

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

IS THE **TAVR VALVE** RIGHT FOR YOU?

The TAVR valve is for people with severe aortic stenosis (AS) and are at high risk or greater risk for surgical aortic valve replacement. Your doctor can help you decide if this device is right for you. This booklet will help you learn more about the TAVR/ TAVI valve.

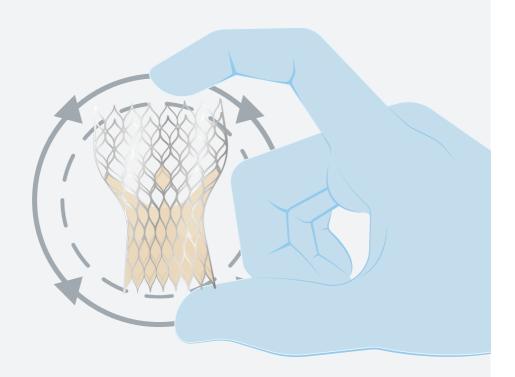


TABLE OF CONTENTS

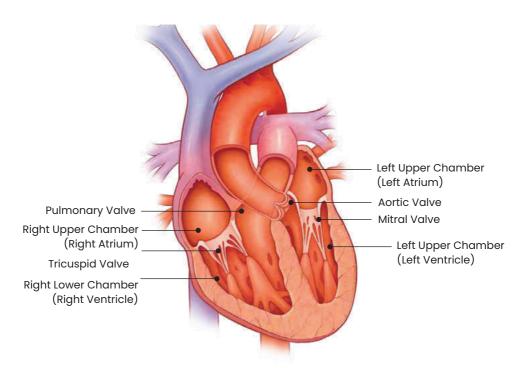
About the Heart	1-2		
Aortic Stenosis	2-3		
Treatment Options for Your Severe			
Aortic Stenosis	4		
Treatment of Your Severe Aortic Stenosis			
Using a TAVR Valve	5		
Understanding the TAVR Procedure	6		
After the TAVR Procedure	7		
Benefits and Risks	8		
Warnings and Precautions	9		
Frequently Asked Questions (FAQs)	10		
TAVR Clinical Trials			
Other Potential Risks	12		

About the Heart

How the Heart Works?

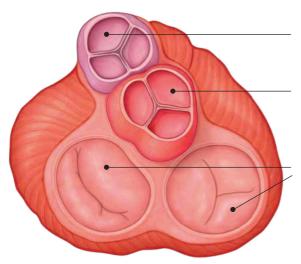
A healthy heart beats around 100,000 times a day. The heart's job is to supply the body with oxygen-rich blood.

The heart has four chambers. Blood is pumped through the four chambers with the help of four heart valves.



What Heart Valves Do?

Heart valves open when the heart pumps to allow blood to flow. They close quickly between heartbeats to make sure blood does not flow backward. Any trouble in this normal flow will make it hard for the heart to pump the blood where it needs to go.



The pulmonic valve controls the flow of blood to the lungs to get oxygen

The aortic valve controls the flow blood as it exits the heart and is pumped to the rest of the body.

The mitral and tricuspid valves control blood flow as it moves between the chambers of the heart

Severe Aortic Stenosis

Severe Aortic Stenosis (Severe AS) of Your Native Valve

Your native valve is the valve you were born with. Severe AS occurs when your aortic valve does not open as it should. This makes your heart work harder to pump blood through your body. This aects your health and limits your normal daily activities.

Severe AS may be caused by the following:

- Age
- Calcium buildup that narrows the aortic valve
- Radiation therapy
- Infection of the heart
- Left untreated, severe AS can lead to heart failure or even sudden death.

Failing Surgical Aortic Valve

Some people have had their own valve replaced with surgery. Surgical valves wear out over time. The surgical valve can start to fail. The Medtronic TAVR valve might be an option for these people.

Signs of Severe Aortic Stenosis

Severe AS may cause you to feel:

- Chest pain
- Fain

Dizzy

- Tired
- Out of breath
- Irregular heart beat



Normal Valve



Stenotic Valve

Treatment Options for Your Severe Aortic Stenosis

Medication and Balloon Valvuloplasty (BAV)

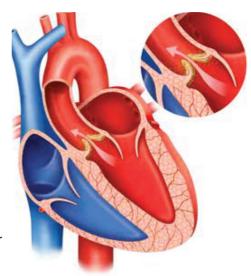
Your doctor may give you medicine to help ease the symptoms of your disease. A procedure called BAV may also be done. BAV is not surgery. This is where a balloon is placed in the aortic valve and inflated. This may help the valve function better, but is only a temporary fix. Without valve replacement you could feel worse over time.

Surgical Aortic Valve Replacement (SAVR)

SAVR is an option for some people with severe AS. The native valve is removed and replaced with a new valve.

