

Regional Anaesthesia or General
Anaesthesia in Obstetrics

Patient's name and address

Dear Mother-to-be,

This informed consent form is provided for your information. Please read it carefully before the due date but at the latest before the patient-doctor discussion and complete the questionnaire carefully and completely.

Pain relief in obstetrics

A major part of natural births and, in most cases, births via Caesarean section are carried out under **regional anaesthesia** nowadays; only a small portion is carried out under general anaesthesia. In the patient-doctor discussion, the doctor will explain to you the advantages and disadvantages of regional anaesthesia and general anaesthesia compared to **other methods to alleviate pain** which may be taken into consideration (e.g. administering sedatives and pain medications, infiltration anaesthesia of the perineum, pudendus block), in particular the different demands on the body and risks.

Prior to every regional anaesthesia or general anaesthesia, an **indwelling catheter** is placed in a hand or arm vein, enabling administration of infusions and medications.

Regional anaesthesia in obstetrics (epidural/
spinal anaesthesia)

During regional anaesthesia, due to the numbing of the nerve fibres running from the spinal cord, the forwarding of labour and/or surgery pain to the brain is blocked. Contrary to general anaesthesia, the mother-to-be consciously experiences giving birth, is mostly pain-free and able to relax. This is favourable for the course of the birth and beneficial for the child.

The effects of regional anaesthesia are first felt as a warm feeling, prickling and numbness in the lower abdomen and the legs. In most cases, epidural anaesthesia does not restrict mobility of the legs or only restricts it partially. With

spinal anaesthesia, however, the legs can generally be moved only slightly or not at all. Sensations and mobility of the legs return when the anaesthesia wears off.

Due to the relaxing effect of regional anaesthesia, however, the **urge to press** can weaken and **labour can be reduced**, necessitating infusion of uterotonics. In an occasional case, the birth must be completed by means of suction cup or forceps. However, use of these devices is facilitated by regional anaesthesia.

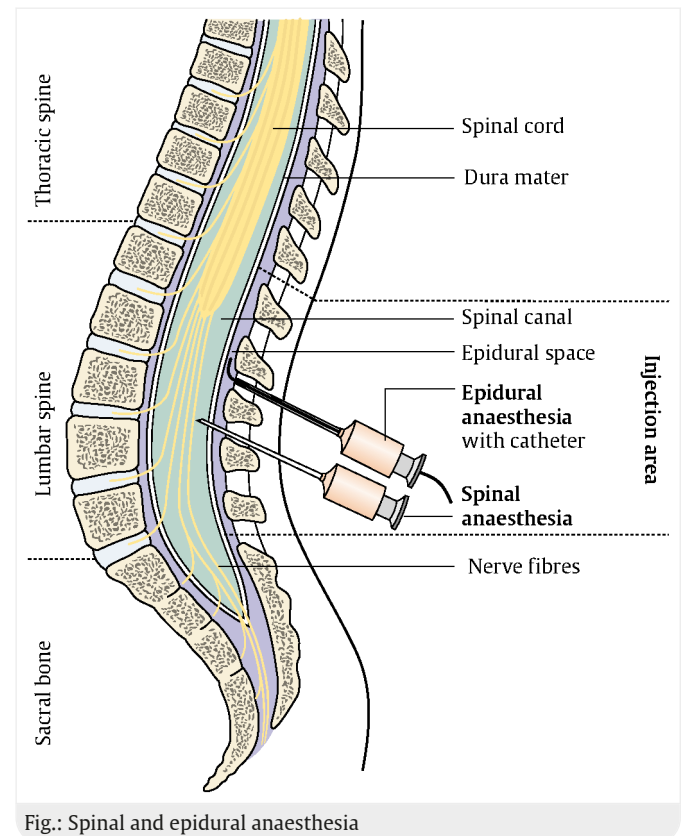


Fig.: Spinal and epidural anaesthesia

Spinal anaesthesia

Spinal anaesthesia is the most frequently applied anaesthesia procedure with planned Caesarean sections and particularly suitable for pregnant women for whom a Caesarean section is very likely due to individual risk factors (e.g. multiple pregnancies, pre-eclampsia, adiposity per magna). Spinal anaesthesia is also used if complications occur during birth and an urgent Caesarean section becomes necessary. For the introduction of spinal anaesthesia, the doctor injects a **local sedative** into the **region of the lumbar spine** filled with cerebrospinal fluid (liquor) through the dura mater (see fig.). Usually, the effect sets in after a couple of minutes. Therefore, spinal anaesthesia is also suitable for cases in which an urgent Caesarean section is required.

