

Replacing your heart's narrowed aortic valve with a transcatheter valve (TAVI)

Department of Cardiology

Information for Patients

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Introduction

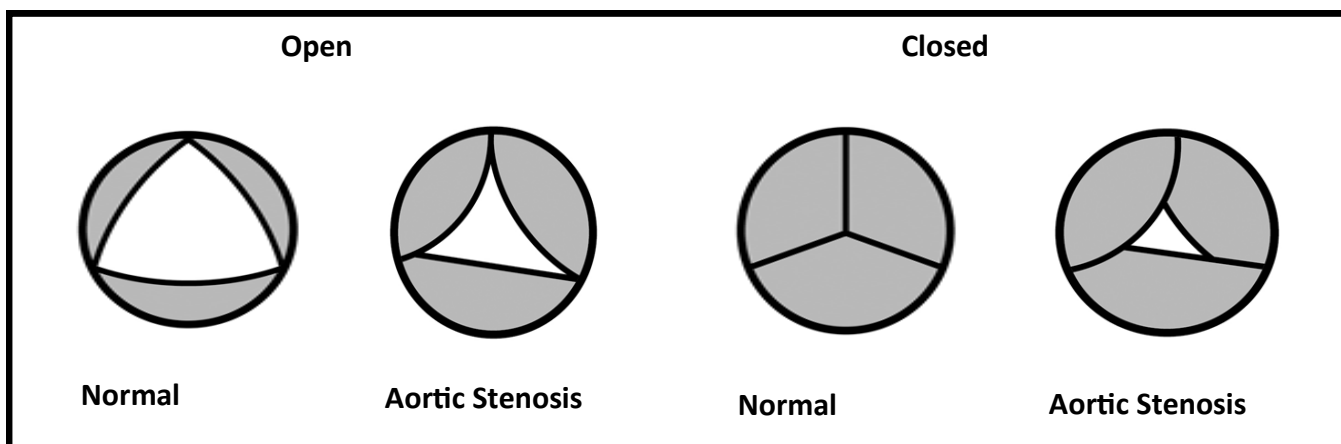
This leaflet provides information about transcatheter aortic valve implantation (TAVI), a treatment for a heart condition called aortic stenosis. This is the main treatment for severe aortic stenosis.

If you have any questions, please contact us using the telephone numbers given at the end.

What is aortic stenosis (AS)?

The aortic valve is one of the 4 valves in the heart. The valves control the flow of blood from the heart. Aortic stenosis can happen when the aortic valve has narrowed, does not work properly, and then fails to open fully. This makes the heart work harder to pump blood through the valve. The narrowing is often caused by a build up of calcium inside and around the valve, which can happen over the course of a lifetime.

As the valve gets narrower, less blood is able to pass through it each time when the main chamber of the heart (left ventricle) pumps.



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or call 111 for non-emergency medical advice

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This makes the heart muscle work harder and can cause heart failure. Fluid can sometimes collect on the lung tissue caused by heart failure, resulting in shortness of breath and even chest pain.

