

General Anaesthesia and/or Regional Anaesthesia

in Adults and Adolescents

Patient's name and address

Narkoseaufklärungsbogen Muster Muster					
Vorname Nachname					
,					
Anschrift					
11					
Fall-ID / Geburtsdatum / Patienten-ID					
1					
Krankenkasse / Versicherungsnummer					

Hello, Muster Muster,

This informed consent form is intended to prepare you for the patient-doctor discussion. Please read it carefully and complete the questionnaire carefully and completely. For better readability, we use male pronouns but are addressing all genders with them.

Selection of the type of anaesthesia

To prevent you from feeling any pain in the scheduled procedure,

- you can receive general anaesthesia, which will render you unconscious and temporarily eliminates the sensation of pain in the entire body;
- the **body part** to **undergo an operation** can be numbed (**regional anaesthesia**).

It is possible to combine both treatment methods. The doctor will discuss with you the most suitable anaesthesia procedure for you and, if other procedures are an option, the advantages and disadvantages of such procedures as well as the various demands on your body and the related risks.

Before the anaesthesia, an **indwelling catheter** is placed in a **vein** (**e.g. of your hand or arm**), through which infusions and, if applicable, medications (e.g. anaesthetic agent, pain medications, antibiotics) will be administered.

General anaesthesia

For induction of general anaesthesia, the doctor injects a fast-acting anaesthetic agent via the **indwelling catheter**.

To maintain general anaesthesia, the doctor continues to administer further anaesthetic/pain medications through the indwelling catheter (**intravenous anaesthesia**) or administers **gaseous anaesthetic agents** via the air you breathe. Often, both procedures are **combined**.

To ensure that you receive sufficient **oxygen** and, if necessary, **gaseous anaesthetic agents**,

- a breathing mask is placed over mouth and nose, or, if you are already asleep,
- a **breathing tube** is inserted into your trachea through your mouth (or the nose) (**intubation anaesthesia**), or
- a laryngeal mask, i.e. a breathing tube with an inflatable cuff at the tip, is advanced through the mouth and placed over the laryngeal opening (laryngeal mask anaesthesia).

The breathing tube in particular reduces the risk of **aspiration** of saliva and stomach contents into the lungs. A **muscle relaxant**, which can also improve the conditions for the operation, will be administered to facilitate gentle introduction of the breathing tube.

Regional anaesthesia

During regional anaesthesia, the doctor injects a **local anaesthetic agent** in the proximity of the pain-conducting nerves. This "blocks" the transmission of pain stimuli from the surgical site to the brain. Generally, pain sensation is eliminated for several hours.

At first, anaesthesia becomes noticeable by a feeling of warmth and tingling. Next, the body parts under anaesthesia (e.g. shoulder, arm, lower body or legs) become heavy and numb. As long as anaesthesia is in effect, the body parts under anaesthesia can be moved only a little or not at all.

In the case of **regional anaesthesia**, you will be awake but can receive a **sedative** ("**twilight sleep**"/**sedation**). If this is planned for you, your doctor will counsel you about it in a separate patient-doctor discussion. After sedation, you will have only a **limited recollection of the operation or no recollection at all**.

It may be advisable to use **regional anaesthesia in addition to general anaesthesia**. In this case, you will need less anaesthetics, recover faster after the procedure and experience little pain directly after the operation. However, the additional regional anaesthesia is also associated with inherent risks.

Spinal anaesthesia and epidural anaesthesia

They are well-suited for **operations** on the **lower half of the body** (e.g. **legs**, **hips**, **groin**). Additionally, thoracic epidural anaesthesia is suitable for **procedures on the thorax** and **upper abdomen**. Both procedures **numb the pain-conducting nerve fibres of the spinal cord**.

The doctor injects the anaesthetic agent

- into the lumbar spine, through the dura mater (the membrane encasing the brain and spinal cord) into the spinal canal filled with cerebrospinal fluid (fig. 1, c) for spinal anaesthesia.
- with epidural anaesthesia, into the epidural space in front of the dura mater, either at the level of the lumbar spine (lumbar epidural anaesthesia, fig. 1, b) or at the level of the thoracic spine (thoracic epidural anaesthesia, fig. 1, a).

Both procedures may be combined.

