Avenue®-T Exp Ti

Expandable Posterior Lumbar Curved 3D Printed Titanium Cage

Surgical Technique Guide




ZimVie

Avenue®-T Exp Ti

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Features and Characteristics

Avenue®-T Exp Ti Expandable Posterior Lumbar Curved 3D Printed Titanium Cage:

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 Angles

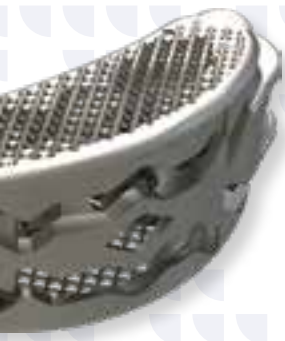
- One system intended to match patients' natural anatomy and surgeons' preferences.

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 Expansion Feature

- Avenue®-T Exp Ti has a special multi-direction expansion mechanism: it allows active cranial-caudal height expansion and amendment to the required lordosis angle by a passive adjustment of the implant's cranial and caudal contact surfaces to the natural anatomy of the patient. With this feature This feature is designed to enable surgeons to make the implant fit the natural anatomy the natural anatomy or achieve the required restoration of balance at one or more affected levels.
- Both implantation and the individual expansion features are being performed with one and the same implant introducer; no additional instruments are required. Intended to be easy to use and save time. For Avenue®-T Exp Ti, ZimVie offers two footprints and a range 8-13 mm heights, with possible lordosis angles ranging from 2° to 14°, thanks to its innovative expansion feature.



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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. 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-T Exp Ti is offered in 2 footprints with a
8 to 13mm height range with a 2° to 14° lordotic angle range:

Surgical Technique

Patient in prone position

Patient Positioning

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

Skin Incision

- By using fluoroscopy the appropriate level of the lumbar spine must be verified. Skin incision should allow adequate approach to reach the targeted spine segment(s). Additional instruments like a vertebral distractor and soft tissue retractors are subject of consideration to allow easier access to the required vertebral segment.
- To maintain proper vision on the surgical field a tissue retractor system is highly recommended. It is up to surgeon's experience to define and perform the soft tissue approach and bone decompression procedure. In some cases, specific patient's positioning may be required.

Surgical Technique (Continued)

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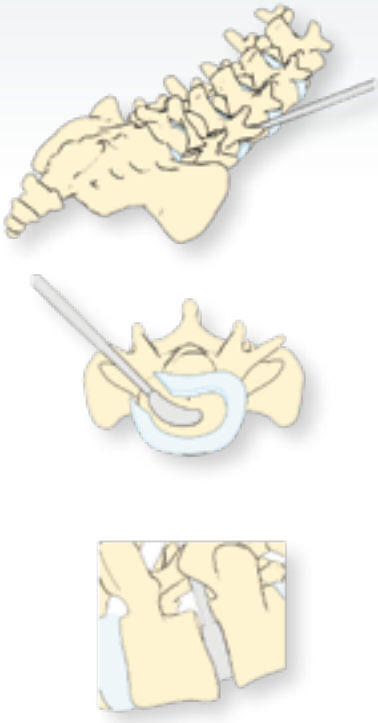


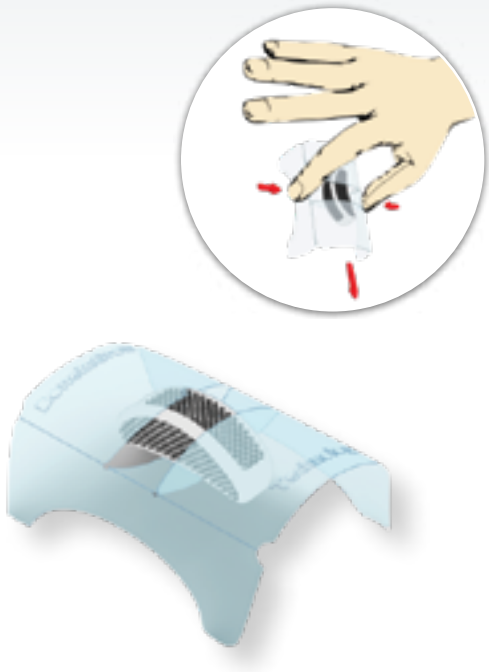
Implant dimension choice procedure.

