spacevision®

Posterior Lumbar Interbody Fusion

Surgical Technique

SpineVision®

Innovation that matters

spacevision™

Posterior Lumbar Interbody Fusion

Surgical Technique

English Version

Reference document: GPL1-ST_04GB

See package insert for labeling limitation

CE 0123

Intended use

The SpaceVision® PLIF (Posterior Lumbar Interbody Fusion) Cage is intended to be used as an internal spacer between the vertebral bodies of the lumbar spine (L2-S1), to correct and stabilize the lumbar spine.

The system is also intended to enhance the development of a solid fusion and has to be associated with a posterior fixation system (e.g: UNI-Thread™, X-PLUS™, U.L.I.S.™ or Lumis™ SpineVision systems).
Among several approaches, SpaceVision® PLIF is specifically adapted to bilateral posterior midline approach.

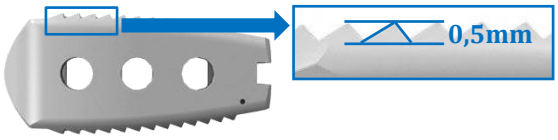
The SpaceVision® PLIF Set consists of cages of varying heights, lengths and lordosis, instruments for lumbar disc preparation and specific instrumentation for handling, positioning and removal of the cages. All cages are machined from implant grade PEEK (Polyetheretherketone, compliant with ASTM-F2026) and supplemental tantalum markers are embedded in the implants to enable the fluoroscopic control of their positioning

Presentation of Implants

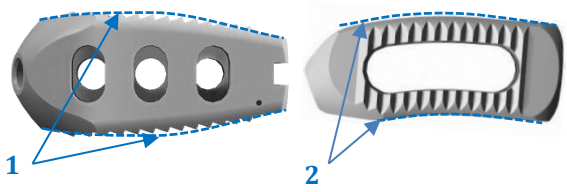
Made of PEEK, SpaceVision® PLIF cage material is close to bone module of elasticity and so have an optimal mechanical resistance and enhance bone fusion.

PLIF Cages have been designed to allow:

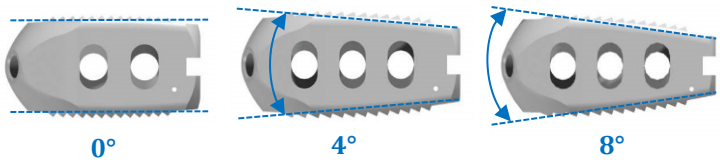
- Good primary stability thanks to anti-back-out teeth (height D = 0.5mm)



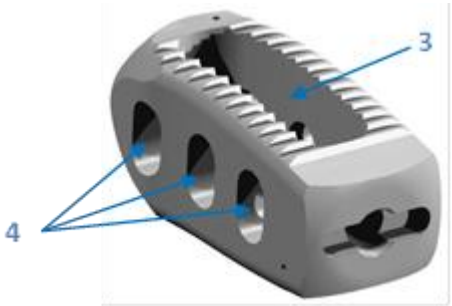
- An easy insertion thanks to their:
  - Convex superior and inferior surfaces to fit vertebral endplates and ovoid shape [**1**]
  - Cage slightly curved in the horizontal plane to fit vertebral body shape [**2**]



- Sagittal balance restoration with wedge shape cages to restore lordosis (0°, 4° and 8° lordosis)

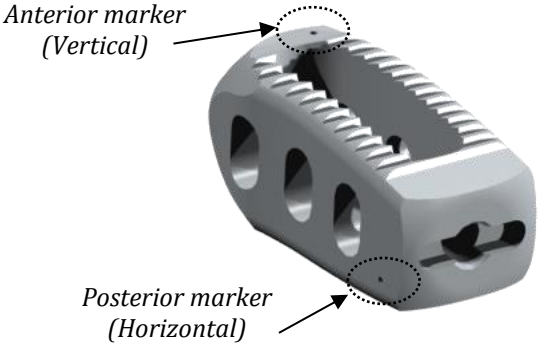


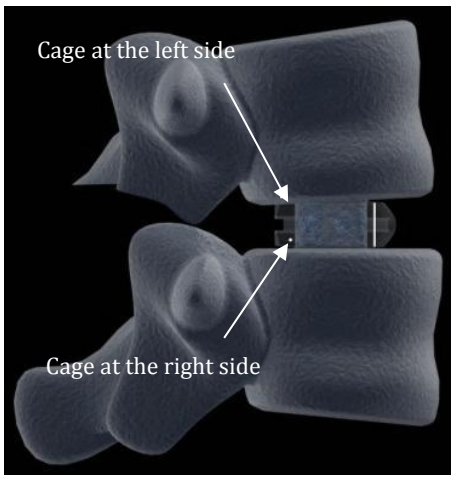
- Good fusion
  - Between graft and endplates in comparison to cage surface [**3**]
  - Lateral windows to enhance lateral bony fusion [**4**]



- Easy radiographic check:
  - 1 Tantalum vertical marker on the anterior wall,
  - 1 horizontal marker on the posterior wall,

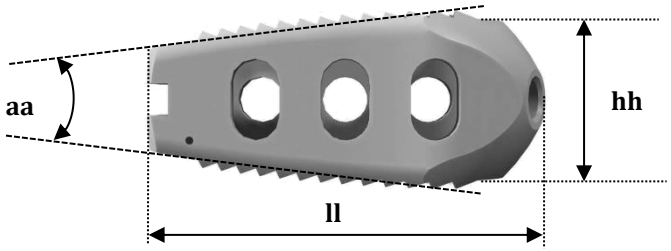
enabling a good positioning of both left and right SpaceVision® PLIF cages.





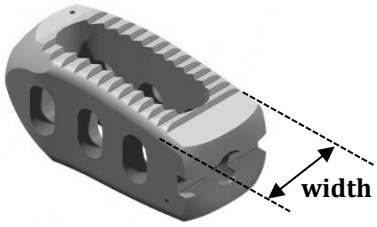
Range

Cage reference is: PL1-C**hh**-**ll**-**aa** where **hh** is the cage height in mm (without teeth), **ll** the cage length in mm and **aa** the angulation.



