

THE MEDTRONIC **TRANSCATHETER** AORTIC VALVE REPLACEMENT (TAVR) SYSTEM

**A Guide for Patients
With Severe
Aortic Stenosis**

INTERMEDIATE RISK

Medtronic

We have created this booklet to help you learn more about severe aortic stenosis and about your treatment options, including the Medtronic transcatheter aortic valve replacement (TAVR) procedure.



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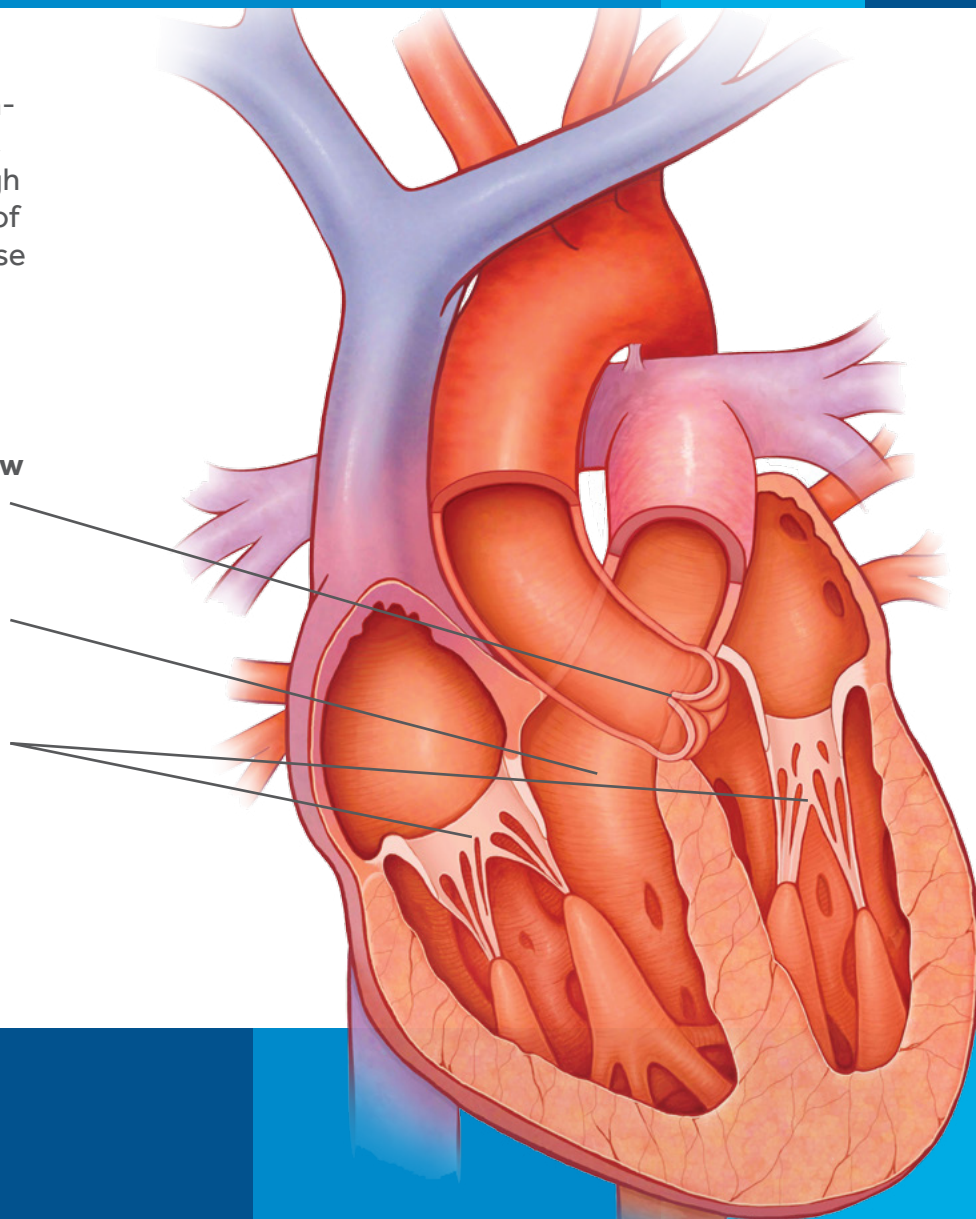
Inside the Heart

Your heart's job is to supply oxygen-rich blood to the rest of the body. It does that by pumping blood through four heart chambers with the help of four heart valves that open and close with every heartbeat.

