



Queensland Government

Embolisation of an Intracranial Aneurysm Consent

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?

Complete for ADULT patient only

- 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:

Complete for CHILD/YOUNG PERSON patient only

- Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure and the consequences of non-treatment – ‘Gillick competence’ (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)
 → **GO TO section B**
- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
 → **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person → Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

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 OR substitute decision-maker OR parent/legal guardian/other person confirms the following procedure(s)

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

Embolisation of an intracranial aneurysm: Yes No

Site/side of procedure:

Name of referring doctor/clinician:

D. Risks specific to the patient in having an embolisation of an intracranial aneurysm

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

E. Risks specific to the patient in *not* having an embolisation of an intracranial aneurysm

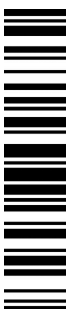
(Doctor/clinician to document specific risks in not having an embolisation of an intracranial aneurysm):

F. Alternative procedure options

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

DO NOT WRITE IN THIS BINDING MARGIN

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SW9625

EMBOLISATION OF AN INTRACRANIAL ANEURYSM CONSENT



Embolisation of an Intracranial Aneurysm Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

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 OR substitute decision-maker OR parent/legal guardian/other person.

I have explained to the patient OR substitute decision-maker OR parent/legal guardian/other person 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 OR substitute decision-maker OR parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Embolisation of an Intracranial Aneurysm' 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:
 - an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
 - a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
- 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/parent/legal guardian/other person have received the following consent and patient information sheet(s):

- 'Embolisation of an Intracranial Aneurysm'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having an embolisation of an intracranial aneurysm.

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Signature:

Date:

If the patient is a child/young person:

- I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (*not applicable if the child/young person is Gillick competent and signs this form*).

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 OR substitute decision-maker OR parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other person 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

Embolisation of an Intracranial Aneurysm

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person 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, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.



1. What is an embolisation of an intracranial aneurysm and how will it help me?

An embolisation of an intracranial aneurysm is a procedure to treat a blood vessel in your brain that is causing a problem. The procedure can be used to block an intracranial aneurysm, control excessive bleeding, or to redirect the blood flow within the arteries that led to the aneurysm.

An **intracranial aneurysm**, also known as a brain or cerebral aneurysm, is a bulge or sac in an artery that develops because of a weak area in the blood vessel wall. Aneurysms can enlarge and push on other structures inside your head. They can also burst, causing bleeding into the fluid space around your brain or into your brain tissue.

There are 2 steps in an embolisation of an intracranial aneurysm:

- 1. Angiogram:** a diagnostic procedure using x-rays and iodinated contrast (also known as x-ray dye) to review and measure the shape and size of the blood vessel leading to the area to be treated and the size and shape of the aneurysm to be treated.
- 2. The Embolisation:** when an embolic product is used to control blood flow in the aneurysm. Embolic agents used may include small soft metal coils and small soft metal stents (a mesh cage to keep a vessel open). The shape and location of the aneurysm will determine which products are used.

Filling the aneurysm with tiny soft coils stops the blood flow into the aneurysm. This reduces the chance of the aneurysm bursting and bleeding.

These products stay in for life. Aneurysm coils are generally Magnetic Resonance Imaging (MRI)-safe. You will be given information about any implanted devices after your procedure.

This procedure is less invasive and done instead of surgery to treat aneurysms.

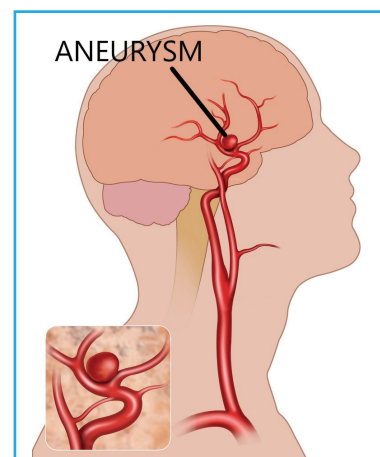


Image 1: Illustration of saccular aneurysm in internal carotid artery. ID: 475242880 (adapted). www.shutterstock.com

