# VERTACONNECT T

## Transforaminal Lumbar Interbody Fusion

For distribution in the USA only

**Minimal Access – Maximal Effect**

HIGH-END MADE IN GERMANY

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SIGNUS The Spine Sign®


HIGH-END
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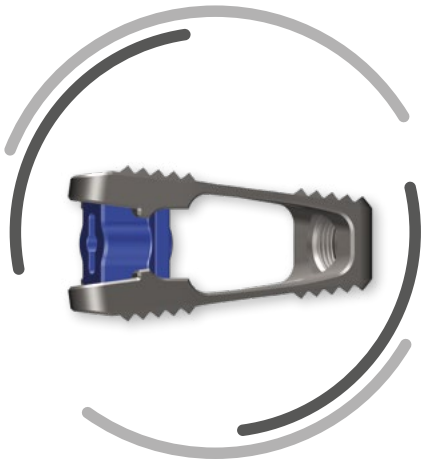


## CONTENTS

# ABOUT SIGNUS

## SIGNUS – THE SIGN FOR SPINE:

PASSIONATE! DYNAMIC! WORLDWIDE!

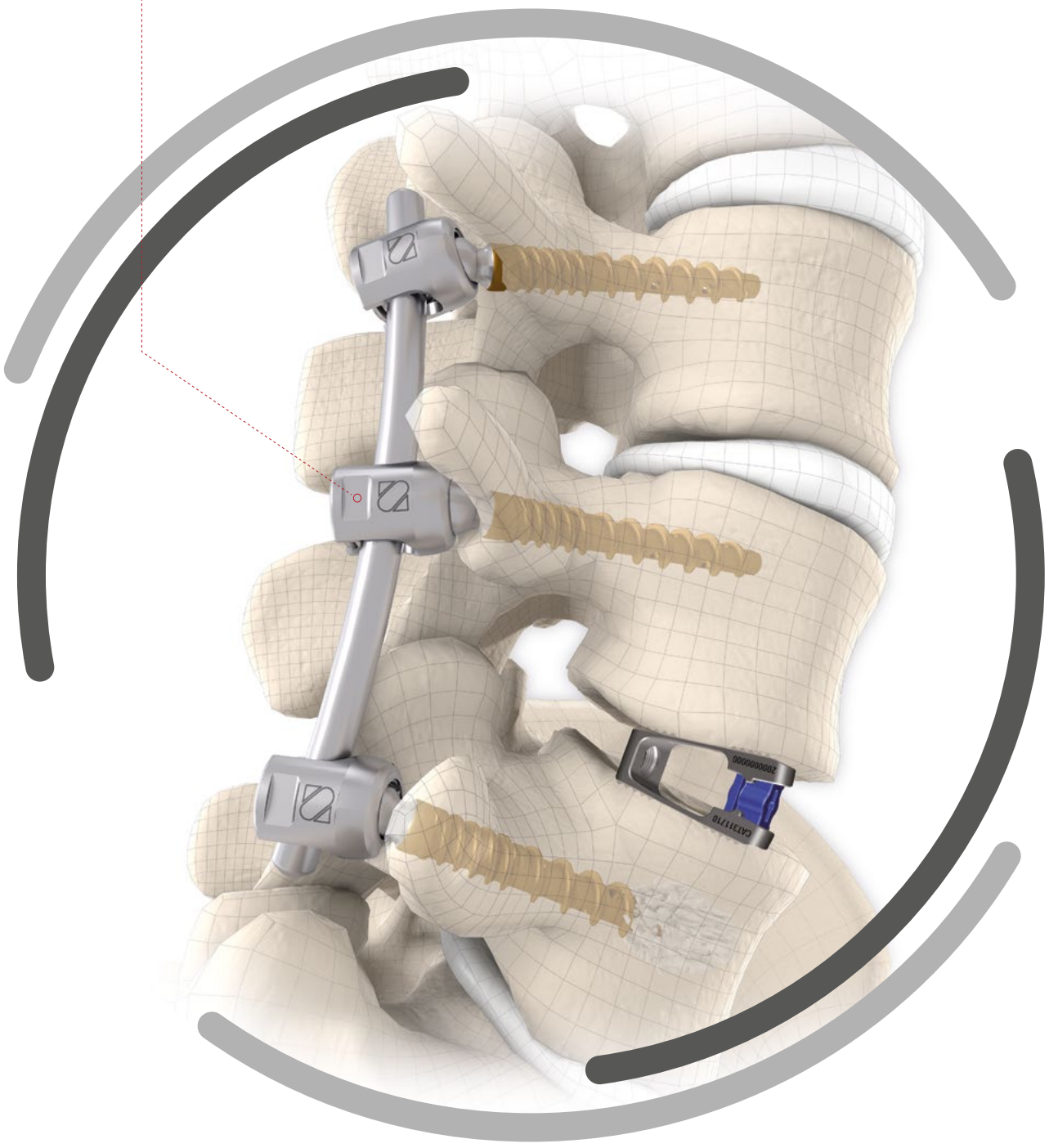
Innovative high-end implants made in Germany: For more than 30 years, SIGNUS has been the experienced specialist for comprehensive solutions in the surgical spine care sector. Founded in 1994 in Germany's Lower Franconian city of Alzenau by Susanne and Uwe Siedler, our family-owned company currently has staff of approx. 80 at sites in Germany, Australia, Switzerland and USA. SIGNUS offers the comprehensive product range of cervical spine to SIG sacroiliac joints, which are predominately manufactured at the nearby production site of ProCon Medizintechnik. In addition to Europe (CE) and the USA (FDA), we sell our certified implants throughout the world on every continent. Target-oriented further development of the products in connection with the continuous exchange with the users as well as international further education and hospitalization programs make SIGNUS a reliable global partner.

