WHAT YOU NEED TO KNOW ABOUT EPIC™ VALVE THERAPY

Preparing for Your Surgical Valve Replacement Procedure

See Important Safety Information referenced within.

Abbott

TABLE OF CONTENTS

ABOUT
THE EPIC™ VALVE

The Epic™ valve is a stented bioprosthetic valve made partly with tissue from porcine (pig) or 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 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 valve

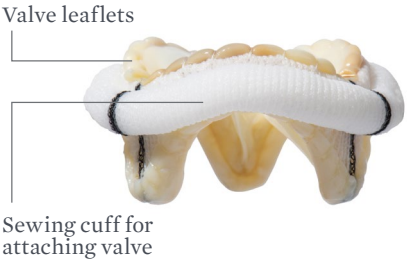


FIGURE 2
Epic™ Supra aortic valve

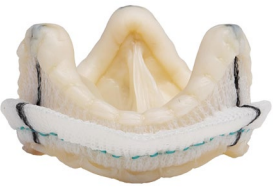
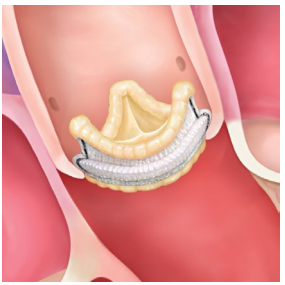


FIGURE 3
Positions where the Epic™ valve replace the original heart valve


Epic™ mitral valve


Epic™ Supra aortic valve

See Important Safety Information referenced within.

HOW SHOULD YOU PREPARE FOR YOUR PROCEDURE?

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

- Take all of your prescribed medications
- 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 be returned. 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.

See Important Safety Information referenced within.

Long-term management of your health requires your active participation. With your physician, you can work toward 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 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

See Important Safety Information referenced within.

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. Long-term studies of patients who received an Epic™ valve showed excellent durability over time:

PATIENTS OF ALL AGES AT 10 YEARS

Did not have deterioration of their Epic™ mitral valve that required a re-operation[1]

Did not have deterioration of their Epic™ aortic valve that required a re-operation[2]

IMPORTANT SAFETY INFORMATION

Rx ONLY EPIC™/ EPIC™ SUPRA STENTED PORCINE TISSUE VALVES

INDICATIONS FOR USE

The Epic™ valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Supra different valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS

None known.

WARNINGS

- Valve size selection is based on the size of the recipient annulus, and for supra-annular aortic placement, the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical™ Bioprosthetic Heart Valve Sizer Set Model B1000 with the Epic and Epic Supra valves.
- Accelerated deterioration due to calcific degeneration of the Epic and Epic Supra valve may occur in:
  - children, adolescents, or young adults;
  - patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure); or
  - individuals requiring hemodialysis.
- For single use only. Do not reuse or resterilize. Attempts to resterilize the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.
- Do not use if:
  - the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
  - the expiration date has elapsed;
  - the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
  - the storage solution does not completely cover the valve.

PRECAUTIONS

- The safety and effectiveness of the Epic™ and Epic™ Supra valves has not been established for the following specific populations:
  - patients who are pregnant
  - nursing mothers
  - patients with chronic renal failure
  - patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome)
  - patients with chronic endocarditis
  - patients requiring pulmonic or tricuspid valve replacement
  - children, adolescents, or young adults
- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.
- Do not pass the flanged portion of the valve replica sizing tool through the annulus.
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
- Do not add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.
- Do not allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Do not use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside of the 5 °C to 25 °C range.
- Do not implant the valve without thoroughly rinsing as directed.
- Do not lacerate the valve tissue. If a valve is

IMPORTANT SAFETY INFORMATION
(CONTINUED)

damaged, the valve must be explanted and replaced.
- Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, unprotected forceps, or sharp instruments as they may cause structural damage to valve.
- Never handle the leaflet tissue.
- Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.
- Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

ADVERSE EVENTS

The clinical investigation of the Epic valve supports the safety and effectiveness of the Epic valve and the Epic Supra valve. Between January 2003 and March 2006, seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 patient-years (s.d. = 0.71 patient-years, range 0 – 3.10 patient-years).

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of bioprosthesis heart valves (in alphabetical order) include:
- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage, anticoagulant/antiplatelet-related
- leak, transvalvular or paravalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:
- reoperation
- explantation
- permanent disability
- death

REFERENCES:

1. Lehmann S, Jawad, K, Meyer, A. Long-term follow-up after porcine xenograft mitral valve replacement. Presented at: 2017 American Association For Thoracic Surgery Mitral Conclave. April 27-28, 2017; New York, NY USA.
2. Lehmann S, et al. Porcine xenograft for aortic, mitral and double valve replacement: long-term results of 2544 consecutive patients. *Eur J Cardiothorac Surg.* 2016;49:1150-1156.

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.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1 800 227 9902

www.cardiovascular.abbott

MAT-2002840 v1.0 | Item approved for U.S. use only.

Abbott