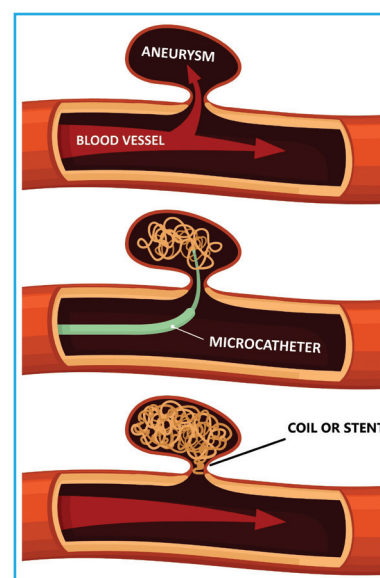


Image 2: The endovascular treatment of cerebral aneurysm. ID: 1287262261 (adapted). www.shutterstock.com

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 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.

This procedure will require the use of a general anaesthetic.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the anaesthetic. If you have a drug or medication dependence, please tell your doctor/clinician.

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

Please read the information sheet *About Your Anaesthetic (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

On the day of the procedure

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
 - your doctor/clinician will provide specific instructions about your medicines

- take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements. This may include and is not limited to blood thinning medicines, the contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin).
- If you feel unwell, telephone the Medical Imaging department for advice.
- Tell your doctor/clinician if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
 - had previous problems and/or known family problems with anaesthesia
 - false teeth, caps, loose teeth or other dental problems
 - allergies/intolerances of any type and their side effects.
- You will be required to change into a hospital gown and remove some of your jewellery. Your belongings will be kept in a safe location during the procedure.

For a parent/legal guardian/other person of a patient having an embolisation of an intracranial aneurysm

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff you may be able to see them off to sleep. Once they are asleep, you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/adult.

During the procedure

1. Angiogram

You will be transferred to the procedure room and be given a general anaesthetic.

After you are asleep, a nurse will insert an Indwelling Catheter (IDC) to drain urine from your bladder, and collect it in a bag while you are asleep.

The skin of your groin (or arm) will be cleaned and a sterile drape will be applied to cover your body. The doctor/clinician will use local anaesthetic to numb the skin and then make a small cut where a needle, angiography catheter and guidewire will enter.

A needle will be placed into the artery (or vein) using ultrasound image guidance. Iodinated contrast and x-rays will be used by the doctor/clinician to guide the angiography guidewire and catheter up through the blood vessels to the area of interest. Once the catheter is in place the needle is removed.

The neuro-radiologist (specialised x-ray doctor) will review and measure the shape and size of the vessel leading to the area to be treated, and the size and shape of the aneurysm. This helps to determine the best and safest way to embolise.

2. Embolisation of the intracranial aneurysm

Once the aneurysm is located a smaller catheter is passed through the bigger catheter and up into the aneurysm. The embolic agents (coils) are passed through this catheter into the aneurysm until the blood flow in the aneurysm and risk of it bursting are reduced. Depending on the shape of the aneurysm a stent may be required. The neuro-radiologist will determine the best option for you.

After the procedure is complete the catheter is removed, and firm pressure applied to the area where the catheter was inserted (puncture site). Sometimes a closure device is used to seal the artery to prevent bleeding. A small dressing will be applied to the puncture site.

You will be transferred to a recovery area for observation, before being transferred to a High Dependency Unit (HDU) or an Intensive Care Unit (ICU) for close observation for 1–2 days. If you had a burst aneurysm, the close observation time will be extended.



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

- post-procedure headache, this may require treatment
- bruising, bleeding or swelling and discomfort at the puncture site, this may be relieved with additional pressure and/or an icepack applied to the puncture site
- bleeding 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
- temporary epilation (hair loss) on your head caused by x-ray radiation.

Uncommon risks and complications

- the procedure may not be possible due to medical and/or technical reasons
- allergic reactions to injected medications, requiring further treatment
- infection at the puncture site may occur, requiring antibiotics and further treatment

- damage to the structures surrounding the puncture site, such as blood vessels and muscles. This may result in a clot or excessive bleeding from the puncture site and may require additional treatment and/or corrective surgery.

