Clariance

Idys®-C ZP 3DTi

STAND ALONE CERVICAL CAGE

3DTi

Surgical Technique - USA/ROW

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Idys-**C ZP 3DTi**

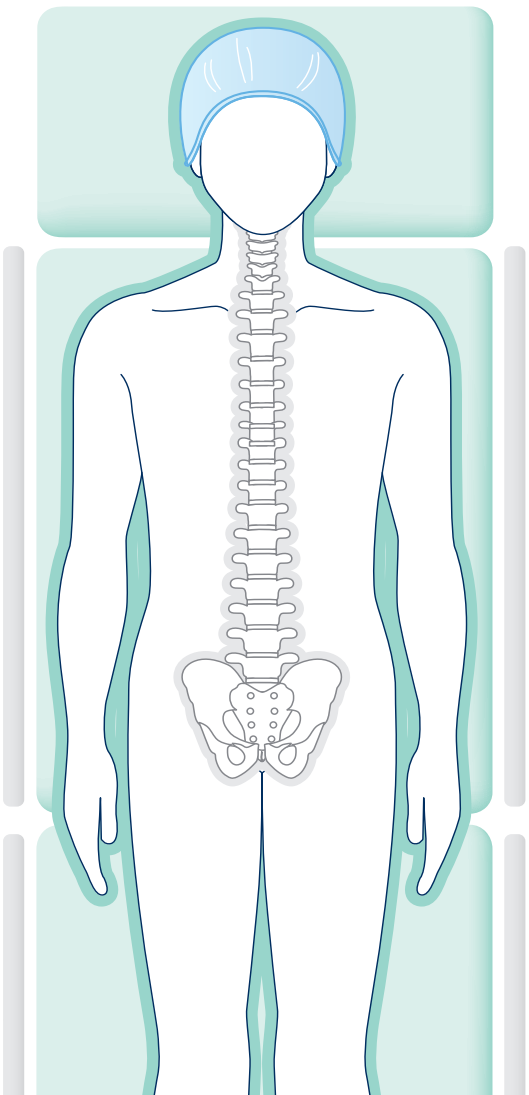
STAND ALONE CERVICAL CAGE

CONTENTS

Surgical Technique

To become the architects of spine, Clariance has developed its products in collaboration with expert surgeons in their practice from all backgrounds including from France and the US. Because of this diversity, Clariance offers solutions that meet all practices. This surgical technique guide is the result of the proximity between the surgeons and Clariance.

Prior to using any Clariance device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.



1 | PATIENT POSITIONING

- The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis.

Final positioning of the patient and surgical approach are based on known techniques routinely used by surgeons.

2 | DISC LOCATION & APPROACH

- Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination.
- The approach of the intersomatic space can be realized after identifying the affected level(s) under fluoroscopy.
- The surgical protocol and the technique used for the exposure of the intersomatic space are the same as for a standard anterior approach for cervical vertebral surgery.

3 | CASPAR DISTRACTOR POSITIONING (OPTIONAL)

- The **Distractor Pins** have to be positioned centered laterally and when possible at least 6 mm from the superior and inferior endplates of the treated level in order not to impede insertion of the implant and parallel to the endplates.
- Once the pins are well positioned, place the **Distractor** on the pins.
- Distract the intersomatic space in order to perform appropriate discectomy.

IMPORTANT:

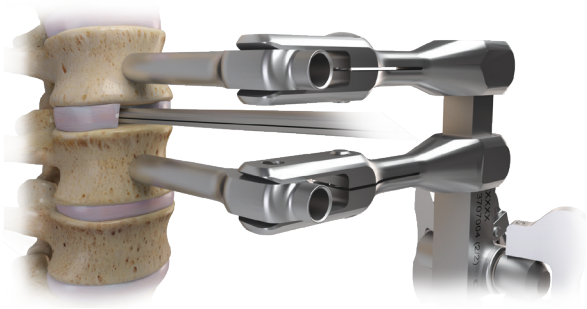
*Always check on the **Distractor** pins condition before insertion. If damaged or bent prior to usage, do not use and discard.*

4 | DISCECTOMY

- Start disc resection with a thin, long scalpel and disc forceps.
- Continue the discectomy to the back of the endplates and according to surgeon's habits.

