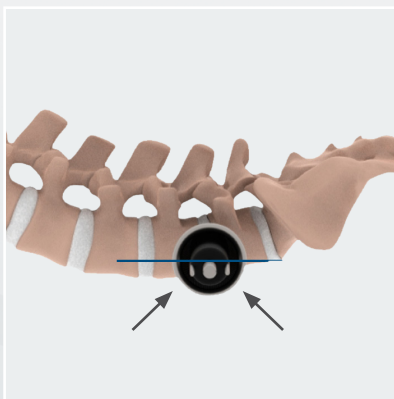
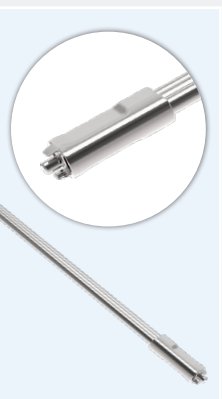




# Avenue<sup>®</sup>-L Fix Ti

Built-In Fixation Lateral Lumbar  
3D Printed Titanium Cage

Surgical Technique Guide





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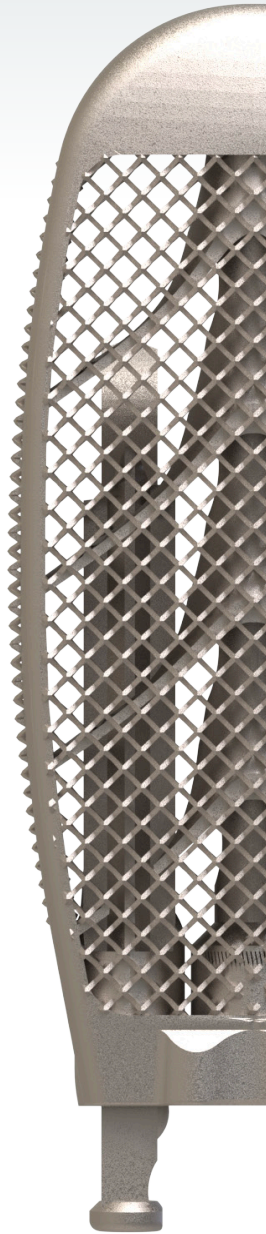
ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual guide based on surgical techniques. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.



# Avenue<sup>®</sup>-L Fix Ti

## Built-In Fixation Lateral Lumbar

### 3D Printed Titanium Cage



## Features and Characteristics

### Primary Stability

- The special “net” structure, obtained through additive manufacturing technology, is designed to provide strong primary fixation and to minimize implant migration risk.

### Wide Variety of Footprints, Heights, and Lordosis Angle

- One system intended to match patients’ natural anatomy and surgeons’ preferences.

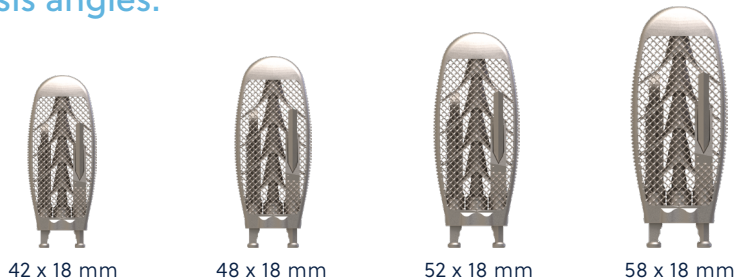
### Fusion Promotion

- Pore size of the net structure and the surface roughness of the implant edges intended to facilitate fast and effective osteo-integration. The elasticity modulus of the implant, similar to PEEK, is designed to be close to natural bone characteristics.

### Additional Built-in Fixation

- Built-in pins are intended to enhance primary fixation, and it is complementary to the stability offered by the “net” structure itself. Pins design incorporate a locking system to secure the pins once deployed. No compromise on implant elasticity and fusion promotion thanks to the small footprint of the built-in fixation. The diagonal position of the pin is intended to secure rotational stability and prevent risk of conflict in case of posterior instrumentation in adjacent vertebrae. Avenue<sup>®</sup>-L Fix Ti is manufactured in one production step, thanks to the additive manufacturing technology used. No additional instruments are required for implantation. In case of revision, or if required, locked pins can be released using Pin Extractor.

Avenue-L Fix Ti is offered in 2 widths, 4 lengths, 4 heights, and with 3 lordosis angles:



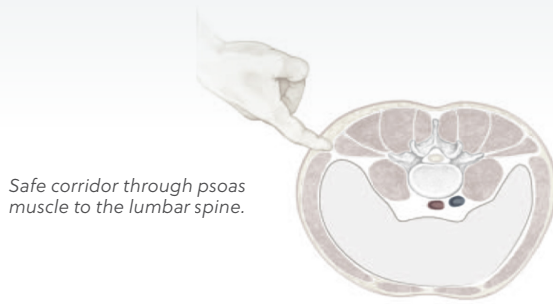
*Selected lengths are also available in 22 mm widths.*



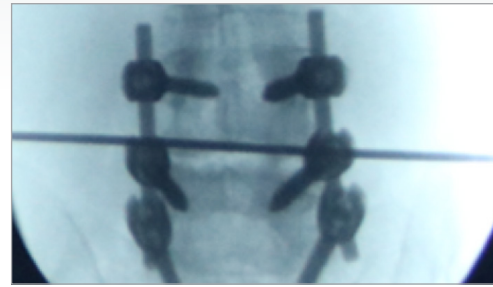
*Selected heights come only in selected footprints and lordosis angle.*



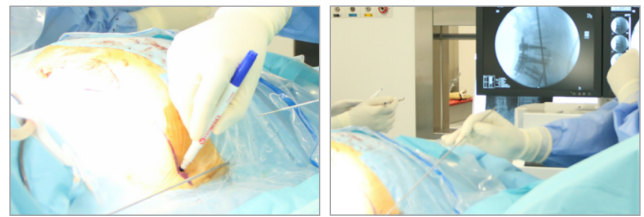
## Surgical Procedure



Patient in prone position



X-ray of skin incision.



Two moments of the skin incision procedure during surgery.

## Patient Positioning

- Patient position should expose the spine level which is going to be addressed.
- Surgeons should evaluate the most appropriate position considering the surgical approach, decompression procedure, and fusion technique.
- For this surgical procedure, place the patient in prone position for Direct Posterior or Posterior Transforaminal approach to lower levels of the spine. Approach the required level following the known surgical technique.

