

TREATING YOUR AORTIC STENOSIS

THE MEDTRONIC TRANSCATHETER
AORTIC VALVE REPLACEMENT
(TAVR) SYSTEM



Medtronic
Further Together



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

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Discover more at [medtronic.com/TAVR](https://www.medtronic.com/TAVR)

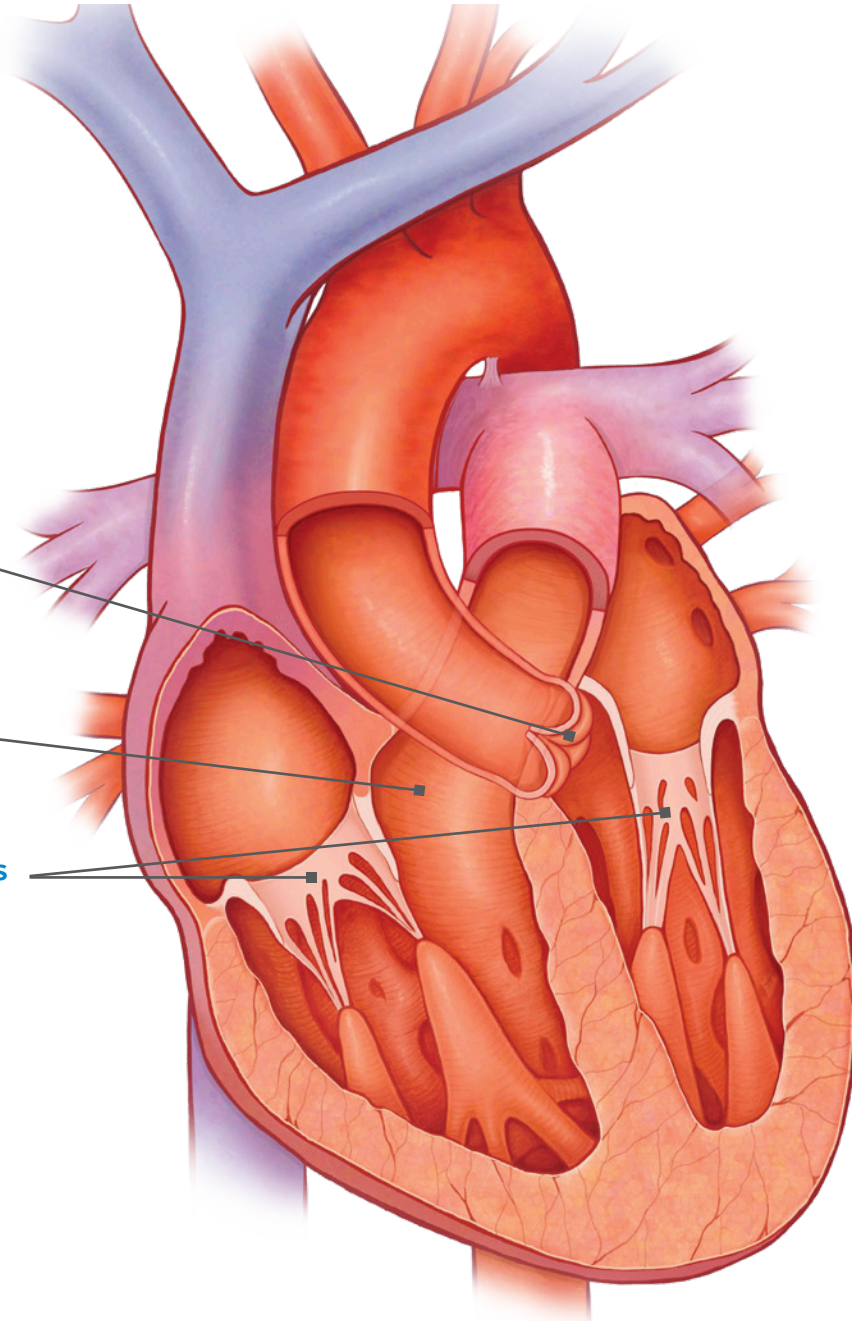
INSIDE YOUR HEART

Your heart's job is to supply oxygen-rich blood to the rest of your 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** controls blood flow 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?

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.

Some causes of severe aortic stenosis include:

- Age
- Calcium buildup
- Radiation therapy
- Infection of the heart

Symptoms of severe aortic stenosis include, but may not be limited to:

- Chest pain
- Dizziness
- Fatigue
- Shortness of breath
- Irregular heartbeat

See an aortic heart valve animation at [medtronic.com/TAVR](https://www.medtronic.com/TAVR)



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.

COMMON TREATMENT OPTIONS

Medication

Certain medications may ease some of your symptoms.

