Hospital Data Imprint/Stamp

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proCompliance

Obstetric Procedures

Patient identification sticker

Dear Mother-to-be,

Your doctor will explain the different possibilities for the course of the delivery to you. The purpose of this information form is to help you to prepare for the patient-doctor discussion. Please read it carefully before the discussion and complete the questionnaire carefully and completely.

On childbirth

Childbirth is a natural process. Medical assistance is only given if necessary for your or your child's safety. Modern obstetric procedures, in particular also the methods of monitoring the delivery, have significantly reduced the risks for mother and child. Today, dangerous situations are identified early in most cases so that measures can frequently be taken in due time. However, you need to consent to the medical procedures needed for this.

Measures before delivery

At the start of delivery, an elastic hypodermic needle is frequently placed in an arm vein so that medications, including pain medication or medications to improve your child's well-being, can be administered as needed without losing any time.

In some cases, e.g. in case of premature rupture of membranes, it is necessary to induce labour artificially by administration of medications (oxytocin, homoeopathic medications). If induction of labour is planned in your case, your doctor will inform you about it in a separate patient-doctor discussion.

Alleviation of labour pain

The birth is very physically exhausting and painful. If the methods you have learned (e.g. relaxation exercises, breathing techniques) are not sufficient, the pain can be alleviated with medications. The following methods are available:

- The **dilating pains** – from the onset of labour to full dilation of the cervix of about 10 cm – can be relieved by naturopathic measures (e.g. aroma bath, various homoeopathic medications) or by sedatives and pain medications in the form of tablets, suppositories, injections or infusions. Another method is **acupuncture** which is not offered in all obstetric departments, however. In it, you are pricked with very thin needles in various places; heat or low electric currents can be used to strengthen the pain-relieving effect (stimulation).

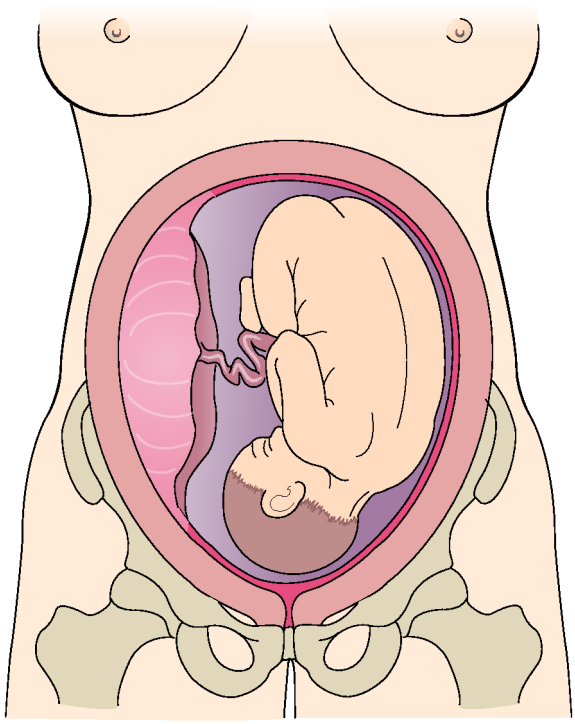

Fig. 1: Normal presentation (cephalic presentation)

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- In the last phase of delivery, the so-called **expulsive phase**, the pelvic floor can be made insensitive to pain in addition (**pudendal anaesthesia**). For this, a local anaesthetic agent is injected through the vagina in the proximity of the pain-conducting nerves. If episiotomy is required, local anaesthesia can be used here also.
- **Epidural anaesthesia** (PDA) is a particularly effective anaesthetic method. It numbs the nerves of the space close to the spine. If this is an option for you, you will be informed about the procedure and its associated risks in a separate discussion.

Your doctor will inform you about the pain-relieving methods and your specific risks and possible complications in a separate patient-doctor discussion. Afterwards, you can decide together which procedures should be used.

How is the birth monitored?

