Queensland Government

Transcatheter Aortic Valve Implant (Transfemoral Approach) 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?

☐ Yes → ***GO TO** section B*

☐ No → ***COMPLETE** section A*

i. a) Is the patient aged under 18 years?

☐ Yes (document parent/guardian name below)

☐ No → ***GO TO** ii*

You must adhere to the Advance Health Directive (AHD) or the consent obtained from a substitute decision-maker.

ii. a) Does the patient have an AHD that is applicable to the procedure, treatment or investigation?

☐ Yes

☐ No → ***GO TO** iii*

b) If *yes*, has the AHD been sighted and a copy in the medical record?

☐ Yes

☐ No → ***GO TO** iii*

iii. a) Substitute decision-maker (select one only):

☐ Attorney(s) for health matters under an Enduring Power of Attorney or AHD

☐ Tribunal-appointed guardian

☐ Statutory Health Attorney

☐ If none of these, the Office of the Public Guardian must provide consent (ph: 1300 653 187)

Name of substitute decision-maker(s) or parent/guardian:

Signature of substitute decision-maker(s) or parent/guardian:

Relationship to the patient (e.g. substitute decision-maker or parent/guardian):

Date: Phone number:

B. Does the patient need Interpreter/ cultural services?

i. a) Is a language interpretation service required?

☐ Yes

☐ No → ***GO TO** ii*

b) If *yes*, is a qualified Interpreter present?

☐ Yes (complete section K)

☐ No

☐ N/A

ii. a) Is a cultural support person required?

☐ Yes

☐ No → ***GO TO** section C*

b) If *yes*, is a cultural support person present?

☐ Yes

☐ No

☐ N/A

C. Condition and treatment

The doctor/clinician has explained that I have the following condition *(doctor/clinician to document in patient's words)*:

This condition requires a Transcatheter Aortic Valve Implant *(doctor/clinician to document, include site and/or side where relevant to the procedure)*:

DO NOT WRITE IN THIS BINDING MARGIN

TRANSCATHETER AORTIC VALVE IMPLANT (TRANSFEMORAL APPROACH) CONSENT

v1.00 - 05/2017

SW9450

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Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

The following will be performed:

A plastic tube (introducer) is inserted into an artery in your groin (femoral artery). A balloon catheter is passed through the introducer sheath and directed to your aortic valve. The balloon is inflated to open your valve prior to the valve implant. This balloon catheter is removed.

Another catheter with your loaded valve implant is inserted and directed towards your aortic valve. Some valve implants on the market are SELF EXPANDING and do not require inflation with a balloon. The new valve starts functioning straight away after insertion. Your own diseased valve will not be cut or removed.

In addition, xrays and a transeosaphageal echo are performed during the procedure. These assist with correct positioning of your new valve.

A temporary pacemaker is also inserted in a large vein either in your neck or your groin. The pacemaker is utilised during the procedure and is left in for a short period afterwards. A tube (sheath) is also placed in the artery of the opposite leg to allow a catheter (tube) to be positioned in the aorta to inject dye to assess the valve, aorta and arteries.

A Transcatheter aortic Valve implant is a relatively new treatment and long term durability of the new valve beyond five years is still to be determined. You will be required to have ongoing medication and follow up with a Cardiologist after your surgery.

D. Risks and complications of a Transcatheter Aortic Valve Implant

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- swelling, bruising or haematoma (abnormal collection of blood outside of a blood vessel) at the puncture site
- femoral artery aneurysm or pseudoaneurysm (false aneurysm) which may require surgical repair or stent placement
- hypertension/hypotension (high or low blood pressure)
- abnormal heart rhythms
- a permanent pacemaker implant may be required
- **bleeding** from the groin. A blood transfusion may be required
- increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for **people who are obese**.

Uncommon risks and complications include:

- **infection** requiring antibiotics
- worsening or failure of kidney function sometimes requiring dialysis
- stroke (blood clot or bleeding in the brain) which can cause permanent disability
- heart attack caused by the new valve blocking the coronary arteries
- lung collapse. This may need antibiotics, physiotherapy or tube insertion to remove air or fluid from the chest
- **blood clot** in the leg causing pain and swelling. In rare cases, part of the clot may break off and go to the lungs.