Balloon Valvuloplasty (BAV)

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

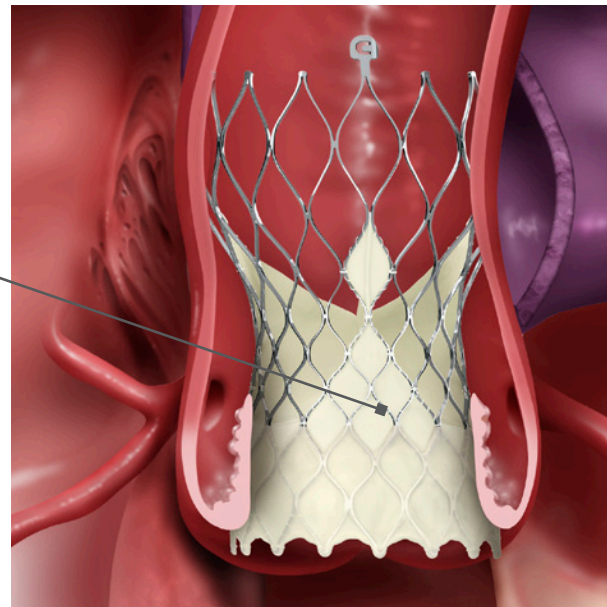
Surgical Aortic Valve Replacement (SAVR)

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. Your doctor will make a small incision on your body. After, a thin, flexible tube is inserted into an artery to guide the artificial heart valve up to your heart to replace the diseased valve.

Medtronic **TAVR**
heart valve



TAVR procedures
were first performed in 2002.

WHAT IS THE BEST TREATMENT OPTION FOR YOU?

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

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

Common tests performed may include:

- Cardiac catheterization
- CT scan
- Echocardiogram
- Carotid ultrasound
- Blood tests
- Physical exam
- Frailty testing

See descriptions of common tests
performed in the valve clinic at
[medtronic.com/TAVR](https://www.medtronic.com/TAVR)



MEDTRONIC TAVR

The Medtronic TAVR heart valve is designed to work like your own heart valve.

The metal frame is a blend of nickel and titanium. This material allows the frame to shape itself to your anatomy.

There are two types of Medtronic heart valves — Evolut™ R and Evolut PRO valves — that come in different sizes.

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



The **Evolut PRO** valve has tissue leaflets and an outer wrap made from pig heart tissue.

Image is larger than its actual size.



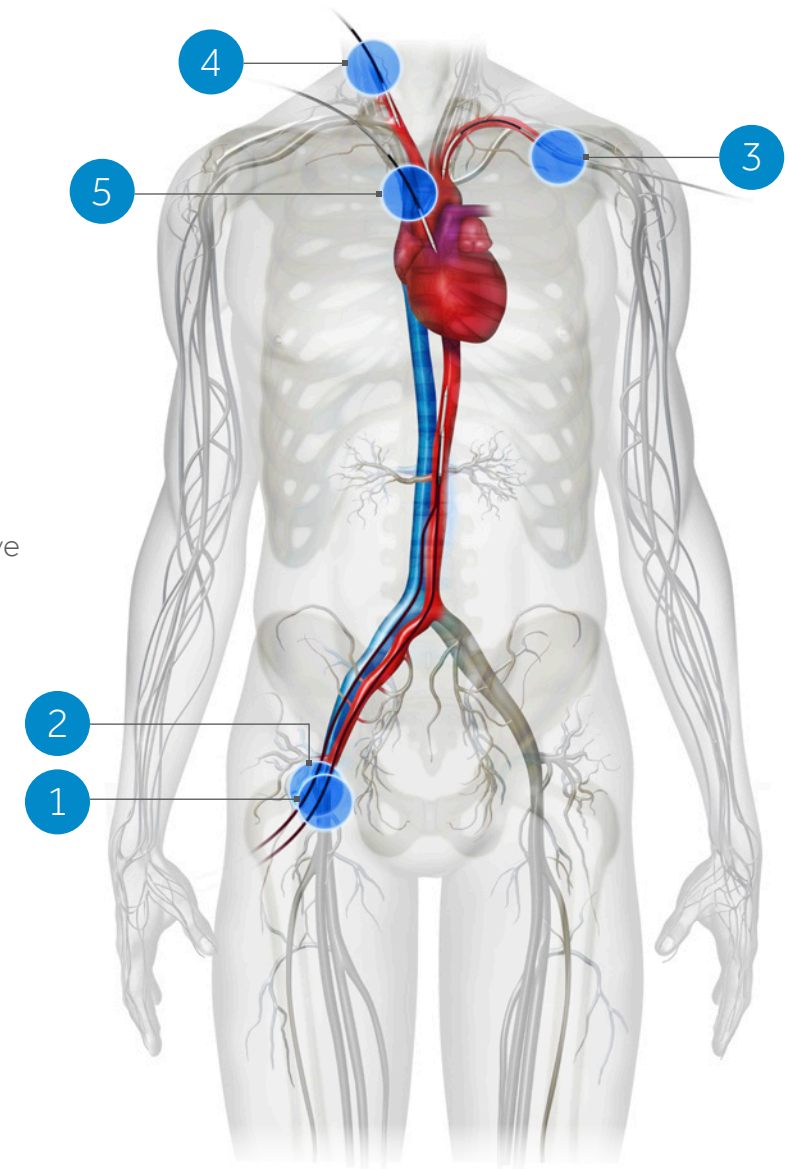
MEDTRONIC TAVR PROCEDURE

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**, **2** the neck **3**, **4** or a space between your ribs **5** and guide a thin, flexible tube with the heart valve into your artery and 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 typically 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

After your procedure, you may spend a day or more 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.

