DIPLOMAT® MIS

Minimally Invasive Posterior Instrumentation

reddot award 2016
winner

"Open" and "MIS" without system switch

Easy augmentation

HIGH-END MADE IN GERMANY

www.signus.com

SIGNUS
The Spine Sign®

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ABOUT SIGNUS

SIGNUS – THE SIGN FOR SPINE:

PASSIONATE! DYNAMIC! WORLDWIDE!

Innovative high-end implants made in Germany: For more than 25 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 and Australia. 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 hospitalisation 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

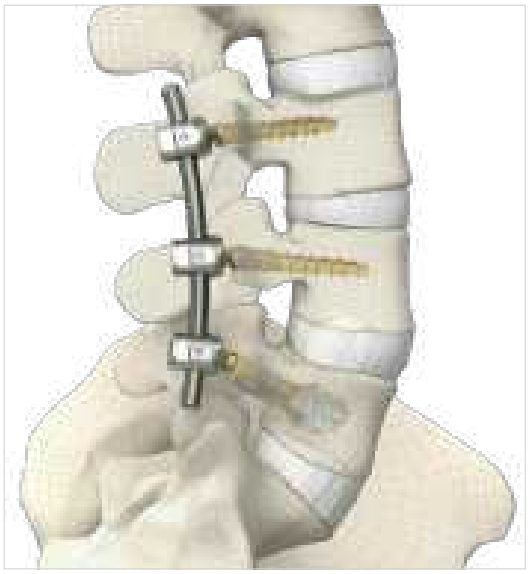
WOMBAT® ST – Transforaminal Lumbar Interbody Fusion
Easy implantation – maximum support

MOBIS® II ST – Transforaminal Lumbar Interbody Fusion
Variable and reliable implantation

CONCEPT

To provide an optimal patient treatment the demands placed on a pedicle screw system are very high – regardless of the particular indication. Both simple and complex spine treatments require a maximum of security and stability. Therefore reliable, ergonomic and functional instrument sets are an absolute must for surgeons. It is a safe, modular and economical fixation system for all interventions on spine.

DIPLOMAT® from SIGNUS combines all of these features.



DIPLOMAT® provides great options:

- **Minimally invasive and structure-preserving surgical procedure**
- **Modular extension of DIPLOMAT® pedicle screw system**
- **High level of security, stability and optimal patient care**
- **No system change necessary to change to an open procedure**
- **Modular and economical fixation system**

Clinical experience

Along with impressive clinical outcomes, the removable tulip also shows outstanding results in laboratory tests:

Tulip disengagement testing:

The locking mechanism ensures an extremely strong connection between the screw and tulip (Figure 1).

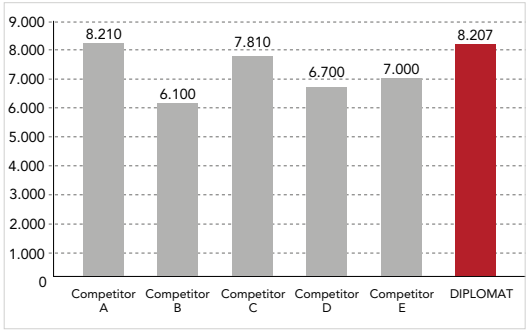


Figure 1: Tulip disengagement strength (N)

Rod push-out testing:

The set screw, with its Torx T30 connection, provides a higher torque on insertion and enables a very strong grip of the screw on the rod (Figure 2).

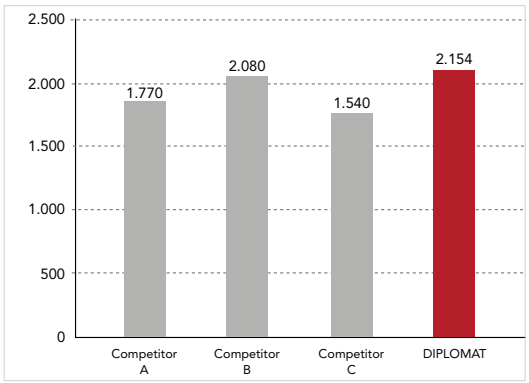
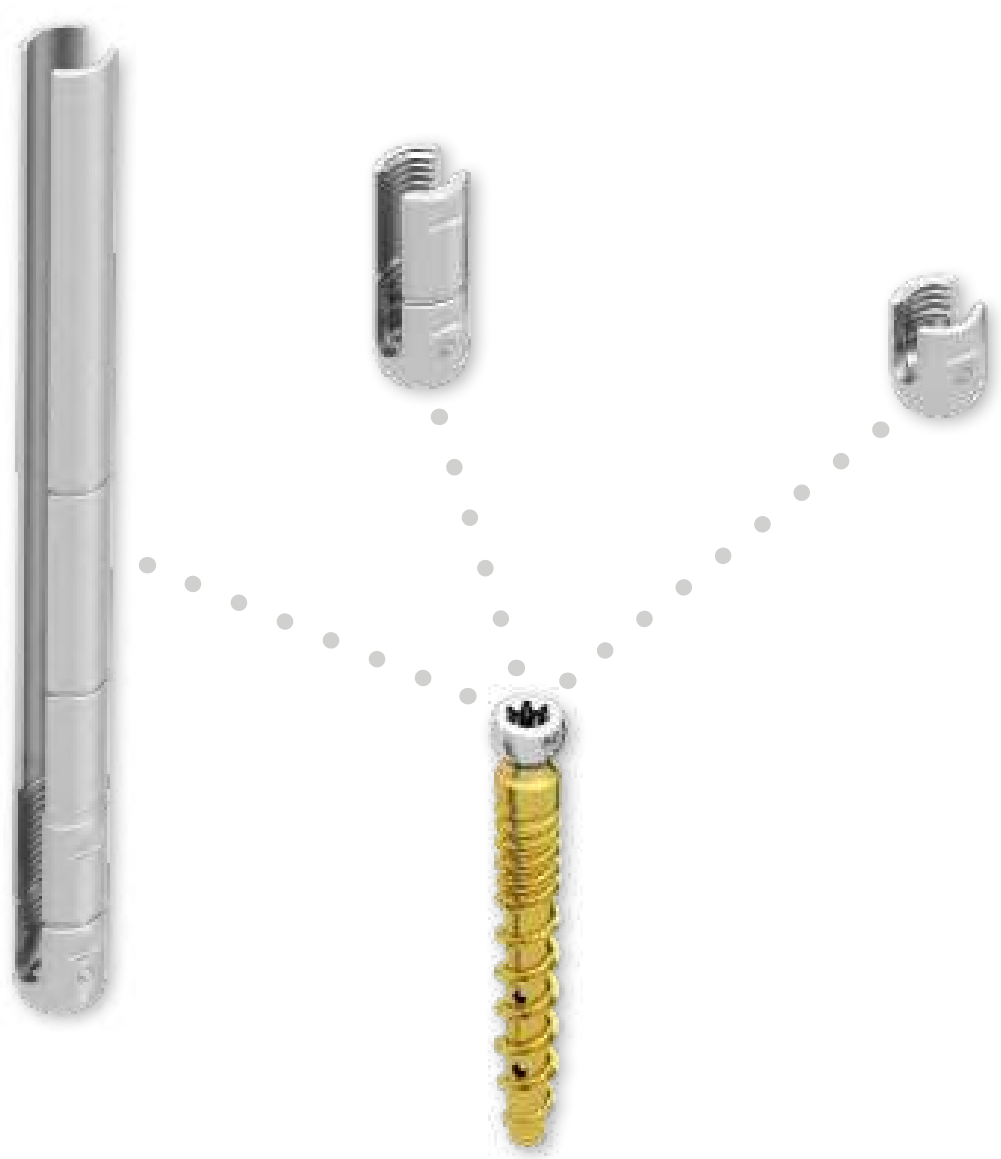


Figure 2: Rod push-out test results (N) of comparator implants with FDA and CE approval. Testing in accordance with ASTM F1798-97.

