

3D PRINTED TITANIUM TLIF CAGE

3D PRINTED
INTERBODIES



Hexanium® TLIF



SURGICAL TECHNIQUE

SPINEVISION

INNOVATION THAT MATTERS

SURGICAL STEPS

I	.. Patient preparation.	02
II	.. Exposure.	02
III	.. Endplate preparation.	03
IV	.. Implant's size estimation.	06
V	.. Cage connection.	08
VI	.. Cage bone graft filling.	09
VII	.. Cage insertion.	10
VIII	.. Cage positioning.	11
IX	.. Cage repositioning.	12
X	.. Cage removal.	13

REFERENCES

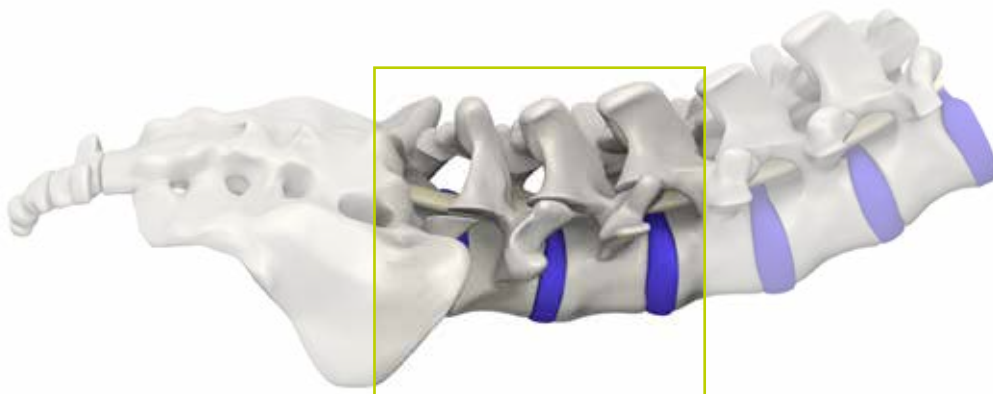
1	.. Instruments.	15
2	.. Implants.	19

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-AO11 *



Nerve Root Retractor
TL1-AO12 *

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.

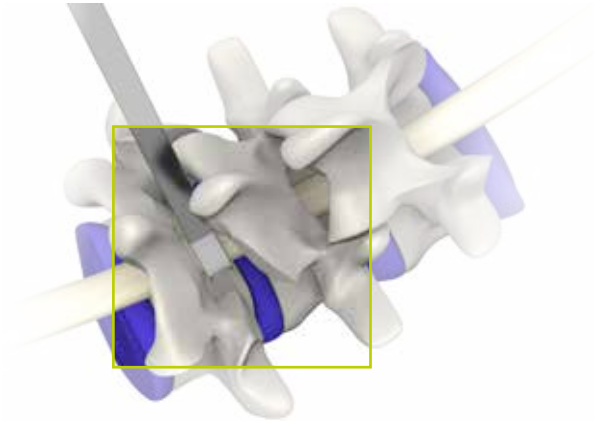
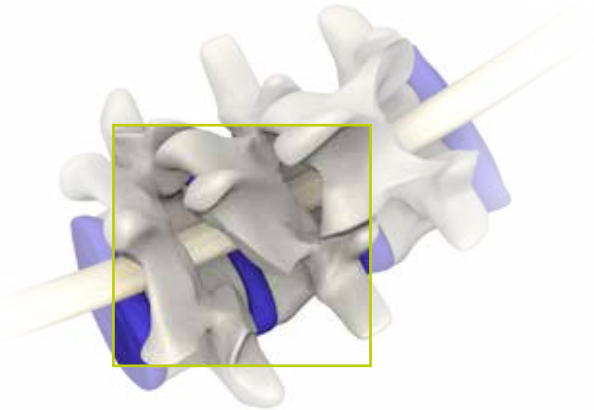
According to patient and indication the surgeon may choose a more lateral approach, leaving the facet joint intact.

* Not available in European Union

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.

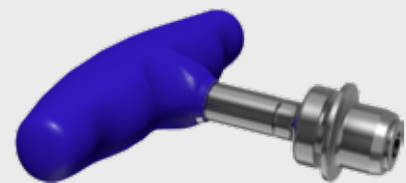
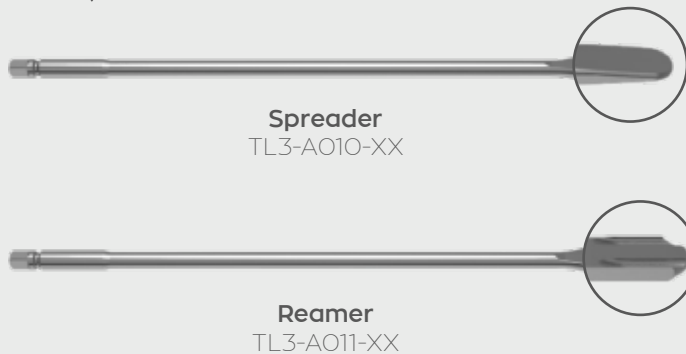
The dura and nerve root are protected using the **dura retractor** *TL1-A011 ** and/or the **nerve root retractor** *TL1-A012 **.



