



Avenue[®]-L Ta

Lateral Lumbar 3D Printed Tantalum Cage

Surgical Technique Guide

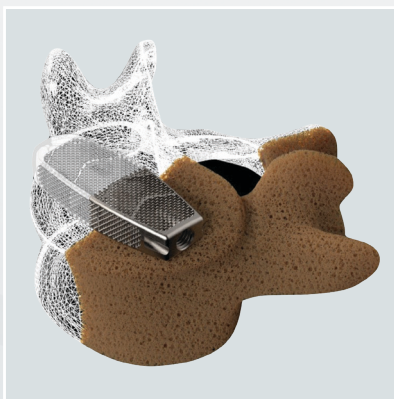


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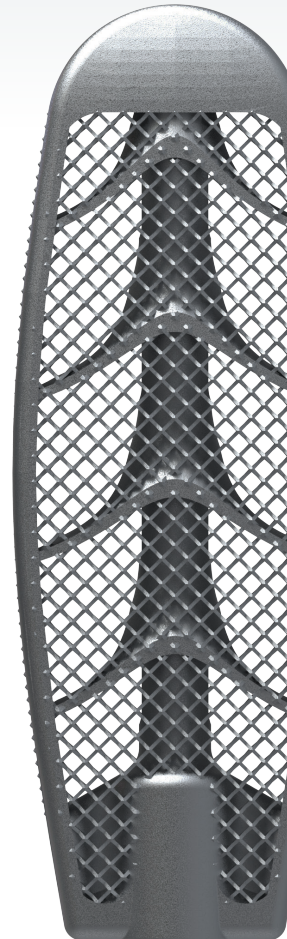
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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual 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®-L Ta

Lateral Lumbar 3D Printed Tantalum 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.

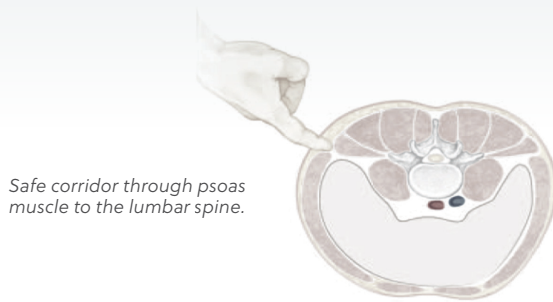
Tantalum is one of the most Chemically Stable Metals

- Porous Trabecular Metal in Tantalum has been used in Orthopaedic implants for more than 25 years with plenty of clinical publications evaluating its use.

Avenue-L Ta is offered in 4 lengths, 4 heights, and with 3 lordosis angles:



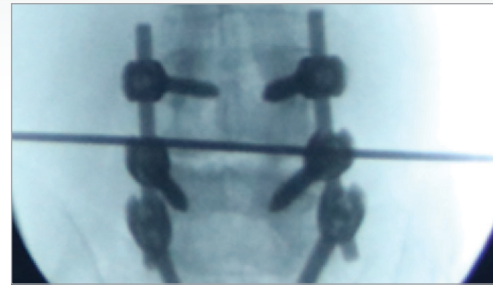
Surgical Procedure



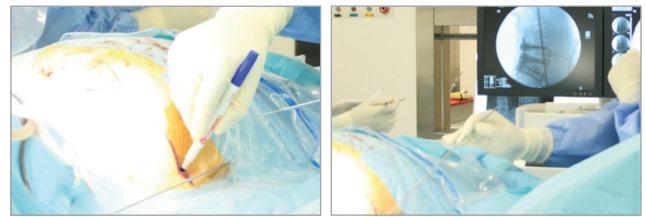
Safe corridor through psoas muscle to the lumbar spine.



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.

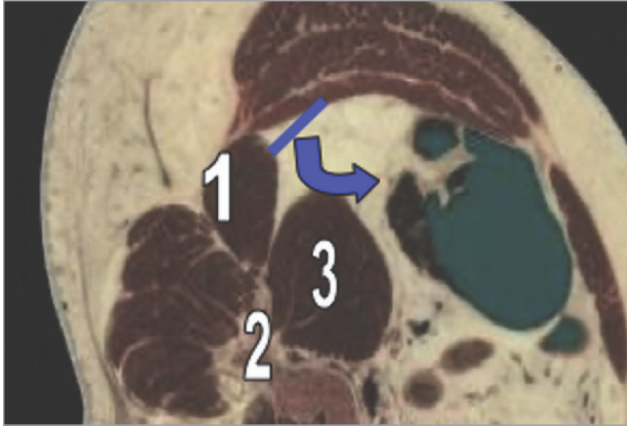
Surgical Incision Preparation

- 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.

