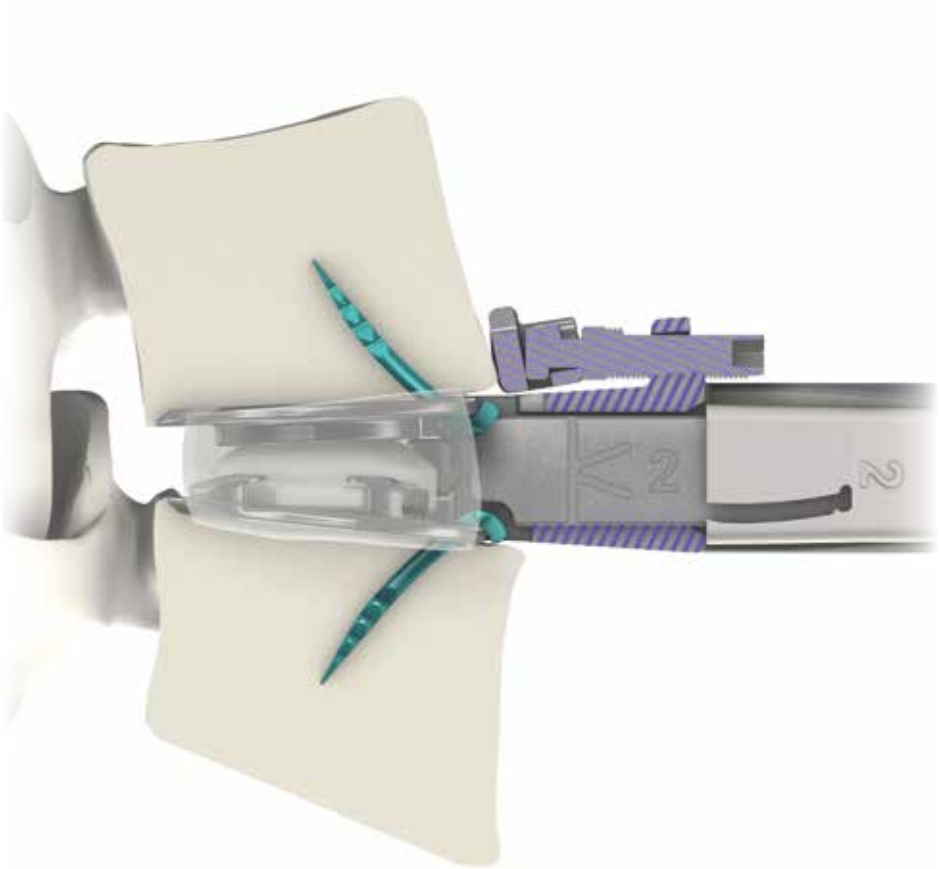
Mobidisc® L
Lumbar Disc Prostheses

Surgical Technique Guide

ZimVie



Mobidisc L Lumbar Disc Prostheses' anchoring technology combined with a mobile core offers controlled mobility, providing a unique solution that fulfills two requirements of lumbar arthroplasty: restoring the physiological mobility of the treated segment and optimal positioning of the implant.

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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Surgical Technique

The following surgical technique guide describes the recommended placement and use of Mobidisc L Lumbar Disc Prosthesis.

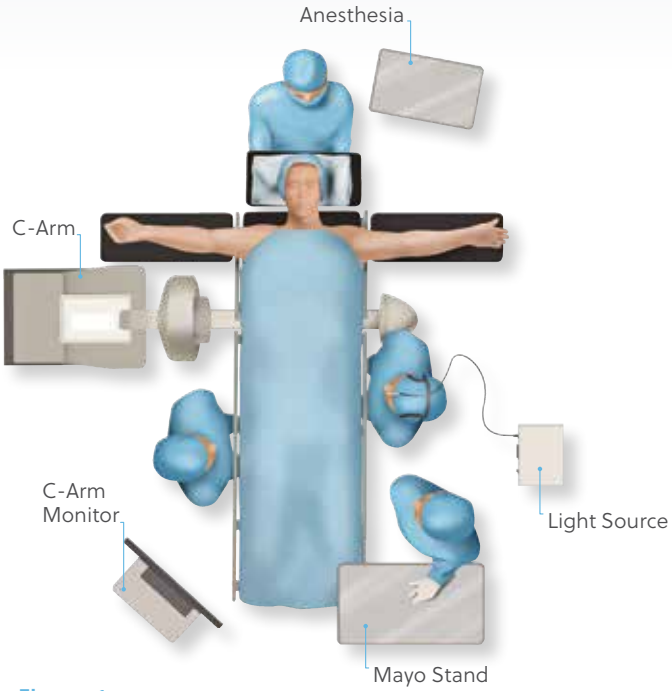


Figure *1*
Surgical exposure and site preparation

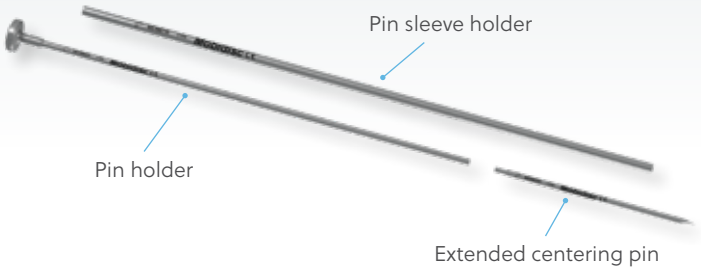
PATIENT POSITIONING

During fluoroscopic assessment, it is important to respect the following patient positioning:

- Dorsal decubitus strict ("French position" possible)
- Without block

Note:

- *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 intraoperatively 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 and 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.*



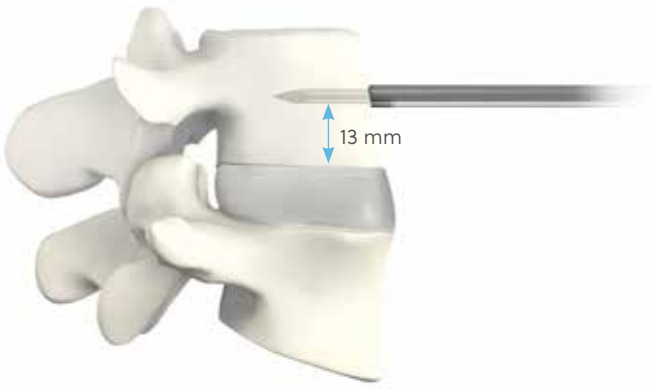


Figure 2

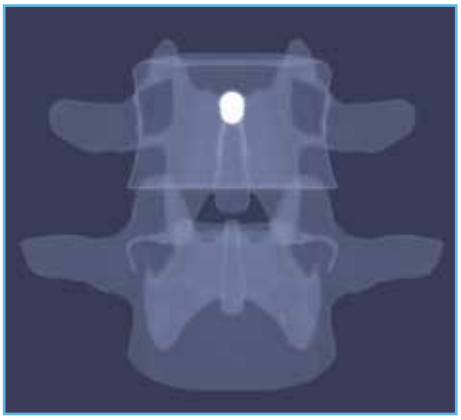


Figure 3

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* ***(Figure 2)****.*

Alternatively, the offset centering pin, MD9131R, can also be used in this step (optional instrument). In this case, slide the pin sleeve holder over the pin holder. Screw the offset centering pin onto the pin holder through the pin sleeve holder.

- Unscrew the pin holder and remove the pin sleeve holder, then confirm proper placement under fluoroscopy **(Figure 3)**.

Offset centering pin

Surgical Technique *(Continued)*

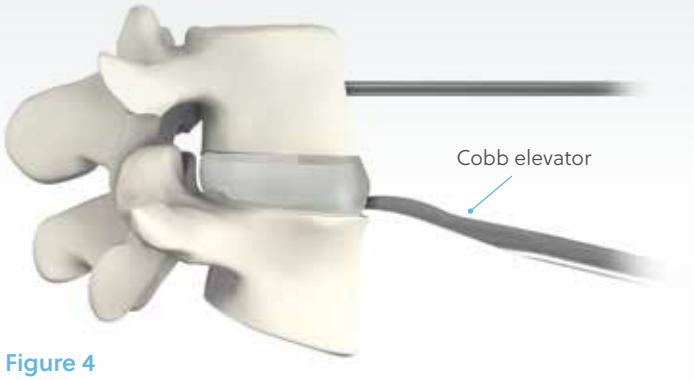


Figure 4

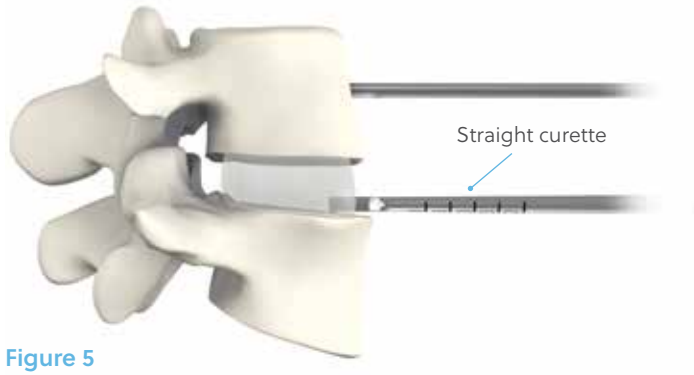


Figure 5

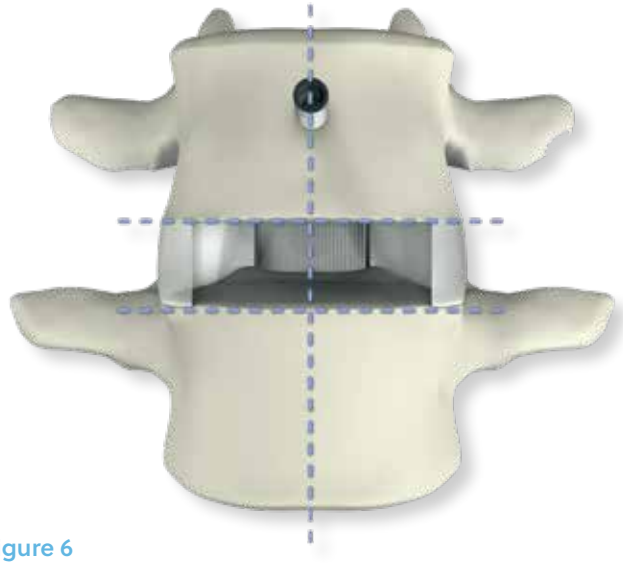


Figure 6

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 **(Figure 4)**.
- Remove the disc with a disc forceps and the straight curette **(Figure 5)**. This step allows removal of most 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* ***(Figure 6)****.*

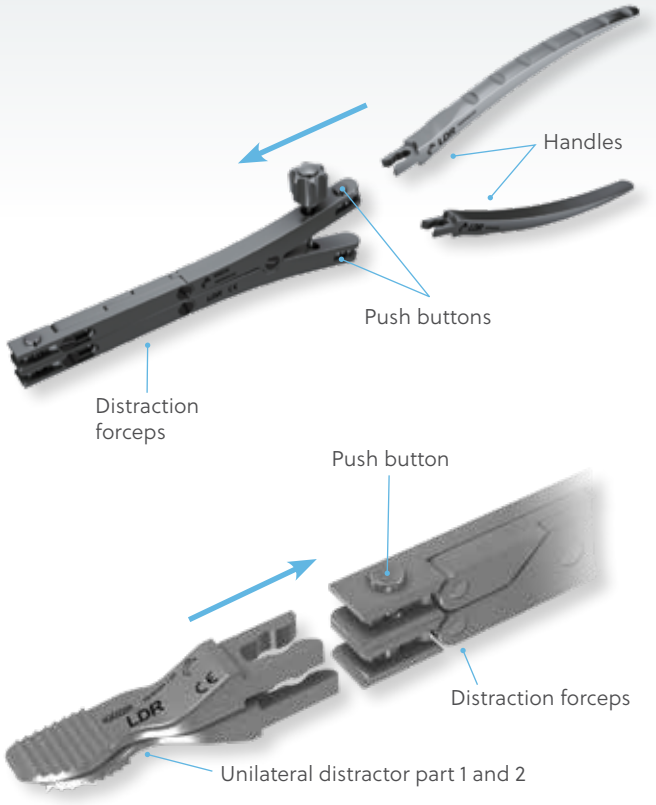


Figure 7

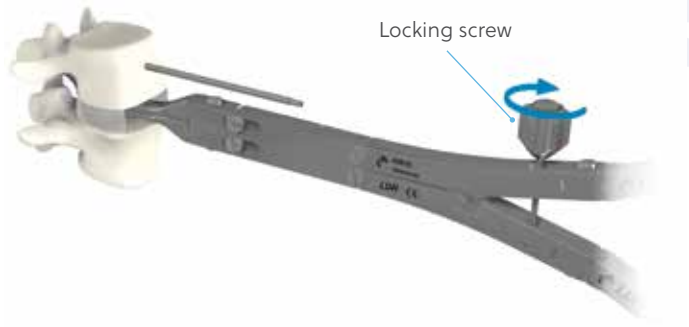


Figure 8

- Assemble the distraction forceps with the handles and unilateral distractor part 1 and 2 by pressing the push buttons **(Figure 7)**.
- Distract one side of the intervertebral space with the distraction forceps and maintain its position by tightening the locking screw **(Figure 8)**.
- 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 right to complete the discectomy.

