Hospital Data Imprint/Stamp

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Thieme Compliance
Geb 2 *GB*
proCompliance

Caesarean Section

Delivery by Section (Caesarean Section)

Patient identification sticker

The delivery is planned for _____.
date

Dear Mother-to-be,

A caesarean section is planned for you. The purpose of this informed consent form is to help you prepare for the patient-doctor discussion. Please read it carefully before the discussion and complete the questionnaire carefully and completely.

When is a caesarean section performed?

There are situations which make a normal delivery impossible or difficult or increase the risk of delivery for the child or the mother. These can be, e.g.: atypical presentation of the child, the size of the child, an impending threat for the child (e.g. if abnormalities of the foetal heart rate are present on CTG [cardiotocograph]), pregnancy with multiples, premature delivery, previous operations of the uterus or also diseases of the mother. A caesarean section can be planned (e.g. if a disease of the child is present or if it is in an anomalous presentation, etc.), its necessity can become apparent during delivery (e.g. if delivery does not progress), or an emergency caesarean section can become necessary (e.g. if the child is at acute risk).

In some situations, such as e.g. breech presentation or possibly a very big child, caesarean section can be an alternative to normal delivery. In these cases or if you prefer a caesarean section for personal reasons, we will discuss the advantages and disadvantages of a caesarean section compared to natural delivery (by means of suction cup or forceps if applicable) in more detail with you so that you can make your own decision.

How is the procedure performed?

Caesarean section is performed under regional anaesthesia (spinal/epidural anaesthesia) or under general anaesthesia. The anaesthesiologist/consultant anaesthetist will counsel you on this type of anaesthesia and the associated risks in a separate patient-doctor discussion.

A catheter is inserted into the bladder to drain the bladder and may remain in place for several hours up to one day.

The doctor initially opens the abdominal wall with an incision, in most cases shortly above the pubic hairline, and then opens the wall of the uterus. Alternatively, a smaller incision

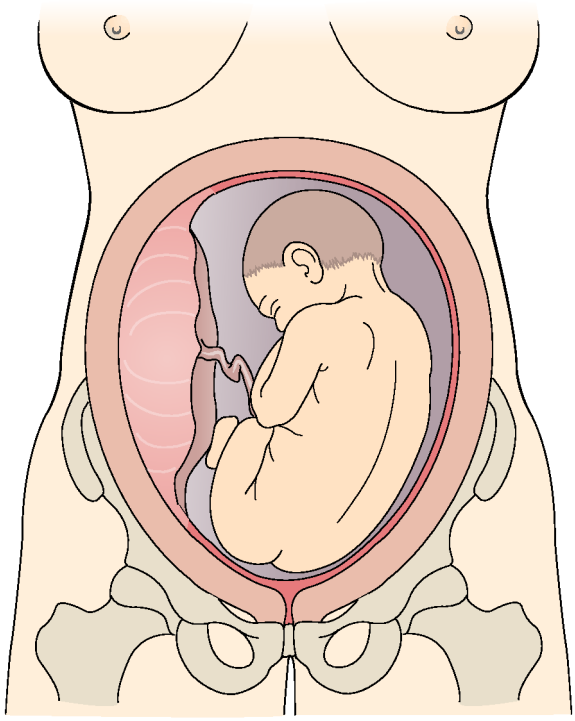

Fig.: Pelvic presentation

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can be made, and the tissue is stretched more severely. The doctor then carefully removes the child from the uterus. Subsequently, the doctor also removes the placenta and closes the uterine cavity, the abdominal wall and the skin.

In rare cases (if the child's head is already positioned very low), the child's head must be pushed upwards through the vagina during the procedure.

Before the abdominal cavity is closed (sutured or stapled), drains are placed, if required, to drain wound secretions and blood.

Furthermore, a dilation of the cervical os can be required, e.g. if no labour has occurred and the cervical os is still closed. This ensures a better discharge of the lochia.

Will a more extensive procedure be necessary?

