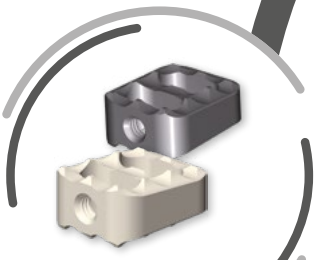
PRODUCT INFORMATION | ACDF | US

RABEA® | NUBIC®

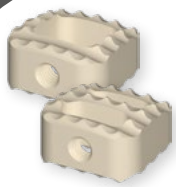
Anterior Cervical Fusion

For distribution in the USA only

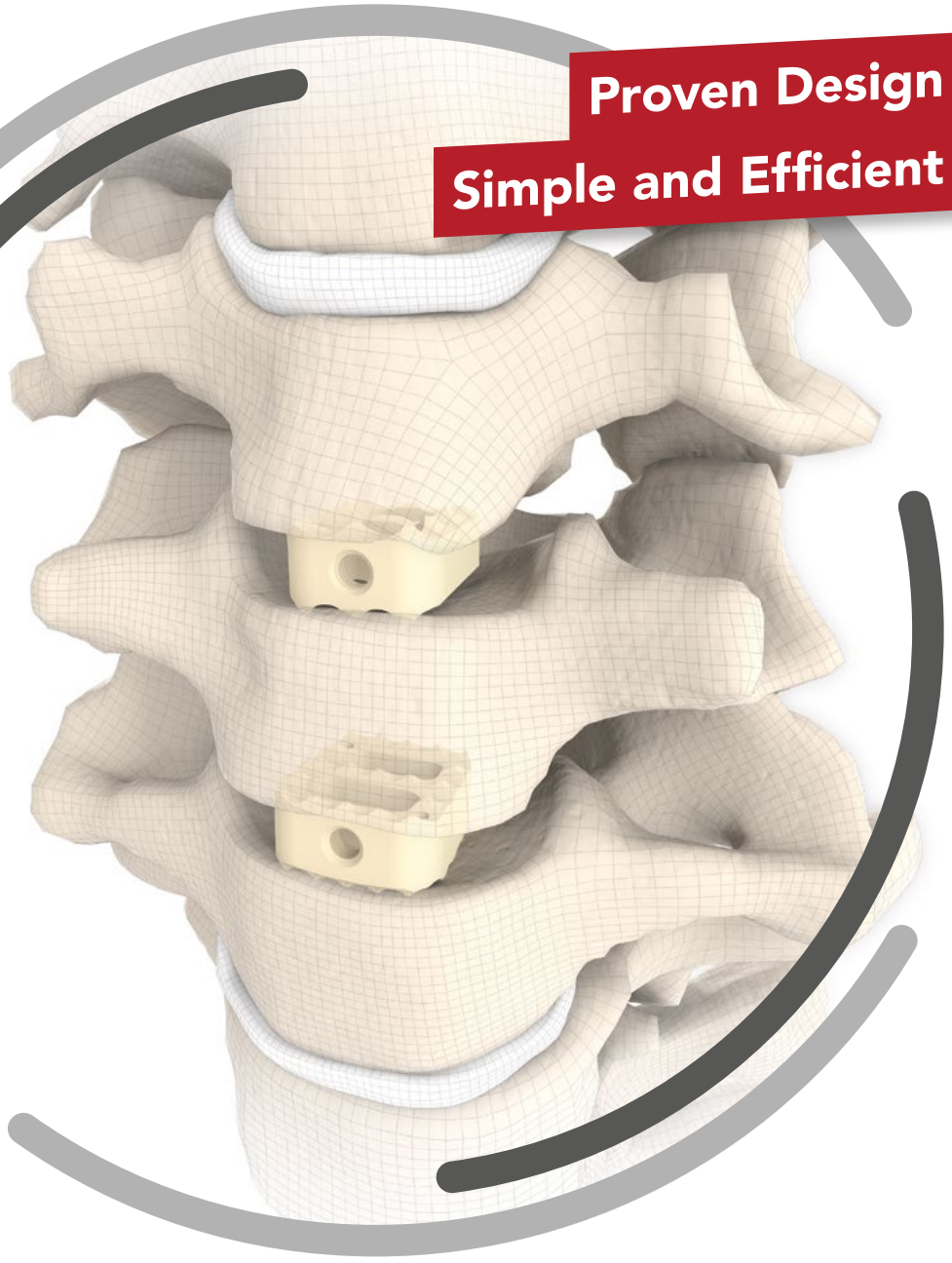
Proven Design
Simple and Efficient



RABEA®



NUBIC®

