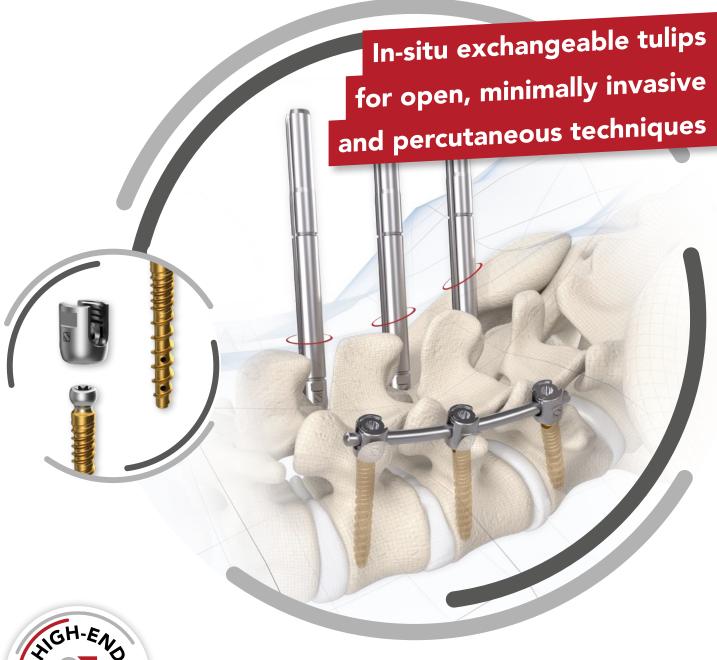
DIPLOMAT®

Posterior Instrumentation

For distribution in the USA only









SIGNUS Medizintechnik GmbH thanks the following doctors for their collaboration:

Dr D. Kaiser (DIPLOMAT® and LSZ)

Frankfurt Höchst Hospital (Germany)

Dr. J.-U. Müller (DIPLOMAT®)

Ernst Moritz Arndt University Greifswald (Germany)

Dr A. Hunn (DIPLOMAT®)

Hobart (Australia)

Dr A. Miles (DIPLOMAT®)

Perth (Australia)

Prof. J. Stulik (DIPLOMAT®)

Center for Spinal Surgery – University Hospital Prague-Motol (Czech Republic)

Dr J. Kryl (DIPLOMAT®)

Center for Spinal Surgery – University Hospital Prague-Motol (Czech Republic)





CONTENTS

About SIGNUS	4
Additional products	5
Concept	6
Implants	12
Implants – Optional	13
Product-specific advantages	14
Instruments	15
Instruments MIS	19
Indications, contraindications, warnings and MRI	21
Surgical technique – open instrumentation	22
1 Preparation	22
2 Implantation of the pedicle screw	26
3 Implantation of the rod	32
4 Repositioning the rod	35
5 Finalization of the instrumentation	37
6 Additional options: connector family	40
7 Additional techniques	43
Surgical technique – MIS	48
1 Preparation of the pedicle	49
2 Implantation of the pedicle screw	50
3 Implantation of the rod	50
4 Finalization of the instrumentation	53
5 Additional techniques	55
Notes	57



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

TETRIS™ ST - Posterior Lumbar Interbody Fusion

Two implants – One reliable treatment



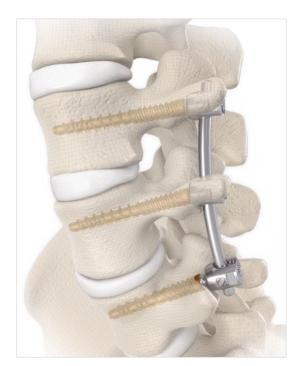
The requirements for a pedicle screw system (PSS) for optimal patient treatment are very high – regardless of the particular indication. Both simple and complex treatments of the spine always require maximum security and stability.

DIPLOMAT® is a well-conceived, modular and versatile fixation system that was designed in close collaboration with experienced and qualified spinal surgeons. This is also reflected in the tray design. With just one basic tray and a small MIS extension tray, the instruments meet the demands for an easy to handle system.

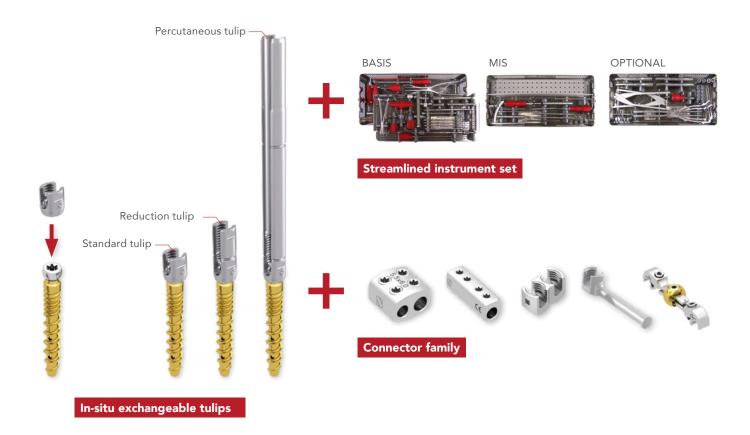
The cannulated and fenestrated pedicle screws combined with 5.5 mm titanium rods allow the DIPLOMAT® system to stabilize and comfortably correct all types of spinal diseases and deformities in a controlled manner.

In collaboration between surgeons, engineers and nursing staff, we work continuously to adapt the system to market requirements.

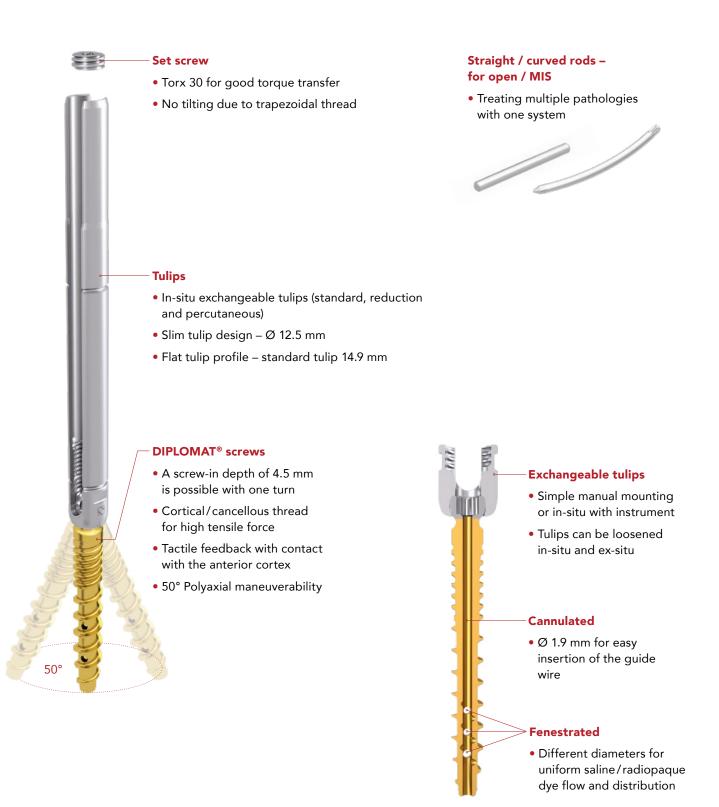
The additional implants DIPLOMAT® Deformity and DIPLOMAT® Dynamic round off the DIPLOMAT® portfolio. For information on these products, please refer to the respective product information.



One screw, numerous options



DIPLOMAT®: One system for all indications



Secure locking of tulip and screw

The secure connection of the removable tulip to the screw has been extensively verified in laboratory tests. The results show that the locking mechanism ensures maximum strength of the screw-tulip connection.



