



Idys[®] - **PTLIF**

POSTERIOR INTERBODY FUSION



Surgical technique - USA

Idys[®]-PTLIF

POSTERIOR INTERBODY FUSION



CONTENTS

Surgical Technique TLIF-Oblique P04

- | | |
|--------------------------|--------------------------------------|
| 1 Disc exposure | 6 Implant Preparation |
| 2 Distraction | 7 Cage Insertion |
| 3 Discectomy | 8 Final Positioning |
| 4 Endplate Preparation | 9 Supplementary posterior fixation |
| 5 Cage Selection | |

Surgical Technique PLIF P12

- | | |
|--------------------------|---------------------------------------|
| 1 Disc exposure | 6 Implant Preparation |
| 2 Distraction | 7 Cage Insertion |
| 3 Discectomy | 8 Insertion of the second cage |
| 4 Endplate Preparation | 9 Final Positioning of the Cages |
| 5 Cage Selection | 10 Supplementary posterior fixation |

Instruments P20

Implants P22

Surgical Technique

TLIF-OBLIQUE

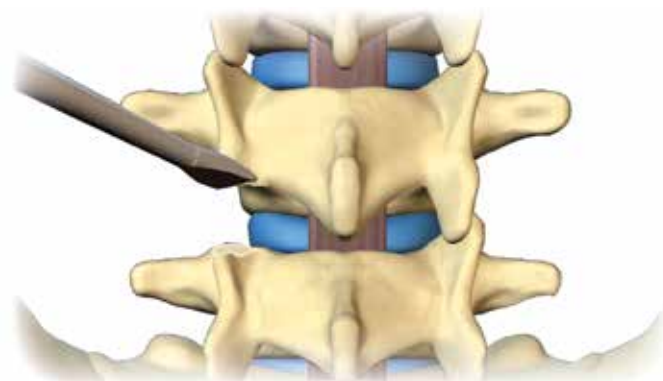
To become the architects of spine, Clariance has developed its products in collaboration with expert surgeons in their practice from all backgrounds including from France and the US. Because of this diversity, Clariance offers solutions that meet all practices. This surgical technique guide is the result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

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



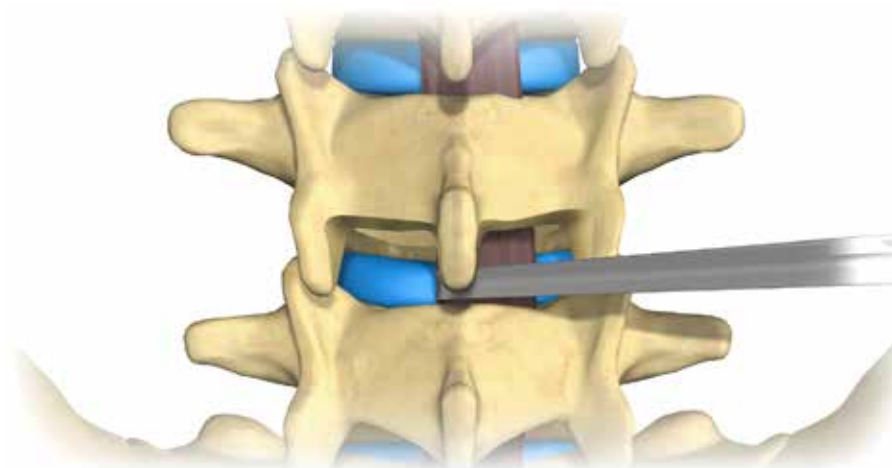
1 | DISC EXPOSURE

Using **the Osteotome**, perform a unilateral facetectomy on the appropriate side to obtain transforaminal access to the disc space. Resection must be sufficient to allow access of the instruments and insertion of the Cage into the disc space.



*In accordance with safety procedures in force, the patient is placed in **the ventral decubitus** position on the operating table. The surgical approach is based on the usual techniques used by the surgeon.*

The nerve root retractor is used to protect the surrounding nerve structures throughout the surgical procedure.



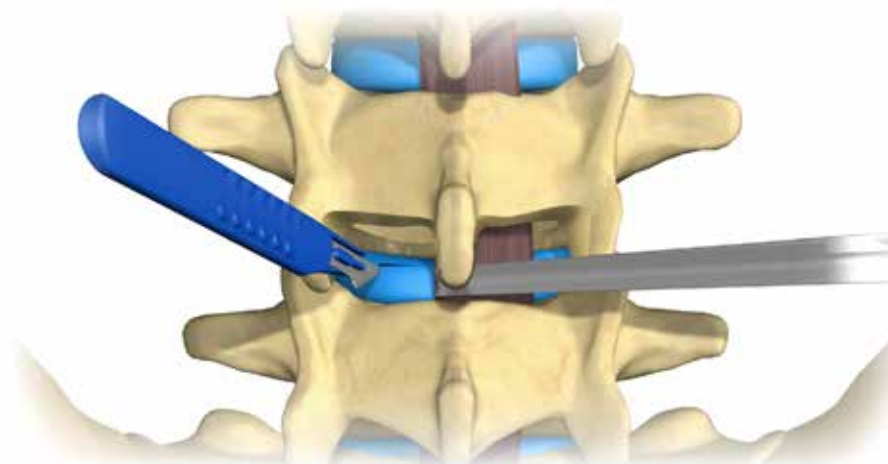
2 | DISTRACTION

Progressive distraction tension is applied in accordance with the surgeon's habits and preferences;

This maneuver temporarily opens the posterior disc space and promotes increased exposure for discectomy, decompression and delivery of the implant.