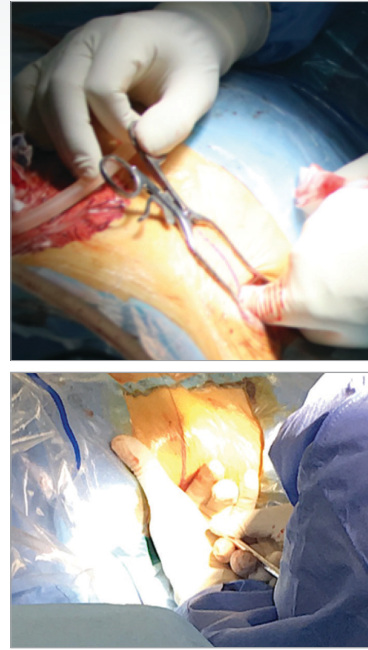
Skin Incision

- 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.



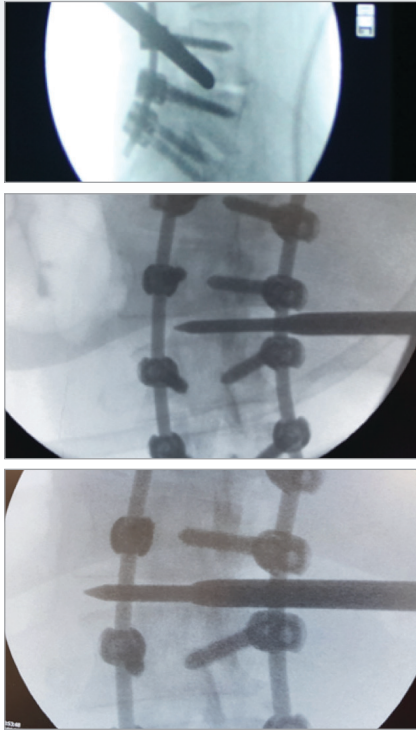
Two moments of the vertebral disc entering procedure during surgery.

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).

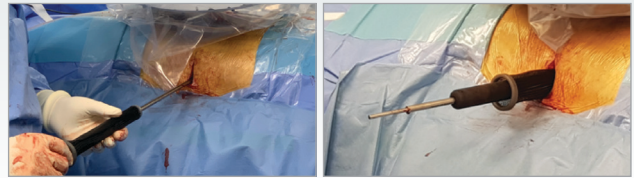
Cannulated Instrument.



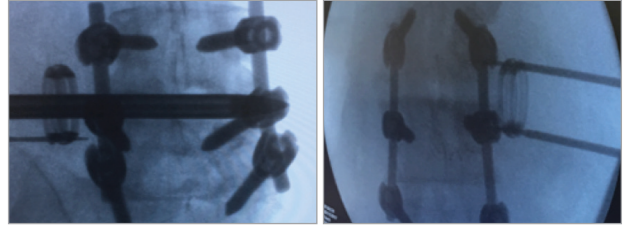
Enlargement of psoas muscle fibers during surgery.

Dissection Cannulas

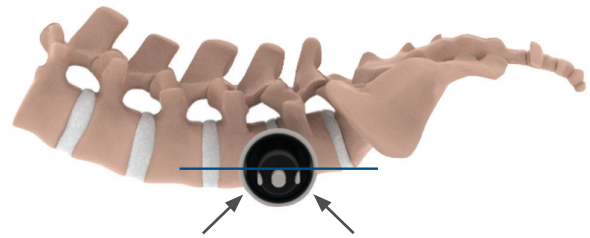
- When surgeons deem necessary to add an additional bone growth accelerator, a Universal Filling System effectively supports the bone substitute filling procedure, either at pre-implantation or post-implantation stage of the surgical procedure.
- Is very useful to also push the cannula inside the disc 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.



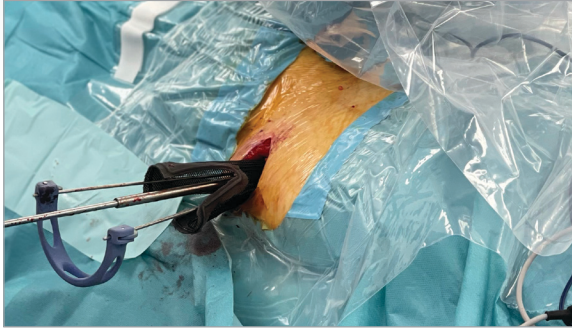
Correct positioning of the Ghost retractor.

Retractor Assembling

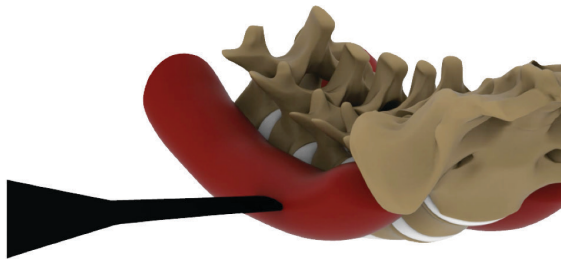
- Slide the retractor holder inside the Ghost retractor and push the square end of the holder into the metallic ring of the retractor till it stops (there is a hard stop on the holder).

