



CoreValve[®]

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) PLATFORM

An approach to treat
severe aortic stenosis for
those who are at high risk for
or who cannot have surgery.





Is CoreValve® Transcatheter Aortic Valve Replacement (TAVR) Right for You?

CoreValve TAVR may be right for you if you feel sick from severe aortic stenosis and your doctor has determined that you are at high risk or are not a candidate for valve replacement surgery. Your doctor can help decide if the CoreValve device is the appropriate treatment option for you.

This brochure provides information about the heart, severe aortic stenosis (AS) and the Medtronic CoreValve TAVR procedure that can treat this disease.

This booklet is provided to help you and your loved ones learn more about CoreValve Transcatheter Aortic Valve Replacement. Please discuss any questions with your heart doctor. Only a doctor can decide if CoreValve is the right treatment for you.

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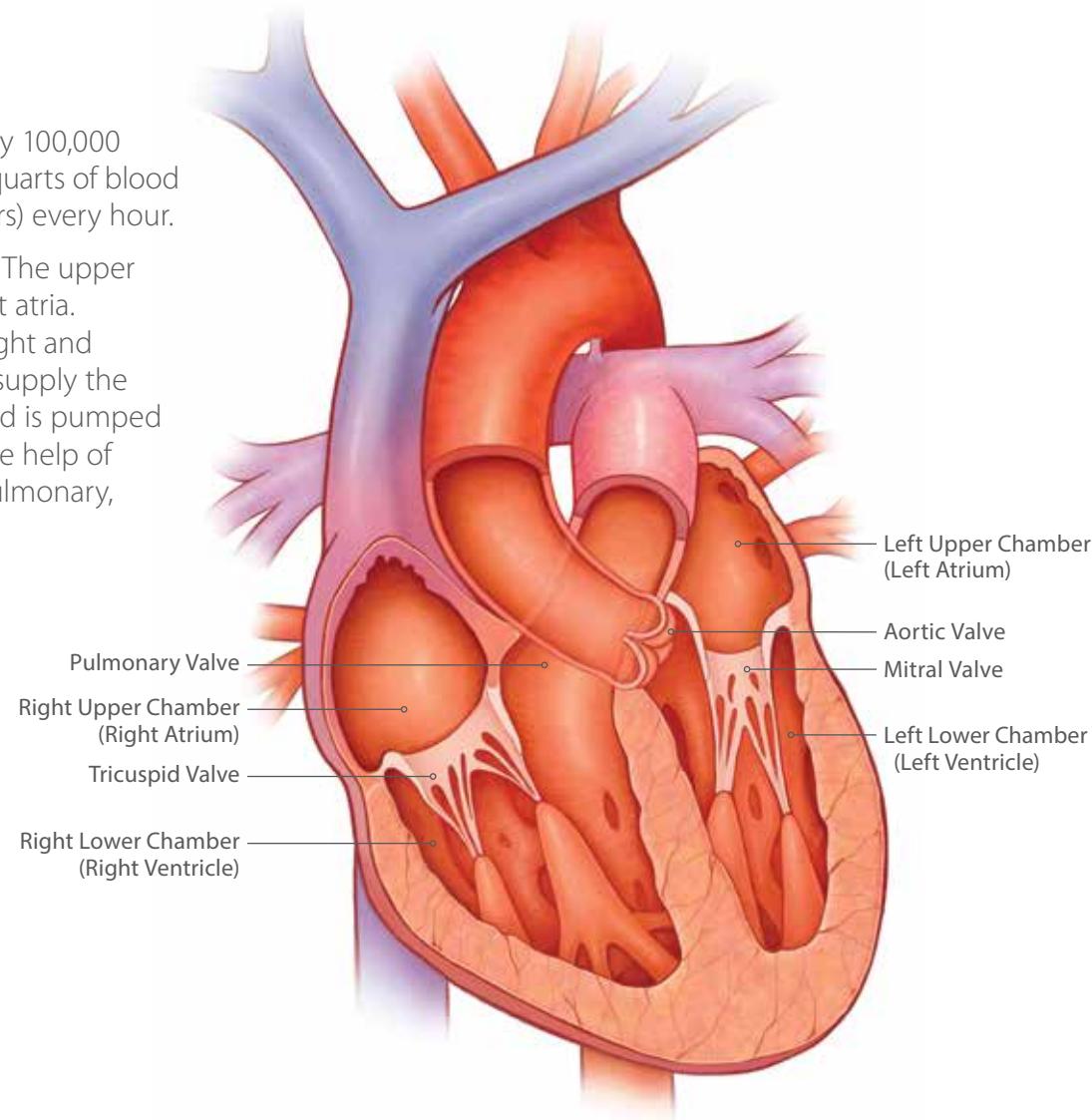
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About the Heart

How the Heart Works

A healthy heart beats approximately 100,000 times a day and pumps about five quarts of blood each minute, or 75 gallons (284 liters) every hour.