SAVR often includes the following:

- Your chest is opened to access the heart.
- Your heart is stopped.
- A machine pumps blood through your body.
- Your diseased valve is removed.
- The new valve is sewn into place.
- You may be in the hospital for more than a week.



Treatment of your Severe Aortic Stenosis using the TAVR system

Transcatheter Aortic Valve Replacement

The TAVR valve is another option for people with severe AS. It does not require open heart surgery. It is implanted using an artery that leads to the heart.

The TAVR valve is made from pig heart tissue. This tissue valve is held by a metal frame. It is designed to work like your own heart valve.

The TAVR valve is recapturable, allowing your doctor to accurately position your new heart valve.



Evolut PRO Valve



Edwards Sapien 3



My Vac - 1

Understanding the TAVR Procedure

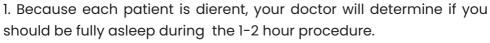
How Does the TAVR Valve Get to My Heart?

The arteries in your body are like a system of roads. They branch out rom the heart. There are dierent "routes" that your doctor can use to get to your heart.

These include:

- 1 An artery in your leg
- 2 An artery in your neck
- 3 A space between your ribs
 Or another entry point determined
 by your doctor

Each route has risks.
Discuss them with your doctor.



- 2. The doctor will make a cut and guide a long tube (sheath) into your artery.
- 3. Your doctor will place the TAVR valve in position within your own diseased heart valve or your failing surgical valve. (Figures 1 and 2)
- 4. Your new TAVR valve will begin opening and closing. (Figure 3) The doctor will conduct a test to confirm it is working properly.
- 5. The thin, flexible tube will be removed, the cut will be closed, and the operation will be complete.



Figure 1
Catheter with
Compressed
Valve



Figure 1 Valve Starting to Expand



Figure 1 Valve fully Expanded

After the TAVR Procedure

Follow-up Care

When you leave the hospital your doctor will give you care instructions. You may have to limit certain activities. You will need to take medicine and have your heart checked from time to time. Talk to your doctor any time you have questions or concerns about your new heart valve.

If you require an MRI* scan, tell the doctor that you have a TAVR valve. Tell your doctor if you have a TAVR valve inside a surgical valve. Not doing so could result in injury or death. Your dentist and all doctors need to know about your valve.

You will get a card with your TAVR heart valve information. Keep this card with you. Show it to any doctors who may be treating you. If you do not get a card, contact your doctor.

The lifespan of the TAVR valve will vary from patient to patient. It has been tested to mimic 5 years of use without failure.

Keep appointments with your doctor. Follow all care instructions to ensure the best possible results.

Hospital Stay

You will stay in the hospital until your doctor decides you are able to leave. Patients are often walking in a day or two.



^{*}Magnetic Resonance Imaging

The TAVR System Benefits and Risks

Benefits

You should start feeling better right away. This is because your heart valve is now working properly. Some patients may take longer to feel better.

Most patients felt less pain and less anxious. They could take care of themselves better and go back to everyday activities.

If you are interested, ask your doctor for more information on additional clinical studies.

Risks

Most medical procedures have risks.

The TAVR procedure's most serious risks are:

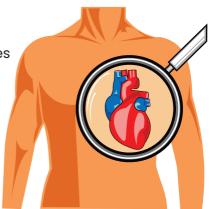
- DeathStroke
- Serious damage to the arteries Serious bleeding

The TAVR Procedure is Not Right for Everyone

The TAVR Valve Should NOT be Used for the Following People:

- · Have an infection
- · Have a mechanical valve
- Cannot take blood thinning medicines
- Have a reaction to some metals
- Have a reaction to some imaging solutions

If the TAVR valve is used in the patients mentioned above, it may not work properly. This could make you feel very sick or even cause death. For some patients, the risk of the TAVR procedure may outweigh the benefits. See page 9 for the risks and benefits associated with the TAVR procedure.



Available valves in India and Metro Hospitals are

- Sapien 3 from Edward life sciences
- Evolute R and Pro from Medtronic
- Myvalve from Meryl Life sciences
- Hydra from SMT lifesciences

Warnings and Precautions

Warnings

Some patients may have a disease that results in more calcium in their blood. This may cause early wear.

The TAVR valve is only for certain patients. This includes patients with severe AS or failing surgical valves that:

Cannot have surgery

· Are at high risk for surgery

Precautions

- At some point the TAVR valve may need to be replaced. How long it lasts varies from patient to patient.
- It has been tested to mimic 5 years of use without failure. Keep appointments with your doctor. Follow all care instructions to ensure the best possible results.
- Antibiotics are recommended for patients who are at risk of infections.
- Patients should stay on blood-thinning medicines after the procedure as instructed. Patients who do not, are more likely to have a stroke.
- If you require an MRI scan, tell the doctor that you have a TAVR valve. Tell your doctor if you have a TAVR valve inside a surgical valve. Not doing so could result in injury or death. Your dentist and all doctors need to know about your TAVR valve.