CONCEPT

DIPLOMAT®: One system for all indications



In-situ exchangeable tulips

CONCEPT

The DIPLOMAT® system is characterised by the following features:

Screw thread

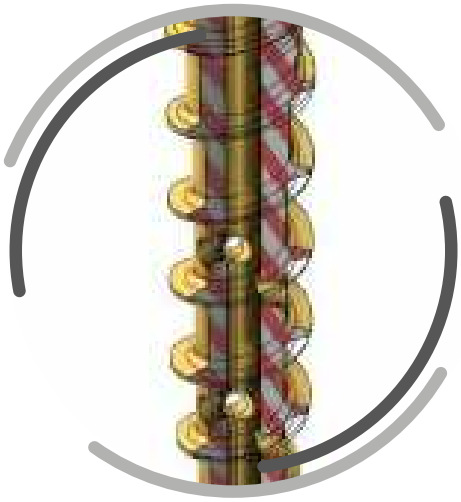
- Cortical / cancellous thread for high pull-out strength
- Self-tapping
- Cylindrical screw shaft
- 4.5 mm thread pitch enables rapid screw implantation

Screw tip

- Secure screw implantation
- Protects neural structures
- Tactile feedback on contact with the anterior cortex

Screw shaft

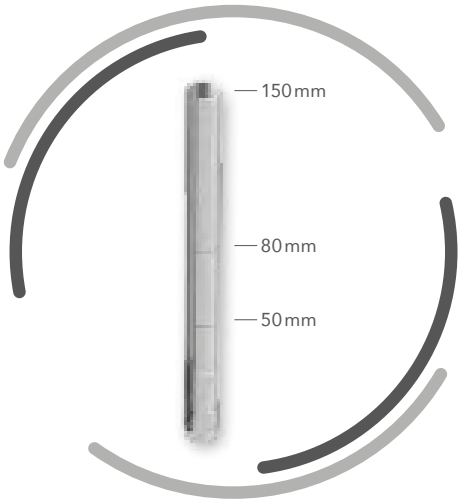
- Cylindrical shaft
- Cannulated 1.9 mm (for 1.8 mm guide wire) and fenestrated
- Optional augmentation from Ø 5.5 mm upwards (special cement applicators for controlled application available)
- Anatomically-adapted perforations for safe cement application



CONCEPT

Percutaneous tulips

- 12.5 mm tulips for small incision
- Minimal tissue and muscle trauma
- Reduction / repositioning manoeuvres possible
- Tulip length can be adjusted for the patient (150 mm / 80 mm / 50 mm)
- Pre-defined breaking points simplify conversion to an open procedure



Set screw

- Torx 30 enables transfer of a high torque
- Special thread design (trapezoid) for secure tulip locking
- Thread profile avoids cross-threading
- Firm connection to inserter

Instruments

- Stringent standards for trays based on latest guidelines and surgeon requirements
- Self-explanatory – easy to indentify
- No need to change system during surgery
- Process-designed tray (costs and space reduction)
- Easy handling for all the surgical support team

IMPLANTS

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

Pedicle screw, without tulip, cannulated, NOT fenestrated, polyaxial

Art. no. AB0221-45030 – AB0221-45055
Ø 4.5 × 30 mm to 55 mm, 5 mm increments

Pedicle screws, without tulip, cannulated, fenestrated, polyaxial

Art. no. AB0321-55055 – AB0321-55055
Ø 5.5 × 30 mm to 55 mm, 5 mm increments

Art. no. AB0321-65030 – AB0321-65060
Ø 6.5 × 30 mm to 60 mm, 5 mm increments

Art. no. AB0321-75040 – AB0321-75055
Ø 7.5 × 40 mm to 55 mm, 5 mm increments

Art. no. AB0321-75070 – AB0321-75100
Ø 7.5 × 70 mm to 100 mm, 10 mm increments

Art. no. AB0321-85045 – AB0321-85055
Ø 8.5 × 40 mm to 55 mm, 5 mm increments

OPTIONAL – NOT SHOWN

Additional sizes depending on diameter
Ø 4.5 – 9.5 × 30 mm to 100 mm
available upon request

OPTIONAL

Pedicle screws, without tulip, cannulated, fenestrated, polyaxial

Art. no. AB0321-95040 – AB0321-95100
Ø 9.5 × 40 mm to 100 mm

OPTIONAL – NOT SHOWN

Pedicle screws, without tulip, cannulated, not fenestrated, polyaxial

Art. no. AB0221-45025
Ø 4.5 × 25 mm

Art. no. AB0321-55025
Ø 5.5 × 25 mm

Art. no. AB0321-65025
Ø 6.5 × 25 mm

Art. no. AB0321-75025
Ø 7.5 × 25 mm

OPTIONAL

Pedicle screws, with tulip, cannulated, fenestrated, monoaxial

Art. no. AB1331-55030 – AB1331-55060
Ø 5.5 × 30 mm to 100 mm

Art. no. AB1331-65030 – AB1331-65065
Ø 6.5 × 30 mm to 100 mm

Art. no. AB1331-75035 – AB1331-75065
Ø 7.5 × 30 mm to 100 mm

Art. no. AB1331-85040 – AB1331-85100
Ø 8.5 × 30 mm to 100 mm

Art. no. AB1331-95040 – AB1331-95100
Ø 9.5 × 30 mm to 100 mm

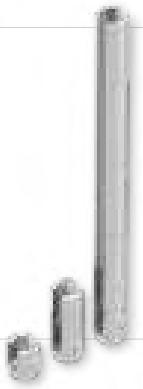
Tulips

Art. no. AB0030-55001
Percutaneous tulip Ø 12.5 × 150 mm

OPTIONAL

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

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



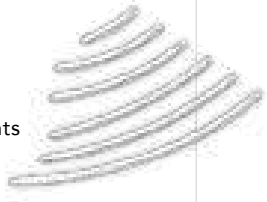
Set screw

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

TITANIUM rod, curved

Art. no. AB0755-00030 – AB0755-00125
Ø 5,5 × 30 mm to 125 mm, 5 mm increments

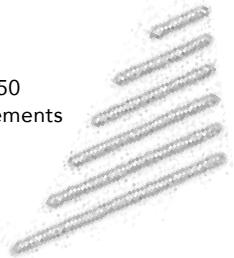
Art. no. AB0755-00130 – AB0755-00150
Ø 5,5 × 130 mm to 150 mm, 10 mm increments



OPTIONAL

TITANIUM rod, straight

Art. no. AB0655-00050 – AB0655-00150
Ø 5.5 × 50 mm to 150 mm, 10 mm increments

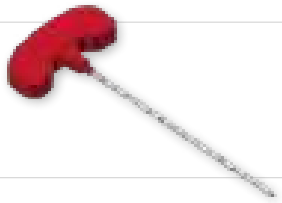


IMPLANTS

OPTIONAL

Cement cannula

Art. no. SM-SF0927



OPTIONAL

Bone access needle

Art. no. SM-BAN1115D
11G / Length 15 cm

OPTIONAL – NOT SHOWN

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

Art. no. SM-IN0001
INTROX Bone Cement & Mixer
(Note: not available in all markets)

INSTRUMENTS

Art. no. AC0101-1
MIS Screwdriver polyaxial - inner part

Art. no. AC0111
MIS Dilator outside

Art. no. AC0101-2
MIS Screwdriver polyaxial - guide handle

Art. no. AC0112-W
MIS Awl cannulated

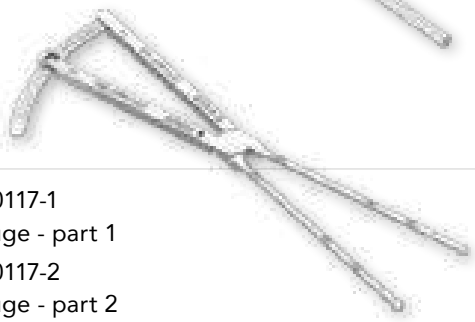
Art. no. AC0103
MIS Dilator-insert for tap

