

SURGICAL TECHNIQUE

Mobidisc® L

LUMBAR DISC PROSTHESIS



Mobidisc® L

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Important points & Comments

- During fluoroscopic assessment, it is important to respect the following patient positioning:
 - Dorsal decubitus strict ("French position" possible)
 - Without block
- Prior to surgery, a CT scan can be used to measure the inferior vertebral endplate of the operative space in order to estimate the prosthesis size. The final prosthesis dimensions will be verified intra-operatively by direct measurement using the trial endplates.
- The osteophytes must be removed before measuring the depth of the vertebral endplates.
- For any hybrid procedure (prosthesis, cage,...), sufficient height of the vertebral bodies must be ensured to avoid contact between the fixation systems of the implants.
- Approach: Retro- or trans-peritoneal.
- Disc exposure: With special retractor or Steinman pins.

Step

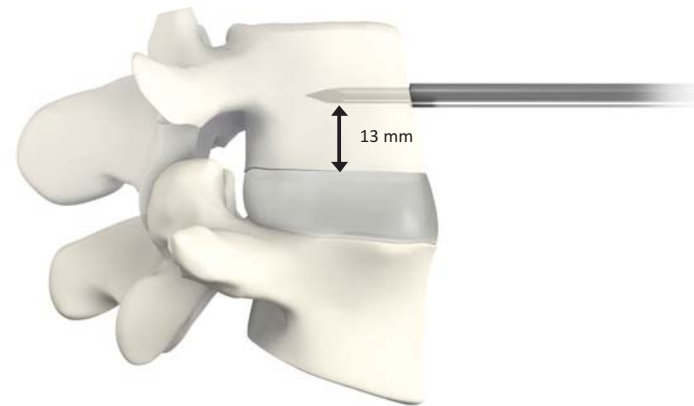
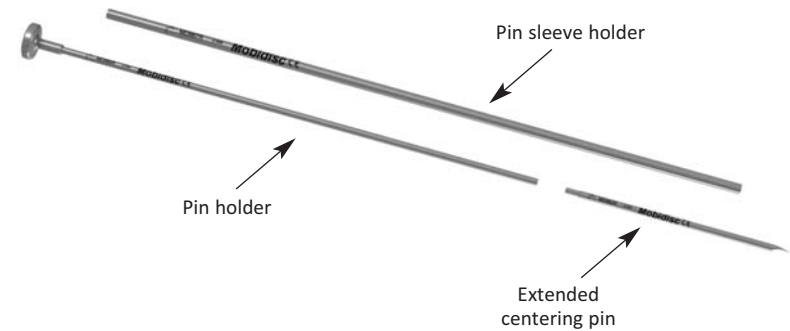
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Midline determination

- Screw the **extended centering pin** onto the **pin holder**. Slide the **pin sleeve holder** over the pin holder/pin assembly.
- Determine the midline of the superior vertebra.
- Keeping the extended centering pin inside the pin sleeve holder, position it against the vertebra and impact the extended centering pin until it stops.

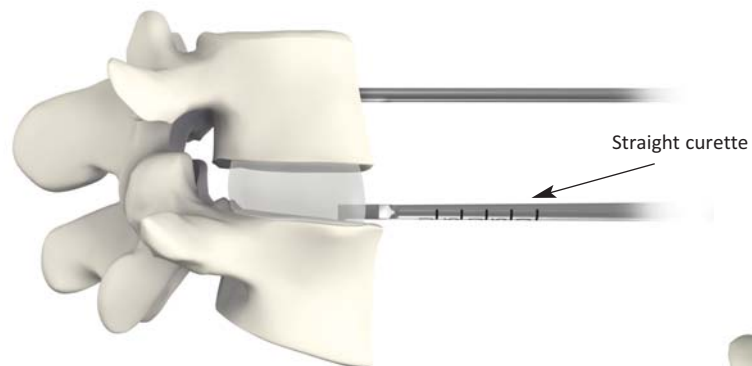
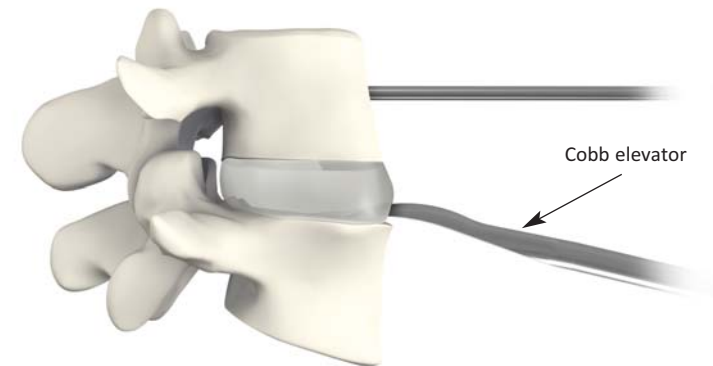
Note: Make sure to place the centering pin at least 13 mm from the lower vertebral endplate to prevent any interference with the implant holder's adjustable stop.

- Unscrew the pin holder and remove the pin sleeve holder, then confirm proper placement under fluoroscopy.

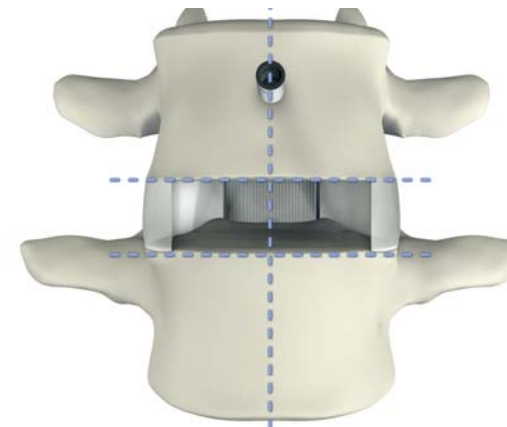


Step 2 Discectomy and release of the intersomatic space

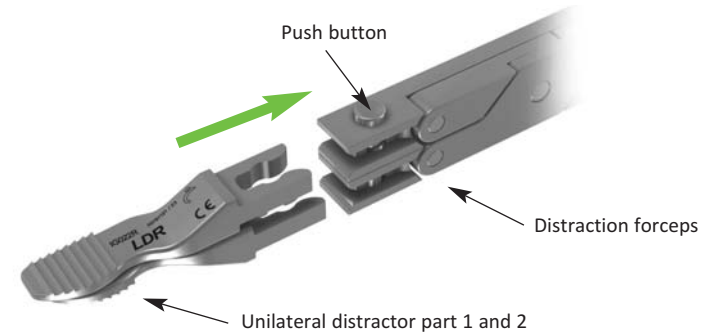
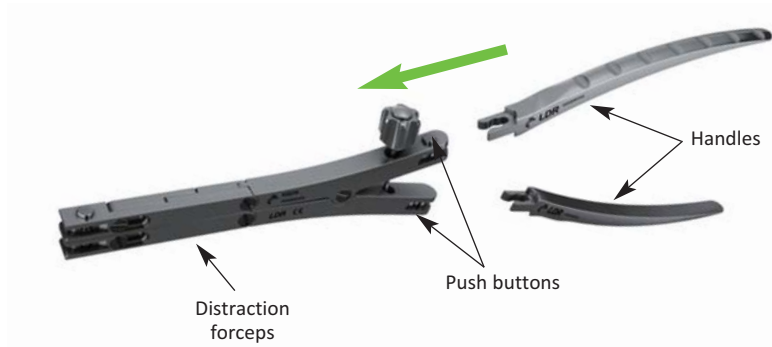
- Incise the disc with a scalpel like a standard ALIF surgery.
- Use the **cobb elevator** to release the disc from the superior and inferior endplates.
- Remove the disc with a disc forceps and the **straight curette**. This step allows removal of almost all the disc tissue for prosthesis placement.



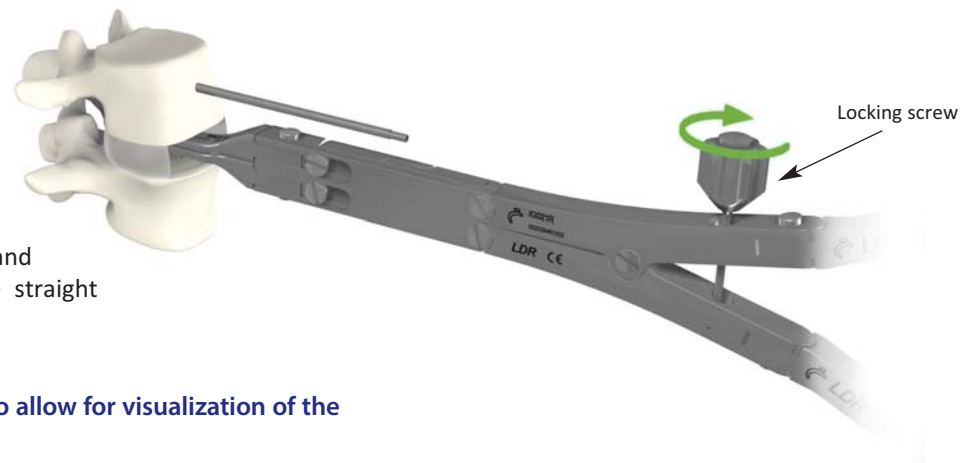
Note: It is important to dissect the lateral parts of the disc thoroughly and symmetrically to ease the prosthesis insertion, optimize its centering, and keep the endplates parallel in the frontal plane.



- Assemble the **distraction forceps** with the handles and **unilateral distractor part 1 and 2** by pressing the push buttons.



- Distract one side of the intervertebral space with the distraction forceps and maintain its position by tightening the locking screw.
- Finish the discectomy on the opposite side of the distraction. Take care to remove any anterior or posterior osteophytes and continue to prepare the upper and lower endplates using the straight curette.



