3D PRINTED TITANIUM TLIF CAGES

3D PRINTED INTERBODIES

# Hexanium® TLIF

# SURGICAL TECHNIQUE

SPINEVISION

INNOVATION THAT MATTERS

## SpineVision® Hexanium TLIF: Transforaminal Lumbar Intervertebral body Fusion device

The Hexanium TLIF (Transforaminal Lumbar Interbody Fusion) system is intended as intervertebral body fusion device for the lumbar spine (L2-S1). It is intended to be implanted via a transforaminal approach to give a primary stability of the anterior column (with or without restoring disc height) until fusion occurs.
Hexanium TLIF intervertebral body fusion device must be combined with an appropriate posterior lumbar fixation device, e.g. the SpineVision® UNI-Thread™, PLUS®, ULIS™ or LUMIS™.

### Description

The Hexanium TLIF system consists of a cage of various widths and heights, which can be inserted between two vertebral bodies of L2-S1 segment to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.
**For the Hexanium TLIF system, one cage** must be used per segment for fusion in order to stabilize the segment concerned.
The Hexanium TLIF must be filled with autogenous bone graft or a bone graft substitute to enhance the bone fusion. The choice of graft will always be the surgeon's responsibility.
All cages are manufactured from implant grade Titanium (Ti6Al4V compliant with ASTM F136).

### Indications

The Hexanium TLIF (Transforaminal Lumbar Interbody Fusion) system is 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 Hexanium TLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via transforaminal approach.
**Note for US audience only**: The Hexanium TLIF system must be used in combination with supplemental internal spinal fixation which has been cleared by the FDA for use in the lumbar spine.

### Contraindications

This device is not intended for thoracic or cervical spine use. Contraindications 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 contraindications 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.

### Potential Adverse Events

In addition to the risks associated with spinal surgery without instrumentation, the following potential adverse events can occur (non-exhaustive list):

- delayed union;
- non-union (or pseudoarthrosis);
- bone fracture or stress shielding at, above, or below the level of surgery, microfracture, resorption, or damage of any spinal bone (including pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site;
- retropulsed graft;
- loosening, or migration of implant, that may result in paralysis, neurological disorders or blood vessel erosion due to the proximity of the device;
- infection;
- hemorrhage of blood vessels and/or hematomas;
- discitis, arachnoiditis, and/or other types of inflammation;
- subsidence of implant into adjacent vertebral bodies resulting in loss of height and possible impingement of neural structures;
- loss of proper spinal curvature, correction, height, and/or reduction;
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus, disc disruption or degeneration above, or below the level of surgery;
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- foreign body reaction due to the presence of implants, such as a mass, auto-immune disease and/or impaired healing;
- cessation of any potential growth of the operated portion of the spine,
- deep venous thrombosis, thrombophlebitis;
- development of respiratory problems, e.g pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.;
- bone graft donor site complication;
- urinary retention or loss of bladder control or other types of urological system compromise;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- change in mental status;
- incapacity to resume the activities of normal everyday life;
- death.

**Note**: Some potential adverse events may require an additional surgical revision procedure.

### Storage and 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. For implant supplied in a sterile form, carefully check that the seal on the cardboard box is intact before you open the box. Damaged packages or products must not be used. If in doubt, please send them back to SpineVision®.

### Cleaning and sterilization

Hexanium TLIF implants are delivered sterile by exposure to a minimum dose of 25kGy of gamma radiation. They must be never resterilized.
Hexanium TLIF implants must only be used with the Hexanium TLIF ancillary equipment. Hexanium TLIF ancillary equipment are supplied not sterile. They must be sterilized before use.
All packaging and labeling materials must be removed prior to sterilization. Decontamination and cleaning must be performed before 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 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 of soaking, cleaning and rinsing.
Dismantle the 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 formaldehyde, may damage certain components and must not be used, except for aluminum instruments used on high-risk patients.

### Sterilization

Prior to use, Hexanium TLIF instruments should be steam sterilized according to the following parameters:

| Method | Steam | Steam |
|---|---|---|
| Cycle | Prevacuum | Prevacuum |
| Temperature | 134° (273°F) See note 1 | 132° (270°F) |
| Minimum exposure time | 18 minutes | 4 minutes |
| Minimum drying time | 30 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 cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

### Lubrication specifications

SpineVision® recommends the lubrication instruments with moving or articulating parts. The instruments must be lubricated after each pre-disinfction / decontaminationand before each steam sterilization.

### Verification

The 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)

### Warnings and precautions

**PREOPERATIVE**

The use of the Hexanium TLIF has 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 titanium 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 Hexanium TLIF implant, filling it with autogenous 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 Hexanium TLIF components have been designed for use with this system. Do not use the Hexanium TLIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium TLIF cannot be inserted via an anterior approach.
- The Hexanium TLIF 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.

**Magnetic Resonance (MR) Safety**: The Hexanium TLIF has not been evaluated for safety and compatibility in the MR environment. The Hexanium TLIF has not been tested for heating or migration in the MR environment.

### Product complaints

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identification, durability, reliability, safety, effectiveness and/or performance, should notify SpineVision®. Further, if any of the implanted Hexanium TLIF components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, SpineVision® should be notified immediately.
If any SpineVision® product may have caused or contributed to the death or serious injury of a patient, SpineVision® should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from SpineVision®.

### FOR ALL INFORMATION OR COMPLAINTS, CONTACT:


**In Europe**
SpineVision
10 Rue de la Renaissance
92160 Antony France Tél.:
+33 (0) 1 5333 2525 Fax:
+33 (0) 1 5333 2539

**In USA**
SpineVision Inc.
155 Federal Street, 6th Floor – Suite 604
Boston, MA 02110 - USA
Phone: +1 888 770 4118
Fax: +1 888 770 4119

**Email: corp.quality@spinevision.com**


| | |
|---|---|
|  | See package insert for labeling limitation |
|  | Do not use if package is damaged |
|  | Expiration date |
|  | Do not re-use |
|  | Keep dry |
|  | Keep away from sunlight |
|  | Sterilized using Irradiation |
|  | Federal law (US) restricts this device to sale by or on the order of a physician |
|  | Consult instructions for use |
|  | Batch code |
|  | Manufacturer |
|  | Catalog number |
|  | Do not re-sterilize |

CE 0123

**IMPORTANT INFORMATION CONCERNING HEXANIUM TLIF INSTRUMENTATION**

# SURGICAL STEPS

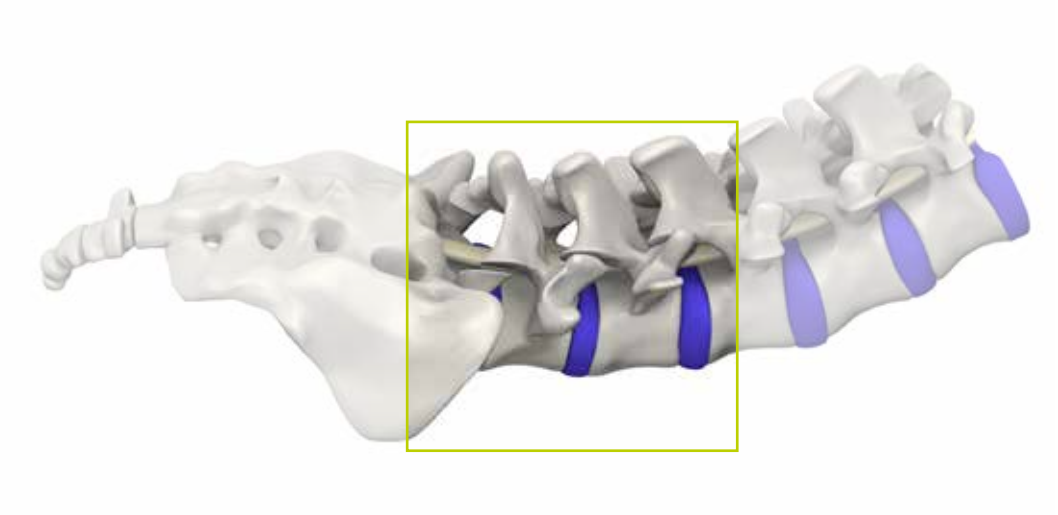


# REFERENCES

# PATIENT PREPARATION

The patient is placed on the OR (Operating Room) table using the standard position indicated for Transforaminal Lumbar Interbody Fusion (TLIF).

