3D PRINTED TITANIUM STAND ALONE ACIF CAGE

3D PRINTED
INTERBODIES

Hexanium® ACIF

SURGICAL TECHNIQUE

SPINEVISION

INNOVATION THAT MATTERS

SpineVision® Hexanium ACIF: Anterior Cervical Interbody Fusion device

Purpose
The Hexanium ACIF (Anterior Cervical Interbody Fusion) system is intended as a standalone intervertebral body fusion device of the cervical spine (C3-T1). It is intended to be implanted via an anterior approach to give a primary stability of the cervical column (with or without restoring disc height) until fusion occurs.

Description
The Hexanium ACIF system consists of a cage and two bone screws for standalone intervertebral body fusion of the cervical spine (C3-T1). The Hexanium ACIF cages are available in various endplate shape, height, width and depth. The Hexanium ACIF screws are available in various length and diameter.
The hollow geometry of the cages allows them to be packed with autogenous bone graft.
The Hexanium ACIF must be filled with autogenous bone graft to enhance the bone fusion.
All cages and bone screws are manufactured from implant grade Titanium (Ti6Al4V ELI compliant with ASTM F3001 and F136, respectively).

Indications
The Hexanium ACIF (Anterior Cervical Interbody Fusion) system is intervertebral body fusion device indicated for use with autogenous bone graft in skeletally mature patients with Degenerative Disc Disease (DDD) at one level from C3-T1. DDD is defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least 6 weeks of non-operative treatment prior to treatment with Hexanium ACIF system. This device has to be filled with autogenous bone graft material. This device is implanted via an anterior approach.

Contraindications
This device is not intended for thoracic or lumbar spine use.
Contraindications include, but are not limited to:
- infection, local to the operative site;
- signs of local inflammation;
- fever or leukocytosis;
- morbid obesity;
- pregnancy;
- pediatric cases, or patient still having general skeletal growth;
- spondylolisthesis unable to be reduced to Grade I;
- suspected or documented allergy or intolerance to composite materials;
- any case where the implant components selected for use would be too large or too small to achieve a successful result;
- any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality;
- any patient in which implant utilization would interfere with anatomical structures or expected physiological performance;
- prior fusion at the level to be treated;
- any case not needing a bone graft or fusion;
- any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis;
- any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- mental illness;
- any patient unwilling to cooperate with postoperative instructions.

The contraindications of these devices are similar to those of other spinal interbody systems. This spinal instrumentation is not designed, or intended, or sold for uses other than those indicated.

Potential Adverse Events
In addition to the risks associated with spinal surgery without instrumentation, the following potential adverse events can occur (non-exhaustive list):
- delayed union;
- non-union (or pseudoarthrosis);
- bone fracture or stress shielding at, above, or below the level of surgery, microfracture, resorption, or damage of any spinal bone (including pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site;
- retropulsed graft;
- loosening, or migration of implant, that may result in paralysis, neurological disorders or blood vessel erosion due to the proximity of the device;
- loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain, neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury, cerebral spinal fluid leakage
- infection;
- hemorrhage of blood vessels and/or hematomas;
- discitis, arachnoiditis, and/or other types of inflammation;
- subsidence of implant into adjacent vertebral bodies resulting in loss of height and possible impingement of neural structures;
- loss of proper spinal curvature, correction, height, and/or reduction;
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus, disc disruption or degeneration above, or below the level of surgery;
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- foreign body reaction due to the presence of implants, such as a mass, auto-immune disease and/or impaired healing;
- cessation of any potential growth of the operated portion of the spine,
- deep venous thrombosis, thrombophlebitis;
- development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.;
- bone graft donor site complication;
- urinary retention or loss of bladder control or other types of urological system compromise;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- change in mental status;
- incapacity to resume the activities of normal everyday life;
- Death.

Note: Some potential adverse events may require an additional surgical revision procedure.

Storage and packaging
Packages for each of the components should be intact upon receipt. Care should be taken not to damage the implants when opening the packaging. For implant supplied in a sterile form, carefully check that the seal on the cardboard box is intact before you open the box. Damaged packages or products must not be used. If in doubt, please send them back to SpineVision®.

Cleaning and sterilization
Hexanium ACIF implants are delivered sterile by exposure to a minimum dose of 25kGy of gamma radiation. They must be never resterilized.
Hexanium ACIF implants must only be used with the Hexanium ACIF ancillary equipment. Hexanium ACIF ancillary equipment is not supplied sterile and must be sterilized before use.
All packaging and labeling materials must be removed prior to sterilization. Decontamination and cleaning must be performed before sterilization. For details regarding the following sections, please refer to instructions for cleaning, sterilization, inspection and maintenance (lubrication) of SpineVision® medical devices provided with the sets.

For cleaning and decontamination of the non-sterile instruments at the Healthcare facility:
It is recommended to use a neutral pH, enzymatic and alkaline (pH < 11) cleaning agents solution and deionized or distilled warm (room temperature) water of soaking, cleaning and rinsing.
Dismantle the necessary instruments. Articulated instruments must be opened.
Inspect each device and repeat the washing in the presence of any residual debris, paying close attention to threads, cannulas, hinges and hard to reach areas.
Note: Certain cleaning solutions, such as those containing bleach or formaldehyde, may damage certain components and must not be used, except for aluminum instruments used on high-risk patients.

Sterilization
Prior to use, Hexanium ACIF instruments should be steam sterilized according to the following parameters:

Method	Steam	Steam	Steam
Cycle	Pre-vacuum	Pre-vacuum	Pre-vacuum
Temperature	134° (273°F) See note 1	134° (273°F) See note 1	132° (270°F)
Minimum exposure time	3 minutes	18 minutes	4 minutes
Minimum drying time	30 minutes	30 minutes	30 minutes

Validations were performed with dynamic-air-removal steam sterilization process.

Note 1: These sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Lubrication specifications
SpineVision® recommends the lubrication instruments with moving or articulating parts. The instruments must be lubricated after each pre-disinfection / decontamination and before each steam sterilization.

Verification
The devices must always be verified before use: any devices presenting signs of weakness or surface scratches must not be used. (Return to the manufacturer or distributor any implants showing deterioration).

Warnings and precautions
PREOPERATIVE
- The use of the Hexanium ACIF has to be done using dedicated adequate instrumentation by a trained orthopedic surgeon or neurosurgeon familiar with these recommendations as well as with the operating techniques relating to these implants.
- The surgeon must be aware of not only the medical and surgical aspects of the implant, but also of the material limitations of titanium implants. The patient must be instructed in the limitations of the implant, especially with regard to the weight bearing and other body stresses on the device before a solid fusion occurs. The patient must be instructed that non-compliance with postoperative instructions could lead to failure of the device. The patient must be instructed that device failure could lead to the need for additional surgery to remove failed components.
- Only patients that meet the criteria described in the indications should be selected and patients corresponding to the aforementioned contra-indications should not be selected. The following factors may be of importance when selecting patients for internal stabilization devices:
  * foreign body sensitivity;
  * certain degenerative diseases;
  * senility, mental illness, alcoholism, or drug abuse;
  * obesity;
  * patient's occupation or activity level;
  * smoking.
- Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE
- Correct handling of the implants is extremely important. The implants must be transported in a way not to incur any damage. The implants must not be scratched and must not collide during handling.
- Care must be taken when picking up the Hexanium ACIF implants, filling it with autogenous bone graft and inserting it between the vertebral bodies. Alterations may produce defects in surface finish and may become the focal point for eventual breakage of the implant or for decreased efficacy in withstanding post-operative migration (e.g. when teeth of implant are damaged).
- Correct selection of the implant size is extremely important. The chance of adequate stabilization is increased by the selection of the proper size of the implant regarding the anatomy and conditions of the patient. Proper selection of the implant can minimize, but not eliminate risks.
- The Hexanium ACIF components have been designed for use with this system. Do not use the Hexanium ACIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium ACIF cannot be inserted via a posterior approach.
- The Hexanium ACIF cannot be used in thoracic and lumbar spine.
- The implant should be placed on the peripheral cortical bone of the endplates to minimize the risk of post-operative subsidence.
- Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

POSTOPERATIVE
- Careful patient monitoring for the first two to four months following the operation is very important while the fusion mass matures and becomes able to share load with the implant. Adequately instruct the patient in the appropriate postoperative care. The patient must be instructed to reduce stress on the implants in order to avoid clinical problems that may accompany failed fixation. The patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be instructed in the limitations of the implant, and that physical activity and full weight bearing may cause premature failure of internal stabilization devices by migrating, loosening or fracture. The patient must be instructed that an implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on the implant. An active, debilitated, or demented patient who is unable to use orthotic weight bearing devices may be particularly at risk.
- No internal stabilization device can withstand activity levels equal to those withstood by normal healthy segment. No implant can be expected to withstand unsupported weight-bearing stress indefinitely.
- Implants may fail when subjected to the increased loading associated with delayed union or non-union. Internal stabilization devices are intended as load-sharing devices until normal healing occurs. If normal healing does not occur or is delayed, the device may break due to fatigue. Patients should be informed of the risks of implant failure.

Magnetic Resonance (MR) Safety: The Hexanium ACIF has not been evaluated for safety and compatibility in the MR environment. The Hexanium ACIF has not been tested for heating or migration in the MR environment.

Product complaints
Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identification, durability, reliability, safety, effectiveness and/or performance, should notify SpineVision®. Further, if any of the implanted Hexanium ACIF components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, SpineVision® should be notified immediately.
If any SpineVision® product may have caused or contributed to the death or serious injury of a patient, SpineVision® should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from SpineVision®.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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	See package insert for labeling limitation
	Do not use if package is damaged
	Expiration date
	Do not re-use
	Keep dry
	Keep away from sunlight
	Sterilized using Irradiation
	Federal law (US) restricts this device to sale by or on the order of a physician
	Consult instructions for use
	Batch code
	Manufacturer
	Catalog number
	Do not re-sterilize

