



Queensland
Government

Coronary 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

This consent form and patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.

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 translated:

- in person over the telephone

A verbal translation is a summary of the form.

Name of interpreter:

National Accreditation Authority for Translators and Interpreters (NAATI) code:

Language:

C. Procedure details

I confirm that the referring doctor has informed me about the following procedure(s) and I consent to:

- Angiogram: Yes No
Angioplasty: Yes No
Stenting: Yes No
Intravascular ultrasound: Yes No
Optical coherence tomography: Yes No
Fractional flow reserve: Yes No

Site/side of procedure/additional component:

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

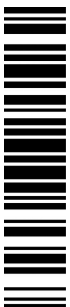
(Doctor to document additional risks not included in the patient information sheet)

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

(Doctor to document specific risks in not having a coronary angioplasty and stenting)

DO NOT WRITE IN THIS BINDING MARGIN

v7.00
Clinical content review: 2024
Clinical check: 06/2024
Published: 06/2024



SW9019

CORONARY ANGIOPLASTY AND STENTING CONSENT



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F. Alternative procedure options

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

I have received the following consent and patient information sheet(s):

- 'Coronary Angioplasty and Stenting'
- 'About Your Anaesthetic'
- 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)'
- Other (*specify*):

G. Acknowledgment and consent

I acknowledge that the doctor has explained and I understand:

- the 'Coronary Angioplasty and Stenting' patient information sheet
- the medical condition and proposed procedure, including the possibility of additional treatment
- this procedure requires sedation or general anaesthetic
- 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 the procedure leads to the need for a blood or blood products transfusion, an additional consent form will be required
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if an immediate life-threatening event happens during the procedure, health care will be provided based on my AHD (Advance Health Directive) or ARP (Acute Resuscitation Plan). If no AHD or ARP is in place, health care will be provided in accordance with good clinical practice and the *Guardianship and Administration Act 2000 (Qld)*
- that a doctor other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor undergoing further training under supervision
- that if the doctor 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.
- I understand I have the right to change my mind regarding consent at any time, including after signing this form.

On the basis of the above statements,

I consent to having a coronary angioplasty and stenting.

Name of patient/substitute decision-maker:

Signature:

Date:

H. Doctor confirms

I have explained to you the contents of this form and am of the opinion that the information has been understood.

Name of doctor:

Designation:

Signature:

Date:

I. Clinical student involvement

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

I 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

Note: you will also have the opportunity to say yes or no to student involvement, on the day of your procedure.

For further information please see www.health.qld.gov.au/consent/students

Coronary Angioplasty and Stenting

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

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This patient information sheet has been given to you to read carefully and allow time to ask your doctor any questions about this procedure. Your doctor will include the consent form and a copy of this patient information sheet in your medical record.

This patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.



1. What is a coronary angioplasty and stenting and how will it help me?

Angioplasty is often used instead of surgery. It is a procedure to treat fatty plaque build-up in your heart's blood vessels. Angioplasty uses a tiny balloon catheter which opens narrowed or blocked heart blood vessels. These blood vessels supply blood to the heart and are called coronary arteries. Angioplasty is often combined with the placement of a stent.

A stent is a small mesh tube or coil and is inserted to reduce the risk of the coronary arteries narrowing again. Most stents are coated with an anti-clotting medication, this is to prevent any clots forming within the stent, helping to keep your artery open.

Opening your blood vessels using angioplasty and stenting can improve your symptoms, such as, shortness of breath or chest pain. They can also be used during a heart attack to reduce the damage to your heart by opening a blocked artery quickly.

To help with the procedure, images may be taken, and tests done to identify anything unusual, or abnormalities. These are done while the catheter (thin tube) is in the artery of interest. These include:

- **Coronary angiogram:** Uses x-rays and iodinated contrast (also known as x-ray dye) to produce an image of the artery.
- **Intravascular Ultrasound (IVUS):** Uses sound waves to produce an image.
- **Optical Coherence Tomography (OCT):** Uses light to produce an image.
- **Fractional Flow Reserve (FFR):** Compares blood flow on either side of the blockage using a pressure wire in your coronary artery to show how severe the narrowing (stenosis) is.

Angioplasty and stenting may have been recommended for you if:

- lifestyle changes and medication have not improved your heart health
- you have worsening chest pain (angina)
- you have a heart attack.