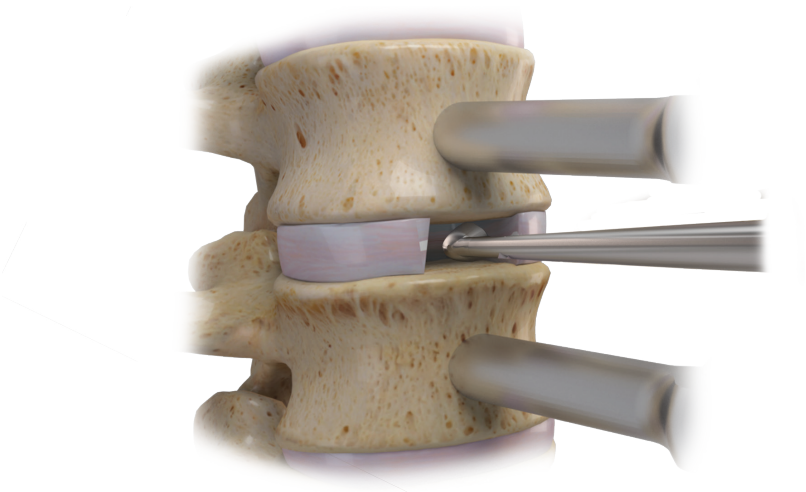
IMPORTANT:

The use of a microscope/ magnifying glasses is recommended to achieve a perfect release.



5 | ENDPLATE PREPARATION

- Prepare the implant space and the grafting surfaces with a curette and/or a rasp.
- Thorough preparation of the endplates favors the fusion.



ADDITIONAL PREPARATION

- Remove any protruding bone spurs on anterior lip of the intersomatic disc space to allow the trial/implant to be placed correctly in the disc space.

IMPORTANT:

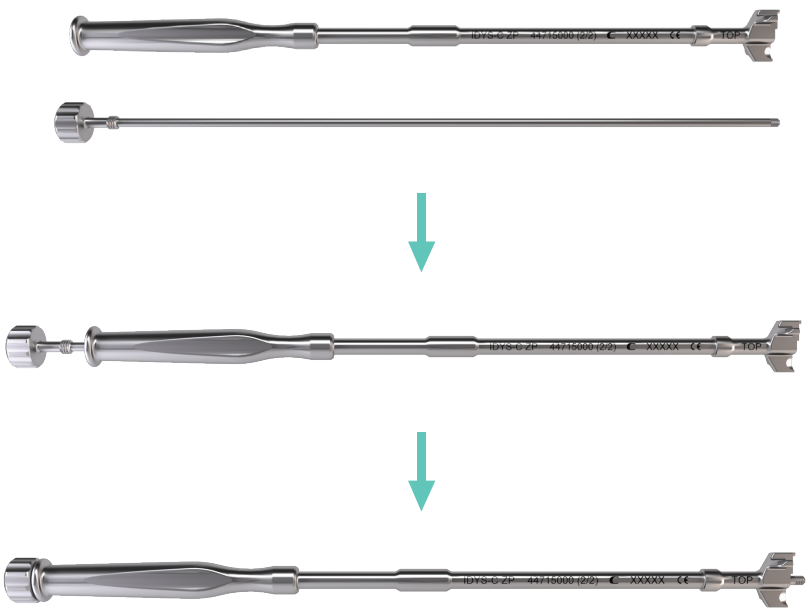
When preparing the disc space, care should be taken to remove all cartilage and endplate preparation should be completed without significant violation of the endplates to avoid subsidence.