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IMPORTANT INFORMATION CONCERNING HEXANIUM ACIF INSTRUMENTATION

SURGICAL STEPS

REFERENCES

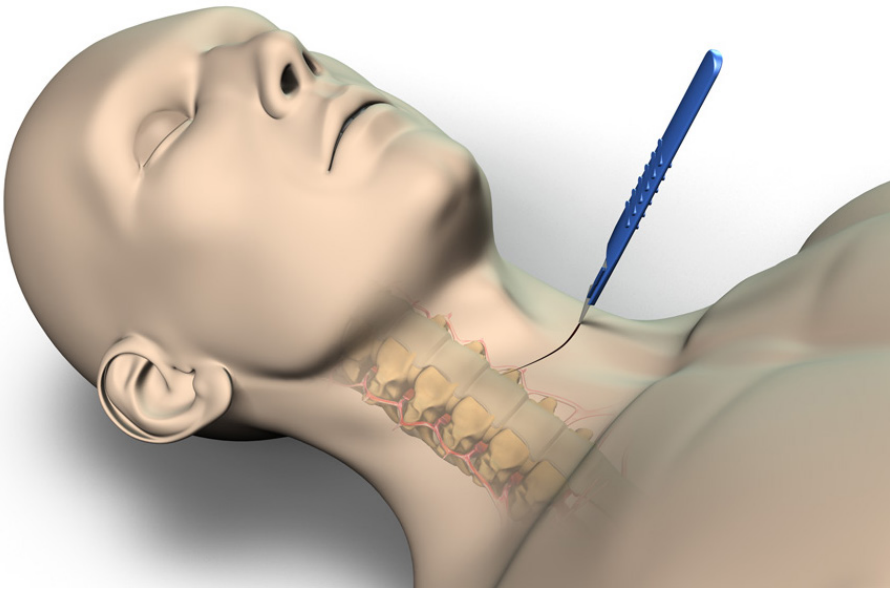
PATIENT POSITIONING AND DISCECTOMY

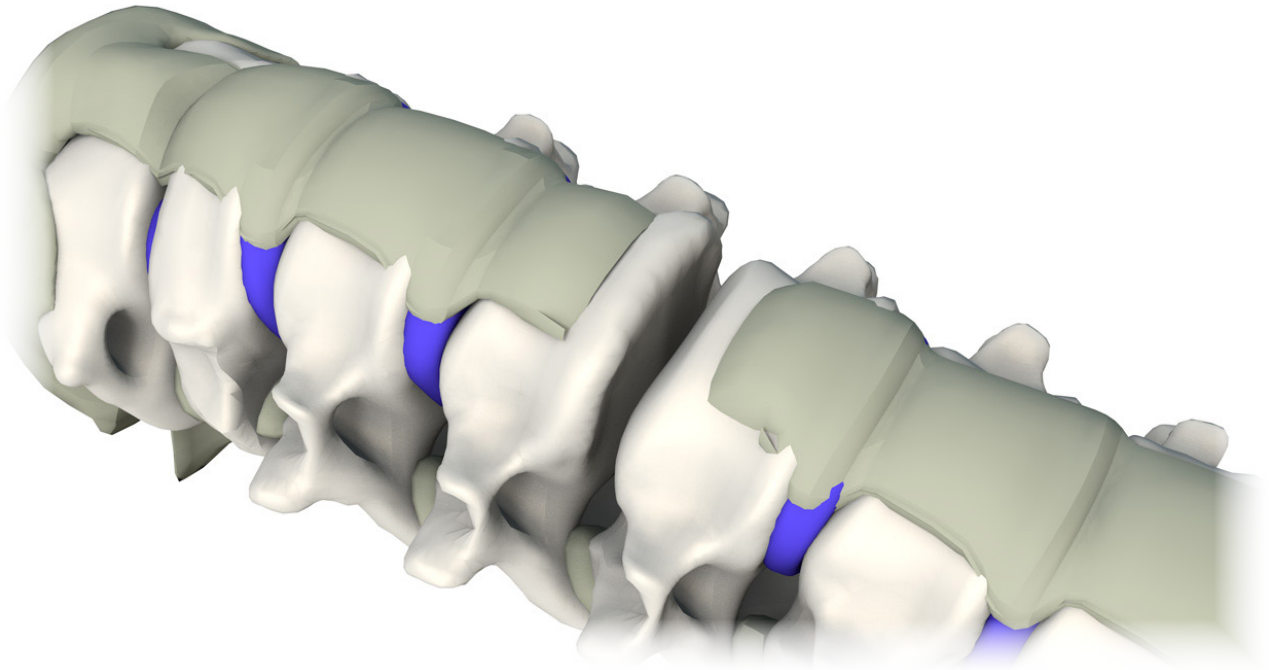
The patient is placed on the OR table using the standard position indicated for Anterior Cervical Interbody Fusion procedure: supine position with maintenance of cervical lordosis.

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.



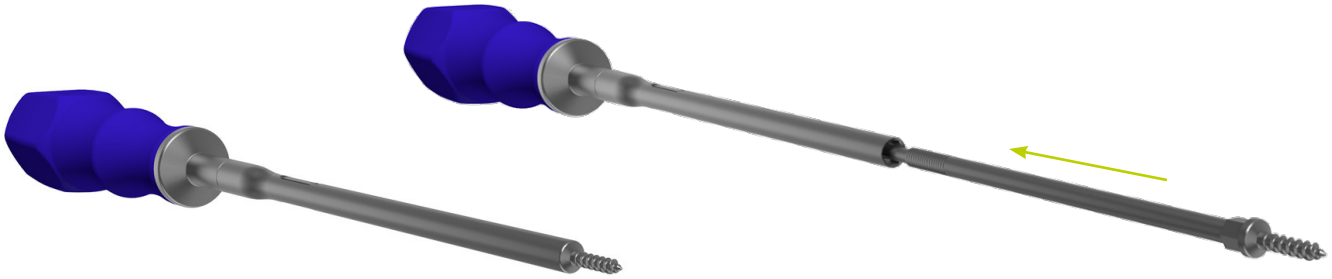


PINS ASSEMBLY AND INSERTION

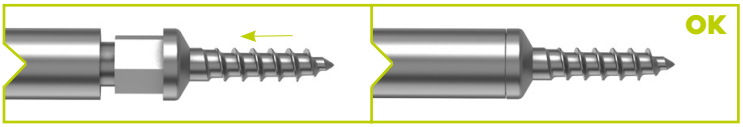
Pins for Distractor/Compressor
AC2-A206

Driver for Pins
AC2-A216

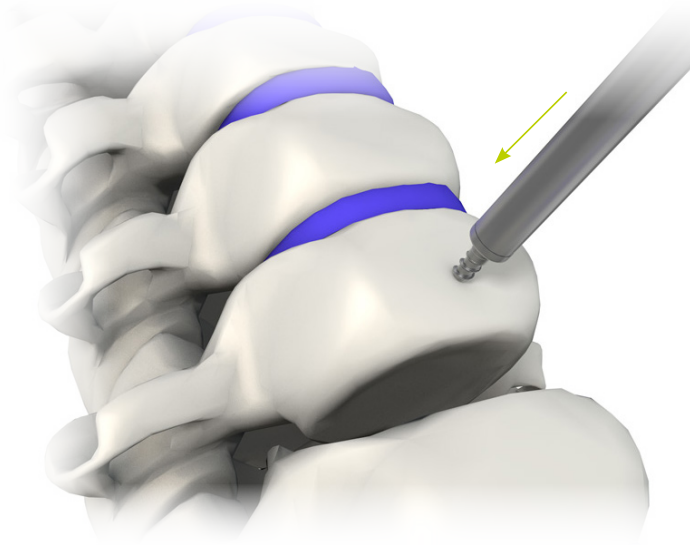
To connect the **pins for distractor/compressor** *AC2-A206* to the **driver for pins** *AC2-A216*, slide the proximal part of the pins (without hexagonal tip) into the outer tube of the driver for pins.



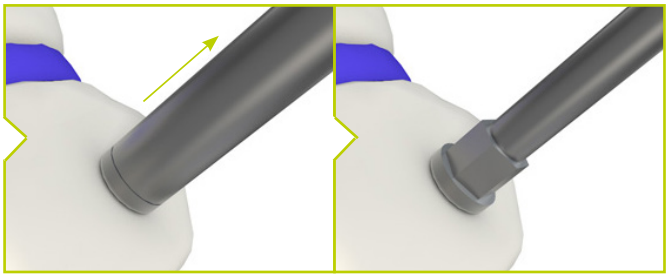
Be cautious that the hexagonal part of the pin is fully inserted into the driver for pin.

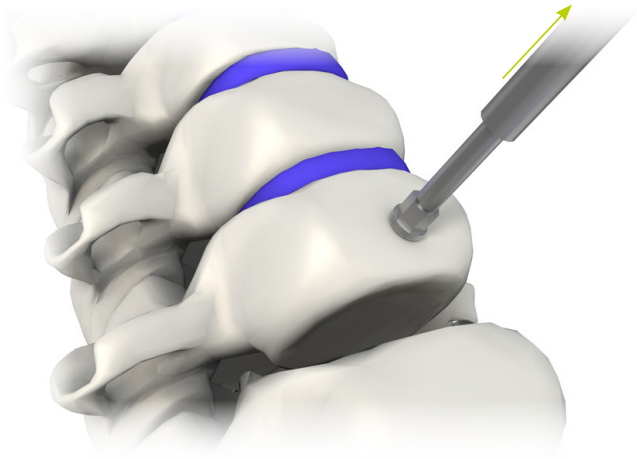


Directly insert the **pin for distractor/compressor** into the vertebral body. The entry hole of the pin should be on the medial line and at the sagittal center of the vertebral body. Insert the pin until it is fully inserted into the vertebral body.



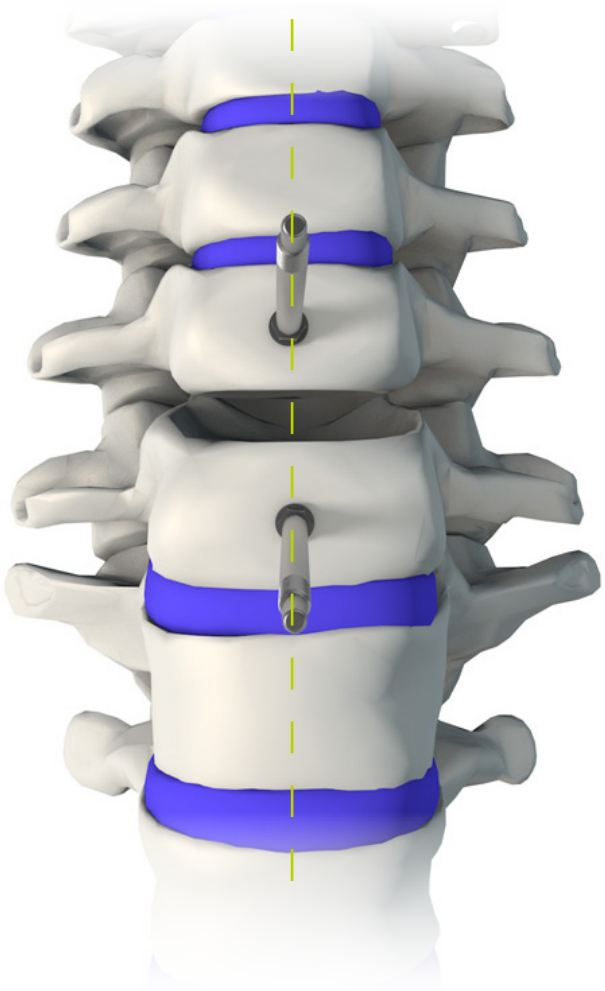
Once the pin is fully inserted, disconnect the **driver for pins** by pulling it upward leaving the pin into the vertebral body.





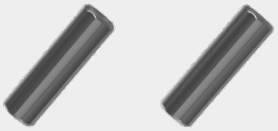
The second **pin for distractor/compressor** must be placed into the vertebral body of the lower vertebrae of the operated level. The two pins must be sagitally aligned together on the medial line.

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

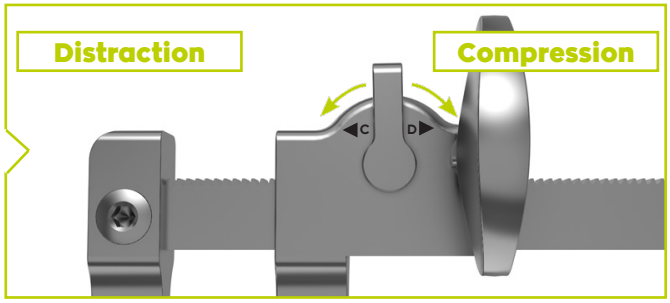
Distractor/Compressor
AC2-A201



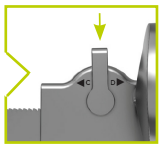
Plugs for Pins
AC2-A210

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

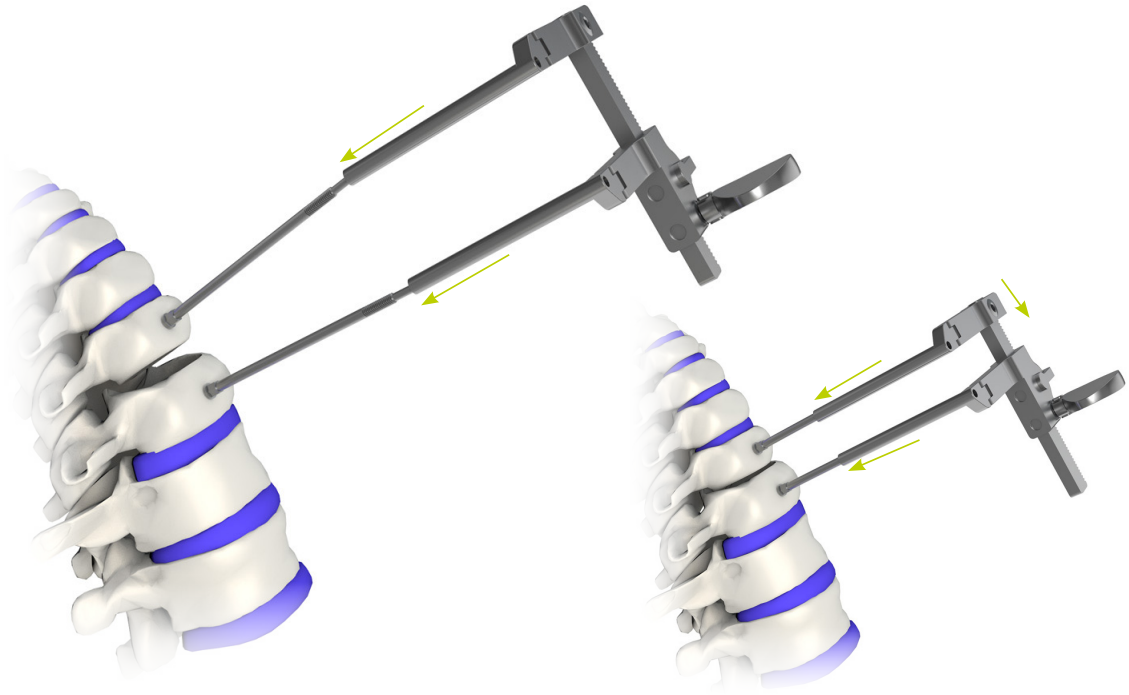
Segmental distraction is mandatory to restore disc height and ensure an accurate and safe placement of the cage.



