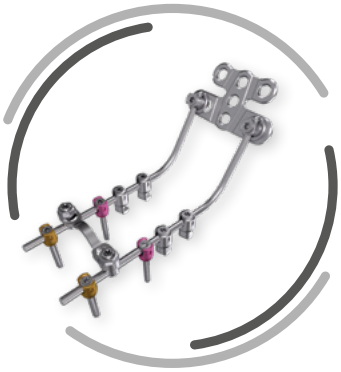
COSY®

Cervicothoracic Occipital Rod-Screw System

Dear Patient,

Changes in the spine due to wear and tear or disease are often accompanied by pain and can severely impair your quality of life. This brochure provides you with information on "stiffening" (fusion) of the spine. It is of a general nature and does not constitute medical advice or a medical recommendation. The information does not make any diagnostic or therapeutic statement about the respective individual medical case.

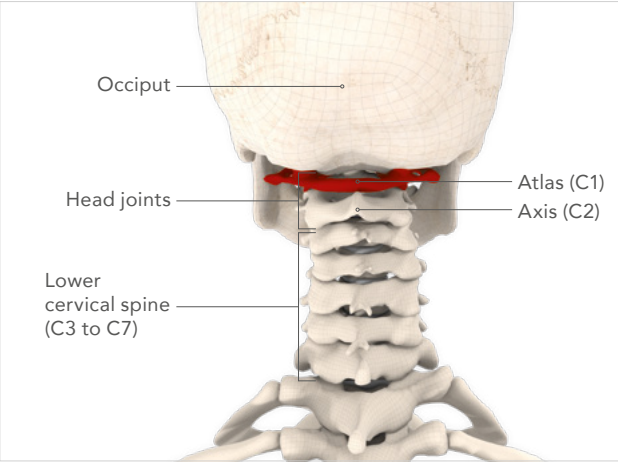


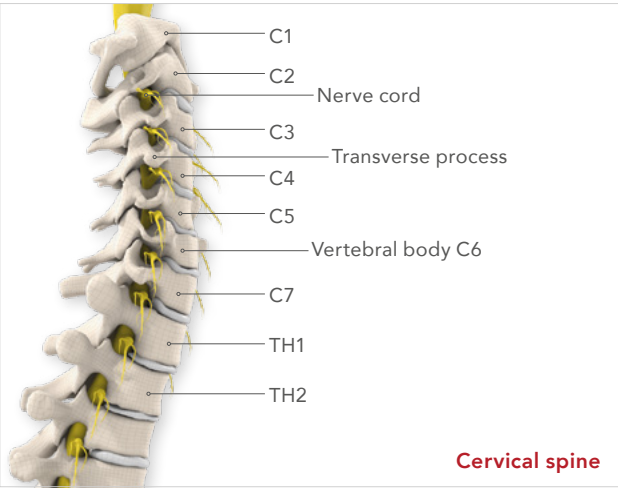
HIGH-END MADE IN GERMANY

The Cervical Spine

The spine is an extremely complex system of bones, cartilage, muscles and nerves and has both static and dynamic functions. It also forms a protective channel for the spinal cord, the exiting nerves and the vertebral arteries that supply blood to the spinal cord, brainstem and cerebellum.

The cervical spine, commonly abbreviated as C (C1 – C7), is the most mobile segment of the spine. It consists of seven vertebrae, numbered from one to seven from top to bottom. The uppermost cervical vertebra is in contact with the occiput, and the lowermost is in contact with the first thoracic vertebrae. Physiologically, the cervical spine has a forward curvature called lordosis. The cervical vertebrae, with the exception of the first two vertebrae (atlas and axis) are firmly connected by intervertebral discs.





