

3D PRINTED TITANIUM ACIF CAGE



Hexanium ACIF



SURGICAL TECHNIQUE

SPINEVISION®

SURGICAL STEPS


I	· · · · · Patient positioning and discectomy	· · · · · 2
II	· · · · · Pins assembly and insertion	· · · · · 3
III	· · · · · Distractor / compressor placement and segmental distraction	· · · · · 5
IV	· · · · · Endplates preparation	· · · · · 7
V	· · · · · Implant's size estimation	· · · · · 8
VI	· · · · · Cage holder assembly and cage connection	· · · · · 9
VII	· · · · · Cage bone graft filling	· · · · · 11
VIII	· · · · · Cage insertion	· · · · · 12
IX	· · · · · Pilot hole preparation	· · · · · 13
X	· · · · · Drilling (optional)	· · · · · 15
XI	· · · · · Screw insertion	· · · · · 17
XI	· · · · · Cage final release	· · · · · 19
XII	· · · · · Cage removal (optional)	· · · · · 21

REFERENCES

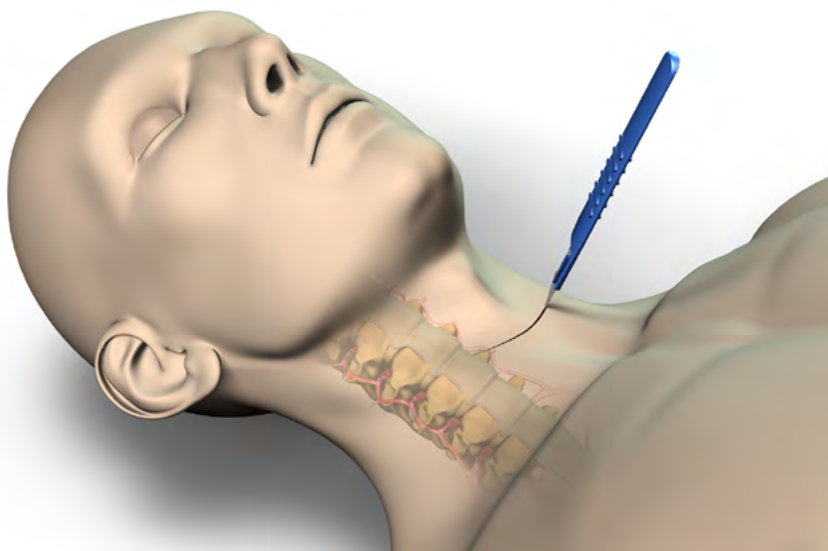
1	· · · · · Instruments	· · · · · 24
2	· · · · · Implants	· · · · · 27

PATIENT POSITIONING AND DISCECTOMY

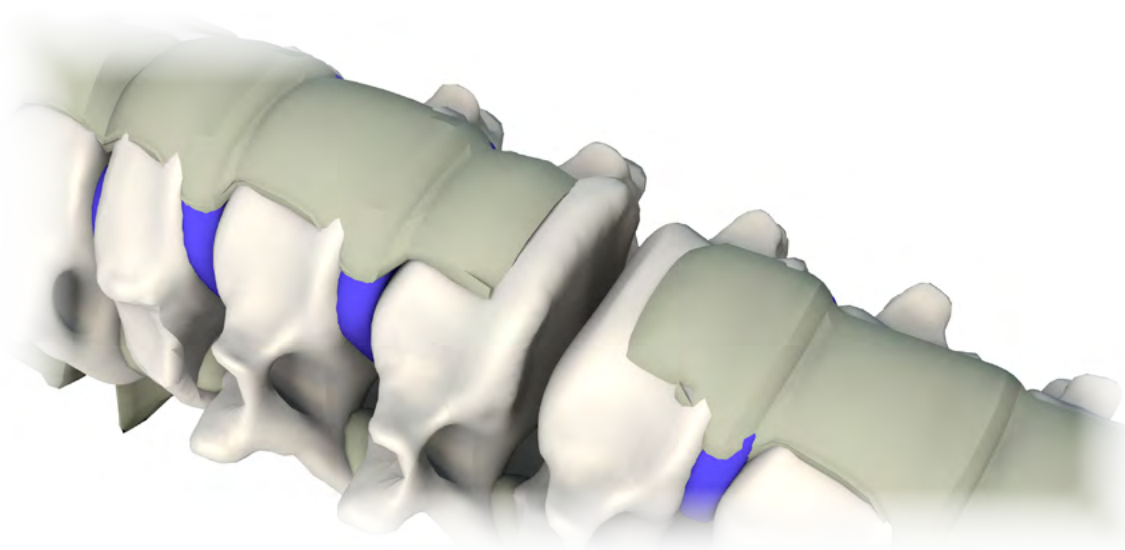
The patient is placed on the OR table using the standard position indicated for Anterior Cervical Interbody Fusion procedure: supine position with maintenance of cervical lordosis.

 X-ray shall be used during the entire procedure: to confirm identification of the affected disc, to confirm proper positioning of the trial device and the final position of the Hexanium ACIF cage.

Once the correct operating level is well identified, use the standard anterior approach for cervical spine paying attention not to damage soft tissues while placing retractors and/or distractors.



Once the prevertebral structures are retracted, use the standard methods used for anterior discectomy.



PINS ASSEMBLY AND INSERTION



Pins for Distractor/Compressor
AC2-A206



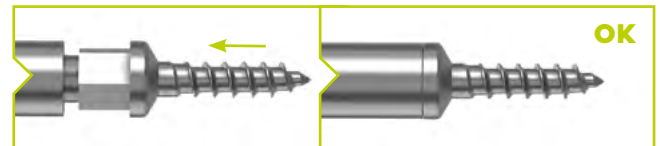
Driver for Pins
AC2-A216

To connect the **pins for distractor/compressor** AC2-A206 to the **driver for pins** AC2-A216, slide the proximal part of

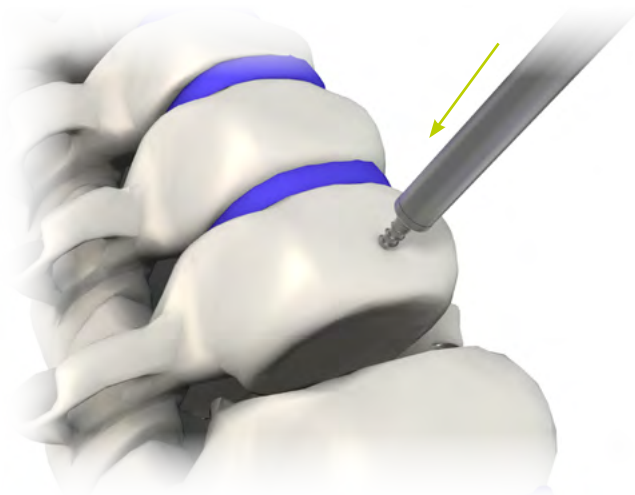
the pins (without hexagonal tip) into the outer tube of the driver for pins.



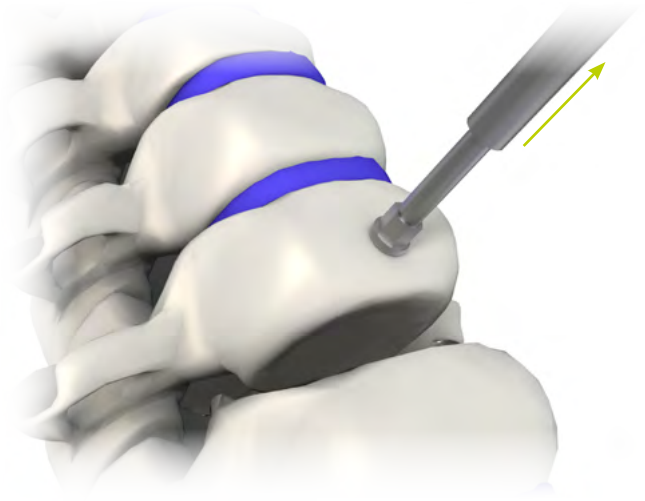
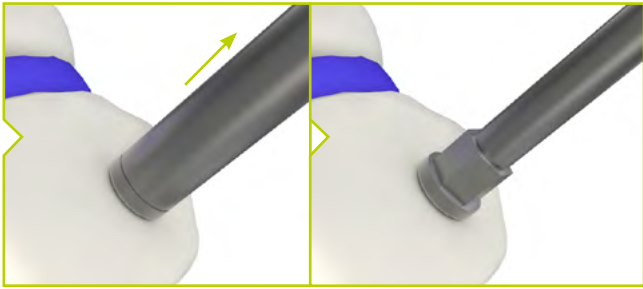
Be cautious that the hexagonal part of the pin is fully inserted into the driver for pin.



Directly insert the **pin for distractor/compressor** into the vertebral body. The entry hole of the pin should be on the medial line and at the sagittal center of the vertebral body. Insert the pin until it is fully inserted into the vertebral body.

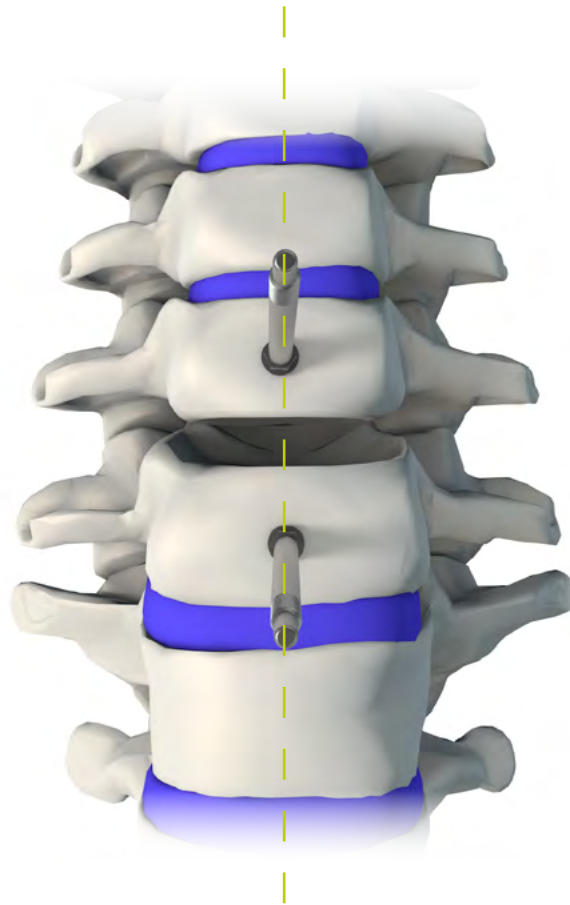


Once the pin is fully inserted, disconnect the **driver for pins** by pulling it upward leaving the pin into the vertebral body.