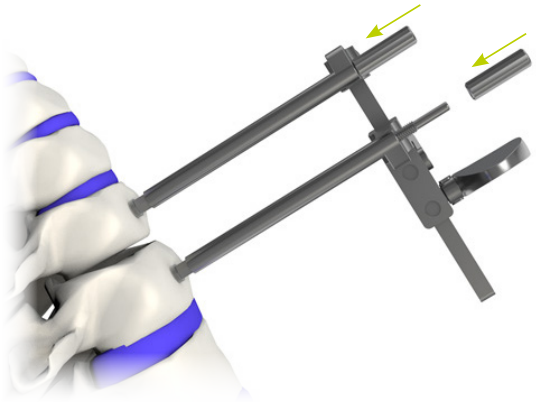
Position the pivoting « arm » of the **distractor/compressor** above the free part of the **pins for distractor/compressor** *AC2-A206* and slide the arms of the distractor/compressor down through the pins.

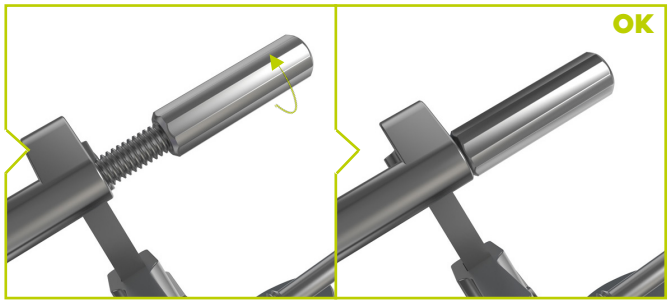


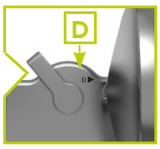
Place the D/C into neutral position to adjust the « spacing » between the D/C arms and facilitate the D/C placement.



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.



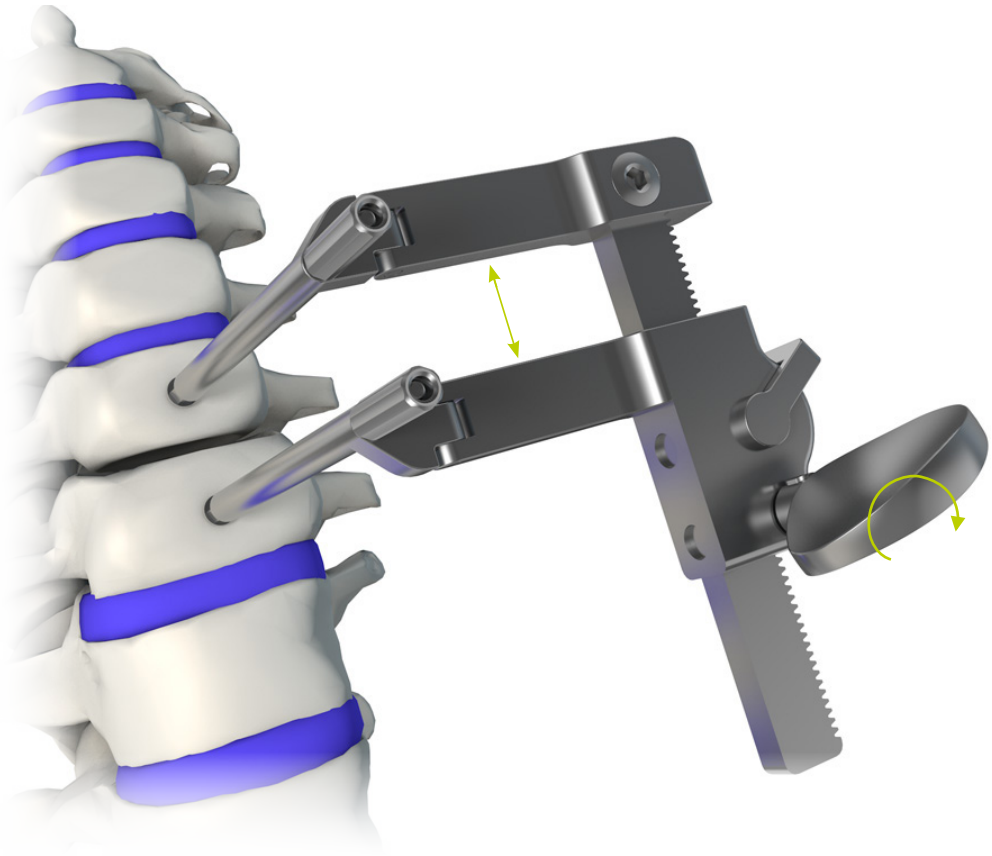




To distract the intervertebral space prior to cage positioning, place the **distractor/compressor** *AC2-A201* on distraction position **D**.

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.



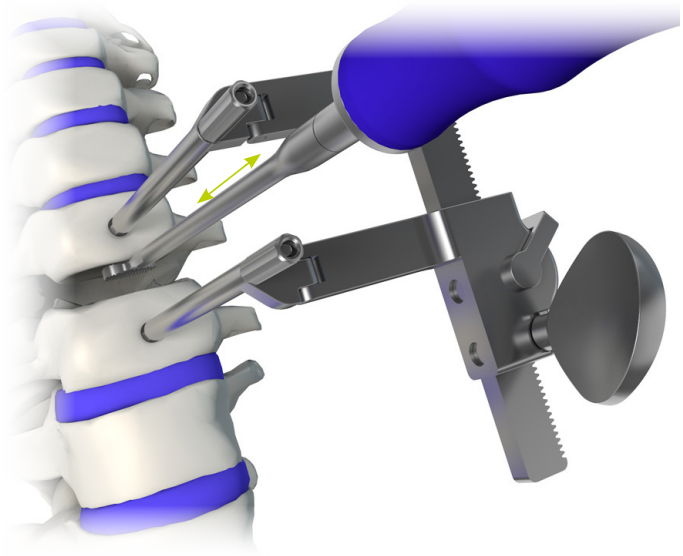
ENDPLATE PREPARATION

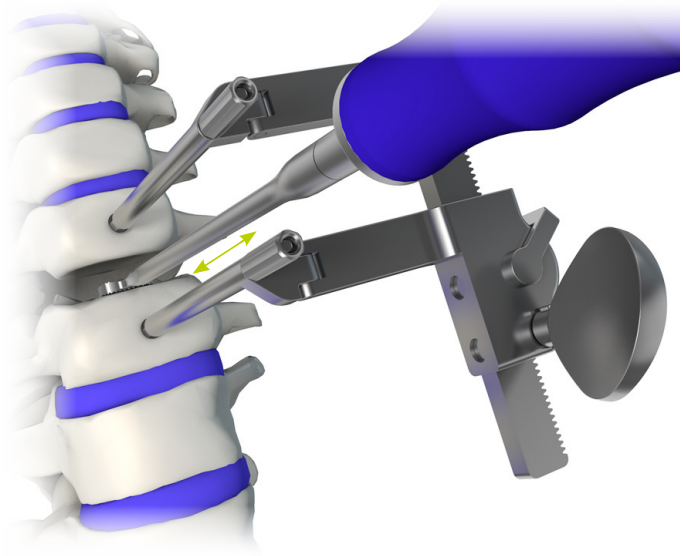
Rasp
AC2-A010

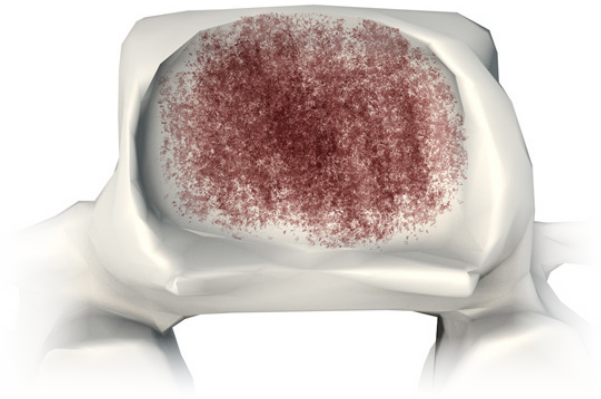
Once distraction of the intervertebral space is performed, use the **rasp** *AC2-A010* to prepare the enplates. Enter the intervertebral space placing the rasp parallel to endplates and use it to remove superficial cartilaginous tissue of the endplates.

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.





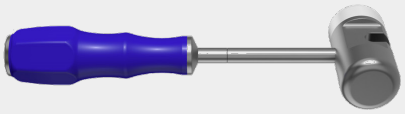


IMPLANT'S SIZE ESTIMATION

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

or

Lordotic or Convex Ti Cervical Cage Trial Without Stop
AC2-A012-XXXX



Mallet
AC2-A023

Once the endplate preparation is done and the bleeding bone revealed, use the **lordotic or convex ti cervical cage trial** (or **Without Stop**) *AC2-A011-XXXX* (or *AC2-A012-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

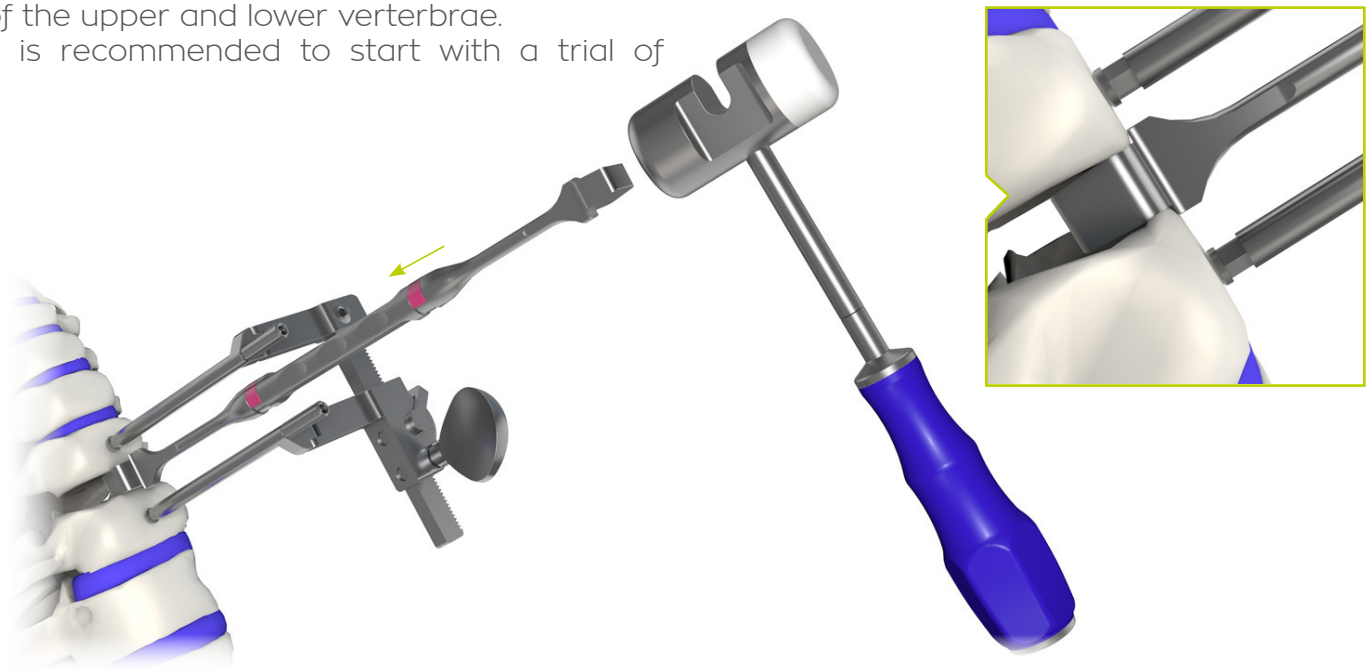
AC2-A01X-**XXXX**

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 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