Cervical spine

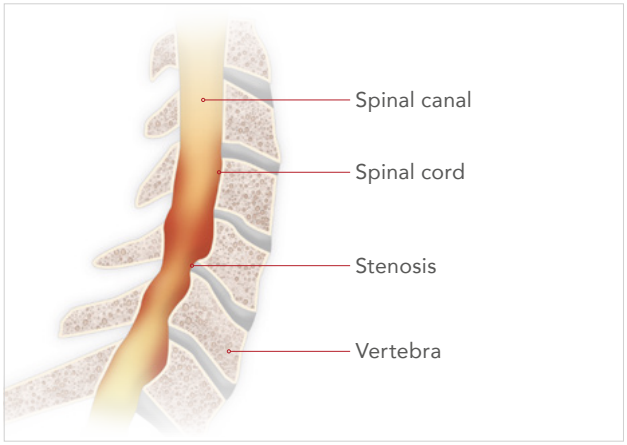
Disease of the cervical spine

The cervical spine is the upper part of the spine and consists of seven vertebrae, referred to as C1 through C7. The two most important segments of the cervical spine are the transitional area between the head and neck and the 7 cervical vertebrae below. The cervical spine is also surrounded by muscles, nerves, tendons and ligaments. Each cervical vertebra performs a specific task in the cervical spine. All elements work together to support the cervical spine so that it can function properly. While C1 supports the weight of the skull, C2 allows the head to rotate further. C3, C4 and C5 provide stability and support for the neck. C6 is also responsible for the movement and stability of the neck, while C7 provides the transition to the thoracic spine.

Like all other bones in the body, the cervical spine can cause pain due to inflammatory diseases, wear and tear (degeneration) as a result of arthritic changes in the joints. Constrictions (stenoses) and deformities can disturb the function of nerves and spinal cord.

Surgical treatment is necessary if symptoms do not improve with conservative therapy or if impending neurological disorders cannot be treated in any other way.

For example, in case of sensory disturbances in the hands, stiffness of the limbs or unsteady gait.



This brochure is intended to give you the important basic facts but it cannot replace individual advice from your doctor. Please ask your doctor for further questions in regard to your individual pathology indications. This and the implantation are the responsibility of the surgeon.

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SIGNUS
The Spine Sign®

Fusion of the cervical spine

If symptoms cannot be eliminated or sufficiently reduced by conservative therapy or appropriate pain medication, surgery may be necessary.

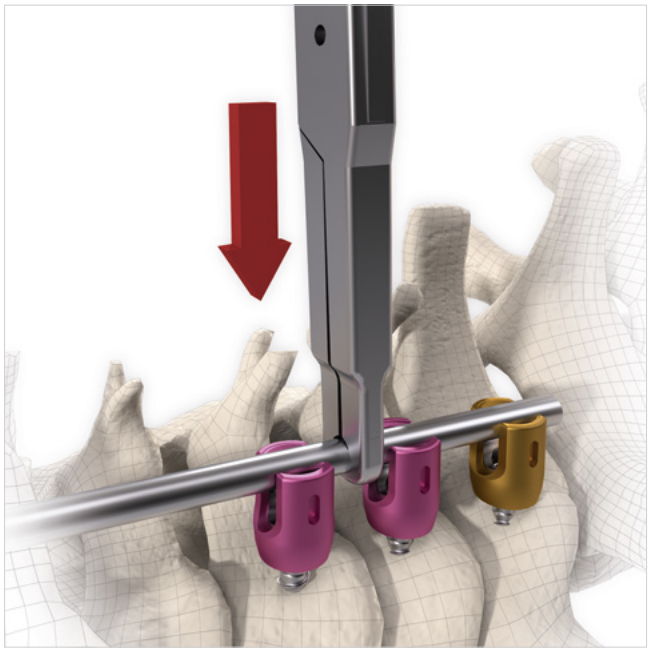
Depending on your personal clinical picture, this may require a rod-screw system in which the diseased part of the spine is stiffened (fused). For example, in the case of fractures, dislocations or instabilities. The goal is always to ensure a long-term improvement in your symptoms.

The operation with COSY®

The operation is usually performed in the prone position with the head held securely in position with a head holder (Mayfield or Halo). Prior to instrumentation, direct visualization is used to ensure that the position of the head is anatomically correct. This is particularly important if the occiput has to be connected and fixed to the cervical and thoracic spine.

