



CLINICAL INSIGHTS

EPIC™ MITRAL STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY



Epic Mitral Continues the Biocor Legacy: Strength of Design, Tested Over 35 Years¹

Clinical Studies Find Consistent Durability in Multiple Analyses and Patient Populations

DURABILITY FOR THE MITRAL POSITION

Valve durability should be the primary factor when choosing a replacement valve for the mitral position where structural valve deterioration (SVD) can occur more quickly.¹ The durability of the Epic™ Mitral valve design has been demonstrated in four key clinical studies (see Figure 1 and Table 1).

- In the Epic IDE study from 2011 there was no structural valve deterioration at 4-years²
- In 2019 Nakazato, et al, reported freedom from SVD of 93.1% at 5 years for the Epic Mitral valve.³
- 10-Year freedom from SVD was 95.7% in patients with singular valve replacement.⁴
- 10 year freedom from SVD in the Rennes study was 89.6%, including an 87.7% freedom from SVD in patients 59 and younger⁵

This growing body of evidence supports Epic Mitral as an important option for a variety of patients undergoing MVR procedures.

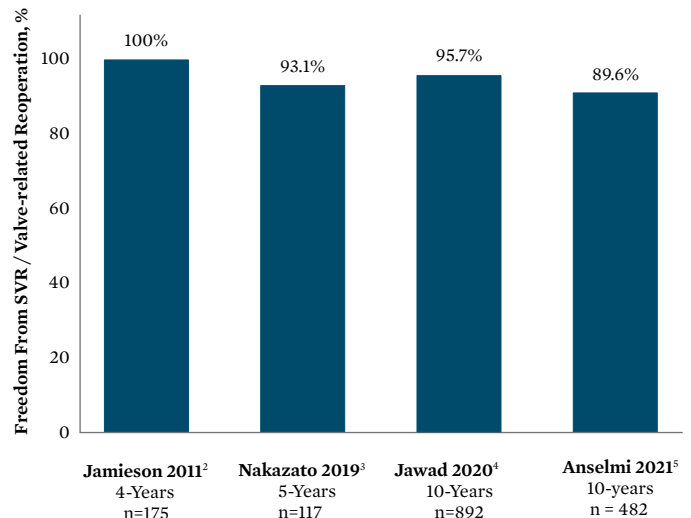
MEETING THE COMPLEX DEMANDS OF MVR

Durability is not an accident. Supported by over 20 years of published study results, the Epic Mitral valve design and construction empower surgeons to personalize care.

- Three separate porcine leaflets are matched to optimize coaptation.
- The Epic Mitral valve's suture-friendly cuff minimizes drag and parachuting forces.

- FlexFit™ stent uses proprietary polymer construction allowing safe deflection and return to original shape.
- A pericardial shield covers the outflow edge, providing tissue-to-tissue interface and helps prevent abrasion.²
- True annular sizing and precise labeling ensures each valve will fit into the corresponding patient annulus.
- Linx™ AC anticalcification treatment can significantly reduce SVD incidence.⁶

Figure 1. Cross-study comparison of freedom from structural valve deterioration and/or valve-related reoperation for patients receiving Epic Mitral valve during MVR.* See Table 1 for additional details.



*Heterogeneous data. Studies ordered by duration of implant.
⁵Study of structurally-identical Biocor valve in mitral position.

PROVEN DURABLE OVER TIME

The Epic™ Mitral valve design has been scrutinized in clinical studies for over 35 years and consistently demonstrated excellent rates of freedom from SVD and valve-related reoperation in the four recent studies described below.

TABLE 1. KEY DATA FROM STUDIES OF THE BIOCOR AND EPIC MITRAL VALVES (2001-2018)

LEAD AUTHOR	N (MVR)	IMPLANT YEARS	FOLLOW UP	FREEDOM FROM SVD
Jamieson 2011 ²	175	2004-2006	4 years	100%
Nakazato 2019 ³	117	2011-2017	5 years	93.1%
Jawad 2020 ⁴	892	2001-2017	10 years	95.7%
Anselmi 2021 ⁵	482	2009-2018	10 years	89.6%

N, number of study participants; MVR, mitral valve replacement; SVD, structural valve deterioration.

CHOOSING THE RIGHT VALVE FOR EACH PATIENT

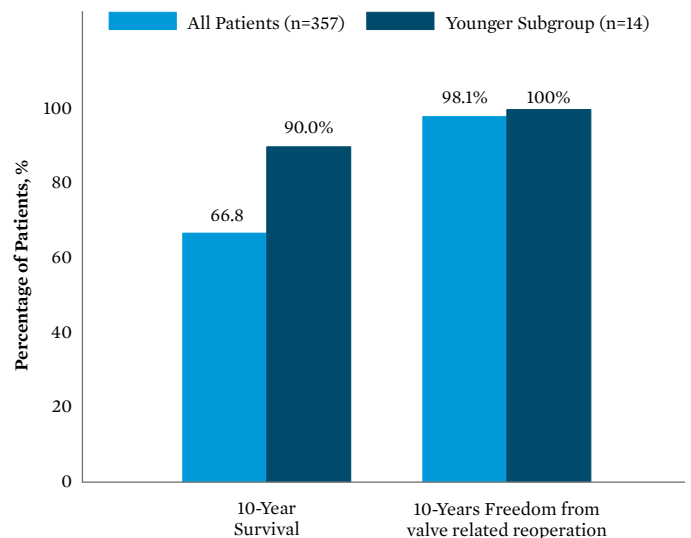
Complex patient- and valve-related factors need to be considered when selecting a prosthetic for mitral valve replacement. The Epic Mitral valve performs well across all sizes and is a reliable choice for active patients where higher valve stress may be anticipated,⁷ repair is not an option, and long-term anticoagulation therapy is undesirable.

- Younger age at implant has been associated with accelerated SVD in some prosthetics.⁸
- Epic Mitral valve's unique features can be the right option for specific patients, and a more durable choice than other treatment options.⁹
- In a study of isolated MVR with Epic Mitral, Garbade and colleagues found very low SVD rates even in younger patients.¹⁰
 - Subgroup (n=14) mean age of 43.3 years
 - 90.0% Ten-year survival
 - No valve-related reoperations

THE DURABILITY STANDARD

Extensive data demonstrates Epic Mitral valve's low structural valve deterioration rates and exceptional long-term performance. From initial studies of its predecessor, the Biocor valve to recently presented data, its unique combination of features have been shown to provide specific benefits and make Epic Mitral a good option for patients undergoing MVR procedures.

Figure 2. In analysis by Garbade and colleagues, Epic Mitral demonstrated excellent freedom from reintervention in all study patients and a younger subgroup with a mean age of 43.3 years.¹⁰



TO LEARN MORE
CONTACT YOUR REPRESENTATIVE OR
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See Important Safety Information referenced within.

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R IMPORTANT SAFETY INFORMATION ONLY 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 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.

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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- 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 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.
- When implanting the Epic valve, assess the suitability of the selected valve size and stent position for a potential future valve-in-valve procedure and whether the transcatheter valve-in-valve procedure may result in left ventricular outflow tract of coronary ostia obstruction. For a future valve-in-valve procedure in an Epic valve, refer to the instructions for use supplied with the transcatheter heart valve along with the reference dimensions in Table 1 (in the IFU) to determine compatibility. The safety and effectiveness of valve-in-valve procedures in an Epic™ valve or Epic™ Supra valve have not been established.
- 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