

Regional Anaesthesia or General Anaesthesia in Obstetrics

Patientenname und -adresse

Hello,

This informed consent leaflet provides you with information on how pain can be numbed during birth. Please read it as soon as possible and complete the questionnaire carefully and completely.

Anaesthesia in obstetrics

Labour pain and pain due to possibly necessary obstetric measures (e.g. caesarean section) can be eliminated or alleviated significantly using various anaesthetic procedures:

- **Regional anaesthesia suppresses pain in the lower half of the body.** This allows you to relax and consciously experience the birth of your child.
- **General anaesthesia induces controlled unconsciousness and blocks pain sensation in the whole body.**

Prior to a regional anaesthesia or general anaesthesia, an **indwelling catheter** is placed in a **hand or arm vein**. This allows for administration of **infusions and medications** (e.g. fluids to prevent low blood pressure, antibiotics in case of a caesarean section).

In the **patient-doctor discussion**, the doctor will inform you about the respective advantages and disadvantages and the various demands on your body and the risks of the anaesthetic procedures considered in your case and discuss with you which procedure is the most suitable for you.

Regional anaesthesia

It is preferred in both **natural deliveries** and **caesarean sections**.

There are 2 methods: **spinal anaesthesia** and **epidural anaesthesia**.

In both methods, the doctor injects an **anaesthetic agent** in the region of the **lumbar spine**. This "blocks" the transmission of pain stimuli to the brain. Thus, **pain perception is eliminated or reduced for a few hours, primarily in the abdominal and pelvic region**.

At first, **anaesthesia becomes noticeable as a feeling of tingling and warmth**. With its increasing effect, you will only feel **very little labour pain**.

With a **low dosage**, the **legs remain mobile** as normal. With a **higher dose for caesarean section**, the **legs become numb and cannot be moved temporarily**. **Sensations and mobility return** when the anaesthesia wears off.

Spinal anaesthesia

The doctor inserts a **thin needle** in the back and advances it **carefully into the spinal canal** through the **dura mater** (fig.). The spinal canal holds the **spinal cord** with the **nerves**

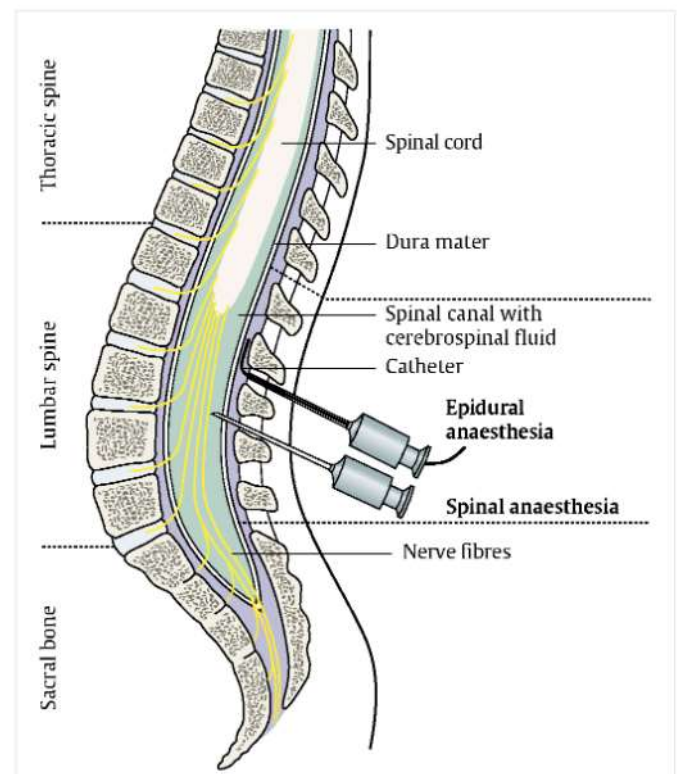


Fig.: Injection area for the obstetric regional anaesthesia

emerging from it and is filled with **cerebrospinal fluid (CSF)**. The **anaesthetic agent** is frequently injected into the spinal canal together with **pain medications**. Usually, the effect of the anaesthesia sets in after a couple of minutes.

Spinal anaesthesia is the preferred anaesthetic procedure mainly for **planned caesarean sections** and **urgent caesarean sections**.