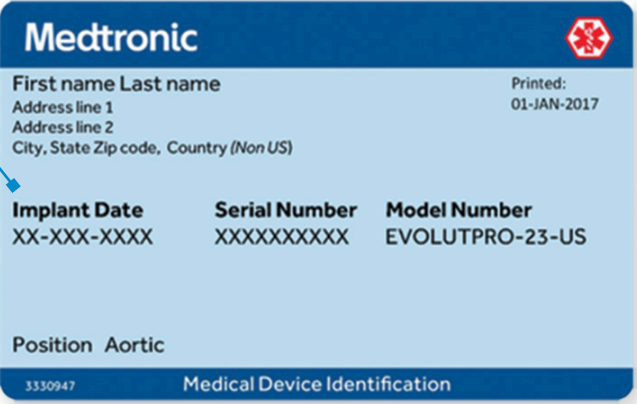
Before you leave the hospital, your doctor will explain what kinds of activities you can do, if you need to take medication, and when you will need to see your doctor again.

You will also be given a card with information about your TAVR heart valve. Share this card with your family members and 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, and as recommended by your physician.

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 with you at all times.

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 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.

Defining Your Surgical Risk

The Medtronic TAVR procedure is currently approved for:

- Patients with heart disease due to severe aortic stenosis of their native valve;
- Patients with a failing surgical aortic valve who are at high risk or extreme risk for complications during surgery; and

Your doctor can determine your risk category based upon several factors, including age and other medical conditions that might make surgery more dangerous for you.

Risks

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

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding - a bleeding event that requires a blood transfusion
- Need for permanent pacemaker

The chance of an adverse event from the TAVR procedure depends on many factors, including your underlying medical conditions.

The Medtronic TAVR Valve Cannot Be Used for Certain People

Patients who:

- Have an infection
- Cannot take blood-thinning medicines
- Have a reaction to some metals

OTHER POTENTIAL RISKS

- Heart attack
- Cardiogenic shock — failure of the heart to pump enough blood to the body organs
- Cardiac tamponade — the constriction or inability of the heart to pump due to buildup of blood or fluid around the lining of the heart
- Perforation of the myocardium or vessel - a hole in the heart muscle or a blood vessel
- Partial or complete block of coronary artery (that supplies blood to the heart)
- Ascending aorta trauma — injury to the large blood vessel leading blood away from the heart
- Additional cardiac surgery, vascular surgery, or intervention, including removal of the TAV
- Dysfunctions of 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
- Valve migration - upward or downward movement of the device from where it was originally placed
- Embolism - an abnormal particle (air, blood clots) floating in the blood stream or attached to an object, including the valve or delivery system component
- Infection of the heart, blood or other areas
- Thrombosis (including valve thrombosis) - blood clot, including a blood clot on the valve
- Prolonged procedure time
- Individual or multi-organ insufficiency or failure
- 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)
 - Decreased blood flow to your leg or arm

If the Medtronic TAVR valve is used in the patients mentioned above, it will not work properly. This could make you feel very sick or even cause death.

For some patients, the Medtronic TAVR procedure risks may outweigh the benefits.

OTHER POTENTIAL RISKS

- 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
- Damage to the red blood cells
- Bowel ischemia - decreased blood supply to the intestines
- Lab values that are not normal
- 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
- Exposure to radiation
- Permanent disability

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

MEDTRONIC TAVR CLINICAL DATA

Multiple clinical trials have been conducted to provide information about the chance of a risk from the Medtronic TAVR procedure.

TAVR currently is approved for patients with heart disease due to severe aortic stenosis of the native valve, and patients with a failing surgical aortic valve who are at high risk or extreme risk for complications during surgery.

A number of factors determines a patient's risk, including age and other medical conditions that make surgery more dangerous. Your doctor can let you know which risks will most likely apply to you.

Please review the clinical trial data your doctor has inserted in this booklet for more information about the results that apply to you.



WARNINGS AND PRECAUTIONS

Warnings

Younger patients, or patients with a disease that results in more calcium in their blood may have early wear of their valve.

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 in the laboratory 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 may be recommended for patients who are at risk of infections.
- Patients should stay on blood-thinning medicines after the procedure as instructed by your physician. 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.

