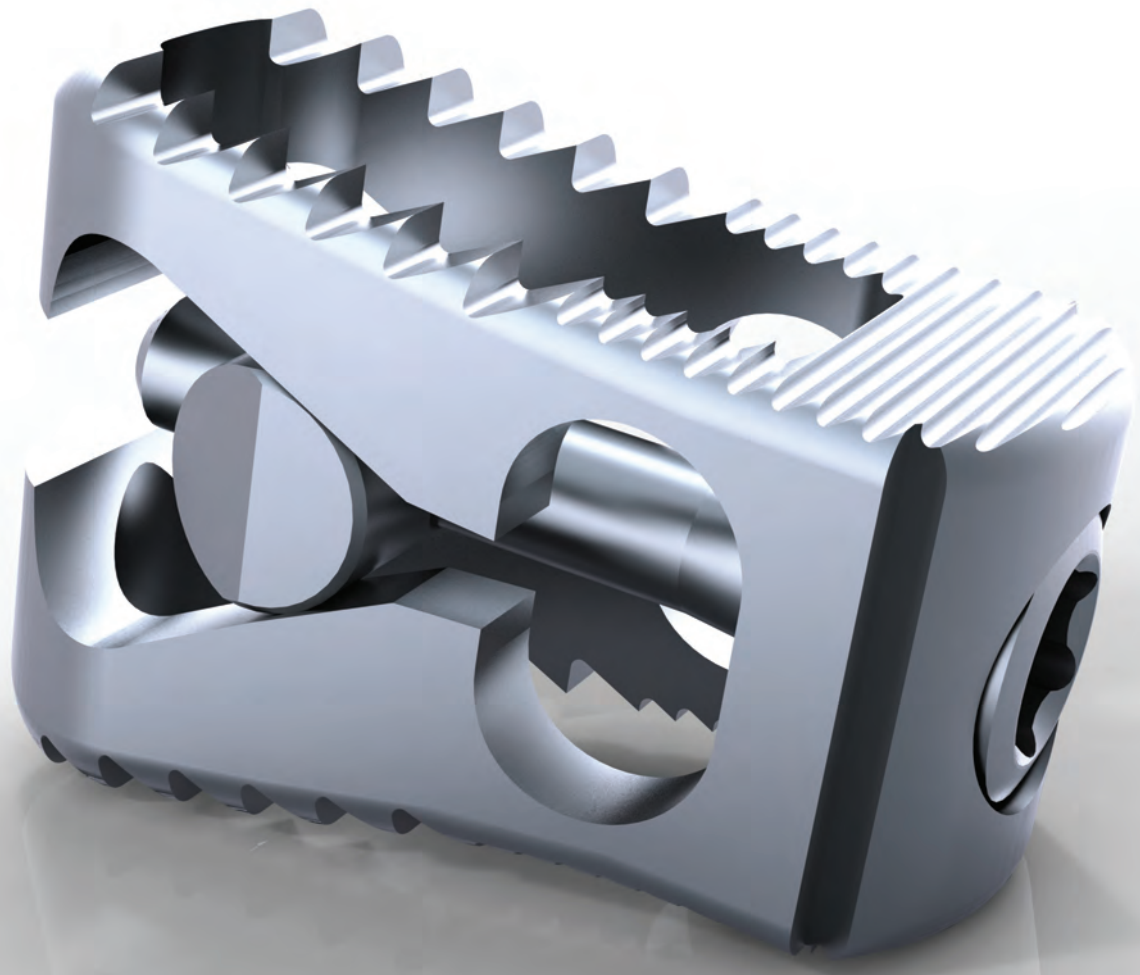
L-VARLOCK

Posterior Lumbar Cage with adjustable lordosis



Surgical Technique

KISCO international

Introduction

Designed and manufactured by KISCO International, L-VARLOCK cages are made of titanium alloy Ti 6Al 4V *(standards ASTM F 136 and ISO5832-3)*.

L-VARLOCK cages are designed for posterior lumbar interbody fusion *(PLIF)* with restoration of disc height and physiological lordosis.

L-VARLOCK is a lumbar interbody fusion cage allowing in situ adjustment of lordosis. The cage can be expanded progressively, allowing restoration of the ideal lordosis determined by the surgeon.

L-VARLOCK cages must be inserted by surgeons qualified in spinal surgery. Product training is available. Contact KISCO International for more information.

Surgeons must use the instruments of the associated kit for insertion of L-VARLOCK implants *(see L-VARLOCK sales catalogue)*.

Note: Insertion of L-VARLOCK cages must be systematically combined with a posterior fusion system such as the ODALYS system.

Warning: the present surgical technique may be modified in order to ensure continuing improvement of the safety and comfort of patients and the surgical team. Make sure that you have the latest version of the surgical technique: www.kisco.fr.

Indications

- Advanced degenerative osteoarthritis *(mainly of the lumbo-sacral junction)* with:
    - compressed disc,
    - disc with conserved height.
- Spondylolisthesis
    - by isthmal lysis,
    - degenerative.
- Serious disc disease

Contraindications

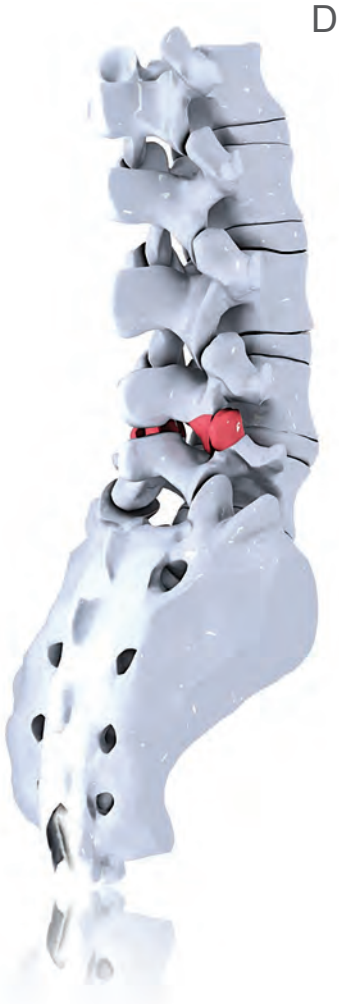
- A bone disorder *(ex: massive osteoporosis)* making the procedure risky in terms of mechanical behaviour of the implant
- Congenital spinal stenosis
- Comminuted fractures involving several vertebrae
- Tumours on several successive vertebrae
- Allergy, intolerance and/or hypersensitivity to the titanium component Ti 6Al 4V
- Primary or secondary infection
- Local inflammation
- Fever, leucocytosis
- Obesity
- Pregnancy
- Mental illness
- Congenital abnormal anatomy
- Rapidly progressive joint disease, severe osteoporosis
- Unsuitable anatomical disposition
- Patient who does not have a sufficient amount of soft tissue to cover the site of implantation.

Contents

1 Patient installation and surgical approach

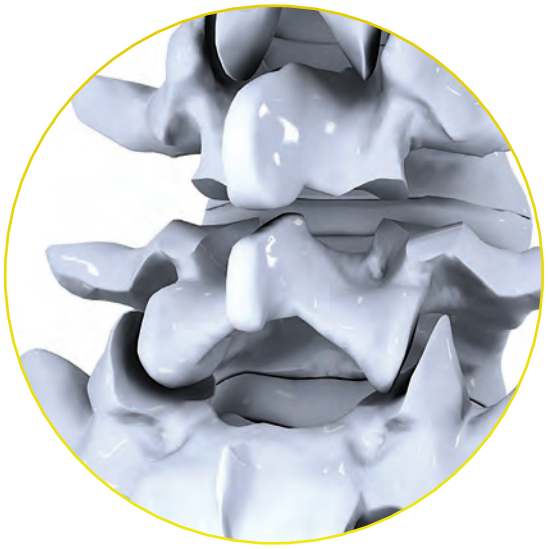
The patient is placed in the prone position on an operating table allowing the lordosis of the lumbosacral spine.
The level to be treated is identified by image intensifier.
The operation is performed via a midline incision.

2 Release and discectomy



Disc exposure must allow sufficient space for the placement of the implants.

Bilateral resection of the inferior laminae is therefore necessary.



