INFORMATION

DIPLOMAT®

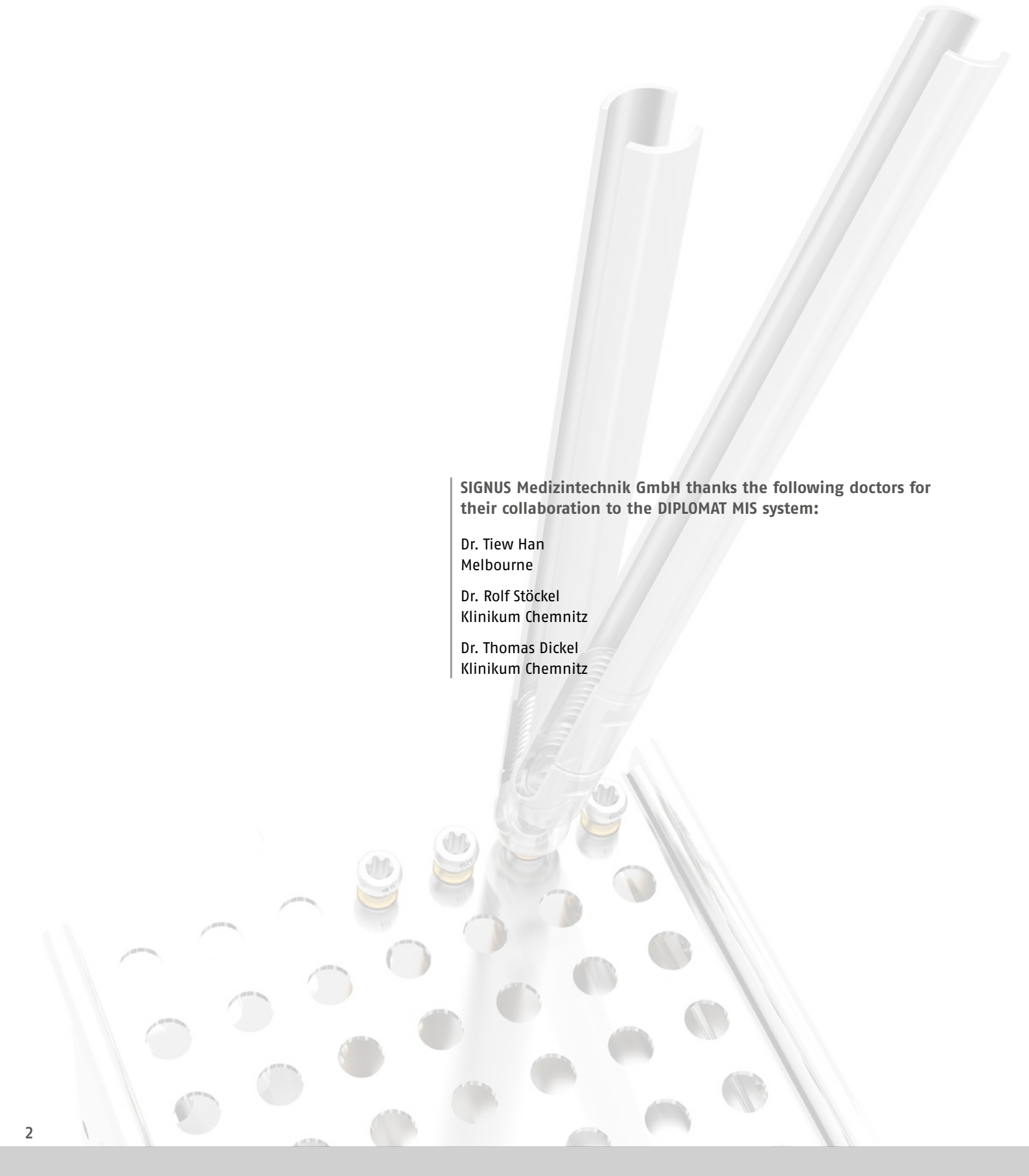
Minimally invasive posterior instrumentation

PRODUCT INFORMATION

reddot award 2016
winner

SIGNUS MEDIZINTECHNIK

FIXATOR



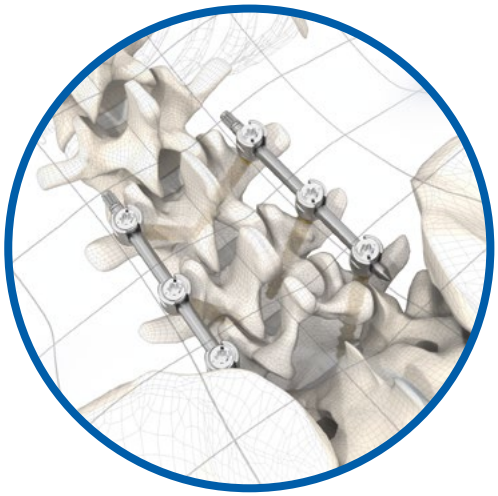
SIGNUS Medizintechnik GmbH thanks the following doctors for their collaboration to the DIPLOMAT MIS system:

Dr. Tiew Han
Melbourne

Dr. Rolf Stöckel
Klinikum Chemnitz

Dr. Thomas Dickel
Klinikum Chemnitz

Contents



Concept

As is the case in many other fields of surgery, spine surgery has gone through a development from open surgery to less traumatizing surgical procedures. The term "minimally invasive" in this context is taken to mean the opposite of "open surgery" (i.e. extensive exposure of the surgical target region), and the corresponding procedures are characterized by "mini-open" and percutaneous techniques. While there is no question that these modern technologies contribute toward the preservation of the functional integrity of the musculo-skeletal system of the back. The low invasiveness often leads to limitations of the options for use in surgery.

With the DIPLOMAT MIS system, SIGNUS offers a modular extension of the DIPLOMAT pedicle screw system, allowing the full functionality of the pedicle screw system to be extended by minimally-invasive access instrumentation, thereby achieving optimized tissue protection. This leaves all options at the surgeon's disposal: segmental distraction and compression as well as sagittal repositioning (grade I) on a minimally invasive basis without the need to change screw systems. The surgical strategy can be adapted from "minimally invasive" to "open" at any time, using the same instrumentation. The DIPLOMAT MIS system uses pedicle screws of the DIPLOMAT system. A complete stand-alone MIS instrument set enables the user to perform complete minimally invasive treatment of the patient without the need to open additional sets. If the user should have to change to an "open" surgical strategy, it is not necessary to change systems for either the screw or for the instruments.

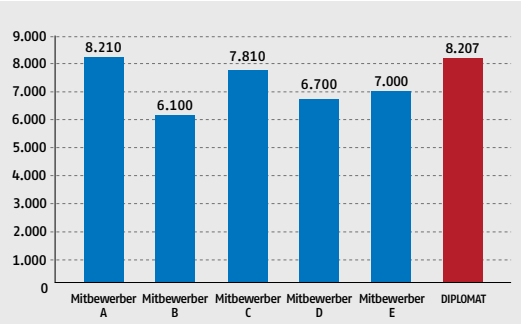


Figure 1: Locked head pop-off testing in N

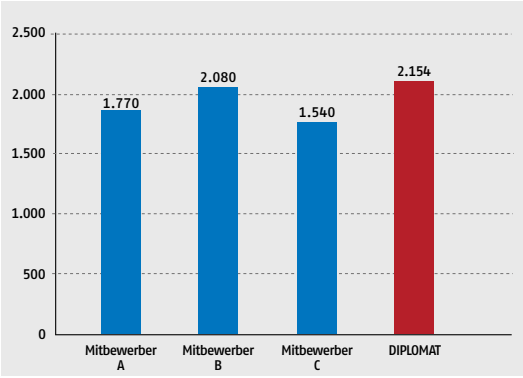


Figure 2: Rod pushing through testing in N
Comparator implants with FDA and CE approval.
Testing in accordance with ASTM F1798-97.

