Aortic Stenosis Diagnosis

Heart Valve Clinic Visit

Aortic Valve Replacement

Living with a Valve Replacement

CoreValve™
Transcatheter Aortic Valve Implantation (TAVI) platform

THE AORTIC STENOSIS PATIENT JOURNEY

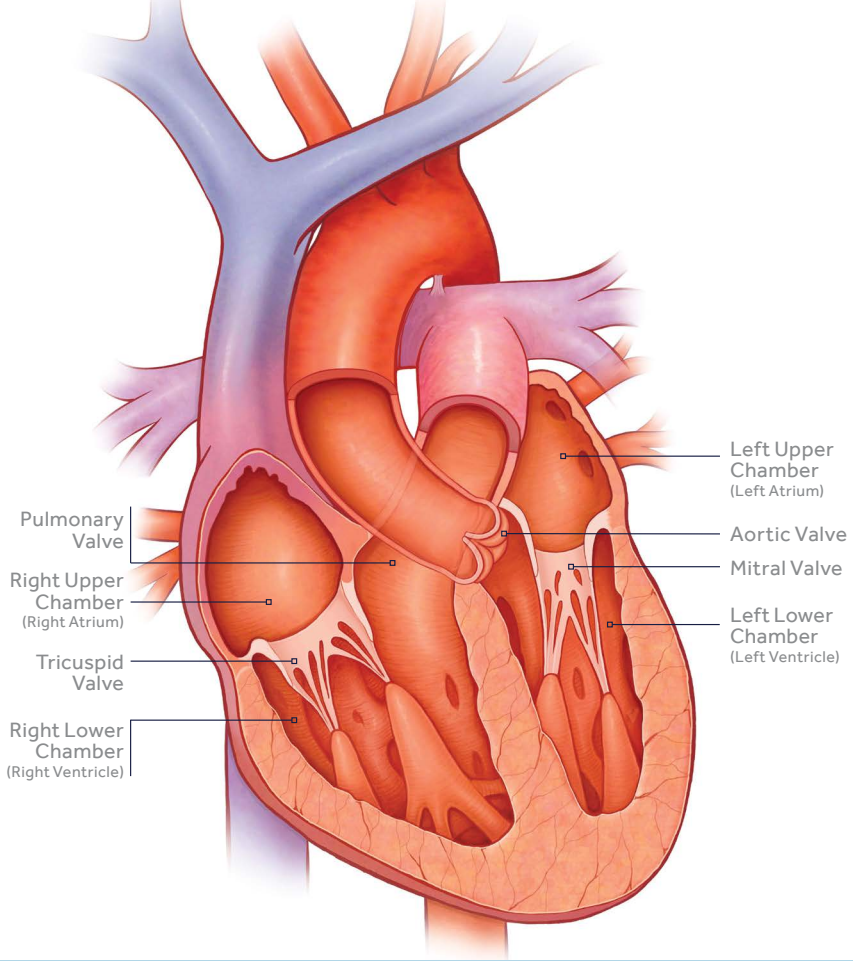
Patient Education Support in the Heart Valve Clinic

Medtronic
Further, Together

AORTIC STENOSIS
OVERVIEW

How the Heart Works

- The heart's job is to pump oxygen-rich blood through the body
- Blood is pumped through 4 chambers of the heart with the help of heart valves
- The aortic valve controls the flow of blood as it exits the heart and is pumped to the rest of the body



DID YOU KNOW?

A healthy heart beats about 100,000 times a day.

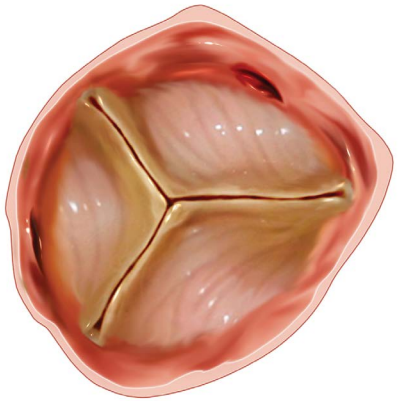
SYMPTOMS OF AORTIC STENOSIS

When an aortic valve has narrowed, usually due to a buildup of calcium:

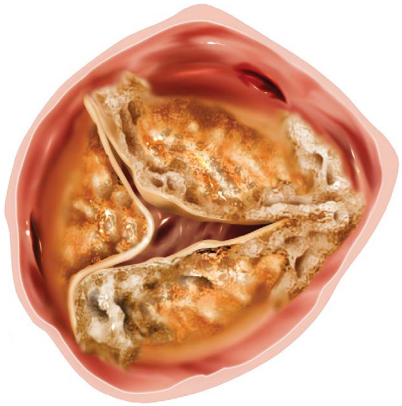
- The valve is unable to fully open
- Your heart cannot pump blood like it needs to

Symptoms of aortic stenosis

- Chest pain or tightness
- Feeling faint or fainting
- Dizziness
- Feeling tired
- Shortness of breath
- Irregular heart beat
- Heart murmur



Normal Valve



Stenotic Valve

Aortic Stenosis Diagnosis

DID YOU KNOW?