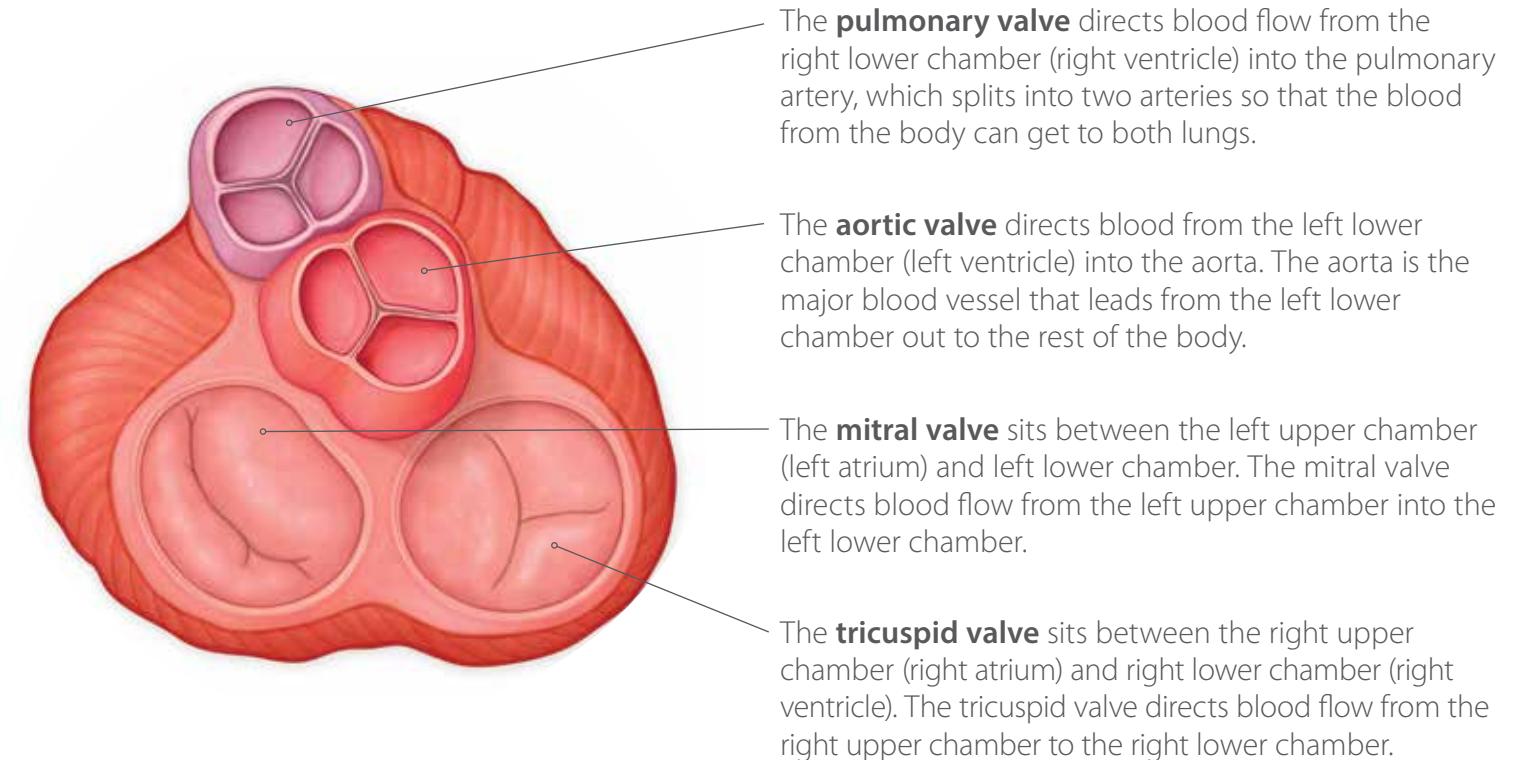
A normal heart has four chambers. The upper two chambers are the right and left atria. The lower two chambers are the right and left ventricles. The heart's job is to supply the body with oxygen-rich blood. Blood is pumped through the four chambers with the help of four heart valves—the tricuspid, pulmonary, mitral and aortic valves.



About the Heart

What Heart Valves Do

Heart valves open when the heart pumps to allow blood to flow forward, and close quickly between heartbeats to make sure blood does not flow backward. Any disruption in this normal flow will make it difficult for the heart to effectively pump the blood where it needs to go.



Severe Aortic Stenosis

Severe Aortic Stenosis

Severe aortic stenosis (AS) occurs when the aortic valve doesn't open properly. This forces your heart to work harder to pump blood throughout your body. Over time, the heart muscle weakens. This affects your overall health and keeps you from participating in normal daily activities.

