PREPARING FOR YOUR **SURGICAL VALVE REPLACEMENT PROCEDURE**

WHAT YOU NEED TO KNOW ABOUT EPIC™ VALVE THERAPY

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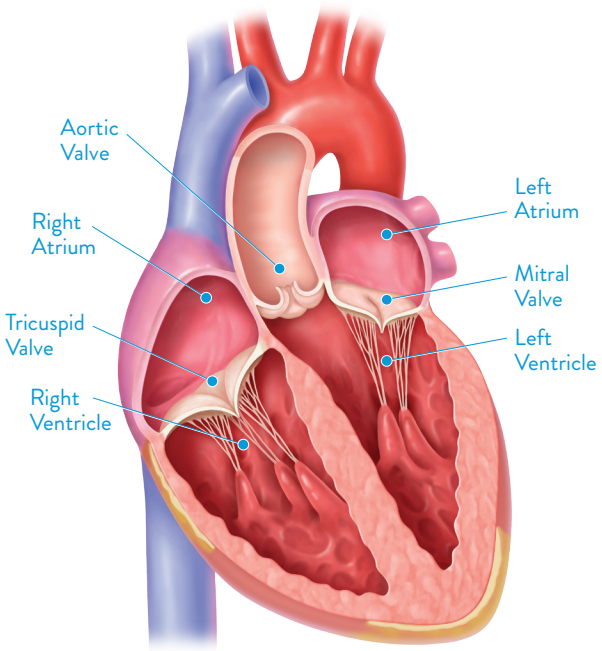
ABOUT
MITRAL REGURGITATION

Your heart has four valves that direct blood flow between the chambers of the heart. The valve between the left atrium and the left ventricle is called the mitral valve and it opens and closes to ensure that blood flows in only one (forward) direction. Mitral regurgitation is a condition in which the mitral valve does not close completely during the contraction of the left ventricle, causing blood to leak backward into the left atrium. This can make your heart muscle work harder to deliver oxygen-rich blood to the brain and the rest of the body.

Surgical mitral valve replacement is an option to treat mitral regurgitation by replacing the diseased mitral valve with an artificial (prosthetic) valve.



ABOUT
AORTIC STENOSIS

On the left side of the heart, blood flows from the left ventricle into the aorta through the aortic valve. Aortic stenosis is a condition in which the aortic valve leaflets become thick or stiff, reducing their ability to fully open and close. This narrowing of the valve results in reduced blood flow from the left ventricle to the aorta, making your heart muscle work harder to deliver oxygen-rich blood to the brain and the rest of the body.

Surgical aortic valve replacement is an option to treat aortic stenosis by replacing the diseased aortic valve with an artificial (prosthetic) valve.

ABOUT
THE EPIC™ VALVE

The Epic™ valve is a stented bioprosthetic valve made partly with tissue from porcine (pig) and bovine (cow) hearts that functions similarly to human heart valves.

Design features help prevent your immune system from reacting negatively to the valve. The Epic™ valve is stented, meaning it also includes a device that provides support for the tissue inside the valve.

ABOUT YOUR VALVE REPLACEMENT PROCEDURE

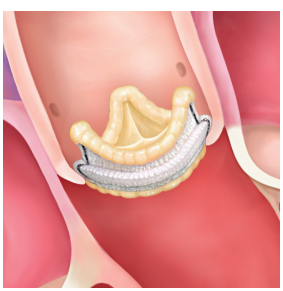
During this procedure, your surgeon will replace your diseased, damaged, or malfunctioning heart valve with the appropriate Epic™ prosthetic valve. It may also be used as a replacement for a previously implanted prosthetic heart valve. The Epic™ valve is designed to mimic the function of a natural, healthy heart valve.

▶ **FIGURE 1**
Epic™ Mitral Series

▶ **FIGURE 2**
Epic™ Aortic Series

▶ **FIGURE 3**
Positions where the Epic™ valve replaces the original heart valve

Placement in the mitral valve



Placement in the aortic valve

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HOW SHOULD YOU PREPARE FOR YOUR PROCEDURE?

In the days before your procedure it is important that you:

- ☐ Take all of your prescribed medications as directed by your doctor
- ☐ Tell your doctor if you are taking any other medications
- ☐ Make sure your doctor knows of any allergies you have
- ☐ Follow all instructions given to you by your doctor or nurse

WHAT WILL HAPPEN DURING YOUR PROCEDURE?

You will be placed under general anesthesia to put you in a deep sleep and the surgeon will make an incision in your chest to reach your heart. Your heart will be stopped temporarily so that the valve can be implanted, and you will be placed on a heart-lung machine to help maintain blood flow in your body during the procedure.