Note: The posterior portion of the space must be fully exposed to allow for visualization of the Common Posterior Vertebral Ligament (CPVL).

- Continue releasing the intersomatic space by alternatively using the distraction forceps on the left and on the right to complete the discectomy.

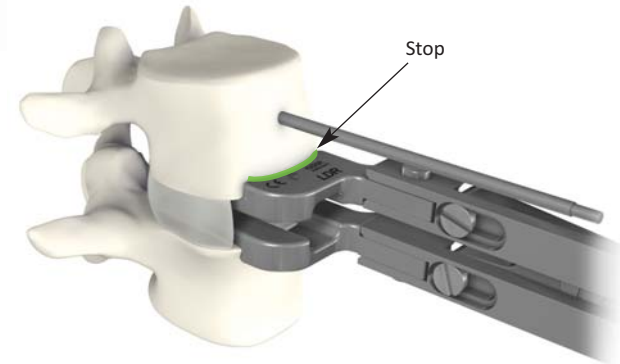
Step 3 Parallel distraction and height selection

- Replace the unilateral distractors with the **bilateral distractor part 1 and 2**.

Bilateral distractor
part 1 and 2

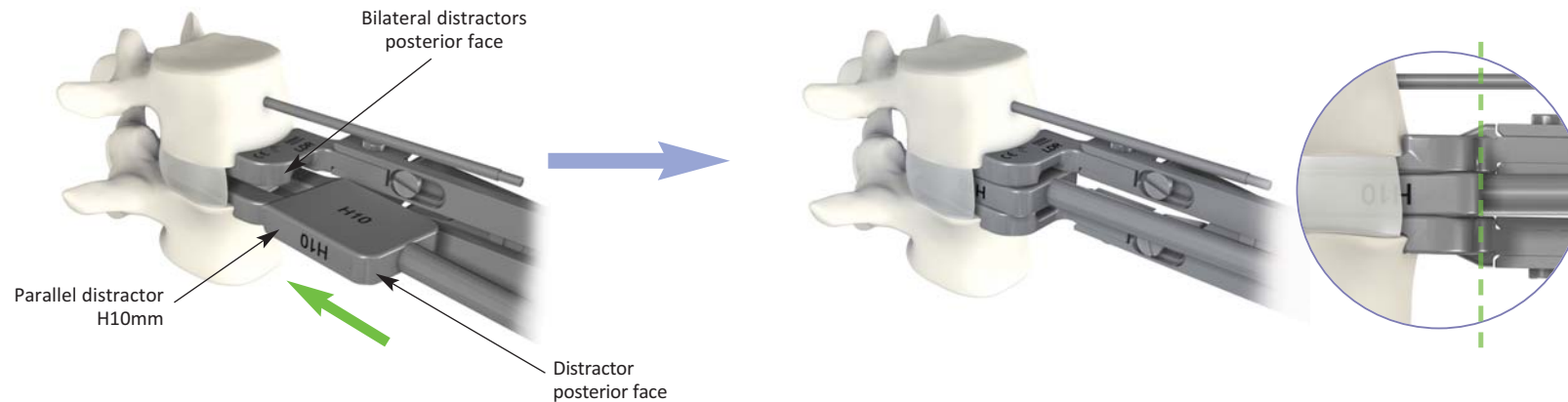


- Place the distraction forceps into the intersomatic space until it stops on the anterior face of the vertebral bodies. Carry out the distraction and maintain the position by tightening the locking screw. Maintaining this distraction allows for the final preparation of the posterior portion of the disc space and exposure of the CPVL.



- Insert the **parallel distractor H10mm** between the bilateral distractors. Progressively impact the distractor to obtain parallel opening of the intersomatic space.

- Stop the insertion of the distractor when its posterior face is aligned with the posterior face of the bilateral distractors.



Note: Do not exceed the height of the adjacent discs. If necessary, a parallel distractor H12mm may be used. The height of the parallel distractor determines the most suitable prosthesis height for the intersomatic space.

Step 4

Trial plate selection

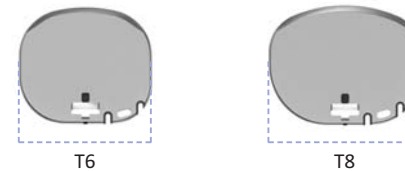
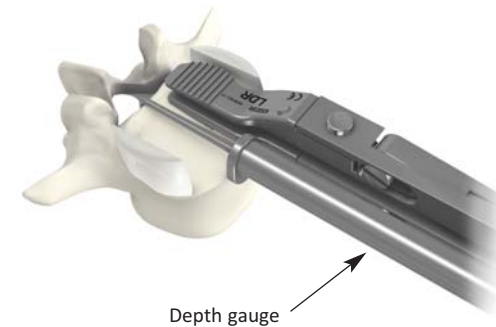
Optional: Depth gauge

The **depth gauge** can be used before trialing in order to determine the depth of the prosthesis.

- Use the unilateral distractors to allow the depth gauge hook to be placed at the posterior edge of vertebral body.
- Take care to thoroughly clean the anterior edge of the vertebral endplate (osteophytes and fibrous tissue) and to measure the most central part of the vertebra.
- Once the depth has been measured, remove the depth gauge and read the anteroposterior dimension of the vertebral body directly from the reading windows, as well as the depth of the prosthesis corresponding to the measurement.
 - T6 small, medium or large
 - T8 small, medium or large

Important: If the line falls between two depths, choose the smaller size.

Note: In case of a direct reading on the depth gauge, a difference of 4 mm larger than the preoperative measurement made on the CT scan may be observed if fibrous material is present.

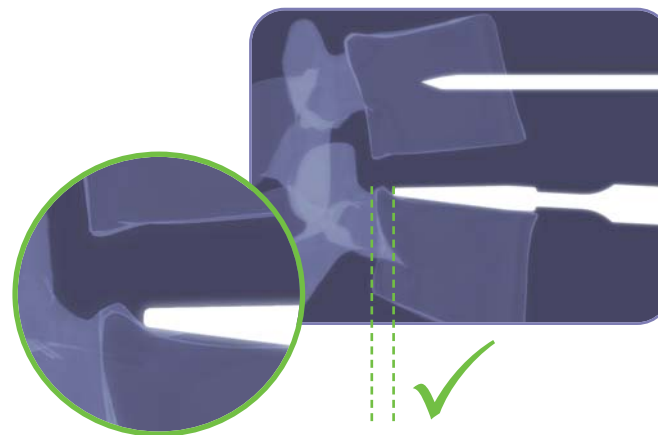
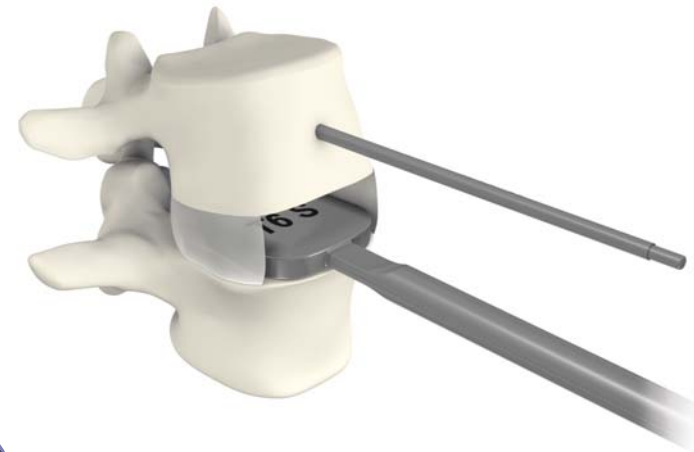


Trial plate selection

Trial plates are used to define the width and the depth of the prosthesis in order to ensure adequate coverage of the vertebral bodies.

- Place the trial plate on the inferior vertebral body.
- Validate prosthesis depth choice with a lateral fluoroscopic image.




Note: During fluoroscopy, the trial plate should be centered on the vertebral endplate without overlaying anterior and posterior osteophytes.




Important: For safety reasons, ease of positioning, and bone anchorage, trial plates are oversized by 1.5 mm anteriorly and posteriorly.

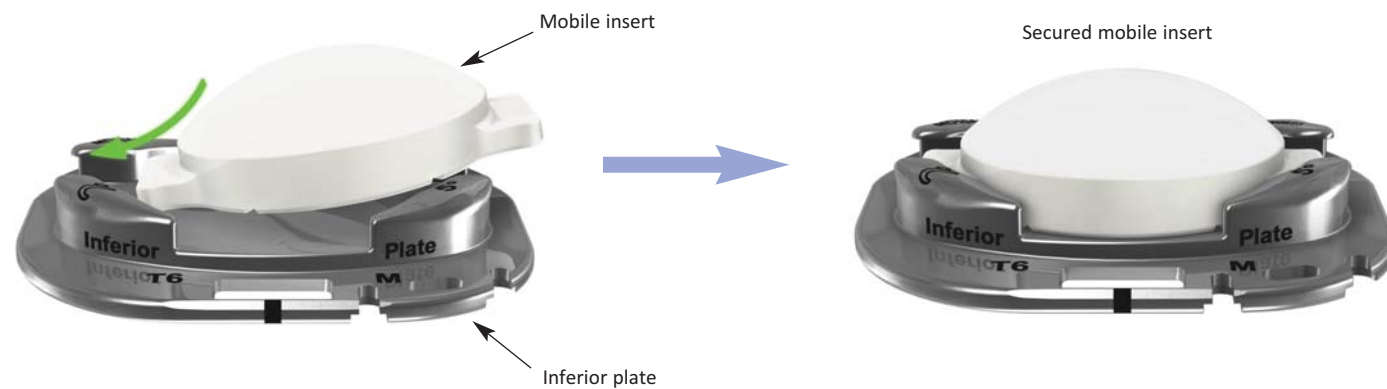
Prosthesis assembly

In order to obtain the desired prosthesis height, refer to the chart below to choose the appropriate mobile insert height.

