DIANA®

Fusion of the Sacroiliac Joint

Dear patient,

pain in the sacroiliac joint is called sacroiliac joint dysfunction, sacroiliac joint syndrome or sacroiliac joint arthropathy.

This brochure is intended to provide you with a brief overview of its background and the treatment options for this illness.

HIGH-END MADE IN GERMANY

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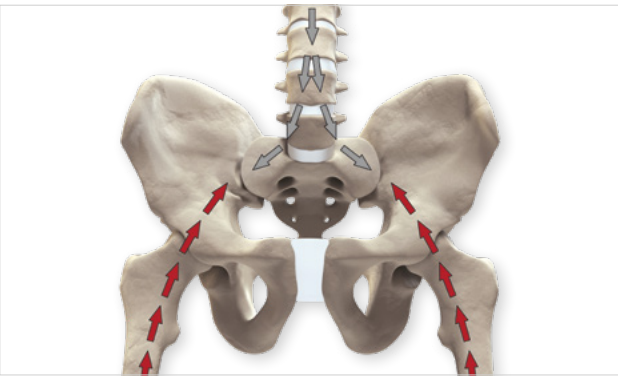
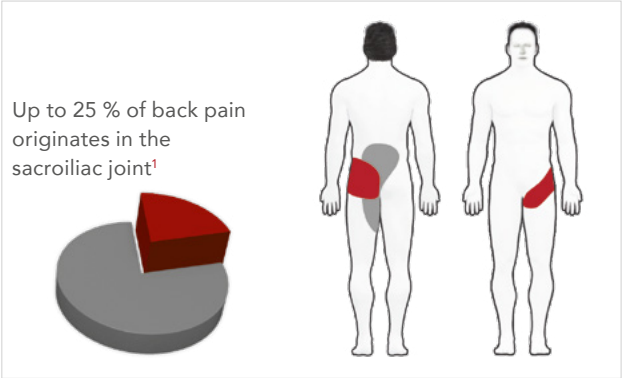
What is the Sacroiliac Joint?

The sacroiliac joints (SIJ) are weight-bearing joints that are situated between the hip joints and the spine. The sacroiliac joint is a true joint that can be exposed to the same wear and tear as other joints. Although the joint only has a small range of movement (up to 3°), it plays an important role in almost every physical activity in everyday life.



What causes Sacroiliac Joint Pain?

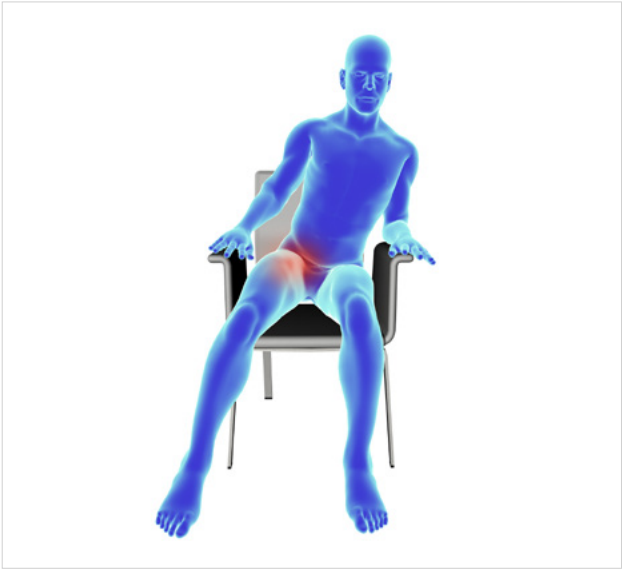
For many years it has been known that the sacroiliac joint can cause severe pain that is associated with considerable reduction in the quality of life. The nature of the pain is comparable to that of other pain that arises in the region of the lower lumbar spine. Besides normal wear and tear, a disorder of the joint can result from preceding surgery to the lumbar spine, long-term sequels of a pelvic fracture, pregnancy, a fall, or inflammation.



1 Cohen S. P.: Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis and Treatment. Sacroiliac Anesth Analg 2005; 101:1440-1453

How can a SIJ Syndrome be diagnosed?

A sacroiliac syndrome can only be clearly diagnosed on the basis of a combination of numerous individual examinations. Thus, for instance, radiological imaging (X-ray, MRI, CT) of the SIJ often yields largely inconspicuous findings, and these examinations are therefore not sufficient in themselves. A clarifying anesthetization of the joint by a specialist can in some cases confirm an SIJ syndrome. The medical history and physical examination by the doctor provide decisive indications. All the results of these examinations must be interpreted carefully and must be in line with each other when considered as a whole in order to rule out other causes of pain.



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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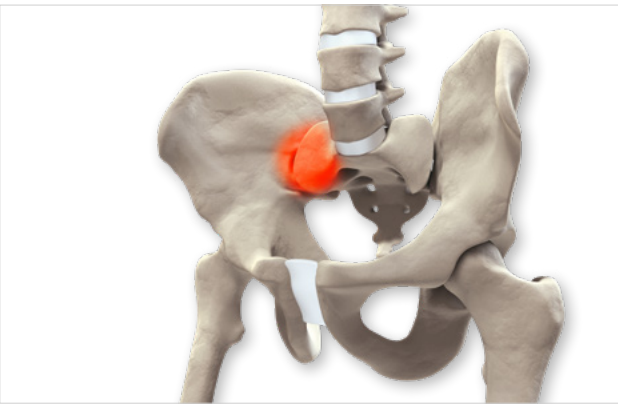
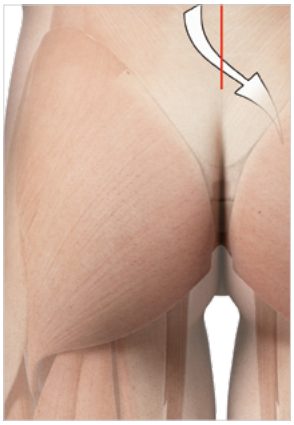
When is a DIANA® Operation recommended?