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.



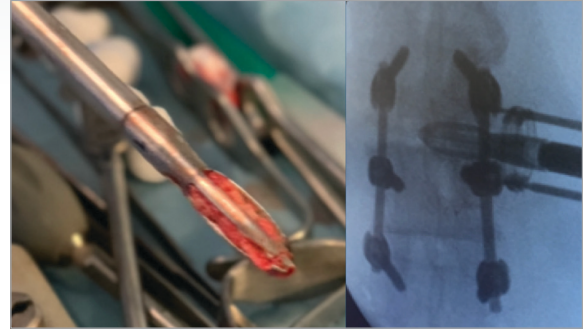
Fixing wire spreader attached onto the fixing wires during surgery.



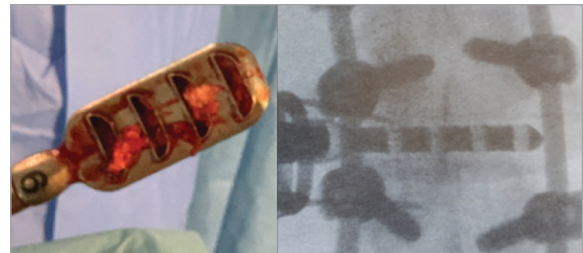
Position of Ghost retractor through the psoas muscle.

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.



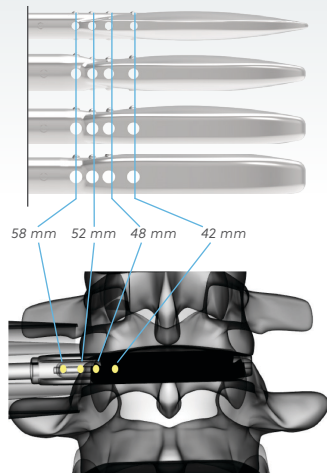
Round shaver during surgery, live picture and X-rays.



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

Discectomy

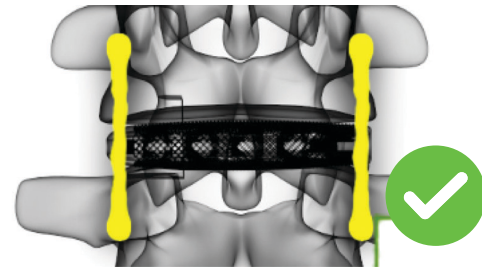
- Two different shavers are available in the instrument set. First use the round shavers to prepare the space for the parabolic ones.
- The parabolic shavers are particularly indicated to prepare the vertebral endplate. Proceed progressively from the smaller to the bigger size to prepare the disc space 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.



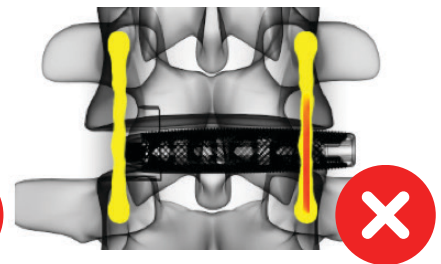
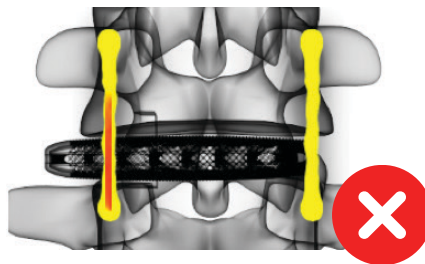
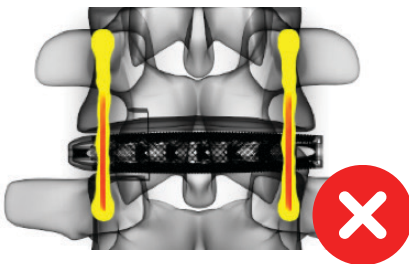
Practical example on length definition through probe usage.



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).

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.

Example

| | |
|---|-------|
| Cage Length | 52 mm |
| Cage Width | 18 mm |
| Cage Height | 9 mm |
| Cage Lordosis Angle | 8° |
| <i>(to be chosen after evaluating radiological imaging)</i> | |



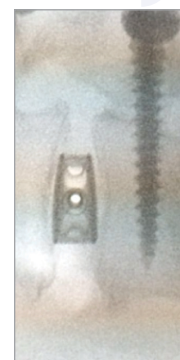
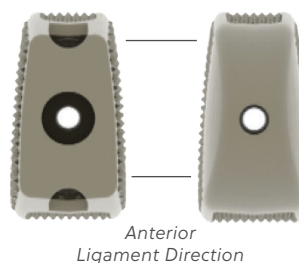
Implant Reference Code

- 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 connected onto the assembled implant holder.

