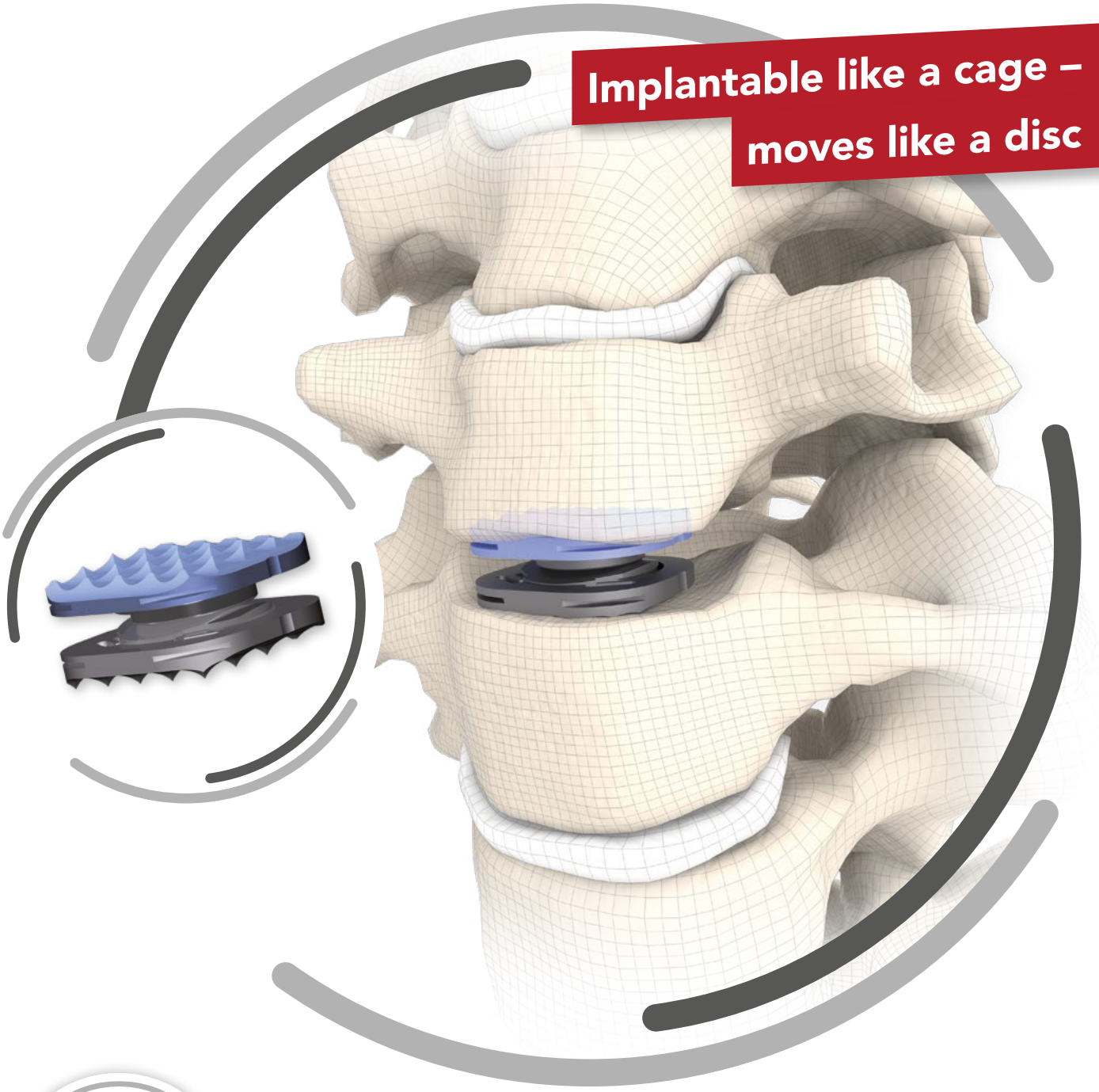
ROTAIO®

Cervical Disc Prosthesis

Implantable like a cage –
moves like a disc



HIGH-END MADE IN GERMANY

www.signus.com

SIGNUS
The Spine Sign®

**SIGNUS Medizintechnik GmbH thanks
the following doctor for his collaboration:**

Univ.-Prof. Dr Claudius Thomé,
University Hospital for Neurosurgery, Innsbruck (Austria)

CONTENTS

ABOUT SIGNUS

SIGNUS – THE SIGN FOR SPINE:

PASSIONATE! DYNAMIC! WORLDWIDE!

