Abbott

CLINICAL INSIGHTS

EPIC™ MITRAL STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY

Epic Mitral Continues the Biocor Legacy: Strength of Design, Tested Over 35 Years[1]

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).

- No structural deterioration at 4 years[2]
- 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 98.1% in patients with singular valve replacement.[4]
- 79.3% actuarial freedom from explant for SVD at 20 years of the structurally-identical Biocor valve in mitral position, and 88% for patients over 65[1]

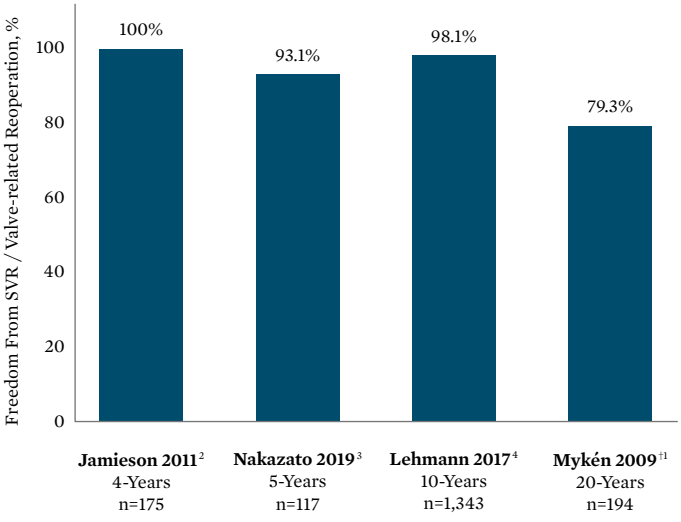
This growing body of evidence supports Epic Mitral as an important option for a variety of patients undergoing MVR procedures.

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.[5]

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.
† Study of structurally-identical Biocor valve in mitral position.

See Important Safety Information referenced within.

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 studied described below.

TABLE 1. KEY DATA FROM STUDIES OF THE BIOCOR AND EPIC MITRAL VALVES (1983-2017)

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%
Lehmann 2017[4]	1,343	2001-2016	10 years	98.1%
Mykén 2009*[1]	194	1983-2003	20 years	79.3%

N, number of study participants; MVR, mitral valve replacement; SVD, structural valve deterioration.
** Study of structurally-identical Biocor valve in mitral position.*

CHOOSING THE RIGHT VALVE FOR EACH PATIENT

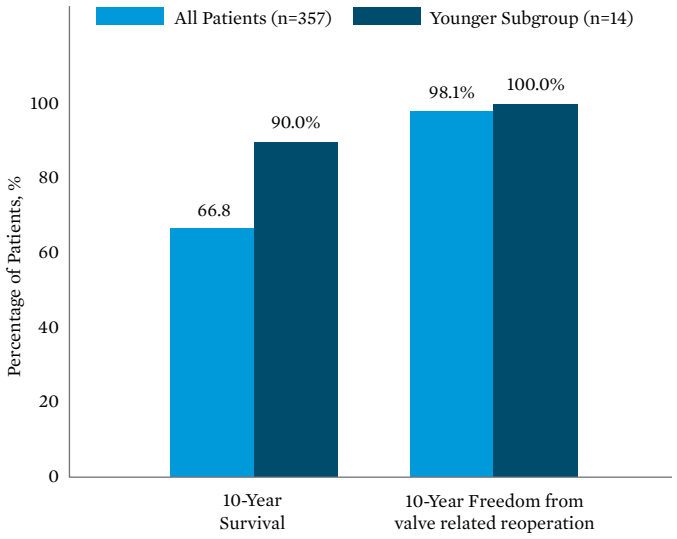
Complex patient- and valve-related factors need to be considered when selecting a prosthetic for mitral valve replacement. The Epic Mitral valve performs well across all sizes and is a reliable choice for active patients where higher valve stress may be anticipated,[6] repair is not an option, and long-term anticoagulation therapy is undesirable.

