



Avenue[®]-T Ta

Posterior Lumbar Curved
3D Printed Tantalum Cage

Surgical Technique Guide

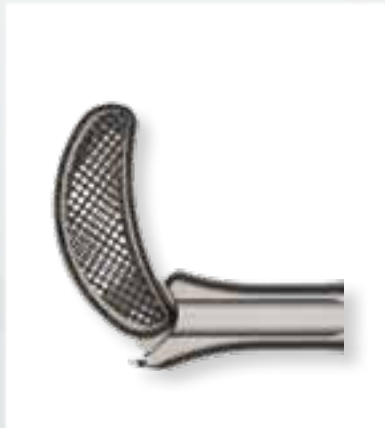






Table of Contents

Surgical Technique	5
Implant Overview	15
Instrument Overview	19
Instructions for Use	20

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 Ta

Posterior Lumbar Curved Interbody Fusion Cage

Features and Characteristics

Avenue®-T Ta Posterior Lumbar Curved 3D printed Interbody Fusion 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.

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-T Ta is offered in 3 footprints and 9 heights with 3 lordosis angles:

Footprint:



29 x 9 mm



32 x 9 mm



32 x 10 mm

Height:



7 mm



9 mm



11 mm



13 mm



15 mm



8 mm



10 mm



12 mm



14 mm

Lordosis Angle



5°



8°



15°

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

- Verify the appropriate level of the lumbar spine with fluoroscopy. 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 the surgeon to define and perform the soft tissue approach and bone decompression procedure. In some cases, specific patient positioning may be required.

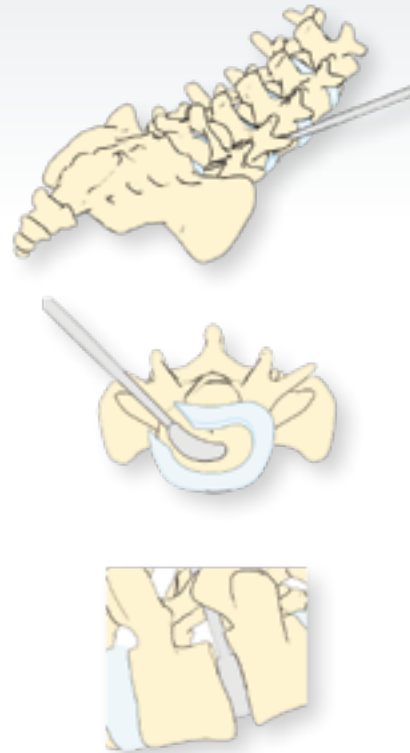
Surgical Technique (Continued)



Shaver

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 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.



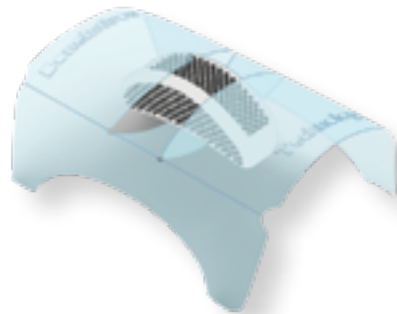
Implant dimension choice procedure.

Implant Dimension Choice

- To select the appropriate implant size, implant trials should be used. 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: The trial Implant must fit firmly with a tight press-fit between the endplates. Keep the same trajectory and angulation as intended for implant insertion.



Trial Implant



Implant packaging and release process.

Implant Packaging

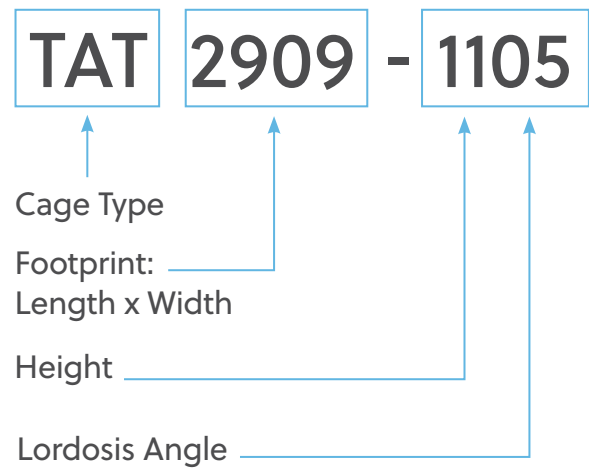
- When trialing is performed, fluoroscopic imaging is strongly recommended, in order to have a clear idea about the implant's height and length. Please note that implant trials are designed "flat" (0 degrees of lordosis). In case larger lordosis restoration is intended, select an implant with either 5, 8, or 15 degrees angulation.
- Pre-operative radiological imaging is strongly recommended to decide on the lordosis angulation of the implant.
- Because Implant Trials are "flat" (no lordosis angle), the required angulation should be determined based on pre-operative X-Rays; Avenue-T Ta Implants have 5° lordosis angle.
- After sizing and end-plate preparation, choose the Implant dimension according to the outcome of the trial procedure.