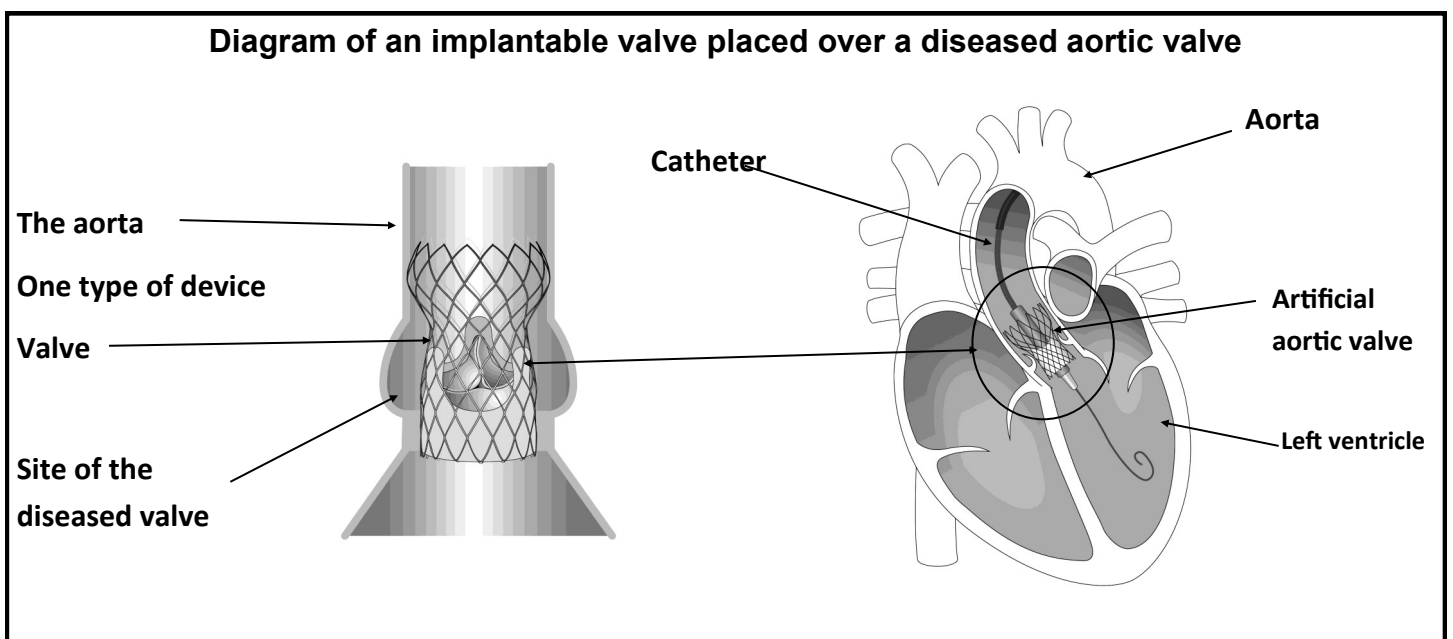
What are the symptoms of aortic stenosis?

- Shortness of breath
- Dizziness
- Chest pain or tightness
- Blackouts
- Feeling tired
- Swelling of the ankle

Once the aortic stenosis causes symptoms, the condition is serious and will get worse. The symptoms will limit how much of your normal activities you can do and will also affect how long you may live without treatment.

What are the treatment options available for aortic stenosis?

- **Tablets** - tablets may help to improve some of your symptoms for a short time but they won't treat or slow down its progress. The only long term treatment is to treat the diseased valve.
- **Heart valve replacement** - it may be possible for you to have heart surgery to take out your aortic valve and replace it with a new one. For older people and those who may be at high risk, an operation may not be possible. High risk people can be offered a different procedure called a transcatheter aortic valve implantation (TAVI). Your cardiologist will decide which of the treatments is best for you.

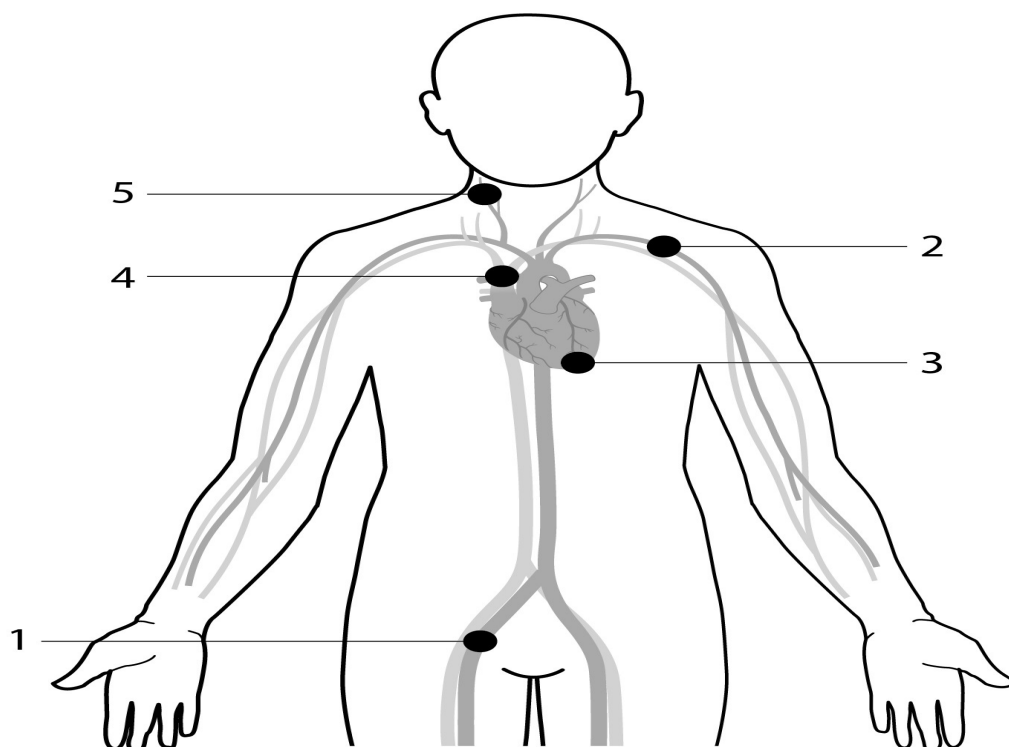


What is transcatheter aortic valve implantation (TAVI)?

