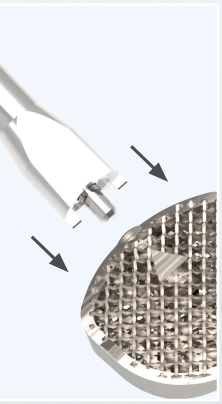
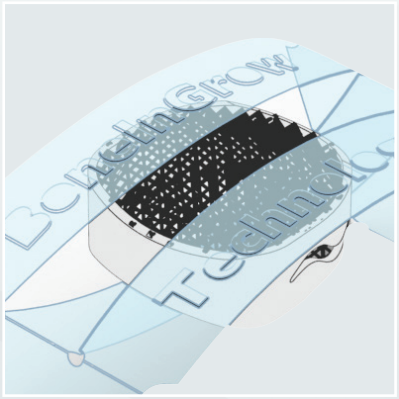
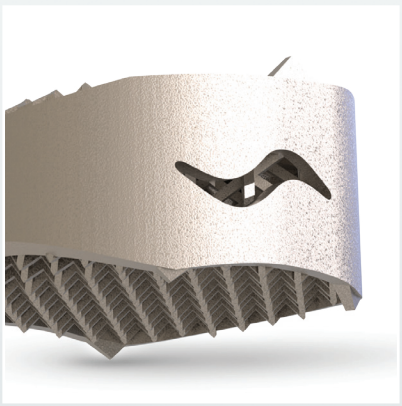
Avenue®-C Ta

Anterior Cervical 3D Printed Tantalum Cage

Surgical Technique Guide







ZimVie

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ZimVie 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. A written copy of the surgical technique is available at www.zimvie.com. 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®-C Ta

Anterior Cervical 3D Printed Tantalum Cage

Features and Characteristics

Primary Stability

- The special "net" structure, obtained through additive manufacturing technology, is intended to provide strong primary fixation and 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, and 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-C Ta is offered in 4 footprints and 5 heights with 5° lordosis:

Footprint:

14 x 12 mm | 14 x 14 mm | 16 x 14 mm | 18 x 16 mm

Height:

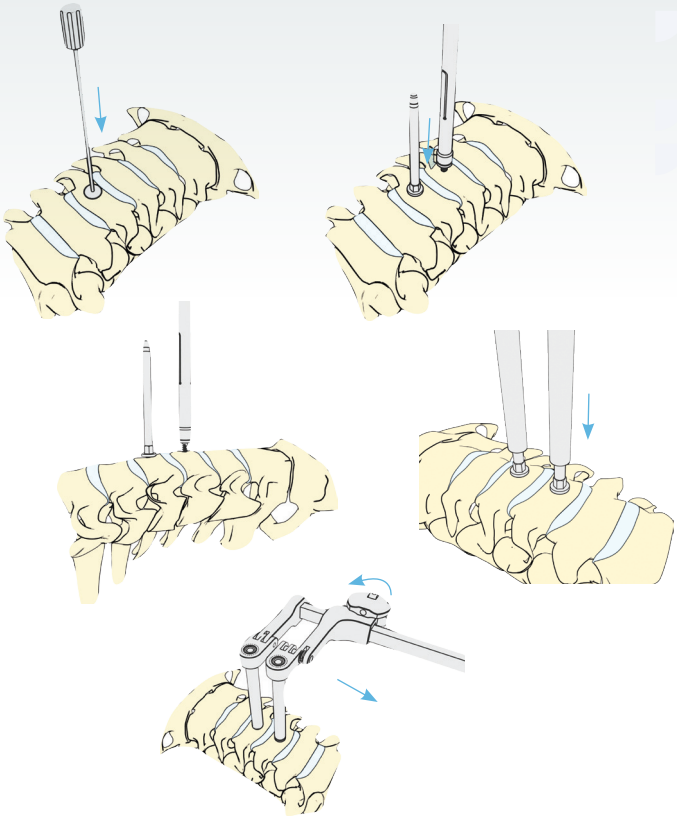
5 mm | 6 mm | 7 mm | 8 mm | 9 mm

Lordosis Angle

5°

Surgical Technique

Patient in supine position



Vertebral distraction procedure

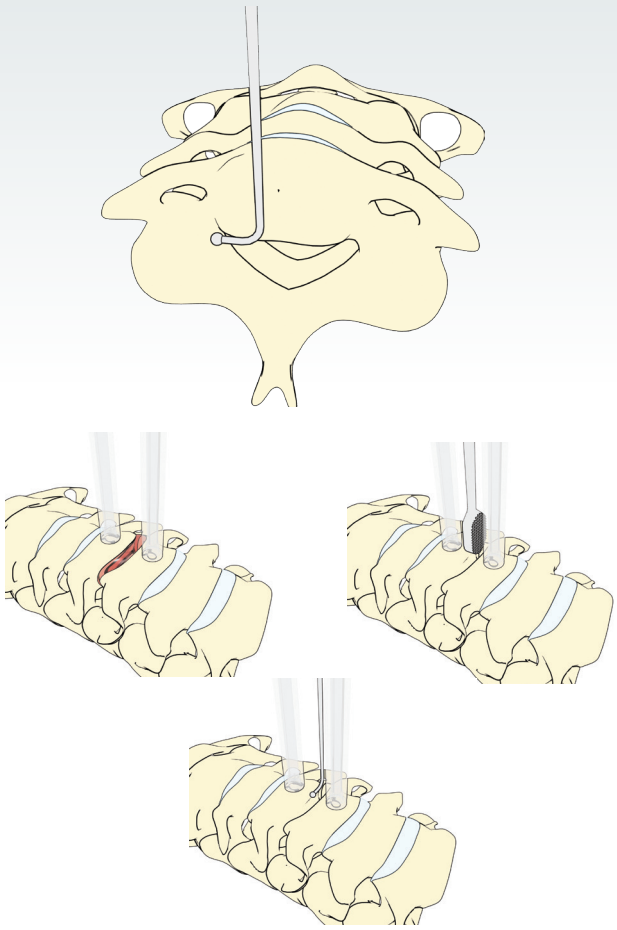
Patient Positioning

- Patient position should expose the spine level, which is going to be fused. Hyper-lordosis or kyphosis should be avoided. By using the C-Arm, the proper level of the cervical spine must be verified.
- Skin incision should allow an adequate approach to the stabilising spine segment(s).
- Additional instruments like a Vertebral Distractor and Soft Tissue Retractors are subject of additional spacing requirements.
- To maintain a comfortable surgical field, a Tissue Retractor System is highly recommended after bone preparation.

Vertebral Distraction

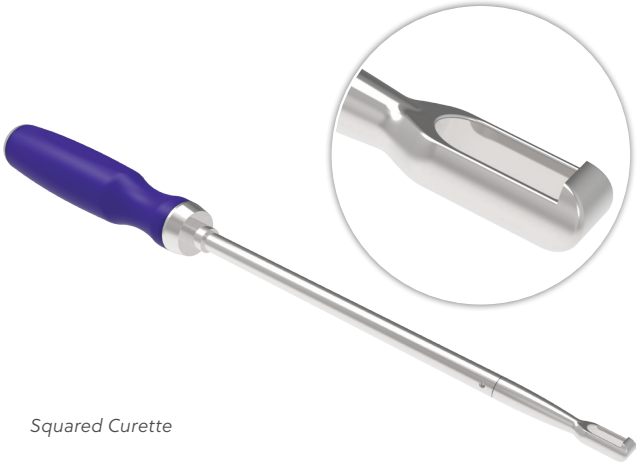
- Determine the length of the Distraction Screw on a lateral X-ray. Assemble an appropriate Distraction Screw into the Distraction Screw Driver.
- Define the midline and mark up the entering point by using the Vertebral Body Perforator.
- Insert the Distraction Screws, install the Caspar Distractor and perform vertebral distraction.