WARNINGS AND PRECAUTIONS

The Medtronic TAVR Valve Has Not Been Studied in Patients:

- Who are children
- Who have a blood clot
- With an abnormal growth in the heart or arteries
- Who have an infection
- Who have severe mitral valve disease
- With poor left ventricle function
- Whose failing 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 a reaction to some imaging solutions, cannot take blood thinning medicines, or who have a reaction to some metals
- 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 block the heart from pumping blood
- Who are pregnant or breastfeeding
- Who have bicuspid valves and are at low surgical risk
- With liver failure
- Who need to have a surgical procedure on their aorta

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 patients, the Medtronic TAVR procedure risks may outweigh the benefits. See pages 12-14 for the risks and benefits.

FREQUENTLY ASKED QUESTIONS

Please review clinical trial data with your doctor for risk information
and more details about the results that apply to you.

1. 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.

2. What kinds of exercise can I do?

Discuss this with your doctor. He or she can help you decide what activities are safe for you.

3. 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.

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

The Medtronic TAVR heart valve cannot be used for patients who:

- Have an infection
- Cannot take blood thinners
- Have a reaction to some metals

5. 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
- Need for permanent pacemaker

FPO pocket — need dieline

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

For information about the Medtronic TAVR heart valve, visit **[medtronic.com/TAVR](https://www.medtronic.com/TAVR)**.

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

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MEDTRONIC TAVR CLINICAL DATA

LOW & INTERMEDIATE RISK

Evolut Low Risk Trial

The Medtronic TAVR heart valve was studied in approximately 1,400 patients at 86 hospitals in the United States, Australia, Canada, Europe, New Zealand, and Japan who were at low risk for surgery. Patients were randomly placed in either the Medtronic TAVR procedure or surgery group.

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

The study results showed the Medtronic TAVR systems had an acceptable safety and effectiveness profile in treating aortic stenosis in patients at low risk for surgery.

Potential risks with TAVR and SAVR at 30 days, 1 year, and 2 years are listed in the table below. The risk for surgery depends on the health of a patient. If you are at low risk for surgery, the clinical data listed below may be like what you can expect.

	Evolut TAVR			Surgery		
	Risks within 30 Days	Risks within 1 Year	Risks within 2 Years	Risks within 30 Days	Risks within 1 Year	Risks within 2 Years
Death from any cause	0 out of 100 patients	2 out of 100 patients	4 out of 100 patients	1 out of 100 patients	3 out of 100 patients	4 out of 100 patients
Death from a heart-related cause	0 out of 100 patients	2 out of 100 patients	3 out of 100 patients	1 out of 100 patients	3 out of 100 patients	3 out of 100 patients
Disabling stroke	0 out of 100 patients	1 out of 100 patients	2 out of 100 patients	2 out of 100 patients	2 out of 100 patients	3 out of 100 patients
New permanent pacemaker	17 out of 100 patients	19 out of 100 patients	23 out of 100 patients	6 out of 100 patients	7 out of 100 patients	8 out of 100 patients
Life-threatening or disabling bleeding	2 out of 100 patients	4 out of 100 patients	4 out of 100 patients	8 out of 100 patients	9 out of 100 patients	9 out of 100 patients
Major vascular complications	4 out of 100 patients	4 out of 100 patients	4 out of 100 patients	3 out of 100 patients	3 out of 100 patients	4 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	2 out of 100 patients	2 out of 100 patients	1 out of 100 patients	2 out of 100 patients	2 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients	1 out of 100 patients	1 out of 100 patients

SURTA VI Intermediate Risk Study

The Medtronic TAVR heart valve was studied in 1,660 patients at 87 hospitals in the U.S., Europe, and Canada that were at intermediate risk for surgery. Patients were randomly placed in the Medtronic TAVR procedure or surgery group.

Patients were examined at 30 days, 6 months, and 1 year. Yearly checkups will continue for up to 10 years.

The study results showed the CoreValve™ and Evolut™ R heart valves were found to have an acceptable safety profile and were effective in treating severe aortic stenosis patients at intermediate risk for surgery.

Potential risks with TAVR at 30 days, 1 year, and 2 years are listed in the table below.

	TAVR risks within 30 Days	TAVR risks within 1 Year	TAVR risks within 2 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

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.

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Evolut™ R System Study

The Medtronic Evolut R heart valve was studied in 166 patients at 24 hospitals in the U.S., Australia, New Zealand, and the United Kingdom that were at high risk or were too sick for surgery.

Patients were examined 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.

	Risks within 30 Days	Risks within 1 Year
Death from any cause	1 out of 100 patients	8 out of 100 patients
▪ From a heart-related cause	1 out of 100 patients	7 out of 100 patients
All stroke	4 out of 100 patients	6 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	16 out of 100 patients	19 out of 100 patients
Major vascular access site complication	7 out of 100 patients	7 out of 100 patients
Heart attack	1 out of 100 patients	1 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients

Evolut™ PRO System Study

The Medtronic Evolut PRO heart valve was studied in 45 patients at 8 hospitals in the U.S. that were at high risk or were too sick for surgery.