Epidural anaesthesia

The doctor inserts a **hollow needle** into the **epidural space** in the back and threads a **thin synthetic tube (catheter)** through it (fig.). The epidural space is **in front of the dura mater** and contains the **spinal nerves**. After the doctor has removed the needle, the catheter can be used to repeatedly administer **anaesthetic agents** and **additional pain medications** or also continuously administer them after the birth.

Frequently, the catheter is connected to a **dosage pump**. This allows the pregnant woman to administer a **predetermined amount of anaesthetic agents and/or pain medications** herself in certain intervals as needed.

A low-dosage epidural takes effect after about **15 minutes** the earliest. Therefore, it is recommended to **perform an epidural early in the course of the delivery**, allowing the **pain relief to set in in time for the birth**.

If the epidural is performed only in the **further course of the delivery**, it may possibly be **too late in taking effect**. If there is **no longer enough time to perform an epidural and wait for it to take effect**, it is possible to perform a **spinal anaesthesia** in most cases.

Usually, an epidural performed in good time does not cause the contractions and the urge to push to become weaker, the birth to take longer, the child having to be delivered by caesarean section or vacuum extractor or forceps if not planned or the condition of the new-born to change.

If the epidural is performed at a late point in the course of the delivery only, it is more likely that the **administration of labour-inducing medications** is necessary or **other obstetric measures** will be necessary under certain circumstances.

If **caesarean section** becomes necessary, the epidural anaesthesia can be increased. Therefore, the **epidural anaesthesia** is usually also **ideal for women** for whom a caesarean section must be expected due to **risk factors** (e.g. multiple pregnancies, breech presentation, pre-eclampsia). However, it can take up to **20 minutes** until the increase in strength takes effect. If it is not possible to wait that long, **general anaesthesia** is necessary. An alternative to the epidural anaesthesia is **spinal anaesthesia**.

Combined spinal and epidural anaesthesia

In isolated cases, **spinal anaesthesia** and **epidural anaesthesia** can be combined. This makes use of the fast effect of **spinal anaesthesia** and the **long effective period of epidural anaesthesia**. However, this approach is also associated with the risks of both procedures.

A still relatively new form of the combined regional anaesthesia is an **epidural anaesthesia** in which the **dura mater** is **punctured with a fine needle** first before the **anaesthetic agent** is injected into the **epidural space** using a slightly larger **needle** or a **catheter**. The anaesthetic agent then gains access to the **spinal canal** through the small hole in the **dura mater**. This causes the epidural anaesthesia to **take effect more quickly**.

General anaesthesia

It is primarily performed in emergencies.

To **induce the general anaesthesia**, a **fast-acting anaesthetic agent** is injected via the **venous catheter** in the hand or arm.

Once the pregnant woman has fallen asleep, the doctor introduces a **breathing tube** into the **trachea** via the mouth. The breathing tube **keeps the airways open** and ensures the **oxygen supply**. In addition, it reduces the risk of **aspiration** of saliva and stomach contents into the lungs. A **muscle relaxant** will be administered to facilitate the gentle introduction of the breathing tube.

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

General anaesthesia allows the medical staff to act fast if **complications occur** and the **child must be delivered (very) fast** via caesarean section (e.g. due to cardiovascular problems and breathing difficulties of the pregnant woman, severe bleeding, premature detachment of the placenta, umbilical cord prolapse or slowing of the heartbeat of the child).

In isolated cases, general anaesthesia can also be necessary despite **not being planned** if **regional anaesthesia is not sufficiently effective or spreads too far**.

General anaesthesia planned from the beginning is an option in particular if **regional anaesthesia is not possible** for medical reasons (e.g. due to a coagulation disorder of the mother-to-be) or if **regional anaesthesia is refused**.

Off-label use of medication

In **obstetric regional anaesthesia** or **general anaesthesia**, **anaesthetic agents**, **pain medications** or **other medication** which have proved to be effective but are **not formally approved for the use in pregnant women (off-label use)** are frequently used. However, this does not mean that their administration beyond the approved use is prohibited.

For example, **pain medications (opioids)** not approved for use during pregnancy are administered in addition to **spinal anaesthesia** or **epidural anaesthesia**. However, this usually makes sense and is recommended because the administration of anaesthetic agents alone would impair mobility and muscle strength of the pregnant woman too much.