X-ray shall be used during the entire procedure: to confirm identification of the affected disc, to confirm good positioning of the trial device and the final position of the Hexanium TLIF cage.



# EXPOSURE

**Dura Retractor**
TL1-A011

**Nerve Root Retractor**
TL1-A012

Mark the affected segment after c-arm control. Perform the incision over the level on which the cage must be inserted.

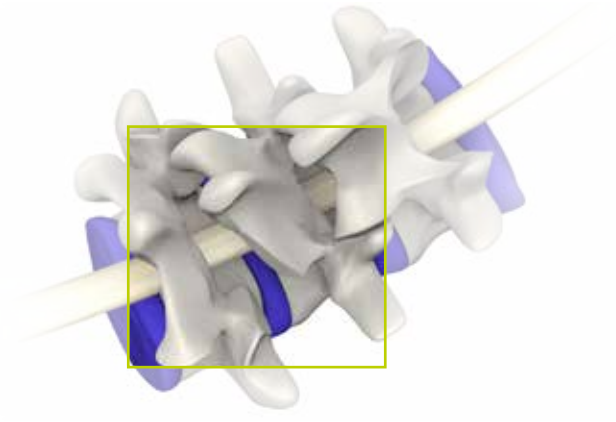
Expose the facets and the lateral parts of facet joints on the affected side.

Normally (part of) the inferior facet of the upper vertebra and (part of) the superior facet of the lower vertebra are removed on the affected side with an osteotome, burr or kerrison.

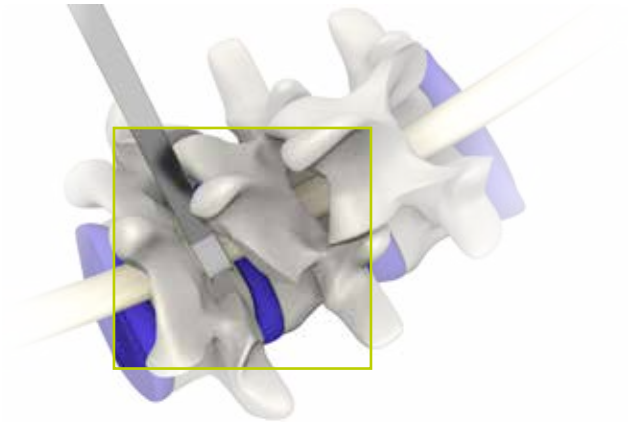
According to patient and indication the surgeon may choose a more lateral approach, leaving the facet joint intact.

Decompress the central spinal canal and the neural foramen if necessary.

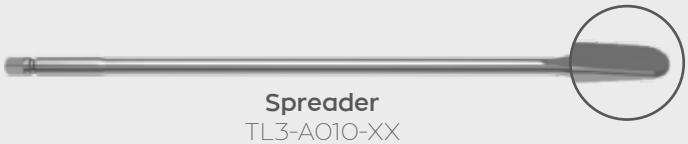
Create a window in the posterolateral portion of the annulus to access the intervertebral space.



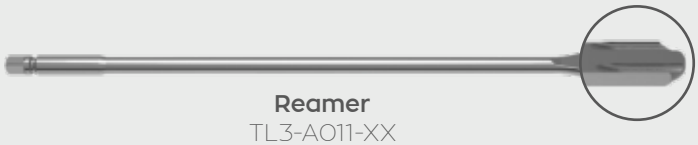
The dura and nerve root are protected using the **dura retractor** *TL1-A011* and/or the **nerve root retractor** *TL1-A012*.



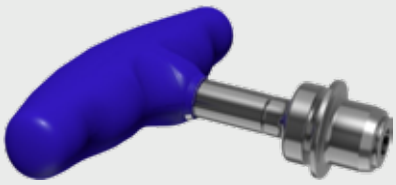
## ENDPLATE PREPARATION



**Spreader**
TL3-A010-XX



**Reamer**
TL3-A011-XX

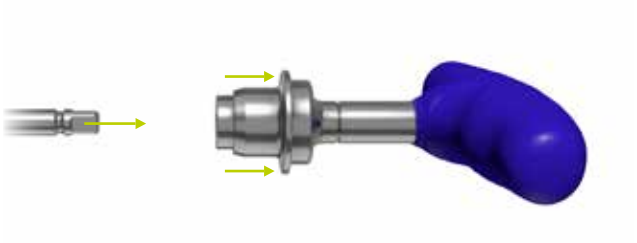


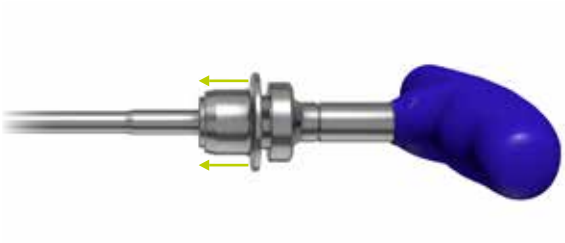
**Snap-On Cannulated Silicon T-Handle**
SD-ATSH1169214C5

To connect a **spreader** *TL3-A010-xx* or a **reamer** *TL3-A011-xx* to the **snap-on cannulated silicon T-Handle** *SD-ATSH1169214C5*, pull the ring of the silicon T-handle towards the silicon part.

While maintaining this position, insert the square tip of the **spreader** or **reamer** into the handle and release the ring of the handle to secure the connection between the two instruments.

***Always double check the connection of the two pieces.***





To ensure good primary stability of the implant after implantation, it is mandatory to adequately distract the intervertebral disc space.

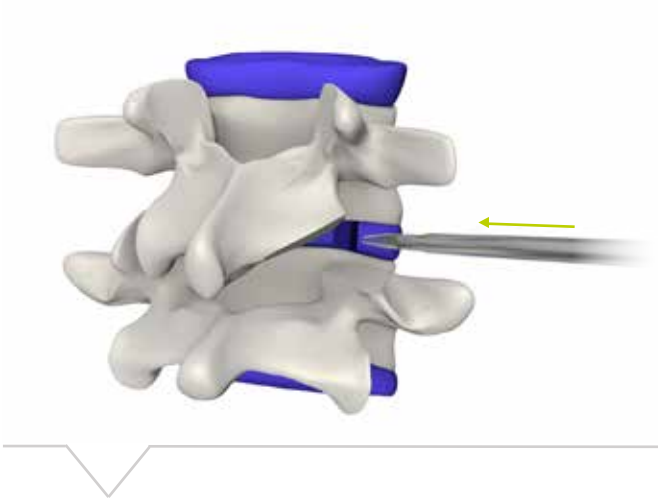
To perform this distraction, you can use the **spreaders** *TL3-A010-xx* 7 to 16.