The TAVR valve has not been studied in patients:

- · Who are not sick from AS
- Who are children
- With an aortic valve that has only one or two leaflets
- Who have a blood clot
- With an abnormal growth in the heart or arteries
- · Who have an infection
- Who have AS in their own valve and a condition that allows blood to leak backwards through the aortic valve
- · Who have severe mitral valve disease
- · With poor left ventricle function
- Whose diseased valve is too small or too big
- · Whose arteries are too small for the device
- · Whose arteries that deliver blood to the heart may be blocked by the device
- · Whose arteries that deliver blood to the heart need to be treated
- Whose arteries that deliver blood to the brain need to be treated
- Who have severe problems with bleeding or blood clotting
- Who have specific types of surgical valves implanted in the pulmonary valve
- Who have specific types of surgical valves implanted in the mitral valve
- · Who have thick heart muscles making it dicult for the heart to pump blood
- Who have thick heart muscles that blocks the heart from pumping blood

If the TAVR valve is used in these patients, it may not work right. This could make you feel sick or cause death. For some, the risks of the TAVR valve procedure may outweigh the benefits. See page 9 for the risks and benefits.

Frequently Asked Questions

Q. Are physical activities safe?

A. Discuss this with your doctor. They can help decide what is best for you.

Q. Is it safe to have an x-ray with a TAVR valve?

A. Yes. The a TAVR valve is safe for x-rays.

Q. Is it safe to have a MRI with a TAVR valve?

A. Yes, under certain conditions. If you require an MRI scan, tell the doctor that you have a TAVR valve. Tell your doctor if you have a TAVR heart valve inside a surgical valve. Not doing so could result in injury or death.

Q. How will I know if my TAVR valve is working right?

A. Attend regular follow-up doctor visits to check your valve.

Clinical Studies

TAVR System Clinical Studies

The TAVR heart valve has been tested in many studies.

Ask your doctor for more information on the clinical studies on the following patient groups:

• High Risk Patients

- Extreme Risk Patients
- Failing Surgical Valve Patients
- Severe Renal Disease Patients
- · Low-Flow/Low-Gradient (LFLG) Patients

Evolut R System Study Overview

These patients were at high risk or were too sick for surgery. This group included 166 patients at 24 hospitals in the US, Australia, New Zealand and the United Kingdom.

Patients were seen at 30 days and I year.

Yearly checkups will continue for 5 years.

The Evolut R valve works like the previous generation CoreValve valve. The CoreValve TAVR System study results at 1 year showed:

- The CoreValve procedure was a safe and eective alternative to surgery
- More CoreValve heart valve patients were alive than surgical patients

Quality of Life Improvements

A standard tool* was used to assess health at 30 days.

Most TAVI Patients valve patients:

• Felt less pain

- Had improved health
- Were less anxious
- Could take care of themselves better
- Went back to everyday activities

The improvement in the patients was similar to the first generation TAVR valve patients at 1 year.

^{*} This quality of life tool is called the Kansas City Cardiomyopathy Questionnaire (KCCQ)

HEART VALVECLINIC DIAGNOSTIC **TESTS**

CHECK	TEST	DESCRIPTION	PURPOSE
	Cardiac Catheterization	 A long, thin tube called a catheter is inserted into your leg or arm and threaded through your blood vessels to your heart. The tube releases dye, which helps the heart and blood vessels show up clearly on an X-ray. The tube also collects information about the pressure and blood flow in your heart. 	Detects disease of the heart muscle, valves, or coronary arteries.
	CT Scan	You will lie on a table that moves into a scanner (a big machine with a hole in the middle). The scanner will take detailed X-ray pictures of your heart and blood vessels.	Measures the shape and size of your heart and your artery system.
	Echocardiogram	Uses sound waves to make an image of your heart. There are two types of echocardiograms. The transthoracic echocardiogram (TTE) uses a small device that is pressed against your chest, and the transesophageal echocardiogram (TEE) uses a small device placed directly down your throat.	Allows your doctor to see how blood flows through the heart chambers, heart valves, and blood vessels.
	Carotid Ultrasound	Uses sound waves to create pictures of the insides of arteries in your neck.	Checks for blocked or narrowed arteries.
	Pulmonary Function Test (PFT)	Pulmonary function tests are sometimes called breathing tests.	PFTs determine how well you move air inand out of your lungs.
	Laboratory Tests	Blood tests	Detects abnormalities in your blood.
	Physical Exam	General examination	Check your overall health.
	Frailty Testing	Physical tests to assess strength, balance, and mobility	Check your overall health.
	Additional Testing		



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- Metro Premier Medical Centre Muscat, Oman
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EDUCATION WING

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3000+ Beds



80 Lakhs+



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3500+ Staff

Metro Heart Institute

Cardiac Wing: X-1, Sector-12, Noida 201301

For any assistance, please call: 8447 666 333