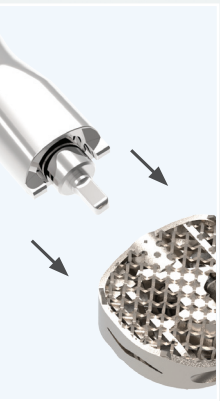
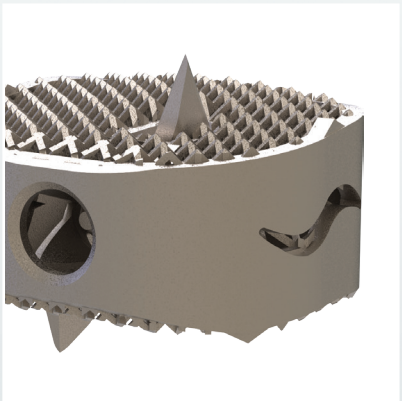
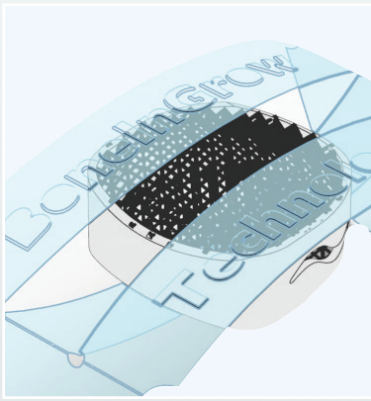
Avenue®-C Fix Ti

Built-in Fixation Anterior Cervical 3D Printed Titanium 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. Rx only.

Avenue®-C Fix Ti

Built-in Fixation Anterior Cervical 3D Printed Titanium Cage

Features and Characteristics

Primary Stability

- The special "net" structure, obtained through additive manufacturing technology, is designed to provide strong primary fixation and intended to minimize implant migration risk.

Wide Variety of Footprints, Heights, and Lordosis Angles

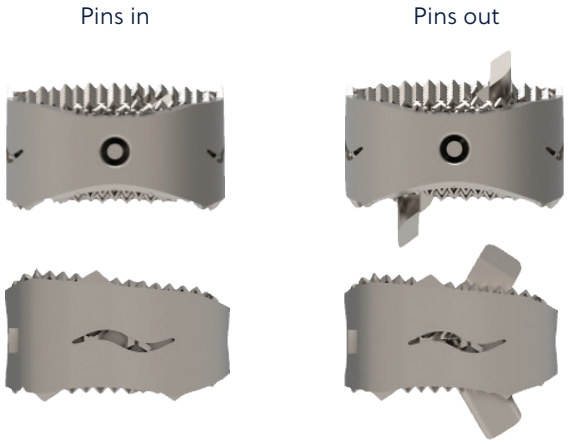
- One system intended to match patients' natural anatomy and surgeons' preferences.

Bone InGrowth Technology

- Pore size of the net structure and the surface roughness of the implant edges is 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 and is a key success factor.

Additional Built-in Fixation

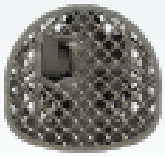
Built-in pins are intended to enhance primary fixation, and it is complementary to the stability offered by the "net" structure itself. Pins design incorporate a locking system to secure the pins once deployed. No compromise on implant elasticity and fusion promotion thanks to the small footprint of the built-in fixation. The diagonal position of the pins is intended to secure rotational stability. Avenue-C Fix Ti is manufactured in one production step, thanks to the additive manufacturing technology used. No additional instruments are required for implantation: the pins are extracted by a feature on the amended original implant inserter. In case of revision, or if required, locked pins can be released using Pin Extractor.



Avenue-C Fix Ti is offered in 4 footprints and 5 heights with 5° lordosis:

Footprint:

14 x 12 mm



14 x 14 mm

16 x 14 mm

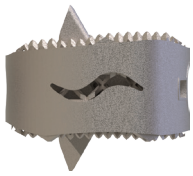
18 x 16 mm

Height:

