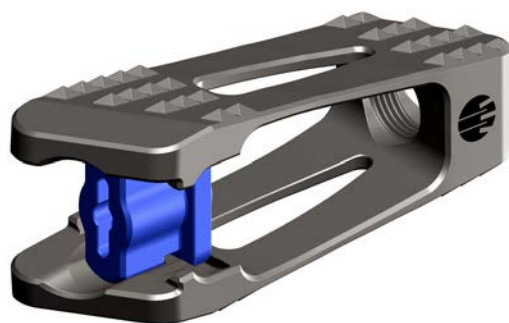


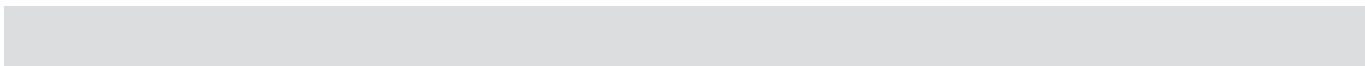
**vertaconnect** ™ TLIF Cage Instrumentation

# vertaconnect ™

**Instructions for Use and Surgical Technique**



 **spontech**  
spine intelligence



# **vertaconnect** **TLIF Cage Instrumentation**

## **Instructions for Use and Surgical Technique**



For order numbers see Chapter 6 „Product Overview and Ordering Information“



**spontech spine GmbH** declares this medical device (**vertaconnect** Ⓢ TLIF Cage) to be conformant with the regulations of the Council Directive 93/42/EEC, appendix VII of June 14, 1993 for medical devices.



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# 1 Information on Use

## 1.1 The vertasystem

The revolutionary vertasystem represents a new approach for the best possible patient-specific treatment of the spine. The system comprises diagnostic procedures, implants, special instrumentation as well as software for calculating the precise adjustment of the spine geometry to the exact angle and millimeter, which to date is unique.

The long-term successful outcome of spine surgery depends on how precisely the patient's original anatomy can be restored. The risk of early degeneration of the adjacent spine segments can be minimized only by means of precise adjustment of the diseased segment.



## 1.2 Intended Use

The primary function of the interbody implant is to distract the disc space and restore the natural geometry of the disc space as a place holder, supporting the completion of the bony fusion. The vertaconnect TLIF cage is intended for the treatment of one or more segments in the lumbar spine region between L1 and S1.

The **vertaconnect** Ⓢ TLIF instrumentation is used to implant the TLIF cage on the basis of the surgical technique and to transport, store and reprocess the cage based on the instructions for use.

## 1.3 Indications

Degenerative changes in the lumbar spine, where monosegmental or multisegmental fusion is indicated:

- Degenerative Disc Disease (DDD)
- Degenerative and post-traumatic instabilities
- Spinal canal stenosis with or without paralysis and loss of motor control
- Elimination or reduction of pain in cases of DDD (degenerative disc disease) that have been diagnostically substantiated and confirmed by means of X-ray
- Spondylolisthesis up to grade 1-2 of the affected segments.



Caution

Indication for the use of the **vertaconnect** Ⓢ TLIF cage instrumentation together with the **vertaconnect** Ⓢ TLIF Cage is established by the surgeon, taking into account the individual clinical and biomechanical situation of the patient.

## 1.4 Contraindications

### Absolute contraindications

- Severe bone defects in the affected vertebral segment that cannot guarantee stable anchoring of the implant in the disc space
- Discitis and other acute and chronic infections
- Bone tumors in the affected vertebral segments
- Spinal tumor
- Severe deformation of the spine
- Fractured vertebrae
- Spondylolisthesis as of grade 3
- Intolerance to the implant material (titanium Ti6AL4V)

### Relative contraindications

- Poor general state of health
- Severe osteoporosis or condition with similar loss of bone density
- Inadequate cooperation of the patient during subsequent rehabilitation
- Drug abuse, alcoholism



## 1.5 Risks and Side-effects

### In connection with the TLIF surgical procedure

- Damage to the dura, vessels and nerves
- Neurological deficits
- Bleeding, hematomas
- Persistence of symptoms
- Chronic pain syndrome
- Spondylolisthesis following unsuccessful fusion
- Infections, wound-healing complications
- Adjacent segment degeneration

### In connection with implantation of the vertaconnect ⊕ TLIF cage

- Implant subsidence with loss of disc space height
- Pseudarthrosis in the event of incomplete or failed fusion
- Wrong positioning of implant
- Dislocation of implant
- Implant fracture resulting from excessive strain
- Allergic foreign-body reactions to implant materials
- Damage to the nerve root

Please also observe the information in the instructions for use for the **vertaconnect ⊕ TLIF cage** and the **vertaplan** software.

Caution



## 1.6 Important Information and Precautionary Measures

Use of the **vertaconnect ⊕ TLIF cage** requires comprehensive proficiency in spine surgery.

- Meticulous pre-operative planning with the help of radiological imaging and the **vertaplan** software is explicitly recommended for selecting the appropriate implant.
- Spondylolisthesis should be realigned before implantation.
- Prior to implantation of the TLIF cage check that the identification labeling on the implant that is intended for implantation corresponds to the implant that has been selected:
  - Reference number on implant and implant packaging
  - Details of implant size on the implant packaging
  - The reference number indicates the length, the anterior height in expanded state and the posterior height of the implant.
- The **vertaconnect ⊕ TLIF cage** may only be inserted using the corresponding **vertaconnect** instrumentation.
- Under no circumstances may the implant be used if it is in any way damaged or if there is any risk that its function is not guaranteed. These implants must be properly disposed of in compliance with the hospital's policies and guidelines.
- The **vertaconnect ⊕ TLIF cage** is intended for single use only.
- Reuse or clinical reprocessing of the **vertaconnect ⊕ TLIF cage** can compromise the properties and condition of the implant and result in its malfunction. It also increases the risk of contamination by potential transmission of germs. This can cause bodily harm to the patient and/or the user. Due to the complex design of the product and the assembly and disassembly of the expansion element that are involved, clinical reprocessing of the **vertaconnect ⊕ TLIF cage** is not allowed and has not been validated by **spontech**. Contaminated implants may not be reused and must be properly disposed of in compliance with the hospital's policies and guidelines. This also applies to implants from damaged or open packages as well as to implants previously implanted and then removed.

## 2 General Safety Information

These instructions for use are intended solely for qualified medical staff, in particular for physicians and operating room staff, and provide general information on these medical devices. Reading the instructions for use and the surgical procedure cannot substitute the obligatory product training by a **spontech** product specialist.



Observe the instructions for use

For use of the **vertaconnect** Ⓢ TLIF cage and the vertaplan software, please observe the associated instructions for use.

Upon delivery, all containers and instruments must be checked as to whether the containers have been opened beforehand, whether obvious damage during transport, moisture, condensation or contamination are in evidence and whether the contents are complete.



Non-sterile

The **vertaconnect** Ⓢ TLIF cage instrumentation is non-sterile when delivered.

Before the instrumentation is used in surgery and before defective products are returned for repair, the instrumentation must be completely reprocessed and sterilized in accordance with the reprocessing instructions given in Chapter 5.

The user must ensure that all transport and packaging materials are completely removed from the set and/or instruments before reprocessing is performed.



Store in a dry place

Safe, dry transportation of the instrumentation to the processing site or to **spontech** spine GmbH in a closed container as well as safe, dry storage must be guaranteed in order to avoid environmental contamination and damage to the instrumentation.



Store in a dry place

The sterilized instruments must be stored in a dry, clean and dust-free environment at a moderate temperature within a range of 5 °C to 40 °C.



Caution

Do not deposit or store other instruments or objects on top of the instruments or perforated instrument trays. This could cause damage to the instruments and/or the trays, which could compromise the safe functioning of the instrumentation.



Caution

Improper use of the instruments or use of damaged instruments or sharp or pointed edges can cause injury to the tissue, nerves and vessels of the patient and the user. Injury can also occur if a faulty instrument slips or is badly positioned or as a result of excessive pressure.

Because of the required mechanical properties, the instruments are not made of implantable materials. If an instrument breaks, ensure that all fragments are removed from the patient, as these could lead to complications (e.g. allergies, infection) in connection with the release of metallic components

### 3 Constituent Parts of the **verta**system

#### 3.1 The **vertaplan** Software for Preoperative Planning

With our **vertaplan** software, spine surgery can be precisely planned in advance. During surgery, too, the software facilitates ideal, patient-specific adjustment of the spine geometry. Not only does the software calculate the optimum correction, but it also provides information on the effect of the operation on the overall spine profile. With the instrumentation that is specially designed for this system and the accurately fitting **vertaconnect** <sup>®</sup> TLIF cage implants, the planning can be directly implemented. The potential risk of adjacent segment degeneration is thus reduced. All steps are documented in the process.



#### 3-1

#### **vertaplan** software results

**vertaplan** Standardized X-rays of the lumbar spine are required for the selection of the appropriate implants and their positioning. First of all, the vertebrae are all labeled in the images from S1 to T12. These parameters are requisite for assessing the individual spine geometry of the patient.