During the birth, you and your child will be monitored by midwives and doctors. The listed monitoring options provide a large extent of security since a possible danger to your child can be identified early.

- **Cardiotocography (CTG)**

  By means of electrodes placed on the mother's abdominal wall, labour and heart beat of the child can be recorded.

  If the water has already broken, an electrode can be attached to the child's scalp – if necessary – which causes a small injury to the child's skin. A probe can be advanced into the uterus through the vagina to measure the pressure of the contractions.
- **Micro blood analysis**

  If there is suspicion that there is danger to the child in the womb, a few drops of blood are taken from the skin of the child's head or rump – depending on its presentation – for examination. Thereby, information (e.g. about a possible oxygen deficiency) can be obtained and necessary measures for further management of the delivery can be taken.

Additional procedures

Ecbolic/tocolytic medications

Ecbolic medications (medications promoting labour) are required e.g. if the contractions are insufficient. Tocolytic medications (labour suppressants) are administered if e.g.

- the birth process must be slowed down to enable changing the child's position,
- contractions are too frequent,
- the child should be allowed a period of rest due to changes in the CTG,
- some time must be bridged for an emergency caesarean section.

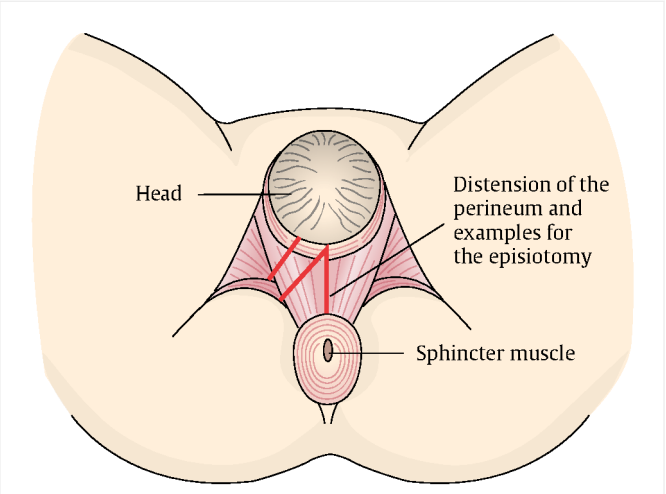

Fig. 2: Episiotomy

Episiotomy

Today, childbirth takes place without episiotomy if possible. However, episiotomy can be helpful or necessary. In most cases, extreme overextension of the pelvic floor and lacerations (also of the urethra and the anal sphincter) can be avoided with it. In addition, episiotomy provides for reduced pressure on the child's head when passing the pelvic floor and often shortens the critical expulsion stage. Therefore, episiotomy is more frequently performed in the event of CTG changes indicating oxygen deficiency, a prolonged expulsion stage, a very small or very big child and suction or forceps delivery. Your doctor will decide on the method of incision best suited for you (see fig. 2).

Suction or forceps delivery

In a dangerous situation for the child or the mother (e.g. obstructed labour or decrease of the child's heartbeats in the expulsion stage while the child's head is already positioned low enough), the doctor uses a suction cup or forceps to accelerate delivery. The tool is inserted into the vagina, is positioned laterally (forceps) or at the top of the child's head (suction cup) and allows to support the mother during expulsion by carefully pulling on the child.

Caesarean section

If certain risk factors (e.g. abnormal presentation of the child such as breech presentation) are known in advance, a caesarean section can be a **true alternative** to spontaneous vaginal delivery in some cases. We will discuss the advantages and disadvantages of a caesarean section compared to vaginal delivery in more detail with you so that you can make your own decision.

Even if conventional delivery is planned for you, it is possible that a situation necessitating caesarean section (e.g. excessive bleeding, prolapse of the umbilical cord, rupture of the uterus, change of the child's heartbeat indicating danger to the child, underlying diseases of the mother, if delivery does not progress) arises during delivery. We may no longer be able to discuss the advantages and disadvantages, risks and demands of the caesarean section on your body and ask for your consent. Therefore, we ask you to now consent to caesarean section in case of an emergency.