- 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.

Caution:

When using the modular trials (as shown above) in combination with the implant inserter, it is strongly recommended to properly clean the distal part of the implant inserter before attaching a different size trial. It is likely that during the trialing process tissue debris remains on the distal tip of the implant inserter, which may negatively influence or even block proper attachment and/or functioning of the next trial.

Surgical Technique (Continued)



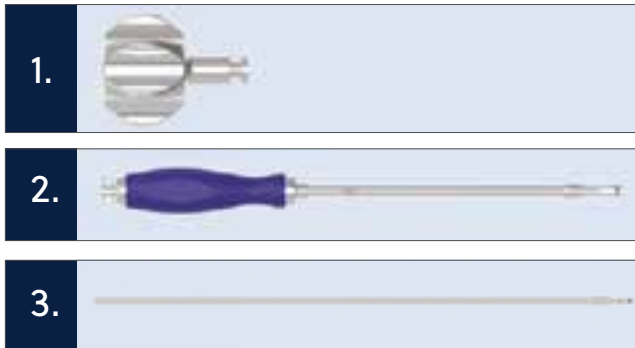
Implant Preparation

- When surgeons deem necessary to add an additional bone growth accelerator, an Universal Filling System supports the bone substitute filling procedure, either at preimplantation or post-implantation stage of the surgical procedure, in an effective way.

Implant Reference Code

- The correct implant size corresponds to the height and length of the trial implant (either 29 or 32 mm); the trial implant has no lordosis angle (lordosis angle 0°).
- The lordosis angle for the implant is determined after evaluating the (pre-OP) fluoroscopic imaging

Components:



1. Implant Knob - BOK-LT-90-02
2. Implant Holder - BOK-LT-95
3. Implant Holder Shaft - BOK-LT-95-10

Cage Fixation



Cage Rotation



Cage Release



Assembly of Implant Holder

- Assemble the Implant Holder Shaft into the implant holder and fix with the Implant Knob.

Warning: The Implant Holder Shaft should be assembled into the Implant Holder in a specific way: Insert from the tip of the instrument upwards; Please make sure that the arrow on Implant Holder Shaft aligns with the arrow on the Implant Holder.



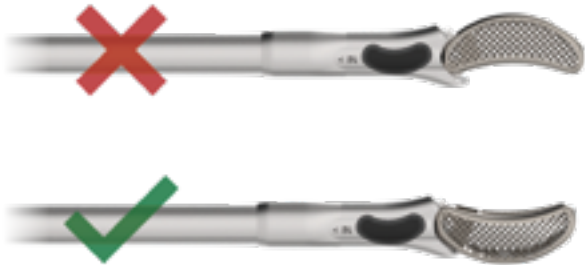
Cage Fixation on Implant Holder

- The Implant inserter was developed to facilitate implantation by the multi-axiality of the implant positioning throughout the procedure. Surgeons have full control over every function of the instrument, also thanks to the display in the window of the Implant Inserter shaft.

Caution:

Similar to using modular trials (as shown on page 7) it is strongly recommended to properly clean the distal part of the implant inserter before attaching the implant. It is likely that during the trialing process tissue debris remains on the distal tip of the implant inserter, which may negatively influence or even block proper attachment and/or functioning of the implant during implantation.

Surgical Technique (Continued)



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".

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

- 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.
- 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 implantation 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.