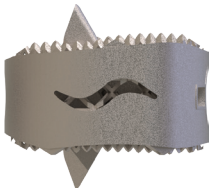
5 mm

6 mm

7 mm

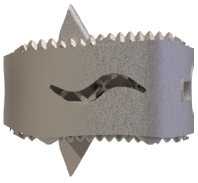


8 mm



9 mm

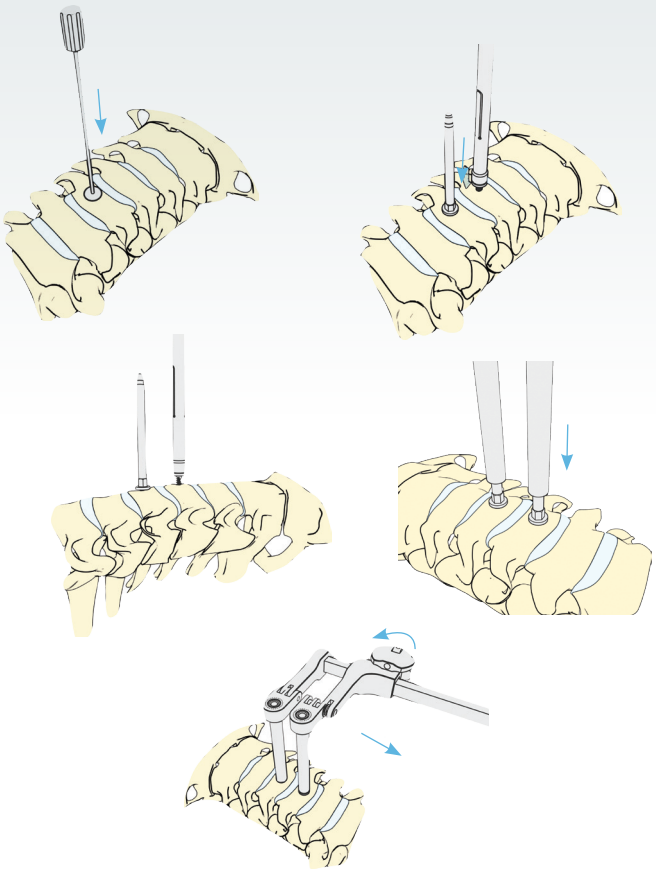
Lordosis Angle



5°

Surgical Technique

Patient in supine position



Vertebral distraction procedure

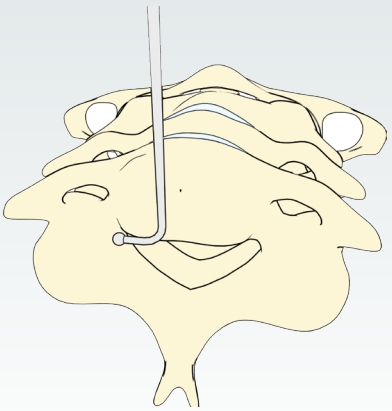
Patient Positioning

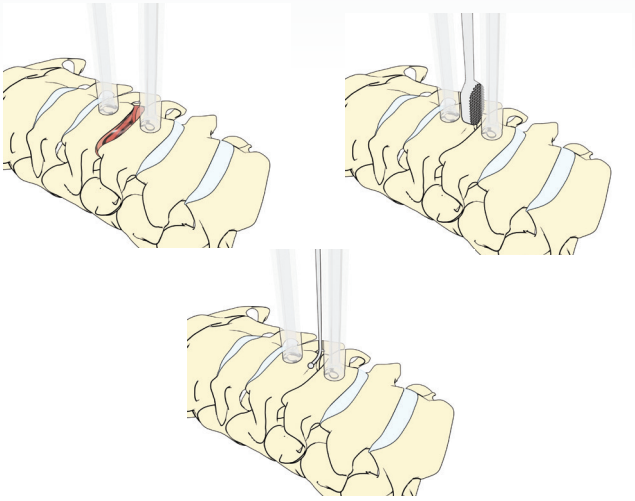
- Patient position should expose the spine level, which is going to be fused. Hyper-lordosis or kyphosis should be avoided. By using the C-Arm, the proper level of the cervical spine must be verified.
- Skin incision should allow an adequate approach to the stabilising spine segment(s).
- Additional 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 the 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.*