If you refuse caesarean section, life-threatening situations both for your child that can be profoundly disabled or that can die in the uterus in an extreme case and for yourself (e.g. if the placenta is detached prematurely) can occur.

During caesarean section, the abdominal wall is first opened up with an incision – in most cases just above the edge of the pubic hair –, if necessary, the urinary bladder situated between the abdominal wall and uterus is detached carefully, the uterus is opened and the child is taken out. After that, the placenta is removed, and both the uterus and the abdominal wall are closed with sutures.

Water birth

If you wish to have a water birth, the doctor will inform you separately about the associated risks.

Rhesus prophylaxis (anti-D prophylaxis)

If you are Rh negative but your child is Rh positive, you will receive vaccination after the birth to avoid complications in

later pregnancies. If this applies in your case, we will provide counselling about it in a separate patient-doctor discussion.

Other additional measures

In an individual cases, other measures can be required (e.g. certain manoeuvres for breech presentation); your doctor will inform you about them in advance in the individual case.

Spontaneous vaginal delivery after caesarean section

On principle, even after previous caesarean section, a normal course of the birth (spontaneous vaginal delivery) is possible. In an occasional case, the wall of the uterus must be palpated after the spontaneous vaginal delivery to make sure that the old scar has stayed closed. However, there are also reasons to perform caesarean section again (e.g. if the placenta is positioned before the cervix).

Which possible risks/complications are to be expected?

Childbirth entails certain risks, and it is therefore not possible to guarantee a healthy child despite professional management of childbirth on principle.

Despite the greatest care taken, complications can arise which can even become life-threatening under certain circumstances and necessitate additional treatment or further surgery. 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 disease and individual unusual circumstances can significantly influence the rate of complications.

General risks

- **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). During pregnancy, childbirth and the puerperium, the risk is higher on principle and is increased additionally by medical procedures (e.g. caesarean section). Frequently (in particular for caesarean section), blood-thinning medications are given as a prophylaxis. However, they all increase the risk of bleeding. The active substance heparin can also cause a life-threatening formation of blood clots (HIT II), however.
- **Amniotic fluid embolism:** In an exceptional case, amniotic fluid can also enter the blood vessels and cause an embolism.

In pain management

- **Allergy/hypersensitivity/incompatibility** (e.g. to latex, medications) can cause acute circulatory shock and necessitate intensive care. Severe damage (e.g. organ failure, brain damage, paralysis), which can be permanent under certain circumstances, is very rare.
- **Haematomas** (bruises) and **infections** occur at the injection site in very rare cases; however, in most cases they tend to resolve after a few days and require treatment only in rare cases.
- **Respiratory disorders** can occur in the child in rare cases, in particular if it was born shortly after administration of a sedative or pain medications. In this case, appropriate countermeasures are taken (e.g. administration of oxygen).

In monitoring measures

- A rare **wound infection** at the child's scalp caused by the CTG probe or blood sampling does not require treatment in most cases. This also applies for a possible **infection of the uterus** caused by the probe used to measure the pressure of the contractions.
- In very rare cases, persistent bleeding of the child can occur secondary to taking a blood sample at the child's head, necessitating intensive care after delivery with a possible blood transfusion. In very rare cases, severe local inflammation of the scalp has also been described.

