MOBIS® II ST

Transforaminal Lumbar Interbody Fusion

For distribution in the USA only

Variable and reliable implantation

HIGH-END MADE IN GERMANY

www.signus.com

SIGNUS The Spine Sign®


HIGH-END
MADE IN GERMANY

CONTENTS

About SIGNUS 4

Additional products 5

Concept 6

Implants 6

Product-specific advantages 9

Instruments 10

Indications, contraindications, warnings and MRI 12

Surgical technique 13

1 Preparation 13

2 Implantation 14

3 Revision 19

ABOUT SIGNUS

SIGNUS – THE SIGN FOR SPINE:

PASSIONATE! DYNAMIC! WORLDWIDE!

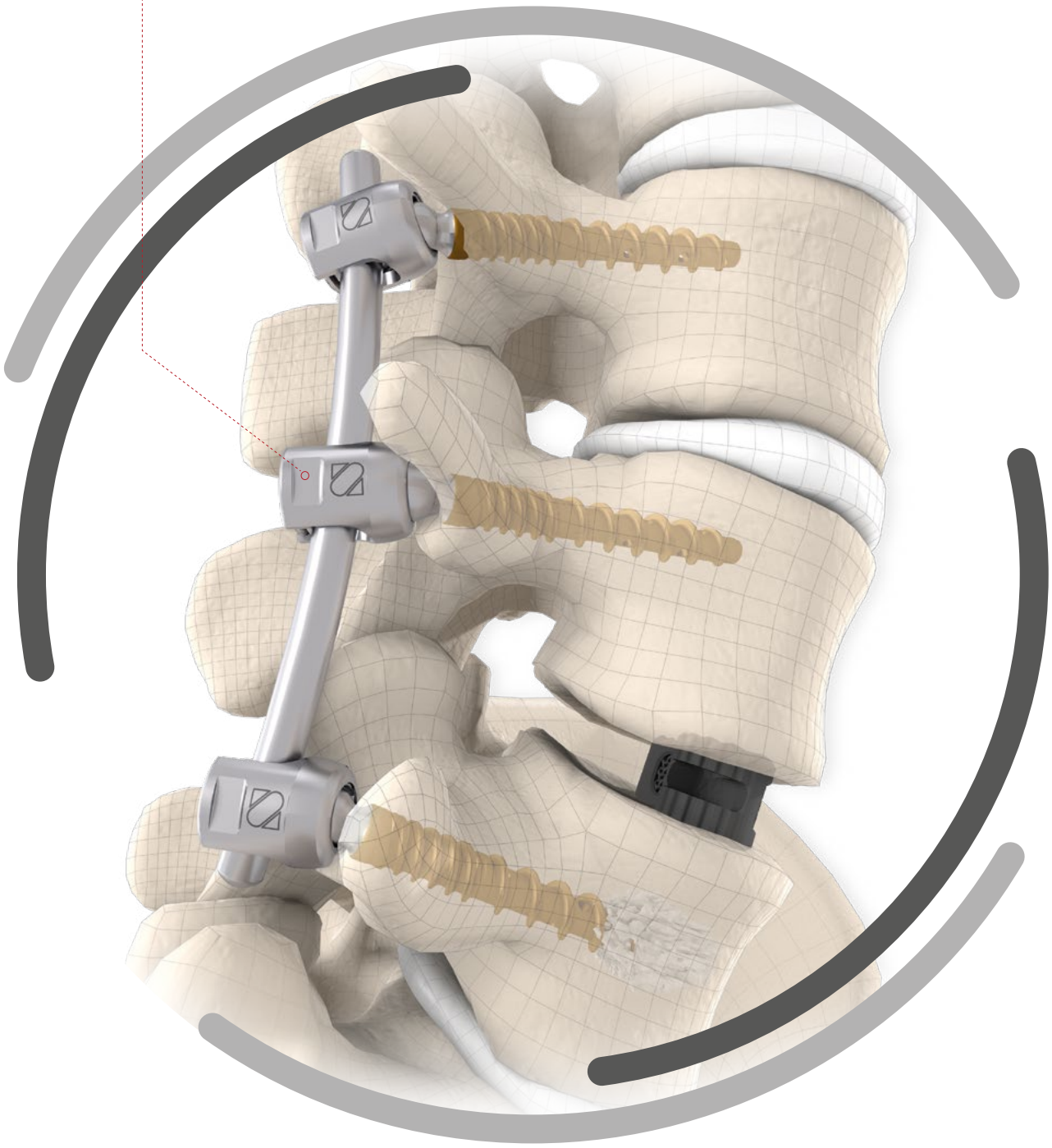
Innovative high-end implants made in Germany: For more than 30 years, SIGNUS has been the experienced specialist for comprehensive solutions in the surgical spine care sector. Founded in 1994 in Germany's Lower Franconian city of Alzenau by Susanne and Uwe Siedler, our family-owned company currently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