The second **pin for distractor/compressor** must be placed into the vertebral body of the lower vertebrae of the operated level. The two pins must be sagittally aligned together on the medial line.

Connect the second pin to the driver for pins as described above and fully insert it in the vertebral body

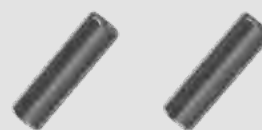




DISTRACTOR / COMPRESSOR PLACEMENT AND SEGMENTAL DISTRACTION



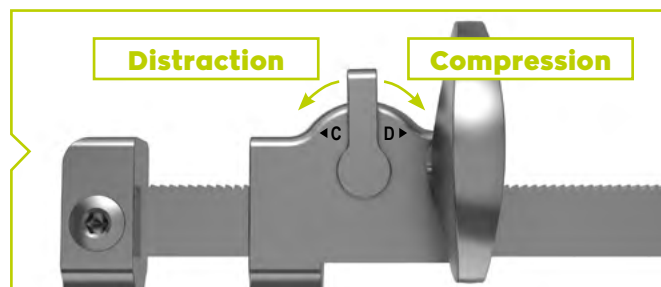
Distractor/Compressor
AC2-A201



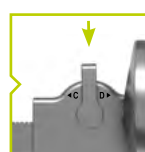
Plugs for Pins
AC2-A210

The Hexanium ACIF offers a unique **distractor/compressor AC2-A201** allowing both distraction **D** and compression **C**.

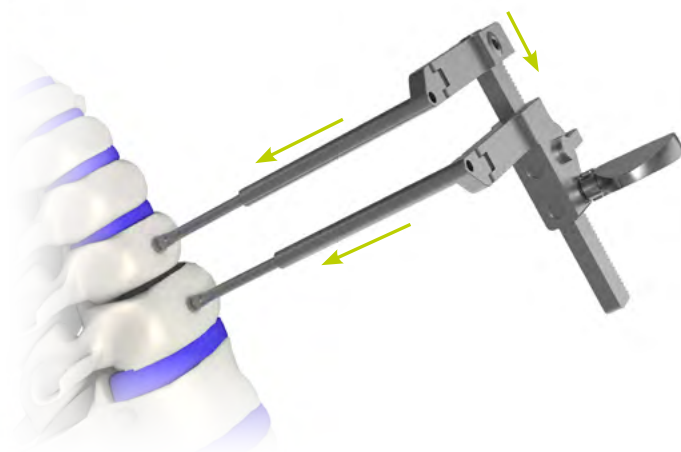
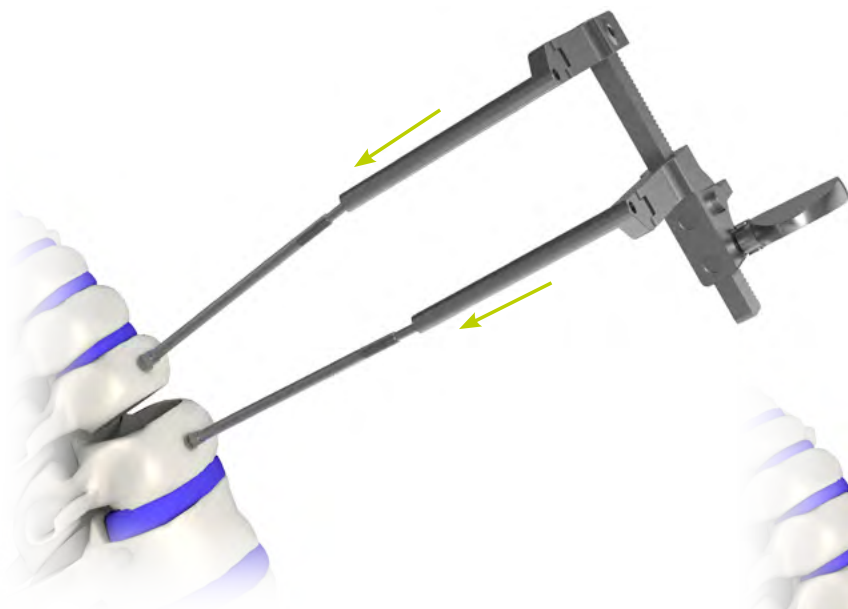
Segmental distraction is mandatory to restore disc height and ensure an accurate and safe placement of the cage.



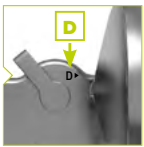
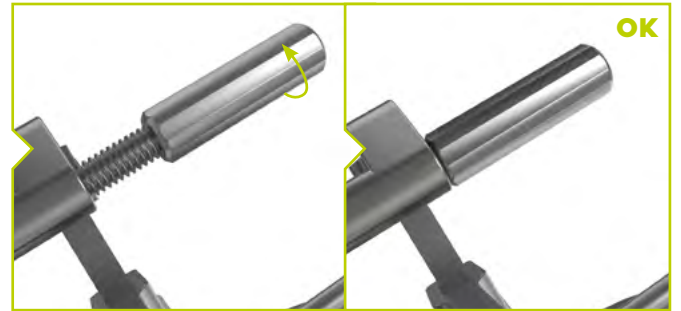
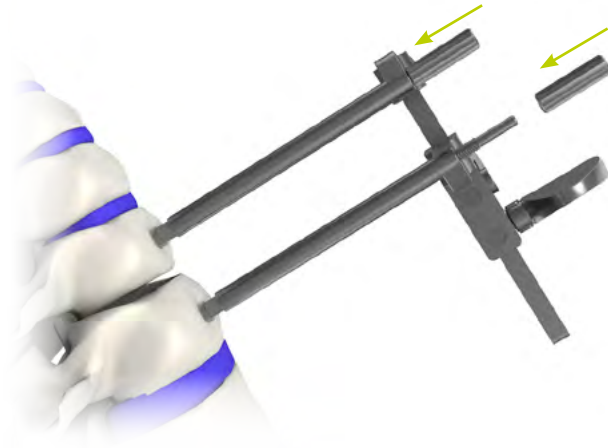
Position the pivoting « arm » of the **distractor/compressor** above the free part of the **pins for distractor/compressor AC2-A206** and slide the arms of the distractor/compressor down through the pins.



Place the D/C into neutral position to adjust the « spacing » between the D/C arms and facilitate the D/C placement.



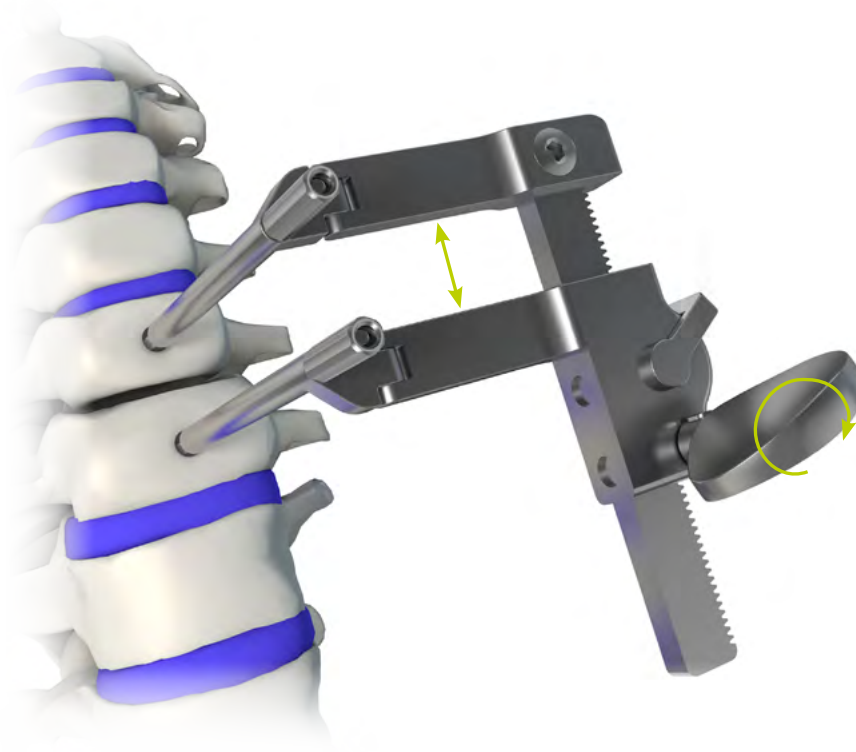
Once it is in position, place one **plug for pins AC2-A210** on each pins : screw the plug on the proximal free end of the pins.



To distract the intervertebral space prior to cage positioning, place the **distractor/compressor AC2-A201** on distraction position **D**.

Turn clockwise the butterfly handle of the D/C to distract the intervertebral space until the desire height is obtained.

Segmental distraction is mandatory to restore disc height and ensure a good access of the affected level.