3 | DISCECTOMY

A window is created in the intervertebral disc using a scalpel.



OSTEOTOME

04705010



NERVE ROOT RETRACTOR

04781006



T-HANDLE

99781001



SHAVERS

047070xx

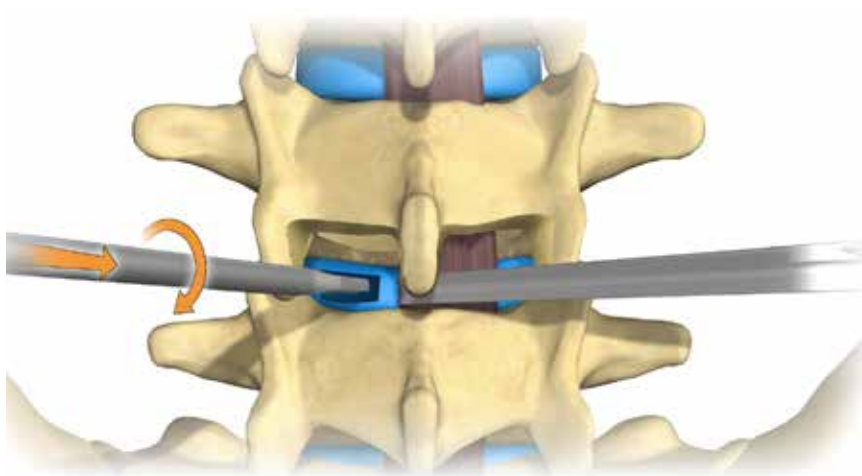


DISC RONGEUR

06708001



- **Rounded shavers** are used in rotation to start the discectomy and gradually restore the disc height.
- Shavers are available in heights ranging from 7 - 14mm in 1mm increment.



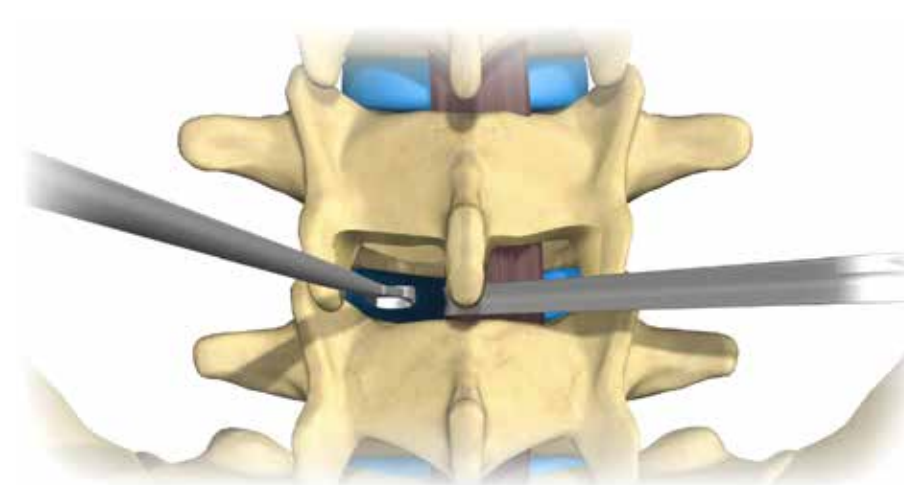
- The disc material is removed using **disc rongeurs**.



When possible, the anterior and lateral walls of the annulus are preserved in order to provide additional stability for the cages.

4 | ENDPLATE PREPARATION

- The endplates are prepared using **the curette** and **the cup curette** to remove the remaining layers of the entire cartilaginous endplates and expose bleeding bone.



RECOMMENDATION:

Thorough cleaning of the endplates is important for the vascular supply of the bone graft. Caution : a too aggressive endplate preparation can fragilize cortical bone and thus weaken the vertebral endplates.

CURETTE

04704015



CUP CURETTE

04704005



PTLIF TRIALS

04714xxx



PLIF CAGE HOLDER

04715002



SLAP HAMMER

04762000



5 | CAGE SELECTION

RECOMMENDATION :

The size and height of the final implant are determined by selecting the trial that restores the desired disc height and lumbar lordosis of the treated segment.

The trial is connected and secured to the PLIF cage holder by turning the locking knob clockwise.



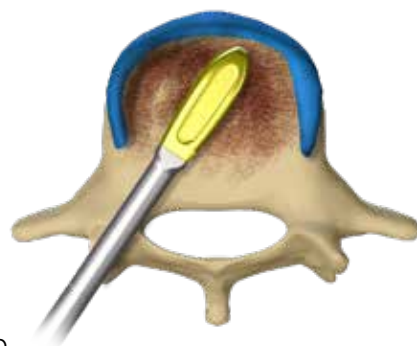
The trial is then inserted in the intervertebral space using a surgical mallet. The trial is not dissociated from the PLIF cage holder.



Distraction is momentarily released and an X-ray check is performed to verify the trial position and validate the size and height of the final implant.