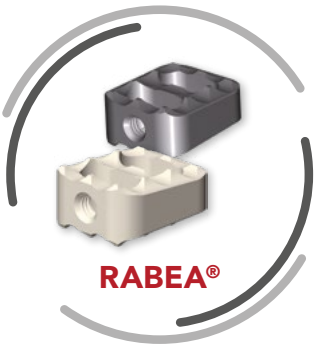


HIGH-END MADE IN GERMANY

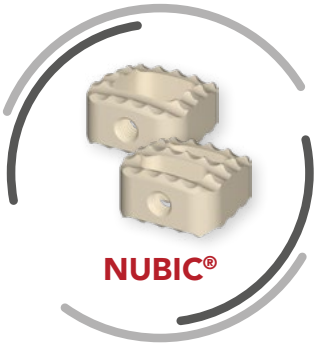
www.signus.com

SIGNUS The Spine Sign®


HIGH-END
MADE IN GERMANY



RABEA®



NUBIC®

CONTENTS

ABOUT SIGNUS

SIGNUS – THE SIGN FOR SPINE:

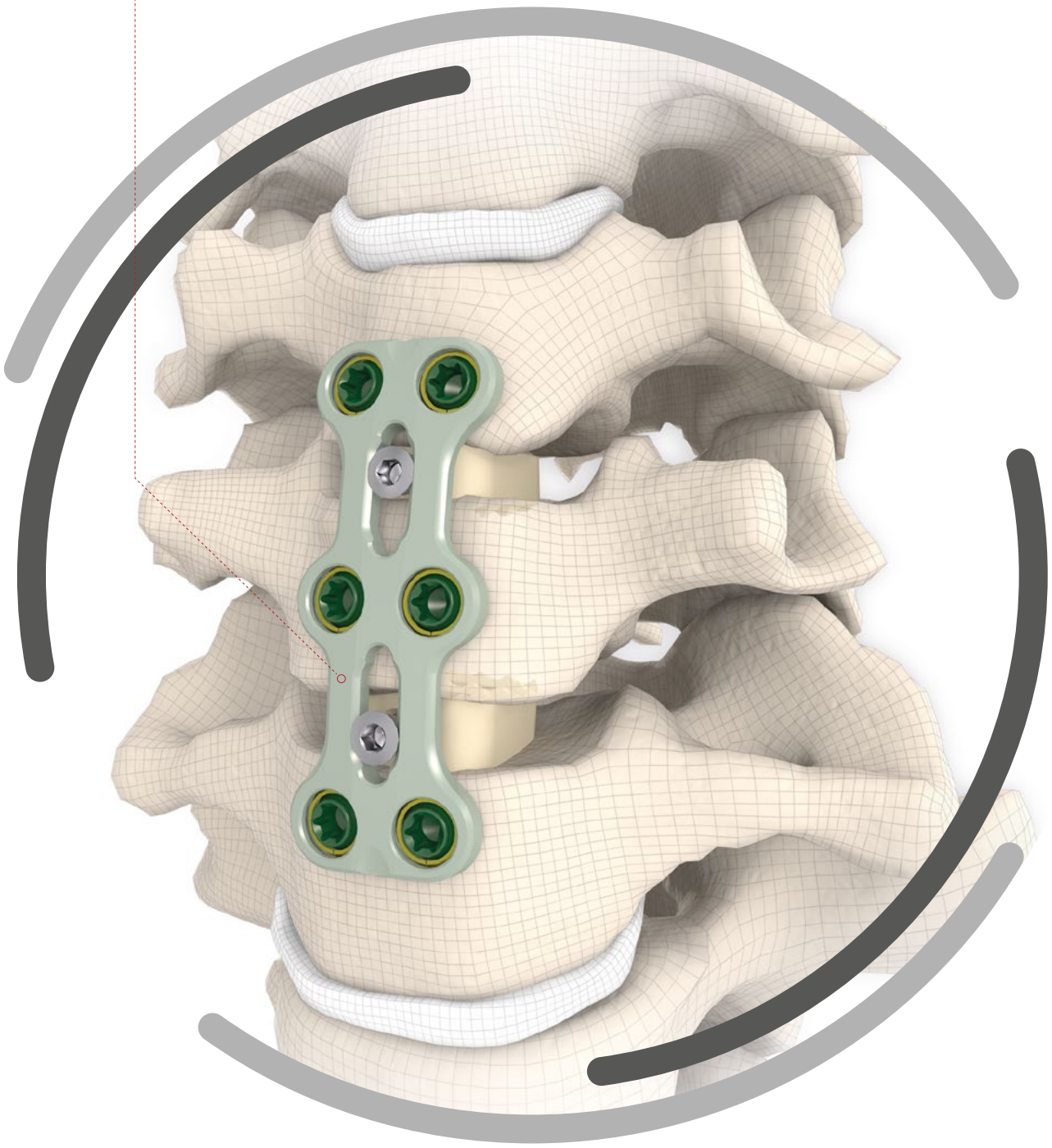
PASSIONATE! DYNAMIC! WORLDWIDE!