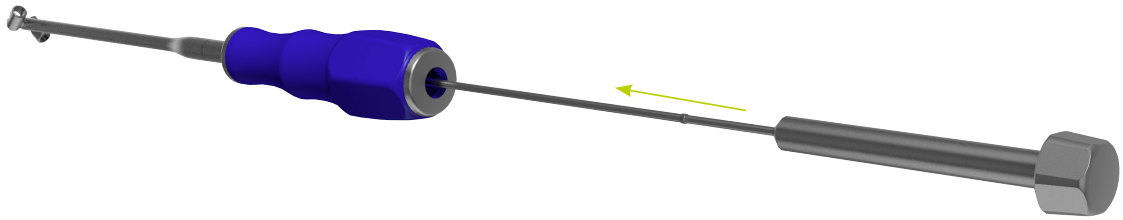
Or

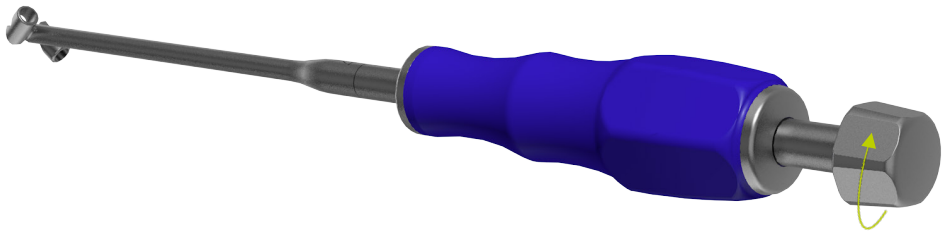
Ti Cervical Cage Holder Without Stop
AC2-A003

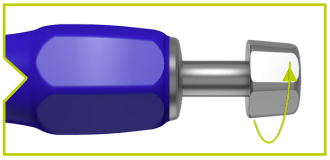
The Hexanium ACIF kit comes with three options for cage holding : **Ti SA cervical cage holder with guide** *AC2-A001G-XX* with integrated guide adapted for each implant height (XX = Height from 05 to 12) and the **Ti cervical cage holder** *AC2-A001* or the **Ti cervical cage holder Without Stop** *AC2-A003* without any guide nor height specification.

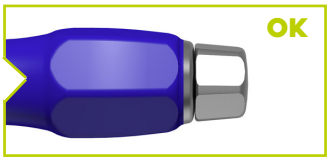
Prior to connect the cage (applying to all cage holders), insert the **inner shaft for Ti cervical cage holder** *AC2-A002* into the cage holder.

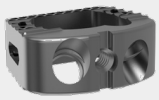
When you feel a resistance, turn clockwise the knob of the inner shaft until it reaches the proximal end of the cage holder handle.







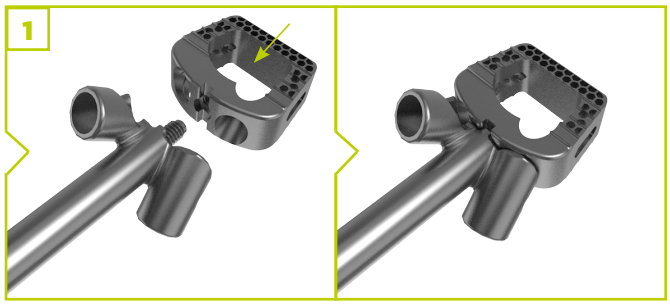


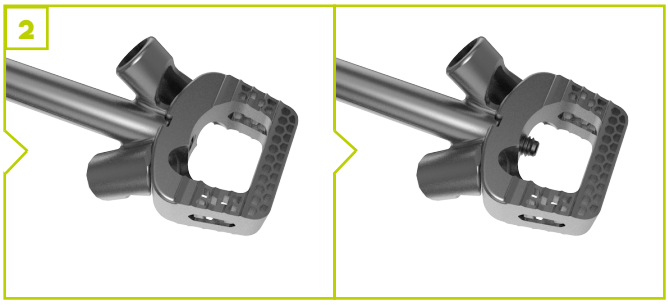


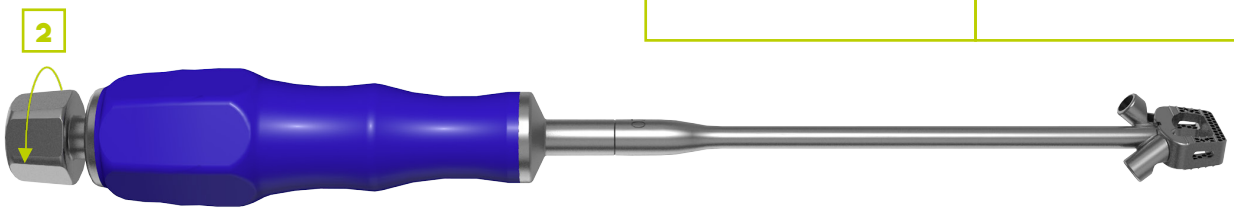
Ti SA Cervical Cage
AC2-CSXXXX

1 To connect the Hexanium ACIF cage 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*.

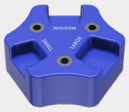
2 Then, turn clockwise the knob of the inner shaft until it meets the proximal end of the cage holder handle and you can't screw the knob anymore.







VII BONE GRAFT FILLING



Ti Cervical Cage Graft Packing Block
AC2-A020

Ti Cervical Cage Cancellous Bone Impactor
AC2-A021

OR

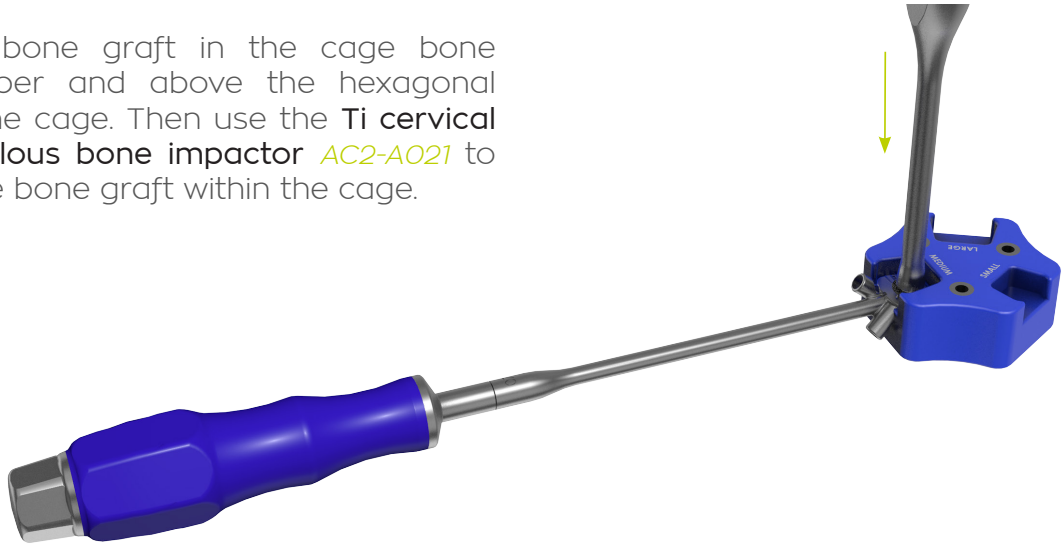
Cage connected to the Cage Holder (or Cage Holder Without Stop)
AC2-CSXXXX + AC2-A001 (or AC2-A003) + AC2-A002

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).

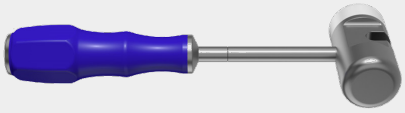
Add some bone graft in the cage bone graft chamber and above the hexagonal canals on the cage. Then use the **Ti cervical cage cancellous bone impactor** *AC2-A021* to compact the bone graft within the cage.

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



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

VIII CAGE INSERTION



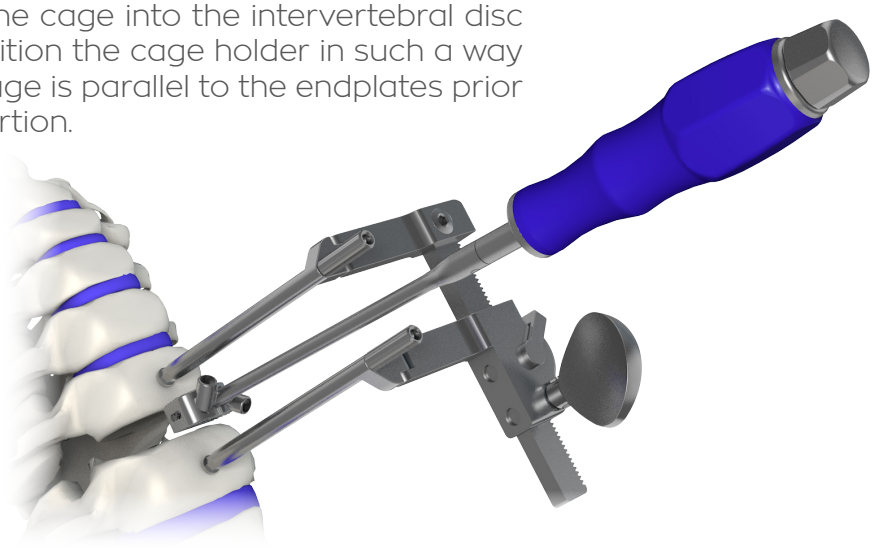
Mallet
AC2-A023

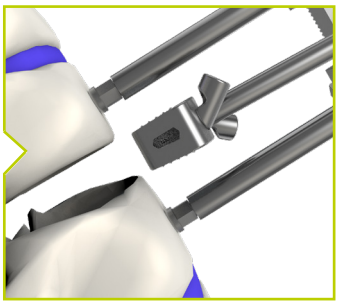
OR

Cage connected to the Cage Holder (or Cage Holder Without Stop)
AC2-CSXXXX + AC2-A001 (or AC2-A003) + AC2-A002

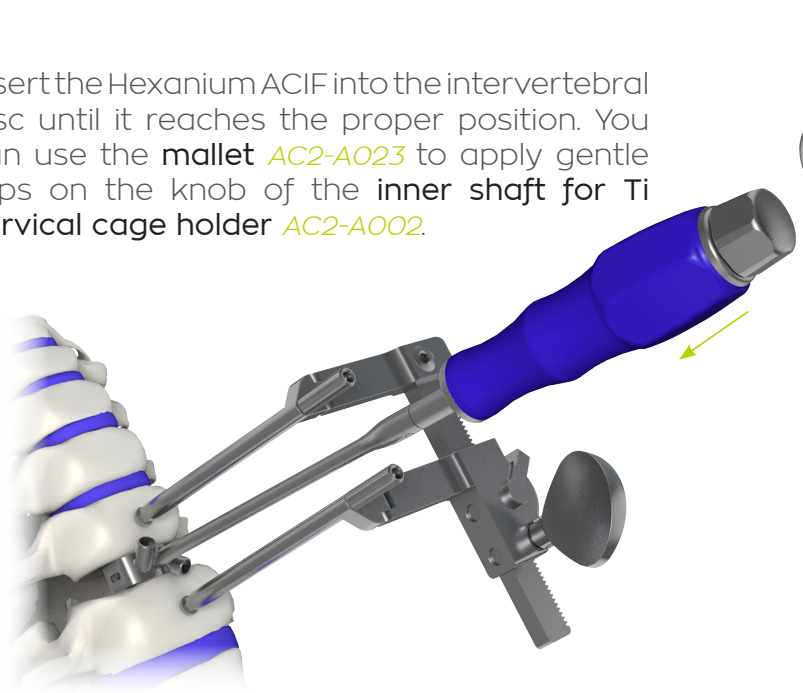
Cage connected to the Cage Holder with Guide
AC2-CSXXXX + AC2-A001G-XX + AC2-A002