The entire SIGNUS Portfolio with detailed information and descriptions are available for you online at www.signus.com

# ADDITIONAL PRODUCTS

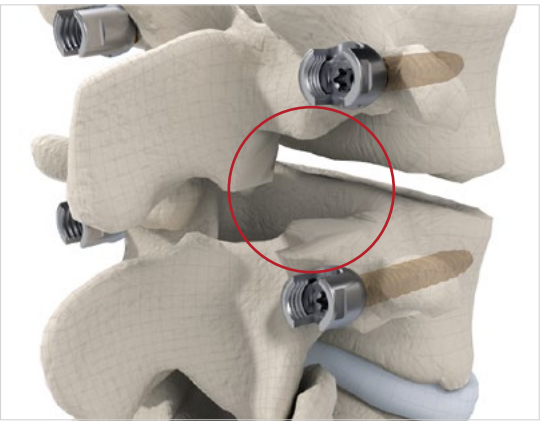
**DIPLOMAT® – Posterior Instrumentation**

- In-situ exchangeable tulips
- Faster inserting
- Stronger hold



# CONCEPT

Intersomatic fusion via the transforaminal approach TLIF (Transforaminal Lumbar Interbody Fusion) is largely consistent with the principle of PLIF (Posterior Lumbar Interbody Fusion). The transforaminal approach (TLIF) requires unilateral resection of the joint. This enables convenient access to the disc space while also preserving the contralateral lamina and facet joint as an additional fusion surface.
VERTACONNECT Ⓣ is a cage for implanting into the prepared disc space of the lumbar spine. It is characterized by stable contact areas, toothed surfaces and a large fenestration for easy filling with bone material. The open design of the implant encourages the growth of bone into the disc space.
The spreading at the ventral part of the VERTACONNECT Ⓣ implant enables the restoration of the sagittal alignment with a simultaneously minimal approach preparation.



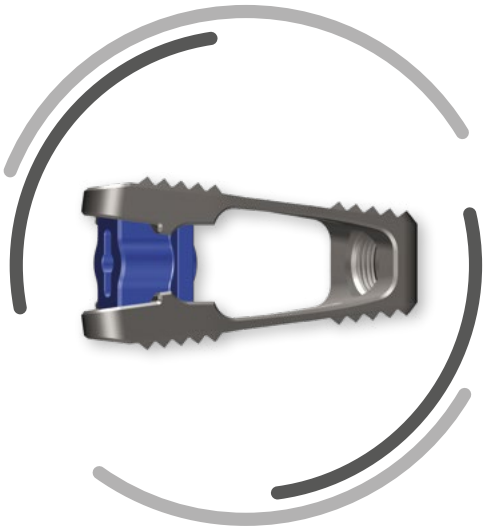
# IMPLANTS

VERTACONNECT Ⓣ is placed by a TLIF (Transforaminal Lumbar Interbody Fusion) approach in the L2–S1 spinal region. As well as the simple implantation procedure, the area of contact with the implant and the filling volume can be maximized by utilising the entire diagonal diameter of the vertebral body.

The open design of the implant permits the cage to be packed with autogenous bone graft and/or allograft comprised of cancellous and/or corticancellous bone graft.

The inserted cage, combined with additional posterior instrumentation, leads to immediate biomechanical stabilization. This establishes the ideal conditions for vertebral body fusion.

The large range of implants provides for a high degree of intraoperative flexibility and ensures the restoration of the intervertebral space.



**Material details**
Manufactured from a biocompatible titanium alloy (Ti-6Al-4V) with proven strength.

# IMPLANTS

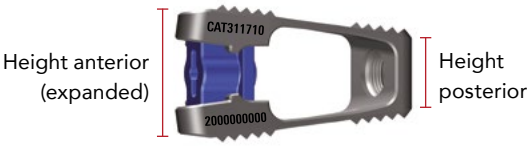
| VERTACONNECT Ⓣ | | | | | |
|---|---|---|---|---|---|
| **Length (mm)** | **Width (mm)** | **Angle, height (mm) anterior, not expanded** | **Angle, height (mm) anterior, expanded** | **Posterior height* (mm)** | **Art. no. Implants** |
| 31 | 12 | 3°, 9 | 11°, 13 | 8 | CAT311308 |
| | | 7°, 11 | 15°, 15 | 8 | CAT311508 |
| | | 3°, 11 | 11°, 15 | 10 | CAT311510 |
| | | 7°, 13 | 15°, 17 | 10 | CAT311710 |
| | | 3°, 13 | 11°, 17 | 12 | CAT311712 |
| 34 | | 3°, 10 | 11°, 14 | 8 | CAT341408 |
| | | 7°, 12 | 15°, 16 | 8 | CAT341608 |
| | | 3°, 12 | 11°, 16 | 10 | CAT341610 |
| | | 7°, 14 | 15°, 18 | 10 | CAT341810 |
| | | 3°, 14 | 11°, 18 | 12 | CAT341812 |
| 37 | | 3°, 10 | 11°, 15 | 8 | CAT371508 |
| | | 7°, 12 | 15°, 17 | 8 | CAT371708 |
| | | 3°, 12 | 11°, 17 | 10 | CAT371710 |
| | | 7°, 14 | 15°, 19 | 10 | CAT371910 |
| | | 3°, 14 | 11°, 19 | 12 | CAT371912 |

*Implant height without tooth height

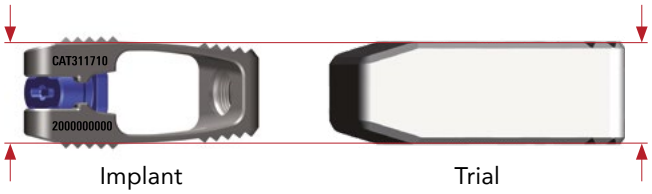
All implants are in individual sterile packaging ready for immediate use.

