ROTAIO®

Cervical Disc Prosthesis

Dear Patient,

Changes to the spine due to wear or disease are often accompanied by pain that can greatly affect the quality of your life.

In this brochure we would like to tell you about a the treatment for persistent symptoms in the neck (cervical spine).

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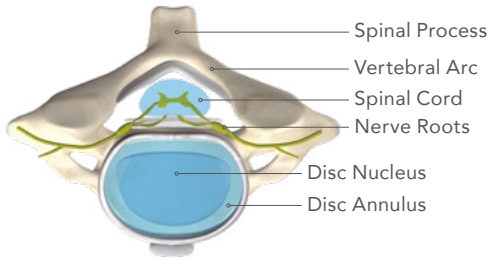
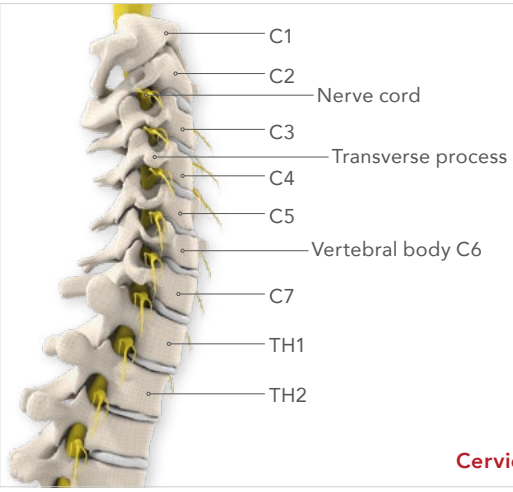
The cervical spine

The spine is an extraordinarily complex system of bones, cartilage, muscles and nerves, that has both static and dynamic functions. In addition it protects the spinal cord that lies within it.

The cervical spine begins at the base of the scull (occiput) and consists of 7 small bones, called the cervical vertebrae: these (with the exception of the first two vertebrae) are joined firmly together by intervertebral discs. These discs consist of a firm ring enclosing a jelly-like core. The perfect interplay of the ring and core stabilises the cervical spine and, at the same time, allows a controlled range of movement between the vertebral bodies.



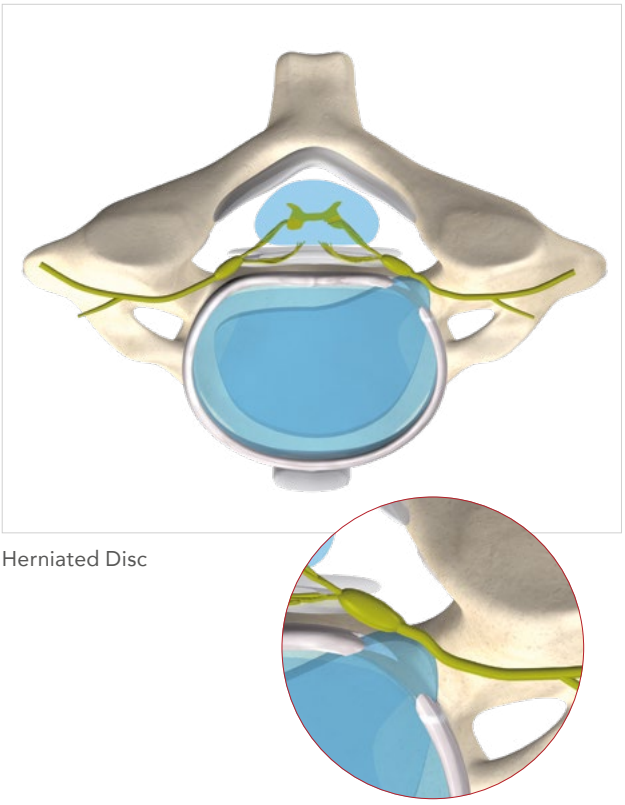
Healthy Disc



Cervical spine

Degeneration of the Disc

The spine is continually exposed to daily stresses and is also subject to natural ageing. This process, called degeneration, can start as early as your 20s and can result in bulging (prolapse) of the discs and bony changes (e.g. bony spurs) of the joints of the spine and the openings through which the nerves exit. This can, in turn, exert pressure on the neighbouring nerves or the spinal cord which can cause severe pains that often radiate through the shoulder and arm, and disturbances of sensation (numbness, oversensitivity, etc.).



Herniated Disc

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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Treatment of intervertebral disc disease

Often these symptoms can be treated by conservative methods (medicines, physiotherapy, etc.). However, if the symptoms are not resolved or adequately eased, then an operation may become necessary. This surgery involves removing the disc bulge and any bony spurs in order to relieve the pressure on the compressed nerves and the spinal cord. To ensure lasting relief, this section of the spine may be stiffened (fused). Your surgeon may use autologous bone or special implants to achieve this.

In some cases your surgeon might decide to also implant an additional fixating plate. This plate is placed in front of the cage and fixated in the adjacent vertebrae with two screws above and two screws underneath the treated disc.