The calculations give the ventral and dorsal height of the disc space, the angle and the range of motion of the segment which is to be operated on. The motion from the flexion position to the extension position can be graphically simulated with and without the implant.

The displayed calculation data enables optimum evaluation and planning. The software recommends the most suitable **vertaconnect** implant, which must then be approved for surgery by the physician. Systematic planning is significantly simplified by the software, thus facilitating fast, reliable implementation in the daily work routine.

For further information please see the Instructions for Use for the **vertaplan** software.

Please note



### 3.2 The **vertaconnect** Ⓢ TLIF cage

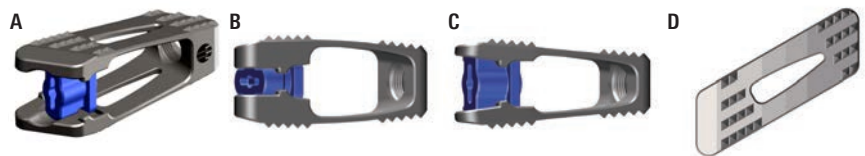
The **vertaconnect** Ⓢ TLIF cage is a spacer for implantation in a prepared disc space in the lumbar spine. It features stable contact surfaces, toothed surfaces and large cage windows. The open design of the implant promotes bone through-growth in the disc space.

The **vertaconnect** Ⓢ TLIF cage

- optimally adapts to the patient's individual anatomy thanks to the expansion function
- permits simple application and easy handling
- enables easy insertion due to low entry height
- provides immediate stability due to the toothed surface and stable contact surface
- achieves high biocompatibility for good long-term outcomes thanks to the time-proven titanium alloy (Ti6Al4V)

#### 3-2

**A** Front view **B** Side view, not expanded **C** Side view, expanded **D** Top view



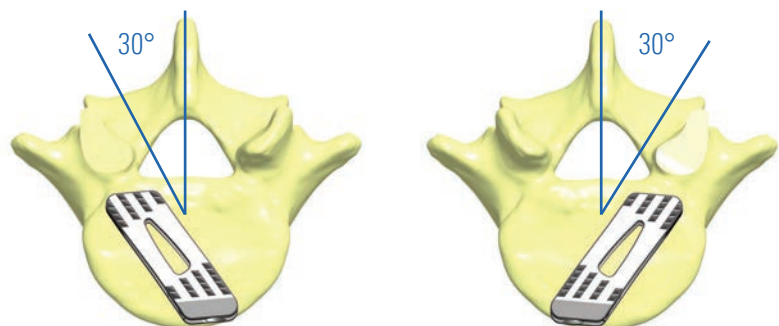
The **vertaconnect** Ⓢ TLIF cage is available with the following geometric options (see also Chapter 6.2):

- Length 31/34/37 mm
- Posterior height 8/10/12 mm
- Lordotic angle 3°/11°/7°/15°
- Anterior height from 9 to 19 mm

The TLIF (transforaminal lumbar interbody fusion) procedure is an established procedure for transforaminal interbody fusion of two adjacent vertebrae by means of dorsolateral access. The objective of interbody fusion is to stabilize the segment and reconstruct the sagittal and coronal balance for the elimination of pain on a sustained basis. Interbody fusion makes sense when all other therapy options have been exhausted and have not led to the desired result.

#### 3-3

**Positioning the implant** on the cortical part of the vertebra. Posterior access is possible from the right or the left side.



Caution

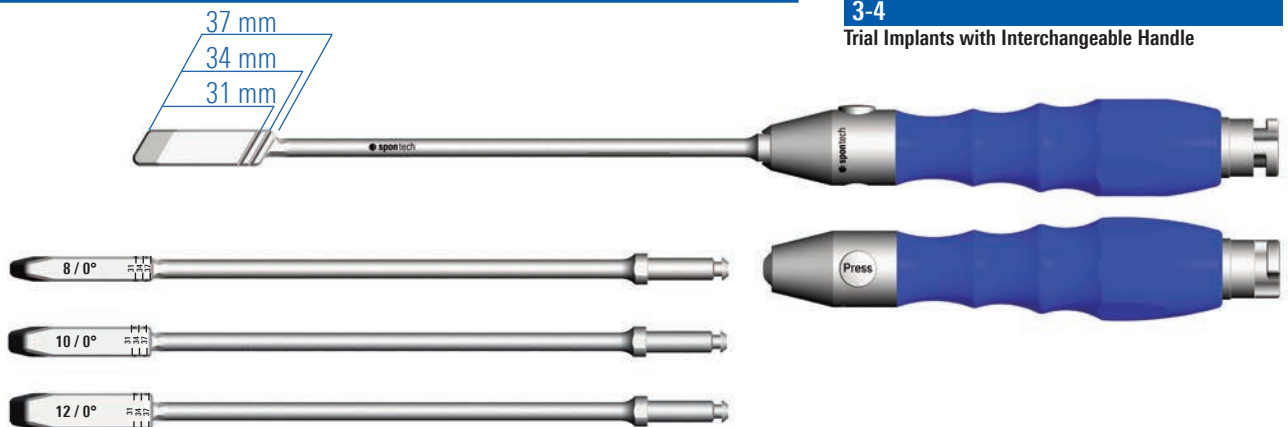
The **vertaconnect** Ⓢ TLIF cage may only be used in conjunction with the appertaining TLIF cage instrumentation.

### 3.3 The vertaconnect ⊕ TLIF cage Instrumentation

A set of instrumentation that is specially adapted to the implants is available for reliable implantation of the **vertaconnect** ⊕ TLIF cage. It consists of a selection of trial implants, a take-apart inserter with compatible drive for the expanding element, a visual indicator for turning the expanding element, a slide hammer, a nerve root retractor and a mallet. A revision tool for restoring the cage to non-expanded state is available as an option. The instruments are stored on a sterilizable instrument tray.

#### 3.3.1 Trial Implants with Interchangeable Handle

Three trial implants with an interchangeable handle are provided. These can be used to confirm once more during surgery the correct choice of the optimum posterior implant height and implant length. The trial implants are available in heights of 8, 10 and 12 mm and they all have indentations to indicate the three different implant lengths 31, 34 and 37 mm (Fig. 3-4).



**3-4**  
Trial Implants with Interchangeable Handle

#### 3.3.2 Interchangeable Handle for Trial Implants and Revision Tool

The interchangeable handle with button release is used to accept and guide the trial implants (Fig. 3-4) and the revision tool (Fig. 3-15). At the rear end it has a bayonet fitting for the slide hammer (Fig. 3-6), which can help remove the trial implants.

#### 3.3.3 Slide Hammer

The slide hammer can, if necessary, be used to facilitate removal of the trial implants and implants via the inserter.

#### 3.3.4 Mallet with Plastic Pads

The mallet can, if necessary, be used to facilitate insertion of the trial implants and implants via the inserter. The mallet pads are disposable and available as spare parts (see page 26)

#### 3.3.5 Nerve root retractor

The nerve root retractor is used to safely retract and protect the nerve root.



**3-5**  
Interchangeable Handle for Trial Implants and Revision Tool



**3-6**  
Slide hammer for trial implants and inserter



**3-7**  
Mallet with plastic pads



**3-8**  
Nerve root retractor

### 3.3.6 Implant Inserter

#### 3.3.6.1 Take-apart Inserter Complete with Indicator and Drive for Expanding Element

The inserter is used to accept and implant the **vertaconnect** Ⓢ TLIF cage. The complete inserter consists of the inserter as pictured below, a fixing shaft for the implant, a drive for the expanding element, a visual indicator for the expansion procedure and the corresponding interchangeable handle. Assembly of the inserter is described in Chapter 3.3.6.5.

#### 3-9

**Take-apart inserter** complete with indicator and drive for expanding element



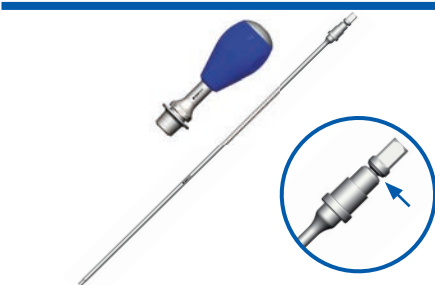
#### 3.3.6.2 Inserter with Fixing Shaft

The implant is inserted into the disc space using the inserter with inserted fixing shaft. The **vertaconnect** Ⓢ TLIF cage is screwed on to the thread of the fixing shaft (Fig. 3-10).



#### 3-10

Detailed view of **inserter with fixing shaft** Cage on fixing shaft in inserter



#### 3-11

Detailed view of **drive for expanding element with interchangeable handle**: predetermined breaking point as protection against overload



#### 3-12

**Visual indicator** for rotation of expanding element

#### 3.3.6.3 Drive for Expanding Element with Interchangeable Handle and Visual Indicator

First, mount the visual indicator (see Fig. 3-12) between the interchangeable handle and the drive and then connect the handle securely to the drive for the expanding element (see Fig. 3-13). Once the cage is positioned in the intended final position, the drive for the expanding element can inserted through the fixing shaft of the inserter.

