DIPLOMAT®

Product description:
The modular DIPLOMAT pedicle screw system is a rod-screw system which firmly connects two or more screws via the screw head and a rod in a force-fit or form-fit connection. Additional fixation elements, such as cross bars, hooks and connectors, can also be used. The DIPLOMAT pedicle screw system is applied temporarily to provide internal posterior stabilisation until bone fusion in the lumbar or thoracic spine has taken place. The surgeon makes the final decision as to the indwelling time of the implant in the patient's body and the time when the implant is to be explanted. The pedicle screw system is implanted from a posterior approach. The implant is screwed into the vertebral body via the pedicle and it can be applied in a single segment or multiple segments. This can be carried out as an open, mini-open or minimally invasive (MIS) procedure using the corresponding instruments. The percutaneous tulips for the MIS technique (AB0030-55001) can be preoperatively shortened to two different lengths (50 mm and 80 mm) by the surgeon. For this purpose, SIGNUS supplies a breaking sleeve (AC0120). After breaking the sleeve, the safety sleeve for percutaneous tulip AC0121 must be placed on the tulip to prevent possibly injury to the surgeon due to protruding burrs on the end pieces. The rods must not be bent either repeatedly or too acutely. The rods must not be repeatedly bent back and forth at the same point. It is particularly important to ensure that the surfaces of the implant are not scratched or notched because this can have a negative effect on the functional stability of the construction. It must also be ensured that the tulip projects at least 5 mm over the rods and that the rods lie level in the tulip. Inserting the implants has been tested and developed using SIGNUS instruments exclusively. The augmentable DIPLOMAT pedicle screw system can be optionally used with cement for improved anchorage in bone that is of lower density (osteoporosis). For treatment of spinal deformities, DIPLOMAT and the hook-rod system LSZ3 can be used as a hybrid system. Our product information provides further system-related information on the surgical method. Separate instructions for use are available for the LSZ3 fixation system. If there are any preoperative uncertainties relating to the implant, information must be obtained from SIGNUS.

Indications:
The system is indicated for stabilisation of the spine until stability has been achieved in patients who have undergone surgical fusion of the spine:
- Fractures
- Postoperative or degenerative instability
- Tumours and spondylodiscitis
- Spondylolisthesis
- Disc prolapse
- Stenosis
- Disc resection
- Pathological lordosis/kyphosis/scoliosis
- Osteoporosis
- Revision surgery

The system is furthermore indicated in situations where external immobilisation 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 leucocytosis
- 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 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 disorders, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance)
- Cases not mentioned under Indications

Material:
Titanium alloy (Ti6Al4V) as per ASTM F 136 / ISO 5832-3.
For all products made of titanium alloy Ti6Al4V:
Nickel-free as per ASTM F 136 / DIN ISO 5832-3
Nitrogen 0.05% max., carbon 0.08% max., hydrogen 0.012% max., iron 0.25% max., oxygen 0.13% max., aluminium 5.5–6.5%, vanadium 3.5–4.5%, remainder titanium.

Cobalt-chrome-molybdenum alloy as per
ASTM F 1537 / ISO 5832-12: Carbon 0.14% max., chrome 30.0% max., molybdenum 7.0% max., nickel 1.0% max., iron 0.75% max., silicon 1.0% max., manganese 1.0% max., nitrogen 0.25% max., remainder cobalt.

The implants are coated with oxide layers in different colours for easy identification. Colour changes are due to product-specific factors and have no impact on the functionality.
All materials used are biocompatible.
This product was not tested with regard to safety and compatibility in an MR environment. This product was not tested with regard to heating or migration in an MR environment.

Sterility:
- Non-sterile implants are supplied in suitable protective packaging or in the implant tray.
- Store implants in the original packaging or in the implant tray.
- Sterile implants are delivered in double sterile packaging and are gamma-sterilised in accordance with DIN EN ISO 11137.

Warnings for sterile implants:
- Store implants in the original packaging
- Check expiry date and intactness of the sterile packaging before use
- Do not remove implants from their protective packaging until directly before use
- Sterile implants are intended for single use. They are not reusable – re-use can lead to infection, implant failure and/or death
- Implants with opened sterile packaging are not accepted back by SIGNUS

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CE 0483

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Reprocessing:
Non-sterile implants and instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing
- Products with cavities as well as gaps, threads, joints and springs must be placed in an ultrasound cleaning bath for 10 minutes at 40° C in a 0.5 % alkaline cleaning solution and then rinsed / flushed for 20 seconds with cold mains water at about 4 bar static pressure (mains pressure).
- Sterilisation must be carried out under the conditions described
  - Procedure: Steam sterilisation method (fractionated pre-vacuum method)
  - Temperature: Minimum 132° C, maximum 137° C
  - Cycles: At least 4 pre-vacuum pulses
  - Sterilisation duration: At least 4 minutes
  - Drying time: 30 minutes
- Observe the validated reprocessing procedure in the instructions included with the tray (valid version: eifu.signus.com)!

