Transcatheter mitral valve replacement (TMVR) with the SAPIEN M3 system

This factsheet contains information about having a procedure called transcatheter mitral valve replacement (TMVR). It explains what TMVR is, what the procedure with the SAPIEN M3 system involves and what the possible risks are. We hope it helps you to decide whether this procedure is right for you. If you have any further questions or concerns about having this procedure, please contact us using the details at the end of this factsheet.

What is the mitral valve?

The mitral valve is one of the main valves that controls the blood flow through the heart. It sits in between the left upper chamber and the left lower chamber of the heart, separating the two chambers.

The mitral valve consists of two parts:

- **Leaflets** - These work like a door. The leaflets open to allow forward blood flow and close to prevent backward blood flow.
- **Chordae tendinae** – These are strong, fibrous cords of tissue that act as a support structure, keeping the leaflets in their correct positions.

If either of the above parts fail to work normally, the heart has to work harder and less efficiently. This is commonly known as ‘heart failure’.

Symptoms of heart failure include:

- feeling breathless
- feeling tired
- swollen ankles

What is TMVR?

TMVR is a new procedure that has been developed over the past 10 years to treat heart failure caused by a damaged or incorrectly working mitral valve. The procedure involves placing an artificial (man-made) heart valve inside the pre-existing mitral valve, helping the valve to work normally.

What is the SAPIEN M3 system?

Open-heart surgery is the main procedure used to fix abnormalities of the mitral valve. Open-heart surgery is a type of heart surgery that involves a surgeon opening your chest wall, placing your body on a heart and lung machine (a machine that helps pump blood around your body during surgery) and working directly on your heart. This is a major surgery and is not suitable for many people.

The SAPIEN M3 system is the latest TMVR system and is designed for people who are not fit enough to safely go through and recover from open-heart surgery.

Is the SAPIEN M3 system suitable for everyone?

To determine whether the SAPIEN M3 system is suitable for you, we will invite you to our cardiac outpatient clinic (located on D level at Southampton General Hospital). At this appointment, a doctor will:

- discuss your symptoms
- perform a physical examination
- explain the procedure and answer any questions you may have
- perform the following tests:
  - blood tests
  - an electrocardiogram (ECG) (a test that records the electrical activity of your heart, including the rate and rhythm)
  - an echocardiogram (a scan of your heart that is done to see how well your heart is working)
  - a transoesophageal echocardiogram (TOE) (a type of echocardiogram where a thin tube containing a small ultrasound device is passed into your mouth and down into your oesophagus (gullet or foodpipe) to create a more detailed image of your heart)
  - a heart CT scan (a scan that uses x-rays to create detailed pictures of your heart and surrounding blood vessels)
- review all your test and investigation results

Based on this information, the doctor will then make a decision with you (and your family) if this procedure is suitable for you. If it is, we will place you on the waiting list for the procedure.

Are there any alternatives?

Alternative treatment options for heart failure include:

- open-heart surgery
- medication

If the SAPIEN M3 system is not suitable for you or you do not wish to have this procedure, we will discuss these alternative options with you, including explaining the benefits and risks of each.

How should I prepare for the procedure?

Personal hygiene

It is important to maintain good hygiene. Have a shower the night before your procedure. Pay special attention to washing under any skin folds, such as under the breasts, the groin, and the genital area.

Do **not** shave or remove hair from your chest, arms, legs, or groin before the procedure. If any areas of your body need to be shaved for the procedure, we will do this in the hospital before your procedure.

Eating and drinking

Do **not** eat or drink anything after midnight on the day of your procedure, except for water, which you may drink up until 6am on the day of your procedure (unless we tell you otherwise).

Medication
You can continue to take your medications as usual unless your doctor has asked you not to do so.

Items to bring with you
You will need to stay in hospital overnight after having the procedure. Please pack an overnight bag containing the following items:

- all your current medications (in their original packaging)
- a dressing gown and well-fitting slippers
- loose, comfortable clothes
- toiletries (for example, a toothbrush and toothpaste)
- reading material (for example, a book or an electronic device with headphones)

Travel arrangements
You will need to arrange for a responsible adult to collect you from the hospital and drive you home, as you will not be able to drive or travel home on your own after the procedure.

What will happen before the procedure?

