

MOBIS[®] II PEEK

Transforaminal Lumbar Interbody Fusion

For distribution in the USA only

**Variable and
reliable implantation**



www.signus.com

SIGNUS
The Spine Sign[®]





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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.

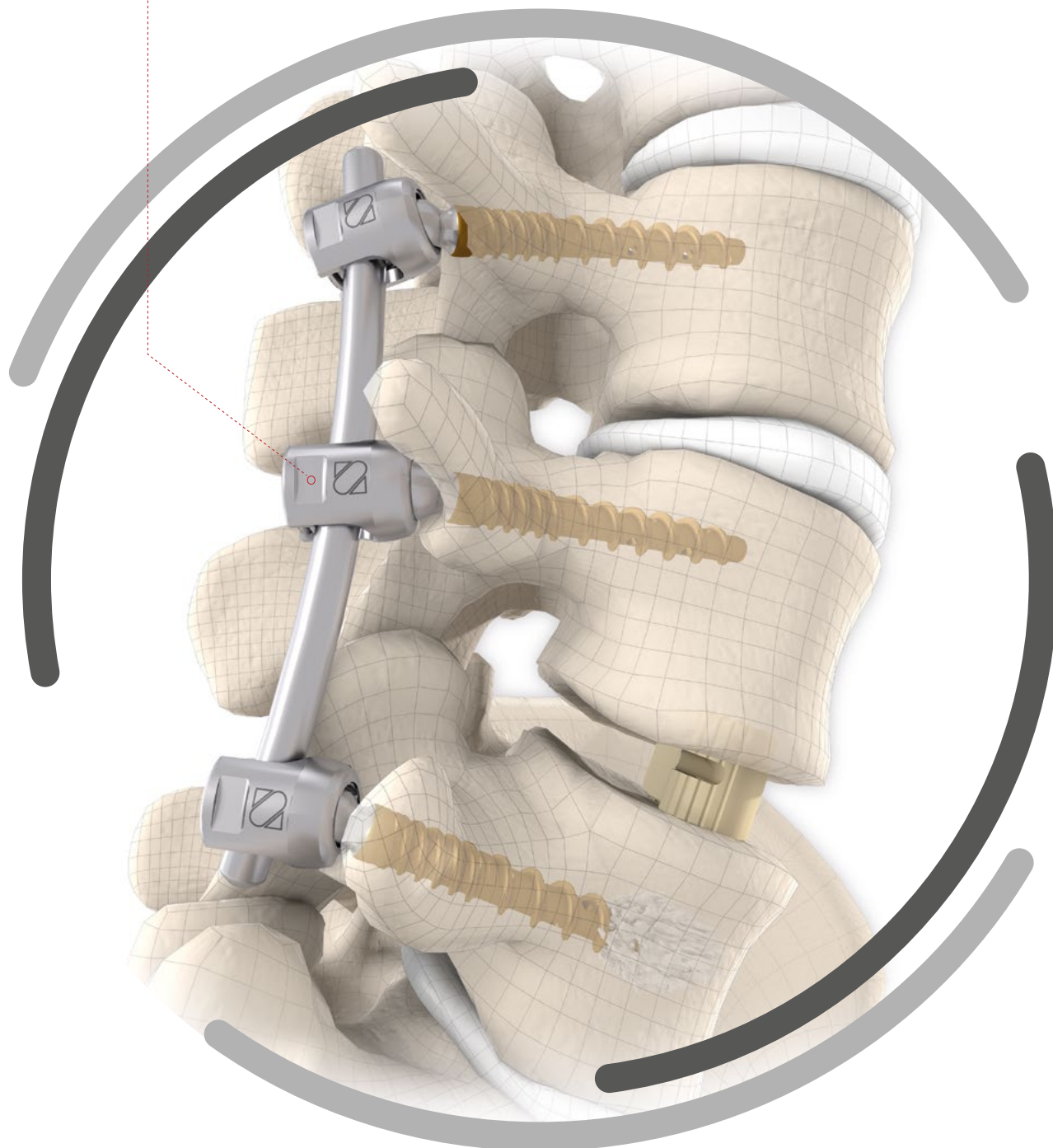
The entire SIGNUS Portfolio with detailed information and descriptions are available for you online at www.signus.com



