



Patient Information

Detailed ultrasound examination

(Detailed diagnostic, malformation ultrasound)

Dear expectant mother,

You have attended our practice today to undergo a detailed ultrasound examination during pregnancy. Prior to the examination, it is important for us to give you some background information on the purpose, possibilities or limitations, and potential problems associated with this examination, which the following pages should provide. This information serves as the basis for the pre-procedural medical discussion prior to examination.

Background:

High-resolution ultrasound technology is an imaging procedure that has been used for over five decades, and which has been significantly further developed in the last 20 years. According to current scientific knowledge, when used correctly by experienced physicians this procedure has no negative effects on the mother or the unborn child. This also applies to repeated applications.

When performing this procedure, contact gel is applied to the mother's skin and an ultrasonic probe is then used to transmit ultrasound waves through the maternal abdominal wall into the uterus; the echoed signal received makes it possible to view maternal and foetal tissue.

Indications for the performance of a detailed examination arise from the prehistory (particular diseases or malformations in the family or previous pregnancies, intake of medications, status post sterility therapy, age etc.) or abnormal findings in the course of the pregnancy (abnormalities or ambiguities in the basic ultrasound, infections, imminent premature birth). The desire for further information about the development of the foetus may also be a reason for performing this examination.

Aim of the ultrasound examination

The aim of this examination is to obtain information about the pregnancy and the status of the unborn child. The visible organs (brain, heart, kidneys, spinal column, limbs, ...) are examined to determine correct formation and timely development. In this way, threats to the unborn child can often be detected at an early stage, and helpful surgeries may be possible, e.g. by treating the foetus within the uterus via the mother, preparing for a treatment after birth, or preparing for decisions on the type, place and time of birth.

Limitations of the validity of the ultrasound examination

The validity of the examination depends on various factors. The best time for the examination is between the 20th and 22nd week of pregnancy. Examinations performed earlier or later may provide incomplete information in certain circumstances. The examination conditions are also important: if the abdominal wall is somewhat thicker or the child is in an awkward position, the assessability of the examination may also be limited. Its meaningfulness also depends on the developmental status of the organs (e.g. brain). In the hands of an experienced and specialised examiner, around 90% of all malformations identifiable by ultrasound can be detected.

However even with top quality equipment, the maximum care and the most experienced examiner, depending on the time of the examination and the prevailing examination conditions (see above), *not all* malformations and mutations can be identified.

Chromosomal disorders (e.g. Trisomy 21 = Down's syndrome), metabolic disorders or syndromes *cannot* be identified if they do not cause any physical mutations or malformations visible in the ultrasound. Only an invasive examination such as an amniotic fluid test can safely exclude chromosomal disorders.

A detailed ultrasound examination cannot therefore give you any guarantee of a completely healthy child.

Please consider the following points:

Most examinations reveal no abnormalities, which can help to relieve anxieties and contribute to an uneventful pregnancy.

However, if abnormalities are detected in the examination, this often leads to upset and conflict, which in some cases can be significant. In this case we will inform you promptly and support you, in consultation with other physicians also (e.g. human geneticists, paediatricians or paediatric surgeons). We also advise you to seek psychosocial counselling in these situations particularly and can arrange contact at your request.

Genetic counselling:

In addition to this patient information, the Gene Diagnostics Act (GenDG) stipulates that expectant mothers must be offered genetic counselling before a detailed ultrasound diagnostic and after the examination results are obtained.

Genetic counselling before a genetic test pursuant to GenDG includes:

Answering your personal questions,

- Evaluation of existing medical findings or reports on findings,
- Examination-based compilation of abnormalities in your personal and family health prehistory (anamnesis),
- Provision of information on the need for a genetic test arising from your questions or prehistory, and information on the possibilities, limitations and material extraction-associated risks of the examination procedure outlined here,
- Estimation of the genetic risks including discussion of the significance of all information for your life and family planning, and possibly for your health,
- Support options available for dealing with the physical and psychological stresses caused by the examination and its results,
- Assessment of the need for detailed genetic counselling by a specialist in human genetics.

We usually provide this counselling directly in conjunction with the pre-procedural discussion and the communication of results, but if you feel that you have already received sufficient information and counselling, you can waive further genetic counselling in writing.

Please tick here to indicate whether you wish further counselling, want to waive this, or have already received genetic counselling.

Consent:

I have already received genetic counselling in preparation for the detailed ultrasound examination:

Yes: No:

I wish to receive further genetic counselling before the examination:

Yes: No:

I wish to receive genetic counselling when the examination findings are available

Yes: Only if findings are abnormal: No:

Communication of examination results:

The physician who performed the ultrasound examination will inform you of the examination results.

Other people (partner, attending gynaecologist) can only be informed with your express written consent.

You have the right not to acknowledge the results of the examination or parts thereof and to have these destroyed.

I consent to disclosure of the results of the ultrasound examination to my

Gynaecologist _____ at:

Other physicians: _____

Other people: _____

Personal questions: _____

Physician's notes: _____

I received detailed information about the planned examination in the pre-procedural discussion with Dr. _____

All questions I feel were important regarding the type of examination and its significance were discussed and answered for me comprehensibly. I feel well informed, have no further questions and consent to the examination. I do not need any further time for consideration.

You can revoke all of your consents at any time with effect for the future.

Place/date Signature of expectant mother

Place/date Signature of physician