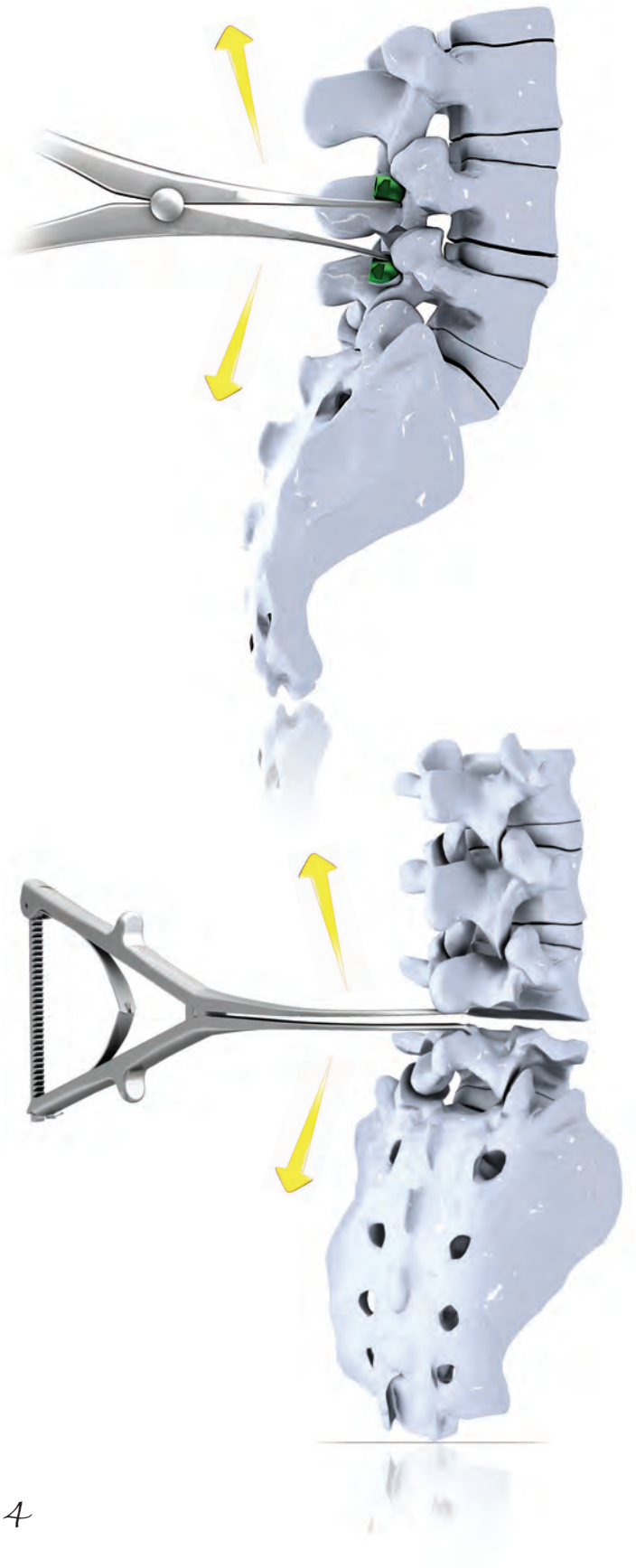
The dural sheath is retracted and the nerve root is protected by a nerve root retractor.

3 Preparation of the intervertebral space

Two distraction methods are proposed.

a. Distraction of the screw heads, using ODALYS distraction forceps

If the surgeon had previously decided to place the screws in the pedicle *(ODALYS screws)*, the interspinous distractor can be positioned on these screws in order to expand the disc space.

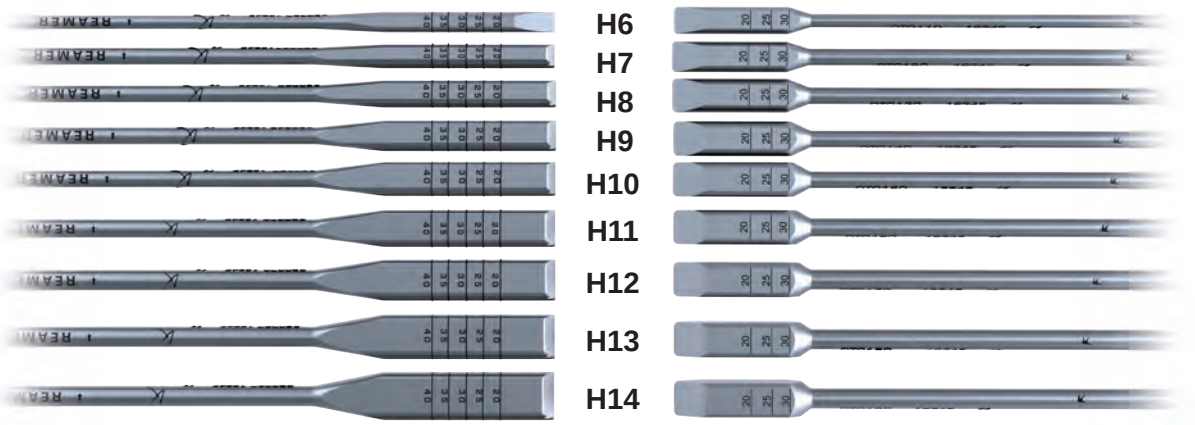


b. Interspinous distraction using the L-VARLOCK distractor

The interspinous distractor is self-stabilizing, allowing safe and progressive distraction.

4 Distraction, discectomy and preparation of the vertebral endplates

Distraction is performed using the distractors/reamers or simple distractors (depending on the kit composition).
These distractors are used to restore disc height, in order to facilitate the discectomy procedure.



Bougies de distraction/Reamer :
Use for distraction and to roughen he surface of the endplates.

Distractors:
Use for distraction only.

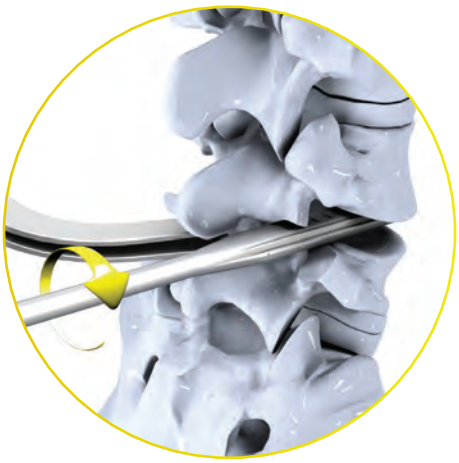
Connect the distractor to the snap-in T-handle.

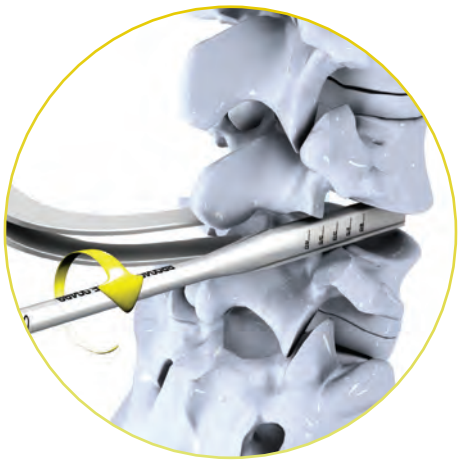
① Pull ② Snap-in ③ Release

Caution: Make sure that the gloves do not caught in the handle when clicking it on the handle.

a. Distraction of the intervertebral space

When using distractors/reamers, clockwise rotation allows distraction of the intervertebral space.





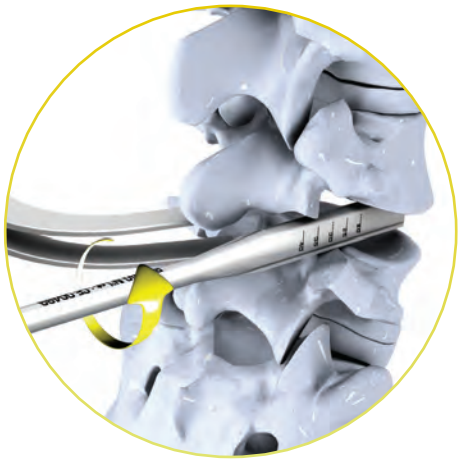
Distractors and distractors/reamers are graduated to allow an initial estimation of the implant length required.

When using simple distractors, no rotation is required. Distraction is ensured directly when impacting the distractor.

Caution: Distractors must be introduced progressively (from 6 mm to 14 mm).

b. Preparation of the vertebral endplates

Use of distractors/reamers



When fully rotated anticlockwise in the intervertebral space, the distractor can be used in Reamer mode for cleaning and effective roughening of the surfaces of the vertebral endplates. The number 6 instrument cannot be used in Reamer mode, but can be used to expand the intervertebral space for narrow segments.