Total height of the prosthesis 	Mobile insert height selection according to the inferior plate lordosis	
		
10 mm	8 mm	7 mm
11 mm	9 mm	8 mm
12 mm	10 mm	9 mm
13 mm	11 mm	10 mm

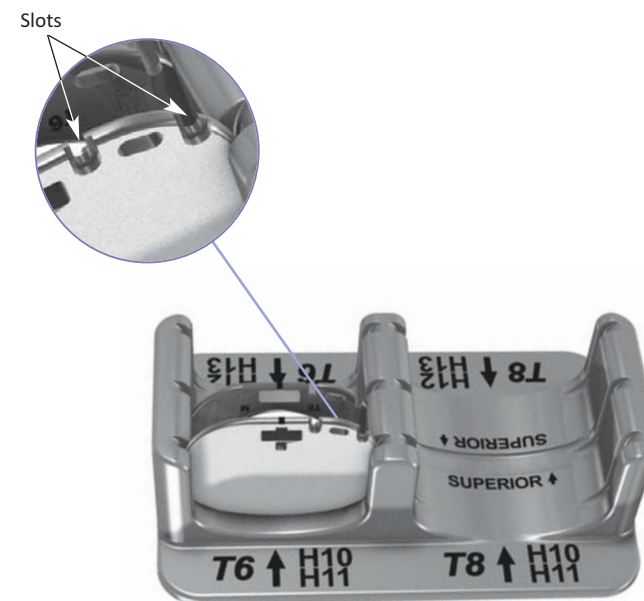


- Insert and secure the mobile insert between the stops of the inferior plate.



- Position the superior and inferior plates in the **assembly block** at the position corresponding to the selected size and height. The superior plate should be placed on the side with the "**superior**" mark.

Note: The slots on the plates should be oriented upwards so they can be engaged by the implant holder.



Step 6

Implant holder assembly and loading the prosthesis

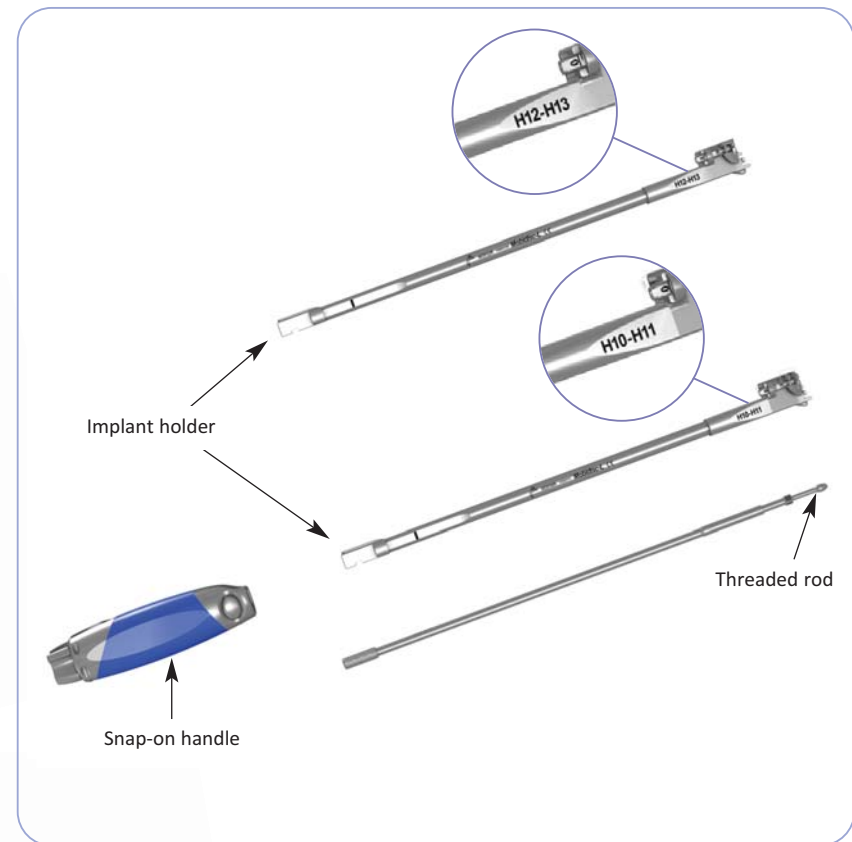
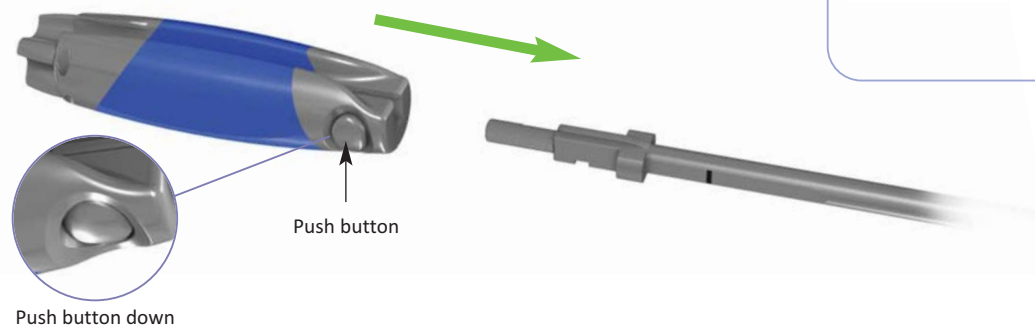
- Select the **implant holder** to the corresponding prosthesis height (H10-H11 or H12-H13).

Note: In case of a severely lordotic segment, the H12-H13 implant holder can be used to adapt a prosthesis of 10 or 11mm height into the intersomatic space.

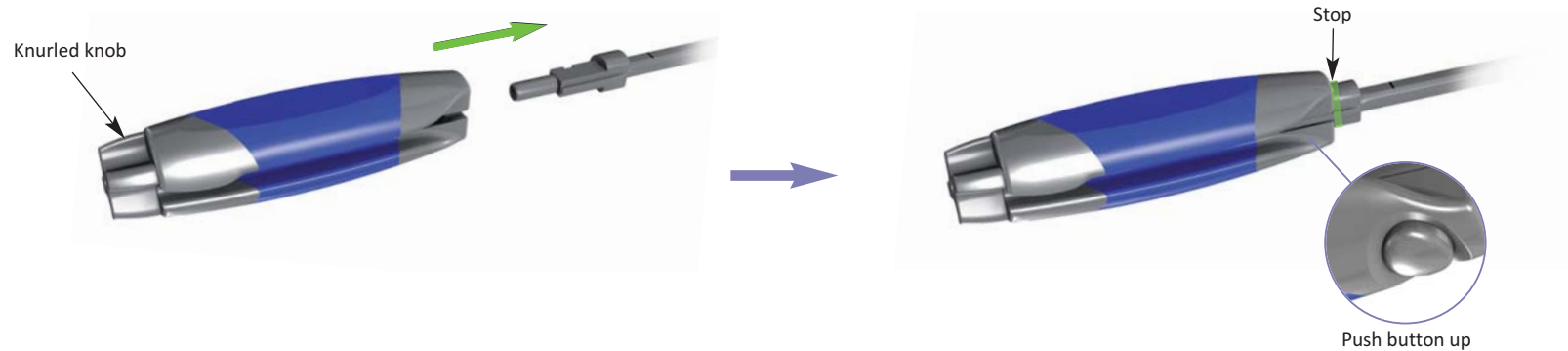
- Insert and screw the threaded rod into the implant holder.



- Insert the snap-on handle onto the implant holder by pressing on the push button.



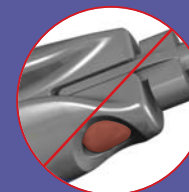
- Check that the snap-on handle is engaged onto the implant holder until the stop and that the push button is up.



Note: If the handle is not flush with the implant holder, turn the knurled knob to finalize handle insertion.
If the handle is still not correctly positioned, take it off and insert it again.



Important: During the prosthesis insertion step, it must be checked that the handle is perfectly connected to the implant holder before malleting and inserting the prosthesis into the intersomatic space.
These checks must be repeated and the knurled knob must be retightened when the handle is put back in place after fluoroscopy.