Left untreated, severe AS is a very serious, life-threatening condition, leading to heart failure and increased risk for sudden cardiac death.

Severe AS is often not preventable, causes narrowing of the aortic valve, and may be related to the following:

- Age
- A buildup of mineral (calcium) deposits that narrows the aortic valve (stenosis)
- Radiation therapy
- A history of a bacterial infection of the heart (rheumatic fever)
- Increased fat in the blood vessels (high cholesterol)

Symptoms of Severe AS

Signs and symptoms of severe AS can include:

- Chest pain or tightness
- Feeling faint or fainting with activity
- Dizziness
- Fatigue
- Shortness of breath
- Irregular heart beat (palpitations)
- Unusual sound heard during a heartbeat (murmur)



Normal Valve

Stenotic Valve

Treatment Options for Severe AS

Medical Management and Balloon Valvuloplasty

Patients with severe AS who are too sick for surgery may take **medications** that help control irregular heartbeats or prevent blood clots. These medications may help control your symptoms for a period of time; however, without aortic valve replacement, severe AS could worsen to a more serious condition.

In addition to medications and if your physician determines appropriate, a procedure called **Balloon Valvuloplasty** can be performed to relieve symptoms. It is a non-surgical procedure that is performed by placing a balloon into the aortic valve and inflating the balloon. Balloon valvuloplasty does not treat severe AS, which could worsen to a more serious condition without valve replacement.

Medical Management and Balloon Valvuloplasty do not treat severe AS or alter its progression. Risks will vary, so talk about adverse risk events with your doctor.

Surgical Aortic Valve Replacement (SAVR)

Surgical aortic valve replacement surgery is an effective, life-saving treatment option for some people with severe AS. Depending on your risk factors, such as health, diagnosis, and age, your health care providers will be able to recommend the appropriate valve replacement for you.

A traditional aortic valve replacement surgery often requires a median sternotomy, where the sternum is split down the middle (some are performed without splitting the sternum). The chest is then opened with special retractors. This provides the surgeon with necessary access to the heart and chest cavity, in order to replace your aortic valve.

The risks of a SAVR procedure are discussed on pages 11-14. Because each patient has his or her unique medical history, this information cannot replace discussions with your doctor.

Summary of Surgical Aortic Valve Replacement

- General anesthesia
- Patient on heart-lung bypass machine
- Chest open, 7-inch incision (often, but alternatives exist)
- Valve replaced during 2-4 hour procedure (typical)
- 12 day hospital stay (typical)

Treatment of Severe AS Using CoreValve

CoreValve® Transcatheter Aortic Valve Replacement (TAVR)

The CoreValve transcatheter aortic heart valve is made of natural tissue obtained from the heart of a pig. The leaflets that control the flow of blood are secured to a flexible, self-expanding metal frame (nickel-titanium) for support. The CoreValve aortic heart valve is available in four sizes with different diameters. Your doctor will determine which valve size is right for you.

The CoreValve aortic valve is implanted via a thin, flexible tube (catheter). It is a less invasive treatment option than valve surgery.