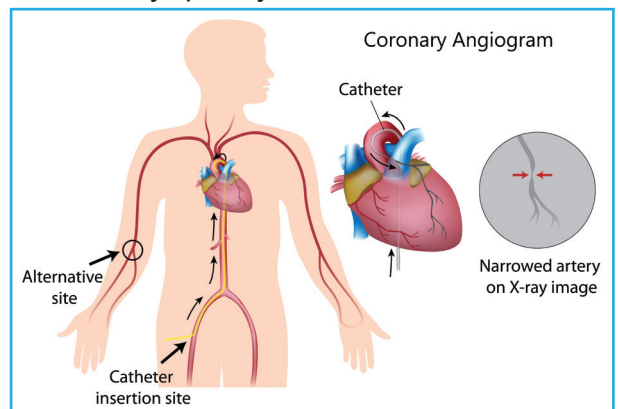


Image 1: Coronary angiogram.
ID: 127004951 (adapted). www.shutterstock.com

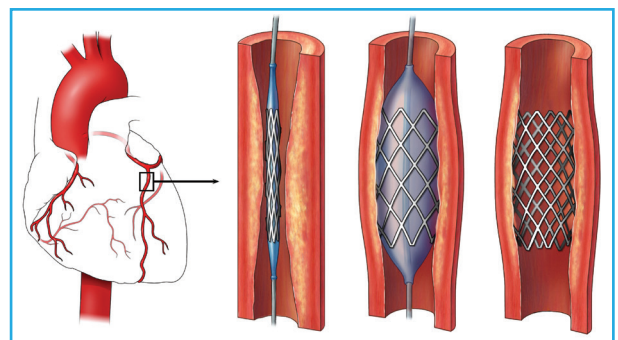


Image 2: Coronary stent.
Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

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Preparing for the procedure

Patients having this procedure are usually in hospital for 1 night. Your doctor will be able to confirm that this estimate is likely to be true for your procedure.

The Cardiology 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.

Cardiology staff will notify you beforehand if you are required to stop taking any blood-thinning medication.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. If you are having sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

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 anaesthetic.

Please tell the doctor if you:

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

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 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 Cardiology department for advice.
- Tell your doctor 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.

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.

Coronary Angioplasty and Stenting

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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.

For a substitute decision-maker of an adult without capacity to consent to having a coronary angioplasty and stenting

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.

If the patient is having a general anaesthetic, 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.

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

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 medication or fluid required during the procedure, including sedation.

Routine observations will be measured before and during the procedure, these may include cardiac rhythm, blood pressure, heart rate, respiratory (breathing) rate and oxygen levels.

The skin over your lower arm and/or groin will be cleaned and a sterile drape will cover your body.

The doctor will use local anaesthetic to numb the skin and make a small cut in your groin or arm. An access port, a thin hollow tube called a sheath, will be placed in the artery to allow equipment to be inserted into your vessel. Using contrast and x-ray guidance, the doctor will guide a fine tube (catheter), via the sheath up to the affected artery.

While the catheter is in the artery, a number of additional mechanical devices may be used. These may include pressure wires, IVUS and OCT (see page 3).

A tiny wire is passed into the artery so a balloon can be passed over it, and into the part that is narrowed or blocked.

To open up the artery, the balloon is inflated with fluid, which then presses against the plaque, pushing it out of the way.

Some people may experience the following complications from the balloon:

1. the coronary artery may be split or damaged, or
2. the artery may become narrowed again as the balloon goes down, or
3. the artery may become blocked again.

On occasion, an additional device is used to prepare the artery for stenting. If the vessel is very hardened (calcified), a device called a rotator is used. This device is a small drill (the size of a bead of rice) that passes through the artery over a thin wire. This softens the vessel and allows the stent to be placed and properly expanded. While there is a small risk of complications with this procedure (e.g. tear in vessel), if the rotator is not used when the situation requires it, the stenting result can be unsatisfactory.

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Most of the time, one or more stents are placed in the artery to help keep the artery open. A stent is passed into the diseased part of your artery using a balloon. The balloon is removed once the stent is in place.

The stent stays in for life. After the procedure, you will be given medicines which reduce your risk of blood clotting and the stent blocking.

If the heart becomes unstable during the procedure, an additional balloon pump device, to stabilise the heart, may be required. An intracardiac balloon pump can improve your heart's ability to pump blood to your body and can help to improve blood flow to your coronary arteries. If required, your cardiologist will discuss this with you.

At the end of the procedure, the sheath will be removed and the artery will be closed with pressure or a special plug to stop the bleeding. Your cardiologist will discuss this with you.