Footprint 29 x 9 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Ta 29 x 9 x 7 mm; 5°	TAT2909-0705	0*
Avenue-T Ta 29 x 9 x 8 mm; 5°	TAT2909-0805	0*
Avenue-T Ta 29 x 9 x 9 mm; 5°	TAT2909-0905	0*
Avenue-T Ta 29 x 9 x 10 mm; 5°	TAT2909-1005	0*
Avenue-T Ta 29 x 9 x 11 mm; 5°	TAT2909-1105	0*
Avenue-T Ta 29 x 9 x 12 mm; 5°	TAT2909-1205	0*
Avenue-T Ta 29 x 9 x 13 mm; 5°	TAT2909-1305	0*
Avenue-T Ta 29 x 9 x 14 mm; 5°	TAT2909-1405	0*
Avenue-T Ta 29 x 9 x 15 mm; 5°	TAT2909-1505	0*

Footprint 29 x 9 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Ta 29 x 9 x 7 mm; 8°	TAT2909-0708	0*
Avenue-T Ta 29 x 9 x 8 mm; 8°	TAT2909-0808	0*
Avenue-T Ta 29 x 9 x 9 mm; 8°	TAT2909-0908	0*
Avenue-T Ta 29 x 9 x 10 mm; 8°	TAT2909-1008	0*
Avenue-T Ta 29 x 9 x 11 mm; 8°	TAT2909-1108	0*
Avenue-T Ta 29 x 9 x 12 mm; 8°	TAT2909-1208	0*
Avenue-T Ta 29 x 9 x 13 mm; 8°	TAT2909-1308	0*
Avenue-T Ta 29 x 9 x 14 mm; 8°	TAT2909-1408	0*
Avenue-T Ta 29 x 9 x 15 mm; 8°	TAT2909-1508	0*

**Optional. Available by special order.*

Implant Overview - Continued

Footprint 32 x 9 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Ta 32 x 9 x 7 mm; 5°	TAT3209-0705	1
Avenue-T Ta 32 x 9 x 8 mm; 5°	TAT3209-0805	2
Avenue-T Ta 32 x 9 x 9 mm; 5°	TAT3209-0905	2
Avenue-T Ta 32 x 9 x 10 mm; 5°	TAT3209-1005	2
Avenue-T Ta 32 x 9 x 11 mm; 5°	TAT3209-1105	2
Avenue-T Ta 32 x 9 x 12 mm; 5°	TAT3209-1205	2
Avenue-T Ta 32 x 9 x 13 mm; 5°	TAT3209-1305	2
Avenue-T Ta 32 x 9 x 14 mm; 5°	TAT3209-1405	1
Avenue-T Ta 32 x 9 x 15 mm; 5°	TAT3209-1505	1

Footprint 32 x 9 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Ta 32 x 9 x 7 mm; 8°	TAT3209-0708	2
Avenue-T Ta 32 x 9 x 8 mm; 8°	TAT3209-0808	2
Avenue-T Ta 32 x 9 x 9 mm; 8°	TAT3209-0909	2
Avenue-T Ta 32 x 9 x 10 mm; 8°	TAT3209-1008	2
Avenue-T Ta 32 x 9 x 11 mm; 8°	TAT3209-1108	2
Avenue-T Ta 32 x 9 x 12 mm; 8°	TAT3209-1208	2
Avenue-T Ta 32 x 9 x 13 mm; 8°	TAT3209-1308	2
Avenue-T Ta 32 x 9 x 14 mm; 8°	TAT3209-1408	1
Avenue-T Ta 32 x 9 x 15 mm; 8°	TAT3209-1508	1

Footprint 32 x 10 mm

Description (L x W x H)	Part Number	QTY
Avenue-T Ta 32 x 10 x 8 mm; 15°	TAT3210-0815	0*
Avenue-T Ta 32 x 10 x 9 mm; 15°	TAT3210-0915	0*
Avenue-T Ta 32 x 10 x 10 mm; 15°	TAT3210-1015	0*
Avenue-T Ta 32 x 10 x 11 mm; 15°	TAT3210-1115	0*
Avenue-T Ta 32 x 10 x 12 mm; 15°	TAT3210-1215	0*
Avenue-T Ta 32 x 10 x 13 mm; 15°	TAT3210-1315	0*
Avenue-T Ta 32 x 10 x 14 mm; 15°	TAT3210-1415	0*
Avenue-T Ta 32 x 10 x 15 mm; 15°	TAT3210-1515	0*

*Optional. Available by special order.

