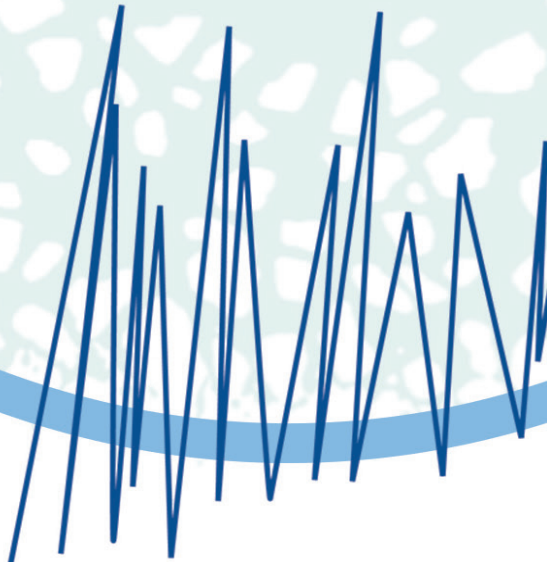
NHS

Royal Papworth Hospital

NHS Foundation Trust

Transcatheter aortic valve implantation (TAVI)

A patient's guide and consent form



Compassion
Excellence
Collaboration

Valvular heart disease

The heart is a muscle which pumps blood to your lungs and around the body. There are four valves within the heart. These valves normally open to let blood flow through, or out, of the heart, and then shut to prevent blood flowing backwards.

If a valve becomes diseased or damaged this can affect the flow of blood in two ways:

1. If the valve does not open fully, it will obstruct the flow. This is called valve stenosis.
2. If the valve does not close properly, it will allow blood to flow backwards in the wrong direction. This is called valve regurgitation.

Aortic valve stenosis

You have been diagnosed with aortic valve stenosis. The aortic valve is on the left side of the heart. When the valve opens blood is normally pumped from the left pumping chamber of the heart (ventricle) around the body. When the aortic valve is narrowed the blood flow out of the heart is restricted. This can cause symptoms of tiredness, chest pain, breathlessness and /or dizziness when exercising, and can lead to fainting. The restriction may also put a strain onto your heart pump over time, leading to heart muscle weakness, fluid on the lungs or swollen ankles. The traditional treatment for severe symptomatic aortic valve stenosis is conventional aortic valve replacement.

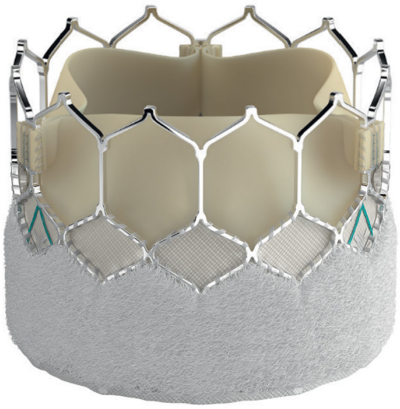
This involves open-heart surgery to replace the narrowed valve with a valve prosthesis. However, due to your overall medical condition and / or age, you may be more suitable for a transcatheter aortic valve implantation.

Aortic regurgitation

More rarely some patients with severe aortic regurgitation are suitable for a transcatheter aortic valve implantation. Aortic regurgitation can also put strain on the heart causing breathlessness and fluid overload.

What is transcatheter aortic valve implantation?

Transcatheter aortic valve implantation (TAVI) involves inserting a prosthetic heart valve inside your narrowed or leaky valve using a catheter. The valve is made up of a metal frame (stent) and the outer lining (pericardium) of a cow's or pig's heart. The procedure is usually carried out under consious sedation with local anaesthetic. General anaesthetic is used in cases where transfemoral access is not possible (surgical approaches). There are two types of valve we use: balloon expanded and self-expandable.



Edwards SAPIEN 3TM transcatheter heart valve
Image courtesy of Edwards Lifesciences

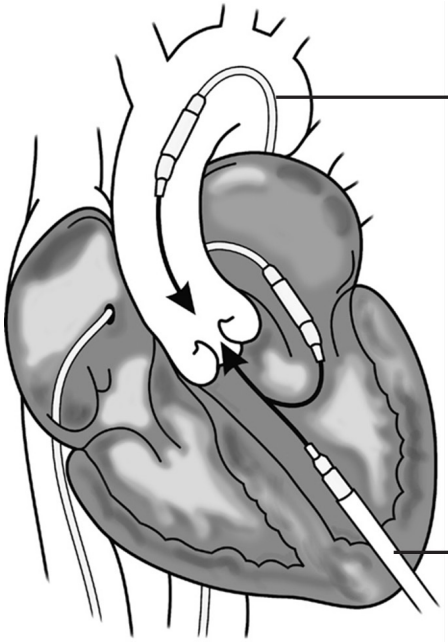
Medtronic Evolut PRO valve
Reproduced with permission of Medtronic

The TAVI team, including your cardiologist, cardiac surgeon and anaesthetist, will review your medical condition and screening tests to decide the most appropriate treatment and access route for you.