* Not available in European Union



ENDPLATE PREPARATION



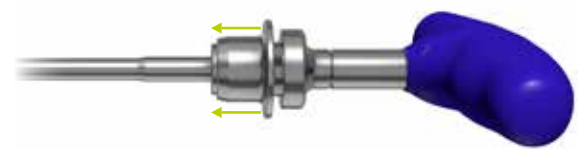
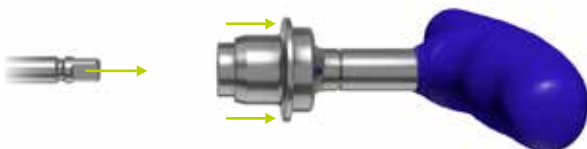
Snap-On Cannulated Silicon T-Handle
SD-ATSH1169214C5

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.

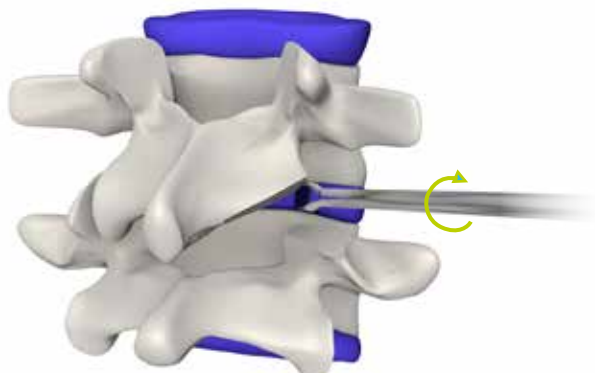
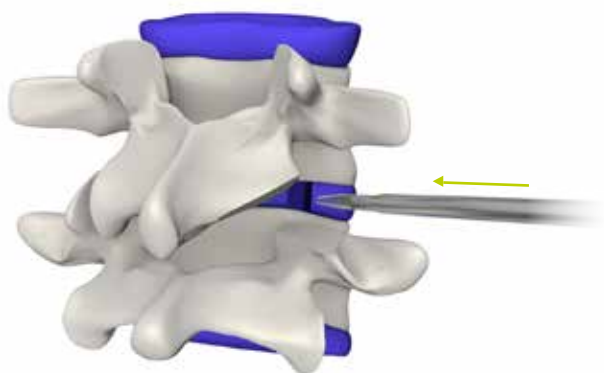
To perform this distraction, you can use the **spreaders** *TL3-A010-xx* 7 to 16.

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.

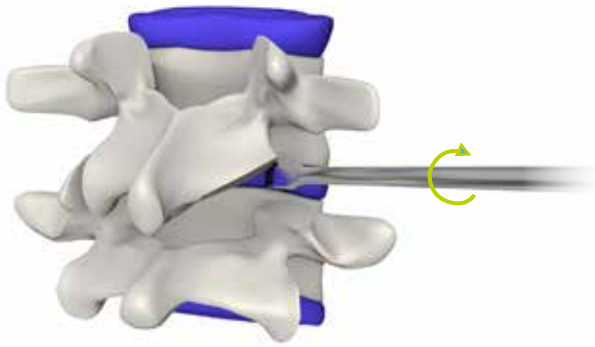
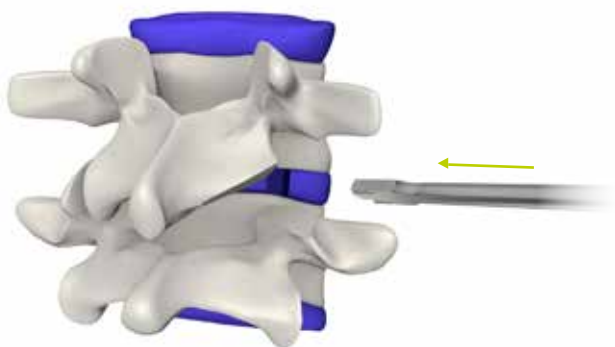


Reamer *TL3-A011-xx* can also be used to remove disc material and prepare the endplates.

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 Hexanum 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-AO33



Ring Curette (Left or Right)
TL3-AO35-L/R

If needed, the **straight rake curette** TL3-AO33 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-AO35-L/R.



Following the disc space material removal, it's recommended to perform a new distraction with the last used **spreader** TL3-AO10-xx.