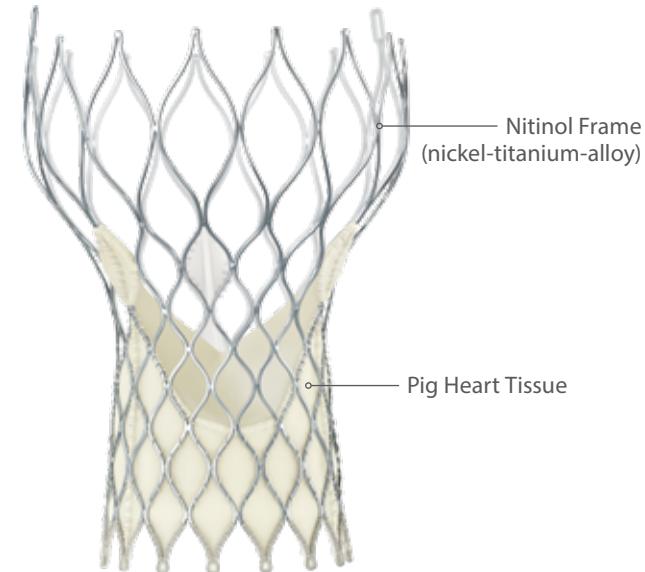


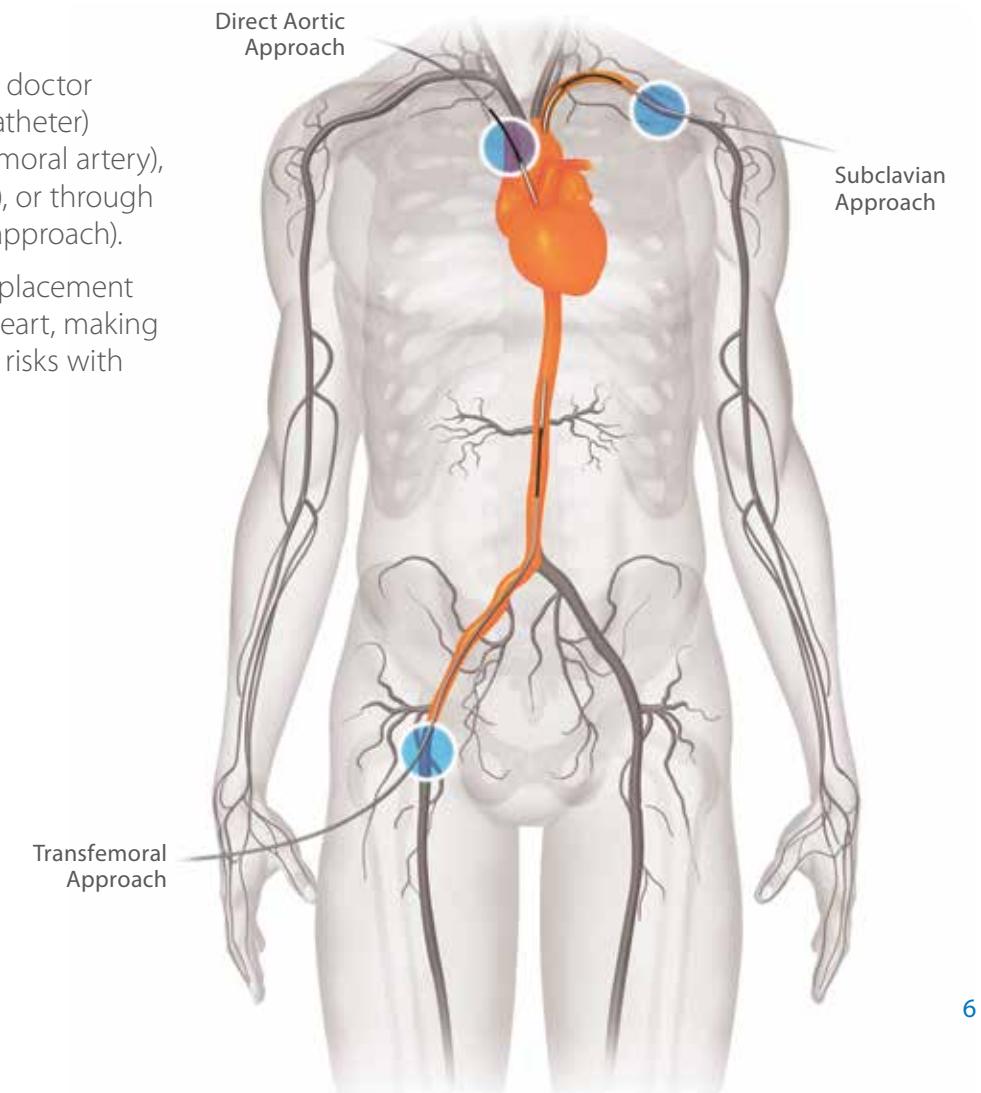
Image is bigger than actual valve

Treatment of Severe AS Using CoreValve

Where Does the Catheter, Which Holds the Valve, Enter My Body?

Depending on your vessel anatomy, your doctor will determine if the thin, flexible tube (catheter) should enter via the artery in your leg (femoral artery), the artery in your neck (subclavian artery), or through a space between your ribs (direct aortic approach).

The direct aortic approach for CoreValve placement involves additional steps to access your heart, making the procedure more invasive. Discuss the risks with your physician.



What You Can Expect

During the Procedure

Patients may be sedated during the 1-2 hour procedure. You may first have a test that uses sound waves or X-rays to take a closer look at the inside structures of the heart. Your doctor will decide what sites are best for inserting the thin, flexible tube (catheter) required for the procedure. Additionally, your doctor will decide if performing a surgical incision to any of the sites is necessary. With CoreValve TAVR, a small incision is made and a thin, flexible tube (catheter) holding the CoreValve aortic heart valve is guided to the heart. Special imaging equipment is used to guide positioning and placement of the CoreValve aortic heart valve.

After the Procedure

Following CoreValve TAVR, you will be moved to an intensive care unit or cardiac care unit. Patients typically are able to be up and walking within 24-48 hours after their procedure. Your doctor will determine when you are ready to move to a standard hospital room. The typical hospital stay for CoreValve TAVR is approximately 8 days.