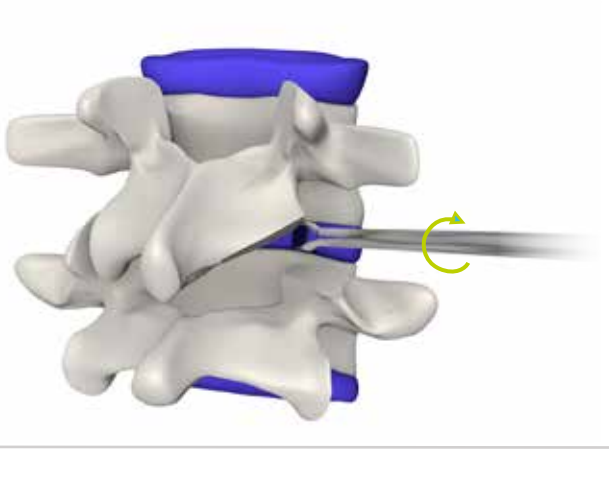
It is recommended to start with the smallest size **spreader** to avoid over distraction.

Apply the **spreader** parallel to the intervertebral space and carefully do a quarter turn clockwise to open up the disc space.

Proceed progressively with bigger **spreaders** step by step to reach the required distraction.

Use rongeurs and forceps to remove disc material thanks to the window created with the spreader. Leave only the anterior and lateral part of the annulus.



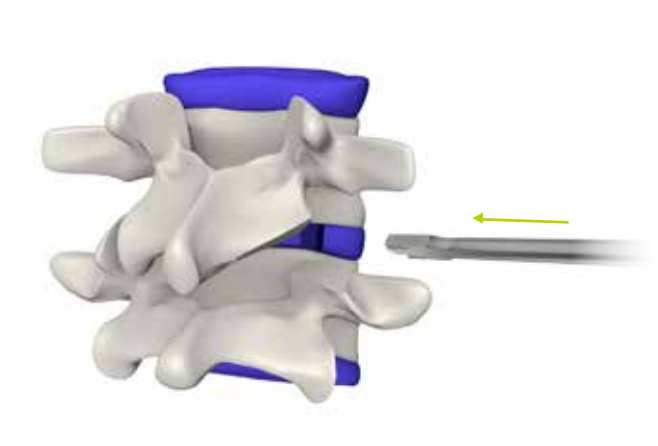


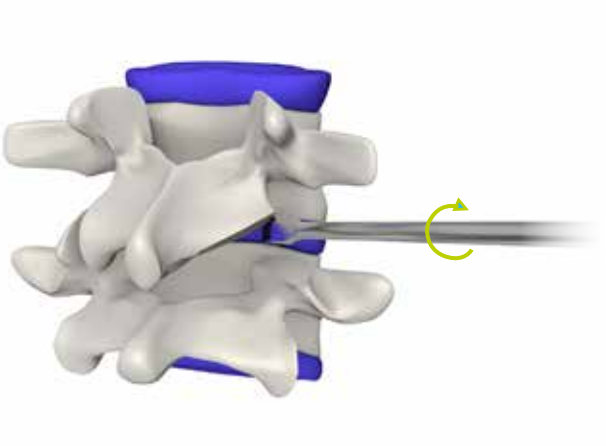
**Reamer** *TL3-A011-xx* can also be used to remove disc material and prepare the endplates.

Apply the **reamer** parallel to the intervertebral space and carefully do a quarter turn clockwise.

***It is recommended to preserve as much of the annulus as possible to provide additional support for the Hexanium TLIF implant.***

Use the **reamer** to ream out disc space material or for final removal of the disc space material and cartilaginous tissue.



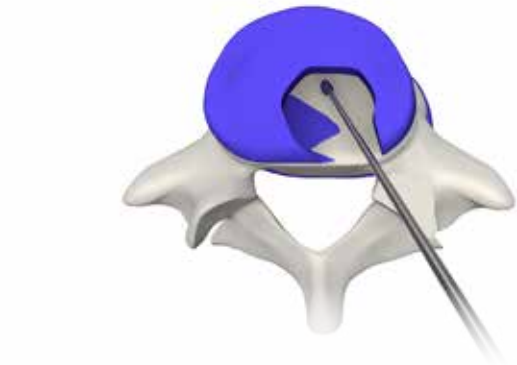


**Straight Rake Curette**
TL3-A033

**Ring Curette (Left or Right)**
TL3-A035-L/R

If needed, the **straight rake curette** *TL3-A033* is available to complete the endplate preparation. Insert the curette parallel to endplate and use it to remove disc space material.

In order to remove the tissue in the far lateral disc space, use the **ring curette (left or right)** *TL3-A035-L/R*.



Following the disc space material removal, it's recommended to perform a new distraction with the last used **spreader** *TL3-A010-xx*.

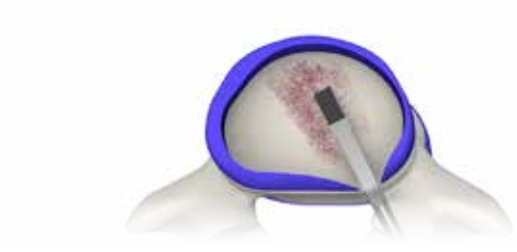
**Straight Convex Rasp**
TL3-A037-01

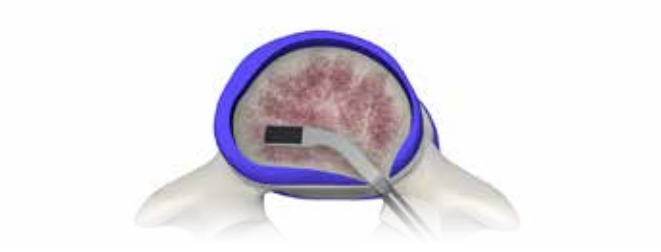
**Curved Convex Rasp**
TL3-A037-02

After completing the discectomy, use the **straight convex** or the **curved convex rasp** *TL3-A037-01* & *TL3-A037-02* to remove superficial cartilaginous tissue of the endplates.

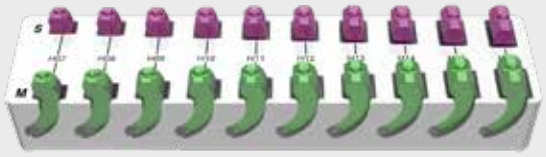
**Rasps** are used to reveal the bleeding bone and ensure good vascularization of the implant.