**Note:** Patient in "classic" Lateral Position and Universal Lateral Retractor Instruments can be used as well. Use corresponding STG for surgical steps needed in that case levels will be fused.

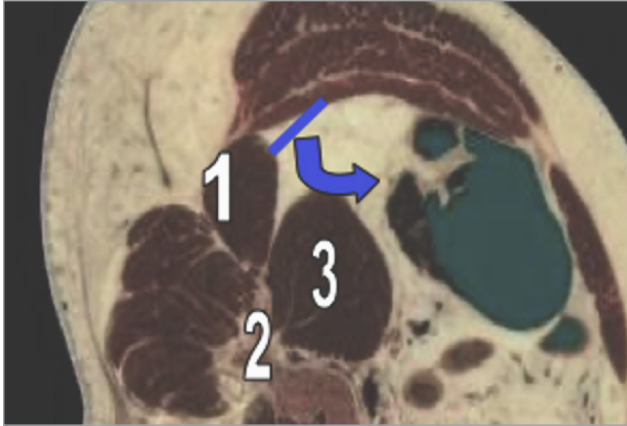
## Surgical Incision Preparation

- Map out through one abdominal pre-surgery MRI in prone position (like the surgical position) a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended, to ensure targeting the anterior two-third of the affected disc.
- The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.

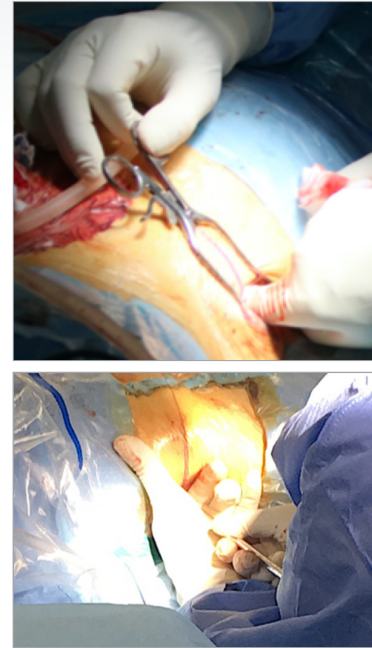
## Skin Incision

- Use fluoroscopy to verify the appropriate level of the spine.
- The skin incision should allow adequate approach to reach the targeted spine segment(s). Additional instruments like a vertebral distractor and soft tissue retractors may allow easier access to the required vertebral segment.
- To maintain proper vision of the surgical field a tissue retractor system is highly recommended. It is up to the surgeon to define and perform the soft tissue approach and bone decompression procedure. In some cases, specific patient positioning may be required.

**Note:** Use a longitudinal incision if multiple levels will be fused.



Summary image.



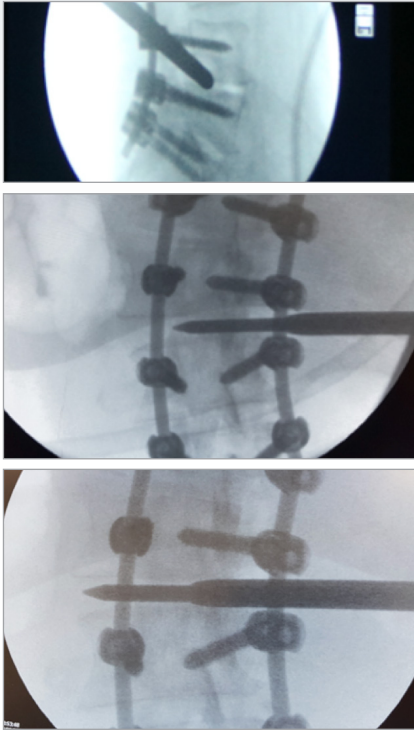
Two moments of the vertebral disc entering procedure during surgery.

## First Steps' Summary

- The Direct Observation of Muscle Layers
- Follow Internal Abdominal Wall
- Posterior to Anterior Abdominal Wall Finger Sweep
- Feel for:
  - Quadratus Muscle
  - Transverse Process
  - Surface of the Psoas Muscle

## Vertebral Disc Entering Procedure

- Once the skin incision is made and the subcutaneous tissue is released, the oblique muscles of the abdomen should be visible. Separate the muscle fibers with blunt dissection and enter the retroperitoneal space.
- Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the transverse process. Slide forward to the psoas muscle.
- After reaching the psoas muscle using the finger, it is time to enter with the first access instrument it is possible to connect the instrument to a neuro monitoring system. The initial instrument has to be fixed in the disc space, using the hammer if necessary. This instrument has to be positioned with maximum accuracy, in the middle of the disc space, and will guide the positioning of the retractor system in the next steps.
- The first access instrument is composed by one internal mandrel, with round tip, and a smooth cannula this allows the surgeon to reach the disc through the psoas muscle without risk of possible damage to muscle and nerve systems.



*X-rays portraying three moments of the vertebral disc entering procedure with Stromboli First Access Guide (BOK-LD-14-1,2,3,4).*

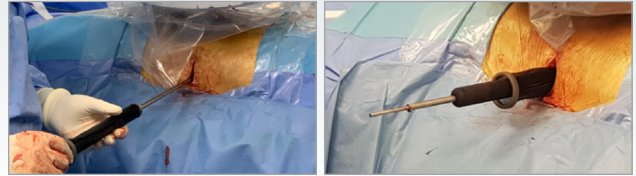
*Cannulated Instrument.*



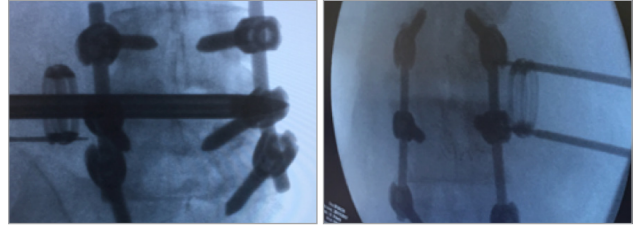
*Enlargement of psoas muscle fibers during surgery.*

## Dissection Cannulas

- When surgeons deem necessary to add an additional bone growth accelerator, a Universal Filling System effectively supports the bone substitute filling procedure, either at pre-implantation or post-implantation stage of the surgical procedure.
- Is very useful to also push the cannula inside the disc space to assure a strong and reliable fixation, which is very important for the next steps of the surgical procedure.
- To support easy entry of the disc space, a special cannulated instrument is available to push the cannula into the disc space.
- Three additional cannulas, each with an increased diameter, need to be placed on the initial cannula to gently enlarge the psoas muscle fibers, creating the space to position the GHOST retractor.