Rare risks and complications

- stroke due to blocking of the arteries with an embolic agent or blood clot. This may be temporary or permanent
- bursting of an aneurysm causing bleeding, usually into the membranes or thin layers of the tissue that cover the brain (also known as a subarachnoid haemorrhage). This is a medical emergency and would require immediate treatment
- skin burn or permanent epilation (hair loss) to head caused by x-ray radiation
- allergic reactions to contrast rarely occur, but when they do, they usually occur within the first hour, with most happening in the first five minutes. Late reactions have been known to occur up to 1 week after the injection, but these delayed reactions are mild. Note: Allergy to topical iodine and/or seafood does not imply an allergy to iodinated contrast. The reactions vary from:
 - mild: hives, sweating, sneezing, coughing, nausea
 - moderate: widespread hives, headache, facial swelling, vomiting, shortness of breath
 - severe: severe reactions are rare but include life-threatening heart palpitations, very low blood pressure, throat swelling, seizures and/or cardiac arrest
- death because of this procedure is very rare.

If general anaesthetic is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems, such as heart attack or pneumonia
- stroke resulting in brain damage.

Intra-arterial contrast and risk to kidney function

As contrast is not suitable for some people, you will be asked a series of questions before the contrast is given. The answers allow staff to identify any risk factors you may have.

Contrast is removed from the blood by the kidneys through the urine. It is easily removed from the body if you have normal kidney function. You may be asked to have a blood test to find out how well your kidneys are functioning. In patients with severe renal impairment or acute kidney injury, careful weighing of the risk versus the benefit of iodinated contrast media administration needs to be undertaken. However, severe renal function impairment should not be regarded as an absolute contraindication to medically indicated iodinated contrast media administration¹.

When significant worsening of kidney function is seen, such as in kidney disease, there is often more than one factor causing stress to the kidneys such as certain medications, infection, dehydration or low blood pressure. To minimise stress to your kidneys your doctor/clinician may recommend you have extra fluid to ensure good hydration, stop some medications temporarily or have extra blood tests to monitor your kidney function around the time of your procedure.

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 procedure².

What are the risks of not having an embolisation of an intracranial aneurysm?

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 an aneurysm bursts, there is a significant chance of death or permanent disability. Treating the aneurysm reduces the chance of it bursting. An aneurysm that is found before it bursts will be assessed by your doctors and given a level of risk of bursting, or enlarging, in the future.

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?

Alternatives to intracranial embolisation may include:

- surgery
- monitoring of the aneurysm (if small), with regular scans, and other conditions, such as blood pressure, that may need treatment to limit the effect on the aneurysm.

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



4. What should I expect after the procedure?

You will be given a Patient Implant Card (PIC) for your records with the specific details of any implanted devices used. This information may be helpful for future safety for any Magnetic Resonance Imaging (MRI) scans.

If you experience anything other than minor discomfort, you need to return to the hospital where you had treatment or to your referring doctor to ensure there are no complications.

The neuro-radiologist will discuss the results of the procedure with a family member you have nominated after the procedure, and with you once you have fully recovered from the anaesthetic. You will be required to have follow up scans to monitor the abnormal vessel and ensure it doesn't re-develop.

Follow up scans may consist of MRI and/or an angiogram.

Your healthcare team will discuss with you what to expect after your procedure and what level of activity is suitable after your procedure.

No unnecessary or strenuous activity for 4–5 days.

The puncture site may remain tender, swollen or bruised for a few days.

On discharge, please go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- a cool or cold limb
- slurred speech, balance problems or trouble using your arm or leg
- pain unrelieved by simple pain relief medicines
- continuous bleeding or swelling at the skin puncture site in your groin or arm
- signs of infection such as redness, inflammation at the puncture site or fever.



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 you while you are under anaesthetic.

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 First Nations People's culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.

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. Iodinated Contrast Media Guideline, V2.3 The Royal Australian and New Zealand College of Radiologists, March 2018. Available from www.ranzcr.com/college/document-library/ranzcr-iodinated-contrast-guidelines
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au