***Removing too much subchondral bone may weaken the vertebral endplate. A subsidence and a loss of segmental stability may happen if the entire endplate is removed.***





# IV IMPLANT'S SIZE ESTIMATION



**Ti TLIF Trials Rack** TL3-RACK
**Ti TLIF Cage Trial (Small)** TL3-A013-Sxx
**Ti TLIF Cage Trial (Medium)** TL3-A013-Mxx

- - OR - -

**Ti Straight TLIF Trials Rack** TL3-RACK1
**Ti Straight TLIF Cage Trial (Small)** TL3-A014-Sxx
**Ti Straight TLIF Cage Trial (Medium)** TL3-A014-Mxx

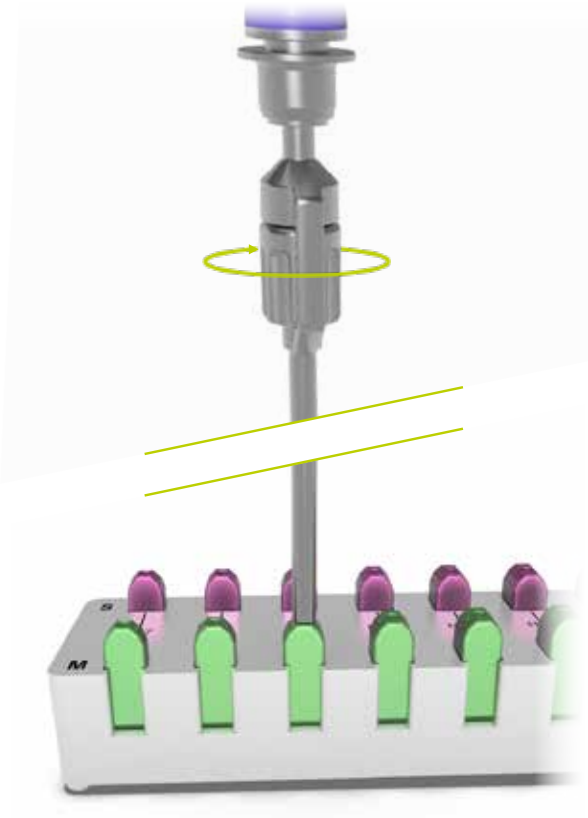
**Ti TLIF Cage & Trial Holder**
TL3-A012

**Cage Holder Handle**
TL3-A002

**Ti TLIF cage trials** *TL3-A013-Sxx* & *TL3-A013-Mxx* or *TL3-A014-Sxx* & *TL3-A014-Mxx* are available to match the footprint and height of each implant. Trials are separated in the **Ti TLIF trials rack** *TL3-RACK* or in the **Ti Straight TLIF trials rack** *TL3-RACK1* according to their footprint (« S » for Small footprint and « M » for Medium footprint).

To attach the **Ti TLIF cage trials** *TL3-A013-Sxx* & *TL3-A013-Mxx* or *TL3-A014-Sxx* & *TL3-A014-Mxx* to the **Ti TLIF cage & trial holder** *TL3-A012*, place the distal part of the **trial holder** completely perpendicular to the **trials rack** so the **trial holder** and the **cage trial** are vertically aligned.

Turn the **Ti TLIF cage & trial holder** *TL3-A012* knob clockwise to tighten the **cage trial** against the **trial holder**. Make sure that it is tightened enough and the connection is secure.



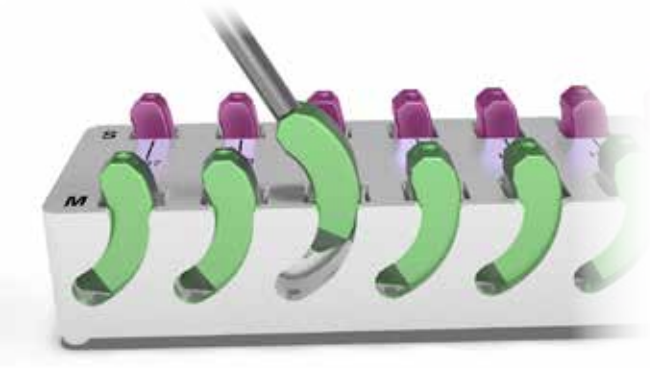
**! WARNING !**
***Recheck and make sure the cage trial is firmly connected to the Ti TLIF Cage & Trial Holder, which can be checked manually by applying pressure on the lateral side of the cage trial with the thumb to make sure that the trial is strongly connected.***

The proper alignment of the trial and the **Ti TLIF Cage & Trial Holder** *TL3-A012* ensure a straight introduction of the trial along the transforaminal route.

Insert the **Ti TLIF cage trial** *TL3-A013-Sxx* & *TL3-A013-Mxx* or *TL3-A014-Sxx* & *TL3-A013-Mxx* with gentle taps on the back of the **Ti TLIF cage holder handle** *TL3-A002* until it is just inside the intervertebral space.

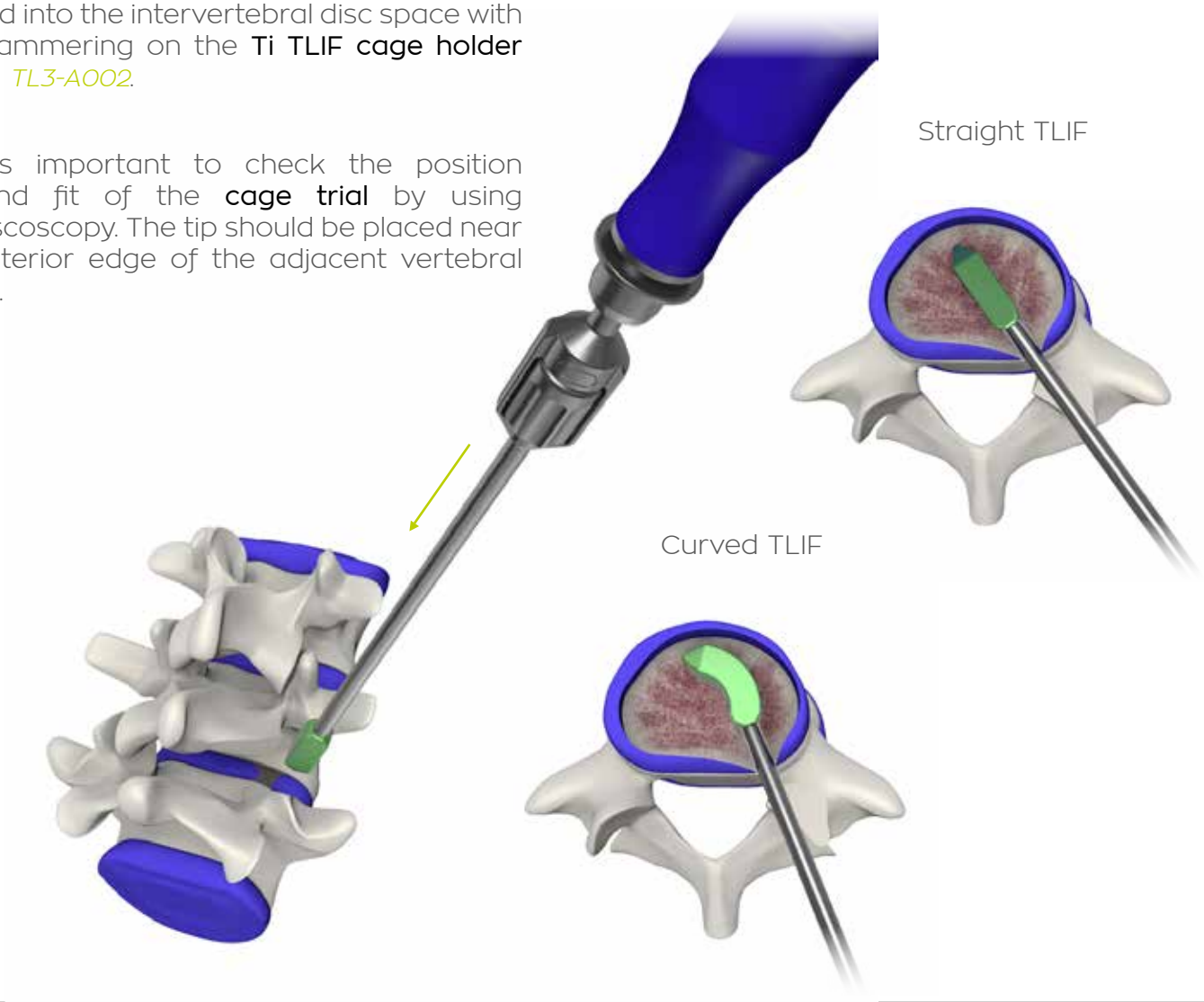
If necessary, the **cage trial** can be pushed forward into the intervertebral disc space with light hammering on the **Ti TLIF cage holder handle** *TL3-A002*.

