COSY® Cervicothoracic Occipital Rod-Screw System

Product description:
COSY® Cervicothoracic Occipital Rod-Screw System is a posterior system for use in the cervical spine. The implants are used for surgical immobilisation, stabilization and correction of malpositions of the human cervical spine and the cervicothoracic junction, including the occipitocervical junction if necessary. The implants are available in various lengths, diameters and sizes to enable adaptation to different patient anatomies. The decision about possible removal of an implant is the responsibility of the attending physician. The system comprises rods, hooks, screws, polyaxial screws, fixation screws, connecting pieces, occipital plates and occipital screws in various sizes that can be firmly connected to a rod in various configurations.
The system includes transition rods (hybrid rods) from 3.5 mm to 5.5 or 6.0 mm in diameter and parallel rod-to-rod connectors that allow connection of 3.5 mm rods to 5.5 or 6.0 mm rods. These components are intended to allow connection of the COSY® Cervicothoracic Occipital Rod-Screw System to a thoracolumbosacral pedicle screw system (DIPLOMAT® and MONOPOLY™).
The implants are made from a titanium alloy (Ti-6Al-4V). Rods are available in versions made from a titanium alloy or a cobalt-chrome alloy.
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.

The use of the thoracolumbosacral pedicle screw systems (DIPLOMAT® and MONOPOLY™) is not described here and can be found in the corresponding product information.

Indications:
The COSY® Cervicothoracic Occipital Rod-Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 – C7), and the thoracic spine from T1 – T3:
- Traumatic spinal fractures and / or traumatic dislocations
- Instabilities or deformity
- Failed previous fusions (e.g. pseudoarthrosis)
- Tumours involving the cervical spine
- Degenerative disease including intractable radiculopathy and / or myelopathy
- Neck and / or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability

The COSY® Cervicothoracic Occipital Rod-Screw system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumours involving the cervical spine in whom life expectancy is of limited duration to permit achievement of fusion. In order to achieve additional levels of fixation, the COSY® Cervicothoracic Occipital Rod-Screw System may be connected to the components of the DIPLOMAT® System or MONOPOLY™ System using the rod-to-rod connectors or transition rods.

Contraindications:
- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Infectious processes in, on or in adjacent regions of the spine
- Allergy or intolerance to 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, patients in poor general health, systemic or metabolic diseases, lack of patient compliance)
- Surgery precluded due to the physical condition of the patient, e.g. fever or leucocytosis
- 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
- Patient stature too small or too large for the range of instruments and implants
- The use of different metals or components not belonging to the screw system is not permitted
- Cases that are 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.

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®

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° C – 137° C, 4 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.

Labelling:
Explanation of the symbols (according to ISO 15223-1 Medical Device – Symbols to be used with medical device labels, labelling and information to be supplied – Part: General Requirements) that may be used on the packaging of SIGNUS products:

	Do not re-use		Double sterile barrier system
REF	Item number	MD	Medical Device
	Use by	UDI	Unique Device Identifier
	Do not resterilise	LOT	Batch code
	Temperature limit		Consult the electronic instructions for use (eifu.signus.com)
	Manufacturer and date of manufacture		Do not use if package is damaged
STERILE R	Sterilized using irradiation		Caution
	Non-sterile		

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

Warnings:
The spinal implants are intended for single use only and are not reusable. Reuse can result in infection and / or loss of function, including patient death.
- SIGNUS implants may only be inserted with the instruments provided for this purpose. If the implants are inserted using other instruments, correct implantation cannot be guaranteed.
- The indication, selection and implantation are the responsibility of the surgeon performing the procedure, which must be experienced and instructed in performing spinal surgery.
- Unless otherwise stated, SIGNUS products must not be directly connected to the materials / components of other systems.
- Inspection of the implant for scratches or other obvious damage. A damaged implant must not be used.
- Due to potential damage, the implant must not be reinserted after removal from the site.
- When inserting the implant, special attention should be paid to protecting the nerve structures and blood vessels, and refraining from using excessive force.
- The final fixation of the locking screws must be carried out with the SIGNUS torque limiter.
- 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.

Follow-up care and follow-up examinations must be individually tailored to the patient and defined by the attending physician. After the operation, the patient should only be allowed to exercise to a very limited extent for an appropriate postoperative period. This applies in particular to lifting loads, rotating movements and any type of sport. Falls or sudden jerky movements of the operated region should be avoided.

