3D PRINTED TITANIUM ACIF CAGE

3D PRINTED INTERBODIES

# Hexanium® ACIF

# SURGICAL TECHNIQUE

SPINE VISION

INNOVATION THAT MATTERS

# SURGICAL STEPS

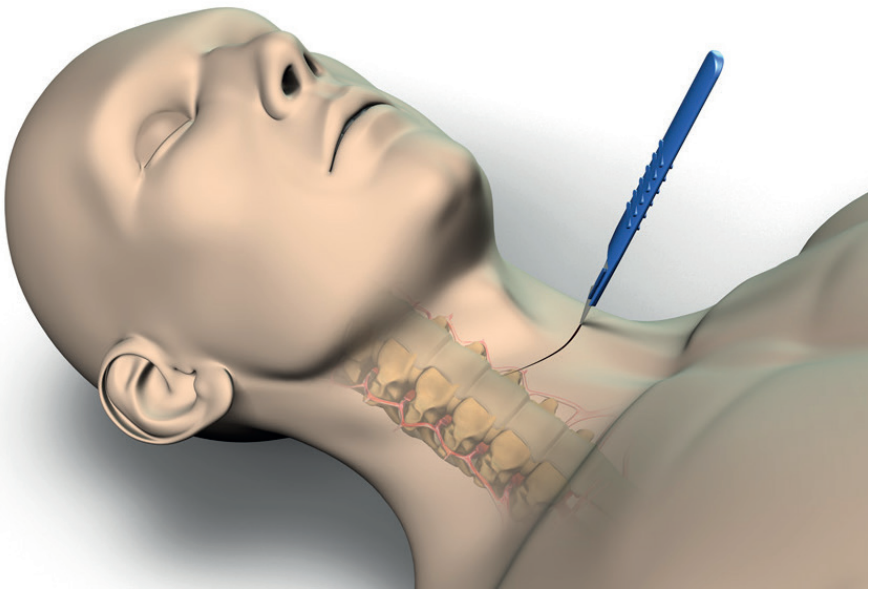


# REFERENCES

# PATIENT POSITIONING AND DISCECTOMY

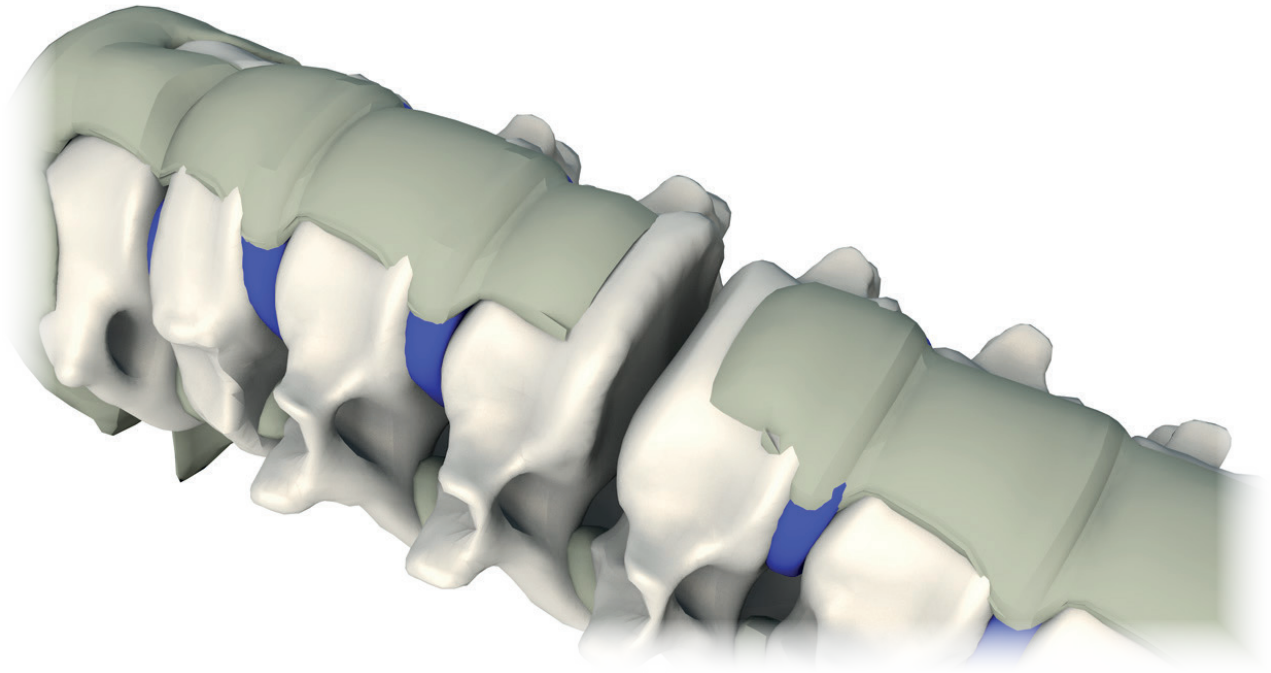
The patient is placed on the OR table using the standard position indicated for Anterior Cervical Interbody Fusion procedure: supine position with maintenance of cervical lordosis.

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.

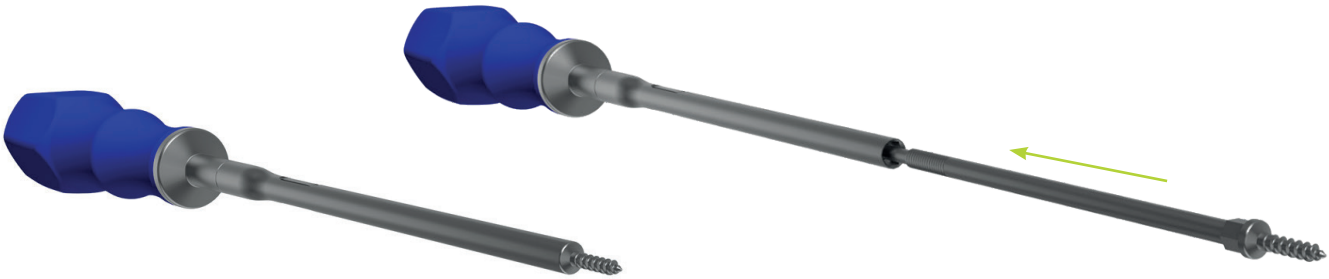


# PINS ASSEMBLY AND INSERTION

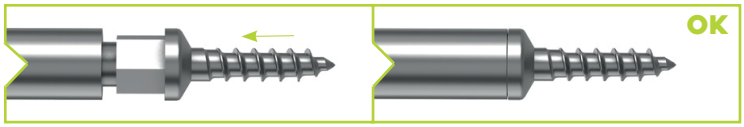
**Pins for Distractor/Compressor**
AC2-A206

**Driver for Pins**
AC2-A216

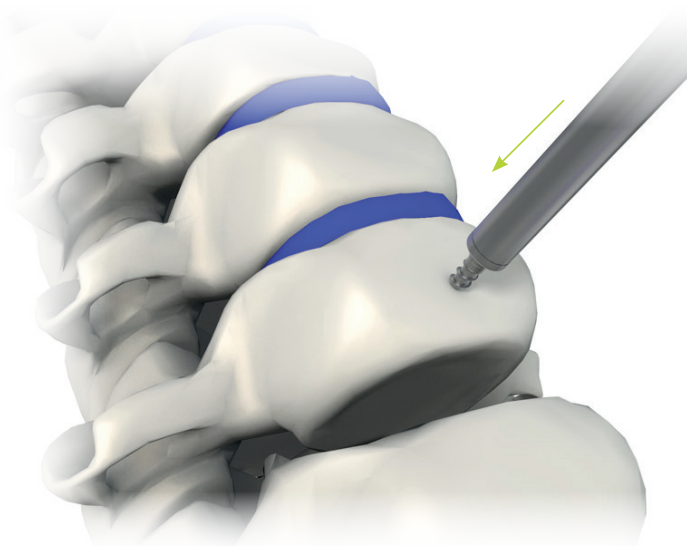
To connect the **pins for distractor/ compressor** *AC2-A206* to the **driver for pins** *AC2-A216*, slide the proximal part of the pins (without hexagonal tip) into the outer tube of the driver for pins.