Brachial plexus anaesthesia

During **shoulder**, **arm and hand surgery**, the **brachial plexus** is numbed – a network of nerves which run from the cervical spine through the shoulder and armpit and down the arm into the fingers. The anaesthetic agent is injected at one of the following sites:

- in the arm pit (axillary, fig. 2, a),
- below the clavicle (infraclavicular, fig. 2, b),
- above the clavicle (**supraclavicular**, fig. 2, c),
- at the side of the neck, between two muscles (interscalene, fig. 2, d).

The correct position of the tip of the needle close to the nerve is determined in advance with the aid of **ultrasound** and/or a **nerve stimulator** by the doctor. In the short term,

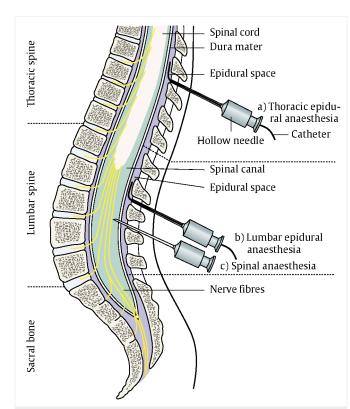


Fig. 1: Injection sites for spinal and epidural anaesthesia

nerve stimulation can cause muscle twitching and "electrification".

Switch from regional anaesthesia to general anaesthesia

In isolated cases, if it is not possible to eliminate pain completely with regional anaesthesia, if the regional anaesthesia spreads too far or if complications occur, general anaesthesia may become necessary.

Regional pain therapy after the procedure

Pain in the area of the body that has undergone surgery can be effectively treated by the administration of medications via a thin plastic tube (regional catheter). The latter is placed near the pain-conducting nerves before, during or after surgery. If it is placed before surgery, it can be used for regional anaesthesia and then left in place for pain treatment. If pain therapy with a regional catheter is recommended in your case, your doctor will explain this procedure to you in a separate patient-doctor discussion.

Additional and subsequent procedures

Your doctor will also inform you separately about any foreseeable **ancillary and subsequent procedures** (e.g. placement of a central venous catheter).

If a transfusion of blood from a foreign donor is also seriously considered in your case, you will be informed about the procedure, its risks (e.g. hypersensitivity/incompatibility reactions, infection, e.g. hepatitis or HIV infection [AIDS] in extremely rare cases, under certain circumstances also infection with unknown pathogens) as well as any measures to avoid using foreign donor blood in a separate patient-doctor discussion.

Risks and possible associated complications

The doctor ensures your safety by **monitoring** your vital body functions (e.g. heart activity, breathing and blood circulation) during the entire procedure and **supports them** if necessary (e.g. by administering circulation medications). However, despite the greatest care taken, complications can arise which can even become life-threatening and necessitate additional treatment or further surgery under certain circumstances. The frequency rates are only a general estimate and are intended for weighing the risks against each other. They are not the same as the definitions of side-effects stated in the package inserts of medications. Pre-existing/underlying diseases and individual unusual circumstances can significantly influence the rate of complications.

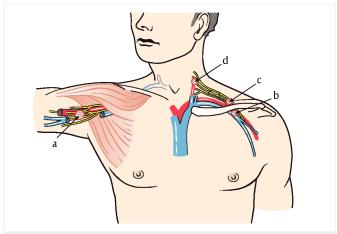


Fig. 2: Injection sites for brachial plexus anaesthesia

If the doctor intends to use medications which have been proven to be successful in anaesthesia but do not have formal approval (off-label use), s/he will discuss his/her reasons for it with you and inform you about the known risks. Unknown risks cannot be excluded, however, and under certain circumstances, the manufacturer will not accept any liability.

General risks of injections/cannulas/catheters

- Injury to blood vessels and nerves by injection needles, cannulas or catheters can cause bleeding and haematomas. Treatment, especially an operation, is necessary in rare cases only.
- Infection can occur at the site where an indwelling catheter/catheter has been placed or in its further course. Possible consequences are venous inflammation, purulent abscesses, necrosis of tissue and scarring. In rare cases, this infection causes a life-threatening blood poisoning (sepsis).
- Nerve injury/damage caused by needles, cannulas or catheters can cause temporary, but in unfavourable cases also permanent, symptoms, e.g. pain, disorders of sensation, sensitivity to touch, numbness and disorders of movement.
- Chronic pain and permanent paralysis after severe nerve injury, haematomas or inflammation are very rare.
- Thrombosis/embolism: If blood clots are formed or are carried through the blood stream and block a blood vessel, life-threatening damage can occur (e.g. pulmonary embolism, stroke, heart attack).