Positioning of the assembled Ghost retractor during surgery.

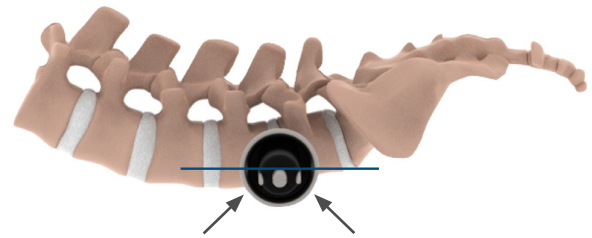


X-rays of two moments of the Ghost retractor positioning.



Ghost Retractor.

Retractor holder.



Correct positioning of the Ghost retractor.

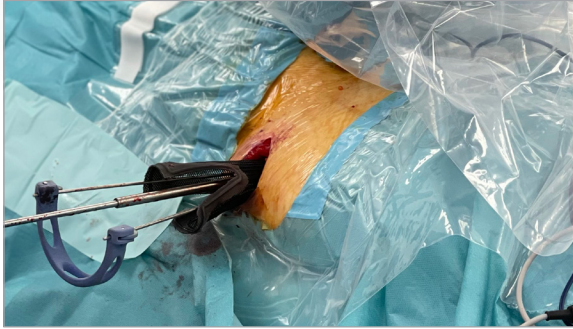
## Retractor Assembling

- Slide the retractor holder inside the Ghost retractor and push the square end of the holder into the metallic ring of the retractor till it stops (there is a hard stop on the holder).

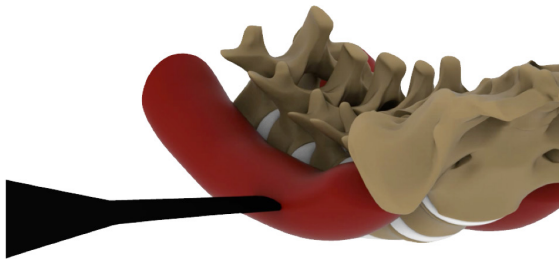
## Retractor Positioning

- Remove all the dissection cannulas, leaving only the initial instrument well fixed into the disc space.
- Once all the dissection cannulas have been introduced, reaching the disc wall, position the assembled GHOST retractor.
- Gently push the GHOST retractor on the cannulas inside the patient, till reaching the vertebral body, gently rotating the retractor helps to cross the soft tissues.
- Use fluoroscopic control when reaching the vertebrae.
- After reaching the vertebral body, crossing the psoas muscle, fix the GHOST on the vertebral body, using the pin wires.
- Gently hammer the pin wires into the vertebral body to support fixation of the metallic ring of the GHOST retractor on the lateral part of the vertebral body.
- For correct positioning of the fixation wires, use the two channels on the retractor holder, and slide the wires inside. The channels are designed to guide the wires through the fixing holes on the GHOST metallic ring, and enter the vertebral body.
- Control the position of the GHOST retractor: the wire channels have to be in cranio/caudal position.





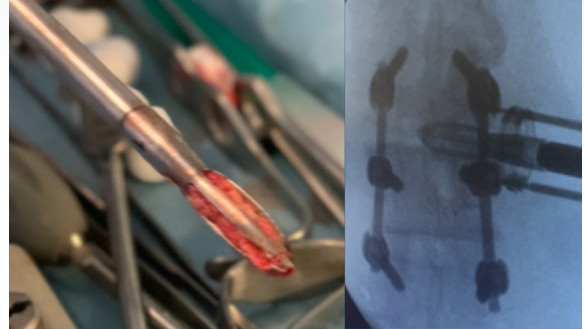
Fixing wire spreader attached onto the fixing wires during surgery.



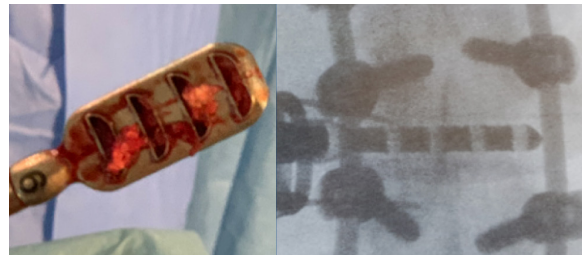
Position of Ghost retractor through the psoas muscle.

## Fixation Wires Spreading

- Patient position should expose the spine level which is going to be addressed.
- Surgeons should evaluate the most appropriate position considering the surgical approach, decompression procedure, and fusion technique.
- For this surgical procedure, place the patient in prone position for Direct Posterior or Posterior Transforaminal approach to lower levels of the spine. Approach the required level following the known surgical technique.



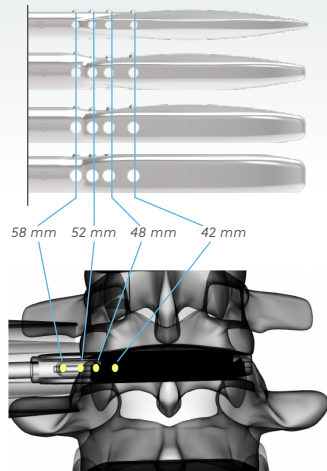
Round shaver during surgery, live picture and X-rays.



Parabolic shaver during surgery, live picture and X-rays.

## Discectomy

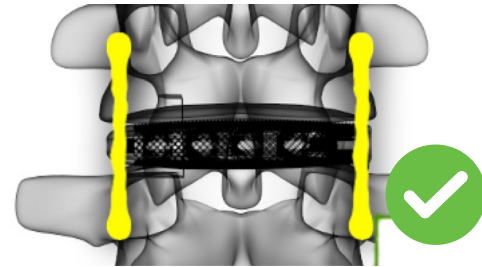
- Two different shavers are available in the instrument set. First use the round shavers to prepare the space for the parabolic ones.
- The parabolic shavers are particularly indicated to prepare the vertebral endplate. Proceed progressively from the smaller to the bigger size to prepare the disc space for the implant. The anatomic patient structure needs to be verified and respected to use the most suitable one as last one: once the cartilage on the endplates has been removed, the right size (in height) has been reached.
- Adequate cleaning of the endplates is important to enable the provision of a blood supply to the implant. However, excessive cleaning or use of a rasp may weaken the endplate and result in subsidence of the implant.