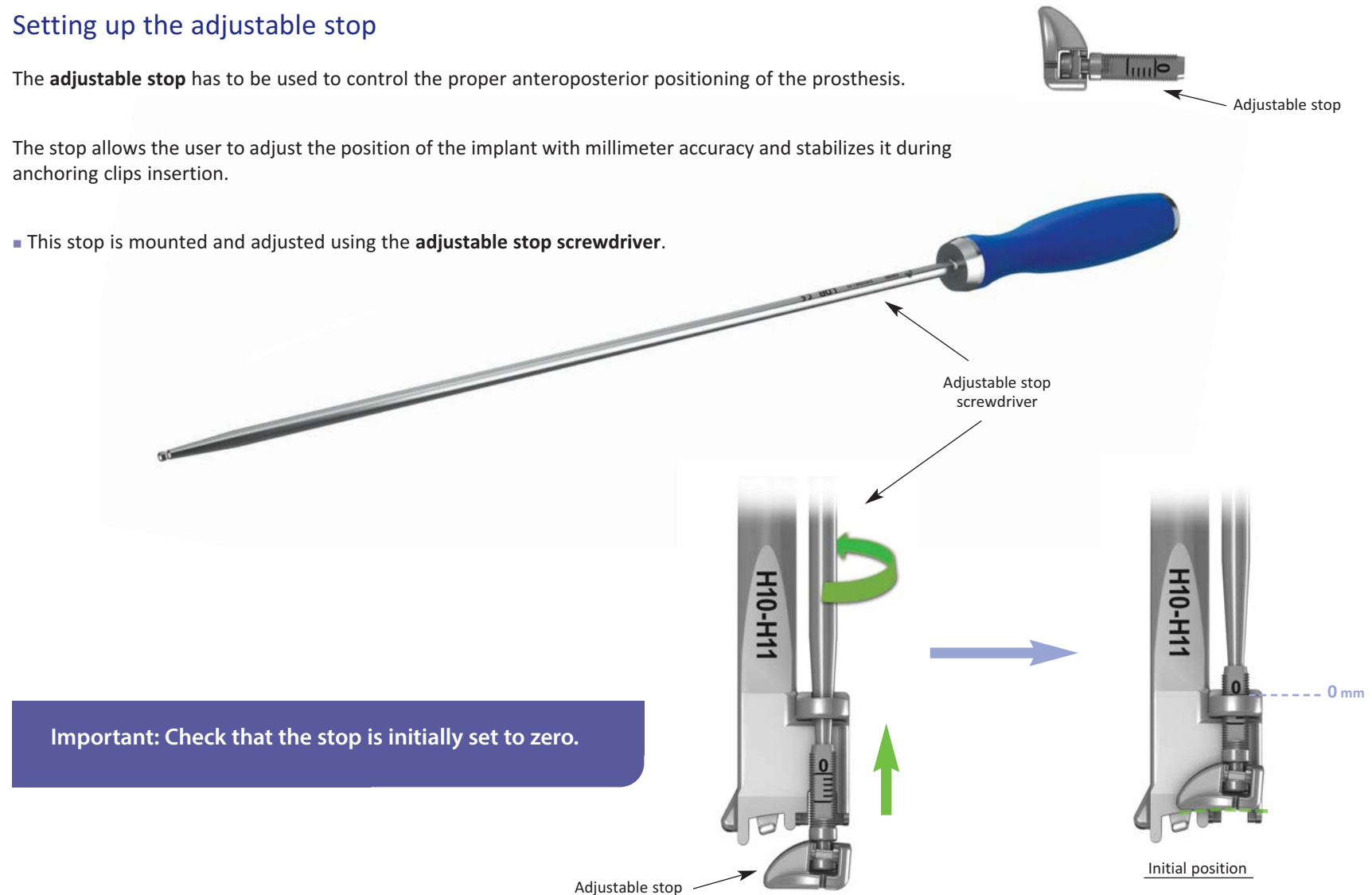


Setting up the adjustable stop

The **adjustable stop** has to be used to control the proper anteroposterior positioning of the prosthesis.

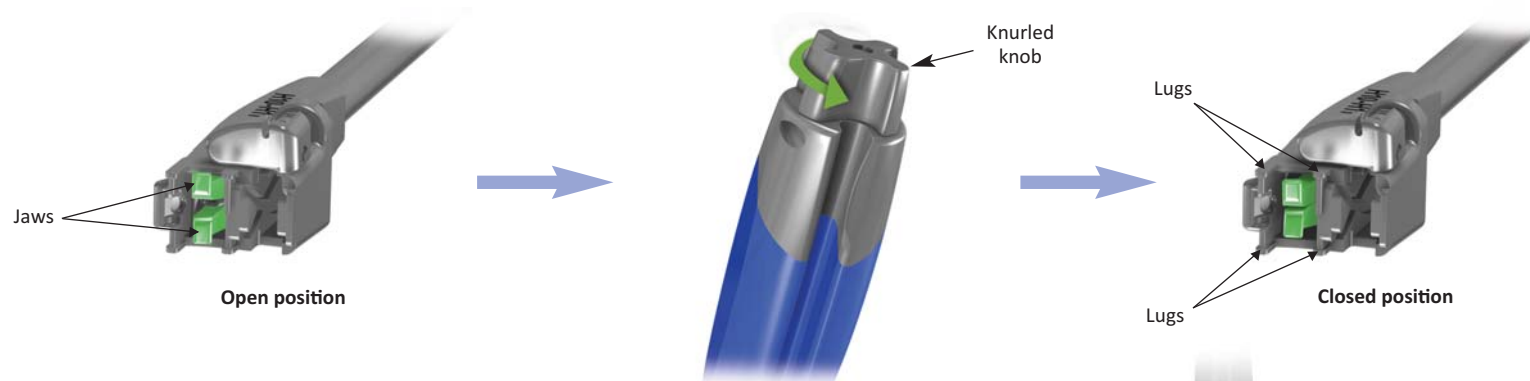
The stop allows the user to adjust the position of the implant with millimeter accuracy and stabilizes it during anchoring clips insertion.

- This stop is mounted and adjusted using the **adjustable stop screwdriver**.

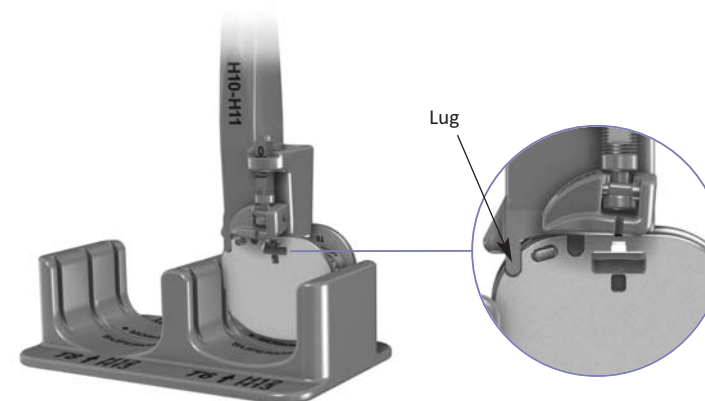


Prosthesis loading

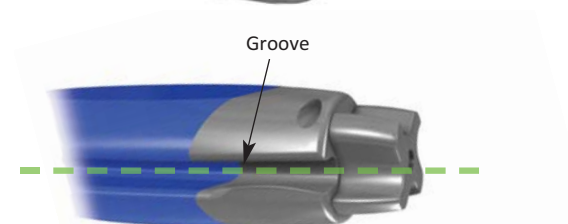
- Check that the implant holder jaws are completely closed.
If they are open, unscrew the knurled knob on the snap-on handle until the two jaws are in contact with one another.



- Engage the four lugs of the implant holder in the corresponding slots on the prosthesis.
- Lock the prosthesis onto the implant holder by firmly tightening the knurled knob.



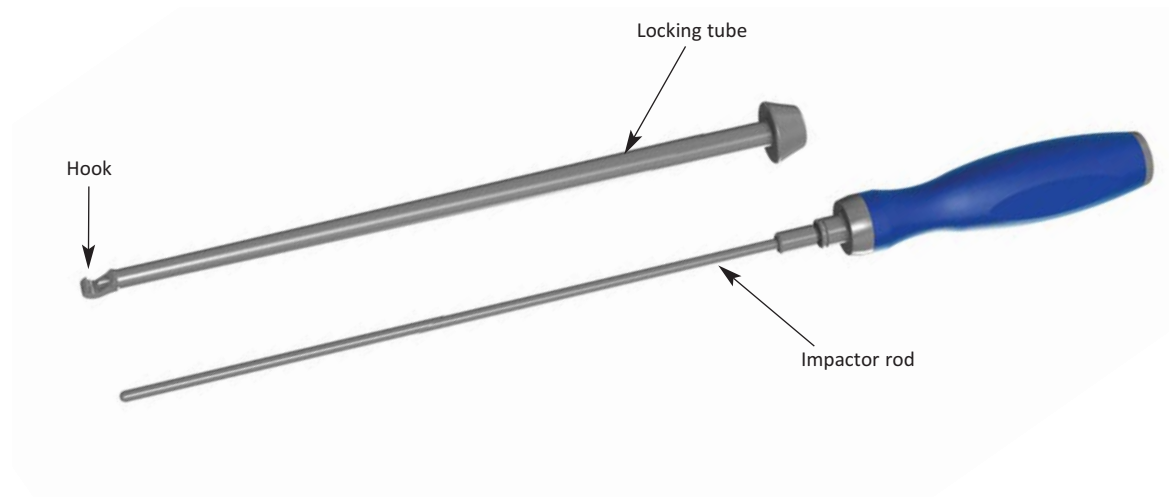
Important: Make sure that the knurled knob on the handle is positioned so that the access to the groove on the implant holder is left free for the passage of the bone chisel and the anchoring clip impactor.



Option: Assembly of the lateral impactor

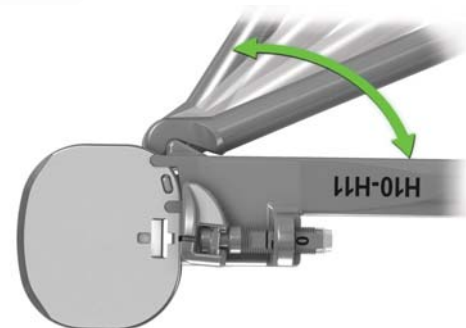
For an anterolateral approach, the **lateral impactor** has to be used for mediolateral positioning of the prosthesis.

- Insert the **impactor rod** into the **locking tube** and turn it all the way round three times to lock the two components together.
- Position the locking tube's hook in its place on the implant holder.



- Lock the tube onto the implant holder by screwing the handle of the impactor's rod.

Note: The lateral impactor's position can be adjusted by tightening/loosening the rod according to the requirements associated with the approach.