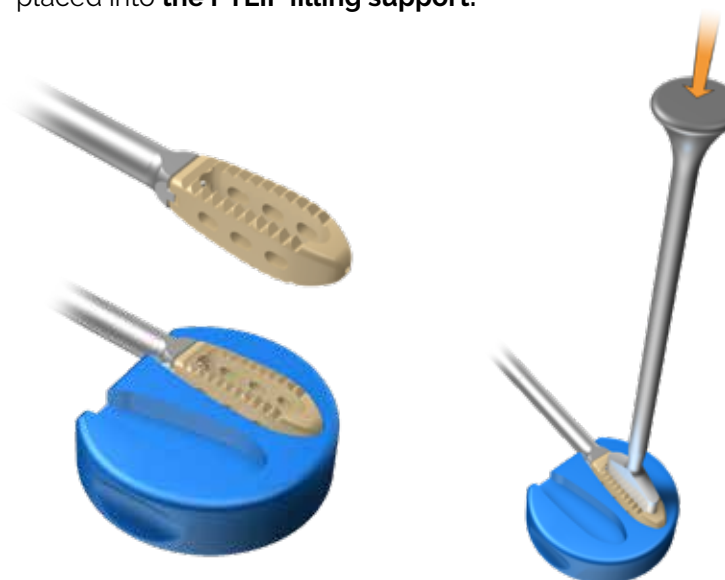
Distraction is re-established and the trial is removed using the slap hammer.

The PLIF cage holder is disconnected from the trial by completely turning the locking knob.



6 | IMPLANT PREPARATION

- The selected cage is connected to the PLIF cage holder and placed into the PTLIF filling support.

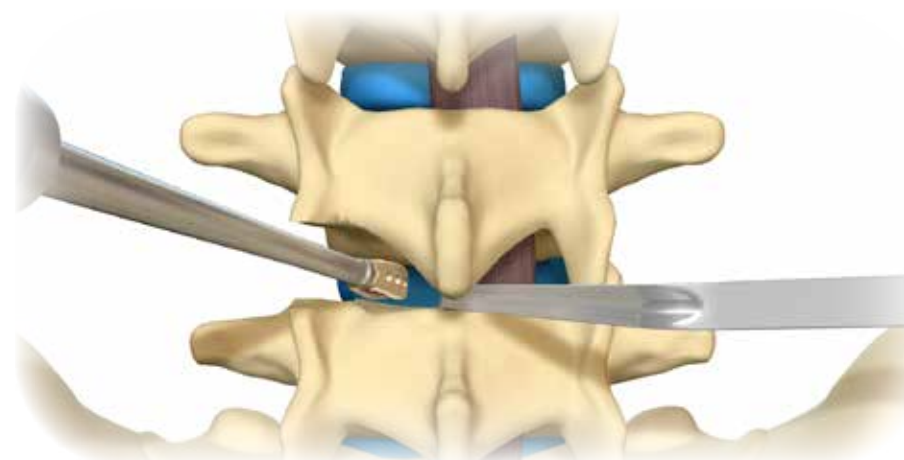


- The PTLIF graft impactor is used to firmly pack the graft into the implant cavity.



7 | CAGE INSERTION

The prepared cage is inserted into the intervertebral space with light impactions.



Important:

It is important to completely fill the implant cavity in order to ensure optimal contact between the graft material and the vertebral endplates.

PLIF CAGE HOLDER

04715002



PTLIF FILLING SUPPORT

04717004

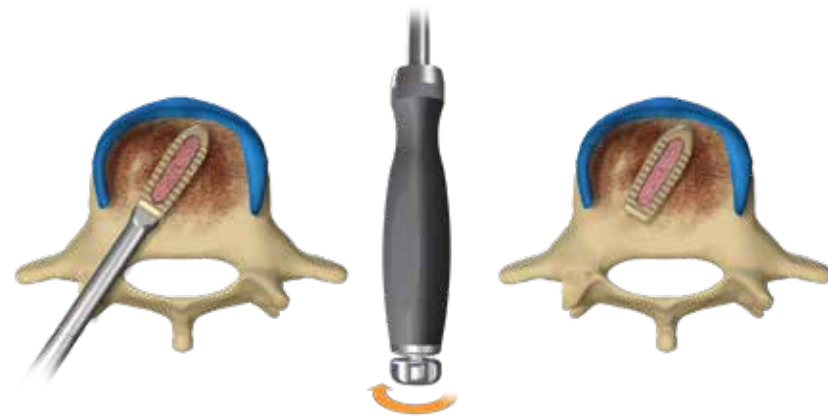


PTLIF GRAFT IMPACTOR

0476100x

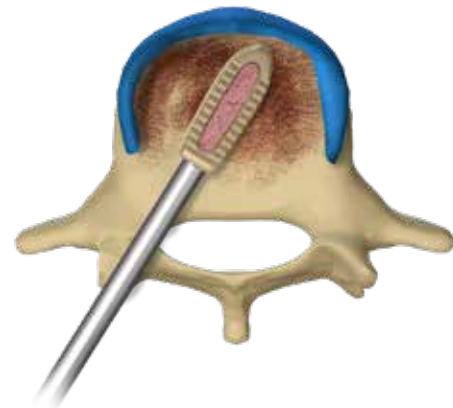


- An X-ray check is performed and the cage is disconnected.



8 | FINAL POSITIONING OF THE CAGE

- If needed, **the PLIF cage impactor** may be used to adjust the position and the depth of the cage within the intervertebral space.

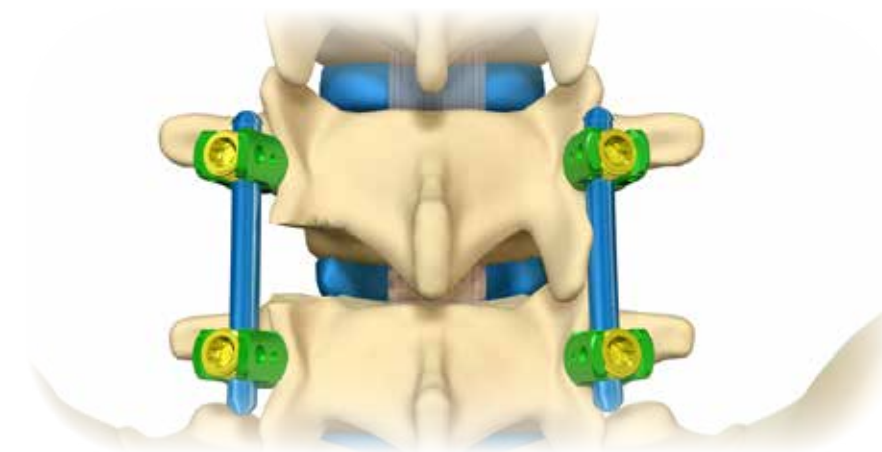


- Distraction is released and a final X-ray check is performed.