It's important to check the position and fit of the **cage trial** by using fluoroscopy. The tip should be placed near the anterior edge of the adjacent vertebral bodies.



Remove the **cage trial** Implant after cage size determination.

**! WARNING !**
***The trial device must never be disconnected from the Ti TLIF cage & trial holder during this step (from insertion & positioning to removal from intervertebral space).***



# CAGE CONNECTION

**Ti TLIF Cage (Small or Medium)**
TL3-CSxx or TL3-CMxx

- - OR - -

**Ti Straight TLIF Cage (Small or Medium)**
TL3-SCSxx or TL3-SCMxx

**Cage Holder**
TL3-A001

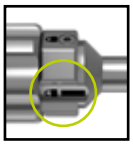
**Ti TLIF Cage & Trial Holder**
TL3-A012

**Cage Holder Handle**
TL3-A002

Select the implant which corresponds to the **Ti TLIF cage trial** used in the previous steps.

For the **straight TLIF cage**, attach the cage to the **Ti TLIF cage & trial holder** *TL3-A012* as described in the previous part.

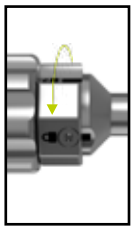
**1** For the **TLIF cage** place the jaws of the **cage holder** *TL3-A001* or the threaded part of the **Ti TLIF cage & trial holder** *TL3-A012* over the proximal end of the cage.



Be sure to be in the released position on the locking ring : laser mark on the cage holder aligned with the unlocked padlock of the ring.

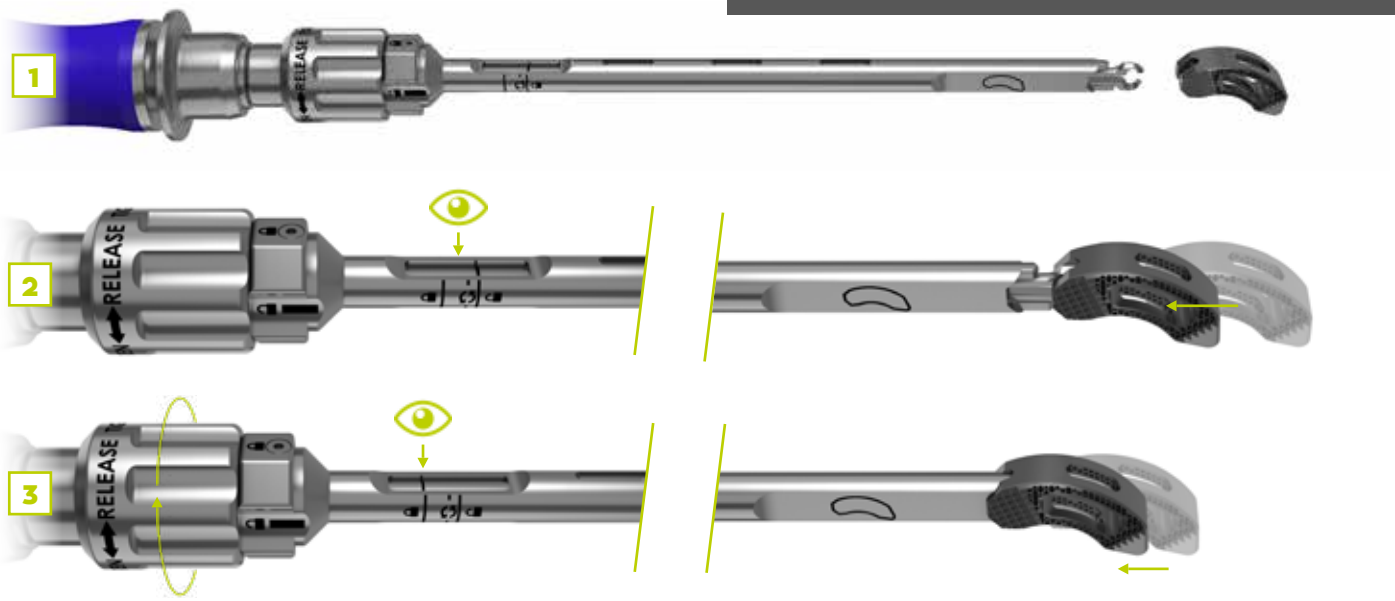
**2** Turn the **cage holder** knob clockwise to close the jaws. During this closing procedure the laser mark moves upwards towards the closed padlock.

**3** Continue to turn the knob until it is tightened and the laser mark of the shaft meets the closed padlock mark of the outer tube.

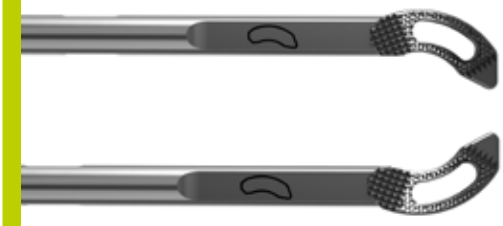


Once the cage is fully connected, secure the connection by turning the locking ring to align the laser mark of the shaft with the closed padlock. The cage is now secured.

***The Ti TLIF cage (TL3-CSxx or TL3-CMxx) cannot pivot or detach when the cage holder knob remains tightened.***



**! WARNING !**
*The cage must be tightened with the orientation of the laser marking. (longest teeth of the cage holder must be on the concave side before impaction.)*



# VI CAGE BONE GRAFT FILLING

**Ti TLIF Cage (Small or Medium)**
TL3-CSxx or TL3-CMxx

**Cage Support for Graft**
TL3-A020

**Ti Straight TLIF Cage (Small or Medium)**
TL3-SCSxx or TL3-SCMxx

**Ti Straight TLIF Cage Packing Block**
TL3-A023

- - OR - -

**Graft Compactor**
TL3-A021

**Ti Straight TLIF Graft Compactor**
TL3-A024

Place the implant in the correct slot on the **cage support for graft** *TL3-A020* or *TL3-A023* according to the footprint of the chosen cage : small or medium.

**1** Add some bone graft or bone substitute in the **Ti TLIF cage** bone graft chambers.

**2** To compact the graft into the implant, use the tip of the **graft compactor** *TL3-A021* or *TL3-A024* which corresponds to the proper footprint (small or medium).

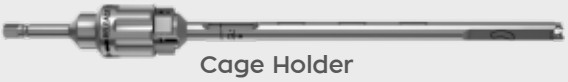
**3** Repeat this step until the desired bone graft volume have been compacted in the cage chamber.

