DIPLOMAT®

Posterior Instrumentation

Dear Patient,

Changes in the spine due to wear and tear or disease are often accompanied by pain and can severely impair your quality of life.

This brochure provides you with information on “stiffening” (fusion) of the spine. It is of a general nature and does not constitute medical advice or a medical recommendation.
The information does not make any diagnostic or therapeutic statement about the respective individual medical case.

HIGH-END MADE IN GERMANY

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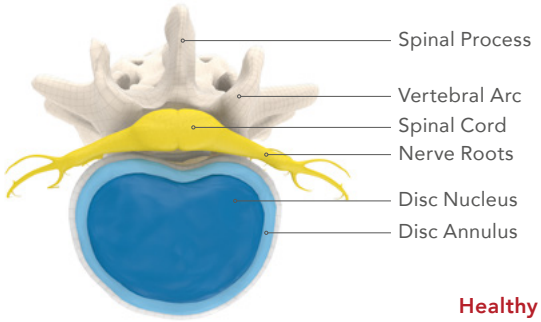
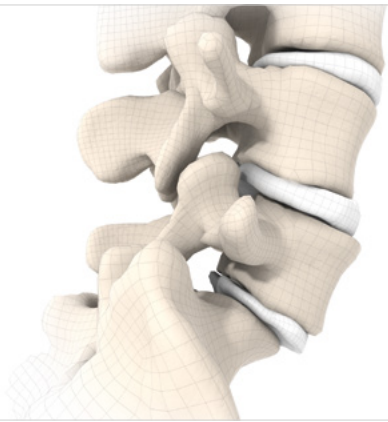
The Spine

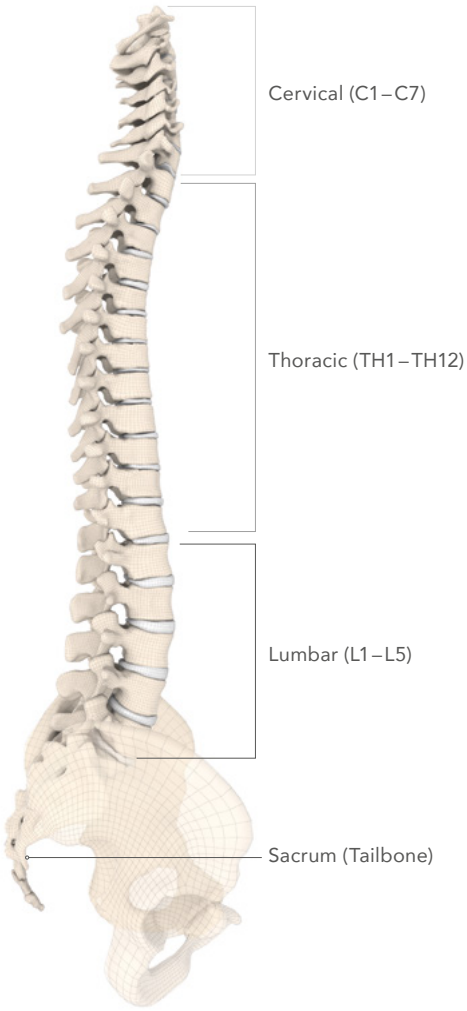
The spine is an extraordinarily complex system of bones, cartilage, muscles, ligaments and nerves that combines both static and dynamic functions. It also protects the spinal cord that lies within it. The spine is divided into the cervical (Cervical, C1–C7), thoracic (Thoracic, TH1–TH12) and lumbar (Lumbar L1–L5) regions. Adjacent to the lumbar is the sacrum. The sacrum is an ossification of four to five vertebrae fused together to form a unified bone. Between the individual vertebrae sit the intervertebral discs. Together with the ilium, the coccyx forms the sacroiliac joint (SIG). This provides the connection of the spine to the pelvis. If you look at the spine from the side, you can see a double-S-shaped curvature, which serves to protect against shocks and to best cope with the stresses and demands of everyday life. This curvature is created by the different bending of each spinal segment. The cervical and lumbar spine is curve forward, which is called lordosis. The thoracic spine and sacrum, on the other hand, curve backward and are termed kyphosis.



Healthy Disc



Spondylolisthesis



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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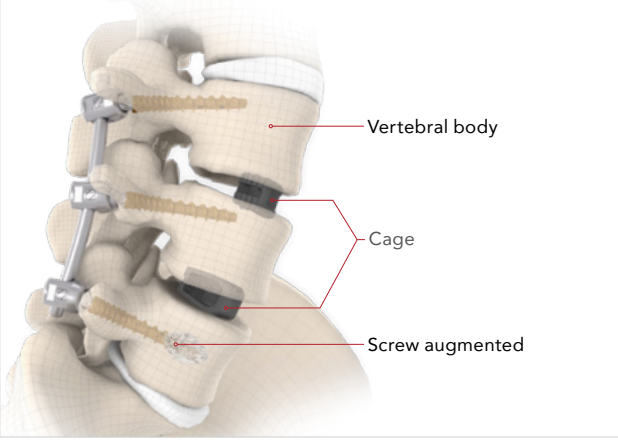
Fusion of the Lumbar Spine

If symptoms cannot be eliminated or sufficiently alleviated by conservative therapy or appropriate pain medication, surgery may be necessary. Depending on your personal clinical picture, this may require a rod-screw system, whereby the diseased part of the spine is stiffened (fused). This could be for example, in the case of massive constriction of the nerves or spinal cord (spinal canal stenosis), in order to prevent permanent damage, or in the case of instabilities such as spondylolisthesis. The goal is always to ensure a long-term improvement in your symptoms. In the case of a treatment using a rod-screw system, an additional insertion of a cage (shaped placeholder) is often required (see also SIGNUS patient information MOBIS®, WOMBAT®).