Patients were examined at 30 days and will be seen at 6 months and 1 year. Yearly checkups will continue 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.

	Risks within 30 Days
Death from any cause	2 out of 100 patients
▪ From a heart-related cause	2 out of 100 patients
All stroke	0 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	12 out of 100 patients
Major vascular access site complication	9 out of 100 patients
Heart attack	0 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients

- More CoreValve heart valve patients were alive than surgical patients.

Potential risks at 30 days and 1 year are listed in the table below. Almost all received the Evolut R heart valve through a leg artery. This is a common access site. Few used the space between their ribs or an artery in the neck. These sites are not often used. Therefore, the results are grouped together. Access site is selected by your doctor.

Potential risks at 30 days are listed in the table below. Almost all received the Evolut PRO heart valve through a leg artery. This is a common access site. Few used the space between their ribs or an artery in the neck. These sites are not often used. Therefore, the results are grouped together. Access site is selected by your doctor.

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

EXTREME & HIGH RISK

CoreValve™ U.S. Pivotal Trial: Extreme Risk Study

The Medtronic CoreValve heart valve was studied in 639 patients at 41 hospitals in the U.S. that were too sick for surgery.

Four hundred eighty-nine (489) received the CoreValve heart valve through an artery in their leg. One hundred fifty (150) through a space between their ribs or an artery in their neck.

Patients were examined at 30 days, 6 months, and 1 year. Yearly checkups will continue for 5 years.

Potential risks at 30 days and 1 year are listed in the table below. The data is divided by access site. Access site is selected by your doctor.

Extreme Risk Patients Risks within 30 Days and 1 Year after Your CoreValve (TAVR) Procedure	Risks within 30 Days		Risks within 1 Year	
	Access via an artery in your leg	Access via a space between your ribs or an artery in your neck	Access via an artery in your leg	Access via a space between your ribs or an artery in your neck
Death from any cause	8 out of 100 patients	11 out of 100 patients	24 out of 100 patients	36 out of 100 patients
▪ From a heart-related cause	8 out of 100 patients	11 out of 100 patients	18 out of 100 patients	28 out of 100 patients
▪ From a heart valve-related cause	3 out of 100 patients	3 out of 100 patients	5 out of 100 patients	5 out of 100 patients
All stroke	4 out of 100 patients	9 out of 100 patients	6 out of 100 patients	12 out of 100 patients
▪ Major stroke	2 out of 100 patients	7 out of 100 patients	4 out of 100 patients	9 out of 100 patients
Bleeding event	37 out of 100 patients	58 out of 100 patients	42 out of 100 patients	64 out of 100 patients
▪ Serious bleeding	25 out of 100 patients	37 out of 100 patients	28 out of 100 patients	40 out of 100 patients
▪ Life-threatening or disabling bleed	13 out of 100 patients	24 out of 100 patients	17 out of 100 patients	29 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	29 out of 100 patients	22 out of 100 patients	35 out of 100 patients	29 out of 100 patients
Serious damage to the arteries	8 out of 100 patients	9 out of 100 patients	8 out of 100 patients	9 out of 100 patients
Acute kidney injury	12 out of 100 patients	14 out of 100 patients	12 out of 100 patients	14 out of 100 patients
Hospitalization due to complications with aortic valve	6 out of 100 patients	8 out of 100 patients	19 out of 100 patients	18 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	2 out of 100 patients	2 out of 100 patients	2 out of 100 patients
Need for additional procedures on your aortic valve	1 out of 100 patients	0 out of 100 patients	2 out of 100 patients	1 out of 100 patients
▪ Surgical aortic valve replacement	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients
▪ Less invasive procedure (not including replacement)	1 out of 100 patients	0 out of 100 patients	2 out of 100 patients	1 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	1 out of 100 patients	1 out of 100 patients	1 out of 100 patients

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CoreValve™ U.S. Pivotal Trial: High Risk Study

The Medtronic CoreValve heart valve was studied in 747 patients at 45 hospitals in the U.S. that were at high risk for surgery.

Most received the CoreValve heart valve through an artery in their leg. Some received the valve through a space between their ribs or an artery in their neck. Patients were randomly put in the CoreValve procedure or surgery group.

Patients in both groups were examined at 30 days, 6 months, and 1 year. Yearly checkups will continue for 5 years.

Potential risks at 30 days and 1 year are listed in the table below. The data is divided by access site. Access site is selected by your doctor.

