Dear patient,

This Informed Consent Form is intended to prepare you for an Informed Consent Discussion. During this discussion, the anaesthetist will talk to you about the following: the method of anaesthesia planned for you, the other options that come into consideration, the pros and cons of each method, and the associated risks and possible complications in your case. Please read the form carefully and answer the questions about your health as precisely as you can.

I. General anaesthesia

General anaesthesia makes you lose consciousness completely and feel no pain. The following types of general anaesthesia can be considered:

1. **Intravenous general anaesthesia:**
   A fast acting anaesthetic is injected in a vein through a hollow needle or a thin tube (catheter). For longer procedures, anaesthetics are administered repeatedly or continuously (intravenous anaesthesia) or combined with one of the following methods (combined anaesthesia).

2. **Face mask anaesthesia:**
   Anaesthetic gases and oxygen are administered through a breathing mask placed tightly over the mouth and nose.

3. **Laryngeal mask airway or endotracheal intubation anaesthesia:**
   These methods are used after inducing anaesthesia intravenously.
   a) **Laryngeal mask airway anaesthesia:**
      The doctor places a respiratory tube through the patient's mouth up to the opening of the larynx where an inflatable cuff protects the airway.
   b) **Endotracheal intubation anaesthesia:**
      The doctor inserts a respiratory tube through the mouth or nose of the patient and pushes it between the vocal cords all the way into the trachea. An inflatable cuff at the end of the tube seals the trachea.

Both methods maintain an open airway and permit administration of oxygen and anaesthetic gases as well as mechanical ventilation. Intubation also reduces the life-threatening risk of saliva or the contents of the stomach entering the lung (aspiration). One of the reasons why medication to relax the muscles (muscle relaxants) are almost always given in association with endotracheal intubation anaesthesia, and sometimes when using a laryngeal mask airway, is to allow the respiratory tube to be introduced gently.

II. Regional anaesthesia

This works by eliminating the sensation of pain in specific regions of the body by blocking pain-transmitting nerve fibres with local anaesthetics. After injection of the anaesthetics, these regions first become warm, then heavy and numb. The patient cannot move his or her legs/arms at all or only to a limited extent for several hours.

Additional **pain killers** and/or **sedatives**, reducing the patient's awareness and memory of the intervention are administered if necessary (twilight sleep/sedation analgesia).
Regional anaesthesia near the spinal cord:
For interventions in the abdominal, perineal, pelvic and groin areas, as well as on the leg, the doctor injects the anaesthetic drug using a hollow needle or catheter
1. in the case of **spinal anaesthesia** into the subarachnoid space containing cerebrospinal fluid (CSF) (Fig. 1).
2. in the case of **epidural anaesthesia (EA)** in the epidural space (Fig. 1) in the lumbar region of the spine (lumbar EA), the sacrum (caudal EA) or for procedures on the upper abdomen and thorax, near the thoracic region of the spine (thoracic EA).

How fast the nerve fibres running from the spine to the body regions are blocked depends on the method used: it takes a few minutes for spinal anaesthesia and normally 15-30 minutes for epidural anaesthesia. A **combination** of the two methods results in faster and longer action.

2. Brachial plexus anaesthesia:
For interventions on the hand, arm or shoulder, the brachial plexus - an arrangement of branched nerve fibres can be blocked (hence the alternative name 'brachial nerve block') in a number of different places (Fig. 2):
1. in the armpit (axillary plexus anaesthesia),
2. below the clavicle (vertical infraclavicular plexus anaesthesia),
3. above the clavicle (supraclavicular plexus anaesthesia) or
4. on the side of the neck (interscalene plexus anaesthesia).

The doctor makes use of ultrasound or an injection needle connected to a nerve stimulator to locate the nerves to be blocked. The latter may cause temporary abnormal 'electrifying' skin sensations. The onset time of the anaesthetic is about 15 minutes.

In all of the regional anaesthesias mentioned above, the doctor can place a **catheter** for additional injection of anaesthetics, for continuous administration of medication, or for **post-operative pain relief**.