Straight Convex Rasp
TL3-AO37-01

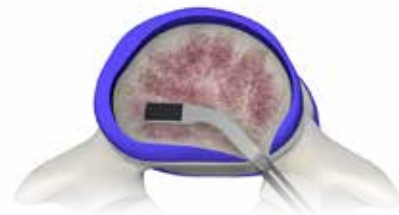
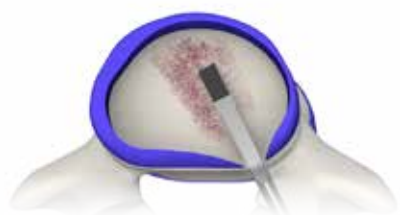


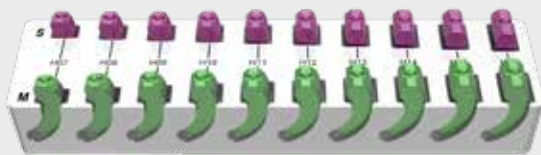
Curved Convex Rasp
TL3-AO37-02

After completing the discectomy, use the **straight convex** or the **curved convex rasp** TL3-AO37-01 & TL3-AO37-02 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.





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



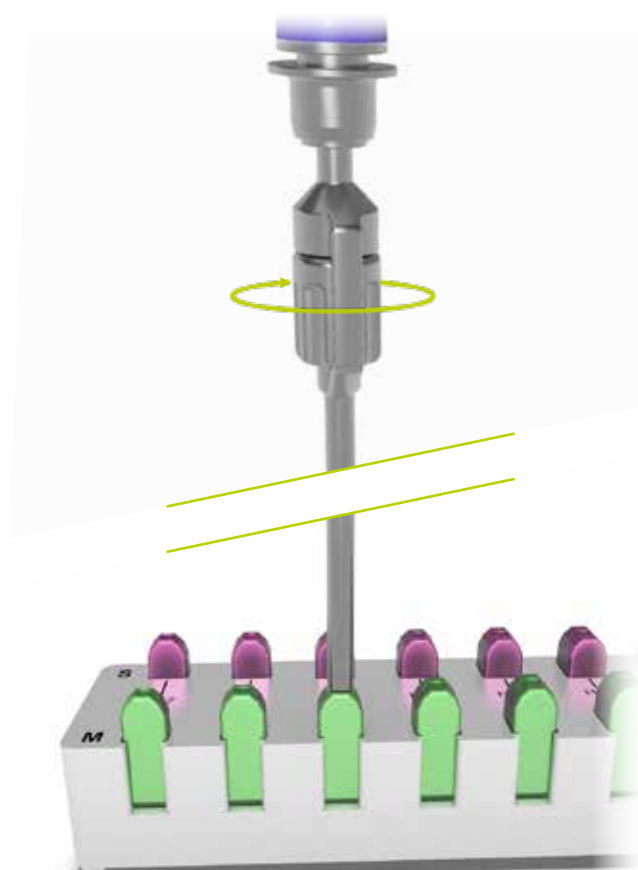
Cage Holder Handle
TL3-A002

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

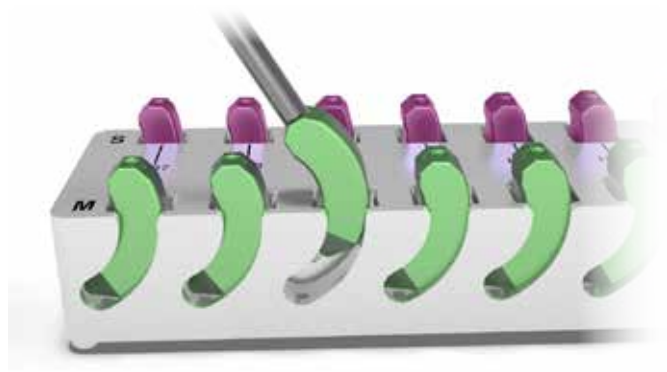
TL3-A012, place the distal part of the trial holder completely perpendicular to the trials rack so the trial holder and the cage trial are vertically aligned.

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.



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).