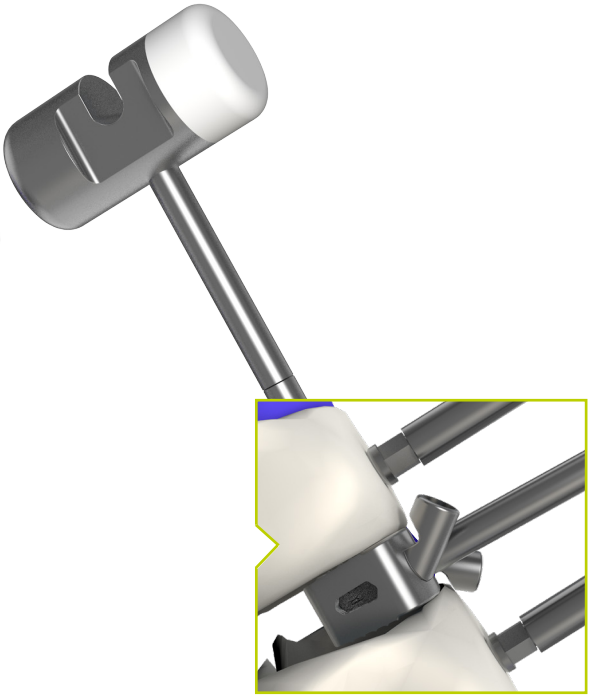
To insert the cage into the intervertebral disc space, position the cage holder in such a way that the cage is parallel to the endplates prior to the insertion.





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.

IX PILOT HOLE PREPARATION

Bone Awl
AC2-A030

OR

Angulated Bone Awl
AC2-A031

OR

Short Angulated Bone Awl
AC2-A038

Cylindrical Snap-On Handle
SD-ALSH26123PCAO

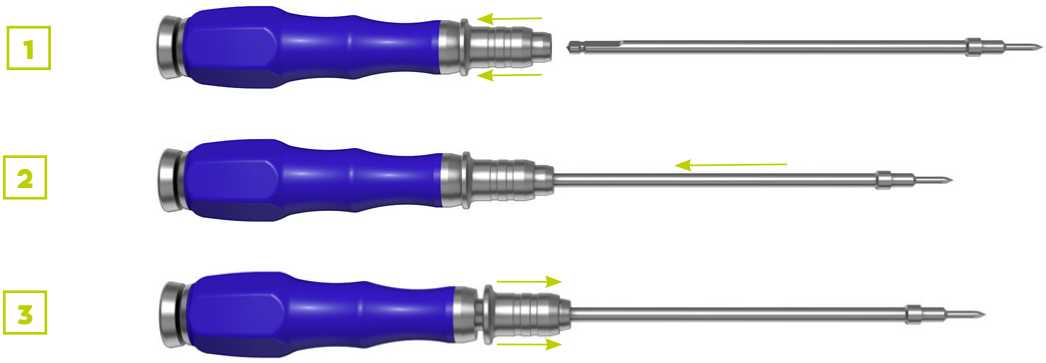
The Hexanium ACIF set offers three options for bone awl: a straight **bone awl** *AC2-A030*, an **angulated bone awl** *AC2-A031* and a **short angulated bone awl** *AC2-A038*.

To connect one of the bone awls 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.



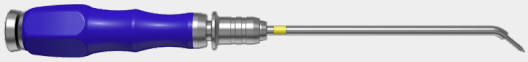
Yellow ring or knob indicates instruments NOT compatible with cage holder with guide

OR

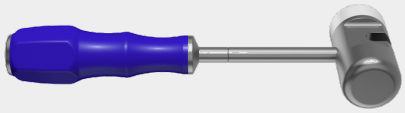
Bone Awl connected to the Handle
AC2-A030 + SD-ALSH26123PCAO

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

OR

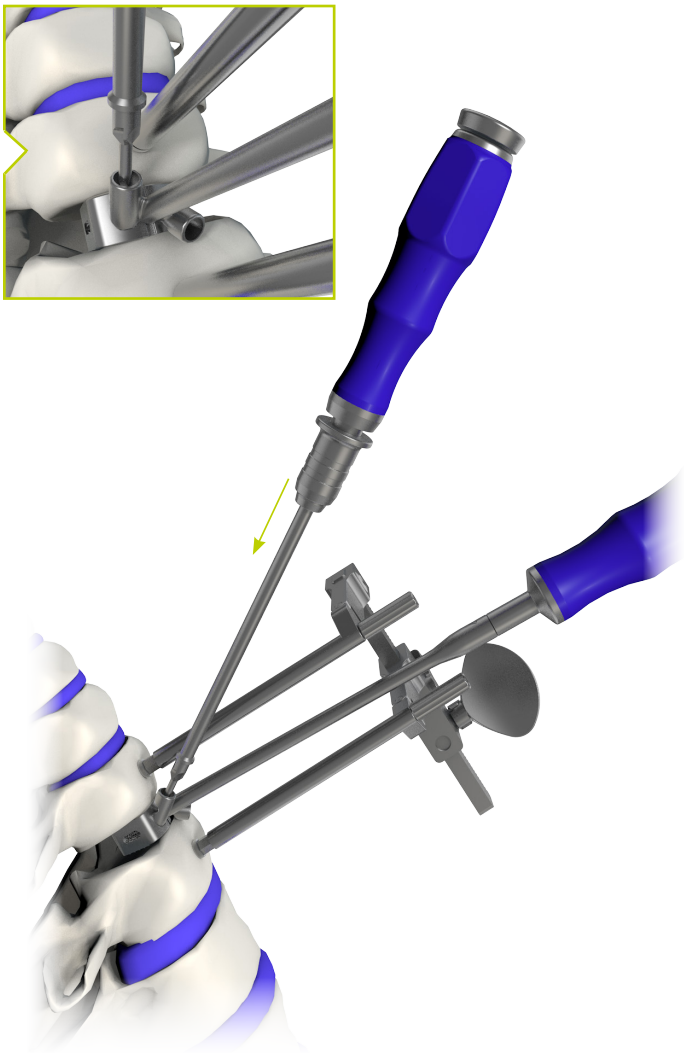


Short Angulated Bone Awl connected to the Handle
AC2-A038 + SD-ALSH26123PCAO

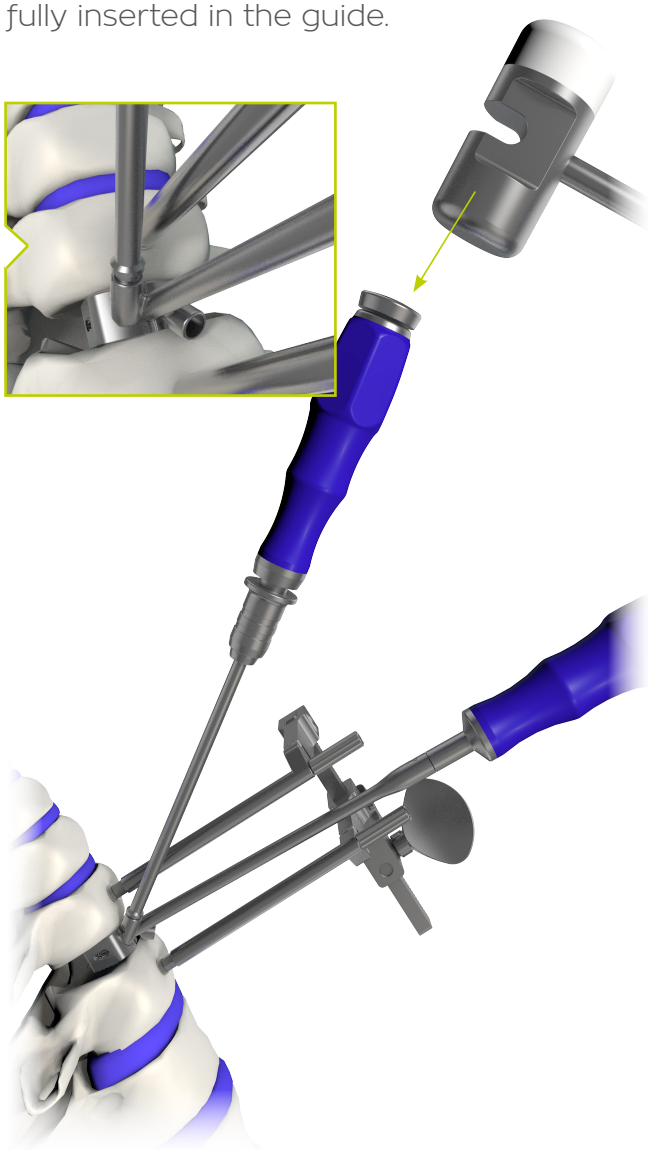


Mallet
AC2-A023

To prepare the entry point for screws, insert the distal part of the **straight** or **angulated** or **short angulated bone awl** *AC2-A030* or *AC2-A031* or *AC2-A038* 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

Sleeve for U-Joint
AC2-A036

+

U-Joint Drill
AC2-A033

OR

Sleeve for Short U-Joint
AC2-A041

+

Short U-Joint Drill
AC2-A039

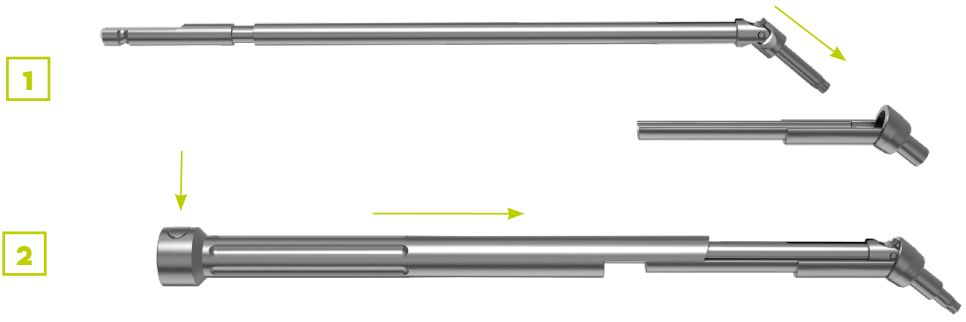
The Hexanium ACIF kit offers three instruments for drilling : a **straight drill** *AC2-A032*, a **U-joint drill** *AC2-A033* or a **Short U-joint drill** *AC2-A039* which can respectively be assembled with the **Sleeve for U-joint** *AC2-A036* or the **Sleeve for Short U-joint** *AC2-A041*.