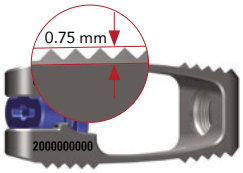
Width: 12 mm / Length: 31, 34, 37 mm

Additional sizes available upon request.

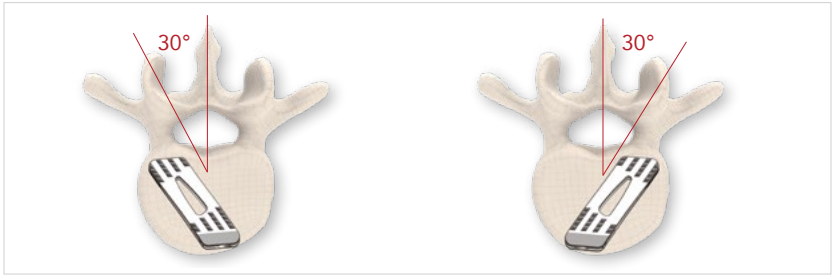



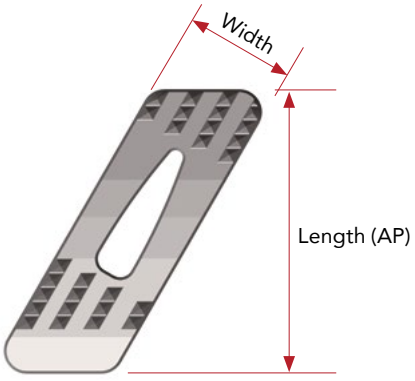

**Just starting out? We'll help you with our clearly arranged starter kit: your mobile storehouse with all implant components.**



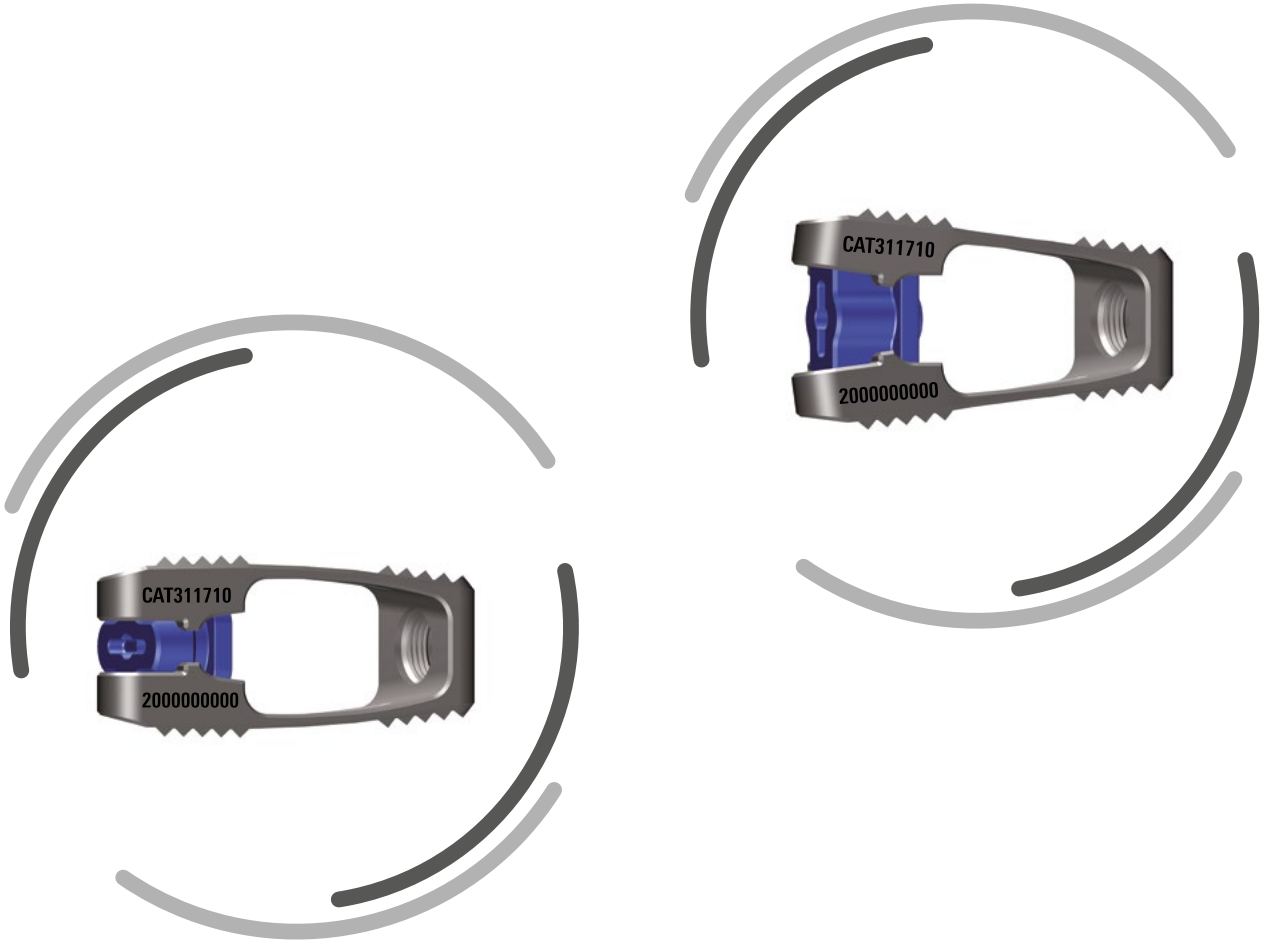

The TLIF (Transforaminal Lumbar Interbody Fusion) technique is an established method for interbody fusion of two adjacent vertebral bodies using a dorsolateral approach. The aim of interbody fusion is to stabilize the segment and reconstruct the sagittal and coronal balance for sustained analgesia. Fusion makes sense when all other therapy options have been exhausted and have not led to the desired outcome.