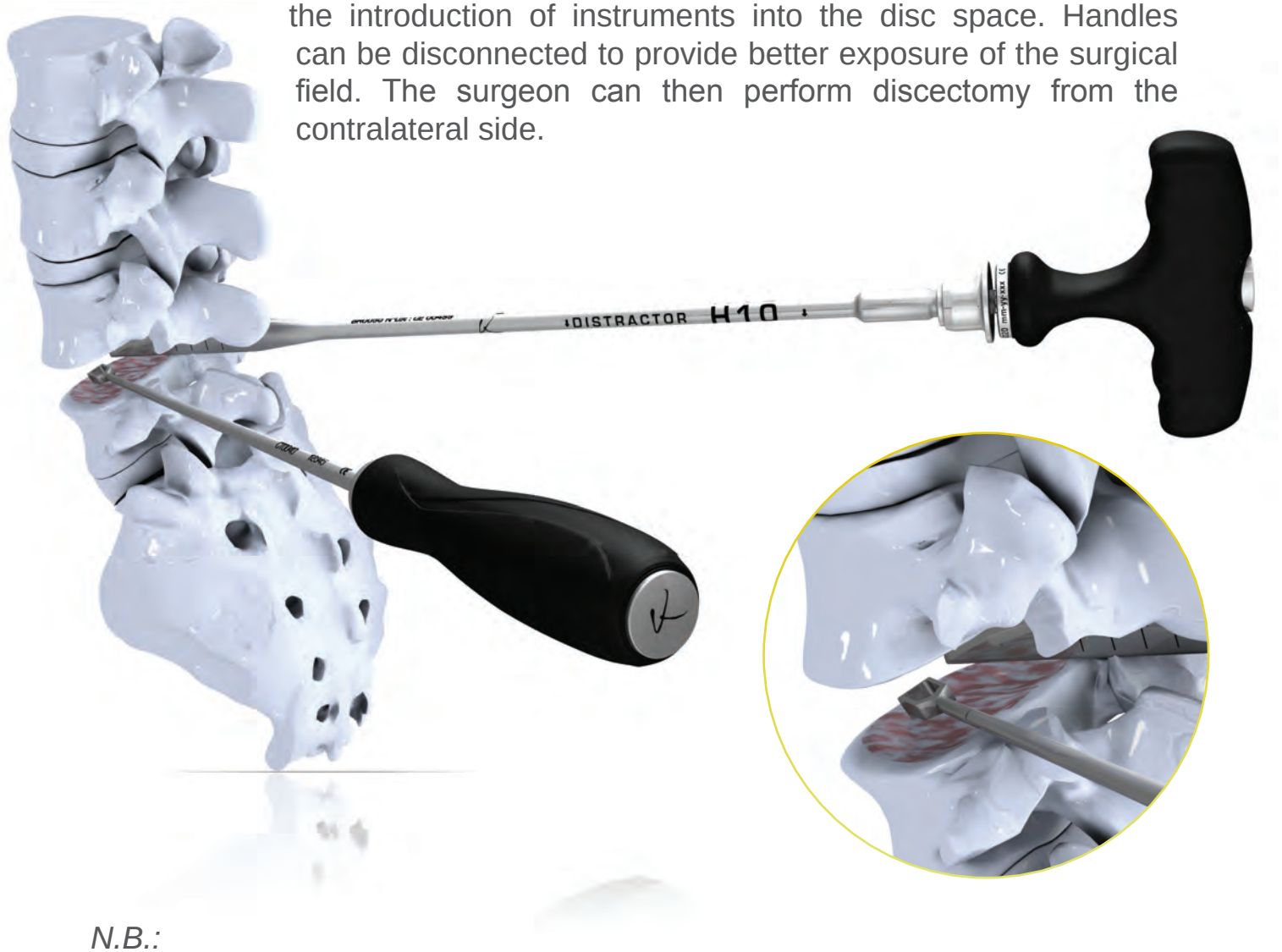
Use of curettes

Two fenestrated straight curettes are available:

- One straight curette ;
- One sharp straight curette.

The sharp curette ensures effective roughening of the surfaces of the vertebral endplates.

Insertion of a distractor on one side of the dural sheath, facilitates the introduction of instruments into the disc space. Handles can be disconnected to provide better exposure of the surgical field. The surgeon can then perform discectomy from the contralateral side.



N.B.:

- Disc rongeurs should be used during this stage (not provided in the kit).

- Avoid direct blows to instruments for which the use of a hammer is not recommended in the surgical technique to avoid damage to adjacent structures.

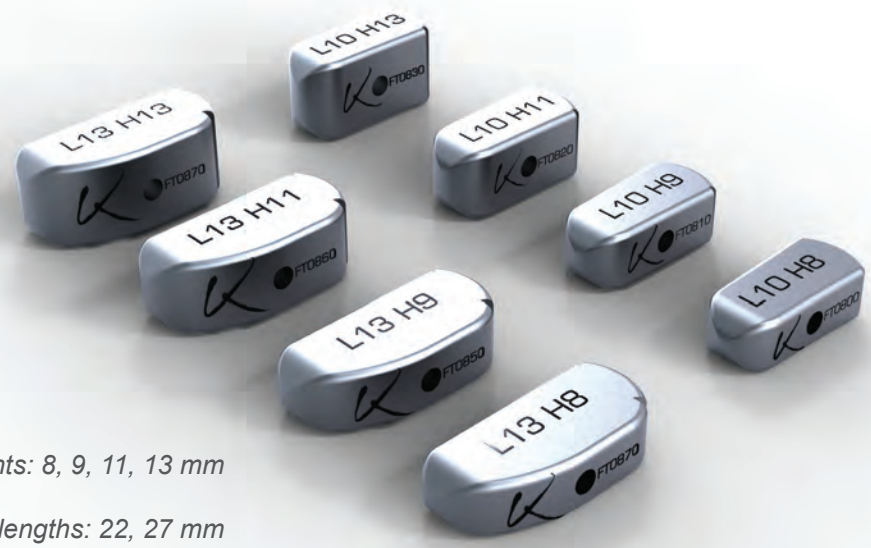
- When the use of a hammer is proposed, hammering must be performed gradually by gentle blows to avoid damage to adjacent structures.

Caution: Avoid any penetration of the cortical bone when roughening the surfaces of the vertebral endplates.

5 Selection of the implant

If the final implant height has not been determined by the use of distractors/ reamers or distractors, it can be determined by using trial implants.

Trial implants are used to determine the desired height and shape.



Available heights: 8, 9, 11, 13 mm

Available lengths: 22, 27 mm

Available widths: 10, 13 mm

The width and height are indicated on each trial implant.

Caution: Trial implants must not be implanted.

6 Assembly of the trial implant on the cage holder

Position the cage holder over the implant rack.

Trial implants can be found in the first row of the rack.

Grasp the desired trial implant by closing the metal handle of the holder.

The jaws of the holder must be positioned over the notches of the trial implant.

A metallic click indicates correct locking of the trial implant.

Then insert the trial implant extractor inside the holder to ensure optimal grip.