If, in individual cases, the sensation of pain is not completely eliminated, a strong pain killer (e.g. an opioid) is additionally administered. If the effect of both anaesthetics and analgesics is not enough for the intervention, or if the regional anaesthesia acts on an area larger than intended, it may be necessary to switch to general anaesthesia.

A **combination of general and regional anaesthesia** may be favourable for specific operations. Advantages include: less anaesthetics are required, the time required for recovery from anaesthesia is shorter and post-surgical pain is reduced. You will be informed separately, if other methods of anaesthesia come into consideration (e.g. plexus anaesthesia of the leg, single nerve blocks, intravenous regional anaesthesia, extensive local anaesthesia).

### III. Risks and possible complications

Despite careful planning and conduction of the anaesthetic procedures and monitoring of vital body functions, risks and complications cannot be ruled out completely. This also applies to the rare cases of **awareness** and the even rarer cases of **pain sensation** during general anaesthesia.

**General risks and possible complications of anaesthetic procedures:**
- **Significant bleeding** (haemorrhage) and **bruises** (haematomas) as a result of injections, as well as infections near the injection or catheter site (e.g. injection site abscess, tissue death, vein irritations/inflammations), requiring treatment, as well as temporary or lasting minor **nerve damage** (e.g. abnormal skin sensations, sensitivity to touch, numbness, movement disorders, pain) are rare. Infections, leading to a life-threatening case of **blood**
poisoning (sepsis), and chronic pain or lasting paralyses after nerve damage, haematomas or inflammations are extremely rare.

Skin and tissue damage caused by positioning on the operating table, as well as nerve damage and paralyses in the arms/legs due to pressure, strain or overstretching during anaesthesia cannot be excluded absolutely; although these effects usually subside within a few months, they may also be persistent in very rare cases.

Allergic reactions and hypersensitivities may occur in response to anaesthetics, analgesics, contrast agents, disinfectants, antibiotics or latex and others, or due to pre-existing conditions that we ask about in the Medical History Questionnaire. Possible reactions range from temporary, slight intolerance reactions (e.g. itching, skin rash, nausea), breathing and circulatory problems, that can normally be treated effectively, to very rare life-threatening allergic shock with cardiac, circulatory, respiratory and organ failure, necessitating intensive medical care.

Other life-threatening complications, e.g. cardiac, circulatory or respiratory arrest, organ damage, blockage of blood vessels (embolism) by blood clots (thrombi) moving in the blood stream, occur extremely rarely in all methods of anaesthesia, even in patients of advanced age, in a poor general state of health and with concomitant diseases.

In older patients, the stress of surgery and anaesthesia, coupled with displacement from their accustomed surroundings, can lead to – usually temporary – confusion.

2. Specific risks and possible complications of general anaesthesia:

Nausea and vomiting have become rarer. Life-threatening incidents due to saliva or stomach contents entering the lung (aspiration), necessitating intensive medical supervision/care, are very rare. Sudden abnormal constriction of the airways (laryngo-/bronchospasm), which can however be controlled with medication, is rare. An extreme temperature rise due to a massive, life-threatening metabolic crisis is extremely rare (malignant hyperthermia). This would require immediate treatment with medication and intensive medical care.

Endotracheal intubation/use of a laryngeal mask airway may cause temporary swallowing problems and hoarseness. Injury of the pharynx, larynx and trachea, as well as vocal cord damage with lasting voice problems (hoarseness) and shortness of breath are very rare. Damage, especially to loose or carious teeth, implants and fixed artificial dentures (e.g. crowns, bridges, prosthesis), and tooth loss may occur.

3. Specific risks and possible complications of regional anaesthesia:

If the anaesthetic enters a blood vessel during injection, it may spread to other parts of the body and cause a severe headache, loss of consciousness, and serious, in very rare cases even life-threatening cardiovascular response.

- Spinal and epidural anaesthesia (EA):

  Severe headache after spinal anaesthesia, less often after epidural anaesthesia, may require special treatment (e.g. injection of the patient’s own blood in the epidural space, a procedure called an epidural blood patch). The headaches normally subside after a few days. In exceptional cases, headaches have however been reported to have persisted for months or even years. Severe back pain may occasionally be experienced for several days after spinal anaesthesia, but this can normally be effectively controlled with medication. Prolonged pain in the region of the sacrum after a caudal EA is rare.

