



Queensland
Government

Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS) 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 to provide consent?

- 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?

- Yes No

If yes, the interpreter has:

- provided a sight translation of the informed consent form in person
 translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code:

Language:

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

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Radio-guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS): Yes No

Site/side of procedure:

Name of referring doctor/clinician:

Persons of child-bearing capacity

This procedure would generally not be performed if you are pregnant unless the benefits outweigh the risks of conducting the procedure.

Are you or could you be pregnant?

- Yes No Unsure

If unsure, please look at the following checklist and tick if you:

- have had a recent negative pregnancy test
 have had a normal menstrual period in the last 14 days
 have had a hysterectomy (the removal of all or part of your uterus)
 have had a tubal ligation more than 3 months ago
 reached menopause more than 6 months ago

If unsure or none of the above apply, do you agree to have a urine or blood pregnancy test?

- Yes No

Are you breastfeeding?

- Yes No

The health practitioner will review these answers, consult with and obtain further advice with a doctor regarding your pregnancy or breastfeeding status. Any risks specific to your pregnancy will be documented in section D.

D. Risks specific to the patient in having Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS)

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

E. Risks specific to the patient in *not* having Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS)

(Doctor/clinician to document specific risks in not having Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds [ROLLIS]):

DO NOT WRITE IN THIS BINDING MARGIN

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ROLLIS CONSENT



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**Radio-Guided Occult Lesion
Localisation using Iodine-125 Seeds
(ROLLIS) Consent**

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Sex: M F I

F. Alternative procedure options

(Doctor/clinician to document alternative procedure 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:

H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the 'Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS)' 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 procedure options
- that there is no guarantee the procedure will improve the medical condition
- that if a life-threatening event occurs during the procedure, 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; 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):

- 'Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS)'
- 'About Your Anaesthetic'

On the basis of the above statements,

1) I/substitute decision-maker consent to having Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS).

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

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Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS)

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

A copy of this patient information sheet should be given to the patient or 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.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker when used in the context of the person providing consent to the procedure.



1. What is Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS) and how will it help me?

Radio-Guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS) is a procedure in which a tiny metal seed, about the size of a small sesame seed, is placed into the abnormal breast tissue to mark its location. Once in position the seed will not move.

This procedure is usually recommended if the abnormal tissue is too small to be seen or felt by hand. The seed contains a small amount of low-level radiation.

The radioactive metal seed will be inserted into the breast by a radiologist before your breast surgery using imaging (mammography or ultrasound) as guidance.

Surgery to remove the seed and abnormal tissue will be performed by a surgeon who is experienced using ROLLIS. The surgeon will use a detector, called a gamma probe, to locate the seed.

The seed will be removed with the abnormal tissue during surgery.

The seeds have a low-level radioactive compound contained within a titanium shell. The low-level energy means the radiation does not travel far from the seed source. Some radiation from the seeds will be deposited in a small volume of breast tissue close to the seed while the remaining distant tissue receives very little exposure.

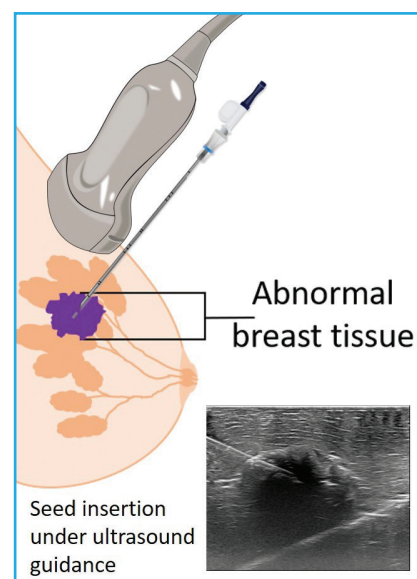


Image: Seed insertion under ultrasound guidance. RBWH, 2023.

Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all of the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood-thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

Please tell the doctor/clinician if you are breastfeeding or pregnant, or suspect that you may be pregnant.

You may be required to change into a hospital gown and remove some of your jewellery.

On the day of the procedure, don't put anything on your breasts, nipples, or under your arms. This includes talcum powder, deodorant, perfumes, colognes, and creams.

This procedure will require a local anaesthetic.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic*. If you do not have one of these information sheets, please ask for one.

During the procedure

Your ROLLIS procedure will either be done during a mammogram while your breast is compressed, or with ultrasound if the abnormal tissue is better seen under ultrasound imaging.

First, the doctor/clinician will take images of your breast using a mammogram or ultrasound. Once they see where the abnormal tissue is, they will give you an injection of local anaesthetic to numb the area.

After the area is numb, the doctor/clinician will insert a needle with the seed inside of it into your breast. After inserting the needle, they will take more images of your breast.

When the needle is in the correct place, the seed will be released into the tissue and the needle will be removed. The seed will stay in your breast until your surgery.

Images confirming the location of the seed will be taken. Your surgeon will use these images as a map to guide your surgery.

A small dressing will be applied where the needle was inserted.

Your ROLLIS procedure will take about 30 minutes.



2. What are the risks?

In recommending the procedure, the doctor/clinician believes that the benefits to you from having the procedure exceed the risks involved.

There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- pain or discomfort at the procedure site. This may require medication
- bleeding or bruising may occur at the procedure site
- bleeding or bruising is more common if you have been taking blood thinning medicines, 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
- failure of local anaesthetic, which may require a further injection of anaesthetic or a different method of anaesthesia.

Uncommon risks and complications

- suboptimal localisation. This may happen for a number of technical reasons; a secondary procedure may be required, your treating doctor/clinician will discuss this with you.
- infection at seed insertion site. This may require treatment with antibiotics
- an adverse/allergic reaction to the seed may occur, requiring further treatment.

Rare risks and complications

- seed migration, seeds have been reported to travel (less than 1mm) within the breast tissue
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this procedure is very rare.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure¹.

What are the risks of not having ROLLIS?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring 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. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available.

Hookwire localisation is a possible alternative. This is when a fine wire called a hookwire is placed in the breast with its tip in the abnormal breast tissue.

Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

You may carry on with your usual daily activities until you are required to attend the hospital for your surgery.

The items you touch and clothes that you wear won't become radioactive.



5. Who will be performing the procedure?

Doctors, radiographers, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your procedure.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include 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 this 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.

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. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students.



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.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this 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 proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.

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.

References:

1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au