A TAVI procedure is a treatment for severe aortic stenosis and another option to having a heart operation. It is lower in risk than heart surgery. Tubes called catheters are passed into the artery through a small cut at the top of the leg and moved up to the heart. A new valve is fixed to the catheter and then positioned over the narrowed valve (see previous page). The new valve can then start working. You will be able to go home after a short hospital stay, and hopefully get better quicker at home.

The arteries in our body are like a system of roads that branch out from the heart. There are 4 starting points that your doctor can use to implant the heart valve. The main one is through the artery in the top of your leg called the femoral artery; this is called the transfemoral approach. Sometimes this may be difficult to use so another starting point is used. Other options are through the chest wall using the subclavian artery, or a space between the ribs (transapical), or through the carotid artery in your neck (see diagram below).

The transfemoral approach is normally carried out using local anaesthetic, with drugs to relax you (sedation) as needed throughout the procedure. All other approaches are done under a general anaesthetic.



Possible access routes which can be used to implant the valve are:

1. An artery in your leg (transfemoral).
2. An artery under your collar bone (subclavian).
3. A space between your ribs (transapical).
4. Direct through the aorta (transaortic).
5. An artery in your neck (transcarotid).

What are the benefits of having a TAVI procedure?

The intended benefit is to treat severe disease of the aortic valve.

The new aortic valve will help your heart to work better and relieve some of your symptoms. It can also improve how you feel whilst doing normal activities and help you to live longer compared to having no treatment. The benefits may be individual to you and different for each person. Health problems related to other areas of the heart or other body organs may not necessarily improve.

What are the risks of a TAVI procedure?

Every procedure carries some risks and these can be different for each person. There are a number of risks related to TAVI which you have to consider before giving your consent to have the procedure done.

Common risks:

- bruising/ discomfort at the place the catheter is introduced is common.
- 1 to 3 in 100 risk of bleeding which may need an operation.
- 1 to 3 in 100 risk of heart attack/ stroke/ emergency angioplasty.
- 2 to 3 in 100 risk of contrast related kidney damage.
- 2 to 3 in 100 risk of valve infection.
- 10 to 20 in 100 risk of needing permanent pacemaker if there is a slow heart rate after the procedure.
- 1 to 3 in 100 risk of death from the procedure for a transfemoral approach.
- 5 to 20 in 100 risk of death from the procedure when using other surgical access routes (subclavian, transaortic and transcarotid).
- 20 in 100 risk of death from the procedure for a transapical approach.

Uncommon risks:

- Less than 1 in 1000 to 10,000 risk of radiation induced cancer.
- Less than 1 in 100 risk of valve dislodgement.
- Less than 1 in 100 risk of fluid collecting around the heart.

Other procedures may become necessary during surgery:

- Blood transfusion
- Urgent haemodynamic support or emergency cardiac surgery.

Your risks are always judged by a team including a consultant cardiologist, a doctor who specialises in imaging (radiologist), cardiac surgeon and referring specialist. You should discuss your individual risk with your consultant before giving your consent.

How do I know if TAVI is suitable for me?

The decision on whether TAVI is right for you will depend on a number of factors. A multidisciplinary team (MDT) meeting will be held to discuss your case in detail and work out the best treatment for you. This will be attended by various specialists, including interventional cardiologist, cardiothoracic surgeon, cardiac anaesthetist, cardiologist with specialist imaging expertise, and a specialist nurse. You will get a letter after the meeting to explain the outcome.