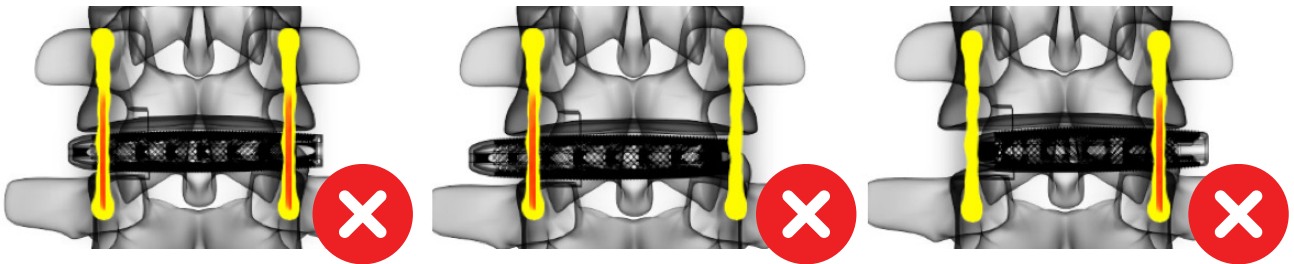
Practical example on length definition through probe usage.



Probe



Correct implant length choice.



Three examples of **not correct** implant length choice.

## Implant Dimension Choice

### Height

- After completing disc cleaning, position the implant probe on the silicone handle and gently enter into the disc space.
- Gentle and controlled blows with the hammer can support entering the disc space, when needed.
- Trials are available in four heights dimensions (7, 9, 11, 13 mm) and they are flat (0 degrees lordosis angle).

### Width

- Trials are only available in 18mm wide
- Pre-operative radiological imaging and intra-operative fluoroscopy is to be used to choose desired width.

### Lordosis Angle

- Pre-operative radiological imaging is strongly recommended to decide on the lordosis angulation of the implant.

### Length

- After defining the required height, the required length of the implant is defined based on the holes in the instrument which should be examined through fluoroscopic control (AP):
- The tip of the trial should hit the contralateral wall of the vertebral bodies, whereas the holes in the instrument indicate the length of the implant: the hole that shows on the wall at the entry point represents the required length: see also images below.
- A lateral cage should cover as much of the vertebral bodies' endplates as possible, and thus should be placed from cortex to the contralateral cortex, but it should never exceed the lateral cortex wall.

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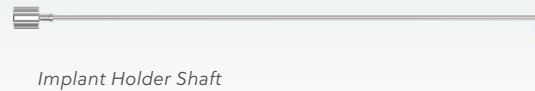
### Example

Cage Length	52 mm
Cage Width	22 mm
Cage Height	9 mm
Cage Lordosis Angle	8°

(to be chosen after evaluating radiological imaging)

TILF	—	5222	—	0908
Type		Footprint: Length x Width		Height Lordosis Angle

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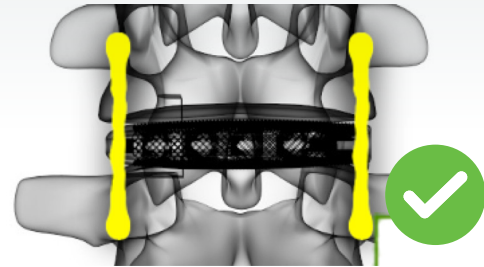


## Implant Reference Code

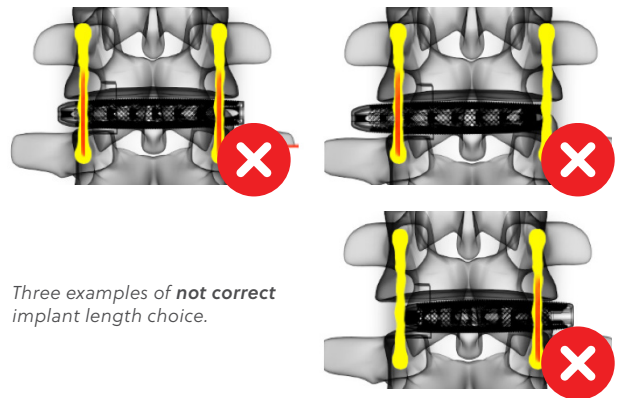
- The correct implant size is the one that corresponds with the height of the probe and the length, indicated by the holes in the probe.
- The required lordosis angle is determined after evaluation of (pre-OP) fluoroscopy imaging.

## Implant Preparation

- The implant is delivered in a double rigid blister packaging.
- Remove the blister in the unsterile field (rotation preservation of the sterility of the implant, which is in the internal blister. Drop the internal blister into the sterile field for further processing by the scrub technician.
- Assemble the implant holder shaft into the implant holder.
- Connect the implant to the assembled implant holder by screwing till reaching a solid fixed position in order to avoid any problems during final implant positioning.
- In case of using an implant with a lordosis angle: the implant holder has an arrow that should be seen by the surgeon during implantation (arrow facing up); applicable with the patient in prone position.



Correct implant length choice.



Three examples of **not correct** implant length choice.

## Implant Positioning

- Make sure the hammer surfaces on the lateral side of the Implant Holder are fully "up", which allows the pins of the implant to fully retract and be positioned into the Implant Holder for a secure fixation on the Implant Inserter; before implantation the superior and inferior surfaces of the implant don't show any of the pins sticking out, to allow a smooth insertion of the implant.
- Gently push the implant through the Ghost retractor till reaching the intervertebral space. The shape of the nose of the implant will help smooth entrance into the disc space.
- Place the implant into its final position. Introduction may require gentle hammering on the backside of the Implant Inserter. The implant Inserter may be used to manipulate the cage within the disc space, if required.

**Note:** The Holder safety clip is to be used during cage insertion to avoid unintentional push of the pins, so they do not protrude during this insertion step.

- Use the hammer to extract the pins by tapping on the hammer surfaces on the lateral side of the implant Holder to final, which securely locks the pins into the implant.
- Once the cage is in the correct position and the pins are fully extracted, the Implant Inserter should be removed: The Implant is released by turning the knob counterclockwise, leaving the implant in its optimal and securely fixed position.
- Only when needed, the pins can be retracted by using the pin extractor. This operation has to be carefully monitored with fluoroscopy support: both AP and Lateral view.