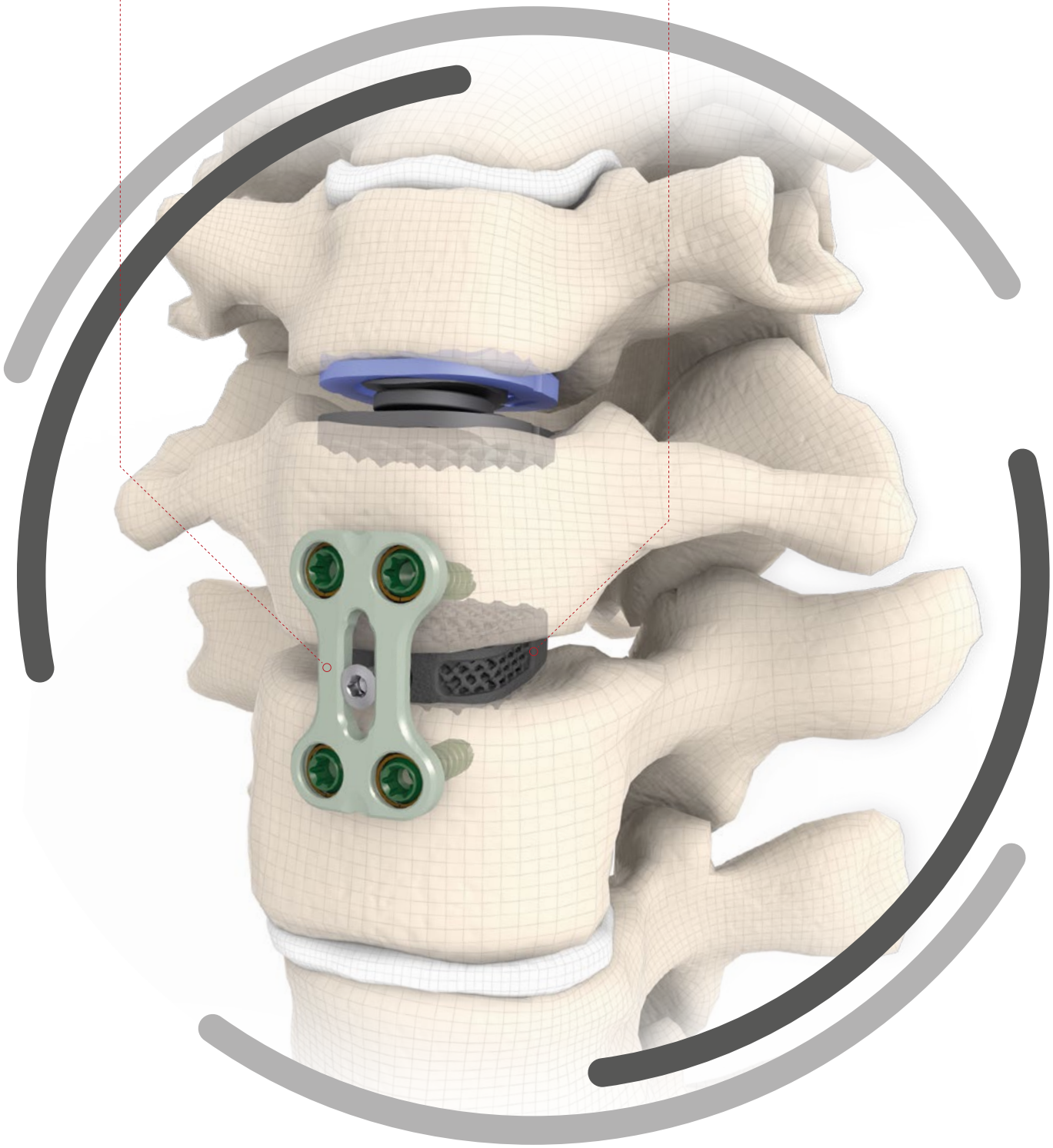
Innovative high-end implants made in Germany: For more than 30 years, SIGNUS has been the experienced specialist for comprehensive solutions in the surgical spine care sector. Founded in 1994 in Germany's Lower Franconian city of Alzenau by Susanne and Uwe Siedler, our family-owned company currently 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 hospitalisation 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

ASCOT® – Anterior Cervical Stabilization
Maximum Stability – Minimal Stiffness

JASPIS® ST – Anterior Cervical Fusion
Proven design – Now also in ST



CONCEPT

The ROTAIO® disc prosthesis was developed for the specific requirements of the cervical spine (C3–C7). Despite the highly complex joint kinematics of ROTAIO®, the surgical implementation remains simple. ROTAIO® is implanted 'in one piece' using the proven Smith–Robinson technique.

The prosthesis is available in various footprints and heights to enable adaptation to different patient anatomies.

IMPLANTS

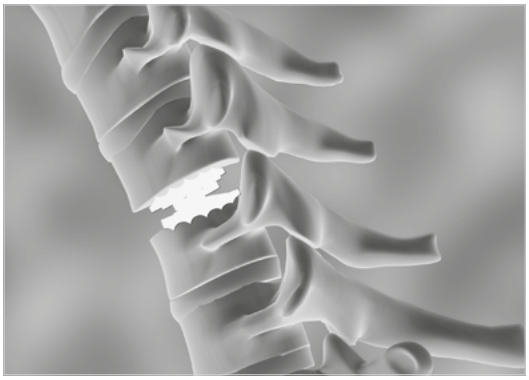
ROTAIO® is inserted in the C3–C7 spinal region. As well as the simple implantation procedure, the large footprints of the disc prosthesis maximise the area of contact with the vertebral body. This helps to prevent unwanted fusion of the segment. We have retained the product features of our proven RABEA® cages in the form of the tried and tested endplate serrations. This ensures secure primary stabilisation of the segment while at the same time minimising bone resection.

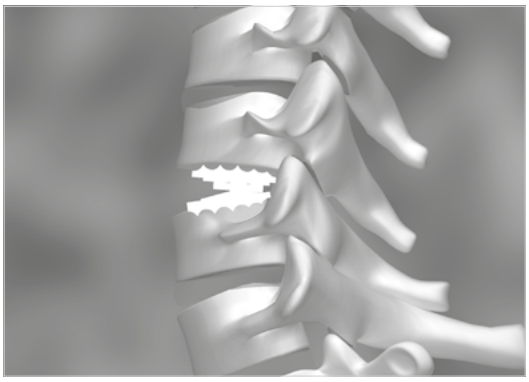
To reproduce the natural movement of a healthy intervertebral disc – that is the goal of ROTAIO®. This means not merely the preservation but above all the quality of movement of a natural intervertebral disc is prioritised. Along with rotation, flexion/extension and lateral bending, ROTAIO® therefore enables the option of uncoupled translation and thus of physiological facet-guided segment movement.

ROTAIO® can thus be summed up in one sentence:
implantable like a cage – moves like a disc.

Material details

The ROTAIO® disc prosthesis is made up of several material components that offer a number of benefits for application. A cobalt-chrome-molybdenum (CoCrMo) alloy was selected for the bearing surfaces. This metal is characterised by very good biomechanical and tribological properties. The endplates are manufactured from a titanium alloy (Ti-6Al-4V) that improves the osteointegration thanks to the specially roughened surface.





ROTAIO® flexion/extension images: physiological, facet-guided movement without gaping joints.