# VII CAGE INSERTION

**Ti TLIF Cage (Small or Medium)**
TL3-CSxx or TL3-CMxx

- - OU - -

**Ti Straight TLIF Cage (Small or Medium)**
TL3-SCSxx or TL3-SCMxx



**Cage Holder**
TL3-A001

**Ti TLIF Cage & Trial Holder**
TL3-A012

**Cage Holder Handle**
TL3-A002

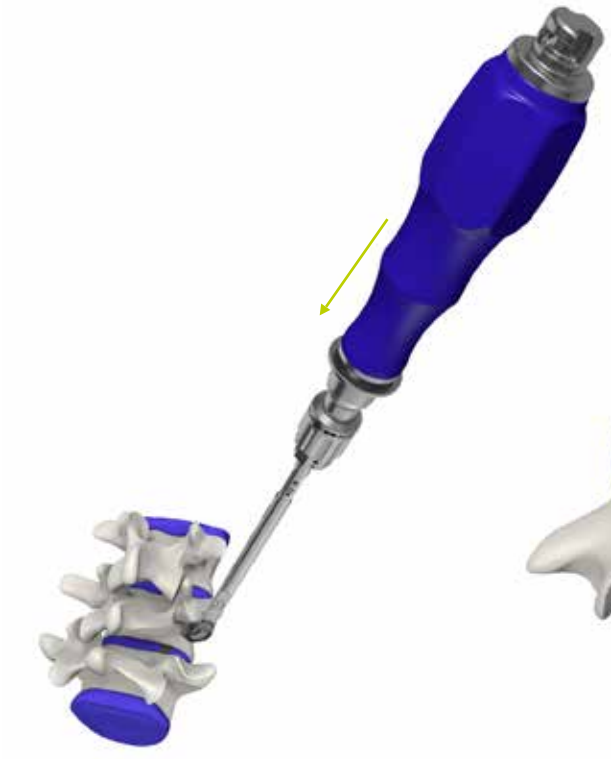
The **Ti TLIF cage** *TL3-CSxx* & *TL3-CMxx* or *TL3-SCSxx* & *TL3-SCMxx* should be oriented medially.

If necessary, apply controlled and light hammering on the **cage holder** *TL3-A001* or *TL3-A012* to insert the cage into the intervertebral space.

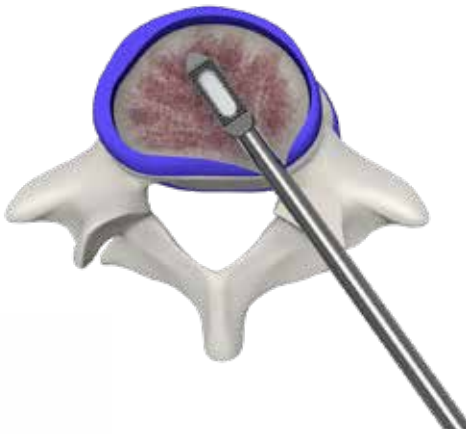
It is recommended to use fluoroscopy to confirm position of the cage.

The tip should be positioned near the anterior edge of the adjacent vertebral bodies.

**! WARNING !**
***Recheck and make sure the cage holder is firmly connected to the Ti TLIF Cage, which can be checked manually by applying pressure on the lateral side of the cage with the thumb to make sure that the cage is strongly connected.***



Straight TLIF



Curved TLIF

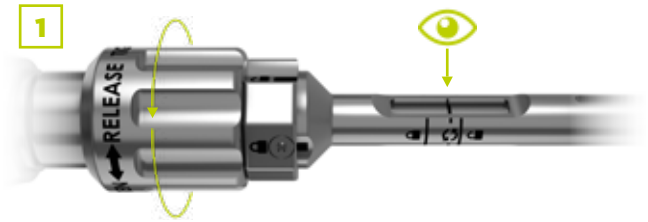
# VIII CAGE POSITIONING

**Ti TLIF Cage (Small or Medium)**
TL3-CSxx or TL3-CMxx

**Cage Holder**
TL3-A001

**Cage Holder Handle**
TL3-A002

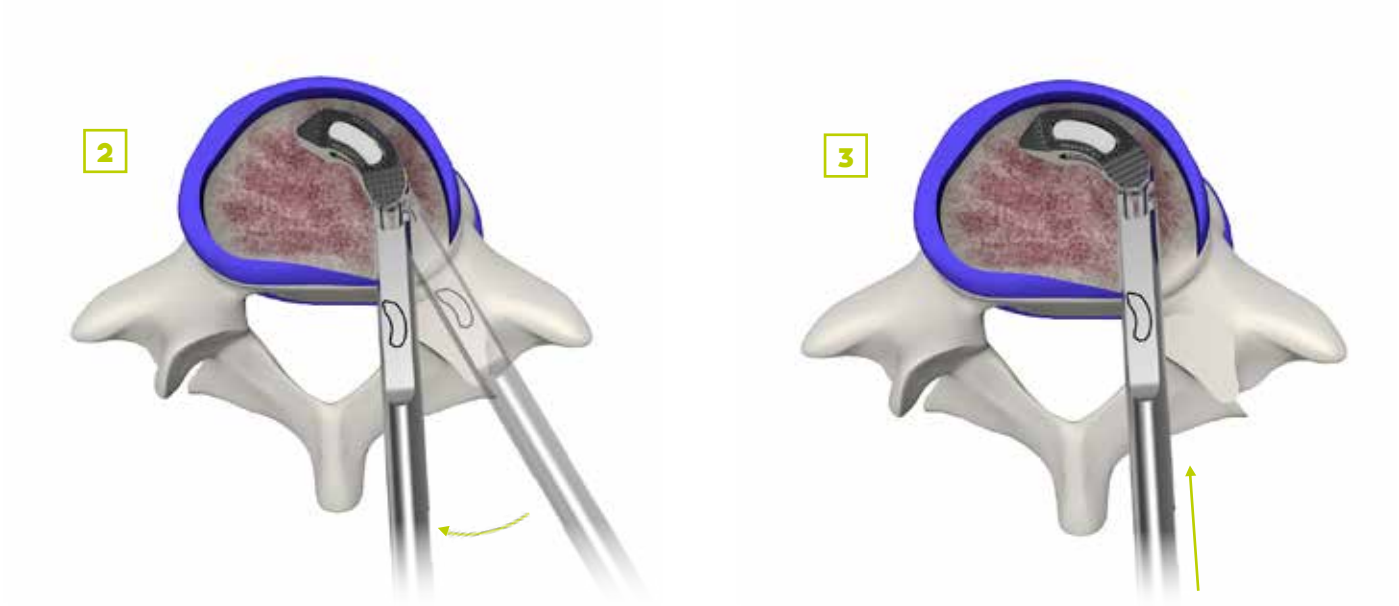
**1** Unlock the cage by making a turn counter-clockwise on the knob to allow the **cage holder** to rotate around the cage pivot axis. Laser mark on the inner shaft will align with the « rotation position » of the outer shaft.

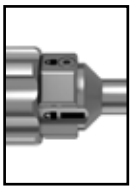



**2** Reposition the cage holder medially approximately 20-25°.

**3** The cage can then be pushed in a more anterior position with light hammering on the **cage holder handle** *TL3-A002*.

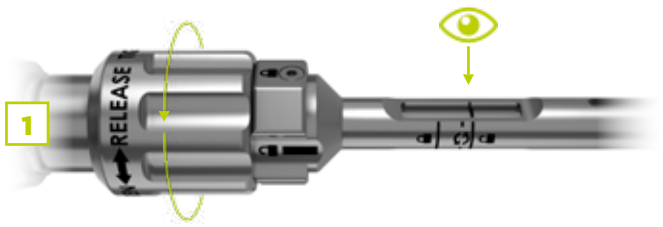
It is recommended to use fluoroscopy to confirm the final position of the cage.