You will be asked to have some tests as an outpatient to make sure this procedure is suitable for you. You will need to have:

- A physical examination (listening to your breathing and sounds from your heart).
- An electrocardiogram (ECG) - a test to check your heart's rhythm and electrical activity.
- A chest X-ray.
- Blood tests.
- Transthoracic echocardiogram (ECHO) - a test using a probe and jelly on the chest to see pictures of the heart and how well it is working.
- A transoesophageal echocardiogram (TOE) – a test is sometimes done to take clearer pictures of the heart using a probe down your throat. You will be asked to lie down and swallow the tube. You may be given some drugs to help you relax before this is done. This test gives us more information before your procedure.
- A coronary angiogram - a test done as a day case by injecting a contrast dye through a small needle in your hand to look for any blockages or narrowing on the surface of your heart.
- A cardiac CT scan – a scan using X-rays to take pictures of the heart and blood vessels to check we are able to pass through the right sized valve into your heart. Contrast dye will be given through a small needle in your vein whilst the X-ray pictures are taken.

All the results we obtain from these tests will be assessed. You will only be accepted for a TAVI procedure after all the tests are completed and a decision made by your MDT. It is only at this stage that you will be placed on the waiting list for a date to have the procedure done. Once we have a date for you, we will send you a letter giving you the details of when to come into hospital.

What type of valve will I have?

There are lots of different types of valves available and your medical team will choose the best type for you.

Preparing for the procedure: pre-admission assessment clinic

You will be asked to attend a pre-admission appointment as an outpatient at Glenfield Hospital, before having the procedure:

- A nurse will assess your present condition and medical history. Further information will be given to you at this appointment and you will have an opportunity to ask questions.

- You will also need to have an electrocardiograph (ECG) and blood tests.
- Swab samples will be taken from your nose, perineum (an area of skin between your legs) and any wounds on your skin (e.g. from a leg ulcer), to check for MRSA.
- If your swabs show you are a carrier of MRSA you will be contacted and given advice on any treatment you may need.
- You will be given an antimicrobial wash (Stellisept) and nasal preparation (mupirocin/ Naseptin) with instructions on how to use them before you come into hospital.
- If you are taking any blood thinning medication (such as warfarin, apixaban, edoxaban, rivaroxaban and dabigatran), it is very important that you tell us as soon as possible as these may need to be stopped up to 2 days before your procedure.

If your are on aspirin, clopidogrel and tricagrelor, it is usually continued.

Giving your consent for the procedure

You will be asked to give your legal consent by signing a consent form, either when you see the operating cardiologist at your outpatient appointment or on the day of the procedure.

It is very important that you ask any questions or raise any concerns that you may have before signing the form.

Admission to hospital

- You will be admitted to hospital the day before your procedure.
- It is very important that you tell us if you have any known allergies (medication or others).
- The admission ward will repeat some blood tests. Blood will also be taken to cross-match in case you need a blood transfusion during or after the procedure.

What happens on the day?

- You will need to fast before your procedure. Solid food will need to be stopped 6 hours before your procedure, and all fluids must be stopped 2 hours before the procedure. Ward staff will inform you from when you have to be nil-by-mouth.
- Hair will be removed from your groin area, arms and chest.
- You will need to shower with an antibacterial wash then dress in a gown.
- A needle called a cannula will be inserted into the back of your hand.
- One dose of antibiotics will be given just before the procedure, before you are taken to the procedure room.

What happens during a TAVI procedure?

You will be taken on your bed to the catheter laboratory/ theatre. You will be helped onto the table and attached to monitoring equipment. There will be a number of staff in the room with you.

There are 5 ways the TAVI can be inserted:

1) Through an artery in your leg/ groin (transfemoral approach):

Most patients having transfemoral TAVI will have the procedure under a local anaesthetic with mild sedation. If your cardiologist has recommended local anaesthesia for you, it will be because it is considered safer than a general anaesthetic in your case.

If patients with poor kidney function weren't able to have a CT scan to determine the size of valve needed, you will need to have a transoesophageal echocardiogram (TOE) on the day of the procedure to determine this. In this case transfemoral procedures are done under a general anaesthetic, so you will be asleep.

- A short tube (sheath) is used to introduce the catheters and will be placed in both sides of the groin to allow catheter access to your heart through the femoral arteries. Another sheath will be placed on one side of the groin so that a small wire can be passed via a vein to the right side of your heart to ensure your heart beat does not run too slowly or fast during the procedure.
- The new valve is then carefully compressed and put onto a delivery catheter and threaded inside your existing diseased valve.
- Depending on the specific type/ brand of valve, when in position, it is expanded with a balloon or released to self-expand.
- Contrast dye will be injected through the catheter in the other groin to check the positioning of the artificial valve.
- At the end of the procedure the sheath used for the valve catheter will be removed and the small incision in your groin closed. The nurse will press on your groin for at least 15 minutes or so, to stop any bleeding. Once bleeding stops, a dressing will be applied.
- The one remaining sheath in your groin vein will usually be removed later in the day once your heart rate is stable. Once this final sheath is removed, you may still need 1 to 2 hours bed rest before you can move about.