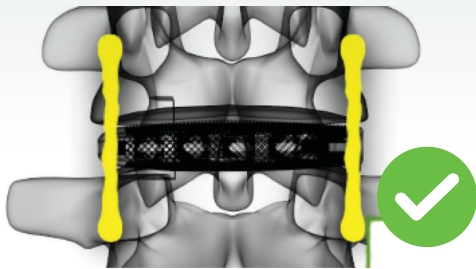
Foramen Direction



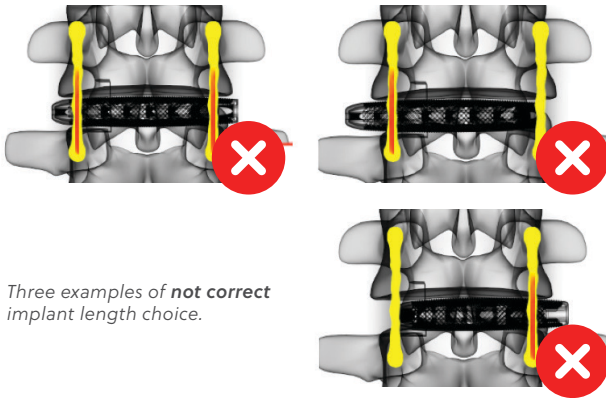
X-ray showing the correct positioning of implant

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.

Wire Spreader.



Ghost Retractor.



Retractor Holder.



Fixing wire Screwdriver.



Implant Positioning

- 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. By using the hammer (TH002) gently push the cage inside the disc space, keeping attention to reach the contralateral edge (bi-cortical positioning).
- This operation has to be carefully monitored with fluoroscopy support: both AP and Lateral view. Using the hammer and the fluoroscopy control, push the cage inside the disc space, keeping attention to centre the cage into the disc.

Note: The implant should never exceed the lateral walls of the vertebral bodies.

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 Ta LxWxH 42 x 18 x 7 mm; 5° | TAL4218-0705 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 9 mm; 5° | TAL4218-0905 | 2 |
| Avenue-L Ta LxWxH 42 x 18 x 11 mm; 5° | TAL4218-1105 | 2 |
| Avenue-L Ta LxWxH 42 x 18 x 13 mm; 5° | TAL4218-1305 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 7 mm; 8° | TAL4218-0708 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 9 mm; 8° | TAL4218-0908 | 2 |
| Avenue-L Ta LxWxH 42 x 18 x 11 mm; 8° | TAL4218-1108 | 2 |
| Avenue-L Ta LxWxH 42 x 18 x 13 mm; 8° | TAL4218-1308 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 7 mm; 14° | TAL4218-0714 | 0* |
| Avenue-L Ta LxWxH 42 x 18 x 9 mm; 14° | TAL4218-0914 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 11 mm; 14° | TAL4218-1114 | 1 |
| Avenue-L Ta LxWxH 42 x 18 x 13 mm; 14° | TAL4218-1314 | 1 |

Footprint 48 x 18 mm

| Description (L x W x H) | Part Number | QTY |
|--|--------------|-----|
| Avenue-L Ta LxWxH 48 x 18 x 7 mm; 5° | TAL4818-0705 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 9 mm; 5° | TAL4818-0905 | 2 |
| Avenue-L Ta LxWxH 48 x 18 x 11 mm; 5° | TAL4818-1105 | 2 |
| Avenue-L Ta LxWxH 48 x 18 x 13 mm; 5° | TAL4818-1305 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 7 mm; 8° | TAL4818-0708 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 9 mm; 8° | TAL4818-0908 | 2 |
| Avenue-L Ta LxWxH 48 x 18 x 11 mm; 8° | TAL4818-1108 | 2 |
| Avenue-L Ta LxWxH 48 x 18 x 13 mm; 8° | TAL4818-1308 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 7 mm; 14° | TAL4818-0714 | 0* |
| Avenue-L Ta LxWxH 48 x 18 x 9 mm; 14° | TAL4818-0914 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 11 mm; 14° | TAL4818-1114 | 1 |
| Avenue-L Ta LxWxH 48 x 18 x 13 mm; 14° | TAL4818-1314 | 1 |