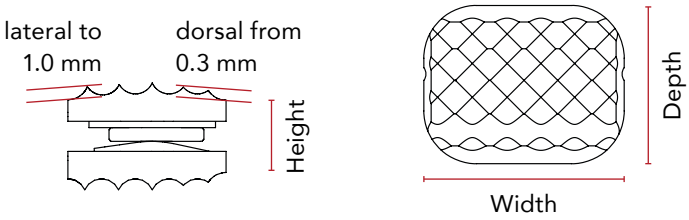
IMPLANTS

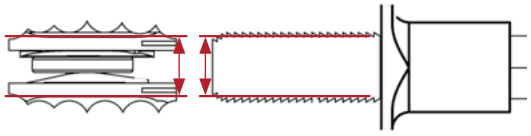
Implants		
Width × depth (mm)	**Height* (mm)**	**Art. no.**
15×13	5	GA051513
	6	GA061513
17×13	5	GA051713
	6	GA061713
17×15	5	GA051715
	6	GA061715
19×15	5	GA051915
	6	GA061915

* Implant height without tooth height

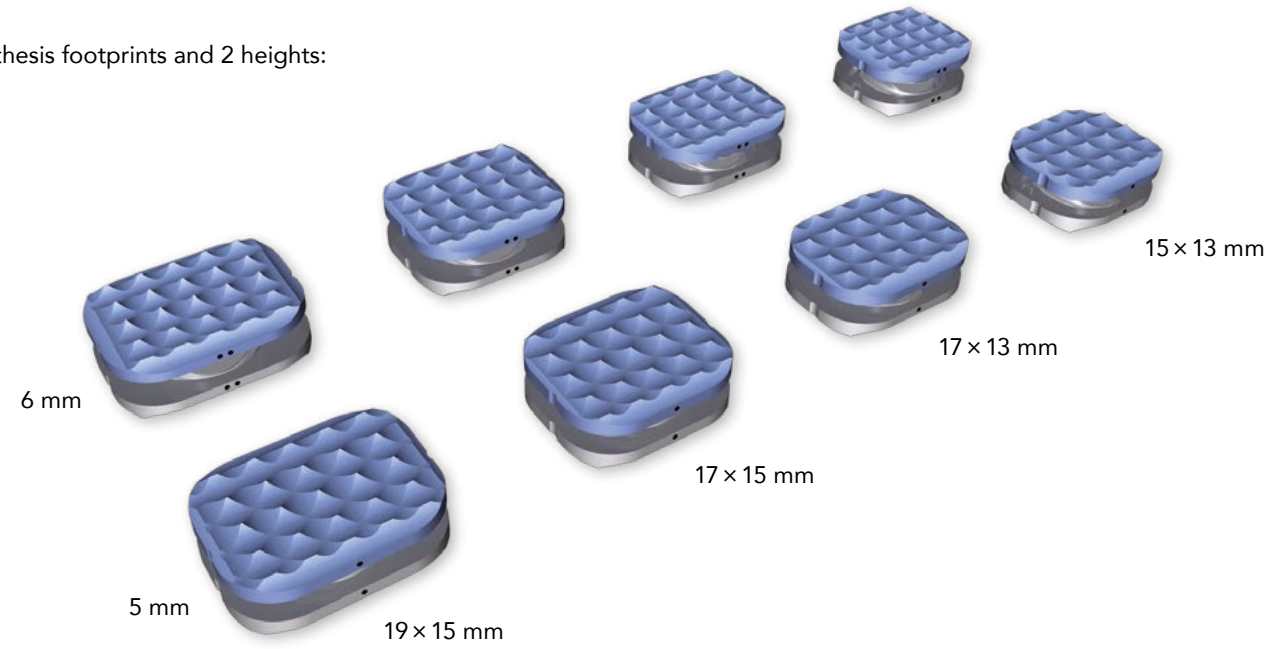
All implants are in individual sterile packaging for immediate use.

Additional heights available upon request.





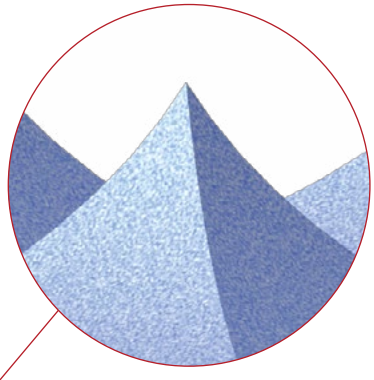
4 prosthesis footprints and 2 heights:



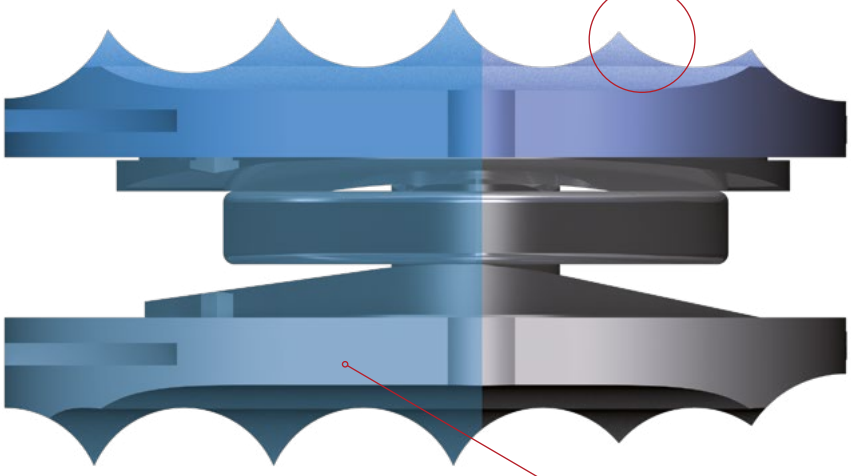
Just starting out? We'll help you with our clearly arranged starter kit: your mobile storehouse with all implant components.