The Operation with DIPLOMAT®

The operation is usually performed in the prone position on special positioning pillows. Through a skin incision on the back, the muscles are pushed aside and the spine is exposed. DIPLOMAT® screws are then inserted into the vertebral bodies and attached with connecting rods. Often it is as well necessary to remove excess bone tissue or disc material, which presses on the sensitive nerves and thus causes the pain. Together with the screws, after removal of the intervertebral disc, a shaped placeholder (cage) is usually also inserted into the intervertebral space. It restores the physiological (natural) height of the disc segment.

The screws and rods ensure the stability of the spine and guarantee immobilization until the bone, with or without the cage, has fused (stiffened) the vertebral bodies .

After the Operation

After lumbar spine surgery, you will need to stay in the hospital for a few days. Nevertheless, aftercare and follow-up examinations will be tailored to your individual needs by your attending surgeon. After surgical treatment, you will be allowed limited physical activity for a period of time. This includes lifting heavy objects, rotational movements and any type of sports. Falls and jerky movements should be avoided at all costs.

Your surgeon will give you more information about the above measures and will create an individualized aftercare plan with you (physiotherapy, mobilization, strength exercises) so that you can quickly return to everyday life. Your surgeon will also suggest further aftercare if necessary.

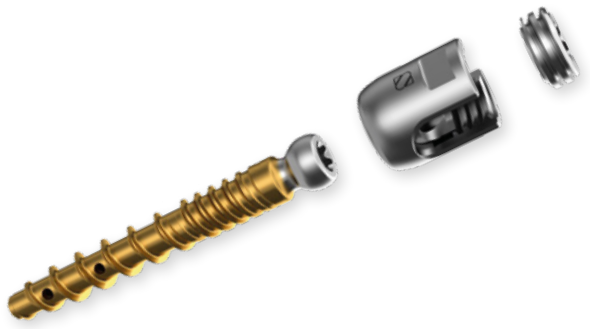
Please always follow the doctor's advice.

Identification of the Implant

Information identifying your implant, as well as the SIGNUS name, address and website can be found on your implantation card, which will be given to you by your treating physician.

About DIPLOMAT®

The DIPLOMAT® system is a well thought-out modular and proven screw-rod-system for stabilization of the spine. It was developed in close collaboration with experienced qualified spine surgeons. The cannulated and fenestrated DIPLOMAT® screws in combination with 5.5 mm titanium rods allow the system to stabilize and comfortably correct all types of spinal disorders and deformities in a controlled manner. The screws are available in different diameters and lengths, the rods in different lengths. This enables adaptation to different patient anatomies.



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DIPLOMAT® Material

The implants are made of the following materials:

- Titanium alloy (Ti-6Al-4V) according to ASTM F 136 / ISO 5832-3
- Cobalt-chromium-molybdenum alloy according to ASTM F 1537 / ISO 5832-12

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

For easy identification, the implants are coated with oxide layers of different colours. Colour changes are due to production and processing and do not affect functionality.

The safety and compatibility of DIPLOMAT® in an MRI environment has not been determined. The products have not been tested for heating, migration or artefact formation in an MRI environment.

Undesirable Side Effects

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

The following are possible risks and complications associated with the implant that may require revision surgery:

- Pseudoarthrosis/failure to fuse.
- Foreign body sensitivity, allergic or other local/systemic side effects regarding the implant materials used
- Misplacement
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Pedicle fracture
- Pedicle/nerve root perforation
- Nerve root/spinal canal injury
- Injury and vascular damage due to bone cement leakage (e.g., PMMA)
- Visceral injury/infection and deep wound infection
- Temporary para paresis
- Wear, bending or fracture of implant components
- Screw loosening
- Pain or recurrent pain

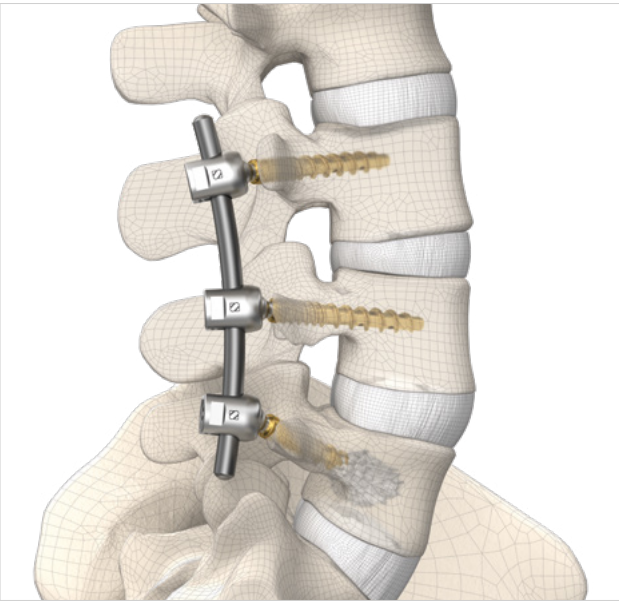
When you should consult a Health Professional

If you experience one or more of the following, we recommend to contact your physician or any health professional:

- Progressive leg pain
- New or progressive tingling, pain, or weakness in your legs/feet
- New symptoms of paralysis
- Incontinence (bladder or rectum)
- Fever or elevated temperature
- Redness, swelling, or discharge from the wound

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