THE MEDTRONIC TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) SYSTEM

A Guide for Patients With Severe Aortic Stenosis

medtronic.com/TAVR
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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Discover more at medtronic.com/TAVR
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.

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
- Failing aortic surgical valve

**Symptoms:**
- Chest pain
- Dizziness
- Fatigue
- Out of breath
- Irregular heart beat

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

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

What is the best treatment option for you?

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 or failing surgical valve.

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 first TAVR procedure was performed in 2002.
The Medtronic TAVR Heart Valve

The Medtronic TAVR heart valve is designed to work like your own heart valve. The Medtronic TAVR valve is “repositionable,” which allows your doctor to accurately place your new heart valve. Your physician may refer to your heart valve by a few different names including CoreValve™, Evolut™ R or Evolut™ PRO. 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

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 or failing surgical valve. Your new valve will work immediately.

Your doctor will remove the tube and close the incision. The entire procedure takes approximately 1–2 hours.

Watch a video on the TAVR procedure at medtronic.com/TAVR
After Your Medtronic TAVR Procedure

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, and if you also have a surgical 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 1 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

The Medtronic 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.

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.
**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 AS or failing surgical valves 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 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 Medtronic TAVR valve. Tell your doctor if you have a Medtronic 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 Medtronic TAVR valve.
- 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 page 13 for the risks and benefits.

**The Medtronic 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 difficult for the heart to pump blood
- Who have thick heart muscles that blocks the heart from pumping blood
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 and if your Medtronic TAVR heart valve is inside a surgical 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 complications from the Medtronic TAVR procedure are rare, they can include:
- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding

SURTAVI Intermediate Risk Study
The risk for surgery depends on the health of a patient. If you are at intermediate-risk for surgery, these clinical data may be like what you can expect.

As part of the SURTAVI clinical trial, the Medtronic TAVR valve was studied in patients at intermediate risk for surgery. This group included 1660 patients at 87 hospitals in the US, Europe and Canada. Patients were randomly put in the Medtronic TAVR procedure or surgery group.

Patients were examined at 30 days, 3 months, 6 months, and 1 year after the procedure and will continue to be followed every year for up to 10 years.

<table>
<thead>
<tr>
<th>SURTAVI Intermediate Risk Study Outcomes</th>
<th>Risks Within 30 Days</th>
<th>Risks Within 1 Year</th>
<th>Risks Within 2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death from any cause</td>
<td>2 out of 100 patients</td>
<td>7 out of 100 patients</td>
<td>12 out of 100 patients</td>
</tr>
<tr>
<td>Death from a heart related cause</td>
<td>2 out of 100 patients</td>
<td>5 out of 100 patients</td>
<td>8 out of 100 patients</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>1 out of 100 patients</td>
<td>2 out of 100 patients</td>
<td>3 out of 100 patients</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>28 out of 100 patients</td>
<td>31 out of 100 patients</td>
<td>35 out of 100 patients</td>
</tr>
<tr>
<td>Life threatening or disabling bleeding</td>
<td>6 out of 100 patients</td>
<td>7 out of 100 patients</td>
<td>8 out of 100 patients</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>6 out of 100 patients</td>
<td>6 out of 100 patients</td>
<td>7 out of 100 patients</td>
</tr>
<tr>
<td>Heart attack (myocardial infarction)</td>
<td>1 out of 100 patients</td>
<td>2 out of 100 patients</td>
<td>3 out of 100 patients</td>
</tr>
<tr>
<td>Valve inflammation or infection (endocarditis)</td>
<td>0 out of 100 patients</td>
<td>0 out of 100 patients</td>
<td>1 out of 100 patients</td>
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</table>
Clinical Studies Data

The risk for surgery depends on the health of a patient. If you are at high-risk or extreme-risk (too sick) for surgery, these clinical data may be like what you can expect with an Evolut R or Evolut PRO TAVR valve.

Evolut R System Study

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 1 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 effective alternative to surgery.
• More CoreValve heart valve patients were alive than surgical patients.

Evolut PRO System Study

These patients were at high risk or were too sick for surgery. This group included 45 patients at 8 hospitals in the US. Patients were seen at 30 days after the procedure and will continue to be seen at 6 months, 1 year, and every year for 5 years.

The Evolut PRO valve works like the previous generation CoreValve and Evolut R heart valves. It was also found reasonably safe and effective.

Additional Clinical Studies

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

### TAVR Clinical Data for High or Extreme-risk Patients

<table>
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<tr>
<th>Evolut R Study and Evolut PRO Study Outcomes</th>
<th>Evolut R Study Outcomes Risks Within 30 Days</th>
<th>Evolut R Study Outcomes Risks Within 1 Year</th>
<th>Evolut PRO Study Outcomes Risks Within 30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death from any cause</td>
<td>1 out of 100 patients</td>
<td>8 out of 100 patients</td>
<td>2 out of 100 patients</td>
</tr>
<tr>
<td>Death from a heart related cause</td>
<td>1 out of 100 patients</td>
<td>7 out of 100 patients</td>
<td>2 out of 100 patients</td>
</tr>
<tr>
<td>All stroke</td>
<td>4 out of 100 patients</td>
<td>6 out of 100 patients</td>
<td>0 out of 100 patients</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>16 out of 100 patients</td>
<td>19 out of 100 patients</td>
<td>11 out of 100 patients</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>7 out of 100 patients</td>
<td>7 out of 100 patients</td>
<td>9 out of 100 patients</td>
</tr>
<tr>
<td>Heart attack (myocardial infarction)</td>
<td>1 out of 100 patients</td>
<td>1 out of 100 patients</td>
<td>0 out of 100 patients</td>
</tr>
<tr>
<td>Valve inflammation or infection (endocarditis)</td>
<td>0 out of 100 patients</td>
<td>0 out of 100 patients</td>
<td>0 out of 100 patients</td>
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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.

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.