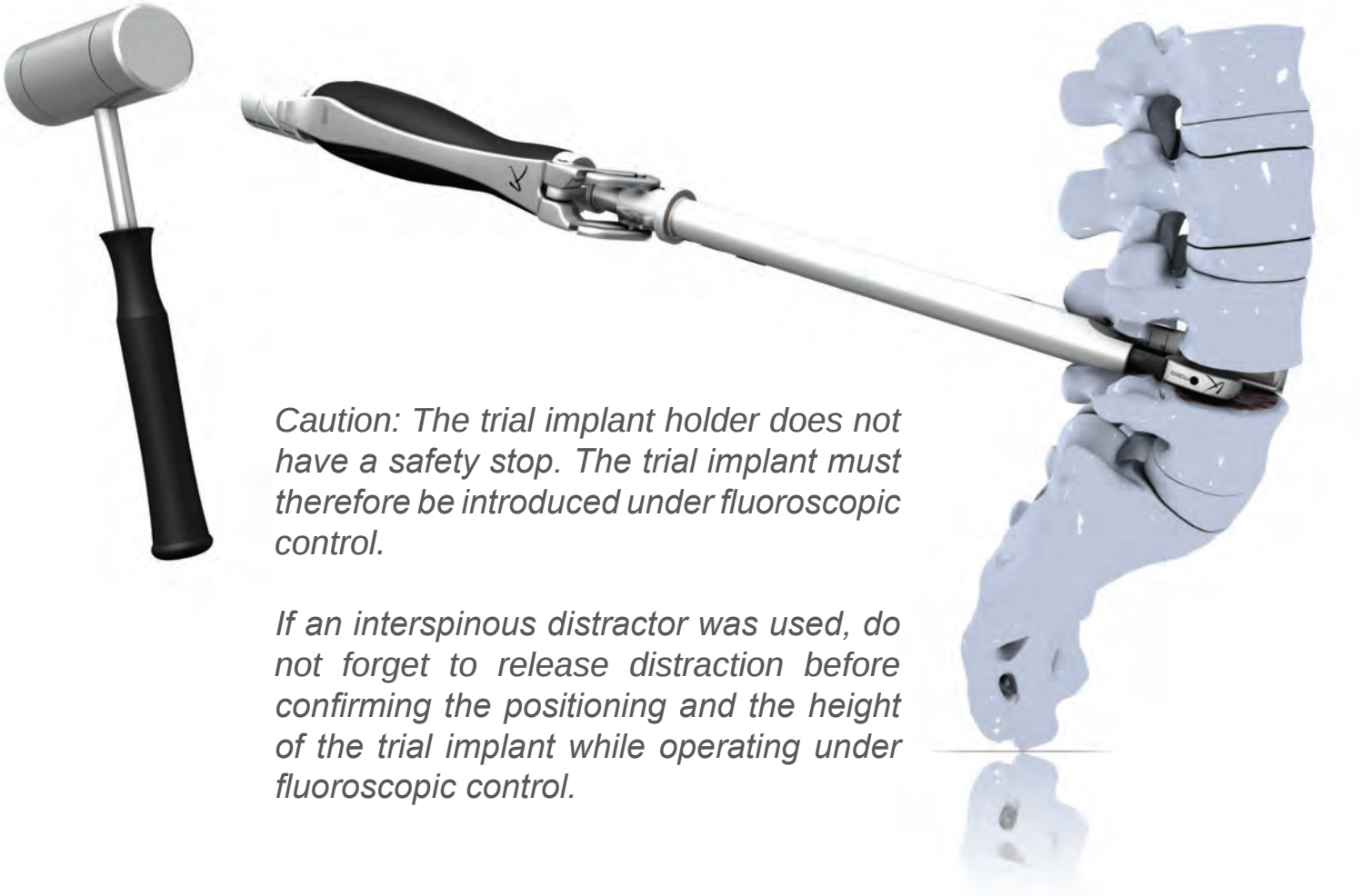
Screw the extractor into the trial implant.

Note: Check that the trial implant holder is correctly centered over the trial implant to facilitate the positioning of the extractor.

7 Placement of the trial implant

The distractor of the desired height is maintained in the contralateral interbody space.

Introduce the trial implant from the opposite side. Introduction of the trial implant can be facilitated by gentle impaction using the hammer.

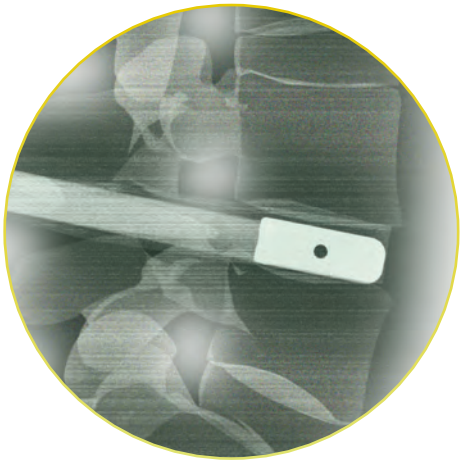


Caution: The trial implant holder does not have a safety stop. The trial implant must therefore be introduced under fluoroscopic control.

If an interspinous distractor was used, do not forget to release distraction before confirming the positioning and the height of the trial implant while operating under fluoroscopic control.

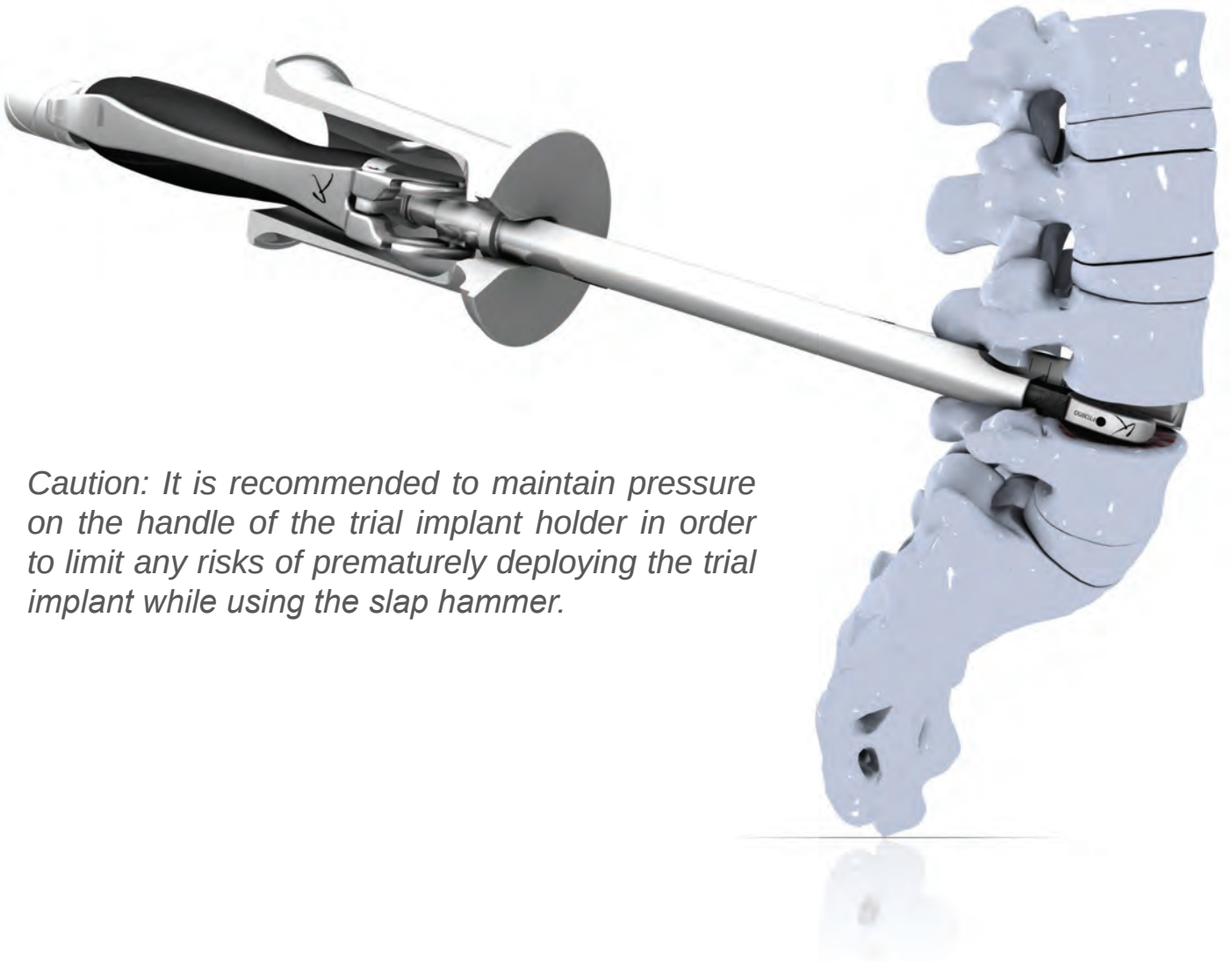
Fluoroscopic control: The central hole must be positioned in the middle of the intervertebral space.

Complete visualization of the central hole confirms the absence of rotation of the trial implant.



8 Removal of the trial implant

The trial implant can be removed by reapplying distraction. A slap hammer supplied in the L-VARLOCK instrument kit will facilitate trial implant removal.



Caution: It is recommended to maintain pressure on the handle of the trial implant holder in order to limit any risks of prematurely deploying the trial implant while using the slap hammer.

Lower the handle to release the trial implant from the holder.

