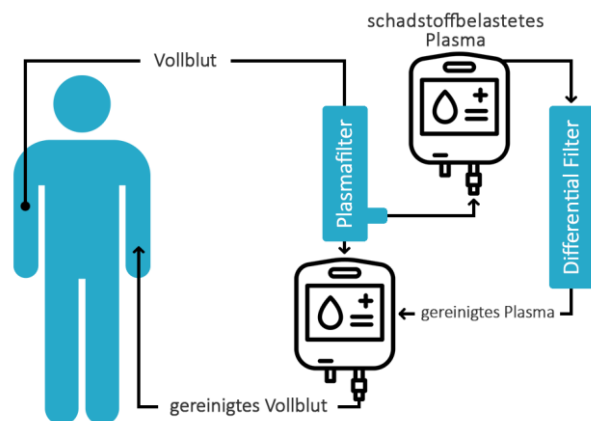


# Informed consent & consent to INUSpheresis®-treatment

INUSpheresis® is a special form of high-tech blood plasma purification.  
In this biophysical elimination procedure, the patient's entire blood plasma is passed through a special filter and freed from various harmful substances.  
INUSpheresis® thus helps the body to rid itself of harmful metabolic products:

- Heavy metals
- complex infectious toxins
- various environmental toxins, pesticides
- pathogenic antibodies
- inflammatory substances (interleukins, TNF-alpha)
- lipids such as cholesterol, etc.
- microplastics
- allergens
- pathogenic proteins (paraproteins, tumor-associated proteins, circulating immune complexes, pathoproteins, haptens)



## Procedure of INUSpheresis®

The pathogenic substances are filtered out - the purified plasma is returned to the body with all the good components. The inflammatory cascade is contained, metabolism and immune system are relieved and can regenerate.

After anamnesis and certain preliminary examinations (ECG, blood findings, abdominal ultrasound), an appointment is made for the Inuspheresis® treatment.

One treatment lasts about 2-4 hours. This treatment is performed by a specially trained and qualified staff of doctors and assistants of the New Energy Medical Center. You will lie on a comfortable couch and can watch TV, listen to music or simply relax during the treatment.

Blood is collected and returned via 2 arm veins with special cannulas and continuously fed via a blood pump to a plasma filter (in this case: immune filter), which separates the pathologically altered plasma in a ratio of 3:1 (3 parts by volume of blood to 1 part by volume of plasma). The extracted plasma is fed to the special filter via a plasma pump.

The immune filter has the ability to recognize pathologically altered components/proteins and to capture them from the plasma (filtering). Typically, the fibers of the filter change color and the pressure in the fibers increases. At a certain pressure in the fibers of the filter, the proteins are discharged by rinsing into a bag. This "retinate" is available for laboratory analysis.

For the duration of the treatment, the blood must be temporarily rendered non-coagulable. For this purpose, the drug Heparin® is added to the system at the beginning of INUSpheresis®. The dose of the drug is precisely calculated for it, so that at the end of the treatment the effect of the drug is more than 80% cancelled.

In the 48 hours following the first INUSpheresis®, post-mobilization may take place. Therefore, in order to benefit maximally from the treatment, it is recommended to have a second INUSpheresis® performed after 48 hours.

INUSpheresis® is a well-tolerated procedure that relieves the organism and poses few risks if performed with the necessary care.

INUSpheresis® performed in our clinic is NOT a PLASMA EXCHANGE and consequently it is not burdened with the side effects of the same. No electrolytes or other healthy components are filtered out, but only pathogenic loads.

## Contraindications:

- acute heart disease (shortly after infarction, stroke)
- massive circulatory problems, extreme hypotension
- Multimorbid, very poor general condition
- severe coagulation disorders, pronounced thrombocytopenia (therapy may be possible if the patient is well medically adjusted)
- terminal cancer
- Acute inflammation and fever
- Organ failure such as severe renal insufficiency

## Possible side effects:

### - Dizziness, drop in blood pressure, rarely cardiac arrhythmia

At the same time as blood is drained from the arm veins, physiological saline solution is infused so that a volume shift due to blood withdrawal is compensated for in a ratio of 1:1. As a result, drops in blood pressure, dizziness and cardiac arrhythmias are very rare (less than 1:1000). An ECG is taken before INUSpheresis® to document the heart rhythm and any changes. During the treatment, the circulation, blood pressure and pulse are continuously monitored by a cardiovascular monitor.

- **Postoperative bleeding from the puncture sites**

Tends to occur with poor vascular conditions. After completion of INUSpheresis®, the cannulas in the arm veins are withdrawn by qualified personnel and a professional dressing is applied.

- **Formation of a bruise at the puncture sites**

A bruise may form at the injection site, especially if the vascular conditions are poor (e.g. diabetes), but it will heal over the next few days.

- **Nerve injury of a cutaneous nerve/arm nerve.**

Very rare complication, usually caused by atypical anatomy of the nerve course. Before a puncture is performed, a preliminary examination is performed to check for vascular conditions and anatomy, and to determine the puncture sites.

- **Allergic reaction to the blood thinner Heparin®.**

Rare complication. Signs are: Itching, redness of the skin. Please report to your attending physician or nurse if you experience such symptoms during and after treatment (even if you are already home). The reaction will subside after a few hours. **If you are aware of any intolerance, please inform us about it now.**

- **allergic reaction to foreign material (rare 1:1000000)**

ery rare complication. The main sign is the appearance of itching and redness of the skin. Please inform us if this occurs during treatment or afterwards.

## What should be observed on the day of INUSpheresis® ?

- drink a lot the day before the treatment. On the day of the treatment drink moderately, have breakfast or lunch. This ensures that the vessels are "well filled".
- wear comfortable clothes during the treatment
- any prescribed medication should be taken normally and as every day.
- any prescribed medication should be taken normally and as every day.

## Immedaitely after INUSpheresis®:

- Rest - avoid exertion and stress
- No sports, physical exertion or sauna
- No obligatory/urgent appointments directly after INUSpheresis
- **No independent driving:** Please have someone pick you up, as you should not drive a motor vehicle 24h after treatment

After INUSpheresis® an increased feeling of hunger and increased tiredness is normal. A worsening of the symptoms is possible in the days after the treatment, but it does not worsen the final result.

**For the successful execution of the planned INUSpheresis® we depend on the information about your medical history, current medication, existing allergies (especially drug allergies). Please provide all important information in the "patient history form"!**

- I have read and understood everything and agree to the treatment.
- I will bring the following current (max. 1 month old) findings from the preliminary examinations to the treatment:
  - EKG
  - Upper abdominal sonography
  - complete laboratory incl. coagulation status (PTZ+fibrinogen, hematocrit)
- I confirm that INUSpheresis is a special treatment and according to common opinion is not considered medically necessary. No guarantee of success can be given.
- The information was provided in detail by the doctor personally, taking into account my registered previous diagnoses.
- I am aware that (partial) reimbursement of the costs by statutory health insurance companies has not yet been made, whether reimbursement by private health insurance is possible must be clarified in each case.
- I am aware that I should not drive a motor vehicle after the treatment on the same day.
- I still have the following questions:

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Place, date

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Signature

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Name in Block letters