Summary of CoreValve TAVR

- Local numbing or sedation (local or general anesthesia)
- Heart pumps normally during procedure
- Catheter delivers the CoreValve device into the heart
- Valve replaced during 1-2 hour procedure (typical)
- Approximately 8 day hospital stay (typical)

Understanding the CoreValve Procedure

A Typical CoreValve® Transcatheter Procedure

1. Patients are normally sedated during the approximately 1-2 hour procedure. Because each patient is different, your doctor may determine whether or not you should be fully asleep for the procedure.
2. The interventional cardiologist or cardiac surgeon will make an incision and guide a long, hollow tube (sheath) into your blood vessel.
3. Using special imaging equipment to look at your arteries, a thin, flexible tube (catheter) with a balloon on the tip is threaded through the sheath and into your heart. If you're not fully sedated, you may have a "fluttering" feeling in your chest.
4. When the end of the balloon is in your aortic valve, the balloon will be inflated and will force your narrowed aortic valve open to prepare it for your CoreValve aortic heart valve.
5. Again, using the special imaging equipment, your doctor will place the CoreValve aortic heart valve in position over your own diseased aortic valve. (Figures 1 and 2)
6. Your new CoreValve aortic heart valve will begin opening and closing; the doctor will conduct a test to confirm it is working properly. (Figure 3)
7. The thin, flexible tube will be removed, the incision will be closed, and the procedure will be complete.

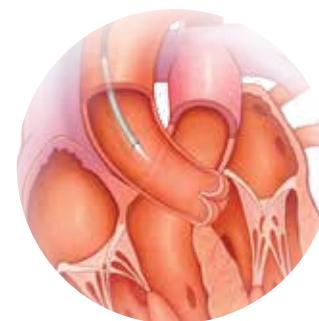


Figure 1

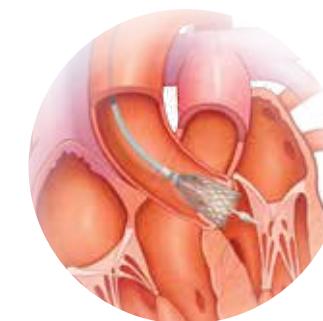


Figure 2

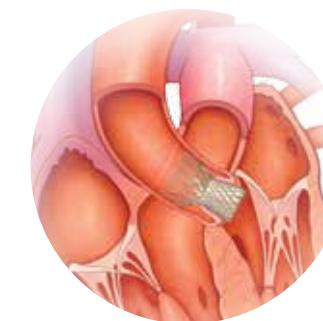


Figure 3

CoreValve Clinical Experience

Experience from the Medtronic CoreValve US Pivotal Trial

The Medtronic CoreValve US Pivotal Trial evaluated the safety and effectiveness of the CoreValve system. The trial was divided into two patient groups—those who were at High Risk for surgery and those who were too sick for surgery (Extreme Risk). Doctors decided whether these patients were “Extreme Risk” or “High Risk” based on each patient’s anatomy, medical condition and history.