General risks of anaesthetic procedures and side effects of medications

- Skin, tissue and nerve damage, with paralysis of the arms/legs in the most extreme case, as a result of pressure, strain or overextension while positioning the patient during anaesthesia cannot be excluded with certainty. In most cases, such damage will disappear within a few months; however, in rare cases, it may become permanent. Damage to the cornea of the eye is extremely rare thanks to protective measures; this kind of damage usually heals without any consequences.
- The required medications and materials (e.g. anaesthetic agents, muscle relaxants, disinfectants, latex gloves) can cause adverse reactions, e.g. nausea, vomiting, muscle tremors, itching, skin rash or respiratory distress (difficulty breathing) and circulatory reactions. These rather milder reactions, frequently caused by an allergy, can generally be treated well and quickly. Severe side-effects, severe allergic reactions and even an acute circulatory shock or unexpected complications like seizures or heart, circulatory, respiratory and organ failure are rare. Under certain circumstances, however, they can cause severe permanent damage (e.g. brain damage, damage to other organs, paralysis).

Furthermore, each medication has its own inherent risks. For example, metamizole, a pain medication that is frequently administered during and/or after the procedure, can cause changes in the blood count (e.g. a life-threatening reduction of white blood cells [agranulocytosis]) in very rare cases, especially in case of pain therapy administered for several days. Therefore, your doctor will inform you about the possible

- severe side-effects of the individual medications proposed in your case, their risk-benefit ratio and possible alternatives in a separate patient-doctor discussion.
- Life-threatening metabolic imbalance with increase
 of the body temperature to an extreme extent (malignant hyperthermia) after administration of gaseous
 anaesthetic agents or certain muscle relaxants occurs
 in patients with a specific genetic predisposition in extremely rare cases. This necessitates treatment on an
 intensive care unit.
- Confusion or restricted mental ability can be caused by the unfamiliar environment, the operation and the administered medications, among others, especially in older patients. Usually, these impairments only persist for a few hours or days, possibly also a few months, but are permanent in very rare cases only.

Specific risks of general anaesthesia

- If stomach contents get into the lungs (aspiration), this can have life-threatening consequences. Examples of this are pneumonia, acute lung failure or permanent lung damage. If the patient has been fasting, aspiration is rare.
- Convulsive blockage of the airways (laryngeal spasms/ bronchospasms) can occur when inserting or removing the tube or less often the laryngeal mask; it can usually be remedied quickly by the administration of medications. In an exceptional case, this necessitates intensive care.
- Difficulty swallowing and hoarseness can be caused by the tube in particular but also by the laryngeal mask and are temporary in most cases. Permanent damage to the vocal folds (e.g. paralysis of the vocal folds) with permanent dysphonia (hoarseness), shortness of breath, injury to the pharynx, jaw, larynx and windpipe are rare. Permanent disorders of sensation at the tongue are also rare.
- Damage to teeth, implants and non-removable dentures (e.g. crowns, bridges, prosthesis) as well as a loss of teeth can occur, in particular in patients with caries, loose teeth or loosened dentures.
- Despite the careful monitoring of the anaesthetic procedure, patients can regain consciousness during general anaesthesia in rare cases and, in very rare cases, can experience pain. In isolated cases, the patient may be able to recall the event which can have post-traumatic stress consequences, necessitating treatment.

General risks of regional anaesthesia

- Seizures, loss of consciousness and severe, in very rare cases also life-threatening cardiocirculatory and respiratory reaction can occur if the anaesthetic agent gains direct access to the blood stream during injection or passes from the tissue into the blood stream very quickly. These complications as well as temporary paralysis can occur also if, during spinal anaesthesia, the anaesthetic agent spreads too far in the body or, during epidural anaesthesia, accidentally accesses the spinal canal or takes effect on the cervical spinal cord during interscalene brachial plexus anaesthesia. Short-term treatment on an intensive care unit would then be necessary.
- Due to injury to the pleura, air can gain ingress into the thoracic cavity (pneumothorax) during thoracic

epidural anaesthesia and brachial plexus anaesthesia techniques – except for axillary plexus anaesthesia –, **impairing breathing** and **causing pain in the chest**. This would necessitate removal of the intruded air by suctioning if indicated.

