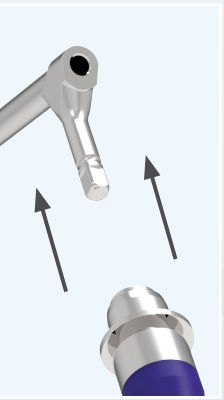
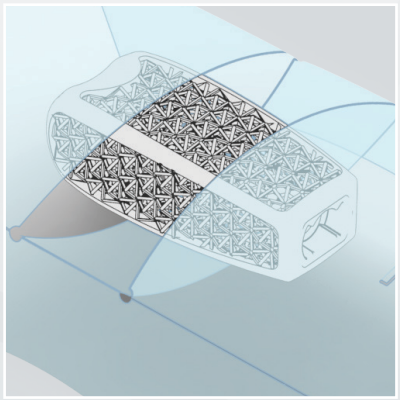
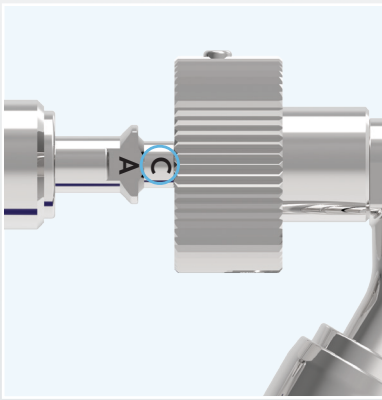
Avenue®-P Exp Ti

Expandable Posterior Lumbar Straight 3D Printed Titanium Cage

Surgical Technique Guide







ZimVie

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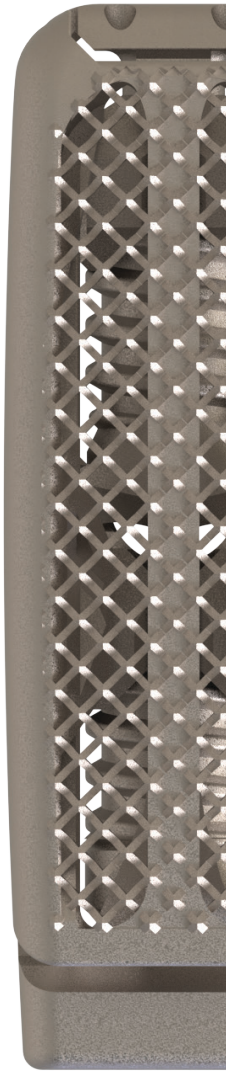
ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual guide based on surgical techniques. Each surgeon should 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®-P Exp Ti
Expandable Posterior Lumbar 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

- Avenue® P Exp Ti has a special multi-direction mechanism: it allows cranial-caudal height extension and amendment to the required lordosis angle by individual and gradual expansion in anterior and posterior direction. This feature is designed to enable surgeons to make the implant fit 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 the same implant holder; no additional instruments are required. Intended to be easy to use and save time.

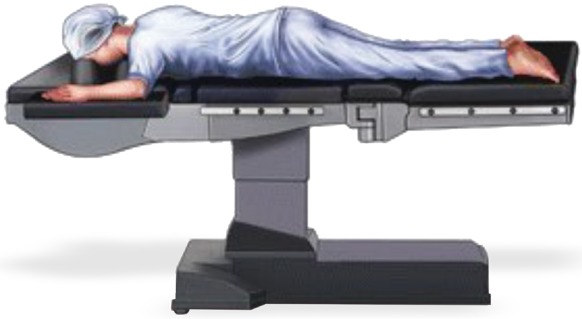
Avenue-P Exp Ti is offered in two lengths and a 9 to 14mm height range, with a 0° to 20° lordotic angle range:

