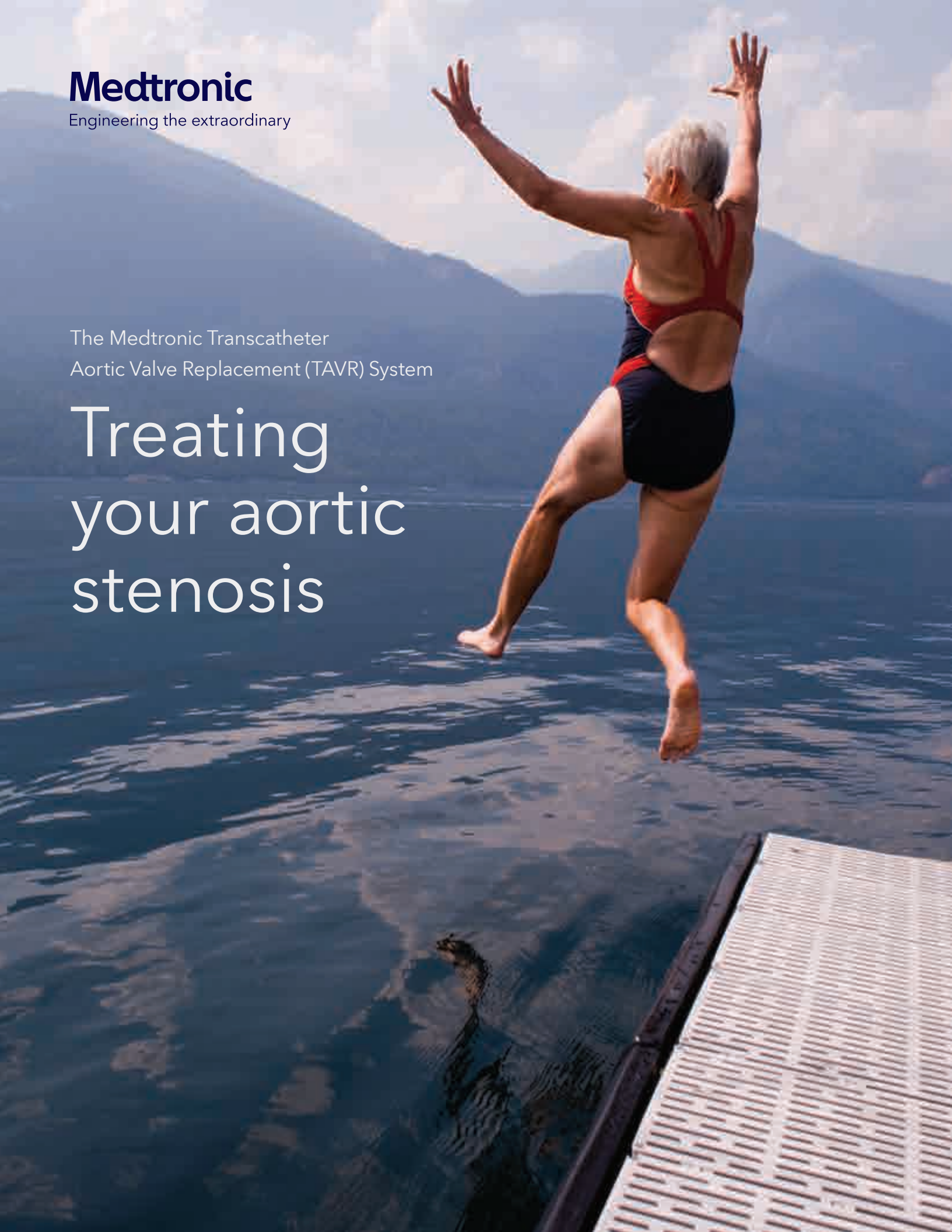
Medtronic

Engineering the extraordinary



The Medtronic Transcatheter
Aortic Valve Replacement (TAVR) System

# Treating your aortic stenosis

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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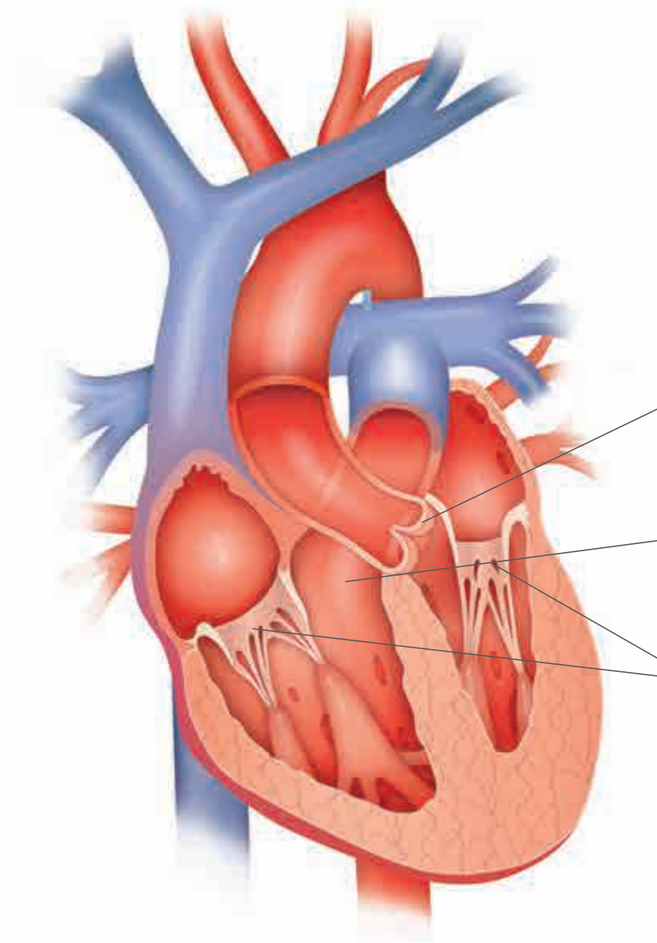
# Table of contents