Disc Removal and Endplate Preparation

- The discectomy procedure should be performed using standard disc cleaning instruments.
- The choice of appropriate instruments depends on approach, surgeons' preferences and projected results. Using rasps 13 with 1 mm increments and curettes is recommended while cleaning the disc (removal of nucleus material) and when preparing the vertebral endplate in order to create efficient bone contact (removal of superficial layers of the cartilage on the endplates). Adequate cleaning of the endplates is important to enable the provision of a blood supply to the implant. However, excessive cleaning may weaken the vertebral endplate and result in subsidence of the implant.

Implant Dimension Choice (Optional)

- Trialing step is optional for Avenue-T Exp Ti implant. Thanks to its expansion capability it will adapt to desired height and lordosis. Trials not included in Surgical Set by default. To be ordered separately if needed.

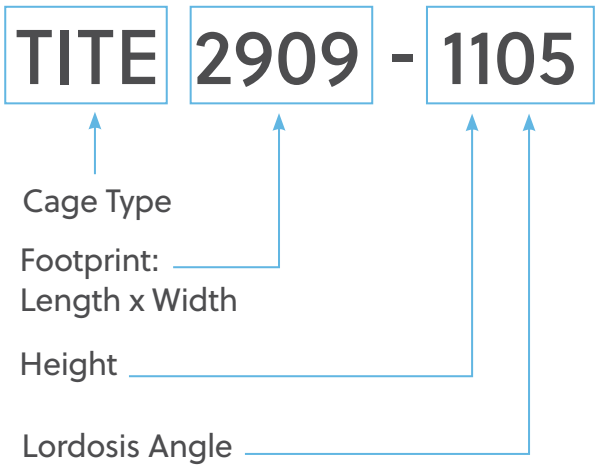


Implant packaging and release process.

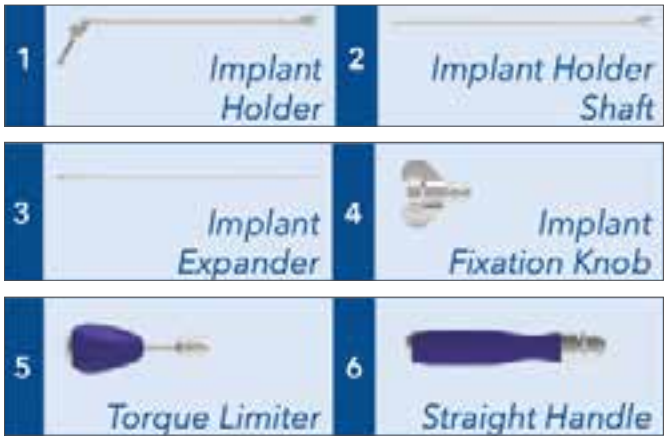
Implant Packing

- The implant is supplied in a double rigid blister pack with a special internal holder.
- The rotation nurse opens the outer (non-sterile) blister of the implant and hands the implant to the sterile OR nurse or scrubtech. The sterile OR nurse removes the inner (sterile) blister, opens it, takes out the holder and presses as indicated next to this text to release the implant.
- Always ensure that the sterility of the implant, which is located in the inner blister, is maintained.

Surgical Technique (Continued)



Components:



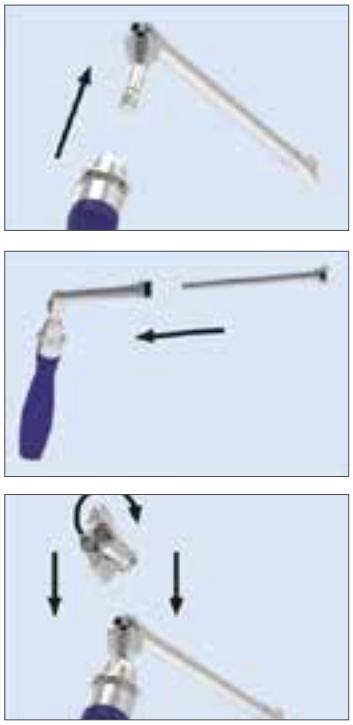
Implant Reference Code

- The correct implant size corresponds to the length and width of the trial implant (footprint); also an idea of the projected height can be achieved; the trial implant has no lordosis angle (lordosis angle 0 °).
- The projected lordosis angle for the implant is determined after evaluating the (pre-OP) fluoroscopic imaging