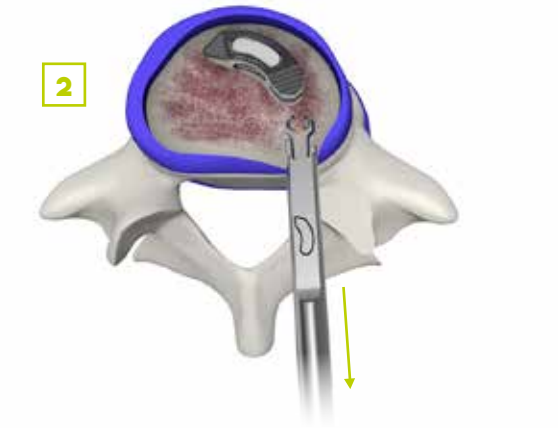
Prior to disconnecting the cage, you must turn the locking ring to the unlocked position : align the laser mark of the shaft with the unlocked padlock of the ring.

**1** Once on the « release » position, turn the cage holder knob counter-clockwise until it stops and the laser mark reaches the distal part of the position control window.




**2** The **cage holder** can now be removed from the cage.

Use fluoroscopy to confirm final position of the cage.




# IX CAGE REPOSITIONING

**Tamp**
TL3-A022

- - OR - -

**Ti TLIF Cage (Small or Medium)**
TL3-CSxx or TL3-CMxx

**Ti Straight TLIF Cage Repositioner**
TL3-A026

**Ti Straight TLIF Cage (Small or Medium)**
TL3-SCSxx or TL3-SCMxx

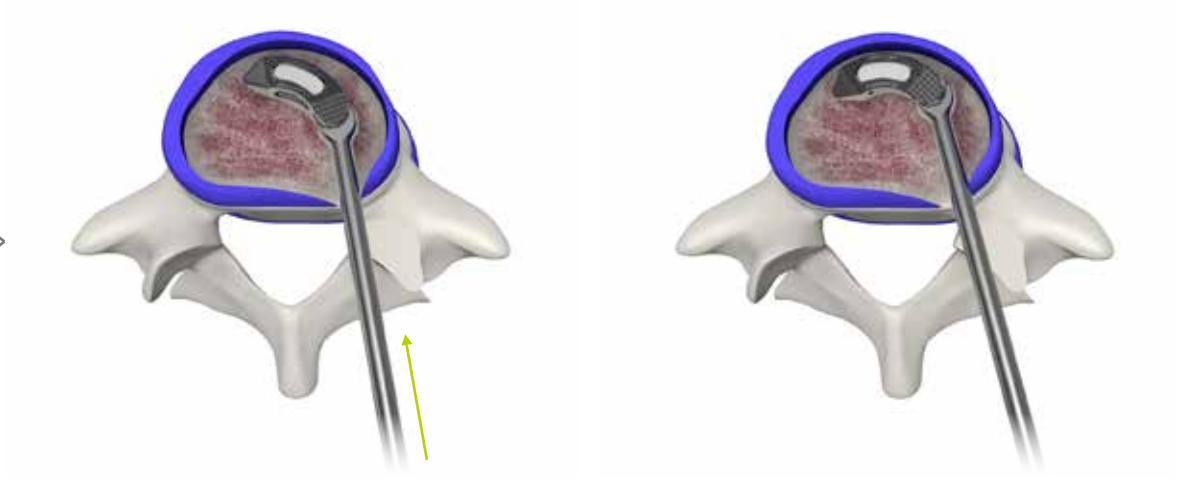
**OPTIONAL**

To reposition the cage, use the **tamp** *TL3-A022* or *TL3-A026*.

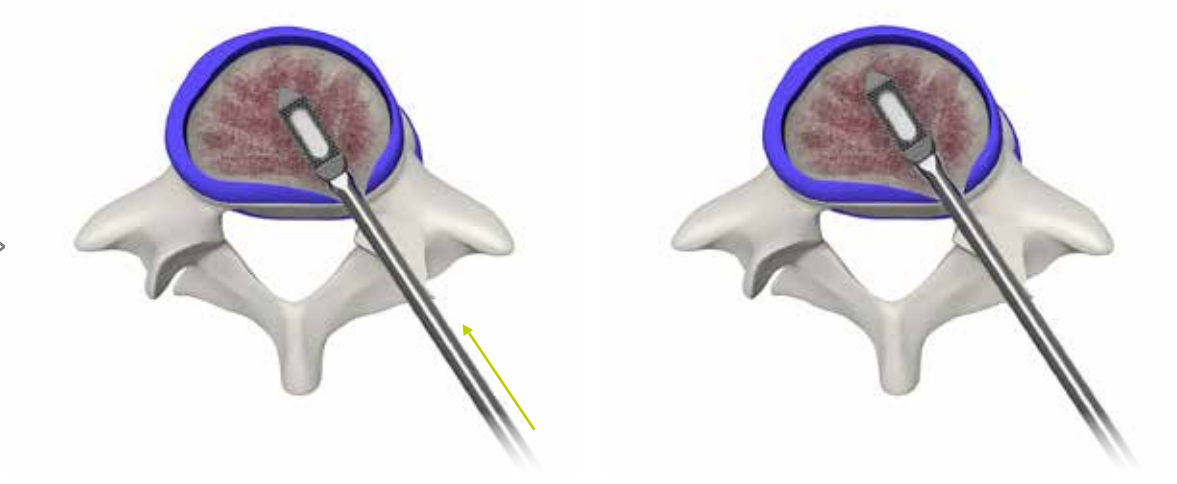
Insert it into the intervertebral space, putting it in contact with the lateral end of the cage and use it to push the cage into a more anterior and/or lateral position.

Use fluoroscopy to confirm final position of the cage.

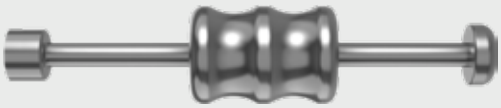
Curved TLIF



Straight TLIF



# CAGE REMOVAL



**Sliding Hammer**
TL3-A025

**Cage Holder Handle**
TL3-A002

**Cage Holder**
TL3-A001

- - OR - -

**Ti TLIF Cage & Trial Holder**
TL3-A012

**1** Connect the **cage holder** *TL3-A001* to the implanted cage. For *TL3-A001*, approach the jaws of the **cage holder**, ensuring that it is on the «open» position (laser mark at the distal part of the position control window). 🔓

**2** When the **cage holder** meets the cage, turn the knob clockwise until the laser mark aligns with the proximal line on the cage holder (locked padlock). 🔒


**1** Connect the **Ti TLIF Cage & Trial holder** *TL3-A012* to the implanted cage. Approach the threaded part of the **cage holder** to the cage.