To assemble the sleeve with its corresponding drill (**Sleeve for U-joint** *AC2-A036* and **U-joint drill** *AC2-A033* or **Sleeve for Short U-joint** *AC2-A041* and **Short U-joint drill** *AC2-A039*):

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



Short versions of instruments are identified by a yellow ring or knob

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

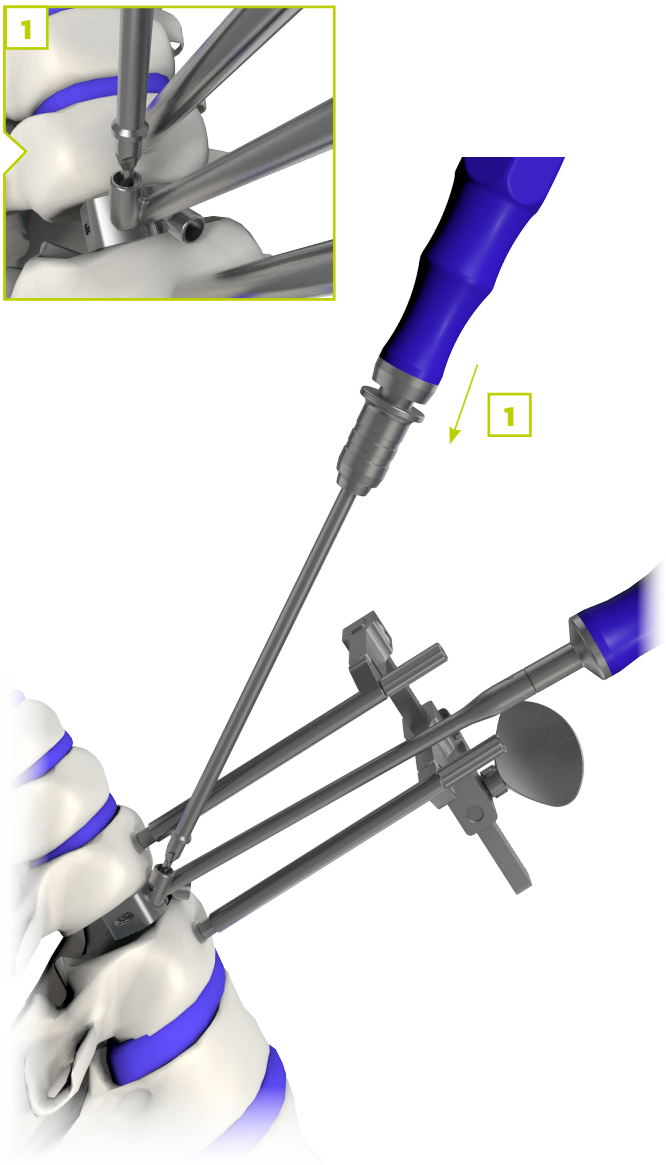
U-Joint Drill with Sleeve connected to the Handle
AC2-A033 + AC2-A036 + SD-ALSH26123PCAO

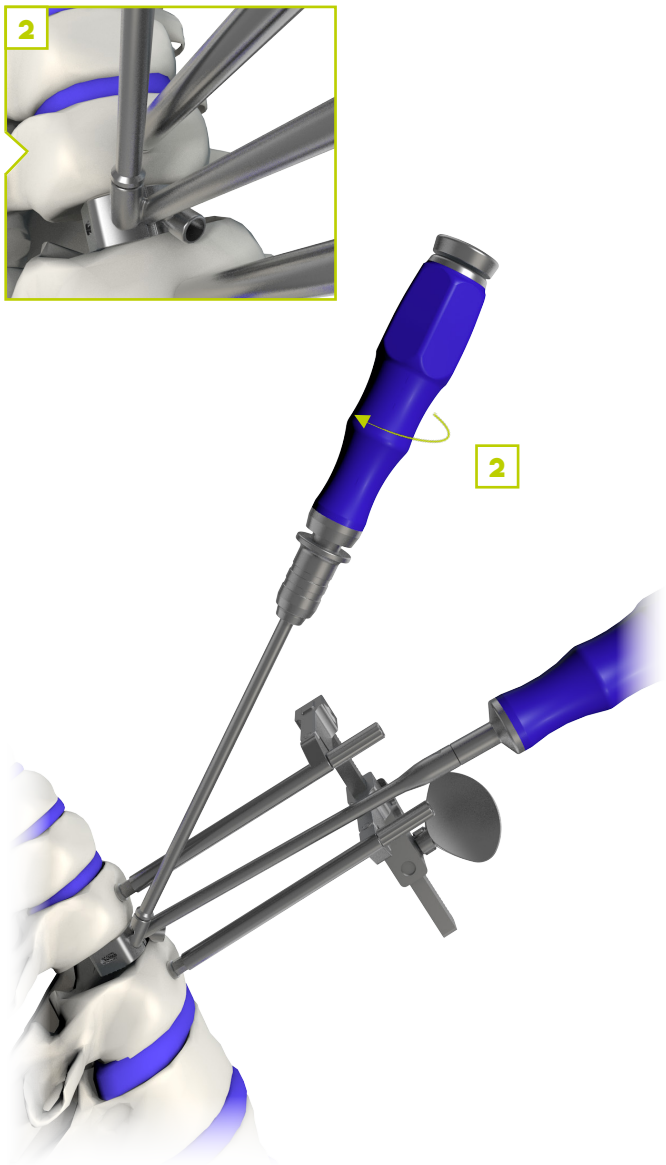
OR

Short U-Joint Drill with Short Sleeve connected to the Handle
AC2-A039 + AC2-A041 + 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*, or the Short U-joint drill *AC2-A039* assembled with the Sleeve for Short U-joint *AC2-A041* into the guide/inserter.

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.



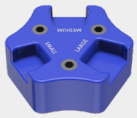


XI SCREW INSERTION

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

OR

Short U-Joint Screwdriver with Sleeve connected to the Cylindrical Snap-On Torque Limiting Handle
SD-ALSH26123PCAOTL13 + AC2-A040 + AC2-A041

Screw may be inserted using either the screwdriver shaft *AC2-A037*, the U-joint screwdriver *AC2-A035* associated with the Sleeve for U-Joint *AC2-A036*, or the Short U-joint screwdriver *AC2-A040* associated with the Sleeve for Short U-Joint *AC2-A041*, 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)

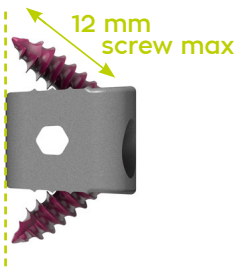
Diameter : **3.5 mm**
Length: 10 / 12 / 14 / 16 mm
Ref : AC2-SD35XXS (XX = Length)

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.

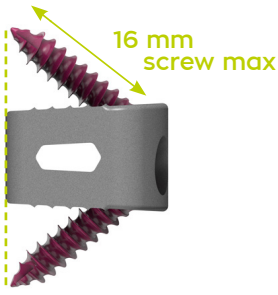
! WARNING !
Pay attention that according to the footprint, screws may protrude or not beyond the cage's posterior edge

Small Footprint
12mm screws almost come flush with posterior edge of cage. Longer screw will protrude.



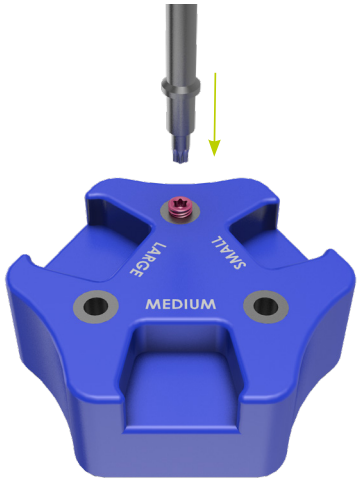
Medium Footprint
14mm screws almost come flush with posterior edge of cage. Longer screw will protrude.

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

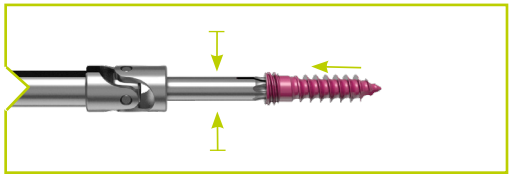


The **Screwdriver shaft** *AC2-A037*, the **U-joint screwdriver** *AC2-A035* or the **Short U-joint screwdriver** *AC2-A040* feature a self retaining tip.

Before conecting 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.

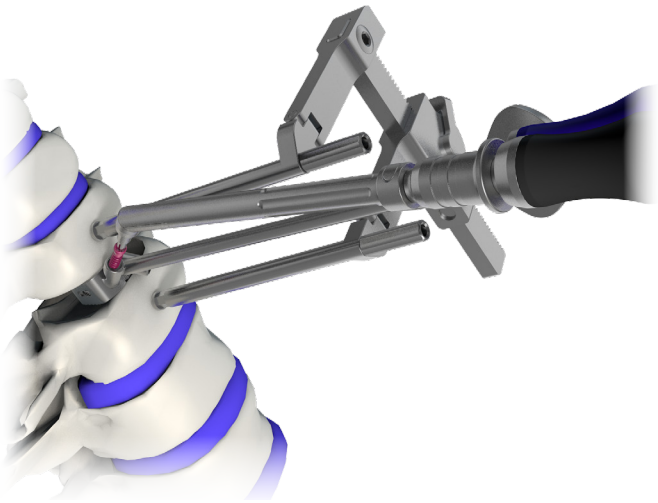


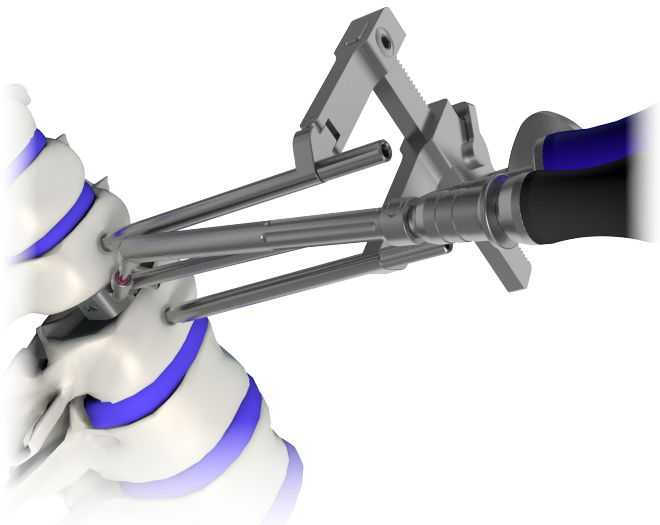
If using the U-joint screwdriver without sleeve, pay attention to hold the screwdriver by the u-joint part to avoid any motion of the tip during the connection.

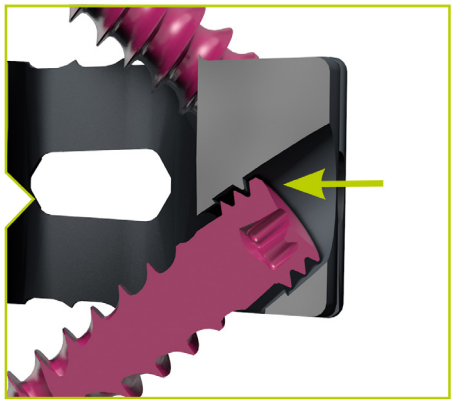


Once connected, slide the screw and screwdriver's tip through the guide into the hole prepared in the previous steps. When the screw meets the bone, screw clockwise to insert it.

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







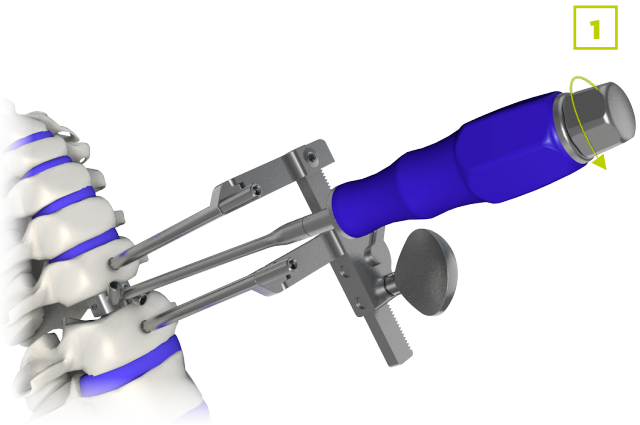
The thread of the screw head must be present in the most anterior thread of the cage which should not be visible when removing the screwdriver.