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

ASCOT® – Anterior Cervical Stabilization
Maximum Stability – Minimal Stiffness



CONCEPT

The RABEA® and NUBIC® disc replacement implants were developed for the specific requirements of anterior cervical vertebral fusion (C3–TH1). The implant ranges are available in various designs, footprints, heights and angles to enable adaptation to different patient anatomies.

IMPLANTS

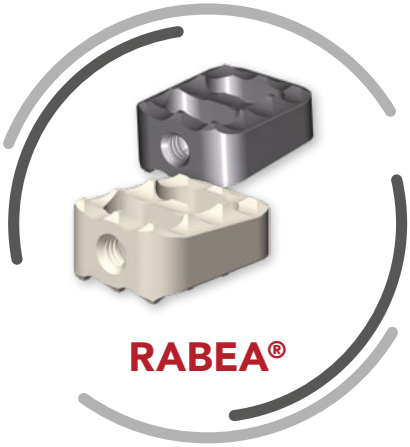
RABEA® and NUBIC® are implanted in the C3–TH1 cervical spinal region using the proven Smith-Robinson technique.

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.

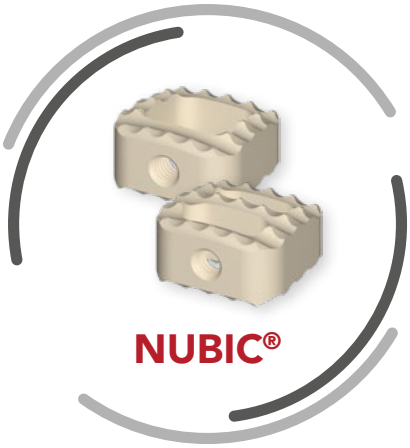
The large selection of implants provides for a high degree of intraoperative flexibility and ensures restoration of the intervertebral space. NUBIC® has a curved surface that fits optimally with the adjacent vertebral bodies. For RABEA® there are cages available in a 5° lordotic angle as well as plane-parallel implants.

Material details

The implants are made either of titanium aluminium vanadium (Ti-6Al-4V) or the high-performance medical polymer PEEK-OPTIMA®. The radiolucent PEEK-OPTIMA® implants have anterior and posterior X-ray markers made of titanium alloy (Ti-6Al-4V) to enable intraoperative and post-operative verification.