# PRODUCT-SPECIFIC ADVANTAGES

- **Diagonal implant placement**
  - Easy and rapid implantation in a single surgical step
  - No complicated turning of the implant as needed for banana-shaped cages
- **Open implant design**
  - Can be packed with natural or synthetic bone graft material
  - Promotes osseointegration
- **Expandable cage**
  - Adapts optimally to the individual anatomy of the patient
  - Enables easy insertion due to low entry height
- **Biconvex shape with two different lordotic angles**
  - Anatomical adaptation in the intervertebral space
  - Optimal restoration of the sagittal alignment
- **Large contact area with the vertebral body**
  - Secure implant positioning
  - Reduced risk of subsidence
- **Toothed surface**
  - Secure anchoring in the bone thanks to high primary stability
  - Reduced risk of implant migration



# INSTRUMENTS

**Art. no.** CAT3010
Trial instrument 8 mm

**Art. no.** CAT3012
Trial instrument 10 mm

**Art. no.** CAT4002
Inserter – fixing shaft

**Art. no.** CAT3004
Handle straight

**Art. no.** CAT4004
Palm handle for
drive expanding element 1/4“

**Art. no.** CAT3005
Slap hammer
for fixing shaft

**Art. no.** CAT4003
Inserter –
drive expanding element 1/4“

**Art. no.** INT1002
Mallet with
exchangeable plastic jaws

**OPTIONAL**

**Art. no.** CAT4005
Inserter – indicator
for position of expanding element

**Art. no.** INT1001
Nerve root retractor 6 mm

**NOT SHOWN**

**Art. no.** CAT2011
Instrument tray

**Art. no.** CAT4001
Inserter – outer part

# INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

## INDICATIONS

The VERTACONNECT® TLIF cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and is intended for use with autograft to facilitate fusion.

## CONTRAINDICATIONS

- Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Spinal tumours
- Infections
- Signs of local inflammation
- Fever or leukocytosis
- Allergy or intolerance to implant material
- Myelopathic focus in the fused segment (only for titanium alloy implants)
- Spondylolisthesis ≥grade 3
- Prior fusion at the level(s) to be treated
- Surgical conditions that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies, inadequate tissue coverage)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, systemic or metabolic diseases, substance abuse, senility, lack of patient compliance)
- Cases that are not mentioned under Indications

## WARNINGS

- The spinal implants are intended for single use only and may not be reused. Reuse can cause implant failure, infections and/or death.
- The attending physician is responsible for establishing the indication, selecting the implant and carrying out the implantation procedure, and must be experienced as well as trained in the requisite surgical technique.
- The general surgical procedure can be learned out of the surgical technique described in the product information. This document can be obtained from SIGNUS or the representative.
- Implant components and instruments not belonging to the system must not be used.
- Instruments specially developed by SIGNUS are available for application of the implants. These ensure safe application.
- Prior to surgery, ensure that the instruments belonging to the system are sterile and fit for purpose.
- Prior to implantation, examine the implant for integrity and check the given size with the instruments for comparison.
- Before surgery, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and from use of the implant, as well as of postoperative behavior.
- The operation must be carried out under fluoroscopy. The correct position of the implant system used must be verified radiographically.
- The implant must not be scratched or notched, as this can lead to a reduction in mechanical stability.
- The implant should be placed on the anterior and support the posterior portion of the cortical ring, but may cannot be placed beyond it. The VERTACONNECT® can be implanted in an unspread condition and can be spread in the disc space. The drive shaft must be pushed into the expansion element up to the stop. The rotation of the expansion element for adjusting the lordotic angle can be controlled via a removable optical display. The implantation instruments must first be removed, when the position of the VERTACONNECT® is secured.
- The implants must not be used as stand-alone devices but rather must be combined with a spinal fixator cleared for use in the US.
- All implant components used, must be documented in the patient file with item numbers, name and lot number.
- Aftercare must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity. This applies in particular to the lifting of loads, rotating movements and all kinds of sporting activities. Falls and sudden jerking movements of the spine must be avoided.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to his individual requirements.

## MRI SAFETY INFORMATION

The safety and compatibility of VERTACONNECT® in an MRI environment was not determined. The product has not been tested with regard to heating, migration or artefact formation in an MRI environment.

