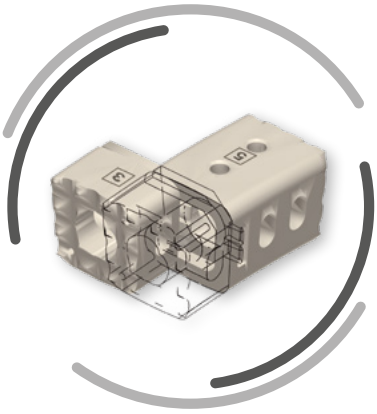
ATHLET®

Cervical Vertebral Body Replacement

Dear Patient,

Destructive damage of the vertebral body, such as that caused by tumours, fractures or inflammations, can greatly affect the quality of your life.

In this brochure we would like to tell you about the treatment of these damages of the cervical spine.



HIGH-END MADE IN GERMANY

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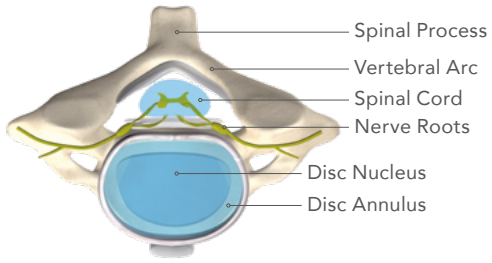
The cervical spine

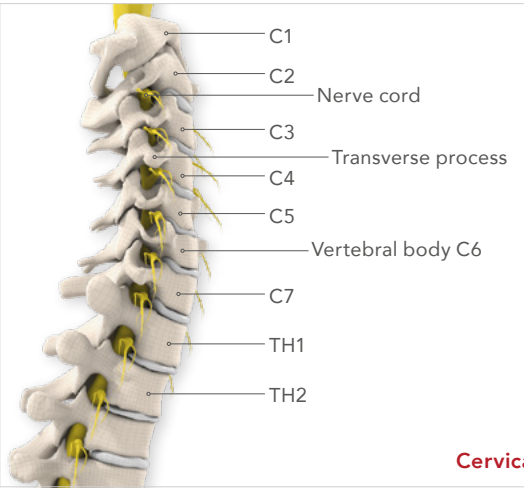
The spine is an extraordinarily complex system of bones, cartilage, muscles and nerves, that has both static and dynamic functions. In addition it protects the spinal cord that lies within it as well as exiting nerves and vertebral arteries, that supply blood to the spinal cord, brain stem and cerebellum.

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.

The vertebral body consists of a soft core (spongiosa) and a hard layer of bone (cortical bone) and form the weight-bearing part of our spine.



Healthy Disc



Cervical spine

Destructive Damage of the Cervical Spine

The individual vertebrae in the spinal column are made up of the vertebral body, the spinous process and the vertebral arch. Like all other bones in the body, these structures can also break (fracture) – whether due to a fall or an accident or a bone density decreases with age (osteoporosis or thinning bones). 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.

A spinal tumor is an abnormal mass of tissue within or surrounding the spinal cord and/or spinal column. These cells grow and multiply uncontrollagly, semmingly unchecked by the machanisms that control normal cells. Spinal tumors can be beign (non-cancerous) or malignant (cancerous). Primary tumors originate in the spine or spinal cord, and metastatic or secondary tumors result from cancer spreading from another site to the spine.

The bony spinal column is the most common site for bone metastasis. The most common primary spine tumor (originated in the bony spine) is vertebral hemangiomas. These are benign lesions and rarely cause symptoms such as pain.

Inflammatory disorders of the spine can be caused by a wide range of conditions, including arthritis, osteoporosis, and infection. Inflammation in the spine is rare but can be a significant source of pain and disability, especially if these hard-to-diagnose conditions go untreated. Ankylosing spondylitis, a form of arthritis in the spine, is one of the most common spinal inflammatory disorders.

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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Replacement of a Vertebral Body

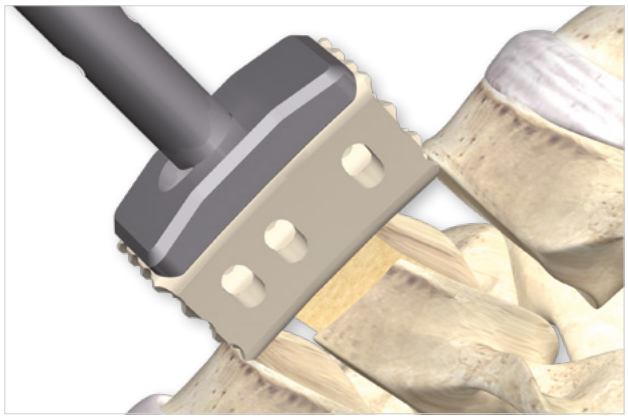
If these symptoms cannot be resolved or adequately eased, then an operation may become necessary. In this case, the related vertebrae has to be removed and replaced by an implant so that the stability of the spine can be maintained. So that these implants are stably anchored, the top and bottom of the implant are placed directly on the neighbouring vertebral bodies and not the discs. Therefore adjacent discs are also removed, before placing the implant.

