Avenue®-A Fix Ti

Built-in Fixation Anterior Lumbar 3D Printed Titanium Cage

Surgical Technique Guide




ZimVie

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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. 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®-A Fix Ti

Built-in Fixation Anterior Lumbar 3D Printed Titanium Cage

Features and Characteristics

Avenue®-A Fix Ti Built in Fixation Anterior Lumbar 3D Printed Titanium Cage

Primary Stability

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

Wide Variety of Footprints, Heights and Lordosis Angles

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

Fusion Promotion 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.

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 pin is intended to secure rotational stability and prevent risk of conflict in case of posterior instrumentation in adjacent vertebras. Avenue®-A Fix Ti is manufactured in one production step, thanks to the additive manufacturing Technology used. No additional instruments are required for implantion. In case of revision, or if required, locked pins can be released using Pin Extractor.

Avenue®-A Fix Ti is offered in 2 footprints and 7* heights with two angles of lordosis:

Footprint:

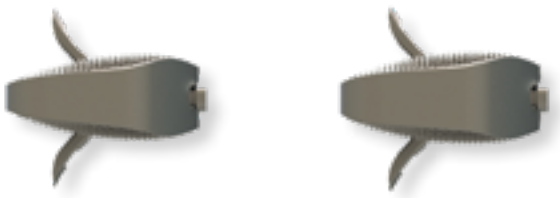
32 x 22 mm

38 x 28 mm

Height:

9 mm | 10 mm | 11 mm | 12 mm | 13 mm | 14 mm | 15 mm

Lordosis Angle



8° | 14°

**Refer to Overview below for reference status.*

Surgical Technique

Patient in supine position.

Patient Positioning

- Patient position should expose the spine level which going to be operated on.
- Surgeons should evaluate the most appropriate position considering the surgical approach technique, decompression procedure and fusion technique.
- For this Anterior surgical approach to the lower lumbar levels, the patient is placed in a supine position (Trendelenburg).
- Approach the required level following the known surgical technique hereto.

Level Exposure

- For anterior insertion, the intervertebral disc is exposed, such that there is a clear space on both sides of the vertebral midline.
- If the vessels and/or other soft tissues cannot be retracted sufficiently, insertion from an anterolateral direction may be indicated.

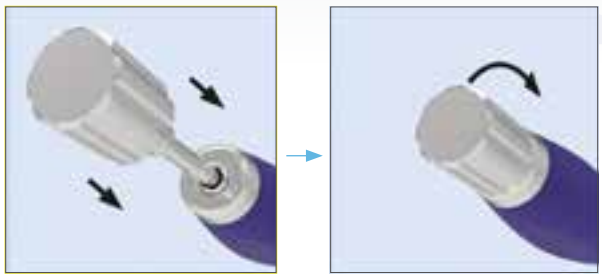
Surgical Technique (Continued)

Anterior Window Cut

- A rectangular opening in the anterior longitudinal ligament and the disc's annulus fibrosus is performed. A trial implant may be used as a template to indicate the width of the annular window required (for assembly of the trial implant on the implant holder, see page 8: similar to assembling the implant on the implant holder).
- Care needs to be taken to retain as much anatomical structures as possible, because these are important for the stability of the instrumented segment.

Disc Removal and Endplate Preparation

- The discectomy procedure should be performed using standard disc cleaning instruments through the window in the anterior longitudinal ligament and annulus fibrosus.
- The choice of appropriate instruments depends on approach, surgeons' preferences and projected results. Using rasps (standard in the set: 13, with 1 mm increments) and curettes is recommended while cleaning the disc (removal of nucleus material) and when preparing both the superior and inferior vertebral endplates in order to create efficient bone contact (removal of superficial layers of cartilage on the endplates).



Implant holder shaft assembling into the implant holder.

