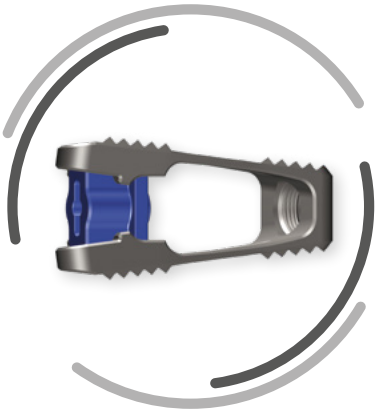
VERTACONNECT T

Transforaminal Lumbar Interbody Fusion

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 the treatment for persistent symptoms in the lower back (lumbar spine).

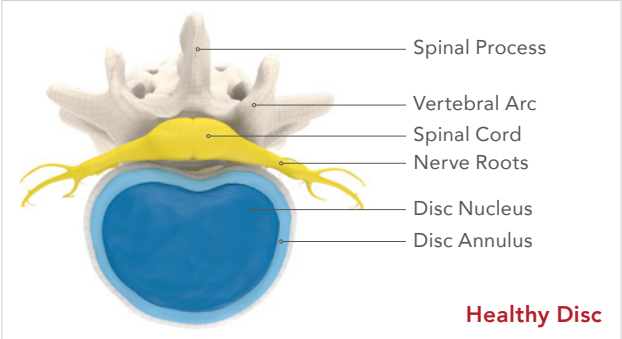


HIGH-END MADE IN GERMANY

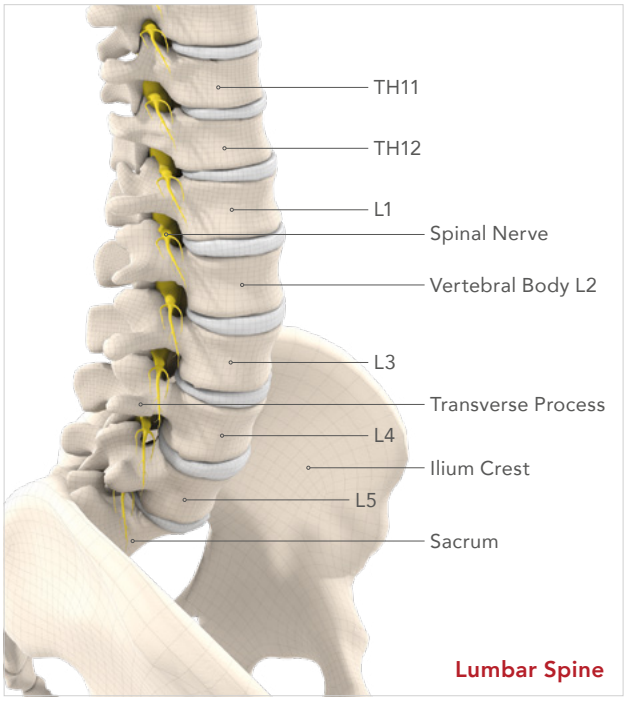
The Lumbar Spine

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 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.



