Medtronic

CoreValve®

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) PLATFORM

Patient Booklet

Is the CoreValve® Heart Valve Right for You?

The CoreValve heart valve is for people with aortic valve disease. Your doctor can help you decide if the CoreValve device is right for you. This booklet will help you learn more about the CoreValve heart valve.

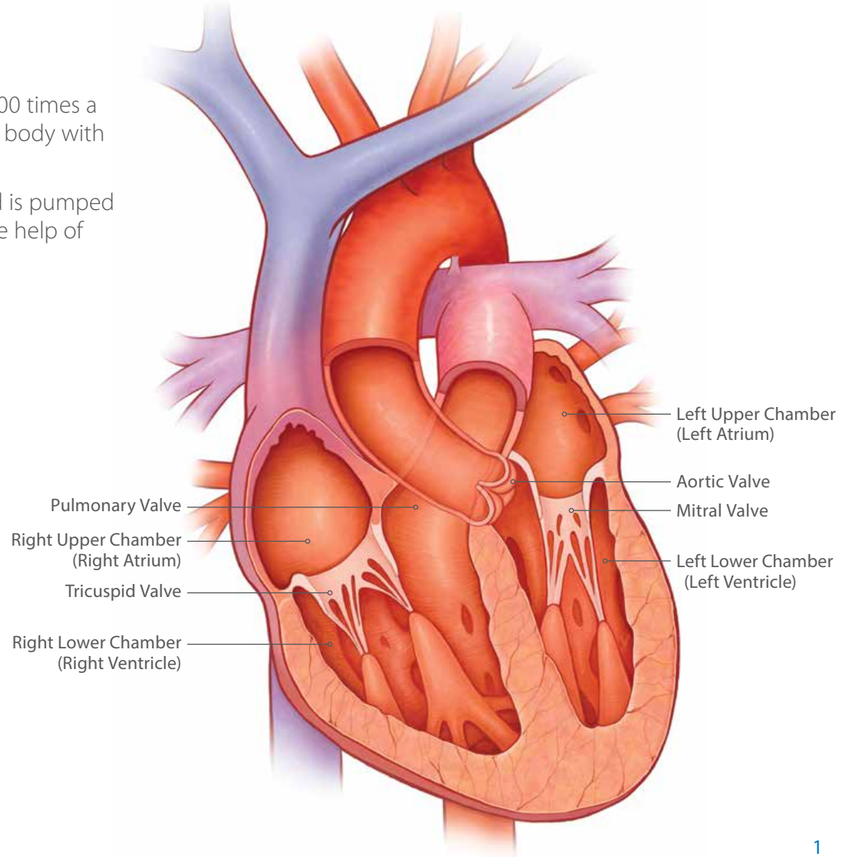
Table of Contents

About the Heart

How the Heart Works

A healthy heart beats around 100,000 times a day. The heart's job is to supply the body with oxygen-rich blood.

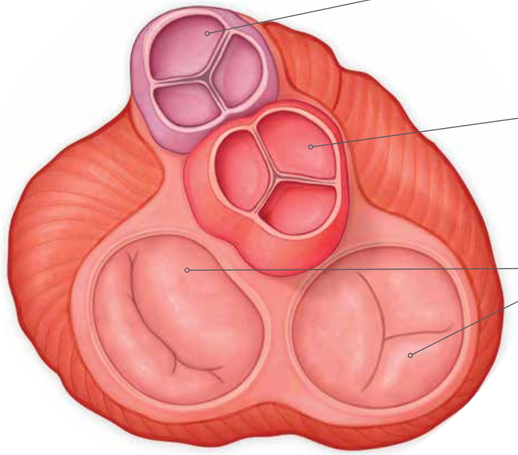
The heart has four chambers. Blood is pumped through the four chambers with the help of four heart valves.



About the Heart

What Heart Valves Do

Heart valves open when the heart pumps to allow blood to flow. They close quickly between heartbeats to make sure blood does not flow backward. Any trouble in this normal flow will make it hard for the heart to pump the blood where it needs to go.



The **pulmonic valve** controls the flow of blood to the lungs to get oxygen

The **aortic valve** controls the flow blood as it exits the heart and is pumped to the rest of the body.

The **mitral and tricuspid valves** control blood flow as it moves between the chambers of the heart

Aortic Valve Diseases Treated with the CoreValve Heart Valve

Severe Aortic Stenosis (AS) of Your Native Valve

Your native valve is the valve you were born with. AS occurs when your aortic valve does not open as it should. This makes your heart work harder to pump blood through your body. This affects your health and limits your normal daily activities.