When you arrive at the ward (please see your appointment letter for specific location details), a nurse will meet you and show you to your bed. We will explain the procedure to you, including the benefits and potential risks. This is a good opportunity for you to ask any questions you may have. We will then ask you to sign a consent form if you are happy to proceed with the TMVR.

An anaesthetist (a specially trained doctor who gives medication to send you to sleep during a procedure) will then meet with you to discuss having a general anaesthetic (medication to send you to sleep). The general anaesthetic will either be given as:

- a liquid that is injected into your veins through a cannula (a thin, plastic tube that is placed into a vein in your hand or arm) **or**
- a gas that you breathe in through a mask **or**
- a combination of both options.

Please note that if you are scheduled to have an afternoon procedure, we cannot give you an exact start time as this will depend on earlier procedures. We thank you for your patience.

What will happen during the procedure?

The TMVR will be performed in the cardiac catheterisation suite (located on E level at Southampton General Hospital) by a cardiologist (a doctor who specialises in treating conditions of the heart and blood vessels).

When you arrive, we will check your identification and go through a checklist with you. The anaesthetist will then send you to sleep in preparation for your procedure.

Once you are asleep, we will make a 1cm cut in your groin. We will then place a catheter (a thin, flexible tube) into a vein in your groin and guide it up to your heart. Once the catheter is in the correct place, we will insert a new artificial valve across your existing mitral valve. Occasionally, we may need to place more than one valve to get the best possible outcome. Lastly, we will remove the catheter from your body and stitch up the cut in your groin.

How long will the procedure take?

The procedure usually takes between two and three hours.

What will happen after the procedure?

After your procedure, we will take you to one of our cardiac wards where you will need to stay overnight so that we can monitor your recovery.

After you have recovered from the general anaesthetic, the doctor who performed your procedure will check on you and give you your results.

You will be able to eat and drink as soon as you feel ready.

The day after your procedure, a nurse will check the area in your groin where the catheter was inserted and cover the wound with a dressing. Please note that the area around your groin may have some bruising and may feel a little tender for several days.

We will arrange for you to have an echocardiogram the day after your procedure to check that the valve is working well. If you are feeling well and your doctor is happy with your results, you will then be able to go home.

Recovering at home

When you are back at home, you can gradually return to your normal activities. However, you must avoid strenuous exercise or heavy lifting for a week after the procedure.

You must **not** drive for 72 hours after your procedure.

It is important that you keep the area around your groin clean and dry. The cut will form a scab and heal within a week. If the area becomes red or starts to itch, ooze or swell, contact us for advice using the details at the end of this factsheet.

Are there any risks or potential complications?

As with all surgical procedures, TMVR with the SAPIEN M3 system does have some potential risks and complications. We have included the risks and complications below in the likelihood of them occurring.

Common

- Major bleeding (8.7%)
- Atrial fibrillation (a type of heart rhythm problem where your heartbeat is not steady) (7.9%)
- Haemolysis (the breakdown of red blood cells) (4.3%)
- Complications in the groin such as bleeding or infection (3%)
- Stroke (2.7%)
- The need for a permanent pacemaker (a small device that can be used to treat heart rhythm problems) (2.6%)
- The need for further mitral valve surgery (2.3%)
- Structural damage to the heart that needs emergency surgery (2.3%)
- Blood clot formation on the valve (2.3%)
- Kidney injury that needs dialysis (a procedure to remove waste products from your blood if your kidneys are not working properly) (1.7%)

Rare
- Death (less than 1%)

Very rare
- Trauma to the oesophagus caused by the TOE probe (0.08%)

Your doctor will explain all these risks and potential complications to you in more detail and answer any questions you may have.

When should I seek medical help?

Go to your nearest emergency department immediately if you experience any of the symptoms below:
- extreme shortness of breath
- a fever (a temperature of 38°C or above)
- chest pain

Will I need any follow-up care?

We will arrange a follow-up appointment about six weeks after your procedure. We will also arrange for you to have an echocardiogram at this appointment to check how well your valve is working.

Contact us

If you have any questions or concerns, please contact us.

Cardiology secretary
Telephone: **023 8120 4240** (Monday to Friday, 9am to 3pm)

Useful links

www.nhs.uk/tests-and-treatments/echocardiogram

www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/tests/ct-scans-of-the-heart

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For help preparing for your visit, arranging an interpreter or accessing the hospital, please visit **www.uhs.nhs.uk/additionalsupport**

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