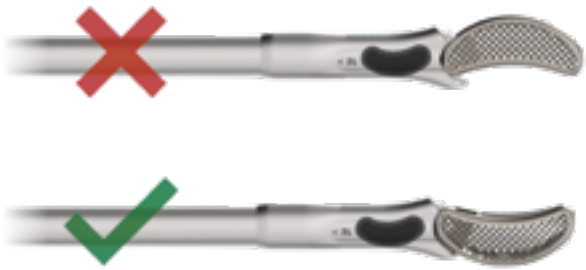
Assembly of Implant Holder

- Attach the straight handle to the implant holder and insert the implant holder shaft into the implant holder.
- Please note there is only one way to properly insert the implant holder shaft: the "clamp" on the distal part should allow the implant to get attached.
- Once in the correct position, attach the implant holder shaft to the implant fixation knob by tuning the knob clockwise after an initial first fixation of the thread of the implant holder shaft into the knob.

Caution: *ALWAYS make sure to attach the straight Silicone handle on the 90 degrees angled attachment of the implant holder and the Torque limiter on the ACPH expansion shaft and NEVER the other way around; If you'd use the straight Silicone handle on the ACPH expansion shaft: during the expansion process the implant may damage the vertebral endplates or the expansion shaft might damage the cage or even break.*



- Attach the Straight Handle to the Implant holder.
- Insert the holder Shaft.
- Attach the Implant Fixation Knob to the Implant Holder.



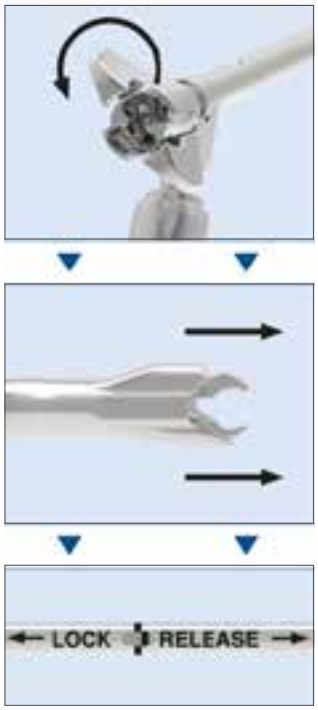
Cage Fixation on Implant Holder

Warning: DO NOT ASSEMBLE THE CAGE IN THE WRONG POSITION

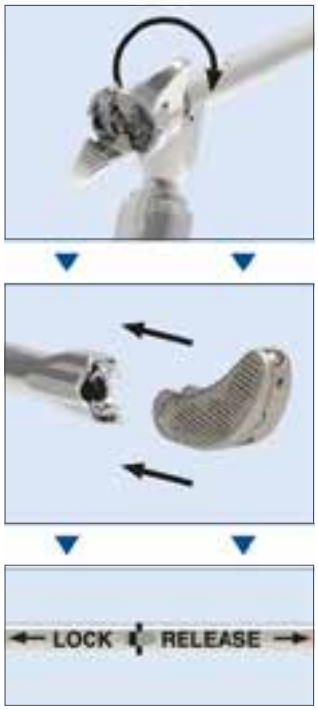
- Follow the directions as indicated in the picture above: align as indicated on the Implant Holder.
- Fix the implant with the inner line in the display of the Implant Holder shaft in the "release position" and turn the knob clockwise until the line reaches the "locked position".

Surgical Technique (Continued)

Position 1



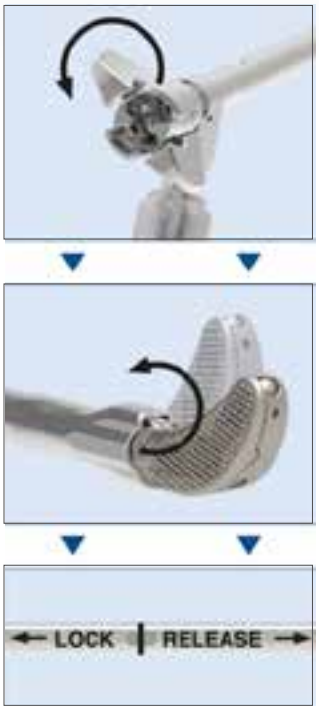
Position 2



Cage Fixation on Implant Holder and Implantation

- Position 1: Turn the Implant Fixation Knob to the left to expand the clamp and attach the implant.
- Position 2: Turn the Implant Fixation Knob to the right to lock the implant on the implant holder.

