Abbott

CLINICAL INSIGHTS

EPIC™ MITRAL STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY

Epic Mitral Valve Continues the Biocor Legacy: Strength of Design, Tested Over 35 Years[1-5]

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 SVD 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 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 younger.[5]

This growing body of evidence supports Epic Mitral Valve as an important option for a variety of patients undergoing mitral valve replacement (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 suture-friendly cuff of the Epic Mitral Valve minimizes.
- 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]

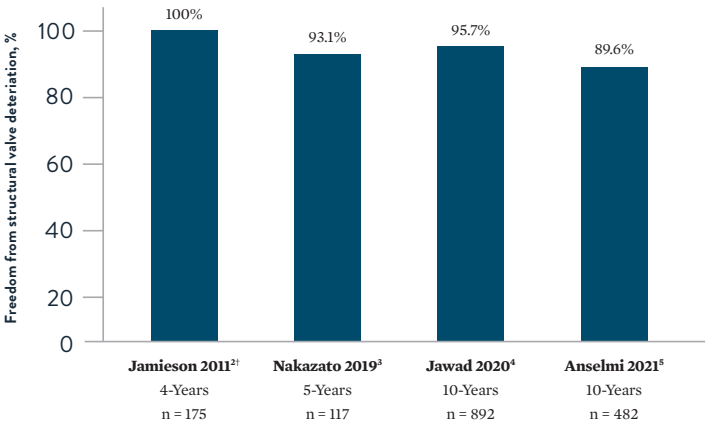

Figure 1. Freedom from structural valve deterioration and/or valve-related reoperation for patients receiving Epic™ Mitral Valve during MVR.
*See Table 1 for additional details.

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

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For audiences outside of the U.S., always check the regulatory status of the device in your region.

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.

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.

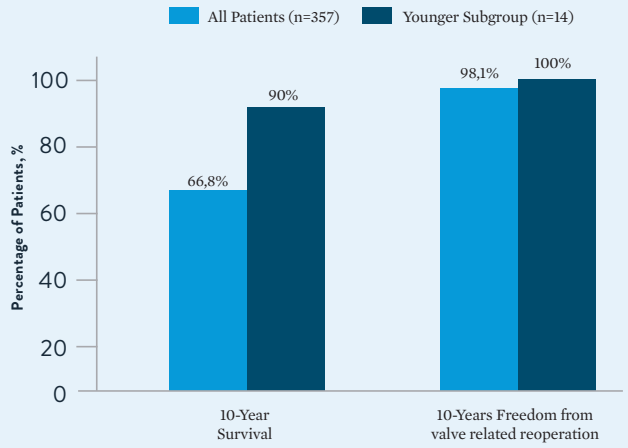

Figure 2. In analysis by Garbade and colleagues, Epic Mitral demonstrated excellent freedom from reintervention in all study patients and a younger subgroup with a mean age of 43.3 years.[10]

*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

References

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For U.S. Audience Only

Rx Only
Important Safety Information

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 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.

POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with the use of bioprosthetic 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: Product(s) 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 www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA

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