SSIPM Swiss Society for Interventional Pain Management

FMH Verbindung der Schweizer Ärztinnen und Ärzte
Fédération des médecins suisses
Federazione dei medici svizzeri
Swiss Medical Association

spo PATIENTEN SCHUTZ

Patient information (informed consent)

Dear Patient,
This Patient Information sheet is intended to prepare you for the informed consent discussion and to document your consent to the proposed therapy, intervention.

Diagnosis/disease:
You are suffering from a _____ that you wish to have treated by the minimally invasive interventional measure.

Course with treatment:
The intervention is intended to improve your pain situation or to improve your limiting symptoms and/or neurological deficits or to clarify the cause.

Treatment alternatives:
The various alternative treatment options have been presented to you. Minimally invasive interventional pain therapy is usually not an emergency situation. It is therefore an elective procedure. Therefore, it is important that you take enough time before deciding on this treatment. In individual cases, at your request, a procedure can be carried out on the day you sign the consent form.

Intervention procedure:
This Patient Information sheet is intended to explain this procedure to you and to make you aware of the positive effects, but also of the adverse consequences, which occur very rarely. Please read it carefully or have it read to you. If you are unclear, ask questions before you give your consent to the procedure.

The procedure is carried out under sterile conditions, and guided with X-ray imaging, CT or ultrasound with contrast. A local anaesthetic before the procedure usually reduces the pain sensations associated with the procedure. The type and dosage of medication used also depends on the underlying condition. Some interventions require you to be fasting, i.e. not eating food for 6 hours beforehand. Drinking clear liquids in small quantities is permitted up to 2 hours before intervention. Establishment of an intravenous line is for your safety and will be done if needed. In addition, monitoring of your cardiovascular function as well as your breathing may be required and may also be necessary after the intervention. In addition, you may be given a sedative medication if necessary.

The interventions often have a therapeutic approach, but frequently also show the origin of your symptoms to confirm the diagnosis or determine the further course of action.

In image-guided interventions, X-rays are used to a very small extent. The radiation dose is kept extremely low in order to avoid medium- or longer-term damage to health according to human judgement. Ultrasound is done without radiation. CT-guided interventions usually require higher doses, also according to human judgement without medium- or longer-term damage to health.

During the intervention there may be a brief increase in pain, which may also have local diagnostic significance (memory pain).

At the end of the intervention, you will receive a sterile plaster dressing if necessary.

You should refrain from driving on the day of the intervention because of the possible impairment caused by the medication used.

Extension measures:
If during the intervention the need arises to execute the intervention in a modified form, I also agree to the discussed modifications and extensions that prove necessary during the intervention.

Possible complications:
The following complications occur only very rarely:

Because the skin is pierced with a needle, the focus is on local or deep-seated infection. Sterile conditions and clean work in hygienic procedure rooms minimize the risk of infection. Patients with acute or chronic infections or reduced immune competence (diabetics, transplant patients, rheumatic patients, etc.) have an increased risk of infection. The benefits and risks are weighed up together for all patients.

Local and general effects of cortisone and weight changes are possible in some cases, and may even be longer lasting.

Short-term effects of the medication consist, for example, in changes in the menstrual cycle, vegetative symptoms such as circulatory fluctuations, dizziness, malaise and an increased feeling of warmth with sweating and facial flushing.

Hypersensitivity reactions to the medications used are possible but can usually be well controlled due to the precautionary measures described above. Extremely rare are haemorrhages locally or in the vicinity of individual nerves as well as in the spinal canal or inflammations of the meninges. These very rarely occurring damages (complete paralysis in the affected nerve supply area, vascular damage, loss of sensitivity) can be temporary or permanent.

Contraindications:
If there are signs of an infection, the proposed treatment should generally be dispensed with. If you are taking a blood thinner (Plavix, Marcumar, Xarelto or others), it must not be

taken for a limited period of time; if necessary, it should be replaced by another product in consultation with the prescribing physician.

If you are taking ASA (aspirin, max. 100 mg daily), the suggested treatment may be carried out. We will discuss with you in each individual case whether you should stop taking the aspirin or other medication beforehand.

After the intervention:
As a rule, incapacity to work after a minimally invasive interventional procedure is 1 day, rarely longer.

On request, we are happy to confirm this incapacity for work for the day of the procedure and the day after.

The medicines used have been tried and tested for many years and do not show any tolerance issues. In particular, I have been informed (see Information Sheet for patients on *off-label use*) that the treatment method and the use of medicines in the context of medicines in the context of my treatment may be *off-label*. In the case of *off-label use*, there is no guarantee that the costs will be covered by the compulsory health insurance. For a few interventions or for patients at higher risk due to several general diseases, we recommend an inpatient stay in order to be able to intervene immediately in case of complications.

In the event of complications, about which the undersigned patient has been fully informed of, it has been agreed that he/she will be contacted immediately and, if necessary, be seen again.

Should new symptoms occur after your discharge from hospital, such as muscle weaknesses, sensory disturbances, fever, headaches when standing up, incontinence or other physical sensations that worry you, we ask you to contact us immediately.

Informed consent of the patient:
I assure that I have mentioned in the medical history all ailments and complaints known to me, also of a general nature.

I know that no guarantee can be given for the success of the procedure.

I hereby declare that I have understood the explanations given overleaf and that I have also been informed in detail by a doctor about the procedure.

I have had sufficient opportunity to clarify any ambiguities with the doctor and to ask questions which have been fully answered.

Notes by the doctor on the informed consent discussion (waiver of informed consent with details of the reason, individual risk-increasing circumstances: age, heart disease, high blood

pressure, overweight, etc.):

_____
_____
_____
_____
_____
_____
_____

Dr _____ held an informed consent discussion with me. I understood the explanations and was able to ask all the questions that were important to me. I was given a copy of the minutes of the consultation.
I agree with the planned intervention, as well as with the discussed changes and extensions that prove necessary during the intervention.

_____
Place and date Signature of the patient

_____
Date and time Signature of the doctor

Information sheet for patients on "*off-label use*"
I also agree that on the occasion of my treatment by

Dr _____, the method of treatment or the use of medicines may be off label.

This is understood to mean the use of a medicinal product or treatment procedure authorised in Switzerland outside the authorisation approved by the competent authority (Swissmedic). An unauthorised use may exist with regard to the indication, the application possibilities, the dosage, the type of application, the duration of treatment or due to the patient group. Off-label use is permissible on the basis of the doctor's therapeutic freedom and is based on many years of experience, particularly in anaesthesiological pain therapy. The off-label use of a medicinal product or a specific procedure is always carried out according to the recognized rules of medical and pharmaceutical science and with the greatest care. If you have any questions, especially about the specific medicinal product used or the chosen treatment method, you may of course contact your attending doctor at any time.

Signature of patient and date:

_____

If you do not agree with this procedure, your doctor may decide to refuse treatment on a case-by-case basis.

The data routinely collected in the course of your pain therapy care can be analysed anonymously for quality assurance purposes. It is also possible for a member of your treatment team to contact you personally after treatment as part of quality assurance.
These data can also be analyzed anonymously for scientific purposes and possibly published, for example in quality assurance and control registers.
Anonymous means that your name will not be mentioned in any way in analyses or publications resulting from the analyses. Please contact your pain therapist if you do not agree to an anonymized scientific analysis of your routinely collected data.

Signature of patient and date:

_____