TRILOGY
Heart Valve System

Transcatheter Aortic Valve Replacement for Aortic Regurgitation

A GUIDE FOR PATIENTS

JENAVALVE

TABLE OF CONTENTS

INTRODUCTION

This booklet explains severe aortic regurgitation and common treatment options. It also describes the Trilogy transcatheter aortic valve replacement (TAVR) procedure.

Talk with your doctor about all treatment options. Ask about the possible risks and benefits of each option.

UNDERSTANDING AORTIC REGURGITATION

HOW THE HEART WORKS

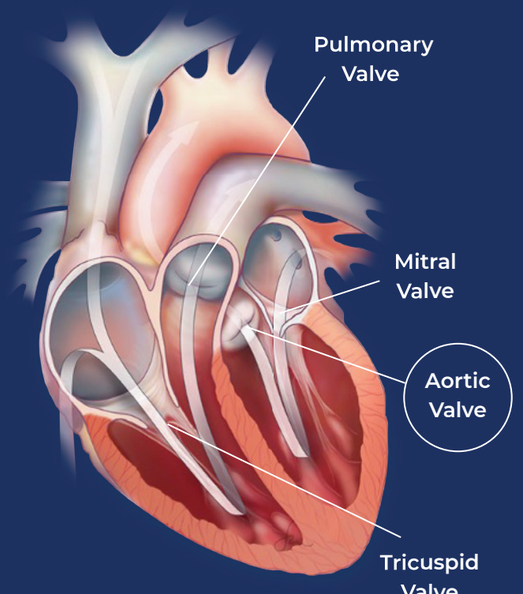
The heart beats to supply oxygen-rich blood to the rest of your body. There are four valves in your heart that keep blood moving in the right direction.

The aorta is the main blood vessel that carries oxygen-rich blood from the heart to the rest of the body. When blood leaves the heart through the aorta, the aortic valve seals to keep blood from leaking back into the heart.

WHAT IS AORTIC REGURGITATION?

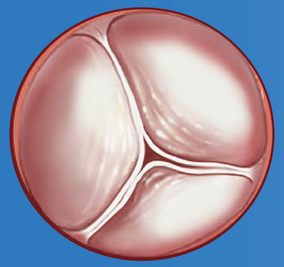
Aortic regurgitation (AR) happens when the aortic valve does not close all the way. When this happens, the heart cannot pump blood through the body as well as it should.

Some of the blood that should move forward, leaks back into the heart. This extra blood makes the heart work harder than normal. Over time, this can lead to heart failure.[1]

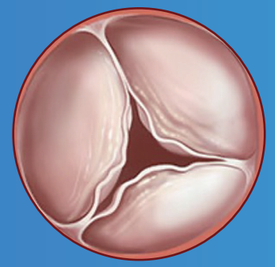


THE HEART

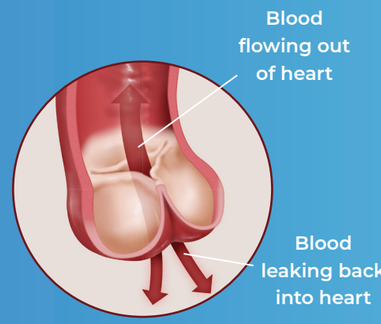
COMPARING A HEALTHY AORTIC VALVE TO AN AORTIC VALVE WITH AORTIC REGURGITATION



Healthy aortic valve



Damaged valve with incomplete seal



Incomplete seal causing aortic regurgitation

HOW AORTIC REGURGITATION MAY AFFECT YOU

Many people with AR may live for a long time before they notice symptoms.[1] During this time, the heart has to work harder than normal to pump blood throughout the body.

