

INFORMED CONSENT SHEET FOR A DOUBLE-LUMEN INGUINAL CATHETER

Dear patient, dear parents,

You have decided to have an INUSphere[®] or another extracorporeal blood purification procedure performed with machine support. For this purpose, access to the bloodstream must be created, in your case through a double-lumen catheter. The following informed consent sheet is provided as a source of information for you. We ask you to read it carefully before the informed consent discussion and to fill out the questionnaire conscientiously.

Why an inguinal catheter?

Two accesses are required for the blood purification procedure specifically adapted to your case. These are usually placed in the crook of the arm via a special vein catheter. However, this option cannot be implemented in your case due to the nature of your arm vessels or for personal reasons, so we are planning to use a double-lumen inguinal catheter.

This meets exactly the same requirements as central venous catheters. Due to the double-lumen tube system of the inguinal catheter, only a single access is required.

We deliver your blood through it to what is called a plasma filter using a blood pump. After purification, the blood is returned to your body through the same catheter.

Insertion of the catheter

After a local anesthetic has been administered at the puncture site, the catheter is inserted into a vein near the groin from either the right or left side (see image). As a rule, advancing the catheter into the inferior vena cava does not cause any pain. To finish, the catheter is usually sutured in place (rarely taped) and protected with a bandage. The bandage is opened only to use the catheter. Extension of the planned procedure

In rare cases, e.g. if there are physical anomalies, it may be necessary to expand the approach during the procedure (e.g. a small skin incision). If there are any indications of these circumstances in advance, your doctor will inform you separately.

Please give your consent to medically necessary extensions or changes to the planned procedure now so that they can be carried out during the same anesthetic procedure and an additional procedure can be avoided.

Risks and possible complications

Insertion of the catheter has long been a proven routine procedure. The frequency information is not an exact number as on drug leaflets, but serves only to provide a general assessment and to compare the risks. Despite the utmost care, life-threatening complications may occur that require further treatment or surgery. Previous illnesses and individual characteristics can influence the risk of complications.

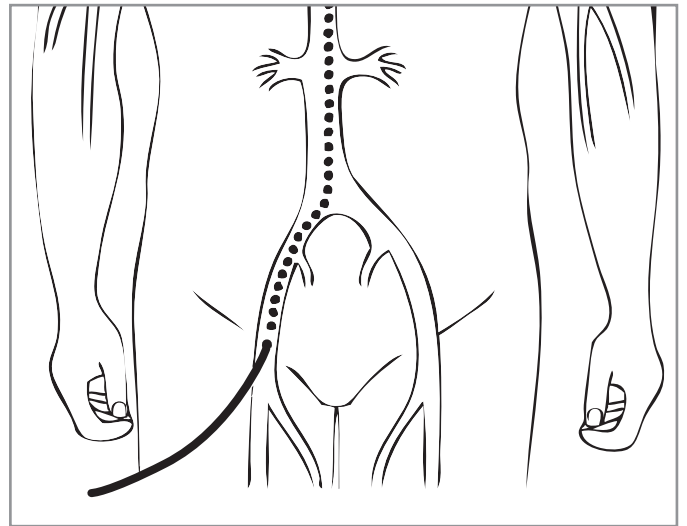
Bleeding rarely occurs. Sometimes local bruises form near the puncture site. Bleeding that requires surgery is extremely rare. If the catheter is in place for a long time, blood clots can develop (thrombosis), which sometimes prevent fluid from draining from the leg (edema). When carried away by the bloodstream, they can clog blood vessels. In the worst case, this can lead to a life-threatening pulmonary embolism that requires intensive care treatment. Rarely, a pulmonary embolism is caused by blood clots that are detached from the vein wall when the catheter is advanced. If blood clots get into the heart or brain, this can in extreme cases lead to a heart attack or stroke with permanent damage. In all of these cases, intensive care treatment and/or further surgical procedures may become necessary. In rare cases, the vessel wall can be damaged or punctured (perforation) when inserting and advancing the catheter.

Occasionally, the catheter may become blocked, defective, or form knots and loops in the punctured vessel that restrict blood flow. If simple measures (such as flushing with IV fluid or Heparin[®]) do not help, the catheter may need to be replaced. In extremely rare cases, the tip of the catheter breaks off and is washed into the heart or lungs. Then it has to be surgically removed. Inflammation of the veins (thrombophlebitis) can develop, usually starting from the puncture site.

Allergies or intolerances (e.g. to latex, medication or disinfectants) very rarely lead to acute circulatory shock, which requires intensive care measures. Serious, potentially permanent damage (such as organ failure, brain damage or paralysis) is extremely rare.

Skin, tissue or nerve damage caused by positioning and accompanying measures (e.g. injections, disinfection) is rare. Possible, in some cases permanent consequences: Pain, inflammation, tissue death, scars as well as sensory disorders, functional disorders or paralysis.

During the informed consent discussion, please ask any questions that you think are important or if anything is unclear.



Please note! – Unless otherwise ordered by a doctor!

Before the procedure:

Please inform your doctor if you take anticoagulant medication (e.g. Marcumar[®], Aspirin[®], Plavix[®], Pradaxa[®], Xarelto[®], Eliquis[®], Heparin[®]). Your doctor will decide if and when these medications need to be stopped or replaced with others.