Art. no. AC0113
MIS Screw length ruler

Art. no. AC0104–AC0109
MIS Tap cannulated
Ø 4.5 mm – Ø 9.5 mm

Art. no. AC0127
MIS Screw lenght ruler

Art. no. AC0110
MIS Dilator inside



Art. no. AC0117-1
MIS Rod gauge - part 1

Art. no. AC0117-2
MIS Rod gauge - part 2

Art. no. AC0102-1
MIS Forceps with handle

Art. no. AC0102-2
MIS Forceps - part 2

Art. no. AC0102-3
MIS Forceps - part 3

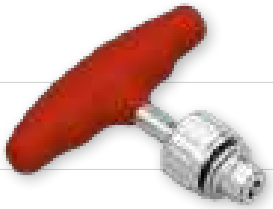
Art. no. AC0118-W
MIS Blade remover for percutaneus tulip

INSTRUMENTS

Art. no. AC0119
MIS guide for tap remover

Art. no. AC0032-A
T-handle with
torque limiter
set screw 11 Nm

Art. no. AC0120
MIS Break-off sleeve percutaneous tulip

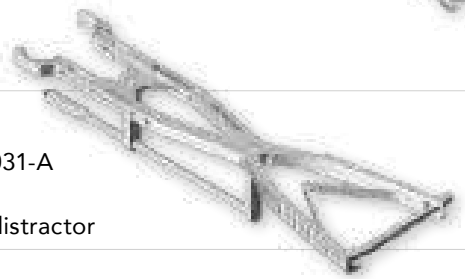


Art. no. AC0031-W
T-handle with ratchet

Art. no. AC0121-A
MIS Tulip sleeve

Art. no. AC0022-WA
Tulip adjuster cannulated

Art. no. AC0129-A
Assembly / Disassembly instrument
percutaneous tulip cannulated

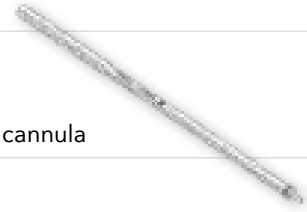


OPTIONAL
Art. no. MP1031-A
Combined
compressor / distractor

Art. no. AC0020-B
Counter torque pedicle screw

OPTIONAL
Art. no. AC0124
Distraction / Compression
support sleeve

Art. no. AC0018-W
Set screwdriver intermediate



OPTIONAL
Art. no. AC0040-A
Alignment device cement cannula

Art. no. AC0017-A
Set screwdriver

INDICATIONS, CONTRAINDICATIONS AND WARNINGS

INDICATIONS

The system is indicated for stabilisation and fusion of the thoracic/lumbar spine (TH2–S2) for:

- Fractures
- Postoperative or degenerative instability
- Tumors and spondylodiscitis
- Spondylolisthesis
- Disc prolapse
- Stenosis
- Disc resection
- Pathological lordosis/kyphosis/scoliosis
- Osteoporosis
- Revision surgery
- Instability or deformity of the spine

CONTRAINDICATIONS

- Infectious processes in, on or in regions adjacent to the spine.
- Surgery is excluded 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 density 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 to or incompatibility with the 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 disorders, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance)
- Cases that are not mentioned under Indications

WARNINGS

- The spinal implants are intended for single use only and must not be re-used. Re-use can result in infection and/or loss of function, which in extreme cases can lead to the death of the patient.
- Implants must be considered as potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines. At the end of their service life, instruments must be similarly disposed of or prepared correctly before disposal.
- SIGNUS implants must be used only with the specified instruments. Correct implantation cannot be guaranteed if implants are placed with other instruments.
- Unless otherwise specified, SIGNUS products must not be combined with materials or components from other systems.

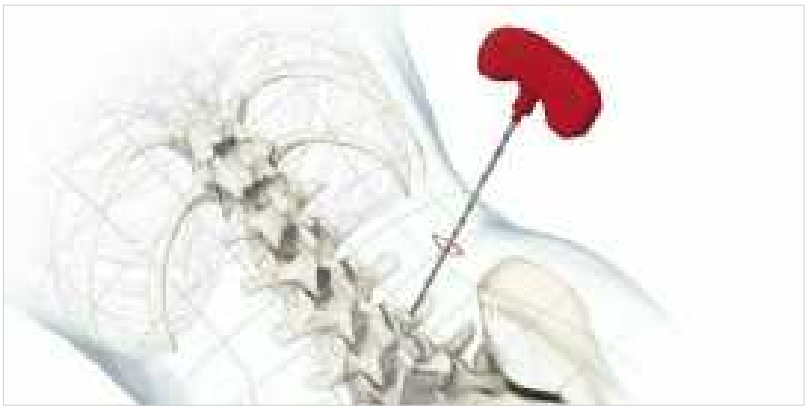
NOTE

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

SURGICAL TECHNIQUE

1 PREPARATION

1. After patient positioning and draping patient and setting up image intensifier, the segment to be treated is indentified and a bone access needle is positioned percutaneously under radiographic guidance.



2. After the bone access needle has been positioned, the stylet is removed. The laser-marked guide wire is inserted into the bone access needle. The guide wire is inserted into the vertebral body to the required screw length under radiographic guidance.

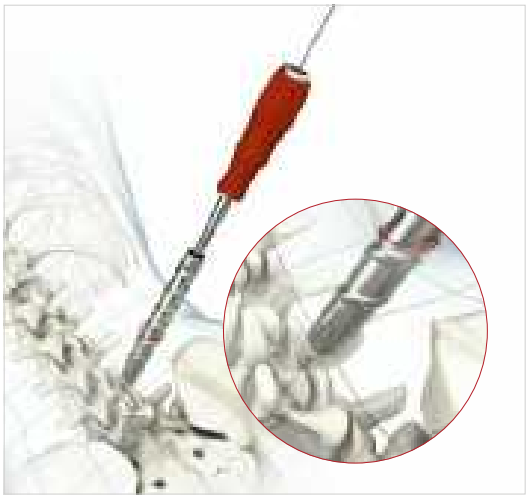
3. After removing the bone access needle, the incision is extended slightly. The inner dilator (AC0110) is used to dilate the incision. It must be placed over the guide wire. The dilator should be located on the pedicle.

4. To further dilate the tissue, the outer dilator (AC0111) is positioned up to the pedicle over the inner dilator. The inner dilator is then removed.

5. The outer dilator remains in place to protect the soft tissue and the working channel. The cannulated pedicle probe (AC0112) will be inserted through the working channel, over guide wire, to open the pedicle. The pedicle probe has a depth stop at 15 mm and cannot be advanced into pedicle beyond this depth.
6. After opening the pedicle, the pedicle probe is removed. It must be ensured the guide wire remains in place in the vertebral body.

NOTE

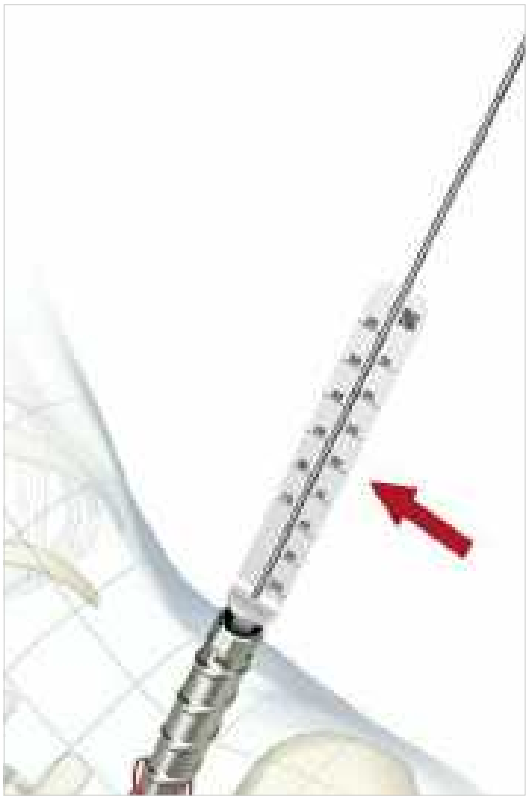
For this and other manoeuvres the guide wire should be prevented from penetrating the anterior cortical bone (for example, with a clamp) at its proximal end.