The opioids used are mainly **sufentanil** and **fentanyl**. Both have **not been approved for obstetric spinal anaesthesia**. However, they are so frequently used for **spinal anaesthesia** in caesarean sections nowadays that it is a **scientifically recognised standard procedure (established off-label use)**. Sufentanil is approved for **obstetric epidural anaesthesia** but fentanyl is not.

The doctor will explain to you a possible **off-label use of medications** in your obstetric regional anaesthesia or general anaesthesia and inform you about the known risks. However, unknown risks cannot be ruled out. Furthermore, the manufacturer will not accept any liability under certain circumstances.

Additional and subsequent procedures

Your doctor will also inform you separately about any **foreseeable ancillary and subsequent procedures** (e.g. placement of a urinary catheter). If **transfusion of blood from a foreign donor** is seriously considered, you will be informed about how it is performed and its risks (e.g. hypersensitivity/incompatibility reactions, infection, also with

unknown pathogens under certain circumstances) and about measures to avoid using foreign donor blood in a **separate patient-doctor discussion**. The risk of transmission of HIV infection or hepatitis by transfusion of foreign donor blood is extremely rare nowadays.

Risks and possible associated complications

During anaesthesia, your **vital body functions** (most importantly pulse, blood pressure and breathing, cardiac activity) are **monitored**. Since there is hardly a medical measure without risks, complications can arise despite the greatest care taken, which can even become life-threatening under certain circumstances and necessitate additional treatment or further operations. 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.

General risks of injections/indwelling catheters/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 **life-threatening blood poisoning (sepsis)**.
- **Skin, tissue and nerve damage** can be caused by needles/cannulas/catheters, injections and measures in conjunction with the procedure (e.g. skin disinfection) as well as due to **pressure, tension or over-stretching during anaesthesia** ("damage due to positioning"). Consequences can be **pain, alterations in sensation, numbness, movement disorders** and even **paralysis** in the arm/leg. In most cases, they resolve by themselves within a few months and are permanent in rare cases only.
- **Thrombosis/embolism**: If blood clots are formed or are carried through the blood stream and block a blood vessel, severe damage can occur (e.g. pulmonary embolism, stroke, heart attack), which can be life-threatening under certain circumstances.
- The required **medications and materials** (e.g. anaesthetic agents, opioids or other pain medications, 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**. However, **severe permanent damage** (e.g. brain damage, other damage to organs, paralysis) only occurs in isolated cases.

Specific risks of the spinal and epidural anaesthesia

- **Seizures, loss of consciousness and severe, in very rare cases also life-threatening cardiocirculatory disorders**

and respiratory distress 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. In addition, **temporary paralysis** can also occur if, during spinal anaesthesia, the anaesthetic agent spreads too far in the body or, during epidural anaesthesia, inadvertently accesses the spinal canal. Short-term treatment on an intensive care unit would then be necessary.

- **Direct injury to the spinal cord** is almost completely excluded in obstetric spinal anaesthesia and epidural anaesthesia since the anaesthetic agent is generally injected below the spinal cord.
- **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 can 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 of time.
 - **Life-threatening cerebral haemorrhage**, an **accumulation of blood or fluid under the dura mater** that encases the brain (**subdural haematoma/hygrogram**) as well as **cerebral venous thrombosis** with possible **permanent damage to the brain** (e.g. hemiplegia, speech disorders) 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 **urinary catheter** must possibly be placed for a short time. This can cause **bleeding and urinary tract infection/injury**.
- If an epidural catheter is placed, **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 general anaesthesia

- If **stomach contents get into the lungs (aspiration)**, this can have **life-threatening consequences** under certain circumstances. Examples of this are e.g. **pneumonia, acute lung failure or permanent lung damage**.
- **Spasms of the airways** 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 only, this necessitates intensive care.
- **Difficulty swallowing and hoarseness** can be caused by the tube in particular but are temporary in most cases.

Permanent damage to the vocal folds (e.g. paralysis of the vocal folds) with **permanent dysphonia (hoarseness)**, **breathing difficulties**, **injury to the pharynx, jaw, larynx and windpipe** and **alterations in sensation on the tongue** are rare.

