



## Carotid Stenting

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex:  M  F  I

### A. Interpreter / cultural needs

- An Interpreter Service is required?  Yes  No  
If Yes, is a qualified Interpreter present?  Yes  No  
A Cultural Support Person is required?  Yes  No  
If Yes, is a Cultural Support Person present?  Yes  No

### B. Procedure

The following will be performed (*Doctor/doctor delegate to document – include site and/or side where relevant to the procedure*)

.....

.....

A Carotid Stent is a procedure in which a small metal mesh tube is placed into the narrowed part of the carotid artery. It is used to stretch and open up the inside of the artery.

The stent stays in for life.

This procedure will require an injection of local anaesthetic and the use of a sedation or general anaesthetic.

### C. Risks of the procedure

In recommending the Carotid Stenting, the doctor believes the benefits to you from having this procedure exceed the risks involved.

The risks and complications with this procedure can include but are not limited to the following.

#### Common risks and complications include:

- Minor pain, bruising and/or infection from the IV cannula. This may require treatment with antibiotics.
- Pain or discomfort at the puncture site. This may require medication.
- Bleeding or bruising could occur. This is usually stopped by applying pressure and/or ice to the puncture site. This is more common if you take Aspirin, Warfarin, Clopidogrel (Plavix and Iscover) or Dipyridamole (Persantin and Asasantin).
- Low blood pressure and slow heart rate caused by pressure placed on nerves during stent insertion. This is only temporary and will resolve on its own once the pressure is released. Sometimes drugs will be required to treat this.
- The artery can become narrowed or blocked again. This may require further treatment.
- Failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia may be used.

- Nerve damage, is usually temporary, and should get better over a period of time. Permanent nerve damage is rare.

#### Less common risks and complications include:

- Between 3 and 5 people in every 100 will have a stroke or stroke like complication due to the catheter causing damage to the artery. This can cause weakness in the face, arms and legs; it could be temporary or permanent.
- 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.
- An allergy to injected drugs may occur, requiring further treatment.
- The procedure may not be possible due to medical and/or technical reasons.

#### Rare Risks and complications include:

- Rupture of a blood vessel requiring other procedures and/or corrective surgery.
- The stent may suddenly close. This may require further treatment.
- An increased lifetime cancer risk due to the exposure to x-rays.
- 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 very rare.

#### If sedation is given extra risks include:

- faintness or dizziness, especially when you start to move around
- fall in blood pressure
- nausea and vomiting
- weakness
- an existing medical condition getting worse
- heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. This may require emergency treatment
- stroke resulting in brain damage.



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## D. Risks of Iodinated Contrast for patients with renal impairment

**Specific Risks** of Iodinated Contrast to patient's identified as having *Renal Impairment*.

- Giving the Contrast to people with weakened kidneys (renal impairment), can cause further kidney damage, which may in turn cause the kidneys to stop working properly (acute renal failure).

## E. Patient consent

I acknowledge that the doctor/doctor delegate has explained the proposed procedure.

I understand;

- the risks and complications, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor/doctor delegate or my Acute Resuscitation Plan.
- a doctor/doctor delegate undergoing further training may conduct this procedure.

**I have been given the following Patient Information Sheet/s:**

- Carotid Stenting**
- Iodinated Contrast**
- About Your Anaesthetic** (if applicable)

- I was able to ask questions and raise concerns with the doctor/doctor delegate about the proposed procedure and its risks. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time including after I have signed this form but, preferably following a discussion with my doctor/doctor delegate.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I understand that Queensland Health may release my relevant de-identified information obtained from this and related procedures for education and training of health professionals.

On the basis of the above statements,

## I request to have the procedure

Name of Patient:.....

Signature:.....

Date:.....

### Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

Yes ▶ Location of the original or certified copy of the AHD:.....

No ▶ Name of Substitute Decision Maker/s:.....

Signature:.....

Relationship to patient:.....

Date:..... PH No:.....

**Source of decision making authority** (tick one):

- Tribunal-appointed Guardian
- Attorney/s for health matters under Enduring Power of Attorney or AHD
- Statutory Health Attorney
- If none of these, the Adult Guardian has provided consent. Ph 1300 QLD OAG (753 624)

## F. Doctor/delegate Statement

I have explained to the patient all the above points under:

- the Patient Consent section (E)
- Iodinated Contrast - Patients with Renal Impairment Section (D) (for renal impaired patients only)

and I am of the opinion that the patient/substitute decision-maker has understood the information.

**Name of Doctor/delegate:**.....

**Designation:**.....

**Signature:**..... **Date:**.....

## G. Interpreter's statement

I have given a sight translation in

.....  
(state the patient's language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

**Name of Interpreter:**.....

**Signature:**..... **Date:**.....

DO NOT WRITE IN THIS BINDING MARGIN

## 1. What is a Carotid Stenting?

A Carotid Stent is a procedure in which a small metal mesh tube is placed into the narrowed part of the carotid artery. It is used to stretch and open up the inside of the artery.

The stent is inserted by placing a needle and thin plastic tube (catheter) into the artery in your groin. Carotid Stenting is commonly used instead of open surgery. The stent stays in for life.