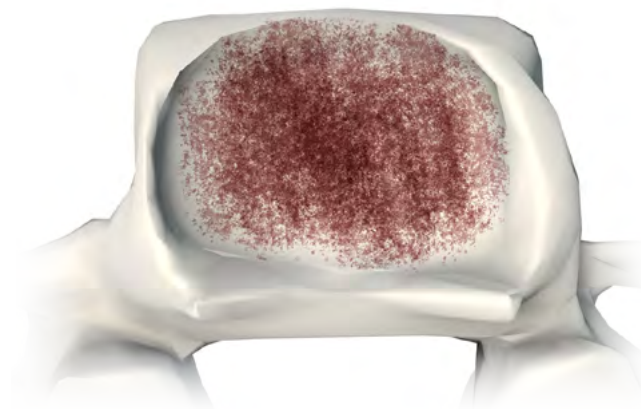
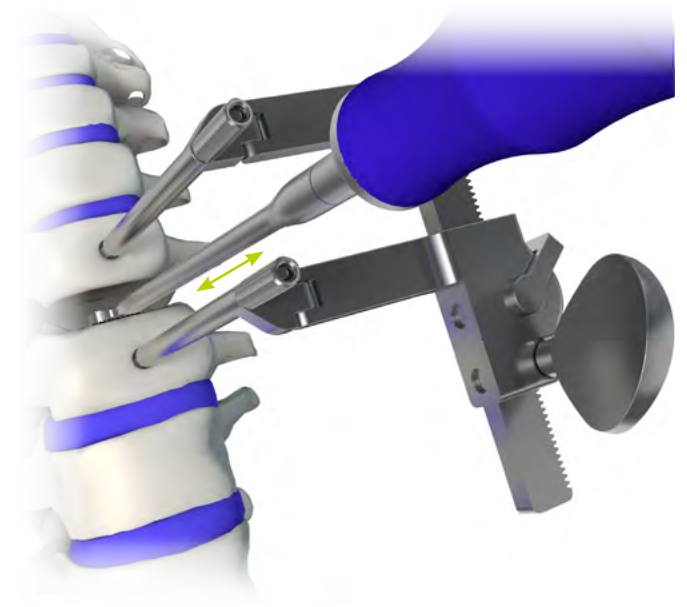
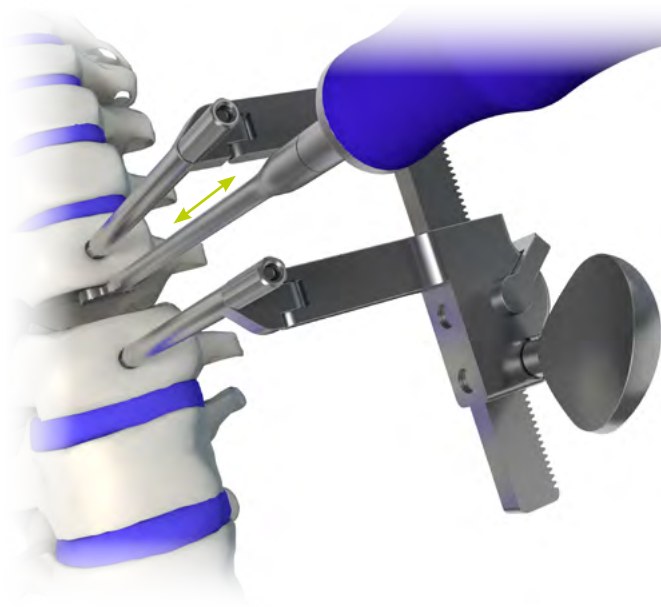


Rasp
AC2-A010

Once distraction of the intervertebral space is performed, use the rasp AC2-A010 to prepare the endplates. Enter the intervertebral space placing the rasp parallel to endplates and use it to remove superficial cartilaginous tissue of the endplates.

The rasp is used to reveal the bleeding bone and ensure good vascularization of the Hexanum ACIF.

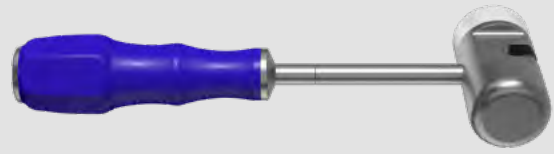
Removing too much subchondral bone may weaken the vertebral endplate. A subsidence and a loss of segmental stability may happen if the entire endplate is removed.



IMPLANT'S SIZE ESTIMATION



Lordotic or Convex Ti Cervical Cage Trial
AC2-A011-XXXX



Mallet
AC2-A023

Once the endplate preparation is done and the bleeding bone revealed, use the **lordotic or convex ti cervical cage trial** **AC2-A011-XXXX**. Trials are available to match the three different footprints Small, Medium & Large (*) and offer one different trial's size at each ends.

A colour coded ring based on footprints and cage's shape is used at each trial ends to help trials identification. In case of any doubt, please check the trial reference.

COLOR CODE FOR TRIALS

SMALL & WEDGE



MEDIUM & WEDGE



LARGE & WEDGE (*)



SMALL & CONVEX



MEDIUM & CONVEX



LARGE & CONVEX (*)



REFERENCE EXPLANATION

AC2-A011-**XXXX**

Size footprints :

X = S (small) / **M** (medium) / **L** (large) (*)

Height :

XX = 05 / 07 / 09 / 11 (**) with two different height at both trial sides.
(ex : XX = 05 for height 05 & 06)

Type :

X = L : WEDGE / **C** : CONVEX

(*) Footprint L is not available in Europe

(**) Heights 11 and 12 are not available in Europe

Insert the **Ti cervical cage trial** (using gentle taps with the **mallet AC2-A023** at the proximal end if needed) until it is just in the intervertebral space and the stop meets the anterior edge of the upper and lower vertebrae.

It is recommended to start with a trial of minimum height and follow with higher trials until the proper disc height restoration is obtained.



VI

CAGE HOLDER ASSEMBLY AND CAGE CONNECTION



Inner shaft for Ti Cervical Cage Holder
AC2-A002



Ti SA Cervical Cage Holder with Guide
AC2-A001G-XX

OR



Ti Cervical Cage Holder
AC2-A001

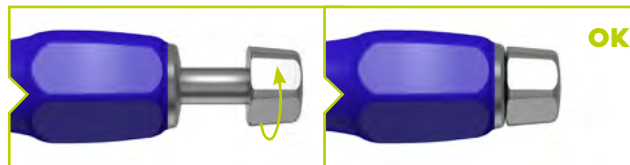
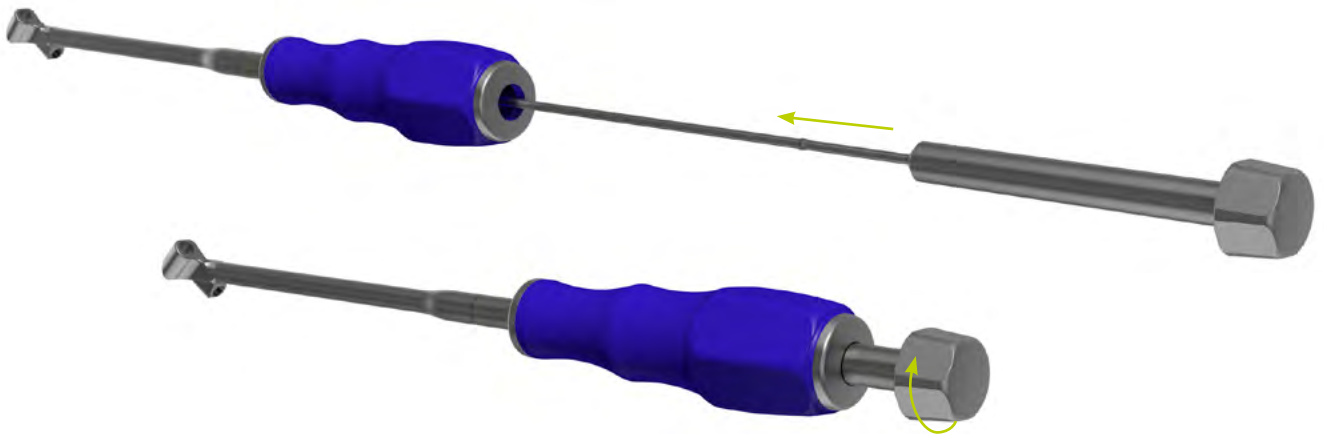
The Hexanium ACIF kit comes with two options for cage holding : **Ti SA cervical cage holder with guide AC2-A001G-XX** with integrated guide adapted for each implant

height (XX = Height from 05 to 12 (*)) and the **Ti cervical cage holder AC2-A001** without any guide nor height specification.

(*) Heights 11 and 12 are not available in Europe

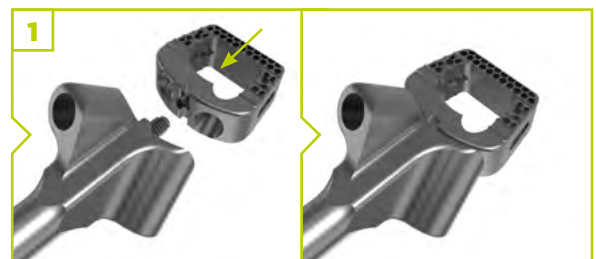
Prior to connect the cage (applying to both cage holders), insert the **inner shaft for Ti cervical cage holder AC2-A002** into the cage holder. When you feel a resistance,

turn clockwise the knob of the inner shaft until it reaches the proximal end of the cage holder handle.

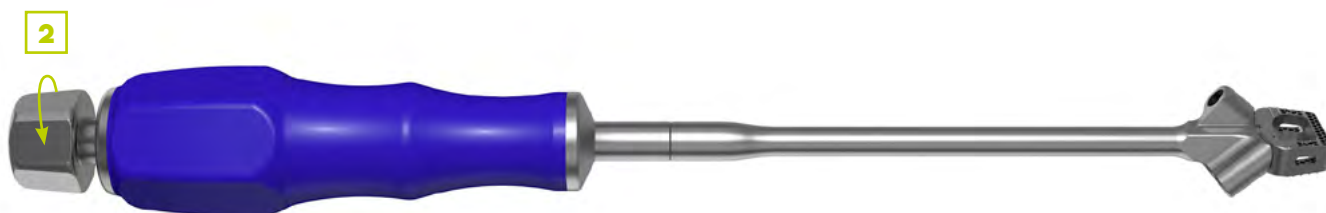
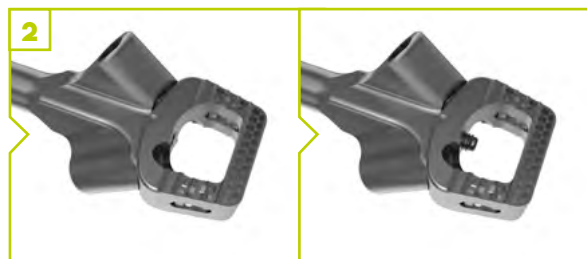


Ti SA Cervical Cage
AC2-CSXXXX

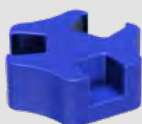
1 To connect the Hexanium ACIF corresponding to the last trial used (according lordotic or convex / footprints & height), place the distal tip of the chosen cage holder against the central slot of the **Ti SA cervical cage AC2-CSXXXX** engaging the threaded part of the **inner shaft for Ti cervical cage holder AC2-A002**.



2 Then, turn clockwise the knob of the inner shaft until it meets the proximal end of the cage holder handle and you can't screw the knob anymore.



CAGE BONE GRAFT FILLING



Ti Cervical Cage Graft Packing Block
AC2-A020



Ti Cervical Cage Cancellous Bone Impactor
AC2-A021



Cage connected to the Cage Holder
AC2-CSXXXX + AC2-A001 + AC2-A002

OR



Cage connected to the Cage Holder with Guide
AC2-CSXXXX + AC2-A001G-XX + AC2-A002

To pack some bone graft in the **Ti SA cervical cage AC2-CSXXXX**, position the cage in the **Ti cervical cage graft packing block AC2-A020** according the footprint of the chosen cage (Small : 15*12, Medium: 17*14 or Large : 15*19 (*)).