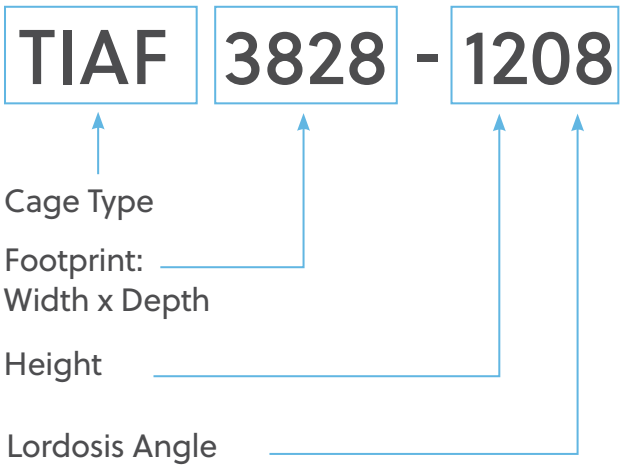
Implant trial example.

- 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.

  Note:
  Adequate nucleus pulposus material removal is mandatory to promote bone in-growth. This also prevents displacement of residual disc material into the spinal canal and potential misplacement of the implant.

Implant Dimension Choice

- Assemble the implant trial holder shaft into the implant trial holder and attach the implant trial that fits the intervertebral disc space best.
- Connect the implant trial to the assembled implant trial holder by turning the knob clockwise on the silicone handle till a solid fixed position has been reached in order to avoid any problems during final trial implant positioning.
- If a tight fit is not achieved, repeat the process using incrementally larger sizes of implant trials. Conversely, if the implant trial cannot be inserted, repeat using incrementally smaller sizes of implant trials.
- The trial Implant must fit firmly with a tight pressfit between the endplates
- Use fluoroscopy to check the trial implant position.

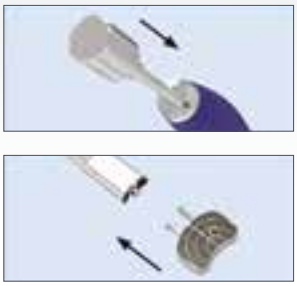


Implant Reference Code

- The correct implant size is the one that corresponds with the footprint, height and the lordosis angle of the implant trial.
- The lordosis angle for the implant is determined after evaluating the (pre-OP) fluoroscopic imaging

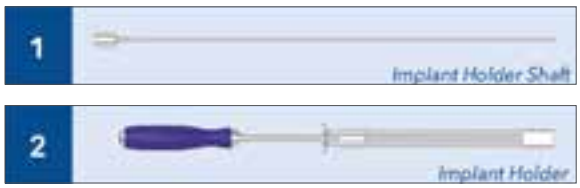
Implant Packaging

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

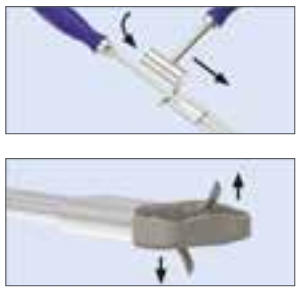


1. Insert the Holder Shaft.

2. Screw the knob to lock the cage.



3. Use the hammer to facilitage the insertion of pushers.



4. Press the pusher to extend the pins.

Cage Implantation

- Firmly connect the right size implant to the assembled Implant Inserter.
- Make sure the hammer surfaces on the lateral side of the Implant Holder are fully "up", which allows the pins of the implant to fully retract and be positioned into the Implant Holder for a secure fixation on the Implant Inserter; before implantation the superior and inferior surfaces of the implant don't show any of the pins sticking out, to allow a smooth insertion of the implant.
- Place the implant into its final position. Introduction may require gentle hammering on the backside of the Implant Inserter. The implant Inserter may be used to manipulate the cage within the disc space, if required.
- Use the hammer to extend the pins by tapping on the hammer surfaces on the lateral side of the implant Holder to final, which securely locks the pins into the implant.
- Once the cage is in the correct position and the pins are fully extended, the Implant Inserter should be removed: The Implant is released by turning the knob of BOK-ACA J-0 2 counterclockwise, leaving the implant in its optimal and securely fixed position.
- Only when needed, the pins can be retracted by using the pin extractor.