Fusion can lead to excessive stress on the adjacent segments, which accelerates the natural ageing process. This may require further fusion surgery. For several years now, attempts have been made to develop surgical treatments that prevent wear caused by stress on adjacent segments and preventing their further degeneration, but instead ensure that natural mobility is maintained. A disc prosthesis serves as a replacement for the removed disc and ensures normal cervical spine function as far as possible.

It is not possible to implant a prosthesis in every patient. Severe degenerations in the cervical spine area, poor bone quality (osteoporosis), but also inflammatory processes in the spine, fractures, or tumours are some of the diseases that can make it impossible to use a prosthesis. Your surgeon will advise you in detail.

The Operation with ROTAIO®

Your surgeon gains access to the spine through a small incision in the front of your neck. The wound might be spread open using a retractor system. Next, the diseased disc and other compressing structures such as bony spurs are removed in order to relieve nerves and the spinal cord. Then, the ROTAIO® implant is positioned into the available space and the wound is closed.

After the Operation

An operation on the cervical spine is generally not a major procedure and the ROTAIO® implant is immediately stable, so you can get out of bed on the day of the operation if you are feeling well. Nevertheless aftercare and follow-up examinations are determined by your treating physician to your individual requirements.

After the intervention, you will 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.

Your surgeon will give you more detailed information about what you can do after the operation and will also provide an individual plan for your aftercare (physiotherapy, mobilisation, muscle strengthening, etc.), so that you can quickly get back into your daily routine. Your doctor will also inform you if further follow-up examinations are necessary.

Please follow your doctor´s advice.

Implant Identification

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

About ROTAIO®

ROTAIO® is a disc replacement implant for use in the cervical spine and serves as motion preservation. The parts of the ROTAIO® prosthesis that glide on one another are made from a cobalt-chrome alloy. This metal meets the most stringent demands regarding stress and, for that reason, has been used successfully for many years for artificial joints such as the hip and knee.

In general, they are not explanted again but remain in the patient. The implants are available in various footprints and heights to enable adaption to different patient anatomies.

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ROTAIO® Material

The implant is made of 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

The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant and non-toxic in the biological environment.

Non-clinical trials demonstrated that the ROTAIO® implant is 'MRI conditional'. A patient with this implant can be safely examined in an MRI environment that complies with the following criteria:

- Static magnetic fi eld strength of 1.5 T
- Maximum spatial magnetic fi eld gradient of 5.3 T/m
- Maximum mean whole-body specifi c absorption rate (SAR) stated by the MRI system of 3.9 W/kg

Under these examination conditions a temperature increase in the implant of max 3.1°C (1.5 T) can be expected during a continuous examination over 15 minutes.

Undesirable Side Effects

Your doctor will inform you about general risks and possible complications of the spinal surgery.

The following are potential risks and complications related to the implant and which may necessitate repeat surgery:

- Loss of anchorage/fixation, subsidence or dislocation of the implant
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used
- Incorrect placement
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Wear or breakage of implant components
- Temporary or permanent noise production
- Pain or recurrent pain

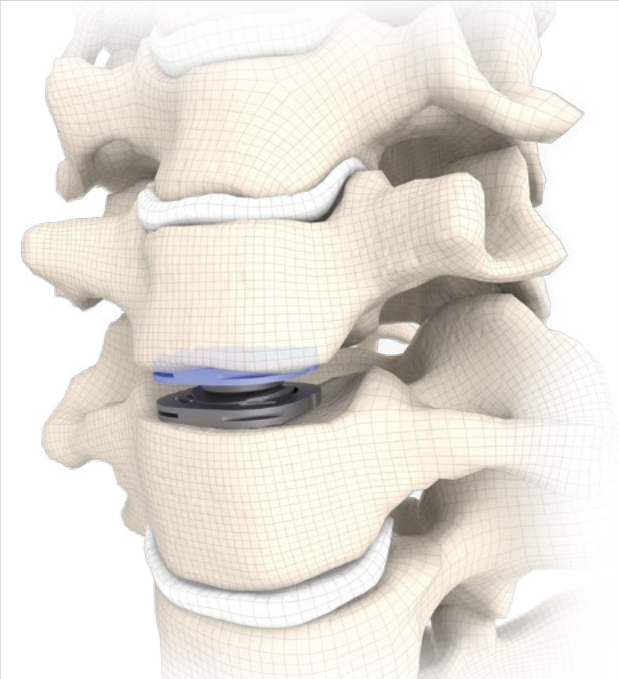
When you should consult a Health Professional

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

- Worsening arm or leg pain
- Any new or worsening weakness in your arms or legs
- Any new pins and needles or numbness in your arms or legs
- Incontinence (bladder or bowel)
- A fever or a high temperature
- Redness, swelling or discharge from the wound
- Increasing neck pain
- Difficulties swallowing
- Problems with breathing

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

If you are resident in Australia, please also report to the Therapeutic Goods Administration (https://www.tga.gov.au/reporting-problems).



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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