ADDITIONAL PRODUCTS

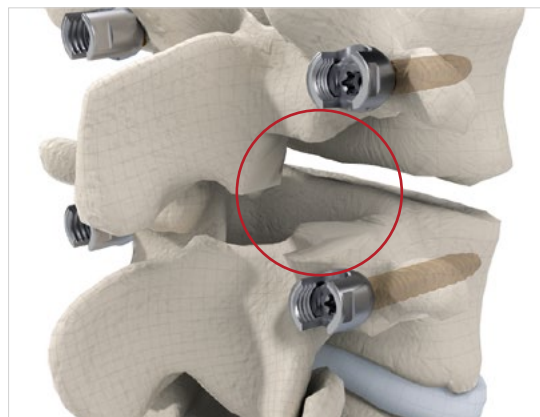
DIPLOMAT® – Posterior Instrumentation

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



CONCEPT

Intersomatic fusion via the transforaminal approach is largely consistent with the principle of PLIF (Posterior Lumbar Interbody Fusion). The transforaminal (TLIF) approach entails unilateral resection of the joint. This enables convenient access to the disc whilst at the same time preserving the contralateral lamina and facet joint as an additional fusion surface.



IMPLANTS

MOBIS® II is placed by a TLIF (Transforaminal Lumbar Interbody Fusion) approach in the L2–S1 spinal region. Its arc-like profile with large hollow openings guarantees a large contact surface with the bone. With its shape MOBIS® II is an ideal fit to the anterior curve of the vertebral body.

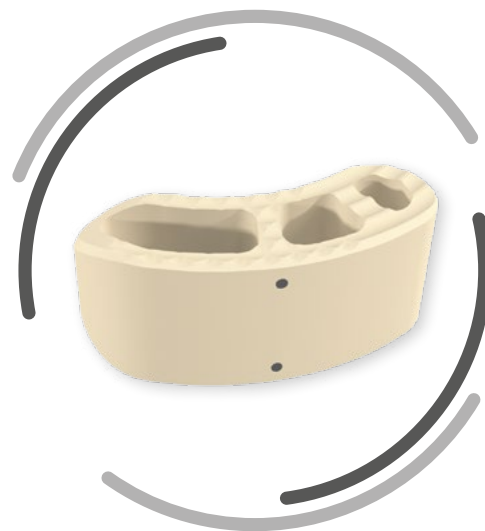
The large fenestration in the implant permits the cage to be packed with bone graft.

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

The selection of implants provides for a high degree of intraoperative flexibility and ensures restoration of the intervertebral space as well as the anatomical lordosis of the lumbar spine.

Material details

PEEK-OPTIMA® is a biocompatible polymer offering a number of benefits in this indication. In its strength it is comparable to cortical bone and due to its excellent MRI compatibility permits artifact-free follow-up examinations. The tantalum markers are used with x-ray or CT during and after surgery to check that the implant is correctly positioned.



IMPLANTS

MOBIS® II PEEK		
Height* (mm)	5° Lordosis	Filling volume
7	B25070929	0.66
8	B25080929	0.75
9	B25090929	0.85
10	B25100929	0.94
11	B25110929	1.04
12	B25120929	1.13

* Implant height without tooth height

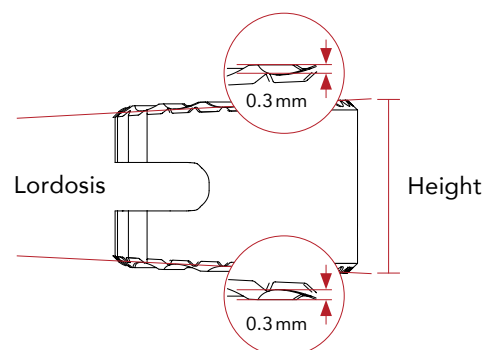
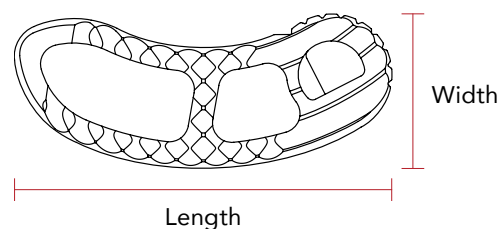
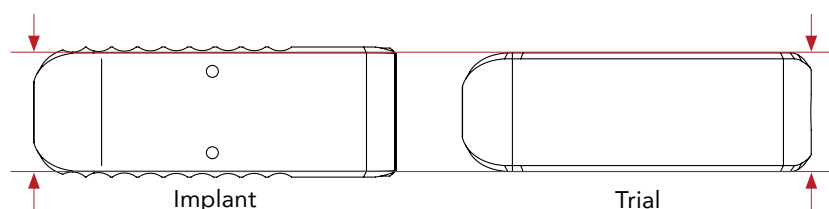
All implants are in individual sterile packaging for immediate use.