There are several access routes to deliver the TAVI valve:

1. **Transfemoral** - through the femoral artery, the main artery in your groin which leads back to the heart (most common route).
2. **Transcarotid** - through a small incision in your neck into the carotid artery leading back to the heart.
3. **Transaxillary** - (sometimes referred to as subclavian) through a small incision under the collar bone to the artery leading back to the heart.
4. **Transaortic** - through a small cut in the chest directly into the aorta (main artery).
5. **Transapical** - through a small cut on the left side of your chest to get to the apex (tip) of your heart.

Transcatheter aortic valve implantation techniques



Retrograde transfemoral, transcarotid, transaxillary and transaortic approaches

The delivery system is introduced through the access site artery allowing positioning of the prosthetic valve within the native stenotic aortic valve.

Transapical approach

The heart is reached by a small incision under the left breast. The valve delivery system is introduced into the heart and the new prosthetic valve positioned inside the narrowed aortic valve.

Screening tests

You will have at varying times:

- A physical examination
- An electrical heart trace (ECG)
- A chest X-ray (CXR)
- Blood tests
- An ultrasound probe and gel placed on the chest to obtain pictures of your heart (transthoracic echocardiogram).
- A CT scan to look at the blood vessels from the neck to the groin.

You may also have the following tests:

- A transoesophageal echocardiogram (TOE) if clearer pictures are needed (this involves inserting an ultrasound probe into your gullet under sedation).
- An angiogram, which involves passing a tube (catheter) into your groin or wrist artery and taking X-ray pictures of your blood vessels supplying your heart (coronary arteries), your body's main blood vessel (aorta) and groin arteries.

Potential benefits of a TAVI procedure

Treatment with the new valve should improve your symptoms. It will improve the aortic valve performance and your overall heart function. We would hope this will improve your quality of life and increase your lifespan.

Potential risks of the procedure

(Reference Papworth Outcomes - November 2024)

- Death at 30 days: 1-2%
- Stroke: 3-5%
- Heart attack: 1%
- Permanent pacemaker requirement: 6-12% (20% with the Trilogy valve used for aortic regurgitation)
- Major bleeding: 3%
- Damage to blood vessels: 2%
- Damage to nerves: 1%
- Kidney failure: 1%
- Emergency open heart surgey: 1%
- Infection (wound or valve related): 1%

Hospital admission

Once accepted by the medical team, you will be invited to come in for the procedure. You will receive a letter with your admission details. You may be asked to stop any blood thinning medications four days or less before your procedure.

You attend a pre-admission clinic a week before your scheduled procedure and come to hospital the same day as your procedure or be admitted the day before. Before the procedure, you will be seen by members of the team.

You will be kept 'nil by mouth' for a few hours prior to your procedure and the nurses will assist you to shave your chest, wrists, and groins and also to shower.

The procedure will be done in the catheter laboratory (cath labs) using contrast dye, X-ray screening and echocardiography to guide the valve into the correct position.

X-rays

X-rays used during the procedure involve a dose of ionising radiation equivalent to a small dose of natural background radiation which we are exposed to every day.

- The risk of cancer due to radiation exposure is between 1 in 1,000 to 1 in 10,000
- There may be a small risk of an excess radiation dose to the skin. This may happen during a long procedure and can lead to short and long-term effects such as reddening of the skin and burns.

Procedure

Following your sedation or general anaesthetic, you will have some tubes put through the blood vessels in your groin and/or wrist to deliver the contrast dye and a pacing wire to speed up the heart during the valve insertion.

The operator will gain access making a small incision either in your groin, neck, or chest wall. Dependent on the chosen route for your procedure a catheter (narrow tube) is passed either through the femoral artery in the groin (transfemoral), neck artery (transcarotid), artery below the collar bone (transaxillary) to the aorta. Or a catheter (narrow tube) is inserted directly into the aorta (transaortic) or through the heart muscle to the aortic valve (transapical).