**Discover more at 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:**

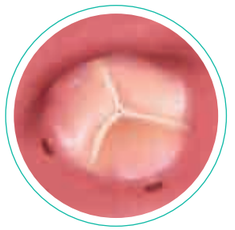
- Age
- Calcium buildup
- Radiation therapy
- Infection of the heart

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

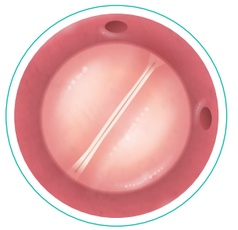
- Chest pain
- Dizziness
- Fatigue
- Shortness of breath
- Irregular heartbeat

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.

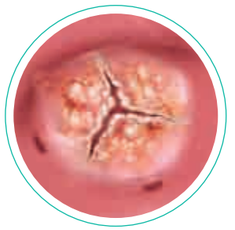


Tricuspid valve

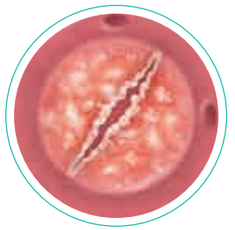


Bicuspid valve

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

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

# 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 the incision is made, 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 that will help you and the team discuss the best treatment option. 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
- Pulmonary function test
- Electrocardiogram (EKG)

**See descriptions of common tests performed in the valve clinic at 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.

The Evolut™ FX+ valve frame has gold markers beneath the outer wrap so your doctor can better see the valve on X-ray during the procedure. The valve also has three larger cells to help your doctor get access to your coronary arteries.

The Medtronic TAVR heart valve comes in four different sizes.

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

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

**Image is larger than its actual size.**



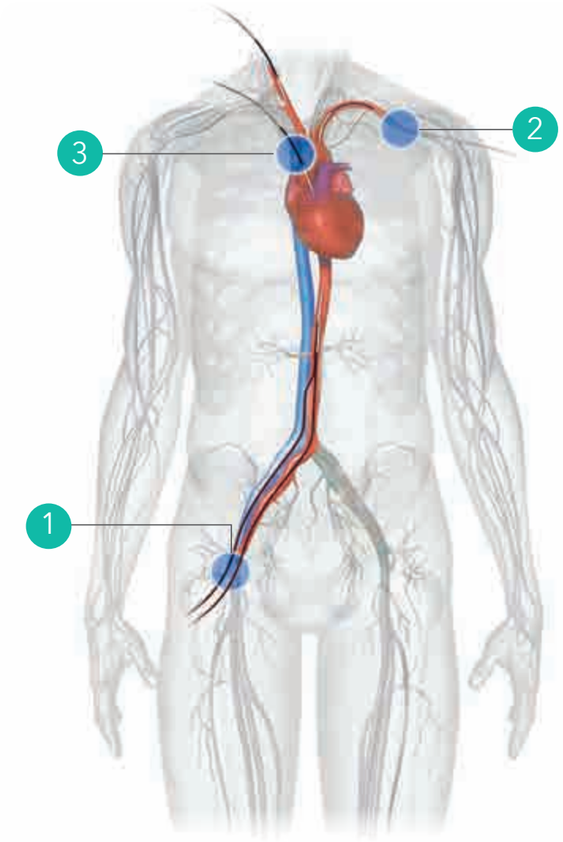
# Medtronic TAVR procedure

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, the neck 2, or a space between your ribs 3 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 natural valve or failed implanted valve. Your new valve will work immediately.

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



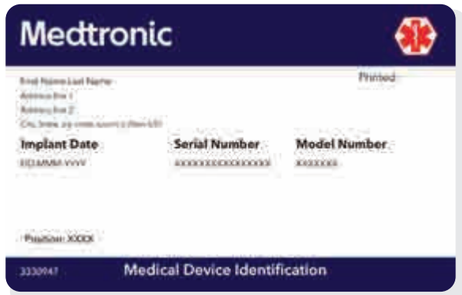

**Watch a video on the TAVR procedure at medtronic.com/TAVR**

# After your procedure

After the procedure, most patients spend a few hours in the intensive care unit (ICU) before transferring to a patient room. Typically, patients begin walking the same day as their Medtronic TAVR procedure and are discharged within a day or two.