Footprint 52 x 18 mm

| Description (L x W x H) | Part Number | QTY |
|--|--------------|-----|
| Avenue-L Ta LxWxH 52 x 18 x 7 mm; 5° | TAL5218-0705 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 9 mm; 5° | TAL5218-0905 | 2 |
| Avenue-L Ta LxWxH 52 x 18 x 11 mm; 5° | TAL5218-1105 | 2 |
| Avenue-L Ta LxWxH 52 x 18 x 13 mm; 5° | TAL5218-1305 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 7 mm; 8° | TAL5218-0708 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 9 mm; 8° | TAL5218-0908 | 2 |
| Avenue-L Ta LxWxH 52 x 18 x 11 mm; 8° | TAL5218-1108 | 2 |
| Avenue-L Ta LxWxH 52 x 18 x 13 mm; 8° | TAL5218-1308 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 7 mm; 14° | TAL5218-0714 | 0* |
| Avenue-L Ta LxWxH 52 x 18 x 9 mm; 14° | TAL5218-0914 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 11 mm; 14° | TAL5218-1114 | 1 |
| Avenue-L Ta LxWxH 52 x 18 x 13 mm; 14° | TAL5218-1314 | 1 |

Footprint 58 x 18 mm

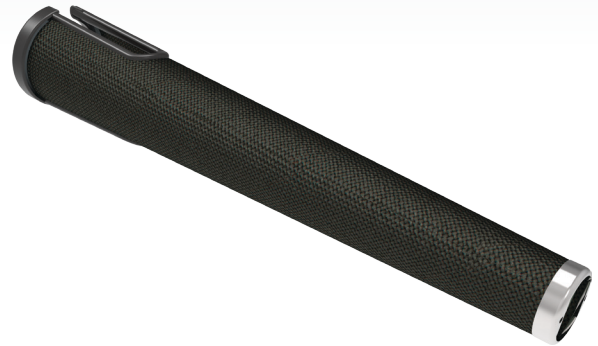
| Description (L x W x H) | Part Number | QTY |
|--|--------------|-----|
| Avenue-L Ta LxWxH 58 x 18 x 7 mm; 5° | TAL5818-0705 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 9 mm; 5° | TAL5818-0905 | 2 |
| Avenue-L Ta LxWxH 58 x 18 x 11 mm; 5° | TAL5818-1105 | 2 |
| Avenue-L Ta LxWxH 58 x 18 x 13 mm; 5° | TAL5818-1305 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 7 mm; 8° | TAL5818-0708 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 9 mm; 8° | TAL5818-0908 | 2 |
| Avenue-L Ta LxWxH 58 x 18 x 11 mm; 8° | TAL5818-1108 | 2 |
| Avenue-L Ta LxWxH 58 x 18 x 13 mm; 8° | TAL5818-1308 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 7 mm; 14° | TAL5818-0714 | 0* |
| Avenue-L Ta LxWxH 58 x 18 x 9 mm; 14° | TAL5818-0914 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 11 mm; 14° | TAL5818-1114 | 1 |
| Avenue-L Ta LxWxH 58 x 18 x 13 mm; 14° | TAL5818-1314 | 1 |

*Optional. Available by special order

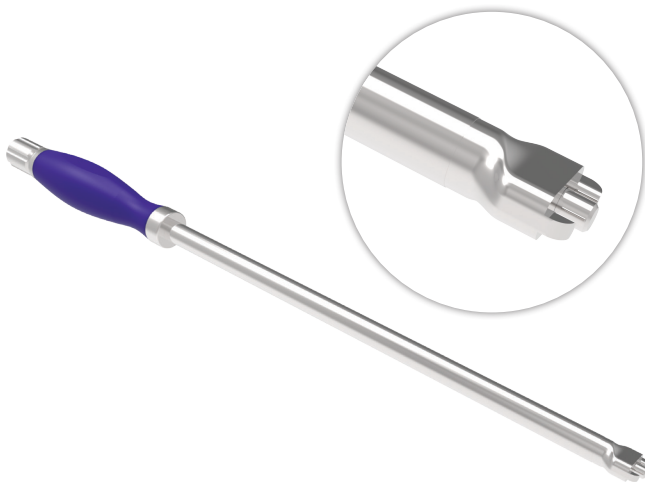
Instrument Overview



| | |
|--|-------------|
| Fast Connection Straight Handle | PART NUMBER |
| | BOK-LC-55 |



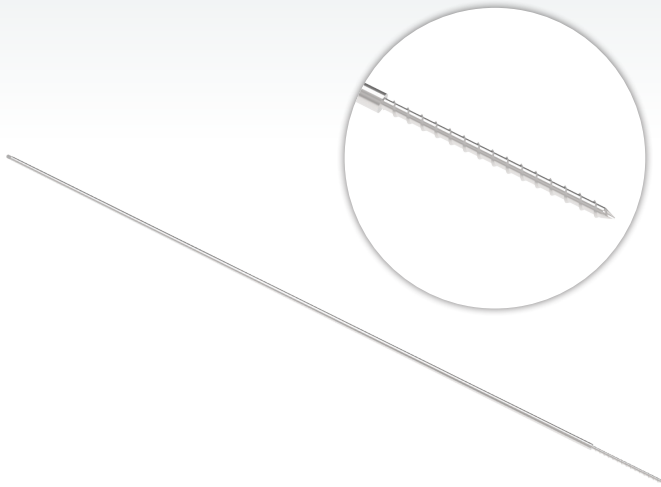
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|------------------------|--------------|
| Ghost Retractor | PART NUMBER |
| | BOK-LD-04-22 |