After the procedure is complete, you will be transferred from the procedure room to a recovery area. Routine observations, as described above, will be taken, your puncture site will be reviewed regularly for swelling, oozing of blood and bruising. You may be required to rest in bed for 2 to 4 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

Blood-thinning medications (e.g. Aspirin, Clopidogrel, Ticagrelor) are typically used after this procedure. Often two blood thinners are given in combination, to limit the risk of blood clots. These medications are usually taken for a long time after stenting, which will be explained to you after the procedure.



2. What are the risks?

Factors such as age, underlying heart disease, poor heart function, diabetes and kidney disease will affect the risks of the procedure. The nature of the narrowing (total blocks, blocks related to forks in the arteries or hardened arteries) also affect the risks of the procedure. The risks are higher if you are having the procedure for unstable symptoms or a heart attack.

In recommending the procedure, the doctor 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.

Your doctor will discuss any additional risks, specific to your individual condition and circumstances, with you. These should be written on the consent form before you sign it.

Common risks and complications

- loss of pulse in the arm after a radial artery is used for procedural access. This could be temporary or permanent
- major bruising or swelling at the puncture site
- vasospasm (narrowing of the artery caused by spasm of the muscular wall of the artery) which usually resolves with time
- failure of local anaesthetic which may require a further injection of anaesthetic or a different anaesthesia
- nerve damage, is usually temporary, and should get better over time.

Uncommon risks and complications

- the coronary artery can become narrowed or blocked again. Many factors can influence this, and your doctor will discuss these with you

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- serious bleeding where the catheter was inserted. Serious bleeding in the brain, stomach or abdominal cavity may need surgical or endoscopic procedures to correct. Blood transfusion may be needed
- bleeding or bruising is more common if you have been taking blood-thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover), prasugrel, dipyridamole (Persantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- abnormal heart rhythm which may need an electric shock to correct
- a heart attack because of the closure of smaller side branches of the artery, caused by clots or debris
- infection, requiring antibiotics and further treatment
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- damage to the artery where the tubes are inserted. This may need surgical repair
- permanent damage to the nerve in the leg or arm where the tubes were inserted
- the stent may close suddenly because of a clot. Sometimes this is related to not taking prescribed blood thinners. This can cause angina or a heart attack. It may be treated with another angioplasty or with surgery
- emergency heart surgery due to complications with the procedure
- a reaction to the medications given to prevent blood clotting
- (*iodinated contrast only*) allergic reactions rarely occur, but when they do, they 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

- a stroke. This can cause long-term disability
- rupture or a tear of a blood vessel requiring surgical repair and blood transfusion
- skin burns or damage from exposure to x-rays
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death as a result of this procedure is rare.

If a 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 a heart attack or pneumonia
- stroke resulting in brain damage.

Iodinated contrast and risk to kidney function

Contrast is removed from the blood by the kidneys through the urine.

Your blood test results will be checked to find out how well your kidneys are functioning.

In patients with severe renal function impairment or actively deteriorating renal function (acute kidney injury) careful weighing of the risk versus the benefit of giving iodinated contrast, needs to be undertaken. However, severe renal function impairment does not mean that iodinated contrast should not be given, if medically indicated¹. Your treating doctor will discuss your specific circumstances with you.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated.

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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 coronary angioplasty and stenting?

There may be adverse consequences for your health if you choose not to have the proposed procedure. You and your doctor should discuss these.

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.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Your doctor will discuss any alternative procedure options and their risks or benefits with you, 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.

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

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- pain unrelieved by simple pain relievers or those prescribed for you
- bleeding, swelling, redness or inflammation at the puncture site
- a fever
- other warning signs the doctor may have asked you to be aware of.

If you had sedation or an 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?

Doctors, cardiac scientists, radiographers, cardiac sonographers, pharmacists, nurses, patient support officers and administration staff make up the cardiology team.

A doctor other than the consultant/specialist may assist with/conduct your procedure. This could include a registered doctor who is undergoing further training. All trainees are supervised according to relevant professional guidelines.

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

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Clinical students

For the purpose of undertaking professional training in this teaching hospital, subject to your consent, a clinical student(s) may observe medical examination(s) or procedure(s). A clinical student may also, subject to your consent, assist with/conduct a clinically necessary examination or procedure on you while you are under the influence of anaesthetic.

You are under no obligation to agree to an examination(s) or a procedure(s) being observed or 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.

Queensland Health respects the privacy of patients and their families. To learn more about health records and personal information visit our website www.health.qld.gov.au/system-governance/records-privacy/health-personal

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.

Queensland Health recognises that First Nations Peoples' 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 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 Cardiology 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/iodinated-contrast-guidelines-2016
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au