During childbirth

- **Injury of the vagina** (e.g. laceration of the vagina, lacerations in the labia minora, to the clitoris) **and the perineum** can occur; in most cases, it can be treated easily. Only in a very rare case, a fistula (unnatural connecting passage) between the intestine and the vagina or the bladder and vagina or a membranous perineum (with the possible consequence of pain during intercourse) can occur. This can possibly necessitate several other operations.
- **Injury to the external anal sphincter** and **the intestine** can occur secondary to perineal tear or episiotomy, in particular if obstetric forceps or a suction cup are used. However, in most cases, it heals swiftly and without complications after being sutured. Formation of a fistula between the intestine and the vagina or stool incontinence cannot be excluded, however. Further treatment measures or other operations (possibly with temporary placement of an artificial anus) can be required.
- **Overextension of the pelvic floor muscles** can cause urine or stool incontinence in the long term. This deficiency can be remedied by means of Kegel exercise in most cases. However, in an occasional case, an operation at a later time is required.
- The uterus is **ruptured** during the contractions in a rare case, or an old scar in the uterus can **rupture** (e.g. from an earlier caesarean section). This is dangerous for mother and child. In this case, immediate caesarean section and surgical treatment are inevitable.
- **Urinary tract infection** (urinary bladder, ureter) can occur even several days after the delivery. However, it is easily managed with antibiotics.
- **Severe bleeding** from the uterus can occur if the placenta is not detached or is detached incompletely or if injuries occur. This risk is increased after a previous caesarean section. This bleeding can be stopped with further surgical procedures, by manual detachment of the placenta, curettage and medications. If the placenta is ingrown in the uterus or bleeding cannot be stopped, **removal of the uterus** can be necessary. In this case, further pregnancies are impossible. Severe bleeding can also occur secondary to injury of the vagina, the perineum and the uterus. Bleeding/rebleeding can necessitate an operation to stop it (haemostasis) and/or transfusion of blood. The risk of infection (e.g. with hepatitis, AIDS) after transfusion of foreign donor blood has become extremely rare. After a transfusion, it is possible to perform follow-up laboratory evaluation.
- In an occasional case – especially after caesarean section during an earlier birth – **the placenta does not detach or detaches incompletely**. This can be treated with medications in frequent cases. Under certain circum-

stances, removal of the placenta or its residues and subsequent curettage under general anaesthesia or after administration of pain medications is required.

- There is a risk of **infection** secondary to injury, delayed involution (decrease in size) of the uterus or placenta residue; in most cases, it can be treated easily with medications. However, it can also lead to pathogens spreading through the body (causing peritonitis – inflammation of the membrane lining the abdominal cavity) or even life-threatening sepsis (blood poisoning) under adverse circumstances. In a very rare case, an infection can be so severe that the uterus and possibly also the ovaries must be removed in an operation.
- Ascending **infection** is generally easily managed with antibiotics. In very rare cases, it can cause **impaired function and adhesions of the fallopian tubes**. Permanent sterility cannot be excluded in this case.
- **Shoulder dystocia** (in particular in case of a high weight at birth, if the mother is overweight, diabetes): This is a situation in which the shoulder of the child unexpectedly becomes stuck in the mother's pelvis after the child's head has been expelled since it does not obtain the right position. The longer it is in this position, the greater is the danger of insufficient oxygen supply to the child. This necessitates immediate action. This may be done by the doctor and midwife stretching and bending the legs of the expectant mother at the hip (possibly several times) to provide more space for the child's shoulder. In addition, they may exert pressure on her abdomen above the pubic bone. Changing position may also help. Inserting a hand deeply into the mother-to-be's vagina to loosen the child's shoulder is also an effective method. Frequently, the perineal incision must also be enlarged. Despite all these measures, injury to the child' shoulder, collar bone and/or upper arm of the child can occur. Injury to nerves can cause permanent paralysis of the child's arm to a varying extent.

In forceps/suction delivery (for the mother)

- In an occasional case, **the vagina or wall of the uterus is injured**, in a rare case, **rupture of the uterus** can occur. This requires immediate surgical treatment; it is possible that the uterus must be removed. This risk of injury is more rare in suction delivery.
- **Injury to the bladder and intestine** is extremely rare and can cause urinary or stool incontinence or formation of a fistula which may necessitate further operations.