With this force one could lift approx. 7 hospital beds²



² 8.206 N corresponds to approx. 837 kg, a Hill-Room (Model 900) hospital bed weighs 120 kg.



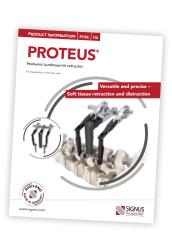
Withstands a tensile force up to 8.206 N¹

Can be used with PROTEUS® (Posterior lumbosacral retractor)

PROTEUS® is a versatile retractor system for use in the posterior lumbosacral spine and can be used for both soft tissue retraction as well as distraction.

The retractor arms are used for distraction. Use of the DIPLOMAT® screws is possible with or without tulips. Elements that are in situ are black to prevent reflections.

Further information on PROTEUS® can be obtained from the product information or your SIGNUS representative.





Can be used with screws with tulips – optionally with soft tissue retraction



Optional: only soft tissue retraction



Can be used with screws without tulips – optionally with soft tissue retraction



Connector family



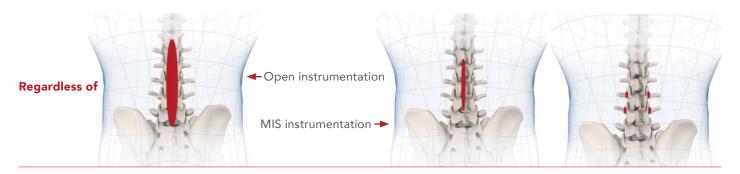








Streamlined instrument set for various techniques







Implantation without tulip



Implantation with tulip

Regardless of





Regardless of





1 screw



Everything possible with



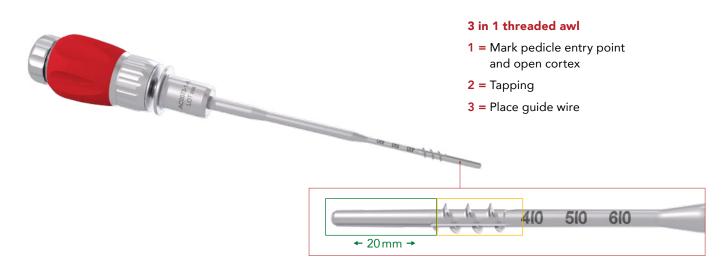






OPTIONAL

Features of the DIPLOMAT® instruments







MIS inserter

Ergonomic angle facilitates minimally invasive insertion of the rods

IMPLANTS

Pedicle screws, without tulip, cannulated, fenestrated, polyaxial

Art. no. AB0321-55040 – AB0321-55050 \varnothing 5.5 × 40 mm to 50 mm, 5 mm increments

Art. no. AB0321-65035 – AB0321-65055 \varnothing 6.5 \times 35 mm to 55 mm, 5 mm increments

Art. no. AB0321-75040 – AB0321-75050 \varnothing 7.5 × 40 mm to 50 mm, 5 mm increments

Additional sizes, diameters and lengths (polyaxial/monoaxial) available upon request.

TITANIUM longitudinal rod, curved

Art. no. AB0955-00040-AB0955-00050 \varnothing 5.5 \times 40 mm to 50 mm, 5 mm increments

Art. no. AB0955-00065-AB0955-00125 Ø 5.5×65 mm to 125 mm, 20 mm increments

Additional rods (curved and straight) are available upon request.



Tulips

Art. no. AB0010-55001 Standard tulip Ø 12.5 \times 14.9 mm

Art. no. AB0020-55001 Reduction tulip Ø 12.5 × 32.2 mm

MIS stabilization

Art. no. AB0030-55001

Percutaneous tulip Ø 12.5×135 mm



Set screw

Art. no. AB0140-55000 T30 Ø 9.7 × 4.2 mm



MIS stabilization

TITANIUM MIS longitudinal rod, curved

Art. no. AB0755-00035-AB0755-00055 \emptyset 5.5 \times 35 mm to 55 mm, 5 mm increments

Art. no. AB0755-00065-AB0755-00095 \emptyset 5.5 \times 65 mm to 95 mm, 10 mm increments

Art. no. AB0755-00140-AB0755-00150 Ø 5.5 × 140 mm to 150 mm, 10 mm increments

Additional rods (curved and straight) are available upon request.



Longitudinal rod, straight – TITANIUM

Art. no. LSZ3001

Ø 5.5 × 500 mm, hex connection SW5

Longitudinal rod, straight – cobalt-chrome

Art. no. AB1855-00500

Ø 5.5 × 500 mm, hex connection SW5

MIS longitudinal rod, straight – TITANIUM

Art. no. AB0655-00500

 $Ø 5.5 \times 500 \text{ mm}$



IMPLANTS - OPTIONAL

Cross connector

Art. no. AB0155-35045 Cross connector S, 35–45 mm

Art. no. AB0155-41058 Cross connector M, 41–58 mm

Art. no. AB0155-54082 Cross connector L, 54–82 mm

Offset connector open

Art. no. AB0156-55020 Ø 5.5 x 20 mm

Art. no. AB0156-55030 Ø 5.5x30 mm

Art. no. AB0156-55040

Ø 5.5 x 40 mm



Extension sleeve

Art. no. AB0151-55055/S Ø 5.5 mm, sterile



Parallel connector

Art. no. AB0150-55045/S Ø 4.5 mm/5.5 mm, sterile

Art. no. AB0150-55055/S Ø 5.5 mm/5.5 mm, sterile

Art. no. AB0150-55060/S Ø 6.0 mm/5.5 mm, sterile



Parallel connector UU

Art. no. AB0153-55255 Ø 5.5 mm/5.5 mm, L15 mm

Art. no. AB0153-60255 Ø 6.0 mm/5.5 mm, L15 mm



PRODUCT-SPECIFIC ADVANTAGES

Versatility and flexibility

- DIPLOMAT® can be used with open, minimally invasive or percutaneous surgical techniques.
- The modular design allows for constructions that can be customized to the individual needs of patients.

Modular and cost-effective system

- Owing to the interchangeable tulips, the same screw can be used for all indications.
- The instrument set has been reduced to the bare essentials to support ergonomic and efficient handling.

Optimized screw design

- The screws are cannulated with a \varnothing of 1.9 mm, which enables precise guidance of the guide wire.

- Fenestration of the screws ensures even saline/radiopaque dve distribution.

- A single turn of the screw enables a screw-in depth of 4.5 mm.

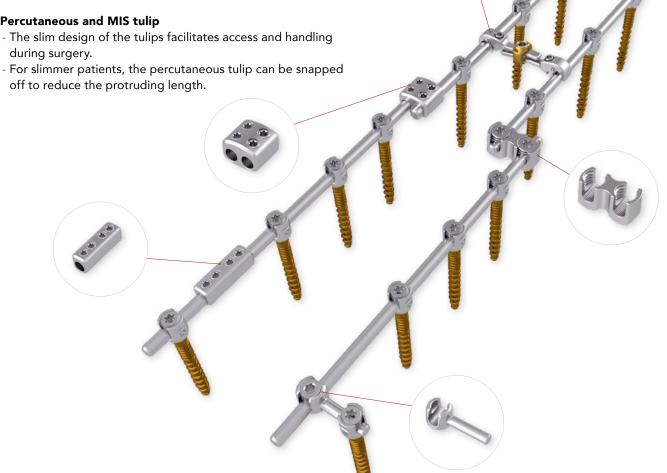
Stable and secure connection

- Tensile strength test confirms: the locking mechanism ensures maximum strength of the screw-tulip connection.

Percutaneous and MIS tulip

- The slim design of the tulips facilitates access and handling during surgery.

off to reduce the protruding length.