Product-specific advantages

- **Small tulip diameters enable minimal approaches**
  With a mere 12.5 mm tulip diameter, the DIPLOMAT MIS system permits the smallest possible invasive surgical approach
- **Fewer components for higher efficiency**
  The DIPLOMAT system screws are suitable for open procedures as well as percutaneous and minimally invasive procedures, meaning that there is no need to change systems. This streamlines logistics and minimizes costs.
- **Integrated reduction option of the MIS rods**
  The percutaneous tulips have a 17 mm reduction thread, which covers 95% of all MIS reduction maneuvers.
- **Fenestrated screws starting from 5.5 mm diameter**
  Spontaneous augmentation of the vertebral body possible for unexpectedly poor bone quality from 5.5 mm to 9.5 mm screw diameter.
- **Maximum resistance to pullout forces**
  Both in the pedicle and in the vertebral body, the self-tapping, double thread provides the best possible fixation and perfect anchoring in the bone – and without tapping.
- **DIPLOMAT MIS distractor/compressor**
  Genuine parallel distraction or compression for perfect decompression of the intervertebral disc space.

Implants

The DIPLOMAT MIS system uses pedicle screws of the DIPLOMAT pedicle screw system. This allows the greatest possible selection of screws available on the market, even for minimally invasive procedures:

Cannulated and fenestrated screws in 5.5 mm, 6.5 mm, 7.5 mm, 8.5 mm and 9.5 mm screw diameter. *Screws with a diameter of 4.5 mm are available only as cannulated screws! All screws are available in lengths ranging from 25 mm to 100 mm in relation to the screw diameter.

Pedicle screws, without tulip, augmentable, polyaxial

Fig.	Art. No.	Dimensions	Incr.
1	AB0221-45025 to -45060	Ø 4.5x25 mm to 60 mm*	5 mm
2	AB0321-55025 to -55060	Ø 5.5x25 mm to 60 mm	5 mm
	AB0321-65025 to -65065	Ø 6.5x25 mm to 65 mm	5 mm
	AB0321-75025 to -75075	Ø 7.5x25 mm to 75 mm	5 mm
	AB0321-75080 to -75100	Ø 7.5x80 mm to 100 mm	10 mm
	AB0321-85040 to -85075	Ø 8.5x40 mm to 75 mm	5 mm
	AB0321-85080 to -85100	Ø 8.5x80 mm to 100 mm	10 mm
	AB0321-95040 to -95075	Ø 9.5x40 mm to 75 mm	5 mm
	AB0321-95080 to -95100	Ø 9.5x80 mm to 100 mm	10 mm

Percutaneous tulip

Fig.	Art. No.	Dimensions
3	AB0030-55001	Ø 12.5 mm x 150 mm

Set screw

Fig.	Art. No.	Dimensions
4	AB0140-55000	Set screw T30

MIS rods

Fig.	Art. No.	Dimensions
5	AB0655-00030	Titanium MIS rod, straight, Ø 5.5x30 mm
	AB0655-00035	Titanium MIS rod, straight, Ø 5.5x35 mm
	AB0655-00040	Titanium MIS rod, straight, Ø 5.5x40 mm
	AB0655-00045	Titanium MIS rod, straight, Ø 5.5x45 mm
	AB0655-00050	Titanium MIS rod, straight, Ø 5.5x50 mm
	AB0655-00055	Titanium MIS rod, straight, Ø 5.5x55 mm
	AB0655-00060	Titanium MIS rod, straight, Ø 5.5x60 mm
	AB0655-00065	Titanium MIS rod, straight, Ø 5.5x65 mm
	AB0655-00070	Titanium MIS rod, straight, Ø 5.5x70 mm
	AB0655-00075	Titanium MIS rod, straight, Ø 5.5x75 mm
	AB0655-00080	Titanium MIS rod, straight, Ø 5.5x80 mm
	AB0655-00085	Titanium MIS rod, straight, Ø 5.5x85 mm
	AB0655-00090	Titanium MIS rod, straight, Ø 5.5x90 mm
	AB0655-00095	Titanium MIS rod, straight, Ø 5.5x95 mm
	AB0655-00100	Titanium MIS rod, straight, Ø 5.5x100 mm
	AB0655-00105	Titanium MIS rod, straight, Ø 5.5x105 mm
	AB0655-00110	Titanium MIS rod, straight, Ø 5.5x110 mm

MIS rods

Fig.	Art. No.	Dimensions
	AB0655-00115	Titanium MIS rod, straight, Ø 5.5x115 mm
	AB0655-00120	Titanium MIS rod, straight, Ø 5.5x120 mm
	AB0655-00125	Titanium MIS rod, straight, Ø 5.5x125 mm
	AB0655-00130	Titanium MIS rod, straight, Ø 5.5x130 mm
	AB0655-00140	Titanium MIS rod, straight, Ø 5.5x140 mm
	AB0655-00150	Titanium MIS rod, straight, Ø 5.5x150 mm
	AB0755-00030	Titanium MIS rod, curved, Ø 5.5x30 mm
	AB0755-00035	Titanium MIS rod, curved, Ø 5.5x35 mm
	AB0755-00040	Titanium MIS rod, curved, Ø 5.5x40 mm
	AB0755-00045	Titanium MIS rod, curved, Ø 5.5x45 mm
	AB0755-00050	Titanium MIS rod, curved, Ø 5.5x50 mm
	AB0755-00055	Titanium MIS rod, curved, Ø 5.5x55 mm
	AB0755-00060	Titanium MIS rod, curved, Ø 5.5x60 mm
	AB0755-00065	Titanium MIS rod, curved, Ø 5.5x65 mm
5	AB0755-00070	Titanium MIS rod, curved, Ø 5.5x70 mm
	AB0755-00075	Titanium MIS rod, curved, Ø 5.5x75 mm
	AB0755-00080	Titanium MIS rod, curved, Ø 5.5x80 mm
	AB0755-00085	Titanium MIS rod, curved, Ø 5.5x85 mm
	AB0755-00090	Titanium MIS rod, curved, Ø 5.5x90 mm
	AB0755-00095	Titanium MIS rod, curved, Ø 5.5x95 mm
	AB0755-00100	Titanium MIS rod, curved, Ø 5.5x100 mm
	AB0755-00105	Titanium MIS rod, curved, Ø 5.5x105 mm
	AB0755-00110	Titanium MIS rod, curved, Ø 5.5x110 mm
	AB0755-00115	Titanium MIS rod, curved, Ø 5.5x115 mm
	AB0755-00120	Titanium MIS rod, curved, Ø 5.5x120 mm
	AB0755-00125	Titanium MIS rod, curved, Ø 5.5x125 mm
	AB0755-00130	Titanium MIS rod, curved, Ø 5.5x130 mm
	AB0755-00140	Titanium MIS rod, curved, Ø 5.5x140 mm
	AB0755-00150	Titanium MIS rod, curved, Ø 5.5x150 mm

Other consumables

Fig.	Art. No.	Dimensions
	AC0003-2	Guide wire for obturator Ø 1.8 mm × 252 mm
	MP0058	Guide wire Ø 1.8 mm × 500 mm, round
6	SM-SF0927	Cement cannula
	SM-IN0001	INTROX FIX-Cement with Mini Mixer
7	DBMNJ1106TL	Bone access needle

Some items are not for distribution outside EU.

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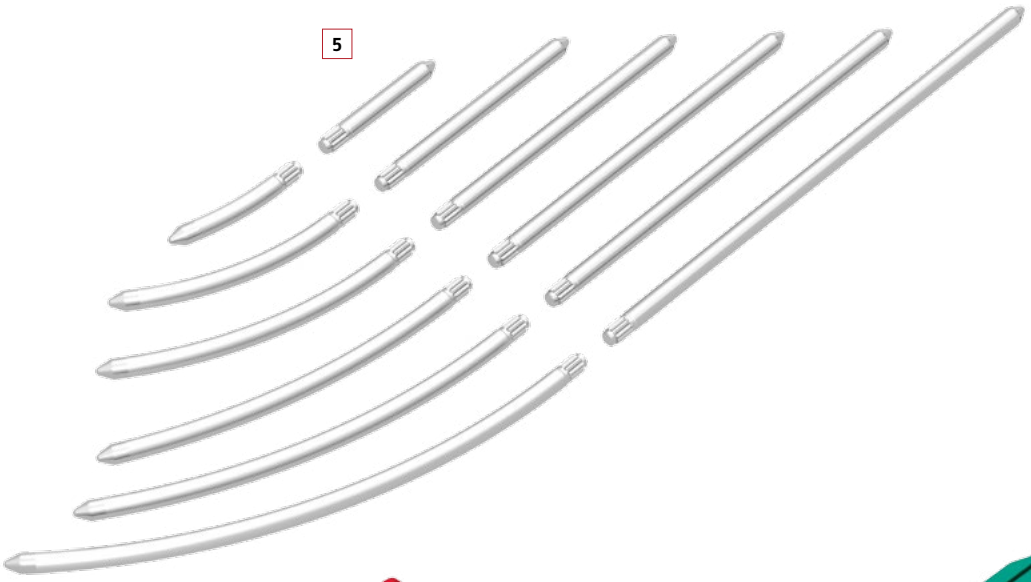