High Risk Patients Risks within 30 Days after Your Aortic Valve Procedure	Patients eligible for access via an artery in your leg		Patients eligible for access via a space between your ribs or an artery in your neck	
	CoreValve (TAVR) 323 patients	Surgery (SAVR) 300 patients	CoreValve (TAVR) 67 patients	Surgery (SAVR) 57 patients
Death from any cause	3 out of 100 patients	4 out of 100 patients	3 out of 100 patients	5 out of 100 patients
▪ From a heart-related cause	3 out of 100 patients	4 out of 100 patients	3 out of 100 patients	5 out of 100 patients
▪ From a heart valve-related cause	3 out of 100 patients	0 out of 100 patients	2 out of 100 patients	2 out of 100 patients
All stroke	5 out of 100 patients	5 out of 100 patients	5 out of 100 patients	12 out of 100 patients
▪ Major stroke	4 out of 100 patients	2 out of 100 patients	5 out of 100 patients	9 out of 100 patients
Bleeding event	35 out of 100 patients	68 out of 100 patients	66 out of 100 patients	68 out of 100 patients
▪ Serious bleeding	25 out of 100 patients	34 out of 100 patients	44 out of 100 patients	35 out of 100 patients
▪ Life-threatening or disabling bleed	11 out of 100 patients	35 out of 100 patients	27 out of 100 patients	35 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	27 out of 100 patients	9 out of 100 patients	22 out of 100 patients	6 out of 100 patients
Serious damage to the arteries	7 out of 100 patients	2 out of 100 patients	3 out of 100 patients	2 out of 100 patients
Acute kidney injury	5 out of 100 patients	14 out of 100 patients	11 out of 100 patients	19 out of 100 patients
Hospitalization due to complications with aortic valve	3 out of 100 patients	4 out of 100 patients	11 out of 100 patients	13 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	1 out of 100 patients	0 out of 100 patients	2 out of 100 patients
Need for additional procedures on your aortic valve	1 out of 100 patients	0 out of 100 patients	3 out of 100 patients	0 out of 100 patients
▪ Surgical aortic valve replacement	0 out of 100 patients	0 out of 100 patients	3 out of 100 patients	0 out of 100 patients
▪ Less invasive procedure (not including replacement)	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients
High Risk Patients Risks within 1 Year after Your Aortic Valve Procedure				
Death from any cause	13 out of 100 patients	18 out of 100 patients	18 out of 100 patients	27 out of 100 patients
▪ From a heart-related cause	10 out of 100 patients	12 out of 100 patients	12 out of 100 patients	17 out of 100 patients
▪ From a heart valve-related cause	6 out of 100 patients	2 out of 100 patients	5 out of 100 patients	6 out of 100 patients
All stroke	9 out of 100 patients	11 out of 100 patients	8 out of 100 patients	22 out of 100 patients
▪ Major stroke	6 out of 100 patients	5 out of 100 patients	6 out of 100 patients	19 out of 100 patients
Bleeding event	38 out of 100 patients	70 out of 100 patients	66 out of 100 patients	74 out of 100 patients
▪ Serious bleeding	27 out of 100 patients	36 out of 100 patients	44 out of 100 patients	40 out of 100 patients
▪ Life-threatening or disabling bleed	14 out of 100 patients	38 out of 100 patients	29 out of 100 patients	41 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	29 out of 100 patients	15 out of 100 patients	26 out of 100 patients	6 out of 100 patients
Serious damage to the arteries	7 out of 100 patients	2 out of 100 patients	3 out of 100 patients	2 out of 100 patients
Acute kidney injury	5 out of 100 patients	14 out of 100 patients	11 out of 100 patients	19 out of 100 patients
Hospitalization due to complications with aortic valve	15 out of 100 patients	11 out of 100 patients	24 out of 100 patients	25 out of 100 patients
Heart attack (myocardial infarction)	2 out of 100 patients	1 out of 100 patients	0 out of 100 patients	2 out of 100 patients
Need for additional procedures on your aortic valve	2 out of 100 patients	0 out of 100 patients	3 out of 100 patients	0 out of 100 patients
▪ Surgical aortic valve replacement	1 out of 100 patients	0 out of 100 patients	3 out of 100 patients	0 out of 100 patients
▪ Less invasive procedure (not including replacement)	1 out of 100 patients	0 out of 100 patients	0 out of 100 patients	0 out of 100 patients
Valve inflammation or infection (endocarditis)	1 out of 100 patients	1 out of 100 patients	0 out of 100 patients	2 out of 100 patients

CoreValve™ U.S. Expanded Use Study: Patients with Severe Kidney Disease

The Medtronic CoreValve heart valve was studied in 105 patients at 35 hospitals in the U.S. that had severe kidney disease and were too sick for surgery. Severe kidney disease is when kidneys do not function as they should. Kidneys help filter and clean your blood. Some patients require dialysis (use of a machine to help filter blood outside the body).

Patients were examined at 30 days and 1 year. Yearly checkups will continue for 5 years.

Potential risks at 30 days and 1 year are listed in the table below. Almost all patients received the CoreValve heart valve through a leg artery. This is a common access site. Few used the space between their ribs or an artery in the neck. These sites are not often used. Therefore, the results are grouped together. Access site is selected by your doctor.