SpaceVision® PLIF cages widths depend on the cages height.

For instance, PL1-C**09-25-08** corresponds to a SpaceVision® PLIF cage whose height is **9mm**, length is **25mm** and angulation is **8°**.



PL1-Chh-ll-aa

0° lordosis		II		
ww	hh	21	25	29
8	07	PL1-C07-21-00	*PL1-C07-25-00*	
9	08	PL1-C08-21-00	PL1-C08-25-00	*PL1-C08-29-00*
10	09	PL1-C09-21-00	PL1-C09-25-00	*PL1-C09-29-00*
10	10	PL1-C10-21-00	*PL1-C10-25-00*	*PL1-C10-29-00*
10	11	*PL1-C11-21-00*	*PL1-C11-25-00*	*PL1-C11-29-00*
11	12	*PL1-C12-21-00*	*PL1-C12-25-00*	*PL1-C12-29-00*
11	13	*PL1-C13-21-00*	*PL1-C13-25-00*	*PL1-C13-29-00*
12	14		*PL1-C14-25-00*	*PL1-C14-29-00*
12	15		*PL1-C15-25-00*	*PL1-C15-29-00*
12	16		*PL1-C16-25-00*	*PL1-C16-29-00*

4° lordosis		II		
ww	hh	21	25	29
8	07			
9	08	*PL1-C08-21-04*	PL1-C08-25-04	
10	09	*PL1-C09-21-04*	PL1-C09-25-04	*PL1-C09-29-04*
10	10	*PL1-C10-21-04*	PL1-C10-25-04	*PL1-C10-29-04*
10	11	*PL1-C11-21-04*	PL1-C11-25-04	*PL1-C11-29-04*
11	12	*PL1-C12-21-04*	PL1-C12-25-04	*PL1-C12-29-04*
11	13	*PL1-C13-21-04*	*PL1-C13-25-04*	*PL1-C13-29-04*
12	14		*PL1-C14-25-04*	*PL1-C14-29-04*
12	15		*PL1-C15-25-04*	*PL1-C15-29-04*
12	16		*PL1-C16-25-04*	*PL1-C16-29-04*

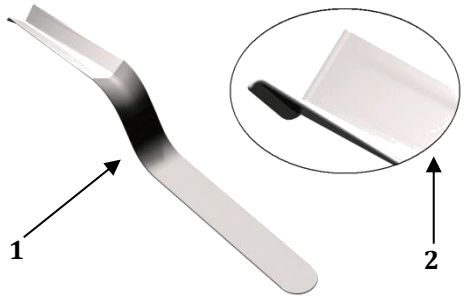
8° lordosis		II		
ww	hh	21	25	29
8	07			
9	08			
10	09	*PL1-C09-21-08*	*PL1-C09-25-08*	
10	10	*PL1-C10-21-08*	PL1-C10-25-08	*PL1-C10-29-08*
10	11	*PL1-C11-21-08*	PL1-C11-25-08	*PL1-C11-29-08*
11	12	*PL1-C12-21-08*	PL1-C12-25-08	*PL1-C12-29-08*
11	13	*PL1-C13-21-08*	*PL1-C13-25-08*	*PL1-C13-29-08*
12	14		*PL1-C14-25-08*	*PL1-C14-29-08*
12	15		*PL1-C15-25-08*	*PL1-C15-29-08*
12	16		*PL1-C16-25-08*	*PL1-C16-29-08*

References written in italic are on demand references

Presentation of Instruments

Dura Retractors (PL1-A001-xx)

Dura retractors (PL1-A001-xx) are useful to protect the Dura and the nerve roots during the discectomy.



They have an ergonomic bend [**1**] and a V-shaped protector [**2**].

Two different Dura retractors are available depending on the patient anatomy:

- PL1-001-06
- PL1-001-08.

6 or 8mm

Note: Discectomy is performed by using a combination of standard instruments which are not provided in the SpaceVision® PLIF set.

Distraction Instruments (PL1-A002-HH)

Spreaders (PL1-A002-HH) are used to perform gradual interbody distraction.
They must be assembled with the T handle (PL1-A011) and are available in different sizes to fit patient's anatomy.

The 10 sizes of Spreaders (from 7mm to 16mm) are colour coded :

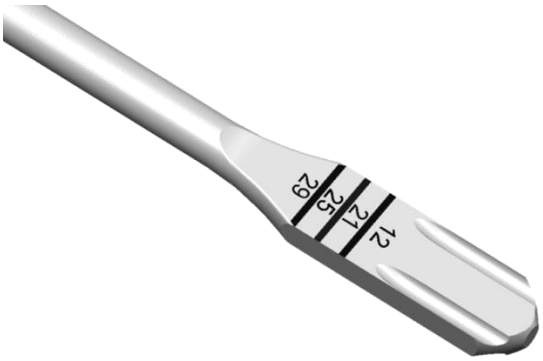
Size	Colour	Reference
7mm	**Magenta**	**PL1-A002-07**
8mm	**Yellow**	**PL1-A002-08**
9mm	**Blue**	**PL1-A002-09**
10mm	**Green**	**PL1-A002-10**
11mm	**Brown**	**PL1-A002-11**
12mm	**Orange**	**PL1-A002-12**
13mm	*Purple*	*PL1-A002-13*
14mm	*Grey*	*PL1-A002-14*
15mm	*Light green*	*PL1-A002-15*
16mm	*Light blue*	*PL1-A002-16*

Note: Only bold references are provided in standard set composition. Italic references are provided solely on demand.

Endplates Preparation Instruments

REAMERS (PL1-A003-HH OR PL1-A015-HH)

The Reamers are mounted on the T-Handle (PL1-A011) and have the same colour code as the spreaders.