Width: 9 mm

Length: 29 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.



PRODUCT-SPECIFIC ADVANTAGES

- **Controlled variable insertion**
 - In four steps of 0°–72° (4 x 18°) to the final position
 - Slender design of the instrument for enhanced intraoperative visibility
- **Open implant design**
 - Can be packed with natural or synthetic bone graft substitute
 - Promotes osseointegration
- **Flattened implant apex**
 - Easier implantation with self-distracting design
 - No removal of the posterior edges of vertebral bodies
- **Smooth lateral surfaces**
 - Less preparation required
 - Protection of nerve roots
- **Proven SIGNUS toothed cage design**
 - Secure anchoring in the bone owing to high primary stability
 - Reduced risk of implant migration
- **Tantalum markers**
 - Easy and reliable identification and positioning of the implant

INSTRUMENTS

Art. no. BZ0001
Inserter 6–10 mm



Art. no. BZ0002
Inserter 11–18 mm



Art. no. B0728AHA
Positioner 6–10 mm



Art. no. B1028AHA
Positioner 11–18 mm



Art. no. BZ0005-A
Graft loading platform



Art. no. BZ0006
Graft impactor



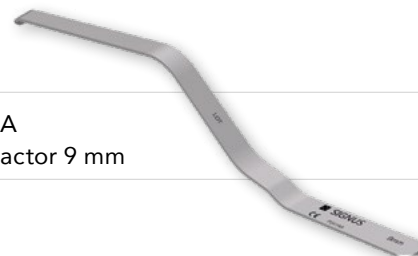
Art. no. KC0004
Bone tamp



Art. no. MI-0803
Lamina distactor



Art. no. P041AA
Nerve root retractor 9 mm



Art. no. P042AA
Nerve root retractor 11 mm

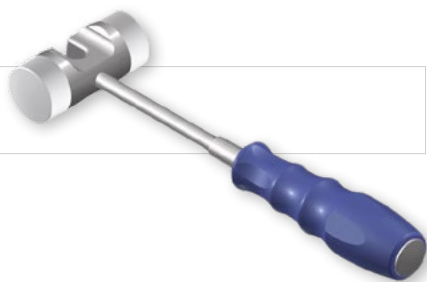


Art. no. B024AH-A
Guiding slide



INSTRUMENTS

Art. no. BZ0007
Slotted mallet



Art. no. BZ0008-2-B
Inserter for trials inner part

Art. no. BR0008-1
Inserter for trials outer part



Art. no. BZ00729–BZ01229
Trials



NOT SHOWN

Art. no. BZ01AY
Instrument tray

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS

When used as an intervertebral fusion device in skeletally mature patients, the MOBIS® devices are intended for use at one level in the lumbar spine, from L2 to S1, 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 lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

CONTRAINDICATIONS

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

WARNINGS

- The spinal implants are intended for single use only and may not be re-used. Re-use 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.
- 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.
- 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.

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

MRI SAFETY INFORMATION

The MOBIS® PEEK has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment.

The safety of MOBIS® PEEK in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

NOTE

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

SURGICAL TECHNIQUE

1 PREPARATION

Patient positioning

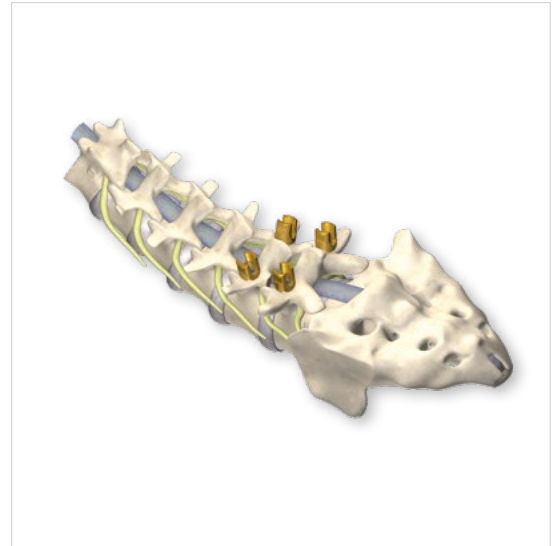
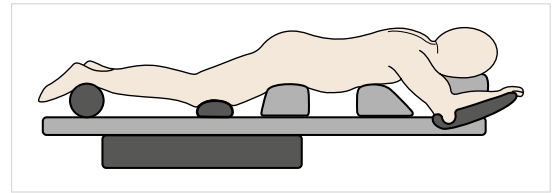
Place the patient in a prone position, with physiological lordosis restored. Make sure that the abdomen is not overloaded in such a position in order to counteract venous stasis. The patient should be positioned on a radiolucent operating table that permits free movement of the C-arm at the sagittal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

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.



