

Patient agreement to investigation or treatment

Breast surgery: mastectomy and sentinel lymph node (SLN) biopsy +/- axillary clearance

Authors: Cambridge Breast Unit

Brief description:

- You have been recommended to have a mastectomy and removal of lymph glands in the armpit (axilla) as the surgical treatment for your breast cancer. The operation generally lasts one to one to two hours and requires a stay in hospital of up to five days. This will be performed under general anaesthetic.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke's website: <http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (For example, requires an interpreter or other additional communication method)

.....
.....

Breast Surgery: Mastectomy and sentinel lymph node (SNL) biopsy +/- axillary clearance

Breast Side:

Before your procedure

- You will be seen at the pre-admission clinic by a member of the Surgical Breast Team.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring with you details of anything you are taking (for example bring the packaging with you).
- You will normally be admitted to hospital on the day of surgery.
- This procedure involves the use of general anaesthesia, which means you will not be conscious during the surgery.
- The anaesthetist will see you before the procedure to assess your state of health and discuss the details with you.

During the procedure

- At the start of your procedure, you will be given the necessary anaesthetic and/or sedation - see below for details of this.
- **Mastectomy:** This involves making incisions around the breast, removing most of the breast tissue, including the nipple and areola (dark skin around the nipple), and some of the breast skin, which leaves a scar that is flat against the chest wall. The mastectomy will usually be performed in conjunction with the removal of the lymph glands from under your arm.
- **Sentinel lymph node biopsy:** This involves making a small incision in the armpit (axilla) and removing about one to four lymph nodes. The information obtained from this procedure will help us plan the next stage of your treatment.
- Lymph nodes ('glands') are concentrations of immune cells within the lymphatic system. Lymph draining from the tissues passes through them. Cancer cells can also escape from a tumour and lodge in lymph nodes. We call the first lymph nodes draining the breast, sentinel lymph nodes (SLNs). If there are no cancer cells present in these sentinel lymph nodes, we can be reasonably certain that the remaining lymph nodes in the axilla are also free of tumour cells.
- A few hours (usually between 2 to 24 hours) before your surgery, a small amount of radioactive tracer will be injected. Immediately before your operation and under general anaesthesia, blue dye will be injected around the areola (the pigmented area around the nipple). Both the radioactive tracer and the blue dye will help us to identify the SLNs during the operation, which are then removed, and sent to the pathology department for analysis.
- Very rarely during the operation, we may not be able to identify your sentinel lymph nodes, or alternatively it may be apparent that the SLNs are affected by

cancer. This happens overall in 4-5% of cases. If this is the case, we will remove the remaining lymph glands in your armpit. This is called axillary clearance.

- In all other cases, we will do no further surgery to the armpit. After your operation, we will need to wait for the result of the detailed pathological analysis. This will show us whether the SLNs have cancer cells in them. If we find cancer cells in the SLNs, you will be offered a second operation to remove further lymph nodes in the armpit. This second operation will usually take place approximately two weeks after your pathology results are available.

After the procedure

- If you have had a general anaesthetic you will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- You will have an intravenous line (called a drip) in your arm. This may be attached to a bag of fluid (called a drip), which provides fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to the ward.
- Sometimes, people feel sick after an operation and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you feel more comfortable.
- When you wake up, you may have a drain (plastic tube) coming from your wound. The drain collects tissue fluid in a small collecting chamber, which is measured daily. When there is less than a certain amount (usually 50mls) of fluid collected in the drain over 24 hours, the drainage tube will be removed, which is a simple procedure. It might be possible for you to be discharged with your drain in place after 1-2 nights. Your district nurse will take over your care and remove the drain. If not, you can stay in hospital until the drain is removed, this will usually be up to five days after your surgery. In occasional patients it may be possible to avoid the use of drains.
- **Eating and drinking:** After the operation, you will be able to eat and drink when you are awake again. This usually takes two to four hours. How quickly you return to a normal diet will depend on how you feel. Most patients recover their appetite very quickly.
- **Getting around and about:** Generally, it is best to get out of bed as soon as you feel you can. If, on the first day, you cannot get out of bed, you will be encouraged to move your legs in bed to prevent blood clots forming.
- We will arrange for the physiotherapist to visit you on the ward to give advice and exercises.
- **When you can leave hospital:** The time that you stay in hospital will depend on how you are feeling after your operation, the type of operation, and your doctor's opinion.
- **When you can resume normal activities including work:** You can usually begin gentle work within a week or two, but you might need to wait a little longer for more vigorous activity.
- It is not uncommon to feel a bit 'down' after any operation, so do ask your doctor or breast care nurse if you feel you need more psychological support.
- **Special measures you need to take after the procedure:** You will be given more detailed information about any special measures you need to take after the

procedure. You will also be given information about things to watch out for that might be early signs of problems (for example, infection).