Iodinated 'Contrast' is used to map your arteries so the doctor can insert the stent into the narrowing. For more information on Iodinated Contrast and the risks involved in its use, please read the **Iodinated Contrast Patient Information Sheet** (If you do not have this information sheet please ask for one).

## 2. Will there be any discomfort, is any anaesthetic needed?

This procedure will require an injection of local anaesthetic and the use of a sedation or general anaesthetic. If you are booked for a general anaesthetic please read the **About your Anaesthetic** patient information sheet (If you do not have this information sheet please ask for one).

## 3. What is sedation?

Sedation is the use of drugs that give you a 'sleepy-like' feeling. It makes you feel very relaxed during a procedure. You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but has a risk with side effects and complications.

Whilst these are usually temporary, some of them may cause long-term problems.

## 4. Preparation for the procedure

The medical imaging department will give you instructions on how to prepare for your procedure.

- You will be told when to have your last meal and drink. This is to make sure your stomach is empty so that if you vomit during the procedure there will be nothing to go into your lungs.
- Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.
- If you take Aspirin, Warfarin, Clopidogrel (Plavix and Iscover) or Dipyridamole (Persantin and Asasantin) or any other drug that is used to thin your blood ask your doctor/health practitioner if you should stop taking it before the procedure as it may affect your blood clotting.
- List or bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements.
- Do not drink any alcohol and stop recreational drugs 24 hours before the procedure as these

may alter the affects of the sedation anaesthetic. If you have a drug habit please tell your doctor.

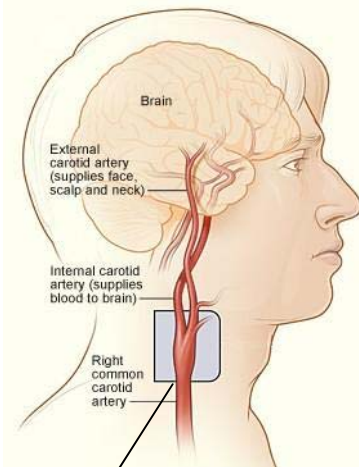


Fig.1 National Heart, Lung and Blood Institute

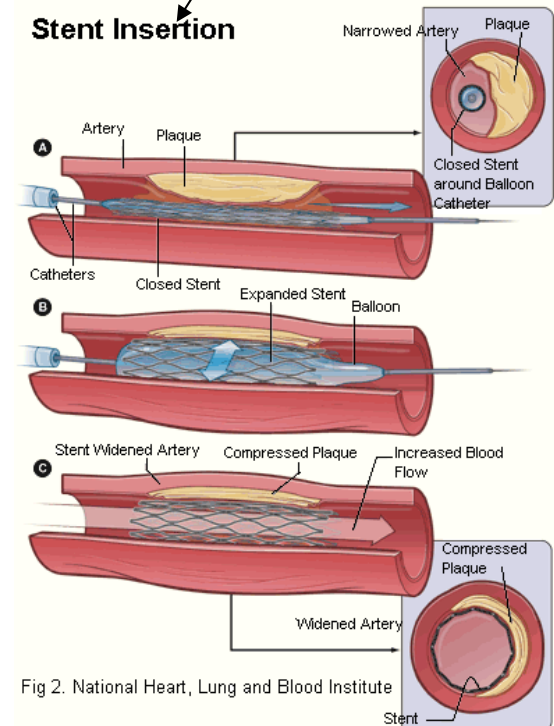


Fig 2. National Heart, Lung and Blood Institute

## 5. During the procedure

A fine needle (IV cannula) will be put into a vein in your arm.

You will be given a sedation or general anaesthetic.

The doctor will inject local anaesthetic into the skin. A needle and catheter are inserted into the artery in your groin; sometimes your arm may be used. Once the catheter is in place the needle is removed.

The catheter is guided through the main blood vessels in your body until it reaches your carotid artery. You should not be able to feel the catheter inside your body.

X-ray pictures are taken while the Contrast is injected into your arteries.

If required, a specially designed wire with a filter is placed past the narrowing. This filter device is called

an embolic protection device (EPD). The EPD looks like an umbrella or wind sock and contains a basket to catch clots and plaque broken off during the stenting process. Catching these prevents them from travelling in the blood to the brain and reduces the risk of blood clot or stroke.

Once the narrowing has been identified the stent will be inserted through the catheter.

When the procedure is finished the catheter and EPD will be removed. Firm pressure will be put over the area where the catheter went into your skin (puncture site). This allows the artery to seal so you will not bleed.

### 6. After the procedure

You may be monitored in the hospital's Intensive Care Unit (ICU) or ward overnight. You will need to lie flat and keep your leg (or arm) still and straight for 4 to 6 hours. Moving too soon after the procedure may cause bleeding at the puncture site.

The IV cannula will be removed after you have recovered.

Staff will discuss with you the need to *restrict your activities* at home for up to 5 days. Follow these instructions carefully.

### 7. What are the risks of this specific procedure?

The risks and complications with this procedure can include but are not limited to the following.