Over time, this extra work can lead to symptoms that may affect daily life, including:

- Chest pain
- Fainting (syncope)
- Feeling your heart beat fast or irregularly (heart palpitations)
- Shortness of breath (dyspnea) during activity, when lying down, or when trying to sleep
- Swelling (edema) in your ankles and feet
- Cough

If AR gets worse over time, it can lead to heart failure and it can become life-threatening.[2]

HOW DOCTORS DIAGNOSE AORTIC REGURGITATION

Aortic regurgitation can be hard to diagnose. A full exam helps your doctor understand how serious the problem is and choose the right treatment for you.[3]

Echocardiogram: An echocardiogram uses sound waves to take pictures of your heart. It also shows how blood moves through your heart valves.

The most common test is a transthoracic echocardiogram (TTE). This test takes pictures from outside your body.

If your doctor needs more detail, they may use a transesophageal echocardiogram (TEE). This test takes clearer pictures from inside the body.[3]

Cardiac MRI: In some cases, doctors use a cardiac MRI to better understand how severe the aortic regurgitation is. This test can also show heart damage and how well your heart chambers and valves are working.[3]

TREATING AORTIC REGURGITATION

CHOOSING THE RIGHT OPTION FOR YOU

Your heart team will assess your symptoms, review your tests results and help you decide which treatment option is best for you.

MEDICINES

Some medications may help reduce symptoms of aortic regurgitation. However, medicines do not cure the condition or fix the aortic valve.

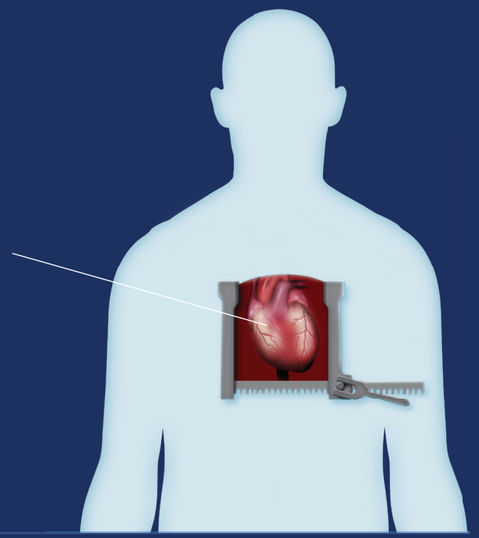
AORTIC VALVE SURGERY

Open-heart surgery is one treatment option for people with aortic regurgitation (AR).

Based on how severe the disease is and how much damage there is to the valve, the surgeon may repair the valve or replace it with an artificial valve.

During surgery, the surgeon makes a cut along the breastbone (sternum) to open the chest. A heart-lung machine temporarily does the work of the heart while the valve is repaired or replaced.

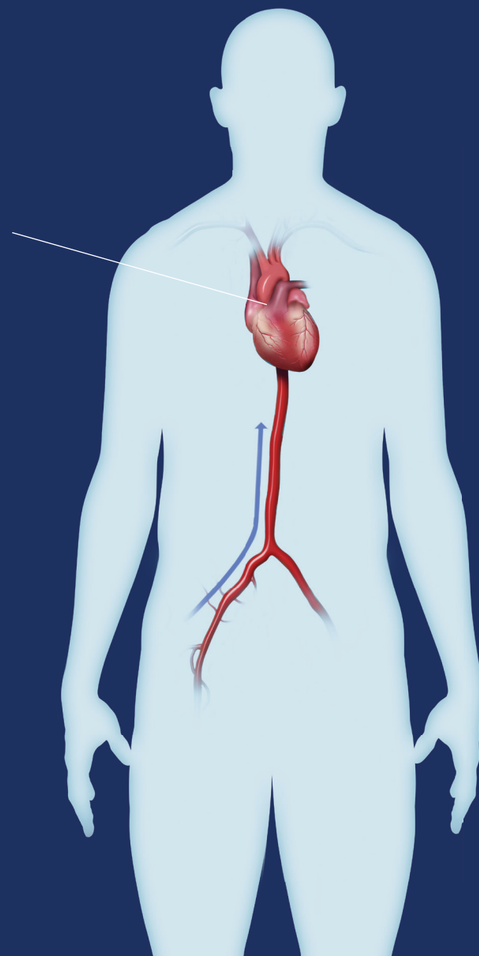
After the procedure, the breastbone is then wired closed and the skin incision is closed.



TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Transcatheter aortic valve replacement (TAVR) is a less invasive way to treat aortic valve disease.

During the TAVR procedure, a thin tube called a catheter is inserted into a blood vessel through a small cut in your upper leg. The catheter is guided through the blood vessel to your heart. A new valve is then delivered through the catheter and placed inside your damaged aortic valve. Once the new valve is in place, the catheter is removed and the small cut is closed.



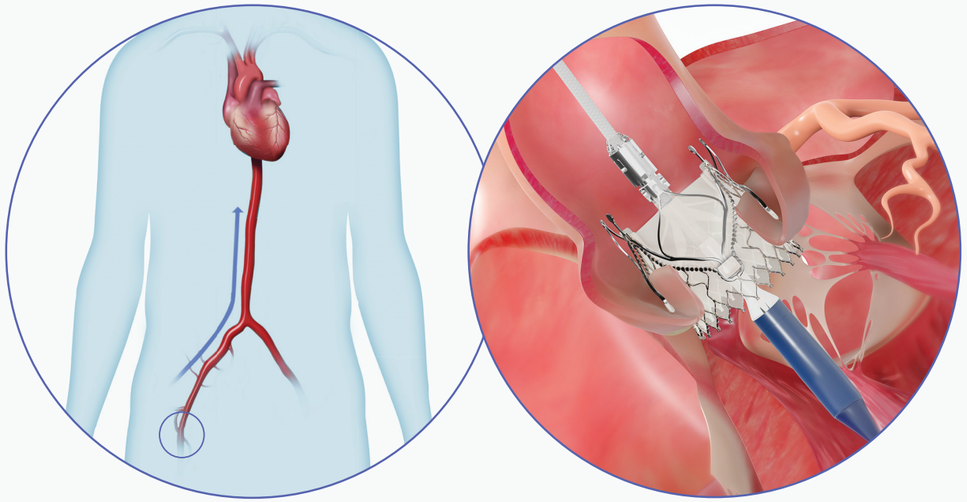
WHO MAY BE ELIGIBLE FOR THE TRILOGY VALVE

Patients with severe aortic regurgitation who cannot have open-heart surgery will have more tests to see if a Trilogy valve is right for them. The JenaValve Trilogy TAVR procedure is not for everyone. In some cases, the risks of the procedure may be higher than the benefits. Review pages 8-9 for the risks of the JenaValve Trilogy TAVR procedure.

THE JENAVALVE TRILOGY TAVR PROCEDURE

STEPS OF THE JENAVALVE TRILOGY TAVR PROCEDURE

1. Your doctor makes a small cut in your upper leg and inserts a small tube, called a catheter, into a blood vessel.
2. The catheter is guided through the blood vessel to your heart.
3. The Trilogy valve is carefully placed inside your damaged aortic valve.
4. The catheter is removed and the small cut in your leg is closed.



Catheter inserted in femoral artery in leg

Trilogy valve placed within damaged aortic valve

WHAT HAPPENS AFTER THE PROCEDURE?

The TAVR procedure usually takes about 1 to 1.5 hours. After the procedure, you may stay in the hospital for a few days.[4] Everyone recovers at a different speed. Most people can go back to normal activities within days, depending on their overall health.

Before you leave the hospital, your doctor will explain your aftercare plan. This plan may include a special diet, return to exercise, and any medication you may need to take to help with your recovery. It is important to carefully follow your doctor's directions.

TAVR FOLLOW-UP VISITS

Regular check-ups with your doctor are very important. You will be asked to return to see your doctor to have your Trilogy Heart Valve checked 30 days and 1 year after your procedure. Your physician may schedule additional follow-up visits to monitor your Trilogy Heart Valve. If you have questions or concerns about your health, call or see your doctor right away.