RABEA®

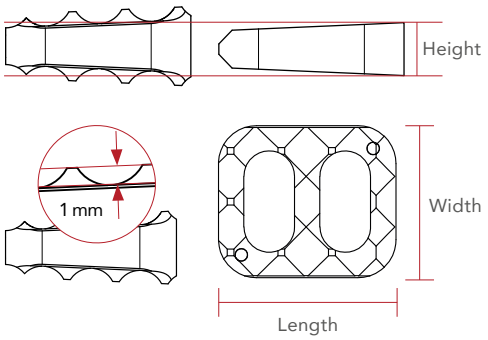


NUBIC®

IMPLANTS

RABEA®				
Lordosis	**Width × length (mm)**	**Height* (mm)**	**Art. no. TITANIUM**	**Art. no. PEEK**
0°	12 × 12	4	P041212	PK041212
		5	P051212	PK051212
		6	P061212	PK061212
		7	–	PK071212
		8	–	PK081212
	12 x 14	4	P041214	PK041214
		5	P051214	PK051214
		6	P061214	PK061214
		7	P071214	PK071214
		8	–	PK081214
5°	12 x 12	4	W041212	WK041212
		5	W051212	WK051212
		6	W061212	WK061212
	12 x 14	4	W041214	WK041214
		5	W051214	WK051214
		6	W061214	WK061214
		7	W071214	WK071214
		8	–	WK081214

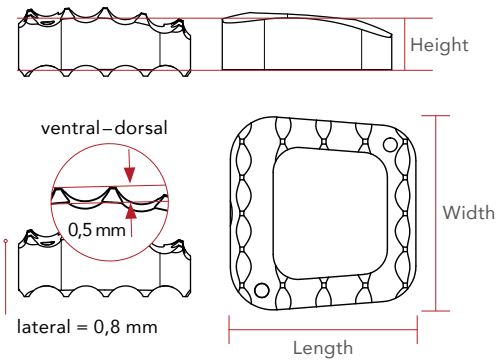
RABEA®



Width: 12 mm
Length: 12 mm, 14 mm, 16 mm

NUBIC®			
	Width × length (mm)	**Height* (mm)**	**Art. no.**
with bar	14 × 13	4	N041314
		5	N051314
		6	N061314
		7	N071314
		8	N081314
without bar	14 × 13	4	NB041314
		5	NB051314
		6	NB061314
		7	NB071314
		8	NB081314
	17 x 13	4	NB041317
		5	NB051317
		6	NB061317
		7	NB071317
		8	NB081317

NUBIC®



Width: 14 mm, 17 mm
Length: 13 mm

* Implant height without tooth height

All implants are in individual sterile packaging for immediate use.

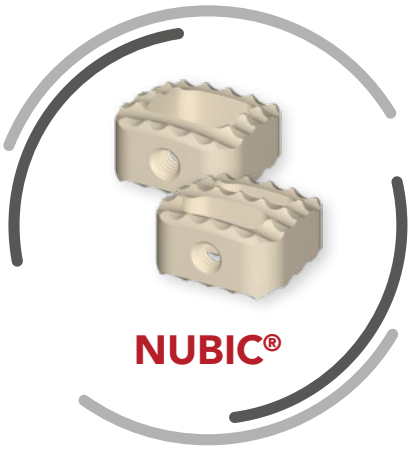
Additional sizes available upon request.