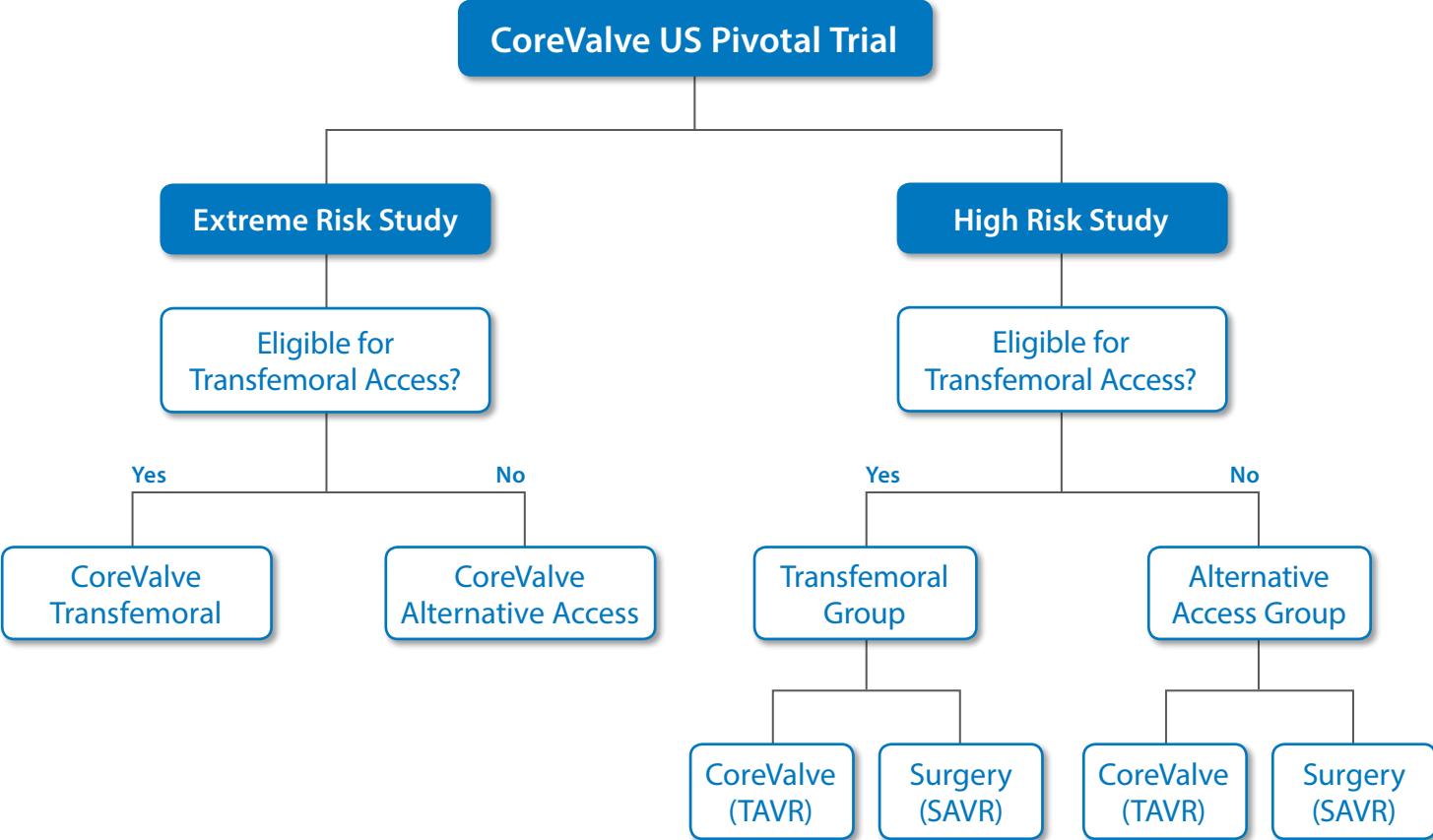
High Risk Study

The High Risk arm of the Trial included 747 patients treated at 45 hospitals in the US. These patients had severe aortic stenosis and had been determined by their doctors to be at high risk for surgery to treat their illness. All patients were evaluated to determine if they were eligible for a procedure through an artery in their leg (transfemoral), which is the first choice for CoreValve (TAVR), or if they required alternative access through a space between their ribs (direct aortic) or an artery in their neck (subclavian). Then the patients in each of these groups were randomized to CoreValve (TAVR) or surgery (SAVR). Both groups were examined at 30 days, 6 months, and 1 year after the procedure, and will continue to be examined each year for 5 years. To determine the safety and effectiveness of CoreValve (TAVR) for these high risk patients, the study results for CoreValve (TAVR) were compared statistically with the results for patients

treated with surgery (SAVR). The comparison at one year showed that CoreValve (TAVR) was a safe and effective alternative to surgery (SAVR) for High Risk patients. The study also found that more CoreValve (TAVR) patients were alive at one year than surgical (SAVR) patients.

Extreme Risk Study

The Extreme Risk arm of the Trial included 639 patients (489 transfemoral and 150 direct aortic and subclavian access) treated at 41 hospitals in the US. These patients had severe aortic stenosis and had been determined by their doctors to be too sick to have surgery. All patients were treated with CoreValve (TAVR) and were examined 30 days, 6 months, and 1 year after the procedure, and will continue to be examined each year for 5 years. Study results for CoreValve (TAVR) were compared statistically with alternative therapies (other than TAVR) for safety and performance. The comparison demonstrated that CoreValve (TAVR) was safe and effective for Extreme Risk patients and met its success criteria.



High Risk Patients | Risks You Should Know

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

As with any major medical procedure, there is a risk of complications after a CoreValve (TAVR) procedure or a surgical (SAVR) procedure.

The major risks 30 days after your aortic valve procedure for High Risk patients are as follows:

- **Death from any cause** - death due to any cause, whether heart related or not.
- **Stroke** - a condition when decreased blood flow to the brain causes brain cells to die, which results in disability.
- **Major vascular complications** - a condition affecting the blood vessels, including blood collecting under the skin (hematoma), or a tear or hole in a blood vessel.
- **Major bleeding** - a bleeding event causing abnormal lab values or requiring blood to be put back into the body.

The following table summarizes the potential risks 30 days after your aortic valve procedure for High Risk patients and is divided by access site. The access site that applies to you is determined 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 (transfemoral)		Patients eligible for access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)	
	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
Major bleed	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
Major vascular complication	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 You Should Know

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

The major risks 1 year after your aortic valve procedure for High Risk patients are as follows:

- **Death from any cause** - death due to any cause, whether heart related or not.
- **Stroke** - a condition when decreased blood flow to the brain causes brain cells to die, which results in disability.
- **Major vascular complications** - a condition affecting the blood vessels, including blood collecting under the skin (hematoma), or a tear or hole in a blood vessel.
- **Major bleeding** - a bleeding event causing abnormal lab values or requiring blood to be put back into the body.