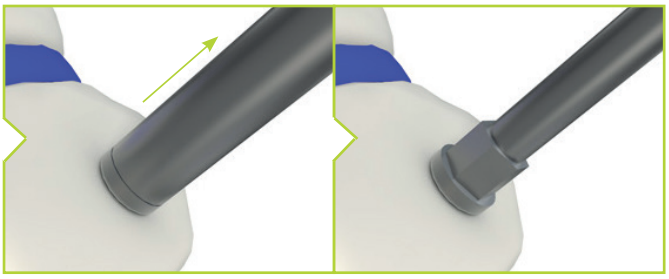
Be cautious that the hexagonal part of the pin is fully inserted into the driver for pin.

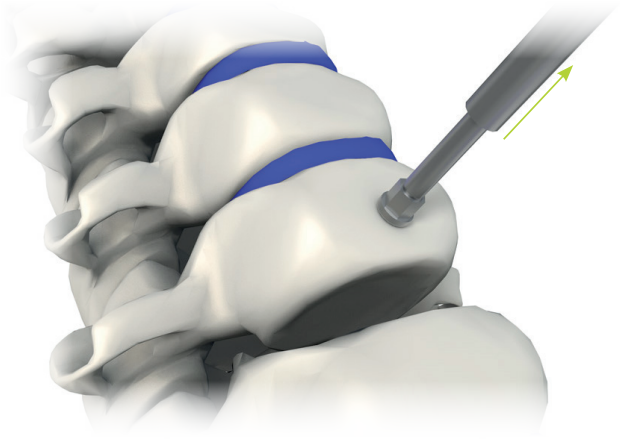



Directly insert the **pin for distractor/ compressor** into the vertebral body. The entry hole of the pin should be on the medial line and at the sagittal center of the vertebral body. Insert the pin until it is fully inserted into the vertebral body.



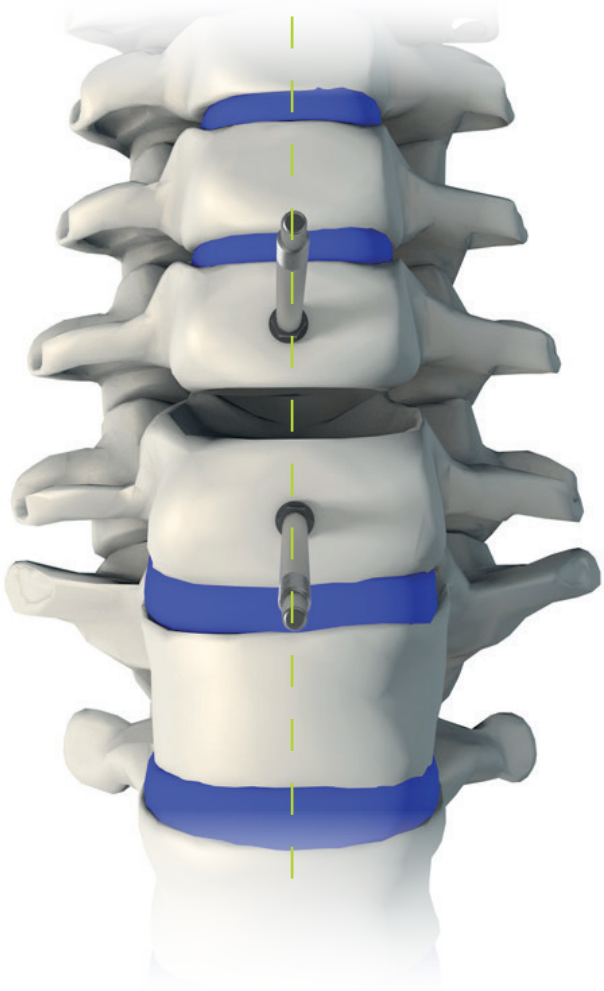
Once the pin is fully inserted, disconnect the **driver for pins** by pulling it upward leaving the pin into the vertebral body.



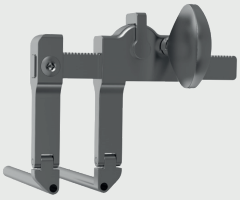


The second **pin for distractor/compressor** must be placed into the vertebral body of the lower vertebrae of the operated level. The two pins must be sagitally aligned together on the medial line.

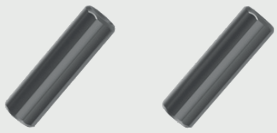
Connect the second pin to the driver for pins as described above and fully insert it in the vertebral body.



# DISTRACTOR / COMPRESSOR PLACEMENT AND SEGMENTAL DISTRACTION



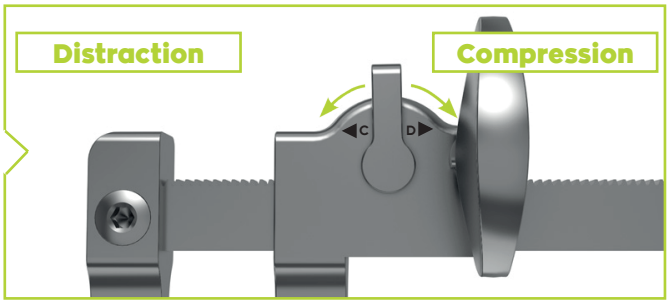
**Distractor/Compressor**
AC2-A201



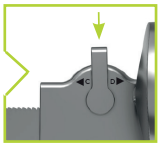
**Plugs for Pins**
AC2-A210

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

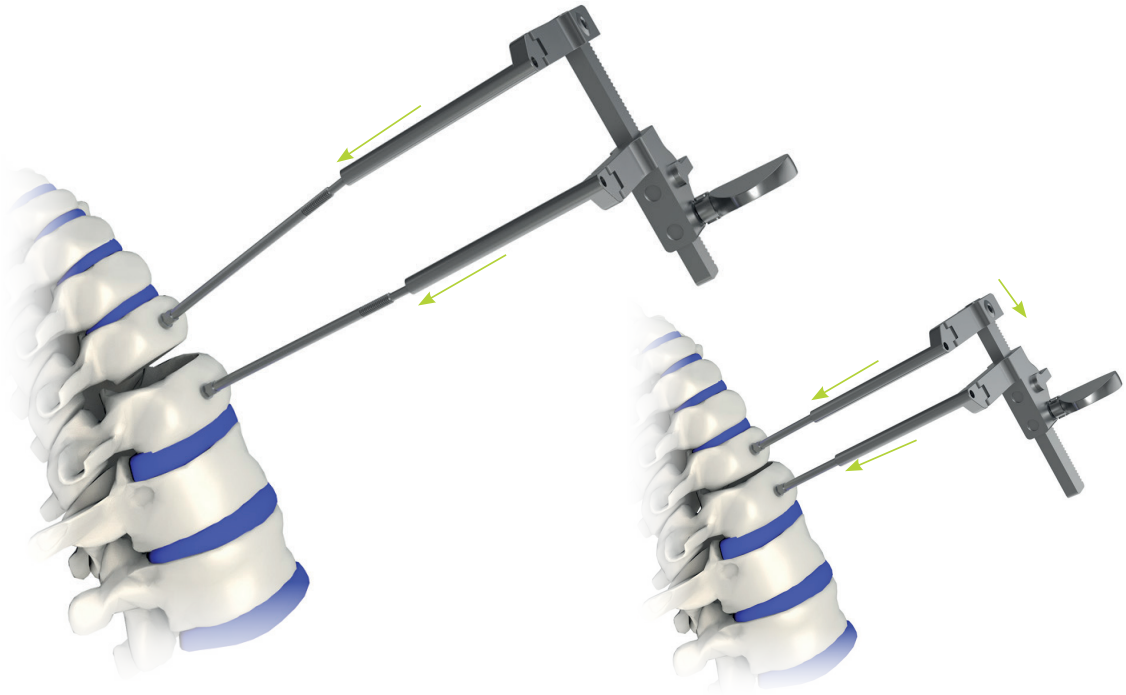
Segmental distraction is mandatory to restore disc height and ensure an accurate and safe placement of the cage.