Patients with Severe Kidney Disease Risks within 30 Days and 1 Year after Your CoreValve (TAVR) Procedure	Risks within 30 Days	Risks within 1 Year
	Access via an artery in your leg or a space between your ribs or an artery in your neck	Access via an artery in your leg or a space between your ribs or an artery in your neck
Death from any cause	5 out of 100 patients	33 out of 100 patients
▪ From a heart-related cause	4 out of 100 patients	18 out of 100 patients
▪ From a heart valve-related cause	1 out of 100 patients	1 out of 100 patients
All stroke	2 out of 100 patients	2 out of 100 patients
▪ Major stroke	1 out of 100 patients	1 out of 100 patients
Bleeding event	25 out of 100 patients	35 out of 100 patients
▪ Serious bleeding	21 out of 100 patients	22 out of 100 patients
▪ Life-threatening or disabling bleed	4 out of 100 patients	14 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	29 out of 100 patients	32 out of 100 patients
Major vascular complication	7 out of 100 patients	7 out of 100 patients
Acute kidney injury	0 out of 100 patients	0 out of 100 patients
Hospitalization due to complications with aortic valve	5 out of 100 patients	12 out of 100 patients
Heart attack (myocardial infarction)	3 out of 100 patients	7 out of 100 patients
Need for additional procedures on your aortic valve	0 out of 100 patients	0 out of 100 patients
▪ Surgical aortic valve replacement	0 out of 100 patients	0 out of 100 patients
▪ Less invasive procedure (not including replacement)	0 out of 100 patients	0 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients

CoreValve™ U.S. Expanded Use Study: Patients with Low-Flow/Low-Gradient

The Medtronic CoreValve heart valve was studied in 193 patients at 38 hospitals in the U.S. that had low flow/low gradient and were too sick for surgery. Low flow/low gradient is a type of aortic stenosis which can seem different than typical AS because your heart is not moving as much blood through the narrow valve. Patients with low flow/low gradient aortic stenosis have the same physical symptoms as typical AS.

Patients were examined at 30 days and 1 year. Yearly checkups will continue for 5 years.

Potential risks at 30 days and 1 year are listed in the table below. Almost all patients received the CoreValve heart valve through a leg artery. This is a common access site. Few used the space between their ribs or an artery in the neck. These sites are not often used. Therefore, the results are grouped together. Access site is selected by your doctor.

Patients with Low-Flow/Low-Gradient (LFLG) Risks within 30 Days and 1 Year after Your CoreValve (TAVR) Procedure	Risks within 30 Days	Risks within 1 Year
	Access via an artery in your leg or a space between your ribs or an artery in your neck	Access via an artery in your leg or a space between your ribs or an artery in your neck
Death from any cause	11 out of 100 patients	24 out of 100 patients
▪ From a heart-related cause	9 out of 100 patients	15 out of 100 patients
▪ From a heart valve-related cause	0 out of 100 patients	2 out of 100 patients
All stroke	7 out of 100 patients	10 out of 100 patients
▪ Major stroke	3 out of 100 patients	5 out of 100 patients
Bleeding event	23 out of 100 patients	32 out of 100 patients
▪ Serious bleeding	15 out of 100 patients	21 out of 100 patients
▪ Life-threatening or disabling bleed	8 out of 100 patients	13 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	33 out of 100 patients	37 out of 100 patients
Major vascular complication	9 out of 100 patients	9 out of 100 patients
Acute kidney injury	15 out of 100 patients	15 out of 100 patients
Hospitalization due to complications with aortic valve	8 out of 100 patients	24 out of 100 patients
Heart attack (myocardial infarction)	2 out of 100 patients	3 out of 100 patients
Need for additional procedures on your aortic valve	2 out of 100 patients	2 out of 100 patients
▪ Surgical aortic valve replacement	1 out of 100 patients	1 out of 100 patients
▪ Less invasive procedure (not including replacement)	1 out of 100 patients	1 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	1 out of 100 patients

MEDTRONIC TAVR CLINICAL DATA

TAV-IN-SAV*

Failed Surgical Aortic Valve

Some people have had their diseased aortic valve replaced with a surgical valve. Surgical valves wear out over time and can start to fail.

When your surgical valve starts to fail, one or both of these conditions can occur:

- Stenosis — when the valve narrows and does not open completely
- Regurgitation — when the valve does not fully close and blood flows backwards through the valve

Causes:

- Calcification
- Wear and tear over time

Symptoms:

- Chest pain
- Dizziness
- Fatigue
- Shortness of breath
- Irregular heartbeat

CoreValve™ U.S. Expanded Use Study: Extreme Risk

TAVR in Failing Surgical Valve Cohort

The Medtronic CoreValve heart valve was studied in 143 patients at 37 hospitals in the U.S. that were at extreme risk for surgery and had a transcatheter valve implanted in a failed surgical valve.