Rare risks and complications include:

- perforation or damage of vessels, myocardium or valve structures which may require emergency major surgery
- valve moving from where it was initially placed. The valve may need to be removed with a special catheter or open heart surgery
- opening or tear in the lining of the Aorta (aortic dissection)
- infection settling on new valve
- significant leakage around new valve
- **death** as a result of this procedure is rare

E. Specific risks for you in having this procedure

(Doctor/Clinician to document in space provided. Continue in Medical Record if necessary):

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F. Risks of not having this procedure

(Doctor/Clinician to document in space provided. Continue in Medical Record if necessary):

G. Alternative procedure, treatment or investigation options

(Doctor/Clinician to document in space provided. Continue in Medical Record if necessary):

H. Anaesthetic

This procedure may require an anaesthetic *(doctor/clinician to document type of anaesthetic discussed)*:

I. Anticoagulant/Antiplatelet checklist

Information to discuss with your doctor about blood thinning drugs:

Aspirin ☐ Yes ☐ No

Antiplatelet agents ☐ **YES** ☐ No

Clopidogrel, Prasugrel, Ticagrelor, Dipyridamole, Other.

If the procedure is elective, can the antiplatelet be withheld and the patient maintained on aspirin alone for 7 days prior? ☐ Yes ☐ **NO**

Date Authorising doctor/clinician ordered antiplatelet ceased/to be ceased:

Warfarin/Dabigatran/ Rivaroxaban/Apixaban/Heparins/ Other new anticoagulants ☐ **YES** ☐ No

If elective procedure, can all anticoagulation be ceased before the procedure? ☐ Yes ☐ No

Where there have been changes (i.e. ceased, withheld) to the above drugs, is there a management plan documented in the patient's medical record? ☐ Yes ☐ No

J. Patient/Substitute decision-maker consent

I acknowledge the doctor/clinician has explained:

- my/the patient's medical condition and the proposed procedure/treatment/investigation may require and include additional treatment if the doctor/clinician finds something unexpected. I understand the risks and benefits, including the risks specific to me
- my/the patient's requirement for anaesthetic for this procedure/treatment/investigation - I understand the risks associated with anaesthetic, including the risks specific to me (see *Anaesthetic* information sheet)
- my/the patient has alternative procedure/treatment/investigation options
- my/the patient's prognosis, and the risks of not having the procedure/treatment/investigation
- no guarantee has been made that the procedure/treatment/investigation will improve my/the patient's condition even though it has been carried out with due professional care
- my/the patient's procedure/treatment/investigation may include a blood transfusion
- my/the patient's tissues/blood may be removed and be used for diagnosis/management of my condition, stored and disposed of sensitively by the hospital

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- if an immediate life-threatening event happens during my/the patient's procedure/treatment/ investigation, I/the patient will be treated based on my discussions with the doctor/clinician or *Acute Resuscitation Plan*
- a doctor/clinician other than the consultant/ specialist may conduct the procedure/treatment/ investigation. I understand this could be a doctor undergoing further training who will be supervised according to relevant professional body guidelines

I/the patient was able to ask questions and raise concerns with the doctor/clinician about my/the patient's condition, the proposed procedure/ treatment and its risks, and my/the patient's treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I/the patient 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 a doctor/clinician.

I/the patient understand 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/clinician to provide appropriate treatment.

On the basis of the above statements,

I consent to having this Transcatheter Aortic Valve Implant.

Name of patient:

Signature: Date:

I consent to Open Heart Surgery/ Cardiopulmonary Bypass in the event of Transfemoral TAVI complication during surgery.

Signature: Date:

I consent to:

Name of patient having procedure:

Name of substitute decision-maker:

Signature: Date:

I have received the following information sheet(s):

☐ *'About your anaesthetic'*
☐ *'Transcatheter aortic valve implant'*
☐ *'Blood and blood products transfusion'*

K. Interpreter's statement

I have:

☐ provided a sight translation
☐ translated as per clinician explanation in:

Patient's language:

of this consent form and assisted in the provision of any verbal and written information given to the patient/substitute decision-maker by the doctor/clinician.

Name of patient:

Language of patient:

Name of Interpreter service:

Name of Interpreter:

Interpreter's signature: Date:

L. Doctor/Clinician/Delegate statement

Information for Doctor/Clinician/Delegate:

The information contained within this form is not, and is not intended to be, a substitute for direct communication between the doctor/clinician/delegate and the patient/substitute decision-maker regarding the medical procedure, treatment or investigation described in this form. I have explained to the patient all the content in this patient consent form and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of doctor/clinician/delegate:

Designation:

Signature: Date:

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Transcatheter aortic valve implant (transfemoral approach)

Informed consent: patient information

Give this patient information sheet to the patient or substitute decision-maker(s) to read carefully and allow time to ask any questions about the procedure.

