DIPLOMAT® Deformity

Treatment Of Spinal Deformities

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.

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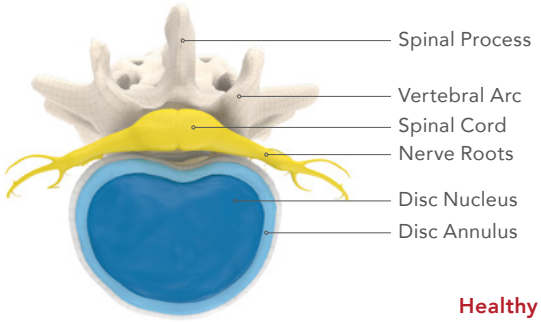
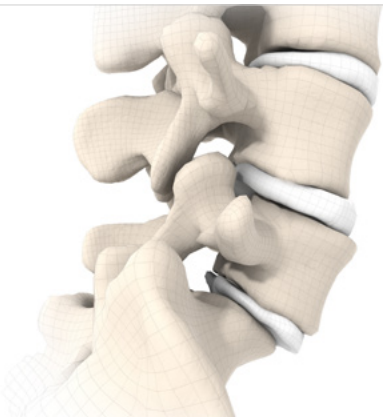
The Spine

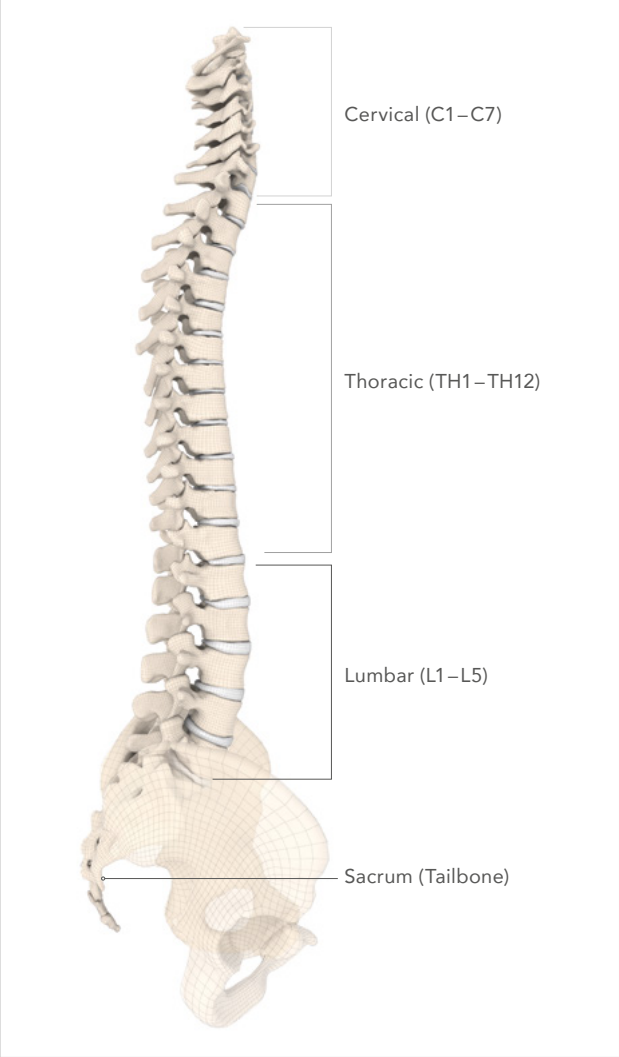
The spine is an extraordinarily complex system of bones, cartilage, muscles, ligaments and nerves that combines both static and dynamic functions. It also protects the spinal cord that lies within it. The spine is divided into the cervical (Cervical, C1–C7), thoracic (Thoracic, TH1–TH12) and lumbar (Lumbar 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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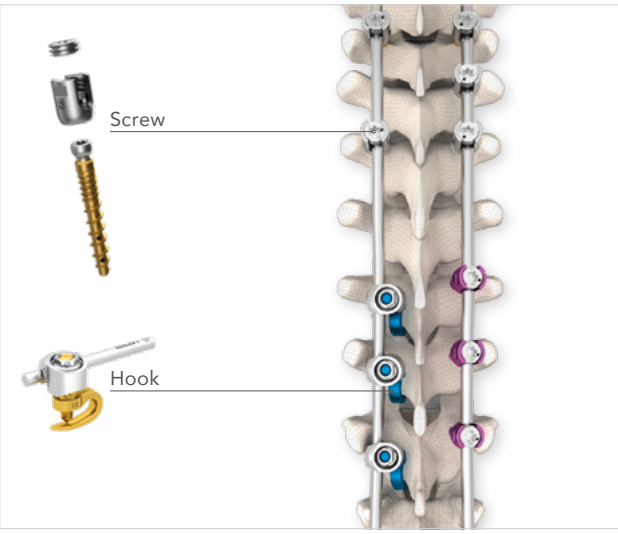
Fusion of the Lumbar Spine