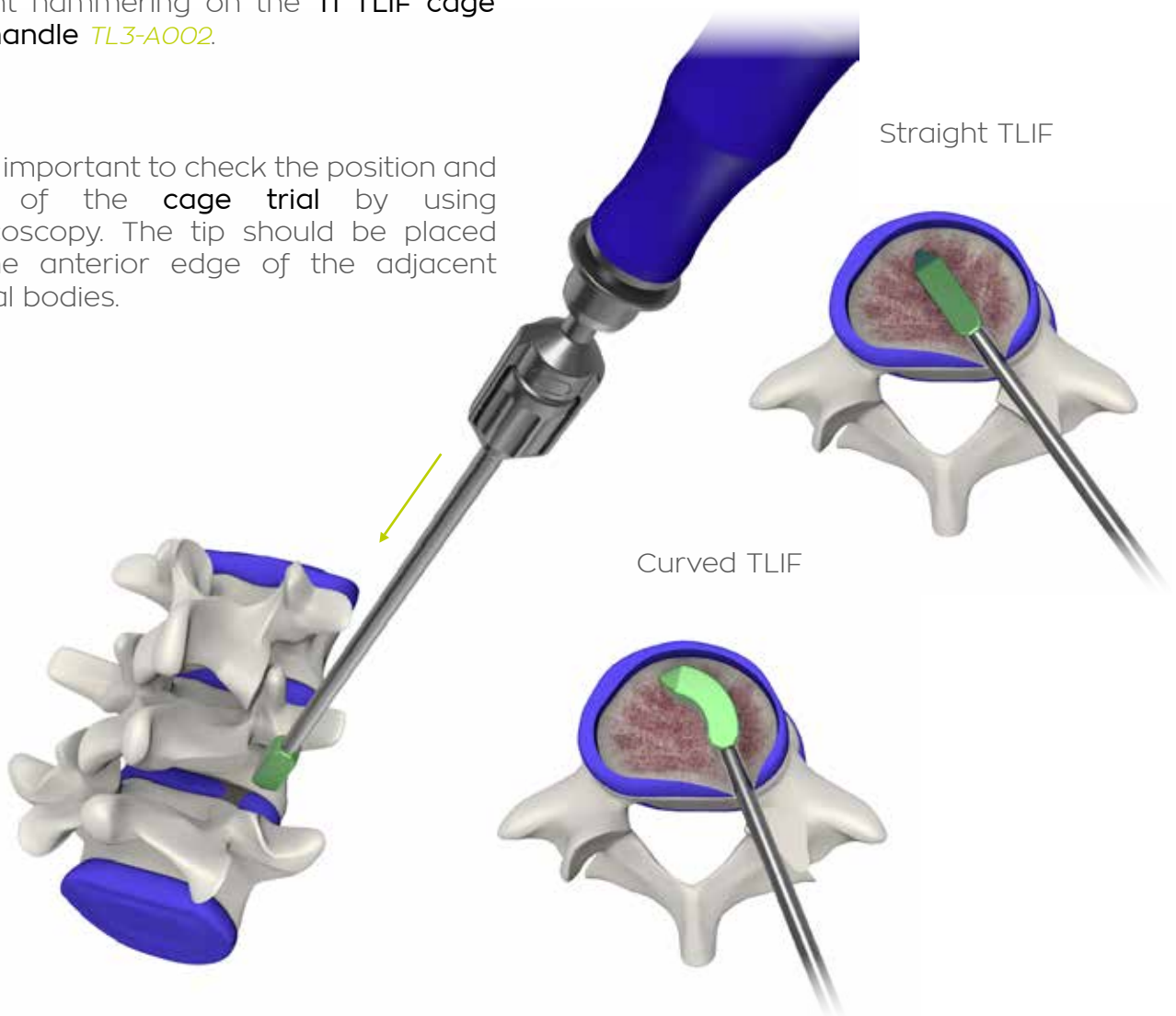
The proper alignment of the trial and the **Ti TLIF Cage & Trial Holder** TL3-A012 ensure a straight introduction of the trial along the transforaminal route.

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.

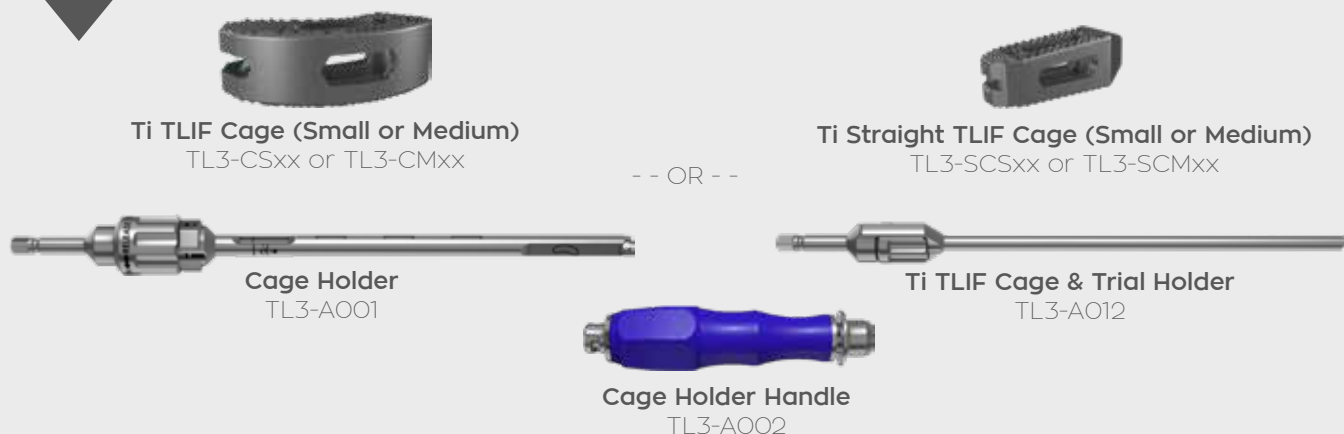
If necessary, the **cage trial** can be pushed forward into the intervertebral disc space with light hammering on the **Ti TLIF cage holder handle** TL3-A002.



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.



CAGE CONNECTION



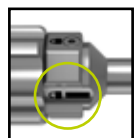
Select the implant which corresponds to the **Ti TLIF cage trial** used in the previous steps.