Add some bone graft in the cage bone graft chamber and above the hexagonal canals on the cage. Then use the **Ti cervical cage cancellous bone impactor AC2-A021** to compact the bone graft within the cage.

Repeat this step until the desired amount of bone graft is obtained.



(*) Footprint L is not available in Europe



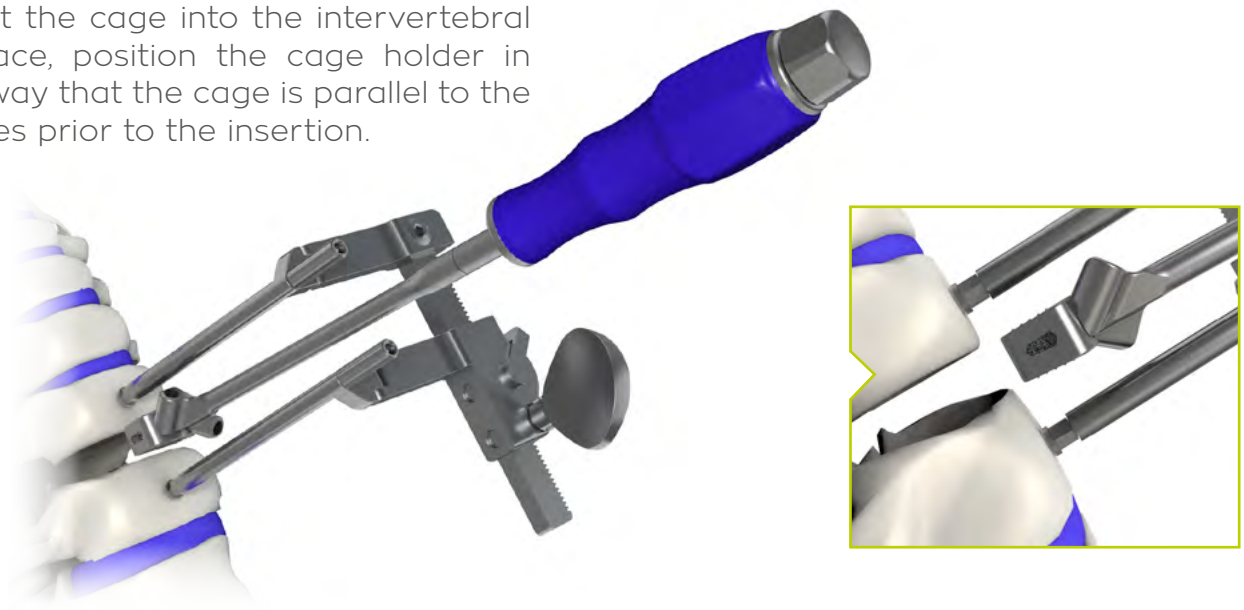
Mallet
AC2-A023



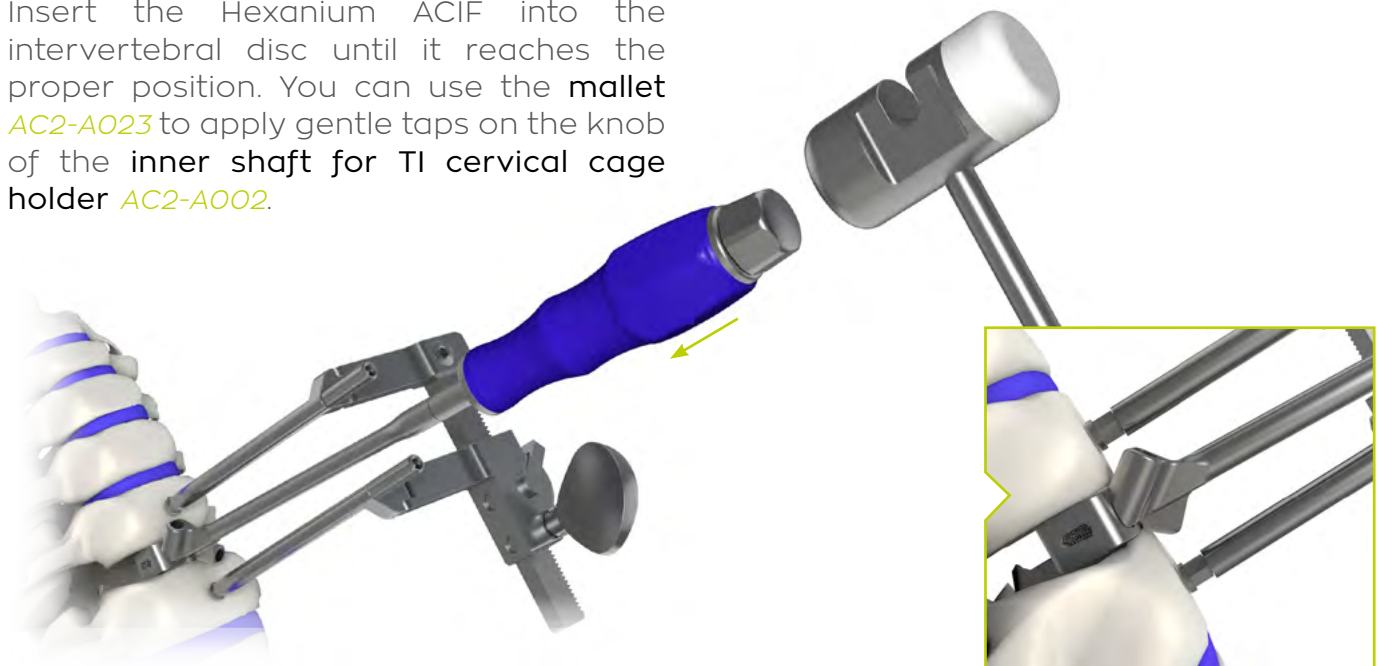
Cage connected to the Cage Holder
AC2-CSXXX + AC2-A001 + AC2-A002

Cage connected to the Cage Holder with Guide
AC2-CSXXX + AC2-A001G-XX + AC2-A002

To insert the cage into the intervertebral disc space, position the cage holder in such a way that the cage is parallel to the endplates prior to the insertion.



Insert the Hexanium ACIF into the intervertebral disc until it reaches the proper position. You can use the mallet AC2-A023 to apply gentle taps on the knob of the inner shaft for TI cervical cage holder AC2-A002.





Proper positioning of the cage must always be confirmed with x-rays before going any further in the procedure.



PILOT HOLE PREPARATION



Cylindrical Snap-On Handle
SD-ALSH26123PCAO



Bone Awl
AC2-A030

OR



Angulated Bone Awl
AC2-A031

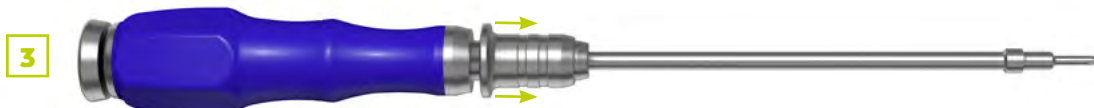
The Hexanium ACIF kit offers two options for bone awl: a straight **bone awl** [AC2-A030](#) and an **angulated bone awl** [AC2-A031](#).

To connect one or the other bone awl to the cylindrical **snap-on handle** [SD-ALSH26123PCAO](#) :

1 Pull the ring of the silicon handle towards the silicon part.

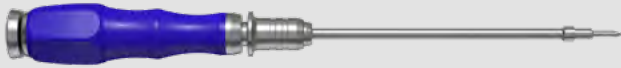
2 While maintaining this position, insert the proximal part of the bone awl into the handle

3 Release the ring of the handle to secure the connection between the two instruments.





Mallet
AC2-A023



Bone Awl connected to the Handle
AC2-A030 + SD-ALSH26123PCAO

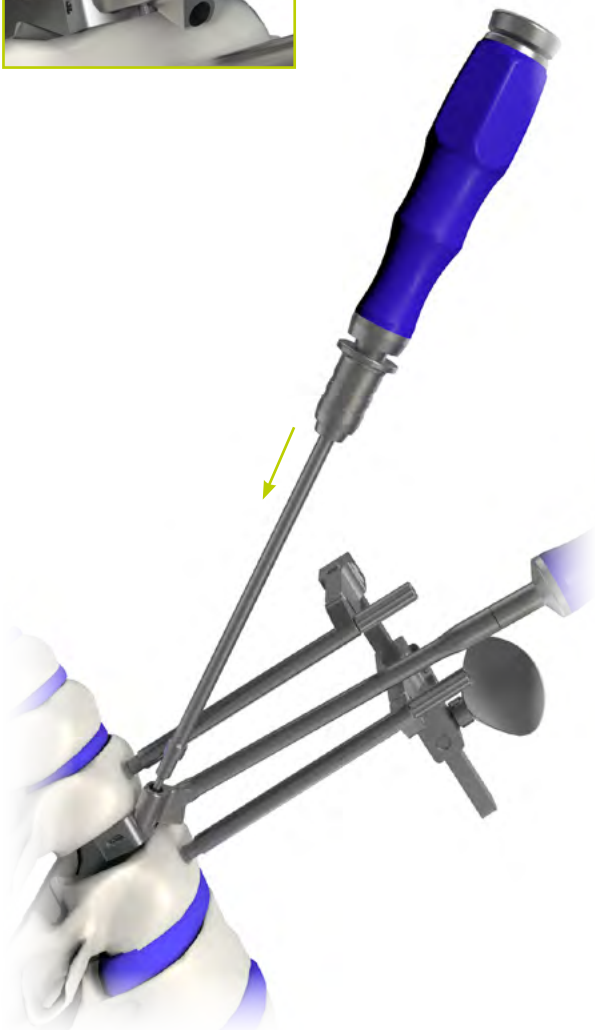
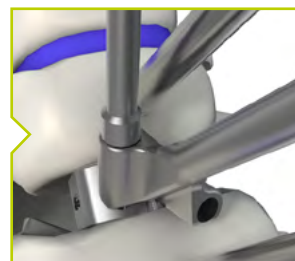
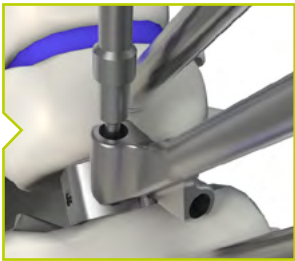
OR



Angulated Bone Awl connected to the Handle
AC2-A031 + SD-ALSH26123PCAO

To prepare the entry point for screws, insert the distal part of the **straight** or **angulated bone awl** AC2-A030 or AC2-A031 in the cage holder with guide.

