Patient information on the pro**disc**[®] L intervertebral disc prosthesis for the lumbar spine.



Tasks and functions of the spine

Stability

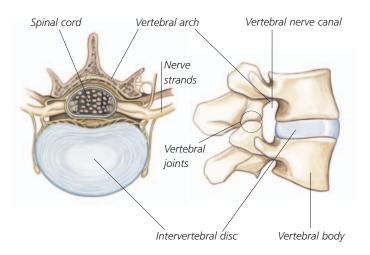
The spine provides stability for the head and upper body and determines posture. The vertebral bodies are mainly responsible for this. The anatomy of these box-shaped bones make them especially tolerant and fracture-proof against forces directed from above to below, e.g. jumping, climbing stairs, walking.

Mechanical protection

The vertebral body and vertebral arch encase the spinal cord to provide protection. When stacked on top of each other anatomically, they form the spinal column. The spinal cord and the nerve exits are located within the spinal canal.

Shock absorbing and mobility

The intervertebral discs are located between the vertebral bodies. These discs cushion shock forces gently, acting as "shock absorbers". The discs in conjunction with the vertebral joints facilitate motion by turning, stretching and bending.



Degenerative lesions of the spine

Degenerative changes of the spine involve any natural aging process associated with pathological changes of the vertebral bodies, intervertebral discs, ligaments and vertebral joints. These changes can greatly limit both the **mobility** and **stability** of the spine.

The stability of the spine can also be compromised by the natural aging process, unnatural weight distribution caused by a hereditary abnormality, or a lack of movement associated with a sedentary lifestyle. Any previous operation on an intervertebral disc or the spinal column can also cause a loss of stability.

Any form of instability can progress to become a pain generator.

Herniated Discs

The described degenerative changes or strong, jerky movements can cause tears in the intervertebral disc. The escape of the nucleus (or soft interior) of the intervertebral disc outward through these tears causes the disc to protrude; in other words, the intervertebral disc bulges outward. When the nucleus breaks through completely, this is called a prolapse or herniated disc.

Sequestration of the intervertebral disc occurs when the soft nucleus not only prolapses but separates completely from the intervertebral disc. As a result, the intervertebral disc and the sheared off tissue are no longer firmly connected.

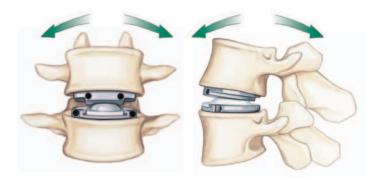
The bulging intervertebral disc or the prolapsed soft nucleus can now impinge on the nerve paths. Depending on the location of the prolapse, this can cause **pain or paralysis symptoms in the back, or also in the legs and feet**. In the extreme case, the prolapse can cause **paraplegia**.

The treatment concept with prodisc

The treatment goal of the pro**disc L** intervertebral disc prosthesis, is to restore the normal dynamic function of the spine and to bring about a clear reduction in pain.

This is achieved through the re-establishment of the disc height, as maintained by the prosthesis. Constricted nerve paths are "opened" and the vertebral joints are restored to their physiological position.

Prior to the development of artificial discs the only surgical option was a customary fusion, in which adjacent vertebral bodies are "fused together" permanently using implants, bone chips and/or cages. The goal of the intervertebral disc prosthesis is to **maintain mobility** at the affected intervertebral disc and to **reduce the extra loading** on the neighbor-ing intervertebral discs.



The prosthesis

The prodisc L intervertebral disc prosthesis consists of two cobalt chromium molybdenum plates which are sprayed with a titanium coating to enable the bone to grow onto the prosthesis. A plastic core (polyethylene) located between the plates guarantees the mobility in the segment (ball joint principle). All of these materials are clinically proven to be tolerated very well by the body.

This design prevents overloading of the neighboring intervertebral discs, as can occur after traditional spinal fusion.

Different sizes of the individual components are available to the surgeon, so that he can assemble the correct size of prosthesis that fits best with your anatomy.

Attachment of the prosthesis

To achieve short-term, primary stability directly after the operation, the pro**disc L** intervertebral prosthesis is equipped with a keel which is anchored directly on the vertebral body and two spikes. The necessary stability is thus guaranteed immediately upon implantation.



In addition the entire surface is coated with a highly porous patented pure titanium layer which facilitates the growth of bone on the metal components due to its extremely rough and porous surface.



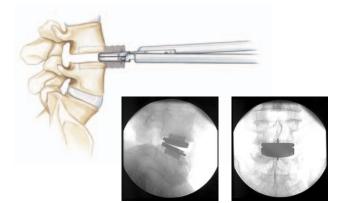
Course of the operation

The operation is performed under general anesthesia through the abdominal wall. The access to the spine is made according to the location of the diseased intervertebral discs either through a lower abdominal cross-section or a longitudinal section in the skin of approx. 4–6 cm.

After the large vessels and nerves located on the anterior surface of the spine have been pushed carefully to the side, the defective intervertebral disc is removed completely.



The intervertebral disc space is then expanded with special instruments to approximately 10–14 mm to decompress the nerve roots and to create space for the prosthesis. Following precise preparation of the implant area and measurement of the suitable size, the implant is inserted under X-ray control.



What happens after the operation?

You will remain in the hospital after the operation. Since the prosthesis is immediately stable under movement and pressure, you may begin ambulating one day after the operation. If necessary, as advised by your surgeon, you should wear an orthopaedic corset for a few weeks after the operation to support your spine.

In contrast to the fusion operation, you may sit during this time. However, similar to fusion operations you should avoid leaning forwards under load, lifting heavy objects and twisting your spine excessively.

Special post-operative treatment as recommended by your surgeon could include physiotherapy, mobilization, muscle build-up etc. Approximately **3 months after surgery** the bony ingrowth has occurred on the titanium layer of the prosthesis. This can be verified by X-ray during a follow-up examination. Follow-up examinations are performed at regular intervals to guarantee the greatest possible safety and care in this surgical method.

Please discuss your occupational and sporting activities directly with your physician.

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