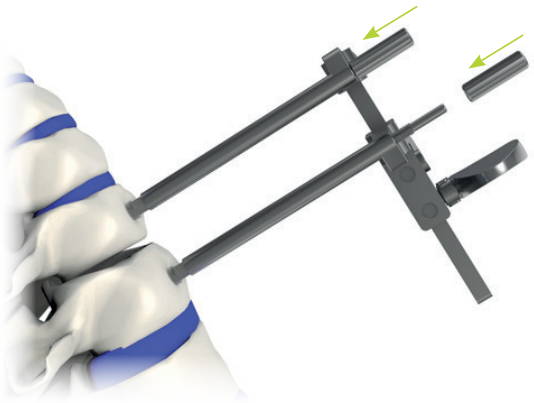

Position the pivoting « arm » of the distractor/compressor above the free part of the pins for distractor/compressor *AC2-A206* and slide the arms of the distractor/compressor down through the pins.

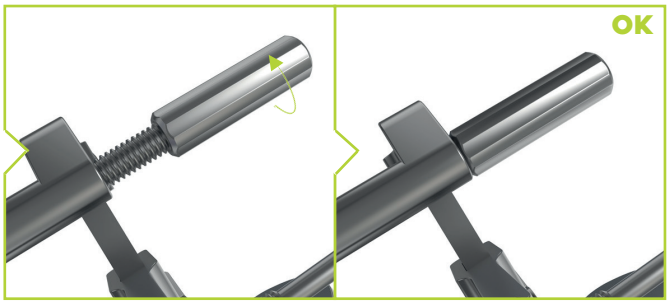


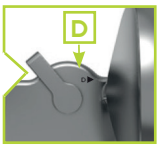
Place the D/C into neutral position to adjust the « spacing » between the D/C arms and facilitate the D/C placement.



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.



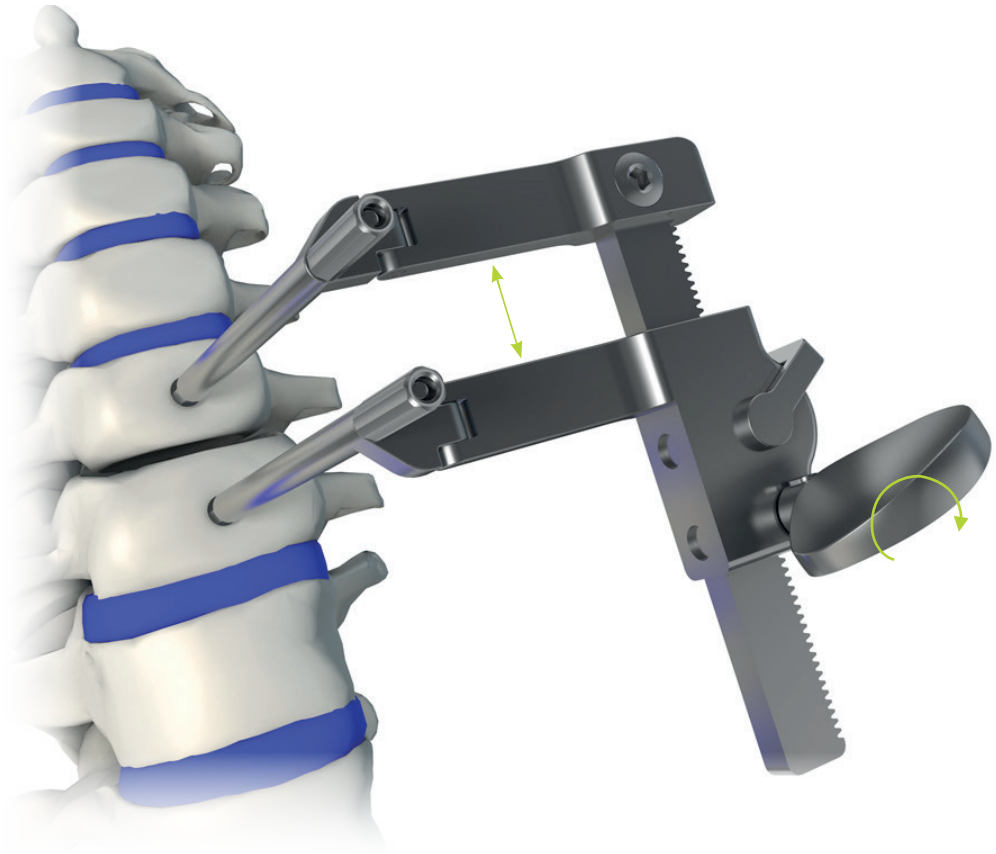



To distract the intervertebral space prior to cage positioning, place the **distractor/compressor** *AC2-A201* on distraction position **D**.

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.***



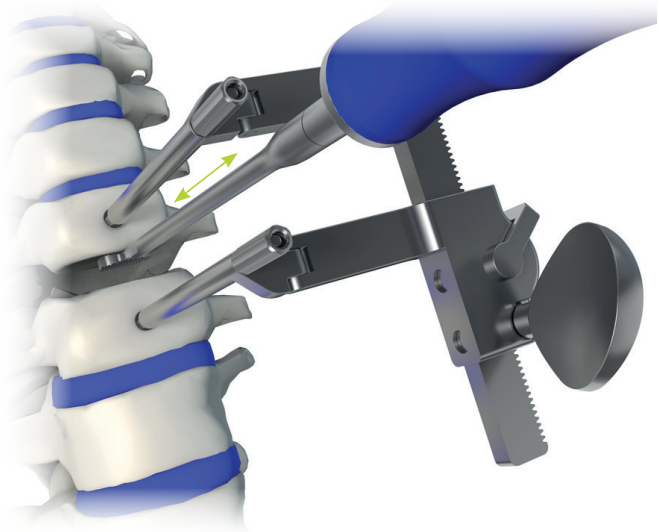
# ENDPLATE PREPARATION

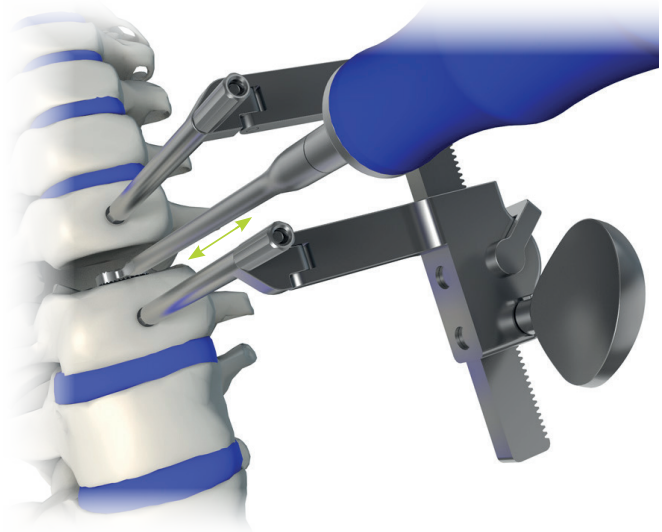
**Rasp**
AC2-A010

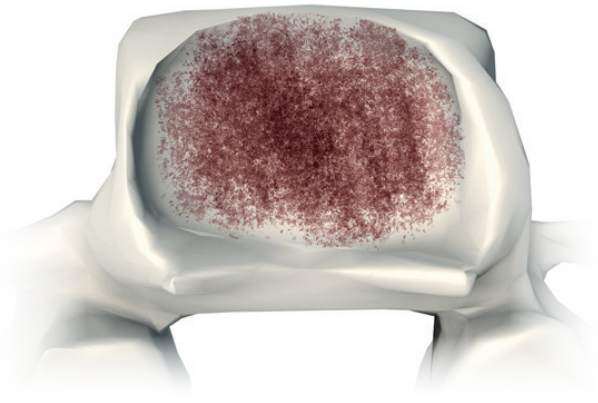
Once distraction of the intervertebral space is performed, use the **rasp** *AC2-A010* to prepare the enplates. Enter the intervertebral space placing the rasp parallel to endplates and use it to remove superficial cartilaginous tissue of the endplates.