| | |
|--|-------------|
| Implant Holder | PART NUMBER |
| Implant Holder with soft silicone handle | BOK-LD-01 |
| Implant Holder Shaft | BOK-LD-02 |



| | |
|------------------------------|--------------|
| Ghost Retractor Shaft | PART NUMBER |
| | BOK-LD-05-22 |



| | |
|---|-------------|
| Ghost Retractor Fixing Wire (4x) | PART NUMBER |
| | BOK-LD-06 |



| | |
|---------------------------|-------------|
| Fixing Wire Pusher | PART NUMBER |
| | BOK-LD-08 |



| | |
|--------------------------------|-------------|
| Fixing Wire Screwdriver | PART NUMBER |
| | BOK-LD-07 |



| | |
|------------------------------------|----------------|
| Flat Shaver Fast Connection | PART NUMBER |
| 7 mm | BOK-LD-1007-FC |
| 9 mm | BOK-LD-1009-FC |
| 11 mm | BOK-LD-1011-FC |
| 13 mm | BOK-LD-1013-FC |



Fast Connection Trials

PART NUMBER

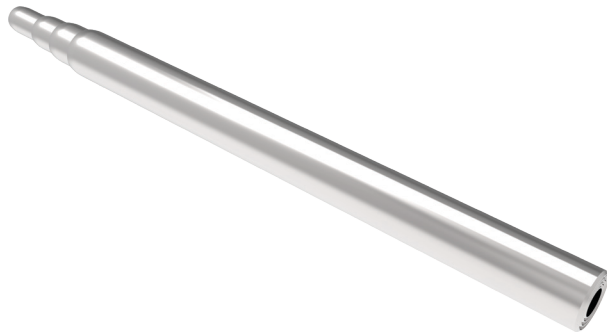
| | |
|-------|----------------|
| 7 mm | BOK-LD-1207-FC |
| 9 mm | BOK-LD-1209-FC |
| 11 mm | BOK-LD-1211-FC |
| 13 mm | BOK-LD-1213-FC |



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 |



Tissue Dissectors

PART NUMBER

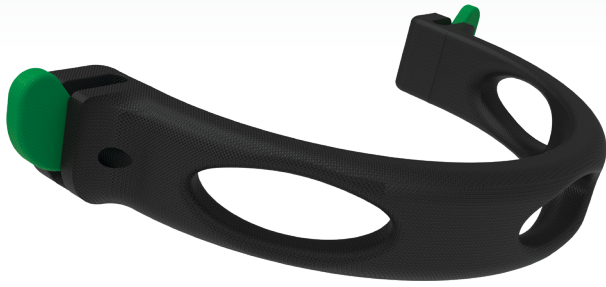
| | |
|--------------------|--------------|
| Tissue Dissector 1 | BOK-LD-13-1 |
| Tissue Dissector 2 | BOK-LD-13-2B |
| Tissue Dissector 3 | BOK-LD-13-3B |
| Tissue Dissector 4 | BOK-LD-13-4B |



First Access Guide

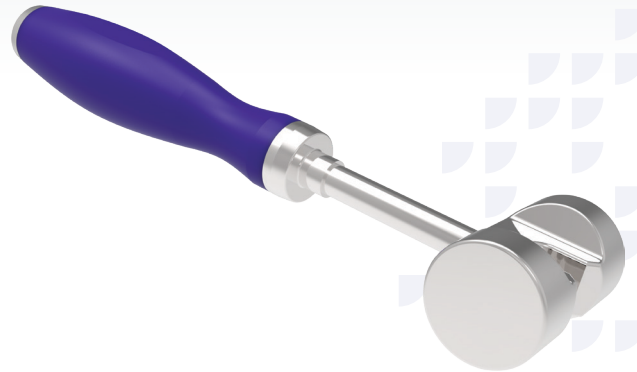
PART NUMBER

| | |
|---------|-------------|
| Guide 1 | BOK-LD-14-1 |
| Guide 2 | BOK-LD-14-2 |
| Guide 3 | BOK-LD-14-3 |
| Guide 4 | BOK-LD-14-4 |



Fixing Wire Spreader

PART NUMBER
BOK-LD-15



Hammer

PART NUMBER
TH002



Universal Slide Hammer

Double Fork Slide Hammer

PART NUMBER
BOK-LT-81



Trays Avenue®-L Tx

Tray 1
Tray 2

PART NUMBER
K3721-TXL1
K3721-TXL2

Instructions for Use

DEVICE DESCRIPTION

Tantalum arthrodesis cages are produced in variable sizes and shapes. The dimension of the implant depends on anatomical conditions and physician's decision. The cages are manufactured through a validated laser sintering process.