SURGICAL TECHNIQUE

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.

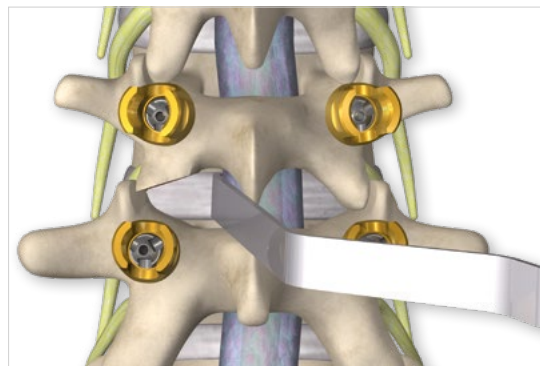
NOTE

The extracted bone material can later be used for implant packing, inter-body 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.

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

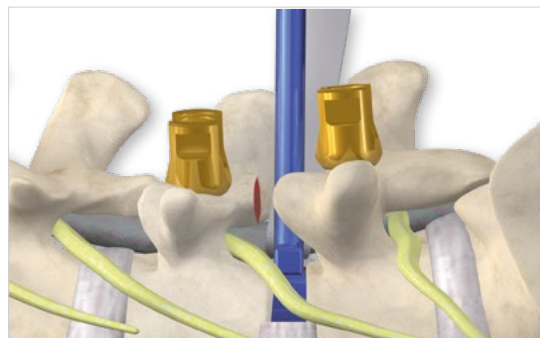
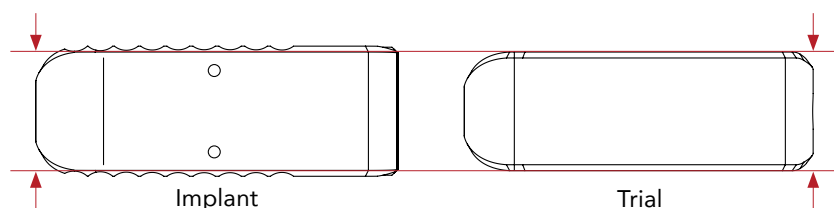


2 IMPLANTATION

Distraction and selection of the implant

Distraction and, if necessary, repositioning can be achieved using the repositioning system of the posterior instrumentation, where available. Otherwise a retractor is available, which engages with the spinous processes after the spinal fixator has been mounted unilaterally. After distraction, the endplates can be straightened by resecting the osteophytes. The implant site should be prepared to the extent that as little cartilage as possible remains.

The size of the implant can be estimated once the intervertebral space has been prepared. The trials can be used to determine the height. Start with the height estimated during preoperative planning. The trials are inserted through the access of the annulus fibrosus.



NOTE

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

NOTE

The trials correspond to the implant height not including teeth.

SURGICAL TECHNIQUE

Packing the implant

Once the size of the implant has been determined, the implant is removed from the sterile packaging by turning it 90° without contact and it is fixed to the variable inserter.

To improve the fusion outcome it is advisable to insert bone chips and/or bone graft substitute in and around the implant. The graft loading platform and graft impactor can be used to pack the implant.