9 | SUPPLEMENTARY POSTERIOR FIXATION

Posterior fixation is required to place the treated segment under compression and to enhance the stability of the cages.



PLIF CAGE IMPACTOR

04716001



Surgical Technique

PLIF

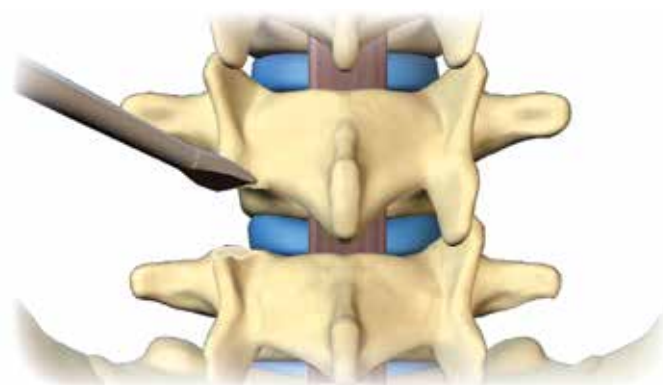
To become the architects of spine, Clariance has developed its products in collaboration with expert surgeons in their practice from all backgrounds including from France and the US. Because of this diversity, Clariance offers solutions that meet all practices. This surgical technique guide is the result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

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



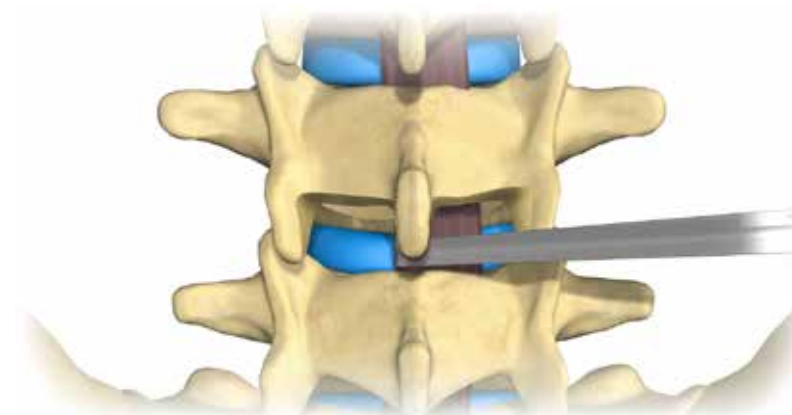
1 | DISC EXPOSURE

Access to the disc space is obtained by performing a bilateral lamino-facetectomy using **the osteotome**. Resection must be sufficient to allow access of the instruments and insertion of the cage into the disc space.



*In accordance with safety procedures in force, the patient is placed in **the ventral decubitus** position on the operating table. The surgical approach is based on the usual techniques used by the surgeon.*

The nerve root retractor is used to protect the surrounding nerve structures throughout the surgical procedure.



RECOMMENDATION:

It is advisable to preserve the facet joints in order to guarantee the stability of the treated segment and minimize disruption to adjacent segments.

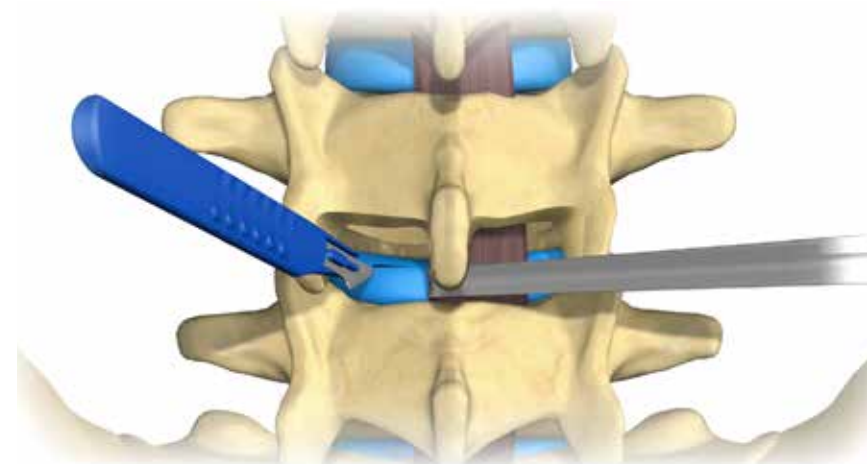
2 | DISTRACTION

Progressive distraction tension is applied in accordance with the surgeon's habits and preferences;

This maneuver temporarily opens the posterior disc space and promotes increased exposure for discectomy, decompression and delivery of the implant.

3 | DISCECTOMY

A window is created in the intervertebral disc using a scalpel.