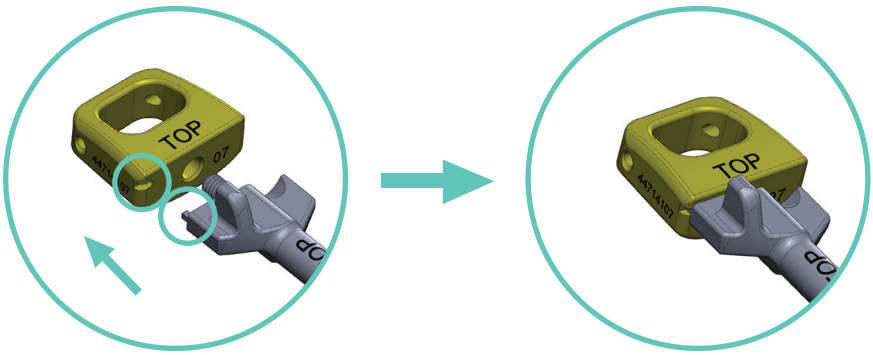
6 | CAGE TRIAL SELECTION & PREPARATION

- The cage trials vary in footprint (depth x width) and height. They are recognizable with color code: each color representing a foot-print (depth x width).

The **Cage Holder** has to be assembled prior to usage. Assemble the appropriate **Cage Trial** onto the **Cage Holder** taking care to:

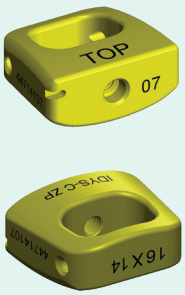
- Align the 2 laser marks "TOP",
- Insert the lateral prong present on the tip of the implant holder into the slot present on the up-left corner of the trial.
- And by screwing the top knob until the cage trial is flush with the implant holder. **Do not overtighten.**





TRIAL FOR ANATOMICAL CAGE

447140xx

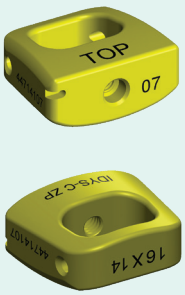


CAGE HOLDER

44715000

TRIAL FOR ANATOMICAL CAGE

447140xx



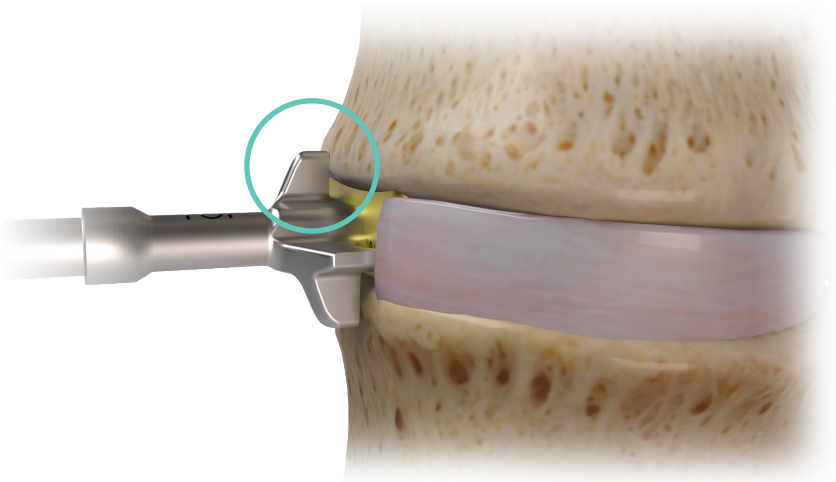
CAGE HOLDER

44715000

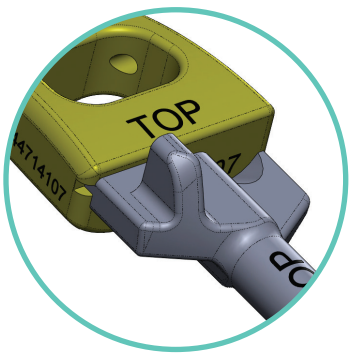
7 | CAGE TRIAL INSERTION & IMPLANT SIZING

TRIAL INSERTION

- The **Cage Holder** has a fixed depth stop located at 2 mm from the anterior wall of the vertebra meaning that when the depth stop is in contact with the anterior wall of the vertebra, the trial is 2 mm deeper inserted into the intersomatic space.
- Insert the **Cage Trial** into the intervertebral space under fluoroscopic control to avoid canal impingement until the trial is in appropriate position.
- If a **Caspar Distractor** is used, release the Distraction momentarily to assess if the size is correct.



