

## Informed patient consent

Dear patient

The information provided in this form will prepare you for the informed consent discussion.

### Diagnosis/disease:

You are suffering from

\_\_\_\_\_, which you wish to have treated with a minimally invasive interventional measure (injection of medication).

### Progression with treatment:

The intended purpose of this procedure is to treat and improve your pain situation /improve your physical impairments and/or neurological deficits (muscle weakness, sensory deficits).

### Alternative treatment options:

The different alternative treatment options have been presented to you. Minimally invasive interventional pain therapy is usually not an emergency situation. As it is an elective procedure it is important that you take sufficient time before deciding to start with this treatment. In individual cases a procedure can be carried out on the day that the declaration of informed consent is signed.

### Course of procedure:

The following information will provide you with an explanation of the procedure that will be performed. Although inherent side effects are very rare, they can, however, occur and they will be outlined in this document. Please read the information carefully or have someone else read it to you. If any aspects are unclear, please do not hesitate to ask questions before providing your consent to the procedure.

The procedure will be performed under sterile conditions. X-ray guidance or ultrasound and the aid of contrast dye will be used. Local anaesthesia administered before the procedure usually reduces the sensation of pain associated with the procedure. You will also be given a sedative if required. An intravenous line will be fitted for your safety. For this reason it is also necessary to monitor your cardiovascular function and your respiration and this may also be necessary after the procedure. The type and dosage of the medication used depends on the underlying disease. With some procedures it is necessary for you to be nil-by-mouth, i.e. not to have eaten anything 6 hours beforehand. Drinking small quantities of fluids up to 2 hours prior to the procedure is permitted.

The procedures often have a therapeutic purpose, although they frequently also show the cause of your symptoms to confirm the diagnosis.

During the procedure you may experience an increase in your pain for a short time. This so-called memory pain can also be important for localizing the source of pain.

At the end of the procedure, we will apply a sterile plaster dressing.

You should not drive motor vehicles after the intervention on the day of the procedure because of possible impairment caused by the medication used.

**Additional measures:**

Should it be necessary to carry out the intervention in a revised form, I agree that the discussed changes or additional steps that may be necessary during the procedure can be performed.

**Possible complications:**

In general the following complications only occur on rare occasions:

Because the skin is pierced with a needle, local or deep-seated infection is the main concern. Sterile conditions and clean working practices in hygienic operating rooms minimize the risk of infection. Patients who suffer from an acute or chronic infection or who have an immune deficiency (including diabetics, transplant patients, patients with rheumatic diseases) have an increased risk of infection. The benefits and risks will be considered together with these patients.

The local and general side effects of cortisone and weight changes – also lasting for a longer period of time – are possible in some cases.

Short-term side effects of the medication consist of changes in menstrual cycle in women and autonomic symptoms, such as fluctuations in circulation, dizziness, nausea and increased feeling of heat with sweating and facial flushing.

Allergic reactions to the medications used are possible. However, with the applied safety precautions (see above) these conditions are usually easy to manage. In extremely rare instances local bleeding, or bleeding in close proximity to individual nerves or into the spinal canal / cerebral membrane can occur. This damage (complete paralysis in the perfusion area of the affected nerve, vascular damage, sensory deficits), which occurs very rarely, can last for a limited period of time or can be permanent.

In recent years neither a deep infection nor bleeding has occurred in a total of more than \_\_\_\_\_ procedures in our department.

**Contraindications:**

If you are currently suffering from an infection, the recommended treatment should generally be postponed. If you are taking blood thinners (Plavix, Marcoumar, Xarelto etc.) these should not be taken for a limited period of time or, in consultation with the prescribing physician, should be replaced with a different preparation.

If you are taking ASS (Aspirin, maximum 100 mg daily), the recommended treatment may be continued. In certain cases we will discuss with you whether you should discontinue the Aspirin beforehand.

**Post-intervention:**

Generally, after a minimally invasive procedure, you will be unfit for work for 1 day, rarely longer.

On request, we will be pleased to provide confirmation of your unfitness for work for the day of the procedure and the day following it.

The medication used has been tried and tested for many years and there have been no tolerance problems. For some procedures or for patients with a higher risk due to several generalized diseases, we recommend an inpatient hospital stay in order to be able to intervene immediately in the event of complications.

In the event of complications, about which the undersigned patient has been completely informed, you must contact us/your physician immediately and, if appropriate, a further consultation will be arranged.

Should new symptoms occur after your discharge, such as muscle weakness, sensory deficits, fever, headache when getting up, incontinence or other disturbing body sensations, please contact us immediately.

**Patient's informed consent**

I certify that I have mentioned all ailments and complaints, including those of a general nature, contained in my medical history.

I know that the success of the procedure cannot be guaranteed.

I herewith declare that I have understood the explanations listed above and that I have been sufficiently informed by a qualified physician about the procedure.

I was given sufficient opportunity to clarify any uncertainties with my physician and ask any questions, which were comprehensively answered.

Doctor's remarks in reference to the informed consent discussion (waiver of informed consent discussion with details of the reason, individual circumstances increasing the risk: age, heart disease, raised blood pressure, overweight, etc.):

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Dr. \_\_\_\_\_ has carried out an informed consent discussion with me. I have understood the explanations and was able to ask all the questions, which were important to me. I have received a copy of the informed consent discussion protocol.

I give my informed consent to the planned procedure, including any changes and additional steps, which prove to be necessary during the intervention, as discussed above.

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Place and date

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Patient's signature

The entire text of the declaration of informed consent and all pertaining questions were discussed with the patient. A copy of this explanatory protocol was handed to the patient.

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Date and time

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Physician's signature