Due to complications during the procedure (e.g. stuck placenta which cannot be removed manually, bleeding which cannot be stopped), additional measures (e.g. curettage, suction cup, hysterectomy) may be required for medical reasons. In this case, if there is no other choice, the doctor will have to presume that you are in agreement with these measures. If your doctor already believes that more extensive surgery is likely to be necessary in your case, s/he will inform you about the advantages and disadvantages, the associated risks and the long-term consequences of these additional measures in a separate patient-doctor discussion.

If you are Rh negative but your child is Rh positive, you will receive vaccination after the birth to avoid rhesus complications in later pregnancies (rhesus prophylaxis, anti-D prophylaxis). If this applies to your case, you will be counselled about it in a separate patient-doctor discussion.

In the course of caesarean section, sterilisation can be performed. However, you should consider this measure carefully, and under no circumstances should you make the decision shortly before giving birth. If you desire sterilisation, you will receive a separate form to inform you about its risks and consequences.

Are complications to be expected?

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.

- **Damage to adjacent organs** (e.g. blood vessels, urinary bladder, ureter, intestines, stomach) is possible and, depending on the injured organ, it may necessitate e.g. extensive haemostasis (procedure to stop bleeding), surgical placement of a long-term suprapubic catheter, a renal fistula or an artificial anus. The risk is increased after previous operations or if adhesions or difficult anatomic conditions (e.g. excessive weight) are present.
- **Severe, uncontrollable bleeding** or post-surgical bleeding can occur, requiring a **transfusion of blood** or **blood components** or, in isolated cases (e.g. if the placenta is located in front of the cervical os or has grown into the uterus), even requiring hysterectomy. Post-surgical bleeding can occur even several days after the procedure. The risk of transmission of hepatitis or HIV infection (AIDS) by a transfusion of foreign donor blood has become extremely rare nowadays. After transfusion, it can be determined by a check-up whether such an infection has occurred contrary to expectations.
- In some cases, involution (shrinkage) of the uterus after the birth of the child and passage of the placenta is not adequate. This may lead to massive **blood loss**. In the event of uterine atony, an attempt will generally be made to resolve this by external massage of the uterus and by administering medications to promote contractions (e.g. the labour hormone oxytocin, prostaglandin preparations). If this is not adequate, it may become necessary in very rare cases to insert a balloon into the uterine cavity as a tamponade or to use a special suturing technique through the walls of the uterus to achieve compression of the uterus or to remove the uterus.
- A temporary **impairment of bladder activity** is possible, which, generally, does not require treatment. It can be treated without difficulty by inserting a temporary catheter into the bladder to drain the urine in most cases. When a urinary catheter is in place, **bladder infection** requiring treatment with medications occurs at an increased rate.
- **Infection** (for example of the uterus, the urinary tract, the lungs, peritonitis) can occur which can usually be treated by administering antibiotics (in the event of an uterus infection with the additional administration of contraction-inducing medications). Under unfavourable circumstances, generalised blood poisoning (sepsis) can occur which necessitates intensive medical care.
  In the event of a **massive uterus infection**, another operation, if applicable including **removal of the uterus** and **ovaries**, may have to be performed.
  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 (e.g. opening the scar and irrigating the wound).
- **Impaired function of the fallopian tubes** due to an upward spread of infection is very rare; it is generally easily managed with antibiotics, however. In very rare cases, however, **adhesions of the fallopian tubes** also develop, thus leading to permanent **sterility**.
- **Intestinal obstruction** due to temporary **intestinal paralysis** or **adhesions** in the abdominal cavity, even after several years, is very rare. Another operation may then be necessary.
- As a consequence of any operation and related to the pregnancy, blood clots can occur in the large veins and can block a blood vessel (**thrombosis**). If a clot is transported into the lung via the bloodstream, a **life-threatening pulmonary embolism** can develop. This risk is higher in pregnancy and birth and is further increased over a regular delivery if caesarean section is performed. Generally, blood-thinning medications are administered to prevent this, which, on the other hand, increases the risk of bleeding. After an injection of heparin, in rare cases, a life-threatening disorder of coagulation can occur with increased formation of blood clots and vessel blockage (heparin induced thrombocytopenia – HIT II). If an amniotic fluid embolism occurs, this necessitates intensive care.
- **Skin/Tissue/Nerve damage** due to positioning of the patient and measures needed in conjunction with the procedure (e.g. injections, disinfection, laser, electric current) is rare. Side-effects/Complications which can be

