



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).

- No structural 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 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 65¹

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

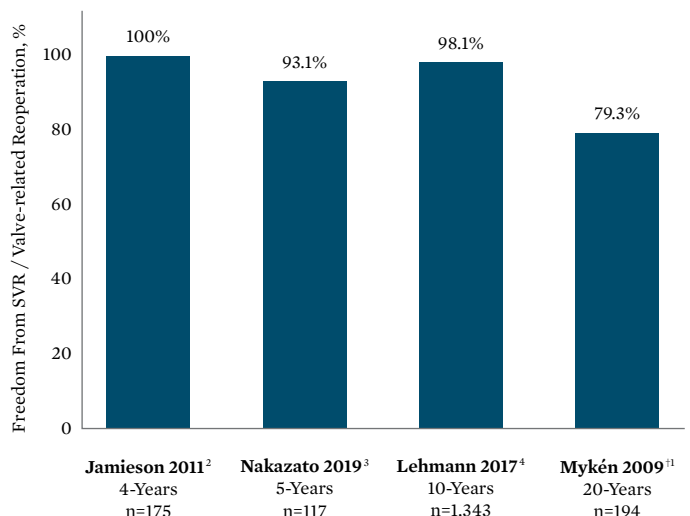
MEETING THE COMPLEX DEMANDS OF MVR

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.



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*Heterogeneous data. Studies ordered by duration of implant.

¹ Study 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 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

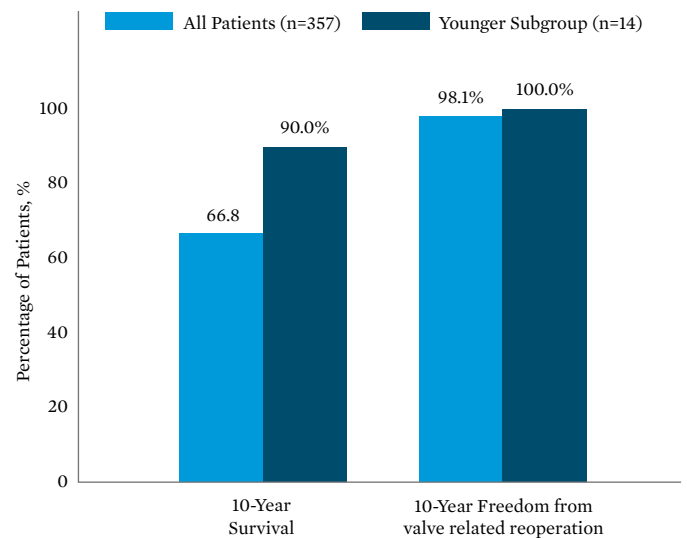
Complex patient- and valve-related factors need to be considered when selecting a prosthetic for mitral valve replacement. The Epic Mitral valve performs well across all sizes and is a reliable choice for active patients where higher valve stress may be anticipated,⁶ repair is not an option, and long-term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



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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., Kshetry, 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., Vercauteren, 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., Schrickler, 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.

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