After the procedure:

Never open the catheter plugs as this can result in a life-threatening air embolism. The locking clamps on the catheter (usually blue and red) must also not be opened. Tell your doctor immediately about any changes in the locking mechanisms of the catheter or any leaks with fluid or blood escaping. Avoid working with scissors or a knife near the catheter to prevent cuts. Should the catheter nevertheless slip out of the entry point due to tensile stress or the like, apply pressure to the bleeding site immediately with a gauze compress or, if necessary, a clean cloth and contact your doctor. If your doctor is not immediately available, contact an emergency doctor.

Overweight patients

Additional difficulties and complications may arise in overweight patients. They include:

- Difficulty puncturing the femoral vein in the groin area
- Kinking or slipping of the catheter
- Multiple puncture attempts required with possible need to switch sides
- Successful placement of the catheter may not be possible, resulting in discontinuation of treatment

Costs:

If additional costs arise due to the aforementioned complications (due to being overweight), they must be borne by the patient.

Doctor's notes _____ **on the informed consent discussion** (please underline the text passages)

For example, the following was discussed: Necessity/urgency of the procedure, choice and implementation of the procedure, advantages and disadvantages compared to other methods, possible extensions or changes to the procedure, risks and possible complications, special features that increase risk, possible secondary and follow-up procedures, chances of success, instructions for conduct and (in particular, document individual characteristics here, e.g. rejection of individual measures, determination of the ability of minors to understand, legal representation, patient with guardian, authorized person and, if necessary, special notes on the information section.)

The following procedure is planned: Insertion of a Sheldon catheter Scheduled appointment (date): _____

Consent:

I have read and understood the informed consent sheet. I was able to ask any questions I wanted during the informed consent discussion. They were answered completely and understandably. I am sufficiently informed, I have considered my decision well and do not need any further time to think about it.

I consent to the procedure noted above.

I also consent to pain relief, to unforeseeable changes or extensions that prove to be medically necessary only after starting the procedure, and to necessary secondary and follow-up procedures.

I filled out the questionnaire (anamnesis) to the best of my knowledge. I will follow the rules of conduct.

Place, date: _____ Signature of patient: _____ Signature of the doctor: _____

Refusal:

I do not consent to the proposed procedure. I was expressly informed that INUSphere[®] treatment cannot take place without functioning access points. If access via the arm veins fails, treatment must be discontinued. Any costs incurred are to be borne by the patient.

Place, date: _____ Signature of patient: _____ Signature of the doctor: _____

If one parent signs alone, he/she also declares with his/her signature that he/she has custody and that he/she is acting in agreement with the other parent. In the case of serious procedures, both parents should always sign.

QUESTIONNAIRE (ANAMNESIS)

Please answer the following questions carefully so that we can better prevent any risks. Please check the relevant box and underline or complete as appropriate. If necessary, we will be happy to help you fill it out.

(n = no / y = yes)

Age: _____ years Height: _____ cm Weight: _____ kg Gender: _____

- | | |
|---|---|
| <p>1. Do you take any medication regularly or at the present time? <input type="checkbox"/> n <input type="checkbox"/> y
E.g. anticoagulants (e.g. Marcumar[®], Aspirin[®], Plavix[®], Xarelto[®], Pradaxa[®], Eliquis[®], Lixiana[®], Heparin[®]). Painkillers, cardiovascular drugs, hormone preparations, sleeping pills or sedatives, anti-diabetics (especially those containing metformin)?
If yes, please specify. _____
_____</p> <p>2. Do you or your blood relatives have an increased tendency to bleed, e.g. frequent nose/gum bleeding, bruises, bleeding after operations? <input type="checkbox"/> n <input type="checkbox"/> y</p> <p>3. Do you have an allergy such as hay fever or allergic asthma or an intolerance to certain substances (e.g. medication, latex, disinfectants, anesthetics, X-ray contrast media, iodine, adhesive bandages, pollen)? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____</p> <p>4. Have any X-ray contrast examinations been carried out in the past? <input type="checkbox"/> n <input type="checkbox"/> y
If so, were there any complications?
If yes, please specify. _____
_____</p> <p>5. Do you have an infectious disease (e.g. hepatitis, tuberculosis, HIV/AIDS)? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____</p> <p>6. Have you ever had vascular occlusion due to blood clots (thrombosis/embolism)? <input type="checkbox"/> n <input type="checkbox"/> y</p> | <p>7. Do you have/have you had any vascular disease (e.g. circulatory disorders, atherosclerosis, aneurysms, varicose veins)? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____</p> <p>8. Have you ever had surgery on your neck or blood vessels, in particular in the neck, groin or leg area? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____
_____</p> <p>9. Do you have/have you had any cardiovascular disease (e.g. heart defect, heart valve defect, angina pectoris, heart attack, stroke, arrhythmias, myocarditis, high blood pressure)? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____</p> <p>10. Do you have any implants in your body (e.g. pacemaker/defibrillator, joint endoprosthesis, heart valve, stent, metal, plastic, silicone)? <input type="checkbox"/> n <input type="checkbox"/> y
If yes, please specify. _____</p> <p>11. Have you had similar catheters placed in the past? <input type="checkbox"/> n <input type="checkbox"/> y
If so, when and where? _____
_____</p> <p>12. Regular tobacco use <input type="checkbox"/> n <input type="checkbox"/> y
If yes, what and how much? _____</p> <p>13. Regular alcohol consumption <input type="checkbox"/> n <input type="checkbox"/> y
If yes, what and how much? _____</p> <p>14. Additional question for women: Could you be pregnant? <input type="checkbox"/> n <input type="checkbox"/> y</p> |
|---|---|

I filled out the questionnaire (anamnesis) to the best of my knowledge.

Place, date: _____ Signature of patient: _____ Signature of the doctor: _____

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