Sometimes, due to the position of the arteries in your body, the procedure may need to be done a different way instead of by the femoral (groin) artery. Your consultant will explain the alternatives to you (see below).

2) Through an artery underneath the collarbone (subclavian approach):

If you are having a subclavian approach you will have a surgical wound underneath your collarbone about 5 to 7 cm (2 to 3 inches) long. This allows access to the subclavian/ axillary artery. This is carried out under a general anaesthetic so you would be asleep.

Specific complications to this approach include possible damage to the nerve supply to the arm, due to the surgical manipulation needed to access the artery (a nerve sending signals from your shoulder, arm and hand (brachial plexus) sits close to the subclavian artery). Such damage could cause loss of function which may be temporary or permanent.

3) Through a space between your ribs (transapical approach):

If you are having a transapical approach there will be a surgical cut (incision) about 7 to 10cm (3 to 4 inches) long on the lower part of the left side chest wall. This is carried out under a general anaesthetic so you would be asleep. You will need painkillers after the operation.

There are slightly greater risks of bleeding complications than with the transfemoral approach. There is a slightly lower risk of a stroke.

The transapical route is only used in patients with no other form of access, as there is a higher risk of death from this approach than from any of the other approaches.

4) Through the breastbone (direct transaortic approach):

Some patients are best suited for treatment by transaortic implantation. This is a surgical approach through the very upper part of the breastbone. It is a smaller incision than the one used by surgeons in an open heart surgery (around 7 to 10cm (3 to 4 inches)). This approach is carried out under a general anaesthetic. As with any surgical wound, there is a small risk of bleeding, pain or infection.

5) Through an artery in your neck (transcarotid approach):

In a small number of cases when the transfemoral approach is not feasible, as well as those above (subclavian, transapical and transaortic approaches), the left carotid artery can be used. A surgical incision is made on the left side of the neck below the lower jaw. This is carried out under a general anaesthetic.

Specific complications to this approach include possible dislodgement of fragment of calcium to the brain, causing a small risk of brain damage which may be temporary or permanent (stroke). This is mainly due to the carotid artery supplying blood to your brain.

What happens after the procedure?

- You will be taken to a recovery area for a short period of time for observation and then moved to a monitored bed in a cardiology ward (for transfemoral and subclavian approach).
- Patients who have been treated using the transapical, transcarotid or direct transaortic approach, will recover in the Intensive Care Unit under the guidance of the consultant.
- You will be attached to a heart monitor and a nurse will continue to monitor you and check the small wound at the top of your leg (groin) or wound site, as there is a risk of bleeding or swelling.
- You will have to bed rest for 3 to 4 hours after the procedure.

- If there are no issues with your groin site after 4 hours of bed rest, then we will try to mobilise you.
- Ward staff will get you something to eat and drink. You will usually be given sips of water first.
- Your hospital stay will normally be between 1 to 2 days. However, your stay may be longer if there are any complications after the procedure (see page 4).

Will I feel any pain?

You may feel uncomfortable at the site of the TAVI procedure, but this will wear off in a few days. There may be bruising or pain to your groin. The nurse looking after you will give you painkillers if needed.

Delirium

After a TAVI procedure it is possible for you to experience temporary changes to your thinking and behaviour (delirium). You may become disoriented, forgetful or have difficulty thinking clearly. Your health care team will ask you questions to assess your level of delirium and determine the best ways to help prevent or manage this.

How long does the TAVI procedure take?

The operation usually takes about 40 to 60 minutes if using the transfemoral approach. All other approaches mentioned can usually take around 2 to 3 hours.

How long will my TAVI valve last?

From our research and trial experience, the TAVI valve is showing that it will be as long lasting as a surgical valve used in an open heart operation, which can last up to 15 to 20 years. If the valve appears to be weakening this can be dealt with by a further TAVI operation.

