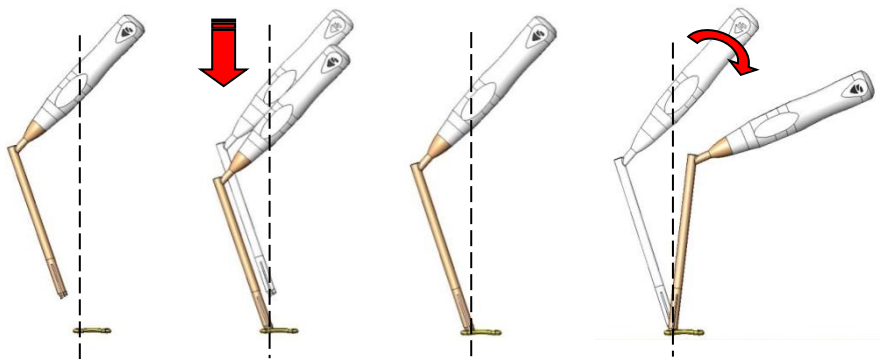
CAUTION: If screw angulations are not correct, the SLS may not lie flush which could irritate soft tissue.

Placement of the drill guide :

- In the sagittal plane



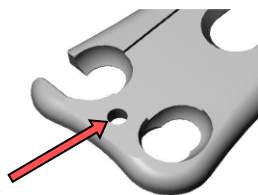
- In the horizontal plane



Once the holes are finished, screws can be put in place to attach the plate to the vertebrae.

TEMPORARY FIXATION PIN OPTION

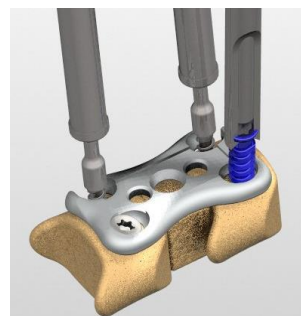
In case the distractor-compressor is not used, it is possible to stabilize the plate on the vertebral body with Temporary Fixation Pins (C1-A222N1) before drilling the screw holes.



- Pick-up a TFP from the rack with the C1-A234 screwdriver
- Insert the Temporary Fixation Pin (C1-A222N1) into the vertebral body through the additional small hole.

SCREW INSERTION

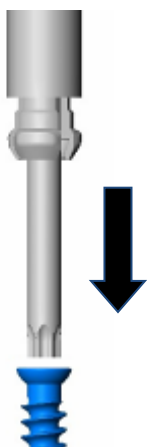
Pick-up the screw from the screw rack with the C3 Screwdriver (C1-A204 or C1-A234).



C1-A204



C1-A234



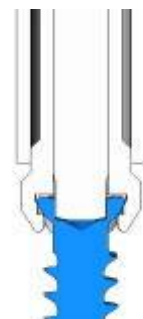
Insert the tip of the screwdriver C1-A234 in the screw head



Slide down the tip of the sleeve on to the screw head



Lock the screw by turning the sleeve clockwise



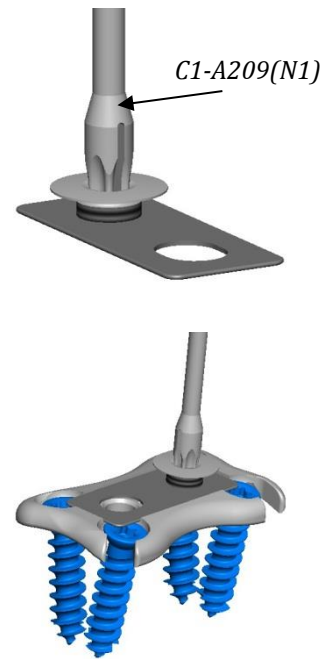
Once the two first screws are inserted on the side opposite to the distractor-compressor, remove the distractor-compressor and follow the same procedure to insert the two remaining screws.

Tightening of the screws can be completed with the C3 screwdriver (C1-A234).

SPRING LOCKING SYSTEM POSITIONING

- The Spring Locking System (SLS) plate is already mounted with a SLS screw.
- Pick up the SLS, which corresponds exactly to the chosen plate, with the SLS Screw Holder C1-A209(N1)
- Screw it slightly onto the plate into the corresponding small hole
- Pick up the second SLS screw from the Screw Rack with SLS Screw Holder and fix it lightly in the other SLS hole
- Gently tighten both SLS screws until they are flush with the plate

CAUTION: Tighten the SLS screws carefully (“three-fingers-tight”) until they are flush with the plate. An over-tightening of the SLS Screws may cause the SLS to break or the four corners of the SLS to point upward which could cause irritation of soft tissue.



Removal

To remove the implants, observe the following surgical steps:

- SLS removal
- Screw removal
- Plate removal



SpineVision®

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