Severe AS may be caused by the following:

- Age.
- Calcium buildup that narrows the aortic valve.
- Radiation therapy.
- Infection of the heart.

Left untreated, severe AS can lead to heart failure or even sudden death.

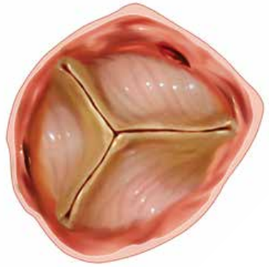
Failing Surgical Aortic Valve

Some people have had their own valve replaced with surgery. Surgical valves wear out over time. The surgical valve can start to fail. The CoreValve heart valve might be an option for these people.

Signs of Severe AS

Severe AS may cause you to feel:

- Chest pain.
- Faint.
- Dizzy.
- Tired.
- Out of breath.
- Irregular heart beat.



Normal Valve

Stenotic Valve

Treatment Options for Your Aortic Valve Disease

Medication and Balloon Valvuloplasty (BAV)

Your doctor may give you medicine to help ease the symptoms of your disease. A procedure called BAV may also be done. BAV is not surgery. This is where a balloon is placed in the aortic valve and inflated. This may help the valve function better, but is only a temporary fix. Without valve replacement you could feel worse over time.

Surgical Aortic Valve Replacement (SAVR)

SAVR is an option for some people with severe AS. The native valve is removed and replaced with a new valve.

SAVR often includes the following:

- Your chest is opened to access the heart.
- Your heart is stopped.
- A machine pumps blood through your body.
- Your diseased valve is removed.
- The new valve is sewn into place.
- You may be in the hospital for more than a week.

The risks of SAVR are listed on pages 16-18.

Treatment of Your Aortic Valve Disease Using the CoreValve Heart Valve

CoreValve® Aortic Valve Replacement

The CoreValve heart valve is another option for people with severe AS. It does not require open heart surgery. It is implanted using an artery that leads to the heart.

The CoreValve heart valve is made from pig heart tissue. This tissue valve is held by a metal frame. It is designed to work like your own heart valve

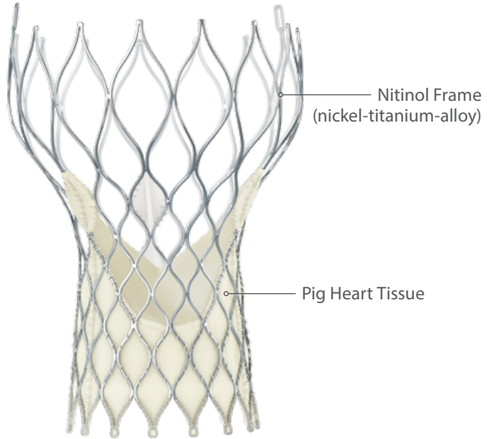


Image is bigger than actual valve

Understanding the CoreValve Procedure

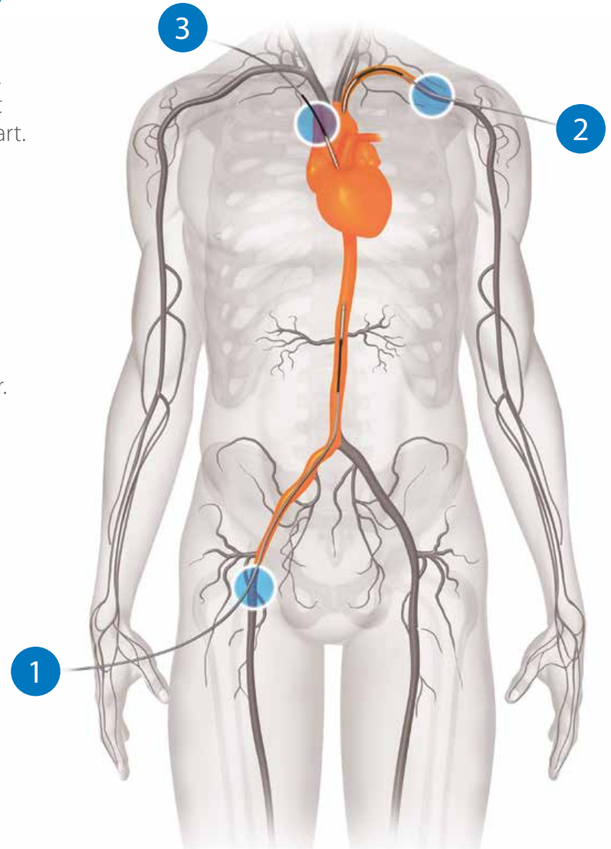
How Does the CoreValve Heart Valve Get to My Heart?

