

Date of vacuum-assisted biopsy \_\_\_\_\_

## Patient information: Magnetic-Resonance Imaging (MRI)-guided vacuum-assisted breast biopsy

Side:                      right   
                                 left

Dear patient,

The aim of this information sheet is to provide you with information about your planned breast biopsy. It is not intended to replace the conversation with a doctor that will take place prior to the biopsy. During this conversation, you will be able ask any questions you may have and the doctor will inform you about the procedure, complications and alternatives regarding vacuum-assisted biopsy (VAB).

Your breast examination yielded a finding that needs further investigation by collecting a sample of tissue (biopsy). Despite the increasing certainty of modern-day examination methods, a biopsy is the only way to distinguish between a malignancy and a similar-looking change that is benign. Since breast cancer is curable nowadays in most cases, particularly if diagnosed early, we recommend having the biopsy. Suspicious areas of the breast used to have to be removed during open surgery under general anaesthesia in the past, but it is now possible to obtain a larger tissue sample for histological examination using vacuum-assisted biopsy under local anaesthesia.

### Procedure

You do not have to fast before the biopsy. We recommend eating a light meal beforehand. Most patients find it helpful to be accompanied to the appointment by a trusted companion. The biopsy is guided by a breast MRI to ensure the abnormal area is located. The breast is therefore held in a special device during the MRI. This requires you to lie still on your stomach for 30-60 minutes. Make sure you are in a comfortable position from the start. Otherwise, tell a member of staff. Please tell your doctor if you are not able to lie still for a prolonged period. After positioning the breast, the abnormal finding is visualised with a breast MRI. Local anaesthetic is then applied to the skin (e.g., Lidocaine) and a biopsy needle is introduced through an incision in the skin measuring approx. 3 mm. The biopsy is performed after the correct position of the needle is checked with the images. This is not usually painful. If you feel any pain, please tell the staff immediately. It is normal to feel some movement during the procedure. You may be moved in and out of the MRI machine multiple times.

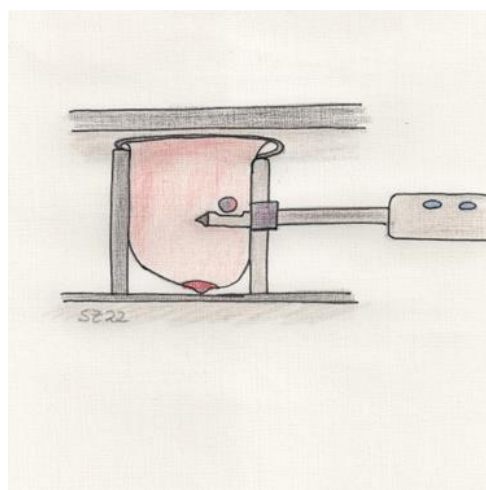


Figure on left: Example position during an MRI-guided VAB.

Figure on right: Biopsy with a VAB needle.

A marker clip is often inserted after the biopsy. This is usually made from metal, sometimes with a gel coating, and it is inserted at the site of the biopsy. This marker clip means the biopsy site can be located again at a later date, e.g. in the case of surgery. If surgery isn't required after the biopsy, the tissue simply grows around the clip.

The small incision is covered with a plaster, which you should leave in place for 7 days. A normal plaster is also applied just in case – to prevent any blood from getting onto clothing. Then a pressure dressing is applied to help prevent any large bruising. You should leave this pressure dressing in place for at least 24 hours.

### Risks and complications

This is a minimally-invasive procedure in which complications may occur such as allergic reaction to the medications used (e.g. local anaesthetic), bleeding, nerve damage with possible persistent numbness or pain, infection or excessive scarring. Bruising commonly occurs after the biopsy, which may cause a harmless discolouration of the skin over a large area. In very rare cases, vascular damage may cause severe bleeding, which may require open surgery subsequently.

Serious complications such as damage to internal organs or persistent damage are extremely rare. Despite the utmost care, we cannot guarantee that the abnormal change will be located during the biopsy. To keep this risk as low as possible, all histology results after the biopsy are compared again against the images before, during and after the biopsy.

### After the procedure

If you are given a sedative, you must not drive a car or operate dangerous machinery until the next day for safety reasons. Keep the biopsy site clean and dry over the next few days. You should not take a bath, swim or have a sauna for 3 days. You may shower after the pressure dressing has been removed. You should avoid heavy physical activity such as sport or carrying heavy objects for 3 days. If you experience any bleeding, heavy pain, fever or oozing from the wound, please go to the institution where the biopsy was performed, your doctor or the emergency department immediately.

Your treating physician will discuss the result with you after the tissue has been examined by the pathology department. If the changes are benign, you will at most require a follow-up examination. If the changes are malignant or precursors to malignant changes are found, your treating physician will discuss the next steps with you.

### In order to better assess the risk of the procedure for you, please answer the following questions:

- Are you taking blood thinners (e.g. Marcumar®, Xarelto®, Plavix®, Clopidogrel, Sintrom®, Aspirin®, ASA, Eliquis®, Lixiana®, etc.)?  Yes  No  
If yes: please specify \_\_\_\_\_
- Do you have any allergies or have you ever had a hypersensitivity reaction to medication, latex or plasters for example?  Yes  No  
If yes: please specify \_\_\_\_\_
- Do you have an infectious disease (e.g. hepatitis, HIV)?  Yes  No
- For women of child-bearing age: could you be pregnant?  Yes  No
- Do you agree to a marker clip being inserted after the biopsy?  Yes  No

### Please use the space below to write down any notes or questions for the doctor:

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## Informed consent form for a vacuum-assisted breast biopsy

Dr. \_\_\_\_\_ has conducted a detailed informed consent discussion with me.

- I have understood the information, have been sufficiently informed and have no further questions. A copy of this information has been given to me.  
**I consent to undergoing the vacuum-assisted breast biopsy.**
- I need further information and/or thinking time.**
- I decline to undergo the procedure on my own responsibility against medical advice.**

....., on .....  
Place Date

.....  
Signature of the patient

.....  
Signature of the doctor

.....  
Signature of the witness (if applicable)

In the course of your treatment, personal data will be collected from you for quality assurance and research. This data can be made available in anonymised form to experts and authorities (e.g., the Federal Office of Public Health) for evaluation within the framework of quality assurance and research. Competent experts may also inspect your original data as part of a so-called monitoring or audit (e.g., as part of a certification). During the aforementioned checks, confidentiality is strictly maintained, and data protection regulations are fully complied with. Your name will not be published in any way in reports or publications resulting from these evaluations. You have the right to refuse your consent to the collection of data at any time without giving reasons. This will have no influence on your medical treatment and will not result in any disadvantages for you.