IMPORTANT:
The size selection steps must be performed with the distraction fully released.



IMPLANT SIZING

- Check Under fluoroscopy the correct positioning of the cage trial implant in depth.

DEPTH SELECTION

- The posterior side of the cage trial should be a minimum of 1 mm from the posterior edge of the vertebra. If it is not the case, choose a cage trial of inferior depth and refer to chapter 6.

WIDTH SELECTION

- The trial implant should be as large as possible, while allowing stable seating on the vertebral endplate. If needed replace the cage trial by another one having a more appropriate width.
- Match implant width to the intervertebral slope if possible.

HEIGHT SELECTION

Under Fluoroscopy, check:

- the consistency between the selected trial and the disc heights of the adjacent levels.
- the congruency between the trial and the superior and inferior endplates.
- The restoration of the lordotic curve.

Once the implant size has been chosen, restore a slight distraction and remove the cage trial from the intervertebral space.

CAGE HOLDER

44715000

*Product availability may vary upon markets

8 | CAGE PREPARATION

CAGE SELECTION*

- Select in the implant case the cage corresponding to the size previously validated.

ASSEMBLY ON THE CAGE HOLDER

Assemble the selected cage onto the **Cage Holder**:

- Insert the lateral prong present on the tip of the **Cage Holder** into the slot present on the anterior part of the cage
- Screw the top knob until the anterior part of the cage is flush with the **Cage Holder**. **Do not overtighten**.

- To be checked prior to continue : If the cage has been correctly assembled, the 2 holes are free and not hidden by the **Cage Holder**. If not please unscrew and reassembled correctly.

CAGE FILLING

- The graft chamber of the cage has to be filled with autograft, or allograft being composed of cancellous and/or corticocancellous bone graft.
- Take the **Graft Support** and the **Graft Compactor**.
- Place the implant in the **Graft Support** as shown.
- Compact the graft in the cage using the corresponding side of the **Graft Compactor** that fits with the footprint of the cage.

9 | CAGE INSERTION

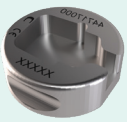
IMPORTANT:

*The **Cage Holder** has a fixed stop located at 2 mm from the edge of the cage meaning that if the depth stop is in contact with the anterior wall of the vertebra, that means that the cage is 2 mm deeper inserted into the intersomatic space*

- Insert progressively the cage centered laterally in the intersomatic space taking care to orientate the laser mark "TOP" toward the cranial side of the patient and under fluoroscopy in order to check its correct positioning.
- The posterior side of the cage should be a minimum of 1 mm from the posterior edge of the vertebra and the cage fully seated into the disc space without protruding outside once the insertion is over.
- Once the final positioning is reached, release the distraction.
- Remove the **Distractor** (and the **Distractions Pins** if not at 6 mm from endplate and fully centered) to avoid any conflict during the bone screw pathway preparation.

GRAFT SUPPORT

44717000



GRAFT COMPACTOR

44761000

DRILL GUIDE

44706001

CAGE HOLDER

44715000

10 | BONE SCREW SELECTION AND PATHWAY PREPARATION FOR THE 1ST SCREW

BONE SCREW SELECTION

- Select the size of screw adapted to the patient anatomy and to the cage's height.