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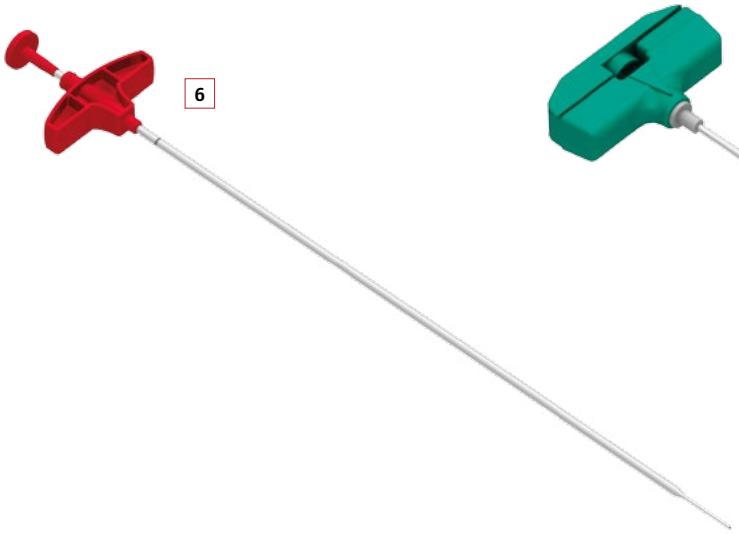

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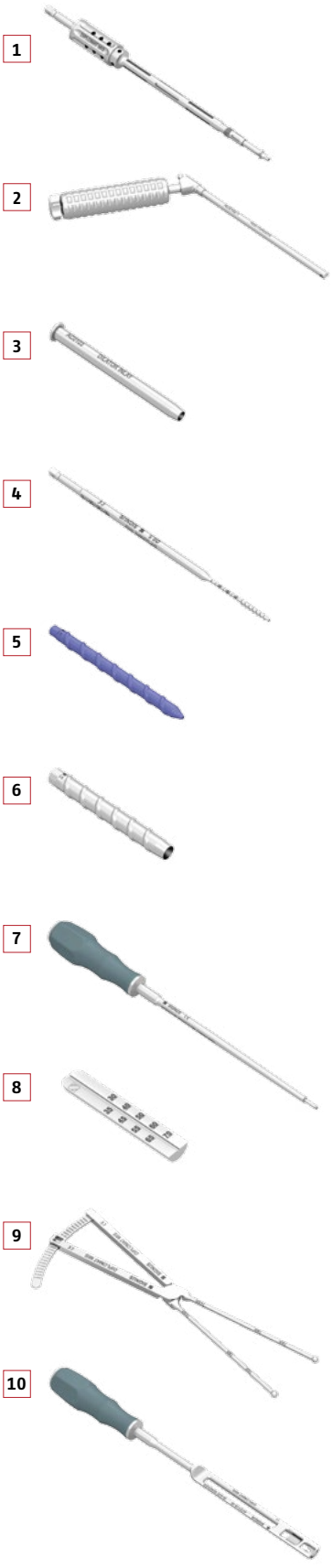
Instruments

Fig.	Art. No.	Description
	AC05AY	MIS Instrument tray
1	AC0101-1	MIS Polyaxial screwdriver inner part
	AC0102-1	MIS Forceps with handle
2	AC0102-2	MIS Forceps - part 2
	AC0102-3	MIS Forceps - part 3
3	AC0103	MIS Dilator insert for tap
4	AC0104–AC0109	MIS Tap cannulated Ø 4.5 mm – Ø 9.5 mm
5	AC0110	MIS Dilator inside
6	AC0111	MIS Dilator outside
7	AC0112	MIS Pedicle Awl cannulated
8	AC0113	MIS Screw length ruler
9	AC0117-1	MIS Rod gauge - part 1
	AC0117-2	MIS Rod gauge - part 2
10	AC0118	MIS Blade remover for percutaneus tulip
11	AC0119	MIS guide for tap remover
12	AC0121	MIS Tulip sleeve
13	AC0020	Counter torque pedicle screw
14	AC0018	Set screwdriver, intermediate
15	AC0017	Set screwdriver
16	AC0032	T-handle with torque limiter 11 Nm
17	AC0031	T-handle with ratchet
18	AC0022	Tulip adjuster
19	MP1031-A	Combined compressor/distractor (optional)
20	AC0040	Cement delivery cannula (optional)
Retractor		
	AC06AY	Retractor tray
21	AC0131	Retractor rack
22	AC0132-1	Adjustment unit
	AC0132-2	Adjustment key
23	AC0133	MIS arm
Optional		
24	AC0134	Screw to screw arm
25	AC0135	Medial arm
26	AC0136	Medial arm key
27	AC0141-1	Blade 20 x 40 mm
28	AC0141-2	Blade 20 x 60 mm
29	AC0141-3	Blade 20 x 80 mm
30	AC0141-4	Blade 20 x 100 mm



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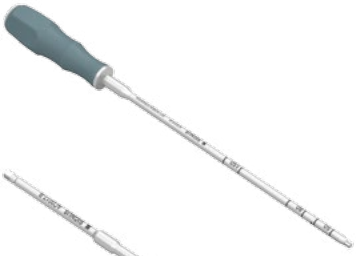
14 

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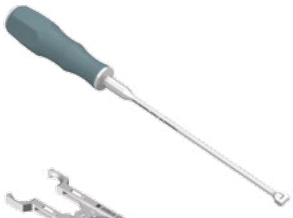
18 

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21 

22 

23 

21, 22 AND 23 ASSEMBLED

OPTIONAL

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29 

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21, 22, 25 AND 30 ASSEMBLED

Indications and contraindications, warnings

Indications

The system is indicated for stabilization of the spine until solid spinal fusion is achieved in patients with:

- Instability or malposition of the spine
- Fractures
- Postoperative or degenerative instability
- Tumors and spondylodiscitis
- Spondylolisthesis
- Disc prolapse
- Stenosis of the lumbar spine
- Disc resection
- Abnormal lordosis/kyphosis/scoliosis
- Degenerative segmental disease
- Osteoporosis
- Bone tumors (metastatic or primary)
- Revision surgery
- Rheumatic diseases with associated poor bone density or quality

The system is furthermore indicated in situations where external immobilization by means of a plaster cast or splint is not possible.

Contraindications

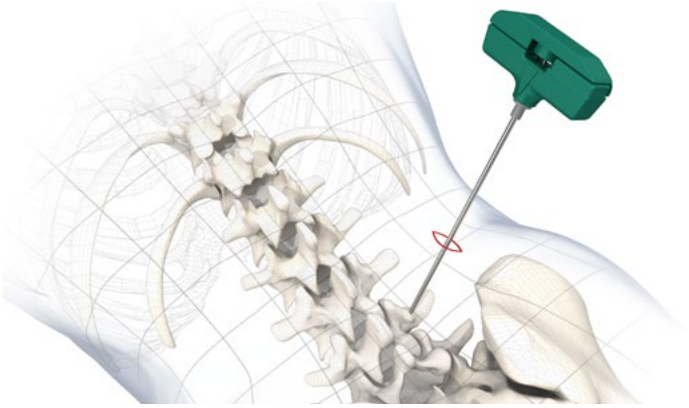
- Infectious processes in, on, or in adjacent regions of the spine
- Severe osteoporosis is a relative contraindication and may prevent adequate fixation of the spinal anchorage and thus exclude the use of this or other spinal instrumentation systems
- Surgery precluded due to the physical condition of the patient, e.g., fever or leukocytosis
- The use of different metals or components not belonging 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 that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies)
- Medical conditions that could prevent successful implantation (e.g., obesity, mental illness, pregnancy, pediatric cases, patients in poor general health, lack of patient compliance)
- Cases not mentioned under indications

Warnings

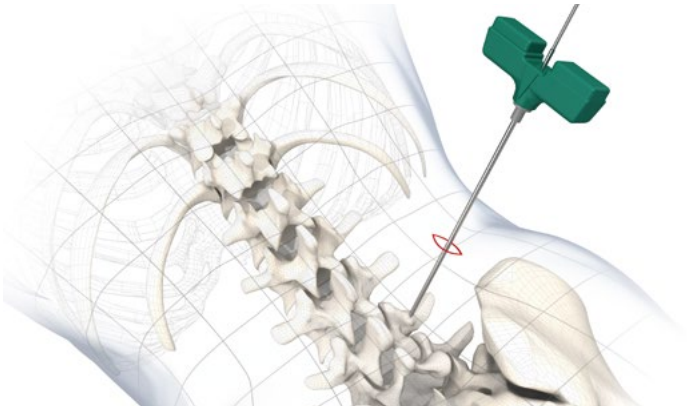
The attending physician, who must be both trained and experienced in carrying out spinal interventions, is responsible for determining the indication, selecting the implant and performing the implantation. More information about application is available in the instructions for use accompanying the product.