Implant insertion

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

NOTE

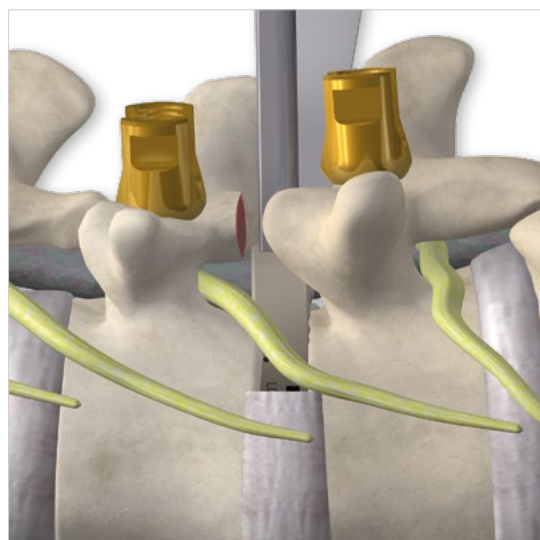
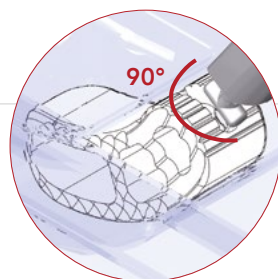
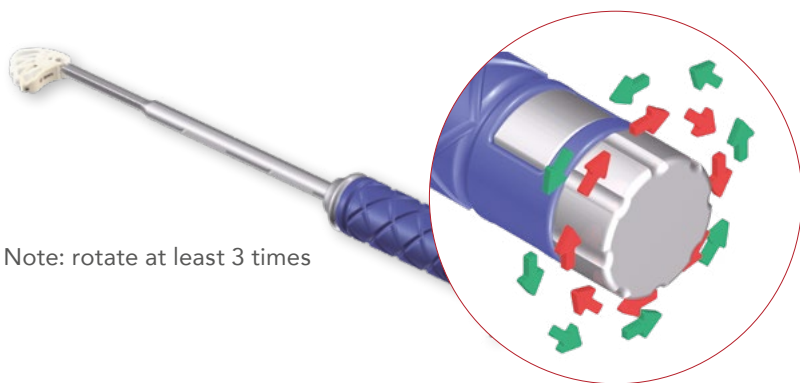
The implant must be kept in its original packaging. The packaging must be stored in a dry place, protected from sunlight. It should only be opened immediately prior to use of the implant. Check expiry date and integrity of the sterile packaging before use. All of the packaging must be removed.

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

The implant is correctly attached to the instrument if the grooves at both ends are meshed together and the T-shaped end of the inserter is fixed.

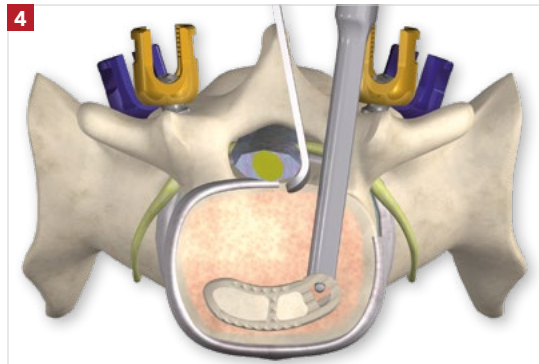
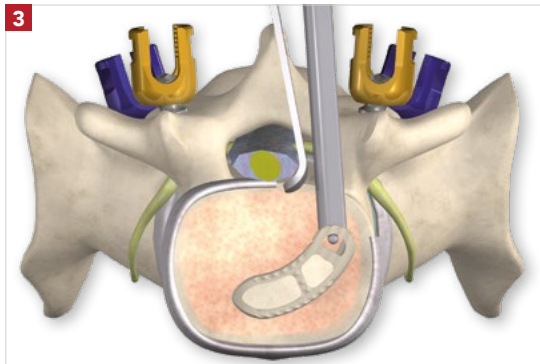
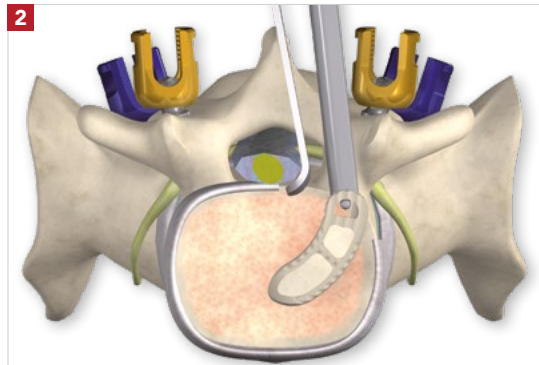
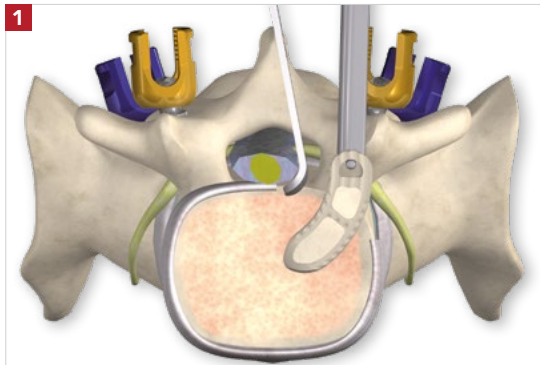
During the first step, bring the implant as far into the insertion position of the disc space as possible. The inserter can now be definitively loosened from the implant, enabling the angle to be adjusted between the implant and instrument. Repeat fixation (hand-tight) at the selected angle will permit the implant to be rotated into its final position. The implant can be loosened from 0°–72° max. in 4 steps (4x18°) ← and can then be attached to the inserter again →. The working steps can be repeated 4 times until the final position of the implant at the anterior vertebral edge has been reached.