Surgical Technique *(Continued)*

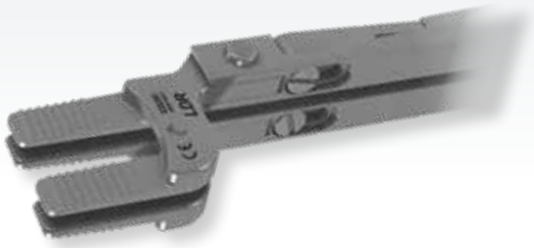
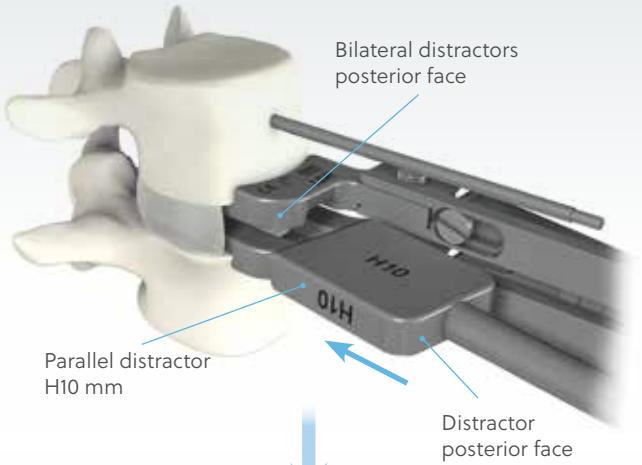


Figure 9



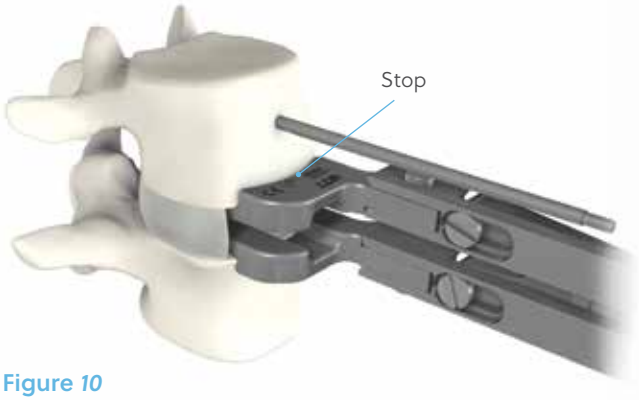


Figure *10*

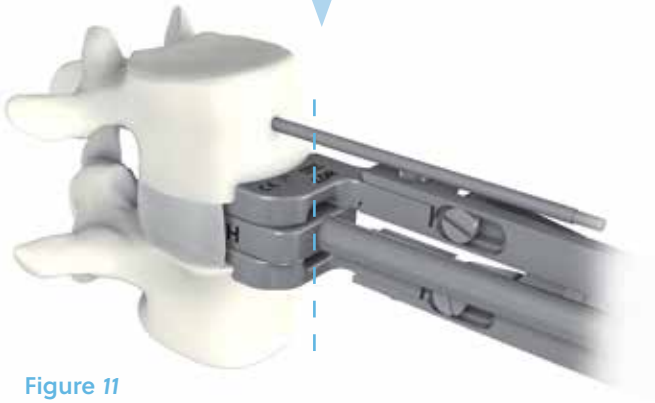


Figure *11*

PARALLEL DISTRACTION

- Replace the unilateral distractors with the bilateral distractor part 1 and 2 **(Figure 9)**.
- Place the distraction forceps into the intersomatic space until it stops on the anterior face of the vertebral bodies **(Figure 10)**. 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 H10 mm 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 **(Figure 11).**
- **Note:** *Do not exceed the height of the adjacent discs. If necessary, a parallel distractor H12 mm may be used.*

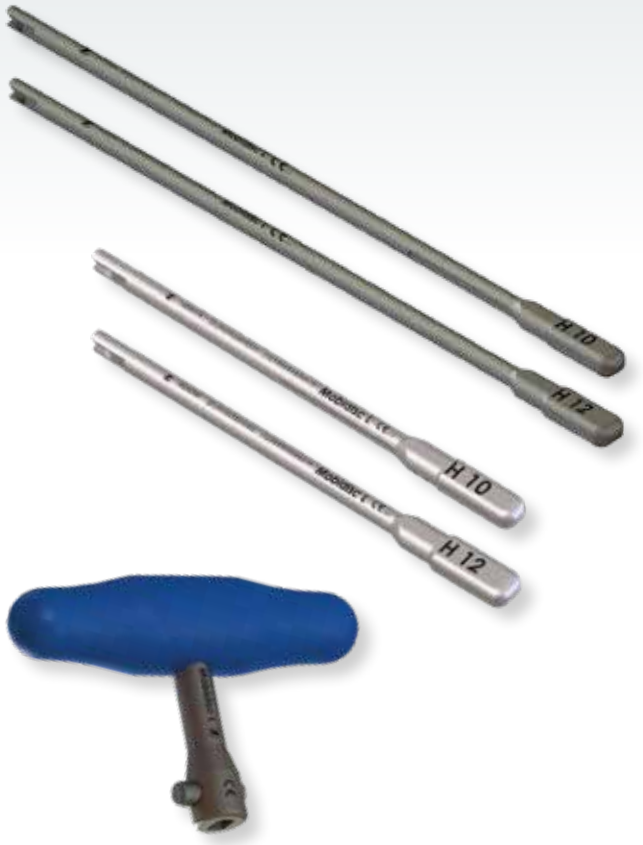


Figure *12*

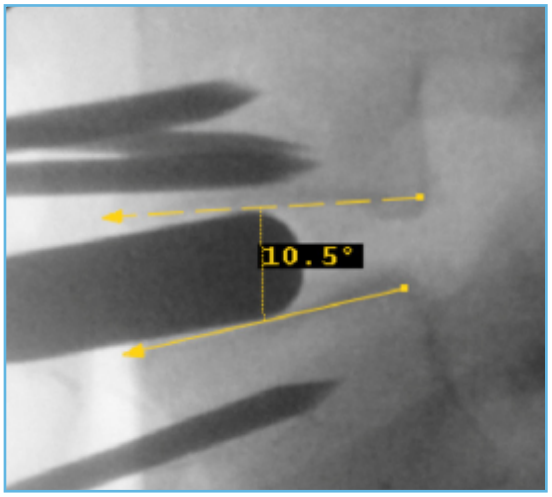


Figure *13*

HEIGHT AND LORDOSIS SELECTION

- The height of the prothesis is determined per-op with the parallel distractors inserted thru the bilateral distractors assembled onto the distractor forceps. Insert first the 10 mm, if it fits properly, 10 mm high prosthesis might be chosen. If it does not fit the space tightly, then use the 12 mm parallel distractor, and depending on the fit select either 11, 12 or 13 mm high prosthesis instead **(Figure 11)**.
- Alternatively, the short height measurers or standard height measurers 10 mm or 12 mm can be used to determine most suitable height. In order to do this, attach the height measurers to the snap-lock T-handle **(Figure 12)**. Insert first the 10 mm directly into the disc space, if it fits properly, 10 mm high prosthesis might be chosen, if it does not fit the space tightly, then use the 12 mm height measurer, and depending on the fit select either 11, 12 or 13 mm high prosthesis instead.
- **Note:** *Take a lateral fluoroscopy to validate height. Do not insert the height measurer too far posterior, and do not go beyond the posterior wall. Do not exceed the height of the adjacent discs.*
- For lordosis selection, height measurers are to be placed at the mid-vertebral endplates, i.e., midway between anterior and posterior walls **(Figure 13)**.
- Choice of endplate lordotic angulation (5° or 10°) is guided by the intraoperative measurement of segmental lordosis variation (remaining stable or increasing) before and following the insertion of the previously chosen height measurer **(Figure 13)**.
- **Note:** *On the lateral view, check fluoroscopy angle of incidence is perpendicular to the vertebral endplates, so a true lateral view is shown.*

Surgical Technique *(Continued)*

Figure *14*

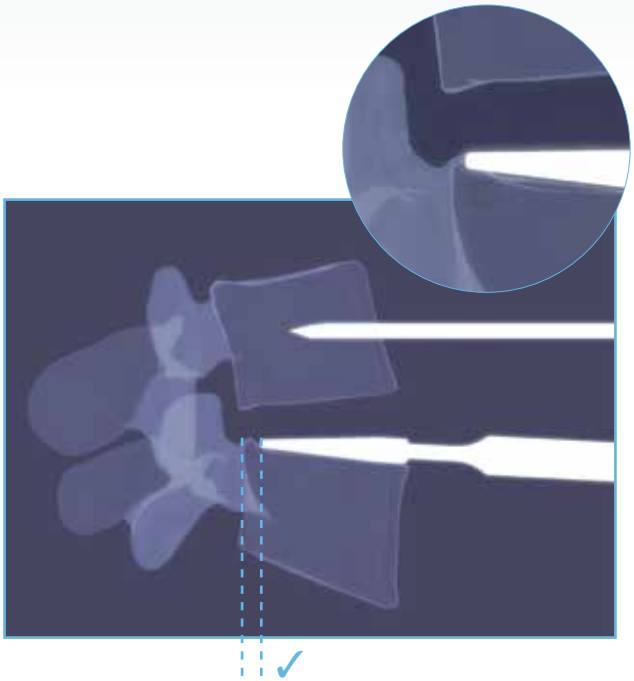


Figure *15*

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 **(Figure 14)**.
- 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.*

Note: *For safety reasons, ease of positioning, and bone anchorage, trial plates are oversized by 1.5 mm anteriorly and posteriorly* ***(Figure 15)****.*

Figure *16*

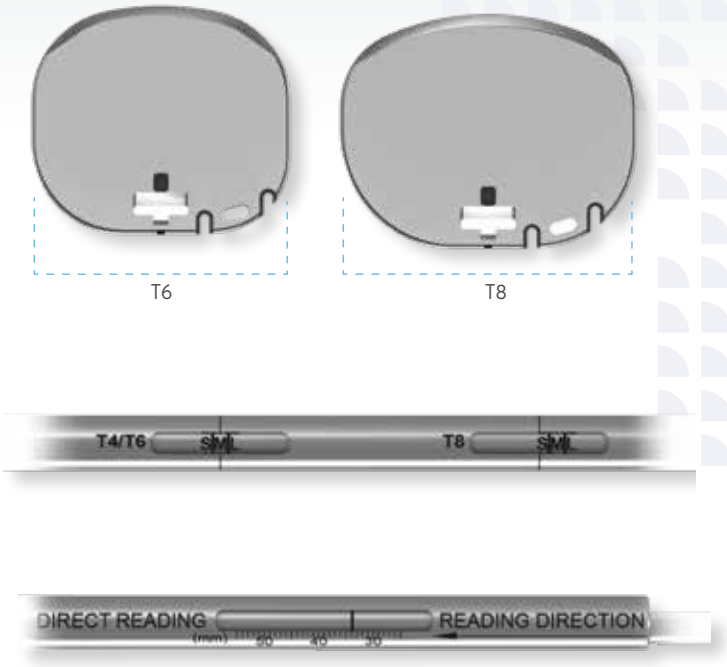


Figure *17*

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 **(Figure 16)**.
- 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 **(Figure 17)**.