The drive has a predetermined breaking point (see detail image 3-11), which breaks in the event of overload. If the predetermined breaking point is activated during the expansion procedure, check the anatomical situation for damage to the surrounding tissue as a result of the expansion procedure. There is always a second drive in the tray as a spare.

#### 3.3.6.4 Visual Indicator for Turning the Expanding Element

Rotation of the expanding element to set the lordotic angle can be monitored using the removable visual indicator. See also expansion procedure and Fig. 4-5 on page 18.



Please note

For information on reprocessing and care of the instrumentation, please refer to Chapter 5 of these instructions.

### 3.3.6.5 Assembly of Inserter with Drive for Expanding Element

Introduce the fixing shaft ③ into the inserter ② and connect the cage. The visual indicator ⑤ for rotation of the expanding element can be mounted on the drive ⑥ between the interchangeable handle ④ at your option.

**3-13**

- ① Inserter, complete, consisting of:
- ② Implant inserter
- ③ Fixing shaft for the implant
- ④ Interchangeable handle for the expanding element drive
- ⑤ Visual indicator for the position of expanding element
- ⑥ Drive for the expanding element





**3-14**

Connecting the vertaconnect ① TLIF cage to the inserter

### 3.3.6.6 Connecting the vertaconnect ① TLIF cage to the Inserter

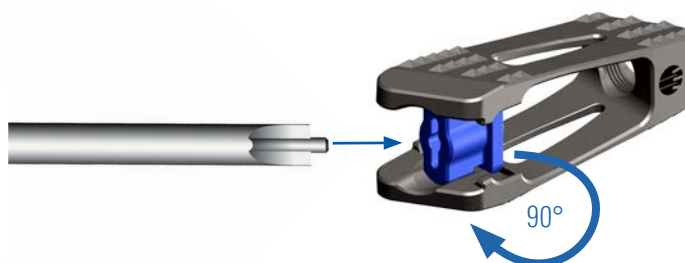
Connect the **vertaconnect** ① TLIF cage by turning the fixing shaft in the inserter. When doing so, check that the implant sits correctly on the distal end of the inserter (see detailed view). During fixation, hold the implant securely with one hand to prevent it from canting.

**3-15**

Revision tool with interchangeable handle

### 3.3.7. Revision Tool

The revision tool is used with the interchangeable handle for trial implants (see Fig. 3-5). It is used to restore the **vertaconnect** ① TLIF cage to non-expanded state by means of anterior access. To do this, insert the tool into the slot of the expanding element and turn it 90°. After this you can remove the cage using forceps or similar.





## 4 Surgical Technique

### 4.1 Access, Discectomy and Distraction

Before it is used for surgery, the instrumentation must be completely processed and sterilized in accordance with the reprocessing instructions in Chapter 5.

A standardized TLIF surgical procedure is used to gain access to the disc space in question. To enable this, the patient is positioned face down. The joint facets are removed to reveal the foramen. After the annulus fibrosus has been opened, the disc and any bone outgrowths are carefully removed to guarantee secure insertion of the implant and subsequent bone fusion of the segment.

For successful fusion, it is expressly recommended that you abrade the bony vertebral end plates. When you do so, it is important to avoid excessive mechanical processing of the bony structure. The **vertaconnect** Ⓢ TLIF cage should sit on the anterior and posterior part of the cortical ring, but must not be positioned beyond. Exact positioning must be verified by means of X-ray.

For implantation of the **vertaconnect** Ⓢ TLIF cage, dorsal stabilization of the treated segment is recommended in the form of a transpedicular screw-rod system or similar stabilization method. If the transpedicular screw-rod system was installed before distraction, make sure that during distraction the screw-rod combination is not yet screwed tight. Repositioning with the transpedicular screw-rod system can only be performed before the **vertaconnect** Ⓢ TLIF cage is implanted.

Before implantation, distraction should be performed using a distractor with the planned anterior implant height. Ensure that the disc space is sufficiently mobilized with the distractor.

Caution



Caution



Caution

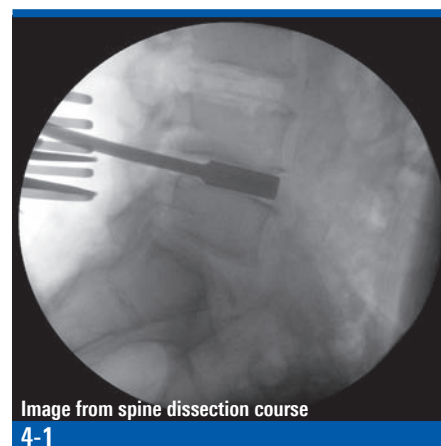


Image from spine dissection course

4-1

Distraction procedure

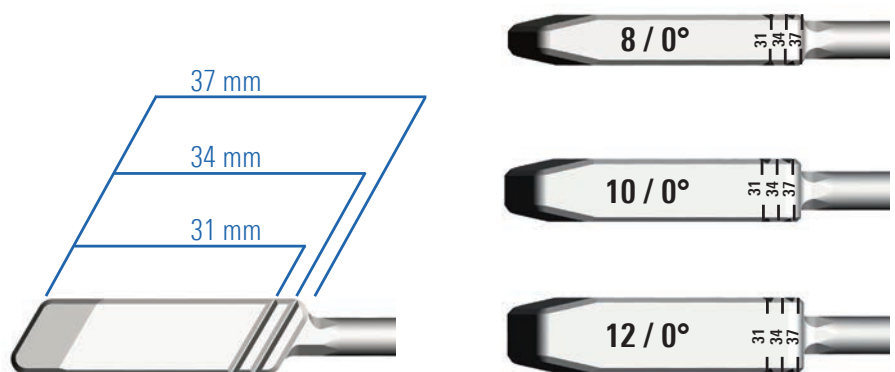
## 4.2 Implantation of the vertaconnect ® TLIF cage

The individual steps for the implantation of a **vertaconnect** ® TLIF cage are described in the following.

After complete removal of the disc tissue and adequate mobilization of the disc space, the correct selection of the ideal posterior implant height can be verified again intraoperatively using the trial implants. To do this, insert the selected trial implant into the disc space at an angle of 30°. In doing so, pay attention to the markings indicating the three implant lengths 31, 34 and 37 mm. Once the trial implant has reached its final position, perform an X-ray check.

### 4-2

**vertaconnect** ® TLIF cage trial implants in implant lengths 31, 34 and 37 mm and posterior implant heights of 8, 10 and 12 mm