SURGICAL TECHNIQUE

Four steps to the final position

View from above



CAUTION

Intraoperative levering and tilting must be avoided at all costs.

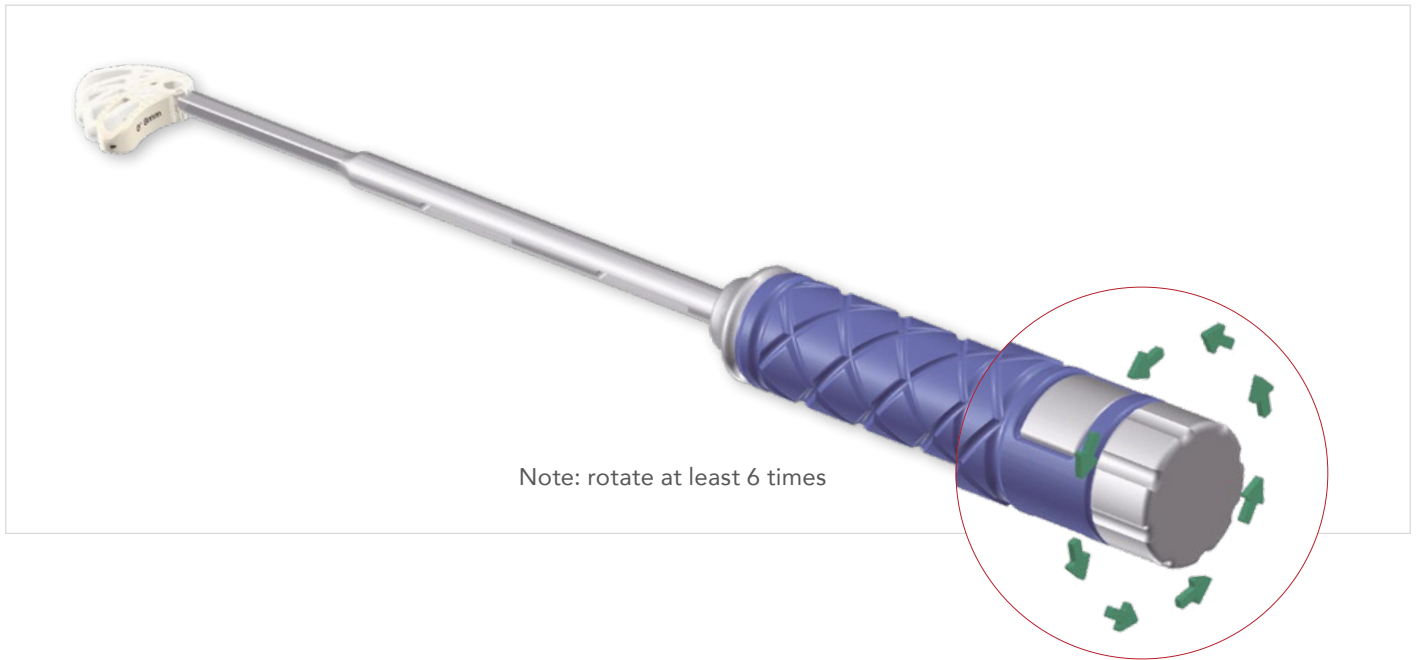
SURGICAL TECHNIQUE

NOTE

Before loosening the inserter from the implant, take a control X-ray to check the final position of the implant.

Releasing the instrument

Once the final position of the cage has been defined, the implant can be loosened completely with the rotary knob on the instrument  and then released by turning the T-piece holding the cage 90°. The instrument can then be removed from the surgical site.



Posterior instrumentation

After using lateral and AP beam paths to check that the implant is correctly positioned, the final steps for posterior stabilization of MOBIS® II follow.