Surgical technique

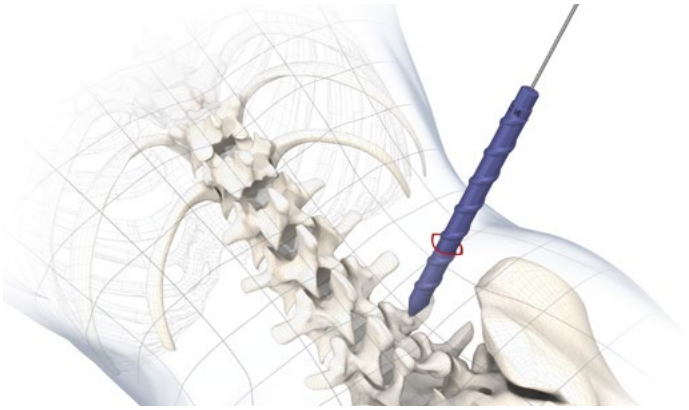
1 After positioning and draping the patient and setting up the image converter, the segment to be treated is defined. First, a bone access needle is placed under X-ray surveillance. Then the bone access needle is inserted according to the relevant pedicles visualized in the X-ray.



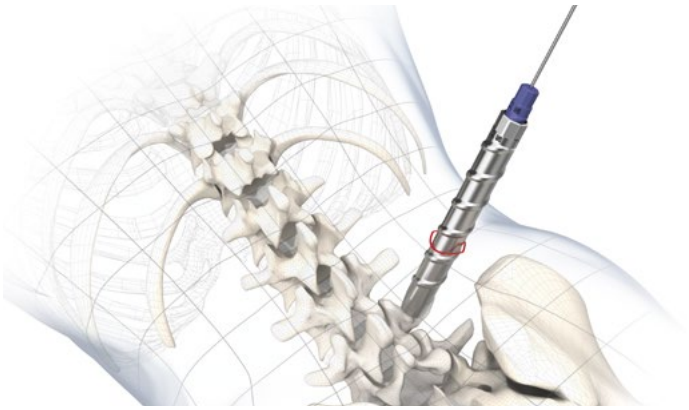
2 The bone access needle is used to open the pedicle and the mandrill is removed. The guide wire (MP0058) is first introduced into the bone access needle with the distal laser marking and under X-ray surveillance is advanced into the vertebral body in accordance with the desired screw length.



3 After removal of the bone access needle, the cut is extended slightly and the guide wire is used to put the inner blue plastic dilator (AC0110) for dilating the tissue in place up to the pedicle.



4 The outer dilator (AC0111), which is X-ray transparent, is placed over the inner dilator up to the pedicle for further dilation.

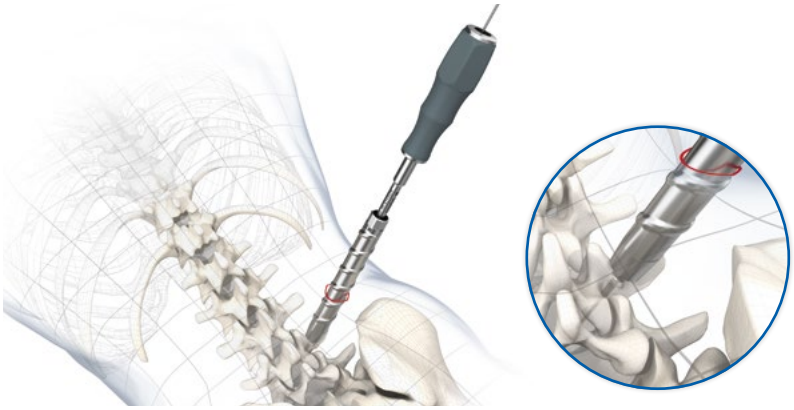


Surgical technique

5 In the next step, the first, inner dilator is removed, while the outer dilator remains in place as a soft-tissue protector and constitutes the working channel. The cannulated pedicle awl (AC0112) is passed over the guide wire to the pedicle in order to open it up further. The pedicle awl has a depth stop at 15.0 mm and is not advanced into the pedicle beyond this depth.

Note

For this and other maneuvers, the guide wire is secured from penetrating the anterior cortical bone, for example, with a clamp at the proximal end!



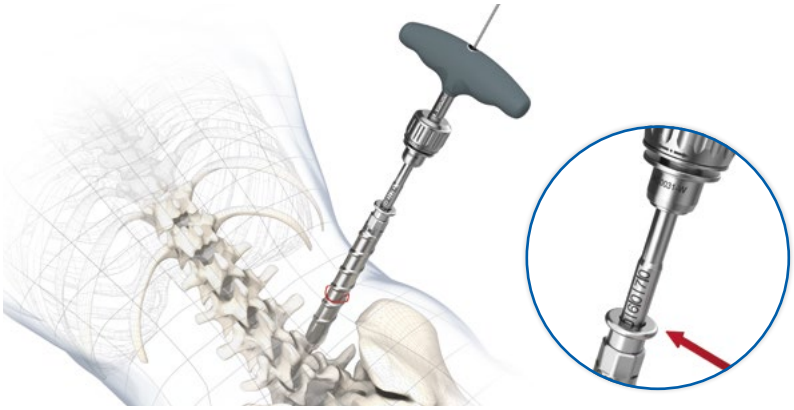
6 It is verified radiographically that the distal tip of the guidewire is seated at the exact place where later on the tip of the pedicle screw is to be seated. With the cannulated pedicle awl in the appropriate position, the screw length to be selected can be determined at the lower laser marking of the guide wire using the screw length ruler (AC0113). To this end, the ruler is placed on the pedicle awl handle and the guide wire is introduced into the guide groove of the ruler. The laser marking indicates the screw length. After the screw length is measured, the pedicle awl is carefully removed. When doing so, make sure that the guide wire remains in position and that the proximal end remains sterile and is not contaminated.

7 All DIPLOMAT pedicle screws are self-tapping. Nevertheless, tappers are available in the appropriate diameters, e.g. for sclerotic bones. The dilator insert for tappers (AC0103) is introduced into the outer dilator and is placed directly on the bone surface of the pedicle. The selected tapper is placed in the opened pedicle by means of the guide wire and the thread is cut. Depth marks on the tapper provide orientation about the depth.

Notes

The thread length on the tappers is 36 mm! The diameter of the tappers is 0.5 mm less than that of the screws!

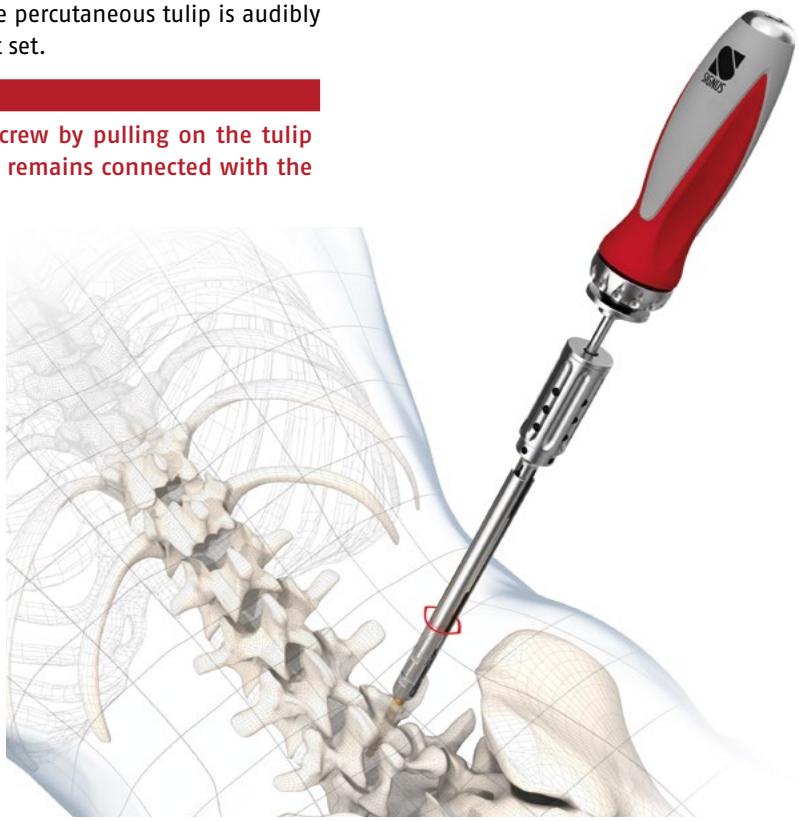
The tapper is then removed and the dilator insert is carefully removed. Make sure that the guide wire remains in position. The outer dilator continues to remain in position for soft-tissue protection.