7. The length of the screw is determined by using the rod length indicator (AC0127). The indicator is slid over the guide wire. The screw length can be identified using the laser marking on the guide wire.

NOTE

Ensure that the rod length indicator sits on the pedicle. It is verified under radiographic guidance that the distal tip of the guide wire is seated at the exact place where the tip of the pedicle screw will later be seated.



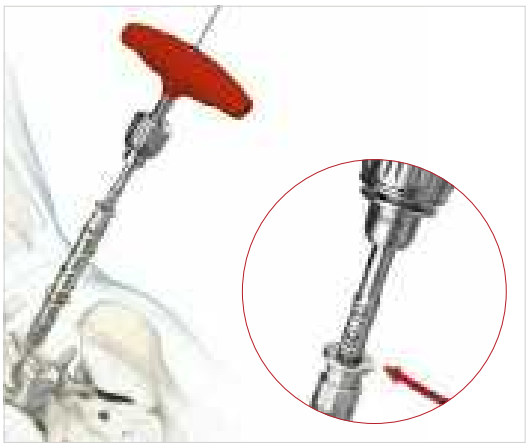
8. After length measurement, the screw length indicator is removed. When doing so, ensure that the guide wire remains in position.
9. DIPLOMAT® pedicle screws are all self-tapping. If required, for example for sclerotic bone, there are tabs available in the appropriate diameters. The sleeve for the tab (AC0103) is inserted into outer dilator. The appropriate tab is then inserted over the guide wire and the thread is cut. The depth marks on the tabs provides the guidance about the screw length.

NOTE

The thread length on the tab is 36 mm!

The diameter of the tabs are 0.5 mm less than that of the screws!

10. After tapping, the tab and dilator are removed. The guide wire remains in the vertebral body. The outer dilator remains in position to protect soft tissues.



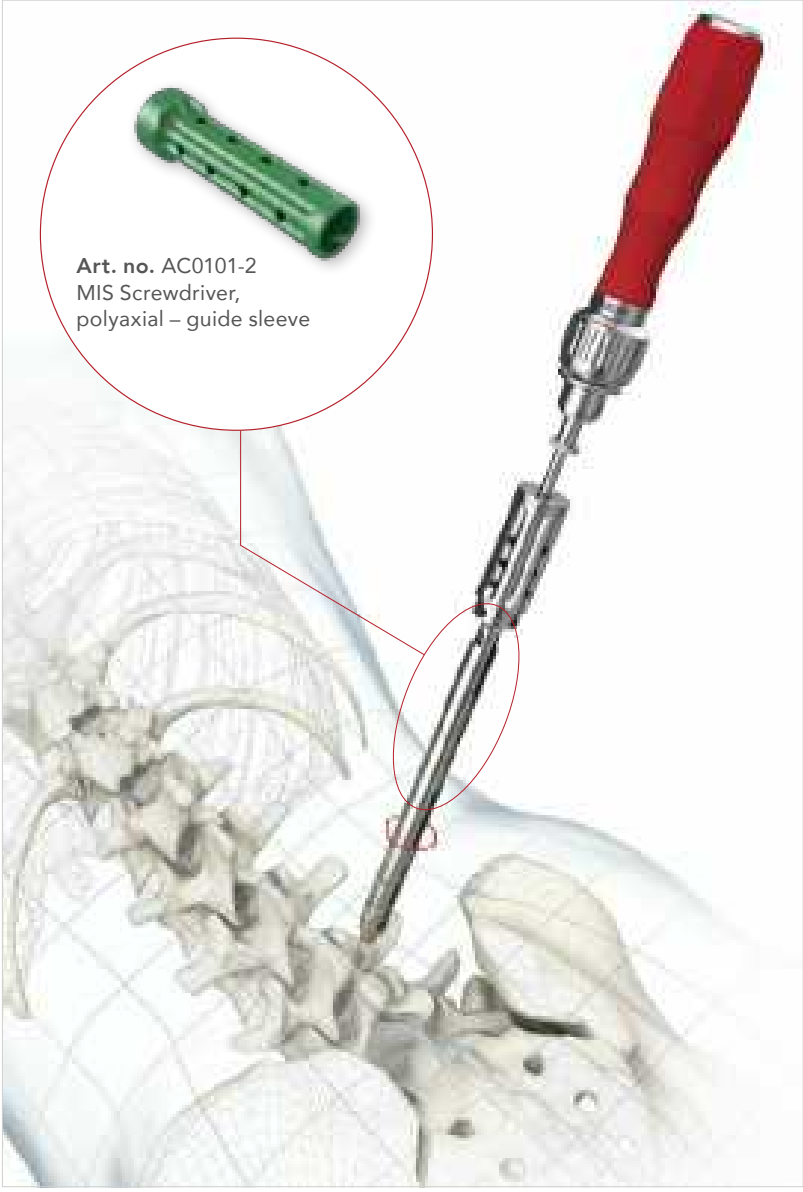
2 IMPLANTATION

Once the desired screw length has been defined, the screw can be connected with the percutaneous tulip. The screw and tulip are engaged by firmly pressing the tulip onto the screw head. An audible 'click' indicates the connection has been made.

CAUTION

Confirm that tulip is securely engaged on the screw.

To do so, pull on the tulip while firmly holding onto the shaft of screw. If the tulip remains connected to the screw, the connection is secure.

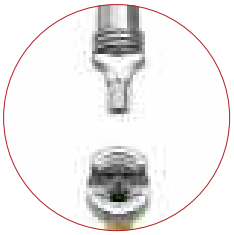


Connect the screw to the screwdriver (AC0101) and insert the pedicle screw

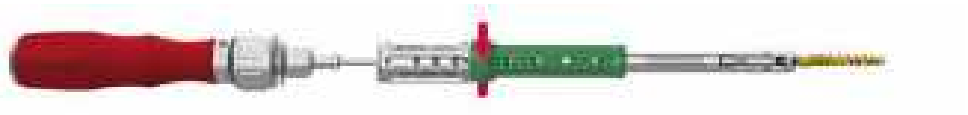
SURGICAL TECHNIQUE

Using the polyaxial screwdriver

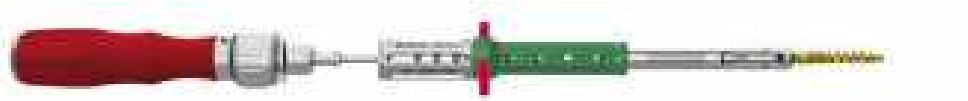
1. Before using the screwdriver, the tissue protection sleeve (AC0101-2) is placed over shaft of the screwdriver and secured by engaging the ball detents provided for this purpose.
2. The Torx fitting at the distal end of the screwdriver must be inserted into the corresponding recess in the screw head



3. The fixation sleeve of the screwdriver is pushed downward and connected with the screw. To tighten the screw, turn clockwise.



4. To loosen the screwdriver from the screw, turn the fixation sleeve in an anticlockwise direction until it detaches from the screw.



NOTE

The procedure described applies equally to all tulips and screws.

CAUTION

Ensure the Torx fitting of the screwdriver is inserted completely into the screw head. Otherwise, there is a risk that the fixation sleeve will not thread properly into the tulip.

Implantation of the rod

1. After all screws have been placed, the rod template (AC0117) can be used to determine the rod length.

2. The rod template is inserted through the two outer tulips (cranial and caudal) into the poly-axial 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.

NOTE

The measured rod length refers to the functional rod length (see figure). The distance is measured from tulip to tulip and does not include the excess length (Figure 1).