The rasp is used to reveal the bleeding bone and ensure good vascularization of the Hexanium 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.***

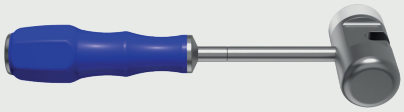






# IMPLANT'S SIZE ESTIMATION

**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 heights at both trial sides.
(Ex. : XX = 05 for height 05 & 06)

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

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 verterbrae.

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

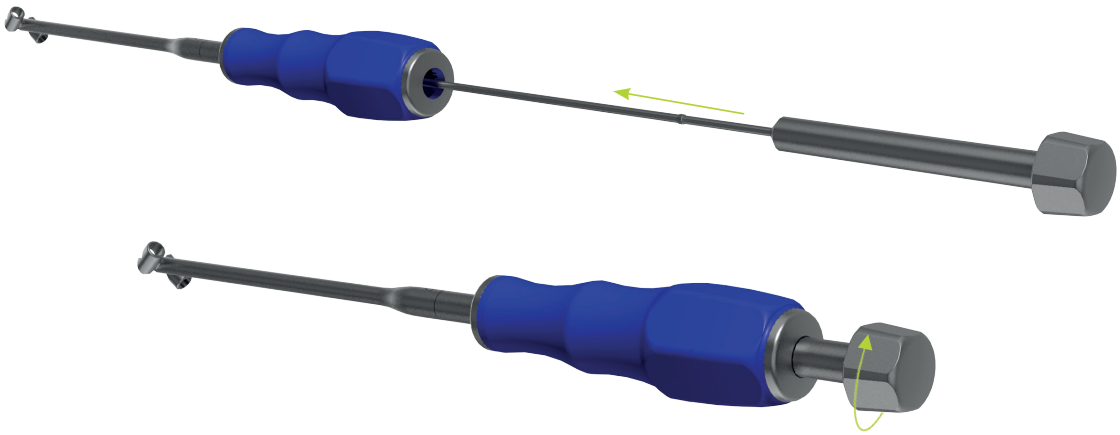
**Ti SA Cervical Cage Holder with Guide**
AC2-A001G-XX

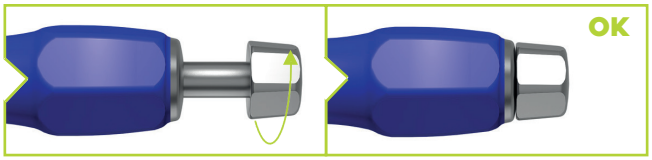
OR

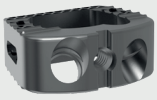
**Ti Cervical Cage Holder**
AC2-A001

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.

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

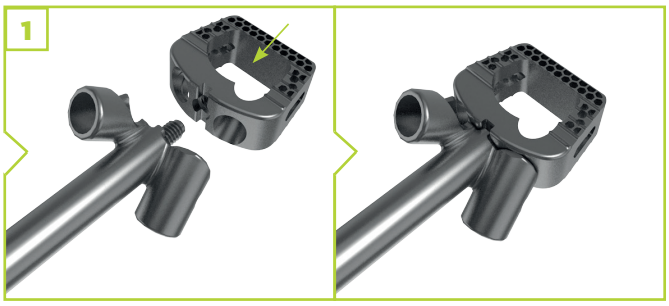




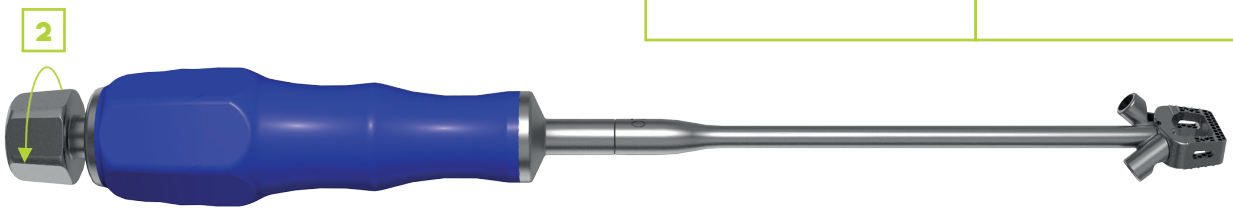



**Ti SA Cervical Cage**
AC2-CSXXXX

**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 clockwisely 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.


# VII CAGE BONE GRAFT FILLING

**Ti Cervical Cage Graft Packing Block**
AC2-A020

**Ti Cervical Cage Cancellous Bone Impactor**
AC2-A021

OR

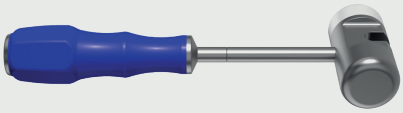
**Cage connected to the Cage Holder**
AC2-CSXXXX + AC2-A001 + AC2-A002