Note: *The Holder safety clip is to be used during cage insertion to avoid unintentional push of the pins, so they do not protrude during this insertion step.*

Note: *If Pins need to be retrieved back, first take Implant Holder Shaft, attach it to the cage, and hold firmly, to avoid cage migration, while you hammer back the Pins with the Pin Extractor.*

Implant Overview

Footprint 32 x 22 mm

Description (WxDxH)	Part Number	QTY
Avenue-A Fix Ti 32 x 22 x 9 mm; 8°	TIAF3222-0908	0
Avenue-A Fix Ti 32 x 22 x 10 mm; 8°	TIAF3222-1008	2
Avenue-A Fix Ti 32 x 22 x 11 mm; 8°	TIAF3222-1108	0
Avenue-A Fix Ti 32 x 22 x 12 mm; 8°	TIAF3222-1208	2
Avenue-A Fix Ti 32 x 22 x 13 mm; 8°	TIAF3222-1308	0
Avenue-A Fix Ti 32 x 22 x 14 mm; 8°	TIAF3222-1408	2
Avenue-A Fix Ti 32 x 22 x 15 mm; 8°	TIAF3222-1508	0

**Optional. Available by special order.*

Description (WxDxH)	Part Number	QTY
Avenue-A Fix Ti 32 x 22 x 9 mm; 14°	TIAF3222-0914	0
Avenue-A Fix Ti 32 x 22 x 10 mm; 14°	TIAF3222-1014	2
Avenue-A Fix Ti 32 x 22 x 11 mm; 14°	TIAF3222-1114	0
Avenue-A Fix Ti 32 x 22 x 12 mm; 14°	TIAF3222-1214	2
Avenue-A Fix Ti 32 x 22 x 13 mm; 14°	TIAF3222-1314	0
Avenue-A Fix Ti 32 x 22 x 14 mm; 14°	TIAF3222-1414	2
Avenue-A Fix Ti 32 x 22 x 15 mm; 14°	TIAF3222-1514	1

**Optional. Available by special order.*

Footprint 38 x 28 mm

Description (WxDxH)	Part Number	QTY
Avenue-A Fix Ti 38 x 28 x 9 mm; 8°	TIAF3828-0908	0
Avenue-A Fix Ti 38 x 28 x 10 mm; 8°	TIAF3828-1008	2
Avenue-A Fix Ti 38 x 28 x 11 mm; 8°	TIAF3828-1108	0
Avenue-A Fix Ti 38 x 28 x 12 mm; 8°	TIAF3828-1208	2
Avenue-A Fix Ti 38 x 28 x 13 mm; 8°	TIAF3828-1308	0
Avenue-A Fix Ti 38 x 28 x 14 mm; 8°	TIAF3828-1408	2
Avenue-A Fix Ti 38 x 28 x 15 mm; 8°	TIAF3828-1508	0

**Optional. Available by special order.*

Description (WxDxH)	Part Number	QTY
Avenue-A Fix Ti 38 x 28 x 9 mm; 14°	TIAF3828-0914	0
Avenue-A Fix Ti 38 x 28 x 10 mm; 14°	TIAF3828-1014	2
Avenue-A Fix Ti 38 x 28 x 11 mm; 14°	TIAF3828-1114	0
Avenue-A Fix Ti 38 x 28 x 12 mm; 14°	TIAF3828-1214	2
Avenue-A Fix Ti 38 x 28 x 13 mm; 14°	TIAF3828-1314	0
Avenue-A Fix Ti 38 x 28 x 14 mm; 14°	TIAF3828-1414	2
Avenue-A Fix Ti 38 x 28 x 15 mm; 14°	TIAF3828-1514	1

**Optional. Available by special order.*

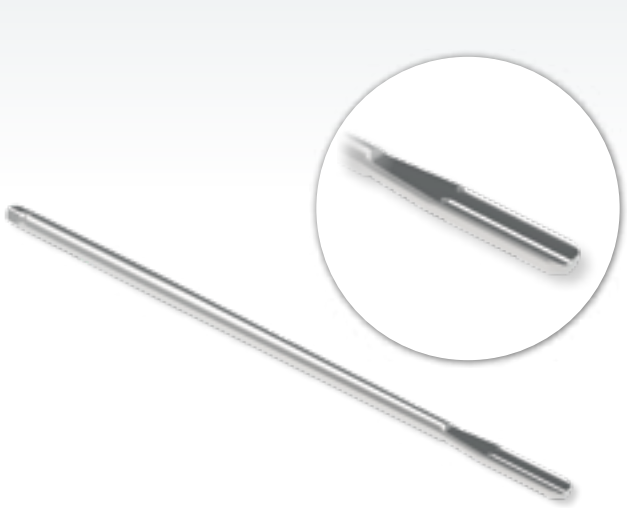
Instrument Overview

Implant Holder	Part Number
	BOK-ACAJ-01
	BOK-ACAJ-02

Fast Connection Straight Handle	Part Number
	BOK-LC-55

Pin Extractor	Part Number
	BOK-J-EX01

Hammer	Part Number
	TH002



Shavers	Part Number
7 mm	BOK-LC-250-07
8 mm	BOK-LC-250-08
9 mm	BOK-LC-250-09
10 mm	BOK-LC-250-10
11 mm	BOK-LC-250-11
12 mm	BOK-LC-250-12
13mm	BOK-LC-250-13