PRODUCT-SPECIFIC ADVANTAGES

- **Safety oriented prosthesis design**
  - One-piece prosthesis design for safe handling: Implantable like a cage
  - Rectangular geometry with large contact surface area with the vertebral body – for secure implant seating and reduced risk of subsidence
- **Tested mechanics**[1]
  - A comprehensive series of cyclic, dynamic and static tests going beyond the studies required for marketing authorisation
- **Increased roughness**[2] **in conjunction with proven SIGNUS toothed cage design**
  - Secure anchoring in the bone owing to high primary stability
  - No keel preparation required
  - Reduced risk of implant migration
- **Physiological mobility**
  - Range of motion is defined by anatomical structures and not by the disc prosthesis
  - Posteriorly-accentuated implant design
  - Perfectly adapted to the natural anatomy
  - Variable centre of rotation corresponds to the natural centre of motion of the cervical spine
  - Controlled translation uncoupled from rotation
  - Allows for facet-guided movement, with no gaping joints
- **Pre-mounted, in sterile packaging**
  - No assembly necessary, ready for use



Tried and true cage serration
- High primary stability without the need for keel preparation

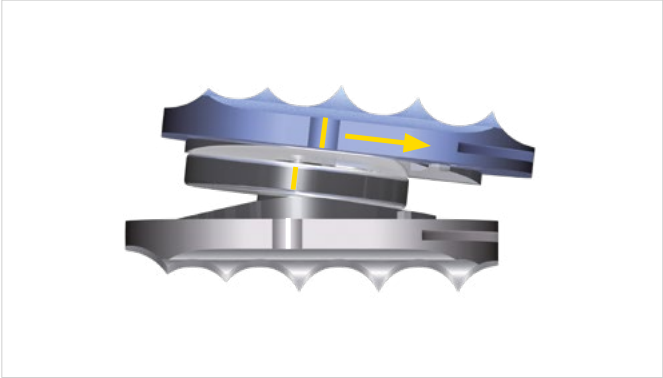


Posteriorly-accentuated implant design
- Perfectly adapted to the natural anatomy

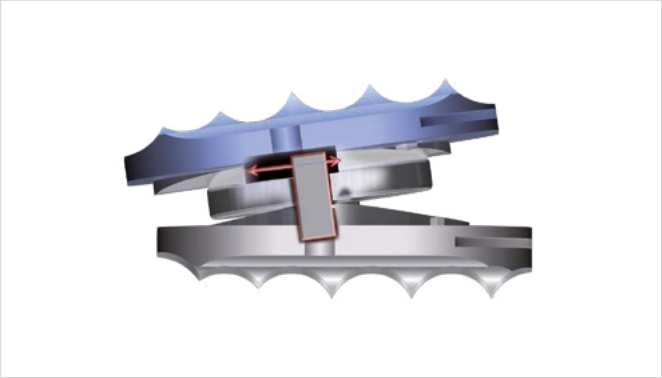
1 We will happily provide you with the detailed test protocols

2 ROTAIO® has a specially roughened surface to improve osteointegration. Various studies have shown that for implants the adhesion of proteins and subsequent colonisation by bone cells (osteoblasts, osteoclasts, etc.) is fundamentally influenced by the roughness of the material surface. The activity of osteoblasts is evidently particularly increased if the roughness (Ra) lies in the range of 1 to 7 µm. In a number of studies of blasted titanium surfaces, it was also demonstrated that the roughness achieved as a result is also associated with improved osteointegration. This was demonstrated in both animal studies and, for example, in studies of hip endoprostheses inserted without cement and implant dentistry.

PRODUCT-SPECIFIC ADVANTAGES

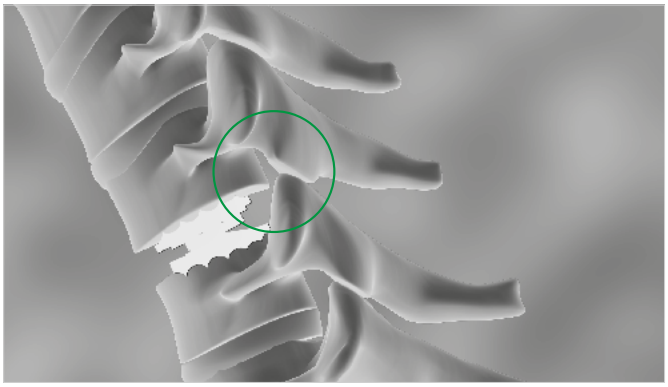


Variable centre of rotation
- Corresponds to the centre of rotation of a healthy disc

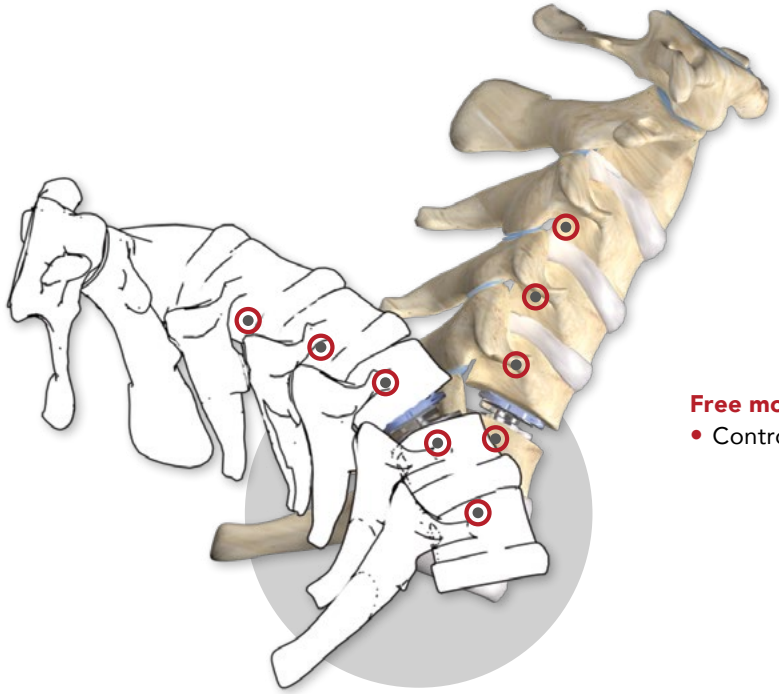


One-piece implant design
- Implantable like a cage

Pre-mounted, in sterile packaging
- No assembly necessary – ready for use



Pure translation, uncoupled from rotation
- Allows for facet-guided movement, with no gaping joints



Free motion – physiologically limited
- Control through natural joint kinematics

INSTRUMENTS

Art. no. GB1513 – GB1915
Footprint Template
15 x 13
17 x 13
17 x 15
19 x 15

Art. no. SN0020-A
Slotted mallet

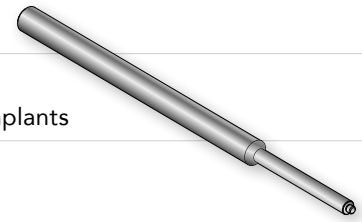
Art. no. GB0003
Revision Clamp

Art. no. GB051513 – GB061915
Trial
5 x 15 x 13, 5 x 17 x 13, 5 x 17 x 15, 5 x 19 x 15;
6 x 15 x 13, 6 x 17 x 13, 6 x 17 x 15, 6 x 19 x 15