29 x 9 mm 32 x 9 mm

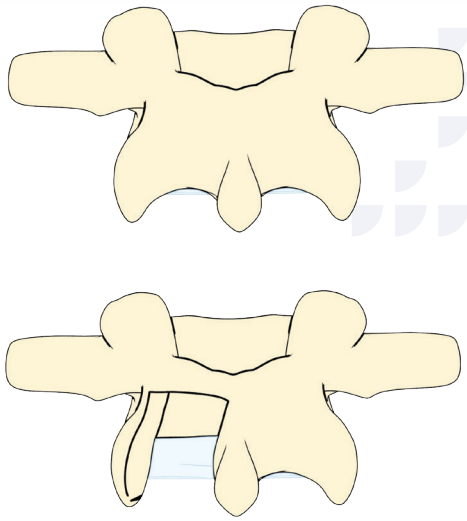
From 9 to 14 mm

From 0° to 20° *Lordosis*

Surgical Procedure



Patient in prone position



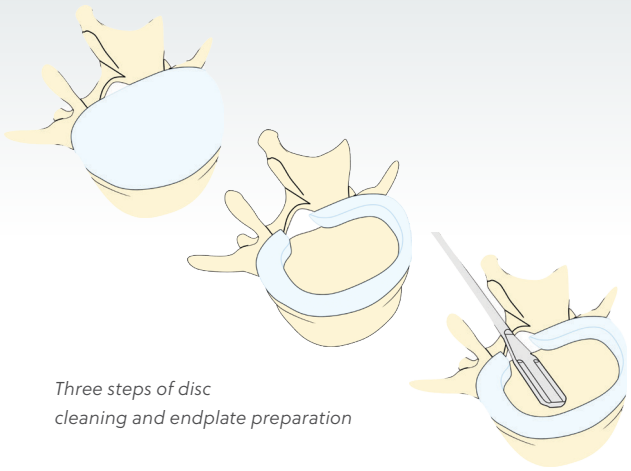
Skin incision procedure

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.

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.



Three steps of disc cleaning and endplate preparation

Shaver

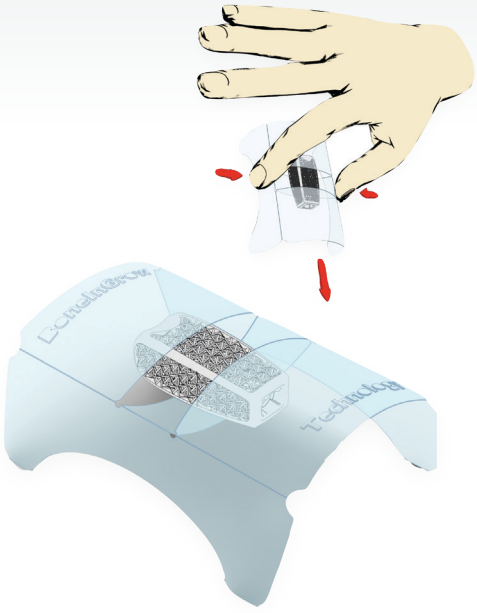
Squared Curette

Disc Removal / Endplate Preparation

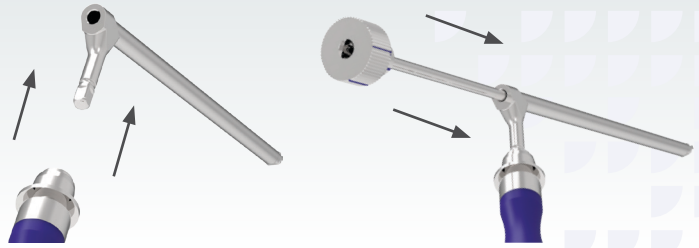
- The discectomy procedure should be performed using standard disc cleaning instruments. The choice of appropriate instruments depends on surgical approach, surgeons' preferences and projected results. Using Rasps (standard in the set with 1 mm increments) and One Side Squared Curette is recommended 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

- Trialing step is optional for Avenue-P 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. Imaging is strongly recommended to decide on the lordosis angulation of the implant.

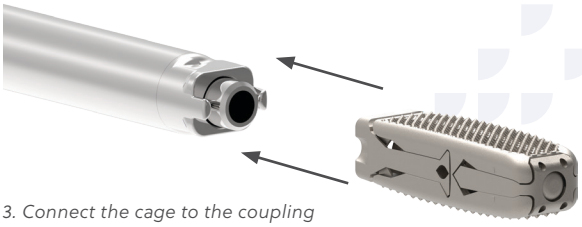


Implant packaging and release process



1. Connect the Straight Handle to the Holder

2. Insert the Holder Shaft



3. Connect the cage to the coupling

Components:

1	Implant Holder
2	Implant Holder Shaft
3	Expansion Shaft
4	TRQ-01
5	Straight Handle

Implant Packaging

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

Implant Preparation

- Insert the implant holder shaft into the implant holder and attach the straight Silicone handle, which has a quick coupler for the attachment, on the 90 degrees angled attachment on the implant holder;
- To avoid confusion or even cause damages on implants or instruments:
  - Connect the implant to the assembled implant holder by turning the knob clockwise on the silicone handle till a solid fixed position has been reached in order to avoid any problems during final implant positioning.
  - The straight Silicone handle is attached before implant implantation; the Torque limiter (TRQ-01) is assembled after implant implantation.