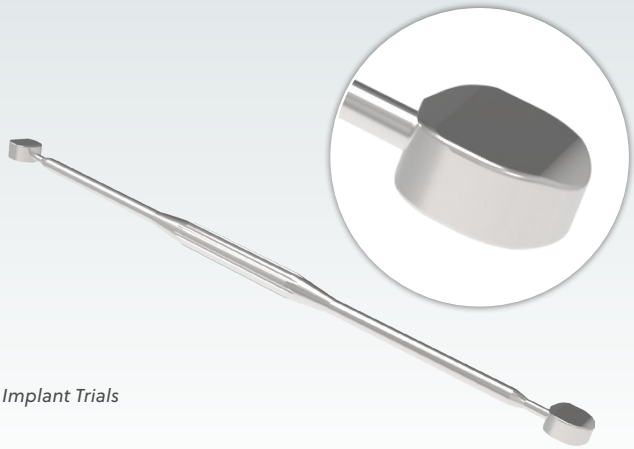
Endplate preparation

Squared Curette

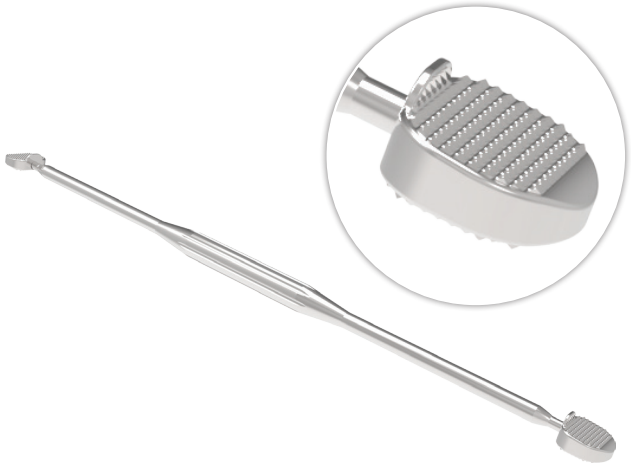
Shaver

Disc Removal and Endplate Preparation

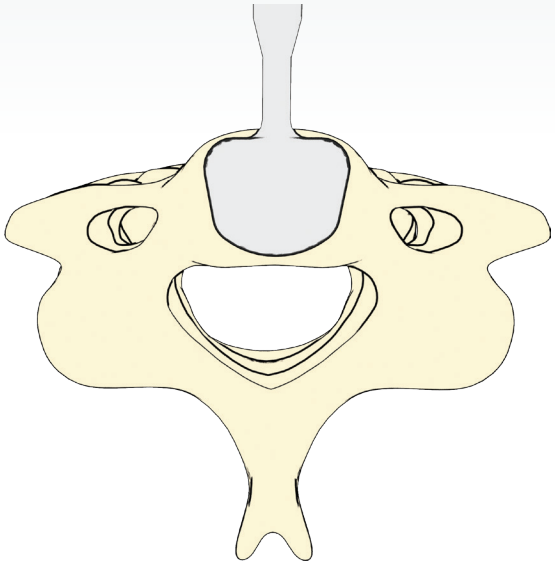
- Remove the disc and cartilage layer on both the superior and inferior vertebral endplates. Use the Squared Curette to facilitate cartilage removal. In order to check root decompression a Cervical Nerve Hook may be used.
- The use of the Shaver is recommended when preparing the endplates in order to create efficient bone contact.



Implant Trials



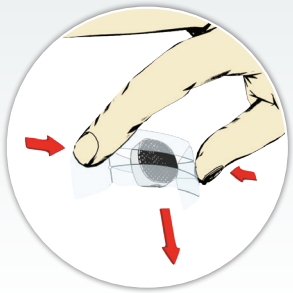
Trial Rasp

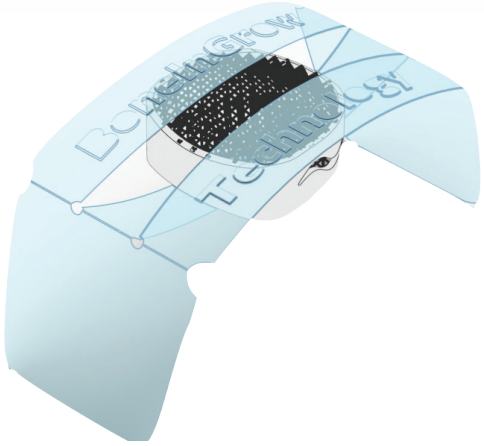


Trialing procedure

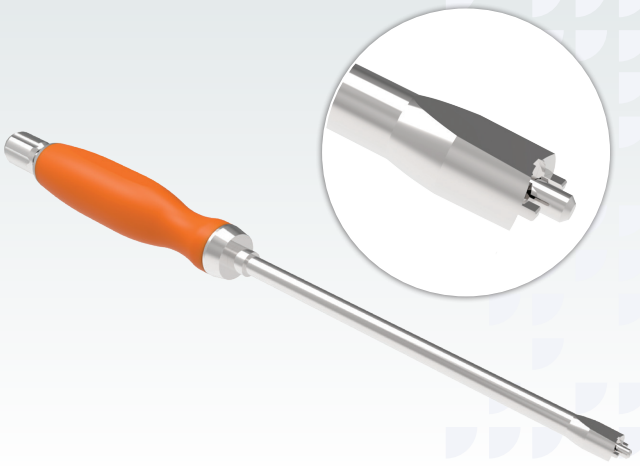
Implant Dimension Choice

- 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. The Implant's 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.
- Once the appropriate size and footprint is selected, the use of Trial Rasps is mandatory to facilitate expansion of the the Implant's Fixation Pins.
- After sizing and end-plate preparation, choose the Implant dimension according to the outcome of the trial procedure.