  Direct injury of the spinal cord in the course of spinal anaesthesia, as well as lumbar and caudal epidural anaesthesia, can however be ruled out almost completely, since the end of the spinal cord is normally located above the site of injection (cf. Fig. 1); such injuries are very rare in association with thoracic EA. Lasting paralyses, in the worst case paraplegia, as a result of haematomas, inflammations, nerve or spinal cord injuries are extremely rare. The same applies for lasting hearing and sight impairment, erectile dysfunction, meningitis and brain haemorrhage.

  Temporary urinary retention is common after spinal/epidural anaesthesia; a urinary catheter may have to be inserted to empty the bladder.

- Brachial plexus anaesthesia:

  Action of the anaesthetic on the spinal cord in the neck region with serious cardiovascular response, necessitating mechanical ventilation and intensive medical care, is very rare.

  A disturbance of sensation in the arm or nape of the neck normally disappears within three months. Lasting paralyses (e.g. of the vocal cord nerve or the nerve of the diaphragm with impaired breathing and arm paralyses) are very rare.

  A feeling of warmth in the face and hoarseness, a drooping eyelid and slight difficulties in breathing may occur temporarily.

  If air enters the pleural cavity (pneumothorax), this may be manifested by laboured breathing and chest pain. It may be necessary to remove the air by suction in such a case.
Risks and possible complications of additional and secondary procedures:
Preparative, accompanying or subsequent measures, e.g. for monitoring and for maintenance of vital body functions during and after surgery, as well as for administration of preventive medication, are also not risk-free.

Despite the care taken with the production of donor blood units, plasma derivatives and other blood products, specific risks in association with transfer/use cannot be completely ruled out, in particular infections, e.g. very rarely with hepatitis viruses (liver inflammation) and extremely rarely with HIV (AIDS), as well as possibly with agents causing BSE or new variant Creutzfeldt-Jakob disease, or with other as yet unknown pathogens. A follow-up examination to rule out infections may therefore be recommendable in specific cases. Your doctor will tell you if and when this would be appropriate. These risks may be avoided by returning the blood lost by the patient during the operation to the patient, and/or by means of an autologous blood donation (i.e. a donation of the patient’s own blood) before the operation. It should however be noted that such options are not suitable for all patients and all types of surgery.

Please note: Extremely rare risks and complications are also included in this information. In general an event with serious consequences occurs in only one out of ten thousand anaesthesias.

IV. Directions concerning patient behaviour

For your own safety, please follow the directions given here exactly (unless your anaesthetist has given you other directions). The directions apply for general as well as regional anaesthesia, irrespective of whether the scheduled intervention is carried out on an inpatient or outpatient basis.

Before the procedure:
- Up to 6 hours before the anaesthesia you are permitted to have a snack (e.g. a slice of white bread and jam, a glass of milk). After that, you may **not eat anything** (not even a sweet/candy, chewing gum or similar), **not smoke any more** and **not drink anything**, with the following exceptions:

- Up to 2 hours before anaesthesia you are permitted to have 1–2 glasses/cups of clear fluid without fat and solids (e.g. mineral water, tea), but **no milk and no alcohol**

Please make sure to tell us if you have eaten or drunk anything different to the instructions above!

You can take required medication with a sip of water until just before the procedure. Ask us which **medication** has to be taken or stopped.

- Remove contact lenses, removable artificial dentures, rings, jewellery (including piercing jewellery!), artificial hairpieces and store safely. Do not use any face cream and cosmetics (make-up, nail polish etc.)!

On the evening before and/or immediately before the procedure, a sedative (tablet, pessary, injection) is often given as **premedication**.

After the procedure:
The vital body functions are monitored – normally in the anaesthetic recovery room – continuously. A **transfer to an intensive care unit** may be necessary in some cases. A measure necessary to protect you from injury may include restriction of your freedom of movement (e.g. protective bars on the bed) after the premedication and/or after surgery until the anaesthesia has worn off.