Once the tip of the bone awl meets the endplate, apply gentle taps on the handle with the **mallet** AC2-A023 until the bone awl is fully inserted in the guide.





DRILLING (OPTIONAL)



Cylindrical Snap-On Handle
SD-ALSH26123PCAO



Straight Drill
AC2-A032

OR



U-Joint Drill
AC2-A033

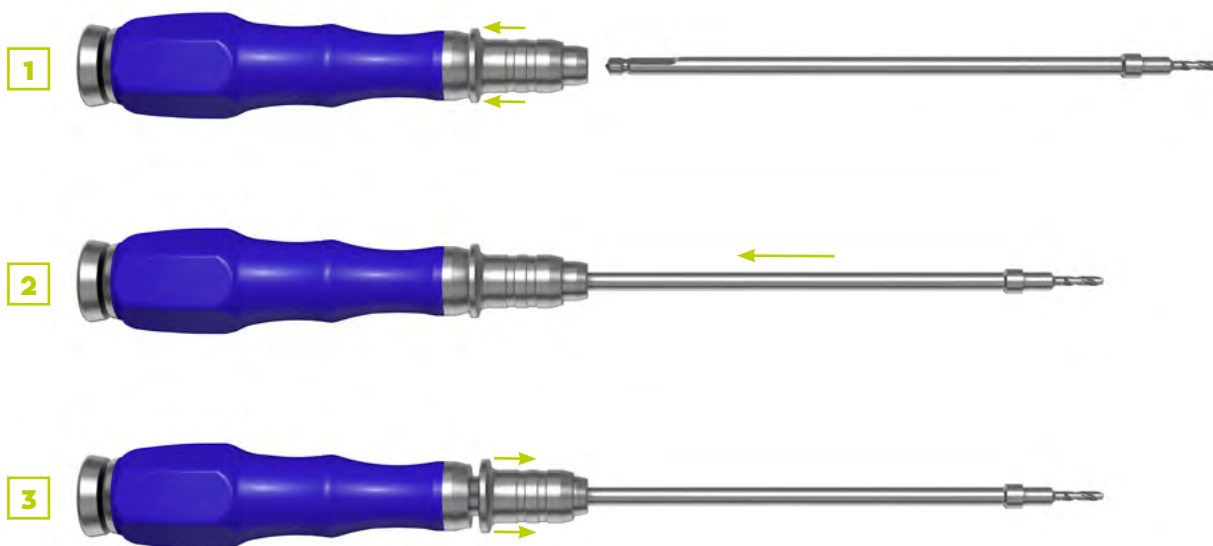
The Hexanium ACIF kit offers two instruments for drilling : a **straight drill** [AC2-A032](#) and a **U-joint drill** [AC2-A033](#).

To connect one or the other drill to the cylindrical **snap-on handle** [SD-ALSH26123PCAO](#),

1 Pull the ring of the silicon handle towards the silicon part.

2 While maintaining this position, insert the square tip of the drill into the handle

3 Release the ring of the handle to secure the connection between the two instruments.



Please note that Hexanium ACIF screws are self drilling screws, the drilling step being optional.



OR

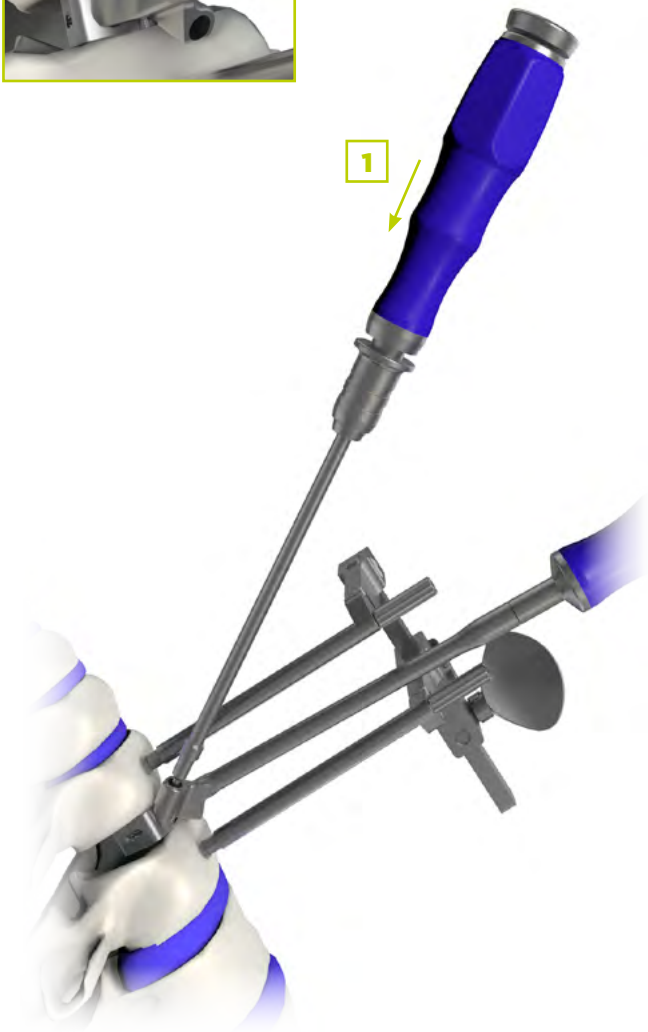
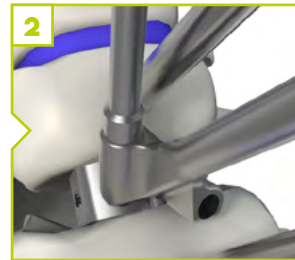
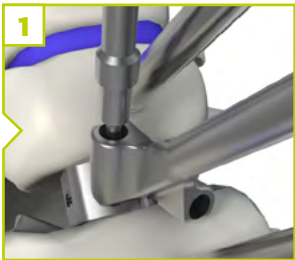


Drill connected to the Handle
AC2-A032 + SD-ALSH26123PCAO

Angulated Drill connected to the Handle
AC2-A033 + SD-ALSH26123PCAO

To prepare the hole for screws, insert the drill AC2-A032 or the u-joint drill AC2-A033 into the guide/inserters.

Once the tip of the drill meets the endplate **1**, turn clockwise to drill the hole into the vertebral body. Continue to drill until the drill is fully inserted into the guide **2** and then turn counter clockwise to remove the drill.





SCREW INSERTION



Screwdriver
AC2-A034

OR



U-Joint Screwdriver
AC2-A035

Screw may be inserted using either the screwdriver AC2-A034 or the u-joint screwdriver AC2-A035.

Hexanium ACIF screws are provided in a sterile packaging.

Screws Ø3,8 are intended for use in revision surgeries.



Diameter : **3.5mm**
Length : 10 / 12 / 14 / 16mm (*)
Ref : AC2-SD35XXS (XX = Length)

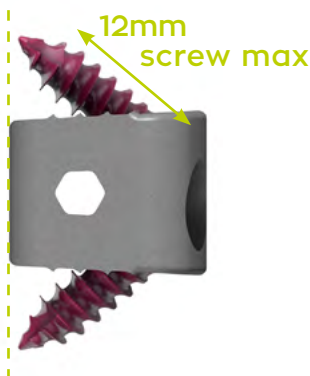


Diameter : **3.8mm**
Length : 10 / 12 / 14 / 16mm (*)
Ref : AC2-SD38XXS (XX = Length)

WARNING
Pay attention that according to the footprint, screws may protude or not beyond the cage's posterior edge :

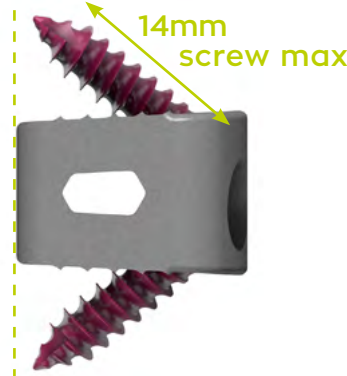
Small Footprint

12mm screws almost come flush with posterior edge of cage. Longer screw will protude.



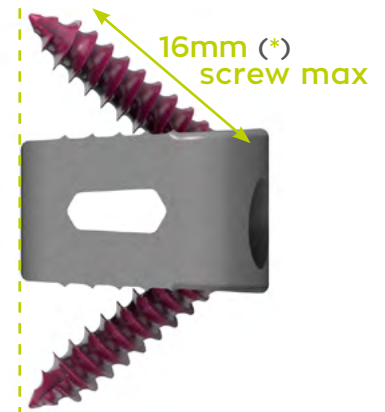
Medium Footprint

14mm screws almost come flush with posterior edge of cage. Longer screw will protude.



Large Footprint (**)

16mm screws (*) almost come flush with posterior edge of cage.



(*) Length 16mm is not available in Europe

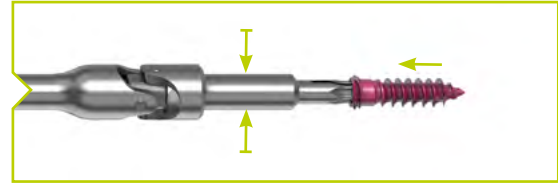
(**) Footprint L is not available in Europe

Both screwdrivers (straight AC2-A034 or the u-joint AC2-A035) feature a self retaining tip.

To connect the screw on the screwdriver, use a « stab & grab » motion and make sure that the screw is strongly attached to the screwdriver.

