

Hospital Data Imprint/Stamp

Skin Biopsy

(Removal of Skin Samples)

Patient Identification Sticker

Affected area: _____

Dear Patient, Dear Parents,

Removal of a skin sample and its examination in a laboratory is proposed for you. The purpose of this informed consent form is to help you prepare for the patient-doctor discussion and to document the most important points. Please read it carefully and complete the questionnaire carefully and completely.

Why is the procedure necessary?

Many skin diseases can be identified based on their appearance. However, for some it is necessary to first examine a skin sample in a laboratory. Once the type of disease is known, the doctor is able to suggest a targeted therapy.

If malignant skin changes are suspected, they are generally removed completely with a margin of healthy surrounding tissue.

If the removal is performed for aesthetic reasons only, the health insurance providers generally **do not assume** the costs of the procedure, any complications requiring treatment and the tissue examination. It is, therefore, recommended that you discuss the question of costs with the doctor/insurance provider in advance in this case.

How is the sample removed?

Usually, the procedure is performed on an outpatient basis and under local anaesthesia.

There are several methods available for removing the sample. For superficial skin changes, superficial removal of tissue is sufficient; however, it should catch all of the skin change down to its deep margin. Ideally, this is ensured by performing a flat or horizontal biopsy with a scalpel or a shave biopsy with a razor blade. Curettage with a sharp

spoon removes the cells from their structure and frequently no longer allows to identify the disease without fail. Stalked skin changes elevated above the skin level can be removed with scissors or an electric loop, if indicated. The piece of skin can also be cut out with a device similar to a hole punch (**punch biopsy**). Larger tissue samples are usually removed by a spindle-shaped incision with the scalpel.

Your doctor will explain the advantages and disadvantages of the described techniques and which one s/he has chosen for you during the patient-doctor discussion.

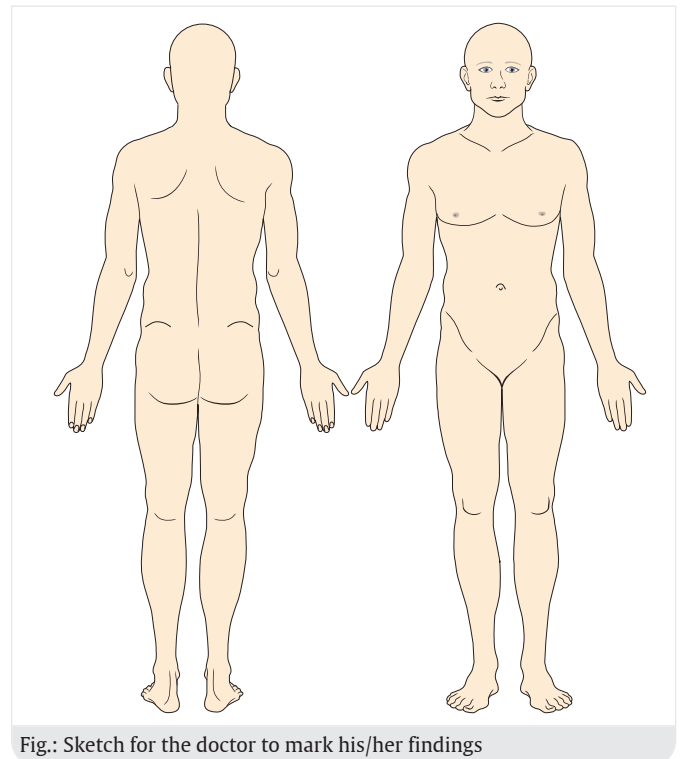


Fig.: Sketch for the doctor to mark his/her findings

After the sample is removed, the resulting skin defect is treated; larger defects are generally sutured. Usually, the resulting scar is very thin and frequently is no longer noticeable after only a short time.

In rare cases, X-rays, ultrasound, magnetic resonance imaging or similar procedures can assist in establishing a diagnosis; however, skin biopsy with subsequent histological examination is still the most reliable method for diagnosing skin diseases.

Are complications to be expected?

Despite the greatest care taken, complications can arise which necessitate additional treatment/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.

Generally, removing small skin samples does not cause any problems.