  Note: *Tissue Retractor and Distraction Screws above are offered as optional instruments. Use of equivalent ones is possible.*



Endplate preparation

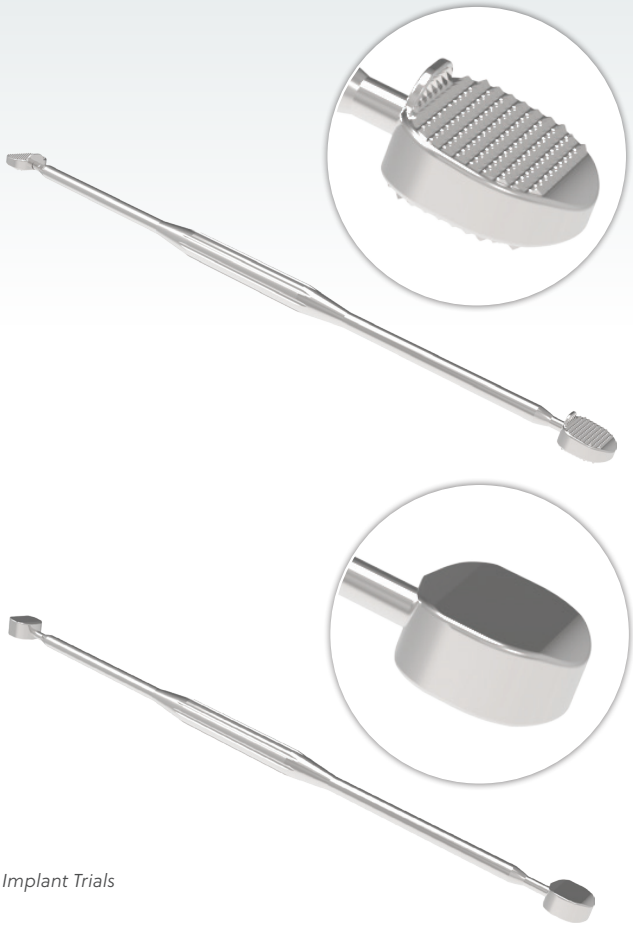
Shaver



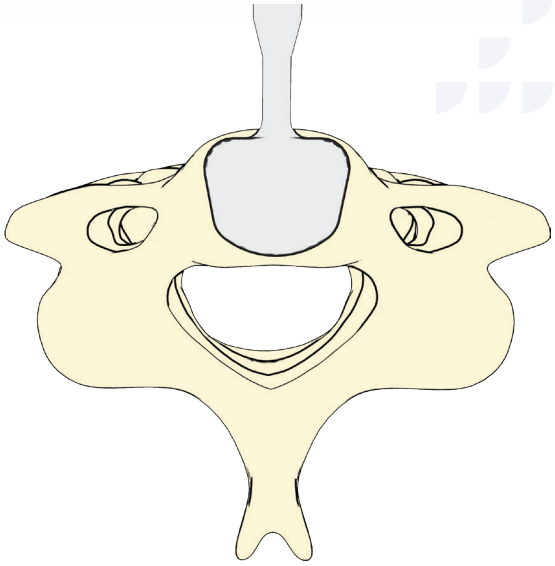
Squared Curette

Disc Removal and Endplate Preparation

- Remove the disc and cartilage layer on both the superior and inferior vertebral endplates. Use the Squared Curette to facilitate cartilage removal. In order to check root decompression a Cervical Nerve Hook may be used.
- The use of the Shaver is recommended when preparing the endplates in order to create efficient bone contact.
- Implant Trial Rasps, in addition to smooth Implant Trials, have the same purpose as the Shaver and may be considered following surgeons' preference.



