POSEIDON®

Expandable Vertebral Body Replacement

Dear Patient,

Destructive damage of the vertebral body, such as that caused by tumors, 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 in the thoracic and lumbar regions of the spine.

HIGH-END MADE IN GERMANY

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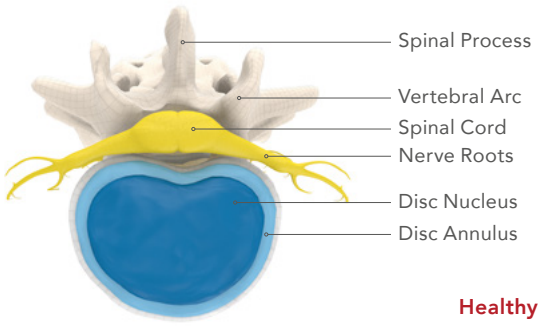
The Thoracolumbar Spine

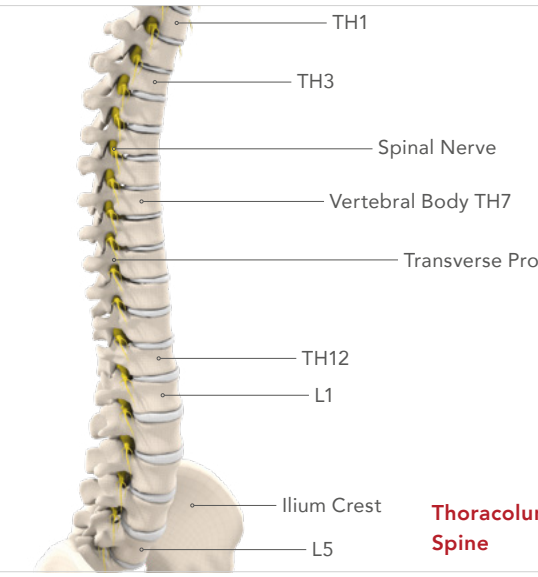
The spine is an extraordinarily complex system of bones, cartilage, muscles and nerves, that has both static and dynamic functions. In addition it protects the spinal cord that lies within it.

The thoracic spine is the second segment of the vertebral column, located between the cervical and lumbar vertebral segments. It consists of 12 small bones (TH1 – TH12), called the thoracic vertebrae.

The lumbar spine (low back) is the third major region of the spine. It is below the cervical and thoracic spine and consists of 5 small bones (L1 – L5), called the lumbar vertebrae. Each vertebra is stacked on top of the other and between each vertebra is a jelly-like cushion, called an intervertebral disc. The discs help to absorb pressure, distribute stress, and keep the vertebrae from grinding against each other.



Healthy Disc



Thoracolumbar Spine

Destructive Damage of the Thoracolumbar 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, 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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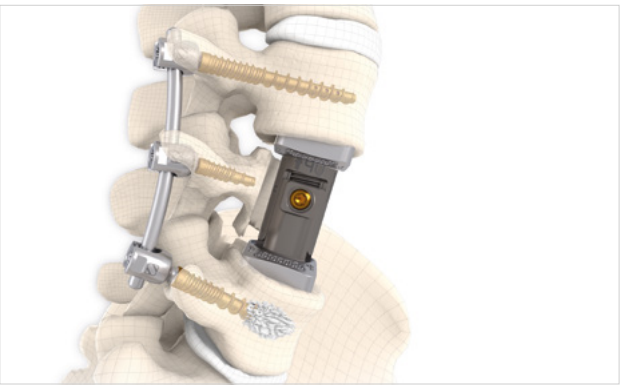
Replacement of a Vertebral Body

If these symptoms cannot be resolved or adequately eased, then an operation may become necessary. In this case, the related verebrae 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).



Vertebral Body Replacement

The Operation with POSEIDON®

Before placing the implant your surgeon will decide which access is best for you. This decision is made respecting indication (level of the spine that has to be treated) and your individual anatomy. 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. POSEIDON® 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 POSEIDON®

POSEIDON® 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 various designs, footprints, heights and angles to enable adaptation to different patient anatomies. The implant consists of one main body, which is expandable within the patient to obtain the needed height accoring to the patients´ anatomy. Various endplates of different footprints and angles are mounted on both sides of the main body for maximal cortical contact and therefore maximum stability of the implant.

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Material of POSEIDON®

The implants are made from the following materials:
- Titanium alloy (TiAl6V4) as per ASTM F 136 / ISO 5832-3
- Titanium as per ASTM F67 / ISO 5832-2

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 POSEIDON® ST 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 field strength of 1.5 T or 3 T
- Maximum spatial magnetic field gradient of 11 T/m (1.5 T) or 7 T/m (3 T) or less
- Maximum mean whole-body specific absorption rate (SAR) stated by the MRI system of 4.5 W/kg

Under these examination conditions a temperature increase in the implant of max 7.7°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 3.5 cm around the POSEIDON® ST implant when using a gradient echo sequence and a 3 T MRI system.

The safety and compatibility of POSEIDON® in an MRI environment was not determined. The product has not been tested with regard to heating, migration or artefact formation in an MRI environment.

Undesirable Side Effects

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

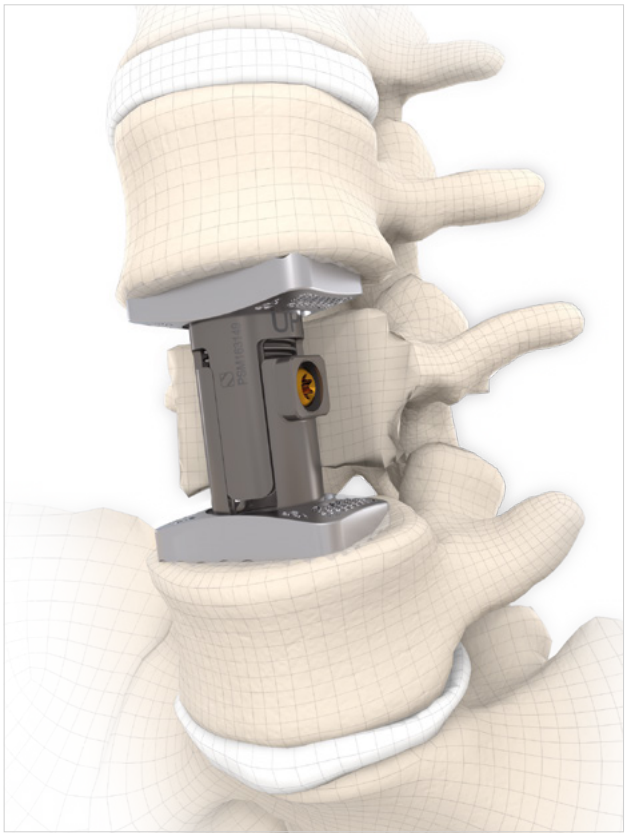
The following are potential risks and complications related to the implant and which may necessitate repeat surgery:
- Loss of anchorage/fixation, subsidence or dislocation of the implant
- Pseudoarthrosis/absence of fusion
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse 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
- Residual loose powder in the internal metal lattice

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 leg pain
- Any new or worsening weakness in your legs
- Any new pins and needles or numbness in your legs
- Incontinence (bladder or bowel)
- A fever or a high temperature
- Redness, swelling or discharge from the wound
- Increasing back pain
- Difficulties of breathing
- General malaise

If you experience any serious incident in relation to POSEIDON®, 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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