#### Common risks and complications include:

- Minor pain, bruising and/or infection from the IV cannula. This may require treatment with antibiotics.
- Pain or discomfort at the puncture site. This may require medication.
- Bleeding or bruising could occur. This is usually stopped by applying pressure and/or ice to the puncture site. This is more common if you take Aspirin, Warfarin, Clopidogrel (Plavix and Iscover) or Dipyridamole (Persantin and Asasantin).
- Low blood pressure and slow heart rate caused by pressure placed on nerves during stent insertion. This is only temporary and will resolve on its own once the pressure is released. Sometimes drugs will be required to treat this.
- The artery can become narrowed or blocked again. This may require further treatment.
- Failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia may be used.
- Nerve damage, is usually temporary, and should get better over a period of time. Permanent nerve damage is rare.

#### Less common risks and complications include:

- Between 3 and 5 people in every 100 will have a stroke or stroke like complication due to the

catheter causing damage to the artery. This can cause weakness in the face, arms and legs; it could be temporary or permanent.

- 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.
- An allergy to injected drugs may occur, requiring further treatment.
- The procedure may not be possible due to medical and/or technical reasons.

#### Rare Risks and complications include:

- Rupture of a blood vessel requiring other procedures and/or corrective surgery.
- The stent may suddenly close. This may require further treatment.
- An increased lifetime cancer risk due to the exposure to x-rays.
- 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 *very rare*.

#### If sedation is given extra risks include:

- faintness or dizziness, especially when you start to move around
- fall in blood pressure
- nausea and vomiting
- weakness
- an existing medical condition getting worse
- heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. This may require emergency treatment
- stroke resulting in brain damage.

### 8. What are the safety issues when you leave hospital?

Go to your nearest Emergency Department or GP 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 killers
- continuous bleeding or swelling at the puncture site
- redness or inflammation at the puncture site
- a fever
- other warning signs the doctor may have asked you to be aware of.

## 1. What is Iodinated Contrast?

The medical imaging procedure your doctor has asked you to have uses Iodinated 'Contrast' (once called X-ray dye). Contrast is a colourless liquid which includes iodine. Contrast is injected into your blood stream to allow your organs to be seen more clearly on x-rays. Contrast is not a dye. It does not stain the inside of your body. Your doctor needs to use Contrast to be able to get all the information needed to assist with your diagnosis.

**This information sheet must be read together with the information sheet of the procedure you are booked for (if you do not have this information sheet please ask for one).**

## 2. During the procedure

When the Contrast is injected you may feel:

- A very warm or 'flushed' feeling over your body, this may also make you think you have passed urine. You will *not* pass urine – it is only a feeling.
- A 'metallic' taste or smell may also happen. This usually lasts less than a minute.

## 3. After the procedure

It is recommended that you drink 2 to 4 glasses of water after your procedure to help flush the Contrast from your body.

Contrast does not affect your ability to carry out normal activities; you should be able to continue with your day as normal.

## 4. Precautions

Contrast is not suitable for some people; you will be asked a series of questions before it is given to you. Your answers allow staff to identify any risk factors that you may have.

- Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.

### Kidney function

- Contrast is removed from your blood by your kidneys through your urine. It is easily removed from the body of people who have normal kidney function.
- Giving Contrast to people with weakened kidneys (renal impairment), can cause further kidney damage, which may in turn cause the kidneys to stop working properly (acute renal failure).
- You may be asked to have a simple blood test to find out the level of their kidney function.

### Diabetic Drug interactions - Metformin

(Other Drug names: Avandamet, Diabex, Diaformin, Formet, Glucohexal, Glucomet, Glucophage, Glucovance, Metforbell)

If kidneys suffer damage from the Contrast then the kidneys may not be able to remove Metformin from the body. It is safer to briefly stop taking Metformin when having Contrast. Staff will inform you when to stop and when it is safe to take Metformin again.

*Contact your GP to monitor your diabetes if you are told to stop your Metformin.*

## 5. What are the risks of Iodinated Contrast?

The risks and complications with this injection can include but are not limited to the following.

### **Common risks and complications include:**

- No known common risks.

### **Less common risks and complications include:**

- Injected Contrast may leak outside of the blood vessel, under the skin and into the tissue. This may require treatment. In very rare cases, further surgery could be required if the skin breaks down.
- Acute Renal Failure occurs when one or both of your kidneys suddenly stop working. Failure can last for days or weeks. It may take the kidneys a long time to regain their previous level of function and you may require dialysis to filter your blood during this time. There is a risk your kidneys could be permanently damaged. To reduce this risk the smallest possible dose of Contrast will be given.
- The injection may not be possible due to medical and/or technical reasons.

### **Rare risks and complications include:**

- Allergic reactions occur within the first hour with most happening in the first 5 minutes. Late reactions have been known to occur up to a week after the injection.

*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* – wide spread hives, headaches, facial swelling, vomiting, shortness of breath.

*Severe* – Severe reactions are rare but include: life-threatening heart palpitations, very low blood pressure, throat swelling, fits and/or cardiac arrest.

- Death as a result of Iodinated Contrast is *very* rare.

## 6. What are the safety issues when you leave the hospital?

Go to your nearest Emergency Department or GP if you become unwell.