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

NOTE

When using curved rods, after the set screws have been inserted, the percutaneous tulips may cross in the proximal area. In this case it is nearly impossible to use the MIS distractor/compressor! If distraction or compression manoeuvres are desired, straight rods should be used. If needed, bending pliers can be used to slightly bend straight rods.

3. To insert the rod, the rod holder (AC0102) must be assembled (Figure 2).
4. The desired rod is connected to the rod holder (AC0102). To do so, the proximal end of the rod (pinion shape) is inserted into the distal receiving slot of the rod holder. The rod is fixed by tightening the knob on the end of the rod holder's handle (Figure 3).

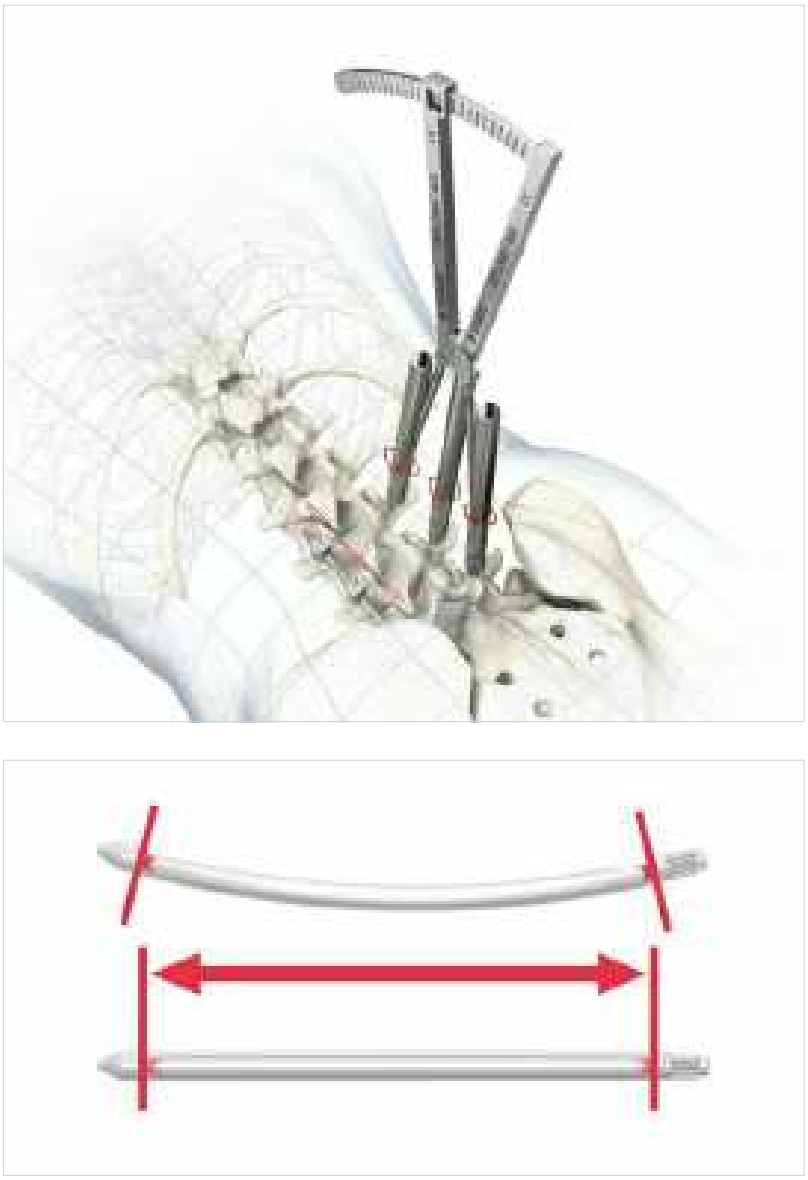


Figure 1: Functional rod length

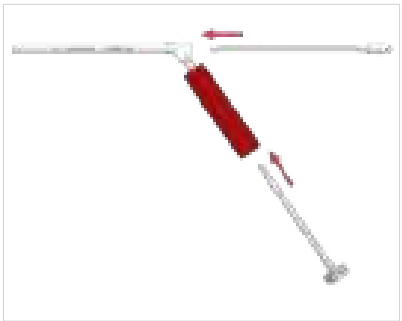


Figure 2: Assembly of the rod holder

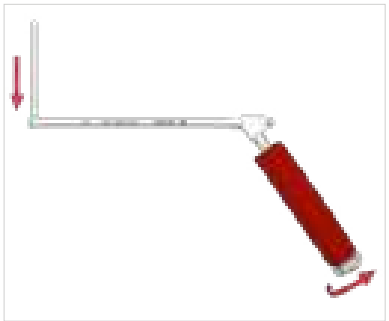
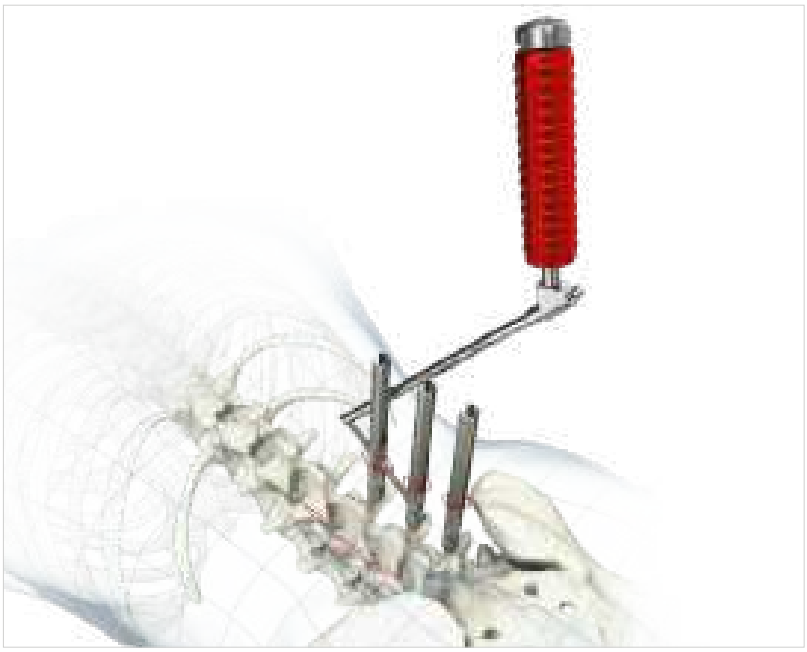


Figure 3: Connect the rod to the rod holder by turning clockwise

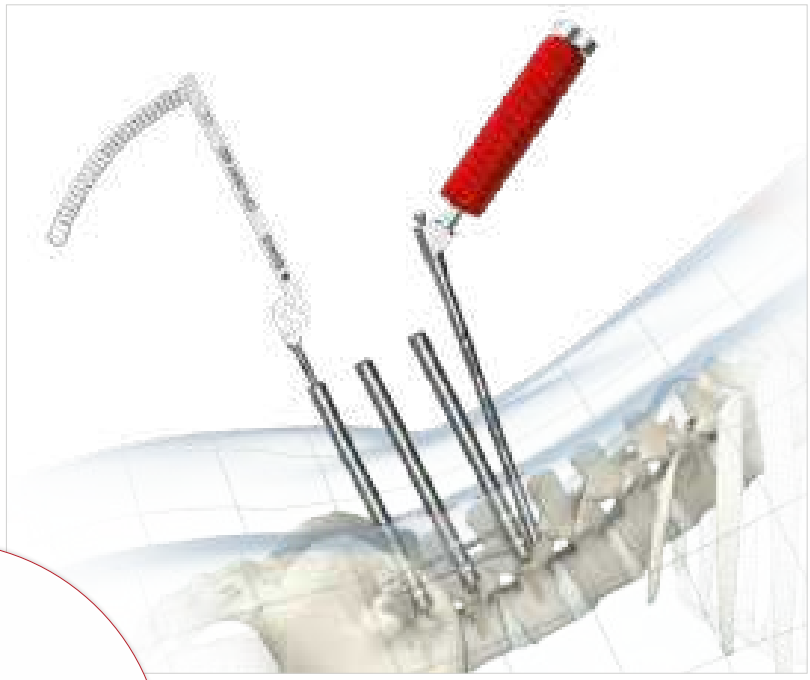
5. The rod is inserted through the first tulip using the rod holder. To assist with insertion of the rod into additional tulips, the process can be checked under radiographic guidance.



