CONKLUSION®, DIPLOMAT®, DIPLOMAT® Deformity, MONOPOLY™

Product description:
CONKLUSION®, DIPLOMAT®, MONOPOLY™ are rod/screw systems for use in the thoracic and lumbar spine and are used for internal posterior stabilisation.
The systems are used in one or multiple segments until bony fusion of the spine has occurred. SIGNUS provides a complete selection of components for the system, all with sophisticated design. The DIPLOMAT® pedicle screws are available as one- or two-part implants. The polyaxial screws can be individually combined with the separately available standard, reduction and MIS tulips depending on the indication and surgical situation. The tulip can be exchanged in situ if required. The monoaxial screws are available as one-part implants. MONOPOLY™ and CONKLUSION® are not modular and are only available as one-part implants.
DIPLOMAT® or MONOPOLY™ (combined with NEVIO®) can be used in open, percutaneous or minimally invasive (MIS) procedures with the corresponding instruments.
CONKLUSION® is used exclusively in open instrumentation. With the help of the repositioning device, complex repositioning manoeuvres can be performed.
The cannulated and fenestrated DIPLOMAT® and MONOPOLY™ pedicle screws can alternatively be cemented for improved anchorage in bone with low density (osteoporosis). CONKLUSION® screws are not cannulated and fenestrated. Augmentation through the screw is not possible. For the treatment of spinal deformities, DIPLOMAT® Deformity can be used together with the infralaminar hooks. LSZ is a hook-based system for use on the thoracic and lumbar spine (TH2–S2). It joins two or more hooks to a rod using frictional and positive locking connection. The laminar hook is inserted infralaminar and is an alternative fixation method. The implants are available in various dimensions to enable adaptation to different patient anatomies and are supplemented by additional implant components such as cross-connectors and parallel connectors as well as straight and curved rods.
Implantation is facilitated by use of the specially developed accessories for insertion and positioning of the implant. Only these accessories ensure safe use. The corresponding product information provides further system-related information on the surgical method.

Product family	Product variants	Instruments
MONOPOLY™	MONOPOLY™	MONOPOLY™
	MONOPOLY™ VC	MONOPOLY™ VC
	MONOPOLY™ VC (MIS)	NEVIO® + MONOPOLY™ VC
	MONOPOLY™ II	MONOPOLY™ II
	MONOPOLY™ II SP	MONOPOLY™ II
	MONOPOLY™ II VC	MONOPOLY™ II VC
	MONOPOLY™ II SP VC	MONOPOLY™ II VC
	MONOPOLY™ II SP FS	MONOPOLY™ II VC
DIPLOMAT®	DIPLOMAT®	DIPLOMAT®
	DIPLOMAT® MIS	DIPLOMAT®
	DIPLOMAT® Deformity DIPLOMAT® Deformity-LSZ	DIPLOMAT®
CONKLUSION®		CONKLUSION®

Reduction screws must not be used in conjunction with NEVIO®.

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
  (does not apply for MONOPOLY™ and CONKLUSION®)
- 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
- Rapidly progressive arthropathy, bone absorption, osteopenia (depending on the pedicle screw system used), osteomalacia or osteoporosis. Osteoporosis and osteopenia are relative contraindications, as these conditions may limit the scope of redressement or mechanical immobilisation (this does not apply for usage of DIPLOMAT®, DIPLOMAT® MIS, MONOPOLY™ II SP FS)

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Material:
The implants are made from the following materials:
- 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

Composition:
Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3.

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 %, rest 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. Re-use can result in infection and/or loss of function, which in extreme cases can lead to the death of the patient. 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 that appropriate validated cleaning and sterilisation processes have been established. Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly. Broached packaging units will not be accepted as a matter of principle.
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 reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing.
- All non-sterile implants and instruments must be reprocessed in the SIGNUS trays.
- Follow the validated reprocessing procedure in the instructions included with the tray.
- Products with cavities as well as gaps, threads, joints and springs must be placed in an ultrasonic 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).

During sterilisation the following must be noted:
- 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: Adjust the drying time in accordance with the loading of the steriliser; items to be sterilised must be dry

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 Sterilised using irradiation
REF Item number	NON STERILE Non-sterile
Use by	LOT Batch code
Do not resterilise	eIFU Consult the electronic instructions for use (eifu.signus.com)
0°C 35°C Temperature limit	Do not use if package is damaged

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 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.

