



Queensland
Government

Carotid Artery Angioplasty and Stenting 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:

Carotid artery angioplasty and stenting : Yes No

Site/side of procedure:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a carotid artery angioplasty and stenting

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

E. Risks specific to the patient in *not* having a carotid artery angioplasty and stenting

(Doctor/clinician to document specific risks in not having a carotid artery angioplasty and stenting):

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:

DO NOT WRITE IN THIS BINDING MARGIN

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H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the 'Carotid Artery Angioplasty and Stenting' 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 tissues/blood may be removed and used for diagnosis/management of the 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):

- 'Carotid Artery Angioplasty and Stenting'
 'About Your Anaesthetic'

On the basis of the above statements,

1) I/substitute decision-maker consent to having a carotid artery angioplasty and stenting.

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

Carotid Artery Angioplasty and Stenting

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 a carotid artery angioplasty and stenting and how will it help me?

Carotid artery angioplasty and stenting is a procedure in which a small metal mesh tube is placed in a narrowed part of a carotid artery with the guidance of an angiogram procedure.

The carotid arteries are located on each side of your neck and are the main arteries supplying blood to your brain.

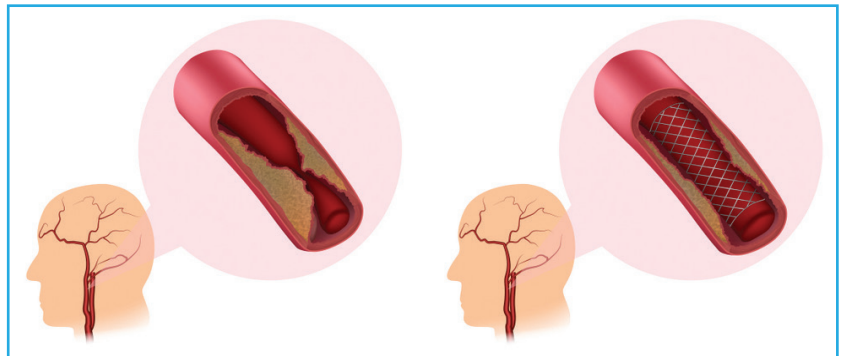


Image: A narrowed carotid artery (left) and carotid artery stenting (right).
ID: 1553521886. www.shutterstock.com

An **angiogram** is a procedure where x-rays and iodinated contrast (also known as x-ray dye) are used to examine the blood flow in your carotid artery. An angiogram is done by placing a needle and a thin plastic tube (catheter) into an artery either in your groin or your arm.

Angioplasty is a procedure that occurs during an angiogram, when a special balloon is inflated into the narrowed blood vessel to help open it up and improve the blood flow to your brain. The stent is inserted once the carotid artery has been widened.

This procedure is often performed to treat or prevent strokes. The stent stays in for life.

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 local anaesthetic and either sedation or 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 sedation or anaesthetic.

Tell your doctor/clinician if you:

- are breastfeeding or pregnant, or suspect that you may be pregnant
- have a drug or medication dependence.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath, when instructed by the doctor/clinician.

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.

On the day of your 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.

During the procedure

An intravenous (I.V.) cannula is a small plastic tube that will be inserted into a vein usually in your hand or arm. This is for any medication or fluids required during the procedure, including sedation.

Routine observations, such as your heart rate and blood pressure, will be taken before the start and regularly throughout the procedure.

The skin of your groin area (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 the needle enters. A special needle will be placed into the artery using ultrasound imaging. The doctor/clinician will be able to guide a guidewire and a catheter up through the blood vessels to the area of interest, using iodinated contrast and x-ray. Once the catheter is in place the needle is removed. You should not feel the catheter moving through your vessels.

When the catheter tip is in the carotid artery, contrast is used to provide a detailed view of the narrowed artery and blood flow to the brain. A filter is placed in the artery past the narrowing. The filter is a protection device, to help catch any tiny fragments that may break off from the plaque that narrowed the carotid artery.

A balloon tip catheter is placed into the narrowed area and inflated to widen the narrowing. A stent is placed to provide support to the artery and prevent the artery narrowing again.

Once the procedure is complete the catheter will be removed. Firm pressure will be applied to the area where the catheter went into your skin (puncture site). This allows the artery to seal over so you will not bleed. A small dressing will be applied to cover the puncture site.

After the procedure is complete, you will be transferred from the procedure room to a recovery area. Routine observations and checks of your groin (or arm) puncture site will be monitored for swelling, oozing of blood and bruising. You may be required to rest in bed for up to 6 hours.

Moving too soon after this procedure may cause bleeding at the puncture site.

After you have recovered, you will be transferred to an Intensive Care Unit (ICU) or a specialty ward for overnight observation.



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

- minor pain, bruising and/or infection from the I.V. cannula
- minor pain or discomfort may occur around the puncture site
- bleeding or bruising could occur at the puncture site. This is usually stopped by applying pressure and/or ice to the puncture 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

- low blood pressure and slow heart rate caused by pressure placed on nerves in your neck during stent insertion. This is only temporary and will resolve on its own once the pressure is released. Sometimes medications will be required
- the carotid artery may become narrowed again. This may require further treatment
- failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia
- nerve damage, is usually temporary, and should get better over time. Permanent nerve damage is rare
- temporary epilation (hair loss) to head or neck, caused by x-ray radiation.

Uncommon risks and complications

- the procedure may not be possible due to medical and/or technical reasons
- stroke or stroke like complication due to the catheter causing damage to the artery. This can cause weakness in the face, arms and legs; these complications could be temporary or permanent
- allergic reactions 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
- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment
- a blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery.

Rare risks and complications

- bursting of a blood vessel requiring other procedures and/or corrective surgery
- the stent may suddenly close, requiring further treatment
- permanent nerve damage
- skin burns or permanent epilation (hair loss) from exposure to x-ray radiation
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this procedure is very rare.

If general anaesthetic or sedation 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 a carotid artery angioplasty and stenting ?

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?

A surgical alternative to carotid artery angioplasty and stenting is endarterectomy.

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?

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

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 assessing your safety for any future Magnetic Resonance Imaging (MRI) scans.

You will be monitored on the ward by your treating team, you may have an ultrasound of your carotid artery. Your treating team will decide when you are able to be discharged.

If it is no longer required, the I.V. cannula will be removed after you have recovered.

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.

If you had sedation or a general anaesthetic, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.



5. Who will be performing the procedure?

Radiographers, doctors, 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