

## **C8. St. Jude Medical Epic Porcine Bioprosthesis - Results Of Regulatory Evaluation**

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**OBJECTIVES:** The St. Jude Medical (SJM) Epic porcine bioprosthesis was evaluated in the regulatory, Food & Drug Administration, pre-market approval study. The SJM Epic is the successor to the SJM Biocor, with calcium mitigation, ethanol-based therapy. These prostheses are low-pressure, glutaraldehyde-fixed of tri-composite design. The purpose of the study was to report clinical performance.

**METHODS:** Between 2003-2006, 761 patients (mean age 73.9±9.2yrs, range 24-93yrs; females-43.9%, males-56.1%) were implanted with the prosthesis: aortic valve replacement (AVR) - 557, mitral valve replacement (MVR) - 175 & double replacement - 29. Concomitant coronary artery bypass was performed in 50.8% of AVR & 36.6% of MVR. Previous cardiac surgery was performed in 23.3% of AVR & 31.4% of MVR. The patient characteristics for AVR and MVR, respectively, were: hypertension 76.5% & 69.1%; diabetes mellitus 26.2% & 20.0%; stroke/RIND/CVA 6.6% & 6.9%; pulmonary hypertension 14.2% & 34.9%; myocardial infarction 13.1% & 16.6%; and congestive heart failure 36.3% & 57.1%. Total follow-up was 1675.47yrs (mean 2.2±1.2yrs). Closing interval of the study was a 4-month period ending in 2008. Analysis reported early mortality, late mortality, adverse valve-related events (linearized occurrence rates), survival & actuarial freedom from valve-related complications.

**RESULTS:** Early mortality: AVR-3.59% (20) & MVR-2.29% (4). Late mortality: AVR5.2%/pt-yr & MVR-6.6%/pt-yr. Valve-related mortality: AVR-0.4%/pt-yr & MVR1.1%/pt-yr. Major thromboembolic (TE-CVA+RIND) rate: AVR-0.98%/pt-yr (12) & MVR-2.6%/pt-yr (9). Anti-thrombotic hemorrhage rate: AVR-1.3%/pt-yr (16) & MVR-1.7%/pt-yr (6). There were two cases of mitral thrombosis: 0.6%/pt-yr. Survival & freedom rates are based on 4-year evaluation. Overall survival: 76.0% (70.1-80.9). Freedom from valve-related mortality: 98.1% (96.5-99.0). Freedom from reoperation: 92.3% (86.3-95.8). Freedom from TE-CVA: 95.2%

(93.1-96.7). Freedom from TE-RIND: 98.4% (96.8-99.2). Freedom from prosthetic valve endocarditis: 93.2% (86.6-96.6). Freedom from antithrombotic hemorrhage: 90.7% (88.0-92.8).

**CONCLUSIONS:** The 4-year evaluation of the SJM Epic reveals satisfactory clinical performance

### **Freedom from Reoperation and Events**

Valve-Related Complication	Freedom		Events
	%	95% CI	
Reoperation (Overall)	92.3%	86.3- 95.8	21
Reoperation - SVD*	99.4%	97.6- 99.9	2
Reoperation - NSD	97.3%	92.8- 99.0	8 (PPL - 6)
Reoperation - PVE	96.2%	90.0- 98.6	7
Reoperation - Thrombosis	99.6%	98.1- 99.9	2
*Freedom from SVD Overall 99.2% Note: 2 of the 21 reoperations - 1 heart transplantation & 1 repair of aorto-mitral annular continuity dehiscence			