**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.

# CAGE INSERTION



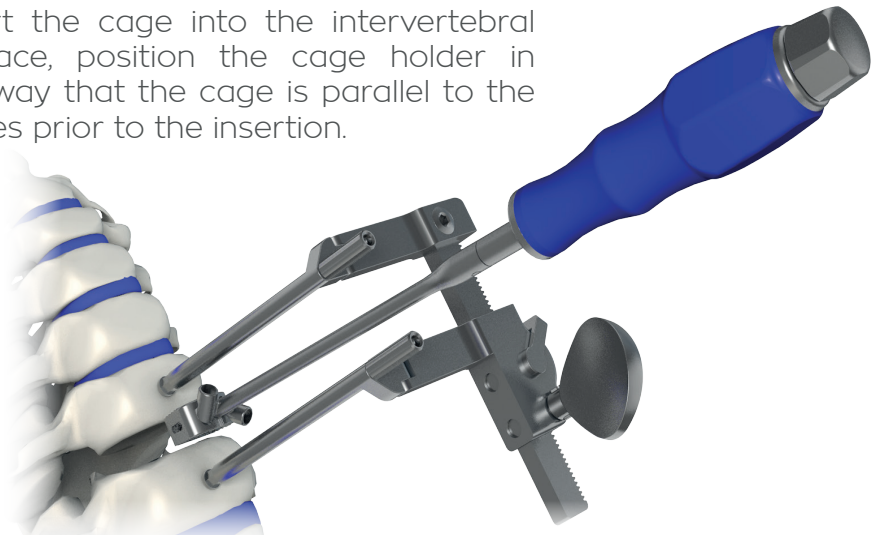
**Mallet**
AC2-A023

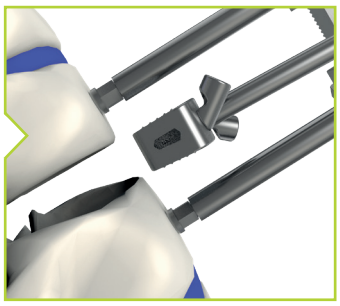
OR

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

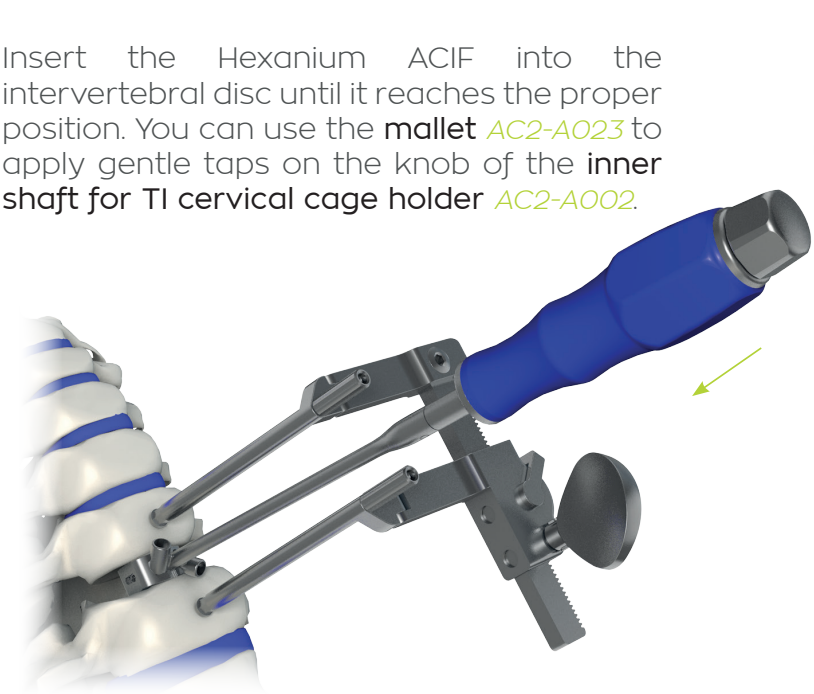
**Cage connected to the Cage Holder with Guide**
AC2-CSXXXX + AC2-A001G-XX + AC2-A002

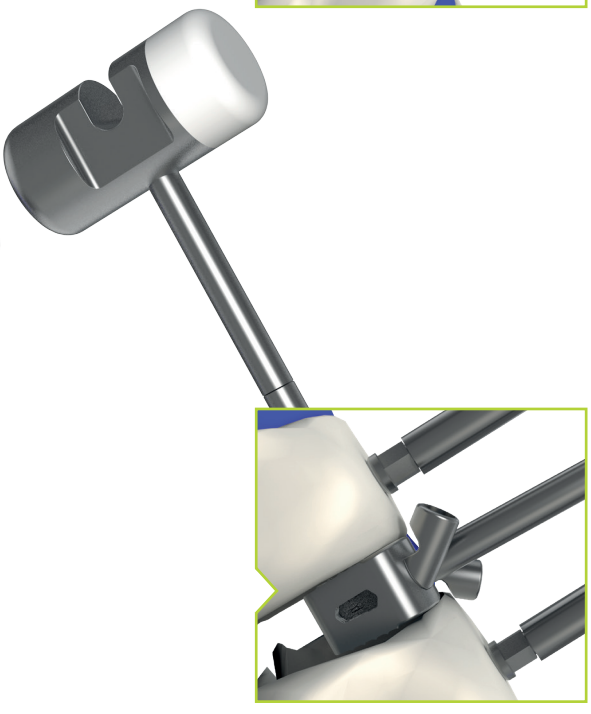
To insert the cage into the intervertebral disc space, position the cage holder in such a way that the cage is parallel to the endplates prior to the insertion.





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.***

**! WARNING !**
***The cage cannot be implanted without the screws! Screws MUST be locked into the cage before closing up.***

# IX PILOT HOLE PREPARATION

**Cylindrical Snap-On Handle**
SD-ALSH26123PCAO

OR

**Bone Awl**
AC2-A030

**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** *SDALSH26123PCAO*:

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

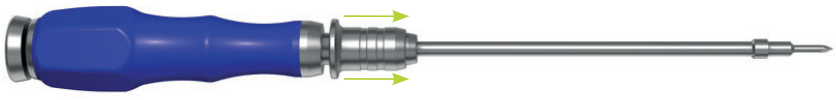
**2** While maintaining this position, insert the proximal part of the bone awl into the handle.

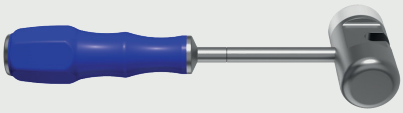
**3** Release the ring of the handle to secure the connection between the two instruments.

1

2

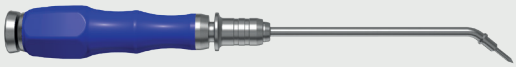
3





**Mallet**
AC2-A023

OR



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

**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

OR

**Straight Drill**
AC2-A032

**U-Joint Drill**
AC2-A033

+

**Sleeve for U-joint**
AC2-A036

The Hexanium ACIF kit offers two instruments for drilling: a **straight drill** *AC2-A032* or a **U-joint drill** *AC2-A033* which can be assembled with the **Sleeve for U-joint** *AC2-A036*.

To assemble the **Sleeve for U-joint** *AC2-A036* to its **U-joint drill** *AC2-A033*:

**1** Place the tip of the drill into the distal part of the sleeve, and leave the shaft of the drill inside the half-sleeve.

**2** Slide the second part of the sleeve along the first part, while pressing on the knob of the sleeve, until it connects. Release the knob when connected.

**3** Connect the **cylindrical snap-on handle** *SDALSH26123PCAO* *(see details on page 13)*.

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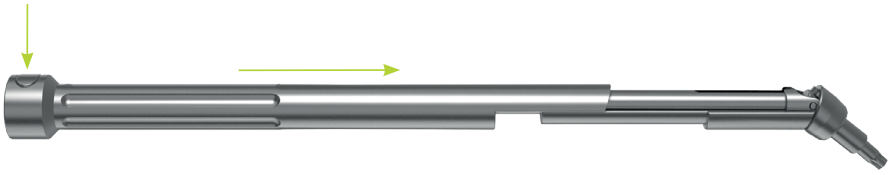


***Please note that Hexanium ACIF screws are self drilling screws, the drilling step being optional.***

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

OR

**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* assembled with the Sleeve for U-joint *AC2-A036*, into the guide/inserter.

Once the tip of the drill meets the endplate **1**, turn clockwisely 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 clockwisely to remove the drill.


# XI SCREW INSERTION

Screwdriver Shaft connected to the Cylindrical Snap-On Torque Limiting Handle
SD-ALSH26123PCAOTL13 + AC2-A037

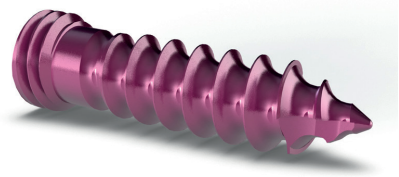
OR

U-Joint Screwdriver with Sleeve connected to the Cylindrical Snap-On Torque Limiting Handle
SD-ALSH26123PCAOTL13 + AC2-A035 + AC2-A036

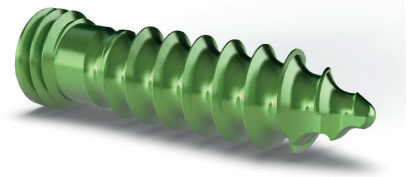
Ti Cervical Cage Graft Packing Block
AC2-A020

Screw may be inserted using either the screwdriver shaft *AC2-A037* or the U-joint screwdriver *AC2-A035* associated with the Sleeve for U-Joint *AC2-A036*, all connected to the Cylindrical Snap-On Torque Limiting Handle *SD-ALSH26123PCAOTL13*.
Hexanium ACIF screws are provided in a sterile packaging.

**! WARNING !**
***Screwdrivers MUST be use with the torque limiting (black handle). It is forbidden to use the ratcheting handle (blue handle)***



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

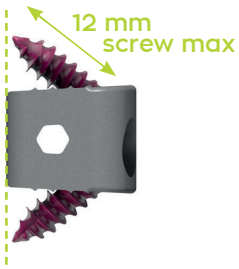


Diameter : **3.8 mm**
Length: 10 / 12 / 14 / 16 mm
Ref : AC2-SD38XXS (XX = Length)

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

**! 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.



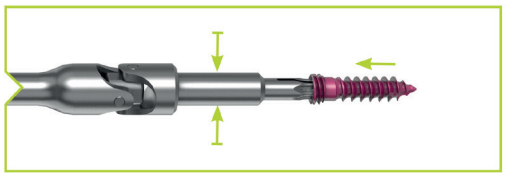

**Medium Footprint**
14mm screws almost come flush with posterior edge of cage. Longer screw will protude.


**Large Footprint**
16mm screws almost come flush with posterior edge of cage.

The **Screwdriver shaft** *AC2-A037* or the **u-joint screwdriver** *AC2-A035* feature a self retaining tip.