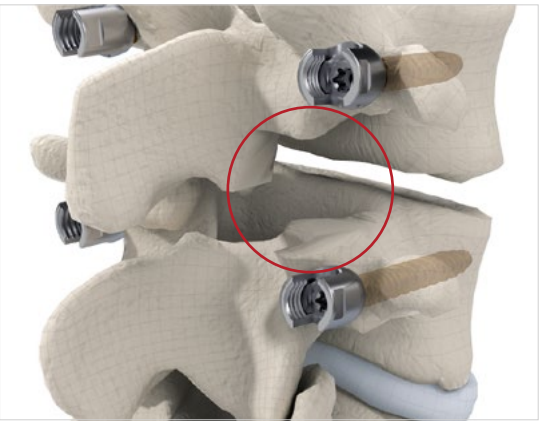
DIPLOMAT® – Posterior Instrumentation

- 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 ST 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 ST 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.

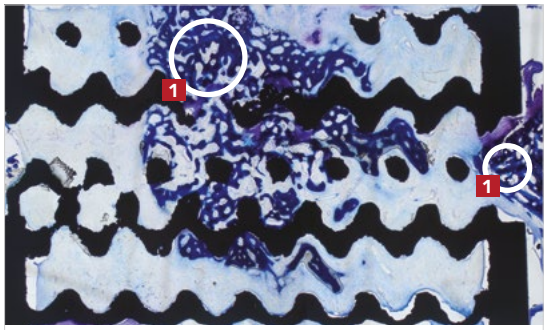
MOBIS® II ST

The implant is manufactured from proven titanium alloy (Ti-6Al-4V).
"ST" – Structural Titanium – is an open-pore titanium grid structure with anatomic parameters to optimize inter-corporeal fusion.
The structured interior with defined porosity offers the bone an ideal "anchor" for ingrowth of blood vessels and bone cells.
With good to excellent fusion results, porous implants have become established as the gold standard for endoprostheses.[1] With our MOBIS® II ST fusion implant, we are now building on these results for use in the spine: MOBIS® II ST consists of a titanium grid structure that, with its defined pore design, imitates the architecture of natural bone. The interconnection between the pores ensures optimal oxygen and nutrient supply, creating the optimal foundation for osseointegration. The implant also offers more room for fusion, with 70% of MOBIS® II ST consisting of pores. The roughness of the implant – in addition to its toothed endplate design that has been tried and tested by SIGNUS – optimizes the primary stability and counteracts migration of the implant. In addition, the lateral surfaces are embedded in a smooth frame to minimize the required preparation and to protect the nerve structures during the implantation procedure.

ST – Structural Titanium

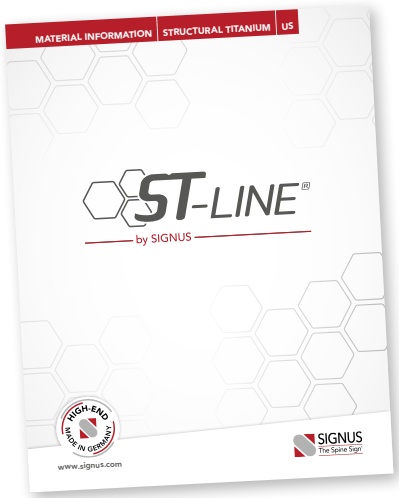
ST LINE ADVANTAGES

- **Greater contact area thanks to defined surface topology**
  - Secure anchorage in the bone owing to high primary stability
  - Reduced risk of implant migration
- **Open, macroporous titanium structure**
  - Resembles natural cancellous architecture
  - Enables not only attachment of bone but also osseointegration
- **70% pores**
  - Little foreign material - more room for fusion
  - Optimized visibility in the image converter