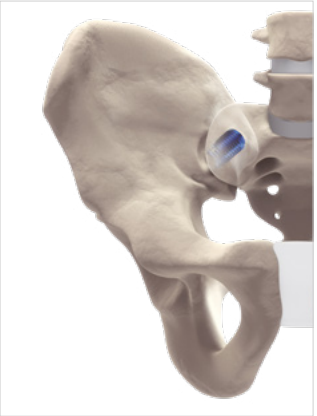
This surgical intervention is recommended in cases where the possibilities offered by all the aforementioned therapies have been exhausted and when symptom-free intervals become shorter over time. Also, there must be no general medical reasons for refraining from surgery.



How is the Operation carried out?

The DIANA® implant is inserted through a small incision (approx 5 cm) bringing the ligaments and the articular surfaces of the sacroiliac joint to the normal state. This process is called »ligamentotaxis «. At the same time, bone material or bone replacement material is added to ensure stable, permanent immobilization of the joint after completion of the healing phase.



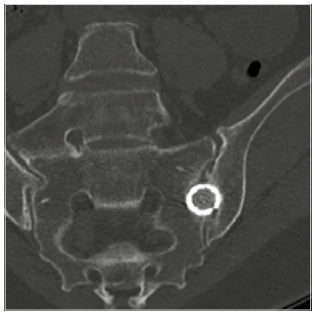


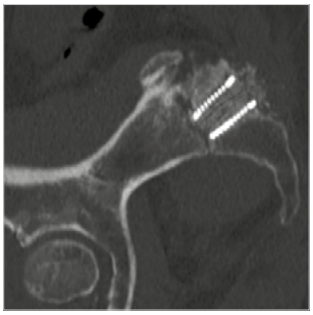
About DIANA®

DIANA® provides a simple and safe treatment technique for the sacroiliac joint. In a gentle and low-risk procedure, the DIANA® method (Distraction-Interference-Arthrodesis sparing Neurovascular (nerve and blood vessel related) Aspects) anchors an interference implant via a posterior access distally in the iliac bone. The proximal and central implant area is located in the extra-articular recess without affecting the actual articular surfaces.

Important Information for after the Operation

Be patient! Avoid falling! Follow your surgeon's instructions for 'tip toe' weight-bearing to a maximum of 20 kg for 8 weeks! Increase weight-bearing gradually! Avoid sexual activities during the partial weight-bearing period! Don't engage in any sports for a period of 6 months after the surgery! You should only have physical therapy after bone healing has been confirmed!





Experience with the Operation

Clinical experience since this surgical technique was first used (2010) show a clear improvement in the quality of life and a reduction in the SIJ pain culminating in complete freedom from pain.

The long-term use of pain medication is reduced culminating in cessation of pain medication altogether.

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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.

Material of DIANA®

The implants described are made from the following materials:

- Titanium alloy (Ti-6Al-4V) as per ASTM F136 / 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 DIANA® 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
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used
- Incorrect placement
- Infection
- Wear or breakage of implant components
- Pain or recurrent pain
- Residual loose powder in the internal metal lattice
- Absence of fusion

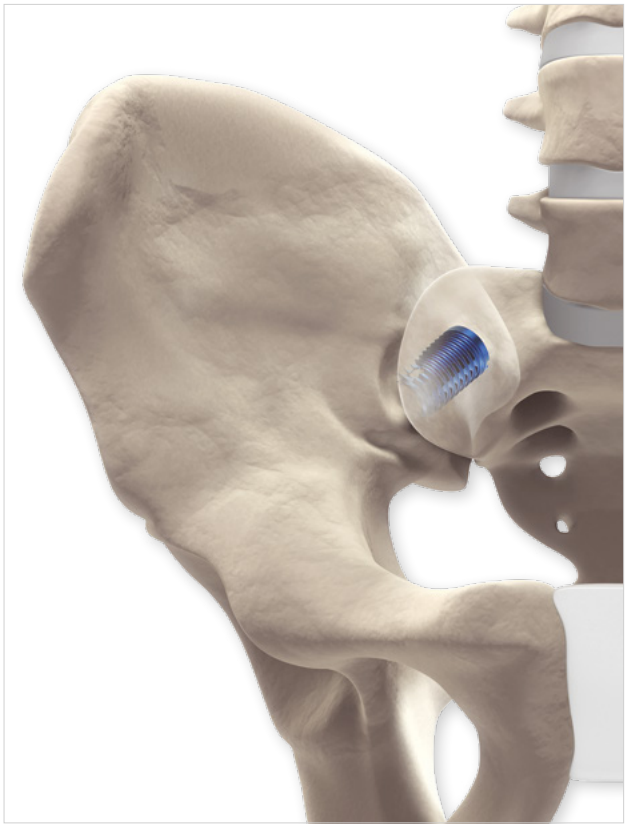
When you should consult a Health Professional

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
- General malais

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