X-RAY/CT CHECK IMAGE – MOBIS® II WITH MONOPOLY™

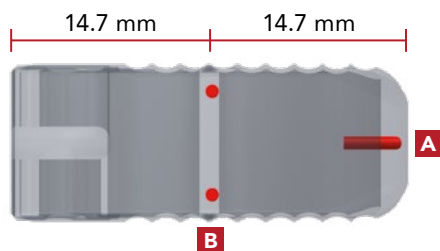
Verification image for MOBIS® II PEEK

The position of the MOBIS® II implant can be checked in the X-ray image as follows using the tantalum markers:

Position of pins:

Length: 3 mm

Diameter: 1 mm

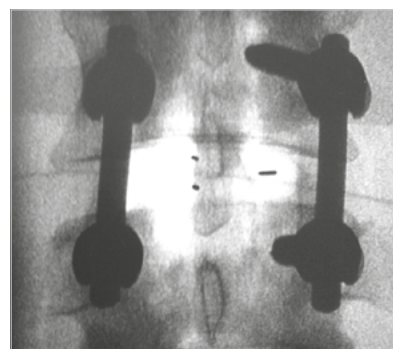
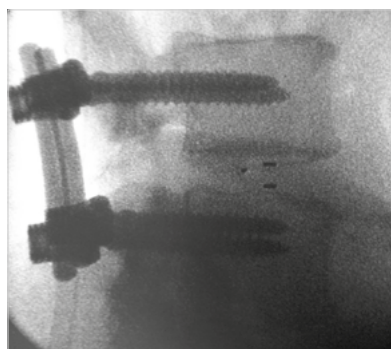
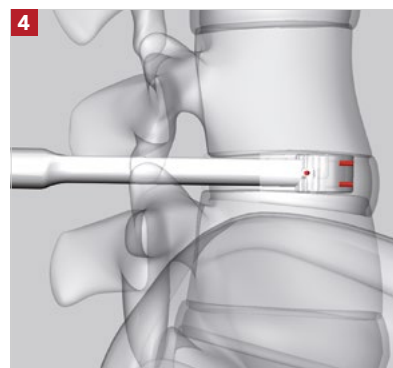
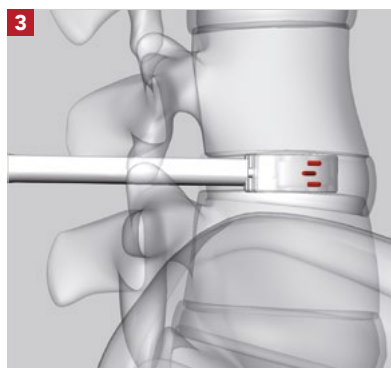
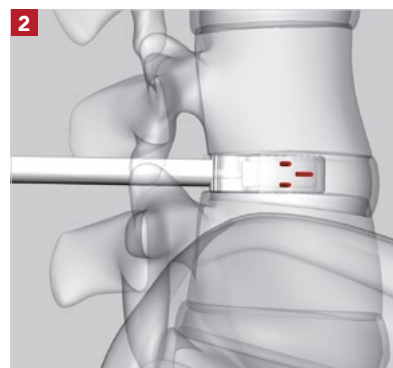
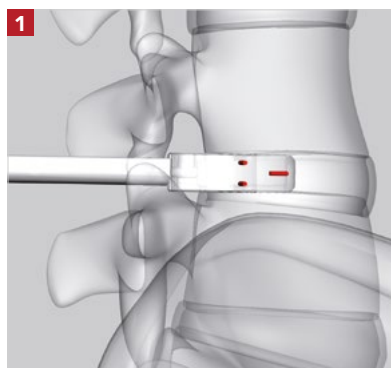