Microscopic histological image of the cross-section of a structured titanium implant removed from an ovine model after 12 weeks. In the pore volume of the diamond grid structure of the implant, there is evidence of the formation of a large area of cancellous bone structure 1, extending from the central area of the cross-section to the superior margin. (Histological findings from a formalin-fixed titanium lattice cage removed from an ovine model; Foundation: Hannover Veterinary Medicine School)

Further information on the ST Line can be obtained from the material information or your SIGNUS representative.



[1] Rader CP; Hendrich C; Löw S; Walther M; Eulert J. Unfallchirurg 103, 846-852, 2000. Selmitsch M. In: Zweymüller K (Hrsg): 10 Jahre Zweymüller-Hüftendoprothese; S. 14-19, 1990

IMPLANTS

MOBIS® II ST		
Height* (mm)	**5° Lordosis**	**Filling volume**
7	B2L5070929	0.31
8	B2L5080929	0.36
9	B2L5090929	0.41
10	B2L5100929	0.45
11	B2L5110929	0.50
12	B2L5120929	0.55
13	B2L5130929	0.60

* Implant height without tooth height

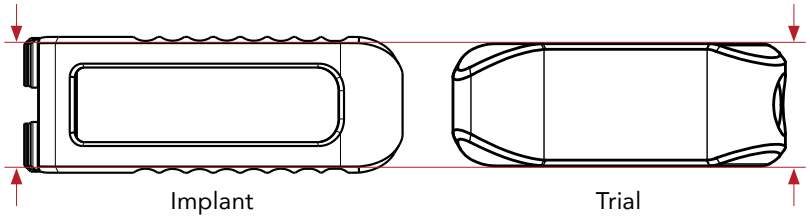
All implants are in individual sterile packaging for immediate use.

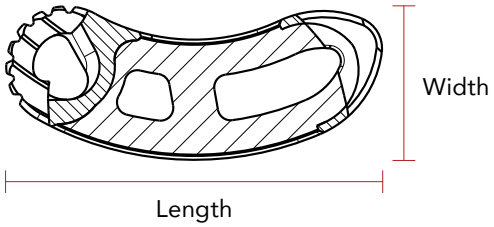
Width: 9 mm

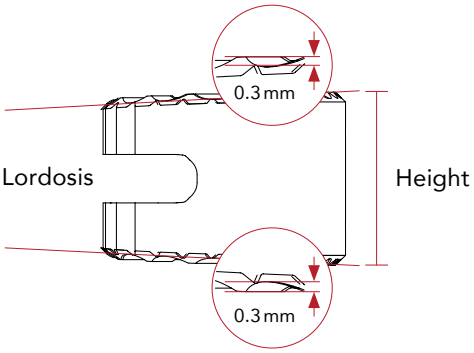
Length: 29 mm

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.