- **Damage to teeth, implants and non-removable dentures** (e.g. crowns, bridges) as well as a **loss of teeth** can occur, in particular in patients with caries, loose teeth or loosened dentures.
- **Damage to the cornea of the eye** is extremely rare thanks to protective measures (e.g. covering the eyes during general anaesthesia). If it occurs nevertheless, it usually heals without any consequences.
- **Life-threatening metabolic imbalance with increase of the body temperature to an extreme extent (malignant hyperthermia)** after administration of gaseous anaesthetic agents or a certain type of muscle relaxants can be triggered in extremely rare cases but only if the mother-to-be has a specific genetic predisposition. Malignant hyperthermia necessitates treatment on an intensive care unit.
- Despite the greatest care taken, a patient can **regain awareness** during general anaesthesia, and in rarer cases, the patient may also have **pain awareness**. These perceptions, which usually persist for a short time only, cannot be ruled out completely with pregnant women specifically since they receive as little anaesthetic agents as possible to keep the effects on the child low. However, stressful memories necessitating treatment occur in isolated cases only.

Possible effects of anaesthetic agents and pain medication on the child

- It cannot be completely excluded with absolute certainty that the **child is affected by the medications**. The anaesthetic agents and pain medications can cause **respiratory distress** in the child. After delivery, the child can be “sleepy” and inactive for some time.
- 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. This can necessitate an emergency caesarean section.

Instructions

Before anaesthesia/delivery

Instructions on fasting if the doctor instructs you to do so or you are scheduled for a caesarean section:

You 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 anaesthesia/delivery**. After that, you may no longer eat anything!
- During the time frame of **6–2 hours before the anaesthesia/delivery**, 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. You may not smoke for **2 hours before the anaesthesia/delivery!**

Please inform your doctor or any other staff if you have not been able to adhere exactly to these fasting instructions!

Please list **all medications** that you are currently taking in the questionnaire (also herbal remedies and over-the-counter medications). The doctor will then decide if specific medications should be stopped or replaced by another substance.

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

Please **remove contact lenses, rings, jewellery (including piercings) and artificial hair pieces** before the anaesthesia. Please **do not use any facial creams or cosmetic products** (make-up, 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 an accompanying person since there is a **risk of falling**.

After the anaesthesia/delivery

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.

Please **inform a doctor immediately if you develop symptoms**, e.g. **breathing difficulties or problems with circulation, impairment of consciousness, pain, fever, chills, nausea, vomiting, difficulties with defecation/urination, alteration in sensation** (e.g. at an injection site or in the limbs), **back pain radiating into the legs** after the regional anaesthesia has resolved, **disorders of movement, signs of paralysis or sore throat** after general anaesthesia, **hoarseness, speech disorders or difficulties swallowing**.

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

Questions on your pregnancy

n = no/y = yes

1. What was your weight prior to the pregnancy (kilograms)? _____
2. Have you ever been pregnant? n y
If yes, did any complications occur during or after the pregnancy/birth (e.g. severe bleeding, thrombosis, pre-eclampsia, miscarriage)? n y
If yes, please indicate! _____
3. Have you ever had a caesarean section? n y

Questions on coagulation

1. Is there a disorder of blood coagulation?
 no
 haemophilia
 thrombocytopenia
 von Willebrand-Jürgens disease
 factor deficiency
 and/or: _____
2. Is there a coagulation disorder among blood relatives? n y
3. Is/was there a disease of the blood?
 no
 anaemia
 leukaemia
 multiple myeloma
 and/or: _____
4. Is there an increased tendency to bleed, e.g., frequent nosebleeds, bruises, extended period of bleeding after injuries? n y
5. Is there an increased tendency to bleed among blood relatives? n y
6. Have you ever noticed dot-shaped bleeding on your body (e.g. on the trunk or limbs), even if you did not bang into anything recently? n y
7. Have you ever had bleeding in a joint, soft tissue or a muscle? n y
8. Does your menstruation persist for more than 7 days? n y
9. Does increased menstruation occur, requiring frequent pad or tampon changes? n y
10. Have you ever had a tooth extracted? n y

If yes, did you experience severe/prolonged rebleeding? n y

11. Have you ever received a transfusion of blood/ blood components? n y
If yes, did any complications develop? n y
If yes, please indicate! _____
12. Has a vascular obstruction due to a blood clot (thrombosis/embolism) occurred before? n y
13. Did a thrombosis or embolism occur among blood relatives before? n y