If symptoms cannot be eliminated or sufficiently alleviated by conservative therapy or appropriate pain medication, surgery may be necessary. Depending on your personal medical condition, a hook-based system (possibly in combination with a rod-screw-system) may be necessary, whereby the pathological part of the spine is stiffened (fused). For example, increasing instability of the motion segments can cause slippage and twisting of the spine (deformity).

The aim is to always ensure a lasting improvement of your symptoms. For a treatment using a rod-screw system, an additional cage (shaped placeholder) is often required (see also SIGNUS Patient Information MOBIS®, WOMBAT®).



The Operation with DIPLOMAT® Deformity

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, the spine is exposed and the spinal deformity is eliminated. For this purpose, DIPLOMAT® Deformity hooks are inserted at the lamina and connected with connecting rods (bars). Often in connection with DIPLOMAT® screws which are placed in the vertebral body. Regularly it is also necessary to remove excess bone tissue or disc material, which presses on the sensitive nerves and thus causes the pain. Additional support is then provided by a placeholder (cage), which is inserted into the intervertebral space. It restores the physiological (natural) height of the disc segment.

The hooks, screws and rods contribute to the stability of the spine and ensure immobilization until the bone has fused (stiffened) with or without the cage.

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® Deformity

The DIPLOMAT® Deformity system is a sophisticated hook-rod-system for stabilizing the spine. It was developed in close cooperation with experienced qualified spine surgeons. The DIPLOMAT® Deformity hooks (with screws if necessary) in combination with 5.5 mm titanium rods allow the system to stabilize all types of spinal disorders and deformities in a controlled manner and to correct them comfortably. The hooks and screws are available in different diameters and lengths, the rods in different lengths. This allows for adaptation to different patient anatomies.

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DIPLOMAT® Deformity 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 bio-compatible, 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® Deformity 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

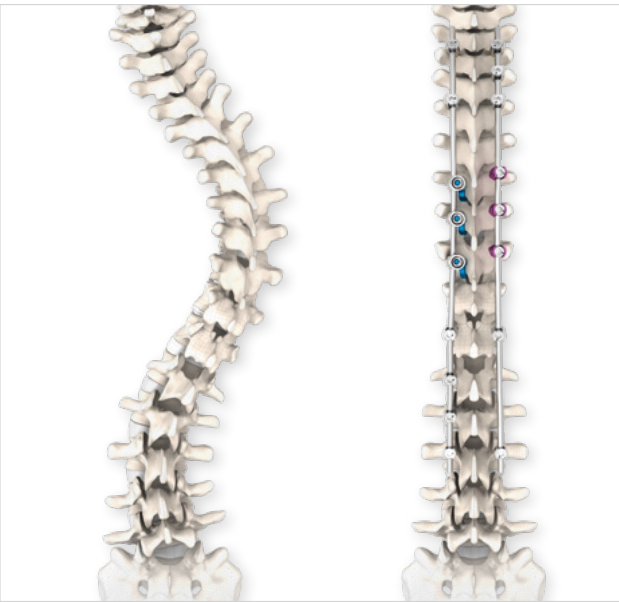
When you should consult a Health Professional

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® Deformity, 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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