The prosthetic valve for implantation will be prepared and inserted. When the valve is in the correct position your heart rate will be increased using the temporary pacing wire for a few seconds in some but not all cases. This reduces the blood pressure and the motion of the heart making the procedure safer.

The prosthetic valve is then expanded into it's permanent position. The tubes are removed and the valve starts to function immediately.

The procedure site is repaired by the operator. A chest drain is inserted for transapical and transaortic procedures. The procedure overall takes about two hours.

Blood transfusion

When having a procedure it is likely that you will lose some blood. If only a small amount is lost your body will naturally replace this over the next few weeks. If more blood is lost, it may be necessary for you to have a blood transfusion so that you do not suffer any ill effects from the blood loss. Although blood transfusion is quite safe, there are some potential risks associated with this treatment. Your doctor or nurse will explain these risks to you and will offer you an information leaflet.

In the UK, the risk of contracting a viral infection, such as hepatitis or HIV from blood transfusion is extremely small. Very rarely patients receiving blood transfusion may experience an allergic reaction or develop other complications, such as haemolysis (breakdown of red cells in your blood) or a bacterial infection. The actual risk of contracting vCJD through blood is unknown but appears to be extremely small. There is also a very small risk of inadvertently receiving unsuitable blood, however there are stringent procedures in place to minimise this risk.

By signing the consent form, you are consenting to receiving a blood transfusion. If you do not wish to receive blood or blood products please make this known to your consultant.

General anaesthesia

You may be recommended by your cardiologist, or by an anaesthetist to have a general anaesthetic for this procedure. This depends on your specific circumstances and medical history. It may also become necessary to give a general anaesthetic during a TAVI procedure once it has started if difficulties are encountered.

Please let your team know if you have had prior problems with anaesthetics or have a family history of serious problems with anaesthetic agents, such as a rare condition called malignant hyperpyrexia or an allergy to an anaesthetic.

You may not meet an anaesthetist at all if your TAVI is planned to be under sedation. If your TAVI is planned to be under a general anaesthetic then you will either meet the anaesthetist who will be looking after you during your procedure when you come into hospital, or you will be offered to attend the anaesthetic pre-assessment clinic.

If you feel particularly anxious about the possibility of a general anaesthetic and would like to discuss this with an anaesthetist prior to admission to hospital please let your TAVI team know so that they can book you into the anaesthetic clinic.

Common risks (1 in 10) after a general anaesthetic include:

- Bruising or bleeding around the site of the cannula
- Dry mouth or lips
- Sore throat
- Shivering
- Itching
- Nausea and vomiting
- Difficulty passing urine which may require a catheter to be inserted into your bladder. This is more likely if the procedure takes a long time or if you have experienced this type of problem before.
- Temporary memory loss

These common risks are temporary and should settle down soon afterwards.

Less common risks (1 in 100 – 1 in 3,000) include:

- Infection of a cannula or arterial line
- Corneal abrasion (1 in 2,800). We will protect your eyes whilst you are asleep, however occasionally patients may suffer an accidental scratch to the eye called a corneal abrasion. This can cause pain and blurred vision for a few days, but usually heals without long term consequences. More serious damage to the eyes resulting in permanent loss of vision is very rare
- Hoarse voice
- Vocal cord damage
- Dental damage. Please let us know if you have any loose teeth or fragile dental work
- Peripheral nerve damage that is permanent

Uncommon risks (1 in 10,000 – 1 in 20,000):

- Aspiration of gastric contents into the lungs
- Allergy to an anaesthetic drug
- Awareness (1 in 20,000)

There may be some risks in addition to these which your anaesthetist may discuss with you if they think they are relevant for you. The risk of death or brain damage resulting from a general anaesthetic is extremely rare (around 1 in 100,000) and is a smaller risk compared to the risk from the TAVI procedure itself.

This procedure will involve either general anaesthetic or conscious sedation. By signing the consent form you are consenting to your anaesthetic.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

PIC 43: patient agreement to PI 43 - Transcatheter aortic valve implantation (TAVI)

Statement of health professional

(To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy).

I have explained the procedure to the patient. In particular I have explained:

The intended benefits: This procedure is carried out with the intention of improving symptoms which may be related to obstruction of blood flow out of the heart. These symptoms may include angina, breathlessness, exercise restriction, dizziness or collapse.