  – T6 small, medium or large
  – T8 small, medium or large

Note: *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.*

Surgical Technique *(Continued)*

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

Figure *18*

PROSTHESIS ASSEMBLY

In order to obtain the desired prosthesis height, refer to the chart above **(Figure 18)** to choose the appropriate mobile insert height.

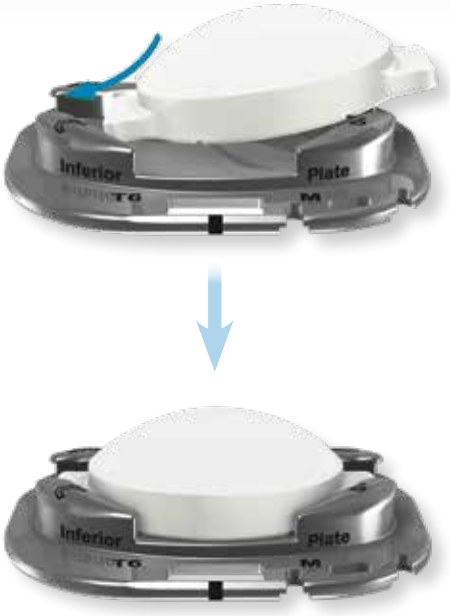


Figure *19*

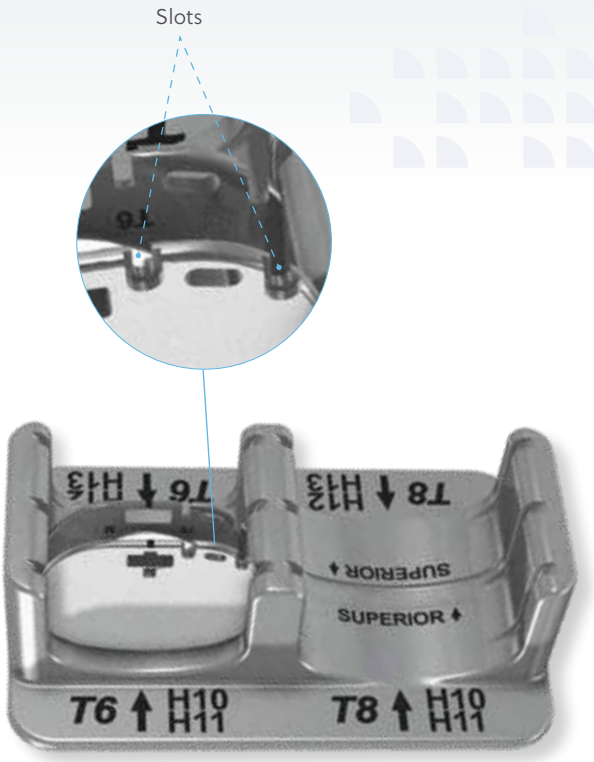


Figure *20*

- Insert and secure the mobile insert between the stops of the inferior plate **(Figure 19)**.

- 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* ***(Figure 20)****.*

Surgical Technique *(Continued)*

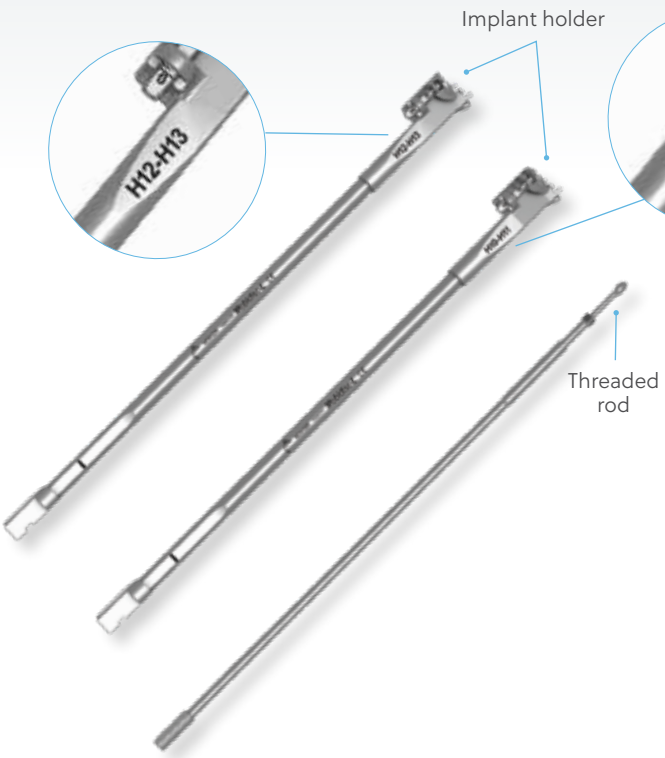


Figure 21

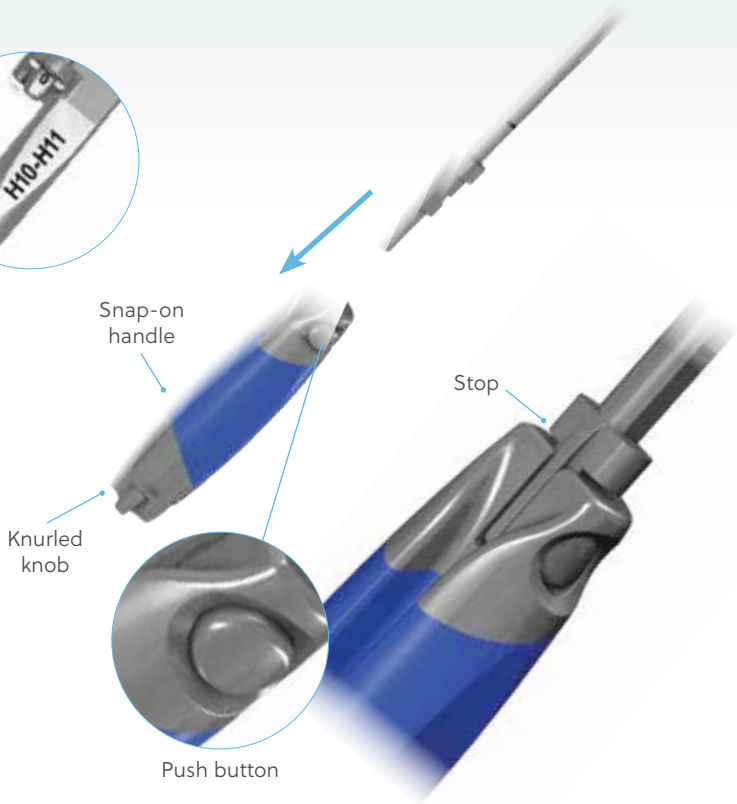


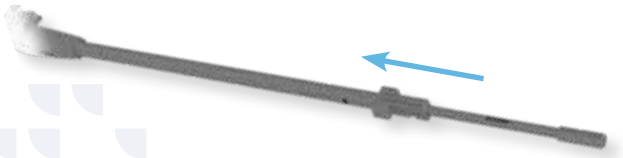
Figure 22

IMPLANT HOLDER ASSEMBLY AND LOADING THE PROSTHESIS

- Select the implant holder to the corresponding prosthesis height (H10-H11 or H12-H13) **(Figure 21)**.

  Note: *In case of a severely lordotic segment, the H12-H13 implant holder can be used to adapt a prosthesis of 10 mm or 11 mm 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 **(Figure 22)**.

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.*

Note: *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.*

Figure 23

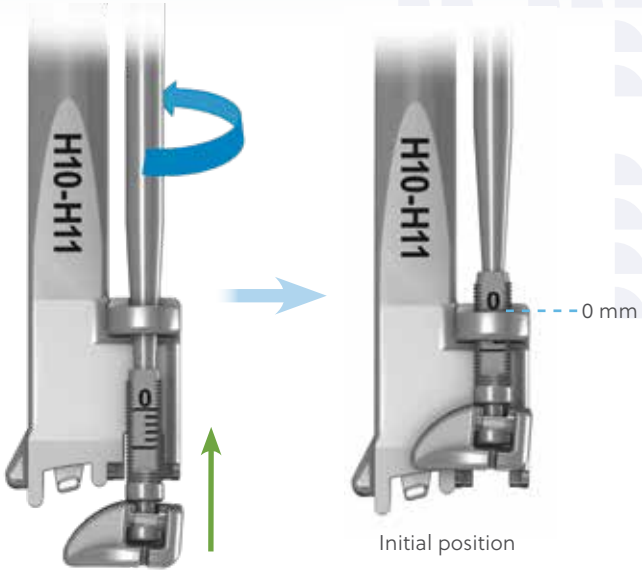


Figure 24

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 **(Figure 23)**.

- This stop is mounted and adjusted using the adjustable stop screwdriver **(Figure 24)**.

  Note: *Check that the stop is initially set to zero.*

Surgical Technique *(Continued)*

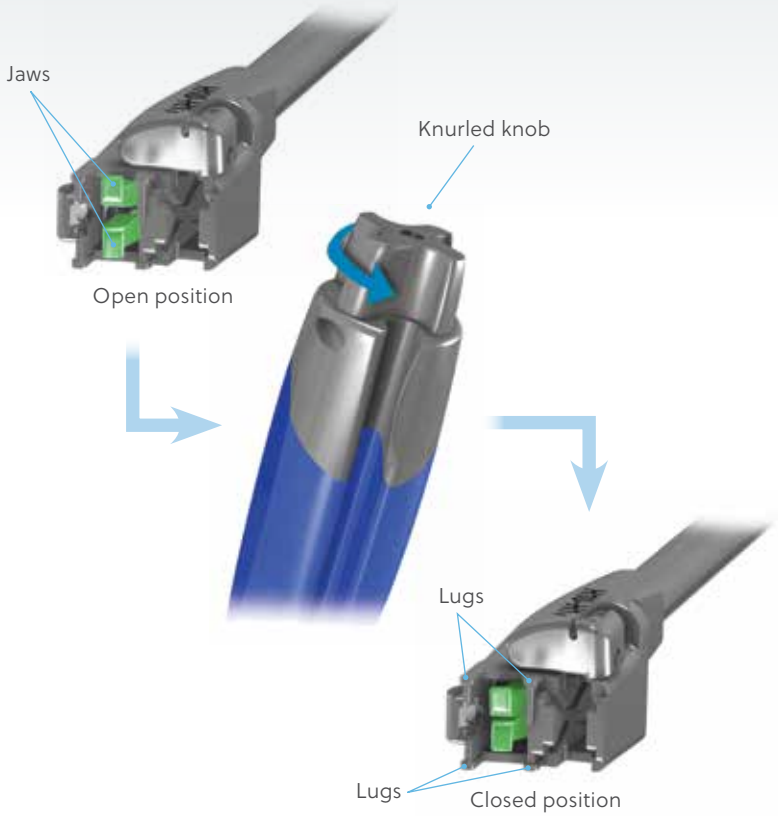


Figure *25*

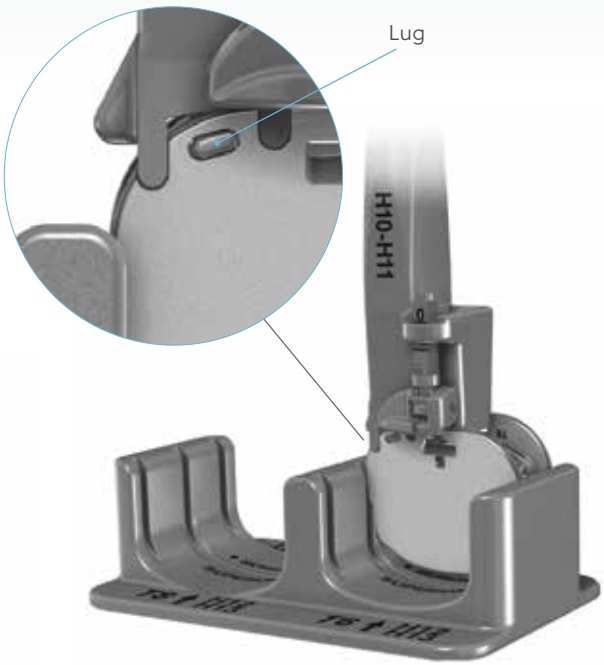


Figure *26*

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 **(Figure 25)**.
- Engage the four lugs of the implant holder in the corresponding slots on the prosthesis **(Figure 26)**.
- Lock the prosthesis onto the implant holder by firmly tightening the knurled knob.