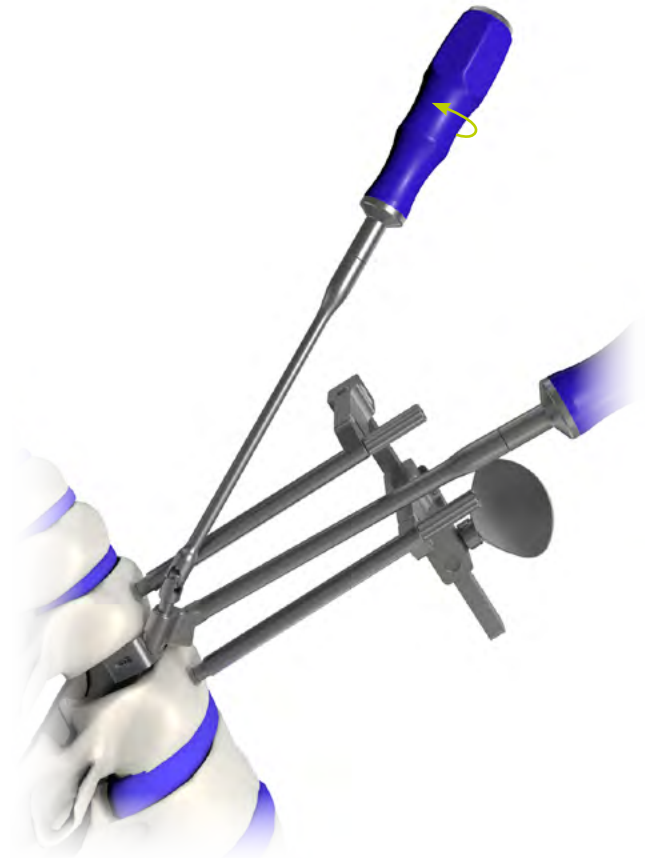
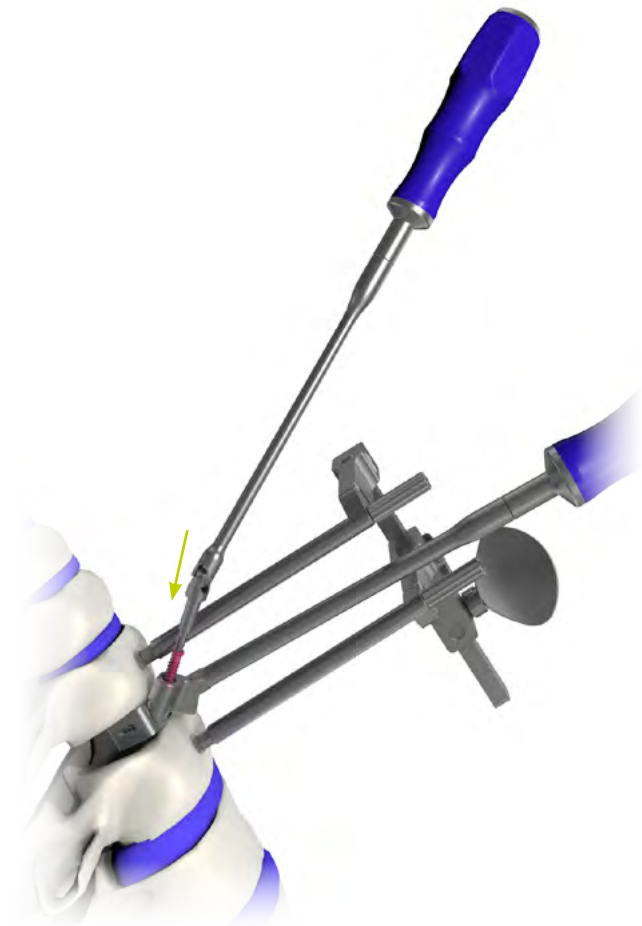


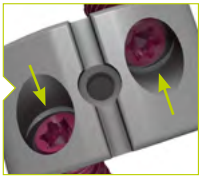
If using the U-joint screwdriver, pay attention to hold the screwdriver by the u-joint part to avoid any motion of the tip during the connection.



Once connected, slide the screw and screwdriver's tip through the guide into the hole prepared in the previous steps.

When the screw meets the bone, screw clockwise to insert it.





Screw head must pass the most anterior thread of the cage which should be visible when removing the screwdriver.

If using the u-joint screwdriver, pay attention not to angle too much the shaft and the u-joint part which could lead to block the u-joint the system.



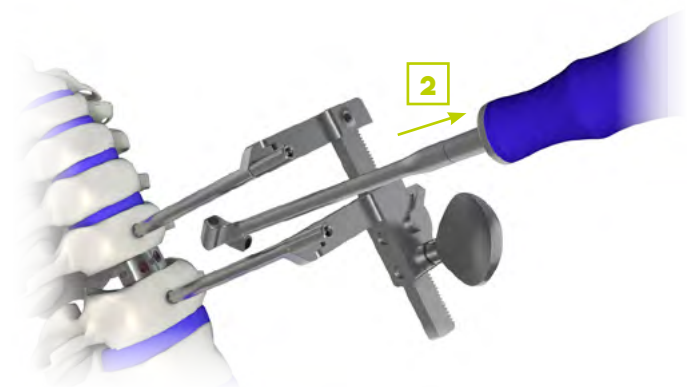
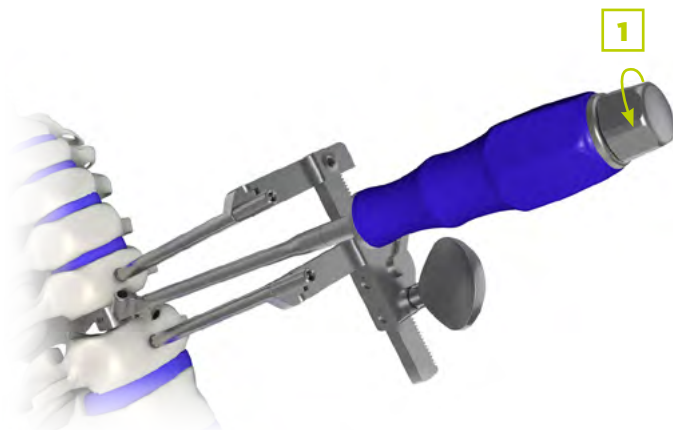
Repeat the 3 previous steps on the other side to insert the second screw.

XII

CAGE RELEASE

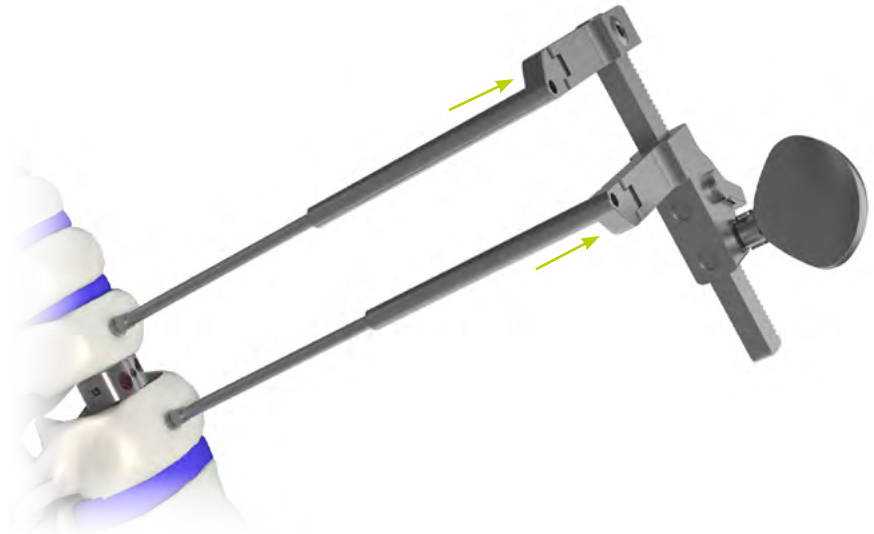
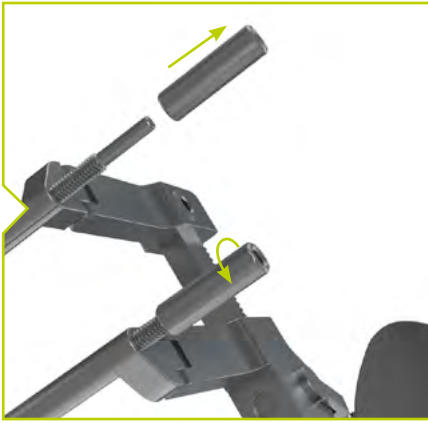
To release the Hexanium ACIF cage once both screws are placed, turn counter-clockwisely the inner shaft for Ti cervical cage holder

knob until the cage is free **1** and the cage holder can be disconnected **2**.



To remove the distractor/compressor : first counter clockwise turn the **plug for pins** AC2-A210 on each pins to remove it.

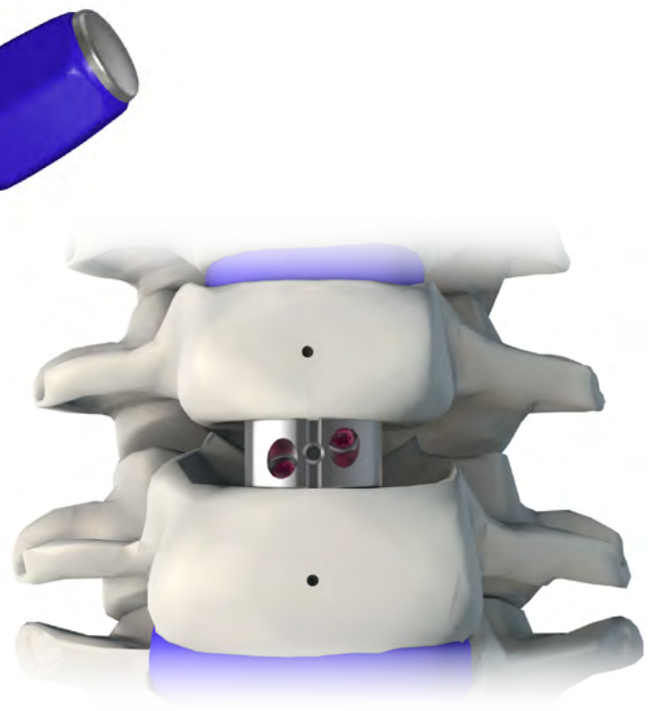
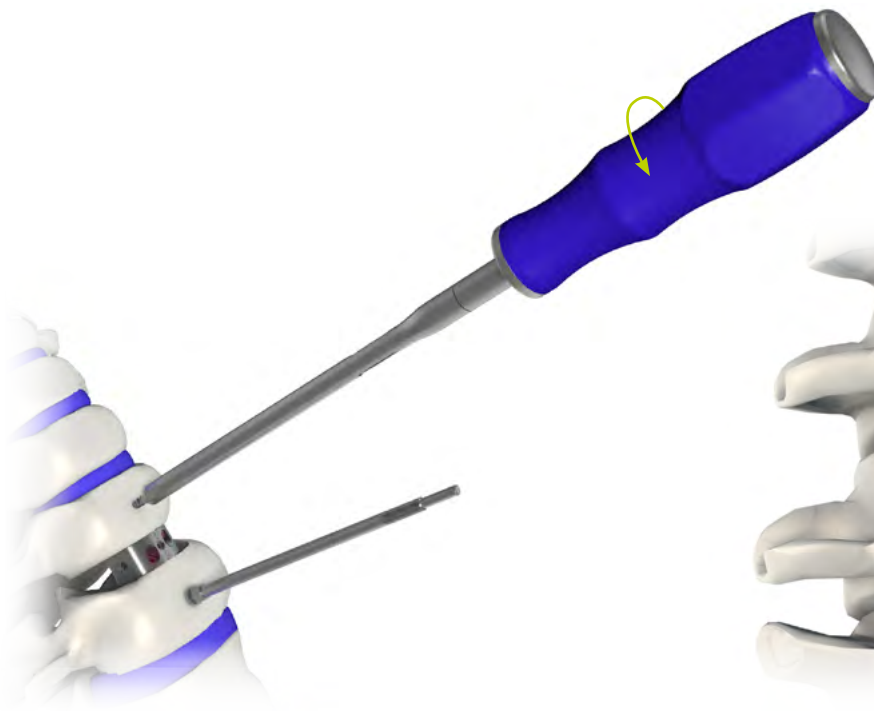
Then slide the arm of the D/C up the pins until you can entirely remove it.