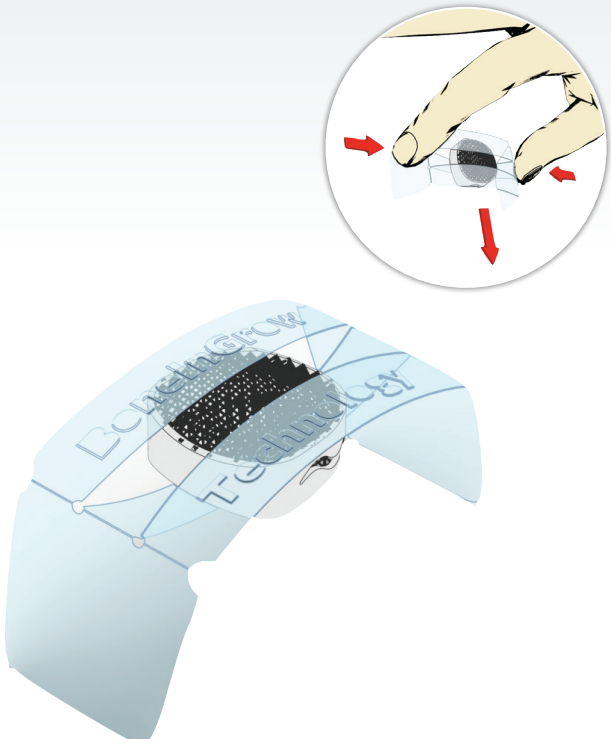
Implant Trials



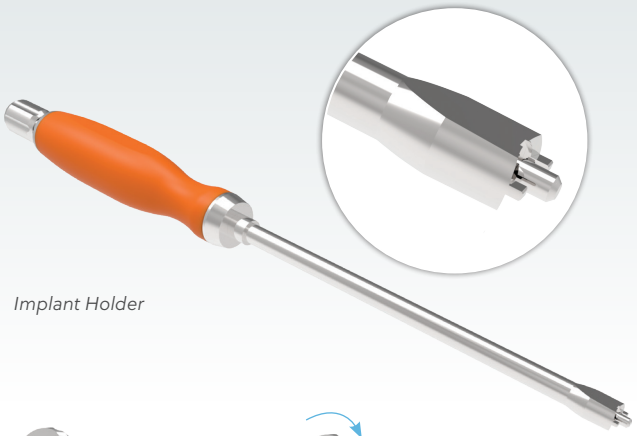
Trialing procedure

Implant Dimension Choice

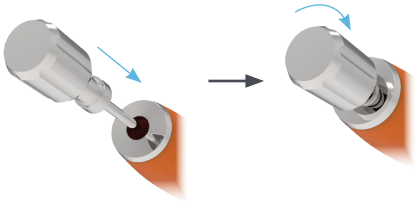
- When trialing is performed, using the Implant Trials in accordance with the appropriate footprint, a lateral X-ray is highly recommended in order to determine the implant's height and depth. The Trial should be inserted in the mid-line. Width is determined based on visual evaluation.
- Release the distraction of the Caspar Distractor and check if the Trial fits firmly between the endplates.
- Because Implant Trials are "flat" (no lordosis angle), the required angulation should be determined based on pre-operative X-Rays. Implants have 5° lordosis angle.
- After sizing and end-plate preparation, choose the Implant dimension according to the outcome of the trial procedure.