OSTEOTOME

04705010



NERVE ROOT RETRACTOR

04781006



T-HANDLE

99781001



SHAVERS

047070xx

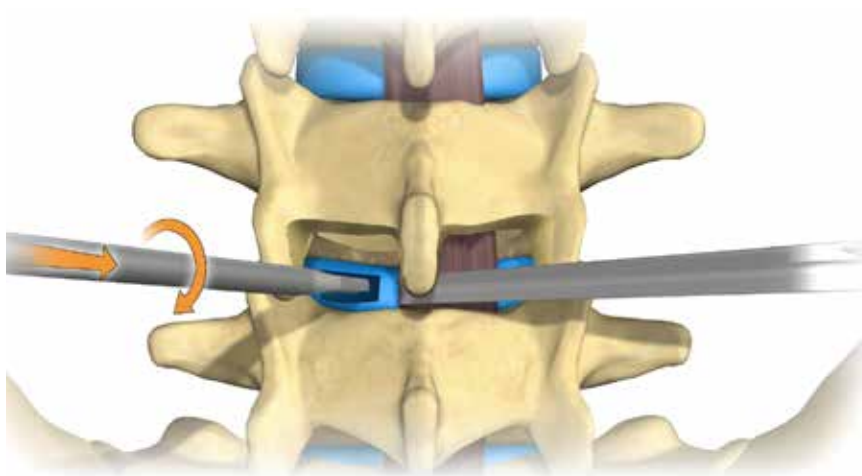


DISC RONGEUR

06708001



- **Rounded shavers** are used in rotation to start the discectomy and gradually restore the disc height.
- Shavers are available in heights ranging from 7 - 14mm in 1mm increment.



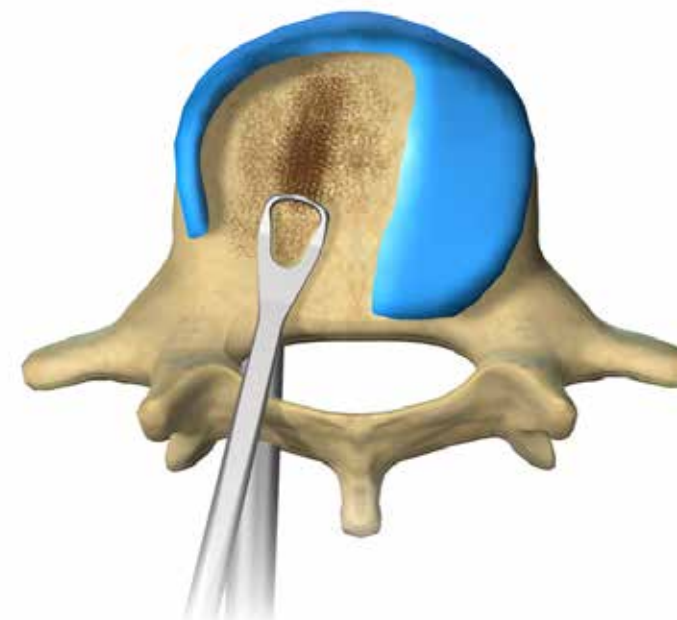
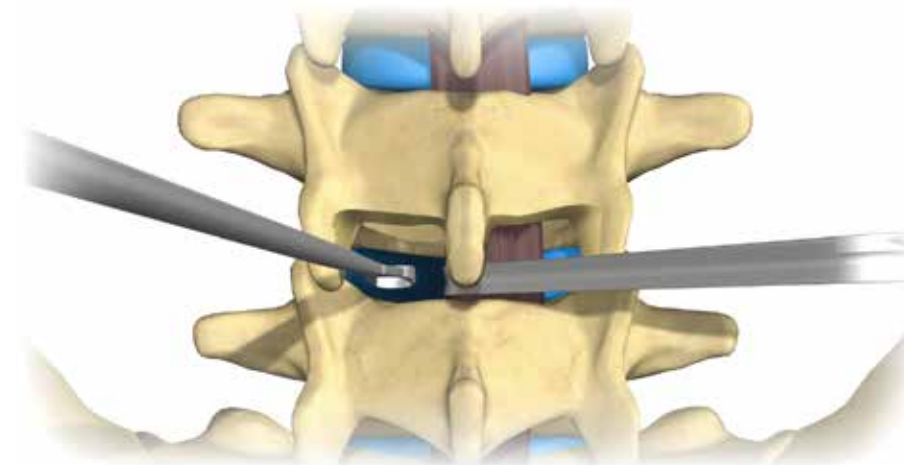
- The disc material is removed using **disc rongeurs**.



When possible, the anterior and lateral walls of the annulus are preserved in order to provide additional stability for the cages.

4 | ENDPLATE PREPARATION

- The endplates are prepared using **the curette** and **the cup curette** to remove the remaining layers of the entire cartilaginous endplates and expose bleeding bone.



RECOMMENDATION:

Thorough cleaning of the endplates is important for the vascular supply of the bone graft. Caution : a too aggressive endplate preparation can fragilize cortical bone and thus weaken the vertebral endplates.

CURETTE

04704015



CUP CURETTE

04704005



PTLIF TRIALS

04714xxx



PLIF CAGE HOLDER

04715002



SLAP HAMMER

04762000



5 | CAGE SELECTION

RECOMMENDATION :

The size and height of the final implant are determined by selecting the trial that restores the desired disc height and lumbar lordosis of the treated segment.

The trial is connected and secured to the PLIF cage holder by turning the locking knob clockwise.



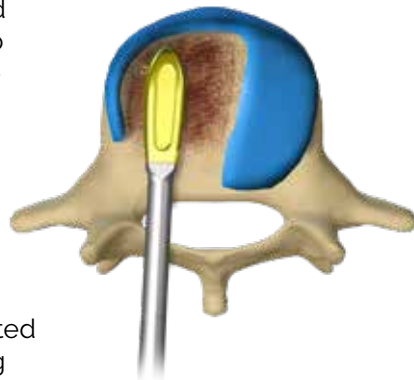
The trial is then inserted in the intervertebral space using a surgical mallet. The trial is not dissociated from the PLIF cage holder.