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

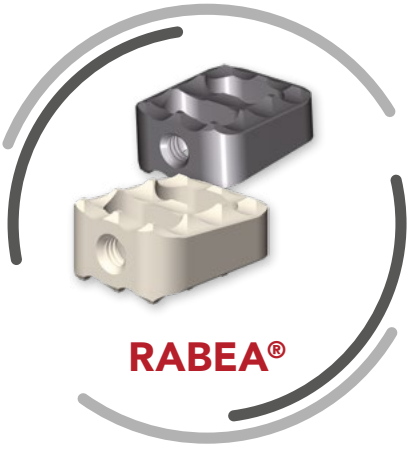
PRODUCT-SPECIFIC ADVANTAGES

- **Rectangular design**
  - Familiar Smith-Robinson surgical technique
- **Open implant design**
  - Can be packed with natural or synthetic bone graft substitute
  - Promotes osseointegration
- **Artefact-free MRI imaging***
  - Optimal postoperative monitoring
- **Proven SIGNUS serrated cage design**
  - Secure anchoring in the bone owing to high primary stability
  - Reduced risk of implant migration
- **Titanium marker***
  - Easy and reliable identification and positioning of the implant
- **Only one instrument required for implantation**
  - Simple and safe handling
  - Economically efficient

**Applicable only for RABEA® PEEK and NUBIC®*



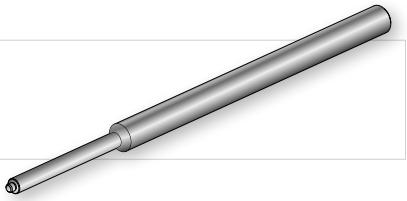
NUBIC®



RABEA®

INSTRUMENTS – RABEA®

Art. no. P6025AH
Inserter for
cervical implants



NOT SHOWN

Art. no. P003AY
Instrument tray

Art. no. P6040AH
Cervical trial implant, 4 mm, 0°

Art. no. P6050AH
Cervical trial implant, 5 mm, 0°

Art. no. P6060AH
Cervical trial implant, 6 mm, 0°

Art. no. P6070AH
Cervical trial implant, 7 mm, 0°

Art. no. P6080AH
Cervical trial implant, 8 mm, 0°

Art. no. W6040AH
Cervical trial implant, 4 mm, 5°

Art. no. W6050AH
Cervical trial implant, 5 mm, 5°

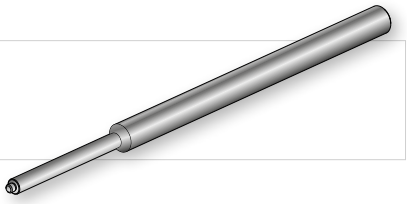
Art. no. W6060AH
Cervical trial implant, 6 mm, 5°

Art. no. W6070AH
Cervical trial implant, 7 mm, 5°

Art. no. W6080AH
Cervical trial implant, 8 mm, 5°

INSTRUMENTS – NUBIC®

Art. no. P6025AH
Inserter for
cervical implants



OHNE ABBILDUNG

Art. no. P003AY
Instrument tray

Art. no. P004AY
Instrument tray

Art. no. N6040AH
Cervical trial implant, 13 x 14 x 4 mm

Art. no. N6050AH
Cervical trial implant, 13 x 14 x 5 mm

Art. no. N6060AH
Cervical trial implant, 13 x 14 x 6 mm

Art. no. N6070AH
Cervical trial implant, 13 x 14 x 7 mm

Art. no. N6080AH
Cervical trial implant, 13 x 14 x 8 mm

Art. no. NXL6040AH
Cervical trial implant, 13 x 17 x 4 mm

Art. no. NXL6050AH
Cervical trial implant, 13 x 17 x 5 mm

Art. no. NXL6060AH
Cervical trial implant, 13 x 17 x 6 mm

Art. no. NXL6070AH
Cervical trial implant, 13 x 17 x 7 mm

Art. no. NXL6080AH
Cervical trial implant, 13 x 17 x 8 mm

INDICATIONS, CONTRAINDICATIONS, CAUTION AND MRI

INDICATIONS

When used as an intervertebral fusion device, the NUBIC® devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One NUBIC device is used per intervertebral space. A connecting screw is available which allows the NUBIC® device (without strut) to be physically attached to the SIGNUS TOSCA® or TOSCA® II anterior cervical plate system if desired.

When used as an intervertebral fusion device, the RABEA® devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One RABEA® device is used per intervertebral space.