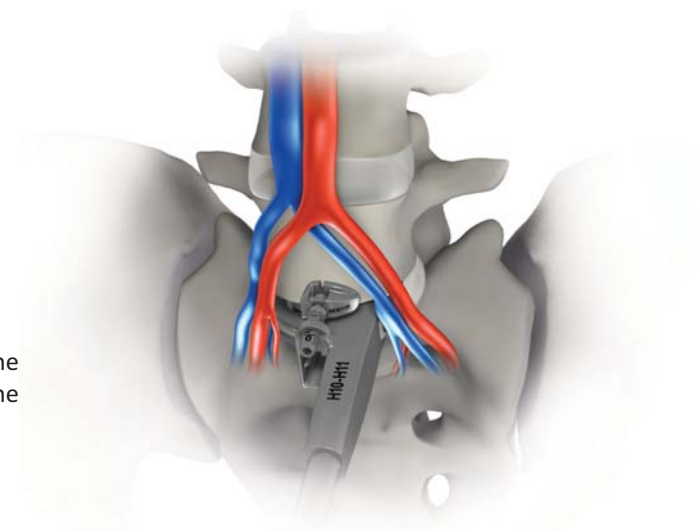
Step 7

Prosthesis insertion and positioning

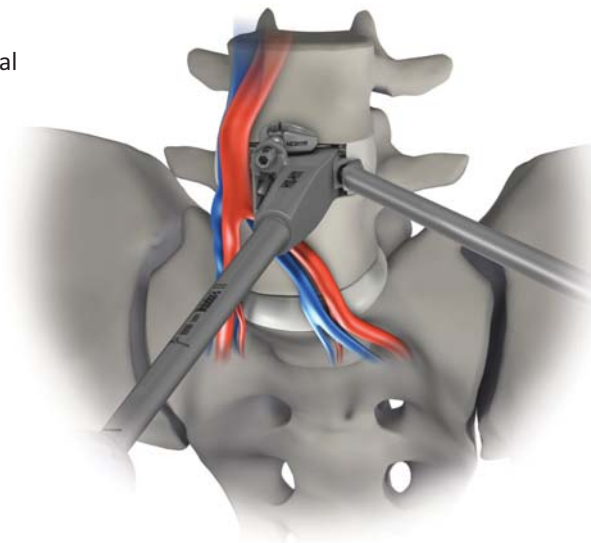
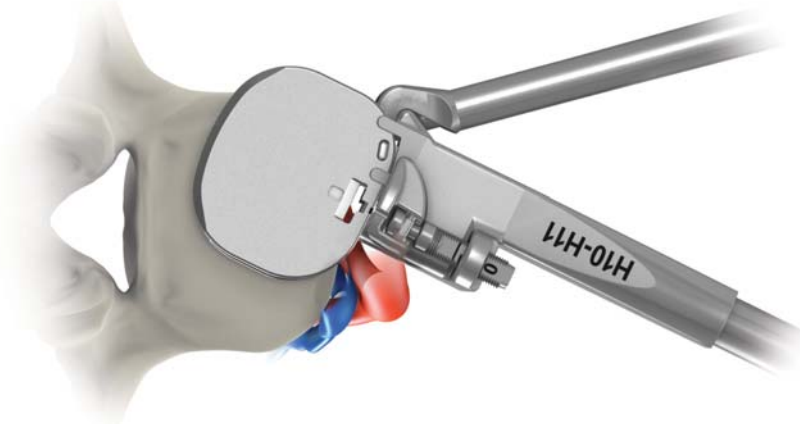
Important: If a block is being used, it must be removed for the prosthesis insertion step.

Anterior approach:

- Insert the prosthesis into the intervertebral space by successive impactions on the implant holder in the anteroposterior axis until its mechanical stop on the vertebra.

**Anterolateral approach:**

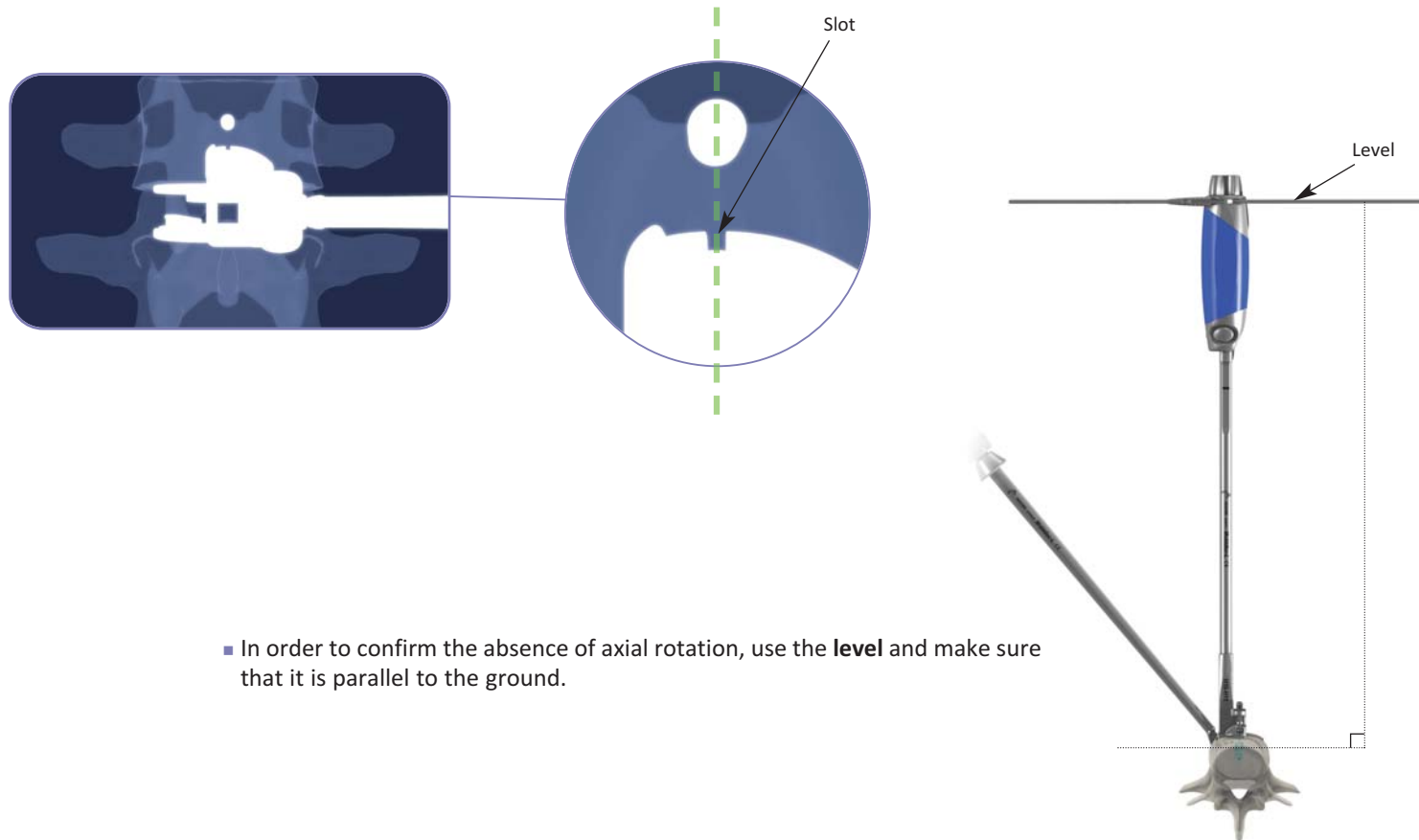
- Insert the prosthesis into the intersomatic space from the patient's left.
- Adjust the mediolateral position of the prosthesis by successive impactions on the lateral impactor until its mechanical stop on the vertebra.



- Check that the prosthesis is well centered using antero-posterior fluoroscopy.

Note: The implant holder's handle is removable to allow antero-posterior fluoroscopy.

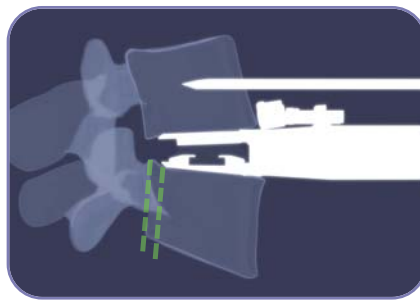
Important: The slot on the adjustable stop indicates the middle of the prosthesis. Its alignment with the extended centering pin confirms that the implant is neither rotated nor lateralised.



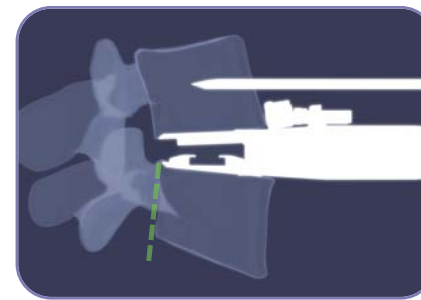
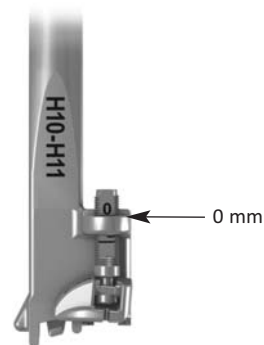
- In order to confirm the absence of axial rotation, use the **level** and make sure that it is parallel to the ground.

- Under fluoroscopy, proceed to millimetric adjustment to insert the prosthesis as close as possible to the posterior vertebral wall.

Important: When the desired position has been obtained, check that the stop is in contact with the anterior vertebral wall before inserting the anchoring clips.



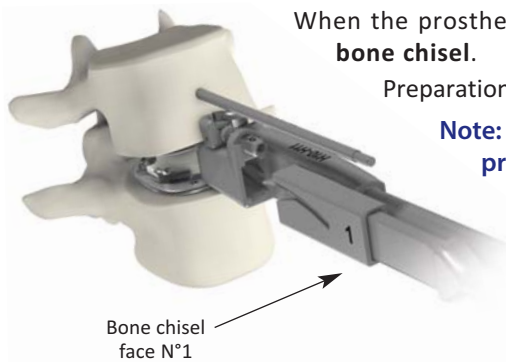
Initial position



Stop adjustment for an optimal positioning of the prosthesis in the intersomatic space



Step 8 Anchoring clips insertion

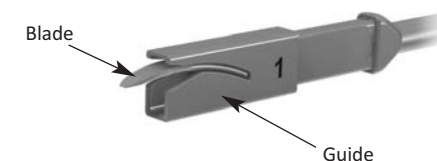


When the prosthesis positioning is optimal, anchoring clips can be inserted. Anchoring clips insertion is prepared using the **bone chisel**.