Before connecting the screw to the screwdriver, you can place the screw inside the dedicated location of the **Ti cervical cage graft packing block** *AC2-A020*. To connect the screw on the screwdriver, , then use a « stab & grab » motion and make sure that the screw is strongly attached to the screwdriver.

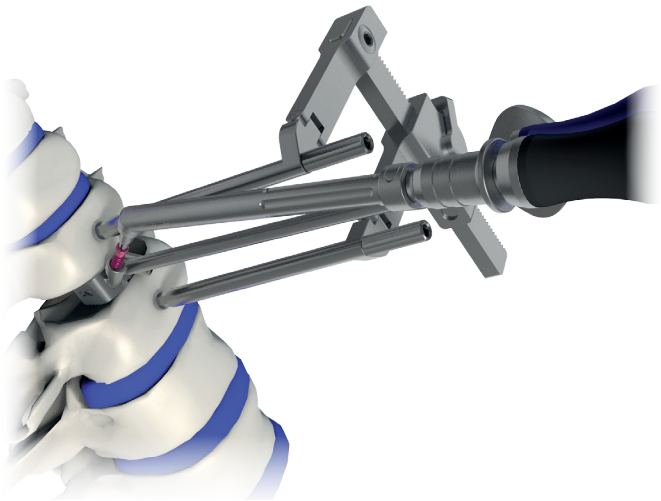
***If using the U-joint screwdriver without sleeve, pay attention to hold the screwdriver by the u-joint part to avoid any motion of the tip during the connection.***

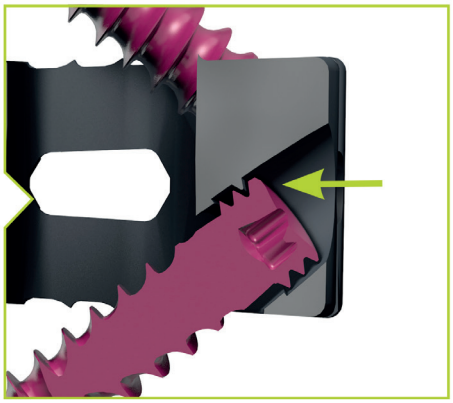


Once connected, slide the screw and screwdriver's tip through the guide into the hole prepared in the previous steps.

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

Use the **Cylindrical Snap-On Torque Limiting Handle** *SD-ALSH26123PCAOTL13* for the final tightening. Turn clockwise until it clicks 3 times.





*The thread of the screw head must be present in the most anterior thread of the cage which should not be visible when removing the screwdriver.*

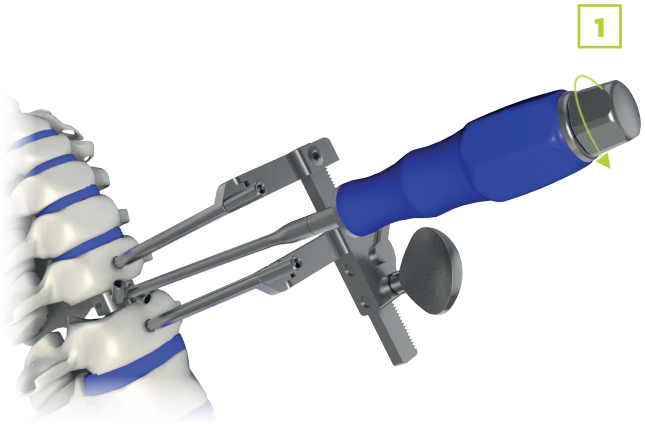
Repeat the 3 previous steps on the other side to insert the second screw.

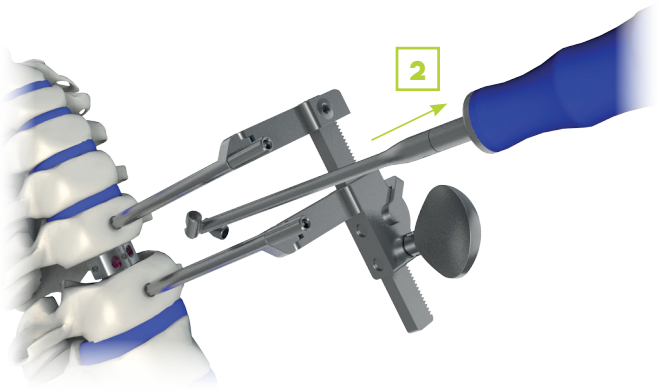
**! WARNING !**
*Final tightening MUST be done with the torque limiting handle (black handle)*

XII

## CAGE RELEASE

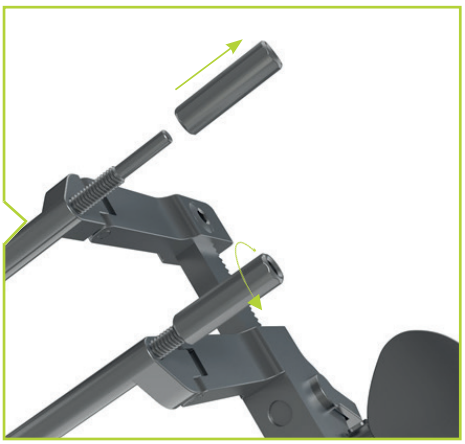
To release the Hexanium ACIF cage once both screws are placed, turn the inner shaft for Ti cervical cage holder knob counter-clockwise until the cage is free **1** and the cage holder can be disconnected **2**.

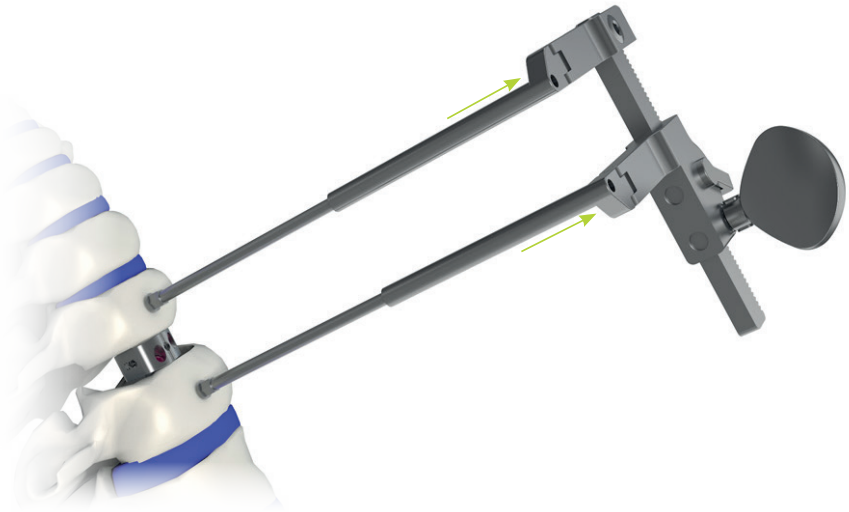


To remove the distractor/compressor : first counter clockwisely turn the **plug for pins** *AC2-A210* on each pins to remove it.