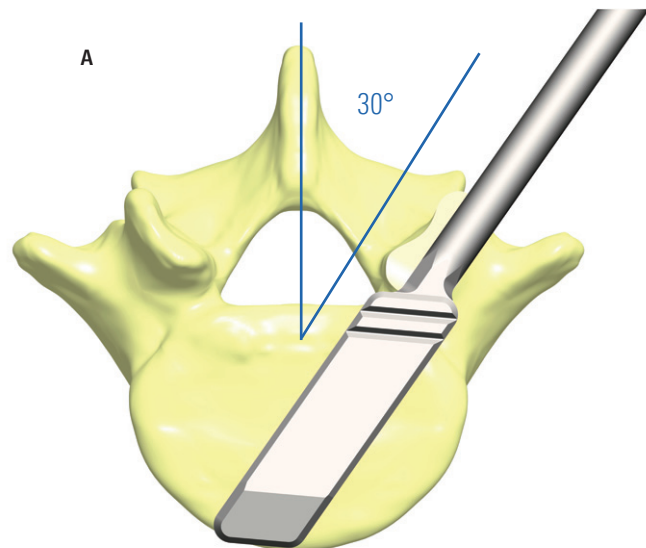


### 4-3

#### Vertebra with trial implant

**A** View from above

**B** C-arm image, sagittal with trial implant.

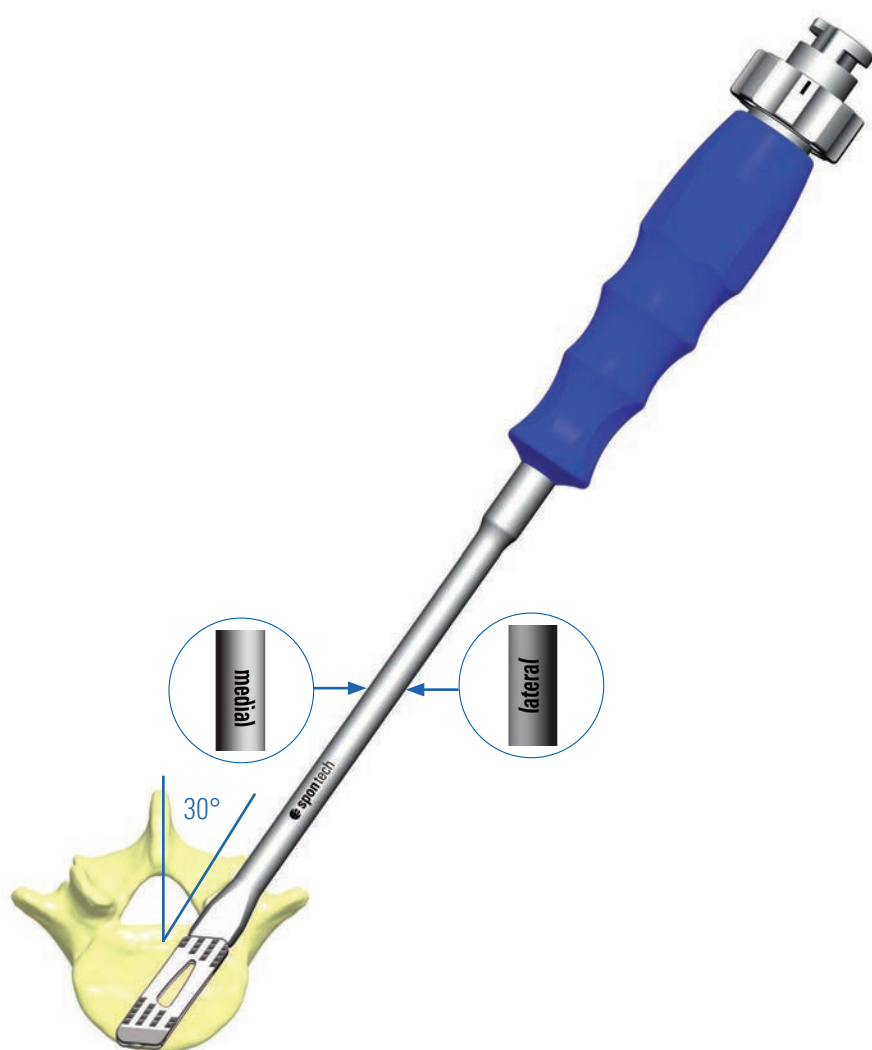


Caution

The **vertaconnect** ® trial implants are plane parallel and do not have an implant angle. They show the posterior height and the length of the implant.

The **vertaconnect** <sup>®</sup> TLIF cage must be screwed accurately on to the fixing shaft of the inserter. The assembly instructions for the inserter can be found in Chapter 3.3.6.5 and the instructions for the cage in Chapter 3.3.6.6.

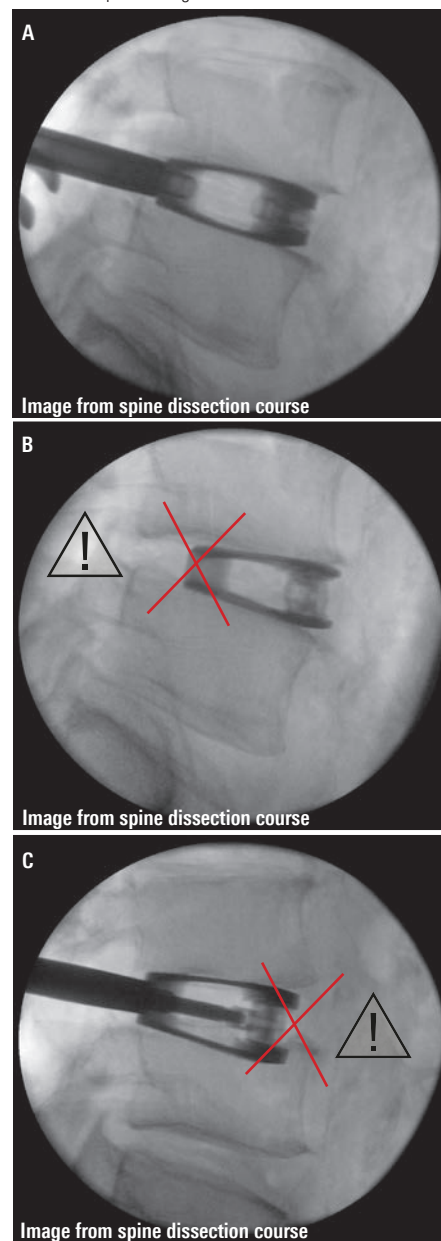
The **vertaconnect** <sup>®</sup> TLIF cage is implanted in non-expanded state. To ensure the correct alignment of the cage and the inserter, pay attention to the labeling „lateral“ and „medial“ on the inserter shaft. Using the inserter and the mallet, the designated **vertaconnect** <sup>®</sup> TLIF cage is inserted into the disc space at an angle of 30° until it rests stably on the front and rear of the cortical ring. Make sure that the selected cage is not too short. If the cage is to remain non-expanded due to the angle calculation for the segment in question, you can now begin to fill the cage and the disc space as described on page 20.



#### 4-4

##### Positioning the TLIF cage in the disc space

- A** TLIF cage with adapted inserter
- B** Cage too short, without bicortical support
- C** Subsidence into the end plates can be avoided by bicortical positioning.



The **vertaconnect** Ⓢ TLIF cage can be expanded in the disc space in accordance with the angle calculation for the segment in question. Check once more the optimum angle adjustment for the segment in the preoperative planning. If angle adjustment by means of cage expansion was indicated, proceed as follows:

After precise positioning of the **vertaconnect** Ⓢ TLIF cage, insert the mounted drive shaft for the expanding element through the hollow fixing shaft of the inserter. During expansion hold the inserter firmly in position to avoid dislocation or tilting of the cage.

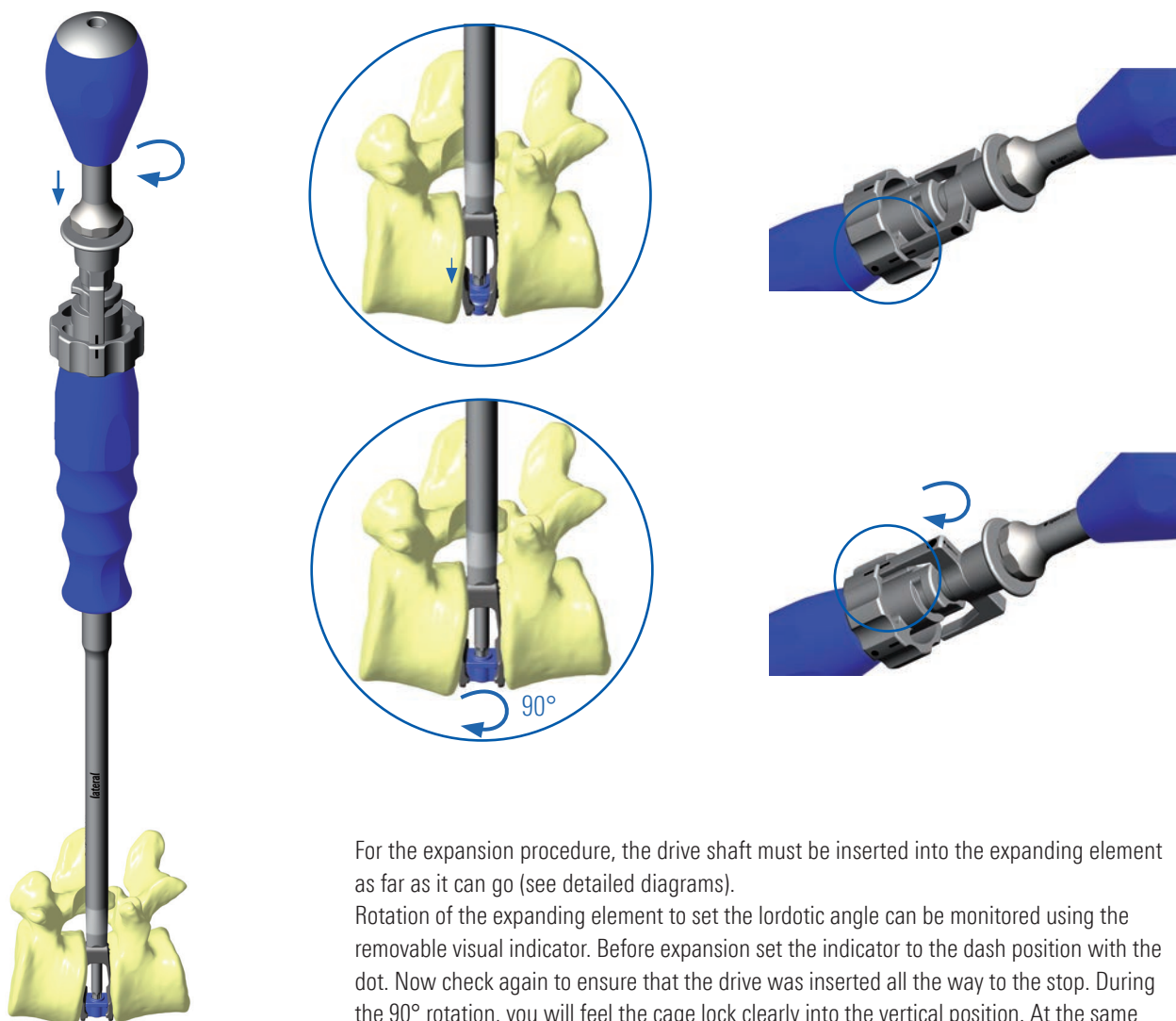


Caution

Before expanding the **vertaconnect** Ⓢ TLIF cage, check the exact placement of the implant on the cortical ring using X-ray in order to avoid any possibility of subsidence into the end plates.