Please tell the doctors immediately if you have one of the following complaints after anaesthesia/surgery: nausea, vomiting, fever, chills, laboured breathing, chest pain, signs of paralyses; sore throat, hoarseness, speech problems after anaesthesia using a laryngeal mask airway or endotracheal intubation; headache, stiff neck, back pain, abnormal skin sensations (also at the injection site) after spinal/epidural anaesthesia.

V. Additional directions concerning patient behaviour for outpatient procedures

After an outpatient procedure, you are required to have yourself **collected and looked after by an adult person** during the first 24 hours or the period of time specified by the doctor. After regional anaesthesia, please protect the parts of your body that are still numb from external injury (e.g. heat, cold, pressure). Because of the after-effects of the anaesthetics/medication, you may not actively participate in road traffic (drive a car, ride a bike or as a pedestrian), engage in dangerous activities, drink alcohol, smoke or make any important decisions **during the first 24 hours after the procedure**, unless ordered otherwise by the doctor. You may only take medication as directed by your doctor.

Place, date, doctor's signature: __________________________
QUESTIONNAIRE on the Medical History of the Patient

Please present any personal documentation concerning your health that you may have, such as Pacemaker/Endocarditis/Prophylaxis/Blood Donor/Aneesthesia ID Cards or an Advance Directive.

Respiratory tracts/lung: e.g. chronic bronchitis, asthma, pneumonia, pneumoconiosis (lung disease caused by the inhalation of dust), tuberculosis, pulmonary emphysema (anatomical alteration of the lungs), sleep apnoea (pauses during sleep), paralysis of the diaphragm/vocal cord

Liver/bile: e.g. jaundice, hepatitis (inflammation of the liver), hardening of the liver, fatty liver, gallstones

Kidneys/bladder: e.g. elevated creatinine levels, requirement of dialysis, inflammation of the kidney (nephritis), kidney/bladder stones

Oesophagus(gullet)/stomach/intestine: e.g. ulcer, constipation, digestive disorders, heartburn, reflux disease

Metabolism: e.g. diabetes, gout

Thyroid gland: e.g. underactive or overactive thyroid, goitre (enlarged thyroid gland)

Skeletal system: e.g. joint diseases, back or spinal disc problems, shoulder-arm syndrome

Muscles: e.g. muscle weakness, muscular diseases, including your blood relatives, susceptibility to malignant hyperthermia (condition triggered by exposure to certain anaesthetics), muscle weakness (myasthenia gravis)

Nerves/disposition: e.g. seizures (epilepsy), paralyses, restless legs syndrome, chronic pain, frequent headaches, depressions

Eyes: e.g. glaucoma, cataracts, contact lenses

Ears: e.g. hard of hearing, hearing aid

Allergy (e.g. hay fever) or intolerance reactions to food, medication, anaesthetics/analgescics/disinfectants, iodine, plasters, latex (e.g. rubber gloves)

Other diseases/impairments?

Loose teeth, caries, periodontitis?

Artificial dentition (prosthesis, bridge, crown, implant)?

Notes by the doctor: ____________________________

Please underline and add all the disorders or symptoms of disorders that you have or had:

Cardiovascular: e.g. heart rhythm disturbances, cardiac defect, chest pain (angina pectoris), heart attack, inflammation of the heart muscle (myocarditis); high/low blood pressure, shortness of breath on exertion

Vessels: e.g. varicose veins, thrombosis/embolism, impaired perfusion (poor blood flow), stroke

Blood/coagulation: e.g. coagulation disorders, also in blood relatives, frequent nose bleeds/bleeding gums, tendency to bruise, secondary bleeding after surgery/injury

Do you have an infection (e.g. cold) at the moment? ☐ n ☐ y

Have you taken blood-thinning (anticoagulant) medication (e.g. Aspirin®, ASS®, Marcumar®, heparin, Tyklid®, Plavix®, Iscover®) in the last 4 weeks?

Have you taken other medication (e.g. blood pressure medication, heart medication, pain killers, sleeping pills, tranquilisers, psychopharmaceuticals, metformin-containing antidiabetics, laxatives, contraceptive pill) recently, either regularly or occasionally?

Have you had surgery before? If yes, what type and when (year)?