A X-ray marker at the implant tip

- The individual positioning steps can be monitored here

B Two X-ray markers on the anterior side

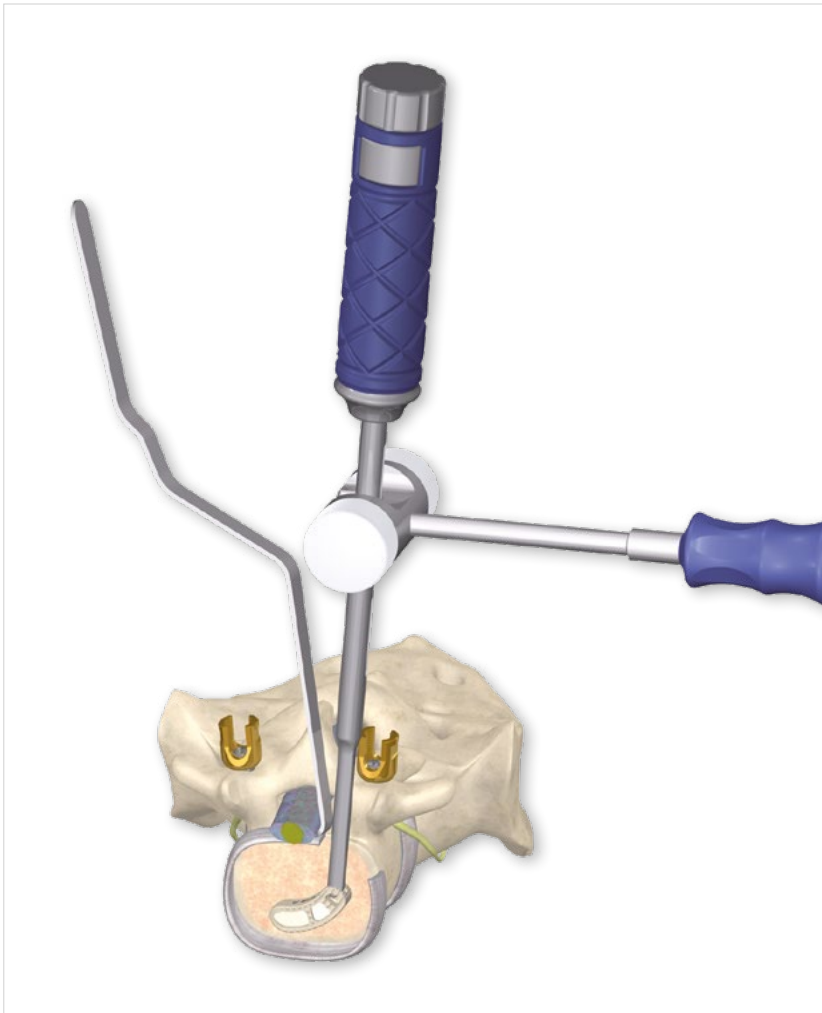
- To visualize the front edge of the implant in the AP view



SURGICAL TECHNIQUE

3 REVISION

MOBIS® II 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. The tissue must first be removed in order to extract the implant. To remove the implant, connect it to the variable inserter by rotating the T-profile by 90 degrees and turn it. Using the slotted mallet, remove the implant from the disc space. While doing so, ensure that the integrity of the nerve structures is preserved.



NOTE

The revision must be performed using fixed distraction and a tight connection between the implant and the inserter.

CAUTION

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

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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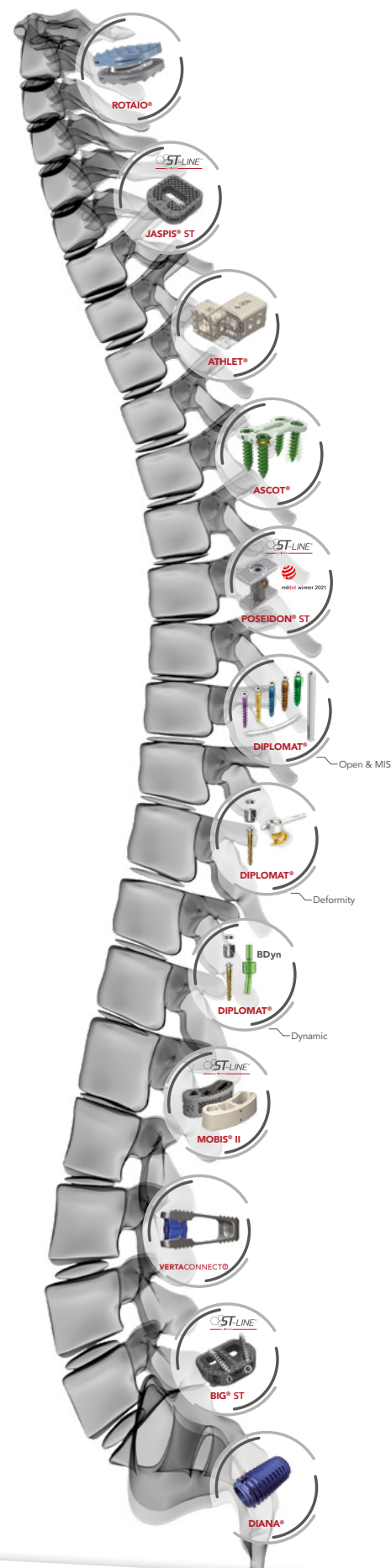
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