Art. no. AC0073-3-A Obturatorwire Ø 1.8 mm (single use)

OPTIONAL

Art. no. AC0125-A Guide wire, round/round Ø 1.8 x 500 mm (single use)

Art. no. AC0126-A Guide wire, trocar/round Ø 1.8 x 500 mm (single use)



Art. no. AC0073-1-A Palm handle, obturator, ratchet 1/4"











NOT SHOWN

Art. no. AC20AY Instrument tray BASIC

Art. no. AC20AZ

Instrument tray BASIC - Insert

Art. no. AC22AY

Instrument tray BASIC – Additional

INSTRUMENTS - DIPLOMAT® MIS





Art. no. AC0127

MIS Length indicator

INSTRUMENTS - DIPLOMAT® MIS











INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS FOR USE

The DIPLOMAT® Spinal System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture
- Dislocation
- Scoliosis
- Kyphosis
- Spinal tumor
- Pseudoarthrosis
- Failed previous fusion

In addition, the DIPLOMAT® Spinal System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5 – S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and / or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum / ilium.

The DIPLOMAT® Spinal System is intended to be used with autograft and / or allograft.

CONTRAINDICATIONS

- Infectious processes in, on, or in adjacent regions of the spine.
- Severe osteoporosis is a relative contraindication and may prevent adequate fixation of the spinal anchorage and thus exclude the use of this or other spinal instrumentation systems.
- Surgery precluded due to the physical condition of the patient, e.g. fever or leucocytosis.
- The use of different metals or system components that do not belong to the pedicle screw system is not permitted.
- Patients whose tissue cover above the surgical site or whose bone mass or bone quality at the surgical site is inadequate.
- Patients in whom placement of an implant would influence the anatomic structures or the anticipated physiological performance.
- Systemic or metabolic diseases.
- Allergy or intolerance to implant material.
- Surgical conditions which 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 could prevent successful implantation (e.g. obesity, mental illness, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance).
- Cases not mentioned under indications.

WARNINGS

- The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use with poor bone quality (e.g. osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.
- 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 all implants and instruments belonging to the system are sterilee 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.
- Prior to wound closure the seating of all rods, screws and any interconnections should be checked once again to ensure that they have not loosened.
- 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.
- Metallic implants may pose a risk of heating of the device when exposed to a high magnetic field such as an MRI. High heating could lead to patient injury.
- Metallic implants may generate image artifacts when exposed to a high magnetic field, such as an MRI, which could lead to difficulty in reading the MRI.

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

MRI SAFETY INFORMATION

The DIPLOMAT® pedicle screw system 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 the DIPLOMAT® pedicle screw system 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

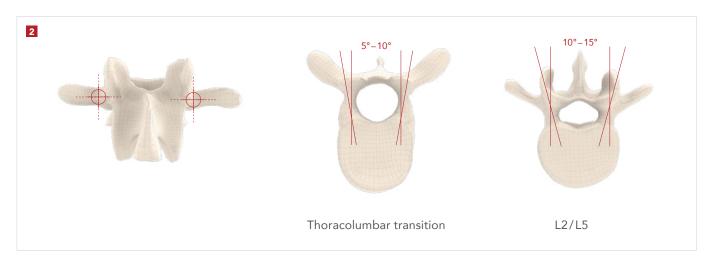
The surgeon is always responsible for correctly positioning the patient. Using direct visualization, ensure that the patient is anatomically positioned and cushioned prior to instrumentation, that is, the patient is positioned with acceptable flexion and extension. The patient should be fixed in the final position with straps. The operating table must be radiolucent.

Patients are most commonly placed in a prone position. When doing so, ensure that appropriate positioning cushions are used that allow the abdomen to hang freely. This generates lordosis and may already lead to a reduction with fractures. The arms are placed at a slight angle in the cranial direction to enable unimpeded radiography (Image 1). Before surgical scrubbing and draping of the surgical site, an X-ray should be taken in both planes as a check. This is used to check correct imaging of the pedicle eyes in the AP plane. Visualization of the rear edge or the pedicle arch must also be possible in the lateral plane in all vertebrae that will be instrumented.



Pedicle screw entry point

The entry points for the screws must be identified using anatomical land-marks (Image 2). Traditionally, the entry point in the lumbar vertebrae lies on the intersection of the vertical line through the lateral portion of the facet joints and the horizontal line through the base of the transverse processes. The entry point for the screws in the thoracic vertebrae is also on the vertical line through the lateral portion of the facet joints, always just below the facet joint. However, the pedicle anatomy varies greatly in the thoracic region.



The pedicle screws are inserted at the level of the thoracolumbar transition at an angle of 5° – 10° to the midline.

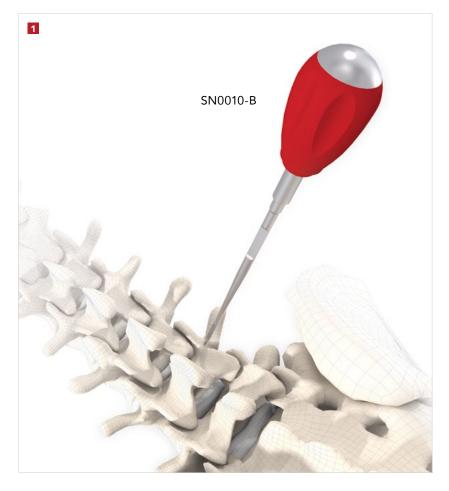
The screws are inserted converging at the L2 level at an angle of 10° and at the L5 level at an angle of 15°.



Option 1:

Preparation of the pedicle without guide wire

- **1.** The awl (SN0010-B) can be used to open the pedicle entry point (Image 1).
- 2. Under X-ray control, a thread is pre-cut into the pedicle using the threaded awl (e.g. AC0085) (the use of the threaded awl is described on the following pages).
- 3. The pedicle probe (SN0021) should be used to check the integrity of the bone wall (Images 2 + 3).
- **4.** The choice of screw length and screw diameter is based on preoperative measurement and/or intraoperative X-ray monitoring.
- **5.** For each pedicle to be instrumented, repeat the procedure described above.







Option 2:

Preparation of the pedicle with guide wire

The threaded awl is used to place the pedicle screws via a guide wire. This must first be assembled.

Instructions for threaded awl

The threaded awl is structured as follows (Image 1): The proximal part is an awl and is used to open the pedicle (green). The distal part can be used to cut a thread (yellow). The threaded awl is available in different diameters.

- Ø 5.5 mm (AC0085)
- Ø 6.5 mm (AC0086)
- Ø 7.5 mm (AC0087)

OPTIONAL

- Ø 8.5 mm (AC0088)
- Ø 9.5 mm (AC0089)

The threaded awls features depth markings.

Assembly of the threaded awl

- 1. Connect the threaded awl to the palm handle (AC0073-1-A) (Image 2).
- **2.** Clamp the obturator wire into the obturator knob (AC0073-2).

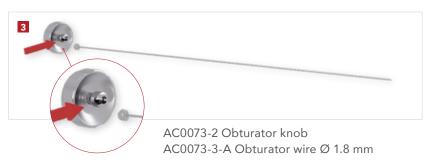
The wire (AC0073-3-A) has a trocar tip and an attachment end. The attachment end has a flat and a rounded side. Pushing the rounded side of the wire into the side opening of the obturator knob connects the wire to the obturator knob (Image 3).

3. Then firmly screw the obturator knob (with the wire) into the palm handle by turning clockwise to the stop position (Image 4).

CAUTION

The obturator wire (AC0073-3-A) is intended for single use only. It is removed and disposed of after use. A new wire must be used for each additional surgery.









Opening the pedicle

After localizing the pedicle entry point, the cortical bone is opened with the threaded awl (Image 5). The screw length can be read off using the markings on the instrument.