OPTIONAL

Art. no. GB0001
Cervical Inserter with Shaft

Art. no. GB0004
Depth Stop



Art. no. P6025AH
Inserter for cervical implants

NOT SHOWN

Art. no. GB01AY
Instrument tray

Art. no. GB14
Backup brackets for heights 6–8 mm

Art. no. GB58
Backup brackets for height 5 mm

Art. no. GB0002
Positioner

INDICATIONS, CONTRAINDICATIONS AND WARNINGS

INDICATIONS

In addition to restoring height of the vertebral disc, the primary function of ROTAIO® is to preserve physiological mobility in the affected segment. ROTAIO® can be used with the following cervical diseases (C3–C7):

- Discopathy
- Disc herniation
- Foraminal and spinal canal stenosis

CONTRAINDICATIONS

- Osteoporosis, osteopenia
- Tumour
- Acute or chronic systemic, spinal or localised infections
- Allergy or intolerance to implant material
- Systemic or metabolic diseases
- Instability
- Severe facet joint and spinal disc degeneration
- Immobility of the affected segment
- History of surgery to the affected segment
- Deformity
- Ossification of the posterior longitudinal ligament
- Traumatic lesions of the cervical spine
- 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)
- Medical conditions that may prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance)
- Cases that are not mentioned under Indications

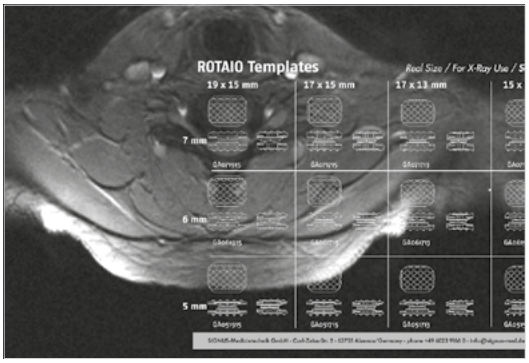
WARNINGS

- The spinal implants and single-use instruments (GB58) are intended for single use only and must not be re-used. Re-use of an implant can cause failure of the implant or instrument, infections and/or death.
- Implants and single-use instruments must be considered as potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines. At the end of their service life, instruments must be similarly disposed of or prepared correctly before disposal.
- SIGNUS implants must be used only with the specified instruments. Correct implantation cannot be guaranteed if implants are placed with other instruments.
- Unless otherwise specified, SIGNUS products must not be combined with materials or components from other systems.

NOTE

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

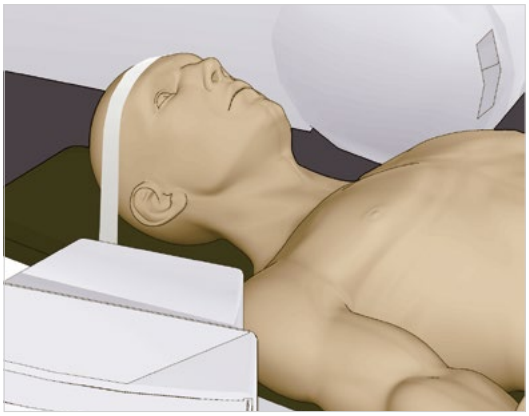
1 Preparation



Preoperative planning

Once the indication has been established in the usual manner, templates can be used during preoperative planning to estimate the optimal size of the ROTAIO® prosthesis. They can be used with a variety of imaging procedures (X-ray, CT and MRI).

Patient positioning



The patient is placed in the supine position as for anterior cervical decompression and fusion (ACDF). The head is positioned on a radiolucent surgical table in neutral position, supported with a soft roll and secured. The image converter is positioned so that fluoroscopy in both sagittal and frontal planes is possible.

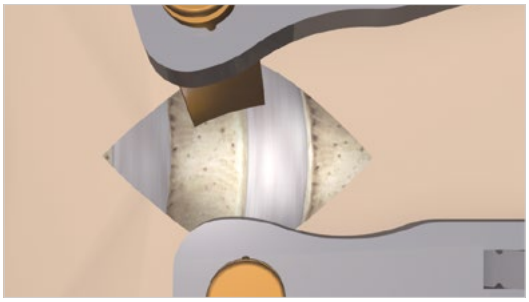
NOTE

In the lateral image of the cervicothoracic transition the inferior CS mobile segment may be overlaid by overlapping shoulder soft tissues. Pulling down and fixing the arm in the inferior direction can correctly image the complete examination area.

CAUTION

Hyperflexion and hyperextension must be avoided.
The surgical outcome may otherwise not be optimal.

Approach

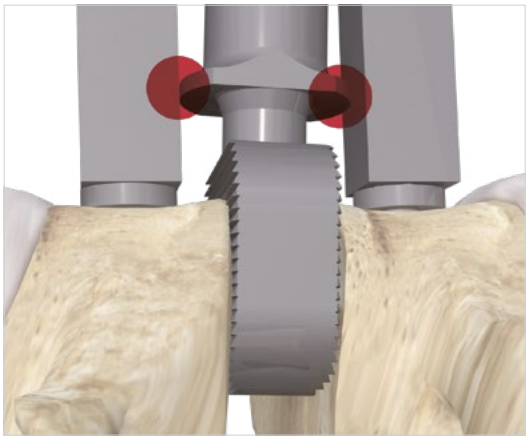


The section that is to be implanted is exposed by a ventral approach to the cervical spine using either the Cloward or the Smith-Robinson technique. For the soft tissue retraction the CERCCESS™ cervical retractor system can be used.

Distraction, decompression and preparation of the intervertebral space

In the first step, the intervertebral disc is incised and partially removed with a scalpel to facilitate subsequent distraction.

The CERCCESS™ distractor pins can be used for this purpose. The distractor pins are inserted into the superior and inferior vertebral body of the affected segment and provide orientation throughout the entire implant procedure.