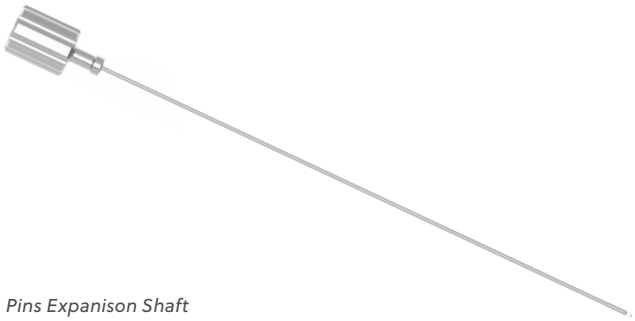




Implant packaging and release process



Insert the Shaft into the Holder and screw the knob clockwise



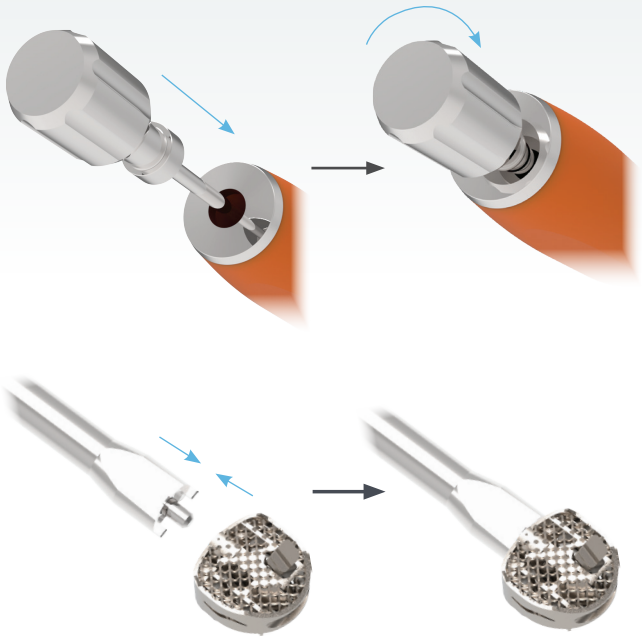
Pins Expanison Shaft

Implant Packaging

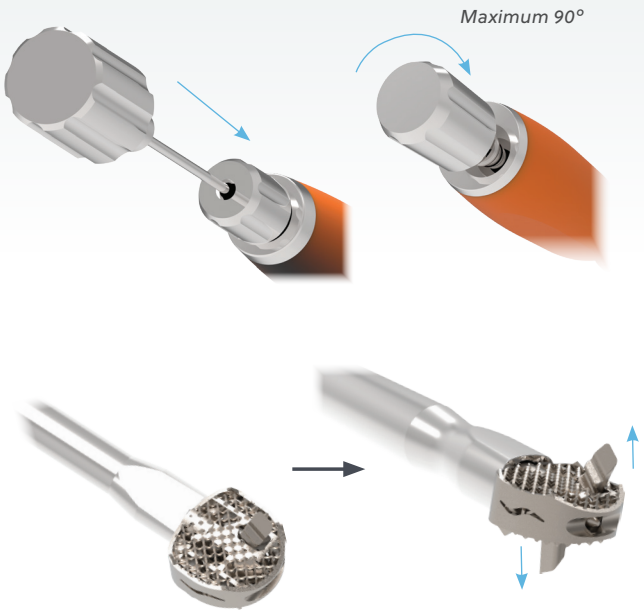
- The Implant is supplied in a double rigid blister pack with a special internal holder.
- The rotation nurse opens the outer (non-sterile) blister of the Implant and hands the Implant to the sterile OR nurse or scrub-tech. The sterile OR nurse removes the inner (sterile) blister, opens it, takes out 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 Holder Shaft and screw the knob to lock the Cage.



Insert the Pins Expansion Shaft and screw the knob to expand the Pins

Implant Preparation *(continued)*

- 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.
- Once firmly secured, insert the Pins Expansion Shaft into the Implant Holder.

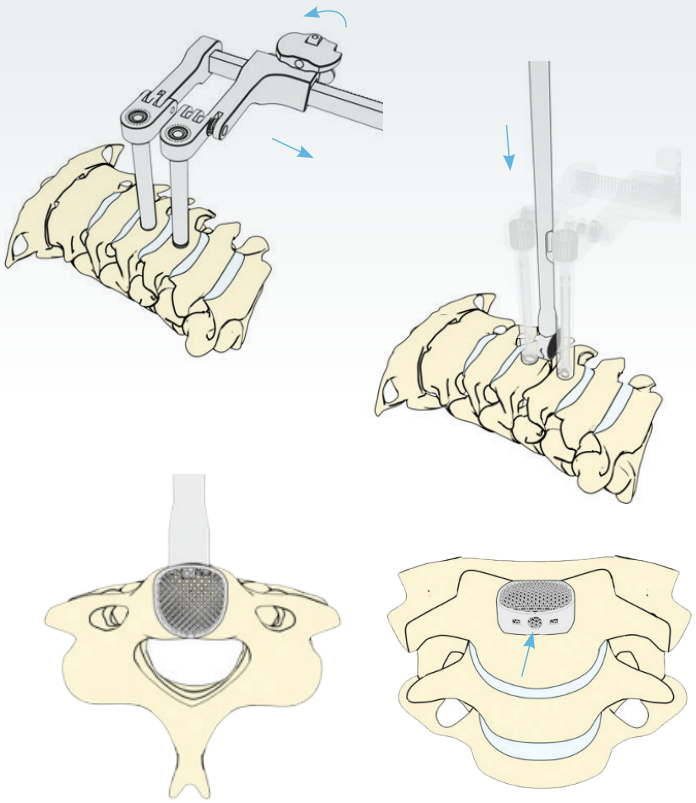
Implant Reference Code

- 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).

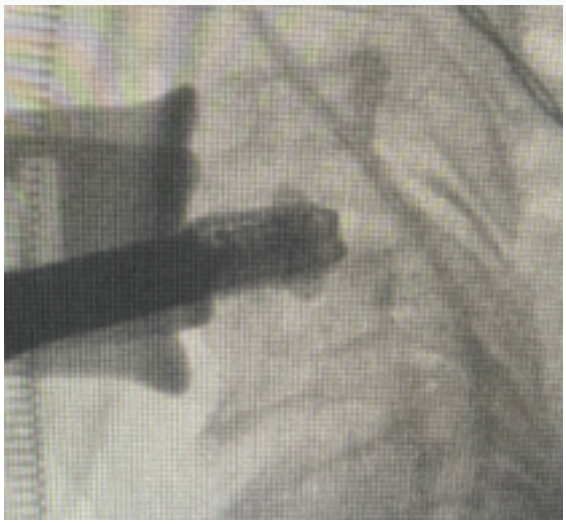
Example

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

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



Cage implantation procedure



X-rays during implantation

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 and turn the Pins Expansion Dhaft clockwise to final, to maximally extend the Pins to a locked position.