6. To ensure that the rod is located correctly in the tulip, the MIS Rod gauge part 1 (AC0117-1) is inserted into the tulips as shown. If the 150 mm marking is flush with the end of the tulip the rod is correctly positioned (see illustration).

CAUTION

Make sure that the rod protrudes about 5 mm on both sides of the tulip and is secure in the tulip. Otherwise the stability of the construct may be inadequate and it may fail after surgery.



SURGICAL TECHNIQUE

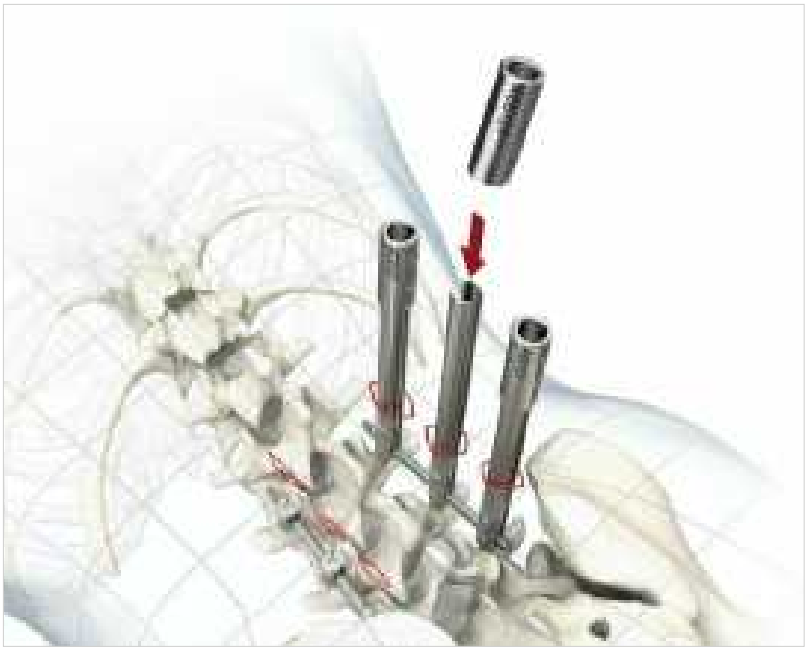
7. Once the rod has been guided through all of the tulips it is then fixed in the final position with the set screws.

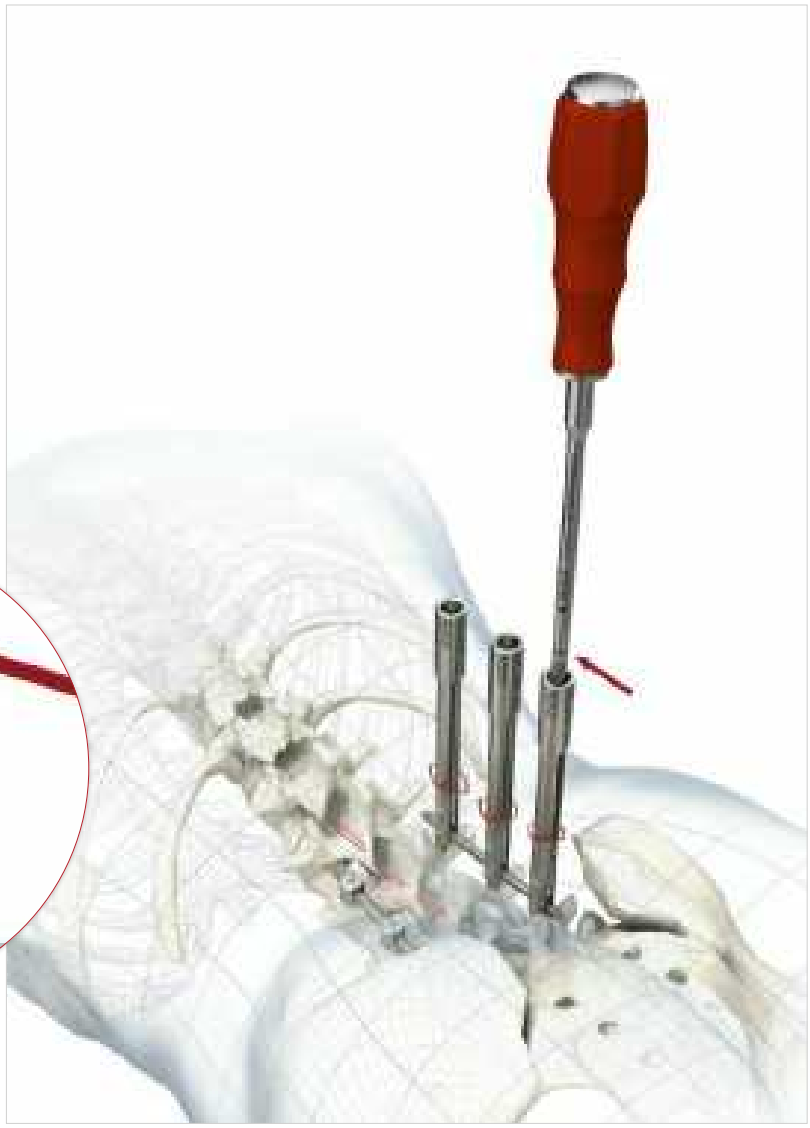
8. Safety sleeves (AC0121) are placed on the tulips. The sleeves prevent the tulips from collapsing or spreading apart.

9. With the intermediate set screwdriver (AC0018), the set screw is picked up and screwed into the tulip.

10. The inserter has two laser markings that refer to the reduction length for the rod. A total of 17 mm reduction is possible.

11. The set screw is correctly inserted if the 150 mm marking on the inserter is level with the proximal end of the tulip and safety sleeve (see detail).





Laser marking must be level with the proximal end of the safety sleeve after the set screw has been completely inserted.

Optional – Distraction and compression

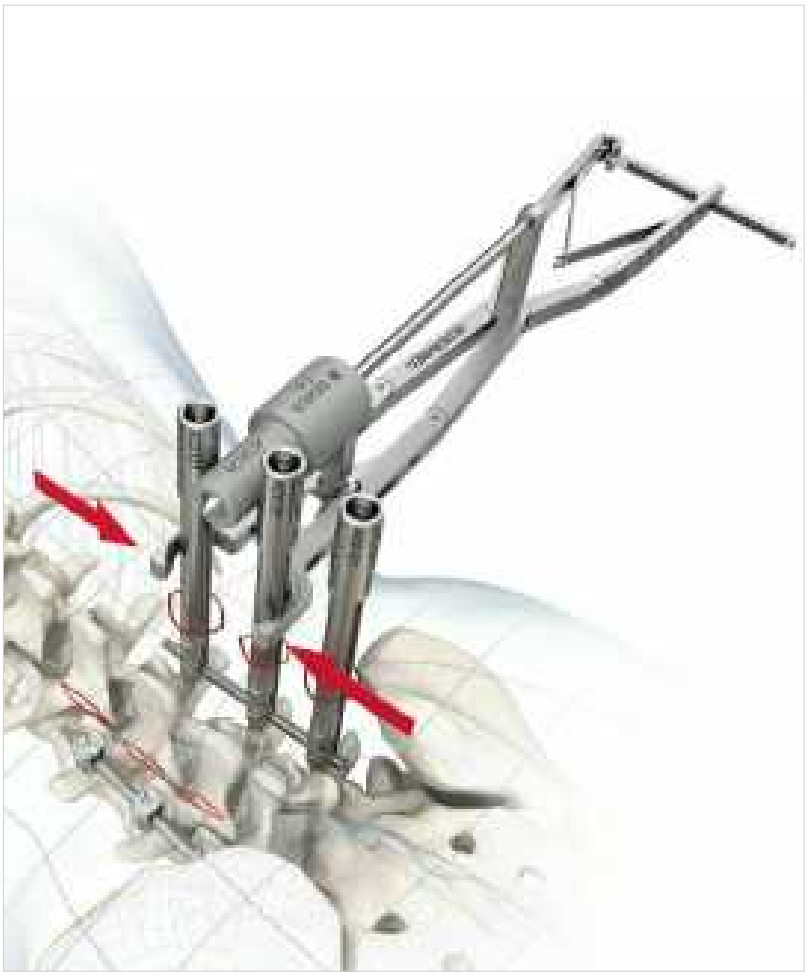
Before the set screws are definitively tightened with the torque limiter (AC0017 and AC0032), distraction or compression manoeuvres can be carried out using the distractor/compressor (MP 1031) with the associated sleeve (AC0124). The distractor/compressor is multifunctional combining both functions in a single instrument. The orientation of the instrument for the desired application is determined when the laser-marking of the application is visible.