#### 4-5

**Inserting the drive shaft for the expanding element**  
and expansion monitored with the removable visual indicator.



For the expansion procedure, the drive shaft must be inserted into the expanding element as far as it can go (see detailed diagrams).

Rotation of the expanding element to set the lordotic angle can be monitored using the removable visual indicator. Before expansion set the indicator to the dash position with the dot. Now check again to ensure that the drive was inserted all the way to the stop. During the 90° rotation, you will feel the cage lock clearly into the vertical position. At the same time the visual indicator moves in the direction of the second marking, a dash without a dot. Rotation can be performed in both directions. The visual indicator turns simultaneously in the selected direction.

During surgery, the implant size and the implant position must be monitored by means of X-ray imaging. The implantation instruments should not be removed until the position of the **vertaconnect** Ⓢ TLIF cage has been verified.

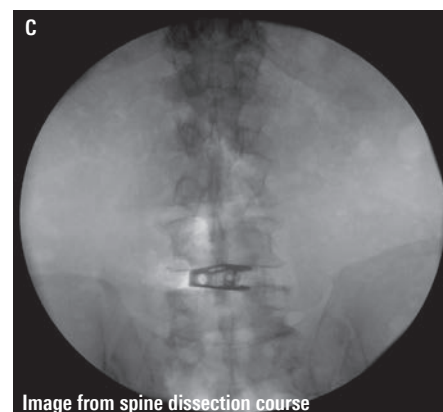
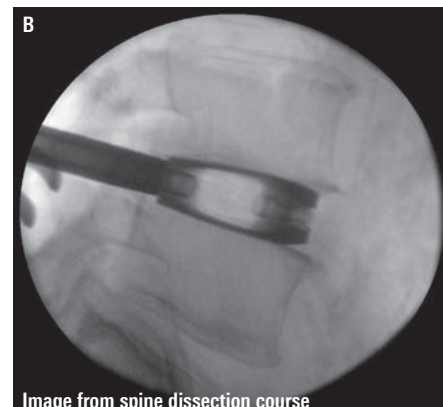
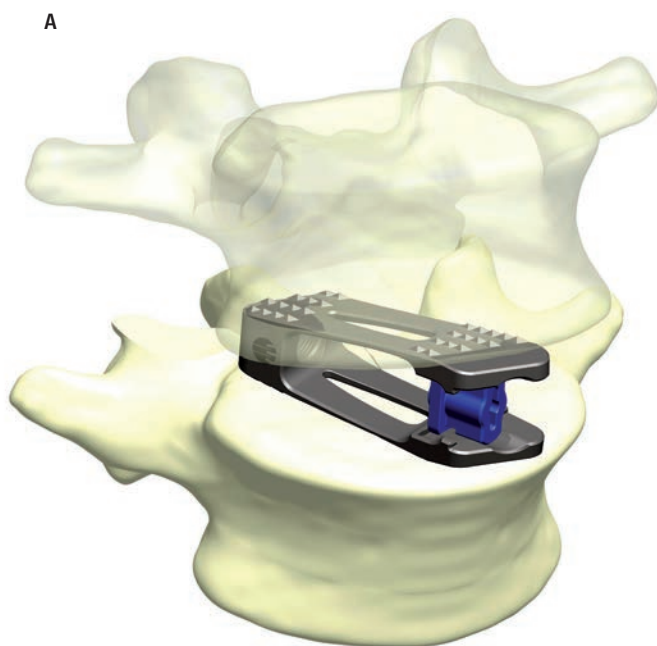
Caution



## 4-6

**Checking the position of the vertaconnect Ⓢ TLIF cage:**

- A** Diagram of cage positioning  
**B** Sagittal C-arm image with adapted inserter  
**C** C-arm image AP



After the final implant position has been verified by means of X-ray imaging, the **vertaconnect** Ⓢ TLIF cage can be disengaged from the inserter by turning the fixing shaft.

The cavities in the **vertaconnect** Ⓢ TLIF cage should be filled with the autograft bone tissue that was previously obtained from the patient or with osteoconductive bone substitute material.

If, in accordance with the preoperative planning, the cage will not be expanded once it has been inserted, it is advisable to fill it beforehand with bone graft (Fig. 4-7 C).

If the cage is to be expanded, the bone graft could potentially cause a blockage of the interface between the expansion mechanism and the expansion shaft. In this case, it is advisable to fill the cage after implantation.

To introduce gelatinous bone graft, it is recommended that you use a Luer-lock syringe via the opening at the back of the cage.

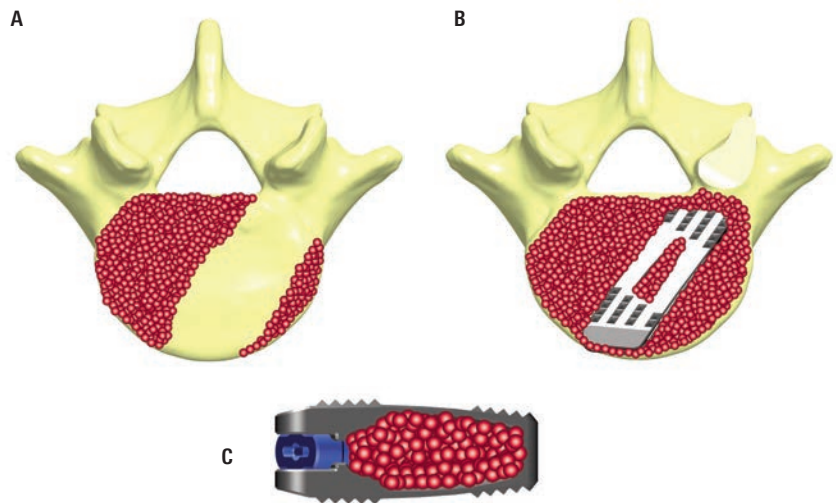
To promote optimum bone growth, distribute the bone graft throughout the entire disc space, also around the cage (Figs. 4-7 A and B):

## 4-7

**A** Placing bone graft around the implant

**B** Placing bone graft in and around the implant

**C** Placing bone graft in the implant



### 4.3 Multi-segment Treatment

The procedure for multiple segments is the same as the procedure described above for single segments. If possible, start with the segment with the weakest structure.

### 4.4 Dealing with Residual Spondylolisthesis



Please note

The final positioning of the **vertaconnect** © TLIF cage is on the load-bearing edge structure of the cortical ring. Spondylolisthesis should be realigned before implantation. During surgery, the implant size and the implant position must be monitored by means of X-ray imaging.

The diagrams below show (1) an optimum situation and (2-4) three difficult situations with spondylolisthesis or residual spondylolisthesis (after repositioning), which can compromise the successful outcome of surgery.

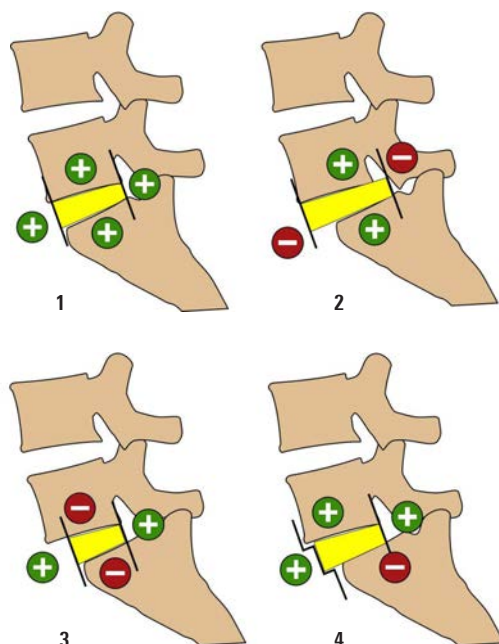
## 4-8

**1** Shows positioning without spondylolisthesis. The implant size and position (shown in yellow) are ideal.

**2** The implant (shown in yellow) is too long for this situation with residual spondylolisthesis. In this position, damage can be caused to nerves, ligaments and vessels both anterior and posterior.

**3** The implant (shown in yellow) is too short for this case with residual spondylolisthesis. In this position subsidence into the vertebral endplates can occur.

**4** The implant (shown in yellow) is too short (posterior) and potentially too long (anterior) for this situation with residual spondylolisthesis. In this position subsidence into the endplate of the lower vertebra can occur.





## 5 Reprocessing and Care of the Instruments

### 5.1 Reprocessing

Before the instruments are used in surgery and before defective products are returned for repair, the instrumentation must be completely cleaned and sterilized in accordance with the reprocessing instructions below.

Caution



#### Preparation at Site of Deployment

- Remove any coarse residue from the instruments.
- Flush the cavities with sterile water using a syringe.
- Do not use fixing agents or hot water, as they could compromise the cleaning outcome.