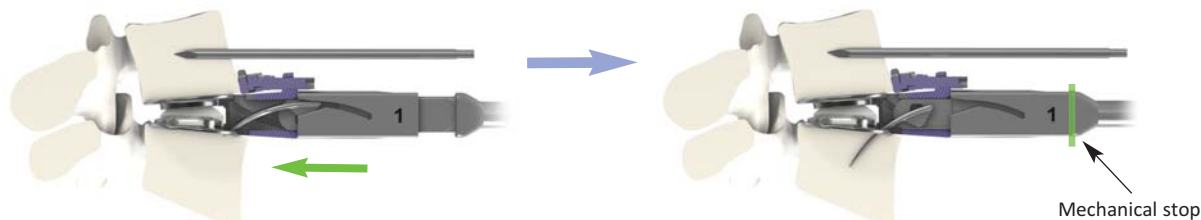
Preparation and impaction of the two anchoring clips are made one after another.

Note: the knurled knob should be completely tightened before this operatory step in order to ensure that the prosthesis is well locked while taking care to leave free access to the groove on the handle.

- Slide the guide manually in order to maintain the blade inside and to ease the guidance of the blade at the entry of the implant holder head.
- Insert the blade of the bone chisel in the superior slot of the implant holder taking care to leave face N°1 visible.
- Then, engage the thinnest part of the bone chisel in the groove of the implant holder's handle.



- Bring the blade in contact with the bone (slight resistance) by thumb pressure on the bone chisel.
- Bone chisel impaction must be done progressively and in several steps with complete withdrawal of the blade from the vertebral body between each step.
 - Start the insertion with a series of 3 to 4 impactions with a mallet. The blade will be partially inserted into the vertebral body.
 - Remove progressively and completely the bone chisel with the mallet before starting another series of impactions.
 - Repeat these steps until the mechanical stop of the bone chisel on the guide.



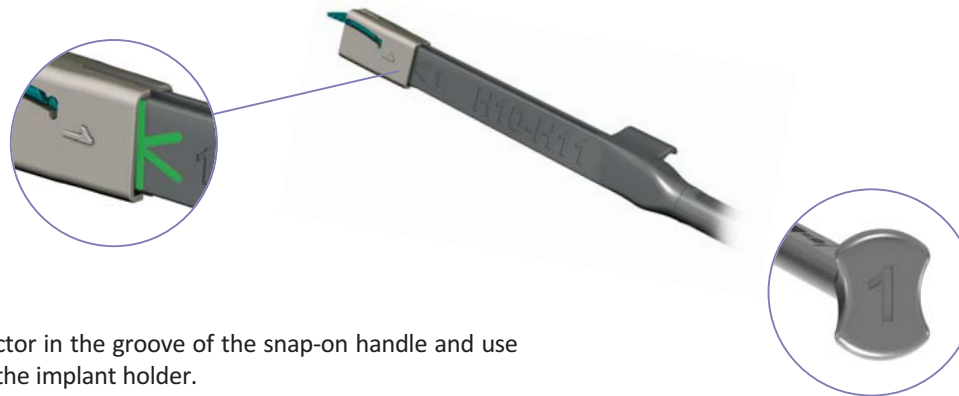
- Check blade trajectory under fluoroscopy.

- Remove the bone chisel with a mallet.

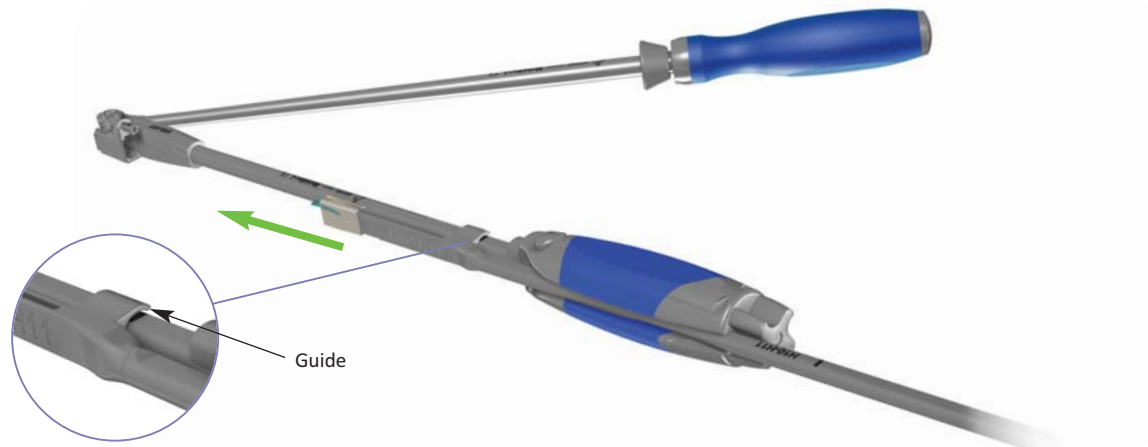
Sequential and progressive insertion of bone chisel helps preparing the trajectory of the first anchoring clip. Anchoring clips are pre-assembled on a single use PEEK Classix[®] holder.

Important: The height of the 2 impactors must correspond to the one of the implant holder (H10/11 or H12/13).

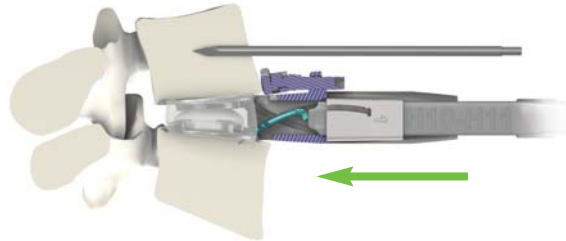
- Insert the first holder with face number "1" facing the K mark on impactor n°1.



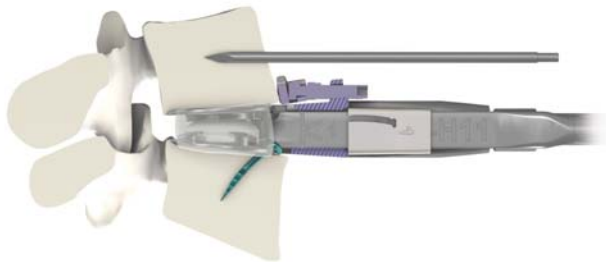
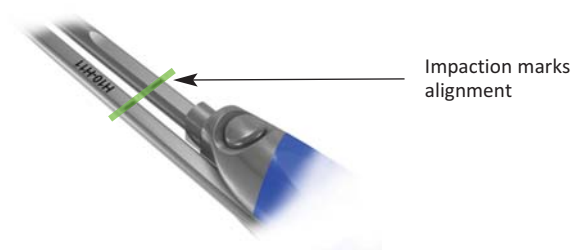
- Engage the thinnest part of the impactor in the groove of the snap-on handle and use the guide to slide the impactor along the implant holder.



- Bring the first anchoring clip in contact with the bone (slight resistance) by thumb pushing on the impactor.



- Continue the impaction with the mallet until the stop and check the alignment of impaction marks.



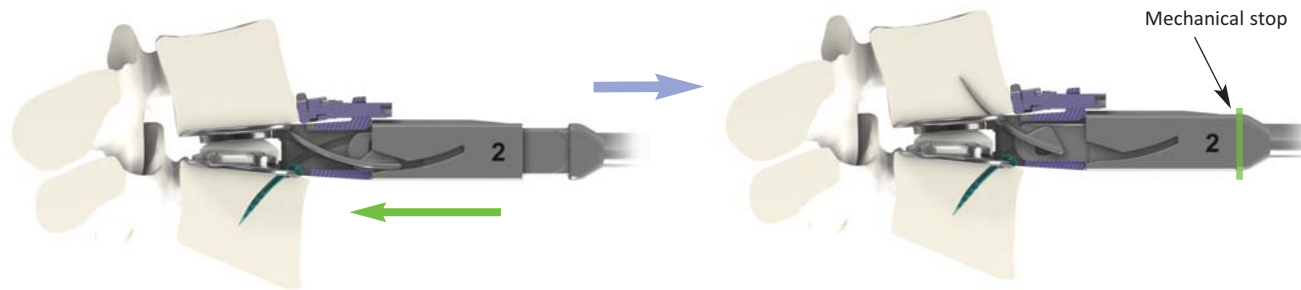
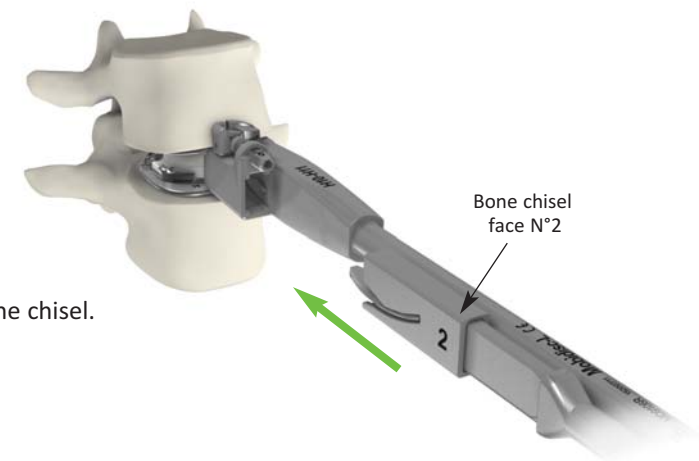
Note: The anchoring clip is automatically released from its holder. The holder slides up along the impactor.

- Under fluoroscopy, check that the first anchoring clip is correctly positioned and remove the impactor.



Important: During the preparation of the anchoring clip's trajectory inside the superior vertebra, remove the extended centering pin with the pin sleeve holder, the pin holder, and the slap-hammer in order to prevent any conflict with the blade.