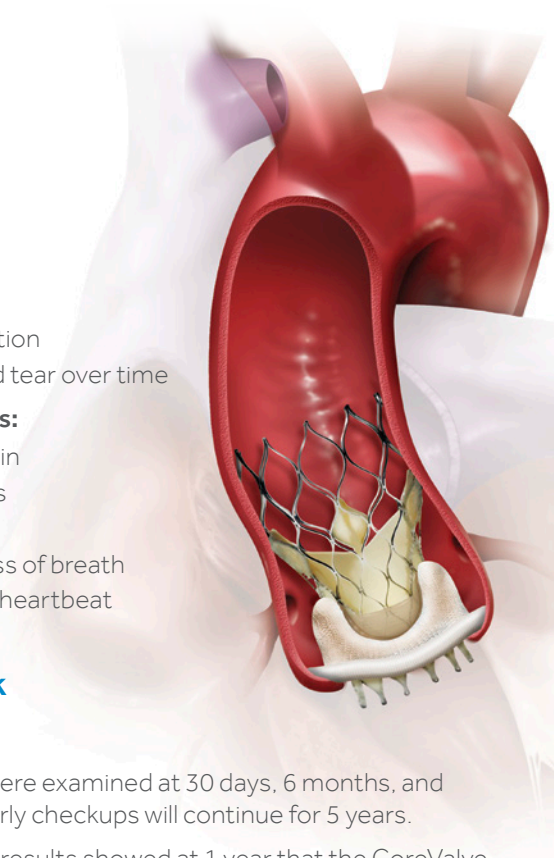
Most patients received the CoreValve heart valve through a leg artery. This is a common access site. Few used the space between their ribs or an artery in the neck. These sites are not often used. Therefore, the results are grouped together. Access site is selected by your doctor.

Patients were examined at 30 days, 6 months, and 1 year. Yearly checkups will continue for 5 years.

The study results showed at 1 year that the CoreValve procedure had an acceptable safety profile and was an effective treatment option for patients with a failing surgical aortic valve.

Potential risks at 30 days and 1 year are listed in the table below.

	Risks within 30 Days	Risks within 1 Year
Death from any cause	4 out of 100 patients	14 out of 100 patients
Death from a heart-related cause	3 out of 100 patients	7 out of 100 patients
Major stroke	1 out of 100 patients	2 out of 100 patients
New permanent pacemaker	9 out of 100 patients	18 out of 100 patients
Life-threatening or disabling bleeding	6 out of 100 patients	11 out of 100 patients
Major vascular complications	12 out of 100 patients	12 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	1 out of 100 patients
Valve inflammation or infection (endocarditis)	0 out of 100 patients	0 out of 100 patients



*Only approved for patients who are at high or extreme risk for complications during surgery.

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 United States) or 1-763-526-7890 (from outside the United States), or email us at rs.cstechsupport@medtronic.com.

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

Medtronic TAVR systems have been approved by the 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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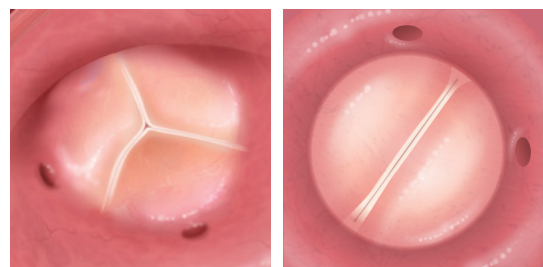
MEDTRONIC TAVR CLINICAL DATA

BICUSPID

Severe Aortic Stenosis in a Bicuspid Valve

A normal aortic valve has three thin leaflets. Some people are born with a bicuspid aortic valve, which has only two leaflets.

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



Tricuspid valve

Bicuspid valve

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



Tricuspid valve

Bicuspid valve

Bicuspid Data from the STS/ACC TVT Registry™†

Intermediate Risk and Higher

The table below summarizes the 30-day and 1-year results of 545 patients with bicuspid aortic valve stenosis who were treated with a Medtronic TAVR device.

The data came from the TVT Registry, a national registry run by The Society of Thoracic Surgeons and American College of Cardiology Foundation. The registry collects certain safety and efficacy data from participating hospitals in the U.S. treating patients with a TAVR device.

	Risks within 30 Days	Risks within 1 Year
Death from any cause	2 out of 100 patients	8 out of 100 patients
All stroke	3 out of 100 patients	3 out of 100 patients
New permanent pacemaker	17 out of 100 patients	16 out of 100 patients
Life-threatening or major bleeding	7 out of 100 patients	9 out of 100 patients
Major vascular complications	1 out of 100 patients	1 out of 100 patients
Immediate need for another aortic valve procedure	1 out of 100 patients	2 out of 100 patients

†The views or opinions presented in this document are solely those of Medtronic and do not represent those of the American College of Cardiology, The Society of Thoracic Surgeons, or the STS/ACC TVT Registry.

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

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