**Note:** If Pins need to be retrieved back, first take Implant Holder Shaft, attach it to the cage, and hold firmly to avoid cage migration, while you hammer back the Pins with the Pin Extractor.



## Retractor Removal

- Once the final implant position is reached, remove the implant holder and after a last fluoroscopy control, the Ghost retractor can be removed; To this, the following procedure MUST BE RESPECTED:
- Detach and remove the Fixing wire spreader.
- Re-insert the retractor holder inside the Ghost retractor, making sure the fixing wires fit the grooves in the the retractor holder and push the end of the holder into the metallic ring of the retractor till it stops (there is a hard stop on the holder). Use the Fixing wire Screwdriver to remove the fixing wires first. Then remove the retractor holder and the Ghost retractor WHILE STILL ASSEMBLED (so together in one piece).

### Footprint 42 x 18 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 42 x 18 x 7 mm, 5°	TILF4218-0705	1
Avenue-L Fix Ti LxWxH 42 x 18 x 9 mm, 5°	TILF4218-0905	2
Avenue-L Fix Ti LxWxH 42 x 18 x 11 mm, 5°	TILF4218-1105	2
Avenue-L Fix Ti LxWxH 42 x 18 x 13 mm, 5°	TILF4218-1305	1
Avenue-L Fix Ti LxWxH 42 x 18 x 9 mm, 8°	TILF4218-0908	2
Avenue-L Fix Ti LxWxH 42 x 18 x 11 mm, 8°	TILF4218-1108	2
Avenue-L Fix Ti LxWxH 42 x 18 x 13 mm, 8°	TILF4218-1308	1
Avenue-L Fix Ti LxWxH 42 x 18 x 9 mm, 14°	TILF4218-0914	1
Avenue-L Fix Ti LxWxH 42 x 18 x 11 mm, 14°	TILF4218-1114	1
Avenue-L Fix Ti LxWxH 42 x 18 x 13 mm, 14°	TILF4218-1314	1

### Footprint 48 x 18 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 48 x 18 x 7 mm, 5°	TILF4818-0705	1
Avenue-L Fix Ti LxWxH 48 x 18 x 9 mm, 5°	TILF4818-0905	2
Avenue-L Fix Ti LxWxH 48 x 18 x 11 mm, 5°	TILF4818-1105	2
Avenue-L Fix Ti LxWxH 48 x 18 x 13 mm, 5°	TILF4818-1305	1
Avenue-L Fix Ti LxWxH 48 x 18 x 9 mm, 8°	TILF4818-0908	2
Avenue-L Fix Ti LxWxH 48 x 18 x 11 mm, 8°	TILF4818-1108	2
Avenue-L Fix Ti LxWxH 48 x 18 x 13 mm, 8°	TILF4818-1308	1
Avenue-L Fix Ti LxWxH 48 x 18 x 9 mm, 14°	TILF4818-0914	1
Avenue-L Fix Ti LxWxH 48 x 18 x 11 mm, 14°	TILF4818-1114	1
Avenue-L Fix Ti LxWxH 48 x 18 x 13 mm, 14°	TILF4818-1314	1

### Footprint 52 x 18 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 52 x 18 x 7 mm, 5°	TILF5218-0705	1
Avenue-L Fix Ti LxWxH 52 x 18 x 9 mm, 5°	TILF5218-0905	2
Avenue-L Fix Ti LxWxH 52 x 18 x 11 mm, 5°	TILF5218-1105	2
Avenue-L Fix Ti LxWxH 52 x 18 x 13 mm, 5°	TILF5218-1305	1
Avenue-L Fix Ti LxWxH 52 x 18 x 9 mm, 8°	TILF5218-0908	2
Avenue-L Fix Ti LxWxH 52 x 18 x 11 mm, 8°	TILF5218-1108	2
Avenue-L Fix Ti LxWxH 52 x 18 x 13 mm, 8°	TILF5218-1308	1
Avenue-L Fix Ti LxWxH 52 x 18 x 9 mm, 14°	TILF5218-0914	1
Avenue-L Fix Ti LxWxH 52 x 18 x 11 mm, 14°	TILF5218-1114	1
Avenue-L Fix Ti LxWxH 52 x 18 x 13 mm, 14°	TILF5218-1314	1

### Footprint 58 x 18 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 58 x 18 x 7 mm, 5°	TILF5818-0705	1
Avenue-L Fix Ti LxWxH 58 x 18 x 9 mm, 5°	TILF5818-0905	1
Avenue-L Fix Ti LxWxH 58 x 18 x 11 mm, 5°	TILF5818-1105	1
Avenue-L Fix Ti LxWxH 58 x 18 x 13 mm, 5°	TILF5818-1305	1
Avenue-L Fix Ti LxWxH 58 x 18 x 9 mm, 8°	TILF5818-0908	1
Avenue-L Fix Ti LxWxH 58 x 18 x 11 mm, 8°	TILF5818-1108	1
Avenue-L Fix Ti LxWxH 58 x 18 x 13 mm, 8°	TILF5818-1308	1
Avenue-L Fix Ti LxWxH 58 x 18 x 9 mm, 14°	TILF5818-0914	1
Avenue-L Fix Ti LxWxH 58 x 18 x 11 mm, 14°	TILF5818-1114	1
Avenue-L Fix Ti LxWxH 58 x 18 x 13 mm, 14°	TILF5818-1314	1

### Footprint 42 x 22 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 42 x 22 x 7 mm, 5°	TILF4822-0705	1
Avenue-L Fix Ti LxWxH 42 x 22 x 9 mm, 5°	TILF4222-0905	1
Avenue-L Fix Ti LxWxH 42 x 22 x 11 mm, 5°	TILF4222-1105	1
Avenue-L Fix Ti LxWxH 42 x 22 x 13 mm, 5°	TILF4222-1305	1
Avenue-L Fix Ti LxWxH 42 x 22 x 9 mm, 8°	TILF4222-0908	1
Avenue-L Fix Ti LxWxH 42 x 22 x 11 mm, 8°	TILF4222-1108	1
Avenue-L Fix Ti LxWxH 42 x 22 x 13 mm, 8°	TILF4222-1308	1
Avenue-L Fix Ti LxWxH 42 x 22 x 9 mm, 14°	TILF4222-0914	1
Avenue-L Fix Ti LxWxH 42 x 22 x 11 mm, 14°	TILF4222-1114	1
Avenue-L Fix Ti LxWxH 42 x 22 x 13 mm, 14°	TILF4222-1314	1