NOTE

If required, the threaded awl with the integrated thread-cutting grooves can be driven further to cut a thread. The thread-cutting grooves start at 20 mm from the tip of the awl. The diameter of the threaded section is 0.5 mm less than the diameter of the screw.



Placing the guide wire

To insert the guide wire (AC0125-A), first remove the obturator from the threaded awl (Image 6).

The guide wire is then inserted through the cannulation from the rear (Image 7). Positioning of the guidewire should be performed under radiological control.

The threaded awl can now be carefully removed so that the guide wire remains in-situ.

NOTE

The guide wire is intended for single use only and must be disposed of after use.





2 IMPLANTATION OF THE PEDICLE SCREW

Selection of the tulip

- 1. Once the pedicle has been prepared and both the length and diameter of the screw have been determined, prepare the screw for the implantation.
- 2. To do this, connect the screw to a tulip (Image 1).
 - Standard tulip (AB0010-55001)
 - Reduction tulip (AB0020-55001)
 - Percutaneous tulip (AB0030-55001)

Generate the connection between the screw and tulip by firmly pressing the tulip onto the screw. An audible "CLICK" when pressing indicates that a secure connection has been made (Image 2).

3. The pedicle screw can then be connected to the screwdriver and implanted.

CAUTION

ALWAYS check that there is a secure hold between the tulip and screw. To do so, pull on the tulip while firmly holding onto the shaft of the screw. If the tulip remains coupled to the screw, the connection is secure.

CAUTION

Using radiological monitoring, check the length and position of the screw.

All pedicle screws are inserted in the same manner.





Option 1:

Implantation of screw with tulip

- 1. First, the screwdriver (AC0090-1-H) is fitted with a handle (e.g. ratchet handle AC0073-1-A) (Image 1).
- 2. The screwdriver sleeve (AC0090-6-H) is then pushed on and closed by sliding the locking element (Image 2).
- 3. The screwdriver can now be used for all tulips. To adjust to the tulip, press the "Push" button on the locking element and slide it up or down (Image 3). For the percutaneous and reduction tulips, the locking element must be pushed completely upwards, for the standard tulips downwards.







- **4.** After selecting the suitable screw, this is picked up with the screwdriver. To do this, hold the handle firmly and turn the locking element clockwise until the screw is hand-tightened. (Image 4) It is recommended to check for a firm fit of the screw on the screwdriver.
- 5. When inserting the screw into the bone, the sleeve serves as a guide to maintain the correct trajectory (Image 5).

NOTE

When inserting the screws via a guide wire, this must be pulled out in time to prevent it from being pushed further into the pedicle when screwing in.

6. To release the screw from the screwdriver once it has been inserted, turn the locking element anti-clockwise and remove the screwdriver (Image 6).







Option 2:

Implantation of screw without tulip

- 1. First, the screwdriver is assembled without the tulip. To do this, the inner part (AC0072-1-H) is inserted into the outer part and screwed in clockwise (2 3 turns are sufficient). Then a handle is attached (e.g. ratchet handle AC0073-1-A) (Image 1).
- 2. To pick up the screw without the tulip, it is mounted and the outer part is screwed down hand-tight (Image 2).
- **3.** When screwing the screw into the bone, the trajectory can be maintained on the outer sleeve while screwing with the handle. (Image 3)
- **4.** The screwdriver without tulip has been designed such that it always maintains the required distance from the bone so that a tulip can then be attached. Nonetheless, for easier handling, it is advisable to create space for the tulip with the head cutter before application. For this purpose, the head cutter (AC0071-H + handle, e.g. AC0073-1-A) is guided over the screw head and the bone is abraded with rotary movement (Image 4).

NOTE

Please note that the head cutter (AC0071-H) cuts with a CLOCKWISE and ANTI-CLOCKWISE rotation. Care must therefore be exercised during in-situ insertion.

CAUTION

Before attaching a tulip, ensure that the screw head is free of tissue and bony structures.









- 5. To finalize the instrumentation, connect the screw to a tulip (standard tulip AB0010-55001, reduction tulip AB0020-55001, percutaneous tulip AB0030-55001). Generate the connection between the screw and tulip by firmly pressing the tulip onto the screw. An audible 'CLICK' when pressing indicates that a secure connection has been made.
- **6.** The tulip can be connected in situ manually or optionally with the tulip assembly instrument (AC0081) (Image 5).
- 7. Then check that there is a secure hold between the tulip and the screw. To do so, pull the tulip with the rod holder or optionally with the tulip assembly instrument. If the tulip remains coupled to the screw, the connection is secure (Image 6).



If required, the percutaneous tulips can be shortened using the snap-off sleeve (AC0120). This may prove necessary to provide better visibility or more space for compression or decompression maneuvers (Image 7).



The tulip assembly instrument is attached to the proximal 'recess' on the tulip.





Optional:

Loosening the tulip

CAUTION

One part of the philosophy behind the DIPLOMAT® system is the insertion of the screw with a tulip with the option of being able to exchange the tulips during surgery.

The polyaxial screw head must remain freely mobile and must not be constricted by bony structures. If necessary, the screw height must be adjusted.

If the anatomical situation in situ does not permit the insertion of the screw with a tulip, the screw can be implanted without a tulip. To enable free movement of the tulip around the screw head, the corresponding instruments must be used. See the instructions for the screwdriver without tulip.

Each tulip may only be attached and removed once! This ensures that there is a secure connection between the screw and the tulip. With repeated removal and attachment, the connection made between the screw and tulip may no longer be secure.

NOTE

Tulips that have already been placed can be exchanged in situ. To do so, the tulip must be freely moveable. If necessary, the screw must be turned back 1–2 rotations. To exchange the tulip, connect the tulip disassembly instrument (AC0129-H) to the tulip (Image 1).

When doing so, ensure that the tulip and the disassembly instrument are on the same axis. Rotate the instrument, without applying force, until the tulip detaches loosely from the screw. Then couple the newly selected tulip to the screw.

This is done manually or optionally with the tulip assembly instrument (AC0081). Always check that there is a secure hold between the tulip and the screw. To do so, pull the tulip with the rod holder or optionally with the tulip assembly instrument (AC0081). If the tulip remains coupled to the screw, the connection is secure.



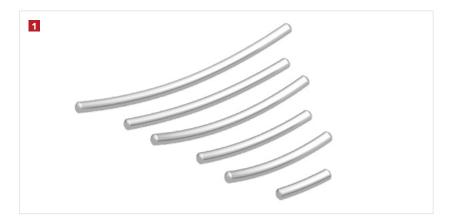
Detaching the tulip using the assembly/disassembly instrument

3 IMPLANTATION OF THE ROD

Selecting and customizing the rod

Rods are available in different lengths (Image 1).

- 1. Using the bendable rod template (AC0082), the required rod length can be determined, preshaped and used for contouring the final rod. (Image 2)
- **2.** Bending pliers are available for bending the rod. (Image 3)
- **3.** Optionally, the rod can also be bent in situ; the in situ bending irons left/right (AC0058-A/AC0059-A) are available for this purpose (Image 4).





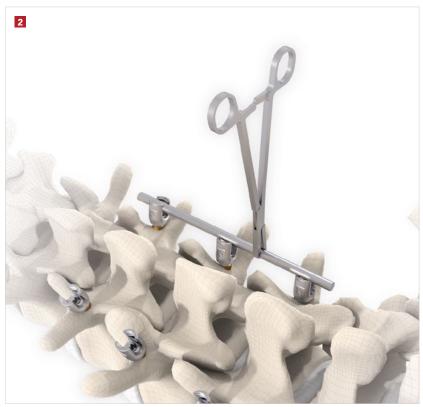




Insertion of the rod

- 1. Prior to inserting the rod, the tulip heads should be aligned. Use the tulip adjuster (AC0015-H) to align the tulip heads (Image 1).
- **2.** The rod holders (500027) or the holding pliers for rods (AC0056-H) are used to insert the rod into the tulip (Image 2).