Position 3



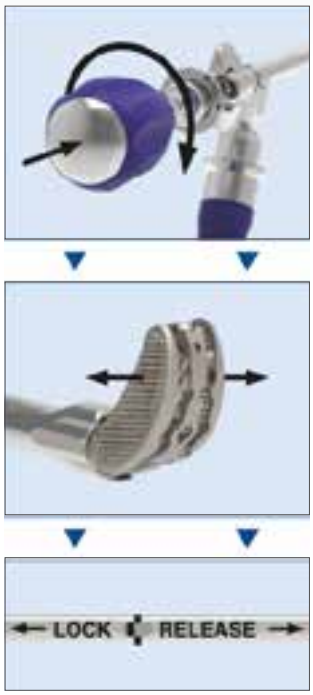
Position 4

- Position 3: Slightly turn the implant Fixation Knob to the left to allow the implant to turn.
- Position 4: Turn the Implant Fixation Knob to the right to lock the implant once in the desired position.

Surgical Technique (Continued)

Position 5

Position 6

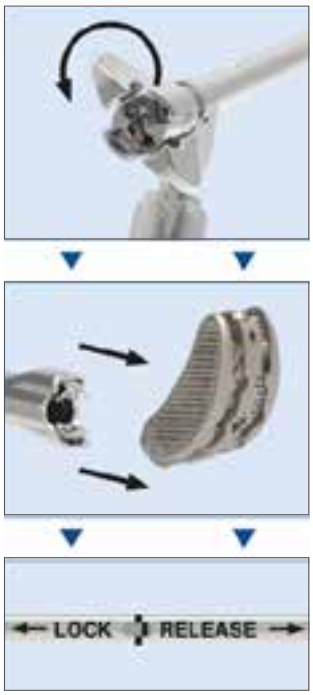


Cage Expansion and Release

- Position 5: Attach the Torque Limiter to the Implant Expander. Insert the Implant Holder til and audible "Click".
- Position 6: Insert the Implant Expander and turn to the right until the cage is expanded as desired.

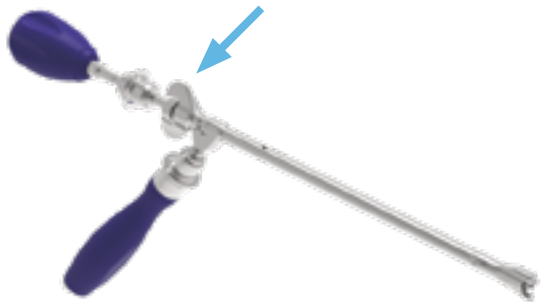
Position 7

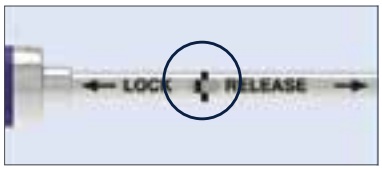
Position 8



- Position 7: Push simultaneously the small buttons on the Implant Fixation Knob to release and remove the Implant Expander.
- Position 8: Turn the Implant Fixation Knob to the left to release the implant.

Surgical Technique (Continued)



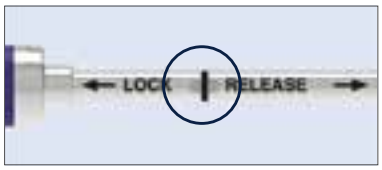


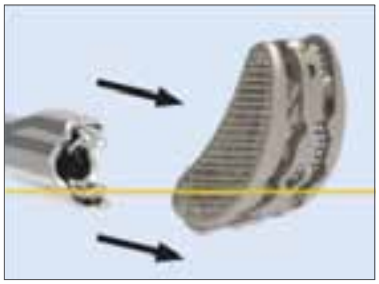
Control of Cage-Rotation

- There is a window in the Implant Holder shaft to recognise the cage fixation situation in 3 different positions