- Younger age at implant has been associated with accelerated SVD in some prosthetics.[7]
- Epic Mitral valve's unique features can be the right option for specific patients, and a more durable choice than other treatment options.[8]
- In a study of isolated MVR with Epic Mitral, Garbade and colleagues found very low SVD rates even in younger patients.[9]
  - Subgroup (n=14) mean age of 43.3 years
  - 90.0% Ten-year survival
  - No valve-related reoperations

THE DURBAILITY 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, through 20-year performance results, 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.[9]



TO LEARN MORE
CONTACT YOUR REPRESENTATIVE OR
VISIT CARDIOVASCULAR.ABBOTT

See Important Safety Information referenced within.

REFERENCE:

1. Mykén, P. S. U., & Bech-Hansen, O. (2009). A 20-year experience of 1712 patients with the Biocor porcine bioprosthesis. The Journal of Thoracic and Cardiovascular Surgery, 137(1), 76–81. https://doi.org/10.1016/j.jtcvs.2008.05.068
2. Jamieson, W. R. E., Lewis, C. T. P., Sakwa, M. P., Cooley, D. A., Kshettry, V. R., Jones, K. W., ... Bach, D. S. (2011). St Jude Medical Epic porcine bioprosthesis: Results of the regulatory evaluation. The Journal of Thoracic and Cardiovascular Surgery, 141(6), 1449-1454.e2. https://doi.org/10.1016/j.jtcvs.2010.05.055
3. Nakazato, T., Hata, H., Toda, K., Miyagawa, S., Yoshikawa, Y., Saito, S., ... Sawa, Y. (2018). Midterm Clinical Outcomes of the St Jude Medical Epic Porcine Bioprosthesis in the Mitral Position. Circulation Journal, 83(1), 110–116. https://doi.org/10.1253/circj.CJ-18-0483
4. Lehmann, S. (2017). Long-term Follow-up After Porcine Xenograft Mitral Valve Replacement [Poster 92]. In 2017 AATS Mitral Conclave. New York, NY.
5. Flameng, W., Rega, F., Vercalsteren, M., Herijgers, P., & Meuris, B. (2014). Antimineralization treatment and patient-prosthesis mismatch are major determinants of the onset and incidence of structural valve degeneration in bioprosthetic heart valves. The Journal of Thoracic and Cardiovascular Surgery, 147(4), 1219–1224.
6. Rizzoli, G., Bottio, T., Vida, V., Nesseris, G., Caprili, L., Thiene, G., & Gerosa, G. (2005). Intermediate results of isolated mitral valve replacement with a Biocor porcine valve. The Journal of Thoracic and Cardiovascular Surgery, 129(2), 322–329. https://doi.org/10.1016/j.jtcvs.2004.06.034
7. Roselli, E. E. (2006). Failure modes of the Carpentier-Edwards Pericardial Bioprosthesis in the Aortic Position. J Heart Valve Dis, 15, 421–428.
8. Eichinger, W. B., Hettich, I. M., Ruzicka, D. J., Holper, K., Schricker, C., Bleiziffer, S., & Lange, R. (2008). Twenty-year experience with the St. Jude medical Biocor bioprosthesis in the aortic position. The Annals of Thoracic Surgery, 86(4), 1204–1210. https://doi.org/10.1016/j.athoracsur.2008.05.058
9. Garbade, J., Davierwala, P., Jawad, K., Meyer, A., Seeburger, J., Misfeld, M., ...Lehmann, S. (2017). Long-term Effectiveness of Xenograft Bioprosthesis in Isolated Mitral Valve Replacement - Does the Age Matter? [Abstract 96]. In 2017 AATS Mitral Conclave. New York, NY.

℞ ONLY IMPORTANT SAFETY INFORMATION

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.
- 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.
- 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

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.

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

MAT-1900825 v1.0 | Item approved for U.S. use only.

Abbott