  Note: *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.*

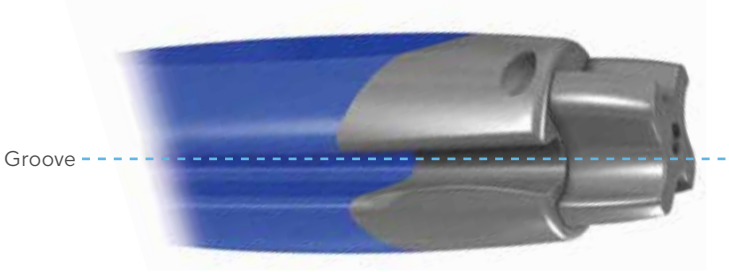


Figure 27

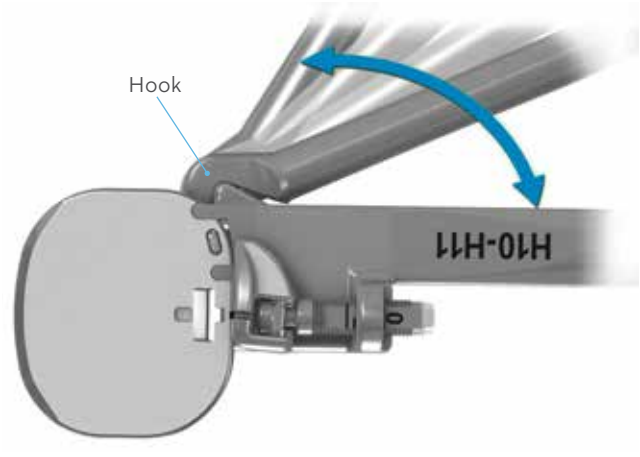


Figure 28

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 **(Figure 27)**.
- 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 **(Figure 28)**.

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

Surgical Technique *(Continued)*

Figure *29*

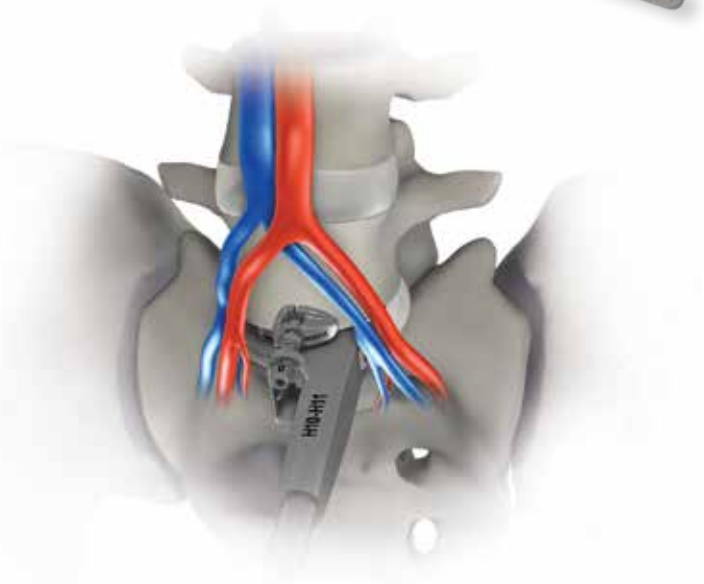


Figure *30*

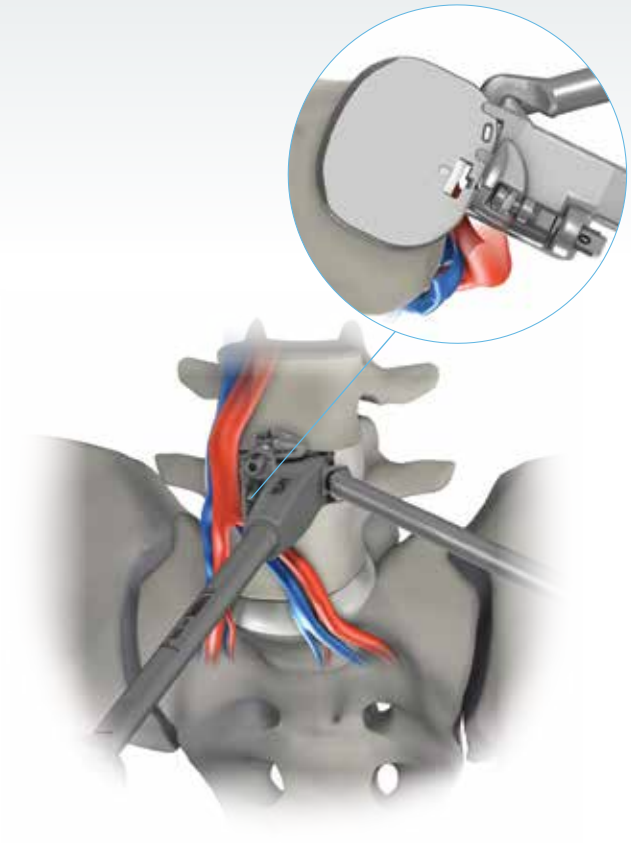


Figure *31*

PROSTHESIS INSERTION AND POSITIONING

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

Note: *If deemed necessary, attach the distractor blade* **(Figure 29)** *to the snap-lock T-handle, and insert the tip of the blade into the disc space, laterally, to facilitate the initial insertion of the prosthesis in between the vertebral bodies.*

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 **(Figure 30)**.

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 **(Figure 31)**.

Note: *The slap hammer can also be used onto the lateral impactor to navigate the prosthesis back until desired position is reached.*

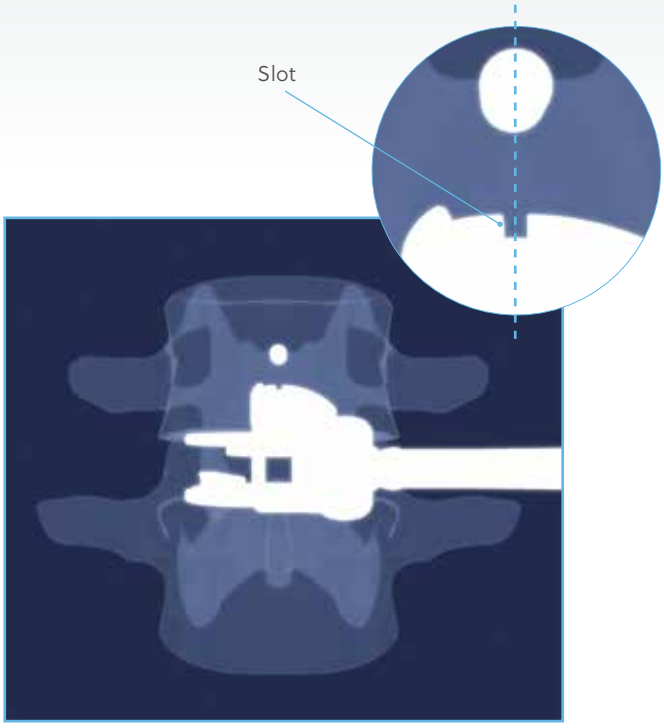


Figure 32

Figure 33

- Check that the prosthesis is well centered using antero-posterior fluoroscopy **(Figure 32)**.

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

  Note: *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 lateralized.*

- In order to confirm the absence of axial rotation, use the level and make sure that it is parallel to the ground **(Figure 33)**.

Surgical Technique *(Continued)*

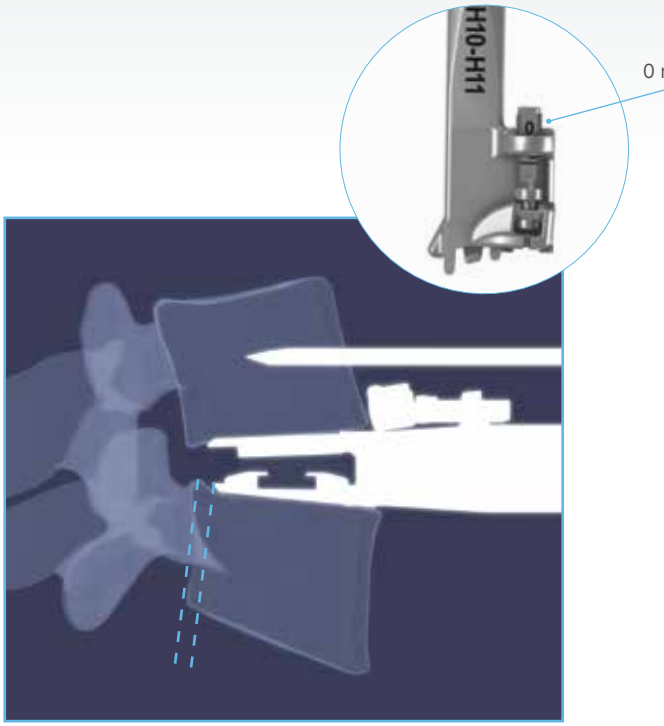


Figure 34
Initial position.

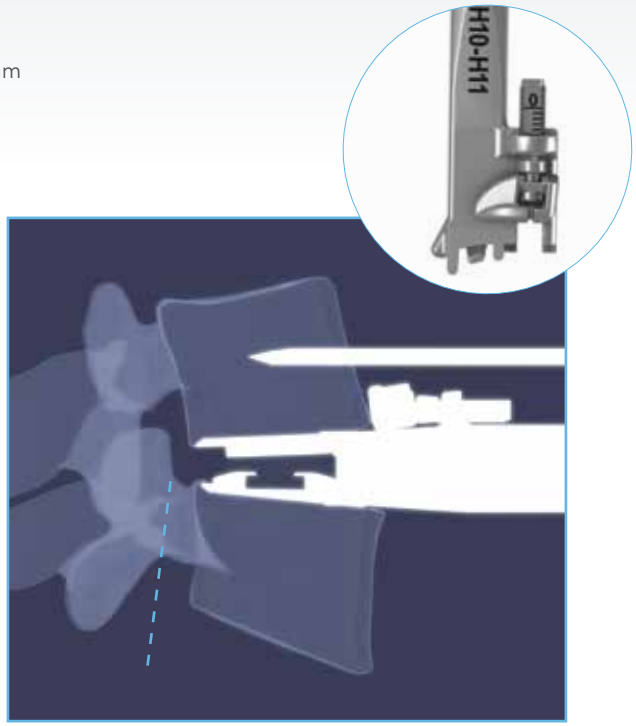
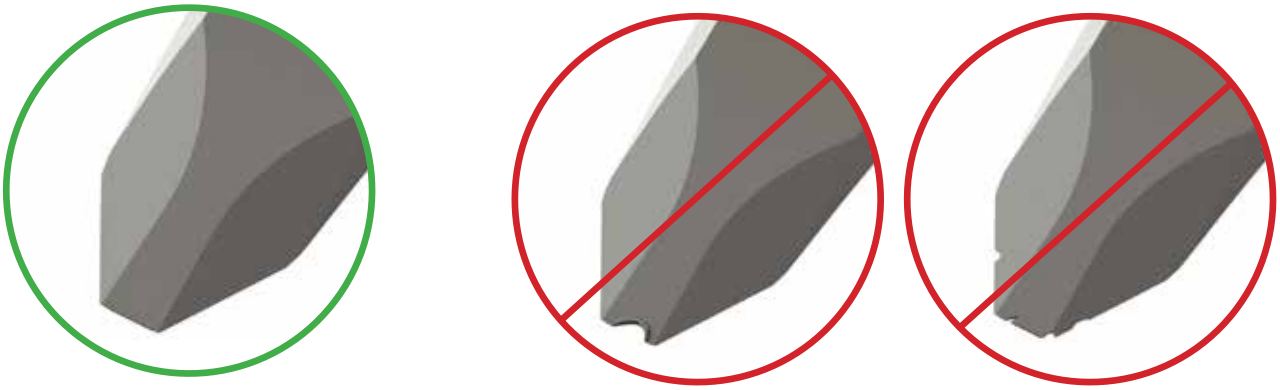


Figure 35
Stop adjustment for an optimal positioning of the prosthesis in the intersomatic space.