Implants:
If not precluded on the commercial packaging or the primary packaging, a non-sterile implant may be reprocessed, provided this is compatible with the hospital guidelines and provided appropriate validated cleaning and sterilisation processes have been established.
- Completely remove all components of the packaging prior to reprocessing
- Where applicable, implants must be stored in the SIGNUS implant trays only

The implant and instrument tray must undergo a validated cleaning process before being returned to SIGNUS. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

Labelling:
Explanation of the symbols that may be used on the packaging of SIGNUS products:

CE 0483	CE marking		Manufacturer and date of manufacture
	Do not re-use	STERILE R	Radiation sterilised
REF	Article number	NON STERILE	Non-sterile
	Use by	LOT	Batch code
	Do not resterilise		Observe instructions for use
0°C 35°C	Temperature limitation		Do not use if packaging is damaged

Warnings:
- The spinal implants are intended for single use and must not be re-used. Re-use of an implant can cause implant failure, infections and/or death.
- 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.

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

Precautions:
- Store implants and sterile instruments in their original packaging.
- Do not remove implants from their protective packaging until directly before use.
- Check expiration date and intactness of the sterile packaging before use.
- Before opening the packaging, check that the packaging is intact.
- The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.
- Do not forcibly hammer the implant into place.
- Particular attention must be paid to the protection of nerve roots.
- The DIPLOMAT pedicle screw system has exchangeable tulips. After mounting the tulips, verify correct connection between tulip and screw. Each tulip may not be changed more than once. Detailed information in this regard is provided in the product information.

Application:
- The attending physician, who must be trained and experienced in carrying out spinal interventions, is responsible for determining the indication, selecting the implant and performing the implantation.
- All information about the surgical technique, the range of implants, the instruments and their use is provided in detail in the SIGNUS product information. This information must be available on-site and must be known to the surgical team.
- Before performing the surgical intervention, it must be ensured that all required implants and instruments are available on-site and that they are in good working order.
- If there are any preoperative uncertainties relating to the implant system, information must be obtained from SIGNUS.
- Before the surgical intervention, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and with use of the implant.
- When inserting the implant, refrain from using excessive force in order to protect the adjacent vertebral bodies.
- During and after the implantation process, the correct position of the pedicle screws and the rods must be verified radiographically
- The implant used must be documented in the patient record, indicating the article number, designation and batch 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 sporting activities of any kind. Falls and sudden, jerky 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 the patient's individual requirements.

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Risks:
General risks associated with a surgical intervention and complications that can arise in connection with a surgical intervention on the spine are not listed in detail in these instructions for use.
Possible, but not typical consequences of a surgical intervention on the spine are:

- Neurological loss of function, including paralysis, occurrence of nerve root disorders
- Pain with possible follow-up surgery
- Pressure on the skin by component parts in patients with inadequate tissue cover above the implant
- Death

Potential risks and complications that are related to pedicle screw systems may necessitate a repeated surgical intervention. These comprise, but are not limited to:

- Wear, bending out of shape or breakage of implant components
- Loss of fixation, dislocation, subsidence
- Sensitivity to foreign bodies, allergic reactions to the implant materials used
- Incorrect placement
- Infection
- Pedicle fracture
- Pedicle/nerve root perforation
- Nerve root/spinal canal injury
- Injury and vascular damage due to bone cement leakage (e.g. PMMA)
- Visceral injury/deep infection
- Temporary paraparesis
- Pseudoarthrosis
- Screw loosening

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, nerve structures and blood vessels.
Adverse events related to the use of bone cement must be taken into account. The pedicle screw system is intended for single use and is not reusable. Re-use can lead to infection and/or breakage of implant components.

Product warranty:
SIGNUS Medizintechnik GmbH guarantees that every spinal implant has been manufactured, packaged and tested with the greatest possible care using selected materials and that all processes involved are subject to continuous quality control. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which a spinal implant is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the spinal implant after it has left the factory, SIGNUS Medizintechnik GmbH gives no warranty either for the success of the procedure or for the non-occurrence of complications. Please inform SIGNUS immediately of any (potential) malfunction of which the user is aware, including the article number(s) and the lot number(s).