Reamers (PL1-A003-HH)

Reamers are available in the following sizes:

Size	Colour	Reamer
7mm	Magenta	**PL1-A003-07**
8mm	Yellow	**PL1-A003-08**
9mm	Blue	**PL1-A003-09**
10mm	Green	**PL1-A003-10**
11mm	Brown	**PL1-A003-11**
12mm	Orange	**PL1-A003-12**
13mm	*Purple*	*PL1-A003-13*
14mm	*Grey*	*PL1-A003-14*
15mm	*Light green*	*PL1-A003-15*
16mm	*Light blue*	*PL1-A003-16*

Note: Only bold references are provided in standard set composition. Italic references are provided solely on demand. Anatomical Reamers (PL1-A015-HH) are available on demand and are to be used with the same surgical technique as Reamers (PL1-A003-HH)

STANDARD PREPARATION INSTRUMENTS

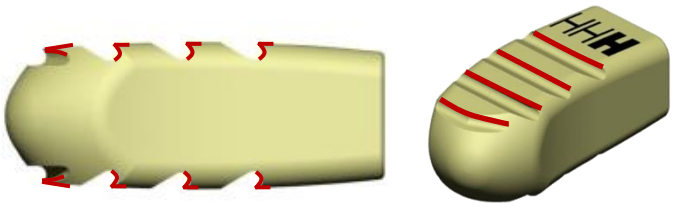
Curettes, rongeurs, scrapers and rasps can be provided for endplate preparation.

Implant Selection

TRIAL DEVICES (PL1-A012-HH)

Trial Devices (PL1-A012-HH) are available for each implant height (HH). The height of the Trial Device itself corresponds to the height of the cage without teeth.
Regardless of the height of the Trial Device, its length is 21mm and its sagittal angulation is 0°.

In addition, their cutting edges on the superior and inferior surfaces allow the endplates to be adapted to the shape of the cage.



PL1-A012-HH: Trial Devices

Ten (10) different heights of Trial Devices are available: 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16mm.

Implant holding and positioning

CAGE HOLDER (PL1-A008N1)

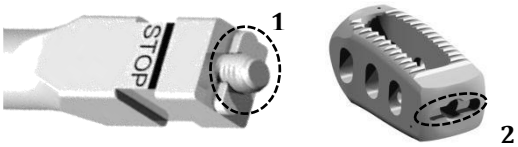
The cage holder (PL1-A008N1) has been designed to be used with either the SpaceVision® PLIF cages (PL1-Chh-ll-aa) or the Trial devices (PL1-A012-HH).

PL1-A008N1: Cage holder

To pick a SpaceVision® PLIF cage / Trial device:

1. Pull the inner part of the cage holder back

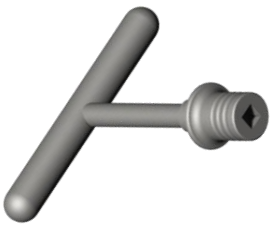
2. Insert the tip [**1**] of the inner part of the cage holder (PL1-A008N1) in the posterior window of the SpaceVision® PLIF cage (PL1-Chh-ll-aa) [**2**] or the Trial device (PL1-A012-HH). The 'STOP' mark prevents from any too deep insertion of the SpaceVision® PLIF cage when introduced into the intervertebral disc.



3. Screw the inner part of the cage holder with a three-fingers tight into the SpaceVision® PLIF cage or the Trial Device until it is firmly engaged in the implant/instrument.

PL1-Cxx-xx-xx mounted on PL1-A008N1

FINAL IMPACTOR (PL1-A005)



PL1-A011 : T-handle

PL1-A005 : Final Impactor

To adjust the depth of the SpaceVision® PLIF cages, use the Final impactor (PL1-A005).

Cage filling

PL1-A010 : Cage support

PL1-A009: Graft impactor

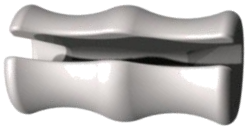
A cage support (PL1-A010) has been designed to maintain the SpaceVision® PLIF cage whilst the bone graft is inserted and impacted with the Graft impactor (PL1-A009).

PL1-A009:Detail of Graft impactor

Laser marks indicate which extremity of the Graft impactor (PL1-A009) must be used depending on the SpaceVision® PLIF cage length : 21 or 25mm.

Cage removal

If a SpaceVision® PLIF cage needs to be removed, use the sliding hammer (PL1-A007) over the cage holder (PL1-A008N1).

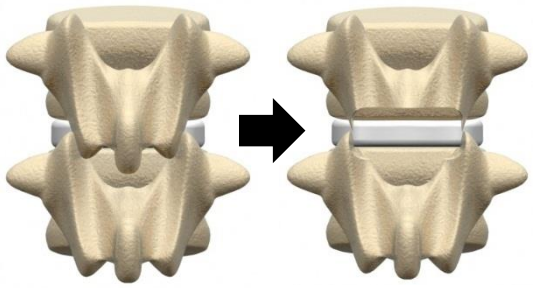


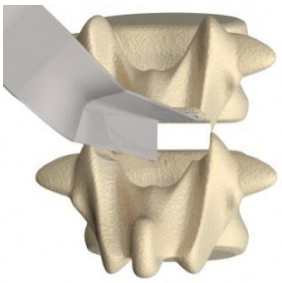
PL1-A007 : Sliding hammer

Surgical steps

Laminectomy/Decompression and Discectomy

A partial laminectomy with a hemi laminectomy and partial facetectomy is performed to expose the Dura and the intervertebral disc.



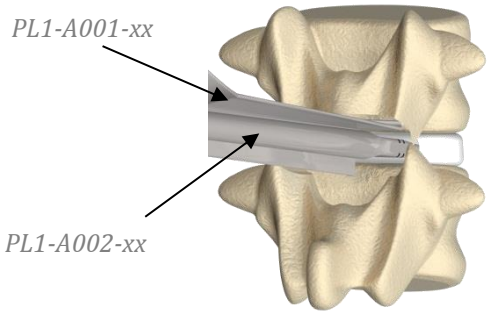


While protecting the dura and the nerve roots above with the Dura Retractor (PL1-A001-06 / PL1-A001-08), the discectomy is performed using a combination of standard instruments (not provided in the SpaceVision® PLIF cage system).