Significant, unavoidable or frequently occuring risks: Heart attack: 1%, stroke: 3-5%, death at 30 days: 1-2%, permanent pacemaker requirement: 6-12% (20% with the Trilogy valve), major bleeding: 3%, damage to blood vessels: 2%, damage to nerves: 1%, infection: 1%, emergency open heart surgery: 1%, kidney failure: 1% (Reference Papworth Outcomes - November 2024)

Due to the high-risk nature of your condition, in the event of your heart stopping during the procedure your doctors may have limited options available to help you.

Any extra procedures, which may become necessary during the procedure:

☐ Blood transfusion

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

This procedure will involve:

☐ General anaesthetic ☐ Transaxillary

☐ Conscious sedation ☐ Transaortic

☐ Transfemoral ☐ Transapical

☐ Transcarotid ☐ Other route

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

Healthcare professional

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Contact details

……

……

Has a ReSPECT form been considered and, if relevant, appended to this form?

☐ Yes ☐ No

Statement of patient

Please read the patient information and this form carefully. If the treatment has been planned in advance, you should already have your own copy of which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

Yes	No	
☐	☐	**I agree** to the procedure or course of treatment described on this form and have read this information leaflet on Transcatheter aortic valve implantation (TAVI) (PI 43) and had the opportunity to ask questions.
☐	☐	**I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.

- **I understand** what the procedure is and I know why it is being done, including the risks and benefits.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

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- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

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I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt Jakob disease) or vCJD (variant Creutzfeldt Jacob disease).

☐ Yes ☐ No

(Where patient indicates 'yes' health professional to refer to Trust CJD procedure DN092)

Statement of interpreter

If an interpreter was present to support this consent, please state the name and number of the interpreter present.

Date: ……

Interpreter's number:……

Name (PRINT): ……

If a telephone / video service has been used, please document the name of the interpreter and company below

.....

.....

Patient

Patient signature: ……

Date: ……

Name (PRINT): ……

Confirmation of consent

(To be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment (e.g. Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ……

Date: ……

Name (PRINT): ……

Please use and attach Consent form C for a young person who is not Gillick competent.

Following your procedure

You will go from the catheter laboratory (cath labs) to the recovery area for up to a couple of hours where you will be closely monitored. Following this you will return either to the ward or the high dependency unit. If you have general anaesthetic, you will be woken up early after the procedure but occasionally you may need to stay asleep so will be kept sedated and if necessary admitted to intensive care.

It is not uncommon to access both groin and / or wrist blood vessels. Whilst there are tubes in your groin you will have to be on bed rest. A few hours after these tubes are removed you can sit out and start to walk about.

Patients that have a chest drain will have drips and drains removed over the next 48 hours.

Patients who have the transfemoral procedure with sedation are usually quick to recover. The expected length of stay is one to two days, or sometimes you can be discharged home on the same day if you have had your procedure early in the morning.

Transaortic and transapical patients will take a few days longer. Expected length of stay is two to four days.

Recovery at home

The following are only general guidelines as everyone's recovery is slightly different. It is advisable that you have someone to support you for the first week after discharge. Please speak to your nurse or doctor as soon as possible if you think this will be a problem.

Activity

You should avoid strenuous activity for two weeks, six weeks if your procedure was via the transapical/transaortic approach. This includes heavy lifting (eg shopping, suitcases) or pushing and pulling (eg cutting grass, vacuum cleaning).

You may feel a little 'washed out' and tired and need to rest in the afternoon. However, it is important for your recovery to have a short walk every day. This can be gradually increased. You do not have to avoid climbing stairs or walking up inclines, you may have to start off at a slower pace. You may feel slightly out of breath on walking, which should improve as your fitness level increases.

There can be some fluid retention as a result of the procedure; you may notice some swelling of your ankles. If this swelling travels further than your ankles please get reviewed by your GP.

Wounds

If you had a surgical procedure your chest or neck incision should be healing by the time you leave hospital, if they still require a dressing we will organise a district or practice nurse to continue this.

The stitches are dissolvable so do not have to be removed, apart from one stitch if you had a chest drain. If your wound becomes red or inflamed, please get your GP or practice nurse to check it.

If your procedure was done via groin approach, you may have bruising to your groin which is not uncommon and may take several weeks to resolve. You may have a hard lump under the skin due to a collection of blood (haematoma). Please consult your GP if this becomes painful or grows bigger. The dressings within the groin should be removed five days after your procedure date. You can take this off yourself at home.