Distraction is momentarily released and an X-ray check is performed to verify the trial position and validate the size and height of the final implant.

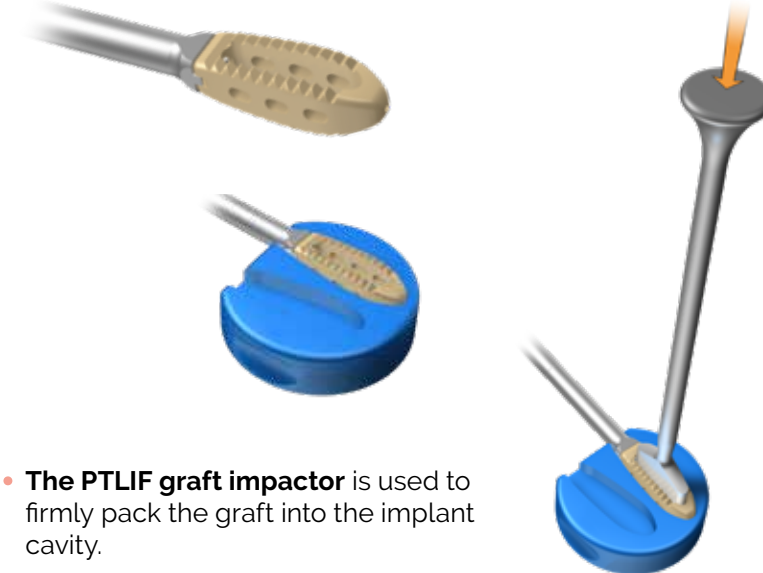
Distraction is re-established and the trial is removed using the slap hammer.

The PLIF cage holder is disconnected from the trial by completely turning the locking knob.



6 | IMPLANT PREPARATION

- The selected cage is connected to the PLIF cage holder and placed into the PTLIF filling support.

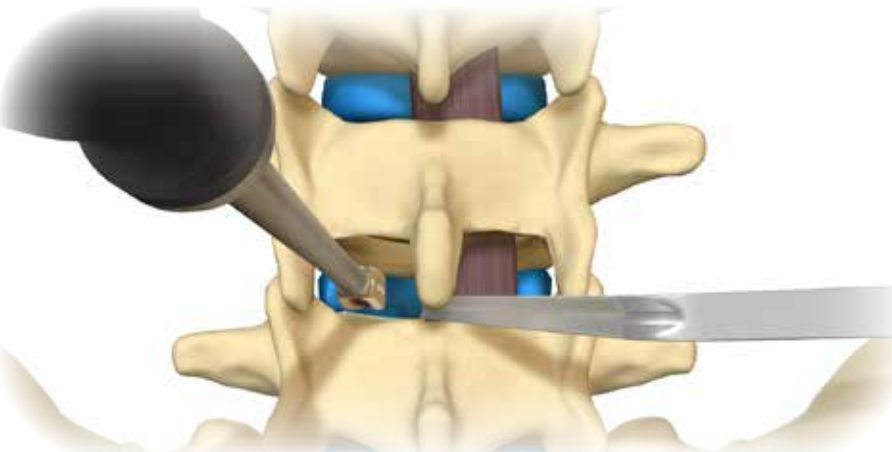


- The PTLIF graft impactor is used to firmly pack the graft into the implant cavity.



7 | CAGE INSERTION

The prepared cage is inserted into the intervertebral space with light impactions. When inserting the cage, the PLIF cage holder must be turned medially to ensure that the tip of the cage is facing the entry point. During cage impaction, the PLIF cage holder must be held straight so that the implant is inserted into the disc space laterally.



Important:

It is important to completely fill the implant cavity in order to ensure optimal contact between the graft material and the vertebral endplates.