Driver for Pins
AC2-A216

To remove the pins, reconnect the **driver for pins** AC2-A216 according step II and unscrew the pin until it comes off from the

vertebral body. Repeat this step on the other one.





Inner Shaft for Ti Cervical Cage Holder
AC2-A002



Ti SA Cervical Cage Holder with Guide
AC2-A001G-XX

OR



Ti Cervical Cage Holder
AC2-A001

To remove the cage if needed, connect the Ti cervical cage holder [AC2-A001](#) or the Ti SA cervical cage holder with guide [AC2-A001G-XX](#) to the cage by putting the tip of the cage holder into the slot of the anterior edge of the cage **1**.

Once it is in position, turn the knob of the inner shaft for Ti Cervical Cage holder [AC2-A002](#) clockwise to screw the inner shaft in the cage's thread **2**.





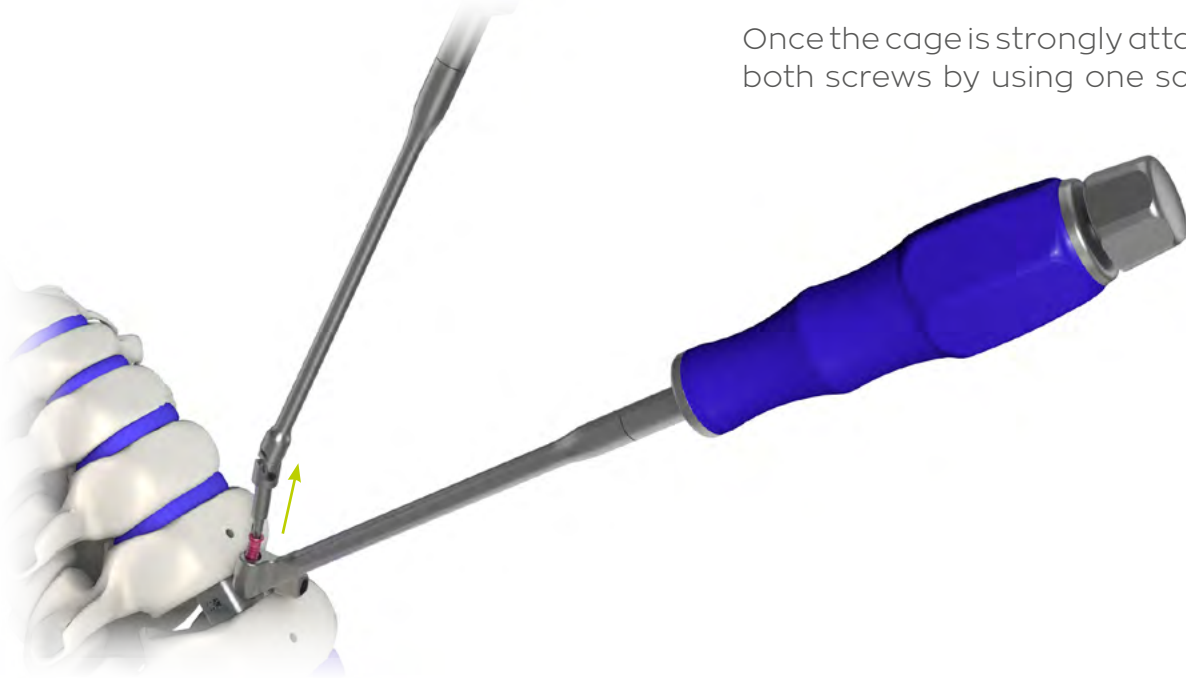
OR



Screwdriver
AC2-A034

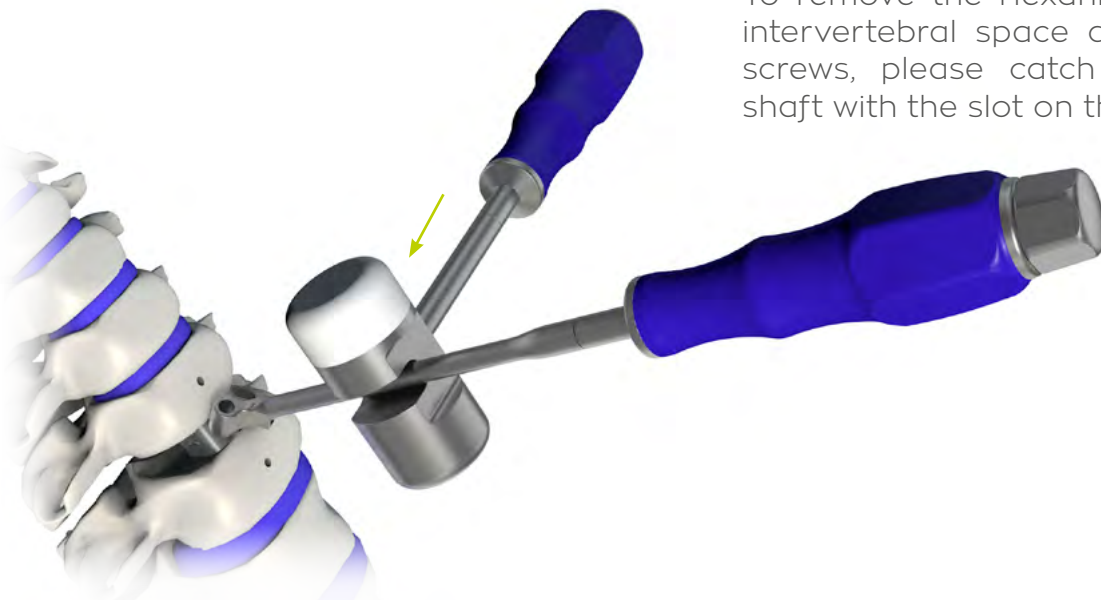
U-Joint Screwdriver
AC2-A035

Once the cage is strongly attached, remove both screws by using one screwdriver.



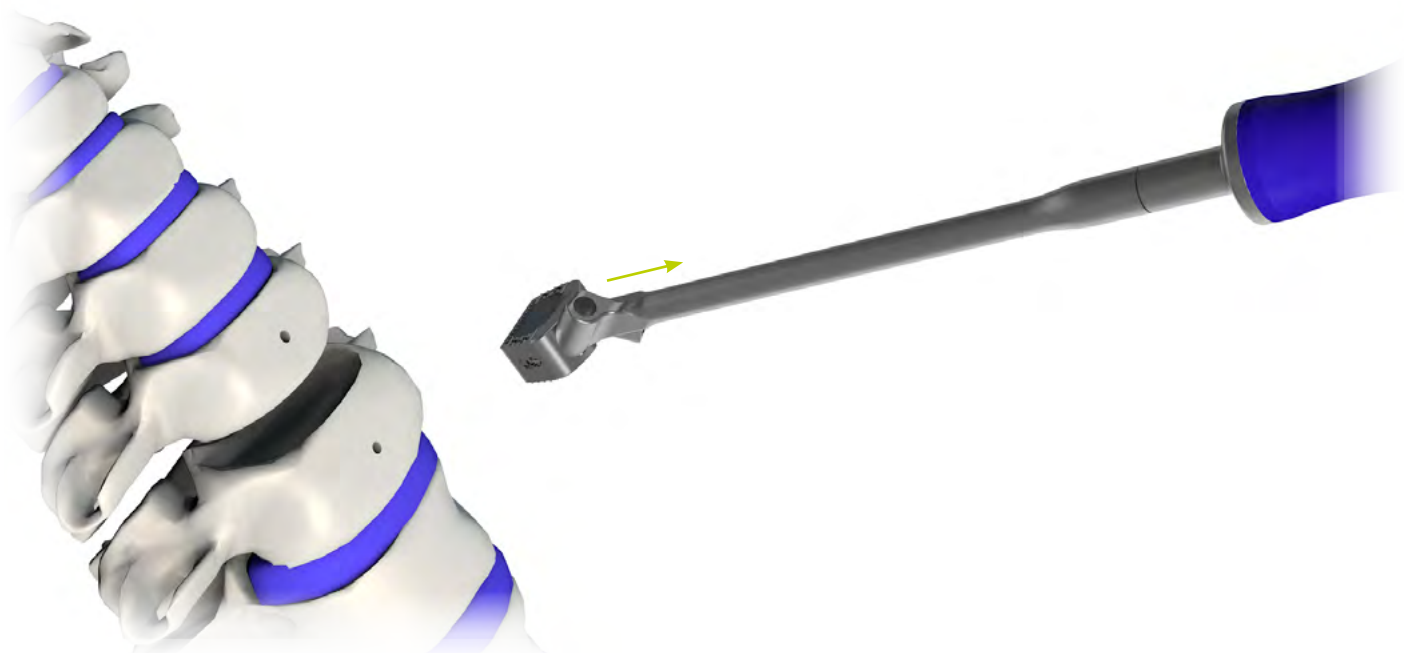
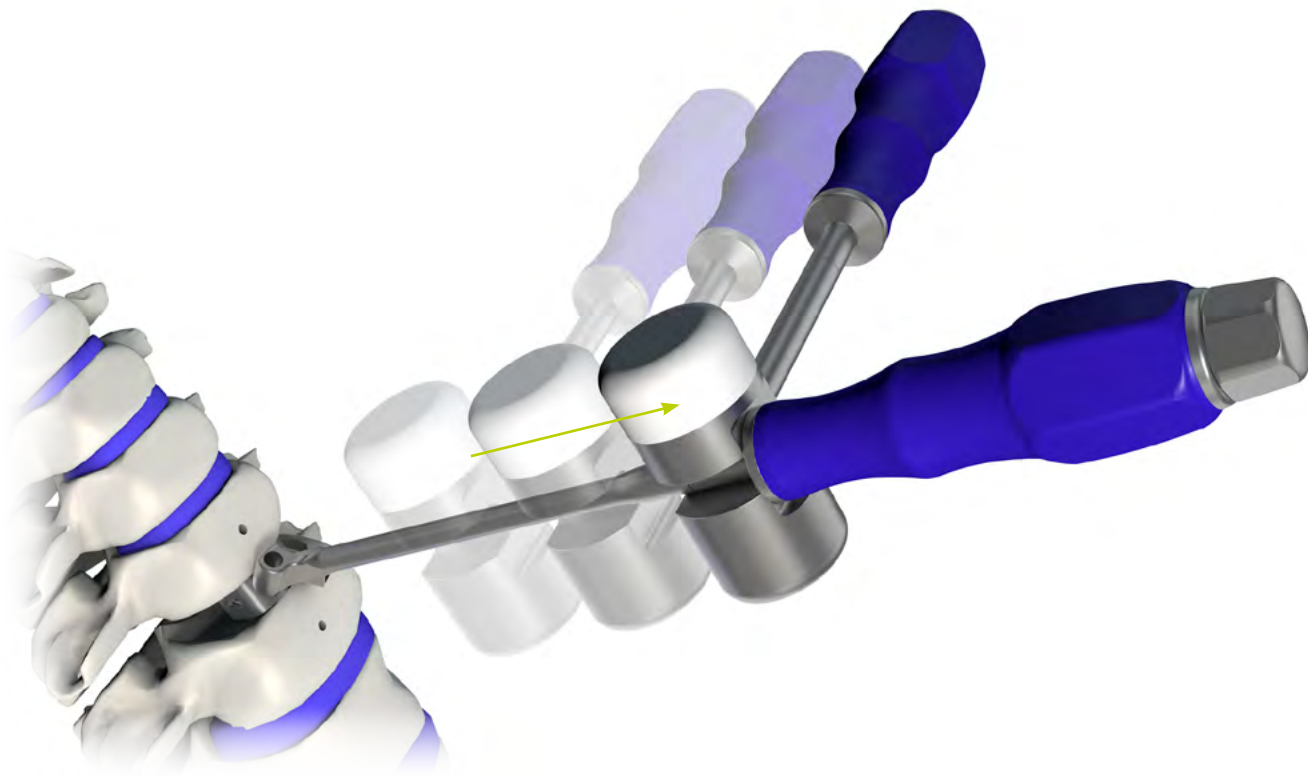
Mallet
AC2-A023

