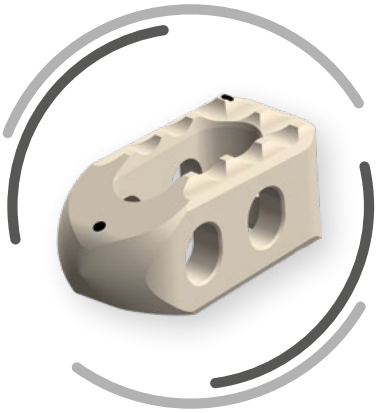
TETRIS™ | TETRIS™ II

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



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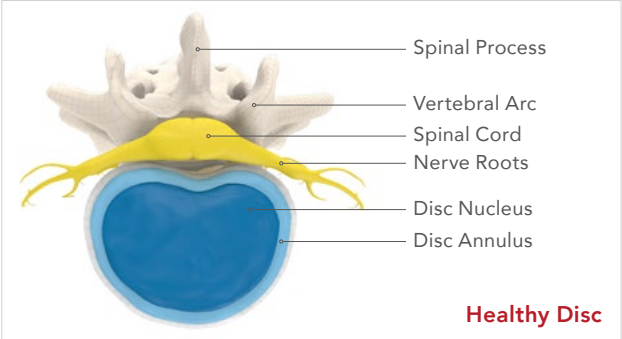
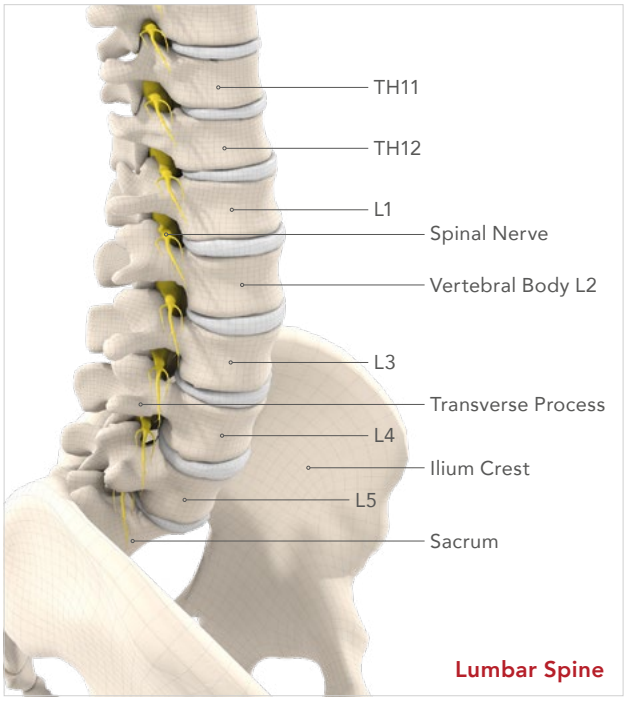
The Lumbar Spine

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.