Further questions

1. Occupation/profession (current/previous): _____
2. Has an operation been performed before? n y
If yes, please indicate: _____
If yes, did any complications occur? n y
If yes, please indicate: _____
3. Has any other medical treatments been provided in the last few weeks? n y
If yes, for what reason? _____
4. Has anaesthesia ever been performed? n y
If yes, please indicate:
 general anaesthesia
 regional anaesthesia
 local anaesthesia (e.g., dental treatment)
 sedation
 and/or: _____
If yes, did any complications occur? n y
If yes, please indicate: _____
5. Is there a tendency to have nausea/vomiting? n y
6. Has a congenital tendency to have high fever and muscle stiffness during/after general anaesthesia (malignant hyperthermia) been found? n y
7. Has a congenital predisposition to malignant hyperthermia been found among blood relatives? n y
8. Has there been an infection in the last 4 weeks?
 no
 airways

- gastrointestinal
 urinary tract
 and/or: _____
9. Is/was there an infectious disease?
 no
 hepatitis
 HIV/AIDS
 tuberculosis
 and/or: _____
10. Are there any medications (including herbal n y and over-the-counter medications) being taken or applied regularly or currently?
 If yes, please indicate in full: _____

11. Do you take anti-rheumatic medications? n y
 If yes, please indicate! _____
12. Are there herbal medications/supplementary preparations that are being taken?
 no
 St John's wort
 ginkgo
 vitamins
 and/or: _____
13. Is there an allergy?
 no
 medications
 anaesthetic agents
 contrast medium
 latex
 disinfectants
 iodine
 plaster
 synthetic materials
 and/or: _____
14. Is/was there a (another) vascular disease?
 no
 arteriosclerosis
 varicose veins
 disease of coronary vessels
 circulatory disorders
 aneurysm
 constriction of the carotid artery
 and/or: _____
15. Is/was there a (another) cardiovascular disease?
 no
 coronary heart disease
 hypertension
 cardiac arrhythmia
 stroke
 heart attack
 angina pectoris
 myocardial inflammation
 cardiac valve defects
 and/or: _____
16. Is there low blood pressure? n y
17. Do breathing difficulties occur when climbing n y the stairs?
 If yes, how many stairs can you climb before needing to stop? _____
18. Is/was there a disease of the airways/lungs?
 no
 chronic bronchitis
 pneumonia
 bronchial asthma
 pulmonary emphysema
 congenital malformation
 and/or: _____
19. Does respiratory distress (difficulty breathing) occur during the night?
 no
 severe snoring
 sleep apnoea
 and/or: _____
20. Is there paralysis of the vocal folds? n y
21. Is there a paralysis of the diaphragm? n y
22. Is/was there a disorder of the digestive system?
 no
 oesophagus
 stomach
 intestine
 and/or: _____
23. Does heartburn occur frequently? n y
24. Is there a reflux disorder (reflux of stomach n y acid into the oesophagus)?
25. Is/was there a disease of the upper abdominal organs?
 no
 liver inflammation/hepatitis
 fatty liver
 cirrhosis
 biliary colics
 bile stones
 jaundice
 pancreatitis
 and/or: _____
26. Is/was there ever a disease or malformation of the kidneys/urinary organs?
 no
 dysfunction of the kidneys
 kidney stones
 chronic urinary tract infection
 nephritis/inflammation of the kidneys
 congenital malformation (e.g. duplex kidney)
 bladder emptying disorder/delayed bladder emptying
 and/or: _____
27. Is there a metabolic disease?
 no
 diabetes
 gout
 and/or: _____
28. Is/was there a disease of the thyroid gland?
 no
 overactivity

Statement of Consent

I have read the informed consent form, and I understand it. The above-named anaesthesia in particular, its nature and significance, alternatives, the risks and possible associated complications, possible necessary changes in/additions to the procedure as well as additional/subsequent procedures have been fully explained to me in a patient-doctor discussion with doctor _____.

My questions were answered completely and clearly.

I have **no further questions**, feel that the **counselling was satisfactory**, do **not need any further time for consideration and consent** to the proposed anaesthesia and any medically necessary, including unforeseeable, changes in/additions to the procedure, additional/subsequent procedures. I will follow the doctor's **instructions**.

I have received a duplicate/copy of this leaflet.

Place, date

Mother-to-be

Doctor