"LOCK" Position

- The cage is locked to the Implant Inserter and cannot rotate





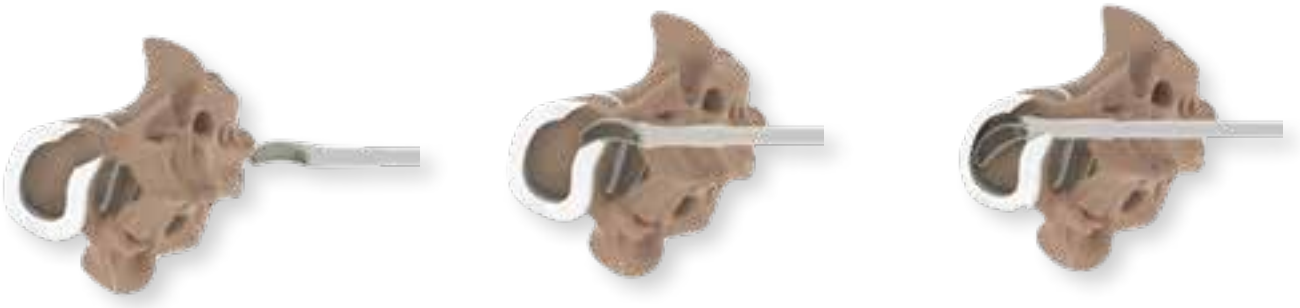
"CENTRAL" Position

- The cage can be rotated freely, but is still attached to the Implant Inserter to enable manipulation and rotation of the implant.
- Rotation is possible anywhere in between the Locked and Central position, but the Central position should never be surpassed.

"RELEASE" Position

- The cage is released from the Implant Inserter; The Implant Inserter can be removed, with the cage remaining in the intervertebral space

Surgical Technique (Continued)

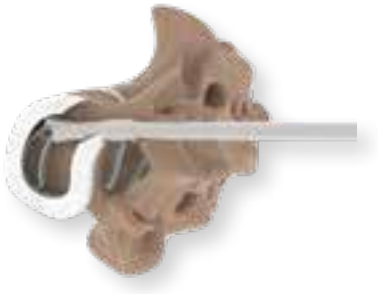


Cage Implantation Procedure

- Fix the implant firmly on the insertion tool: start with the indicator line in the "release position" and turn the fixing knob clockwise until the line reaches the "locked position" (See picture above). Then enter the disc space at an oblique angle.
- Continue inserting until the cage reaches the anterior annulus without turning the knob.

NOTE: *If impactation is needed for implant insertion and final positioning, make sure Torque limiting handle and Expander Shaft are removed from the Implant Holder. Reassemble once implant is in desired position and no further impactation is needed.*

- To rotate the cage in the intervertebral space, loosen the knob by turning counterclockwise, approximately to where the indicator lines align (see picture above); the cage rotates under pressure (apply light hammer blows), but remains attached to the implant holder.



- Push and manipulate the cage until the ideal position has been reached, keeping the indicator lines in between the "Locked" and Central (aligned) position, but never surpass the aligned position into the direction of the "release position" (see picture above on left).

- To release the cage, turn the fixing knob counterclockwise again until the display line arrives at the end of the display window in the direction of "Release" or disappears (see picture above)

Surgical Technique (Continued)

- (1) If necessary increase distraction to facilitate implant insertion. Insert the cage by gently hammering. Keep appropriate space for insertion. Guiding the procedure, Lateral X-rays are highly recommended during the implantation procedure.
- (2) After passing the posterior wall of the vertebral body, release the brackets that fix/hold the implant on the Implant Inserter into a multi axial position by slightly turning the fixation knob counterclockwise until the line in the window on the Implant inserter shaft moves to the middle till approximately fully aligned; do not surpass this Central/aligned position. the brackets holding the implant move into a Semi-Open position, anywhere in between the fully "Locked" and Central Position.
- When surpassing the Central/aligned position in the direction of the "Release" position, there is a serious chance to release the implant from the Implant Holder, which at this stage of the procedure would create serious challenges. Change the sagittal angulation of the Implant Holder by continuing gentle hammer blows to rotate the TLIF implant into the required position. Changing the angulation of the Implant Holder increases turning forces and facilitates the implant rotation procedure.
- (3) After final positioning has been reached, release the brackets fully by turning the knob counterclockwise until the display line arrives at the end of the display window in the direction of "Release" or disappears. Detach the Implant Holder. Remove the Implant Holder and check the implant position, both in AP and Lateral X-rays.