#### Transportation

To avoid environmental contamination and damage to the instruments, the instruments must be stored safely in a closed container for transportation to the reprocessing site.

#### Preparation for Decontamination

Before processing, the instruments must be disassembled and the mallet pads removed (see Chapter 3.3.4).

#### Preliminary Cleaning

The exterior surfaces of the instruments are cleaned with a soft plastic brush to remove all visible residue. Finally, the instruments are rinsed with a water pistol (4.2 bar) for 15 seconds, whereby the movable parts are repeatedly activated. In the absence of a water pistol, a 50-ml syringe can be used instead. Additional preliminary cleaning can be performed in an ultrasonic cleaner.

#### Automated Cleaning

Instruments with cavities (implant inserter) are connected to the MIS-rack and the remaining instruments are loaded into the machine in the **vertaconnect** ® TLIF cage instrument rack.

#### Vario TD Program (without disinfection step):

- Prewash instruments with cold water for 2 minutes
- Emptying
- Wash with an alkaline detergent (e.g. neodisher® MediClean, Dr. Weigert, Hamburg) for 5 minutes at a temperature of at least 55 °C
- Emptying
- Neutralize for 3 minutes with an acidic neutralizing agent (e.g. neodisher® Z, Dr. Weigert, Hamburg) and purified water (< 40 °C)
- Emptying
- 2 minutes' intermediate rinse with purified water (< 40 °C)
- Emptying

#### Automated Disinfection

Automated thermal disinfection is performed with due regard to the national requirements concerning the A0 value in accordance with DIN EN ISO 15883.



Please note

The use of purified water is mandatory!

### Drying

The instruments are dried using the drying cycle of the cleaning / disinfection equipment. If necessary, additional manual drying can be done with a lint-free cloth. The instrument cavities are dried with sterile compressed air.

### Functional Test, Maintenance, Care

After the instruments have been visually inspected for cleanliness, they are reassembled and a function test performed as described in Chapter 5.2. If necessary, the reprocessing process is repeated until the instrument is visibly clean. Before each sterilization procedure, the parts of the individual components of the inserter that are subject to mechanical stress as well as the area for the interchangeable handles in the instrument tray should be very lightly sprayed with a suitable instrument care product. For this please consult the instructions for use from the manufacturer of the care product.



Caution

The manufacturer must provide proof that the instrument care product has been successfully tested and validated for biocompatibility to DIN EN ISO 10993 in compliance with the European Directive 93/49/EEC. The product must be demonstrably suitable for steam sterilization in accordance with DIN EN 13683 and for hot-air sterilization up to max. 180 °C!



Caution

The mallet pads are wear parts and must be replaced if they are damaged, e.g. if they are cracked, deformed or worn. This applies particularly if there is an increased risk of mechanical chipping, fragments or other functional loss developing. The mallet pads must also be replaced when cleanliness and sterility can no longer be guaranteed because of damage.

### Preparing for Sterilization

The instruments are loaded into the **vertaconnect** ® TLIF cage instrument tray and wrapped for sterilization in compliance with DIN EN ISO 11607 and DIN EN 868.

### Sterilization

Sterilization of the products using the fractionated pre-vacuum procedure (as per DIN EN ISO 17665/GOST R ISO 11134), taking the respective national requirements into account.

Minimum requirements:

- Fractionated pre-vacuum (3 cycles)
- 3 min holding time at min. 132 °C, drying time at least 1 min
- Maximum sterilization temperature: 138 °C

### Storage

The sterilized instruments must be stored in a dry, clean and dust-free environment at a moderate temperature within a range of 5 °C to 40 °C. Ensure that there are no chemicals in the immediate vicinity.

### Important information on validating the reprocessing

The user is responsible for ensuring that the reprocessing process, including resources, material and staff, is suitable for achieving the required outcomes. The state of the art and national legislation demand the use of validated processes. If the described chemicals and machines are not available, it is the responsibility of the user to validate his/her procedure accordingly.



The following test instructions, materials and machines were used for validation:

Cleaning agent:	neodisher® MediClean (Dr. Weigert, Hamburg)
Neutralization:	neodisher® Z (Dr. Weigert, Hamburg)
Cleaning/disinfecting machine:	Miele G 7736 CD

The **vertaconnect** ⓘ TLIF cage instruments can be reprocessed and used as long as they are functional.

Please note



Incomplete or improper cleaning or sterilization can lead to infection of the patient or the user through the instrumentation.

Caution



Damaged or inadequately cleaned and sterilized instruments and accessories may not be used.

Caution



## 5.2 Functional Tests and Checks upon Receipt, during Processing and before Use



Caution

Never deposit or store other instruments/objects on top of the instruments and instrument trays (with or without instruments). This would damage the instruments and instrument trays, which would compromise the safe functioning of the instrumentation (do not put heavy instruments / objects on top of sensitive devices!)



Caution

A functional test and check must be performed after cleaning, when preparing for surgery and during deployment.



Caution

Damaged or inadequately cleaned and sterilized instruments and accessories may not be used.



Please note

Faulty instruments must be cleaned and sterilized (please provide proof) before being returned to **spontech**.

### 5.2.1 Transport Container, Container, Lid, Instrument Tray and Filter

#### Visual Inspection and Functional Check

##### Transport container, container, lid, instrument tray and filter

Check the general condition of all individual parts for visible residue, damage, dents, distortion, visible deformations on the seals and sealing joints of the containers and the lid, evident wear and tear, legibility of the labeling and corrosion.

##### Instrument tray

Check the silicone racks that hold the instruments

##### Container, lid and filter

Check assembly and disassembly

##### All instruments and their individual components

Check that the instruments can be loaded and removed from the tray

### 5.2.2 All Instruments and their Component Parts

Visual Inspection and Functional Check
<b>All instruments and their component parts</b>
<ul style="list-style-type: none"> <li>• Check the general condition of the instruments for visible residue, general damage, distortion, visible dents or deformities, evident wear and tear, cracks, broken off parts and corrosion.</li> <li>• Check the legibility of the labeling</li> </ul>
<b>Mallet</b>
<ul style="list-style-type: none"> <li>• Check for crack formation, nicks or chip formation on the plastic pads (also on the thread)</li> <li>• Check for crack formation on or damage to the silicone handle</li> <li>• Check that the plastic pads can be removed and mounted effortlessly.</li> </ul>
<b>Interchangeable handles</b>
<ul style="list-style-type: none"> <li>• Check the connection between handle and instrument</li> <li>• Check the connection for damage, distortion and jamming</li> <li>• Check for crack formation on or damage to the silicone</li> <li>• Check the spring lock mechanism</li> <li>• Check the pushbutton function on the interchangeable handle for trial implants and revision tool</li> <li>• Lubricate the movable parts with a suitable instrument care product (activating them repeatedly).</li> </ul>
<b>Implant inserter</b>
<ul style="list-style-type: none"> <li>• Check the front area of the implant retainer for visible damage to the thread</li> <li>• Check for effortless assembly and disassembly</li> </ul>
<b>Inserter fixing shaft</b>
<ul style="list-style-type: none"> <li>• Check the front area of the fixing shaft for visible damage to the thread</li> <li>• Check the fixing shaft for distortion or visible damage</li> <li>• Check for effortless assembly and disassembly</li> </ul>
<b>Drive for the expanding element</b>
<ul style="list-style-type: none"> <li>• Check the drive for distortion or visible damage</li> <li>• Check the distal working end for damage, distortion, jamming, skew, wear and tear</li> <li>• Check the connection to the interchangeable handle for distortion, wear and tear and visible damage</li> </ul>

## 6 Product Overview and Ordering Information

### 6.1 Instruments and Accessories

Part number (REF)	QTY	Description
CAT9001	1	<b>vertaconnect</b> ⊕ TLIF cage Instrumentation „Gebrauchsanweisung und Operationstechnik/deutsch“
CAT9002	1**	<b>vertaconnect</b> ⊕ TLIF cage Instrumentation “Instructions for Use and Surgical Technique/English”
CAT2000	(1)*	<b>vertaconnect</b> ⊕ TLIF cage instrumentation, complete, consisting of:
CAT2011	1	<b>vertaconnect</b> ⊕ TLIF cage instrument tray
CAT2012	1	<b>vertaconnect</b> ⊕ TLIF cage tray cover
CAT2013	2	<b>vertaconnect</b> ⊕ TLIF cage label insert
CAT3004	1	<b>vertaconnect</b> ⊕ TLIF cage interchangeable handle for trial implants and revision tool
CAT3005	1	<b>vertaconnect</b> ⊕ TLIF cage slide hammer for trial implant and inserter fixing shaft
CAT3008	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 8
CAT3010	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 10
CAT3012	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 12
CAT4001	1	<b>vertaconnect</b> ⊕ TLIF cage inserter
CAT4002	1	<b>vertaconnect</b> ⊕ TLIF cage fixing shaft for inserter
CAT4003	2	<b>vertaconnect</b> ⊕ TLIF cage drive for expanding element
CAT4004	1	<b>vertaconnect</b> ⊕ TLIF cage interchangeable handle for expanding element drive
CAT4005	1	<b>vertaconnect</b> ⊕ TLIF cage indicator for position of expanding element
INT1001	1	<b>spontech</b> nerve root retractor
INT1002	1	<b>spontech</b> mallet 250 g with plastic pads
INT4001	(1)*	<b>spontech</b> steri-container 580 x 280 x 100 mm complete, consisting of:
INT4002	1	<b>spontech</b> steri-container 580 x 280 x 100 mm
INT4003	1	<b>spontech</b> steri-container lid 580 x 280 mm
INT4004	1	<b>spontech</b> steri-container safety lid 580 x 280 mm
INT4006	(1)*	<b>spontech</b> transport box complete, consisting of:
INT4007	1	<b>spontech</b> transport box for steri-container 580 x 280 mm
INT4008	1	<b>spontech</b> transport box intermediate plate
INT4009	1	<b>spontech</b> transport box protective plate
INT4010	1	<b>spontech</b> transport box belt strap

\* If the quantity is given in brackets, this article is made up of the components listed below it. \*\* Is only supplied to non-German-speaking countries.