Going home after the procedure

Patients often feel some improvement immediately, particularly with their breathing. You may have some discomfort where the catheters were inserted, but over a week or two this should get better. You can have medication to help with the pain if needed. It is important to remember that it may take 2 to 3 months for a full recovery from the procedure.

If you live alone, we suggest you arrange to have someone stay with you for at least the first 1 or 2 days after your discharge to help you to recover.

Please do ask any questions you may have before your discharge.

Medications:

- The majority of your medications will stay the same after your TAVI procedure.
- You will need to take blood thinning tablets after the procedure to prevent clots from forming on the new valve, if you are not already taking this. This will be for life.
- Your new prescription will be written on the discharge summary. A copy of this will be given to you and also sent to your GP. This will show what has happened to you in the hospital and which medications you are on.
- You will be told what medications to take before discharge, including any changes to your existing medication.

Eating and drinking:

You will be able to start eating and drinking as normal. If you had to restrict the amount of fluids you could drink before your procedure, you must continue to do so until you speak with your GP or your cardiologist tells you otherwise.

Activity and exercise:

- Keeping active is very important and everyone has a slightly different recovery speed based on their own general health. Most people will take 2 to 3 weeks to feel fully better.
- Avoid anything that may put a strain on your groin/ wound for 2 weeks after the procedure. **Do not** lift, push or pull anything heavier than 2 pounds during this period. For example **do not** do any vacuuming, laundry, grocery shopping, gardening or moving a golf cart.
- Exercise little and often. Start by walking around the house and increase gradually. For the first week take things slowly and rest if you need to. Aim to gradually increase exercise by walking only.
- Avoid strenuous activity for 3 to 4 weeks after the procedure. You don't have to avoid climbing stairs or walking up inclines, but you may have to start off at a slower rate.

Remember, everyone is different so exercise at a level that feels right for you.

Taking care of the wound site:

You will have a small wound and bruising at the site where the catheters were inserted, this is most commonly in the groin. If you had a transapical, transaortic or subclavian incision, then you will have a small wound at the site. It is usual for there to be some discomfort at the wound site. You should not need a dressing in place by the time you go home.

Any stitches remaining in the groin will either dissolve over the following weeks, or your medical team may tell you that you need to visit your practice nurse to have them removed.

Avoid putting soap, creams or talcum powder directly onto your wound until it has healed.

Check your wound site everyday. Contact your GP as soon as possible if you have:

- redness and warm that doesn't go away.
- yellow or green discharge from the wound.
- fever and chills.
- numbness in your leg which gets worse.
- pain at the site which gets worse.

In the unlikely event that your groin/ wound site starts to bleed, dial 999 (do not drive yourself to the Emergency Department). Whilst you wait for help:

- lie down flat.
- ask someone to apply pressure to the area. They must continue the pressure until bleeding stops or you get medical help.
- keep your leg as straight as possible and head down.

Bathing and showering:

- Avoid using very hot water for the first 2 weeks.
- It is better to shower rather than have a bath during this time.
- No need to cover the wound unless told to do so.
- Avoid putting soap, creams or talcum powder directly onto your wound until it has healed.
- Pat the wound site dry with a clean towel.

Blurred vision/ dots in front of the eyes:

This can be due to the contrast dye used by the doctor during the procedure. It should resolve shortly after the procedure. If it does not, please contact the nurse using the number on page 13.

Dental care:

Good oral care is important. If you have your own teeth and have not had a dental exam within 6 months, you should arrange a dental appointment as soon as possible. If any dental procedures are needed, have them done before your TAVI procedure as bacteria in the mouth can infect the new valve.

After a valve procedure, you must always tell your dentist or other doctors that you have a prosthetic valve in place. You may need to take antibiotics for any high risk dental work to prevent infection, such as:

- extractions.
- subgingival scaling.
- any procedures involving manipulation of the gingival tissue or the periapical region of teeth.
- perforation of the oral mucosa.

Sex life:

You can have sex when you feel ready. This is normally 4 to 6 weeks after the procedure. Discuss it with your partner and start once you are both happy and comfortable. It is normal to feel anxious the first time you think about having sex after your procedure.

Driving:

The Driver and Vehicle Licensing Agency (DVLA) state that you must not drive for at least 4 weeks after your procedure; you do not need to inform them.

HGV license holders must not drive for 3 months, **and must notify the DVLA.**

You should tell your insurance company to avoid problems with any claims you may make in the future.