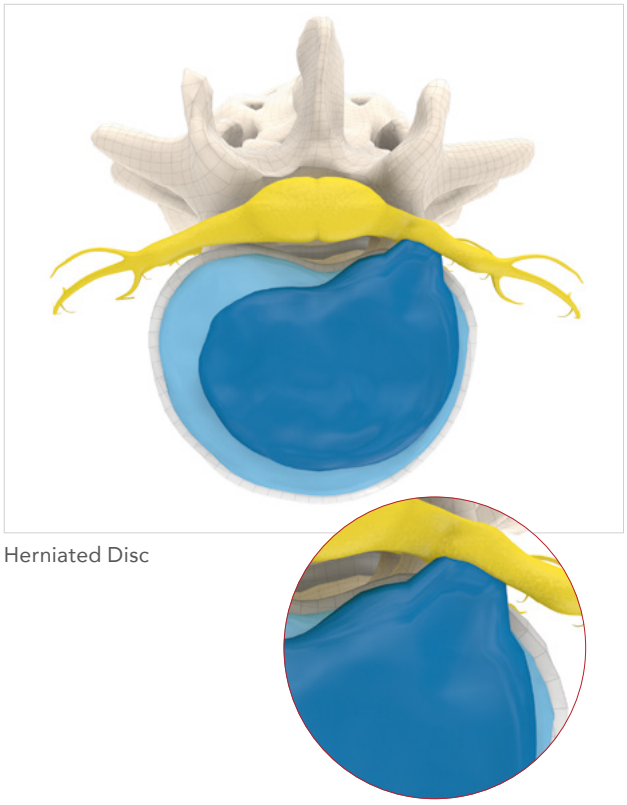
Healthy Disc



Lumbar 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 hips and legs, 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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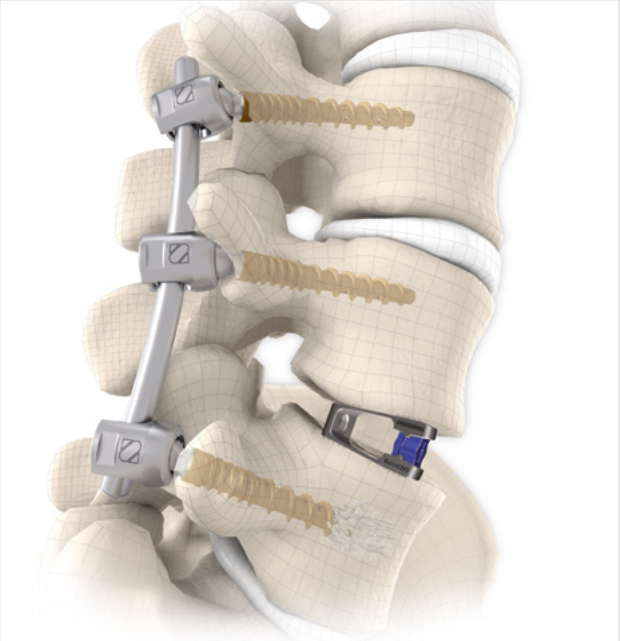
Fusion of the Lumbar Spine

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.



Lumbar Spine Fusion

The Operation with VERTACONNECT Ⓣ

During TLIF (Transforaminal Lumbar Interbody Fusion) a small incision is made in the back. The surgeon clears the path to the spine with special attention to nerves and vessels. VERTACONNECT Ⓣ is used as an expandable spacer between two vertebral bodies to restore the height, correct the spinal curvature and to relive impinched nerves. As the body heals, new bone grows around and through the VERTACONNECT Ⓣ to fuse the two vertebral bodies into one solid piece of bone.

Depending on the symptoms, a one-level or multi-level fusion may be performed. Fusion will take away some flexibility in your spine, but most patients do not notice.

After the Operation

An operation on the lumbar spine is generally not a major procedure and the VERTACONNECT Ⓣ implant is – in combination with the additional fixation – 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.

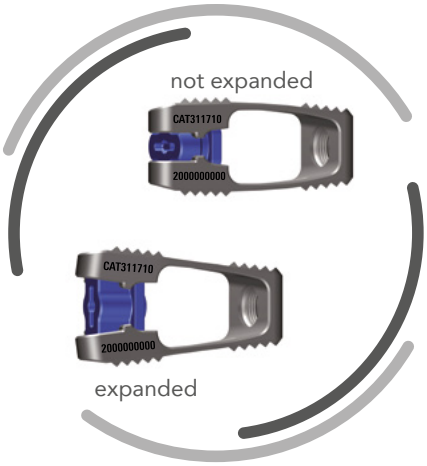
Your surgeon will give you more detailed information about what you can do after the operation and will also provide an individual plan for your aftercare (physiotherapy, mobilisation, muscle strengthening, etc.), so that you can quickly get back into your daily routine. Your doctor will also inform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

VERTACONNECT Ⓣ is a disc replacement implant for use in the lumbar spine. It serves as a temporary placeholder to restore disc height until firm bony fusion has taken place. VERTACONNECT Ⓣ is not explanted again but remains in the patient. The implants are available in various designs, footprints and heights to enable adaptation to different patient anatomies with/without lordosis (angles).



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Material of VERTACONNECT Ⓣ

The implants are made from the following materials:
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.

The safety and compatibility of VERTACONNECT Ⓣ 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

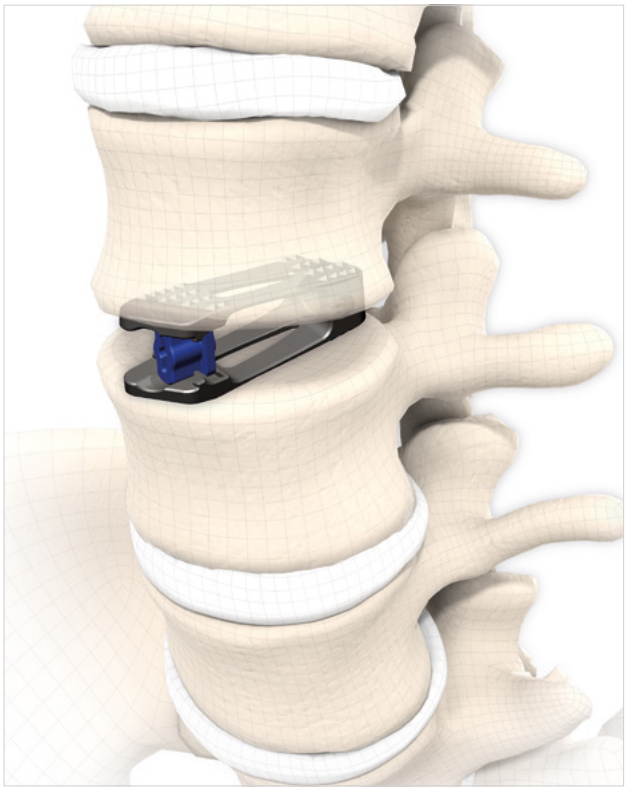
When you should consult a Health Professional

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 lower back pain
- Difficulties of breathing
- General malais

If you experience any serious incident in relation to VERTACONNECT Ⓣ, 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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