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.

Example

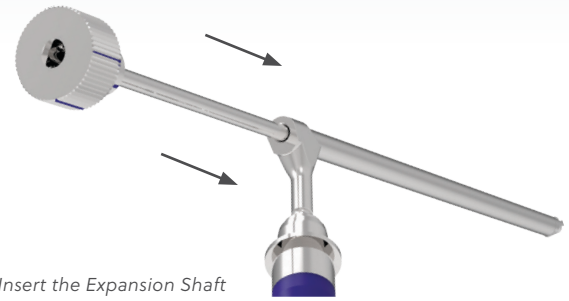
Cage Length	52 mm
Cage Width	29 mm
* Cage Height:	9-14 mm
** Cage Lordosis Angle:	0° - 20°

(to be chosen after evaluating radiological imaging)

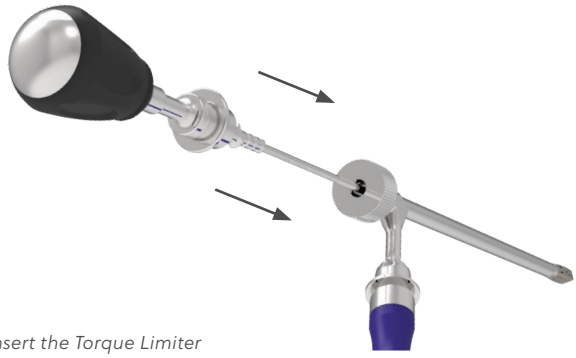
TIPE	–	2909	–	0900
		Footprint: Length x Width		*Height* *Lordosis Angle*

* *Cage Length > Ranges from 9-14 mm; minimal height (9mm) is shown in the reference code.*

** *Lordosis Angle > Ranges from 0° -20°; minimal angle (0° mm) is shown in the reference code.*



4. Insert the Expansion Shaft



5. Insert the Torque Limiter

Implant Reference Code

- Height and Lordosis Angle are controlled by the implant's expansion mechanism: determined after evaluation of (pre-OP) fluoroscopy imaging. Length (either 32 or 29 mm) is also following (pre-OP) fluoroscopy imaging and surgeon's preference..
- The footprint and lordosis angle are determined after evaluating the (pre-OP) fluoroscopic imaging.

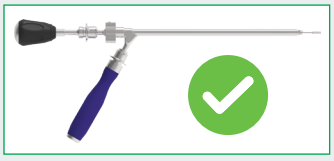
Cage Implantion

- If necessary, increase the distraction of the vertebral segment to facilitate implant insertion.
- Insert the cage, giving gentle hammer blows on the back side (which is facing you) of the implant holder shaft, using the hammer till final positioning has been reached.

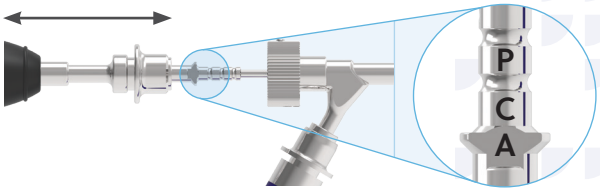
Expansion Preparation

- Only after the implant is in the correct position, and no further impaction is needed,, insert the ACPH expansion shaft. To complete the implant inserter assembly, assemble the Torque limiter (TRQ-01), which has a quick coupler for the attachment on the ACPH expansion shaft.

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.*

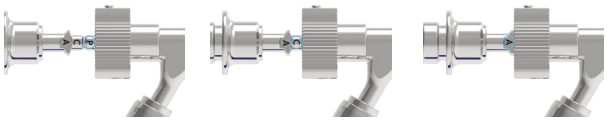


Straight Silicone Handle and Torque Limiter Attachment



Position of the Expansion Nodes

6. Screw the Torq Limiter to expand the cage



Position P *Position C* *Position A*

Expands the posterior part *Expands both sides* *Expands the anterior part*

Expansion of Implant

- Expand the implant "parallel" first by turning the Torque limiter (TRQ-01) clockwise, starting in position "C" till an initial lock in the intervertebral disc space has been reached , after which amendments can be made adjusting the height of the anterior and/or posterior parts of the implant; to this, follow the scheme in the different positions of the expansion nodes at the proximal part of the ACPH expansion shaft (BOK-LCH-03). The Torque limiter prevents "over-expansion" and thus potentially damaging the vertebral endplates and/or the implant's expansion mechanism.