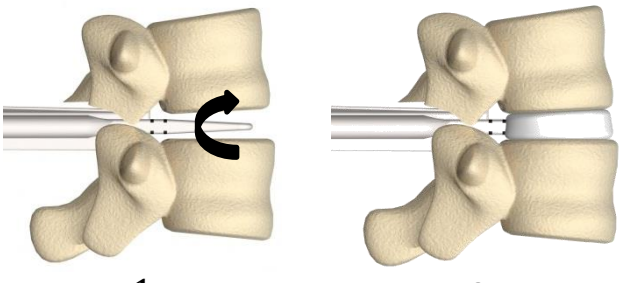
Distraction

Interbody distraction is made gradually, using the Spreader (PL1-A002-HH) assembled with the T-handle (PL1-A011) to restore the height of interbody space.

Dura retractors (PL1-A001-xx) can be used to protect the Dura and the nerve roots during the distraction using the spreaders (PL1-A002-HH).



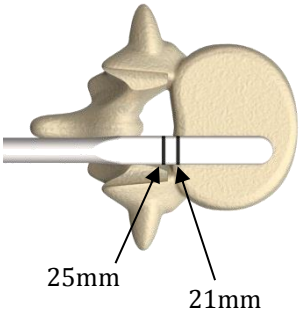
Distraction starts with the smallest spreader (7 mm) which is inserted flat into the disc space [**1**] and then rotated by 90° [**2**].



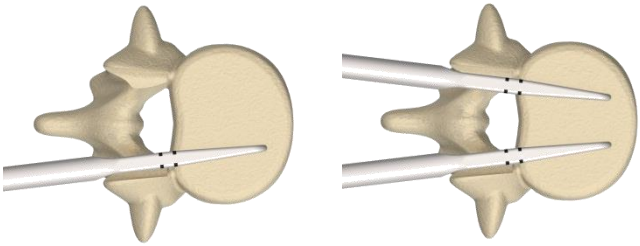
1 **2**

Check the spreader position using X-Ray and adjust its insertion depth if necessary.

The insertion depth can then be identified by the marks on the instrument and correspond to the cages length: 21 mm, 25 mm or 29mm.



Until the required disc height is restored, the Spreaders (PL1-A002-HH) are alternatively inserted into each side.
The disc interbody space is then increased progressively by 1 mm for each change of spreader.

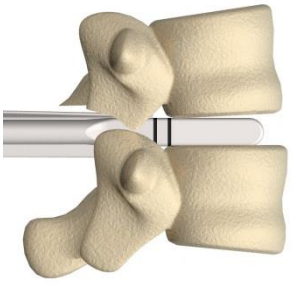


Endplates preparation

Remove osteophytes in the usual manner and prepare endplates.

PREPARATION USING TRIAL DEVICES (PL1-A012-HH)

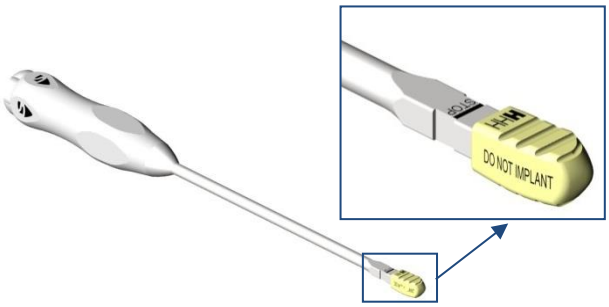
The last Spreader (PL1-A002-HH) used during the distraction, provides an estimation of the disc space height before placement of the Trial Device (PL1-A012-HH).

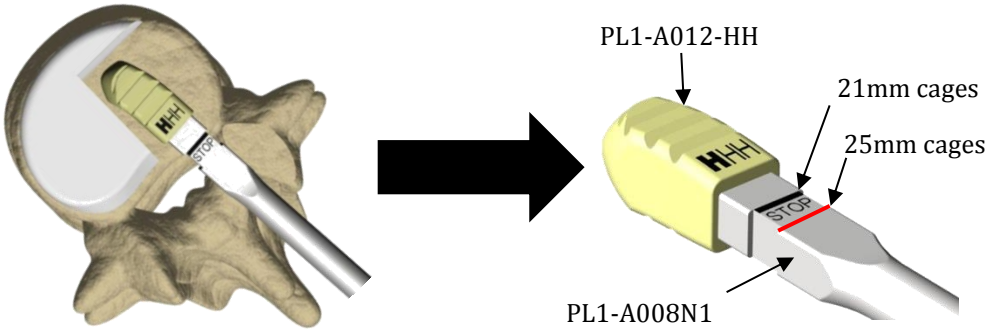


Example: If the last Spreader used was PL1-A002-**09**, then the first Trial Device to use is PL1-A012-**09**. If the disc space is too narrow, it is recommended to use an inferior size since it will allow easy handling of the instrument in the disc space.

Mount the Trial Device (PL1-A012-HH) on the Cage Holder (PL1-A008N1).

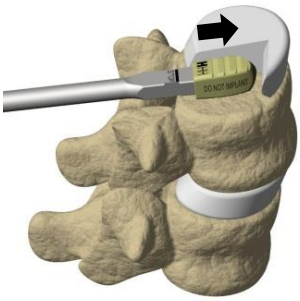
To prevent the Trial Device from being inserted too deeply, there is a "**STOP**" marked on the cage holder.





The depth of insertion of the Trial Device (PL1-A012-HH) mounted on the cage holder (PL1-A008N1) will give an estimation of the length of the SpaceVision® PLIF cage to implant.

If the Cage Holder (PL1-A008N1) can be inserted until the second rim, then a 25mm long SpaceVision® PLIF cage must be used. The 29mm long cages have to be kept for deeper intervertebral spaces.