The **aortic valve** controls blood flow to the body (except the lungs).

The **pulmonary valve** sends blood to the lungs.

The **mitral and tricuspid valves** control blood flow between the heart chambers.



Did you know that a healthy heart beats approximately 100,000 times a day?

What is Severe Aortic Stenosis?

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Severe aortic stenosis prevents your aortic valve leaflets from opening and closing properly. This makes your heart work harder to pump blood to the rest of your body. A diseased valve affects your health and limits your daily activities.

Causes:

- Age
- Calcium build-up
- Radiation therapy
- Infection of the heart

Symptoms:

- Chest pain
- Dizziness
- Fatigue
- Out of breath
- Irregular heart beat



In a healthy aortic valve, three thin leaflets open and close properly.



In a diseased (stenotic) valve, the leaflets become stiff and thickened, limiting the amount of blood pumped out to the body.

See an animation of the
aortic heart valve at
medtronic.com/TAVR

Medication

Certain medications may ease some of the symptoms of severe aortic stenosis.

Balloon Valvuloplasty (BAV)

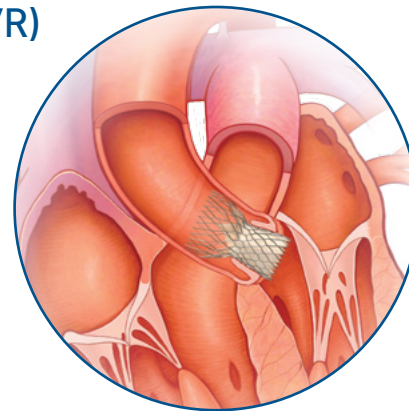
A tiny balloon is inflated in the aortic valve to try and improve blood flow, but this treatment provides only temporary relief.

Surgical Aortic Valve Replacement (SAVR)

Open heart surgery is done to remove the damaged valve and replace it with an artificial valve. Patients usually need to stay in the hospital for a week or more, before beginning a long period of recovery.

Transcatheter Aortic Valve Replacement (TAVR)

TAVR is less invasive than open heart surgery. The doctor will make a small incision on your body. After, a thin, flexible tube is inserted into an artery to guide the heart valve up to your heart to replace the diseased valve.



**Medtronic
TAVR heart
valve**

**The first TAVR procedure
was performed in 2002.**

What is the best treatment option for you?

Your heart team will conduct tests to help determine the best treatment plan for you. These tests will tell your doctor:

- The shape and size of your heart
- The structure of your artery system
- If you have any other medical problems

Common tests performed in the valve clinic:

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



The Medtronic TAVR Heart Valve



The Medtronic TAVR heart valve includes three different valves, the CoreValve, the Evolut R, and the Evolut PRO valve. It is designed to work like your own heart valve. The Evolut R and Evolut PRO valves have the added feature of being recapturable to assist your doctor with placing your new heart valve.

Your doctor can help you decide which Medtronic TAVR heart valve is right for you.



Metal frame is made of Nitinol, a nickel-titanium alloy

Tissue leaflets and outer wrap are made from pig heart tissue

Image of Evolut™ PRO valve is larger than its actual size.