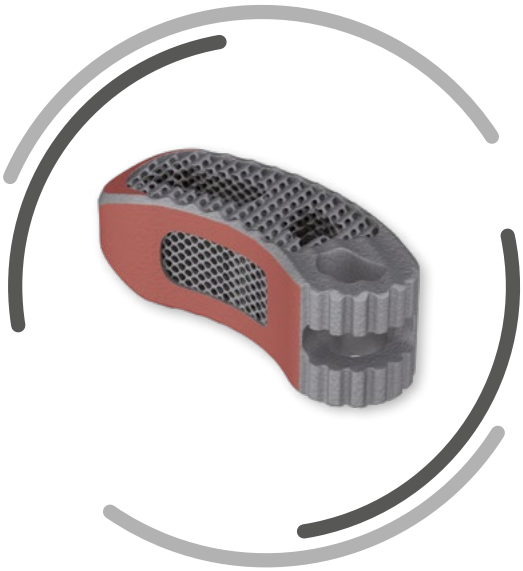


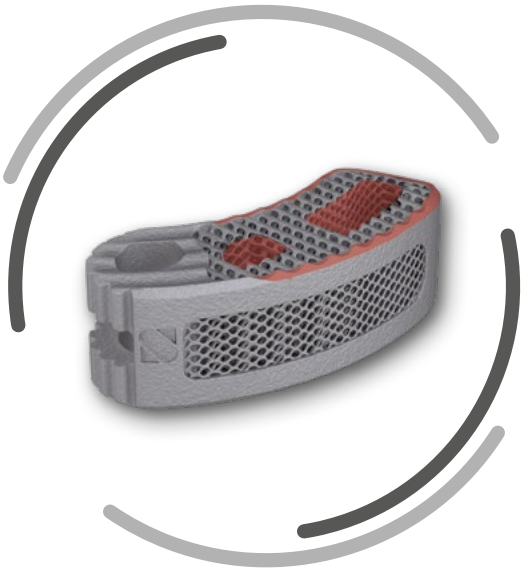




PRODUCT-SPECIFIC ADVANTAGES

- **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
- **Open, macroporous titanium structure**
  - Resembles natural cancellous architecture
  - Enables both growing-on and growing-in of bone
- **Increased roughness in conjunction with proven SIGNUS toothed cage design**
  - Secure anchoring in the bone owing to high primary stability
  - Reduced risk of implant migration





INSTRUMENTS

Art. no. BR0001-1-A
Inserter 6 – 10 mm

Art. no. BR0002-1-A
Inserter 11 – 18 mm

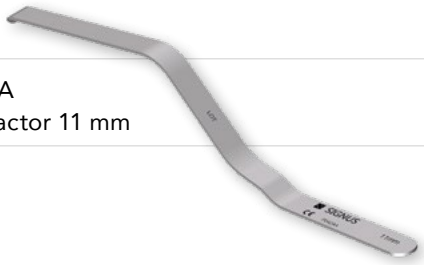
Art. no. B0728AHA
Positioner 6 – 10 mm

Art. no. B1028AHA
Positioner 11 – 18 mm

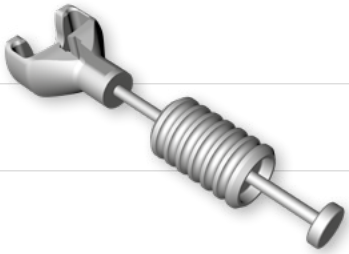
Art. no. BZ0005-A
Graft loading platform

Art. no. BZ0006
Graft impactor

Art. no. P041AA
Nerve root retractor 9 mm



Art. no. P042AA
Nerve root retractor 11 mm



Art. no. SK-0401
Slap mallet

Art. no. T001AQ
Mallet with exchangeable
plastic cheaks

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

Art. no. BR0008-2
Inserter for trials inner part

INSTRUMENTS

Art. no. BR00729-A–BR01329-A
Trials

OPTIONAL
Art. no. KC0004
Bone tamp

NOT SHOWN
Art. no. BR01AY
Instrument tray

Art. no. 500012
Release instrument

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS

When used as an intervertebral fusion device in skeletally mature patients, the MOBIS® II ST 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 licensed healthcare practitioner.

MRI SAFETY INFORMATION

The MOBIS® II ST 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® II ST 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.