PLIF CAGE HOLDER

04715002



PTLIF FILLING SUPPORT

04717004

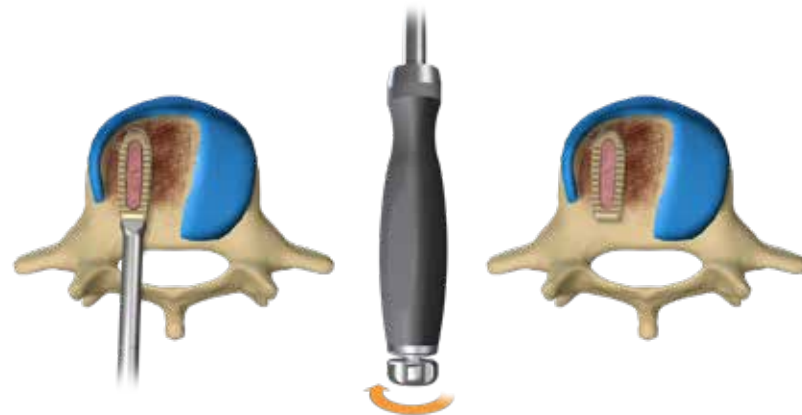


PTLIF GRAFT IMPACTOR

0476100x

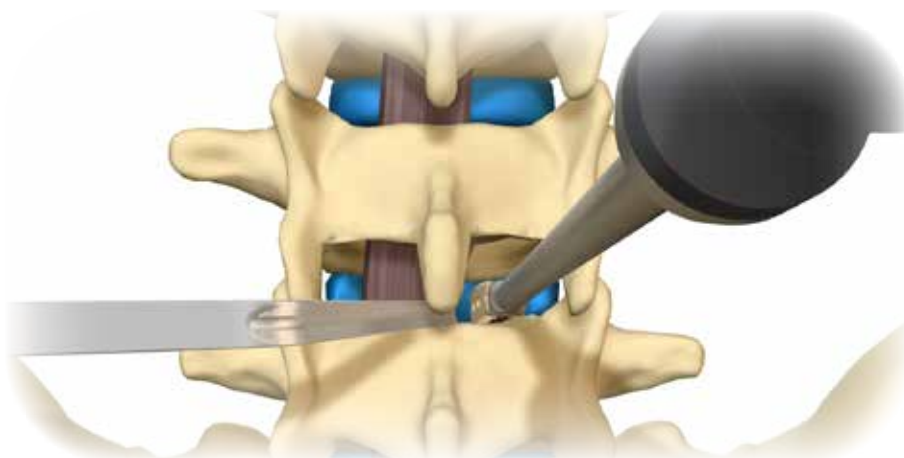


An X-ray check is performed and the cage is disconnected.



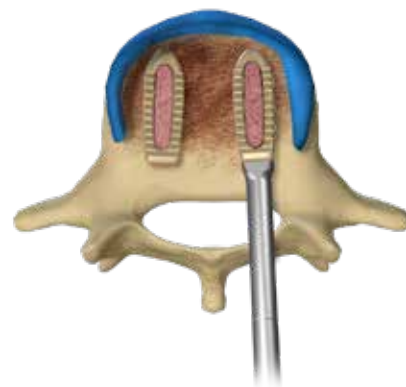
8 | INSERTION OF THE SECOND CAGE

The opposite side is prepared as described in steps 2 to 6 and the second cage is inserted similarly.



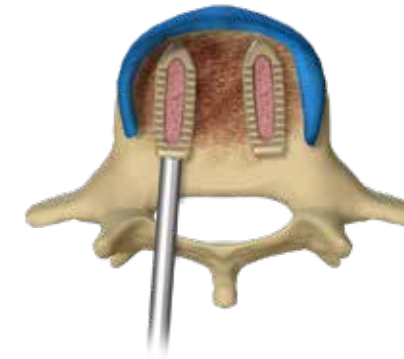
RECOMMENDATION :

Prior to insertion of the second cage, graft can be inserted between the two implants.



9 | FINAL POSITIONING OF THE CAGES

- If needed, the **PLIF cage impactor** may be used to adjust the position and the depth of the cage within the intervertebral space.

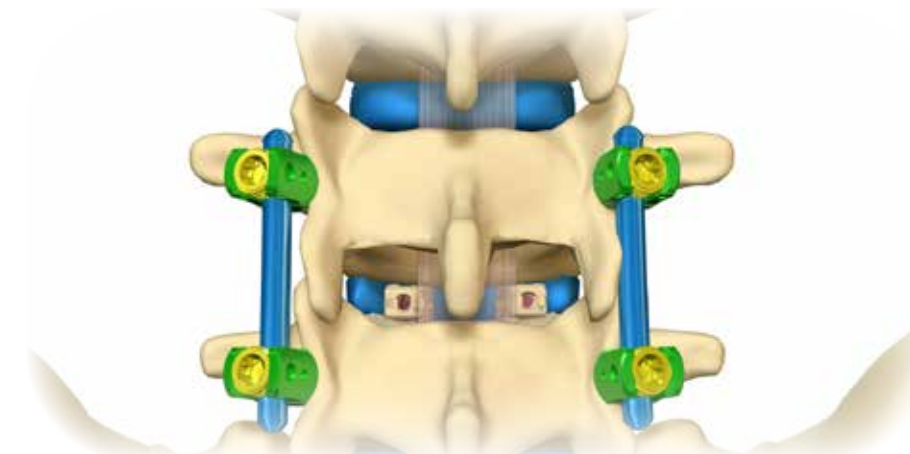


- Distraction is released and a final X-ray check is performed.



10 | SUPPLEMENTARY POSTERIOR FIXATION

Posterior fixation is required to place the treated segment under compression and to enhance the stability of the cages.