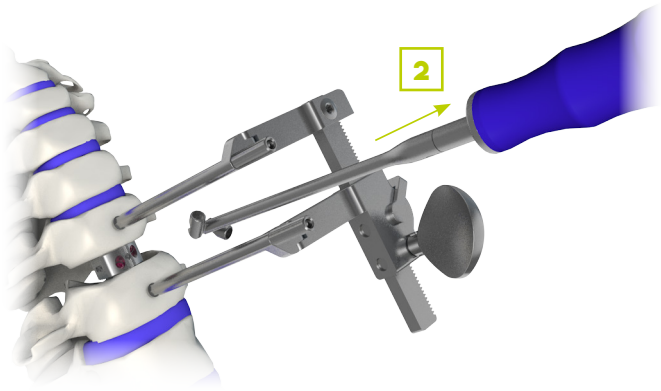
Repeat the 3 previous steps on the other side to insert the second screw.

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

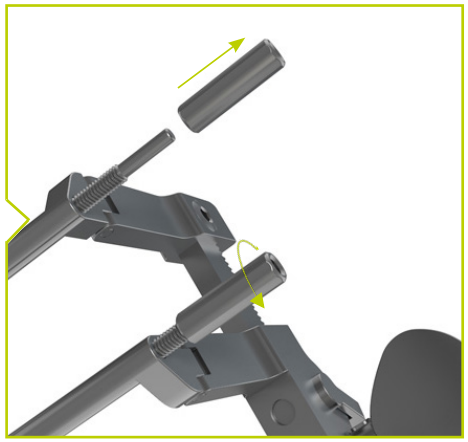
XII CAGE RELEASE

To release the Hexanium ACIF cage once both screws are placed, turn 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**.

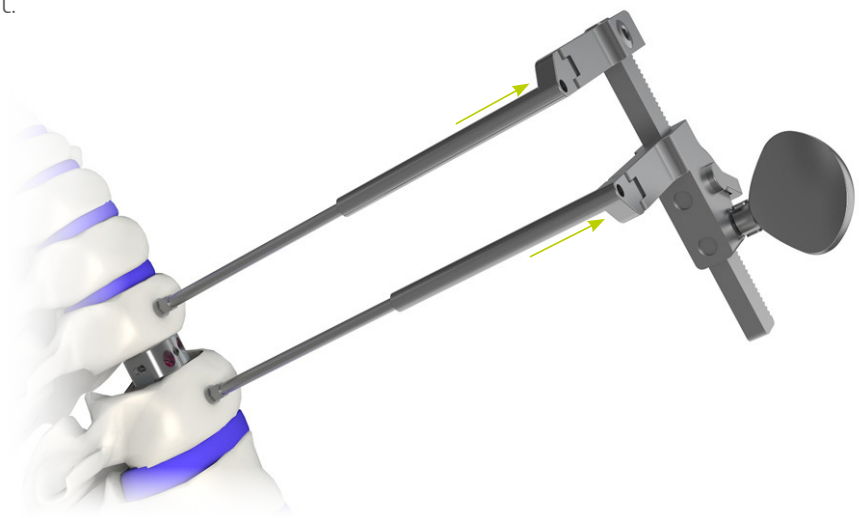




To remove the distractor/compressor : first counter clockwise turn the **plug for pins** *AC2-A210* on each pins to remove it.

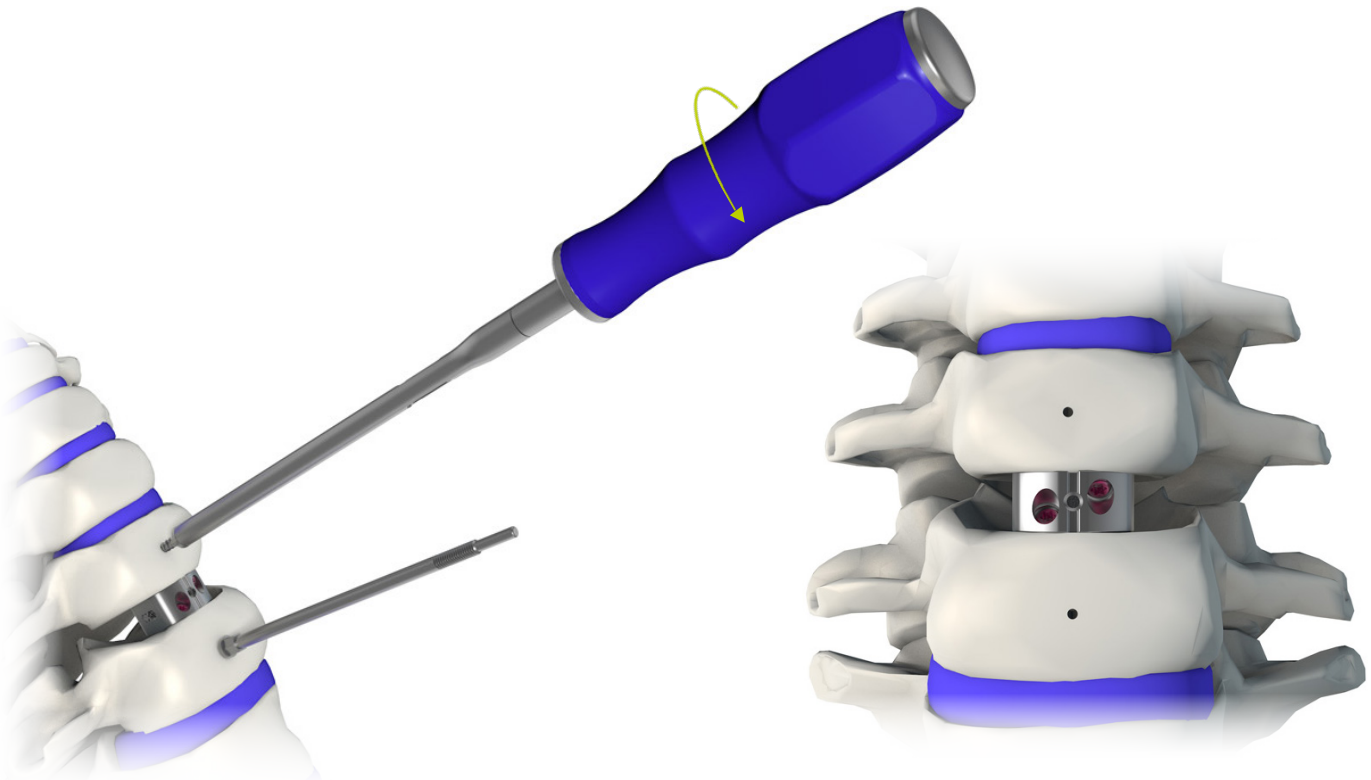


Then slide the arm of the D/C up the pins until you can entirely remove it.



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.



CAGE REMOVAL (OPTIONAL)

Inner Shaft for Ti Cervical Cage Holder
AC2-A002

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

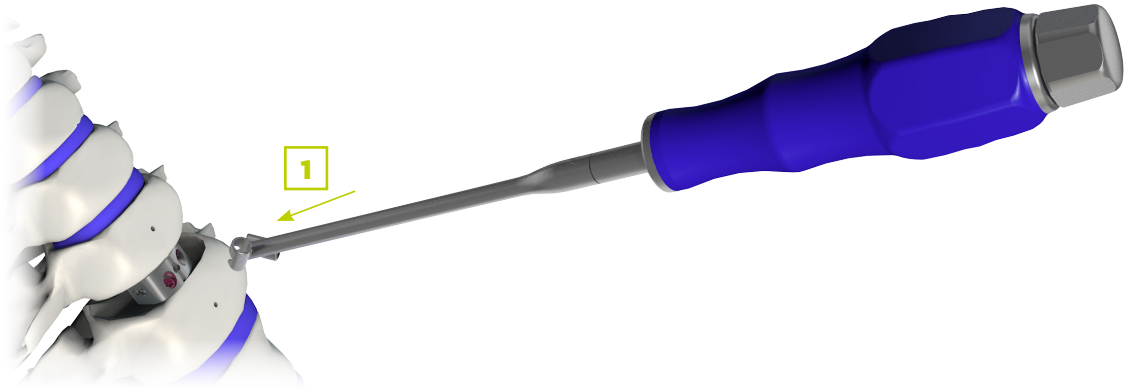
OR

Ti Cervical Cage Holder
AC2-A001

OR

Ti Cervical Cage Holder Without Stop
AC2-A003

To remove the cage if needed, connect the **Ti SA cervical cage holder with guide** *AC2-A001G-XX* or the **Ti cervical cage holder** *AC2-A001* or the **Ti cervical cage holder without stop** *AC2-A003* 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**.

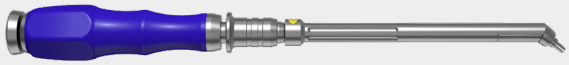


Screwdriver Shaft connected to the Cylindrical Snap-On Handle
SD-ALSH26123PCAO + AC2-A037

OR

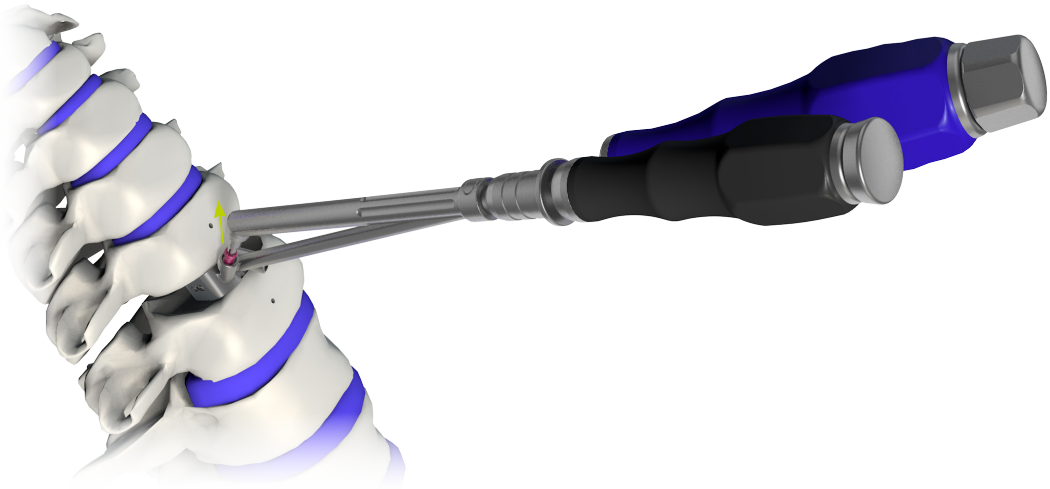
U-Joint Screwdriver with Sleeve connected to the Cylindrical Snap-On Handle
SD-ALSH26123PCAO + AC2-A035 + AC2-A036

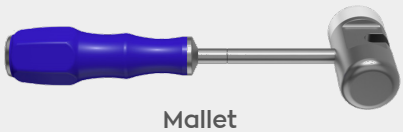
OR



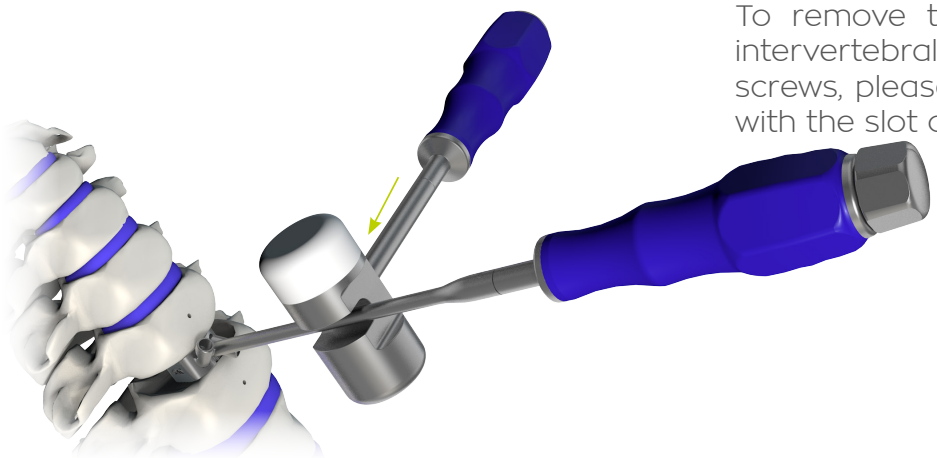
Short U-Joint Screwdriver with Sleeve connected to the Cylindrical Snap-On Handle
SD-ALSH26123PCAO + AC2-A040 + AC2-A041

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.