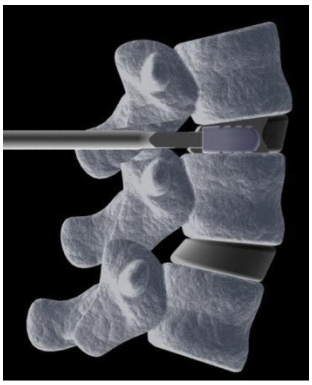


Impact the Trial Device (PL1-A012-HH) into the disc space with gentle taps on the Cage Holder (PL1-A008N1) to prepare endplates.

CAUTION: Trial Device (PL1-A012-HH) has cutting edges, use with caution.

Check the position of the Trial Device (PL1-A012-HH) using X-Ray and increase its size if necessary.

As for distraction, if the size of the Trial Device must be increased, it is recommended to proceed alternatively on both sides of the disc space.



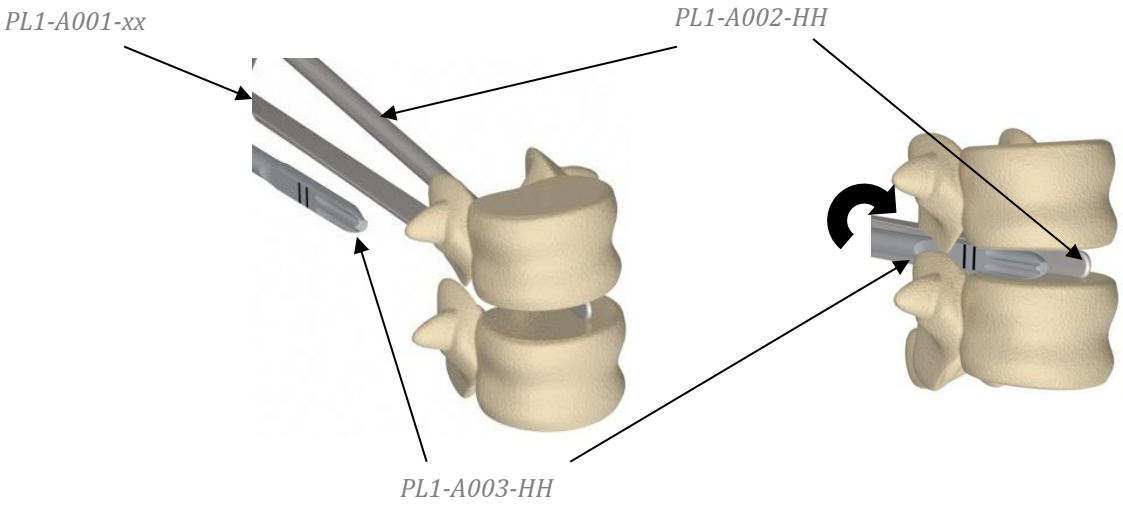
CAUTION:

- Do not remove more of the cortical endplate than necessary. Otherwise, it may increase the risk of implant subsidence.
- Ensure that no bone or disc material remains in the interbody space prior to cage insertion.

PREPARATION WITHOUT TRIAL DEVICES

- ***Using reamers (PL1-A003-HH)***

The reamer size (PL1-A003-HH) must be determined according to the last inserted spreader (PL1-A002-HH). The colour-code must be the same as the one of the last introduced spreader (PL1-A002-HH).



Sharp grooves of the Reamer (PL1-A002-HH) will allow remaining disc material removal by a rotation manoeuvre.
It is possible to protect the Dura and nerve roots at the same time using the Dura retractors (PL1-A001-xx).

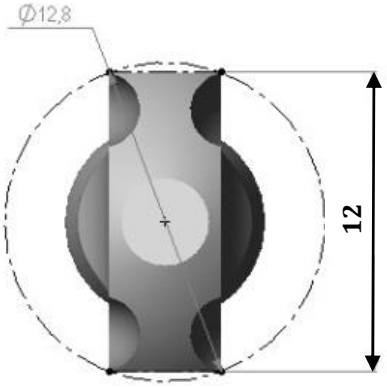
Standard preparation instruments can be used to finalize the superior and inferior endplates preparation by removing soft tissue and cartilaginous endplates coverings.

❖ ***Using Cylindrical reamers (PL1-A014-HH)***

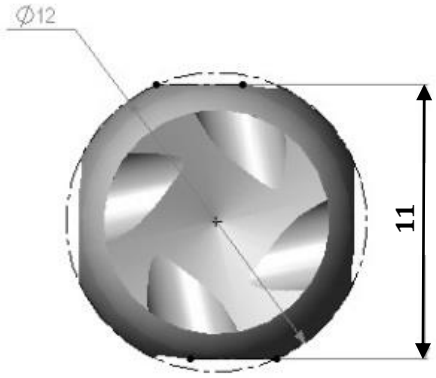
Reminder: Cylindrical reamers (PL1-A014-HH) are not part of a standard SpaceVision® PLIF kit and are provided solely ON DEMAND.

The reamer size (PL1-A014-HH) must be determined according to the last inserted spreader (PL1-A002-HH) and considering the disc material to remove.

Note: The Cylindrical Reamer (PL1-A014-HH) corresponding to the height of the last spreader (PL1-A002-HH) used does not have the same colour-code because the height might not correspond (see below).