Before you leave the hospital, your doctor will explain what kinds of activities you can do, what medications you need to take, 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.**



# Benefits and risks

**The Medtronic TAVR procedure is currently approved for:**

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

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.

**Find stories about real Medtronic TAVR patients at 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.

Many Medtronic TAVR patients report benefits like:

- Having more energy
- Breathing normally
- Experiencing less pain
- Experiencing fewer symptoms
- Feeling less anxious

After the procedure, most patients can take care of themselves better and go back to everyday activities.

### Risks

Most medical procedures have risks.

The most serious risks of the Medtronic TAVR procedure 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 patients who†:

- Have a serious infection
- Cannot take medications that reduce the risk of blood clots
- Have a reaction to some metals

†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.**
**See pages 11–15 for the risks and benefits.**



# 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 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

# Other potential risks

- 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



# Other potential risks

- 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
- Mitral valve regurgitation – blood leaking backward 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.

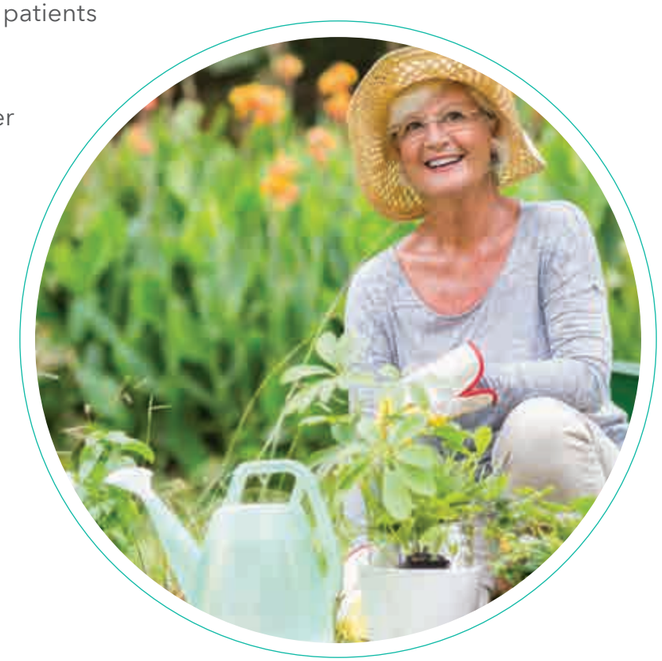
# Warnings and precautions

## 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 medications that reduce the risk of blood clots 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 medications that reduce the risk of blood clots, 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
- 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.

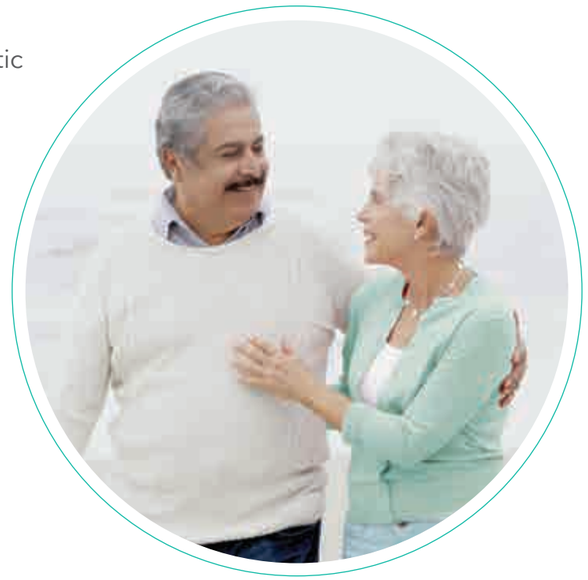
**For some patients, the Medtronic TAVR procedure risks may outweigh the benefits.**
**See pages 12–15 for the risks and benefits.**

# Medtronic TAVR clinical data

The Medtronic TAVR heart valve has been tested in multiple clinical trials to provide information about the chance of risk from the Medtronic TAVR procedure. The results of these trials are summarized on the following pages.

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

A number of factors determine 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.





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

The Medtronic CoreValve™ heart valve was studied in 639 patients at 41 hospitals in the United States who were too sick for surgery. Patients were examined at 30 days, 6 months, and 1 year after the procedure. If you are at extreme risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| ● Within 30 days<br>● Within 1 year | Access via an artery in the leg (489) | Access via a space between the ribs or an artery in the neck (150) |
|---|---|---|
| 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 |
| All stroke | 4 out of 100 patients | 9 out of 100 patients |
| | 6 out of 100 patients | 12 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 |
| Heart attack (myocardial infarction) | 1 out of 100 patients | 2 out of 100 patients |
| | 2 out of 100 patients | 2 out of 100 patients |