In forceps/suction delivery (for the child)

- **Pressure marks, abrasions, haematomas** or **swelling on the head** can occur but resolve spontaneously without special treatment in most cases.
- **An increased tendency to bleed** in the brain can occur; therefore, vitamin K is administered in frequent cases to promote coagulation.
- **Severe complications** in the child (e.g. **skull fracture**, **brain haemorrhage**, **facial paralysis**) are very rare in both procedures but cannot be excluded with absolute certainty despite the greatest care taken.

In episiotomy

- **Bleeding** and **rebleeding** are stopped by suturing the perineum; this can be performed under general anaesthesia but is performed under local anaesthesia in most cases. **Pain** in the first days after delivery, minor **haematomas, wound healing disorders** and **infection** cannot be excluded for perineal tear and episiotomy both; however, they can also occur secondary to the stretching of the vagina and the connective tissue if the perineum stayed intact. Since a wound in the vaginal region never can heal in a sterile manner, the sutures can be expelled after a few days, with the wound splitting open in part or completely. This can necessitate suturing the wound again after cleaning it, or depending on the situation, you may also wait for the wound to heal by itself; this can take several weeks.
- **Wound infection** can necessitate treatment with medications or an operation (e.g. administration of antibiotics, reopening of sutures/the wound). In very rare cases, generalised blood poisoning (sepsis) can occur which necessitates intensive medical care. However, it is easily managed with antibiotics in most cases.
- **Scars with excessive scar tissue** (keloids) secondary to a genetic predisposition or impaired wound healing can occur in rare cases. Consequences can be skin discolouration, pain – also during sexual intercourse – and restriction of movement. A corrective procedure may be possible at a later time.

Specific risks of the caesarean section

This information form can provide information on the most important risks of a caesarean section only. If a caesarean section is planned for you, you are informed about it with a separate form.

For the mother

- **Injury to adjacent organs** (e.g. blood vessels, nerves, intestine, urinary bladder, ureter) can occur in rare cases, necessitating another operation to prevent the associated consequences (e.g. severe bleeding, painful disorders of sensation, peritonitis, intestinal obstruction, formation of fistulas, uraemia). The risk is increased after previous operations or if adhesions or difficult anatomic conditions are present.
- In very rare cases, **severe bleeding can occur which cannot be stopped**. This necessitates blood transfusion and possibly removal of the uterus.
- **Skin/tissue/nerve damage** secondary to positioning the patient and measures that may be needed in conjunction with the procedure (e.g. injections, disinfection, laser, electric current) is rare. Possible consequences that can be permanent under certain circumstances: Pain, inflammation, necrosis of tissue, scars and disorders of sensation or function, paralysis.
- **Infection** (e.g. urinary tract infection, pneumonia, peritonitis) can occur in rare cases but is easily managed with antibiotics in most cases. **If a wound becomes infected**, disorders of wound healing can occur with the consequence of **scars with excessive scar tissue** or **incisional hernia**, necessitating another operation.
- **Intestinal obstruction** can occur secondary to temporary **intestinal paralysis** or **adhesions** in the abdominal cavity in rare cases, even after several years; this can necessitate reopening of the abdominal cavity and – in isolated cases – even placement of an artificial anus.
- **Rupture of scars in the uterus** can occur during the next birth which can necessitate an emergency caesarean section in isolated cases.

- **Pain** and **disorders of sensation in the region of the incision** occur frequently in the first days after the birth and are no reason to be alarmed even if they sometimes persist for several months and are very slow to improve.

For the child

- **Minor cuts** can occur when opening the uterus; in most cases, they heal spontaneously. In rare cases, the injury must be sutured.
- **Adaptive disorders** can occur in an occasional case after the birth (e.g. respiratory disorder requiring administration of oxygen).

During the patient-doctor discussion, you should ask all questions that are important to you or about anything that is still unclear!

Instructions

If you experience fever of more than 38 °C, increasing abdominal pain or bleeding exceeding the usual menstruation, increasing redness in a breast or both breasts, please inform your doctor immediately, even if the symptoms do not develop for several days after your discharge from the hospital.