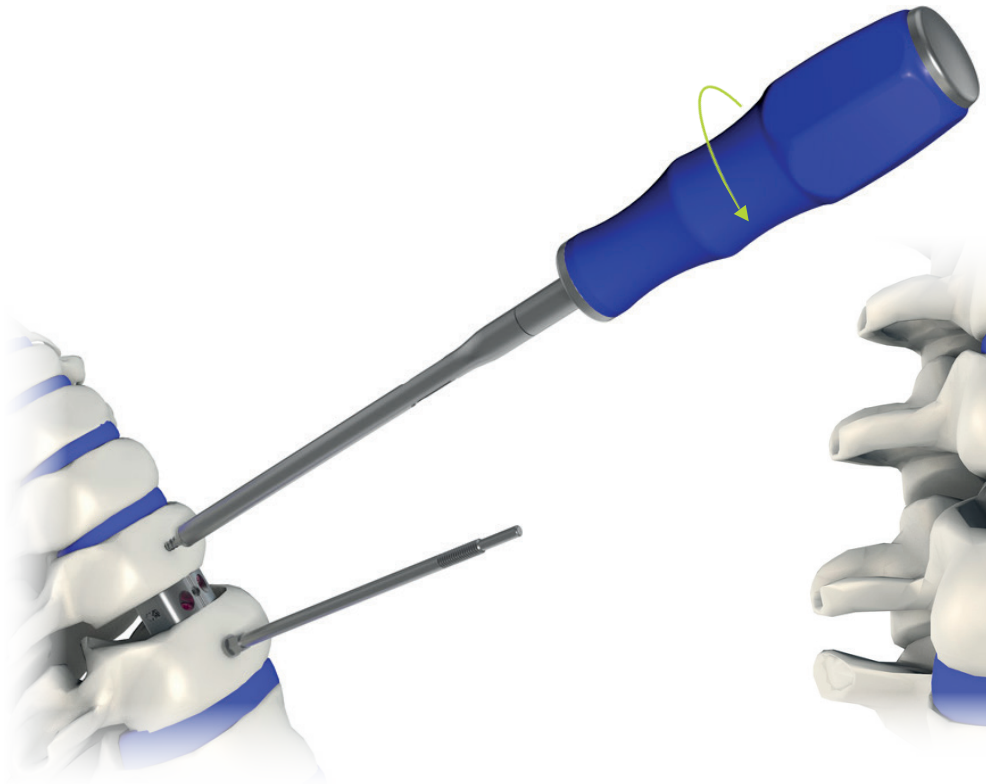
Then slide the arm of the D/C up the pins until you can entirely remove it.

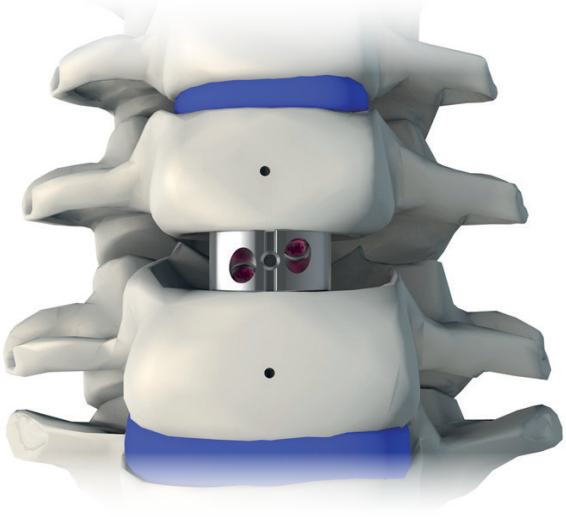




**Driver for Pins**
AC2-A216

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.





# XIII CAGE REMOVAL (OPTIONAL)

**Inner Shaft for Ti Cervical Cage Holder**
AC2-A002

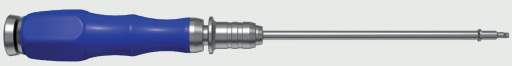
**Ti SA Cervical Cage Holder with Guide**
AC2-A001G-XX

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* clockwisely to screw the inner shaft in the cage's thread **2**.

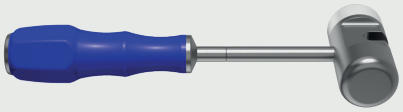



OR

**Screwdriver Shaft connected to the Cylindrical Snap-On Handle**
SD-ALSH26123PCAO + AC2-A037

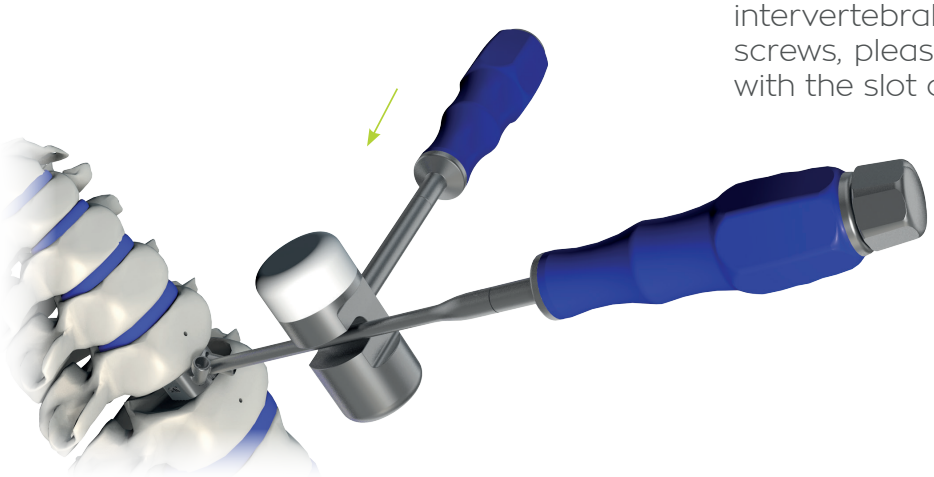
**U-Joint Screwdriver with Sleeve connected to the Cylindrical Snap-On Handle**
SD-ALSH26123PCAO + AC2-A035 + AC2-A036

Connect the **screwdriver shaft** *AC2-A037*, or the **U-joint screwdriver** *AC2-A035*, or the **Short U-joint screwdriver** *AC2-A040*, to the **Cylindrical Snap-On Handle** *SD-ALSH26123PCAO* *(see details of previous step on page 13)*.
Once the cage is strongly attached, remove both screws by using one screwdriver.