9 Placement of the implant on the cage holder

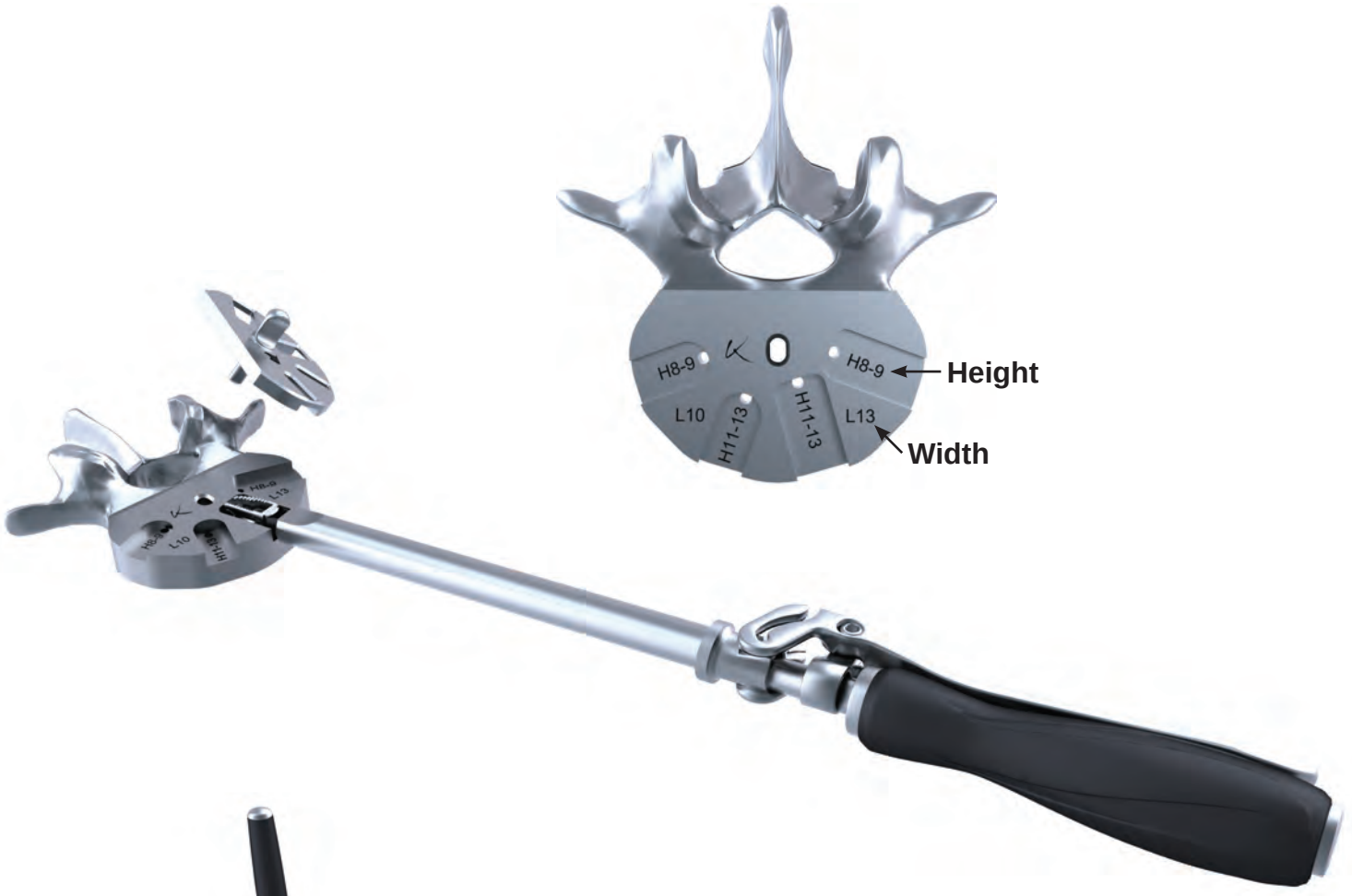
Select the appropriate implants in the rack.

Grasp the selected implant with the cage holder *(the extractor is not used for cage placement)*.

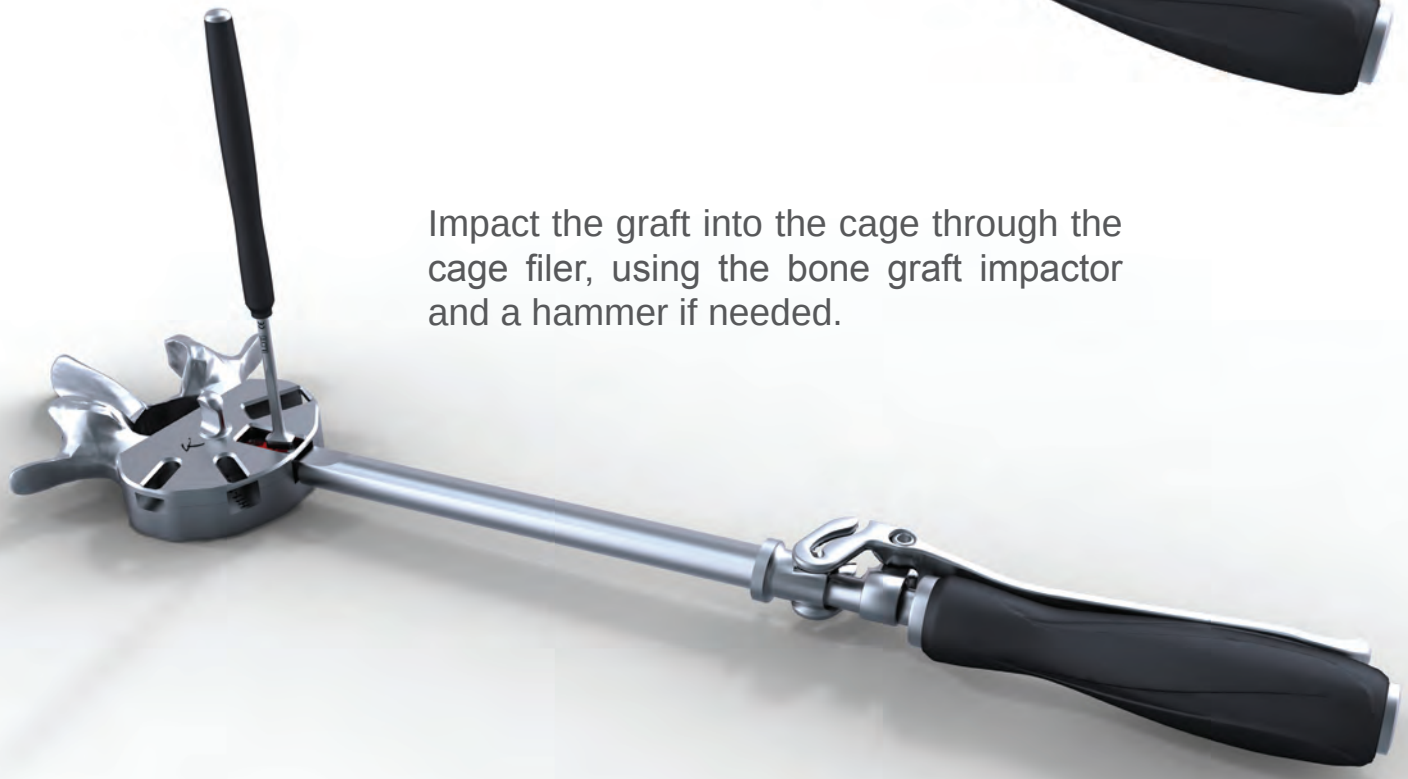
Gripping is identical to that of the trial implant.

10 Graft preparation

Position the cage, mounted on the cage holder, onto the cage filler plate. Choose the appropriate site according to the height and width of the selected cage.



Impact the graft into the cage through the cage filer, using the bone graft impactor and a hammer if needed.