PROSTHESIS INSERTION AND POSITIONING *(continued)*

- Under fluoroscopy, proceed to millimetric adjustment to insert the prosthesis as close as possible to the posterior vertebral wall **(Figure 34)**.

Note: *When the desired position has been obtained, check that the stop is in contact with the anterior vertebral wall before inserting the anchoring clips* ***(Figure 35)****.*



Acceptable bone chisel

Non acceptable bone chisel

Figure 36

ANCHORING CLIPS INSERTION

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

Important: *Always check the bone chisel's integrity (the cutting edge of the blade) before impaction* **(Figure 36)**.

Note: *During its use, the bone chisel comes in contact with the Mobidisc L instrumentation and the patient's cortical bone, superficial marks could be visible, without compromising its integrity.*

Non acceptable damage to the bone chisel can be observed for instance in case of contact with an obstacle on its trajectory (e.g. pins) or after a large number of impactions with hard bone.

Surgical Technique *(Continued)*

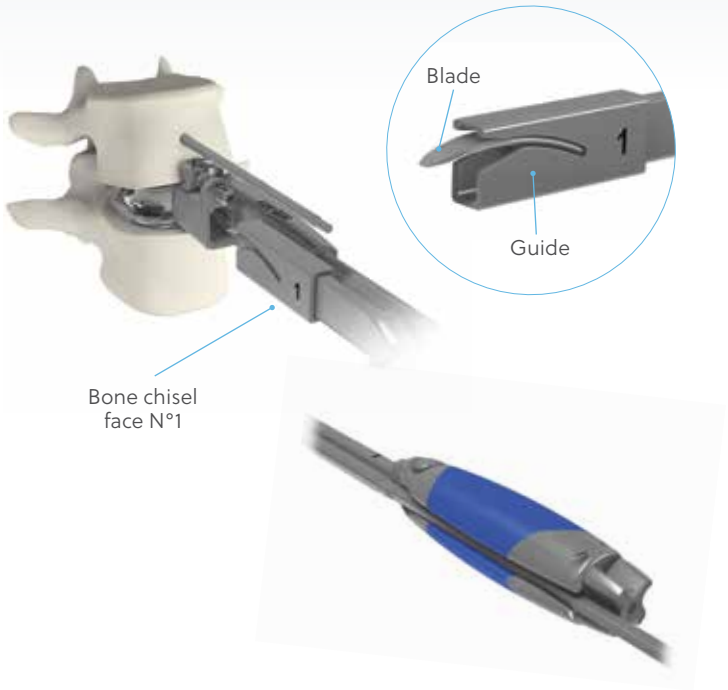


Figure *37*

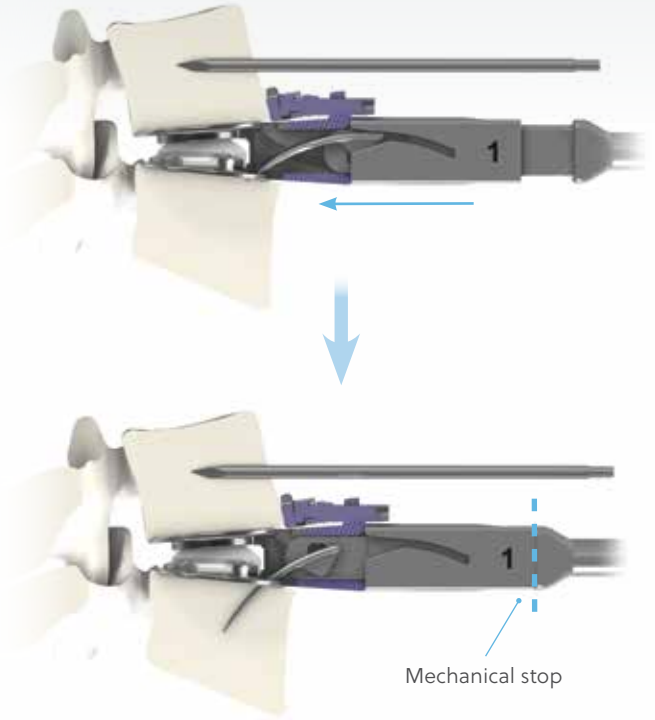


Figure *38*

ANCHORING CLIPS INSERTION *(continued)*

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 **(Figure 37)**.
- 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 **(Figure 38)**.
  - 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.

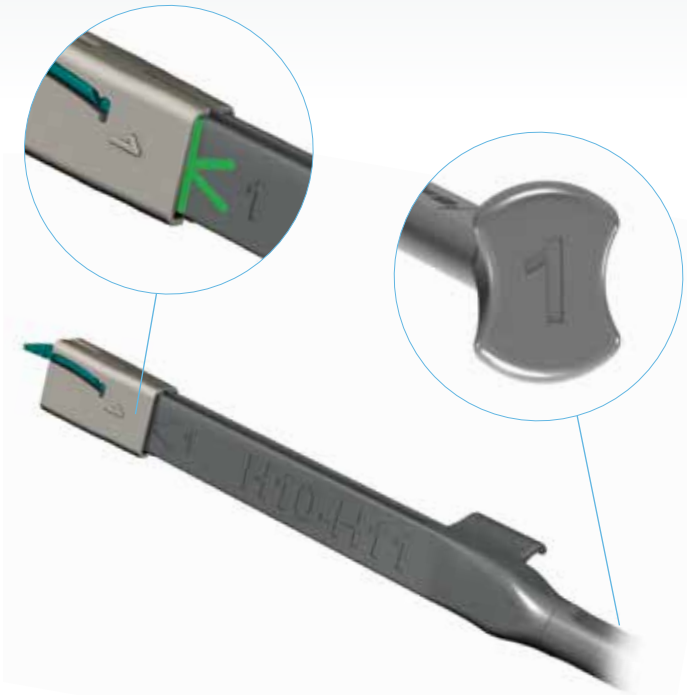


Figure *39*

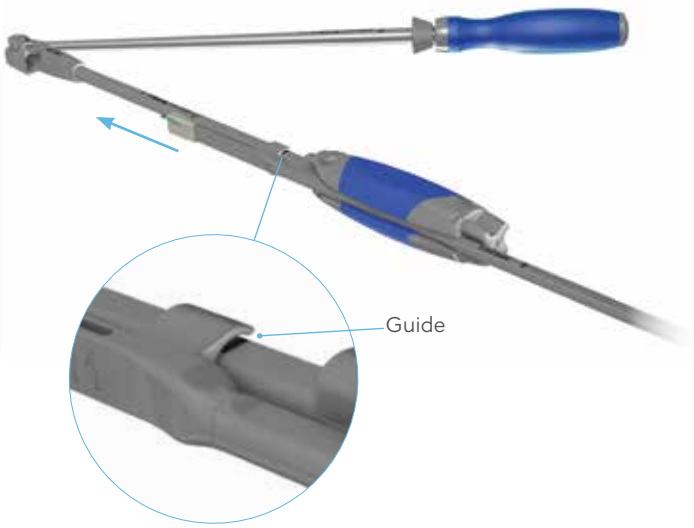
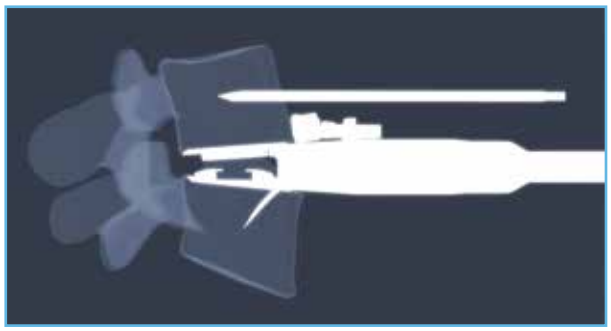


Figure *40*

- Check blade trajectory under fluoroscopy.



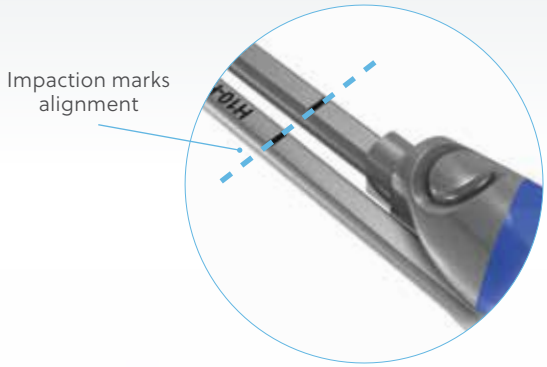
- Remove the bone chisel with a mallet.

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.

Note: 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 **(Figure 39)**.
- 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 **(Figure 40)**.

Surgical Technique *(Continued)*



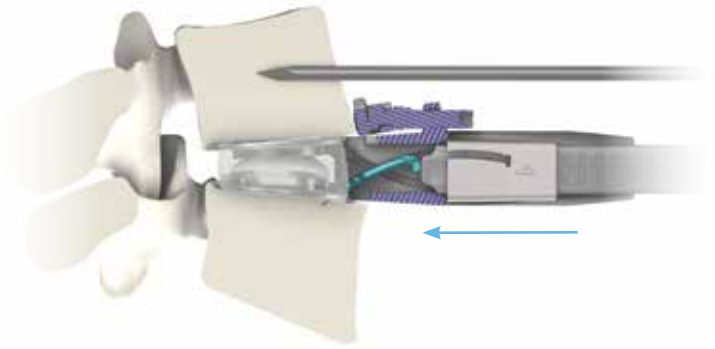


Figure *41*

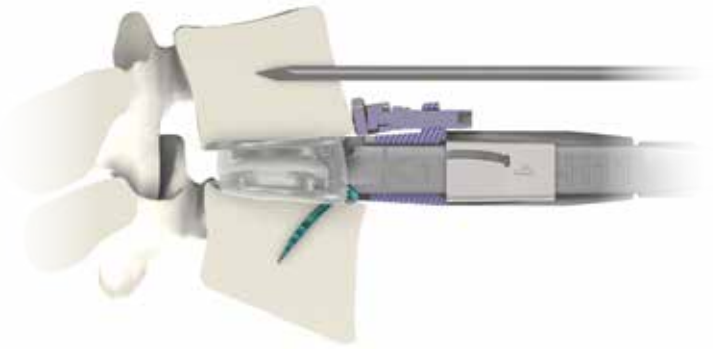
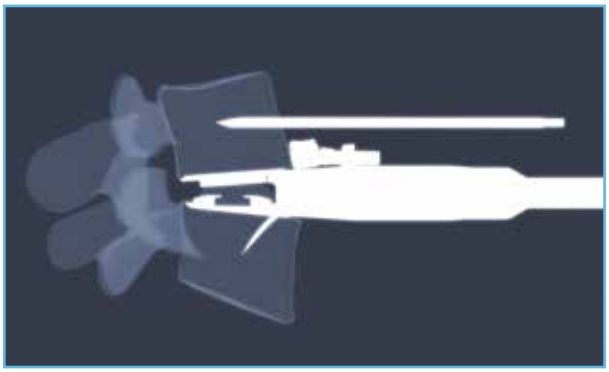


Figure *42*

ANCHORING CLIPS INSERTION *(continued)*

- Bring the first anchoring clip in contact with the bone (slight resistance) by thumb pushing on the impactor ***(Figure 41)***.
- 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* ***(Figure 42)***.
- Under fluoroscopy, check that the first anchoring clip is correctly positioned and remove the impactor.