- Experienced staff are available to help you. Please tell your nurses or doctors about any concerns that you have, they will try to help you resolve them.
- The skin stitches are dissolvable and will not need to be removed. You will have a light dressing covering your wound to keep it clean, and this will usually be in place for the first day or so. The wound may be secured with steri-strips which are like small pieces of tape. They help healing and support the wound. These will gradually come off in the bath or the shower.
- **Check-ups and results:** You will be given a date to return to clinic for the results of your surgery. By then the tissue removed at the operation will have examined and your results discussed by the Breast Care Team. Any further treatment, if recommended, will be discussed with you then.
- Before you leave the ward, you will be given two temporary prostheses 'comfies'. You will be contacted about arrangements for being fitted with a longer-term prosthesis. The fitting will be about six to eight weeks after your operation and the service is provided free of charge.

Intended benefits of the procedure

- To remove the cancer in the breast
- To assess the sentinel lymph glands under the armpit to help us to plan the next stage of your treatment. To help prevent recurrence and improve your outcome.

Who will perform my procedure?

- This procedure will be performed by a breast surgeon who is a member of the Breast Team.

Alternative procedures that are available

- In some cases it is possible to treat cancer by removing part of the breast only. The axilla can be assessed and treated by axillary clearance. However, the present recommendation by the Breast Team is that in your case, mastectomy and axillary clearance is the best form of treatment at this stage.
- Other forms of treatment may be utilised in the treatment of cancer such as radiation therapy (using high-dose x-rays to kill cancer cells), chemotherapy (using drugs to kill cancer cells), and hormone therapy (using hormones to stop the cells from growing)..These will be discussed with you if and when appropriate.

Serious or frequently occurring risks

- **Mastectomy:**
 - **Altered sensation:** You might have tingly feelings or shooting pain where the breast was removed, this can last for six months or longer. Additionally, some women notice a change in their balance due to the loss of the breast weight. Wearing a prosthesis helps with this problem.
 - **Seroma** is a collection of fluid under your chest scar after surgery. It is relatively common after mastectomy and axillary clearance, but is easily

treated by drainage through a small needle. Draining is a very simple procedure that can be done by a member of the Breast Team.

- **Sentinel node biopsy:** There is a small possibility when we remove only one or two nodes that an occasional node containing cancer cells might be left behind. This occurs in less than 5% of all patients who have diseased lymph glands in the armpit.
- We do not expect any risks or side effects from the low-dose radioactive tracer because the total amount of radiation that you receive is less than you would receive from the environment over three months.
- The blue dye itself is not known to be harmful. You might, however, notice some blue discolouration of your urine for a few days following the operation. The remaining skin of the breast can also stay blue for several months after the operation (sometimes up to 12 months), fading gradually over time. Mild allergic reactions to the blue dye can occur in 1.8 % of patients. More severe allergic reactions are rare and can occur in 0.2 % of patients (ie in two patients for every 1000 patients treated).
- It is hoped that the complications and side-effects of the sentinel node biopsy will be minimal, but it is possible that you may experience some of those associated with axillary clearance.
- **Axillary clearance:**
 - **Numbness:** You may experience numbness and discomfort in the armpit and upper arm. The numbness usually lessens slowly, after treatment, but might not resolve completely
 - **Shoulder stiffness:** The shoulder may become stiff and painful after your operation. Performing shoulder exercises (taught to you after the operation) improves mobility.
 - **Lymphoedema** is a swelling in the tissue below the skin caused by lymph fluid which cannot drain away. This can occur when the lymph glands are removed (by surgery) or blocked (by radiotherapy) secondary to scar tissue formation. The hand and or arm may swell at any time after the surgery. It can affect about 15 to 20% of women but only around 5% to a significant degree. There are certain precautions you need to take to prevent lymphoedema, these will be discussed with you by the Breast Care Nurse.
- **Surgery:** All operations have a small risk of side effects, such as pain, bleeding and infection. The risks associated with general anaesthesia include potential breathing and heart problems, as well as possible reactions to medications. For a woman who is otherwise in good health, the risk of a serious complication due to general anaesthesia is less than 1%.