Your surgeon will first remove the diseased valve and determine the correct replacement valve size. This new valve will be positioned in the original valve location and firmly sewn into place. Your surgeon will then close the incision, restart your heart, and close all the other incisions. Finally, the heart-lung machine will be removed and your natural heart rhythm will return. The length of the procedure varies for each patient.

WHAT WILL HAPPEN AFTER YOUR PROCEDURE?

You may be placed in the intensive care unit (ICU), where you can be monitored continuously. You may wake up with a breathing tube still in position that will be removed as soon as you are stable and awake enough to breathe on your own. Intravenous lines will give you fluid, blood, and medications as needed, and you will have a temporary chest tube and bladder catheter for drainage.

Your heart rate, heart rhythm, blood pressure, and other measurements will be monitored to assess your recovery status. You may receive medications to ease your pain and anxiety as needed.

WHAT WILL HAPPEN DURING YOUR HOSPITAL STAY?

While every patient recovers at a different rate, the typical length of stay in the ICU is one or two days. The nursing staff will monitor your recovery and remove the tubes as appropriate.

From the ICU, you will be moved to a cardiac medical-surgical floor. Your heart will continue to be monitored, but you may be more independent and active. Your healthcare team will continue to support and instruct you in recovery care, rehabilitation, medications, nutrition, and other needs.

WHAT WILL HAPPEN WHEN YOU RETURN HOME?

Once you leave the hospital, it will typically be six to eight weeks before you are able to return to your normal routine. Your energy and strength may improve over the first few weeks following the surgery, but it's important that you take special care of yourself and allow time to rest regularly until you are fully recovered.

Your doctor will advise you on any medications you should take, such as a low dose of aspirin or anticoagulant therapy to reduce the risk of blood clots and embolism. It is important that you carefully follow your doctor's instructions regarding medications.

At your follow-up visits to your doctor, you may need to undergo tests such as an electrocardiogram, echocardiogram, or chest X-ray to evaluate how your new valve is working. Your doctor may also perform blood work to assess your medication levels.

Long-term management of your health requires your active participation. With your physician, you can work towards a healthy recovery.

WHEN TO CALL THE DOCTOR

Contact your physician(s) if you develop any of these symptoms:

- Redness or drainage of your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder or arm pain
- A rapid heart beat or strong palpitations of your heart
- Blood in your urine
- Bloody or black tarry bowel movements (blood will typically look like tar after it has been exposed to the body's digestive juices)
- Excessive bleeding
- Bruising
- Unusual nosebleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred vision or loss of vision
- Unusual chest sensation

IMPORTANT STEPS TO HELP YOU MAINTAIN A HEALTHY HEART

- Tell your dentist or physician you have an artificial heart valve, because you will need to take antibiotics prior to any dental work or surgery to prevent infection of your heart valve.
- Follow an exercise program as outlined by your physician and enjoy a heart-healthy diet.
- Follow-up with blood tests as directed by your physician.
- If you are told you need to have an MRI (magnetic resonance imaging), tell the doctor you have an artificial heart valve and show them your patient identification card. It contains important information about how to perform an MRI safely with your valve.

POTENTIAL ADVERSE EFFECTS

Adverse events potentially associated with the use of bioprosthetic heart valves include, but are not limited to, the following:

- Angina (chest pain)
- Cardiac arrhythmias (abnormal heart rhythm)
- Endocarditis (infection of the heart's inner lining or valves)
- Heart attack
- Heart failure
- Hemolysis (change or destruction of red blood cells)
- Hemolytic anemia (anemia caused by excessive destruction of red blood cells)
- Hemorrhage (excessive bleeding)
- Leak near the valve
- Nonstructural dysfunction of the valve
- Prosthesis regurgitation (valve unable to close completely, thus allowing blood to flow backward through the valve)
- Stroke
- Structural deterioration (calcification, leaflet tear, perforation, or other)
- Thromboembolism (blood clot that travels through the bloodstream, eventually blocking a vessel)
- Valve thrombosis (formation of a blood clot near or attached to the valve)

It is possible that these complications could lead to:

- Reoperation
- Surgical removal of the valve
- Permanent disability
- Death

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HOW LONG WILL MY EPIC™ VALVE LAST?

The length of time your heart valve will last depends on many factors, including your medical condition and age.

LIFETIME MANAGEMENT OF YOUR HEART VALVE

The Epic™ valve is designed with features that can help facilitate future intervention in patients who may require a new prosthetic valve due to valve deterioration. Valve-in-valve* is a minimally invasive procedure that is performed by implanting a new prosthetic valve within the failing prosthetic valve.

*The safety and effectiveness of a valve-in-valve procedure in an Epic™ valve has not been established.

Information provided is not intended for medical diagnosis or treatment as a substitute for professional medical advice. Consult with a physician or qualified healthcare provider for appropriate medical advice.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *eifu.abbottvascular.com* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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