A. For distracted/compressed one set screw is tightened in order to create a fixed point. The set screw of the screw to be distracted/compressed should be loosened by a quarter rotation.

B. The distractor/compressor (MP1031) is positioned between the tulips to be distracted or compressed and the tulips are distracted or compressed until desired result is achieved.

C. To help with the lever action, a distraction/compression sleeve (AC0124) with a diameter of 20/30 mm can be mounted on the central lever arm.

D. After completing the distraction/compression, the set screws are tightened using the torque limiter and the distractor is removed.



CAUTION

To create a fixed point for the distraction, it must be ensured that only the set screw is tightened and the set screw of the screw to be distracted/compressed is lightly tightened by hand otherwise misalignment may occur!

Final fixation of the set screws

1. Before final fixation of the screws the counter torque (AC0020) must be positioned on the screw head with the handle either perpendicular to or in parallel with, the rod.

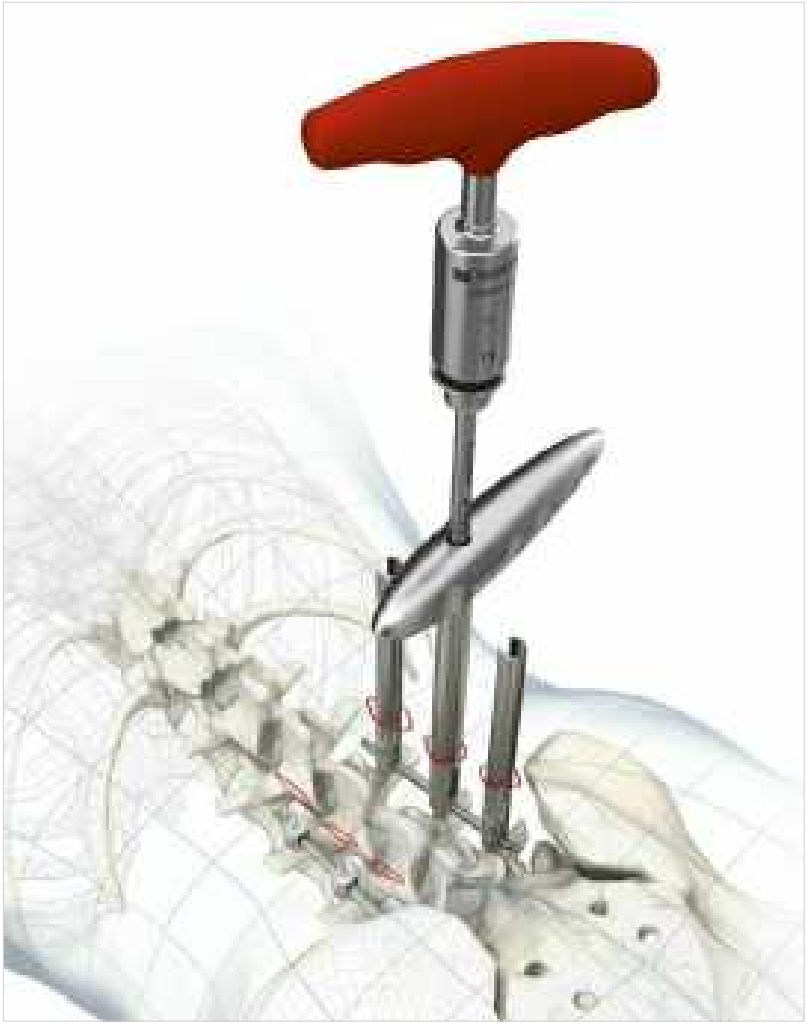
2. The final set screwdriver (AC0017-B) is connected to the 11 Nm torque limiter.

3. The set screws are tightened until a click is felt and heard. This indicates that the required torque has been reached.

4. Repeat the process for all the set screws.

CAUTION

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

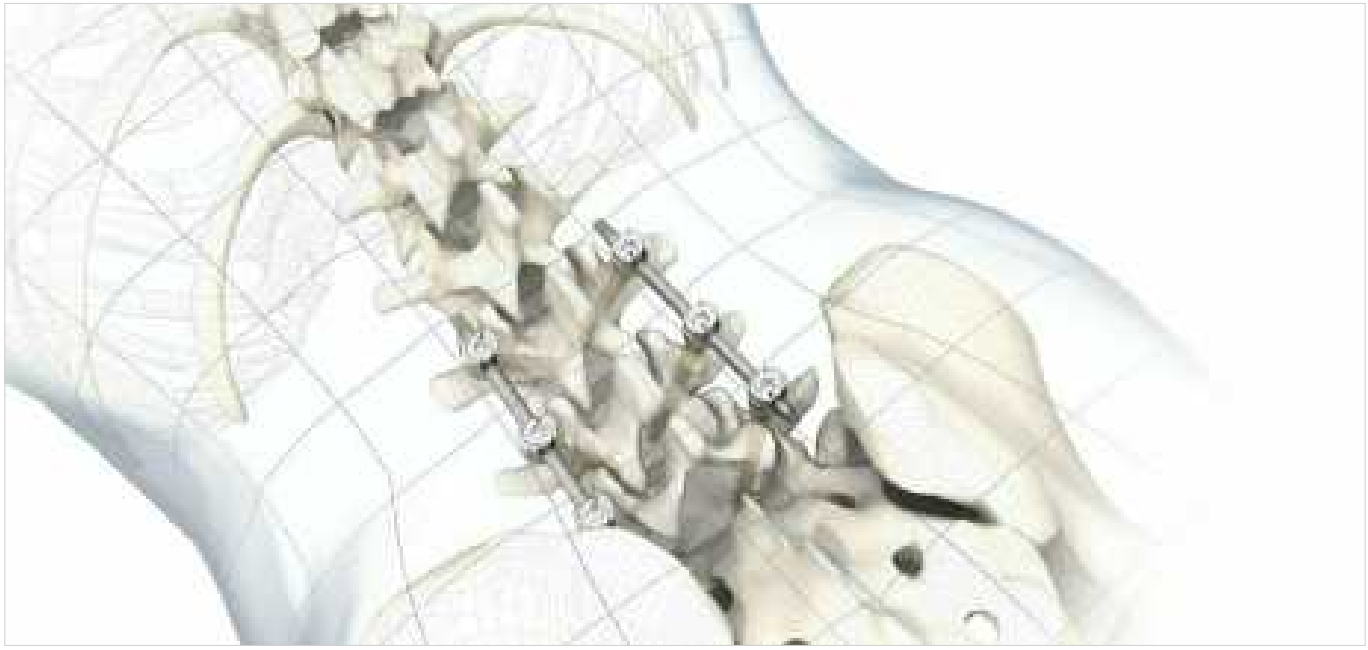


SURGICAL TECHNIQUE

Breaking the tulip tabs

1. To break off the tabs of percutaneous tulips, first introduce the guide instrument for the tab remover (AC0119) over the tulip up to the rod. The instrument prevents the tulip splaying when the tab is broken off.
2. The tab remover (AC0118) is inserted over a tab of the tulip. Move the instrument carefully back and forth from lateral to medial. This safely breaks off the tab. The separated tab remains in the instrument and must be removed.

