



Queensland
Government

Breast Surgery – Wide Local Excision +/- Sentinel Lymph Node Biopsy Consent

Adult (18 years and over)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: ☐ M ☐ F ☐ I

A. Does the patient have capacity?

☐ Yes → **GO TO section B**

☐ No → **COMPLETE section A**

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

B. Is an interpreter required?

If yes, the interpreter has:

☐ provided a sight translation of the informed consent form in person

☐ translated the informed consent form over the telephone

Name of interpreter:

Interpreter code:

Language:

C. Patient/substitute decision-maker requests the following procedure(s)

☐ Wide local excision

☐ Sentinel lymph node biopsy

Site/side of procedure:

D. Risks specific to the patient in having breast surgery – wide local excision +/- sentinel lymph node biopsy

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in *not* having breast surgery – wide local excision +/- sentinel lymph node biopsy

(Doctor/clinician to document specific risks in not having breast surgery – wide local excision +/- sentinel lymph node biopsy):

F. Alternative treatment options

(Doctor/clinician to document alternative treatment not included in the patient information sheet):

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient/substitute decision-maker.

I have explained to the patient/substitute decision-maker the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

DO NOT WRITE IN THIS BINDING MARGIN

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SW9114

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H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the “Breast surgery – wide local excision +/- sentinel lymph node biopsy” patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- the specific risks and benefits of the procedure
- the prognosis, and risks of not having the procedure
- alternative treatment options
- that there is no guarantee the procedure will improve the medical condition
- that the procedure may involve a blood transfusion
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if a life-threatening event occurs during surgery, I will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure/treatment/investigation/examination; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (*this should be in consultation with the doctor/clinician*).

I/substitute decision-maker have received the following consent and patient information sheet(s):

- ☐ “Breast surgery – wide local excision +/- sentinel lymph node biopsy”
- ☐ “About your anaesthetic”
- ☐ “Fresh blood and blood products transfusion”

On the basis of the above statements,

1) I/substitute decision-maker consent to having breast surgery – wide local excision +/- sentinel lymph node biopsy.

Name of patient/substitute decision-maker:

Signature:

Date:

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient/substitute decision-maker consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s) ☐ Yes ☐ No
- assist with examination(s)/procedure(s) ☐ Yes ☐ No
- conduct examination(s)/procedure(s) ☐ Yes ☐ No

Breast surgery – wide local excision +/- sentinel lymph node biopsy

Adult (18 years and over) | Informed consent: patient information

A copy of this form should be given to the patient/substitute decision-maker to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.



1. What is breast surgery – wide local excision +/- sentinel lymph node biopsy and how will it help me/the patient?

The breast is a glandular tissue (can secrete substances). Around the breast are lymph nodes. These are part of the lymphatic system.

Lymphatic vessels run from the limbs towards the heart, usually beside veins. They carry fluid called lymph, which is a collection of dead cells, waste material and leakage from ordinary blood vessels. At various points along a lymphatic vessel lie lymph nodes. These are usually small – 5mm or less in most places. Lymph nodes are scattered at various points around the body, but the most important ones for breast disease are in the armpit.

Cancer cells travel along lymphatic vessels and collect in lymph nodes. In breast cancer, the lymph nodes of the armpit are usually the first site of spread.

Wide local excision is the complete removal of the breast lump. Whilst still under anaesthetic, the pathologist may examine the lump to confirm that it did contain cancer. Some of the lymph nodes in the armpit on the same side of the cancer will also be removed for pathology tests for any evidence of cancer spread.

Sentinel lymph node biopsy may be an alternative to routine axillary (under the arm) dissection in selected patients. This involves the removal of the lymph node(s) that the area of the breast, in which the tumour lies, would drain to first. These are localised (pin pointed) by a nuclear scan (lymphoscintigraphy) and/or blue dye (patent blue V) injection, just prior to surgery.

If the sentinel lymph node is not involved, then it is highly unlikely that any of the other lymph nodes in the armpit are involved and the risk of complications from standard axillary dissection (shoulder stiffness, armpit tenderness and lymphoedema) are reduced.

The decision whether or not to have a mastectomy is made before the operation, and will not be made during the operation.

Other types of breast surgery

It is important to understand that breast surgery for cancer is not cosmetic surgery. The appearance of the breast after surgery will be different from that before surgery. Each form of treatment has its advantages.

- **Partial or segmental mastectomy** – the removal of the tumour as well as some of the breast tissue around it and the lining over the chest muscles below. Usually some of the lymph nodes under the arm are taken out and tested for possible spread of cancer.
- **Total or simple mastectomy** – the removal of the whole breast. Sometimes lymph nodes under the arm are also taken out and tested for possible spread of cancer.
- **Modified radical mastectomy** – the removal of the breast, many of the lymph nodes under the arm, the lining over the chest muscles, and sometimes part of the chest wall muscles.

- **Radical mastectomy** – the removal of the breast, chest muscles, and all of the lymph nodes under the arm. It is used only when the tumour has spread to the chest muscles and the wound may burst open.
- **Reconstruction** – breast reconstruction involves the use of prostheses (artificial breast tissue) or tissue from other parts of the body. The type of prosthesis can be either silicone filled but are usually saline filled implants. Soft tissue may be taken from the other breast, the back or abdomen depending on body shape and size.