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

The Medtronic CoreValve heart valve was studied in 390 patients at 45 hospitals in the United States who were at high risk for surgery. Patients were examined at 30 days, 6 months, and 1 year after the procedure. If you are at high risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| ● Within 30 days<br>● Within 1 year | Access via an artery in the leg (323) | Access via a space between the ribs or an artery in the neck (67) |
|---|---|---|
| Death from any cause | 3 out of 100 patients | 3 out of 100 patients |
| | 13 out of 100 patients | 18 out of 100 patients |
| • From a heart-related cause | 3 out of 100 patients | 3 out of 100 patients |
| | 10 out of 100 patients | 12 out of 100 patients |
| All stroke | 5 out of 100 patients | 5 out of 100 patients |
| | 9 out of 100 patients | 8 out of 100 patients |
| Life-threatening or disabling bleed | 11 out of 100 patients | 27 out of 100 patients |
| | 14 out of 100 patients | 29 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 27 out of 100 patients | 22 out of 100 patients |
| | 29 out of 100 patients | 26 out of 100 patients |
| Serious damage to the arteries | 7 out of 100 patients | 3 out of 100 patients |
| | 7 out of 100 patients | 3 out of 100 patients |
| Acute kidney injury | 5 out of 100 patients | 11 out of 100 patients |
| | 5 out of 100 patients | 11 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients | 0 out of 100 patients |
| | 2 out of 100 patients | 0 out of 100 patients |



## Evolut R System Study

The Medtronic Evolut™ R heart valve was studied in 166 patients at 24 hospitals in the United States, Australia, New Zealand, and the United Kingdom who were at high risk or were too sick for surgery. Patients were examined at 30 days and 1 year after the procedure. The results from this trial confirmed the safety and effectiveness of the design updates of the Evolut R system compared to its previous generation CoreValve system. If you are at high or extreme risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| ● Within 30 days ● 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 |
| Serious damage to the arteries | 7 out of 100 patients |
| | 7 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients |
| | 1 out of 100 patients |

## Evolut PRO System Study

The Medtronic Evolut™ PRO heart valve was studied in 45 patients at 8 hospitals in the United States who were at high risk or were too sick for surgery. Patients were examined at 30 days, 6 months, and 1 year after the procedure. The results from this trial confirmed the safety and effectiveness of the design updates of the Evolut PRO system compared to its previous generations CoreValve and Evolut R systems. If you are at high or extreme risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| 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 |
| Serious damage to the arteries | 9 out of 100 patients |
| Heart attack (myocardial infarction) | 0 out of 100 patients |



## SURTAVI Intermediate Risk Study

The Medtronic TAVR heart valve was studied in 879 patients at 87 hospitals in the United States, Europe, and Canada who were at intermediate risk for surgery. Patients were examined at 30 days, 6 months, and 1 year after the procedure. 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. If you are at intermediate risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| | ● Within 30 days<br>● Within 1 year | Within 2 years |
|---|---|---|
| Death from any cause | 2 out of 100 patients<br>7 out of 100 patients | 11 out of 100 patients |
| • From a heart-related cause | 2 out of 100 patients<br>5 out of 100 patients | 8 out of 100 patients |
| Disabling stroke | 1 out of 100 patients<br>2 out of 100 patients | 2 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 28 out of 100 patients<br>31 out of 100 patients | 35 out of 100 patients |
| Life-threatening or disabling bleed | 6 out of 100 patients<br>7 out of 100 patients | 8 out of 100 patients |
| Serious damage to the arteries | 6 out of 100 patients<br>6 out of 100 patients | 6 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients<br>2 out of 100 patients | 3 out of 100 patients |

## Evolut Low Risk Trial

The Medtronic TAVR heart valve was studied in 725 patients at 86 hospitals in the United States, Australia, Canada, Europe, New Zealand, and Japan who were at low risk for surgery. Patients were examined at 30 days, 6 months, and 1 year after the procedure. 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. If you are at low risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| Evolut TAVR (725) | ● Within 30 days<br>● Within 1 year | Within 2 years |
|---|---|---|
| Death from any cause | 0 out of 100 patients<br>2 out of 100 patients | 4 out of 100 patients |
| • From a heart-related cause | 0 out of 100 patients<br>2 out of 100 patients | 3 out of 100 patients |
| Disabling stroke | 0 out of 100 patients<br>1 out of 100 patients | 2 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 17 out of 100 patients<br>19 out of 100 patients | 23 out of 100 patients |
| Life-threatening or disabling bleed | 2 out of 100 patients<br>4 out of 100 patients | 4 out of 100 patients |
| Serious damage to the arteries | 4 out of 100 patients<br>4 out of 100 patients | 4 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients<br>2 out of 100 patients | 2 out of 100 patients |



## Evolut Low Risk Trial, cont'd.

| Surgery (SAVR) (678) | ● Within 30 days<br>● Within 1 year | Within 2 years |
|---|---|---|
| Death from any cause | 1 out of 100 patients<br>3 out of 100 patients | 4 out of 100 patients |
| • From a heart-related cause | 1 out of 100 patients<br>3 out of 100 patients | 3 out of 100 patients |
| Disabling stroke | 2 out of 100 patients<br>2 out of 100 patients | 3 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 6 out of 100 patients<br>7 out of 100 patients | 8 out of 100 patients |
| Life-threatening or disabling bleed | 8 out of 100 patients<br>9 out of 100 patients | 9 out of 100 patients |
| Serious damage to the arteries | 3 out of 100 patients<br>3 out of 100 patients | 4 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients<br>2 out of 100 patients | 2 out of 100 patients |

## Bicuspid data from the STS/ACC TVT Registry™*†

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 United States treating patients with a TAVR device. If you are at intermediate risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| | ● Within 30 days | ● 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 device to help regulate the heart (pacemaker) | 17 out of 100 patients | 16 out of 100 patients |
| Life-threatening or disabling bleed | 7 out of 100 patients | 9 out of 100 patients |
| Serious damage to the arteries | 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.