  Note: *The pins are being extended simultaneously.*

- When needed, for example when the surgeon would like to amend the final Implant position, Pins can be retracted back into the implant by turning the Pins Expansion Shaft counterclockwise, after which above procedure can be repeated.
- A lateral X-ray during the procedures is highly recommended to control the final (height / depth) position of the Implant before releasing distraction and extending the pins. An AP X-ray is recommended to control the final center position. Proper extension of the Pins can be seen both in lateral and AP X-rays.

Cage Fixation

- After final positioning has been confirmed detach the Implant Holder by turning the Implant Holder Shaft counterclockwise. Remove the Implant Holder and check again the implant positioning with X-rays, both in AP and lateral direction.

Implant Overview

Rectangular Footprint 14 x 12 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Fix Ti 14 x 12 x 5 mm, 5°	TICF1412-0505	2
Avenue-C Fix Ti 14 x 12 x 6 mm, 5°	TICF1412-0605	2
Avenue-C Fix Ti 14 x 12 x 7 mm, 5°	TICF1412-0705	2
Avenue-C Fix Ti 14 x 12 x 8 mm, 5°	TICF1412-0805	1
Avenue-C Fix Ti 14 x 12 x 9 mm, 5°	TICF1412-0905	1

Rectangular Footprint 16 x 14 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Fix Ti 16 x 14 x 5 mm, 5°	TICF1614-0505	2
Avenue-C Fix Ti 16 x 14 x 6 mm, 5°	TICF1614-0605	2
Avenue-C Fix Ti 16 x 14 x 7 mm, 5°	TICF1614-0705	2
Avenue-C Fix Ti 16 x 14 x 8 mm, 5°	TICF1614-0805	1
Avenue-C Fix Ti 16 x 14 x 9 mm, 5°	TICF1614-0905	1

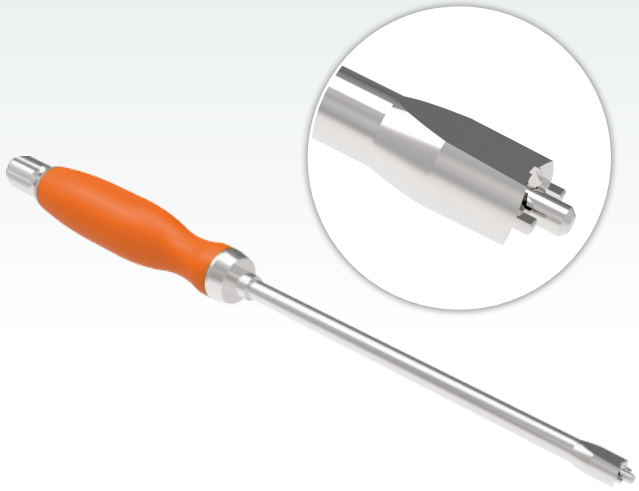
Square Footprint 14 x 14 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Fix Ti 14 x 14 x 5 mm, 5°	TICF1414-0505	2
Avenue-C Fix Ti 14 x 14 x 6 mm, 5°	TICF1414-0605	2
Avenue-C Fix Ti 14 x 14 x 7 mm, 5°	TICF1414-0705	1
Avenue-C Fix Ti 14 x 14 x 8 mm, 5°	TICF1414-0805	1
Avenue-C Fix Ti 14 x 14 x 9 mm, 5°	TICF1414-0905	1

Rectangular Footprint 18 x 16 mm

Description (W x D x H)	Part Number	QTY
Avenue-C Fix Ti 18 x 16 x 5 mm, 5°	TICF1816-0505	2
Avenue-C Fix Ti 18 x 16 x 6 mm, 5°	TICF1816-0605	2
Avenue-C Fix Ti 18 x 16 x 7 mm, 5°	TICF1816-0705	1
Avenue-C Fix Ti 18 x 16 x 8 mm, 5°	TICF1816-0805	1
Avenue-C Fix Ti 18 x 16 x 9 mm, 5°	TICF1816-0905	1