The following table summarizes the potential risks 1 year after your aortic valve procedure for High Risk patients and is divided by access site. The access site that applies to you is determined 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 (transfemoral)		Patients eligible for access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)	
	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
Major bleed	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
Major vascular complication	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

Extreme Risk Patients | Risks You Should Know

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

As with any major medical procedure, there is a risk of complications after a CoreValve (TAVR) procedure.

The major risks 30 days after this procedure for Extreme Risk patients are as follows:

- **Death from any cause** - death due to any cause, whether heart related or not.
- **Stroke** - a condition when decreased blood flow to the brain causes brain cells to die, which results in disability.
- **Major vascular complications** - a condition affecting the blood vessels, including blood collecting under the skin (hematoma), or a tear or hole in a blood vessel.
- **Major bleeding** - a bleeding event causing abnormal lab values or requiring blood to be put back into the body.

The following table summarizes the potential risks 30 days after CoreValve (TAVR) for Extreme Risk patients (patients who are too sick for surgery) and is divided by access site. The access site that applies to you is determined 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 (transfemoral)	Access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)
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
Major bleed	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
Major vascular complication	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

Extreme Risk Patients | Risks You Should Know

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

The major risks associated with this procedure for Extreme Risk patients include:

- **Death from any cause** - death due to any cause, whether heart related or not.
- **Stroke** - a condition when decreased blood flow to the brain causes brain cells to die, which results in disability.
- **Major vascular complications** - a condition affecting the blood vessels, including blood collecting under the skin (hematoma), or a tear or hole in a blood vessel.
- **Major bleeding** - a bleeding event causing abnormal lab values or requiring blood to be put back into the body.

The following table summarizes the potential risks 1 year after CoreValve (TAVR) for Extreme Risk patients (patients who are too sick for surgery) and is divided by access site. The access site that applies to you is determined 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 (transfemoral)	Access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)
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
Major bleed	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
Major vascular complication	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

Other Potential Risks Associated with CoreValve TAVR

- 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 build up 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
 - The valve frame does not open (expand) all the way
 - Build up of minerals on the valve (calcification)
 - 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
 - The 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 - a leaking valve between the left upper (left atrium) and left lower (left ventricle) chambers of the heart where blood flows backward through the valve
 - Hypotension or hypertension - low or high blood pressure
 - Unfavorable reaction by the body (allergic reaction) to:
 - antiplatelet agents - drugs 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 opened the skin or related to opening 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 vessel (artery)
- In addition, you may experience other problems that have not been previously observed with this procedure.

High Risk Patients | Benefits

Symptom Relief

More patients receiving a CoreValve (TAVR) can expect immediate symptom relief at 30 days compared to patients who had surgery (SAVR). The symptomatic relief at 1 year is similar for both patients receiving CoreValve (TAVR) heart valve and for patients who had surgery (SAVR). The table below shows the number of patients who showed improvement 30 days and 1 year after their procedure using a standard tool (New York Heart Association heart failure class) to measure how much better they felt.

receiving a CoreValve (TAVR) compared to surgery (SAVR) experienced substantial improvement in their health 30 days after the procedure. These assessments showed patients continued to experience similar improvement for both patients receiving CoreValve (TAVR) and open-heart surgery (SAVR) at 1 year. Patients reported significant improvements in many quality of life measurements including reduced pain and anxiety, and increased ability to take care of themselves and participate in everyday activities.

Ratio of Days Alive and Not in Hospital

The clinical trial assessed the number of days each patient was alive and out of the hospital at 1 year after a procedure. At 1 year, more CoreValve (TAVR) patients were alive and had spent fewer days in the hospital than did surgical (SAVR) patients.

Quality of Life Improvements

The clinical trial assessed quality of life using a combination of standardized tools* to determine the improvement in patients' health after the procedure. More patients

Patients Showing Symptomatic Relief

Patients eligible for access via an artery in your leg (transfemoral)				Patients eligible for access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)			
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

Extreme Risk Patients | Benefits

Symptom Relief

Most patients receiving a CoreValve heart valve can expect immediate symptom relief. The table below shows the number of patients who showed improvement 30 days and 1 year after their procedure using a standard tool (New York Heart Association heart failure class) to measure how much better they felt.

Quality of Life Improvements

The clinical trial assessed quality of life using a combination of standardized tools* to determine the improvement in patients' health after the procedure. These assessments showed substantial improvement in patients' health 30 days after the procedure and patients continued to experience the improvement at 1 year. Patients reported significant improvements in many quality of life measurements including reduced pain and anxiety, and increased ability to take care of themselves and participate in everyday activities.