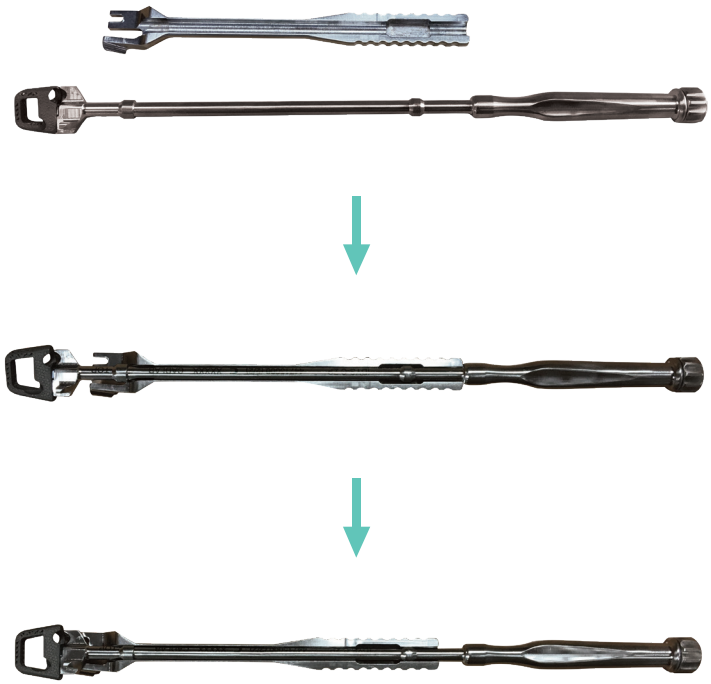
IMPORTANT:

For cages with height of 9mm, the minimum screw length allowed is 16 mm. Do not use shorter screws on H9 mm cages.

SCREW PATHWAY PREPARATION

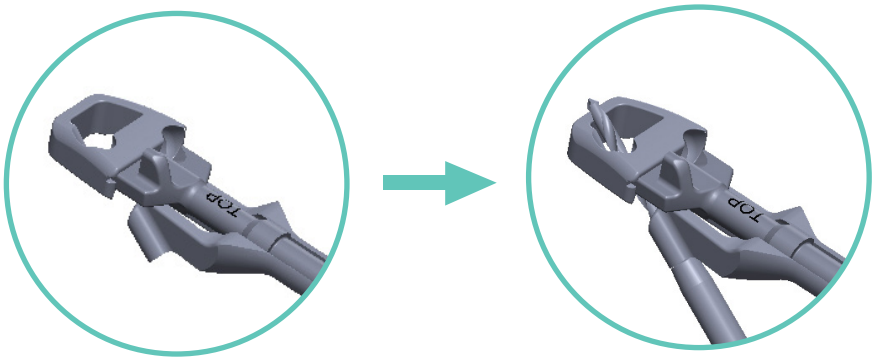
We recommend to start by implanting the screw that will be inserted in the cranial vertebra

- In order to prepare the 1st hole for the 1st screw in the cranial vertebra, insert the **Drill Guide** over the **Cage Holder** at the opposite side of the laser mark "top" just below the handle and push it down taking care to align the slot of the guide with the prong present on the **Cage Holder** as shown on the picture.



- Insert the **Punch Awl** (straight version or Angled version) inside the hole of the drill guide until reaching mechanical stop.
- **Drill** through the hole previously initiated until reaching the mechanical stop.
  - Assemble it on the **AO Cylindrical handle**.
  - Remove the **Drill Guide** prior to 1st screw insertion.

IMPORTANT:
*2 types of **Drills** are available in the set : Flexible or fixed – Please select the most adapted design to the patient anatomy*



11 | 1ST BONE SCREW INSERTION

SCREW INSERTION

- 2 types of Screwdrivers are available in the set : Flexible or Fixed. Please select the one most adapted to the patient anatomy.
- Insert the tip of the selected screwdriver into to the screw head and clip the screws onto the instrument.
- Insert the screw into the previously prepared pathway but do not screw it fully. Leave the head of the screws a bit out from the cage.