### Footprint 48 x 22 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 48 x 22 x 7 mm, 5°	TILF4822-0705	1
Avenue-L Fix Ti LxWxH 48 x 22 x 9 mm, 5°	TILF4822-0905	1
Avenue-L Fix Ti LxWxH 48 x 22 x 11 mm, 5°	TILF4822-1105	1
Avenue-L Fix Ti LxWxH 48 x 22 x 13 mm, 5°	TILF4822-1305	1
Avenue-L Fix Ti LxWxH 48 x 22 x 9 mm, 8°	TILF4822-0908	1
Avenue-L Fix Ti LxWxH 48 x 22 x 11 mm, 8°	TILF4822-1108	1
Avenue-L Fix Ti LxWxH 48 x 22 x 13 mm, 8°	TILF4822-1308	1
Avenue-L Fix Ti LxWxH 48 x 22 x 9 mm, 14°	TILF4822-0914	1
Avenue-L Fix Ti LxWxH 48 x 22 x 11 mm, 14°	TILF4822-1114	1
Avenue-L Fix Ti LxWxH 48 x 22 x 13 mm, 14°	TILF4822-1314	1

### Footprint 52 x 22 mm

Description (L x W x H)	Part Number	QTY
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Avenue-L Fix Ti LxWxH 52 x 22 x 9 mm, 5°	TILF5222-0905	1
Avenue-L Fix Ti LxWxH 52 x 22 x 11 mm, 5°	TILF5222-1105	1
Avenue-L Fix Ti LxWxH 52 x 22 x 13 mm, 5°	TILF5222-1305	1
Avenue-L Fix Ti LxWxH 52 x 22 x 9 mm, 8°	TILF5222-0908	1
Avenue-L Fix Ti LxWxH 52 x 22 x 11 mm, 8°	TILF5222-1108	1
Avenue-L Fix Ti LxWxH 52 x 22 x 13 mm, 8°	TILF5222-1308	1
Avenue-L Fix Ti LxWxH 52 x 22 x 9 mm, 14°	TILF5222-0914	1
Avenue-L Fix Ti LxWxH 52 x 22 x 11 mm, 14°	TILF5222-1114	1
Avenue-L Fix Ti LxWxH 52 x 22 x 13 mm, 14°	TILF5222-1314	1

### Footprint 58 x 22 mm

Description (L x W x H)	Part Number	QTY
Avenue-L Fix Ti LxWxH 58 x 22 x 7 mm, 5°	TILF5822-0705	1
Avenue-L Fix Ti LxWxH 58 x 22 x 9 mm, 5°	TILF5822-0905	1
Avenue-L Fix Ti LxWxH 58 x 22 x 11 mm, 5°	TILF5822-1105	1
Avenue-L Fix Ti LxWxH 58 x 22 x 13 mm, 5°	TILF5822-1305	1
Avenue-L Fix Ti LxWxH 58 x 22 x 9 mm, 8°	TILF5822-0908	1
Avenue-L Fix Ti LxWxH 58 x 22 x 11 mm, 8°	TILF5822-1108	1
Avenue-L Fix Ti LxWxH 58 x 22 x 13 mm, 8°	TILF5822-1308	1
Avenue-L Fix Ti LxWxH 58 x 22 x 9 mm, 14°	TILF5822-0914	1
Avenue-L Fix Ti LxWxH 58 x 22 x 11 mm, 14°	TILF5822-1114	1
Avenue-L Fix Ti LxWxH 58 x 22 x 13 mm, 14°	TILF5822-1314	1

## Instrument Overview



<b>Fast Connection Straight Handle</b>	PART NUMBER
	BOK-LC-55



<b>Pin Extractor</b>	PART NUMBER
Implant Holder with soft silicone handle	BOK-J-EX01

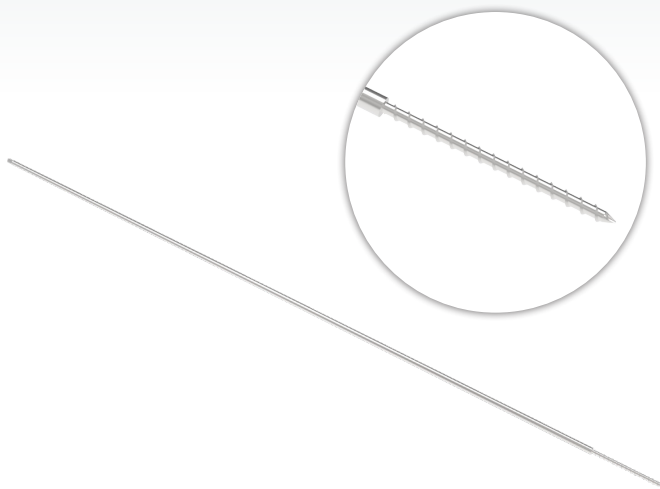


<b>Implant Holder</b>	PART NUMBER
Implant Holder with soft silicone handle	BOK-LDJ-01
Implant Holder Shaft	BOK-LDJ-02



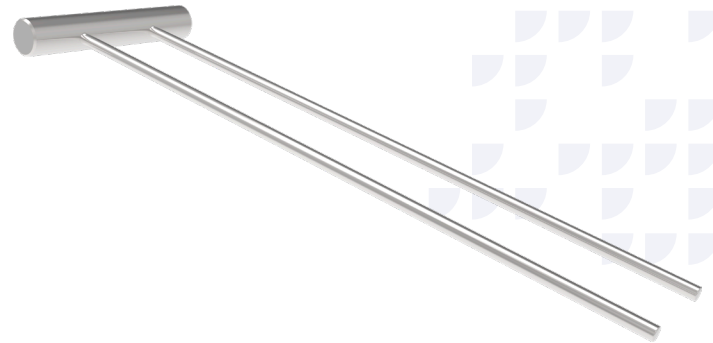
<b>Ghost Retractor</b>	PART NUMBER
	BOK-LD-04-22