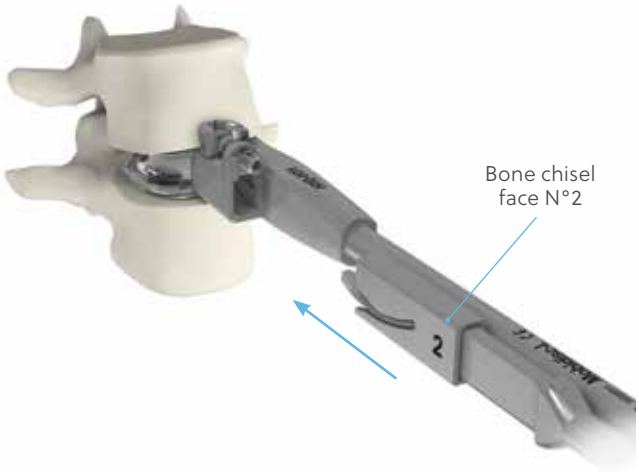


Figure *43*

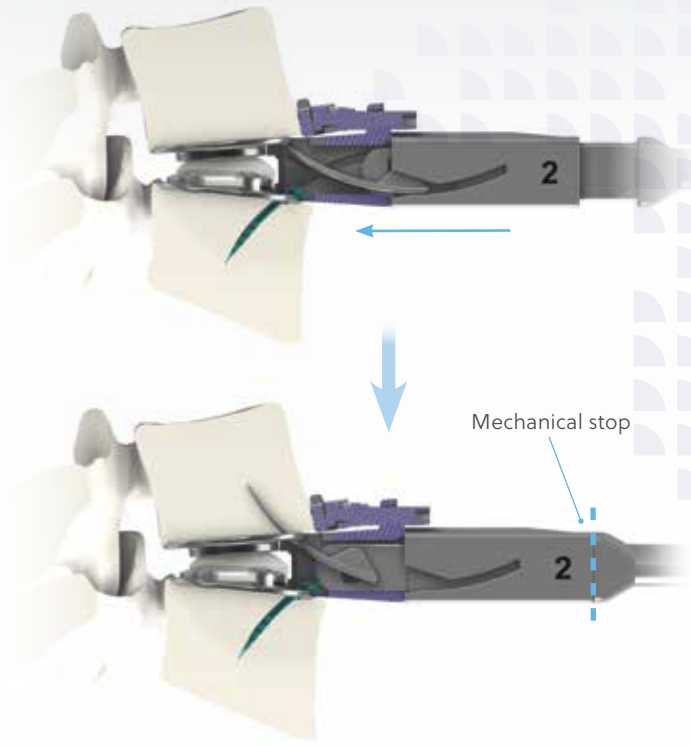


Figure *44*

Note: *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 **(Figure 43)**.
- 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 **(Figure 44)**.
- Check blade trajectory under fluoroscopy.

- Remove the bone chisel with a mallet.

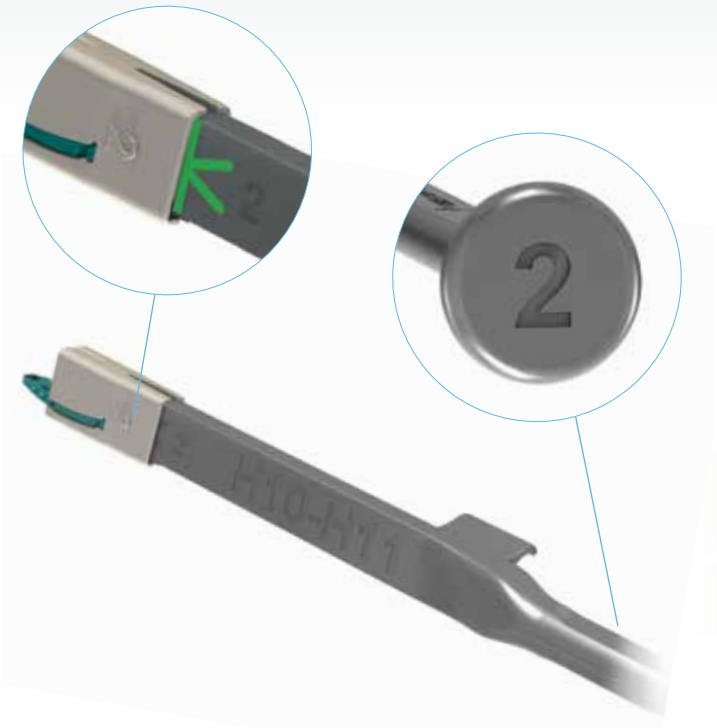


Figure *45*

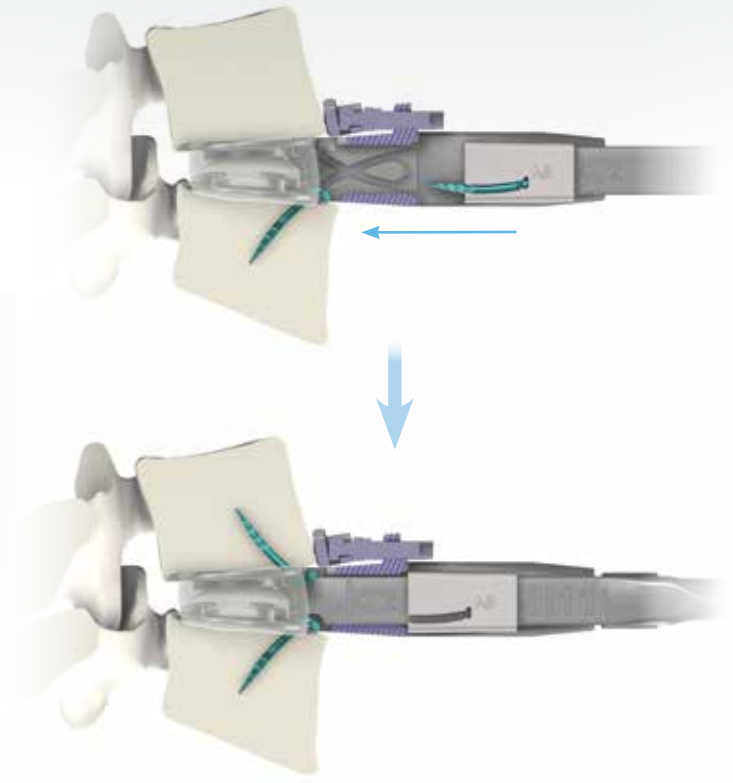


Figure *46*

ANCHORING CLIPS INSERTION *(continued)*

- 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 **(Figure 45)**.
  - Thumb push on the impactor to bring the anchoring clip in contact with the bone **(Figure 46)**.
  - Impact with the mallet until the stop and check impaction marks alignment.
- Under fluoroscopy, check that the second anchoring clip is correctly positioned.

- Remove the impactor.

Figure 47

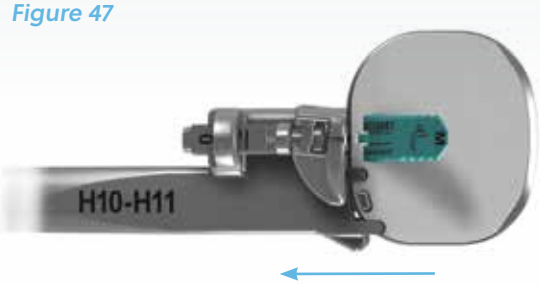


Figure 48

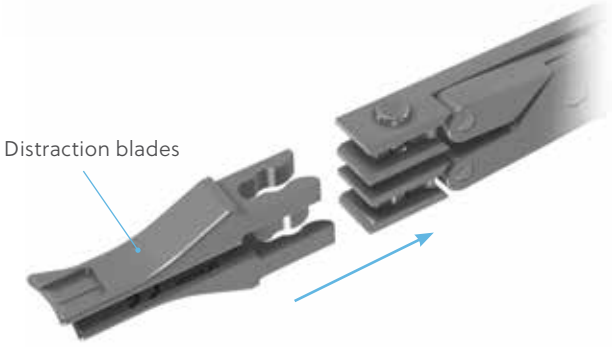


Figure 49

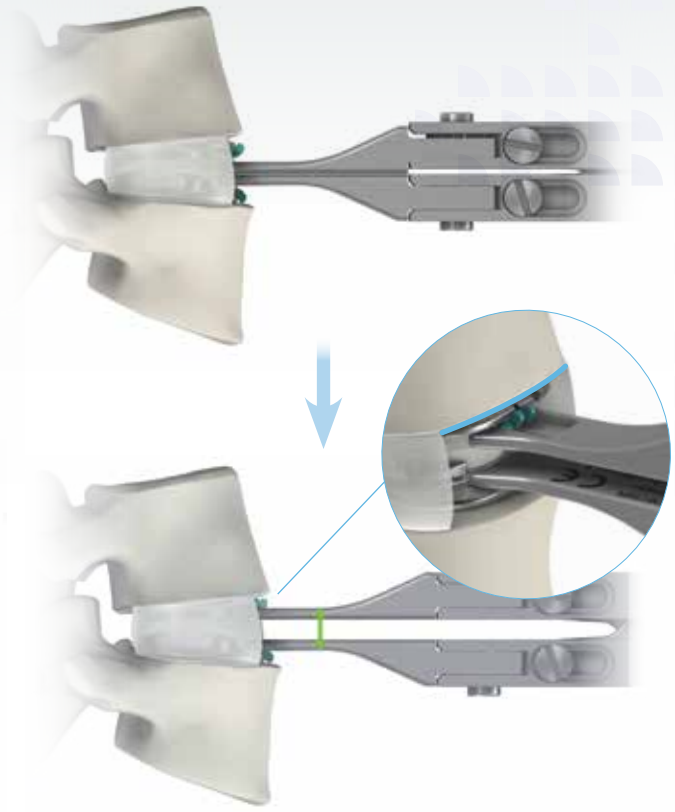


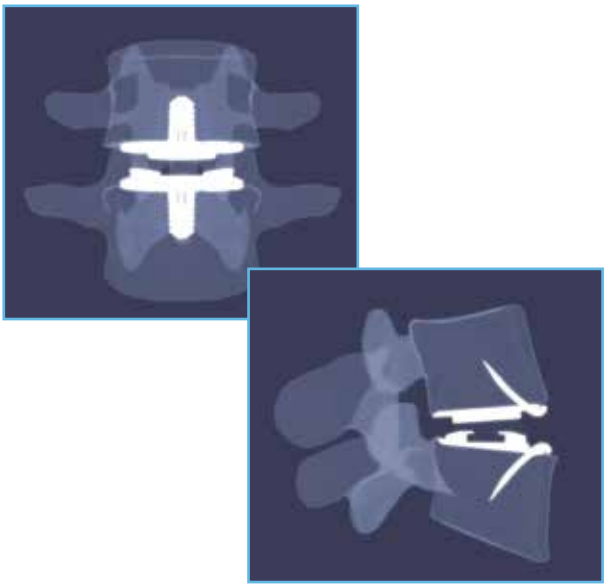
Figure 50

IMPLANT HOLDER REMOVAL AND ANCHORAGE OPTIMIZATION

- Unscrew the knurled knob to unlock the prosthesis from the implant holder. If needed, use the unlocking key **(Figure 47)** to facilitate loosening of the knurled knob.
- Remove the implant holder in the axis of the disc **(Figure 48)**.
- Assemble distraction blades on the distraction forceps **(Figure 49)**.
- 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 **(Figure 50)**.
- Continue distraction until the prosthetic plates are flat against the vertebral endplates.

Final assessment:

- Check the optimal positioning of the prosthesis under fluoroscopy.



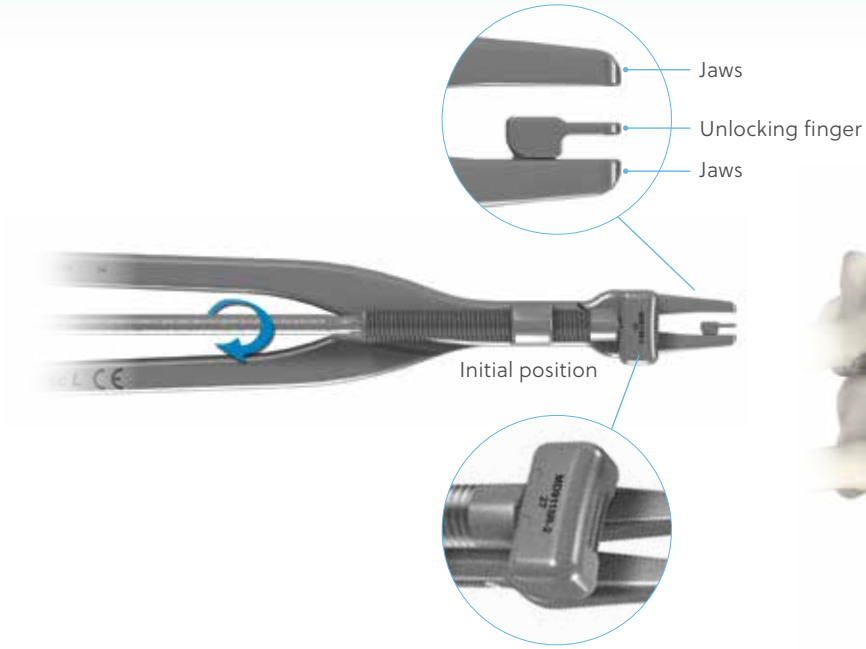


Figure *51*

Figure *52*

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 **(Figure 51)**.
- 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 **(Figure 52)**.