## Medtronic Low Risk Bicuspid Study

The Medtronic TAVR heart valve was studied in approximately 150 patients at 25 hospitals in the United States who were at low risk for surgery and had a bicuspid aortic valve. Safety and efficacy data were collected 30 days after the procedure. If you are at low risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| Risks within 30 days | |
|---|---|
| Death from any cause | 1 out of 100 patients |
| • From a heart-related cause | 1 out of 100 patients |
| All stroke | 4 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 15 out of 100 patients |
| Life-threatening or disabling bleed | 4 out of 100 patients |
| Serious damage to the arteries | 1 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients |

## Redo TAV data from the STS/ACC TVT Registry†

The table below summarizes the 1-year‡ results of the 744 patients with a failed transcatheter valve who were then treated with a Medtronic TAVR device. The data came from the TVT Registry, a national registry run by the Society of Thoracic Surgeons and the American College of Cardiology Foundation. The registry collects certain safety and efficacy data from participating hospitals in the United States treating patients with a TAVR device. If you are in need of a second TAVR, the clinical data shown below may be like what you can expect.

| ● 1 year ● In-hospital | |
|---|---|
| Death from any cause | 16 out of 100 |
| • From a heart-related cause | 5 out of 100 |
| All stroke | 4 out of 100 |
| Serious damage to arteries | 2 out of 100 |
| Life threatening or disabling bleed | 9 out of 100 |
| Heart attack (myocardial infarction) | 1 out of 100 |
| New permanent device to help regulate the heart (pacemaker) | 8 out of 100 |
| Need for a new aortic valve or reintervention on existing valve | 8 out of 100 |
| Valve thrombosis | 1 out of 100 |
| Coronary compression or obstruction | No reported events§ |

† 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.

‡ Rate of coronary obstruction from patients in hospital

§ No events were reported, however, coronary compression or obstruction remains a risk in a redo-TAVR procedure.



# Frequently asked questions

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Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free: 800.328.2518
Tel: +1.763.514.4000

**medtronic.com/TAVR**

**LifeLine**
**CardioVascular Technical Support**
Toll-free: 877.526.7890
Tel: +1.763.526.7890
rs.structuralheart@medtronic.com



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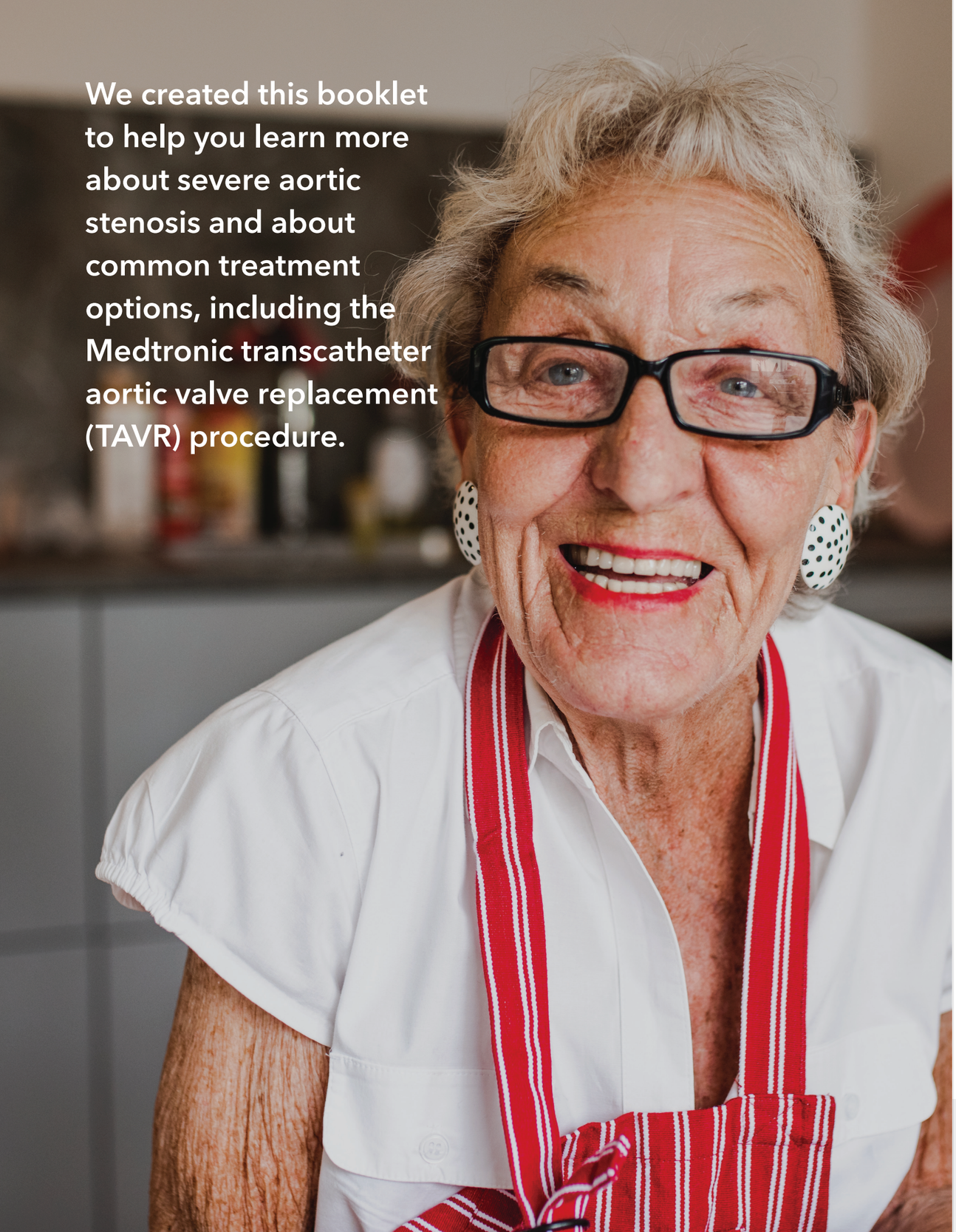
Medtronic