#### Optional Accessories

Part number (REF)	QTY	Description
CAT4006	1	<b>vertaconnect</b> ⊕ TLIF cage revision tool (optional)

#### Spare Parts

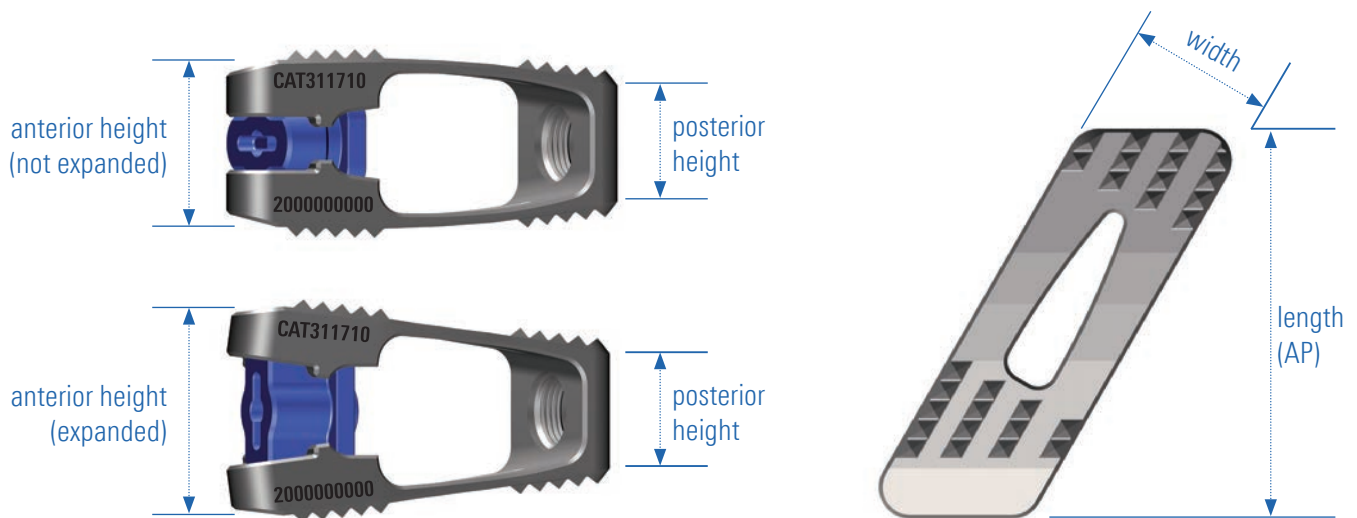
Part number (REF)	Description
INT1003	<b>spontech</b> spare pads for mallet 250 g with plastic pads
CAT4003	<b>vertaconnect</b> ⊕ TLIF cage drive for expanding element

## 6.2 vertaconnect ⊕ TLIF cage Implants

The implant is available in 15 different size variants. It is available in three lengths: 31, 34 and 37 mm. The posterior heights measure 8, 10 and 12 mm. Two lordotic angles (3° or 11° and 7° or 15°, respectively) can be set for each implant, using the integrated rotary expanding element at the anterior end. This permits anterior heights of between 9 and 19 mm.

### 6-1

#### Specified dimensions of the vertaconnect ⊕ TLIF cage



The **vertaconnect ⊕ TLIF cage** is made of a titanium alloy (Ti6Al4V) in accordance with ASTM F136. It is nickel and latex-free. The implant packaging can contain latex components.

The vertaconnect TLIF cage is approved for MRI investigation

Some specified dimensions of **vertaconnect ⊕ TLIF cage** were deposited in the part number (REF).

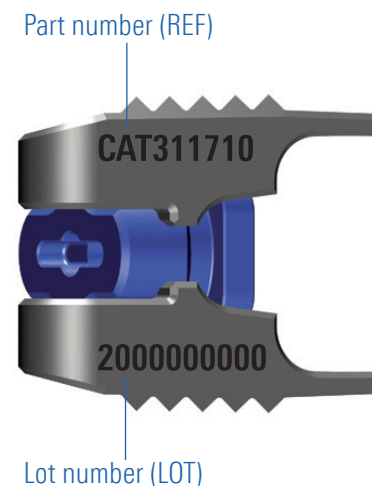
length (AP)      posterior height

**CAT311710**















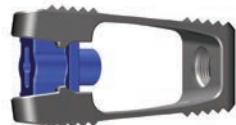
anterior height (expanded)

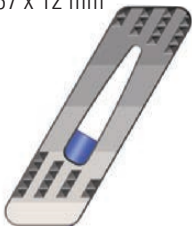


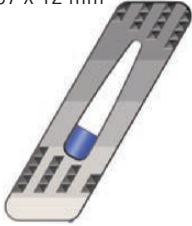

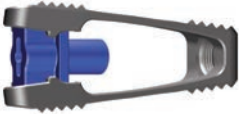
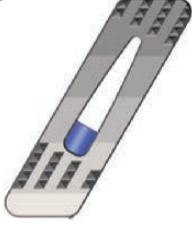


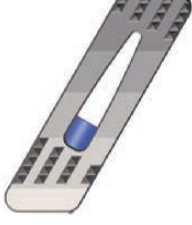





### 6-2

#### Labeling of the vertaconnect ⊕ TLIF-Cage



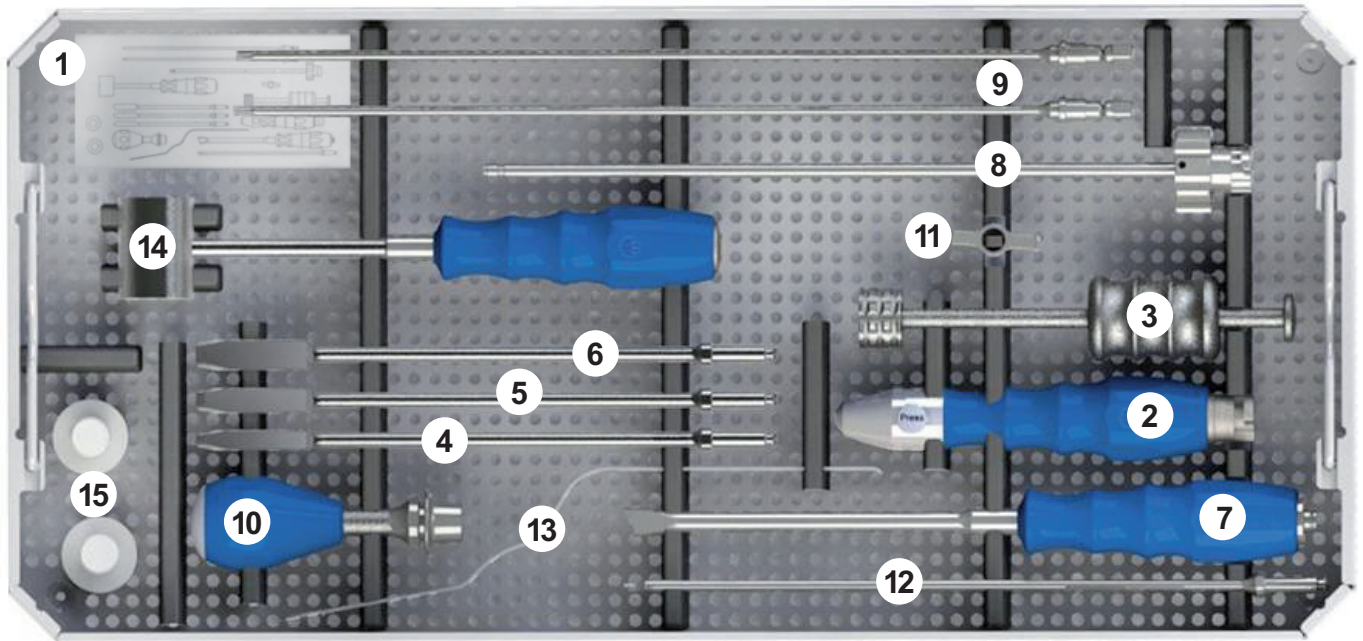
Part number (REF)	Length	Angle anterior height, not expanded	Angle anterior height, expanded	Posterior height
CAT311308	31 x 12 mm 	3°   9 mm 	11°   13 mm 	8 mm
CAT311508	31 x 12 mm 	7°   11 mm 	15°   15 mm 	8 mm
CAT311510	31 x 12 mm 	3°   11 mm 	11°   15 mm 	10 mm
CAT311710	31 x 12 mm 	7°   13 mm 	15°   17 mm 	10 mm
CAT311712	31 x 12 mm 	3°   13 mm 	11°   17 mm 	12 mm