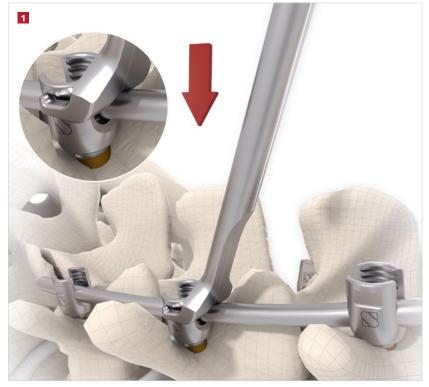


Inserting the rod using the rod holder

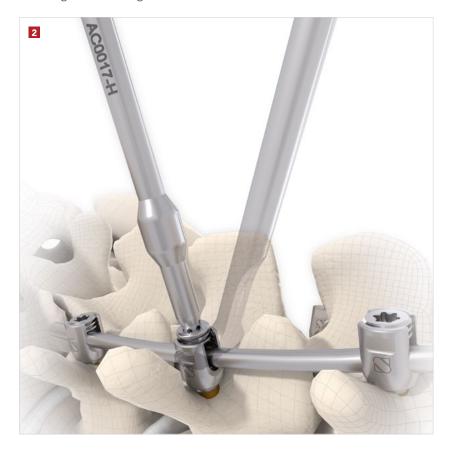
Use of a rod fork

Use the rod fork (AC0021-H) to push the rod into the base of the pedicle screw head.

- 1. Mount the rod fork onto the lateral indentations on the tulip (Image 1).
- **2.** By pressing the rod fork down in the direction of the arrow, the rod is levered into the screw head.
- **3.** By attaching a set screw, the rod is held in position and fixed (Image 2).



Inserting the rod using the rod fork



4 REPOSITIONING THE ROD

Use of the reduction tower

The reduction tower consists of the following parts:

A: Outer sleeve (AC0100-1-H)



C: Rotary knob (AC0100-3-H)



D: Quick coupling (AC0115)



and is used with the T-handle (AC0031-WA).

- 1. Attach the rotary knob (C) to the inner sleeve (B) by pushing it in laterally (Image 1).
- Insert the connected parts C and B (rotary knob and inner sleeve) into the outer sleeve (A) (Image 2).

NOTE

Ensure that the barrel of the outer sleeve faces downward and the slots are visible (A). The inner sleeve must be inserted into the notches to ensure a proper connection.

The thread of the rotary knob (C) should be flush with the top of the outer sleeve (A) (Image 3).

3. Screw the connected parts C and B into the outer sleeve (A) by rotating clockwise once (Image 4). If more than one rotation is made, this can lead to the clamping mechanism obstructing the insertion of the tulip.









- 4. Insert the tulip into the outer sleeve (A).
- **5.** As soon as the clamping mechanism of the inner sleeve (B) is visible, the tulip is fixed (Image 5).

NOTE

Ensure that the tower engages correctly on the tulip before proceeding.

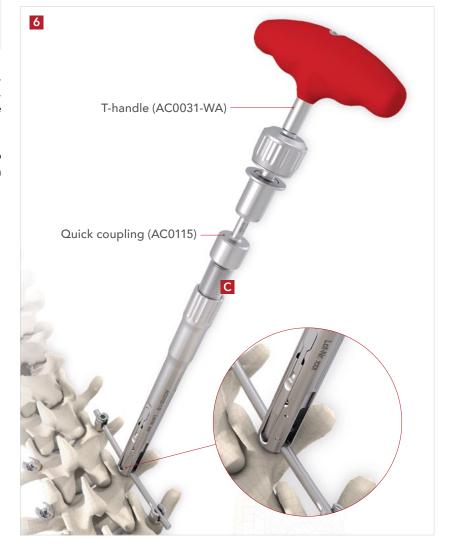
- **6.** When the clamping mechanism of the inner sleeve (B) is visible, one can continue.
- **7.** Turn the rotary knob (C) further clockwise to achieve optimal reduction (Image 6).

NOTE

Attach the T-handle (AC0031-WA) and quick coupling (D) to the rotary knob (C). This makes it easy to control the turning movements during the reduction process.

- 8. To release the reduction tower from the tulip, unscrew the rotary knob (C) anticlockwise. This releases the clamping mechanism on the lateral indentations on the tulip.
- 9. As soon as the rotary knob (C) has returned to its starting position, withdraw the reduction tower from the tulip.





5 FINALIZATION OF THE INSTRUMENTATION

Insertion of the set screws

1. Once the screws and rods have been implanted, the set screw is inserted using the set screwdriver (AC0017-H; with handle, e.g. AC0073-1-A). The set screwdriver is self-retaining and is connected to the set screw by pressing firmly (Image 1).



Final tightening of the set screws

- 2. A torque of 11 Nm is required for the final tightening of the set screws. Please only use the AC0032-C handle with 11 Nm for this step. The handle is connected to the set screwdriver (AC0017-H) (Image 2).
- **3.** Then place the counter torque (AC0020-H) on the tulip and insert the screwdriver.

NOTE

If you use a different screwdriver (e.g. AC0057-H), you will find it more difficult to connect with the screw head at the first attempt. The AC0017-H set screwdriver mentioned above has been designed in such a way that it is optimally guided by the counter-holder and automatically contacts the screw head.



4. Then tighten all set screws one after the other. A noticeable and audible "CLICK" indicates that the required torque of 11 Nm has been reached (Image 3).

CAUTION

To fix the set screws, one should always use the counter torque (AC0020-H). Secure locking of the DIPLOMAT® screws is only guaranteed if the required torque of 11 Nm was applied when tightening the screws.



NOTE

Tighten with 11 Nm torque limiter (AC0032-C).



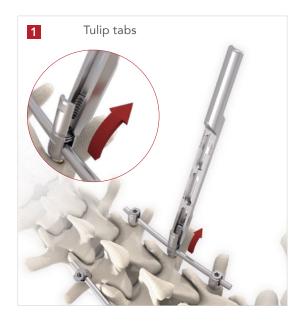
Removing tabs from reduction tulips/percutaneous tulips

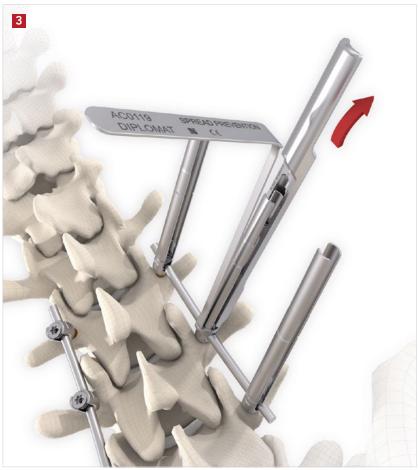
- 1. To break the tabs off the reduction or percutaneous tulips, place the tab remover (AC0118-H) onto the tulip tabs. When placed up correctly, one can hear a "click".
- 2. After positioning, move the instrument back and forth from the lateral to the medial position. This safely breaks off the tab (Image 1).

NOTE

The tab remover has a reservoir for 1 percutaneous or 5 reduction tabs. When the reservoir is full, the tabs are automatically ejected from the proximal opening on the instrument (Image 2).

3. For the MIS technique, use the persuader (AC0119) (Image 3). This prevents the tulip being bent when snapping off the tab.