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

Precautions:
- Store sterile implants in their original packaging.
- Do not remove instruments from their protective packaging until immediately before use.
- Check expiry date and integrity of the sterile packaging before use.
- Check the implant for scratches and other obvious damage. A damaged implant must not be used.
- It is not permitted to combine implants made of different metallic materials unless this is expressly intended by SIGNUS.
- The DIPLOMAT® pedicle screw system has exchangeable tulips. After mounting the tulips, verify correct connection between tulip and screw. A tulip must not be changed more than once. Detailed information about this is provided in the product information.
- The DIPLOMAT® pedicle screw must not be implanted without a tulip! There is a risk of inserting the screw too deeply and subsequent attachment of the tulip cannot be reliably guaranteed. The polyaxial screw head must remain freely mobile and must not be constricted by bony structures. If necessary, the screw height must be adjusted.
- When using cement applicators, a 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 into the pedicle screw head using the cement applicator. Slowly, and under radiographic guidance, the cement is pushed through the screw into the vertebral body using the obturator.
- To protect the spinal cord and nerve roots, when using guide wires ensure that the wires are not advanced beyond the desired position during surgery.
- 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. Detailed information about this is provided in the product information.
- To create a stabilisation point for the distraction manoeuvres, it must be ensured that only one set screw is tightened and the set screw of the screw to be shifted is only tightened by hand. Otherwise, misalignment might occur!
- When using DIPLOMAT® Deformity with infralaminar hooks LSZ, the tip of the hook must remain in contact with the interior surface of the lamina throughout in order to prevent injury to the dura.

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 surgery, ensure that all necessary implants and instruments are to hand and fit for purpose.
- 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 spinal cord, the nerve roots and the adjacent vertebrae.
- The surgery must be carried out under fluoroscopic guidance. The correct position of the implant must be verified using radiography.
- The implant must be firmly connected to the inserter intended for the implant to prevent damage to the implant and potential injury to the patient. The instructions for assembling the instrument are described in the corresponding product information.
- For osteoporotic bone, the use of bone cement is recommended.
- The position of the rods should be checked after implantation. It is necessary that they extend beyond the tulip, particularly MIS rods.
- For DIPLOMAT® a secure hold between the tulip and screw must be checked. To do so, pull on the tulip while firmly holding onto the shaft of the screw. If the tulip remains coupled to the screw, the connection is secure.
- The final fixation of the set screws must be performed with the SIGNUS torque limiter with the user of the counter torque pedicle screw. The required torque (Nm) is specified in the corresponding product information.
- The implant used must be documented in the patient record, indicating the article number, designation and batch number. All necessary data are indicated on the labels in the original packaging or are printed on the implants and must be pasted into the patient record to ensure lot traceability.
- Aftercare and follow-up examinations 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 for an appropriate postoperative period. This applies in particular to the lifting of loads, rotating movements and any type of sport. Falls and sudden, jerky movements of the operated region 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.

Explanation of the symbols that may be used on SIGNUS implants:

	Lordosis angle	**SW**	Wrench size
	Height of the cage	**CoCr**	Material cobalt-chrome
	Footprint of the cage		

Risks:
These instructions for use do not list the general risks associated with surgery or the complications that can arise from spinal surgery. The following are potential risks and complications related to the implant and which may necessitate repeat surgery:
- Pseudoarthrosis / absence of fusion
- Sensitivity to foreign bodies, allergic reactions or other local / systemic adverse reactions to the implant materials used
- Incorrect placement
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Pedicle fracture
- Lamina fracture (when using lamina hooks)
- Pedicle / nerve root perforation
- Nerve root / spinal canal injury
- Injury and vascular damage due to bone cement leakage (e.g. PMMA)
- Visceral injury / infection and deep wound infection
- Temporary paraparesis
- Wear, bending out of shape or breakage of implant components
- Screw loosening
- Pain or recurrent pain
- Pressure on the skin by components in patients with inadequate tissue coverage above the implant

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, the nerves and blood vessels, which can in extreme cases even lead to death.
Adverse events that are related to the use of bone cement must be taken into account.

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MRI notes:
The safety and compatibility of CONKLUSION®, DIPLOMAT®, DIPLOMAT® Deformity and MONOPOLY™ in an MRI environment have not been not determined. The products have not been tested with regard to heating, migration or artefact formation in an MRI environment.

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).

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