Instrument Overview



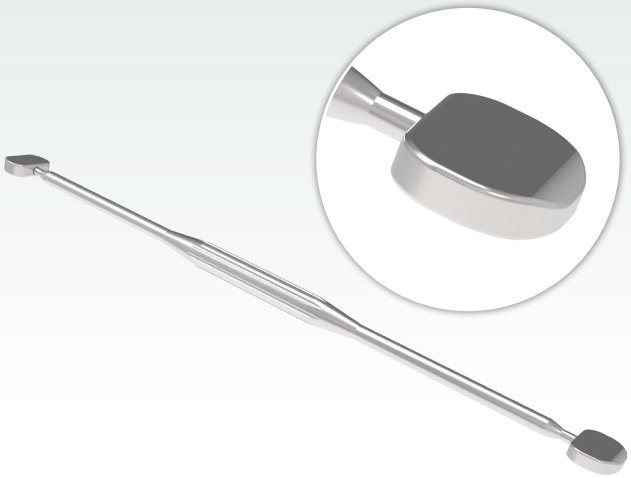
Implant Holder	Part Number
	BOK-CSZ-01

One Side Squared Curette	Part Number
	BOK-CS-04

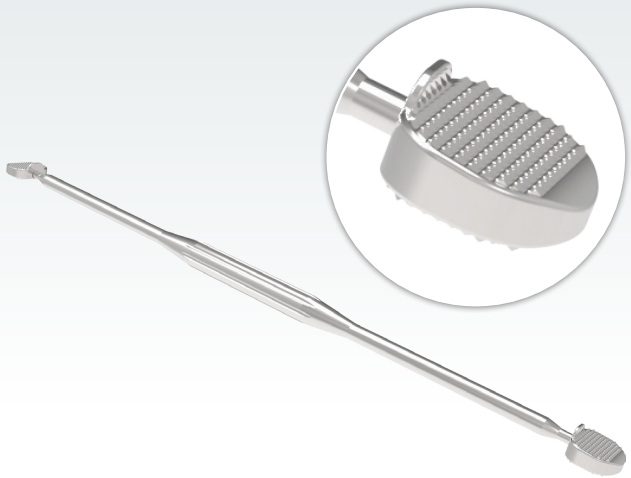
Implant Holder Shaft	Part Number
	BOK-CSZ-02

Shaver	Part Number
	BOK-CS-03

Pins Expansion Shaft	Part Number
	BOK-CSZ-03

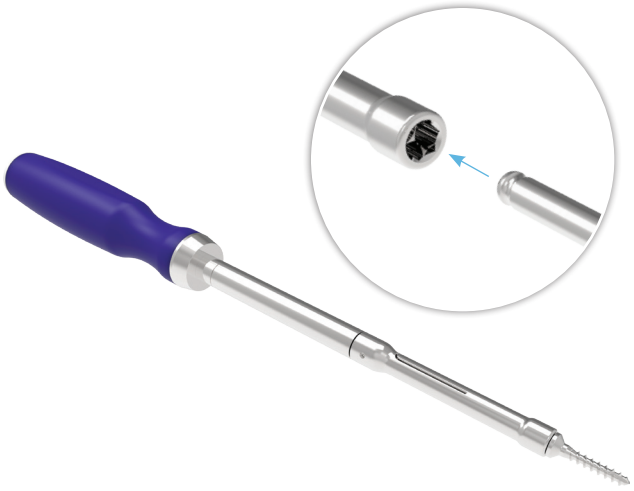


Implant Trial	Part Number
4-5 Small (14 x 12 mm)	BOK-CS-0405WS
6-7 Small (14 x 12 mm)	BOK-CS-0607WS
8-9 Small (14 x 12 mm)	BOK-CS-0809WS
4-5 Medium (14 x 14 mm)	BOK-CS-0405M
6-7 Medium (14 x 14 mm)	BOK-CS-0607M
8-9 Medium (14 x 14 mm)	BOK-CS-0809M
4-5 Medium (16 x 14 mm)	BOK-CS-0405WM
6-7 Medium (16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

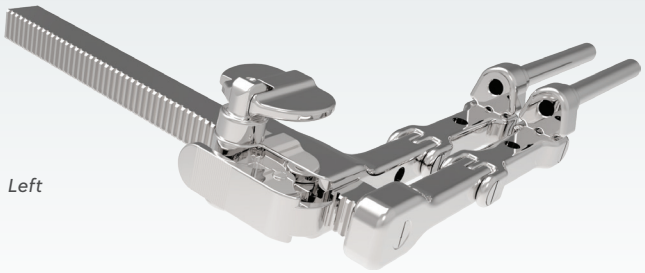


Implant Rasp	Part Number
4-5 Small (14 x 12 mm)	BOK-CSZ-R0405WS
6-7 Small (14 x 12 mm)	BOK-CSZ-R0607WS
8-9 Small (14 x 12 mm)	BOK-CSZ-R0809WS
4-5 Medium (14 x 14 mm)	BOK-CSZ-R0405M
6-7 Medium (14 x 14 mm)	BOK-CSZ-R0607M
8-9 Medium (14 x 14 mm)	BOK-CSZ-R0809M
4-5 Medium (16 x 14 mm)	BOK-CSZ-R0405WM
6-7 Medium (16 x 14 mm)	BOK-CSZ-R0607WM
8-9 Medium (16 x 14 mm)	BOK-CSZ-R0809WM
4-5 Large (18 x 16 mm)	BOK-CSZ-R0405WL
6-7 Large (18 x 16 mm)	BOK-CSZ-R0607WL
8-9 Large (18 x 16 mm)	BOK-CSZ-R0809WL