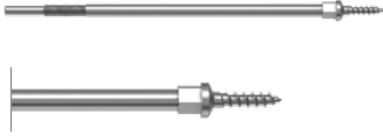
To remove the Hexanium ACIF from the intervertebral space after removing the screws, please catch the cage holder shaft with the slot on the **mallet AC2-A023**.



Once in position apply an upward force with the mallet toward the cage holder

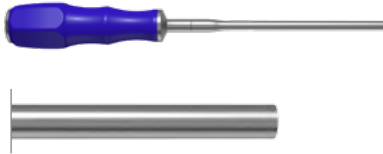
handle and repeat it until the cage is completely removed.





Pins for
Distractor/Compressor

AC2-A206



Driver for Pins

AC2-A216



Distractor/Compressor

AC2-A201



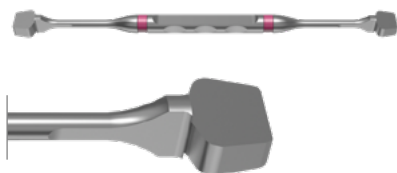
Plugs for Pins

AC2-A210



Rasp

AC2-A010



Lordotic or Convex
Ti Cervical Cage Trial

AC2-A011-XXXX



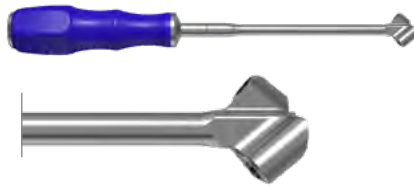
Mallet

AC2-A023



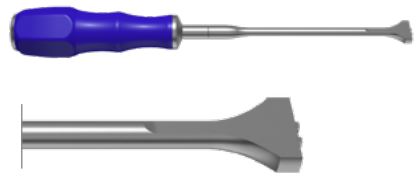
**Inner Shaft for
Ti Cervical Cage Holder**

AC2-A002



**Ti SA Cervical Cage
Holder with Guide**

AC2-A001G-XX



Ti Cervical Cage Holder

AC2-A001



**Ti Cervical Cage
Graft Packing Block**

AC2-A020



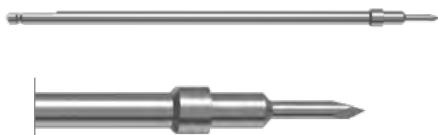
**Ti Cervical Cage
Cancellous Bone
Impactor**

AC2-A021



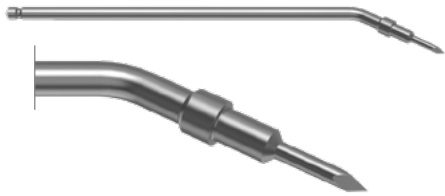
**Cylindrical
Snap-On Handle**

SD-ALSH26123PCAO



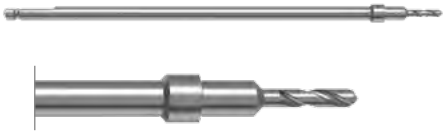
Bone Awl

AC2-A030



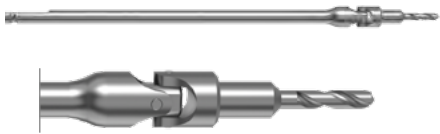
Angulated Bone Awl

AC2-A031



Straight Drill

AC2-A032



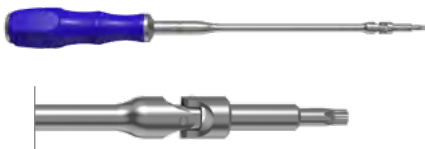
U-Joint Drill

AC2-A033



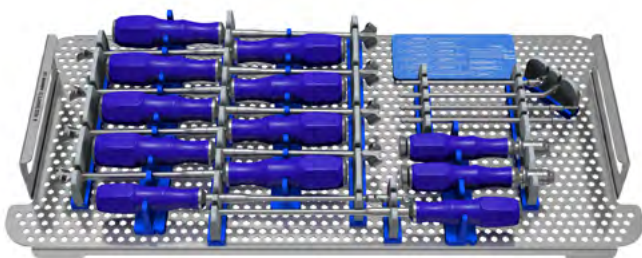
Screwdriver

AC2-A034



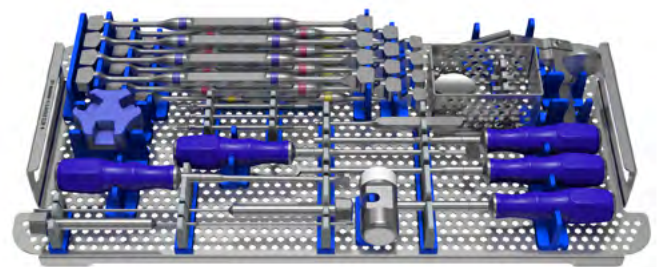
U-Joint Screwdriver

AC2-A035



Ti SA Cervical Tray

AC2-TRAY112



Ti Standard Cervical Tray

AC2-TRAY111

SV Common Base

SD-BASE11117 / SD-BASE1168

SCREWS



Length	Diameter : 3.5mm	Diameter : 3.8mm
10mm	AC2-SD3510S	AC2-SD3810S
12mm	AC2-SD3512S	AC2-SD3812S
14mm	AC2-SD3514S	AC2-SD3814S
16mm (*)	AC2-SD3516S (*)	AC2-SD3816S (*)

(*) Length 16mm is not available in Europe

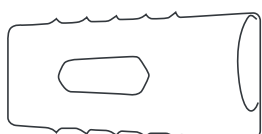
CAGES

AC2-CSXXX

X = Size Small (S) / Medium (M) / Large (L) (*)

XX = Height from 05 to 12mm (**)

X = WEDGE (L) / CONVEX (C)



WEDGE CAGE



Height	Wedge Cage Small 12 x 15mm	Wedge Cage Medium 14 x 17mm	Wedge Cage Large (*) 15 x 19mm
05mm	AC2-CSS05L	AC2-CSM05L	AC2-CSL05L
06mm	AC2-CSS06L	AC2-CSM06L	AC2-CSL06L
07mm	AC2-CSS07L	AC2-CSM07L	AC2-CSL07L
08mm	AC2-CSS08L	AC2-CSM08L	AC2-CSL08L
09mm	AC2-CSS09L	AC2-CSM09L	AC2-CSL09L
10mm	AC2-CSS10L	AC2-CSM10L	AC2-CSL10L
11mm (**)	AC2-CSS11L (**)	AC2-CSM11L (**)	AC2-CSL11L (**)
12mm (**)	AC2-CSS12L (**)	AC2-CSM12L (**)	AC2-CSL12L (**)

(*) Footprint L is not available in Europe

(**) Heights 11 and 12 are not available in Europe

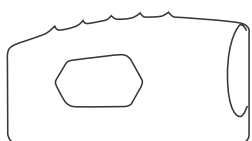
HEXANIUM ACIF FOOTPRINTS

Size Length x Width

S Small 12 x 15mm

M Medium 14 x 17mm

L Large (*) 15 x 19mm



CONVEX CAGE



Height	Convex Cage Small 12 x 15mm	Convex Cage Medium 14 x 17mm	Convex Cage Large (*) 15 x 19mm
05mm	AC2-CSS05C	AC2-CSM05C	AC2-CSL05C
06mm	AC2-CSS06C	AC2-CSM06C	AC2-CSL06C
07mm	AC2-CSS07C	AC2-CSM07C	AC2-CSL07C
08mm	AC2-CSS08C	AC2-CSM08C	AC2-CSL08C
09mm	AC2-CSS09C	AC2-CSM09C	AC2-CSL09C
10mm	AC2-CSS10C	AC2-CSM10C	AC2-CSL10C
11mm (**)	AC2-CSS11C (**)	AC2-CSM11C (**)	AC2-CSL11C (**)
12mm (**)	AC2-CSS12C (**)	AC2-CSM12C (**)	AC2-CSL12C (**)

(*) Footprint L is not available in Europe

(**) Heights 11 and 12 are not available in Europe

SPINEVISION®

Distributed by



SPINEVISION
10 Rue de la Renaissance
92160 ANTONY - FRANCE
Phone : +33 1 53 33 25 25

www.spinevision.net

CE 0123



See package insert
for labeling limitation

Non contractual
document GAC2-ST_03GB