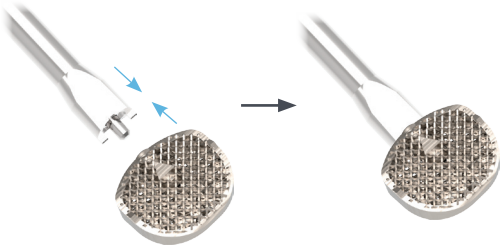
Implant packaging and release process



Implant Holder



Insert the Shaft into the Holder and screw the knob clockwise



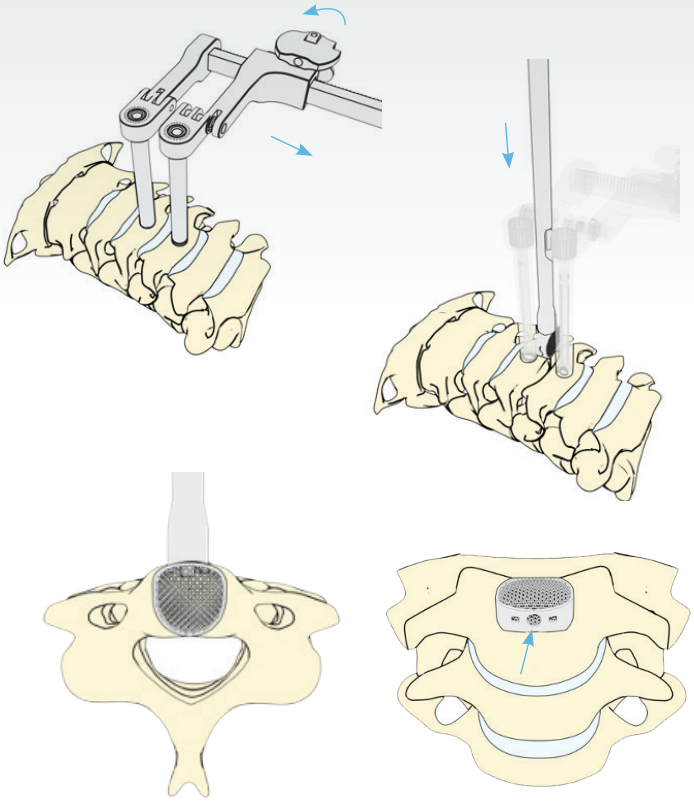
Apply the Cage to the coupling

Implant Packaging

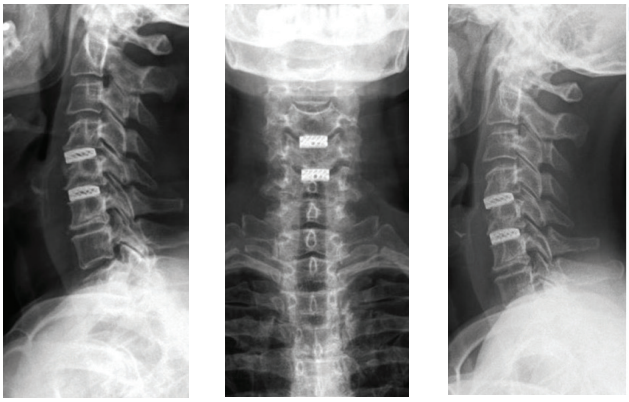
- The Implant is supplied in a double rigid blister pack with a special internal holder.
- The rotation nurse opens the outer (non-sterile) blister of the Implant and hands the Implant to the sterile OR nurse or scrub-tech. The sterile OR nurse removes the inner (sterile) blister, opens it, takes out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

Implant Preparation

- The Cages may be filled with a bone substitute. This should be delivered in paste/putty-like form. The implant can be filled before or after the implantation procedure.
- Insert the Implant Holder Shaft into the Implant Holder. Connect the Implant Holder to the Cage and secure the position by turning the knob clockwise on the silicone handle. Double check if the UP sign corresponds with the upper side of the Cage.



Cage implantation procedure



X-rays of Avenue-C Ta cage, three months post implantation

Implant Reference Code

- The correct Implant size is the one that corresponds with the footprint and height of the appropriate Implant Trial, as determined after evaluation of fluoroscopy imaging: Lateral X-Ray for height and depth, width based on visual evaluation.
- Lordosis angle based on pre-OP fluoroscopy imaging, because trial instruments are "flat" (no lordosis angle).

Example

Cage Height:	6 mm
Cage Width x Depth:	14 x 12 mm
Cage Lordosis Angle:	5°

TAC	1412	–	0605
	Footprint: Width x Depth		*Height* *Lordosis Angle*

Cage Implantation

- Implant the cage. After the final position of the cage has been reached, release the distraction device and check the firm fixation of the implant.
- Detach the Implant Holder from the Implant by turning the Implant Holder Shaft counterclockwise.
- A lateral X-ray during the procedures is highly recommended to control the final (height / depth) position of the Implant before releasing distraction. An AP X-ray is recommended to control the final center position.

Implant Overview

Rectangular Footprint 14 x 12 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Ta 14 x 12 x 5 mm, 5°	TAC1412-0505	2
Avenue-C Ta 14 x 12 x 6 mm, 5°	TAC1412-0605	2
Avenue-C Ta 14 x 12 x 7 mm, 5°	TAC1412-0705	2
Avenue-C Ta 14 x 12 x 8 mm, 5°	TAC1412-0805	1
Avenue-C Ta 14 x 12 x 9 mm, 5°	TAC1412-0905	1

Rectangular Footprint 16 x 14 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Ta 16 x 14 x 5 mm, 5°	TAC1614-0505	2
Avenue-C Ta 16 x 14 x 6 mm, 5°	TAC1614-0605	2
Avenue-C Ta 16 x 14 x 7 mm, 5°	TAC1614-0705	2
Avenue-C Ta 16 x 14 x 8 mm, 5°	TAC1614-0805	1
Avenue-C Ta 16 x 14 x 9 mm, 5°	TAC1614-0905	1