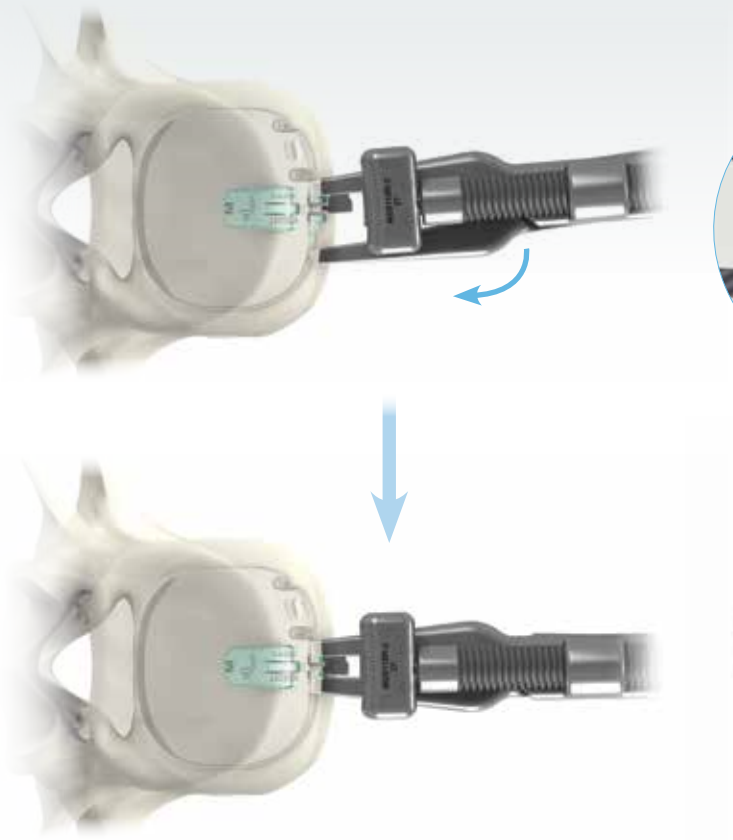


Figure *53*

Figure *54*

REVISION: ANCHORING CLIPS REMOVAL *(continued)*

- Toggle the forceps to grab the second lug and tighten it **(Figure 53)**.
- The central clip of the anchoring clip is automatically unlocked.
- Continue tightening the forceps by screwing the knob until contact between the 2 arms **(Figure 54)**.

Revision *(Continued)*

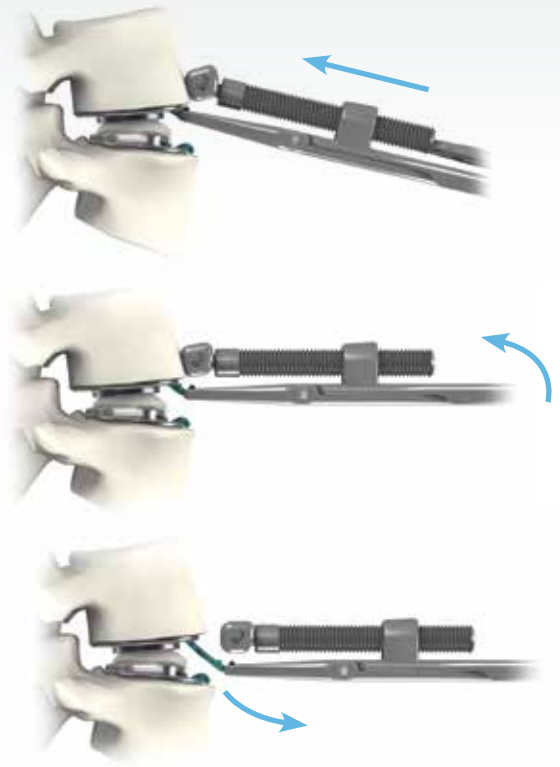


Figure *55*

Figure *56*

Figure *57*

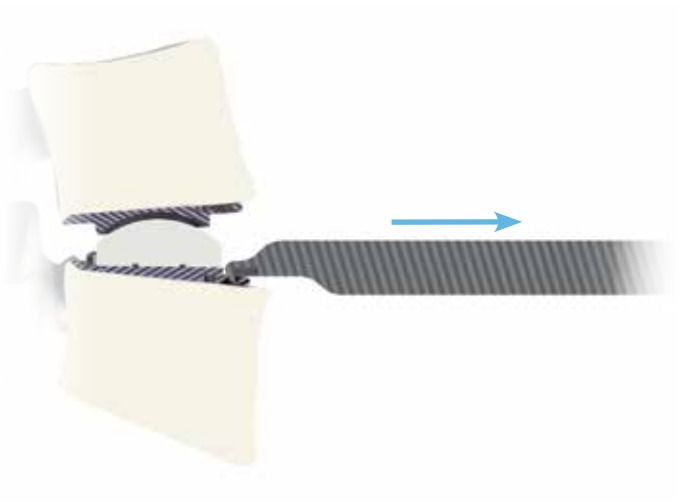
REVISION: ANCHORING CLIPS REMOVAL *(continued)*

- 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 **(Figure 55)**.

  Note: *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 **(Figure 56)**.
- 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 **(Figure 57)**.

Figure *58*



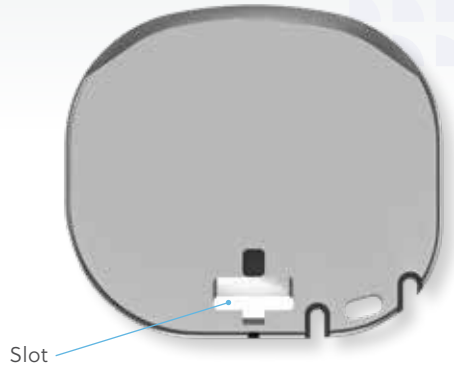


Figure *59*

REVISION: REMOVING PROSTHESIS PLATES AND INSERT

- When the two anchoring clips have been extracted, position the plate extractor in the plate slot, and with the help of the slap hammer **(Figure 58)** remove each plate **(Figure 59)**.

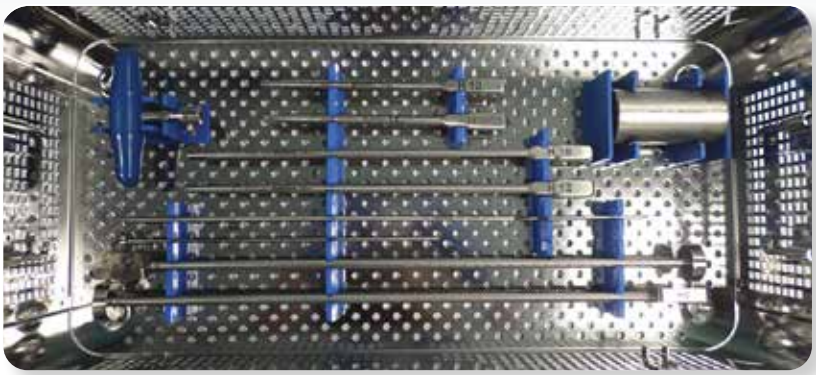
  Note: *Make sure to protect the blood vessels from the prosthesis' superior and inferior plates during the extraction.*

  Note: *In order to help with prosthesis plates removal, the optional ablation osteotome (MD9076R) can be used.*

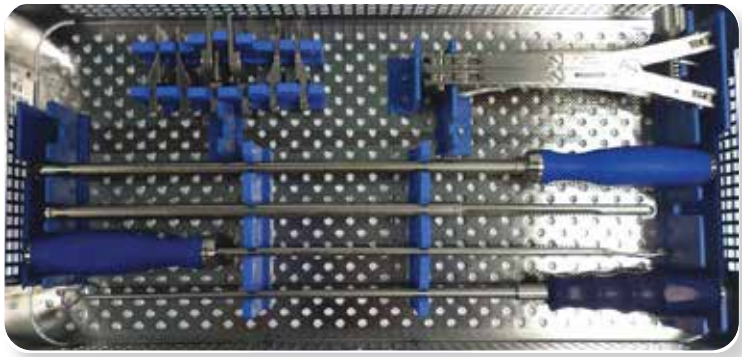
Instrument Kits

Mobidisc L Ancillary Instrument Set n°1, Kit Number:

Instrument Tray



Base



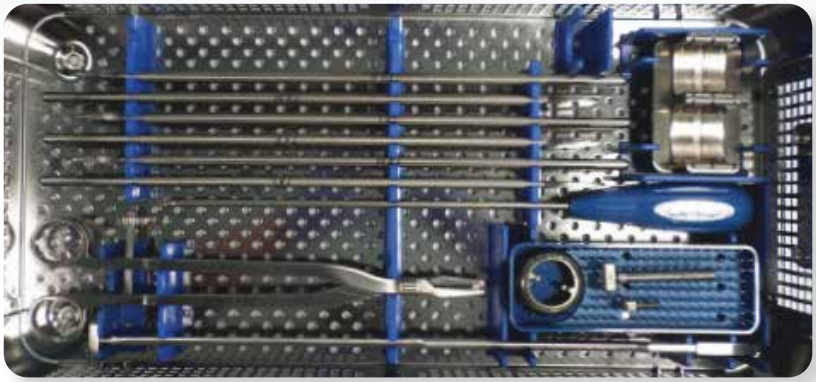
Upper tray

DESCRIPTION	QTY	PART NUMBER
Screwdriver T25 long	1	ES914R
Straight curette	1	IG012R
Cobb elevator	1	IG016R
Adjustable stop screwdriver	1	IG019R
Distraction forceps body	1	IG021R-1
Distraction forceps arm	2	IG021R-2
Unilateral Distractor Part 1	1	IG022R
Unilateral Distractor Part 2	1	IG023R
Bilateral Distractor Part 1	1	IG024R
Bilateral Distractor Part 2	1	IG025R
Parallel Distractor H10 mm	1	IG026R
Parallel Distractor H12 mm	1	IG027R
Unlocking Key	1	IG029R
Level	1	IG030R
Snap-Lock T-Handle	1	MD9000R

DESCRIPTION	QTY	PART NUMBER
Height Measurer 10 mm	1	MD9005R
Height Measurer 12 mm	1	MD9006R
Depth Gauge	1	MD9008R
Mobidisc Slap-Hammer	1	MD9033R
Plate Extractor	1	MD9049R
Short Height Measurer 10mm	1	MD9097R
Short Height Measurer 12mm	1	MD9098R
Extended Centering Pin	2	MD982R
Pin Holder	1	MD986R
Pin Sleeve Holder	1	MD987R
Implant Holder Body H10-H11	1	MD9106R-4
Implant Holder H10-H11 Threaded Rod	1	MD9106R-2
Ablation Ostoeotome (optional)	1	MD9076R

Mobidisc L Ancillary Instrument Set n°2, Kit Number:

Instrument Tray



Base

Upper tray

DESCRIPTION	QTY	PART NUMBER
Assembled Mobidisc L Snap-On Handle	1	IG002R-MDL
Trial Plate T6s	1	MD973R
Trial Plate T6m	1	MD989R
Trial Plate T6l	1	MD974R
Trial Plate T8s	1	MD976R
Trial Plate T8m	1	MD990R
Trial Plate T8l	1	MD977R
Lateral Impactor	1	MD9109R
Distractor Blade	1	MD9110R
Adjustable Stop	1	MD9111R
Assembly Block	1	MD9113R
Revision Forceps	1	MD9115R
Distraction Blade 1	1	MD9119R
Distraction Blade 2	1	MD9120R