The arteries in your body are like a system of roads. They branch out from the heart. There are different "routes" that your doctor can use to get to your heart.

These include:

- An artery in your leg **(1)**.
- An artery in your neck **(2)**.
- A space between your ribs **(3)**.
- Another entry point determined by your doctor.

Each route has risks. Discuss them with your doctor.



A Typical CoreValve® Procedure

1. Because each patient is different, your doctor will determine if you should be fully asleep during the 1-2 hour procedure.
2. The doctor will make a cut and guide a long tube (sheath) into your artery.
3. A thin, flexible tube (catheter) with a balloon on the tip may be placed into your heart. When the end of the balloon gets to your aortic valve, the balloon will be inflated. This will force your diseased aortic valve open and prepare it for the CoreValve heart valve.
4. Your doctor will place the CoreValve heart valve in position over your own diseased heart valve or your failing surgical valve. (Figures 1 and 2)
5. Your new CoreValve heart valve will begin opening and closing. The doctor will conduct a test to confirm it is working properly. (Figure 3)
6. The thin, flexible tube will be removed, the cut will be closed, and the operation will be complete.

Machines that use sound waves or X-rays to look at your heart and arteries will be used during the procedure.

Note: Step 3 may not apply to you if you have a failing surgical valve based on your valve condition.

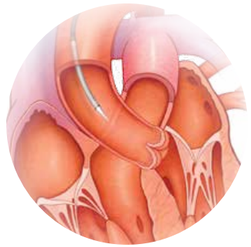


Figure 1

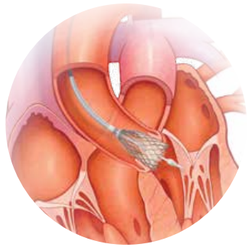


Figure 2

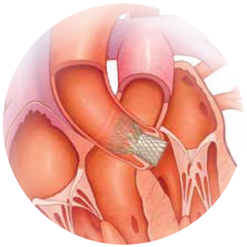


Figure 3

After the CoreValve Procedure

Hospital Stay

You will stay in the hospital until your doctor decides you are able to leave. Patients are often walking in a day or two. The usual hospital stay is about 8 days.

Follow-up Care

When you leave the hospital your doctor will give you care instructions. You may have to limit certain activities. You will need to take medicine and have your heart checked from time to time. Talk to your doctor any time you have questions or concerns about your new heart valve.

If you require an MRI* scan, tell the doctor that you have a CoreValve heart valve. Tell your doctor if you have a CoreValve heart valve inside a surgical valve. Not doing so could cause injury or death. Your dentist and all doctors need to know about your CoreValve heart valve.

You will get a card with CoreValve heart valve information. Keep this card with you. Show it to any doctors who may be treating you. If you do not get a card, contact your doctor.

The lifespan of the CoreValve heart valve will vary from patient to patient. It has been tested to mimic 5 years of use without failure.

Keep appointments with your doctor. Follow all care instructions to ensure the best possible results.

*Magnetic Resonance Imaging

CoreValve Clinical Experience

CoreValve Clinical Studies

The CoreValve heart valve has been tested in many studies. The results of 3 studies are summarized below.

Benefits

You should start feeling better right away. This is because your heart valve is now working properly. Some patients may take longer to feel better.

Most patients felt less pain and less anxious. They could take care of themselves better and go back to everyday activities.

Risks

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

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

There is more information about the CoreValve clinical studies. Your doctor can tell you which results apply to you:

- High risk patient information starts on page 14.
- Extreme risk patient information starts on page 20.
- Failing surgical valve patient information starts on page 26.

The CoreValve Procedure is Not Right for Everyone

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

Patients who:

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

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

For some patients the risk of the CoreValve procedure may outweigh the benefits. See pages 14-31 for the risks and benefits associated with the CoreValve procedure.

Warnings and Precautions

Warnings

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

The CoreValve heart valve is only for certain patients. This includes patients with severe AS or failing surgical valves that:

- Cannot have surgery.
- Are at high risk for surgery.