**USA: Federal law restricts the sale of this device by or on the order of a physician**

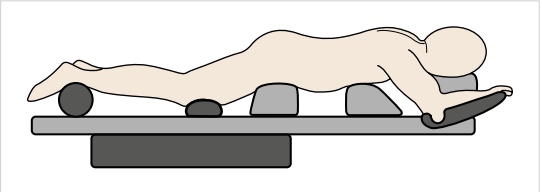
**NOTE**

Please note the instructions for use
(current version: eifu.signus.com)

## 1 PREPARATION

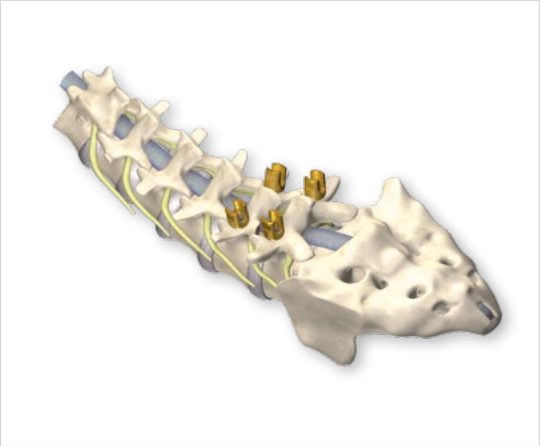
### Patient positioning

Place the patient in a prone position, with physiological lordosis restored. Make sure that the abdomen is not overloaded in such a position in order to counteract venous stasis. The patient should be positioned on a radiolucent operating table that permits free movement of the C arm at the sagittal and AP plane.



### Approach

Perform a vertical skin incision in the midline or 2 to 3 fingerbreadths lateral to the spine at the level of the treatment segment. Then perform a unilateral partial facetectomy or foraminotomy for transforaminal insertion of the cage on the symptomatic side. To protect the neural structures, it is advisable to use nerve root retractors during all further steps of the procedure.



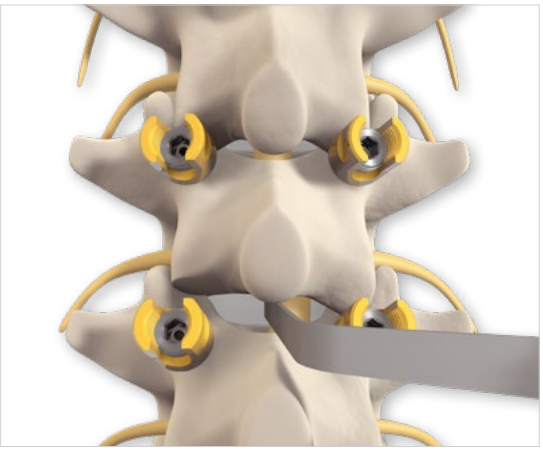
### Posterior instrumentation

After exposing the treatment segment, first position the pedicle screws of the posterior instrumentation, for example with the DIPLOMAT® system. To begin with, the desired correction to the position can be undertaken and secured.

### Discectomy and preparation of the intervertebral space

Determine the entry site in the lateral disc space depending on the decompression and the patient's pathology. After unilateral decompression, the epidural space and neural structures should be adequately exposed.

Decompression should involve both the affected disc and further space-occupying structures (e.g. posterior osteophytes), preserving only the anterior and lateral segments of the annulus fibrosus.



**NOTE**

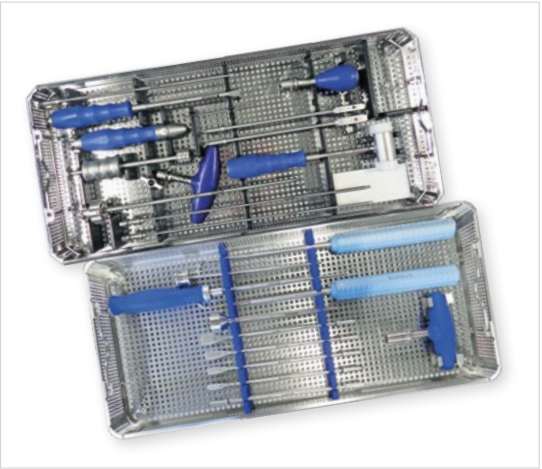
The extracted bone material can later be used for implant packing, interbody impaction and adhesion.

To achieve optimal fusion results, freshen the exposed vertebral body endplates.

**NOTE**

Avoid removing too much or all of the cortical inferior and superior plates. This may weaken the endplates and thus lead to subsidence of the implant into the adjacent vertebral body.

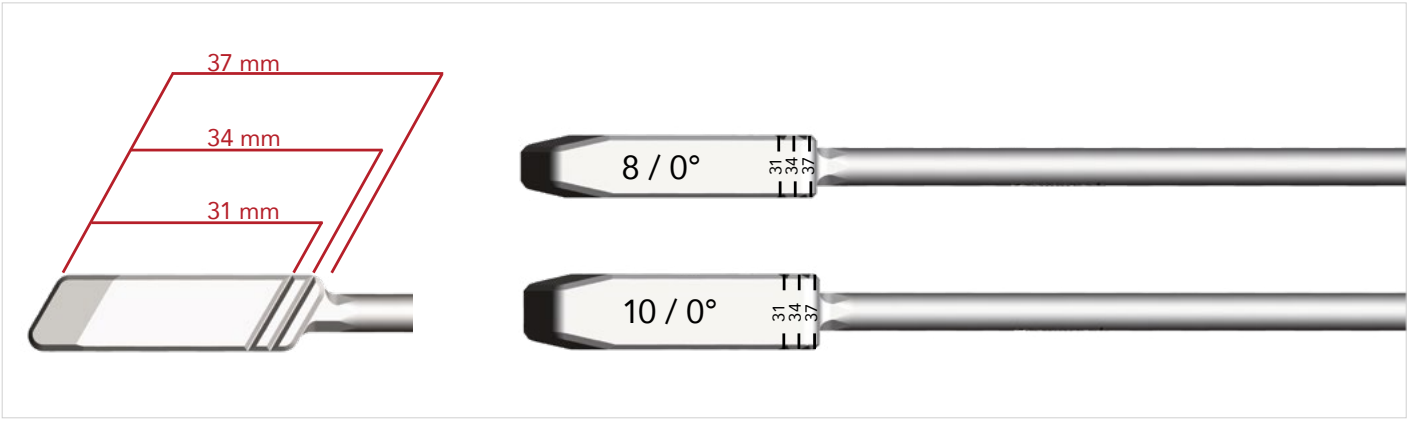
The SIGNUS lumbar preparation set (refer to the brochure '***Lumbar preparation***') can also be used for resecting the disc and working on the endplates.