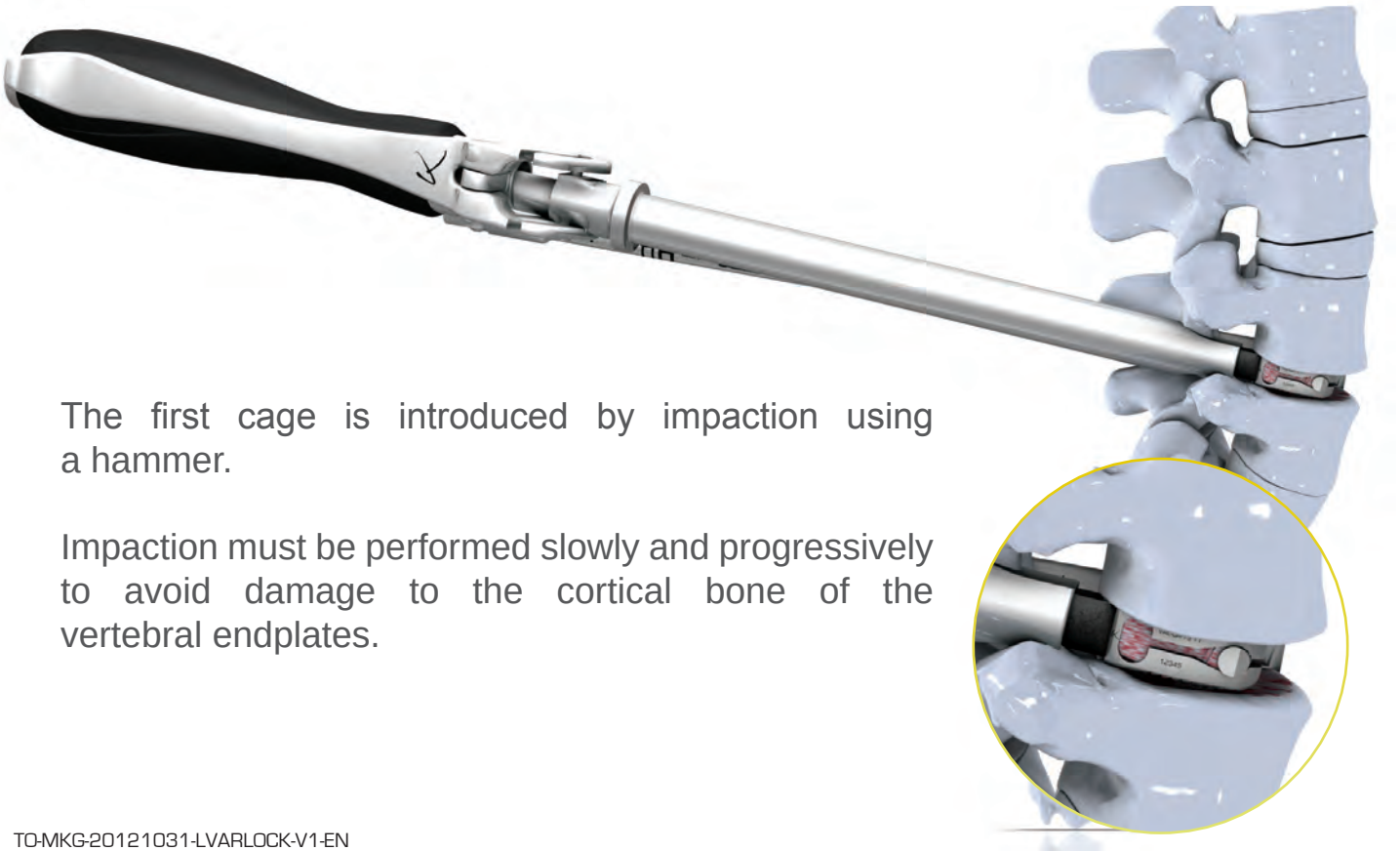


Turn the cage over and repeat the previous step to ensure that the bone graft is correctly distributed on both sides of the cage.

The cage is ready to be inserted.

11 Placement of the implant in the intervertebral space

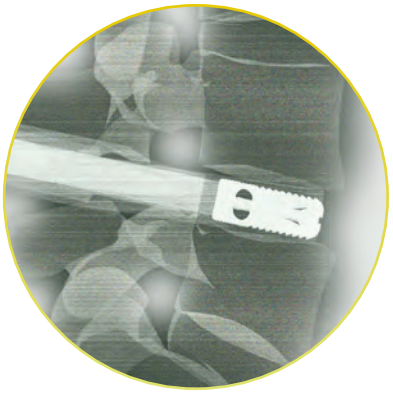
As with the placement of the trial implant, the distractor can be kept in place on the contralateral side during placement of the first cage.



The first cage is introduced by impaction using a hammer.

Impaction must be performed slowly and progressively to avoid damage to the cortical bone of the vertebral endplates.

Check the positioning of the cage using an image intensifier in order to re adjust the anteroposterior positioning of the cage.

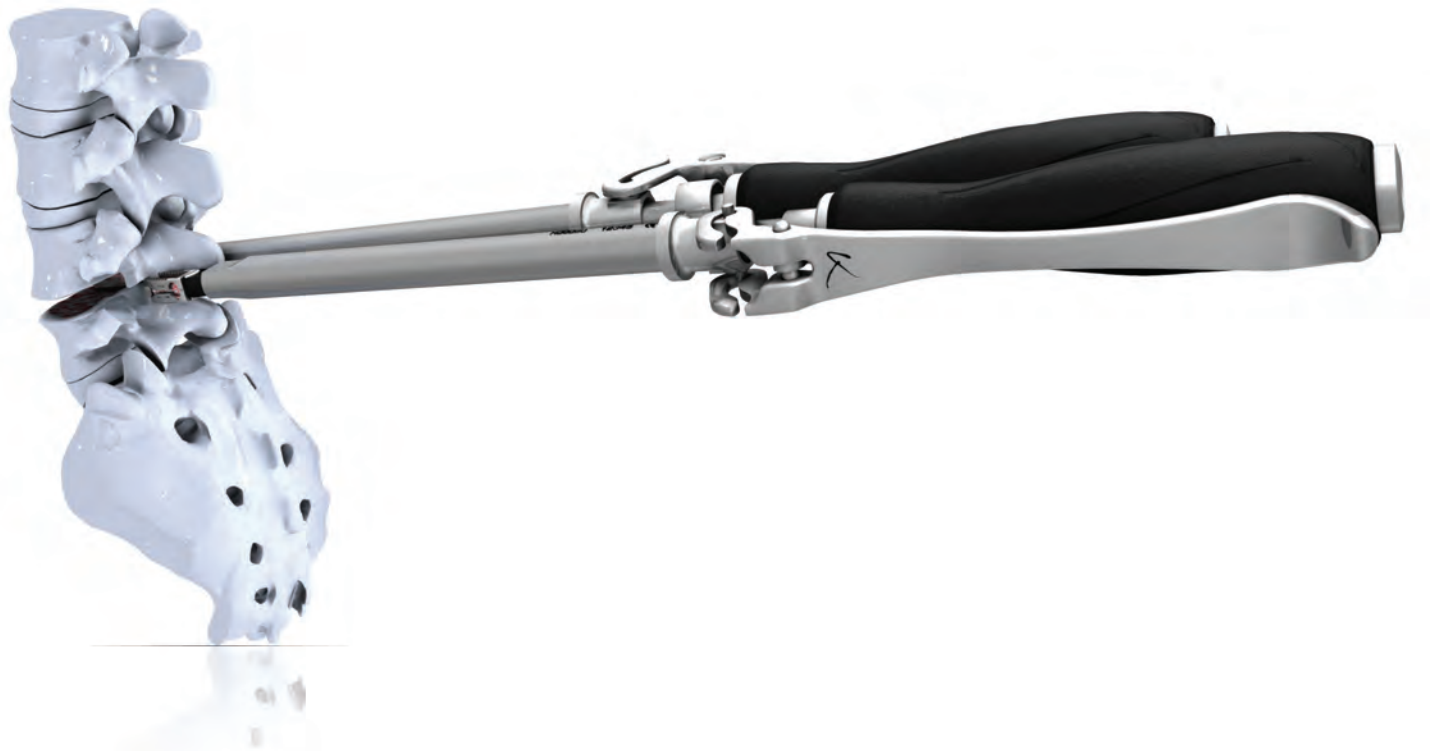


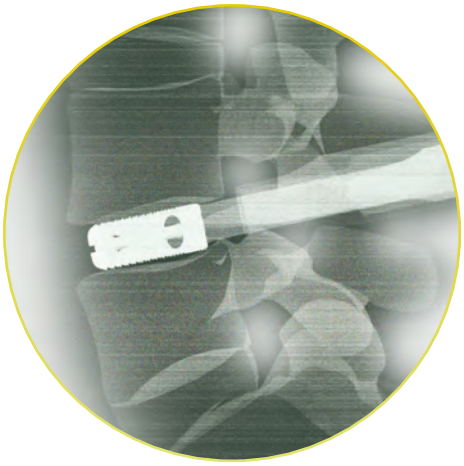
Caution: If an interspinous distractor was used, do not forget to release distraction before confirming the positioning and the height of the cage while operating under fluoroscopic control.

Leave the cage holder on the implant.

12 Placement of the second cage

Once the first cage has been correctly positioned in the interbody space, repeat the previous steps to insert the second cage. Distraction is ensured by the first cage without using a distractor.





Note: If the cage has been released from the cage holder and needs to be repositioned, the cage holder can be reconnected to the cage in order to withdraw the implant, or a secondary impactor can be used to further impact the cage.