Leonardo Da Vinci studied how the heart works as a hobby. He referred to the 3 aortic valve leaflets as the “little doors of the heart.”

AORTIC STENOSIS
DIAGNOSIS

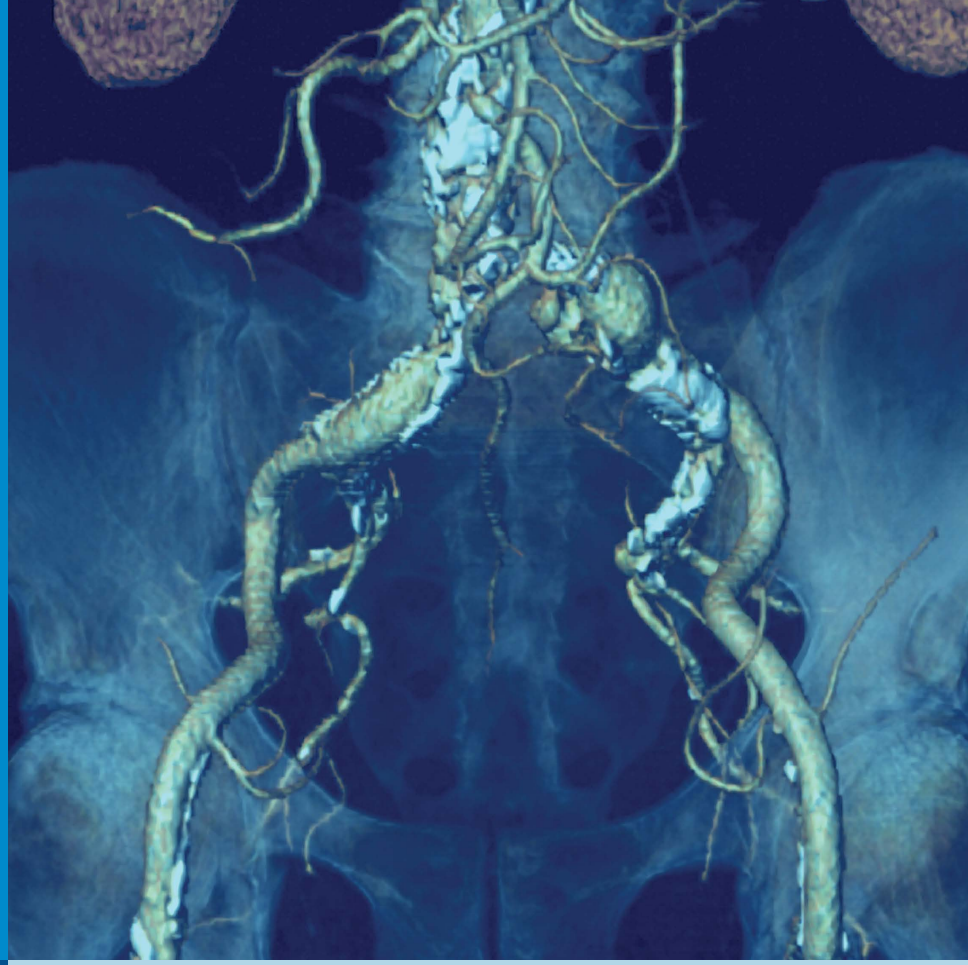
Your doctor can detect a heart valve problem by:

- Talking to you about your symptoms
- Listening to your heart
- Performing tests

EVALUATION & TESTING

Your heart team will conduct tests to determine your treatment plan. Common tests for diagnosing AS:

- Cardiac Catheterization
- CT Scan
- Echocardiogram
- Carotid Ultrasound
- Laboratory Tests
- Physical Exam
- Frailty Testing
- Additional Testing



DID YOU KNOW?

Using a CT scan of your heart and arteries, your medical team can create a 3D image to help with your treatment.

TREATMENT OPTIONS

Your heart team will decide which of the following treatment options is best for you.

Heart Valve Replacement

Transcatheter Aortic Valve Implantation (TAVI)
Your natural valve is replaced during an operation without open heart surgery.