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permanent under certain circumstances: Pain, inflammation, necrosis (death) of tissue, scars and disorders of sensation or function, paralysis.

- Sensitive or **painful scarring** in the region of the abdominal incision can occur. Frequently, the alterations in sensation persist for a long period but improve over time in most cases.
- **Allergy/Hypersensitivity/Incompatibility** (e.g. to latex, medications) can cause acute circulatory shock, necessitating intensive care. Severe damage (e.g. organ failure, brain damage, paralysis), which can be permanent under certain circumstances, is very rare.
- Due to dissemination of cells of the uterine mucosa, endometriosis in the abdominal cavity or within the scar (**scar endometriosis**) can occur in rare cases. This can cause pain or in the event of endometriosis in the abdominal cavity also reduced fertility.

During the patient-doctor discussion, your doctor will counsel you in more detail about any specific risks and associated complications that may apply in your case. During the patient-doctor discussion, you should ask all questions that are important to you or about anything that is still unclear.

Are there any risks for the child?

- Due to the effect of the anaesthetic agent during general anaesthesia, e.g. sleepiness and a delayed onset of spontaneous breathing may occur in the newborn. Therefore, or due to the reasons which have already given rise to the caesarean section, occasionally, more extensive medical treatment (administration of oxygen, suction, ventilation etc.) is required.
- In children which are born via caesarean section, temporary adaptation disorders (e.g. breathing difficulty necessitating the administration of oxygen or artificial ventilation) are more common than in spontaneous births. The rate of complications is higher the earlier in the pregnancy caesarean section is performed.
- If the child is trapped in the uterus in an unfavourable position, injuries in the region of the arms, shoulders, legs or hips such as fractures or luxations of joints can occur in very rare cases when removing the child from the uterus. This necessitates further medical treatment.
- There are indications that children delivered by caesarean section suffer from asthma, diabetes, allergies, inflammatory intestinal diseases, coeliac disease (hypersensitivity to wheat components in food) and narrowing of tear ducts more frequently than children born by vaginal delivery.
- **Minor cuts in the child** when opening the uterus are rare; in most cases, they heal spontaneously. In an extremely rare case, a small suture is required to treat this injury.
- In rare cases, it can be necessary that a suction cup or forceps are used during the caesarean section. Any possible pressure marks and/or abrasion, haematoma and swellings of the skin on the baby's head caused by this will generally quickly disappear by themselves after a couple of days and do not require specific treatment in most cases.

Impact on subsequent pregnancies

- Generally, after a caesarean section, a natural birth is possible with subsequent pregnancies. Naturally, after a caesarean section, there may be factors which make another caesarean section necessary. After two or more caesarean sections, spontaneous birth is not recommended.
- In rare cases, it might be the case that with later pregnancies and/or spontaneous birth, the old scar on the uterus breaks open again and then requires an emergency caesarean section and surgical treatment. In order to recognise this at an early stage, you will be monitored intensively.
- In subsequent pregnancies after a caesarean section, disorders of placenta attachment occur more frequently. These include e.g. incorrect placement of the placenta (e.g. in front of the cervical os – placenta praevia). Subsequently, the **risk of premature birth and life-threatening bleeding** for mother and child is significantly increased. In this case, another caesarean section is necessary again which may be complicated by a stronger tendency to bleed and can necessitate removal of the uterus if indicated. No further pregnancies are possible after this. Adhesion of the placenta to the uterus (placenta accreta/increta) also occurs more frequently than after spontaneous delivery. Disorders of placenta detachment in which the placenta needs to be detached and abraded manually and the uterus must be removed if indicated also occur more frequently than after spontaneous births.
- In very rare cases, an ectopic pregnancy occurs in the uterine caesarean section scar. Such a pregnancy is not viable and poses a very high risk for the mother (uterus rupture with severe bleeding in early pregnancy) so that it has to be terminated by an operation or medication.
- If the uterus must be removed due to complications, no further pregnancies are possible.