8 After the desired screw size has been verified, the percutaneous tulip is audibly clicked onto the pedicle screw located in the implant set.

Caution

Check that the tulip is securely fitted onto the screw by pulling on the tulip while holding the screw shaft. If the screw shank remains connected with the tulip, the connection is secure.



Then connect the screw with the screwdriver (AC0101) and insert the pedicle screw.

Using the polyaxial pedicle screwdriver AC0101

The instrument's locking mechanism has a built-in spring that upon detaching the pedicle screw is intended to provide clear feedback about whether the instrument was fully detached from the tulip. For this reason, when assembling the Torx drive, the screw head must be pushed forward and then screwed into the tulip.

Caution

Make sure that the Torx bit of the screwdriver is completely recessed in the screw head. Otherwise, there is a risk that the tulip will cant and jam with the screwdriver, possibly culminating in damage to the instrument.

Press the screwdriver forward in the tulip and insert it completely into the Torx screw head.

To tighten the screw, turn it clockwise.

To loosen the screw, turn it counterclockwise.

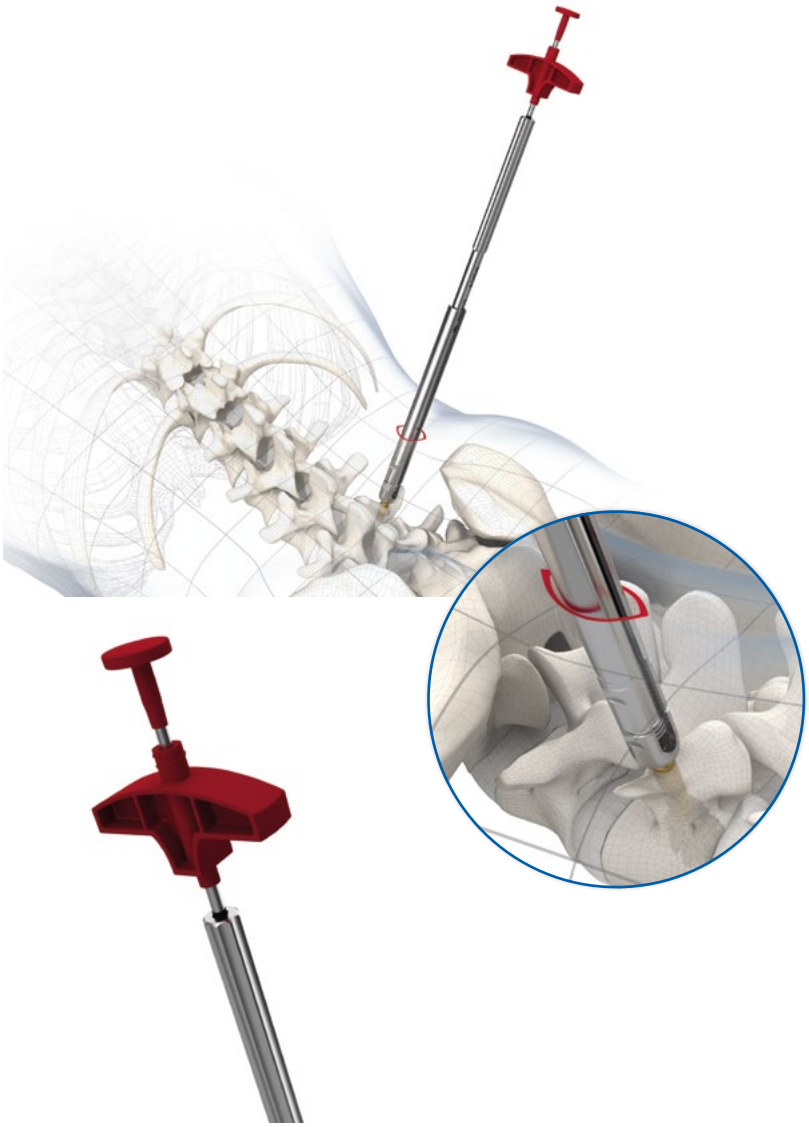
Surgical technique

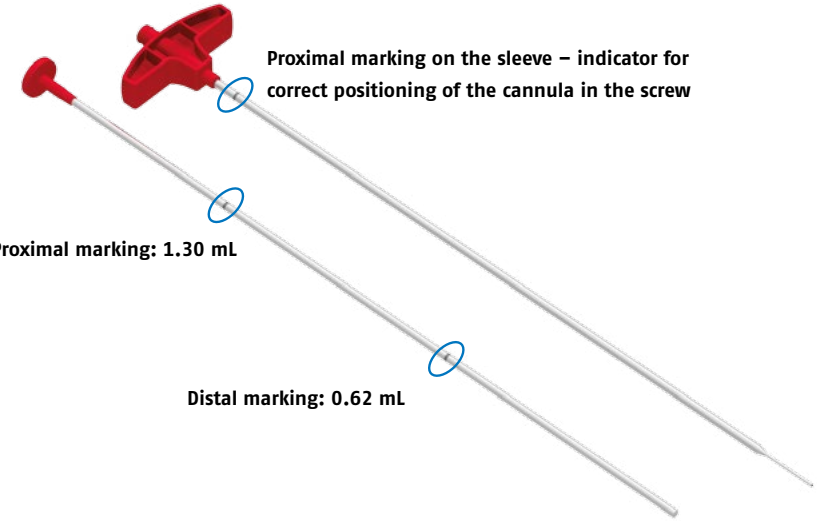
8a Optional augmentation

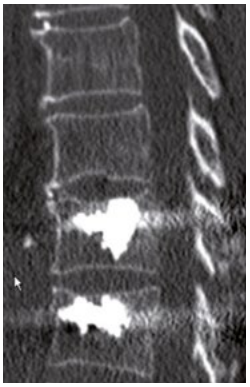
Use augmentable DIPLOMAT screws together with low-viscosity bone cement for vertebroplasty. It is essential to read the instructions for use and the recommendations of the bone cement manufacturer prior to application! For optimal cement flow behavior, INTROX FIX-Cement with Mini Mixer (SM-IN0001) is highly recommendable in practice. Mix the cement as described in its instructions for use and fill it into the accompanying Luer-Lock syringes. For each pedicle screw, connect one cement delivery (AC0040) with the screw by driving the sleeve into the tulip up to the stop. You must also ensure that the tip of the guide sleeve sits inside the screw head. Remove the obturator from the cement cannula by turning it and connect the syringe to the cannula. Press cement into the cannula until cement emerges from the distal end and can be removed. Each cement delivery cannula holds a maximum of 2 mL of cement. Laser markings on the plunger indicate the volume of cement that has been applied.

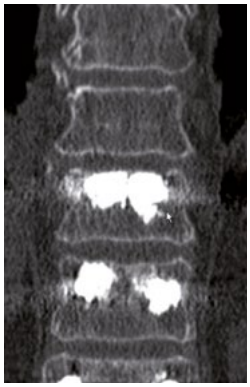
Distal marking: 0.62 mL
Proximal marking: 1.30 mL

The marking on the proximal sleeve indicates whether the cannula is seated correctly in the screw. It must be flush with the guide sleeve. Once the cement is ready for injection, insert the cannula through the cement delivery into the pedicle screw head and slowly press the cement through the screw into the vertebral body by means of the obturator under X-ray surveillance.