STRAIGHT TLIF

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

CURVED TLIF

1 For the **curved TLIF cage** Place the jaws of the **cage holder** **TL3-A001** over the proximal end of the cage.



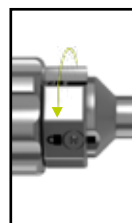
Be sure to be in the released position on the locking ring : laser mark on the cage holder aligned with the unlocked padlock of the ring. 🔒

2 Turn the **cage holder** knob clockwise to close the jaws. During this closing procedure

the laser mark moves upwards towards the closed padlock. 🔒

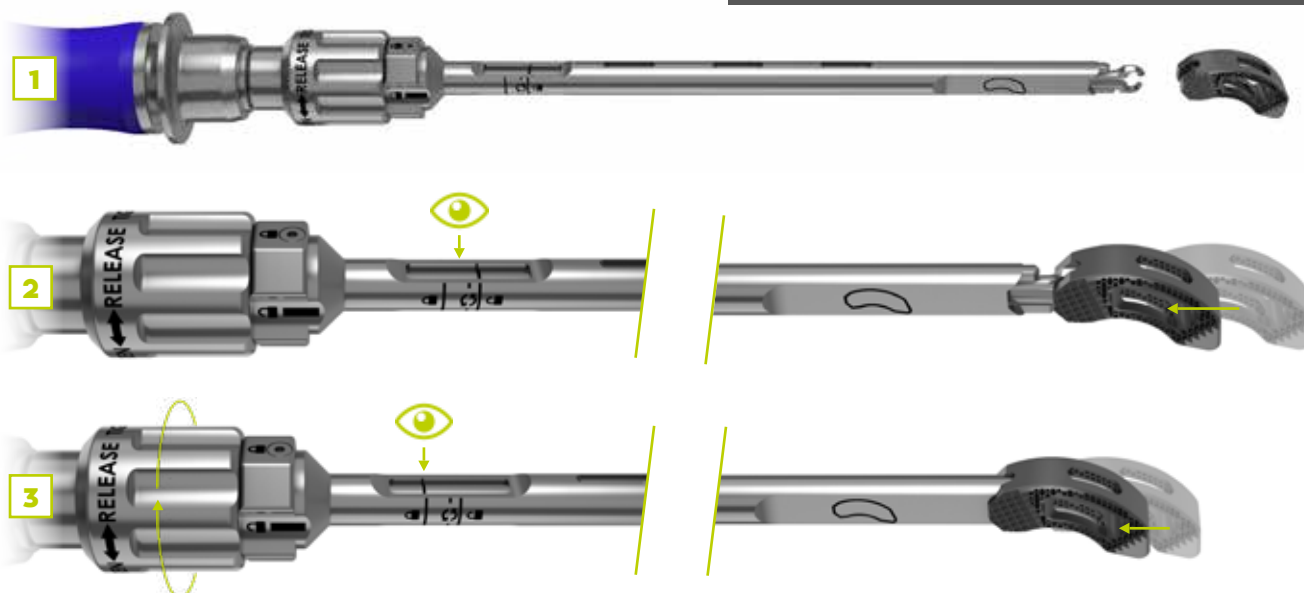
3

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.)



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



Graft Compactor
TL3-A021

-- OR --



Ti Straight TLIF Graft Compactor
TL3-A024

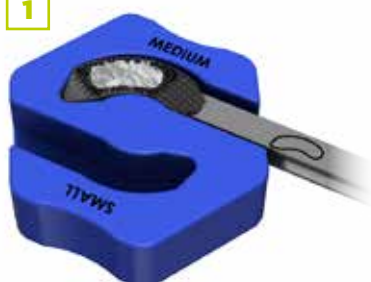
Place the implant in the correct slot on the **cage support for graft** *TL3-A020* or *TL3-A023* according to the footprint of the chosen cage : small or medium.

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.

1

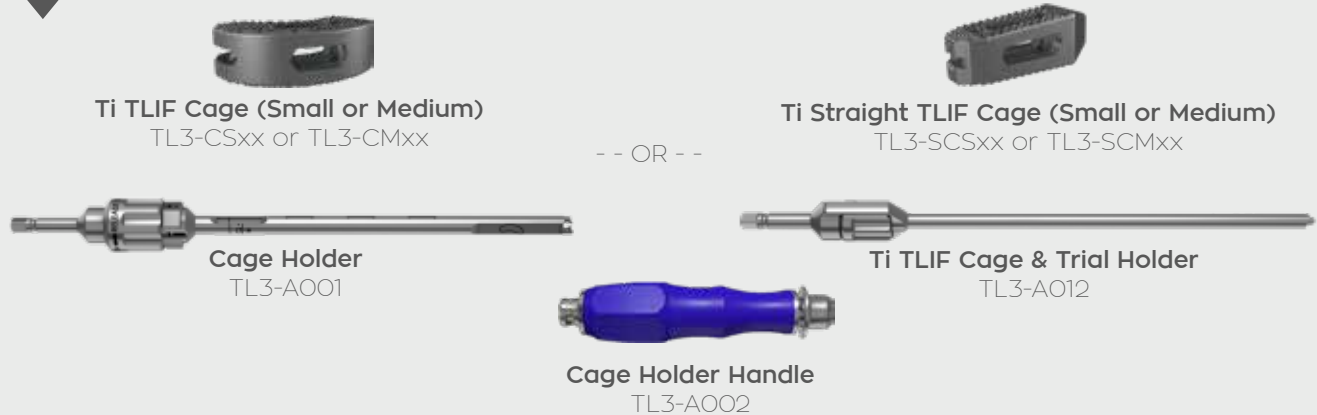


2



3





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.