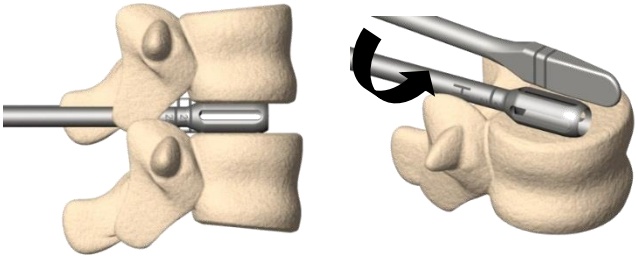


PL1-A003-12 ➔ 12mm height



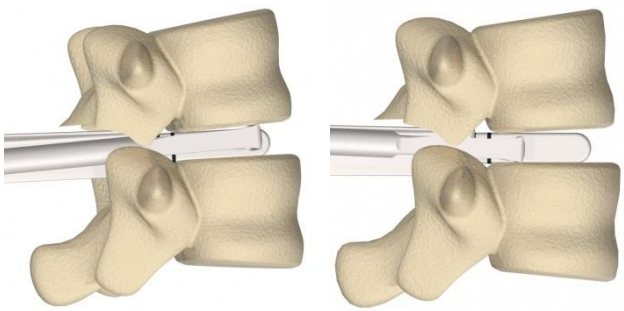
PL1-A014-12 ➔ 11mm height

The Cylindrical Reamer (PL1-A014-HH) must be rotated clockwise into the intervertebral space to remove remaining material with its sharp grooves.



❖ ***Scraping of endplates***

Small or Medium scrapers (PL1-A004-xx) are used to finalize the superior and inferior endplates preparation by removing soft tissue and cartilaginous endplates coverings.



CAUTION:

- Do not remove more of the cortical endplate than necessary. Otherwise, it may increase the risk of implant subsidence.
- Ensure that no bone or disc material remains in the interbody space prior to cage insertion.

Cage size selection

The height of the cage has to be chosen as the size of the last reamer (PL1-A003-HH / PL1-A014-HH / PL1-A015-HH) or the Trial device (PL1-A012-HH) used to prepare the disc space.

The length of the cage: 21,25mm or 29mm will be determined according to the depth of insertion of the spreader or reamer.

Example:
The last reamer which was used is PL1-A003-10 and was inserted until the first mark (i.e.: 21mm), then a 10mm high and 21 mm long SpaceVision® PLIF cage should be chosen : PL1-C10-21-**aa** (its angulation '**aa**' will be chosen by the surgeon depending on the patient's anatomy).

CAUTION: Do not use a bigger or smaller SpaceVision® PLIF cage size than the one determined by the instruments since a larger cage may cause over-distraction and a smaller cage may migrate post operatively.

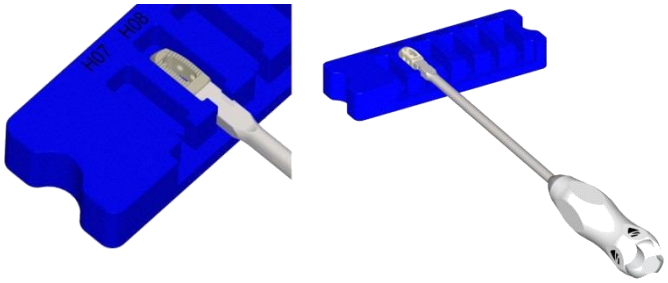
Cage Filling

Use the Cage holder (PL1-A008N1) to pick the appropriate SpaceVision® PLIF cage (PL1-Chh-ll-aa).

Note: Check if the implant has not been damaged during transportation or sterilization (e.g. deformation or damaged teeth).

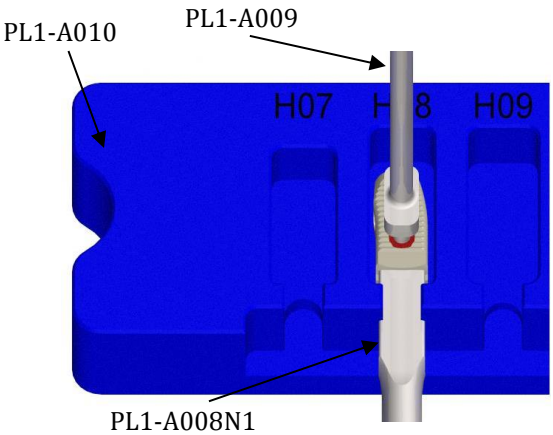
PL1-Chh-ll-aa mounted on PL1-A008N1

Position the assembly into the cage support (PL1-A010) and fill the cage with bone graft. Place the SpaceVision® PLIF cage in the appropriate holder (the cage size is printed above the appropriate opening).



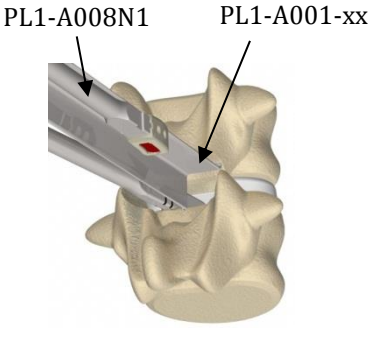
Fill the cage with bone graft or bone graft substitute using the appropriate side (21 or 25) of the Graft Impactor (PL1-A009) and compress the graft in the cage.

PL1-A009: Graft impactor

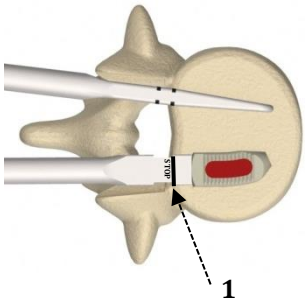


Cage Insertion

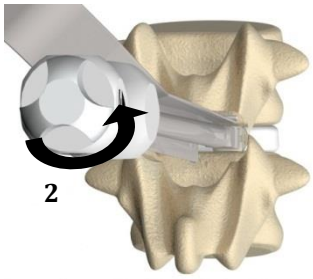
FIRST CAGE INSERTION



Impact the filled cage on one side into the disc space with gentle taps on the Cage holder (PL1-A008N1) while maintaining the height of the disc space with the appropriate spreader (PL1-A002-HH) on the other side. The Dura retractor (PL1-A001-xx) can also be used to protect the Dura and the nerve roots.

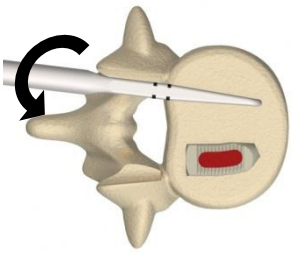


Regardless to the cage length, the cage holder (PL1-A008N1) must not be inserted farer than the 'STOP' mark [**1**].