Part number (REF)	Length	Angle anterior height, not expanded	Angle anterior height, expanded	Posterior height
CAT341408	34 x 12 mm	3°   10 mm	11°   14 mm	8 mm
				
CAT341608	34 x 12 mm	7°   12 mm	15°   16 mm	8 mm
				
CAT341610	34 x 12 mm	3°   12 mm	11°   16 mm	10 mm
				
CAT341810	34 x 12 mm	7°   14 mm	15°   18 mm	10 mm
				
CAT341812	34 x 12 mm	3°   14 mm	11°   18 mm	12 mm
				

Part number (REF)	Length	Angle anterior height, not expanded	Angle anterior height, expanded	Posterior height
CAT371508	37 x 12 mm 	3°   10 mm 	11°   15 mm 	8 mm
CAT371708	37 x 12 mm 	7°   12 mm 	15°   17 mm 	8 mm
CAT371710	37 x 12 mm 	3°   12 mm 	11°   17 mm 	10 mm
CAT371910	37 x 12 mm 	7°   14 mm 	15°   19 mm 	10 mm
CAT371912	37 x 12 mm 	3°   14 mm 	11°   19 mm 	12 mm



### 6.3 Overview and Packing List for Instrument Tray



Pos.	REF	QTY	Description
1	CAT2011	1	<b>vertaconnect</b> ⊕ TLIF cage instrument tray
2	CAT3004	1	<b>vertaconnect</b> ⊕ TLIF cage interchangeable handle for trial implants and revision tool
3	CAT3005	1	<b>vertaconnect</b> ⊕ TLIF cage slide hammer
4	CAT3008	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 8
5	CAT3010	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 10
6	CAT3012	1	<b>vertaconnect</b> ⊕ TLIF cage trial implant height 12
7	CAT4001	1	<b>vertaconnect</b> ⊕ TLIF cage inserter
8	CAT4002	1	<b>vertaconnect</b> ⊕ TLIF cage fixing shaft for inserter
9	CAT4003	2	<b>vertaconnect</b> ⊕ TLIF cage drive for expanding element
10	CAT4004	1	<b>vertaconnect</b> ⊕ TLIF cage interchangeable handle for expanding element drive
11	CAT4005	1	<b>vertaconnect</b> ⊕ TLIF cage indicator for position of expanding element
12	CAT4006	1	<b>vertaconnect</b> ⊕ TLIF cage revision tool (optional)
13	INT1001	1	<b>spontech</b> nerve root retractor
14	INT1002	1	<b>spontech</b> mallet 250 g
15	INT1003	2	<b>vertaconnect</b> ⊕ TLIF-Cage plastic pads for the mallet

## 7 Post-operative Monitoring

The patient must attend the checkups and consultations prescribed by the attending physician. The surgeon monitors the proper functioning after surgery and guarantees monitoring.

When discharged from hospital, the patient must accept and follow the instructions and precautionary measures regarding treatment and therapy he/she receives from the physician in charge.

Furthermore he/she must be instructed about any restrictions on his/her daily routine or physical and sporting activities.

The attending physician must inform the patient who is to receive the implant system that the safety and longevity of the implant is dependent on his/her weight, behavior and especially his/her physical activity. If there are any noticeable changes in his/her condition and/or the performance of the implanted system, the patient must inform the responsible physician without delay.

## 8 Contact

If you have any questions concerning **spontech** products or if you need support, please contact us at our service address:

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Olgastrasse 57a  
70182 Stuttgart  
Germany

Reception:

Phone +49 (0)711 238 492 0

Fax +49 (0)711 238 492 11











E-Mail [info@spontech-spine.com](mailto:info@spontech-spine.com)

Web [www.spontech-spine.com](http://www.spontech-spine.com)

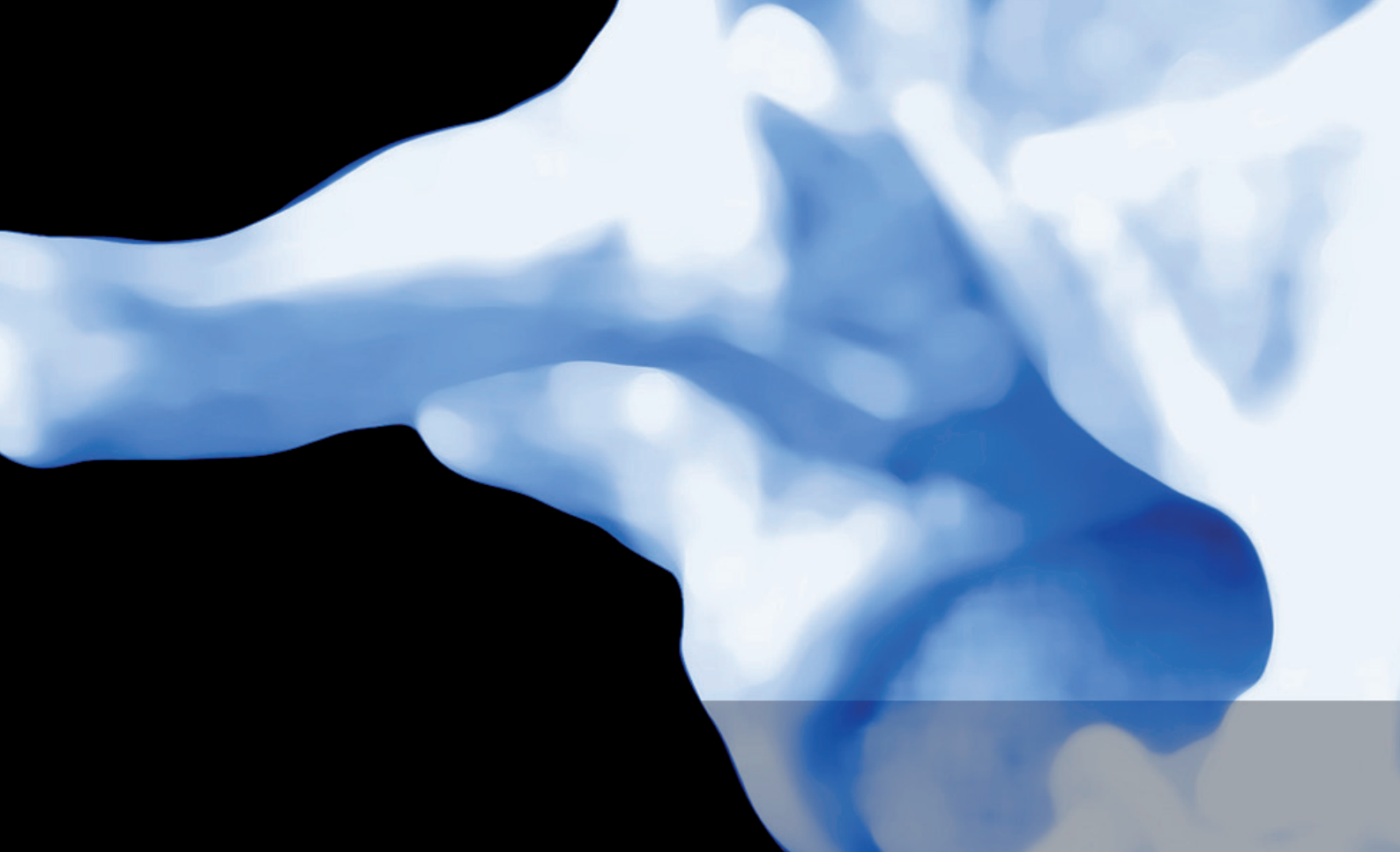
Manufacturer



## 9 Explanation of Symbols

<b>QTY</b>	Quantity / Contents
<b>MATERIAL</b>	Implant material
<b>REF</b>	Order number
<b>LOT</b>	Lot number
<b>STERILE R</b>	Radiation-sterilized (only applies to implants)
	Use by (only applies to implants)
	Date of manufacture
	Do not use if packaging is damaged
	Do not reuse! (only applies to implants)
	Do not re-sterilize (only applies to implants)
	Consult instructions for use!
	Caution: Observe important and special information and precautions!
	Keep product dry during transport and storage!
	Store away from sunlight
<b>CE</b> 0124	CE conformity and number of notified body
	Manufacturer's address





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