YOUR JENAVALVE TRILOGY IMPLANT CARD

As you leave the hospital, your care team will provide you with an implant card. This card has information about your Trilogy Heart Valve and your physician's contact information. Keep this card in your possession and share this card with all members of your healthcare team, including your dentist. It is important to share information about your heart valve replacement before any medical, dental, or MRI (magnetic resonance imaging) procedures. If you need an MRI, tell your doctor that you have a JenaValve Trilogy heart valve.

BENEFITS OF THE JENAVALVE TRILOGY TAVR PROCEDURE

Most patients start feeling better right away, but it can take a little longer for others. Many TAVR patients report benefits like:

- Having more energy
- Breathing normally
- Being able to do everyday activities
- Experiencing less pain

POSSIBLE RISKS OF THE JENAVALVE TRILOGY TAVR PROCEDURE

As with any medical procedure, there is a possibility of risks. The most serious risks are:

- Death
- Stroke
- Damage or injury to a blood vessel or heart muscle
- Serious bleeding that may require blood transfusion
- Need for a permanent pacemaker
- The valve may slip due to device problems. This may require urgent surgery.

THE TRILOGY TAVR VALVE CANNOT BE USED FOR CERTAIN PATIENTS:

- Patients who cannot take blood-thinning medicines
- Patients that have a reaction to some metals
- Patients with an infection

If the Trilogy 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.

ADDITIONAL RISKS MAY INCLUDE:

- Temporary stroke, seizures, severe headaches, seeing spots, or other neurological problems
- Infection of the valve or blood. Antibiotics should be taken before dental work or other procedures that can put bacteria into the bloodstream.
- Blockage or tears in blood vessels or the heart muscle. This can cause bleeding, leaking of contrast dye, or loss of blood flow to parts of the body such as the heart, intestines, nerves, or other organs. Emergency repair, including surgery, may be needed.
- Irregular or abnormal heart rhythms
- Heart murmur
- Chest pain
- Breathing problems or breathing failure
- Trouble with exercise or general weakness
- Fainting or passing out
- Blood clots, infection, or fluid in or around the lungs
- Very high or very low blood pressure
- Heart attack or heart failure, which can reduce blood flow to the body and cause breathing problems or shock
- Problems with the heart's electrical system that may require a pacemaker
- Bleeding around the heart or elsewhere in the body which may require drainage
- Problems placing the replacement valve, such as blood clots, leaking, narrowing, or leakage around or through the valve. This may require placing a second valve or doing other procedures.
- The valve may slip or be placed in the wrong position due to device problems. This may require another valve, repositioning, or surgery. Attempts to reposition the valve can injure blood vessels or require urgent surgery.
- The valve may wear out over time, causing narrowing or leaking. This may require another procedure, including valve removal, at a later date. Regular follow-up is needed.
- Bleeding, anemia, or damage to blood cells
- Temporary or permanent kidney injury from contrast dye or other causes
- Allergic reactions to contrast dye, the device or medications used during the procedure
- Fever, swelling or infection of the heart, groin access site or other areas
- Skin irritation or burn from X-rays
- Blood collections (hematomas) or bruising in different parts of the body
- Faster valve damage may occur in people with abnormal calcium metabolism
- Pain or changes at treatment sites

CLINICAL DATA FROM THE TRILOGY TAVR STUDY

The risks of a TAVR procedure depend on the patient's overall health. Many factors affect risk, including age and other health problems that can make surgery more dangerous. Your doctor can explain which risks are most likely for you.

The JenaValve Trilogy TAVR procedure was studied in over 500 patients in the United States who had severe aortic regurgitation and were at high risk or too sick for open-heart surgery. Doctors checked the patients 30 days and 1 year after the procedure.[4]

If you are at high risk or cannot have open-heart surgery, the results in this chart may help show what you can expect.