Recommendation: *The patient must be informed about any residual risk, side-effect, contraindication, warning, precaution, measure, recommendation and/or any other safety info.*

INTENDED USE

Tantalum cages are intended to recreate and maintain distance between vertebrae to support biologic fusion in the cervical, thoracic, lumbar or sacral spine zone.

TACC systems are designed to be applied with anterior approach only (ACIF); they can be used alone ("stand-alone") up to two levels or in combination with other spinal fixation systems (e.g.: cervical plates) in order to achieve better stabilization, according to the physician's decision only. In some cases, an additional spinal fixation device is highly recommended.

TACT are interbody devices to which posterior fixation in addition is advised. For the TACA additional fixation (either anterior or posterior) is advised. The systems are designed to be applied with Transforaminal Lumbar posterior approach (TLIF) and Anterior Lumbar approach (ALIF) respectively.

Warning: *The effectiveness and safety of interbody fixation is only applicable for certain conditions with significant instability which require the fusion to be supported by a medical device. Correct placement and appropriate size selection are crucial to achieve optimal results. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.*

Precaution: *Patients with obesity, smokers, alcohol abused are at risk for non-fusion. Also, patients with weak muscle or bone conditions, 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 patients' or implants' correction, X-ray or CT-scan or any other diagnostic examinations, either invasive or non-invasive, may be necessary.*

Warning: *Extensive bending or contouring of the implant should be avoided. Sharp edged cutting, reversed bending, scratching or notching may generate internal stresses, which may weaken the implants or construct.*

INDICATIONS FOR USE

TACC is indicated for cervical interbody fusion in case of degenerative disc diseases, spinal stenosis, revision surgery for failed disc surgery or progressive degenerative discopathies, foraminal stenosis or nerve compression, pseudoarthrosis, instability of motion segments.

TACT, TACA, TACP, TACX and TACL are intended for lumbar interbody fusion in case of degenerative disc disease, spondylolisthesis, spinal stenosis, trauma, tumors, pseudoarthrosis, instability of motion segments.

Recommendations: The devices may only be used in combination with original products provided by manufacturer or on behalf of him. Each system component (e.g.: TACC) must not be used with other families (e.g.: TACT) at the same level.

Warning: *Non-compliance with these instructions may lead to users/patients' injuries and/or other unforeseeable risks. Use the device only for the described purposes. Using it for different purposes may cause device's functional failure, injuries to the patients or even their death.*

Recommendations: *The ignition temperature of tantalum is 630°C. Although such a temperature is never likely to be reached during a surgical procedure, it is recommended to use electrocoagulation and high-speed drills in the vicinity of the device carefully.*

PATIENT TARGET POPULATION

- Gender: not relevant
- Age Range: between 25 and 83
- Weight: not intended for morbid obesity
- Nationality: not relevant
- Any other contraindicated patient

PATIENT SELECTION CRITERIA

The physician is responsible and has the appropriate skills to define criteria for patient selection depending on its clinical conditions. The device shall be selected and used for the defined patient, following manufacturer's intended use, indications for use, contraindications and target population.

CONTRAINDICATIONS

Do not use the devices whether one or more below listed condition is detectable:

- Current metastatic tumors of the vertebrae adjacent to the implant
- Risk of infections, fever or inflammation
- Active local infection in or near the operative region
- Active systemic infection and/or disease

- Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation
- Known or suspected sensitivity to the implant materials
- Bleeding disorder, healing problems and/or compromised immune system
- Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism, etc)
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs
- Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g., current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury, etc.)
- Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy and multiple sclerosis
- Patients unwilling to follow postoperative instructions
- Prior fusion at the level(s) to be treated
- Prior surgical procedure using the desired operative approach
- Any anatomical, medical or surgical conditions which may preclude potential or intentional benefits of spinal implants application
- Bone, joints or ligaments conditions such as but not limited to osteopenia, bone absorption, osteomalacia. Osteoporosis is relative contraindications and must be carefully evaluated prior surgery
- Mixing of implants with other manufacturer's devices or with other fixation systems
- Skeletal immaturity
- Grossly distorted anatomy
- Symptomatic cardiac disease
- Obesity
- Pregnancy

RESIDUAL RISKS AND/OR SIDE EFFECTS

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

- Residual pain;
- Hematoma;
- Numbness;
- Radiculopathy;
- Re-operation;
- Vascular injuries, vein thrombosis, embolism;
- Intraoperatively developed pneumothorax;
- Lymphocele;
- Subsidence, disassembly, bending, and/or breakage of any or all of the system's components;
- Misplaced and/or migrations of any of 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 instruments;
- Sympathetic chain injury
- Dura leakage, distortion or damage;
- Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypesthesia, or any others related to surgery in general associated to anesthesia;
- Infection and/or wound complications;
- Loss of urinary functions;
- Permanent or temporary or developing sexual dysfunctions;
- Postoperative change of body curvature, change of physiological range of movement;
- Pseudoarthrosis 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 development of respiratory problems;
- Permanent or temporary or development of cardiovascular deteriorations or dysfunctions;
- Transient hoarseness, swallowing complaint;
- Transient motor-evoked potential deficit;
- Iliopsoas and quadriceps weakness and/or complications;
- retrograde ejaculation;death.