PUNCH AWL

4470200x

AO CYLINDRICAL HANDLE

99782008

DRILLS

44700000 Flexible drill
44700228 Fixed drill

FLEXIBLE SCREWDRIVER

44710000

FIXED SCREWDRIVER

43710020

DRILL GUIDE

44706001

CAGE HOLDER

44715000

12 | BONE SCREW SELECTION AND PATHWAY PREPARATION FOR THE 2ND SCREW

BONE SCREW SELECTION

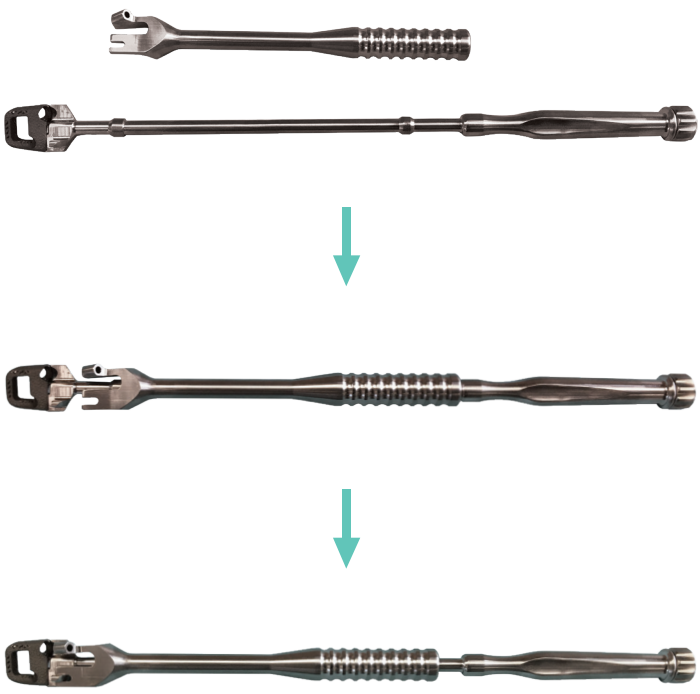
- Select the size of screw adapted to the patient anatomy and to the cage's height.

IMPORTANT:

For cages with height of 9mm, the minimum screw length allowed is 16 mm. Do not use shorter screws on H9 mm cages.

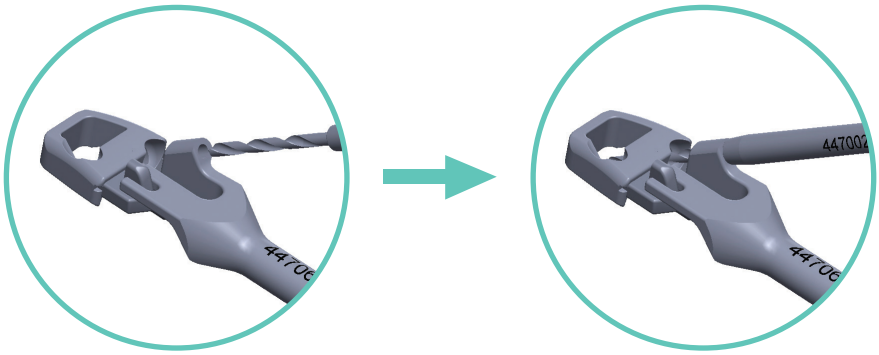
SCREW PATHWAY PREPARATION

- In order to prepare the 2nd hole for the screw that will be implanted into the caudal vertebra, insert the **Drill Guide** over the **Cage Holder** just below the handle on the same side of the laser mark "TOP" and push it down taking care to align the slot of the guide with the depth stop present on the **Cage Holder** as shown on the picture.



- Insert the **Punch Awl** (straight version or Angled version) inside the hole of the drill guide until reaching mechanical stop.
- **Drill** through the hole previously initiated until reaching the mechanical stop.
  - Assemble it on the **AO Cylindrical handle**.
  - Remove the **Drill Guide** prior to 2nd screw insertion.

IMPORTANT:
*2 types of **Drills** are available in the set : Flexible or fixed – Please select the most adapted design to the patient anatomy*



13 | 2ND BONE SCREW INSERTION

SCREW INSERTION

- 2 types of Screwdrivers are available in the set : Flexible or Fixed. Please select the one most adapted to the patient anatomy.
- Insert the tip of the selected screwdriver into to the screw head and clip the screws onto the instrument.
- Insert the screw into the previously prepared pathway but do not screw it fully. Leave the head of the screws a bit out from the cage.