Implant Trial	Part Number
Trial 32 x 22 x 10 mm - 8°	BOK-ACA-S1008
Trial 32 x 22 x 12 mm - 8°	BOK-ACA-S1208
Trial 32 x 22 x 14 mm - 8°	BOK-ACA-S1408
Trial 32 x 22 x10 mm - 14°	BOK-ACA-S1014
Trial 32 x 22 x 12 mm - 14°	BOK-ACA-S1214
Trial 32 x 22 x1 4 mm - 14°	BOK-ACA-S1414
Trial 32 x 22 x 15 mm - 14°	BOK-ACA-S1514
Trial 38 x 28 x 10 mm - 8°	BOK-ACA-L1008
Trial 38 x 28 x 12 mm - 8°	BOK-ACA-L1208
Trial 38 x 28 x 10 mm - 14°	BOK-ACA-L1408
Trial 38 x 28 x 12 mm - 14°	BOK-ACA-L1214
Trial 38 x 28 x 14 mm - 14°	BOK-ACA-L1414
Trial 38 x 28 x 15 mm - 14°	BOK-ACA-L1514

Trial Implant Holder	Part Number
	BOK-ACA-01
	BOK-ACA-02

Holder Saftey Clip	Part Number
	BOK-ACAJ-03

Large Tray Avenue-A Fix Ti	Part Number
	K3721-TIAF

Instructions for Use

The LUMBAR TITANIUM INTERBODY FUSION CAGE is intended to recreate and maintain distance between vertebras to support biologic fusion in the thoracic, lumbar or lumbar-sacral spine zone. As complementary device, it should NOT be used as stand-alone. The device must always be within the limits of the vertebral cortices. If this indication is not followed, the device can be crushed because it protrudes from the spinal column and may not withstand the forces involved in such conditions

DESCRIPTION

The LUMBAR TITANIUM INTERBODY FUSION CAGE consists of cages in variable sizes and shapes. The dimensions of implants are designed based on anatomical conditions and decisions hereto are made by physicians.

LUMBAR TITANIUM INTERBODY FUSION CAGE components should be used in combination with other spinal systems or other fixation systems in order to obtain stabilization. All components of LUMBAR TITANIUM INTERBODY FUSION CAGE cannot be re-used under any circumstances.

LUMBAR TITANIUM INTERBODY FUSION CAGE is designed to be applied for posterior, posterior-lateral, anterior and lateral approach. In particular, this instruction for use is applicable for codes:

- ACT Cage for transforaminal arthrodesis "TLIF"
- ACA "ALIF" anterior arthrodesis cage
- ACP Cage for posterior arthrodesis "PLIF"
- ACX Cage for lateral arthrodesis "XLIF"
- ACL Cage for posterolateral oblique arthrodesis "OLIF"
- ACO Anterior Cage for Lumbar Arthrodesis
- ACTH Expandable lumbar cage
- ACXH Expandable extra-lateral cage and variable lordosis for lumbar arthrodesis
- ACPH Variable lordosis expandable cage for posterolateral arthrodesis
- MM Expandable anterior cage for lumbar arthrodesis
- CT Expandable anterolateral cage for lumbar arthrodesis
- MMJ Self-locking expandable anterior cage for lumbar arthrodesis
- ACXJ Self-locking extra-lateral cage for lumbar arthrodesis
- ACAJ Self-locking anterior cage for lumbar arthrodesis
- ACOJ Self-locking anterior cage for lumbar arthrodesis
- ACTZ Lumbar Cage

MATERIALS

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

INDICATIONS

LUMBAR TITANIUM INTERBODY FUSION CAGE is intended for lumbar interbody fixation for the following indications:

1. Degenerative disc disease.
2. Spondylolisthesis.
3. Spinal stenosis.
4. Trauma.
5. Tumour.
6. Pseudo-arthrosis.
7. Instability of motion segments.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Risk of infection or infection in progress, or fever or inflammation.
2. Obesity.
3. Pregnancy.
4. Mental illness.
5. Allergy on any system components.
6. Any anatomical, medical or surgical conditions which may preclude potential or intentional benefits of spinal implants application.
7. Bone, joints or ligaments conditions such but

not limited as: osteopenia, bone absorption, osteomalacia.