 If a regional catheter is placed for pain treatment, loops may form or catheter parts may tear off in very rare cases, causing injury to vessels and nerves. Surgical treatment and/or surgical removal of the catheter/the torn-off catheter parts can be necessary in this case.

Specific risks of the spinal and epidural anaesthesia

- Direct injury to the spinal cord is almost completely excluded in spinal anaesthesia and lumbar epidural anaesthesia since, generally, the anaesthetic agent is injected below the spinal cord. This injury is very rare with thoracic epidural anaesthesia.
- Permanent paralysis (e.g. disorders of urination/defecation), in an extreme case even paraplegia, is rare. It can be caused by haematomas or infections (abscesses) in the spinal/epidural space or by damage to spinal cord nerves or the spinal cord.
 - In a rare case, an ascending infection can also cause meningitis.
- If the dura mater has been punctured accidentally in spinal or epidural anaesthesia, the following complications may occur:
 - Irritation of cerebral nerves, which can cause temporary and, in rare cases, permanent disorders of vision and impaired hearing and severe headache. If the headache does not subside despite the administration of medications, autologous blood may be injected in order to seal the location in which the needle has punctured the dura mater. In most cases, this leads to an elimination of the headache. In very rare cases, the headache may persist for a longer period (e.g. in very rare cases for several months).
 - Life-threatening brain haemorrhage, an accumulation of blood or fluid under the hard membrane that encases the brain (subdural haematoma/hygroma) as well as cerebral venous thrombosis with possible permanent damage to the brain occur in rare cases.
- **Temporary back pain** is frequent; **chronic back pain** is very rare.
- Temporary problems with passing urine (retention of urine) are also frequent. Therefore, a bladder catheter must possibly be placed for a short time. This may cause bleeding and infection of/injury to the urinary tract. Anaesthesia may also cause temporary impotence.

Specific risks of brachial plexus anaesthesia

- Disorders of sensation (e.g. tingling, numbness of the arm or neck) and disorders of mobility and even paralysis resolve within a few weeks or months in most cases. Permanent disorders of sensation, chronic pain and permanent paralysis (e.g. paralysis of the arm) after infection, injury or damage to the arm plexus nerves are rare.
- Temporary paralysis of the diaphragmatic nerve frequently occurs during interscalene and supraclavicular plexus anaesthesia, in individual cases also with infraclavicular but not with axillary plexus anaesthesia. Gen-

erally, the paralysis remains unnoticed. In some cases, respiratory distress occurs, which resolves by itself in most cases and only very rarely requires artificial ventilation. In particular after interscalene plexus anaesthesia, permanent paralysis of the diaphragmatic nerve with respiratory distress is possible in some cases. Temporary paralysis of the nerve that supplies the vocal folds may cause temporary hoarseness.

A drooping eyelid (Horner syndrome), a warm sensation in the face and hoarseness are typical temporary consequences of brachial plexus anaesthesia, with the exception of axillary plexus anaesthesia.

Instructions

Before anaesthesia

Please observe the following instructions on FASTING, unless OTHERWISE INSTRUCTED by your doctor:

- · Adults may
 - still eat a **light meal** (e.g. 1 slice of white bread with jam, 1 glass of milk) **up to 6 hours before the general anaesthesia**.
 - During the time frame of 6-2 hours before the general anaesthesia, you may not drink more than 1-2 glasses/cups of clear fluids (e.g. water, tea without milk). The liquid may not contain any fat, solid particles and alcohol.
- Adolescents up to an age of 18 may
 - eat something up to 6 hours before the general anaesthesia.
 - drink clear liquids without fat, solid pieces and alcohol (e.g. water, tea without milk) during the time frame of 6 hours to 1 hour before general anaesthesia is started.

As of the times applicable for you, you may no longer eat or drink anything! Please inform your doctor or any other staff if you have not been able to adhere exactly to these fasting instructions!

SMOKING generally increases the risks associated with anaesthesia and an operation (e.g. increased risk of pneumonia, circulatory disorders, cardiocirculatory disorders).

Your doctor will discuss with you which **medications** you can or should **take** and which you should **stop taking** or **replace**.

Please present any **patient ID** you have (e.g. general anaesthesia, allergy, vaccination pass, Marcumar, diabetes, pacemaker ID card). If a **living will**, **health care proxy** or **medical power of attorney** exists, please bring a copy with you.