Epidural anaesthesia

For initiating the epidural anaesthesia, the doctor inserts a hollow needle into the lumbar spine and threads a thin synthetic tube (**catheter**) through it into the so-called **epidural space** (see fig.) in front of the dura mater. After removing the needle, this catheter can be used for administering **sedatives** and additional **pain medications** (e.g. opioids) repeatedly or continuously. Frequently, the catheter is also connected to a **dosing pump** which you can use yourself to administer a defined volume of sedatives yourself if necessary (**patient-controlled analgesia**). The anaesthetic agent takes effect after about 15 minutes the earliest, and it generally lasts several hours. If **Caesarean section** becomes necessary, the epidural anaesthesia must be increased which can take up to 20 minutes. If the specific situation does not allow waiting, spinal anaesthesia or general anaesthesia is required.

Combined spinal and epidural anaesthesia (CSE)

In isolated cases, **spinal anaesthesia and epidural anaesthesia** can also be **combined** to utilise the fast effect of spinal anaesthesia and the long effectiveness of the epidural anaesthesia.

General anaesthesia

General anaesthesia is performed primarily in **emergencies**, e.g. if **Caesarean section** has to be performed immediately, if **regional anaesthesia does not have a sufficient effect or spreads too far** or if **complications** occur (e.g. heart, circulation and breathing problems of the mother-to-be, severe bleeding, premature detachment of the placenta, severe bradycardia [slowed heartbeat] of the child, prolapse of the umbilical cord). General anaesthesia is planned from the very beginning if, due to a specific illness (e.g. coagulation disorders), no regional anaesthesia can be carried out or if the mother-to-be rejects regional anaesthesia.

General anaesthesia results in a loss of consciousness and pain perception and creates a state resembling deep sleep. **To introduce general anaesthesia**, an anaesthetic agent is injected into a vein. After the mother-to-be has fallen asleep, a breathing tube via which oxygen and gaseous anaesthetic agents are administered is inserted into the trachea (**intubation anaesthesia**).

To insert the tube, administering muscle-relaxing agents is required. These also improve the conditions for surgical delivery. **Intubation** simplifies ventilation and reduces the risk of saliva or stomach contents flowing into the lungs (**aspiration**). If intubation is difficult or not possible, oxygen and anaesthetic agents are given through a breathing mask placed before the larynx (**larynx mask**).

Risks and possible associated complications of anaesthetic procedures

The frequency rates stated are not the same as those stated in the package inserts of medications. They are only a general estimate and are intended for weighing the risks against each other. Despite the greatest care taken, complications can arise which can even become life-threatening under certain circumstances and necessitate additional treatment or further surgery. Pre-existing/Underlying disease and individual unusual circumstances can influence the rate of complications. During general anaesthesia, all vital body functions (e.g. pulse, ECG, blood pressure, breathing, oxygen saturation in the blood) are monitored so that possible complications can be treated quickly.

In an occasional case, medications are administered that have been proven and tested for application during pregnancy but which are not expressly approved for such use (**off-label use**). If these medications are considered for you, the doctor will explain to you the reasons for their use and their known risks. The doctor will also inform you that these medications may possibly still have unknown hazards and liability of the manufacturer may be excluded under certain circumstances.