Precautions

- At some point the CoreValve heart valve may need to be replaced. How long it lasts varies from patient to patient. It has been tested to mimic 5 years of use without failure. Keep appointments with your doctor. Follow all care instructions to ensure the best possible results.
- Antibiotics are recommended for patients who are at risk of infections.
- Patients should stay on blood-thinning medicines after the procedure as instructed. Patients who do not are more likely to have a stroke.
- If you require an MRI scan, tell the doctor that you have a CoreValve heart valve. Tell your doctor if you have a CoreValve heart valve inside a surgical valve. Not doing so could cause injury or death. Your dentist and all doctors need to know about your CoreValve heart valve.

The CoreValve heart valve has not been studied in patients:

- Who are not sick from AS.
- Who are children.
- With an aortic valve that has only one or two leaflets.
- Who have a blood clot.
- With an abnormal growth in the heart or arteries.
- Who have an infection.
- Who have AS in their own valve and a condition that allows blood to leak backwards through the aortic valve.
- Who have severe mitral valve disease.
- With poor left ventricle function.
- Whose diseased valve is too small or too big.
- Whose arteries are too small for the device.
- Whose arteries that deliver blood to the heart may be blocked by the device.
- Whose arteries that deliver blood to the heart need to be treated.
- Whose arteries that deliver blood to the brain need to be treated.
- Who have severe problems with bleeding or blood clotting.

Warnings and Precautions (Continued)

- Who have severe kidney disease that requires dialysis.
- Who have specific types of surgical valves implanted in the pulmonary valve.
- Who have specific types of surgical valves implanted in the mitral valve.
- Who have thick heart muscles making it difficult for the heart to pump blood.
- Who have thick heart muscles that blocks the heart from pumping blood.

If the CoreValve heart valve is used in these patients, it may not work right. This could make you feel sick or cause death.

For some, the risks of the CoreValve procedure may outweigh the benefits. See pages 14-31 for the risks and benefits.

FAQs

Frequently Asked Questions

Are physical activities safe?

Discuss this with your doctor. They can help decide what is best for you.

Is it safe to have an X-ray with a CoreValve heart valve?

Yes. The CoreValve heart valve is safe for X-rays.

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

Yes, under certain conditions. If you require an MRI scan, tell the doctor that you have a CoreValve heart valve. Tell your doctor if you have a CoreValve heart valve inside a surgical valve. Not doing so could cause injury or death.

How will I know if my CoreValve heart valve is working right?

Attend regular follow-up doctor visits to check your valve.

Experience from the CoreValve US Pivotal Trial: High Risk Study

High Risk Study Overview

These patients were at high risk for surgery. This group included 747 patients at 45 hospitals in the US.

Most received the CoreValve heart valve through an artery in their leg. Some received it through a space between their ribs. And others through an artery in their neck. Patients were randomly put in the CoreValve procedure or surgery group. Both groups were examined at:

- 30 days.
- 6 months.
- 1 year.

Yearly checkups will continue for 5 years.

The study results at 1 year showed:

- The CoreValve procedure was a safe and effective alternative to surgery.
- More CoreValve heart valve patients were alive than surgical patients.

Quality of Life Improvements

A standard tool* was used to assess health at 30 days and 1 year. At 30 days, compared to surgery, more CoreValve heart valve patients:

- Felt less pain.
- Had improved health.
- Were less anxious.
- Could take care of themselves better.
- Went back to everyday activities sooner.

This improvement was similar at 1 year for both groups.

* This quality of life tool is called the Kansas City Cardiomyopathy Questionnaire (KCCQ) and EuroQol/EQ-5D

Symptom Relief

Compared to surgery, more CoreValve heart valve patients had symptom relief at 30 days. This relief of symptoms was similar at 1 year for both patient groups. The table below shows the number of patients who improved at 30 days and 1 year. A standard tool was used for this assessment.

Ratio of Days Alive and Not in Hospital

CoreValve and surgical patients were compared. More CoreValve patients were alive at 1 year. They also spent fewer days in the hospital.

Patients Showing Symptomatic Relief Using New Your Heart Association Functional Class

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)		Surgery (SAVR)		CoreValve (TAVR)		Surgery (SAVR)	
30 Days	1 Year	30 Days	1 Year	30 Days	1 Year	30 Days	1 Year
8 out of 10 patients	8 out of 10 patients	7 out of 10 patients	7 out of 10 patients	7 out of 10 patients	7 out of 10 patients	6 out of 10 patients	6 out of 10 patients

What are the Potential Risks **30 Days** After Your Aortic Valve Procedure?

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

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

Potential risks at 30 days are listed in the table. It is divided by access site. Access site is selected by your doctor. Talk to your doctor about these risks.