DESCRIPTION	QTY	PART NUMBER
Anchor Chisel	1	MD9121R
Implant Holder H12-H13	1	MD9122R
Impactor 1 H10-H11	1	MD9124R
Impactor 2 H10-H11	1	MD9125R
Impactor 1 H12-H13	1	MD9126R
Impactor 2 H12-H13	1	MD9127R
Mobidisc L Instrument Box Cover 1/2	1	MD993A-A
Mobidisc L Insert 1/2	1	MD993A-B
Mobidisc L Instrument Box Base 1/2	1	MD993A-C
Mobidisc L Instrument Box Cover 2/2	1	MD993B-A
Mobidisc L Instrument Box Insert 2/2	1	MD993B-B
Mobidisc L Instrument Box Base 2/2	1	MD993B-C

Implants

Inferior Plates 

LORDOSIS ANGLE	FOOTPRINT (depth x width)	PART NUMBER
5°	T6 S 27 x 34 mm	MD1034K
10°	T6 S 27 x 34 mm	MD1035K
5°	T6 M 30 x 34 mm	MD1044K
10°	T6 M 30 x 34 mm	MD1045K
5°	T6 L 33 x 34 mm	MD1054K
10°	T6 L 33 x 34 mm	MD1055K
5°	T8 S 30 x 39 mm	MD1074K
10°	T8 S 30 x 39 mm	MD1075K
5°	T8 M 33 x 39 mm	MD1084K
10°	T8 M 33 x 39 mm	MD1085K
5°	T8 L 36 x 39 mm	MD1094K
10°	T8 L 36 x 39 mm	MD1095K

Superior Plates 

FOOTPRINT (depth x width)	PART NUMBER
T6 S 27 x 34 mm	MD1032K
T6 M 30 x 34 mm	MD1042K
T6 L 33 x 34 mm	MD1052K
T8 S 30 x 39 mm	MD1072K
T8 M 33 x 39 mm	MD1082K
T8 L 36 x 39 mm	MD1092K

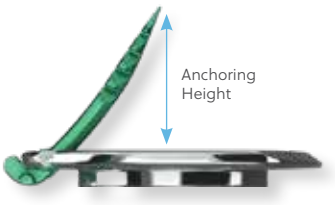
Mobile Insert 

HEIGHT	PART NUMBER
7 mm	MD401P
8 mm	MD402P
9 mm	MD403P
10 mm	MD404P
11 mm*	MD405P

*Optional

Anchoring Clips

DESCRIPTION	HEIGHT	PART NUMBER
Anchoring Clip S	12 mm	MD008T
Anchoring Clip M	14 mm	MD009T



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

Important information on Mobidisc l Lumbar disc prostheses

Device Description

Mobidisc L Lumbar Disc Prostheses are devices for lumbar intervertebral disc replacement for one or two levels (L3-L4, L4-L5, L5-S1) in order to restore segmental motion and disc height.

Mobidisc L prostheses consist of a superior prosthetic plate, a lordotic inferior prosthetic plate, an insert and a fixing system for the plates with anchoring clips.

Various sizes of these prostheses are available, so that adaptations can be made to take into account the patient's pathology and anatomy. The selection of the mobile insert height is done according to the inferior plate lordosis to obtain the total height of the prosthesis required.

Indications

Mobidisc L prostheses are indicated in the treatment of chronic and disabling discogenic low back pain with or without radicular symptom, having resisted to conservative treatments, in skeletally-mature patients younger than 60 years, having a degenerative disc disease and/or a symptomatic herniated intervertebral disc. One or two pathologic discs can be replaced by total disc prostheses for levels L3-L4, L4-L5 or L5-S1. The indication shall be placed based on the patient's history, clinical and radiological examination. The prosthesis shall be implanted by an anterior approach, after complete discectomy of the pathological disc(s).

Contraindications

Contraindications include, but are not limited to:

- Structural spinal stenosis.
- Spondylolysis - Spondylolisthesis.
- Non contained herniated nucleus pulposus
- Inadequate vertebral endplate sizes
- Lumbago of psychiatric nature.
- Severe muscle wasting of the erectile muscles of the spinal column characterised in the MRI.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the prosthesis.
- Obesity can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Acute or chronic, systemic, spinal or localized infection, fever.
- Bony abnormalities preventing safe plate fixation.
- Bone absorption, osteopenia and/or osteoporosis.
- Pregnancy.
- Excessive local inflammation.
- Other medical (for example: anesthetics risks) or surgical conditions which would preclude the potential benefit of spinal prosthesis surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases.
- Cardiac problems.
- Abuse of medicine, drugs, tobacco or alcohol.
- Material sensitivity, documented or suspected.
- Systemic diseases and metabolic disorders.
- Osteochondrosis.
- Posterior arthrosis, developed degenerative arthrosis of the facet.
- Spinal deformity.
- Lack of patient cooperation.

Warnings

One or more components of this device contain the following substance defined as CMR 1B substances in a concentration above 0.1% weight by weight:

- Cobalt; CAS No.: 7440-48-4; EC No.: 231-158-0

There are a few case studies in which patients were diagnosed with cancer while having a device manufactured from cobalt containing alloys in place that hypothesized at a causal nexus between the device and the diagnosis. However, current overwhelming peer-reviewed scientific evidence supports that the incidence of developing cancer or suffering from adverse reproductive effects for patients with a device manufactured from cobalt containing alloys or stainless-steel alloys containing cobalt is comparable to the respective incidence for the general population.

Following are specific warnings, precautions and adverse effects associated with use of Mobidisc L that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Potential risks associated with the use of this system, which may require additional surgery, include device component fracture, loss of fixation, fracture of the vertebra, neurological injury and vascular injury.
- All the prostheses damaged in any way that can infringe on their aspect or functioning must not be implanted.
- Under no circumstances may the prosthesis be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the prosthesis.
- Prosthesis removed from a patient or that came in contact with bodily tissues or fluids should never be reused at risk of contamination of the patient.
- In order to promote the anchoring of prosthetic plates to the vertebral plates during a post-operating period to be determined by the surgeon, implanted prostheses must not be subjected to excessive movements and constraints as this may result in displacement and even expulsion of prostheses from the intersomatic space.

Important information on Mobidisc l Lumbar disc prostheses *(Continued)*

- Contouring or bending of an implant may reduce its fatigue strength and cause its failure. If implants are bent or otherwise damaged during insertion or adjustment, they cannot be implanted and must be replaced.
- Mixing Metal: some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process, or even produce electric shocks. The presence of corrosion may accelerate fatigue fracture of prostheses and the amount of metal compounds released into the body system may also increase. Internal fixation devices which come into contact with other metal objects must be made from identical or compatible metals.
- Manufacturers employ different materials, manufacturing specifications and different design parameters. Components of the Mobidisc L system should not be used in conjunction with components from any other manufacturer. Any such use will negate the responsibility ofZimViefor the performance of the implant.
- Any decision by a surgeon to remove the system should take into consideration such factors as the risk for the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal must be followed by adequate postoperative management.
- The setting and possible repositioning of the prosthesis must be done with the implant holder attached to the prostheses.
- Do not attempt to reposition the prosthesis after anchoring clips or keels fixation to the vertebral plates, unless using the dedicated removal system.
- In case of return of products, potential scrapping is managed by Zimmer Biomet. If there is no return, distributor or health care center is responsible for the scrapping of products according to the local regulation.

Precautions

- Check the position of the prosthesis using fluoroscopy before inserting the anchoring clips to ensure that it is well centered in antero-posterior and laterally.
- Check the position of the two anchoring clips using fluoroscopy before removing the implant holder to ensure that they are well impacted.
- Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of the lumbar disc prosthesis should be performed only by experienced spine surgeons with specific training in the use of these systems and who have knowledge of the present instructions for use and the associated surgical technique.
- The assembly of the components of the Mobidisc L prostheses (superior plate, insert and inferior plate) must be carried out in the specific « implant assembly block » in accordance with the surgical technique.
- The surgeon must consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which has an impact on the performance of the system based on fatigue test results of the system.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the prosthesis (e.g., running, lifting of important loads, or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life of the system. In such cases, orthopedic devices can only be considered as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the lumbar disc prosthesis. This device is recommended for use only by surgeons familiar with preoperative and postoperative surgical techniques, cautions and potential risks associated with spinal surgery. Knowledge of surgical techniques, proper correction, selection and placement of prosthesis, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the prostheses, including the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Risks associated with general surgery, orthopaedic surgery, the use of general anaesthesia as well as the per-operative lesions inflicted on the nervous system, possibly leading to temporary or permanent weaknesses, pain or functional lameness, and postoperative vascular disorders should be explained to the patient prior to surgery.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanical and other extrinsic factors, which limit service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life.
- Care must be taken to protect the components from being damaged (nicks, scratches ...) as a result of a contact with metallic or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the prosthesis.

- Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
- It is of particular importance to provide personalized information to the patient about mobility and muscle training.
- Any damage to the weight-bearing structures may give rise to loosening, dislocation or migration of the prosthesis components, as well as other serious complications. To ensure the earliest possible detection of such catalysts of dysfunction, the lumbar disc prosthesis must be periodically checked postoperative, using appropriate techniques.
- After any surgery, it is necessary to check the proper position of the implant and to follow post-operative changes using appropriate techniques.

Adverse Effects

General adverse events related to surgery

- Post-operative lumbar pain and/or radicular pain (including articular facet pain, muscular pain, minor intervertebral disturbance)
- Early postoperative lumbar stiffness
- Superficial or deep Infection, sepsis
- Reaction to drugs or treatments used during and after the surgery (including antibiotics, anticoagulants)
- Complication related to the anesthesia
- Wound healing disorder
- Cardiopulmonary complications particularly heart attack, pneumopathy
- Deep vein or arterial thrombosis, phlebitis, pulmonary embolism, arterial embolism
- Very rarely, cerebrovascular stroke, death
- Reactional mental disturbance
- Dural tear with CSF leak
- Neurologic disorders leading to sensitive and/or motor troubles (including: paresia, paresthesia, dysesthesia, sympathectomy troubles)
- Vascular injury: arterial or venous injury, haemorrhage or clinically significant blood loss
- Urinary injury (including ureter wound)
- Visceral injury: digestive troubles (ileus)
- Parietal injury: parietal hematoma, peritoneal tear, hernia or eventration
- Intraspinal hematoma
- Urinary or sexual disorders: including urge to urinate, pollakiuria, incontinence, vaginal dryness, retrograde ejaculation

Adverse events related to lumbar arthroplasty

- Degradation (wear, fissure) of the prostheses that could lead to a reaction to the wear debris
- Reduction in bone density due to different distribution of mechanical stresses
- Modification of spinal curvature, particularly in case of prostheses poor positioning
- Peri-prosthetic osteolysis
- Allergic and/or inflammatory reactions to prostheses materials
- Incorrect fixation, displacement, migration, fracture of the device or of one of its components or of the instrumentation, that could lead to a surgical revision due to loss of device fixation or to vascular or neurologic risk
- Impaction or subsidence of the prostheses into the adjacent vertebral body that can lead to interbody height loss and/or pain requiring a surgical revision
- Heterotopic ossification, formation of osteophytes that can lead to a spontaneous fusion of the intervertebral segment and / or generate painful symptoms
- Degenerescence of adjacent disc
- Lumbar stiffness temporary of definitive
- Inefficiency to improve pain or initial state
- Impossibility to treat the concerned level (particularly in case of difficulty to access the disc) that can lead to a change in the surgical strategy

MRI Safety Information

Non-clinical testing has demonstrated that the Mobidisc L Lumbar Disc Prostheses are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m) or less.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of 2W/kg for 1.5T and 3.0T systems.
- When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.

Under the scan conditions defined, the Mobidisc L Lumbar Disc Prostheses is expected to produce a maximum temperature rise of 2.5˚C after 15-minutes of continuous scanning. Allow a 15-minute wait period before proceeding with additional scans.

In non-clinical testing, the image artifact caused by the device extends approximately 4.8 cm from the Mobidisc L Lumbar Disc Prostheses when imaged with a gradient echo pulse sequence in either a 1.5T or a 3.0T MRI system.

Notes

For more information, visit ZimVie.com

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