Ejection of the tabs

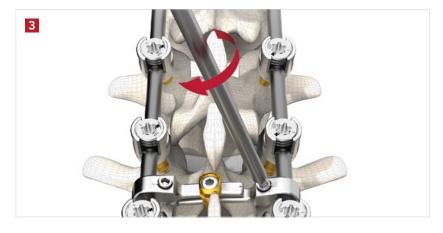
6 ADDITIONAL OPTIONS: CONNECTOR FAMILY

To meet the requirements of different indications and differences in patient anatomy, additional options are available for the DIPLOMAT® screw-rod system.

- Cross connector: for additional stabilization of the instrumentation.
- Offset connector: to compensate for a lack of distance between the rod and screw.
- Extension sleeve / parallel connector: for connecting adjacent fixations.

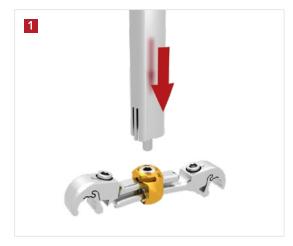
Use of the cross-connectors

- **1.** When treating long segments of the spine and to create rotational stability, a cross-connector can be used.
- 2. After measuring the distance between the rods, connect the corresponding cross-connector with the application sleeve (AC0051-2). To do so, rotate the sleeve anticlockwise by 90° (Images 1 + 2).
- **3.** The central screws of the cross-connector should not be tightened firmly so that the telescopic function is not negatively impacted. If necessary, loosen the screws with the screwdriver (AC0051-3).
- **4.** Place the cross-connector onto the rods. Press both ends of the connector onto the rods until a 'CLICK' is heard.
- **5.** Then tighten the two outer screws of the cross-connecter with the cross-connector torque limiter (AC0051-1-A) with 2.5 Nm (Image 3).
- **6.** Finally, tighten the central screw with 2.5 Nm using the screwdriver, which is inserted through the application sleeve.
- 7. After fixing all screws, release the application sleeve by turning clockwise.





Parallel connector UU





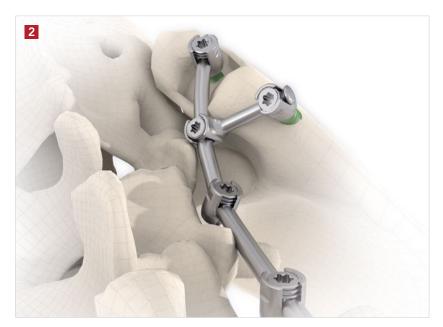
Connecting the cross-connector to the application sleeve

Offset connectors

Insert the offset connector into the tulip of the polyaxial screw and fix with a set screw. Then place the rod into the offset connector and also fix with a set screw (Image 1).

After checking the correct positioning, definitively tighten both set screws with the torque limiter (AC0032-C) with 11 Nm (Image 2).





Extension sleeve (Inline connector)

The extension sleeve enables final instrumentation with a rod diameter of \emptyset 5.5 mm (Image 3).

It is recommended to first pretension the extension sleeve on the new rod and provisionally tighten it with the set screw. After checking the correct positioning, hand tighten the set screws.

Alternatively, fix the connector with a torque limiter (5 Nm) (AC0027-1/2).



Parallel connector

The closed parallel connectors enable final instrumentation with rod combinations (Image 1):

- Ø 4.5 × 5.5 mm
- Ø 5.5 × 5.5 mm
- Ø 5.5 × 6.0 mm

It is recommended to first pretension the inline connector on the new rod and provisionally tighten it with the set screw. After checking the correct positioning, hand tighten the set screws.

Alternatively, fix the connector with a torque limiter (5 Nm) (AC0027-1/2).

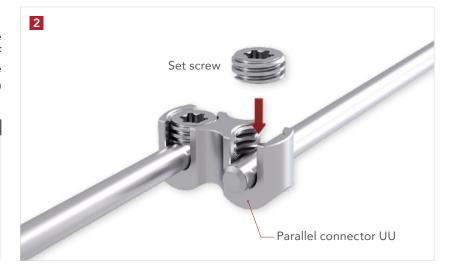


Parallel connector UU

The open parallel connectors UU enable final instrumentation with rod combinations of \varnothing 5.5 × 5.5 mm and \varnothing 5.5 × 6.0 mm. Fix the parallel connector UU into the final position with set screws with 11 Nm (Image 2).

TIP

Fractures that require vertebral body replacement with, e.g. SIGNUS POSEIDON® ST, can also be treated with a DIPLOMAT® short screw (25 mm length) in the fractured vertebral body. The 25 mm long screws are available in diameters of 4.5 mm, 5.5 mm, 6.5 mm and 7.5 mm upon request.



7 ADDITIONAL TECHNIQUES

Compression and distraction with open technique

Distraction or compression maneuvers can still be carried out as needed before the set screws are definitively tightened with 11 Nm.

- **1.** For distraction or compression, place the distractor (MP0010) or compressor (MP0011) on the rod.
- 2. For distraction, the distractor is placed between the tulips (Image 1), while for compression, the compressor is placed outside the tulips (Image 2). The distraction and compression are initiated by pressing the handles together.
- **3.** Lock the distraction/compression that is performed into position by tightening the set screws. The distractor/compressor can be removed when the set screws have been definitively tightened with the torque limiter (11 Nm) (see pages 37 / 38).









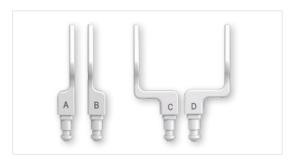
Compression

Optional:

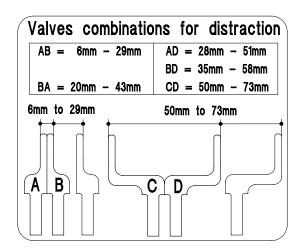
Use of parallel distractor / compressor

For elaborate maneuvers, the modular parallel compressor (570501-A) and distractor (570500-A) can be used as an alternative.





Valve portfolio



Optional: applying saline or radiopaque dye

- 1. Place the screws through a guide wire (Image 1).
- **2.** Leave the guide wires in position until the saline or radiopaque dye are applied. This prevents filling of the screws with bone material.
- 3. Check screw placement and inspect the cortex for perforations.
- 4. Insert alignment devices (AC0040-H) in the same number as the screws.
- **5.** Prepare the saline or radiopaque dye according to the manufacturer's instructions.
- 6. Filling the cannula (SM-SF1820).
- **7.** Apply the saline or radiopaque dye until the required quantity is reached while continuously monitoring with an image intensifier.



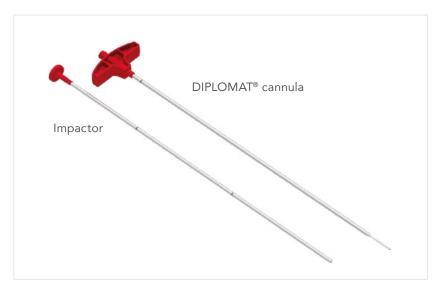
Option 1:

Using the cannula without a guide sleeve

NOTE

The maximum filling of the cannula (SM-SF1820) yields approximately 1,48 ml.

- 1. Pull the impactor out of the cannula.
- 2. Fill the cannula with saline or radiopaque dye.
- 3. Insert the cannula into the screw.
- 4. Saline or radiopaque dye application using the impactor



NOTE

The cannula is used exclusively in conjunction with DIPLOMAT $^{\! \circ}$ screws.

Option 2:

Use of the cannula with a guide sleeve

First insert the alignment device (AC0040-H) into the tulip. The sleeve is designed so that it sits on the screw head while aligning the tulip at the same time (Image 1). This provides a safe entry point for the cannula in the cannulation of the screw.