Holidays and air travel:

If your procedure went well you may be able to fly after 4 to 6 weeks. Despite this, if you are planning a holiday it may be better to wait at least 6 weeks before travelling, as it is unlikely that you will get the best out of your break before then.

Check with your doctor first if you wish to fly within 3 months of your procedure. Also check with the airline as different companies will have their own procedures.

Remember to make sure you have valid travel insurance.

Returning to work:

This will depend on various factors such as the overall state of your health and the type of work you do. Please discuss this in more detail with your doctor.

If you need to have an MRI scan:

It is safe to have a magnetic resonance imaging (MRI) scan after a TAVI procedure, however, you must inform the scanning department that you have had a TAVI so they can check the safety of your scan. The scanning department can contact us if they need more information.

Important – if you are in need of immediate help, for example if you have chest pain, breathlessness, noticeable heartbeats (palpitations) or dizziness, please contact your GP immediately or go to your local Emergency Department.

Remember – if in doubt call 999.

Your follow-up appointments

We will arrange for you to have an outpatient appointment usually within 6 to 12 weeks after your discharge. After this, you will be asked to attend another follow-up appointment several months or 1 year later. If you were originally referred from another hospital, you will be discharged to your local cardiologist.

What if I need an interpreter?

Please tell a member of staff if you need an interpreter. We are committed to promoting equality for all patients.

Contact details

Structural Heart Valve Clinical Nurse Specialist: 07950 870853 (Monday to Friday, 8am to 4pm)

Structural Heart Valve Co-ordinator: 0116 258 3361 (Monday to Friday, 8am to 4pm)

Further information

British Heart Foundation – www.bhf.org.uk

The British Heart Foundation funds research into all heart and circulatory diseases and their causes. Their website has helpful information including:

- tests for heart conditions.
- heart valve disease.
- caring for someone with a heart condition.
- cardiac rehabilitation.
- a video about the TAVI procedure.

British Heart Valve Society – www.bhvs.org.uk

This is a group made up of medical staff with an interest in heart valve disease. It includes patient representatives. It is linked to the British Cardiovascular Society. It aims to improve the care of patients with valve disease by education and training programmes, literature and online information. It also aims to set standards of care for individuals, services and hospitals.

Heart Valve Voice – www.heartvalvevoice.com

This is a collection of people with real experiences of heart valve disease, including a group of experts in the field (cardiologists, cardiac surgeons, GPs), cardiac patient societies, and patients themselves. Their leaflets include “Recovering from treatment”, “Post-treatment checklist”, and “10 surprising things you may not be able to do right after your treatment.”

Glossary of terms

Cardiac catheterisation: this is a procedure to examine how well your heart is working. It is also to find out if you have disease of the heart muscle, valves or heart (coronary) arteries. During this test, doctor's put a long, narrow tube called a catheter into a blood vessel in your arm or leg and guide it to your heart with the aid of a special X-ray machine. Doctors use contrast dye that they inject into your blood vessel through the catheter to create X-ray videos of your valves, arteries, and heart chambers.

Catheter laboratory (cath lab): this is an examination room in a hospital or clinic with diagnostic imaging equipment used to look at the arteries and chambers of the heart, and treat any stenosis or abnormality found.

Contrast dye: this is a solution that radiologists use to see your organs and tissues more clearly in medical images such as X-rays, MRI and CT scan.

Coronary angioplasty: your doctor inserts a catheter with a tiny balloon at the tip into your arteries supplying blood to your heart. When this balloon is inflated, it pushes plaque out and widens your artery. A tiny mesh tube called a stent is placed into your artery to help keep it open.

Haemodynamic support: this means to use medications to keep your blood pressure and heart rate within the normal range.

Intensive Care Unit (ICU): this is a specialist ward within a hospital that provides close monitoring and treatment for patients who are very ill.

Multidisciplinary team (MDT): this is a group of professionals from one or more clinical areas, who together make decisions about the best form of treatment for individual patients.

Percutaneous: this is a method to access the inner organs via a needle puncture of the skin.

Radiologist: this is a doctor who is specially trained to interpret diagnostic images such as X-rays, MRI and CT scans.

Transcatheter aortic valve implantation (TAVI): this is a procedure using catheters to replace a narrowed aortic valve in the heart.

Transoesophageal echocardiogram (TOE): a test is sometimes done to take clearer pictures of the heart using a probe down your throat. You will be asked to lie down and swallow the tube. You may be given some drugs to help you relax before this is done.