Perform a fluoroscopic control in lateral plane to check on the trajectories of both screws. Once the trajectories are validated, finalize the screwing until the 2 screws are fully integrated in the cage **(Avoid over torqueing)**.

PUNCH AWL

4470200x

AO CYLINDRICAL HANDLE

99782008

DRILLS

44700000 Flexible drill
44700228 Fixed drill

FLEXIBLE SCREWDRIVER

44710000

FIXED SCREWDRIVER

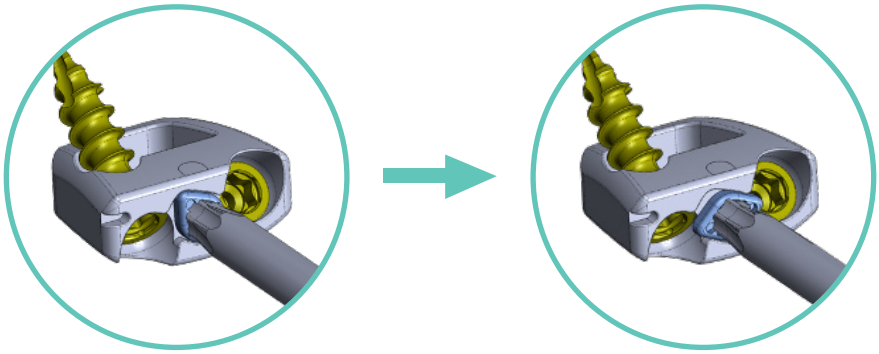
43710020

FIXED SCREWDRIVER

43710020

14 | SCREW LOCKING

- Remove the **Cage Holder** by unscrewing the top knob and pulling out the instrument.
- In order to lock the screws into the cage please turn the locking mechanism counter-clockwise using the **Fixed Screwdriver** until it covers the 2 screw heads (Visual control).



- Perform a final fluoroscopic control.
- Closure of the incision according to surgeon's habits.

15 | REVISION

In case of revision please follow the instructions below:

- Carefully distract the segment. If you want to use a **Caspar Distractor** please refer to the Chapter "Caspar Distractor Positioning".
- First unlock the locking mechanism by turning it clockwise using either the **Fixed Screwdrive**r or the **Rescue Screwdriver for Locking Mechanism** assembled on the **AO Cylindrical handle**.
- Remove all screws using either the **Fixed Screwdriver**, or the **Flexible Screwdriver**.
- Then connect the cage to the **Cage Holder :**
  - Insert the lateral prong present on the tip of the **Cage Holder** into the slot present on the anterior part of the cage.
  - Screw the top knob until the anterior part of the cage is flush with the **Cage Holder**. **Do not overtighten**.
- Gently pull on the **Cage Holder** to remove the implant.

IMPORTANT:

If the connection between the Cage Holder and the cage is difficult, you can use the internal part of the Cage Holder alone to remove the cage by screwing it into the thread present on the locking mechanism and by pulling the cage out.

CAUTION:

This procedure definitively damages the implants. Those implants must not be used again.

CAGE HOLDER

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AO CYLINDRICAL HANDLE

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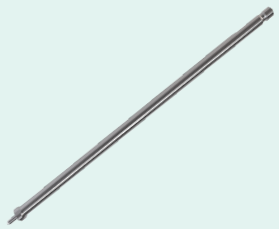
RESCUE SCREWDRIVER