When replacing a vertebral body there is always an additional fixation required. Therefore your surgeon might decide to also implant fixating screws (pedicle screws) from the back. Depending on the surgeons´ choice of access, this screw-rod-system will be implanted in one step with the implant. If a second step is needed, your surgeon might either way decide to turn you around during the operation to place the screws or to do these two steps in two different surgeries (within approx. two weeks).

The Operation with ATHLET®

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. After the incision is made the surgeon clears the path to the spine and to the related vertebrae. The damaged vertebrae as well as adjacent discs will be removed. ATHLET® is used as a spacer between the bones to restore the height, correct the spinal curvature, and to relieve pinched nerves. In a next step the screw-rod-system is placed to increase stability.

Depending on the symptoms and the damaged vertebrae, 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 the vertebral body replacement procedure, 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.

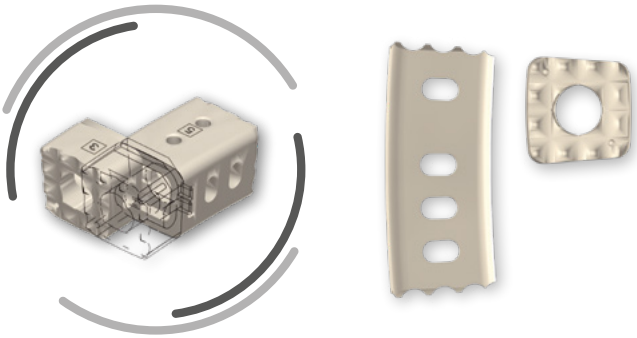
Please follow your doctor´s advice.

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 ATHLET®

ATHLET® is a vertebral body replacement implant for use in the spine. The implants serve as temporary placeholders to restore the spine until firm bony fusion has taken place. They are not explanted again but remain in the patient. The implants are available in one footprint and variuos, heights to enable adaptation to different patient anatomies. The implant consists of a basic and end body, which are joined together using a click mechanism to ensure secure fixation. The surface has maximal cortical contact and therefore maximal stability of the implant.



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ATHLET® Material

The implants are made from the following materials:
Polyether ether ketone (PEEK-OPTIMA®) as per ASTM F2026

X-ray markers:
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 and non-toxic in the biological environment and enable interference-free X-ray imaging.

An expert report recommends labelling ATHLET® as 'MRI conditional'. A patient with this implant can be safely scanned in an MRI system in accordance with the justification and the test methods in ASTM F2502.

Testing of the effects due to forces (ASTM F2052) or torque (ASTM F2213), heating (ASTM F2182) or artefact formation (ASTM F2119) was not carried out for the following reasons:

1. Long metallic objects less than 20 mm
2. Non-metallic PEEK as base material
3. Metal content less than 16 % proportional weight
4. Medical devices made of titanium and tantalum are labelled as 'MRI conditional' with < 25 T/m
5. The counterforces of the body hold the implant in position.

Undiserable 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
- Pseudoarthrosis / absence of fusion
- 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
- Pain or recurrent pain

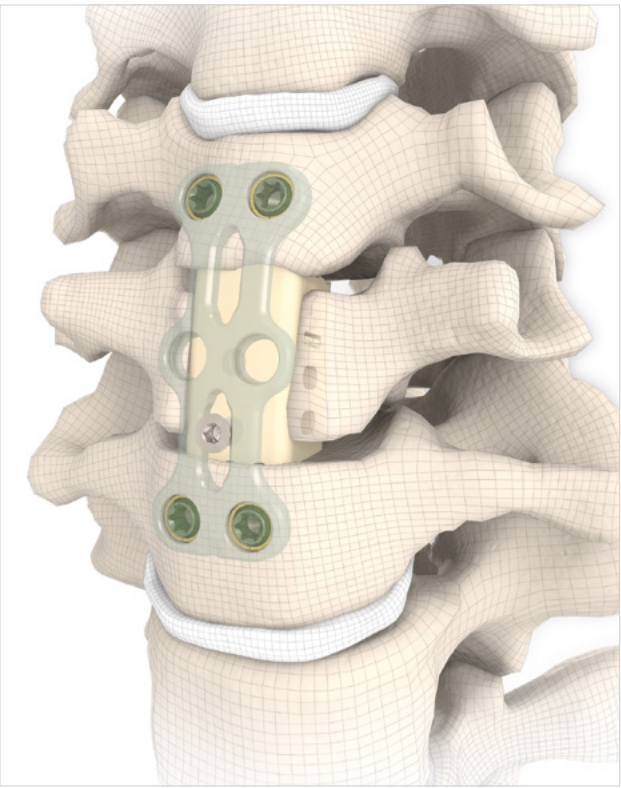
When you should consult a Health Professional

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 ATHLET®, 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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