1. What is this procedure and how will it help me?

A Transcatheter Aortic Valve Implant/ Replacement (TAVI/TAVR) is utilised to treat Aortic Stenosis and reduce symptoms such as chest pain, fatigue, shortness of breath, difficulty when exercising, dizziness and fainting.

A plastic tube (introducer) is inserted into an artery in your groin (femoral artery). A balloon catheter is passed through the introducer sheath and directed to your Aortic heart valve. The balloon is inflated to open your valve prior to the valve implant. This balloon catheter is removed. Another catheter that is loaded with your new valve implant is inserted and directed towards your Aortic valve. Some valve implants on the market are SELF EXPANDING and do not require inflation with a balloon. The new valve starts functioning straight away. Your own diseased valve will not be cut or removed. In addition, xrays and a transeosaphageal echo are performed during the procedure. These procedures assist with correct positioning of your new valve. A temporary pacemaker is also inserted in a large vein either in your neck or your groin. The pacemaker is utilised during the procedure during balloon inflation and is left in for a short period afterwards. A tube (sheath) is also placed in the artery of the opposite leg to allow a catheter (tube) to be positioned in the aorta to inject dye to assess the valve, aorta and arteries.

A Transcatheter aortic Valve implant is a relatively new treatment and long term durability of the new valve beyond five years is still to be determined. You will be required to have ongoing medication and follow up with a Cardiologist after your surgery.

2. My anaesthetic

This procedure will require an anaesthetic. For more information about the anaesthetic and the risks involved please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with your clinician.

If you have not been given an anaesthetic sheet, ask for one.

3. What are the specific risks of a Transcatheter Valve Implant?

Common risks and complications include:

- swelling, bruising or haematoma (abnormal collection of blood outside of a blood vessel) at the puncture site
- femoral artery aneurysm or pseudoaneurysm (false aneurysm) which may require surgical repair or stent placement
- hypertension/hypotension (high or low blood pressure)
- abnormal heart rhythms
- a permanent pacemaker implant may be required
- bleeding from the groin. A blood transfusion may be required
- increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for people who are obese.

Uncommon risks and complications include:

- infection requiring antibiotics
- worsening or failure of kidney function sometimes requiring dialysis
- stroke (blood clot or bleeding in the brain) which can cause permanent disability
- heart attack caused by the new valve blocking the coronary arteries
- lung collapse. This may need antibiotics, physiotherapy or tube insertion to remove air or fluid from the chest
- blood clot in the leg causing pain and swelling. In rare cases, part of the clot may break off and go to the lungs.

Rare risks and complications include:

- perforation or damage of vessels, myocardium or valve structures which may require emergency major surgery
- valve moving from where it was initially placed. The valve may need to be removed with a special catheter or open heart surgery
- opening or tear in the lining of the Aorta (aortic dissection)
- infection settling on new valve
- significant leakage around new valve
- death as a result of this procedure is rare.

SWP19450

4. Other special considerations for this procedure

- Although the transcatheter aortic valve procedure is usually less traumatic than conventional open cardiac surgery it is still a major procedure with major and significant risks.
- The procedure will require ongoing follow-up with your specialist and treatment with medication therapy.
- This is a relatively new treatment and the long term durability of the new valve beyond 5 years is to be determined and will require ongoing follow-up with your specialist.
- **Bacterial Endocarditis Awareness:** After your new valve is inserted if you require any invasive procedures (including dental treatment) it is important you let your treating doctor/dentist know about your valve replacement as you may require antibiotics prior to the procedure to reduce the risk of your new valve becoming infected.

5. What are the risks specific to me?

There may also be risks specific to your individual condition and circumstances. Please discuss these with your clinician and ensure they are written on the consent form before you sign it.

6. What are the risks of not having this procedure?

There may be consequences if you choose not to have the proposed procedure/treatment/investigation. Please discuss these with your clinician.

If you choose not to have the procedure you will not be required to sign a consent form.

7. Who will be performing my procedure?

A doctor/clinician other than the consultant or specialist may conduct the procedure/treatment/investigation. I understand this could be a doctor/clinician undergoing further training. All surgical trainees are supervised according to the relevant professional body guidelines.

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

8. Useful sources of information

Hospital care: before, during and after is available on the Queensland Health website: www.qld.gov.au/health/services/hospital-care/before-after/index.html

You can read about:

- Healthcare choices
- Hospital admission
- Medical records
- During your stay
- Practical information
- Going home
- Compliments and complaints

9. Questions to ask my doctor/clinician

Please ask your doctor/clinician if you do not understand any aspect of the information in this patient information sheet or any other information you have been given about your condition, treatment options and proposed procedure.

10. Contact us