Instrument Overview



Fast Connection T Handle

Part Number

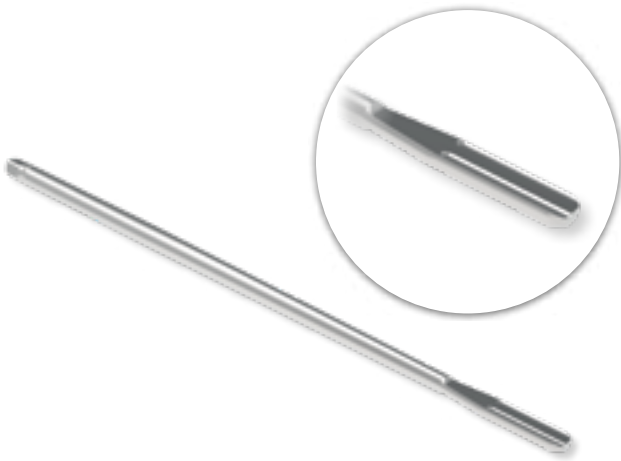
BOK-LC-52



Fast Connection Straight Handle

Part Number

BOK-LC-55

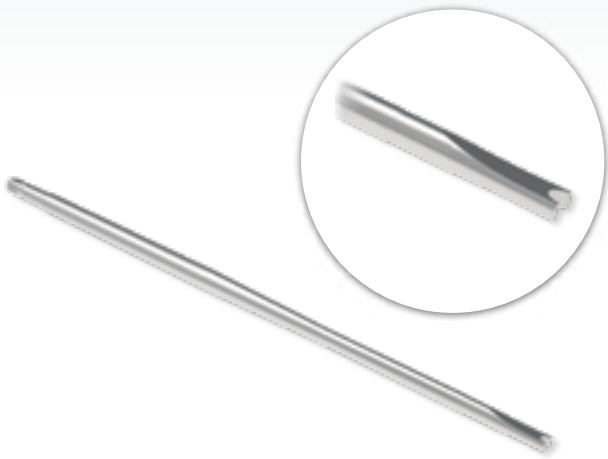


Shavers

Part Number

	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

Instrument Overview (Continued)



Implant Impactor	Part Number
	BOK-LT-73L



Implant Holder (Dismantable)	Part Number
Implant Holder	BOK-LT-95
Straight Implant Holder Shaft	BOK-LT-95-10
Straight Implant Knob	BOK-LT-95-02



Trial	Part Number
32 x 07 mm	BOK-LT-T3207
32 x 08 mm	BOK-LT-T3208
32 x 09 mm	BOK-LT-T3209
32 x 10 mm	BOK-LT-T3210
32 x 11 mm	BOK-LT-T3211
32 x 12 mm	BOK-LT-T3212
32 x 13 mm	BOK-LT-T3213
32 x 14 mm	BOK-LT-T3214



Hammer

Part Number
TH002



Medium Tray Avenue-T Tx

Part Number
K3725-TXT



Double Side Curved Squared Curette

Part Number
BOK-LT-72

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)



Biomet 3i Dental ibérica S.L.U.
WTC Almeda Park, Ed. 4, Planta 2
C/Tirso de Molina, 40
08940 - Cornellà de Llobregat
(Barcelona) Spain



Tsunami Medical, S.r.l.
HQ: Via E. Giorgi 27 - 41124 Modena, Italy
OHQ: Via XXV Aprile 22 - 41037 Mirandola, Italy
Phone: +39 0535 38397
Fax: +39 0535 38399

 **ZimVie**
Restoring Daily Life.®

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to ZimVie, Inc. or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of ZimVie. For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimvie.com for additional product information. Product clearance and availability may be limited to certain countries/regions. This material is intended for health care professionals only and does not comprise medical advice or recommendations. Distribution to any other recipient is prohibited. ZVINST0108 REV A 06/23 ©2023 ZimVie, Inc. All rights reserved. CE mark in brochure is not valid unless there is a CE mark on the product label. These are medical devices that comply with the current regulation. Cages / Implants (Class IIb), Instruments / Tools (Class I).
Not for distribution in France.


0476