- In an occasional case, slight **bleeding and haematomas** can occur; in most cases, they do not require treatment.
- **Skin/Soft tissue and nerve damage** at the removal site or due to injections are possible (injection track abscess, necrosis [death] of tissue, irritation of nerves and veins) and can also lead to **persistent** or even **permanent symptoms** (e.g. scars, painful alteration in sensation, sensation of numbness, paralysis) under certain circumstances.
- In very rare cases, subjacent nerves or larger blood vessels are injured. If this causes extensive **disorders of sensation, paralysis of muscles** or **rebleeding** (e.g. around the eyes), it can necessitate a second operation (surgical haemostasis, removing a haematoma).
- **Scars with excessive scar tissue** (keloids) can occur due to a genetic predisposition or **impaired wound healing** in rare cases. Consequences can be skin discolouration, pain and restricted mobility. A corrective procedure may be possible at a later time.
- **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.
- **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.
- **Changes of the skin colour** (pigment shifts) at the removal site are possible; in very rare cases, they do not resolve completely.
- In very sensitive patients, **cardiocirculatory reactions** can occur.

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

What are the chances of success?

In most cases, removal of the skin change and the subsequent histological examination enable identification of the type of skin change and its full removal, and a satisfactory aesthetic result can also be achieved. Success cannot be

guaranteed, however. We will be able to discuss the further process with you only once all results of the tissue examination are available.

Instructions

The doctor treating you will decide if and when blood-thinning medications (e.g. Aspirin®, Marcumar®, Plavix®, Pradaxa®) should be stopped or replaced by another medication.

If you have received an **anaesthetic agent, a sedative or pain medication**, we will advise you on whether you have to be picked up by an adult because your reactions can still be slowed. We will inform you when it will be safe for you to again be actively involved in road traffic or carry out dangerous activities. During this time frame, you should not drink alcohol, nor should you make important decisions.

If the patient smokes, this has a negative effect on circulation, thus significantly increasing the risk of wound healing disorders. Therefore, please **refrain from smoking** for 4 weeks after the procedure.

The appearance of the scar later not only depends on the procedure itself but also on the post-surgical care and your own behaviour. Please avoid unnecessary movements which cause traction or tension on the edges of the wound and intensive exposure of the scars to the sun for 2 to 3 months if possible.

Please inform the doctor immediately if you suffer from increasing pain, bleeding, a fever greater than 38 °C or other symptoms, even if these symptoms do not present for several days after the procedure!

Important questions

The risks involved in medical procedures are affected by the patient's physical condition and any previous/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

Gender: _____

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. 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)?
If yes, please indicate! _____
3. 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?

4. Does the patient have or has the patient ever n y had an **infectious disease** (e.g. hepatitis, tuberculosis, HIV/AIDS)?

If yes, please indicate! _____

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

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

If yes, please indicate! _____

7. Does the patient have or has the patient ever n y 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)?

If yes, please indicate! _____

8. Does the patient have or has the patient ever n y had a **vascular disease** (e.g. circulation disorder, arteriosclerosis, aneurysm, varicose veins)?

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. Has the patient ever had **skin biopsy** in the n y past?

If yes, please provide details: _____

12. Does the patient use tobacco products regularly? n y

If yes, which type and how much? _____

13. Does the patient drink alcohol regularly? n y

If yes, which type and how much? _____

Additional question for women

1. Could the patient possibly be **pregnant**? n y

Doctor's notes on the patient-doctor discussion

(e.g. individual risks and complications associated with them; possible additional and subsequent procedures/treatment; special concerns of the patient; instructions; restricted ability to be involved in road traffic; follow-up care/appointment; determination of a minor's ability to comprehend; 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)

In case of refusal to consent

I/We do not consent to the proposed removal of a skin sample. I/We have read and have understood the informed consent form. I/We have been explicitly counselled that diagnosis and treatment of a possible disease could be significantly delayed and hindered by this.

Place, date, time

Patient/parents*

Witness (if applicable)

Doctor

Patient's/Parents' Statement of Consent

The above-named treatment, the nature and significance of the treatment, the risks and possible associated complications, chances of success, alternative treatments and any additional/subsequent procedures/treatment that may be needed have been fully explained to me/us in a patient-doctor discussion with doctor _____.

I was/We were afforded the opportunity to ask any questions that I/we considered important.

I/We have **no further questions** and feel that the counselling was satisfactory; therefore, I/we hereby **consent** to the proposed treatment. I/We further give my/our consent to any unforeseen more extensive procedures that may become necessary for medical reasons.

I/We have received **instructions and recommendations for follow-up care** after outpatient procedures.

Place, date, time

Patient/parents*

Doctor

* If only one parent signs, with this signature, s/he declares that s/he has sole custody of the child or that s/he is acting in complete agreement with the other parent. As a rule, both parents should sign for major procedures.

MUSTER
Dieser Musterbogen darf nicht für die
Patientenaufklärung verwendet werden