Instructions

Please do not use sanitary tampons, only sanitary pads.

If you experience any symptoms, e.g. fever, abdominal pain or bleeding exceeding the usual menstruation, 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 ☐ 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! _____

2. Is the patient taking **herbal medicine/supplements** (e.g. St John's wort, ginkgo, vitamins)? ☐ n ☐ y

   If yes, please indicate! _____

3. 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! _____

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

5. Does the patient have a congenital or acquired **impairment of blood coagulation** (e.g. thrombophilia, haemophilia)? ☐ 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 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 have a **metabolic disease** (e.g. diabetes, gout)? ☐ n ☐ y

   If yes, please indicate! _____

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

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

    If yes, please indicate! _____

    _____

11. Does the patient have **implants** in place (e.g. cardiac pacemaker/defibrillator, joint endoprosthesis, artificial heart valve, stent, metal, synthetic materials, silicone)? ☐ n ☐ y

    If yes, please indicate! _____

12. Does the patient have a **coil** (intrauterine device) or a **piercing** (e.g. genital piercing) in place? ☐ n ☐ y

    If yes, please indicate! _____

    _____

13. Has the patient ever needed an **operation of the uterus** (e.g. previous caesarean section)? ☐ n ☐ y

    If yes, please provide details! _____

    _____

    _____

14. Has the patient **given birth** (once or several times) before? ☐ n ☐ y

    If yes, how many times? _____

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

    If yes, please provide details! _____

    _____

    _____

Doctor's notes on the patient-doctor discussion

(e.g. reasons for the caesarean section; advantages and disadvantages compared to spontaneous vaginal delivery; possibility that a more extensive procedure or a change in the procedure will be necessary; risks and possible associated complications for mother and child; special circumstances that increase the risks; additional/subsequent procedures/treatment that may be necessary; possible consequences of the caesarean section; determination of a minor's ability to comprehend; patient has a surrogate decision-maker/a legal guardian; patient has appointed a legal proxy/provided a medical power of attorney; duration of the discussion)

In case of refusal to consent

I do not consent to the proposed delivery by caesarean section. I have read the informed consent form and I understand it. I have been emphatically informed about any possible disadvantages, in particular the acute risks for the child (even death or life-long severe damage) apart from the mother's own risk, which are involved in such refusal.

_____
Place, date, time

_____
Mother-to-be

_____
Witness (if applicable)

_____
Doctor

Patient's Statement of Consent

The above-named procedure, the nature and significance of the procedure, the risks and possible associated complications, additional/subsequent procedures and possible additions to/changes of the procedure (for example curettage) 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, after **adequate time for consideration,** I hereby **consent** to the proposed operation. I also consent to any unforeseen additional or subsequent treatment which may become necessary for medical reasons during the operation.

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

_____ _____

Place, date, time Mother-to-be

_____

Doctor

Statement of consent of the accompanying person

After consultation with the doctor, a person which is close to the patient giving birth (for example the father of the child) may be admitted to attend to the operation if this does not pose any additional risk for the patient giving birth. In this case, the **accompanying person** must provide the following declaration of consent:

I am aware that my presence during the caesarean section is only tolerated, and I am prepared to leave the operating room immediately upon request.
I am aware that I am attending the caesarean section at my own risk and peril. If I suffer any physical/psychological damage due to unconsciousness or other events due to my presence in the operating room, I hereby waive any claim to damages towards the doctors, the hospital owners and any other persons (midwives, nurses and care workers, etc.).

_____

Place, date, time

_____

Signature of the accompanying person

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