- **Position "P"**
  Expands the posterior part of the implant.

  Position "C"
  Expands both sides (Parallel expansion).

  Position "A"
  Expands the anterior part of the implant.

After Cage Implantaion and Expansion

- Detach the implant inserter once a firm fixation in the intervertebral space has been achieved: remove the assembled Torque limiter and ACPH expansion shaft first by gently toggling the ACPH expansion shaft out; then turn the knob of the the implant holder shaft counterclockwise to release the implant from the inserter.
- Lateral fluoroscopic imaging control during both the implantation and expansion procedure is strongly recommended.
- Prior to placement of the second implant, autologous bone or bone substitutes could be inserted into the intervertebral disc space close to the implant, leaving enough space for the second implant.
- Repeat the assembly and implantation procedure for the insertion of the second cage on the contralateral side.

Implant Overview

Description (L x D x H)	Part Number	QTY
Avenue-P Exp Ti 29 x 9; 9-14 mm; 0°- 20°	TIPE2909-0900	3
Avenue-P Exp Ti 32 x 9; 9-14 mm; 0°- 20°	TIPE3209-0900	3

Instrument Overview

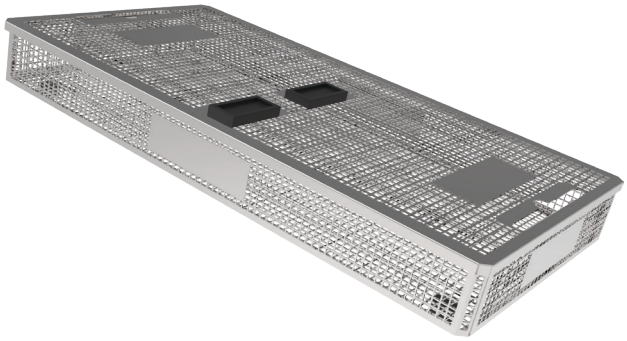
Implant Holder (Assembly)	PART NUMBER
Implant Holder with soft silicone handle	BOK-LCH-01
Implant Holder Shaft	BOK-LCH-02
ACPH Expander	BOK-LCH-03
Fast Connection Straight Handle	BOK-LC-55
Torque Limiter 2 NM Fast Connection	TRQ-01

Fast Connection T Handle	PART NUMBER
	BOK-LC-52

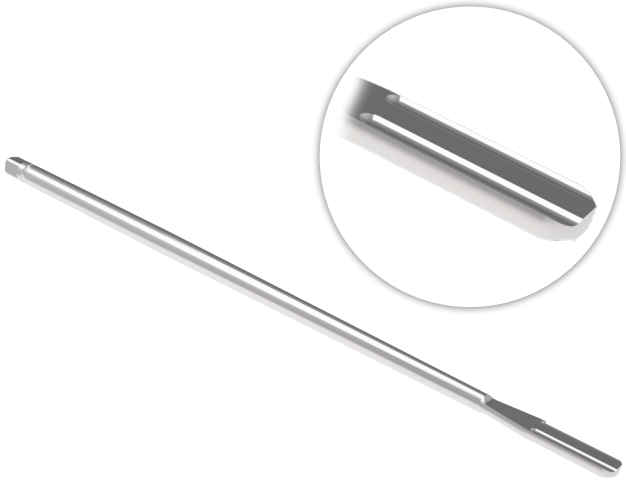
Footprint Sizer	PART NUMBER
29 x 05 mm	BOK-LC-280-2905
32 x 05 mm	BOK-LC-280-3205

Hammer	PART NUMBER
	TH002

One Side Squared Curette	PART NUMBER
	BOK-LC-70



Medium Tray Avenue-P Exp Ti	PART NUMBER
	K3725-TIPE



Shavers	PART NUMBER
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
13 mm	BOK-LC-250-13

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 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

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