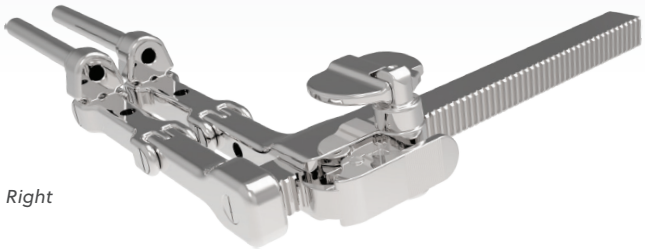
Vertebral Body Perforator (optional)	Part Number
	BOK-CS-08



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

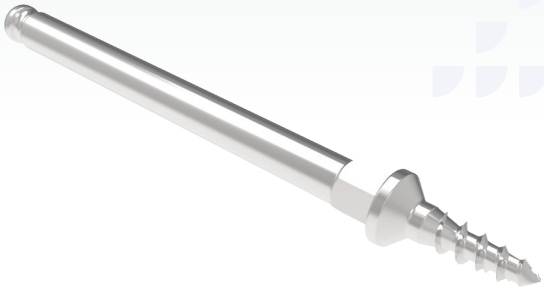


Left

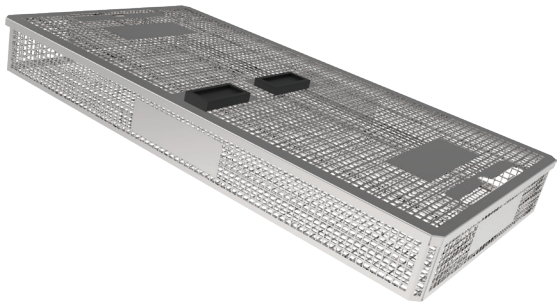


Right

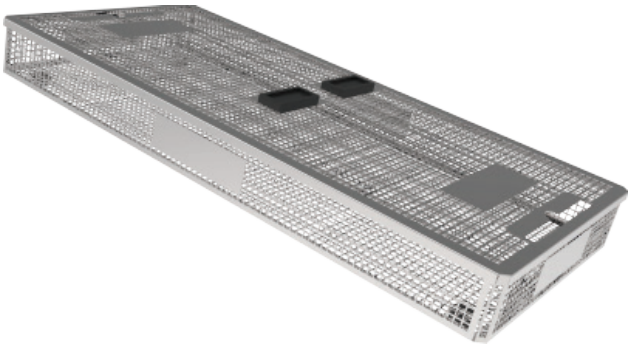
Caspar Distractor (optional)	Part Number
Left	BOK-CS-07L
Right	BOK-CS-07R



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



Small Tray Avenue-C Fix Ti	Part Number
	K3729-TICF



Large Tray Avenue-C Fix Ti	Part Number
	K3721-TICF

Instructions for Use

The ACC/ACCK/ACCZ Spinal System is intended to recreate and maintain distance between vertebras to support biologic fusion in the cervical spine. Can be used independently up to two levels or used with additional fixation device whatever appropriate.

DESCRIPTION

The ACC/ACCK/ACCZ Spinal System consists of cages in variable sizes and shapes. The dimensions of implants are designed based on anatomical conditions and decisions hereto are made by physicians.

ACC/ACCK/ACCZ Spinal System can be used as a single implant option ("stand-alone") up to two levels, or with other spinal or other fixation systems in order to achieve better stabilization, according to the physician's indication only.

Any application of any of the components from the ACC/ACCK/ACCZ Spinal System in combination with any other systems or other manufactures releases ZimVie from any liability. Do not use titanium implant systems in combination with steel implant systems.

All components of ACC/ACCK/ACCZ Spinal System cannot be reused under any circumstances. ACC/ACCK/ACCZ Spinal System is designed to be applied with anterior surgical approach only.

In particular, these instructions for use apply to the following code: ACC/ACCK/ACCZ Arthrodesis Cervical Cage.

MATERIALS

The entire system is made of medical grade titanium described by ISO 5832-3 or 10993-5 or ASTM F2026 or ASTM F136 standards. All devices are manufactured from one of the foregoing material specifications. Please see the product brochure for further information.

INDICATIONS

ACC/ACCK/ACCZ Spinal System is intended for cervical interbody fixation for the following indications:

- Degenerative disc disease.
- Spinal stenosis.
- 3. Revision surgery for failed disc surgery or progressive degenerative discopathies.
- 4. Foraminal stenosis or nerve compression.
- 5. Pseudoarthrosis.
- 6. Instability of motion segments.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Risk of infection or infection in progress, or fever or inflammation.
- Obesity.
- Pregnancy.
- Mental illness.
- Allergy on any system components.
- Any anatomical, medical or surgical conditions which may preclude potential or intentional benefits of spinal implants application.
- Bone, joints or ligaments conditions, including -but not limited to-: osteopenia, bone absorption, osteomalacia. Osteoporosis is a relative contraindication and must be carefully evaluated prior to surgery.
- Implant's size, shape or anchorage functionality might not be sufficient to achieve expected clinical results.
- Combination with implants from other manufacturers.
- Potential risk of unexpected patient's anatomy destruction, interference with neurological, functional, or other deficits.
- Any risk of patient's unwillingness to follow postoperative instructions.
- Any other not described in indications.