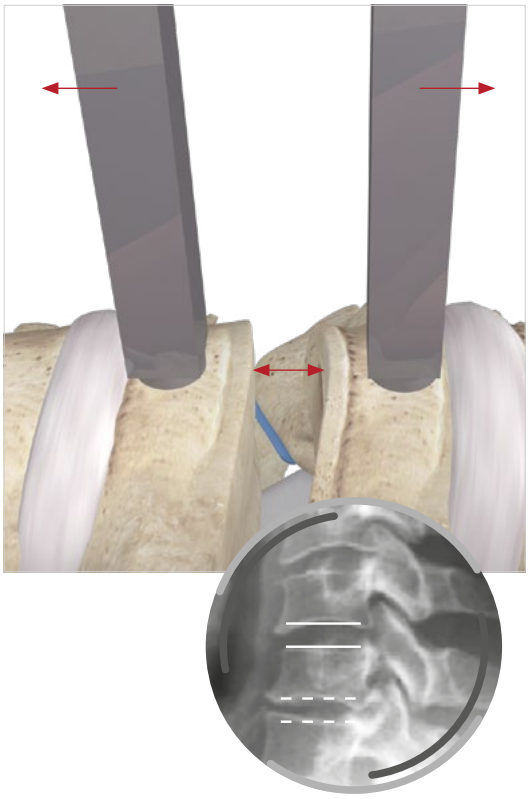


CAUTION

Position the distractor pins parallel to the particular endplate. Ensure that there is adequate distance from the intervertebral disc being evacuated.

CAUTION

If the distance between the distractor pins and the endplates is insufficient, this can lead to problems when inserting the trial instrument. In this case you must rotate the depth stop of the trial instrument accordingly.



As soon as the segment is mobilised, the intervertebral disc space is restored to the required height. The heights of the adjacent intervertebral disc spaces can be used as a reference with the distractor. This is followed by careful decompression of the nerve roots and / or the spinal canal. Other space-occupying structures such as the posterior osteophytes can also be included in addition to the intervertebral disc.

The inferior and superior endplates of the vertebral body are then carefully flattened in parallel planes. Residual intervertebral disc material is removed to maximise the contact area and to ensure that the implant sits securely.

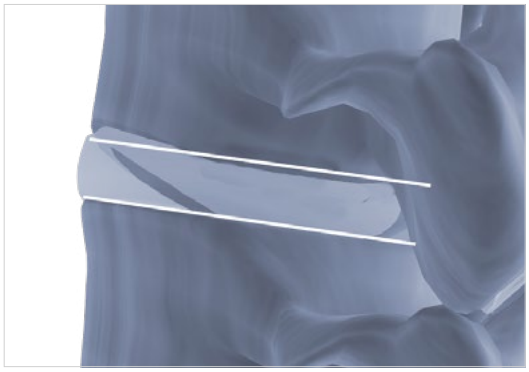
For subsequent symmetrical positioning of ROTAIO®, the centrally placed distractor pins are a helpful orientation.

NOTE

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

NOTE

The implantation of ROTAIO® does not necessarily require resection of the posterior longitudinal ligament. Removal should only be carried out as part of any necessary decompression.



CAUTION

It is important to smooth the endplates gently to preserve the load-bearing cortical layer in the lateral area of the vertebral body in particular.

2 Implantation

Selection of the implant

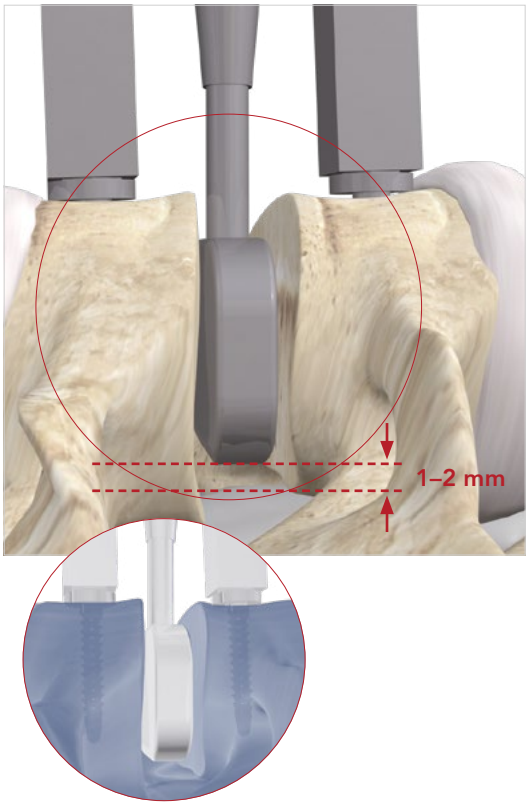
The footprint is defined with the help of the size templates. The footprint should be selected so that it covers most of the vertebral body superior endplates to prevent subsequent subsidence of the implant. Under some circumstances this can require a slight resection of the medial edges of the uncinate process. The size template is inserted centrally into the intervertebral space and placed on the superior endplate of the inferior vertebral body. Using lateral fluoroscopy the optimal depth can be defined.

CAUTION

The size template should be placed about 1–2 mm in front of the posterior edge of the vertebral body. This corresponds to the optimal position of ROTAIO®.

NOTE

During preparation of the intervertebral space, ensure that the adapter of the disc prosthesis also spreads laterally.



Art. no. GB1513
15 × 13 mm

Art. no. GB1713
17 × 13 mm

Art. no. GB1715
17 × 15 mm

Art. no. GB1915
19 × 15 mm

SURGICAL TECHNIQUE

After defining the footprint, the optimal height is determined using the trial instruments. The design of the trial instruments matches the dimensions of ROTAIO® overall (without endplate serrations for anchoring).

Size templates as well as trial instruments to determine the height are colour coded. To determine the height, the trial instruments with the colour that matches the previously selected size template are used.

NOTE

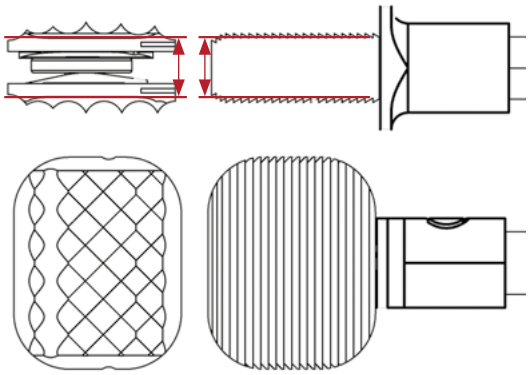
The trials correspond to the implant height not including the serration.