9 After all the screws have been placed, the rod template (AC0117) can be used to determine the rod length. Insert the ball points of the template through the two outermost tulips (cranial and caudal) onto the polyaxial screw heads. If other tulips are located between the two outer tulips (more than one segment), they are carefully moved aside. The rod length is read on the upper scale of the ruler.

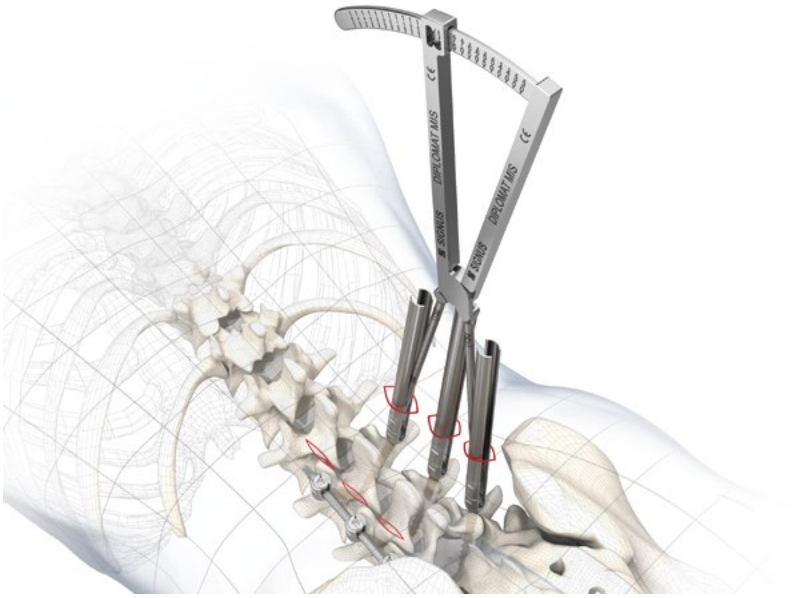
Note

The measured rod length is related to the functional rod length (see figure). The distance is measured from tulip to tulip and does not include the excess length (Figure 9a).

If distraction is planned, a longer rod must be selected.

Note

When using precurved rods, after the set screws have been screwed in, crossing of the percutaneous tulips may occur in the proximal area. It is nearly impossible to use the MIS distractor/compressor! If distraction or compression maneuvers are desired, straight screws must be used. If needed, bending pliers can be used to slightly bend straight screws. Caution: Overcontouring does not allow the instrumentation to be locked securely and restricts the angulation of the tulip.



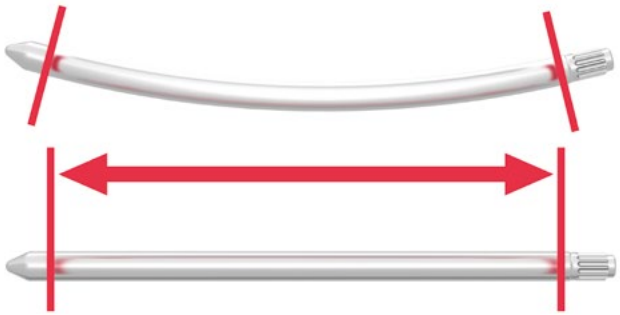


Figure 9a–Functional rod length

10 The desired rod is connected with the rod holder (AC0102) (see Figure 10b). To this end, the proximal end of the rod (pinion shape) is inserted into the distal receiving slot of the rod holder. The connection with the set screw at the handle end of the rod holder is then securely locked (turn clockwise).

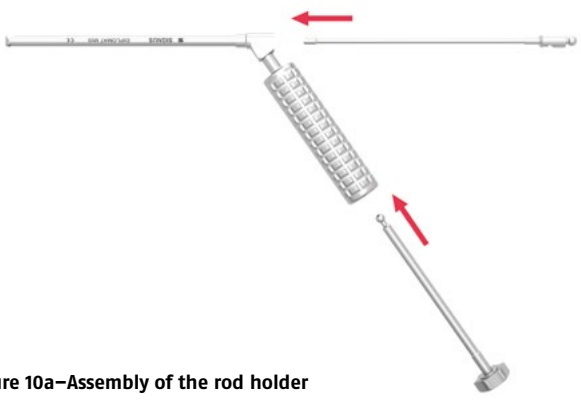


Figure 10a–Assembly of the rod holder

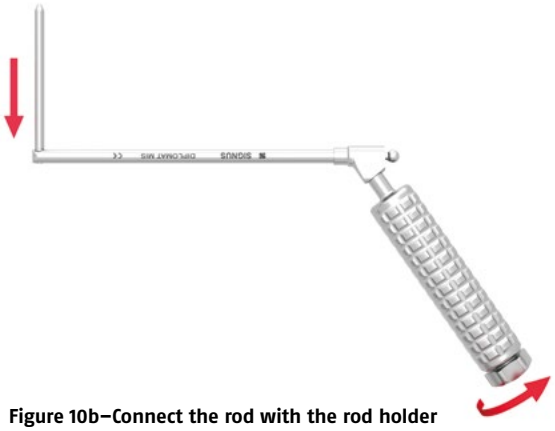
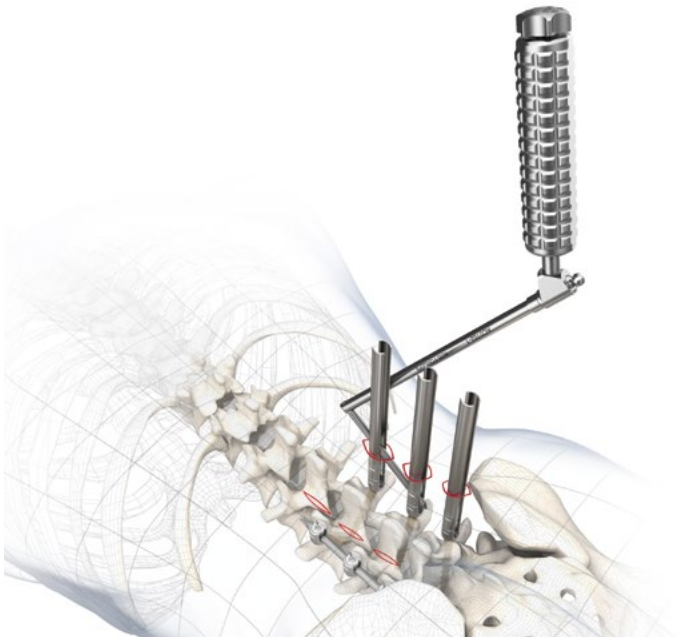


Figure 10b–Connect the rod with the rod holder

Surgical technique

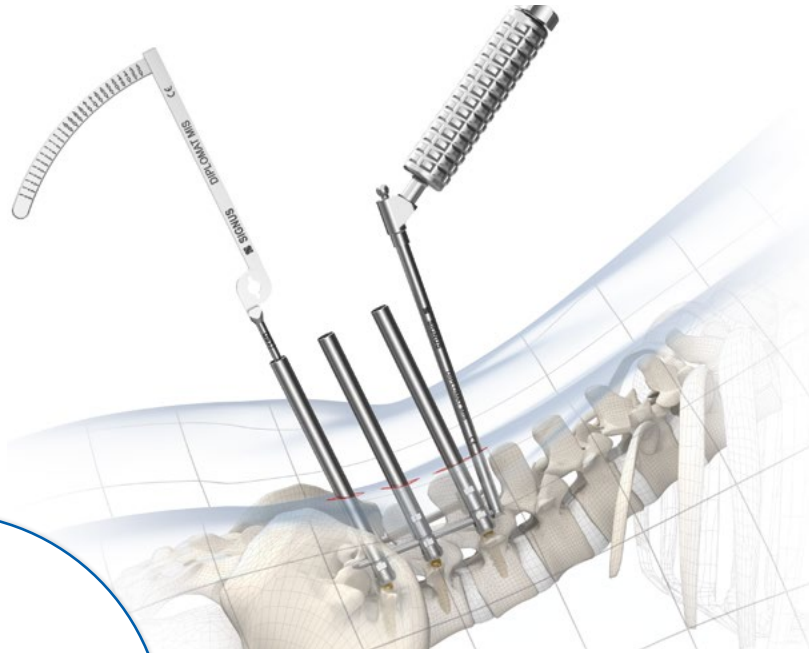
11 The rod holder is used to introduce the rod through the first tulip and through the additional tulips using X-ray surveillance as needed.