CONTRAINDICATIONS

- Advanced osteoporosis
- Specific metal allergy (Titanium only)
- Infection

CAUTION

- These Spinal Implant Devices are intended for single use only and should not be re-implanted

USA: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

MRI SAFETY INFORMATION

The NUBIC® implant is conditionally MR safe. A patient with this implant can be safely scanned in an MRI system in accordance with the justification and the test methods in ASTM F2502. Testing of the effects due to forces, torque, heating or artefact formation was not carried out.

RABEA® PEEK implants are conditionally MR safe. A patient with this implant can be safely scanned in an MRI system in accordance with the justification and the test methods in ASTM F2502. Testing of the effects due to forces, torque, heating or artefact formation was not carried out.

Non-clinical trials demonstrated that the RABEA® (titanium) implant is 'MRI conditional'. A patient with this implant can be safely examined in an MRI environment that complies with the following criteria:

- Static magnetic field strength of 3 T or less
- Maximum spatial magnetic fi eld gradient of 720 Gauss/cm or less
- Maximum mean whole-body specific absorption rate (SAR) stated by the MRI system of 2.9 W/kg

Under these examination conditions a temperature increase in the implant of max. 1.7° C (1.5 T) can be expected during a continuous examination over 15 minutes.

In non-clinical trials the image distortion caused by the product extended to about 15 mm around the RABEA® titanium implant when using a gradient echo sequence and a 3 T MRI system.

NOTE

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

1 PREPARATION

Preoperative planning

After the standard clarification of the indication, the degree of the resection and thus the height of the disc replacement implant can be estimated preoperatively in the standard procedure.

Patient positioning

The patient should be placed in a supine position with the head secured in a slightly reclined position on a radiolucent table. The image converter is positioned so that fluoroscopy in both sagittal and frontal planes is possible.

NOTE

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

Approach

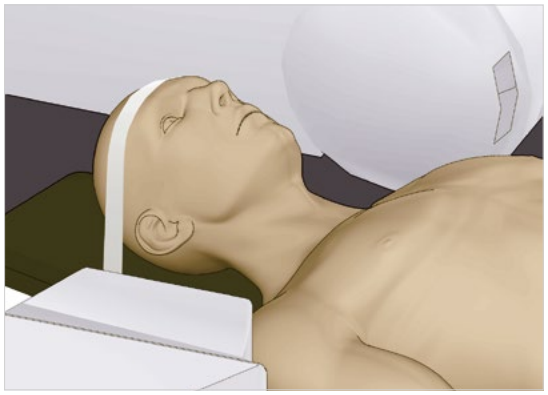
The section that is to be implanted is exposed by a ventral approach to the cervical spine using either the Cloward or the Smith-Robinson technique. For the soft tissue retraction the CERCCESS™ cervical retractor system can be used.

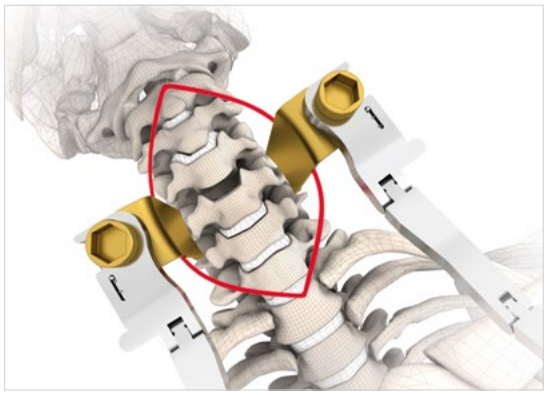
Distraction, decompression and preparation of the intervertebral space

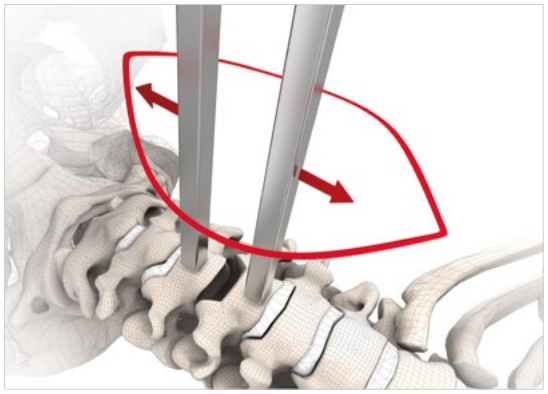
In the first step, the intervertebral disc is incised and partially removed with a scalpel to facilitate subsequent distraction. The CERCCESS™ distractor with pins can be used for this purpose.

