ASCOT®

Anterior Cervical Stabilization

Dear Patient,

Changes to the spine due to wear or disease of the disc as well as destructive damage of the vertebral body, such as that caused by tumours, fractures or inflammations 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 treatment for persistent symptoms in the neck (cervical spine).

HIGH-END MADE IN GERMANY

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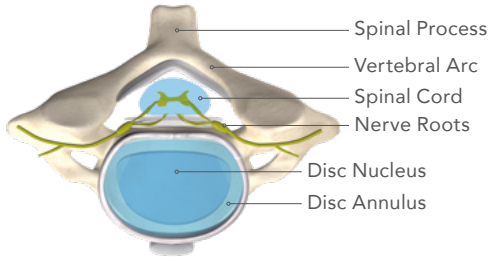
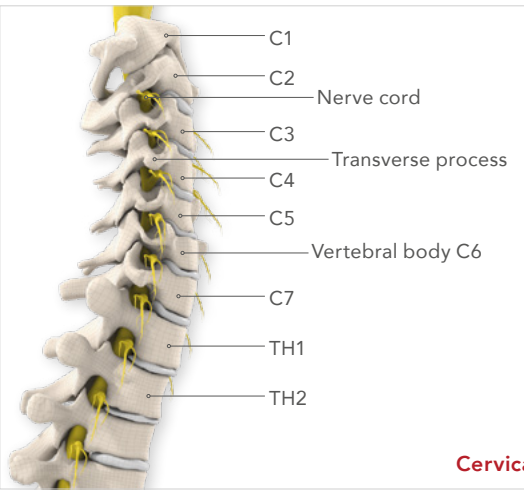
The Cervical Spine

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 as well as exiting nerves and vertebral arteries, that supply blood to the spinal cord, brain stem and cerebellum.

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.).

Due to a fall or an accident or a bone density decreases with age (osteoporosis or thinning bones), the vertebrae and its structures can break. Bone fractures can heal again. Only if the fracture is unstable parts of the bone or bone splinters can jeopardise the spinal cord or the nerves.

Another reason that may make surgical intervention necessary are spinal tumours which grow and multiply within or surrounding the spinal cord and/or spinal column. Spinal tumours can be beign (non-cancerous) or malignant (cancerous). Primary tumours originate in the spine or spinal cord, and metastatic or secondary tumours result from cancer spreading from another site to the spine.

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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Fusion of the Cervical Spine

If these symptoms cannot be neither treated by conservative methods nor resolved or adequately eased, then an operation may become necessary. Depending to the symptoms of your disease this may require a disc or vertebral body replacement. To ensure lasting relief, this section of the spine may be stiffened (fused).

When replacing a vertebral body (please see SIGNUS patient leaflet for ATHLET®) there is always an additional fixation required.

In case of removal of the intervertebral disc in the affected segment (please see SIGNUS patient leaflet JASPIS® ST, RABEA®, NUBIC®) your surgeon might decide to also implant an additional fixating plate.

This additional fixating plate is placed in front of the implant and fixated in the adjacent vertebrae with two screws to achieve greater stability of the affected segment.

The Operation with ASCOT®

When removing the intervertebral disc or replacing the vertebral body 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, depending on your symptoms, either the diseased disc or the affected vertebral body will be removed.

By using the same access the plate will be placed in front of the implant. With two screws above and two screws underneath the treated disc the plate is fixated in the adjacent vertebrae.

Depending on the severity of the pathology to be treated, a one-level or multi-level fusion may be performed. New bone mass will gradually grow in and around the implant, creating a fusion which makes the area stable. This procedure will take away some flexibility in your spine, but most patients do not notice.

After the Operation

After a treatment at the cervical spine you will need to stay in the hospital for a few days. 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 ASCOT®

ASCOT® is a complete screw-plate-system for stabilisation of the cervical spine. It serves to temporarily stabilise the spine until firm bony fusion has taken place. They are not explanted again but remain in the patient. The plates have a thickness of 1.8 mm, anatomic shape and are available in different lengths. The corresponding screws are also available in different lengths and diameters, to enable adaption to different patient anatomies.

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ASCOT® Material

The implants are made from the following material:
Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3

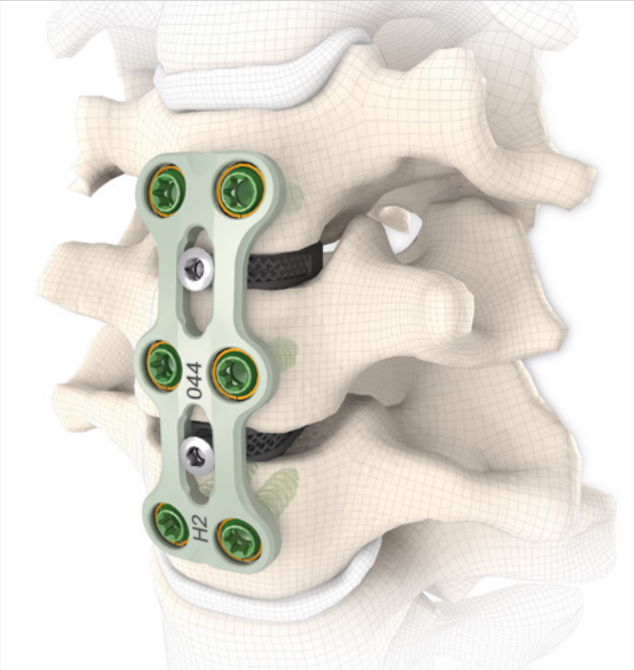
The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant, non-toxic in the biological environment. The implants are coated with oxide layers in different colours for easy identification. Colour changes are caused by factors related to production and reprocessing and do not affect the functionality.

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

- Static magnetic field strength of 1.5 T
- Maximum spatial magnetic field gradient of 700 Gauss/cm or less
- Maximum mean whole-body specific absorption rate (SAR) stated by the MRI system of 4 W/kg

Under these examination conditions a temperature increase in the implant of max 3.2°C (1.5 T) can be expected during a continuous examination over 15 minutes.

In non-clinical trials the image distortion caused by the product extended to about 15 mm around the ASCOT® implants when using a gradient echo sequence and a 3 T MRI system.



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
- 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
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis Postoperative dysphagia with cervical plate systems
- Infection

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 ASCOT®, 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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