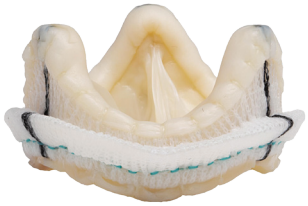
CLINICAL INSIGHTS

EPIC™ SUPRA
AORTIC STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY



Ten-Year Outcomes of a Contemporary Supra-annular Porcine Aortic Bioprosthesis in a Medicare Population[1]

INTRODUCTION

Bioprosthetic surgical aortic valve replacement (SAVR) remains an important treatment option for older patients with aortic valve disease in the era of transcatheter valve interventions. Gaining insights into the **real-world** long-term clinical outcomes of SAVR and the impact of underlying comorbidities and concomitant procedures would be informative to surgeons counseling patients needing to undergo an aortic valve replacement.

STUDY METHOD

- This study was a single-arm observational study using Medicare fee-for-service (FFS) claims data.
- Deidentified patients undergoing SAVR in the U.S. between 1/1/2008-12/31/2019 were selected by ICD-9/10 procedure codes and then probabilistically linked to a manufacturer registration database using implant date, date of birth, gender, and implant hospital.
- Western Institutional Review Board approval was received with a waiver of informed consent for utilizing a deidentified database.

All-cause mortality, aortic valve reintervention (surgical replacement or transcatheter valve-in-valve* implantation) and heart failure rehospitalization were evaluated at 10-years using the Kaplan Meier method, and a multivariable Cox regression was used to identify predictors of mortality following SAVR. 10-year survival was also stratified based on underlying HF and concomitant procedures.

DEMOGRAPHICS

- **N=11,685**
- Average patient age at implant was 76.3 years
- 39.5% female
- 51.6% with a history of heart failure
- Concomitant CABG was performed in 44.9% of cases and concomitant valve surgery was performed in 11.2% of cases.

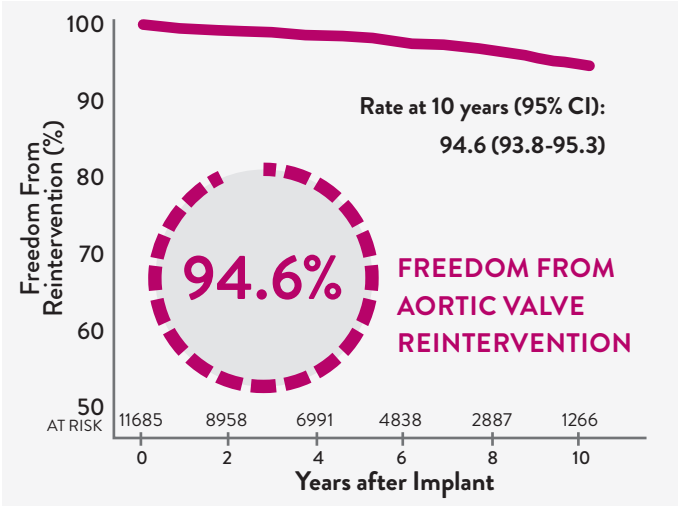
FINDINGS

A key finding from this study was that at 10 years post implant the **freedom from all-cause aortic valve reintervention 94.6%**. This finding is comparable to the 97.3% Epic Aortic valve freedom from reintervention due to SVD for all patient ages at 10 years post-implant reported from Leipzig University.[2]

Freedom from HF hospitalization was 64%. The 10-year survival for the study population was 33.5% representing a survival rate greater than that of a contemporary population of 2.3 million Medicare beneficiaries (16.7%).

CONCLUSIONS

This real-world study of the Epic Supra valve demonstrates at 10-years a **94.6% freedom from valve reintervention** and freedom from HF hospitalization of 64%. The long-term survival was found to be impacted by baseline comorbidities and the need for concomitant procedures. Overall, these results exhibit excellent outcomes and are in-line with existing Epic Supra data publications.



*Note: The safety and effectiveness of valve-in-valve procedures in an Epic™ or Epic™ Supra valve have not been established.

See Important Safety Information referenced within.

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.

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.
- 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

REFERENCES

1. Wiechmann, R. et. al. (2022, May). Ten-Year Outcomes of a Contemporary Supra-annular Porcine Aortic Bioprosthesis in a Medicare Population. Poster presented at the AATS Annual Meeting, Boston.
2. Jawad, Khalil, Sven Lehmann, Alex Koziarz, Maja Dieterlen, Stefan Feder, Martin Misfeld, Jens Garbade, Vivek Rao, and Michael Borger. "Midterm results after St Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement." Journal of Cardiac Surgery 35, no. 8 (2020): 1769-1777.

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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