Engineering the extraordinary

The Medtronic Transcatheter Aortic Valve Replacement (TAVR) System

# Treating your aortic stenosis



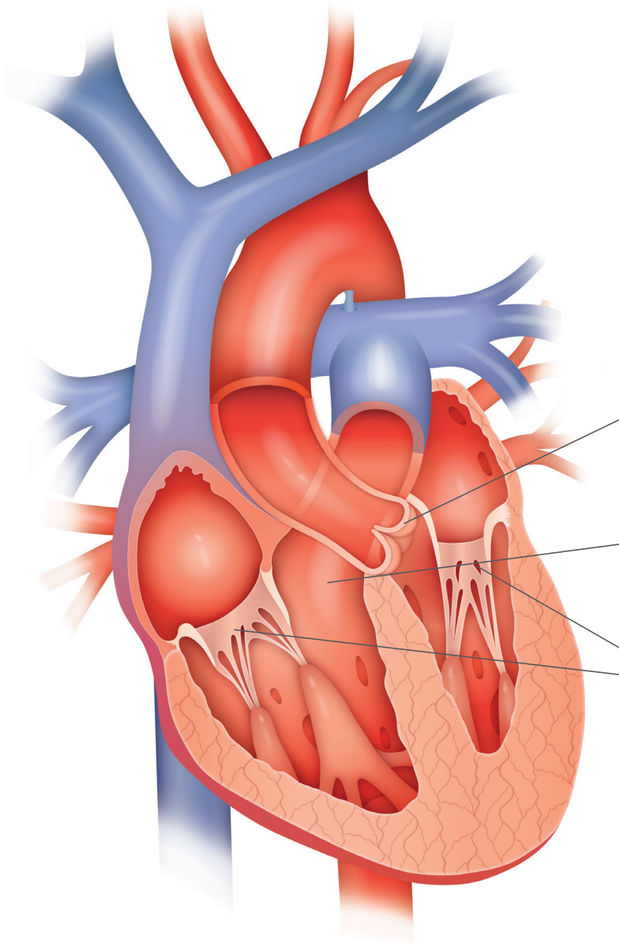
We created this booklet to help you learn more about severe aortic stenosis and about common treatment options, including the Medtronic transcatheter aortic valve replacement (TAVR) procedure.

# Table of contents



**Discover more at 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?

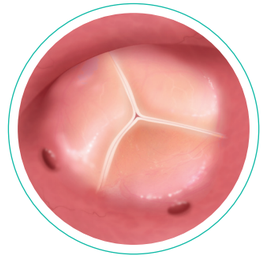
Severe aortic stenosis prevents your aortic valve leaflets from opening and closing properly. This makes your heart work harder to pump blood to the rest of your body. A diseased valve affects your health and limits your daily activities.

**Some causes of severe aortic stenosis include:**

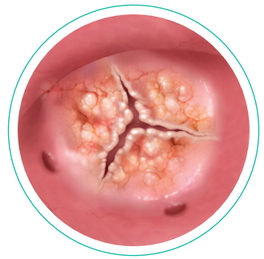
- Age
- Calcium buildup
- Radiation therapy
- Infection of the heart

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

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



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 aortic heart valve animation at medtronic.com/TAVR**

# 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 the incision is made, a thin, flexible tube is inserted into an artery to guide the artificial heart valve up to your heart to replace the diseased valve.