Then insert the cannula through the alignment device and engage it noticeably on the proximal end of the alignment device. This creates a secure connection between the alignment device and the cannula (Images 2 + 3).

The cannula and the sleeve can be removed by screwing out when the process is complete.

On the proximal end of the sleeve, there is a 1/4 inch connector. A handle can be connected to this connector as needed to enable a tight connection with the tulip.

CAUTION

After removing the cannula, inspect the screw head for traces of saline or radiopaque dye. Residual saline or radiopaque dye must always be removed. If saline or radiopaque dye penetrates into the screw head, this can negatively affect the function.





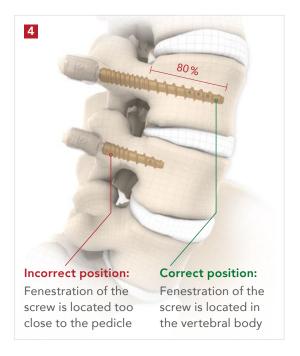


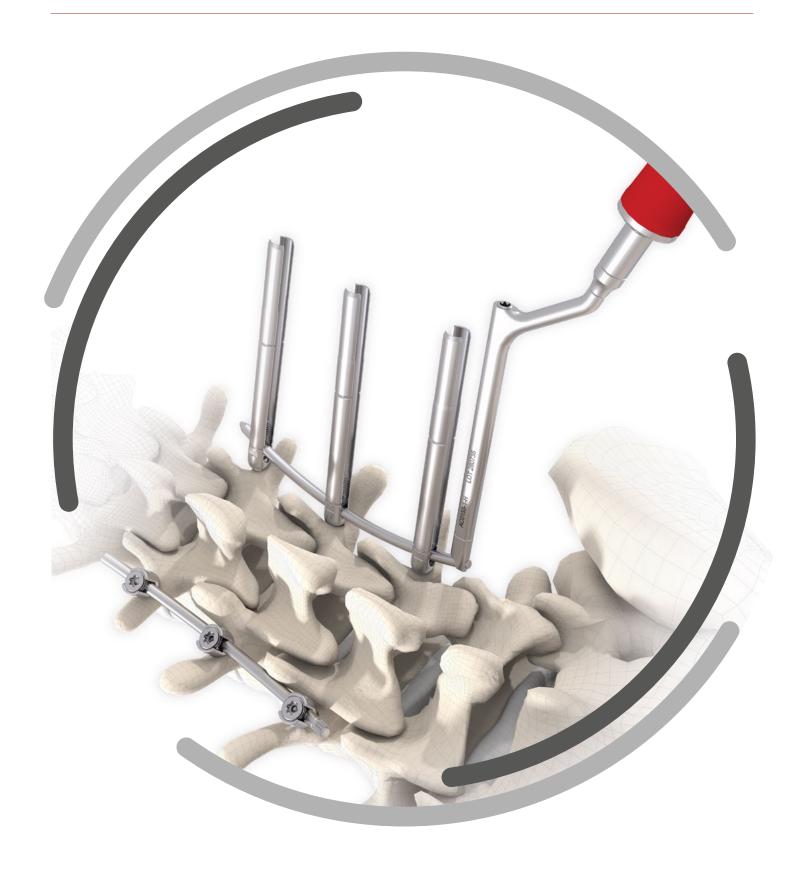
Cannula penetrates deeply into the cannulation

Application recommendation

It is recommended to insert the screws so that they penetrate deeply into the vertebral bodies.

The perforations on the screws should be positioned in the vertebral bodies. If the selected screws are too short, saline or radiopaque dye may be injected into the pedicle (Image 4).





The patient is positioned in the usual manner.

The site is exposed as usual for MIS procedures.

1 PREPARATION OF THE PEDICLE

- After identifying the segment to be instrumented using X-ray control, make a longitudinal incision of about 2 cm length through the skin and fascia.
 - Dilator, inside (AC0110)
 - Dilator, outside (AC0111-H)
- 2. This is followed by opening the pedicle with the threaded awl (see page 24) (Image 1). The tip of the awl should sit on the bony anatomy of the required segment and be located in the pedicle. There are markings on the instrument to determine the screw length. If necessary, cut a thread by advancing the instrument. The threads start 20 mm from the tip. The thread stop is noticeable.
- **3.** After positioning the threaded awl, remove the obturator wire (Image 2) and replace with a guide wire (e.g. AC0125-A/AC0126-A). The guide wire should always be positioned under radiographic guidance.



Insert the wire into the vertebral body to the required screw length. This is the only way to determine the correct screw length.

4. To measure the screw length, slide a screw length ruler (AC0127) over the guide wire. The screw length ruler should sit on the pedicle. On the guide wire, there is a laser marking that is used to read the screw length (Image 3).

NOTE

To determine the correct screw length, use radiographic guidance to check that the distal tip of the guide wire is located in the exact place where the pedicle screw tip will later be located.

CAUTION

For all manipulations on the guide wire, ensure that it is not advanced or prematurely withdrawn. To ensure that the anterior wall of the vertebral body has not been penetrated, check the location of the guide wires with an image intensifier. The guide wires should remain in place until the trajectory can no longer be lost while implanting the screw or the screw is securely positioned in the pedicle.







Using the rod length indicator with guide wire

2 IMPLANTATION OF THE PEDICLE SCREW

Connect and implant the screws with a percutaneous tulip (for the procedure see page 26 – **Implantation of the pedicle screw**).

3 IMPLANTATION OF THE ROD

Determining the required rod length

The MIS rods are available in different lengths.

1. Determine the required rod length with the MIS rod template (AC0117-1/-2).

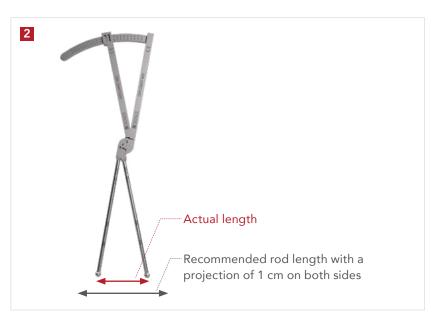
Insert the rod template through the two external tulips (superior and inferior) into the screw heads. If other tulips are located between the two outer tulips (more than one segment), move them carefully aside. Read the required length of the rod on the upper scale (Image 1).

CAUTION

The rod template is not a ruler to measure length but a length indicator (Image 2). It is not designed to subsequently measure the length on the rods. The rod lengths are measured as functional rod lengths (see Images 3+4) and includes a projection on each side of the instrumentation. Only select a longer rod as needed if a distraction is planned.

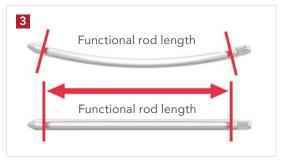
CAUTION

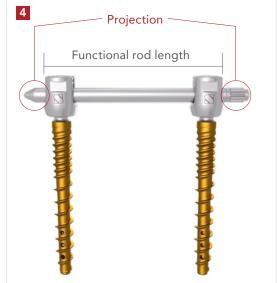
Make sure that the rod extends past the two outermost tulips by approx. 5 mm and rests completely in the tulip. Otherwise, the stability of the instrumentation may fail after surgery.





Reading off the length







Implantation of the rod with the rod holder

- 1. The fixing element (AC0153-1-H) is inserted into the rod holder (AC0153-2-H) (Image 1).
- 2. Insert the rod into the opening provided and fix with the screwdriver (AC0054-H + handle e.g. AC0030-WA) (Image 2).

TIP

When inserting the fixing element, ensure that both laser markings are aligned with each other (Image 1).

NOTE

The fixing element must be tightened firmly enough to ensure that the rod sits securely on the rod holder.

Comment:

The screwdriver (AC0054-H) can also be used to retighten pedicle screws.