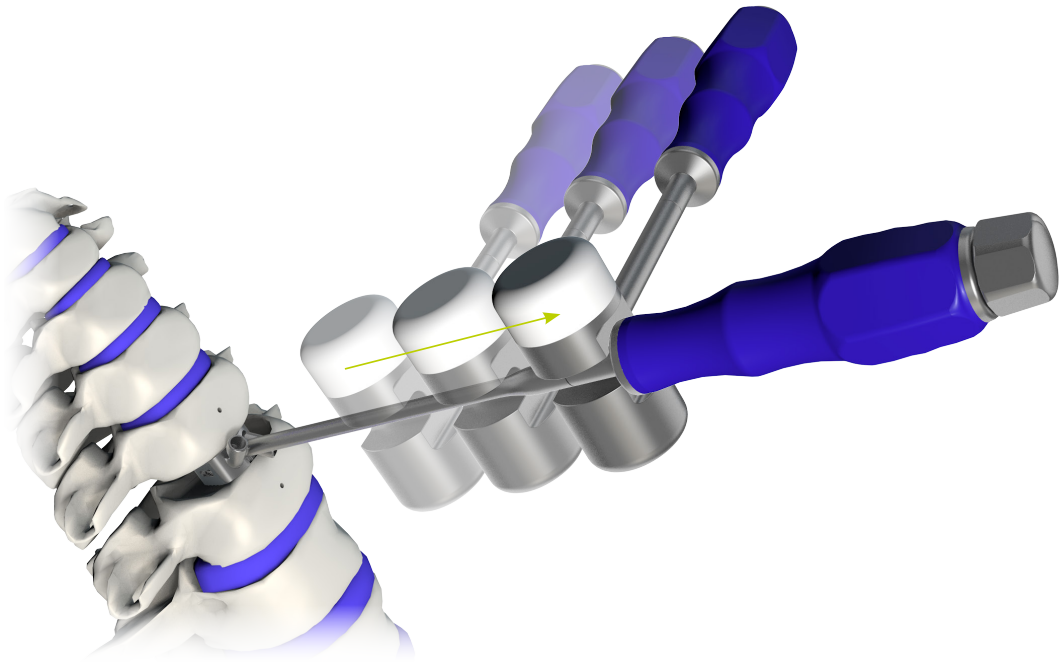


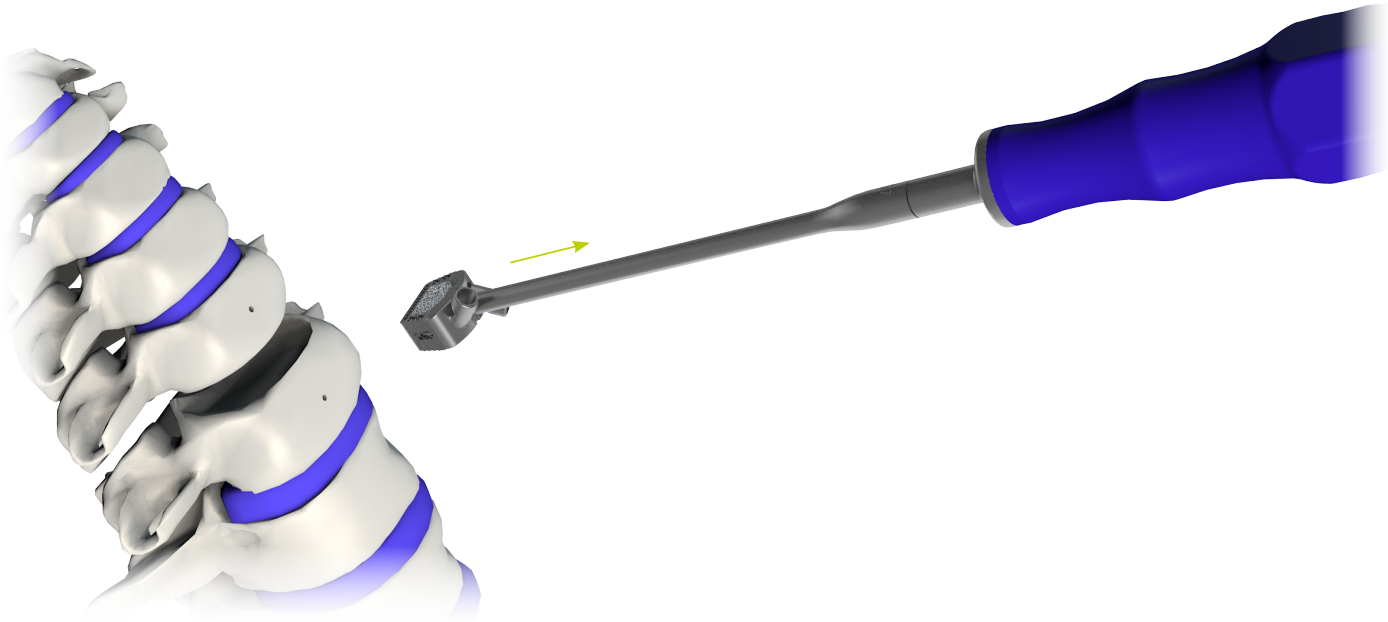
Mallet
AC2-A023



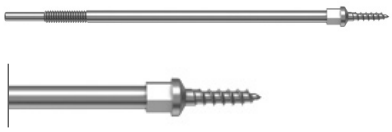
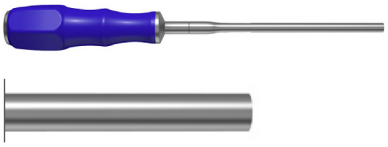
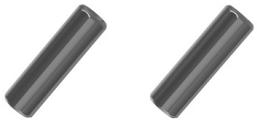
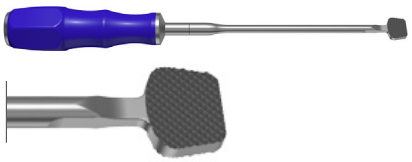
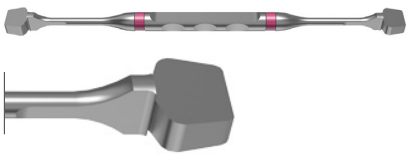
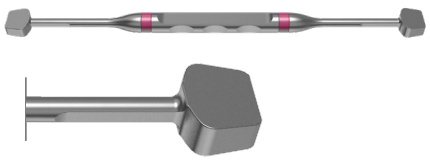
To remove the Hexanium ACIF from the intervertebral space after removing the screws, please catch the cage holder shaft with the slot on the mallet *AC2-A023*.

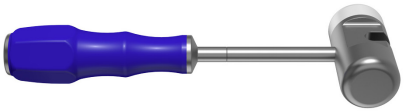
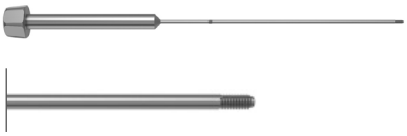
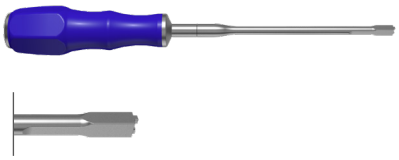
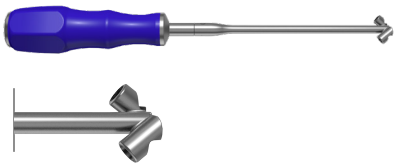
Once in position apply an upward force with the mallet toward the cage holder handle and repeat it until the cage is completely removed.

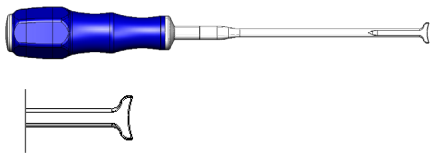




INSTRUMENTS

	**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
	**Lordotic or Convex Ti Cervical Cage Trial Without Stop**	AC2-A012-XXXX

	**Mallet**	AC2-A023
	**Inner Shaft for Ti Cervical Cage Holder**	AC2-A002
	**Ti Cervical Cage Holder**	AC2-A001
	**Ti Cervical Cage Holder Without Stop**	AC2-A003
	**Ti SA Cervical Cage Holder with Guide**	AC2-A001G-XX
	**Ti Cervical Cage Graft Packing Block**	AC2-A020
	**Ti Cervical Cage Cancellous Bone Impactor**	AC2-A021

	**Ti Cervical Cage Repositioner**	AC2-A022
	**Cylindrical Snap-On Handle**	SD-ALSH26123PCAO
	**Cylindrical Snap-On Torque Limiting Handle**	SD-ALSH26123PCAOTL13
	**Bone Awl**	AC2-A030
	**Angulated Bone Awl**	AC2-A031
	**Short Angulated Bone Awl**	AC2-A038
	**Straight Drill**	AC2-A032
	**U-Joint Drill**	AC2-A033

Short U-Joint Drill AC2-A039

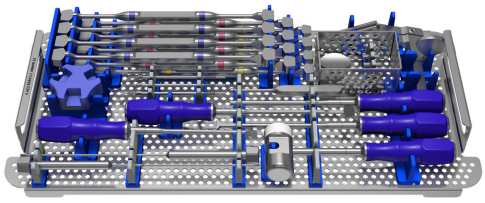
Screwdriver Shaft AC2-A037

U-Joint Screwdriver AC2-A035

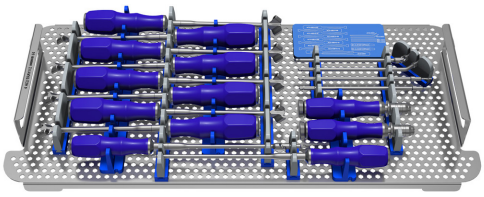
Sleeve for U-Joint AC2-A036

Short U-Joint Screwdriver AC2-A040

Sleeve for Short U-Joint AC2-A041



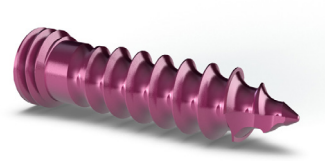
Ti Standard Cervical Tray
AC2-TRAY111

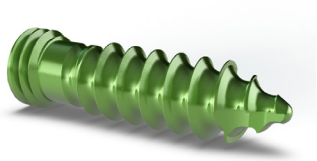


Ti SA Cervical Tray
AC2-TRAY112

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

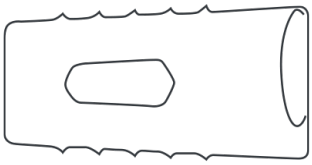
CAGES

AC2-CSXXXX

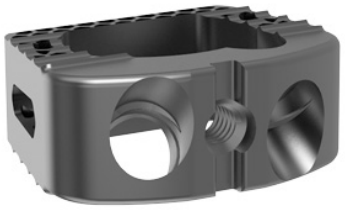
X = Size Small (S) / Medium (M) / Large (L)

XX = Height from 05 to 12mm

X = WEDGE (L) / CONVEX (C)



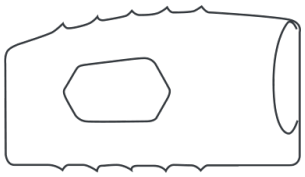
WEDGE CAGE



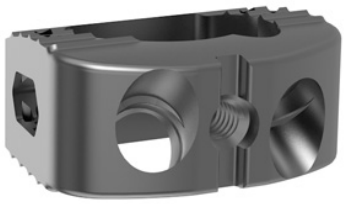
Height	Wedge Cage Small 12 x 15 mm	Wedge Cage Medium 14 x 17 mm	Wedge Cage Large 15 x 19 mm
05 mm	AC2-CSS05L	AC2-CSM05L	AC2-CSL05L
06 mm	AC2-CSS06L	AC2-CSM06L	AC2-CSL06L
07 mm	AC2-CSS07L	AC2-CSM07L	AC2-CSL07L
08 mm	AC2-CSS08L	AC2-CSM08L	AC2-CSL08L
09 mm	AC2-CSS09L	AC2-CSM09L	AC2-CSL09L
10 mm	AC2-CSS10L	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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