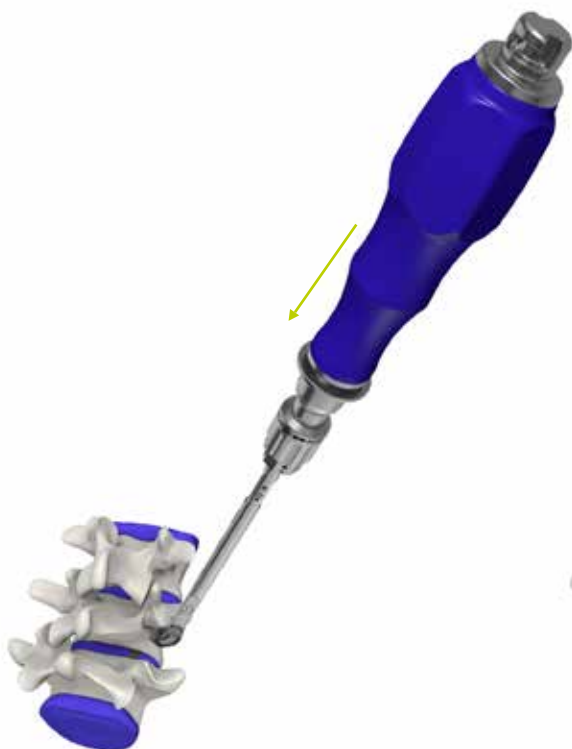


It is recommended to use fluoroscopy to confirm position of the cage.

! 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.

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



Straight TLIF



Curved TLIF





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

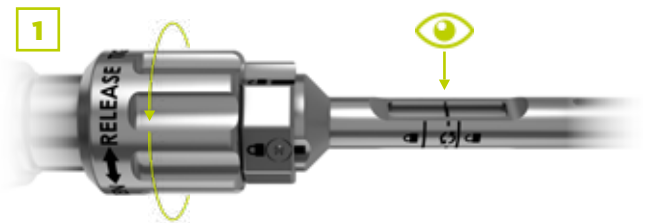


Cage Holder
TL3-A001



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.

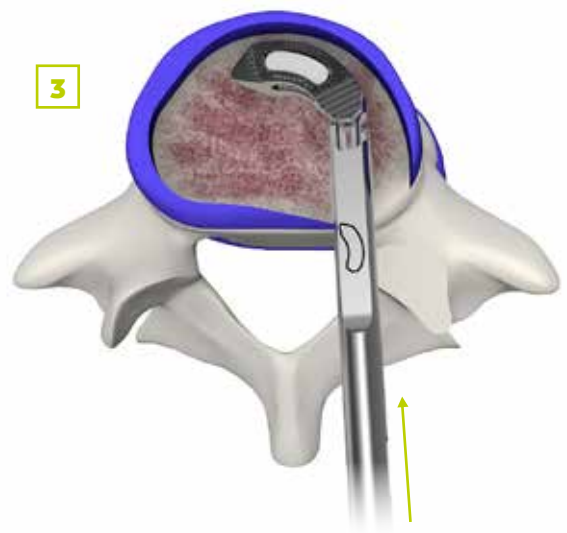
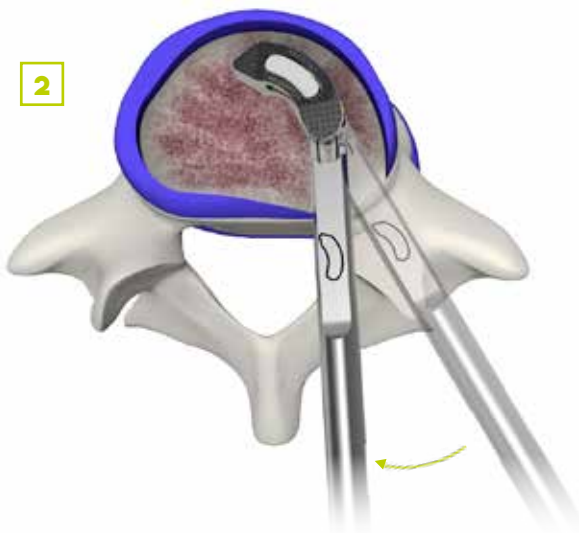


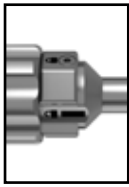
2 Reposition the cage holder medially approximately 20-25°.