Via a midline skin incision on the neck, the musculature is pushed aside and the spine is exposed. The COSY® screws are then inserted into the vertebral bodies and fixed with connecting rods. If the occiput must be fixed to the cervical and thoracic spine, a plate is also attached to the occiput and connected to the COSY® screws with rods.

Plate, screws and rods provide spine stability and ensure immobilization until the bone has fused the vertebral bodies.



After the operation

After cervical spine surgery, you will need to stay in the hospital for a few days. Aftercare and follow-up examinations will be tailored to your individual needs by your attending physician. After surgical treatment, you will be allowed limited physical activity for a period of time. This includes lifting heavy objects, rotational movements and any type of sports. Falls and jerky movements should be avoided at all costs.

Your surgeon will give you more information about the above measures and will create an individualized aftercare plan with you (physiotherapy, mobilization, strength exercises) so that you can quickly return to everyday life. Your surgeon will also suggest further aftercare if necessary.

Please always follow the doctor's advice.

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Identification of the implant

You will find information on the identification of your implant as well as the name, address and website of SIGNUS on your implantation ID card, which will be given to you by your treating physician.

About COSY®

The COSY® Cervicothoracic Occipital Rod-Screw System is a system for use in the cervical spine. The implants are used for surgical immobilization, stabilization and correction of deformities of the human cervical spine and cervicothoracic junction, as well as the occipito-cervical junction, if necessary.

The screws are available in different diameters and lengths, the rods in different lengths. This enables adaptation to different patient anatomies. The decision regarding possible removal of an implant is the responsibility of the treating surgeon.

COSY® Material

The implants are made of the following materials:

- Titanium alloy (Ti-6Al-4V) according to ASTM F 136 / ISO 5832-3
- Cobalt-chromium-molybdenum alloy according to ASTM F 1537 / ISO 5832-12

For easy identification, the implants are coated with oxide layers of different colors. Color changes are due to production and processing and have no influence on functionality.

The materials are established for use as implants. They are bio-compatible, corrosion resistant and non-toxic in the biological environment.

COSY® has not been tested for safety in the MRI environment. It has not been tested for heating or undesirable changes in the MRI environment. The safety of the COSY® Cervicothoracic Occipital Rod-Screw System in the MRI environment is unknown.

Undesirable side effects

Your doctor will inform you of the general risks and possible complications of the surgery. The following are possible risks and complications associated with the implant that may require revision surgery:

- Loosening and / or fracture (e.g., with failure or delayed fusion).
- Postoperative loss of correction or changes in spinal curvature.
- Pseudoarthrosis / lack of fusion
- Foreign body sensitivity, allergic or other local / systemic side effects with regard to the implant materials used
- Misplacement
- In rare cases, epidural hematoma may develop postoperatively in patients with coagulation disorders on anticoagulant therapy.
- Vascular lesion
- Neural lesions with reversible or permanent neurologic deficits or paralysis.
- Infection
- Nerve root / spinal canal injuries
- Dural tears, pseudo meningocele, fistula, persistent CSF leakage, meningitis

When you should consult a Health Professional

If you experience one or more of the following, we recommend to contact your physician or any health professional:

- Progressive arm pain
- New or progressive pain or weakness in arms and / or legs
- New or progressive tingling or numbness in arms or legs
- Incontinence (bladder or rectum)
- Fever or increased temperature
- Redness, swelling, or discharge from the wound
- Progressive neck pain
- Difficulty swallowing
- Difficulty breathing

If you experience any serious incident in relation to COSY®, please report to the manufacturer SIGNUS Medizintechnik GmbH (qm@signus.com).

Important information: Please keep in mind that SIGNUS Medizintechnik GmbH just provides general information about the treatment. Specific questions can only be answered by your doctor. SIGNUS assumes no liability for wrong indication or medical malpractice.

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