Medication

As well as your normal medicines you will be discharged home on a single blood thinning medication (antiplatelet or anticoagulant). In some circumstances an additional blood thinning medication may be required.

If you have had a chest incision we recommend taking over the counter pain relief, until you are no longer getting discomfort from your wound.

Recommended summary plan for emergency care and treatment (ReSPECT)

What is ReSPECT?

ReSPECT stands for 'Recommended summary plan for emergency care and treatment'. It is a process that helps people to think about what treatment is suitable in an emergency, should they be unable to make decisions at the time.

Why is it important?

We know that, when people are very unwell, they are often unable to think clearly about what treatment they may or may not want because their brain and body are overwhelmed by the illness. It is also normal for people to feel anxious about what is happening when they are sick and in hospital, and this can also make it difficult to think clearly. This is why we think it is a good idea, where possible, for decisions about medical treatment to be made in advance – before there is an emergency situation or crisis.

How does it work?

The ReSPECT process is designed to help conversations between you and your healthcare professionals: they need to make sure you understand your health problems and which treatments may or may not benefit you. You need to make sure the healthcare professionals understand what matters most to you and whether there is anything you are particularly worried about or would want to avoid.

This conversation is used to complete a ReSPECT form that records a person's health problems, their preferences and which medical treatments may or may not be suggested. The original form should stay with the patient, though it is extremely helpful to have a record of the content of the form on their electronic patient record.

A ReSPECT form is NOT a legally binding document and can be changed or withdrawn at any point.

The ReSPECT form is often used to indicate treatments that someone may not want and/or treatments that their healthcare professionals consider would no longer be of benefit to them.

If people are getting worse from progressive conditions, it may be helpful to consider in advance about things such as whether they would wish to go back into hospital and, if in hospital, what sort of treatments might or might not be helpful for them.

This often includes a decision on whether or not they should have attempted cardiopulmonary resuscitation (CPR) if their heart were to stop.

Who is it for / is this relevant for me?

This process has increasing relevance for people who have complex health needs, people who may be nearing the end of their lives and those who are at risk of sudden deterioration or cardiac arrest.

However, many people come to Royal Papworth to have major procedures or surgery with the intention of curing a progressive disease or with the intention of substantially prolonging their life and, if that is you, you may wonder how a ReSPECT discussion applies to you and others like you.

One of the key things to understand about the ReSPECT process is that it can be used simply to document a person's wishes and priorities, without setting any limitations on what treatment they should have.

This is important because all the procedures and operations we do here come with the risk of complications. In the unlikely event that things do not go as planned, it is really helpful to have some idea about a person's preferences and about their fears, worries and hopes.

Once again, the document is not legally binding, but it can help those looking after you to know what you might want if you were not able to say for yourself.

Driving

DVLA does not allow driving until four weeks post your procedure. If you have a LGV or PCV licence you will need to undergo an exercise test before getting your licence back.

Work

If you were working before your procedure there is no reason why you cannot return to this after a period of recovery up to two weeks if transfemoral, four to six weeks if chest incision.

Cardiac rehabilitation

You may be invited to attend cardiac rehabilitation about six weeks after your procedure if your local area offers this service. This is a programme of graduated exercise and general health discussions. Patients who attend generally feel more confident about coping with everyday life. It will also help to increase your fitness level.

Follow-up care

On discharge you will be given a copy of the letter for your GP explaining what you have had done and a list of your medications.

The valve / TAVI specialist nurses will phone you a week after discharge to check on your progress.

You will be invited to attend a telephone follow-up appointment with the nurse specialist in due course following your procedure. At a further appointment in due course you will have an ultrasound scan of your heart and have either a virtual or face to face appointment with a TAVI consultant based on their judegment. The doctor will then decide about any future appointments.

How to contact us

If you have any concerns you can call the TAVI specialist nurses on 01223 638411 (Monday to Friday 07:30 - 17:30). We would like to hear sooner rather than later about any potential problems. If you get the answerphone please leave your name, RGM number, a brief message and a contact number and we will get back to you. If you call outside of these times and you are unwell please contact 111 or 999 for emergency help.

Notes:

Royal Papworth Hospital NHS Foundation Trust

A member of Cambridge University Health Partners

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View a digital version of this leaflet by scanning the QR code.

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Scan the QR code or head to royalpapworth.nhs.uk/our-hospital/how-we-are-run/foundation-trust-members to find out more.

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