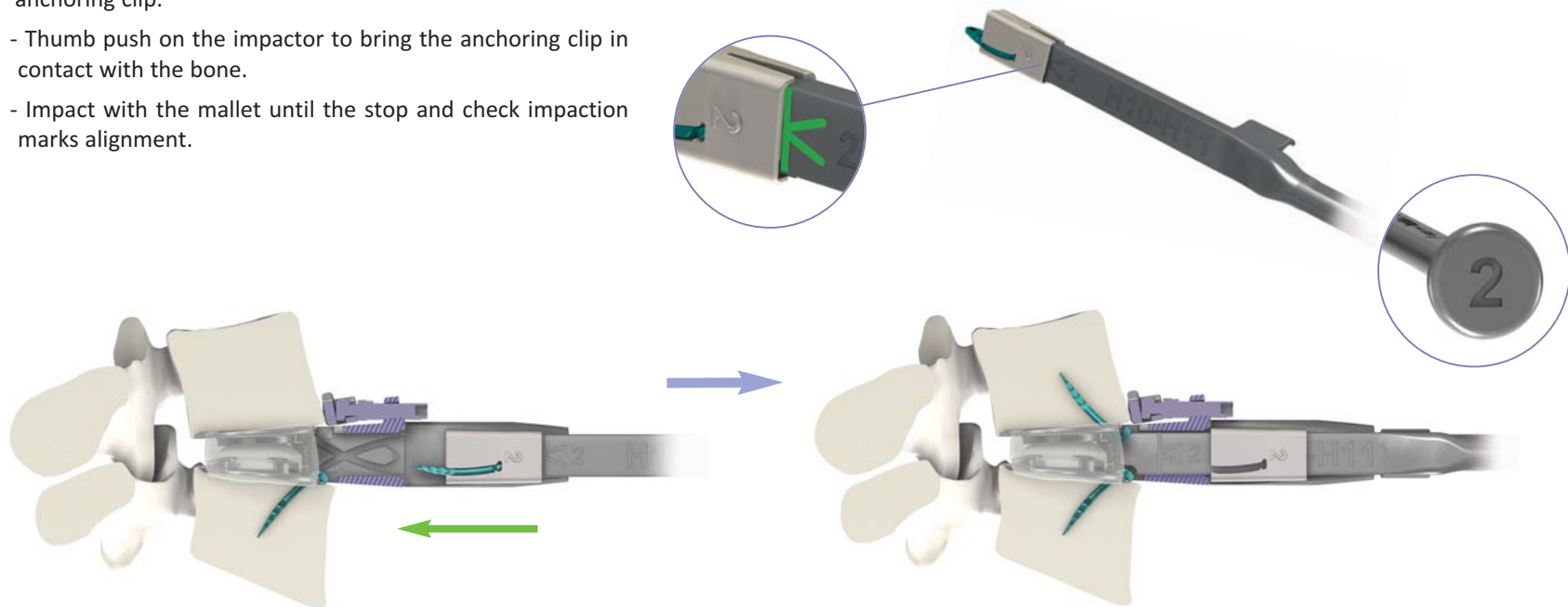
- The trajectory for the second anchoring clip is also prepared using the bone chisel. Take care to leave bone chisel face N°2 visible.
- Bring the blade in contact with the bone (slight resistance) by thumb pushing on the bone chisel.
 - Start the insertion with a series of 3 to 4 impactions with the mallet.
 - Pull-out completely the bone chisel.
 - Start again these steps until the mechanical stops of the bone chisel on the guide.



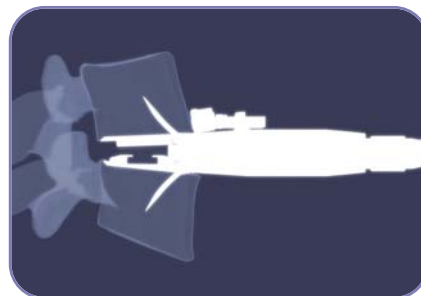
- Check blade trajectory under fluoroscopy.
- Remove the bone chisel with a mallet.



- Insert the second holder with face number “2” facing the K mark on impactor n°2 and proceed in the same way as for the first anchoring clip.
- Thumb push on the impactor to bring the anchoring clip in contact with the bone.
- Impact with the mallet until the stop and check impactation marks alignment.



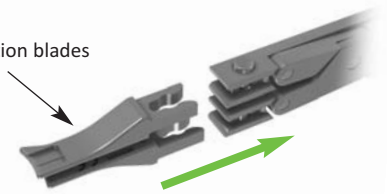
- Under fluoroscopy, check that the second anchoring clip is correctly positioned.
- Remove the impactor.



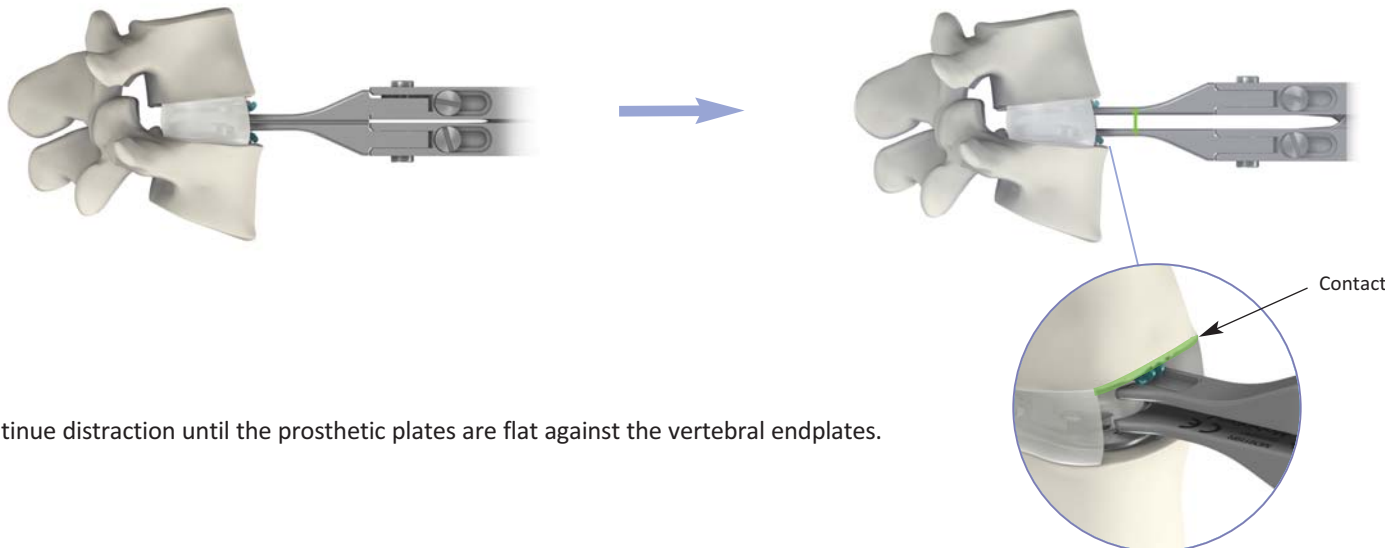
Step 9 Implant holder removal and anchorage optimization

- Unscrew the knurled knob to unlock the prosthesis from the implant holder.
- Remove the implant holder in the axis of the disc.
- Assemble **distraction blades** on the distraction forceps.

Distraction blades



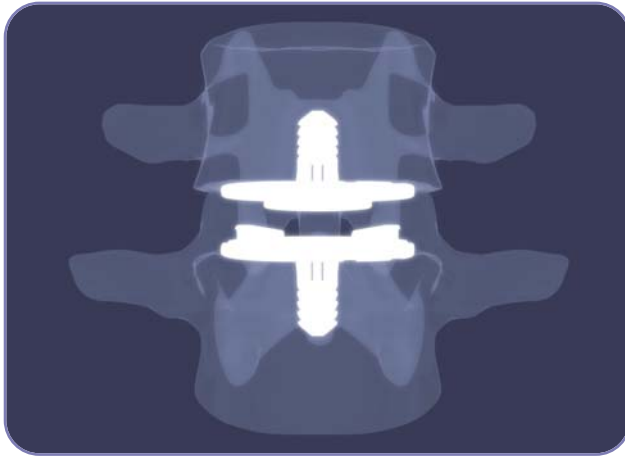
- Insert the closed instrument between the prosthetic plates and tighten the distraction forceps handles to open the distractor and apply pressure on the anchoring clips.



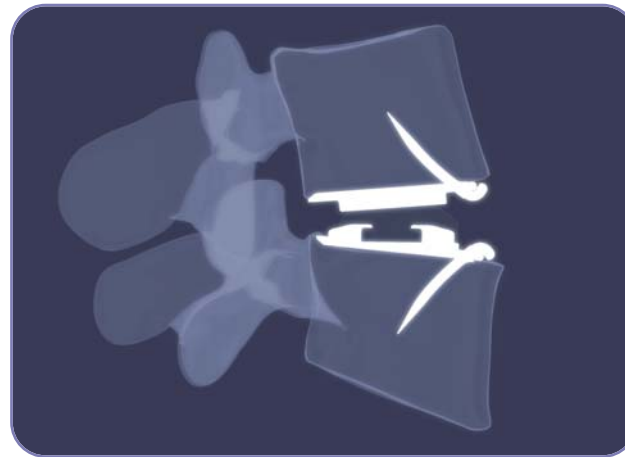
- Continue distraction until the prosthetic plates are flat against the vertebral endplates.

Step 10 Final assessment

- Check the optimal positioning of the prosthesis under fluoroscopy.