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

What are the Potential Risks **1 Year** After Your Aortic Valve Procedure?

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

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

Potential risks at 1 year are listed in the table. It is divided by access site. Access site is selected by your doctor. Talk to your doctor about these risks.

High Risk Patients Risks Within 1 Year 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	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

Experience from the CoreValve US Pivotal Trial: Extreme Risk Study

Extreme Risk Study Overview

These patients were too sick for surgery. This group included 639 patients at 41 hospitals in the US.

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 seen at:

- 30 days.
- 6 months.
- 1 year.

Yearly checkups will continue for 5 years.

The CoreValve procedure results were assessed at 1 year. It was found safe and effective versus other options. Other options include BAV or medicines.

Quality of Life Improvements

A standard tool* was used to assess health at 30 days and 1 year. At 30 days most CoreValve heart valve patients:

- Felt less pain.
- Had improved health.
- Were less anxious.
- Could take care of themselves better.
- Went back to everyday activities.

This improvement was maintained at 1 year.

* This quality of life tool is called the Kansas City Cardiomyopathy Questionnaire (KCCQ) and EuroQol/EQ-5D

Symptom Relief

Most CoreValve heart valve patients had symptom relief at 30 days. This relief of symptoms was maintained at 1 year. The table below shows the number of patients who improved at 30 days and 1 year. A standard tool was used for this assessment.

Patients Showing Symptomatic Relief

Access via an artery in your leg		Access via a space between your ribs or an artery in your neck	
30 Days	1 Year	30 Days	1 Year
8 out of 10 patients	7 out of 10 patients	7 out of 10 patients	5 out of 10 patients

What are the Potential Risks **30 Days** After CoreValve (TAVR)?

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

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

Potential risks at 30 days are listed in the table. It is divided by access site. Access site is selected by your doctor. Talk to your doctor about these risks.

Extreme Risk Patients Risks Within 30 Days After Your CoreValve (TAVR) Procedure	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
From a heart related cause	8 out of 100 patients	11 out of 100 patients
From a heart valve related cause	3 out of 100 patients	3 out of 100 patients
All stroke	4 out of 100 patients	9 out of 100 patients
Major stroke	2 out of 100 patients	7 out of 100 patients
Bleeding event	37 out of 100 patients	58 out of 100 patients
Serious bleeding	25 out of 100 patients	37 out of 100 patients
Life threatening or disabling bleed	13 out of 100 patients	24 out of 100 patients
New permanent device to help regulate the heart (pacemaker)	29 out of 100 patients	22 out of 100 patients
Serious damage to the arteries	8 out of 100 patients	9 out of 100 patients
Acute kidney injury	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
Heart attack (myocardial infarction)	1 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
Surgical aortic valve replacement	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
Valve inflammation or infection (endocarditis)	0 out of 100 patients	1 out of 100 patients

What are the Potential Risks **1 Year** After CoreValve (TAVR)?

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

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

Potential risks at 1 year are listed in the table. It is divided by access site. Access site is selected by your doctor. Talk to your doctor about these risks.

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

Experience from the CoreValve US Expanded Use Study: Failing Surgical Valve Patients

Expanded Use Study: Failing Surgical Valve Patients Overview

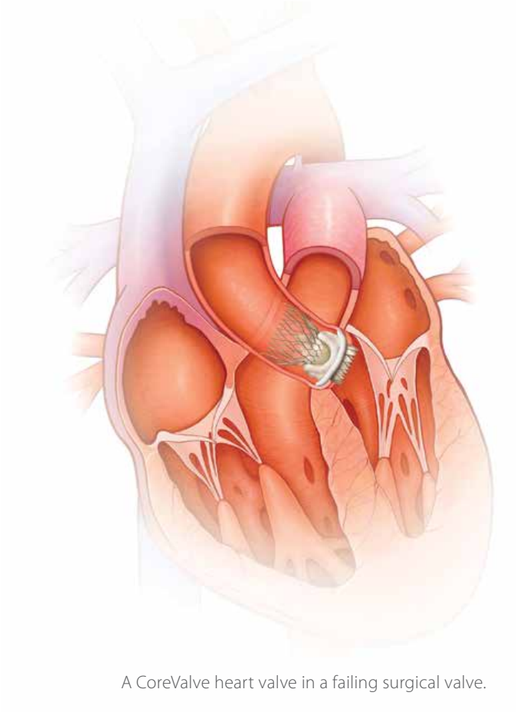
This group included 147 patients at 37 hospitals in the US. They had a failing surgical valve and were too sick for surgery.