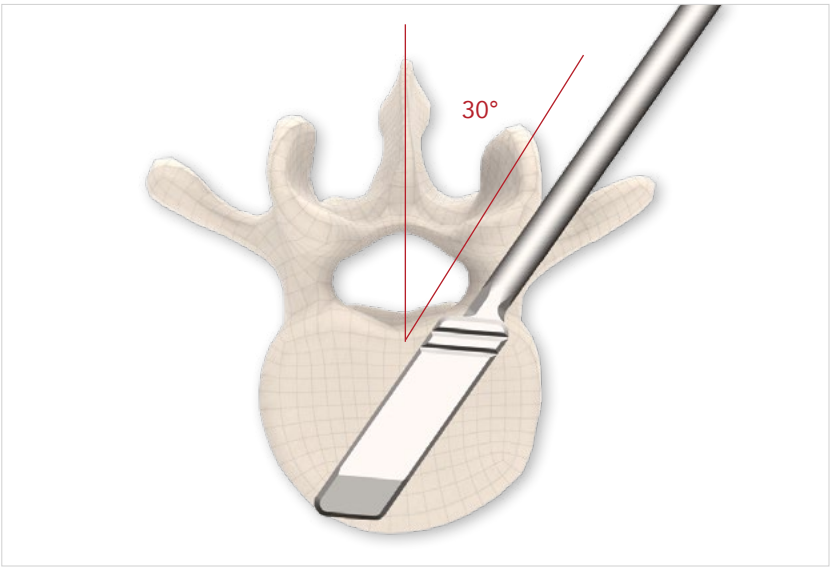


## 2 IMPLANTATION

### Distraction and selection of the implant

After complete removal of the disc tissue and adequate mobilization of the disc space, the surgeon can verify the correct choice of the ideal posterior implant height intraoperatively using the trial implants. To do so, it is necessary to insert the selected trial implant at an angle of 30° into the disc space. When doing so, note the markings of the three implant lengths 31, 34 and 37 mm. As soon as the trial implant is in the final position, carry out a radiographic control. The length of the cage must not be too short.




Trial implant connected to the handle

# SURGICAL TECHNIQUE

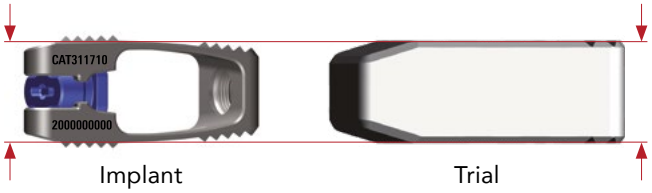
**NOTE**

With regard to secure positioning of the implant and the clinical outcome, avoid overdistraction.

**NOTE**

The trials correspond to the implant height not including the teeth.

The VERTACONNECT® trial implants have parallel planes and do not have an implant angle. They only indicate the posterior height and length of the implant.




## Implant insertion

After determining the correct implant height and lordosis, remove the appropriate implant from the sterile packaging.

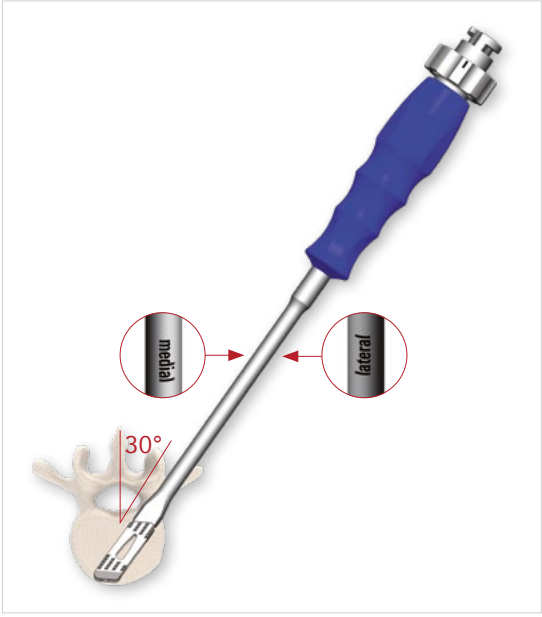
**NOTE**

The implant must be kept in its original packaging. The packaging must be stored in a dry place, protected from sunlight. It should only be opened immediately prior to using the implant. Check expiry date and intactness of the sterile packaging before use. All of the packaging must be removed.

The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.

The VERTACONNECT® inserter is made up of an outer part and a fixing shaft as well as a drive expanding element with a corresponding handle. The fixing shaft is inserted into the outer sleeve and the implant with the appropriate size is picked up.

The implant can now be attached to the inserter via the screw thread and can be inserted in the intervertebral space. The 'medial/lateral' label on the inserter indicates how to correctly insert the implant into the intervertebral space.