**2** When the **cage holder** meets the cage, turn the knob clockwise to tighten the cage against the holder.

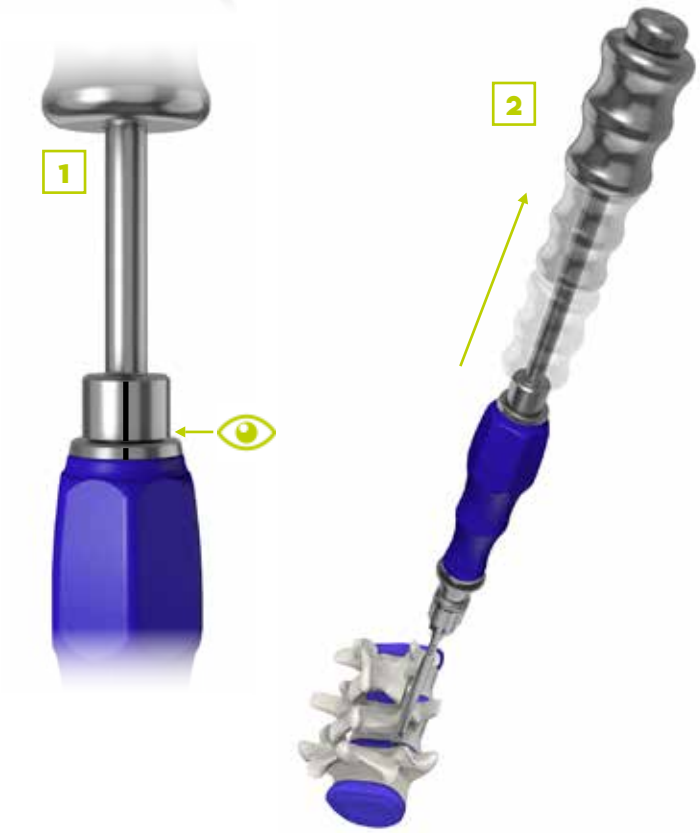
Remove the **Ti TLIF cage** using the slot of the **sliding hammer** *TL3-A025*.

Connect the **sliding hammer** on the **cage holder handle** *TL3-A002* cap.

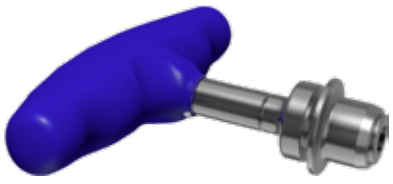
**1** Bind the two together by doing one quarter turn with the hammer until the laser mark on the **sliding hammer** meets the mark on the **cage holder handle** cap.

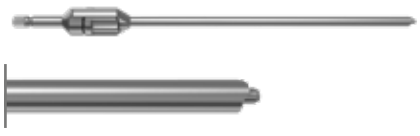
**2** While holding the **cage holder handle** with one hand, apply an upward force to the **sliding hammer** with the other hand.

Repeat this procedure until the cage is completely removed from the intervertebral disc space.

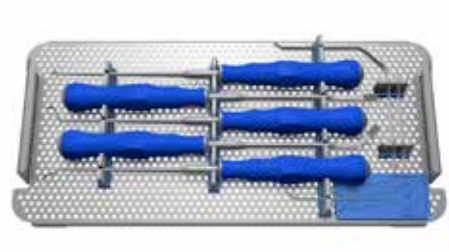


# INSTRUMENTS

| | | |
|---|---|---|
|  | **Dura Retractor** | TL1-A011 |
|  | **Nerve Roots Retractor** | TL1-A012 |
|  | **Spreader (7 To 16)** | TL3-A010-XX |
|  | **Reamer (7 To 16)** | TL3-A011-XX |
|  | **Snap-On Cannulated Silicon T-Handle** | SD-ATSH1169214C5 |
|  | **Straight Rake Curette** | TL3-A033 |

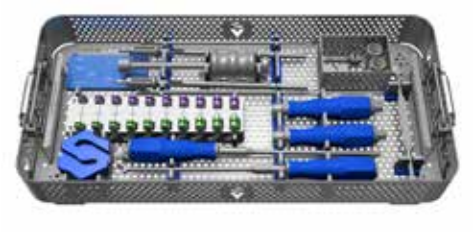
| | | |
|---|---|---|
|  | **Ring Curette Left** | TL3-A035-L |
|  | **Ring Curette Right** | TL3-A035-R |
|  | **Straight Convex Rasp** | TL3-A037-01 |
|  | **Curved Convex Rasp** | TL3-A037-02 |
|  | **Cage Holder** | TL3-A001 |
|  | **Ti TLIF Cage Holder Handle** | TL3-A002 |
|  | **Ti TLIF Cage & Trial Holder** | TL3-A012 |

| | | |
|---|---|---|
|  | **Sliding Hammer** | TL3-A025 |
|  | **Tamp** | TL3-A022 |
|  | **Ti Straight TLIF Cage Repositioner** | TL3-A026 |
|  | **Ti TLIF Cage Trial (Small 7 To 16)** | TL3-A013-Sxx |
|  | **Ti TLIF Cage Trial (Medium 7 To 16)** | TL3-A013-Mxx |
|  | **Ti Straight TLIF Cage Trial (Small 7 To 16)** | TL3-A014-Sxx |
|  | **Ti Straight TLIF Cage Trial (Medium 7 To 16)** | TL3-A014-Mxx |



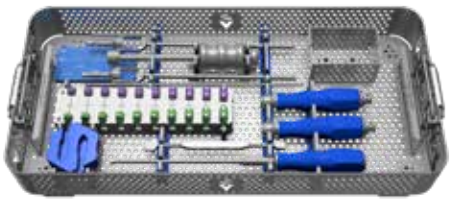
**Curettes Tray**
TL3-TRAY111

**Spreaders Tray**
TL3-TRAY112



**Ti TLIF Instruments Tray**
TL3-TRAY113

- - OR - -



**Ti Straight TLIF Instruments Tray**
TL3-TRAY114

**SV Common Base**
SD-BASE11117 / SD-BASE1168

**Ti TLIF Cage Small**

**Length 28 mm**
**Width 9 mm**

**Ti TLIF Cage Medium**

**Length 32 mm**
**Width 10.5 mm**

| | **Height** | |
|---|---|---|
| TL3-CS07 | **07 mm** | TL3-CM07 |
| TL3-CS08 | **08 mm** | TL3-CM08 |
| TL3-CS09 | **09 mm** | TL3-CM09 |
| TL3-CS10 | **10 mm** | TL3-CM10 |
| TL3-CS11 | **11 mm** | TL3-CM11 |
| TL3-CS12 | **12 mm** | TL3-CM12 |
| TL3-CS13 | **13 mm** | TL3-CM13 |
| TL3-CS14 | **14 mm** | TL3-CM14 |
| TL3-CS15 | **15 mm** | TL3-CM15 |
| TL3-CS16 | **16 mm** | TL3-CM16 |

| Ti Straight TLIF Cage Small<br>Length 28 mm<br>Width 10 mm | Height | Ti Straight TLIF Cage Medium<br>Length 32 mm<br>Width 10 mm |
|---|---|---|
| TL3-SCS07 | 07 mm | TL3-SCM07 |
| TL3-SCS08 | 08 mm | TL3-SCM08 |
| TL3-SCS09 | 09 mm | TL3-SCM09 |
| TL3-SCS10 | 10 mm | TL3-SCM10 |
| TL3-SCS11 | 11 mm | TL3-SCM11 |
| TL3-SCS12 | 12 mm | TL3-SCM12 |
| TL3-SCS13 | 13 mm | TL3-SCM13 |
| TL3-SCS14 | 14 mm | TL3-SCM14 |
| TL3-SCS15 | 15 mm | TL3-SCM15 |
| TL3-SCS16 | 16 mm | TL3-SCM16 |

# NOTES

SPINEVISION

INNOVATION THAT MATTERS

*Distributed by*

SPINEVISION SAS
3 Rue de la Renaissance
92160 ANTONY - FRANCE
Tél : +33 1 53 33 25 25

www.spinevision.net

CE 0123 CE 2460

See package insert
or labeling limitation

Non contractual
document TL3-STG01-US-2025A

2025-06-30