Please remove contact lenses, removable tooth replacements, rings, jewellery (including piercings) and artificial hair pieces before the anaesthesia. Please check where you can keep your belongings and whether you can take your glasses and hearing aids up to the foyer of the operating theatre. Please do not use any facial creams or cosmetic products (make-up, nail polish, etc.)!

After the anaesthesia

You will be **monitored** until your vital body functions are stable again; this may be done in a recovery room or the intensive care unit. **To protect you against injury**, it can be necessary to **temporarily restrict your movements** (e.g. by **bed rails**).

Due to the **risk of falling**, you **may not get up on your own** at first! Please **protect** any body regions that are still numb due to anaesthesia from damage caused by compression/pressure and injury. You may take **medications** only in accordance with your doctor's instructions.

In **women** using **hormonal contraception** (e.g. the "pill", a coil), the **contraceptive effect** may remain **impaired** for at least 7 days after anaesthesia.

Please inform your doctor immediately if you develop symptoms such as respiratory distress or problems with circulation, impairment of consciousness, pain, fever (greater than 38 °C), chills, nausea, vomiting, aching throat, hoarseness, disturbance of speech, difficulty swallowing as well as inflammation, e.g. in the mouth, difficulty passing stool/urine, alteration in sensation (e.g. at an injection site or in the limbs), disorders of movement or signs of paralysis.

Instructions for after an outpatient procedure

After an **outpatient procedure**, your reactions will be temporarily impaired due to the anaesthetic agents, analgesics and other medications. Therefore, please arrange to **be picked up by an adult** and **have somebody stay with you and take care of you** for the first 24 hours after the procedure or the length of time stipulated by your doctor.

Due to the lingering effects of the medication, you may not actively participate in road traffic, may not perform any dangerous activities, may neither drink any alcohol nor smoke within the first 24 hours or the length of time stipulated by your doctor. During this time frame, you should also not make any important decisions.

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Narkoseaufklärungsbogen Muster Muster Vorname Nachname , Anschrift | | Fall-ID / Geburtsdatum / Patienten-ID | Krankenkasse / Versicherungsnummer

(Adults/Adolescents)

General/Regional Anaesthesia

Questionnaire (patient history)

Please answer the following questions carefully and completely to aid us in avoiding all possible risks. Please mark boxes where applicable and underline or add text where appropriate. If necessary, do not hesitate to ask for our assistance in filling out the form.

filling o	filling out the form.						
Age:	years • Height:	cm • Weight:	kg	If yes, please indicate:			
Gender	:		= no/y = yes	8. Has anaesthesia ever been performed? If yes, please indicate:	□ n □ y		
1. Occ	upation/profession (cur			☐ general anaesthesia ☐ regional anaesthesia			
ded	any other medical trea in the last few weeks? es, for what reason?			□ local anaesthesia (e.g. for dental treatments)□ sedation□ and/or:			
	.s, for what reason:			If yes, did any complications occur?	\square n \square y		
_	there been an infection i	in the last 4 weeks?	•	If yes, please indicate:			
	airways			9. Is there a tendency to have nausea/vomiting?	□n □y		
□ gastrointestinal□ urinary tract□ and/or:			10. Has a congenital tendency to have high fever □ n □ and muscle stiffness during/after general anaesthesia (malignant hyperthermia) been found?				
	no			11. Has a congenital predisposition to malignant hyperthermia been found among blood relatives?	□n□y		
□ hepatitis □ HIV/AIDS		12. Has a transfusion of blood/blood components ever been performed?	□n□y				
	☐ tuberculosis ☐ and/or: 5. Are there any medications (including herbal ☐ n ☐ y		13. Is there an increased tendency to bleed, e.g. fre- □ n □ y quent nosebleed/bleeding gums, bruises, longer period of bleeding after injury?				
and over-the-counter medications) being tak- en or applied regularly or currently?		14. Is/was there a (another) vascular disease? □ no					
If ye	es, please indicate in full:			☐ arteriosclerosis ☐ varicose veins			
		☐ disease of coronary vessels ☐ circulatory disorders					
6. Is there an allergy? □ no □ medications (e.g. antibiotics, metamizole, paracetamol) □ anaesthetic agents □ contrast medium		aneurysmconstriction of the carotid artery					
		□ and/or:					
	latex disinfectants iodine			16. Is/was there a (another) cardiovascular disease? □ no □ coronary heart disease			
	plaster synthetic material			hypertensioncardiac arrhythmia			
□ and/or:		□ stroke□ heart attack□ angina pectoris□ myocardial inflammation					
 If ve	es, did any complication	ns occur?	 □ n □ v	☐ heart valve defect			