CLINICAL PATIENT INFORMATION

TAVR Patients	Risk Within 30 Days	Risk Within 1 Year
Death from any cause	3 out of 100	8 out of 100
Death from Heart Related Cause	2 out of 100	7 out of 100
Disabling Stroke	2 out of 100	2 out of 100
New Permanent Pacemaker	24 out of 100	28 out of 100
Life-Threatening or Major Bleeding	5 out of 100	6 out of 100
Major Vascular Complications	4 out of 100	4 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	2 out of 100

The frequency is shown as number of patients out of every 100.

WARNINGS AND PRECAUTIONS

WARNINGS

- Stroke can occur in patients who have a TAVR procedure.
- Serious blood vessel problems can occur during the TAVR procedure.
- The valve implant may not last as long in patients whose bodies process calcium abnormally.
- Tell your doctor if you have allergies to any implant or procedure materials. These may include anesthesia medicines, blood thinners, latex, contrast dye, nickel, titanium, silicone, polymers or thermoplastics.
- Contrast dye used during the procedure may cause temporary or permanent kidney injury, especially in patients with prior kidney disease.
- X-ray used during the procedure may cause skin injury from radiation.

PRECAUTIONS

How long your new valve will last is unknown at this time. Long-term clinical durability has not been established for the Trilogy transcatheter heart valve. Engineering testing has demonstrated a valve durability equivalent to 3.5 years in the laboratory, which did not meet the 5 years recommended by the relevant international standard. Regular check-ups with your doctor are very important.

Patients who have TAVR should take blood-thinning medicine as their doctor recommends. Patients who do not take blood-thinning medicine may have a higher risk of dangerous blood clots forming on the valve, which can lead to a stroke. Blood-thinning medicine can also increase the risk of bleeding.

Patients who have TAVR and need dental work or other procedures that may release bacteria into the bloodstream should take antibiotics. This helps to lower the risk of valve infection.

THE TRILOGY TAVR VALVE HAS NOT BEEN STUDIED IN PATIENTS WHO HAVE:

- No signs that they are at high risk for open-heart surgery
- A recent heart attack
- Severe weakness of the left or right side of the heart, or shock
- A recent stroke, mini-stroke, or temporary loss of blood flow to part of the brain
- Severe kidney failure, including people who need dialysis
- Severe blood vessel disease that prevents safe placement of the device
- An aortic valve with only one or two leaflets, or more than three leaflets
- An aortic valve that is too large or too small for the device
- An aortic valve with heavy calcium buildup
- An aortic valve that is infected or severely narrowed
- An artificial aortic valve already in place
- An aorta or aortic valve shape or size that makes valve placement risky
- Blood vessels that are very small, badly diseased, or abnormally shaped, including vessels with enlargement or bulging that make device placement unsafe
- A mitral valve that is severely leaking or narrowed
- Severe thickening of the heart muscle that blocks blood flow out of the heart
- Low white blood cells, red blood cells, or platelets
- Other blood disorders that affect clotting or bleeding
- Blood clots in the heart
- An inability to take blood-thinning medicines such as heparin, aspirin, or clopidogrel during or after the procedure
- People who are pregnant or breastfeeding
- Very high pressure in the lungs (pulmonary hypertension)

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

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

References

1. Bekeredjian R, et al. Circulation. 2005;112(1):125–134.
2. Dujardin KS, et al. Circulation. 1999;99:1851–1857.
3. Zoghbi WA, et al. J Am Soc Echocardiogr. 2017;30(4):303–371.
4. Makkar RR, Thourani VH, Vahl TP, et al. Transcatheter aortic valve implantation with the Trilogy valve for symptomatic native aortic regurgitation (ALIGN-AR): a pivotal, multicentre, single-arm, investigational device exemption study. Lancet 2025;406(10521):2757–2771.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

4 Cromwell
Irvine, CA 92618

JenaValve.com
+1 (866) 588-8287
PatientSupport.us@jenavalve.com

JENAVALVE