As soon as the segment is mobilized, the intervertebral disc space can be restored to the required height. The heights of the adjacent intervertebral disc spaces can be used as a reference.

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 prepared. Residual intervertebral disc material is removed to ensure that the implant sits securely. However, to prevent the cage subsiding, the integrity of the vertebral body endplates should be retained during subsequent freshening. If plate osteosynthesis is to occur in addition to fusion, the anterior section of the vertebral body is carefully smoothed to ensure that the plate is securely seated.







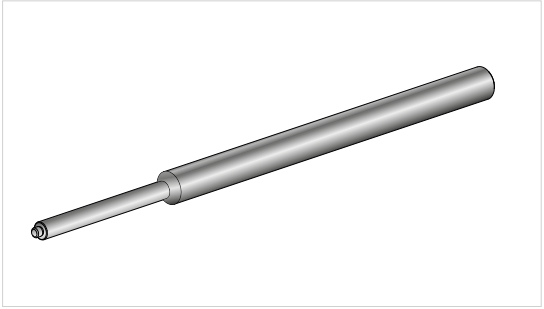
NOTE

The extracted bone material can later be used for implant packing, interbody impaction and adhesion. To achieve optimal fusion results, freshen the exposed vertebral endplates.

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.

2 IMPLANTATION



Selection of the implant

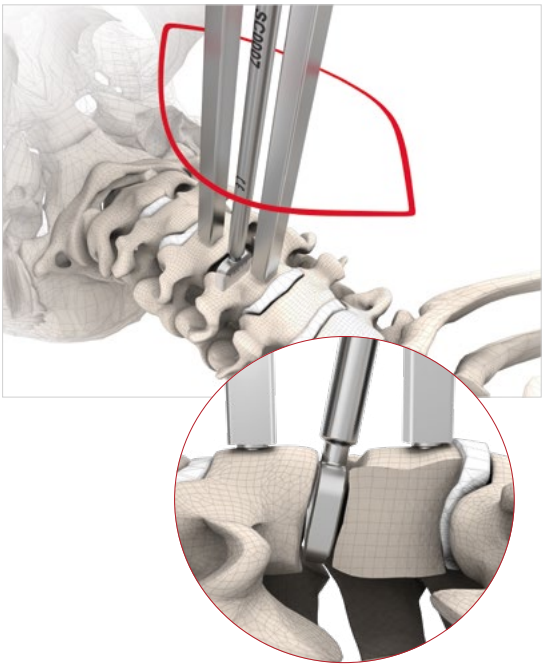
The optimal implant size is estimated with the trial instruments corresponding to the implant system. The footprint should be selected so that it covers most of the vertebral body endplates to prevent subsequent subsidence of the cage. Under some circumstances this can require a slight resection of the medial edges of the uncinate process.

Start with a trial implant footprint with a size somewhat smaller than that preoperatively estimated. The trial implant is now fixed to the inserter using the thread.

The trial is carefully inserted into the intervertebral space with gentle taps of the plastic mallet. This must be done under continuous fluoroscopic control.

The trial implant 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 gaps are visible here, the implant site must be prepared further. If the trial sits very firmly in the intervertebral space, a slotted mallet (with a slot width of 6–9 mm) can be used to tap out the trial.



NOTE

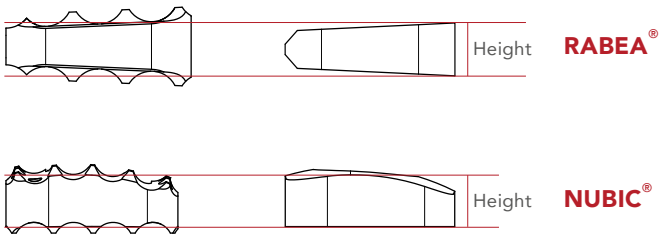
The trials correspond to the implant height not including the serration.