NOTE

With a view to secure positioning of the implant and the clinical outcome, over-distraction should be avoided.

Comparison:

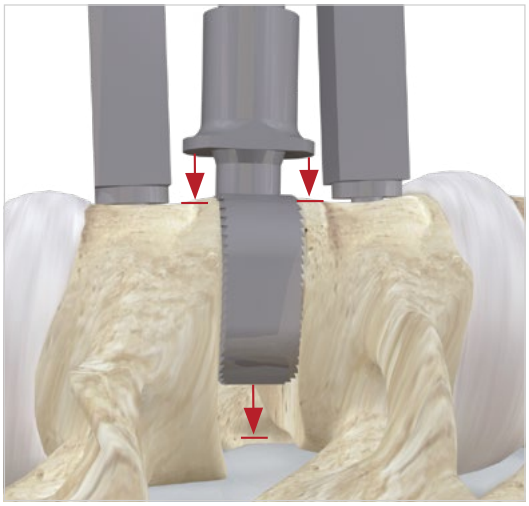
Cage design Trial instrument



The trial instrument is carefully inserted centrally into the intervertebral space with gentle taps of the slotted mallet. This must be done under continuous fluoroscopic control. The variable depth stop of the trial instrument is set depending on the required depth. When the trial instrument has reached the optimal position (about 1–2 mm before the edge of the vertebral body), the vertebral body distraction is released.

The trial instrument must be seated firmly in the intervertebral space. If the trial is loose or can even be removed after releasing the distraction, the next size up should be selected.

The lateral view should also be used to check whether the trial instrument sits flush against the vertebral body endplates. If there are gaps apparent between the vertebral body and the instrument in the lateral view, you must flatten the endplates in parallel planes in a further preparation step.

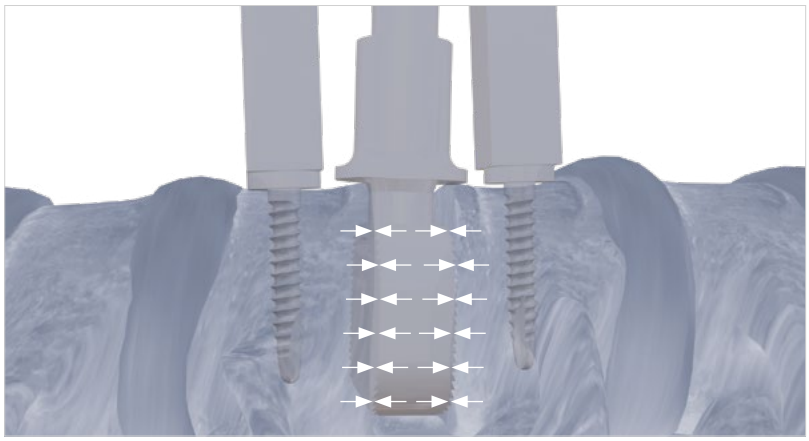


NOTE

If the trial sits very firmly in the intervertebral space, the slotted mallet can be used as a retractor.

NOTE

No additional surgical step is required to refresh the vertebral body endplates. This is achieved during insertion by the toothed surface of the trial instrument.



Variable depth stop

SURGICAL TECHNIQUE

Implant insertion

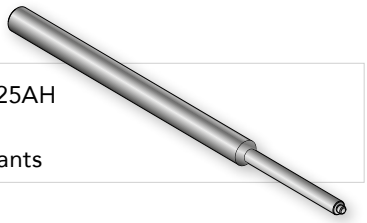
Once an adequate footprint and height have been determined, the appropriate ROTAIO® disc prosthesis is removed from the sterile packaging and fixed to the inserter using the mounter attached to the implant.

ROTAIO® can now be inserted on the front midline into the intervertebral space. This must be done under continuous fluoroscopic control. The optimal position of the prosthesis is about 1–2 mm in front of the vertebral body edge.

Because of the height difference between the trial instrument and the implant*, it is recommended to slightly raise the distraction during the implantation.

*(Serration height: +0.8 mm per side for 5 mm prosthesis and +1.0 mm per side for prostheses > 5 mm)

After the final positioning of ROTAIO®, the distraction must first be released again and the inserter with the adapter must be removed from the site of the patient. The inserter should be carefully withdrawn upwards when doing so. To secure the implant position and to protect the prosthesis as well as the surrounding tissue, ensure that the inserter is withdrawn in a steady and controlled manner. Excessive back and forth movement in the intervertebral space must be avoided.



Art. no. P6025AH
Inserter for
cervical implants

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 use of the implant. Check expiry date and intactness of the sterile packaging before use. All of the packaging must be removed.

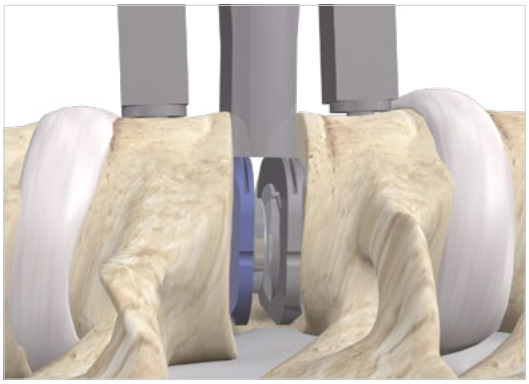
The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.

NOTE

If the resistance during withdrawal is too high, the distraction must be increased slightly again.

CAUTION

During implant placement, the blue endplate of ROTAIO® and the label ‘Top’ on the adapter must be aligned in a superior direction.



After unscrewing the inserter, the positioner can be used for the final positioning of ROTAIO®.