12 To ensure that the rod has passed through the tulips properly, one of the tabs of the rod template can be introduced into the tulip up to the "150" marking. If the marking is flush with the proximal end of the tulip, the rod is in proper position (figure).

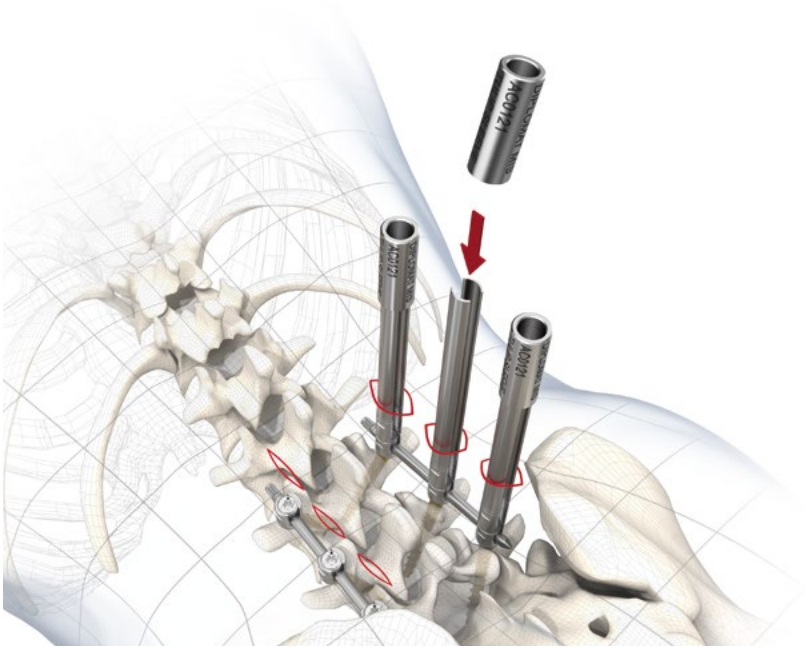
Note

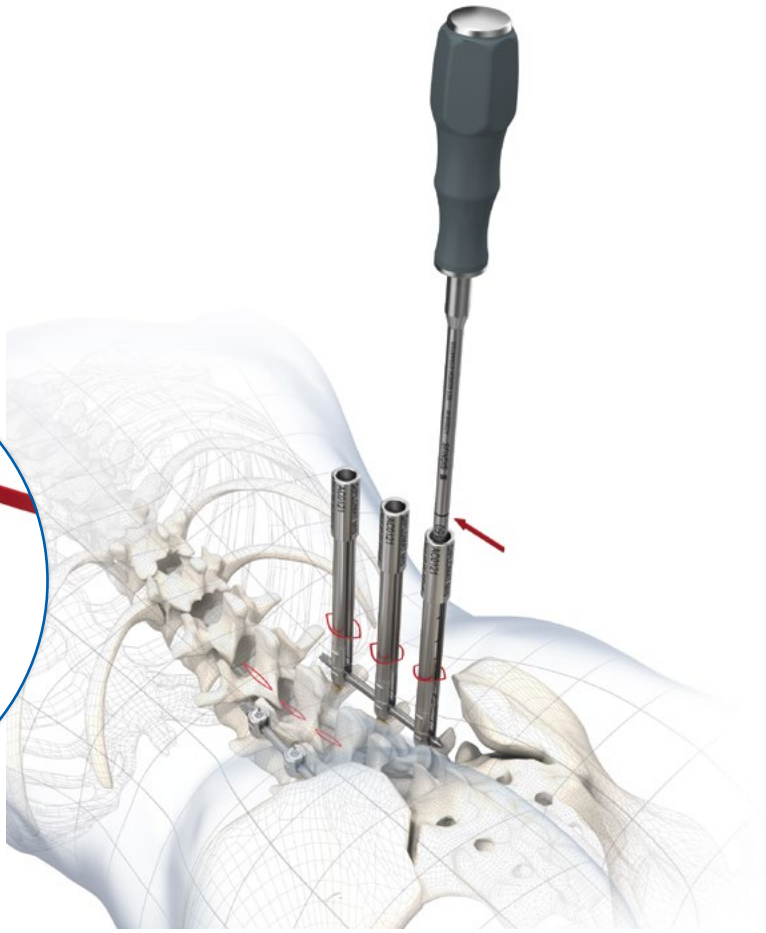
Make sure that the rod extends past the two outermost tulips by approx. 5 mm and rests completely in the tulip. Otherwise the stability of the instrumentation may fail after surgery.



13 Once the rod has been introduced through all of the tulips, the rod is placed in the final position of the tulips with the set screws. To this end, the safety sleeves (AC0121) are placed on the tulips. The sleeves prevent the tulips from spreading apart and keep the set screws from canting or becoming lost while they are screwed in.

With the intermediate set screwdriver (AC0018), a set screw is then picked up and screwed into the tulip. The instrument has two laser markings related to the reduction height for the rod. A total of 17 mm reduction height is available. The set screw is placed in the correct final position when the marking above the 150 is flush with the proximal end of the tulip. (see cut-out).





Cut-out: Laser marking must be flush with the safety sleeve after the set screw has been screwed in completely.

Surgical technique

13a Optional – Distraction and compression

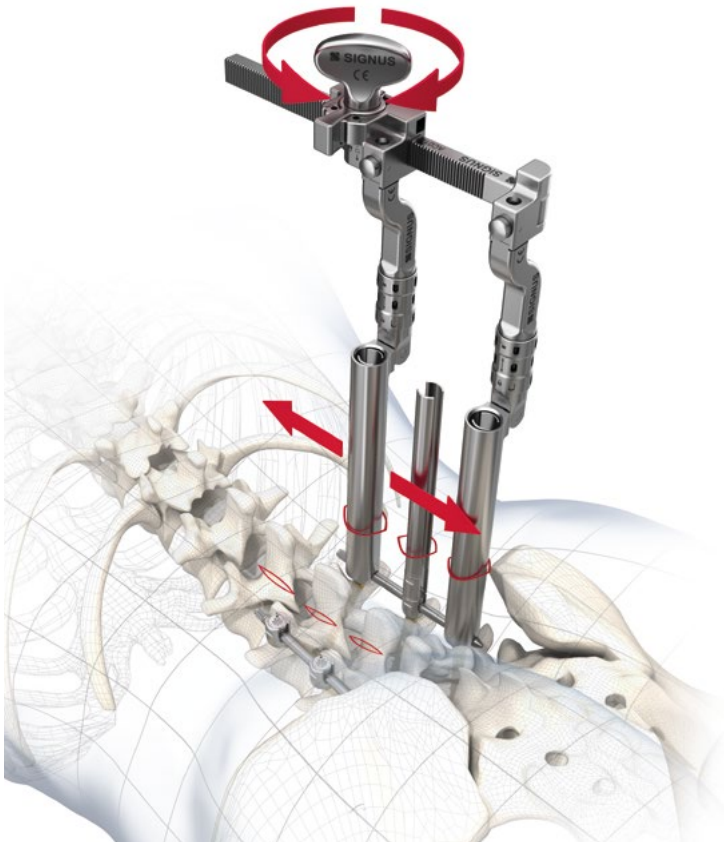
Before the set screws are definitively tightened using the torque limiter (AC0017 and AC0032), distraction or compression maneuvers can still be carried out. Tighten a set screw to create a stabilization point for the distraction. The set screw of the screw to be shifted should be loosened by a quarter rotation.

The DIPLOMAT MIS retractor is assembled in accordance with the separate instructions for use.

The two sleeves are pushed over the tulips to be distracted and compressed and are tilted upward. The distraction or compression is performed with the adjustment key (turn left or right). After the maneuver is completed, the torque key can be used to tighten the loose set screw in its final position and the distractor can be removed. Alternatively, unisegmental distraction/compression can also be performed with the combined compressor/distractor (MP1031-A). available as an option.