**TAVR procedures were first performed in 2002.**



# Failed surgical or transcatheter aortic valve

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

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

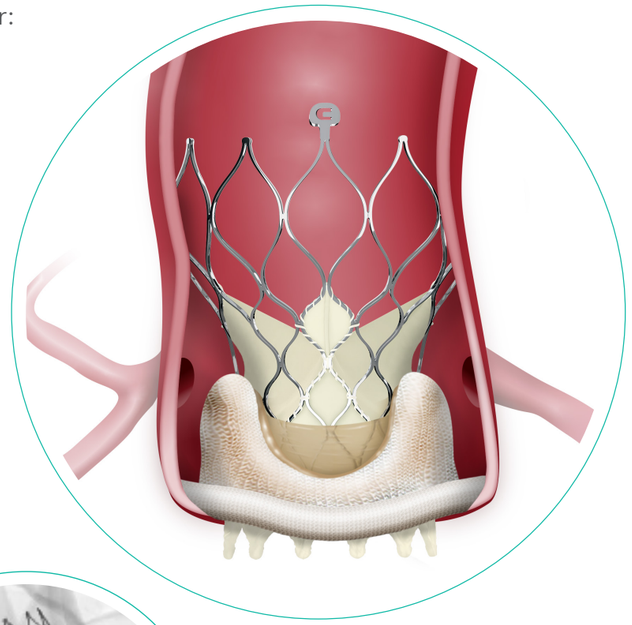
- Stenosis – when the valve narrows and does not open completely
- Regurgitation – when the valve does not fully close and blood flows backwards through the valve

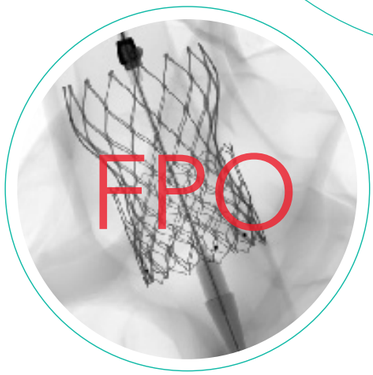
### Causes:

- Calcification
- Wear and tear over time

### Symptoms:

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





# What is the best treatment option for you?

Your heart team will conduct tests that will help you and the team discuss the best treatment option. 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
- Pulmonary function test
- Electrocardiogram (EKG)

**See descriptions of common tests performed in the valve clinic at 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. The Evolut™ FX+ valve frame has gold markers beneath the outer wrap so your doctor can better see the valve on X-ray during the procedure.

The valve also has three larger cells to help your doctor get access to your coronary arteries.

The Medtronic TAVR heart valve comes in four different sizes.

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

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

**Image is larger than its actual size.**

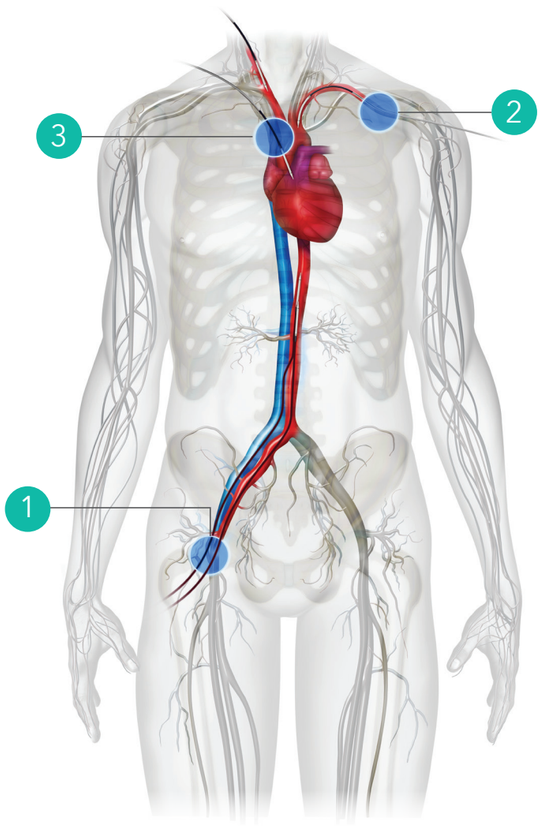
# Medtronic TAVR procedure

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, the neck 2, or a space between your ribs 3 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 natural valve or failed implanted valve. Your new valve will work immediately.

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




**Watch a video on the TAVR procedure at medtronic.com/TAVR**

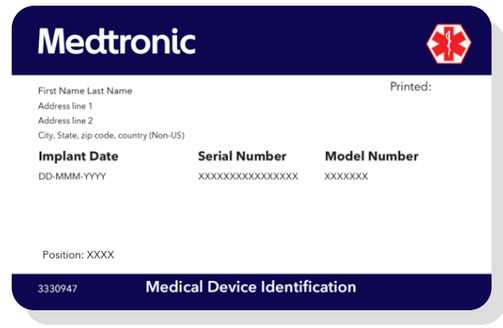


# After your procedure

After the procedure, most patients spend a few hours in the intensive care unit (ICU) before transferring to a patient room. Typically, patients begin walking the same day as their Medtronic TAVR procedure and are discharged within a day or two.

Before you leave the hospital, your doctor will explain what kinds of activities you can do, what medications you need to take, 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.


Medtronic

First Name Last Name
Address line 1
Address line 2
City, State, zip code, country (Non-US)

Printed:

| Implant Date | Serial Number | Model Number |
|---|---|---|
| DD-MMM-YYYY | XXXXXXXXXXXXXXX | XXXXXXX |

Position: XXXX

3330947 Medical Device Identification

## 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.**

# Benefits and risks

**The Medtronic TAVR procedure is currently approved for:**

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

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.