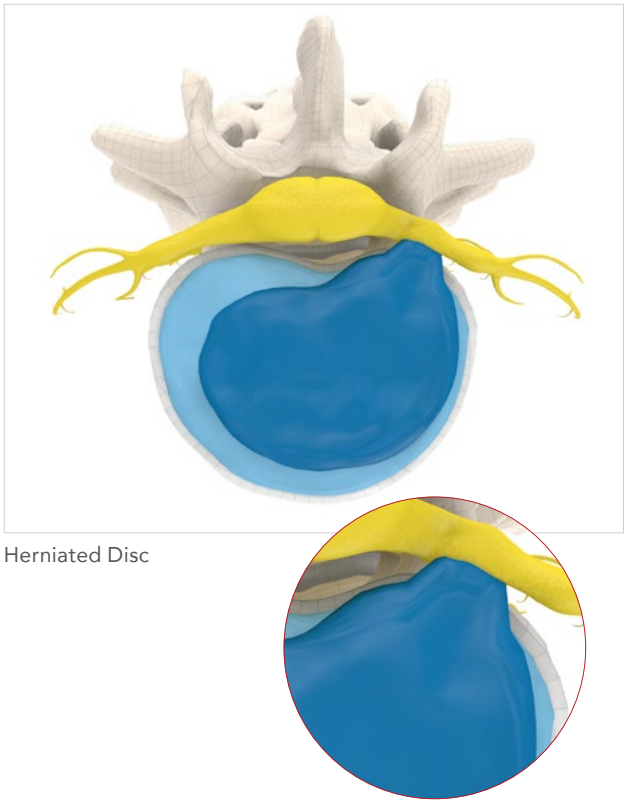
Healthy Disc



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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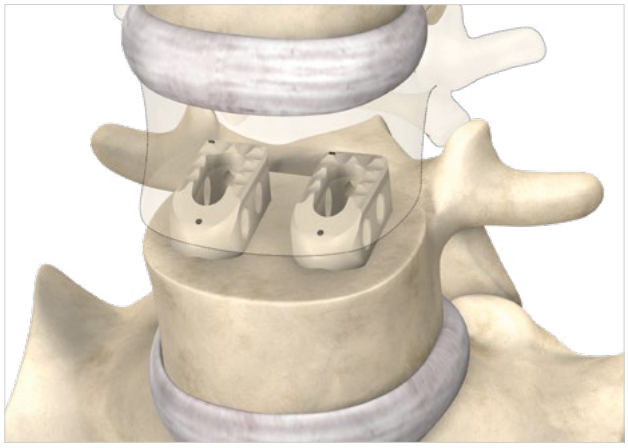
Fusion of the Lumbar Spine

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.

For fusion of the lumbar spine 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).



Lumbar Spine Fusion

The Operation with TETRIS™/TETRIS™ II

During Posterior Lumbar Interbody Fusion (PLIF), an incision is made in your back. The surgeon clears the path to the spine, carefully moving aside the neural structures, and removes the damaged disc. TETRIS™/TETRIS™ II is used as a spacer between the bones to restore the height, correct the spinal curvature, and to relieve pinched nerves. As the body heals, new bone grows around and through the TETRIS™/TETRIS™ II spacer to fuse the two vertebrae 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 TETRIS™/TETRIS™ II 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.

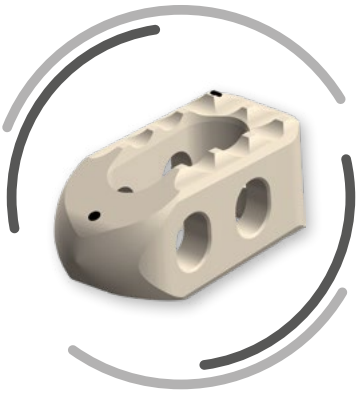
Your surgeon will give you more detailed information about what you can do after the operation and will also provide an individual plan for your aftercare (physiotherapy, mobilisation, muscle strengthening, etc.), so that you can quickly get back into your daily routine. Your doctor will also inform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

TETRIS™/TETRIS™ II is a spinal fusion implant for use in the lumbar spine. The implants serve as temporary placeholders to restore disc height 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 and heights to enable adaptation to different patient anatomies.



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Material of TETRIS™/TETRIS™ II

The implants and X-ray markers described are made from the following materials:

- PEEK-OPTIMA® as per ASTM F2026
- Titanium alloy (Ti-6Al-4V) as per ASTM F136 / ISO 5832-3
- Titanium as per ASTM F67 / ISO 5832-2
- Tantalum as per ASTM F560

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

Non-clinical testing has demonstrated the TETRIS™ TITANIUM implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less
- Maximum spatial field gradient of 720 gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning (i.e., per pulse sequence)

Under the scan conditions defined above, the TETRIS™ TITANIUM implant is expected to produce a maximum temperature rise of less than 1.8°C (for 1.5 T MRI) and 2.1°C (for 3.0 T MRI) after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the device extends approximately 15 mm from the TETRIS™ TITANIUM implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

An expert report recommends labelling TETRIS™ II PEEK as 'MR 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 'MR conditional' with < 25 T/m
5. The counterforces of the body hold the implant in position.

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:

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

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 malais

If you experience any serious incident in relation to TETRIS™/TETRIS™ II, 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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