- **3.** Before inserting the rod, align the tulip heads again as necessary. To do so, use the tulip adjuster (AC0022-H).
- **4.** The rod should be positioned vertically above the MIS tulips so that the tip of the rod faces downward.

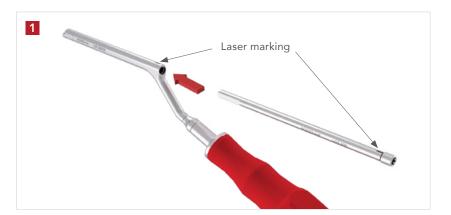
Then insert the rod slowly through the percutaneous tulips into the segments being instrumented (Images 3 and 4).

NOTE

The rod should be guided atraumatically through the muscles. Check the correct positioning of the rod by monitoring with an image intensifier.

TIP

Rotate the percutaneous tulips to easily check if the rod is correctly inserted. The tulips cannot rotate freely if the rod is correctly positioned.







Keep rod vertical



- 5. To check the correct positioning of the rod in the tulips, the front section of the rod template can be used. If the laser marking is flush with the end of the reduction tulip, the rod is correctly positioned (Image 5).
- **6.** Once the rod has been safely positioned in all tulips, fix the rod into the final position with the set screws.

NOTE

If the rod is not fully positioned in the screw head of the pedicle screw, push it downward using a reduction tower.



Push the rod horizontally



4 FINALIZATION OF THE INSTRUMENTATION

Insertion of the set screws

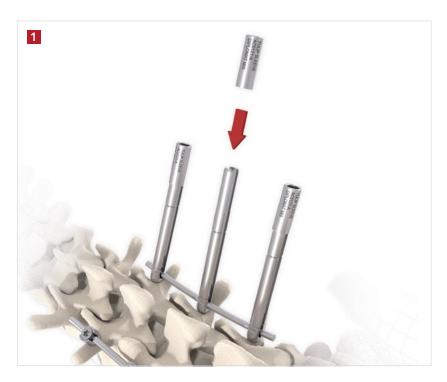
1. Before the rod is fixed in the final position with the set screws, place the MIS tulip sleeve (AC0121-A) onto the tulips (Image 1).

NOTE

in completely.

Using MIS tulip sleeves is recommended because they prevent the tulips spreading or collapsing. They also prevent the set screws from canting when being screwed in and stop the tulip tabs breaking off early.

2. Use the set screwdriver (AC0018-H + handle e.g. AC0073-1-A) to screw the set screws handtight into the tulips. The set screw is correctly inserted if the laser marking on the set screwdriver is flush with the safety sleeve (Image 2).





- 3. Then remove the safety sleeves (AC0121-A), and connect the final set screwdriver (AC0017-H) with the torque limiter (AC0032-C) and place on the counter torque (AC0020-H) (Image 3).
- **4.** Tighten the set screws until a "CLICK" is felt and heard. This indicates that the required torque of 11 Nm has been reached.
- 5. When all set screws have been definitively tightened, break off the tulip tabs.
 For description see page 39:

Removing tabs from reduction tulips/ percutaneous tulips

CAUTION

To fix the set screws, always use the counter torque pedicle screw and the T-handle with the 11 Nm torque limiter. Secure locking of the DIPLOMAT® screws is only guaranteed if the required torque of 11 Nm was applied during the tightening process.



5 ADDITIONAL TECHNIQUES

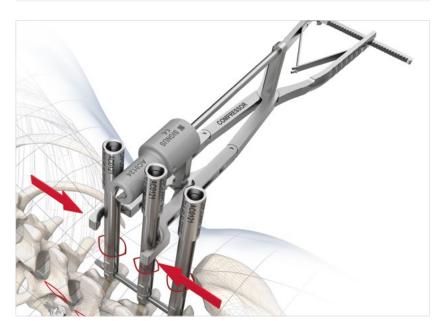
Compression and distraction with MIS technique

For MIS procedures, the combined distractor/compressor (MP1031-A) is used with the associated sleeve (AC0124). The distractor/compressor is multifunctional, combining both functions in a single instrument. The required application is indicated on the instrument.

- To create a secure stabilization point for distraction or compression maneuvers, only tighten one set screw definitively. Only fix the set screw of the screw to be shifted hand tight.
- 2. For the distraction, position the lever arm below the combined distractor/compressor, while for compression, position the lever arm above the combined distractor/compressor. The distraction and compression are initiated by pressing the handles together.
- 3. To support the lever action, attach a distraction/compression sleeve (AC0124) with a diameter of 20/30 mm to the central lever arm.
- 4. Lock the distraction/compression that is performed into position by tightening the set screws. Remove the distractor/compressor when the set screws have been definitively tightened with the torque limiter (11 Nm).

NOTE

For distraction and compression maneuvers, after the set screws have been screwed in, the percutaneous tulips may cross in the proximal area. The use of a distractor/compressor is then almost impossible when using curved rods! Therefore, for distraction or compression maneuvers, straight rods should be used.





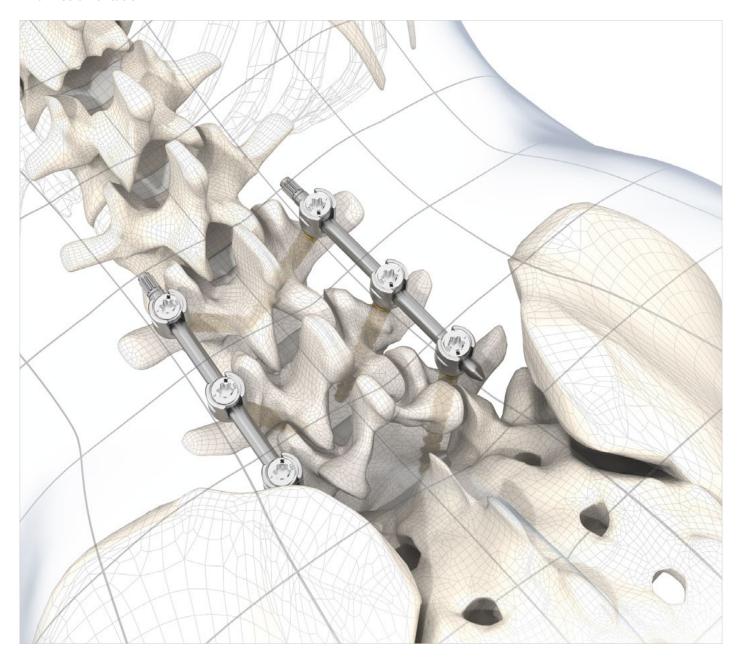
OPTIONAL

Art. no. AC0124 Distraction/compression Expansion sleeve





Final instrumentation



NOTES



NOTES



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 USA Inc.

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

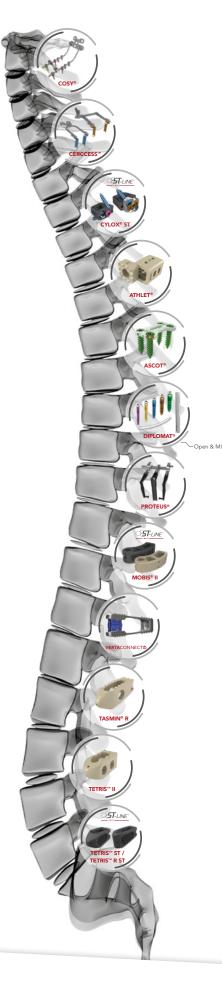
SIGNUS Medizintechnik GmbH

Industriestr. 2 63755 Alzenau/Germany

t. +49 (0) 6023 9166 0

f. +49 (0) 6023 9166 161

info@signus.com www.signus.com



Rev. 2025-08 / 06_US