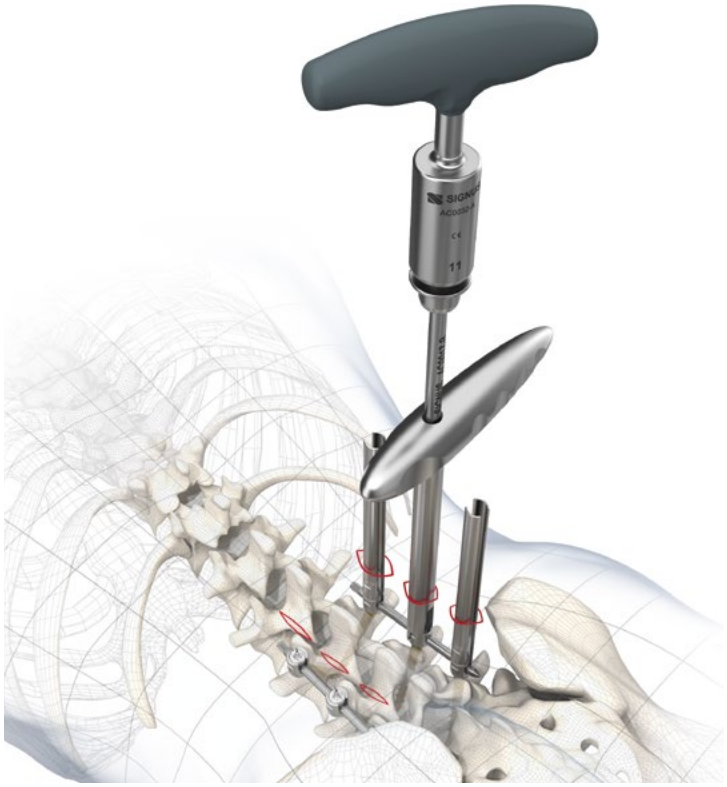
Caution

Ensure that all set screws have been completely reset and provisionally tightened. Otherwise, misalignment might occur!



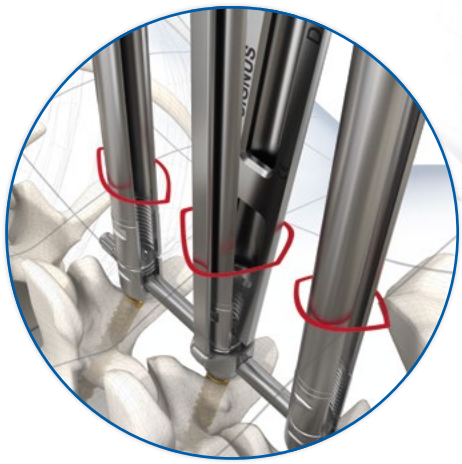
14 Final tightening of the set screws

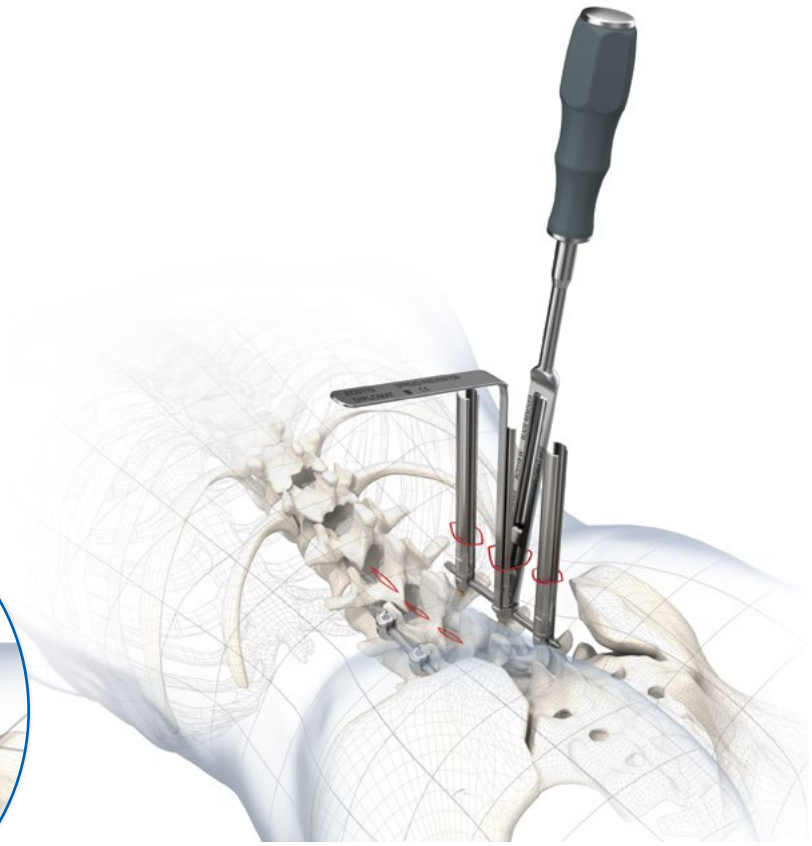
Position the counter torque pedicle screw (AC0020) as an abutment onto the screw head either in a perpendicular position or parallel to the rod. Attach the T-handle with the 11 Nm torque limiter to the set screwdriver. The instrument assembly can be inserted through the counter torque into the drive of the locking screw. Ensure that the polyaxial screw head and rod are aligned perpendicularly to one another. Then tighten the set screw until a noticeable and audible click is felt and heard. This indicates that the required torque has been reached. Repeat this process for all the set screws. After tightening all the screws for the first time, tighten all of the set screws in order. Start with the caudal left screw of the construction and proceed clockwise in order to systematically re-tighten all set screws definitively.

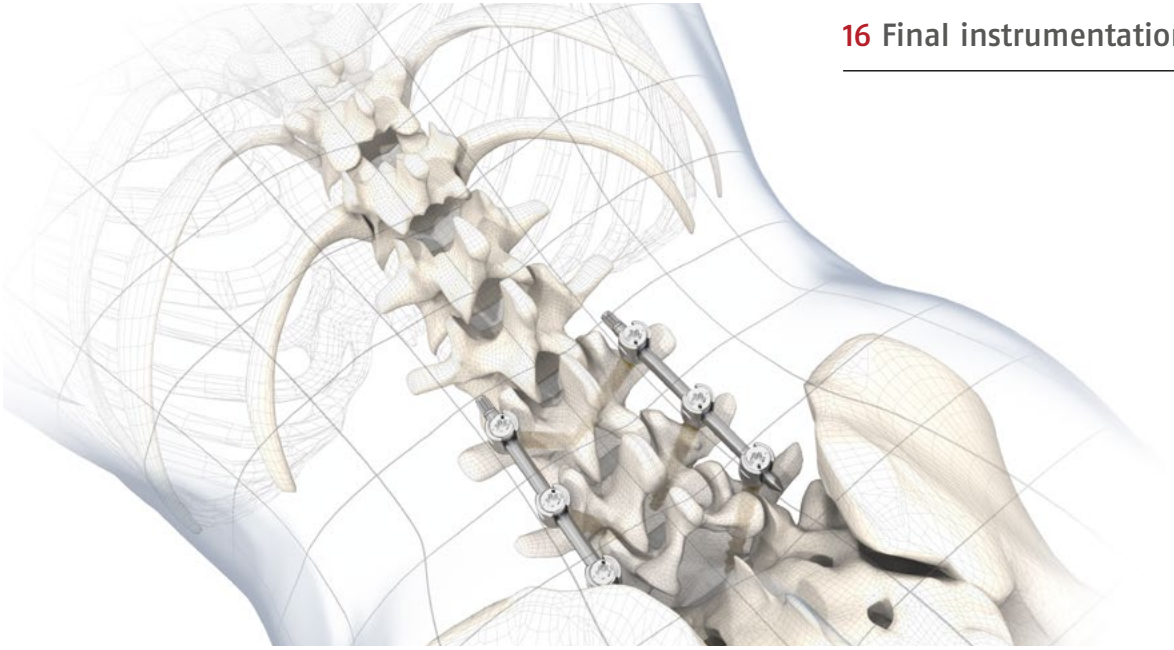


15 Breaking off the screw tabs

To break off the tabs of the percutaneous tulips, first introduce the guide instrument for tab remover (AC0119) over the tulip up to the rod. This instrument prevents the tulip from spreading when the tabs are broken off. Then place the tab remover (AC0118) over the screw head. Carefully move the tab remover back and forth from the lateral position to the medial position to break off the tab. The tabs remain in the instrument and can be released by moving a clamp distally, for example.







16 Final instrumentation

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

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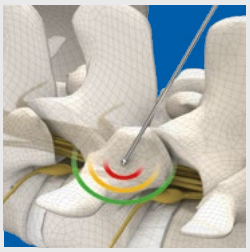

Intraoperative Neuromonitoring

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