Caution: *In case of reuse there is a danger of cross contamination; any reuse is therefore not permitted.*

POTENTIAL ADVERSE EVENTS

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

- Disassembly, bending, and/or breakage of any or all of the system's components.
- Migration of any of the system's components.
- Pressure on the skin from component parts in patients with inadequate tissue coverage.
- Tissue or nerve damage caused by improper positioning and placement of implants or improper use of instruments.
- Dura leakage, distortion, or damage.
- Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypertension, or any others related to surgery in general associated to anesthesia.
- Infections.
- Loss of urinary functions.
- Permanent or temporary or developing sexual dysfunctions.
- Postoperative change of body curvature, change of physiological range of movement.
- 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 developing respiratory problems.
- Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
- Death.

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

WARNINGS

The effectiveness and safety of interbody fixation is only applicable for certain conditions with significant instability, which require fusion supported by a medical device. Correct placement and appropriate size selection are crucial to achieve optimal results. The device might be supportive for mechanical instability such as – but not limited to - deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.

PRECAUTIONS

The ACC/ACCK/ACCZ Spinal cage, may be supported by an additional fixation device. In some cases additional fixation is highly recommended. The applications of pedicle screws, cervical screws and/or interbody cages should be performed by experienced surgeons with specific training when using the ACC/ACCK/ACCZ Spinal System. The spinal screw fixation system and/or inter body cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful result is not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in the overall treatment process. Patients with obesity, smokers and alcoholics are at risk for non-fusion. Also, patients with weak muscle or bone conditions and/or nervous system dysfunctions are poor candidates for spinal fusion. Prior or during or after the surgery to evaluate or check the positioning of the implants or patient's anatomy or implant correction, X-ray or CT or any other diagnostic examinations may be necessary.

The proper, patient's individual implant selection in terms of type, size, shape, or design is vital to successful surgery performance. Proper implants and instruments' handling are crucial. Extensive bending or contouring should be avoided. Sharp cutting edges, reversed bending, scratching, or notching may generate internal stress, which may weak the implants or construct.

Important: *All necessary information about surgery, potential risks, benefits, and adverse effects should be conveyed to the patient prior to surgery.*

MAGNETIC RESONANCE ENVIRONMENT

The ACC/ACCK/ACCZ front cage is normally used for analysis using MRI devices. For the ACC / ACCK/ ACCZ anterior cages for cervical arthrodesis, the tesla limit to which the product can be subjected was not analyzed, generating artifacts that do not compromise the radiological analysis.

PRE-OPERATIVE

- Patients that meet the criteria described in the indications should only be selected.
- Patients' conditions should be checked prior to surgery; any required diagnostics should be performed.
- The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
- All implants, instruments and any other components should be cleaned and sterilised before use. Any implants, instruments or components delivered in sterile packaging must be checked on sterility and expiration date of sterility prior surgery.
- Implants and instruments should be stored in certain conditions to warrant the sterility and protection from any contamination or corrosive environment.
- It's highly recommended that all personnel interacting with any mechanical components of the spinal system should be familiar with all components before use.

INTRA-OPERATIVE

- Extreme caution should be taken when working close to or around the spinal cord and nerve roots.
- Whenever possible or required, intra-operative diagnostic systems should be used to facilitate surgery.
- Breakage, bends, scratch, slippage, part loosening or improper use of any implant or instrument during the surgery may cause injury to OR personal or patient.
- It's very important to follow the surgical technique carefully. Proper application of any instrument or implant may facilitate surgery.
- Before closing of soft tissue, double check of all implants' positioning, geometrical relations, and fixing, tightening, or mounting manoeuvres for all screws, nuts or other fixing parts have been performed. Image diagnostics is highly recommended at this stage.
- When trialing is performed, lateral x-ray is highly recommended to asset implants' height, angulation, and footprint size. Implant Trials should be inserted in the mid-line. Release the distraction and check if the Implant Trial fits firmly between the endplates of the superior and inferior vertebral bodies. Once the appropriate size is selected, please follow the implant preparation in accordance with the marks on the Implant Trial.

POST-OPERATIVE

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

- Detailed instructions about the use and limitations of the device should be communicated with the patient.
- The patient should be warned to avoid falls or sudden jolts in spinal position.
- The patient should be warned for this possibility and instructed to limit and restrict physical activities, especially lifting and twisting movements and any type of sports participation. The patient should be advised not to smoke, or to consume alcohol or non-steroids or use anti-inflammatory medications such as aspirin during the bone graft healing.
- As a precaution, before patients with implants receive any subsequent surgery (such as surgical dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- Any retrieved implants should be treated in such a manner that re-use in another surgical procedure is not possible. As with all orthopaedic implants, the ACC/ACCK/ACCZ Spinal System components should never be re-used under any circumstances.

PACKAGING

ACC/ACCK/ACCZ Spinal System is sterile packaged; to control the correct sterilization, make sure that the package arrives properly closed. Do not use if the blister is open or damaged.

STORAGE

The implant components of the ACC/ACCK/ACCZ Spinal System should be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapours and extreme changes in temperature and humidity. Sterile parts must be stored in original packages as a precaution for prevented to any damages.

For more information, visit ZimVie.com

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