**Find stories about real Medtronic TAVR patients at 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.

Many Medtronic TAVR patients report benefits like:

- Having more energy
- Breathing normally
- Experiencing less pain
- Experiencing fewer symptoms
- Feeling less anxious

After the procedure, most patients can take care of themselves better and go back to everyday activities.

**Risks**

Most medical procedures have risks. The most serious risks of the Medtronic TAVR procedure 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 patients who†:**

- Have a serious infection
- Cannot take medications that reduce the risk of blood clots
- Have a reaction to some metals

†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.**
**See pages 13–16 for the risks and benefits.**

# 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 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



# Other potential risks

  - 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

# Other potential risks

- 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
- Mitral valve regurgitation – blood leaking backward 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.



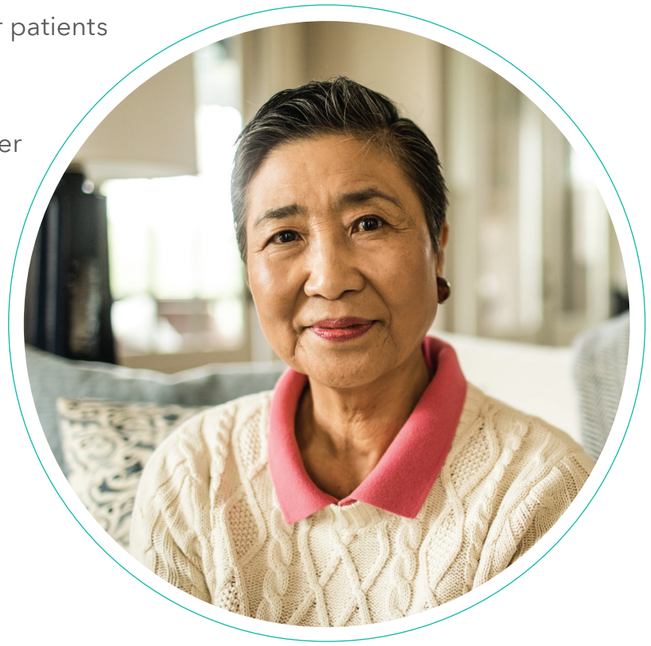
# Warnings and precautions

## 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 medications that reduce the risk of blood clots 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 medications that reduce the risk of blood clots, 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
- 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.**
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# Medtronic TAVR clinical data

The Medtronic TAVR heart valve has been tested in multiple clinical trials to provide information about the chance of risk from the Medtronic TAVR procedure. The results of these trials are summarized on the following pages.

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

A number of factors determine 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.

## 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 United States who were at extreme risk for surgery and had a transcatheter valve implanted in a failed surgical valve. Patients were examined at 30 days, 6 months, and 1 year after the procedure. The study results showed at one year that the CoreValve procedure had an acceptable safety profile and was an effective treatment option for patients with a failing surgical aortic valve. If you are at extreme risk for open-heart surgery, the clinical data shown below may be like what you can expect.

| ● Within 30 days ● Within 1 year | |
|---|---|
| Death from any cause | 4 out of 100 patients |
| | 14 out of 100 patients |
| • From a heart-related cause | 3 out of 100 patients |
| | 7 out of 100 patients |
| All stroke | 1 out of 100 patients |
| | 3 out of 100 patients |
| New permanent device to help regulate the heart (pacemaker) | 9 out of 100 patients |
| | 18 out of 100 patients |
| Life-threatening or disabling bleed | 6 out of 100 patients |
| | 11 out of 100 patients |
| Serious damage to the arteries | 12 out of 100 patients |
| | 12 out of 100 patients |
| Heart attack (myocardial infarction) | 1 out of 100 patients |
| | 1 out of 100 patients |



## Redo TAV data from the STS/ACC TVT Registry†

The table below summarizes the 1-year‡ results of the 744 patients with a failed transcatheter valve who were then treated with a Medtronic TAVR device. The data came from the TVT Registry, a national registry run by the Society of Thoracic Surgeons and the American College of Cardiology Foundation. The registry collects certain safety and efficacy data from participating hospitals in the United States treating patients with a TAVR device. If you are in need of a second TAVR, the clinical data shown below may be like what you can expect.

| ● 1 year ● In-hospital | |
|---|---|
| Death from any cause | 16 out of 100 |
| • From a heart-related cause | 5 out of 100 |
| All stroke | 4 out of 100 |
| Serious damage to arteries | 2 out of 100 |
| Life threatening or disabling bleed | 9 out of 100 |
| Heart attack (myocardial infarction) | 1 out of 100 |
| New permanent device to help regulate the heart (pacemaker) | 8 out of 100 |
| Need for a new aortic valve or reintervention on existing valve | 8 out of 100 |
| Valve thrombosis | 1 out of 100 |
| Coronary compression or obstruction | No reported events§ |

† 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.

‡ Rate of coronary obstruction from patients in hospital

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Minneapolis, MN 55432-5604
USA

Toll-free: 800.328.2518
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