DIPLOMAT®

Device description:
The modular DIPLOMAT® pedicle screw system is a rod-screw system that firmly connects two or more screws via the screw head and a rod using a force-fit or form-fit connection. Additional fixation elements, such as cross bars, hooks, connectors and washers, can also be used. The DIPLOMAT® pedicle screw system is applied temporarily to provide internal posterior stabilization 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. Implantation is facilitated by use of the specially developed instruments for inserting and positioning the implants. Only these instruments ensure safe use. Our product information provides further system-related information on the surgical method. If there are any preoperative uncertainties relating to the implant, information must be obtained from SIGNUS.
Instruments specially developed by SIGNUS to ensure safe application are available for use with the implant system.

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.

Material:
The implant is made of the following material:
- Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3
- Cobalt-chrome-molybdenum alloy as per ASTM F 1537 / ISO 5832-12:

For all products made of titanium alloy Ti-6Al-4V:
Nickel-free as per ASTM F 136 / 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: 0.014 % 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 caused by factors related to production and reprocessing and do not affect the functionality. The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant and non-toxic in the biological environment.

Sterility:
Sterile implants are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137. They are intended for single use only and are not reusable. Reprocessing and / or reuse can result in infection and / or loss of function and in extreme cases may lead to the death of the patient. Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly. Implants and instruments supplied non-sterile must be processed before use in accordance with hospital guidelines. The implants and instruments are shipped in implant / instrument trays provided by SIGNUS or in a suitable protective packaging for re-orders. Implants and instruments must be stored in their original packaging or in the implant / instrument tray.

Reprocessing:
Non-sterile implants and instruments must be prepared before use. Before processing, all parts of the packaging must be completely removed.

- Maximum permissible temperature during processing: 137° C
- Processing approved by the manufacturer
- All non-sterile products must be processed in the SIGNUS trays
- Preparation before cleaning, if necessary ultrasonic bath
- Recommended cleaning: Mechanical, cleansing and disinfection device, validated according to EN ISO 15883, mild-alkaline cleaner.
- Recommended disinfection: Thermal, > 90° C, > 5 min. or A0 value ≥ 3000
- Drying: up to 120°C, 20 min.
- Packaging: According to EN ISO 11607 and EN 868.
- Recommended sterilization: Moist heat, 132° C4 min hold time, EN ISO 17665
- Sterile items must be dry

Before returning the used implant and instrument tray must go through a validated cleaning process. This must be documented on the accompanying document and enclosed with the return.

- Due to the product design and the basic materials used and their processing, a limit on the number of reprocessing cycles cannot be set across the board.
- The service life of the products is rather determined by their function, the gentle preparation according to these instructions and the careful handling of the products.
- The user recognises the end of the usage cycle by the possible errors in the visual inspection specified in the reprocessing instructions.

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

	Do not re-use		Sterilised using irradiation
	Item number		Non-sterile
	Use by		Batch code
	Do not resterilise		Consult the electronic instructions for use (eifu.signus.com)
	Temperature limit		Do not use if package is damaged
	Manufacturer and date of manufacture		

Storage and transport conditions:
Store the products between 0°C and 35°C. During transport, temperatures of up to 40°C for short periods can be tolerated.

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 sterile and fit for purpose.
- Prior to implantation, examine the implant for integrity and check the given size with the instruments for comparison.
- Before surgery, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and from use of the implant, as well as of postoperative behavior.
- The operation must be carried out under fluoroscopy. The correct position of the implant system used must be verified radiographically.
- The implant must not be scratched or notched, as this can lead to a reduction in mechanical stability.
- 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.

SIGNUS Medizintechnik GmbH I Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161 I info@signus.com I www.signus.com

SIGNUS The Spine Sign®

Precautions:
- The physician / surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions which may impact the performance of the systems.
- Carefully check and remove any bone splinters following resection.
- Prior to implantation, check the required implant size.
- The selection of size and implantation of the implant remain the exclusive responsibility of the user surgeon who must be experienced in spinal surgery.
- It is imperative that dissimilar metals do not come into contact in vivo. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
- The devices have not been evaluated for safety and compatibility in the MR environment.
- The DIPLOMAT® pedicle screw system has exchangeable tulips. After mounting the tulips, verify correct connection between tulip and screw. Detailed information in this regard is provided in the product information.

Risks:
These instructions for use do not list the general complications associated with surgery or the complications that can arise in connection with spinal surgery. The following are potential risks and complications that are related to the implant and that may necessitate a repeat operation:
Potential adverse effects may include, but are not limited to the following:
- Bending, disassembly or fracture of any or all implant components.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin, seroma or wound dehiscence.
- Dural leak, pseudomeningocele, or fistula requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed / nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture.
- Early or late loosening of spinal fixation implants.
- Peripheral neuropathies, nerve damage, neurovascular compromise, paralysis, loss of bowel or bladder function, or foot-drop. Other neurologic adverse events may include motor or sensory loss, spasms, parasthesia, paraparesis, cauda equina syndrome, numbness and decrease or total loss of reflexes and / or muscle tone.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders; including thrombus; bronchopulmonary disorders, including emboli, atelectasis, pneumonia and ARD; bursitis, hemorrhage, seroma, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of the bone graft, the intervertebral body, pedicle, and / or sacrum above and / or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.
- Heterotopic bone formation.
- Graft site pain, fracture or wound healing problems.
- Tissue reaction to the implant, debris or corrosion of the implant material.
- Disc herniation and degeneration of adjacent discs.
- Decreased ability to perform activities of daily living.
- These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, nerves and blood vessels.

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.

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 leaving 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). All serious incidents that occur in relation to the product must also be reported to the competent authorities of the Member State where the user and / or patient resides.