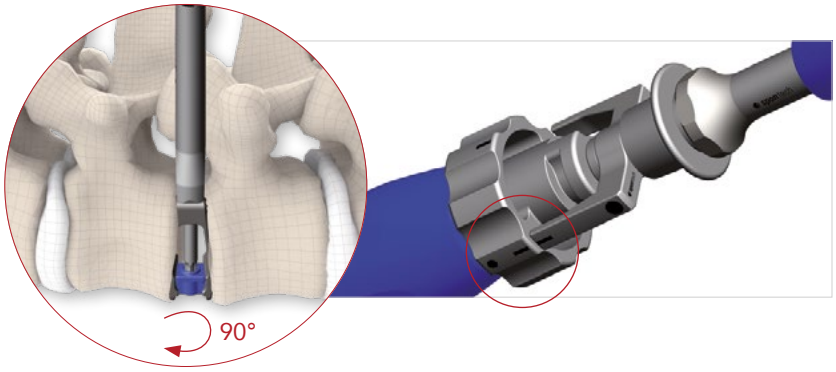
# SURGICAL TECHNIQUE

The VERTACONNECT® TLIF cage can be expanded in accordance with the angle calculation for the segment concerned:
After precisely positioning VERTACONNECT®, the drive expanding element, including the handle, is pushed through the cannulation of the inserter.

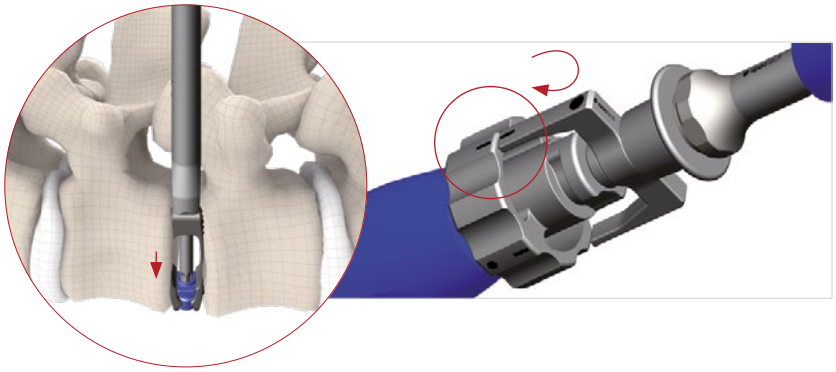
**CAUTION**

Before expanding the VERTACONNECT® TLIF cage, check the precise positioning of the implant on the cortical ring using radiographic control.

For the expansion process, the drive expanding element must be inserted as far as possible into the inserter. The rotation of the expanding element for adjusting the lordosis angle can be monitored using the removable visual indicator.
To do so and if the visual indicator (optionally available) is used, the wings with the dots are placed on the line position before the expansion.




During the 90° rotation, it can be clearly seen how the cage moves into the expanded position. At the same time the visual indicator, if used, rotates to the second marking (line without a dot).

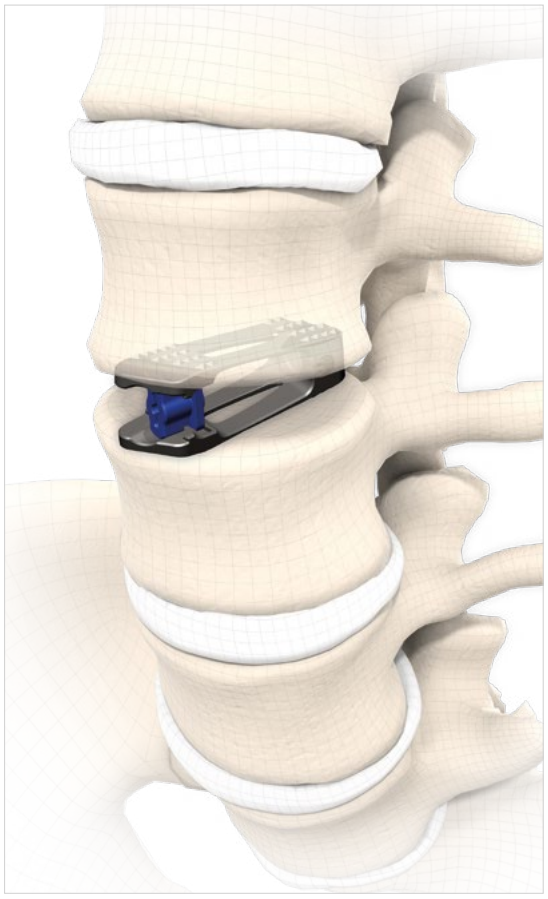


The rotation can be made in both directions. The visual indicator rotates in the direction chosen at the same time. Then the drive expanding element can be removed by pulling on the inserter.

# SURGICAL TECHNIQUE

After the final implant position has been verified in the radiograph AP and lateral, the VERTACONNECT® TLIF cage can be released from the inserter by rotating the fixing shaft.

The hollow space of the VERTACONNECT® TLIF cage should be filled with autologous bone material that has previously been harvested from the patient.



### Packing the implant

To improve the fusion outcome it is advisable to insert bone chips and/or bone graft material in and around the implant. If the cage is not to be expanded, it is advisable to fill the cage before implantation.