Final instrumentation



SURGICAL TECHNIQUE – OPTIONAL AUGMENTATION

Augmentation

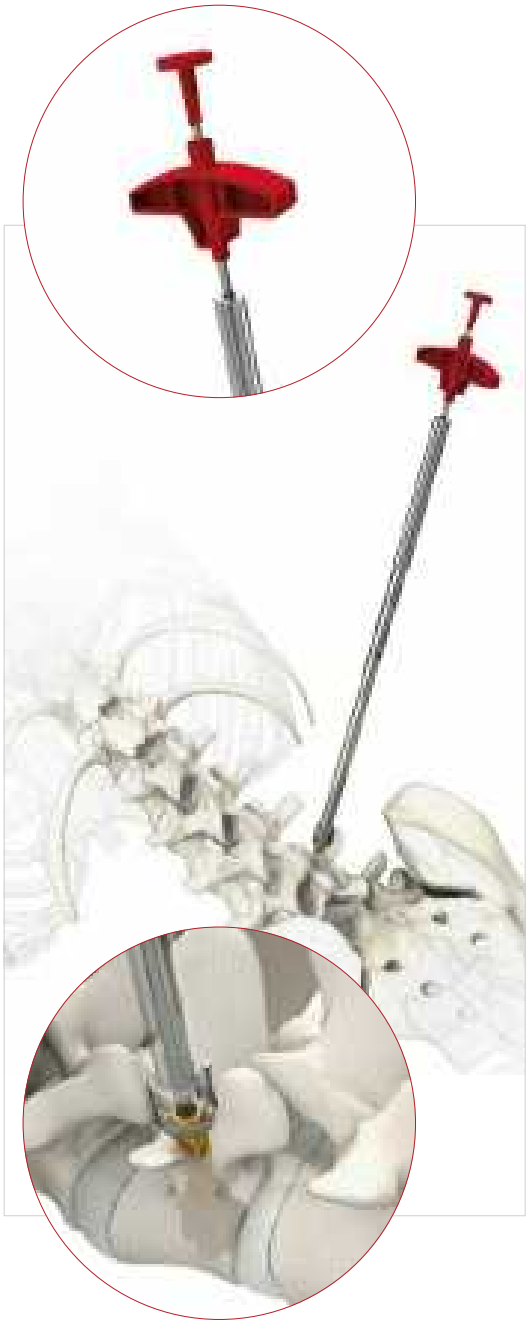
Depending on the indication cemented may be injected into the vertebral body. Such augmentation is performed before inserting the rod.

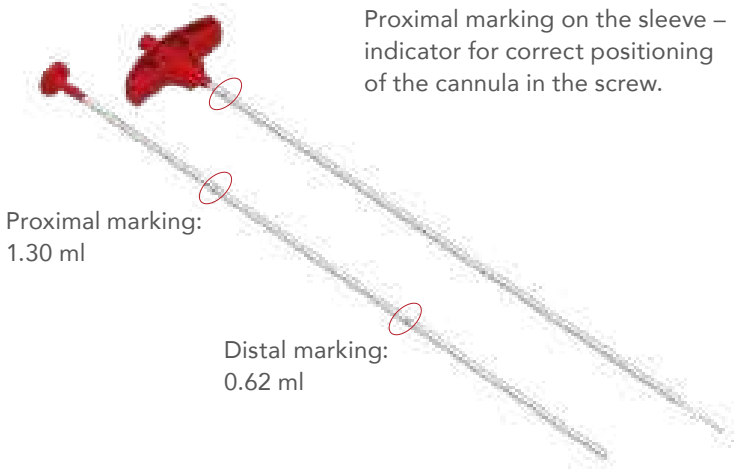
1. DIPLOMAT® screws can be used with either low viscosity or high viscosity vertebroplasty bone cement.
2. Before using the cement, it is essential to read the instructions and recommendations of the bone cement manufacturer!
3. Cement must be mixed according to the manufacturer's instructions before filling the cement cannulas. It should have a toothpaste-like consistency and should not be too liquid.
4. A guide sleeve (AC0040) is threaded into the tulip of each screw to be augmented. Thread it into the tulip by turning the guide sleeve clockwise.
5. It is ESSENTIAL to ensure that the TIP of the guide sleeve sits completely inside the screw head!
6. Remove the obturator from the cement cannula (SM-SF0927) and fill the cannula with cement.
7. Push cement into the cannula using the obturator until it emerges from the distal end. Remove the extruded cement from the end of cannula and wait until the cement can be applied according to the manufacturer's instructions.
8. Each cement cannula holds a maximum of 2 ml of cement. Laser markings on the plunger indicate the volume of cement that has been injected.

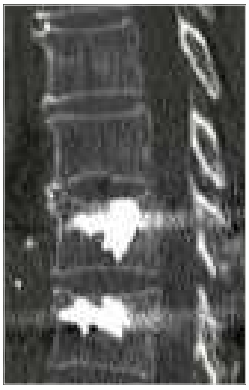
   Distal marking: 0.62 ml
   Proximal marking: 1.30 ml

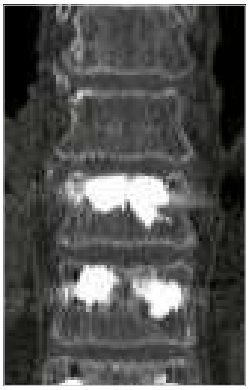
CAUTION

The marking on the proximal sleeve indicates when the cannula is seated correctly in the screw. It must be flush with the proximal end of the guide sleeve. Once the cement is ready for injection, inject the cement through the cement cannula. Slowly, under radiographic guidance, the cement is forced out of the screw into the vertebral body by advancing the obturator.









NOTES

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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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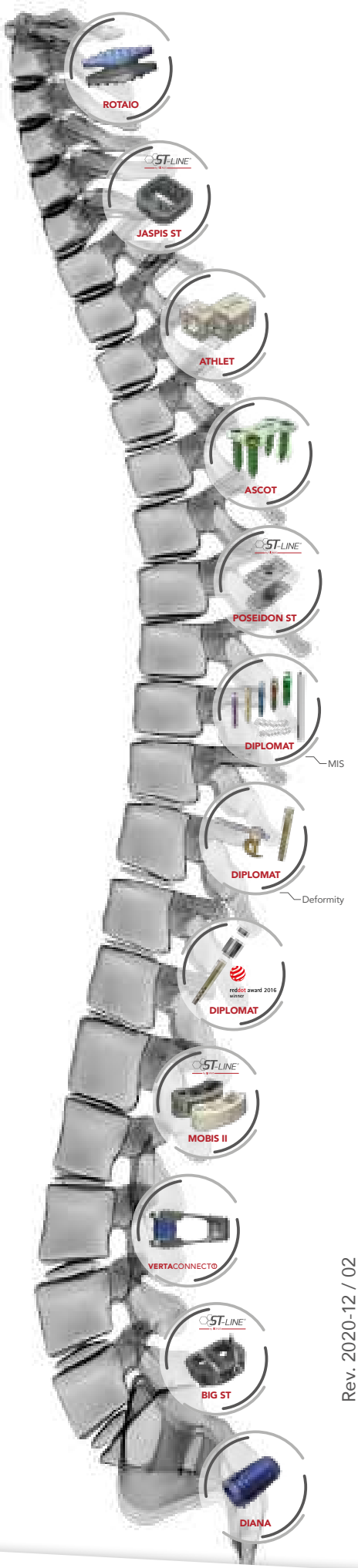

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