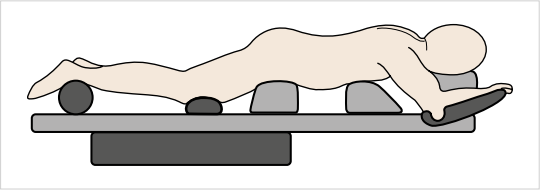
NOTE

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

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

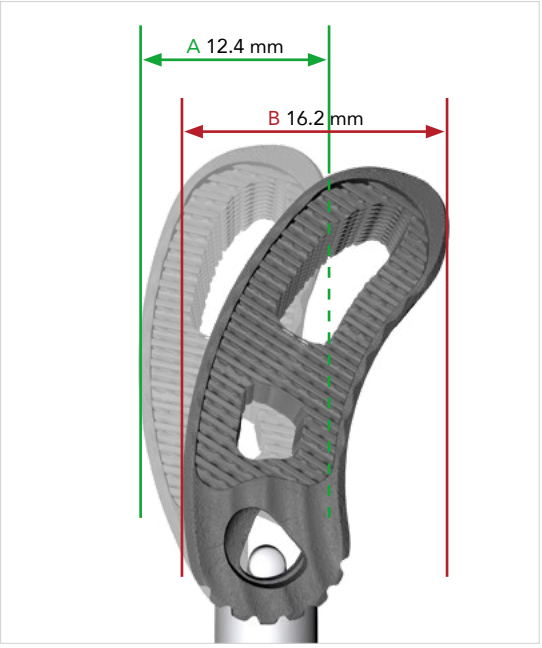
Perform a vertical skin incision in the midline or 2 to 3 fingerbreadths lateral to the spine at the level of the treatment segment. Then perform a unilateral partial facetectomy or foraminotomy for transforaminal insertion of the cage on the symptomatic side. To protect the neural structures, it is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

NOTE

The implant connection on the inserter allows two insertion positions (A/B) which enable the cage to be implanted with different surgical approaches.

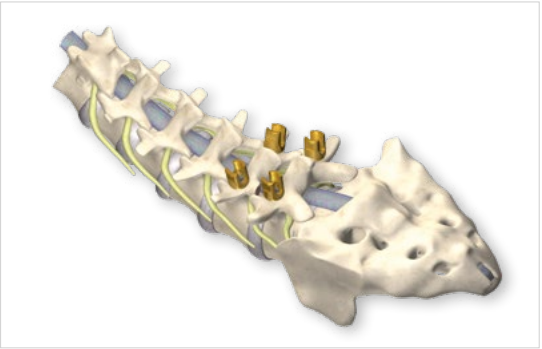
For a transforaminal approach (TLIF, transforaminal lumbar interbody fusion), position A makes it easier to position the implant at the ventral apophysis (marginal ridge) of the vertebral body. This insertion position requires an approach width of at least 12.4 mm.

If a surgical approach using the PLIF (posterior lumbar intervertebral fusion) technique is selected, insertion position B makes it easier to correctly position the implant on the anterior edge of the vertebral body. The curved shape of the cage indicates the direction of the ventral and medial intervertebral space. The minimal access width here is 16.2 mm.



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 of 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.

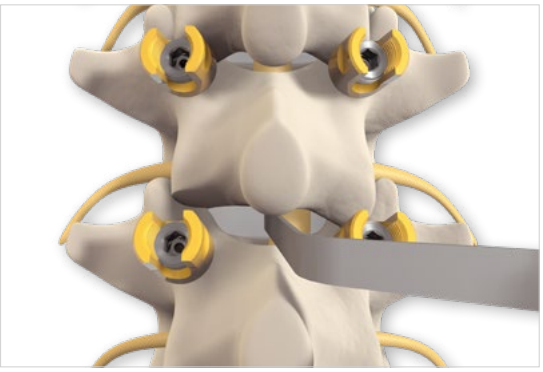
NOTE

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

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

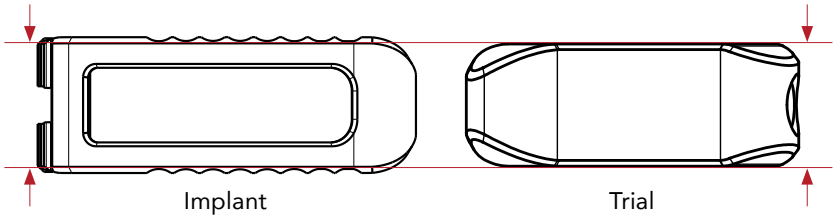


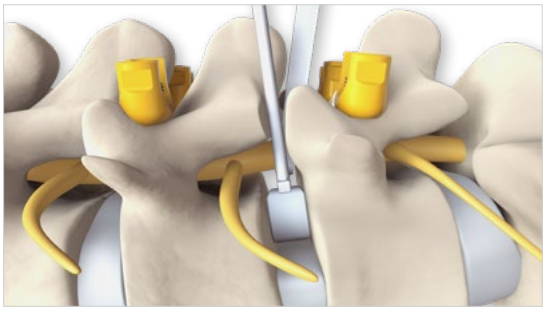
2 IMPLANTATION

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 anulus 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

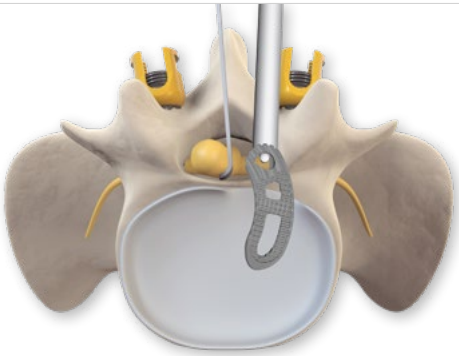
The implant is correctly attached to the instrument if the grooves at both ends are meshed together and the T-shaped end of the inserter is fixed.