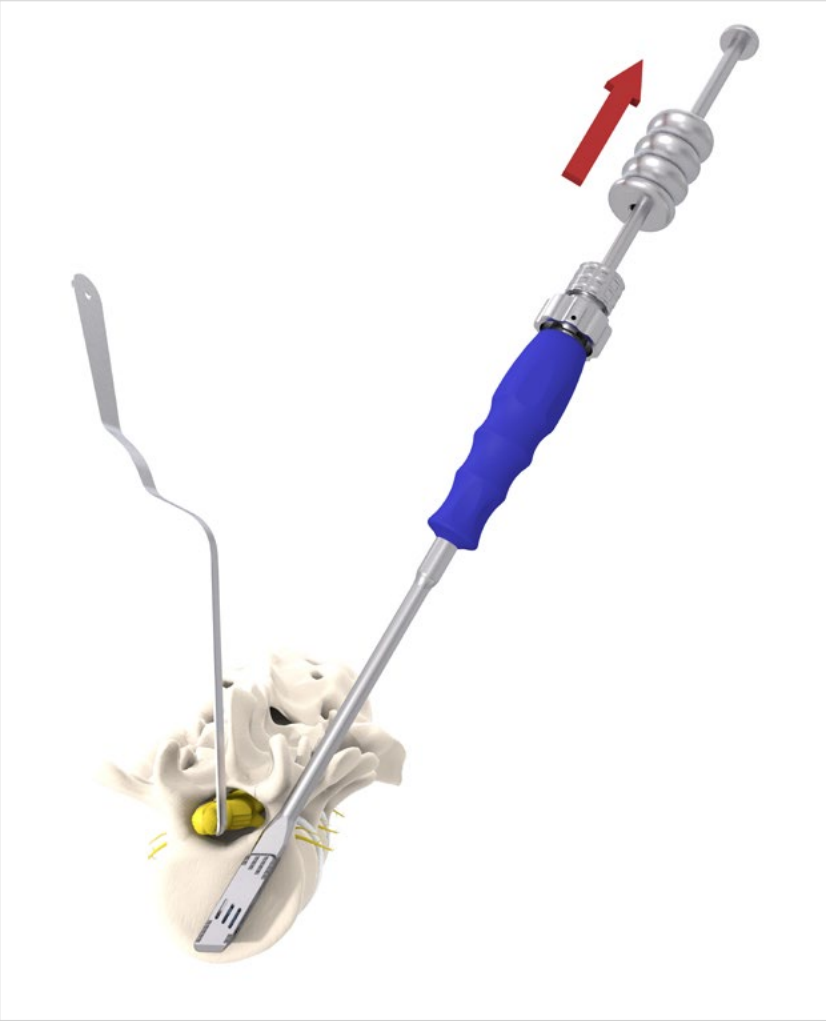
If the cage is to be expanded, the bone graft material may possibly block the interface between the expansion mechanism and the expanding element. In this case it is advisable to fill the cage after implantation.
If the cage has been expanded, it is now filled with bone chips and/or bone graft material and bone chips or bone graft material is also placed around the cage. A Luer lock syringe can be connected through the opening on the back of the cage for this purpose.

### Posterior instrumentation

After using lateral and AP radiographs to the check that the implant is correctly positioned, the final steps for posterior stabilization of VERTACONNECT® are taken.

## 3 REVISION

VERTACONNECT® can be revised if necessary. Select the described approach in section **"1 Preparation"** and prepare the implant. Special attention should be paid to preparation of the nerve tissue and any scar tissue that has already developed. The tissue must first be removed in order to extract the implant. To remove the implant, reattach it to the inserter and, if the cage was expanded, it is returned to the initial condition using the drive expanding element used to expand the implant. Remove the implant from the disc space with the slap hammer. While doing so, ensure that the integrity of the nerve structures is preserved.



**CAUTION**

Because the implant may have been damaged, do not reinsert the implant after it has been removed from the intervertebral space.

# NOTES

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**NOTE:** This document was written by the technical department at SIGNUS Medizintechnik GmbH. Despite being reviewed by trained personnel, the sole purpose of this brochure is to provide an explanation of the technical aspects of handling the product described.
This document, in particular the description of the surgical procedure, should not be considered medical scientific literature.

# SIGNUS – THE SIGN FOR SPINE

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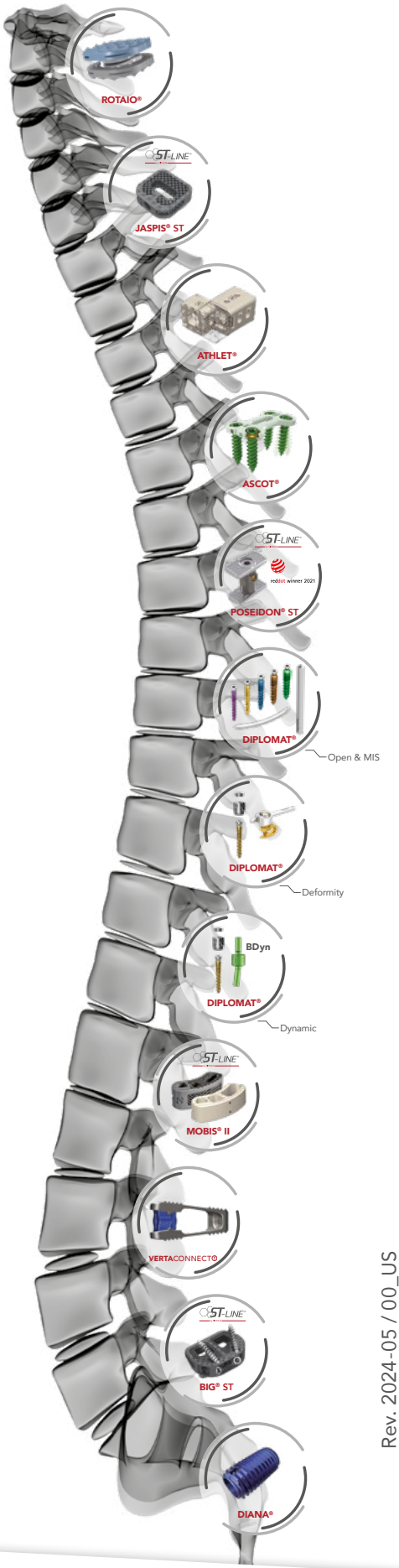
The entire SIGNUS Portfolio with detailed information and descriptions are available for you online at www.signus.com

SIGNUS key visual. Not all products are available in the US market and have FDA approval.

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