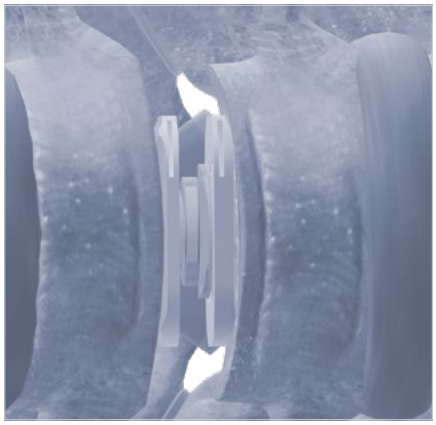
CAUTION

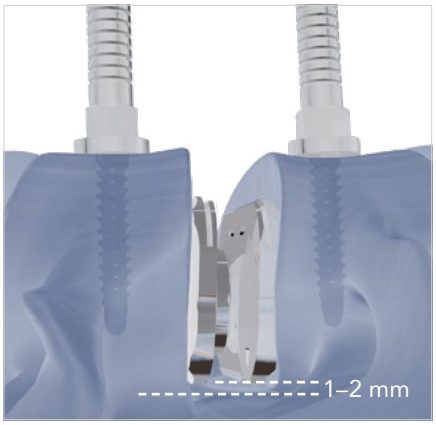
Avoid overdistraction of the segment with a view to the clinical outcome.

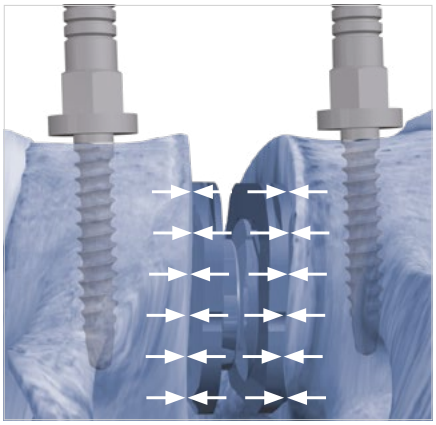
VERIFICATION IMAGE – ROTAIO®

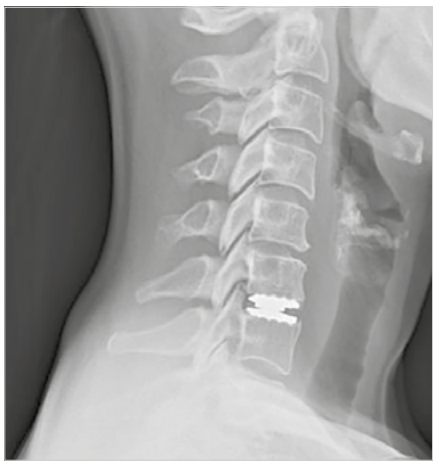
The correct seating of the ROTAIO® disc prosthesis should be verified prior to wound closure:

ROTAIO® is positioned on the front midline and 1–2 mm in front of the posterior edge of the vertebral body. ROTAIO® is correctly and firmly seated in the implant site and sits flush against the vertebral body endplates (AP view / lateral view).

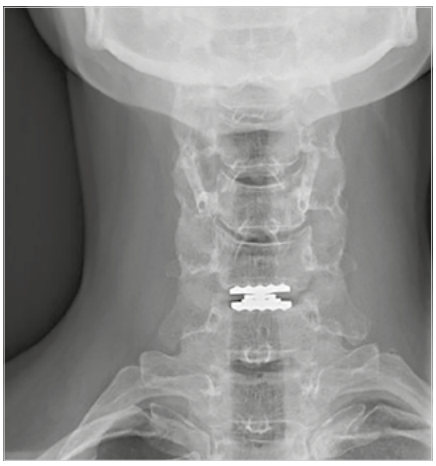








Lateral



AP

The Caspar retractor can now be removed and the ROTAIO® teeth can be secured using slight manual compression of the distractor pins.

3 Revision

ROTAIO® can be revised if necessary.

Select the described approach in section **"1 Preparation"** and show the implant. Special attention should be paid to preparation of the nerve tissue and the scar tissue that has already developed.

Remove the implant from the disc space with the extraction forceps. To do so, the gripping arms of the extraction forceps are positioned around the implant disc and the catch on the handle is closed. ROTAIO® can now be withdrawn from the intervertebral space. If the implant sits very firmly in the intervertebral space, the slap mallet can be used as a retractor. While doing so, ensure that the integrity of the nerve structures is preserved.

CAUTION

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

NOTES

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.

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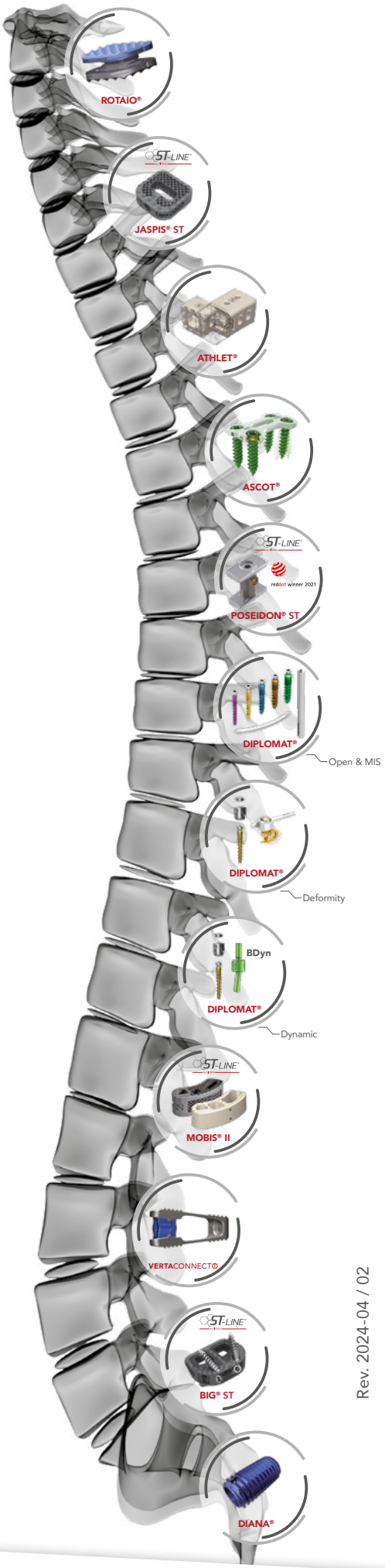

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