General risks and complications

- The following complications can be caused by **injections and placement of indwelling cannulas and, if applicable, catheters**, e.g. also for pain management:
 - **Nerve injury and minor nerve damage** can occur and can cause symptoms such as disorders of sensation, sensitivity to touch, numbness, disorders of movement and pain, which are temporary in most cases but in an unfavourable case, they can also be permanent.
 - **Large haematoma and injury to blood vessels** can occur, which, however, can cause severe bleeding in rare cases.
 - **Infection**, e.g. at the injection site or along the course of the needle track or the catheter, can occur. Possible consequences in rare cases are e.g. an injection track abscess, necrosis (death) of tissue, scarring or irritation/inflammation of the vein. In extremely rare cases, infection causes life-threatening **blood poisoning (sepsis)**.
 - **Chronic pain or permanent paralysis** can occur after severe nerve injuries, haematoma or inflammation. However, these are also extremely rare.
- **Skin, tissue and nerve damage**, with **paralysis of the arms/legs** in the most extreme case, as a result of pressure, strain or overextension/stretching while **positioning the patient on the examination/treatment/operating table during regional or general anaesthesia (damage due to positioning of the patient)** cannot be excluded with certainty; in most cases, the damage will disappear within a few months; however, in very rare cases, it may become permanent.
- As unwanted effects of specific sedatives, local anaesthetic agents or pain medications (e.g. opioids), during and after childbirth, in some cases, **nausea and vomiting**, in rare cases also **respiratory disorders and disorders of circulation** can occur; these can mostly be remedied easily by medications but may also require other forms of treatment in some cases (e.g. artificial ventilation).

- **Hypersensitivity/Incompatibility reaction or mild allergic reaction** (e.g. to sedatives, local anaesthetic agents, pain medications, other medications, sterilising agents, latex) is rare. This can manifest e.g. as nausea, itching and a skin rash. **Breathing difficulty or reactions affecting the circulation** (e.g. drop in blood pressure, slowing of the heartbeat) can be treated quickly in most cases.

Severe allergic reaction and life-threatening complications of other origin (e.g. cardiocirculatory, respiratory and organ failure, formation of blood clots that are carried through the blood stream and vessel blockage) with **severe consequences which can be permanent under certain circumstances** (e.g. brain damage, damage to other organs, paralysis, pulmonary embolism, stroke) are very rare and require immediate treatment and/or intensive care.

- In extremely rare cases, as a result of a massive, life-threatening metabolic derailment, an **extreme increase in body temperature** (“overheating”, **malignant hyperthermia**) occurs in mothers-to-be with a specific genetic predisposition. Immediate treatment with medications on an intensive care unit would then be necessary.

Specific risks and possible complications of the spinal and epidural anaesthesia

- If the anaesthetic agent gains immediate ingress into the blood stream during injection or if it spreads too extensively, this could elicit **seizures** and lead to **loss of consciousness** and severe **cardiocirculatory and respiratory reaction** which can also be life-threatening in very rare cases and necessitate artificial respiration and treatment on an intensive care unit.

- A direct **injury to the spinal cord** during both procedures can be virtually excluded, because as a rule, the spinal cord ends above the level of the injection site (see fig.).

Permanent paralysis (e.g. impairment of intestine/bladder emptying), in the most extreme case **paraplegia**, due to haematoma, inflammation/infection as well as nerve or spinal cord injuries or caused by the injected agents, occur in extremely rare cases. Similarly, **meningitis** only occurs in extremely rare cases.

- **Back pain** occurs frequently but goes away within a few days as a rule. **Chronic back pain** as a consequence of spinal or epidural anaesthesia is very rare.
- After spinal anaesthesia but also after epidural anaesthesia in which the dura mater is punctured unintentionally,

- **severe headache**, which generally goes away after a few days but may also require specific treatment (e.g. injection of the patient's own blood into the epidural space) and may persist for a longer period of time, in exceptional cases up to several months or even years, can occur.

- life-threatening **brain haemorrhage** and **accumulation of blood or fluid** under the dura mater (the membrane surrounding the brain) (**subdural haematoma/hygroma**) and also **permanent worsening of hearing and vision** can occur in very rare cases. A **cerebral venous thrombosis** is possible but extremely rare.

- Temporary **urine retention** occurs frequently after spinal/epidural anaesthesia; this can necessitate placement of a bladder catheter for a short period.

- A **loop** can occur in the epidural catheter, making removal more difficult and causing **injury to vessels and nerves**; in very rare cases, this can also lead to **breakage of the catheter**. Under certain circumstances, this can necessitate an operation to remove it.

Specific risks and possible associated complications of general anaesthesia

- In some cases, **nausea and vomiting** occur. **Life-threatening incidents** due to **aspiration of saliva or stomach contents into the lungs** occur very rarely but are severe; this complication necessitates intensive care monitoring/treatment.