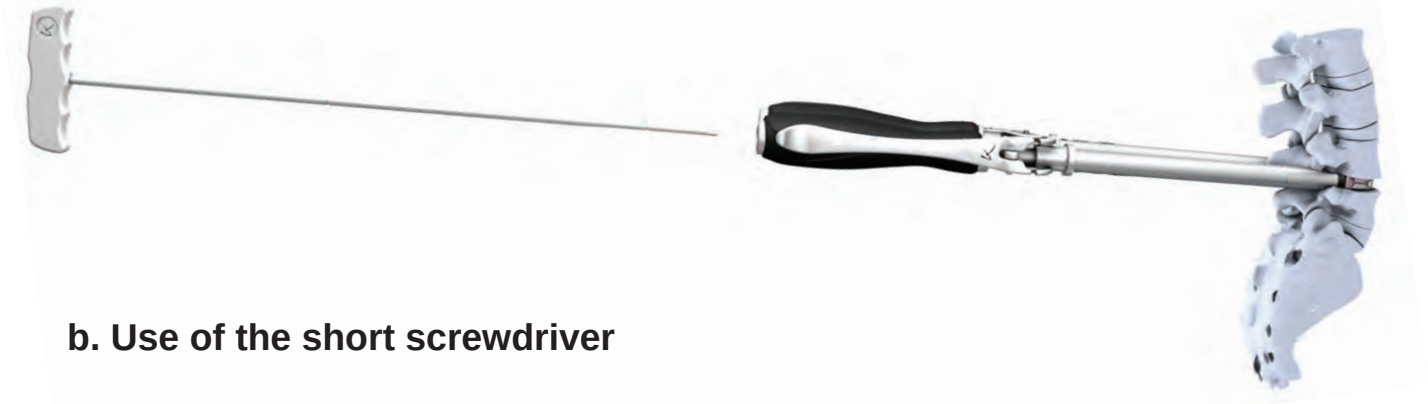
Caution: If an interspinous distractor was used, do not forget to release distraction before confirming the positioning and the height of the cage while operating under fluoroscopic control.

13 Cage expansion

The two cages must be expanded after releasing intervertebral distraction. Cages are expanded by tightening the posterior screw of the cage using either the long expansion screwdriver, or the short expansion screwdriver.

a. Use of the long screwdriver

When using the long screwdriver for cage expansion, expansion can be performed by leaving the cage holder in place and by using it as a counter-torque.



b. Use of the short screwdriver

The short screwdriver for cage expansion must be connected to the snap-in T handle.

The cage holder must be removed before using the short screwdriver

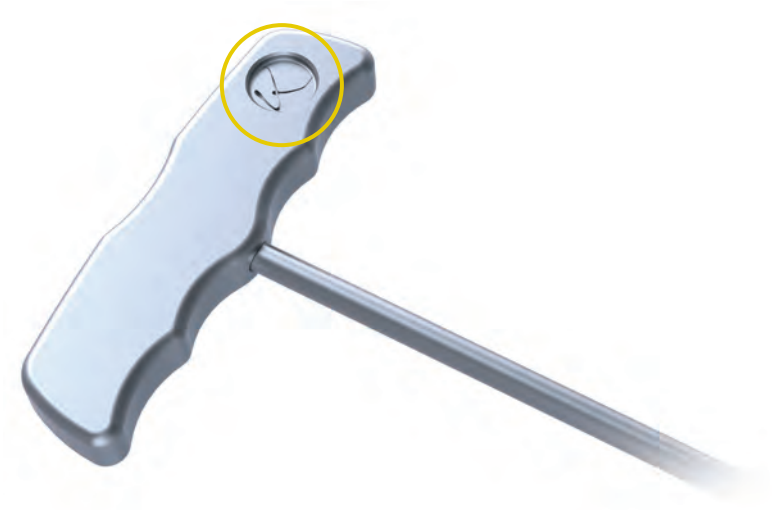
The 2 cages must be expanded gradually and alternately. For example: the right cage is expanded by 2 turns, then the left cage is then expanded by 2 turns, and so on until the desired expansion is achieved. Cage expansion is strictly sagittal.

Cage expansion adds lordosis according to the following nomogram:

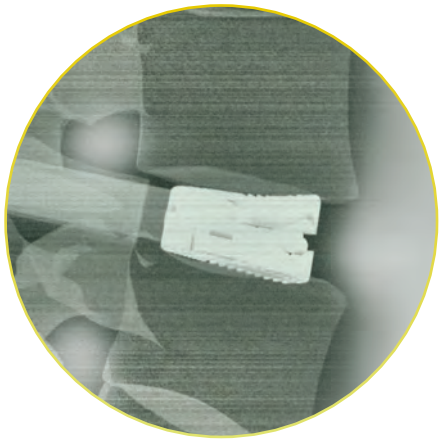
Number of turns	L-VARLOCK L10 cage		L-VARLOCK L13 cage	
	Adjusted height (mm)	Adjusted lordosis (°)	Adjusted height (mm)	Adjusted lordosis (°)
1	0,3	1	0,3	1
2	0,7	2,5	0,6	2
3	1,1	4	0,9	3
4	1,6	6	1,3	4
5	2,2	8	1,8	5
6	2,8	10	2,3	6,5
7	3,7	12,5	2,8	8
8	4,6	15,5	3,4	9,5
9	5,7	19	4	11
10	7,1	24,5	4,7	13

It is difficult to continue expansion of the implanted cage beyond 7 turns.

The machined logo on the long screwdriver will indicate the position of the handle and can therefore be used to keep track of the number of turns.



Caution: The expansion screws must never be unscrewed, except of course in the case of cage removal.

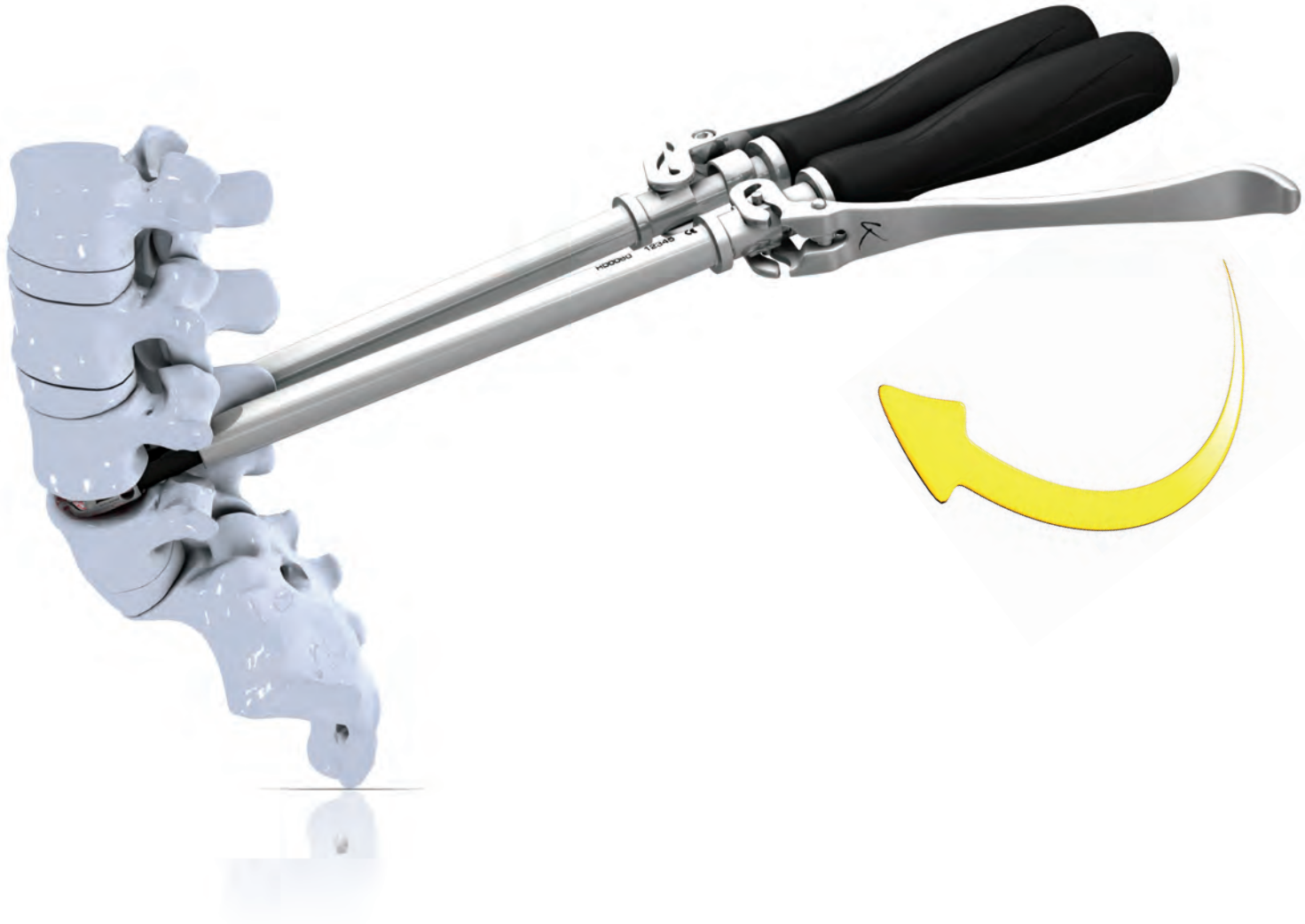


Cage expansion must be verified intraoperatively using an image intensifier.