**Ghost Retractor Fixing Wire (4x)**

PART NUMBER  
BOK-LD-06



**Fixing Wire Pusher**

PART NUMBER  
BOK-LD-08



**Ghost Retractor Shaft**

PART NUMBER  
BOK-LD-05-22

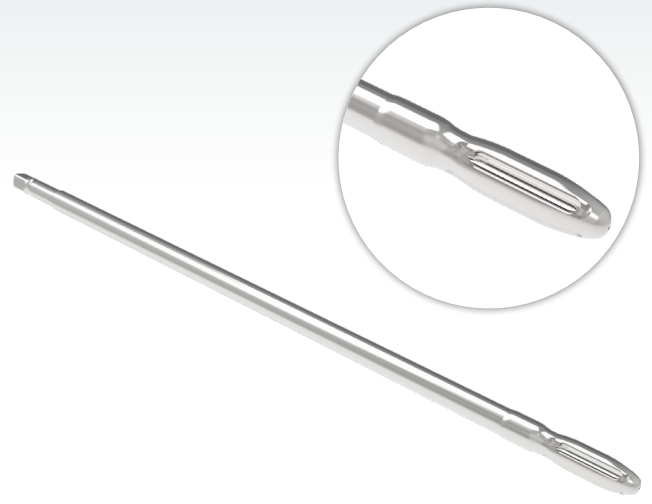


**Fixing Wire Screwdriver**

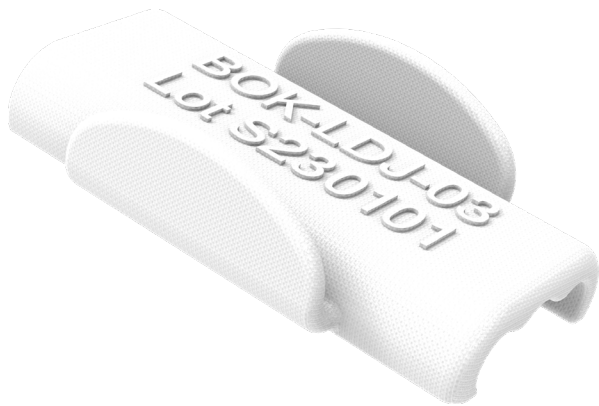
PART NUMBER  
BOK-LD-07



Flat Shaver Fast Connection	PART NUMBER
6 mm	BOK-LD-1006-FC
7 mm	BOK-LD-1007-FC
9 mm	BOK-LD-1009-FC
13 mm	BOK-LD-1013-FC



Parabolic Shaver Fast Connection	PART NUMBER
7 mm	BOK-LD-1107-FC
9 mm	BOK-LD-1109-FC
11 mm	BOK-LD-1111-FC
13 mm	BOK-LD-1113-FC



Holder Safety Clip	PART NUMBER
	BOK-LDJ-03



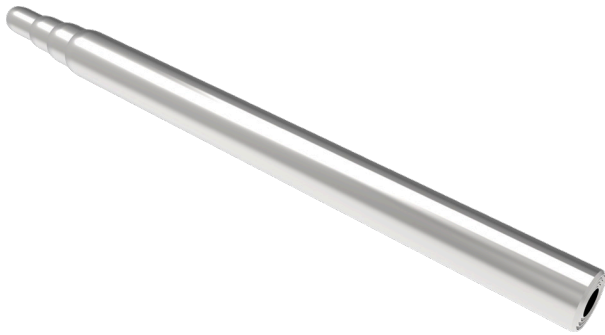
Fast Connection Trials	PART NUMBER
7 mm	BOK-LD-1207-FC
9 mm	BOK-LD-1209-FC
11 mm	BOK-LD-1211-FC
13 mm	BOK-LD-1213-FC



First Access Guide	PART NUMBER
Guide 1	BOK-LD-14-1
Guide 2	BOK-LD-14-2
Guide 3	BOK-LD-14-3
Guide 4	BOK-LD-14-4



Universal Slide Hammer	PART NUMBER
Double Fork Slide Hammer	BOK-LT-81



Tissue Dissectors	PART NUMBER
Tissue Dissector 1	BOK-LD-13-1
Tissue Dissector 2	BOK-LD-13-2B
Tissue Dissector 3	BOK-LD-13-3B
Tissue Dissector 4	BOK-LD-13-4B



Fixing Wire Spreader	PART NUMBER
	BOK-LD-15



**Hammer**

PART NUMBER

TH002



**Trays Avenue®-L Ti**

PART NUMBER

Tray 1

K3721-TILF1

Tray 2

K3721-TILF2

## Instructions for Use

### IMPORTANT INFORMATION ABOUT THE LUMBAR TITANIUM INTERBODY FUSION CAGE SYSTEM

The Lumbar Titanium Interbody Fusion Cage is intended to recreate and maintain distance between vertebrae to support biologic fusion in the thoracic, lumbar or lumbar-sacral spine zone. As complementary device, it should NOT be used as stand-alone. The device must always be within the limits of the vertebral cortices. If this indication is not followed, the device can be crushed because it protrudes from the spinal column and may not withstand the forces involved in such conditions.

### DESCRIPTION

The Lumbar Titanium Interbody Fusion Cage consists of cages in variable sizes and shapes. The dimensions of implants are designed based on anatomical conditions and decisions hereto are made by physicians.

The Lumbar Titanium Interbody Fusion Cage components should be used in combination with other spinal systems or other fixation systems in order to obtain stabilization.

All components of The Lumbar Titanium Interbody Fusion Cage cannot be re-used under any circumstances.

The Lumbar Titanium Interbody Fusion Cage is designed to be applied for posterior, posterio-or-lateral, anterior and lateral approach.

In particular, this instruction for use is applicable for codes:

ACT Cage for transforaminal arthrodesis "TLIF"

ACA "ALIF" anterior arthrodesis cage

ACP Cage for posterior arthrodesis "PLIF"

ACX Cage for lateral arthrodesis "XLIF"

ACL Cage for posterolateral oblique arthrodesis "OLIF"

ACO Anterior Cage for Lumbar Arthrodesis

ACTH Expandable lumbar cage

ACXH Expandable extra-lateral cage and variable lordosis for lumbar arthrodesis

ACPH Variable lordosis expandable cage for posterolateral arthrodesis

MM Expandable anterior cage for lumbar arthrodesis

CT Expandable anterolateral cage for lumbar arthrodesis

MMJ Self-locking expandable anterior cage for lumbar arthrodesis

ACXJ Self-locking extra-lateral cage for lumbar arthrodesis

ACAJ Self-locking anterior cage for lumbar arthrodesis

ACOJ Self-locking anterior cage for lumbar arthrodesis

ACTZ Lumbar Cage

### MATERIALS

The entire system is made of medical grade titanium described by ISO 5832-3 or 10993-5 or ASTM F2026 or ASTM F136 standards. All devices are manufactured from one of the foregoing material specifications.