Patients were seen at:

- 30 days.
- 6 months.
- 1 year.

Yearly checkups will continue for 5 years.

This procedure was found safe and effective for patients with a failing surgical valve.



A CoreValve heart valve in a failing surgical valve.

Failing Surgical Valve Patients | Benefits

Quality of Life Improvements

A standard tool* was used to assess health at 30 days, 6 months, and 1 year. At 30 days most CoreValve heart valve patients:

- Felt less pain.
- Had improved health.
- Were less anxious.
- Could take care of themselves better.
- Went back to everyday activities.

This improvement was maintained at 6 months and 1 year.

* This quality of life tool is called the Kansas City Cardiomyopathy Questionnaire (KCCQ) and EuroQol/EQ-5D

Symptom Relief

Most CoreValve heart valve patients had symptom relief at 30 days. This relief of symptoms was maintained at 6 months and 1 year. The table below shows the number of patients who improved at 30 days, 6 months, and 1 year. A standard tool was used for this assessment.

Patients Showing Symptomatic Relief (NYHA)		
Access via an artery in your leg or a space between your ribs or an artery in your neck		
30 Days	6 Months	1 Year
9 out of 10 Patients	9 out of 10 Patients	7 out of 10 Patients

What are the Potential Risks After CoreValve (TAVR)?

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

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

Potential risks at 30 days, 6 months, and 1 year are listed in the table.

Almost all 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. Talk to your doctor about these risks.

Failing Surgical Valve Patients Risks Within 30 Days, 6 Months and 1 Year After Your CoreValve (TAVR) Procedure	RISKS WITHIN 30 DAYS Access via an artery in your leg or a space between your ribs or an artery in your neck	RISKS WITHIN 6 MONTHS Access via an artery in your leg or a space between your ribs or an artery in your neck	RISKS WITHIN 1 YEAR Access via an artery in your leg or a space between your ribs or an artery in your neck
Death from any cause	4 out of 100 Patients	9 out of 100 Patients	14 out of 100 Patients
From a heart related cause	3 out of 100 Patients	5 out of 100 Patients	8 out of 100 Patients
From a heart valve related cause	0 out of 100 Patients	0 out of 100 Patients	3 out of 100 Patients
All stroke	1 out of 100 Patients	3 out of 100 Patients	3 out of 100 Patients
Major stroke	1 out of 100 Patients	2 out of 100 Patients	2 out of 100 Patients
Bleeding event	20 out of 100 Patients	22 out of 100 Patients	24 out of 100 Patients
Serious bleeding	14 out of 100 Patients	14 out of 100 Patients	14 out of 100 Patients
Life threatening or disabling bleed	6 out of 100 Patients	9 out of 100 Patients	12 out of 100 Patients
New permanent device to help regulate the heart (pacemaker)	10 out of 100 Patients	11 out of 100 Patients	19 out of 100 Patients
Serious damage to the arteries	12 out of 100 Patients	12 out of 100 Patients	12 out of 100 Patients
Acute kidney injury	3 out of 100 Patients	3 out of 100 Patients	3 out of 100 Patients
Hospitalization due to complications with aortic valve	5 out of 100 Patients	9 out of 100 Patients	14 out of 100 Patients
Heart attack (myocardial infarction)	1 out of 100 Patients	1 out of 100 Patients	1 out of 100 Patients
Need for additional procedures on your aortic valve	1 out of 100 Patients	2 out of 100 Patients	7 out of 100 Patients
Surgical aortic valve replacement	1 out of 100 Patients	2 out of 100 Patients	4 out of 100 Patients
Less invasive procedure (not including replacement)	0 out of 100 Patients	0 out of 100 Patients	3 out of 100 Patients
Valve inflammation or infection (endocarditis)	0 out of 100 Patients	0 out of 100 Patients	0 out of 100 Patients

Other Potential Risks Associated with CoreValve

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

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

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

Resources

For More Information on the CoreValve TAVR Procedure

Please contact your doctor or nurse for more information. For product information, visit **www.CoreValve.com**.

For Technical Support Information

Toll-free phone number in the USA: 1-877-526-7890

Phone number from outside the USA: 1-763-526-7890

Email address: rs.cstechsupport@medtronic.com

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

The CoreValve transcatheter aortic valve has been approved by FDA for specific patient populations only. Refer to the Instructions for Use for a full list of warnings, precautions, indications, and adverse events.

CoreValve is a registered trademark of Medtronic CV Luxembourg S.a.r.l.

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