NOTE

To ensure secure positioning of the implant and the clinical outcome, over-distraction should be avoided.

Comparison:

Cage design Trial instrument



Filling and inserting the implant

Once an adequate footprint, height and lordosis have been determined, the appropriate implant is removed 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 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.

Adhesion of bone material

To improve the fusion outcome, it is advisable to appose bone material in and around the implant.

The implant is attached to the inserter using the screw thread and can now be inserted into the intervertebral space. This must be done under continuous fluoroscopic control. Because of the height difference between the trial instrument and the implant (cage serration height RABEA® 1 mm each side, NUBIC® 0,5 mm each side), it is recommended to slightly increase the distraction during the implantation.

Additional fixation

The TOSCA® or ASCOT® ventral fixation systems can be used for additional anterior fixation. The preshaped plates are matched to the lordosis of the cervical spine.

ASCOT®
Anterior Cervical Stabilization

- Semi-rigid design with large angular variability
- Locking, self-drilling screws
- Thin plate design of 1.8 mm

TOSCA® Expansion
Anterior Cervical Stabilization

- Expansion screws
- Self-tapping fixed-angle and variable-angle bone screws
- Thin plate design of 1.6 mm

3 REVISION

RABEA® and NUBIC® 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. Using the slotted mallet, remove the implant from the disc space. 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

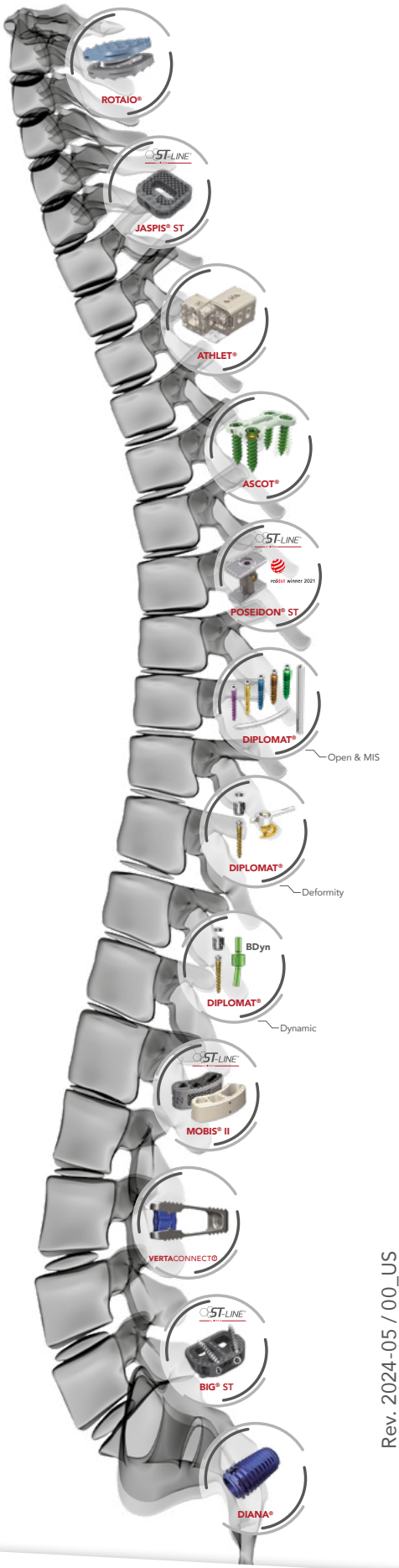
NOTE: This document was written by the technical department at SIGNUS Medizintechnik GmbH. Despite being reviewed by trained personnel, the sole purpose of this brochure is to provide an explanation of the technical aspects of handling the product described.
This document, in particular the description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

SIGNUS – THE SIGN FOR SPINE

PASSIONATE!
DYNAMIC!
WORLDWIDE!

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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Rev. 2024-05 / 00_US

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