Visual inspection of the nerve roots after the cage implantation procedure must also be performed.

14 Release of the implants

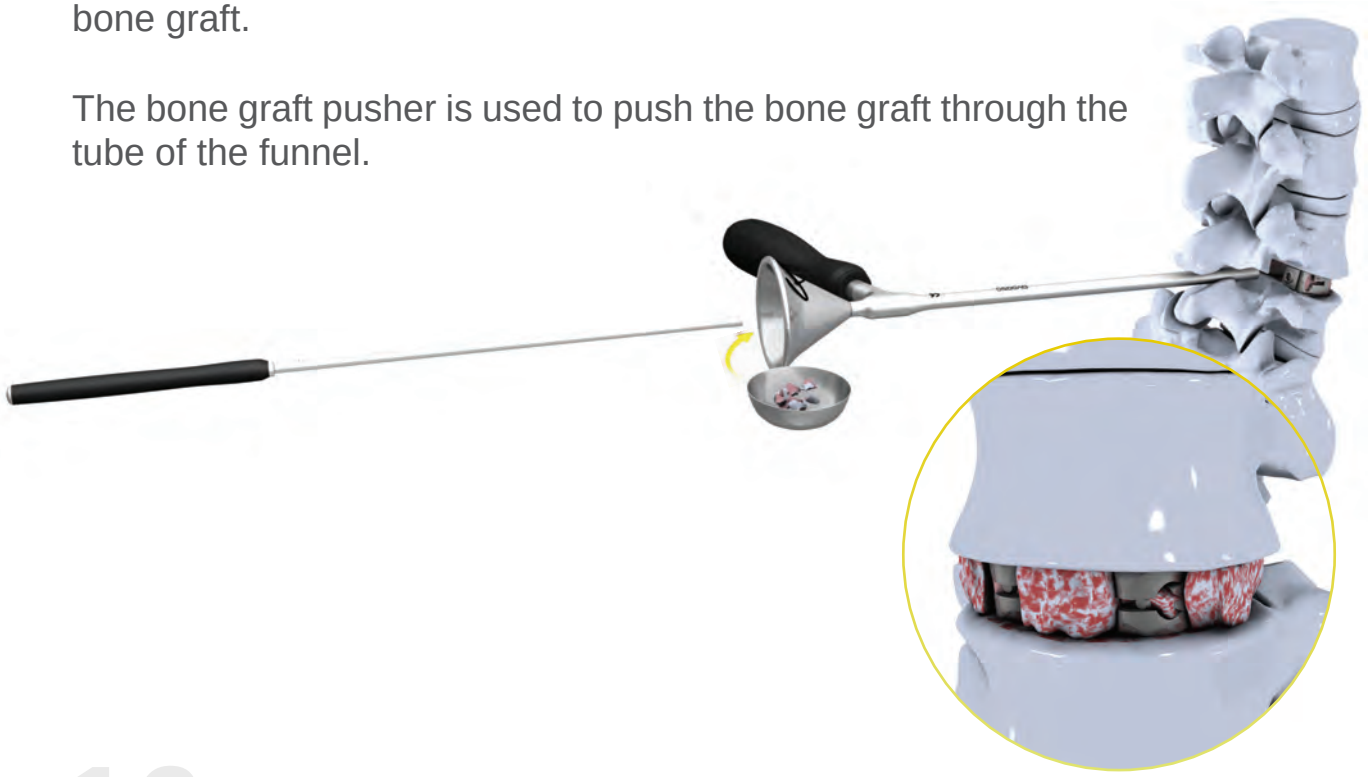
When cage expansion was performed with the cage holders and the long expansion screwdriver, lower the metal handles of the cage holders to release the cages.



15 Additional bone graft

Use the bone graft funnel to fill any remaining spaces between the cages with bone graft.

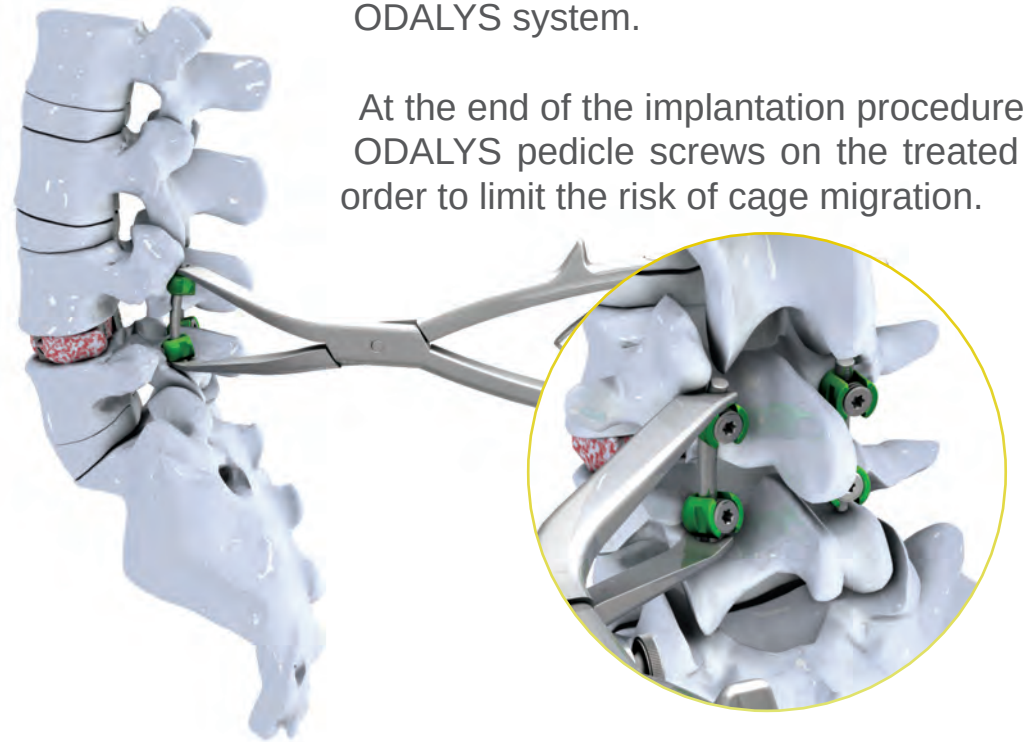
The bone graft pusher is used to push the bone graft through the tube of the funnel.



16 Compression of the implant

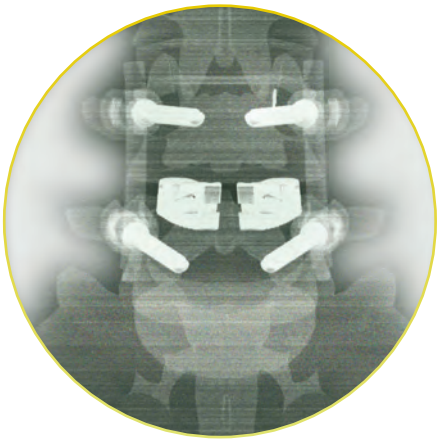
L-VARLOCK cage placement must be systematically combined with a posterior fusion system, such as the ODALYS system.

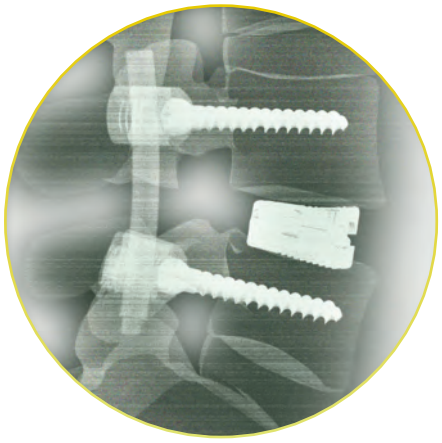
At the end of the implantation procedure, tighten the ODALYS pedicle screws on the treated segment in order to limit the risk of cage migration.



17 Final check

Final lateral and AP x-rays may be useful to confirm correct cage positioning.





18 Redo or removal

To remove a L-VARLOCK cage, apply vertebral distraction and unscrew the implant screws by using the short expansion screwdriver connected to the snap-in T handle. Connect a cage holder, then remove the cage using the slap hammer.

NOTES

Manufactured by

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