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



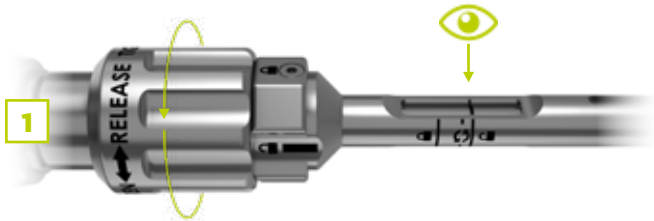
It is recommended to use fluoroscopy to confirm the final position of the cage.





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. 🔒

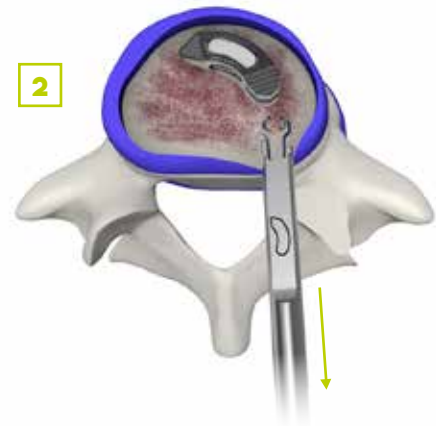
1 Once on the « release » position, turn the cage holder knob counter-clockwise until it stops and the laser mark reaches the distal part of the position control window. 🔒



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



Use fluoroscopy to confirm final position of the cage.



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*.

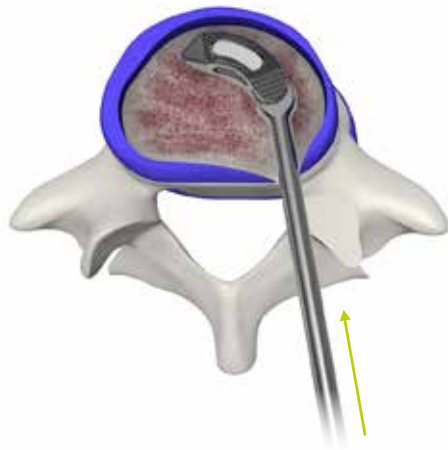
Insert it into the intervertebral space, putting

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 --

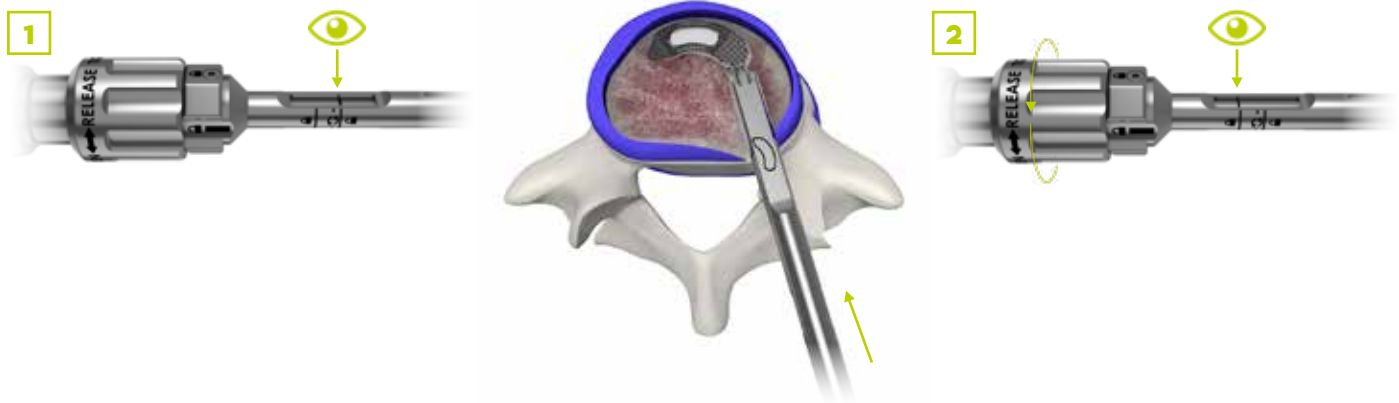


Ti TLIF Cage & Trial Holder
TL3-A012

CURVED TLIF

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). 🔒



STRAIGHT TLIF

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.