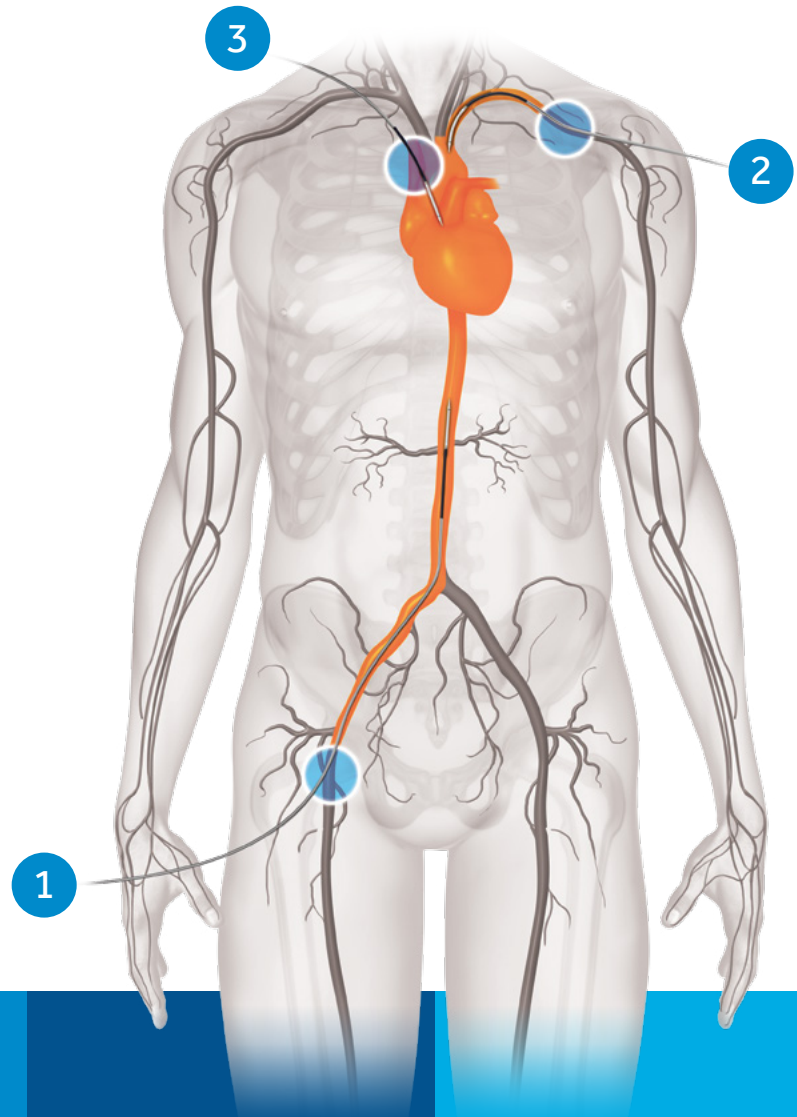
The Medtronic TAVR Procedure

Your heart team will determine whether you should have a mild sedative or general anesthesia.

At the start of the procedure, your doctor will make a small cut in the groin **1**, or the neck **2** or a space between your ribs **3** and guide a thin, flexible tube with the heart valve into your artery and up to your diseased valve. Throughout your procedure, your doctor will be viewing images of your heart.

The Medtronic TAVR heart valve will be placed in your diseased valve. Your new valve will work immediately.

Your doctor will remove the tube and close the incision. The entire procedure takes approximately one to two hours.



Watch a video on the
TAVR procedure at
[medtronic.com/TAVR](https://www.medtronic.com/TAVR)

After your procedure, you may spend a day in the ICU (intensive care unit) and another day or two in a patient room. Most patients begin walking within a day of their Medtronic TAVR procedure.

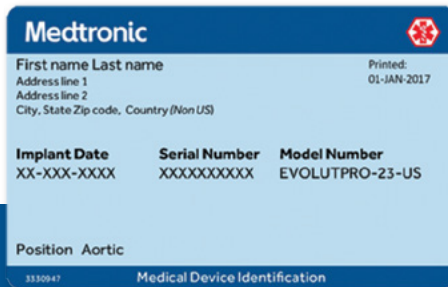
Before you leave the hospital, your doctor will explain what kinds of activities you can do, if you need to take medication and when you will need to see your doctor again.

You will also be given a card with information about your TAVR heart valve. Share this card with all members of your healthcare team, including your dentist. If you need an MRI, tell your doctor that you have a Medtronic TAVR heart valve.

TAVR Follow-Up Visits

You will be asked to return to the valve clinic to have your heart valve checked at 30 days and one year after your procedure.

If you have concerns, discomfort or changes in your health, be sure to let your doctor know right away



Keep your
**Medtronic TAVR Valve
Information Card**
in your wallet.