Additional treatments

Also known as adjuvant therapy, they are used in some women in addition to surgery. The treatment may be local (radiation) or systemic (whole body e.g. chemotherapy, hormone therapy). The aim is to treat undetectable tumours before surgery. The treatment of breast cancer depends very much on the type of tumour, the size and stage of the tumour and your age and health.

You need to carefully discuss with your doctor/clinician, treatments that are best for you.

The following treatments are all used either separately or together in the treatment of breast cancer.

Radiotherapy

Radiotherapy after breast conserving surgery can reduce the risk of cancer coming back in the same breast. Radiation is used to damage or kill cancer cells. Most women have radiotherapy to the breast find their health is not greatly affected by it. Tiredness is a most common problem.

Chemotherapy and hormone therapy

Chemotherapy is most effective if more than one drug is used and is more effective in women under the age of 50 years. The main side effects are nausea, vomiting, hair loss, marked tiredness and mood changes. They do not last for long periods and most can be controlled with good medical care. There are other side effects from chemotherapy, which you need to discuss with your doctor/clinician.

High dose chemotherapy

The theory is that high doses will kill off more cancer cells than normal doses of chemotherapy. However, it is experimental, very toxic and can be fatal.

Tamoxifen

Tamoxifen is a drug that works by blocking the effects of oestrogen on cells. It is thought that oestrogen may be causing the cancer to grow. In most cases, the cancer stops growing although it does not kill cancer cells.

Ovarian treatment

The purpose of ovarian treatment is to reduce the amount of oestrogen produced by the ovary. It is only useful in women who have not yet reached menopause. Ovarian treatment is performed using either implants under the skin, surgical removal of the ovaries or radiation to the ovaries.

Combined treatments

Overall, the evidence of benefits from using one or more treatments at the same time does not suggest that there is any large benefit to be gained, but there may be some benefit if the cancer cells are hormone sensitive.



2. What are the risks?

There are risks and complications with this procedure. There may also be risks specific to each person's individual condition and circumstances. Please discuss these with the doctor/clinician and ensure they are written on the consent form before you sign it. Risks include but are not limited to the following:

Specific risks

- the operation site under the arm continues to ooze fluid, which collects beneath the cut. This may need to be drained with a needle and syringe
- the layers of the wound may not heal adequately and the wound may burst open. This may require long-term wound care with dressings and antibiotics
- the wound may not heal normally. The scar can be thickened and red and may be painful. This is permanent and can be disfiguring

- loss of sensation to the nipple when the surgery is close to the nipple. This may be permanent
- difficulty with arm movement due to shoulder stiffness and scarring under the arm after the operation. This is usually temporary when treated with physiotherapy and/or exercises
- swelling of the arm (lymphoedema) on the side of the operation. It is usually treated with a special type of garment, which squeezes the arm to reduce the fluid build-up. Regular massage is also used
- loss of sexuality due to distress at the change in body image or depression due to the disease. Professional counselling before and after the surgery may help
- the tumour may grow again in or around the scar. This may need further treatment, such as surgery, chemotherapy or radiotherapy or a combination of all three
- feelings of anxiety and depression due to the disease and possible recurrence
- increased risk in smokers of wound and chest infections, heart and lung complications, and thrombosis.

Further risks if sentinel lymph node biopsy performed

- small risk of incorrect information (i.e. negative sentinel lymph node biopsy) with positive axillary (armpit) nodes being left behind
- there is a possibility that subsequent treatment decisions will be altered by such information
- if sentinel lymph node biopsy is positive, then it is likely that formal axillary dissection (cutting up of) will be required, with attendant risks of that procedure
- if sentinel lymph node biopsy is unable to be located at the time of surgery, the axillary dissection will be performed immediately (there is a possibility that the technique did not work because of malignant – cancerous – lymph nodes)
- sometimes the sentinel lymph node is an unusual site, such as the internal mammary nodes (between the ribs) where a further incision may be required with temporary partial separation of the ribs. There is a small risk of lung injury and bleeding in this situation

- possibility of an additional incision depending on the location of the sentinel lymph node – this will not be known until immediately prior to the operation
- small risk of permanent skin staining from the blue dye used
- allergy to the blue dye
- passage of blue/green urine for a short time after surgery (because of the blue dye used)
- small radiation risk (from the nuclear study to localise the sentinel lymph node) if pregnant.

General risks

- infection can occur, requiring antibiotics and further treatment
- bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy
- increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis
- heart attack or stroke could occur due to the strain on the heart
- blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs
- death as a result of this procedure is possible.

This procedure will require an anaesthetic.

For more information about the anaesthetic and the risks involved, please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with the doctor/clinician.

If you have not been given an anaesthetic information sheet, please ask for one.

What are the risks of not having breast surgery – wide local excision +/- sentinel lymph node biopsy?

There may be consequences if you choose not to have the proposed procedure/treatment/investigation/examination. Please discuss these with the doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure/treatment/investigation/examination. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires the patient/substitute decision-maker to understand the options available. Please discuss any alternative treatment options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.



5. Who will be performing the procedure?

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure/treatment/investigation/examination. This could be a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/

conduct an examination or procedure on a patient while the patient is under anaesthetic.

If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way. You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss with your doctor/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.



7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your/the patient's medical condition, treatment options and proposed procedure/treatment/investigation/examination.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.