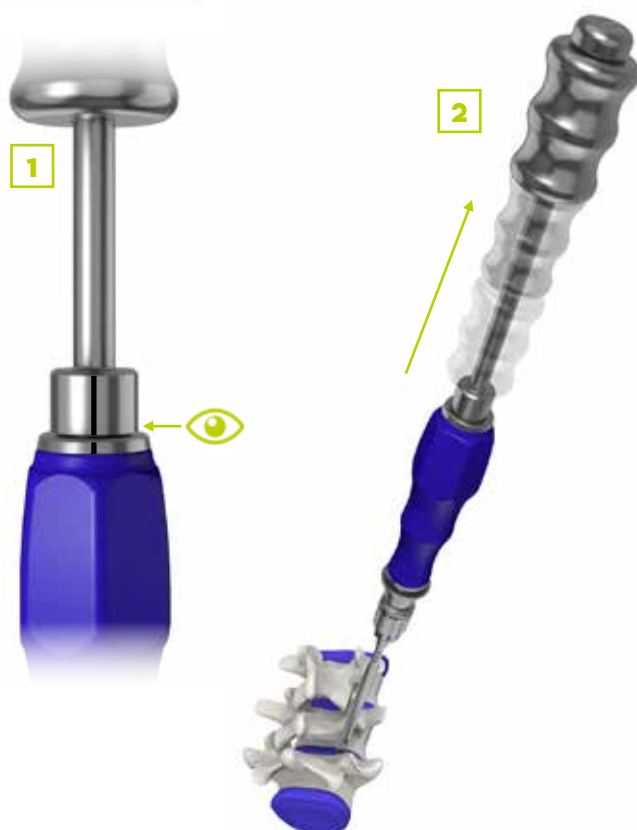
Remove the **Ti TLIF cage** using the slot of the **sliding hammer** *TL3-A025*.

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.





Dura Retractor

TL1-AO11 *

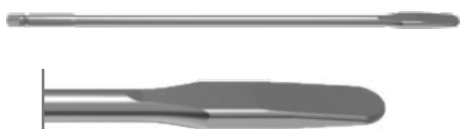
* Not available in European Union



Nerve Roots Retractor

TL1-AO12 *

* Not available in European Union



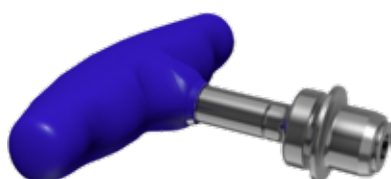
Spreader (7 To 16)

TL3-AO10-XX



Reamer (7 To 16)

TL3-AO11-XX

Snap-On Cannulated
Silicon T-Handle

SD-ATSH1169214C5



Straight Rake Curette

TL3-AO33



Ring Curette Left

TL3-AO35-L



Ring Curette Right

TL3-AO35-R



Straight Convex Rasp

TL3-AO37-O1



Curved Convex Rasp

TL3-AO37-O2



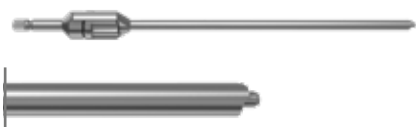
Cage Holder

TL3-AO01



Ti TLIF Cage Holder
Handle

TL3-AO02



Ti TLIF Cage & Trial Holder

TL3-AO12



Sliding Hammer

TL3-AO25



Tamp

TL3-AO22



Ti Straight TLIF
Cage Repositioner

TL3-AO26



Ti TLIF Cage Trial
(Small 7 To 16)

TL3-AO13-Sxx



Ti TLIF Cage Trial
(Medium 7 To 16)

TL3-AO13-Mxx



Ti Straight TLIF Cage Trial
(Small 7 To 16)

TL3-AO14-Sxx



Ti Straight TLIF Cage Trial
(Medium 7 To 16)

TL3-AO14-Mxx



Cage support for Graft

TL3-AO20



Graft Compactor

TL3-AO21



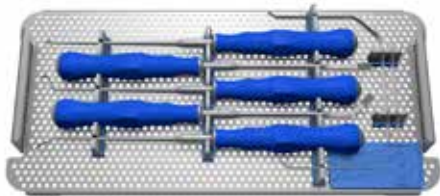
Ti Straight TLIF Cage
Packing Block

TL3-AO23



Ti Straight TLIF Graft
Compactor

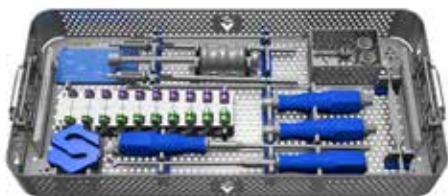
TL3-AO24



Curettes Tray
TL3-TRAY111

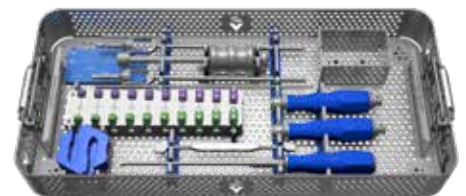


Spreaders Tray
TL3-TRAY112



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

Length 28 mm
Width 10 mm



Ti Straight TLIF Cage Medium

Length 32 mm
Width 10 mm

Height

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

The image shows a full-page view of a notepad. At the top, there is a solid blue header bar with the word "NOTES" in white, uppercase, sans-serif font. Below the header, the page is filled with horizontal blue lines on a light gray background, providing space for writing. At the bottom, there is a gray footer bar. On the left side of the footer bar is the word "NOTES" in white. In the center is a logo consisting of a hexagon with the letters "SV" inside. To the right of the logo is the text "Hexanium TLIF" in white. On the far right of the footer bar is the page number "21" in white.

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CE 0123

CE 2460



See package
insert for labeling
limitation

Non contractual document
TL3-STG01-EN-2025A

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The Hexanium TLIF system is made of medical devices. Please refer to the instructions for use or, if applicable, the specific labelling of each device for more information.