What to Expect

Most patients start feeling better right away, but it can take a little longer for others. Many Medtronic TAVR patients report benefits like:

- Having more energy
- Being able to do everyday activities
- Breathing normally
- Experiencing less pain
- Feeling less anxious



Find stories about real
Medtronic TAVR patients at
[medtronic.com/TAVR](https://www.medtronic.com/TAVR)

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.

Risks

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

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

The Medtronic TAVR 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 Medtronic 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 Medtronic TAVR procedure may outweigh the benefits.

SURTAVI Intermediate Risk Study

The Medtronic TAVR heart valve was studied in patients at Intermediate Risk for surgery (the SURTAVI clinical trial). The trial included 1660 patients at 87 hospitals in the United States, Europe and Canada. Patients were randomly put in the Medtronic TAVR procedure or surgery group.

Patients were examined at 30 days, 6 months, and 1 year after the procedure and will continue to be followed every year for up to 10 years.

The risk for surgery depends on the health of a patient. If you are at intermediate risk for surgery, the clinical data listed below may be like what you can expect.

SURTAVI Intermediate Risk Study Outcomes	Risks Within 30 Days	Risks Within One Year	Risks Within Two Years
Death from any cause	2 out of 100 patients	7 out of 100 patients	11 out of 100 patients
Death from a heart related cause	2 out of 100 patients	5 out of 100 patients	8 out of 100 patients
Disabling stroke	1 out of 100 patients	2 out of 100 patients	2 out of 100 patients
New permanent pacemaker	28 out of 100 patients	31 out of 100 patients	35 out of 100 patients
Life threatening or disabling bleeding	6 out of 100 patients	7 out of 100 patients	8 out of 100 patients
Major vascular complications	6 out of 100 patients	6 out of 100 patients	6 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	2 out of 100 patients	3 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients	1 out of 100 patients

Other Potential Risks Associated with Medtronic TAVR System Procedures

- 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
- Dysfunctions of a Medtronic TAVR valve 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.

Warnings

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

The Medtronic TAVR valve is only for certain patients. This includes patients with severe aortic stenosis that:

- Cannot have surgery
- Are at intermediate risk or greater for surgery

Precautions

- At some point the Medtronic TAVR valve may need to be replaced. How long it lasts varies from patient to patient.
- The Medtronic TAVR valve has been tested to mimic five years of typical 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 Medtronic TAVR valve. Not doing so could result in injury or death. Your dentist and all doctors need to know about your Medtronic TAVR valve.

The Medtronic TAVR valve has not been studied in patients:

- Who are not sick from severe aortic stenosis
- 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 severe aortic stenosis 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 difficult for the heart to pump blood
- Who have thick heart muscles that blocks the heart from pumping blood

If the Medtronic 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 Medtronic TAVR valve procedure may outweigh the benefits.
See pages 12–15 for the risks and benefits.**

How do I know if my Medtronic TAVR heart valve is working properly?

Your doctor will check your valve during your regular follow-up visits.

What kinds of exercise can I do?

Discuss this with your doctor. They can help you decide what activities are safe for you.

Is it safe to have an MRI with a Medtronic TAVR heart valve?

If you need an MRI, tell your doctor that you have a Medtronic TAVR heart valve. Not doing so could result in injury or death.

Can the Medtronic TAVR heart valve be used for all patients?

The Medtronic TAVR heart valve should not be used for patients who:

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

What are the risks of the Medtronic TAVR procedure?

All medical procedures come with risks. Although serious or major complications from the Medtronic TAVR procedure are rare, they can include:

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



For Information about the Medtronic TAVR procedure,
please contact your doctor or nurse.

For information about the Medtronic TAVR heart valve,
visit www.medtronic.com/TAVR.

For technical support, call 1-877-526-7890 (from the U.S.)
or 1-763-526-7890 (from outside the U.S.),
or email us at rs.cstechsupport@medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or
on the order of a physician.

Medtronic TAVR systems have been approved by FDA for
specific patient populations only. Refer to the Instructions
for Use for a full list of warnings, precautions, indications and
adverse events.

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