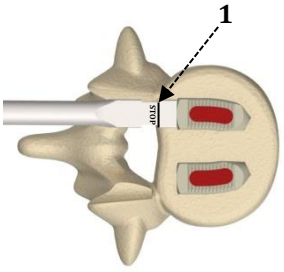


To remove the Cage holder (PL1-A008N1), unscrew the inner part [**2**].

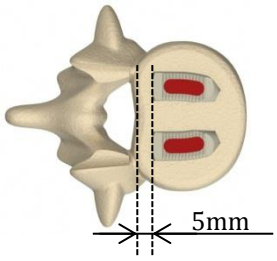
SECOND CAGE INSERTION



Remove the spreader (PL1-A002-HH) on the opposite side with a 90° rotation.



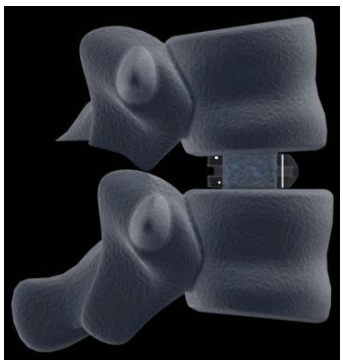
Impact the second filled cage into the disc space with gentle taps on the Cage holder (PL1-A008N1).
As for the first cage, whatever the cage length is, the cage holder (PL1-A008N1) must not be inserted further than the 'STOP' mark [**1**].

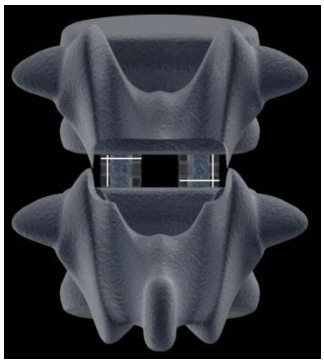


Check the position of the first impacted cage while the second cage is inserted.

It is recommended to have 5mm of safety distance between the posterior walls of the cages and the Dura.

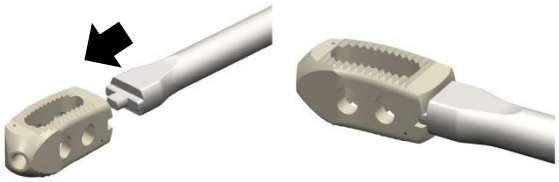
FINAL CHECKING





Check radiographically if the two SpaceVision® PLIF cages lie properly between the vertebral endplates. Tantalum markers will allow you to assess the position of the radiolucent SpaceVision® PLIF cages and to adjust their position if needed using the Final impactor (PL1-A005).

Final impactor (PL1-A005)
mounted on the T-handle (PL1-A011)



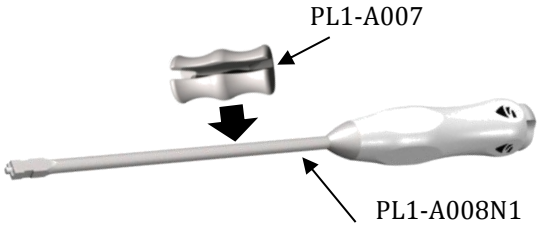
Light impaction under fluoroscopic control can be performed to adjust the depth position of the SpaceVision® PLIF cages.

SpaceVision® PLIF Cage Removal

In case removal of SpaceVision® PLIF cage is required, the Sliding hammer (PL1-A007) is used with the Cage holder (PL1-A008N1) to remove the cage while the use of spreaders (PL1-A002-HH) will facilitate the manoeuvre by opening the intervertebral space.

- Insert the cage holder (PL1-A008N1) into the SpaceVision® PLIFcage.
- Assemble the sliding hammer (PL1-A007) onto the cage holder.

The SpaceVision® PLIF cage can then be removed gently using the sliding hammer (PL1-A007).



Indications and Handling

Indications

The SpaceVision® PLIF (Posterior Lumbar Interbody Fusion) system is an intervertebral body fusion device indicated for use with autogenous bone graft in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two continuous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least 6 months of non-operative treatment prior to treatment with SpaceVision® PLIF system. These devices are to be filled with autogenous bone graft material. These devices can be implanted via posterior or transforaminal approaches. SpaceVision® PLIF system must be used in combination with supplemental internal spinal fixation which has been cleared by the FDA for use in the lumbar spine.

Contra-indications

This device is not intended for cervical spine use.
Contra-indications include, but are not limited to:

- infection, local to the operative site;
- signs of local inflammation;
- fever or leukocytosis;
- morbid obesity;
- pregnancy;
- pediatric cases, or patient still having general skeletal growth;
- spondylolisthesis unable to be reduced to Grade I;
- suspected or documented allergy or intolerance to composite materials;
- any case where the implant components selected for use would be too large or too small to achieve a successful result.
- any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- prior fusion at the level to be treated.
- any case not needing a bone graft or fusion;
- any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis;
- any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- mental illness;
- any patient unwilling to cooperate with postoperative instructions.

The contra-indications of these devices are similar to those of other spinal interbody systems. This spinal instrumentation is not designed, or intended, or sold for uses other than those indicated.

Packaging

Packages for each of the components should be intact upon receipt. Care should be taken not to damage the implants when opening the packaging. Damaged packages or products must not be used and should be returned to SpineVision®.

Cleaning and Sterilization

The SpaceVision® PLIF instruments are supplied clean but not sterile. They must be sterilized before use.
The SpaceVision® PLIF system consist of clean but not sterile implants which must be sterilized before use.
All packaging and labeling materials must be removed prior to sterilization. Decontamination and cleaning must be completed prior to sterilization. For details regarding the following sections, please refer to instructions for cleaning, sterilization, inspection and maintenance (lubrication) of SpineVision® medical devices provided with the sets.