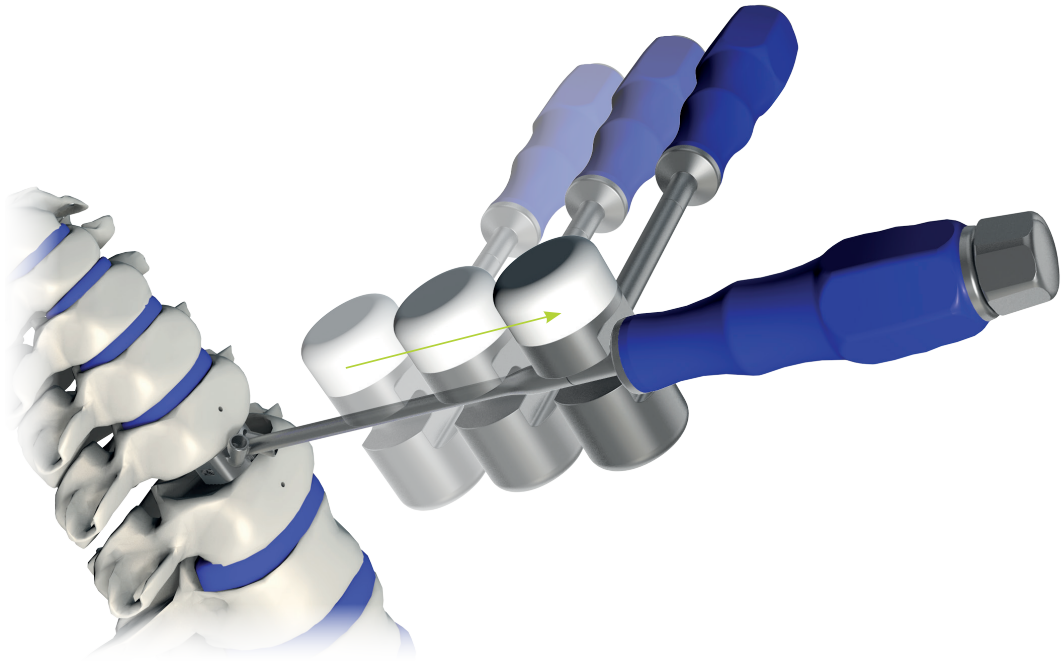


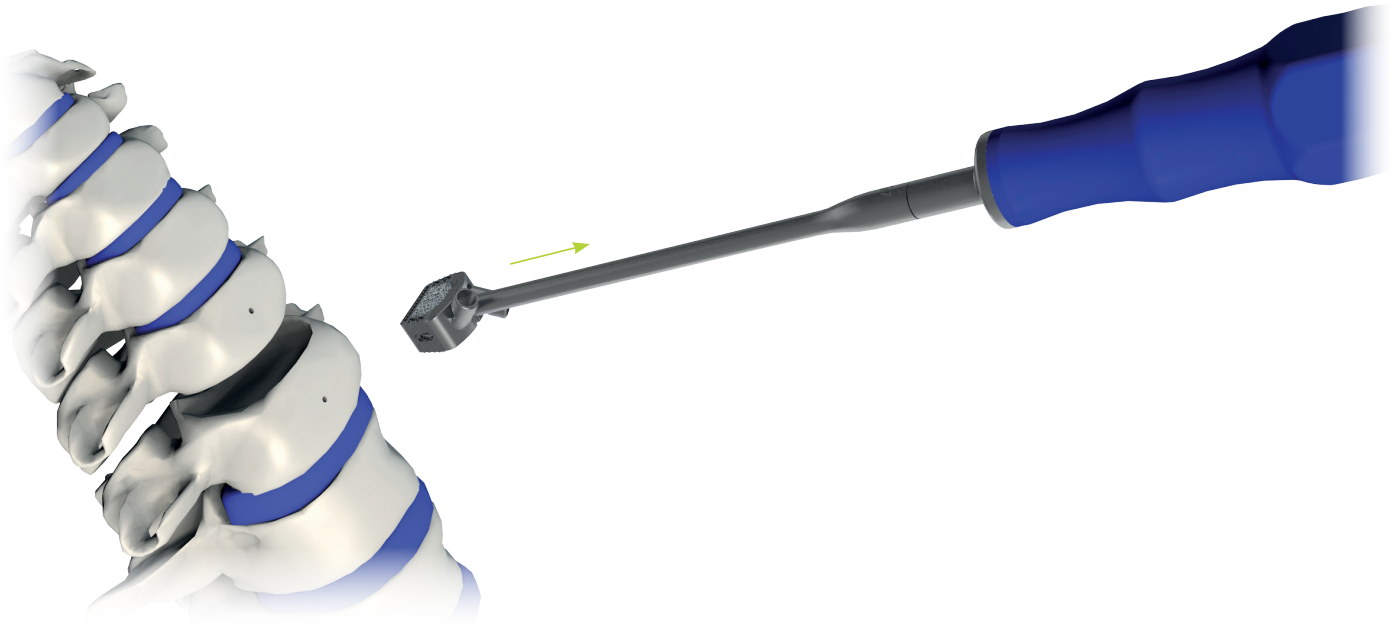
**Mallet**
AC2-A023

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*.

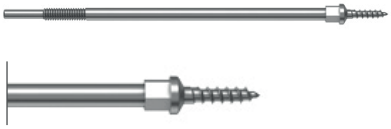
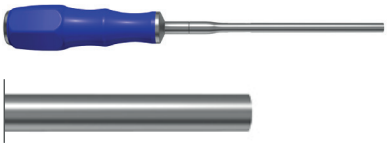
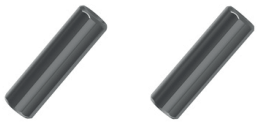
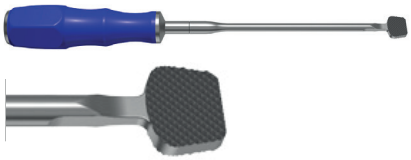
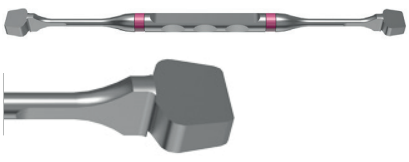
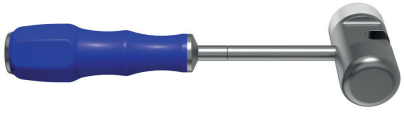


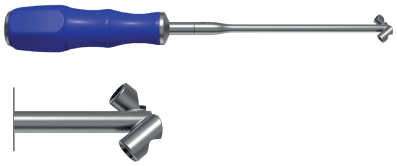
Once in position apply an upward force with the mallet toward the cage holder handle and repeat it until the cage is completely removed.



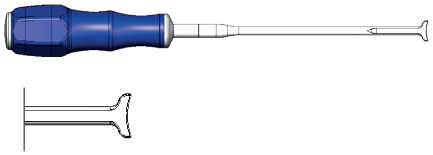


# INSTRUMENTS

| | | |
|---|---|---|
|  | **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 |

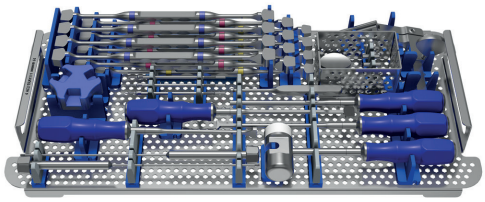
| | | |
|---|---|---|
|  | **Inner Shaft for Ti Cervical Cage Holder** | AC2-A002 |
|  | **Ti SA Cervical Cage Holder with Guide** | AC2-A001G-XX |
|  | **Ti Cervical Cage Holder** | AC2-A001 |
|  | **Ti Cervical Cage Graft Packing Block** | AC2-A020 |
|  | **Ti Cervical Cage Cancellous Bone Impactor** | 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 Shaft** | AC2-A037 |
|  | **U-Joint Screwdriver** | AC2-A035 |
|  | **Cylindrical Snap-On Torque Limiting Handle** | SD-ALSH26123PCAOTL13 |
|  | **Sleeve for U-Joint** | AC2-A036 |

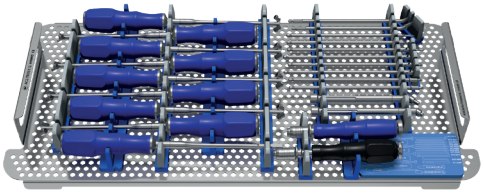


**Ti Cervical Cage Repositioner**

AC2-A022



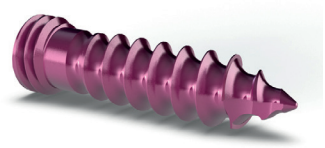
**Ti Standard Cervical Tray**
AC2-TRAY111

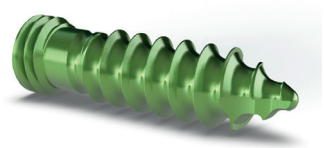


**Ti SA Cervical Tray**
AC2-TRAY112

**SV Common Base**
SD-BASE11117

# SCREWS





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

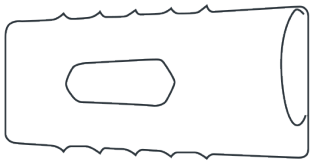
# CAGES

AC2-CSXXXX

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

XX = Height from 05 to 12mm

X = WEDGE (L) / CONVEX (C)

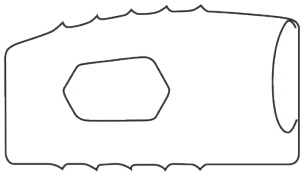


WEDGE CAGE

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

# HEXANIUM ACIF FOOTPRINTS

| Size | | Length x Width |
|---|---|---|
| S | Small | 12 x 15 mm |
| M | Medium | 14 x 17 mm |
| L | Large | 15 x 19 mm |



## CONVEX CAGE

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

# NOTES

# NOTES

# NOTES

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