Important Questions

In general, risks involved in medical procedures are affected by the general health of the patient and any underlying medical conditions. In order to help us to identify any risks involved in this procedure for you as early as possible, we ask you to answer the following questions carefully and completely:

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

n = no/y = yes

1. Is the patient regularly or currently taking **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])? ☐ n ☐ y

   If yes, please indicate! _____

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

   If yes, please indicate! _____

3. Does the patient or does one of their relatives have an **increased tendency to bleed** such as e.g. frequent nosebleeds/bleeding gums, bruises, rebleeding after operations? ☐ n ☐ y

4. 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! _____

5. 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! _____

6. Has the patient ever had a vascular obstruction due to a blood clot (**thrombosis/embolism**)? ☐ n ☐ y

7. Does the patient have an **impairment of blood coagulation**? ☐ n ☐ y

8. Does the patient have a **metabolic disease** (e.g. diabetes, gout)? ☐ n ☐ y

   If yes, please indicate! _____

9. Does the patient have **other diseases**? ☐ n ☐ y

   If yes, please indicate! _____

10. Has the patient ever had **disorders of wound healing** such as e.g. infection/inflammation, abscess, fistula? ☐ n ☐ y

11. Does the patient have a **piercing** (e.g. genital piercing) in place? ☐ n ☐ y

    If yes, please indicate in which part of the body! _____

12. Has the patient ever had an **operation of the uterus**? ☐ n ☐ y

13. Did the patient **give birth** (once or several times) before? ☐ n ☐ y

    If yes, how many times? _____

    If yes, were there **any problems during previous childbirths**? ☐ n ☐ y

    If yes, please indicate! _____

14. Were there any problems during the **current pregnancy**? ☐ n ☐ y

    If yes, please indicate! _____

Doctor's comments on the patient-doctor discussion

(e.g. advantages and disadvantages of the surgical obstetric procedures [suction cup, forceps delivery, caesarean section]; individual risks/possible complications – for example if the child is in breech presentation, possible additional/subsequent measures; refusing certain obstetric procedures; possible consequences of refusal; patient has a legal surrogate decision-maker/a legal guardian; patient has appointed a legal proxy/provided a medical power of attorney; duration of the discussion)

Patient's Statement of Consent

The above-named obstetric procedures (e.g. monitoring, pain relief, episiotomy, suction cup, forceps), risks and possible associated complications, alternatives (e.g. caesarean section) and additional/subsequent procedures/treatment that may be needed (e.g. suturing of a perineal tear) and possible additions to these measures (e.g. surgical release of the placenta, caesarean section) have been fully explained to me in a patient-doctor discussion with

doctor _____.

I was afforded the opportunity to ask any questions that I considered important.

I have **no further questions** and feel that **the counselling was satisfactory**; therefore I hereby **consent** to the proposed measures explained to me in the discussion on principle. I further give my consent to any additional procedures or changes to the proposed course of delivery that may be necessary in the event that any unforeseen conditions arise during the delivery.

I have received a duplicate/copy of this information form.

_____ _____

Place, date, time Mother-to-be

_____

Doctor

Statement of consent of the accompanying person

If you want to attend a childbirth as an accompanying person, you are taking a minor risk the doctor cannot prevent (e.g. secondary to loss of consciousness or also emotional damage). Therefore, we require that you sign the following statement of consent:

I am aware that I am attending the childbirth at my own risk and peril. If I suffer any consequences for my health secondary to my presence in the delivery room or operation theatre, I hereby waive any claim to damages towards the doctors, the hospital owners and any other persons (midwives, nurses and care workers).

_____

Place, date, time

_____

Signature of the accompanying person

In case of refusal to consent

I do not consent to the proposed obstetric measure(s). I have read the information form and I understand it. I was informed of the possible consequences involved in this refusal (e.g. brain damage of the child or even stillbirth).

_____

Place, date, time

_____

Mother-to-be

_____

Witness (if applicable)

_____

Doctor