Implant Overview

Footprint 32 x 9 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Exp Ti 32 x 9 x 8-13 mm; 2°- 8°	TITE3209-0805	2
Avenue-T Exp Ti 32 x 9 x 9-13 mm; 6°- 14	TITE3209-0808	4

Footprint 40 x 9 mm (Optional)

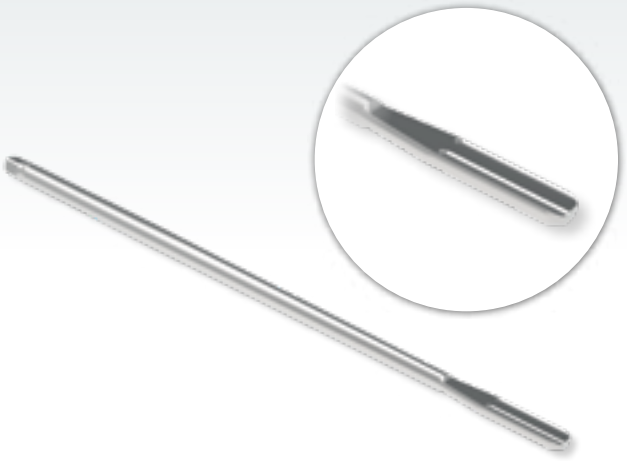
Description (L x W x H)	Part Number	QTY
Avenue-T Exp Ti 40 x 9 x 8-13 mm; 2°- 8°	TITE4009-0805	0
Avenue-T Exp Ti 40 x 9 x 9-13 mm; 6°- 14°	TITE4009-0808	0

**Optional. Available by special order*

Instrument Overview

Fast Connection T Handle	Part Number
	BOK-LC-52

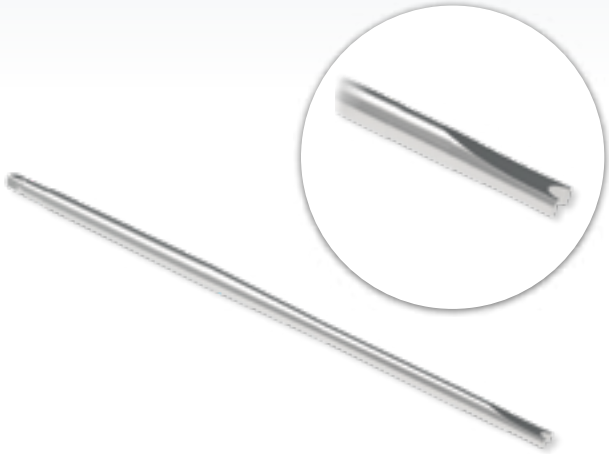
Implant Holder (Dismantable)	Part Number
ACTH Implant Holder	BOK-LTH-01
ACTH Implant Holder Shaft	BOK-LTH-02
ACTH Implant Expansion Shaft	BOK-LTH-03
ACTH Implant fixation Knob	BOK-LTH-04
Straight Handle Fast Connection	BOK-LC-55
Torque Limiter 2 NM Fast Connection	TRQ-01



Shavers	Part Number
	BOK-LC-250-**
7 mm	BOK-LC-250-07
8 mm	BOK-LC-250-08
9 mm	BOK-LC-250-09
10 mm	BOK-LC-250-10
11 mm	BOK-LC-250-11
12 mm	BOK-LC-250-12
13mm	BOK-LC-250-13

Double Side Curved Squared Curette	Part Number
	BOK-LT-72

Instrument Overview (Continued)



Implant Impactor	Part Number
	BOK-LT-73L

Footprint Sizer	Part Number
32 x 07 mm	BOK-LT-280-3207
40 x 08 mm	BOK-LT-280-4007

Hammer	Part Number
	TH002

Medium Tray Avenue-T Exp Ti	Part Number
	K3725-TITE

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 vertebras 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.

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 Lumbar Titanium Interbody Fusion Cage cannot be re-used under any circumstances.

Lumbar Titanium Interbody Fusion Cage is designed to be applied for posterior, posteri-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, oste-omalacia. 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, func-tional 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 treat-ment 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 protection 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

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