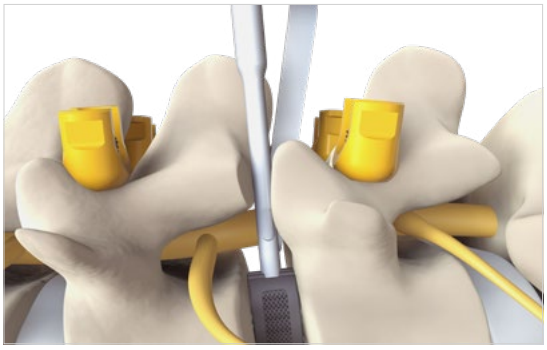
During the first step, bring the implant as far into the insertion position of the disc space as possible. The inserter can now be definitively loosened from the implant, enabling the angle to be adjusted between the implant and instrument. Repeat fixation (hand-tight) at the selected angle will permit 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

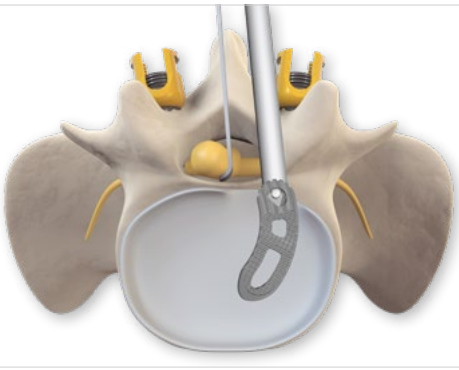
Four steps to the final position
View from above

1

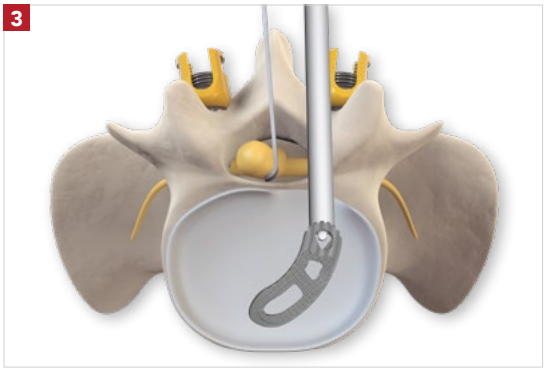




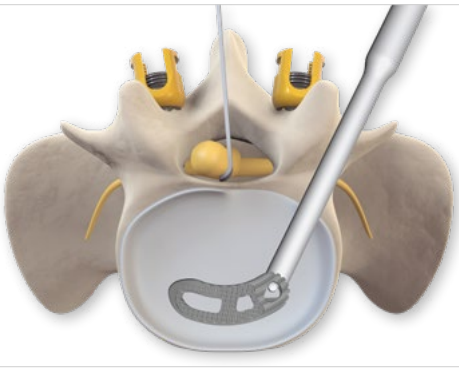
2



3



4



CAUTION

Intraoperative levering and tilting must be avoided at all costs.

NOTE

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

Releasing the instrument

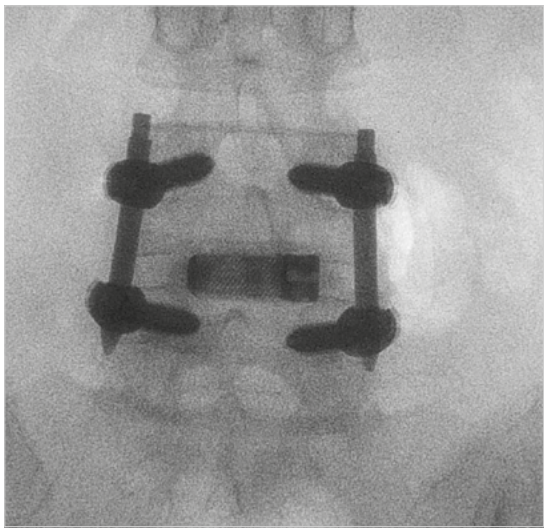
Once the final position of the cage has been defined, the implant can be loosened completely with the rotary knob on the instrument ⬅ and then released by turning the T-piece holding the cage 90°. The instrument can then be removed from the surgical site.