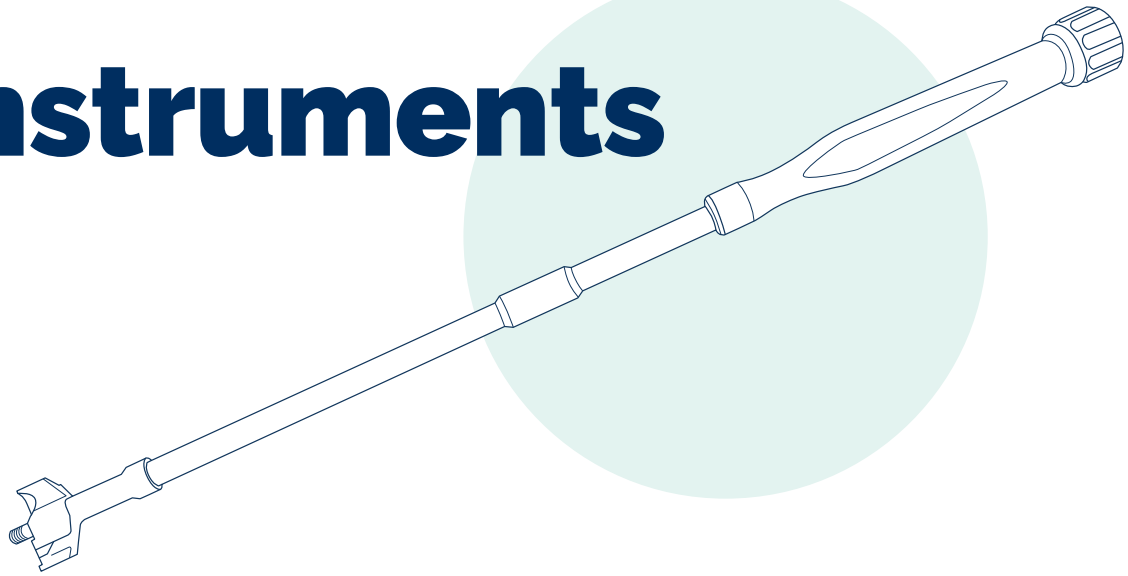
44710001



FIXED SCREWDRIVER

43710020

Instruments



Instruments IDYS-C ZP 3DTi

IDYS-C ZP 3DTi INSTRUMENT BASE

44991000	Base
44991001	Instruments Lid
44991005	Instruments Tray
44991004	Trial Rack

IDYS-C ZP 3DTi TRIAL 16x14MM

44714105	H05mm
44714106	H06mm
44714107	H07mm
44714108	H08mm
44714109	H09mm

IDYS-C ZP 3DTi TRIAL 18x15MM

44714206	H06mm
44714207	H07mm
44714208	H08mm
44714209	H09mm

CYLINDRICAL HANDLE

99782008

IDYS-C ZP 3DTi CAGE HOLDER

44715000

IDYS-C ZP 3DTi GRAFT SUPPORT

44717000

IDYS-C ZP 3DTi GRAFT COMPACTOR

44761000

IDYS-C ZP 3DTi DRILL GUIDE

44706001

IDYS-C ZP 3DTI STRAIGHT PUNCH AWL

44702001

IDYS-C ZP 3DTI ANGLED PUNCH AWL

44702002

IDYS-C ZP 3DTI FIXED DRILL

44700228

IDYS-C ZP 3DTI FLEXIBLE DRILL

44700000

IDYS-C ZP 3DTI FIXED SCREWDRIVER

43710020

IDYS-C 3DTi ZP FLEXIBLE SCREWDRIVER

44710000

IDYS-C ZP 3DTi LOCKING MECHANISM RESCUE SCREWDRIVER

44710001

Implants
Sterile

Product availability may vary upon markets. Please check with your Clariance representative.

IDYS-C ZP 3DTi CAGES 16x14MM

H	W16 x D14mm
H05mm	44581105-S
H06mm	44581106-S
H07mm	44581107-S
H08mm	445811085-S
H09mm	44581109-S

IDYS-C ZP 3DTi CAGES 18x15MM

H	W18 x D15mm
H05mm	-
H06mm	44581106-S
H07mm	44581207-S
H08mm	44581208-S
H09mm	44581209-S

IDYS-C ZP 3DTi SCREW Ø3.5MM

L14mm	L16mm	L18mm
44053514-S	44053516-S	44053518-S

IDYS-C ZP 3DTi SCREW Ø4.0MM

L14mm	L16mm	L18mm
44054014-S	44054016-S	44054018-S

Clariance

CE 0459

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