Patients Showing Symptomatic Relief

Access via an artery in your leg (transfemoral)		Access via a space between your ribs (direct aortic) or an artery in your neck (subclavian)	
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

* Kansas City Cardiomyopathy Questionnaire (KCCQ) and EuroQol/EQ-5D

What You Should Do After the Procedure

Follow-up Care

Your doctor will provide you with more specific care instructions as well as any restrictions you may have. You will still need to take medications as prescribed and have your heart and valve function checked from time to time. Ask your heart doctor or nurse about your follow-up appointment schedule or any other questions you have about living with your new heart valve.

As a precaution, you'll want to inform your dentist and other doctors about your heart valve before any dental or medical procedure. If you require a magnetic resonance imaging (MRI) scan, tell the doctor or MRI technician that you have had a heart valve procedure. Failure to do so could result in damage to your implanted heart valve or death.

You will receive a patient card that has information about your heart valve. It is important to keep this card with you and to show it to any medical personnel who may be treating you. If you do not receive a card after your CoreValve procedure, contact your doctor.

It is not known at this time how long your CoreValve heart valve will last. The CoreValve device has been tested in a laboratory to simulate 5-year durability.

Because of the uniqueness of each heart patient, it is difficult to predict how long the CoreValve aortic heart valve will last.

It is important to keep appointments with your heart doctor and to follow recommended daily care to ensure the best possible results.

Transcatheter Aortic Valve Replacement is Not Right for Everyone

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

- Patients who have an infection in the heart or elsewhere
- Patients who have an artificial (mechanical) aortic valve
- Patients who cannot take aspirin, heparin and bivalirudin, ticlopidine (Ticlid), clopidogrel (Plavix), or have sensitivity to Nitinol (Titanium or Nickel) or contrast media (fluid used during the procedure to see internal structures)

If the CoreValve transcatheter aortic 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 TAVR procedure may outweigh the benefits. See pages 11-22 for the risks and benefits associated with the CoreValve procedure.

Warnings and Precautions

Warnings

Patients who have a known blood disorder that causes them to have more minerals (calcium) in their blood may cause the CoreValve device to wear (deteriorate) faster.

The safety of the CoreValve has only been established in patients who:

- have severe aortic stenosis which is causing them to feel sick
- are at high risk or are not able to have their heart valve replaced surgically

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

For some patients the risk of the TAVR procedure may outweigh the benefits. See pages 11-22 for the risks and benefits associated with the CoreValve procedure.

Precautions

- Long term durability has not been established for the CoreValve aortic heart valve. Follow-up appointments with your doctor are recommended to evaluate your heart valve over time.
- Antibiotics are recommended after the CoreValve procedure for patients who are at risk of infections.
- Patients should stay on blood-thinning medication after the procedure, as directed by their doctor. Patients who do not take blood-thinning medication after the procedure have an increased chance of developing a blood clot, which could lead to a stroke.
- If you require a magnetic resonance imaging (MRI) scan, tell the doctor or MRI technician that you have had a heart valve procedure. Failure to do so could result in damage to your implanted heart valve or death.

The safety of the CoreValve aortic heart valve has not been established in the following:

- Patients who are not sick from aortic stenosis
- Children
- Patients who were born with an aortic valve that has only one or two leaflets

- Patients who have a blood clot or an abnormal growth
- Patients who have an infection in the heart or elsewhere
- Patients who have aortic stenosis along with severe aortic regurgitation (when your primary aortic valve illness is that your valve does not fully close and allows blood to leak backwards through the valve)
- Patients who have severe disease with their mitral valve (the heart valve that allows blood to fill the left lower chamber/left ventricle)
- Patients whose left lower chamber (left ventricle) does not pump enough blood out of the heart
- Patients whose aortic valve diameter is either too small or too big for the device
- Patients whose vessels cannot accommodate the device
- Patients whose aortic anatomy may prevent proper blood supply to the heart after CoreValve implant
- Patients whose blood vessels that supply blood to the heart (coronary arteries) are not working and need to be treated
- Patients who are sick from problems with the blood vessels that supply blood to the brain (carotid or vertebral arteries)
- Patients who have severe problems with bleeding or blood clotting
- Patients who have a severe kidney disease and require mechanical assistance to work properly
- Patients who have an artificial heart valve already implanted in any of their four heart valves
- Patients who have a condition in which the heart muscle becomes thick and makes it difficult for the heart to pump blood
- Patients who have a condition in which the heart muscle becomes thick and blocks the heart from pumping blood

FAQs

Frequently Asked Questions

Are physical activities safe?

Discuss your activity level with your heart doctor to determine what is best for you.

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

The CoreValve aortic heart valve is completely safe with X-ray examinations.

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

The CoreValve can be safely scanned under certain conditions. If you have had a CoreValve procedure, inform your physician about your implanted transcatheter valve prior to having an MRI. Failure to do so could result in damage to the valve or death.

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

Your heart doctor will schedule regular follow-up appointments to check your valve.

Resources

For More Information on the CoreValve TAVR Procedure

Please contact your physician 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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