Post surgical treatment

When deciding if you need post-surgical treatment (called adjuvant therapy), your team will assess several factors, including the risk of the cancer recurring, the characteristics of the cancer, and how much the treatment will benefit you. This will be discussed with you by a member of the Breast Team.

Information and support

Additional information will be given to you in the form of a Patient Information Breast Care Pack. Do feel free to speak to a member of staff if you have any questions or anxieties.

Breast Care Nurses

Telephone: 01223 586756
01223 586573
01223 596291
01223 216313
01223 348272

Prosthetics Nurse

Telephone: 01223 216572

Further information**Cancer BACKUP**

Telephone: Freeline 0808 800 1234

www.cancerbackup.org.uk

Breast Cancer Care

Nationwide Free Call: 0808 800 6000

www.breastcancercare.org.uk

General anaesthesia**Before your operation**

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. If you are a day case patient it may not be until just before your operation. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets or injections. They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that your fears and worries can be allayed.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe.

During your operation

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of

anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.
- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



Addenbrooke's is smoke-free. You cannot smoke on site. For advice on quitting, contact your GP or the NHS smoking helpline free, 0800 169 0 169

Please ask if you require this information in other languages, large print or audio format: 01223 216032 or patient.information@addenbrookes.nhs.uk

Informacje te można otrzymać w innych językach, w wersji dużym drukiem lub audio. Zamówienia prosimy składać pod numerem: 01223 216032 lub wysyłając e-mail: patient.information@addenbrookes.nhs.uk

Polish

Se precisar desta informação num outro idioma, em impressão de letras grandes ou formato áudio por favor telefone para o 01223 216032 ou envie uma mensagem para: patient.information@addenbrookes.nhs.uk

Portuguese

Если вам требуется эта информация на другом языке, крупным шрифтом или в аудиоформате, пожалуйста, обращайтесь по телефону 01223 216032 или на вебсайт patient.information@addenbrookes.nhs.uk

Russian

若你需要此信息的其他語言版本、大字體版或音頻格式，請致電 01223 216032 或發郵件到: patient.information@addenbrookes.nhs.uk

Cantonese

Bu bilgiyi diger dillerde veya büyük baskılı ya da sesli formatta isterseniz lütfen su numaradan kontak kurun: 01223 216032 veya asagidaki adrese e-posta gönderin: patient.information@addenbrookes.nhs.uk

Turkish

এই তথ্য বাংলায়, বড় অক্ষরে বা অডিও টেপে পেতে চাইলে দয়া করে 01223 216032 নম্বরে ফোন করুন বা patient.information@addenbrookes.nhs.uk ঠিকানায় ই-মেইল করুন।

Bengali

Document History

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Consent Form (Adults)

Patient agreement to
investigation or treatment

For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)

title

Special requirements
(For example, other language/other communication method)

Name of proposed procedure or course of treatment

**Mastectomy and sentinel lymph node (SNL) biopsy +/-
axillary clearance**

Side (left/right).....

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure.....
 - To remove the cancer in the breast
 - To assess the sentinel lymph glands under the armpit to help us to plan the next stage of your treatment. To help prevent recurrence and improve your outcome.

- Any serious or frequently occurring risks from the procedures including those specific to the patient
Altered sensation, seroma, numbness, shoulder stiffness, lymphoedema, pain, bleeding, infection; There is a small possibility when we remove only one or two nodes that an occasional node containing cancer cells might be left behind. Blue discolouration of your urine. The remaining skin of the breast can also stay blue for several months. Mild allergic reactions to the blue dye can occur in 1.8 % of patients. More severe allergic reactions are rare and can occur in 0.2 % of patients.

- Any extra procedures that might become necessary during the procedure
- Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: CF341 version 4, October 2008

This procedure will involve:

- General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

- I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

.....
I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** If you wish to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature:..... Date:

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature:..... Date:

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature..... Date:

Name (PRINT): Job Title:

Copy accepted by patient: yes / no (please circle)