Surgical Aortic Valve Replacement (SAVR)
Your natural valve is removed and replaced during an open heart surgery.

Medication and Balloon Valvuloplasty (BAV)

Medication may help relieve some symptoms of AS.

BAV is a non-surgical procedure that may help relieve symptoms. A balloon is placed in the aortic valve and inflated to create a larger opening.

Medication and BAV may alleviate some of your symptoms, but do not treat severe AS or alter its progression.

Heart Valve Clinic Visit

TAVI DEVICE

The CoreValve™ Heart Valve

- A valve made from the heart tissue of a pig
- The valve tissue is held by a Nitinol (nickel-titanium) metal frame
- Three valve leaflets control the flow of blood like your natural valve

After a CoreValve heart valve procedure, people usually start feeling better right away. This is because their hearts are now able to pump the right amount of blood to the body. Some patients may take longer to feel better.

Most medical procedures have risks. The most serious risks of the CoreValve procedure are:

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding

Aortic Valve Replacement

DID YOU KNOW?

Nitinol has shape memory which means the metal can be squeezed into a thin tube (catheter) when it is cooled but is able to recover its original shape when warmed up to body temperature.

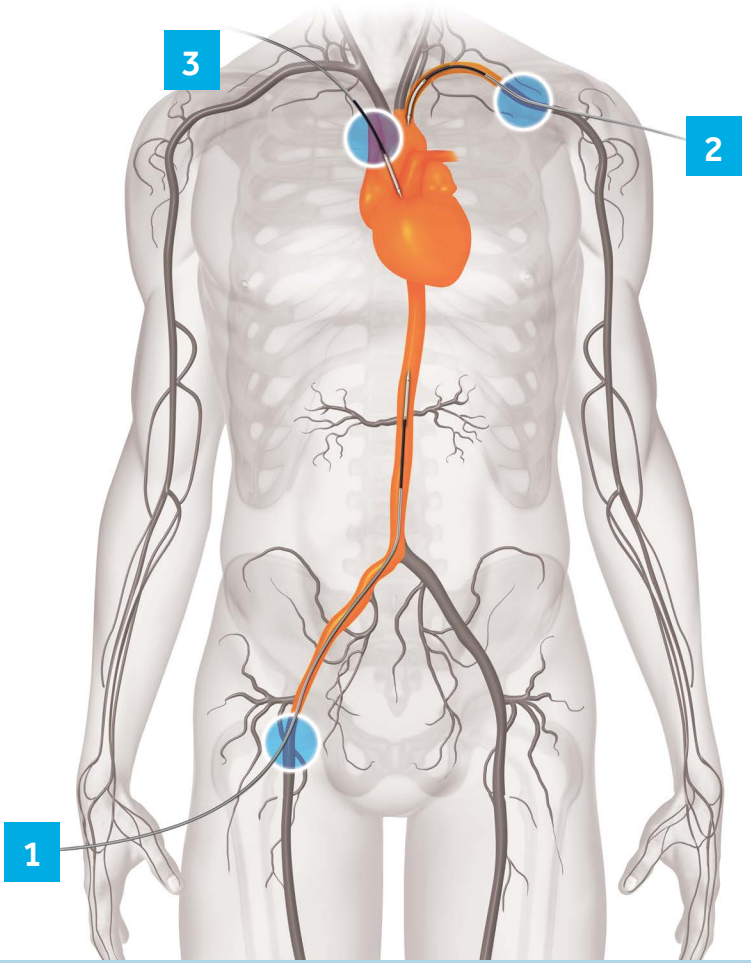
TAVI
PROCEDURE

In the CoreValve procedure, a thin, flexible tube (catheter) is inserted into one of several "access routes":

- An artery in your leg (**1**)
- An artery in your neck (**2**)
- An space between your ribs (**3**)
- Other

Throughout the procedure you will be under anesthesia or sedation.

A temporary pacemaker will be inserted to allow your doctor to control your heart rate as needed.



DID YOU KNOW?

The arteries in your body are like a system of roads that branch out from the heart.

There are different "routes" that your doctor can use to implant the CoreValve heart valve.

TAVI RECOVERY & DISCHARGE

Aortic Valve Replacement

STEP 1: INITIAL RECOVERY

After surgery you will start the recovery process.

TAVI RECOVERY & DISCHARGE

STEP 2: HOSPITAL STAY

- You should be up and walking within a day or two
- 3-10 days is a **typical** hospital stay for this procedure, but varies by patient

Aortic Valve Replacement

TAVI RECOVERY & DISCHARGE

Aortic Valve Replacement

STEP 3: DISCHARGE

- At discharge, your doctor will determine whether you'll head home or to a cardiac rehab facillity
- You will also recieve information about medications, activities, and follow-up visits

TAVI
CONTINUING CARE & CARDIAC REHABILITATION

When you leave the hospital, you will either go home or to a cardiac rehab facility. Exercise-based cardiac rehab, supervised by doctors and cardiac rehab specialists, may be part of your recovery plan.