For cleaning and decontamination of the non-sterile implants and instruments at the Healthcare facility:
It is recommended to use a neutral pH, enzymatic and alkaline (pH<11) cleaning agents solution and deionized or distilled warm (room temperature) water for soaking, cleaning and rinsing.
Disassemble necessary instruments. Articulated instruments must be opened.
Inspect each device and repeat the washing in the presence of any residual debris, paying close attention to threads, cannulas, hinges and hard to reach areas.
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices, and should not be used, except in the case of aluminium instruments used on high risk patients.
New requirements related to high risk patients for European audiences only**:** In the case of high risk patients**,** i.e. being suspected of contact with Non-Conventional Transmissible Agents (e.g. prions), decontamination should be performed according to requirements of the World Health Organization (WHO). In this case, SpineVision® instruments can be decontaminated with sodium hydroxide, with the strict exception of instruments made out of aluminium, where bleach should be used**.**

Lubrication specification:
SpineVision® recommends the lubrication of instruments with moving or articulating parts. The instruments must be lubricated after pre-disinfection/decontamination and before steam sterilization.

Sterilization: Prior to use, the SpaceVision® PLIF instruments and non-sterile implants should be steam sterilized according to the following parameters:

Method	Cycle	Temperature	Mini exposure time	Mini drying time
Steam	Pre-vacuum	134°C (273°F) **See note 1**	18 minutes	30 minutes
Steam	Pre-vacuum	132°C (270°F) **See note 2**	4 minutes	30 minutes

Validations were performed with dynamic-air-removal steam sterilization process.

Note 1: This sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).
Note 2: Remove all the silicon handles from the trays for this cycle and sterilize them separately in a double wrap.

Verification: The instruments and implants must be completely dried before use.
Devices must always be verified before use: any devices presenting signs of weakness or surface scratches must not be used. (Return to the manufacturer or distributor any implants showing deterioration)

IMPORTANT NOTE: As the PEEK glass transition temperature is 145°C (293°F), it is important not to use a higher sterilization temperature than 134°C (273°F). Otherwise the implant could suffer deformation.
To minimize the risk of deformation due to too high temperatures, do not place any load on top of the implants during cleaning and sterilization.

Precautions and Warnings

PREOPERATIVE

- The use of SpaceVision® PLIF is to be done using dedicated adequate instrumentation by a trained orthopedic surgeon or neurosurgeon familiar with these recommendations as well as with the operating techniques relating to these implants.
- The surgeon must be aware of not only the medical and surgical aspects of the implant, but also of the material limitations of PEEK-OPTIMA® implants. The patient must be instructed in the limitations of the implant, especially with regard to the weight bearing and other body stresses on the device before a solid fusion occurs. The patient must be instructed that non-compliance with postoperative instructions could lead to failure of the device. The patient must be instructed that device failure could lead to the need for additional surgery to remove failed components.
- Only patients that meet the criteria described in the indications should be selected and patients corresponding to the aforementioned contra-indications should not be selected. The following factors may be of importance when selecting patients for internal stabilization devices :
  - foreign body sensitivity
  - certain degenerative diseases
  - senility, mental illness, alcoholism, or drug abuse
  - obesity
  - patient's occupation or activity level
  - smoking
- Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE

- Correct handling of the implants is extremely important. The implants must be transported in a way not to incur any damage. The implants must not be scratched and must not collide during handling.
- Care must be taken when picking up the SpaceVision® PLIF implants, filling it with bone graft or bone substitute and inserting it between the vertebral bodies. Alterations may produce defects in surface finish and may become the focal point for eventual breakage of the implant or for decreased efficacy in withstanding post-operative migration (e.g. when teeth of implant are damaged).
- Correct selection of the implant size is extremely important. The chance of adequate stabilization is increased by the selection of the proper size of the implant regarding the anatomy and conditions of the patient. Proper selection of the implant can minimize, but not eliminate risks.
- The SpaceVision® PLIF components have been designed for use with this system. Do not use the SpaceVision® PLIF with any components not specifically recommended, or with any components from another manufacturer.
- The SpaceVision® PLIF cannot be inserted via an anterior approach.
- The SpaceVision® PLIF cannot be used in cervical and thoracic spine.
- The implant should be placed on the peripheral cortical bone of the endplates to minimize the risk of post-operative subsidence.
- Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage

POSTOPERATIVE

- Careful patient monitoring for the first two to four months following the operation is very important while the fusion mass matures and becomes able to share load with the implant. Adequately instruct the patient in the appropriate postoperative care. The patient must be instructed to reduce stress on the implants in order to avoid clinical problems that may accompany failed fixation. The patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be instructed in the limitations of the implant, and that physical activity and full weight bearing may cause premature failure of internal stabilization devices by migrating, loosening or fracture. The patient must be instructed that an implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on the implant. An active, debilitated, or demented patient who is unable to use orthotic weight bearing devices may be particularly at risk.
- No internal stabilization device can withstand activity levels equal to those withstood by normal healthy segment. No implant can be expected to withstand unsupported weight-bearing stress indefinitely.
- Implants may fail when subjected to the increased loading associated with delayed union or non-union. Internal stabilization devices are intended as load-sharing devices until normal healing occurs. If normal healing does not occur or is delayed, the device may break due to fatigue. Patients should be informed of the risks of implant failure.

CAUTION For us audiences only: FEDERAL LAWS (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Interconnection of the parts and connection to other devices

When used as an internal spacer between the vertebral bodies of the lumbar spine the SpaceVision® PLIF cages are not intended to have interconnection with any other implant.

During their implantation the SpaceVision® PLIF cages are connected with the following devices:

- Cage holder (PL1-A008N1), used to handle, insert or remove implants,
- Graft support (PL1-A010), used to hold cage during graft filling
- Graft impactor (PL1-A009), used to pack graft in the cage
- Final impactor (PL1-A005), used for repositioning the cage at the end of the procedure

SpineVision®

Innovation that matters

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