- Also in rare cases, when inserting/removing the tube and/or the laryngeal mask, a **spasmodic closure of the airway (laryngospasm/bronchospasm)** occurs; this can, however, be managed with medications.

- Intubation anaesthesia and/or the application of the laryngeal mask may cause temporary **hoarseness** and **difficulty swallowing**. Very rarely, **injury** to the pharynx, jaw, larynx, vocal chords and trachea with **permanent dysphonia (hoarseness)** and **shortness of breath** may occur; in rare cases, injury to the trachea may lead to **life-threatening inflammation of the thorax**. Intensive care treatment, including with antibiotics, and additional surgery may be required in such case. In rare cases, temporary disorders of sensation of the tongue can occur which can be permanent in even rarer cases. **Damage**, in particular to loose or carious teeth, to implants but also to fixed dentures (e.g. crowns, bridges, prosthesis), as well as **loss of teeth** can occur.

Additional and subsequent procedures

- **Measures that may be necessary in preparation for, during or after the anaesthesia**, e.g. for monitoring and maintaining vital bodily functions, such as placement of vascular access or a bladder catheter, administration of medications or a blood transfusion that may become necessary, are also not risk-free. The **risk of infection** (e.g. with hepatitis, AIDS) after transfusion of foreign donor blood is extremely low. After a transfusion, a follow-up examination is possible to rule out infection. If it is expected that you **will need to receive foreign donor blood or blood components**, you will receive counselling about this and its associated risks in a separate discussion.

Possible effects of the anaesthetic procedure to the child

- It cannot be completely excluded with absolute certainty that the **child is affected by the medications**. The anaesthetic agents can cause **respiratory distress** in the child. After delivery, the child can be “**sleepy**” and **inactive** for some time. Therefore, as little anaesthetic agents as possible are administered. Thus, it cannot be excluded that **awareness**, in rare cases also **sensation of pain**, occur during the surgical delivery.

- If the mother's blood pressure drops due to regional anaesthesia, general anaesthesia or administration of pain medication, this can lead to **bradycardia** in the child.

- Generally, in regional anaesthesia, the medications are only transferred to the child in ineffective concentrations.

Please be sure to comply with the following instructions, unless otherwise instructed by the doctor!

Before regional anaesthesia/general anaesthesia/delivery

Up to 6 hours before regional anaesthesia/general anaesthesia/delivery, you may still have a light meal (e.g. a slice of white bread with jam, a glass of milk). After this point, **you are not allowed to eat anything else** (including candy/sweets, chewing gum or similar foods) and **you must refrain from smoking!** However, you should **stop smoking much earlier!**

During the time frame of **6 to 2 hours before regional anaesthesia/general anaesthesia/delivery**, you are only allowed to drink 1–2 glasses/cups of **clear fluids without fat and solid components** (e.g. mineral water, tea with sugar, isotonic sports drinks) at most but **no milk and no alcohol!** Thereafter, you may not drink anything!

Please inform us if, contrary to these instructions, you have had anything to eat or drink! If you had not been fasting sufficiently, there is a risk of life-threatening influx of saliva and stomach contents into the lungs (aspiration) if general anaesthesia is required or planned or complications occur.

Please talk to your doctor in advance about the **medications** you are taking (in particular anticoagulant medications) and clarify which of them you may continue to take or may have to discontinue.

Please present your **patient IDs** (e.g. maternity card; diabetes, anaesthesia records or allergy records).

Please remove contact lenses, rings, jewellery (also piercings) and artificial hair pieces and leave them in a secure place. Do not use any face creams and cosmetics (makeup, nail polish, etc.)!

While under epidural anaesthesia

Please note that **with a low-dose epidural anaesthesia only**, you are allowed to stand up and walk around, but only with the **doctor's approval** and with a **person accompanying you** since there is a risk of falling.

After regional anaesthesia/general anaesthesia/delivery

Please inform the doctors immediately if symptoms such as the following occur:

- Pain or disorders of sensation (also at the puncture site), seizure-like events, symptoms of paralysis (pins and needles, numbness, muscle weakness or back pain radiating into the legs after regional anaesthesia has lost effect are a warning sign!)
- Nausea, vomiting, fever, chills, laboured breathing, chest pain, disorders of circulation/low blood pressure, altered consciousness as well as problems passing urine/stool
- Sore throat, difficulty swallowing, hoarseness or speech disturbances in the event of general anaesthesia.