Your doctor will also provide instructions for your care:

- Use of medications, including blood thinners
- Restrictions on activities
- Plans for follow-up appointments
- Other special instructions (MRI, dentist, etc.)

You will get a patient card with CoreValve heart valve patient information. Keep this card with you and show it to doctors who may be treating you.

TAVI
FOLLOW-UP VISITS

Typically you will be asked to return to the heart valve clinic to have your heart valve checked at 30 days and 1 year after your procedure. Your doctor will set up regular follow-up appointments with you to check how you're doing with your new heart valve.

IMPORTANT RISKS AND CAUTIONS FOR TAVI AND SAVR

Risks

Most medical procedures have risks. The CoreValve procedure's most serious risks are:

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding

Warnings

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

The CoreValve heart 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 CoreValve heart 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 CoreValve heart valve. Tell your doctor if you have a CoreValve heart valve inside a surgical valve. Not doing so could cause injury or death. Your dentist and all doctors need to know about your CoreValve heart valve.

IMPORTANT RISKS AND CAUTIONS FOR TAVI AND SAVR

The CoreValve heart 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
- 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 severe kidney disease that requires dialysis
- 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 difficult for the heart to pump blood
- Who have thick heart muscles that blocks the heart from pumping blood

If the CoreValve heart 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 CoreValve procedure may outweigh the benefits.

THE COREVALVE PROCEDURE **IS NOT RIGHT FOR EVERYONE**

The CoreValve Heart Valve Should NOT be Used for the Following People:

Patients who:

- 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 CoreValve heart 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 CoreValve procedure may outweigh the benefits.

OTHER POTENTIAL RISKS
ASSOCIATED WITH THE COREVALVE PROCEDURE

- Cardiogenic shock - failure of the heart to pump enough blood to the body organs
- Perforation of the myocardium or vessel - a hole in the heart muscle or a blood vessel
- Cardiac Tamponade - the constriction or inability of the heart to pump due to buildup of blood or fluid around the lining of the heart
- Ascending aorta trauma - injury to the large blood vessel leading blood away from the heart
- Embolism - an abnormal particle (air, blood clots) floating in the blood stream or attached to an object, including the valve
- Thrombosis (including valve thrombosis) - blood clot, including a blood clot on the valve
- Valve migration - upward or downward movement of the device from where it was originally placed
- Valve dysfunctions of the CoreValve device including but not limited to:
  - Break (fracture) in the valve frame
  - Bending of the valve frame
  - Valve frame does not open (expand) all the way
  - Buildup of calcium on the valve
  - Pannus - the formation of scar tissue that may cover or block the valve from functioning normally
  - Wear, tear or movement forward (prolapse) or backward (retraction) from the normal position of the valve leaflets
  - Valve leaflets do not close together
  - A break in the stitches (sutures) of the valve frame or leaflets
  - Leakage through or around the valve or valve frame

- Incorrect size of the valve implanted
- Incorrect position of the valve, either too high or too low
- Regurgitation - backward flow of blood through the valve
- Stenosis - narrowing of the opening of the valve

- Mitral valve regurgitation - blood leaking backwards through the valve between the left lower chamber of the heart to the left upper chamber of the heart
- Hypotension or hypertension - low or high blood pressure
- Unfavorable reaction by the body (allergic reaction) to:
  - Antiplatelet agents - blood thinning medicines that keep blood clots from forming
  - Contrast medium - a substance used to increase the visualization of body structures such as X-ray dye
- Bowel ischemia - decreased blood supply to the intestines
- Complications at the area where the doctor cut the skin or related to cutting the skin, including but not limited to:
  - Pain
  - Bleeding
  - Hematoma - blood collecting under the skin
  - Pseudoaneurysm - blood collecting on the outside of a vessel wall causing a balloon-like widening
  - Irreversible nerve damage - permanent damage to nerves
  - Compartment syndrome - squeezing of nerves and muscles in a closed space that could cause muscle or nerve damage
  - Stenosis - narrowing of a blood vessel (artery)

In addition, you may experience other problems that have not been previously observed with this procedure

INTERNATIONAL
CAUTION: For distribution only in markets where CoreValve Evolut R has been approved.
Please refer to the Instructions for Use for a full list of warnings, precautions, indications and adverse events.

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