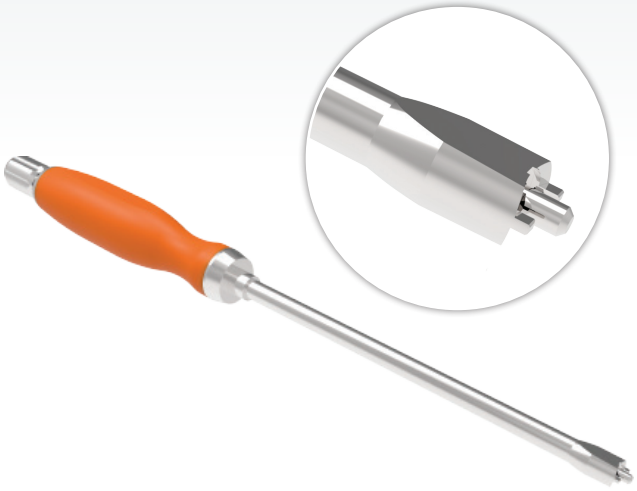
Square Footprint 14 x 14 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Ta 14 x 14 x 5 mm, 5°	TAC1414-0505	2
Avenue-C Ta 14 x 14 x 6 mm, 5°	TAC1414-0605	2
Avenue-C Ta 14 x 14 x 7 mm, 5°	TAC1414-0705	1
Avenue-C Ta 14 x 14 x 8 mm, 5°	TAC1414-0805	1
Avenue-C Ta 14 x 14 x 9 mm, 5°	TAC1414-0905	1

Rectangular Footprint 18 x 16 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Ta 18 x 16 x 5 mm, 5°	TAC1816-0505	2
Avenue-C Ta 18 x 16 x 6 mm, 5°	TAC1816-0605	2
Avenue-C Ta 18 x 16 x 7 mm, 5°	TAC1816-0705	1
Avenue-C Ta 18 x 16 x 8 mm, 5°	TAC1816-0805	1
Avenue-C Ta 18 x 16 x 9 mm, 5°	TAC1816-0905	1

Instrument Overview



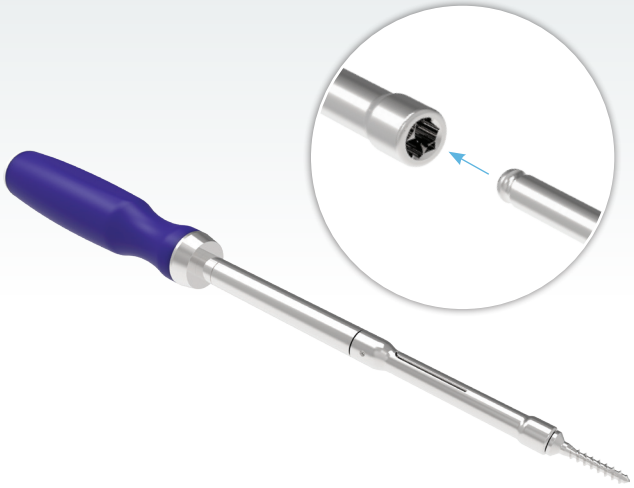
Implant Holder	Part Number
	BOK-CS-01

One Side Squared Curette	Part Number
	BOK-CS-04

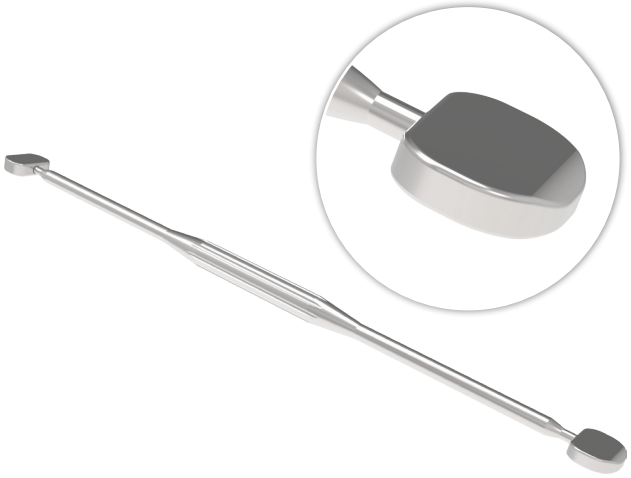
Implant Holder Shaft	Part Number
	BOK-CS-02