Because of the **risk of falling**, please do not get up on your own; get up only if **someone is there to help you!**

Place, date, time

Doctor

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.

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

n = no/y = yes

1. Weight prior to pregnancy (kilograms): _____
2. Occupation/Profession: _____
3. Is the patient regularly or currently taking n y **medications** (e.g. anticoagulant medications [e.g. Marcumar®, aspirin®, Plavix®, Xarelto®, Pradaxa®, Eliquis®, Lixiana®, heparin], pain medications, cardiovascular medications, hormone preparations, sleep-inducing medications or sedatives, diabetes medications [in particular those containing metformin])?

If yes, please indicate! _____
4. Is the patient taking **herbal medicine/supplements** (e.g. St John's wort, ginkgo, vitamins)? n y

If yes, please indicate! _____
5. Does the patient have an **allergy** such as hay n y fever or bronchial asthma or **hypersensitivity** to certain substances (e.g. medications, latex, disinfectants, sedatives, X-ray contrast media, iodine, plaster, pollen)?

If yes, please indicate! _____
6. Does the patient have an **allergy/hypersensitivity to soy**? n y
7. Does the patient have or has the patient ever had an **infectious disease** (e.g. hepatitis, tuberculosis, HIV/AIDS)? n y

If yes, please indicate! _____
8. Does the patient or does one of their relatives n y have an **increased tendency to bleed** such as e.g. frequent nosebleeds/bleeding gums, bruises, re-bleeding after operations?
9. Has the patient ever had a vascular obstruction n y due to a blood clot (**thrombosis/embolism**)?
10. Does the patient have or has the patient ever had a **vascular disease** (e.g. circulation disorder, arteriosclerosis, aneurysm, varicose veins)? n y

If yes, please indicate! _____
11. Does the patient have or has the patient ever had a **cardiovascular disorder** (e.g. heart defect, heart valve defect, angina pectoris, cardiac infarct, stroke, cardiac arrhythmia, myocarditis [inflammation of a heart muscle], hypertension)? n y

If yes, please indicate! _____
12. Does the patient have **low blood pressure**? n y
13. Does the patient experience **respiratory distress (difficulty breathing)** on exertion? n y
14. Does the patient have or has the patient ever had a **disease of the respiratory tract/lungs** (e.g. bronchial asthma, chronic bronchitis, pneumonia, emphysema)? n y

If yes, please indicate! _____
15. Does the patient **snore loudly**, does the patient have **sleep apnoea or paralysis of the recurrent nerve/diaphragm**? n y

If yes, please indicate! _____
16. Does the patient have or has the patient ever had a **disorder of the digestive tract** (e.g. oesophagus, stomach, pancreas, intestines)? n y

If yes, please indicate! _____
17. Does the patient suffer from heartburn or gastric reflux? n y
18. Does the patient currently have or has the patient ever had a **disease of the liver, gall bladder/bile duct** (e.g. inflammation, fatty liver, cirrhosis, gallstones)? n y

If yes, please indicate! _____
19. Does the patient presently have or has the patient ever had **jaundice**? n y
20. Does the patient have or has the patient ever had a **disease or malformation of the kidneys/urinary organs** (e.g. renal impairment, inflammation of the kidneys, kidney stones, impairment of bladder emptying)? n y

If yes, please indicate! _____
21. Does the patient have a **metabolic disease** (e.g. diabetes, gout)? n y

If yes, please indicate! _____
22. Does the patient have or has the patient ever had a **disorder of the thyroid gland** (e.g. overactivity, underactivity, goitre)? n y

If yes, please indicate! _____
23. Does the patient have or has the patient ever had a **muscle or skeletal disease** (e.g. muscle weakness, joint disease, osteoporosis)? n y

If yes, please indicate! _____
24. Does the patient have a genetic predisposition to become "overheated" (**malignant hyperthermia**), also in blood relatives? n y
25. Does the patient have **spinal injuries**? n y