Note: rotate at least 6 times

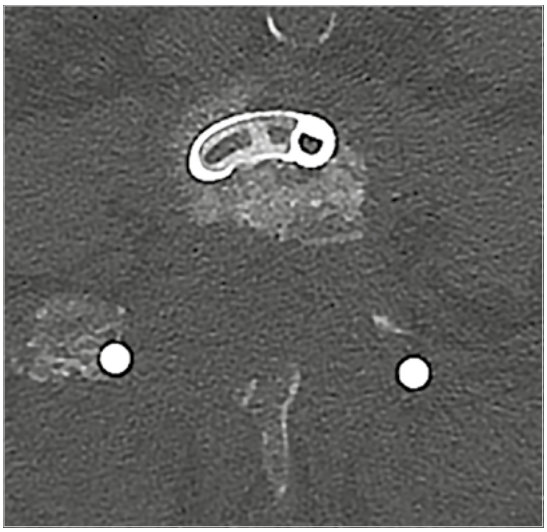
Posterior instrumentation

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

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



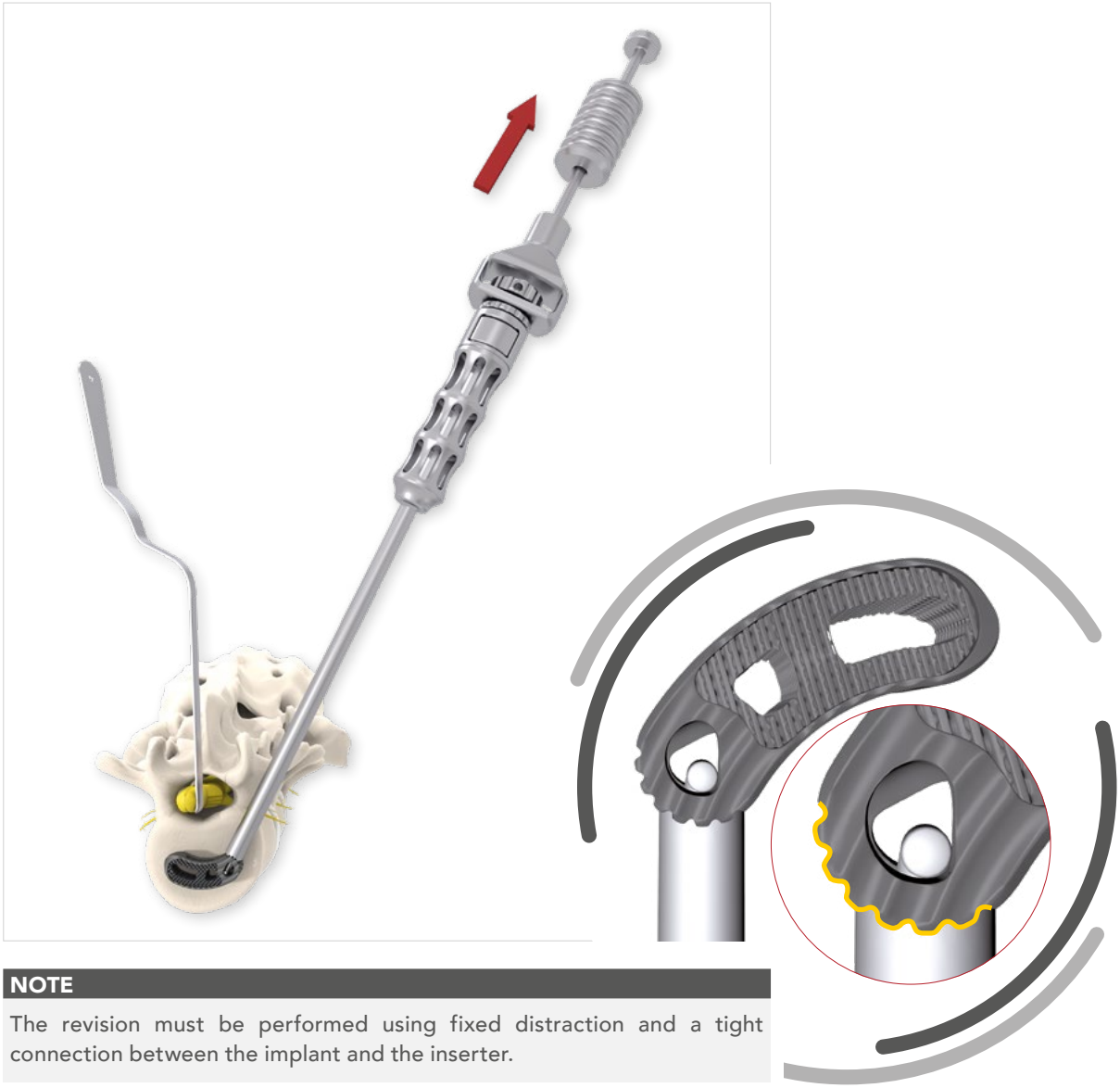
AP radiography



CT image

3 REVISION

MOBIS® II ST 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. Remove the implant from the disc space with the slap mallet. 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.

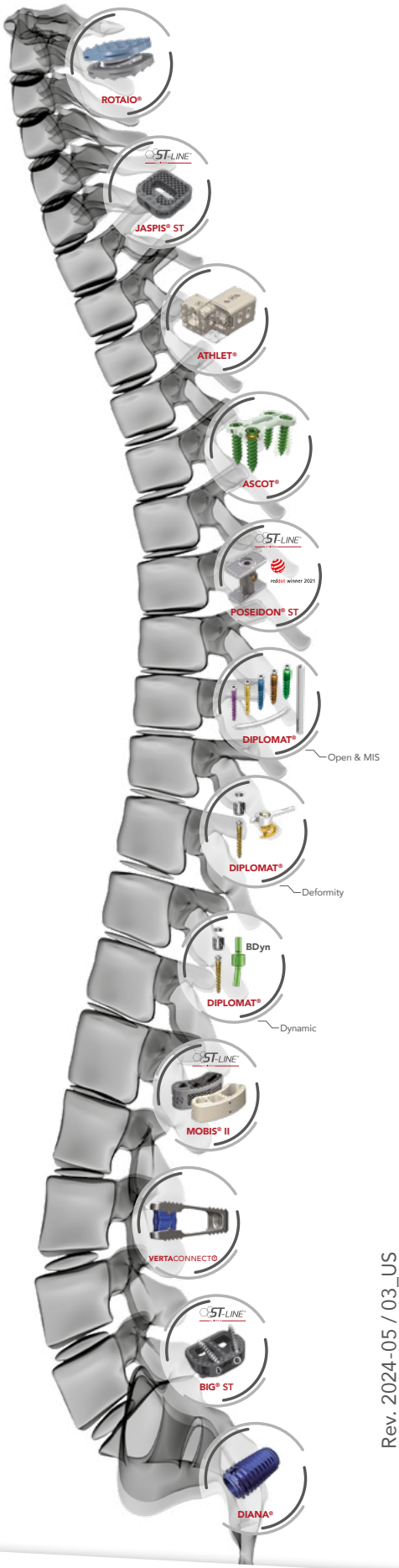
NOTE: This document was written by the technical department at SIGNUS Medizintechnik GmbH. Despite being reviewed by trained personnel, the sole purpose of this brochure is to provide an explanation of the technical aspects of handling the product described.
This document, in particular the description 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.



SIGNUS USA Inc.
560 Lexington Avenue, 16th Floor
New York, NY 10022 / USA

SIGNUS Medizintechnik GmbH
Industriestr. 2
63755 Alzenau / Germany

t. +49 (0) 6023 9166 0
f. +49 (0) 6023 9166 161

info@signus.com
www.signus.com

Rev. 2024-05 / 03_US

SIGNUS
The Spine Sign®