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

SAFETY IN MAGNETIC RESONANCE IMAGING NOT EVALUATED

The Tantalum Arthrodesis Cages have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Tantalum Arthrodesis Cages in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

SPECIAL CONSIDERATIONS

The device neither contains nor incorporates medicinal substances, including human blood or plasma derivative, human or animal tissues, cells and derivatives.

INTENDED USER AND USE ENVIRONMENT

ZimVie Spine assumes that users have experience and knowledge of standard protocols regarding Arthrodesis Cages procedures. Users must have appropriate technical knowledge, experience and education concerning the use of the products. The devices may only be used by orthopedic surgeons and neurosurgeons pursuant to their indications. Where necessary, users must attend specific training courses, as these instructions contain only a limited amount of information. The factors like proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant size and type are considerably important in the treatment process.

The proper, patient's individual implants selection in terms of type, size, shape or design is vital to a successful surgical performance.

The devices must be managed in aseptic environments.

SURGICAL PROCEDURES

Generic preoperative, intraoperative and postoperative aspects are addressed in this document. ZimVie Spine expects that users read the specific surgical techniques applicable to their purpose. Surgical techniques are available at ZimVie Spine's webpage and available upon request to your local sales representative, distributor or sales agent.

The five primary interbody fusion approaches are shown here schematically: Anterior Lumbar Interbody Fusion (ALIF), Direct Lateral or extreme lateral Interbody Fusion (DLIF), Oblique Lumbar Interbody Fusion/anterior to the Psoas muscle (OLIF/OLLIF), Transforaminal Lumbar Interbody Fusion (TLIF), and Posterior Lumbar Interbody Fusion (PLIF).

Pre-operative

- Select only patients that meet the criteria described in the indications;
- Patient's condition should be checked prior to surgery; Any required diagnostics should be performed;
- The efficient and adequate implants' and instruments' inventory must be secured and be available during the surgery;
- All instruments and any other non-sterile components should be cleaned and sterilized before use.
- Any implants, instruments or components delivered sterile must be checked for sterility and expiration date prior to surgery;
- Implants and instruments should be stored in certain conditions to warrant the sterility and protect against any contamination or corrosive environment;
- It's highly recommended that all personnel interacting with any mechanical components from 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, an intra-operative diagnostic system 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 personnel or patient;
- It's very important to carefully follow the surgical technique. Proper use of any instrument or implant may facilitate an uneventful surgery;
 - Before closing the soft tissue, double check if implants' positioning, geometrical relations, and fixing, tightening or mounting manoeuvres for all screws, nuts or other fixing parts should be performed. Imaging diagnostics is highly recommended at this stage;
 - When trialing is performed, lateral x-ray is highly recommended in order to assess implants' height, angulation and footprint size. Implant Trial should be inserted in mid-line. Release the distraction and check if the Implant Trial fits firmly between the endplates. Please note that, once the appropriate implant size has been selected the implant preparation in accordance to the marking on the Implant Trial should be followed.

Postoperative

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

- Detailed instructions about the use and limitations of the device should be given to the patient;
- The patient should be warned to avoid falls or sudden jolts in spinal position;
- The patient should be warned of this possibility and instructed to limit physical activities, especially lifting and twisting motions and any type of sport participation.
- The patient should be advised not to smoke tobacco or nicotine containing products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process;
- As a precaution, before patients with implants receive any subsequent surgery (such as spine procedures), prophylactic antibiotics may be considered, especially for high-risk patients;
- Any retrieved devices should be treated in such a

manner that re-use in another surgical procedure is not possible. As with all orthopedic implants, the arthrodesis cages and components should never be re-used under any circumstances.

STORAGE AND HANDLING CONDITIONS

Sterile cages must be stored in their original packages and must be protected against any damages. These devices must be stored in a suitable environment. The storage room has to be dust-free, insect-free, with low microbiological contamination, dark and free of chemical vapors, humidity and temperature fluctuations.

DISPOSAL

Expired and obviously not used implants must be disposed as "Not Dangerous Hospital Waste" following all applicable laws in the country of use.

In the unlikely event that an implant is used and not deemed appropriate (e.g.: wrong selected dimension), it must be disposed as "Dangerous Hospital Waste" following all applicable laws in the country of use.

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



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