### INDICATIONS

Lumbar Titanium Interbody Fusion Cage is intended for lumbar interbody fixation for the following indications:

- Degenerative disc disease.
- Spondylolisthesis.
- Spinal stenosis.
- Trauma.
- Tumour.
- Pseudo-arthrosis.
- Instability of motion segments.

### CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Risk of infection or infection in progress, or fever or inflammation.
- Obesity.
- Pregnancy.
- Mental illness.
- Allergy on any system components.
- Any anatomical, medical or surgical conditions which may preclude potential or intentional benefits of spinal implants application.

- Bone, joints or ligaments conditions such but not limited as: osteopenia, bone absorption, osteomalacia. Osteoporosis is relative contraindications a must be carefully evaluated prior surgery.
- Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
- Combination with implants from other manufacturers.
- Potential risk of unexpected patient's anatomy destruction, interference with neurological, functional or other deficits.
- Any risk of patient's unwillingness to follow postoperative instructions.
- Any other not described in indications.

**Caution:** *in case of reuse there is a danger of cross contamination ; any reuse is therefore not permitted.*

#### POTENTIAL ADVERSE EVENTS

Possible adverse events which might occur after spinal surgery with or without instrumentation including, but are not limited to:

- Disassembly, bending, and/or breakage of any or all of the system's components.
- Migration of any of the system's components.
- Pressure on the skin from component parts in patients with inadequate tissue coverage.
- Tissue or nerve damage caused by improper positioning and placement of implants or improper use of instruments.
- Dura leakage, distortion or damage.
- Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypertension, or any others related to surgery in general associated to anesthesia.
- Infections.
- Loss of urinary functions.
- Permanent or temporary or developing sexual dysfunctions.
- Postoperative change of body curvature, change of physiological range of movement.
- Pseudo-arthrosis or non-fusion or delayed fusion.
- Bone loss or overgrowth, or any other bone malformations.

- Permanent or temporary limitation or inability to perform daily activities.
- Change in mental behavior.
- Permanent or temporary or developing respiratory problems.
- Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
- Death.

In some cases, additional surgery or surgeries might be necessary to correct or change potential adverse events.

#### WARNINGS

The effectiveness and safety of interbody fixation is only applicable for certain conditions with which require the fusion supported by medical device. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumour, pseudo-arthrosis. The effectiveness and safety for any other conditions are unknown.

#### PRECAUTIONS

The Lumbar Titanium Interbody Fusion Cage are complementary implants to posterior fixation systems. The applications of pedicle screw and/or interbody cages should be performed by experienced surgeons with specific training in use of Lumbar Titanium Interbody Fusion Cage. The spinal screw fixation system and/or interbody cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful result is not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in treatment process. Patients with obesity, smokers and alcoholics are at risk for non-fusion. Also, patients with weak muscle or bone conditions and/or nervous system dysfunctions are poor candidates for spinal fusion. Prior or during or after the surgery, in order to evaluate or check the positioning of the implants or patient's anatomy or any other patient or implant correction, X-ray or CT or any other diagnostic examinations may be necessary. The proper, patient's individual implant selection in terms of type, size, shape or design is vital to successful surgery performance.

Proper implants and instruments' handling is crucial. Extensive bending or contouring should be avoided. Sharp cutting edges, reversed bending, scratching or notching may generate internal stress, which may weak the implants or construct.

**IMPORTANT:** All necessary information about surgery, potential risks, benefits and adverse effects should be conveyed to the patient prior to surgery.

#### PRE-OPERATIVE

- Patients that meet the criteria described in the indications should only be selected.
- Patients' conditions should be checked prior to surgery; any required diagnostics should be per-formed.
- The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
- All implants, instruments and any other components should be cleaned and sterilized before use. Any implants, instruments or components delivered in sterile packaging must be checked on sterility and expiration date of sterility prior surgery.
- Implants and instruments should be stored in certain conditions to warrant the sterility and protec-tion from any contamination or corrosive environment.
- It's highly recommended that all personnel interacting with any mechanical components of the spinal system should be familiar with all components before use.

#### INTRA-OPERATIVE

- Extreme caution should be taken when working close to or around the spinal cord and nerve roots.
- Whenever possible or required, intra-operative diagnostic systems should be used to facilitate surgery.
- Breakage, bends, scratch, slippage, part loosening or improper use of any implant or instrument during the surgery may cause injury to OR personal or patient.
- It's very important to follow the surgical technique carefully. Proper application of any instrument or implant may facilitate surgery.

- Before closing of soft tissue, double check of all implants' positioning, geometrical relations, and fixing, tightening or mounting maneuvers for all screws, nuts or other fixing parts have been performed. Image diagnostics is highly recommended at this stage.

#### POST-OPERATIVE

The physician's post-operative directions and warnings to the patient, and the corresponding patient's compliance, are extremely important.

- Detailed instructions about the use and limitations of the device should be communicated with the patient
- The patient should be warned to avoid falls or sudden jolts in spinal position.
- The patient should be warned for this possibility and instructed to limit and restrict physical activities, especially lifting and twisting movements and any type of sports participation. The patient should be advised not to smoke, or to consume alcohol or non-steroids or use anti-inflammatory medications such as aspirin during the bone graft healing.
- As a precaution, before patients with implants receive any subsequent surgery (such as surgical dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the LUMBAR TITANIUM INTERBODY FUSION CAGE components should never be reused under any circumstances.

#### PACKAGING

Lumbar Titanium Interbody Fusion Cage is sterile packaged; in order to control the correct sterilization, make sure that the package arrives properly closed. Do not use if the blister is open or damaged.

#### STORAGE

The components of the Lumbar Titanium Interbody Fusion Cage must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapours and extreme changes in temperature and humidity. Sterile parts must be stored in original packages as a precaution for prevented to any damages.

For more information, visit [ZimVie.com](https://www.zimvie.com)



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