Frontal plane



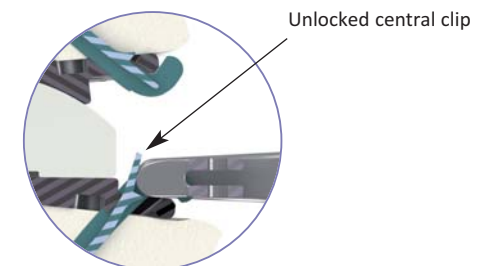
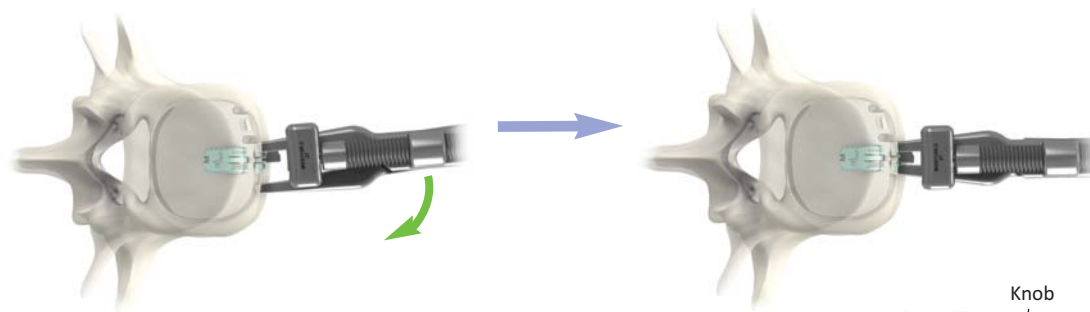
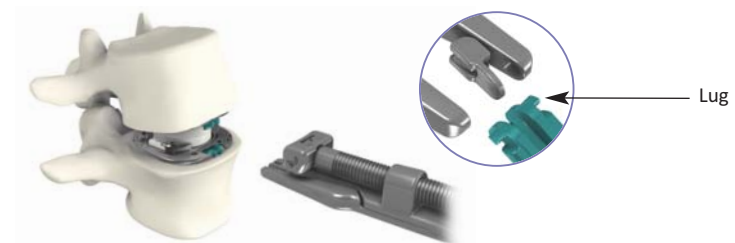
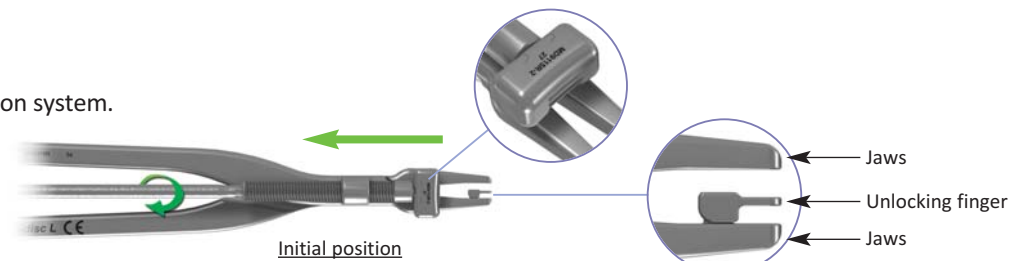
Sagittal plane

Revision

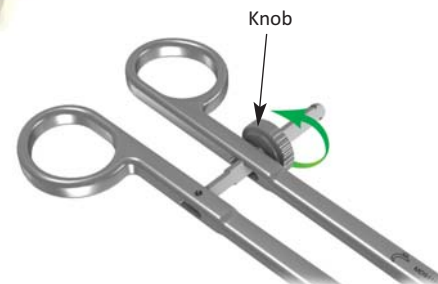
Anchoring clips removal

If necessary, the prosthesis can be removed with the ablation system.

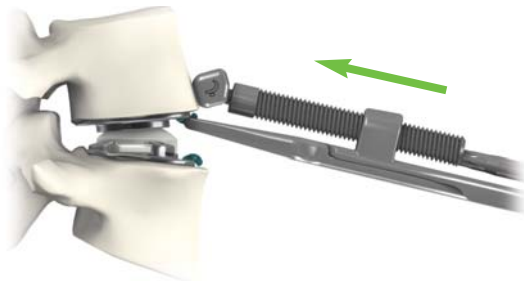
- Assemble the lever arm on the **revision forceps** by tightening it with the **screwdriver T25**. Make sure that the laser mark is facing up.
- Stop screwing when the unlocking finger of the forceps is completely visible.
- Position the lever arm in front of the anchoring clip to be removed.
- Position the jaw with the unlocking finger on the anchoring clip's lug. (The unlocking finger must be in the center of the anchoring clip between the two lugs.)
- Toggle the forceps to grab the second lug and tighten it. The central clip of the anchoring clip is automatically unlocked.



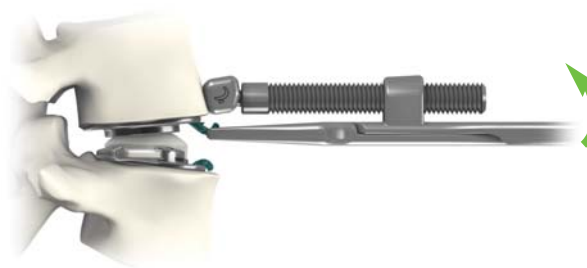
- Continue tightening the forceps by screwing the knob until contact between the 2 arms.



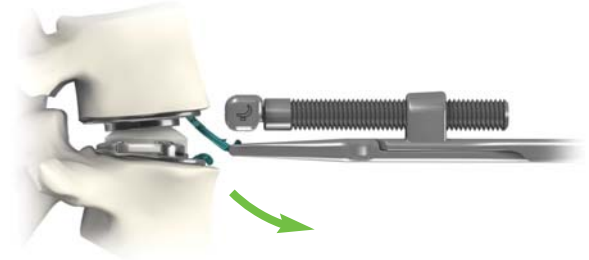
- Using screwdriver T25, tighten the lever arm until it comes in contact with the anterior wall of the vertebra.



- Continue tightening the lever arm to proceed to the anchoring clip extraction. It is possible to use the lever arm to ease the extraction.

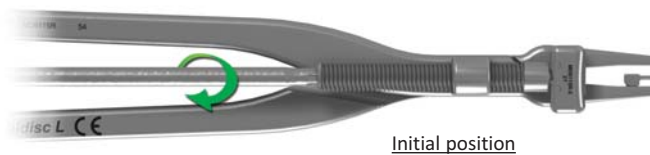


- Extract the anchoring clip in the axis of its curvature.



Important: Never reuse an anchoring clip that has already been implanted.

- Put back the lever arm in its initial position to be able to grab the second anchoring clip.

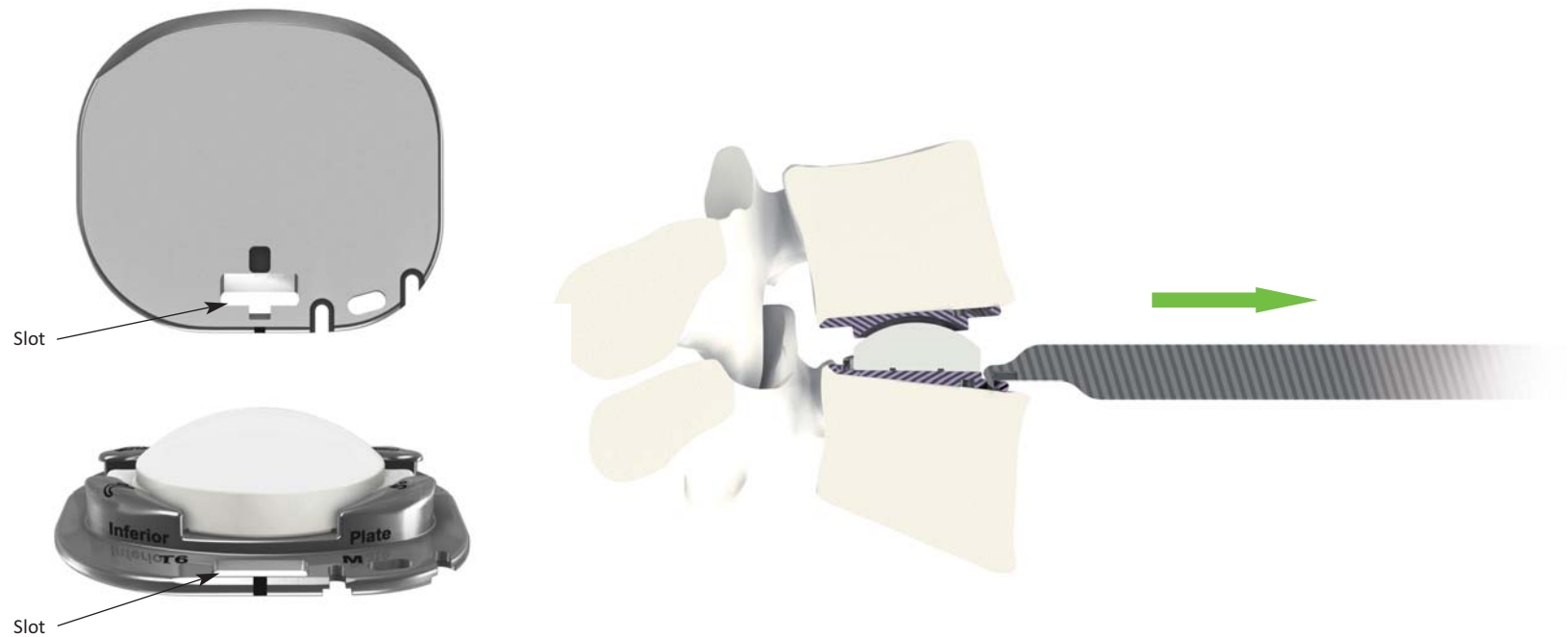


- Repeat the previous steps to extract the second anchoring clip taking care to turn over the instrument to position the lever arm in front of the second anchoring clip to be removed.



Removing the prosthetic plates and the insert

- When the two anchoring clips have been extracted, position the **plate extractor** in the slot to remove each plate.



Important: Make sure to protect the blood vessels from the prosthetic plates during the extraction.



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