Shaver	Part Number
	BOK-CS-03

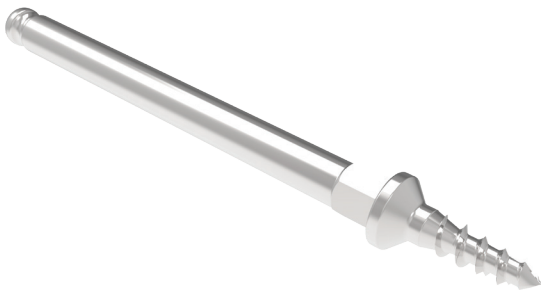
Vertebral Body Perforator (optional)	Part Number
	BOK-CS-08



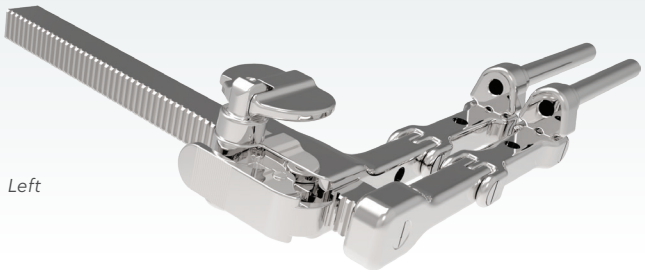
Distraction Screwdriver (optional)	Part Number
	BOK-CS-05



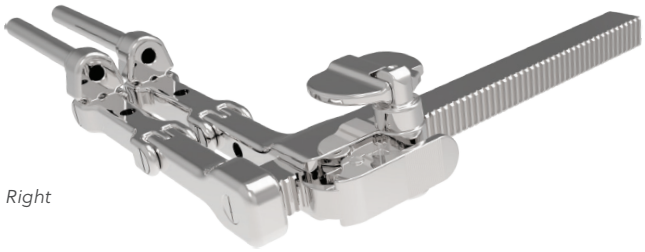
Implant Trial	Part Number
4-5 Small (14 x 12 mm)	BOK-CS-0405WS
6-7 Small (14 x 12 mm)	BOK-CS-0607WS
8-9 Small (14 x 12 mm)	BOK-CS-0809WS
4-5 Medium (14 x 14 mm)	BOK-CS-0405M
6-7 Medium (14 x 14 mm)	BOK-CS-0607M
8-9 Medium (14 x 14 mm)	BOK-CS-0809M
4-5 Medium (16 x 14 mm)	BOK-CS-0405WM
6-7 Medium (16 x 14 mm)	BOK-CS-0607WM
8-9 Medium (16 x 14 mm)	BOK-CS-0809WM
4-5 Large (18 x 16 mm)	BOK-CS-0405WL
6-7 Large (18 x 16 mm)	BOK-CS-0607WL
8-9 Large (18 x 16 mm)	BOK-CS-0809WL



Distraction Screw (optional)	Part Number
Distraction Screw 12 mm	BOK-CS-12
Distraction Screw 14 mm	BOK-CS-14
Distraction Screw 16 mm	BOK-CS-16

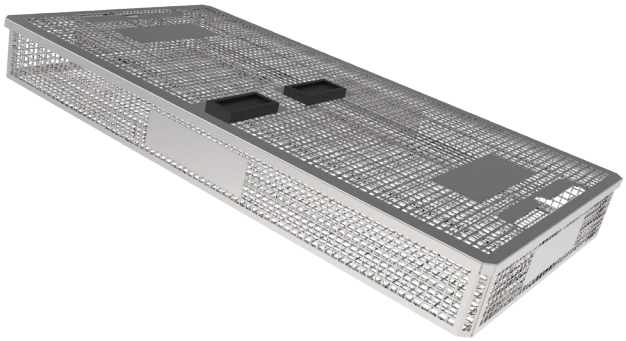


Left



Right

Caspar Distractor (optional)	Part Number
Left	BOK-CS-07L
Right	BOK-CS-07R



Small Tray Avenue-C Tx	Part Number
	K3729-TXC

Instructions for Use

DEVICE DESCRIPTION

ZimVie Spine produces tantalum arthrodesis cages 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

ZimVie Spine 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.: pedicle screws) 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 complementary devices that can be used independently, while the TACA cannot be used as a standalone device. The systems are designed to be applied with Transforaminal Lumbar posterior approach (TLIF) and Posterior Lumbar approach (PLIF) 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
- Lnown 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 by 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

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