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

Precautions:
The spinal implants are intended for single use only and are not reusable. Reuse can result in infection and / or loss of function, including patient death.
- Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and / or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and / or verify device placement, as necessary.
- Use of posterior cervical screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.
- All information on the surgical technique, the range of implants, the instruments and their use are described in detail in the SIGNUS product information. This information must be available on site and known to the surgical team.
- Before carrying out the operation, it must be ensured that all necessary implants and instruments are available and functional on site.
- Implants (non-sterile, sterile) and single use instruments are to be regarded as potentially infectious after use and are to be disposed of professionally (hazardous medical waste) in accordance with the applicable hygiene and waste disposal regulations. Instruments are to be disposed of analogously at the end of their life or to be professionally processed prior to disposal. Care must be taken to ensure that sharp-edged or pointed implants and instruments are handled with care in order to avoid injuries.
- Storing of sterile implants in the original packaging.
- Only remove products from the protective packaging immediately before use.
- Before use, check the expiry date and the integrity of the sterile packaging. The product must not be used if the sterile packaging is damaged or the expiry date has passed.

- The operation must be performed under fluoroscopy. The correct position of the implant must be checked with an X-ray.
- The implant must be securely attached to the implant placement tool to avoid damage to the implant and potential patient injury.
- In the postoperative phase, it is particularly important to ensure that the treating doctor provides the patient with individual information.

Application:
- Information from SIGNUS must be obtained if the preoperative situation is unclear and is related to the implant system.
- Prior to the surgery, the patient must be informed of all the potential risks and complications associated with the surgery itself and the use of the implant.
- The implant used must be documented in the patient file with article number, designation and lot number. All the data required for this is contained on the labels in the original packaging or printed on the implants and must be stuck into the patient file for batch tracing.
- 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.
- When inserting the implant, refrain from using excessive force in order to protect the spinal cord, the nerve roots and the adjacent vertebrae.
- Particular attention must be paid to protecting the nerve structures and blood vessels.
- The surgery must be carried out under fluoroscopic guidance. The correct position of the implant must be verified using radiography.
- The use of posterior cervical screws, the occipital plate and occipital screws near the cervical vertebrae C0 to C6 requires careful preoperative and intraoperative considerations and planning due to the proximity to spinal arteries and neurological structures. Preoperative planning includes the use of imaging procedures (e.g. CT or MRI images) to evaluate the cervical spine anatomy of the patient, including the transverse foramen and the path of the spinal arteries, prior to implanting posterior screws, occipital plate and occipital screws. If the results should negatively affect the positioning of the lateral mass screws, pedicle screws or occipital screws, other surgical approaches should be considered. The use of intraoperative imaging procedures should be considered to guide and check the positioning of the implants.
- For the use of the occipital plate, the thickness of the occiput must be determined before surgery using imaging procedures so that the correct screw length can be identified.
- When implanting the occipital plate, ensure that it lies flat against the bone. So that the integrity of the occipital plate is not compromised, the plate may only be adjusted between the holes in the bending zones using the corresponding instrument set. The plate may only be bent in one direction and not by more than 15°.
- The screws for the occipital plate must first be fixed hand tight before they are definitively tightened with the torque wrench.
- 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.
- Rods should only be contoured with the appropriate contouring instruments. The rods must not be bent repeatedly, excessively or more than is necessary. The rods must not be bent in the opposite direction at the same point.
- If the rods are cut to the correct length, they should be cut so that a flat, not sharp surface is formed vertically to the midline of the rod. Cut the rods outside the surgical field and use available rod length if possible.
- The final length of the rod should extend 2 mm beyond the end of the screw tulip so that the screw locking mechanism is unaffected.
- If pseudoarthrosis has developed or the components loosen, bend and / or break, the device(s) must be checked and / or immediately removed to prevent serious injuries.

Risks:
General risks of surgery and requirements that may arise in spinal surgery are noted in this use manual. Potential risks and risks associated with the implant that may require revision surgery are:
- Loosening and / or breakage (e.g. with absent or delayed fusion).
- Postoperative loss of correction or changes in the spinal curvature.
- Pseudoarthrosis / absence of fusion.
- Pressure exerted on surrounding tissue by component parts in patients with inadequate tissue cover.
- Sensitivity to foreign bodies, allergic reactions or other local / systemic adverse reactions to the implant materials used.
- Incorrect placement
- In rare cases (0.2 %) an epidural haematoma can develop postoperatively in patients with clotting disorders under anticoagulant therapy.
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis.
- Infection
- Pedicle fracture
- Nerve root/spinal canal injury
- Wear, bending out of shape or breakage of implant components.
- Improper interlocking of the construction can lead to the tulip and rod disassembling.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Bone loss or reduction in bone density, possibly caused by stress shielding.
- Hernia of the nucleus pulposus, intervertebral disc disorder or degeneration at, above or below the level of the surgical procedure.

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.

MRI Safety Information:
The COSY® Cervicothoracic Occipital Rod-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 COSY® Cervicothoracic Occipital Rod-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.