Have you or any of your blood relatives had problems with general, regional or local anaesthesia (e.g. nausea, fever) in the past?

Which ones?

Do you tend to suffer from nausea and vomiting (e.g. when travelling)?: ☐ n ☐ y

Did any complications occur in association with a transfusion/use of blood/blood components?: ☐ n ☐ y

Did you give your own blood for the planned procedure (autologous blood donation)?

Please underline and add all the disorders or symptoms of disorders that you have or had:

Cardiovascular: e.g. heart rhythm disturbances, cardiac defect, chest pain (angina pectoris), heart attack, inflammation of the heart muscle (myocarditis); high/low blood pressure, shortness of breath on exertion

Vessels: e.g. varicose veins, thrombosis/embolism, impaired perfusion (poor blood flow), stroke

Blood/coagulation: e.g. coagulation disorders, also in blood relatives, frequent nose bleeds/bleeding gums, tendency to bruise, secondary bleeding after surgery/injury

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1. Do you smoke? ☐ n ☐ y
   If yes, what and how much per day? ____________________________

2. Do you drink alcohol? ☐ n ☐ y
   If yes, what and how much per day? ____________________________

3. Do you take or have you taken drugs? ☐ n ☐ y

4. For female patients: Could you be pregnant? ☐ n ☐ y
   Do you breastfeed? ☐ n ☐ y

5. Do you have an advance directive? ☐ n ☐ y

ADDITONAL QUESTIONS FOR OUTPATIENT PROCEDURES:

1. Where can you be reached at all times during the first 24 hours after the procedure?

2. Who will look after you all the time during these 24 hours? Name, age

3. How far away is the next hospital/emergency clinic from where you are staying? _______ km, driving time: _________

4. Could you be brought there quickly? ☐ n ☐ y

Documentation of the Informed Consent Discussion and Consent

Instructions for the doctor: Please underline the appropriate parts of the text and add individual text by hand if applicable.

Note by the doctor (Name) ____________________________ on the Informed Consent Discussion:

The discussion chiefly included: the planned method of anaesthesia, advantages and disadvantages compared to other methods, risks and possible complications of the methods of anaesthesia, possible switch to another type of anaesthesia, sedation, analgesia, possible additional and secondary procedures (e.g. catheter placement, blood transfusion, autologous blood donation), directions concerning patient behaviour. Please make sure to document information provided about special risk-increasing factors that could arise from pre-existing and concomitant diseases or from specific circumstances (e.g. the patient’s occupation), as well as from refusal of individual procedures/measures. Specific additions to the information part should be noted if applicable.

Note for the doctor: Please make sure to mark the scheduled method(s) of anaesthesia with a cross.

☐ General Anaesthesia: ☐ Intravenous General Anaesthesia ☐ Face Mask Anaesthesia ☐ Laryngeal Mask Airway Anaesthesia ☐ Endotracheal Intubation Anaesthesia
☐ Spinal Anaesthesia: ☐ Epidural Anaesthesia (EA): ☐ Thoracic ☐ Lumbar ☐ Caudal
☐ Brachial Plexus Anaesthesia: ☐ Axillary ☐ Vertical infraclavicular ☐ Supraclavicular ☐ Interscalene
☐ Other anaesthetic procedure:
☐ Administration of a sedative and/or analgesic (Twilight Sleep/Sedation Analgesia)
   ☐ Intervention and anaesthetic procedure will be performed on an outpatient basis.

Statement by Patient on the Informed Consent Discussion and Consent

I have read and understood the Informed Consent Form. I was able to ask all the questions of interest to me during the Informed Consent Discussion. My questions were answered completely and understandably. I have been informed sufficiently, have thought about my decision carefully and do not need any more time for consideration.

I consent to have the anaesthetic procedure(s) specified above.

My consent also includes any changes or extensions to the procedure that may become medically necessary during the procedure, as well as any additional and secondary procedures that may be required.

I have answered the questionnaire (Medical History) to the best of my knowledge. I will observe the directions concerning patient behaviour.
The detached information part or a copy of the form was given to me to keep.

If the signature of only one parent is provided, then the signatory confirms at the same time to be acting with the consent of the other parent or that he/she has sole custody of the child.