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 accessories for inserting and positioning the implants. Only these accessories 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.

Caution:
- These implants are intended for single use only and should not be re-implanted.
- Federal law restricts this device to sale by or on the order of a physician.

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.

Complications:
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.

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

SIGNUS The Spine Sign®

- 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.

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.

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.

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

Material:
The implant systems are made from titanium alloy (Ti6Al4V) in accordance with ASTM F 136 / ISO 5832-3 and cobalt chromium per ASTM 75-12.

The implants are coated with oxide layers of different colors for easy identification. Color changes are due to product-specific factors and have no impact on the functionality.

All materials used are biocompatible. The DIPLOMAT® pedicle screw system has not been evaluated for safety and compatibility in the MR environment. The DIPLOMAT® pedicle screw system has not been tested for heating or migration in the MR environment.

Sterility:
The SIGNUS DIPLOMAT® components are provided non-sterile and should be stored in their original packaging until sterilized according to the recommended guidelines accompanied by the implant and instrument trays. Implants are single-use devices, thus do not clean or resterilize an implant that has been in contact with or contaminated by blood or other infectious substances. If the product is sterilized by the hospital in a tray or case, it should be sterilized in a tray or case provided by SIGNUS. The manufacturer and distributor assume no responsibility for cleaning and resterilization of implants, components, or reusable instruments performed by the individual or hospital.
It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications listed below:

Recommended Sterilization Parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 minutes	30 minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

Reprocessing:
Implants: If not precluded on the commercial packaging or the primary packaging, a non-sterile implant may be reprocessed, provided that this is compatible with the hospital guidelines and appropriate validated cleaning and sterilization 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.

Instruments: Instruments must be reprocessed before use. See the SIGNUS Processing Instructions for cleaning instructions for reusable instruments below.

Pre-Cleaning
- Disassembly of the products, if possible.
- Immerse the products in cold regular tap water without any bubbles for a minimum of 5 minutes.
- Depending on the severity of contaminational moveable components have to be moved several times under regular running tap water; free accessible sections have to be brushed.
- Products with cavities as well as connections, threads, joints, hinges and springs have to be soaked in an ultrasonic bath for 10 minutes at 40°C with 0.5% solution of alkaline cleaner (e.g. neodisher FA) and then rinsed from the inside and outside with a water spray gun at 4 bar static power for minimum 20 sec. with cold regular tap water.
- Surfaces have to be brushed with a soft brush until visable contaminations are removed completely.

Automated Cleaning
- Products have to be placed in the tray of the purifier/disinfector (e.g. Miele G7735). Products with a cannula have to be placed in the MIS-Tray and have to be connected to the wash up system [MIS=minimal invasive surgery].
- Clean the products e.g. with the Vario TD program as follows:
  - Minimum 2 min pre-washing with cold regular tap water
  - Drain
  - Dose the cleaning agent (e.g. neodisher FA Dr. Weigert, Hamburg, Germany)
  - 5 min cleaning with neodisher FA 0.5% at 55°C or equal cleaning agent
  - Drain
  - 3 min neutralization with warm water (> 40°C)
  - Drain
  - 2 min intermediate rinsing with warm water (> 40°C)
  - Drain

Disinfection
Automated operation: Automatic thermal disinfection, maximum 93°C in the purifier/disinfector (part of the Vario TD program) following the national requirements regarding the A0 value. [In the standard EN DIN ISO 15883-1:2009, appendix A the definiton A0 is as a measuring unit of time and kinetics regarding the killing of microorganismus at the procedure with most heat].

Drying
Automated operation: Dry the products in the purifier/disinfector (one drying cycle, part of the Vario TD program), if necessary the products can be dryed with a lint-free fabric.

Functional check maintenance package
- Visual auditing of results of the previous steps; assembling of all disassembled products; function check.
- Maintenance and care measures: Maintenance or care means targeted application of care agents to moving parts, the joints, hinges, locks, threads etc. or friction surfaces of products after they have been carefully cleaned and disinfected. This prevents metal-on-metal friction and therefore constitutes a preventive measure against corrosion caused by such friction. In this way, the products are kept functional and hinge action maintained. Requirements for care agents: Paraffin/white oil basis, in accordance with the current European or United States Pharmacopoeia, suitable for steam sterilization, vaporpermeable and biocompatible. Single products have to be double-packed in sterile bags, Trays have to be wrapped in sterile fabric.

Sterilization
- Operation: Steam sterilization (fractionated prevacuum-operation)
- Temperature: minimum 132°C, maximum 137°C
- Cycles: minimum 4 times pre-vacuum
- Sterilization duration: minimum 4 min;
- Drying duration: Drying time in accordance to the setting of the sterilizer, sterile products have to be dry for DIPLOMAT® tray 30 min.

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.

Storage:
Store the sterilised instruments in a dry, clean and non-fuzzing environment at room ambient temperature.

Further Information:
Recommended directions for the use of these systems (surgical operative techniques) are available at no charge upon request. For additional information please contact:

SIGNUS Medizintechnik GmbH
Industriestr. 2
63755 Alzenau/Germany
Phone: +49 (0) 6023 9166-0
Fax: +49 (0) 6023 9166-161
info@signus.com
www.signus.com

Product Guarantee:
SIGNUS Medizintechnik GmbH guarantees that each individual spinal SIGNUS Medizintechnik GmbH guarantees that each individual spinal implant is manufactured with the greatest of care and from selected material. The entire process, from manufacture to final packaging, is under constant quality control. However, given that SIGNUS Medizintechnik GmbH has no influence over the selection or use of the implant, the diagnosis of the patient or the surgical technique used, or the handling of the implant following dispatch from our company, no guarantees can be given regarding a successful surgical result or the lack of complications.