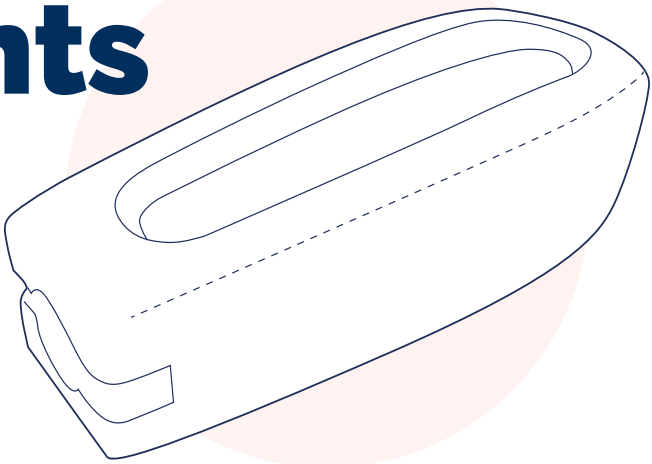


PLIF CAGE IMPACTOR

04716001



Instruments



Idys-PTLIF Instruments



IDYS-LIF INSTRUMENT TRAYS

04990030 LIF Base
04990047 LIF Base Lid



IDYS-PLIF/PTLIF INSTRUMENTS TRAYS

04990040 PLIF/PTLIF
Instruments Base
04990042 PLIF/PTLIF
Instruments Base Lid



OSTEOTOME

04705010



NERVE ROOT RETRACTOR

04781006



DISC RONGEUR

06708001 Right



CURETTE

04704015



CUP CURETTE

04704005 5mm



PLIF CAGE HOLDER

04715002



SLAP HAMMER

04762000



PTLIF FILLING SUPPORT

04717004



PTLIF GRAFT IMPACTOR

04761002 L28mm



PTLIF GRAFT IMPACTOR

04761003 L32mm



PLIF CAGE IMPACTOR

04716001



CYLINDRICAL HANDLE

99782003



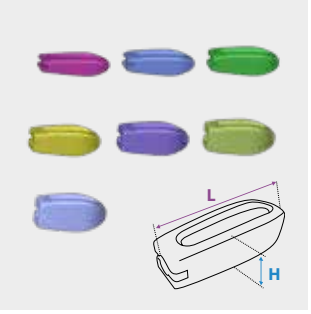
T-HANDLE

99781001



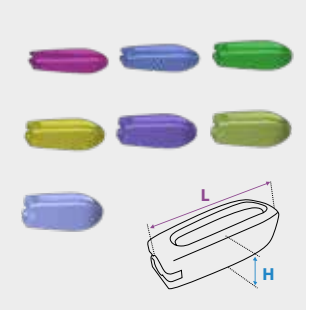
SHAVERS

04707007	H07mm
04707008	H08mm
04707009	H09mm
04707010	H10mm
04707011	H11mm
04707012	H12mm
04707013	H13mm
04707014	H14mm



PTLIF TRIALS - L28

04714408	H08mm
04714409	H09mm
04714410	H10mm
04714411	H11mm
04714412	H12mm
04714413	H13mm
04714414	H14mm

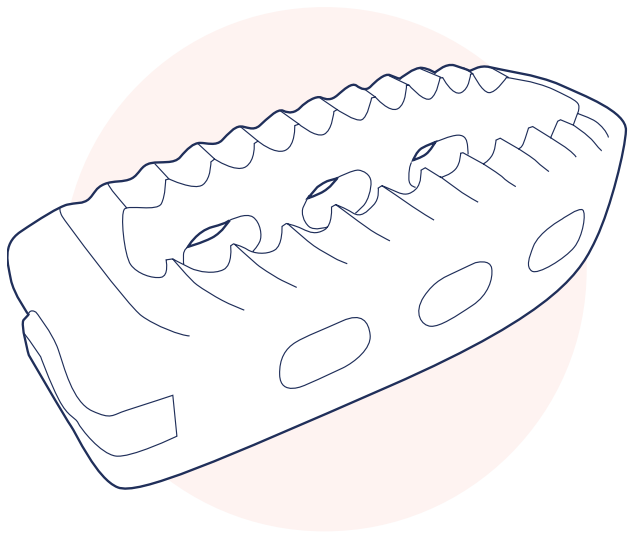


PTLIF TRIALS - L32

04714508	H08mm
04714509	H09mm
04714510	H10mm
04714511	H11mm
04714512	H12mm
04714513	H13mm
04714514	H14mm

Sterile Implants

Product availability may vary upon markets. Please contact your Clariance representative.

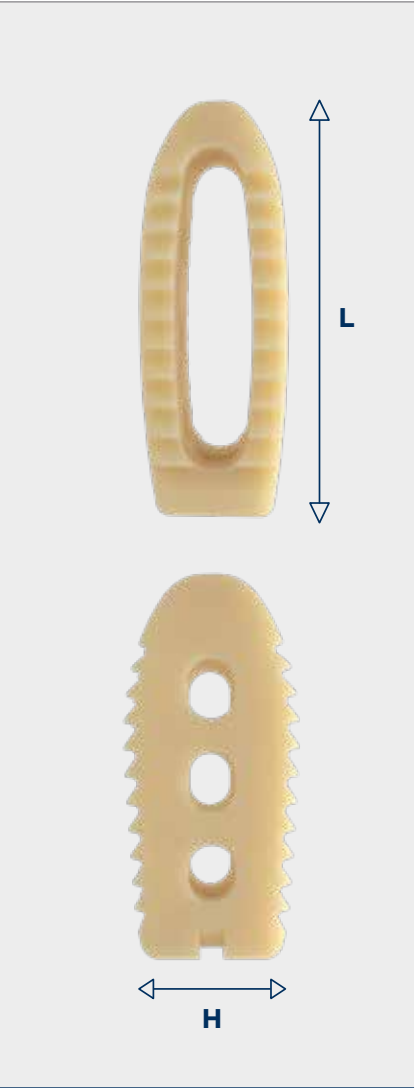


PTLIF - L28MM

	H08mm	H09mm	H10mm	H11mm	H12mm
L28mm	04522808-S	04522809-S	04522810-S	04522811-S	04522812-S
	H13mm	H14mm	-	-	-
	04522813-S	04522814-S	-	-	-

PTLIF - L32MM

	H08mm	H09mm	H10mm	H11mm	H12mm
L32mm	04523208-S	04523209-S	04523210-S	04523211-S	04523212-S
	H13mm	H14mm	-	-	-
	04523213-S	04523214-S	-	-	-





Clariance, Inc.

2547 Farrington Street Dallas, TX 75207

T : +1 773-832-7554

F : +1 773-904-2348

contact@clariance-spine.us

Clariance SAS

18 Rue Robespierre

62217 Beaurains France

T : +33 (3) 21 16 12 15

F : +33 (3) 21 15 50 73

contact@clariance-spine.com

www.clariance-spine.com

Notified Body N°2460 - As some references are not covered by the CE marking, refer to the product label which bears the CE marking.