8. Osteoporosis is relative contraindications a must be carefully evaluated prior surgery.
9. Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
10. Combination with implants from other manufacturers.
11. Potential risk of unexpected patient's anatomy destruction, interference with neurological, functional or other deficits.
12. Any risk of patient's unwillingness to follow postoperative instructions.
13. 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:

1. Disassembly, bending, and/or breakage of any or all of the system's components.
2. Migration of any of the system's components.
3. Pressure on the skin from component parts in patients with inadequate tissue coverage.
4. Tissue or nerve damage caused by improper positioning and placement of implants or improper use of instruments.
5. Dura leakage, distortion or damage.
6. Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hypertension, or any others related to surgery in general associated to anesthesia.
7. Infections.
8. Loss of urinary functions.
9. Permanent or temporary or developing sexual dysfunctions.
10. Postoperative change of body curvature, change of physiological range of movement.
11. Pseudo-arthrosis or non-fusion or delayed fusion.
12. Bone loss or overgrowth, or any other bone malformations.
13. Permanent or temporary limitation or inability to perform daily activities.
14. Change in mental behavior.
15. Permanent or temporary or developing respiratory problems.
16. Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
17. Death.

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

WARNINGS

The effectiveness and safety of interbody fixation is only applicable for certain conditions with which require the fusion supported by medical device. The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumour, pseudo-arthrosis. The effectiveness and safety for any other conditions are unknown.

PRECAUTIONS

The LUMBAR TITANIUM INTERBODY FUSION CAGE are complementary implants to posterior fixation systems. The applications of pedicle screw and/or interbody cages should be performed by experienced surgeons with specific training in use of LUMBAR TITANIUM INTERBODY FUSION CAGE. The spinal screw fixation system and/or interbody cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful result is not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in 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, in order to evaluate or check the positioning of the implants or patient's anatomy or any other patient or implant correction, X-ray or CT or any other diagnostic examinations may be necessary.

Instructions for Use (Continued)

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

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

PRE-OPERATIVE

1. Patients that meet the criteria described in the indications should only be selected.
2. Patients' conditions should be checked prior to surgery; any required diagnostics should be performed.
3. The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
4. All implants, instruments and any other components should be cleaned and sterilized before use. Any implants, instruments or components delivered in sterile packaging must be checked on sterility and expiration date of sterility prior surgery.
5. Implants and instruments should be stored in certain conditions to warrant the sterility and protection from any contamination or corrosive environment.
6. 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

1. Extreme caution should be taken when working close to or around the spinal cord and nerve roots.
2. Whenever possible or required, intra-operative diagnostic systems should be used to facilitate surgery.
3. 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.
4. It's very important to follow the surgical technique carefully. Proper application of any instrument or implant may facilitate surgery.
5. Before closing of soft tissue, double check of all implants' positioning, geometrical relations, and fixing, tightening or mounting maneuvers for all screws, nuts or other fixing parts have been performed. Image diagnostics is highly recommended at this stage.

POST-OPERATIVE

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

1. Detailed instructions about the use and limitations of the device should be communicated with the patient.
2. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. 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.
4. 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.
5. Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the LUMBAR TITANIUM INTERBODY FUSION CAGE components should never be reused under any circumstances.

PACKAGING

LUMBAR TITANIUM INTERBODY FUSION CAGE is sterile packaged; in order to control the correct sterilization, make sure that the package arrives properly closed. Do not use if the blister is open or damaged.

STORAGE

The components of the LUMBAR TITANIUM INTERBODY FUSION CAGE must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapours and extreme changes in temperature and humidity. Sterile parts must be stored in original packages as a precaution for prevented to any damages.

For more information, visit ZimVie.com

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