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17. Do breathing difficulties occur when climbing $\ \square$ n $\ \square$ y the stairs?	☐ goitre ☐ Hashimoto's disease
If yes, how many stairs can you climb before needing to stop?	☐ and/or:
18. Is/was there a disease of the airways/lungs? no chronic bronchitis pneumonia bronchial asthma pulmonary emphysema congenital malformation and/or:	□ no □ muscle weakness □ joint disease □ osteoporosis □ osteomalacia □ and/or: □ 30. Is/was there ever a disease of the nervous system? □ no
19. Does respiratory distress (difficulty breathing) occur during the night? □ no □ severe snoring □ sleep apnoea □ and/or:	☐ gait abnormalities/paralysis ☐ seizure disorders (epilepsy) ☐ Parkinson's ☐ somatosensory disorders ☐ polyneuropathy ☐ pain
20. Is there paralysis of the vocal folds? \square n \square y	□ and/or:
21. Is there a paralysis of the diaphragm? \Box n \Box y	31. Is there an eye disease? □ no
22. Is/was there a disorder of the digestive system? ☐ no ☐ oesophagus ☐ stomach	☐ cataract ☐ glaucoma ☐ and/or:
□ intestine □ and/or:	32. Are there any other diseases/impairments? ☐ no
23. Does heartburn occur frequently? \square n \square y	☐ spinal injury
24. Is there a reflux disorder? □ n □ y	☐ shoulder-arm syndrome☐ multiple sclerosis
25. Is/was there a disease of the upper abdominal organs? □ no □ liver inflammation/hepatitis □ fatty liver □ cirrhosis	☐ restless legs syndrome ☐ frequent headache ☐ depression ☐ hearing loss ☐ and/or:
 □ biliary colics □ bile stones □ jaundice □ pancreatitis □ and/or: 	33. Are there any unusual disorders/features with respect to the condition of the teeth? □ no □ loose teeth □ braces
26. Is/was there ever a disease or malformation of the kid-	□ prosthesis
neys/urinary organs?	□ bridge
□ no□ dysfunction of the kidneys	□ crown
☐ kidney stones	☐ implant ☐ retainer
☐ chronic urinary tract infection	□ paradontosis
☐ nephritis/inflammation of the kidneys	☐ and/or:
 □ congenital malformation (e.g. duplex kidney) □ bladder emptying disorder/delayed bladder emptying □ and/or: 	34. Are there any implants in the body? ☐ no
27. Is there a metabolic disease?	☐ cardiac pacemaker
	☐ defibrillator☐ cardiac valve
□ diabetes	□ stent
□ gout	☐ artificial joint
□ and/or:	□ silicone
28. Is/was there a disease of the thyroid gland?	□ hydrogel
□ no□ overactivity	□ teeth □ metal
□ overactivity □ underactivity	☐ metal ☐ and/or:

☐ inpatient

Date of the procedure:

doctor

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Statement of Consent

I have read the informed consent form, and I understand it. The planned anaesthesia, the type and significance of the anaesthesia, possible alternative procedures, risks and possible complications, possible changes or additions to the anaesthetic procedure (e.g. changing from regional anaesthesia to general anaesthesia) and additional/subsequent procedures possibly required for medical reasons (e.g. placing a catheter) have been fully explained to me in a patient-doctor discussion with

My questions were answered completely and clearly. I have **no further questions** and feel that **the counselling was satisfactory**; I do not need **any further time for consideration** and **consent** to the proposed anaesthesia. I also agree to any possibly unforeseeable changes in or additions to the anaesthetic procedure which may be necessary for medical reasons. I will follow the doctor's **instructions**.

Place, date			
Patient			
Patient's guardian*			
Doctor			

^{*} Only if the patient is a minor: If only one of the patient's guardians signs, with this signature, he confirms that he has sole custody of the child or that he is acting in agreement with the other of the patient's guardians. As a rule, both of the patient's guardians should sign for major procedures. Minor patients who are able to comprehend should also always cign.